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# Prostep

## Instructions for Use




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# Prostep

## 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: Prostep**

**GMDN: 41575-Orthotic Insole, Prefabricated, Non-antimicrobial**

**UDI-DI (if applicable): 506012332LLOFOYG**

**Packaging contents (list what is included in the package): 1 Pair Prostep Insoles and Multiple Extrinsic Wedging Options**

## Manufacturer Details

**Manufacturers Registered Address**

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

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## Device Description

- Prefabricated EVA foot orthosis with microfibre top cover
- Alters how force is distributed across the plantar surface of the foot
- This device is intended for **single-patient use only** and must not be shared between users

- Prostep is available in 2 lengths (full and ¾ length), 2 densities (medium 45 shore, firm 60 shore) and 8 sizes (ranging from children's UK size 13.5-1.5 to adult UK size 11-12)
- Multiple extrinsic wedging options

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## Intended Use

Prostep are **prefabricated orthotic insoles** intended to **alter how force is distributed across the plantar surface of the foot.**
The specific design plays a crucial role in **modifying the speed at which the joints move** and consequently, the stresses exerted on soft tissues and joints within the foot and lower limb.

Target users are healthcare professionals and laypeople.

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

## Indications

Prostep insoles are recommended for:

- Tibialis Posterior Dysfunction
- Dorsal Midfoot Interosseus Compression Syndrome (DMICS)
- Midfoot Osteoarthritis
- Plantar Forefoot Pain
- Plantar and Posterior Heel Pain
- Hallux Rigidus / Limitus
- Anterior Knee Pain
- Shin Splints

## Contraindications

- 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 | Skin irritation, blistering, callus, | Ensure correct sizing and placement inside footwear. |
| | due to improper fit | injury | 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
- Device should not be used without a wedge or zero post applied to recess under heel
- 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

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# Instructions for Use

## 1. Purpose of the Device

Prostep is a prefabricated insole intended to **alter how force is distributed across the plantar surface of the foot** in the presence of a range of musculoskeletal problems.

## 2. Before Use

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

- Prostep insoles are supplied with a wedge pack to allow clinicians to immediately modify the way forces are applied through the device to the foot.
- The wedges are applied by removing the self-adhesive backing allowing the wedges to be applied securely onto the device
- Heel wedge/post must be applied to device prior to patient use
- 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 Prostep 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 Prostep 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 Prostep 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.

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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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