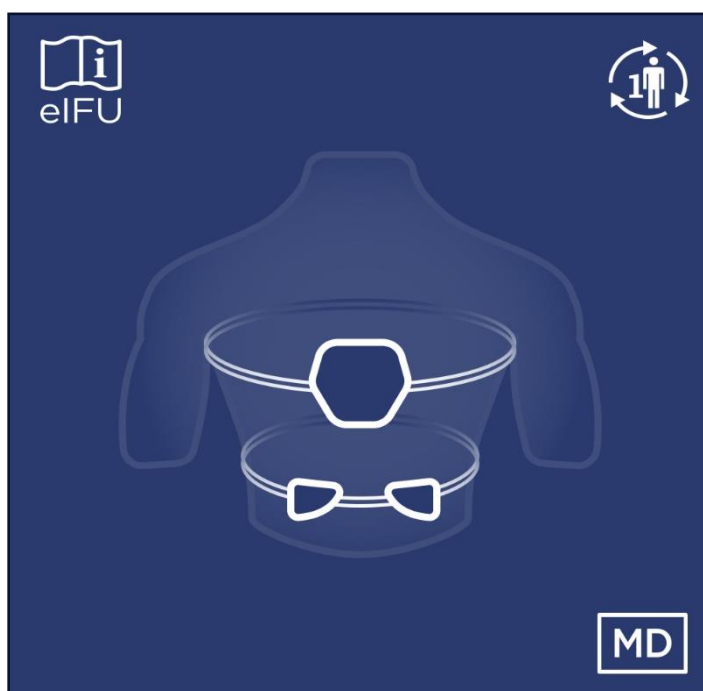


# Custom-Made PECTUS BRACE (Pectus Carinatum & Rib Flaring Brace)

## CONTENTS

1. PRODUCT NAME / IMAGE
2. MANUFACTURER DETAILS
3. DEVICE DESCRIPTION
4. INTENDED USE
5. INDICATIONS
6. CONTRAINDICATIONS
7. WARNINGS
8. PRECAUTIONS
9. INSTRUCTIONS FOR USE
10. CLEANING & MAINTENANCE
11. STORAGE CONDITIONS
12. DISPOSAL INSTRUCTIONS
13. REGULATORY COMPLIANCE
14. WARRANTY INFORMATION
15. CONTACT INFORMATION
16. DATE OF ISSUE & VERSION



This guide is meticulously designed to provide comprehensive information and instructions on the proper use, maintenance, and care of our custom-made orthotic devices. At The London Orthotic Consultancy, we are committed to delivering exceptional quality and precision in orthotic solutions, tailored to meet the unique needs of each individual patient.

Our orthotic devices are developed with the latest technology and innovative design to ensure optimal functionality, comfort, and support. They are essential tools in rehabilitation, pain reduction, and the enhancement of mobility and stability for various medical conditions.

**This IFU (Instruction for use) is a vital resource for both healthcare professionals and patients, ensuring that our orthotic devices are used safely and effectively. It is crucial to read and understand this document thoroughly before using any of our products.**

By adhering to the guidelines and recommendations outlined in this document, users can maximize the benefits of their orthotic devices, ensuring a seamless integration into their daily lives and rehabilitation programs.

Should you have any queries or require further assistance, our team of dedicated professionals is always available to provide support and guidance.

*[The following sections of this document will include detailed instructions and safety information specific to each orthotic device provided by The London Orthotic Consultancy.]*

## 1. Product Name

CUSTOM-MADE PECTUS BRACE (Pectus Carinatum & Rib Flaring Brace)

### Related Product Codes:

PECT-DCC1-PA\*2  
PECT-DCC2-PA\*2

## 2. Manufacturer Details

L.O.C. MANUFACTURING LIMITED / THE LONDON ORTHOTIC CONSULTANCY LIMITED  
1 Elm Crescent, Kingston Upon Thames, Surrey, England. K 2 6HL

Tel: 020 8974 9989  
Email: [info@londonorthotics.co.uk](mailto:info@londonorthotics.co.uk)

## 3. Device Description

Custom-Made brace designed for the correction of pectus carinatum (pigeon chest) and rib flaring. Made of lightweight, medical-grade materials with adjustable pressure pads and straps for a comfortable, tailored fit.

### Custom Fitting:

Each brace is tailored to the individual's measurements, ensuring a precise fit that optimises the corrective pressure on the protruding sternum and ribs.

### Materials:

Constructed from high-quality, lightweight materials that are durable and designed for medical use. The brace is made up of a combination of rigid and flexible elements that provide both strength and comfort.

### Pressure Pads:

Equipped with adjustable pressure pads lined with soft, skin-friendly material. These pads are strategically placed to exert optimal pressure on the chest wall, which is essential for effective correction.

### Adjustability:

Features a versatile strap system that allows for fine-tuning of pressure levels and ensures the brace remains effective even as the patient grows or their condition improves.

### Ergonomic Design:

The brace's design follows the natural contours of the body, ensuring maximum contact and effectiveness while minimising discomfort. It is slim enough to be worn discreetly under clothing.

### Breathability:

Incorporates breathable fabrics and padding to reduce heat and moisture buildup, ensuring comfort during extended wear.

### Safety Features:

Includes quick-release mechanisms for easy removal in case of discomfort or emergency. The materials used are hypoallergenic to minimise the risk of skin irritation.

### Compliance Indicators:

Some models may include compliance indicators, which help track how often and how long the brace is worn, aiding in treatment monitoring.

## 4. Intended Use

Intended for non-surgical correction of pectus carinatum and rib flaring, providing external pressure to flatten the protruding sternum and/or ribs.

## 5. Indications

### Pectus Carinatum (Pigeon Chest):

Ideal for patients with protruding sternum and ribs, characteristic of pectus carinatum. Particularly effective in severe cases, where the chest deformity is flexible and can be reshaped with external pressure.

### Adolescent Growth Spurts:

Highly recommended for use during adolescence when rapid growth spurts occur, as the chest wall is more malleable and responsive to bracing. Suitable for pre-teens and teenagers, typically between the ages of 10 and 17, when the majority of skeletal growth occurs.

**Rib Flaring:**

Indicated for patients with rib flaring, often accompanying pectus carinatum or Pectus Excavatum, where the lower ribs protrude outward. Effective in minimising the visual and structural impact of rib flaring.

**Post-Surgical Support:**

Can be used as a post-operative support mechanism after surgical correction of chest wall deformities to maintain the surgical outcomes.

**Non-Surgical Candidates:**

An option for patients who are not candidates for surgery due to medical reasons or personal preference. Beneficial for those seeking a non-invasive treatment method.

**Symptom Management:**

Helps in alleviating physical discomfort and respiratory issues associated with pectus carinatum and rib flaring.

**Psychosocial Considerations:**

Recommended for patients experiencing psychosocial impacts, such as self-consciousness or social discomfort, due to the appearance of their chest.

**Preventive Use:**

In early diagnosed cases, the brace can prevent the progression of the deformity, especially when started at a younger age.

**Compliance-Dependent Treatment:**

Suitable for patients who are able and willing to adhere to a strict wearing schedule, as the effectiveness of the brace is highly dependent on consistent and prolonged use.

**Customisation Requirement:**

Indicated for patients who require a customised fit due to unique chest wall shapes or sizes not accommodated by off-the-shelf braces.

*Each patient's suitability for the device should be evaluated by a healthcare professional, considering the individual's specific medical condition, lifestyle, and overall treatment goals.*

**6. Contraindications**

**Severe Respiratory Conditions:**

Patients with severe respiratory diseases or conditions that compromise lung function should not use the brace, as it may exacerbate breathing difficulties.

**Open Chest Wounds or Recent Surgery:**

The brace is contraindicated for individuals with open wounds on the chest or those who have recently undergone chest surgery until fully healed, as it can interfere with the healing process.

**Skin Infections or Severe Dermatological Conditions:**

Patients with active skin infections, severe eczema, psoriasis, or other significant skin disorders in the area where the brace will be worn should avoid using the brace until these conditions are resolved.

**Severe Spinal Deformities:**

Individuals with severe spinal deformities, such as advanced scoliosis or kyphosis, may not benefit from the brace and could experience increased discomfort or worsening of their condition. In these circumstances it is recommended that you seek advice from your healthcare provider.

**Allergies to Brace Materials:**

Patients with known allergies to any of the materials used in the brace, such as certain plastics, foams, or metals, should not use the brace.

**Cardiovascular Complications:**

Those with underlying cardiovascular conditions that could be aggravated by the external pressure exerted by the brace should avoid its use.

**Rigid or Non-Flexible Pectus Carinatum:**

The brace is less effective for individuals with rigid or non-flexible pectus carinatum, where the chest wall does not respond to external pressure.

**Cognitive or Behavioural Challenges:**

Patients, especially children, who are unable to understand or comply with the brace-wearing schedule due to cognitive or behavioural challenges, may not be suitable candidates for this treatment.

**Osteoporosis or Bone Fragility:**

In cases of osteoporosis or other conditions leading to bone fragility, the brace might pose a risk of fractures or other injuries and should be avoided.

**Uncontrolled Asthma:**

For patients with uncontrolled asthma, the constriction caused by the brace may trigger asthma attacks or worsen respiratory function.

**Circulatory Impairments:**

If there are any circulatory impairments in the upper body, the brace may exacerbate these conditions.

*Each patient's situation and medical condition should be thoroughly evaluated by healthcare professionals to determine the suitability of the device. These contraindications serve as a guide to ensure patient safety and the effective use of the device.*

**7. Warnings**

**⚠ Risk of Skin Irritation or Damage:**

Prolonged contact or excessive pressure may lead to skin irritation, bruising, or pressure sores. Regularly inspect the skin under the brace for any signs of damage.

**⚠ Improper Adjustment:**

Incorrect adjustment of the brace can lead to inadequate correction of the chest deformity or can even worsen the condition. It's crucial that adjustments are made by a trained professional or under their guidance.

**⚠ Over-Tightening:**

Tightening the brace excessively can cause discomfort, restrict breathing, or impair circulation. Ensure the brace is snug but not overly tight.

**⚠ Discomfort or Pain:**

If the patient experiences significant discomfort or pain while wearing the brace, they should remove it and seek advice from a healthcare professional. Pain may indicate improper fit or use.

**⚠ Interference with Physical Activities:**

The brace may restrict certain physical activities. Patients should be advised about the limitations and avoid activities that could be harmful while wearing the brace.

**⚠ Avoiding Modifications:**

Unauthorized modifications to the brace are strongly discouraged as they can compromise its effectiveness and safety. All adjustments should be carried out by a qualified professional.

**⚠ Monitoring for Respiratory Issues:**

Patients, especially those with pre-existing respiratory conditions, should be monitored for any breathing difficulties when using the brace.

**⚠ Impact on Posture and Movement:**

Long-term use of the brace may affect posture and movement patterns. Regular follow-up and physical therapy may be necessary to address these issues.

**⚠ Compliance with Treatment Plan:**

Failure to wear the brace according to the prescribed schedule can lead to suboptimal results. Patients should be warned about the importance of adherence to the treatment plan.

**⚠ Heat and Moisture Accumulation:**

The brace can cause heat and moisture accumulation, particularly in warm climates or during physical activity, which can lead to skin issues.

**⚠ Check for Allergic Reactions:**

Monitor for any allergic reactions to the brace materials. Signs of an allergic reaction include persistent redness, itching, or swelling.

**⚠ Emergency Situations:**

Patients and caregivers should be instructed on how to remove the brace quickly in case of an emergency, such as severe discomfort or difficulty breathing.

**⚠ Growth and Size Adjustments:**

In growing adolescents, regular adjustments may be needed to accommodate growth and ensure the brace remains effective and comfortable.

*It's important that these warnings are communicated clearly to the users and caregivers of the device. Adhering to these warnings helps in minimising risks and ensures the safe and effective use of the device. Healthcare professionals should provide thorough guidance and support to users, especially during the initial period of adjustment.*

**8. Precautions**

**Regular Skin Checks:**

Frequently inspect the skin under the brace for any signs of redness, irritation, or sores. This is crucial to prevent skin damage and ensure the brace is being tolerated well.

**Correct Fit and Alignment:**

Ensure the brace is properly fitted and aligned each time it is worn. Incorrect positioning can reduce effectiveness and cause discomfort or harm.

**Gradual Increase in Wear Time:**

Gradually increase the duration of brace wear to allow the body to adapt. Starting with shorter periods and progressively increasing to the prescribed duration helps improve tolerance and compliance.

**Breathing and Comfort:**

Monitor breathing and overall comfort while wearing the brace. If there are difficulties in breathing or severe discomfort, the brace should be adjusted or removed.

**Activity Level Adjustment:**

Be cautious with physical activities, especially those that involve bending or twisting of the torso. Some activities may need to be modified or avoided.

**Hydration and Overheating:**

Encourage regular hydration, especially in hot weather or during physical activity, as the brace can increase body temperature and lead to overheating.

**Wearing Schedule Adherence:**

Adhere to the prescribed wearing schedule as closely as possible for optimal results. Irregular use can significantly diminish the brace's effectiveness.

**Regular Follow-Up Appointments:**

Keep regular appointments with the healthcare provider for brace adjustments and to monitor progress. This is essential for the success of the treatment.

**Avoiding Direct Sunlight and Heat:**

Avoid exposing the brace to direct sunlight or high temperatures for extended periods, as this can deform the materials and reduce its efficacy.

**Donning and Doffing Care:**

Be careful when putting on (donning) and taking off (doffing) the brace to avoid injury. Follow the provided instructions for safe handling.

**Awareness of Body Changes:**

Be aware of any changes in body shape, size, or response to the brace. Growth or weight changes may require brace adjustments.

**Emergency Removal Knowledge:**

Ensure that the patient and caregivers know how to remove the brace quickly and safely in case of an emergency, such as severe pain or difficulty in breathing.

**Mental Health Consideration:**

Monitor the psychological impact of wearing the brace, especially in adolescents. Supportive counselling or therapy may be beneficial to address any body image or self-esteem issues.

*By following these precautions, the risk of complications can be minimised, and the effectiveness of the device can be maximised. It is important to remember that each patient's experience may vary, and ongoing consultation with healthcare professionals is crucial.*

## 9. Instructions for Use

**Initial Fitting:**

1. The brace should be initially fitted by a trained orthotist or healthcare professional. Ensure that it fits snugly but comfortably, with pressure distributed across the prominence on the chest.

**Wearing Schedule:**

1. Start with wearing the brace for short periods, gradually increasing the duration as recommended by your healthcare provider.
2. Typically, the brace is worn for several hours each day, eventually reaching up to 20-23 hours for optimal effectiveness.

**Putting on the Brace:**

1. Wear a thin, soft cotton shirt underneath the brace to protect your skin.
2. Open all straps or fastenings of the brace.
3. Place the brace against your chest, ensuring it is central and the pressure pads are correctly aligned with the protruding areas.
4. Secure the straps snugly but not too tightly. The brace should feel firm but not cause pain or difficulty breathing.

**Adjusting the Brace:**

1. Follow the instructions provided by your orthotist for adjusting the pressure.
2. Adjustments should be made gradually and never abruptly.

**Monitoring for Discomfort:**

1. Regularly check for any signs of discomfort, pain, or difficulty in breathing. Any of these signs indicate that the brace may need adjustment.

**Daily Skin Care:**

1. Inspect your skin daily for any signs of redness, bruising, or sores.
2. Apply a non-irritant barrier cream, if necessary.

**Physical Activity:**

1. Engage in light to moderate physical activities while wearing the brace.
2. Avoid activities that involve heavy impact or risk of injury to the chest.

**Removing the Brace:**

1. Loosen and unfasten the straps carefully.
2. Gently remove the brace from your chest.
3. Perform gentle stretches or posture exercises after removing the brace, or as advised by your healthcare provider.

**Cleaning the Skin and Brace:**

1. Clean your skin daily where the brace makes contact.
2. Follow the cleaning instructions for the brace to maintain hygiene and functionality.

**Follow-up Appointments:**

1. Attend regular follow-up appointments for professional adjustments and to monitor the progress of your treatment.

**Knowing When to Stop Using the Brace:**

1. Continue using the brace as directed by your healthcare provider.
2. Discontinuation will typically depend on the progress made and the discretion of your orthotist.

**Emergency Protocol:**

1. Know how to remove the brace quickly in case of an emergency, such as severe pain or difficulty in breathing.

*Following these detailed instructions is crucial to ensure the effectiveness of the device whilst maintaining comfort and safety. Regular communication with healthcare providers and adherence to the prescribed regimen are key to achieving the best outcomes.*

## 10. Cleaning & Maintenance

**Daily Cleaning:**

Wipe the interior and exterior surfaces of the brace daily using a clean, damp cloth. Use a mild soap or a non-irritating disinfectant cleaner that is safe for skin contact and compatible with the brace materials. Avoid using harsh chemicals, alcohol-based cleaners, or abrasive materials, as they can damage the brace and irritate the skin.

**Drying the Brace:**

After cleaning, thoroughly air-dry the brace away from direct heat sources such as radiators, heaters, or direct sunlight. Ensure the brace is completely dry before reapplying it.

**Padding and Straps Care:**

Check the condition of the padding and straps regularly. They should be cleaned with a damp cloth and mild soap. If the padding or straps are worn out or damaged, contact your healthcare provider for advice or potential replacements and repairs.

**Regular Inspection:**

Inspect the brace for any cracks, breaks, or deformities. Pay special attention to areas under stress, like buckles and joints. Look for signs of wear and tear, especially in areas that undergo frequent movement or adjustments.

**Avoid Immersion in Water:**

Do not submerge the brace in water, as this can compromise the integrity of the materials and the brace's structure.

**Odour Management:**

To manage odour, consider using a light, hypoallergenic spray specifically designed for braces or a mixture of water and baking soda. Avoid heavily scented sprays or allergenic substances.

**Handling and Transportation:**

Handle the brace with care, avoiding unnecessary bending or twisting. When transporting, protect the brace in a bag or case to prevent damage.



**15. Contact Information**

For queries or more information, please refer to "Section 2. Manufacturer Details".

**16. Date of Issue & Version**

[Version: 1.0]  
[Date of Issue: 2023]  
[Latest Revision: May-24]