EN

Hexasole

Instructions for Use



TalarMade
Made with clinical excellence in mind

eIFU MD CE UK CA

TalarMade
Made with clinical excellence in mind

Hexasole

CONTENTS

1. **Product Details**
2. **Manufacturer Details**
3. **Device Description**
4. **Intended Use**
5. **Indications**
6. **Contraindications**
7. **Warnings**
8. **Precautions**
9. **Instructions for Use**
10. **Cleaning & Maintenance**
11. **Storage Conditions**
12. **Disposal Instructions**
13. **Regulatory Compliance**
14. **Warranty Information**
15. **Contact Information**
16. **Date of Issue and Version**

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: Hexasole

GMDN: 41575

Basic UDI-DI (if applicable): 0552043LLOFOFD

Packaging contents (list what is included in the package): 1 x Pair Hexasole Insoles

Manufacturer Details

Manufacturers Registered Address

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

Tel: +44 (0)1246 268 456 | talarmade.com | Email: info@talarmade.com

Device Description

- A configurable insole designed to reduce mechanical load and pressure through a specific site on the sole of the foot
- This device is intended for **single-patient use only** and must not be shared between users

- Available in 4 sizes (Small, Medium, Large, Extra Large)
- Available in 2 thicknesses (4mm and 6mm)
- Sold in pairs

Intended Use

The Hexasole insole is a configurable orthotic insole intended to alter how force is distributed across the plantar surface of the foot.

Its removable honeycomb plug system enables clinicians to create customised pressure-relief zones beneath painful or vulnerable tissues while maintaining support across the surrounding foot.
The device is intended to assist in the conservative management of localised plantar pressure where temporary or longer-term offloading is required.

Target users are healthcare professionals and laypeople.

Hexasole insoles should be worn in appropriate footwear as described in the instructions for use.

Indications

Hexasole insoles are recommended for:

- Painful plantar lesions, corns or calluses.
- Post-operative care
- A wound or area that needs protection from pressure.
- Diabetes ulcerations

Contraindications

- For treatment of individuals with severe fixed deformities. Alternative solutions may include custom foot orthotics

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 inside 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.
⚠ **Check Footwear Interior**	Objects or seams in footwear causing pressure hot-spots	Skin damage leading to injury	Check shoes daily for foreign objects, rough seams, or debris.
⚠ **Keep Dry / Moisture Hazard**	Use of wet or contaminated insole	Skin maceration, microbial growth, reduced device performance	Ensure device is dry before use.
⚠ **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 insole 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 the insole.
- Remove the insole from the shoe regularly to visually inspect it for damage, deformation, or trapped debris.
- If the insole becomes soiled or contaminated, clean it according to the manufacturer's instructions and allow it to dry fully before reuse.
- Ensure the insole is used only in footwear that fits properly and provides enough support, depth and width to avoid new pressure points.
- Make sure the 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 insole if it becomes 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
- Should not be used without any wedges applied to base

Instructions for Use

1. Purpose of the Device

Hexasole is a configurable insole intended to alter how force is distributed across the plantar surface of the foot in the presence of elevated plantar loading.

2. Before Use

Ensure the insole corresponds to the required function, correct size and thickness for the intended user.

- Hexasole insoles are configurable to allow for targeted offloading and should be fitted/set up by a healthcare professional
- Surface additions with self-adhesive backing can be applied to the surface of the device by healthcare professionals
- Patients using the device should not change or modify the insole/s (unless instructed by a healthcare professional)

How to set up your Hexasole:

- Select the correct insole size using the sizing template supplied.
- Mark the anatomical site requiring offloading using the card template before modifying the insole.
- Transfer the marked position accurately to the underside of the Hexasole insole.
- Remove only the hexagonal plugs required to create the planned offloading zone.
- Apply the supplied self-adhesive backing to secure the modified area.
- Inspect the finished surface to ensure it is smooth, secure and free from raised edges or trapped air.
- Confirm that the offloading aperture aligns correctly with the anatomical area requiring pressure relief before patient use.

Once the above has been addressed, then consider the following:

- Inspect the insole for visible damage, deformation, cracks, or contamination.
- Check inside the shoe for foreign objects or irregularities before inserting the insole.
- Ensure footwear provides adequate depth and width to avoid new pressure points.
- Footwear should be deep enough to accommodate the insole

3. Insertion and Fit

- Remove existing insoles from the footwear unless otherwise advised.
- Place Hexasole insoles flat inside the shoe, ensuring full contact with the shoe

base.

- Trim front of insole (if required and using full length) to improve fit
- Check that the edges lie smoothly without lifting or folding.
- Confirm that the foot sits comfortably without pressure or rubbing.

4. 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.
- Use Hexasole insoles only with supportive, closed footwear recommended by your clinician.
- Avoid high-impact activities whilst getting used to wearing devices unless approved by a healthcare professional.

5. Removal and Inspection

- Remove the insoles daily to inspect the top and bottom surfaces for:
    - Wear, cracking, compression, or deformation
    - Trapped debris or foreign objects
- Inspect the inside of the shoe for stones, seams, or debris that may create pressure.

6. 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 insole becomes worn, cracked, or unstable

Cleaning & Maintenance

If Hexasole insoles become soiled or contaminated, clean according to the following procedure:

- Wipe with a damp cloth using mild soap or a non-abrasive cleanser.
- Rinse lightly if needed; do not saturate the insole.
- Allow to air-dry completely away from direct heat sources.
- Do not machine wash, machine dry, bleach, or expose to extreme heat.

Inspect regularly and replace the insole if it shows signs of structural breakdown such as:

- Cracking
- Loss of cushioning or shape

The insole should be replaced after 12 months of regular use, even if no visible damage is present, to ensure continued performance.

Storage Conditions

- Store in a **cool, dry place**, protected from direct sunlight and heat
- Avoid placing heavy items on top of the insole to prevent deformation

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.

Made with clinical excellence in mind

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.

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

Tel: +44 (0)1246 268 456 | talarmade.com | Email: info@talarmade.com

Date of Issue and Version

Issue 1 | March-2026