

# Custom-Made SCOLIOSIS BRACE

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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.]*

**1. Product Name/Image**

CUSTOM-MADE SCOLIOSIS BRACE

**Related Product Codes:**

SCOLI-NV  
SCOLI-NV-21

**2. Manufacturer Details**

L.O.C. MANUFACTURING LIMITED / THE LONDON ORTHOTIC CONSULTANCY LIMITED  
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Email: [info@londonorthotics.co.uk](mailto:info@londonorthotics.co.uk)

**3. Device Description**

Custom-made, rigid orthopaedic brace designed for scoliosis management. Made to fit each individual's torso, it is constructed from a lightweight, durable plastic with padding for comfort. It features adjustable straps for a secure fit and easy adjustments.

**Overall Design:**

The Custom-Made Scoliosis Brace is a state-of-the-art orthotic device specifically tailored for the management of scoliosis. It is designed to encompass the critical regions affected by scoliosis, typically covering the thoracic (mid-back) and lumbar (lower back) regions. The brace extends vertically along the spine, with a design contoured to fit the unique curves of the patient's body, providing targeted support and corrective pressure.

**Material Composition:**

This brace is fabricated using a blend of materials that balance rigidity and flexibility, essential for effective scoliosis management. It comprises high-grade medical plastics known for their durable yet lightweight properties and may incorporate elements of carbon fibre and metal components for added strength without significant weight. Soft padding, foams or gel materials can be applied to the internal sections of the brace to reduce skin irritation.

**Custom Fitting:**

Each brace is custom fitted to the patient using a combination of digital imaging and manual measurements. This ensures a precise fit that conforms to the individual's specific spinal curvature and body shape. The custom fitting process is vital for the brace's effectiveness in correcting the spinal deformity, providing proper support, and ensuring patient comfort.

**Adjustable Closure System:**

The brace typically includes Velcro straps or a lacing system for secure closure, allowing for adjustability.

**4. Intended Use**

Intended for the management and treatment of idiopathic scoliosis in adolescents and adults. To be used as prescribed by a certified orthotist.

**5. Indications**

**Age and Development Stage:**

Primarily recommended for adolescents during their growth spurt, as this is when scoliosis tends to progress rapidly. However, it may also be used by adults in specific cases as advised by a healthcare professional.

**Cobb Angle Measurement:**

Ideal for patients with a Cobb angle (a measure of spinal curvature) between 20° and 40°. It can be effective in halting or slowing the progression of the spinal curve at these angles. The braces can be used outside of this measurement range, but this is on a case-by-case basis and should always be determined by your healthcare practitioner.

**Post-operative Support:**

Suitable for post-operative stabilisation and support after spinal surgery, as recommended by the surgeon or orthopaedic specialist.

**Non-surgical Management:**

An option for patients seeking a non-surgical approach to manage mild to moderate scoliosis and to potentially avoid the need for surgery in the future.

**Symptom Alleviation:**

Helps in alleviating back pain and improving posture in patients with scoliosis, thereby enhancing the quality of life.

**Progress Monitoring:**

Used as a part of an overall treatment plan that includes regular check-ups and imaging tests to monitor the progress on of scoliosis.

**Flexibility and Mobility:**

Designed to allow a certain degree of flexibility and mobility while wearing, which is beneficial for maintaining muscle strength and daily activities.

**Customisation for Unique Curves:**

Especially beneficial for patients with unique or atypical spinal curves that may not be adequately addressed 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 Skin Conditions:**

Patients with severe skin diseases such as eczema, psoriasis, or severe dermatitis in the area where the brace will be worn. The brace may aggravate these conditions.

**Open Wounds or Infections:**

Presence of open wounds, cuts, or serious infections near the application area is a contraindication. The brace may inhibit healing and increase the risk of infection spreading.

**Allergy to Brace Materials:**

Patients with known allergies to materials used in the brace, such as certain plastics, latex, or metal components, should not use this device.

**Severe Respiratory Issues:**

Patients with severe respiratory conditions may find it difficult to breathe when wearing a tightly fitted brace. Caution and medical supervision are advised.

**Non-Idiopathic Scoliosis:**

This brace is not suitable for non-idiopathic forms of scoliosis, such as those caused by neuromuscular diseases, infections, or tumours.

**Severe Spinal Deformities:**

Patients with severe spinal deformities or curves greater than 70° (Cobb angle) which typically require surgical intervention.

**Recent Spine Surgery:**

Patients who have recently undergone spinal surgery should not use the brace until approved by their surgeon, as it may interfere with the healing process.

**Neurological Impairment:**

Patients with neurological impairments that significantly affect sensation or movement in the torso may not be suitable candidates for this brace.

**Cognitive or Behavioural Issues:**

Patients who are unable to understand or comply with brace-wearing schedules or have behavioural issues that prevent consistent use.

**Severe Osteoporosis:**

In patients with severe osteoporosis, the pressure exerted by the brace may increase the risk of fractures.

**Cardiovascular Conditions:**

Certain cardiovascular conditions may be exacerbated by the restrictive nature of the brace. Patients with these conditions should consult their physician.

**Existing Pressure Sores:**

If pressure sores are present in the torso area, the brace may worsen these sores or hinder healing.

*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. Stretch marks on the skin are possible with rapid growth and we ask patients and parents/caregivers to monitor.

**⚠ Discontinuing Use:**

Abrupt discontinuation of brace use without medical guidance can lead to rapid progression of scoliosis. 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. Adjustment or alterations to the brace may be required.

*It is 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**

**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 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 an emergency, such as difficulty breathing or severe discomfort. Keep the instructions accessible.

**Psychological Impact:**

Be aware of the potential psychological impact of wearing a brace, especially in adolescents. Support from family, friends, and possibly professional counseling can be beneficial.

**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. Minor strap adjustments can be made for comfort.
2. 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 practitioner 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, recognising when adjustments are needed, and knowing when to seek advice from your healthcare practitioner.

*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 the manufacturer or healthcare provider for 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.

### 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 D.I.Y. repairs as they might compromise the structural integrity of the brace and original prescription.

*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 scoliosis brace 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 scoliosis brace away from direct sunlight as prolonged exposure can degrade the materials and affect the fit and comfort of the device.

### Moisture-Free Area:

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

### Laid Flat or Properly Supported:

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

### Keep Away from Chemicals and Sharp Objects:

Avoid storing the scoliosis brace 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]