EN

Lumbar Supports

Instructions for Use



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CONTENTS

1. **Product Details**
2. **Manufacturer Details**
3. **Device Description**
4. **Intended Use**
5. **Indications**
6. **Contraindications**
7. **Warnings**
8. **Precautions**
9. **Instructions for Use**
10. **Cleaning & Maintenance**
11. **Storage Conditions**
12. **Disposal Instructions**
13. **Regulatory Compliance**
14. **Warranty Information**
15. **Contact Information**
16. **Date of Issue and Version**

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: Lumbar Supports

GMDN: 66086 – Multiple spinal region orthosis

BASIC UDI-DI (if applicable): 50552043SOLSOK7

Packaging contents (list what is included in the package): 1 x Lumbar Support

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

- High quality, ventilated elastic lumbar support with fully bound edges
- Four strong, non-removable flexible stays
- Simple, anterior, touch-and-close fastening
- Dual, rear elasticated fulcrums provide additional compression and support to stabilise the spine

- Available in 6 sizes (Small, Medium, Large, X-Large, XX-Large and XXX-Large)
- Available in 2 heights – 23cm and 28cm

Intended Use

The Lumbar Support is intended to provide adjustable external support and compression to the lumbar spine.

Target users are healthcare professionals and laypeople, both in hospital/healthcare

environments and at home.

The Lumbar Support should be worn/used under the guidance of a healthcare professional and as outlined in the instructions for use.

Indications

The Lumbar Support is indicated for use in the following situations:

- Lower back muscular injury
- Sciatica
- Osteoporosis
- Prolapsed intervertebral disc
- Sacro-lumbar pain

Contraindications

- **Unstable or untreated conditions:**
    - Do not use in the presence of untreated or unstable abdominal conditions (e.g., suspected internal bleeding, or severe uncontrolled pain).
- **Compromised skin integrity:**
    - Open wounds, active skin infections, severe dermatitis, or ulceration in the area of application, unless the lumbar support is specifically prescribed with appropriate wound dressings in place.
- **Severe cardiopulmonary compromise:**
    - Conditions where increased intra-abdominal pressure or restricted chest expansion may worsen breathing or circulation (e.g., severe COPD, advanced heart failure), unless explicitly approved by a health care professional.
- **Known material hypersensitivity:**
    - Known allergy or hypersensitivity to any component materials of the lumbar support (e.g., elastic fibres, foam, touch-and-close).

- **Incompatibility with other devices or therapies:**
    - Situations where the lumbar support would interfere with essential medical devices (e.g., certain abdominal drains, stomas, or monitoring equipment) unless specifically adapted and approved by a clinician.

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Application Over Open Wounds	Delayed Healing or Infection	Do not use over open wounds without appropriate dressings and medical supervision.
⚠ **Warning**	Incorrect Application/Sizing (Both too large or too small)	Ineffective function/impaired breathing or circulation	Application should be performed by healthcare professionals or trained caregivers. If the device is incorrectly fitted, incorrectly sized or positioned, function may be reduced, and the risk of pressure related issues may increase.
⚠ **Warning**	Skin Monitoring	Patient Injury	The patient's skin must be inspected regularly for signs of redness or irritation. If irritation or skin damage occurs, discontinue use and consult a healthcare professional.
⚠ **Infection Control**	Cross-contamination, loss of performance	Infection transmission	The device is intended for single patient use only. The device may be cleaned during use according to the cleaning instructions provided.
⚠ **Do Not Modify**	Device Condition	Ineffective function, increased injury risk	Do not cut, pierce, or modify the device, as this may affect safety, performance, and function.
⚠ **Fire Hazard**	Fire	Fire, Patient injury	Keep the device away from open flames, lit cigarettes, or other sources of ignition.
⚠ **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

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
- The device should be worn as instructed by the prescriber

Instructions for Use

Preparation Before Use

1. **Unpack the device:**
    - Remove the lumbar support from its packaging.
    - Retain packaging and instructions for future reference.
2. **Inspect the binder:**
    - **Check integrity:** Ensure there are no tears, holes, or damaged seams.
    - **Check fastening:** Confirm the hook-and-loop closure is clean and functional.
    - Do not use if damaged.
3. **Prepare the patient:**
    - Ensure the abdomen and surrounding skin are clean and dry.
    - If recommended, place a thin undergarment or liner between the skin and lumbar support.

Application Procedure

1. **Positioning:**
    - Wrap the lumbar support around the patient's lower back – ensuring that flexible stays are equidistant apart from either side of the spine
2. **Initial fastening:**
    - Overlap the ends of the lumbar support at the front and attach using the touch-and-close fastening.
    - For additional support and compression, pull the fulcrum straps and attach at the front in a similar fashion to before
    - The patient should be able to breathe comfortably and move without excessive restriction.
3. **Final checks:**
    - Confirm the lumbar support is smooth, without folds or creases that could cause pressure points.
    - Check that the lumbar support does not ride up or cut into the ribs, hips,

or groin.

Removal

1. Release touch-and-close straps
2. Unwrap the lumbar support
3. Inspect skin - Check for any signs of irritation, redness, or pressure marks.

During Use

- Wearing schedule
    - Follow the duration and daily wear time recommended by the healthcare professional.
- Monitoring:
    - Periodically check skin condition and comfort.
    - Adjust tension as needed throughout the day (e.g., when changing position from lying to standing).

Cleaning & Maintenance

- **Cleaning method:**
    - Hand wash using mild detergent.
    - Use lukewarm water (e.g., up to 30–40°C) unless otherwise specified on the product label.
    - Ensure hook-and-loop closures are fastened before washing to prevent damage.
- **Agents to avoid:**
    - Do not use bleach, harsh chemicals, or fabric softeners.
    - Do not dry clean.
- **Drying:**
    - Gently squeeze out excess water—do not wring.
    - Air dry flat or hang in a well-ventilated area away from direct heat sources (radiators, tumble dryers) and direct sunlight.

Storage Conditions

- Store in a cool, dry place away from direct sunlight.
- Keep away from moisture, dust, and contaminants.

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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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