

Custom-Made CRO (Cranial Remoulding Orthosis)

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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 the 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.]

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| <p>1. Product Name/Image</p> |
| <p>CUSTOM-MADE CRO (CRANIAL REMOULding ORTHOSIS)</p> <p>Related Product Codes:</p> <p>LOCB-PP LOCB-PA'2-1 LOCB-PA'2-2 CRAN-S CRAN-PA'2-1 CRAN-PA'2-2 CRAN-PA'2-3</p> |
| <p>2. Manufacturer Details</p> |
| <p>L.O.C. MANUFACTURING LIMITED / THE LONDON ORTHOTIC CONSULTANCY LIMITED 1 Elm Crescent, Kingston Upon Thames, Surrey, England, K 2 6HL</p> <p>Tel: 020 8974 9989 Email: info@londonorthotics.co.uk</p> |
| <p>3. Device Description</p> |
| <p>Custom-made cranial remoulding helmet designed to treat and correct infant cranial deformities. Each orthosis is precisely fabricated using the latest in 3D scanning and printing technology to ensure a perfect fit tailored to the unique contours of the infant's head.</p> <p>Material Composition: Crafted from a medical-grade, lightweight polymer that is both durable and flexible, providing safe and effective cranial correction. The interior is lined with a soft, foam lining that cushions the infant's head, ensuring comfort during extended wear.</p> <p>Custom Fit: Utilising digital scans of the infant's head, the orthosis is custom moulded to address specific cranial deformities, including plagiocephaly, brachycephaly, and scaphocephaly. This personalized approach allows for targeted correction and optimal growth.</p> <p>Ventilation System: Integrated ventilation holes are strategically placed throughout the orthosis to promote airflow and reduce heat buildup, ensuring the infant remains comfortable and cool.</p> <p>Closure System: Features a 3D-printed strap for secure closing of the orthosis.</p> <p>Ease of Use: Designed with both infants and caregivers in mind, the orthosis is easy to put on and remove, with a secure closure system that prevents accidental removal by the infant.</p> <p>Hygienic and Skin-friendly: The materials used are hypoallergenic, skin-friendly, toxic-free, washable, heat mouldable, reducing the risk of skin irritation. The foam lining can be easily cleaned to maintain hygiene.</p> |
| <p>4. Intended Use</p> |
| <p>Intended for the treatment of positional cranial deformities, including plagiocephaly (flat head syndrome), brachycephaly (short head syndrome), and scaphocephaly (narrow head syndrome). It's used in infants aged 4-24 months, during the critical period of skull growth, to achieve optimal head shape correction.</p> |
| <p>5. Indications</p> |
| <p>Plagiocephaly (Flat Head Syndrome): Indicated for infants showing unilateral flattening of the skull, which may result from prolonged pressure on one area of the head. This condition often occurs in infants who consistently rest their heads in the same position due to limited mobility or preference.</p> <p>Brachycephaly: Suitable for infants with a disproportionately wide head due to extended periods of supine positioning (lying on the back), leading to flattening across the back of the skull.</p> <p>Scaphocephaly: Recommended for infants with an elongated head shape, often seen in premature infants who have spent extended periods in</p> |

neonatal intensive care units, where the head may grow preferentially in a longitudinal direction due to positioning.

Post-operative Cranial Shape Management:

Utilised following craniostyostosis surgery (a condition involving the premature fusion of one or more cranial sutures) to guide the skull into a more normal shape as it grows.

Torticollis-Related Cranial Asymmetry:

Indicated for infants with congenital muscular torticollis, a condition that limits neck movement and leads to preferential head positioning, which can result in cranial asymmetry.

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

Craniosynostosis:

The orthosis is contraindicated for infants diagnosed with craniosynostosis, a condition characterized by the premature fusion of one or more cranial sutures. This condition typically requires surgical intervention before cranial remoulding can be carried out, as the orthosis cannot correct the suture fusion.

Open Skin Lesions or Severe Dermatitis:

Infants with open wounds, skin lesions, or severe dermatitis on the scalp should not use the orthosis until these conditions have fully healed to prevent exacerbation or infection.

Severe Neurological Conditions:

Infants with severe neurological conditions that affect head shape or growth may not be suitable candidates for cranial remoulding orthoses due to the specific needs and considerations of their condition.

Respiratory Compromise:

The orthosis should not be used in infants with respiratory compromise or conditions that could be exacerbated by wearing a cranial orthosis, as it may interfere with ventilation or exacerbate pre-existing conditions.

Over the Recommended Age Limit:

The effectiveness of the orthosis significantly decreases after the age of 18 months due to the natural closure of cranial sutures. Therefore, it is contraindicated for use in older infants where cranial suture closure is likely to have begun.

Severe Hypotonia or Hypertonia:

Infants with severe muscle tone disorders, either hypotonia (low muscle tone) or hypertonia (high muscle tone), may not be suitable for the orthosis due to the potential impact on fit, comfort, and safety.

Allergic Reactions to Orthosis Materials:

Infants with known allergies to the materials used in the construction of the orthosis, such as certain plastics or foam padding, should avoid use to prevent allergic reactions.

Inadequate Supervision for Compliance:

The orthosis requires consistent and supervised use to ensure safety and effectiveness. It is contraindicated in situations where adequate supervision and compliance with the wearing schedule cannot be guaranteed.

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 Breakdown:

Continuous pressure or friction from the orthosis may cause skin irritation, redness, or breakdown. It is crucial to regularly inspect the infant's skin for any signs of distress and to ensure proper hygiene and care where the orthosis makes contact with the skin.

⚠ Proper Supervision Required:

Constant supervision and regular adjustments by a trained professional are required to ensure the orthosis does not become too tight as the infant grows. Failure to adjust the orthosis properly can lead to inadequate correction or discomfort.

⚠ Avoid Unsupervised Prolonged Use:

The orthosis should not be worn by the infant for prolonged periods without regular checks for fit and comfort.

⚠ Ensure Correct Placement:

Incorrect placement or fitting of the orthosis can lead to ineffective treatment or exacerbate cranial asymmetries. Follow the healthcare provider's instructions meticulously for placing and fitting the orthosis.

⚠ Monitoring for Growth and Development:

Regular monitoring of the infant's cranial growth and development is essential to assess the effectiveness of the orthosis and to make timely adjustments. Delay in adjustments can hinder progress or result in negative outcomes.

⚠ Heat Exposure:

Avoid exposing the orthosis to excessive heat, such as from direct sunlight or heaters, as this can cause the materials to warp or degrade, potentially altering its effectiveness.

⚠ Handling and Storage:

Handle the orthosis with care to prevent damage. Improper handling or storage can deform the orthosis, affecting its fit and function.

⚠ Use as Directed:

The orthosis is intended for use only under the guidance and prescription of a qualified healthcare provider. Using the orthosis without proper medical advice or not following the prescribed treatment plan can lead to poor outcomes or potential harm to the infant.

⚠ Alterations and Modifications:

Do not attempt to alter or modify the orthosis at home. Any necessary modifications should be performed by a professional to ensure the safety and effectiveness of the device.

⚠ Emergency Removal:

Caregivers should be instructed on how to remove the orthosis quickly and safely in case of an emergency, such as difficulty breathing or acute distress.

It's important that these warnings are communicated clearly to the users and caregivers of the device. Adhering to these warnings helps in minimizing 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

Consistent Monitoring for Fit and Comfort:

Regularly monitor the infant's head for signs of marking to assess the fit of the orthosis. The side opening should be fully closed throughout treatment. Parents or Caregivers should contact their healthcare practitioner if they are concerned about any marking or the fit of the orthosis.

Skin Care Routine:

Establish a routine for skin care under the orthosis. Keep the infant's head clean and dry to prevent skin irritation or breakdown. Any signs of redness, irritation, or pressure sores should be addressed immediately by consulting with a healthcare provider.

Scheduled Follow-up Appointments:

Adhere to scheduled follow-up appointments with the orthotist or healthcare provider. These appointments are crucial for tracking progress, making necessary adjustments, and addressing any concerns regarding the orthosis use.

Avoid Extended Wear Without Breaks:

Ensure the infant receives regular breaks from wearing the orthosis, as advised by a healthcare professional. Continuous wear without appropriate breaks can lead to discomfort and skin issues.

Proper Handling and Application:

Handle the orthosis with care to avoid damage. When placing the orthosis on the infant's head or removing it, follow the instructions provided by the healthcare provider to avoid causing discomfort or harm to the infant.

Environmental Considerations:

Be mindful of the infant's environment while wearing the orthosis. Avoid excessive heat and ensure the infant remains well-hydrated, especially in warmer climates or during hot weather, to prevent overheating.

Awareness of Infant's Discomfort:

Stay alert to the infant's behaviour and signs of discomfort, which could indicate issues with the orthosis fit or the need for adjustment. Changes in sleep patterns, irritability, or decreased appetite may signal discomfort.

Safe Storage When Not in Use:

When the orthosis is not in use, store it in a safe, dry place out of reach of children and pets. Ensure it is placed in a manner that maintains its shape and prevents any damage.

Use in Conjunction with Physical Therapy:

If the infant is undergoing physical therapy for conditions such as torticollis, ensure that the use of the orthosis is coordinated with the therapy regimen to support overall treatment goals.

Educating Caregivers:

Educate all caregivers on the proper use, application, and care of the orthosis to ensure consistent handling and to minimize the risk of misuse or improper application.

Emergency Protocols:

Familiarise yourself with how to quickly remove the orthosis in emergency situations where immediate removal is necessary for the infant's safety.

Adjustment Period:

Acknowledge there may be an adjustment period for both the infant and caregivers in getting accustomed to the regular use of the orthosis. Patience and gradual introduction can help ease this transition.

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

9. Instructions for Use

Initial Fitting:

The initial fitting should be conducted by a qualified healthcare provider who will adjust the orthosis to fit the infant's head securely but comfortably. Pay close attention to the instructions given during this fitting, as they will be crucial for daily use.

Placing the Orthosis:

Position the orthosis over the infant's head, ensuring that it sits evenly from front to back and side to side. The orthosis should cover the skull uniformly without tilting or shifting.

Securing the Orthosis:

The orthosis is equipped with a strap that should be fully closed during the treatment; secure this as demonstrated by your healthcare provider.

Daily Wear Schedule:

Begin with a wearing schedule as recommended by your healthcare provider. It's important to follow the advised schedule closely to ensure effective treatment.

Monitoring Comfort and Response:

Regularly check the infant's comfort level while wearing the orthosis. Look for any signs of distress, discomfort, or irritation.

Skin Care:

Inspect the infant's skin each time the orthosis is removed. Look for any redness, pressure marks, or irritation. Clean the skin gently with mild soap and water, and ensure it is completely dry before reapplying the orthosis.

Cleaning the Orthosis:

Use the cleaning solution recommended by your healthcare practitioner, allow it to air dry completely before placing it back on the infant's head.

Adjustments for Growth:

As the infant grows, the orthosis may require adjustments to accommodate changes in head size and shape. Do not attempt to make these adjustments yourself. Schedule appointments with your healthcare provider for professional adjustments.

Breaks and Comfort Checks:

Provide regular breaks from the orthosis as recommended by your healthcare provider. Use these breaks to check for any areas of discomfort or concern and to carry out skin care.

Activity While Wearing the Orthosis:

The infant can engage in normal activities while wearing the orthosis, including tummy time, which is essential for development. Ensure the infant is always supervised, especially during active play or movement.

Sleeping with the Orthosis:

Follow your healthcare provider's guidance on whether the orthosis should be worn during sleep. Ensure the infant's sleeping environment is safe and that their head and neck are not positioned awkwardly due to the orthosis.

Communication with Healthcare Providers:

Maintain open communication with the healthcare team overseeing the infant's treatment. Report any issues, concerns, or progress regularly, and consult them for any questions regarding the use of the orthosis.

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:

1. Wipe the exterior surface of the orthosis using a clean damp cloth.
2. Wipe the interior surfaces using the cleaning solution recommended by your healthcare practitioner.

Drying the Brace:

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

Padding and Straps Care:

1. Check the condition of the padding and straps regularly. They should be cleaned with a damp cloth and mild soap.
2. If the padding or straps are worn out or damaged, contact the manufacturer or healthcare provider about replacements.

Regular Inspection:

1. Inspect the brace for any cracks, breaks, or deformities. Pay special attention to areas under stress, like buckles and joints.

2. Look for signs of wear and tear, especially in areas that undergo frequent movement or adjustments.

Proper Storage:

1. When not in use, store the brace in a cool, dry place, away from direct sunlight and extreme temperatures to prevent warping or material degradation.

Avoid Immersion in Water:

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

Odour Management:

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

Handling and Transportation:

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

Scheduled Maintenance:

1. Schedule regular maintenance appointments with the orthotist or healthcare provider to ensure the brace remains in optimal condition.

Replacement Parts:

1. If any part of the brace needs replacement, such as straps, pads, or buckles, ensure that these are replaced with parts recommended or provided by the manufacturer to maintain the brace's effectiveness and safety.

Emergency Repairs:

1. In case of an emergency repair, consult the manufacturer or healthcare provider immediately.
2. Do not attempt DIY repairs as they might compromise the structural integrity of the brace.

Adhering to these detailed cleaning and maintenance guidelines is crucial for maintaining the integrity, functionality, and longevity of the device. Regular care ensures that the device remains effective in the management of the end user whilst maintaining comfort and hygiene.

11. Storage Conditions

Temperature Control:

Store the orthosis in a temperature-controlled environment. Extreme temperatures, both hot and cold, can affect the material properties of the orthosis, potentially causing it to warp or become brittle.

Avoid Direct Sunlight:

Keep the orthosis away from direct sunlight when not in use. Prolonged exposure to UV rays can degrade the materials and fade any colours or patterns on the orthosis.

Dry Environment:

Ensure the storage area is dry and free from excessive moisture. High humidity can contribute to the growth of mould or mildew, especially on any soft lining or padding materials.

Flat Surface:

Place the orthosis on a flat surface to maintain its shape. Avoid hanging or propping it up in a manner that could cause it to deform over time.

Safe From Compression:

Store the orthosis in an area where it will not be compressed by other objects. Compression can misshape the orthosis, affecting its fit and function.

Clean Before Storing:

Always clean the orthosis according to the recommended cleaning instructions before storing it for any length of time. This helps maintain hygiene and prevent the buildup of odours.

Pet Safety:

Store the orthosis out of reach of pets to prevent accidental damage or choking hazards from detachable parts.

Proper Ventilation:

Ensure the storage area is well-ventilated. Good air circulation helps prevent odours and keeps the orthosis in optimal condition.

Avoid Contaminants:

Keep the orthosis away from chemicals, oils, and sharp objects that could cause damage. Exposure to harsh substances can deteriorate the materials used in the orthosis.

By following these detailed storage conditions, you can help ensure that the device remains in optimal condition, retaining its

shape, functionality, and hygiene for which it is needed. Proper storage is essential for prolonging the life of the device and ensuring its effectiveness.

12. Disposal Instructions

Dispose of as per local regulations for medical devices.
The brace should not be reused by another patient due to the custom fit.

13. Regulatory Compliance

The device conforms to the essential requirements (Part II of the UK MDR 2002, Annex I, as modified by Part II of Schedule 2A to the UK MDR 2002).
Devices are labeled with unique identification order numbers with a written prescription by a registered healthcare practitioner.

14. Warranty Information

Please refer to the Warranty section of the Product Information Portal for further information.
For products containing third-party componentry such as metal joints, please ensure the supplier Maintenance and Warranty schedules are covered as advised by your healthcare practitioner.

15. Contact Information

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

16. Date of Issue & Version

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