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Melker Universal Cricothyrotomy Catheter Set

Instructions for Use

COOK[®]



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MELKER UNIVERSAL CRICOTHYROTOMY CATHETER SET

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care.

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

DEVICE DESCRIPTION

The Melker Universal Cricothyrotomy Catheter Set consists of components used for both Seldinger and surgical placement of a cricothyrotomy tube including:

- #15 and #11 scalpels
- 12 cc syringe
- 18 gage introducer needle
- 18 gage TFE catheter introducer needle
- Amplatz Extra Stiff Wire Guide .038 inch
- Curved Seldinger dilator
- Curved blunt dilator
- Airway catheter
- Tracheal hook
- Trousseau dilator
- Cloth tracheostomy tape

Set also includes a drape and gauze pads

INTENDED USE

The Melker Universal Cricothyrotomy Catheter Set has been designed to establish emergency airway access when endotracheal intubation cannot be performed. Airway access is achieved utilizing either percutaneous entry (Seldinger) technique or surgical technique via the cricothyroid membrane.

The product is intended for use by physicians trained and experienced in proper emergency airway techniques. Standard emergency techniques for the placement of a Seldinger or surgical cricothyrotomy should be employed.

CONTRAINDICATIONS

No absolute contraindications known.

WARNINGS

- The Melker Universal Cricothyrotomy Catheter Set is not specifically designed for pediatric applications. Use with pediatric patients should be determined by attending physician. Use in children below the age of 12 is not recommended.
- Consideration should be given to the following medical and anatomic conditions:
 - Distorted anatomy
 - Subcutaneous abscess
 - Hematoma
 - Post-operative scarring/radiation
 - Coagulopathies or systemic thrombolytic therapy

PRECAUTIONS

- 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.

INSTRUCTIONS FOR USE

Seldinger Technique

1. Identify the cricothyroid membrane between the cricoid and thyroid cartilages.



Figure 1

2. Carefully palpate the cricothyroid membrane and while stabilizing the cartilage, make a vertical incision in the midline using the #15 short handle scalpel blade. A sufficient incision to allow the passage of the dilator and cuffed airway is recommended. (Figure 1)

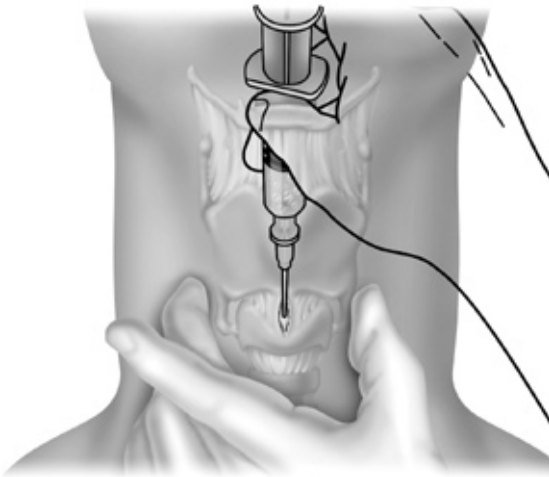


Figure 2

3. With the supplied syringe attached to the 18 gage TFE catheter introducer needle or the 18 gage thinwall introducer needle, advance it through the incision into the airway at a 45° angle to the frontal plane in the midline in a caudad direction. **When advancing the needle forward, verification of entrance into the airway can be confirmed by aspiration on the syringe resulting in free air return.** (Figure 2)

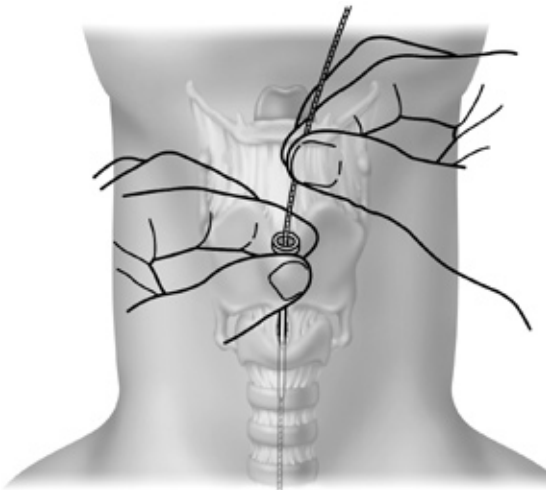


Figure 3

4. Remove the syringe and needle, leaving the TFE catheter in place. If using the 18 gage thinwall introducer needle, remove only the syringe leaving the needle in place. Advance the soft, flexible end of the wire guide through the TFE catheter and into the airway several centimeters. (Figure 3)

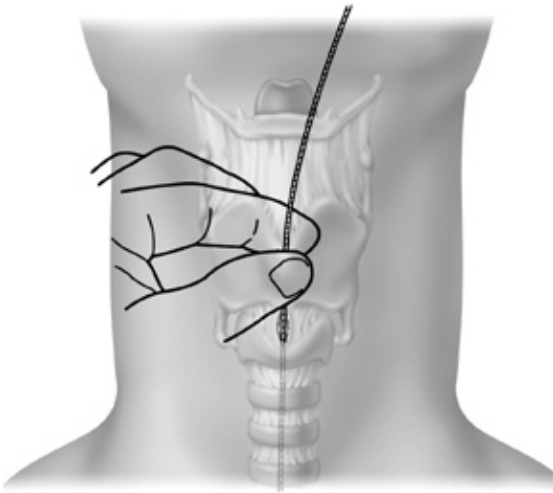


Figure 4

5. Remove the TFE catheter or the needle, leaving wire guide in place. (Figure 4)

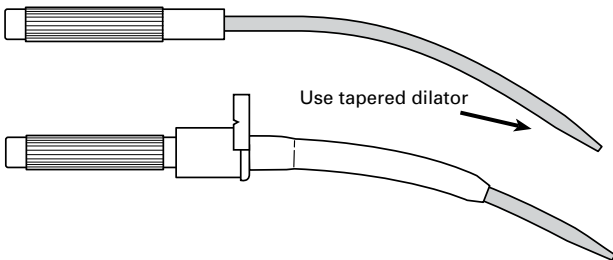


Figure 5

6. Advance the handled dilator, tapered end first, into the connector end of the airway catheter until the handle stops against the connector.

NOTE: This step may be performed prior to beginning procedure. Use of lubrication on the surface of the dilator may enhance fit and placement of the cuffed emergency airway catheter. (Figure 5)

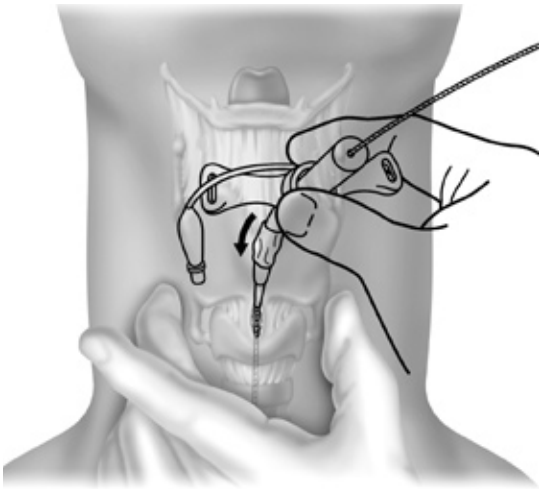


Figure 6

7. Advance the cuffed emergency airway access 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. **It is important to always visualize the proximal end of the wire guide during the airway insertion procedure to prevent its inadvertent loss into the trachea.**

Maintaining the wire guide position, advance the cuffed emergency airway access assembly over the wire guide with a reciprocating motion, and completely into the trachea. **Care should be taken not to advance the tip of the dilator beyond the tip of the wire guide within the trachea.** (Figure 6)

8. Remove the wire guide and dilator simultaneously.

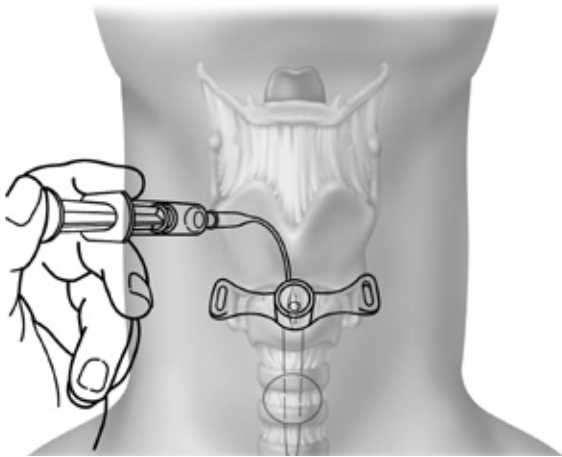


Figure 7

9. Inflate the cuff using a syringe; 8-10 cc volume in the cuff will yield a cuff diameter of 22-29 mm. The inflation and deflation procedure is at the discretion of the physician. (Figure 7)

Warning: Inflation of the cuff with more than 20 cc is not recommended.

10. Fix the emergency airway catheter in place with the cloth tracheostomy tape strip in a standard fashion.
11. Connect the emergency airway catheter, using its standard 15 mm adapter to an appropriate ventilatory device.

Surgical Technique

1. Identify the cricothyroid membrane between the cricoid and thyroid cartilages.

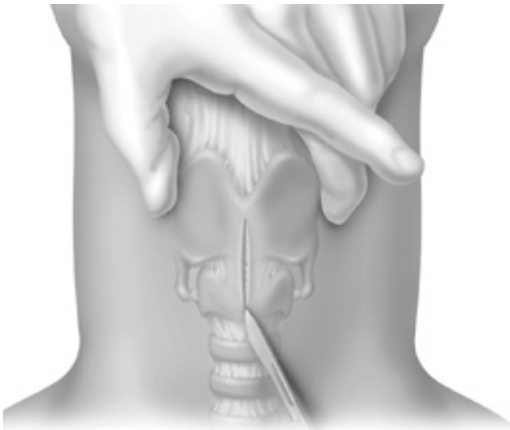


Figure 8

2. Firmly immobilize the larynx and make a vertical, midline skin incision down to the depth of the laryngeal structures. (Figure 8)

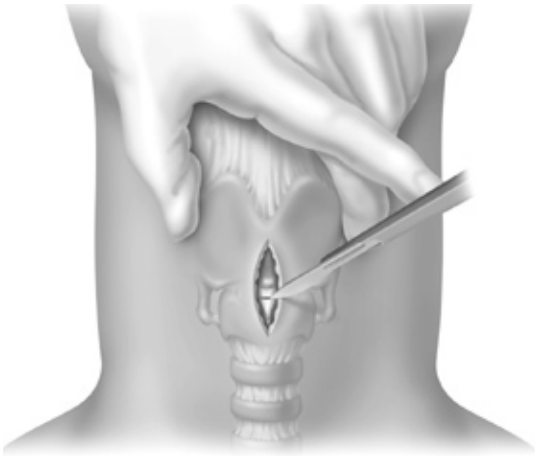


Figure 9

3. Make a horizontal membrane incision near the inferior edge of the cricothyroid membrane. The index finger may be swung aside or may remain in the wound, palpating the inferior edge of the thyroid cartilage, to “guide” the scalpel to the membrane. A low cricothyroid incision avoids the superior cricothyroid vessels, which run transversely near the top of the membrane. (Figure 9)



Figure 10

4. Orient the tracheal hook transversely during insertion. After insertion, apply cephalad traction to the inferior margin of the thyroid cartilage. (Figure 10)

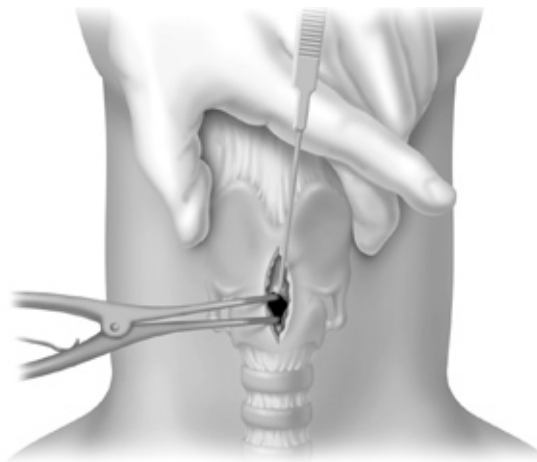


Figure 11

5. Insert the Trousseau dilator a short distance into the incision. In this orientation, the dilator enlarges the opening vertically. (Figure 11)

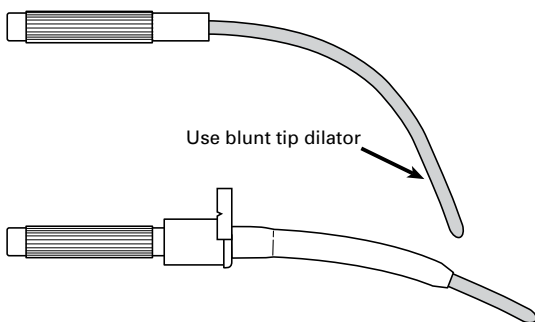


Figure 12

6. Advance the handled dilator with the blunt tip, blunted end first, into the connector end of the airway catheter until the handle stops against the connector.

CAUTION: Use only blunt tip dilator with surgical procedure.

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 emergency airway catheter. (Figure 12)

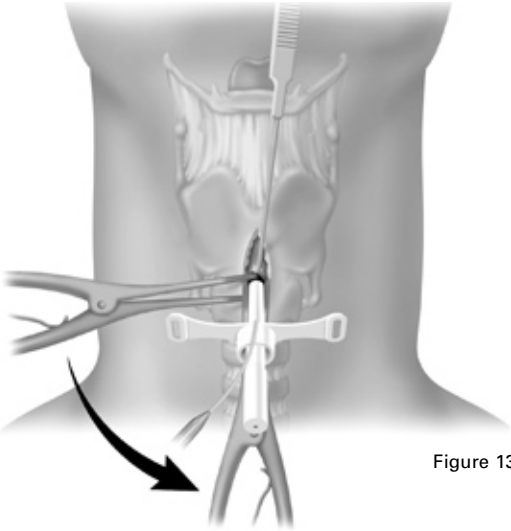


Figure 13

- 7. Insert the cuffed emergency airway access assembly. As the airway assembly is passed between the blades of the Trousseau dilator, rotate the Trousseau dilator 90 degrees counterclockwise to orient the blades longitudinally in the airway to facilitate passage of the airway assembly. (Figure 13)

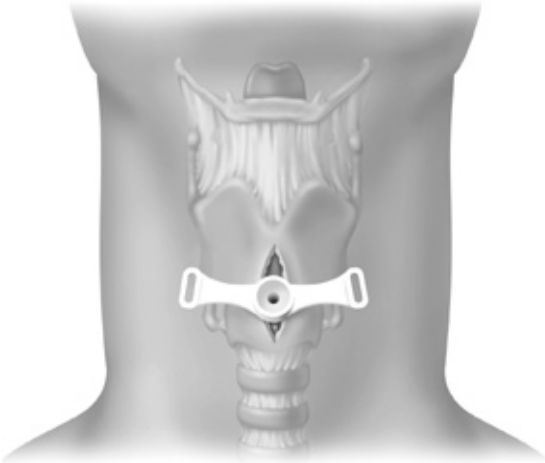


Figure 14

- 8. Fully insert the cuffed emergency airway access assembly. Remove dilator and instruments. (Figure 14)

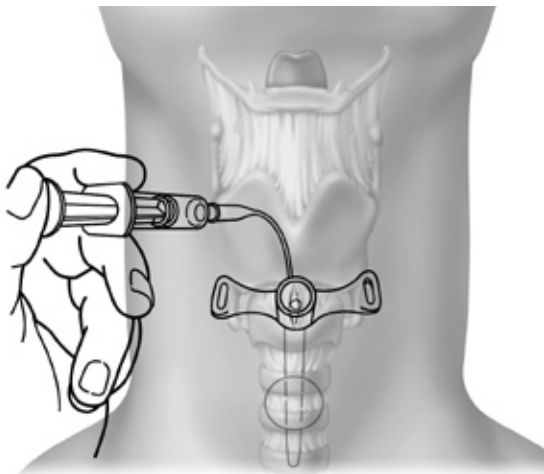


Figure 15

- Inflate the cuff using a syringe; 8-10 cc volume in the cuff will yield a cuff diameter of 22-29 mm. The inflation and deflation procedure is at the discretion of the physician. (Figure 15)

Warning: Inflation of the cuff with more than 20 cc is not recommended.

- Fix the emergency airway catheter in place with the cloth tracheostomy tape strip in a standard fashion.
- Connect the emergency airway catheter, using its standard 15 mm adapter 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 or 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.