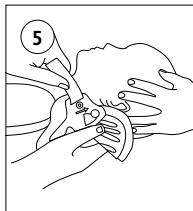
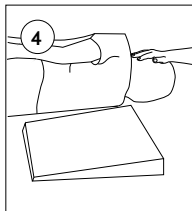
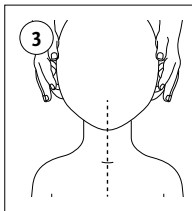
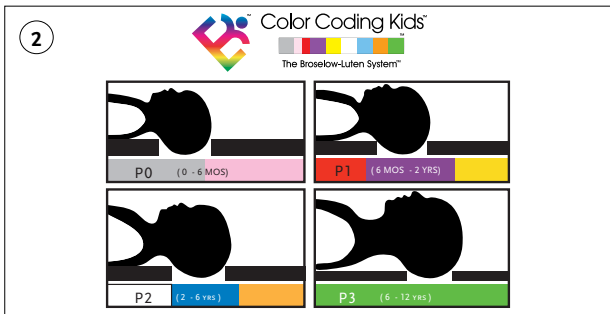
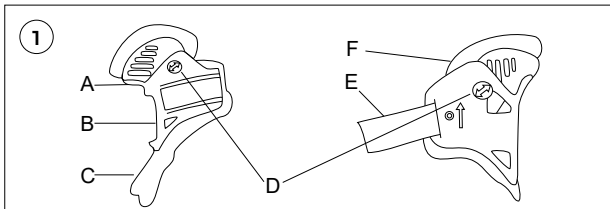
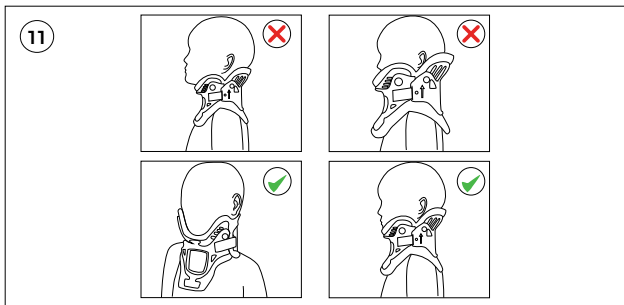
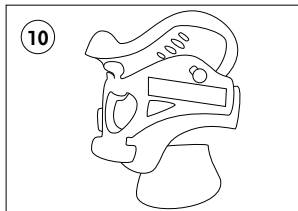
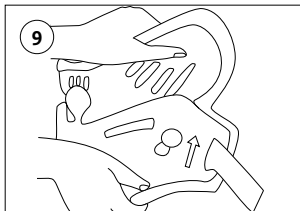
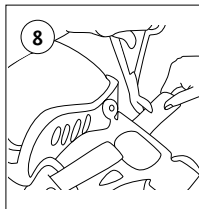
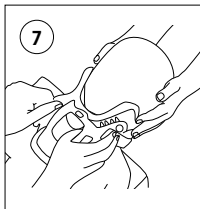
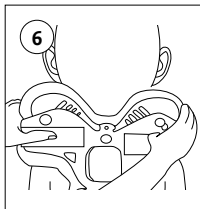


Instructions for Use

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MIAMI JR<sup>®</sup>





# ENGLISH

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## SYMBOLS



Medical Device



Magnetic Resonance (MR) safe

### **Product overview (Fig. 1):**

- A. Chin Support
- B. Tracheal Opening
- C. Sternal Pad
- D. Angulation Buttons
- E. Hook-and-Loop Strap
- F. Occipital Support

### **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

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

- Increased pain and discomfort, which may lead to increased spinal movement
- Impaired swallowing

**Caution:** Perfumes and harsh cleaning agents should not be used on or under the collar, as they may compromise the integrity of materials.

**Caution:** Use of a cervical collar for cervical spine immobilization is not recommended in situations where patients are awake, alert, not intoxicated, without neck tenderness or pain and without abnormal sensory or motor findings on examination.

**Caution:** Regular cleaning of the collar, pads and the skin beneath along with inspection of the skin for any signs of irritation is required to reduce the risk of skin ulceration. Bedridden patients are at an increased risk for skin ulceration.

**Precautions:**

- At least two persons are needed for initial collar placement: one to maintain the patient's head and neck in proper alignment, the second to fit the collar.
- 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.

The device is for single patient – multiple use.

## **FITTING INSTRUCTIONS**

### ***Size Selection***

Select the Miami Jr collar size based upon: Broselow-Luten color-code (**Fig. 2**) or Age.

### ***Sizing Tips***

- If you are deciding between two consecutive sizes, try the smaller size first.
- Use the largest size that fits comfortably and maintains desired treatment positioning.

### ***Supine Application***

Ensure that correct spinal protocol is followed.

1. Position patient with arms to the side, shoulders down and head aligned centrally (nose over belly button). (**Fig. 3**). Remove any pillows from behind the patient's head.
2. Elevate patient's thorax to bring c-spine and airway into proper anatomical alignment. Log roll the patient to the side and place a bolster under the patient extending from the top of the shoulders to base of the spine. Bolster should be made from any suitably padded material (i. e. blankets, sheets) and be of an appropriate height to offset the occipital prominence (**Fig. 4**).
3. Log roll the patient back into the supine position.

- Slide the Back behind the patient's neck and center it, noting arrow on panel pointing up (**Fig. 5**). Ensure the Sorbatex™ padding extends beyond the edge of the plastic.  
**Note:** Long hair should be placed outside of the plastic.
- Flare sides of the Front out, slide it up the chest, and scoop it up under the chin (**Fig. 6**). Sides of the Front should be oriented up, off the shoulder, and toward the ears.
- While holding the Front securely, curl the ends snugly against patient's neck (**Fig. 7**).

With the Front of the collar inside the Back, apply the Hook-and-Loop Strap and secure the opposite side of the collar in the same fashion. Tighten straps alternately to an equal length on both sides.

- Hook-and-Loop straps must be aligned to the Front adhesive sections. Excess may be trimmed (**Fig. 8**).

**Note:** Collar application must be secure to ensure proper fit, maintain alignment, and prevent the chin from slipping inside. If the patient can slip his/her chin inside the collar, it is a clear indication that it is not snug enough.

### ***Device Adjustments***

**Angulation Buttons:** May be used to fine-tune the fit of the collar for better anatomical conformity, pressure distribution, and comfort. It is easier to adjust the Angulation Buttons if you first remove the collar (**Fig. 9**).

### **Chin Support Positioning Guidelines:**

- Slide up to relieve chin tip pressure or discomfort.
- Slide down to relieve jaw mandibular pressure or discomfort



### **Occiput Support Positioning Guidelines:**

- Slide up to relieve occipital pressure or discomfort.
- Slide down to enhance extension control.

**Note:** For a predominately supine patient keep Occipital Support Buttons set to top position. This will direct the top edge of the collar shell into the bed.

**Sternal Pad:** The sternal pad may be removed if the anatomy dictates, for comfort during sleep and/or during meals to make chewing and swallowing easier (**Fig. 10**).

### ***Final Fitting Checklist***

**A properly applied device will look like Fig. 11.**

- Collar extends from mandible to just below sternal notch.
- Chin is centered comfortably in Chin Support. Chin should not extend over edge of Sorbatex™ pad, nor fall inside collar.
- Straps are aligned to the Hook landing area and are an equal length.
- Sides of Back should overlap sides of Front.
- Front of collar angled up toward ears. Lower plastic edge should not be resting on patient's clavicles nor digging into trapezius.
- No plastic touching skin. Sorbatex™ pads extend beyond all plastic edges.
- No slack or gaps in any of the straps.
- Tracheal opening and posterior vent are midline.
- Collar sits away from the neck. There should be a “finger” gap between the tracheal opening and the neck.

### ***Accessories and Replacement Parts***

Please refer to the Össur catalog for a list of available replacement parts or accessories.

## USAGE

### *Cleaning and care*

- Remove the pads from the plastic shells.
- Hand-wash using mild detergent and rinse thoroughly.
- Wring out the excess water and squeeze in a towel. Lay flat to air dry.

**Note:** Do not machine-wash, tumble dry, iron, bleach, or wash with fabric softener.

**Note:** Avoid contact with salt water or chlorinated water. In case of contact, rinse with fresh water and air dry.

Device plastic can be washed with a damp cloth and mild soap.

- Replace the pads by attaching the grey/dull side to the hook on the inside of the plastic shells.

## DISPOSAL

The device and packaging must be disposed of in accordance with respective local or national environmental regulations.

## LIABILITY

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 condition, application, or environment.