

Caution:

In the United States of America federal law restricts the device to sale or use by, or on the order of a physician or other practitioner licensed by the laws of the state in which he/ she practices.

Instruction manual

Conductive Garment Accessory Kit & Baxolve XP Lumbar Support Kit Types 297 & 298

Embrace Life.

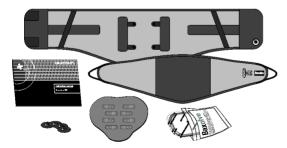
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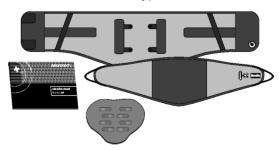
There are two distinct types of BAXOLVE XP belt. The first, Type 297, combines both lumbar support and either TENS or EMS stimulation. This belt is supplied with adhesive electrodes and your medical practitioner will also supply you with an electronic stimulator to use with the belt. The second type of belt is Type 298. This is for lumbar support only and is not supplied with electrodes.

Contents for Type 297



- BAXOLVE XP belt (2 layers)
- 1 Pelotte
- 1 pack of 4 adhesive electrodes
- 4 stud connection covers
- Instruction manual

Contents for Type 298



- BAXOLVE XP belt (2 layers)
- 1 Pelotte
- Instruction manual

WELCOME

Dear Customer,

Welcome to the BAXOLVE XP Conductive Garment Accessory Kit & BAXOLVE XP Lumbar Support Kit from **neurotech**® - an innovative means of controlling back pain using two support layers in each integrated belt. The BAXOLVE XP belts effectively manage back pain by providing support for both the lumbar and abdominal regions. The BAXOLVE XP Conductive Garment, however, may also be used with a separate TENS or EMS device for additional treatment options. All TENS/ EMS devices will be supplied with their own instruction manuals, but you should also read the BAXOLVE XP Quick Start Guide supplied with BAXOLVE XP Type 297 for instructions on how to connect these devices to your BAXOLVE XP Conductive Garment Accessory Kit.

For ease of reference, both BAXOLVE XP Kits will be referred to as BAXOLVE XP belt in this manual.

The anatomically shaped BAXOLVE XP belt offers you a greater range in the level of compression you can achieve. Together, the two layers give high levels of compression. When reduced levels of compression are required, the outer layer may be detached. A "pelotte" pad provides the added advantage of visco-elastic massage in the lumbar region.

Please refer to a trained specialist for correct fitting of the belt. The belt fits waist size from 64cm to 142cm / 25" - 56".

Please read the instructions before using this device to ensure optimum comfort and effectiveness.

The Baxolve XP belt is covered by a two-year warranty against manufacturing faults. $\mathbf{neurotech}_{@}$ will undertake to replace with no charge for labour or materials, provided the unit has been used for its intended purpose and in the manner described in this instruction manual. It has not been subjected to misuse or neglect and it has not been modified or repaired by anyone other than an approved $\mathbf{neurotech}_{@}$ agent.

If you have any questions regarding our products or services please contact our customer service team on the relevant number, below. Lines are open Mon - Fri. 09.00 - 17.30.

Customer Carelines:

Ireland: FREEPHONE 1800 511 511 UK/ N.I.: LOCALL 0845 600 1332

SAFETY INFORMATION

Validity

The information and technical data contained in this document relates to the BAXOLVE XP lumbar support belt provided with this manual.

The information and technical data disclosed in this document are proprietary to Bio-Medical Research Ltd. and may be used and disseminated only for the purposes and to the extent specifically authorised in writing by the company.

Disclaimers

All units manufactured and sold by Bio-Medical Research Ltd. are rigorously checked and tested prior to shipment. However, the company is not responsible for the product's use. Bio-Medical Research Ltd. accepts responsibility only for the safety, reliability and performance of the equipment when it is operated in accordance with instructions herein and within the given specifications. Therefore, the user must bear full responsibility for any actions arising out of the use or misuse of this equipment. Any modifications, repairs or servicing must be undertaken by authorized Bio-Medical Research Ltd. personnel.

Restrictions

The sale and/or operation of this equipment is subject to law in the various states/ countries. Compliance with this legislation rests with the importer, dealer, or user of the equipment as appropriate.

Intended Use Type 297

Can be used on its own as a lumbar support device or as a conductive garment for use with cleared Transcutaneous Electrical Nerve Stimulation (TENS) devices for the following:

- The symptomatic relief and management of chronic and intractable pain in the lower back region.
- Consistent electrode placement on the back.
- · Lumbar support

Can be used on its own as a lumbar support device or as a conductive garment for use with cleared Neuromuscular Electrical Stimulation (NMES) devices for the following:

- Relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation and muscle re-education
- Consistent electrode placement on the back.
- · Lumbar support

Intended Use Type 298

Can be used on its own as a lumbar support device only.

Lumbar Support

Lumbar Support can be used to ease existing lower back pain and also to help prevent the onset of lower back pain. The BAXOLVE XP belt works by providing support to both the spinal and the abdominal muscles. Lumbar and abdominal support, when applied firmly and comfortably, should assist lower back pain through the interrelated mechanisms of:

- · Restricting painful movement.
- Improving positional awareness and posture.
- Providing warmth to the affected area, which stimulates local circulation generating a feeling of well being.

Specific contraindications, precautions and warnings related to the use of the BAXOLVE XP belt are listed below.

Contra-Indications

Side effects harmful to health have not been reported to date. Please consult your clinician if you have the following:

- Skin disorders or injuries in the relevant part of the body particularly if inflammation, raised scars with swelling, redness or excessive heat build up are present.
- · Impaired sensation.
- · Heart or lung conditions.

Precautions and Warnings

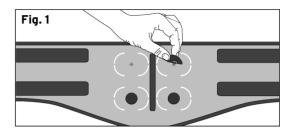
If in doubt always seek medical advice.

- The BAXOLVE XP belt should only be used for its intended purpose in the manner described in this manual. No liability is accepted for improper use of the product.
- It is not recommended that you use the lumbar support for more than 8 hours a day.
- Sharing of the BAXOLVE XP belt is not recommended.
- Please keep the BAXOLVE XP belt out of the reach of children.
- Should you notice any unusual changes (e.g. increased symptoms), please contact your healthcare specialist without delay.
- Ensure the BAXOLVE XP belt is fastened comfortably. If fastened too tightly, it may restrict breathing and blood flow.
- The BAXOLVE XP belt is *not* intended for use during sports or physical exertion.
- Avoid the use of ointments/ lotions or any substances including grease or acids during use of Baxolve XP belt.
- Should your BAXOLVE XP Type 297 be damaged in such a way as to expose the internal wiring, please return it immediately for replacement or repair.

INSTRUCTIONS FOR USE (Applying The Garment Only)

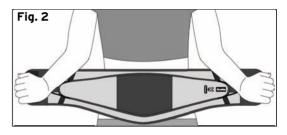
Important:

1. If you are using the BAXOLVE XP belt designed for TENS or EMS stimulation (i.e. Type 297), you must first press the 4 stud covers into the connectors on the belt, as shown - Fig. 1. ensure that the stud covers are in position so that there is no metal in contact with your skin.

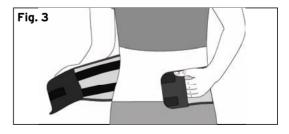


2. Centre the garment on your spine - Fig. 2.

Note: Ensure the fabric fasteners at the ends of the outer layer are not yet fastened to the inner layer.



3. Place your hands inside the pockets at either end of the belt and pull the two ends around to meet in front of you. Wrap the lefthand side around your body first - Fig. 3.



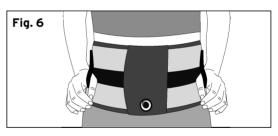
4. Next, wrap the right-hand side over the left and press the two ends together so that the belt fastens comfortably. Press the ends of the belt against your body to ensure it is securely fastened - Fig. 4.



5. To increase the amount of compression, grip the handles on the outer layer with your thumbs and pull the ends around to the front of your body - Fig. 5.

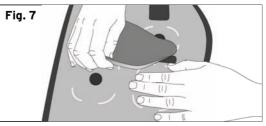


6. Then simply press the outer layer against the inner layer to fasten - Fig. 6.



7. Using BAXOLVE XP With The Pelotte

Position the pelotte as recommended by your medical specialist. You can separate the pelotte from the garment and reposition it if necessary - Fig. 7.

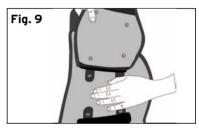


Using BAXOLVE XP Without The Outer Layer

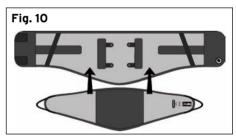
8. When reduced compression is required, you can remove the outer layer by carefully unfastening the "hook & loop" strips and then pulling apart the four metal stud connections - Fig. 8.



9. Pull the two layers apart and simply use the belt as described in points 1 - 4.



10. To put the layers back together again, just align the layers as shown in Fig. 10, press the metal studs together and refasten the "hook & loop" strips. Please ensure that all four studs are connected correctly.



Using BAXOLVE XP With A TENS Or EMS Unit

When using a BAXOLVE XP lumbar support belt in combination with a TENS or EMS unit, you must read the Quick Start Guide supplied with your BAXOLVE XP Conductive Garment Accessory Kit and also the Instructiona Manual supplied with the stimulation device before use.

FREQUENTLY ASKED QUESTIONS

out the second support layer?

	,		
How does the Baxolve XP belt work?	The Baxolve XP belt eases back pain by providing effective support in the lum bar and abdominal regions.		
How often can I use the Baxolve XP belt?	You can use the Baxolve XP belt to relieve pain as and when needed, however it is not recommended that you use the lumbar support for longer than 8 hours a day.		
Can the Baxolve XP belt be used with other forms of pain relief?	The Baxolve XP belt may be used safely in conjunction with nearly all forms of therapy for lower back pain. Please consult a trained specialist if you have any concerns.		
Who should not use the Baxolve XP belt?	Almost all adults can use the Baxolve XP belt safely and effectively.		
Can I move around whilst wearing the garment?	Yes. The garment is designed to provide comfortable lumbar support for general use. It should <i>not</i> be used for excessive or exerting activities.		
Is Baxolve XP belt safe?	Used correctly, the Baxolve XP belt is a safe form of treatment for lower back pain with minimal potential side effects.		
Can the Baxolve XP belt be worn with-	Yes. For conditions where less compression is required, the second layer may be		

detached.

WASHING INSTRUCTIONS



Never machine wash. Hand wash in water at 30°C. Do not wring the belt to remove water. This is to protect the internal components from damage.



Do not dry clean.



Do not bleach.



Do not tumble-dry. Always dry lying flat. Do not dry with heat. (E.g. over a radiator).



Do not iron.

Garment Materials

Main Panels: 40 % Nylon, 40 % Cotton, 10 % Polyester, 10 % Elastane; Binding: 80 % Nylon, 20 % Elastane Non Stretch Panel: 100 % Polyester on 100 % Polyurethane; Hook & Loop Fastener: 90 % Nylon, 10 % Elastane

FITTING GUIDE

To allow for different body shapes, it is recommended that the larger circumference of either the hips or waist should be used when selecting the appropriate size.

Sizes available:

Size 1	Size 2	Size 3	Size 4	Size 5
64 cm - 78 cm	78 cm - 92 cm	92 cm - 106 cm	106 cm - 120 cm	120 cm - 142 cm
25" - 31"	31" - 36"	36" - 42"	42" - 47"	47" - 56"

- If your waistline is in between two sizes we recommend to choose the larger belt.
- Please refer to a trained specialist for correct fitting of your garment.

TECHNICAL SPECIFICATIONS

Description of your unit's symbols:

There are a number of technical markings on your unit. These can be explained as follows:



This symbol means "Attention, consult the accompanying documents".



Indicates conformity to the requirements of the Medical Device Directive (93/42/EEC).

The garment's batch number is represented on the garment packaging, by the number corresponding with the LOT symbol.

Accessories

Only electrodes specified by Bio-Medical Research Ltd. for use with BAXOLVE XP (Type 297) may be used. Using other electrodes may degrade performance levels.

• Replacement Electrodes: Pack of 4 (Type 612)

Used electrodes must never be disposed of in a fire but in accordance with your country's national or state laws governing the disposal of such items.

Electrodes wear out over time: If they are dirty or no longer adhere properly, they need to be replaced.

Branding Registration

neurotech is a registered trademark In the EU and the USA. Baxolve is a registered trademark in the EU.

WARRANTY

Should your unit develop a fault within two years of purchase, $neurotech_{\circledcirc}$ will undertake to replace or repair the unit and parts found to be defective with no charge for labour or materials, provided the unit:

- has been used for its intended purpose and in the manner described in this instruction manual.
- has not been connected to an unsuitable power source.
- has not been subjected to misuse or neglect.
- has not been modified or repaired by anyone other than an approved neurotech_® agent.

This warranty complements existing national guarantee obligations and does not affect your statutory rights as a consumer.



If you have questions or require other information please contact:

neurotech®

Bio-Medical Research Ltd Parkmore Business Park West, Galway, Ireland.

Tel: +353 (0)91774 377 Fax: +353 (0)91774 303 Email: info@neurotech.ie Web: www.neurotech.co.uk

Customer Carelines:

Ireland: FREEPHONE 1800 511 511 UK/ N.I.: LOCALL 0845 600 1332

Mon - Fri. 09.00 - 17.30

Part No.: 2401-4805 - Rev.: 1 - Issue Date: 9/08