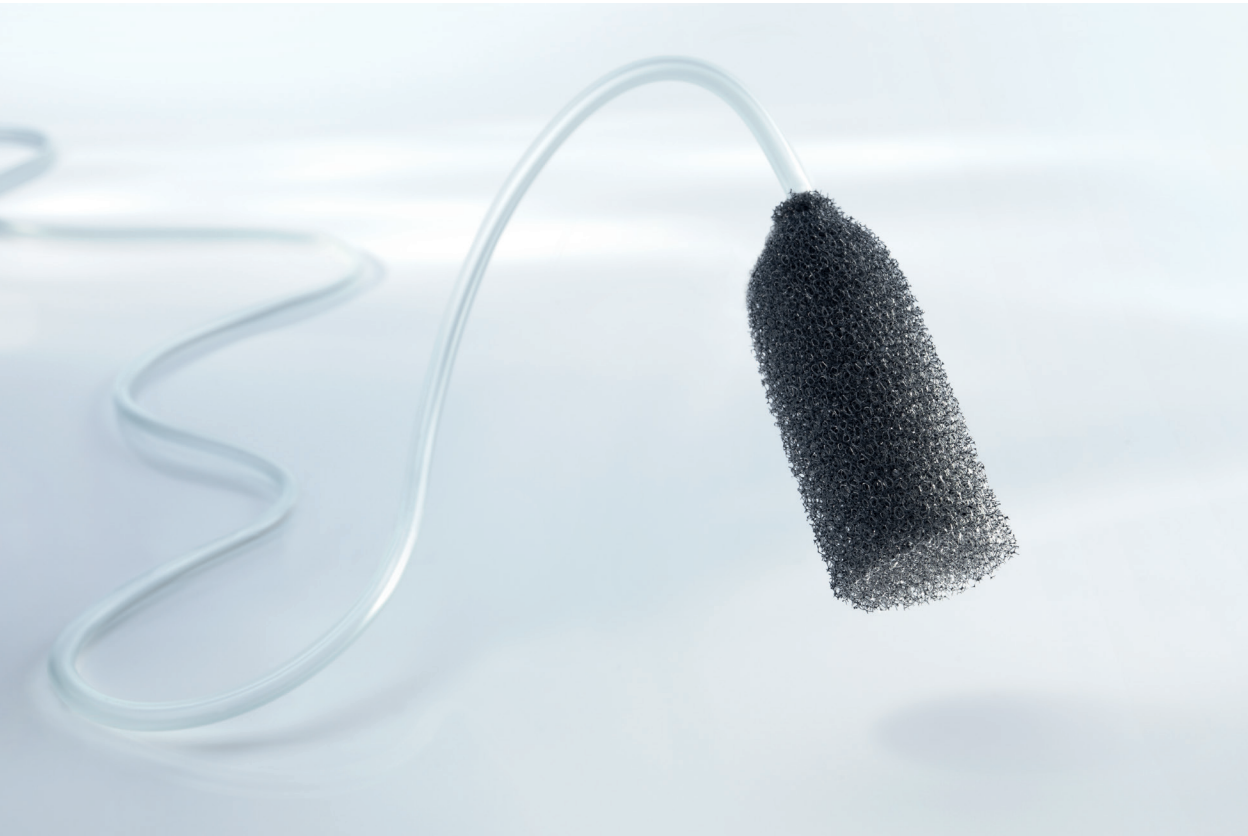


NEW
PREVENTIVE USE



Eso-SPONGE®

ENDOLUMINAL VACUUM THERAPY FOR THE TREATMENT
AND PREVENTION OF ANASTOMOTIC LEAKAGES, AND FOR
THE TREATMENT OF PERFORATIONS, IN THE UPPER GI TRACT

Eso-SPONGE®

ENDOLUMINAL VACUUM THERAPY FOR THE TREATMENT OF ANASTOMOTIC LEAKAGES AND PERFORATIONS IN THE UPPER GI TRACT

Anastomotic leakages or other defects in the upper gastrointestinal tract can have serious consequences for the affected patients. Different parameters, like the size, location, time to diagnosis of the lesion, but also the general condition of the patient, have a significant influence on the clinical outcome of the patient. Often this situation is accompanied by symptoms of sepsis and a significant morbidity rate with corresponding substantial mortality rate. For this reason the treatment of this clinical situation is often a challenge for the clinician.

Besides surgical examination and the endoscopic stent system, good experiences have been obtained with the Endo-SPONGE® therapy for the lower gastrointestinal tract.

Now also the endoluminal vacuum therapy for the upper gastrointestinal is available – Eso-SPONGE®.





ANASTOMOTIC LEAKAGE IS A SEVERE COMPLICATION FOLLOWING GASTRIC AND ESOPHAGEAL SURGERY

Anastomotic leakage (AL):

- Is associated with high morbidity and mortality.¹⁻¹⁰
- Can occur after oesophageal surgery in up to 30% of cases.¹⁻¹⁰
- Can occur after gastric bypass and sleeve gastrectomy surgery in 1.5% and 4.9%.¹⁻¹⁰
- Has higher leak rate in cervical anastomosis (12.3% – 13.6%) than in thoracic anastomosis (2.9% – 9.3%).^{11, 12}
- Increases hospital costs.¹⁻¹⁰
- Increases length of stay.¹³
- Increases the reoperation risk.¹³
- Increases the risk of cancer recurrence.¹⁴
- Is related to worse long-term survival.¹³
- Increases the risk of stricture formation.¹³
- Delays oral feeding.¹³

ANASTOMOTIC LEAKAGE (AL) DIRECTLY AFFECTS THE MORTALITY RATE

- Mortality in patient with AL is reported to be between 2% – 35%.^{13, 15, 16}
- AL increases the mortality rate compared to no leakage.¹⁵
- Mortality is increased 2x in delayed AL diagnostic & treatment > 24h.¹⁶

Eso-SPONGE®

ENDOLUMINAL VACUUM THERAPY FOR THE TREATMENT OF ANASTOMOTIC LEAKAGES
AND PERFORATIONS IN THE UPPER GI TRACT



SUGGESTED BENEFITS OF VACUUM THERAPY ON THE TISSUE

- Increase blood flow and edema reduction.¹⁷
- Granulation tissue formation and extracellular synthesis.¹⁷
- Decrease of bacterial contamination and secretion.¹⁸

VACUUM THERAPY FOR THE UPPER GI

- Endoluminal Vacuum Therapy (EVT) is a feasible, safe and high efficient approach to treat anastomotic leaks and perforations within the upper GI.^{8-10, 19-38}
- EVT is used as the first method of choice for oesophageal leaks or perforations already in several hospitals.^{8, 10, 19-35}
- EVT has the potential to become the new standard of care for this indication.^{8, 10, 19-35}

Eso-SPONGE® TREATMENT SUGGESTED BENEFITS

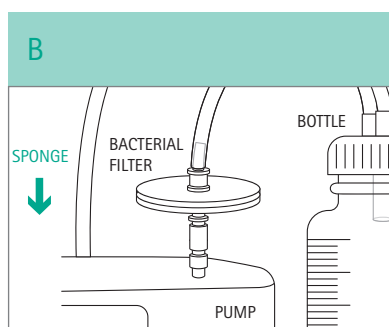
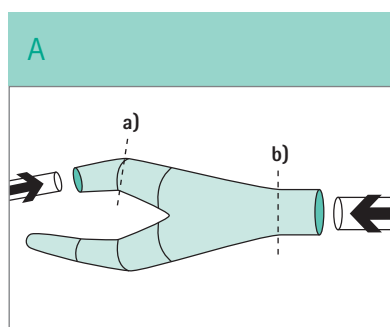
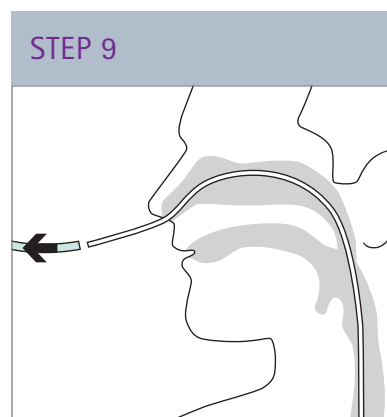
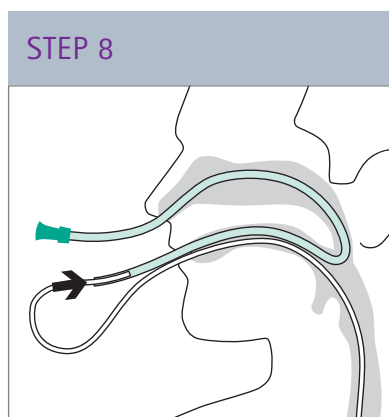
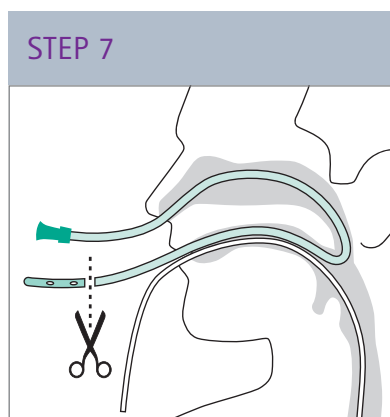
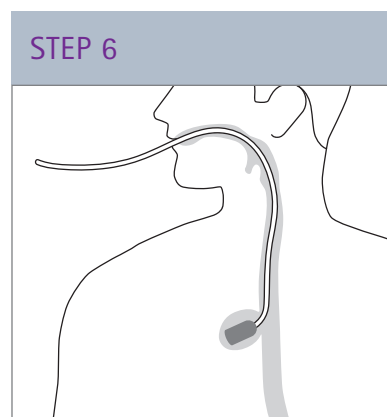
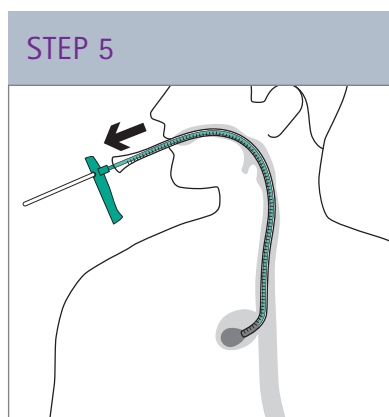
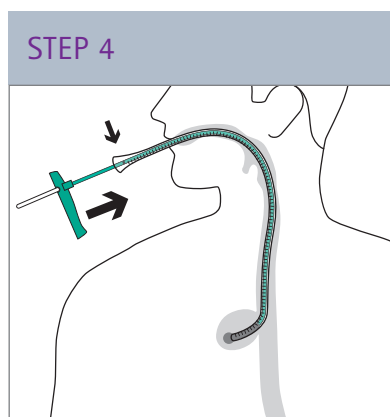
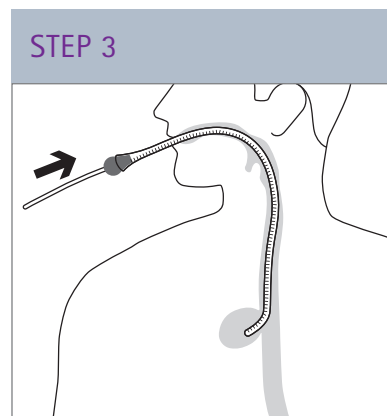
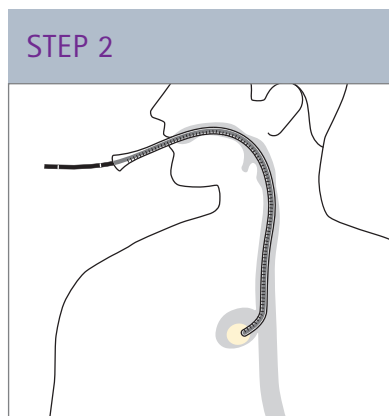
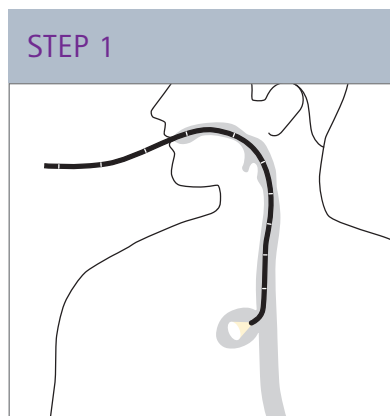
- The mean treatment duration time reported is less than 30 days.^{8, 9, 20, 24, 28, 29, 36-39}
- The average rate of successful treatment with Eso-SPONGE has been reported to occur in 84 % of patients.*^{8, 9, 10, 24, 28, 29, 36-39}
- Early treatment is likely to achieve faster healing, shorter duration of treatment & hospital stay and less complications.^{5, 8-10, 24, 25, 28, 30, 36, 40}
- Continuous drainage, no secretion accumulation.^{8-10, 24, 28, 29, 36-38, 41-43}
- Infection control.^{8-10, 24, 28, 29, 36-38, 41-43}
- Debridement, quick cleaning of the wound cavity.^{8-10, 24, 28, 29, 36-38, 41-43}
- Promotion of granulation tissue ingrowth.^{8-10, 24, 28, 29, 36-38, 41-43}
- Mechanical reduction of the wound cavity.^{8-10, 24, 28, 29, 36-38, 41-43}
- Can be combined with enteral feeding.^{8, 24, 28, 36, 37, 39}
- If necessary, Eso-SPONGE can be combined with stent placement or operative revision for better control of the septic focus.^{8-10, 24, 44, 28, 29, 37, 38, 45}
- Contribute significantly to the reduction of morbidity and mortality of the patients.^{8-10, 19-37, 39, 41}
- Well tolerated with good short- and long-term clinical outcomes.^{8-10, 19-37, 39, 41}
- Likely to be superior to stent treatment and reduced need for surgical revision, and with less strictures.^{1, 10, 22, 23, 27-30}

* According to the product-related literature covered herein, wound closure or repair was achieved principally by Eso-SPONGE®, though some patients in some studies required additional stent therapy or surgical revision to ensure complete closure repair.

Eso-SPONGE®

ENDOLUMINAL VACUUM THERAPY FOR THE TREATMENT OF ANASTOMOTIC LEAKAGES
AND PERFORATIONS IN THE UPPER GI TRACT

THERAPY PROCEDURE



TREATMENT CRITERIA

Eso-SPONGE® THERAPY PRINCIPLE

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.

*For use in the upper gastrointestinal tract understood as esophagus, stomach and duodenum, and endoscopically accessible within the range of the overtube length.

Eso-SPONGE® TREATMENT

Intraluminal and intracavitary therapy possible, see below instructions for intracavitary positioning of the Eso-SPONGE®.

STEP 1: The wound cavity should be measured (length and diameter) with an appropriate endoscope (leave the overtube at the distal part of the endoscope to be used in the next step). Cut the sponge slightly smaller than the cavity.

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

STEP 3: 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, through the overtube.

STEP 4: Push the Eso-SPONGE® to the mark with the pusher. The sponge is now at the end of the overtube (uncut sponge).

STEP 5: Advance gently until the sponge is expelled from the overtube, the resistance will fade once the sponge is released. Withdraw the overtube and pusher together.

STEP 6: The sponge will now expand in the leakage cavity. Check the position of the sponge using the endoscope to make sure that the sponge has not migrated and apply appropriate correction by means of endoscopic grasping forceps if necessary.

STEP 7: Transnasal channelling: Feed a 16 CH gastric tube in through the nose and out through the mouth. Cut off the atraumatic tip.

STEP 8: Connect the drain to the gastric tube in front of the mouth. Pull the stomach tube together with the drain back through the nose.

STEP 9: Disconnect the gastric tube. The drain is now transnasally channelled.*

* Remove of the sponge only through the mouth and never through the nose (!)

CONNECTION TO THE VACUUM SOURCE

How to use the variable speed medical vacuum pump MV 1 (MTG Sulzbach, Germany – distributed by B. Braun):

Fig. A:

- The redon drain must be introduced in the Y-connector to the minimum depth marked by dashed line.
- The connection of the secretion bottle must be introduced in the Y connector to the minimum depth marked by dashed line.

Fig. B: Connect the filter using a Luer Lock to the pump. Then attach the cylinder hose from the secretion bottle to the filter.

Suction is applied, if possible, under endoscopic inspection of the sponge at a negative pressure of 50 to 125 mmHg. Regular checking of the system is mandatory.

The system must be changed every 48 - 72 hours and, where appropriate, a new sponge inserted.

For more information look at the instructions for use.

Eso-SPONGE®

ENDOLUMINAL VACUUM THERAPY FOR THE TREATMENT OF ANASTOMOTIC LEAKAGES
AND PERFORATIONS IN THE UPPER GI TRACT

MV1 VACUUM PUMP

- Pre-set at 125 mmHg
- Patient mobility thanks to battery
- Closed system
- 1000ml filling volume
- Alarm system



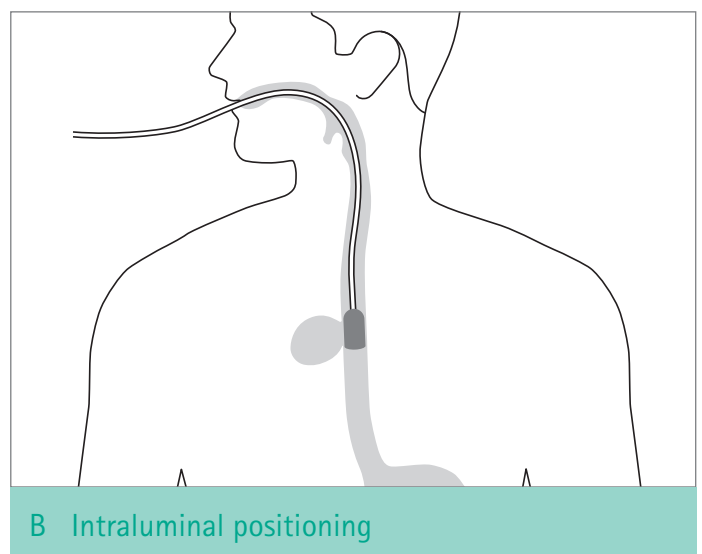
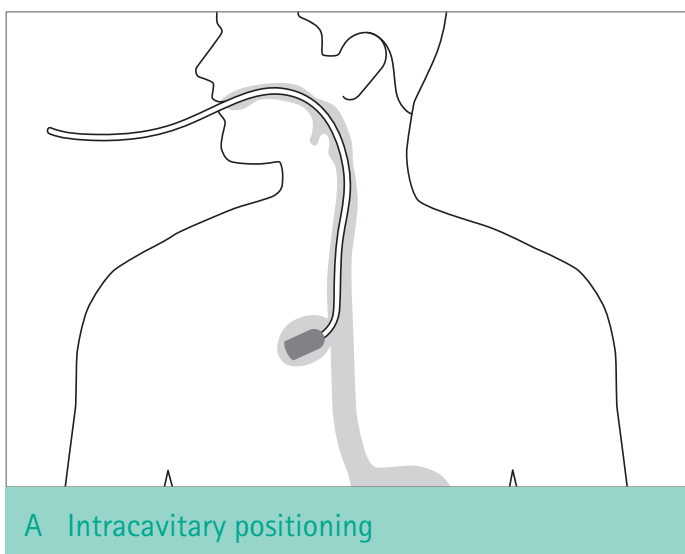
LITERATURE SUMMARY ON THE USE OF VACUUM THERAPY TO TREAT ANASTOMOSIS INSUFFICIENCY AND PERFORATIONS IN THE UPPER GI TRACT

YEAR	PAPER REFERENCE	N	INDICATION	TREATMENT DURATION (DAYS)	NUMBER OF SPONGE CHANGES	RATE OF HEALING	TYPE OF DEFECT (N)		
							AL	IP	O
2018	Bludau et al. ²⁸	77	Esophageal perforations and leak-ages from esophagogastrostomies	11 (1 - 65)	2.75 (1-9)	77.90%	59	18	0
2016	Kuehn et al. ⁸	21	Esophageal and gastric resections, esophageal perforation	15 (3-46)	5 (1-14)	90.5%	11	8	2
2020	Jung et al. ⁴⁸	30	Esophageal anastomotic leaks and perforations	16.1 (2-58)	AL=3.6 (1-13) IP=5.1 (1-12)	83.3%	23	7	0

AL: anastomotic leak, IP: iatrogenic perforation, O: other

RECOMMENDED PLACEMENT OF THE SPONGE

- Place the sponge preferentially in the cavity created by the leak or perforation: **Intracavitary positioning**.
- When intracavitary placement is challenging or not possible it is an option to place the sponge in the lumen in front of the defect: **Intraluminal positioning**.^{18, 34}



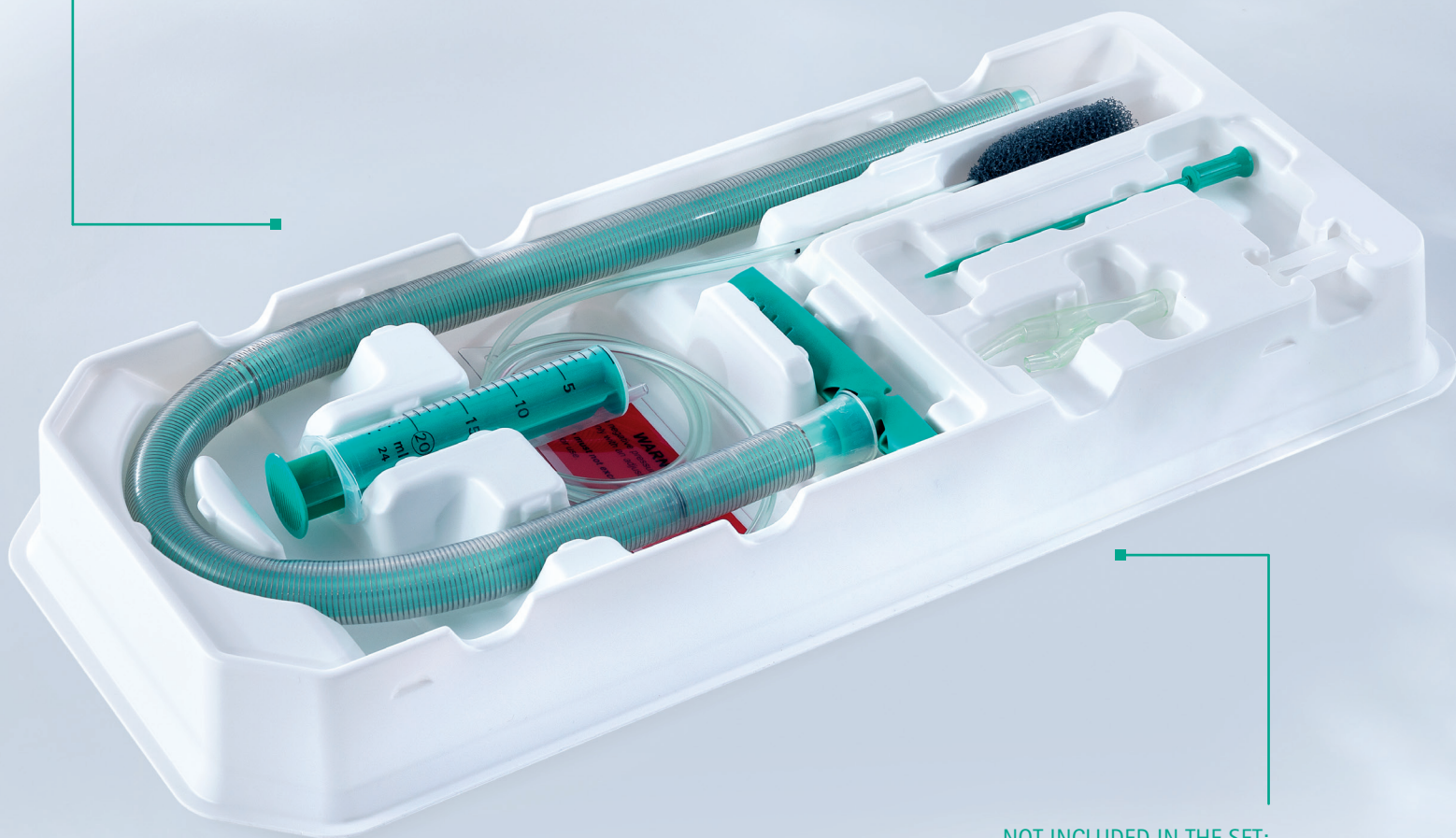
Eso-SPONGE®

ENDOLUMINAL VACUUM THERAPY FOR THE TREATMENT OF ANASTOMOTIC LEAKAGES
AND PERFORATIONS IN THE UPPER GI TRACT

PRODUCT AND ORDERING INFORMATION

Eso-SPONGE®

- Overtube (2 sizes available)
- Pusher
- Irrigation set
- Y-shaped connector
- Slide clamp



NOT INCLUDED IN THE SET:

- Sterile hydrogel (glycerol based)
- Gastric tube CH 16
- Variable speed medical vacuum pump (see information about MV1 pump in this brochure)

ART.-NO.	NAME	DIAMETER OVERTUBE	CONTENT
5526550	Eso-SPONGE® 13 mm	Inner: 13 mm Outer: 17 mm	1 intervention set
5526540	Eso-SPONGE® 15 mm	Inner: 15 mm Outer: 19 mm	1 intervention set

Vacuum source (MV1, MTG Sulzbach)

ART.-NO.	NAME	CONTENT
MTG19116	MV1	1x Low vacuum pump
MTG18022	Bacterial filter	20 units
MTG18032	Collecting bottle	15 units

* This therapy requires the use of a standard or therapeutic gastroscope.

Eso-SPONGE®

NEW INDICATION: ENDOLUMINAL VACUUM THERAPY FOR PREVENTION OF ANASTOMOSTIC LEAKAGES IN THE UPPER GI TRACT

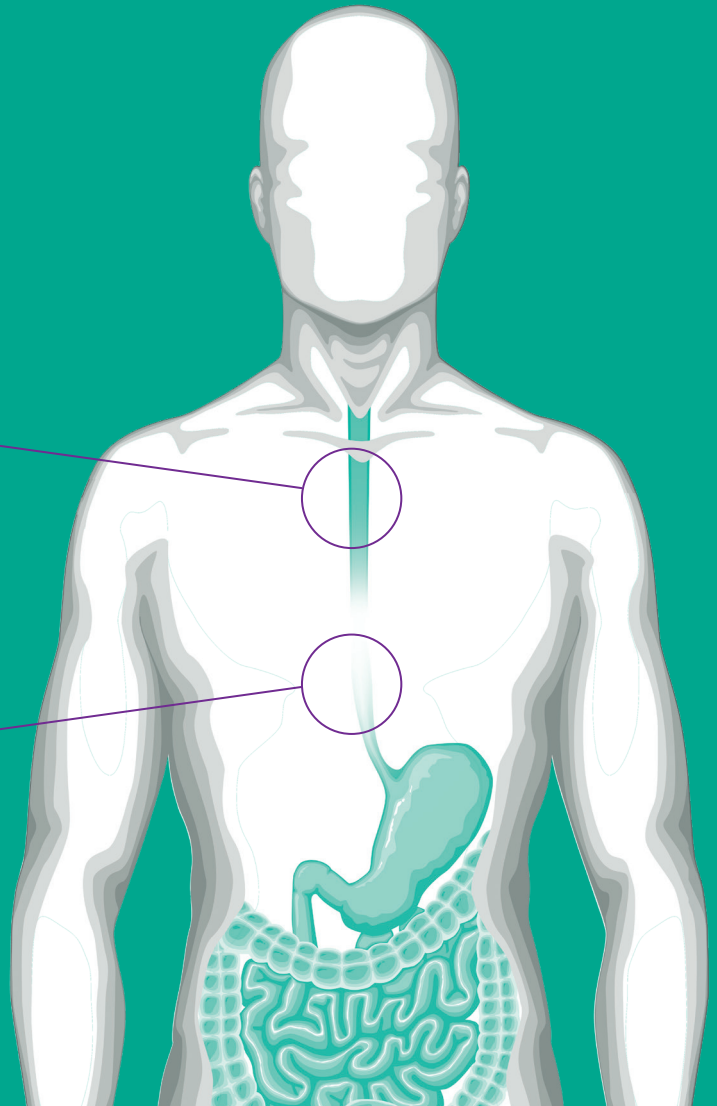
NEW PREVENTIVE USE

12.3 % – 13.6 %

LEAKAGE RATE IN CERVICAL ANASTOMOSIS ^{11, 12}

2.9 % – 9.3 %

LEAKAGE RATE IN THORACIC ANASTOMOSIS ^{11, 12}



1ST CHOICE IS ALWAYS PREVENTION!

Some patients have higher risk of developing an anastomotic leakage after esophagectomy due existing conditions such as:

- Calcification or arteries ⁴⁶
- Heart failure, hypertension, renal insufficiency ¹¹
- Obesity ⁴⁷
- Diabetes ¹¹

Now it is possible to use Eso-SPONGE® to reduce the risk of anastomotic leakages.

PILOT STUDY FOR PREEMPTIVE USE OF Eso-SPONGE®²⁴

Preemptive endoluminal vacuum therapy to reduce anastomotic leakage after esophagectomy: a game-changing approach?

Dis Esophagus. 2019 Jul 1;32(7)

Authors

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Abstract

Endoluminal vacuum therapy (EVT) is an accepted treatment for anastomotic leakage (AL) after esophagectomy. A novel concept is to use this technology in a preemptive setting, with the aim to reduce the AL rate and postoperative morbidity. Preemptive EVT (pEVT) was performed intraoperatively in 19 consecutive patients undergoing minimally invasive esophagectomy, immediately after completion of esophagogastrostomy. Twelve patients (63%) were high-risk cases with severe comorbidity. The EVT device was removed routinely three to six (median 5) days after esophagectomy. The endpoints of this study were AL rate and postoperative morbidity. There were 20 anastomoses at risk in 19 patients. One patient (5.3%) experienced major morbidity (Clavien-Dindo grade IIIb) unrelated to anastomotic healing. He underwent open reanastomosis at postoperative day 12 with pEVT for redundancy of the gastric tube and failure of transition to oral diet. Mortality after 30 days was 0% and anastomotic healing was uneventful in 19/20 anastomoses (95%). One minor contained AL healed after a second course of EVT. Except early proximal dislodgement in one patient, there were no adverse events attributable to pEVT. The median comprehensive complication index 30 days after surgery was 20.9 (IQR 0-26.2). PEVT appears to be a safe procedure that may have the potential to improve surgical outcome in patients undergoing esophagectomy.

Keywords: anastomotic leakage; complications; minimally invasive esophagectomy; outcome research.

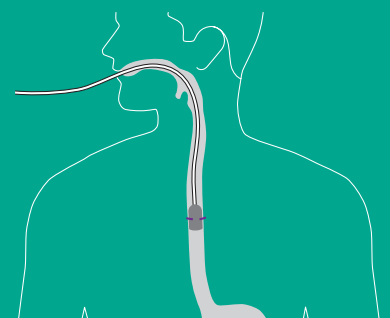
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RESULTS OF THE PILOT STUDY FOR PREEMPTIVE USE OF Eso-SPONGE®

- n=20 patients
- 1/20 leakage
- 20 patients had a sponge post surgery at the anastomotic site for 4-6 days.
- 19 patients recovered with no leakage.
- 1 patient develop a non symptomatic leak which was resolved with a second round of vacuum therapy.

PREVENTIVE USE OF Eso-SPONGE®

- Follow the insertion system as described for the treatment in steps 1 to 6 placing the end of the overtube at the anastomosis site.
- Release the Eso-SPONGE®, so that the sponge must be positioned at the anastomosis site.
- The drainage can be positioned transnasally (see steps 7 to 9).
- Connect the device to the vacuum source, low vacuum pump from MTG.
- Apply a continuous negative pressure of 75 mmHg as previously described.
- Leave the sponge for 4 to 6 days and retire the sponge.



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