

ACTIMOVE INSTRUCTIONS FOR USE

Actimove® Vertebrace Neck Collar (spinal support)

Medical device, medical accessory.

Expiry date and size: see on the packaging.

Manufacturer: BSN Medical GmbH, Germany, Schützenstrasse 1-3 22761 Hamburg

Storage: at room temperature, protected from direct heat.

Distributed by Essity Hungary Ltd. Budakeszi Road 51. 1021 Budapest

Dear Customer,

Thank you for choosing Actimove® Vertebrace Neck Collar. Actimove®Vertebrace Neck Collar is an easy-to use, lightweight cushioned support device designed to maintain the head and neck in a stable position during acute and emergency situations with effectively restricting the range of motion. With proper application the collar completely encircles the neck providing rigid support for the head, jaw, and base of the skull. This single-piece device can be quickly and easily applied, whether the patient is in a seated or supine position. The chin support unfolds from its flat storage location during collar adjustment and patient fitting and then placed into the proper position. The collar can be rapidly and securely fastened with using the quick-locking elements. The large front opening enables emergency cricothyrotomy (incision through the cricothyroid membrane) or tracheostomy (windpipe incision) if necessary.

Please follow the instructions below. We wish you a fast recovery!

Intended use and Indications:

The intended use of the product is to stabilize the neck. Its applications include, but are not limited to:

- Postoperative care
- Short-term use after sudden neck sprain
- Spondylarthrosis deformans (abnormal changes in the vertebral joints)
- Deformity (dislocation)
- Strain
- Acute or chronic painful cervical spine syndrome
- Acute and emergency care

Please contact a healthcare professional if you are unsure whether the product is suitable for you.

Contraindications:

Do not use the Actimove®Vertebrace Neck Collar if you have severe neck injury such as cervical vertebral fracture.

Instructions for use:

A.) Application:

The determination of the appropriate size is made with the Actimove® spinal support sizing scale, which can be found in the foreign language instructions for use. The sizing scale assists in determining the appropriate size for the neck collar. Please note that the sizing scale includes two different size variations on each side: one for adults and one for children. It is important to use the proper side.

a. In cases of any suspected cervical spine injury requiring a collar, this sizing scale can be applied in almost any body position in which the patient is found (Figure 1).

b. Place the sizing scale on the lateral aspect of the patient's head so that its lower edge rests on the upper part of the shoulder (trapezius). Align the coloured end with the front of the ear (Figure 2). Each coloured section marked with a letter corresponds to one of the six sizes of the Actimove® Vertebrace Neck Collar.

c. Identify which coloured section and corresponding letter are at the same level with the centre of the ear's opening (earcup).

Important: The sizing scale assists in selecting the correct size during the initial examination. Before making the final decision, please take into account the size of the upper body: for individuals with a stronger or more muscular build, a shorter size may be required. If removing thick winter clothing is contraindicated, a shorter size may be required. For individuals with a slimmer build, a one collar size longer may be needed.

B.) General Application Instructions:

1. Hold the collar as shown in the diagram.
2. Bend the collar to open the chin support.
3. Pre-shape the collar for easier application.
4. While another person keeps the patient's head motionless slide the collar with the strap under the patient's neck.
5. With avoiding excessive movement of the head place the chin support under the chin.
6. Tighten the strap to ensure a comfortable and snug fit, then firmly press the fuzzy side onto the hook-and-loop fastening on the collar.

C) Instructions for use in acute and emergency care

Only qualified healthcare professionals are capable of providing pre-hospital emergency care and have expertise in performing initial patient examinations and using assisting devices should attempt to apply the neck collar on a patient suspected of having a cervical spine injury before transportation to the hospital. It should be applied with increased precaution and combined with a cervical spine board or another recognized immobilization system. Whenever feasible, at least two assistants should apply the neck collar, with one of them

holding the head and neck in a straight line and motionless during the application procedure as described above (Section B: General Application Instructions). The neck collar should be sufficiently comfortable. When properly positioned, it should be comfortably loose while providing enough support, and adequately restricts the range of motion for the patient's head and neck. In any case make sure that the patient's respiratory tract is clear. For maximum support of the cervical spine the neck collar should remain on the neck until it can be removed by a medical practitioner or other qualified health care professional. The Actimove® spinal support is designed for a single-patient use.

Warnings and Precautions: The initial application of the collar should be performed by a qualified healthcare professional, and its usage should be continuously supervised by a medical practitioner. Keep the skin area under the collar as clean and dry as possible to prevent local irritation. If redness, irritation, or swelling occurs, please consult a medical professional.

Warning:

- Generally there is no side effects when wearing a device recommended by your medical practitioner and properly fitting.
- In case of existing sensory disorders, numbness may lead to circulatory problems due to compression at the pressure points.
- In such cases, always check the position of the product and the strength of the fastening.
- Improper application and fastening of the device may cause skin changes and impairment of arterial blood supply.
- If the symptoms are unchanged, please consult your treating physician immediately.

Note

Please immediately report any serious and unexpected events related to the use of the device to BSN medical GmbH (BSN Medical GmbH, Germany, Schützenstrasse 1-3, 22761 Hamburg) or Essity Hungary Ltd. (Budakeszi Road 51. 1021 Budapest), as well as to the relevant local authorities (National Institute of Pharmacy and Nutrition - OGYÉI, 1051 Budapest 3 Zrínyi str. Budapest, Tel: (1) 8869-300, E-mail: amd.vig@ogyei.gov.hu, 1372 P.O. Box 450).



Closing date: July 22, 2022.