

Custom-Made CTLSO (Cervical 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

CUSTOM-MADE CILSO (Cervical Thoracic Lumbar Spinal Orthosis)

Related Product Codes:

CILSO-PP
CILSO-BI-PP

2. Manufacturer Details

L.O.C. MANUFACTURING LIMITED / THE LONDON ORTHOTIC CONSULTANCY LIMITED
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3. Device Description

Custom-Made Cervicothoracolumbosacral Orthosis designed for comprehensive spinal support. Includes features of a TLSO, with an added cervical component for neck support.

Overall Design:

The custom-made CILSO is an advanced orthotic device designed to provide support and stabilisation for the cervical, thoracic, lumbar, and sacral regions of the spine. It typically extends from the neck, covering the entire torso down to the pelvis.

Material Composition:

This orthosis is constructed using a combination of rigid and flexible materials, such as high-grade medical plastics, carbon fibre, and metal components for structural support, along with foam or gel padding for comfort and cushioning.

Custom Fitting:

Each CILSO is tailor-made based on precise measurements and moulds of the patient's body, ensuring an exact and personalised fit. This custom fitting is crucial for optimal efficacy in terms of support, immobilisation, and comfort.

Cervical Support:

The cervical component is specifically designed to support the neck. It may include adjustable features to control the range of motion of the cervical spine and maintain proper alignment.

Thoracolumbosacral Stabilisation:

The brace encompasses the thoracic to sacral spine regions, with particular focus on maintaining proper alignment and stability. It includes elements like posterior and anterior panels, along with lateral supports.

Adjustable Closure System:

The CILSO typically features Velcro straps or a similar closure system, allowing for adjustability to accommodate changes in body size, swelling, or clothing.

4. Intended Use

Intended for the management and treatment of various spinal disorders, including severe scoliosis, spinal fractures, post-surgical stabilisation, and other conditions requiring cervical to lumbar spine immobilisation.

5. Indications

Post-operative Spinal Surgery:

Ideal for use after complex spinal surgeries, such as spinal fusion, to provide immobilization and support during the recovery period.

Multi-level Spinal Fractures:

Indicated for stabilisation and support in cases of multiple spinal fractures, particularly those affecting different regions of the spine, including cervical, thoracic, and lumbar areas.

Spinal Cord Injury Rehabilitation:

Suitable for patients undergoing rehabilitation for spinal cord injuries where comprehensive support is required to promote healing and prevent further injury.

Degenerative Spinal Conditions:

Recommended for conditions like severe kyphosis, lordosis, or degenerative disc disease that affect multiple areas of the spine, necessitating full spinal support.

Neurological Disorders Affecting the Spine:

Useful in managing spinal issues related to neurological disorders, such as cerebral palsy or muscular dystrophy, where extensive spine support is needed.

Congenital Spinal Deformities:

Indicated for congenital deformities that affect the spine's alignment and stability, requiring full spinal bracing for correction or support.

Chronic Pain Management:

Appropriate for patients with chronic spinal pain conditions where stabilization of the cervical, thoracic, and lumbar spine can aid in pain reduction and improve quality of life.

Preventive Care for Progressive Conditions:

Recommended for early intervention in progressive spinal conditions to prevent further deterioration and preserve existing spinal function.

Enhanced Posture and Mobility:

Indicated for conditions where improved posture and enhanced mobility are desired outcomes, and full spinal support can contribute to these goals.

Respiratory Function Support:

Suitable for patients where spinal deformities affect respiratory function. The brace can aid in maintaining a more optimal rib cage position, thereby assisting in better breathing.

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 Skin Conditions:

Patients with acute dermatitis, eczema, psoriasis, or other severe skin conditions in the areas where the brace will be worn. These conditions may be exacerbated by brace contact.

Open Wounds or Lesions:

Presence of open wounds, cuts, or lesions within the brace application area. The brace may impede healing and increase the risk of infection.

Material Allergies or Sensitivities:

Known allergies or sensitivities to materials used in the brace, such as certain plastics, foams, or metals. Exposure could lead to allergic reactions or skin irritation.

Severe Respiratory Conditions:

Patients with severe respiratory conditions where the brace may restrict lung expansion and breathing, especially given the comprehensive nature of the C-TL-LSO brace.

Cervical Spine Conditions Requiring Mobility:

Conditions where mobility of the cervical spine is crucial for treatment or daily functioning. The C-TL-LSO brace limits neck movement significantly.

Severe Circulatory Disorders:

Circulatory disorders in the upper body or limbs that could be aggravated by the pressure exerted by the brace.

Recent Surgeries:

Patients who have recently undergone surgery in the areas to be covered by the brace, unless the brace is part of post-surgical treatment as advised by a physician.

Spinal Infections:

Active spinal infections or tuberculosis of the spine. The brace could hinder the treatment and exacerbate the condition.

Unstable Spinal Fractures:

Unstable spinal fractures that require surgical intervention or other forms of treatment that are incompatible with bracing.

Severe Osteoporosis:

Advanced osteoporosis that makes the spine highly susceptible to fractures under pressure. The rigidity of the C-TL-LSO brace could pose a risk.

Cognitive Impairments Affecting Compliance:

Patients with cognitive impairments who cannot understand or comply with brace wearing instructions, as effective use of the C-TL-LSO brace requires patient cooperation.

Severe Deformities Not Accommodating Bracing:

Severe spinal deformities that cannot be accommodated by the brace design, where the use of the brace would be ineffective or harmful.

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 professionals.

⚠ 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. A poorly fitted brace can be ineffective or cause harm.

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 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 initially affect posture and balance. 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.

Adjusting the Cervical Collar:

1. Adjust the cervical collar so that it supports the neck without causing discomfort or restricting breathing.
2. Check that the chin and occiput (back of the head) are adequately supported.

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 noted, 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 its 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.
2. 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, recognising 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. When transporting, protect the brace in a bag or case to prevent damage.

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 C.T.LSO 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 C.T.LSO away from direct sunlight as prolonged exposure can degrade the materials and affect the fit and comfort of the C.T.LSO.

Moisture-Free Area:

Ensure the storage area is free from moisture to prevent mould, mildew, or material degradation. Do not store the C.T.LSO 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 C.T.LSO.

Laid Flat or Properly Supported:

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

Keep Away from Chemicals and Sharp Objects:

Avoid storing the C.T.LSO 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 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 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

[Version 1.0]
[Date of Issue: 2025]
[Latest Revision: May-24]