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Instruction For Use

Endobronchial Tube

DESCRIPTION

The Endobronchial Tube is used for one-lung ventilation, in the OPS of bronchus, thoracic surgery and so on. It is available in standard left and right styles. It has a radiopaque line on all styles to assist in radiographic visualization. The Endobronchial Tube is usually inserted into the airways through the mouth of the patient. The air outlet of one of the channels is here placed in one of the bronchi, while the air outlet of the other channel, which is shorter, is then situated in the trachea. The windpipe is then closed by inflating a balloon which is arranged around the respiratory tube. The bronchus in which the air outlet of the longer channel is situated is likewise closed by inflating a balloon arranged there around.

The Endobronchial Tube is made from medical grade PVC, consists of main tube, tracheal connected tube, bronchial connected tube, tracheal cuff, bronchial cuff, valve, bronchial balloon, tracheal balloon, bronchial inflating line, tracheal inflating line, connector, switch connector, super-slip stylet.

FEATURES

- Latex-free
- Available with two types product including left-sided and right-sided for thoracic surgery
- Atraumatic soft rounded beveled tip
- Softer rounded Murphy eye is less invasive
- Radio opaque line along the whole tube
- The cuffs, two lumens and pilt balloons are imprinted with TRACHEAL (clear) or BROCHIAL (blue color) for easy identification
- Smooth inner lumens allow easy passage of bronchoscopes
- Pre-loaded with stylet to help tube maintain shape for easier intubation
- Packed with switch connector and two low friction suction catheters
- The product features a standard 15 mm connector, allowing for connection to the same standard connector for swivel adapters, breathing circuits, and ventilation support devices.
- The one-way valve connector complies with the requirements of ISO 80369-7, enabling connection with syringes or pressure gauges that comply with the same standard for cuff pressure control.

INTENDED USE

The Endobronchial (Tracheobronchial) Tube is usually inserted into the bronchus and trachea through mouth, and is intended for one-lung ventilation during thoracic surgery or for anesthesia during pulmonary surgery.

INDICATIONS

The Endobronchial (Tracheobronchial) Tube is indicated for use in thoracic and pulmonary surgical procedures requiring one-lung ventilation.

CLINICAL BENEFITS

By facilitating one-lung ventilation, the Endobronchial (Tracheobronchial) Tube can effectively manage respiratory support during thoracic and pulmonary surgeries, thereby improving patient outcomes and enhancing the efficiency of surgical procedures.

The clinical benefits associated with the Endobronchial (Tracheobronchial) Tube are direct, as it is applied for patients undergoing thoracic surgery or pulmonary operations.

PATIENT TARGET GROUP

Child, adult patients.

INTENDED USER

Must be operated by trained professionals.

CONTRAINDICATIONS

Any airway abnormalities that could affect the path of the double-lumen tube (such as airway stenosis, tumors, or tracheobronchial ruptures), or external compression of the airway (such as from mediastinal tumors or aortic arch aneurysms), should be considered absolute contraindications. Relative contraindications include: (1) Patients with a full stomach; (2) Patients at high risk of aspiration; (3) Critically ill patients on mechanical ventilation who cannot tolerate the temporary cessation of ventilation required for tube replacement; (4) Cases where tracheal intubation is expected to be difficult to perform under direct visualization; (5) Evidence of tenting of the left main bronchus, forming an angle greater than 90° with the trachea (this situation not only makes intubation of the left main bronchus particularly difficult but also increases the risk of left main bronchus injury).

ADVERSE REACTIONS

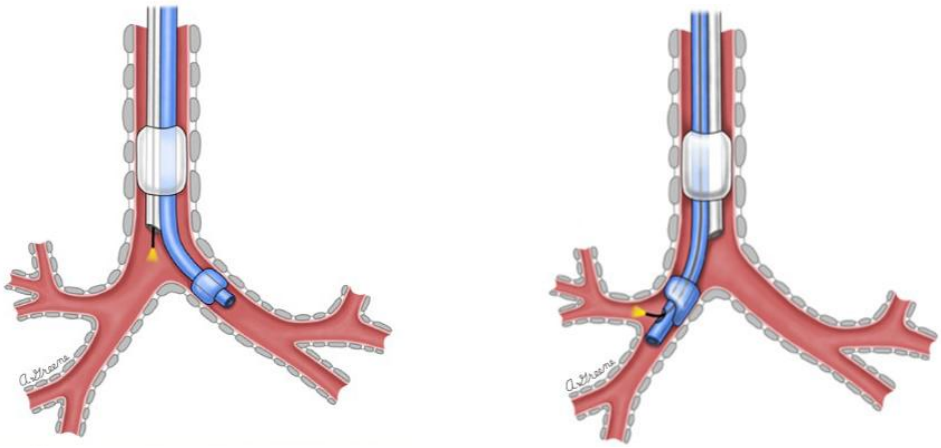
- During intubation, the respiratory tract may be injured, potentially causing sore throat, hoarseness, and vocal cord damage.
- Hypoxemia during OLV (One Lung Ventilation).

DIRECTIONS FOR USE

- Choose appropriate size of Endobronchial Tube
- Before insertion, test the tracheal balloon and bronchial cuff by inflation to check if any leakage
- Lubricate the proximal tip and cuffs
- Bend the tube with preloaded stylet to suitable curve
- After the patient is anaesthetize, use laryngealscope to expose patient glottis, and insert the proximal of Endobronchial Tube to pass the glottis.
- After the proximal of Endobronchial Tube passes the glottis, remove the

stylet.

- Gently rotate the tube to the left 90 degree if operate with left-sided Endobronchial Tube, rotate to the right 90 degree if operate with right-sided Endobronchial Tube.
- Keep on pushing slowly the Endobronchial Tube to the desired depth. Attention: The insertion depth have relation with the patient's height. Clinical doctor need to estimate the insertion depth according to the actual situation of the patient.
- Connect the switch connector to Endobronchial Tube. Attention: Connect the blue tube of the switch connector to the blue bronchial connecting tube. Connect the clear tube of the switch connector to the clear tracheal connecting tube.
- Connect the switch connector with anesthesia machine or respirator.
- Inflate the tracheal cuff and bronchial cuff.
- Use stethoscope or fiber bronchoscope to check if the Endobronchial Tube reach the correct position as figure 1. Attention: The position of Endobronchial Tube should be judged by professional clinical doctors.
- Inflate the tracheal cuff and bronchial cuff, and it is recommended to maintain the cuff pressure at between 25 and 30 cm H_2O.
- Place bite-block and then stabilize the Endobronchial Tube.
- If the position of the patient changed, need to re-check the position of Endobronchial Tube.



Left bronchial Right bronchial

Figure 1 Final position of the Endobrochial Tube

WARNINGS

- Read all warnings and instructions before use. Improper use can result in serious or fatal illness or injury.
- This device can only be used by trained professionals.
- Do not use if the sterile packaging is damaged or unintentionally opened before use.

- Do not use if it's damaged or irregularly shaped.
- Do not use after the expiry date.
- For single use only.

PRECAUTIONS

- Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in injury, illness or death of the patient. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- 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.
- When a patient's position or tube placement is altered after intubation, it is essential to verify that the tube position remains correct. Any tube displacement should be corrected immediately.
- If the Endobronchial Tube is lubricated prior to intubation, it is essential to verify that lubricant does not enter and occlude the tube lumen thereby preventing ventilation.
- Check the placement of the tube (auscultation, bronchoscopy, radiography, etc.) periodically and whenever the patient is repositioned.
- Expert clinical judgment should be exercised in the selection of the appropriate size tube for each patient.
- Caps should be securely closed when ports are not in use.
- For tracheo-bronchial suctioning of mechanically ventilated patients, without disconnection of the mechanical ventilator, it may result in a negative patient airway pressure excursion.
- Dispose of product and packaging in accordance with hospital administrative and/or local government policy.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the user's place.
- Deflate both cuff prior to repositioning the tube. Movement of the tube with cuff inflated could result in patient injury or damage to the cuff.

STORAGE CONDITIONS

- Store in a cool and dry place, keep away from sunlight.
- Protect product from moisture and excessive heat.
- Avoid prolonged exposure to ultraviolet, sunlight and fluorescent light.
- Store in manner preventing crushing.

Shelf life: 5 years.

The Key Performance characteristics

Endobronchial Tube/ Endobronchial Tube(Bull Nose tip)

Endobronchial Tube(Left)	28Fr	32Fr	35Fr	37Fr	39Fr	41Fr
Endobronchial Tube(Right)	28Fr	32Fr	35Fr	37Fr	39Fr	41Fr

Endobronchial Tube/ Endobronchial Tube(Bull Nose tip)

Type / Size	28Fr	32 Fr	35 Fr	37 Fr	39 Fr	41 Fr
Left bronchial cuff inflation diameter /mm	15	15	21	21	21	21
Right bronchial cuff inflation diameter /mm	16	16	22	22	22	22
Tracheal cuff inflation diameter /mm	21	27	31	31	32	32
Tube length /mm	330					

Endobronchial Tube/ Endobronchial Tube(Bull Nose tip) Sign size

Type	28Fr	32 Fr	35 Fr	37 Fr	39 Fr	41 Fr
Max Bronchial diameter OD mm	9.0	10.0	10.5	11.5	11.5	12.0
Effective inner diameter of the tube body ID mm	3.2	3.8	4.0	4.4	4.6	5.0

Respiratory suction catheter dimensional information table

Type	OD.mm	ID./mm	Color identification	L±5%(mm)
6Fr	2.00	1.00	Reseda	490
8Fr	2.67	1.50	Wathet	490
10Fr	3.33	2.00	Black	490
12Fr	4.00	2.45	White	490

Endobronchial Tube and Respiratory suction catheter matching model

Endobronchial Tube	28Fr	32Fr	35Fr/37Fr/39Fr	41Fr
Respiratory suction catheter	6Fr	8Fr	10Fr	12Fr

Endobronchial Tube and Intubating Style matching model

Endobronchial Tube	28Fr/32Fr	35Fr/37Fr/39Fr/41Fr
Intubating Style	10Fr	14Fr

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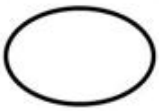
Instruction For Use

MEANING OF SYMBOLS ON PACKAGE

	**Date of manufacture**		**Use-by-date**		**Batch code**
	**Do not re-use**		**Consult instructions for use**		**Do not use if package is damaged**
	**Sterilized using ethylene oxide**		**Do not resterilize**		**Single sterile barrier system**
	**Medical Device**		**Manufacturer**		**Authorized representative in the European Community**
	**Catalogue number**		**Keep dry**		**Keep away from sunlight**
	**Importer**		**This way up**		**Fragile, handle with care**
	**Unique Device Identifier**		**Not contains or presence of phthalate. (if applicable)**		**CE Marked Product**

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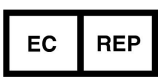

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