



ENGLISH

SYMBOLS



Medical Device



Magnetic Resonance (MR) safe

INTENDED USE

The device is intended to provide gross immobilization to the cervical spine. The device must be fitted and adjusted by a healthcare professional. X-ray and CT lucent.

Indications for use

Conditions requiring gross immobilization of the cervical spine. This may include:

- C-spine precaution for trauma patients
- Immobilization for pre and post-c-spine surgery
- Other conditions requiring gross immobilization of the mid-cervical spine

Contraindications

Patients with a compromised airway or known spinal deformities such as ankylosing spondylitis. Patients with penetrating trauma injuries.

Warnings and Cautions:

Warning: If an unstable fracture is suspected or unknown, with or without a sustained trauma, ensure additional spinal precautions are implemented to immobilize the spine.

Warning: Use of a cervical collar may increase intracranial pressure (ICP) through jugular venous compression.

Warning: Use of a cervical collar may increase complexity of airway management.

Warning: Cervical spine immobilization, including use of a cervical collar, has been associated with:

- Impaired respiratory effort and forced expiratory volume
- Pneumonia
- Aspiration
- Worsening of existing cervical spine injury
- Severe neurological deterioration in patients with ankylosing spondylitis
- Triggering of non-compliance or agitation
- Delay to definitive treatment
- Impaired physical examination/secondary survey

Spine Application

Ensure that correct spinal protocol is followed.

- Assemble the front/back piece by pushing the black fastener through the hole (Fig. 2).
- Flare the sides of the front piece out, slide it up the chest wall and scoop it up under the chin

DEUTSCH

SYMBOLE



Medizinprodukt



MRT-sicher

VERWENDUNGSZWECK

Das Produkt ist zur Immobilisierung der Halswirbelsäule vorgesehen. Das Produkt darf nur von einer orthopädiotechnischen Fachkraft angelegt und angepasst werden. Röntgen- und CT-durchlässig.

Indikationen

Erkrankungen, die eine Ruhigstellung der Halswirbelsäule erfordern. Dazu zählen:

- Vorsichtige Immobilisierung der Halswirbelsäule bei Traumapatienten
- Immobilisierung für die Zeit vor und nach Eingriffen an der Halswirbelsäule
- Sonstige medizinische Zustände, die eine weitgehende Immobilisierung der mittleren Halswirbelsäule erfordern

Kontraindikationen

Patienten mit Obstruktion der Atemwege oder bekannten Wirbelsäulenfehlformen wie Spondylitis ankylosans.

Warnings and Cautions:

Warning: If an unstable fracture is suspected or unknown, with or without a sustained trauma, ensure additional spinal precautions are implemented to immobilize the spine.

Warning: Use of a cervical collar may increase intracranial pressure (ICP) through jugular venous compression.

Warning: Use of a cervical collar may increase complexity of airway management.

- Collar removal or any adjustments to the collar should be done with physician permission only and according to the physician's instructions.
 - Unless otherwise specified by the physician, the patient should not remove the collar except to wash under it and change the pads.
 - The patient will need a second person to help when cleaning the collar.
- These instructions do not supersede hospital protocol and/or direct orders of the patient's healthcare professional.

GENERAL SAFETY INSTRUCTIONS

The healthcare professional should inform the patient about everything in this document that is required for safe use of this device. Any serious incident in relation to the device must be reported to the manufacturer and relevant authorities. The patient should immediately contact a healthcare professional:

- If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions.
- If any pain, skin irritation, or unusual reaction occurs with the use of the device.

Device Removal

Ensure that correct spinal protocol is followed. Undo the straps, remove the front piece and slide the back piece out from behind the head.

FITTING INSTRUCTIONS

Size Selection

Proper sizing is critical to achieve comfort and proper immobilization.

The adult sizes are phenotype-driven. To determine the appropriate size, identify your patient's phenotype according to the Sizing Silhouettes (Fig. 1A).

The junior device sizes are based upon Broselow-Luten color-code (Fig. 1B) or age.

Quick Size Check (Fig. 1C)

Use your fingers to measure the vertical chin-to-trapezius distance.

On the collar, this measurement corresponds to the distance from the top of the hook and loop adhesive section to the bottom edge of the collar plastic.

LIAIBILITY

Össur does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use section, application, or environment.

ALLGEMEINE SICHERHEITSHINWEISE

Die orthopädiotechnische Fachkraft sollte den Patienten über alle in diesem Dokument genannten Aspekte informieren, die für die sichere Verwendung dieses Produkts erforderlich sind.

Jeder schwerwiegende Vorfall in Bezug auf das Produkt muss dem Hersteller und den zuständigen Behörden gemeldet werden.

Der Patient sollte sofort eine orthopädiotechnische Fachkraft aufsuchen:

- Wenn sich die Funktionalität des Produkts verändert oder verloren geht, wenn das Produkt Anzeichen von Beschädigung oder Verschleiß aufweist, die seine normalen Funktionen beeinträchtigt.
- Wenn bei der Verwendung des Produkts Schmerzen, Hautreizungen oder ungewöhnliche Reaktionen auftreten.

ANWEISUNGEN ZUM ANLEGEN

Auswahl der Größe

Die richtige Größe ist entscheidend für den Komfort und die richtige Ruhigstellung.

Um die geeignete Größe zu bestimmen, identifizieren Sie den Phänotyp Ihres Patienten anhand der Großen-Silhouetten (Abb. 1A).

Die Größen der Junior-Produkte basieren auf dem Broselow-Luten-Farbcode (Abb. 1B) oder dem Alter.

Kontraindikationen

- Patienten mit Obstruktion der Atemwege oder bekannten Wirbelsäulenfehlformen wie Spondylitis ankylosans.
 - Patienten mit penetrierenden Trauma-injuries.
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- Warning: Use of a cervical collar may increase intracranial pressure (ICP) through jugular venous compression.
- Warning: Use of a cervical collar may increase complexity of airway management.

- Fig. 3.** Sides of the front piece should be oriented up, off the trapezius, and toward the ears. Attach the retaining strap.
- Slide the back piece behind the patient's neck and center it, noting the arrow on the panel pointing up (Fig. 4). Ensure the padding extends beyond the edge of the plastic.
- Note:** Long hair should be placed outside of the plastic.
- These instructions do not supersede hospital protocol and/or direct orders of the patient's healthcare professional.

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