

Custom-Made Medical Device

Instructions for Use

829030 Pectus Bracing

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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.

A Pectus Carinatum Brace is a custom-made medical device.

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 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 device at once.



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



The Pectus Brace must be regularly maintained to the maintenance schedule in this IFU by a 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 Pectus Brace.

-  **Pectus Brace 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 Pectus Brace display any unusual behaviour, changes of performance or fittings or the device comes loose please immediately stop use and contact your healthcare professional.**
-  **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.**
-  **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 the failure of the device.**
-  **Avoid strong magnetic fields, sources of electrical interference.**
-  **Clips or fasteners can entrap fingers or clothing, be cautious of this when operating the brace.**
-  **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.**

3 Everyday Use

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

The 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 materials
- 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, 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 30 minutes 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.

Indications

You should always have agreement from a consultant specializing 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 the Pectus Brace is no longer required, it must be safely disposed. Please follow the guidelines below:

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

4 Intended Performance

Environment

Avoid exposing the Pectus Brace 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 $+50^{\circ}\text{C}$ (14 F to 122 F).



Suitable for outdoor use

Activity

Our Pectus Braces 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 every 12 months of use as a minimum to determine continued suitability of use.

5 Maintenance

Cleaning

Cleaning any Pectus Brace 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 utilizing domestically available anti-bacterial cleaning products. Do not pressure wash your device. Use a clean cotton cloth to wipe the area and dry the surface of the device after cleaning.

5.1 Maintenance Schedule

Daily

- Inspect Pectus Carinatum Brace 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

6 Monthly

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

5.2 Transport & Storage

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

Ensure the Pectus Brace is thoroughly protected from damage in transit.

6 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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