EN

Protect Mitts

Instructions for Use



TalarMade
Made with clinical excellence in mind

eIFU MD CE UK CA

PROtect Mitts

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: PROtect Mitts

GMDN: 16210 - Hand/finger splint, single-use

BASIC UDI-DI (if applicable): 50552043ULOHOJN

Packaging contents (list what is included in the package): Sold in Pairs or Boxes of 10 Pairs

Products In this Range:

- PROtect Coolmesh Finger Control Mitt
- PROtect Coolmesh Mitt
- PROtect Double Padded Mitt
- PROtect Peep Mitt
- Optional Retaining Straps

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

PROtect Peep Mitts – PTPM/U

The PROtect Peep Mitt is a double-padded patient safeguard mitt designed to help reduce the risk of patients scratching, picking, or interfering with medical treatment devices. The mitt incorporates an inspection flap to allow easy access for routine hand and finger inspection whilst the mitt remains in place.

Product Features

- Double padded construction
- Hook and loop wrist closure
- Inspection flap at fingertip area
- Fits either hand

- One size fits most adults
- Machine washable

PROtect Double Padded Mitts – PTDPM/U

The PROtect Double Padded Mitt is a fully enclosed, double-padded patient safeguard mitt intended to reduce the ability of patients to scratch themselves or interfere with medical devices and dressings.

Product Features

- Double padded construction
- Hook and loop wrist closure
- Fits either hand
- One size fits most adults
- Machine washable

PROtect Coolmesh Mitts – PTCM/U

The PROtect Coolmesh Mitt is a breathable mesh-backed patient safeguard mitt designed to improve airflow around the hand whilst helping reduce scratching and interference with treatment devices.

Product Features

- Breathable mesh-backed construction
- Hook and loop wrist closure
- Fits either hand
- One size fits most adults
- Machine washable

PROtect Coolmesh Finger Control Mitts – PTCFCM/U

The PROtect Coolmesh Finger Control Mitt incorporates internal finger separators to assist in reducing finger dexterity and control whilst maintaining airflow through a breathable mesh-backed design.

Product Features

- Breathable mesh-backed construction
- Internal finger separators

- Hook and loop wrist closure
- Fits either hand
- One size fits most adults
- Machine washable

Optional Retaining Straps

The PROtect retaining straps can be used with all TalarMade Protect Mitts to secure the MITT and patients limb to the bed frame in accordance with local restraint and safeguarding policies.

Intended Use

The PROtect Mitts range is intended to help reduce the risk of patients scratching, picking, pulling, or interfering with medical treatment devices, dressings, wounds, or skin conditions whilst allowing supervised clinical management.

Indications

The PROtect Mitts range may be suitable for:

- Patients considered to be at risk of line pulling or disrupting lifesaving treatment via tube pulling
- Patients with skin conditions where scratching, picking, or peeling may exacerbate the condition
- Patients whose scratching could cause self-harm or compromise wound integrity
- Psychiatric patients for whom temporary limitation of hand movement may be beneficial for safety purposes
- Post hand surgery patients requiring cushioned hand protection

Contraindications

DO NOT USE:

- If the patient's IV site, wound site, or medical device could be compromised by the mitt
- If the affected limb is fractured or dislocated

- On highly aggressive, severely agitated, or suicidal patients
- Without regular clinical monitoring
- As a substitute for appropriate patient supervision and safeguarding procedures

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Excess local pressure or friction due to improper fit i.e. too loose	Skin irritation, blistering, callus, ulceration	Ensure correct application Discontinue use if redness, irritation, or skin breakdown re-occurs and seek professional advice
⚠ **Follow instructions for use**	User misapplication	Ineffective immobilisation, 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 hand, wrist or fingers	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

- Use only under the direction of an appropriately trained healthcare professional.
- The patient should be regularly monitored whilst wearing the mitts.
- If the applied device severely limits movement or causes discomfort, emotional distress, agitation, or behavioural deterioration, discontinue use and reassess suitability.
- Ensure mitts are properly secured. Mitts fitted too tightly may compromise circulation; mitts fitted too loosely may be ineffective.
- Check skin condition regularly for signs of pressure damage, irritation, redness, swelling, or impaired circulation.
- Ensure mitts are not torn, damaged, or excessively worn before use.
- Ensure the patient cannot remove the mitt using their teeth.

- Do not allow patients to ingest mitt materials or components.
- Patients wearing mitts whilst mobilising may be at increased risk of falls and should be appropriately supervised.
- Retaining straps, where used, should only be attached to suitable fixed areas of the bed frame in accordance with local restraint and safeguarding policies.

This device is intended as an aid to patient protection and does not eliminate the need for clinical supervision.

Instructions for Use

PROtect Peep Mitts

1. Place the patient's hand into the mitt with the palm facing downwards.
2. Ensure the inspection flap is positioned on the dorsal surface of the hand.
3. Secure the wrist strap around the narrowest part of the wrist.
4. Pass the strap through the plastic ring and fasten securely using the hook and loop closure.
5. Ensure one finger can be comfortably inserted between the strap and the patient's wrist.

To Access Fingers and Hand

1. Open the inspection flap by separating the hook and loop closure.
2. Lift the flap to expose the fingers and hand for inspection or monitoring.
3. Re-secure the flap following inspection.

PROtect Double Padded Mitts

1. Place the patient's hand into the mitt with the palm facing downwards.
2. Secure the wrist strap around the narrowest part of the wrist.
3. Pass the strap through the plastic ring and fasten using the hook and loop closure.
4. Ensure one finger can be comfortably inserted between the strap and the wrist.

PROtect Coolmesh Mitts / Coolmesh Finger Control Mitts

1. Place the patient's hand into the mitt with the mesh surface positioned on the dorsal surface of the hand.

2. Secure the wrist strap around the narrowest part of the wrist.
3. Pass the strap through the plastic ring and fasten securely.
4. Ensure one finger can be comfortably inserted between the strap and the patient's wrist.

Retaining Straps (Optional)

1. Place the restraining strap through the loop in the tongue of the product.
2. Fasten around bed frame or static device as determined by organisation safeguarding and restraint protocols
3. Monitor patient frequently

Cleaning & Maintenance

- Machine washable.
- Wash at temperatures up to 70°C for a minimum of 25 minutes where local infection control policies require.
- Suitable bleach solutions may be used in accordance with manufacturer guidance.
- Tumble dry on a low heat setting.
- Inspect the product after cleaning and before reuse.
- Do not use if damaged, excessively worn, or if fastening systems are compromised.

Storage Conditions

- Store in a **cool, dry place**, protected from direct sunlight and heat

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

Date of Issue and Version

Issue 1 | Oct-2025