



TTC INTUITIVE DEPTH EXCHANGE™ CATHETER INSTRUCTIONS FOR USE

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 TTC Intuitive Depth Exchange™ Catheter is a 15 French, 70 cm long, rounded-tip, non-patent catheter with centimeter markings as well as color zonal markings to facilitate placement.

INTENDED USE

For use in replacement of endotracheal tubes whose inner diameter (ID) is 6 mm or larger in adult patients.

The TTC Intuitive Depth Exchange™ Catheter is intended for uncomplicated, atraumatic endotracheal tube exchange in conjunction with a laryngoscope.

CONTRAINDICATIONS

- Inability to place a laryngoscope into patient's airway
- Pediatric patients
- Adults with abnormal lower airway anatomy
- Inability to visualize the color-depth-zone system throughout the procedure
- Do not use with double-lumen endotracheal or endobronchial tubes.

NOTES

- The TTC Intuitive Depth Exchange™ Catheter **cannot be used for ventilation**.
- The need to ventilate the patient during the exchange procedure should be carefully considered by the physician. If warranted an airway exchange catheter with ventilation capacity should be considered.
- The color zonal depth system is sized for normal adult tracheal anatomy.
- To avoid trauma to the lungs, bronchial injury, or pneumothorax, examine the patient's anatomy to help determine the optimal placement for the TTC Intuitive Depth Exchange™ Catheter. Ensure the introducer is in the physician-preferred location relative to the carina by referencing its centimeter markings or color-depth-zones.
- Lubricate the Intuitive Depth Exchange™ Catheter and endotracheal tube before use.
- The Intuitive Depth Exchange™ Catheter should slide freely into the existing endotracheal tube. If resistance is encountered while placing the Intuitive Depth Exchange™ Catheter into the existing endotracheal tube, the procedure should be abandoned.
- Care must be taken when introducing/removing the Intuitive Depth Exchange™ Catheter from the endotracheal tube; contact with sharp edges on the internal surface of the endotracheal tube may cause small fragments to be shaved off the Intuitive Depth Exchange™ Catheter during introduction/removal.
- The product is intended for use by clinicians trained and experienced in airway management techniques. Standard techniques for placement and exchange of endotracheal tubes should be employed.
- This product is not intended for intravascular use.

POTENTIAL ADVERSE EVENTS

- Trauma to the lungs, bronchial injury, or pneumothorax.
- Injury to the epiglottis and glottis, perforation of the sinus pyriformis, bronchus, or trachea.
- Bronchospasm.
- Unintended endobronchial intubation.
- Esophageal intubation.
Introduction of foreign material into the lungs.











INSTRUCTIONS FOR USE

- 1) Lubricate an appropriately sized single lumen endotracheal tube and the exchange catheter.
- 2) Place a laryngoscope to visualize the glottis and confirm that the existing endotracheal tube is properly placed into the trachea.
- 3) Disconnect the existing endotracheal tube from the ventilator.
- 4) Place the TTC Intuitive Depth Exchange™ Catheter (color-depth-zone tip first) into the endotracheal tube to be removed. Advance the TTC Intuitive Depth Exchange™ Catheter, while visualizing the glottis, into the existing endotracheal tube until the colors of the color-depth-zones are seen through the wall of the existing endotracheal tube at the level of the glottis.
NOTE: If resistance is encountered while placing the Intuitive Depth Exchange™ Catheter into the existing endotracheal tube, the procedure should be abandoned.
- 5) Halt advancement of the TTC Intuitive Depth Exchange™ Catheter when the green zone of the color-depth-zones lies at the glottis.
- 6) If present, deflate the cuff of the existing endotracheal tube.
- 7) Withdraw the existing endotracheal tube from the trachea over the TTC Intuitive Depth Exchange™ Catheter while continuously observing the color-depth-zones with the goal of keeping the green zone at the glottis throughout the procedure.
- 8) Place a new endotracheal tube over the back of the TTC Intuitive Depth Exchange™ Catheter.
- 9) While maintaining the green zone of the color-depth-zone system at the vocal cords, pass tube over the exchange catheter into the trachea.
- 10) While leaving ET tube in place, remove the exchange catheter.
NOTE: Examine the introducer for any missing material; if foreign material is suspected in the lungs, take appropriate action.
- 11) Remove laryngoscope.
- 12) Inflate the cuff of the ET tube (if present).
- 13) Ventilate patient.
- 14) Confirm proper placement of the endotracheal tube using standard methods (e.g. capnography, breath sounds, chest x-ray, visualization of entry into the trachea).

HOW SUPPLIED

Supplied sterilized by radiation 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.

SYMBOLS

	Manufacturer		Do not re-use
	Catalogue number		Consult instructions for use
	Batch code		Sterilized using irradiation
	Date of manufacture		European Authorized Representative
	Use-by-date		Caution



MANUFACTURER

THROUGH THE CORDS LLC
1788 S Redwood Rd
Salt Lake City, UT 84104
U.S.A.
www.ttcmed.com

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