EN

Foot Orthosis Additions

Instructions for Use



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Foot Orthosis Additions

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TalarMade Ltd is a UK-based manufacturer of Class I medical devices, committed to providing high-quality, safe, and effective products designed to support healthcare professionals and patients.

This Instruction for Use (IFU) document provides essential information for the correct and safe use of TalarMade products, in compliance with the requirements of the UK Medical Devices Regulations 2002 (as amended) and the EU Medical Device Regulation (EU) 2017/745 (MDR), as applicable.

All TalarMade medical devices are designed, manufactured, and distributed under a certified Quality Management System in accordance with ISO 13485:2016, ensuring that they consistently meet both regulatory and customer requirements for safety, performance, and reliability.

Prescribers and users are advised to read this document carefully before use. Proper

understanding and adherence to the instructions, warnings, and precautions outlined herein are essential to ensure optimal product performance and to minimise the risk of misuse or adverse events.

Product Details

Product Name: Foot Orthosis Additions including: Metatarsal Sulcus Pads, PMP Pads, Dancer Pads, Metatarsal Domes, Arch Pads and Teardrop Met Domes

GMDN: 41575

Basic UDI-DI (if applicable): 50552043LLOFOFD

Packaging contents (list what is included in the package): 1 x Pair OR Pack of 5 of chosen addition

Manufacturer Details

Manufacturers Registered Address

TalarMade Ltd. Edinburgh House, Millennium Way, Chesterfield, Derbyshire, S41 8ND

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Device Description

Talarmade have developed a unique range of surface additions to allow immediate customisation of prefabricated and custom-made foot orthosis.

- Available with MicroGrip (for use with microfibre-covered foot orthoses) or self-adhesive backing (for use with vinyl, leather, foams, EVA, composites and thermoplastics).
- Available as a pair or a pack of 5 (pairs)
- Range of sizes – see website or catalogue for further information
- Made from A30 shore EVA or PU gel (dependant on size/product chosen)
- Easily trimmable

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Item		Impact	Recommended For
PMP Pads		Reduces 1st MTH load	Sesamoiditis Functional Hallux Limitus Lateral Ankle Instability Peroneal Tendinopathy Plantarfasciopathy
Arch Pads		Increase arch height	High arched feet Increased forces under medial or lateral arches
Teardrop Metatarsal Domes		Reduces site metatarsal head load / pressure	Morton's Neuroma
Metatarsal Domes		Reduces metatarsal head load / pressure	Plantar forefoot pain

Metatarsal Sulcus Pads		Once trimmed, offloads plantar plate / metatarsal head	Plantar plate dysfunction Offloading corns Freiberg's
Dancer Pads		Reduces forefoot loads on MTH 2–5 (metatarsal bar)	Plantar forefoot pain Retracted 2–5 toes

Intended Use

The Foot Orthosis Additions are a unique range of surface additions to allow immediate customisation of prefabricated and custom-made foot orthosis without the need for a workshop.

Target users are healthcare professionals and laypeople.

Indications

Talarmade Foot Orthosis Additions are indicated for a range of MSK presentations. More information can be found on the chart on the previous page.

Contraindications

Talarmade Foot Orthosis Additions should be carefully considered in the presence of the following:

- For treatment of individuals with severe fixed deformities
- Individuals with plantar surface wounds or ulcers

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Excess local pressure or shear due to improper fit	Skin irritation, blistering, callus, injury	Ensure correct sizing and placement on insole/in footwear. Discontinue use if redness, irritation, or skin breakdown occurs.
⚠ **Follow Instructions For Use**	User misapplication or non-compliance	Ineffective treatment, increased injury risk	Read the IFU thoroughly before first use. Only use as directed by a healthcare professional.
⚠ **Consult A Healthcare Professional**	Device irritating foot	Foot injury	Do not use if active ulcer or wound present
⚠ **Single Patient Use**	Cross-contamination, loss of performance	Infection transmission, foot injury	The device is intended for a single user only. Do not share or reuse between users.
⚠ **Do Not Heat**	Heating or exposure to extreme heat	Fire, loss of mechanical performance	Do not modify the device unless explicitly instructed by a qualified clinician.
⚠ **Gradual Wear-In Required**	Abrupt full-time use	Skin stress due to sudden biomechanical change	Increase usage gradually over several days, monitoring skin condition.
⚠ **Material Degradation**	Compression set or wear of addition materials	Loss of pressure/shear reduction	Inspect device regularly. Replace if worn, cracked, or deformed.
⚠ **Stability/ Falls Risk**	Change in foot mechanics affecting balance	Risk of instability or falls in at-risk patients	Patients with balance issues should consult a clinician before use. Use caution during initial adaptation.
⚠ **Report Serious Incidents**	Undetected adverse events	Safety risk to user and others	Report serious incidents to the manufacturer and the relevant competent authority (EU) or MHRA (UK).

Precautions

- This device is for single patient use only. Reuse by another individual may increase the risk of cross-contamination, improper fit, or compromised device performance
- Users should always wear hosiery when using device
- Check inside the shoe for foreign objects before inserting or wearing an adapted insole.
- Remove insole from the shoe regularly to visually inspect it and any surface additions for damage, deformation, or trapped debris.
- If the insole and/or additions becomes soiled or contaminated, clean it according to the manufacturer's instructions and allow it to dry fully before reuse.
- Ensure the adapted insole is used only in footwear that fits properly and provides enough support, depth and width to avoid new pressure points.
- Make sure the adapted insole lies flat and secure inside the shoe with no folding or edge lift.
- Gradually increase wear time when first using the insole to monitor comfort and skin response.
- Perform daily foot checks, especially for users with diabetes or reduced sensation.
- Replace the additions if they become worn, compressed, cracked, or misshapen, as performance may be reduced.
- Do not modify, cut, or heat-mold the insole unless instructed by a healthcare professional.
- Be cautious if you have balance or mobility issues, as changes to footwear may alter gait

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Instructions for Use

1. Before Use

Ensure the surface addition corresponds to the required mechanical dose, correct size and shape for the intended user - trim if required.

2. Apply Chosen Surface Addition

Using either MicroGrip or self-adhesive backing (dependant on insole top cover material) apply surface addition to top surface of insole.

Addition placement should be directed by a healthcare professional. Patients should not remove or reposition any surface addition and should seek advice from a medical professional if they have any concerns

3. Wearing Instructions

- Start with 1–2 hours of wear and increase gradually as tolerated.
- Perform daily foot checks for any signs of irritation or pressure marks.
- Avoid high-impact activities whilst getting used to wearing devices unless approved by a healthcare professional.

4. When to Stop Using the Device

Stop using it and seek clinical advice if:

- Redness, blistering, hot spots, callus buildup, or open wounds occur
- Discomfort, pain, or instability is experienced
- The surface addition moves or becomes worn

Cleaning & Maintenance

Talarmade Orthosis Additions can be wiped clean using a damp cloth.

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Storage Conditions

- Store in a **cool, dry place**, protected from direct sunlight and heat

Disposal Instructions

Dispose of the device and its packaging in accordance with applicable local, regional, or national regulations.

Regulatory Compliance

EU REP

EUROPEAN AUTHORIZED REPRESENTATIVE

MedNet EC-REP GmbH, Borkstrasse 10, 48163 Muenster, Germany

SRN number: DE-AR-000000002

CH REP

SWISS AUTHORIZED REPRESENTATIVE

MedNet SWISS GmbH, D4 Platz 4, 6039 Root D4, Switzerland

CHRN: CHRN-AR-20000730

Warranty Information

The device is supplied under the manufacturer's warranty as outlined in the current Terms and Conditions available on our website. Users are advised to review these terms prior to use.

Contact Information

We are committed to continuously improving our products.
Please scan the QR code to share your feedback with us.

No camera? Click here or on the QR code to open the product feedback form.

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Date of Issue and Version

Issue 1 | March-2026