

Reprocessed by



HEALTH SERVICES

434 Industrial Lane Birmingham, AL 35211
1-866-943-6670

Instructions for Use
Hygia Ambu Perfit ACE Collar
Reprocessed Device for Single Use.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

NON-STERILE NOT MADE WITH NATURAL RUBBER LATEX

Description

Hygia Reprocessed Ambu® Perfit ACE® Cervical Collar

Indications for Use

The Hygia Reprocessed Ambu® Perfit ACE® collar is a one-piece rigid cervical spine immobilization device designed to assist the rescuer with the maintenance of neutral alignment, prevention of lateral (side-to-side) sway and anterior-posterior (forward and backward) flexion and extension of the cervical spine during transport and routine patient care or movement. The Ambu Perfit ACE is the only collar with 16 sizes for patient immobilization, the most accurate sizing for proper immobilization.

Warnings

- The Ambu Perfit extrication collar is intended for application by licensed health care practitioners as directed by a physician or other medical authority. Permanent injury may result from use other than as directed by a physician or other medical authority. An extrication collar is only part of total patient immobilization.
- It is important that practitioners are trained and practiced in the use and application of the device and that all instructions are read and understood prior to application of the collar.
- All directions are to be considered as guidelines and not an attempt to define medical practice.
- Use the device only after review and approval from the supervising medical authority.

Directions for Use

1. Have one rescuer manually stabilize the head and neck, gently holding the head and neck in the neutral alignment position. Note: If resistance is felt or an increase in patient discomfort is noted, follow your established protocols for immobilization of the cervical spine in the presence of known or suspected cervical dislocation.
2. Once the head and neck are manually stabilized, a second rescuer should apply an Ambu Perfit ACE collar to the patient. Size the collar as determined below. Applied collar must not hyperextend patient's neck.
3. Measure the distance between an imaginary plane drawn horizontally and immediately below the patient's chin and second horizontal plane drawn immediately on top of the patient's shoulder.
4. Compare this distance with the distance from the collar sizing line to the lower aspect of the plastic collar body (not the foam).
5. Sizing the Perfit ACE collar is preset to Neckless Size 3. If a larger size collar is needed, disengage the safety locks by pulling UP on the safety buttons.
6. Adjust the collar to the appropriate size: the Perfit ACE provides 16 ratchet settings between the traditional Neckless (Size 3) and Tall (Size 6). Simply pull the collar apart until the distance between the sizing line and the plastic collar body equals your finger measurement.
7. Engage the safety locks by pushing DOWN on the safety buttons.
8. If the Perfit ACE needs to be resized, disengage the safety locks and pull "OUT" on the ratchet latches ("arrows"). The Perfit ACE may now be adjusted to smaller sizes. Reset the ratchet latches by pressing "IN" on the "arrows". Now engage the safety locks by pressing DOWN on the safety buttons.

PRESETTING TO FOUR STANDARD ADULT POSITIONS The collar can be sized to four standard settings (neckless - size 3, short - size 4, regular - size 5 and tall - size 6) by simply bringing the guide arrow in line with the middle of the number marked (3, 4, 5 and 6) on four color label. Note: The Perfit ACE collar is preset to Neckless Size 3. Reset ratchet latches (guide arrow) and safety buttons as described earlier.

Reprocessed Ambu Perfit ACE Collar

Collar Assembly

The collar is assembled as follows:

Hold the collar near the tracheal opening with one hand. Place the index finger on the foam side of the chin piece (on the center rivet) and the thumb on the plastic side of the chin piece (on the center rivet) and simply flip the chin piece from the back of the collar to the front of the collar.

This automatically forms the chin piece and places it in the position of function.

Application

Proper application of any extrication collar requires two individuals. The first rescuer should maintain stabilization and neutral alignment of the head and neck by grasping the head with a spread finger technique.

1. The second rescuer should slide the front of the collar along the patient's chest and position the chin piece. The collar body should rest on the top of the patient's shoulder and against the sternum without gaps. The patient's chin must rest securely in the chin piece in neutral alignment position.
2. While holding the front of the collar in place, wrap the back of the collar around the back of the patient's head and neck and secure to the front of the collar with the Velcro tab.
3. Adjust the Velcro tab as necessary by holding the front cutout of the collar and tightening the Velcro tab.
4. Adjustment of the size of the collar may be done on the patient as per your local protocol.

Warning

Maintain neutral head and neck alignment during the entire procedure. Once the collar is properly applied and the patient is immobilized, the head should not be released. Further immobilize the head and neck with head blocks or a head immobilizer and secure the patient to the backboard with appropriate retention straps.

Supine Application

If the patient is supine, slide the back portion of the collar directly behind the patient's neck.

The collar may be applied from either side. Once the back portion of the collar is evenly positioned behind the head, the front portion of the collar can be positioned under the chin. While maintaining the proper positioning of the collar with one hand, attach the Velcro with the other hand. Ensure that the loop Velcro tab is firmly attached and parallel to the fixed hook Velcro tab on the front of the collar.

Warning

Maintain neutral head and neck alignment during the entire procedure. Once the collar is properly applied and the patient is immobilized, the head should not be released. Further immobilize the head and neck with head blocks or a head immobilizer and secure the patient to the backboard with appropriate retention straps.

The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

This product and its packaging have been exposed to ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, proposition 65, a State of California voter initiative, requires the following notice:

Warning: this product and its packaging have been exposed to ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.