COOK MEDICAL

Cook Retrograde Intubation Sets with Rapi-Fit® Adapters

Instructions for Use

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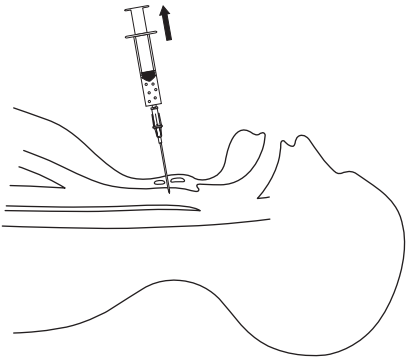

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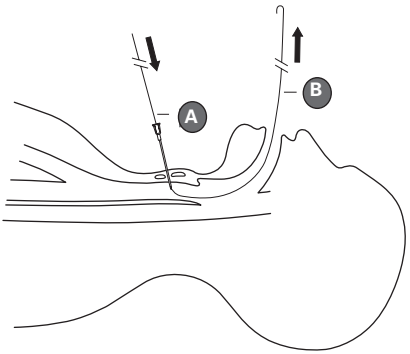

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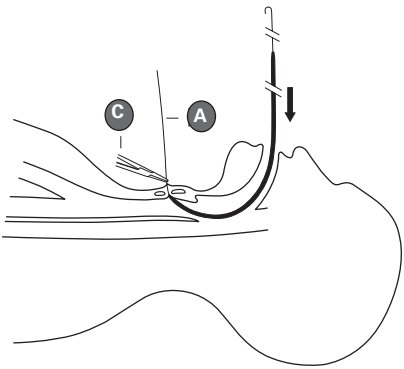
A. Proximal Positioning Mark
B. Distal Positioning Mark
C. Hemostat



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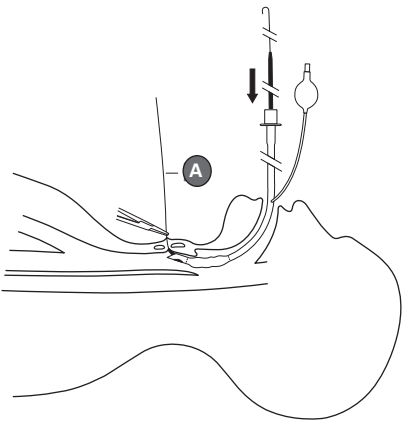

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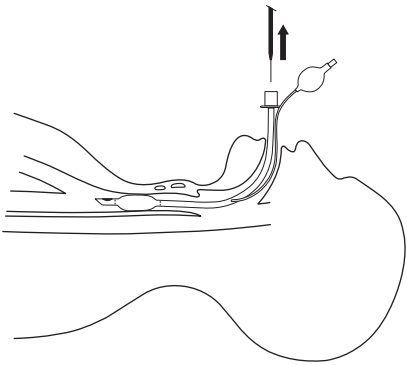
A. Proximal Positioning Mark



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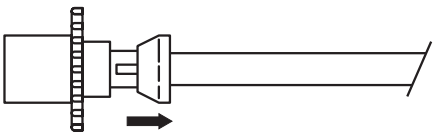

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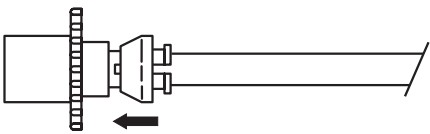

7

COOK RETROGRADE INTUBATION SETS WITH RAPI-FIT® ADAPTERS

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

The Cook Retrograde Intubation Sets contain a taper-tipped, radiopaque intubation catheter and a wire guide with positioning marks to help facilitate intubation of an endotracheal tube (ETT). The device and the components do not contain natural latex.

The device consists of the following components:

- Intubation catheter
- Wire guide
- Introducer needle
- Catheter introducer needle
- Syringe
- Hemostat
- Rapi-Fit adapter - 15 mm connector (in 14 French size only)
- Rapi-Fit adapter - Luer lock connector (in 14 French size only)

INTENDED USE

The Cook Retrograde Intubation Set is intended to assist in intubation during difficult airway access procedures in adult and pediatric patients.

The 6 French intubation catheter is recommended for placement of an endotracheal tube with an inner diameter of 2.5 mm or larger.

The 11 French intubation catheter is recommended for placement of an endotracheal tube with an inner diameter of 4.0 mm or larger.

The 14 French intubation catheter is recommended for placement of an endotracheal tube with an inner diameter of 5.0 mm or larger.

When used for high-pressure oxygenation with a Luer lock connector, the 14 French intubation catheter is recommended for patients older than 12 years of age.

CONTRAINDICATIONS

- Coagulopathy
- Laryngotracheal disease
- Obscure cricothyroid anatomy
- Infection of cricothyroid membrane
- Mass (i.e., goiter)
- Lack of anatomical markers
- Impossible access to the airway

WARNINGS

- Clinicians should first select the appropriate sized endotracheal tube (ETT) based on individual patient anatomy, weight, and recommendations from the manufacturer of the ETT. The appropriate sized intubation catheter for the retrograde intubation procedure may then be determined based on the chosen ETT.
- Do not advance the intubation catheter beyond the carina.
- Attention should be paid to the insertion depth of the intubation catheter into the patient's airway and correct tracheal position of replacement endotracheal tube (ETT). Markers on the intubation catheter refer to distance from the distal tip of intubation catheter.
- Take care to avoid injuring the epiglottis and glottis, and to avoid perforating the sinus pyriformis, trachea, or bronchus while using this device.

For the 14.0 Fr Retrograde Intubation Catheter:

- Use of the Rapi-Fit adapter for oxygenation may be associated with a risk of barotrauma.
- To avoid barotrauma, ensure that the tip of the intubation catheter is always above the carina, preferably 2-3 cm.
- Ensure proper sizing of the intubation catheter within an ETT.
- Use of an oxygen source should be considered only if the patient has sufficient egression of the insufflated gas volume.
- Oxygen insufflation may not be appropriate for all patient subgroups and with all products. Please refer to the Catheter Oxygenation Table for product and patient subgroup details.
- If a high-pressure oxygen source is used for insufflation (e.g., jet ventilator), begin at a lower pressure (i.e., 5 psi) and work up gradually. Rising chest wall, pulse oximetry, and oral air flow should be carefully monitored.
- Ensure that the Rapi-Fit Adapter is securely connected to the intubation catheter prior to oxygen delivery. Failure to properly secure the adapter to the intubation catheter may result in hypoxia and serious adverse events.
- High pressure oxygenation with Luer lock connector should only be used in patients older than 12 years old. If used in patients 12 years old or younger, the maximum airway pressure may be higher than 28 cm H_20.

PRECAUTIONS

- This product is intended for use by clinicians trained and experienced in retrograde intubation techniques. This device is limited to use in hospitals, surgical centers, and acute care centers. Standard techniques for retrograde intubation should be employed.
- Patients in need of retrograde intubation 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.

POTENTIAL ADVERSE EVENTS

- Barotrauma
- Esophageal perforation
- Airway bleeding
- Pneumomediastinum
- Pneumothorax
- Hypoxia
- Subcutaneous emphysema
- Infection
- Hematoma
- Catheter dislodgment or migration
- Wire guide dislodgment or migration
- Failed endotracheal tube placement

PRODUCT RECOMMENDATIONS AND SPECIFICATIONS

Recommended endotracheal tube size selection

Real Part Number (RPN)	Minimum Endotracheal tube size (ID)
C-RETRO-6.0-50-38J-110-01	2.5mm
C-RETRO-11.0-70-38J-110-01	4.0mm
C-RETRO-14.0-70-38J-110-CAE-01	5.0mm

INSTRUCTIONS FOR USE

1. Prepare the access site in a standard sterile fashion. Select the appropriate sized endotracheal tube and prepare it by applying sterile lubricant to the distal tip.
2. Advance either the introducer needle or the catheter introducer needle (attached to syringe) in a cephalad direction through the cricothyroid membrane and into the larynx. Confirm positioning via free flow aspiration of air into the syringe. (**Fig 1**)
3. If using the introducer needle, remove the syringe, leaving the needle in place. If using the catheter introducer needle, remove the inner needle and syringe, leaving the catheter introducer in place.
4. Advance the "J" end of the wire guide through the catheter or needle and into the upper airway in a cephalad direction. The tip of wire guide can be retrieved through the patient's mouth or nose, using the hemostat or an equivalent retrieval device such as a pair of forceps. **NOTE:** The black positioning marks on wire guide should be visible both at the access site and where the wire guide exits the nares or mouth. (**Fig. 2**) This will ensure that enough wire is exposed orally or nasally for control of subsequent intubation catheter introduction.
5. Remove the catheter or needle, leaving the wire guide in place.
6. Secure the position of the wire guide by clamping the hemostat flush with the skin at the insertion site. Advance the intubation catheter antegrade over the wire guide via the mouth or nose and into the trachea until tenting is noted at the cricothyroid access site. (**Fig. 3**) **NOTE:** Alternatively, after initial wire guide positioning, a bronchoscope may be used for direct visualization of endotracheal tube placement. A wire guide may be placed through the suction port of the scope.
7. With the intubation catheter in position, prepare and advance the endotracheal tube over the intubation catheter and into position below the vocal cords. (**Fig. 4**) **NOTE:** Always maintain control and position of the wire guide during advancement of the endotracheal tube. **NOTE:** It is recommended that a sterile lubricant be applied to the tip of the endotracheal tube prior to advancing the tube.
8. Remove the wire guide and intubation catheter from the endotracheal tube. (**Fig. 5**)
9. Advance the endotracheal tube to optimal position, and inflate the balloon cuff if provided.
10. Confirm correct position of the endotracheal tube in accordance with the endotracheal tube device labeling and secure in standard fashion.

Use of the Rapi-Fit Adapter with 14.0 French Intubation Catheter

Rapi-Fit adapters should only be used when oxygen requirements are high and intubation is unsuccessful. Use of an oxygen source should only be considered if the patient has sufficient egression of the insufflated gas volume. If an oxygen source is used for insufflation, begin at a lower pressure (e.g., 5 psi) and work up gradually. Observe the chest for outward and inward movements to confirm oxygen insufflation and egression. Pulse oximetry and oral air flow should be carefully monitored as well. In cases of upper airway obstruction, gas discharge from the patient's lungs may require more time.

1. To attach the Rapi-Fit Adapter, position the adapter on the intubation catheter, then push the white collar forward and lock into position. **(Fig. 6**)
2. To remove the adapter, pull the white collar back to release, and then remove from the intubation catheter. **(Fig. 7)**

CATHETER OXYGENATION WITH 14.0 FRENCH INTUBATION SET

The 14 French Retrograde Intubation Set is designed for both positive airway pressure ventilation (Rapi-Fit adapter - 15 mm connector) and jet ventilation (Rapi-Fit adapter - Luer lock connector) for both adult and pediatric patients. In the table below, delivered minute volume and measured average maximum airway pressure are given for jet ventilation in adult and pediatric patients with healthy lung tissue.

Catheter Oxygenation

Real Part Number (RPN)	Patient Subgroup and Age Range	Delivered Minute Volume[1] (L/min)	Measured Average Maximum Airway Pressure[1] (cm H_2O)	
			Mean	Maximum
C-RETRO-14.0-70-38J-110-CAE-01	Adolescent > 12 years through 21 years	2.9	14.3	15.0
	Adult > 21 years	9.0	12.1	13.4

1 The test conditions were used in an active model. See *Testing Conditions* table for additional details.

The presented values are mean values. The following testing conditions were used in an active model mode, tested with ASL 5000, Ingmar Medical, Ltd, for each patient subgroup.

Testing Conditions

Input pressure was set to 50 psi for both patient type models.

Patient Type	Model Body Weight (kg)	Inspiratory Time(s)	Expiratory Time(s)	Breaths per minute	Resistance (cm H_2O/L/s)	Lung Compliance (mL/cm H_2O)
Adolescent (> 12 years to 21 years)	50	0.9	2.1	20	5	40
Adult (> 21 years)	80	1.0	4.0	12	3	100

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

Manufacturer
COOK INCORPORATED
750 Daniels Way
Bloomington, IN 47404 U.S.A.

www.cookmedical.com

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