

All Silicone Sengstaken Blakemore Tube (Type 32)

Do not reuse

[WARNINGS]

- Do not increase the esophageal balloon pressure to 5.3 kPa (about 40 mmHg) or more.
[Suffering or esophageal rupture may occur.]
- If it is found that the esophageal balloon causes any obstruction in the respiratory tract, immediately remove air in the balloons or cut the tube to pull out.
[Dyspnea may occur.]

[CONTRAINDICATIONS, PROHIBITIONS]

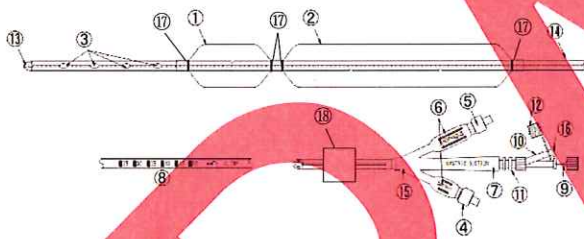
- Do not reuse the product (single use for one case).
[The product is single use only and disposable, and its quality or performance after one use is not guaranteed. Further, reuse carries the possible risk of contamination (infection) to patients. Contamination of the product may lead to patient injury, illness or death.]
- Prohibition of reprocessing, re-sterilization.
[Reprocessing of the product may lead to defects. It may also cause patient injury, illness or death.]
- Use only air for the inflation of gastric and esophageal balloons.

[SHAPE, STRUCTURE AND PRINCIPLE]

- The product is sterilized with ethylene oxide gas.
- Metals are used in the product (valve, stylet).

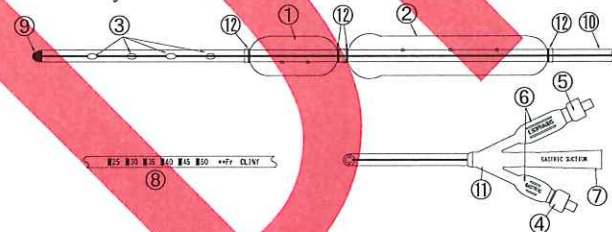
< Shape >

- With stylet



- ①Gastric balloon ②Esophageal balloon ③Gastric suction hole
- ④Valve for gastric balloon ⑤Valve for esophageal balloon
- ⑥Pilot balloon ⑦ Funnel for gastric suction
- ⑧Depth mark ⑨Stylet ⑩Lubricant port ⑪Connector
- ⑫Luer cap ⑬Tip stopper ⑭Tube
- ⑮Branch part ⑯Inlet for lubricant ⑰Fixing thread
- ⑱Spongy pad

- Without stylet



- ①Gastric balloon ②Esophageal balloon
- ③Gastric suction hole ④Valve for gastric balloon
- ⑤Valve for esophageal balloon ⑥Pilot balloon
- ⑦Funnel for gastric suction ⑧Depth mark ⑨Tip stopper
- ⑩Tube ⑪Branch part ⑫Fixing thread

< Specifications >

Size designation	Outer diameter	Effective length	Number of gastric suction holes	Depth mark
14Fr	4.8mm	950mm	4 holes	Placed at 5cm intervals between 25cm and 50cm from the distal end of the esophageal balloon (25cm, 30cm, 35cm, 40cm, 45cm and 50cm)
15Fr	4.8mm			
16Fr	5.2mm			
18Fr	6.0mm			
21Fr	7.0mm			

Gastric balloon		Esophageal balloon		
Length	Regulated volume (Air)	Length	Internal pressure on inflation with O.D. 32 mm (Maximum pressure)	Recommended pressure
60mm	300mL	140mm	5.3kPa (40mmHg)	4.0kPa (About 30 mmHg)

< Raw Materials >

Silicone rubber, polyester, polyacetal (with stylet), polypropylene (with stylet) and polyvinyl chloride

< Principle >

Insert the product into the esophagus and stomach nasally, and inflate the balloons for fixation and placement. At the same time, perform pressure hemostasis for esophageal varices. The gastric contents can be suctioned from the funnel for gastric suction.

[INTENDED USE]

It is used for hemostasis by inserting into the esophagus or the stomach.

[EFFECT]

- Pressure hemostasis of esophageal varices can be performed.
- The gastric contents can be suctioned from the funnel for gastric suction.

[PERFORMANCE]

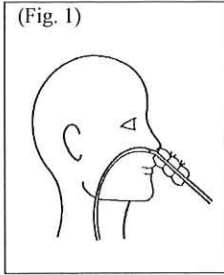
- Secure the sterility assurance level (SAL) 10⁻⁶.
- Sterile residues: Shall conform to ISO10993-7.
- Shall not contain biological substance and conform to biological safety requirements.
- Shall be durable for 48 hours continuous use.
- Shall maintain the stability and durability for 5 years.
- When attaching a syringe and injecting 1.0 to 1.3 times as much as the regulated volume, the balloons shall be inflated almost roundly. And when observing after injecting and removing the syringe, there shall be no leakage from anywhere.

[OPERATING OR USING METHOD]

The general operational procedure is described below.

- [1] Inject air into the gastric and esophageal balloons with a syringe from each valve. Then, confirm no leakage of air from the balloons. After that, remove air completely.
- [2] Connect the stylet and lubricant port tightly. Confirm that the tip of the stylet is put in the tube.
(With stylet)
- [3] Inject about 10 mL of olive oil into the lubricant port.
(With stylet)
- [4] Fold the gastric and esophageal balloons. Then apply demulcent/surface anesthetic sufficiently to the surface of balloons and the tip of the tube.
- [5] Anesthetize nasal cavities and pharynx, and insert the tube through the nose into the esophagus and stomach.
- [6] After inserting the tube into the stomach, remove the stylet and detach the lubricant port.
(With stylet)
- [7] Inject the regulated volume of air into the gastric balloon slowly. Then, pull the tube till the balloon slightly presses the junction of esophagus and stomach.

- [8] Tract the tube with a force of 2.9 ~ 4.9 N (300 ~ 500 gf). Then, fix it with adhesive tape, etc. Use the sponge or gauze to prevent it slipping. (Fig. 1)
- [9] Inject air through the valve for esophageal balloon until the internal pressure reaches the recommended pressure. The recommended pressure is measured with a manometer connected between the valve and syringe via a three-way stopcock.
- [10] Suction gastric contents from the funnel for gastric suction. Then, wash the tube and the stomach with cold water to prevent the inner lumen from clogging.
- [11] After sufficiently washing and suctioning the stomach, connect the funnel for gastric suction to the suction device, and suction for 12 hours.
- [12] After suctioning for 12 hours, deflate the gastric and esophageal balloons carefully and slowly to confirm that the bleeding is discontinued. If air is removed rapidly, blood clot may also peel off to cause bleeding again. If the bleeding still continues, inject air again into the esophageal balloon and check every 4-6 hours if bleeding is discontinued or not.
- [13] If hemostasis is confirmed, remove air slowly from the esophageal balloon to reduce traction of the tube. Stop traction after 3 hours and remove air slowly from the gastric balloon.
- [14] If bleeding is not observed after 1 hour, remove the tube slowly and gently.



< Combination Devices >

- [1] When using the product, use it in combination with the following devices.

Name	Specification
Syringe	- Slip type - Volume: 20 ~ 50 mL
Syringe	Catheter tip type
Sterile distilled water	-
Suction device	Connecting tube of suction device, Catheter tip shape or bamboo shoot shape
Manometer	Tip shape: Slip type shape

- [2] Drugs that can be used concomitantly with the product

Product name	Generic name
Olive oil	Olive oil
Xylocaine jelly	Lidocaine

Do not use the drugs other than the above concomitantly

< Precautions for Use Related to the Operating Procedures >



- [1] Please note the following when inflating and deflating the balloons.
- Use only air to inflate the gastric and esophageal balloons.
[When physiological saline, contrast medium, etc. are used, the ingredients may coagulate and water may not be removed.]
 - For the balloon inflation or deflation, use a general slip-type disposable syringe.
[Luer lock-type syringe cannot be inserted into the end of the valve firmly. And using a syringe with unfitted taper may cause breakage of the valve.]
 - Insert the tip of the syringe firmly to the end of the valve to inflate or deflate the balloon.
[If insertion of the tip of the syringe into the valve is insufficient, the valve may not operate properly to inflate or deflate the balloon.]
 - Inflate the balloons slowly and carefully.
[The valve may slip off rarely or it may come off in some cases due to the pressure when injected rapidly.]
 - Do not inject more than the regulated volume of air into the gastric balloon.
[Excessive injection will overload the balloons and cause a burst.]
 - When removing the syringe, make sure to press the valve and rotate the syringe to remove.
[In rare cases, the valve may be dislocated or come off.]
- [2] Check before use whether the product corresponds to the suction device to be used.
- [3] Be sure to refer to the instructions, etc. of the suction device before using it.
- [4] When connecting a tube, etc. to the end of the funnel, select the one that fits surely. After the start of use, check the connection for leakage or loosening as appropriate, and use it in a state where it is

securely connected.

- [5] Before using the product, confirm that the balloon is inflated and deflated properly.
- [6] When fixing the stylet, take care not to protrude the tip of the stylet from the gastric suction hole.
(With stylet)
- [7] If it is difficult to remove the stylet, rotate the stylet or re-inject olive oil.
[The tube may be cracked.]
(With stylet)
- [8] At the insertion, confirm that the balloons surely enter into the stomach and esophagus. (Confirm with X-ray fluoroscopy or ultrasound.) Then, inflate the gastric balloon with the regulated volume of air and tract it.
- [9] When injecting air into the gastric and esophageal balloons, always monitor the patient's condition. Lightly grasp the pilot balloon to prevent over-inflation.
- [10] When connecting a tube, etc. to the end of the funnel, select the one that fits surely. During use, check the connection for leakage or loosening as appropriate, and use it in a state where it is securely connected.
- [11] When connecting the connector to the funnel, insert the connector straight along the lumen of the funnel. Do not apply load on the funnel, such as by bending, twisting, or pinching it under this condition.
[The tip of the connector may damage the lumen of the funnel, it may cause a crack or rupture to the funnel.]
- [12] Fix the product with adhesive tape, etc., and do not use any adhesive.

[PRECAUTIONS FOR USE]

< Important Precautions >

- [1] During placement of the catheter, appropriately control the status of catheter placement.
[The lumen of the tube may be obstructed by suction materials such as blood clots.]
[The balloons may burst due to esophageal or gastric contents or the balloons may deflate due to spontaneous leak.]
- [2] Use the product under controlled environment when placing it.
- [3] To prevent erosion of the esophagus and esophagogastric junction, do not leave the product in place for more than 48 hours. To prevent mucosal injury, remove air from the esophageal balloon for 5 minutes every 6 hours.
- [4] Before using the product, check whether there is any abnormality in each part.
- [5] Do not insert forcibly. If insertion is difficult, discontinue the use and take appropriate measures.
[Tissues may be damaged.]
- [6] Do not insert or remove the product forcibly. Operate the product with great care.
[The product may be damaged.]
- [7] If any abnormality is observed, discontinue the use of the product immediately and take appropriate measures.
- [8] Do not pull or bend the product forcibly during use. Handle it carefully.
- [9] Do not modify the product.
[If a side hole, etc. is added, the tube may be cut.]
- [10] Do not grip the product strongly with forceps, etc.
[Tube cut, lumen occlusion and balloon breakage may occur.]
- [11] Metals are used inside the valve of the product. Therefore, when an MRI (Magnetic Resonance Imaging) examination is performed, note that artifacts or local high-frequency heating may occur in the image.
- [12] Do not use the product if the packaging is damaged or if any abnormality such as damage is found in the product.
- [13] Use immediately after opening and dispose in a safe manner for each country after use.
- [14] If drug solution is injected into the patient's body by using the product, select the appropriate drug solution under the responsibility of the physician.
- [15] During placement, keep the product under full control to prevent its handling by an untrained person.
- [16]  printed on the label means that the product does not contain pyruvic acid in the contact part of the body fluid/drug solution.
- [17]  printed on the label means that the product should not be used if the package is damaged or opened.
- [18] Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

< Defects >

- [1] Balloon burst.
[Burst due to the following causes.]
 - Damage caused by tweezers, forceps, scissors, scalpel, or other instruments.
 - Excessive injection volume (injection of more than the regulated volume).
 - Injection of the wrong substance for balloon inflation (substance that is likely to cause coagulation of components such as physiological saline and contrast medium).
 - Sudden load on the product due to self (accidental) removal, etc.
 - Other complex causes due to factors such as the above events.
- [2] Obstruction of the tube.
[The lumen of the tube may be obstructed by suction materials such as blood clots.]
- [3] Cut of the tube.
[Cut due to the following causes.]
 - Damage caused by handling during insertion (Damage caused by tweezers, forceps, scissors, scalpel, or other instruments).
 - Sudden load on the product due to self (accidental) removal, etc.
 - Excessive load on the product when peeling off adhesive tape, etc. suddenly.
 - Other complex causes due to factors such as the above events.
- [4] Valve breakage or leakage.
[Valve breakage or leakage may occur due to local high-frequency heating.]

< Adverse Events >

The following adverse events and contraindications are generally assumed by the use of the product.

- Aspiration
- Closure of the respiratory tract
- Esophageal erosion
- Esophageal rupture
- Erosion at gastroesophageal junction
- Pain due to chest compression
- Burns due to local high-frequency heating

< Use During Pregnancy, Delivery or Lactation and Pediatric Use >

Be careful when using X-ray to the patient who is pregnant or has some possibility of pregnancy.

[The influence of X-ray to the fetus is concerned.]

[STORAGE METHOD AND DURATION OF USE]

< Storage Method >

Store the product cleanly. Avoid wetting, direct sunlight, high temperature and humidity, and ultraviolet rays such as germicidal lamp, etc.

< Duration of Use >

Do not leave the product in place for 48 hours or more.

[Based on self-certification (our company data).]

< Expiration Date >

When the proper storage method has been maintained, refer to the expiration date on the individual package.

[Based on self-certification (our company data).]