

INK COLOR	BLACK
PAPER STOCK: COLOR	WHITE
PAPER STOCK: WEIGHT	20 LB.
LABEL/INSERT SIZE	8.5" X 11"

# RELEASE FOR PRODUCTION

## Control-Cric™

### Directions For Use

**Product Description:**  
The Control Cric™ is a Cricothyrotomy System which verifies tracheal location during a surgical airway procedure, without the need for visualization, an aspirator, or reliance of the operator skills.

**The System includes the Cric-Knife™ and Cric-Key™.**  
The Cric-Knife: A 19mm 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 cuff tube with cuff.

**Package Contents:**

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

**Instructions For Use:**

- 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 breadths). 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.
- 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 expose from airway.
- 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.

By: **Pulmonary®**

**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 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 regional injury.
- Dispose of Control Cric according to local established protocols when finished with use.

**Warnings:**

- Store in clean, dry conditions away from excessive heat and light.
- Considerations should be given to:
  - Disrupts a sealant
  - Subcutaneous abscess
  - Hematuria
  - Respiratory stridor
  - Coagulopathy 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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NOTE: REFER TO FILE "2851C.pdf" FOR ARTWORK

NOTE: PART TO BE FOLDED ON DASHED LINES

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TOLERANCES:				
ANGULAR ±0.5°		COMMENTS: UPDATED DFU TO ADD ADDITIONAL CE REQUIREMENT INFORMATION		
TWO PLACE DECIMAL ±0.010 THREE PLACE DECIMAL ±0.005				
APPROVED VENDOR COMBAT MEDICAL DYNAMARK		TITLE:  <b>ACUTE CARE CONTROL CRIC DFU</b>		
MATERIAL/VENDOR ITEM NUMBER PAPER (70 g/m2)				
COLOR WHITE		SIZE <b>A</b>	DWG. NO. <b>2851</b>	REV <b>C</b>
DO NOT SCALE DRAWING		SCALE: 1:2	SHEET 1 OF 1	
DRAWN Kevin Sempstrott		DATE 10/31/2016		
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