Custom-Made KAFO (Knee Ankle Foot Orthosis)

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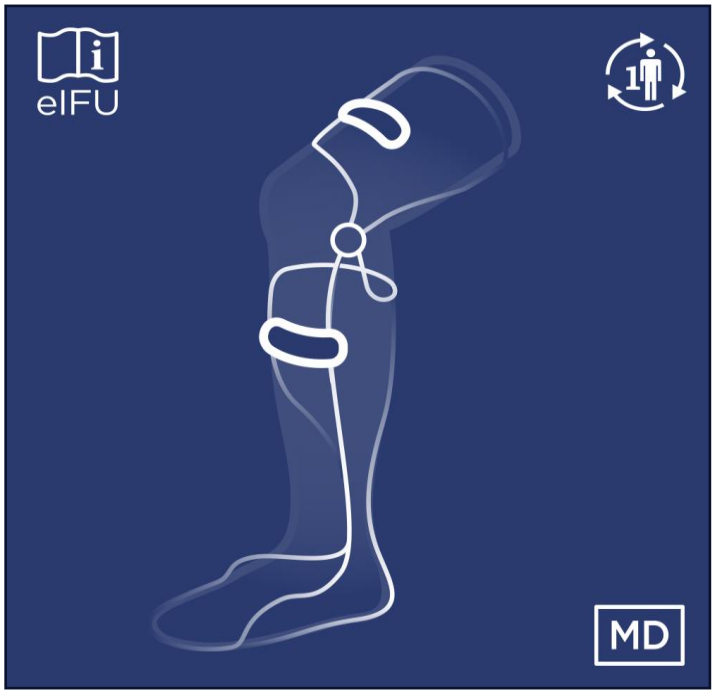

This guide is meticulously designed to provide comprehensive information and instructions on the proper use, maintenance, and care of our custom-made orthotic devices. At The London Orthotic Consultancy, we are committed to delivering exceptional quality and precision in orthotic solutions, tailored 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 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 KAFO (KNEE ANKLE FOOT ORTHOSIS) **Related Product Codes:** KAFO-PP KAFO-CI KAFO-NEU-CI
2. Manufacturer Details
L.O.C. MANUFACTURING LIMITED / THE LONDON ORTHOTIC CONSULTANCY LIMITED 1 Elm Crescent, Kingston Upon Thames, Surrey, England. KT2 6HL Tel: 020 8974 9989 Email: info@londonorthotics.co.uk
3. Device Description
Custom-Made Knee Ankle Foot Orthosis (KAFO) is an orthopaedic device designed to provide comprehensive support and stabilisation to the entire lower limb, specifically the knee, ankle, and foot. Tailored to individual patient specifications, it addresses various neuromuscular and musculoskeletal issues. **Overall Design:** The custom-made KAFO is a specialized orthotic device designed to provide support and stabilisation to the knee, ankle, and foot. It extends from below the hip, encompassing the entire leg down to the foot. **Material Composition:** The device is constructed from a combination of lightweight and durable materials, typically comprising high-grade medical plastics for the structural components, carbon fibre for strength and reduced weight, and padded linings for comfort. Metal joints and supports are incorporated for added stability and functionality. **Custom Fitting:** Each KAFO is individually tailored based on precise measurements and moulds/scans of the patient's leg to ensure an accurate fit. This customisation is crucial for optimal support, comfort, and functionality. **Knee Joint Mechanism:** The KAFO includes a knee joint that can be locked or set to allow controlled motion. This feature is essential for managing knee stability and movement, accommodating different levels of mobility and activity. **Ankle-Foot Support:** The ankle-foot component is designed to maintain proper alignment and support of the ankle and foot. It may include features like adjustable ankle joints, footplates, and toe-off assists, depending on the patient's needs. **Strapping System:** The device is equipped with a series of straps and closures to secure it comfortably and firmly around the leg. These straps are adjustable to accommodate mild changes in the soft tissues.
4. Intended Use
Intended for patients with complex lower limb conditions, including paralysis, muscle weakness, joint instability, and/or deformities affecting the knee, ankle, and foot.
5. Indications
Knee Instability: Ideal for patients with ligamentous laxity or weakness in the knee, such as ACL, PCL, MCL, LCL deficiencies. **Neuromuscular Disorders:** Suitable for managing lower limb weaknesses due to conditions like polio, muscular dystrophy, or multiple sclerosis. **Post-Surgical Rehabilitation:** Useful in post-operative care for surgeries involving the knee, ankle, or lower extremities. **Severe Lower Limb Deformities:** Beneficial for individuals with congenital or acquired deformities that affect the knee, ankle, and foot alignment and function.

Joint Protection:
Provides stabilisation for degenerative joint conditions like severe osteoarthritis or rheumatoid arthritis in the knee and ankle.

Fracture Stabilisation:
Aids in the healing process of fractures in the lower limb by providing support and limiting unwanted movement.

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:
Avoid use in patients with significant circulatory problems in the lower limbs.

Active Skin Infections:
Contraindicated for areas with skin infections, ulcerations, or severe dermatitis.

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

Uncontrolled Edema:
Inadvisable for patients with severe, unmanaged swelling in the leg or foot.

Severe Osteoporosis:
Avoid in patients with brittle bones in the lower extremities, where additional support may pose a risk of fractures.

Sensory Neuropathy:
Not recommended for patients who cannot feel pressure or pain in the lower limbs, as they may not detect injury or discomfort caused by the device.

Severe Deformities:
Not suitable for deformities that cannot be accommodated or safely corrected by the KAFO.

Cognitive Impairments:
Caution advised in patients unable to understand or comply with usage instructions due to cognitive issues.

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 KAFO.

⚠ **Interference with Other Devices:**
The KAFO may interfere with other orthopaedic or medical devices.

⚠ **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 KAFO 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 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

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:
Be aware of how the KAFO affects mobility and adapt 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 KAFO 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 KAFO may affect mobility and reaction times.

Children's Supervision:
Ensure children using the KAFO are supervised, and the device is used correctly.

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

General Use:

Preparing to Wear:

1. Sit in a stable, comfortable position.
2. Ensure the leg and foot are clean and dry.
3. Wear a smooth, thin sock to protect the skin.

Positioning the KAFO:

1. Slide the leg into the KAFO, aligning the knee and foot properly in their respective sections.

Securing the KAFO:

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. Select shoes that can comfortably accommodate the KAFO. Wide-opening shoes with removable insoles are preferable.
2. Put your shoe on over the KAFO, ensuring it fits comfortably without pinching.

Adjusting the KAFO:

Fit Adjustments:

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

Comfort Check:

1. Check for any discomfort or areas of pressure before and during use.
2. If the KAFO 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 KAFO each day to allow your body to adjust.

Activity Monitoring:

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

Removal of the KAFO:

Taking Off:

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

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 KAFO 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 KAFO:
After cleaning, wipe the KAFO 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 KAFO for any signs of wear, damage, or loose components.
Pay special attention to areas under stress, such as the knee 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 KAFO 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 KAFO.

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 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 KAFO 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 KAFO 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 KAFO 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 KAFO.

Laid Flat or Properly Supported:
Store the KAFO in its natural shape. Do not fold or hang the KAFO in a manner that may cause it to deform.

Keep Away from Chemicals and Sharp Objects:
Avoid storing the KAFO 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 labelled 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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