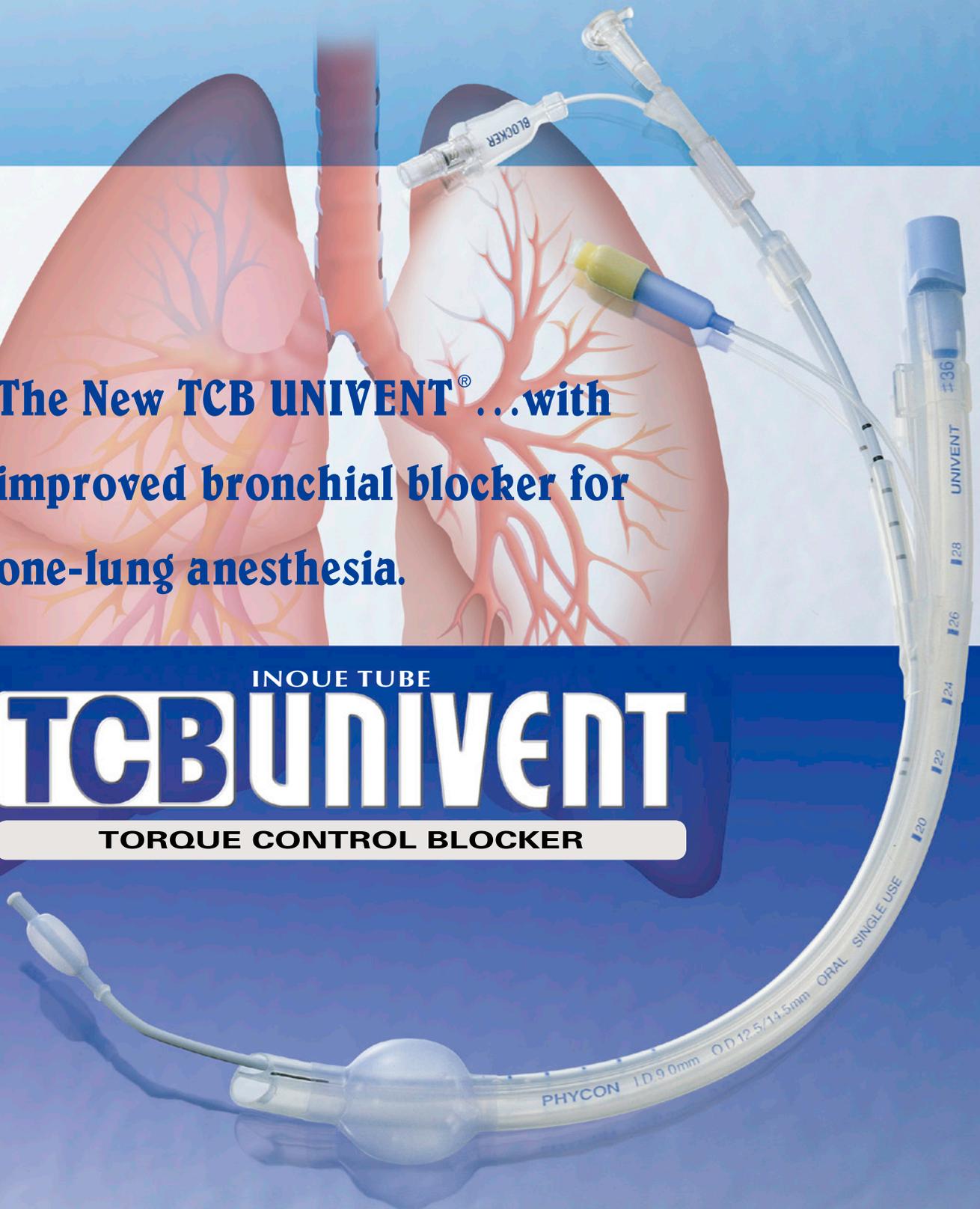


PHYCON

The New TCB UNIVENT[®] ...with
improved bronchial blocker for
one-lung anesthesia.

INOUE TUBE
TCB UNIVENT

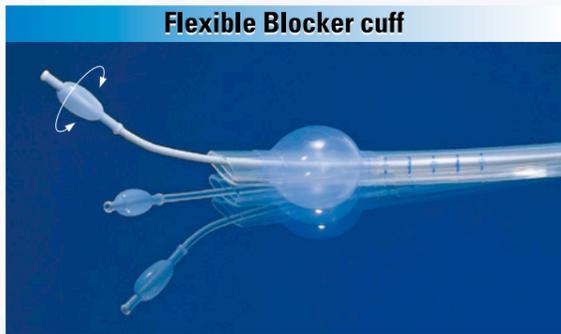
TORQUE CONTROL BLOCKER



Fuji Systems Corporation

FEATURES:

- Easier to direct by twisting than previous nylon catheter.
- High torque control malleable shaft for smooth intubation into target bronchus.
- Flexible blocker shaft with softer open lumen tip for smoother manipulation.
- More compliant blocker.
- May be used in either left or right bronchus.
- LATEX FREE.

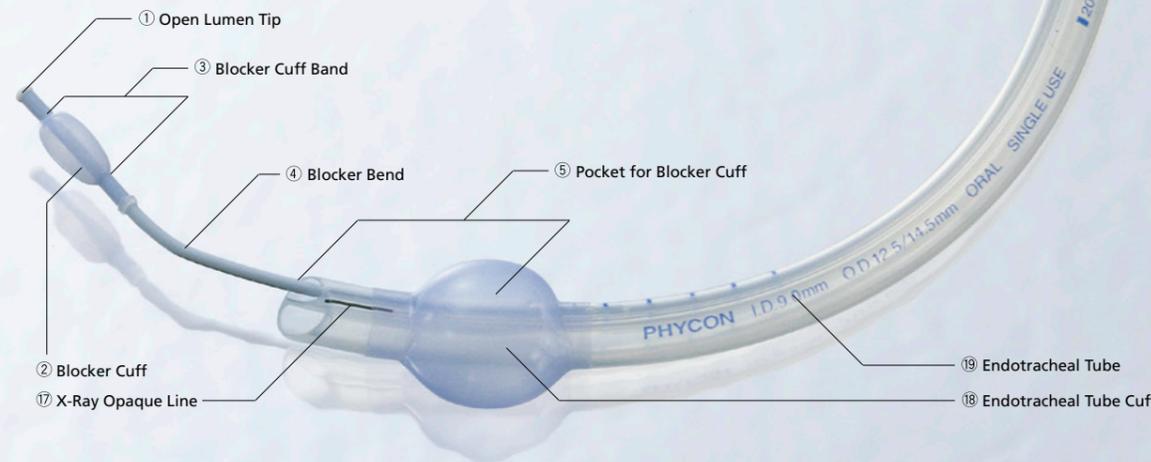
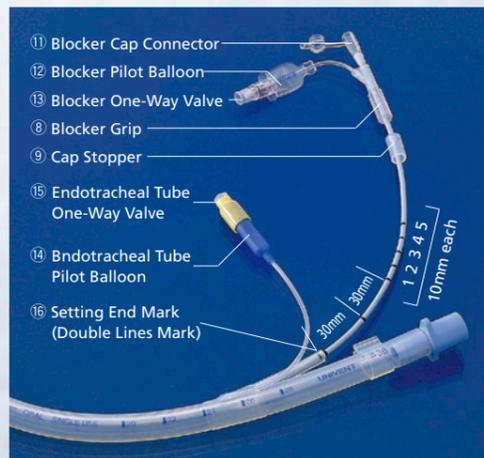


DESCRIPTION: (See below picture)

1. Blocker ⑦ has silicone blue cuff (blocker cuff ②) at the tip.
2. Blocker ⑦ has a blocker grip ⑧ for easier handling.
3. At the base of blocker cuff ②, a slight bend is formed (blocker bend ④) for easy insertion into the targeted main stem bronchus.
4. Blocker tip opening ① is radio-opaque.
5. Blocker ⑦ can be adjusted to the desired position with a cap stopper ⑨ and band stopper ⑩.
6. Check the air pressure inside blocker cuff ② from time to time with a blocker pilot balloon ⑫, and add the air to cuff as necessary.

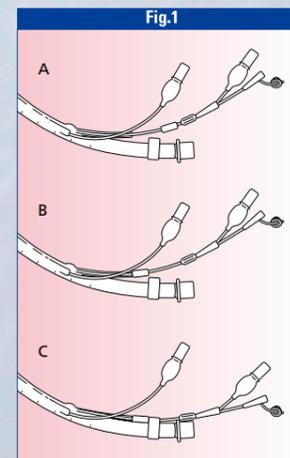
[Precautions When Setting the Blocker]

- A. Before retracting the blocker cuff ② into the pocket ⑤ of the endotracheal tube ⑱, make sure that air has been removed from the blocker cuff ② completely and a lubricant anesthetic jelly (such as xylocaine jelly) is applied to the entire surface of the blocker cuff ②. Then gently pull back the blocker until the setting end mark (double-line mark) ⑯ on blocker ⑦ appears at the end of the blocker mantle tube ⑥. Now the blocker is set.
- B. When retracting the blocker cuff ② into the pocket ⑤, do not pull blocker ⑦ beyond the setting end mark (double-line mark) ⑯.



Procedures for setting the blocker: (Fig. 1)

- A. B. Move the cap stopper ⑨ while giving it a twist and put it into the end of blocker mantle tube ⑥.
- C. Fix the blocker ⑦ with the band stopper ⑩.



DESCRIPTION FOR USE

Check tracheal and blocker cuffs for leaks, lubricate the blocker with anesthetic jelly; deflate the blocker cuff and retract the blocker into the main tube assembly.

1) Tube Rotation Method (Fig. 2)

A. TCB UNIVENT is inserted into the trachea.

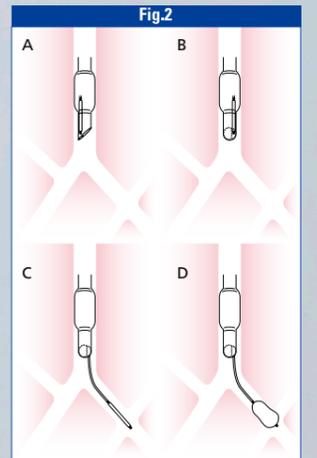
B. Turn the tube 90 degrees towards the operative side, this may be facilitated by turning the patient's head; to check the degree to tube rotation make sure the tube exits the patient's mouth on the side for thoracotomy. Rotate the tube with the tracheal cuff deflated.

C. Push the blocker shaft; the blocker will follow the lateral wall of the trachea and enter the target main stem bronchus. Blocker should be positioned as deeply as possible to prevent cuff herniation into the carina and to prevent blocker dislodgment when the patient is turned on their side. Please see figure 6 for Right side placement. (Note the position of the blocker cuff in the Fig. 2 & 6)

Following this, fix the blocker to the endotracheal tube with the cap stopper and band stopper. — FOLLOW Procedures for setting the blocker (Fig. 1).

D. After the patient has been turned on the side and thoracotomy has taken place, place 5-6 ml of air into the blocker cuff, checking cuff pressure (blocker usually requires 5-6 ml air to block bronchus). Pitting of the lung surface which appears and remains following finger compression is completely blocked. Use a bronchofiberscope to view inflation of the blocker to ensure a proper seal.

The lung may be collapsed by having the surgeon gently squeeze the air out of the lung and then inflate the blocker cuff, or air may be evacuated from the blocked lung by applying suction to the blocker lumen.

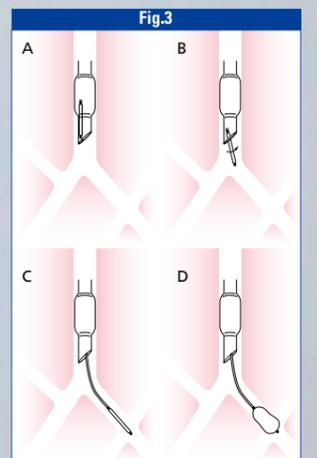


2) Blocker Rotation Method (Fig. 3)

A. Insert TCB UNIVENT into the trachea, inflate the endotracheal tube cuff and fix the tube firmly at the patient's mouth with cloth tape.

B. C. Insert bronchofiberscope into the endotracheal tube lumen under direct vision out of the endotracheal tube pocket and push the blocker forward while twist the blocker to the target main stem bronchus.

D. The rest of the procedures are same as Tube Rotation Method.



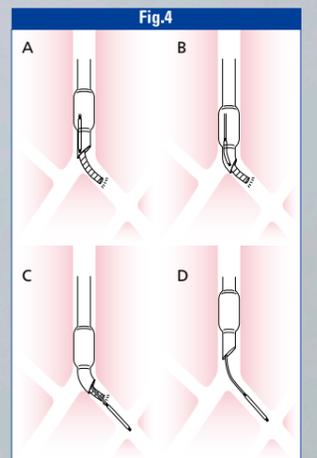
3) Stylet Method Using Bronchofiberscope (Fig. 4)

A. Insert TCB UNIVENT and then insert a bronchofiberscope into the left (right) main stem bronchus through the main lumen.

B. Using the bronchofiberscope as a stylet, advance the tube toward the take off of the left (right) main stem bronchus.

C. Blocker can be advanced into the left (right) main stem bronchus with a push. Make sure to insert the blocker as deep as possible at this time.

D. Pull back the endotracheal tube to the desired position in the trachea. The blocker then will remain within the left (right) bronchus.



NOTICE

- Instruct recovery room nurses that a Univent Tube is being used !
- The blocker can be positioned to ventilate the right upper lobe by blocking the intermediate bronchus in a similar fashion (Fig.6).
- To ventilate the patient postoperatively just deflate the blocker and retract into the pocket for blocker cuff ②. There is no need to change tubes for proper ventilation.

[PRECAUTIONS]

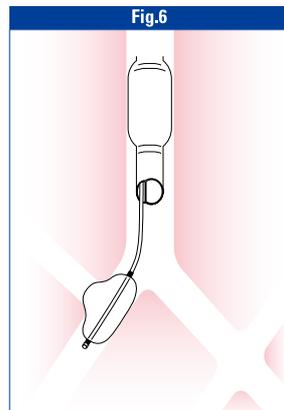
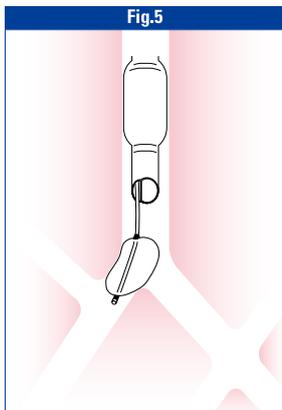
1. Always use a flexible bronchofiberscope to position and set the TCB UNIVENT Tube blocker.
2. Make sure to fix the blocker firmly to the endotracheal tube with the cap stopper and band stopper.
3. The bronchus should be blocked only after the patient has been positioned on the side, the thoracotomy started and the pleura opened so as to reduce the amount of pulmonary blood flow to the upper lung.
4. When the bronchus is blocked the inspired oxygen concentration should be increased to 50% or more, and the patient mechanically ventilated.
5. PaO₂ 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 PaO₂ should not decrease thereafter owing to "Hypoxic Pulmonary Vasoconstriction". However, it is desirable to check the PaO₂ again to make sure that one lung anesthesia is correctly taking place.
6. SaO₂ should be monitored with a pulse oximeter at all times.
7. Problems likely to become evident while the tube is in use:

A. POTENTIAL PROBLEMS after blocking the main stem bronchus

- (1) In case of pressure limited ventilator - a reduction of tidal volume (e.g. from 500ml down to 200ml) while ventilating.
- (2) In case of volume limited ventilator - a rise of the original inspiratory pressure (e.g. from 15cmH₂O up to 25 cmH₂O).

[Cause]

The above may be attributed to the fact the blocker cuff has been dislodged into the lumen of the trachea (herniation), narrowing it (Fig. 5).



[Treatment or Counter Measures]

- (1) 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 should be far enough distally, so that the proximal end of the blocker cuff may go into the main bronchus as far as possible beyond the tracheal bifurcation, clearing the trachea.
- (2) Position of the blocker cuff should be reconfirmed with a flexible bronchofiberscope after the patient has been positioned for a thoracotomy.
- (3) Fix the endotracheal tube firmly to the mouth with tape to prevent it from moving.
- (4) 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.

- (5) In cases where the left lung and the upper lobe of the right lung may be ventilated, blocking of the middle and lower lobes of the right lung can be achieved by placing the blocker in the intermediate bronchus.
- (6) Airway pressure should be monitored with a pressure gauge on the anesthesia circuit, and tidal volumes with an appropriate meter (e.g. Respirometer, Ventimeter, etc.) at all times.
- (7) SaO₂ should be monitored with a pulse oximeter during one lung anesthesia.
- (8) Any problems considered to be due to one lung anesthesia (unilateral ventilation) with this device should be easily rectified by evacuating the air from the blocker cuff. Any hypoxemia resulted from one lung ventilation should immediately improved after the above procedure is carried out.

B. Another problem may occur, presenting as swelling of the operated and blocked lung.

[Cause]

The blocker cuff has most likely been dislodged by traction of the operated lung into the lumen of the trachea causing one way valve obstruction.

[Counter Measure or Treatment]

The air should be evacuated from the blocker cuff, during the period of traction, and when this is finished the blocker cuff should be simply reinflated under direct observation with a flexible bronchofiberscope.

[WARNINGS]

1. This product is a disposable device and good for single use only. Do not re-use.
2. Do not use the product in case the sterile package is damaged or opened before use.
3. The stylets and the aeration cap attached on the blocker should be removed and discarded prior to use, as they are unnecessary for use.
4. Lubricant should be applied on the whole surface of the blocker cuff.
5. Never inject excessive volume of air into the endotracheal cuff and the blocker cuff over the specified below.
Maximum injection air volume (for inflation test) for main cuff per size:
For I.D. size 4.5mm max. 15mL
For I.D. size 6.0 ~ 7.0mm max. 40mL
For I.D. size 7.5 ~ 9.0mm max. 50mL
Maximum injection air volume (for inflation test) for blocker cuff per size:
For I.D. size 3.5 ~ 4.5mm max. 3mL
For I.D. size 6.0 ~ 9.0mm max. 6mL
6. Care must be taken to avoid damage by knives, forceps or needles. The product should not be used if damaged.
7. Do not cut short, force to stretch or punch additional holes on the product.
8. Store the product in dark, dry, cool and clean conditions.

ORDER INFORMATION:

Product No.	Size		
	I.D. (mm)	O.D. (mm)	
1202716	3.5	7.5 / 8.0	Pediatric, without cuff
1202720	4.5	8.5 / 9.0	Pediatric, with cuff
1202927	6.0	9.7 / 11.5	TCB UNIVENT Adult sizes
1202928	6.5	10.2 / 12.0	
1202930	7.0	10.7 / 12.5	
1202931	7.5	11.2 / 13.0	
1202933	8.0	11.7 / 13.5	
1202935	8.5	12.2 / 14.0	
1202936	9.0	12.7 / 14.5	

* The figures of O.D. are approximate value.
* Packaging : 1pc / box

MANUFACTURED BY



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DISTRIBUTOR

* The specifications, configuration and other part of this product may be changed for improvement without prior notice.

