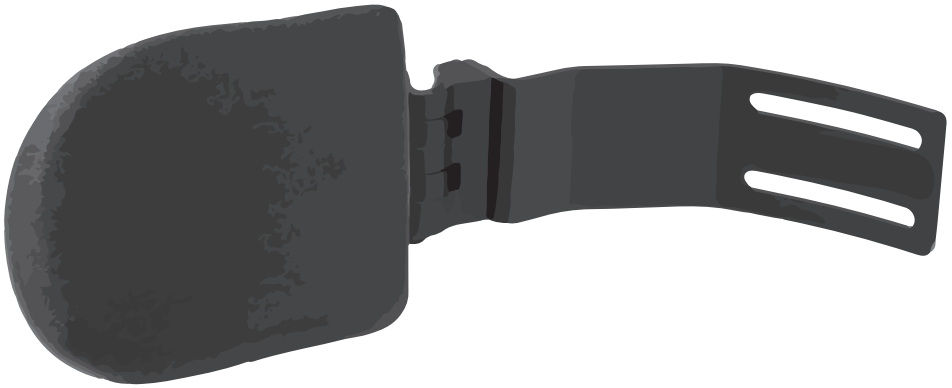
Blatchford

Custom Made Thoracic Support 819051

Custom-made Medical Device

EN Instructions For Use



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About Us

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

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

Product Description

Custom Thoracic Supports (Laterals) provide a bespoke postural support solution to the occupant. Multiple shape and size varations provide optimum support and correction combined with excellent accommodation for the user. Blatchford custom made Laterlas are designed to offer high levels of support and pressure relief and can be interfaced onto most wheelchairs in the marketplace whilst being easily removable for cleaning and maintenance.

Blatchford Laterals are custom made devices. They are defined by the Medical Devices Regulation as devices 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. This provides under their responsibility, specific characteristics as to its design and is intended for the sole use of a named patient. This 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.

Pre-Use Checks

Important Safety Information

Before using your custom made Thoracic Support (Lateral) please check the following:

* The Thoracic Support (Lateral) is secured to the wheelbase and/or seating securely.
* The Thoracic Support (Lateral) is not restricting any hoist equipment or belts and harnesses.
* The Thoracic Support (Lateral) is correctly orientated and free from excessive movement.
* The occupants arm cannot be trapped within the Thoracic Supports (Laterals)
* The Thoracic Support (Lateral) is free from dirt/debris and the materials are free from defects.

Safety Information

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If after use, 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 Custom Laterals and contact your healthcare professional for advice as they may need adjusting. Should you develop any sores or blisters you should stop use of the device at once.

Custom Thoracic Supports (Laterals) are designed and prescribed for an individual's needs and should only be used by the sole user.

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

Custom Laterals must be regularly maintained to the mainenance schedule in this IFU.

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

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

• 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.

Do not remove any serial or warning labels from the Custom Thoracic Supports (Laterals).

Custom-made Thoracic Support (Laterals) may include flammable materials. Always be aware of fire hazards.

The custom Thoracic Support (Lateral) must only be used with the wheelchair it was manufactured for. If a different wheelchair is going to be used contact the Approved Healthcare Professional for help or advice.

No alteration should be made to the Laterals nor should 3rd party manufacturers' products be fitted without the prior agreement of your healthcare professional.

Never leave an occupant unattended. Ensure the Thoracic Support (Lateral) is fitted correctly and ensure they are fitted during transportation. If the user shows any continued signs of distress or discomfort, stop using the product and immediately contact the wheelchair service provider.

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Intended Use

Custom Laterals are intended for occupants of a mass less than 100kg with moderate to high postural needs. The Lateral is made to the prescription of the healthcare professional and they will provide advice on related custom products and add-on 3rd party products such as straps, controls and postural belts.

The most common conditions include:

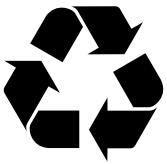
* Cerebral Palsy
* Muscular Dystrophy
* Scoliosis
* Spinal muscular Atrophy
* Aquired Brain Injuries

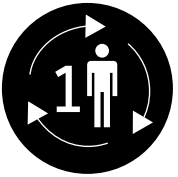
Blatchford products are prescribed and designed to meet the functional loss needs of each individual user rather than to treat an individual condition or pathology. Blatchford products are suitable for use on one or more wheelbases and can be used by most ages. Custom made Laterals are always and only intended to be used where specified.

Custom made Laterals are intended for users of 100kg or less are designed for low impact levels. Your healthcare professional will advise on the optimum Blatchford Custom made Laterals for your needs.

Custom made Laterals are intended for the sole use of the patient named on the conformity documentation. If the Blatchford item is no longer required it must be safety disposed of. 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. Always wear gloves when dismantling and ensure the Custom made Lateral is secured on a table to perform the task.**
*** Do not re-use any components unless a healthcare professional has provided a local risk assessment.**





Everyday Use

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The Lateral materials have been designed to avoid unacceptable pressure on and stress levels in body tissues.

When seating an occupant with a headrest the following steps should be taken:

1. Check the Lateral is secured, free from debris and moves/functions correctly.
2. Seat the occupant, ensuring the Laterals are correctly orientated. Ensure creases are removed and Belts and harnesses engaged (if applicable).

It is normal to see red marks where pressure has been applied. These should disappear within 30mins. IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL.

The fit and feel of the Custom Lateral may take some time to get used to. The Custom Lateral should not be painful; however, it is not unusual to feel some initial discomfort. If you experience rubbing or blistering, please book an appointment with your Healthcare professional for immediate attention. If you are experiencing pain after two weeks please book a follow up appointment with your healthcare professional.

Safe Transportation

The Custom Lateral has been tested in combination with seating products to allow the seat and its user to be transported in a forward facing position in a vehicle designed for the purpose (for example, in a suitably equipped minibus).

This information should be made available for services making transport arrangements (e.g. schools and other organisations).

Securing the user, the Custom Laterals and the host wheelchair in a vehicle:

1. During travel the Custom Laterals must be securely fastened into its wheelchair as described earlier in this manual.
2. Posture belts and postural harnesses supplied as part of the seating system are designed to give postural support only. Where these items are fitted they should be used during travel but they must not be used as the only safety restraints.
3. The wheelchair itself must be fastened down in the vehicle – this must be in accordance with the wheelchair manufacturer's instructions. (The wheelchair manufacturer will issue these instructions separately. In case of query contact your healthcare professional).
4. A suitable, separate, passenger seat belt (fastened in to the vehicle) must be used by the occupant during travel. In order to achieve occupant restraint and optimum protection in a crash situation the seatbelt should have both pelvic and upper body sections (for example a 3 point type with the upper section fastened into the vehicle at the upper level) as a minimum standard.
5. The Laterals can always be used during travel.
6. Always follow guidance from the wheelbase manufacture, 3rd party devices and accessory IFUs in combination with this manual.

Never leave an occupant unattended. Ensure the Lateral is fitted correctly and secured during trnsportation. Check that all secondary support devices are secure and function correctly. Always remove trays and knee blocks prior to transportation. Always secure your wheelchair with WTORS four-point, strap-type tiedowns. Where posture belts and posture harnesses are installed, they should be used during travel, but they must not be used as the only safety restraints. Ensure your seating system is fully attached to the wheelbase prior to transportation. Check before and after fitting the tiedowns.

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Intended Performance of Device

Environment: Avoid exposing the laterals 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. Sytems are recommended for use between -10 C and 50 C (14 F to 122 F).

Activity: Our laterals are not designed for high activity sports such as wheelchair basketball, or wheelchair skate ramps Any such activities undertaken are done so completely at the users' own risk.

Lifetime : It is recommended that Custom Laterals are evaluated by a healthcare professional after 12 months of use to determine suitability of use.

Maintenance:

Cleaning

Cleaning any Custom lateral is very important for both user safety and ensuring the longevity of the medical device. The device should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the device use a soapy soft cotton cloth and gently rub with circular movements to remove stubborn dirt utilising domestically available anti-bacterial cleaning products. Do not pressure wash your pommel. For more stubborn marks a dilute bleach solution can be used: 5% bleach to 95% water. Use a clean cotton cloth to wipe the area and dry the surface of the system after cleaning.

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 system please contact your prescribing medical professional.

Maintenance Schedule

Weekly

- User visual inspection.
- Inspect all over generally for any obvious signs of wear & tear.
- Check that the user's shape is still accommodated by the shape of the Custom Thoracic Supports (Laterals)
- Check that the Custom Lateral is not too restrictive for the user.
- Check there is no structural damage to the shells or any of the brackets and that all securing bolts are still in place.
- Check the quality of the foam, particularly load areas.
- Check that all locking knobs on the brackets are in place and functioning correctly.

Six months

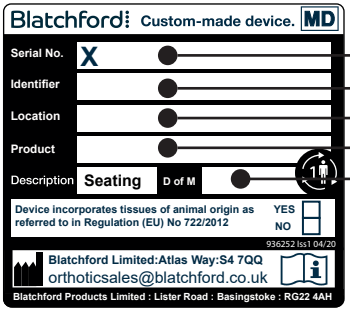
We recommend each device is fully serviced by the manufacturer and any worn parts should be repaired and replaced as appropriate. Ensure all labels on the product are intact and never remove any warning or serial numbers from the device. Failure to comply may invalidate the warranty

Warranty

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

Label Indentifier

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



Serial No. Quote this number with any enquiry

Identifier. Customer name or Initials (if applicable)

Location. Hospital/Clinic

Product. Product descrption

D of M . Date of Manufacture

Single user Use Only

Must consult information for user

Manufacturer of Medical Device

MD **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.