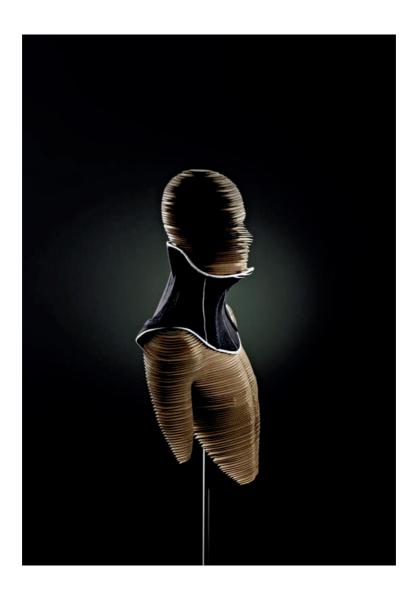


Applicable to product code: HUC/M



Intended Use

The HeadUp Collar is designed to provide supplementary head and neck Support for people with head control issues or cervical muscular weakness.

Indications for Use

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

- Head Drop
- Neuromuscular Torticollis
- Neck extensor muscular weakness
- Conditions requiring neck Support and improved alignment/control

Contraindications

The HeadUp Collar must not be used:

- for treatment of individuals with severe fixed deformity
- over open wounds that may come in to contact with the HeadUp Collar

Symbols Glossary



Consult instructions for use



Caution



Manufacturer



Date of Manufacture



Catalogue Number



Batch code



CE logo

General Instructions

- The Instructions for Use must be read and understood before attempting to use the device.
- Every component of the HeadUp is designed to be customised to the patients' needs and should not be used direct from the box without modification.
- Let it is recommended that the initial fitting of the HeadUp Collar and Support Struts must be carried out by a qualified healthcare professional.
- Putting on and taking off the HeadUp Collar will be easier with a relative/carer assisting.
- All persons involved in the fitting and maintenance of this device must read and understand the Instructions for Use prior to applying the HeadUp Collar and Support Struts.
- Care should be taken to instruct the user and carer on the correct fitting procedure as shown under "Fitting Instructions".
- During the initial fitting the individual applying the HeadUp Collar should ensure that the HeadUp Collar is fitted securely enough to provide postural head Support, but not lead to discomfort or unexpected issues such as light-headedness.
- If any pressure points can be felt from the location of the HeadUp Support Struts, adjust/reposition them slightly to alleviate the load on tissues.
- The HeadUp Collar should never dig in or cause pain. Consult your medical team if this occurs.
- In the case of an emergency the HeadUp Collar should be removed prior to performing CPR.
- For removal it is not required to detach the HeadUp Support Struts first.
- Visually check the HeadUp Collar before each use.
- ZINDo 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.
- If in doubt, please refer to your medical team treating you for advice before using or modifying the HeadUp Collar.
- If users have sensitive skin, a small proportion may experience minor irritation from the HeadUp Collar material. Prior to fitting the HeadUp Support Struts, the HeadUp Collar should be fitted to the user for a short period first, then removed and a visual inspection of the area made to ensure no skin reaction has taken place.
- In the unlikely event that if while wearing the HeadUp Collar, that any of the following issues are experienced: Discomfort / skin irritation / light-headedness the HeadUp Collar must be removed.

If symptoms do not resolve swiftly after its removal, contact your medical team treating you for advice. If any continued symptoms are experienced following use of the HeadUp Collar, please contact your medical team treating you.

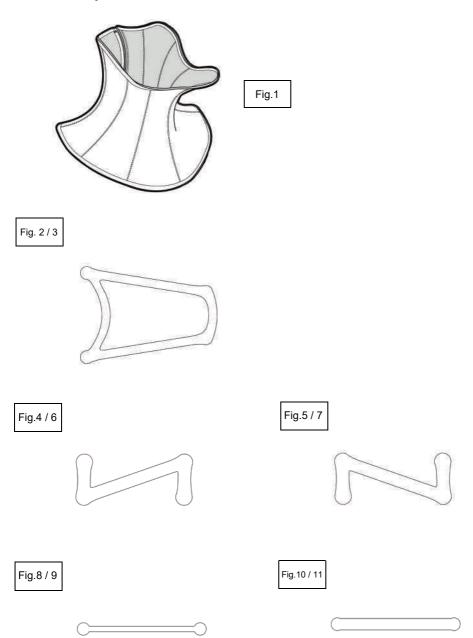
- The HeadUp Collar and its Support Struts <u>must not</u> be brought into close proximity or direct contact with any form of naked flame or electrical heating
- The HeadUp Collar is not recommended for use whilst smoking

HeadUp Kit available sizes

Product Code	Description	Device Identifier
HUC/M	HeadUp Collar - Medium	5055204324938

Components Included

Fig. No.	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
n/a	HeadUp Component Pouch	1
n/a	Cervical Extension Strap	1



Fitting Instructions

Putting on and taking off the HeadUp Collar will be easier with an assistant; please ask them to read the instructions for use in full first.

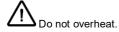


The HeadUp Collar must be fitted by an appropriately trained medical professional.

Each component of the HeadUp Collar must be customised or moulded to conform to the patient's body shape whilst delivering the required amount of Support/correction.

Applying the HeadUp Collar

- Step 1 Select the appropriate size HeadUp Collar from the measurement chart in the size guide.
- Step 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.



 Step 3 – Apply the HeadUp Snood whilst it is warm aligning the chin of the patient with the Chin section of the HeadUp Snood



- Step 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 patients' head/neck
- Step 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

• Step 6 – The cervical extension strap can be added to the collar if the HeadUp snood does not overlap around the occiput



(Fig 12 Cervical Extension strap)

- Step 7 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
- Step 8 The HeadUp Snood may require adjustments/modifications and repetition of these processes to ensure an accurate and comfortable fit.

Do not leave the wearer of the HeadUp Collar after application without ensuring correct fitment and user comfort.

If while wearing the HeadUp Collar any of the following issues are experienced: Discomfort / skin irritation / light-headedness – the HeadUp Collar must be removed and adjusted.

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.
- 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).

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 than acute curves.





examples of a gradual curves applied to the Support Struts



Do not shape the struts without heating them first.



Do not heat the HeadUp Support Struts whilst attached to the HeadUp Collar.

- The HeadUp Support Struts can be added/removed to provide different levels of Support/protection as required by each patient.
- Different strut configurations may be required for different patient activities (eating, drinking, driving).

The applied HeadUp Support Struts should never dig in or cause pain/discomfort. (If this occurs reposition the Support Struts or heat Support Struts to shape of patient).

 The Support Struts can be used in multiple configurations based upon the patients' needs/comfort (Guidance can be found in "HeadUp Support Strut Position Options" and "Commonly Used Support Strut Configurations")

The HeadUp Collar or its Support Struts <u>must not</u> be allowed close to or be brought into contact with any form of naked flame or electrical heating element.

Do not overheat the HeadUp Support Struts. Overheating may weaken the Support Strut and cause the Micro Grip to delaminate from the Support Strut.

HeadUp Support Strut Position Options

 A-Frame Support Strut Placement: flex the heated Support Strut after whilst fitting it, attaching 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 hyper extension



Removing the HeadUp Collar

- Step 1 Separate the hook and loop fastening closure at the back of the HeadUp Collar.
- Step 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.
- Step 3 Move chin profile down and away from user's chin to complete removal.

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.

When to Consult a Healthcare Professional

The HeadUp Collar should be removed if any of the following issues are experienced:

- Discomfort
- Skin irritation
- light-headedness

If any continued adverse symptoms are experienced following use of the HeadUp Collar, please contact the medical team treating you.

Before making any change to the fit or Support level of the HeadUp Collar, ensure that you have read in full HeadUp instructions for use. If in doubt, please refer to your medical team treating you.

Care and Cleaning Instructions

- No specific maintenance of the HeadUp Collar is required.
- The user should visually inspect the integrity of the HeadUp Collar and its Support Struts before each use.

Do not use if any damage is apparent – replacement parts can be purchased from the

 Periodically the HeadUp Collar assembly, which is worn next to the skin (Fig.1), will require washing.



All HeadUp Support Struts (Fig.2-11) should be removed first.

Refer to the Fitting Instructions to re-apply the HeadUp Collar and Support Struts after washing.

- If machine-washing the HeadUp Collar, use the "delicates" cycle setting at low temperature (30 degrees Celsius) and a low spin speed. Leave to air dry.
- Do not use bleach.
- Do not tumble dry.
- Do not iron any part of the HeadUp Collar or the Support Struts.
- Do not machine wash the HeadUp Support Struts.
- If required, hand-wash Support Struts separately from the HeadUp Collar using lukewarm water with a gentle detergent only and leave to air dry.

HeadUp Kit Size Guide

	Neck Circumference			
Product Code	Description	(cm)	(inches)	Device Identifier
HUC/M	HeadUp Collar - Medium	35-44	14-17"	5055204324938

Spare and Accessories

For spares and accessories please visit shop.talarmade.com

HeadUp Kit Components						
Description	Small (HUC/S)	Medium (HUC/M)	Large (HUC/L)			
HeadUp Snood	HU-RFC/S	HU-RFC/M	HU-RFC/L			
A Frame – Support Strut, Medium (2mm thick)	HU-RAF/2S	HU-RAF/2	HU-RAF/2L			
A Frame – Support Strut, Firm (3mm thick)	HU-RAF/3S	HU-RAF/3	HU-RAF/3L			
Z - Support Strut, Left Side, Medium (2mm thick)	HU-RZS/2LS	HU-RZS/2L	HU-RZS/2LL			
Z - Support Strut, Right Side, Medium (2mm thick)	HU-RZS/2RS	HU-RZS/2R	HU-RZS/2RL			
Z – Support Strut, Left Side, Firm (3mm thick)	HU-RZS/3LS	HU-RZS/3L	HU-RZS/3LL			
Z - Support Strut, Right Side, Firm (3mm thick)	HU-RZS/3RS	HU-RZS/3R	HU-RZS/3RL			
Standard 8mm – Support Strut, Medium (2mm thick)	HU-RSS/2S	HU-RSS/2	HU-RSS/2L			
Standard 8mm – Support Strut, Firm (3mm thick)	HU-RSS/3S	HU-RSS/3	HU-RSS/3L			
Wide 16mm – Support Strut, Medium (2mm thick)	HU-RWS/2S	HU-RWS/2	HU-RWS/2L			
Wide 16mm – Support Strut, Firm (3mm thick)	HU-RWS/3S	HU-RWS/3	HU-RWS/3L			
HeadUp Component Pouch	HU-RFR	HU-RFR	HU-RFR			
Cervical Extension Strap	HU-EXTSTRAP/S	HU-EXTSTRAP	HU-EXTSTRAP/L			

Additional Guidance and Training

For additional guidance and training resources please visit www.talarmade.com

HeadUp Collar Fitting Instructions Video is available to view please scan the QR Code below:



Disposal

The disposal and recycling of used devices and packaging must comply with the applicable legal regulation in each country.

Terms and Conditions

For terms and conditions please visit www.talarmade.com



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