EN

HeelPro
Heel Offloading Boots
(HeelPro/HeelPro Advance/HeelPro Petite)

Instructions for Use



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Product Name

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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: HeelPro Heel Offloading Boots

Device Variants Covered by this IFU:

- HeelPro
- HeelPro Advance
- HeelPro Petite

GMDN: 41435

UDI-DI (if applicable): 50552043LLOFOFD

Packaging contents (list what is included in the package): 1 HeelPro Offloading Boot

CE Mark: Class I medical device (self-declared conformity)

UKCA Mark: Class I medical device (self-certified)

Use Type: Single patient use device.

Sterility: Supplied non-sterile

Product Details: The batch number and product reference are located on the device label and packaging for traceability.

This device conforms to:

EU Regulation (EU) 2017/745

UK Medical Devices Regulations 2002 (as amended)

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

HeelPro heel offloading boots are non-invasive, non-active medical devices designed to assist in the prevention and management of heel pressure ulcers.

The device supports the lower leg and foot while suspending the heel away from the bed or support surface, reducing pressure, friction, and shear forces acting on the heel.

The device consists of a padded boot that wraps around the lower leg and foot, incorporating a heel aperture to ensure the heel remains free from contact with the support surface.

The device is secured using elastic stretch fastening panels around the shin and forefoot.

Some configurations may be used with an optional stability wedge to limit internal or external rotation of the leg during use.

When correctly applied, the device:

- Offloads pressure from the heel
- Redistributes pressure away from bony prominences
- Helps maintain resting alignment

The devices are intended for external contact with intact skin or dressings and are supplied non-sterile.

Device Variants Covered by this IFU:

- HeelPro (Textile offloading boot filled with fibre cushioning)
- HeelPro Advance (Wipe-clean offloading boot designed for improved infection control)
- HeelPro Petite (Smaller version of HeelPro designed for smaller or frail ankles)

Intended Use

HeelPro heel offloading boots are intended to prevent or treat heel pressure ulcers by offloading the heel and redistributing pressure from bony prominences in contact with the device.

The device is applied to the patient's lower leg and foot while the patient is lying or

resting in bed, suspending the heel away from the supporting surface.

The device is intended for use on patients who are at risk of developing heel pressure ulcers or who require heel pressure offloading as part of pressure injury management.

The device is intended for use by:

- Healthcare professionals
- Caregivers
- Laypersons under the supervision of a healthcare professional

The device may be used in:

- Hospitals
- Care homes
- Home care environments

The device is intended for external use only and for contact with intact skin or dressings/bandages.

Indications

HeelPro devices are indicated for use in patients:

- At risk of developing heel pressure ulcers
- Requiring pressure redistribution away from the heel
- Requiring heel suspension during periods of immobility
- Requiring reduction of friction and shear forces acting on the heel
- With existing ulcers/wounds to the heel where pressure offloading is required
- Requiring separation or protection of the ankles

Contraindications

Do not use the device in the following situations:

- Patients with high-volume discharging wounds

- Patients who are likely to attempt to stand or walk while wearing the device.
- Patients for whom heel offloading devices have been deemed unsuitable by a healthcare professional.
- Patients with conditions where compression or immobilisation of the lower limb is clinically inappropriate, unless advised by a healthcare professional.

A healthcare professional should assess suitability before use.

Warnings

Failure to follow these warnings may result in **reduced therapeutic benefit, patient discomfort, injury, or device failure**.

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Not Intended for walking	Falls, Injury	The device must only be used while the patient is lying or resting in bed. Patients must not stand or walk while wearing the device, as this may lead to falls or injury.
⚠ **Warning**	Incorrect Application/Sizing	Ineffective offloading, increased injury risk	Application should be performed by healthcare professionals or trained caregivers trained in pressure injury prevention. If the device is incorrectly fitted, incorrectly sized or positioned, heel offloading may be reduced, and the risk of pressure damage may increase.
⚠ **Warning**	Slipping/Limb moves in device during use	Ineffective offloading, increased injury risk	The device and patient should be checked regularly to ensure the device is achieving its goal and is positioned correctly
⚠ **Warning**	Skin Monitoring	Patient Injury	The patient's skin must be inspected regularly for signs of redness, irritation, or pressure injury. If irritation or skin damage occurs, discontinue use and consult a healthcare professional.
⚠ **Infection Control**	Cross-contamination, loss of performance	Infection transmission, foot injury	The device is intended for single patient use only. The device may be cleaned during use according to the cleaning instructions provided.

⚠ **Do Not Modify**	Device Condition	Ineffective offloading, increased injury risk	Do not cut, pierce, or modify the device, as this may affect safety, performance, and pressure offloading capability.
⚠ **Fire Hazard**	Fire	Fire, Patient injury	Keep the device away from open flames, lit cigarettes, or other sources of ignition.
⚠ **Keep dry / moisture hazard**	Use of wet or contaminated device	Skin maceration, microbial growth, reduced device performance	Ensure device is dry before use and is cleaned regularly
⚠ **Report Serious Incidents**	Undetected adverse events	Safety risk to user and others	Any serious incident occurring in relation to the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Precautions

- Single patient use
- Inspect the device before each use.
- Do not use if the device is damaged, torn, or excessively worn.
- Do not over-tighten fastening panels.
- Inspect the device regularly during use.
- Ensure the heel is fully suspended and not in contact with the bed surface.
- Patients with peripheral vascular disease, diabetes, or neuropathy should be carefully assessed before use.
- Remove the device periodically to assess the skin according to local clinical protocols.
- Avoid contact with sharp objects that may damage the product.
- Do not expose the device to radiators, heaters, or prolonged direct sunlight.

Instructions for Use

Application

1. Remove both wide stretch panels from the device.
2. Turn the HeelPro inside out so that the inner surface faces outward.
3. Place the device on the bed with the longest side next to the patient's leg.
4. Position the patient's leg on top of the device, ensuring the heel is positioned over the heel opening.
5. Pull the sides of the device up around the foot and lower leg.
6. Ensure the washing instructions label sits beneath the foot.
7. Attach one stretch panel to the outer side of the shin and gently stretch across the shin to secure.
8. Attach the second stretch panel across the forefoot and secure.

Optional Stability Wedge

To resist external rotation of the leg:

- Attach the stability wedge to the lateral side of the device so that it contacts the HeelPro and the bed.

To resist internal rotation of the leg:

- Attach the stability wedge to the medial side of the device.

Cleaning & Maintenance

Cleaning requirements vary depending on the device variant.

HeelPro and HeelPro Petite

- Clean using mild detergent and warm water.
- Rinse thoroughly with clean water and allow to air dry completely before reuse.

Do not:

- Bleach
- Machine wash or dry
- Use abrasive cleaning materials

The device may also be cleaned with a damp cloth or hospital-grade disinfectant wipe.

HeelPro Advance

HeelPro Advance is manufactured with wipe-clean materials designed for infection control environments.

Recommended cleaning:

- Clean using soap/detergent and warm water
- Disinfect using hospital-grade disinfectant wipes in accordance with local infection control policy
- Allow to dry before reuse

Storage Conditions

- Store in a clean, dry environment.
- Keep away from direct sunlight, heat sources, and moisture.
- Store in original packaging where possible.
- Do not stack or compress products in a way that may damage their structure.

The device is intended for single patient use during a treatment episode. The expected functional lifetime of the device is **up to 6 months**, provided the device remains undamaged and is used according to these instructions.

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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