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).

INTENDED USE

The TTC Runnels Steerable Introducer™ is intended to facilitate endotracheal intubation.

NOTE: This includes both nasal and oral endotracheal intubation with a video laryngoscope or direct laryngoscope.

DEVICE DESCRIPTION

The TTC Runnels Steerable Introducer™ product family includes dynamic introducers capable of steerable navigation into the trachea to facilitate endotracheal tube placement during tracheal intubation. The devices have rounded tips 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 to facilitate steering through the upper airway and into the trachea under visualization with a laryngoscope. Intended for one-time use. The devices are supplied sterilized by Ethylene Oxide (EO) in peel-open packages.

Different sizes and subtypes of the Runnels Steerable Introducer™ are available to facilitate single lumen endotracheal tubes in adult and pediatric patients and double lumen tubes in adults. The subtype and size TTC Runnels Steerable Introducer™ (RSI™) should be appropriate for patient and endotracheal tube (ETT) type. Endotracheal tube and size capabilities of each size and subtype of the Runnels Steerable Introducer™ are detailed below.

TTC Runnels Steerable Introducer™ Models

RSI™ size	Patient Age (years)	Route	ETT Type	Min ETT Size
#2 Pediatric	2y-5y	Oral/Nasal	Oral/Nasal	4.5 mm ID
#2.5 Pediatric	6y-10y	Oral/Nasal	Oral/Nasal	4.5 mm ID
#3 Pediatric	11y-16y	Oral/Nasal	Oral/Nasal	6.0 mm ID
#4 Adult Oral	>16y	Oral	Oral	6.0 mm ID
DLT 35F, 37F Nasal	Adult	Oral/Nasal	Double Lumen Tube Nasal	35 French 37 French 4.5 mm ID
DLT 39F, 41F Nasal	Adult	Oral/Nasal	Double Lumen Tube Nasal	39 French 41 French 6.0 mm ID

CONTRAINDICATIONS

- 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
- Patients with abnormal tracheal anatomy Patients with existing or potential tracheal trauma Inability to visualize the color-depth-zone system throughout the procedure
- Children under the age of 2 years old
- Do not use via the nasal route in patients with abnormal coagulation
- Do not use via the nasal route in patients with midface trauma

WARNINGS

- CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- The TTC Runnels Steerable Introducers™ are supplied sterile for single use only. It should be discarded after use and must not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.
- Store devices in an environment that avoids direct sunlight and extremes of temperatures.
- Excessive force must be avoided at all times.
- 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.
- Ensure that the appropriate TTC Runnels Steerable Introducer™ subtype is appropriate for patient age and size.
- Ensure that the appropriate TTC Runnels Steerable Introducer™ subtype is appropriate for endotracheal tube size and type.
- Lubricate the introducer tip, front shaft and back shaft surfaces and the endotracheal tube before loading on the back of the introducer.
- Preload the endotracheal tube onto the back of the introducer behind the handle prior to use.
- 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. If the handle is prematurely detached or the introducer is inadvertently backed out of the trachea, remove the introducer from the patient and ventilate and reassess the intubation plan. Open a new TTC Runnels Steerable Introducer if the intubation plan indicates use.

PRECAUTIONS

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

INSTRUCTIONS FOR USE

1. Confirm the TTC Runnels Steerable Introducer™ package is unopened and undamaged. Note: Do not use the product if there is doubt as to whether the product is sterile. Upon removal from the package, inspect the product to ensure no damage has occurred.
2. Confirm that the appropriate subtype and size of TTC Runnels Steerable Introducer™ is used according to the patient and procedure needs.
3. Lubricate and preload the endotracheal tube (ET tube) on the appropriate subtype TTC Runnels Steerable Introducer™.
4. Place video laryngoscope (VLS) or direct laryngoscope to visualize vocal cords.
5. Straighten tip of the TTC Runnels Steerable Introducer™ by squeezing the trigger with right hand.
6. Insert the introducer tip into mouth or nose parallel to the blade of the VLS or direct laryngoscope under direct visualization until the tip of the introducer is no longer directly visible.
7. Once the tip is no longer directly visible, release the trigger to articulate the tip anteriorly into the field of view of the VLS.
8. If direct laryngoscope is used, the tip of the introducer should be directly visualized at all times until it has entered the trachea.
9. Use the trigger to articulate the tip in the anterior or posterior direction as necessary. Rotate the handle to move the tip side to side as necessary to steer the tip to the opening of the vocal cords.
10. Once the tip is in the opening of the vocal cords, squeeze the trigger to articulate the tip posteriorly to facilitate passage down the trachea.
11. If resistance is encountered, DO NOT force the introducer. The trigger may be used to move the tip gently anteriorly and posteriorly as needed to maneuver down the center of the trachea. If resistance is continued to be encountered, remove the introducer, ventilate the patient and reassess the intubation plan.

12. Insert the device into the trachea until the green zone of the color-depth-zone system is at the level of the vocal cords.
13. Remove fingers from the trigger entirely.
14. Release handle from the introducer by pushing handle top forward using the thumb stop on the left rear of the top until a click is heard.
15. Open the top and remove the handle from the introducer shaft.
16. Pass control of the VLS to an assistant to maintain the view of the relationship between introducer shaft and the vocal cords.
17. While maintaining the green zone of the color-depth-zone system at the vocal cords, advance the ET tube over introducer into the trachea.
18. Leaving the ET tube in place in the trachea, remove the introducer from the ET tube.
19. Remove VLS.
20. Inflate the cuff of the ET tube (if present).
21. Ventilate patient.
22. Confirm an endotracheal intubation with end tidal CO_2.

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.

	MANUFACTURED FOR THROUGH THE CORDS LLC 6886 Bateman Dell Way West Jordan, UT 84084 U.S.A. www.ttcmed.com
	For Single Use Do not Reuse
	Sterilized using Ethylene Oxide