IFU

Double-lumen Endobronchial Tube

Description

This product is suitable for left or right bronchial insertion in surgical operation and to ensure the left lung or right lung is unobstructed. In thoracic surgery, the operative lung (or diseased lung) can be completely separated from the healthy lung. Through making the collapsion of the operative side lung, it can provide the operator with enough operating space, reduce the damage to the operative lung and protect the healthy lung. Moreover, it can prevent secretions (pus, phlegm, blood) or cancer thrombus from flowing into the healthy lung from falling into the healthy lung, resulting in the spread of infection and (or) suffocation caused by the occurrence of acute respiratory obstruction.

The product preset stylet, which can stiffen and/or maintain the shape of Double-lumen Endobronchial tube and is beneficial to the accurate insertion. At the same time, it is incorporated with a suction tube, which is convenient for patients to suck sputum, ensures the smooth of the airway and can effectively prevent VAP.

Category and sizes

Product name	Categories	Model codes	Sizes
Double-lumen Endobronchial Tube	Left	DLT-L10	26Fr，28 Fr，32Fr，35 Fr，37 Fr，39 Fr，41 Fr
		DLT-L11	
	Right	DLT-R10	
		DLT-R11	
Note: DLT-L10 (with check valve(left)), DLT-L11 (with AccuCuff™ (left)), DLT-R10 (with check valve (right)), DLT-R11 (with AccuCuff™(right))			

Intended use：

All areas of thoracic or pulmonary surgery, endobronchial anaesthesia, bronchospirometry and ventilation requiring unilateral pulmonary respiration.

Intended patient population

Children, adults.

Intended users

Professionally trained doctors or clinical nurses

Indications

a) Unilateral lung abscess or cyst
b) Unilateral lung hemorrhage (e.g., thromboembolism, aneurysm)
c) Lobectomy
d) pneumonectomy
e) Lung tumors
f) esophageal procedure
g) Thoracotomy
h) Lung lavage
i) Atrial septal defect closure

Contraindications

The left-sided versions are contraindicated in patients with obstructions or stenosis in the left main bronchus. The right-sided versions are contraindicated in patients with obstructions or stenosis in the right main bronchus.

Combination devices

Devices used in surgery: Syringe, laryngoscope, bite block, gloves, lubricating oil；
Devices used during ventilating: ventilator (to provide oxygen to the patient while monitoring various parameters during breathing).

Attentions

a. Sterile product. Sterilized by Ethylene Oxide.
b. Single use only. Do not re-sterilize or reuse which will cause cross infection.
c. It is not suitable for anesthesiologists who have not mastered the basic knowledge of intubation or not highly skilled in intubation. And it is not suitable for condition that combinative devices are not sufficient.
d. Check the package before use. It is strictly prohibited to use if the single package damage or exceeds the expiry date.

e. Pay attention to distinguish the Cuff Pressure Indicator (white) or check valve (white) of tracheal cuff from the Cuff Pressure Indicator (blue)or check valve (blue) of bronchial cuff during inflating/deflating the Double-lumen Endobronchial Tube.

f. Please strictly abide by the corresponding surgical procedures, do not violate the rules of operation.

g. After use, the product should be completely scrapped. And the products should be completely scrapped, and put into the disposable product waste designated by the hospital, which will be treated by the hospital in accordance with local laws and regulations.The indwelling time of the human body should not exceed 7 days. For cuffed products, monitor the cuff pressure every 1 hour.

h. This product can only be operated by professionally trained doctors and clinical nurses, and the instructions should be read carefully before use.

i. According to the patient's condition, the appropriate depth of anesthesia and the placement of dental pads should be applied to prevent the patient from gum occlusion, resulting in tube broken or collapsed and obstruction of the airway.

j. Non-routine deflating or adjusting the cuff pressure shall be carried out according to the disease to prevent the cuff from compressing the tracheal wall for a long time and causing mucous membrane injured.

k. Do not use the Double-lumen Endobronchial Tube with a reinforced spring during MRI scan. (Note: Intubation with reinforced spring can produce displacement, artifact,heat generation, and magnetic torsion forces under MRI, which can be life-threatening in severe cases).

l. Syringes, 3-way pistons or other lure connector devices should not be inserted in the Cuff Pressure Indicator or check valve for a long time for the resulting stress could crack the valve housing and allow the cuff to deflate.

m. Do not use a laser near the Double-lumen Endobronchial Tube as this may cause combustion and injury. (Note: Contact of the beam or electrode with the Endobronchial Tube, 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 (HCI).)

Pre-use checks

a. Do not use this product unless these checks are completely qualified.

b. Product packaging should be unopened, undamaged, sterilized and provided within shelf life.

c. Visually check the integrity, fading, damage and defects of the whole product.

d. If the pre-use inspection fails, please do not use the product and return the product to the supplier for inspection.

Direction for use

These directions are general guidelines for qualified medical personnel. Any given instructions, indications and contraindications are not exhaustive and the clinicians should ensure the safety and correct use of this product.

The product should be handled by professional trained doctors .

a. Open the package and take out the product.

b. First inject gas with a syringe and observe whether there is leakage.

c. Expose the glottis with a laparoscopy. After the tip of the tube has entered the glottis, rotate it 90 degrees so that the curved tip points to the corresponding side of the main bronchus and move forward the tube until it reaches the appropriate depth.

d. Inflate the cuff with a syringe.

e. Inject air separately through check valve or Cuff Pressure Indicator of Double-lumen Endobronchial Tube to inflate the bronchial cuff and tracheal cuff. Fill cuff by the check valve with the minimum necessary volume. When filling the cuff with Cuff Pressure Indicator, make the black line within the green safety zone.

f. Note: When using the syringe to inject air into the Cuff Pressure Indicator, you need to turn the syringe forward and rotate 90° to the right.

g. Connect a ventilator for oxygen supply.

h. In the process of oxygen supply, pay attention to the sputum secretion in the patient's airway, and conduct sputum aspiration immediately.

i. Disconnect the ventilator and insert the suction tube into the airway slowly, interrupting suction with negative pressure , rotating and pulling out.

j. Before extubation, the patient must have sufficient spontaneous respiration. Syringe aspiration method is not available on deflation. Instead, only open the inflation port of the oral outer cuff, that is, push the gas valve with the a syringe withdrawing the plunger, or slide the one-way valve with a knife so that the secretions around the cuff can be removed when extubated.

SHELF LIFE

5 years

Duration of use

Less than 7 days.

Storage condition

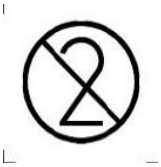
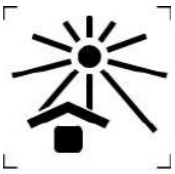
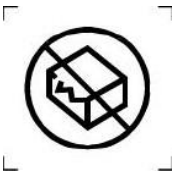
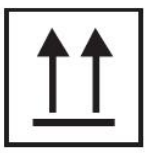
Store product inside containers or outer boxes in a clean, dry area.

Storage should be within a temperature range of 10–30℃.

Do not expose to direct sunlight or UV light.

Made in China

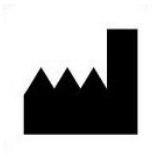
The meaning of the mark on the package

	Do not re-use		Manufacturer
	Use-by date		Date of manufacture
	Batch code		Authorized representative in the European Community
	Sterilized using ethylene oxide		Keep away from sunlight
	Do not use if package is damaged		Keep dry
	Consult instructions for use		Catalogue number
	Caution		Doesn't contain DEHP
	CE marking of conformity		Latex free
	This way up		Fragile,Handle with care

MR Safe

MR unsafe

MR Conditional



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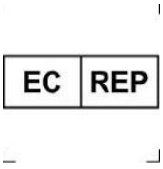

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