EN

Prolevo Wedge

Instructions for Use

TalarMade
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eIFU MD CE UK CA

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: Prolevo Wedge

GMDN: 47476 - Air-filled bed mattress overlay

UDI-DI (if applicable): 5055204347180

Packaging contents (list what is included in the package): 1 Prolevo Wedge, 1 Inflation Pump

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

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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 Prolevo Wedge is intended to prevent and treat heel pressure ulcers by offloading the heel.

The device consists of a medical-grade polyurethane (PU) wedge that is attached to the patient's bed. When positioned correctly, the patient's lower legs rest on the wedge while the heels extend beyond the end of the device, ensuring that the heels remain suspended in the air and free from contact with the mattress or bed surface.

This design redistributes the patient's weight away from the heel region and onto the calf, helping to reduce localised pressure and support pressure ulcer prevention and management.

The device is intended for use in clinical, care home, and home care environments.

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

Intended Use

The Prolevo Wedge is intended to assist in the prevention and management of heel pressure ulcers by offloading the heel and redistributing pressure away from the heel.

The device is attached to the patient's bed. When positioned correctly, the patient's lower legs rest on the wedge while the heels extend beyond the end of the device, ensuring that the heels remain suspended in the air and free from contact with the mattress or bed surface.

The device is intended for use as a positioning device for patients who are at risk of developing heel pressure ulcers or who require heel pressure offloading as part of pressure ulcer management, as determined by a healthcare professional.

The Prolevo Wedge 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 should be positioned between the mattress and bottom sheet of the patient's bed.

Indications

The Prolevo Wedge 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 ulcer prevention strategy.
- Patients who require heel elevation to prevent contact between the heel and the bed or mattress surface.
- 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 Prolevo Wedge in the following situations:

- The patient has **conditions where limb elevation is contraindicated**
- The patient has **unstable fractures or injuries in the lower limb or spine**
- The device causes **circulatory restriction or increased discomfort**

Clinical judgement should always be used when applying positioning devices.

Warnings

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

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Incorrect Positioning	Ineffective offloading, increased ulcer risk	Application should be performed by healthcare professionals or trained caregivers trained in pressure ulcer prevention. If the device is incorrectly positioned, heel offloading may be reduced, and the risk of pressure damage may increase.
⚠ **Warning**	Patient Repositioning	Increased Ulcer Risk	This device does not replace regular patient repositioning and should be used as part of a comprehensive care programme to treat and prevent pressure ulcers.
⚠ **Warning**	Skin Irritation	Patient Ulcer	Regularly inspect the patient's skin condition, particularly the calf and heel.
⚠ **Infection Control**	Cross-contamination, loss of performance	Infection transmission, foot ulcer	The device should be cleaned according to local infection control guidelines to prevent cross-contamination between users.
⚠ **Warning**	Pressure redistribution failure	Ineffective offloading, increased ulcer 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 ulcer risk	Do not cut, pierce, or modify the device, as this may affect safety, performance, and pressure offloading capability.
⚠ **Fire Hazard**	Fire	Fire, Patient ulcer	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 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 MHRA via the Yellow Card Scheme (UK) or the relevant competent authority in the EU Member State.

Precautions

- The device must be securely positioned and attached to the bed before use.
- Ensure the calf is supported by the wedge and the heel extends beyond the end of the device.
- 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 ulcers.
- 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 users.
- Inspect the device regularly for signs of wear, damage, or contamination, and discontinue use if the device no longer functions as intended.
- Patients with poor circulation, neuropathy, or fragile skin should be monitored closely.

Instructions for Use

Preparation

1. Inspect the device to ensure it is clean and undamaged.
2. Ensure the attachment method to the bed frame or mattress platform is secure.
3. Explain the procedure to the patient where appropriate.

Inflation

1. Inflate the product by inserting the pump through the blue inflation valve
2. Inflate the device until the material of the product is taught. Do not over inflate.
3. Seal the blue inflation valve and push valve into product.
4. Remove the cap from the exhaust valve (attached via the red mount)
5. Leave valve open for 30 seconds (it will automatically exhaust excessive air pressure)
6. Reconnect valve cap (red cap)

Application

1. Position the Prolevo Wedge on the bed and secure it as follows:
    - Ensure largest air cell is facing towards the end of the bed and the exhaust valves are pointing down as per instructions on the product.
    - Position the Prolevo Wedge to ensure the heels extend beyond the end of the wedge

- Fasten the straps under the bed frame or mattress to secure the device

2. Apply a bed sheet over the device prior to use ensuring the sheet conforms to the full shape of the wedge and bed.
3. Do not over tension bed sheet beyond the Prolevo Wedge
4. Gently place the patient's lower legs onto the wedge so the calves are supported.
5. Ensure the heels extend beyond the end of the wedge and remain suspended in the air.
6. Confirm that no part of the heel is contacting the mattress or bed surface.
7. Check that the patient is comfortable and properly aligned to the device.

During Use

- Regularly verify that the heels remain fully offloaded.
- Inspect the skin on the calf and heel at regular intervals.
- Reposition the patient in accordance with local pressure care protocols.

Inspection (Recommended Daily)

Check that:

- The polyurethane wedge retains its structural integrity
- There are no tears, cracks, or deformation
- The device maintains adequate support and positioning
- The device has been cleaned appropriately between users

Do not use it if damaged.

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
- Do not Use heat sterilisation methods that could damage the polyurethane material

NB - Depending on patient and continence status, more frequent cleaning or disinfection may be required in accordance with local infection control procedures.

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.

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