EN

DiabetiX

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.

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Product Details

Product Name: DiabetiX

GMDN: 41575

Packaging Contents: 1 Pair DiabetiX insoles

Manufacturer Details

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

- Prefabricated injection moulded 2-layer foot orthosis
- DX-1 Top Cover with injection moulded PU base
- Reduces plantar foot pressures and shear
- This device is intended for **single-patient use only** and must not be shared between users

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Item No.	Item Description
TM-DX/EU34/PR	TalarMade DiabetiX EU Size 34-35 Pair
TM-DX/EU36/PR	TalarMade DiabetiX EU Size 36-37 Pair
TM-DX/EU38/PR	TalarMade DiabetiX EU Size 38-39 Pair
TM-DX/EU40/PR	TalarMade DiabetiX EU Size 40-41 Pair
TM-DX/EU42/PR	TalarMade DiabetiX EU Size 42-43 Pair
TM-DX/EU44/PR	TalarMade DiabetiX EU Size 44-45 Pair
TM-DX/EU46/PR	TalarMade DiabetiX EU Size 46-47 Pair
TM-DX/EU48/PR	TalarMade DiabetiX EU Size 48-49 Pair
TM-DX/EU50/PR	TalarMade DiabetiX EU Size 50-51 Pair

Intended Use

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DiabetiX is a **prefabricated orthotic insole** intended to **reduce plantar foot pressures and shear forces** during weight-bearing activities.

The device functions by redistributing mechanical loads at the foot–ground interface through its engineered geometry and material properties.

Target users are healthcare professionals and adult laypeople. DiabetiX insoles should be worn in appropriate footwear as described in the instructions for use.

Indications

Adults who require reduction of plantar pressure and shear forces for medical purposes including individuals with

- Diabetes
- Peripheral Neuropathy
- Fat Pad Atrophy
- Painful plantar soft-tissue conditions aggravated by mechanical stress
- Inflammatory Arthropathies
- Aching Feet

Contraindications

- Plantar foot deformity
- Charcot Arthropathy
- Active plantar ulceration
- Patients unwilling or unable to wears socks or hosiery
- Patients unwilling or unable to wear appropriate footwear

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Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
Warning	Excess local pressure or shear due to improper fit	Skin irritation, blistering, callus, ulceration	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 offloading, 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.
Do Not Heat	Heating or exposure to extreme heat	Fire, loss of mechanical performance	Do not modify the device unless explicitly instructed by a qualified clinician.
Check footwear interior	Objects or seams in footwear causing pressure hot-spots	Skin damage leading to ulceration	Check shoes daily for foreign objects, rough seams, or debris.
Keep dry / moisture hazard	Use of wet or contaminated insole	Skin maceration, microbial growth, reduced device performance	Ensure device is dry before use.
Gradual wear-in required	Abrupt full-time use	Skin stress due to sudden biomechanical change	Increase usage gradually over several days, monitoring skin condition.
Material degradation	Compression set or wear of insole 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.
Not for Standalone Ulcer Treatment	Reliance on insole without clinical care	Failure to heal, worsening wound	The insole is not a substitute for medical management of active ulcers or severe diabetic foot disease.
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).

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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
- Check **inside the shoe for foreign objects** before inserting or wearing the insole.
- **Remove the insole from the shoe** regularly to visually inspect it for damage, deformation, or trapped debris.
- If the insole becomes **soiled or contaminated**, clean it according to the manufacturer's instructions and allow it to dry fully before reuse.
- Ensure the insole is used **only in footwear that fits properly** and provides enough depth and width to avoid new pressure points.
- Make sure the insole lies **flat and secure** inside the shoe with no folding or edge lift.
- **Gradually increase wear time** when first using the insole to monitor comfort and skin response.
- Perform **daily foot checks**, especially for users with diabetes or reduced sensation.
- Replace the insole if it becomes **worn, compressed, cracked, or misshapen**, as performance may be reduced.
- Do not modify, cut, or heat-mold the insole unless instructed by a healthcare professional.
- Use the insole **only as part of a clinician-guided foot care plan** if you have active ulcers, severe deformity, or high-risk diabetic foot conditions.
- Be cautious if you have **balance or mobility issues**, as changes to footwear may alter gait

Instructions for Use

1. Purpose of the Device

DiabetiX is a prefabricated insole designed to **reduce plantar pressure and shear forces** for patients requiring mechanical offloading, including people with diabetes who are at risk of foot ulceration or re-ulceration.

2. Before Use

- Ensure the insole corresponds to the **correct size and shape** for the intended user.
- Inspect the insole for **visible damage, deformation, cracks, or contamination**.
- **Check inside the shoe for foreign objects** or irregularities before inserting the insole.
- Ensure footwear provides **adequate depth and width** to avoid new pressure points.

- Footwear should be deep enough to accommodate the insole

3. Insertion and Fit

1. Remove existing insoles from the footwear unless otherwise advised.
2. Place DiabetiX **flat inside the shoe**, ensuring full contact with the shoe base.
3. Trim front of insole if required to improve fit
4. Check that the edges lie smoothly without lifting or folding.
5. Confirm that the foot sits comfortably without pressure or rubbing.

4. Wearing Instructions

- Start with **1–2 hours of wear** and increase gradually as tolerated.
- Perform **daily foot checks** for any signs of irritation or pressure marks.
- Use DiabetiX only with **supportive, closed footwear** recommended by your clinician.
- Avoid high-impact activities unless approved by a healthcare professional.

5. Removal and Inspection

- Remove the insole **daily** to inspect the top and bottom surfaces for:
    - wear, cracking, compression, or deformation
    - trapped debris or foreign objects
- Inspect the inside of the shoe for **stones, seams, or debris** that may create pressure.

6. When to Stop Using the Device

Stop using it and seek clinical advice if:

- redness, blistering, hot spots, callus buildup, or open wounds occur
- discomfort, pain, or instability is experienced
- the insole becomes worn, cracked, or unstable
- new pressure areas develop

Cleaning & Maintenance

If DiabetiX becomes **soiled or contaminated**, clean it according to the following procedure:

- Wipe with a **damp cloth** using mild soap or a non-abrasive cleanser.
- Rinse lightly if needed; do not saturate the insole.
- Allow to **air-dry completely** away from direct heat sources.
- Do **not** machine wash, machine dry, bleach, or expose to extreme heat.

- Inspect regularly and **replace the insole** if it shows signs of structural breakdown such as:

    - cracking
    - loss of cushioning or shape

The insole should be replaced after 12 months of regular use, even if no visible damage is present, to ensure continued performance.

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Storage Conditions

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