



**THROUGH
THE CORDS**
Next-Generation Airway Tools

TTC TOTAL CONTROL INTRODUCER™ 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 Total Control Introducer™ is a 15 FR, 70 cm long catheter. It has a rounded-tip with centimeter markings as well as color zonal markings to facilitate placement and use. The distal end of the catheter is curved with a tip that articulates and can be passed with visualization into the trachea.

INTENDED USE

The TTC Total Control Introducer™ is intended to facilitate endotracheal intubation. The introducer has been designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger.

NOTE: Do not use the TTC Total Control Introducer™ with double lumen endotracheal or endobronchial tubes.

CONTRAINDICATIONS

- Do not use if the entrance to the trachea cannot be visualized when performing laryngoscopy, i.e., Grade III or Grade IV Cormack & Lehane laryngoscopy classification.
- 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

WARNINGS

- The color-depth-zone 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 Total Control Introducer™. Ensure the introducer is in the clinician-preferred location relative to the carina by referencing its centimeter markings or color-zoned-tip.
- Care must be taken not to provoke injury to the epiglottis and glottis, perforation of the sinus pyramidalis, bronchus, or trachea.
- Do not use the TTC Total Control Introducer™ with double lumen endotracheal or endobronchial tubes.
- Lubricate the catheter introducer and endotracheal tube before use.
- Ensure proper sizing of the endotracheal tube to be used in combination with the TTC Total Control Introducer™.
- Care must be taken when introducing/removing the catheter introducer 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 catheter introducer during introduction/removal.
- Possible allergic reactions should be considered.
- Do not reattach the handle to the introducer after it has been removed

PRECAUTIONS

- The product is intended for use by clinicians trained and experienced in airway management.
- If intubation can not be completed, the ET tube and the introducer should be removed.

INSTRUCTIONS FOR USE

1. Place video laryngoscope (VLS) to visualize cords
2. Straighten tip by squeezing trigger
3. While inserting into mouth, directly visualize the tip of the introducer until it is no longer directly visible
4. Once the tip appears in the laryngoscope view, release the trigger to bring the tip up

5. Move tip towards the entrance to the trachea
6. Use the trigger and rotate the handle to adjust tip to enter the trachea
7. Once the tip is in the trachea, squeeze the trigger to articulate the tip to facilitate passage down the trachea
8. If resistance is encountered, do not force the introducer
9. Insert the device into the trachea until the green zone of the color-depth-zone system is at the entrance to the trachea
10. Remove fingers from the trigger entirely
11. Release handle by pushing thumb-release forward until it stops, and then down to open the cover
12. Remove the handle from the introducer
13. Pass control of the VLS to an assistant to maintain the view of the relationship between introducer shaft and the vocal cords
14. While maintaining the green zone of the color-depth-zone system at the vocal cords, pass tube over introducer into the trachea
15. While leaving ET tube in place, remove introducer
16. Remove VLS
17. Inflate the cuff of the ET tube (if present)
18. Ventilate patient

HOW SUPPLIED

Supplied sterilized by gamma radiation 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 direct sunlight. Upon removal from the package, inspect the product to ensure no damage has occurred.



MANUFACTURER

THROUGH THE CORDS LLC

1788 S Redwood Rd

SALT LAKE CITY, UT 84104

U.S.A.

www.ttcmed.com

IFU 000171.A