

Custom-Made FFO/TCI (Functional Foot Orthosis / Total Contact Insole)

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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 FUNCTIONAL FOOT ORTHOSIS / TOTAL CONTACT INSOLE

Related Product Codes:

INS-EVA-3050
 INS-EVA-5070
 INS-EVA-70

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

3. Device Description

Custom-Made orthotic insole designed to provide foot support and correct biomechanical imbalances. Made from durable, semi-flexible materials, it features arch support, heel cradle, and cushioning for comfort.

EVA Material:

Constructed primarily from ethylene-vinyl acetate, known for its soft, flexible, and stress-crack resistant properties. EVA provides excellent cushioning and absorbs impact effectively, making it ideal for foot support.

Customized Fit:

Each insole is individually crafted based on precise measurements or 3D scans of the user's feet. This ensures a perfect match to the contours and arch type of the foot, offering unmatched comfort and support.

Arch Support:

Custom-molded arch support is designed to align with the specific arch shape of the user, be it low, neutral, or high. This tailored support helps in evenly distributing foot pressure and reduces arch strain.

Heel Cupping:

Features a defined heel cup that cradles the heel, providing stability and support. This design helps in reducing heel pain and mitigating conditions like plantar fasciitis.

Shock Absorption:

The EVA material excels in absorbing shocks, reducing the impact on the feet, ankles, and knees during walking or running activities.

Lightweight Construction:

Despite its supportive structure, the insole remains lightweight, adding minimal weight to the footwear and ensuring comfort in movement.

4. Intended Use

Intended to provide support and improve foot function for various foot conditions, reducing pain and discomfort in the feet, ankles, and legs.

5. Indications

Plantar Fasciitis:

Ideal for individuals suffering from plantar fasciitis, providing cushioning and support to the plantar fascia, thereby alleviating pain and aiding in recovery.

Flat Feet and Fallen Arches:

Provides necessary arch support for those with flat feet or low arches, helping to distribute pressure more evenly across the foot and improve walking or running mechanics.

Overpronation/Over supination:

Corrects and reduces overpronation/Over supination (excessive inward/outward rolling of the foot), which can lead to various foot, ankle, and knee problems.

Heel Pain and Heel Spurs:

The cushioned heel design is beneficial for individuals experiencing heel pain or dealing with heel spurs, offering shock absorption and relief with each step.

Metatarsalgia:

Alleviates pressure on the metatarsal area (ball of the foot), providing relief for those suffering from metatarsalgia or forefoot discomfort.

Diabetic Foot Care:

Suitable for diabetic patients who require extra cushioning and pressure distribution to prevent foot ulcers and other complications associated with diabetes.

Bunions and Toe Pain:

Offers a comfortable and supportive fit to alleviate pressure on bunions and provide relief from toe pain.

Arch Pain and Strain:

Supports and cushions the arch, reducing the risk of strain and pain, particularly for individuals with high arches or those who experience arch discomfort.

Foot Fatigue:

Ideal for people who experience foot fatigue due to prolonged standing or walking, as it provides cushioning and enhances foot comfort.

Sports and Athletic Activities:

Enhances athletic performance by providing support and reducing the impact on the feet during high-impact sports or activities.

Occupational Use:

Beneficial for individuals in occupations requiring extended periods of standing or walking, such as healthcare, retail, and hospitality.

General Comfort and Wellness:

Suitable for everyday use by individuals seeking improved comfort and foot wellness in their daily activities.

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 goal.

6. Contraindications

Severe Foot Deformities:

Not recommended for individuals with severe foot deformities that require more supportive orthotics. In such cases, a more specialized orthopaedic device may be necessary.

Uncontrolled Swelling (Edema):

Those with uncontrolled swelling in the feet might find the insole inappropriate as it may not fit properly and could exacerbate the condition.

Open Foot Wounds or Ulcers:

The insole should not be used if there are open wounds, ulcers, or sores on the foot as it may hinder the healing process and increase the risk of infection.

Severe Circulatory Disorders:

Individuals with severe circulatory disorders in the lower limbs, such as peripheral artery disease, should avoid using the insole as it could potentially restrict blood flow.

Allergies to EVA or Other Materials:

Those with known allergies to ethylene-vinyl acetate or other materials used in the insole should not use this product.

Recent Foot Surgery:

Patients who have recently undergone foot surgery should consult their healthcare provider before using the insole to ensure it does not interfere with the healing process.

Severe Arthritic Conditions:

In cases of severe arthritis, particularly in the foot or ankle, the insole may not provide sufficient support or pain relief, and a more specialized solution might be needed.

Acute Foot Infections:

The insole should not be used in the presence of acute foot infections as it can impede proper air circulation and exacerbate the condition.

Extreme Foot Sensitivity:

For those with conditions that cause extreme foot sensitivity or pain, such as certain neuropathies, the insole may not be suitable or comfortable.

Incompatible with Certain Footwear:

The insole may not be suitable for use with certain types of footwear that do not have adequate room for inserts, such as high heels or some types of dress shoes.

Gait Abnormalities Requiring Medical Intervention:

Not intended for individuals with gait abnormalities that require medical intervention beyond the scope of a functional foot orthotic.

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

⚠ **Incorrect Fit:**

Using insoles that are not properly fitted to the individual's feet can lead to discomfort, worsening of foot conditions, or injury. It's crucial to use insoles that are custom fitted to ensure proper support and function.

⚠ **Skin Irritation:**

Some individuals might experience skin irritation, especially during initial use. This could be due to material sensitivity, friction, or sweating. Discontinue use if severe irritation, rash, or blistering occurs.

⚠ **Adaptation Period:**

Users may experience discomfort during the initial adaptation period. It is normal to feel some level of discomfort as the feet adjust, but persistent pain is not. Gradually increase wearing time to allow feet to adapt.

⚠ **Use in Proper Footwear:**

The effectiveness of the insoles is partially dependent on the type of footwear used. Shoes that are overly tight, loose, or have too little/too much support may compromise the benefits of the insoles.

⚠ **Potential for Balance Issues:**

New users, especially those with balance or mobility issues, should be cautious as the insoles may initially alter their sense of balance or gait.

⚠ **Physical Activity:**

While EVA insoles can enhance athletic performance, users should be aware that they may need time to adapt to the insoles during physical activities. Overexertion before adaptation could lead to strain or injury.

⚠ **Alteration or Modification:**

Do not alter or modify the insoles, as this can affect their functionality and may cause harm. Any necessary adjustments should be made by a qualified professional.

⚠ **Heat Exposure:**

Avoid exposing the insoles to excessive heat, such as from a radiator, being left on car dashboard or direct sunlight, as EVA material can warp or degrade at high temperatures.

⚠ **Wearing Out:**

Be aware that over time, the insoles will wear out and lose their effectiveness. Regularly inspect for signs of wear and replace as necessary.

⚠ **Use as Directed:**

The insoles are intended for use under the foot and within footwear. Using them for any other purpose could result in injury or the insoles not working as intended.

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 Shoe Fit:

Ensure that your shoes have enough room to accommodate the insoles without being too tight. Overly tight shoes can lead to discomfort and negate the benefits of the insoles.

Gradual Introduction:

Introduce the insoles gradually to your daily routine. Start by wearing them for 1-2 hours a day and gradually increase the duration to allow your feet to adapt comfortably.

Regular Inspection:

Regularly inspect the insoles for signs of wear and tear. Worn out or damaged insoles may not provide adequate support and could potentially cause discomfort or injury.

Foot Hygiene:

Maintain good foot hygiene and ensure that your feet are clean and dry before using the insoles. This helps prevent skin irritation and prolongs the life of the insoles.

Sock Compatibility:

Wear appropriate socks to reduce friction between the insoles and your feet. Socks can also help in managing moisture and enhancing comfort.

Activity Appropriateness:

Be aware that certain high-impact activities may require specific types of insoles. Consult a professional if you engage in intense sports or activities that put significant stress on your feet.

Avoid Sharing:

Do not share your custom-made insoles with others as they are designed for your specific foot contours and biomechanical needs.

Monitoring Physical Response:

Pay attention to how your body responds to the insoles. If you experience persistent pain, discomfort, or changes in your gait, consult a healthcare provider.

Insole Adjustment:

If you feel that the insoles need adjustment, consult with the professional who provided them. Do not attempt to alter them yourself.

Footwear Alternation:

If you use the insoles in different shoes, ensure that they fit correctly in each pair. The effectiveness of the insoles can be impacted by the type and construction of the footwear.

Temperature Sensitivity:

Be mindful that EVA material can be sensitive to temperature changes. Avoid leaving the insoles in extremely hot or cold environments.

Underlying Health Conditions:

If you have any underlying health conditions, particularly those affecting circulation or nerve function in your feet, consult with a healthcare provider before using the insoles.

Wearing Schedule Compliance:

Adhere to any specific wearing schedules or instructions provided by your healthcare provider to ensure the best results from using the insoles.

By following these precautions, the risk of complications can be minimized, and the effectiveness of the device can be maximized. 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 Inspection:

Before using the insoles, inspect them for any defects or irregularities. Ensure they match the shape and size of your feet and are free from damage.

Introducing to Footwear:

Remove any existing insoles from your shoes, if necessary. Place the custom EVA insoles into your shoes, ensuring they lay flat and fit snugly within the shoe. Trim the insoles if advised by a professional for a perfect fit.

First Use:

Wear the insoles for a short period initially, about 1-2 hours, to allow your feet to adjust. Gradually increase the wearing time each day.

Check for Comfort and Fit:

Ensure the insoles feel comfortable and provide support without causing pain or significant discomfort. There should be no pinching or excessive pressure on any area of the foot.

Wear Suitable Shoes:

Use the insoles with shoes that provide adequate space and support. Avoid very tight or narrow shoes that might compress the insoles and reduce their effectiveness.

Daily Wear:

Once accustomed, use the insoles in your daily routine. Unless specified by your healthcare professional they should be worn consistently for the best results, especially in situations where you are standing or walking for extended periods.

Monitor Foot Response:

Pay attention to how your feet respond to the insoles over time. Some discomfort initially is normal, but persistent pain or discomfort is not.

Adjustment Period:

It may take several days to a few weeks to fully adjust to wearing the insoles. During this period, be mindful of any changes in your foot comfort or posture.

Regular Breaks:

If you experience discomfort during the adjustment period, give your feet short breaks from the insoles as needed.

Hygiene Practices:

Keep your feet clean and dry to maintain foot health. Use foot powder if necessary to manage moisture.

Alternate Footwear:

If you plan to use the insoles in multiple pairs of shoes, make sure they fit well in each pair. Consistency in the shoes you wear can aid in the adjustment process.

Follow-up:

If advised, schedule follow-up appointments with your healthcare provider to check the progress and make any necessary adjustments to the insoles.

Physical Activities:

For physical activities or sports, ensure that the insoles provide sufficient support and comfort. Consult a professional if you need specialized insoles for specific activities.

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

Regular Cleaning:

Clean the insoles regularly to maintain hygiene. Remove them from your shoes and gently brush off any loose dirt or debris.

Surface Cleaning:

For a more thorough clean, wipe the surface of the insoles with a cloth dampened with warm water and a mild soap or detergent. Avoid soaking the insoles as EVA material should not be overly saturated.

Spot Cleaning:

For stains or spots, use a soft brush and a mild soap solution. Gently scrub the affected area and wipe clean with a damp cloth.

Drying:

Allow the insoles to air dry completely before placing them back in your shoes. Do not expose them to direct heat sources like radiators or direct sunlight, as this can cause the material to warp or degrade.

Odor Control:

To manage odours, sprinkle baking soda on the insoles and let them sit overnight. In the morning, brush off the baking soda. Alternatively, use an odour-controlling foot spray designed for shoe insoles.

Regular Inspection:

Regularly check the insoles for signs of wear, such as thinning, tears, or deformation. Worn insoles may not provide adequate support and should be replaced.

Avoid Machine Washing:

Do not machine wash or dry the insoles as the agitation and heat can damage the material and structure.

Rotating Insoles:

If possible, rotate between pairs of insoles to extend their life. This gives each pair time to air out and return to their original shape between uses.

Handling:

Handle the insoles gently. Avoid folding or bending them in ways that could crease or damage the material.

Professional Consultation for Repairs:

If the insoles become damaged or significantly worn, consult with the provider for advice on repair or replacement. Do not attempt major repairs yourself.

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

Storage:

When not in use, store the insoles in a cool, dry place away from direct sunlight. Keep them flat or in their original shape to avoid deformation.

Keep Away from Chemicals and Sharp Objects:

Avoid storing insoles 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 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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