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TM OA Knee Brace

Instructions for Use



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TM OA Knee Brace

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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: TM OA Knee Brace

GMDN: 41065 – Knee support orthosis

BASIC UDI-DI (if applicable): 50552043LLOKOFU

Packaging contents (list what is included in the package): 1 x TM OA Knee Brace, Flexion and Extension Stop Kit and Wrench

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

The TM OA Knee Brace is a functional OA knee orthosis that offloads the medial or lateral compartment for patients experiencing mild to moderate osteoarthritis of the knee.

- 3-Point leverage mechanism offloads the affected medial or lateral compartment
- Low profile single upright design
- Return-pull, adjustable touch-and-close straps to customise fit
- Easy-to-use quick release snap fastenings
- Precision unloading lock and crank mechanism
- 4-point numbered strapping system ensures proper application

- Available in left or right - universal design makes brace suitable for medial or lateral offloading
- This device is intended for **single patient use only** and not designed for multi users

Intended Use

The TM OA Knee Brace is a functional OA knee orthosis that offloads the medial or lateral compartment for patients experiencing mild to moderate osteoarthritis of the knee.

Target users are healthcare professionals and laypeople, both in hospital/healthcare environments and at home.

The TM OA Knee Brace should be worn/used under the guidance of a healthcare professional and as outlined in the instructions for use.

Indications

The TM OA Knee Brace can be used in situations such as:

- Mild to moderate uni-compartmental knee osteoarthritis
- Degenerative meniscal tears
- Osteochondral defects
- Articular cartilage defects and repairs

Contraindications

The TM OA Knee Brace should not be used in the following situations:

- When compression is contraindicated
- In the presence of open wounds
- In presence of any known allergy and/or hypersensitivity to any material listed in the product composition
- Fixed gross varus or valgus knee deformities
- Caution should be used if prescribed to patients with diabetes, vascular deficiency and neuropathy

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Excess local pressure or friction due to	Skin irritation, blistering, ulceration	Ensure correct application Discontinue use if redness, irritation, or skin breakdown re-
	improper fit		occurs and seek professional advice
⚠ **Follow instructions for use**	User misapplication	Ineffective function, increased injury risk or skin breakdown	Read the IFU thoroughly before first use. Only use as directed by a healthcare professional.
⚠ **Consult a Healthcare Professional**	Device irritating leg or knee	Skin breakdown injury	Do not use if active ulcer or wound present
⚠ **Warning**	Worn when wet	Skin irritation, blistering or persistent and undue redness	Ensure device is dry after laundering before continuing use
⚠ **Warning**	Odour, contaminated with body fluids	Infection, cross contamination	Ensure device is laundered frequently to maintain its conformability, hygiene and comfort

Precautions

- This device is for **single patient use only**. Re-use by another individual may increase the risk of cross-contamination, improper fit, or compromised device performance
- If the device becomes **soiled or contaminated**, clean it according to the manufacturer's instructions and allow it to dry fully before re-use

Instructions for Use

Preparation

- Remove packaging
- Inspect brace, making sure all parts are intact and without damage

Application

1. Align the brace on the centre of the side of the impacted knee and insert the first strap through the D-ring and tighten. If there is too much excess strap material, refer to strap adjusting options below.
2. Insert the second strap through the D-Ring and tighten. If there is too much excess strap material, refer to strap adjusting options below.
3. Insert the third strap through the D-Ring and tighten. If there is too much excess strap material, refer to strap adjusting options below.
4. Insert the fourth strap through the D-Ring and tighten. If there is too much excess strap material, refer to strap adjusting options below.
5. Once all straps are secured and tight, use the wrench that came with the product to turn the dial CCW (counterclockwise). Make small ¼ inch turns and walk to check relief. Repeat this step until the desired amount of unload is achieved.
6. Following the initial fitting the device, quick release snaps can be used for easy removal and subsequent applications

Strap Adjustment Options

Option 1

1. Following the initial fitting, if any of the straps were too long, place the brace on a table
2. Identify the straps that were initially too long
3. On the inside of the brace, you can adjust the length of the strap
4. Adjust the strap length by pulling the strap toward the middle

Option 2

1. There are numbered tabs at the ends of the straps. Detach the tab from the straps that are too long
2. The extra strap that is not needed can be cut off
3. Reattach the numbered tab to the cut strap

Removal

1. Release quick release snaps
2. Remove TM OA Knee Brace from leg
    - Inspect skin, checking for any signs of irritation, redness, or pressure marks.

During Use

- Wearing schedule - Follow the duration and daily wear time recommended by your healthcare professional or medical care plan
- Monitoring - Periodically check skin condition and comfort.

Cleaning & Maintenance

Cleaning

- To best maintain the brace's quality, wash it by hand with mild soap and warm water
- Do not use bleach, solvents, or abrasive cleaners.
- Allow all components to air-dry completely before reassembly.

Maintenance

- Inspect regularly for damage, worn/frayed straps or compressed padding

Storage Conditions

- Store in a cool clean dry place and away from direct sunlight to prevent discolouration

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.

TalarMade Ltd. Edinburgh House, Millennium Way, Chesterfield, Derbyshire, S41 8ND
Tel: +44 (0)1246 268 456 | talarmade.com | Email: info@talarmade.com

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