ENDOTRACHEAL TUBE

UNIVENT™, 3.5mm, without cuff
UNIVENT™, 4.5mm, with cuff

Fuji Systems

Indications for Use :

UNIVENT™ (TCB Type) is indicated for use in airway management of surgical patients to perform one-lung ventilation.

Complications :

The following adverse reactions have been reported to be associated with the use of UNIVENT™ during the intubation procedure, the intubation period, or in extubation procedure. The order of listing is alphabetical and does not indicate frequency or severity: air trapping; bronchitis; cartilage necrosis; consequences of failure to ventilate including death; damage to the perichondrium; emphysema; excoriated membranes of pharynx; glottic edema; hoarseness; hypercapnia; infections; laryngeal obstruction; laryngeal stenosis; postoperative atelectasis; pulmonary abscess; sore throat; submucosal hemorrhage; tracheal stenosis; tracheorrhagia; traumas (lips, pharynx, trachea, glottis, and etc.).

Warnings / Precautions :

[General]

1. Single use only (If the product is to be re-used, it may cause infection to patients or damage to the product).
2. It should not be replaced with a new piece of the same type after 30 days of use.
3. Do not undergo MRI scans while the product is intubated. Metal parts are used in this product.
4. Do not use if the sterile package is open, wet or damaged.
5. The tube is for oral intubation only. Do not use for nasal intubation.
6. Prior to use, take off and discard the aeration plate mounted at the one way valve on the blocker tube. This aeration plate is used for ventilation to avoid the risk of inflation of the blocker cuff by negative pressure during sterilization. If the aeration plate is detached from one way valve before opening the package, check if the blocker cuff is functioning.
7. When pushing blocker cuff out from main channel or drawing back blocker shaft into the main channel, it is suggested to manipulate blocker shaft close to the blocker mantle tube, because 1) blocker cuff tends to be caught on the inner wall at the tip part of main tube and 2) blocker shaft may kink due to lack of stiffness.
8. Avoid contact with laser beam or an electrosurgical knife in the immediate area of UNIVENT™. Such contact can result a sudden ignition of UNIVENT™ in the presence of mixtures of nitrous oxide and oxygen or pure oxygen.
9. Care must be taken to avoid occlusion at the tip part of main tube and blocker tube when applying lubricant.
10. Pull out the bronchoscope together with the tube, if there is an abnormality while inserting the bronchoscope in the tube.
11. Respiratory circuits of the respirator must be fit with standard 15mm connector. The 15mm connector of this product must be fit firmly with the respiratory circuits.
12. Do not cut the tube to adjust its length.
13. Unlike the ordinary UNIVENT™, blocker tip of 3.5mm & 4.5mm UNIVENT™ are closed end. Lung collapse and suction cannot be done through the blocker lumen. Collapse the desired lung naturally. Do not disconnect the tube from ventilator during the procedure.
14. After use, dispose of this product and packaging based on the hospital, administrative and /or local government policy.
15. If user and/or patient notice any serious incident that has occurred in relation to the device, please report to the manufacturer and the competent authority.

[Cuff Related]

1. Test the cuff, and valve assembly prior to use. If dysfunction is detected in any part of the inflation system, the tube should not be used.
2. After checking blocker cuff, deflate blocker cuff and pull blocker shaft back to the setting end mark (a double line marked on blocker shaft) and have blocker cuff placed at the tip part of the main tube. This is to avoid the bent tip of blocker cuff to narrow the inner lumen of main tube and it also prevents irritation to the lateral wall of trachea and bronchus during the insertion.
3. Do not overinflate the blocker cuff. Overinflation can result in bronchus damage. Inflate the blocker cuff by using Luer-Slip type syringe.
4. The cuff wall should not be damaged during the insertion of the tube. If any damage is detected, the tube should not be used.
5. Apply lubricant on blocker cuff in order to reduce the risk of damage of blocker cuff caused by the friction with the pocket part of the main tube.
6. Iodic disinfectant should not be used. It may deteriorate the material of the cuff.
7. Inflate the cuff until suitable seal can be reached.
   Maximum injected air volume for main cuff:
   I.D. size 4.5mm (with cuff) max. 5mL
   Note: I.D. size 3.5mm (without cuff) does not have main cuff.
   Maximum Injected air volume for blocker cuff per size:
   max. 2mL
8. Cuff inflation and pressure should be monitored at all time. Permeation of mixtures of nitrous oxide (laughing gas) and oxygen can cause the change of cuff volume and increase or decrease pressure of silicone cuff.
9. Air in the cuff must be removed completely before adjusting the position of main tube cuff or blocker cuff. It may damage the trachea, bronchus, or cuff itself while manipulating without completely deflating of the cuff.
10. Before retracting the blocker cuff into the main channel, make sure that the air has been removed from the blocker cuff completely. Then gently pull back the blocker shaft until the setting end mark (a double-line mark) on blocker appears at the end of blocker mantle tube. Do not pull the blocker tube with excessive force. It may damage the blocker cuff.

[Clinical Related]

1. Always use a flexible bronchoscope to position and set the tube blocker.
2. The bronchus should be blocked only after the patient has been positioned on the side, the thoracotomy started and the pleura opened so as to reduce the amount of pulmonary blood flow to the upper lung.
3. The blocker cuff pressure should be checked with cuff pressure gauge to prevent the overinflation of the cuff.
4. When the bronchus is blocked the inspired oxygen concentration should be increased to 50% or more, and the patient mechanically ventilated.
5. PaO_2 should be measured when the blocked lung is either visually confirmed to be collapsed, or twenty minutes have elapsed since the blocking of the bronchus. The value of PaO_2 should not decrease thereafter owing to “Hypoxic Pulmonary Vasoconstriction”. However it is desirable to check the PaO_2 again to make sure that one lung anesthesia is correctly taking place. In addition, SaO_2 should be monitored with a pulse oximeter.

Recommended Procedure :

1. Remove the sterile UNIVENT™ from the package with care.
2. Prior to use, take off and discard the aeration plate mounted at one way valve on blocker tube.
3. Test inflation of the main cuff and blocker cuff prior to use.
   DO NOT USE Luer-Lock syringe; must use Luer-Slip syringe to inflate the cuff.
   Maximum injected air volume for main cuff:
   I.D. size 4.5mm (with cuff) max. 5mL
   Note: I.D. size 3.5mm (without cuff) does not have main cuff.
   Maximum Injected air volume for blocker cuff per size:
   max. 2mL
4. Deflate air in main cuff and blocker cuff completely after the inflation test.
5. Apply lubricant on both cuffs.
6. Pull the blocker shaft back slowly to the setting end mark (a double-line marked on the blocker shaft) and have blocker cuff placed inside the main channel.
7. Move the cap stopper while give it a twist by finger and put it into the end of the blocker mantle tube.
8. Fix the blocker with the band stopper on main tube.
9. When connecting to respirator, make sure the 15mm connector is firmly attached to the respiratory circuit.
10. Intubate UNIVENT™ by referring the following methods:
    [Main Tube Rotation Method]
    A. UNIVENT™ is inserted into the trachea.

B. Turn the tube 90 degrees towards the operative side, this may be facilitated by turning the patient's head; to check the degree to tube rotation make sure the tube exits the patient's mouth on the side for thoracotomy. Rotate the tube with the tracheal cuff deflated. After rotation, inflate trachea cuff and fix the tube firmly at patient mouth with cloth tape.

C. Push the blocker shaft; the blocker will follow the lateral wall of the trachea and enter the target main stem bronchus. Use a flexible bronchoscope to position blocker as deeply as possible to prevent cuff herniation into the carina and to prevent blocker dislodgment when the patient is turned on their side. Following this, fix the blocker to the endotracheal tube with the cap stopper and band stopper.

D. After the patient has been turned on the side and thoracotomy has taken place, place 5mL of air into the blocker cuff, checking cuff pressure. Pitting of the lung surface which appears and remains following finger compression is evidence that the bronchus is completely blocked.

[Blocker Rotation Method]

A. Insert UNIVENT™ and have the tube fixed.

B. Insert bronchoscope into the tube and then push while twisting blocker tube to the target main stem bronchus under direct vision. The rest of the manipulations are same as Main Tube Rotation Method.

11. When extubating UNIVENT™, make sure that the air has been removed from the blocker cuff, then gently pull back the blocker until the setting end mark (a double-line mark) on blocker appears at the end of blocker mantle tube and the blocker cuff is placed in the pocket at the tip part of the main tube. Then deflate the main cuff completely. Extubation should be performed currently accepted medical techniques.

Storage Conditions :

Keep the product dry and store in clean conditions, avoiding high temperature, humidity and direct sunlight.

Symbols Glossary :

MD	Medical device
	Consult instructions for use
	Keep away from sunlight
	Keep dry
	Do not use if package is damaged and consult instructions for use
	Caution
	Do not re-use
Rx.Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
STERILE EO	Sterilized using ethylene oxide
	Single sterile barrier system
	Do not resterilize
REF	Catalogue number
LOT	Lot number
CONT	Contents
	Date of manufacture
	Use-by date
	Manufacturer
UDI	Unique Device Identifier

Manufacturer :

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