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Adjustable Depth Rigid Collar

Instructions for Use



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Adjustable Depth Rigid Collar

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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.

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: Adjustable Depth Rigid Collar

GMDN: 45129 – Cervical spine collar.

BASIC UDI-DI (if applicable): 506012332SOCO4E

Packaging contents (list what is included in the package): 1 x Adjustable Depth Rigid Collar

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

- A two-part ventilated polyethylene collar with leather covered padded sections
- Height adjustable to allow for individualized fit
- Simple touch-and-close fastening
- Available in 3 different sizes based upon height and circumference (Small, Medium, Large)
- Intended to offer support and control while maintaining comfort to the cervical spine

Intended Use

The Adjustable Depth Rigid Collar is intended to provide customisable support and relief of neck pain.

Target users are healthcare professionals and trained/instructed laypeople.

The Adjustable Depth Rigid Collar is intended for use in healthcare environments such

as hospitals, care homes, and in home care settings/patient's homes. It may be applied by healthcare professionals or trained caregivers.

Indications

The Adjustable Depth Rigid Collar is indicated for use in the following conditions:

- Cervical strain or sprain
- Cervical spondylosis or spondylitis
- Rheumatoid conditions affecting the cervical spine
- Osteoarthritis of the cervical spine
- General neck pain requiring mild support
- Postural support during recovery from minor injury

Contraindications

Do NOT use the Adjustable Depth Rigid Collar in the following situations:

- Unstable cervical spine injuries or suspected fractures (Unless told otherwise by Spinal Specialist)
- Conditions requiring rigid immobilisation
- Open wounds, skin infections, or dermatological conditions in the neck area
- Known allergies to any of the materials used
- When advised against use by a healthcare professional

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Use against indications for use (i.e. for unstable cervical fracture)	Inadequate immobilisation, neurology injury, delayed or improper healing	This Adjustable Depth Rigid Collar provides mild support only and is not intended for emergency or trauma use.
⚠ **Warning**	Overuse/Use Against Medical Advice	Possible muscle weakening	Prolonged use without medical supervision MAY lead to muscle weakening – follow wear and care advice provided by healthcare professional.

⚠ **Warning**	Incorrect Application/Sizing	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
- Only trained Health Care Professionals or individuals instructed by a clinician should apply the brace
- Inspect the device before each use for signs of wear, damaged fastening or deformed foam
- Ensure correct sizing; improper fit reduces effectiveness.
- Check the device regularly during use to ensure it remains correctly positioned and securely fastened.
- Maintain good hygiene to prevent skin irritation
- Avoid exposure to excessive heat, which may deform the foam

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Instructions for Use

Preparation

1. Remove the device from packaging.
2. Inspect for any visible damage or defects.
3. Ensure correct size selection.

Application

1. Place the collar around the neck.
2. Position so that the chin rests comfortably on the collar.
3. Wrap the collar evenly around the neck, adjusting height using touch-and-close fastening as needed
4. Secure using the touch-and-close fastening at the back
5. Adjust for a snug but comfortable fit:
    - Ensure support without excessive tightness
    - Confirm normal breathing and swallowing

Removal

1. Gently unfasten the closure
2. Remove the collar carefully from the neck

During Use

- Wear as directed by a healthcare professional
- Periodically check skin condition

Post-Use

- Clean if required (see Cleaning & Maintenance)
- Store appropriately

Cleaning & Maintenance

Cleaning

- Hand wash using warm water and mild detergent
- Do not machine wash or tumble dry
- Rinse thoroughly to remove detergent residues
- Air dry only (away from direct heat sources)

Maintenance

- Check regularly for:
  - Fabric wear
  - Loss of foam shape
  - Fastening effectiveness

Storage Conditions

- Store in a cool, dry environment away from direct sunlight
- Avoid excessive moisture or humidity
- Do not store under heavy objects (to prevent deformation)

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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