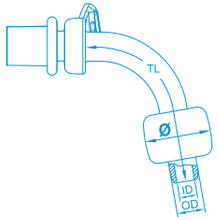
Rota-Trach™

CE 0123

Disposable Standard Tracheostomy Tube Cuffed

General Instructions For Use

Carefully read the following instructions before using this product.
Federal law (U.S.A.) restricts this device to sale by or on the order of a physician



	REF	Tube ID (mm)	Tube OD (mm)	TL (mm)	Cuff Resting Diameter (Ø,mm)
VT530 Series (Cuffed)	5300600	6.0	8.3	55	21
	5300650	6.5	9.0	60	22
	5300700	7.0	9.6	65	23
	5300750	7.5	10.3	70	24
	5300800	8.0	11.0	76	26
	5300850	8.5	11.6	82	28
	5300900	9.0	12.3	89	30
	5301000	10.0	13.3	97	33
VT531 Series (Cuffed+Fenestrated)	5310600	6.0	8.3	55	21
	5310650	6.5	9.0	60	22
	5310700	7.0	9.6	65	23
	5310750	7.5	10.3	70	24
	5310800	8.0	11.0	76	26
	5310850	8.5	11.6	82	28
	5310900	9.0	12.3	89	30
	5311000	10.0	13.3	97	33

Symbol

EN / Caution

EN / Do not contain or presence of phthalate-DEHP

EN / Do not use if package is damaged

EN / Do not resterilise

EN / Temperature limitation
Upper limit: 49°C
Lower limit: 5°C

EN / Sterilized using ethylene oxide

EN / Manufacturer

EN / Catalogue number

EN / Use by date

EN / Keep away from sunlight

EN / Contains or presence of phthalate-DINP

EN / Do not contain or presence of natural rubber latex

EN / Do not reuse

EN / Consult instructions for use

EN / Authorized representative in the European community

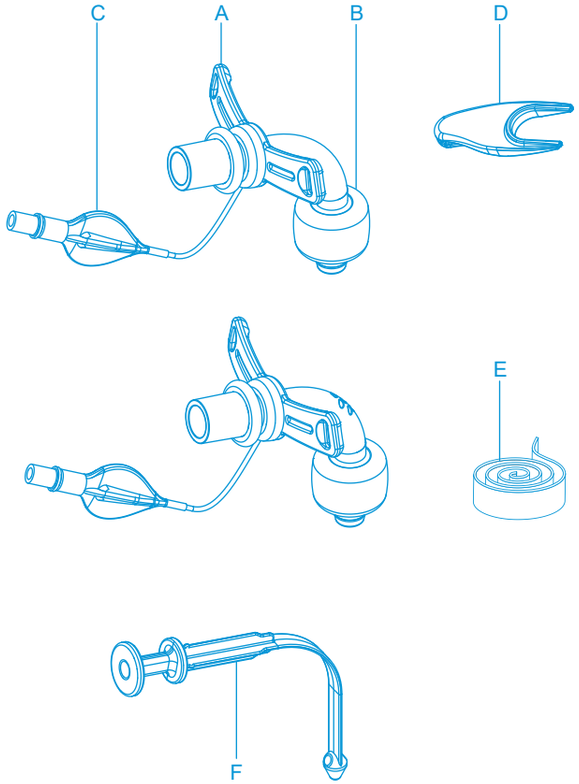
EN / Sale by or on the order of a physician

EN / Date of manufacture

EN / Batch code

EN / Keep dry

EN / Fenestrated tube (REF 5310600,REF 5310650,REF 5310700,REF 5310750,REF 5310800,REF 5310850,REF 5310900,REF 5311000)



General Indications

- Rota-Trach Disposable Standard Tracheostomy Tube is intended for the airway management of tracheostomized adult patients. The device is operated by health professionals in medical institutions for single patient use. It may be continuous use by replacement and each one should be used within 29 days.
- The fenestrated cannula facilitates patient weaning from the tube, which allows a part of air to reach the upper airway through the fenestration for spontaneously breathing and speaking.
- The tube with cuff is suitable for patients who require sealing the trachea. The inflated cuff blocks the upper airways from the lower airways, so air cannot flow to the upper airways from the lungs. It allows patient to breathe through the tube only andprevents secretion from getting into the lower airways.

Warning

- This product is intended for single patient use only.
- This product is sterilized with ethylene oxide (EO). All contents are sterile unless the package is damaged and the seal is broken.
- Check the product package before use. Do not re-sterilize this device after use. Re-sterilization may lead to the device not performing as intended.
- Rota-Trach tracheostomy tubes should not be used for more than 29 days. Frequent replacement of tracheostomy tube is recommended, and should be supervised by the clinician.
- For fenestrated model, cuff must be deflated prior to capping the tracheostomy tube.

Product Description

- Cuffed Rota-Trach Disposable Standard Tracheostomy Tube is a single-lumen device consisting of 3 essential parts: a cannula with a 15 O.D. connector; a pair of neck plate to secure the device; an introducer to assist intubation. The device may be in connection for use with other respiratory care devices. The cannula is with an inflatable cuff for sealing usage. The low pressure cuff can be inflated or deflated via a radiopaque inflation tube.

Contra-indications

The 15 O.D. connector cap/fenestration must not be used for laryngectomised patients (patients without a larynx), and it may cause the danger of suffocation for patients. This device cannot be used for paediatrics. The device is not used in patients with a long depth from skin surface to trachea (e.g. obesity).

Complications

- Bleeding
- Desaturation during procedure
- Skin infection
- Tracheal ring fracture
- Tracheal narrowing
- Granulation tissue
- Noticeable neck scar
- Accidental decannulation
- Tracheal fistula

Precautions

- Check any damage on the product before use. Ensure that the cuff is sealed.
- It is strongly recommended to use the disconnect wedge detaching the tracheostomy tube from breathing system.
- Always keep the 15 O.D. connector clean and dry.
- Make sure that the inflation tube and pilot balloon are functional, and not damaged or jammed at all times.
- In order to prevent skin irritation, it is recommended to place a dressing underneath the neck plate.
- The cuff should not be in contact with Lidocaine topical aerosol or any ointments whichmay cause damage to the material.
- When use in conjunction with other manufacture' s products always refer to their instruction for use.

Warning

- Do not use if the product packaging is damaged.
- When taking electrosurgical or laser treatment, ensure that there is sufficient distance to the tracheostomy tube.
- If the fenestrated cannula is used, it must be verified regularly that fenestration is not blocked by mucus secretions. The airway resistance may increase if a 15 O.D. connector cap is used.
- When the fenestrated tube is used, it will increase the risk of formation of granulation tissue.
- Over inflation of the cuff may increase pressure against the tracheal wall and cause a risk of permanent damage to the trachea.
- If the cuff pressure is insufficient, it may result in a risk of aspiration.
- Using laughing gas or Halogen as an anesthetic can change the cuff pressure.
- Irritation, cough or bleeding may occur during the tube insertion and removal.

Suggested Procedure of Insertion

Pre-Use Check

1. Check the product contents
2. For tube with cuff, test the cuff for leakage before inserting the tube. Inflate the cuff with hand-held manometer to the pressure of 50cmH2O (or 36.78mmHg) for 1 minute, and then observe for air leakage. If the cuff is a leak-tight seal, remove all of air from the cuff by using a syringe.

Suggested Procedure

1. Push tracheostomy tube with the introducer (F) firmly into the trachea.
2. Remove the introducer immediately after inserting into the trachea.
3. Hold the neck plate (A) with the fingertips and attach the neck strap (E) to the neck plate(A) to secure the tube in place.
4. For ventilation, attach the 15 O.D.connector to the breathing circuit firmly.
5. For cuffed tube, inflate the cuff (B) by using the pilot balloon (C). Adjust the cuff pressure to the individual ventilation therapy and check at regular intervals. It is recommended to maintain the pressure between 20 cmH2O (or 15 mmHg) and 30 cmH2O (or 22 mmHg).

   Caution: Attaching a hand-held manometer may cause the cuff pressure declined

6. Deflate the cuff
   To deflate the cuff, connect a syringe to the pilot balloon (C)to remove air completely.
7. Changing the tracheostomy tube
   If viscous secretion is accumulated in the cannula, the tube needs to be replaced with a new one.

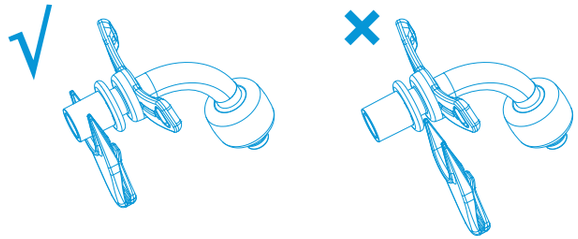
   Caution: Disposal of tracheostomy tube should comply with applicable national regulation for biologically hazardous waste.

- **Fenestrated Tracheostomy Tubes**
  Fenestrated tube is used by the patient who is weaning from ventilation.

  Caution:

  If the fenestrated tube is used, it must be verified regularly that fenestration is not blocked by mucus secretions or in-growing tissue.

- **Disconnect Wedge (D)**
  Disconnect Wedge can help disconnect the attachment from the connector.



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