COOK MEDICAL

Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous

Instructions for Use

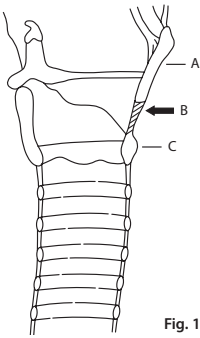


Fig. 1

A. Thyroid Cartilage
B. Cricothyroid Membrane Access Site
C. Cricoid Cartilage

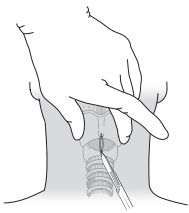


Fig. 2

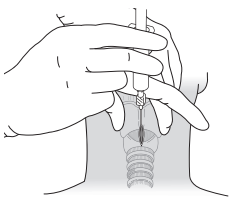


Fig. 3

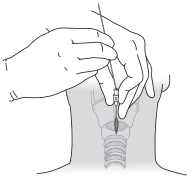


Fig. 4

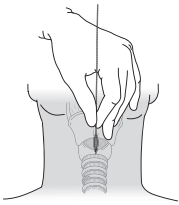
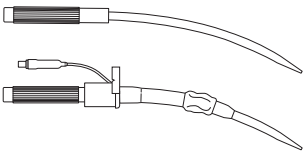
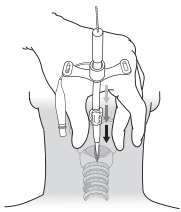


Fig. 5



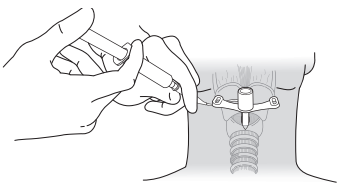
Cuffed Airway Catheter

Fig. 6



Cuffed Airway Catheter

Fig. 7



Cuffed Airway Catheter

Fig. 8

MELKER CUFFED EMERGENCY CRICOTHYROTOMY CATHETER SET – PERCUTANEOUS

CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner).

DEVICE DESCRIPTION

Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous consists of components used for Seldinger placement of a cricothyrotomy catheter. The cuffed catheter has an inner diameter of 5 mm.

COMPONENTS

- Melker Cuffed (5 mm) Cricothyrotomy Catheter
- Introducer needle
- PTFE catheter introducer needle
- Syringe
- Mini scalpel
- Wire guide
- Curved dilator
- Tracheostomy tape

INTENDED USE

The Melker Cuffed Emergency Cricothyrotomy Catheter Set – Percutaneous is intended to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing the percutaneous entry (Seldinger) technique via the cricothyroid membrane.

CONTRAINDICATIONS

No absolute contraindications known.

RELATIVE CONTRAINDICATIONS

- Tracheal transection
- Laryngeal fracture
- Preexisting laryngeal pathology
- Preexisting tracheal pathology
- Coagulopathy

WARNINGS

Consideration should be given to the following medical and anatomic conditions and/or therapies:

- Unfavorable anatomy (e.g., short neck, morbid obesity and/or aberrant anatomy)
- Subcutaneous abscess
- Hematoma
- Scarring
- Irradiated tissue
- Coagulopathies or systemic thrombolytic therapy
- Inflation of the cuff with more than 20 mL is not recommended

PRECAUTIONS

- This product is intended for use by clinicians trained and experienced in emergency airway management techniques. Standard emergency techniques for the placement of Seldinger airway catheters should be employed.
- Patients in need of cricothyrotomy may have significant spinal injury. In patients who have sustained significant trauma, the cervical spine should be immobilized throughout the procedure, if possible.
- Whenever possible and appropriate, utilize aseptic technique and local anesthetic for the procedure.
- The potential effects of phthalates on pregnant/nursing women or children have not been fully characterized and there may be concern for reproductive and developmental effects.

POTENTIAL ADVERSE EVENTS

- Bleeding
- Hematoma
- Failed tube placement
- Subcutaneous emphysema
- Tracheoesophageal fistula
- Pneumomediastinum
- Pneumothorax
- Vocal cord injury
- Voice change or dysphonia
- Infection
- Subglottic/glottic stenosis
- Catheter dislodgement

MRI SAFETY INFORMATION

Nonclinical testing has demonstrated that the Melker Cuffed Emergency Cricothyrotomy Catheter is **MR Conditional** according to ASTM F2503. A patient with this device may be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 tesla or 3.0 tesla only
- Maximum spatial gradient magnetic field of 1900 gauss/cm for a 1.5T / 3.0T MR system, or less
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of ≤ 2.0 W/kg (Normal Operating Mode) for 15 minutes of continuous scanning

As part of the conditions for safety, the Luer valve of the cuff inflation line shall be taped down (e.g., to the patient's shoulder) prior to the patient entering the MR environment.

Under the scan conditions defined above, Melker Cuffed Emergency Cricothyrotomy Catheter is expected to produce a maximum temperature rise of 1.8°C after 15 minutes of continuous scanning.

The image artifact extends approximately 4 mm from the tapered tube portion of the Melker Cuffed Emergency Cricothyrotomy Catheter and approximately 57 mm from the Luer valve of the cuff inflation line as found during nonclinical testing when imaged with a gradient echo pulse sequence and a 3.0 tesla MR system. The image artifact may obscure surrounding anatomy. The Luer valve of the cuff inflation line should be placed away from the intended region to be imaged.

For US Patients Only

Cook recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manners:

Mail: MedicAlert Foundation International
2323 Colorado Avenue
Turlock, CA 95382

Phone: 888-633-4298 (toll free)
209-668-3333 from outside the US

Fax: 209-669-2450

Web: www.medicalert.org

INSTRUCTIONS FOR USE

1. Identify the cricothyroid membrane between the cricoid and thyroid cartilages. (**Fig. 1**)
2. Firmly immobilize the thyroid cartilage with the first and third fingers of the non-dominant hand, leaving the second finger free for palpation of the cricothyroid membrane. Make a vertical, midline skin incision down to the depth of the thyroid and cricoid cartilages. (**Fig. 2**) **NOTE:** Ensure that the incision is sufficient in size to allow passage of the dilator and airway catheter.
3. Attach the supplied syringe to either the introducer needle or the catheter introducer needle and advance the needle through the incision into the airway at a 45 degree angle to the frontal plane in a caudad direction, in the midline. (**Fig. 3**) **NOTE:** Entrance into the airway can be confirmed by aspiration on the syringe, resulting in free air return.
4. If using the catheter introducer needle, remove the syringe and needle, leaving the catheter in place. If using the introducer needle, remove only the syringe, leaving the needle in place.
5. Advance the soft, flexible end of the wire guide through the catheter or needle and into the airway several centimeters. (**Fig. 4**)
6. Remove the catheter or needle, leaving the wire guide in place. (**Fig. 5**)
7. Advance the handled dilator, tapered end first, into the connector end of the airway catheter until the handle stops against the connector (if necessary). (**Fig. 6**) **NOTE:** This step may be performed prior to beginning the procedure. Use of lubrication on the surface of the dilator may enhance fit and placement of the airway catheter.
8. Advance the airway catheter/dilator assembly over the wire guide until the proximal stiff end of the wire guide is completely through and visible at the handle end of the dilator. (**Fig. 7**) **It is important to continually visualize the proximal end of the wire guide during the airway insertion procedure to prevent its inadvertent loss into the trachea.**
9. Maintaining wire guide position, continue to advance the airway catheter/dilator assembly over the wire guide completely into the trachea. (**Fig. 7**) **Take care not to advance the tip of the dilator beyond the tip of the wire guide within the trachea.**
10. Remove the wire guide and dilator simultaneously.
11. Inflate the cuff with air using a syringe; 8-10 mL volume in the cuff will yield a cuff diameter of 22-29 mm. (**Fig. 8**) The inflation and deflation procedure is at the discretion of the clinician.

WARNING: Inflation of the cuff with more than 20 mL is not recommended.

12. Fix the Melker catheter in place with the cloth tracheostomy tape strip in a standard fashion.
13. Connect the Melker catheter, using its standard 15 mm connector, to an appropriate ventilatory device.

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

A symbol glossary can be found at https://cookmedical.com/symbol-glossary

This symbol on the label indicates that this device contains phthalates. Specific phthalates contained in the device are identified beside or below the symbol by the following acronyms:

- **BBP: Benzyl butyl phthalate**
- **DBP: Di-n-butyl phthalate**
- **DEHP: Di(2-ethylhexyl) phthalate**
- **DIDP: Diisodecyl phthalate**
- **DINP: Diisononyl phthalate**
- **DIPP: Diisopentyl phthalate**
- **DMEP: Di(methoxyethyl) phthalate**
- **DNOP: Di-n-Octyl phthalate**
- **DNPP: Di-n-pentyl phthalate**

MR Conditional

Manufacturer
COOK INCORPORATED
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Bloomington, IN 47404 U.S.A.

www.cookmedical.com

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