

Control-Cric™

Directions For Use

By: Pulmodyne®

Product Description:

The Control-Cric™ is a Cricothyrotomy System which verifies tracheal location during a surgical airway procedure, without the need for visualization, air aspiration, or reliance of fine motor skills.

The System includes the Cric-Knife™ and Cric-Key™.

The Cric-Knife: A 10mm long dual sided blade with an integrated sliding tracheal hook.

The Cric-Key: A pre-shaped introducer that provides airway confirmation with tactile feedback from the tracheal rings, along with a soft cric-tube with cuff.

Package Contents:

- 1 Cric-Key introducer/tube
- 1 Cric-Knife with tracheal hook
- 1 Stabilizing strap
- 1 Inflation syringe
- 1 Wedge

Instructions For Use:

1. A. Position patient supine and identify the cricothyroid membrane. Stabilize the larynx with thumb and middle finger with non-dominant hand.

B. Use the Cric-Knife to incise skin. A vertical skin incision from mid-thyroid cartilage to the cricoid cartilage is recommended (usually about 2 finger breaths). **In patients with a thick neck a longer incision may be needed. A horizontal skin incision may be used when landmarks are evident.**

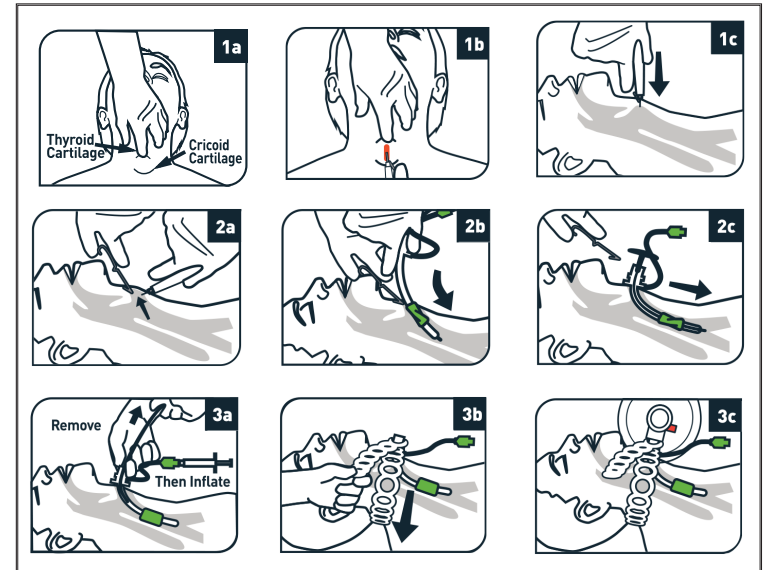
C. After palpating the cricothyroid membrane, turn the Cric-Knife to a horizontal position over the cricothyroid membrane. Push the blade downward, perpendicular to the trachea, until the blade is fully inserted and the airway is entered.
2. A. While maintaining downward force, slide the tracheal hook down the handle with your thumb until the hook is felt to enter the trachea, and it disengages from the handle. Grab the tracheal hook with the non-dominant hand, lifting up on the thyroid cartilage.

B. Insert Cric-Key through incision. Confirm placement by moving the device along anterior wall of trachea to feel for the tracheal rings. Indicators of incorrect placement could be: tenting of the skin, difficulty advancing the Cric-Key tube, or lack of tactile feedback from the tracheal rings.

C. Once placement has been confirmed, advance Cric-Key tube to the flange. Stabilize the Cric-Key tube and pivot the tracheal hook toward the patient's shoulder to remove from airway.
3. A. While stabilizing the Cric-Key tube, remove the Cric-Key introducer. Inflate the cuff until resistance is met.

B. Confirm placement. Secure with stabilizing strap.

C. Attach manual resuscitator. Ventilate and auscultate lung fields. Reassess.



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Recommendations:


- Procedure is best done with the patient's head extended (if cervical spine is intact). If this is not advisable, and if two people are available, one should place both thumbs on patient's maxillae (cheekbones) and your index and middle fingers on both sides of the mandible (lower jaw) where it angles toward the ear. Apply upward pressure with your fingers without tilting the head.
- Use provided 15mm disconnect wedge to disengage attachment from 15mm connection.

Cautions:

- Federal Law (USA) restricts this device to sale by or on the order of a physician
- This product must be used by personnel thoroughly trained in the techniques of emergency airway management.
- Over inflation of cuff may cause cuff failure or tracheal mucosal injury.

Warnings:

- Store in clean, dry conditions away from excessive heat and light.
- Consideration should be given to:
 - Distorted anatomy
 - Subcutaneous abscess
 - Hematoma
 - Post-operative scarring
 - Coagulopathies or systemic thrombolytic therapy
- Excessive force can cause injury to laryngeal cartilages.
- Scalpel and hook insertion through the cricothyroid membrane should be perpendicular to the larynx to avoid injuring the vocal cords.
- Improperly inflated cuff may result in aspiration. It is recommended to monitor the indwelling cuff pressure regularly.
- Removal of tracheal hook prior to full insertion of Cric-Key tube can result in damaged cuff.
- Horizontal skin incision may be associated with a greater risk of bleeding.
- Cuff should be filled with saline in case of altitude change.

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