EN

Heel Elevators

Instructions for Use



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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: Heel Elevators

GMDN: 41575

Basic UDI-DI (if applicable): 50552043LLOFOFD

Packaging contents: 1 x Pair or Pack of 10 Heel Elevators

Manufacturer Details

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

Tel: +44 (0)1246 268 456 | talarmade.com | Email: info@talarmade.com

Device Description

Internal high density EVA heel raises with the following features:

- Self-adhesive backing
- Available in 6 depths (4mm, 6mm, 8mm, 10mm, 12mm and 15mm) and 3 sizes (Small, Medium and Large)
- Sold in pairs or packs of 10

Heel Elevators are intended for **single patient use only** and must not be shared between users

Intended Use

Heel Elevators are easy-to-use internal heel raises used to alter heel height as directed/recommended by a healthcare professional.

Target users are healthcare professionals and laypeople.

Indications

Heel Elevators are recommended for:

- Leg length correction
- Achilles tendinopathy
- Post operative Achilles rehabilitation
- Orthosis tuning

Contraindications

- N/A

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.

⚠ **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.
⚠ **Material Degradation**	Compression set or wear of raise 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
- Check inside the shoe for foreign objects before inserting or wearing the heel raise.
- Remove the heel raise from the shoe regularly to visually inspect it for damage, deformation, or trapped debris.
- If the heel raise becomes soiled or contaminated, clean it according to the manufacturer's instructions and allow it to dry fully before reuse.
- Ensure the heel raise is used only in footwear that fits properly and provides enough support, depth and width to avoid new pressure points.
- Make sure the heel raise lies flat and secure inside the shoe with no folding or edge lift.
- Perform daily foot checks, especially for users with diabetes or reduced

sensation.

- Replace the heel raise if it becomes worn, compressed or misshapen, as performance may be reduced.
- Do not modify or cut the heel raise 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**. Before Use**

Ensure the Heel Elevators correspond to the required mechanical dose, correct size and shape for the intended user.

2**. Insertion and Fit**

1. Place the Heel Elevator inside your shoe
2. Ensure a secure fit by pressing the lift firmly into place and using self-adhesive backing if required
3. Use in both shoes (if needed) to maintain balance and even weight distribution

Cleaning & Maintenance

If Heel Elevators become soiled or contaminated, wipe with a damp cloth using mild soap or a non-abrasive cleanser and allow to air dry before re-inserting into footwear.

Heel Elevators 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

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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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Tel: +44 (0)1246 268 456 | talarmade.com | Email: info@talarmade.com

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