*Ortho**Spine***®

Stabilix®

Cervical Brace

Instructions For Use

Please read these instructions carefully before application.

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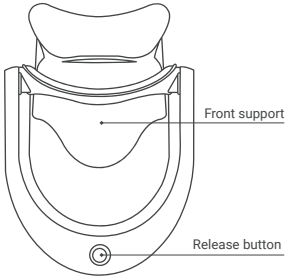
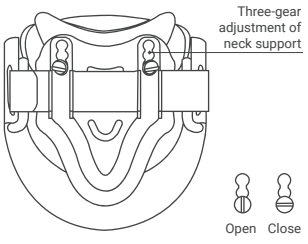
GENERAL DESCRIPTION

Stabilix® Cervical Brace is a lightweight, anatomically contoured designed to stabilize the neck in case of select cervical spine conditions. It features cushioning for comfort and height adjustability for a personalized fit across a variety of sizes. The product ensures effective immobilization while maintaining comfort, and hygiene. The quick-release mechanism and front-opening design allow for easy application and removal, making it suitable for both clinical and home settings.





INTENDED USE

Stabilix® Cervical Brace is intended for use on the advice of a qualified medical practitioner, under appropriate medical supervision, to limit movement of the cervical spine while providing support, stabilization and pain relief. It is designed to limit cervical movement following neck sprains, strains, during post-operative recovery, and in the management of stable cervical spine conditions requiring external support.

The product is designed to limit cervical flexion, extension, lateral bending, and axial rotation. It is intended for use in hospital, clinical, rehabilitation, and home settings. It allows limited adjustment of the flexion-extension angle and is suitable for both short-term and extended wear as prescribed by a Healthcare Professional (HCP).

INDICATIONS FOR USE

- Restriction of cervical spine movement following neck sprains and strains.
- Post-surgical cervical support and stabilization.
- Management of stable cervical spine injuries as prescribed by a Healthcare Professional (HCP).
- Cervical support during rehabilitation.
- Short-term or extended cervical stabilization as part of a prescribed treatment plan.

Note: The decision to apply the brace is to be taken strictly by a Healthcare Professional (HCP) only.

CONTRAINDICATIONS

- This product is not intended for definitive stabilization of unstable cervical spine fractures or injuries requiring rigid external stabilization devices, surgical fixation or halo immobilization.
- Patients with anatomical abnormalities that prevent proper fitting.
- Presence of open wounds, surgical sites, or compromised skin at areas of brace contact, or with whose care the brace will interfere.
- Situations where external pressure from the brace may compromise the airway, impair circulation, or contribute to skin breakdown or pressure injury.
- Inability to achieve secure and proper sizing or fitting, which may reduce immobilization effectiveness and increase patient risk.
- Not for use in case of allergies to materials used in construction - silicone, ABS plastic and fabric.

PATIENT POPULATION

Patients who demonstrate one or more indications listed above and have been prescribed the use of the device by a Healthcare Professional (HCP).

INTENDED USERS

Patients prescribed or guided by a Healthcare Professional (HCP) for intended use.

SIZE CHART

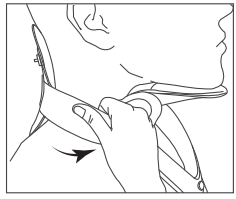
Universal - Height Adjustable.

INSTRUCTIONS FOR APPLICATION

The device has two parts, one for the front of the neck (front-support) and one for the back of the neck (back-panel). When donned appropriately, both parts should be centered with the mid-line of the neck, and held together securely with a hook and loop fastener.

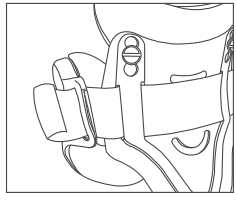
Step 1: Place the device on the patient's neck

Unfasten the hook and loop fastener strap from the front support on the right side, slightly raise the patient's head, and place the front support in front of the patient's neck, and the back panel on the back of the neck. Attach the hook and loop fastener securely to the right side of the front support.



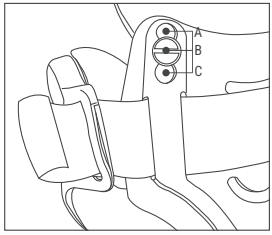
Step 2: Adjust length and secure hook and loop fastener

With the device placed on the neck, loop the Velcro strap through the buckle on the left side, and fasten it back on to itself after adjusting the length for an appropriate, snug fit. Avoid excessive tightness as it can impair circulation and block compress nerves.



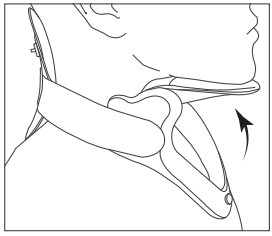
Step 3: Adjust back panel height

The two screws on the back panel can be placed in positions A, B and C as shown in the image. Use these to adjust the height as needed.



Step 4: Adjust chin support angle

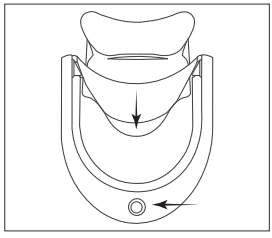
Adjust the angle of the chin support for appropriate neck angle for immobilization, to push it up apply upward pressure, to pull it down, press the button and pull it down.



REMOVAL INSTRUCTIONS

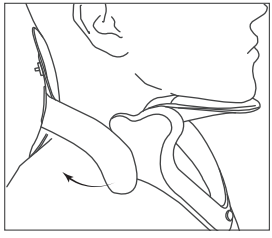
Step 1: Release chin support

Press and hold the release button, then gently press down the chin support to return it to its original position.



Step 2: Unfasten hook and loop fastener to remove brace

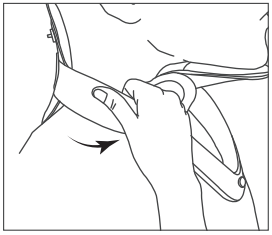
Unfasten the hook and loop fastener to remove the cervical brace from the patient's neck.

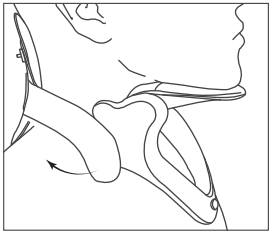


This completes the donning and doffing process for the first application. This ensures a good coarse fit for future applications.

SUBSEQUENT APPLICATION AND REMOVAL

Steps for subsequent use are largely similar to the steps of first use, with the following note: if the hook and loop fastener length, back panel height have been adjusted in the first application (steps 2 and 3), they may need little or no adjustment for subsequent uses. Therefore, during subsequent uses, repeat steps 2 and 3 only as needed.





WASHING INSTRUCTIONS

- The plastic parts can be wiped gently with damp cloth with or without a mild detergent.
- Only the cushion liner is washable.
  - Wash gently by hand with warm water and a mild detergent.
  - Do not machine-wash, tumble dry, iron, bleach, or use fabric softener.
- Air dry completely before using again.

DISPOSAL

Dispose of the Cervical Brace according to local waste management guidelines.

WARNINGS AND CAUTIONS

- Use only under medical supervision as advised by a Healthcare Professional (HCP).
- Discontinue use and seek medical attention if you experience allergies, pain, swelling, numbness, discoloration, or unusual sensations and consult a Healthcare Professional (HCP).
- Incorrect or overly tight application may cause pressure injuries, vascular obstruction, or nerve compression; ensure proper fit and application.
- Do not use the product if worn out, damaged, or malfunctioning.
- Do not use the device continuously for more than time prescribed by Healthcare Professional (HCP).
- The device is intended for multiple uses by a single patient only. Do not share among the multiple patients.

ADVERSE EFFECTS

- Prolonged usage may cause skin irritation, discomfort, or pressure sores. Sensitivity to materials may cause allergic reactions.
- Excessive tightening can lead to poor circulation, numbness, or swelling, and improper fit may cause continued pain or discomfort.

STORAGE CONDITIONS

- Store at room temperature, away from sunlight and moisture.
- Avoid placing heavy or sharp objects on the product to prevent damage.
- Keep out of reach of children and pets.
- Ensure the product is clean and completely dry before storing.

MR COMPATIBILITY

Stabilix® Cervical Brace is not MR compatible.

REPORTING OF ADVERSE EVENTS

In case of any event please notify to 'care@orthoheal.com' or to the competent authority of the respective country.

INSTRUCTIONS FOR PATIENTS

Do's:

- Follow these Instructions For Use.
- Use as per Healthcare Professional (HCP) advice.
- Ensure an appropriate fit (snug but comfortable) for each use.
- Report any complaints to the Healthcare Professional (HCP) immediately.

Don'ts:

- Don't use in case of allergy to any of the product materials.
- Don't use/ stop using the product in case of sores, swelling and ulcers.
- Don't try forcefully bend or twist the neck against the device.
- Avoid using creams, lotions or oily substances on your skin under the brace.

RECOMMENDATION

This product is intended for use only under the supervision of a Healthcare Professional (HCP).

SYMBOL GLOSSARY

MD	Medical Device
℞ Only	Caution: Federal law restricts this device to sale by or on the order of a HCP
	Single patient multiple use.
	Do not use if package is damaged and consult instructions for use
	Non-sterile
	Consult instructions for use.
	Device is not made with natural rubber latex.
	Keep away from sunlight.
	Manufacturer
	Date of Manufacture
REF	Catalogue Number / Reference code
LOT	Batch code / Lot Number
UDI	Unique device identifier
EC REP	Authorised representative in the European Union

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