

Custom-Made AFO (Ankle Foot 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.]

1. Product Name

CUSTOM-MADE AFO (ANKLE FOOT ORTHOSIS)

Related Product Codes:

AFO-IX-PP
 AFO-HIN-PP
 AFO-IX-CI
 AFO-NEU-CI
 GRA-O-PP
 GRA-O-CI
 SMO-PP

2. Manufacturer Details

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3. Device Description

Custom-Made Ankle Foot Orthosis (AFO) is a specialised orthotic device designed to provide support, stabilisation, and alignment for the ankle and foot. It is individually tailored to fit the unique contours and specific needs of each patient, ensuring optimal functionality and comfort.

Overall Design:

The custom-made AFO is a specially designed orthotic device intended to support the ankle and foot. It covers the lower leg, starting below the knee and extending down to encompass the entire foot.

Material Composition:

Constructed from lightweight yet durable materials such as polypropylene or carbon fibre, the AFO offers both strength and flexibility. The device includes soft internal padding or lining to enhance comfort and reduce the risk of skin irritation.

Custom Fitting:

Tailored to each individual's specific measurements, the AFO is custom moulded to the contours of the patient's lower leg and foot. This personalized fitting is vital for effective support and comfort, ensuring proper alignment and function.

Ankle Support Mechanism:

The AFO includes a stabilizing component around the ankle, which can be designed to allow adjustable degrees of motion or to hold the ankle firmly in place, depending on the patient's needs.

Footplate Design:

A footplate is incorporated into the AFO to provide support to the foot. This feature helps in maintaining the correct position of the foot and can assist in improving the patient's gait.

Strapping System:

Equipped with adjustable straps or Velcro closures, the AFO ensures a secure fit around the leg and foot. These straps are essential for maintaining the orthosis in the correct position and can be adjusted for comfort and swelling variations.

4. Intended Use

Intended for patients requiring ankle and foot support due to muscular weakness, or deformities affecting the ankle, and foot

5. Indications

Drop Foot:

Effective in managing drop foot resulting from neurological disorders, muscle weakness, or nerve injuries.

Post-Stroke Foot Deformities:

Assists in the rehabilitation and support of patients recovering from stroke-related foot and ankle complications.

Cerebral Palsy:

Helps in improving gait and stability for individuals with cerebral palsy, enhancing mobility and independence.

Muscular Dystrophy:

Provides necessary ankle and foot support for patients with muscular dystrophy, aiding in the maintenance of functional alignment.

Post-Operative Rehabilitation:

Useful in post-operative care for surgeries involving the foot, ankle, or lower leg, ensuring proper alignment and support during the healing process.

Arthritic Conditions:

Assists in managing symptoms of arthritis in the foot and ankle, such as pain and instability.

Ligamentous Laxity or Weakness:

Offers support for patients with weakened or damaged ligaments around the ankle and foot.

Congenital Foot Deformities:

Suitable for managing a range of congenital foot deformities, assisting in providing a more natural foot position.

Neuromuscular Disorders:

Beneficial for individuals with neuromuscular disorders that affect the strength and control of the ankle and foot.

Preventive Care:

Can be used as a preventive measure for individuals at risk of foot and ankle injuries due to weakened muscles or instability.

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 Peripheral Vascular Disease (PVD):

Patients with severe PVD or those at risk of skin breakdown due to circulatory issues should avoid using the AFO, as it may exacerbate their condition.

Skin Infections or Ulcers:

Any active skin infection, open wounds, or ulcers at the site of application are contraindications, as the device may impede healing or worsen the infection.

Material Allergies:

Patients with known allergies to any materials used in the AFO (e.g., latex, silicone, certain plastics, and adhesives) should not use the device to avoid allergic reactions.

Severe Edema:

Significant swelling in the foot or ankle area may not be suitable for AFO use, as it can lead to improper fit and increased discomfort or risk of injury.

Uncontrolled Osteoporosis:

Patients with severe, uncontrolled osteoporosis in the lower extremities should avoid using the AFO due to the increased risk of fractures.

Severe Deformities:

Extremely severe foot and ankle deformities that cannot be accommodated or safely aligned within the AFO.

Unstable Fractures:

The AFO should not be used in the case of unstable fractures in the foot or ankle until stability is achieved.

Sensory Neuropathy:

Patients with significant sensory neuropathy in the lower limbs, who cannot feel compression or pain, might be at risk of injury without realizing it.

Dermatitis:

Severe dermatitis or eczema in the area where the AFO is to be worn, as the device can irritate or aggravate these conditions.

Impaired Cognition or Compliance Issues:

Patients who are unable to understand the usage instructions or are likely to use the device improperly due to cognitive impairments.

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

⚠ Fit and Adjustment:

Incorrect fitting can lead to discomfort, reduced function, and risk of injury. Always ensure a proper fit.

⚠ Skin Irritation:

Prolonged pressure or friction can cause skin issues. Regularly inspect the skin for any signs of irritation or breakdown.

⚠ Risk of Falls:

The device may alter walking patterns, increasing the risk of tripping, or falling, especially during initial use.

⚠ Circulation Impairment:

Over-tightening or improper positioning can restrict blood flow. Be alert to sensations like numbness or tingling.

⚠ Heat and Swelling:

Extended use or exposure to heat can cause swelling or discomfort. Adjust use accordingly.

⚠ Device Integrity:

Regularly inspect for wear, damage, or malfunction. Do not use a damaged AFO.

⚠ Children and Vulnerable Users:

Extra caution is advised for children or individuals who may not be able to communicate discomfort or pain effectively.

⚠ MRI Safety:

Remove the AFO before undergoing MRI procedures, as it may contain metal components.

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

Gradual Introduction:

Start with short periods of use and gradually increase as tolerated to avoid discomfort.

Regular Fit Checks:

Regularly check the fit and adjust as needed, especially if there are changes in limb size or shape.

Skin Care:

Monitor the skin regularly for signs of pressure or irritation and maintain good hygiene.

Awareness of Mobility Changes:

Be aware of how the AFO affects mobility and adept activities accordingly.

Environmental Hazards:

Exercise caution on uneven surfaces or in environments where stability may be compromised.

Use as Directed:

Follow the usage instructions and recommendations provided by healthcare professionals.

Avoid Modifications:

Do not attempt to alter or repair the AFO without professional guidance.

Check for Damage:

Regularly inspect the device for any signs of wear or damage.

Driving and Machinery Operation:

Exercise caution when driving or operating machinery, as the AFO may affect mobility and reaction times.

Children's Supervision:

Ensure children using the AFO are supervised, and the device is used correctly.

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

General Use:

Preparing to Wear:

1. Begin by sitting in a stable and comfortable position.
2. Make sure your foot and leg are clean and dry.
3. Wear a thin, smooth sock to protect your skin.

Positioning the AFO:

1. Slide your foot into the AFO, ensuring your heel is properly seated at the back of the brace.

Securing the AFO:

1. Fasten the straps or closures, starting from the bottom near the foot and moving up towards the knee.

2. Adjust to ensure a snug fit without causing discomfort or circulation issues.

Wearing Shoes:

1. Choose shoes that can accommodate the AFO comfortably, usually with a removable insole and a wide opening.
2. Put your shoe on over the AFO, ensuring it fits comfortably without pinching.

Adjusting the AFO:

Fit Adjustments:

1. If the AFO has adjustable features, fine-tune these to achieve the best fit. This might include adjusting straps, padding, or other components.

Comfort Check:

1. Walk a few steps to check for any discomfort or areas of pressure.
2. If the AFO causes pain or significant discomfort, remove it, and seek advice from your healthcare provider.

Daily Use:

Gradual Increase in Use:

1. Gradually increase the amount of time you wear the AFO each day to allow your body to adjust.

Activity Monitoring:

1. Be mindful of how the AFO feels during different activities and adjust your use accordingly.

Removal of the AFO:

Taking Off:

1. Carefully unfasten all straps or closures.
2. Gently slide your foot out of the AFO.

Skin Care:

1. Inspect your skin for any signs of irritation or pressure marks.
2. Apply any necessary skin care products as advised by your healthcare provider.

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 AFO regularly using a soft cloth dampened with mild soap and water. Focus on areas that come in direct contact with the skin and any joints or movable parts.

Drying the AFO:

After cleaning, wipe the AFO with a dry cloth. Allow it to air dry completely before use. Do not use direct heat sources like hair dryers.

Inspection for Wear and Tear:

Periodically inspect the AFO for any signs of wear, damage, or loose components. Pay special attention to areas under stress, such as the ankle joint and ankle hinges.

Checking Straps and Fasteners:

Ensure that straps, buckles, or Velcro fastenings are in good condition and function properly. Replace any worn or damaged parts as necessary.

Lubrication of Joints:

If the AFO has movable joints, they may require occasional lubrication. Consult with a healthcare professional or the manufacturer for appropriate lubricants and application methods.

Avoiding Harsh Chemicals:

Do not use harsh chemicals, solvents, or abrasive cleaners that can damage the materials of the AFO.

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 AFO 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 AFO 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 mold, mildew, or material degradation. Do not store the AFO 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 AFO.

Laid Flat or Properly Supported:

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

Away from Chemicals and Sharp Objects:

Avoid storing the AFO 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 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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