PECTUS
Pectus Carinatum Orthosis
Installation Guide
31285-001 REV F 2021-07-23

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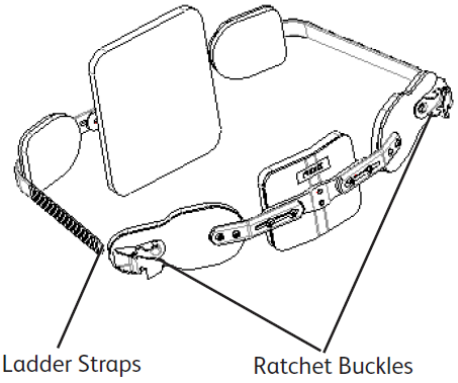
INTRODUCTION

The Pectus Carinatum Orthosis was ordered by your physician for you as an aid in the reduction or correction of an abnormal deformation of the chest.

It provides increased anterior/posterior-directed and compression corrective forces for the reduction of Pectus Carinatum and other anomalies.

Front View



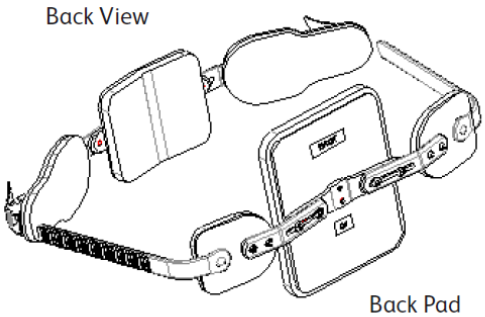
Indications

- Abnormal shape of the chest
- A protrusion of both the sternum (breast bone) and the cartilage portion of the ribs
- Bowed Chest (Pigeon breast)

Contraindicated

- Severe deformations

Back View



Application

- Follow all instructions carefully that were given to you by the fitting specialist and protocols set by your prescribing physician.
- When removing and applying the orthosis only use one side of the ratchet buckle to tighten and remove.
- The ratchet can be loosened by pushing down on the ratchet release lever under the ratchet for removal.
- Place the ladder strap into the ratchet and tighten.

Special Instructions:

Care of the Orthosis

- It is recommended that a snug fitting under shirt be worn between the skin and the Orthosis.
- The foam pads can be washed by hand with mild soap and water and towel dried.

  ⚠ Do not use heat to dry or place near any heating device.

Any questions or problems

- For any physical problems, call your prescribing physician.
- Call you fitting specialist for any problems associated with the orthosis.

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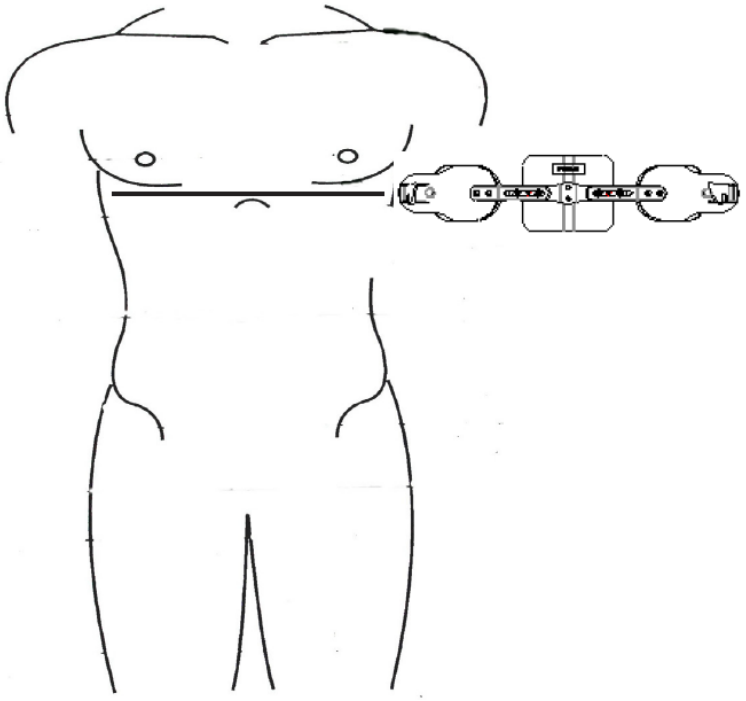
FITTING SPECIALIST INSTRUCTIONS
INSTALLATION AND USE

NOTE: This device should be fit by a qualified fitting specialist to the protocols of the prescribing physician.



Step 1: Measurements and Initial-Adjustments

A. Take a circumferential measurement at or about the xiphoid.

B. Loosen the sternal and posterior adjustment screws to increase or decrease circumference by sliding components and tighten.

C. The anterior and posterior pads can be removed for customizing the shape for each individual's needs.

Step 2: Contouring metal components

A. The metal components can be contoured with the use of bending irons.

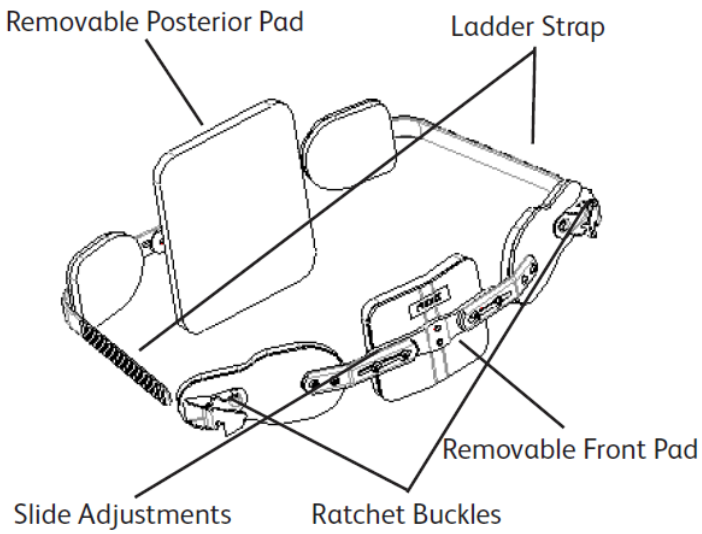
B. If bending irons are necessary, we recommend only round edged bending irons to be used. Care should be taken not to make sharp bends in slotted areas.

C. Apply orthosis and tighten to desired tension by means of the ratchet buckles.

D. For removal, have patient push down on the ratchet release to loosen the ratchet and then slide the strap out of the buckle.

E. The patient should be instructed to only remove the orthosis by loosening just one side which ever they prefer.

F. Instruct patient how to insert ladder strap into ratchet buckle and tighten to desired tension.



STORAGE AND USE

There are no identified restrictions on the temperature of storage and use.

DISPOSAL

There are no hazardous materials in the device. Comply with local and national laws and regulations.

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LEGAL INFORMATION

MD The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.

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LIMITED WARRANTY

Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repaired by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.

As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.

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