EN

Elastic Thumb Spica

Instructions for Use



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Elastic Thumb Spica

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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: Elastic Thumb Spica

GMDN: 41044

BASIC UDI-DI (if applicable): 506012332ULOWHO74

Packaging contents: Individual or Pack of 6 Elastic Thumb Spica/s

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

- Simple thumb spica made from woven elastic material
- Wrap around design with touch-and-close fastenings
- Bound edges for durability
- Removable, anatomically formed thumb stay individually mouldable for a custom fit
- Available in 4 sizes (Small, Medium, Large and X-Large), Left or Right
- Available singly or in packs of 6

Intended Use

The Elastic Thumb Spica is intended for those who require stabilisation/restriction of the CMC and MCP joint.

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

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

Indications

The Elastic Thumb Spica is indicated for use in the following situations:

- Thumb injury requiring immobilisation
- CMC ligament sprains and strains
- R/A or O/A affecting the thumb
- Stable fracture management requiring partial immobilisation of the thumb

Contraindications

- Not designed to be used for complete immobilisation
- 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	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
- Inspect the device integrity before use
- Remove brace and cease use if the brace causes pain, redness or skin breakdown

Instructions for Use

Preparation

- Select correct size by measuring wrist circumference

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

Application

- With all touch-and-close straps unfastened apply hand to Elastic Thumb Spica to ascertain appropriateness of fit
- Removable aluminium thumb stay can be removed and bent to desired position at this stage
- Fasten touch-and-close lay over straps. Strap tension should be firm but not uncomfortable

Removal

1. Release the touch-and-close straps
2. Remove Elastic Thumb Spica from wrist
3. 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.
    - Adjust positioning/shaping of brace as needed

Cleaning & Maintenance

- Remove the aluminium thumb stay and set aside
- Close over all touch-and-close straps
- Woven elastic material can be hand washed in cool water with mild detergent
- Do not use bleach or chlorine-based cleaning products
- Not for use in washing machine or tumble dryer
- Brace should be laid flat and left to dry naturally before re-applying the thumb stay in the same position it was removed

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Storage Conditions

- Store in a cool clean dry place and away from direct sunlight to prevent discolouration
- Do not store in a folded or bent position and refrain from placing heavy objects on top

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

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