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Gel Toe Care & Protection

Instructions for Use



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Gel Toe Care & Protection

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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: Gel Toe Care & Protection including:

Active Gel Bunion Pads, Active Gel Bunion Shield, Active Gel Corn Pads, Active Gel Corn Relief Pads, Active Gel Digital Cap, Active Gel Heel Sleeve, Active Gel Toe Crest, Active Gel Toe Separator, Active Gel Toe Shield, Active Gel Toe Spreader, Active Gel Tubing, Fabric Bunion Protector

GMDN: 61945

Basic UDI-DI (if applicable): 506012332LLOFOYG

Packaging contents (list what is included in the package): See Individual Product Information

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

The **TalarMade Gel Toe Care & Protection** range provides simple, effective solutions for relieving pressure, protecting vulnerable tissues and improving toe alignment.

Manufactured from soft medical-grade materials, many products can be worn comfortably inside everyday footwear, helping to reduce friction, pressure and irritation while supporting normal daily activities.

All available in various quantities and sizes.

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Intended Use

Product	Primary Function	Typical Clinical Applications
Active Gel Bunion Pads	Cushion and protect the first MTP joint	Hallux valgus, bunion pain, footwear irritation
Active Gel Bunion Shield	Protect the bunion while helping separate the hallux from the second toe	Hallux valgus, interdigital rubbing, bunion pain
Active Gel Corn Pads	Cushion and offload localised corns	Dorsal, plantar or digital corns caused by pressure or friction
Active Gel Corn Relief Pads	Offload pressure around painful corns	Painful corns, local pressure lesions
Active Gel Digital Cap	Protect the tip and entire circumference of a toe	Apical lesions, toe ulcers (where appropriate), corns, nail protection
Active Gel Heel Sleeve	Cushion and protect the heel	Heel fissures, pressure, friction, skin protection
Active Gel Toe Crest	Support the lesser toes and reduce digital clawing under load	Hammer toes, claw toes, apical pressure, forefoot discomfort
Active Gel Toe Separator	Separate adjacent toes to reduce friction	Interdigital corns, overlapping toes, mild hallux valgus
Active Gel Toe Shield	Cushion and protect an individual toe	Digital pressure, corns, friction and footwear irritation
Active Gel Toe Spreader	Maintain toe separation and improve alignment	Hallux valgus, overlapping toes, interdigital irritation
Active Gel Tubing	Cushion and protect the entire length of a toe or finger	Corns, digital pressure, friction and post-operative protection
Fabric Bunion Protector	Soft fabric protection over the bunion	Hallux valgus, footwear rubbing and daily comfort

Indications

The Talarmade Gel Toe Care & Protection range is indicated for a range of presentations. More information can be found on the detailed chart earlier in the IFU.

Contraindications

There are no known contraindications to the use of these products, but Talarmade would advise users to read through ‘Warnings’ and ‘Precautions before use.

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 of insole in 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.
⚠ **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
- Users should always wear hosiery when using device – especially if silicone allergy present
- Check inside the shoe for foreign objects before inserting a toe care product.
- Regularly visually inspect products for damage, deformation, or trapped debris.
- If the product becomes soiled or contaminated, clean it according to the

manufacturer's instructions and allow it to dry fully before reuse.

- Ensure the product is used only in footwear that fits properly and provides enough support, depth and width to avoid new pressure points.
- Perform daily foot checks, especially for users with diabetes or reduced sensation.
- Replace the product if it becomes worn, compressed, cracked, or misshapen, as performance may be reduced.
- Do not modify, cut, or heat-mold the product 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

1. Inspect the product for visible damage, deformation, cracks, or contamination.
2. Check inside the shoe for foreign objects or irregularities
3. Ensure footwear provides adequate depth and width to avoid new pressure points.

2. Insertion and Fit

1. Gently place the gel toe device between or around the affected toe(s), ensuring it is correctly positioned.
2. Check that the device sits securely and comfortably in place without slipping or causing discomfort.
3. Confirm that the toes remain in a comfortable, natural position and that the device does not cause rubbing or excessive pressure during use.

Stop using it and seek clinical advice if:

- Redness, blistering, hot spots, callus buildup, or open wounds occur
- Discomfort, pain, or instability is experienced

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Cleaning & Maintenance

- Wipe with a damp cloth using mild soap or a non-abrasive cleanser.
- Allow to air-dry completely away from direct heat sources.
- Do not machine wash, machine dry, bleach, or expose to extreme heat.

All products within the Talarmade Gel Toe Care & Protection range 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

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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