EN

Superflex Insoles

Instructions for Use



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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: Superflex

GMDN: 41575

UDI-DI (if applicable): 50552043LLOFOFD

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

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

Superflex insoles are a range of simple chairside foot orthoses that can be issued as they are or modified in clinic to provide simple treatment solutions for the right patients. The 3 models available have the following features:

Superflex

- Neutrally posted
- Soft EVA material with microfibre top cover
- Offer light support

Superflex Plus

- Neutrally posted
- Soft EVA material with microfibre top cover
- Moderately reinforced heel cup
- Offer mild support

Superflex Ultra

- Neutrally posted
- Soft EVA material with microfibre top cover
- Firmly reinforced heel cup
- Offer moderate support

- All models are available in 5 sizes (X-Small, Small, Medium, Large and X-Large)
- All can be used in conjunction with Talarmade's MicroGrip surface additions
- Superflex insoles are intended for **single-patient use only** and must not be shared between users

Intended Use

Superflex insoles are a range of simple chairside foot orthoses that can be issued as they are or modified in clinic to provide simple treatment solutions for the right patients

Target users are healthcare professionals and laypeople.

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

Indications

Superflex insoles are recommended in the following situations:

- The chairside management of varying foot conditions.

Contraindications

Superflex insoles should not be used in the following situations:

- For treatment of patients requiring high kinetic dosing as part of their treatment
- For treatment of individuals with severe fixed deformities
- Individuals with plantar surface wounds or ulcers

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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

Instructions for Use

1. Purpose of the Device

Superflex Insoles are a range of simple chairside foot orthoses that can be issued as

they are or modified in clinic to provide simple treatment solutions for the right patients.

2. Before Use

Ensure the insole corresponds to the required mechanical dose, correct size and shape for the intended user.

The use of plantar surface wedging:

- Superflex insoles can be adapted with wedging (such as the Talarmade Basic EVA Wedge Strip) to allow clinicians to immediately modify the way forces are applied through the device to the foot.
- Patients using the device should not change or add wedges (unless instructed by a healthcare professional)

The use of surface additions:

- Surface additions with MicroGrip backing can be applied to the microfibre top cover of the device by healthcare professionals
- Patients should not remove or reposition any surface addition and should seek advice from a medical professional if they have any concerns

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

1. Remove existing insoles from the footwear unless otherwise advised.
2. Place Superflex insoles flat inside the shoe, ensuring full contact with the shoe base.
3. Trim front of insole if required to improve fit
4. Check that the edges lie smoothly without lifting or folding.
5. 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 Superflex 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 Superflex 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.

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