



OrthoSpine®
Postura®
Cervical Brace



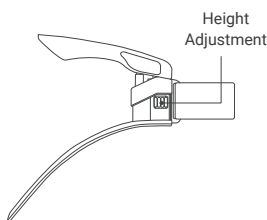
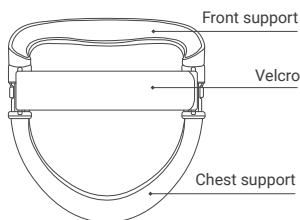
Instructions For Use

Please read these instructions carefully before application.

OrthoSpine® Postura® Cervical Brace

GENERAL DESCRIPTION

Postura® Cervical Brace supports posture training and neck muscle activation. Its rigid ABS core with a soft silicone cover ensures comfort. Height-adjustability ensures a personalized fit across different neck lengths, enhancing user comfort and effectiveness. A built-in spring mechanism delivers a gentle rehabilitative push, encouraging upright posture and helping to strengthen neck muscles. An optional stopper clip offers flexion control, allowing the chin to rest comfortably without active muscle effort. Lightweight, breathable, and secured with a single hook and loop fastener, it's ideal for daily ergonomic support.



INTENDED USE

Postura® Cervical Brace is intended to provide postural guidance, kinesthetic feedback and reminder for individuals requiring neck posture improvement intervention and assistance in maintaining a neutral neck position. It is suitable for use in cases of mild neck strain, postural training, or rehabilitation programs where controlling cervical motion is beneficial. The device is not intended for rigid neck immobilization, as needed in various other injuries and conditions.

INDICATIONS FOR USE

- To promote proper cervical posture and alignment, in patients with postural dysfunction and those at risk for the same.
- To help manage tech-neck, muscle fatigue, and non-specific neck pain, for instance in sedentary office workers.
- To aid neuromuscular re-education and ergonomic assistance in individuals undergoing rehabilitation.
- To provide support during recovery from minor cervical strain/ sprain, as advised by a qualified medical practitioner.

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.
- Not for rigid cervical immobilization (e.g., fractures, post-op care).
- Not for use in case of allergies to materials used in construction - silicone and ABS plastic.
- 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 collar 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.

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

Healthcare professionals and patients for whom the device has been prescribed by a qualified healthcare professional.

SIZE CHART

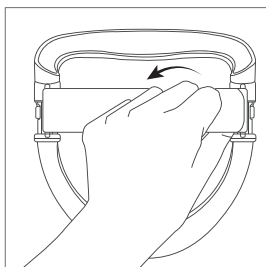
Universal - Height Adjustable

INSTRUCTIONS FOR APPLICATION

The prescription and first time application should be done by a healthcare professional. Subsequent usage, including any adjustments should be done by the patient as per the advice of and under strict supervision of the prescribing healthcare professional.

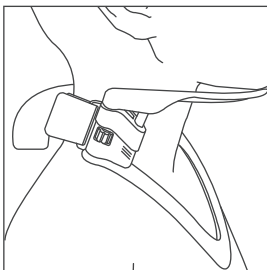
Step 1: Open the hook and loop fastener strap

Pull one side of the hook and loop fastener of the back of the cervical brace apart.



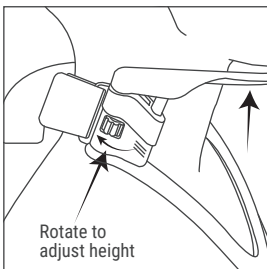
Step 2: Place on the user's neck

Slightly lift the user's head, and place the front support in front of the user's neck.



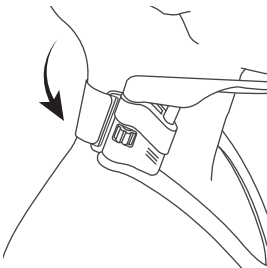
Step 3: Adjust height

Adjust the front support to the required height by using the height adjustment control - setting it at the same level on both sides with the help of marker lines.



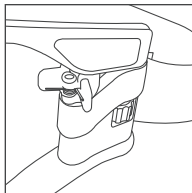
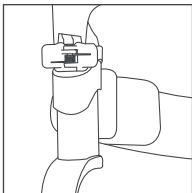
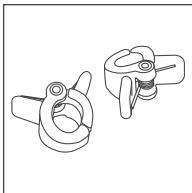
Step 4: Fasten the hook and loop fastener strap

Adjust the left and right side hook and loop fastener to a comfortable position and paste it firmly to complete application.



Step 5: Attach the Stopper Clip

Secure the stopper clip onto the brace on both sides, as shown in the figure. This will limit cervical flexion movement.



REMOVAL INSTRUCTIONS

To remove, unfasten the hook and loop fastener from the right side, gently extend the neck, and remove the device from the patient's neck.

WASHING INSTRUCTIONS

- Can be wiped gently with a damp cloth with or without 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 device after use as per local biomedical waste norms.

WARNINGS AND PRECAUTIONS

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

Postura® 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.

INSTRUCTION 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



Medical Device



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



Catalogue Number / Reference code



Batch code / Lot Number



Unique device identifier



Authorised representative in the European Union

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FDA
LISTED



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