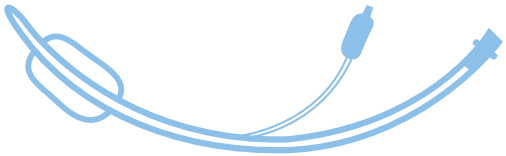
148mm

210mm

flexicare
TOTAL QUALITY - TOTAL CARE

ENDOTRACHEAL TUBES



VENTISEAL (HIGH VOLUME LOW PRESSURE CUFF)

ORAL/NASAL
038-971-XXX series

CURVED (Oral) SOUTH
038-972-XXX series

CURVED (Oral) NORTH
038-973-XXX series

CURVED (Nasal) NORTH
038-974-XXX series

REINFORCED
038-975-XXX series

ORAL/NASAL WITH STYLET
038-976-XXX series

STANDARD CUFF

ORAL/NASAL
038-981-XXX series

CURVED (Oral) SOUTH
038-982-XXX series

CURVED (Nasal) NORTH
038-984-XXX series

PLAIN TUBES (WITHOUT CUFF)

ORAL/NASAL
038-961-XXX series

CURVED (Oral) SOUTH
038-962-XXX series

CURVED (Nasal) NORTH
038-964-XXX series

REINFORCED
038-965-XXX series

ORAL/NASAL WITH STYLET
038-966-XXX series

CE 0120

STERILE EO

PHT DEHP
Product is not made with Phthalate DEHP

LATEX
Product is not made with natural rubber latex

STERILISE

DESCRIPTION

The Flexicare Endotracheal Tube is a sterile, single use device with a standard 15mm connector. Endotracheal Tubes are available either plain (uncuffed) or cuffed in a variety of sizes and styles. Cuffed Endotracheal Tubes are supplied with either a High Volume Low Pressure Cuff (Ventiseal), or a Standard Cuff and all have an attached pilot balloon with a one-way luer valve. All Plain and cuffed Endotracheal Tubes have a Murphy Eye. As a reference during intubation, the Endotracheal Tubes have depth marks in centimetres which indicate the distance to the distal tip. In addition, Endotracheal Tubes are marked with two circumferential lines to aid positioning relative to the vocal cords. Plain tubes 2.0 – 4.5 mm ID also have an orientation guide at the distal tip. All tubes except reinforced tubes have a radio opaque line. The stainless steel wires in the reinforced tubes are visible on X-ray.

INTENDED USE

An Endotracheal Tube is inserted through the mouth or nose into the trachea to maintain an unobstructed airway, to ventilate the patient, to permit the suctioning of mucus or to prevent aspiration of the stomach contents, and deliver air, oxygen enriched air, or anaesthetic gases to the lungs in anaesthesia, critical care, emergency care and/or pre-hospital settings.

CONTRAINDICATIONS

No specific contraindications are declared for Flexicare Medical's Endotracheal Tubes. However, an appropriate size should be selected according to patient characteristics and a suitable shape according to the chosen procedure. The user should be familiar and trained in the use and care of the product and should be aware of clinical contraindications for the use of invasive ventilation.

WARNINGS

Do not use Flexicare Endotracheal Tubes in procedures which will involve the use of a laser beam or electrosurgical active electrode in the immediate area of the endotracheal tube. Contact of the endotracheal tube with a laser beam or electrosurgical active electrode may result in burning of the tube, combustion and the release of corrosive and toxic gases.

Cuffed Tubes

- Deflate cuff prior to repositioning the tube. Movement of the Endotracheal Tube with cuff inflated could result in patient injury or damage to the cuff, requiring a tube exchange.
- Do not over inflate cuff. Over inflation can result in rupture of the cuff with subsequent deflation, or in cuff distortion which may lead to airway blockage.

CAUTIONS

General

- Do not use if packaging is open or damaged.
- Intubation and extubation should be performed using currently accepted medical techniques.
- Should extreme neck flexion or movement of the patient (e.g. from supine to a lateral or prone position) be anticipated after intubation, use of a reinforced Endotracheal Tube should be considered.
- When the patient's position is altered after intubation, verify that the tube position remains correct.
- Endotracheal Tubes should be securely anchored to avoid unnecessary tube movement.
- Seat the connector firmly in both the Endotracheal Tube and adaptor on the ventilation equipment to prevent disconnection during use.
- A bite block should be used in cases where the patient may bite down and occlude the Endotracheal Tube.
- Non-standard dimensioning of some connectors on ventilators or anaesthesia equipment may make secure mating with Endotracheal Tube's 15mm connector difficult.
- After use, this product is contaminated clinical waste and may be a potential biohazard. Handle and dispose of in accordance with hospital policy and applicable local guidelines and regulations.
- Do not resterilise.

Cuffed Tubes

- Each Endotracheal Tube's cuff, pilot balloon and valve should be tested by inflation before use.
- Avoid damaging the thin-walled cuff during intubation. If the cuff is damaged, the Endotracheal Tube should not be used.
- 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. In selecting sealing pressure, an intracuff pressure measuring device should be used in conjunction with Minimal Occluding Volume or Minimum Leak techniques. Cuff pressure should be monitored. Any deviations from the selected seal pressure should be investigated and corrected immediately. Diffusion of nitrous oxide mixture, oxygen or air may either increase or decrease cuff volume and pressure. To decrease such diffusion, inflating the cuff with the same gas mixture that will contact the cuff's external surface is recommended.
- Three-way stopcocks or other devices should not be left inserted in the inflation valve for extended periods of time. The resulting stress could crack the valve housing and allow the cuff to deflate. The use of Lidocaine Topical Aerosol has been associated with the formation of pinholes in PVC cuffs (Jayasuriya, K.D., and Watson, W.F., P.V.C. Cuffs and Lignocaine-based Aerosol. Brit. J Ann. 53:1368, 1981). The same authors report that lidocaine hydrochloride solution does not have this effect.
- Follow the manufacturer's application instructions when using lubricating jellies with Endotracheal Tubes. Excessive amounts of lubricant could result in either a lubricant plug or a clear film that partially or totally blocks the airway.

Reinforced Endotracheal Tubes

- Reinforced Endotracheal Tubes are not intended to be cut to length by the user.

ADVERSE REACTIONS

Reported adverse reactions associated with the use of tracheal tubes are many and diverse. Standard text books and the scientific literature should be consulted for specific adverse reaction information.

DIRECTIONS FOR USE:

Use aseptic technique

Intubation and extubation should be performed following currently accepted medical techniques. Expert clinical judgement should be used in choosing the suitable Endotracheal Tube size and style for each patient.

1. Remove sterile Endotracheal Tube from the protective packaging
2. For cuffed Endotracheal Tubes, test the integrity before intubation. Inflate cuff with a luer-tip syringe then completely deflate air from cuff after test inflation.
3. Ensure 15 mm connector is firmly attached into Endotracheal Tube.
4. Intubate patient following currently accepted medical techniques and connect to the ventilation equipment.
5. For cuffed Endotracheal Tubes, inflate cuff with sufficient gas mixture to provide an effective seal at the desired lung inflation pressure. Use of Minimal Occluding Volume Technique can reduce occurrence of many of the adverse reactions associated with the use of cuffed Endotracheal Tubes. Removal of the luer-tip syringe will close the one-way valve.
6. Once positioned, the connector can be removed, the Endotracheal Tube cut to a desired length, and the connector replaced and connected to the ventilation equipment.
7. For cuffed Endotracheal Tubes, completely deflate the cuff before extubation using a luer-tip syringe until a definite vacuum is noted.
8. Extubate using currently accepted medical techniques.

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SYMBOLS GLOSSARY

Catalogue Number

Batch Code

Use-by Date

Product conforms with Directive 93/42/EEC

Do Not Re-use

Consult Instructions for Use

Caution

Do Not Use If Packaging Is Damaged

Sterilized using Ethylene Oxide

Product is not made with Phthalate DEHP

Product is not made with natural rubber latex

Keep away from sunlight

Manufactured by

Do Not Re-sterilize

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