

This instruction for use applies for:

- Magill shaped Endotracheal Tubes:
 - Cuffed and uncuffed (plain)
 - With and without Murphy eye
- Nasal & oral preformed Endotracheal Tubes
 - Cuffed and uncuffed (plain)
 - With and without Murphy eye
- Oxford Endotracheal Tubes.
- Reinforced Endotracheal Tubes
 - Cuffed and uncuffed (plain)
 - With and without Murphy eye
- Magill shaped, cuffed Endotracheal Tubes with Extended Volume Low Pressure cuff (EVLV). With and without Murphy eye
- Magill shaped, cuffed Endotracheal Tubes with Extended Volume Low Pressure cuff (EVLV), subglottic suction port and Murphy eye
- Extra-Soft Endotracheal Tubes
 - Uncuffed
 - With and without Murphy eye

Notes

All references specific to cuffs may be disregarded when using plain (uncuffed) tubes.

All references specific to subglottic suction may be disregarded when using tubes without subglottic suction port.

Description

Sterile, single use Endotracheal Tubes manufactured from transparent, biocompatible, thermo sensitive polyvinylchloride (PVC) which softens at body temperature and adapts to the patients airway anatomy.

Reinforced Endotracheal Tubes are made from soft, transparent, biocompatible, thermo sensitive polyvinylchloride (PVC) with a flat coiled stainless steel wire inside the wall to increase the flexibility and prevent collapse of the tube.

Plain and cuffed Endotracheal Tubes are available in a variety of sizes and styles as outlined in the following charts (Fig.1). The tubes are available with or without Murphy eye. As a reference during intubation, the tubes have depth marks in centimeters, which indicate the distance to the distal tip. In addition, cuffed Endotracheal Tubes are marked 2 and 4 cm above the cuff for reference in determining the cuff and distal tip position after the first pass through the vocal cords.

Plain (uncuffed) pediatric tubes sizes have a distal marking at the tip as a reference during intubation.

All tubes have a radiopaque line. Reinforced tubes have a radiopaque line from end of wire to the end of distal tip, because the wire itself is x-ray visible.

Endotracheal Tubes with subglottic suction port are equipped with a suction line ending above the cuff, for elimination of secretions, collecting above the cuff. The suction line is equipped with a connector and a closing cap.

Color coding of the 15mm connector of the Endotracheal Tubes indicates the recommended suction catheter size for use with the specific size of the Endotracheal Tube (Fig. 2).

Pilot balloon (on cuffed tubes) with printed size and trace number, for eased size reference and traceability.

Thin walled low pressure cuffs, designed to provide optimal sealing and pressure distribution. Smooth and seamless cuff to tube transition improves the ease of intubation and minimizes the risk of vocal cord lesions.

Smooth and tapered tip facilitates intubation, using standard techniques with a laryngoscope, but also using fiberoptic intubation techniques.

Indications for use

Unomedical Endotracheal Tubes are indicated for airway management by nasal or oral intubation of the trachea (Endotracheal Tubes with subglottic suction line, Oxford Endotracheal Tubes and oral preformed Endotracheal Tubes are only recommended for oral intubation; nasal preformed Endotracheal Tubes are only recommended for nasal intubation). Endotracheal Tubes are available in multiple sizes and styles to accommodate pediatric and adult patients. It is the judgment of the clinical expert to select the right size and style for the individual patient.



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Contraindications

Use of Endotracheal Tubes in procedures which involve the use of laser beam or electrosurgical active electrodes in the immediate area of the device is contraindicated. Especially in the presence of oxygen-enriched mixtures this could result in rapid combustion of the tracheal tube with harmful thermal effects and emission of corrosive and toxic products, including hydrochloric acid (HCl).

Precautions/warnings

Read the following instructions carefully before using the products

- Do not use if package has been previously opened, damaged or inadequate storage.
- Do not re-sterilize.
- When the patient's position is altered after intubation, it is essential to verify that the tube position remains correct in the new patient position.
- Tubes should be securely anchored to avoid unnecessary tube movement.
- It is not recommended to cut endotracheal tubes. Unomedical manufactures a variety of endotracheal tubes in different sizes for varying patient needs. If the endotracheal tube is cut, this is at the healthcare professional's discretion and own clinical judgement.
- For Extra-Soft Endotracheal Tubes, it is recommended to use a stylet or bougie to assist the intubation, especially for sizes below 4.0mm.
- For Extra-Soft Endotracheal Tubes, apply an appropriate fixation to secure the tubes.
- Seat the connector firmly in both the Endotracheal Tube and adapter on the ventilation equipment to prevent disconnection during use.
- Non-standard dimensions of some connectors on ventilators or anesthesia equipment may make secure mating with the Endotracheal Tubes 15mm connector difficult – test securely before anesthesia introduction.
- Federal (USA) law restricts this device for use by or on the order of a physician.
- Reinforced tubes are not compatible with MRI scanners, because of the wire inside the tube is magnetic – and will be attracted in the direction of the Scanner.
- Reinforced tubes are not intended or prepared to be cut to length by the user.

Cuffed Endotracheal Tubes

- Each tubes cuff, pilot balloon and valve should be tested by inflation before use, if the tube is defective before or during intubation - the tube must not be used.
- Choose the right size in order to minimize the risk of Tracheal stenosis and fistula.
- Avoid damaging the cuff during intubation. If the cuff is damaged, the tube should not be used.
- Deflate the cuff prior to repositioning the tube. Movement of the Endotracheal Tube with the cuff inflated could result in patient injury or damage to the cuff, requiring a tube change.
- Do not overinflate the cuff. Overinflating can result in rupture of the cuff with subsequent deflation or in cuff distortion which may lead to airway blockage.
- Overinflating will also prevent the microvasculature in the surrounding tissue.
- Too low cuff pressure will result in a leak of gas, and by that insufficient ventilation.
- Inflation of the cuff by "feel" or by using a measured amount of air is not recommended since resistance is an unreliable guide during inflation. A cuff pressure measuring device should be used in conjunction with minimal occluding volume or minimal leak technique.
- Cuff pressure should be monitored. Any deviation from the selected seal pressure should be investigated and corrected immediately.
- Diffusion of nitrous oxide (N₂O), oxygen, or air from a surrounding gas mixture may either increase or decrease cuff volume and pressure. To decrease such effects, inflating the cuff with the same gas mixture that will contact the cuff's external surface is recommended.



- The use of lidocain topical aerosol has been associated with formation of pinholes in PVC cuffs (Jayasuriya, K.D., Watson, WF: P.V.C. Cuffs and Lidocaine-based aerosol. Brit. J. Ann. 53:1368, 1981). The same authors report that lidocaine hydrochloride solution doesn't have this effect.
- Three-way stopcocks or other devices should not be inserted in the inflation valve for extended periods. The resulting stress could crack the valve housing and allow the cuff to deflate.

Storage conditions

- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet and fluorescent light.
- Store in manner preventing crushing.
- Stock rotation on first in first out basis.

Adverse reactions

Standard textbooks and scientific literature should be consulted for any specific adverse reaction information.

Directions for use

- Use aseptic technique
- Intubation and extubation should be performed following currently accepted medical technique.
- Expert clinical judgment should be used in choosing the suitable Endotracheal Tube size and style for each patient.

Preparation

- For cuffed tubes, test integrity before intubation. Inflate cuff with a Luer-tip syringe then deflate air from cuff after test inflation.
- Ensure that the 15mm connector is firmly attached into the Endotracheal Tube.

Intubation

- Perform intubation following the currently accepted medical techniques, in order to avoid improper handling of the product during intubation.

For cuffed tubes, inflate cuff with sufficient air to provide an effective seal at the desired lung inflation pressure.

For cuffed tubes, remove Luer-tip syringe from the valve to effect closing of the one-way valve.

Tracheo-bronchial suctioning

It is recommended to perform endotracheal suctioning by utilizing a suction catheter/ suction system of appropriate size, indicated by the colour coding system of the 15mm connector.

Subglottic suction

Endotracheal Tubes with a subglottic suction line are equipped with a suction line ending above the cuff.

The suction line ends with a connector with a closing cap.

The connector fits to all standard female suction tubing (e.g. funnel connection) and is compatible to Luer syringes.

- Remove the closing cap from the connector.
- Connect the suction equipment to the connector.
- In case a female connection is required an adapter, (e.g. Suction Adapter REF# 8407818) has to be placed between suction line and connector.
- Remove the secretions above the cuff performing a suction procedure.
- After suctioning and disconnection of the suction equipment, the connector should be resealed using the closing cap.

Caution: Ensure that strong suction is not applied during suctioning. A level of max. 30 mmHg suction power is recommended. Obstruction of the suction line may be removed by rinsing it with 2-3 ml sterile saline solution. After rinsing perform a suction procedure immediately.

Extubation


Deflate the cuff completely using syringe before extubation.


Extubate using current accepted medical technique.

Fig. 2 Colour Coding System

Endotracheal Tubes I.D. (mm)	Recommended Suction Catheter size		Colour Code	
	O.D. (mm)	O.D. (CH)	Suction Catheters	Endotracheal Tubes
3.0 - 3.5	1.3	4	Red	Red
4.0 - 4.5	2.0	6	Green	Green
5.0 - 6.0	2.7	8	Blue	Blue
6.5 - 7.0	3.3	10	Black	Black
7.5 - 8.0	4.0	12	White	White
8.5 - 9.0	4.7	14	Green	Green
9.5 - 11.0	5.3	16	Orange	Orange



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