

Custom-Made TLSO (Thoracic Lumbar Spinal 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 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/Image

CUSTOM-MADE TLSO (Thoracic Lumbar Spinal Orthosis)

Related Product Codes:

TLSO-PP
 TLSO-BHPP

2. Manufacturer Details

L.O.C. MANUFACTURING LIMITED / THE LONDON ORTHOTIC CONSULTANCY LIMITED
 The London Crescent, Kingston Upon Thames, Surrey, England, K12 8HL

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 Email: info@londonorthotics.co.uk

3. Device Description

Custom-Made Thoracolumbosacral Orthosis made of lightweight, durable plastic. It features padded interiors, adjustable straps, and a heat-mouldable design for a personalised fit. Designed to cover the thoracic, lumbar, and sacral areas of the spine.

Overall Design:

The custom-made TLSO is an orthotic device designed to provide support and stabilisation to the thoracic, lumbar, and sacral regions of the spine. It typically extends from under the arms down to the pelvis, encasing the torso.

Material Composition:

The TLSO is fabricated from a combination of rigid and semi-rigid materials, such as high-grade medical plastics or thermoplastics, for structural support, and is lined with foam or gel padding for comfort. It may include metal reinforcements for additional spinal support.

Custom Fitting:

Each TLSO is custom moulded to the individual's body, ensuring a precise fit. This customisation is crucial for the brace's effectiveness in immobilisation and support, based on the specific spinal condition and anatomy of the patient.

Adjustable Closure System:

The brace typically includes Velcro straps or a lacing system for secure closure, allowing for adjustability and accommodation of changes in body size or swelling.

Spinal Support Mechanism:

The design of the TLSO ensures targeted support and offloading of pressure in specific spinal areas, depending on the patient's condition. It often includes features like posterior, anterior, and lateral panels for comprehensive spinal immobilisation.

4. Intended Use

Intended for providing spinal support, immobilisation, and correction in cases of spinal deformities, post-operative recovery, or injuries affecting the thoracic, lumbar, and sacral regions.

5. Indications

Post-Operative Support:

Suitable for patients who have undergone spinal surgeries, such as spinal fusion, to provide support during the healing process and to maintain surgical correction.

Spinal Fractures:

Recommended for stabilisation support in the case of stable spinal fractures, particularly compression fractures in the thoracic and lumbar regions. Helps in aligning the spine and reducing pain during recovery.

Kyphosis Treatment:

Used in the conservative management of kyphotic conditions, including Scheuermann's disease and postural kyphosis, to correct and prevent further progression of abnormal spinal curvature.

Spinal Cord Injury Rehabilitation:

Can be used as part of a rehabilitation program for patients with spinal cord injuries to support the spine in the correct alignment and assist in mobility and daily activities.

Degenerative Spinal Conditions:

Indicated for patients with degenerative conditions like osteoarthritis or disc degeneration, providing relief by stabilizing the affected area and reducing motion that exacerbates pain.

Postural Correction:

Beneficial for patients with poor posture or postural back pain, aiding in the maintenance of proper spinal alignment and reducing strain on the back muscles.

Muscular Support:

Recommended for conditions like muscular dystrophy or other neuromuscular disorders affecting the spine, where additional support is necessary to maintain an upright posture.

Pain Management:

Used in the management of chronic back pain related to various spinal conditions by providing support and off-loading pressure from affected spinal segments.

Congenital Spinal Anomalies:

Suitable for certain congenital spinal anomalies that affect the thoracic and lumbar regions, where support and corrective alignment are needed.

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

Upper Thoracic or Cervical Spine Conditions:

The TLSO brace is not designed to support the upper thoracic or cervical regions of the spine. Patients with conditions affecting these areas may require a different type of brace.

Severe Respiratory Conditions:

Patients with severe respiratory conditions, such as advanced chronic obstructive pulmonary disease (COPD) or severe asthma, may experience further breathing difficulties with the brace, as it restricts the expansion of the thoracic region.

Skin Infections at Application Site:

The presence of active skin infections, open wounds, or severe dermatitis at the site where the brace is to be applied is a contraindication, as the brace can aggravate these conditions.

Allergies to Brace Materials:

Patients with known allergies to any materials used in the brace, such as certain plastics, foams, or metals, should not use this brace. It's important to verify material compatibility before fitting.

Severe Sensory or Neurological Impairments:

Patients with severe sensory deficits or neurological impairments in the torso region may not be suitable for TLSO brace use, as they may not be able to perceive discomfort or pain caused by the brace.

Compromised Circulation in the Torso:

Patients with conditions that significantly compromise blood circulation in the torso may be at risk of further circulatory issues due to the compressive nature of the brace.

Uncontrolled Osteoporosis:

Severe osteoporosis, especially in the spinal region, can be a contraindication due to the increased risk of fractures under the pressure of the brace.

Severe Spinal Deformities:

In cases of severe spinal deformities that are beyond the corrective capacity of a TLSO brace, alternative treatments or different types of support may be recommended.

Post-Surgical Patients Without Clearance:

Patients who have recently undergone spinal surgery should not use the TLSO brace unless they have been specifically cleared for its use by their healthcare provider.

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:

Continuous wear without proper skin care can lead to irritation, rashes, or pressure sores. It's crucial to maintain skin hygiene and check regularly for any signs of skin distress.

⚠ Improper Fit:

An improperly fitted brace can be ineffective and may worsen the condition. Only certified orthotists or trained professionals should adjust the brace.

⚠ Over-Tightening:

Excessive tightening of the brace can lead to discomfort, restricted breathing, or circulation problems. Straps should be snug but not overly tight.

⚠ Avoid Modifications:

Unauthorized modifications to the brace can compromise its effectiveness and safety. Any adjustments should be carried out by a professional.

⚠ Monitoring Progress:

Regular follow-up with healthcare providers is essential. Ignoring scheduled check-ups can lead to the progression of the condition without proper intervention.

⚠ Physical Activity:

While wearing the brace, certain physical activities may be restricted. Patients should consult with their healthcare provider about safe exercises and activities.

⚠ Heat Exposure:

Prolonged exposure to high temperatures can deform the brace, reducing its effectiveness. Avoid leaving the brace in hot environments like a closed car.

⚠ Water Exposure:

The brace should not be submerged in water. Contact with water can damage the materials and structure of the brace.

⚠ Use during Growth Spurts:

During periods of rapid growth, the fit of the brace can change quickly. Regular adjustments may be necessary to ensure effectiveness.

⚠ Discontinuing Use:

Abrupt discontinuation of brace use without medical guidance can lead to rapid changes. Any decision to stop or alter the wearing schedule should be made in consultation with a healthcare provider.

⚠ Allergic Reactions:

If an allergic reaction to the materials of the brace is suspected, such as persistent redness, itching, or swelling, discontinue use immediately and consult a healthcare provider.

⚠ Breathing Difficulty:

If the patient experiences difficulty breathing while wearing the brace, they should remove it and seek medical advice. The brace may need adjustment for proper fit.

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

Proper Fitting:

Ensure the brace is properly fitted by a certified orthotist or trained professional.

Skin Care:

Maintain good skin hygiene to prevent irritation. Use a thin, soft cotton shirt under the brace and check daily for any signs of redness, blisters, or sores.

Gradual Increase in Wear Time:

Start with shorter periods of wearing the brace and gradually increase to the prescribed duration to allow the body to acclimate.

Regular Adjustments:

As the patient grows or the shape of the torso changes, regular adjustments to the brace may be necessary. Schedule follow-up appointments as recommended.

Activity Level:

Consult with a healthcare provider about appropriate activities and exercises while wearing the brace. Some activities may need to be modified or avoided.

Monitoring for Discomfort:

Be attentive to signs of discomfort or pain. While some initial discomfort is normal, persistent or increasing pain should be addressed by a healthcare professional.

Heat Sensitivity:

In hot weather or during physical activity, the brace may cause the wearer to feel warmer. Stay hydrated and take breaks as needed.

Impact on Posture and Balance:

Wearing the brace can affect posture and balance initially. Extra caution is advised during physical activities, especially in unfamiliar environments.

Emergency Removal:

Know how to safely remove the brace in case of an emergency, such as difficulty breathing or severe discomfort. Keep the instructions accessible.

Avoiding Prolonged Wetness:

Keep the brace dry. Prolonged dampness can degrade materials and lead to skin issues. If the brace gets wet, remove it and allow it to dry completely.

Check for Wear and Tear:

Regularly inspect the brace for any signs of damage, such as cracks or loose parts. Contact the provider for repairs or replacements.

Communication with Healthcare Providers:

Keep open communication with healthcare providers regarding the patient's progress, challenges, and any concerns with the brace.

Educating the Patient:

If the patient is a child, ensure they understand the importance of wearing the brace as prescribed and how to communicate any issues.

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:

1. The brace should be initially fitted by a certified orthotist or trained healthcare professional. This ensures an accurate and comfortable fit, tailored to the patient's specific spinal curvature.

Wearing Schedule:

1. Adhere to the prescribed wearing schedule, typically recommended for 18-23 hours per day.
2. Gradually increase wearing time over the first few days to acclimate to the brace.

Putting On the Brace:

1. Wear a thin, seamless, and sweat-absorbent cotton shirt under the brace to protect the skin.
2. Open all straps and position the brace around the torso.
3. Secure the straps starting from the bottom, moving upwards. Adjust each strap so it's snug but not overly tight.

Taking Off the Brace:

1. Loosen and unfasten the straps, starting from the top and moving downwards.
2. Gently remove the brace, being careful not to twist or bend it excessively.

Skin Care:

1. After removing the brace, check the skin for any signs of redness, sore spots, or irritation.
2. Allow the skin to breathe for a short period before reapplying the brace.

Comfort Adjustment:

1. If discomfort is intolerable, check for proper alignment of the brace.
2. Minor strap adjustments can be made for comfort.
3. Avoid adjusting the brace too loosely, as it may compromise the effectiveness.

Activity While Wearing the Brace:

1. Engage in light to moderate activities while wearing the brace.
2. Avoid strenuous activities that may cause the brace to shift or alter its fit.

Sleeping in the Brace:

1. If prescribed for nighttime use, ensure the bed and sleeping position are comfortable with the brace on.
2. Use pillows for support if necessary.

Follow-up Appointments:

1. Regularly scheduled appointments with the healthcare provider are crucial for monitoring progress and making necessary adjustments to the brace.

Warning Signs to Look For:

1. Be aware of signs like increased pain, numbness, or tingling in the torso or limbs. If these occur, consult with the healthcare provider immediately.

Emergency Removal:

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

Patient Responsibility:

1. The patient (and caregivers, if applicable) should be responsible for understanding how to properly use the brace, recognizing when adjustments are needed, and knowing when to seek medical advice.

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-rinsing 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 the manufacturer or healthcare provider about replacements.

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.

Proper Storage:

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:

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. Protect the brace in a bag or case to prevent damage when transporting.

Scheduled Maintenance:

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

Replacement Parts:

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:

In case of an emergency repair, consult the manufacturer or healthcare provider immediately. 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 Controlled Environment:

Store the TLSO in a cool, dry place, away from extreme temperatures. Avoid areas where the temperature may exceed room temperature significantly, such as in a car during summer or near heating sources.

Avoid Direct Sunlight:

Keep the TLSO away from direct sunlight as prolonged exposure can degrade the materials and affect the fit and comfort of the TLSO.

Moisture-Free Area:

Ensure the storage area is free from moisture to prevent mould, mildew, or material degradation. Do not store the TLSO in damp environments like bathrooms.

Dust-Free Environment:

Store in a clean area to prevent dust and dirt accumulation. Consider using a breathable storage bag or container to protect the TLSO.

Laid Flat or Properly Supported:

Store the TLSO in its natural shape. Do not fold or hang the TLSO in a manner that may cause it to deform.

Keep Away from Chemicals and Sharp Objects:

Avoid storing the TLSO near chemicals, solvents, or sharp objects that could damage the materials.

Pets:

Store out of reach of pets to avoid accidental damage or choking hazards.

By following these detailed storage conditions, you can help ensure that the device remains in optimal condition, retaining its shape, functionality, and hygiene for when 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 1 of Schedule 2A to the UK MDR 2002).
 Devices are labeled with unique identification 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 components 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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