Instructions for Use

AnapnoGuard™ Endotracheal Tube

Rx Only STERILE EO 2 CE 0483

HOSPITECH RESPIRATION

DESCRIPTION

The AnapnoGuard™ Endotracheal tube is a sterile device, intended for a single and continuous use, and for no more than 30 days. It is supplied for use in three sizes:
7.0 mm I.D (O.D 10.7 mm and tube length of 310 mm, P/N ETP70PUC1)
7.5 mm I.D (O.D 11.2 mm and tube length of 330 mm, P/N ETP75PUC1)
8.0-mm I.D. (O.D 11.0 mm and tube length of 340 mm, P/N ETP80PUC1) .
All the three sizes come with a standard 15 mm connector and in all three sizes the cuff sealing resting diameters is 28.0 mm.

The tube design models feature a Magill curve, printed depth markings, radio-opaque line to assist with radiographic visualization, with Murphy Eye. a self-sealing valve with attached pilot balloon on the proximal side of an embedded inflate/deflate lumen, a Suction lumen with two openings at the dorsal side of the tube above the cuff aimed for evacuation of secretions from above the cuff and a CO2/Venting lumen at the ventral side of the tube aimed for a) Measuring the CO2 level above the cuff, b) Venting the subglottic while evacuation of secretions is performed, and c) Administration of fluids into the subglottic.

INDICATION FOR USE

The **AnapnoGuard™ Endotracheal Tube** is indicated for airway management by oral or nasal intubation of the trachea and for evacuation or drainage of the subglottic space.

INTENDED USERS

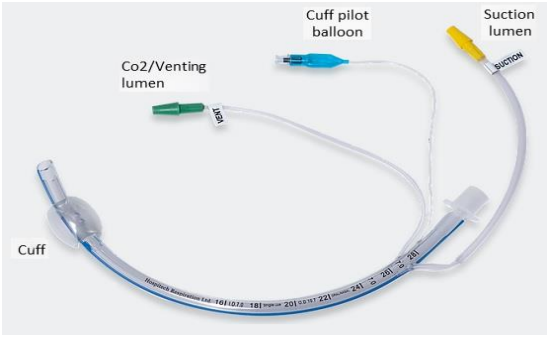
The Intended user population for the **AnapnoGuard™ Endotracheal Tube** includes only medical professional staffs (physicians, nurses and respiratory technicians) which treat mechanically ventilated patients.

CONTRAINDICATIONS

Use of AnapnoGuard™ Endotracheal Tube in procedures using a laser or an electro surgical active electrode in the immediate area of the device is contraindicated. Contact of the beam or electrode with the tracheal tubes, especially in the presence of oxygen-enriched or nitrous oxide-containing mixtures can cause rapid combustion of the tube with harmful the thermal effects and emission of corrosive and toxic combustion products including hydrochloric acid (HCl). It has been reported that mixtures of nitrous oxide and oxygen support combustion nearly identical to pure oxygen. In addition to ignition by direct contact with the beam, the interior of the tube can also be ignited by contact with flaming tissue in close proximity of the tracheal tube.

WARNINGS

- Cuff inflation by “feel” alone or using a measured amount of air is not recommended because resistance is an unreliable guide during inflation.
- Intra-cuff pressure must be closely monitored with a pressure-monitoring device.
- Do not over-inflate cuff. Ordinarily, cuff pressure should not exceed 30 cmH2O. Over-inflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or in cuff distortion leading to air way blockage.
- Deflate cuff prior to repositioning the tube. Movement of the tube with the cuff inflated can result in patient injury, requiring possible medical intervention or damage of the cuff. If this occurs, it can require a tube change. When complete evacuation of air from the cuff is accomplished, a definite vacuum is sensed in the syringe and the tracheal tube cuff is collapsed. Verify correct placement of the tube after each repositioning.
- Verify tube position if a patient’s position or tube placement is changed after intubation. It is essential that tube position remains correct in the center of the mouth. Any tube displacement must be corrected immediately.
- The CO2/Vent lumen is intended for detecting leakage around the cuff, for venting while draining via suction lumens and for rinsing of fluids to above the cuff. This lumen should be used only for these purposes.
- The Evacuation/Suction lumens are intended for evacuation of secretions from above the cuff. These lumens should be used only for these purposes.
- The CO2/Vent and the Suction lumens should be capped when not in use to prevent infiltration of contamination into the subglottic.
- Do not attempt to reuse the ETT in any way



CAUTIONS

• Remove the 15 mm tracheal tube connector if pre-cutting of the tube is desired.
• Follow the SUGGESTED DIRECTIONS FOR USE to evaluate the tube and connector for suitability. Always be sure the connector is firmly connected in both the tracheal tube and the breathing circuit to prevent disconnection during use.
• Use this tube only with equipment having standard 15 mm connectors.
• Exercise expert clinical judgment in the selection of an appropriate-sized tracheal tube for each individual patient.
• Avoid exposure to elevated temperatures and ultraviolet light during storage.
• Syringes, three-way stopcocks, or other devices must not be left inserted in the inflation valve for extended periods of time. The resulting stress can crack the valve housing and cause the cuff to deflate.
•Use Minimal Occluding Volume or Minimum Leak techniques in conjunction with an intra-cuff pressure-measuring device to select the sealing pressure.
• Continuously monitor cuff pressure, and investigate any deviation from the selected seal pressure. Correct deviations immediately.
• Test each tube's cuff and pilot balloon by inflation prior to use. If the inflation system fails to function properly, do not use the tube. Monitor the integrity of the inflation system both initially and periodically during the intubation period.
• The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs. Use expert clinical judgment when prescribing treatment involving the use of this substance. Lidocaine hydrochloride does not have this effect.
• Sharp surfaces, including various bony anatomical structures such as teeth or turbinate, within the intubation routes as well as any intubation tools present a threat to maintaining cuff integrity. Take care to avoid damaging the thin-walled cuffs during insertion. A damaged cuff subjects the patient to the trauma of extubation and re-intubation. If the cuff is damaged, do not use the tube.
• Diffusion of a nitrous oxide mixture, oxygen, or air can either increase or decrease cuff volume and pressure. It is recommended to inflate the cuff with the gas contacting the external surface to reduce the effect of such diffusion.
• If viscous secretions are present, the bore of the tube can occlude. Take care to avoid any buildup of secretions that can possibly affect patient ventilation by blocking the tube.
• Follow the manufacturer's instructions if lubricating jellies are used with the tracheal tube. Excessive amounts of lubricating jellies can dry on the inner surface of the tracheal tube resulting in a lubricant plug or a clear film that partially or totally blocks the airway.
• Use of lubricating jelly to ease connector reinsertion is not recommended as it can contribute to accidental disconnections.
• Perform intubation and extubation following currently accepted medical techniques
• Standard pre-cut tracheal tubes are marketed in a pre-determined length. However, the user is cautioned that anatomical variations, conditions of use, actual O.D. of the tube, inserted length of tube, or other factors can result in the use of a tracheal tube too long or too short for a given patient. Use expert clinical judgment when selecting tube size and length.
• Notice to user and patient: Any serious incident that has occurred in relation to the AG100s should be reported as soon As possible to the Hospitech Respiration Ltd. and the competent authority of the Member State in which the user and/or patient is established

ADVERSE REACTIONS

The following adverse reactions were reported in association with the use of cuffed tracheal tubes during the intubation procedure, during the intubation period, or subsequent to extubation. The list is in alphabetical order and does not indicate frequency or severity of the reaction.

Reported adverse reactions include the following:

abrasion of the arytenoids cartilage vocal process; cartilage necrosis; cicatrix formation; consequences of failure to ventilate including death; damage to the perichondrium; development of dense or diffuse fibrosis invading the entire glottic area; emphysema;

endobronchial aspiration; endobronchial intubation (hypoxemia); endotracheobronchial aspiration; epistaxis; esophageal intubation (stomach distention); excoriated membranes of the pharynx; eye trauma; fibrin deposition; formation of subglottic web; fractureluxation of the cervical column (spinal injury); fragmentation of cartilage; glottic edema (supraglottic, retroarytenoidal); granuloma of the inner arytenoids area; infections (laryngitis, sinusitis, abcess, respiratory tract infection); inflammation; intermittent aphonia and recurrent sore throat; laryngeal fibrosis; laryngeal granulomas and polyps; laryngeal obstruction; laryngeal stenosis; laryngeal ulcers; laryngotracheal membranes and webs; membraneous glottic congestion; membraneous tracheobronchitis; mild edema of the epiglottis; mucosal sloughing; paresis of the hypoglossal and/or lingual nerves; perforation of the esophagus; perforation of the trachea; pnuemothorax; replacement of the trachea wall with scar tissue; respiratory obstruction; retrobulbar hemorrhage; retropharyngeal abscess; retropharyngeal dissection, rupture of the trachea; sore throat, dysphagia; stricture of the nostril; stridor; subglottic annular cicatricial stenosis; submucosal hemorrhage, submucous puncture of the larynx; superficial epithelial abrasion; swallowed tube; synechia of the vocal cords; teeth trauma; tissue burns; tracheal bleeding; tracheal stenosis; trauma to lips, tongue, pharynx, nose, trachea, glottis, palate, tonsil, etc.; traumatic lesions of the larynx and trachea; ulcerations exposing cartilaginous rings and minor erosions at the cuff site; ulceration of the lips, mouth, pharynx; ulcers of the arytenoids; vocal cord congestion; vocal cord paralysis, and vocal cord ulcerations.

SUGGESTED DIRECTIONS FOR USE

1. Before use examine the sterile packaging. In the event of visible damage to the sterile packaging do not open and do not use. Discard the package and ETT
2. Remove the Hospitech Respiration Ltd Tube from its protective package. Test the cuff, pilot cuff, and valve of each tube by inflation prior to use. Insert a luer tip syringe into the cuff inflation valve housing and inject enough air to fully inflate the cuff.
3. After test inflation, prior to intubation, evacuate completely air from cuff, pilot balloon, and valve.
4. Use expert clinical judgment when selecting the appropriate tube size and precut length. Also, use caution when pre-cutting the tube as anatomical variations, conditions of use, or other factors can result in a tube either too long or too short for the patient.
5. If pre-cutting tube is desired, evaluate the tube for pre-cutting prior to intubation. If cutting the tube is required, make sure the cut is at least 1cm above the most proximal luer. Cut the tube at a slight angle to facilitate reinsertion of the 15 mm connector into the tube. To prevent disconnection during use, always verify that the connector is firmly seated in both the tracheal tube and breathing circuit.
6. Follow currently accepted medical techniques for intubation with consideration given to the specific WARNINGS and CAUTIONS stated in this product insert.
7. Once the patient is intubated, inflate the cuff with only enough gas mixture to provide an effective seal at the desired lung inflation pressure.
8. Use Minimal Occluding Volume, Minimum Leak techniques, and monitoring of cuff pressure to reduce occurrence of the adverse reactions associated with cuffed tracheal tubes.
9. Remove the syringe from the valve housing after cuff inflation. Leaving the syringe attached keeps the valve open and deflates the cuff.
10. Verify that the inflation valve is not leaking. Periodically check the inflation system during intubation period. Closely monitor cuff pressure and investigate any deviation from the selected seal pressure.
11. Before performing evacuating secretions assure the cuff is completely sealed. If needed, you may dilute the secretions by rinsing Saline with a syringe into the subglottis via the CO2/Vent lumen. Use a syringe to evacuate secretions from the Suction lumen. Rinse and suction can be done simultaneously or consequently. Make sure the CO2/Vent lumen cap is open while evacuating the secretions through Suction lumen in consecutive mode. After evacuating secretions re-cap the CO2/Vent and Suction lumens.
12. Deflate cuff completely prior to extubation by inserting syringe into valve housing and removing gas mixture until a definite vacuum is noted in the syringe and the pilot balloon collapses.
13. Extubate patient following currently accepted medical techniques.
14. Discard the ETT according to hospital policy for hazardous waste

ADDITIONAL PRODUCT INFORMATION

1. The AnapnoGuard™ Endotracheal Tubes manufactured in the following sizes (in mm):

PVC Tubes with Polyurethane cuff			
ID	**OD**	**Cuff Resting Diameter**	**Tube Length**
7	10.7	28	310
7.5	11.2	28	330
8	11.9	28	340

2. Information relating to the following items, is available upon request:
   - •Tube Collapse
   - •Cuff Symmetry
   - •Cuff Herniation
   - •Cuff Pressure, Volume, and Diameter Assessment and Tube Lumen Closure
   - •Radiopaque Markers
   - •Leak Test

LABEL SYMBOLS GLOSSARY

STERILE EO	Sterilized using ethylene oxide		Keep away from sunlight
	Manufacturer		Keep dry
EC REP	EC Rep		Temperature limit
	Date of manufacture		Do not re-use
	Use-by date		Caution
		Rx only	Prescription only
LOT	Batch code	CE	CE Mark European Conformity
REF	Catalog number	MD	The device is a medical device
	Do not use if package is damaged		Consult operating instructions
	Not made with natural rubber latex		

STORAGE CONDITIONS

Storage Temperature – the product in its original packaging withstands an ambient temperature range of: 0º C to 50º C.

Storage Humidity – 10% and 95% non-condensing.

ADDITIONAL COPIES OF INSTRUCTIONS

Additional copies of these instructions are available at no charge by contacting Hospitech Respiration Ltd. at info@hospitech.co.il. Permission is granted under Hospitech's copyrights to make additional copies of these instructions for use by purchasers of this product from Hospitech Respiration Ltd, or its authorized distributors.

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