EN

Footshield II Shoe and Boot

Instructions for Use



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Footshield II Shoe and Boot

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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.

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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: Footshield II Shoe and Boot

GMDN: 31041

UDI-DI (if applicable): 50552043LLOFOFD

Packaging contents: 1 x Footshield II Shoe or Boot

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

The Footshield II Shoe and Boot is designed to be a temporary treatment/therapeutic shoe/boot which is used post-operatively or in wound care applications.

- Evidence-based rocker sole (at 60% of the shoe length and at a 20° angle)
- 10° toe out angle
- Removable memory foam insole
- Square toe design
- Touch-and-close fastening straps to help minimise pressure on the forefoot yet adjustable to accommodate bulky dressings
- Can be used on its own or with the Hex plantar foot offloading insole
- Fabric, removable toe cap included as standard

- Available in both a shoe and boot model
- Available in 5 sizes (X-Small, Small, Medium, Large and X-Large)
- Separate left and right models

Intended Use

The Footshield II Shoe and Boot is designed to be a temporary treatment/therapeutic shoe/boot which is used post-operatively or in wound care applications.

Target users are healthcare professionals and laypeople, both in hospital/healthcare environments and at home.
The Footshield II Shoe & Boot should be worn/used under the guidance of a healthcare professional and as outlined in the instructions for use.

Indications

The Footshield II Shoe and Boot is indicated for use in the following situation:

- Accommodation of dressings or oedema
- At risk feet
- Pressure redistribution of forefoot

Contraindications

- Do not use on open wounds/fractures

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Application Over Open Wounds	Delayed Healing or Infection	Do not use over open wounds without appropriate dressings and medical supervision.
⚠ **Warning**	Incorrect Application	Ineffective function	Application should be performed by healthcare professionals or trained caregivers.

⚠ **Warning**	Skin Monitoring	Patient Injury	The patient's skin must be inspected regularly for signs of redness or irritation. If irritation or skin damage occurs, discontinue use and consult a healthcare professional.
⚠ **Infection Control**	Cross-contamination, loss of performance	Infection transmission	The device is intended for single patient use only. The device may be cleaned during use according to the cleaning instructions provided.

Precautions

- This device is for **single patient use only**. Re-use by another individual may increase the risk of cross-contamination, improper fit, or compromised device performance
- The device should be worn as instructed by the prescriber
- Inspect the device integrity before use
- Remove brace and cease use if the brace causes pain, redness or skin breakdown

Instructions for Use

Application

1. Choose the correct sized shoe / boot based on shoe size.
2. Open all straps.
3. Insert the foot into the open shoe / boot. If using the provided toe cap, ensure toes are placed inside the toe cap with long side on the top of the foot.
4. Close the touch-and-close fasteners closest to the ankle.
5. Close the touch-and-close fastening over the forefoot.

Use Of Optional Hex Insole

1. Remove memory foam insole.
2. Ensure insole matches shoe/boot size.
3. Using a marker pen or similar draw around the area to be protected on patient's foot.
4. Insert the Hex insole into the shoe/boot.
5. Place patient's foot into shoe/boot and onto Hex Insole to leave an inked mark.

6. Remove the Hex Insole from the shoe/boot and carefully remove the Hex Pegs from within the marked area.
7. Once hex pegs have been removed to create required recess, remove adhesive back from base cover and adhere securely.
8. Re-insert the Hex Insole into the shoe/boot.

Cleaning & Maintenance

- Footshield II Shoe & Boot can be hand washed in cool water with mild detergent
- Do not use bleach or chlorine-based cleaning products
- Not for use in washing machine or tumble dryer
- Brace should be left to dry naturally before re-applying

Storage Conditions

- Store in a cool clean dry place and away from direct sunlight

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.

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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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