EN

FootSafe

Instructions for Use



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Product Name

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: FootSafe

GMDN: 41435

UDI-DI (if applicable): 50552043LLOFOFD

Packaging contents (list what is included in the package): 1 Pair FootSafe Boots

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

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

Use Type: Multi 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

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Device Description

This device is a Class I medical device under Regulation (EU) 2017/745 and UK Medical Devices Regulations 2002.

- The FootSafe Prevention Boot is a non-invasive, non-active medical device designed to help prevent and manage heel pressure ulcers by offloading the heel and redistributing pressure away from bony prominences.
- The device is a pre-inflated boot worn on the lower leg and foot, which elevates

and suspends the heel away from the bed or support surface when correctly applied.

- The boot contains air-filled chambers that provide cushioning and pressure redistribution to reduce compression, friction, and shear forces on the heel area.
- The device is manufactured from medical-grade thermoplastic polyurethane (TPU) film and other latex-free polymeric materials intended for external contact with intact skin.
- The boot is secured using adjustable TPU straps with button fastenings, allowing the device to be fitted around the patient's foot and lower leg.
- The device is supplied non-sterile and intended for use in hospitals, care homes, or home care environments under the supervision of a healthcare professional or trained caregiver.
- The FootSafe Boot is available in multiple sizes, including child, youth, small, large, and extra-large, to accommodate different patient groups.
- The device is multi-patient use but should be replaced after 12 months' use.

The clinical benefit of the device is the reduction of heel pressure and associated risk of pressure ulcer development.

Intended Use

The FootSafe Prevention Boot is intended to assist in the prevention and management of heel pressure ulcers by offloading the heel and redistributing pressure away from the heel and other vulnerable areas of the foot and ankle.

The device is designed to be 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 to reduce pressure, friction, and shear forces on the heel.

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, as determined by a healthcare professional.

The FootSafe Prevention Boot is intended for use in healthcare environments such as hospitals, care homes, and in home care settings or patient's homes. It may be applied by healthcare professionals or trained caregivers.

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

Indications

The FootSafe Prevention Boot is indicated for use in the following situations:

- Patients who are assessed by a healthcare professional as being at risk of developing heel pressure ulcers.
- Adults and children with heel ulcers or at risk of developing heel pressure ulcers due to immobility or reduced mobility.
- Patients who require redistribution of pressure, friction, and shear away from the heel area as part of a pressure injury prevention strategy.
- Patients who require heel elevation to prevent contact between the heel and the bed or mattress surface.
- Patients who require support of the lower leg and foot to assist with heel suspension during periods of immobility or reduced mobility.
- Patients requiring pressure care management as part of a clinical care plan in hospitals, care homes, or home care environments.

Contraindications

Do not use the FootSafe Prevention Boot in the following situations:

- Patients with spasticity causing uncontrolled or involuntary movement of the lower limb.
- 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.
- Patients with severe contractures of the ankle/foot

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 FootSafe Prevention Boot is designed for use when the patient is **lying or resting in bed**. The patient **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 Irritation	Patient Injury	The patient's skin should be inspected frequently for early signs of redness, irritation, or pressure injury.
⚠ **Infection Control**	Cross-contamination, loss of performance	Infection transmission, foot injury	The device should be cleaned according to local infection control guidelines to prevent cross-contamination between users.
⚠ **Warning**	Pressure redistribution failure	Ineffective offloading, increased injury risk	The device should be checked daily to ensure it is operating as intended and is not losing inflation or damaged.
⚠ **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 ignition sources, as the materials are not designed to withstand exposure to fire.
⚠ **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**	Undetected adverse events	Safety risk to user and others	Any serious incident occurring in relation to the device should be

Incidents			reported to the manufacturer and to the MHRA via the Yellow Card Scheme (UK) or the relevant competent authority in the EU Member State.

Precautions

- Ensure the device is applied correctly and that the heel is fully suspended and not in contact with the bed or mattress surface after fitting.
- Patients at risk of pressure damage should be repositioned regularly in accordance with local clinical guidelines and care plans.
- The patient's skin should be inspected frequently for early signs of redness, irritation, or pressure injury.
- Check the device regularly during use to ensure it remains correctly positioned and securely fastened.
- Keep the device away from sharp instruments, blades, or pointed objects that could puncture or damage the material.
- Do not expose the device to radiators, heaters, or prolonged direct sunlight, as excessive heat may damage the material and affect device performance
- Ensure the device is clean and dry before application and follow the recommended cleaning instructions between uses.
- Inspect the device regularly for signs of wear, damage, or contamination, and discontinue use if the device no longer functions as intended.
- Despite correct use, some patients may experience skin irritation or discomfort due to prolonged contact with the device materials.

Instructions for Use

Pre-Inflated Boots

1. The boots are right and left, ensure the straps and the sole fastening always pull to the outside of the leg

2. First fasten the 3 buttons on the side of the footplate to create the foot piece (the print on the calf area should be centre back facing outwards)

3. The boots have been supplied pre-inflated for your convenience

4. Place foot into the device ensuring heel is positioned in the void area

5. Place limb on flat surface and then fasten calf buttons securely
6. Check that the heel is offloaded and not in contact with the supporting surface

Cleaning & Maintenance

The device should be cleaned according to the instructions in this section and in accordance with local infection control policies. There are some precautions which are detailed above.

Where a policy does not exist for cleaning, we recommend the following:

Cleaning

- Weekly cleaning of the product with soap / detergent and water, rinsing with clean water and drying thoroughly.
- The pump used to inflate the product can also be cleaned in the same way, with soap / detergent, and then allowed to dry
- The device should be thoroughly cleaned prior to applying to a different patient in accordance with local infection control guidance
- Abrasives and scourers must not be used

NB - Depending on patient and continence status, more frequent cleaning or disinfection may be required

Disinfection

Where there is visible contamination (e.g. faeces/blood/urine), this should be removed from the product using soap / detergent and water, followed by rinsing with warm water. Following this, a disinfectant solution / wipe should be used which provides between 1,000 and 10,000 ppm available chlorine (this will depend on local protocol), followed by a clean water rinse and thorough drying of the product.

Storage Conditions

- Store in a **cool, dry place**, protected from direct sunlight and heat.
- Avoid placing heavy items on top of the device 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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