CRM Product Guide

Boston Scientific
Delivering what's next.™

Pacing, Defibrillation, and Cardiac Resynchronization Therapy

December 2008

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Pacing Pulse Generators

Defibrillation Pulse Generators

Cardiac Resynchronization Therapy Pulse Generators

Pacing Leads and Accessories

Defibrillation Leads and Accessories

Cardiac Resynchronization Therapy Leads and Accessories

The LATITUDE® Patient Management system is compatible with virtually all Boston Scientific ICD and CRT-D devices.

LATITUDE Wanded Communicator (Model 6481)

CRT-D		ICD		ICD	
H115	CONTAK® CD 2	1850	VENTAK PRIZM® VR	T135	VITALITY® DS VR
H119	CONTAK CD 2 HE	1852	VENTAK PRIZM VR HE	T125	VITALITY DS DR
H135	CONTAK RENEWAL®	1857	VENTAK PRIZM VR HE	T127	VITALITY EL DR
H170	CONTAK RENEWAL 3	1860	VENTAK PRIZM 2 VR	T180	VITALITY HE
H175	CONTAK RENEWAL 3	1851	VENTAK PRIZM DR	T165	VITALITY 2 DR
H177	CONTAK RENEWAL 3 HE	1853	VENTAK PRIZM DR HE	T167	VITALITY 2 EL DR
H179	CONTAK RENEWAL 3 HE	1858	VENTAK PRIZM DR HE	T175	VITALITY 2 VR
		1861	VENTAK PRIZM 2 DR	T177	VITALITY 2 EL VR

LATITUDE Push Button Wireless Communicator (Model 6482)

CRT-D Wireless		CRT-D Wireless		ICD Wireless	
H210	CONTAK RENEWAL 3 RF	H220	LIVIAN™ RF	E030	CONFIENT™ RF HE
H215	CONTAK RENEWAL 3 RF	H225	LIVIAN RF		
H217	CONTAK RENEWAL 3 RF HE	H227	LIVIAN RF HE		
H219	CONTAK RENEWAL 3 RF HE	H229	LIVIAN RF HE		

LATITUDE® Touch Screen Wireless Communicator (Model 6476)

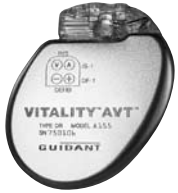
CRT-D Wireless		ICD Wireless	
N118	COGNIS™ RF HE	E102	TELIGEN™ VR RF HE
N119	COGNIS RF HE	E110	TELIGEN DR RF HE

Product	Description	Model	Type	Longevity (years)	Volume (cc)	Thickness (mm)	Header	Diagram
ALTRUA™ 60	-AV Delay extendable to 400 ms -MV Blended Sensor -Stored Onset EGMs -Automatic Capture -AV Search Hysteresis -AutoLifestyle® -Ventricular Rate Regulation -Sudden Brady Response	**S601** **S602** **S603** **S606**	SR DR DR DR	8.6[1] 8.8[1] 6.5[1] 8.8[1]	10.0 12.6 10.8 12.6	8 8 8 8	IS-1 3.2 mm/IS-1 compatible IS-1 IS-1	
ALTRUA 40	-MV Blended Sensor -Stored Onset EGMs -AV Search Hysteresis -Ventricular Rate Regulation -Sudden Brady Response	**S401** **S403** **S404**	SR DR DR	7.7[2] 5.9[2] 8.1[2]	10.0 10.8 12.6	8 8 8	IS-1 IS-1 IS-1	
ALTRUA 20	-Stored Onset EGMs -Accelerometer Sensor -Dynamic AV Delay -Sudden Brady Response	**S201** **S203** **S204** **S205** **S208**	SR DR SR DR DR	9.6[3] 7.1[3] 9.6[3] 9.7[3] 9.7[3]	10.1 10.8 11.0 14.9 12.6	8 8 8 8 8	3.2 mm/IS-1 compatible IS-1 5/6 mm 5/6 mm IS-1	

1 Longevity projections as described in device user manual. Settings: 60 ppm, A=2.5 V, V=1.0 V, 500 ohms, 100% paced, MV Blended Sensor ON, Onset EGMs ON, Automatic Capture ON.
2 Longevity projection as described in user manual. Settings: 60 ppm, A=2.5 V, V=2.5 V, 500 ohms, 100% paced, MV Blended Sensor ON, Onset EGMS ON.
3 Longevity projection as described in user manual. Settings: 60 ppm, A=2.5 V, V=2.5 V, 500 ohms, 100% paced, Accelerometer Sensor ON, Onset EGMS ON.

Product	Description	Model	Type	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
TELIGEN™	-Safety Core™ and Safety Architecture -Quick Convert™ -Rhythm ID® and OBDE in the same device -2-zone nominals - AV Search + (up to 400 ms) -Li MnO_2 battery for extended longevity* and fast, consistent charge times over the life of the device -Programmable shock vectors -Indications-based programming -Respiratory rate trend -17 minutes of EGM storage, 3 channels on -Ventricular Rate Regulation	**E102** **E110**	VR DR	41 41	7	31.5 31.5	9.9 9.9	DF-1/IS-1 DF-1/IS-1	
CONFIENT™	-400 ms AV Delay -AV Search Hysteresis -Compatible with LATITUDE Patient Management System -Stored EGMs w/Onset -Ventricular Rate Regulation - Advanced battery technology	**E030**	DR	41	5	44	14.5	DF-1/IS-1	

*As compared with previous Boston Scientific devices

Product	Description	Model	Type	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
VITALITY® 2	-Rhythm ID -AV Search Hysteresis (DR only) -Ventricular Rate Regulation -FullView™ Stored EGMs w/Onset -Interval Graph -My Patient Profile with Quick Profiles™	**T165** **T175**	DR VR	31 31	5 5	30 30	11	DF-1/IS-1 DF-1/IS-1	
VITALITY 2 EL	-Rhythm ID -AV Search Hysteresis (DR only) -Ventricular Rate Regulation -FullView Stored EGMs w/Onset -Interval Graph -My Patient Profile with Quick Profiles	**T167** **T177**	DR VR	31 31	7 7	35 35	11	DF-1/IS-1 DF-1/IS-1	
VITALITY AVT®	-Automatic Atrial ATP -Atrial Rhythm Classification -Atrial Pacing Preference -Cardioversion -ProACt -Ventricular Rate Regulation -AV Search Hysteresis -FullView Stored EGMs w/Onset -Shock If Unstable -My Patient Profile	**A155**	DR	31	5	30	11	DF-1/IS-1	

Product	Description	Model	Type	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
VITALITY DS	-AV Search Hysteresis -FullView Stored EGMs w/Onset -Daily Measurements -Shock If Unstable -Patient-triggered Monitor	**T125** **T135**	DR VR	31 31	5 5	30 30	11	DF-1/IS-1	
VITALITY EL	-AV Search Hysteresis -FullView Stored EGMs w/Onset -Daily Measurements -Shock If Unstable -Patient-triggered Monitor	**T127**	DR	31	7	35	11	DF-1/IS-1	
VENTAK PRIZM® HE	-AV Search Hysteresis (DR only) -Energy-efficient Episode Onset -3-channel Stored EGMs (DR only) -Shock If Unstable	**1852** **1853** **1857** **1858**	VR DR VR DR	41 41 41 41	4 4 4 4	38 39 43 45	15 15 15 15	DF-1/IS-1 DF-1/IS-1 6.1 mm/4.75 mm 6.1 mm/4.75 mm IS-1 atrial	

Product	Description	Model	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
COGNIS™	-Safety Core and Safety Architecture -Quick Convert -SmartDelay™ algorithm for quick AV delay programming recommendations intended to provide optimally timed CRT -Electronic Repositioning™ with 6 configurations with bipolar leads -BiV Trigger and VRR -Rhythm ID and OBDE in the same device -Programmable shock vectors -Li MnO_2 battery for extended longevity* and fast, consistent charge times over the life of the device -Respiratory rate trend -2-zone nominals -Indications-based programming -17 minutes of EGM storage, 3 channels on	**N118** **N119**	41 41	5 5	32.5 32.5	9.9 9.9	IS-1/DF-1:LV-1 IS-1/DF-1:IS-1	

*As compared with previous Boston Scientific devices

Product	Description	Model	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
LIVIAN™	-SmartDelay algorithm for quick AV delay programming recommendations intended to provide optimally timed CRT -BiV Trigger and VRR -Compatible with LATITUDE Patient Management System -Electronic Repositioning -Stored EGMs with Onset -Advanced battery technology	**H220**	31	4	40	14.5	IS-1	
		H225	31		40	14.5	IS-1/LV-1	
LIVIAN HE		**H227**	41	4	44	14.5	IS-1	
		H229	41		44	14.5	IS-1/LV-1	

Product	Description	Model	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
CONTAK RENEWAL® 3	-Independent channels for right and left ventricular pacing and sensing	**H170** **H175**	31 31	3 + 2	37 37	11.5 11.5	IS-1 LV-1	
CONTAK RENEWAL 3 HE	-Patient-centric diagnostics: -HRV Monitor Footprint -ABM -HRV Monitor Trending -Activity Log -High-energy output -VRR -Fast charge time -Daily measurements	**H177** **H179**	41 41	3 + 1	40 40	11.5 11.5	IS-1 LV-1	

Product	Description	Model	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
CONTAK RENEWAL 3 RF	-Independent channels for right and left ventricular pacing and sensing -Patient-centric diagnostics: -Patient-triggered monitor -Heart rate variability (HRV) Monitor Footprint -Automatic Balance Monitor (ABM) -HRV Monitor Trending -Activity Log -Snapshot viewer -Ventricular Rate Regulation -Fast charge time -Daily measurements -Enhanced telemetry communication with ZIP™ wandless telemetry	**H210** **H215**	31 31	3 + 2	39 39	14 14	IS-1 LV-1	
CONTAK RENEWAL 3 RF HE		**H217** **H219**	41 41	3 + 1	43 43	14 14	IS-1 LV-1	

Product	Description	Model	Energy (J)	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
CONTAK RENEWAL	-Independent channels for right and left ventricular pacing and sensing -Patient-centric diagnostics: -Heart rate variability (HRV) Monitor Footprint -HRV Monitor Trending -Activity Log -Ventricular Rate Regulation	**H135**	31	3 + 2	45	15	LV-1	

Product	Description	Model	Warranty (years)	Volume (cc)	Thickness (mm)	Header	Diagram
CONTAK RENEWAL TR	-Independent channels for right and left ventricular pacing and sensing -Patient-centric diagnostics: -Heart rate variability (HRV) Monitor Footprint -HRV Monitor Trending -Activity Log -Ventricular Rate Regulation -Daily measurements -110 sec EGM storage	**H120** **H125**	5	14 14	8.5 8.5	IS-1 LV-1	

Due to variations among introducer manufacturers, please call CRM Technical Services at 1.800.CARDIAC for specific recommendations regarding introducer sizes

Product	Description	Model	Length (cm)	Insulation	Diagram
FINELINE® II STEROX EZ Active Fixation	-4 turns (55D poly), -6 turns (silicone) -IROX®-coated tip electrode -Thin co-radial design -IS-1 -Steroid elution -Bipolar	**4469** **4470** **4471** **4472** **4473** **4474**	45 52 58 45 52 58	55D Poly 55D Poly 55D Poly Silicone Silicone Silicone	
FINELINE II STEROX ATRIAL-J Passive Fixation	-Preformed J -IROX-coated tip electrode -Thin co-radial design -IS-1 -Steroid elution -Bipolar -Tined fixation	**4479** **4480**	45 52	55D Poly 55D Poly	
FINELINE II STEROX Passive Fixation	-IROX-coated tip electrode -Thin co-radial design -IS-1 -Steroid elution -Bipolar -Tined fixation	**4456** **4457** **4458** **4459**	52 58 52 58	55D Poly 55D Poly Silicone Silicone	

Product	Description	Model	Length (cm)	Insulation	Diagram
DEXTRUS™ Active Fixation	-Extendable/retractable -8 turns (minimum) -Iridium-coated tip electrode -IS-1 -Steroid elution -Bipolar	**4135** **4136** **4137**	45 53 60	Silicone Silicone Silicone	
FLEXTEND® Active Fixation	-Extendable/retractable -6–8 turns -IS-1 -Steroid elution -Bipolar	**4086** **4087** **4088**	45 52 59	Silicone Silicone Silicone	

Product	Model	From	To	Length (cm)	Diagram
Lead Adapter Sleeve	**6016**	(1) 3.2 mm low-profile or IS-1 unipolar connector	(1) 5 mm unipolar terminal	N/A	
Lead Adapter	**6017**	(1) 3.2 mm low-profile or IS-1 bipolar connector	(1) 4.75 mm bifurcated bipolar terminal	16	
Lead Adapter	**6018**	(1) 6.1 mm unipolar connector	(1) 3.2 mm low-profile unipolar terminal	15	
Lead Adapter	**6020**	(1) 4.75 mm unipolar connector	(1) 3.2 mm low-profile unipolar terminal	15	
Lead Adapter Sleeve	**6022**	(1) 3.2 mm low-profile or IS-1 connector	(1) 6 mm unipolar terminal	N/A	
Lead Adapter (Uses 2-unipolar4.75 mm or 1-Bif. Bipolar 4.75 mm)	**6024**	(2) 4.75 mm connectors	(1) IS-1 bipolar terminal	16	

Product	Model	From	To	Length (cm)	Diagram
Lead Cap Kit	**6504**	(2) 3.2 mm or (2) 4.75 mm connectors	N/A	N/A	
Lead Adapter Sleeve	**6526**	(2) 4.75 mm connectors	(1) 6 mm terminal	N/A	
Lead Cap Kit	**6811**	(2) 4.75 mm connectors	N/A	N/A	
Lead Adapter	**6986**	(1) IS-1 or 3.2 mm low-profile bipolar connector	(1) IS-1 bipolar terminal	14	
Lead Extender/Adapter	**6987**	(1) IS-1 or 3.2 mm low-profile bipolar connector	(1) IS-1 bipolar terminal	45	
IS-1 Port Plug (1)	**6998**	N/A	(2) IS-1 terminals	N/A	

Pacing Stylets

Type	Length (cm)	Firmness	Diameter (in)	Model	Knob Color	Cap Color
Wide Atrial J	45	Soft	0.014	**6053**	Green	White
Wide Atrial J	45	Firm	0.016	**6057**	White	White
Wide Atrial J	52	Soft	0.014	**6054**	Green	Red
Wide Atrial J	52	Firm	0.016	**6058**	White	Red
Wide Atrial J	59	Soft	0.014	**6055**	Green	Yellow
Wide Atrial J	59	Firm	0.016	**6059**	White	Yellow
Straight	45	Soft	0.014	**6505**	Green	White
Straight	45	Firm	0.016	**6507**	White	White
Straight	52	Soft	0.014	**6585**	Green	Red

Type	Length (cm)	Firmness	Diameter (in)	Model	Knob Color	Cap Color
Straight	52	Firm	0.016	**6583**	White	Red
Straight	52	Soft	0.014	**6585**	Green	Red
Straight	59	Soft	0.014	**6601**	Green	Yellow
Straight	59	Firm	0.016	**6602**	White	Yellow
Atrial J	45	Soft	0.014	**6506**	Green	White
Atrial J	45	Firm	0.016	**6508**	White	White
Atrial J	52	Firm	0.016	**6584**	White	Red
Atrial J	59	Soft	0.014	**6603**	Green	Yellow
Atrial J	59	Firm	0.016	**6604**	White	Yellow

FINELINE Stylets

Type	Length (cm)	Firmness	Diameter (in)	Model	Knob Color	Cap Color
Tapered	45	Soft	0.013	**6044**	Yellow	Yellow
Tapered	45	Limber	0.014	**6032**	Green	Yellow
Tapered	45	Firm	0.016	**6035**	White	Yellow
Tapered	52	Soft	0.013	**6045**	Yellow	Mint
Tapered	52	Limber	0.014	**6033**	Green	Mint
Tapered	52	Firm	0.016	**6036**	White	Mint
Tapered	58	Soft	0.013	**6046**	Yellow	Purple
Tapered	58	Limber	0.014	**6034**	Green	Purple
Tapered	58	Firm	0.016	**6037**	White	Purple
Atrial J	45	Soft	0.013	**6050**	Yellow	Yellow
Atrial J	45	Limber	0.014	**6038**	Green	Yellow
Atrial J	45	Firm	0.016	**6041**	White	Yellow
Atrial J	52	Soft	0.013	**6051**	Yellow	Mint
Atrial J	52	Limber	0.014	**6039**	Green	Mint
Atrial J	52	Firm	0.016	**6042**	White	Mint

Type	Length (cm)	Firmness	Diameter (in)	Model	Knob Color	Cap Color
Atrial J	58	Soft	0.013	**6052**	Yellow	Purple
Atrial J	58	Limber	0.014	**6040**	Green	Purple
Atrial J	58	Firm	0.016	**6043**	White	Purple
Straight	45	Soft	0.013	**6047**	Yellow	Yellow
Straight	45	Limber	0.014	**6061**	Green	Yellow
Straight	45	Firm	0.016	**6064**	White	Yellow
Straight	52	Soft	0.013	**6048**	Yellow	Mint
Straight	52	Limber	0.014	**6062**	Green	Mint
Straight	52	Firm	0.016	**6065**	White	Mint
Straight	58	Soft	0.013	**6049**	Yellow	Purple
Straight	58	Limber	0.014	**6063**	Green	Purple
Straight	58	Firm	0.016	**6066**	White	Purple

Product	Description	Model	Length (cm)	Insulation	Diagram
ENDOTAK RELIANCE® G Active Fixation	-ePTFE-covered coils -Terminal pin-driven -Extendable/retractable -8 Turns (10 turns(0187)) -Dual-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	0184 0185 0186 0187	59 64 70 90	Silicone Silicone Silicone Silicone	
ENDOTAK RELIANCE SG Active Fixation	-ePTFE-covered coil -Terminal Pin-driven -Extendable/retractable -8 turns -Single-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	0180 0181 0182	59 64 70	Silicone Silicone Silicone	
ENDOTAK RELIANCE G Passive Fixation	-ePTFE-covered coils -High Impedance -Dual-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	0174 0175 0176 0177	59 64 70 90	Silicone Silicone Silicone Silicone	
ENDOTAK RELIANCE SG Passive Fixation	-ePTFE-covered coil -High Impedance -Single-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	0170 0171 0172	59 64 70	Silicone Silicone Silicone	

Product	Description	Model	Length (cm)	Insulation	Diagram
ENDOTAK RELIANCE Active Fixation	-Terminal pin-driven -Extendable/retractable -8 turns (0157, 0158) -10 turns (0159) -Dual-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	**0157** **0158** **0159**	59 64 90	Silicone Silicone Silicone Silicone	
ENDOTAK RELIANCE S Active Fixation	-Terminal pin-driven -Extendable/retractable -8 turns -Single-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	**0137** **0138**	59 64	Silicone Silicone Silicone	
ENDOTAK RELIANCE Passive Fixation	-High Impedance -Dual-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	**0147** **0148** **0149**	59 64 90	Silicone Silicone Silicone	
ENDOTAK RELIANCE S Passive Fixation	-High Impedance -Single-coil -DF-1/IS-1 -Steroid elution -Integrated bipolar	**0127** **0128**	59 64	Silicone Silicone	

Product	Description	Model	Length (cm)	Insulation	Diagram
ENDOTAK® SQ Array XP	-Subcutaneous lead array -DF-1 with built-in DF-1 port -3 common coils -Used with ENDOTAK leads	**0085**	70	Silicone	

Product	Model	From	To	Length (cm)	Diagram
DF-1 Port Plug (1)	**6996**	N/A	(2) DF-1 terminals	N/A	
TVI Tool Kit (For use with RELIANCE G leads)	**7600**	(1) 9F TVI tool (white handle) (1) 11F TVI tool (green handle)	Hemostatic introducer	N/A	
Lead Cap Kit	**6623**	(2) DF-1 (2) IS-1 (2) 4.75 mm connectors	N/A	N/A	
Lead Cap Kit	**6810**	(2) 6.1 mm connectors	N/A	N/A	
Lead Adapter	**6833**	(2) 6.1 mm connectors	(1) DF-1 terminal	15	
Lead Adapter	**6835**	(2) DF-1 connectors	(1) DF-1 terminal	15	

Product	Model	From	To	Length (cm)	Diagram
Lead Adapter	6836	(2) 6.1 mm connectors	(1) 6.1 mm terminal	15	
Lead Adapter	6931	(1) 6.1 mm connector	(1) DF-1 terminal	14	
Lead Adapter	6952	(2) DF-1 and (1) IS-1 connectors	(2) DF-1 and (1) IS-1 terminals	60	

Defibrillation Stylets

Model	Length (cm)	Type	Firmness	Diameter (in)	Knob Color	Cap Color
6601	59	Straight	Soft	0.014	Green	Yellow
6602	59	Straight	Firm	0.016	White	Yellow
6771	90	Straight	Firm	0.016	White	Orange
6772	90	Straight	Soft	0.014	Green	Orange
6826	100	Straight	Firm	0.016	White	White
6828	100	Straight	Soft	0.014	Green	White
6963	70	Straight	Firm	0.016	White	Black
6964	70	Straight	Soft	0.014	Green	Black
6971	64	Straight	Firm	0.016	White	Green
6972	64	Straight	Soft	0.014	Green	Green

Product	Description	Model	Length (cm)	Terminal	Polarity	Diagram
ACUITY™ Steerable	-Coronary venous pace/ sense lead -Either over-the-wire or stylet delivery -IROX electrode coating -IS-1 -Steroid elution -Pre-shaped J fixation	**4554** **4555**	80 90	IS-1	Bipolar	
ACUITY Spiral	-Coronary venous pace/ sense lead -Over-the-wire design -IROX electrode coating -IS-1 -Steroid elution -3-dimensional, spiral fixation	**4591** **4592**	80 90	IS-1	Unipolar	

Product	Description	Model	Length (cm)	Terminal	Polarity	Diagram
EASYTRAK® 2	-Coronary venous pacing lead -Over-the-wire design -Steriod elution -Tined fixation	**4517** **4518** **4520**	80 90 100	LV-1	Bipolar	
EASYTRAK 2	-Coronary venous pacing lead -Over-the-wire design -IS-1 -Steriod elution -Tined fixation	**4542** **4543** **4544**	80 90 100	IS-1	Bipolar	
EASYTRAK 3	-Coronary venous pacing lead -Over-the-wire design -Steriod elution -3-dimensional, spiral fixation	**4524** **4525** **4527**	80 90 100	LV-1	Bipolar	
EASYTRAK 3	-Coronary venous pacing lead -Over-the-wire design -IS-1 -Steriod elution -3-dimensional, spiral fixation	**4548** **4549** **4550**	80 90 100	IS-1	Bipolar	

Product	Description	Intended use and features	units per package	Diagram
RAPIDO® Coronary Sinus Inner Catheter 50 Compact (CS-IC 50C) guide catheter **7720** Working length – 79 cm Overall length – 85 cm **7552** Working length – 69 cm Overall length – 75 cm	-Outer diameter (OD) – 6 French (F) -Inner diameter (ID) – 4.9F/0.064"/1.63 mm -Compatible with RAPIDO ADVANCE® and RAPIDO Cut-Away®	Provides access to the coronary venous system when used with an outer guide catheter • Offers flexibility during coronary sinus (CS) cannulation • Aids in deep-seating outer catheter • Facilitates branch vein subselection • Enables selective venogram	1	
RAPIDO Coronary Sinus Inner Catheter 90 (CS-IC 90) guide catheter **7721** Working length –79 cm Overall length – 85 cm **6776** Working length – 69 cm Overall length – 75 cm	-OD – 6F -ID – 4.9F/0.064"/1.63 mm -Compatible with RAPIDO and RAPIDO Cut-Away	Provides access to the coronary venous system when used with an outer guide catheter • Offers flexibility during coronary sinus (CS) cannulation • Aids in deep-seating outer catheter • Facilitates branch vein subselection • Enables selective venogram	1	

Product	Description	Intended use and features	units per package	Diagram
RAPIDO ADVANCE Coronary Sinus Extended Hook (CS-EH) guide catheter **7711** Working length – 47 cm Overall length – 53 cm **7712** Working length – 52 cm Overall length – 58 cm **7713** Working length – 57 cm Overall length – 63 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the superior vena cava (SVC) to provide access to the CS and branch vein for guide wire and direct lead delivery	1	
RAPIDO ADVANCE Coronary Sinus Extended Hook Right (CS-EH R) guide catheter **7714** Working length – 47 cm Overall length – 53 cm **7715** Working length – 52 cm Overall length – 58 cm **7716** Working length – 57 cm Overall length – 63 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the superior vena cava (SVC) to provide access to the CS and branch vein for guide wire and direct lead delivery	1	

Product	Description	Intended use and features	units per package	Diagram
RAPIDO ADVANCE Coronary Sinus Extended Hook Straight Right (CS-EH ST R) guide catheter **7717** Working length – 47 cm Overall length – 53 cm **7718** Working length – 52 cm Overall length – 58 cm **7719** Working length – 57 cm Overall length – 63 cm	- OD – 8F - ID – 6.6F/0.087"/2.21 mm - Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the SVC to provide access to the CS and branch vein for guide wire and direct lead delivery	1	

Product	Description	Intended use and features	units per package	Diagram
RAPIDO Cut-Away Coronary Sinus Extended Hook (CS-EH) guide catheter **7511** Working length – 42 cm Overall length – 48 cm **7553** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the SVC to provide access to the CS and branch vein for guide wire and direct lead delivery	1	
RAPIDO Cut-Away Coronary Sinus Hook (CS-H) guide catheter **7556** Working length – 42 cm Overall length – 48 cm **7557** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the SVC to provide access to the CS and branch vein for guide wire and direct lead delivery	1	
RAPIDO Cut-Away Coronary Sinus Extended Hook Right (CS-EH R) guide catheter **7519** Working length – 42 cm Overall length – 48 cm **7563** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the SVC to provide right-sided access to the CS for guide wire and lead delivery	1	

Product	Description	Intended use and features	units per package	Diagram
RAPIDO Cut-Away Coronary Sinus Extended Hook Straight Right (CS-EH ST R) guide catheter **7521** Working length – 42 cm Overall length – 48 cm **7564** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the SVC to provide access to the CS for guide wire and lead delivery	1	
RAPIDO Cut-Away Coronary Sinus Multi Purpose Hook (CS-MP) guide catheter **7554** Working length – 42 cm Overall length – 48 cm **7555** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the right atrium to provide access to the CS for guide wire and lead delivery	1	
RAPIDO Cut-Away Coronary Sinus Multi Purpose Hook (CS-MPH) guide catheter **7558** Working length – 42 cm Overall length – 48 cm **7559** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the right atrium to provide access to the CS for guide wire and lead delivery	1	

Product	Description	Intended use and features	units per package	Diagram
RAPIDO Cut-Away Coronary Sinus Wide (CS-W) guide catheter **7516** Working length – 42 cm Overall length – 48 cm **7560** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the SVC to provide access to the CS for guide wire and lead delivery	1	
RAPIDO Cut-Away Coronary Sinus Straight (CS-ST) guide catheter **7599** Working length – 42 cm Overall length – 48 cm **7598** Working length – 47 cm Overall length – 53 cm	-OD – 8F -ID – 6.6F/0.087"/2.21 mm -Compatible with IS-1 and LV-1 EASYTRAK family of leads	Catheter shape gains support from the right atrium to provide access to the CS for guide wire and lead delivery	1	

Product	Description	Intended use and features	units per package	Diagram
HI-TORQUE WHISPER VIEW® ES .014 guide wire **4634,** 190 cm	**Extra support** -Parabolic ground core for transitionless profile Hydrocoat (hydrophilic coating) plus polymer on distal 30 cm -Enhanced radiopacity for exceptional visualization 36% brighter at the tip and 360% brighter proximal to the tip when compared to WHISPER	Aids in selective placement of compatible LV leads • Easy access to distal anatomy • Core-to-tip design • Increased radiopacity • Gradual increase to extra support	1	
HI-TORQUE WHISPER VIEW ES CS-J .014 guide wire **4635,** 190 cm	**Extra support** -Parabolic ground core for transitionless profile Hydrocoat (hydrophilic coating) plus polymer on distal 30 cm -Enhanced radiopacity for exceptional visualization 36% brighter at the tip and 360% brighter proximal to the tip when compared to WHISPER	Aids in selective placement of compatible LV leads • Easy access to distal anatomy • Core-to-tip design • Increased radiopacity • Gradual increase to extra support	1	

Product	Description	Intended use and features	units per package	Diagram
HI-TORQUE WHISPER VIEW DS .014 guide wire **4636,** 190 cm	**Distal support** -Parabolic ground core for transitionless profile Hydrocoat (hydrophilic coating) plus polymer on distal 30 cm -Enhanced radiopacity for exceptional visualization 36% brighter at the tip and 360% brighter proximal to the tip when compared to WHISPER	Aids in selective placement of compatible LV leads • Easy access to distal anatomy • Core-to-tip design • Increased radiopacity • Gradual increase to distal support	1	
HI-TORQUE WHISPER VIEW DS CS-J .014 guide wire **4637,** 190 cm	**Distal support** -Parabolic ground core for transitionless profile Hydrocoat (hydrophilic coating) plus polymer on distal 30 cm -Enhanced radiopacity for exceptional visualization 36% brighter at the tip and 360% brighter proximal to the tip when compared to WHISPER	Aids in selective placement of compatible LV leads • Easy access to distal anatomy • Core-to-tip design • Increased radiopacity • Gradual increase to distal support	1	

Product	Description	Intended use and features	units per package	Diagram
HI-TORQUE WHISPER VIEW EDS .014 guide wire **4638,** 190 cm	**Extra distal support** -Parabolic ground core for transitionless profile Hydrocoat (hydrophilic coating) plus polymer on distal 30 cm -Enhanced radiopacity for exceptional visualization 36% brighter at the tip and 360% brighter proximal to the tip when compared to WHISPER	Aids in selective placement of compatible LV leads • Easy access to distal anatomy • Core-to-tip design • Increased radiopacity • Gradual increase to extra distal support	1	
HI-TORQUE WHISPER VIEW EDS CS-J .014 guide wire **4639,** 190 cm	**Extra distal support** -Parabolic ground core for transitionless profile Hydrocoat (hydrophilic coating) plus polymer on distal 30 cm -Enhanced radiopacity for exceptional visualization 36% brighter at the tip and 360% brighter proximal to the tip when compared to WHISPER	Aids in selective placement of compatible LV leads • Easy access to distal anatomy • Core-to-tip design • Increased radiopacity • Gradual increase to extra distal support	1	

Product	Description	Intended use and features	units per package	Diagram
HI-TORQUE IRON MAN™ guide wire **6725,** 190 cm	**Extra support** -Stainless steel core -Microglide® (hydrophobic coating) on distal 30 cm	Aids in selective placement of EASYTRAK family of leads • Extreme vessel straightening • Core-to-tip design	1	
035" Hydrophilic guide wire **6411,** 180 cm	Manufactured and labeled by Lake Region Manufacturing, Inc. -035" hydrophilic coated guide wire -Performed angled tip -Compatible torque device included	Facilitates placement of the catheter during left ventricular lead implant procedure • Coating durability for multiple insertions/ withdrawals • Nitinol core designed to provide excellent kink resistance • 1:1 torque control to enable vessel navigation • Radiopaque polymer jacket for enhanced visualization • Preformed angled tip for steering and subselection	1	

Product	Description	Intended use and features	units per package	Diagram
FINISHING WIRE SUPPORTRAK® LV-1 **6681,** 65 cm **6682,** 72 cm **6683,** 80 cm **6684,** 90 cm **6685,** 100 cm	-Compatible with EASYTRAK LV-1, EASYTRAK 2 LV-1, and EASYTRAK 3 LV	Smaller tip diameter profile designed for easier tracking through tortuous anatomy	1	
FINISHING WIRE SUPPORTRAK IS-1 **6667,** 80 cm **6668,** 90 cm **6669,** 100 cm	-Compatible with EASYTRAK IS-1, EASYTRAK 2 IS-1, EASYTRAK 3 IS-1, ACUITY Steerable, and ACUITY Spiral	Smaller tip diameter profile designed for easier tracking through tortuous anatomy	1	

Product	Description	Intended use and features	units per package	Diagram
LV-1 hemostasis valve **6789** (packaged with 2 wire guides)	• Bleedback control valve flushing port for LV-1 leads	• Controls bleedback • Facilitates lead flushing during implant	1	
LV-1 lead port plug **6743**	• LV-1 lead port plug	• Seals unused LV-1 port	1	
LV-1 lead cap **6742**	• LV-1 lead cap	• Protects EASYTRAK lead LV-1 connector pin	1	
Rotating hemostatic valve **6745**	• Bleedback control valve • ID—0.096"	• Controls bleedback • Attaches to proximal end of guide catheter	1	

Product	Description	Intended use and features	units per package	Diagram
IS-1 hemostasis valve **6799** (packaged with 2 wire guides)	• Bleedback control valve with flushing port for IS-1 leads	• Controls bleedback • Facilitates lead flushing during implant	1	
IS-1 lead port plug **6998**	• IS-1 lead port plug	• Seals unused IS-1 port	2	
Lead cap kit **6623**	• (2) DF-1 lead caps • (2) IS-1 lead caps • (2) 4.75-mm lead caps	• Protects DF-1, IS-1, and 4.75-mm connector pins	2 of each size (6 total)	

Product	Description	Intended use and features	units per package	Diagram
ACUITY Universal Cutter **7060**	• Cutter compatible with all Boston Scientific left ventricular leads	• Universal lead management system accepts lead bodies up to 6F • Enlarged proximal space accommodates a pre-loaded suture sleeve • Metal lead shield designed to protect lead during cutting	1	
RAPIDO Cut-Away rotating hemostatic valve **7565**	• Bleedback control valve • ID—0.185" • **Compatible with both RAPIDO ADVANCE and RAPIDO Cut-Away**	• Controls bleedback • Attaches to proximal end of guide catheter	1	
RAPIDO Cut-Away bleedback control valve **7568**	• Spring type • Bleedback control valve • ID—0.187" • **Compatible with both RAPIDO ADVANCE and RAPIDO Cut-Away**	• Controls bleedback, minimizes blood loss without restricting device movement • Attaches to proximal end of guide catheter	1	
IS-1 lead delivery system accessory kit **7611**	• Torque device (6740) • (2) Three-way stopcock (6798) • Rotating hemostasis valve (6745) • RAPDIO Cut-Away cutter (7566) • RAPDIO Cut-Away rotating hemostatic valve (7565) • RAPDIO Cut-Away bleedback control valve (7568) • Guide wire introducer	• Conveniently provides commonly used accessories in one kit	1	

Product	Description	Intended use and features	units per package	Diagram
Balloon catheter **6714,** 90 cm **6747,** 110 cm	• 6F • 90 cm • Manufactured by Arrow International	• Aids in obtaining venograms by occluding the CS	1	
Safesheath® introducer **6709,** 9F **6713,** 11F	• Hemostatic • Tear-away • Manufactured by Pressure Products Medical Supplies Inc.	• Introduces various types of pacing leads and catheters into the venous system	5	

Product	Description	Intended use and features	units per package	Diagram
Three-way stopcock **6798**	• Manufactured by DeRoyal Industries	• Provides control to the open port on an RHV	1	
Suture sleeve **6773**	• Adjustable, tubular reinforcement positioned over outer lead insulation • Silicone	• Secures and protects EASYTRAK family of leads at venous entry site after lead placement	1	
Torque device **6740**	• Torque device	• Tracks over the proximal end of the guide wire and locks into position • Steers guide wire into position	1	

Product	Description	Intended use and features	units per package	Diagram
Lead adapter 6744	• Lead adapter • Unipolar	• Joins an IS-1 lead to an LV-1 lead port	1	
Lead adapter 4402	• BLV/BIS-17 • 17 cm, unipolar/bipolar • Manufactured by Oscor, Inc.	• Joins an IS-1 lead to an LV-1 lead port	1	
Lead adapter 4403	• BLV/BIS-17 • 17 cm, unipolar/bipolar • Manufactured by Oscor, Inc.	• Joins an LV-1 lead to an IS-1 lead port	1	

Finishing Wire Compatibility Chart	
Lead	SUPPORTRAK Finishing Wire (6667-6669)
4517-EASYTRAK 2 IS-1 80 cm (LV-1)	6683
4518-EASYTRAK 2 IS-1 90 cm (LV-1)	6684
4520-EASYTRAK 2 IS-1 100 cm (LV-1)	6685
4542-EASYTRAK 2 IS-1 80 cm	6667
4543-EASYTRAK 2 IS-1 90 cm	6668
4544-EASYTRAK 2 IS-1 100 cm	6669
4524-EASYTRAK 3 IS-1 80 cm (LV-1)	6683
4525-EASYTRAK 3 IS-1 90 cm (LV-1)	6684
4527-EASYTRAK 3 IS-1 90 cm (LV-1)	6685
4548-EASYTRAK 3 IS-1 80 cm	6667
4549-EASYTRAK 3 IS-1 90 cm	6668
4550-EASYTRAK 3 IS-1 100 cm	6669
4554-ACUITY Steerable 80 cm	6667
4555-ACUITY Steerable 90 cm	6668
4591-ACUITY Spiral 80 cm	6667
4592-ACUITY Spiral 90 cm	6668

RAPIDO ADVANCE Guide Catheter Length to Lead Length Recommendation		
8F RAPIDO ADVANCE working length	6F inner catheter compatibility	Minimumrecommended EASYTRAK lead length
47 cm	69 cm	80 cm
52 cm	79 cm	90 cm
57 cm	79 cm	90 cm

LATITUDE® Patient Management System from Boston Scientific CRM

Intended Use
The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database.

Contraindications
The LATITUDE system is contraindicated for use with any pulse generator other than a compatible pulse generator from Boston Scientific CRM. Not all Guidant or Boston Scientific pulse generators are compatible with the LATITUDE system. For contraindications for use related to the pulse generator, refer to the System Guide for the pulse generator being interrogated.

Precautions
The LATITUDE system is designed to notify clinicians within 24 hours if new pulse generator alert conditions are detected by the Communicator. Pulse generator data will typically be available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability and alert notification can take up to 24 hours or the next business day. Note that data will not be available and alert notification cannot occur if:

- The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
- The pulse generator and the Communicator cannot establish and complete a telemetry session. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
- The Communicator becomes damaged or it malfunctions.

Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above and additional time may be required for notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission will be available.

Adverse Effects
None known.

Refer to the product labeling for specific instructions for use. Rx only.
(Rev. H)

Pacing Systems and Leads from Boston Scientific CRM

Indications
Pacemaker indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders; bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm. Pacing leads from BSC CRM are intended for chronic pacing and sensing of the atrium and/or ventricle when used with a compatible pulse generator.

Contraindications
Pacemakers are contraindicated for the following patients under the circumstances listed: patients with unipolar pacing leads or in MV mode with an implanted ICD because it may cause unwanted delivery or inhibition of ICD therapy; use of the MV sensor in patients with only unipolar leads, because a bipolar lead is required in either the atrium or the ventricle for MV detection; single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias, which might trigger ventricular pacing; dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms. Pacing leads from BSC CRM are also contraindicated in: patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate and/or 1.0 mg of dexamethasone acetate, patients with tricuspid valvular disease, patients with mechanical tricuspid heart valves, patients with an allergy to mannitol.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death . Inappropriate sustained high-rate pacing occurred in the PULSAR MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced Max Sensor Rate or MV to Passive. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated (4 ΩN) when the patient and pacing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred. The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment.

Precautions
For information on precautions, refer to the following sections of the PG product labeling: clinical considerations, sterilization, storage and handling, lead evaluation and connection, implantation, programming and pacemaker operation, MV initialization, environmental and medical therapy hazards. Advise patients to avoid sources of electric or magnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation. Refer to the lead product labeling for cautions specific to handling, implanting, and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. It has not been determined whether the warnings, precautions or complications usually associated with injectable dexamethasone sodium phosphate/acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the Physician's Desk Reference.

Potential Adverse Events
Potential adverse events from implantation of the pacing system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, procedure-related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
(Rev. J)

ICD Systems and Leads from Boston Scientific CRM

ICD/Lead Indications and Usage
ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. ICDs with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have, or are at risk of developing, atrial tachyarrhythmias. ICD leads provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for ICD systems.

Contraindications
ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker. ICD leads are contraindicated in: patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate and/or 1.0 mg of dexamethasone acetate, or patients with mechanical tricuspid heart valves.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. Such damage can result in patient injury or death. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including area protected by a warnng notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. . Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction. Do not attempt to use the lead system with any device other than a commercially available ICD with which it has been tested and demonstrated safe and effective - potential adverse consequences include, but are not limited to, undersensing of cardiac therapy and failure to deliver necessary therapy. The safety and efficacy of the tip electrode placement above midseptum has not been clinically established (extendable retractable helix leads). Lead fracture, dislodgment, abrasion and/or incomplete connection can cause a periodic or continual loss of rate-sensing, possibly resulting in inappropriate delivery of a PG shock or inadequate delivery of converting energy. The lead is not designed to tolerate excessive flexing, bending or tension. This could cause structural weakness, conductor discontinuity and/or lead dislodgment. Failure to obtain appropriate electrode position may result in higher defibrillation thresholds or may render lead unable to defibrillate a patient whose tachyarrhythmia(s) might otherwise be convertible by an ICD system. In order to deliver defibrillation therapy, the single-coil lead must be implanted with a separate defibrillation electrode. BSC recommends using the single-coil lead with a pectorally implanted device that uses the metallic housing as a defibrillation electrode. When connecting the lead to ECD cables and/or the ICD PG it is very important that proper connections are made. Damage to the heart could result if a high-voltage defibrillating pulse were to be delivered through the pace/sense tip electrode. Use of any component of the lead system to assist in the delivery of external-source rescue shocks could cause extensive tissue damage. Do not kink, twist or braid the lead terminals, as doing so could cause lead insulation abrasion damage.

Precautions
For information on precautions, refer to the following sections of the ICD product labeling: clinical considerations, sterilization, storage and handling; implantation and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Refer to the lead product labeling for cautions specific to handling, implanting and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient. It has not been determined whether the warnings, precautions or complications usually associated with injectable dexamethasone sodium phosphate/acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the Physician's Desk Reference. Tricuspid valvular disease may be exacerbated by the presence of a lead. Use medical judgment when deciding to place a lead in a patient with triscuspid valvular disease. The lead and its accessories are intended only for one-time use. Do not reuse.

Potential Adverse Events
Potential adverse events from implantation of the ICD/lead system include, but are not limited to the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system - patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
(Rev. H)

CRT-D Systems and Leads from Boston Scientific CRM

Indications
Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy, and have left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥ 120 ms. Left ventricular coronary venous, steroid-eluting, pace/sense leads are transvenous leads intended for chronic LV pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator. Extended bipolar pacing and sensing is available using dual-electrode LV leads with an RV pace/sense/defibrillation lead or a bipolar RV pace/sense lead.

Contraindications
There are no contraindications for the CRT-D device. Use of LV leads are contraindicated in patients with a hypersensitivity to a nominal dose of 0.45, 0.7 or 1.0 mg dexamethasone acetate drug. Some LV lead models are contraindicated in patients with mechanical tricuspid heart valves, or obstructed or inadequate vasculature for intravenous catheterization.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including area protected by a warnng notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage/interfere with the device and lead system and cause injury to the patient. Do not subject a patient with an implanted pulse generator and lead system to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. Do not use atrial only modes in patients with heart failure because such modes do not provide CRT. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not use defibrillation patch leads with the CRT-D system, or injury to the patient may occur. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction. When using a RV pace/sense lead in conjunction with an LV pacing lead, it is recommended that a polyurethane-insulated lead be used. Failure to observe this warning could result in insulation damage of the RV lead, which can cause a periodic or continual loss of pacing, sensing or both. Lead fracture, dislodgment, abrasion or an incomplete connection can cause a periodic or continual loss of pacing, sensing or both. The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by leakage currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, tension or injection pressure. This could cause structural weakness, conductor discontinuity or lead dislodgment. When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length If the wrong length finishing wire is used, the finishing wire tip may extend out of the distal end of the lead or not stabilize the lead properly. When placing the lead with a stylet, use only a stylet designed for use with the ACUITY Steerable lead. These stylets are specifically designed to prevent the stylet from extending past the lead tip. Extending the stylet past the lead tip may cause tissue damage.

Precautions
For information on precautions, refer to the following sections of the PG product labeling: clinical considerations, sterilization, storage and handling, implant and device programming, follow-up testing, explant and disposal, environmental and medical therapy hazards; hospital and medical environment; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Refer to the following sections of the lead product labeling: sterilization and handling, and lead evaluation and implantation for cautions specific to handling, implanting, and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the Physician's Desk Reference.

Potential Adverse Events
Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure-related, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
(Rev. K)

CRT-P Systems and Leads from Boston Scientific CRM

Indications
Cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥ 120 ms and remain symptomatic despite stable, optimal heart failure drug therapy (as defined in the clinical trials section in the System Guide). The devices provide atrial-ventricular tracking modes to help preserve AV synchrony and adaptive-rate pacing for patients who would benefit from adjusted pacing rates concurrent with physical activity. Left ventricular coronary venous, steroid-eluting, pace/sense leads are transvenous leads intended for chronic LV pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator. Extended bipolar pacing and sensing is available using dual-electrode LV leads with an RV pace/sense/defibrillation lead or a bipolar RV pace/sense lead.

Contraindications
These devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Use of LV leads are contraindicated in patients with a hypersensitivity to a nominal dose of 0.45, 0.7 or 1.0 mg dexamethasone acetate drug. Some LV lead models are contraindicated in patients with mechanical tricuspid heart valves, or obstructed or inadequate vasculature for intravenous catheterization.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death. Do not kink the leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage/interfere with the device and lead system and cause injury to the patient. Do not expose a patient with an activated implanted pulse generator and lead system to diathermy. Therapeutic diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator system because of induced currents. Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT. The clinical outcomes for patients with chronic refractory atrial tachyarrhythmias are not fully known. Safety and effectiveness studies have not been conducted. If a chronic refractory atrial tachyarrhythmia develops in a patient with these devices, do not use dual-chamber or single-chamber atrial pacing. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. When using a RV pace/sense lead in conjunction with an LV pacing lead, it is recommended that a polyurethane-insulated lead be used. Failure to observe this warning could result in insulation damage of the RV lead, which can cause a periodic or continual loss of pacing, sensing or both. Lead fracture, dislodgment, abrasion or an incomplete connection can cause a periodic or continual loss of pacing, sensing or both. The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by leakage currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, tension or injection pressure. This could cause structural weakness, conductor discontinuity or lead dislodgment. When using a finishing wire accessory kit use the corresponding finishing wire model for the lead length. If the wrong length finishing wire is used, the finishing wire tip may extend out of the distal end of the lead or not stabilize the lead properly. When placing the lead with a stylet, use only a stylet designed for use with the ACUITY Steerable lead. These stylets are specifically designed to prevent the stylet from extending past the lead tip. Extending the stylet past the lead tip may cause tissue damage. Do not kink, twist, or braid the lead terminal with other leads, as doing so could cause lead insulation abrasion or conductor damage.

Precautions
For information on precautions, refer to the following sections of the PG product labeling: clinical considerations, sterilization, storage and handling, implantation and device programming, pulse generator explant and disposal, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Refer to the following sections of the lead product labeling: sterilization and handling and lead evaluation and implantation. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, and/or harm to the patient. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects refer to the Physician's Desk Reference.

Potential Adverse Events
Potential adverse events from implantation of the CRT-P system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (pacing/sensing), infection, lead tip deformation and/or breakage, procedure related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
(Rev. H)

RAPIDO® Cut-Away® and RAPIDO ADVANCE® Guiding Catheter Systems from Boston Scientific CRM

Indications for Use
The Guidant RAPIDO Cut-Away and RAPIDO ADVANCE guiding catheters are intended to access the coronary venous system, and may be used as a dual-catheter assembly. The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

The Guidant Rotating Hemostasis Valve is intended for maintaining a fluid-tight seal around devices, including implantable coronary venous leads, during the implant procedure.

The Guidant Bleedback Control Valve is intended for maintaining a seal around diagnostic / interventional devices with an outside diameter of less than 0.185" in the venous anatomy only, during interventional procedures.

The Guidant Cutter is intended to facilitate RAPIDO Cut-Away or RAPIDO ADVANCE guiding catheter removal after the Guidant coronary venous lead is positioned.

Intended Use
The Guidant RAPIDO Cut-Away and RAPIDO ADVANCE guiding catheters are intended to be used with the Guidant Rotating Hemostasis Valve, a Guidant Cutter and a commercially available luer lock stopcock.

Contraindications
The Guidant Bleedback Control Valve is not intended for use with pressure injections of greater than 30 psi.

Warnings
These devices are distributed STERILE, NON-PYROGENIC and are intended for one time use only. DO NOT resterilize and /or reuse them, as this can potentially result in compromised device performance and risk of inappropriate sterilization and cross contamination. Sideholes should not be placed in the shaft of the guiding catheter by the user. Puncturing the shaft of the guiding catheter with hospital instruments may lead to thrombogenesis or failure of shaft integrity. When this guiding catheter is in the body, it should be manipulated while under high-quality fluoroscopic observation.

Precautions
Prior to use, the guiding catheter, rotating hemostasis valve, cutter and stopcock should be examined to verify functionality and ensure that their sizes and shapes are suitable for the specific procedure for which they are to be used. It is recommended that a guide wire be used to advance the guiding catheter into the venous system, right atrium or coronary sinus.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
(Rev. F)

DEXTRUS™ Pacing Leads from Boston Scientific CRM

Indications

The DEXTRUS transvenous, steroid-eluting, active fixation endocardial leads are indicated for permanent pacing and sensing. Active fixation pacing leads with a bipolar (BP) IS-1 connector configuration are designed for use in conjunction with implantable pulse generators with IS-1 headers. The leads may be used with single or dual chamber pacing systems. The DEXTRUS lead models are intended for placement in either the right atrium or right ventricle.

Contraindications

Transvenous endocardial pacing leads are contraindicated in the presence of severe tricuspid valvular disease and in patients with mechanical tricuspid heart valves. The DEXTRUS lead is additionally contraindicated for patients who cannot tolerate a single systemic dose of up to 1.3 mg of dexamethasone acetate (DXA).

Warnings and Precautions

Potentially Harmful Therapeutic and Diagnostic Procedures As an implanted pacing lead is a direct, low resistance path to the myocardium for electrical current, the observance of high standards of electrical safety is required. Electrosurgical instruments, for example, could generate voltages of such amplitude that a direct coupling between the tip of the electrocautery device and the implanted lead may result, possibly inducing myocardial lesions or serious cardiac arrhythmias (e.g., fibrillation). Some therapeutic and diagnostic procedures (e.g., diathermy, MRI, electrocautery) may result in latent damage to the pacing system. This damage may not be detected when testing the pacemaker function immediately after the procedure, but may become evident at a later time, resulting in pacing system malfunction or failure.

Prevention of Leakage Current Conduction

Pulse generators and testing equipment connected to the lead must be battery-powered. Proper grounding of line-powered devices in the vicinity of the patient is essential to prevent leakage currents arising from such devices to be conducted via the lead's terminal or any other non-insulated part.

Necessary Equipment for Implantation

During implantation the ECG should be recorded; a pacing system analyzer (PSA) and defibrillation equipment should always be readily available.

Handling the Lead

The lead should be handled very carefully at all times. Any severe application of force (bending, stretching, crimping, etc.) may permanently damage the lead. The metal portion of the lead connector should not be touched.

Lead/Pulse Generator Compatibility

Because of the numerous available 3.2 mm configurations, e.g., the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer prior to the implantation of a pacing system.

Extending/Retracting the Fixation Helix

In the event of previous handling or repositioning of the lead, more than the minimum number of rotations may be necessary to fully extend or retract the helix. Full helix extension should always be verified through fluoroscopy.

Chronic Repositioning

It is generally recommended that a chronically implanted endocardial lead not be explanted. Chronic repositioning or removal of active fixation leads may be difficult due to the presence of blood or fibrotic tissue in the helix. If it becomes necessary to remove the lead without successfully retracting the fixation helix, the lead should be rotated counter-clockwise during withdrawal in order to minimize the risk of endothelial laceration. If it becomes necessary to abandon a lead, the connector pin should be capped to prevent the transmission of electrical signals to the heart.

Suture Sleeve

Always use a suture sleeve when implanting a lead. Use of the suture sleeve, which is provided with the lead, will lessen the possibility of lead dislodgment and protect the lead body from damage by a securing ligature.

Potential Adverse Events

Potential complications resulting from the use of endocardial leads include, but are not limited to: thrombosis, embolism, body rejection phenomena, cardiac tamponade, pneumothorax, muscle/nerve stimulation, valve damage, fibrillation, infection, skin erosion, ventricular ectopy and death. Lead perforation through the myocardium has been rarely observed. In rare cases, severe complications or device failures can occur.

Refer to the physician's manual(s) for specific indications, contraindications, warning/precautions and adverse events. Rx only.

(Rev. C)

Guide Wires, Finishing Wires and Other Implant Accessories

Refer to the product labeling for specific indications, intended uses, contraindications, warnings, precautions, and adverse events. Rx only.

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