EN

3 Panel Maternity Support

Instructions for Use



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3 Panel Maternity Support

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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.

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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: 3 Panel Maternity Support

GMDN: 66086 - Multiple spinal region orthosis

UDI-DI (if applicable): 50552043SOLSOK7

Packaging contents (list what is included in the package): 1 x 3 Panel Maternity Support

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

- Soft maternity support offering variable pelvic and lower back relief
- Touch-and-close fastening
- Available in 8 sizes (XX-Small to XXX-Large)

Intended Use

The 3-Panel Maternity Support is intended to provide relief from diagnosed antenatal or postnatal back pain.

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

The 3-Panel Maternity Support should be worn/used under the guidance of a

healthcare professional and as outlined in the instructions for use.

Indications

- Antenatal or postnatal back pain
- Sacroiliac support
- Fatigue

Contraindications

- Must not be used by individuals for whom compression is contraindicated
- Do not use on open wounds
- Any known allergy and/or hypersensitivity to any material listed in the product composition
- Caution should be used if prescribed to patients with diabetes, vascular deficiency and neuropathy

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 offloading, 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

- Unpack the device:
  - Remove the 3-Panel Maternity Support from its packaging.
- Inspect the support:
  - Check integrity: Ensure there are no tears, holes, or damaged seams.
  - Check fastening: Confirm the touch-and-close fastening is clean and functional.
  - Do not use if damaged.
- Prepare the patient:
  - Ensure the skin is clean and dry if applying directly to patient's body

- If recommended, place a thin undergarment or liner between the skin and support.

Application

- Open all touch-and-close fastenings
- Place the square section of the support on the lower back ensuring that the Talarmade logo is on the top strap
- Fasten the lowest set of straps under the bump first, then fasten the middle and upper straps in corresponding order to achieve adequate level of support
- Do not over tighten the straps

Final checks:

- Confirm the support is smooth, without folds or creases that could cause pressure points.
- Check that the support does not ride up or cut into the ribs, hips, or groin.

Removal

1. Release the touch-and-close straps
2. Remove the 3-Panel Maternity 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 on touch-and-close straps 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 touch-and-close 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
  - 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.

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.

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