**ENGLISH**

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# UNIVENT® (TCB Type) REF 12026XX
# UNIVENT® (TCB Type) REF 12029XX

# H-511


**Manufacturer :**

**Fuji Systems Corporation**
**Shirakawa Plant**

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Sterility guaranteed if package is unopened and undamaged.
Discard the product after use.
Sterilized by ethylene oxide gas.
Do not expose the product to high temperature, humid air or ultraviolet light during storage.
Do not reuse. It may cause infection to patients or damage to the product.
LATEX FREE.

## INDICATION :

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

## DESCRIPTION :

1. The movable blocker shaft is guided in the blocker lumen of the endotracheal tube, with blocker cuff attached at the distal end.
2. The pilot balloon, connected to the blocker cuff, is transparent, and "BLOCKER" marking is printed on it.
3. X-ray opaque line is placed at the distal end of the endotracheal tube. Also, the blocker is designed X-ray opaque.
4. Depth markings are printed both on the endotracheal tube and blocker shaft for checking the insertion position.

## FEATURES :

1. Endotracheal intubation can be performed in the conventional manner, just like a single lumen endotracheal tube.
2. One-lung ventilation can be achieved by placement of the blocker to either the left or right lung, or to lung segments in either lung.
3. Insufflation and CPAP can be achieved through the lumen of the blocker shaft.
4. Blocked lung can be collapsed by aspirating air through the blocker lumen.
5. The blocker can be retracted into its pocket to facilitate post operative ventilation.

A. Stylet
B. Open Lumen Tip (X-Ray Opaque)
C. Blocker Cuff
D. Blocker Bend
E. Endotracheal
F. X-Ray Opaque
G. Tracheal Tube Cuff
H. Endotracheal Tube
I. Blocker Mantle Tube
J. Blocker
K. Cap Stopper
L. Blocker Grip
M. Funnel
N. Pilot Balloon
O. One-Way Valve
P. Aeration Plate
Q. 15mm Connector
R. Pilot Balloon
S. One-Way Valve
T. Band Stopper

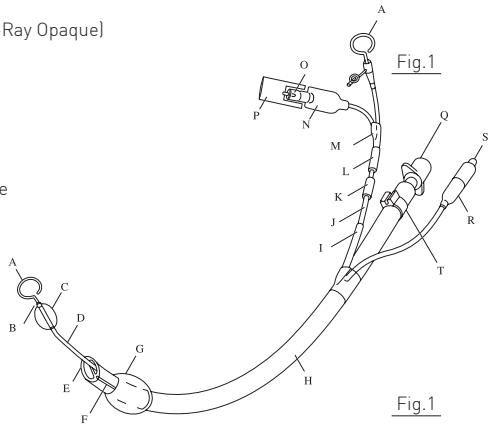


Fig.1

Fig.1

## WARNINGS AND PRECAUTIONS :

### [About Stylets and Aeration Cap]

a) The stylets on both ends of the blocker should be removed and discarded prior to use, as they are placed to maintain the curved shape of the blocker.
b) The aeration cap (blue color) attached at the blocker valve should also be removed and discarded prior to use, as it is attached for ventilation during EOG sterilization process.

### [About Retraction of Blocker Cuff]

a) Before retracting the blocker cuff, be sure to evacuate air completely from the cuff (until the pilot balloon is also collapsed) for smooth retraction.
b) Lubricant (such as Lidocaine jelly) should be applied on the whole surface of the blocker cuff.
c) Pull the blocker carefully until the setting end mark (double-end mark) appears at the proximal end of the blocker mantle tube and retract the blocker cuff into the pocket of the endotracheal tube.
d) Do not apply lubricant on the tip end of the blocker shaft as the lubricant may obstruct the blocker shaft lumen.
e) Do not pull the blocker shaft with excessive force when the setting end mark appears. It may damage the blocker cuff.
f) In case the tip end of the blocker shaft can't be retracted into the pocket of the endotracheal tube, the tube should not be used.

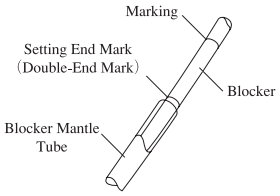


Fig.2

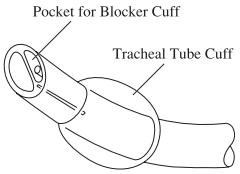


Fig.3

### [About Cuffs]

a) Conduct inflation test for tracheal cuff and blocker cuff prior to use. In case any malfunction such as air leakage or balloon herniation has occurred, the tube should not be used.

**Maximum injection air volume (for inflation test) for tracheal cuff per size:**

| | |
|---|---|
| For I.D. 6.0, 6.5, and 7.0mm | **max. 40mL** |
| For I.D. 7.5, 8.0, 8.5, 9.0, 9.5and 10.0mm | **max. 50mL** |

**Maximum injection air volume (for inflation test) for blocker cuff per size:**

| | |
|---|---|
| All sizes | **max. 6mL** |

*** Do not over inflate as above specified for inflation test.**

b) The cuffs should not be treated with forceps or the like. This may damage the cuff.
c) The internal pressure (or inflation volume) of the tracheal cuff or the blocker cuff should be determined by the clinical judgement of the physician. Excessive inflation may damage the cuff or the patient's trachea or bronchus.
d) After inflation of the tracheal cuff or the blocker cuff, disconnect the syringe from each valve. Leaving the syringe attached will keep the valve open, permitting the cuff to deflate.
e) The inflation condition of the tracheal cuff and the blocker cuff should be monitored at all times. Due to gas diffusion through the cuff, the internal cuff pressure (or inflation volume) changes over time. If the necessity of inflation or deflation of the cuff is necessary, be sure to evacuate air completely from the cuff (until the pilot balloon is also collapsed) first and inflate the cuff again to the appropriate volume.
f) Before intubation, extubation, and adjustment of each cuff position, be sure to evacuate air completely from the cuff (until the pilot balloon is also collapsed). Otherwise it may damage the cuff or the patient's trachea or bronchus.

### [General Warnings & Precautions]

a) Single use only (If the product is to be re-used, it may cause infection to patients or damage to the product).
b) Avoid contact with laser beam or an electrosurgical electrode in the immediate area of this tube. Such contact can result a sudden ignition of this tube in the presence of mixtures of nitrous oxide and oxygen or pure oxygen.
c) Do not use the product in case the sterile package is damaged or opened prior to use.
d) Expiry of the product is indicated on the product label. The product should not be used if expired.
e) Do not cut the tube to length or cut additional holes.
f) Care must be taken to avoid damage by knives, forceps or needles. The product should not be used if damaged.
g) Chemical disinfectants should not be used. It may deteriorate the material of the cuff.
h) If the sterile package is opened but the product is unused, it should be discarded.
i) Depth markings on the endotracheal tube and the blocker shaft are only a guideline of intubation. Actual intubation depth should be determined by clinical judgement of the physician.
j) Care must be taken to avoid occlusion at the tip of endotracheal tube and blocker shaft while applying lubricant.
k) Be sure to retract the tip part of the blocker into the endotracheal tube pocket prior to intubation. Otherwise it may damage the trachea.
l) Make sure that the 15mm connector and anesthetic circuit are firmly connected before intubation.
m) When pushing the blocker tip out of the endotracheal tube pocket, be sure to grip the blocker shaft near the blocker mantle tube (the area between the setting end mark and the first depth marking, as shown in Fig.2). Otherwise it may kink or break the blocker shaft.
n) When rotating and settling the tip part of the blocker, be sure to manipulate at the blocker grip. If manipulate at the blocker junction part, it may damage the junction part.
o) Be sure to retract the blocker cuff into the endotracheal tube pocket prior to extubation. Otherwise it may damage the trachea.

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### [Warnings and Precautions During Use]

a) The insertion position of the endotracheal tube and the blocker should be checked regularly by ausculation, bronchoscope, or X-ray.
b) When patient's position has changed, be sure to check the seal of the endotracheal tube cuff and the blocker cuff.
c) After the bronchus is blocked, the inspired oxygen concentration should be increased to 50% or more, and the patient should be mechanically ventilated.
d) $PaO_2$ Value should be measured when the complete collapse of the lung is confirmed, or twenty minutes after blocking of the bronchus.
e) Tidal volume should be monitored with an appropriate ventilation meter, and peak inspiration pressure with inspirometer attached in the anesthetic circuit.
f) The $SaO_2$ value should be monitored with pulse oximeter at all times.

## DESCRIPTION FOR USE :

The following are general instructions for use.
Expert clinical judgement should be exercised for each individual patient.

### [Preparations before Intubation]

1. Remove the sterile product carefully from its package, and check for damage.
   NOTE: Do not use if any damage is found.
2. Remove and discard the stylets on both sides of blocker and the aeration cap (blue color) at blocker valve.
   NOTE: See [About Stylets and Aeration Cap].
3. Perform inflation test on the tracheal and blocker cuffs.
   NOTE: Do not use if any damage is found.
4. Completely evacuate air from each cuff and disconnect the syringe from the one-way valve.
   NOTE: Evacuate until the pilot balloon is also completely deflated.
5. Retract the blocker into the endotracheal tube pocket.
   NOTE: See [About Retractions of Blocker Cuff].

### [Intubation Methods]

#### A. Tube Rotation Method (Figs.4)

1. Insert the tube orotracheally just like a conventional endotracheal tube (Fig.4-A), and rotate the tube 90 degrees towards the operative side, so that the blocker lumen is on the thoracotomy side (Fig.4-B).
2. After rotation, inflate tracheal tube cuff and fix the tube firmly at the patient's mouth with cloth tape.
3. Push the blocker shaft out from the endotracheal tube pocket.
   NOTE: Be sure to manipulate the blocker shaft near the blocker mantle tube.
4. The blocker will follow the lateral wall of the trachea into the target main stem bronchus (Fig.4-C).
   NOTE: The blocker should be inserted deeply enough.
5. Turn the patient on the side, check the blocker cuff position under bronchoscopy, and fix the blocker shaft on the endotracheal tube using the band stopper (Fig.7).
   NOTE: Make sure that the blocker cuff is positioned deeply enough beyond the tracheal bifurcation. See [Blocker Fixation].
6. After the patient has been turned on the side and the pleura has opened, inject 5-6 ml of air into the blocker cuff to block the bronchus (Fig.4-D).

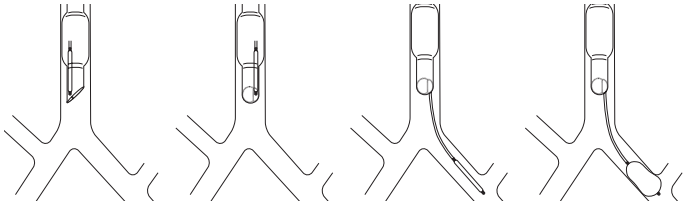

Fig.4-A Fig.4-B Fig.4-C Fig.4-D

#### B. Blocker Rotation Method (Figs.5)

1. Insert the tube orotracheally, inflate the tracheal tube cuff (Fig.5-A) and fix the tube firmly at the patient's mouth with cloth tape.
2. Insert fiberoptic bronchoscope into the endotracheal tube lumen and push the blocker cuff under direct vision out of the endotracheal tube pocket (Fig.5-B).
   NOTE: Be sure to manipulate the blocker shaft near the blocker mantle tube.
3. Push while twist the blocker tube into the target main stem bronchus under direct vision with the fiberoptic bronchoscope (Fig.5-C).
   NOTE: Be sure to manipulate at the blocker grip.
4. The rest of the manipulations are the same as Tube Rotation Method (No.5 and No.6) and block the main stem bronchus (Fig.5-D).

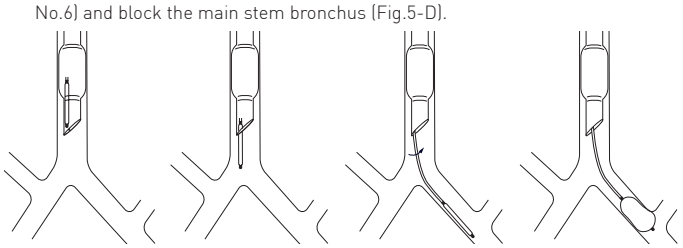

Fig.5-A Fig.5-B Fig.5-C Fig.5-D

### [Blocker Fixation]

1. Move the cap stopper and rotate (if necessary) and mount it on to the blocker mantle tube (Fig.6).
   NOTE: When moving the cap stopper, do not to move the blocker position.
2. Snap the blocker onto the band stopper on the endotracheal tube (Fig.7).
   NOTE: Reconfirm the blocker cuff position under direct vision.

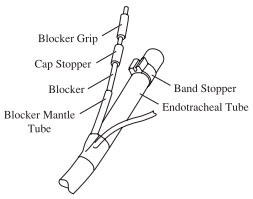


Fig.6

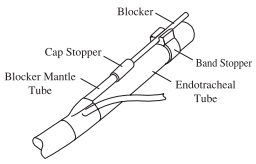


Fig.7

## POTENTIAL PROBLEM :

### [Problems likely to become evident during clinical use]

1. A reduction in tidal volume (e.g. from 500ml down to 200ml) while ventilating with a pressure limited ventilator.
2. A rise in the original inspiratory pressure (e.g. form 15cmH2O up to 25cmH2O) with a volume limited ventilator.
3. A sudden inflation of the blocked lung.

### [Cause]

1.&2. The above may be attributed to the fact that the blocker cuff has been dislodged into the lumen of the trachea (herniation), narrowing it (Fig.8).
3. The above may be attributed to the fact that the blocker cuff slipped back into the trachea, or insufficient blockage due to the reduction of inflation volume.

### [Treatment or Counter Measures]

a) The blocker must be inserted deeply enough into the main stem bronchus. This is the basic principle for the use of this tube. The blocker cuff should be positioned deeply enough beyond the tracheal bifurcation and into main stem bronchus.
b) Position of blocker cuff should be reconfirmed with a flexible fiberoptic bronchoscope after the patient has been positioned for a thoracotomy.
c) For the right thoracotomy, position and inflate the blocker cuff so as to slightly herniate it into the upper lobe bronchus. This will help fix the blocker cuff in position and securely block the right main stem bronchus (Fig.9).
d) For a patient with the upper lobe of the right lung located very close to the tracheal bifurcation, blocking the middle and lower lobes of the right lung, instead of the whole right lung, can be achieved by placing the blocker in the intermediated bronchus (Fig.10).
e) When adjusting the blocker cuff position, be sure to deflate the blocker cuff before moving it.
f) If the reduction in inflation volume of the blocker cuff is occurred, deflate the blocker cuff once and inflate it again.
g) If such herniation as described in Fig.8 is occurred, hypoxemia can be remedied by simply deflating the cuff.

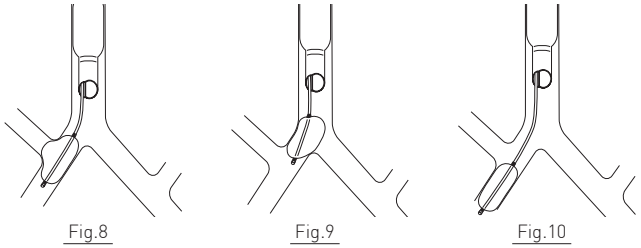

Fig.8 Fig.9 Fig.10

### [I.D / O.D. Dimension of the tube]

| I.D.[mm] | 6 | 6.5 | 7 | 7.5 | 8 | 8.5 | 9 | 9.5 | 10 |
|---|---|---|---|---|---|---|---|---|---|
| O.D.[mm] | 9.7/11.5 | 10.2/12.0 | 10.7/12.5 | 11.2/13.0 | 11.7/13.5 | 12.2/14.0 | 12.7/14.5 | 13.2/15.0 | 13.7/15.5 |

*Two O.D. measures are given due to the oval shape of the tube.

## ADVERSE REACTIONS :

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

Barotrauma is a potential complication of the use of this catheter for oxygen delivery, especially in patients with compromised lung conditions (ie, previous pneumothoraces, pulmonary fibrosis, COPD, previous lung resection/lobectomies, etc).