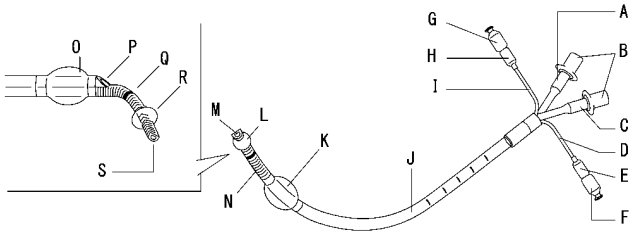
SILBRONCHO（LEFT）
SILBRONCHO（RIGHT）

Fuji Systems

Device Description :

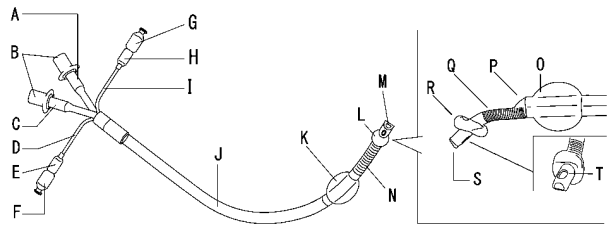
- The SILBRONCHO Endotracheal Tube is a double lumen endotracheal tube equipped with two cuffs for the bronchus and trachea.
- Reinforced wire in the inner wall of the endobronchial tube tip part avoids kinking.
- The stylet is configured to reinforce the tube during intubation.
- A DLT connector assembly is configured to connect between the tube and the respiratory circuit.
- SILBRONCHO Tube (RIGHT LUNG) has a Side Hole on its Endobronchial Tube Lumen Tip.

Figure 1 : **For Left Use**



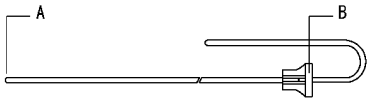
A : Tracheal Lumen Tube (Transparent)
B : 15mm Connector
C : Endobronchial Lumen Tube (Blue)
D : Airway Tube
E : Bronchial Pilot Balloon (Blue)
F : One Way Valve for Endobronchial Cuff (Blue Cover)
G : One way Valve Tracheal Cuff (White Cover)
H : Tracheal Pilot Balloon (Transparent)
I : Airway Tube
J : Tracheal Tube
K : Tracheal Cuff
L : Endobronchial Cuff
M : Endobronchial Tube Lumen Tip
N : Endobronchial Tube
O : Tracheal Cuff
P : Tracheal Tube Lumen Tip
Q : Endobronchial Tube
R : Endobronchial Cuff
S : Endobronchial Tube Lumen Tip

Figure 2 : **For Right Use**



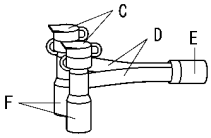
A : Endobronchial Lumen Tube (Blue)
B : 15mm Connector
C : Tracheal Lumen Tube (Transparent)
D : Airway Tube
E : Tracheal Pilot Balloon (Transparent)
F : One way Valve Tracheal Cuff (White Cover)
G : One Way Valve for Endobronchial Cuff (Blue Cover)
H : Bronchial Pilot Balloon (Blue)
I : Airway Tube
J : Tracheal Tube
K : Tracheal Cuff
L : Endobronchial Cuff
M : Endobronchial Tube Lumen Tip
N : Endobronchial Tube
O : Tracheal Cuff
P : Tracheal Tube Lumen Tip
Q : Endobronchial Tube
R : Endobronchial Cuff
S : Endobronchial Tube Lumen Tip
T : Side Hole

Figure 3 : **Stylet**



A : Tip
B : Movable Stopper

Figure 4 : **DLT Connector**



C : Cap
D : Connecting Tube
E : Carlens (Y) Adapter
F : Swivel Connector

Table 1 :
Suggested Maximum Cuff Volume for Inflation Test

Type (#)			33	35	37	39
Maximum Volume (ml)	Endobronchial Cuff	left	5	7		
		right	4.5	5	5.5	6
	Tracheal Cuff		40			50

Table 2 :
Suggested Bronchoscope Size

Type (#)	OD of the Bronchoscope
33, 35	less than 3.1 mm
37, 39	less than 4.0 mm

Table 3 :
Suggested Suction Catheter Size

Type (#)	Size of Suction Catheter
33	Fr. 8
35, 37	Fr. 10
39	Fr. 12

Indications for Use :

SILBRONCHO Tube is intended for use in airway management of surgical patients to perform one-lung ventilation in thoracic surgery, lung resection, VATS, lobectomy and etc.

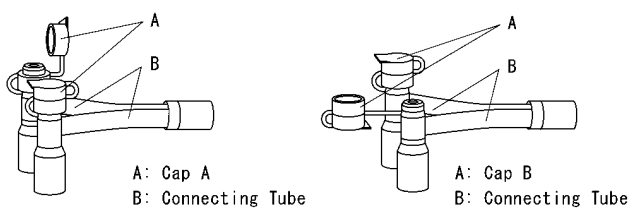
Complications

Possible complications include, but are not limited to the following:
aspiration pneumonia; bronchitis; cartilage necrosis; consequences of failure to ventilate including damage to the perichondrium; emphysema; excoriated membranes of pharynx; fracture or dislocation of cervical vertebra; glottic edema; hypoxemia; infections; laryngeal obstruction; laryngeal stenosis; polyp formation, adhesion, and/or granulation of the vocal cords; post-operative atelectasis; submucosal hemorrhage; tracheorrhagia; tracheal stenosis; traumas (lips, pharynx, trachea, glottis, and etc.)

Warnings :

- Single use only (If the product is to be 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.
- Do not expose the product to high temperature, humid air or ultraviolet light during storage.
- Do not use equipment for laser surgery or electric surgical apparatus near this product. When in contact with a laser or electrode, sudden combustion may occur.
- Do not use any other connector except for the one attached.
- Make sure that the Carlens Adapter and the respiratory circuit can be securely connected. Do not use the product if sufficient connection cannot be obtained. The Carlens Adapter is 15mm female and is compatible with a respiratory circuit equipped with cone-shaped connector.
- Connections between the 15mm connector and the swivel connector and between the Carlens Adapter and the respiratory circuit must be conducted when dry. If the terminal area is wet with lubricant and/or water, it may be disconnected during use.
- Connection status between the 15mm connector and the swivel connector and between the Carlens Adapter and the respiratory circuit must be verified if the product is re-connected or the body position of the patient changes. Severe coughing may cause disconnection of the terminal area.
- When connecting swivel connector with the 15mm connector at tracheal lumen tube and endotrachial lumen tube, make sure that both Cap A and Cap B are completely closed.

Figure 5 :



- Cap A and Cap B should be kept closed except the following purposes.
  - Opening Cap A to insert a bronchoscope to confirm intubation position.
  - Unlocking Cap B to allow air to escape from the tube to deflate one lung.
- When one lung needs to be deflated, clamp the connecting tube, which opens to the lung to be deflated.
- Conduct inflation test for the tracheal cuff and endobronchial cuff prior to use. In case any malfunction such as air leakage or balloon herniation has occurred, the tube should not be used.

- The cuffs should not be treated with forceps or the like. This may damage the cuff.
- After cuff inflation test, remove air completely (until the pilot balloon is completely deflated) from each cuff.
- Thoroughly lubricate the entire cuffs including the tip at the endobronchial tube and tracheal tube before intubation. Not applying lubricant may result in damage to the cuffs, or may be traumatic to the patient's trachea and/or bronchus.
- The internal pressure (or inflation volume) of the endobronchial cuff and tracheal cuff should be determined by the clinical judgement of the physician. Excessive inflation may damage the cuff or may be traumatic to the patient's trachea and/or bronchus.
- After inflation of the endobronchial cuff or tracheal cuff, disconnect the syringe from each valve. Leaving the syringe attached will keep the valve open, permitting air to come out. The inflation condition of the endobronchial cuff and tracheal 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 inflation or deflation of the cuff is required, be sure to evacuate the air completely from the cuff (until pilot balloon is also collapsed) first and then inflate the cuff again to the appropriate volume.
- Before intubation, extubation, and adjustment of each cuff position, be sure to evacuate air completely from the cuff (until pilot balloon is also collapsed). Otherwise, it may damage the cuff or may be traumatic to the patient's trachea and/or bronchus.
- Changing a patient's body position should be only done after the removal of air from the endobronchial cuff. Changing body position while air remains in the cuff may result in the damage of the cuff or may be traumatic to the patient's trachea and/or bronchus.
- Removal of air from each cuff should be performed until the pilot balloon is completely deflated.
- Use with the stylet attached only.
- Make sure that the stylet is inserted into the tube from the endobronchial lumen tube (bronchus side: blue).
- Make sure that the tip of the stylet does not extend beyond the tip of the endobronchial tube before the intubation.
- If the tip of the stylet is sticking out, adjust the mobile stopper to keep the stylet from extending beyond the tube. [Intubation with the stylet sticking out may result in damage to the bronchus.]
- Intubation should be performed by holding the stopper of the 15mm connector and the stylet. [Intubating while holding only the stylet may result in extending the stylet and cause damage to the bronchus.]
- As soon as the tip of the endobronchial tube is inserted beyond the glottis, the stylet should be removed and discarded.

Precautions :

- Avoid contact with laser beam or an electrosurgical knife in the immediate area of this tube. Such contact can result in a sudden ignition of the tube in the presence of mixtures of nitrous oxide and oxygen or pure oxygen.
- Do not use the product if the sterile package is damaged, wet or opened prior to use.
- Expiry of the product is indicated on the product label. The product should not be used if it has expired.
- Do not cut the tube to length or open holes on the tube.
- 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. It may deteriorate the material of the cuff.
- Use air only to inflate the cuffs.
- Depth markings on the tracheal tube are only a guideline for intubation. Actual intubation depth should be determined by clinical judgement of the physician.
- Do not clamp, except the connecting tube at the DLT connector assembly.
- After intubation, the position of the tube should be checked periodically by auscultation, bronchoscope, x-ray, etc. and whenever the patient is repositioned.
- When patient's position has changed, be sure to check the seal of the endobronchial cuff and tracheal cuff.
- Monitor SaO_2 constantly with a pulse oxymeter.
- Refer Table 2 for bronchoscope sizes when confirming the positions of the tube tip and the tip of endobronchial tube with a bronchoscope. Sometimes insertion of the bronchoscope may be difficult due to product specification variation.
- Before use, ensure that the bronchoscope to be used can be inserted into the endobronchial tube.

Recommended Procedure :

The followings are general directions for use.
Expert clinical judgement should be exercised for each individual patient.

1. Remove the product from the sterilized package carefully and check to see that it is not damaged.
2. Check for defects such as air leakage or asymmetrical expansion by injecting air into each the tracheal cuff and the endobronchial cuff individually using a syringe.
3. After checking the cuffs, completely withdraw all air from each cuff and remove the syringe from the valve.
4. Intubate the product orally into the trachea and insert the endobronchial tube into the targeted main bronchus.
5. After injecting air into the endobronchial cuff, make sure the cap of the swivel connector is completely closed; then connect the individual swivel connector to the 15mm connector.
6. Connect the Carlens adapter and respiratory circuit then confirm that both lungs are ventilated by auscultation.
7. After injecting air into the endobronchial cuff, alternately clamp the connecting tubes of the DLT connector and confirm the ventilation of one lung by auscultation.
8. To deflate the lung, open the corresponding tube lumen, which leads the lung to be deflated by unlocking Cap B of the swivel connector to room atmosphere, and then clamp the connecting tube of the deflating side.
9. Before extubation, deflate the tracheal and the endobronchial cuffs completely until the pilot balloon is collapsed.

Storage Conditions :

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

Symbols Used on Product Labels :

	Caution
	Do not re-use
	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**

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CE 2797