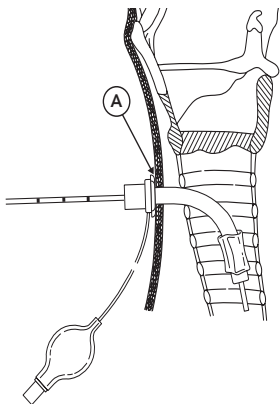


Weinmann Tracheostomy Exchange Set

Instructions for Use

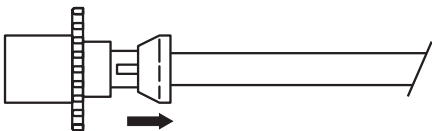


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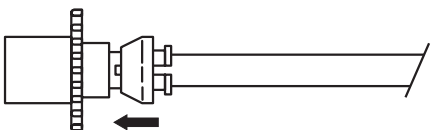


A. Skin Level

1



2



3

WEINMANN TRACHEOSTOMY EXCHANGE SET

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 Weinmann Tracheostomy Exchange Set consists of a Ciaglia Blue Rhino® Tracheostomy Dilator, Cook Airway Exchange (CAE) Catheter, two Rapi-Fit® adapters (one 15 mm connector and one Luer lock connector), and two loading dilators (26 and 28 French). (See Product Recommendations for compatible tracheostomy tubes).

INTENDED USE

The Weinmann Tracheostomy Exchange Set is intended for adult tracheostomy tube exchange.

CONTRAINDICATIONS

- Pediatric applications
- Positive End Expiratory Pressure (PEEP) value greater than or equal to 20
- Uncorrected coagulopathy
- Pre-existing infection at the tracheostomy site
- Pre-existing malignancy at the tracheostomy site
- Unstable cervical spine fracture

WARNINGS

- Only physicians trained and experienced in percutaneous tracheostomy techniques should use this device.
- Exercise care to ensure that the components used in each step are properly positioned within the trachea. Improper placement of the components may lead to potentially life-threatening injury.
- Improper dilation technique or tracheostomy tube placement can lead to delayed complications (e.g., Corkscrew stenosis).
- Aseptic technique must be strictly adhered to during placement of this device.
- Possible allergic reactions (e.g., to butyl rubber) should be considered.
- Attention should be paid to the insertion depth of the Cook Airway Exchange (CAE) Catheter into the patient's airway. Advancing the catheter beyond the carina may introduce additional procedural risks and trauma. Markers on the CAE Catheter refer to the distance from the distal tip of the catheter.
- Take care to avoid injuring the trachea, bronchi, or lung parenchyma while using this device.
- To avoid barotrauma or other airway complications, ensure that the distal tip of all components is always maintained above the carina, preferably 2-3 cm.
- Use of the CAE Catheter with Rapi-Fit adapter for oxygenation may be associated with a risk of barotrauma.
- Use of an oxygen source should be considered only if the patient has sufficient egression of the insufflated gas volume.
- 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 CAE Catheter prior to oxygen delivery. Failure to properly secure the adapter to the CAE Catheter may result in hypoxia and serious adverse events.

PRECAUTIONS

- Tracheostomy tube should fit snugly to the loading dilator for insertion.
- Generous lubrication to the surface of the loading dilators will enhance fit and placement of the tracheostomy tube.
- Loading dilators are designed to be inserted within the tracheostomy tube only. Loading dilators should not be used for the creation of a tracheal stoma.
- This product is intended for use by physicians trained and experienced in percutaneous tracheostomy techniques. Standard techniques for percutaneous placement of tracheostomy tubes should be employed.
- Do not resterilize components.
- Tracheostomy tube position should be verified by a chest X-ray.
- Take care not to advance the Ciaglia Blue Rhino Dilator too far into the patient's airway.
- This product is not intended for intravascular use.
- The CAE Catheter (with Rapi-Fit adapters) should only be used when oxygen requirements are high and exchange of the tracheostomy tube encounters complications and/or is unsuccessful.

POTENTIAL ADVERSE EVENTS

- Barotrauma
- Pneumothorax
- Hypoxia

- Perforation of the trachea, bronchi, or lung parenchyma
- Catheter migration
- Failed tracheostomy tube placement

PRODUCT RECOMMENDATIONS

Recommended Loading Dilator sizes and associated tracheostomy tubes

Loading Dilator	Compatible Jackson Tracheostomy Tube Size
26 French	6
28 French	8

INSTRUCTIONS FOR USE

Tracheostomy Tube Exchange

1. Insert the appropriate size loading dilator into inner lumen of the replacement tracheostomy tube.
2. Upon disconnection of the tracheostomy tube from mechanical ventilatory support, insert the Cook Airway Exchange (CAE) Catheter down the lumen of the existing tracheostomy tube. The distal tip of the exchange catheter should be placed approximately 2-3 cm beyond the distal end of the tracheostomy tube, using the markings on the catheter as a guide. To avoid barotrauma, ensure that the tip of the CAE Catheter is always above the carina.
NOTE: See tracheostomy tube manufacturer's specifications for the length of the tracheostomy tube prior to the exchange procedure. Based on the length of the tracheostomy tube, advance the catheter approximately 3 cm beyond the distal tip of the tube. The skin level (**Fig. 1**) may be used as a reference for the CAE insertion depth markings.
3. Depending on the patient's spontaneous ventilatory capacity, oxygenation may be delivered through the CAE Catheter utilizing a supplied Rapi-Fit adapter connected to an appropriate oxygen source (see Use of Rapi-Fit Adapter and Catheter Oxygenation Section).
NOTE: The CAE Catheter (with Rapi-Fit adapters) should only be used when oxygen requirements are high and exchange of the tracheostomy tube encounters complications and/or is unsuccessful.
4. Deflate the existing tracheostomy tube balloon; temporarily detach the manual resuscitator; and withdraw the tracheostomy tube over the CAE Catheter. If utilized, the Rapi-Fit Adapter shall be removed from the CAE Catheter prior to the withdrawal of the tracheostomy tube.
5. Position the replacement tracheostomy tube with loading dilator over the CAE Catheter while maintaining the position of the CAE Catheter within the airway.
6. Advance the tracheostomy tube with loading dilator as a unit over the CAE Catheter and into the trachea, up to the flange of the tracheostomy tube.
7. Inflate the cuff and secure the replacement tracheostomy tube.
8. Remove the CAE Catheter and loading dilator. Re-institute mechanical ventilatory support.
9. Clinically and radiologically confirm position of tracheostomy tube.

Tracheostomy Tube Exchange with Tracheal Stomal Dilation

If tracheal stoma dilation is necessary due to narrowing or anticipated resistance, the trachea can be dilated using the Ciaglia Blue Rhino dilator.

1. Upon disconnection of the tracheostomy tube from mechanical ventilatory support, insert the Cook Airway Exchange (CAE) Catheter down the lumen of the existing tracheostomy tube. The distal tip of the exchange catheter should be placed approximately 2-3 cm beyond the distal end of the tracheostomy tube, using the markings on the catheter as a guide. To avoid barotrauma, ensure that the tip of the CAE Catheter is always above the carina.
NOTE: See tracheostomy tube manufacturer's specifications for the length of the tracheostomy tube prior to the exchange procedure. Based on the length of the tracheostomy tube, advance the catheter approximately 3 cm beyond the distal tip of the tube. The skin level (**Fig. 1**) may be used as a reference for the CAE insertion depth markings.
2. Deflate the existing tracheostomy tube balloon and withdraw the tracheostomy tube over the CAE Catheter.
3. Activate the hydrophilic coating by immersing the distal end of the Ciaglia Blue Rhino dilator in saline.
4. Advance the Ciaglia Blue Rhino dilator over the CAE Catheter to perform dilation. Ensure to maintain the depth position of the CAE within the airway during dilation. While maintaining the position of the CAE Catheter, advance the Ciaglia Blue Rhino dilator to the skin level mark on the dilator.
NOTE: Proper positioning and alignment of the Ciaglia Blue Rhino dilator to the skin level guide may help minimize complications (e.g., stenosis).
5. Depending on the patient's spontaneous ventilatory capacity, oxygenation may be delivered through the CAE Catheter utilizing a supplied Rapi-Fit adapter connected to an appropriate oxygen source

(see Use of Rapi-Fit Adapter and Catheter Oxygenation Section).

- Advance and pull back the Ciaglia Blue Rhino dilator several times to effectively dilate the tracheal access site.
NOTE: Care should be taken to maintain the depth position of the CAE Catheter within the airway while dilating with the Ciaglia Blue Rhino dilator. This will ensure that access to the airway is not lost during dilation.
- Once dilation of the tracheal stoma is complete, remove the Ciaglia Blue Rhino dilator from the CAE Catheter while maintaining the position of the CAE Catheter in the patient's trachea. If utilized, the Rapi-Fit Adapter shall be removed from the CAE Catheter prior to the withdrawal of the Ciaglia Blue Rhino dilator.
- Load the new, replacement tracheostomy tube on the appropriate loading dilator and insert over the CAE Catheter into the tracheal lumen.
- Inflate the cuff and secure the replacement tracheostomy tube.
- Remove the CAE Catheter and loading dilator. Re-institute mechanical ventilatory support.
- Clinically and radiologically confirm proper position of tracheostomy tube.

Use of Rapi-Fit® Adapter

The CAE Catheter (with Rapi-Fit adapters) should only be used when oxygen requirements are high and exchange of the tracheostomy tube encounters complications and/or 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 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.

- To attach the Rapi-Fit Adapter, position the adapter on the catheter, then push the white collar forward and lock into position. (**Fig. 2**)
- To remove the adapter, pull the white collar back to release, and then remove from the catheter. (**Fig. 3**)

Catheter Oxygenation

The Cook Airway Exchange (CAE) Catheters are designed for both positive airway pressure ventilation (Rapi-Fit Adapter – 15 mm connector) and jet ventilation (Rapi-Fit Adapter – Luer lock connector). In the table below, the delivered minute volume and the measured airway pressure are given for jet ventilation in an adult with healthy lung tissue.

Component	Patient Subgroup and Age Range	Delivered Minute Volume ¹ (L/min)	Measured Airway Pressure ¹ (cmH ₂ O)	
			Mean	Maximum
8 French CAE Catheter	Adult (> 21 years)	0.7	3.0	3.2

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

The following testing conditions were used in an active model mode, tested with ASL 5000, Ingmar Medical, Ltd.

Testing Conditions Input pressure was set to 50 psi for adult patient models.

Patient type	Model Body Weight (kg)	Inspiratory Time(s)	Expiratory Time(s)	Breaths per minute	Resistance (cm H ₂ O/L/s)	Lung Compliance (mL/cm H ₂ O)
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.

Weinmann, Maxwell and Bander Joseph MD. *The Journal of Trauma: Injury, Infection and Critical Care*. "Introduction of a New Tracheostomy Exchange Device After Percutaneous Tracheostomy In a Patient with Coagulopathy". P317-319 vol 40 #2.

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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