

All Silicone Sengstaken Blakemore Tube (Type 32)

Single use only

[WARNINGS]

- Inner pressure of the esophageal balloon reaching 5.3 kPa (about 40mmHg) or more not only gives suffering and pain to patients, but also develops esophageal rupture in some occasions, leading to lethal state. Adequately pay attention not to increase the inner pressure of the balloon too high.
- If obstruction of air way is caused by blockage with the esophageal balloon, immediately aspirate air in the balloon or cut the tube to deflate it and pull out the tube.
- Keep the condition of balloon inflation under control during placement of a silicone balloon as following events may develop. [Balloon deflation due to lots of spontaneous leakage compared with the latex balloon.]

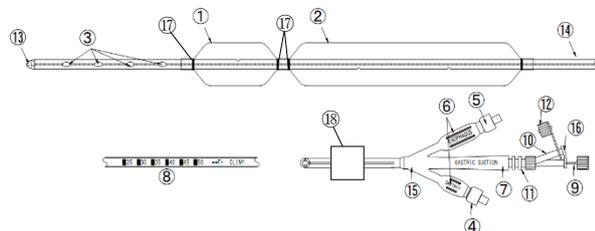
[CONTRAINDICATIONS • PROHIBITION]

- Do not reuse the product (single use only).
[This product is intended for a single use only, and its quality or performance after one use is not guaranteed. Further, reuse carries the possible risk of contamination (infection) to patients. Contamination of this product may lead to patient injury, illness or death.]
- Prohibition of Reprocessing, Resterilization
[Reprocessing of this product may lead to defects. It may also cause patient injury, illness or death.]
- Do not use anything other than air for inflation of the esophageal and gastric balloons.

[Shape, structure, principle, etc.]

- The device has been sterilized with ethylene oxide gas.

<Shape>



- ①Gastric balloon ②Esophageal balloon ③Gastric suction hole
④Valve for gastric balloon ⑤Valve for esophageal balloon ⑥Pilot balloon
⑦Funnel for gastric suction ⑧Depth mark ⑨Stylet ⑩Lubricant port
⑪Connector ⑫Lure cap ⑬Tip stopper ⑭Tube ⑮Branch part ⑯Lubricant inlet
⑰Fixed thread ⑱Pat for fixation

<Materials>

- Tip stopper : Silicone rubber (Radiopacity)
- Tube shaft: Silicone rubber (Radiopacity)
- Branch part : Silicone rubber
- Fixed thread : Polyester
- Gastric balloon, Esophageal balloon: Silicone rubber
- Valve for gastric balloon, valve for esophageal balloon: ABS, Silicone rubber
- Pilot balloon : Silicone rubber
- Funnel for gastric suction: Silicone rubber
- Stylet : Stainless steel, Polypropylene
- Lubricant port : Polyvinyl chloride, Polycarbonate
- Connector : Polyacetal
- Lure cap : Polypropylene
- Pat for fixation: Polyurethane

<Specifications>

Type 32

Size	O.D.	Effective length	Number of gastric suction hole	Depth mark
14Fr	4.8mm	950mm	4	From 25 to 50cm from the tip of esophageal balloon at 5cm intervals.
16Fr	5.2mm			
18Fr	6.0mm			
21Fr	6.7mm			

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

<Principles>

The device is inserted from nose to esophagus and stomach then fixed and placed at the target position by inflating the balloons to stop bleeding from esophageal varices. Suction of substances in stomach can be done from the end of gastric suction funnel.

[Intended purpose, efficacy or effect]

This device is inserted through esophagus to be used for hemostasis and diagnosis.

[Effect]

- Pressure hemostasis of esophagus varices is possible.
- The stomach contents can be sucked from the stomach suction funnels.

[Performance]

- Secure the level of sterility assurance (SAL) 10⁶.
- Sterile residue: must comply with ISO10993-7.
- Do not contain materials of biological origin and be compatible with biological safety.
- To be stable and durable for 5 years.
- When attaching a syringe and injecting 1.0 to 1.3 times more of the balloon volume, the balloon is inflated almost roundly. And when removing a syringe and observing after the injection, there is no leakage from anywhere.

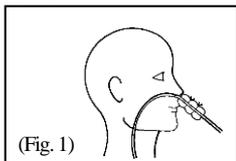
[Operating or using method etc.]

Below is a general procedure.

- (1) Send air with a syringe through the valve to esophageal and gastric balloons to confirm no leakage of air. After that, remove air completely.
- (2) Connect the stylet and lubricant port tightly. Confirm that tip of the stylet is put in tube.
- (3) Pour about 10mL of olive oil into lubricant port.
- (4) Fold gastric and esophageal balloons. Then apply demulcent/surface anesthetic like xylocain jelly sufficiently to the surface of balloons and the tip of the tube.
- (5) Anesthetize nasal cavities and pharynx, and insert an S-B Tube transnasally into esophagus and stomach.
- (6) After entering the tube into the stomach, pull out the stylet and detach the

lubricant port.

- (7) Fill the gastric balloon with specified amount of air slowly. Pull back the tube till the balloon presses the junction of esophagus and stomach lightly.
- (8) Traction the tube with a force of 2.9~4.9N (300~500gf). Then, fix it with adhesive tape. Use sponge (gauze) to prevent it from slipping. (Fig.1)



- (9) Infuse the air through the valve for esophageal balloon until the internal pressure reaches the recommended pressure. Connect to a manometer via a three-way stopcock between the valve and syringe to measure the recommended pressure.
- (10) Wash the inner lumen of the tube and the inside of the stomach with cold water to avoid the obstruction of the inner lumen. And suck substances in the stomach from funnel for gastric suction.
- (11) After wash and suction of the internal stomach are done thoroughly, connect the funnel for gastric suction to aspirator and suck the substances for 12 hours.
- (12) After aspiration for 12 hours, deflate the 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 it is found that bleeding has not stopped, send air again into the balloons and check every 4-6 hours if bleeding is discontinued or not.
- (13) Stop-bleeding is confirmed, release the air slowly from the esophageal balloon, then lessen the tractive force on the tube. After 3 hours, discontinue traction and release the air slowly from the gastric balloon.
- (14) If bleeding is not observed in 1 hour later, remove the tube gently and slowly.

<Precautions for use related to the operating procedures>

- (1) Prior to use, confirm whether the aspirator to be used is applicable to this product.
- (2) When using an aspirator, make sure to refer to the instructions for use of the aspirator.
- (3) In connecting some tubes to the funnel ends, select one which fits assuredly. Moreover after starting the use, confirm no leakage or slack of the connection part properly, and use it only in the status that the connection is surely done.
- (4) Before using the product, confirm that the balloon is inflated and deflated properly.
- (5) Use a common slip type disposable syringe for inflation of the balloon. [A luer-lock syringe may be unable to be inserted into the valve sufficiently. A syringe with unsuitable taper may result in the damage of the valve.]
- (6) When the balloon is inflated or deflated, insert the syringe tip into the valve certainly and operate it. [If the insertion of the syringe tip into the valve is insufficient, there may be the case that the balloon manipulation cannot be made as the valve does not operate properly.]
- (7) In removing the syringe, never fail to push the valve and rotate the syringe. [Rarely the valve may slip off and in some cases, it may come off.]
- (8) Slowly and carefully infuse the air to inflate the gastric or esophageal balloon. [Rarely the valve may slip off and in some cases, it may come off due to the sudden infusion.]
- (9) Do not infuse air into the gastric balloon more than the specified amount. [Excessive infusion leads burst of the balloons due to loads to them.]
- (10) When the stylet is fixed, take care not to stick the tip of the stylet out of the gastric suction holes.
- (11) If it is difficult to remove the stylet, rotate it or re-infuse lubricant such as olive oil.

[The tubes may be cracked.]

- (12) At the insertion, confirm that the balloons surely enter into stomach and esophagus. Thereafter, inflate the gastric balloon with specified volume of air and pull it back.
- (13) When sending air into gastric and esophageal balloons, confirming patient's condition by monitors without failure. Prevent excessive expansion by holding a pilot balloon lightly.
- (14) Use adhesive tape for fixing the device. Never use glue for the purpose.

[Precautions for use]

<Important basic precautions>

- (1) Handle oil-soluble drugs or drug solutions carefully as they may dissolve a plasticizer of polyvinyl chloride, di (2-ethylhexyl) phthalate. Before using products such as pharmaceutical preparations or drug solutions, refer to the package insert or the instructions for use of each product.
- (2) When connecting a guidewire fixing device or bamboo shoot shape connector etc. to the funnel, insert a guidewire fixing device or bamboo shoot shape connector straight along the inner lumen of the funnel. [If inserting a guidewire fixing device or bamboo shoot shape connector etc. forcibly, the inner lumen of the funnel may be damaged by the tip of the guidewire fixing device or bamboo shoot shape connector etc.]
- (3) Do not put any load, such as bend, twist, pinch, on the funnel, with a guidewire fixing device or bamboo shoot shape connector etc. connected to the funnel. [The tip of the guidewire fixing device or bamboo shoot shape connector etc. may damage the inner lumen of the funnel and may lead to crack or rupture of the funnel.]
- (4) Check the condition of the lumens adequately to ensure that the aspiration of internal substances of patient's body can be done securely. [The lumens of the tube may be blocked up with aspirated stuff such as blood clots.]
- (5) For indwelling the product, use it under the controlled circumstances.
- (6) Do not keep the tube in the body for 48 hours or more to prevent the appearance of erosions in the esophagus and the junction region of esophagus and stomach. Moreover, remove air in the esophageal balloon for 5 minutes every 6 hours to avoid the development of the mucous membrane damage.
- (7) 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.]
- (8) Before using the product, confirm if there is no abnormality for each part.
- (9) Do not insert the product forcibly. Stop the use if its insertion is difficult and take appropriate measures. [The forcible insertion may damage tissue.]
- (10) Do not insert and remove the product forcibly. Operate the product with adequate care. [The product may be damaged.]
- (11) If abnormality is detected, stop using the device promptly and take appropriate measures.
- (12) Treat the device carefully and gently without stretching or bending forcibly.
- (13) Do not remodel the device. [Addition of a side port, etc. may cause breakage of the catheter.]
- (14) Do not expose the device to drugs classified into a strong acid or a strong alkali and organic solvents.
- (15) Do not pinch the device with forceps too strongly. [The catheter may be broken or lumen may be occluded.]
- (16) Do not use the device if the package is broken or abnormality such as breakage is detected.
- (17) Use the device promptly after opening the package and dispose the device by a safe method. [The device tends to bear static electricity.]

- (18) For injection of a drug solution through the device, select an appropriate drug solution under the physician's responsibility.
- (19) During placement, keep the device under full control to prevent its operation by an untrained person.
- (20) The device is made of polyvinyl chloride (plasticizer: di (2-ethylhexyl) phthalate =DEHP).
- (21) "Port for lubrication" contains DEHP.
- (22) When  is found on the label, it means the product contains DEHP.
- (23) In case of use of this product on infants or toddlers, who are highly sensitive, or pregnant or nursing mothers, who are also likely to influence these thereby, please sufficiently explain the risks of DEHP and obtain consent before use. There is harm in liver and kidney.
- (24) When  is found on the label, it means that the product should not be used if the package has been damaged or opened.



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<Defects>

- (1) Burst of a balloon
[Bursts caused by the followings.]
- Damage due to handling during insertion (damage caused by tweezers, forceps, scissors, knife or other apparatuses)
 - Excessive injection (injection air or water more than the specified volume for the balloon inflation).
 - Injection of a wrong substance for balloon inflation (substances likely to coagulate such as physiological saline and contrast media).
 - Sudden stress on the product such as self (accidental) removal.
 - Other combined causes due to the above events
- (2) Occlusion of tube
[The lumen of the tube may be occluded by adhesion of aspirated stuff such as blood clots.]
- (3) Cut of tube
[Cut due to following causes]
- Tweezers, forceps, scissors, knife or other apparatuses
 - Sudden stress on the product such as self (accidental) removal.
 - Excessive loads given to the device by peeling adhesive tape etc. for fixation of the tube rapidly.
 - Other combined causes due to the above events

<Adverse events>

It is generally considered that the following adverse events and contraindications may occur with the use of this product.

Miss-swallowing, airway blockage, esophageal erosion, esophageal rupture and distress caused by chest compression.

[Storage conditions and duration of use]

<Storage conditions>

Store the device hygienically avoiding direct rays of the sun, high temperature, high humidity and ultraviolet rays such as a sterilizing lamp and taking care of wetting.

<Duration of use>

Never use the device for a period longer than 48 hours.

<Expiration date>

- See the expiration date given on each package provided that the device is stored appropriately.
- Store the device carefully and never use the device after the expiration date.

[Packaging]

2 pieces/box