UNIBLOCKER

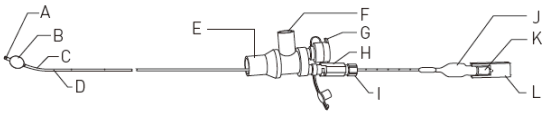
Fuji Systems

Device Description :

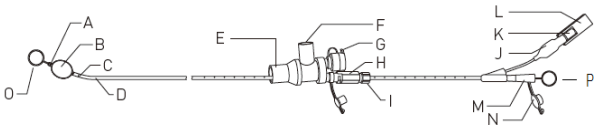
- UNIBLOCKER is a device capable of blocking either the left or right bronchus through an endotracheal tube.
- UNIBLOCKER incorporates a flexible high-torque blocker shaft.
- UNIBLOCKER is supplied with a unique swivel connector with a port for fiberoptic bronchoscopy while connected to the anesthesia circuit.
- Stylets are equipped to maintain its shape during transportation. Stylet B can be used for blocker tube insertion.

Figure 1 : UNIBLOCKER

[5Fr]



[9Fr]



A : Tip
B : Blocker Cuff
C : Bending
D : Blocker Shaft
E : Endotracheal Tube Port
F : Ventilation Port
G : Port A
(Fiberoptic Bronchoscopy Entrance)
H : Locking Assembly
I : Locking Cap
J : Pilot Balloon
K : One-Way Valve
L : Aeration Plate
M : Luer Lock Connector
N : Luer Cap
O : Stylet A
P : Stylet B

Table: Maximum Cuff Volume

5Fr	9Fr
3mL	8mL

Indications for Use :

UNIBLOCKER is intended for one-lung ventilation for endobronchial blockade of the left or right lung in thoracic surgery, lung resection, VATS, lobectomy, etc.

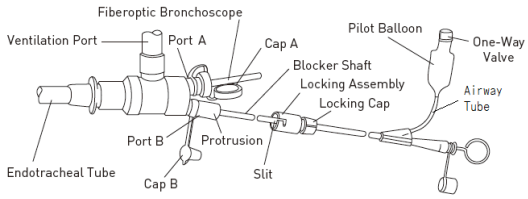
Complications :

Possible complications include, but are not limited to, the following:
Hypoxemia, ventilatory failure, bronchial damage, bronchial walls necrosis, Bronchitis, emphysema, pneumonia, postoperative atelectasis.

Warnings :

- Do not reuse. Discard after one procedure. Structural integrity and / or function may be impaired through reuse or cleaning.
- Care must be taken to avoid damage by knives, forceps or needles. The product should not be used if damaged.
- Chemical disinfectant should not be used, which may deteriorate the cuff material.
- Do not use if the sterile package has been previously opened or damaged.
- Depth markings on the blocker shaft are only a guideline for insertion. Actual insertion depth should be determined by physician's clinical judgment.
- Avoid contact with laser beams or an electrodes in the immediate area of this tube. Such contact may result in a sudden ignition of the tube.
- Refer to the instructions for use of each related medical device, i.e. endotracheal tubes, fiberoptic bronchoscopes, suction tubes, etc.
- Stylet A should be removed and discarded prior to use, as it is placed to maintain the tip angle of the blocker tube.
- Stylet B will be used for insertion. It should be discarded after the blocker tube is placed at the target position.
- The aeration plate attached at the one-way valve should also be removed and discarded prior to use, as it is attached for ventilation during EOG sterilization process.
- Prior to use, always test the blocker cuff by injecting a maximum of 8mL air into the cuff. Over-inflation may damage the blocker cuff.
- In case any malfunction such as air leakage or cuff herniation, do not use the product. Due to the self-adhesive property of silicone rubber, the blocker cuff may fail to inflate or inflate unevenly.
- After cuff inflation test, remove air completely from the cuff.
- Apply lubricant to the blocker cuff for smoother insertion. Damage of the blocker cuff, patient's trachea, or bronchus may occur without lubricant.
- Maximum air volume is suggested for cuff inflation test prior to use. Suitable inflation air volume should be determined by clinical judgement of the physician. Excessive inflation may damage the blocker cuff or the patient's trachea or bronchus.
- After the blocker cuff is inflated, disconnect the syringe from one-way valve. Leaving the syringe attached will keep the valve open, permitting the blocker cuff to deflate.
- The inflation condition of the blocker cuff should be continuously monitored. Due to gas diffusion through the cuff, the internal cuff pressure (or inflation volume) changes over time. If it is necessary to inflate or deflate the blocker cuff, be sure to deflate the blocker cuff first and inflate it again to the appropriate volume.
- Before insertion or removal of the blocker tube and adjustment of the blocker cuff position, ensure the blocker cuff is deflated. Otherwise it may damage the blocker cuff or the patient's trachea or bronchus.
- Do not use any other connector except for the one included in the product.
- Ensure that the ventilation port at the swivel connector assembly and the respiratory circuit are securely connected. Do not use the product if sufficient connection cannot be obtained. The ventilation port at the swivel connector assembly is compatible with respiratory circuits equipped with 15mm female connectors.
- Ensure that the endotracheal tube port at the swivel connector assembly and the endotracheal tube are securely connected. Do not use the product if sufficient connection cannot be obtained. The endotracheal tube port at the swivel connector assembly is compatible with endotracheal tubes equipped with 15mm male connectors.
- Ensure all the ports at the swivel connector assembly (ventilation port and endotracheal tube connection port.) are dry. Connections must be connected when dry. If the ports are wet with lubricant and/or water, they may be disconnected during use.
- During use, occasionally ensure the respiratory circuit and the endotracheal tube are securely connected to the swivel connector assembly. Reconnecting, changing of patient's position, severe coughing by patient may cause disconnections.
- Insert the blocker tube firmly into the endotracheal tube. Do not apply excessive force. This may damage the blocker cuff or cause kinks at the blocker shaft.
- Ensure the tip of blocker tube does not engage the Murphy eye at the endotracheal tube. This cause kinks at the blocker tube, damage the blocker cuff, or damage patient's trachea or bronchus.
- When manipulating the blocker tube while using fiberoptic bronchoscope, ensure that the tip of fiberoptic bronchoscope does not touch the blocker cuff. The blocker cuff may become damaged.
- When inserting a fiberoptic bronchoscope or suction tube, normal respiratory management may not be possible because of the narrowing inner lumen of the endotracheal tube. Monitoring ventilation status is essential.
- Prior to use, twist the locking cap clockwise at the lock assembly and ensure that the locking cap is fixed firmly at the blocker tube. Do not use the product if a secure lock cannot be achieved.
- After the locking system is confirmed, release the lock by twisting the locking cap counter-clockwise.

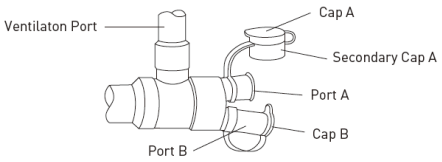
Figure 2 :



- Under direct vision of fiberoptic bronchoscope, further advance the blocker tube until the blocker cuff passes the endotracheal tube tip. Then twist while advancing the blocker tube into the target bronchus.
- When the blocker tube reaches target position, retract and discard Stylet B.
- After the blocker cuff target position is confirmed under direct vision of a fiberoptic bronchoscope, inflate it with a suitable amount of air.
- Twist on the locking cap clockwise to firmly fix the blocker tube.
- After collapse of the target lung is confirmed, lock the cap firmly onto luer lock connector at the distal end of the blocker tube.
- When adjusting the blocker cuff position is required or retracting the blocker tube after the procedure, the blocker cuff must be deflated, and then release the locking cap by twisting it counterclockwise.
- Open Cap A to insert fiberoptic bronchoscope or suction catheter.
- Ensure Cap A is mounted firmly onto Port A when the fiberoptic bronchoscope or suction catheter is not in use.
- Ensure caps at Port A and Port B are firmly closed for respiratory management after the surgery or when blocker tube replacement is required.
- Inserting fiberoptic bronchoscope and suction catheter at the same time is possible by opening the secondary Cap A. However, ensure the inner lumen of the endotracheal tube is large enough to allow multiple devices to pass through.

- During respiratory management, ensure Cap A and the secondary Cap A are always firmly fixed.
- After one lung ventilation procedure is accomplished and the blocker tube is extubated, detach the swivel connector assembly from the endotracheal tube and immediately connect the ventilation circuit to the endotracheal tube for conventional airway management.

Figure 3 :



- If contractile failure of the blocker cuff occurred, insert the straight grasping forceps for endoscopy or the like under direct vision of fiberoptic bronchoscope, burst the blocker cuff and remove the blocker tube from the endotracheal tube.
- Do not pull the airway tube at pilot balloon with excessive forces more than 9.8N (1.0kgf).

Precautions :

- Single use only (If the product is re-used, it may cause infection to patients or damage to the product).
- It should not be replaced with a new piece of the same type after 30 days of use.
- Use by "Use-by" date.
- Upon removal from package, inspect the device to ensure it is not damaged.
- Do not use the product if the sterile package is damaged, wet or opened prior to use.
- Do not use this product if there is not enough space to place the blocker tube and fiberoptic bronchoscope or suction tube into the endotracheal tube lumen.
- Do not use this product if any malfunction is found during cuff test prior to use.
- Lubricant should be applied at the blocker cuff only. Do not apply lubricant at the blocker tip; it may occlude the inner lumen at the blocker tube.
- Use only air to inflate the cuff.
- Do not re-insert any stylet once if they are detached from the blocker tube. Re-insertion may damage the inner lumen of the blocker tube.
- Do not re-intubate to the opposite lung while the blocker tube is already in place at the operative lung. The blocker tip angle may be straightened and it may damage the blocker cuff, patient's trachea and/or bronchi.
- Do not perform MRI while the blocker tube is used to the patient. Metal is used in this product.
- The device is only for sale by or on the order of a physician.

Recommended Procedure :

1. Remove the sterile product carefully from its package, and check for damage.
2. Remove and discard the Stylet A and the aeration plate attached at the one-way valve.
3. Test the blocker by inflating with a syringe.
4. Deflate the blocker cuff and disconnect the syringe from one-way valve.
5. Test the locking assembly at the blocker tube.
6. Ensure the endotracheal tube is fixed into position.
7. Insert the distal tip of the blocker tube into the top of the endotracheal tube.
8. Connect swivel connector assembly to the connector at the endotracheal tube.
9. Insert the blocker tube through Port B, fix the locking assembly on the protrusion at Port B, and advance the blocker tube into the target bronchus under direct vision of fiberoptic bronchoscope.
10. When the blocker tube reaches the target bronchus, remove and discard Stylet B.
11. Inflate the blocker cuff and lock the blocker tube in position firmly by twisting the locking cap clockwise.
12. Prior to extubation, deflate the blocker cuff by connecting luer lock syringe and removing air until the pilot balloon is collapsed.
13. Release the blocker tube by loosening the locking cap and detaching the locking assembly from the swivel connector assembly.
14. Remove the blocker tube from Port B and mount Cap B onto Port B.
15. Discard the blocker tube.

Storage Conditions :

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

Symbols Used on Product Labels :

⚠	Caution
2	Do not re-use
PHT	Contains or presence of phthalate
LOT	Lot number
REF	Catalogue number
STERILE EO	Sterilized using Ethylene Oxide
	Use-by date
CE 2797	CE Marking
EC REP	Authorized Representative in European Community
	Manufacturer

Authorized Representative in European Community :

EC REP **Dr. Hans-Joachim Lau**

Airport Center (Building C),
Flughafenstrasse 52a 22335 Hamburg
Germany
Fax-No. +49 40 53299 - 100

Manufacturer :

Fuji Systems Corporation
Shirakawa Plant

200-2 Aza-Ohira, Odakura, Nishigo,
Nishi Shirakawa Gun, Fukushima
961-8061 Japan

Contact Address :

Fuji Systems

23-14, Hongo 3-Chome, Bunkyo-ku, Tokyo
113-0033 Japan
Tel : +81-(0)3-5689-1913 Fax : +81-(0)3-5689-1915

CE 2797