This product contains DEHP. When used as indicated, very limited exposure to trace amounts of DEHP may occur. There is no clear clinical evidence that this degree of exposure increases clinical risk. However, in order to minimize risk of DEHP exposure in children and nursing or pregnant women, this product should only be used as directed. This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices may result in a biocompatibility, infection or product failure risks to the patient.

DESCRIPTION

The Mallinckrodt Lo-Pro and Lo-Contour Cuffed Tracheal Tubes are supplied sterile with standard 15 mm connectors. The tube design incorporates a Magill curve and features a radiopaque line to assist in radiographic visualization. The tube features a low profile, Lo-Pro cuff and self-sealing valve with attached pilot balloon. An indicator (ORAL: NASAL) is provided on standard length tubes to mark the tracheal tube pre-cut length in millimeters. This pre-cut indicator and all other device features listed above comply with American Society for Testing and Material (ASTM) designation F 1242-96, Standard Specification for Cuffed and Uncuffed Tracheal Tubes. The tube materials meet the requirements of the implantation test as set forth in the United States Pharmacopoeia. Sterilization is by ethylene oxide. 

Lo-Pro Cuffed Tracheal Tube – an opaque white tube available with a Murphy or Magill tip. In addition to the standard length, the Lo-Pro Tracheal Tube with Murphy tip is also available in a standard pre-cut length for oral use only. 

Lo-Contour Cuffed Tracheal Tube – a clear tube available with a Murphy tip. Cut-to-length Specials - Lo-Pro and Lo-Contour Cuffed Tracheal Tubes may be specially ordered cut-to-length for oral use only.

INDICATIONS

The Lo-Pro and Lo-Contour Cuffed Tracheal Tubes are indicated for airway management by oral/nasal intubation of the trachea for anesthesia or other short-term procedures. Ordinarily, the cuff pressure should not exceed 25 cm H2O. Carroll and Grenvik recommend maintaining a seal pressure at or below 25 cm H2O (Carroll, R.G., and Grenvik, A.; Proper use of large diameter, large residual volume cuffs. Critical Care Medicine Vol. 1, No. 3: 153-154, 1973). However, clinical situations may arise where a higher sealing pressure is clinically indicated. Although uncuffed tracheal tubes are ordinarily used in pediatric airway management, in some cases (e.g., pulmonary function testing) use of a small diameter cuffed tracheal tube may be indicated. NOTE: Cut-to-length specials are intended for oral intubation only and are so printed on the tube.

CONTRAINDICATIONS

Use of Lo-Pro and Lo-Contour Cuffed Tracheal Tubes in procedures which will involve the use of a LASER or an electrosurgical 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, could result in the rapid combustion of the tube with harmful thermal effects and with emission of corrosive and toxic combustion products including hydrochloric acid (HCl). It has been reported by Hirshman and Smith that mixtures of nitrous oxide and oxygen support combustion about the same as pure oxygen and that 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 to the tip of the tracheal tube (Hirshman, C. A. and Smith, J.: Indirect Ignition of the Endotracheal Tube during Carbon Dioxide Laser Surgery. Arch Otolaryngol Vol. 106: 639-641, 1980).

WARNINGS/PRECAUTIONS (Cuff-related)

• In cases where the duration of intubation is expected to be more than 24 hours or may not be predictable, consideration should be given to using a tracheal tube with a larger diameter cuff, e.g. Mallinckrodt’s Hi-Lo or Intermediate Hi-Lo Cuffed Tracheal Tubes, to facilitate maintenance of cuff inflation pressure below 25 cm of H2O, to reduce the potential for tissue trauma.

• As these devices may have been subjected to handling, storage conditions, or preparation which compromised functional integrity, each tube’s cuff, pilot balloon and valve should be tested by inflation prior to use. If dysfunction is detected in any part of the inflation system, the tube should not be used. Initiating treatment using a tube already shown to have a dysfunction in the inflation system could unnecessarily subject the patient to the untoward effects of extubation, reintubation, or loss of respiratory support. Furthermore, the integrity of the inflation system should be monitored both initially and periodically during the intubation periods. Uncorrected failure of the inflation system could result in death.

• The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs (Jayasuriya, K.D., and Watson, W. F.; PVC Cuffs and Lignocaine-base Aerosol. Brit. J. Ann. 53: 1368, 1981). Expert clinical judgement must be used when prescribing treatment involving use of this substance to help prevent situations of cuff leaks due to pinholes. The same authors report that lidocaine hydrochloride solution does not have this effect.

• Various bony anatomical structures (e.g., teeth, turbinates) within the intubation routes or any intubation tools with sharp surfaces present a threat to maintaining cuff integrity. Care must be taken to avoid damaging the thin-walled cuffs during insertion which would create the need to subject the patient to the trauma of extubation and reintubation. If cuff is damaged, the tube should not be used.

• Diffusion of nitrous oxide mixture, oxygen, or air may either increase or decrease cuff volume and pressure. Inflating the cuff with the gas mixture that will contact its external surface is recommended as a means to reduce the extent of such diffusion.

• Inflation of the cuff by “feel” alone or by using a measured amount of air is not recommended since resistance is an unreliable guide during inflation. Intracuff pressure should be closely monitored with a pressure measuring device.

• Do not overinflate cuff. Ordinarily, the cuff pressure should not exceed 25 cm H2O. Carroll and Grenvik recommend maintaining a seal pressure at or below 25 cm H2O (Icarroll, R.G., and Grenvik, A.; Proper use of large diameter, large residual cuffs. Critical Care Medicine Vol. 1, No. 3: 153-154, 1973). Overinflation can result in tracheal damage, rupture of the cuff with subsequent deflation, or in cuff distortion which may lead to airway blockage.

• Minimal Occluding Volume or Minimum Leak techniques should be used in conjunction with an intracuff pressure measuring device in selecting the sealing pressure. Cuff pressure should continue to be monitored thereafter, and any deviation from the selected seal pressure should be investigated and corrected immediately.

• Deflate cuff prior to repositioning the tube. Movement of the tube with cuff inflated could result in patient injury, requiring possible medical intervention or damage to the cuff, requiring a tube change. When complete evacuation of the air from
the cuff is accomplished, a definite vacuum will be noted in the syringe and the tracheal tube pilot balloon is collapsed. Verify correct placement of the tube after each repositioning.

- Syringes, three-way stopcocks, or other devices should not be left inserted in the inflation valve for an extended period of time. The resulting stress could crack the valve housing and allow the cuff to deflate.

WARNINGS PRECAUTIONS (General)

- When a patient’s position or the tube placement is altered after intubation, it is essential to verify that the tube position remains correct. Any tube displacement should be corrected immediately.
- Exposure to elevated temperatures and ultraviolet light should be avoided during storage.
- Should extreme flexing (chin-to-chest) of the head or movement of the patient (e.g., to a lateral or prone position) be anticipated after intubation, use of a reinforced tracheal tube should be considered.
- The 15 mm connector is seated so that it can be removed with effort if pre-cutting of the tube is desired. Follow the SUGGESTED DIRECTIONS FOR USE to evaluate the tube and connector for suitability if pre-cutting is considered. Always ensure the connector is firmly seated in both the tracheal tube and the breathing circuit to prevent disconnection during use.
- Non-standard dimensioning of some connectors on ventilatory or anesthesia equipment may make secure mating with the tracheal tube 15 mm connector difficult. Use only with equipment having standard 15 mm connectors.
- Expert clinical judgment should be exercised in the selection of the appropriate size tracheal tube for each individual patient.
- Intubation and extubation should be performed following currently accepted medical techniques.
- The user should be alert for anatomical variations including the length of the airway. Reliance on the precut indicator should not, in any case, be substituted for expert clinical judgment.
- If lubricating jellies are used in conjunction with the tracheal tube, follow manufacturer’s application instructions. Excessive amounts of jelly can dry on the inner surface of the tracheal tube resulting in either 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 may contribute to accidental disconnections.
- Standard pre-cut tracheal tubes are marketed in pre-determined lengths. However, the user is cautioned that anatomical variations, conditions of use, actual O.D. of the tube, inserted length of tube, or other factors may result in the use of a tracheal tube too long or too short for a given patient. Expert clinical judgment should be used in selecting tube size and pre-cut length.
- During an MRI scan the pilot balloon should be secured near the Y connector of the ventilator circuit at least 3 cm from the area of interest to prevent movement and image distortion.

ADVERSE REACTIONS

The following adverse reactions have been reported to be associated with the use of cuffed tracheal tubes during the intubation procedure, during the intubation period, or subsequent to extubation. The order of listing is alphabetical and does not indicate frequency or severity. Reported adverse reactions include: abrasion of the arytenoid cartilage vocal process; cartilage necrosis; cicatrix formation; consequences of failure to ventilate including death; respiratory obstruction; retrobulbar hemorrhage; retrasparyngeal abscess; retrosparyngeal dissection; rupture of the trachea; sore throat; dysphagia; stricture of nostril; stridor; subglottic amnial cicatral stenosis; submucosal hemorrhage; submucosal puncture of the larynx; superficial epithelial abrasion; swallowed tube; syncheia 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 cuff sites; ulceration of the lips, mouth, pharynx; ulcers of the arytenoid; vocal cord congestion; vocal cord paralysis; and vocal cord ulcerations.

* Helpful reference for more detailed discussions of tracheal tube adverse reactions include the following:


SUGGESTED DIRECTIONS FOR USE

1. Remove the sterile Lo-Pro or Lo-Contour Cuffed Tracheal Tube from its protective package. Test the cuff, pilot balloon, 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 cuff.
2. After test inflation, completely evacuate the air.
3. If pre-cutting of the tracheal tube is considered, evaluate suitability of the tube for pre-cutting prior to intubation. Tubes with 15 mm connectors which cannot be removed with reasonable manipulation are not suitable for pre-cutting. If the tube is pre-cut, it should be cut at a slight angle to facilitate reinsertion of the 15 mm connector into the tube. Always ensure the connector is firmly seated in both the tracheal tube and the breathing circuit to prevent disconnection during use.
4. In those situations where it is deemed appropriate to pre-cut the tube, the user is cautioned that anatomical variations, conditions of use or other factors may result in a tracheal tube either too long or too short for a given patient when the standard pre-cut length indicated by (ORAL / NASAL) is used. Expert clinical judgment should be used in selecting the appropriate tube size and pre-cut length.
5. Intubate the patient following currently accepted medical techniques with consideration given to the specific cuff-related WARNINGS and PRECAUTIONS stated in this product insert.
6. Once the patient is intubated, inflate cuff only with enough gas mixture to provide an effective seal at the desired lung inflation pressure. The use of Minimal Occluding Volume, Minimum Leak techniques, and monitoring (measuring) of cuff pressure, can help reduce occurrence of many of the adverse reactions associated with the use of cuffed tracheal tubes.
7. Remove syringe from the valve housing after cuff inflation. Leaving the syringe attached will keep the valve open, permitting the cuff to deflate.
8. Check to verify the inflation system is not leaking. Integrity of the system should be verified periodically during the intubation period. Uncorrected failure of the inflation system could result in death. Cuff pressure should be closely monitored and any deviation from the selected seal pressure should be investigated and corrected immediately.
9. Prior to extubation, deflate cuff by inserting syringe into valve housing and removing gas mixture until a definite vacuum is noted in the syringe and the pilot balloon is collapsed.
10. Extubate patient following currently accepted medical techniques.

ADDITIONAL COPIES OF INSTRUCTIONS

Additional copies of these Instructions are available at no charge by calling Covidien. Also, permission is hereby granted under Covidien copyrights to make additional copies of these instructions for use by purchases of this product form Covidien or its authorized distributors.

Part No. 10048002 Rev B 01/2013

COVIDIEN, COVIDIEN with logo and Covidien logo are U.S. and/or internationally registered trademarks of Covidien AG.
Other brands are trademarks of a Covidien company.

© 2011 Covidien. Covidien Inc., 15 Hampshire Street, Mansfield, MA 02048 USA.
www.covidien.com