



MD

Blatchford: Spinal Range

Custom-made Medical Device

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

EN Instructions For Use



Blatchford is a multi-award-winning manufacturer of some of the world's most advanced prosthetic technology, bespoke seating solutions and orthotic devices.

Our Orthotists work with both NHS Hospitals and GP referrals to supply devices that support the body, encourage active lifestyles and reduce pain or pathological developments

Our team of Orthotists maintains a training regime that ensures they are up to date with the latest technologies and rehabilitation thinking. This means that each patient can be provided with appropriate treatments, optimised designs and lightweight materials.

Blatchford maintains a QMS system which is ISO 9001 and ISO 13485 accredited. Blatchford spinal products and systems meet the essential requirements of EU Medical Devices Regulation 2017 (MDR).

Product Description

Blatchford Spinal orthoses are provided to compensate for muscle weakness, paralysis or skeletal problems which cause spinal instability. Custom Spinal orthoses can be complex medical devices and the designs vary to suit each individual. There are four main types:

Cervical Thoracic lumbo sacral orthosis (CTLSO)

A CTLSO is a two-piece clamshell design. It is used to stabilize the head and neck as well as the spine after surgery or in the event of a spinal fracture to promote healing and decrease pain.

Thoracic lumbo sacral orthosis (TLSO)

The TLSO is used to slow the curve progression of the spine of users with scoliosis. TLSOs are formed from molded plastic and custom made to fit each patient.

(Lumbar Sacral Orthosis) (LSO)

An LSO is predominanatly a two-piece clamshell design An LSO extends from just below the breast bones down to the pelvis. It is designed to stabilise the spine after surgery or in the event of a spinal injury to improve healing and decrease pain.

Cervical Orthosis (CO)

A cervical orthosis is used to protect and immobilise the neck in the event of injury, fracture, or surgery. It is typically a two-piece design made of a thin plastic frame and removable soft liner.

CTSLO, TSLO, LSO and COs are custom made medical devices and are defined by the MDR as a medical device manufactured specifically in accordance with a written prescription of a registered medical practitioner, or other person authorised to write such a prescription by virtue of his professional qualification, which gives under his responsibility, specific characteristics as to its design; and intended for the sole use of a particular patient, but does not include a mass-produced product which comprises a medical device and medicinal product forming a single integral product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user.

The prescription may take the form of a letter from a qualified person or a moulded impression of the shape of the required device together with the order specifying customer details, and a request to 'make as pattern'. It is the qualified person who is responsible for specifying the specific design characteristics of the product. Blatchford, the manufacturer of the devices, meets the particular requirements of the Medical Devices Regulations which relate to custom-made devices. The activities carried out in supplying or fitting a spinal orthosis (e.g. preparation, impression taking, prescribing, final fitting and any adaptation), are not considered to fall within the scope of the Medical Devices Regulations.

Safety Information



If after use of the Spinal Orthosis you see any red marks on your skin that are in contact with the device, which don't disappear after 30 minutes, stop using the 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 orthosis immediately.



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



• Should your functional requirements or condition change during the life cycle of the custom Spinal Orthosis please contact your healthcare professional as this could affect the custom made spinal orthosis performance



• The custom spinal orthosis must be regularly maintained to the maintenance schedule in this IFU.



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



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



Spinal Orthoses can entrap fingers or clothing. Be cautious of this when placing or removing the orthosis.



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



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



• Always use a handrail when descending stairs and at any other time if available.



• Avoid strong magnetic fields, sources of electrical interference, atmospheres containing liquids and/or powders.



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



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 and snow sports, extreme slopes and steps. Any such activities undertaken are done so completely at the users' own risk.



• Do not remove any serial or warning labels from the spinal orthosis



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

Intended Use

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

- **Provide support to weakened or weakening joints and muscles.**
- **Prevent movement which is unhelpful or painful.**
- **Provide protection.**
- **Improve stability for safe standing**

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 spinal problems. An example is scoliosis (a curved spine) in adolescents. The spinal orthosis will help your spine heal and protect it from injury. You may need to wear the spinal orthosis for several months. Adolescents may need to wear the spinal orthosis for a few years, until the end of puberty.

Your healthcare professional will prescribe the optimum spinal orthosis for your needs.

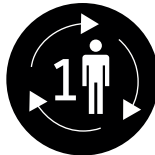


Spinal Orthoses are intended for all ages, sizes and weights and designed for medium activity levels.



Spinal orthoses are intended for the sole use of the patient named on the conformity documentation. If the orthosis is no longer required it must be safely disposed. Please follow the guidelines below.

- * **Removal of the label**
- * **Remove any parts which can be dismantled to reduce the risk of re-use. Follow recycling guidelines where possible.**
- * **Ensure the healthcare professional is aware that the device is no longer required.**
- * **Be careful of sharp edges and finger traps. Always wear gloves when dismantling and ensure the Spinal Orthosis is secured on a table.**
- * **Do not re-use any components.**



Everyday Use

Blatchford Spinal Orthoses applies forces to the body segments to which they are attached. The interface components which 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 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 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. The 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 that 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 ensuring the orthosis is properly positioned.
- At first, it may be easier to tighten the orthosis while lying down. Once your spine accepts the orthosis, you should 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).

LUMBO SACRAL ORTHOSIS (LSO) Fitting Guidelines

- 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 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. The 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.

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's head, the second assistant must carefully slide the back panel under the users's 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.

Intended Performance of Device

Environment: Avoid exposing any othoses 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 C (14 F to 122 F).

Activity: 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 12 months of use to determine suitability of use.

Maintenance:

Cleaning

The hard-plastic outer shell and the inner soft plastic foam must be cleaned every day. Use a cloth with antibacterial sanitizer to clean the lining, then wipe the lining thoroughly with a damp cloth. Make sure all the sanitizer 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.**

Note: These are recommended or suggested methods of cleaning. Blatchford is not responsible for damage incurred while cleaning. If you are not sure how best to clean your Spinal Orthosis please contact your prescribing medical professional.

Maintenance Schedule

Weekly

- * User visual inspection
- * Inspect Spinal Orthosis all over generally for any obvious signs of wear & 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.

Six months




We recommend each orthosis is fully serviced by the manufacturer and any worn parts should be repaired and replaced as appropriate. Ensure all labels on the product are intact and never remove any warning or serial numbers from the orthosis. Failure to comply may invalidate the warranty

Warranty

For all warranty enquiries please refer the website under the warranty section.

Label Identifier

A label is located on each custom-made medical device. Due to the custom nature of the product it may be positioned where practicable.

Blatchford Custom-made device. MD					
Serial No.	X ●				
Identifier	●				
Location	●				
Product	●				
Description	Orthosis D of M ● 				
Device incorporates tissues of animal origin as referred to in Regulation (EU) No 722/2012 <table border="1" style="float: right;"> <tr> <td>YES</td> <td><input type="checkbox"/></td> </tr> <tr> <td>NO</td> <td><input type="checkbox"/></td> </tr> </table>		YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
YES	<input type="checkbox"/>				
NO	<input type="checkbox"/>				
936252 1631 04/20					
 Blatchford Limited: Atlas Way: S4 7QQ orthoticsales@blatchford.co.uk 					
Blatchford Products Limited : Lister Road : Basingstoke : RG22 4AH					

Serial No. Quote this number with any enquiry

Identifier. Customer name or Initials (if applicable)

Location. Hospital/Clinic

Product. Product description

D of M . Date of Manufacture



Single user Use Only



Manufacturer of Medical Device



Must consult information for user



Medical Device



Please report any serious incident that has occurred in relation to the device to the manufacturer and the MHRA

Manufacturer's Registered Address
Blatchford Products Limited, Lister Road, Basingstoke RG22 4AH, UK.

Manufactured by
Blatchford Limited: Atlas Way: S4 7QQ : orthoticsales@blatchford.co.uk : +44 (0) 114 263 7900