

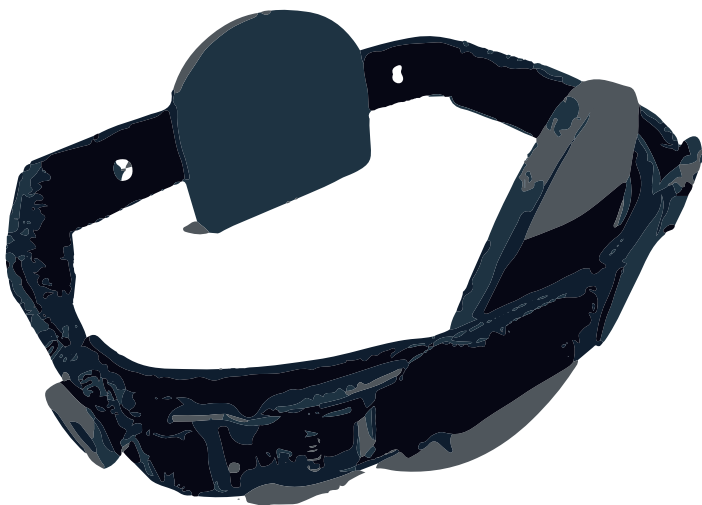


Blatchford: Pectus Brace

Custom-made Medical Device

829030 Pectus Bracing

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. The range of Orthotic devices provided by Blatchford complements the wide variety of specialisations practiced by our mainly dual qualified Orthotic Clinicians. These specialisations include orthotics for diabetes, neurological disorders, orthopaedics, spinal pathologies, orthopaedic footwear and treatment ranges from paediatric provision through to disorders related to old age.

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. Blatchford uses a combination of made to measure and off the shelf devices to ensure optimum treatment effect and comfort. Digital scanning and computer aided manufacture of insoles and braces ensures that our Orthoses are manufactured to a high degree of accuracy.

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. We have access to gait analysis systems in many of our clinics which measures the effectiveness of chosen devices and treatments regimes

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

Product Description

A Pectus Carinatum Brace is a custom-made medical device and is defined by the Medical Devices regulations 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 professional qualification. 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 medical practitioner who is responsible for specifying the specific design characteristics of the product intended for the sole use of an individual user. A Pectus Carinatum Brace is not a mass-produced product and it requires to be adapted to meet the specific requirements of the user and their treating medical practitioner. The activities carried out by Blatchford in supplying or fitting a Pectus Carinatum Brace (e.g. preparation, impression taking, prescribing, final fitting and any adaptation), are not considered to fall within the scope of the Medical Devices Regulations.

Our Pectus Carinatum products are lightweight custom-made devices that wrap around the chest to apply pressure to correct a deformity of the chest wall. Pectus Carinatum Braces can be made of different materials including thermoplastics, metal bands and leather. They are divided into a front and back section, joined together by two side straps. The Pectus Carinatum Brace is held in position by leather or fabric straps and is close fitting to ensure best correction is achieved.

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



If after use of the Pectus Brace 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 Pectus Brace 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 brace immediately.



The Pectus Brace 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 pectus brace please contact your healthcare professional as this could affect the custom pectus brace performance



• The custom Pectus Brace must be regularly maintained to the maintenance schedule in this IFU.



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



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



Clips or fasteners can entrap fingers or clothing, be cautious of this when operating the brace.



All straps must be secured firmly when putting the Pectus Brace on. Appropriate fixation of the strap is very important, as the straps hold the custom Pectus Brace onto the limb 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 Pectus Brace



• Pectus Brace may include flammable material. Be aware of Fire Hazards where possible.

Intended Use

A custom Blatchford Pectus Carinatum Brace is provided for correction of protrusion deformities within the anterior chest wall.

Pectus Carinatum Braces are prescribed and designed to meet the functional correction of each individual user and are suitable for use up until skeletal maturity. The overall design and components used within a Pectus Carinatum Brace are selected at the time of specification based on the needs of the individual user.

It is a lightweight custom-made brace that wraps around the chest and applies pressure on the front of the chest that protrudes. The pressure from the pectus brace will push the breastbone back to a normal position to correct the deformity. The Pectus Brace is designed for Pectus Carinatum.

What is pectus carinatum?

Pectus carinatum (also known as pigeon chest) is a condition in which the breastbone (sternum) of the chest sticks out. This happens because several ribs and the breastbone grow abnormally. It is considered mainly a cosmetic deformity and is rarely related to pain, discomfort or underlying cardio/respiratory issues. If you are still growing, a pectus brace can be used for correction of the chest wall deformity, by compressing the prominence and allowing more symmetrical growth around the deformity to achieve a permanent correction.

Contra-indications

You should always have agreement from a consultant specialising in pectus deformities before starting to use the pectus brace. This will usually confirm no underlying cardio/respiratory related issues, ensuring starting pectus bracing is safe to commence.



Pectus Braces are intended for users of any weight or size and for predominately male users
Your healthcare professional will advise on the optimum Pectus Brace for your needs and may be able to find specific solutions if applicable



Pectus Braces are intended for the sole use of the patient named on the conformity documentation.
If a Pectus Brace 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 brace is secured on a table to perform the task.**
- * **Do not re-use any components unless a healthcare professional**



Everyday Use

Blatchford Pectus Carinatum Braces 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. We advise users to wear a cotton T-shirt or vest under your Pectus Carinatum Brace that is:

- * Well fitting to avoid creases
- * Made from cotton rich material
- * Plain fabric, without patterns or holes

When putting the Pectus Carinatum Braces on the following steps should be taken,

- * Sit upright or stand to put on the brace
- * Make sure there are no wrinkles in the T-Shirt or vest
- * Place the pectus brace around the chest and, if supplied, the shoulder straps over both shoulders
- * Make sure that the front pad is positioned over the main prominence of the chest and adjust the shoulder straps to stop the brace dropping down
- * Tighten up the side straps evenly, as shown by the orthotist

At first, the Pectus Carinatum Brace may feel uncomfortable and may take some time to be tolerated. Wear times should be increased slowly as advised by the prescribing orthotist. The user should check the skin where the Pectus Carinatum Brace has been in contact every time the brace is removed.

It is normal to see red marks where pressure has been applied. These should disappear within 30mins of the brace being removed. "IF NOT CONTACT YOUR HEALTHCARE PROFESSIONAL. The straps and padding may discolour with use, this will not affect the function of the device.

Intended Performance of Device

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

Activity: The device should not be worn during increased cardio exercises or in any extreme or contact sports. Any such activities undertaken are done so completely at the user's own risk.

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

Maintenance:

Cleaning

Cleaning a Pectus Carinatum Brace is very important for both user safety and ensuring the longevity of the medical device. The Pectus Carinatum Brace should be wiped clean daily. Please note that stains caused by bodily fluids should be removed immediately. When cleaning the Pectus Carinatum Brace 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 Pectus Carinatum Brace. 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 Pectus Carinatum Brace after cleaning. Allow to airdry, and exposure to increased heat could cause damage to the padding, fabric covers or deformity of the plastic sections.

Maintenance Schedule

Weekly

- * Inspect Pectus Carinatum Brace 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 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 Identifier

A label is located on each custom-made medical device. Due 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"> <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"/>				
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



Must consult information for user



Manufacturer of Medical Device



Medical Device



MD

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