

Custom-Made Medical Device

Instructions for Use

829026 PLASTIC TLSO
829027 FABRIC TLSO
829026C PLASTIC CTLSO
829027C FABRIC CTLSO
829028 PLASTIC LSO
829029 FABRIC LSO
829028C PLASTIC CO

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1 Description and Intended Purpose

These instructions for use are intended for both the practitioner and user unless otherwise stated.

Please read and ensure you understand all instructions for use, in particular all safety information and maintenance instructions.

CTSLO, TSLO, LSO and CO's are custom made medical devices.

2 Safety Information



If after use, you see any discolouration on your skin that are in contact with the device, which don't disappear after 30 minutes, stop using the Spinal Orthosis and contact your healthcare professional for advice as it may need adjusting. Should you develop any sores or blisters you should stop use of the device at once.



Spinal Orthosis has been designed and prescribed for an individual's needs and should only be used by that sole user.



The Spinal Orthosis must be regularly maintained to the maintenance schedule in this IFU by qualified professional.



Repairs and adjustments to the device must be carried out by qualified, trained healthcare professionals. Please consult a qualified medical professional should you have any problems with this custom product.



Should your functional requirements or condition change during the life cycle of the device please contact your healthcare professional as this could affect the devices performance.



Do not place near any heat source. Do not leave in direct sunshine or inside a car in hot weather.



Do not remove any serial or warning labels from the Spinal Orthosis.

 **Spinal Orthosis may include flammable materials. Be aware of fire hazards where possible.**

 **May contain animal tissues such as leather. Conformity certificate is available for further details should this be required.**

 **Should the Spinal Orthosis display any unusual behaviour, changes of performance or fittings or the device comes loose please immediately stop use and contact your healthcare professional.**

 **All straps must be secured firmly when putting the Spinal Orthosis on. Appropriate fixation of the strap is very important, as the straps hold the custom Spinal Orthosis onto the body and if not fastened correctly could result in the failure of the device.**

 **The device is not intended for use when immersed in water or as a showering orthosis unless specified for this purpose by your healthcare professional.**

 **The device is not suitable for extreme sports, running or cycle racing, ice or snow sports, extreme slopes and steps. Any such activities undertaken are done so completely at the users own risk.**

 **Avoid strong magnetic fields, sources of electrical interference.**

 **Spinal Orthosis can entrap fingers or clothing, be cautious of this when operating the brace.**

3 Everyday Use

The instructions in this section are primarily for the user (wearer)

Blatchford Spinal Orthoses apply forces to the body segments to which they are attached. The interface components have been designed to avoid unacceptable pressure on and stress levels in body tissues.

CERVICAL THORACIC LUMBAR SACRAL ORTHOSIS (CTLSO) Fitting Guidelines

- Apply a well fitting cotton tshirt or body sock. Loose items may cause wrinkles and skin irritation.
- Whilst in bed, roll to the side to allow assistants to help putting on CTLSO.
- Assistants should place the back portion on the patient, matching the profile of the CTLSO with the user's waist.
- Users should slowly roll onto their back. Then assistant must ensure the CTLSO has not moved from position. Adjust as required.
- Place the front portion on user with the sides overlapping the back portion.
- Fasten the middle straps first. Pull straps equally to ensure even tightening and prevent twisting of the Orthosis. Straps should be snug to hold CTLSO in place, however must allow normal breathing.
- Fasten top and bottom straps in same manner.
- Fix the chin strap on the head piece, ensuring the straps are tight and providing full motion.

THORACIC LUMBO SACRAL ORTHOSIS (TLSO) Fitting Guidelines

- Apply a well fitting cotton t-shirt or body sock. Loose items may cause wrinkles and skin irritation.
- When putting the Orthosis on, spread the Orthosis at the bottom of the front opening. Slide the opening over the hip. Reach around the back and pull the rest of the Orthosis around you. Make sure all the straps are on the outside of the Orthosis.
- Make sure the Orthosis is not twisted and is forward facing. The opening of the orthosis should be in the middle. The waist roll of the Orthosis should always sit at your waist, just above the hip bones. Tighten the middle strap first, then follow with the bottom and top straps, always ensure the Orthosis is properly positioned.
- At first, it may be easier to tighten the Orthosis while lying down. Once done, you may be able to tighten the straps while standing up.
- Never wear your Orthosis loosely, you will develop skin problems and discomfort. A loose Orthosis will shift around each time you move and irritate your skin and prominent bones (ribs and hip bones).

LUMBO SACRAL ORTHOSIS (LSO) Fitting Guidelines (Two Piece)

- Apply a well fitting cotton t-shirt or body sock. Loose items may cause wrinkles and skin irritation.
- Whilst in bed, roll to the side to allow assistants to help putting on LSO.
- Assistants should place the back portion on the patient, matching the profile of the LSO with the user's waist.
- Users should slowly roll onto their back. The assistant must ensure the LSO has not moved from position. Adjust as required.
- Place the front portion on user with the sides overlapping the back portion.

- Fasten the middle straps, first. Pull straps equally to ensure even tightening and prevent twisting of the Orthosis straps should be snug to hold LSO in place, however must allow normal breathing.
- Fasten top and bottom straps in the same manner.

LUMBO SACRAL ORTHOSIS (LSO) Fitting Guidelines (One Piece)

- Apply a well fitting cotton t-shirt or body sock. Loose items may cause wrinkles and skin irritation.
- To put the Orthosis on, open the front of the Orthosis and position the back section around your lower back. Bring the front section around your body so that the opening is at the front and centred. Ensure the Orthosis is facing the correct way, sits evenly on the body, and that all straps remain on the outside before fastening.
- Check the Orthosis is centred, forward facing and not twisted, with the waist section sitting just above the hip bones. Tighten the middle straps first, followed by the bottom and top straps.
- At first, it may be easier to tighten the Orthosis while lying down. Once donned and straps tight in lying you may be able to tighten it while standing up.
- Never wear your Orthosis loosely, you will develop skin problems and discomfort. A loose Orthosis will shift around each time you move and irritate your skin and prominent bones (ribs and hip bones).

CERVICAL ORTHOSIS (CO) Fitting Guidelines

- The Cervical Orthoses is typically applied while laying down. Only fit while sitting upright with the express permission of your healthcare professional.
- Where possible have 2 assistants. The second assistant should be able to provide support with placing the back panel under head.

- With one person stabilising the users head, the second assistant must carefully slide the back panel under the users head through the neck crevice.
- Ensure that the back piece is central, behind the head and the sides of panel are positioned carefully between ears and shoulders.
- Place the front portion under chin.
- Securely fasten the strap from the back panel onto the front panel.

4 Intended Use

Blatchford Spinal Orthoses are provided to stabilise the spine after surgery or in the event of a spinal fracture or injury to promote healing and decrease pain.

A Spinal Orthosis may be needed to keep your spine stable after surgery. A Spinal Orthosis may also be used instead of surgery to help correct or stabilise the spine.

Your healthcare profession will prescribe the optimum spinal orthosis for your needs and provide advice on wear time and usage tailored to your requirements

Indications

Spinal Orthoses are intended for users of all ages, sizes and weights. Spinal Orthoses are intended for the sole use of the patient named on the conformity documentation. If the Spinal Orthosis is no longer required, it must be safely disposed. Please follow the guidelines below:

- Ensure the orthotist is aware the device is no longer required.
- Return the device for safe disposal.

5 Intended Performance

Environment

Avoid exposing the Spinal Orthosis to corrosive elements such as water, acids and other liquids. Also avoid abrasive environments such as those containing sand for example as these may promote premature wear. Orthoses are recommended for use between -10°C and $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

Our Spinal Orthoses are not designed for high activity sport such as running, jumping, cycle racing or snow sports. Any such activities undertaken are done so completely at the user's own risk.

Lifetime

It is recommended that Spinal Orthoses are evaluated by a healthcare professional after every 12 months of use as a minimum to determine continued suitability of use.

6 Maintenance

Cleaning

The hard plastic outer shell and inner soft plastic foam must be cleaned every day. Use a cloth with antibacterial sanitiser to clean the lining, then wipe the lining thoroughly with a damp cloth. Make sure all the sanitiser is wiped off the inside, as it could cause skin irritation. Clean the hard-plastic outer shell with a damp cloth as needed. A towel can help dry the Orthosis. The Orthosis will dry by itself in 20 to 30 minutes. **Never put the Orthosis in water or put it under the tap. Make sure the metal and leather parts do not get wet.**

6.1 Maintenance Schedule

Daily

- User visual inspection
- Inspect Spinal Orthosis all over generally for any obvious signs of wear and tear
- Ensure straps remain well adhered and Velcro is retaining fixation
- No visible signs of material fatigue. Signs include cracks, chips and stress lines in the material
- Failure to comply may invalidate the warranty.

6.2 Transport & Storage

Store the Spinal Orthosis in a safe, clean and dry place, out of direct sunlight and away from heat sources such as radiators and ovens.

Ensure the Spinal Orthosis is thoroughly protected from damage in transit.

7 Manufacturer's Declarations and Legal Information

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for any adverse outcome caused by any component combinations that were not authorized by them.



Medical Device



Single Patient – multiple

Warranty

Blatchford Orthotic products are warranted for a period of 12 months. Any straps and liners are warranted for a period of 6 months.

The user should be aware that changes or modifications not expressly approved could void the warranty.

See the Blatchford website for the current full warranty statement.

Reporting of Serious Incidents

In the unlikely event of a serious incident occurring in relation to this device it should be reported to the manufacturer and your national competent authority.

Manufactured by

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