Custom-Made DTKAFO (DYNAMIC TORSIONAL KNEE ANKLE FOOT ORTHOSIS)

CONTENTS

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 DTKAFO (DYNAMIC TORSIONAL KNEE ANKLE FOOT ORTHOSIS)

Related Product Codes:

DTKAFO-PP-1
DTKAFO-PP-1-5
DTKAFO-PP-2
DTKAFO-PP-3
DTKAFO-PP-4
DTKAFO-PP-5
DTKAFO-PP-6

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

A specialised brace designed for the correction and management of club foot in infants and toddlers. Made of medical-grade materials, adjustable straps, and custom mouldable support.

Material Composition:
Made from lightweight and durable materials such as medical-grade plastics and foams, the orthosis is designed for comfort and effective support. The interior is often lined with soft padding to protect the delicate skin of infants and toddlers.

Custom Fitting:
Each orthosis is prescribed based on the precise measurements of the child's foot and leg. The design is modular; your orthotist will adjust the DTKAFO to ensure a perfect fit, crucial for the effective treatment of club foot.

Adjustable Components:
The orthosis features adjustable straps, foot, and lower leg sections to accommodate for growth and movement.

Foot and Ankle Support:
The design is focused on maintaining the foot in a corrected position but allowing dynamic correction so a child can move within the brace but always be taken back to a corrected position.

Ease of Use:
Designed with practicality in mind, the orthosis can be easily put on and taken off by the parent or caregiver, which is essential for adherence to the treatment regimen.

4. Intended Use

Intended to maintain the correction following a successful Ponseti treatment of idiopathic structural club foot.

5. Indications

Club foot (Talipes Equinovarus)
Clubfoot is a congenital foot deformity that affects a child's bones, muscles, tendons, and blood vessels. The front half of an affected foot turns inward and the heel points down. In severe cases, the foot is turned so far that the bottom faces sideways or up rather than down.

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

Uncorrected Club Foot Deformities:
In cases of clubfoot which have not been corrected by the Ponseti method, DTKAFO Bracing should not be attempted.

Severe Dermatological Conditions:
Patients with severe skin conditions such as eczema, psoriasis, or dermatitis in the area where the brace is to be applied should not use this device. These conditions may be exacerbated by the brace.

Open Wounds or Ulcers:
The presence of open wounds, ulcers, or sores near the application area is a contraindication. The brace may hinder healing and increase the risk of infection.

Sensitivity to Brace Materials:
Patients with known allergies or hypersensitivity to any of the materials used in the brace, such as certain plastics, foams, or metals, should avoid using this device.

Severe Circulatory Disorders:
Patients with severe circulatory disorders in the lower limbs, such as deep vein thrombosis or severe peripheral arterial disease, should not use the brace as it may impede blood flow.

Certain Neuromuscular Disorders:
The brace should not be used in patients with certain neuromuscular disorders where the device may cause or exacerbate existing conditions. This includes conditions that severely limit movement or where spasticity may be worsened.

Fractures or Severe Trauma:
Patients with recent fractures or severe trauma to the foot or lower leg should not use the brace until fully healed and cleared by a healthcare professional.

Infections:
Active infections in the foot or lower leg are a contraindication. The brace may aggravate the infection or hinder treatment.

Lymphoedema or Severe Oedema:
The presence of lymphoedema or severe oedema in the lower extremities may be contraindicated as the brace may exacerbate these conditions.

Cognitive Impairment Affecting Compliance:
Patients, especially children, who cannot understand or comply with the wearing schedule due to cognitive impairments may not be suitable candidates for this brace.

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

⚠ **Small Parts:**
Please ensure all screws are tightened on a weekly basis, please report any loose parts to your orthotist immediately. Please wear a sock over the device whilst the baby is sleeping to avoid and small loose parts falling into the sleeping area.

⚠ **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 DTKAFO.

⚠ **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 DTKAFO 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:
Please follow the Wearing in Guide to build up tolerance to the DTKAFO.

- Check for loose or missing parts before each use. THESE ARE CHOKING HAZARDS.
- To protect your child, place a sock over the entire brace to trap any parts that may fall off.
- Stop wearing the brace and call us if you notice any skin breakdown or if there are any concerns with the function of the brace.
- Inspect your child's skin after **each period of use**, particularly at the beginning of the process.
- Redness is normal but should fade in 20 minutes if your skin is tolerating the new pressure.
- If the time indicated seems to be "too much" simply **back up one day** on the chart and continue from that point.
- It's OK to decrease wear time if needed but always progress **gradually**—avoid stopping and starting.

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

Awareness of Mobility Changes:
Be aware of how the DTKAFO affects mobility and adapt activities accordingly.

Use as Directed:
Follow the usage instructions and recommendations provided by healthcare professionals.

Avoid Modifications:
Do not attempt to alter or repair the DTKAFO without professional guidance.

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

- Your child will eventually wear the Orthosis (brace) 23 hours a day but will need several days to adjust to wearing it this much.
- Follow this initialisation schedule to increase the wear time gradually and safely.
- Areas of redness are to be expected but if they persist more than 20 minutes after removing the brace, you'll need to slow down the break-in process. Try backing up and repeating the previous day's schedule.
- Skin checks should be performed each time the orthosis is removed. If there is any skin breakdown, remove the orthosis and contact us immediately.
- Do a thorough check daily for coolness or a dark mottled appearance, this could indicate that the thigh strap is too tight and is possibly causing circulation problems.

DAY WEAR TIME NOTES

1	1 hour on 1 hour off	Repeated throughout the day: Not at Naps, No Night
2	2 hrs on, 30 mins off	Repeated throughout the day: Wear at Nap, No Night
3	4 hrs on, 30 mins off	Repeated throughout the day: W/ Nap & Night
4	6 hrs on, 30 min off	Repeated throughout the day: W/ Nap & Night
5	6 hrs on, 30 min off	Repeated throughout the day: W/ Nap & Night
6	8 hrs on, 30 min off	Repeated throughout the day: W/ Nap & Night
7	12 hrs on, 30 min off	Repeated throughout the day: W/ Nap & Night

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

Cleaning:
At bath time each day, remove and clean the thigh piece and thigh pad with any soap that your child is used to. Once a week, clean these with rubbing alcohol and remove the thigh strap and clean it thoroughly as well using the alternate strap while the first one dries. If a rash develops, use the strap liners until it resolves, cleaning and exchanging them daily.

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 DTKAFO 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 DTKAFO 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 DTKAFO 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 DTKAFO.

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

Keep Away from Chemicals and Sharp Objects:
Avoid storing the DTKAFO 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 II 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

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