GE Healthcare

BioProcess

Product Guide 2008/2009

BioProcess

How to contact us

www.gelifesciences.com/bioprocess

or by phone (T), fax (F), and Email

Europe

Austria
T: +43 1 57 606 1613
F: +43 1 57 606 1614
Email: cust.orderde@ge.com

Belgium
T: 0800 73890
F: 02 416 8206
Email: order.bnl@ge.com

Central and East Europe (Austria)
T: +43 1 97272 2712
F: +43 1 97272 2750
Email: cust.servex@ge.com

Denmark
T: +45 4516 2400
F: +45 4516 2424
Email: orderdk@ge.com

Eire
T: 1800 709 992
F: +44 1494 542 010
Email: orders.gb@ge.com

Finland
T: +358 95123940
F. +358 951239439
Email: orderfl@ge.com

France
T: +33 1 69 35 67 00
F: +33 1 69 41 96 77
Email: productfr@ge.com

Germany
T: 0800 9080 711
F: 0800 9080 712
Email: cust.orderde@ge.com

Great Britain
T: 0800 515 313
F: 0800 616 927
Email: orders.gb@ge.com

Italy
T: +39 02 2600 1300
F: +39 02 2600 1399
Email: orderit@ge.com

Netherlands
T: 0800 82 82 82 1
F: 0800 82 82 82 4
Email: order.bnl@ge.com

Norway
T: +47 815 65555
F: +47 815 65666
Email: orderno@ge.com

Portugal
T: +351 21 4177035
F: +351 21 4173184
Email: cust.servpt@ge.com

Spain
T: +34 935 944 950
F: +34 935 944 965
Email: cust.serves@ge.com

Sweden
T: +46 18 612 19 00
F: +46 18 612 19 10
Email: orderse@ge.com

Switzerland
T: 0848 8028 10
F: 0848 8028 11
Email: cust.orderde@ge.com

North America

In the USA
T: 1-800-526-3593

Press 1 To reach an extension, sales or service representative

Press 2 Customer Service – to place an order or for pricing and product availability
Hours: 8.30 am–7.30 pm Eastern Time

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Hours: 9.00 am–6.30 pm Eastern Time

Press 0 To reach an operator

F: 1-877-295-8102
Email: cs-us@ge.com

In Canada
T: 1-800-463-5800
F: 1-800-567-1008
Email: csdcanada@ge.com

International

Argentina
T: +54 11 4576 30 30
F: +54 11 4576 30 30 Ext. 113
Email: sales.ar@ge.com

Australia
T: +61 2 8820 8299/1800 150 522
F: +61 2 8820 8200
Email: sales.au@ge.com

Belarus
See listing for Russian Federation

Brazil
T: +55 11 3933 7300/0800 136833
F: +55 11 3933 7304
Email: vendas.biosciences@ge.com

China Beijing
T: +86 10 5806 9689
F: +86 10 6787 1162
Email: lifesciences@ge.com

China Guangzhou
T: +86 20 8363 3828 ext 67961
F: +86 20 8363 3291
Email: lifesciences@ge.com

China Hong Kong
T: +852 2100 6300
F: +852 2100 6338
Email: lifesciences@ge.com

China Shanghai
T: +86 21 5257 4650 ext 67337
F: +86 21 5208 2008
Email: lifesciences@ge.com

India
T: +91 44 2434 0747
F: +91 44 2432 3770
Email: supportdesk.india@ge.com

Japan
T: +81 3 5331 9336
F: +81 3 5331 9370
Email: Tech-JP@ge.com

Kazakhstan
See listing for Russian Federation

Korea
T: +82 2 6201 3700
F: +82 2 6201 3804
Email: lifesciencesKR@ge.com

Latin America (Brazil
T: +55 11 3933 7300/0800 136833
F: +55 11 3933 7304
Email: vendas.biosciences@ge.com

Malaysia
T: +60 3 2273 9788
F: +60 3 2273 6508

Mexico
T: +52 55 9177 0300 Ext. 9645
F: +52 55 9177 0388
Email: alberto.suarez@ge.com

Middle East (Greece)
T: +30 210 96 00 687
F: +30 210 96 00 693
Email: biotech@hvd.gr

Moldavia
See listing for Russian Federation

Mongolia
See listing for Russian Federation

New Zealand
T: +64 9 523 5890/0800 733 893
F: +64 9 522 7342
Email: sales.nz@ge.com

Russian Federation and other CIS/NIS Moscow
T: +7 495 956 5177
F: +7 495 956 5176
Email: LSrus@ge.com

Singapore
T: + 65 6773 7303
F: + 65 6773 7302
Email: lifesciences.sg@ge.com

Taiwan
T: +886 2 2888 3570
F: +886 2 2888 3580

Thailand
T: +662 624 8484
F: +662 624 8490

Ukraine
See listing for Middle East (Greece)

Addresses

GE Healthcare Bio-Sciences AB
Björkgatan 30
SE-751 84 Uppsala
Sweden
T: +46 (0) 18 612 00 00
F: +46 (0) 18 612 18 00

GE Healthcare Europe GmbH
Munzinger Strasse 5
D-79111 Freiburg
Germany
T: +0 800 9080 711
T: +49 761 45 43-0
F: +0 800 9080 712

GE Healthcare UK Ltd.
Amersham Place
Little Chalfont
Bucks HP7 9NA
UK
T: +44 (0) 1494 544000
F: +44 (0) 1494 542266

GE Healthcare Bio-Sciences Corp
800 Centennial Avenue
P.O. Box 1327
Piscataway, NJ 08855-1327
USA
T: +1 732 457 8000
F: +1 732 457 0557

GE Healthcare Bio-Sciences KK
Sanken Bldg.
3-25-1, Hyakunincho
Shinjuku-ku
Tokyo 169-0073
JAPAN
T: +81 3 5331 9336
F: +81 3 5331 9370

Sales branch offices

Europe

Austria
GE Healthcare Europe GmbH
Zweigniederlassung Österreich
Europlaza, Gebäude E
Wienerbergstrasse 41
A-1120 Wien

T: +43 1 57606 1613
F: +43 1 57606 1614
Email: cust.orderde@ge.com

Technical Support
T: +43 1 57606 1619

Belgium
GE Healthcare Europe GmbH
Branch office Benelux
Kouterveldstraat 20
B-1831 Diegem
BELGIUM

T: 0800 73 890
F: 02 416 82 06
Email: order.bnl@ge.com

Central & East Europe (Austria)
GE Healthcare Europe GmbH
Branch Vienna International
Europlaza, Building E
Technologiestrasse 10
A-1120 Vienna
Austria

T: +43 1 97272 2712
F: +43 1 97272 2750
Email: cust.servex@ge.com

Sales support to Czech Republic, Hungary, Poland, Slovakia,Slovenia, Croatia, Bulgaria, Romania, Albania, FYROM (Macedonia), Serbia and Montenegro, Bosnia-Hercegowina

Denmark
GE Healthcare Europe GmbH
Huginsvej 8
DK-3400 Hillerød

T: +45 45 16 24 00
F: +45 45 16 24 24

Customer Service
T: 70 25 24 50
Email: orderdk@ge.com

Finland
GE Healthcare Europe GmbH
Suomen sivuliike
PL 3130
FIN-00002 Helsinki

T: +358 9 512 3940
F: +358 9 512 39439
Email: orderfl@ge.com

France
GE Healthcare Europe GmbH
Succursale France
Parc Technologique
Rue René Razel
Saclay
F-91898 Orsay Cedex

T: +33 (0) 169 35 67 00
F: +33 (0) 169 41 96 77
Email: productfr@ge.com

Germany
GE Healthcare Europe GmbH
Munich Commercial Center
Oskar-Schlemmer-Str. 11
80807 München

T: +49 899 6281660
F: +49 899 6281620
Email: cust.servde@ge.com

Technical Support
T: +49 89 96281 660
F: +49 89 96281 620

GE Healthcare Europe GmbH
Munzinger St. 5
79111 Freiburg

Customer Service:
T: 0800 9080 711
F: 0800 9080 712
Email: cust.orderde@ge.com

Great Britain
GE Healthcare UK Ltd
Amersham Place
Little Chalfont
Bucks HP7 9NA
UK

T: +44 1494 544000
F: +44 1494 542 010
Email: orders.gb@ge.com

Italy
GE Healthcare Europe GmbH
Filiale Italiana
Via Galeno 36
I-20126 Milano (MI)

T: +39 02 2600 1300
F: +39 02 2600 1399
Email: orderit@ge.com

Netherlands
GE Healthcare Europe GmbH
Branch office Benelux
Kouterveldstraat 20
B-1831 Diegem
BELGIUM

T: 0800 82 82 82 1
F: 0800 82 82 82 4
Email: order.bnl@ge.com

Norway
GE Healthcare Europe GmbH
P.O. Box 4665 Nydalen
N-0450 Oslo

T: +47 815 65 555
F: +47 815 65 666

Customer service
T: +47 815 65 555
Email: orderno@ge.com

Technical support
T: +47 815 65 888
F: +47 815 65 666
Email: productno@ge.com

Portugal
GE Healthcare Europe GmbH
Sucursal em Portugal
Av. Do Forte no. 6–6A
Edifício Ramazzotti
2790-072 Carnaxide, Portugal

T: + 351 21 417 70 35
F: + 351 21 417 31 84
Email: cust.servpt@ge.com

Spain
GE Healthcare Europe GmbH
Sucursal en España
Parc Tecnològic del Vallés
Argenters, 4, Edificio 2, 1ª Planta
08290 Cerdanyola
Barcelona

T: +34 935 944 950 Centralita/+34 902 117 265 Pedidos
F: +34 935 944 965
Email: cust.serves@ge.com

Sweden
GE Healthcare Europe GmbH
Filial Sverige
Björkgatan 30
Box 605
SE-751 25 UPPSALA

T: +46 (0) 18 612 19 00
F: +46 (0) 18 612 19 10

Customer Service
T: +46 (0) 18 612 19 90
Email: orderse@ge.com

Technical Support
T: +46 (0)18 612 19 80
Email: productse@ge.com

Switzerland
GE Healthcare Europe GmbH
Zweigniederlassung Schweiz
Industriestrasse 30
CH-8112 Otelfingen

T: 0848 8028 10
F: 0848 8028 11
Email: cust.orderde@ge.com

Technical Support
T: 0848 8028 12
F: 0848 8028 13
Email: cust.servde@ge.com

North America

In the USA

GE Healthcare Bio-Sciences Corp
800 Centennial Avenue
P.O. Box 1327
Piscataway, NJ 08855-1327
USA

T: 1-800-526-3593

Technical Support
Email: ts-usa@ge.com

Customer Service
Email: cs-us@ge.com

Instrument Service
Email: labcrew-us@ge.com

Canada

GE Healthcare Bio-Sciences, Inc.
500 Morgan Blvd.,
Baie d'Urfé,
Québec, H9X-3V1
CANADA

Customer Service
T: 1-800-463-5800
F: 1-800-567-1008
Email: csdcanada@ge.com

Technical Support
Email: ts-usa@ge.com

International

Argentina

GE Healthcare Argentina S.A.
Montañeses, 2820
C1429 BLB
Buenos Aires

T: +54 114576 3030
F: +54 11 4576 3030 ext. 113
Email: sales.ar@ge.com

Sales support to Argentina, Uruguay, Paraguay, Chile and Bolivia

Australia

GE Healthcare Bio-Sciences Pty Ltd
Building 4B
21 South Street
Rydalmere NSW, 2116
AUSTRALIA

T: +61 2 8820 8299
F: +61 2 8820 8200
Toll free: 1800 150 522
Email: sales.au@ge.com

Postal address:
PO Box 21
Rydalmere, NSW 1701
AUSTRALIA

Sales support to New Zealand

China, Beijing

GE Healthcare
Beijing Representative Office
No. 1, Yongchong North Road
Beijing Economic & Technological Development Area
Beijing 100176

T: +86 10 5806 9689
F: +86 10 6787 1162

China, Guangzhou

GE Healthcare
Guangzhou Representative Office
Room 1212, Yian Plaza
No. 33 Jianshe 6 Road
Guangzhou 510060

T: +86 20 8363 3828 ext 67961
F: +86 20 8363 4210

China, Hong Kong

GE Healthcare Bio-Sciences Ltd
L12 Office Tower, Langham Place
8 Argyle Street, Mongkok
Kowloon
HONG KONG

T: +852 2100 6300
Fax: +852 2100 6338
Order Hotline: +852 2100 6336
Email: lifesciences@ge.com

China, Shanghai

GE Healthcare
Shanghai Representative Office
24 Floor Maxdo Centre
No. 8 Xinyi Road
Shanghai 200137

T: +86 21 5257 4650 ext 67337
F: +86 21 5208 2008

India

GE Healthcare Bio-Sciences Ltd
India Branch Office
FF3, First Floor, Palani Centre
32, Venkatnarayana Road
T. Nagar, Chennai 600 017
INDIA

T: +91 44 2434 0747
F: +91 44 2432 3770
Email: supportdesk.india@ge.com

Sales support to Bangladesh & Sri Lanka

Japan

GE Healthcare Bio-Sciences KK
Sanken Bldg.
3-25-1, Hyakunincho Shinjuku-ku
Tokyo 169-0073
BioDirect Line

T: +81 3 5331-9336
F: +81 3 5331-9370
Email: Tech-JP@ge.com

Korea

GE Healthcare Bio-Sciences Ltd.
GE Tower 5F, 71-3
Cheongdam-dong, Kangnam-ku
Seoul, 135-100
Republic of Korea

T: +82 2 6201 3700
F: +82 2 6201 3804
Email: lifesciencesKR@ge.com

Latin America (Brazil)

GE Healthcare do Brasil Ltda
Rua Domingos Marchetti, 192
Bairro do Limão
SP 02712-150
Brazil

T: +55 11 3933 7300 or toll free 0800 136833
F: +55 11 3933 7304
Email: vendas.biosciences@ge.com

Sales support to Brazil, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Honduras, Panamá, Perú, Tobago, Trinidad and Venezulea

Malaysia

GE Healthcare Bio-Sciences Ltd.
Level 6, 1 Sentral
Jalan Travers, Kuala Lumpur Sentral
50470 Kuala Lumpur
MALAYSIA

T: +60 3 2273 9788
F: +60 3 2273 6508

Sales support to South East Asia Region including Brunei, Philippines, Indonesia & Vietnam

Mexico

GE Healthcare
Av. Santa Fé, 495
Colonia
Santa Fé
Distrito Federal, CP 05349

T: +52 55 9177 0300 Ext. 9645
F: +52 55 9177 0388
Email: alberto.suarez@ge.com

Sales support to Mexico

Middle East and Africa (Greece)

HVD Biotech Vertriebs GmbH
Vouliagmenis Avenue 16
P.O. Box 70051
GR-16610 Glyfada
GREECE

T: +30 210 96 00 687
F: +30 210 96 00 693
Email: biotech@hvd.gr

Sales support for Greece, Algeria, Bahrain, Cyprus, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Malta, Morocco, Oman, Pakistan, Qatar, Republic of South Africa, Saudi Arabia, Syria, Tunisia, Turkey, Ukraine, UAE, Yemen

New Zealand

GE Healthcare Bio-Sciences (NZ) Ltd
Ground Floor
300 Great South Road
Greenlane
Auckland 1051
NEW ZEALAND

T: +64 9 523 5890
F: +64 9 522 7342
Toll free: 0800 733 893
Email: sales.nz@ge.com

Postal address:
PO Box 17122
Greenlane
Auckland 1546
NEW ZEALAND

Russian Federation and C.I.S. & N.I.S.

GE Healthcare ZAO
(former Amersham Biosciences)
Leninsky prosp. 113/1, office D401,D403
RF-117 198 MOSCOW – MOCKBA
Russian Federation

T: +7 495 956 51 77
F: +7 495 956 51 76
Email: LSrus@ge.com

Contact Moscow office for Armenia, Azerbaidjan, Belarus, Georgia, Kazakhstan, Kirgyzstan, Moldavia, Mongolia, Tadjikistan, Turkmenistan & Uzbekistan

Singapore

GE Healthcare Pte. Ltd.
Singapore Branch Office
77 Science Park Drive
CINTECH III, #03-05/06
Singapore Science Park 1
SINGAPORE 118256

T: +65 6773 7303
F: +65 6773 7302
Email: lifesciences.sg@ge.com

Taiwan

GE Healthcare
Taiwan Branch Office
10F, No.55, Sec 2., Chihshan Road
Shih-Lin District
Taipei 111

T: +886 2 2888 3570
F: +886 2 2888 3580

Thailand

GE Healthcare Bio-Sciences (Thailand) Ltd.
Thanapoom Tower, 12th Floor
1550 New Petchburi Road
Makasan, Ratthewi
Bangkok, 10400

T: +662 624 8484
F: +662 624 8490

Ukraine

See listing for Middle East and Africa (Greece)

Fast Trak services

Global Fast Trak

Email: FastTrak@ge.com
Website: www.gelifesciences.com/fasttrak

Fast Trak Centers

Europe

GE Healthcare Europe GmbH
Oskar-Schlemmer-Strasse 11
80807 München, Germany

Email: ftcourses.europe@ge.com
T: +49 (0) 89 96 28 16 90
F: +49 (0) 89 96 28 16 79

North America

GE Healthcare Bio-Sciences Corp.
800 Centennial Avenue
Piscataway, NJ 08855-1327, USA

Email: FasttrakNA@ge.com
T: +1 732 457 8064
F: +1 732 457 8246

China

GE Healthcare
GE (China) Research and Development Center Co.,Ltd
1800 CaiLun Road
Zhangjiang High-tech Park, Pudong
Shanghai 210203, China

Email: fasttrakasia@ge.com
T: +86 21 50504666-2600
F: +86 21 50808591

India

GE Healthcare Life Sciences
John F. Welch Technology Center
122, EPIP, Whitefield
Bangalore 560 066, India

Email: fasttrakindia@ge.com
T: +91 80 2527 9538
F: +91 80 2526 8423

Administrative offices

Sweden

GE Healthcare
Björkgatan 30
SE-751 84 Uppsala
Sweden

T: +46 18 612 0219
F: +46 18 120 329

Japan

GE Healthcare
Sanken Bldg, 3-25-1
Hyakunincho 3-chome Shinjuku-ku
169-0073 Tokyo
Japan

T: +81 (0) 3 5331 9316
F: +81 (0) 3 5331 9372

Contents

Bioprocessing

Enabling fast development and efficient production

Taking biopharmaceuticals from research to market involves transfer from the lab bench, through first-in-human trials, to widespread use by patients. Great care is needed to ensure high quality, while not jeopardizing efficacy or process economy. Meanwhile, the clock is running – production schemes need to be finalized as quickly as possible to ensure maximal returns.

To help you meet these challenges, GE Healthcare continues to develop products, platform technologies, and services to help you achieve fast development and efficient and robust production.

Time to clinic is key

Optimizing your production processes offers competitive advantages and is essential to both drug discovery and production. However, discovery labs and pilot plants impose very different challenges on these production processes. The challenges are to take methods from an explorative discovery environment, manage them through testing and clinical trials, and then optimize them to meet the stringent demands of a highly regulated production environment. All the time the pressure is on to secure drug safety and ensure process robustness and economy. Our aim is to help teams plan, experiment and optimize, manage regulatory requirements, and make smooth transitions into clinical trials and manufacture. This helps bring drug candidates to market in a faster, simpler, more reliable and cost-effective manner.

Improving efficiencies

The choice of bioprocessing steps has the greatest impact on how efficiently you manage the fermentation, capture, purification and polishing stages. We offer a broad range of products and platform technologies to address these challenges. Our tools and solutions such as bioreactors, cell culture growth media, chromatography selecitvities, membrane cut-offs allow us to provide an integrated and Lean enabling approach to bioprocessing that combines upstream and downstream.

Examples of how GE Healthcare supports more efficient processing are the recently introduced ReadyToProcess platform that includes ready to use and disposable products, and PreDictor filter plates for high-throughput screening of chromatographic conditions.

ReadyToProcess products simplify and speed up bioprocessing by reducing upfront investment and accelerating development. They also help eliminate wasteful practices, facilitating the introduction of Lean production schemes. ReadyToProcess products are designed for smooth interconnectivity and seamless, scalable implementation in biopharmaceutical operations – both upstream and downstream.

PreDictor plates support high-throughput process development by allowing parallel screening of chromatographic conditions. Data generated using PreDictor plates show good correlation with data obtained in column chromatography, making the plates an excellent tool for initial screening of process conditions that facilitate transfer to large-scale.

Other examples include our Capto and MabSelect media that are designed to meet the high-volume-throughput productivity requirements for high-titer feed-streams, and offer high binding capacity for capture of target molecule. These media are available in a range of formats from PreDictor plates, to HiScreen and ReadyToProcess columns, to bulk media providing the flexibility to suit your application scale. Our hardware platforms include AxiChrom columns, ÄKTAexplorer, ÄKTApilot and ÄKTAprocess chromatography systems as well as ÄKTAcrossflow and UniFlux filtration systems. Controlled by UNICORN software, these systems allow for true integration of steps with rapid method transfer, and scale-up/scale-down, enabling process developers to get results quickly and simply.

Comprehensive and reliable support

We aspire to be a trusted, knowledgeable supplier and offer an array of specialized services and support for process development, validation, security of supply, and compliance. Our Fast Trak team provides education courses, process development assistance, and validation services. Our Life Science Performance Solutions team can help introduce Lean enabling and Six Sigma concepts into your processes to improve efficiences. In addition, we offer customized safety stock for media, membranes, and spare parts, as well as service agreements to ensure trouble-free operation. To secure GMP compliance, RSFs (Regulatory Support Files) are available for all BioProcess media, and similar documentation is available for process hardware.

Secure supply

Over the past decades GE Healthcare has supported the rapid growth in biopharmaceutical production – we currently deliver approximately 500 000 laboratory and pilot-scale columns per year, and over the years we have supplied more than 4 250 000 liters/kgs of chromatographic media, more than 12 000 process-scale columns, 2000 BioProcess systems, 200 000 membrane devices, and 1000 filtration skids. We have recently increased our production capacity and services to match demands. We believe security-of-supply is about quality as well as timely delivery of the right quantity, thus we have validated production processes and manufacture according to ISO 9001. Over the past years we have invested over US$100 million in business continuity systems, processes, training, and equipment. We have worked with a combination of market-leading safety and business continuity consulting firms. Customers and regulatory authorities also closely scrutinize our production routines through on-site audits – an important catalyst in our continuous improvement program.

We endeavor to be your best supplier. Our greatest motivation is your success.

Products and platforms across bioprocessing

With the recent launch of the ReadyToProcess platform and the acquisition of WAVE disposable technologies, we are able to support bioprocessing from cell culture and fermentation through recovery and purification to formulation.

Our products and platform solutions are designed to meet the key challenges posed at every stage in the process, delivering the desired product at the require purity and safety: all with fast development and Lean processing in mind.

		Key goals	Technology	Product
Upstream	Cell Culture	• High product titer • Product folding & post translational modifications correct • Product easily transferred to DSP	• High producer cell grown in reactors and fermenters	• WAVE Bioreactors • WAVE Mixers • Microcarriers • ReadyToProcess
Downstream	Recovery	• Isolate and prepare product for purification • Removal cells and cells debris	• Cell disruption methods • Normal flow filtration	• ULTA • ReadyToProcess
	Capture	• Clarification and concentration • Secure process robustness & economy • Initial purification of target molecule	• Filtration • Affinity chromatography • Ion exchange • Multi-modal	• ReadyToProcess • MabSelect, Capto • PreDictor • Sepharose, Sephadex, CDM • Kvick cassettes, ULTA cartridges • ÄKTAsystems, UNICORN, UniFlux • AxiChrom
	Purification	• Removal of bulk of process related impurities from clarified feed, including host cell protein, DNA, viruses and endotoxins	• Ion exchange chromatography • Multi-modal • Hydrophobic interaction	• ReadyToProcess • Capto • PreDictor • Sepharose, Sephadex, SOURCE • PlasmidSelect, CDM • Kvick cassettes, ULTA cartridges • ÄKTAsystems, UNICORN, UniFlux • AxiChrom
	Polishing	• Removal of remaining traces of process- and product-related impurities	• Ion exchange • Reversed phase • Hydrophobic interaction • Gel filtration	• ReadyToProcess • Superdex prep grade • Sephacryl, Sepharose, SOURCE • UniFlux, ÄKTAsystems • AxiChrom
	Formulation	• Long-term product stability	• Ultrafiltration/ diafiltration	• Kvick cassettes, hollow fibers

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Product highlights

ReadyToProcess Platform

New

ReadyToProcess is a new platform of ready for use products designed to provide maximum flexibility. The products simplify and speed up bioprocessing, reducing upfront investment and accelerating development. The platform also helps eliminate wasteful practices, and increases manufacturing agility. ReadyToProcess products provide smooth interconnectivity and seamless, scalable implementation in biopharmaceutical operations.

WAVE
Now part of GE Healthcare

GE Healthcare acquired WAVE Biotech LLC and its subsidiary WAVE Europe Pvt. Ltd., in April 2007. The acquisition enables GE Healthcare to expand its offering of products and services for the manufacture of biopharmaceuticals, especially in its focus areas of antibodies and vaccines.

ReadyToProcess WAVE systems

GE Healthcare's new line of WAVE disposable technologies are state-of-the-art products for the biopharmaceutical industry. These patented products offer a range of advantages including rapid installation, reduced time to market, and lower costs due to the elimination of the need for cleaning and validation.

WAVE Bioreactors, comprise a rocking platform and a cell culture bag to form a closed, sterile system for cell culture. The systems are capable of handling quantities of 0.1 to 500 liters and are designed for cGMP applications including inoculum production as well as clinical and commercial production of human therapeutics.

›› For more information on the new range of WAVE systems, see pages 38.

Cellbag disposable bioreactors

Cellbag* bioreactors are presterilized and disposable, requiring no cleaning or validation and eliminating the risk of cross-contamination. The bags are manufactured from multi-layer laminated, clear plastic films designed to provide mechanical strength and bioinert fluid contact.

*Cell Culture Bag in Switzerland.

›› For more information on Cellbag disposable bioreactors, see pages 48.

ReadyToProcess connectivity

Connectivity is an important component of GE Healthcare's ReadyToProcess manufacturing solutions. Our systems and components can be linked with a set of integrated devices including ReadyMate Disposable Aseptic Connectors, Hot Lips Tube Sealer, and Sterile Tube Fuser. These products provide aseptic connectivity, are simple to use, and are suitable for a wide range of fluid transfer applications.

ReadyToProcess connectivity provides:

- Simple, rapid connection solutions
- Sterility throughout the process
- Seamless connections between ReadyToProcess systems and components

›› For further information on ReadyToProcess Connectivity, see page 50.

ReadyToProcess filtration products

The ReadyToProcess platform offers a comprehensive range of pilot- to process-scale "plug-and-play" devices that includes cross flow filtration and normal flow filtration. Normal flow filtration capsule filters, including the new ULTA range of filters, were designed for processing solutions from laboratory up to process scale and can handle volumes ranging from a few hundred milliliters to thousands of liters of solution. ReadyToProcess cross flow filters are suitable for a wide variety of applications including clarification of lysates and cell cultures, or concentration, diafiltration, and purification of monoclonal antibodies, plasmids, proteins, viruses, vaccines, colloids, and plasma.

ReadyToProcess filtration products offer:

- Time savings during development
- Lowered risk of cross-contamination
- Simple and rapid operations

›› For detailed information on ReadyToProcess Filtration products, see page 54.

ÄKTAready system

ÄKTAready is a liquid chromatography system built for process scale-up and production for early clinical phases. The system operates with ready to use, disposable flow paths and as a consequence, the need for cleaning between products/batches is eliminated and development and validation of cleaning procedures is not required. Replacing flow paths between projects is simple, and when used together with ReadyToProcess columns, the risk for cross-contamination is removed.

Features of ÄKTAready system include:

- Simple exchange of the complete flow path eliminates the need for system cleaning
- Improved economy and productivity due to simpler procedures
- Risk for cross-contamination between products/batches is eliminated
- Scalable processes using UNICORN

›› For more information on ÄKTAready system, see pages 58.

ReadyToProcess columns

ReadyToProcess columns are prepacked, prequalified, and presanitized process-scale columns designed for the purification of biopharmaceuticals intended for phase I and phase II trials, for full-scale manufacturing, and for preclinical studies. Their design allows for easy connectivity to chromatography systems and simplified disposal after production. Materials used to manufacture ReadyToProcess columns were chosen for their biological and chemical compatibility with samples, buffers, and solutions used in biomanufacturing.

Features of ReadyToProcess columns include:

- Rapid delivery, simplified operation, and easy disposal
- Eliminates the need for column packing, qualification, and sanitization
- Prepacked with BioProcess media including MabSelect SuRe, Capto Q, Capto S, Capto adhere, and Phenyl Sepharose 6 Fast Flow

›› For further information on ReadyToProcess Columns, see page 60.

MabSelect media

The clinical success of monoclonal antibodies is one of the most exciting achievements in our industry, resulting in annual production requirements of, in some cases, tons scales. Cell culture bioreactors are today built up to 25 000 liters scale and titers are increasing, currently in the 3 to 5 g/l range and are expected to increase several-fold. New challenges are consequently addressed to Downstream processing and efforts are directed at improving process economics by decreasing the number and cost of unit operations. Current trends in antibody production indicate an increased use of MabSelect and Protein A media for production capture.

MabSelect is a modern range of chromatography media for purification of monoclonal antibodies at large production scale. All MabSelect media feature:

- A base matrix of high-flow agarose
- High chemical stability: compatible with all aqueous buffers commonly used in Protein A chromatography
- Regulatory Support File availability
- Simple scale-up to production-sized columns
- Large-scale quantities available on request

Like all our BioProcess media, MabSelect media meet every requirement for process design and scale-up. Prepacked and ready-to-use columns and bulk quantities are available. For large-scale packing, we recommend AxiChrom, Chromaflow, or BPG columns.

›› For more information, see page 71.

The MabSelect family consists of:

MabSelect

For high purity and throughput at production scale

- Prioritized volume throughput
- Optimized matrix and ligand coupling
- The antibody purification standard

MabSelect SuRe

Withstands rigorous and cost-effective CIP protocols, (e.g., 0.1 to 0.5 M NaOH)

- Alkali-stabilized rProtein A ligand
- Generic and economic CIP/sanitization
- Product safety and process robustness
- Low-leakage media

MabSelect Xtra

For capturing high-titer antibody feedstocks and reducing processing costs

- Outstanding dynamic binding capacity
- Improved process economics and reduced raw material costs
- High-purity capture due to minimal non-specific binding

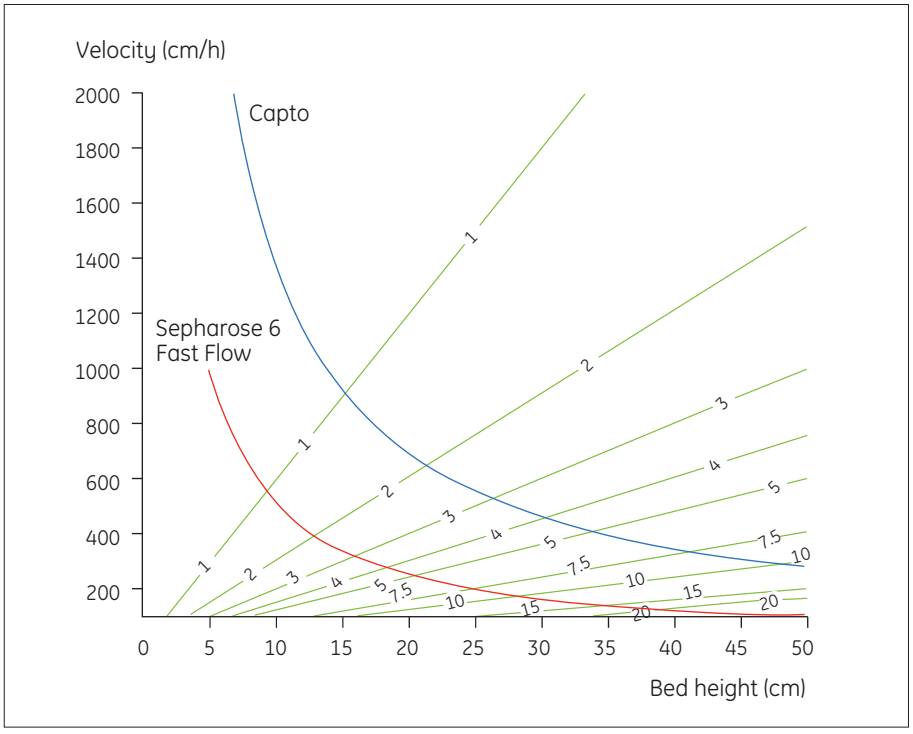
All MabSelect media are now available in convenient 1 and 5 ml HiTrap columns for start-up, and in 10 cm, prepacked HiScreen columns for easy process design-in.

Capto media

Capto is a BioProcess media product line specifically designed to meet the growing need in the biopharmaceutical market to process large feed volumes in a fast, efficient, and cost-effective way. The base matrix is a highly rigid agarose that allows for a broader working range of flow velocities, bed heights, and sample viscosities at large scale. High flow velocities increase volume throughput and reduce process time. Longer bed heights eliminate the need for large equipment and keep footprints small. High-flow processing of viscous samples means less dilution and shorter cycle times. In addition, the chemical stability of agarose assures long media lifetime even if harsh cleaning-in-place procedures are applied.

Capto media are now available in a range of convenient formats including PreDictor plates, and HiTrap, HiScreen, and ReadyToProcess columns.

» For more information, see page 68.



Capto media offer a wide range of operating conditions. This figure shows the predicted working range (the area under and to the left of the curved lines) for Capto (blue) and Sepharose 6 Fast Flow (red) in combinations of bed heights and flow velocities in a 1 m diameter column. The green lines show residence time in the column in minutes.

New

Capto DEAE is a weak anion exchanger for capture and intermediate purification. The diethyl aminoethyl groups are linked to a highly rigid agarose matrix, modified with dextran surface extenders which further increase capacities and mass transfer properties.

Capto DEAE has a different selectivity compared to Capto Q and expands the options for process chromatography.

The following Capto products are available:

Capto Q, DEAE, and S

- Capto Q, a strong anion exchanger for capture and intermediate purification
- Capto DEAE, a weak anion exchanger for capture and intermediate purification
- Capto S, a strong cation exchanger for capture and intermediate purification

Capto MMC

- Capto MMC, a multimodal weak cation exchanger that enables binding of proteins at the conductivity of most standard feed materials

Capto adhere

- Capto adhere, a strong multimodal anion exchanger for post-Protein A purification of monoclonal antibodies

All Capto media are now available in convenient 1 and 5 ml HiTrap columns for start-up, and in 10 cm, prepacked HiScreen columns for easy process design-in.

Chromatography media toolbox for MAb purification platforms

Antibodies are a relatively homogenous group and can successfully be purified using a platform approach (i.e., a standard set of unit operations, methods, and conditions).

Many antibodies can be purified by a 2-step chromatography process, while others may need an additional step to reach desired purity. Capture, using Protein A media, is the common standard followed by alternative routes for removal and polishing.

Large-scale purification of MAbs normally consists of three chromatographic steps:

1. Initial capture using Protein A affinity chromatography to give a product of high purity, typically 99%
2. Initial removal/polishing involving either cationic or anionic exchange chromatography
3. Final polishing with multimodal, strong cationic or anionic exchange chromatography

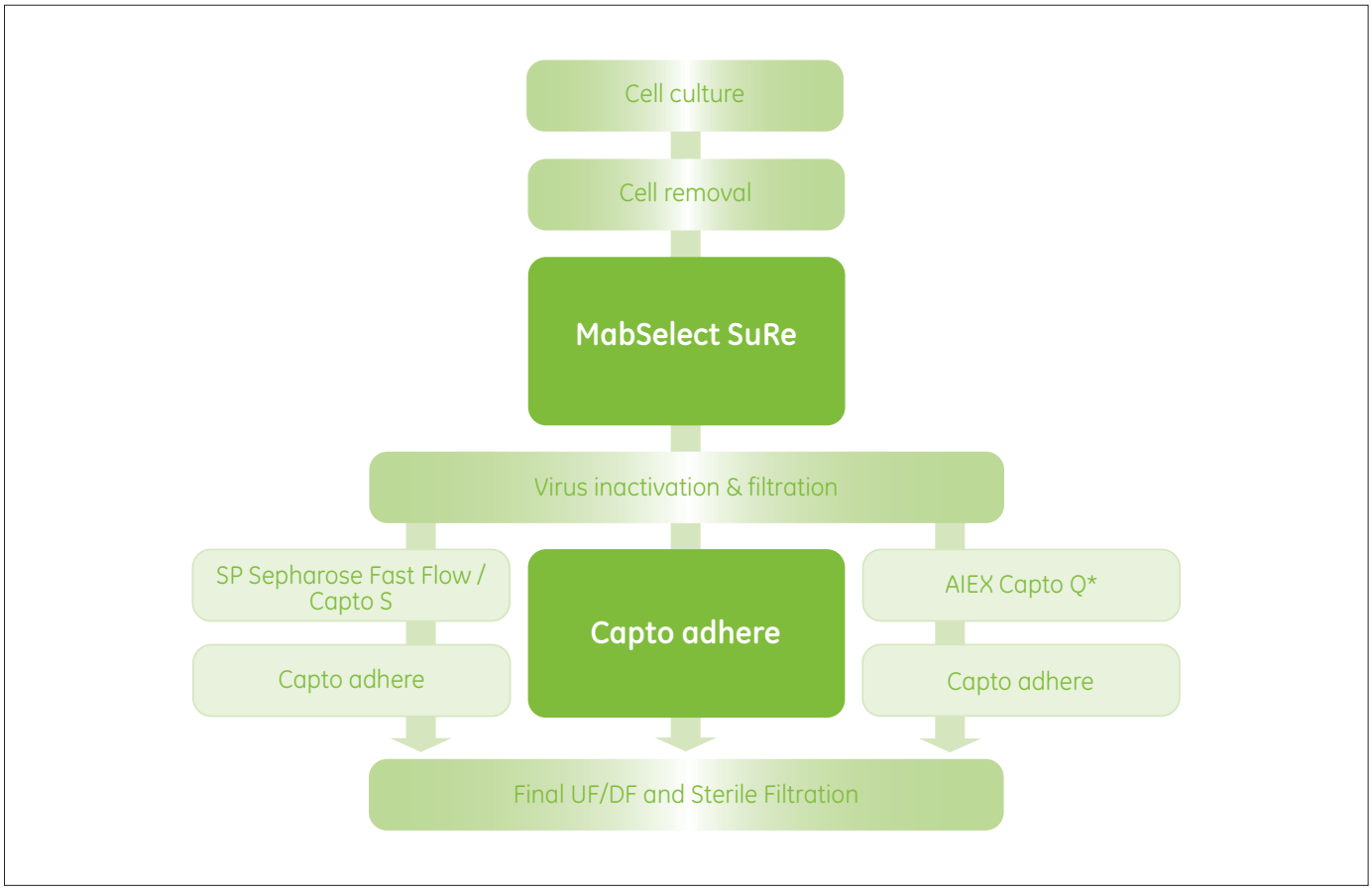
The GE Healthcare chromatography media toolbox for MAb purification simplifies this process.

MabSelect SuRe, characterized by alkaline stability, enhanced protease resistance, and a generic elution profile, is used for the initial Protein A capture step.

The new medium of choice for polishing is Capto adhere. Capto adhere is a strong, multimodal anion exchanger that offers a different selectivity relative to traditional ion exchangers. Capto adhere selectively removes leaked Protein A, aggregates, host cell proteins, nucleic acids, and viruses when run in flow-through mode.

With Capto adhere, the two post-Protein A steps can be replaced by a single polishing step, thereby reducing the overall MAb purification process from three steps to two. If needed, Capto adhere can also be used in combination with Capto Q in a three-step process. An alternative intermediate step is cation exchange chromatography using Capto S for high capacity, or SP Sepharose Fast Flow for high resolution.

» For more information, see page 78.



The GE Healthcare chromatography media toolbox.
*(WO 2004/076485, Lonza)

PreDictor 96-well filter plates New

PreDictor 96-well filter plates are prefilled with GE Healthcare BioProcess chromatography media. PreDictor plates support high-throughput process development (HTPD) by allowing parallel screening of chromatographic conditions, either in a manual or in an automated workflow. Data generated by using PreDictor plates show good correlation with data obtained in chromatography columns, making the plates an excellent tool for initial screening of process conditions.

Using PreDictor plates shortens time-to-clinic and increases productivity in the process development lab by:

- Reduced experimental time: the time-scale for performing screening experiments can be reduced from weeks to hours
- Low sample consumption: new format significantly reduces sample consumption
- Increased process understanding: the enlarged experimental space allows for a significant increase in process understanding

›› For more information, see page 126.

HiScreen columns New

HiScreen columns are part of the process development platform available from GE Healthcare. The columns are prepacked with a range of BioProcess media and designed for method optimization and parameter screening. HiScreen columns have small bed volumes (4.7 ml) reducing the cost of sample and buffer consumption. The media used in HiScreen columns are also available in other column formats and as bulk packs for purification at scales, from development and pilot studies to routine production.

HiScreen columns include a number of benefits:

- Prepacked columns with thirteen different BioProcess media for convenient process development
- Excellent for method optimization and parameter screening due to the 10 cm bed height
- Easily connected in series to achieve 20 cm bed height
- Small bed volume for fast results with minimal sample and buffer consumption
- Reproducible results and scalable to BioProcess columns

›› For more information on HiScreen columns, see page 127.

Multimodal chromatography

Multimodal separations are based on different types of interactions that are dependent on the characteristics of the multimodal ligand as well as the process conditions.

›› For more information on Multimodal chromatography, see pages 76–79.

GE Healthcare's line of multimodal ion exchangers is based on two main types of interaction:

1) selective reversible adsorption of charged molecules to an immobilized multimodal ion exchange group of opposite charge with hydrophobic character, and
2) hydrophobic, together with aromatic and thiophilic interactions.

Media containing multimodal ligands are characterized by interactions that are different from those of "traditional" ligands and have in many cases been designed for a specific purpose. GE Healthcare's multimodal ligands also offer new selectivities that may be beneficial to other purification challenges where more traditional ligands do not offer the required selectivity.

GE Healthcare's line of multimodal chromatography media includes:

Capto MMC, a weak, multimodal cation exchanger offering:

- High capacity at high conductivity
- High productivity
- New selectivity

Capto adhere, a strong multimodal anion exchanger characterized by:

- High capacity and productivity
- Removal of contaminants after a Protein A capture step
- Allows for a two-step purification process of monoclonal antibodies

PlasmidSelect Xtra, which combines an agarose base matrix technology with a multimodal ligand designed for selective separation between supercoiled plasmid DNA and open circular plasmid DNA.

PlasmidSelect Xtra allows plasmid DNA purification that is:

- Flexible
- Easily scalable
- Robust
- Cost efficient

PlasmidSelect Xtra forms the basis of a generic process for purifying supercoiled circular DNA suitable for bulk to clinical-grade applications. The process provides high capacity, delivers high yields, and can be scaled up to fulfill requirements for economical, industrial manufacturing of plasmid DNA in highly regulated environments.

AxiChrom columns New

AxiChrom columns simplify column handling procedures from process development to production. Packing is facilitated by the Intelligent Packing methodology, whereby optimal compression of the bed is achieved through preprogrammed, verified packing methods. Maintenance is also simplified: AxiChrom 50 and 70 columns have a pivot stand that allows the user to empty the column by simply tilting, eliminating heavy lifting and providing easy access to bed supports and o-rings.

For AxiChrom 400 columns and larger, the swing-out tube design gives quick access to the bottom bed support and enables maintenance to be done *in situ*. Interactive guidance from the AxiChrom Master assists users through key process steps.

The AxiChrom column platform features:

Intelligent Packing: Verified, pre-programmed packing methods that save time and assure accurate and reproducible packing results.

Intuitive handling: Simple operation and servicing. Pivot or swing-out column tubes are safer and easy to handle. AxiChrom Master guides users through process steps to reduce time in method creation, set-up and maintenance.

Predictable scale-up: Straightforward scale-up and tech-transfer due to a distribution system designed using the same analytical and CFD modeling tools. Sanitizable columns with full technical and regulatory support.

» For more information, see page 92.

» During 2008, the range of AxiChrom columns will be expanded to include a range of larger sizes.

Media Wand New

Media Wand, together with the Media Handling Unit, is a versatile tool that saves time and effort with a wide range of media handling tasks. The Media Wand is robust, easy to use, and designed for removal of supernatant, addition of water or buffer, creation of homogenous media slurries in shipping containers, and transfer of media to slurry tanks. Media Wand eliminates the need for cumbersome and time-consuming tasks that frequently arise during column packing or when handling large volumes of media.

Media Wand allows:

- Simplified removal of transport solutions from media containers
- Addition of buffers for preparation of media slurry in media containers
- Simple transfer of media slurry to a slurry tank

» For more information, see page 113.

ÄKTAprocess system

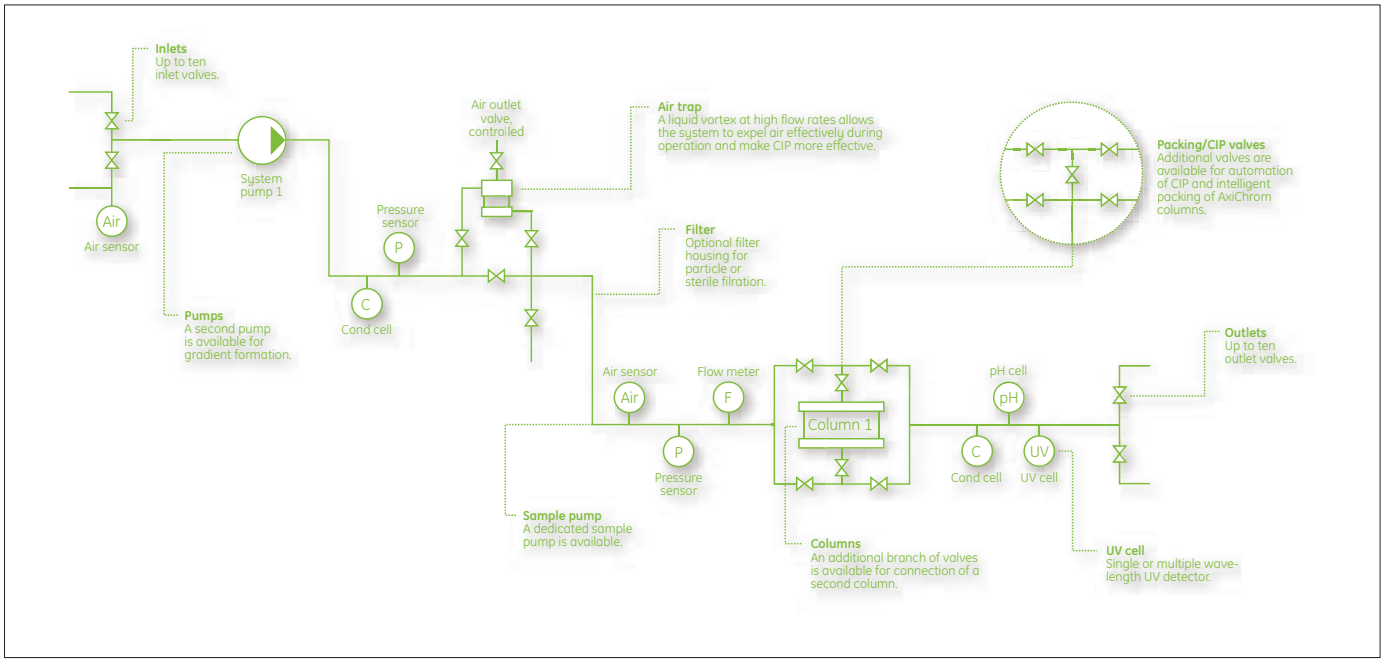
ÄKTAprocess is a chromatography system platform with thousands of configuration possibilities. To meet specific process demands, the system is customizable with variable construction materials, flow rate ranges, additional valves, pumps, and other instrumentation. The flexibility of the system extends to post-purchase modification, which allows a system to be reassigned to other processes, thereby increasing the versatility and working life of the system. The compact design with a built-in computer allows the system to fit neatly into an existing plant.

Security is an integral part of ÄKTAprocess. The materials used are all USP Class VI and are traceable to their original production batches. The system control unit, CU 960, allows process operation even if communication with the system computer is lost due to physical or operating system faults.

System highlights include:

- Versatile user configuration with UNICORN control
- Post-purchase configuration increasing usability and lifespan
- Full regulatory documentation with USP Class VI materials
- Now available with one-inch tubing

›› For more information, see page 116.



The liquid flow path.

ÄKTAcrossflow system

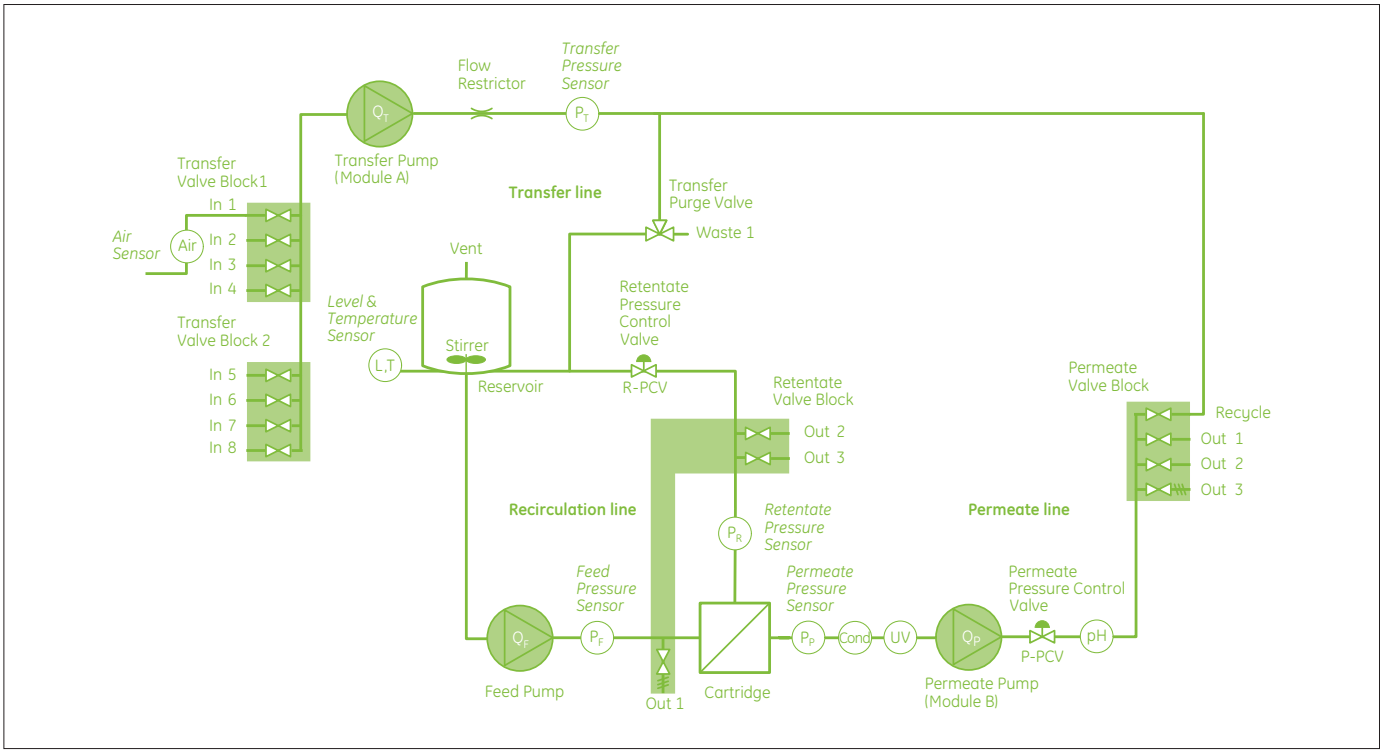
ÄKTAcrossflow is the first fully automated system for cross flow filtration process development and is well-suited for filter screening and process optimization at small-scale. UNICORN software combines intelligent control with ease of use to allow consistent simulation of large-scale conditions and provide data for comprehensive analysis of results.

The system is built with ÄKTAdesign components for reliability, scalability, and flexibility. ÄKTAcrossflow comes complete with UV, pH, and conductivity monitors, as well as air, pressure, and temperature sensors. The valves and fittings are specially developed for hygienic, leak-free operation. Electrically actuated diaphragm valves diminish hold up volumes and prevent dead volumes.

System highlights include:

- Broad application range covering ultrafiltration and microfiltration
- Flexible operation of hollow fiber cartridges or cross flow cassettes
- Thorough and efficient process development with full TMP Trans Membrane Protein and flux scouting

›› For more information, see page 163.



The ÄKTAcrossflow flowscheme.

GrandStand pilot/process systems New

The GrandStand pilot/process system is designed for biological separations at scales from 50 to 10 000 liters. The system accommodates ultrafiltration and microfiltration hollow fiber cartridges or flat sheet cassettes. The GrandStand system is capable of concentration and/or diafiltration. The system is cart-mounted and has a narrow profile, allowing for easy movement between lab, cold room, and manufacturing areas.

The GrandStand pilot/process system is designed around modularity and versatility – the basic system can easily be upgraded with a range of additional modules, providing enhanced flexibility to meet the needs of process development and manufacturing groups.

GrandStand is also backed with IQ/OQ and onsite assembly service options.

›› For more information on GrandStand pilot/process systems, see pages 169.

ULTA Pure SG New

ULTA Pure SG utilizes the unique properties of a patented microbially retentive membrane to provide sterilizing grade filtration. The asymmetrical pore structure with a high voids volume, which offers high dirt holding capacity, results in higher throughputs and higher flow rates than symmetrical membranes.

Typical applications

- Liquid column guard filters for reducing bioburden and prefiltering upstream solutions.

›› For more information, see page 173.

ULTA Pure HC New

ULTA Pure HC capsules and cartridges have been specifically designed to extend the throughput of a traditional sterilizing grade filter through the incorporation of an integral PES pre-filter layer. ULTA Pure HC cartridge filters are high capacity and fast flowing.

Typical applications

- Liquid filter cartridges for clarifying, stabilizing, and reducing bioburden in aqueous solutions, media, and biologicals.

›› For more information, see page 174.

Label-free interaction analysis

New

Biacore systems enable comprehensive, label-free characterization of binding events, giving unique insights into how proteins and other biomolecules interact. Analyses utilizing Biacore systems provide a wealth of information including binding kinetics, affinity, specificity, thermodynamics, and concentration. A wide range of molecules, from proteins to low molecular weight compounds, can by characterized according to binding properties.

The integration of Biacore's protein interaction analysis systems into the product portfolio of GE Healthcare creates a center of excellence that offers a wide range of solutions to life sciences research, including novel insights into disease mechanisms, development and production of therapeutics, detection and characterization of immune responses, and purification and characterization of protein therapeutics.

Biacore systems are designed to meet the high demands for quality, performance, and regulatory compliance needed for research, drug discovery and development, manufacturing, and quality control.

Biacore T100

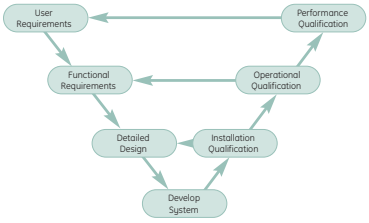
- Versatile, multi-application interaction analysis
- Software Wizard for simplified analysis

Biacore C

- Designed for concentration analysis
- For GLP/GMP regulated working processes

Biacore G × P Services

- Validation to meet G × P (GLP, GCP, GMP) regulations
- 21 CFR Part 11 compliance



›› For more information, see page 188.

Fast Trak BioPharma Services

Fast Trak BioPharma Services provides practical support and advice to those developing biotech products, especially biopharmaceuticals. GE Healthcare experts plus a network of external specialists help you plan, implement, and document downstream purification from start-up to routine production.

›› For more information on our IQ/OQ and other validation services, please see page 198.

Fast Trak courses

Fast Trak Courses help educate and train your personnel in downstream processing. In addition to traditional hands-on courses and laboratory exercises, GE Healthcare now introduces online training.

All course programs undergo continuous improvement. For example, the MAB1 course now includes extensive practical work, and a new UNICORN class for ÄKTAcrossflow has been introduced (SYS3). Successful completion of a course includes formal Training Certification in the particular subject.

New

WAV1
Theory, Setup and Operation of the single-use WAVE Bioreactor

A two-day practical course providing theoretical and technical background knowledge as well as hands-on experience on the operation and optimum performance of the WAVE Bioreactor and related WAVE equipment.

›› For more information, see page 201.
›› For the latest information about our online and standard courses, visit www.gelifesciences.com/fasttrak

New

Fast Trak Center in India

Fast Trak services are available from GE Healthcare Fast Trak Centers in North America, Europe and Asia. Our latest addition strengthens our presence in the rapidly expanding Indian sub-continent.

Fast Trak Center Bangalore India

GE Healthcare Life Sciences
John F. Welch Technology Center
122, EPIP, Whitefield
Bangalore 560 066, India

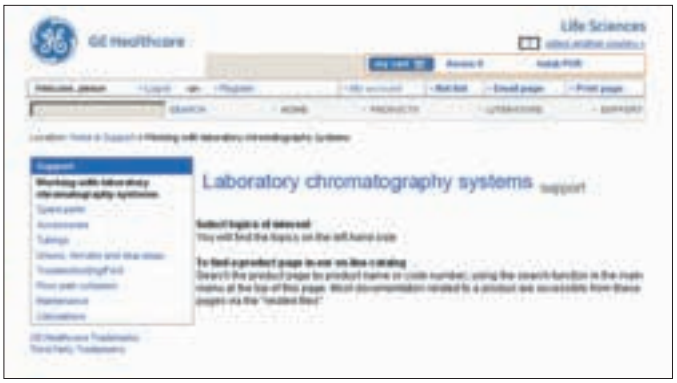
Email: fasttrakindia@ge.com
T: +91 80 2527 9538
F: +91 80 2526 8423

Technical support online

Users of GE Healthcare´s columns and systems may need quick and easy access to information regarding their equipment. To meet these needs GE Healthcare has developed an efficient and enhanced support site on the internet.

From its initial focus on standard process-scale columns and systems, the site has expanded to cover laboratory-scale equipment as well.

›› For more information, see page 205.



The technical support site gives quick access to detailed information regarding:

- ÄKTAdesign selection guide, flow paths and kits
- Columns and system spare parts plus accessories
- Technical specifications
- Packing and testing columns
- Columns and system recommendations
- Maintenance, troubleshooting and FAQ
- Certificates of Analysis for chemical products

System and column support

Installation and validation

Dedicated large-scale system and column support services are now available. They range from having GE Healthcare BioProcess service engineers deliver and assemble your system, perform installation tests, and prepare it for operation, to help with certifying the system and its operation with IQ/OQ services. We can also certify upgrades to systems or UNICORN software.

Spare parts

Spare parts are not neglected. To help minimize downtime, we can provide a list of essential parts to keep on site. Holding a guaranteed stock of critical components on your behalf and, for a monthly fee, delivering any designated part according to an agreed time frame, is also part of the service.

Service agreements

Service agreements for BioProcess systems and large-scale columns include comprehensive preventive maintenance scheduled according to requirements, parts support, engineer labor and travel costs, and guaranteed on-site response.

›› For more information, see page 206.

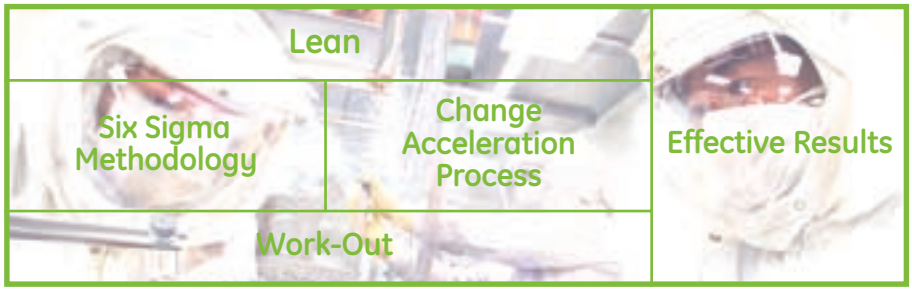
Life Science Performance Solutions New

Building on decades of expertise, GE Healthcare's Life Science Performance Solutions team provides a range of consulting services all aimed at driving and sustaining organizational changes and improvements.

›› For further details on Life Science Performance Solutions, see page 203.

We apply a range of solutions including:

- GE Lean Workflow Improvement
- GE Management and Leadership Systems
- Lean Six Sigma training



Customized programs can also be created to help reach specific performance goals.

Scientific Asset Services New

Pharmaceutical and biotech companies face many challenges today, such as higher operational costs, regulatory pressures, and shrinking profit margins. For corporations, it is critical to reduce costs while improving scientific productivity. To help with these challenges, GE Healthcare offers an array of services, including the Scientific Asset Services asset management program, Performance Solutions, LEAN Six-Sigma, Fast Trak process development and facility validation services.

›› For more information on how GE Healthcare Scientific Asset Services can help your company, visit www.gelifesciences.com/sas

Scientific Asset Services (SAS) is helping leading companies around the world meet the challenges of controlling costs and improving productivity in a difficult business environment.

Our SAS program can help companies:

- Reduce operating costs by up to 20% through the implementation of an asset management program
- Deploy on-site service engineers to improve instrument uptime and output
- Apply LEAN Six-Sigma to operations to enhance productivity
- Remove administrative tasks from your scientists to allow increased scientific productivity
- Gain access to innovative financing solutions

Cell preparation and processing

Building on over 30 years experience in the field, GE Healthcare supports cell-based research and therapy by providing quality tools that facilitate the preparation, processing, and storage of blood-derived cells.

Ficoll-Paque PREMIUM 1.084 and Ficoll-Paque PREMIUM 1.073

New

Ficoll-Paque PREMIUM 1.084 and Ficoll-Paque PREMIUM 1.073 are complementary products to Ficoll-Paque PREMIUM density gradient medium. Manufactured according to the same GMP and ISO 13485:2003 standards as the original Ficoll-Paque PREMIUM product, they have densities of 1.084 and 1.073 g/ml respectively.

Ficoll-Paque PREMIUM 1.084
For isolating a broad range of human mononuclear cells including those of higher density as well as mouse mononuclear cells.

Ficoll-Paque PREMIUM 1.073
For isolation of lower-density human mononuclear cells.

›› For more information, see page 180.

Announcement

GE Healthcare

Plasma Product Biotechnology Meeting 2009

MEETING

Sixth International Meeting
Insotel Club Punta Prima
Menorca, Spain
May 11–15, 2009

For program developments, visit *www.bo-conf.com/ppb09*

imagination at work

Session
Manufacturing
Clinical and Medical Developments
New Approaches to Quality
Pathogen Safety Issues
Innovations in Plasma Processing
New Products
Keynote lecture
Focus lecture

The sixth Plasma Product Biotechnology Meeting is jointly sponsored by CSL Ltd, Melbourne, Australia and GE Healthcare, Uppsala, Sweden.

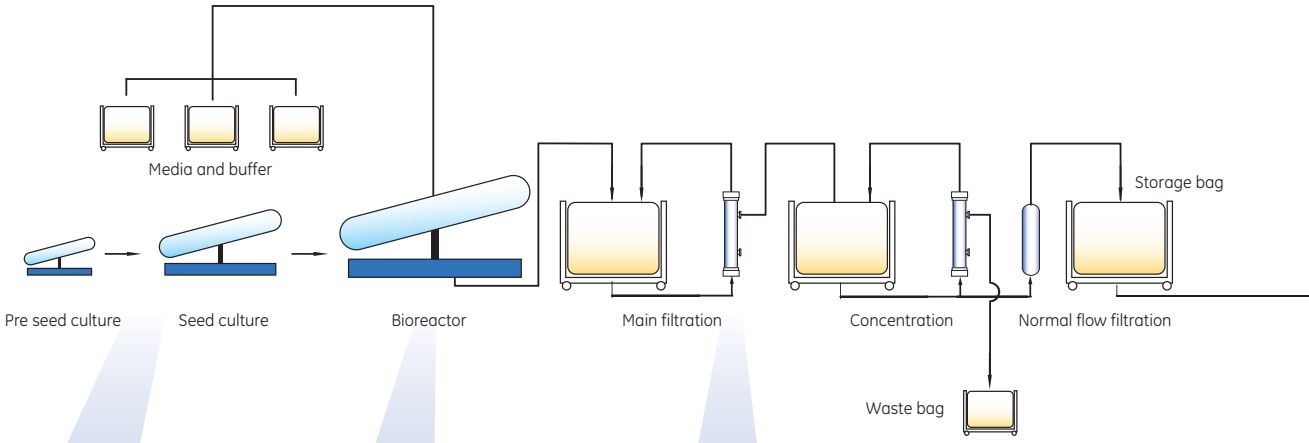
3

ReadyToProcess

New

ReadyToProcess Platform

ReadyToProcess WAVE Bioreactor systems, mixers, and associated devices are an integral part of the ReadyToProcess platform. ReadyToProcess products have features that effectively eliminate the need to clean, sterilize, or validate multiple-use systems in the manufacturing process. ReadyToProcess products are designed to enable Lean and responsive biopharmaceutical development and production with assured safety and cost-efficiency. From cell culture and fermentation to purification, ReadyToProcess allows for faster processing and simpler operations.



Bioreactor feed and media filtration

ReadyToProcess ULTA Cap SG/HC capsules

Bioreactor

WAVE Bioreactor for scalable, single-use operations

Cell liquid clarification filtration

ReadyToProcess Hollow fiber micro- and ultrafiltration cartridges

Connectivity

ReadyMate Disposable Aseptic Connector

Applications

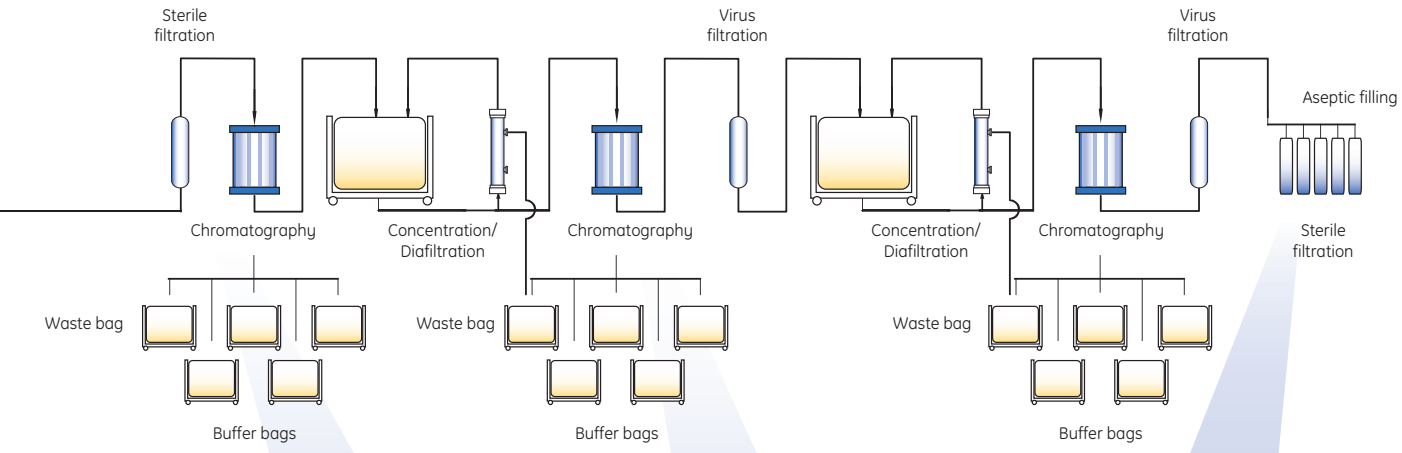
Typical applications of ReadyToProcess products include:

- Aseptic clarification and purification of vaccines, monoclonal antibodies, recombinant proteins, and plasmids
- Aseptic cell processing
- Environments where terminal sterilization is not feasible
- Preclinical through Phase II clinical trials
- Fast-track drug development processes

Lean Manufacturing

The ReadyToProcess line of products simplifies and accelerates bioprocessing, reducing investment and shortening development time. They also help reduce wasteful practices, increasing manufacturing agility and opening doors to new business opportunities.

» Visit us on the web at www.gelifesciences.com/readytoprocess



Column protection

ReadyToProcess ULTA Cap SG/HC capsules

Chromatography

ReadyToProcess chromatography columns and ÄKTAready system

Final fill filtration

ReadyToProcess ULTA Cap SG/HC capsules

New

ReadyToProcess WAVE systems

The WAVE Bioreactor is an effective, cost-efficient device for cell culture. Culture medium and cells contact only a presterile, disposable chamber that is positioned on a special rocking platform. The rocking motion of the platform induces waves in the culture fluid and thereby provides continual mixing and oxygen transfer, resulting in a robust environment for cell growth. The Bioreactor requires no cleaning or sterilization, providing ease of operation and protection against cross-contamination.

›› Visit us on the web at www.gelifesciences.com/wave

*Cell Culture Bag in Switzerland.

Features/benefits of the WAVE Bioreactors include:

- Single-use – eliminating cross-contamination and the need for cleaning and validation
- Closed system – Cellbag* bioreactors, including fittings and filters, are delivered sterile and ready for use
- Validated – suitable for use in cGMP production
- Multiple configurations – specifically designed for suspension, microcarrier, batch, fed-batch, or perfusion culture
- Scalability – WAVE Bioreactors are scaleable over a wide volume range from 50 ml up to 500 l

Applications

Monoclonal antibodies

The WAVE Bioreactor has been used extensively for monoclonal antibody production. Culture can be started at low volume and then fresh media added whenever the cell count is sufficiently high. This enables inoculum scale-up without transfers. Batches ranging from 100 ml to 580 l have been run with cell densities over 10×10^6 cells/ml and productivity and product quality comparable to stirred tank bioreactors. Dissolved oxygen concentrations are not limiting and remain above 50% saturation.

Anchorage-dependent cells

Agitation in the WAVE Bioreactor is powerful enough to mix and aerate the culture, yet it is gentle enough to cultivate anchorage-dependent cells on various microcarriers. The wave motion prevents settling and provides oxygenation without bubbles.

Virus production

The WAVE Bioreactor provides a closed system that is ideal for virus production. In a gene therapy application, human 293 cells have been grown in suspension and then infected with recombinant adenovirus. Cells grew to 4×10^6 cells/ml and virus production was 100 000 virus particles/cell. The WAVE Bioreactor produces viruses under complete containment without the need for a biosafety cabinet.

cGMP production

WAVE Bioreactors are in use in cGMP applications producing inoculum for large conventional bioreactors, and also for clinical and commercial production of human therapeutics. Reduced cleaning and validation requirements make this an ideal system for cGMP applications.

Insect cell/baculovirus

The high oxygen supply capability of the WAVE Bioreactor makes it ideal for insect cell culture. Cell densities over 9×10^6 cells/ml are routinely achieved. Baculovirus yields are higher than with conventional bioreactors. The WAVE Bioreactor System is extremely easy to operate and inoculum scale-up and infection can be done inside the bioreactor, reducing the need for transfers.

Custom uses

The WAVE Bioreactor has many other uses, such as keeping in-process inoculum pools agitated and aerated prior to use; bead-to-bead transfer; thawing, and media mixing. Custom Cellbags can be provided for the WAVE Bioreactor for any working volume between 100 ml and 500 l.

Selection guide – Systems

Culture volume	Cellbag*	WAVE Bioreactor
50 to 250 ml	Cellbag-500 ml	System 2/10
50 to 500 ml	Cellbag-1 l	System 2/10
100 to 1000 ml	Cellbag-2 l	System 2/10; System 20/50 + Kit 20
500 ml to 5 l	Cellbag-10 l	System 2/10; System 20/50 + Kit 20
1 to 10 l	Cellbag-20 l	System 20/50 + Kit 20
1 to 10 l	Cellbag-22 l	System 20/50 + Kit 50
5 to 25 l	Cellbag-50 l	System 20/50 + Kit 50
5 to 50 l	Cellbag-100 l	System 200
10 to 100 l	Cellbag-200 l	System 200
50 to 250 l	Cellbag-500 l	System 500/1000 + Kit 500EH
100 to 500 l	Cellbag-1000 l	System 500/1000 + Kit 1000EH

*Cell Culture Bag in Switzerland.

» For information on Cellbags for use with WAVE systems, see page 48.

Selection guide – Instrumentation options

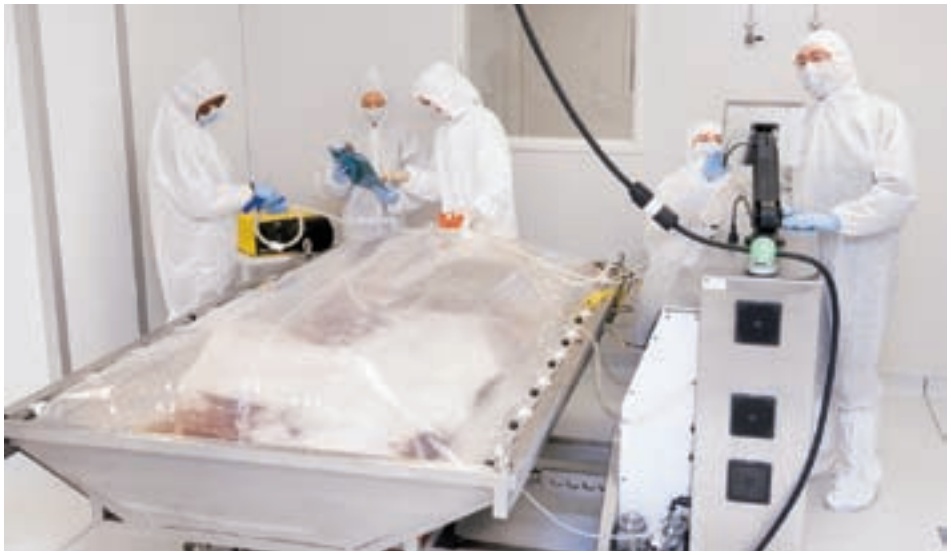
Module[1]	Description
CO_2 /Air Mix Plug-in Controller	• Infrared CO_2 sensor and aeration system provides a continuous supply of CO_2 conditioned air to the Cellbag • Range: 0% to 15% CO_2
Dissolved Oxygen Optical Monitor	• Monitor with miniature fiber-optic microprobes enabling real-time measurement of dissolved oxygen • High accuracy PMT optical detector with phase shift measurement • Range: 0% to 250% saturation with autozero • Reusable DOOPT-PROBE purchased separately
O_2/Air Mix Plug-in Controller	• Provides continuous supply of O_2 enriched gas to the Cellbag for insect cell, virus, and high cell density applications. • Maintains low-oxygen environment for near-anaerobic applications • Range 0% to 50% O_2
pH Controller	• Enables continuous pH measurement and control using CO_2 or acid/base addition. • Electrochemical probe is single use, and available pre-installed in Cellbags.
Loadcell[2]	• Enables online measurement of weight. • Used for automated fill/harvest and perfusion operations where precise volume control is critical.
Perfusion Controller[3]	• Perfusion controller with Loadcell

[1] Instrument Modules are available in WAVEPOD or as stand-alone units for System 2/10 and System 20/50. Fully integrated modules are available for System 200 and System 500/1000.
[2] Fully integrated in System20/50 (option); System200 and System500/1000 (standard).
[3] For System 2/10 instrument only.

Overview – Systems				
Unit	**System 500/1000[2,3]**	**System 200[2]**	**System 20/50[1]**	**System 2/10**
Working volume range	50 to 500 l	5 to 100 l	0.1 to 25 l	0.1 to 5 l
Integral features	• Speed/angle control • Temperature control • Aeration • Loadcell	• Speed/angle control • Temperature control • Aeration • Loadcell	• Speed/angle control • Temperature control • Aeration	• Speed/angle control • Temperature control • Aeration
Options	• CO2MIX • O2MIX • DO • pH	• CO2MIX • O2MIX • DO • pH • Dual air/temperature	• WAVEPOD • CO2MIX • O2MIX • DO • pH • Loadcell • Dual air/temperature	• CO2MIX • O2MIX • DO • pH • Perfusion controller
Weight	**with Kit 500EH:** 925 kg **with Kit 1000EH:** 1020 kg	350 kg	15.5 kg	4.2 kg
Dimensions	201 × 124 × 160 cm **with Kit 500EH:** 226 × 124 × 160 cm **with Kit 1000EH:** 226 × 231 × 160 cm	185 × 110 × 112 cm For installation, if required, unit can be tilted	573 × 465 × 179 mm **with Kit 20:** 711 × 575 × 254 mm **with Kit 50:** 775 × 700 × 254 mm	489 × 330 × 200 mm
Power	• 200 to 240 VAC • 50/60 Hz, 30 A • 3-Phase • Phase-phase ± 5% • NEMA L2130 plug	• 200 to 240 VAC • 50/60 Hz, 15 A • 3-phase • Phase-phase ± 5% • NEMA L2130 plug	• 100/240 VAC • 50/60Hz, 6/3 A	110/220 VAC

[1] System 20/50 requires selection of Kit 20 or Kit 50.
[2] Unit provided with casters.
[3] System 500/1000 requires selection of Kit 500 or Kit 1000.

All BASE units are CE/CSA certified.



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WAVE Bioreactor System 500/1000

New

The WAVE Bioreactor System 500/1000 is designed for R&D, process development, and cGMP production use. The system is self-contained with integrated temperature control, aeration pump, and rocking controller for use with working culture volumes between 50 and 500 liters.

Features of the system include:

- Stainless steel construction with linear motor rocking system
- Integrated temperature controller
- Integrated Loadcell with adjustable color touchpanel operator interface
- Aeration controller

Ordering information

Product	Quantity	Code No.
SYSTEM1000EH with DO	1	28-4115-46
SYSTEM1000EH with CO_2, O_2, DO, PH, ANALOG	1	28-4115-59
SYSTEM1000EH with O_2, DO, ANALOG	1	28-4115-60
SYSTEM1000EH with CO_2, O_2, DO, PH	1	28-4115-61
SYSTEM1000EH with O_2, DO	1	28-4115-62
SYSTEM1000EH with CO_2, PH	1	28-4115-63
Kit 500EH for Base 500/1000EH[1] (includes HOLDER500 and HEATERPAD500)	1	28-4115-31
Kit 1000EH for Base 500/1000EH[2] (includes HOLDER1000 and HEATERPAD1000)	1	28-4115-32

Key
CO_2 = CO_2-air gas mix controller, O_2 = O_2-air gas mix controller, DO = Dissolved oxygen monitor (optical), PH = pH controller, ANALOG = Analog output card

[1] Accomodates 1 × 500 l Cellbag* only.
[2] Accomodates 1 × 1000 l Cellbag only.

Technical specifications

Base Dimensions	• 201 × 124 × 160 cm
With Kit 500EH installed	• 226 × 124 × 160 cm
With Kit 1000EH installed	• 226 × 231 × 160 cm
Power	• 200–240 VAC
	• 50/60 Hz
	• 30 A
	• 3-phase operation
	• Phase–phase ± 5%
	• NEMA L2130 plug
Weight	
With Kit 500EH	• 925 kg
With Kit 1000EH	• 1020 kg

» For information on Cellbags for use with WAVE 500/1000 systems, see page 48.

» Visit us on the web at www.gelifesciences.com/wave

*Cell Culture Bag in Switzerland.

WAVE Bioreactor System 200

New

Ordering information

Product	Quantity	Code No.
SYSTEM200EHDual with DualTemp, DualAir	1	28-9366-86
SYSTEM200EHDual with CO_2	1	28-4126-02
SYSTEM200EHDual with CO_2, ANALOG	1	28-4115-45
SYSTEM200EHDual with CO_2, DO, PH	1	28-4115-49
SYSTEM200EHDual with CO_2, O_2, DO	1	28-4115-47
SYSTEM200EHDual with CO_2, O_2, DO, PH	1	28-4115-48
SYSTEM200EHDual with CO_2, O_2, ANALOG	1	28-4115-44
SYSTEM200EHDual with CO_2, O_2, DO, ANALOG	1	28-4115-43
SYSTEM200EH with CO_2	1	28-4115-57
SYSTEM200EH with CO_2, O_2	1	28-4115-55
SYSTEM200EH with CO_2, PH	1	28-4126-29
SYSTEM200EH with CO_2, DO, PH	1	28-4115-56
SYSTEM200EH with CO_2, ANALOG	1	28-4125-89
SYSTEM200EH with CO_2, O_2, ANALOG	1	28-4115-52
SYSTEM200EH with CO_2, O_2, DO, PH	1	28-4115-54
SYSTEM200EH with CO_2, O_2, DO, PH, ANALOG	1	28-4115-50
SYSTEM200EH with CO_2, O_2, DO, ANALOG	1	28-4115-51
SYSTEM200EH with O_2, DO, PH	1	28-4115-58
SYSTEM200EH with O_2, DO, ANALOG	1	28-4115-53

Key
CO_2 = CO_2-air gas mix controller, O_2 = O_2-air gas mix controller, DO = Dissolved oxygen monitor (optical), PH = pH controller, ANALOG = Analog output card

Designed for R&D and cGMP production use, the WAVE Bioreactor 200 is a self-contained system with integrated temperature control, aeration pump, and rocking controller for use with working culture volumes between 5 and 100 l.

Features include:

- Stainless steel construction with fully gasketed chamber and linear motor rocking control system
- Integrated heaterpad with temperature controller
- Integrated loadcell
- Adjustable color touch panel operator interface
- Aeration controller
- Dual Cellbag* controller systems available

*Cell Culture Bag in Switzerland.

Technical specifications

Dual control	• Requires second set of gas mixers and instrumentation if desired
Base Dimensions	• 185 × 110 × 112 cm
Weight	• 350 Kg
Power	• 200–240 VAC • 50/60 Hz, 15 A • 3-phase operation • Phase–Phase ± 5% • NEMA L2130 plug

» For information on Cellbags for use with WAVE 200 systems, see page 48.

» Visit us on the web at www.gelifesciences.com/wave

WAVE Bioreactor System 20/50

New

WAVE Bioreactor System 20/50 is a versatile, modular system designed for R&D and production use. It consists of a base unit with various options suitable for culture of multiple cell lines.

The WAVE Bioreactor System 20/50 has an extensive line of instrumentation, including weight controllers for perfusion culture, dissolved oxygen amplifiers, and pH controllers. These are available in integrated WAVEPOD configuations or as stand alone options. For benchtop operation, covering the Cellbag* with a lid is recommended. A filter heater for the exhaust filter is strongly recommended otherwise water will condense in the filter and may lead to clogging and overpressure in the bag.

*Cell Culture Bag in Switzerland.

Technical specifications

20/50EHT Electric Model

Dimensions	• BASE20/50EHT: 573 × 465 × 179 mm • With KIT 20EHT: 711 × 575 × 254 mm • With KIT 50EHT: 775 × 700 × 254 mm (for Loadcell models, add 32 mm to height dimension)
Weight (base only)	• 16 kg
Environmental	• Operating conditions: 0°C to 50°C. < 95% rh, non-condensing • Storage conditions: -40°C to +80°C
Power	• 100/240 VAC 6/3 A 50/60 Hz (user selected) • Fuse: 20 × 10 A (Slow blow, long time lag)
Additional configurations	• Dual bag temperature and aeration controls (20/50EHTD) • Integral CO_2 controller (20/50EHT-CO2) • Integral O_2 controller (20/50EHT-O2) • Integral Loadcell Module (all "L" models)
Options	• Optional data acquisition and PC monitor interface (PCDAQ) • Optional RS485/Ethernet (ETHERNET485)

Ordering information

Product	Quantity	Code No.
Electric Rocker Base for 20/50EHT	1	28-4115-08
Electric Rocker Base for 20/50EHT with Loadcell module installed	1	28-4115-10
Electric Rocker Base for 20/50EHT dual-sided air/dual temperature model	1	28-4115-12
Electric Rocker Base for 20/50EHT dual-sided air/dual temperature model with Loadcell module installed	1	28-4115-14
Electric Rocker Base for 20/50EHT (includes CO2MIX20 for mammalian cell culture)	1	28-4115-16
Electric Rocker Base for 20/50EHT (includes CO2MIX20 for mammalian cell culture with Loadcell module installed)	1	28-4115-18
Electric Rocker Base for 20/50EHT (includes O2MIX20 for insect cell culture)	1	28-4115-20
Electric Rocker Base for 20/50EHT (includes O2MIX20 for insect cell culture with Loadcell module installed)	1	28-4115-22
Kit 20EHT[1] for BASE20/50EHT units (includes mounting plate + HOLDER20T + HEATERPAD20 + SRTDX temperature probe)	1	28-4115-26
Kit 20EHTD[1] for BASE20/50EHTD units Dual version (includes mounting plate + HOLDER20T + HEATERPAD20 + SRTDX temperature probe)	1	28-4115-27
Kit 50EHT[2] for BASE20/50EHT units (includes mounting plate + HOLDER50T + HEATERPAD50 + SRTDX temperature probe(s)	1	28-4115-28
Kit 50EHTD[2] for BASE20/50EHTD units Dual version (includes mounting plate + HOLDER50T + HEATERPAD50 + SRTDX temperature probe(s)	1	28-4115-30
Protective rigid, clear PVC lid for use with KIT 20 series	1	28-4115-34
Protective rigid, white PVC lid for use with KIT 20 series (opaque version for light-sensitive applications)	1	28-4115-35
Protective rigid, clear PVC lid for use with KIT 50 series	1	28-4115-37
Protective rigid, white PVC lid for use with KIT 50 series (opaque version for light-sensitive applications)	1	28-4115-38
Electric exhaust filter heater, 5 VDC, 4 W. LED indicator	1	28-4116-39

[1] Accommodates 1 × 20 l, 2 × 10 l, 2 × 2 l, Cellbags.
[2] Accommodates 1 × 50 l or 2 × 22 l Cellbags.

» For information on Cellbags for use with WAVE 20/50 systems, see page 48.

WAVE Bioreactor System 2/10

New

WAVE Bioreactor System 2/10 is for use with working culture volumes between of 100 ml and 5 l. This compact unit is ideal for animal, insect, and plant cell cultures, and includes features such as aeration, heating, and temperature control.

Features of the WAVE Bioreactor System 2/10 include:

- Cellbag* holder
- LCD display and control interface
- Integral airpump with mass flow meter
- Temperature control with heater and sensor

*Cell Culture Bag in Switzerland.

Ordering information

Product	Quantity	Code No.
WAVE Bioreactor System 2/10EH (includes Cellbag Holder)	1	28-4115-00
System 2/10 Perfusion Controller for use with Cellbag2L/P only (includes two Watson-Marlow pumps for feed and harvest)	1	28-4116-35
System 2/10 Perfusion Controller for use with Cellbag2L/P only (includes two pinch valves for feed and harvest)	1	28-4116-36
Protective white opaque PVC lid for use with BASE2/10EH	1	28-4115-33

Technical specifications

Performance	• Adjustable rock rate 3 to 40 rocks/min • Adjustable angle from 2° to 9° • Integral airpump with mass flow meter • RS-485 communications port • LCD display and control interface • Temperature control with heater and sensor
Dimensions	• 230 × 330 × 160 mm • With KIT 2EH: 489 × 330 × 200 mm
Weight	• 4.2 kg
Power	• 110 or 220 VAC • User-programmable
Options	• Optional PERFCONT2E weight-based Perfusion Controller with integral feed/harvest pumps

» For information on Cellbags for use with WAVE 2/10 systems, see page 48.

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WAVEPOD integrated controller

New

The WAVEPOD integrated controller integrates all instrumentation associated with WAVE Bioreactor 20/50EHT, including dissolved oxygen, pH, and CO_2/O_2 gas mixing controls, to meet individual cell culture needs for insect cell, mammalian cell, perfusion, or cell therapy applications. The unit combines these four key instruments into a single compact device, which connects via a digital link to the WAVE Bioreactor base. A large color touchscreen allows easy access to all parameters, including data from the bioreactor.

Detailed features include:

DOOPT: Dissolved oxygen optical monitor with miniature fiber-optic microprobes allows real-time measurement of dissolved oxygen. DOOPT is the only optical DO detector resistant to photobleaching and ambient light and capable of high accuracy measurement.

pH: Enables continuous pH measurement and control using CO_2 or acid/base addition. Electrochemical probe is also available pre-installed in Cellbags.

CO2MIX: Infrared CO_2 sensor and aeration system provides a continuous supply of CO_2 conditioned air to the Cellbag*.

O2MIX: Oxygen-air mixing controller provides continuous supply of O_2 enriched gas to the Cellbag for insect cell, virus, and high cell density applications. O2MIX can also be used to maintain low-oxygen environment for near-anaerobic applications.

*Cell Culture Bag in Switzerland.

By integrating all the controls associated with a WAVE Bioreactor, it is possible to develop complex control schemes by automatically varying rocker speed or oxygen concentration supplied to the Cellbag.

The WAVEPOD and WAVE Bioreactor 20/50EHT form a control cluster that can be accessed remotely over the built-in Ethernet interface for remote data acquisition and supervisory control.

Ordering information

Product	Quantity	Code No.
WAVEPOD Integrated controller and instruments for WAVE Bioreactor 20/50EHT models		
Includes pH, DOOPT, CO2MIX and O2MIX modules, right-facing (R) probe connections	1	28-4116-06
Includes pH, DOOPT, CO2MIX and O2MIX modules, left-facing (L) probe connections	1	28-4115-96
Includes pH, DOOPT and CO2MIX modules, right-facing (R) probe connections	1	28-4116-04
Includes pH, DOOPT and CO2MIX modules, left-facing (L) probe connections	1	28-4115-94
Includes DOOPT and O2MIX modules, right-facing (R) probe connections	1	28-4115-98
Includes DOOPT and O2MIX modules, left-facing (L) probe connections	1	28-4115-88
Includes DOOPT, CO2MIX and O2MIX modules, right-facing (R) probe connections	1	28-4116-00
Includes DOOPT, CO2MIX and O2MIX modules, left-facing (L) probe connections	1	28-4115-90
Includes pH and CO2MIX modules, right-facing (R) probe connections	1	28-4116-02
Includes pH and CO2MIX modules, left-facing (L) probe connections	1	28-4115-92
Accessories		
pH Probe	1	28-4116-71
DOOPT-Probe	1	28-4116-72
RTD Probe	1	28-4116-67
SRTDX Surface Probe	1	28-4116-65

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WAVE Mixers

New

M*Bag allows ingredients to be mixed and dissolved using the WAVE Mixer. Made of a multilayer, laminated clear plastic, the outer layer provides high mechanical strength and a gas-impermeable barrier while the fluid contact layer is typically a medical grade, low-density polyethylene. A large screw cap port allows powders or other solids to be easily poured into the bag, and also a probe (to measure pH) to be inserted. A large outlet port allows the M*Bag to be drained completely.

The WAVE Mixer makes it possible to mix materials contained in bags in a completely sterile manner. The rocking platform induces a wave motion in the liquid without an impeller or other invasive mixer. The WAVE Mixer has been optimized for efficient mixing and dispersion of up to 35 liters of liquid, in a choice of 20 or 50 liter M*Bags, and 10 liters of liquid can be mixed to homogeneity in less than 7 seconds.

The WAVE Mixer performs a number of functions including:

- Thawing
- Pooling
- Mixing
- Media and buffer preparation

WAVE Mixer features include:

- Disposable, single-use system for mixing liquids without the need for a mixing tank or conventional mixer
- No equipment cleaning, sterilization, validation, or cross-contamination
- Mixes liquid volumes from 1 to 35 liters in 20 and 50 liter mixing bags. Larger bag sizes are available on request
- All M*Bag Mixing Chambers are provided with a large screw cap port for the easy addition of powders and solids

Technical specifications

M*Bag	
Film	• Fluid contact layer: medical grade low density polyethylene (LDPE) • Non-contact outer layer: LPDE + EVA or nylon/EVOH copolymer
Biocompatability	• Testing is performed on irradiated film at 50 kGy • USP XXII plastic class VI test and ISO 10993 • Acute intracutaneous reactivity study in rabbit ISO10993-10 • Acute systemic toxicity in mouse ISO 10993-11 • Muscle implantation study in rabbit ISO 10993-6 • Cytotoxicity study using ISO elution method ISO 10993-5 • Hemolysis study *in vitro*, extraction method ISO 10993-4
Maximum operating pressure	• 0.1 bar
Temperature rating	• M*Bags may be used from 0°C to 50°C
Endotoxin	• Lot release requires < 0.125 EU/ml endotoxin

Ordering information

Product	Quantity	Code No.
WAVE Mixer 20/50ET	1	28-4115-65
WAVE Mixer 20/50EHT	1	28-4115-67
WAVE Mixer 500/1000E	1	28-4115-69
WAVE Mixer 500/1000EH	1	28-4115-70
MIXKIT20[1]	1	28-4115-73
MIXKIT20EH	1	28-4115-74
MIXKIT50[2]	1	28-4115-76
MIXKIT50EH	1	28-4115-77
MIXKIT500	1	28-4115-78
MIXKIT500EH[3]	1	28-4115-79
MIXKIT1000	1	28-4115-80
MIXKIT1000EH[4]	1	28-4115-81
MIXLID	1	28-4115-71
pH probe[5]	1	28-4116-71
RTD Probe, insertion type temperature probe (for use with M*Bag-500 l or M*Bag-1000 l only)	1	28-4116-67
M*Bag-20 l	1	MB0020L10-01
M*Bag-50 l	1	MB0050L10-01
M*Bag-500 l	1	MB0500L10-01
M*Bag-1000 l	1	MB1000L10-01

[1] Accommodates M*Bag-20 l.
[2] Accommodates M*Bag-50 l.
[3] Accommodates M*Bag-500 l.
[4] Accommodates M*Bag-1000 l.
[5] Specially developed probes with a diameter < 2.5 mm for easy insertion in to the M*Bag.

Application guide – WAVE Mixers

Mixer 20/50ET

In-process blending
In-process intermediates can be mixed and various ingredients can be added.

In-process pooling
In-process samples collected during chromatography or other operations can be pooled together in a single bag and mixed to form a homogeneous intermediate for sampling and further processing.

Blending for sampling
Mixing stored materials in bags in order to obtain a representative sample for stability and process optimization studies.

Mixing prior to fill
Mixing stored or collected product prior to dispensing in to final vials, bags, or other containers. Mixing the bag ensures each aliquot is identical. Using the bag as the mixing container ensures sterility and GMP operation.

Reconstitution and dissolution
Preparation of media from powdered and concentrated components and preparation of sterile buffers.

In process reactions
Reactions can be carried out in the bag. This may involve adding oxidants or reductants. The headspace in the bag can be controlled to maintain the desired oxygen level.

Mixer 20/50EHT

Thawing of frozen materials.
Warming blood and other biological fluids.
Maintaining temperature during pooling operations.

Selection guide – WAVE Mixers

	MIXER20/50ET[1] MIXER20/50EHT[1]	MIXER500/1000E[2,3] MIXER500/1000EH[2,3]
Working volume Range	1 to 35 l	50 to 500 l
Integral features	Speed/angle control Temperature control (EHT)	Speed/angle control Temperature control (EH) Loadcell
Options	pH	pH
Weight	18 kg	With MIXKIT500: 925 kg With MIXKIT1000: 1020 kg
Dimensions	502 × 381 × 172 mm with MIXKIT20: 502 × 654 × 254 mm with MIXKIT50: 740 × 635 × 300 mm	201 × 124 × 160 cm with MIXKIT500: 226 × 124 × 160 cm with MIXKIT1000: 226 × 231 × 160 cm
Power	110/220 VAC 10 A	208 to 240 VAC 30 A 3-Phase

[1] MIXER 20/50 requires selection of MIXKIT20 or MIXKIT50. MIXKIT20 accommodates M*BAG20L. MIXKIT50 accommodates M*BAG50L.
[2] MIXER 500/1000 requires selection of MIXKIT500 or MIXKIT1000. MIXKIT500 accommodates M*BAG500L. MIXKIT1000 accommodates M*BAG1000L.
[3] Unit provided with casters.

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Cellbag disposable bioreactors

New

Manufactured from multilayered laminated clear plastic, Cellbag* disposable bioreactors are suitable for your specific cell culture process needs for research, development, or cGMP manufacturing operations. Cellbag components are similar to those used for biological storage bags and meet USP Class VI specifications for plastics. Validation data and Cellbag DMF are available to demonstrate biocompatibility. However, we recommend validation for specific applications such as:

- Monoclonal antibodies
- Anchorage-dependent cells
- Virus production
- Vaccine production
- Insect cell/Baculovirus

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Cellbags feature:

- Presterile, single-use chambers for the non-invasive mixing of fluids using a WAVE Bioreactor
- Designed to provide high mechanical strength and bio-inert fluid contact
- Fluid contact layer is a medical grade low density polyethylene
- Outer non-contact layer is made of low density polyethylene, EVA or nylon/EVOH copolymers

All Cellbags have air inlet and outlet filters, a needleless sampling port, an Oxywell2 dissolved oxygen probe insertion port, and a fill/harvest port. However, Cellbags can be customized with optional fittings such as pH probes, dip tubes, screw cap ports, temperature ports, perfusion filters, and special tubing ports.

*Cell Culture Bag in Switzerland.

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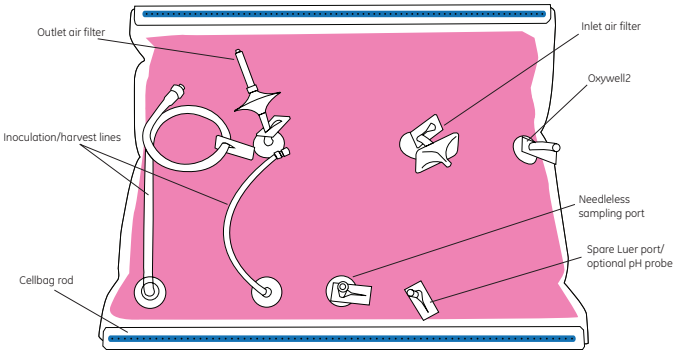

The Cellbag* size you need depends on the culture volume you wish to cultivate. *Cell Culture Bag in Switzerland.

Selection guide – Cellbag

Cellbag*	Culture volume	System 2/10	System 20/50		System 200	System 500/1000	
			Kit 20	Kit 50		Kit 500	Kit 1000
Cellbag-500 ml	50 to 250 ml	●					
Cellbag-1 l	50 to 500 ml	●					
Cellbag-2 l	100 to 1000 ml	●	●				
Cellbag-10 l	500 ml to 5 l	●	●				
Cellbag-20 l	1 to 10 l		●				
Cellbag-22 l	1 to 10 l			●			
Cellbag-50 l	5 to 25 l			●			
Cellbag-100 l	5 to 50 l				●		
Cellbag-200 l	10 to 100 l				●		
Cellbag-500 l	50 to 250 l					●	
Cellbag-1000 l	100 to 500 l						●

Technical specifications

Typical connectors	• Air inlet: 0.2 µm gas filter • Air outlet: 0.2 µm gas filter with check valve • Sampling: Needleless self-sealing syringe port. No laminar hood required • Fill/harvest: C-Flex tubing suitable for sterile fusing terminated with Luer or MPC coupling • Multiuse: Luer port with cap • Oxywell2: Silicone sheath for DO probe
Biocompatability	• Testing is performed on irradiated film (50 kGy): • USP XXII plastic class VI and ISO 10993: • ISO 10993-4 Hemolysis study *in vivo* extraction method • ISO 10993-5 Cytotoxicity study using ISO elution method • ISO 10993-6 Muscle implantation study in rabbit • ISO 10993-10 Acute intracutaneous reactivity study in rabbit • ISO 10993-11 Acute systemic toxicity in mouse
Sterility and endotoxin	• Sterilized by gamma radiation at 25 to 40 kGy • Lot release requires < 0.125 EU/ml endotoxin
Temperature rating	• Cellbags may be used from 0°C to 50°C
Pressure rating	• Maximum operating pressure 1.5 psig (0.1 bar)
Mechanical strength	• Film seal strength > 67 N/cm

Ordering information

Product	Quantity	Code No.
Cellbag-500 ml	1	CB500ML10-01
Cellbag-1 l	1	CB0001L10-01
Cellbag-2 l	1	CB0002L10-01
Cellbag-2 l (includes 20 g FibraCel)	1	CB0002L10-07
Cellbag-2 l (Oxywell version)	1	CB0002L10-02
Cellbag-2 l (perfusion version)	1	CB0002L10-04
Cellbag-2 l (screw cap ports)	1	CB0002L10-03
Cellbag-10 l	1	CB0010L10-01
Cellbag-10 l (includes 100 g FibraCel)	1	CB0010L10-07
Cellbag-10 l (Oxywell version)	1	CB0010L10-02
Cellbag-10 l (perfusion version)	1	CB0010L10-04
Cellbag-10 l (pH version)	1	CB0010L10-05
Cellbag-10 l (screw cap ports)	1	CB0010L10-03
Cellbag-20 l	1	CB0020L10-01
Cellbag-20 l (includes 200 g FibraCel)	1	CB0020L10-07
Cellbag-20 l (Oxywell version)	1	CB0020L10-02
Cellbag-20 l (perfusion version)	1	CB0020L10-04
Cellbag-20 l (pH version)	1	CB0020L10-05
Cellbag-20 l (screw cap ports)	1	CB0020L10-03
Cellbag-22 l (includes 200 g FibraCel)	1	CB0022L10-07
Cellbag-22 l (Oxywell version)	1	CB0022L10-02
Cellbag-22 l (pH version)	1	CB0022L10-05
Cellbag-50 l	1	CB0050L10-01
Cellbag-50 l (includes 500 g FibraCel)	1	CB0050L10-07
Cellbag-50 l (Oxywell version)	1	CB0050L10-02
Cellbag-50 l (perfusion version)	1	CB0050L10-04
Cellbag-50 l (pH version)	1	CB0050L10-05
Cellbag-100 l (Oxywell version)	1	CB0100L10-02
Cellbag-100 l (pH version)	1	CB0100L10-05
Cellbag-200 l (Oxywell version)	1	CB0200L10-02
Cellbag-200 l (pH version)	1	CB0200L10-05
Cellbag-500 l (pH version)	1	CB0500L10-05
Cellbag-1000 l (pHversion)	1	CB1000L10-05
Check valve, 2–50 l (pack of 25)	1	WV050087
Check valve, 100–200 l (pack of 50)	1	WV050088
Clave sampling valve on 1/4" OD C-Flex	1	TK001
PVC tubing with press-in plug	1	TK002
Tube Kit, PVC and Silicone tubing with T-connectors	1	TK003

ReadyToProcess connectivity

New

GE Healthcare's line of ReadyToProcess systems and accessories are supported by integrated devices that help maintain secure connectivity throughout the manufacturing process. Simple, sterile connections between media bags, as well as leak proof seals of thermoplastic tubing are examples of ReadyToProcess connectivity solutions. ReadyToProcess connectivity products provide the links between our systems and components, allowing rapid, secure workflows and maintaining sterile integrity.

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ReadyMate Disposable Aseptic Connectors

Available 2008

The ReadyMate Disposable Aseptic Connector (DAC) provides safe connections for high-fluid throughput and offers a secure, simple, and economical connection for upstream and downstream applications. ReadyMate DAC is autoclave and gamma compatible, and can be part of a sterile circuit. It can be used to connect unit operations and assemblies, upstream and downstream. ReadyMate DAC is manufactured in compliance with the current Good Manufacturing Practices of the FDA and ISO 9000-2000. Strap clamps are disposable and easy to use clamps ensuring leak-proof, traceable connections and meet ISO standard 2852.

ReadyMate provides:

- Safe dry-to-dry aseptic connections made quickly and easily in non aseptic environments
- Genderless design coupled with cross-size connectivity reduces inventory and increases flexibility
- Scalable from bench-top to production. Available in a variety of hose barb sizes and mini TC with the same smooth, uninterrupted flow path design.
- Large inner diameter for high flow rates
- Validated closure mechanism using standard sanitary clamps (ISO 2852) or a disposable clamp to make a tamper evident, single use, light weight connection

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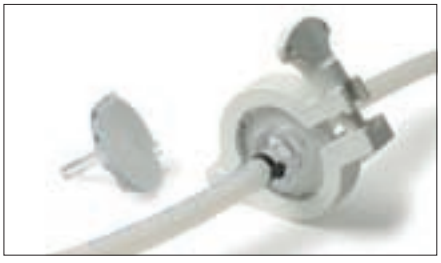
Ordering information

Product	Quantity	Code No.
ReadyMate DAC 250 with 1/4" barb	50	28-9366-91
ReadyMate DAC 375 with 3/8" barb	50	28-9366-92
ReadyMate DAC 500 with 1/2" barb	50	28-9366-93
ReadyMate DAC 750 with 3/4" barb	50	28-9366-94
ReadyMate DAC 750 Mini TC	50	28-9367-07
Strap clamps	25	28-9366-90

Technical specifications

Sizes	1/4" (6.4 mm) hose barb 3/8" (9.5 mm) hose barb 1/2" (12.7 mm) hose barb 3/4" (19.1 mm) hose barb Standard Mini-TC (ID 15.7 mm)
Outside clamp profile	50 mm (1½"), ISO standard 2852
Wetted materials	Polycarbonate Silicone Rubber
Material compliance	USP Class VI CFR 177 Animal free or compliance to EMEA/410/01
Maximum pressure*	5 bar (at 20°C)
Sterilization method	Gamma irradiation (25 kGy) Autoclaving (125 C, 30 min) One sterilization cycle Not intended for Steam In Place (SIP)
Shelf life	2 yrs
Storage temperature	4°C to 30°C

* Depends on strapping and assembly components.



Standard clamp

Strap clamp

Sterile Tube Fuser

New

The Sterile Tube Fuser is a fully automated device for welding together dry or fluid-filled thermoplastic tubing in a sterile operation without the need for a laminar flow cabinet or similar environmental control device. The instrument is useful for connecting tubing between sterile containers, bioreactor bags, and process equipment. The unit can connect large diameter (up to 22.2 mm OD; dry only) tubing for the rapid and safe transfer of large volumes of inoculum, media buffers, process intermediates, and other products.

Applications include:

- Sterile media transfer
- Vaccine manufacture
- Filling and formulation
- Bioreactors feed and harvest
- Pharmaceutical process fluid transfer
- High containment operations
- In-process pooling
- Transferring buffers

Sterile Tube Fuser features include:

- Safe and rapid fluid transfer
- LCD display for prompts and data
- Infrared blade temperature sensor
- PC interface for data printing and parameter download
- PTFE-coated blades for strong welds

Ordering information

Product	Quantity	Code No.
Sterile Tube Fuser-IRc-Compact	1	28-4116-77
Sterile Tube Fuser-IRc for liquid-filled welding (auto switching)	1	28-4116-89
Tube Holder Set for 15.5 mm (5/8") OD tubing	1	28-4116-81
Tube Holder Set for 15.5 mm (5/8") OD tubing (clamped tube holder set for wet welding; for use with STF-IRcWW)	1	28-4116-92
Tube Holder Set for 19.1 mm (3/4") OD tubing	1	28-4116-82
Tube Holder Set for 11.2 mm (7/16") OD tubing	1	28-4116-83
Tube Holder Set for 11.2 mm (7/16") OD tubing (clamped tube holder set for wet welding; for use with STF-IRcWW)	1	28-4116-93
Tube Holder Set for 6.4 mm (1/4") OD tubing	1	28-4116-84
Tube Holder Set for 6.4 mm (1/4") OD tubing (clamped tube holder set for wet welding; for use with STF-IRcWW)	1	28-4116-94
Tube Holder Set for 8.0 mm (5/16") OD tubing	1	28-4116-85
Tube Holder Set for 9.6 mm (3/8") OD tubing	1	28-4116-86
Tube Holder Set for 12.5 mm (1/2") OD tubing	1	28-4116-87
Tube Holder Set for 12.5 mm (1/2") OD tubing (clamped tube holder set for wet welding; for use with STF-IRcWW)	1	28-4116-95
Tube Holder Set for 22.2 mm (7/8") OD tubing	1	28-4116-88
Single use stainless steel cutting blades with PTFE coating. Non-sterile (50 blades/package)	1	28-4117-01
Calibration Verification Kit for Sterile Tube Fuser (includes maintenance manual, validation documents, PC Kit, blade sensor, and security key)	1	28-4116-98

Technical specifications

Sterile Tube Fixer

Tubing OD range	• 6.4 to 22.2 mm (dry tubing model) • 6.4 to 15.5 mm (fluid-filled tubing model)
Tubing condition	• STF-IRc: Dry thermoplastic • STF-IRcWW: Fluid-filled thermoplastic
Fusing cycle	• 2 to 3 min
Weight	• 16 kg
Dimensions	• 395 × 355 × 265 mm
Power	• 110/220 VAC, 1A, Autoswitching
Options	
for STF-IRc	• Tube Holder Set for 6.4, 8, 9.6, 11.2, 12.5, 15.5, 19.1, and 22.2 mm OD Tubing • Calibration Verification Kit
for STF-IRcWW	• Tube Holder Set[1] for 6.4, 11.2, 12.5, and 15.5 mm OD Tubing • Calibration Verification Kit

[1] Clamped tube holder set for wet welding. Use with STF-IRcWW only.

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Hot Lips Tube Sealer

New

The Hot Lips Tube Sealer is a portable device that can heat-seal thermoplastic tubing from 6.4 to 31.8 mm OD. The seal forms a tamperproof and leakproof closure for securing tubes from bags, bottles, and other vessels. The Hot Lips Tube Sealer is preprogrammed for many brands of tubing, is fully automated for validatable operation, and prevents fluids such as inoculum, products, media, and buffers from leaking through tubing, clamps, and plugs.

Hot Lips Tube Sealer has a range of applications including:

- Sealing tubing attached to bags
- Tamperproof sealing
- Sampling
- Shipping/storage
- Sealing transfer/sampling lines

Key features of Hot Lips Tube Sealer include:

- Keypad-selectable programs for virtually all types and sizes of thermoplastic tubing up to 31.8 mm OD
- No adapters required over the entire size range
- Lightweight unit can be used anywhere in the plant or laboratory
- Microprocessor controlled motor ensures reproducible and validatable performance

Ordering information

Product	Quantity	Code No.
Hot Lips Tube Sealer II (preprogrammed to thermally seal C-Flex, Sanipure, PVC, Tygon, and PharMed thermoplastic tubing from 6.4 to 31.8 mm OD)	1	28-4117-04
Calibration Verification Kit (includes maintenance manual, validation documents, PC Kit with security key, and jaw distance calibration tool)	1	28-4117-07

Technical specifications

Tubing OD range	• 6.4 to 31.8 mm
Tubing condition	• Dry or fluid-filled thermoplastic
Fusing cycle	• ~ 2 min
Weight	• 8 kg
Dimensions	• 356 × 165 × 203 mm
Power	• 110/220 VAC, 6 A (maximum) • Autoswitching

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ReadyToProcess filtration products

New

ReadyToProcess filters are a range of single-use cartridges and assemblies for both cross flow and normal flow filtration (NFF) operations. Preconditioned and ready for immediate use, they enable simpler and faster drug development. Factory prepared to Water for Injection quality for endotoxins, TOC and conductivity, they ensure maximum safety.

Applications include aseptic processing; clarification, ultrafiltration, and diafiltration in vaccine and MAb production; media filtration; and NFF prefiltration for bioreactors and columns. A wide range of capacities and pore selections are available.

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ReadyToProcess Hollow Fiber Cartridges

New

ReadyToProcess Hollow Fiber Cartridges enable simpler, safer, and faster drug development by minimizing device preparations steps such as wetting and sanitizing. The cartridges are designed to wet the membrane, lower total organic carbon (TOC) and conductivity, and minimize endotoxin levels. The single-use nature of the columns eliminates the need for cleaning protocols and cleaning validation, as well as eliminating cross-contamination between runs. ReadyToProcess Hollow Fiber Cartridges are packaged in high-purity water and exposed to gamma radiation for bioburden stability.

Typical applications of ReadyToProcess Hollow Fiber Cartridges include:

- Aseptic clarification and purification of vaccines, monoclonal antibodies, recombinant proteins, and plasmids
- Aseptic cell processing
- Environments where terminal sterilization is not feasible
- Preclinical through Phase II clinical trials
- Fast-track drug development processes

ReadyToProcess Hollow Fiber Cartridges are available in a wide variety of ultrafiltration molecular weight cut-offs and microfiltration pore sizes, from lab to pilot scale.

Operating specifications

	Ultrafiltration	Microfiltration
Temperature range	Up to 80°C	0.1 and 0.2 µm: up to 80°C 0.45 and 0.65 µm: up to 50°C
Maximum feed pressure	<10°C: 5.2 barg (75 psig) 10°C–25°C: 4.5 barg (65 psig) 25°C–80°C: 3.4 barg (50 psig)	At 25°C: 0.1 µm: 2.1 barg (30 psig) 0.2 µm: 1.7 barg (25 psig) 0.45 µm: 1 barg (15 psig) 0.65 µm: 1 barg (15 psig)
Maximum transmembrane pressure	10–30 kD: <10°C: 4.1 barg (60 psig) 10°C–25°C: 3.4 barg (50 psig) 25°C–50°C: 3.1 barg (45 psig) 50°C–80°C: 2.4 barg (35 psig)	At 25°C: 0.1 µm: 1.4 barg (20 psig) 0.2 µm: 1 barg (15 psig) 0.45 µm: 0.7 barg (10 psig) 0.65 µm: 0.7 barg (10 psig)
	50–750 kD: <10°C: 3.4 barg (50 psig) 10°C–25°C: 3.1 barg (45 psig) 25°C–50°C: 2.4 barg (35 psig) 50°C–80°C: 1.7 barg (25 psig)	

Technical specifications

Model	Cartridge diameter
3M, 3X2M	0.9 cm (0.375 in)
4M, 4X2M	1.9 cm (0.75 in)
5, 6	3.2 cm (1.25 in)
8, 9	5.1 cm (2 in)
Model	**Cartridge length**
3M	31.7 cm (12.5 in)
3X2M	63.5 cm (25 in)
4M	34.5 cm (13.6 cm)
4X2M	66 cm (26 in)
5	31.8 cm (12.5 in)
6	63.5 cm (25.0 in)
8	34.9 cm (13.75 in)
9	63.5 cm (25.0 in)
Model	**Path length**
3M, 4M, 5, 8	30 cm (12 in)
3X2M, 4X2M, 6, 9	60 cm (24 in)
Model	**Feed/retentate connections**
3M, 3X2M, 4M, 4X2M	0.5-in tri-clamp
5, 6, 8, 9	1.5-in tri-clamp
Model	**Permeate connections**
3M, 3X2M	0.25-in tubing nipple
4M, 4X2M	0.375-in tubing nipple
5, 6, 8, 9	0.5-in tubing nipple
Materials of construction	
Hollow fibers	Polysulfone
Housing components	Polysulfone
Potting	Epoxy
Support net (all cartridge sizes)	Polypropylene
Support net (5, 6, 8, 9)	Polyethylene
Fitting caps	Polyethylene, Vinyl
Regulatory conformance	
USP <88> Class VI	Compliant
EMEA/410/01	Compliant

Ordering information

ReadyToProcess Hollow Fiber ultrafiltration cartridges

Code Number	Model Number	Pore Size (NMWC)	Fiber ID (mm)	Membrane Surface Area (m^2)	Membrane Surface Area (ft^2)	Nominal Flowpath Length (cm)
56-4110-37	RTPUFP-10-C-3X2M	10 000	0.5	0.029	0.31	60
56-4110-38	RTPUFP-30-C-3X2M	30 000	0.5	0.029	0.31	60
56-4110-39	RTPUFP-50-C-3X2M	50 000	0.5	0.029	0.31	60
56-4110-40	RTPUFP-100-C-3X2M	100 000	0.5	0.029	0.31	60
56-4110-41	RTPUFP-300-C-3X2M	300 000	0.5	0.029	0.31	60
56-4110-42	RTPUFP-500-C-3X2M	500 000	0.5	0.029	0.31	60
56-4110-43	RTPUFP-750-E-3X2M	750 000	1	0.023	0.24	60
56-4110-52	RTPUFP-10-C-4X2M	10 000	0.5	0.14	1.5	60
56-4110-53	RTPUFP-30-C-4X2M	30 000	0.5	0.14	1.5	60
56-4110-54	RTPUFP-50-C-4X2M	50 000	0.5	0.14	1.5	60
56-4110-55	RTPUFP-100-C-4X2M	100 000	0.5	0.14	1.5	60
56-4110-56	RTPUFP-300-C-4X2M	300 000	0.5	0.14	1.5	60
56-4110-57	RTPUFP-500-C-4X2M	500 000	0.5	0.14	1.5	60
56-4110-58	RTPUFP-750-E-4X2M	750 000	1	0.085	0.9	60
56-4110-67	RTPUFP-10-C-6	10 000	0.5	0.48	5.2	60
56-4110-68	RTPUFP-30-C-6	30 000	0.5	0.48	5.2	60
56-4110-69	RTPUFP-50-C-6	50 000	0.5	0.48	5.2	60
56-4110-70	RTPUFP-100-C-6	100 000	0.5	0.48	5.2	60
56-4110-71	RTPUFP-300-C-6	300 000	0.5	0.48	5.2	60
56-4110-72	RTPUFP-500-C-6	500 000	0.5	0.48	5.2	60
56-4110-73	RTPUFP-750-E-6	750 000	1	0.28	3	60
56-4110-82	RTPUFP-10-C-9	10 000	0.5	1.15	12.5	60
56-4110-83	RTPUFP-30-C-9	30 000	0.5	1.15	12.5	60
56-4110-84	RTPUFP-50-C-9	50 000	0.5	1.15	12.5	60
56-4110-85	RTPUFP-100-C-9	100 000	0.5	1.15	12.5	60
56-4110-86	RTPUFP-300-C-9	300 000	0.5	1.15	12.5	60
56-4110-87	RTPUFP-500-C-9	500 000	0.5	1.15	12.5	60
56-4110-88	RTPUFP-750-E-9	750 000	1	0.84	9	60

Ordering information

ReadyToProcess Hollow Fiber microfiltration cartridges

Code Number	Model Number	Pore Size (µm)	Fiber ID (mm)	Membrane Surface Area (m^2)	Membrane Surface Area (ft^2)	Nominal Flowpath Length (cm)
56-4110-33	RTPCFP-1-E-3M	0.1	1	0.011	0.12	30
56-4110-34	RTPCFP-2-E-3M	0.2	1	0.011	0.12	30
56-4110-35	RTPCFP-4-E-3M	0.45	1	0.011	0.12	30
56-4110-36	RTPCFP-6-D-3M	0.65	0.75	0.012	0.13	30
56-4110-44	RTPCFP-1-E-3X2M	0.1	1	0.023	0.24	60
56-4110-45	RTPCFP-2-E-3X2M	0.2	1	0.023	0.24	60
56-4110-46	RTPCFP-4-E-3X2M	0.45	1	0.023	0.24	60
56-4110-47	RTPCFP-6-D-3X2M	0.65	0.75	0.027	0.29	60
56-4110-48	RTPCFP-1-E-4M	0.1	1	0.042	0.45	30
56-4110-49	RTPCFP-2-E-4M	0.2	1	0.042	0.45	30
56-4110-50	RTPCFP-4-E-4M	0.45	1	0.042	0.45	30
56-4110-51	RTPCFP-6-D-4M	0.65	0.75	0.046	0.50	30
56-4110-59	RTPCFP-1-E-4X2M	0.1	1	0.085	0.9	60
56-4110-60	RTPCFP-2-E-4X2M	0.2	1	0.085	0.9	60
56-4110-61	RTPCFP-4-E-4X2M	0.45	1	0.085	0.9	60
56-4110-62	RTPCFP-6-D-4X2M	0.65	0.75	0.095	1.02	60
56-4110-63	RTPCFP-1-E-5	0.1	1	0.12	1.3	30
56-4110-64	RTPCFP-2-E-5	0.2	1	0.12	1.3	30
56-4110-65	RTPCFP-4-E-5	0.45	1	0.12	1.3	30
56-4110-66	RTPCFP-6-D-5	0.65	0.75	0.16	1.7	30
56-4110-74	RTPCFP-1-E-6	0.1	1	0.28	3	60
56-4110-75	RTPCFP-2-E-6	0.2	1	0.28	3	60
56-4110-76	RTPCFP-4-E-6	0.45	1	0.28	3	60
56-4110-77	RTPCFP-6-D-6	0.65	0.75	0.37	4	60
56-4110-78	RTPCFP-1-E-8	0.1	1	0.36	3.9	30
56-4110-79	RTPCFP-2-E-8	0.2	1	0.36	3.9	30
56-4110-80	RTPCFP-4-E-8	0.45	1	0.36	3.9	30
56-4110-81	RTPCFP-6-D-8	0.65	0.75	0.41	4.4	30
56-4110-89	RTPCFP-1-E-9	0.1	1	0.84	9	60
56-4110-90	RTPCFP-2-E-9	0.2	1	0.84	9	60
56-4110-91	RTPCFP-4-E-9	0.45	1	0.84	9	60
56-4110-92	RTPCFP-6-D-9	0.65	0.75	0.93	10	60

ReadyToProcess Normal Flow Capsule Filters

ReadyToProcess Normal Flow Capsule Filters are single-use filters designed for laboratory through process scale applications. Volumes range from a few milliliters to thousands of liters of solution. The filters provide sterilizing grade filtration for a wide range of biopharmaceutical solutions. Two capsule filters are available:

RTP ULTA Cap SG, for sterilizing grade filtration of typical biopharmaceutical solutions.

RTP ULTA Cap HC, for sterilizing grade filtration of difficult-to-filter solutions.

ReadyToProcess Normal Flow Capsule Filters offer a range of benefits including:

- decreased risk of cross-contamination
- simplified and rapid bioprocessing
- reduced process development time
- lower capital investment costs

Ordering information

Code Number	Model Number	Description	Pore Size (um)	Capsule Size
28-4002-64	KMPHHC9202HH	ULTA HC RTP 0,2 2IN HBHB 3pk	0.2	2 Inch
28-4002-65	KMPHHC9204HH	ULTA HC RTP 0,2 4IN HBHB 3pk	0.2	4 Inch
28-4002-66	KMPHHC9206HH	ULTA HC RTP 0,2 6IN HBHB 3pk	0.2	6 Inch
28-4002-67	KMPHHC9202TH	ULTA HC RTP 0,2 2IN TCHB 3pk	0.2	2 Inch
28-4002-68	KMPHHC9204TH	ULTA HC RTP 0,2 4IN TCHB 3pk	0.2	4 Inch
28-4002-69	KMPHHC9206TH	ULTA HC RTP 0,2 6IN TCHB 3pk	0.2	6 Inch
28-4002-70	KMPHSG9202HH	ULTA SG RTP 0,2 2IN HBHB 3pk	0.2	2 Inch
28-4002-71	KMPHSG9204HH	ULTA SG RTP 0,2 4IN HBHB 3pk	0.2	4 Inch
28-4002-72	KMPHSG9206HH	ULTA SG RTP 0,2 6IN HBHB 3pk	0.2	6 Inch
28-4002-73	KMPHSG9202TH	ULTA SG RTP 0,2 2IN TCHB 3pk	0.2	2 Inch
28-4002-74	KMPHSG9204TH	ULTA SG RTP 0,2 4IN TCHB 3pk	0.2	4 Inch
28-4002-75	KMPHSG9206TH	ULTA SG RTP 0,2 6IN TCHB 3pk	0.2	6 Inch

Area/Integrity specifications

Product Name	6" Capsule	4" Capsule	2" Capsule	Water Wet Bubble Point Integrity Spec
RTP ULTA Cap SG	0.22 m^2 (2.3 ft^2)	0.11 m^2 (1.2 ft^2)	0.05 m^2 (2.3 ft^2)	3.4 barg (49 psig)
Diffusion Specification w/Water Wet Filter	6.1 mL/min @ 2.8 barg (40.6 psig) @ 20°C	3.0 mL/min @ 2.8 barg (40.6 psig) @ 20°C	1.4 mL/min @ 2.8 barg (40.6 psig) @ 20°C	
RTP ULTA Cap HC	0.22 m^2 (2.3 ft^2)	0.11 m^2 (1.2 ft^2)	0.05 m^2 (2.3 ft^2)	3.4 barg (49 psig)
Diffusion Specification w/Water Wet Filter	6.1 mL/min @ 2.8 barg (40.6 psig) @ 20°C	3.0 mL/min @ 2.8 barg (40.6 psig) @ 20°C	1.4 mL/min @ 2.8 barg (40.6 psig) @ 20°C	

ÄKTAready system

New

ÄKTAready is a liquid chromatography system built for process scale-up and production for early clinical phases. The system operates with ready to use, disposable flow paths and as a consequence, cleaning between products/batches and validation of cleaning procedures is not required. Replacing flow paths between projects is simple, and when used together with ReadyToProcess columns, the risk for cross-contamination is removed.

The ÄKTAready system is biocompatible and hygienic, and meets all GLP and cGMP demands for Phase I-III in drug development and full-scale production. ÄKTAready is controlled by UNICORN software, including a complete guide and documentation for installation of Flow Kits and columns. Highlights of ÄKTAready systems include:

- Simple exchange of the complete flow path removes the need for system cleaning
- Improved economy and productivity due to simpler procedures
- Single-use eliminates risk of cross-contamination between products/batches
- Scalable processes using UNICORN

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ÄKTAready is ReadyToProcess

ÄKTAready is a part of the ReadyToProcess platform, consisting of plug and play, ready-to-use solutions for entire processes. After the completion of a purification task, the columns and the flow path (i.e., the Flow Kits) can be either disposed of or exchanged for reuse. The ReadyToProcess concept can speed up processes considerably due to fewer operations: there is no need to establish and validate cleaning procedures, and no complex setup. The flow path can be changed quickly, with a downtime of less than 1 h. This saves time, capital investment, start-up cost, and costs of labor and consumables.

Validation with UNICORN software

UNICORN software has an installation wizard that checks the setup and the installation and functionality of the new Flow Kit and sensors. A report is generated with completed installation procedures including instructions from the wizard, traceability to Flow Kit, process information, and results from the component test. The installation wizard also contains instructions and reports for column installation. UNICORN has undergone an independent audit and is designed as a control package in FDA 21 CFR part 11 and GMP compliant environments. The record system uses a document locking scheme and traceable audit log. For integration purposes, UNICORN communicates with control systems within the plant via OLE for Process Control (OPC). OPC supports application areas such as data access for real time values and security control to protect sensitive information.

Technical specifications

Width / Depth / Height	1000/800/1650 mm
Weight	230 kg
Control system	UNICORN version 5.11 or higher
Instrument input voltage	AC Voltage, 1 × 100/120/200–208/220–230/240 V, ± 10%, 50/60 Hz
Max. power consumption	1 kVA
Ingress protection	IP45
Compressed air interface	5.5–7 bar, 50 Nl/min, oil- and particle-free
Operating temperature	2°C–30°C
Volumetric flow rates	7.5–510 l/h High Flow Kit 3–175 l/h Low Flow Kit
System pressure rating	5.0 bar (high pressure flow path, upstream column) 3.0 bar (high pressure flow path, downstream column) 0.6 bar (low pressure inlet and outlet manifolds)

Available 2008

Ordering information

Product	Code No.
ÄKTAready system including column trolley and UNICORN	28-9062-61
Accessories	
High Flow Kit, ÄKTAready	28-9301-83
Low Flow Kit, ÄKTAready	28-9301-82
Low flow test kit ÄKTAready	28-9336-80
UV Cond test tools ÄKTAready	28-9336-88
Pressure calib tool ÄKTAready	28-9329-42
ReadyToProcess columns	see page 60

ReadyToProcess columns

New

ReadyToProcess columns are high performance bioprocessing columns that come prepacked, prequalified, and presanitized. ReadyToProcess columns are designed for seamless scalability, delivering the same performance level as available in conventional processing columns such as AxiChrom and BPG. ReadyToProcess columns are currently available with a range of BioProcess media in three different sizes, 2.5 liters, 10 liters and 20 liters. ReadyToProcess columns are designed for purification of biopharmaceuticals for clinical phase I and II studies. Depending on the scale of operations, they can also be used for full-scale manufacturing, as well as for preclinical studies. The columns can be used in a wide range of chromatographic applications for separation of various compounds such as proteins, endotoxins, DNA, plasmids, vaccines, and viruses.

ReadyToProcess columns provide a range of benefits including:

- Time savings – by eliminating several time-consuming steps
- Cost savings – by lowering buffer consumption and reducing cleaning validation demands
- Process security – robust column construction and performance
- Scalability – by facilitating conventional approaches in larger scales
- Reduced cross-contamination

›› Visit us on the web at www.gelifesciences.com/readytoprocess

ReadyToProcess chromatography columns offer the possibility to work in a fully flexible mode in early clinical phases while keeping a conventional re-use option for large-scale manufacturing open. The chromatography media used in ReadyToProcess columns have a long track-record of use in full-scale manufacturing using conventional, large-scale chromatography, where columns can be used for tens or hundreds of cycles. The transition from ReadyToProcess format to full-scale manufacturing is therefore straightforward.

Currently, the following BioProcess media are available in the ReadyToProcess format: MabSelect SuRe, Capto Q, Capto S, Capto adhere, and Phenyl Sepharose 6 Fast Flow (low sub). In addition, several of GE Healthcare's other BioProcess chromatography media are available on request.

Ordering information

Product	Column size	Code No.
RTP Capto Q 2.5	2.5 l	28-9017-23
RTP Capto Q 10	10 l	28-9017-24
RTP Capto Q 20	20 l	28-9017-25
RTP Capto S 2.5	2.5 l	28-9017-29
RTP Capto S 10	10 l	28-9017-30
RTP Capto S 20	20 l	28-9017-31
RTP Capto adhere 2.5	2.5 l	28-9017-14
RTP Capto adhere 10	10 l	28-9017-15
RTP Capto adhere 20	20 l	28-9017-16
RTP MabSelect SuRe 2.5	2.5 l	28-9017-17
RTP MabSelect SuRe 10	10 l	28-9017-18
RTP MabSelect SuRe 20	20 l	28-9017-19
RTP Phenyl Sepharose 6 FF (low sub) 2.5	2.5 l	28-9017-35
RTP Phenyl Sepharose 6 FF (low sub) 10	10 l	28-9017-36
RTP Phenyl Sepharose 6 FF (low sub) 20	20 l	28-9017-37

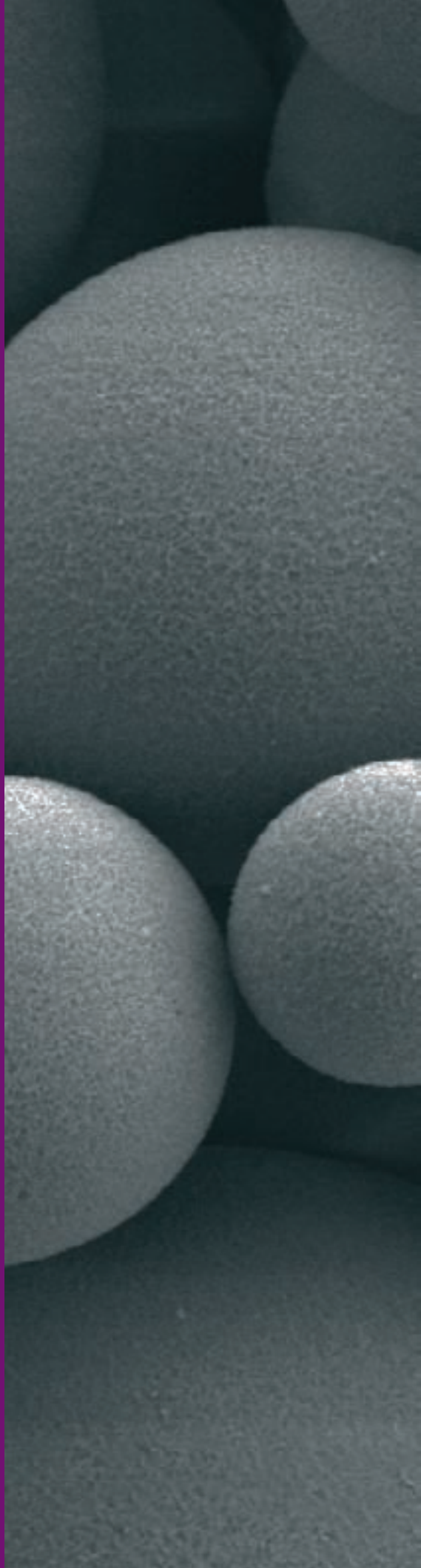
Technical specifications

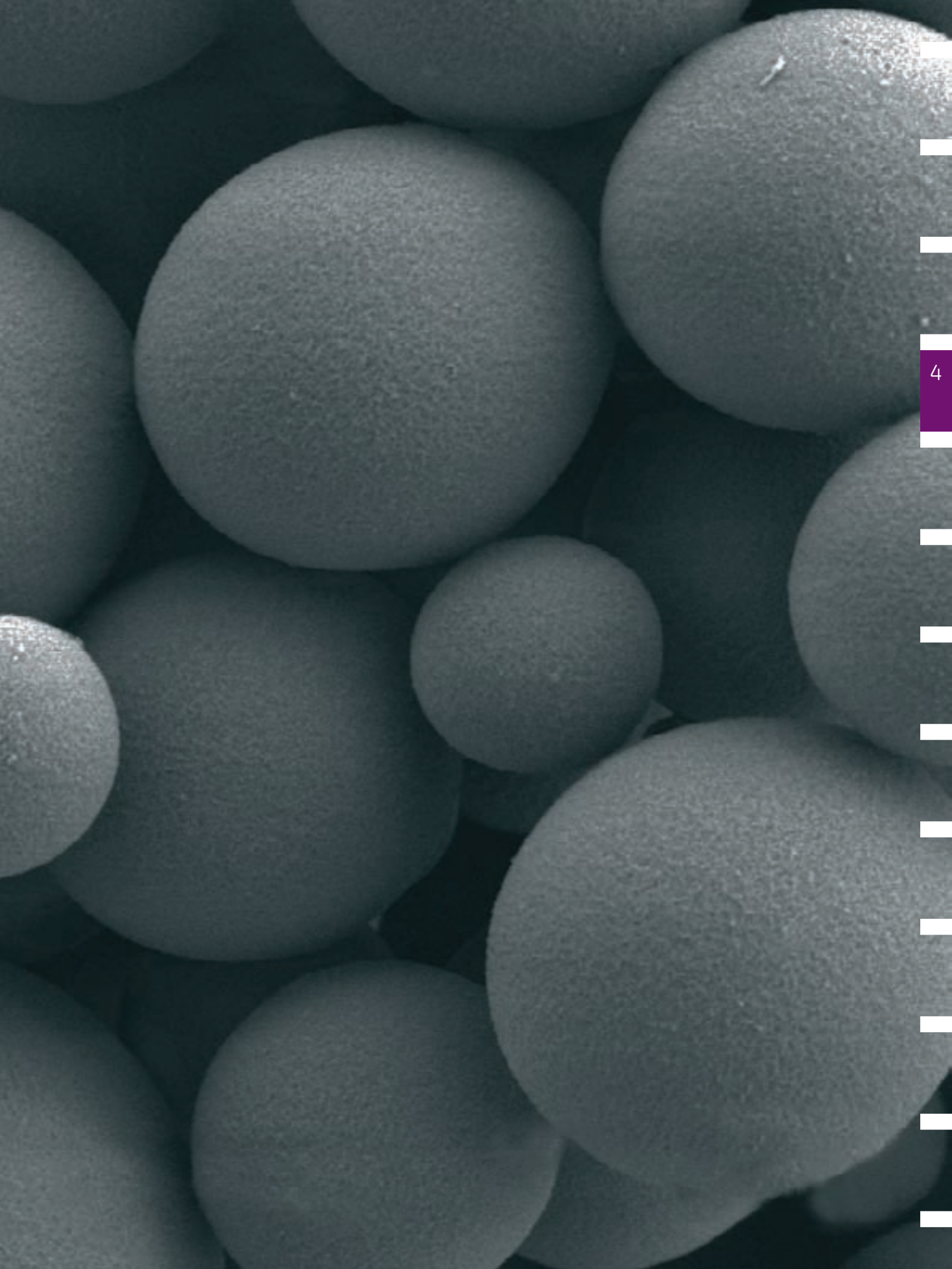
	2.5 l	10 l	20 l
Inner diameter (mm)	126	251	359
Inner cross section (cm^2)	124	495	1012
Column volume (l)	2.5	9.9	20.2
Packed bed height (mm)	200	200	200
Net mesh (µm)	23	23	23
Mechanical compression factor (%)[1]	12.5–15	12.5–15	12.5–15
Outer height (mm)	378	388	407
Outer diameter incl. lid (mm)	195	342	484
Weight (kg)	~6	~25	~55
Inlet TC25 connectors, tubing i.d.	6.3 mm / 0.25"	9.5 mm / 0.375"	12.7 mm / 0.5"
Outlet TC25 connectors, tubing i.d.	6.3 mm / 0.25"	9.5 mm / 0.375"	12.7 mm / 0.5"
Ambient temperature (°C)[2]	4–30	4–30	4–30
Liquid temperature (°C)[2]	4–40	4–40	4–40
Maximum liquid pressure, bar[3]	4	4	4
Estimated shelf life (yr)	1	1	1

[1] The mechanical compression factor varies depending on the medium.
[2] The temperature difference between the fluid running through the column and the ambient temperature in the room should never be greater than 20°C.
[3] While the maximum liquid pressure stated depends on the pressure rating of the column, restrictions for the maximum pressure drop over the column depend on the packed chromatography medium, in order to ensure bed stability. See User Manual for details.

4

Chromatography media





Media selection – our strategy

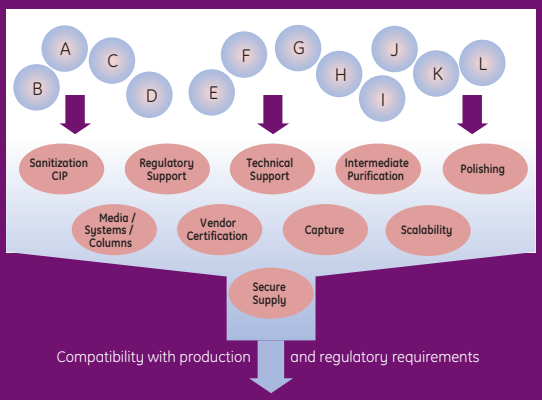
At GE Healthcare we are committed to supplying you with media that pass the rigorous selection requirements demanded for the downstream processing of biopharmaceuticals. Consider three issues:

Performance – The different stages in downstream processing from Capture to Polishing demand media with different characteristics.

Scalability – Is the medium produced at a large enough scale? Can it be packed into large production columns with retained performance?

Security of supply – How is quality assurance? Is the producer geared up to long-term industrial supply issues?

Media selection filter



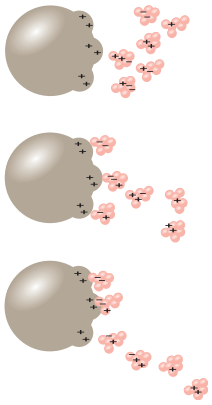
Use only media that pass through this filter.

BioProcess Media – made for bioprocessing

This label designates our media that have been specifically designed to meet the demands of industrial biotechnology:

- **Secure Supply** Large capacity production integrated with clear ordering and delivery routines mean BioProcess Media are available in the right quantity, at the right place, at the right time. Future supplies of BioProcess Media are assured, making them a safe investment for your long-term production.
- **Safety Stock** Our media safety stock agreements offer the right quantity of media, manufactured to specified quality levels, and delivered at the right time. For more information on Safety Stock agreements contact your local GE Healthcare office.
- **Validated Manufacture** Produced following validated methods and tested under strict quality control, BioProcess Media fulfill performance specifications. A certificate of analysis is available with each order.
- **Regulatory Support** Regulatory Support Files contain details of performance, stability, extractable compounds and analytical methods available. The essential information in these files is an invaluable starting point for process validation, as well as support for clinical and marketing applications submitted to regulatory authorities.
- **From Capture to Polishing** Specific BioProcess Media have been designed for each chromatographic stage in a process from Capture to Polishing. Using BioProcess Media for every stage results in a systematic approach to method development.
- **High Productivity** High flow rates, high capacity and high recovery contribute to the overall economy of an industrial process.
- **Sanitization/CIP** All BioProcess Media can be cleaned- and sanitized-in-place.
- **Scalability** Packing methods are established for a wide range of scales. You can use the same BioProcess Media for development work, pilot studies, and routine production.

Ion exchange chromatography



Technique description

Separation in ion exchange chromatography (IEX) is based upon the selective, reversible adsorption of charged molecules to an immobilized ion exchange group of opposite charge. An ion exchanger consists of an insoluble porous matrix to which charged groups have been covalently bound.

Anion exchanger groups

ANX: $-CH_2CHOHCH_2NH^+(CH_2CH_3)_2$

DEAE: Diethylaminoethyl $- O-C_2H_4-N^+(C_2H_5)_2-H$

QAE: Quatenary aminoethyl $- O-C_2H_4-N^+(C_2H_5)_2-CH_2CH(OH)CH_3$

Q: Quatenary ammonium $- O-CH_2CHOHCH_2OCH_2CHOHCH_2-N^+(CH_3)_2-CH_3$

Cation exchanger groups

CM: Carboxymethyl $-O-CH_2COO^-$

S: Sulphoethyl $-O-CH_2-CH_2-SO_3^-$

SP: Sulphopropyl $-O-CH_2CHOHCH_2OCH_2CH_2CH_2SO_3^-$

Q, S and SP are strong ion exchange groups that maintain charge capacity over a very wide pH range. The other groups are weak ion exchangers, and their charge capacity varies with pH.

New and established media

GE Healthcare ion exchangers are well-established in industry. A wide range of base matrices has been developed to address most customer requirements.

Capto is a new product line specifically developed to enable quick and economical handling of large volumes in biopharmaceutical production. The rigidity of Capto media allows for longer bed heights in smaller diameter columns, thereby simplifying column handling as well as reducing investment in large-scale equipment. The Capto line is composed of a strong anion exchanger, Capto Q, a strong cation exchanger, Capto S, a weak anion exchanger, Capto DEAE, a multimodal weak cation exchanger, Capto MMC, and Capto adhere, a strong multimodal anion exchanger.

›› For further information about Capto MMC and Capto adhere, see the Multimodal chromatography section, page 76.

The flexibility offered by Capto media opens new possibilities in large-scale protein purification.

MacroCap SP is a macroporous cation exchanger designed for the purification of PEGylated and other large biomolecules. It allows separation of mono- from oligo- and non-PEGylated proteins with high selectivity, even under high load conditions.

Sepharose Big Beads, Sepharose Fast Flow, Sepharose XL and Sepharose High Performance are other products based on cross-linked agarose. These media are designed for robust, high capacity, high resolution ion exchange chromatography at various stages of process-scale purification. For many years, they have been the industry standard for ion exchange of biomolecules.

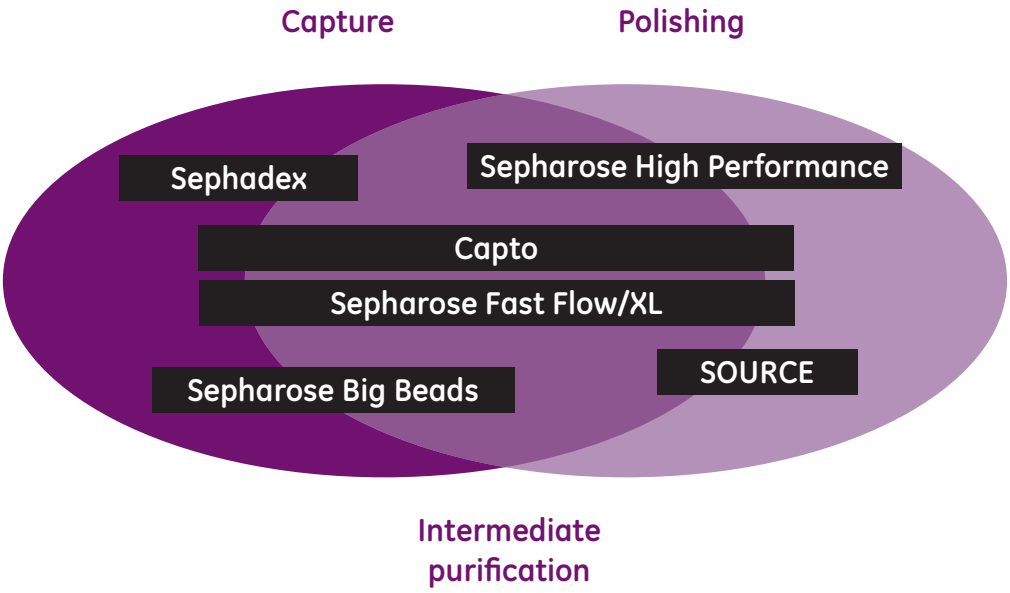
Sephadex: Other key products include Sephadex ion exchangers, based on cross-linked dextran beads and offering high capacities for batch or column mode.

SOURCE media for late-intermediate purification and polishing also belong to a long line of ion exchangers specifically designed to meet the processing needs of the biopharmaceutical manufacturer.

The handbook Ion Exchange Chromatography and Chromatofocusing – Principles and Methods can be obtained through your local GE Healthcare office.

Code No. 11-0004-21.

Selection guide



Getting started

Testing the performance of separation media at the laboratory bench helps you select the best one for process-scale use.

HiTrap columns (1 ml and 5 ml) are a particularly fast, simple, and reproducible way of testing different ion exchange media. They can be operated with a syringe, a peristaltic pump or a chromatography system. HiTrap Capto IEX Selection Kit provides five different ion exchange ligands based on Capto. The HiTrap IEX Selection Kit contains seven ion exchangers based on Sepharose Fast Flow and Sepharose XL media.

Capto Q, Capto S, Capto DEAE, as well as Q and SP Sepharose High Performance are also available in prepacked HiTrap 1 ml and 5 ml columns.

For method development, the new HiScreen as well as HiPrep and HiLoad prepacked column ranges are recommended, depending on scale and column length. They are convenient to use and give reproducible results.

HiScreen columns are 0.77 × 10 cm (4.6 ml) prepacked columns with Capto Q, Capto S, Capto DEAE, Capto adhere, and Capto MMC, designed for process development.

A convenient way of assessing SOURCE 15Q and SOURCE 15S media is to use an ÄKTAdesign system and RESOURCE or 4.6/100 PE (ÄKTAdesign) prepacked columns.

» In addition to prepacked columns, many of the media described in this section can be ordered as laboratory-sized packs. See A–Z of media and chemicals.

Capto

For high productivity capture and intermediate purification

Capto is a new product line to meet large-scale biopharma manufacturers' demands for fast, efficient and cost-effective capture and intermediate purification. It is based on a highly-rigid agarose matrix produced with a manufacturing process that gives significantly improved pressure/flow properties with maintained control over pore structure. The rigid matrix enables high bed heights and purification of viscous samples at high flow rates. Capto Q and Capto S are strong anion and cation exchangers, and Capto DEAE is a weak anion exchanger - all maximize productivity due to fast mass transfer plus high dynamic binding capacity. Capto MMC is a multimodal weak cation exchanger that is salt tolerant and binds proteins at the conductivity of most standard feed materials. Capto adhere is a strong multimodal anion exchanger for intermediate purification and polishing of monoclonal antibodies after capture on Protein A media.

- Capto DEAE **New**
- Capto Q
- Capto ViralQ
- Capto S
- Capto MMC
- Capto adhere

» For further information about Capto MMC and Capto adhere, see the Multimodal chromatography section, page 76.

MacroCap

For purification of large biomolecules

MacroCap is a new product line designed to purify PEGylated and other large biomolecules. MacroCap SP is a cation exchanger that delivers high product purity and yield at high sample loads. Mono-PEGylated proteins are separable from oligo-PEGylated and native protein in a single run. The MacroCap SP base matrix is hydrophilic and chemically stable, thereby increasing media lifetime.

PEGylation is typically performed after purification of the target protein.

- MacroCap SP

Sephadex

High binding capacities for column or batch techniques

Sephadex ion exchangers are very well established and have been used in industry for many years. Their high binding capacities and reliability make them both simple and economical to use. Due to their excellent stability and ease of packing, Sephadex A-25 and C-25 are popular choices for column techniques. Sephadex A-50 and C-50 are also widely used for batch applications, especially processing crude feedstocks, and in plasma fractionation.

- DEAE Sephadex A-25
- QAE Sephadex A-25
- CM Sephadex C-25
- DEAE Sephadex A-50
- QAE Sephadex A-50
- CM Sephadex C-50

Sepharose Big Beads

For capture steps handling very large volumes of feed or viscous feedstocks

Sepharose Big Beads is the natural choice for the capture step in a process where high throughput and capacity are essential in packed column mode. Typical flow velocities for dilute samples are >1000 cm/h. The large particle size combined with high physical stability ensures rapid processing of viscous samples. These media should be chosen for clarified feedstocks when high throughput is required and resolution is of less importance.

- SP Sepharose Big Beads
- Q Sepharose Big Beads

■ = BioProcess Media

CDM = **Custom Designed Media** produced on receipt of order.

Sepharose XL

High loading capacities for more productive capture from clarified feedstocks

Q Sepharose XL and SP Sepharose XL have high loading capacities compared with Sepharose Fast Flow ion exchangers. Combined with high throughput, this helps improve the production economy of manufacturing processes. Both adsorbents are based on the well-established Sepharose Fast Flow media.

- Q Sepharose XL
- Q Sepharose XL virus licensed
- SP Sepharose XL

Sepharose Fast Flow

Proven in validated large-scale production of biopharmaceuticals

These media are the first choice for separating crude mixtures early in purification schemes. Here a combination of good resolution and high flow rate is essential. Typical flow velocities for these media are 100 to 400 cm/h.

- DEAE Sepharose Fast Flow
- CM Sepharose Fast Flow
- Q Sepharose Fast Flow
- SP Sepharose Fast Flow
- ANX Sepharose 4 Fast Flow (high sub)

Sepharose High Performance

Where high resolution is essential for intermediate purification and polishing

These media are well-suited for intermediate purification and polishing. Use them when resolution and capacity have priority. Typical flow velocities are 100 cm/h.

- SP Sepharose High Performance
- Q Sepharose High Performance
- CDM CM Sepharose High Performance

SOURCE

For rapid, high-resolution, preparative separations at low or high pressure

SOURCE ion exchangers are monosized, rigid, polystyrene/divinyl benzene matrices for chromatography of proteins, peptides and oligonucleotides. SOURCE 15Q and 15S media are well-suited for complex separations during polishing. SOURCE 30Q and 30S are for intermediate purification and large-scale polishing. Typical flow velocities are up to 1000 cm/h at large-scale, and even higher on the laboratory bench.

- SOURCE 15S
- SOURCE 15Q
- SOURCE 30S
- SOURCE 30Q

HiTrap Capto IEX Selection Kit (Code no. 28-9343-88)

New

This kit provides five different ion exchange ligands based on Capto, enabling convenient and easy screening. Contains five 1 ml HiTrap columns prepacked with Capto Q, Capto S, Capto DEAE, Capto MMC, Capto adhere, as well as connectors and instructions.

HiTrap IEX Selection Kit (Code No. 17-6002-33)

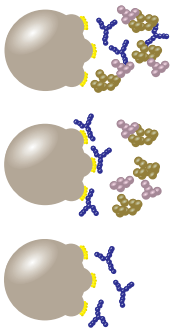
This kit allows fast and easy screening of seven different ion exchange ligands based on Sepharose Fast Flow and Sepharose XL, which is excellent for laboratory studies with small sample quantities before scaling up. Contains SP, Q, CM, ANX (high sub) and DEAE Sepharose Fast Flow and Q and SP Sepharose XL in 1 ml HiTrap columns. The kit contains detailed instructions.

IEX Media Selection Kit (Code No. 17-0939-01)

This kit is an excellent tool for use in industrial process development. The kit contains a selection of ion exchangers based on Sepharose to be used in each of the stages in a purification scheme. A comprehensive instruction manual is also included.

›› For further information, please contact your local GE Healthcare office.

Affinity chromatography



Technique description

The inherent high specificity of ligand – target interactions makes affinity chromatography particularly suitable for the Capture stage of downstream processing. One of the typical advantages of using affinity techniques is that the capacity of the media is usually not affected by the presence of contaminants since they have no affinity for the coupled ligand. The result is reliable product purity, often with purification factors well over 1000, and effective concentration, achieved in a single step. Affinity chromatography may also be suitable for the Intermediate or Polishing stages, to remove small amounts of specific contaminants. In affinity chromatography, the product to be purified adsorbs to an affinity ligand that is coupled to a matrix. The ligand is specific for a single type of protein/peptide molecule, or group of such molecules. The targeted product often binds to the ligand under specific conditions of ionic strength and pH. After unbound impurities are rinsed away, the product can be eluted by using a step gradient of increasing or decreasing ionic strength and/or by changing the pH, or by a more selective elution technique.

Affinity chromatography

The most widely used affinity chromatography purification step today is the capture of antibodies using the Protein A ligand.

Protein A media

The MabSelect family for the capture of monoclonal antibodies has been developed with industrial needs in mind. The expanded product range focuses on better overall process economy and reduced time for optimization.

Group-specific media

Heparin Sepharose 6 Fast Flow and Blue Sepharose 6 Fast Flow are examples of media with affinity for a group of related molecules.

IMAC media

Immobilized Metal Ion Chromatography (IMAC) is a versatile purification technique for proteins, including histidine-tagged proteins, with an affinity for metal ions. Ni Sepharose 6 Fast Flow is precharged with Ni^{2+} ions and is designed for purification of histidine-tagged proteins, suitable for scale-up and accompanied with a Regulatory Support File. IMAC Sepharose 6 Fast Flow is the uncharged version (with the possibility to charge the metal ion of your choice), suitable for histidine-tagged proteins as well as other recombinant proteins and native proteins. Chelating Sepharose Fast Flow is the well-established BioProcess IMAC medium and is being used in several approved biopharmaceutical process.

Pre-activated media

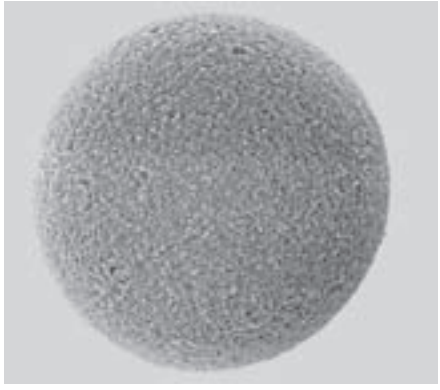
Pre-activated media allow you to couple a ligand appropriate to your application. The choice of medium depends on several factors, for example the groups in the ligand molecule that are suitable for coupling and the chemical stability demands on the resulting affinity medium. CNBr-activated Sepharose 4 Fast Flow and NHS-activated Sepharose 4 Fast Flow are examples of modern pre-activated media suitable for attaching various ligands.

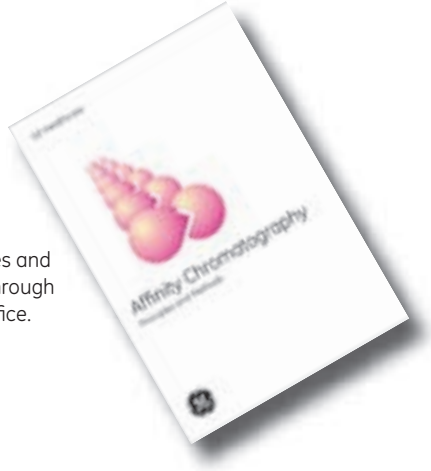
MabSelect media

The commercial success of approved biopharmaceuticals and the growing number of protein-based drug candidates has led to projections of metric tons of monoclonal antibodies (MAbs) being required in a few years. To meet this demand, cell culture capacity is increasing with reactors of 12 000 to 15 000 liters and larger coming on-line. Expression levels, currently in the 1 to 5 g/l range, are expected to increase several-fold. In downstream processing, efforts are directed at improving process economics by decreasing the number and cost of unit operations. Current trends in antibody production indicate an increased use of Protein A chromatography media for product capture.

Benefits of Protein A-based chromatography media

- High selectivity reduces the number and size of subsequent unit operations through high purities and yields
- Insensitivity to variations in additives, pH and conductivity facilitates the use of generic protocols
- Usually validated for both viral clearance and subsequent inactivation





The handbook Affinity Chromatography – Principles and Methods can be obtained through your local GE Healthcare office.

Code No. 18-1022-29.

MabSelect family overview

MabSelect is the common name for a range of process to production-scale chromatography media for monoclonal antibody purification. All MabSelect media feature:

- A base matrix of high-flow agarose
- High chemical stability: compatible with allaqueous buffers commonly used in Protein A chromatography
- Mammalian product-free: no animal-derived components involved in the fermentation or purification of the recombinant Protein A ligand
- Epoxy as coupling chemistry
- Recommended storage reagents: 20% ethanol, 2% benzyl alcohol
- Temperature stability: 4 to 40°C
- Regulatory Support File
- Shelf life: 3 years
- Simple scale-up to production-sized columns
- Available in HiTrap format for convenient media screening
- Large-scale quantities available on request

Like all our BioProcess media, MabSelect meets every requirement for process design and scale-up. Prepacked columns and bulk quantities are available. For large-scale packing, we recommend AxiChrom, Chromaflow or BPG columns.

MabSelect

For high purity and throughput at production scale

- Prioritized volume throughput
- Optimized matrix and ligand coupling
- The antibody purification standard

MabSelect SuRe

Withstands rigorous and cost-effective CIP protocols, (e.g., 0.1 to 0.5 M NaOH)

- Alkali-stabilized rProtein A ligand
- Generic and economic CIP/sanitization
- Product safety and process robustness

MabSelect Xtra

For capturing high-titer antibody feedstocks and reducing processing costs

- Outstanding dynamic binding capacity
- Improved process economics and reduced raw material costs
- High-purity capture due to minimal non-specific binding

Product application guide

Getting started

Testing the performance of separation media at the laboratory bench will help you select the best one for process- scale use. All of the media described in this section can be ordered as laboratory-sized packs.

» Turn to page 212 for the A–Z of media and chemicals.

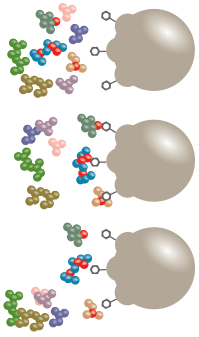
» This table is only a brief guide to application areas for our affinity media. For further information on these applications, please contact your local GE Healthcare office.

Target molecules	Affinity media	Applications
-NH_2	■ NHS-activated Sepharose 4 Fast Flow	Ligand immobilization
-NH_2	■ CNBr-activated Sepharose 4 Fast Flow	Ligand immobilization
-NH_2	CDM 6-AKS Sepharose 4 Fast Flow	Ligand immobilization
-NH_2, -OH, -SH	Epoxy-activated Sepharose 6B	Ligand immobilization
-COOH, -CHO	CDM Amino Sepharose 6 Fast Flow	Ligand immobilization
Immunoglobulins	CDM IgSelect	Human IgG all subclasses
	■ MabSelect	IgG, some IgM and IgA
	■ MabSelect SuRe	IgG, some IgM and IgA
	■ MabSelect Xtra	IgG, some IgM and IgA
	■ rmp Protein A Sepharose Fast Flow	IgG, some IgM and IgA
	■ rProtein A Sepharose 4 Fast Flow	IgG, some IgM and IgA
	■ nProtein A Sepharose 4 Fast Flow	IgG, some IgM and IgA
	■ Protein G Sepharose 4 Fast Flow	IgG
Histidine-tagged proteins	■ Ni Sepharose 6 Fast Flow	Polyhistidine tagged proteins
	■ IMAC Sepharose 6 Fast Flow	Polyhistidine tagged proteins
GST-tagged proteins	Glutathione Sepharose 4 Fast Flow	Glutathione S-transferase (GST), tagged proteins, other glutathione S-transferases and glutathione-binding proteins
Growth factors	■ Heparin Sepharose 6 Fast Flow	Fibroblast growth factor (FGF) endothelial cell growth factor (ECGF)
	■ Blue Sepharose 6 Fast Flow	
Protein synthesis factors	■ Heparin Sepharose 6 Fast Flow	Initiation factors, elongation factors (EF-1)
Hormones and hormone receptors	Con A Sepharose 4B	Follicle-stimulating
	■ Heparin Sepharose 6 Fast Flow	Oestrogen and androgen receptors
Coagulation proteins	■ Heparin Sepharose 6 Fast Flow	Antithrombin III,
	■ Heparin Sepharose 6 Fast Flow	Factors IX, X, XI, XII, XIIa, prothrombin, thrombin
	■ Chelating Sepharose Fast Flow	Factor IX
Nucleic acids	CDM ECH-Lysine Sepharose 4 Fast Flow	Ribosomal RNA, double stranded DNA
Polysaccharides and glycoproteins	Con A Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
	Lentil Lectin Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
Membrane proteins	Lentil Lectin Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
	Con A Sepharose 4B	α-D-Glucosyl, α-D-mannosyl
Lipoproteins	■ Heparin Sepharose 6 Fast Flow	α-lipoprotein
	Con A Sepharose 4B	low density lipoprotein
Enzymes	■ Heparin Sepharose 6 Fast Flow	Restriction endonucleases, DNA ligase, DNAand RNA polymerases, nucleic acid binding
	■ Blue Sepharose 6 Fast Flow	broad range of nucleotide-requiring enzymes
Protease binding	CDM Benzamidine Sepharose 4 Fast Flow (high sub)	Trypsin, urokinase, prekallikrein, kallikrein
Other	Con A Sepharose 4B	α1-antitrypsin
	■ Blue Sepharose 6 Fast Flow	α2-macroglobulin
	■ Chelating Sepharose Fast Flow	α2-macroglobulin
	CDM Gelatin Sepharose 4 Fast Flow	Fibronectin
	■ Heparin Sepharose 6 Fast Flow	Fibronectin
	CDM ECH-Lysine Sepharose 4 Fast Flow	Plasminogen and plasminogen activator
	■ Blue Sepharose 6 Fast Flow	Albumin
	■ Blue Sepharose 6 Fast Flow	Interferon
	■ Heparin Sepharose 6 Fast Flow	Interferon
	■ Chelating Sepharose Fast Flow	Interferon
	CDM AVB Sepharose High Performance	Adeno-associated viruses
	CDM Procainamide Sepharose 4 Fast Flow	Butyrylcholinesterase
	CDM VIIISelect	Beta-domain depleted FVIII
	CDM Plasminogen Removal Gel	Plasminogen

■ = BioProcess Media

CDM = **Custom Designed Media** produced on receipt of order.

Hydrophobic interaction chromatography



Technique description

Proteins and peptides differ from one another in their surface hydrophobicity and this difference forms the basis of a HIC separation. Salt solutions are used to mediate the binding of sample molecules to a hydrophilic matrix substituted with a hydrophobic ligand.

Widespread application

Hydrophobic interaction chromatography (HIC) is well-established within protein purification today and has evolved into one of the most powerful methods in preparative biochemistry. By combining versatility with high selectivity, it is mainly employed in the intermediate or final purification stages of a wide variety of substances. Its speed, resolution, and capacity rival ion exchange chromatography; its selectivity is complementary to ion exchange and size exclusion chromatography; and its ability to clear endotoxins, nucleic acids, and viruses makes it an indispensable tool for the purification of therapeutic proteins.

Choice of adsorbent

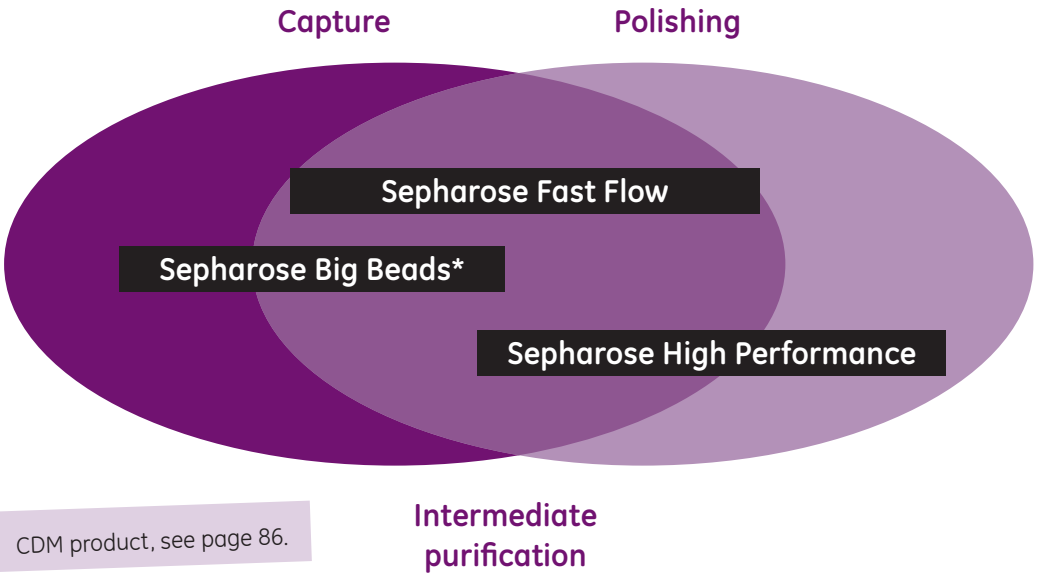
Developing an efficient HIC method involves steps similar to these of other techniques – scouting for potentially suitable adsorbents, optimization and scale-up.

Adsorbents differ in the type of ligand, degree of substitution and base matrix. The correct choice is made after experiments to determine the best selectivity and strength of binding. Choice also depends upon the scale of operation and position in the purification scheme.

Help with experimental design
The theory of HIC, experimental design and process considerations are comprehensively described and discussed in the HIC/RPC handbook. Please contact your local GE Healthcare office to obtain your copy.

Code No. 11-0012-69.

Selection guide



* CDM product, see page 86.

Getting started

Testing the performance of separation media at the laboratory bench will help you select the best one for process- scale use. Note that selectivity cannot always be predicted on the basis of the ligand. To help industrial users compare media, small samples are available on request. Please ask for details.

Many of the media described in this section can be ordered as laboratory-sized packs or as easy-to-use prepacked columns. The small HiTrap columns, operated with a syringe, a peristaltic pump or a chromatography system, allow a particularly fast and simple way of screening key HIC media. They are available as a Selection kit.

HiLoad and HiPrep prepacked columns are convenient and give reproducible results, making them well-suited for method development. The method wizard in UNICORN controlled ÄKTAdesign systems supports the most common scouting procedures, such as automatic media screening.

A tool for screening different HIC media

The HiTrap HIC Selection Kit consists of seven ready to use 1 ml prepacked columns for screening different types of ligands and for method development work at small scale.

- Phenyl Sepharose High Performance
- Phenyl Sepharose 6 Fast Flow (low sub)
- Phenyl Sepharose 6 Fast Flow (high sub)
- Butyl-S Sepharose 6 Fast Flow
- Butyl Sepharose 4 Fast Flow
- Butyl Sepharose High Performance
- Octyl Sepharose 4 Fast Flow

  Code No. 28-4110-07

Sepharose Big Beads

Media for capture steps handling very large volumes of clarified feedstock

CDM Phenyl Sepharose Big Beads

The large particle size combined with high physical stability ensures rapid processing of viscous samples.

Sepharose Fast Flow

Media for capture and intermediate purification. Proven in validated large-scale production of biopharmaceuticals

The excellent flow properties and binding capacities of these media make them especially useful for processing large volumes.

The range of Fast Flow HIC media covers different selectivities. The best choice for each application is difficult to predict and therefore several different media need to be tested to find the best selectivity.

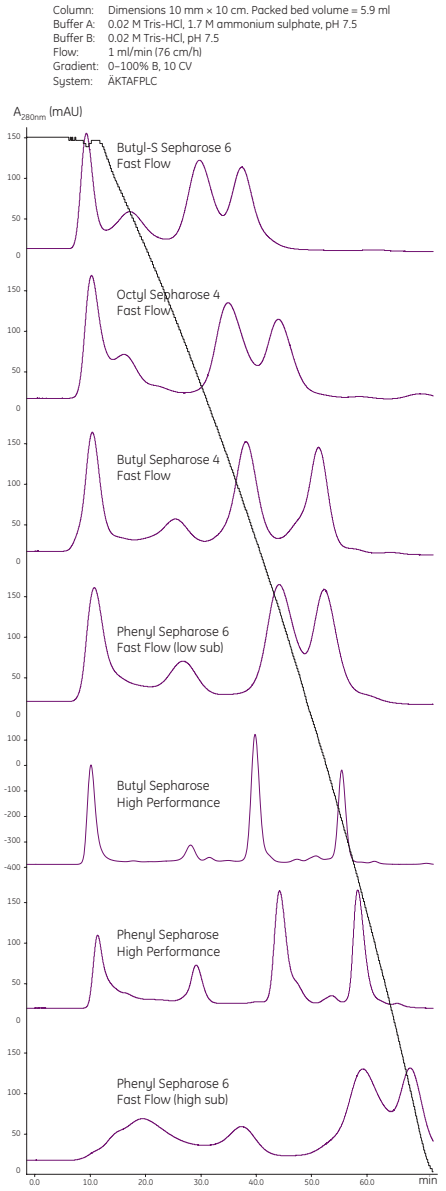
- *Butyl Sepharose 4 Fast Flow*
  The standard aliphatic HIC medium of choice. The ligand gives different selectivity compared with phenyl media.
- *Butyl-S Sepharose 6 Fast Flow*
  A low-hydrohobicity HIC medium for capturing recombinant HBsAg and removing hydrophobic contaminants.
- *Octyl Sepharose 4 Fast Flow*
  Gives different and complementary selectivity compared with phenyl and butyl media.
- *Phenyl Sepharose 6 Fast Flow (high sub)*
  A high capacity HIC medium with a binding capacity for IgG and HSA up to 30 mg/ml at flow velocities of 100 cm/h. Has proven to be a very efficient capture medium.
- *Phenyl Sepharose 6 Fast Flow (low sub)*
  The standard HIC medium of choice with an aromatic ligand.

CDM
- *Butyl Sepharose 6 Fast Flow*
  The butyl ligand on the well-proven Fast Flow matrix.

Sepharose High Performance

Media for intermediate purification and polishing when high resolution is needed

- *Butyl Sepharose High Performance*
  Robust medium for difficult purification problems when high resolution is the main objective. Is also very efficient for polishing monoclonal antibodies.
- *Phenyl Sepharose High Performance*
  Robust medium for difficult purification problems when high resolution is the main objective. Is also very efficient for polishing monoclonal antibodies.

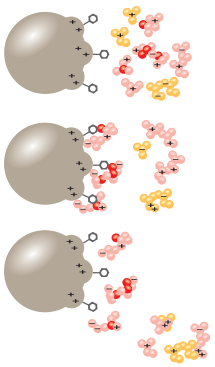


The HIC product portofolio based on Sepharose was screened for selectivity and separation ability for Cytochrome C, RNAse A, Lysozyme and a α-Chymotrypsinogen (eluting in this order). Butyl-S Sepharose 6 Fast Flow is the least hydrophobic medium and Phenyl Sepharose 6 Fast Flow (high sub) the most hydrophobic medium produced by GE Healthcare.

■ = BioProcess Media

CDM = **Custom Designed Media** produced on receipt of order.

Multimodal chromatography



Technique description

Multimodal separation is based on different types of interaction, depending on the nature of the multimodal ligand and overall process conditions. The most common interaction for GE Healthcare's line of multimodal ion exchangers is based upon the selective reversible adsorption of charged molecules to an immobilized multimodal ion exchange group of opposite charge with hydrophobic character. For other multimodal media, such as PlasmidSelect Xtra, the predominate interactions are of aromatic and thiophilic nature. Both types of media consist of an insoluble porous matrix to which the multimodal ligands have been covalently bound. In multimodal chromatography it is important to screen the overall process conditions (e.g. pH and conductivity) in order to evaluate the full potential of the media both for binding and elution mode.

In many cases, the specific interaction between the multimodal ligand and the target molecules is a complex mixture of different interactions which is also very dependant of the overall process conditions. Media containing multimodal ligands are characterized by interactions that are different from those of "traditional" ligands and have in many cases been designed for a specific purpose. GE Healthcare's multimodal ligands also offers new selectivities that may be beneficial in other types of purification challenges where more traditional ligands do not offer the required selectivity.

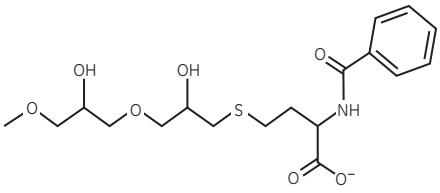
A range of Data Files covering our Multimodal Chromatography media is now available. Please contact your local GE Healthcare office to obtain your copy.

Capto MMC, Code No. 11-0035-45

Capto adhere, 28-9078-88

PlasmidSelect Xtra, 28-4094-87

Capto MMC



The multimodal ligand of Capto MMC, designed for protein binding at high feed conductivities.

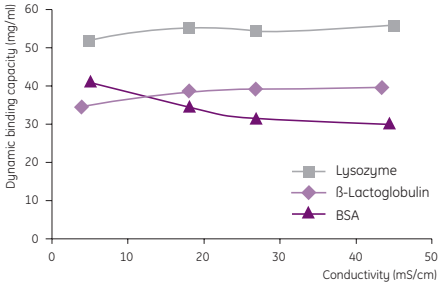
Capto MMC is a weak, multimodal cation exchanger belonging to the Capto family of BioProcess media for fast and cost efficient protein purification. Capto MMC allows for increased productivity and reduced cost with

- High capacity at high conductivity
- High productivity
- New selectivity

Capto MMC combines recent base matrix developments with a new, innovative ligand chemistry. Capto MMC is "salt tolerant" meaning that binding of proteins can be performed at the conductivity of the feed material, thus avoiding costly and time consuming dilutions of large volumes of water for injection in order to lower the conductivity prior to binding the protein to the column. Capto MMC has a multimodal ligand that may interact with the target molecule in multiple ways. It contains a carboxylic group and thus has features that resemble those of a weak cation exchanger. However, in addition to the ionic interactions several other types of interactions are involved including hydrophobic bonding and aromatic interactions.

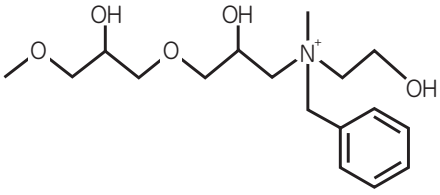
High salt tolerance and new selectivity

Capto MMC has the ability to bind proteins at high conductivities, as demonstrated by dynamic binding capacities of three different proteins under different conductivities.



Dynamic binding capacities of Capto MMC at 1 minute residence time for three different proteins ranging from low to high conductivities.

Capto adhere



The multimodal ligand of Capto adhere designed for selective removal of contaminants after a Protein A capture step.

Capto adhere is a strong multimodal anion exchanger belonging to the Capto family of BioProcess media. Capto adhere allows for increased productivity and reduced cost with:

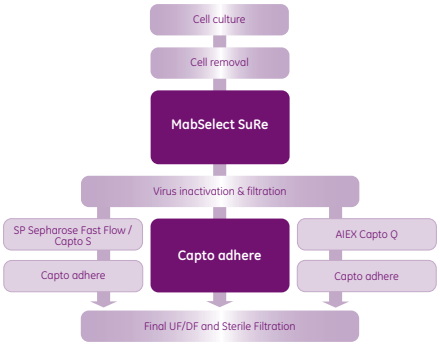
- High capacity and productivity
- Removal of contaminants after a Protein A capture step
- Allowing for a two-step purification process of monoclonal antibodies
- New selectivity

Capto adhere combines recent base matrix developments with a new, innovative ligand chemistry. Capto ahere was designed as a scavenger medium with the ability to selectively remove contaminants such as dimer/aggregates, host cell proteins, and leaked protein A after a Protein A capture step of monoclonal antibodies. Capto adhere has a multimodal ligand that may interact with the target molecule in many different ways.

It contains a quaternary ammonium group and thus has features similar to those of a strong anion exchanger. However, in addition to the ionic interactions, several other types of interactions are involved including hydrophobic bonding and aromatic interactions.

Two-step process for MAb purification

The multimodal functionality of Capto adhere offers features different from more traditional ion exchangers in terms of both the ability to selectively remove contaminants such as host cell proteins, leaked Protein A, aggregates and viruses after a Protein A Capture step of monoclonal antibodies. In addition, the ligand of Capto adhere may also offer new selectivities for other types of purification challenges where more traditional ligands have not been successful. The downstream purification of monoclonal antibodies has traditionally been performed in three-step processes comprising Protein A as a capture step followed by anion exchange, cation exchange, and HIC steps in different combinations. Capto adhere offers the option to reduce the overall number of chromatographic steps in the purification of monoclonal antibodies by combining a highly efficient Protein A step based on MabSelect SuRe with a second step based on Capto adhere.



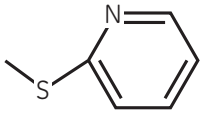
Toolbox concept in the downstream purification of monoclonal antibodies using Capto adhere to reduce the total number of unit operations.

PlasmidSelect Xtra

Purified plasmid DNA is required in increasingly larger quantities to meet the emerging requirements for gene therapy and DNA vaccination. As both human and veterinary applications are in focus, plasmid DNA purity, quantity, and cost-per-dose requirements vary greatly. Process development to purify plasmid DNA at large scale must thus be:

- Flexible
- Easily scalable
- Robust
- Cost efficient

PlasmidSelect Xtra combines agarose base matrix technology allowing for low, non-specific interactions with a multimodal ligand designed for selective separation between supercoiled plasmid DNA and open circular plasmid DNA. PlasmidSelect Xtra has a ligand that may interact with the target molecule in many different ways. It contains both a thioether and a pyridyl functional group and its features partly resemble those of a phenyl-based HIC medium. However, in addition to the hydrophobic interactions, several other types of interactions are involved including thiophilic bonding and aromatic interactions.



The multimodal ligand of PlasmidSelect Xtra showing a high selectivity between supercoiled and open circular plasmid DNA.

The PlasmidSelect Xtra process

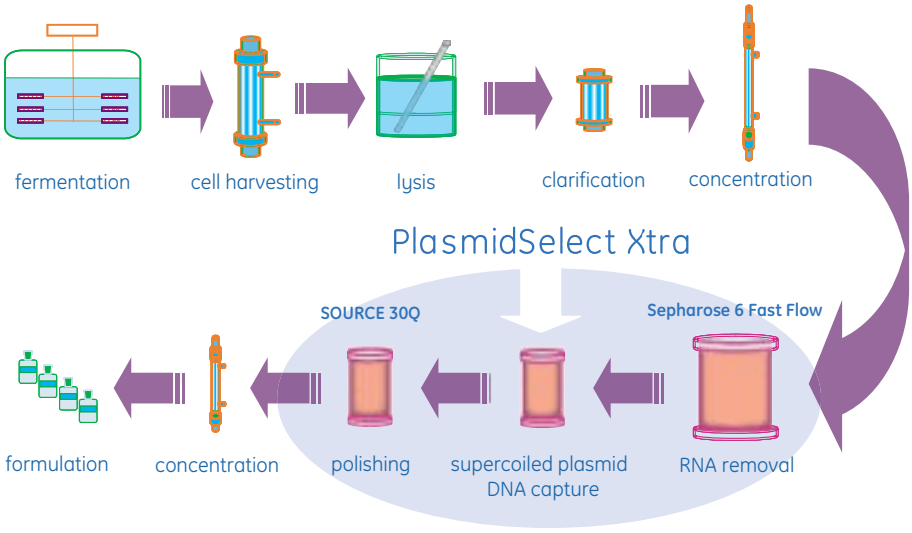
PlasmidSelect Xtra forms the basis of a generic process for purifying supercoiled circular DNA suitable for bulk to clinical-grade applications. The process provides high capacity, delivers high yields, and can be scaled up to fulfill requirements for economical, industrial manufacturing of plasmid DNA in highly regulated environments. The same principle can also be used to rapidly analyze the quantity and quality of plasmid DNA in complex solutions.

PlasmidSelect Xtra, which uses ionic strength to modulate binding to the matrix, is part of a fully scalable chromatographic process for purifying supercoiled plasmid DNA. This process also employs Sepharose 6 Fast Flow and SOURCE 30Q. The complete purification process comprises both chromatography and filtration steps such as clarification and ultrafiltration.

The PlasmidSelect Xtra Starter Kit contains all three media in prepacked columns to purify at least 5 mg of supercoiled plasmid DNA in a single run. The PlasmidSelect Xtra Screening Kit can be used to determine plasmid DNA quantity within 10 minutes and plasmid DNA quality (ration supercoiled, covalently closed plasmid DNA to open circular) within 30 minutes. It also purifies up to 2 mg plasmid DNA within 1 hour.

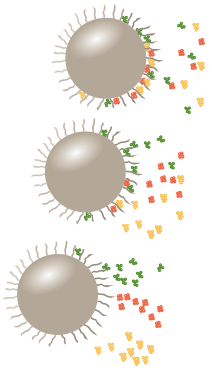
PlasmidSelect Xtra platform

- Generic process for purification of supercoiled plasmid DNA.
- Screening Kit: Quick and easy analysis with an ÄKTAdesign system. Code no. 28-4052-69.
- Starter Kit: Prepacked columns for convenient process development. Code no. 28-4052-68.
- Bulk media: PlasmidSelect Xtra, Sepharose 6 Fast Flow, and SOURCE 30Q are BioProcess media available in large quantities for scale-up and manufacturing. See A-Z of media and chemicals section of this catalog.



The PlasmidSelect Xtra process, designed for the purification of high-quality, supercoiled plasmid DNA.

Reversed phase chromatography



Technique description

Reversed phase chromatography (RPC) is in theory closely related to hydrophobic interaction chromatography. Both techniques are based on the interaction between hydrophobic patches on the surface of biomolecules and the hydrophobic groups covalently attached to the surface of the matrix. In practice, however, they are different. Media for RPC are typically highly substituted with hydrophobic ligands and the binding of substances to RPC media is usually stronger. Organic solvents are usually required for elution. The technique is mainly applicable for peptides, proteins up to M_r 2.5×10^4 and other low molecular weight biomolecules that are stable in aqueous-organic solvents.

Required for polishing

RPC is a widely-used analytical technique but it is also employed in preparative applications, up to process scale, for more demanding polishing problems, such as separating microheterogeneities from the native molecule of recombinant peptides.

RPC is also a standard technique for purifying synthetic peptides and oligonucleotides. The technique often requires medium to high-pressure columns and systems and explosion-proof equipment for handling high concentrations of flammable, volatile organic solvents.

RPC media from GE Healthcare are designed for difficult preparative separations at all scales.

Products

SOURCE 15RPC and SOURCE 30RPC, both BioProcess Media, are designed for fast, high performance preparative separations of biomolecules such as proteins, peptides and oligonucleotides. The media have matrices based on rigid, highly cross-linked, polystyrene/divinyl benzene, with monosized beads of diameters 15 µm and 30 µm respectively. Pore size distribution is controlled and reproducible. Emphasis during development has been on quality, reproducibility and scalability, features that are particularly important for industrial applications.

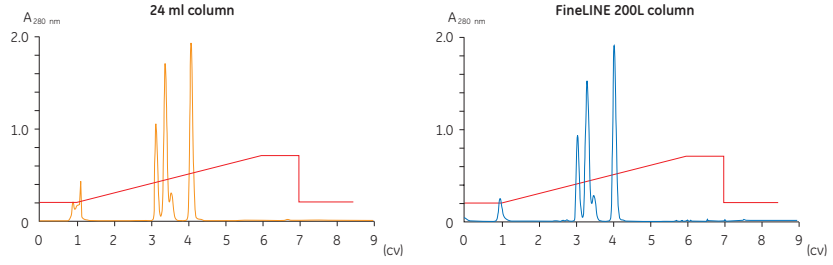
Their wide pH stability (pH 1 to 14) and high capacity make SOURCE RPC media an interesting alternative to silica-based media. The high chemical stability of the matrix offers unmatched flexibility when choosing running and cleaning conditions.

SOURCE 15RPC is intended for polishing where fast, preparative separations with the highest resolution are required. SOURCE 15RPC is also available in prepacked columns – RESOURCE RPC columns and ST 4.6/100 ÄKTAdesign columns – which are well-suited for selectivity screening experiments.

SOURCE 30RPC is well-suited for the polishing stage of industrial processes where high flow velocities and low back-pressures are needed.

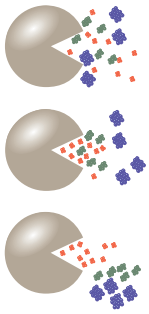
400-fold scale up on SOURCE 30RPC

Column:	SOURCE 30RPC, 10 mm i.d. × 300 mm column (24 ml) 200 mm i.d. × 300 mm column (10 l)
Sample:	Mixture of Angiotensin II, Ribonuclease A and Insulin
Sample load:	0.064 mg/ml media, total load
Solution A:	0.1% TFA/0.05 M NaCl
Solution B:	0.1% TFA/60% n-Propanol
Flow velocity:	150 cm/h
Gradient:	20–70% B, 5 column volumes (cv)



A 400-fold scale up of a model sample mix on SOURCE 30 RPC. Going from a 24 ml laboratory-scale column to a 9.4 liter production-scale column in one step gives what is essentially identical results at both scales.

Gel filtration



Technique description

Gel filtration separates biomolecules according to size. Large molecules elute either in the void volume or early in a chromatographic separation. Smaller molecules, depending on their degree of penetration of the pores of the matrix, elute later. Gel filtration is a simple technique which complements ion exchange, hydrophobic interaction, reversed phase, and affinity.

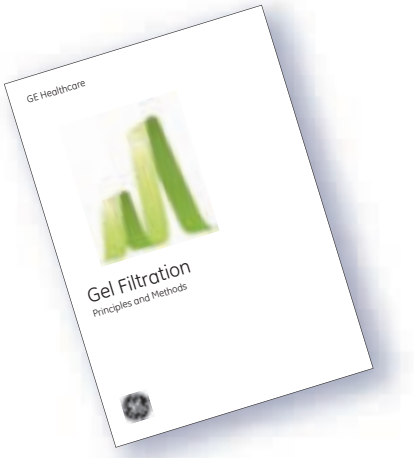
In process chromatography, gel filtration is used principally for desalting the product, for buffer exchange, or for specific removal of contaminants with molecular weights above or below the desired product's molecular weight. Typically, molecules must differ in size by two-fold to yield a good separation, although other adsorptive effects can augment some separations where molecules are similar in size.

Excellent range

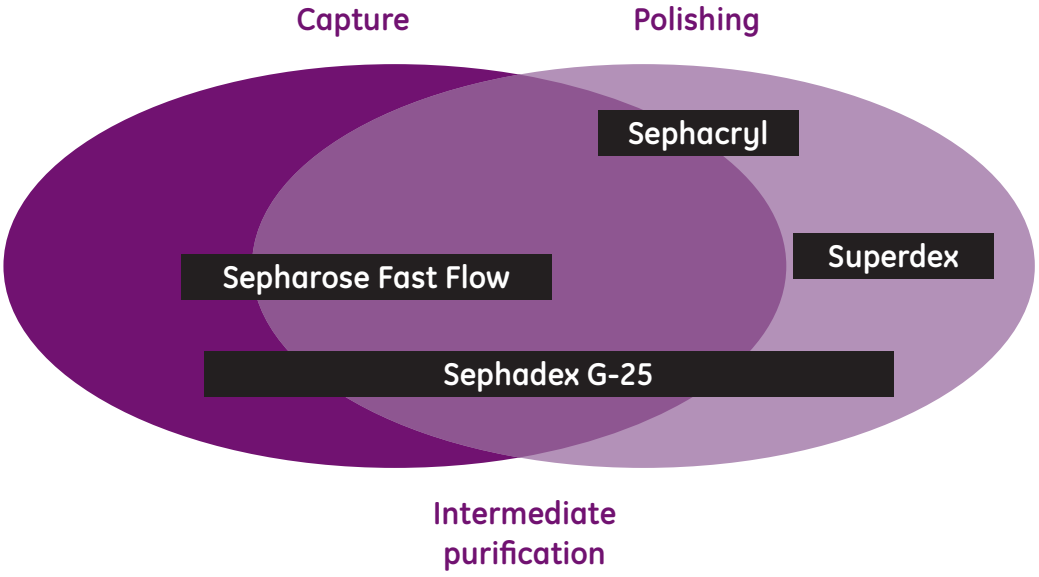
Gel filtration is useful at Polishing or final purification stages where volumes are much lower than at the Capture or Intermediate stages and there is a need to remove dimers or aggregates.
GE Healthcare has an excellent range of gel filtration media ranging from Sephadex G-types and different Sephacryl selectivities, to the Superdex family.

The handbook Gel Filtration – Principles and Methods can be obtained through your local GE Healthcare office or downloaded from our website.

Code No. 18-1022-18.



Selection guide



Important characteristics of media for gel filtration include particle size, pore volume, adsorptive properties and matrix rigidity. Traditionally, media have been manufactured to encompass a broad separation range, but the trend is now towards a focus on a few key separations. These include a renewed interest in separating smaller macromolecules such as peptides and protein fragments, and removing dimers and aggregates. The Sephacryl range of gel filtration products is available in convenient prepacked HiPrep 120 ml and 320 ml columns. The Superdex range of gel filtration media has been specifically designed to solve particular purification problems. The fractionation ranges are narrow and selectivity curves are steep compared with other gel filtration media. Additionally, Superdex media are available in prepacked HiLoad 120 ml and 320 ml columns, which are a convenient way of obtaining reproducible results at lab-scale.

Superdex prep grade

High productivity gel filtration for Polishing

Superdex prep grade is a high resolving gel filtration medium with average particle size of 34 µm. It is a composite of cross-linked agarose and dextran. Superdex 30 prep grade is well-suited for the Polishing and formulation of peptides with molecular weights of less than 1×10^4, Superdex 75 prep grade is designed for the separation of recombinant DNA products, and Superdex 200 prep grade is particularly useful for the separation of monoclonal antibodies from dimers and low molecular weight contaminants (e.g., albumin and transferrin). Typical flow velocity is up to 50 cm/h and back pressure is typically below 3 bar with a 60 cm bed height. All of the Superdex prep grade media are available in prepacked high performance HiLoad 120 ml and 320 ml columns.

- Superdex 30 prep grade
- Superdex 75 prep grade
- Superdex 200 prep grade

Sephacryl High Resolution

Well established high resolution gel filtration for production

Sephacryl High Resolution media give high resolution and are very well established in production process and industrial scale applications. They are a cost effective alternative to Superdex prep grade media. Sephacryl S-100, S-200, and S-300 are available in convenient, prepacked HiPrep 120 ml (16/60) and 320 ml (26/60) columns.

- Sephacryl S-100 High Resolution
- Sephacryl S-200 High Resolution
- Sephacryl S-300 High Resolution
- Sephacryl S-400 High Resolution
- Sephacryl S-500 High Resolution

Sepharose Fast Flow

Industrial scale separations of very large molecules and virus particles

The properties of Sepharose 4 and 6 Fast Flow media make them suitable for industrial scale gel filtration. These media are also well established as matrices for affinity chromatography.

- Sepharose 4 Fast Flow
- Sepharose 6 Fast Flow

Sephadex G-25

Well established for desalting and buffer exchange

Sephadex G-25 media are well established for desalting and buffer exchange in industrial applications. These media have a low exclusion limit and separate macromolecules from salts and buffer substances with a minimum of sample dilution. Prepacked HiPrep 26/10 Desalting columns (53 ml) are available for fast and convenient desalting as well as Hitrap Desalting 1 ml and 5 ml columns.

- Sephadex G-25 Coarse
- Sephadex G-25 Medium
- Sephadex G-25 Fine
- Sephadex G-25 Superfine

Sephadex LH-20

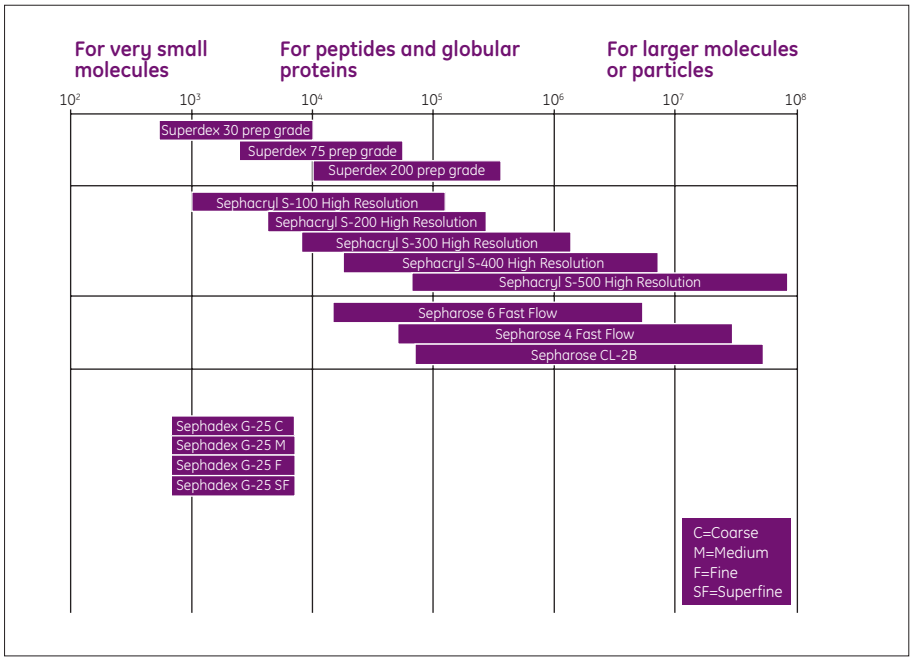
Gel filtration in organic solvents

This medium is for use with organic solvents when separating small molecules, lipids, steroids, fatty acids, hormones, etc.

- Sephadex LH-20

■ = BioProcess Media

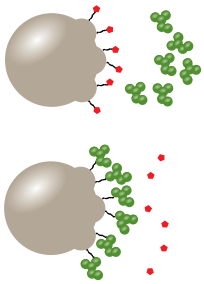
Application guide



Getting started

Testing the performance of separation media at the laboratory bench will help you select the most appropriate for process-scale use. HiLoad and HiPrep prepacked columns are convenient and reproducible and are well-suited for method development.

Custom Designed Media



The Custom Design Media (CDM) group provides large scale operators with chromatography media designed for their specific purification tasks. By tailoring a chromatography medium for your specific problem a CDM project aims to give you a more robust process and improved process economy. The Custom Designed Media can be made on an exclusive basis, but are often launched as a generally available product. Currently available CDM media are listed on the opposite page.

Note: Many CDM media have become standard products and are classed as BioProcess Media. They are supported accordingly. These media are described elsewhere in this catalog in the relevant technique sections.

Custom Designed Media projects

A CDM project is run according to ISO 9001 routines and in collaboration with the customer, often under a confidentiality agreement. An experienced team works with you from the initial discussions right through to bulk delivery: establishing your needs, sorting through choices, and producing and testing the finished product to meet your delivery schedules. The final product is often a new combination of our existing base matrices and a ligand. The ligand could be one of our own, be available from an external supplier, extracted from a ligand library or discovered by you. Projects are carried out in three stages – media definition, media assurance and full-scale production and validation.

Media definition

The first stage involves discussions about the construction (matrix, ligands and coupling chemistry) required to obtain the desired product function. Alternatives can be suggested and samples prepared for your evaluation. From this evaluation and further discussions, the medium is defined.

Media assurance

After proof-of-principle has been obtained, a robust and scalable manufacturing process is developed. This includes optimization of the medium design and development of relevant analytical methods to secure functionality.

Preliminary specifications are set for the mutually agreed test criteria. Pilot scale volumes can be delivered when needed.

Full-scale production and validation

In the final stage the process is scaled up to a manufacturing scale appropriate for the customer needs. Test methods are validated and final specifications are set. If the product has potential as a widely-used product, it will be launched as a CDM product in the catalog. After delivery of several manufacturing batches to the customer, the process is validated. CDM products are not kept in stock but only manufactured on order.

Every CDM product is designed to meet the stringent quality standards for commercial industrial use. Each undergoes full quality control, both during development and at full-scale production. Specific studies, such as stability, can be performed and Regulatory Support Files can be provided.

» For further information about CDM, please contact your local GE Healthcare office.

Custom products

GE Healthcare offers a large selection of prepacked columns and bulk media encompassing most liquid chromatography techniques. Should you require a special configuration or combination of column and medium not offered in the catalog, just contact your local sales office and ask for Custom Products.

» See also Process Development on page 128 for details.

Ordering information

Product	Pack size	Code No.
6-AKS Sepharose 4 Fast Flow	1 l	17-3100-04
Amino Sepharose 6 Fast Flow	1 l	17-3092-09
ANX Sepharose 4 Fast Flow (low sub)	500 ml	17-1286-01
	5 l	17-1286-04
AVB Sepharose High Performance	75 ml	28-4112-01
	1 l	28-4112-02
Benzamidine Sepharose 4 Fast Flow (high sub)	100 ml	17-5123-01
	500 ml	17-5123-02
	5 l	17-5123-03
Benzamidine Sepharose 4 Fast Flow (low sub)	5 l	28-4108-03
Butyl Sepharose 6 Fast Flow	1 l	17-5431-03
	5 l	17-5431-04
Capto Blue (hs)	25 ml	17-5452-01
	500 ml	17-5452-02
Chelating Sepharose Big Beads	1 l	17-5272-03
	10 l	17-5272-05
CM Sepharose High Performance	1 l	17-1277-03
	5 l	17-1277-04
	10 l	17-1277-05
ECH-Lysine Sepharose 4 Fast Flow	500 ml	17-0902-02
	5 l	17-0902-04
Gelatin Sepharose 4 Fast Flow	1 l	17-0976-03
	5 l	17-0976-04
IgG Sepharose 6 Fast Flow	200 ml	17-0969-02
	5 l	17-0969-04
IgSelect	25 ml	28-4113-01
	200 ml	21-4113-02
	1 l	28-4113-03
Phenyl Sepharose Big Beads	1 l	17-5098-03
	10 l	17-5098-05
Plasminogen Removal Gel	1 l	28-4109-03
Procainamide Sepharose 4 Fast Flow	1 l	28-4111-03
	5 l	28-4111-04
VIIISelect	25 ml	17-5450-01
	500 ml	17-5450-02

5

Chromatography columns


AxiChrom
AxiChrom

Columns for process chromatography

When a chromatographic step is developed to be an integral part of a manufacturing process, the choice of column is important to assure consistent performance and reliable operation. With over 30 years experience in process chromatography, GE Healthcare can provide you with a wide range of columns that ensures the highest performance from our separation media and meets the demands of modern biopharmaceutical manufacturing. Know-how in packing methodology is available through our User Manuals. Workshops with lectures and hands-on training can be arranged through our Fast Trak services.

Points to consider when selecting your column

- **Dimensions:** To determine the appropriate column diameter at full-scale, calculate the column volume (or medium quantity) required based on your current scale, keeping bed height constant (usually 5 to 20 cm for adsorptive techniques and 50 to 70 cm for gel filtration). If the exact diameter is not available, choose a wider diameter column, the advantage being increased capacity.

- **Specifications:** Particle size, size distribution, flow rates and the solvent used will affect your choice of column. As particle size decreases, operational pressures increase. Two different media with the same nominal particle size, but with different particle size distributions may have significantly different pressure requirements.

  Solvent systems may restrict the choice of column materials, for example plastic or rubber components are unsuitable for use with some organic solvents. High salt buffers may dictate the grade or type of metal component, such as stainless steel 316L.

- **Design features:** Proven hygienic design and high quality materials are necessary if the column is to be used for biopharmaceutical production. A fixed bed column is more hygienic than the respective variable bed height column, but this must be set against the greater flexibility afforded by the variable height.

  For media requiring additional bed compression at the end of the packing procedure, a variable bed height column would be needed. In process development, diagnostics, or reagent manufacturing, some design criteria are less critical, and for example the use of threaded or sanitary connections may not be as important.

  Select only columns with a proven distribution system since performance can be jeopardized with inadequate distribution of sample and buffer. Bed support porosity is dictated by the particle size of the medium used.

- **Regulatory support:** Columns used in biopharmaceutical production or other regulated environments are scrutinized by regulatory authorities. Increasingly, documentation on materials compliance and toxicological data are requested.

  GE Healthcare supports the columns recommended for use in therapeutic manufacturing with hardware product documentation. The information in these files can save you valuable time when submitting clinical and marketing applications to regulatory authorities. In addition, Fast Trak services can support installation and operational qualifications.

- **Technical support online:** The process chromatography technical support portal provides users with a range of information including column and system recommendations, spare parts and accessories for columns and systems, column packing and testing information, and troubleshooting guides. Refer to Regulatory and Technical Support Services.

›› For further information on Online regulatory and technical support, see page 204.

›› Visit us on the web at www.gelifesciences.com/purification-techsupport

AxiChrom columns

New

AxiChrom 800 mm column

AxiChrom 70 mm column

The AxiChrom column platform simplifies column handling procedures from process development to full-scale manufacturing.

Intelligent Packing

Packing AxiChrom columns is facilitated by the Intelligent Packing methodology, where optimal compression of the bed is achieved by preprogrammed, verified packing methods. Preprogrammed methods reduce the need for extensive packing know-how and facilitate scale-up and tech-transfer.

» Larger columns available during 2008.

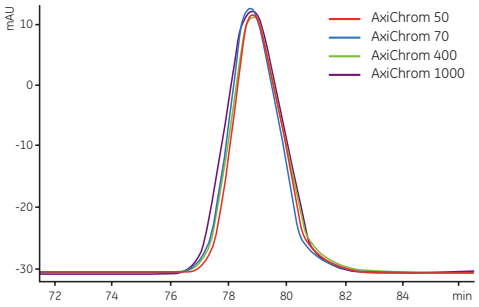
In AxiChrom 400 and larger columns packing is controlled by the AxiChrom Master, a separate unit comprising a touch-screen operator interface, a motor drive, and preprogrammed methods that support Intelligent Packing.

Intuitive handling

The AxiChrom Master provides interactive guidance for all key handling steps, which promotes the development of SOPs, as well as increasing safety. The novel swing-out tube of AxiChrom 400 and larger columns allows easy access to parts and maintenance *in situ*. AxiChrom 50 and 70 columns feature a pivot design that eliminates heavy lifting, promoting safer operation and easy access for maintenance.

Predictable scale-up

The distribution system within the AxiChrom family is based on a theoretical model to ensure uniform flow through the bed, producing reproducible results over a range of scales. The column is sanitizable and has the same seal design across all scales.



Results from HETP test on 10 cm SP Sepharose Fast Flow in different sizes of AxiChrom columns.

AxiChrom features

- Currently available in 50 mm, 70 mm, 400 mm, 600 mm, 800 mm, and 1000 mm diameters
- Small (50–70 mm) columns with two different tube lengths allowing bed volumes between 0.2 to 2 liters
- Large columns with bed volumes of 36 to 393 liters
- Pressure rating at 20 bar g (50 mm), 15 bar g (70 mm), and 4 bar g (400–1000 mm)
- Sanitary design with recommended CIP methods
- Preprogrammed, verified packing methods for Capto, MabSelect and Sepharose Fast Flow media families through Intelligent Packing
- cGMP compliant documentation
- Wetted polymers are approved according to USP Class VI tests for toxicity
- Supported with IQ/OQ documentation packages

What do I need?

Useful accessories

Pivot stand needs to be ordered separately for AxiChrom 50. The column is delivered with a foot stand.

Tubing kits are available for different set ups depending on what type of stand and system you use.

Mechanical locking is recommended for maintaining axial compression between runs and for longer periods of storage. The locking device allows the position of the adapter to be locked without the need for hydraulic pressure.

Useful spare parts to keep on site

Bed supports, a complete set of O-rings and scraper sealing.

Assembly/disassembly of column

The centering plug delivered with the column must be used when assembling the column. A tool kit with the necessary tools can be ordered separately.

Ordering information

Column	Code No.
AxiChrom 50/300	28-9018-31
AxiChrom 50/500	28-9018-41
AxiChrom 70/300	28-9018-40
AxiChrom 70/500	28-9018-47
AxiChrom 400, 600, 800, and 1000	Please contact your GE Healthcare representative

Literature

Data File	Code No.
AxiChrom Columns	28-9290-41
Application Note	
Sanitization of AxiChrom columns	28-9290-42

For more information contact your local GE Healthcare representative or visit www.gelifesciences.com/axichrom

Accessories for AxiChrom 50 and AxiChrom 70

Item	Qty/pk	Material	Code no.	USP Class VI
Pivot stand 50/70/100-300	1	EN 1.4401	28-4017-09	N/A
Pivot stand 50/70/100-500	1	EN 1.4401	28-4017-10	N/A
AxiChrom foot 70	1	PS (Polystyrene)	28-4019-37	N/A
Mechanical locking 50	1	EN 1.4401	28-4018-39	N/A
Mechanical locking 70	1	EN 1.4401	28-4018-40	N/A
Tool kit AxiChrom 50	Wrench (mm): 5, 11, 14; Allen key (mm): 1.5, 2.5, 4; Torque wrench with socket (mm): 10		28-4047-77	N/A
Tool kit AxiChrom 70	Wrench (mm): 6, 16, 27; Allen key (mm): 2, 2.5, 4; Torque wrench with socket (mm): 13		28-4047-78	N/A
Tubing kit AxiChrom 50/ÄKTAexplorer/desk	1	PVDF	28-9055-41	Yes
Tubing kit AxiChrom 50/ÄKTAexplorer/floor	1	PVDF	28-9056-03	Yes
Tubing kit AxiChrom 50/ÄKTApilot/desk	1	PVDF	28-9056-76	Yes
Tubing kit AxiChrom 50/ÄKTApilot/floor	1	PVDF	28-9136-13	Yes
Tubing kit AxiChrom 70(ÄKTApilot/floor	1	PVDF	28-9136-14	Yes
SRV-1, M6	1	EFTE/Titanium	19-2145-01	No
Valve 5/16" straight	1	PEEK	28-9076-74	Yes

Spare parts

Item	50 mm	70 mm	Qty/pk	Material
Bed Support top	28-9245-64	28-9245-76	1	PEEK/EN 1.4404
Bed Support bottom	28-4018-51	28-4019-23	1	PEEK/EN 1.4404
Scraper sealing	28-9245-28	28-9245-70	1	UHMWPE/EPDM
O-ring bed support top	28-9245-57	28-9245-72	1	EPDM
O-ring bed support bottom	28-401774	28-4019-18	1	FPM
O-ring adaptor tube	28-4017-77	28-4017-77	3	EPDM
O-ring adaptor	28-9245-22	28-9245-68	1	EPDM
O-ring bottom plate	28-4017-73	28-4019-17	1	EPDM

›› For the latest updates on the availability and dimensions of AxiChrom columns, visit www.gelifesciences.com/axichrom

INdEX columns

INdEX are easy-to-use, general purpose, glass columns well-suited for applications such as process development and diagnostics production. These columns are characterized by their simple design and the novel, axial compression packing method that yields a densely packed bed in under 10 minutes.

INdEX range

- Scalable from inner diameters of 70 to 200 mm and bed volumes from 0.1 to 25 liters
- Pressure rating 3 bar
- For use with an array of techniques and media, especially Sepharose Fast Flow
- Proven distribution system
- Dynamic axial compression yields densely packed, high efficiency beds
- Materials include electropolished stainless steel, borosilicate glass and polymers
- Packing devices for longer bed heights

Overview of INdEX columns

Column	Tube inner diam (mm)	Tube height (cm)	Cross-sectional area (cm^2)	Bed height (cm) min	Bed height (cm) max[1,2]	Bed volume (l) min	Bed volume (l) max[1,2]	Max pressure (bar)[3]
INdEX 70/500	70	50	38	3	32 (41)	0.1	1.2 (1.6)	3
INdEX 70/950	70	95	38	48	61 (79)	1.8	2.3 (3.0)	3
INdEX 100/500	100	50	79	3	32 (41)	0.2	2.5 (3.2)	3
INdEX 100/950	100	95	79	48	61 (79)	3.8	4.8 (6.2)	3
INdEX 140/500	140	50	154	3	32 (41)	0.5	4.9 (6.3)	3
INdEX 140/950	140	95	154	48	61 (79)	7.4	9.4 (12.2)	3
INdEX 200/500	200	50	314	3	32 (41)	0.9	10.0 (12.9)	3
INdEX 200/950	200	95	314	48	61 (79)	15.1	19.2 (24.8)	3

[1] Maximum bed volumes and bed heights are based on a slurry concentration of 75% and a packing compression of 15%.
[2] The figures within brackets are achievable using a packing device.
[3] Use a manometer to monitor the pressure.

What do I need?

Stands and wheels
INdEX 70 and 100 stands have adjustable feet. Castors with brakes are available. INdEX 140 and 200 stands have castors with brakes as standard.

Useful spare parts
Nets: The column is delivered with 23 µm (polypropylene) nets. For media with an average particle diameter <70 µm, change to 10 µm (polyamide) in both adaptors and end-pieces.
Seals: Inspect the seals on a regular basis for signs of wear.

Spare parts to keep on site
All nets, support screens and O-rings. In some cases, a spare tube may be advisable.

Longer bed heights
Packing extensions are available for all diameters. For packing INdEX columns with the packing device for BPG columns, an extra lid kit has to be ordered.

Isolating the column after packing
We recommend using 25-mm blind flanges with clamp and gasket to prevent contamination of the packed bed.

Connecting the column to your system
A clamp and gasket, 6 mm i.d., is required to connect the 25-mm sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing in 6 mm i.d. is also available.

Assembly/disassembly of column
No tools are required as all fittings are finger-tight.

Useful column accessories
Air Traps: INdEX Air Trap Complete includes the air trap, mounting bracket, steel valves, clamps, gaskets and tubings, 25 mm TC.
Top valve: Manually operated valve recommended at the top of the airtrap as an air outlet control.
Manometers: Manometer kits contain a pressure gauge, T-junction, necessary clamps and gaskets for sanitary connections.
Pressure relief valve: Required for the hydraulic packing procedure. It is connected between the pump and hydraulic inlet to ensure flow delivery at a constant pressure throughout the packing procedure.
Safety valve: Precalibrated valve that releases pressure if the calibrated value is exceeded. Recommended if the column may exceed its maximum pressure limit and no other pressure sensor is included in the chromatographic system. T-junction, clamps and gaskets have to be ordered separately.

Ordering information	
Column	**Code No.**
INdEX 70/500	18-1115-06
INdEX 70/950	18-1115-07
INdEX 100/500	18-1104-15
INdEX 100/950	18-1104-16
INdEX 140/500	18-1115-08
INdEX 140/950	18-1115-09
INdEX 200/500	18-1104-17
INdEX 200/950	18-1104-18
Stand	**Code No.**
INdEX 70 stand	18-1103-60
INdEX 100 stand	18-1103-60
INdEX 140 stand	18-1103-61
INdEX 200 stand	18-1103-61

Stands must be ordered separately

Packing extension.

Air trap, top valve, pressure gauge and safety valve.

Accessories for INdEX columns

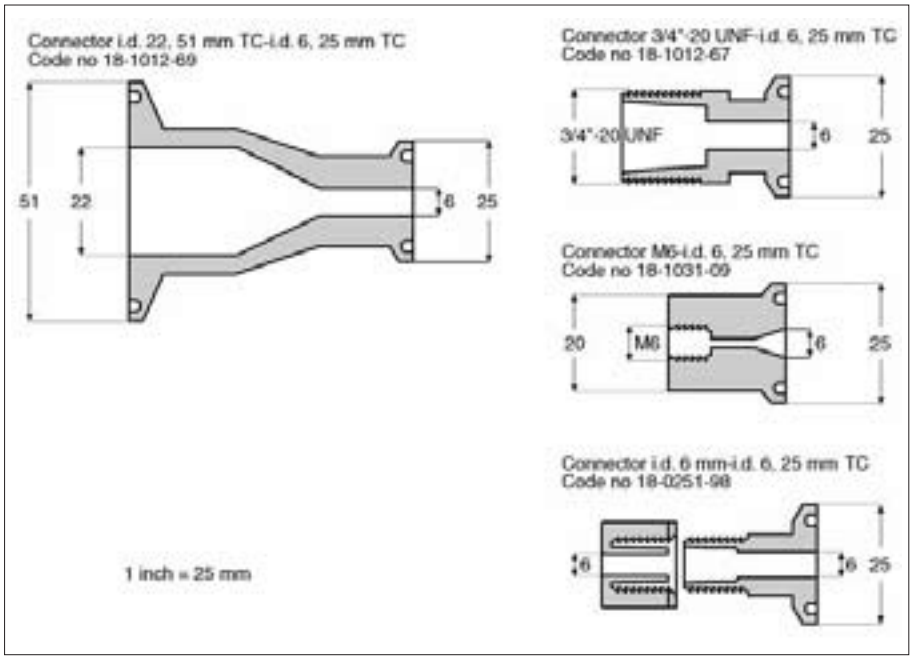
Accessory	INdEX 70	INdEX 100	INdEX 140	INdEX 200	Qty/pack	Material
Air Trap Complete[3]	18-1102-96	18-1102-96	18-1102-97	18-1102-97	1	SS 316/Glass
Top valve[3]	18-1121-44	18-1121-44	18-1121-44	18-1121-44	1	SS 316/EPDM
Valves						
4-port, 2-way[3]	18-5757-01	18-5757-01	18-5757-01	18-5757-01	1	SS 316L/PTFE
4-port, 4-way[3]	18-5758-01	18-5758-01	18-5758-01	18-5758-01	1	SS 316L/PTFE
Valve sealing, washer[6]	18-1128-69	18-1128-69	18-1128-69	18-1128-69	2	PTFE
T-junction[5]	18-1104-29	18-1104-29	18-1104-29	18-1104-29	1	SS 316
Safety valve[4]	18-5738-01	18-5738-01	18-5738-01	18-5738-01	1	SS 316/EPDM
Pressure relief valve[3]	18-1105-36	18-1105-36	18-1105-36	18-1105-36	1	SS 316/FPM
Manometer[4]	18-1119-29	18-1119-29	18-1119-29	18-1119-29	1	SS 316
Manometer kit[4]	18-1119-28	18-1119-28	18-1119-28	18-1119-28	1	–
Castor	18-1001-09	18-1001-09	18-1001-09	18-1001-09	1	–
Adjustable foot	18-1126-93	18-1126-93	18-1126-93	18-1126-93	1	–
Tubing with sanitary fitting						
i.d. 6 mm[3]						
30 cm	18-0005-42	18-0005-42	18-0005-42	18-0005-42	1	PVC
75 cm	18-0005-43	18-0005-43	18-0005-43	18-0005-43	1	PVC
125 cm	18-0005-44	18-0005-44	18-0005-44	18-0005-44	1	PVC
150 cm	18-0005-45	18-0005-45	18-0005-45	18-0005-45	1	PVC
200 cm	18-0005-47	18-0005-47	18-0005-47	18-0005-47	1	PVC
Connectors (see p 97)						
i.d. 6 mm. 25 mm TC						
6 mm threaded	18-0251-98	18-0251-98	18-0251-98	18-0251-98	2	PP
25 mmTC-3/4"-20						
UNF threaded	18-1012-67	18-1012-67	18-1012-67	18-1012-67	2	PP
25 mm TC-M6 threaded	18-1031-09	18-1031-09	–	–	2	PP
25 mm TC-i.d. 22 mm,						
51 mm TC	18-1012-69	18-1012-69	18-1012-69	18-1012-69	2	PP
Clamp 25 mm	18-1001-31	18-1001-31	18-1001-31	18-1001-31	1	SS 304
Clamp 51 mm	44-7134-01	44-7134-01	44-7134-01	44-7134-01	1	SS 304
Gasket 25 mm	18-0019-27	18-0019-27	18-0019-27	18-0019-27	2	EPDM
Gasket 51 mm	18-1012-88	18-1012-88	18-1012-88	18-1012-88	5	EPDM
Blind flange, 25 mm incl. gasket	18-1001-25	18-1001-25	18-1001-25	18-1001-25	1	SS 304/EPDM
Blind flange 51 mm incl. gasket	44-7135-01	44-7135-01	44-7135-01	44-7135-01	1	SS 304/EPDM
Packing device with PP lid[1]	18-1114-35	18-1104-22	18-1114-36	18-1104-23	1	Glass
Lid kit[2] for packing device		18-1108-63	18-1114-37	18-1108-64	1	–

[1] The packing device consists of PP lid, a 380 mm glass tube, flanged, rods, O-rings in EPDM, bed support, adaptor bed support, screws and nuts.
[2] The lid kit consists of PP lid, O-rings in EPDM, bed support, adaptor bed support, screws and nuts. The lid kit can be used together with the packing devices for BPG 100, 140 and 200 columns on INdEX columns of the same size.
[3] 25 mm TC.
[4] 51 mm TC.
[5] 2 × 25 mm, 1 × 51 mm TC.
[6] Fits 2-way and 4-way valves.

Spare parts for INdEX columns

	INdEX 70	INdEX 100 Code No.	INdEX 140 Code No.	INdEX 200 Code No.	Qty/pack Code No.	Material
Column tube 500	18-1114-14	18-1104-49	18-1114-12	18-1104-51	1	Borosilicate glass
Column tube 950	18-1114-15	18-1104-50	18-1114-13	18-1104-52	1	Borosilicate glass
Bed support, adaptor	18-1114-24	18-0251-56	18-1112-99	18-0252-56	2	PP
Bed support 23 µm, adaptor	18-1114-26	18-9251-01	18-1113-01	18-9253-01	2	PP
Bed support 10 µm, adaptor	18-1114-28	18-0251-76	18-1113-03	18-0252-76	2	PA
Bed support, end-piece	18-1114-25	18-0251-55	18-1112-98	18-0252-55	2	PP
Bed support 23 µm, end-piece	18-1114-27	18-9252-01	18-1113-00	18-9254-01	2	PP
Bed support 10 µm, end-piece	18-1114-29	18-0251-77	18-1113-02	18-0252-77	2	PA

Material abbreviations: EPDM=ethylene propylene diene, FPM=fluorocarbon rubber, PA=polyamide, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel.



Literature

Data File	Code No.
INdEX Columns 70-200 series	18-1115-61

BPG columns

BPG columns are glass columns designed for use in the production of biopharmaceuticals or any product made in a regulated or current Good Manufacturing Practice (cGMP) environment. The columns are manufactured with materials carefully selected for their compatibility with the solvents most commonly used in biopharmaceutical manufacture. All polymeric materials are approved according to USP Class VI tests for toxicity.

BPG range

- Scalable from inner diameters of 100 mm to 450 mm and bed volumes from 2 to 121 liters
- Pressure rating up to 8 bar
- Proven hygienic design and easy cleaning-in-place
- For use with a variety of techniques and chromatographic media, especially BioProcess Media (Superdex, Sepharose High Performance and Fast Flow, and Sephacryl)
- Proven distribution system
- Sanitary TC connections throughout
- Materials include electropolished stainless steel, calibrated borosilicate glass, EPDM and fluoroplastics – all with high chemical resistance
- All polymeric materials are approved according to USP Class VI tests for toxicity
- IQ and OQ documentation packages available
- Validation support documentation available on request
- Packing devices available for long bed heights

Overview of BPG columns

Column Diameter (mm)	Column Area (cm^2)	Column Height (cm)	Bed height (cm)				Volume (l)				Max. pressure (bar g)[4]	Total weight (kg)	Adapter weight (kg)	Overall dimensions (cm) D×W×H
			Min	Max[1]	Packing with extension[2]	Running with extension[3]	Min	Max[1]	Packing with extension[2]	Running with extension[3]				
100	78.5	50	0	26	34	45	0.0	2.0	2.7	3.5	8	15	7	48×48×127
100	78.5	75	25	41	55	65	2.0	3.2	4.3	5.1	8	16	7	48×48×152
100	78.5	95	45	54	72	78	3.5	4.2	5.7	6.1	8	17	7	48×48×172
140	154	50	0	26	34	45	0.0	4.0	5.2	6.9	6	25	11	59×59×127
140	154	75	25	41	55	65	3.9	6.3	8.5	10.0	6	26	11	59×59×152
140	154	95	45	54	72	78	6.9	8.3	11.1	12.0	6	27	11	59×59×172
200	314	50	0	26	34	45	0.0	8.2	10.7	14.1	6	34	13	59×59×127
200	314	75	25	41	55	65	7.8	12.9	17.3	20.4	6	36	13	59×59×152
200	314	95	45	54	72	78	14.1	17.0	22.6	24.5	6	39	13	59×59×172
296	688	50	0	26	34	45	0.0	17.9	23.4	31.0	4	68	29	69×69×133
296	688	75	25	41	55	65	17.2	28.2	37.8	44.7	4	73	29	69×69×158
296	688	95	45	54	72	78	31.0	37.2	49.5	53.7	4	78	29	69×69×178
446	1562	50	11	22	30	45	17.2	34.4	46.9	70.3	2.5	200	100	80×80×140
446	1562	75	36	38	51	62	56.2	59.4	79.7	96.8	2.5	215	100	80×80×165
446	1562	100	61	64	72	78	95.3	100.0	112.5	121.8	2.5	230	100	80×80×190

Bed volumes and bed heights are based on a slurry concentration of 75% and a packing compression of 15%. Where compression is the difference in volume between a sedimented bed and a bed under pressure.

[1] Values achievable without a packing extension.

[2] Values achievable when a packing extension is used for sedimentation of the bed (75% of the slurry must fit into the column and extension when the adapter is mounted).

[3] Values achievable when the packing extension remains attached to the column for the duration of column use. The adapter must seal at least 5 cm into the column tube to avoid high tensions in the glass tube.

[4] Use a manometer to monitor the pressure.

What do I need?

The column

BPG 100, 140 & 200; stand kit must be ordered separately. BPG 100 has adjustable feet, wheels with brakes are available. BPG 140 & 200 stands have wheels with brakes as standard. BPG 300 & 450; supplied with stainless steel stand with wheels and foot-operated brakes.

Useful spare parts

Nets: The column is delivered with 23 µm (polypropylene) nets. For media with an average particle diameter <70 µm, change to 10 µm (polyamide) or 12 µm (PEEK) in both adaptors and endpieces. For Sepharose Big Beads use 54 µm nets.

O-rings: FEP adaptor and sealing O-rings if solvents not compatible with the EPDM O-rings supplied with the column.

Gaskets: Use PTFE gaskets if solvent not compatible with EPDM.

Spare parts to keep on site

All nets, support screens and O-rings. In some cases, a spare tube may be advisable.

Longer bed heights

Packing extensions are available for all diameters.

Isolating the column after packing

We recommend using sanitary stainless steel valves of the appropriate inner diameter to prevent contamination of the packed bed. The 2-way or 4-way valves with a 6 mm i.d. are suitable for BPG 100, 140 and 200 columns. The 10 mm i.d. is suitable for BPG 300 and 450 columns. For storage purposes, the 25-mm blind flange with a clamp and gasket can be used to seal off the column.

Standard accessories: packing extension, tubing, valves, safety valves, air trap, T-junction, pressure relief valve, clamps, gaskets, manometer and top-valve.

Connecting the column to your system

A clamp and gasket, 6 or 10 mm i.d., are required to connect the 25-mm sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing in 6 and 10 mm i.d. is available.

Assembly/disassembly of column

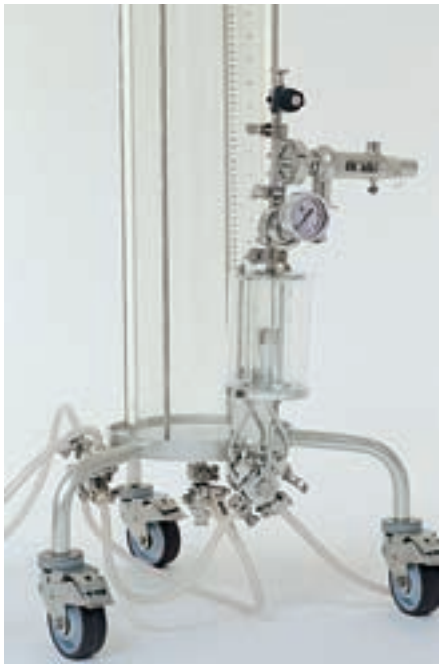
A torque wrench with an appropriate sized socket is required and can be ordered separately.

Useful column accessories

Air Traps: BPG Air Trap Complete includes the air trap, mounting bracket, steel valves, clamps and gaskets. For air traps for BPG 100, 140 and 200, tubing is included.

Top valve: Manually operated valve recommended at the top of the airtrap as an air outlet control.

Manometers: Manometer kits contain a pressure gauge, T-junction, and necessary clamps and gaskets for sanitary connections.



Air trap, top valve, manometer and safety valve.

Pressure relief valves: Connected between the pump and column inlet permit flow delivery at a constant pressure throughout the packing procedure.

Safety valve: Precalibrated valve that releases pressure if the calibrated value is exceeded. Recommended if the column may exceed its maximum pressure limit and no other pressure sensor is included in the chromatographic system. T-junction, clamps and gaskets have to be ordered separately.

Earlier design: For ordering accessories and spare parts to the former design of the BPG 100, 200 and 300 columns, design pressure 3 bar, see Instruction Manual Code No. 18-1030-99.

Suitable systems: BPG columns are designed for use with ÄKTAprocess Systems and have design pressures of 8 bar (BPG 100), 6 bar (BPG 140 and 200), 4 bar (BPG 300) and 2.5 bar (BPG 450). Please contact your local GE Healthcare representative for details.

Ordering information

	Tube height			
Column	500 mm	750 mm	950 mm	Stand
BPG 100	18-1103-01	18-1103-02	18-1103-03	18-1031-10
BPG 140	18-1113-08		18-1113-09	18-1031-20
BPG 200	18-1103-11	18-1103-12	18-1103-13	18-1031-20
BPG 300	18-1103-21	18-1103-22	18-1103-23	included
			1000 mm	
BPG 450	18-1103-71	18-1103-72	18-1103-73	included

Each column includes as standard: 23 µm polypropylene filter bed supports and polypropylene coarse bed supports, 2 clamps, 2 EPDM gaskets, 2 blank caps and O-rings in EPDM.

Column with packing extension.

Accessories for BPG columns

Accessory	BPG 100	BPG 140	BPG 200	BPG 300	BPG 450	Qty/pk	Material
Air Trap Complete[2]	18-1102-96	18-1102-97	18-1102-97	18-1102-98	18-1103-00	1	SS 316/Glass
Top valve[2]	18-1121-44	18-1121-44	18-1121-44	18-1121-44	18-1121-44	1	SS 316L/EPDM
Valves[2]							
4-port, 2-way i.d. 6 mm	18-5757-01	18-5757-01	18-5757-01	–	–	1	SS 316L/PTFE
4-port, 2-way i.d. 10 mm	–	–	–	18-1012-56	18-1012-56	1	SS 316L/PTFE
3-port, 2-way i.d. 15 mm	–	–	–	–	44-5499-90	1	SS 316L/PTFE
4-port, 4-way i.d. 6 mm	18-5758-01	18-5758-01	18-5758-01	–	–	1	SS 316L/PTFE
4-port, 4-way i.d. 10 mm	–	–	–	18-1012-57	18-1012-57	1	SS 316L/PTFE
Valve sealing washer[5]	18-1128-69	18-1128-69	18-1128-69	18-1128-69	18-1128-69	2	PTFE
Pressure relief valve[2] i.d. 6 mm	18-1105-36	18-1105-36	18-1105-36	18-1105-36	–	1	SS 316/FPM
Safety valve[3, 5]	18-1035-80	18-1035-81	18-1035-81	18-1035-82	18-1103-65	1	SS 316/EPDM
T-junction[4]	28-4057-65	28-4057-65	28-4057-65	28-4057-75	28-4057-75	1	SS 316
Manometer kit[3]	18-1031-07	18-1031-07	18-1031-07	18-1031-08	18-1031-08	1	–
Manometer[3]	18-1103-67	18-1103-67	18-1103-67	18-1103-68	18-1103-68	1	SS 316
Castor	18-1001-09	28-9270-79	28-9270-79	28-9270-79	28-9226-77	1	–
Adjustable foot	18-1126-93	18-1126-93	18-1126-93	–	–		–
Manometer 0–10 bar	11-0011-18	11-0011-18	11-0011-18	–	–	1	SS 316
Manometer 0–6 bar	–	–	–	11-0011-19	11-0011-19	1	SS 316
Tubing with sanitary fitting[2]							
30 cm i.d. 6 mm	18-0005-42	18-0005-42	18-0005-42	–	–	1	PVC
30 cm i.d. 10 mm	–	–	–	18-1012-85	18-1012-85	1	PVC
40 cm i.d. 10 mm	–	–	–	18-1012-86	18-1012-86	1	PVC
75 cm i.d. 6 mm	18-0005-43	18-0005-43	18-0005-43	–	–	1	PVC
75 cm i.d. 14 mm	–	–	–	–	18-1027-28	1	PVC
90 cm i.d. 10 mm	–	–	–	18-1012-62	18-1012-62	1	PVC
125 cm i.d. 6 mm	18-0005-44	18-0005-44	18-0005-44	–	–	1	PVC
140 cm i.d. 10 mm	–	–	–	18-1012-63	18-1012-63	1	PVC
150 cm i.d. 6 mm	18-0005-45	18-0005-45	18-0005-45	–	–	1	PVC
170 cm i.d. 10 mm	–	–	–	18-1012-64	18-1012-64	1	PVC
180 cm i.d. 14 mm	–	–	–	–	18-1027-29	1	PVC
200 cm i.d. 6 mm	18-0005-47	18-0005-47	18-0005-47	–	–	1	PVC
200 cm i.d. 10 mm	–	–	–	18-1012-87	18-1012-87	1	PVC
Connectors (see p 111–112)							
i.d. 6, 25 mm TC- 6 mm threaded	18-0251-98	18-0251-98	18-0251-98	–	–	2	PP
i.d. 6, 25 mm TC- 3/4"-20 UNF threaded	18-1012-67	18-1012-67	18-1012-67	–	–	2	PP
i.d. 6, 25 mm TC- M6 threaded	28-4057-64	–	–	–	–	2	PP
i.d. 6, 25 mm TC- i.d. 22, 51 mm TC	18-1012-69	18-1012-69	18-1012-69	–	–	2	PP
i.d. 10, 25 mm TC – 3/4"-20 UNF threaded	–	–	–	18-1012-68	18-1012-68	2	PP
i.d. 10, 25 mm TC- i.d. 14, 51 mm TC	–	–	–	18-1027-25	18-1027-25	2	PP
i.d.14, 51 mm TC- i.d. 22, 51 mm TC	–	–	–	–	18-1027-26	2	PP
Clamp 25 mm	18-1001-31	18-1001-31	18-1001-31	18-1001-31	18-1001-31	1	SS 304
Clamp 51 mm	44-7134-01	44-7134-01	44-7134-01	44-7134-01	44-7134-01	1	SS 304
Gasket 25 mm i.d. 6 mm	18-0019-27	18-0019-27	18-0019-27			2	EPDM
Gasket 25 mm i.d. 6 mm	18-0019-28	18-0019-28	18-0019-28			2	PTFE
Gasket 25 mm i.d. 10 mm	–	–	–	18-1035-79		2	EPDM
Gasket 25 mm i.d. 10 mm	–	–	–	18-1012-40		2	PTFE
Gasket 25 mm i.d. 12 mm	–	–	–	–	18-0200-00	2	EPDM
Gasket 25 mm i.d. 12 mm					44-5506-20	2	PTFE
Gasket 51 mm i.d. 10 mm				18-1012-88	18-1012-88	5	EPDM
Gasket 51 mm i.d. 14 mm				–	18-1017-57	5	EPDM
Gasket 51 mm i.d. 22 mm	44-7133-01	44-7133-01	44-7133-01	44-7133-01	44-7133-01	5	EPDM
Gasket 51 mm i.d. 22 mm	44-5512-03	44-5512-03	44-5512-03	44-5512-03	44-5512-03	2	PTFE
Blind flange 25 mm incl gasket	18-1001-25	18-1001-25	18-1001-25	18-1001-25	18-1001-25	1	SS 304/EPDM
Blind flange 51 mm incl gasket	44-7135-01	44-7135-01	44-7135-01	44-7135-01	44-7135-01	1	SS 304/EPDM
Torque wrench	18-0251-37	18-0251-37	18-0251-37	18-0251-37	18-0251-37	1	SS 304
12-point opening socket	18-1031-03	18-1031-04	18-1031-04	18-1031-05	18-1105-31	1	SS 304
Allen key	18-1030-98	18-1030-98	18-1030-98	18-1030-98	18-1030-98	1	SS 304
Packing device glass[1]	18-1104-75	18-1113-33	18-1104-77	18-1108-16	–	1	Glass
Packing device[1]	–	–	–	–	18-1105-32	1	SS 316
Media stirrer (80 mm Ø)	28-9191-03	28-9191-03	28-9191-03	-	-	1	-
Media stirrer (150 mm Ø)	-	-	-	28-9191-04	28-9191-04	1	-

[1] The packing device for BPG 100-200 consists of a 380 mm high glass tube, flanges, rods, O-rings in EPDM, nuts and screws. The packing device for BPG 300 consists of a 380 mm high glass tube, flanges, rods, O-rings in EPDM, nuts and a clamp. The packing device for BPG 450 consists of a 300 mm high stainless steel tube, O-rings, nuts and a clamp.

[2] 25 mm TC.

[3] 51 mm TC.

[4] 2×25, 1×51 mm TC.

[5] BPG 100 - 8 bar, BPG 140-200 - 6 bar, BPG 350 - 4 bar.

Spare parts for BPG columns

Spare part	BPG 100	BPG 140	BPG 200	BPG 300	BPG 450	Qty/pack	Material
Column tube 500	18-0251-01	18-1112-95	18-1152-01	18-1012-28	18-1103-14	1	Borosilicate glass
Column tube 750	18-0251-02	–	18-1152-02	18-1012-29	18-1103-15	1	Borosilicate glass
Column tube 950	18-0251-03	18-1112-96	18-1152-03	18-1012-30	–	1	Borosilicate glass
Column tube 1000	–	–	–	–	18-1103-16	1	Borosilicate glass
Flange O-ring	18-8494-01	18-1113-06	18-8489-01	18-1012-26	18-1105-33	2	EPDM
Flange O-ring	18-0019-41	18-1113-07	18-0019-51	18-1012-27	18-1117-67	1	FEP
Adaptor O-ring	18-8475-01	18-1113-10	18-0275-01	18-1012-51	18-1017-47*	2	EPDM
Adaptor O-ring	18-0019-40	18-1113-11	18-0019-50	18-1012-52	18-1117-66	1	FEP
U-shaped seal	–	–	–	–	18-1104-40	1	EPDM
U-shaped seal	–	–	–	–	18-1117-55	1	PFR
Bed support, adaptor	18-1103-04	18-1112-99	18-0252-56	18-1012-53	18-1104-34*	2	PP
Bed support, end-piece	18-0251-55	18-1112-98	18-0252-55	18-1012-36	18-1104-35*	2	PP
Bed support, 10 µm, adaptor	18-1103-05	18-1113-03	18-0252-76	18-1012-55	18-1017-46*	2	PA
Bed support, 10 µm, end-piece	18-0251-77	18-1113-02	18-0252-77	18-1012-35	18-1103-18*	2	PA
Bed support, 12 µm, adaptor	18-1148-37	18-1148-39	18-1148-41	18-1148-43	18-1148-45*	2	PEEK
Bed support, 12 µm, end-piece	18-1148-38	18-1148-40	18-1148-42	18-1148-44	18-1148-46*	2	PEEK
Bed support, 23 µm, adaptor	18-1103-08	18-1113-01	18-9253-01	18-1012-54	18-1001-62*	2	PP
Bed support, 23 µm, end-piece	18-9252-01	18-1113-00	18-9254-01	18-1012-34	18-1103-19*	2	PP
Bed support, 54 µm adaptor	18-1126-96	18-1126-98	18-1127-00	18-1127-02	18-1127-04*	2	PP
Bed support, 54 µm end-piece	18-1126-97	18-1126-99	18-1127-01	18-1127-03	18-1127-05	2	PP

* One per pack

Material abbreviations: EPDM=ethylene propylene diene, FEP=fluoroethenepropene, FPM=fluorocarbon rubber, PA=polyamide, PFR=perfluor rubber, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel.

Literature

Data Files	Code No.
BPG Columns 100, 140, 200, 300 and 450 series	18-1115-23
Application Notes	
Sanitization of BPG Columns	18-1020-86
Sanitization of BPG 450 Column	18-1117-76

Documentation to support validation available on request. Contact your local GE Healthcare office.

Chromaflow columns

Chromaflow columns represent an innovative development in process scale chromatography resulting in improved process reliability, safety and economics.

With Chromaflow columns, packing, operation, unpacking and cleaning can be done without removing the lid or adaptor – all due to the design of the nozzle in both the top and bottom end-pieces. With the establishment of packing protocols for individual media, large-scale chromatography is more convenient, scalable and safer for both the operators and the product. Chromaflow columns are intended for GMP production. Materials of manufacture and column design, which are consistent over all scales, meet the demands of regulatory authorities for cGMP facilities producing biopharmaceuticals.

Chromaflow range

- Diameters start at 300 mm and end at 2000 mm
- Design principle is common to all column dimensions making scale-up a simple operation
- 3 bar pressure rating as standard and up to 5 bar as custom made
- Transparent, high quality cast acrylic or electropolished stainless steel tube
- Hygienic design tested in microbial challenge studies
- Packing stations simplify packing and unpacking
- All polymeric materials are approved according to USP Class VI tests for toxicity
- Full documentation package Validation support documentation available on request
- Documentation to support validation delivered with the product

» For customized Chromaflow columns, please contact your local representative.

Properties of Chromaflow columns

Design specifications	
Design temperature	4–30°C
Operating pressure	3 bar
CE-directive compliance	PED/ATEX100
Design standard	GE Healthcare GEP
Surface finishes, stainless steel	
Internal wetted	< 0.5 µm Ra EP
Non-wetted parts	< 3 µm Ra EP

Material specifications	
Tube	Acrylic (PMMA)/316L
Distributor plates	Polypropylene
Bed supports	Polyethylene/316L
Seals	FEP encapsulated silicone & EPDM
Nozzle body	Polypropylene
Nozzle tube	PEEK 450 G/316L
Nozzle tip	PEEK 450G
Stand	316

For more information contact your GE Healthcare representative.

Principle of operation

Nozzles sit in both the top and bottom of the column allowing packing in either an upward or downward direction. There are three nozzle positions: mid-position, for priming and packing; retracted, for running; and fully extended into the column for unpacking and cleaning. The nozzle also enables isolation of slurry lines from the mobile phase during operation, allowing removal of residual medium and cleaning of the slurry lines independently of the rest of the column.
In the example opposite, packing is via the lower nozzle with upward flow.

Packing position

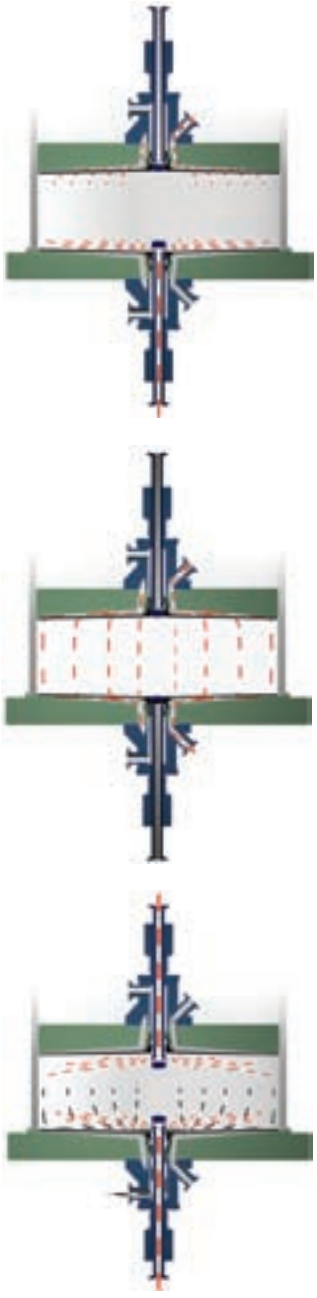
The bottom nozzle extends part of the way (mid position) into the column. The top nozzle is fully retracted. Slurry enters the column via the bottom nozzle and excess liquid exits via the top mobile phase outlet. After packing, the slurry lines are isolated from the mobile phase and can be cleaned independently from the rest of the column.

Running position

The top and bottom nozzles are retracted. Mobile phase enters the column directly into an annulus immediately behind the bed support. The annulus is cut through at an angle to ensure that the linear flow rate is kept constant during distribution of the mobile phase across the bed.

Unpacking position

In this position, both bottom and top nozzles are fully extended into the column, thereby exposing a third passage through which medium leaves the column. Cleaning solution can be pumped through the nozzles and sprayed into the column. In this way, the column is easily and effectively cleaned without exposing the interior or the medium to the outside, or without dismantling the column.



Ordering information

Chromaflow columns with acrylic tubes	Bed support 10 mm SS sinter	Bed support 20 mm SS sinter	Bed support 20 mm PE sinter
I.d. 400 mm Man. nozzle			
Stroke length 100-300	18-1150-40	18-1159-40	18-1161-40
Stroke length 200-400	18-1157-42	18-1159-42	18-1161-42
Stroke length 300-500	18-1157-44	18-1159-44	18-1161-44
I.d. 400 mm Auto. nozzle			
Stroke length 100-300	18-1157-41	18-1159-41	18-1161-41
Stroke length 200-400	18-1157-43	18-1159-43	18-1161-43
Stroke length 300-500	18-1157-45	18-1159-45	18-1161-45
I.d. 400 mm SFP* Man. nozzle			
Stroke length 100-300	18-1170-53	18-1176-12	11-0011-85
Stroke length 200-400	11-0011-80	11-0011-83	11-0011-86
Stroke length 300-500	11-0011-82	11-0011-84	11-0011-87
I.d. 400 mm SFP Auto. nozzle			
Stroke length 100-300	11-0011-89	11-0011-91	11-0011-94
Stroke length 200-400	11-0011-88	11-0011-92	11-0011-95
Stroke length 300-500	11-0011-90	11-0011-93	11-0011-96
I.d. 600 mm Man. nozzle			
Stroke length 100-300	18-1150-60	18-1159-60	18-1161-60
Stroke length 200-400	18-1157-62	18-1159-62	18-1161-62
Stroke length 300-500	18-1157-64	18-1159-64	18-1161-64
I.d. 600 mm Auto. nozzle			
Stroke length 100-300	18-1157-61	18-1159-61	18-1161-61
Stroke length 200-400	18-1157-63	18-1159-63	18-1161-63
Stroke length 300-500	18-1157-65	18-1159-65	18-1161-65
I.d. 800 mm Man. nozzle			
Stroke length 100-300	18-1150-80	18-1159-80	18-1161-80
Stroke length 200-400	18-1157-82	18-1159-82	18-1161-82
Stroke length 300-500	18-1157-84	18-1159-84	18-1161-84
I.d. 800 mm Auto. nozzle			
Stroke length 100-300	18-1157-81	18-1159-81	18-1161-81
Stroke length 200-400	18-1157-83	18-1159-83	18-1161-83
Stroke length 300-500	18-1157-85	18-1159-85	18-1161-85
I.d. 1000 mm Man. nozzle			
Stroke length 100-300	18-1150-10	18-1160-10	18-1162-10
Stroke length 200-400	18-1158-12	18-1160-12	18-1162-12
Stroke length 300-500	18-1158-14	18-1160-14	18-1162-14
I.d. 1000 mm Auto. nozzle			
Stroke length 100-300	18-1158-11	18-1160-11	18-1162-11
Stroke length 200-400	18-1158-13	18-1160-13	18-1162-13
Stroke length 300-500	18-1158-15	18-1160-15	18-1162-15

For column specifications other than listed in the table, please contact your local GE Healthcare representative.
* SFP = Small Flow Path on mobile phase, only available on 400 mm i.d. columns.

Options to the standard configuration

Details	Description
Casters	For columns with a maximum diameter up to 1000 mm.
Nozzle pipings	Extension pipings for the Mobile phase inlet top and Slurry outlet top (avoids tubing getting bent)
Nozzle control	The nozzle can be controlled either by the Chromaflow Nozzle control unit or the Chromaflow Packing station

Chromaflow Packing stations

Chromaflow Packing station Pack 50	18-1163-74
Chromaflow Packing station Pack 100	18-1162-08
Chromaflow Packing station Pack 200	Custom order
Chromaflow Packing station Pack 400	Custom order

Chromaflow Packing station selection guide

Packing Station	Min l/min	Max l/min
Pack 50	10	50
Pack 100	30	100
Pack 200	60	200
Pack 400	100	400

Chromaflow MKIII caster kits

Casters to 400-600 mm MKIII columns	18-1171-51
Casters to 800-1000 mm MKIII columns	18-1171-52

Chromaflow Nozzle control unit

Nozzle control unit	18-1164-61

Chromaflow Nozzle pipings

Chromaflow Nozzle piping 400 1/2"	18-1172-01
Chromaflow Nozzle piping 400 3/4"	18-1172-00
Chromaflow Nozzle piping 400 1"	18-1171-99
Chromaflow Nozzle piping 600 1/2"	18-1172-06
Chromaflow Nozzle piping 600 3/4"	18-1172-05
Chromaflow Nozzle piping 600 1"	18-1172-04
Chromaflow Nozzle piping 800 1/2"	18-1171-94
Chromaflow Nozzle piping 800 3/4"	18-1171-93
Chromaflow Nozzle piping 800 1"	18-1171-92
Chromaflow Nozzle piping 1000 1/2"	18-1172-09
Chromaflow Nozzle piping 1000 3/4"	18-1172-08
Chromaflow Nozzle piping 1000 1"	18-1172-07

Accessories for Chromaflow columns

Accessory	Code No.	Qty/pack	Material
Valves			
4-port 2-way, i.d. 10 mm, 25 mm TC	18-1012-56	1	SS 316L/PTFE
4-port 4-way, i.d. 10 mm, 25 mm TC	18-1012-57	1	SS 316L/PTFE
3-port 2-way, i.d. 15 mm, 25 mm TC	44-5499-90	1	SS 316L/PTFE
4-port 4-way, i.d. 20 mm, 51 mm TC	44-2302-01	1	SS 316L/PTFE
3-port 2-way, i.d. 22 mm, 51 mm TC	44-1583-01	1	SS 316L/PTFE
3-port 2-way, i.d. 35 mm, 51 mm TC	44-5494-65	1	SS 316L/PTFE
Valve sealing washer fits 10 mm 2 and 4-way valves	18-1128-69	2	PTFE
Tubing with sanitary fitting 25 mm TC			
i.d. 10 mm, 900 mm	18-1012-62	1	PVC
i.d. 10 mm, 1400 mm	18-1012-63	1	PVC
i.d. 10 mm, 1700 mm	18-1012-64	1	PVC
i.d. 10 mm, 2000 mm	18-1012-87	1	PVC
i.d. 14 mm, 750 mm	18-1027-28	1	PVC
i.d. 14 mm, 1800 mm	18-1027-29	1	PVC
Tubing with sanitary fitting 51 mm TC			
i.d. 19 mm, 900 mm	28-4042-30	2	PVC
i.d. 19 mm, 1400 mm	28-4042-35	2	PVC
i.d. 19 mm, 2000 mm	28-4042-32	2	PVC
i.d. 19 mm, 4000 mm	28-4042-33	2	PVC
Clamp gasket			
25 mm i.d., 10 mm	18-1035-79	2	EPDM
25 mm i.d., 12 mm	18-0200-00	2	EPDM
51 mm i.d., 22 mm	44-7133-01	5	EPDM
51 mm i.d., 38 mm	44-0515-01	5	EPDM
Clamp 25 mm	18-1001-31	1	SS 304
Clamp 51 mm	44-7134-01	1	SS 304
Blind flange 25 mm incl. gasket	18-1001-25	1	SS 304/EPDM
Blind flange 51 mm incl. gasket	44-7135-01	1	SS 304/EPDM
Safety valve, 3 bar, 51 mm TC	18-5738-01	1	SS 316/EPDM
Safety valve, 5 bar, 51 mm TC	44-5498-97	1	SS 316/EPDM
T-junction i.d. 10 mm, 2 × 25 mm, 1 × 51 mm TC	18-1003-63	1	SS 316
T-junction i.d. 22 mm, 3 × 51 mm TC	44-5509-89		SS 316
Castors, assembly kit 400-600	18-1171-51	*	
Castors, assembly kit 800-1000	18-1171-52	*	
Pressure sensor i.d. 10 mm 25 mm TC	44-0507-02	1	SS 316
Pressure sensor i.d. 22 mm 51 mm TC	44-0507-03	1	SS 316
Connectors			
i.d. 10, 25 mm TC-3/4"-20 UNF threaded	18-1012-68	2	PP
i.d. 10, 25 mm TC-i.d. 14, 51 mm TC	18-1027-25	2	PP
i.d. 14, 51 mm TC-i.d. 22, 51 mm TC	18-1027-26	2	PP
i.d. 22, 51 mm TC – i.d. 10, 25 mm TC	18-1174-11	1	PP
i.d. 22, 51 mm TC – i.d. 14, 25 mm TC	18-1174-12	1	PP

* The kit contains a complete set for a column
Material abbreviations: EPDM=ethylene propylene diene, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel

Literature

Data File	Code No.
Chromaflow columns	18-1138-92
Application Note	
Sanitization of Chromaflow 400 column	18-1118-85

Documentation to support validation available on request. Contact your local GE Healthcare office.

FineLINE columns

The FineLINE range of columns has been developed for use with all SOURCE media. The novel, hydraulic packing method packs SOURCE in a matter of minutes, giving densely packed beds and very high packing efficiencies: more than 22 000 plates/m with SOURCE 15 and more than 11 000 plates/m with SOURCE 30.

FineLINE Pilot 35 is well-suited for both downscaling from the larger FineLINE columns and upscaling from laboratory RESOURCE and ÄKTAdesign columns. This 35-mm inner diameter column has a tube manufactured from calibrated borosilicate glass. FineLINE Pilot 35 can also be run on ÄKTAexplorer.

The larger FineLINE 70, 100P, 200P and 350P columns are intended for scale-up work and small-scale production. Column tubes are manufactured in electropolished stainless steel and are available in two tube lengths: 350 mm and 700 mm.

FineLINE range

- Standard inner diameters of 35, 70, 100, 200 mm and 350P
- Optimized for use with all SOURCE media
- Proven single inlet/outlet distribution with special multilayer bed supports for uniform flow at low back pressures
- Very easy and fast to pack
- Materials include electropolished stainless steel, calibrated borosilicate glass and EPDM
- All polymeric materials are approved according to USP Class VI tests for toxicity
- Documentation to support validation delivered with the product

Overview of FineLINE columns

Column	Tube inner diam (mm)	Tube height (mm)	Cross sectional area (cm^2)	Bed height min (mm)	Bed height max (mm)	Bed vol min (ml)	Bed vol max (ml)	Design pressure (bar)
FineLINE Pilot 35	35	330	10	30	150	29	144	20
FineLINE 70	70	350	38	30	150	115	577	20
FineLINE 70L	70	700	38	50	300	192	1155	20
FineLINE 100P	100	350	79	30	150	236	1178	20
FineLINE 100LP	100	700	79	50	300	393	2355	20
FineLINE 200P	200	350	314	30	150	942	4710	20
FineLINE 200LP	200	700	314	50	300	1570	9420	20
FineLINE 350P	350	350	962	30	150	2884	14424	20
FineLINE 350LP	350	700	962	50	300	4808	28848	20

What do I need?

The stand for FineLINE 70/70L and FineLine 100P/100LP has adjustable feet. Wheels with brakes are available as an accessory.

The stand for FineLINE 200P/200LP has wheels with brakes as standard.

Note: For FineLINE 70, 100, and 200 columns, the stand must be ordered as an optional component.

Useful spare parts

Bed supports

Columns are delivered with 2-µm nets; 10-µm nets are also available.

Seals

Order solvent-resistant seals (O-ring kit PFR) if the EPDM O-rings supplied with the columns are not compatible with the solvent to be used.

Spare parts to keep on site

A complete set of O-rings.

FineLINE Pilot 35
Complete set of O-rings, flanging start-up, extra tubing and connectors.

Isolating the column after packing

We recommend using stainless steel valves 2- or 4-way with i.d. 6 mm to close off the top and bottom of the column and prevent contamination of the bed. For storage purposes, the 25-mm blind flanges with clamps and gaskets can be used to seal off the column.

For FineLINE Pilot 35, an extra SRV-1 valve is inserted to close of the bottom of the column. The stop plug for the upper column inlet is supplied with the column.

Connecting the column to your system

Clamps and gaskets with i.d. 6 mm are required to connect the 25-mm sanitary flanged inlet/outlet to either valves or tubing of the same type. Preflanged tubing with i.d. 6 mm is available from GE Healthcare.

FineLINE Pilot 35 is delivered with flanged 1.2 mm i.d. propylene tubing and M6 connectors. A separate tubing kit is needed to connect the column to ÄKTAdesign systems.

Assembly/disassembly of column

Standard wrenches are recommended in a non-explosive environment.
In potentially explosive atmospheres, only tools and protective equipment specially adapted to that environment should be used for operation and maintenance.

Note: Standard wrenches are not supplied with the column, except for FineLINE Pilot 35.

Useful column accessories

Pressure gauge

We recommend fitting a pressure gauge capable of measuring a negative pressure of –1 bar at the top mobile phase connection to indicate the pressure in the column. This monitors the operating pressure and ensures that the correct axial compression packing pressure is set when packing the column.

Pressure relief valve

Required for the packing procedure. It is connected between the pump and the hydraulic inlet to ensure flow delivery at constant pressure. A suitable pressure relief valve designated RL4 is available.

Note: The valve is not supplied with the column and should therefore be ordered separately.

As the pressure relief valve is just required when packing the column, only one valve will generally be needed irrespective of the number of columns in use.

(A manometer is seldom needed for FineLINE Pilot 35 since the pressure-relief valve is preset to 10 bar).

Ordering information

Column	Code No.
FineLINE Pilot 35	18-1102-02
Pressure Relief Valve	18-1110-90
FineLINE 70	18-1152-98
FineLINE 70L	18-1152-99
FineLINE 100P	11-0027-98
FineLINE 100LP	11-0027-99
Stand 100	18-1031-10
FineLINE 200P	11-0031-14
FineLINE 200LP	11-0031-15
Stand 200	18-1031-20
Pressure Relief Valve	18-1105-36
FineLINE 350P EPDM 2 µm	11-0027-90
FineLINE 350P EPDM 10 µm	11-0027-91
FineLINE 350P PFR 2 µm	11-0027-92
FineLINE 350P PFR 10 µm	11-0027-93
FineLINE 350P PFR 2 µm Oligo	11-0027-94
FineLINE 350P PFR 10 µm Oligo	11-0027-95
FineLINE 350LP EPDM 2 µm	11-0027-84
FineLINE 350LP EPDM 10 µm	11-0027-85
FineLINE 350LP PFR 2 µm	11-0027-86
FineLINE 350LP PFR 10 µm	11-0027-87
FineLINE 350LP PFR 2 µm Oligo	11-0027-88
FineLINE 350LP PFR 10 µm Oligo	11-0027-89

Accessories for FineLINE Pilot 35 column

Designation	Code No.	Qty/ pack	Material
Tubing Kit for ÄKTAexplorer	18-1121-65	1	-
Tubing Connector, SRTC2	19-2143-01	5	PEEK
Tubing Connector	19-7476-01	5	PP
Tubing D-flanged i.d. 1.2 mm, 420 mm	18-1102-20	1	ETFE/PEEK/PP
Tubing D-flanged i.d. 1.2 mm, 750 mm	18-4546-01	1	ETFE/PEEK/PP
Tubing i.d 1.2 mm, 2000 mm	19-4370-01	1	ETFE
Stop Plug	18-1102-21	1	-
Domed Nut M6	18-2450-01	4	PP
Flanging/Start up Kit 120 V	18-4603-70	1	-
Flanging/Start up Kit 220 V	18-4603-71	1	-
Flanging Tip Kit i.d. 1.2 mm	18-4597-01	1	-
Pressure Relief Valve	18-1110-90	1	SS 316/ETFE/ PEEK/PP
On/Off Valve i.d. 1.5 SRV-1	19-2145-01	1	FP
Valve SRV-3	18-1110-95	1	FP
Mechanical locking	28-9172-95	1	-
O-rings 28.3 × 2.6 mm*	18-1102-15	1	PFR

*Adaptor filter rings in PFR.

Spare parts for FineLINE Pilot 35 column

Designation	Code No.	Qty/pack	Material
Glass tube	18-1102-16	1	Borosilicate glass
Adaptor bed support 2 µm	18-1102-10	1	PP/SS 316L
Bottom bed support 2 µm	18-1102-11	1	PP/SS 316L
*Sealing Kit comprising:	18-1102-12	1	EPDM
-O-ring 39.2 × 1.6		1	
-O-ring 28.25 × 2.62		4	
-O-ring 12.3 × 2.4		1	
-O-ring 19.2 × 3		1	
-O-ring 3.6 × 1.6		2	

* includes all O-rings for FineLINE Pilot 35 column.

Accessories for FineLINE 70/70L, 100P/100LP and 200P/200LP columns

Designation	Code No.	Qty/pack	Material
O-ring Kit RPC FineLINE 70/70L	18-1155-43	1	
O-ring Kit RPC FineLINE 100/100L[1]	18-1105-45	1	
O-ring Kit RPC FineLINE 200/200L[2]	18-1106-23	1	
Set of spare gaskets for the pressure relief valve	18-1105-52	1	SS 316L/FPM
Air trap complete, FineLINE 100/200[4,5]	18-1102-96	1	SS 304/316/Glass/EPDM
Air trap complete, FineLINE 200/200L[4,5]	18-1102-97	1	SS 304/316/Glass/EPDM
Manometer kit[6]	18-1031-07	1	SS 304/316/EPDM
Valves[5]			
4-port, 2-way	18-5757-01	1	SS 316L/PTFE
4-port, 4-way	18-5758-01	1	SS 316L/PTFE
Hydraulic inlet valve (Ball valve)	18-1105-37	1	SS 316L/PTFE
Valve sealing washer[3]	18-1128-69	2	PTFE
Tubing with sanitary fitting i.d. 6 mm[5]			
30 cm	18-0005-42	1	PVC
75 cm	18-0005-43	1	PVC
125 cm	18-0005-44	1	PVC
150 cm	18-0005-45	1	PVC
200 cm	18-0005-47	1	PVC
Connectors (see p 111)			
i.d. 6, 25 mm clamp-3/4"-20 UNF threaded	18-1012-67	2	PP
i.d. 6, 25 mm clamp-6 mm threaded	18-0251-98	2	PP
i.d. 6, 25 mm clamp-M6 threaded	18-1031-09	2	PP
i.d. 6, 25 mm TC-id 22, 51 mm TC	18-1012-69	2	PP
Clamp 25 mm	18-1001-31	1	SS 304
Clamp 25 mm	44-0568-01	12	SS 304
Gaskets 25 mm i.d. 6 mm	18-0019-27	2	EPDM
Gaskets 25 mm i.d. 6 mm	18-0019-28	2	PTFE
Blind flange 25 mm incl. gasket	18-1001-25	1	SS 304/EPDM
Clamp 51 mm	44-7134-01	1	SS 304
Gaskets 51 mm i.d. 22 mm	44-7133-01	5	EPDM
Gasket 51 mm i.d. 22 mm	44-5512-03	2	PTFE
Castors	18-1001-09	1	–

[1] Includes
- One O-ring 104.33 × 3.53 — 18-1105-50 — PTFE
- One O-ring 91.67 × 3.53 — 18-1105-49 — PFR
- Two O-rings 5.3 × 2.4 — 18-1105-51 — PFR

[2] Includes
- One O-ring 202.79 × 3.53 — 18-1106-30 — PFR
- One O-ring 187.3 × 6.99 — 18-1106-29 — PFR
- Two O-rings 7.3 × 2.4 — 18-1106-31 — PFR

[3] Fits 18-5757-01 and 18-5758-01.
[4] Maximum working pressure 8 bar.
[5] 25 mm TC.
[6] 51 mm TC.

Spare parts for FineLINE 70/70L, 100P/100LP, 200P/200LP and 350P/350LP columns

	FineLINE					
Description	70/70L	100P/100LP	200P/200LP	350P/350LP	Quantity	Material
	Code No.					
Bed support, adaptor complete, 2 mm	18-1153-61	11-0034-04	11-0034-06	11-0034-08	1	SS 316 L
Bed support, adaptor complete, 10 mm	18-1153-67	11-0034-72	11-0034-74	11-0034-10	1	SS 316 L
Bed support, end piece complete, 2 mm	18-1153-62	11-0034-05	11-0034-07	11-0034-09	1	SS 316 L
Bed support, end piece complete 10 mm	18-1153-68	11-0034-73	11-0034-75	11-0034-11	1	SS 316 L
O-ring 104.37 × 3.53		18-1103-89			3	EPDM
O-ring 104.37 × 3.53		18-1105-50			1	PTFE
O-ring 202.79 × 3.53			18-8489-01		2	EPDM
O-ring 202.79 × 3.53			18-1106-30		1	PFR
O-ring 5.3 × 2.4		18-1103-92			5	EPDM
O-ring 5.3 × 2.4		18-1105-51			2	PFR
O-ring 7.3 × 2.4			18-1103-90		5	EPDM
O-ring 7.3 × 2.4			18-1106-31		2	PFR
O-ring 64.5 × 3		18-1105-48	18-1105-48		1	EPDM
O-ring 91.67 × 3.53		18-1103-91			2	EPDM
O-ring 91.67 × 3.53		18-1105-49			1	PFR
O-ring 187.3 × 6.99			18-1106-26		1	EPDM
O-ring 187.3 × 6.99			18-1106-29		1	PFR
Piston seal	18-1039-56*	18-1106-28*			1	EPDM
Piston seal			18-1149-99*		2	EPDM
O-ring 350 × 5				18-1153-72	1	EPDM
O-ring 350 × 5				18-1153-76	1	PFR
O-ring 15.2 × 3.5				18-1153-74	2	EPDM
O-ring 15.2 × 3.5				18-1153-78	2	PFR
O-ring 55.35 × 3.53				18-1153-73	1	EPDM
O-ring 55.35 × 3.53				18-1153-77	1	PFR
O-ring 329.5 × 6.99				18-1153-75	1	EPDM
O-ring 329.5 × 6.99				18-1153-79	1	PFR
Piston seal				18-1149-99	2	EPDM

Material abbreviations: EPDM=ethylene propylene diene, ETFE=ethylene tetrafluoroethylene, FP=fluoroplastic, PEEK=polyetheretherketone, PFR=perfluor rubber, PP=polypropylene, PTFE=polytetrafluoroethene, PVC=polyvinyl chloride, SS=stainless steel

* When ordering piston seals for pre-2007 FineLINE columns, please contact your GE Healthcare sales representative for the correct code number.

Photo: Courtesy of Avecia, UK.

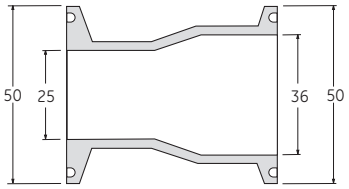
Literature

Data File	Code No.
FineLINE Pilot 35 Column	18-1104-95
FineLINE 70/70L, 100/100L, 200/200L	18-1130-00
Application Note	
Scaling up high performance chromatography on SOURCE media and FineLINE columns	18-1117-49

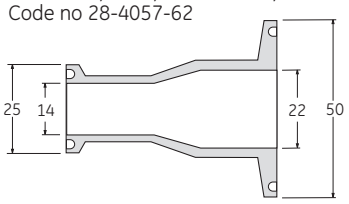
Documentation to support validation available on request. Contact your local GE Healthcare office.

A guide to plastic connectors for process-scale columns

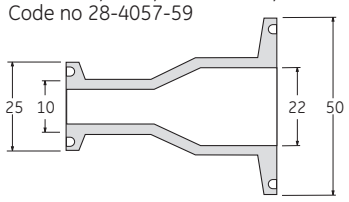
Connector i.d. 25 mm, 50 mm TC- i.d. 36 mm,
50 mm TC, PEEK, USP Class VI,
Code no 28-4057-58



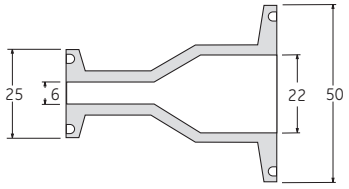
Connector i.d. 14 mm, 25 mm TC- i.d. 22 mm,
50 mm TC, PEEK, USP Class VI,
Code no 28-4057-62



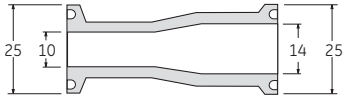
Connector i.d. 10 mm, 25 mm TC- i.d. 22 mm,
50 mm TC, PEEK, USP Class VI,
Code no 28-4057-59



Connector i.d. 6 mm, 25 mm TC- i.d. 22 mm,
50 mm TC, PEEK, USP Class VI,
Code no 28-4057-61



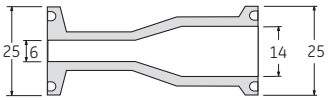
Connector i.d. 10 mm, 25 mm TC- i.d. 14 mm,
25 mm TC, PEEK, USP Class VI,
Code no 28-4057-57



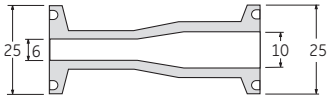
1 inch = 25 mm

UNF = Standard for finer pitch which fits a lot of female connectors

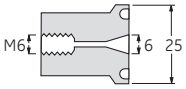
Connector i.d. 6 mm, 25 mm TC- i.d. 14 mm,
25 mm TC, PEEK, USP Class VI,
Code no 28-4057-56



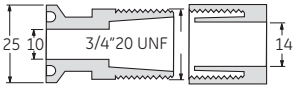
Connector i.d. 6 mm, 25 mm TC- i.d. 10 mm,
25 mm TC, PEEK, USP Class VI,
Code no 28-4057-55



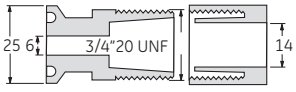
Connector M6 - i.d. 6 mm, 25 mm TC,
PEEK, USP Class VI,
Code no 28-4057-64



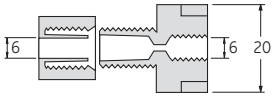
Connector 3/4"-20 UNF - i.d. 10 mm,
25 mm TC, PP,
Code no 18-1012-68



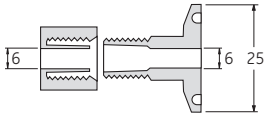
Connector 3/4"-20 UNF - i.d. 6 mm,
25 mm TC, PP,
Code no 18-1012-67

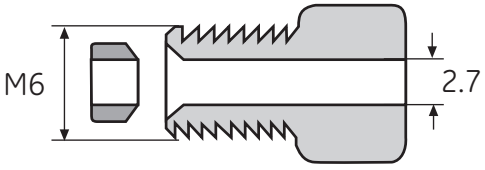


Connector i.d. 6 mm, Jaco- i.d. 6 mm,
M6 , PP, Code no 18-4603-89.

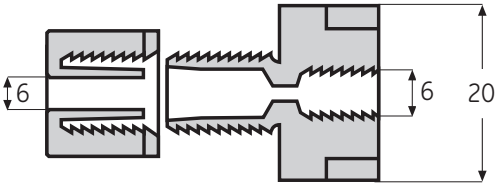


Connector i.d. 6 mm-i.d. 6,
25 mm TC, PP,
Code no 18-0251-98

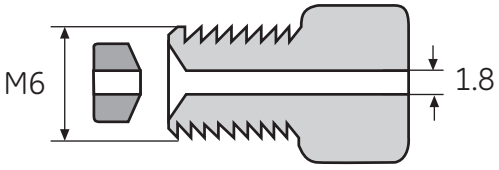




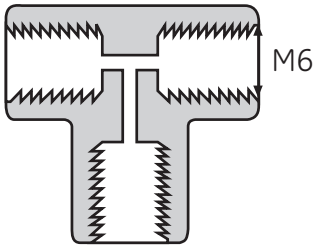
Connector i.d. 2.7 mm – M6
Code No. 18-4652-01



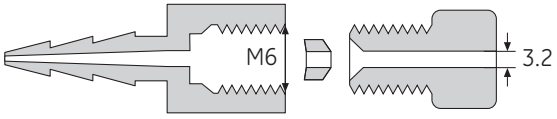
Connector i.d. 3 mm – M6 – Jaco 6 mm
Code No. 18-4603-89



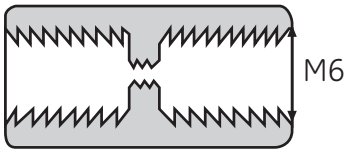
Connector i.d. 1.8 mm – M6
Code No. 19-7476-01



Connector SRTC-3 M6-M6
Code No. 19-2144-01



Connector i.d. 3.8 mm – M6
Code No. 18-1124-16



Connector SRTC-2 M6-M6
Code No. 19-2143-01

Manufacturing Solutions New

Manufacturing Solutions is a new venture aimed at developing products and services that simplify the daily work in process development and manufacturing. The first products from this venture are the Media Wand and Media Handling Unit, devices that enable efficient and simple handling of large-scale media volumes.

Media Wand

Media Wand 50 and Media Wand 100 simplify a number of time-consuming tasks such as:

- removal of supernatant from the shipping container
- addition of buffer or WFI (Water-For-Injection)
- generation of slurry
- transfer of slurry from the shipping container

In addition, Media Wand and Media Handling Unit (MHU) eliminate the need for heavy lifting and shaking, enabling faster handling of media volumes with reduced labor.

Media Wand 50 is designed for use with containers containing 5 to 10 liters of media, and Media Wand 100 for the containers with up to 60 liters of media. While the Chromaflow Pack Station 100 can also be used with Media Wand, the Media Handling Unit offers more functions and thereby provides easier and safer operations.

Decanting Device 50 (for Media Wand 50) and Decanting Device 100 (for Media Wand 100) are shields, connected to the spray nozzle of the Media Wand, which act to prevent loss of media during decanting. The Media Handling Unit CIP-manifold simplifies the cleaning-in-place process of the Media Handling Unit.

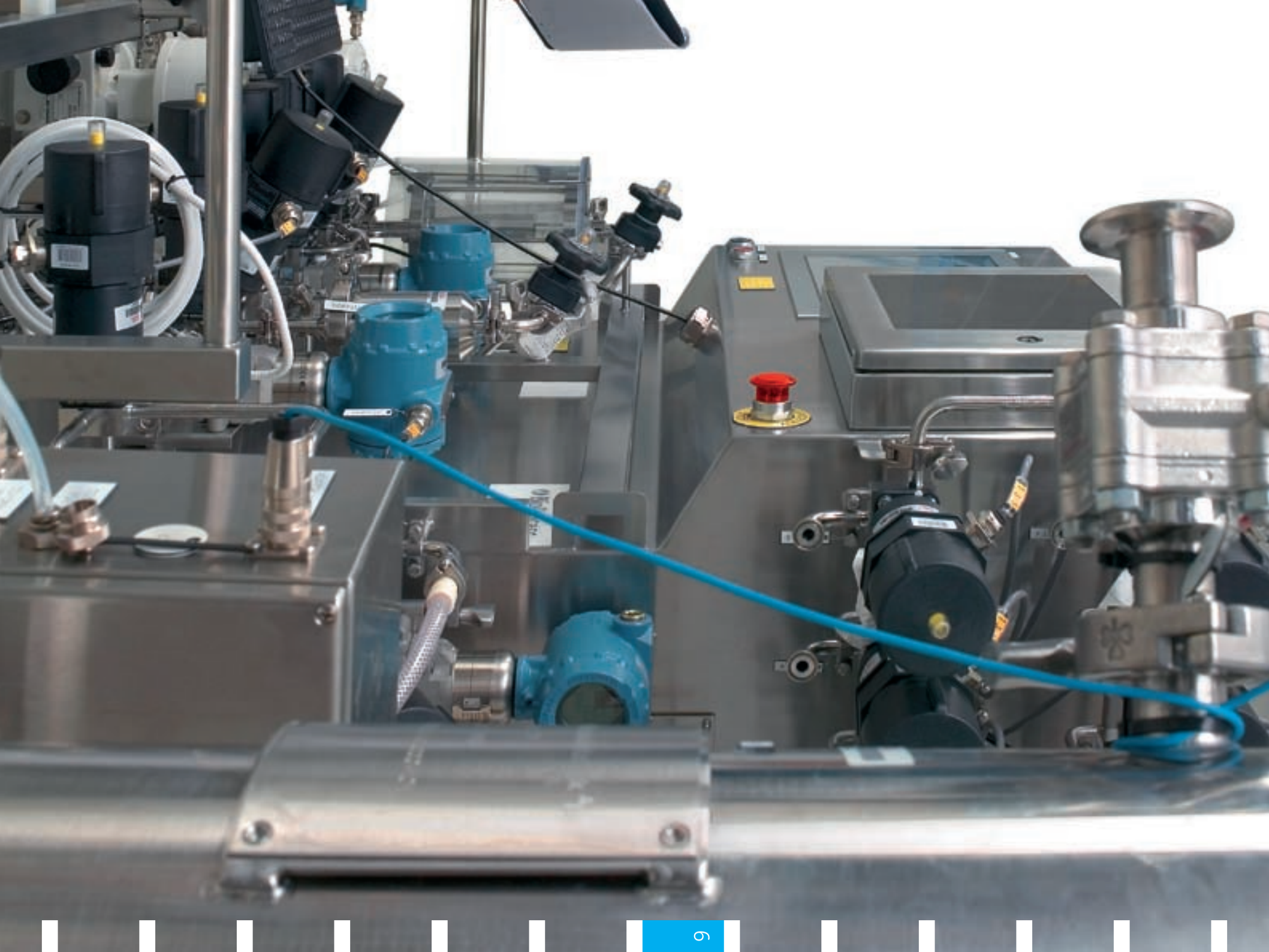
When working with solvents, PTFE tubing (2 m stainless steel over braid and silicon covered tubing) should be used to connect the Media Wand to the Media Handling Unit. PTFE tubing eliminates any potential differences in static electricity between the Media Wand and the Media Handling Unit. For more controlled/careful removal of supernatant, a decanting filter can be used instead of the decanting device.

Ordering information

Product	Quantity	Code No.
Media Wand 50	1	28-9227-64
Media Wand 100	1	28-9227-67
Media Handling Unit	1	28-9227-69
Decanting Device 50	1	28-9227-70
Decanting Device 100	1	28-9227-71
CIP-manifold MHU	1	28-9227-73
PTFE-tubing	1	28-9230-74
Filter for Media Wand	1	28-9297-73

6

Chromatography systems



ÄKTAprocess system

ÄKTA platform enters production-scale chromatography

ÄKTAprocess is an automated liquid chromatography system built for process scale-up and large-scale biopharmaceutical manufacturing. The proven design has been verified during development and can be user configured to meet specific process demands. It is the obvious choice of system to use when scaling up processes developed on smaller ÄKTAexplorer and ÄKTApilot systems.

- Versatile user configuration with UNICORN control
- Post-purchase configuration increasing usability and lifespan
- Traceable USP Class VI materials
- Full regulatory documentation and services
- One-inch tubing size now available

Versatile user configuration

ÄKTAprocess offers a versatile platform providing thousands of configuration possibilities. The system is available in three flow rate ranges that extend up to 1800 l/h for large volume manufacturing. The compact design with a built-in computer allows the system to fit neatly into a plant. ÄKTAprocess can be constructed in either electropolished stainless steel or polypropylene, depending on your process conditions and plant requirements.

The systems can be configured to develop gradients at any flow rate with feedback loop technology. This ensures thorough mixing of liquids/solvents without air bubbles so that even challenging gradients can be created with 2% accuracy. The UNICORN software allows standalone operation or integration into any plant-wide control system. Additional configurations include, for example, the choice of extra inlets and outlets, the type and quantity of selected monitors, and isocratic versus gradient functionality.

Sanitary design

ÄKTAprocess has a number of features that make sanitization with 1 M sodium hydroxide simple and effective. UNICORN allows automated cleaning-in-place (CIP) and a new type of air trap makes CIP more efficient. All wetted parts can be changed to prevent cross-contamination when the system is used for campaigning.

In a sanitization study, the system was subjected to high level of microbial challenge organisms (1×10^6 Colony Forming Units CFU/ml). The yeast *Pichia pastoris* was used for antimicrobial testing. The results show that the system is sanitized effectively and that the numbers of viable organisms are efficiency reduced.

» For more information, please contact your local GE Healthcare representative. See also chromatography system at www.gelifesciences.com/bioprocess

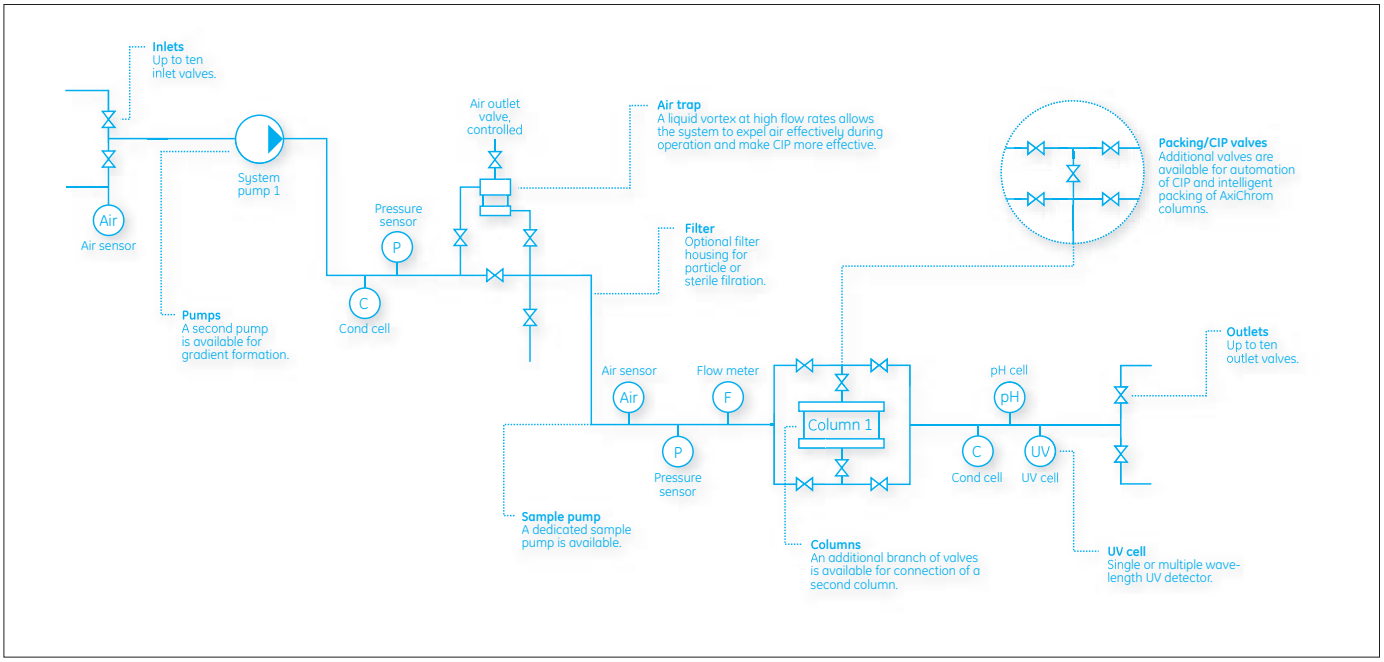


Fig 1. The liquid flow path.

Validatable control with UNICORN software

UNICORN software is a single familiar interface for both chromatography and membrane separations that provides efficient control of process, flexible method programming, extensive data evaluation, and powerful reporting functionality. Improved and cost-effective process security is now provided as a standard. The system control unit, CU 960, allows process operation even if communication with system computer and UNICORN is lost either physically or due to operating system faults.

For integration purposes, UNICORN communicates with control systems within the plant via OLE for Process Control (OPC). OPC supports application area such as data access for real time values and security control to protect sensitive information.

Safety stock of spare parts and consumables

Securing the supply of spare parts and consumables ensures maximum uptime of your ÄKTAprocess system. Our safety stock agreements for ÄKTAprocess can be tailored to meet your unique availability needs.

Table 1. System specifications.

System specifications	System flow rate
6 mm i.d. PP*	4–180 l/h
3/8" o.d. (7.7 mm i.d.) SS†	4–180 l/h
10 mm i.d. PP	13–600 l/h
½" o.d. (9.4 mm i.d.) SS	13–600 l/h
1" o.d. (20.4 mm i.d.) PP	45–1800 l/h
1" o.d. (22.1 mm i.d.) SS	45–1800 l/h
UV wavelength range	Single (280 nm) or multiple wavelengths
pH range	0–14 (spec. valid between 2 and 12)
Conductivity range	1 mS/cm to 200 mS/cm
Ingress protection, cabinet electrical	NEMA 4X / IP 56
Electrical standards	UL 508A, EN 61010-1
Tubing size	PP: 6 mm, 10 mm, SS: 3/8" and ½"
Skid size	
6 mm, 10 mm, 3/8" and 1/2"	(W×D×H): 850 mm × 1205 mm × 1670 mm (D=750 mm if monitor and keyboard included)
1" PP and SS	(W×D×H): 1050 mm × 1730 mm × 1900 mm (D=2275 mm if monitor and keyboard included)

* PP = polypropylene,
† SS = 316 L stainless steel.

Table 2. Operating conditions.

Operating pressure and temperature	
PP (6 mm, 10 mm, and 1")	6 bar (max 40°C)
SS (3/8" and ½")	10 bar (max 40°C)
SS (1")	6 bar (max 40°C)
Surrounding temperature:	2–30°C
Applied solutions:	PP systems: 4–60°C (max 3 bar at 40–60°C)
Applied solutions:	SS systems: 4–80°C (max 3 bar at 40–60°C and max 1 bar at 60–80°C)

Literature	
Data File	
ÄKTAprocess	11-1135-43

Customized BioProcess Solutions

For some applications only customized solutions fit the bill. Through its Customized BioProcess Solutions (CBS) group, GE Healthcare can offer a wide range of engineered solutions for chromatography, membrane filtration and oligonucleotide synthesis. The CBS group has more than 20 years' experience of engineering systems and columns to meet customer's application needs, specifications, and regulatory requirements. The choice of components, materials, manufacturing methods and system configuration are made by the customer in consultation with our engineers to ensure performance and compatibility. Choice of control software includes DeltaV, UNICORN, PLC or any other requirement. Auxiliary equipment can also be manufactured according to specifications.

A key element of GE Healthcare's offering is its service organization. Service agreements ensure rapid service and replacement spare parts delivered within 48 hours minimize expensive downtime.

» For more information, please contact your local GE Healthcare representative or visit the CBS homepage www.gelifesciences.com/cbs

CBS DeltaV Standard Control Platform

CBS DeltaV Standard Control Platform is a flexible control software that simplifies process automation of protein purification by industrial-scale chromatography. The control platform employs Emerson DeltaV software, which has a solid track record of providing excellent control capability in the pharmaceutical and biotechnology industries.

Benefits of the CBS DeltaV Standard Control Platform include:

- Efficient and dedicated control solutions for chromatography purification of proteins
- Flexible operation (recipe) development and assessment
- Extensive analytical functions for chromatography data with UNICORN Evaluation
- Full integration with existing DeltaV systems
- Extensive support (e.g., audit trails) for regulatory support compliance

» For more information on CBS DeltaV Standard Control Platform, see datafile: 28-4074-95

UNICORN control

UNICORN is the control system for real-time control of protein purification unit operations (column packing, chromatography and filtration) from laboratory bench, through development, to full-scale production. UNICORN is used world-wide in over a thousand laboratories and controls hundreds of process development and production systems.

UNICORN control system meets the needs of full-scale production with manufacturing systems, while maintaining the flexibility needed for method and process development with the range of systems in the ÄKTA family.

This flexibility allows quick and simple transition from one stage of a project to the next. Clinical trial equipment can be turned into a final production installation overnight. Documentation and user interface remain consistent from one step to the next and re-investment and validation requirements are reduced to a minimum. UNICORN can also be adapted to control other liquid handling process units, or to connect to other control systems in a plant via the OPC interface.

Among the many features of UNICORN are easy method programming, powerful functions for method assessment, a dynamic display to keep you posted on process status, and the configurable user access profiles to keep your methods secure. In addition, UNICORN can simultaneously supervise up to four liquid handling units from a single work-station, independently or in a pre-programmed sequence. Full validation support for the control system software is available to help speed your product to market.

The software consists of separate modules for method programming, system control and data evaluation.

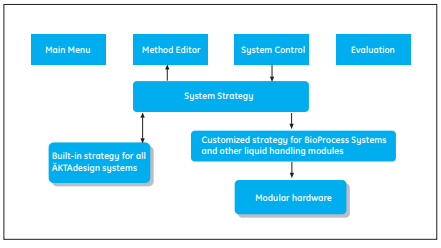
Easy method programming

Most complex valving sequences are handled through valve macros. Programming can be done in time, volume or column volume base.

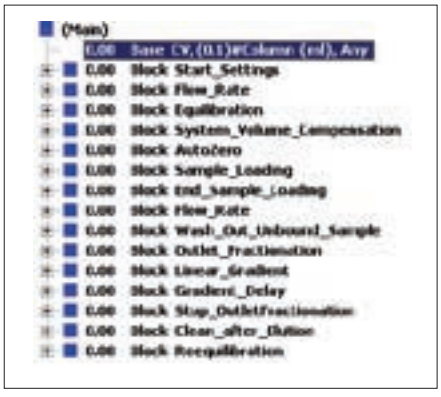
Automatic scouting of important separation variables is easily performed. Conditional responses to specific monitor signals (UV, conductivity, pH, pressure and air) are established through simple WATCH commands.

Real-time process monitoring

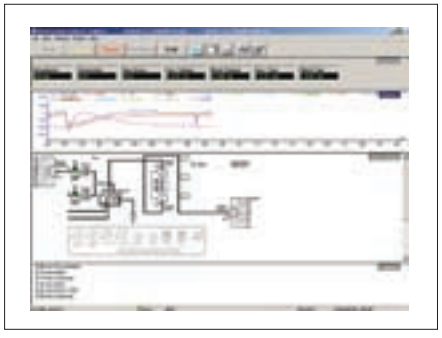
As the chromatography run progresses, selected monitor signals are displayed numerically or as trend curves. The process picture with actual flow path and the continuously updated logbook can be displayed.



UNICORN architecture.



Method text editor.



UNICORN control module.

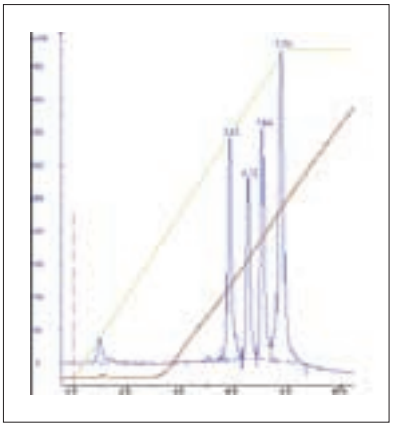
Real-time control

Up to four systems can be connected to one UNICORN workstation where individual controllers handle the real-time control of each system. Data evaluation or methods programming can be done while the systems are running.

The control unit CU 950 (Ethernet and USB) provides a high degree of security for control and data. The unit secures started runs even if the local PC and communication is disrupted. CU 950 Advanced also contains an internal memory that collects data in case of communication failure.

Extensive data evaluation

All monitor data are stored in a Result File for storage and evaluation. Extensive data processing routines include curve smoothing, differentiation, normalization, baseline calculation, peak integration and height equivalent to a theoretical plate (HETP) calculations.



Evaluation procedures can be retrieved from a programmed method to process data and generate reports as part of an automated procedure.

Batch documentation

Along with the chromatographic results of each run, the Result File also includes the programmed method, start protocols, notebooks and the logbook. These files are protected and cannot be manipulated. Processed data generated from an evaluation procedure are stored in the Result File, but separate from the original data.

Start protocols are user-defined questions that must be answered before a run can be started. Questions can vary between simple operator prompts to those requiring mandatory answers and authorized approval.

Notebooks permit additional text to be included in the process documentation. Separate files are generated for method notes, start notes, run notes, and evaluation notes. These notes can be entered at the designated time and cannot be altered after the run is complete.

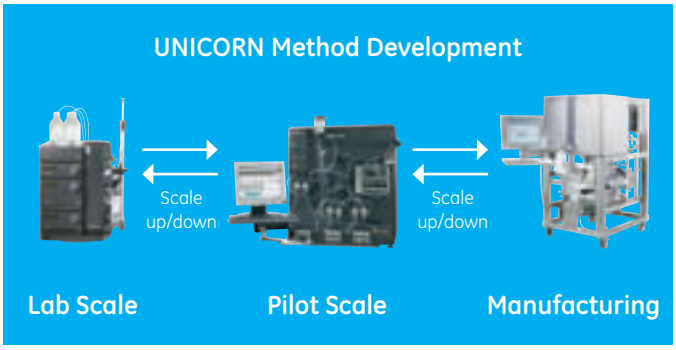
All programmed and manual events occurring during the run, including alarms and warnings, are documented in the logbook and cannot be altered.

Security

UNICORN provides a system for password authorization and access control. Operators log in by name and password. The user profile includes an access level that defines system functions available to each operator.

Scalability

Using UNICORN for method or process development on ÄKTAdesign systems simplifies scale-up to BioProcess system. Personnel retraining is minimized and continuity exists in batch documentation and report generation.



UNICORN methods can be transferred between systems at different scales.

Validation support

UNICORN is fully compliant with 21 CFR Part 11 and is extensively documented for validation purposes.

A Validation Support File is available describing our software development model including routines and test models.

›› Installation and Operational Qualification documentation packages consisting of preprinted forms and test methods are also available (see p 198).

OPC Connectivity

The UNICORN OPC server provides a standardized integration interface to support integration between UNICORN and other software systems such as laboratory information systems (LIMS) and manufacturing execution systems like DCS and MES. OPC enables open connectivity via open standards created in collaboration with a number of worldwide leading automation manufacturers, including Microsoft.

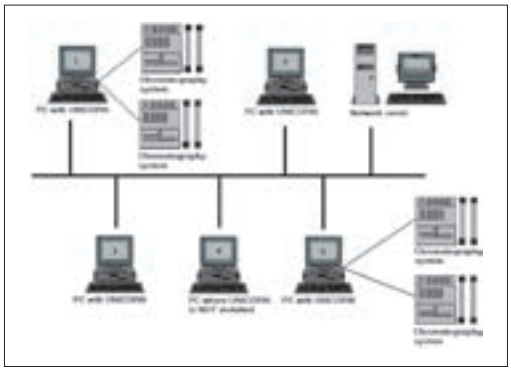
UNICORN OPC server supports the following four areas:

- UNICORN OPC Data Access gives access to all process data (e.g., real time values, valve status, process step information and commands)
- UNICORN Alarm & Events server informs an OPC client application that a system parameter has exceeded an upper or lower limit value. The UNICORN Alarm & Events server also provides information about the process (LogBook).
- UNICORN Historical Data Access allows any OPC client application access to the entire batch result generated by UNICORN
- UNICORN OPC Security controls client access to the UNICORN OPC DA, A&E and HDA to protect sensitive information and to guard against unauthorized modification of process parameters. This is an important security feature.

Network support

Network support allows control and monitoring of systems from any connected UNICORN workstation, subject to access rights defined by the system administrator. UNICORN is specifically designed for Windows networks operating system control. The figure below illustrates how it can be applied in a fully networked system. This facility gives a larger number of operators access to what is happening. Nevertheless, security is still very controlled and subject to strict user-defined access rights.

Network support also enables results to be automatically saved on a server. Evaluation and generation of reports can then be made locally or at a remote PC.



UNICORN network allows sharing of systems and a central location for data storage.

Computer and networking specifications

System Recommendations for UNICORN v. 5.11

Workstation

PC – Pentium 4, 1.5 GHz or higher
1024 Mb RAM
500 Mb disk space available at all times
NTFS file system

Controller

CU-900 requires 1/2 length PCI slot
CU-950 USB requires USB 1.1 Port
CU-950 Advanced requires a 10 Mbit network interface card

Network server

Microsoft Windows 2003 Server, TCP/IP

Operating system

Windows 2000 SP4 or later and Windows XP Professional SP1 or later

Ordering information

Please contact your local GE Healthcare sales office.

Literature

Data File	Code No.
UNICORN control system	18-1156-35
Validation support and service	18-1104-73
Validation Support File UNICORN 5.1	11-0029-16

Information on OPC-based integration

Application Note	
DeltaV* integration	04-0021-64
iFix integration	04-0030-58
MS SQL Server integration	04-0030-59
InTouch integration	04-0030-60
Data File	
OPC	11-0004-15
Manual	
OPC	04-0023-04

* DeltaV is a trademark owned by Fisher-Rosemount Systems, Inc.

7

Products for process development


GE Healthcare
PreDictor™
Capto™ Q 2 µl
28-9257-73
lot 20070830
est exp 2009-02
store at +4 to +30°C

Products for process development

GE Healthcare supports all stages of the drug development process, from early discovery to the development of clinical material and the final transfer to full-scale production. Process development, the design and scale-up of a process for clinical production, is supported by numerous products and services.

High-throughput process development (HTPD) is a new way of working that shortens development time and increases the amount of information available during early process development. PreDictor 96-well filter plates, pre-filled with GE Healthcare BioProcess chromatography media, support HTPD by allowing parallel screening of chromatographic conditions, either in a manual or in an automated workflow. As a result, a large number of experimental conditions may be evaluated simultaneously.

There are different types of prepacked columns containing various types of BioProcess media. The new 10 cm bed height HiScreen columns contain media from the Capto and MabSelect families, as well as Sepharose Fast Flow HIC media.

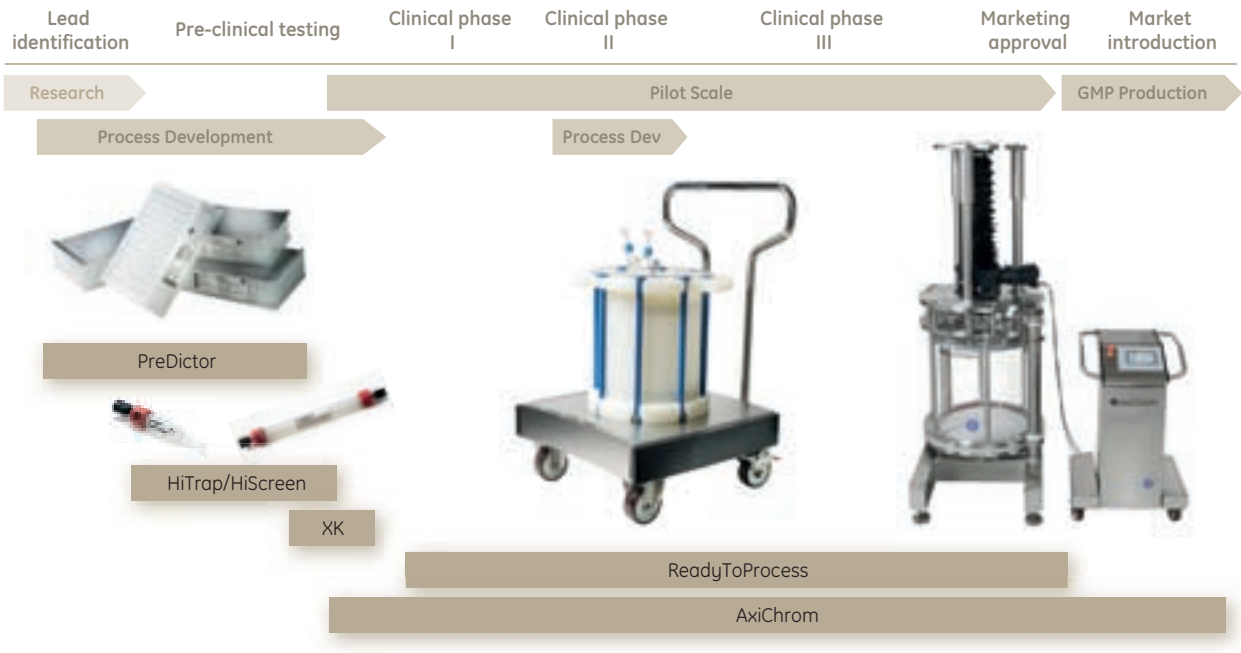
ÄKTAexplorer and ÄKTApilot are members of the ÄKTAdesign family of chromatography systems and are well-suited for process development. As well as operating a wide range of prepacked columns, ÄKTAexplorer can also operate FineLINE Pilot 35 and AxiChrom 50 columns. FineLINE 70, AxiChrom 50, 70, and 100, and BPG 100 can be connected to ÄKTApilot. The control software for ÄKTAdesign systems is UNICORN, which can also be used for pilot-scale systems and full production. UNICORN combines the flexibility needed for method and process development with the stringent requirements for commercial manufacture of biopharmaceuticals.

ReadyToProcess is our new platform of ready-to-use products, engineered for convenience and speed. The product line is designed to meet the biopharmaceutical industry's need for increased flexibility and Lean enabling solutions – from cell culture and fermentation to purification and final filling. ReadyToProcess products include WAVE Bioreactors, WAVE Mixers, fluid handling as well as ready-to-use filtration and chromatography solutions.

» For more information on ReadyToProcess products, see pages 34–61.

At any stage of your process development, optimization or evaluation, GE Healthcare can support you by offering professional services such as Fast Trak Biopharma Process Development and Consulting Services.

» For more information on Biopharma Services, see page 198.

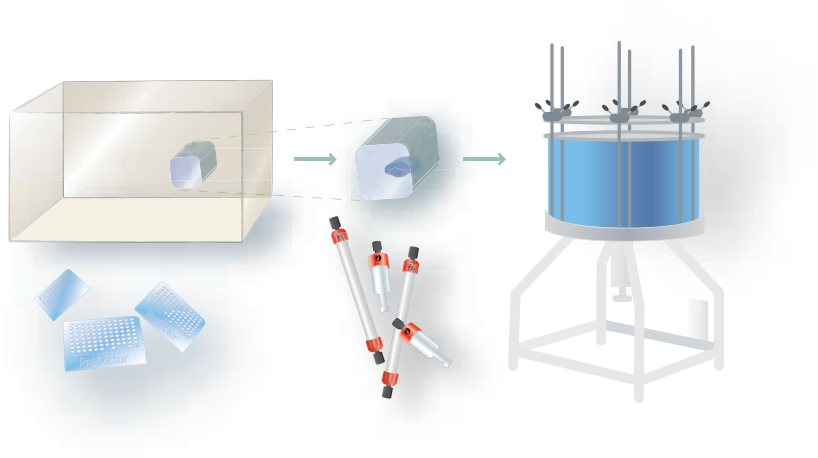


GE Healthcare's formats for process development through manufacturing.

High-Throughput Process Development

The challenge of Process Development

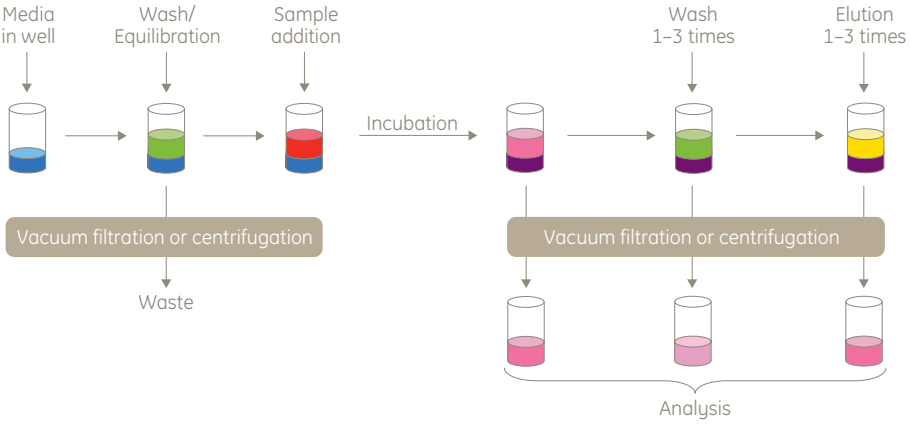
Efficient process development is crucial for the overall efficiency of biopharma development. By pushing more projects through the early pipeline and rapidly identifying and discontinuing the unsuccessful ones, resources can be focused on those that are likely to succeed. In addition, purification processes should be well characterized to increase robustness and to minimize the need for additional optimization during further clinical development.



Conceptual visualization of a workflow for process development. Parallel screening using PreDictor plates makes it possible to explore a large experimental space (left). Once optimal conditions have been identified, fine-tuning and verification are carried out on columns using ÄKTAdesign systems (middle). The design space, shown in blue (middle), is identified and scaled up to a robust production scale process (right).

Increased throughput with parallel operation

High-Throughput Process Development (HTPD) is a new way of working that shortens development time and increases the amount of information available during early process development, while keeping sample consumption low. Chromatographic conditions are evaluated in parallel using 96-well filter plates. As a result, a large number of experimental conditions may be evaluated simultaneously. This allows screening of a large experimental space, to identify the subspace that is most favourable with respect to one or several defined responses. Once this subspace has been found, optimization and scale-up may be done on columns using ÄKTAdesign systems.



A batch uptake experiment occurring in the wells of PreDictor filter plates. The steps in PreDictor plate experiments are the same as in a typical chromatography experiment: equilibration, sample loading, wash, and elution.

PreDictor 96-well filter plates

New

PreDictor plates shorten time-to-clinic and increase productivity in the process development lab by:

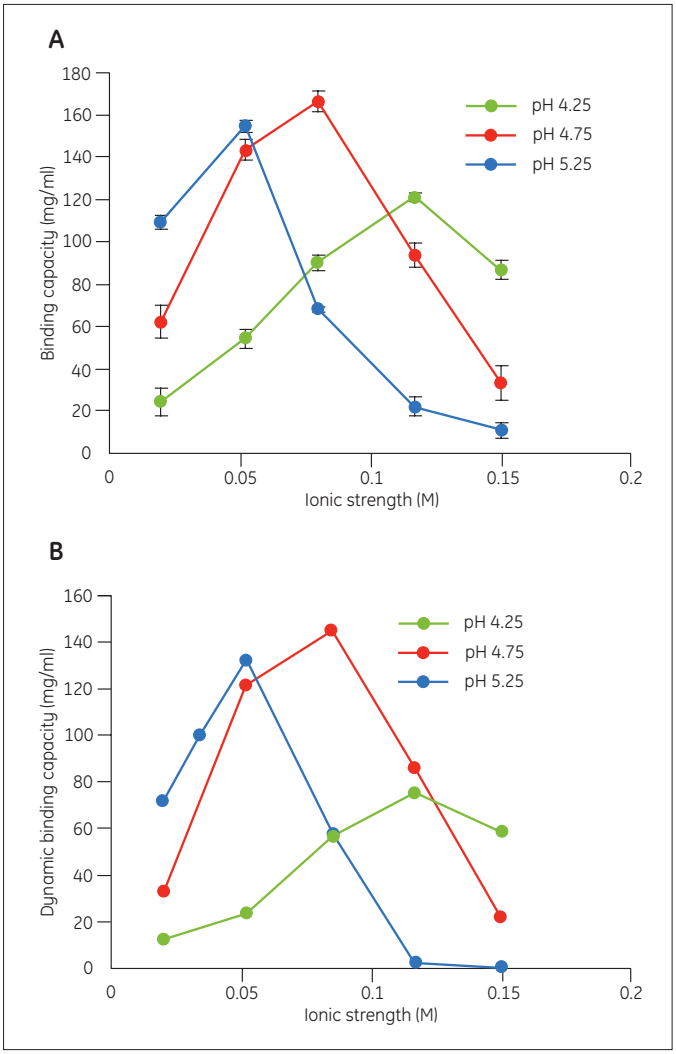
- reducing experimental time: the time-scale for performing screening experiments can be reduced from weeks to hours
- lowering sample consumption: the amount of sample required for these experiments is significantly lower than for column experiments
- increasing process understanding: the ability to screen a large experimental space leads to an increase in process understanding and in the potential to design a robust process early in development

PreDictor 96-well filter plates are prefilled with BioProcess chromatography media. They are developed to support HTPD by allowing parallel screening of chromatographic conditions, either in a manual or in an automated workflow. Data generated by using PreDictor plates show good correlation with data obtained in chromatography columns, which makes the plates an excellent tool for initial screening of process conditions.

Ordering information

Product	Quantity	Code No.
PreDictor Capto Q, 2 µl	4 × 96-well filter plates	28-9257-73
PreDictor Capto Q, 20 µl	4 × 96-well filter plates	28-9258-06
PreDictor Capto Q, 50 µl	4 × 96-well filter plates	28-9258-07
PreDictor Capto S, 2 µl	4 × 96-well filter plates	28-9258-08
PreDictor Capto S, 20 µl	4 × 96-well filter plates	28-9258-09
PreDictor Capto S, 50 µl	4 × 96-well filter plates	28-9258-10
PreDictor Capto DEAE, 2 µl	4 × 96-well filter plates	28-9258-11
PreDictor Capto DEAE, 20 µl	4 × 96-well filter plates	28-9258-12
PreDictor Capto DEAE, 50 µl	4 × 96-well filter plates	28-9258-13
PreDictor Capto MMC, 6 µl	4 × 96-well filter plates	28-9258-14
PreDictor Capto MMC, 20 µl	4 × 96-well filter plates	28-9258-15
PreDictor Capto MMC, 50 µl	4 × 96-well filter plates	28-9258-16
PreDictor Capto adhere, 6 µl	4 × 96-well filter plates	28-9258-17
PreDictor Capto adhere, 20 µl	4 × 96-well filter plates	28-9258-18
PreDictor Capto adhere, 50 µl	4 × 96-well filter plates	28-9258-19
PreDictor MabSelect, 6 µl	4 × 96-well filter plates	28-9258-20
PreDictor MabSelect, 20 µl	4 × 96-well filter plates	28-9258-21
PreDictor MabSelect, 50 µl	4 × 96-well filter plates	28-9258-22
PreDictor MabSelect SuRe, 6 µl	4 × 96-well filter plates	28-9258-23
PreDictor MabSelect SuRe, 20 µl	4 × 96-well filter plates	28-9258-24
PreDictor MabSelect SuRe, 50 µl	4 × 96-well filter plates	28-9258-25

Note: For optimal results, different applications will require different amount of chromatography media in the wells. Thus plates with each chromatography medium are available with three different volumes of media. Generally, for binding studies plates with 2 or 6 µl chromatography media should be used. For wash and elution studies larger gel volumes are required and both feed/sample concentration and the actual load (load density) will determine what plate to use. The first option for wash studies is the 50 µl plates. For elution studies the 20 µl plate should be tested first.



Determination of loading conditions for conalbumin on Capto S. **A**: binding capacities at 60 minutes in PreDictor Capto S plates (2 µl). Error bars represent one standard deviation, based on triplicates.
B: dynamic binding capacities (DBC) at 10% breakthrough for conalbumin on Capto S. Residence time 2 minutes, column Tricorn 5/100 (CV 2 ml).

HiScreen columns

New

HiScreen columns benefits:

- Ideal for method optimization and parameter screening due to the 10 cm bed height
- Easy connection in series to achieve 20 cm bed height
- Convenient and time-saving due to prepacked format
- Small column volume gives fast results and minimal sample/buffer consumption
- Reproducible results comparable to BioProcess scale columns packed with the same media as the same linear fluid velocity can be used

HiScreen columns are prepacked with 13 different BioProcess media designed for method optimization and parameter screening in process development. The 10 cm bed height makes it possible to perform scalable experiments at relevant fluid velocities.

The HiScreen columns are part of the process development platform available from GE Healthcare. All media prepacked in HiScreen columns are available in different formats and bulk packs, for all scales, from development work and pilot studies to routine production.

The volume of the HiScreen column is small, 4.7 ml, which reduces costs by decreasing sample and buffer consumption. The 10 cm bed height of these prepacked columns makes them ideal for method optimization and parameter screening (e.g., selectivity, capacity, binding and elution conditions) and following scale-up. If possible, two columns can be connected in series to give a bed height of 20 cm.

Ordering information

Product	Quantity	Code No.
HiScreen MabSelect	1 × 4.7 ml	28-9269-73
HiScreen MabSelect Xtra	1 × 4.7 ml	28-9269-76
HiScreen MabSelect SuRe	1 × 4.7 ml	28-9269-77
HiScreen Capto Q	1 × 4.7 ml	28-9269-78
HiScreen Capto S	1 × 4.7 ml	28-9269-79
HiScreen Capto MMC	1 × 4.7 ml	28-9269-80
HiScreen Capto adhere	1 × 4.7 ml	28-9269-81
HiScreen Capto DEAE	1 × 4.7 ml	28-9269-82
HiScreen Butyl FF	1 × 4.7 ml	28-9269-84
HiScreen Butyl-S FF	1 × 4.7 ml	28-9269-85
HiScreen Octyl FF	1 × 4.7 ml	28-9269-86
HiScreen Phenyl FF (high sub)	1 × 4.7 ml	28-9269-88
HiScreen Phenyl FF (low sub)	1 × 4.7 ml	28-9269-89

›› Visit us on the web at www.gelifesciences.com/protein-purification

Prepacked columns

Affinity columns for ÄKTAdesign systems

Ordering information		
Product	Quantity	Code No.
HiTrap Benzamidine FF (high sub)	2 × 1 ml	17-5143-02
HiTrap Benzamidine FF (high sub)	5 × 1 ml	17-5143-01
HiTrap Benzamidine FF (high sub)	1 × 5 ml	17-5144-01
HiPrep 16/10 Heparin FF	1 × 20 ml	17-5189-01
HiPrep IMAC FF 16/10	1 × 20 ml	17-0921-06
HiTrap IMAC FF	5 × 1 ml	17-0921-02
HiTrap IMAC FF	5 × 5 ml	17-0921-04
HiScreen MabSelect SuRe New	1 × 4.7 ml	28-9269-77
HiScreen MabSelect New	1 × 4.7 ml	28-9269-73
HiScreen MabSelect Xtra New	1 × 4.7 ml	28-9269-76
HiTrap MabSelect SuRe	5 × 1 ml	11-0034-93
HiTrap MabSelect SuRe	1 × 5 ml	11-0034-94
HiTrap MabSelect SuRe	5 × 5 ml	11-0034-95
HiTrap MabSelect	5 × 1 ml	28-4082-53
HiTrap MabSelect	1 × 5 ml	28-4082-55
HiTrap MabSelect	5 × 5 ml	28-4082-56
HiTrap MabSelect Xtra	5 × 1 ml	28-4082-58
HiTrap MabSelect Xtra	1 × 5 ml	28-4082-60
HiTrap MabSelect Xtra	5 × 5 ml	28-4082-61
HiTrap rProtein A FF	2 × 1 ml	17-5079-02
HiTrap rProtein A FF	5 × 1 ml	17-5079-01
HiTrap rProtein A FF	1 × 5 ml	17-5080-01
HiTrap rProtein A FF	5 × 5 ml	17-5080-02

Order online at www.gelifesciences.com/orderonline

Gel filtration columns for ÄKTAdesign systems

Ordering information		
Product	Quantity	Code No.
HiLoad 16/60 Superdex 30 pg	1 × 120 ml	17-1139-01
HiLoad 16/60 Superdex 75 pg	1 × 120 ml	17-1068-01
HiLoad 16/60 Superdex 200 pg	1 × 120 ml	17-1069-01
HiLoad 26/60 Superdex 30 pg	1 × 320 ml	17-1140-01
HiLoad 26/60 Superdex 75 pg	1 × 320 ml	17-1070-01
HiLoad 26/60 Superdex 200 pg	1 × 320 ml	17-1071-01
HiPrep 16/60 Sephacryl S-100 HR	1 × 120 ml	17-1165-01
HiPrep 16/60 Sephacryl S-200 HR	1 × 120 ml	17-1166-01
HIPrep 16/60 Sephacryl S-300 HR	1 × 120 ml	17-1167-01
HiPrep 26/60 Sephacryl S-100 HR	1 × 320 ml	17-1194-01
HiPrep 26/60 Sephacryl S-200 HR	1 × 320 ml	17-1195-01
HiPrep 26/60 Sephacryl S-300 HR	1 × 320 ml	17-1196-01

Order online at www.gelifesciences.com/orderonline

Hydrophobic interaction chromatography columns for ÄKTAdesign systems

Ordering information		
Product	Quantity	Code No.
HiScreen Butyl FF New	1 × 4.7 ml	28-9269-84
HiScreen Butyl-S FF New	1 × 4.7 ml	28-9269-85
HiScreen Octyl FF New	1 × 4.7 ml	28-9269-86
HiScreen Phenyl FF (high sub) New	1 × 4.7 ml	28-9269-88
HiScreen Phenyl FF (low sub) New	1 × 4.7 ml	28-9269-89
HiPrep 16/10 Butyl FF	1 × 20 ml	17-5096-01
HiPrep 16/10 Octyl FF	1 × 20 ml	17-5097-01
HiPrep 16/10 Phenyl FF (high sub)	1 × 20 ml	17-5095-01
HiPrep 16/10 Phenyl FF (low sub)	1 × 20 ml	17-5094-01
HiLoad 16/10 Phenyl Sepharose HP	1 × 20 ml	17-1085-01
HiLoad 26/10 Phenyl Sepharose HP	1 × 53 ml	17-1086-01
HiTrap HIC Selection Kit	7 × 1 ml	28-4110-07
HiTrap Butyl HP New	5 × 1 ml	28-4110-01
HiTrap Butyl HP New	5 × 5 ml	28-4110-05
HiTrap Butyl-S FF	5 × 1 ml	17-0978-13
HiTrap Butyl-S FF	5 × 5 ml	17-0978-14
HiTrap Butyl FF	5 × 1 ml	17-1357-01
HiTrap Butyl FF	5 × 5 ml	17-5197-01
HiTrap Octyl FF	5 × 1 ml	17-1359-01
HiTrap Octyl FF	5 × 5 ml	17-5196-01
HiTrap Phenyl FF (high sub)	5 × 1 ml	17-1355-01
HiTrap Phenyl FF (high sub)	5 × 5 ml	17-5193-01

Order online at www.gelifesciences.com/orderonline

Ordering information		
Product	Quantity	Code No.
HiTrap Phenyl FF (low sub)	5 × 1 ml	17-1353-01
HiTrap Phenyl FF (low sub)	5 × 5 ml	17-5194-01
HiTrap Phenyl HP	5 × 1 ml	17-1351-01
HiTrap Phenyl HP	5 × 5 ml	17-5195-01

Order online at www.gelifesciences.com/orderonline

Ion exchange columns for ÄKTAdesign system

Ordering information		
Product	Quantity	Code No.
HiLoad 16/10 Q Sepharose HP	1 × 20 ml	17-1064-01
HiLoad 16/10 SP Sepharose HP	1 × 20 ml	17-1137-01
HiLoad 26/10 Q Sepharose HP	1 × 53 ml	17-1066-01
HiLoad 26/10 SP Sepharose HP	1 × 53 ml	17-1138-01
HiPrep 16/10 ANX FF (high sub)	1 × 20 ml	17-5191-01
HiPrep 16/10 CM FF	1 × 20 ml	17-5091-01
HiPrep 16/10 DEAE FF	1 × 20 ml	17-5090-01
HiPrep 16/10 Q FF	1 × 20 ml	17-5190-01
HiPrep 16/10 Q XL	1 × 20 ml	17-5092-01
HiPrep 16/10 SP FF	1 × 20 ml	17-5192-01
HiPrep 16/10 SP XL	1 × 20 ml	17-5093-01
HiScreen Capto adhere New	1 × 4.7 ml	28-9269-81
HiScreen Capto DEAE New	1 × 4.7 ml	28-9269-82
HiScreen Capto MMC New	1 × 4.7 ml	28-9269-80
HiScreen Capto Q New	1 × 4.7 ml	28-9269-78
HiScreen Capto S New	1 × 4.7 ml	28-9269-79
HiTrap Capto IEX Selection Kit New	5 × 1 ml	28-9343-88
HiTrap IEX Selection Kit	7 × 1 ml	17-6002-33
HiTrap ANX FF (high sub)	5 × 1 ml	17-5162-01
HiTrap ANX FF (high sub)	5 × 5 ml	17-5163-01
HiTrap Capto adhere New	5 × 1 ml	28-4058-44
HiTrap Capto adhere New	5 × 5 ml	28-4058-46
HiTrap Capto DEAE New	5 × 1 ml	28-9165-37
HiTrap Capto DEAE New	5 × 5 ml	28-9165-40
HiTrap Capto MMC	5 × 1 ml	11-0032-73
HiTrap Capto MMC	5 × 5 ml	11-0032-75
HiTrap Capto Q	5 × 1 ml	11-0013-02
HiTrap Capto Q	5 × 5 ml	11-0013-03
HiTrap Capto S	5 × 1 ml	17-5441-22
HiTrap Capto S	5 × 5 ml	17-5441-23
HiTrap Capto ViralQ	5 × 5 ml	28-9078-09
HiTrap CM FF	5 × 1 ml	17-5056-01
HiTrap CM FF	5 × 5 ml	17-5155-01
HiTrap DEAE FF	5 × 1 ml	17-5055-01
HiTrap DEAE FF	5 × 5 ml	17-5154-01
HiTrap Q FF	5 × 1 ml	17-5053-01
HiTrap Q FF	5 × 5 ml	17-5156-01
HiTrap Q HP	5 × 1 ml	17-1153-01
HiTrap Q HP	5 × 5 ml	17-1154-01
HiTrap Q XL	5 × 1 ml	17-5158-01
HiTrap Q XL	5 × 5 ml	17-5159-01
HiTrap SP FF	5 × 1 ml	17-5054-01
HiTrap SP FF	5 × 5 ml	17-5157-01
HiTrap SP HP	5 × 1 ml	17-1151-01
HiTrap SP HP	5 × 5 ml	17-1152-01
HiTrap SP XL	5 × 1 ml	17-5160-01
HiTrap SP XL	5 × 5 ml	17-5161-01

Order online at www.gelifesciences.com/orderonline

Reversed phase chromatography column for ÄKTAdesign system

Ordering information		
Product	Quantity	Code No.
SOURCE 15RPC ST 4.6/100*	1	17-5068-01

Order online at www.gelifesciences.com/orderonline
*Column not suitable for use with ÄKTAprime plus chromatography system.
Please contact us for assistance with selection of columns for ÄKTAprime plus.

Prepacked columns for purification of high-quality plasmid DNA

Ordering information		
Product	Quantity	Code No.
PlasmidSelect Xtra Starter Kit	1	28-4052-68
PlasmidSelect Xtra Screening Kit	1	28-4052-69

Order online at www.gelifesciences.com/orderonline

Selection kits

In addition to the individual columns, there are a number of selection kits available. These kits usually contain three to seven prepacked columns that enable you to quickly screen potential media.

IEX Selection Kit

Eight different Sepharose media differentiated by process stage

For Capture, Q Sepharose Big Beads and SP Sepharose Big Beads in 50 ml packs. For Intermediate Purification, Q Sepharose Fast Flow, SP Sepharose Fast Flow, CM Sepharose Fast Flow, and DEAE Sepharose Fast Flow in 50 ml packs. For Polishing, Q Sepharose High Performance and SP Sepharose High Performance in 1 ml prepacked HiTrap columns.

HiTrap Capto IEX Selection Kit (28-9343-88)

New

Five different ion exchange ligands on Capto enable convenient and easy screening

Contains five 1 ml HiTrap columns prepacked with Capto Q, Capto S, Capto DEAE, Capto MMC, Capto adhere as well as connectors and instructions.

HiTrap IEX Selection Kit (17-6002-33)

Seven different ion exchange ligands on Sepharose Fast Flow and Sepharose XL enable fast and easy screening

Contains seven 1 ml HiTrap columns prepacked with SP Sepharose Fast Flow, Q Sepharose Fast Flow, CM Sepharose Fast Flow, DEAE Sepharose Fast Flow, ANX Sepharose 4 Fast Flow (high sub), SP Sepharose XL and Q Sepharose XL as well as connectors and instructions.

HiTrap HIC Selection Kit (28-4110-07)

For screening different HIC media and experimental conditions

Contains seven 1 ml HiTrap columns prepacked with Phenyl Sepharose High Performance, Phenyl Sepharose 6 Fast Flow (high sub), Phenyl Sepharose 6 Fast Flow (low sub), Butyl Sepharose High Performance, Butyl Sepharose 4 Fast Flow, Butyl-S Sepharose 6 Fast Flow, Octyl Sepharose 4 Fast Flow, connectors and instructions.

PlasmidSelect Xtra platform kits

PlasmidSelect Xtra Starter Kit (28-4052-68)

Fast and convenient process development

Contains one HiPrep 26/10 Sepharose 6 FF column (53 ml), one HiTrap PlasmidSelect Xtra column (5 ml) and one HiTrap SOURCE 30Q column (5 ml) plus accessories. Does not include buffers.

PlasmidSelect Xtra Screening Kit (28-4052-69)

Quick and easy analysis with an ÄKTAdesign system

Contains five 5 ml HiTrap Sepharose HP and five 1 ml HiTrap PlasmidSelect Xtra columns plus accessories. Does not include buffers.

Custom-packed columns

Custom products adapt the exact combination of media and column to solve specific purification problems. With years of experience in chromatography and column packing, you can rely on the Custom Products group to tailor a solution to fit your separation objectives and save you time. The group works with you from the initial discussions right through to delivery, establishing your needs and sorting through the choices.

- Each custom column is packed and tested under stringent ISO 9001 standards
- A result of analysis and user instruction that describe the column performance is supplied with the column
- Delivery time is between two and four weeks, depending on media and column specifications

GE Healthcare offers the largest selection of prepacked columns and bulk media available, encompassing most liquid chromatography techniques. However, should you require a special configuration – contact the Custom Products group through your local GE Healthcare office to discuss your ideas and receive a free quotation.

Systems for method and process development

ÄKTAexplorer

ÄKTAexplorer is designed for scouting, development and optimization of methods for all chromatographic techniques. Flexibility and high levels of automation in combination with reproducibility and reliable operation make it an excellent choice for laboratories involved in method and process development.

Flexibility from laboratory to production

- Easy system modification
- Fast transfer of methods to ÄKTApilot

Easy, safe selection of columns optimally suited to each purification

- Comprehensive column library for support of HiTrap, HiScreen, RESOURCE, Tricorn, HiPrep and HiLoad. Also supports FineLINE Pilot 35, and XK columns

Fast systematic method optimization

- Automatic media screening
- Vary any run parameter in automated scouting schemes

The flexibility to combine and run several methods in series is often needed if high purity is a requirement. ÄKTAexplorer meets this need and enables faster completion of method optimization. Variable wavelength monitoring with UV-900 lets you record up to three wavelengths simultaneously, so target protein and critical impurities can be viewed at the same time.

The UNICORN method wizard and optimized system configurations allow fast and easy media screening, method scouting, method optimization and scale-up experiments. Parameters can be varied over repeated runs in automated scouting schemes. The optimized methods can be quickly and easily scaled up and transferred to ÄKTApilot for small-scale production.

ÄKTAexplorer systems are available in different standard configurations to suit most purification needs, but are easily modified if required. Systems can be used for flow rates up to 100 ml/min (at 10 MPa) to ensure minimized runtime at maximum flow rates, or at 10 ml/min (25 MPa pressure) for applications using columns with higher back pressure and resolution.

Ordering information	
Product	Code No.
ÄKTAexplorer 100	18-1112-41
ÄKTAexplorer 100 Air	18-1403-00
ÄKTAexplorer 10	18-1300-00
ÄKTAexplorer 10S	18-1145-05

›› For detailed information about ÄKTAexplorer systems, please refer to ÄKTAexplorer chromatography systems data file, Code No. 18-1124-09.

›› Visit us on the web at www.gelifesciences.com/akta

ÄKTApilot system

ÄKTApilot is a high-performance, automated liquid chromatography system designed for process development, process scale-up, scale-down and small-scale production. The system has the capacity to purify from milligrams to tens of grams of product and is biocompatible, hygienic and sanitizable. ÄKTApilot meets all GLP and cGMP demands for Phase I–III in drug development and final-scale production.

- Hygienic design enables purification of microbial-free and contaminant-free products
- High dynamic capacity
  - flow capacity 4 to 400 ml/min with 0 to 100% gradient
  - 4 to 800 ml/min flow with limited gradient
  - possibility to purify 10 g product per cycle
- Built-in and EVB sanitary fraction collection valves for maximum use of bench space
- Fast and convenient start with UNICORN
  - Method Wizard for easy programming
  - preprogrammed sanitization method and column lists
  - constant pressure regulation of flow rate during sample application and during column packing
- Validation support
  - IQ/OQ documentation available
  - UNICORN supports FDA 21 CFR Part 11 for Electronic Signatures and Electronic Records
- Bench top design — fits in small areas
- All wetted parts are externally mounted and are easily changeable for
  - convenient product change-over when campaigning
  - simplified cleaning validation

The sanitary system for rapid process development and small-scale production

The system consists of the ÄKTApilot separation unit, a computer including a flat-screen monitor and UNICORN control system. UNICORN ensures quick, simple communication between systems and users and meets the stringent control and data handling procedures of modern production and laboratory facilities. Method wizards provide easy method generation. Optimized methods are transferred easily from laboratory to production scale.

In addition to the two outlet fraction valves, you can connect four extra EVB 988 valves (External Valve Block). Two extra EVB 981 inlet valves can also be connected on the outlet valve rack.

Trouble-free sanitization

ÄKTApilot system is easily sanitized with 1 M sodium hydroxide (NaOH). Microbial challenge tests that subject the system to infection with solutions containing three strains of bacteria recommended by the United States Pharmacopoeia (USP 25), and a strain of yeast commonly found in production environments gave 6 log reduction results that fulfill the USP 25 requirements.

Ordering information

Product	Code No.
ÄKTApilot	18-1170-63
Additional items	
EVB 981 (Inlet)	28-4079-75
EVB 988 (Outlet)	28-4079-78
EVB Rack	28-4079-72
CIP Manifold	28-4009-03
ÄKTApilot Tubing Kit Column	18-1167-68
ÄKTApilot Valve Membrane CPL	18-1169-10
ÄKTApilot Elbow 90 TC25 Short	18-1169-19
ÄKTApilot TUBE S7 CPL	18-1169-71
ÄKTApilot TUBE S8 CPL	18-1169-75
Wetted parts kit	18-1171-07
O-ring, top air trap	18-1169-12
Connector M6 fem. – 5/16 fem.	18-1169-17
Connector M6 fem. – 5/16 male	18-1169-16
Clamp TC 25	18-1169-18
Connector TC – 5/16 fem.	18-1169-22
Connector TC – 5/16 male	18-1169-23
TC-gasket 25/4 mm	18-1169-24
TC-gasket 25/6.5 mm	18-1169-25
T-connector 5/16 – 24	18-1170-59
Connector 5/16 fem. – 5/16 fem.	18-1173-51
Data Files	
ÄKTApilot	18-1167-90
UNICORN Control System	18-1156-35

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Fraction Collector Frac-950

Fraction Collector Frac-950 is an automated fraction collector for reliable and flexible collection of fractions based on time or volume from ÄKTAdesign chromatography systems.

Fraction collector Frac-950 can be used together with ÄKTApurifier, ÄKTAexplorer, or ÄKTApilot at flow rates up to 100 ml/min. Fractions can be collected in 96-well microplates, in standard 12, 18, or 30 mm tubes, or in 250 ml bottles. To deal with large fraction volumes, preparative mode allows fraction collection in eighty 30 mm standard tubes, twenty 250 ml bottles, or in 30 funnels, which connect to practically any vessel. Collection is in volume or time mode and different fraction sizes can be collected during different stages of a separation.

Automatic peak fractionation, based on peak detection using slope or level sensing, minimizes peak dilution and cross-contamination. Event marks correlate the fractions with the chromatogram. A recycle function enables collection from repetitive runs.

Technical specifications	
Fraction Collector Frac-950	
Flow rate range	0.001 ml/min–100 ml/min
Rack A	120 × 18 mm tubes 8 × 30 mm tubes
Optional racks	
Rack B	240 × 12 mm tubes
Rack C	8 × 30 mm tubes 4 microplates (96 wells per plate)
Rack D	45 × 30 mm tubes
Rack E*	80 × 30 mm tubes
Rack F*	20 × 250 mm bottles
* Rack options E and F require Prep Mode Conversion Kit (see Ordering Information).	

Ordering information	
Product	**Code No.**
Fraction Collector Frac-950 (including Rack A)	18-6083-00
Standard mode	
Rack A, complete with bowl for 18 mm and 30 mm tubes	18-6083-11
Rack B, complete with bowl for 12 mm tubes	18-6083-12
Rack C, complete with bowl for 96-well microtiter plates and 30 mm tubes	18-6083-13
Rack D, complete with bowl for 30 mm tubes	18-6083-14
Prep mode	
Prep Mode Conversion Kit (for use with Rack E and Rack F)	18-6083-18
Rack E, complete for 30 mm tubes	18-6083-15
Rack F, complete for 250 ml bottles	18-6083-16
Funnel to Flask Kit with funnels, tubing, and tubing organizer (for use with Rack E)	18-6083-17

www.gelifesciences.com/orderonline

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Filtration products

Filtration

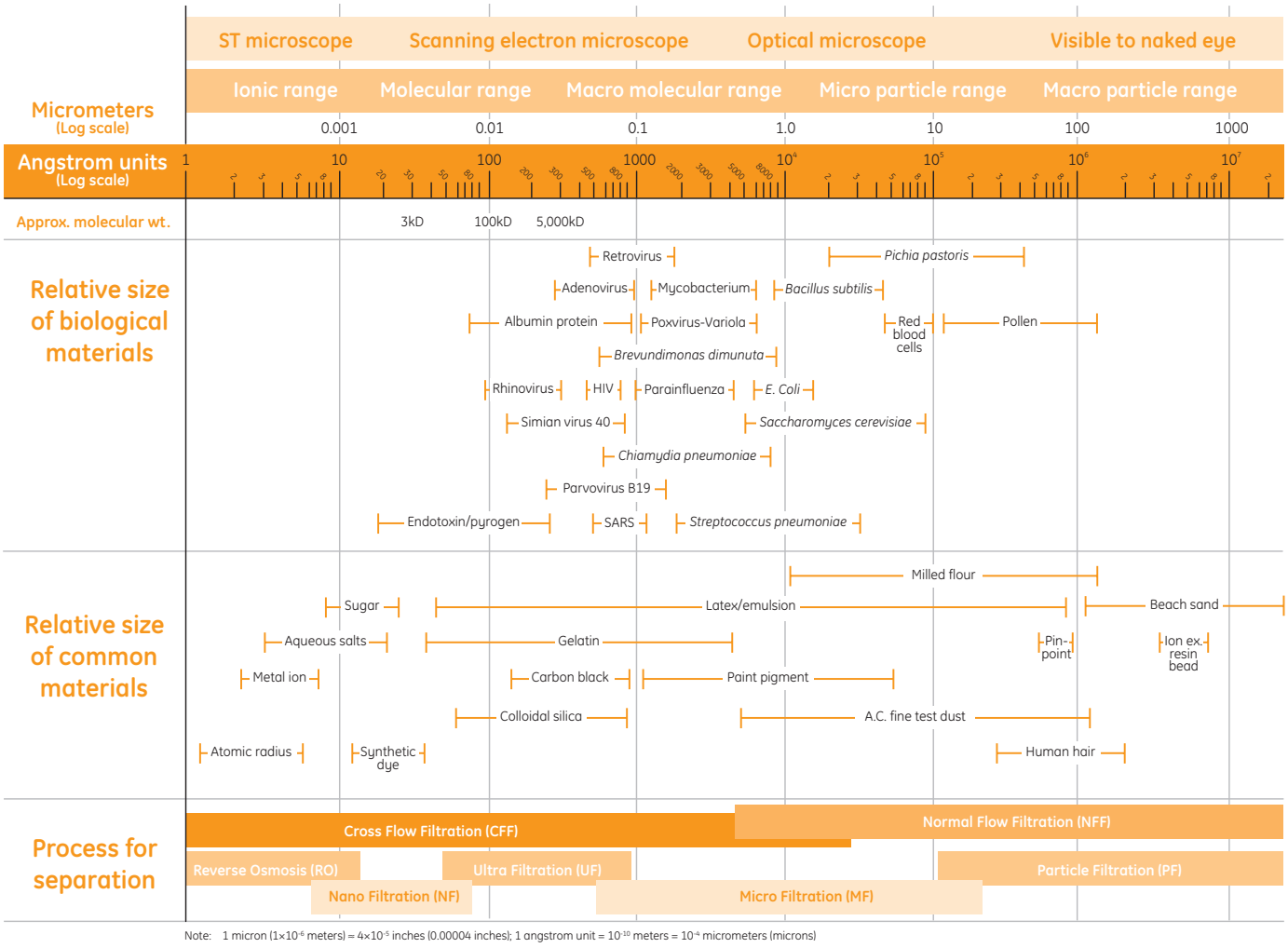
Cross flow filtration (CFF), normal ("dead-end") flow filtration (NFF), and chromatographic separations are all frequently required in the purification process of biological fluids. CFF and NFF are "positive barrier" separations and thus complement chromatography.

GE Healthcare provides filtration solutions and support for integrated bioprocessing applications at every step and every scale of the drug development, validation and manufacturing process.

The following classes of filtration products are available:

- **Hollow Fiber:** Hollow Fiber Cartridges & Systems
- **Cassettes:** Kvick Cassettes, Holders & Systems – (flat sheet membrane devices)
- **Normal Flow:** ULTA Normal Flow Cartridges & Hardware

The above classes comprise membranes and systems that provide optimum membrane packing density, ease of validation, and reliable scale up from laboratory to production volumes.



Note: 1 micron (1×10^{-6} meters) = 4×10^{-5} inches (0.00004 inches); 1 angstrom unit = 10^{-10} meters = 10^{-4} micrometers (microns)

GE Healthcare's products span a wide range of filtration applications.

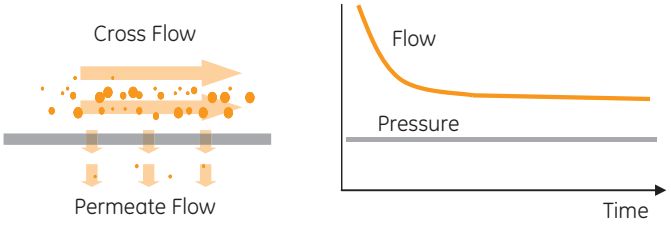
›› For the latest information about our filtration products, visit www.gelifesciences.com/filtration

Filtration – how it works

Membrane filters retain matter primarily due to size differences between the molecules and the pores in the membrane. The precise nature of GE Healthcare's porous synthetic membranes used in the CFF product range makes them ideal for bioprocess purification and recovery. The key advantage of a positive barrier is GE Healthcare's advanced void-free technology, which allows optimal performance with a wide variety of feed stream constituents. Our manufacturing technology provides sharp cut-off to enhance clarification and fractionation applications. Our filters are engineered specifically for accurate linear scale-up, and our family of CFF and NFF devices offers consistent performance, excellent durability, and ease of use.

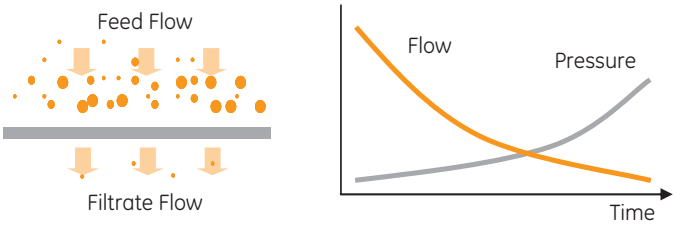
The GE Healthcare array of CFF and NFF filtration devices.

How cross flow membranes work



The feed stream moves parallel to the membrane surface (cross flow) and purified liquid passes through the membrane (permeate). Most of the particulates and aggregates are carried away by the cross flow.

How normal or dead-end flow filters work



The feed stream moves perpendicular to the membrane and purified liquid passes through the membrane (filtrate). Particulates and aggregates remain behind as 'filter cake', reducing flow and/or increasing pressure over time.

Cross flow filtration vs. Normal flow filtration

Both technologies purify bioprocess solutions by removing contaminates with a fixed porous medium, yet each format has unique advantages. Generally, normal flow filters (NFF) are used where clarification and/or bio-burden reduction is desired in relatively low solid streams, for protecting or enhancing downstream operations, or when final polishing is required to achieve sterility. Cross flow filters (CFF) are best suited for higher solids, more viscous feed solutions, and/or where concentration or purification of cells or target species is desired.

The guide below provides further information. Where functional needs overlap, a GE Healthcare Filtration Specialist can help you find the optimum configuration for your specific operation.

Guide to selecting Normal flow or Cross flow filtration

	NFF	CFF
MF Range	×	×
UF Range		×
High solids handling		×
Diafiltration		×
Concentration		×
Disposable	×	[1]
Recirculation required		×
Clean & reuse		×
Air applications	×	
Aseptic environment	×	×
Sterile applications	×	
Integrity-testable	×	
Validation guides	×	×
Self-contained available	×	×
SIP	×	×
Autoclavable	×	×

× = suitable for use.

[1] some models available; contact GE Healthcare.

Cross flow filtration

GE Healthcare separation cassettes and cartridges are designed for cross flow (tangential flow) operation. Unlike single pass or normal flow (dead end) filtration, cross flow filtration continuously sweeps the membrane surface by circulating the feed stream across it. This circulation minimizes blinding of the membrane pores and promotes consistent, long-term productivity. It also allows units to be cleaned, stored, and re-used as needed.

As the feed stream is pumped through the cassette or cartridge, the retentate (the materials excluded by the membrane pores) continues through the recirculation loop, while the permeate, including solvent and solutes, is transported through the membrane pores and collected separately.

Cross flow filtration format selection guide

Attribute	Hollow fiber	Cassette
Low binding	Best	Best
Aseptic processing	Best	Good
Reliable liner scale up	Best	Best
High solids	Best	Good
Low solids concentration	Good	Best
Perfusion	Best	NR
Cell clarification	Best	Good
Plasma concentration	Good	Best
Diafiltration	Best	Good
Single use	Good[1]	Good[1]
Laboratory scale	Best	Best
Low hold up	Good	Best
UF	Best	Best
MF	Best	NA
Steam-in-Place	Best	NR
Multiple feed channel heights	Best	Limited

[1] some models available; contact GE Healthcare.

Normal flow filtration

GE Healthcare provides comprehensive normal flow filtration products designed to maximize process efficiency from early-phase product development through to full bioprocess production.

Liquid sterilization

Filters incorporating high-flow membrane formats minimize filtration system sizes while meeting full validation and integrity test requirements.

Bioburden reduction

Extensive range of membrane and depth media products meet individual application requirements.

Clarification

Range of absolute-rated, prefiltration products providing consistent performance with broad chemical compatibility.

Range of Normal flow filtration filters

Formats	Prefilters	Bio-burden reduction*	Sterilizing grade
Flat disc	×	×	×
Syringe filters		×	×
Capsules	×	×	×
10" cartridges	×	×	×
20" cartridges	×	×	×
30" cartridges	×	×	
Pore sizes			
0.1			×
0.2		×	×
0.45		×	
0.65	×		
1.0	×		
3.0	×		
5.0	×		
10.0	×		
20.0	×		

* 1 to 5 Logs

Systems

GE Healthcare filtration systems are engineered with consistent flow paths for straightforward scale-up/scale-down, easing the transition from research to pilot to full production. In addition, GE Healthcare has highly experienced technical resources available for consultation and input into process development.

ÄKTAcrossflow

The purification of biomolecules normally uses filtration to concentrate and wash feed prior to chromatography. ÄKTAcrossflow is a fully automated system for cross flow filtration (ultrafiltration/diafiltration and cell separation) designed for process development and optimization. ÄKTAcrossflow is suitable for installation in a laboratory environment, which reduces facility and infrastructure expenditure. The benchtop system is compact and has a sanitary design with changeable wetted parts.

Hollow fiber cartridge systems

GE Healthcare provides a range of cartridge-based systems, from small systems for laboratory scale to larger-scale systems that are modular in design.

MidJet Systems are compact and self-contained. They use MidGee Cross flow Filters to facilitate rapid processing of volumes up to 200 ml. Low hold-up volumes allow concentration of volumes as small as 2 to 5 ml.

QuixStand Basic Systems are compact, self-contained units designed for Xampler laboratory cartridges for rapid processing of volumes up to 10 liters, plus linear scale up from pilot to process-scale.

FlexStand Basic Systems accommodate Pilot/Process Scale Cartridges from 0.14 to 3.4 m^2 for processing volumes from 5 to 100 liters and more.

GrandStand pilot/process systems are self-contained and designed for MaxCell Large Process Scale Cartridges up to 13 m^2. Process volumes range from 50 to 1000 liters and higher.

Kvick cassette systems

The Kvick Lab separation system uses up to five Kvick Lab cassettes, and includes a 2.5 liter reservoir, rotary-lobe pump, pressure gauges, and necessary valves, piping, connectors, and fittings. The pilot/process scale system can accommodate up to 10 Kvick Flow cassettes.

UniFlux systems

UniFlux systems provide a highly flexible means for incorporating filtration solutions into an overall downstream process. Available in 4 sizes (10, 30, 120, and 400 lpm) for pilot to production scales, UniFlux is a fully automated system with UNICORN control software, now expanded to encompass filtration as well as chromatography.

Designed to maximize productivity in cross flow filtration, UniFlux works in concert with other GE Healthcare components to provide consistent, repeatable – and validatable – results. UniFlux was developed with input from several GE Healthcare customers with needs ranging from research and development to biopharmaceutical manufacturing, thus helping ensure the relevance of each feature.

All UniFlux systems are skid-mounted, mobile, and can fit through a standard doorway. The automated systems include the following features:

- Rotary-lobe pump for reliable, shear-sensitive operation (diaphragm pump for UniFlux 10)
- Sanitary diaphragm valves
- Overpressure protection
- Zero dead-leg piping in stainless steel
- Product contact material 316L stainless steel
- Monitoring of all major process parameters

Automated systems also include the additional benefit of GE Healthcare UNICORN control system. UNICORN software, a single interface for the control of both filtration and chromatography systems, has become a standard in the industry with over 25 000 systems in use, many in approved manufacturing operations. The UNICORN operating system is an extremely powerful tool for process development and production control, providing flexibility to control processes with automatic TMP control or regulated flow control.

Scale-up

In addition to laboratory-scale cross flow devices and systems, GE Healthcare also offers a complete range of products for biopharmaceutical scale-up to pilot and production operations. Hollow fiber ultrafiltration and microfiltration products are supplied as 25 different self-contained cartridge designs ranging from 16 cm^2 to 28 m^2 of effective membrane area.

MidGee, MidGee Hoop and Xampler scale hollow fiber cartridges can be optimized in larger processes by using pilot scale cartridges/process scale cartridges. Steam-in-place hollow fiber cartridge elements for pharmaceutical manufacturing are also available. For complete systems offerings for hollow fiber cartridges, see MidJet, QuixStand, FlexStand or GrandStand.

Like cartridges, Kvick Cassette offerings provide scalability from laboratory through pilot to production scale. Both Kvick Lab System and Kvick Flow System benefit from a design and engineering approach usually reserved for large-scale production equipment.

Automated cross flow systems are available for hollow fiber and Kvick cassettes at laboratory-scale as ÄKTAcrossflow and at pilot/production-scale as UniFlux.

Cross flow filtration – Hollow fiber cartridges

Start AXM/AXH cross flow cartridges

Hollow fiber Start AXM and Start AXH cross flow cartridges.

- Rapid concentration and/or diafiltration of biological solutions and suspensions using an open flow path design
- Integrated UNF fittings for feed, and retentate permeate connections allows direct connection to ÄKTAcrossflow system
- Membrane area of 40 cm^2 (AXH) or 50 cm^2 (AXM) allows direct performance comparison when evaluating multiple membrane pore sizes
- Standard path lengths of 30 and 60 cm enables accurate scale-up and scale-down studies

Hollow fiber Start AXM and Start AXH cross flow cartridges are self-contained, disposable filtration devices. They enable process development and optimization of ultrafiltration (UF) and microfiltration (MF) operations for cell processing and upstream clarification of biopharmaceutical solutions.

The cartridges are designed for small scale processing, rapid laboratory concentration, and/or diafiltration of biological solutions at research-scale volumes with convenience and speed. The cartridges are easy to use and minimize membrane polarization due to the "sweeping action" generated by a recirculation pump. Typical application areas for Start cross flow cartridges include cell harvesting and washing, clarification of lysates and cell cultures, and concentration, diafiltration, and purification of monoclonal antibodies, plasmids, proteins, viruses, vaccines, colloids, and plasma.

Start hollow fiber cartridges are comprised of polysulfone (PS)-based membranes of seven UF molecular weight ratings and four MF micron ratings for processing a wide range of cells, viruses, and biomolecules. These membranes exhibit sharp rejection curves, leading to reproducible, precise separations and maximized protein yield. Each of these membranes is identical to membranes in the GE Healthcare's pilot- and process-scale hollow fiber cartridges to ensure relevance of performance data generated by using hollow fiber Start AXM and Start AXH cross flow cartridges.

Ordering information

Product	Quantity	Code No.
Start AXM (UFP-3-C-2U)	1	11-0005-43
Start AXM (UFP-10-C-2U)	1	11-0005-44
Start AXM (UFP-30-C-2U)	1	11-0005-45
Start AXM (UFP-100-C-2U)	1	11-0005-46
Start AXM (UFP-300-C-2U)	1	11-0005-47
Start AXM (UFP-500-C-2U)	1	11-0005-48
Start AXM (UFP-500-E-2U)	1	11-0005-49
Start AXM (UFP-750-E-2U)	1	11-0005-50
Start AXM (CFP-1-E-2U)	1	11-0005-51
Start AXM (CFP-2-E-2U)	1	11-0005-52
Start AXM (CFP-4-E-2U)	1	11-0005-53
Start AXM (CFP-6-D-2U)	1	11-0005-54
Start AXH (UFP-3-C-H24U)	1	11-0005-37
Start AXH (UFP-10-C-H24U)	1	11-0005-38
Start AXH (UFP-30-C-H24U)	1	11-0005-39
Start AXH (UFP-100-C-H24U)	1	11-0005-40
Start AXH (UFP-300-C-H24U)	1	11-0005-41
Start AXH (UFP-500-C-H24U)	1	11-0005-42

Technical specifications

	Start AXM	Start AXH
Diameter	0.6 cm (0.25 in)	0.3 cm (0.125 in)
Path length	30 cm (12 in)	60 cm (24 in)
Connections:		
Feed/retentate	UNF fitting	UNF fitting
Permeate	UNF fitting	UNF fitting
Membrane area (nominal)	50 cm^2 (7.75 in^2)	40 cm^2 (6.2 in^2)
Hold-up volume (nominal):		
Lumen side	1–1.5 ml	< 1 ml
Shell side	1 ml	< 1 ml
Materials of Construction:		
Hollow fibers	Polysulfone	Polysulfone
Housing components	Polysulfone	Polysulfone
Potting	Epoxy	Epoxy
Fitting caps	Vinyl	Vinyl

MidGee cross flow cartridges

MidGee Cross flow cartridges are for biological solution volumes up to 200 ml.

- Rapid concentration and/or diafiltration of critical biological solutions and suspensions
- Ultrafiltration pore sizes from 1000 to 750 000 NMWC, microfiltration pore sizes from 0.1 to 0.65 microns
- Maximum product recovery due to cross flow design.
- Sealed system permits convenient, continuous hands-free diafiltration
- Contaminating proteins and electrolytes can be washed through membrane fibers and reduced to undetectable levels
- Low hold-up volume for concentration of 2 to 5 ml (cartridge hold-up volume 0.5 ml)
- Quick, convenient Luer-Lok connections

MidGee disposable cross flow cartridges are for small-scale processing, rapid laboratory concentration and/or diafiltration of biological solution volumes up to 200 ml with a convenience and speed impossible to achieve with stirred cells or dialysis tubing.

MidGee cartridges are optimized for use in our compact MidJet cross flow filtration system. Test data can be used to linearly scale up to larger cartridge and system designs or for scale-down process optimization and trouble-shooting experiments.

Ordering information

Product*	Quantity	Code No.
MidGee Cartridge, 0.1 micron, 0.5 mm lumen (CFP-1-C-MM01A)	1	56-4100-60
MidGee Cartridge, 0.2 micron, 0.5 mm lumen (CFP-2-C-MM06A)	1	56-4100-69
MidGee Cartridge,100 kD, 0.5 mm lumen (UFP-100-C-MM01A)	1	56-4100-36
MidGee Cartridge, 100 kD, 1.0 mm lumen (UFP-100-E-MM06A)	6	56-4100-41
MidGee Cartridge, 10 kD, 1.0 mm lumen (UFP-10-E-MM01A)	1	56-4100-16
MidGee Cartridge, 1 kD, 0.5 mm lumen (UFP-1-C-MM06)	6	56-4100-01
MidGee Cartridge,30 kD, 0.5 mm lumen (UFP-30-C-MM01A)	1	56-4100-20
MidGee Cartridge, 30 kD, 1.0 mm lumen (UFP-30-E-MM06A)	6	56-4100-25
MidGee Cartridge, 500 kD, 1.0 mm lumen (UFP-500-E-MM01A)	1	56-4100-56
MidGee Cartridge, 750 kD, 1.0 mm lumen (UFP-750-E-MM06A)	6	56-4108-07

Order online at www.gelifesciences.com/orderonline

** This table shows examples of MidGee cartridges currently available. For complete product lists and ordering information, please contact your local GE Healthcare representative.*

Technical specifications

MidGee Cross Flow Cartridges	
Diameter	0.3 cm (0.125 in.)
Length	30.8 cm (12.125 in.)
Endfitting connections	Male Luer-Lok
Permeate connections	Male Luer-Lok
Membrane area (nominal)	16 to 26 cm^2 (2.3–4.03 in^2)
Hold-up volume (nominal):	
Lumen side	0.25 ml
Shell side	0.25 ml
Autoclavable	All except 1000 NMWC models
Materials of construction:	
Hollow fibers	Polysulfone
Shell	Polysulfone
Luer Lok fittings	Polycarbonate
Potting	Epoxy

MidGee Hoop cross flow cartridges

MidGee Hoop cross flow cartridges are perfect for scaling trials.

- Rapid concentration and/or diafiltration of critical biological solutions
- Ultra-compact design
- Full range of UF/MF pore sizes and lumen diameters
- 60 cm and 110 cm pathlengths match pilot/production scale designs
- Autoclavable
- Require minimal solution volume/pump capacity
- High product recoveries with minimal shear denaturation
- No 'wall effects' to distort scale-up projections

Throughout the R&D process, access to product is often limited. As a result, investigations into optimization of operating conditions are sometimes postponed or avoided entirely. Now scale-up and scale-down using minimum product volumes is easy with our MidGee Hoop cross flow cartridges. Hoop cartridges provide all the critical features of full production scale in a miniature cross flow device, allowing simulation of process parameters – including path length – with minimal solution volume and pump capacity. The uniform flow path design from laboratory to production scale makes hollow fibers the most attractive of the various cross flow configurations for linear scale-up. MidGee Hoop cartridges are optimized for use in our compact MidJet cross flow filtration system, which includes a miniature peristaltic pump with exchangeable saddles to accommodate size 14 and 16 tubing; reservoirs for retentate, diafiltrate and permeate; precision backpressure control valve; and a convenient platform for mounting the cartridge and pump with recesses to accommodate three reservoirs.

Ordering information

Product*	Quantity	Code No.
MidGee Hoop Cartridge, 0.1 micron, 1.0 mm lumen, 60 cm (CFP-1-E-H22LA)	1	56-4100-96
MidGee Hoop Cartridge, 0.2 micron, 1.0 mm lumen, 60 cm (CFP-2-E-H22LA)	1	56-4100-97
MidGee Hoop Cartridge, 0.45 micron, 1.0 mm lumen, 60 cm (CFP-4-E-H22LA)	1	56-4100-98
MidGee Hoop Cartridge, 0.65 micron, 0.75 mm lumen, 60 cm (CFP-6-D-H22LA)	1	56-4100-99
MidGee Hoop Cartridge, 100kD, 0.5 mm lumen, 60 cm (UFP-100-C-H24LA)	1	56-4101-03
MidGee Hoop Cartridge, 100kD, 1.0 mm lumen, 60 cm (UFP-100-E-H22LA)	1	56-4100-92
MidGee Hoop Cartridge, 10kD, 0.5 mm lumen, 110 cm (UFP-10-C-H42LA)	1	56-4101-08
MidGee Hoop Cartridge, 10kD, 1.0 mm lumen, 110 cm (UFP-10-E-H22LA)	1	56-4100-89
MidGee Hoop Cartridge, 300kD, 0.5 mm lumen, 60 cm (UFP-300-C-H42LA)	1	56-4101-15
MidGee Hoop Cartridge, 300kD, 1.0 mm lumen, 60 cm (UFP-300-E-H22LA)	1	56-4100-93
MidGee Hoop Cartridge, 30kD, 0.5 mm lumen, 110 cm (UFP-30-C-H42LA)	1	56-4101-10
MidGee Hoop Cartridge, 30kD, 1.0 mm lumen, 60 cm (UFP-30-E-H22LA)	1	56-4100-90
MidGee Hoop Cartridge, 3kD, 0.5 mm lumen, 60 cm (UFP-3-C-H42LA)	1	56-4101-06
MidGee Hoop Cartridge, 3kD, 1.0 mm lumen, 60 cm (UFP-3-E-H22LA)	1	56-4100-88
MidGee Hoop Cartridge, 500kD, 0.5 mm lumen, 110 cm (UFP-500-C-H42LA)	1	56-4101-17
MidGee Hoop Cartridge, 50kD, 1.0 mm lumen, 60 cm (UFP-50-E-H22LA)	1	56-4100-91
MidGee Hoop Cartridge, 750kD, 1.0 mm lumen, 110 cm (UFP-750-E-H42LA)	1	56-4101-19

* This table shows examples of MidGee Hoop cartridges currently available. For complete product lists and ordering information, please contact your local GE Healthcare representative.

Technical specifications

MidGee Hoop Cross Flow Cartridges	
Diameter	0.3 cm (0.125 in.)
Length (nominal)	60 cm (23.6 in.)
	110 cm (43.3 in.)
Endfitting connections	Male Luer-Lok
Permeate connections	Male Luer-Lok
Membrane area (nominal)	29–73 cm^2 (4.5–11.3 $in.^2$)
Hold-up volume (nominal):	
60 cm model	0.5 to 1.0 ml each (lumen and shell side)
110 cm model	0.6 to 2 ml each (lumen and shell side)
Materials of construction:	
Hollow fibers	Polysulfone
Shell	Polysulfone
Luer Lok fittings	Polycarbonate
Potting	Epoxy

Xampler laboratory cartridges

Xampler cartridges, available for QuixStand and Kvick Lab benchtop systems, can be manifolded together to achieve a wide range of process requirements.

- Nominal flow path lengths of 30 and 60 cm allow optimization of process conditions and assist future scale-up
- Low flow rate requirements allow the use of smaller pumps
- Polysulfone membrane minimizes non-specific protein binding and provides high product recovery
- Range of membrane areas suits different processing needs
- Offered with Tri-Clamp end fittings for quick and easy aseptic connection
- Autoclavable (with the exception of 1000 NMWC) devices address the need for small-volume sanitary processing

Xampler ultrafiltration and microfiltration cartridges are for laboratory scale processing with solution volumes typically ranging from a few hundred milliliters to about five liters.

Nominal flow path lengths are 30 and 60 cm and membrane areas range from 0.01 to 0.14 m^2 (0.12 to 1.5 ft^2). Moreover, they are directly scalable to pilot and process scale cartridges with equivalent path lengths.

Xampler cartridges have self-contained housings that match QuixStand and Kvick Lab benchtop systems. Vertical operation achieves complete process fluid drainage and maximum product recovery.

Ordering information

Product*	Quantity	Code No.
Xampler Cartridge, 0.1 micron, 0.75 mm lumen, size 3M, autoclavable (CFP-1-D-3MA)	1	56-4101-40
Xampler Cartridge, 0.2 micron, 1.0 mm lumen, size 3X2M, autoclavable (CFP-2-E-3X2MA)	1	56-4101-57
Xampler Cartridge, 0.45 micron, 1.0 mm lumen, size 3M, autoclavable (CFP-4-E-3MA)	1	56-4101-43
Xampler Cartridge, 0.65 micron, 0.75 mm lumen, size 3M, autoclavable (CFP-6-D-3MA)	1	56-4101-44
Xampler Cartridge, 100kD, 0.5 mm lumen, size 3M, autoclavable (UFP-100-C-3MA)	1	56-4101-33
Xampler Cartridge, 10kD, 1.0 mm lumen, size 3M, autoclavable (UFP-10-E-3MA)	1	56-4101-28
Xampler Cartridge, 1kD, 0.5 mm lumen, size 3M (UFP-1-C-3M)	1	56-4101-20
Xampler Cartridge, 300kD, 0.5 mm lumen, size 3M, autoclavable (UFP-300-C-3MA)	1	56-4101-35
Xampler Cartridge, 30kD, 1.0 mm lumen, size 3M, autoclavable (UFP-30-E-3MA)	1	56-4101-30
Xampler Cartridge, 3kD, 0.5 mm lumen, size 3M, autoclavable (UFP-3-C-3MA)	1	56-4101-22
Xampler Cartridge, 3kD, 0.5 mm lumen, size 3M, autoclavable (UFP-3-C-3X2MA)	1	56-4101-45
Xampler Cartridge, 3kD, 1.0 mm lumen, size 3M, autoclavable (UFP-3-E-3MA)	1	56-4101-23
Xampler Cartridge, 500kD, 0.5 mm lumen, size 3M, autoclavable (UFP-500-C-3MA)	1	56-4101-37
Xampler Cartridge, 50kD, 1.0 mm lumen, size 3M, autoclavable (UFP-50-E-3MA)	1	56-4101-32
Xampler Cartridge, 5kD, 0.5 mm lumen, size 3M, autoclavable (UFP-5-C-3MA)	1	56-4101-24

* This table shows examples of Xampler cartridges currently available. For complete product lists and ordering information, please contact your local GE Healthcare representative.

Technical specifications

Xampler Cross Flow Cartridges

Diameter:	
3M, 3X2M	0.9 cm (0.375 in.)
4, 4M, 4X2M	1.9 cm (0.75 in.)
Length:	
3M	31.7 cm (12.5 in.)
3X2M	63.5 cm (25 in.)
4	36.2 cm (14.25 in.)
4M	34.5 cm (13.6 in.)
4X2M	66 cm (26 in.)
Endfitting connections:	
3M, 3X2M, 4M, 4X2M	0.5-in. Tri-Clamp
4	0.375-in. Tubing barb
Permeate connections:	
3M, 3X2M	0.25-in. Tubing nipple
4, 4M, 4X2M	0.375-in Tubing nipple
Membrane area (nominal)	110–1400 cm^2 (17–216 $in.^2$)
Hold-up volume (nominal):	
Lumen side	2–30 ml
Shell side	5–75 ml
Autoclavable	All except 1000 NMWC models
Materials of construction:	
Hollow fibers	Polysulfone
Shell	Polysulfone
Luer Lok fittings	Polycarbonate
Potting	Epoxy
Fiber bundle	Polypropylene

Pilot scale hollow fiber cartridges

To bridge the several steps between research and production volumes, GE Healthcare offers a full range of pilot scale ultrafiltration and microfiltration hollow fiber membrane cartridges. These cartridges feature industry standard 1.5 in Tri-Clamp sanitary feed and retentate fittings. Both 30 and 60 cm flowpath lengths are offered with cartridges that provide an order-of-magnitude membrane area span from 0.12 to 1.15 m^2 (1.3 to 12.5 ft^2). Please feel free to contact our technical support team for guidance with linear scaling parameters for small volume processing.

GE Healthcare's FlexStand benchtop system product line is designed to suit the entire range of pilot scale cartridges. Two basic models are offered with optional peristaltic or rotary lobe pumps and polysulfone feed reservoirs. These systems can be cart-mounted for ease of movement between the laboratory and the cold room.

Ordering information for pilot scale microfiltration cartridges

Code number	Model number	Pore size (µm)	Fiber ID (mm)	Membrane area (m^2)	(ft^2)	Nominal flowpath length (cm)
56-4102-46	CFP-1-D-5A	0.1	0.75	0.16	1.7	30
56-4102-47	CFP-1-E-5A	0.1	1	0.12	1.3	30
56-4102-48	CFP-2-E-5A	0.2	1	0.12	1.3	30
56-4102-49	CFP-4-E-5A	0.45	1	0.12	1.3	30
56-4102-50	CFP-6-D-5A	0.65	0.75	0.16	1.7	30
56-4102-69	CFP-1-D-6A	0.1	0.75	0.37	4	60
56-4102-70	CFP-1-E-6A	0.1	1	0.28	3	60
56-4102-71	CFP-2-E-6A	0.2	1	0.28	3	60
56-4105-61	CFP-2-G-6A	0.2	1.75	0.23	2.5	60
56-4102-72	CFP-4-E-6A	0.45	1	0.28	3	60
56-4102-73	CFP-6-D-6A	0.65	0.75	0.37	4	60
56-4102-86	CFP-1-D-8A	0.1	0.75	0.41	4.4	30
56-4102-87	CFP-1-E-8A	0.1	1	0.36	3.9	30
56-4102-88	CFP-2-E-8A	0.2	1	0.36	3.9	30
56-4102-89	CFP-4-E-8A	0.45	1	0.36	3.9	30
56-4102-90	CFP-6-D-8A	0.65	0.75	0.41	4.4	30
56-4103-09	CFP-1-D-9A	0.1	0.75	0.93	10	60
56-4103-10	CFP-1-E-9A	0.1	1	0.84	9	60
56-4103-11	CFP-2-E-9A	0.2	1	0.84	9	60
56-4105-62	CFP-2-G-9A	0.2	1.75	0.59	6.3	60
56-4103-12	CFP-4-E-9A	0.45	1	0.84	9	60
56-4103-13	CFP-6-D-9A	0.65	0.75	0.93	10	60

Note: All pilot scale cartridges are autoclavable except those with 1000 NMWC ultrafiltration membranes.

Ordering information for pilot scale ultrafiltration cartridges

Code number	Model number	Pore size (NMWC)	Fiber ID (mm)	Membrane area (m^2)	(ft^2)	Nominal flowpath length (cm)
56-4102-26	UFP-1-C-5	1000	0.5	0.20	2.1	30
56-4102-28	UFP-3-C-5A	3000	0.5	0.20	2.1	30
56-4102-29	UFP-3-E-5A	3000	1	0.12	1.3	30
56-4102-30	UFP-5-C-5A	5000	0.5	0.20	2.1	30
56-4102-31	UFP-5-E-5A	5000	1	0.12	1.3	30
56-4102-33	UFP-10-C-5A	10 000	0.5	0.20	2.1	30
56-4102-34	UFP-10-E-5A	10 000	1	0.12	1.3	30
56-4102-35	UFP-30-C-5A	30 000	0.5	0.20	2.1	30
56-4102-36	UFP-30-E-5A	30 000	1	0.12	1.3	30
56-4102-37	UFP-50-C-5A	50 000	0.5	0.20	2.1	30
56-4102-38	UFP-50-E-5A	50 000	1	0.12	1.3	30
56-4102-39	UFP-100-C-5A	100 000	0.5	0.20	2.1	30
56-4102-40	UFP-100-E-5A	100 000	1	0.12	1.3	30
56-4102-41	UFP-300-C-5A	300 000	0.5	0.20	2.1	30
56-4102-42	UFP-300-E-5A	300 000	1	0.12	1.3	30
56-4102-43	UFP-500-C-5A	500 000	0.5	0.20	2.1	30
56-4102-44	UFP-500-E-5A	500 000	1	0.12	1.3	30
56-4102-45	UFP-750-E-5A	750 000	1	0.12	1.3	30
56-4102-51	UFP-1-C-6	1000	0.5	0.48	5.2	60
56-4102-52	UFP-3-C-6A	3000	0.5	0.48	5.2	60
56-4102-53	UFP-3-E-6A	3000	1	0.28	3	60
56-4102-54	UFP-5-C-6A	5000	0.5	0.48	5.2	60
56-4102-55	UFP-5-E-6A	5000	1	0.28	3	60
56-4102-56	UFP-10-C-6A	10 000	0.5	0.48	5.2	60
56-4102-57	UFP-10-E-6A	10 000	1	0.28	3	60
56-4102-58	UFP-30-C-6A	30 000	0.5	0.48	5.2	60
56-4102-59	UFP-30-E-6A	30 000	1	0.28	3	60
56-4102-60	UFP-50-C-6A	50 000	0.5	0.48	5.2	60
56-4102-61	UFP-50-E-6A	50 000	1	0.28	3	60
56-4102-62	UFP-100-C-6A	100 000	0.5	0.48	5.2	60
56-4102-63	UFP-100-E-6A	100 000	1	0.28	3	60
56-4102-64	UFP-300-C-6A	300 000	0.5	0.48	5.2	60
56-4102-65	UFP-300-E-6A	300 000	1	0.28	3	60
56-4102-66	UFP-500-C-6A	500 000	0.5	0.48	5.2	60
56-4102-67	UFP-500-E-6A	500 000	1	0.28	3	60
56-4102-68	UFP-750-E-6A	750 000	1	0.28	3	60
56-4102-74	UFP-3-C-8A	3000	0.5	0.53	5.7	30
56-4102-76	UFP-10-C-8A	10 000	0.5	0.53	5.7	30
56-4102-77	UFP-30-C-8A	30 000	0.5	0.53	5.7	30
56-4102-78	UFP-50-C-8A	50 000	0.5	0.53	5.7	30
56-4102-79	UFP-100-C-8A	100 000	0.5	0.53	5.7	30
56-4102-80	UFP-100-E-8A	100 000	1	0.36	3.9	30
56-4102-81	UFP-300-C-8A	300 000	0.5	0.53	5.7	30
56-4102-82	UFP-300-E-8A	300 000	1	0.36	3.9	30
56-4102-83	UFP-500-C-8A	500 000	0.5	0.53	5.7	30
56-4102-84	UFP-500-E-8A	500 000	1	0.36	3.9	30
56-4102-85	UFP-750-E-8A	750 000	1	0.36	3.9	30
56-4102-91	UFP-1-C-9	1000	0.5	1.15	12.5	60
56-4102-92	UFP-3-C-9A	3000	0.5	1.15	12.5	60
56-4102-93	UFP-3-E-9A	3000	1	0.84	9	60
56-4102-94	UFP-5-C-9A	5000	0.5	1.15	12.5	60
56-4102-95	UFP-5-E-9A	5000	1	0.84	9	60
56-4102-96	UFP-10-C-9A	10 000	0.5	1.15	12.5	60
56-4102-97	UFP-10-E-9A	10 000	1	0.84	9	60
56-4102-98	UFP-30-C-9A	30 000	0.5	1.15	12.5	60
56-4102-99	UFP-30-E-9A	30 000	1	0.84	9	60
56-4103-00	UFP-50-C-9A	50 000	0.5	1.15	12.5	60
56-4103-01	UFP-50-E-9A	50 000	1	0.84	9	60
56-4103-02	UFP-100-C-9A	100 000	0.5	1.15	12.5	60
56-4103-03	UFP-100-E-9A	100 000	1	0.84	9	60
56-4103-04	UFP-300-C-9A	300 000	0.5	1.15	12.5	60
56-4103-05	UFP-300-E-9A	300 000	1	0.84	9	60
56-4103-06	UFP-500-C-9A	500 000	0.5	1.15	12.5	60
56-4103-07	UFP-500-E-9A	500 000	1	0.84	9	60
56-4103-08	UFP-750-E-9A	750 000	1	0.84	9	60

Note: All pilot scale cartridges are autoclavable except those with 1000 NMWC ultrafiltration membranes.

Process scale hollow fiber cartridges

Process scale hollow fiber cartridges offered by GE Healthcare are provided in eight basic configurations covering a membrane area range of 0.92 to 28 m^2 (9.9 to 300 ft^2) depending on the fiber internal diameter.

All of these process scale cartridges feature sanitary connections for both the feed/retentate and permeate ports. Use of this industry standard makes for easy connections to tanks, pumps, manifolds, and instrumentation.

GE Healthcare GrandStand systems are cart-mounted units designed to accommodate the full range of ultrafiltration and microfiltration process scale cartridges offered by the company. The various GrandStand configurations are capable of concentration and/or diafiltration of solution volume ranging from 50 to 1000 liters or more.

Ordering information for process scale microfiltration cartridges

Code number	Model number	Pore size (µm)	Fiber ID (mm)	Membrane area (m^2)	Membrane area (ft^2)	Nominal flowpath length (cm)
56-4103-30	CFP-1-D-35A	0.1	0.75	1	10.8	30
56-4103-31	CFP-1-E-35A	0.1	1	0.92	9.9	30
56-4103-32	CFP-2-E-35A	0.2	1	0.92	9.9	30
56-4103-33	CFP-4-E-35A	0.45	1	0.92	9.9	30
56-4103-34	CFP-6-D-35A	0.65	0.75	1	10.8	30
56-4103-69	CFP-1-D-55A	0.1	0.75	2.5	27	60
56-4103-70	CFP-1-E-55	0.1	1	2.1	23	60
56-4103-72	CFP-1-E-55A	0.1	1	2.1	23	60
56-4103-73	CFP-2-E-55	0.2	1	2.1	23	60
56-4103-75	CFP-2-E-55A	0.2	1	2.1	23	60
56-4105-63	CFP-2-G-55	0.2	1.75	1.8	19.4	60
56-4103-76	CFP-4-E-55	0.45	1	2.1	23	60
56-4103-78	CFP-4-E-55A	0.45	1	2.1	23	60
56-4103-79	CFP-6-D-55A	0.65	0.75	2.5	27	60

Note: Process scale microfiltration cartridges with model numbers that end in "A" are autoclavable.

Ordering information for process scale ultrafiltration cartridges

Code number	Model number	Pore size (NMWC)	Fiber ID (mm)	Membrane area (m^2)	(ft^2)	Nominal flowpath length (cm)
56-4103-14	UFP-3-C-35	3000	0.5	1.35	14.5	30
56-4103-15	UFP-3-E-35	3000	1	0.92	9.9	30
56-4103-16	UFP-5-C-35	5000	0.5	1.35	14.5	30
56-4103-17	UFP-5-E-35	5000	1	0.92	9.9	30
56-4103-19	UFP-10-C-35	10 000	0.5	1.35	14.5	30
56-4103-20	UFP-10-E-35	10 000	1	0.92	9.9	30
56-4103-21	UFP-30-C-35	30 000	0.5	1.35	14.5	30
56-4103-22	UFP-30-E-35	30 000	1	0.92	9.9	30
56-4103-23	UFP-100-C-35	100 000	0.5	1.35	14.5	30
56-4103-24	UFP-100-E-35	100 000	1	0.92	9.9	30
56-4103-25	UFP-300-C-35	300 000	0.5	1.35	14.5	30
56-4103-26	UFP-300-E-35	300 000	1	0.92	9.9	30
56-4103-27	UFP-500-C-35	500 000	0.5	1.35	14.5	30
56-4103-28	UFP-500-E-35	500 000	1	0.92	9.9	30
56-4103-29	UFP-750-E-35	750 000	1	0.92	9.9	30
56-4103-35	UFP-3-C-55	3000	0.5	3.25	35	60
56-4103-37	UFP-3-E-55	3000	1	2.1	23	60
56-4103-39	UFP-5-C-55	5000	0.5	3.25	35	60
56-4103-41	UFP-5-E-55	5000	1	2.1	23	60
56-4103-43	UFP-10-C-55	10 000	0.5	3.25	35	60
56-4103-45	UFP-10-E-55	10 000	1	2.1	23	60
56-4103-47	UFP-30-C-55	30 000	0.5	3.25	35	60
56-4103-49	UFP-30-E-55	30 000	1	2.1	23	60
56-4103-51	UFP-50-C-55	50 000	0.5	3.25	35	60
56-4103-53	UFP-50-E-55	50 000	1	2.1	23	60
56-4103-55	UFP-100-C-55	100 000	0.5	3.25	35	60
56-4103-57	UFP-100-E-55	100 000	1	2.1	23	60
56-4103-59	UFP-300-C-55	300 000	0.5	3.25	35	60
56-4103-61	UFP-300-E-55	300 000	1	2.1	23	60
56-4103-63	UFP-500-C-55	500 000	0.5	3.25	35	60
56-4103-65	UFP-500-E-55	500 000	1	2.1	23	60
56-4103-67	UFP-750-E-55	750 000	1	2.1	23	60
56-4103-80	UFP-3-C-75	3000	0.5	6	65	110
56-4103-82	UFP-3-E-75	3000	1	3.7	40	110
56-4103-84	UFP-5-C-75	5000	0.5	6	65	110
56-4103-86	UFP-5-E-75	5000	1	3.7	40	110
56-4103-88	UFP-10-C-75	10 000	0.5	6	65	110
56-4103-90	UFP-10-E-75	10 000	1	3.7	40	110
56-4103-92	UFP-30-C-75	30 000	0.5	6	65	110
56-4103-94	UFP-30-E-75	30 000	1	3.7	40	110
56-4103-96	UFP-50-E-75	50 000	1	3.7	40	110
56-4103-98	UFP-100-C-75	100 000	0.5	6	65	110
56-4104-00	UFP-100-E-75	100 000	1	3.7	40	110
56-4104-02	UFP-300-C-75	300 000	0.5	6	65	110
56-4104-04	UFP-300-E-75	300 000	1	3.7	40	110
56-4104-06	UFP-500-C-75	500 000	0.5	6	65	110
56-4104-08	UFP-500-E-75	500 000	1	3.7	40	110
56-4104-10	UFP-750-E-75	750 000	1	3.7	40	110
56-4104-10	UFP-750-E-75	750 000	1	3.7	40	110

Note: Process scale ultrafiltration cartridges are not autoclavable; however, autoclavable versions of select housing sizes 35 and 55 are available on special order.

MaxCell process scale hollow fiber cartridges

MaxCell cartridges for high-volume, cross flow bioprocessing applications.

- Superior processing economies
- Streamlined design utilizes space very effectively

MaxCell cartridges can be manifolded with spacing as close as 18 cm (7 inches) on center for incorporation into a compact membrane separations system. System sizing can be accurately scaled from testing laboratory and pilot scale cartridges, such as MidGee and Xampler cartridges. In addition, MaxCell cartridges can be used in place of other manufacturer's cartridges.

MaxCell cartridge ordering information

Housing size 45

Code No. Ultrafiltration	Model No.	NMWC	Membrane fiber inner diameter mm	Cartridge length cm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-67	UFP-3-C-45	3000	0.5	39.4*	15.5*	3.5	37
56-4104-68	UFP-5-C-45	5000	0.5	39.4*	15.5*	3.5	37
56-4104-69	UFP-10-C-45	10 000	0.5	39.4*	15.5*	3.5	37
56-4104-70	UFP-30-C-45	30 000	0.5	39.4*	15.5*	3.5	37

Code No. Microfiltration	Model No.	Pore size µm	Membrane fiber inner diameter mm	Cartridge length mm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-71	CFP-1-E-45	0.1	1	39.4*	15.5*	2.5	27
56-4104-72	CFP-2-E-45	0.2	1	39.4*	15.5*	2.5	27
56-4104-73	CFP-4-E-45	0.45	1	39.4*	15.5*	2.5	27
56-4104-74	CFP-6-D-45	0.65	0.75	39.4*	15.5*	2.8	30

Housing size 65

Code No. Ultrafiltration	Model No.	NMWC	Membrane fiber inner diameter mm	Cartridge length cm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-75	UFP-3-C-65	3000	0.5	62.5*	24.6*	6.1	66
56-4104-76	UFP-3-E-65	3000	1	62.5*	24.6*	4.4	47
56-4104-77	UFP-5-C-65	5000	0.5	62.5*	24.6*	6.1	66
56-4104-78	UFP-5-E-65	5000	1	62.5*	24.6*	4.4	47
56-4104-79	UFP-10-C-65	10 000	0.5	62.5*	24.6*	4.4	47
56-4104-81	UFP-30-C-65	30 000	0.5	62.5*	24.6*	6.1	66
56-4104-82	UFP-30-E-65	30 000	1	62.5*	24.6*	4.4	47
56-4104-85	UFP-100-C-65	100 000	0.5	62.5*	24.6*	6.1	66
56-4104-86	UFP-100-E-65	100 000	1	62.5*	24.6*	4.4	47
56-4104-87	UFP-300-C-65	300 000	0.5	62.5*	24.6*	6.1	66
56-4104-88	UFP-300-E-65	300 000	1	62.5*	24.6*	4.4	47
56-4104-89	UFP-500-C-65	500 000	0.5	62.5*	24.6*	6.1	66
56-4104-90	UFP-500-E-65	500 000	1	62.5*	24.6*	4.4	47

Code No. Microfiltration	Model No.	Pore size µm	Membrane fiber inner diameter mm	Cartridge length mm	Cartridge length in	Membrane area m^2	Membrane area ft^2
56-4104-92	CFP-1-E-65	0.1	1	62.5*	24.6*	4.4	47
56-4104-93	CFP-2-E-65	0.2	1	62.5*	24.6*	4.4	47
56-4104-94	CFP-4-E-65	0.45	1	62.5*	24.6*	4.4	47

*Add 4.25 in (10.8 cm) for straight adaptors

Housing size 85							
Code No. Ultrafiltration	Model No.	NMWC	Membrane fiber inner diameter mm	Cartridge length cm	in	Membrane area m^2	ft^2
56-4104-95	UFP-3-C-85	3000	0.5	120*	47.3*	13	140
56-4104-96	UFP-3-E-85	3000	1	120*	47.3*	8.8	95
56-4104-97	UFP-5-C-85	5000	0.5	120*	47.3*	13	140
56-4104-98	UFP-5-E-85	5000	1	120*	47.3*	8.8	95
56-4104-99	UFP-10-C-85	10 000	0.5	120*	47.3*	13	140
56-4105-00	UFP-10-E-85	10 000	1	120*	47.3*	8.8	95
56-4105-01	UFP-30-C-85	30 000	0.5	120*	47.3*	13	140
56-4105-02	UFP-30-E-85	30 000	1	120*	47.3*	8.8	95
56-4105-05	UFP-100-C-85	100 000	0.5	120*	47.3*	13	140
56-4105-06	UFP-100-E-85	100 000	1	120*	47.3*	8.8	95
56-4105-08	UFP-500-C-85	500 000	0.5	120*	47.3*	13	140
56-4105-09	UFP-500-E-85	500 000	1	120*	47.3*	8.8	95

*Add 4.25 in (10.8 cm) for straight adaptors

MaxCell cartridge accessories

Code No.	Model No.	Description
56-4107-26	RBMX-16PS-ST	Straight adaptor for MaxCell Cartridge, polysulfone
56-4107-27	RBMX-16PS-EL	Elbow adaptor for MaxCell Cartridge, polysulfone
56-4107-21	RB16-12SS	2-in TC to 1.5-in TC Concentric Adaptor, 316L SS
56-4107-22	RB16-12FNPTSS	2-in TC to 1.5-in female NPT Adaptor, 304 SS
56-4107-23	RB16-16FNPTSS	2-in TC to 2-in female NPT Adaptor, 304 SS
56-4107-28	EL16-16SS	2-in TC elbow, 316LSS
56-4107-37	KAMX-16PS	Straight Adaptor Kit for Installation. Either kit KAMX-16PS or kit KAMX-16EL-PS required for each new MaxCell Cartridge. Contains 2 each: RBMX-16PS-ST straight adaptors, polysulfone cartridge end nuts, polysulfone O-rings, silicone.
56-4107-38	KAMX-16EL-PS	Elbow Adaptor Kit for Installation. Either kit KAMX-16PS or kit KAMX-16EL-PS required for each new MaxCell Cartridge. Contains 2 each: RBMX-16PS-EL elbow adaptors, polysulfone cartridge end nuts, polysulfone O-rings, silicone.
56-4107-70	CL16-LT	2-in TC toggle clamp, 304 SS
56-4106-79	G16S	2-in TC gasket, silicone
56-4107-92	K04ORS	MaxCell O-ring set, 2 each, silicone
56-4107-39	SWR-MX01	MaxCell Wrench Set, standard
56-4107-40	SWR-MX02	MaxCell Wrench Set, applied torque

MaxCell cartridge physical dimensions

Technical specifications						
Housing size	Diameter cm	in	Length cm	in	Endfitting connections	Permeate connections
45	10.8	4.25	39.4*	15.5*	2-in sanitary	1.5-in sanitary
65	10.8	4.25	62.5*	24.6*	2-in sanitary	1.5-in sanitary
85	10.8	4.25	120.0*	47.3*	2-in sanitary	1.5-in sanitary

*Add 4.25 in (10.8 cm) for straight adaptors (2) at retentate ends.

MaxCell cartridge membrane area as a function of housing size and lumen diameter

Housing size	Membrane Fiber inner diameter mm	Membrane area m^2	ft^2
45	0.5	3.5	37
	0.75	2.65	28.5
	1	2.3	25
65	0.5	6.1	66
	1	4.4	47
85	0.5	13	140
	1	9	95

ProCell hollow fiber cartridges

ProCell hollow fiber cartridges of 15 cm (6 inch) diameter are for large production scale processes and are installed inside sanitary stainless steel housings.

- Sanitary design for production scale applications
- Selection of UF/MF pore sizes and lumen diameters
- 316 L stainless steel housings
- Efficient processing of thousands of liters
- Compact design with low hold-up volume
- Multiple cartridges can be manifolded into compact production systems

ProCell hollow fiber cartridges of 15 cm (6-inch) diameter are for large production scale ultrafiltration and microfiltration. Containing up to 28 m^2 (300 ft^2) of membrane area in a single, compact module, these cartridges are well suited to a wide range of bioprocessing applications.

ProCell cartridges are available in two path lengths and in a selection of ultrafiltration nominal molecular weight cut-offs and microfiltration pore sizes, as well as several membrane fiber inner diameters.

ProCell cartridge ordering information

ProCell ultrafiltration cartridges

Code No.	Model No.	NMWC	Membrane fiber ID mm	Membrane area m^2	Membrane area ft^2
56-4105-13	UFP-10-C-154	10 000	0.5	28	305
56-4105-11	UFP-500-E-152	500 000	1	9	97
56-4105-14	UFP-500-E-154	500 000	1	19.5	210

ProCell microfiltration cartridges

Code No.	Model No.	Pore size	Membrane fiber ID mm	Membrane area m^2	Membrane area ft^2
56-4105-12	CFP-2-E-152	0.2µ	1	9	97

ProCell stainless steel housings (one housing required per cartridge)

Code No.	Model No.	Description
56-4106-35	SS-152TC	Housing assembly for ProCell – 152M cartridges 316LSS with 2 each gaskets and 2 each clamps
56-4106-36	SS-154TC	Housing assembly for ProCell – 154M cartridges 316LSS with 2 each gaskets and 2 each clamps

ProCell cartridge and housing accessories

Code No.	Model No.	Description
56-4106-77	G12S	1.5-in TC gasket, silicone
56-4106-79	G16S	2-in TC gasket, silicone
56-4106-88	G48S	6-in TC [schedule 5 pipe gasket], silicone
56-4106-67	CL12	1.5-in TC quick disconnect clamp 304SS
56-4106-70	CL16	2-in TC quick disconnect clamp 304SS
56-4106-74	CL48	6-in TC [schedule 5 pipe] clamp 304SS
56-4106-96	K06ORS	ProCell cartridge O-ring set, 2 each, silicone

ProCell housing physical dimensions*

Technical specifications

Housing size	Diameter** cm	Diameter** in	Length** cm	Length** in	Endfitting connections	Permeate connections
152	16.8	6.6	81	32	2-in TC	1.5-in TC
154	16.8	6.6	139	55	2-in TC	1.5-in TC

*Stainless steel housing dimensions. **Nominal, not for design purposes.

Steam-in-place hollow fiber cartridges

Steam-in-place hollow fiber cartridges/housings (STM style)

- Strong polysulfone cartridge elements
- Leak-proof, sanitary closure
- Available in UF and MF pore sizes

Polysulfone cartridge elements have the strength and integrity to withstand the rigors of steam-in-place operations. Cartridges slip into stainless steel housings for safety and containment. A double O-ring seal at the inlet and outlet of the cartridge element ensures leak-proof, sanitary closure within the housing.

The element design allows quick yet thorough steam penetration of the membranes. Furthermore, all cartridge components are USP 24 Biologicals Test for Plastics Class VI tested. Cartridges are available in both ultrafiltration (UF) and microfiltration (MF) pore sizes in a choice of cartridge lengths.

STM cartridge ordering information

STM ultrafiltration cartridges

Code No.	Model No.		Fiber ID	Membrane area	
		NMWC*	mm	m^2	ft^2
56-4104-12	UFP-10-E-35STM	10 000	1	0.8	8.5
56-4104-13	UFP-30-E-35STM	30 000	1	0.8	8.5
56-4104-14	UFP-100-E-35STM	100 000	1	0.8	8.5
56-4104-15	UFP-500-E-35STM	500 000	1	0.8	8.5
56-4104-21	UFP-10-E-55STM	10 000	1	2.1	23
56-4104-23	UFP-30-E-55STM	30 000	1	2.1	23
56-4104-26	UFP-100-E-55STM	100 000	1	2.1	23
56-4104-27	UFP-500-E-55STM	500 000	1	2.1	23
56-4104-19	UFP-3-C-55STM	3000	0.5	3.25	35
56-4104-20	UFP-10-C-55STM	10 000	0.5	3.25	35
56-4104-22	UFP-30-C-55STM	30 000	0.5	3.25	35
56-4104-24	UFP-50-C-55STM	50 000	0.5	3.25	35
56-4104-25	UFP-100-C-55STM	100 000	0.5	3.25	35

*Nominal molecular weight cut off

STM microfiltration cartridges

Code No.	Model No.	Pore size micron	Fiber ID mm	Membrane area m^2	ft^2
56-4104-16	CFP-1-E-35STM	0.1	1	0.8	8.5
56-4104-17	CFP-2-E-35STM	0.2	1	0.8	8.5
56-4104-18	CFP-4-E-35STM	0.45	1	0.8	8.5
56-4104-28	CFP-1-E-55STM	0.1	1	2.1	23
56-4104-29	CFP-2-E-55STM	0.2	1	2.1	23
56-4104-30	CFP-4-E-55STM	0.45	1	2.1	23
56-4109-25	CFP-6-D-55STM	0.75	1	2.5	27

STM housings and accessories

Code No.	Model No.	Description
56-4106-27	SS-35STM	Housing Assembly for -35STM cartridges, 316L SS with 2 each gaskets and 2 each clamps
56-4106-28	SS-55STM	Housing Assembly for -55STM cartridges 316L SS with 2 each gaskets and 2 each clamps
56-4106-75	G4S	0.5-in TC gasket, silicone
56-4106-77	G12S	1.5-in TC gasket, silicone
56-4106-81	G24S	3-in TC [Schedule 5 pipe] gasket, silicone
56-4106-65	CL4	0.5-in quick disconnect clamp, 304 SS
56-4106-69	CL12	1.5-in quick disconnect clamp, 304 SS
56-4106-71	CL24	3-in [Schedule 5 pipe] clamp, 304 SS
56-4106-90	K02ORS	STM cartridge O-ring set, 8 each, silicone
56-4105-90	VPC4	0.5-in TC permeate condensate drain or vent valve, 316L SS

Technical specifications

Cartridge housing assembly

All housing assemblies are of 316L stainless steel with sanitary construction. The O-ring material is silicone. The retentate and permeate ports are 1.5-in sanitary clamp configuration allowing for quick and easy connection to steam and process piping. In operation, the housing should be piped in a vertical orientation. It is recommended to steam the complete element and housing assembly for 30 minutes at 121°C to 123°C and at 1 barg (15 psig). Steam should be delivered to both sides of the membrane to ensure full steam penetration and to minimize the delta P across the membrane during the steam sterilization cycle. A 0.5-in sanitary clamp port is positioned on the low point of the housing shell to ensure complete removal of concentrate.

GE Healthcare offers a complete SIP protocol. To ensure that the cycle will support the rigors of a full validation and maximize the cartridge lifetime, GE Healthcare strongly suggests that customers adhere to all recommendations of the SIP protocol.

Cross flow filtration – Kvick cassettes and holders

Kvick Start cassettes

Kvick Start cassettes are for research, product development, lab scale evaluations and process development where starting material is limited.

- UNF fittings for use in the ÄKTAcrossflow instrument and Luer-lok adapters for use in virtually all other crossflow instruments
- Minimal working volume and minimum hold-up volume gives maximum product recovery
- USP XXVIII Biological Test for Plastics Class VI compliant.
- Low extractables
- PES (polyethersulfone) membrane resists a wide range of chemicals
- Precise, reproducibly selective membranes with a macrovoid-free structure for superior performance

Kvick Start cassettes maximize product recovery by offering a small-area device capable of handling low working volumes with minimal hold-up. The cassettes offer easy setup and linear scalability to facilitate membrane evaluation trials, product screening, process development work and optimization of UF processes in downstream purification. When manifolded together, they allow concentration or diafiltration of product from less than 15 milliliters to over two liters.

Highly selective membranes provide reproducible and precise separations, thus maximizing yields. The cassettes are provided with UNF fittings for use with ÄKTAcrossflow, and with luer lok adapters for use with other systems. Kvick Start cassettes are available with 50 or 100 square centimeters of membrane surface area and five molecular weight cut-offs (5k, 10k, 30k, 50k, and 100k) to fit a broad range of cross flow applications.

Ordering information

Code number	Model number	Membrane area cm^2	Cassette NMWC	Quantity
11-0006-02	UFEST0005050ST	50	5 kD	1
11-0006-04	UFEST0010050SE	50	10 kD *	1
11-0006-03	UFEST0010050ST	50	10 kD	1
11-0006-05	UFEST0030050ST	50	30 kD	1
11-0006-06	UFEST0050050ST	50	50 kD	1
11-0006-08	UFEST0100050ST	50	100 kD	1
11-0006-61	UFESTCPAK045ST	50 per cassette	5, 10, 10*, 30, 50 and 100 kD	5

* 10 kD Select membrane is a tighter 10 kD membrane and is particularly effective for recombinant proteins.

Technical specifications

Materials of construction:	
Housing	Urethane
Membrane	Polyethersulfone
Membrane screen	Polypropylene
Port Sealer	Solvent-free urethane (meth)acrylate blend
Inner plates	Polyester copolymer
Shipping solution	20–22% glycerin by weight
Retentate hold-up volume	1.4 ml
Operating Conditions:	
pH range, long term	Storage 2–13
pH range, short term	Cleaning 1–14
Maximum operating temperature	50°C
Maximum inlet pressure	4 barg (60 psig)
Typical operating cross flow	27–36 ml/min

Kvick Lab SCU cassette

Ordering information

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Qty
56-4115-30	UFESC 0010 010 SE	0.11	1.2	10 000*	1
56-4115-31	UFESC 0010 010 ST	0.11	1.2	10 000	1
56-4115-32	UFESC 0030 010 ST	0.11	1.2	30 000	1
56-4115-33	UFESC 0050 010 ST	0.11	1.2	50 000	1
56-4115-35	UFESC 0100 010 ST	0.11	1.2	100 000	1
56-4113-70	KLSC o10 ST	Kvick Lab SCU holder			1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick SCU cassette specifications

Materials of construction:	
Housing	Polyethersulfone
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulent	Silicone
Preservative solution	0.1–0.2N NaOH and 20–22% glycerine
Hold-up volume	1.2 ft^2 – 20 ml

Recommended operating conditions

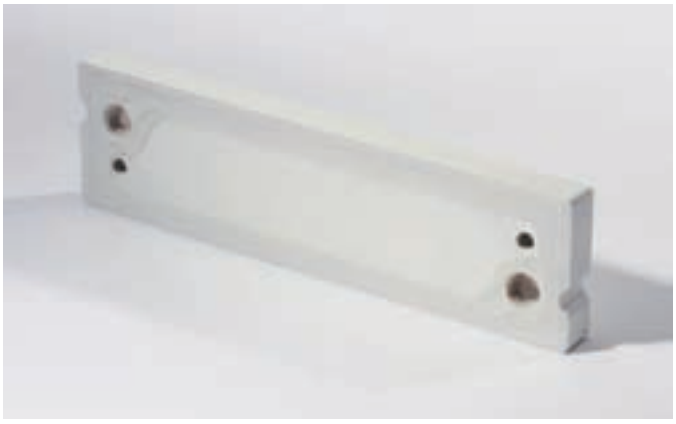
pH range, long-term	Storage 2 to 13
pH range, short-term	Cleaning 1 to 14
Maximum operating temperature	50°C (122°F)
Maximum inlet pressure	3 barg (45 psig)
Operating cross flow rate	850 ml/min (1.2 ft^2)

Easy use with minimum hold-up volume and maximum product recovery.

- Precise, reproducibly selective membranes
- Low extractables
- PES (polyethersulfone) membrane resists a wide range of chemicals
- Anti-dead space technology
- 100% integrity tested on delivery
- Macrovoid-free membrane structure for superior performance
- Consistent fluid path for linear scale-up
- USP 24 Biologicals Test for Plastics Class VI compliant

Kvick SCU cassettes give easy set-up, enhanced clean-ability, minimum product hold-up volume, and optimum membrane selectivity. They are ideally suited for laboratory work with starting volumes of less than 250 milliliters to 25 liters. The self-contained holder does not require cassette installation, thus promoting easy set-up and use.

Kvick Lab cassettes



Ordering information

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Quantity
56-4112-02	UFELA0005001ST	0.009	0.1	5000	1
56-4112-06	UFELA0010001SE	0.009	0.1	10 000*	1
56-4112-04	UFELA0010001ST	0.009	0.1	10 000	1
56-4112-08	UFELA0030001ST	0.009	0.1	30 000	1
56-4112-10	UFELA0050001ST	0.009	0.1	50 000	1
56-4112-14	UFELA0100001ST	0.009	0.1	100 000	1
56-4113-31	UFELA0005010ST	0.11	1.2	5000	1
56-4113-26	UFELA0010010SE	0.11	1.2	10 000*	1
56-4113-25	UFELA0010010ST	0.11	1.2	10 000	1
56-4113-27	UFELA0030010ST	0.11	1.2	30 000	1
56-4113-28	UFELA0050010ST	0.11	1.2	50 000	1
56-4113-29	UFELA0100010ST	0.11	1.2	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

The wide range of Kvick Lab cross flow cassette designs can handle almost any application.

- Precise, reproducibly selective membranes
- Minimum hold-up volume and maximum product recovery
- Low extractables (silicone versus polyurethane encapsulant)
- PES (polyethersulfone) membrane resists a wide range of chemicals
- 100% integrity tested on delivery
- Macrovoid-free membrane structure for superior performance

The Kvick family of cassettes is designed for easy set-up, enhanced cleanability, minimum product hold-up volume, and optimum membrane selectivity.

Kvick Lab cassettes are for laboratory work with starting volumes of less than 0.5 liters up to 100 liters. They fit exactly into the Kvick Lab cassette holder, and can be retro-fitted to other types of holders, allowing existing equipment to benefit from high product recovery and better flux gains.

Kvick Lab cassettes are available with a membrane area of 0.11 m^2 (1.2 ft^2), and six molecular weight cut-offs (5k, 10k select, 10k, 30k, 50k, and 100k) to fit a broad range of cross flow applications.

Technical specifications

Fit the following holders	Kvick Lab holders, Kvick packet holders, and other industry standard holders
Materials of construction:	
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulent	Silicone
Preservative solution	0.1–0.2 N NaOH and 20–22% glycerine
Hold-up volume	Approximately 20 ml per 0.09 m^2 (1 ft^2)

Recommended operating conditions

pH range, long term	Storage 2–13
pH range, short term	Cleaning 1–14
Maximum operating temperature	50°C
Maximum inlet pressure	4 barg (60 psig)
Operating cross flow	85 ml/min for each 0.009-m^2 (0.1-ft^2) cassette installed
Operating cross flow	850 ml/min for each 0.11-m2 (1.2-ft^2) cassette installed

Kvick Lab cassette holder

Designed for fast assembly, Kvick Lab cassette holder utilizes sanitary connections.

- Capacity of 1 to 5 Kvick Lab cassettes
- Three forward facing ports for convenience
- Vertical inlet and outlet flow paths for excellent drainage and product recovery, with less than 30 ml hold-up volume
- Perfectly sized to fit Kvick Lab cassettes
- Adjustable stand for ease of use on the laboratory bench

The Kvick Lab cassette holder is for cross flow membrane separations at volumes from less than 0.5 liters to 25 liters. The holder is easy to set-up and quick and convenient to use. Its design with fewer parts and connections makes assembly very fast. Drainage and product recovery are excellent with less than 30 ml hold-up volume. Together, this holder and Kvick cassettes enable fast and accurate concentration and diafiltration of biological solutions.

Furthermore, trial data can be scaled quickly to larger systems. Product development scale-up is linear from laboratory to production.

Ordering information

Product	Quantity	Code No.
Kvick Lab Holder (KLHR0105000SS)	1	56-4112-79
Accessories		
Diaphragm Valve, stainless steel, 1/2-inch sanitary connections (KFSY01071DV05)	1	56-4112-95
1/2-inch Sanitary Clamp (KFSY0107TCL05)	1	56-4112-85
1/2-inch Sanitary Gasket, EPDM (KFSY0107TCG05)	1	56-4112-86
Kvick Lab Holder torque wrench (KLTW0001)	1	56-4112-84
Kvick Lab Cassette Gasket (KYLAGS001011)	1	56-4113-64
Kvick Lab Cassette Gasket (KYLAGS001033)	3	56-4113-65
In-line pressure gauge, 0–4 barg (0–60 psig) (KLSY0105PGA60)	1	56-4113-07
Kvick Lab Pressure Gauge Kit (KLSY0105PRKIT)	1	56-4113-69
1/2-inch Sanitary to 1/4-inch Hose Barb Adaptor (KLSY0105HB4F01)	1	56-4115-26
1/2-inch Sanitary to 3/8-inch Hose Barb Adaptor (KLSY0105HBF01)	1	56-4113-97

Technical specifications

Kvick Lab cassette holders

Feed, retentate and permeate port fittings	1/2-in sanitary
Dimensions (W × L × H)	13.2 × 22.6 × 16.7 cm (5.2 × 8.9 × 6.6-in.)
Weight	7.7 kg (17 lb)
Max. temperature	121°C (250°F)
Max. operating pressure	4 bar (60 psi)
Installable membrane area	0.01–0.55 m^2 (0.11–6.0 ft^2)
System hold-up volume	30 ml
Materials of construction:	
Wetted parts	Polished 316L stainless steel, Ra v 0.8 µm
Non-wetted parts	Tie rods, washers, stand: Stainless steel
Tie rod nuts	Bronze

Kvick Flow cassettes

Kvick Flow cassettes are for batch sizes with 5 to 1000 liter starting volumes.

- Precise, reproducibly selective membranes
- Minimum hold-up volume and maximum product recovery
- Low extractables
- PES (polyethersulfone) membrane resists a wide range of chemicals
- Anti-dead space technology
- 100% integrity tested on delivery
- Macrovoid-free membrane structure for superior performance
- Consistent fluid path for linear scale-up
- USP 24 Biologicals Test for Plastics Class VI compliant

Kvick Flow cassettes fit exactly into the Kvick Flow cassette holder, and can be retro-fitted into other types of cassette holders, allowing existing equipment to benefit from high product recovery and better flux gains.

Ordering Information

Kvick Flow cassettes

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Qty
56-4113-49	UFEFL00050505 S	0.46	5	5000	1
56-4113-50	UFEFL 0010 050 SE	0.46	5	10 000*	1
56-4113-47	UFEFL 0010 050 ST	0.46	5	10 000	1
56-4113-51	UFEFL 0030 050 ST	0.46	5	30 000	1
56-4113-52	UFEFL 0050 050 ST	0.46	5	50 000	1
56-4113-54	UFEFL 0100 050 ST	0.46	5	100 000	1
56-4113-37	UFEFL 0005 250 ST	2.33	25	5000	1
56-4113-39	UFEFL 0010 250 SE	2.33	25	10 000*	1
56-4113-38	UFEFL 0010 250 ST	2.33	25	10 000	1
56-4113-40	UFEFL 0030 250 ST	2.33	25	30 000	1
56-4113-41	UFEFL 0050 250 ST	2.33	25	50 000	1
56-4113-43	UFEFL 0100 250 ST	2.33	25	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick Flow cassette specifications

Fits the following holders	GE Healthcare Kvick Flow holder and other industry standard holders
Materials of construction:	
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulant	Silicone
Housing	Polyethersulfone
Preservative solution	0.1–0.2 N NaOH and 20–22% glycerine
Hold-up volume	1 ft^2 – 20 ml per cassette
	5 ft^2 – 30 ml per cassette
	25 ft^2 – 150 ml per cassette

Recommended operating conditions

pH range, long term	Storage 2–13
pH range, short term	Cleaning 1–14
Maximum operating temperature	50°C
Maximum inlet pressure	4 barg (60 psig)
Operating cross flow	3400 ml/min for each 0.46-m^2 (5-ft^2) cassette installed
Operating cross flow	17000 ml/min for each 2.33-m^2 (25-ft^2) cassette installed

Kvick Pilot and Process cassettes

For linear scale up to pilot and production scale.

- Precise, reproducibly selective membranes
- Minimum hold-up volume and maximum product recovery
- Low extractables
- PES (polyethersulfone) membrane resists a wide range of chemicals
- Anti-dead space technology
- 100% integrity tested on delivery
- Macrovoid-free membrane structure for superior performance
- Consistent fluid path for linear scale-up
- USP 24 Biologicals Test for Plastics Class VI compliant
- Dimensions that match competitive holders, providing a drop-in-replacement for this size cassette format

Kvick Pilot and Process cassettes enable linear scale up to pilot and production scale operations, either via multiple Kvick Pilot and Process cassettes or by scaling up from Kvick Pilot to Kvick Process. Pilot cassettes are ideally suited for pilot and small scale production processes with volumes of 500 ml to 100 l. Process cassettes are for pilot and production facilities with starting volumes of 50 liters or greater.

Ordering Information

Kvick pilot cassettes

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Qty
56-4115-69	UFEPT 0005 025 ST	0.23	2.5	5000	1
56-4115-70	UFEPT 0010 025 SE	0.23	2.5	10 000*	1
56-4115-71	UFEPT 0010 025 ST	0.23	2.5	10 000	1
56-4115-72	UFEPT 0030 025 ST	0.23	2.5	30 000	1
56-4115-73	UFEPT 0050 025 ST	0.23	2.5	50 000	1
56-4115-75	UFEPT 0100 025 ST	0.23	2.5	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick process cassettes

Code No.	Model No.	Membrane area m^2	Membrane area ft^2	Cassette NMWC	Qty
56-4115-55	UFEPR 0005 300 ST	2.79	30	5000	1
56-4115-56	UFEPR 0010 300 SE	2.79	30	10 000*	1
56-4115-57	UFEPR 0010 300 ST	2.79	30	10 000	1
56-4115-58	UFEPR 0030 300 ST	2.79	30	30 000	1
56-4115-59	UFEPR 0050 300 ST	2.79	30	50 000	1
56-4115-63	UFEPR 0100 300 ST	2.79	30	100 000	1

* 10 kD Select membrane is a tighter 10 kD membrane

Kvick Pilot and Process specifications

pH range, long-term	storage 2 to 13
pH range, short-term	cleaning 1 to 14
Maximum operating temperature	50°C (122°F)
Maximum inlet pressure	4 barg (60 psig)
Typical operating cross flow rate:	
30 ft^2	24 l/min.
2.5 ft^2	2 l/min.
Holders, Pilot cassettes	GE Healthcare Kvick Pilot holders and other industry standard holders
Holders, Process cassettes	GE Healthcare Kvick Process holderand other industry standard holders
Materials of construction:	
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulant	Silicone
Preservative solution	0.1–0.2 N NaOH and 20–22% glycerin

Kvick Lab packet and Kvick Lab packet holder

Kvick Lab packet

The Kvick Lab packet is the smallest filtration device in the line of Kvick Lab and Kvick Flow ultrafiltration (UF) cassettes from GE Healthcare. The Kvick Lab packet is intended for the concentration and diafiltration of small process volumes ranging from approximately 50 to 2000 ml. Kvick cassettes are constructed of identical materials and have identical flow path geometries to ensure performance scalability and reproducibility across the full product range.

Kvick Lab packets are specifically designed for use by process development engineers who are interested in developing process parameters for an ultrafiltration step that will be transitioned to full manufacturing scale. The packet is well suited to experimentation that will yield concentration and diafiltration process settings for downstream purification of biotechnology products. Kvick Lab packets are simple to use and effective for laboratory scientists with a need for rapid ultrafiltration of biomolecules.

Kvick Lab packet holder

The Kvick Lab packet holder is the latest in the GE Healthcare line of design-in tools for crossflow applications involving Kvick cassettes. The Kvick Lab packet holder is a versatile device that houses Kvick Lab packets and facilitates their use on ÄKTAcrossflow and on other small-scale crossflow systems.

The holder will support linear cross flow versus pressure drop (ΔP) through the range of 0.7 and 4 barg (10 and 60 psig), indicating the structural strength of the unit. The holder is designed with UNF fittings for direct connection to the GE Healthcare ÄKTAcrossflow system. It also comes with an accessory kit for installation onto systems that use luer-style fittings.

The Packet & Holder combination is designed for:

- Performing crossflow trials in preparation for scale up
- Working with filters that have the same flow path lengths and geometries as our larger Kvick cassettes
- Applications that require a surface area for processing larger volumes than is practical by using Kvick Start cassettes (50 cm^2). The holder is designed to also hold one Kvick Lab (0.11 m^2) cassette. Many Packet applications will involve 200 to 2000 ml of feed material per Packet (100 cm^2).

Ordering information

Product	Code No.	Model No.	Qty
Kvick Lab packet, 5 kD	56-4112-02	UFELA0005001ST	1
Kvick Lab packet, 10 kDselect	56-4112-06	UFELA0010001SE	1
Kvick Lab packet, 10K kD	56-4112-04	UFELA0010001ST	1
Kvick Lab packet, 30 kD	56-4112-08	UFELA0030001ST	1
Kvick Lab packet, 50 kD	56-4112-10	UFELA0050001ST	1
Kvick Lab packet, 100 kD	56-4112-14	UFELA0100001ST	1
Packet holder	11-0006-70	KLPH001SSU	1
Kvick UNF accessory Kit	11-0006-71	KSP001AKT	1
Kvick Lab packet holder torque wrench	56-4112-84	KLTW0001	1

Technical specifications

Materials of construction

Kvick Lab packet:	
Membrane	Polyethersulfone
Screen	Polypropylene
Encapsulant	Silicone
Gasket	Silicone
Preservative solution	0.1–0.2N NaOH and 20–22% glycerin
Kvick Lab packet holder:	
Holder	316L stainless steel with electropolished inner surface with Ra less than 0.63 µm (25 µin) 400 stainless steel threaded posts
Luer lock adapters	Polypropylene
Luer lock adapter gasket	EPDM
UNF block	PEEK

Operating conditions

Long-term storage pH	2–13
Cleaning/sanitization	1–14
Maximum inlet pressure	4 barg (60 psig)
Operating cross flow rate	60 ml/min per 100 cm^2 filter

Literature

Data File for Kvick Lab packet and holder	18-1171-60 AB
User Manual for Kvick Lab packet holder	11-0003-86 AA

Cross flow filtration – Systems

ÄKTAcrossflow system

Automated cross flow filtration for process development.

- Broad range of applications that cover ultrafiltration and microfiltration
- Flexible operation of either hollow fiber cartridges or cross flow cassettes
- Thorough and efficient process development with full TMP and flux scouting
- Single familiar UNICORN interface for both chromatography and membrane separations
- No disruption to proteins or cells with low shear force pumps that require no cooling
- Minimum working volume of 25 ml ensures operation of complete processes using filters between 40 cm^2 and 150 cm^2
- Supported with hardware product documentation to simplify validation
- Well-suited for small scale processing of material for protein or clinical studies

Membrane separations are normally used to concentrate and wash feed prior to chromatography. ÄKTAcrossflow is a fully-automated system for cross flow filtration (ultrafiltration/diafiltration and cell separation) during process development and optimization. The benchtop system is compact and has a sanitary design with changeable wetted parts. It can be installed in a laboratory, which reduces facility and infrastructure expenditure.

UNICORN control software means one common control platform and user-interface for all scales of operation in filtration and chromatography. Scouting gives automatic support to process development and optimization. Method wizards and pre-programmed cleaning methods provide a high degree of efficiency. UNICORN is compatible with all applicable regulations, including 21 CFR Part 11.

The system is for use with flat sheet cassettes and hollow fibers. A wide range of cross flow devices include MidGee hollow fiber cross flow cartridges and Kvick Start flat sheet cassettes. The cassettes require small working volumes and are well-suited for ultrafiltration and diafiltration process development. The cassettes have a surface are of 50 cm^2 and can be combined for a total surface area of 150 cm^2.

Product	Quantity	Code No.
ÄKTAcrossflow	1	18-1180-00

Technical specifications	
Operating range	
Feed flow rate	1–600 ml/min
Transfer flow rate	0.1–200 ml/min
Permeate flow rate	0.1–200 ml/min
Max. system pressure	5.2 bar (75.4 psi)
Min. recirculation volume	less than 25 ml (excluding cartridge)
Detection and control	
Pressure transducers	Less than ± 0.01 bar (0.15 psi)
TMP control accuracy	Less than ± 0.05 bar (0.73 psi)

Literature	
Data File	
ÄKTAcrossflow systems	11-0032-71

MidJet systems

Advanced MidJet System is complete with peristaltic pump, pressure transducers, and a dual digital panel meter. Optional autoclavable reservoirs are shown.

- Rapid processing of volumes up to 200 ml
- Quick and easy cartridge change out using Luer-Lok fittings
- Low system hold-up volume for concentration down to 2 to 5 ml (cartridge hold-up volume 0.5 ml)
- Easy scale-up to pilot and process volumes
- Perfect sizing for MidGee and MidGee Hoop hollow fiber cartridges
- Attaches to syringe for easy removal of retentate

MidJet Labscale System enables you to separate, concentrate, and diafilter small volumes (up to 200 ml) of biological solutions. Using hollow fiber cartridges, processing is easy and fast compared to other techniques. In addition, hollow fiber cartridges let you scale your laboratory data linearly to pilot and production-scale systems.

The Basic MidJet System includes a peristaltic pump, reservoirs, tubing, fittings, a back-pressure valve, and a stand to mount the system components. The Advanced MidJet System comprises the basic system plus pressure transducers and displays for precise pressure and flow control. Such control ensures high product recovery and minimal shear denaturation, and provides data for scale-up.

Ordering information

Product	Quantity	Code No.
Basic MidJet System (MDG-3SP)	1	56-4106-37
Advanced MidJet System (MDG-4SP)	1	56-4106-38
Accessories		
MidGee Starter Kit (KMDG-1)	1	56-4105-79
MidGee Reservoir Kit, 175 ml, Autoclavable (KMDG-175R01A)	1	56-4105-86
MidGee Replacement Reservoir Kit, 175 ml, Autoclavable (KMDG-175R02A)	1	56-4105-87
MidJet System Accessory Kit (KMDG-2)	1	56-4105-82

Technical specifications

	Basic MidJet system	Adv. MidJet System
Max. process volume	200 ml	200 ml
Min. working volume	2–5 ml	2–5 ml
Pump power requirement	24 VDC	24 VDC
Max. Recirculation Rate	size 14 tubing 50 ml/min	50 ml/min
	size 16 tubing 140 ml/min	140 ml/min
Materials of construction:		
Reservoir	Polystyrene (std) Polycarbonate (autoclavable)	Polystyrene (std) Polycarbonate (autoclavable)
Reservoir fittings/tubing	PVC, nylon, silicone	PVC, nylon, silicone
CE Compatible Components	Yes	Yes
Basic and Advanced MidJet	1 peristaltic recircualtion pump	
	1 mounting platform	
	1 backpressure tubing valve	
	1 accessory kit (includes reservoirs)	
	1 assembly guide	
Advanced MidJet only	1 digital panel meter	

Kvick Lab systems

Kvick Lab system with feed tank and sanitary rotary-lobe pump for shear-sensitive products.

- Stainless steel jacketed feed tank with multiple ports for process flexibility
- Low-shear, rotary-lobe pump with touch controls and LCD display
- Sanitary diaphragm valves and zero dead-leg pressure gauges
- Protection against over pressurization
- For Kvick cassettes and hollow fiber cartridges

Engineered for consistency and precise control, Kvick Lab System is a flexible cross flow laboratory scale separations system. With a complementary 2.5 liter reservoir, pump, pressure gauges, cassette holder, piping, and fittings, the system quick to set up and easy to use.

As with all Kvick products, trial data can be scaled to larger systems. The GE Healthcare range of cross flow equipment is consistent and repeatable across all size ranges to allow linear scale-up on laboratory, pilot and production equipment.

Ordering information

Product	Quantity	Code No.
Kvick Lab System 115 V (KLSY0105 RLPSS15)	1	56-4112-77
Kvick Lab System 220 V (KLSY0105RLPSS20)	1	56-4112-78
Accessories		
Flowmeter Kit, 115 V for Kvick Lab System (KLSY0105FLKIT15)	1	56-4113-66
Flowmeter Kit, 220V for Kvick Lab System (KLSY0105FLKIT20)	1	56-4113-67
Pressure gauge w CPM fitting, 0–4 barg (0–60 psig) (KLSY0105APGA60CPM)	1	56-4113-91
Kvick Lab Pressure Gauge Kit (KLSY0105PRKIT)	1	56-4113-69
Kvick Lab 2 Liter Tank Cover (KLSY0105TC001)	1	56-4113-58
2-inch Sanitary Clear Acrylic Tank Cap (KLSY0105SAC20)	1	56-4113-16
1/2-inch Sanitary to 1/4-inch Hose Barb Adaptor (KLSY0105HB4F01)	1	56-4115-26
1/2-inch Sanitary to 3/8-inch Hose Barb Adaptor (KLSY0105HBF01)	1	56-4113-97
1/2-inch Sanitary CPM Fitting (KLSY010CPM05)	1	56-4113-92
CPM O-ring (KFSY0107CPMORI)	6	56-4113-89
Clamps		
1/2-inch Sanitary Clamp (KFSY0107TCL05)	1	56-4112-85
2-inch Sanitary Clamp (KLSY0105TCL20)	1	56-4113-12
6-inch Sanitary Clamp (KYSL0105TCL60)	1	56-4113-13
Gaskets		
1/2-inch Sanitary Gasket, EPDM (KFSY0107TCG05)	1	56-4112-86
3/4-inch Sanitary Gasket, EPDM (KYSL0105TCG10)	10	56-4113-17
Kvick Lab Cassette Gasket (KYLAGS001011)	1	56-4113-64
Kvick Lab Cassette Gasket (KYLAGS001033)	3	56-4113-65
2-inch Sanitary Gasket, EPDM (KLSY0105TCG20)	1	56-4113-18
6-inch Sanitary Gasket, EPDM (KYSL0105TCG60)	1	56-4113-19
Valves		
Diaphragm Valve, stainless steel, 1/2-inch sanitary connections (KFSY01071DV05)	1	56-4112-95
Dual Diaphragm Diverter Valve, stainless steel (KLSY0105DDV05)	1	56-4113-08
Related products		
Kvick Lab Holder (KLHR0105000SS)	1	56-4112-79
Kvick Lab Holder torque wrench (KLTW0001)	1	56-4112-84

Technical specifications

Kvick Lab Systems	
Feed, retentate and permeate port fittings	1/2 in. sanitary
Dimensions, approximate (W × L × H)	38 × 61 × 53 cm (15 × 24 × 21in.)
Weight, approximate	68 kg (150 lb)
Max. operating temperature	60°C (140°F)
Max. temperature	121°C (250°F)
Max. inlet pressure	4 bar (60 psi)
Installable membrane area	0.01 to 0.55 m^2 (0.11 to 6.0 ft^2)
System hold-up volume	v 30 ml
Materials of construction:	
Wetted parts	Polished 316L stainless steel, Ra v 0.8 µm

QuixStand systems

Versatile QuixStand system accommodates Xampler cartridge sizes 3M, 3X2M, 4, 4M, and 4X2M.

- Rapid processing of volumes up to 10 liters
- Quick, easy cartridge change-out
- Low hold-up volume allows concentration to as low as 30 to 50 ml
- Reservoir can be pressurized for gentle recirculation of labile solutions
- Accommodates Xampler cartridge sizes 3M, 3X2M, 4, 4M, and 4X2M

QuixStand benchtop system is a compact, laboratory-scale separation system that uses GE Healthcare membrane cross flow filtration cartridges. Fitted with a hollow fiber cartridge, QuixStand gives quick, efficient concentration and diafiltration of a wide range of biological solutions. The system rapidly processes solution volumes up to 10 liters. As well as concentrating to volumes as low as 30 to 50 ml, the low hold-up design provides speed, efficiency and true scale-up data impossible to achieve using conventional dialysis or stirred cells.

The basic QuixStand system consists of a cartridge support stand, inlet and outlet pressure gauges, and 400 ml and 1 liter reservoirs. The self-contained system also incorporates a precision back-pressure control valve and a convenient sampling/drain valve. An optional peristaltic pump with a nominal maximum recirculation rate of 2 liters/minute is available.

Ordering information

Product	Quantity	Code No.
QuixStand in Case (KCQSM03SP)	1	56-4108-05
QuixStand System (QSM-02S)	1	56-4107-41
QuixStand System, 50 Hz pump (QSM-02SP/50)	1	56-4107-77
QuixStand System, Sanitary (QSM-03S)	1	56-4107-42
QuixStand System, Sanitary, 50 Hz pump (QSM-03SP/50)	1	56-4107-78
QuixStand System, Autoclavable (QSM-04SA)	1	56-4107-43
QuixStand System, Autoclavable, 50 Hz pump (QSM-04SAP/50)	1	56-4107-79
Accessories		
QuixStand Reservoir Kit, 0.4 l (KQRVA-0.4)	1	56-4107-48
QuixStand Reservoir Kit, 1 l (KQRVA-1.0)	1	56-4107- 49
QuixStand Accessory Kit (QAK-2)	1	56-4107-50
QuixStand Reservoir, 2.5 l (QRV-2.5)	1	56-4107-47
QuixStand Carrying Case (QSM-CC)	1	56-4109-57
QuixStand Reservoir Replacement Cap (QSM-RCP)	1	56-4107-51
Peristaltic pump dual voltage (PRP-09WM)	1	56-4106-53

Technical specifications

	Basic QuixStand system	Adv. QuixStand system
Max. process volume	10 l	10 l
Min. working volume	n/a	30–50 ml
Pump power requirement	n/a	110V/60 Hz or 220 V/50 Hz
Max. recirculation rate	size 17 tubing n/a 1.4 l/min	size 18 tubing n/a 2.0 l/min
CE Compatible	n/a	Yes

Components

Basic and Advanced QuixStand
- 1 cartridge stand
- 2 support rods
- 2 pressure guages, 0–2 bar (0–30 psi)
- 1 backpressure tubing valve
- 1 reservoir kit (includes 400 ml and 1 l reservoirs)
- 1 sample/drain valve
- 1 accessory kit
- 1 assembly guide

Advanced QuixStand only
- 1 peristaltic recirculation pump
- 1 system stand

FlexStand benchtop pilot system

Versatile processing system with a compact, modular design.

- Accommodates a variety of cartridge sizes up to 3.5 m^2 (37 ft^2)
- Process volumes from 5 to 100 liters and more
- Quickly change from lab to pilot scale
- Stainless steel fittings and USP XXIV Class 6 polymers/ elastomers ensure compatibility with cleaning regimens
- 316L stainless steel wetted surfaces ensures compatibility with process and cleaning fluids
- Sturdy base holds cartridges in vertical position and allows maximum product recovery

FlexStand benchtop pilot system accommodates GE Healthcare laboratory cartridges as well as up to 2-inch diameter pilot-scale cartridges with 1.5-inch Tri-Clamp fittings.

The standard pilot system is a compact, sanitary device with autoclavable pressure gauge, pinch-type backpressure valve, tubing connector kit and associated gaskets and clamps. It takes up minimal bench space and is easily moved from laboratory to cold room.

Various pump and reservoir options create a versatile processing system capable of concentration and/or diafiltration of process volumes ranging from 5 to 100 liters or more.

FlexStand benchtop pilot systems

Code No.	Part No.	Description
56-4107-54	FS-01S	Standard FlexStand Benchtop Pilot Cartridge Support Assembly with 1.5-in Tri-Clamp connections.
Includes:		Qty Description
		1 Stand and support rods
		1 Pressure gauge, back mount, 0–4 barg (0–60 psig), mechanically dampened
		1 Backpressure valve, pinch-type
		1 Blank-off cap
		6 Clamp, 1.5-in sanitary
		6 Gasket, 1.5-in sanitary, silicone
		1 Tubing connector kit [KTC-2]
		1 Assembly guide
56-4107-55	FS-03LVS	Low void volume FlexStand Benchtop Pilot Cartridge Support Assembly with fractional Tri-Clamp connections. Includes:
		Qty Description
		1 Stand and support rods
		1 Pressure gauge, back mount, 0–4 barg (0–60 psig), mechanically dampened
		1 Backpressure valve, pinch-type
		1 Blank-off cap
		6 Clamp, fractional sanitary
		6 Gasket, fractional sanitary, silicone
		1 Tubing connector kit [KTC-FS-03VS]
		1 Assembly guide

FlexStand benchtop pilot processing systems

Code No.	Part No.	Description
56-4107-56	FS-02RLP	Standard FlexStand Benchtop Pilot Cartridge Support Assembly with 1.5-in Tri-Clamp connections, rotary lobe pump. Includes:
		Qty Description
		1 Stand and support rods with manifold
		2 Pressure gauge, back mount, 0–4* barg (0–60 psig), mechanically dampened
		1 Rotary lobe recirculation pump, FlowTech LABTOP® 350 with low point drain
		1 Gear box for LABTOP 350 pump
		1 Diaphragm valve, 1.5-in sanitary (retentate)
		1 Diaphragm valve, fractional sanitary (drain)
		1 High pressure shut-off switch
		1 Tubing connector kit [KTC-2]
		1 Set of clamps, gaskets, piping, tubing
		1 Assembly guide
56-4107-57	FS-02RLP/50	Same as FS-02RLP except with 220 v 50 Hz electrical system
56-4107-58	FS-04LVS-RLP	Low void volume FlexStand Benchtop Pilot Cartridge Support Assembly with fractional Tri-Clamp connections, rotary lobe pump. Includes:
		Qty Description
		1 Stand and support rods with manifold
		2 Pressure gauge, back mount, 0–4* barg (0–60 psig), mechanically dampened
		1 Rotary lobe recirculation pump, FlowTech LABTOP 250 with low point drain
		1 Gear box for LABTOP 250 pump
		2 Diaphragm valve, fractional sanitary
		1 High pressure shut-off switch
		1 Tubing connector kit [KTC-FS-03VS]
		1 Set of clamps, gaskets, piping, tubing
		1 Assembly guide
56-4107-59	FS-04LVS-RLP/50	Same as FS-04LVS-RLP except with 220 v 50 Hz electrical system

*0–2 barg (0–30 psig) gauges may be substituted

FlexStand benchtop pilot options

Pumps, rotary lobe

FlowTech LABTOP rotary lobe pumps incorporate variable-speed drive and a manual control system. LABTOP 250 pumps have a vertical pump head, fractional Tri-Clamp fittings and produce approximately 10 lpm at 25 psig. LABTOP 350 pumps have a low point drain port, 1.5-in Tri-Clamp fittings and produce approximately 30 lpm at 25 psig.

Code No.	Part No.	Description
56-4106-39	RLP-250FT	LABTOP 250, Teflon rotors
56-4106-54	RLP-250FT-HPS	LABTOP 250, Teflon rotors, high pressure shut-off
56-4106-40	RLP-250FT/50	LABTOP 250, Teflon rotors, 220 v 50 Hz
56-4106-55	RLP-250FT/50-HPS	LABTOP 250, Teflon rotors, 220 v 50 Hz, high pressure shut-off
56-4106-41	RLP-250FT/SS	LABTOP 250, stainless steel rotors
56-4106-56	RLP-250FT/SS-HPS	LABTOP 250, stainless steel rotors, high pressure shut-off
56-4106-42	RLP-250FTSS/50	LABTOP 250, stainless steel rotors, 220 v 50 Hz
56-4106-57	RLP-250FTSS/50-HPS	LABTOP 250, stainless steel rotors, 220 v 50 Hz, high pressure shut-off
56-4106-43	RLP-350DPFT	LABTOP 350, stainless steel rotors
56-4106-58	RLP-350DPFT-HPS	LABTOP 350, stainless steel rotors, high pressure shut-off
56-4106-44	RLP-350DPFT/50	LABTOP 350, stainless steel rotors, 220 v 50 Hz
56-4106-59	RLP-350DPFT/50-HPS	LABTOP 350, stainless steel rotors, 220 v 50 Hz, high pressure shut-off
56-4107-60	YS-01-12TCSS	"Y" strainer for RLP-350DPFT suction protection, 1.5-in Tri-Clamp

Pumps, peristaltic

Masterflex peristaltic pumps incorporate variable-speed drive and a manual control system. Masterflex Easy-Load pump heads deliver up to 13 lpm.

Code No.	Part No.	Description
56-4106-45	PRP-01MF	Masterflex peristaltic pump with Easy-Load head, tubing
56-4106-46	PRP-01MF/50	Masterflex peristaltic pump with Easy-Load head, tubing, 220 v 50 Hz
56-4106-47	KPRP-02MF	Dual head add-on kit for PRP-01MF and PRP-01MF/50. Provides flow rates up to 26 lpm. Includes Easy-Load head, tubing, clamps, Y-connectors and mounting hardware.
51-4106-22	PTPM12	Peristaltic pump tubing – Bioprene size 82, 12.7 mm (0.5 in) ID, 7.6 m (25 ft)
51-4106-23	PTSL12	Peristaltic pump tubing – silicone size 82, 12.7 mm (0.5 in) ID, 7.6 m (25 ft)
56-4106-24	FTTY06	Flexible tubing – Tygon S-50-HL, 6.3 mm (0.25 in) ID, 15.2 m (50 ft)
56-4106-25	FTTY09	Flexible tubing – Tygon S-50-HL, 9.5 mm (0.375 in)
56-4106-26	FTTY12	Flexible tubing – Tygon S-50-HL, 12.7 mm (0.5 in) ID, 15.2 m (50 ft)

Reservoirs

All polysulfone reservoir kits come with associated supports, gaskets, clamps and adaptors. Sealable-top reservoirs are for use with diafiltration operations

Code No.	Part No.	Description
56-4107-63	TK01-30SS	Stainless steel tank, ASME code, adjustable legs, 30-liter capacity, sanitary ports for retentate return, vent filter and continuous diafiltration. Withstands up to 275°C for steam sterilization Electropolished.
56-4107-66	RVK-1	2-Liter polysulfone reservoir kit with open top, graduated. Not autoclavable.
56-4107-67	FRV-2A	2-Liter polysulfone reservoir kit with sealable top. Autoclavable.
56-4107-68	FRV-PPK-2A	Replacement 2-liter polysulfone reservoir. Autoclavable.
56-4107-70	FRV-5A	5-Liter polysulfone reservoir kit with sealable top. Autoclavable.
56-4107-71	FRV-PPK-5A	Replacement 5-liter polysulfone reservoir. Autoclavable.
56-4107-69	FRV-CP2/5A	Replacement cap for 2- and 5-liter polysulfone reservoirs. Autoclavable.

Other options

Code No.	Part No.	Description
56-4107-62	KFSM04	Conversion kit to change standard FlexStand to low void volume assembly
56-4107-61	KFSM12	Conversion kit to change low void volume FlexStand to standard assembly
56-4107-64	KTC-2	Tubing connector kit for FS-01S
56-4107-65	KTC-FS-03VS	Tubing connector kit for FS-03LVS
56-4106-03	PG-TCP30	Pressure gauge, 0–2 barg (0–30 psig), mechanically dampened, autoclavable
56-4106-04	PG-TCP60	Pressure gauge, 0–4 barg (0–60 psig), mechanically dampened, autoclavable
56-4106-06	PG-TCV30P30	Vacuum/pressure gauge -2 to 2 barg (-30 to 30 psig), mechanically dampened, autoclavable
56-4107-72	KDV-F1	Drain valve kit for FS-01S, includes custom tee, sanitary plug valve, gasket and clamp
56-4107-73	KPCM-1	Manual permeate control kit, includes vacuum/pressure gauge, backpressure valve, supports, adaptors, clamps and gaskets
56-4105-92	VDM-6SS	Diaphragm valve, fractional Tri-Clamp, stainless steel
56-4105-93	VDM-12SS	Diaphragm valve, 1.5-in Tri-Clamp, stainless steel
56-4105-91	VBF12	Butterfly valve, 1.5-in Tri-Clamp, stainless steel, silicone seat
56-4105-95	HX12-L1-8	Heat exchanger, 1.5-in Tri-Clamp, 5.1 cm diameter, 34 cm long
56-4105-96	HX12-L2-9	Heat exchanger, 1.5-in Tri-Clamp, 5.1 cm diameter, 63 cm long
56-4107-76	SSCRT-RLP	Heavy-duty stainless steel cart with locking castors

GrandStand pilot/process systems

New

The GrandStand pilot/process system is a versatile, cart-mounted system intended for pilot through production scale biological separations from 50 to 10 000 liters. It accommodates ultrafiltration and microfiltration hollow fiber cartridges or flat sheet cassettes. The GrandStand system is capable of concentration and/or diafiltration.

Feature rich basic system

The basic GrandStand system consists of a heavy-duty stainless steel frame, positive displacement rotary lobe pump for gentle recirculation of biological solutions, diaphragm type backpressure valve, sanitary inlet and outlet pressure gauges, and a cone bottom clean-in-place (CIP) tank. A programmable AC inverter features a multitude of functions including the ability to set the pump acceleration time as well as to monitor pump speed. A high-pressure switch is incorporated for equipment and operator safety.

Robust streamlined design

The GrandStand system's narrow profile allows it to fit through standard door openings for easy transport from the lab to the cold room to the manufacturing area. Heavy-duty swivel casters with a total locking feature provide mobility and stability. The system is designed to interchange easily between process and cleaning cycles. The modular design enhances the versatility of the GrandStand system to address changing needs associated with scale-up and sophistication from pilot to process scale.

Modular kits enhance the flexibility of the GrandStand systems to meet the needs of process development and process manufacturing groups without the delivery issues associated with custom systems. Simply purchase the base system and the modules needed for your specific application. The system and selected modules ship together with easy instructions to assemble them on site. A service option is available for on site assembly combined with IQ/OQ. For those with changing requirements, simply select the modules that provide the necessary system upgrade thereby eliminating the need to purchase a completely new system.

Available modules facilitate customization for:

- Varying process volumes
- Data acquisition
- Flow rate
- Pressure
- Temperature
- Conductivity
- UV
- Permeate flow control
- Filter type flexibility: hollow fiber or cassette
- Steam-in-place (SIP)

GrandStand system specifications

Base system	GrandStand 450	GrandStand 550
Weight (approximate)	1576 lbs (715 kg)	1876 lbs (851 kg)
Materials of Construction:		
Frame	304 stainless steel	304 stainless steel
Fluid path	316 L stainless steel	316 L stainless steel
Fluid path surface finish	< 20 Ra µ in. (0.5 Ra µm)	< 20 Ra µ in. (0.5 Ra µm)
Kvick Flow holder surface finish:		
Front and back plate	< 25 Ra µ in. (0.6 Ra µm)	< 25 Ra µ in. (0.6 Ra µm)
Feed, retentate, permeate ports	< 20 Ra µ in. (0.5 Ra µm)	< 20 Ra µ in. (0.5 Ra µm)
CIP tank	15 gal. Polypropylene 30 gal.	Polypropylene
Pump Type	Rotary lobe	Rotary lobe
Max Pump Flow rate	120 L/min@ 30 psig	400 L/min@ 30 psig
O-rings, gaskets, valve diaphragms	EPDM	EPDM
Power requirements	230/460 vac 3 Phase 50/60 Hz (except 380 vac 3 Phase 50/60 Hz for GSMRLP450380V and GSM550380V)	
System dead volume*	9.5 L	18.9 L

*Approximate base system without tank or filter cartridge

Note: To determine minimum working volume, add volume of filter holder, tank working volume to system dead volume.

Ordering Information –Catalog Numbers Modular GrandStand Systems and Accessory Kits		
Code Number	**Catalog Number**	**Description**
Base System		
28-4005-31	GSMRLP550SYS[4]	GrandStand 550 Modular System
28-4005-32	GSMRLP450SYS[4]	GrandStand 450 Modular System
28-4004-48	GSMRLP550380V[4]	GrandStand 550 Mod Sys 380VAC
28-4004-49	GSMRLP450380V[4]	GrandStand 450 Mod Sys 380VAC
Filter Modules		
28-4005-45	GSM550HF4KIT	GS 550 HF 4 Position Exp. Kit
28-4005-33	GSMKF2MFDKIT	GS 2 Kvick Flow Adapter Kit
11-0006-67	KFHR0115TQE[3]	Kvick Flow Manual Cassette Holder
Data Acquisition		
28-4005-34	GSMDAQENCLKIT[1]	GrandStand PLC Enclosure
28-4005-35	GSMDAQPRESTRA	0–150 psig Pressure Transmitter
28-4005-36	GSMDAQTEMPKIT	Temperature Transmitter
28-4004-46	GSMDAQMFM550	GS 550 Magnetic Flow Meter
28-4004-47	GSMDAQMFM450	GS 450 Magnetic Flow Meter
28-4005-38	GSMDAQUV1KIT	280 µm UVSensor With Display
28-4005-39	GSMDAQCONTRA	Conductivity Sensor With Display
SIP Modules		
28-4005-40	GSMSIPCMPKIT	GS HF SIP Manifold Kit
56-4106-27	SS-35STM[3]	Housing assembly for-35STM cartridges
56-4106-28	SS-55STM[3]	Housing assembly for-55STM cartridges
56-4106-29	SS-35SMO-DP[3]	Housing assembly for-35SMO cartridges
56-4106-30	SS-55SMO-DP[3]	Housing assembly for-55SMO cartridges
56-4106-31	SS-45MSM-DP[3]	Housing assembly for-45MSM cartridges
56-4106-32	SS-65MSM-DP[3]	Housing assembly for-65MSM cartridges
56-4106-33	SS-85MSM-DP[3]	Housing assembly for-85MSM cartridges
56-4106-34	SS-85MSM-EL-DP[3]	Housing assembly for-85MSM cartridges
Permeate Pump		
28-4005-41	GSM450PERPRP	GS 450 Permeate Pump Kit
28-4005-42	GSM550PERPRP	GS 550 Permeate Pump Kit
28-4005-43	GSM550PERPRH	GS 550 Add on Permeate Pump Head
Service		
44-8200-07	44-8200-07[2]	GrandStand Module Assembly to System and IQ/OQ

[1] GSMDAQENCLKIT is required to power any data acquisition module that is purchased.
[2] Assembly of module kits is not available without IQ/OQ service.
[3] Items are not included in modular accessory kits and must be purchased separately.
[4] Includes one set of documentation. Additional set of documents can be supplied at an aditional cost.

UniFlux systems

The UniFlux series is a standard line of membrane separations filtration systems that utilizes UNICORN software for full automation with data logging capabilites of the entire cross flow process.

- Available in 4 sizes (10, 30, 120, and 400 lpm) for pilot to production-scales
- Fully automated using UNICORN control software
- Maximizes productivity in cross flow filtration
- Consistent, repeatable, and validatable results
- Developed using input from biopharmaceutical manufacturers

UniFlux membrane separation systems incorporate cross flow membranes and high performance hardware in a single system. The systems are configured to operate hollow fiber cartridges ideal for microfiltration applications such as cell clarification/harvesting, or cassettes for ultrafiltration applications, such as protein concentration and diafiltration in downstream unit operations.

UniFlux systems are delivered with pH and conductivity measurement on the permeate side as well as flow meters on the feed and permeate side. A range of standard options is available for all systems sizes - these include UV sensor on the permeate side for detection of protein leakage, permeate flow control, transfer pump, and filter configuration conversion kits.

Automated configurations use a membrane separations-specific version of GE Healthcare UNICORN control system. UNICORN supports FDA 21 CFR Part 11 compliant software in a form familiar to many operators conversant with GE Healthcare chromatography systems from bench-top ÄKTAdesign to production-scale ÄKTAprocess.

Uniflux Systems & Accessories

System	Description
UniFlux 30 AH	CFF system for Hollow fiber, 60 lpm
UniFlux 120 AH	CFF system for Hollow fiber, 120 lpm
UniFlux 400 AH	CFF system for Hollow fiber, 400 lpm
UniFlux 10 AC	CFF system for Kvick Lab cassette, 10 lpm
UniFlux 30 AC	CFF system for Kvick Flow cassette, 60 lpm
UniFlux 120 AC	CFF system for Kvick Flow cassette, 120 lpm
UniFlux 400 AC	CFF system for Kvick Flow cassette, 400 lpm
Accessories	**Description**
UniFlux 10 UV	Permeate UV sensor
UniFlux 30 UV	Permeate UV sensor
UniFlux 120 UV	Permeate UV sensor
UniFlux 400 UV	Permeate UV sensor
UniFlux 10 Transfer pump	Transfer pump, 2.3 lpm
UniFlux 30 Transfer pump	Transfer pump, 19 lpm
UniFlux 120 Transfer pump	Transfer pump, 19 lpm
UniFlux 400 Transfer pump	Transfer pump, 60 lpm
UniFlux 10 Permeate control pump	Permeate control pump, 2.3 lpm
UniFlux 30 Permeate control pump	Permeate control pump, 19 lpm
UniFlux 120 Permeate control pump	Permeate control pump, 19 lpm
UniFlux 400 Permeate control pump	Permeate control pump, 60 lpm
UniFlux 10 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 30 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 120 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 400 Conversion Cass to HF	Kit for conversion from cassette to Hollow fiber system
UniFlux 30 Conversion HF to Cass	Kit for conversion from Hollow fiber to cassette system
UniFlux 120 Conversion HF to Cass	Kit for conversion from Hollow fiber to cassette system
UniFlux 400 Conversion HF to Cass	Kit for conversion from Hollow fiber to cassette system
UniFlux 30 Spool kit 35	Spool piece for size 35 Hollow fiber cartridge
UniFlux 30 Spool kit 75	Spool piece for size 75 Hollow fiber cartridge
UniFlux 120 Spool kit 35	Spool piece for size 35 Hollow fiber cartridge
UniFlux 120 Spool kit 75	Spool piece for size 75 Hollow fiber cartridge
UniFlux 400 Spool kit 45	Spool piece for size 45 Hollow fiber cartridge
UniFlux 400 Spool kit 85	Spool piece for size 85 Hollow fiber cartridge

Literature

Data File	
UniFlux membrare separation systems	18-1177-25

System performance

System size		10 LPM	30 LPM	120 LPM	400 LPM
Hollow fiber membranes					
No. of cartridges		1	1	2	up to 4
Min / Max area	ft^2	1.3/5.2	3.9/65	19.8/130	108/560
	m^2	0.12/0.48	0.36/6	1.8/12	10/52
Cartridge size		5, 6	35, 55, 75	35, 55, 75	45, 65, 85
Lumen diameter		Consult your GE Healthcare representative for application specific information.			
Cassette membranes					
No. cassette holders		1	1	2	6
Min / Max cassettes		1/5 Kvick Lab	1/10 Kvick Flow	2/20 Kvick Flow	6/60 Kvick Flow
Min / Max area	ft^2	1.2/6	5/50	10/100	30/300
	m^2	0.11/0.55	0.46/4.6	0.92/9.2	2.76/27.6

System specifications

System size		10	30	120	400
Max recirculation flow rate		10 lpm @ 4 bar	60 lpm @ 4 bar	120 lpm @ 4 bar	400 lpm @ 4 bar
Min recirculation flow rate		0.5 lpm @ 4 bar	3 lpm @ 4 bar	12 lpm @ 4 bar	40 lpm @ 4 bar
Feed connection, TC		3/4"	1"	1 1/2"	3"
Retentate connection, TC		3/4"	1"	1 1/2"	2"
Permeate connection, TC		3/8"	1/2"	3/4"	1"
Jacketed feed tank capacity	liter	5	N/A	N/A	N/A
System dimensions (W × L × H)	mm	1010 × 880 × 1770*	880 × 1500 × 1800*	880 × 1640 × 1840*	890 × 1700 × 1800
Cassette membrane cart dimensions (W × L × H)	mm	N/A	N/A	N/A	920 × 1410 × 1820

* If a transfer or permeate control pump is used, the system length will increase by up to 300 mm.

Utility requirements		
Compressed air		6–10 Barg (87–145 psig) 0.12–10 SCFM. Dry particle free, non-condensing
Power requirements		
Pump, hydraulic unit	30–400 lpm	3-Phase, 400/480 VAC; 50/60 Hz; 10A to 30A
	10 lpm	1-Phase; 110/230 VAC; 50/60 Hz; 16/10A
Control system hardware		1-Phase; 110/230 VAC; 50/60 Hz; 16A
Materials of construction		
Wetted materials	30–400 lpm	316L/ N08904 (EN 1.4539) / PTFE / PFA / Glass / EPDM / SiC / PEEK / Hastelloy C22 / Polypropylene / Pt-cured Silicone (Only on Hollow fiber system), UV option: Quartz glass, Transfer/permeate control pump option: STA-PURE, PVDF
	10 lpm	316L / Glass / EPDM / PTFE / Silicone / Al_2O_3 / PFA / Kynar® / Titanium / Santoprene / Polypropylene / Buna UV option: Fused quartz, Transfer/permeate control pump option: STA-PURE, PVDF, Santroprene (depending on hose)
Frame		316 stainless steel

Normal flow filtration – ULTA cartridges

ULTA Pure SG

New

ULTA Pure SG utilizes the unique properties of a patented microbially retentive polyethersulphone membrane to provide sterilizing grade filtration to meet the specific needs of the pharmaceutical industry. ULTA Pure SG membranes have an asymmetrical pore structure with a high voids volume, which offers high dirt holding capacity, resulting in higher throughputs and higher flow rates than symmetrical membranes.

ULTA Pure SG filters have low chemical and protein binding characteristics, which result in minimal levels of material lost to adsorption. They can handle a wide range of liquids across the full pH range including many organic solvents. The filter cartridges have low extractable levels. The membrane is inherently hydrophilic and the filters can be easily and repeatedly integrity tested.

ULTA Pure SG filters feature:

- 0.2 micron polyethersulphone membrane
- Microbially retentive and validated to ASTM F838-83 methodology
- High throughputs and flow rates
- Low adsorption of chemicals and proteins
- Wide range of chemical compatibility
- Inherently hydrophilic membrane

Technical specifications

Filtration area	2" Capsule 0.05 m^2 (0.6 ft^2)
Recommended operating conditions	4" Capsule 0.11 m^2 (1.2 ft^2). Capsules may be operated up to a temperature of 40°C (104°F) at line pressures up to 5.0 bar (72 psig) for liquids and 4.0 bar (58 psi) in air/gas.
Materials of construction	
Filtration media	Polyethersulphone
Upstream support	Polyester
Downstream support	Polyester
Inner support core	Polypropylene
Outer protection cage	Polypropylene
End caps	Nylon
End cap insert	316 stainless steel
Standard o-ring / Gaskets	Silicone
Capsule body	Nylon
Capsule vent seals	Silicone

Literature

Data file

ULTA Pure HC	11-0012-06

For ordering information, contact your local GE Healthcare sales representative.

ULTA Pure HC

New

The inherent low protein binding properties of the HC membrane minimize product loss due to adsorption. The filters have low extractable levels and broad chemical compatibility. The membrane is inherently hydrophilic and the filters can be easily and repeatedly integrity tested.

ULTA Pure HC features include:

- Optimized membrane configuration allows up to ten times the throughput to blockage
- Integral prefilter layer can condense filter trains for greater processing economy
- Fully validated and integrity testable membrane for assurance of sterility
- Low adsorption of proteins for minimal loss of expensive pharmaceutical product

Technical specifications	
Filtration area	0.54 m^2 (5.8 ft^2) per 250 mm (10 inch) module.
Recommended operating conditions	Up to 70°C (158°F) continuous operating temperature and higher short-term temperatures during CIP.
Materials of construction	
Filtration membrane	Polyethersulphone
Prefilter Membrane	Polyethersulphone
Upstream Support	Polyester
Downstream Support	Polyester
Inner Support Core	Polypropylene
Outer Protection Cage	Polypropylene
End Caps	Nylon
Standard O-rings/Gaskets	Silicone

Literature	
Data file	
ULTA Pure HC	28-9094-70

For ordering information, contact your local GE Healthcare sales representative.

ULTA Pure HC capsules and cartridges have been specifically designed to extend the throughput of a traditional sterilizing grade filter through the incorporation of an integral PES pre-filter layer. The optimized ULTA Pure HC membrane configuration features a highly asymmetric membrane prefilter layer, which significantly extends throughput and prevents problems associated with premature filter blockage with complex solutions. The integral prefilter layer can also result in compression of filter trains for greater economy on a wide variety of intermediate and final sterilizing applications. ULTA Pure HC cartridge filters are high capacity and fast flowing.

ULTA Prime CG

Liquid column guard filters for reducing bioburden and prefiltering upstream solutions.

- Can be repeatedly steam sterilized *in situ*, autoclaved at up to 130°C, or sanitized with hot water at up to 90°C
- Compatible with a wide range of chemicals
- Materials conform to the relevant biological safety requirements of 21 CFR Part 177 and current USP Plastics Class VI - 121°C and ISO10993 equivalents
- Meet current USP quality standards for oxidizable substances
- Aqueous extracts from ULTA Prime CG contain <0.125 EU/ml when tested in accordance with the standard (LAL) test for endotoxins
- Effluent quality conforms to the requirements of USP 28<643>(TOC) and USP 28<645> (conductivity)
- Full pharmaceutical validation guide available on request

ULTA Prime CG filter cartridges and capsules are specifically designed for bioburden control and particle retention in a variety of pH ranges and feed streams. They can act immediately before chromatography columns and prefilter solutions upstream of the sterilizing grade filter. For general bioburden control, they give log reduction of bacteria when sterility is not required.

The cartridges are validated to give an LRV > 5 when challenged with *Brevundimonas diminuta* in accordance with methods specified in ASTM F838-05 (10^7 organisms/cm^2 minimum).

Pleated polyethersulfone (PES) membranes combined with thermal-bonded construction in both capsule and cartridge formats ensure low extractables and quick flush-up devices. All products are 100% integrity tested before release and are shipped with a certificate of quality. Filters are flushed with pharmaceutical-grade purified water prior to packaging.

Technical specifications

Filtration area	0.54 m^2 (5.8 ft^2) per 250 mm (10 inch) module.
Recommended operating conditions	Up to 70°C (158°F) continuous operating temperature and higher short-term temperatures during CIP.
Materials of construction	
Filtration membrane	Polyethersulphone
Prefilter layer	Polyester
Upstream support	Polyester
Downstream support	Polyester
Inner support core	Polypropylene
Outer protection cage	Polypropylene
End caps	Nylon
End cap insert	316 stainless steel
Standard o-ring / gaskets	Silicone

Literature

Data file	
ULTA Prime CG	28-9094-69
Validation guide	
ULTA Prime CG capsule and cartridge pleated filters	28-9094-73

For ordering information, contact your local GE Healthcare sales representative.

ULTA Prime GF

Liquid filter cartridges for clarifying, stabilizing and reducing bioburden in aqueous solutions, media and biologicals.

- High dirt-holding capacity and exceptional flow performance compared with polypropylene filters
- Compatible with a wide range of chemicals
- Cartridges can be repeatedly steam sterilized *in situ*, autoclaved at up to 121°C, or sanitized with hot water at up to 90°C. Capsules can be repeatedly autoclaved up to 121°C
- Materials conform to the relevant biological safety requirements of 21 CFR Part 177 current USP Plastics Class VI – 121°C and ISO10993 equivalents. (Low concentrations of surfactant maybe present)
- Full pharmaceutical validation guide available on request.

ULTA Prime GF cartridges utilize a glass microfiber filter medium encased within an upstream polypropylene mesh and a downstream non-woven filter support material. ULTA Prime GF filter cartridges are dimensionally stable with no media migration. The pleat pack is supported by an inner polypropylene core and outer polypropylene cage, heat-bonded to polypropylene end caps. The hydrophilic nature of ULTA Prime GF filter cartridges also makes them suitable for gravity-fed systems.

Retention characteristics have been determined through controlled laboratory tests challenging with a standard aqueous suspension of ACFTD (AC Fine Test Dust) using on-line laser particle counters.

Technical specifications

Filtration area	Up to 0.6m^2 (6.3ft^2) per 250 mm (10 inch) module.
Recommended operating conditions	Recommended operating conditions Up to 70°C (158°F) continuous operating temperature and higher short-term temperatures during CIP. Capsules may be operated up to a temperature of 40°C (104°F) at line pressures up to 5.0 barg (72 psi) for liquids and 4.0 bar (58 psi) in air/gas.
Materials of construction	
Filtration media	Glass Microfiber
Prefilter layer	Polyester
Upstream support	Polypropylene
Downstream support	Polypropylene
Inner support core	Polypropylene
Outer protection cage	Polypropylene
End caps	Polypropylene
End cap insert	316 stainless steel
Standard o-ring / gaskets	Silicone/EPDM
Capsule body	Polypropylene
Capsule vent seals	Silicone
Filling bell	Polycarbonate

Literature

Data file	
ULTA Prime GF	11-0026-26
Validation guide	
ULTA Prime GF capsule and cartridge filters	28-9094-72

For ordering information, contact your local GE Healthcare sales representative.

ULTA Prime PP

Liquid filter cartridges for clarifying and prefiltering in biopharmaceutical and ultra-pure applications.

- Cartridges can be repeatedly steam sterilized *in situ*, autoclaved at up to 135°C, or sanitized with hot water at up to 90°C. Capsules can be repeatedly autoclaved up to 135°C
- Compatible with a wide range of chemicals
- Materials conform to the relevant biological safety requirements of 21 CFR Part 177 and current USP Plastics Class VI - 121°C and ISO10993 equivalents
- Full pharmaceutical validation guide available on request

The all-polypropylene construction of ULTA Prime PP cartridges ensures a wide range of chemical compatibility and makes them particularly suitable for filtering viscous and aggressive and chemicals and solvents. Cartridges do not hydrolyze in aggressive solutions and thus do not contaminate process fluids.

Filter media of continuously-graded fiber density provide progressively finer particulate retention throughout the depth of the media. This, combined with optimized media pleating density, gives ULTA Prime PP cartridges exceptional lifetime performance.

Retention characteristics have been determined by a single-pass technique using suspensions of ISO 12103 Part 1 A2 Fine and A4 Coarse test dust in water.

Technical specifications

Filtration area	Up to 0.6m^2 (6.3ft^2) per 250 mm (10 inch) module.
Recommended operating conditions	Recommended operating conditions Up to 70°C (158°F) continuous operating temperature and higher short-term temperatures during CIP. Capsules may be operated up to a temperature of 40°C (104°F) at line pressures up to 5.0 barg (72 psi) for liquids and 4.0 bar (58 psi) in air/gas.
Materials of construction	
Filtration media	Glass Microfiber
Prefilter layer	Polyester
Upstream support	Polypropylene
Downstream support	Polypropylene
Inner support core	Polypropylene
Outer protection cage	Polypropylene
End caps	Polypropylene
End cap insert	316 stainless steel
Standard o-ring / gaskets	Silicone/EPDM
Capsule body	Polypropylene
Capsule vent seals	Silicone
Filling bell	Polycarbonate

Literature

Data file	
ULTA Prime PP	11-0012-07
Validation guide	
ULTA Prime PP capsule and cartridge filters	28-9094-71

For ordering information, contact your local GE Healthcare sales representative.

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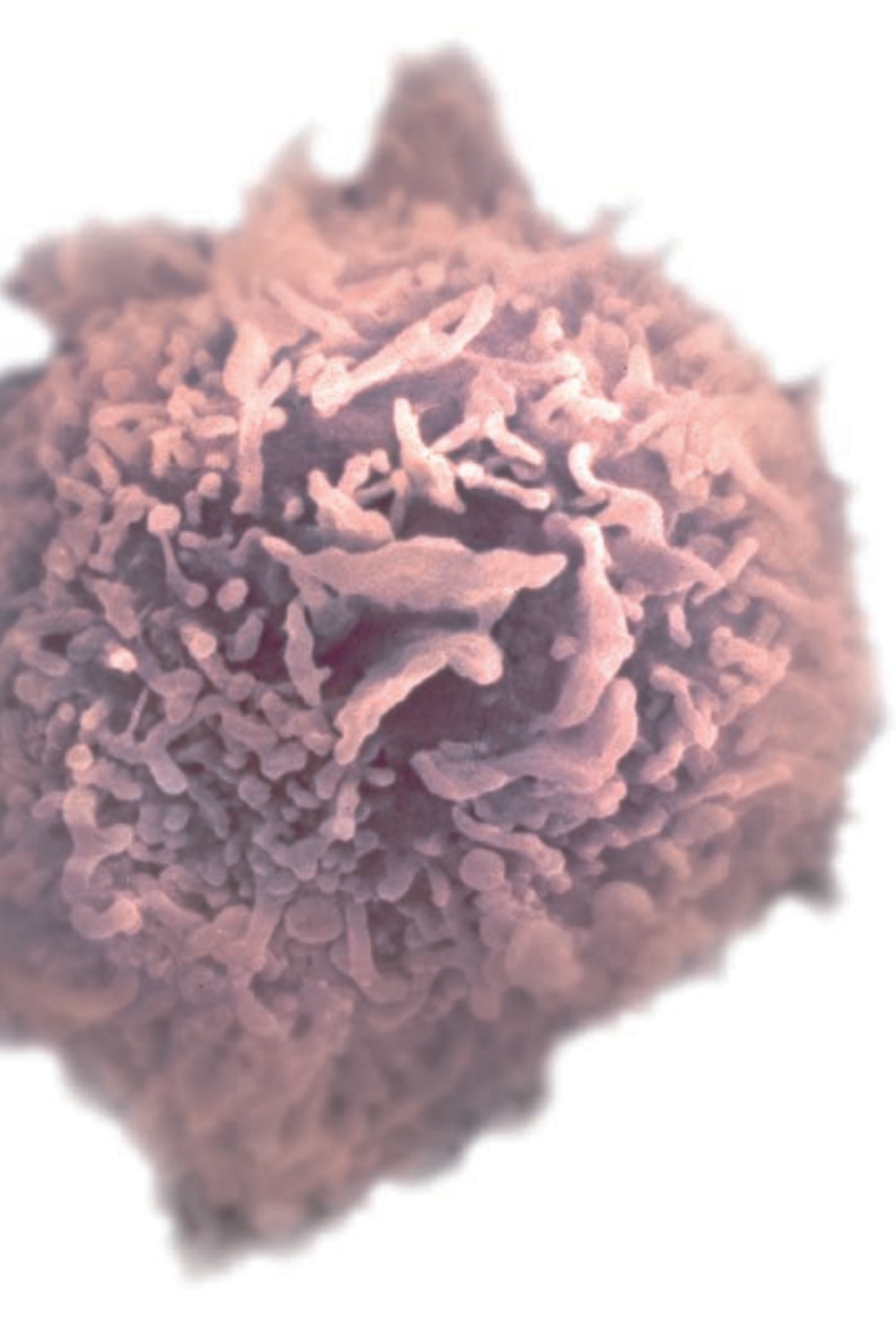


Cell preparation and processing

GE Healthcare is one of the world's largest suppliers of density gradient media for cell preparation. Our cell preparation product range is used to isolate mononuclear cells, sub-cellular particles and organelles, and large viruses, for example.

Cell preparation using density gradient media is a convenient and reliable technique for isolating and purifying cells, viruses and sub-cellular particles. By centrifuging the cell solution in a medium containing particles that form a sedimentation gradient, cells can be separated according to their density (isopycnic centrifugation) or size (rate zonal centrifugation). Gradients can be either preformed or formed *in situ*. In comparison with other techniques commonly used for cell separation (e.g., fluorescent cell sorters and magnetic beads), density gradient separation offers several important advantages:

- No antibodies or reagents are needed to bind the cells to a matrix. Thus, no such substances risk being carried along with the cells
- No labeling of the cells is required. Your cells remain in their native state. The technique does not affect their receptors or genetic make-up
- The method is fast and allows you to work with large volumes

Ficoll-Paque PREMIUM 1.084 and Ficoll-Paque PREMIUM 1.073

New

Ficoll-Paque PREMIUM 1.084 and Ficoll-Paque PREMIUM 1.073 are complementary products to Ficoll-Paque PREMIUM density gradient medium. Manufactured according to the same GMP and ISO 13485:2003 standards as the original Ficoll-Paque PREMIUM product, they have densities of 1.084 and 1.073 g/ml respectively. As with all Ficoll-Paque products, endotoxin levels are kept very low (<0.12 EU/ml).

Ficoll-Paque PREMIUM 1.084 can be used for isolating a broad range of human mononuclear cells including those of higher density as well as mouse lymphocytes and Ficoll-Paque PREMIUM 1.073 is recommended when mononuclear cells of lower density are to be isolated.

Ficoll-Paque PREMIUM

Ficoll-Paque PREMIUM is based on Ficoll-Paque PLUS, which has a proven track record as a sterile density medium for the isolation of high yields of mononuclear cells from bone marrow, peripheral blood, and umbilical cord blood. Ficoll-Paque PREMIUM differs from Ficoll-Paque PLUS in that it is manufactured in a strictly controlled environment compliant with ISO 13485:2003 and in accordance with GMP (Good Manufacturing Practice) guidelines and the recommendations of the United States Pharmacopeia for the manufacture of cell therapy products. ISO 13485 and GMP compliance requires stringency in validation and documentation of manufacturing procedures.

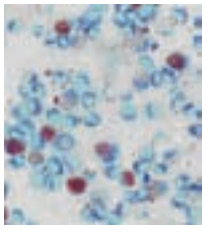
›› For technical specifications see page 221.

Ficoll-Paque PLUS

Ficoll-Paque PLUS is a ready to use, sterile medium for isolation of lymphocytes in high yield from peripheral blood using a simple and rapid centrifugation procedure. It maintains the viability and a representative distribution of B and T lymphocytes.

Ficoll PM400

Ficoll PM400 is a synthetic neutral, highly-branched hydrophilic polymer of sucrose with an average molecular weight of 400 000. It has long been used to form density gradients for separating and isolating eukaryotic cells, organelles and bacterial cells, as a stabilizing agent, and as a preparation medium for isolating mononuclear cells. Applications can also be found in defined culture media, nucleic acid hybridization, electrophoresis, and immunological studies.



›› For the latest information about our cell preparation products, visit www.gelifesciences.com/cellprep

Percoll PLUS

Percoll PLUS is a sterile density gradient separation medium with low endotoxin level plus low osmolality, toxicity and viscosity. Percoll PLUS comprises silica particles covalently coated with silane and has the same physical properties and features as Percoll, which is cited in more than 5000 references.

No antibodies or reagents are needed to bind cells with Percoll PLUS, so cells always stay in their native, natural state. Percoll PLUS is also well-suited for making finally-formulated sterile density gradient solutions. Gradient formulations may even be re-sterilized by autoclaving, which helps save time and money.

Percoll PLUS is particularly useful for clinical research applications where its stability and flexibility help provide reproducible results.

Percoll

Percoll is the density gradient medium of choice for thousands of researchers around the world. The physical characteristics of Percoll facilitate its use in separating cells, organelles, viruses, and other subcellular particles.

Percoll is especially useful as a first step to enrich cell populations before attempting finer resolution or extracting nucleic acids.

Percoll is used to separate and isolate lymphocytes, monocytes, erythrocytes, neutrophils, liver cells, leydig cells, spermatozoa, bone marrow cells, macrophages, mast cells, mitochondria, granules, plant organelles and many other cells and organelles.

Separation of human blood cells in a gradient of Percoll. Bottom layer contains red blood cells, the middle band is polymorphonuclear cells and top band is mononuclear cells.

AXP AutoXpress Platform

The AXP AutoXpress Platform (designed by and a trademark of Thermogenesis Corp.) is an automated, functionally-closed, sterile system that reduces cord blood volume to a precise 20 ml in less than 40 min, while retaining more than 99% mononucleated cells (MNCs)*. The AXP platform is comprised of the AXP device, docking station, processing set, and XpressTRAK software that assists cGMP and cGTP compliance. A range of accessories is also available.

The microprocessor-controlled AXP device is self-powered by a NiMH battery that is recharged from a docking station concurrent with data downloading. It contains flow-control optical sensors that separate a concentrated MNC fraction of uniform volume (nominally 20 ml). The device fits into standard, refrigerated blood bank centrifuge buckets. Six units of cord blood can be processed at one time.

AXP AutoXpress Platform captures data essential for quality assurance and compliance with current good tissue practices (cGTP). XpressTRAK software tracks and documents each cord blood unit's separation data during and after centrifugation.

- Consistently high recoveries of stem-cell rich, MNC cells from cord blood*
- Simultaneous processing of multiple cord blood units
- Sterile sample collection through integrated sample pillows
- Quick and accurate data capture/ tracking
- No HESpan required

*Performance data provided by (CBR) Cord Blood Registry (99.3%).

Ordering information

Product	Quantity	Code No.
AXP Startup Accessory Kit[1]	1	28-9137-65
AXP Cell Preparation Device[2]	1	28-4044-58
Docking Station, Main	1	28-4044-59
Docking Station, Satellite	1	28-4044-65
AXP Device Stand	1	28-4044-66
Counterweight	1	28-4044-60
Weight Kit	1	28-4044-62
Processing Set	24	28-4044-64
QC Bag Set	10	28-4044-72
Battery Replacement Kit for AXP	1	28-4052-22
AXP Freezing/Processing Bag Labels	1	28-9079-20
Weight Compensation Cap	1	28-4044-67
ABC Switch Box	1	28-4044-68
Oval Bucket Adapter	2	28-4044-69
Wireless Barcode Scanner	1	28-4044-70

[1] Includes: XpressTrak Software, Device Stand, Counterweight, Weight Kit, Wireless Barcode Scanner, and Operator Manual.
[2] Includes: Weight Compensation Cap.

Microcarrier cell culture

Microcarrier selection guide

Industrial-scale cell culture using microcarriers has proven to be reliable and cost-effective for the manufacture of both human and animal healthcare products including viral vaccines, interferons, and animal and human growth hormones. Microcarrier technology can reduce culture medium and serum costs by over 50%, decrease labor and lessen the risk of contamination. Interest in microcarrier technology has grown today to include *in vivo* use in a number of therapeutic applications. GE Healthcare supplies microcarriers for a wide range of applications for cell immobilization, particularly in the area of eucaryotic cell culture. Microcarriers can be used to grow a variety of cell types, and with different hardware investments, or production technology.

Our range of microcarrier products includes Cytodex, Cytopore, Cytoline and their derivatives.

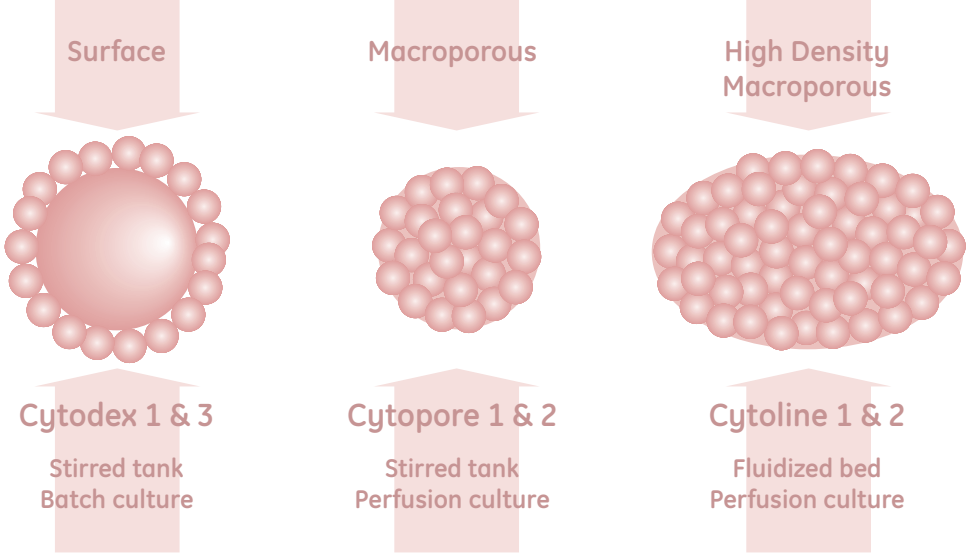
Quality control

The entire line of microcarriers from GE Healthcare is thoroughly quality controlled, including a function test on all batches with at least one cell type. Certificates of Analysis are available.

Regulatory Support Files

Regulatory Support Files have been prepared for Cytodex, Cytopore and Cytoline microcarriers. These files contain information to help industrial scale manufacturers validate their own production processes.

›› For more information, please visit www.gelifesciences.com/cellcult



Cytodex 1 and 3

Cytodex microcarriers are based on cross-linked dextran beads. The microporous beads are transparent, spherical and hydrated, and are substituted with positively charged groups. The microcarriers have a mean diameter of 200 µm and a density of 1.04 g/ml. Their small size allows them to be easily transported through tubing. Cytodex has been derivatized to form two types, 1 and 3. Cytodex 3 has been coated with porcine collagen (gelatin).

Cytodex microcarriers are designed for use in stirred tank cultures – homogeneous environments for cell growth in which culture parameters are easily monitored and controlled. Cells grow on the surface of Cytodex, which facilitates inspection, harvesting and infection of the cells. The microporosity of Cytodex enables nutrient supply to all sides of the cells. Cytodex microcarriers are autoclavable at 121°C for 20 minutes.

Application areas

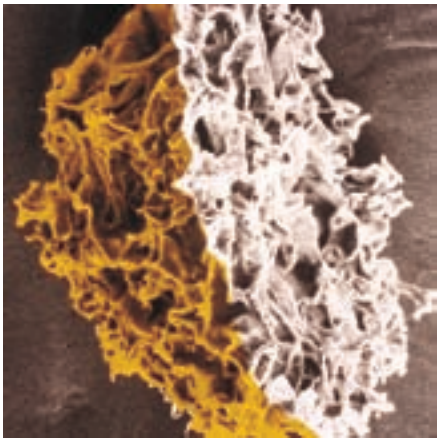
Cytodex is intended for the culture of truly anchorage-dependent cells, a large proportion of which are used in the production of viral vaccines. Another major application for Cytodex is in the production of recombinant proteins. Epithelial and endothelial cells connect through tight junctions and form a cellular layer around the microcarriers.

Cytodex microcarriers are used in batch and perfusion systems, in stirred cultures, and wave bioreactors, as well as to increase the surface area of traditional stationary monolayers and roller cultures.

Transmission electron micrograph of pig kidney cells growing on Cytodex 1. (Original photograph by B. Meignier and J. Tektoff, IFFA-Mérieux, Lyon, France, reproduced with kind permission.)

Cytopore 1 and 2

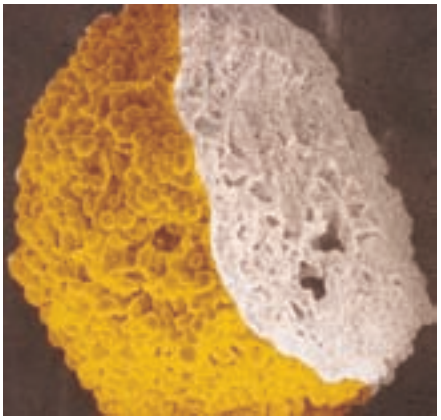
Cytopore microcarriers are hydrophilic DEAE exchangers with a mean diameter of 230 µm and a density of 1.03 g/ml. They are based on a cross-linked cotton cellulose matrix and have an average pore size of 30 µm. The microcarriers are both macroporous and microporous. Cells can enter the interior of the microcarrier where they are protected from shear forces generated by the stirrer, aeration, spin filter or bubbles created through sparging. The microporosity facilitates nutrient supply to all sides of the cells. Cytopore microcarriers are transparent and easily transported through tubing. They can be autoclaved at 121°C for 20 minutes.



The macroporous structure of Cytopore is clearly seen on an "empty" microcarrier.

Application areas

Cytopore 1 has a charge density of 1.0 meq/g and is designed primarily for the production of recombinant CHO cells in stirred tank cultures. Cytopore 2, with a charge density of 1.8 meq/g, is optimized for truly anchorage-dependent cells which require a higher charge capacity for optimal cell growth. Cytopore functions well in the final stages of protein production when anchorage-dependent cells remain on the microcarriers for prolonged periods of time, protected from shear forces. Cytopore is suitable for the culture of other shear-sensitive cells including some hybridomas, insect cells and even some bacteria.



Cytopore 1 filled with CHO cells.

Cytoline 1 and 2

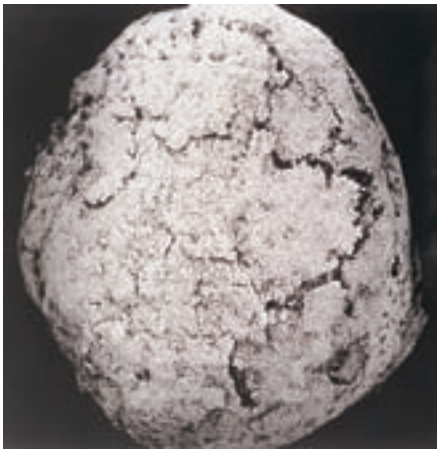
Cytoline microcarriers are based on a matrix of polyethylene and silica. The polyethylene makes the microcarrier hydrophobic while the silica gives it a slightly negative charge. The silica also increases the density of the microcarriers, enabling them to be used in fluidized bed cultures. Cytoline 1 has a density of 1.3 g/ml and Cytoline 2 has a density of 1.03 g/ml. Cytoline microcarriers are macroporous with a pore size between 10 and 400 µm. Cells gain easy access to the interior of Cytoline, where they are protected from shear forces. Since the microcarriers are not microporous, nutrients can only reach the cells through the macroporous structure.

Cytoline microcarriers are lentil-shaped with a length of 2 to 2.5 mm. This size makes their transfer through tubing more difficult, but facilitates their retention in fluidized bed or perfusion cultures.

Weighted Cytoline microcarriers are intended for use in fluidized bed reactors such as Cytopilot Mini, but can also be used in stirred tank, packed bed and suspension cultures. They are autoclavable at 121°C, but melt at higher temperatures.

Application areas

Cytoline 1 is intended for the culture of CHO cells. It can also be used for the culture of other cells that attach well, are less sensitive to shear forces, and require a high circulation rate in the reactor. Cytoline 2 is more suitable for hybridomas and other cells that attach less well. Its lower density requires a lower circulation rate and as a consequence shear forces are less. Cytoline microcarriers can also be used to immobilize insect cells and bacteria.



Cytoline 1 with recombinant CHO attached.

WAVE Bioreactor

The WAVE Bioreactor and components are now available for Cell Therapy applications.

10

Label-free interaction analysis

New

Biacore systems allow for rapid, label-free interaction analyses, giving unique insights into the interactions of proteins with other molecules. The integration of Biacore's world-leading protein interaction analysis systems into the product portfolio of GE Healthcare creates a product portfolio that offers a wide range of solutions to the life science community. Biacore systems can provide solutions to elucidate disease mechanisms, develop and produce novel therapeutics, detect and characterize immune responses, or purify and characterize protein therapeutics.

Biacore systems characterize molecules in terms of their:

- specificity of interaction
- on and off rates (kinetics)
- binding strength (affinity)

The systems also provide sensitive, accurate concentration measurements. This is based on the ability of the biomolecule of interest to interact with a specific binding partner, and may therefore be more informative than generic measurement techniques (total protein concentration for example).

›› For more information, please visit: www.gelifesciences.com/biacore

Biacore T100

New

Regulatory compliance

An optional G × P support package saves significant time during validation procedures. Biacore T100 has been specifically designed with a high level of built-in GLP/GMP/GCP support for 21 CFR Part 11 compliance.

The versatility of the Biacore T100 system allows users to:

- Elucidate disease mechanisms by characterizing native or recombinant protein interactions
- Select the best antibodies as research tools, assay components or therapeutics by fully defining their interaction behavior
- Define potential drug targets and diagnostic markers
- Characterize protein: LMW compound interactions in drug discovery
- Select protein therapeutic candidates according to their on/off rates
- Detect and characterize immune responses during preclinical and clinical development
- Characterize protein therapeutics and implement QC methods
- Recover interaction partners for characterization by mass spectrometry

Productive research and development

Biacore T100 offers a versatile, multi-application solution that sets the performance standard for interaction analysis. Software wizards assist with the evaluation of every interaction parameter, making the system very straightforward to use. Applications, such as antibody characterization, which could take weeks by conventional methods, can be completed in days.

Technical specifications	
Detection technology	Surface Plasmon Resonance (SPR) biosensor
Information provided	Kinetic and affinity data (KD, ka, kd), specificity, concentration and thermodynamics data
Data presentation	Result tables, result plots and real time monitoring of sensorgrams
Analysis time per cycle	Typically 2–15 min
Automation	48 hours unattended operation
Sample type	Low MW drug candidates to high molecular weight proteins (also DNA, RNA, polysaccharides, lipids, cells and viruses), in various sample environments (e.g., in DMSO-containing buffers, plasma, serum
Required sample volume	Injection volume + 20–50 µl (application dependent)
Injection volume	2–350 µl
Flow rate range	From 1–100 µl/min
Flow cell volume	0.06 µl
Flow cell height	40 µm
Sample/reagent capacity	1 × 96, or 384 well microplate + up to 33 reagent vials
Analysis temperature range	4–45 °C (maximum 20 degrees below ambient temperature)
Sample storage	4–45 °C (maximum 15 degrees below ambient temperature)
Sample refractive index range	1.33–1.39
Buffer selector	Automatic switching between 4 buffers
In-line reference subtraction	Automatic

Literature	
Brochure	Code No.
Biacore T100	28-9168-13 AA

Biacore C

New

The Biacore C system is optimized for quantitative and qualitative analysis of biomolecules. Biacore C is unique in quality control (QC) applications, combining the advantage of Biacore's label-free Surface Plasmon Resonance(SPR) technology with advanced instrumentation. The SPR-based system provides high quality, real-time data, meeting the highest demands for precision, accuracy, and reproducibility.

Key application areas

Biacore C has been designed for concentration analysis in Good Laboratory Practice (GLP)/Good Manufacturing Practice (GMP) regulated key areas of drug development and manufacturing:

- Manufacturing QC and IPC (In-Process Control)
- Release assays

System design and evaluation support

Biacore C Control Software is designed to support the GLP/GMP regulated working processes with built-in validation features for compliance with worldwide regulations. Assay development, concentration analysis and evaluation of test data are straightforward with the user-friendly Wizard-based software.

Validation support

Biacore C is fully supported with validation services, including Installation and Operational qualification (IQ/OQ) documentation upon system delivery and on-site IQ/OQ performance by a certified GE Healthcare engineer. To maintain the system in a validated state, a maintenance re-qualification service is also included.

Technical specifications	
Detection technology	Surface Plasmon Resonance (SPR)
Data presentation	Result tables, plots, and real-time monitoring
Automation	Unattended working capacity for 2 x 96 well microtiter plates (automatic control of sample handling and injection)
Flow rate range	1-100 µl/min in steps of 1 µl/min
Flow rate precision	Typically <1%
Injection volume	5-325 µl
Analysis temperature	25°C ± 0.1°C
Power requirements	Autorange 100 – 230 VAC, 47-63 Hz
Power consumption	Max 400 VA
Safety standard	EN 61010-1: 1993
EMC	EN 61326-1 with A1

» For more information, please visit: www.gelifesciences.com/biacore

Biacore G × P Services

New

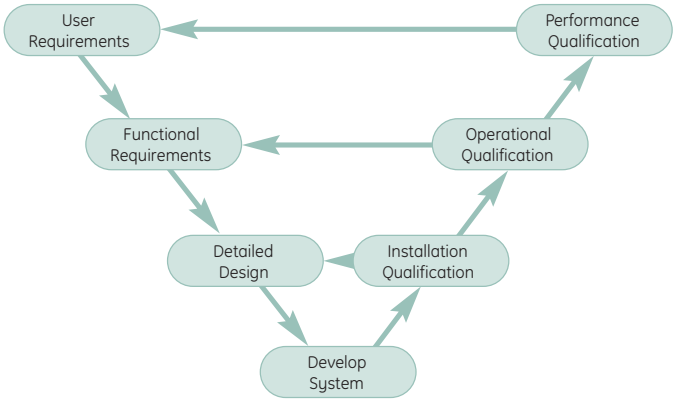
Laboratories involved in pharmaceutical drug development and manufacturing must satisfy the G × P (GLP, GCP, GMP) regulations. Computer-controlled analytical systems used in G × P applications must be validated and properly maintained. Failure to comply with regulatory demands is not a viable option from either a safety or economic standpoint.

Validation is the process of establishing documented evidence of control and is absolutely necessary for gaining product approval. Computer system validation ensures that:

- Hardware and software function as designed
- The process is controlled at all stages
- Data are processed as intended

Validation lifecycle model

A validation life cycle model is applied to keep a system in a validated state during the entire product life cycle.



The validation life cycle ensures adequate validation of computerized systems.

Security of electronic records

21 CFR Part 11 from the U.S. FDA applies to all new and existing systems. Protecting the security and integrity of electronic records is essential for compliance with the Rule. This includes ensuring the reliability and trustworthiness of electronic records used to support critical decisions, such as:

- Release of a production batch
- Pre-clinical and clinical trials

Key issues in complying with Part 11 are:

- Validation of system
- Accurate, complete copies
- Protection of records
- Limiting system access
- Audit trails
- Authority checks

Qualification in the G × P laboratory

Equipment Qualification is the overall process of ensuring that a system performs according to specifications agreed by the user and vendor. It is commonly broken down into:

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Qualifications should only be conducted by GMP trained and experienced personnel. To ensure that the system is maintained in a validated state, periodic maintenance, calibrations, and re-qualifications are mandatory requirements.

» For more information, please visit: www.gelifesciences.com/biacore

Oligonucleotide synthesis

Oligonucleotides are a major tool in drug discovery and diagnostic chip technology. They are used in initial research and screening through to target validation and drug production. Developers of oligonucleotide-based drugs have a clear need for regulatory compliant material to use in pre/early-phase clinical trials. Similarly, companies involved in molecular diagnostics need cost-effective oligonucleotide-based probes to include in commercial kits. Oligonuleotides synthesized on our instruments and supports are currently in several clinical trials.

All our synthesizers are based on flow-through column technology (described opposite). This gives cost-efficient synthesis, creates less waste and allows simple scale-up. It also permits exact control of flow rate and thus fine control of reactions.

All systems are compatible with most synthesis chemistries used today, including RNA synthesis. Recirculation of monomers over the column reactor is included. The common use of UNICORN control software means convenient scale-up from research to full production, and enables use of PAT (Process Analytical Technology) in combination with in-line monitors.

System selection guide	
System	Nominal scale*
ÄKTA oligopilot plus 10	1–50 µmol
ÄKTA oligopilot plus 100	250 µmol – 9 mmol
OligoPilot 400	4–30 mmol
OligoProcess	50–500, 100–1000 mmol (or higher)

* All scale examples used Primer Support 200 loaded at 200 µmol/g, except the lower range in which custom Primer Support 40s was used with ÄKTA oligopilot plus 10. Longer oligos might require a lower loading and thus the corresponding scale is affected.

ÄKTA oligopilot plus

ÄKTA oligopilot plus is a flexible, fully-automated DNA/RNA oligonucleotide synthesizer for use in research, process development and production. This compact, pump-driven system meets the needs of new synthesis chemistries like RNAi and enables cost-efficient, high-quality synthesis.

ÄKTA oligopilot plus employs flow-through reactor technology and features column re-circulation, an important factor when performing RNA synthesis. It is available in two configurations: ÄKTA oligopilot plus 10 for synthesis in the 1 to 50 µmol range, and ÄKTA oligopilot plus 100 for the range 50 µmol to 9 mmol.

The system is compatible with a range of column reactors, small scale cassettes and pre-packed disposable Oligosynt columns. For larger scale synthesis, the adjustable FineLINE 35 oligo column has been specifically developed to allow synthesis at scales from 250 µmol to 3.8 mmol. Adjustable Column 200 ml enables 9 mmol synthesis.

ÄKTA oligopilot plus is controlled via an external computer using UNICORN software specially designed for production needs.

OligoPilot 400

OligoPilot 400 is specifically developed for synthesizing oligonucleotides in quantities suitable for pre-clinical and early-phase clinical trials. The system uses flow-through column technology, UNICORN software and comes with the same level of technical support as ÄKTA oligopilot plus and OligoProcess Systems to allow seamless scale-up/scale-down.

Synthesis scale range is from 4 to 30 mmol using column diameters of 70 and 100 mm. As much as 150 gram crude 20-mer oligo per run can be produced with the 100 mm column.

The synthesizer is designed in an integrated manner with reagent bottles and column reactors forming a single unit in the system. The system reduces facility expenditure since it can be installed in a laboratory. The tilted bottle holder allows organized and cost-efficient use of amidite. A rotating column holder that simplifies unpacking of the columns is also included.

Ordering information	
Product	Code No.
ÄKTA oligopilot plus 10	18-1140-42
ÄKta oligopilot plus 100	18-1136-79

For OligoPilot 400 and OligoProcess contact your local representative

OligoProcess

OligoProcess systems are custom-designed for reliable and cost-effective industrial production. They use the same flow-through column technology as the other synthesizers. Production range is from 50 mmol to over 1 mol, or more, of therapeutic oligonucleotides.

The systems are explosion-proof and constructed with industrial grade components that withstand harsh synthesis chemicals. UNICORN control allows rapid scale-up of methods developed on OligoPilot 400. OligoProcess systems are the world's first, validated industrial scale systems for oligonucleotide production. They are installed and qualified for GMP production by GE Healthcare personnel.

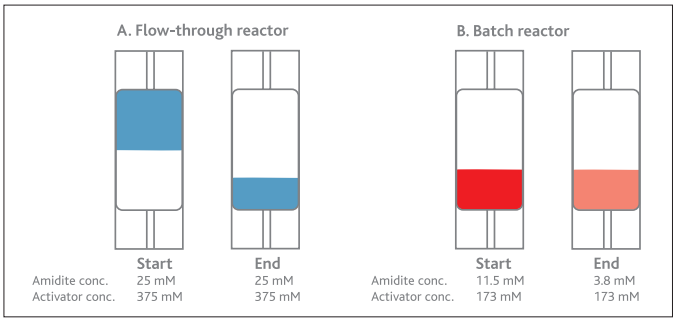
Flow-through technology

The flow-through reactor is a feature common to ÄKTA oligopilot plus, OligoPilot 400 and OligoProcess synthesizers. It is superior to the inefficient batch reactors found in other systems. The better efficiency of a flow-through reactor is due to the way the coupling mixture behaves. The figure illustrates this behavior. Coupling mixture is added to the solid support as a reagent zone (shown in blue) and is pushed through the column as a well-defined zone. Reagents at the front of this zone are consumed by the coupling reaction at a continuous rate. As this zone moves down the reactor, new reagents continuously replace those used. Smooth liquid distribution ensures that coupling efficiencies remain the same, even in different parts of the column. This continuous replacement of consumed reagents by new keeps the concentration constant throughout the zone. Both the amidite concentration and the reaction rate remain the same throughout the reaction.

In a batch reactor, on the other hand, consumed reagents are not replaced. Amidite concentration (red zone) decreases continuously, thus lowering the overall reaction rate. Moreover, flow-through technology delivers three further advantages; its synthesis cycle time is faster, which thus reduces overall production time, it produces less waste and, in combination with high accuracy pumps, it allows more exact control of reagent contact times.

A) Flow-through reactor. The coupling mixture moves down as a reagent zone, continuously replacing reagents consumed by the reaction. The amidite concentration is the same at the end of the reaction as at the beginning.

B) Batch reactor. Reagents consumed by the coupling reaction are not replaced. Amidite concentrations fall to low levels.



The efficiency of the flow-through reactor (A) is superior to that found in a batch reactor (B). At the end of the reaction, when one equivalent has been consumed, the active concentration of amidite in OligoPilot 400 for example, can be more than 6 times higher.

Solid supports

Polystyrene-based supports have been produced by GE Healthcare since the mid-1980's. They allow high scales of synthesis per reaction volume and are suitable for synthesis chemistries that are incompatible or ineffective with glass beads.

These solid supports not only exceed what you can achieve with glass beads, they also enable the synthesis of substantially higher yields of pure full-length products and reduce reagent consumption. A significant cost reduction, in other words.

Our supports are produced in large quantities and are available world-wide via our global distribution network.

» For more information, please visit: www.primersupport.com

Primer Support 200

Primer Support 200 is polystyrene-based solid support for synthesizing oligonucleotides. The 30-µm beads are loaded at 200 µmol/g as our standard offering for cost-effective production of therapeutic oligonucleotides

(<30 mer). The advantages of this high degree of substitution in the same column volume include larger-scale synthesis per reaction volume plus lower consumption of reagents and solvents. This can reduce the cost of synthesis by up to 30% compared with conventional controlled-pore glass beads. Primer Support 200 is guaranteed to be free from BSE/TSE contamination.

- **Cost-effective synthesis**
  Minimal reagent consumption.
  High synthesis scale per reaction volume
  Typically > 125 OD/µmol synthesis scale †.
- **High quality oligonucleotide**
  Typically > 75% full-length †.
  Typically < 4% (n-1) contamination †.
- **Scalable and secure material supply**
  Process development to production-scale synthesis. Manufacturing capacities to meet industrial demands.
- **Regulatory support**
  Product support information available for regulatory compliance.
- **For therapeutic oligonucleotide production**
  Reagents and instrumentation for process development to full production scale.

† Test 20mer sequence used: 5'ATACCGATTAAGCGAAGTTT

Oligosynt – prepacked disposable columns

Long oligonucleotides (30 to 90 or more bases) are used as probes in analytical or diagnostic methods for applications such as blood testing, gene expression studies and genetic profiling or identification. To ensure optimal purity and yield of long oligonucleotides, GE Healthcare provides Primer Support 200 loaded at nucleoside densities of 40 µmol/g. For convenience and ease of use, the solid support is prepacked in disposable Oligosynt columns that run on ÄKTA oligopilot instruments. Oligosynt combined with ÄKTA oligopilot is well-suited for GMP production of long oligonucleotides.

- **High quality and yield of long oligonucleotides**
  More than 50% pure full-length product ††.
  Less than 4% (n-1) contamination ††.
  More than 300 OD/µmol crude yield ††.
- **Convenience**
  Columns are prepacked and disposable
  UNICORN method templates simplify operation.
  On-column cleavage possibility.
- **Reproducibility and reliability**
  Reproducible performance with each batch of prepacked columns.
  All batches of solid support certified for use in long oligonucleotide synthesis.
- **Long oligonucleotide production**
  Reagents and instrumentation from process development to production syntheses.
  Primer Support regulatory support files available for product registration.
  IQ/OQ installation service available for ÄKTA oligopilot instruments.

†† *Test 60mer sequence used:*
5'ATACCGATTAAGCGAAGTTTATACCGATTAAGCGAAGTTTATACC GATTAAGCGAAGTTT

Custom Primer Support 200

GE Healthcare offers Custom Primer Support 200 to meet your exact needs by coupling with linkers, labels, modified bases, alternative protecting groups or almost any molecule of your choice. The support can be loaded at 20 to 250 µmol/g and delivered in bulk or in prepacked, disposable Oligosynt columns. The A-Z listing at the end of this catalog gives the most frequently requested Custom Primer Support 200 products that are kept in stock for immediate delivery:

Nucleoside Loading µmol/g
DNA (A^{bz}, C^{bz}, G^{ibu}, T): 40, 80, 200
RNA (A^{bz}, C^{bz}, G^{ibu}, U): 40, 80

›› For more information, please visit www.primersupport.com or contact your local GE Healthcare office.

Note: Use of THF-based synthesis reagents from other vendors is NOT recommended for GE Healthcare synthesizers. They may cause irreparable instrument damage.

11

Service and support

Fast Trak BioPharma Services

Fast Trak BioPharma Services provides practical support and advice to the developer of biotech products, in particular biopharmaceuticals. We can help you plan, implement and document upstream and downstream purification processes, from start-up to routine production, as well as train your personnel.

The services described here are supported by experts in a wide range of relevant specialist fields both from within GE Healthcare and from a network of outside suppliers.

Validation

Validation is a key activity integrated into the development and implementation of a downstream process.

Fast Trak Validation staff continuously monitor world-wide regulatory trends and, together with the Fast Trak network of advisory consultants, provide a wealth of knowledge relevant to your specific biotech project. We can help you design, document and implement downstream purification processes, thus simplifying the journey to market. The end results are time-savings and cost-efficiency.

Validation Documentation

- System and Column Installation and Operational Qualification packages (IQ/OQs)
- Change Control Protocols (CCPs) for software updates and other modifications
- Standard Operating Procedures (SOPs) for UNICORN controlled systems and Process columns

Installation Qualification and Operational Qualification (IQ/OQ)

Fast Trak can help you get new equipment quickly into operation in your facility. Our IQ/OQ document packages are developed according to all current and relevant US FDA and European EMEA guidelines and regulations. They are available for a wide range of our systems and columns including ÄKTApilot, ÄKTAcrossflow, ÄKTAexplorer, ÄKTAprocess, ÄKTApurifier, ÄKTAFPLC, BioProcess Chromatography and UniFlux Membrane systems, OligoProcess and ÄKTA oligopilot Systems, as well as BPG, Chromaflow and BioProcess columns.

The documents are always system-specific, indicating the correct number of valves, tag numbers, etc. They are also designed so that text can only be entered in permitted areas, thereby securing valuable system information.

Each IQ/OQ document consists of printed forms, detailed test protocols and "expected results". There are also descriptions of the software program and hardware components for UNICORN, which are necessary for validating the control system.

Change Control Protocols (CCPs)

CCP document packages are available for a range of systems for upgrading UNICORN software and for other system modifications. The documents are intended for companies working in a regulated environment and describe procedures for upgrading GE Healthcare systems in a controlled manner.
In this way, changes to software and hardware will be carefully evaluated, verified, documented and reviewed.

» Visit us on the web at www.gelifesciences.com/fasttrak

IQ/OQ and CCP documentation

IQ/OQ documentation	Code No.
IQ/OQ BioProcess LPLC system, customized	44-8100-03
IQ/OQ BioProcess LPLC system, standard	44-8100-40
IQ/OQ BioProcess LPLC system with PLC	44-8100-50
IQ/OQ BioProcess MPLC/HPLC system, isocratic PLC	44-8100-70
IQ/OQ BioProcess MPLC/HPLC system, gradient PLC	44-8100-71
IQ/OQ BioProcess MPLC/HPLC system, isocratic UNICORN	44-8100-74
IQ/OQ BioProcess MPLC/HPLC system, gradient UNICORN	44-8100-75
IQ/OQ BioProcess system MPLC/HPLC Pilot	44-8100-81
IQ/OQ BioProcess Column LPLC/MPLC	44-8100-72
IQ/OQ BioProcess Column HPLC	44-8100-73
IQ/OQ OligoProcess system	44-8100-08
IQ/OQ OligoPilot 400 system	44-8100-80
IQ/OQ ÄKTA oligopilot system	44-8100-43
IQ/OQ OligoProcess PPSM system	44-8100-53
IQ/OQ ÄKTAexplorer	44-8100-11
IQ/OQ ÄKTApurifier	44-8100-13
IQ/OQ ÄKTA$_{FPLC}$	44-8100-23
IQ/OQ ÄKTAprime	44-8100-44
IQ/OQ ÄKTApilot	44-9100-49
IQ/OQ ÄKTAcrossflow system	44-8100-77
IQ/OQ ÄKTAprocess system	44-8100-61
IQ/OQ UniFlux Automated system, standard	44-8200-58
IQ/OQ UniFlux Automated system, customized	44-8200-59
IQ/OQ Kvick Benchtop system	44-8200-03
IQ/OQ Membrane Benchtop system	44-8200-06
IQ/OQ Chromaflow column	44-8100-12
IQ/OQ BPG column	44-8100-24
IQ/OQ BPSS column	44-8100-28
IQ/OQ STREAMLINE column	44-8100-14
IQ/OQ FineLINE column	44-8100-29
IQ/OQ Packing station/Pressure vessel	44-8100-35
IQ/OQ BioProcess LPLC/MPLC column	44-8100-72
IQ/OQ BioProcess HPLC column	44-8100-73
IQ/OQ Slurry tank	44-8100-76
IQ/OQ Control Cab ETTAN LC	44-8101-02
CCPs Change Control Protocols	
CCP/UNICORN upgrade BioProcess system	44-8100-25
CCP/UNICORN upgrade OligoProcess system	44-8100-37
CCP/UNICORN upgrade ÄKTA oligopilot	44-8100-38
CCP/UNICORN upgrade ÄKTAexplorer	44-8100-30
CCP/UNICORN upgrade ÄKTA$_{FPLC}$	44-8100-32
CCP/UNICORN upgrade ÄKTApurifier	44-8100-34
CCP/UNICORN upgrade ÄKTAprime	44-8100-39
CCP/UNICORN upgrade ÄKTApilot	44-8100-52
CCP/UNICORN upgrade ÄKTAcrossflow system	44-8100-79
CCP/UNICORN upgrade OligoPilot II system	44-8100-54
CCP/UNICORN upgrade UniFlux system	44-8100-82

Standard Operating Procedures

SOP for backup	44-8102-02
SOP for restore	44-8102-03
SOP for revalidation	44-8102-04
SOP for log book	44-8102-08
SOP for system security	44-8102-09
SOP for audit trail	44-8102-10
SOP BioProcess system, wetted parts replacement	44-8102-11
SOP ÄKTApilot system, wetted parts replacement	44-8102-13
SOP Chromaflow packing	44-8102-12

Performance of IQ/OQ and CCP

In addition to providing IQ/OQ and CCP documentation packages, we have Service Engineers who can execute the IQ/OQ and CCP testing for your company. This will save valuable time and prepare you for process validation. Our engineers are specially trained and certified to perform these procedures. On completion of the testing, all requisite documentation is completed and handed over.

Standard Operating Procedures (SOPs)

Fast Trak offers SOPs for all important functions in a UNICORN controlled computer system, as well as for column packing. SOPs describe how to use and maintain the system and equipment during regular operation. They need to be in place for systems and equipment used in an environment regulated according to cGMP.

SOPs are offered in sets of related documents as hard copy or in Microsoft Word. The electronic copy can be used to modify or customize the template SOPs. The benefits of using these template SOPs are shorter implementation time, reduced development costs, and fewer regulatory setbacks.

» For further information about these packages, and for assistance with your IQ/OQ and CCP procedures or validation support, please see Data File, 18-1117-32 or contact your nearest Fast Trak Center or GE Healthcare office.

Process Development services

Fast Trak Biopharma services can support you with hands-on process development assistance in the screening and optimization of purification protocols using both standard chromatographic media and Custom Designed Media prototypes; scale-up and scale-down studies; and troubleshooting of both filtration and chromatographic operations.

At our centers in the USA, Europe, China, and India, we have fully-equipped laboratories and highly skilled scientists with many years of experience in industrial bioprocessing. Fast Trak process development projects can be run at your facility or at one of our Fast Trak Centers as your needs dictate.

Typically, a Fast Trak process development project starts during the pre-clinical phase. However, even at later stages, or during second-generation process planning, we can provide the skills to help you develop a cost-efficient, cGMP-compliant manufacturing process.

Typical projects

- Development of chromatographic or filtration protocols for the purification of monoclonal antibodies, viruses, vaccines, plasmids, peptides, oligonucleotides, and proteins from recombinant or natural sources
- Trouble-shooting, optimization of an existing unit operation as well as an entire downstream process
- Screening and optimization of chromatographic steps using automated, high-throughput PreDictor 96-well plate technology (currently only available in Europe)
- Automated screening for normal and crossflow unit operations using ÄKTAcrossflow system
- Process scale-up, technical transfer support and assessment of corresponding hardware requirements

Our service can significantly enhance the speed and value of your downstream process development or optimization project. Together with our Life Science Performance Solution team (see also related section on page 203), we can support you in running process improvement projects and skills transfer sessions that will drive and sustain change throughout your organization. We have a long history of working with the pharmaceutical and biopharmaceutical industries under strict confidentiality agreements.

Consulting

Both newly started and well-established biopharmaceutical companies are challenged by the demands of regulatory agencies and the need to assure product quality and safety. You must also be able to withstand the economic and time pressures associated with developing a new biologic.

Fast Trak staff can save you time and money by providing useful advice on a range of topics.

We can help you:

- Understand the latest regulatory trends
- Perform internal audits
- Plan process and system validation
- Review the status of purification development projects
- Facilitate Technology Transfer of bioprocesses

Typically, we arrange a first visit to define the nature and scope of the activity, time lines and deliverables. Follow-up may require deeper discussions, on-site reviews and generation of reports with descriptive sections and recommendations.

Don't risk delays at the end of a project. Call in the experts as early as possible.

Training and education courses

Fast Trak training & education courses can improve skill levels and ways of working in your development labs and production halls. They are designed for research, development and production staff and are directed at training both innovators and operators. Hands-on training courses and laboratory exercises are run at our regional Fast Trak Centers or they can be customized and run at your facility.

All course programs undergo continuous updates and improvement, for example the MAB1 course now includes extensive practical work, and a new UNICORN class for ÄKTAcrossflow has been introduced (SYS3).

» Visit the web for the latest information about our standard courses, detailed program descriptions, content and schedules in North America, Europe, China and India: www.gelifesciences.com/fasttrak

Customized training

Customized training courses can deal with specific practical or theoretical topics within downstream processing. They are an excellent way to increase the efficiency of your team and to train personnel to comply with cGMP requirements. Modules can be given at a Fast Trak Center or on-site at your facilities, depending on the equipment involved. Formal "Training Certification" is provided to trainees upon successful completion of the course.

Lectures or experiments may be used in different combinations, and other topics may be included to match your specific requirements. English is the language for most of our standard courses, but we can offer customized modules in a variety of languages.

The format may be a seminar open to everybody in your company, or a strictly confidential discussion about your specific work.

Workshops

These one or two-day Fast Trak workshops cover the latest topics related to regulatory and validation issues in bioprocessing, e.g. column packing validation & cleaning, virus clearance validation etc.

Standard courses

MEM1
Bioprocessing using Membrane Separations. A two-and-a-half day practical course on membrane separation techniques in downstream processing.

MAB1
Downstream Bioprocessing of Monoclonal Antibodies. A three-and-a-half day practical course on the downstream processing of antibody molecules using chromatographic techniques.

DEV1
Introduction to Chromatography Techniques and Bioprocessing. A three-day basic hands-on course on chromatographic techniques suitable for production-scale biomolecule purification.

DEV2
Downstream Bioprocess Development. A five-day hands-on course for people with basic experience who want to improve their knowledge in downstream process development.

DEV4
Bioprocess Scale-up and Technology Transfer. A three-day hands-on course focused on designing and scaling up a laboratory scale process to production.

COL1
Large-scale Column Packing. A three-day practical course on packing, qualifying and maintaining production chromatography columns.

SYS1
Introduction to UNICORN System Control for Chromatography Systems. A two-day basic course on practical and theoretical control of the system as well as the report functions.

SYS2
Advanced UNICORN System Control for Chromatography Systems. A three-day advanced course on conditional control programming to achieve optimal performance of the system, document and report results, as well as network considerations.

SYS3
UNICORN System Control for Automated Filtration Systems. A two and a half-day intensive course on how to control an ÄKTAcrossflow system.

WAV1
Theory, Setup and Operation of the single-use WAVE Bioreactor. A two-day practical course providing theoretical and technical background knowledge as well as hands-on experience on the operation and optimum performance of the WAVE Bioreactor and related WAVE equipment.

Web-based courses

eSYS1
Basic control of ÄKTAexplorer and ÄKTApurifier using UNICORN. The online course is interactive and can be completed at your own pace. Animations, audio instructions and interactive exercises are included demonstrating system controls, basic and advanced programming, and report generation.

Fast Trak Centers

Fast Trak services, including training & education, consulting, and validation are available from GE Healthcare throughout the world via our Fast Trak Centers. Contact a center listed here or your nearest GE Healthcare office.

›› Global Fast Trak
Email: FastTrak@ge.com
Website: www.gelifesciences.com/fasttrak

Fast Trak Center Europe
GE Healthcare Europe GmbH
Oskar-Schlemmer-Strasse 11
80807 München, Germany

Email: ftcourses.europe@ge.com
Tel: +49 (0) 89 96 28 16 90
Fax: +49 (0) 89 96 28 16 79

Fast Trak Center North America
GE Healthcare Bio-Sciences Corp.
800 Centennial Avenue
Piscataway, NJ 08855-1327, USA

Email: FasttrakNA@ge.com
Tel: +1 732 457 8064
Fax: +1 732 457 8246

Fast Trak Center China
GE Healthcare
GE (China) Research and Development Center Co.,Ltd
1800 CaiLun Road
Zhangjiang High-tech Park, Pudong
Shanghai 210203, China

Email: fasttrakasia@ge.com
Tel: +86 21 50504666-2600
Fax: +86 21 50808591

Fast Trak Center Bangalore India
GE Healthcare Life Sciences
John F. Welch Technology Center
122, EPIP, Whitefield
Bangalore 560 066, India

Email: fasttrakindia@ge.com
Tel: +91 80 2527 9538
Fax: +91 80 2526 8423

Fast Trak administrative offices

Sweden
GE Healthcare
Björkgatan 30
SE-751 84 Uppsala
Sweden

Tel: +46 18 612 0219
Fax: +46 18 120 329

Japan
GE Healthcare
Sanken Bldg, 3-25-1
Hyakunincho 3-chome Shinjuku-ku
169-0073 Tokyo
Japan

Tel: +81 (0) 3 5331 9316
Fax: +81 (0) 3 5331 9372

Life Science Performance Solutions

Improve Operational Excellence and Life Science Performance

The GE Healthcare Life Science Performance Solutions team combines decades of biopharmaceutical expertise with proven GE best practices to transfer skills and lead process improvement projects that will drive and sustain change throughout your organization. Our team can help you:

- Achieve measurable gains in operational efficiency
- Streamline your processes and operations
- Maximize the value you provide to customers
- Adopt proven methods for change management
- Establish a framework for ongoing skills-transfer

Whether you face an immediate challenge or want to build a solid framework for the future, we can help. Our experts work closely with your team to shape a common vision, improve operational outcomes, strengthen your bottom line, and develop strong leaders.

» Visit us on the web at www.gelifesciences.com/lsps

GE Lean Workflow Improvement

- Collaborative approach optimizes process workflows
- Reduces non-value added work
- Improves efficiencies and enhances quality with Lean Six-Sigma methods

GE Management and Leadership Systems

- GE best practices adapt to your organization to develop strong management and leadership systems
- Innovative and sustainable model instills operational rigor, focus, and alignment with your strategic objectives

Life Science Performance Solutions

Our Life Science Performance Solutions offerings include both standard programs based on our proven methodologies as well as customized programs aimed at addressing specific organizational challenges and needs.

Lean

Lean is a set of operational tools and concepts designed to rapidly improve processes by eliminating non-value added steps. In biopharmaceutical production, the use of Lean methods such as Value Stream Mapping can enable a facility to view a process from the 'customer' perspective. Lean makes waste in the system clearly visible and forms the basis for an implementation plan.

Six Sigma

Six Sigma is a rigorous, statistical approach to problem-solving. It is designed to help organizations significantly reduce process variability and errors that can impact cost and quality. Applied within biopharmaceutical production, GE's approach to Six Sigma enables customers to clearly Define, Measure, Analyze, Improve and Control processes that affect quality and operational objectives.

Work-Out

Work-Out was developed at GE to "bust bureaucracy" and improve the decisionmaking process. Using a structured problemsolving approach and facilitation tools, a team is empowered to develop solutions and ensure completion of action plans. Work-Out helps to break down organizational barriers by developing cross-functional teams and creating a culture that can quickly address key issues, reach consensus and implement the best solutions.

Change Acceleration Process (CAP)

GE's Change Acceleration Process (CAP) provides a structured framework and a comprehensive set of tools to quickly mobilize teams and generate enthusiasm. With CAP, organizations are able to overcome resistance, develop a common approach to managing change, build leadership and facilitation skills, and establish organizational alignment.

Online regulatory and technical support

Regulatory Support Files

GE Healthcare pioneered the development of Regulatory Support Files to provide customers with detailed information about performance, stability, extractable compounds, and analytical methods for BioProcess media. This information is an invaluable starting point for process development and validation, for preparing Standard Operating Procedures and quality control, and as support for clinical and marketing applications to regulatory agencies. GE Healthcare has over 15 years of experience in providing customers with Regulatory Support Files.

Change Control Notifications

Change control notifications alert subscribers of changes associated with the manufacture of products, in accordance with a change control policy.

GE Healthcare offers this regulatory support online, including the following features:

- Direct access
- Email notification of updates
- Downloadable files in Adobe Acrobat (.pdf) format
- Online subscriptions
- Sharing subscriptions with colleagues

» Visit us on the web at www.gelifesciences.com/rsf

As some of the information is proprietary, Regulatory Support online is available only after signing a Secrecy agreement.

Technical support online

Users of GE Healthcare´s columns and systems may need quick and easy access to information regarding their equipment. To meet these needs GE Healthcare has developed an efficient and enhanced support site on the internet.

From its initial focus on standard process-scale columns and systems, the site will expand to cover laboratory-scale equipment as well.

When entering the technical support site you quickly get access to detailed information regarding:

- Spare parts for columns, packing stations and systems
- Accessories necessary for packing and running columns
- Columns and systems recommended for your scale and selected medium
- Column packing
- A troubleshooting section will guide you to solutions for specific issues
- Certificates of Conformance for materials available for most requested process chromatography hardware products

» Visit us on the web at www.gelifesciences.com/purification_techsupport

System and column support

Installation

BioProcess Service engineers deliver and assemble your system, perform installation tests and get it ready for operation.

Validation

Installation Qualification & Operational Qualification – IQ/OQ

We can help certify your system and its operation with our IQ/OQ services. GE Healthcare's document packages (from FastTrak) and qualification services cover cGMP requirements and can include 21 CFR Part 11 verification (optional). Our engineers are fully trained on the complexities of both hardware and software and are efficient, quick and precise. Initial certification and annual cGMP training keeps them up to date on the latest cGMP regulations and requirements.

Change Control Protocols – CCPs

GE Healthcare can also certify upgrades to your system or UNICORN software in a controlled manner. Engineers ensure that the changes are carefully evaluated, verified, documented and reviewed.

Parts solutions

Critical parts

To minimize downtime, you should keep a stock of critical parts on site. A list of parts to keep in stock can be provided.

Parts locker

If you prefer that we hold a guaranteed stock of critical components on your behalf, ask about our 'Parts locker' option. For a monthly fee, we deliver any designated critical part according to an agreed time-frame.

» Visit us on the web at www.gelifesciences.com/purification_techsupport

Service agreements

BioProcess chromatography and filtration offerings

Depending on your needs, Service agreements for BioProcess systems can include:

- Comprehensive Preventive Maintenance, including documentation (scheduled according to system requirements)
- Replacement of wetted components after product change
- Calibration and function testing
- Parts coverage (on a part-for-part exchange basis)
- Parts locker with guaranteed delivery times of critical stock
- Engineer labor and travel coverage with unlimited service calls
- Guaranteed on-site engineer response: 1-day or 2-day (selective availability)

Column offerings

Column maintenance

Service agreements for columns can include:

- Comprehensive column maintenance, including documentation (scheduled as required by the process)
- Parts coverage (on a part-for-part exchange basis)
- Parts locker with guaranteed delivery times of critical stock
- Engineer labor and travel coverage with unlimited service calls
- Guaranteed on-site engineer response: 1-day or 2-day (selective availability)

Other column services

- Trouble-shooting
- Column re-packing (scheduled)
- Column performance evaluation
- Functional test (IQ/OQ)

Security of supply

Securing the supply of chromatography media is essential to successful biopharmaceutical development and manufacture. As protein-based drugs and/or vaccines progress further along their route-to-market, manufacturers need to be confident that they can produce enough material, on time, for clinical trials and product launches.

The media must be of consistently high quality and delivered on time during all stages of your production cycle. With an annual media production exceeding 450 000 liters/kilograms, GE Healthcare has the media production capacity to meet your needs.

In part, security-of-supply means being certain that you will receive the right quantity of media, manufactured to specified quality levels, and delivered at the right time. Given today's competitive marketplace, there really is no room for unnecessary risks.

Safety stock of chromatography media

Media safety stock agreements offer assurance of a smooth, continuous supply of chromatography media.

A customized media safety stock agreement guarantees:

- Assured media supply chain efficiency
- Maintained optimum stock levels of media
- Minimized downtime and product loss due to an incident occurring during development, campaign production or regular production
- Minimized cash layout (transfer cost from balance sheet to profit and loss account)
- Simplified management of consumption fluctuations of production material during therapeutic and clinical trials
- Help in meeting security and safety demands of regulatory agencies and insurance companies

GE Healthcare maintains full responsibility for effective media stocking, rotation, and rapid supply during any emergency situation. You choose:

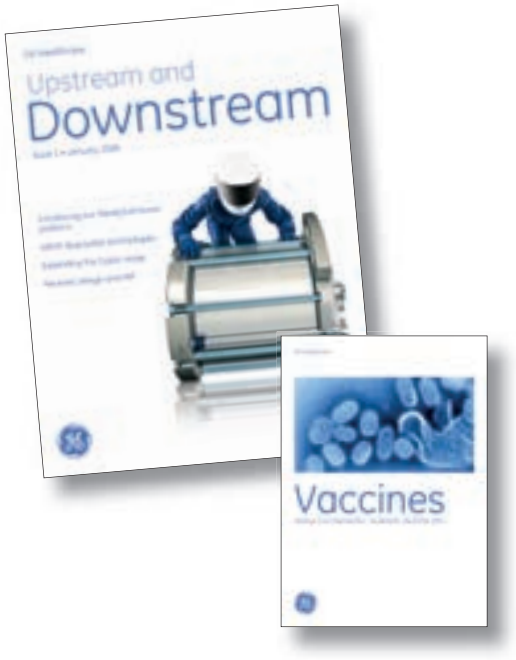
- Stock situation
- Media products and quantities
- Maximum shelf life
- Storage period
- Commencement date

Literature

There is a wealth of literature available from GE Healthcare, and most of it is free. These include our product Data Files, Application Notes, well-known chromatography handbooks, as well as Upstream and Downstream, our magazine for bioprocessors. Most of these can be found in Acrobat pdf file format on our web site, **www.gelifesciences.com/bioprocess**. In addition, we can help you with reference lists and reprints of articles and scientific posters. Contact us through your local GE Healthcare office or via the web site. We look forward to hearing from you.

Upstream and Downstream

With the acquisition of WAVE Biotech, GE Healthcare is better able to support the upstream side of bioprocessing. To reflect this, our customer magazine will cover a range of topics, from cell culture and fermentation through downstream processing. Hence, the change of name to Upstream and Downstream.



Ordering information	
	Code No.
Upstream and Downstream 1	28-9324-58
Vaccines Supplement	28-9324-60
Downstream 41	28-9179-38
Downstream 40	28-9022-57
Downstream 39	28-4021-59
Downstream 38	11-1112-70
Downstream 37	11-0008-46
Downstream 36	18-1171-05
Downstream 35	18-1161-89
Downstream 34	18-1159-24
Downstream 33	18-1150-32

» If you are not already on the mailing list and wish to receive Upstream and Downstream regularly, please contact your nearest GE Healthcare office.

Technique handbooks

These handbooks are designed as an introduction to the principles behind each technique and as a practical guide to the selection and use of the products available from GE Healthcare. They are regularly updated and are frequently used in university education.

Handbooks	Code No.
Gel Filtration: Principles and Methods	18-1022-18
Ion Exchange Chromatography and chromatofocusing: Principles and Methods	11-0004-21
Affinity Chromatography: Principles and Methods	18-1022-29
Hydrophobic Interaction Chromatography & Reversed Phase Chromatography: Principles and Methods	11-0012-69
Protein Purification Handbook	18-1132-29
Microcarrier Cell Culture: Principles and Methods	18-1140-62
Antibody Purification Handbook	18-1037-46
Recombinant Protein Purification Handbook, Principles and Methods	18-1142-75
Cell Separation Media: Methodology and applications	18-1115-69
Isolation of Mononuclear Cells: Methodology and applications	18-1152-69
2-D Electrophoresis: Principles and Methods	80-6429-60
GST Gene Fusion Systems Handbook	18-1157-58
Purifying Challenging Proteins: Principle and Methods	28-9095-31

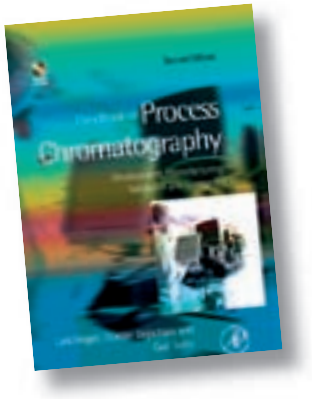
Data Files, Application Notes and Posters

Data files are available on request for most of our products. These are often complemented with specific technical information or relevant case studies published separately as Application Notes or Posters. You can download many of these in PDF format from our web site. Find them under related literature beside product information.

Books

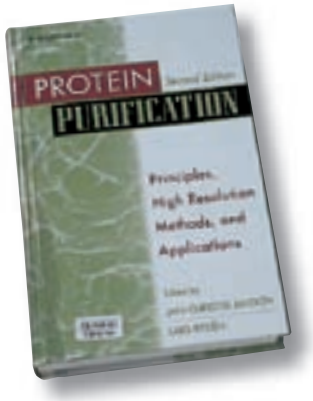
Handbook of Process Chromatography – Development, Manufacturing, Validation and Economics
Hagel, L., G. Jagschies, and G. Sofer.
Academic Press, London, 2007,
(ISBN10: 0123740231, ISBN13: 9780123740236)

A completely revised edition of the book first published in 1997. Over the last 10 years the biotechnology and biologics industries have gained extensive knowledge and experience in downstream processing using chromatography and other technologies associated with recovery and purification unit operations.



Protein Purification Principles, High Resolution Methods and Applications 2nd Edition.
Edited by J-C. Janson and L. Rydén. Wiley-Liss, New York 1998, (ISBN 0-471-1866260).

Protein Purification provides coverage of chromatographic and electrophoretic protein separation and characterization methods. Balancing theory, procedures and applications, it offers professionals and students in biochemistry, organic chemistry and analytical chemistry quick access to a wide range of important techniques.



Ordering information	
Product	**Code No.**
Handbook of Process Chromatography: A Guide to Optimization, Scale-up and Validation (2nd Edition)	18-1121-56
Protein Purification Principles, High Resolution Methods and Applications (2nd Edition)	18-1128-68

12

Indexes and Legal

A–Z of media and chemicals

This is an alphabetical listing of our chromatography media and other chemical products for industrial scale applications; it includes technical and ordering information. For laboratory scale media, columns and equipment, and convenience products and kits for research applications, please consult www.gelifesciences.com. Lot number-specific Certificates of Analysis and country-specific Material Safety Data Sheets are available on the internet.

Note: pH stability (operational) = for long term exposure
CIP = Cleaning-in-Place pH for short term exposure
For ion exchangers, the working pH range is dependent on the titration curve. Pressure is given in kPa; conversion as follows (100 kPa = 0.1 MPa = 1 bar = 14.5 psi).

■ = BioProcess Media CDM = Custom Designed Media

CDM 6-AKS Sepharose 4 Fast Flow. See p 72, 87

Pack size	Code No.
1 l	17-3100-04
Regulatory Support File	11-0028-04

Technical data

Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Coupling chemistry	epoxy
Ligand	carboxylic acid groups on long spacer arm
Ligand density	23–31 µmol carboxylic acid groups/ml drained medium
For coupling to	$-NH_2$
pH stability of medium after coupling	3–13, depending on ligand stability
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

CDM Amino Sepharose 6 Fast Flow. See p 72, 87

Pack size	Code No.
1 l	17-3092-09
Regulatory Support File	11-0028-05

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Coupling chemistry	epoxy
Ligand	amino groups on long spacer arm
Ligand density	~10 µmol primary amino groups/ml drained medium
For coupling to	-COOH, -CHO
Chloride ion capacity	17–22 µmol Cl^-/ml drained medium
pH stability of medium after coupling	3–13, depending on ligand stability
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

■ ANX Sepharose 4 Fast Flow (high sub). See p 69, 130

Pack size	Code No.
25 ml	17-1287-10
500 ml	17-1287-01
5 l	17-1287-04
10 l	17-1287-05
60 l	17-1287-60
Data File	18-1142-25
Regulatory Support File	11-0028-07

Prepacked columns

HiTrap ANX FF (high sub) 5×1 ml	17-5162-01
HiTrap ANX FF (high sub) 5×5 ml	17-5163-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33

Technical data

Composition	highly cross-linked agarose, 4%
Particle size	45–165 µm
Ion capacity	0.13–0.18 mmol Cl^-/ml drained medium
pH stability (operational)	3–13
CIP stability (working)	2–14
Pressure/flow spec.	min 200 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CDM ANX Sepharose 4 Fast Flow (low sub). See p 87

Pack size	Code No.
500 ml	17-1286-01
5 l	17-1286-04
Regulatory Support File	11-0028-06

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ion capacity	0.06–0.08 mmol Cl^-/ml drained medium.
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	min 200 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CDM AVB Sepharose High Performance. See p 72, 87

Pack size	Code No.
75 ml	28-4112-01
1 l	28-4112-02
Regulatory Support File	11-0029-38

Prepacked columns

HiTrap AVB Sepharose High Performance 5×1 ml	28-4112-11
HiTrap AVB Sepharose High Performance 1×5 ml	28-4112-12

Technical data

Composition	highly cross-linked 6% agarose
Particle size	24–44 µm
Coupling chemistry	NHS
Ligand	protein ligand with affinity for Adeno associated virus

CDM Benzamidine Sepharose 4 Fast Flow (high sub).

See p 72, 87

Pack size	Code No.
25 ml	17-5123-10
100 ml	17-5123-01
500 ml	17-5123-02
5 l	17-5123-03
Regulatory Support File	11-0028-08

Prepacked columns

HiTrap Benzamidine FF (high sub) 5×1 ml	17-5143-01
HiTrap Benzamidine FF (high sub) 2×1 ml	17-5143-02
HiTrap Benzamidine FF (high sub) 1×5 ml	17-5144-01

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	amide linkage (carbodiimide)
Ligand	p-aminobenzamidine
Ligand density	>12 µmol/ml drained medium
Trypsin capacity	>35 mg trypsin/ml packed medium
pH stability (operational)	2–8
CIP stability (short term)	2–9
Pressure/flow spec.	min 150 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

CDM Benzamidine Sepharose 4 Fast Flow (low sub).

See p 87

Pack size	Code No.
100 ml	28-4108-01
5 l	28-4108-03
Regulatory Support File	11-0028-09

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	amide linkage (carbodiimide)
Ligand	p-aminobenzamidine
Ligand density	6–10 µmol/ml drained medium
Trypsin capacity	~25 mg trypsin/ml packed medium
pH stability (operational)	2–8
CIP stability (short term)	2–9
Pressure/flow spec.	min 150 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Blue Sepharose 6 Fast Flow. See p 70, 72

Pack size	Code No.
50 ml	17-0948-01
500 ml	17-0948-02
1 l	17-0948-03
5 l	17-0948-04
Data File	18-1060-75
Regulatory Support File	11-0028-10

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	Cibacron Blue F3G-A
Ligand density	~7 µmol Cibacron Blue/ml drained medium
Coupling chemistry	Triazine
Binding capacity	>18 mg HSA/ml drained medium
pH stability (operational)	4–12
CIP stability (short term)	3–13
Pressure/flow spec.	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Butyl Sepharose High Performance.

See p 74–75, 130

Pack size	Code No.
25 ml	17-5432-01
200 ml	17-5432-02
1 l	17-5432-03
5 l	17-5432-04
Regulatory Support File	11-0029-23
Prepacked columns	
HiTrap Butyl HP 5×1 ml	28-4110-01
HiTrap Butyl HP 5×5 ml	28-4110-05
HiTrap HIC Selection Kit 7×1 ml	28-4110-07

Technical data	
Composition	highly cross-linked 6% agarose
Particle size	34 µm average ($d_{50, vol}$)
Ligand	n-butyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	100–200 cm/h, 300 kPa, BioPilot 60/600 column, bed height 30 cm

CDM Butyl Sepharose 6 Fast Flow. See p 75, 87

Pack size	Code No.
1 l	17-5431-03
5 l	17-5431-04

Technical data	
Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Coupling chemistry	epoxy
Ligand	n-butyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Butyl Sepharose 4 Fast Flow. See p 74–75, 130

Pack size	Code No.
25 ml	17-0980-10
200 ml	17-0980-01
500 ml	17-0980-02
5 l	17-0980-04
10 l	17-0980-05
Data File	18-1020-70
Regulatory Support File	11-0028-11
Prepacked columns	
HiTrap Butyl FF 5×1 ml	17-1357-01
HiTrap Butyl FF 5×5 ml	17-5197-01
HiTrap HIC Selection Kit 7×1 ml	28-4110-07
HiPrep 16/10 Butyl FF 20 ml	17-5096-01
HiScreen Butyl FF 4.7 ml (0.77 × 10 cm)	28-9269-84

Technical data	
Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	n-butyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	min 150 cm/h, 100 kPa, XK 50/60column, bed height 25 cm.

Butyl-S Sepharose 6 Fast Flow. See p 74–75, 130

Pack size	Code No
25 ml	17-0978-10
200 ml	17-0978-02
1 l	17-0978-03
5 l	17-0978-04
Data file	11-0026-34
Regulatory Support File	11-0028-44
Prepacked columns	
HiTrap Butyl-S FF 5×1 ml	17-0978-13
HiTrap Butyl-S FF 5×5 ml	17-0978-14
HiTrap HIC Selection Kit 7×1 ml	28-4110-07
HiScreen Butyl-S FF 4.7 ml (0.77 × 10 cm)	28-9269-85

Technical data	
Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	butyl-S
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Capto adhere. See p 66–69, 77, 130

Pack size	Code No.
25 ml	17-5444-10
100 ml	17-5444-01
1 l	17-5444-03
5 l	17-5444-04
10 l	17-5444-05
60 l	17-5444-60
Data File	28-9078-88
Regulatory Support File	11-0029-40
Prepacked columns	
HiTrap Capto adhere 5×1 ml	28-4058-44
HiTrap Capto adhere 5×5 ml	28-4058-46
HiScreen Capto adhere 4.7 ml (0.77 × 10 cm)	28-9269-81
HiTrap Capto IEX Selection Kit 5×1 ml	28-9343-88
96-well filter plates	
PreDictor Capto adhere, 6 µl, 4 × 96 well plates	28-9258-17
PreDictor Capto adhere, 20 µl, 4 × 96 well plates	28-9258-18
PreDictor Capto adhere, 50 µl, 4 × 96 well plates	28-9258-19

Technical data	
Ligand type	multimodal strong anion exchanger
Composition	highly cross-linked agarose
Particle size	75 µm ($d_{50v, vol}$)
Ion capacity	0.09–0.12 mmol Cl-/ml medium
pH stability (operational)	3–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 600 cm/h, 1 m diameter column, 20 cm bed height

CDM Capto Blue (hs). See p 87

Pack size	Code No.
25 ml	17-5452-01
500 ml	17-5452-02

Technical data	
Composition	highly crosslinked agarose
Particle size	75 µm average ($d_{50v, vol}$)
Ligand	Cibacron Blue F3G-A
Ligand density	~18 µmol Cibacron blue/ml drained resin
Coupling chemistry	Amine functional spacer
Pressure/flow spec.	At least 300 cm/h in a BPG 300 column with 20 cm bed height at 20°C using process buffers with the same viscosity as water at < 2 bar (0.2 MPa)

Capto DEAE. See p 66–69, 130

Pack size	Code No.
25 ml	17-5443-10
100 ml	17-5443-01
1 l	17-5443-03
5 l	17-5443-04
10 l	17-5443-05
60 l	17-5443-60
Data File	11-0025-76
Regulatory Support File	11-0029-46
Prepacked columns	
HiTrap Capto DEAE 5×1 ml	28-9165-37
HiTrap Capto DEAE 5×5 ml	28-9165-40
HiScreen Capto DEAE 4.7 ml (0.77 × 10 cm)	28-9269-82
HiTrap Capto IEX Selection Kit 5×1 ml	28-9343-88
96-well filter plates	
PreDictor Capto DEAE, 2 µl, 4 × 96 well plates	28-9258-11
PreDictor Capto DEAE, 20 µl, 4 × 96 well plates	28-9258-12
PreDictor Capto DEAE, 50 µl, 4 × 96 well plates	28-9258-13

Technical data	
Ligand type	weak anion exchange
Composition	highly cross-linked agarose
Particle size	90 µm average ($d_{50v, vol}$)
Ion capacity	0.29–0.35 mmol Cl-/ml
pH stability (operational)	2–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 700 cm/h, 1 m diameter column, 20 cm bed height in water

Capto MMC. See p 66–69, 77, 130

Pack size	Code No.
25 ml	17-5317-10
100 ml	17-5317-02
1 l	17-5317-03
5 l	17-5317-04
10 l	17-5317-05
60 l	17-5317-60
Data File	11-0035-45
Regulatory Support File	11-0029-30
Prepacked columns	
HiTrap Capto MMC 5×1 ml	11-0032-73
HiTrap Capto MMC 5×5 ml	11-0032-75
HiScreen Capto MMC 4.7 ml (0.77 × 10 cm)	28-9269-80
HiTrap Capto IEX Selection Kit 5×1 ml	28-9343-88
96-well filter plates	
PreDictor Capto MMC, 6 µl, 4 × 96 well plates	28-9258-14
PreDictor Capto MMC, 20 µl, 4 × 96 well plates	28-9258-15
PreDictor Capto MMC, 50 µl, 4 × 96 well plates	28-9258-16

Technical data

Ligand type	multimodal weak cation exchanger
Composition	highly cross-linked agarose
Particle size	75 µm average ($d_{50, vol}$)
Ion capacity	0.07–0.09 mmol H^+/ml medium
pH stability (operational)	3–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 600 cm/h, 1 m diameter column, 20 cm bed height in water

Capto Q. See p 66–69, 130

Pack size	Code No.
25 ml	17-5316-10
100 ml	17-5316-02
1 l	17-5316-03
10 l	17-5316-05
60 l	17-5316-60
Data File	11-0025-76
Regulatory Support File	11-0028-45
Prepacked columns	
HiTrap Capto Q 5×1 ml	11-0013-02
HiTrap Capto Q 5×5 ml	11-0013-03
HiScreen Capto Q 4.7 ml (0.77 × 10 cm)	28-9269-78
HiTrap Capto IEX Selection Kit 5×1 ml	28-9343-88
96-well filter plates	
PreDictor Capto Q, 2 µl, 4 × 96 well plates	28-9257-73
PreDictor Capto Q, 20 µl, 4 × 96 well plates	28-9258-06
PreDictor Capto Q, 50 µl, 4 × 96 well plates	28-9258-07

Technical data

Ion exchanger type	Quaternary ammonium strong anion with dextran coating
Composition	highly cross-linked agarose
Particle size	90 µm average ($d_{50, vol}$)
Ion capacity	0.16–0.22 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 700 cm/h, 1 m diameter column, 20 cm bed height in water

Capto ViralQ. See p 68

Pack size	Code No.
25 ml	28-9032-30
100 ml	28-9032-31
1 l	28-9032-32
Datafile	11-0025-76
Regulatory Support File	11-0028-45
Prepacked columns	
HiTrap Capto ViralQ 5×5 ml	28-9078-09

Technical data

Ion exchanger type	Quaternary ammonium strong anion with dextran coating
Composition	highly cross-linked agarose
Particle size	90 µm average ($d_{50, vol}$)
Ion capacity	0.16–0.22 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability	2–14
Pressure/flow spec.	300 kPa at 700 cm/h, 1 m diameter column, 20 cm bed height in water

Capto S. See p 66–69, 130

Pack size	Code No.
25 ml	17-5441-10
100 ml	17-5441-01
1 l	17-5441-03
5 l	17-5441-04
10 l	17-5441-05
60 l	17-5441-60
Datafile	11-0025-76
Regulatory Support File	11-0029-32

Prepacked columns

HiTrap Capto S 5×1 ml	17-5441-22
HiTrap Capto S 5×5 ml	17-5441-23
HiScreen Capto S 4.7 ml (0.77 × 10 cm)	28-9269-79
HiTrap Capto IEX Selection Kit 5×1 ml	28-9343-88

96-well filter plates

PreDictor Capto S, 2 µl, 4 × 96 well plates	28-9258-08
PreDictor Capto S, 20 µl, 4 × 96 well plates	28-9258-09
PreDictor Capto S, 50 µl, 4 × 96 well plates	28-9258-10

Technical data

Ion exchanger type	Sulfonate, strong cation exchanger with dextran coating
Composition	highly cross-linked agarose
Particle size	90 µm average ($d_{50, vol}$)
Ion capacity	0.11–0.14 mmol Na^+/ml
pH stability (operational)	4–12
CIP stability	3–14
Pressure/flow spec.	300 kPa at 700 cm/h, 1 m diameter column, 20 cm bed height in water

CDM Chelating Sepharose Big Beads. See p 87

Pack size	Code No.
1 l	17-5272-03
10 l	17-5272-05
Regulatory Support File	11-0028-12

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Coupling chemistry	epoxy
Ligand	imino diacetic acid
Metal ion capacity	41–51 µmol $Cu2^+$/ml packed medium
pH stability (operational)	3–13
CIP stability (short term)	3–14
Pressure/flow spec.	1200–1800 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Chelating Sepharose Fast Flow. See p 70, 72

Pack size	Code No.
50 ml	17-0575-01
500 ml	17-0575-02
5 l	17-0575-04
Data File	18-1171-41
Regulatory Support File	11-0028-13

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	iminodiaceticacid groups on spacer
Coupling chemistry	ether
Metal ion capacity	30–37 µmol Cu^{2+}/ml medium
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CM Sephadex C-25. See p 68

Pack size	Code No.
100 g	17-0210-01
500 g	17-0210-02
5 kg	17-0210-03
Regulatory Support File	11-0028-86

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 65–235 µm
pH stability (operational)	4–10
CIP stability (short term)	3–13
Pressure/flow spec.	min 120 cm/h, pressure drop cm H_2O/bed height=5, bed height 10 cm, 5 cm i.d.

CM Sephadex C-50. See p 68

Pack size	Code No.
100 g	17-0220-01
500 g	17-0220-02
5 kg	17-0220-03
Regulatory Support File	11-0028-87

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 110–400 µm
pH stability (operational)	4–10
CIP stability (short term)	3–13
Pressure/flow spec.	min 100 cm/h, pressure drop cm H_2O/bed height=10, bed height 10 cm, 5 cm i.d.

CM Sepharose Fast Flow. See p 69, 130

Pack size	Code No.
25 ml	17-0719-10
500 ml	17-0719-01
10 l	17-0719-05
60 l	17-0719-60
Data File	18-1020-66
Regulatory Support File	11-0028-14

Prepacked columns

HiTrap CM FF 5×1 ml	17-5056-01
HiTrap CM FF 5×5 ml	17-5155-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33
HiPrep 16/10 CM FF 20 ml	17-5091-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	50 mg Ribonuclease/ml drained medium
Ion capacity	0.09–0.13 mmol H^+/ml medium
pH stability (operational)	4–13
CIP stability (short term)	2–14
Pressure/flow spec.	300–600 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm

CDM CM Sepharose High Performance. See p 69, 87

Pack size	Code No.
1 l	17-1277-03
5 l	17-1277-04
10 l	17-1277-05
Regulatory Support File	11-0028-15

Technical data

Composition	highly cross-linked 6% agarose
Particle size	24–44 µm
Total capacity H^+	0.06–0.08 mmol/ml medium
pH stability (operational)	4–13
CIP stability (short term)	2–14
Pressure/flow spec.	100–200 cm/h, 300 kPa, BioPilot 60/600 column, bed height 30 cm

CNBr-activated Sepharose 4B.

Pack size	Code No.
15 g	17-0430-01
250 g	17-0430-02
1 kg	17-0430-03
Regulatory Support File	11-0028-16

Technical data

Composition	4% agarose
Particle size	90 µm average ($d_{50, vol}$)
For coupling to	$-NH_2$
Activation method	cyanogen bromide (CNBr) activated
Coupling capacity	25–60 mg α-chymotrypsinogen/ml drained medium
pH stability (operational)	3–11, ligand dependent
CIP stability (short term)	3–11, ligand dependent
Pressure/flow spec	base matrix 70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

CNBr-activated Sepharose 4 Fast Flow. See p 70, 72

Pack size	Code No.
10 g	17-0981-01
250 g	17-0981-03
2 kg	17-0981-05
Data File	18-1113-55
Regulatory Support File	11-0028-16

Technical data

Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
For coupling to	$-NH_2$
Activation method	cyanogen bromide (CNBr) activated
Coupling capacity	13–26 mg α-chymotrypsinogen/ml drained medium
pH stability (operational)	3–11, ligand dependent
CIP stability (short term)	3–11, ligand dependent
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Con A Sepharose 4B. See p 72

Pack size	Code No.
5 ml	17-0440-03
100 ml	17-0440-01
500 ml	17-0440-02
5 l	17-0440-04

Technical data

Composition	4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	Concanavalin A
Ligand density	10–16 mg Con A/ml drained medium
Coupling chemistry	CNBr
pH stability (operational)	4–9
CIP stability (short term)	4–9
Pressure/flow spec	base matrix 70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Cytodex 1. See p 183–184

Pack size	Code No.
25 g	17-0448-01
100 g	17-0448-02
500 g	17-0448-03
2.5 kg	17-0448-25
5 kg	17-0448-04
Data File	18-1060-61
Regulatory Support File	11-0028-70

Technical data

Density*	1.03 g/ml in 0.9% NaCl
Particle size*	d_{50} 190 µm
Particle size*	$d_{5–95}$ 147–248 µm
Approx. area*	4 400 cm^2/g dry weight
Approx. no. microcarriers	$4.3×10^6$ g/dry weight swelling* 20 ml/g dry weight

* In 0.9% NaCl

Cytodex 3. See p 183–184

Pack size	Code No.
10 g	17-0485-01
100 g	17-0485-02
500 g	17-0485-03
2.5 kg	17-0485-25
5 kg	17-0485-04
Data File	18-1060-61
Regulatory Support File	11-0028-72

Technical data

Density*	1.04 g/ml in 0.9% NaCl
Particle size*	175 µm
Particle size*	$d_{5–95}$ 141–211 µm
Approx. area*	2 700 cm^2/g dry weight
Approx. no. microcarriers	$3×10^6$ g/dry weight swelling* 15 ml/g dry weight

* In 0.9% NaCl

Note: For Cytodex, size is based on diameter at 50% of the volume of a sample of microcarriers (d_{50}), or the range between the diameter at 5% and 95% of the volume of a sample of microcarriers ($d_{5–95}$). This size is calculated from cumulative volume distributions.

Cytoline 1. See p 183, 185

Pack size	Code No.
50 ml	17-1268-01
500 ml	17-1268-02
5 l	17-1268-03
Data File	18-1060-65
Regulatory Support File	11-0028-74

Technical data

Sedimentation velocity	120–220 cm/min
Length	1.7–2.5 mm
Thickness	0.4–1.1 mm
Density	1.32 g/ml
Pore size	10–400 µm
Surface area	>0.3 m^2/g

Cytoline 2. See p 183, 185

Pack size	Code No.
50 ml	17-1269-01
500 ml	17-1269-02
5 l	17-1269-03
Data File	18-1060-65
Regulatory Support File	11-0028-74

Technical data

Sedimentation velocity	25–75 cm/min
Length	1.7–2.5 mm
Thickness	0.4–1.1 mm
Density	1.03 g/ml
Pore size	10–400 µm
Surface area	>0.1 m^2/g

Cytopore 1. See p 183–184

Pack size	Code No.
20 g	17-0911-01
100 g	17-0911-02
500 g	17-0911-03
Data File	18-1132-68
Regulatory Support File	11-0028-73

Technical data

Particle diameter	200–280 nm**
Effective surface area	1.1 m^2/g dry weight
Density	1.03 g/ml**
Average diameter of pore openings	30 µm**
Volume	40 ml/g dry weight

* In 0.9% NaCl

** Data from Ashai Chemical Industry Co. Ltd., Japan

Cytopore 2. See p 183–184

Pack size	Code No.
20 g	17-1271-01
100 g	17-1271-02
500 g	17-1271-03
1 kg	17-1271-04
Data File	18-1132-68
Regulatory Support File	11-0028-73

Technical data

Particle diameter	200–280 nm**
Effective surface area	1.1 m^2/g dry weight
Density	1.03 g/ml**
Average diameter of pore openings	30 µm**
Volume	40 ml/g dry weight

** Data from Ashai Chemical Industry Co. Ltd., Japan

DEAE Sephadex A-25. See p 68

Pack size	Code No.
100 g	17-0170-01
500 g	17-0170-02
5 kg	17-0170-03
40 kg	17-0170-07
Data File	18-1117-58
Regulatory Support File	11-0028-17

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 45–190 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 120 cm/h, pressure drop cm H_2O/bed height=5, bed height 10 cm, 5 cm i.d.

DEAE Sephadex A-50. See p 68

Pack size	Code No.
100 g	17-0180-01
500 g	17-0180-02
5 kg	17-0180-03
Data File	18-1117-58
Regulatory Support File	11-0028-17

Technical data

Composition	cross-linked dextran
Particle size	wet (in 0.15 M NaCl), 100–370 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 60 cm/h, pressure drop cm H_2O/bed height=10, bed height 10 cm, 5 cm i.d.

DEAE Sepharose Fast Flow. See p 69, 130

Pack size	Code No.
25 ml	17-0709-10
500 ml	17-0709-01
10 l	17-0709-05
60 l	17-0709-60
IEX Selection Kit	17-0939-01
Data File	18-1020-66
Regulatory Support File	11-0028-18

Prepacked columns

HiTrap DEAE FF 5×1 ml	17-5055-01
HiTrap DEAE FF 5×5 ml	17-5154-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33
HiPrep 16/10 DEAE FF 20 ml	17-5090-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	110 mg HSA/ml drained medium
Ion capacity	0.11–0.16 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability (short term)	2–14
Pressure/flow spec.	300–600 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm

CDM ECH-Lysine Sepharose 4 Fast Flow. See p 72, 87

Pack size	Code No.
500 ml	17-0902-02
5 l	17-0902-04
Regulatory Support File	11-0029-28

Technical data

Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Coupling chemistry	NHS
Ligand	L-lysine
Ligand density	~16 µmol/ml drained medium
pH stability (operational)	3–12
CIP stability (short term)	2–13
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Epoxy-activated Sepharose 6B. See p 72

Pack size	Code No.
15 g	17-0480-01
250 g	17-0480-03

Technical data

Composition	6% agarose
Particle size	90 µm average ($d_{50, vol}$)
For coupling to	-NH_2, -OH, -SH
Active groups	epoxy groups on 12-atom spacer
Amount of active groups	19–40 µmol epoxy groups/ml drained medium
pH stability (operational)	3–13, ligand dependent
CIP stability (short term)	3–13, ligand dependent
Pressure/flow spec	base matrix 100–200 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Ficoll PM400. See p 181

Pack size	Code No.
100 g	17-0300-10
500 g	17-0300-50
5 kg	17-0300-05
40 kg	17-0300-08

Technical data

Composition	sucrose polymer
Molecular weight	3×10^5 to 5×10^5
Specific rotation	+50 to +65 degrees
Stokes radius	10 nm

Ficoll-Paque PLUS. See p 181

Pack size	Code No.
6×100 ml	17-1440-02
6×500 ml	17-1440-03

Technical data

Composition	Solution containing Ficoll PM400 and sodium diatrizoate
Density	1.077 ± 0.001 g/ml

Ficoll-Paque PREMIUM. See p 181

Pack size	Code No.
6×100 ml	17-5442-02
6×500 ml	17-5442-03
Regulatory Support File	11-0029-36

Technical data

Composition	Solution containing Ficoll PM400 and sodium diatrizoate
Density	1.077 ± 0.001 g/ml

Ficoll-Paque PREMIUM 1.073. See p 180

Pack size	Code No.
6×100 ml	17-5446-52
Regulatory Support File	11-0029-36

Technical data

Composition	Solution containing Ficoll PM400 and sodium diatrizoate
Density	1.073 ± 0.001 g/ml

Ficoll-Paque PREMIUM 1.084. See p 180

Pack size	Code No.
6×100 ml	17-5446-02
Regulatory Support File	11-0029-36

Technical data

Composition	Solution containing Ficoll PM400 and sodium diatrizoate
Density	1.084 ± 0.001 g/ml

GammaBind G Type 2.

Pack size	Code No.
1 g	17-0884-06
10 g	17-0884-08
50 g	17-0884-99

CDM Gelatin Sepharose 4 Fast Flow. See p 72, 87

Pack size	Code No.
1 l	17-0976-03
5 l	17-0976-04
Regulatory Support File	11-0029-37

Technical data

Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Coupling chemistry	CNBr
Ligand	bovine gelatin derivative
Ligand density	~5 mg/ml drained medium
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Glutathione Sepharose 4 Fast Flow. See p 72

Pack size	Code No.
25 ml	17-5132-01
100 ml	17-5132-02
500 ml	17-5132-03
Data File	18-1136-89

Prepacked columns

GSTPrep FF 16/10	17-5234-01
GSTrap FF 5×1 ml	17-5130-01
GSTrap FF 2×1 ml	17-5130-02
GSTrap FF 100×1 ml*	17-5130-05
GSTrap FF 1×5 ml	17-5131-01
GSTrap FF 5×5 ml	17-5131-02
GSTrap FF 100×5 ml*	17-5131-05
GST MultiTrap FF, 96-well prepacked plate, 4 plates	28-4055-01

Technical data

Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	glutathione
Ligand density	120–320 µmol glutathione/ml drained medium
Coupling chemistry	epoxy
Binding capacity	~10 mg recombinant GST/ml medium, protein dependent
pH stability	3–12
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

*Special pack size delivered on specific customer order.

Heparin Sepharose 6 Fast Flow. See p 70, 72

Pack size	Code No.
50 ml	17-0998-01
250 ml	17-0998-25
1 l	17-0998-03
5 l	17-0998-04
Data File	18-1060-76
Regulatory Support File	11-0028-19

Prepacked columns

HiPrep 16/10 Heparin FF	17-5189-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	heparin
Ligand density	~4 mg heparin/ml drained medium
Coupling chemistry	reductive amination
pH stability (operational)	4–12
CIP stability (short term)	4–13
Pressure/flow spec	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CDM IgSelect. See p 72, 87

Pack size	Code No.
25 ml	28-4113-01
200 ml	28-4113-02
1 L	28-4113-03
Data File	28-9257-92

Prepacked columns

HiTrap 5×1 ml	28-4113-11
HiTrap 1×5 ml	28-4113-12

Technical data

Composition	highly crosslinked agarose
Particle size	75 µm average ($d_{50, vol}$)
Ligand	14 kD recombinant protein produced in *S. cerevisiae*. Binds to Fc fragments of all human IgG subclasses.
Coupling chemistry	NHS
Dynamic binding capacity	17 mg/ml at 2.4 min residence time
Pressure/flow specification	At least 600 cm/h in a 1 m column with 20 cm bed height at 20°C using process buffers with the same viscosity as water at < 3 bar (0.3 MPa)
pH stability (long term)	3–11
pH stability (short term)	2–13

CDM IgG Sepharose 6 Fast Flow. See p 87

Pack size	Code No.
10 ml	17-0969-01
200 ml	17-0969-02
5 l	17-0969-04

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Coupling chemistry	CNBr
Ligand	human polyclonal IgG
Capacity	~5 mg Protein A/ml drained medium
pH stability (operational)	3–10
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

IMAC Sepharose 6 Fast Flow. See p 70, 72

Pack size	Code No.
25 ml	17-0921-07
100 ml	17-0921-08
1 l	17-0921-09
5 l	17-0921-10
Data File	28-4041-06
Regulatory Support File	11-0029-31
Prepacked columns	
HiTrap IMAC FF 5×1 ml	17-0921-02
HiTrap IMAC FF 5×5 ml	17-0921-04
HiPrep IMAC FF 16/10	17-0921-06

Technical data	
Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Metal ion capacity	~15 µmol Ni^{2+}/ml drained medium
Dynamic binding capacity	~40 mg histidine-tagged protein/ml medium, protein and metal ion dependent
pH stability (operational)	3–12
pH stability (short term)	2–14
Pressure/flow spec.	base matrix 200-400 cm/h, 100 kPa, XK50/60 column, bed height 25 cm

Lentil Lectin Sepharose 4B. See p 72

Pack size	Code No.
25 ml	17-0444-01
1 l	17-0444-03
Regulatory Support File	11-0028-92

Technical data	
Composition	4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	lentil lectin
Ligand density	~2 mg lentil lectin/ml drained medium
Coupling chemistry	CNBr
pH stability (operational)	3–10
CIP stability (short term)	3–10
Pressure/flow spec	base matrix 70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm cm, 5 cm i.d.

MabSelect. See p 71–72

Pack size	Code No.
25 ml	17-5199-01
200 ml	17-5199-02
1 l	17-5199-03
5 l	17-5199-04
10 l	17-5199-06
Data File	18-1149-94
Regulatory Support File	11-0028-20
Prepacked columns	
HiTrap MabSelect 5×1 ml	28-4082-53
HiTrap MabSelect 1×5 ml	28-4082-55
HiTrap MabSelect 5×5 ml	28-4082-56
HiScreen MabSelect 4.7 ml (0.77 × 10 cm)	28-9269-73
96-well filter plates	
PreDictor MabSelect, 6 µl, 4 × 96 well plates	28-9258-20
PreDictor MabSelect, 20 µl, 4 × 96 well plates	28-9258-21
PreDictor MabSelect, 50 µl, 4 × 96 well plates	28-9258-22

Technical data	
Composition	highly cross-linked agarose
Particle size	d_{50v} ~85 µm
Ligand	recombinant Protein A (*E. coli*)
Coupling chemistry	epoxy
Dynamic binding capacity	min 30 mg human IgG/ml medium at 2.4 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–12
Pressure/flow spec	up to 500 cm/h, < 200 kPa, BPG 300, bed height 20 cm

MabSelect SuRe. See p 71–72, 78

Pack size	Code No.
25 ml	17-5438-01
200 ml	17-5438-02
1 l	17-5438-03
5 l	17-5438-04
10 l	17-5438-05
Data File	11-0011-65
Regulatory Support File	11-0029-18

Prepacked columns

HiTrap MabSelect SuRe 5×1 ml	11-0034-93
HiTrap MabSelect SuRe 1×5 ml	11-0034-94
HiTrap MabSelect SuRe 5×5 ml	11-0034-95
HiScreen MabSelect SuRe 4.7 ml (0.77 × 10 cm)	28-9269-77

96-well filter plates

PreDictor MabSelect SuRe, 6 µl, 4 × 96 well plates	28-9258-23
PreDictor MabSelect SuRe, 20 µl, 4 × 96 well plates	28-9258-24
PreDictor MabSelect SuRe, 50 µl, 4 × 96 well plates	28-9258-25

Technical data

Composition	highly cross-linked agarose
Particle size	d_{50v} ~85 µm
Ligand	alkali-stabilized Protein A-derived (*E.coli*)
Coupling chemistry	epoxy
Dynamic binding capacity	min 30 mg human IgG/ml medium at 2.4 min residence time
pH stability (operational)	3–12
CIP stability (short term)	0.1–0.5 M NaOH
Pressure/flow spec	up to 500 cm/h, < 200 kPa, BPG 300, bed height 20 cm

MabSelect Xtra. See p 71–72

Pack size	Code No.
25 ml	17-5269-07
200 ml	17-5269-02
1 l	17-5269-03
5 l	17-5269-04
10 l	17-5269-05
60 l	17-5269-06
Data File	11-0011-57
Regulatory Support File	11-0029-17

Prepacked columns

HiTrap MabSelect Xtra 5×1 ml	28-4082-58
HiTrap MabSelect Xtra 1×5 ml	28-4082-60
HiTrap MabSelect Xtra 5×5 ml	28-4082-61
HiScreen MabSelect Xtra 4.7 ml (0.77 × 10 cm)	28-9269-76

Technical data

Composition	highly cross-linked agarose
Particle size	d_{50v} ~75 µm
Ligand	recombinant Protein A (*E.coli*)
Coupling chemistry	epoxy
Dynamic binding capacity	approx. 40 mg human IgG/ml medium at 2.4 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–12
Pressure/flow spec	up to 300 cm/h, < 200 kPa, BPG 300, bed height 20 cm

MacroCap SP. See p 66, 68

Pack size	Code No.
25 ml	17-5440-10
100 ml	17-5440-01
1 l	17-5440-02
5 l	17-5440-03
10 l	17-5440-05
60 l	17-5440-60
Data File	28-4005-84
Regulatory Support File	11-0029-33

Technical data

Composition	Cross-linked co-polymer of allyl dextran and N,N-methylene bisacrylamide
Particle size	50 µm (d_{50v})
Ion exchanger type	Strong cation
Charged group	SO_3^-
Total ionic capacity	0.10–0.13 mmol H^+/ml medium
Recommended separation range	a) proteins in excess of 150 kDa b) functionalized Dextrans or PEGs ≥ 20 000 MW c) PEG-proteins containing ≥ 10 000 PEG (total) per conjugate
pH stability (operational)	3–12
pH stability (short term)	2–13
pH stability (long term)	4–11
CIP stability	2–13
Chemical stability	all commonly used aqueous buffers, 0.1 M citric acid, 0.5 M NaOH, 25% ethanol, 30% propanol, 30% methanol, 50% ethylene glycol, 1% Tween 20, 1% SDS.
Flow velocity	120 cm/h in BPG 300 columns with 20 cm bed height at 20°C using process buffers with the same viscosity as water at < 300 kPa.

NHS-activated Sepharose 4 Fast Flow. See p 70, 72

Pack size	Code No.
25 ml	17-0906-01
500 ml	17-0906-02
5 l	17-0906-04
Data File	18-1113-53
Regulatory Support File	11-0028-21

Technical data

Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
For coupling to	$-NH_2$
Active groups	NHS ester on 14-atom spacer
Amount of active groups	~18 µmol NHS/ml drained medium
pH stability (operational)	3–13, ligand dependent
CIP stability (short term)	3–13, ligand dependent
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Ni Sepharose 6 Fast Flow. See p 70, 72

Pack size	Code No.
5 ml	17-5318-06
25 ml	17-5318-01
100 ml	17-5318-02
500 ml	17-5318-03
1 l	17-5318-04
5 l	17-5318-05
Data File	11-0008-86
Regulatory Support File	11-0028-43

Prepacked columns

HisTrap FF 5×1 ml	17-5319-01
HisTrap FF 100×1 ml*	17-5319-02
HisTrap FF 5×5 ml	17-5255-01
HisTrap FF 100×5 ml*	17-5255-02
HisPrep FF 16/10	17-5256-01
His GraviTrap 10×1 ml	11-0033-99
His GraviTrap Kit (20×1 ml + buffers)	28-4013-51
His MultiTrap FF, 96-well prepacked plate, 4 plates	28-4009-90

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Metal ion capacity	~15 µmol Ni^{2+}/ml medium
Dynamic binding capacity	~40 mg histidine-tagged protein/ml medium, protein dependent
pH stability (operational)	3–12
CIP stability (short term)	2–14
Pressure/flow spec	base matrix 200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

*Special pack size delivered on specific customer order.

Octyl Sepharose 4 Fast Flow. See p 74–75, 130

Pack size	Code No.
25 ml	17-0946-10
200 ml	17-0946-02
1 l	17-0946-03
5 l	17-0946-04
Regulatory Support File	11-0028-22

Prepacked columns

HiTrap HIC Selection Kit 7×1 ml	28-4110-07
HiTrap Octyl FF 5×1 ml	17-1359-01
HiTrap Octyl FF 5×5 ml	17-5196-01
HiPrep 16/10 Octyl FF 20 ml	17-5097-01
HiScreen Octyl FF 4.7 ml (0.77 × 10 cm)	28-9269-86

Technical data

Composition	highly cross-linked 4% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	n-octyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Oligosynt.

See Solid supports for oligonucleotide synthesis p 239

Percoll. See p 181

Pack size	Code No.
250 ml	17-0891-02
1 l	17-0891-01
6×1 l	17-0891-09

Technical data

Composition	Silica coated with polyvinylpyrrolidone (PVP)
Particle diameter	15–30 nm
Density	1.13 ±0.005 g/ml
Conductivity, max.	100 mS/m
Osmolality, max.	25 mOsm/kg
Viscosity	10 ±5 cP at 20°C
pH	9.0 ±0.5 at 20°C

Percoll PLUS. See p 181

Pack size	Code No.
250 ml	17-5445-02
1 l	17-5445-01
Regulatory Support File	11-0029-39

Technical data

Composition	Silica with covalently linked silane
Particle diameter	15–30 nm
Density	1.13–0.005 g/ml
Osmolality, max.	30 mOsm/kg
Viscosity, max.	15 cP

CDM Phenyl Sepharose Big Beads. See p 75, 87

Pack size	Code No.
1 l	17-5098-03
10 l	17-5089-05
Regulatory Support File	11-0028-25

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Ligand	phenyl
Coupling chemistry	epoxy
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	1 200–1 800 cm/h 100 kPa, XK 50/60 column, bed height 25 cm.

Phenyl Sepharose 6 Fast Flow (high sub).

See p 74–75, 130

Pack size	Code No.
25 ml	17-0973-10
200 ml	17-0973-05
1 l	17-0973-03
5 l	17-0973-04
10 l	17-0973-06
60 l	17-0973-60
Data File	18-1020-53
Regulatory Support File	11-0028-23

Prepacked columns

HiTrap HIC Selection Kit 7×1 ml	28-4110-07
HiTrap Phenyl FF (high sub) 5×1 ml	17-1355-01
HiTrap Phenyl FF (high sub) 5×5 ml	17-5193-01
HiPrep 16/10 Phenyl FF (high sub)	17-5095-01
HiScreen Phenyl FF (high sub) 4.7 ml (0.77 × 10 cm)	28-9269-88

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	phenyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Phenyl Sepharose 6 Fast Flow (low sub).

See p 74–75, 130

Pack size	Code No.
25 ml	17-0965-10
200 ml	17-0965-05
1 l	17-0965-03
5 l	17-0965-04
Data File	18-1020-53
Regulatory Support File	11-0028-23

Prepacked columns

HiTrap HIC Selection Kit 7×1 ml	28-4110-07
HiTrap Phenyl FF (low sub) 5×1 ml	17-1353-01
HiTrap Phenyl FF (low sub) 5×5 ml	17-5194-01
HiPrep 16/10 Phenyl FF (low sub) 20 ml	17-5094-01
HiScreen Phenyl FF (low sub) 4.7 ml (0.77 × 10 cm)	28-9269-89

Technical data

Composition	highly cross-linked 6% agarose
Particle size	90 µm average ($d_{50, vol}$)
Ligand	phenyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Phenyl Sepharose High Performance.

See p 74–75, 130

Pack size	Code No.
75 ml	17-1082-01
1 l	17-1082-03
5 l	17-1082-04
Data File	18-1020-56
Regulatory Support File	11-0028-24

Prepacked columns

HiLoad 16/10 Phenyl Sepharose High Performance 20 ml	17-1085-01
HiLoad 26/10 Phenyl Sepharose High Performance 53 ml	17-1086-01
HiTrap HIC Selection Kit 7×1 ml	28-4110-07
HiTrap Phenyl HP 5×1 ml	17-1351-01
HiTrap Phenyl HP 5×5 ml	17-5195-01

Technical data

Composition	highly cross-linked 6% agarose
Particle size	34 µm average ($d_{50, vol}$)
Ligand	phenyl
pH stability (operational)	3–13
CIP stability (short term)	2–14
Max pressure	300 kPa

PlasmidSelect Xtra. See p 78, 130

Pack size	Code No.
PlasmidSelect Xtra Screening Kit	28-4052-69
PlasmidSelect Xtra Starter Kit	28-4052-68
25 ml	28-4024-01
200 ml	28-4024-02
1 l	28-4024-03
5 l	28-4024-04
Data File	28-4094-87
Regulatory Support File	11-0029-34

Technical data

Composition	highly cross-linked 6% agarose
Particle size	24–44 µm
Ligand	2-mercaptopyridine
Ligand concentration	3.5 mg/ml
Capacity for supercoiled pDNA (6125 bp)	>2 mg/ml
pH stability (operational)	3–11
CIP stability (short term)	2–13
Cleaning-in-place	0.5 M NaOH
Flow velocity for supercoiled plasmid purification	<120 cm/h, XK 16/20 column, bed height 15 cm

CDM Plasminogen Removal Gel. See p 72, 87

Pack size	Code No.
1 l	28-4109-03
Regulatory Support File	11-0029-29

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	epoxy
Ligand	Tranexamic acid
Ligand density	9–13 µmol/ml drained medium
pH stability (operational)	3–12
CIP stability (short term)	2–14
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

Primer Support 200.

See Solid supports for oligonucleotide synthesis p 239

Protein A. See p 70–71, 77

Pack size	Code No.
50 mg	17-0872-50
1 g	17-0872-01
10 g	17-0872-02

CDM Procainamide Sepharose 4 Fast Flow. See p 72, 87

Pack size	Code No.
1 l	28-4111-03
5 l	28-4111-04

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Coupling chemistry	amide linkage (carbodiimide)
Ligand	procainamide
Ligand density	approx. 23 µmol/ml drained medium
Pressure/flow spec	min 150 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm (base matrix)

nProtein A Sepharose 4 Fast Flow. See p 72

Pack size	Code No.
5 ml	17-5280-01
25 ml	17-5280-04
200 ml	17-5280-02
1 l	17-5280-03
5 l	17-5280-05
10 l	17-5280-06
Data File	18-1125-19
Regulatory Support File	11-0029-19

Technical data

Composition	highly cross-linked 4% agarose
Particle size	d_{50v} ~90 µm
Ligand	Protein A from *Staphylococcus aureus*
Coupling chemistry	CNBr
pH stability (operational)	3–9
CIP stability (short term)	2–10
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

rProtein A Sepharose 4 Fast Flow. See p 72

Pack size	Code No.
5 ml	17-1279-01
25 ml	17-1279-02
200 ml	17-1279-03
1 l	17-1279-04
5 l	17-1279-05
10 l	17-1279-06
Data File	18-1113-94
Regulatory Support File	11-0028-35

Prepacked columns

HiTrap rProtein A FF 5×1 ml	17-5079-01
HiTrap rProtein A FF 2×1 ml	17-5079-02
HiTrap rProtein A FF 1×5 ml	17-5080-01
HiTrap rProtein A FF 5×5 ml	17-5080-02

Technical data

Composition	highly cross-linked 4% agarose
Particle size	d_{50v} ~90 µm
Ligand	recombinant Protein A from *E. coli*
Coupling chemistry	epoxy
Dynamic binding capacity	min 27 mg human IgG/ml medium at 3 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–11
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

rmp Protein A Sepharose Fast Flow. See p 72

Pack size	Code No.
5 ml	17-5138-01
25 ml	17-5138-02
200 ml	17-5138-03
1 l	17-5138-04
5 l	17-5138-05
Data File	18-1141-34
Regulatory Support File	11-0029-25

Technical data

Composition	highly cross-linked 4% agarose
Particle size	d_{50v} ~90 µm
Ligand	recombinant Protein A from *E. coli*
Coupling chemistry	reductive amination
Dynamic binding capacity	min 22 mg human IgG/ml medium at 3 min residence time
pH stability (operational)	3–10
CIP stability (short term)	2–11
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Protein G.

Pack size	Code No.
5 mg	17-0619-01
1 g	17-0619-09
10 g	17-0619-10

Protein G Sepharose 4 Fast Flow. See p 72

Pack size	Code No.
5 ml	17-0618-01
25 ml	17-0618-02
200 ml	17-0618-05
1 l	17-0618-06
5 l	17-0618-04
Data File	18-1012-91
Regulatory Support File	11-0028-29

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
Ligand	recombinant Protein G from *E. coli*
Ligand density	~2 mg protein G/ml drained medium
Coupling chemistry	CNBr
pH stability (operational)	3–9
CIP stability (short term)	2–10
Pressure/flow spec	base matrix 150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

CDM VIIISelect. See p 72, 87

Pack size	Code No.
25 ml	17-5450-01
500 ml	17-5450-02

Technical data

Composition	Highly cross-linked high flow agarose
Particle size	75 µm average (d50, vol)
Ligand	13 kD recombinant protein produced in *S. cerevisiae*. Binds to beta-domain depleted factor VIII molecules.
Coupling chemistry	NHS
Pressure/flow spec	At least 300 cm/h in a BPG 300 column with 20 cm bed height at 20°C using process buffers with the same viscosity as water at < 2 bar (0.2 MPa)

Q Sepharose Big Beads. See p 68, 130

Pack size	Code No.
1 l	17-0989-03
10 l	17-0989-05
60 l	17-0989-60
IEX Selection Kit	17-0939-01
Data File	18-1104-91
Regulatory Support File	11-0028-32

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Ion capacity	0.18–0.25 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability (short term)	2–14
Pressure/flow spec.	1 200–1 800 cm/h, 100 kPa, XK50/60 column, bed height 25 cm

Q Sepharose Fast Flow. See p 69, 130

Pack size	Code No.
25 ml	17-0510-10
300 ml	17-0510-01
5 l	17-0510-04
10 l	17-0510-05
60 l	17-0510-60
IEX Selection Kit	17-0939-01
Data File	18-1020-66
Regulatory Support File	11-0028-30

Prepacked columns

HiTrap Q FF 5×1 ml	17-5053-01
HiTrap Q FF 5×5 ml	17-5156-01
HiPrep 16/10 Q FF	17-5190-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	120 mg HSA/ml drained medium
Ion capacity	0.18–0.24 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability (short term)	2–14
Pressure/flow spec.	400–700 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm.

Q Sepharose High Performance. See p 69, 130

Pack size	Code No.
75 ml	17-1014-01
1 l	17-1014-03
5 l	17-1014-04
10 l	17-1014-05
Data File	18-1172-88
Regulatory Support File	11-0028-31

Prepacked columns

HiLoad 16/10 Q Sepharose High Performance 20 ml	17-1064-01
HiLoad 26/10 Q Sepharose High Performance 53 ml	17-1066-01
HiTrap Q HP 5×1 ml	17-1153-01
HiTrap Q HP 5×5 ml	17-1154-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33

Technical data

Composition	cross-linked agarose
Particle size	34 µm average ($d_{50, vol}$)
Binding capacity	120 mg HSA/ml drained medium
Ion capacity	0.14–0.20 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability (short term)	2–14
Pressure/flow spec.	min 75 cm/h, 250 kPa, BioPilot 60/100 column, bed height 30 cm

Q Sepharose XL. See p 69, 130

Pack size	Code No.
300 ml	17-5072-01
5 l	17-5072-04
10 l	17-5072-05
60 l	17-5072-60
Data File	18-1123-82
Regulatory Support File	11-0028-33

Prepacked columns

HiPrep 16/10 Q XL	17-5092-01
HiTrap Q XL 5×1 ml	17-5158-01
HiTrap Q XL 5×5 ml	17-5159-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33

Technical data

Composition	cross-linked 6% agarose with dextran coating
Particle size	45–165 µm
Binding capacity	>130 mg bovine serum albumin/ml medium
Ion capacity	0.18–0.26 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability (working)	2–14
Flow rate	300–500 cm/h

Q Sepharose XL virus licensed. See p 69

Pack size	Code No.
25 ml	17-5437-10
300 ml	17-5437-01
1 l	17-5437-03
5 l	17-5437-04
Regulatory Support File	11-0028-33

Technical data

Composition	cross-linked 6% agarose with dextran coating
Particle size	45–165 µm
Binding capacity	>130 mg bovine serum albumin/ml medium
Ion capacity	0.18–0.26 mmol Cl^-/ml medium
pH stability (operational)	2–12
CIP stability (working)	2–14
Flow rate	300–500 cm/h

QAE Sephadex A-25. See p 68

Pack size	Code No.
100 g	17-0190-01
500 g	17-0190-02
5 kg	17-0190-03
Data File	18-1117-58
Regulatory Support File	11-0028-96

Technical data

Composition	cross-linked dextran
Particle size	dry 40–125 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 100 cm/h, pressure drop cm H_2O/bed height=5, bed height 10 cm, 5 cm i.d.

QAE Sephadex A-50. See p 68

Pack size	Code No.
100 g	17-0200-01
5 kg	17-0200-03
Data File	18-1117-58
Regulatory Support File	11-0028-97

Technical data

Composition	cross-linked dextran
Particle size	dry 40–125 µm
pH stability (operational)	2–10
CIP stability (short term)	2–13
Pressure/flow spec.	min 60 cm/h, pressure drop cm H_2O/bed height=10, bed height 10 cm, 5 cm i.d.

Sephacryl S-100 High Resolution. See p 84–85

Pack size	Code No.
150 ml	17-0612-10
750 ml	17-0612-01
10 l	17-0612-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Prepacked columns

HiPrep 16/60 Sephacryl S-100 HR 120 ml	17-1165-01
HiPrep 26/60 Sephacryl S-100 HR 320 ml	17-1194-01

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	1×10^3–1×10^5
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >125 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-200 High Resolution. See p 84–85

Pack size	Code No.
150 ml	17-0584-10
750 ml	17-0584-01
10 l	17-0584-05
60 l	17-0584-60
Data File	18-1009-28
Regulatory Support File	11-0028-36

Prepacked columns

HiPrep 16/60 Sephacryl S-200 HR 120 ml	17-1166-01
HiPrep 26/60 Sephacryl S-200 HR 320 ml	17-1195-01

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	5×10^3–2.5×10^5
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >150 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-300 High Resolution. See p 84–85

Pack size	Code No.
150 ml	17-0599-10
750 ml	17-0599-01
10 l	17-0599-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Prepacked columns

HiPrep 16/60 Sephacryl S-300 HR 120 ml	17-1167-01
HiPrep 26/60 Sephacryl S-300 HR 320 ml	17-1196-01

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	1×10^4–1.5×10^6
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >150 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-400 High Resolution. See p 84–85

Pack size	Code No.
150 ml	17-0609-10
750 ml	17-0609-01
10 l	17-0609-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	2×10^4–8×10^6
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >150 cm/h, XK 50/30 column, bed height 15 cm

Sephacryl S-500 High Resolution. See p 84–85

Pack size	Code No.
150 ml	17-0613-10
750 ml	17-0613-01
10 l	17-0613-05
Data File	18-1009-28
Regulatory Support File	11-0028-36

Technical data

Composition	allyl dextran and N,N´-methylene bisacrylamide
Particle size	50 µm
Fractionation range, globular proteins	not determined
pH stability (operational)	3–11
CIP stability (short term)	2–13
Pressure/flow spec.	flow at 100 kPa >125 cm/h, XK 50/30 column, bed height 15 cm

Sephadex G-25 Coarse. See p 84–85

Pack size	Code No.
100 g	17-0034-01
500 g	17-0034-02
5 kg	17-0034-03
40 kg	17-0034-07
Data File	18-1115-79
Regulatory Support File	11-0028-38

Technical data

Composition	cross-linked dextran
Particle size	dry, min 90% volume share between 100–300 µm; wet (in 0.15 M NaCl), 75–510 µm
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	480–660 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sephadex G-25 Medium. See p 84–85

Pack size	Code No.
25 g	17-0033-10
100 g	17-0033-01
500 g	17-0033-02
5 kg	17-0033-03
Data File	18-1115-79
Regulatory Support File	11-0028-38

Prepacked columns

Prepacked Disposable Columns PD-10 30×9.1 ml	17-0851-01

Technical data

Composition	cross-linked dextran
Particle size	dry, min 90% volume share between 50–150 µm; wet (in 0.15 M NaCl), 40–250 µm
Typical flow rate	200 cm/h
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	100–150 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sephadex G-25 Fine. See p 84–85

Pack size	Code No.
100 g	17-0032-01
500 g	17-0032-02
5 kg	17-0032-03
Data File	18-1115-79
Regulatory Support File	11-0028-38

Prepacked columns

HiPrep 26/10 Desalting 1×53 ml	17-5087-01
HiPrep 26/10 Desalting 4×53 ml	17-5087-02

Technical data

Composition	cross-linked dextran
Particle size	dry, min 80% volume share between 20–80 µm; wet (in 0.15 M NaCl), 20–130 µm
Typical flow rate	150 cm/h
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	47–68 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sephadex G-25 Superfine. See p 84–85

Pack size	Code No.
100 g	17-0031-01
500 g	17-0031-02
5 kg	17-0031-03
Data File	18-1115-79
Regulatory Support File	11-0028-38

Prepacked columns

HiTrap Desalting 5×5 ml	17-1408-01
HiTrap Desalting 100×5 ml*	11-0003-29

Technical data

Composition	cross-linked dextran
Particle size	dry, min 80% volume share between 20–50 µm; wet (in 0.15 M NaCl), 15–100 µm.
Typical flow rate	100 cm/h
Fractionation range, globular proteins	1×10^3–5×10^3
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	11–26 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

*Special pack size delivered on specific customer order.

Sephadex LH-20. See p 84

Pack size	Code No.
25 g	17-0090-10
100 g	17-0090-01
500 g	17-0090-02
5 kg	17-0090-03
Data File	18-1107-22
Regulatory Support File	11-0029-00

Technical data

Composition	hydroxypropylated, cross-linked dextran (based on Sephadex G-25)
Particle size	dry, min 85% volume share between 30–100 µm, wet (in methanol) 25–165 µm
pH stability (operational)	2–13
CIP stability (short term)	2–13
Pressure/flow spec.	25–45 cm/h, pressure drop cm H_2O/bed height=2, bed height 30 cm, 2.6 cm i.d.

Sepharose 4B.

Pack size	Code No.
1 l	17-0120-01
10 l	17-0120-05
Regulatory Support File	11-0028-39

Technical data

Composition	4% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	6×10^4–2×10^7
pH stability (operational)	4–9
CIP stability (short term)	4–9
Pressure/flow spec.	70–140 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, column 5 cm i.d.

Sepharose 6B.

Pack size	Code No.
1 l	17-0110-01
10 l	17-0110-05
Regulatory Support File	11-0028-39

Technical data

Composition	6% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	1×10^4–4×10^6
pH stability (operational)	4–9
CIP stability (short term)	4–9
Pressure/flow spec.	100–200 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Sepharose CL-2B. See p 85

Pack size	Code No.
1 l	17-0140-01
10 l	17-0140-05
Regulatory Support File	11-0028-40

Technical data

Composition	cross-linked 2% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	7×10^4–4×10^7
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	60–120 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, 5 cm i.d.

Sepharose CL-4B.

Pack size	Code No.
1 l	17-0150-01
10 l	17-0150-05
Regulatory Support File	11-0028-40

Technical data

Composition	cross-linked 4% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	6×10^4–2×10^7
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	80–150 cm/h, pressure drop m H_2O/bed height=15, bed height 10 cm, column 5 cm i.d.

Sepharose CL-6B.

Pack size	Code No.
1 l	17-0160-01
10 l	17-0160-05
Regulatory Support File	11-0028-40

Technical data

Composition	cross-linked 6% agarose
Particle size	45–165 µm
Fractionation range, globular proteins	1×10^4–4×10^6
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	100–200 cm/h, pressure drop cm H_2O/bed height=15, bed height 10 cm, column 5 cm i.d.

Sepharose 4 Fast Flow. See p 84–85

Pack size	Code No.
1 l	17-0149-01
10 l	17-0149-05
Data File	18-1020-52
Regulatory Support File	11-0028-41

Technical data

Composition	highly cross-linked 4% agarose
Particle size	45–165 µm
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	150–250 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

Sepharose 6 Fast Flow. See p 84–85

Pack size	Code No.
1 l	17-0159-01
10 l	17-0159-05
Data File	18-1020-52
Regulatory Support File	11-0028-42

Technical data

Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
pH stability (operational)	3–13
CIP stability (short term)	2–14
Pressure/flow spec.	200–400 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

SOURCE 15ETH.

Pack size	Code No.
50 ml	17-0146-01
200 ml	17-0146-02
1 l	17-0146-04
Data File	18-1128-86
Regulatory Support File	11-0028-46

Prepacked columns

RESOURCE ETH 1 ml	17-1184-01
RESOURCE HIC Test kit	17-1187-01

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15ISO.

Pack size	Code No.
50 ml	17-0148-01
200 ml	17-0148-02
1 l	17-0148-04
Data File	18-1128-86
Regulatory Support File	11-0028-47

Prepacked columns

RESOURCE ISO 1 ml	17-1185-01
RESOURCE HIC Test kit	17-1187-01

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15PHE.

Pack size	Code No.
50 ml	17-0147-01
200 ml	17-0147-02
1 l	17-0147-04
5 l	17-0147-05
Data File	18-1128-86
Regulatory Support File	11-0028-48

Prepacked columns

RESOURCE PHE 1 ml	17-1186-01
RESOURCE HIC Test kit	17-1187-01
SOURCE 15PHE PE 4.6/100	17-5071-01

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15Q. See p 67, 69

Pack size	Code No.
10 ml	17-0947-20
50 ml	17-0947-01
200 ml	17-0947-05
500 ml	17-0947-02
1 l	17-0947-03
Data File	18-1123-65
Regulatory Support File	11-0028-51

Prepacked columns

RESOURCE Q 1 ml	17-1177-01
RESOURCE Q 6 ml	17-1179-01
SOURCE 15Q 4.6/100 PE	17-5181-01
Data File	18-1123-65

Technical data

Ion exchanger type	Quaternary ammonium strong anion exchanger
Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Binding capacity	45 mg BSA/ml drained medium
Typical flow rate	150–900 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 30Q. See p 69, 79

Pack size	Code No.
50 ml	17-1275-01
200 ml	17-1275-02
1 l	17-1275-03
5 l	17-1275-04
Data File	18-1107-12
Regulatory Support File	11-0028-52

Technical data

Ion exchanger type	Quaternary ammonium strong anion exchanger
Composition	polystyrene/divinylbenzene
Particle size	30 µm monosized
Binding capacity	40 mg BSA/ml drained medium
Typical flow rate	300–1 000 cm/h
pH stability (operational)	2–12
CIP stability (short term)	1–14
Pressure/flow spec.	2 000 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15RPC. See p 81

Pack size	Code No.
10 ml	17-0727-20
200 ml	17-0727-02
500 ml	17-0727-03
1 l	17-0727-04
5 l	17-0727-05
Data File	18-1123-50
Regulatory Support File	11-0028-49

Prepacked columns

RESOURCE RPC 1 ml	17-1181-01
RESOURCE RPC 3 ml	17-1182-01
SOURCE 15 RPC ST 4.6/100	17-5068-01
Data File	18-1123-50

Technical data

Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Binding capacity	~10 mg BSA/ml medium at 300 cm/h ~30 mg bacitracin/ml medium at 300 cm/h ~50 mg insulin/ml medium at 300 cm/h
Typical flow rate	150–900 cm/h
pH stability (operational)	1–12
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 30RPC. See p 81

Pack size	Code No.
10 ml	17-5120-20
200 ml	17-5120-02
500 ml	17-5120-03
1 l	17-5120-04
5 l	17-5120-05
Data File	18-1129-73
Regulatory Support File	11-0028-53

Technical data

Composition	polystyrene/divinylbenzene
Particle size	30 µm monosized
Binding capacity	~14 mg BSA/ml medium at 300 cm/h ~23 mg bacitracin/ml medium at 300 cm/h ~72 mg insulin/ml medium at 300 cm/h
Typical flow rate	100–1000 cm/h
pH stability (operational)	1–12
CIP stability (short term)	1–14
Pressure/flow spec.	2 000 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 15S. See p 67, 69

Pack size	Code No.
10 ml	17-0944-10
50 ml	17-0944-01
200 ml	17-0944-05
500 ml	17-0944-02
1 l	17-0944-03
Data File	18-1123-65
Regulatory Support File	11-0028-50

Prepacked columns

RESOURCE S 1 ml	17-1178-01
RESOURCE S 6 ml	17-1180-01
SOURCE 15S 4.6/100 PE	17-5182-01
Data File	18-1123-65

Technical data

Ion exchanger type	Sulfonate strong cation exhanger
Composition	polystyrene/divinylbenzene
Particle size	15 µm monosized
Binding capacity	75 mg lysozyme/ml drained medium
Typical flow rate	150–900 cm/h
pH stability (operational)	2–13
CIP stability (short term)	1–14
Pressure/flow spec.	400 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SOURCE 30S. See p 69

Pack size	Code No.
50 ml	17-1273-01
200 ml	17-1273-02
1 l	17-1273-03
5 l	17-1273-04
Data File	18-1107-12
Regulatory Support File	11-0028-54

Technical data

Ion exchanger type	Sulfonate strong cation exhanger
Composition	polystyrene/divinylbenzene
Particle size	30 µm monosized
Binding capacity	80 mg lysozyme/ml drained medium
Typical flow rate	300–1 000 cm/h
pH stability (operational)	2–13
CIP stability (short term)	1–14
Pressure/flow spec.	2 000 cm/h, 1000 kPa, FineLINE 100 column, bed height 10 cm, i.d. 10 cm

SP Sepharose Big Beads. See p 68, 130

Pack size	Code No.
1 l	17-0657-03
10 l	17-0657-05
60 l	17-0657-60
IEX Selection Kit	17-0939-01
Data File	18-1104-91
Regulatory Support File	11-0028-57

Technical data

Composition	highly cross-linked 6% agarose
Particle size	100–300 µm
Ion capacity	0.18–0.25 mmol H^+/ml medium
pH stability (operational)	4–13
CIP stability (short term)	3–14
Pressure/flow spec.	1 200–1 800 cm/h, 100 kPa, XK 50/60 column, bed height 25 cm

SP Sepharose Fast Flow. See p 69, 130

Pack size	Code No.
25 ml	17-0729-10
300 ml	17-0729-01
5 l	17-0729-04
10 l	17-0729-05
60 l	17-0729-60
IEX Selection Kit	17-0939-01
Data File	18-1020-66
Regulatory Support File	11-0028-55
Prepacked columns	
HiPrep 16/10 SP FF 20 ml	17-5192-01
HiTrap SP FF 5×1 ml	17-5054-01
HiTrap SP FF 5×5 ml	17-5157-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33

Technical data	
Composition	highly cross-linked 6% agarose
Particle size	45–165 µm
Binding capacity	120 mg BSA/ml drained medium
Ion capacity	0.18–0.25 mmol H^+/ml medium
pH stability (operational)	4–13
CIP stability (short term)	3–14
Pressure/flow spec.	400–700 cm/h, 100 kPa, XK 50/30 column, bed height 15 cm.

SP Sepharose High Performance. See p 69, 130

Pack size	Code No.
75 ml	17-1087-01
1 l	17-1087-03
5 l	17-1087-04
10 l	17-1087-05
60 l	17-1087-08
Data File	18-1172-88
Regulatory Support File	11-0028-56
Prepacked columns	
HiLoad 16/10 SP Sepharose High Performance 20 ml	17-1137-01
HiLoad 26/10 SP Sepharose High Performance 53 ml	17-1138-01
HiTrap SP HP 5×1 ml	17-1151-01
HiTrap SP HP 5×5 ml	17-1152-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33

Technical data	
Composition	highly cross-linked 6% agarose
Particle size	34 µm average ($d_{50, vol}$)
Binding capacity	55 mg Ribonuclease/ml drained medium
Ion capacity	0.15–0.20 mmol H^+/ml medium
pH stability (operational)	4–13
CIP stability (short term)	3–14
Pressure/flow spec.	min 100 cm/h, 250 kPa, BioPilot 60/100 column, bed height 30 cm

SP Sepharose XL. See p 69, 130

Pack size	Code No.
300 ml	17-5073-01
5 l	17-5073-04
60 l	17-5073-60
Data File	18-1123-82
Regulatory Support File	11-0028-58
Prepacked columns	
HiPrep 16/10 SP XL 20 ml	17-5093-01
HiTrap SP XL 5×1 ml	17-5160-01
HiTrap SP XL 5×5 ml	17-5161-01
HiTrap IEX Selection Kit 7×1 ml	17-6002-33

Technical data	
Composition	cross-linked 6% agarose with dextran coating
Particle size	45–165 µm
Binding capacity	>160 mg lysozyme/ml medium
Ion capacity	0.18–0.25 mmol H^+/ml medium
pH stability (operational)	4–13
CIP stability (working)	3–14
Flow rate	300–500 cm/h

Superdex 30 prep grade. See p 84–85

Pack size	Code No.
25 ml	17-0905-10
150 ml	17-0905-01
1 l	17-0905-03
5 l	17-0905-04
Data File	18-1020-92
Regulatory Support File	11-0028-67
Prepacked columns	
HiLoad 16/60 Superdex 30 prep grade 120 ml	17-1139-01
HiLoad 26/60 Superdex 30 prep grade 320 ml	17-1140-01

Technical data	
Composition	composite of cross-linked agarose and dextran
Particle size	34 µm
Fractionation range, globular proteins	up to 1×10^4
pH stability (operational)	3–12
CIP stability (short term)	1–14
Max pressure	300 kPa

Superdex 75 prep grade. See p 84–85

Pack size	Code No.
25 ml	17-1044-10
150 ml	17-1044-01
1 l	17-1044-02
5 l	17-1044-04
Data File	18-1020-92
Regulatory Support File	11-0028-66

Prepacked columns

HiLoad 16/60 Superdex 75 prep grade 120 ml	17-1068-01
HiLoad 26/60 Superdex 75 prep grade 320 ml	17-1070-01

Technical data

Composition	composite of cross-linked agarose and dextran
Particle size	34 µm
Fractionation range, globular proteins	3×10^3–7×10^4
pH stability (operational)	3–12
CIP stability (short term)	1–14
Max pressure	300 kPa

Superdex 200 prep grade. See p 84–85

Pack size	Code No.
25 ml	17-1043-10
150 ml	17-1043-01
1 l	17-1043-02
5 l	17-1043-04
10 l	17-1043-05
60 l	17-1043-06
Data File	18-1020-92
Regulatory Support File	11-0028-66

Prepacked columns

HiLoad 16/60 Superdex 200 prep grade 120 ml	17-1069-01
HiLoad 26/60 Superdex 200 prep grade 320 ml	17-1071-01

Technical data

Composition	composite of cross-linked agarose and dextran
Particle size	34 µm
Fractionation range, globular proteins	1×10^4–6×10^5
Flow rate	30–60 cm/h
pH stability (operational)	3–12
CIP stability (short term)	1–14
Max pressure	300 kPa

Solid supports for oligonucleotide synthesis.

Oligosynt, prepacked disposable columns. See p 195

Product*	Code No.
Oligosynt dA	
15 µmol	17-5210-01
30 µmol	17-5210-02
120 µmol	17-5210-03
Oligosynt dC	
15 µmol	17-5211-01
30 µmol	17-5211-02
120 µmol	17-5211-03
Oligosynt dG	
15 µmol	17-5212-01
30 µmol	17-5212-02
120 µmol	17-5212-03
Oligosynt T	
15 µmol	17-5213-01
30 µmol	17-5213-02
120 µmol	17-5213-03

Technical data

Composition	Cross-linked polystyrene
Particle size	30 µm

* The 15 µmol columns are sold in packs of 10, the 30 µmol columns in packs of 5, and the 120 µmol columns in packs of 2.

Primer Support 200. See p 194

Product	Code No.
Primer Support 200 dA Synth	
1 mmol	17-5288-01
10 mmol	17-5288-02
50 mmol	17-5288-03
100 mmol	17-5288-04
Primer Support 200 dC Synth	
1 mmol	17-5289-01
10 mmol	17-5289-02
50 mmol	17-5289-03
100 mmol	17-5289-04
Primer Support 200 dG Synth	
1 mmol	17-5290-01
10 mmol	17-5290-02
50 mmol	17-5290-03
100 mmol	17-5290-04
Primer Support 200 T Synth	
1 mmol	17-5292-01
10 mmol	17-5292-02
50 mmol	17-5292-03
100 mmol	17-5292-04
Regulatory Support File	11-0029-20

Technical data

Composition	Cross-linked polystyrene
Particle size	30 µm
Matrix	Cross-linked polystyrene/ divinylbenzene
Bead size (in acetonitrile)	30 µm, retains size in all oligonucleotide in all synthesis reagents
Bead form	Spherical, porous, monodispersed
Particle size distribution	Max 5% CV
Storage	4 to 30°C
Degree of nucleoside substitution	200 ±10 µmol/g
Max recommended bed height	10 cm

Custom Primer Support 200. See p 195

Product*	Code No.
Primer Support dA 40s	
1 g	17-5214-37
10 g	17-5214-31
100 g	17-5214-11
Primer Support dC 40s	
1 g	17-5214-38
10 g	17-5214-32
100 g	17-5214-12
Primer Support dG 40s	
1 g	17-5214-39
10 g	17-5214-33
100 g	17-5214-13
Primer Support T 40s	
1 g	17-5214-40
10 g	17-5214-34
100g	17-5214-14
Primer Support dA 80s	
1 g	17-5250-83
10g	17-5250-82
100g	17-5250-80
Primer Support dC 80s	
1 g	17-5251-83
10g	17-5251-82
100g	17-5251-80
Primer Support dG 80s	
1 g	17-5252-83
10 g	17-5252-82
100g	17-5252-80
Primer Support T 80s	
1 g	17-5253-83
10 g	17-5253-82
100g	17-5253-80
Primer Support riboA 40	
1 g	17-5225-17
10 g	17-5214-85
Primer Support riboC 40	
1 g	17-5225-18
10 g	17-5214-86
Primer Support riboG 40	
1 g	17-5225-19
10 g	17-5214-87
Primer Support riboU 40	
1 g	17-5225-20
10 g	17-5214-88
Primer Support riboA 80	
1 g	17-5225-13
10 g	17-5214-50
Primer Support riboC 80	
1 g	17-5225-14
10 g	17-5214-51
Primer Support riboG 80	
1 g	17-5225-15
10 g	17-5214-52
Primer Support riboU 80	
1 g	17-5225-06
10 g	17-5214-53

Technical data

Composition	Cross-linked polystyrene
Particle size	30 µm

Base protection is ABz, CBz, Gibu, and T for DNA oligonucleotides.

Base protection is ABz, CBz, Gibu, and U for RNA oligonucleotides.

* The number indicated in the product name refers to loading in µmol/g. The "s" in the product name indicates "spacer". Alternative pack sizes are available.

Glossary of terms

BioProcess Media
This label designates our media that have been specifically designed to meet the demands of industrial biotechnology:

- Scalable from lab to production
- With comprehensive documentation
- Meeting productivity requirements
- Having validated manufacturing procedures
- With developed CIP and sanitization-in-place procedures
- Offering security of supply

Fast Trak
Fast Trak is a range of consulting, process development, validation and training services, available to companies working with downstream processing of biopharmaceuticals and diagnostics.

ISO 9001
This International Standard is one of a series of three quality management standards that ensure consistent and reliable quality. ISO-9001 has the widest scope and covers design/development, production, installation and servicing. ISO-9001 is accepted as a basic qualification for any company supplying the biotechnology industry.

Validation
This is the process of establishing documentary evidence that provides a high degree of assurance that any product, process, activity, procedure, system, equipment or software used in the control and manufacture consistently performs to or meets its predetermined specifications.

Sanitization-in-Place
The use of chemical reagents to reduce microbial populations to very low levels in packed columns, equipment and systems.

CIP
Cleaning-in-place is the *in situ* removal of tightly bound substances or particulate matter from media and equipment used in downstream purification.

Regulatory Support File
This document contains information about our products, in particular our media to support process validation, writing of SOPs, quality control and applications submitted to regulatory authorities. The contents include technical specifications, examples of Certificates of Analysis, instructions for use, and leakage and toxicity data.

Hardware Product Documentation
This documentation contains column information to support process validation. Contents include product descriptions, column wetted components and certificates and statements of materials.

Terms and conditions of sale / Trademarks / Licensing information

Unless otherwise agreed in writing all goods and services are sold subject to the following terms and conditions.

Any use of commercially available software is subject to GE Healthcare Standard Software End-User License Agreement for Life Sciences Software Products.

In no event shall the products be used for *in vivo* applications. Any warranty granted by GE Healthcare shall be deemed void if any goods covered by such warranty are used for any purpose not permitted hereunder.

For the latest information on our trademarks, patent and licensing please go to our website **www.gelifesciences.com/protein_purification**

GE Healthcare Bio-Sciences AB.

English

Translations of the following terms and conditions are available at **www.gelifesciences.com/protein_purification**. In same territories, local variations to these terms and conditions may apply, If so, such variations are available at **www.gelifesciences.com/protein_purification** and at the local sales office, The local variations shall take precedent in the event of any inconsistency with these conditions.

Dansk

Oversættelser af efterfølgende Almindelige forretningsbetingelser findes under **www.gelifesciences.com/protein_purification**. I nogle lande kan der forekomme lokale varianter af de Almindelige forretningsbetingelser. Hvis det er tilfældet, findes disse under **www.gelifesciences.com/protein_purification** eller på de lokale salgskontorer. Hvis de lokale varianter afviger fra de Almindelige forretningsbetingelser, er det altid førstnævnte, der gælder.

Deutsch

Übersetzungen der nachfolgenden Allgemeinen Geschäftsbedingungen können eingesehen werden unter **www.gelifesciences.com/protein_purification**. In einigen Ländern können örtliche Varianten zu den Allgemeinen Geschäftsbedingungen gelten. Wenn dies der Fall ist, so können die örtlich geltenden Varianten unter **www.gelifesciences.com/protein_purification** oder in dem jeweiligen Vertriebsbüro vor Ort eingesehen werden. Falls die örtlich geltenden Varianten von den Allgemeinen Geschäftsbedingungen abweichen, sind die örtlichen geltenden Varianten als maßgebend anzusehen.

Español

Traducciones de las siguientes Condiciones Comerciales Generales pueden verse en **www.gelifesciences.com/protein_purification**. En algunos países pueden tener validez variantes locales de estas Condiciones Comerciales Generales. Si es así, las variantes localmente válidas pueden verse en **www.gelifesciences.com/protein_purification** o en "*in situ*" en la respectiva oficina distribuidora. Si las variantes de validez local difieren de las Condiciones Comerciales Generales, estas variantes deberán considerarse normativas.

Français

Les traductions des Conditions Générales de Vente suivantes pourront être consultées sous **www.gelifesciences.com/protein_purification**. Des variantes locales des Conditions Générales de Vente peuvent être applicables dans certains pays. Si cela est le cas, les variantes en vigueur localement peuvent être consultées sous **www.gelifesciences.com/protein_purification** ou dans les bureaux de distribution sur place. Si les variantes en vigueur localement divergent des Conditions Générales de Vente, les variantes en vigueur localement devront être considérées comme déterminantes.

Italiano

Le traduzioni delle seguenti condizioni generali di contratto possono essere visionate sotto **www.gelifesciences.com/protein_purification**. In alcuni paesi possono trovare applicazione alcune varianti locali. In questo caso, le eventuali varianti vigenti in loco possono essere visionate sotto **www.gelifesciences.com/protein_purification** o negli uffici di vendita in loco. Se queste varianti differiscono dalle condizioni generali di contratto, sono da considerarsi determinanti le varianti locali.

Nederlands

Vertalingen van de navolgende algemene handelsvoorwaarden kunnen ingezien worden onder **www.gelifesciences.com/protein_purification**. In enkele landen kunnen plaatselijke varianten voor de algemene handelsvoorwaarden gelden. Indien dit het geval is, kunnen de plaatselijk geldende varianten onder **www.gelifesciences.com/protein_purification** of in het betreffende verkoopkantoor ter plaatse ingezien worden. Indien de plaatselijk geldende varianten van de algemene handelsvoorwaarden afwijken, dienen de plaatselijk geldende varianten als doorslaggevend te worden aanzien.

Norsk

Oversettelser av de etterfølgende generelle forretningsvilkår finnes på **www.gelifesciences.com/protein_purification**. For enkelte land gjelder lokale tilpasninger av forretningsvilkårene. Der hvor dette er tilfelle, gir **www.gelifesciences.com/protein_purification** eller det lokale salgskontor innsikt i de vilkår som gjelder. Dersom det ikke er samstemmighet mellom lokale og generelle forretningsvikår vil de lokale vilkårene gjelde.

Portugês

As traduções das seguintes regras gerais do comércio podem ser visualizadas em **www.gelifesciences.com/protein_purification**. Em alguns países podem ser válidas variantes locais destas regras gerais de comércio. Se este for o caso, as variantes locais válidas podem ser visualizadas em **www.gelifesciences.com/protein_purification** ou no respectivo escritório de vendas no local. Caso as variantes locais válidas desviem das regras gerais do comércio, as variantes locais válidas devem ser tomadas como determinantes.

Suomi

Seuraavien yleisten kauppaehtojen käännökset voi lukea sivulta **www.gelifesciences.com/protein_purification**. Joissakin maissa näistä yleisistä kauppaehdoista voi olla voimassa paikallisia muunnelmia. Jos näin on, voit lukea paikallisesti voimassa olevat muunnelmat sivulta **www.gelifesciences.com/protein_purification** tai paikallisessa myyntikonttorissa. Jos paikalliset muunnelmat poikkeavat yleisistä kauppaehdoista, paikallisia muunnelmia on pidettävä ratkaisevina.

Svenska

Översättning av nedanstående villkor är tillgängliga under **www.gelifesciences.com/protein_purification**. I några länder tillämpas lokala varianter av dessa bestämmelser och villkor. Dessa varianter är då tillgängliga under **www.gelifesciences.com/protein_purification** och i de lokala försäljningslokalerna. De lokala varianterna har företräde i fall av oförenlighet med dessa villkor.

Terms and conditions of sale

1. General

1.1 In these Terms and Conditions:
The *Buyer* means the person, firm, company or other organization who or which has ordered Products and/or Services from GEHC; *GEHC* means the GE Healthcare group company referred to in the final written offer, quotation or order acknowledgement or, if none, the GE Healthcare company making the supply;

The *Contract* means the contract for the sale and purchase of Products and/or Services between GEHC and the Buyer as may be further evidenced by GEHC's final written offer, quotation or order acknowledgement and no prior proposals, statements, representations or conditions will be binding on either party;

The *Equipment* means all electronic equipment, hardware and other electronic or mechanical items agreed to be supplied by GEHC, excluding any consumables and spare parts sold separately; The *Goods* means all items agreed to be supplied by GEHC other than the Equipment and Software; The *Products* means any Goods, Equipment or Software agreed to be supplied by GEHC; and The *Services* means all advice given and services performed by GEHC; and

The *Software* means any firmware, software or data compilations (i) identified in the Contract or (ii) provided to Buyer by GEHC in connection with installation or operation of the Equipment. For the avoidance of doubt, *Software* shall not include any "open source" firmware, software or data compilations, as any such "open source" firmware, software or data compilations will be subject to the terms and conditions set out in the relevant "open source" license.

1.2 These Terms and Conditions shall be incorporated into the Contract and shall apply to the exclusion of any conditions of the Buyer. These Terms and Conditions may not be varied or waived except with the express written agreement of GEHC. The failure of GEHC to enforce its rights under the Contract at any time, for any period of time, shall not be construed as a waiver of any such rights.

2. Prices and Quotations

The price of the Products and/or Services will be GEHC's quoted price, inclusive of any duties, but exclusive of value added or other taxes. All quotations issued by GEHC for the supply of Products and/or Services shall remain open for acceptance for the period stated in the quotation or, if none is stated, for sixty (60) days. In all other cases, prices payable are those currently in effect in GEHC´s then current pricelist.

3. Payment

3.1 Unless otherwise agreed in writing, payment in full shall be made to GEHC in the currency invoiced, no later than thirty (30) days from the date of invoice.

3.2 In the event of late payment, GEHC reserves the right:
(i) to suspend deliveries and/or cancel any of its outstanding obligations; and
(ii) to charge interest at the lower of (a) an annual rate equal to twelve (12) % and (b) any applicable maximum statutory rate on all unpaid amounts calculated on a day to day basis until the actual date of payment.

4. Changes and Returns

4.1 GEHC reserves the right, subject to prior written notice, to make any change in the specification of the Products, which does not materially affect the installation, performance or price thereof.

4.2 Products may only be returned with prior authorization from GEHC.

5. Delivery/Installation/Acceptance

5.1 Any term of delivery shall be construed according the latest edition of Incoterms. If no other term of delivery has been specified in the Contract the Products will be delivered CIP to Buyer's premises or to the agreed destination.

5.2 Partial deliveries shall be permitted. If the Buyer fails to accept delivery of the Products within a reasonable period after receiving notice from GEHC that they are ready for delivery, GEHC may dispose of or store the Products at the Buyer's expense.

5.3 GEHC will use all reasonable endeavours to avoid delay in delivery on the notified delivery dates. Failure to deliver by the specified date will not be a sufficient cause for cancellation, nor will GEHC be liable for any loss or damage due to delay in delivery.

5.4 The Buyer shall notify GEHC in writing within five (5) working days of delivery of any short delivery or defects reasonably discoverable on careful examination. GEHC's sole obligation shall be, at its option, to replace or repair any defective Products or refund the purchase price of any undelivered Products.

5.5 Where delivery of any Product requires an export license or other authorization before shipment, GEHC shall not be responsible for any delay in delivery due to delay in, or refusal of, such license or authorization.

5.6 Where the Equipment requires installation, the Buyer shall be responsible at its own cost for making the place where the Equipment will be located ready for installation in accordance with GEHC's instructions. Installation will not begin unless such responsibilities are completed.

5.7 Following installation, where applicable, GEHC will proceed with final testing using GEHC's published performance specifications and using its standard instruments and procedures. Upon the satisfactory completion of such final testing demonstrating compliance with the above specifications (with any permitted variations/tolerances) GEHC may issue a Test Certificate which shall be conclusive evidence of such compliance and thereupon installation of the Equipment shall be deemed to be complete and in compliance with GEHC's obligations under the Contract. Buyer agrees that the Equipment is accepted (i) seven (7) days after the date on which GEHC notifies Buyer that final testing was successfully completed, or issues the Test Certificate or (ii) on the date Buyer first uses the Product for operational use, whichever is earlier.

5.8 Buyer, at its reasonable request, shall be entitled to be present at and to witness the testing and shall not be entitled to raise any objection to testing carried out, or to the results thereof, if Buyer failed to attend when advised that testing was to take place.

5.9 Where Products are supplied by GEHC in returnable containers, these must be returned at the Buyer's expense and in good condition, if requested by GEHC. Title to these containers shall remain with GEHC at all times, but they shall be held at the risk of the Buyer until returned to GEHC. Failure by the Buyer to comply with the above provision shall entitle GEHC to invoice the Buyer for the full replacement value of the containers.

6. Risk and Title

6.1 The Buyer shall bear all the risks of loss of and damage to the Products on delivery. Full title to the Goods and Equipment shall pass to the Buyer on full payment. The Buyer agrees not to dispose of or resell the Equipment, until it has been paid for in full.

6.2 In relation to any Equipment used for clinical or diagnostic purposes, the Buyer shall keep adequate written records of the identity of any person or entity to whom the Equipment is transferred and of the location of such Equipment and shall procure that any purchaser of such Equipment is subject to the same requirement in respect of any onward sales.

7. Services

Where GEHC is to provide Services, the Buyer shall ensure that adequate and safe facilities exist at its premises and that GEHC is properly notified of any relevant regulations.

8. Restricted Use

With respect to certain Products, use restrictions are a condition of the purchase which Buyer must satisfy by strictly abiding by the restriction as set forth in GEHC's catalogue and/or on the Product and/or accompanying documentation. Buyer is solely liable to ensure compliance with any regulatory requirements related to the Buyer's use of the Products. Any warranty granted by GEHC to the Buyer shall be deemed void if any Products covered by such warranty are used for any purpose not permitted hereunder. In addition, the Buyer shall indemnify GEHC and hold GEHC harmless from and against any and all claims, damages, losses, costs, expenses and other liability of whatever nature that GEHC suffers or incurs by reason of any such unintended use.

9. General Warranty

9.1 Section 9.2–9.5 shall apply in the event no other specific warranty has been agreed in the Contract.

9.2 Goods – GEHC warrants that its Goods meet GEHC's specifications at the time of delivery. All warranty claims on Goods must be made in writing within ninety (90) days of receipt of the Goods. GEHC's sole liability and Buyer's exclusive remedy for a breach of this warranty is limited to repair, replacement or refund at the sole option of GEHC.

9.3 Equipment – GEHC's Equipment of its own manufacture is warranted from date of delivery or completion of installation, if later, to be free of defects in workmanship or materials under normal usage for a period of one (1) year and any claim shall be submitted in writing within such period. GEHC's sole liability and Buyer's exclusive remedy for a breach of this warranty is limited to repair, replacement or refund at the sole option of GEHC. Such repairs or replacement will not extend the warranty period.

9.4 Software – GEHC warrants, for a period of ninety (90) days from the date of receipt, that the Software substantially conforms to its published specifications and the media on which the Software resides will be free from defects in materials and workmanship under normal use. GEHC does not warrant that the Software is error free or that Buyer will be able to operate the Software without problems or interruptions. GEHC´s sole liability and Buyer's exclusive remedy in the event of breach of this warranty is limited to repair, replacement or refund, at the sole option of GEHC.

9.5 Services – GEHC warrants that all Services will be carried out with reasonable care and skill. GEHC's sole liability for breach of this warranty shall be at its option to give credit for or reperform the Services in question. This warranty shall only extend for a period of ninety (90) days after the completion of the Services.

9.6 To the maximum extent permitted by applicable law GEHC hereby expressly disclaims, and Buyer hereby expressly waives, any warranty regarding results obtained through the use of the Products, including without limitation any claim of inaccurate, invalid, or incomplete results. All other warranties, representations, terms and conditions (statutory, express, implied or otherwise) as to quality, condition, description, merchantability, fitness for purpose or non-infringement (except for the implied warranty of title) are hereby expressly excluded.

9.7 Unless expressly agreed, GEHC is not obliged to carry out dismantling or re-installation of any Product in connection with any warranty claims.

10. Limitation of Liability

10.1 GEHC shall have no liability under the warranties contained in Section 9 in respect of any defect in the Products arising from: specifications or materials supplied by the Buyer; fair wear and tear; wilful damage or negligence of the Buyer or its employees or agents; abnormal working conditions at the Buyer's premises; failure to follow GEHC's use restrictions or instructions (whether oral or in writing); misuse or alteration or repair of the Products without GEHC's approval; or if the Buyer is in breach of its payment obligations under this Contract.

10.2 Subject to any express obligation to indemnify, neither party shall be liable for any indirect or consequential, or punitive damages of any kind from any cause arising out of the sale, installation, use or inability to use any Product or Service, including without limitation, loss of profits, goodwill or business interruption.

10.3 The total liability of GEHC arising under or in connection with the Contract, including for any breach of contractual obligations and/or any misrepresentation, misstatement or tortious act or omission (including without limitation, negligence and liability for infringement of any third party intellectual property rights) shall be limited to damages in an amount equal to the amount paid to GEHC under the Contract.

10.4 The exclusion of liability in these Terms and Conditions shall not apply in respect of death or personal injury caused by GEHC's negligence.

11. Intellectual Property Rights

11.1 Where the Buyer supplies designs, drawings, and specifications to GEHC to enable it to manufacture non-standard or custom made Products, the Buyer warrants that such manufacture will not infringe the intellectual property rights of any third party.

11.2 All intellectual property rights in the Products and/or Services shall at all times remain vested in GEHC or its licensors.

12. Health, Safety and Waste

The Buyer shall ensure that:

(i) the Products (provided such Products comply with its specifications) are suitable and safe for the Buyer´s intended use;
(ii) the Products are handled in a safe manner.
(iii) containers, packaging, labelling, equipment and vehicles, where provided by the Buyer, comply with all relevant national and international safety regulations.

13. Indemnities

Except where a claim arises as a direct result of the negligence or breach of contract of GEHC, the Buyer shall indemnify GEHC in respect of any claim which may be made against GEHC:

(i) arising in connection with the Buyer's use of the Products;
(ii) alleging that the Buyer´s use of the Products infringes the intellectual property rights of any third party.

14. Insolvency

In the event that the Buyer becomes insolvent or applies for bankruptcy or, being a company, goes into liquidation (other than for the purposes of reconstruction or amalgamation), GEHC shall be entitled immediately to terminate the Contract without notice and without prejudice to any other rights of GEHC hereunder.

15. Force Majeure

15.1 GEHC shall not be liable in respect of the non-performance of any of its obligations to the extent such performance is prevented by any circumstances beyond its reasonable control including but not limited to, strikes, lock outs or labour disputes of any kind (whether relating to its own employees or others), fire, flood, explosion, natural catastrophe, military operations, blockade, sabotage, revolution, riot, civil commotion, war or civil war, acts or threats of terrorism, plant breakdown, computer or other equipment failure and inability to obtain equipment.

15.2 If an event of force majeure exceeds one (1) month GEHC may cancel the Contract without liability.

16. Software License

Unless a separate software license agreement has been concluded concerning the Software, the Buyer is hereby granted a non-exclusive license to use the Software solely in object code format and solely for its own internal business purposes subject to the terms contained herein. The Buyer shall not (i) use the Software for purposes other than those for which it was designed; (ii) use the Software in connection with other manufacturers' products unless such connectivity is authorized in the Product documentation; (iii) grant, assign, transfer, or otherwise make available to third parties any right whatsoever in the Software; (iv) disclose to third parties any information contained in the Software; (v) copy or reproduce the Software (except for one copy for back-up purposes or as may otherwise be permitted by applicable law); (vi) alter or modify the Software; or (vii) reverse engineer, decompile, disassemble or create any derivative works based upon the Software except as expressly permitted by law.

17. Export control

The Buyer undertakes not to re-export the Products without the requisite export license from the relevant body of the United Nations or other similar international organization, the United States Government, the country of origin or the original country of export. The requirement to obtain a license may vary depending on the country of destination, the end user, the end use and other factors. Upon request from GEHC the Buyer shall furnish GEHC with copies of all documents relating to such re-export.

18. Waste Electrical and Electronic Equipment (WEEE)

18.1 Where the Buyer sells, disposes of or otherwise transfers the Equipment to any third party and where this would unreasonably increase the cost of the collection, treatment or recycling of the Equipment for GEHC under applicable WEEE legislation, Buyer shall be liable to GEHC and indemnify GEHC for such increased costs.

18.2 Should the Equipment that Buyer acquires from GEHC be Equipment, which is intended to replace on a 'like for like'-basis, any item of Buyer's existing equipment (e.g., the new Equipment is fulfilling the same function as Buyer's existing equipment) Buyer must have clearly indicated to GEHC the following: the brand, type, age, condition, current use and the exact location and all other relevant information. In the event Buyer has not complied with such obligations, GEHC may charge Buyer such reasonable additional fees to reflect any related obligations it may have under national legislation regarding the recycling, reuse and/or disposal of such existing equipment and related costs it may incur.

18.3 Unless the relevant mandatory national legislation provides otherwise, or unless otherwise agreed in writing, GEHC´s obligation does not include without limitation, creation of physical access to the equipment; de-installation; decoupling; disinfecting; craning/lifting; transportation to a ground level loading area or -ramp; packing; or any related similar activities; and Buyer agrees to perform such activities at its own cost as and when required.

19. Governing Law

This Contract shall be governed by and construed in accordance with the substantive laws of the country or state where the GE Healthcare group company (or relevant branch) office referred to in the Contract is situated and the parties hereby submit to the non-exclusive jurisdiction of the courts of that country or state.

20. Product-Specific Terms and Conditions

Additional terms and conditions govern the sale of certain Products and Services. These additional terms and conditions are available from the sales offices of GEHC and shall take precedence in the event of any inconsistency with these Terms and Conditions.

21. Translations and Local Variations

Translations of these terms and conditions are available from the sales offices of GEHC. In some territories, local variations to these Terms and Conditions may apply. If so, such variations shall take precedence in the event of any inconsistency with these Terms and Conditions.

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GE Healthcare trademarks

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Capto ViralQ
Separating viral particles with Capto Q products may require a license under United States patent number 6,537,793 B2 and equivalent patents and patent applications in other countries owned by Centelion SAS. Such a license is not included with the purchase of Capto Q but is included with the purchase of Capto ViralQ products.

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Chelating Sepharose Fast Flow and Ni Sepharose 6 Fast Flow
US patent numbers 5,284,933 and 5,310,663, and equivalent patents and patent applications in other countries (assignee: Hoffman La Roche, Inc) relate to the purification and preparation of fusion proteins and affinity peptides comprising at least two adjacent histidine residues (commonly known as the histidine-tag technology).

Any customer that wishes to use Chelating Sepharose Fast Flow, Ni Sepharose 6 Fast Flow or IMAC Sepharose 6 Fast Flow for non-research/commercial applications under these patents is requested to contact Hoffman-La Roche AG, Corporate licensing, attention Dr Andreas Maurer, CH-4070 Basel, Switzerland, telephone +41 61 687 2548, fax +41 61 687 2113, for the purpose of obtaining a license.

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Any customer that wishes to use Chelating Sepharose Fast Flow, Ni Sepharose 6 Fast Flow or IMAC Sepharose 6 Fast Flow for non-research/commercial applications under these patents is requested to contact Hoffman-La Roche AG, Corporate licensing, attention Dr Andreas Maurer, CH-4070 Basel, Switzerland, telephone +41 61 687 2548, fax +41 61 687 2113, for the purpose of obtaining a license.

IMAC Sepharose products, Ni-Sepharose products and Fe-Sepharose products
IMAC Sepharose products, Ni-Sepharose products and Fe-Sepharose products are covered by US pat No 6 623 655 and their equivalents in other countries.

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Use of these supports for the synthesis of polynucleotides is licensed under the following patents when the synthesis is performed on an instrument provided by a licensed supplier: US patent numbers 4,458,066; 4,973,679; 5,047,524 and 5,262,530, and equivalent patents and patent applications in other countries. No other license is granted to the purchaser either directly or by implication, estoppel or otherwise. Patented reagents suitable for use with this instrument are available from licensed sources.

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ReadyMate
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GE Healthcare UK Ltd.
Amersham Place
Little Chalfont
Buckinghamshire, HP7 9NA
UK

GE Healthcare Europe GmbH
Munzinger Strasse 5
D-79111 Freiburg
Germany

GE Healthcare Bio-Sciences Corp.
800 Centennial Avenue
P.O. Box 1327, Piscataway
NJ 08855-1327
USA

GE Healthcare Bio-Sciences KK
Sanken Bldg., 3-25-1, Hyakunincho
Shinjuku-ku, Tokyo 169-0073
Japan

For contact information for your local office,
please visit: www.gelifesciences.com/contact

GE Healthcare Bio-Sciences AB
Björkgatan 30
751 84 Uppsala
Sweden

www.gelifesciences.com/bioprocess

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