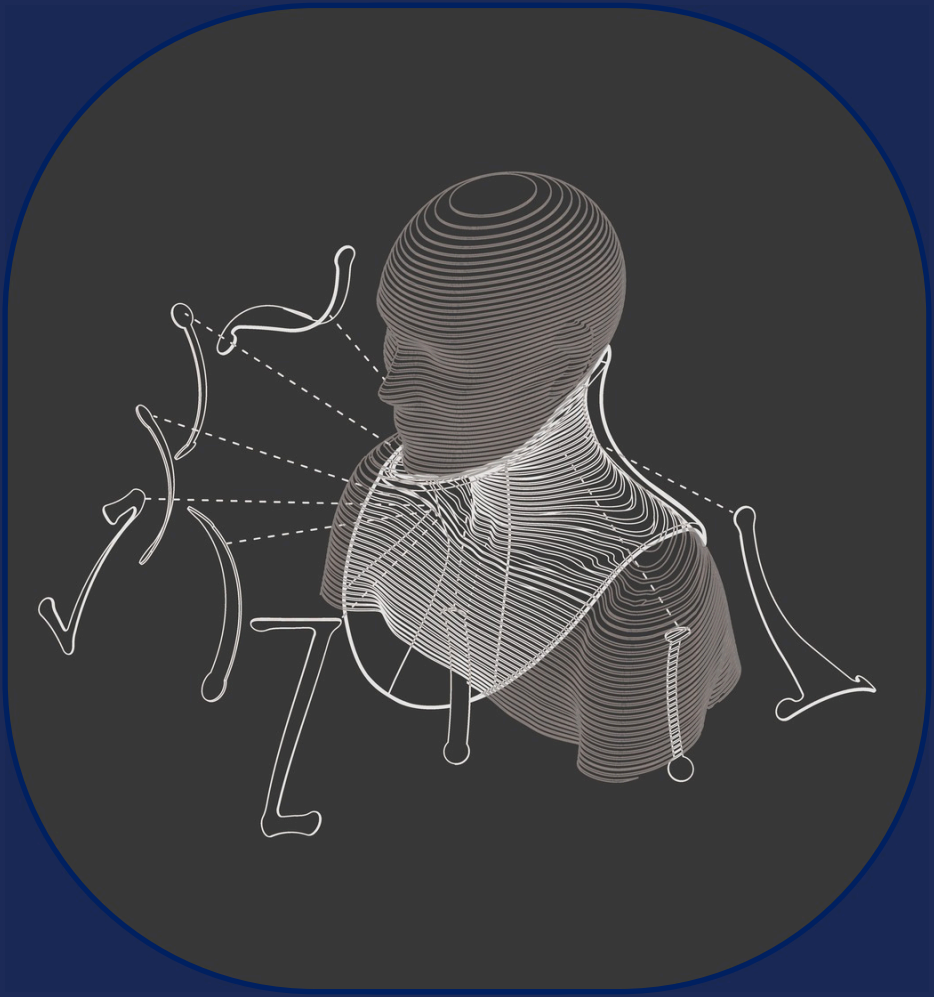
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HeadUp Cervical Orthosis

Instructions for Use



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HeadUp Cervical Orthosis

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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: HeadUp Cervical Orthosis

GMDN: 45129

BASIC UDI-DI (if applicable): 50552043SOCOKS

Packaging contents:

Fig. 1

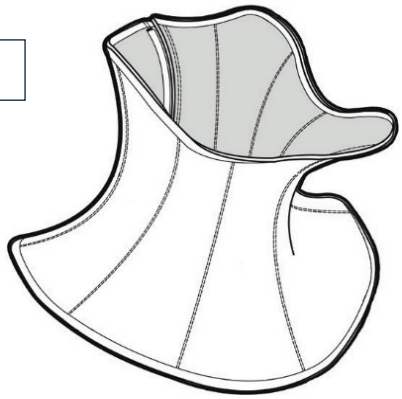


Fig. 8, 9

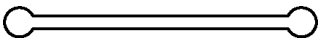


Fig. 2, 3

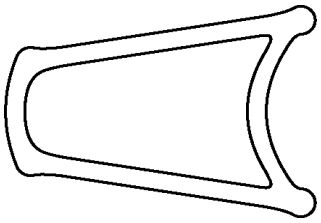


Fig. 10

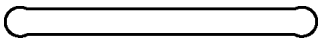


Fig. 4, 6

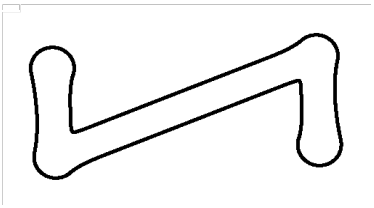


Fig. 12

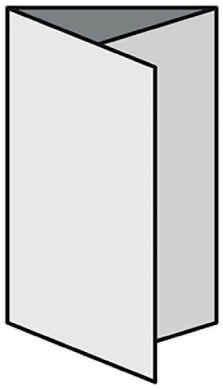
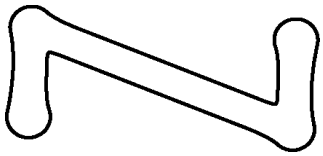


Fig. 5, 7



Item No.	Item Description	Quantity
Fig. 1	HeadUp Snood	1
Fig.2	A-Frame – Support Strut, Medium (2mm thick)	1
Fig.3	A-Frame – Support Strut, Firm (3mm thick)	1
Fig.4	Z – Support Strut, Left Side, Medium (2mm thick)	1
Fig.5	Z – Support Strut, Right Side, Medium (2mm thick)	1
Fig.6	Z – Support Strut, Left Side, Firm (3mm thick)	1
Fig.7	Z – Support Strut, Right Side, Firm (3mm thick)	1
Fig.8	Standard 8mm – Support Strut, Medium (2mm thick)	2
Fig.9	Standard 8mm – Support Strut, Firm (3mm thick)	2
Fig.10	Wide 16mm – Support Strut, Medium (2mm thick)	2
Fig.11	Wide 16mm – Support Strut, Firm (3mm thick)	2
Fig.12	HeadUp Component Pouch	1

Manufacturer Details

Manufacturers Registered Address

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

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Device Description

The HeadUp is a revolutionary cervical collar designed to provide supplementary head and neck support for people with head control issues or cervical muscular weakness. It has the following features and benefits:

- Fully customizable – providing adjustable degrees of support
- Allows support with movement
- Fabric snood which can be trimmed as required
- Heat mouldable, reinforcing struts

- Available in 3 sizes – Small, Medium and Large
- Replacement parts available
- This device is intended for **single patient use only** and not designed for multi users

Intended Use

The HeadUp is a revolutionary cervical collar designed to provide supplementary head and neck support for people with head control issues or cervical muscular weakness

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

The HeadUp Cervical Orthosis should be worn/used as guided by a healthcare professional and as outlined in the instructions for use.

Indications

The HeadUp Cervical Orthosis is recommended for use by individuals experiencing any of the following conditions:

- Motor Neurone Disease (MND)
- Amyotrophic Lateral Sclerosis (ALS)
- Head Drop
- Neuromuscular Torticollis
- Neck extensor muscular weakness
- Conditions requiring neck Support and improved alignment/control

Contraindications

The HeadUp Cervical Orthosis must not be used in the following situations:

- Patients with skin at risk of break down
- Gross fixed deformities
- Open wounds coming into contact with the device
- Unstable cervical fractures

Warnings

Caution	Hazard	Potential Harm	Risk-Control / IFU Warning
⚠ **Warning**	Excess local pressure or friction due to improper fit	Skin irritation, blistering, 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 function, 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 head or neck	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
⚠ **Warning**	Damage / deterioration to Device	Ineffective function, increased injury risk or skin breakdown	Do not use if there is significant damage/ deterioration of the HeadUp Support Struts or HeadUp Snood. The amount of Support provided by the HeadUp Support Struts will reduce over time. When the Support Struts no longer provide the required amount of Support, they must be replaced with new Support Struts following the fitting instructions.
⚠ **Warning**	Fire/Heat	Damage to device and injury to user	The HeadUp Cervical Orthosis and its support struts must not be brought into close proximity or direct contact with any form of naked flame or electrical heating element.

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
- Inspect brace, making sure all parts are intact and without damage
- Putting on and taking off the HeadUp Cervical Orthosis will be easier with an assistant; please ask them to read the instructions for use in full first.

Applying the HeadUp Snood

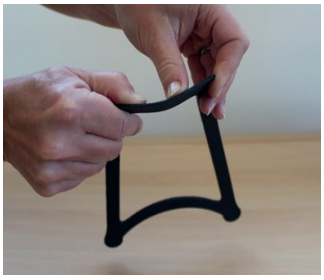
1. Select the appropriate size HeadUp Collar from the measurement chart in the size guide.
2. Heat the HeadUp Snood gently using a heat gun on a low setting (or a hair dryer on medium/high) until the fabric HeadUp Snood is warm to touch. Note: DO NOT OVERHEAT!
3. Apply the HeadUp Snood whilst it is warm aligning the chin of the patient with the Chin section of the HeadUp Snood
4. Mould the HeadUp Snood to the patient's body shape with the head alignment corrected by drawing the two edges of the HeadUp Snood posteriorly to wrap around the back of the patient's head/neck
5. Secure the HeadUp Snood at the back of the neck/head securely by overlapping the Micro Grip fastening onto the outside of the HeadUp Snood
6. The HeadUp Snood can be trimmed with scissors to customise its fit. Apertures can be cut into the collar for tracheotomies or for a carotid cannula
7. The HeadUp Snood may require adjustments/modifications and repetition of these processes to ensure an accurate and comfortable fit.

Applying the HeadUp Support Struts

- The HeadUp Collar comes with 4 different shape Support Struts in 2 different thicknesses (Medium Support 2mm, Firm Support 3mm).
- Each Support Struts are directly attached to the HeadUp Snood using the Micro Grip fastening adhered to the struts
- The HeadUp Support Struts should be applied to provide the appropriate level of Support or correction needed for the activity being undertaken.
- The HeadUp Support Struts can be readjusted with heat to meet the changing needs of the patient. Caution:
- The HeadUp Support Struts should be heated and moulded into shape as they are applied (Using a heat gun on a low setting or a hairdryer on medium/high). Protective gloves should be worn whilst heating and moulding

the HeadUp support struts. Note: DO NOT attempt to shape struts without heating them first and ALWAYS remove Support Struts from HeadUp Snood prior to heating!

- Heat should be applied to the smooth side of the Support Struts not the Micro Grip surface
- The HeadUp Support Struts should be moulded with gradual rather acute curves (see photos)

HeadUp Support Strut Position Options

- **A-Frame Support Strut Placement:**

  Flex the heated Support Strut after whilst fitting it, attaching it under the chin and then gently attaching it down the neck to the chest/sternum area.



- **Z Support Strut Placement:**

  Can either be used in addition to the "A Frame" or instead of the "A Frame". Can be positioned with the "corner" of the Z towards the chin, or with the "corner" of the Z towards the ear. Can be used unilaterally. Position the Z-Support Strut to sit flat against the jaw –the strut should be moulded and shaped by hand to customise the shape and fit.



- **Standard and Wide Support Strut Placement:**

  These can be used in addition to or instead of the A frame or Z Support Struts. These straight struts can offer additional lateral (side) Support, extra Support at the back, or can be used to make a modified "A Frame" shape at the front. They need to be heat moulded to optimise Support and comfort.



Commonly Used support Strut Configurations

1. A-Frame Centre front to prevent head drop







2. A-Frame with single Z-Support Strut to resist head drop with rotation or side head tilt



3. A-Frame with Z-Support Strut over shoulder and behind ear to address head drop with significant side flexion



4. A-frame with bilateral mandibular Z-Support Struts to provide increased head lift whilst limiting rotation and side flexion whilst reducing chin load.



5. Bilateral Z-Support Struts to resist head drop with reduced chin pressure (load transferred to inferior mandible)

6. Bilateral Wide Support Struts only to resist head drop

7. Bilateral   Wide Support Struts with bilateral mandibular Z-Support Strut placement for increased resistance to head drop

8. Bilateral posterior placement of Standard Support Struts to limit cervical hyperextension



Removal

1. Separate the hook and loop fastening closure at the back of the HeadUp Collar.

2. Stretch apart the two free HeadUp Collar edges and draw the HeadUp Collar forward while easing any Support Struts away from the head and neck.
3. Move chin profile down and away from user's chin to complete removal.



NOTE: HeadUp Support Struts do not need to be removed unless for washing or fit modification. For quick removal it is not necessary to detach the HeadUp Support Struts first.

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.

Cleaning & Maintenance

- To clean remove all HeadUp Support Struts from the Snood
- The Snood can be machine-washed using the "delicates" cycle setting at low temperature (30 degrees Celsius) and a low spin speed.
- If required, hand-wash Support Struts using lukewarm water with a gentle detergent only.
- Leave to air dry - Do not use in washing machine or tumble dryer
- Do not use chlorine-based cleaning products
- Do not iron any part of the HeadUp Collar or the Support Struts
- Ensure support is dry before re-application, checking for any apparent damage to either part of the brace before using

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.

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