

TTC RUNNELS STEERABLE 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 Runnels Steerable 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 Runnels Steerable 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 Runnels Steerable 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 Runnels Steerable 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 pyriformis, bronchus, or trachea.
- Do not use the TTC Runnels Steerable 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 Runnels Steerable 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
- 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 Ethylene oxide (EO) 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

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