

Instructions for use

Eso-SPONGE®

Description of the device

Eso-SPONGE, an endoluminal vacuum therapy (EVT) device, is a minimally invasive method for the treatment and prevention of anastomotic leakages and perforations in the upper gastrointestinal tract* (upper GIT).

The Eso-Sponge system consists of a drainage tube with an attached open-pore polyurethane sponge, a connection system (Y-piece), an application system (overtube, pusher) and a rinsing set (syringe, tip). The drainage consists of a Redon-Drainage (12 CH) with the open-pore sponge attached on the end. The area of the drainage tube in the sponge has perforated holes on its side. The size of the sponge on the drainage tube can be cut to size for the respective application.

The connection system consists of a PVC . Y-piece with a double-drain connector on one end and a hole for the pump on the other end of the Y-piece. Up to two Redon-Drainage systems can be connected to the double-drain-Y-connector and an adjustable medical approved vacuum pump (MV1 low vacuum pump).

The Eso-Sponge application system consists of two coaxially arranged tubes, the insertion tube made of silicone (overtube) and the inner more rigid tube with a handle (pusher) . The lumen of the overtube is slightly larger than the outside diameter of the applied endoscope and is used as a guide for the insertion of the sponge system. The pusher is used to push forward and position the sponge.

Contents

1. Eso-SPONGE, open-pore polyurethane sponge (ø 2.4 x 5.5 cm) with 12 CH Redon drain, med. PVC, 100 cm long
2. Pusher, ABS + PVC (inserted into the overtube, to be separated before using)
3. One overtube in the set
 - Silicone tube, 56 cm long
 - Tapered and rounded tip
 - 2 sizes available:
 - Inner diameter 13 mm, outer diameter 17 mm (set article number 5526550)
 - Inner diameter 15 mm, outer diameter 19 mm (set article number 5526540)
4. Irrigation set consisting of 20 ml syringe + attachment + slide clamp
5. Y-shaped connector for connection with a variable speed medical low vacuum pump (MV1 from MTG, Sulzbach)
6. Slide clamp
7. Warning notice (red)

NOT INCLUDED:

- 1) 16 CH gastric tube
- 2) Variable speed medical vacuum pump
(low vacuum pump MV1, Ref. MTG19116, MTG, Sulzbach
order additionally bacteria filter, Ref. MTG18022, MTG, Sulzbach for the low vacuum pump MV1, order additionally secretion bottle, Ref. MTG18032, MTG, Sulzbach for the low vacuum pump MV1)
- 3) Sterile hydrogel based on glycerol
- 4) Standard or therapeutic gastroscope
- 5) Additional endoscopic accessories to be used at the physician discretion.

Materials used

Acrylonitrile Butadiene Styrene (ABS), Polyvinyl chloride (PVC), Polyurethane (PUR), polyethylene terephthalate (PET), hydrogel, silicone, Polyethylene (PE) , Polypropylene (PP), Isoprene rubber

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Indications for use

- Treatment of anastomotic leaks or perforations in the upper gastrointestinal tract* by means of negative pressure including intraluminal or intracavitary therapy of paraoesophageal and mediastinal septic focus or localised abscesses endoscopically accessible.
- Preventive therapy to reduce the risk of anastomotic leaks in the upper gastrointestinal tract*.

**The upper gastrointestinal tract refers to the oesophagus, stomach and duodenum, endoscopically accessible within the range of the overtube length.*

Mode of action

Eso-SPONGE uses negative pressure through a natural orifice (mouth), to control local infections, and allows second-intention healing to perforations or leaks in intracavitary and intraluminal sites of the upper GIT. Negative pressure is applied to gain the desired effect similar to that observed for superficial wound management.

Contraindications

- Malignant tumour wounds
- Necrotic tissue/gangrene
- Untreated osteomyelitis
- Septic focus is not fully drainable endoscopically
- Blood clotting disorder
- Treatment with anti-coagulant substances in a therapeutic dosage
- Generalized peritonitis or sepsis
- Bleeding oesophageal varices
- Sponge placement directly on major vessels
- Eso-SPONGE is contraindicated on patients with known sensitivities or allergies to its components (refer to Materials Used, for details about components name).
- The dimensions of the device should be taken into consideration for its use in specific patient groups (e.g. small framed persons).
- Limited clinical evidence from the use of Eso-SPONGE is available in paediatric population. As a precautionary measure, Eso-SPONGE is not recommended in paediatric population.
- There are no clinical evidence from the use of Eso-SPONGE in pregnant and breastfeeding women. As a precautionary measure, Eso-SPONGE is not indicated for use during pregnancy or breastfeeding.

Mode of Application

1) Treatment of anastomotic leakages

In the Eso-Sponge system, the sponge is connected to a negative pressure of 125 mmHg via a drainage hose. The size of the sponge is adapted to the cavity. The sponges are changed every 48-72 hours until granulated tissue has been developed. The therapy is stopped as far as the defect has reached a size which is too small for a further sponge insertion or until the cavity is completely closed or collapsed.

Insertion of Eso-Sponge

Prepare the patient for endoscopy according to standard practice and explain the treatment procedure

and all associated risks.

For the treatment, the intracavitary therapy is recommended.

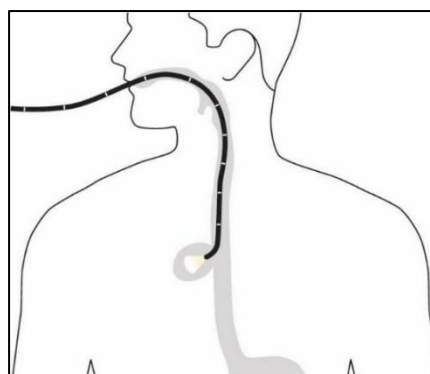
Before use, the wound cavity (intracavitary or intraluminal space) can be cleaned using appropriate methods, such as irrigating with Ringer's solution. The wound cavity should be measured (length and diameter) with an appropriate endoscope of compatible diameter to the overtube. Remove the warning note from the redon drain of the Sponge.

Cut the size of the sponge if necessary with scissor or a scalpel; adapt the size to be slightly smaller than the measured cavity. The sponge can be cut in length and diameter, take into consideration when shortening the length of the sponge that the inner drainage is not exposed, if you can see the drain, cut it to approximately 3mm shorter than the sponge, make sure the sponge is in contact with the tissue.

Chose a flexible endoscope with the appropriate size, it should be slightly smaller than the overtube lumen. At first the overtube should be placed with the non-tapered side over the endoscope. Leave the overtube at the distal part of the endoscope.

Insert the endoscope and measure the wound cavity (length and diameter) to determine the required length and diameter of the sponge. (Fig.1).

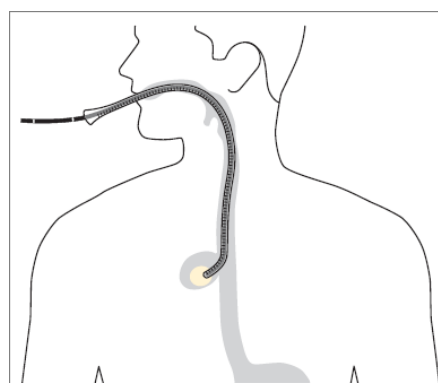
Fig. 1



Reshape the sponge (**see precautions!**).

Cut the size of the sponge if necessary with scissor or a scalpel, adapt the size to be slightly smaller than the measured cavity. The sponge can be cut in length and diameter, take into consideration when shortening the length of the sponge that the inner drainage is not exposed, if you can see the drain, cut it to approximately 3mm shorter than the sponge, make sure the sponge is in contact with the tissue.

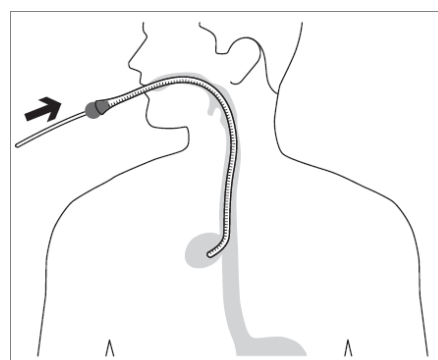
Fig. 2



Push the overtube over the endoscope and introduce the overtube under visual control using the endoscope as a guide until the overtube tip (tapered end) is near the end of the cavity, leaving enough space for the sponge to deploy. (Fig.2)

If the entrance of the cavity is too small for the overtube to enter, use an endoscopic balloon, at the physician discretion, to dilate the entrance until the overtube can access the cavity.

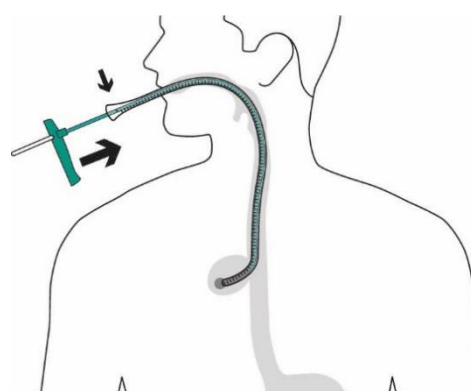
Fig. 3



Hold the overtube firmly by hand and remove the endoscope. After leaving the overtube in the required position, place the drain of the sponge inside the pusher and introduce the sponge ,previously impregnated with **sterile hydrogel based on glycerol**, (not supplied in the set), while holding the overtube firmly in place. (Fig.3).

Use of pusher to advance the sponge forward. As soon as the sponge reaches the end of the overtube (check mark on the pusher), advance gently until the sponge is expelled from the overtube, the resistance will fade once the sponge is released.

Fig. 4



Withdraw the overtube and pusher together. (Fig. 4). To avoid sponge dislodging it is recommended to advance the Eso-SPONGE by pushing the drain inside the pusher channel while gently retiring it. The sponge will now expand in the leakage cavity.

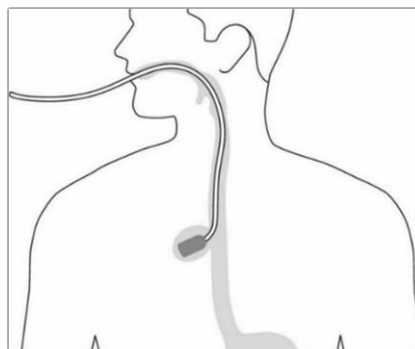
After removal of the pusher and overtube check the position of the sponge using the endoscope to make sure that the sponge has not migrated.

The placement of the drainage tube is always Transoral.

To promote effective cavity closure, it is advisable to place the sponge inside the cavity, with the back of it slightly visible from the lumen. **(Fig. 5)**

In case of deep cavities, insert the sponge at the bottom until it looks clean and is granulating, then place it near the leakage overture as described above. In subsequent sponge changes, reduce the size gradually in length and diameter.

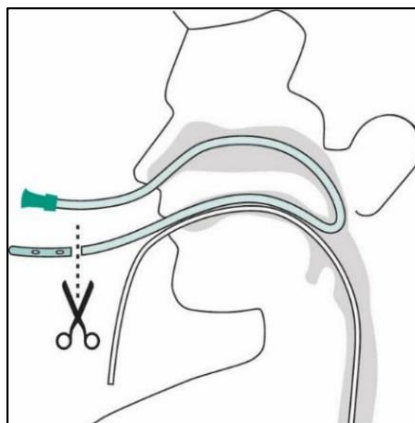
Fig. 5



As an alternative to transoral drainage, the suction drain can also be placed transnasally for intubated patients.

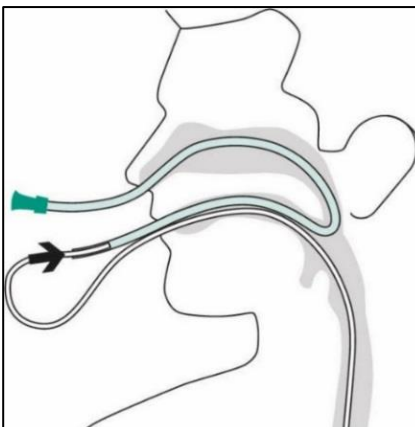
Feed a **16 CH gastric tube** (not supplied in the set) in through the nose and out through the mouth. For grasping of the gastric tube in the pharynx e.g. a Magill forceps can be used. The atraumatic tip is then cut off. **(Fig. 6a)**

Fig. 6a



Connect the drain to the gastric tube in front of the mouth. **(Fig. 6b)**

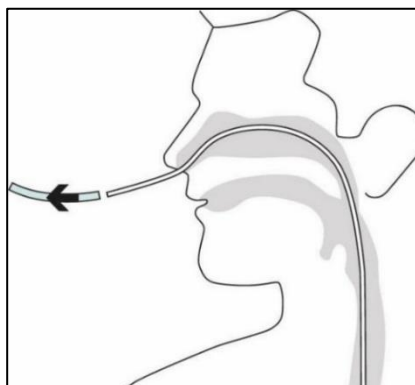
Fig. 6b



Withdraw the combined tubes through the nose.

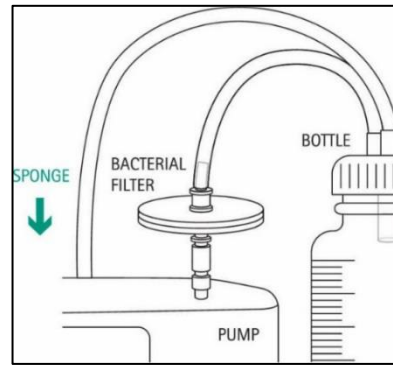
Disconnect the gastric tube. **(Fig. 6c)**

Fig. 6c



In the following section the combination of the **variable speed medical vacuum pump**, Ref. MTG19116, MTG, Sulzbach (not supplied in the set) with the Eso-SPONGE is described:

Fig. 7



Connect the **filter**, Ref MTG18022 from MTG, Sulzbach (not supplied in the set) via Luer Lock to the pump and the tube from the **secretion bottle**, Ref MTG18032 from MTG, Sulzbach (not supplied in the set) to the filter. **(Fig. 7)** Follow Instructions for Use for the pump Low-Vacuum-System model MV1 from MTG, Sulzbach.

Use of the special Y-shaped connector to connect the drain to the secretion bottle tube.

Fig 8a): Redon drain must be introduced in the Y connector to the minimum depth marked by dashed line.

Fig. 8

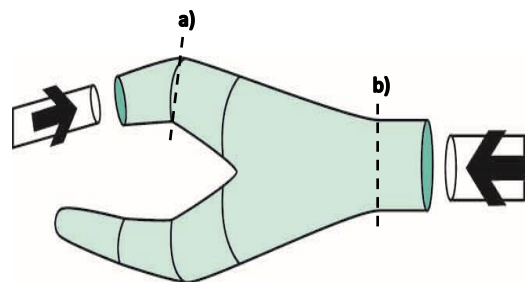


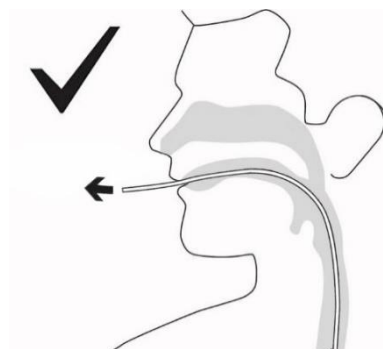
Fig 8b) The connection of the secretion bottle must be introduced in the Y connector to the minimum depth marked by dashed line.

Suction is applied using a **variable speed medical vacuum pump**, Ref. MTG19116 from MTG, Sulzbach (not supplied in the set).

Suction is applied, if possible, under endoscopic inspection of the sponge at a **negative pressure 50 to 125 mmHg (see precautions!)**.

The system must be checked on a regular basis.

Fig. 9



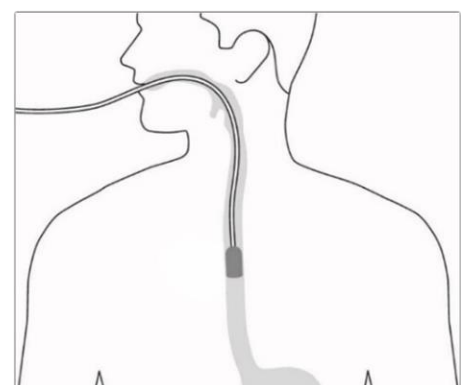
Remove of the sponge only through the mouth and never through the nose **(Fig. 9)**

2) Preventive therapy

To insert a Eso-SPONGE to prevent an anastomotic leakage, follow the insertion system above described but place the end of the overtube at the anastomosis site and release the sponge.

The sponge must be positioned at the anastomosis site **(Fig. 10)** and must be connected to the vacuum source, low vacuum pump MTG19116 from MTG Sluzbach (not supplied with the set), at a negative pressure of 75 mmHg as previously described. Leave the sponge for 4-6 days and retire the sponge.

Fig. 10



Removal of Eso-SPONGE orally

1. Disconnect the Eso-SPONGE from the pump. If the drain exits via the nasal rather than oral route, it must be threaded through the mouth again (Fig. 9).
2. With the Eso-SPONGE drain in place, use the supplied irrigation set to irrigate the wound cavity using approx. 20 mL of Ringer's solution or 0.9 % saline solution, repeat three times.
3. Removing the Eso-SPONGE orally:
 - Pull carefully, intermittently and with increasing force on the drainage tube until the sponge is released from the cavity (loss of resistance).
 - After dislodging the sponge, continue to pull gently to remove the sponge orally.
4. Check that the sponge is in one piece.
5. Examine the treated cavity with the endoscope to check for sponge residue and document the success of the treatment. If you need to insert a new Eso-SPONGE, re-measure the size of the cavity to determine the size of the new sponge, as described in Fig. 1.
6. We recommend the continued use of Eso-SPONGE until the cavity length has been reduced to less than 2 cm and the diameter to less than 1 cm. It is recommended not to exceed a duration treatment of 65 days. The mean treatment duration time reported is 30 days.

Warnings

- The sponge could suffer damages when reshaping and/or removing, generating residual sponge particles.
- The residual sponge particles could cause fistula formation, foreign body reactions. Possible need of surgical removal.
- Sponge placement directly on nerves and heart is not recommended.
- In case of damaged vessels in the esophageal region the application of Eso-SPONGE with a vacuum pump can cause severe bleedings in rare occasions which may lead to death of the patient.
- Eso-SPONGE must not be used in body openings other than indicated.
- Due to the underlying disease most patients have a localized infection which can lead to sepsis (i.e. peritonitis, necrosis...).

Precautions

- This treatment should only be performed by experienced doctors with many years of practice both in the interventional treatment of the upper gastrointestinal tract using flexible endoscopy and in negative pressure wound therapy in general.
- Particles and sponge residues are produced when the sponge is cut to size. The sponge must be cut (e.g. with scissors or a scalpel) at an appropriate distance from the patient and in a suitable environment in which particles are permitted.
- After cutting the sponge, all residues and particles must be removed from the surface by tapping the sponge, collected and disposed of in the usual manner.
- When reshaping the sponge, ensure that there are no sharp edges or points and round it off, otherwise these can easily break off during the removal of the sponge. After cutting no cut in the sponge or the drainage tube should exist.
- When shortening the sponge length also shorten the drainage tube. The sponge must protrude at least 3 mm from the end of the drainage tube.
- The prescribed negative pressure (50 to 125 mmHg) must be ensured. **ATTENTION:** Applied vacuum must never exceed a negative pressure of 200 mmHg.
- The dwell time depends on the local clinical situation. If applicable, it is recommended to

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adjust the time of sponge change depending on the amount of debris and growth of granulation tissue.

- For the treatment of leaks and perforations a dwell time of 48 hours is recommended; more than 72 hours must be ruled out due to the risk of granulation tissue overgrowing into the sponge, as a result the sponge could get broken during removal, leaving part of it into the application area and embedded in granulation tissue. In case this happened, an endoscopic loop must be used to detach the sponge from the surrounding tissue for its removal. The duration of the treatment must not exceed 65 days.

For the preventive use do not exceed a dwell time of 6 days.

- Prior to application, an appropriate imaging procedure must be performed to rule out an abscess in the wound area that can only be treated by a surgical or interventional procedure, which cannot be treated with the Eso-SPONGE.
- The sponge must not be removed through the nose.
- The flow of secretion must be monitored and the quantity checked. The drainage of secretion usually begins immediately. If this is not the case, the connection between Eso-SPONGE and the pump and the settings of the pump must be checked.
- All articles are single-use articles except the variable speed medical pump (MV1, MTG, Sulzbach).
- All articles are only to be used if the packaging is undamaged.
- Be careful not to damage the sheathing of the endoscope
- Damage to cables of endoscope can happen in case of excess bending of flexible distal end within the overtube.















Side effects

- Erosion of structures adjacent to the sponge (e.g. mediastinal vessels, membranous wall of the trachea and lungs, pulmonary artery, pulmonary vein, aorta, vena cava, lymphatic vessels)
- Damage and perforations in the region of approaches (oral cavity, oesophagus, pharynx, nose)
- Sponge dislocation
- Post-interventional stricture / stenosis
- Bleeding, that depending on patient condition could lead to severe bleeding or death.

Storage

Store the Eso-SPONGE at room temperature. Do not expose to extreme temperatures for extended periods of time. Use the product only if it has been stored correctly and before the expiry date indicated on the packaging. Only use Eso-SPONGE if the package is undamaged.

Symbols used on the packaging

	Do not reuse
	Use-by date Year+Month+Day
	Sterile unless package is opened or damaged. Method of sterilization: Ethylene Oxide
	Batch code
	Dimension (*) (*) Overtube internal diameter
	Caution
	Consult Instructions for Use
	Catalogue number
	Medical Device
	Unique Device Identifier
	Date of manufacture
	Single Sterile Barrier System
	Do not use if package is damaged and consult instructions for use
	CE-mark and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC

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