EN

Deluxe Arm Sling

Instructions for Use



TalarMade
Made with clinical excellence in mind

eIFU MD CE UK CA

TalarMade
Made with clinical excellence in mind

Deluxe Arm Sling

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: Deluxe Arm Sling

GMDN: 67638 – Shoulder immobilizer/orthosis, reusable

BASIC UDI-DI (if applicable): 50552043ULOSEWHO4Z

Packaging contents): 1 x Deluxe Arm Sling

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

- Simple arm sling made from breathable, lightweight polyester cotton
- Soft padded plush foam straps
- Easy touch-and-close fastenings
- Thumb loop and full circumferential waist strap
- Height and length adjustable

- Available in 4 sizes (Small, Medium, Large and X-Large)
- Sold singly

Intended Use

The Deluxe Arm Sling is designed to provide immobilisation of the arm/elbow/shoulder.

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

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

Indications

The Deluxe Arm Sling is indicated for use in the following situations:

- Immobilisation of the forearm, elbow and arm
- Post upper limb trauma/surgery
- Weakness /injury to the shoulder capsule
- Paralysis of the arm

Contraindications

The Deluxe Arm Sling should not be used:

- For treatment of individuals with severe fixed deformity
- Over open wounds that may come into contact with the device

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	Ineffective function	Application should be performed by healthcare professionals or trained caregivers. If the device is incorrectly fitted 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,	Do not cut, pierce, or modify the device, as this may affect safety,

		increased injury risk	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

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

Application

1. Wrap the attached strap around your abdomen with the closed end of the sling closest to the affected arm.
2. Thread the end of the attached strap though the ring on the bottom section of the sling and fasten to itself using the Velcro tab.
3. Take the detached second strap. Thread the smallest end (furthest from the padded section) through the ring above the closed end of the sling (elbow section), fold back and attach to itself using the Velcro tab.
4. Place affected arm into the sling with elbow at the closed end, and the thumb through the thumb loop.
5. Take the padded end of the 2nd strap and wrap around the back of the neck. Thread through the two rings closest to the wrist and secure to itself using the Velcro tabs.

Removal

1. Release shoulder and abdomen strap
2. Remove Deluxe Arm Sling
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 of brace as needed

Cleaning & Maintenance

- Close touch-and-close straps
- Deluxe Arm Sling 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 left to dry naturally before re-applying

Storage Conditions

- Store in a cool clean dry place and away from direct sunlight or heat to prevent discolouration or deformation
- Do not place any objects on top of the device

Disposal Instructions

Dispose of the device and its packaging in accordance with applicable local, regional, or national regulations.

TalarMade™
Made with clinical excellence in mind

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

Date of Issue and Version

Issue 1 | March-2026