ENDOTRACHEAL TUBE

INTENDED USE / INDICATIONS

An Endotracheal Tube is used in general anaesthesia, intensive care and emergency medicine for airway management and mechanical ventilation. The tube is inserted into a patient's trachea through the patient's nose or mouth in order to ensure that the airway is not closed off and that air is able to reach the lungs.

CONTRAINDICATIONS

- Use of Endotracheal 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.
- Patients who are suffering from the serious throat edema/ inflammation, hemorrhage or neck vertebra trauma are not recommended to use Endotracheal Tubes.

WARNINGS / PRECAUTIONS (Cuff-related)

- As these devices may have been subjected to handling, storage conditions or reparation 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.
- The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs. Expert clinical judgment 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 re-intubation. If the 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 which will contact its external surface is recommended as a means to reduce the extent of such diffusion.
- Do not overinflate cuff. Ordinarily, the cuff pressure should not exceed 25 cm H2O.
- 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 endotracheal 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 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 endotracheal tube should be considered.
- Non-standard dimensioning of some connectors on ventilatory or anesthesia equipment may make secure mating with the endotracheal 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 endotracheal 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 endotracheal tube, follow manufacturer's application instructions. Excessive amounts of jelly can dry on the inner surface of the endotracheal 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.

ADVERSE REACTIONS

Initially, most patients complain about the breathing tube feeling uncomfortable. It often makes patients cough or gag. Over the time the patients get used to the tube and the initial discomfort fades. During intubating, the respiratory tract may be hurt.

Directions

CUFFED

1. Prior to intubation, deflate the cuff completely.
2. After intubation, inflate the cuff using the minimum volume of air required to provide an effective seal.
3. Immediately after cuff inflation, auscultate both lung fields. If breath sounds diminished over one lung field or absent over one or both fields adjust the tube as required.
4. Endotracheal Tube placement should be confirmed by viewing the position of the tube tip with a chest radiograph.

UNCUFFED

1. Choose proper endotracheal tube size.
2. After intubation auscultate both lung fields. If breath sounds diminished over one lung field or absent over one or both fields, adjust the tube as required.
3. Endotracheal tube placement should be confirmed by viewing the position of the tube tip with chest radiograph.

Warning

CUFFED

1. Single use only.
2. Sterile if package is unopened or undamaged.
3. Do not resterilize.
4. Do not expose to temperaures above 49°.

UNCUFFED

1. Single use only.
2. Sterile if package is unopened or undamaged.
3. Do not resterilize.
4. Store in a dry, cool and dark place.

Storage conditions

- Do not expose to temperatures above 49°C.
- Store in a dry, cool and dark place.
- 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.

CE	Medical Device complies with Directive 93/42/EEC	LOT	Lot number	REF	Product code	EC REP	Authorized representative in the European community
STERILE EO	Sterilized using ethylene oxide		Manufacturer		Disposable device, do not re-use	2 STERILIZE	Do not resterilize
	Keep away from sunlight		Keep in a cool, dry place		Don't use if package is damaged		Expiration date
	Date of manufacture						

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UNCUFFED: 34385 - 34386

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