Brief Summary Document

Overview

Product	Eso-SPONGE® – IFU 508814

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Content

INTENDED USE/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 paraesophageal 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.

Eso-SPONGE is intended for use in adults. However, since limited clinical evidence is available in paediatric population, Eso-SPONGE is not indicated in paediatric population.

Moreover, since there is no clinical evidence from the use of Eso-SPONGE in pregnant and breastfeeding women either, Eso-SPONGE is not indicated for use during pregnancy or breastfeeding.

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.

CONTRAINDICATIONS

Contra-indications derived from the device intended purpose:
- Malignant tumour wounds
- Necrotic tissue/gangrene
- Untreated osteomyelitis
- Blood clotting disorder
- Treatment with anti-coagulant or antiplatelet substances in a therapeutic dosage
- Generalized peritonitis or sepsis
- Bleeding oesophageal varices
- Sponge placement directly on major vessels

Contra-indications derived from the residual risks:
- Eso-SPONGE is contraindicated on patients with known sensitivities or allergies to any of its components (refer to Materials Used section of the IFU, 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).

WARNINGS

- The drain-sponge of Eso-SPONGE is made of plastic materials and it is MRI compatible. See Precautions.
- The sponge could suffer damage 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 forbidden or should be ruled out.
- In case of damaged vessels in the oesophageal 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…).
- Eso-SPONGE® only can be used in combination with the vacuum sources mentioned below:
    - Low-Vacuum-System model MV1, Ref. MTG19116 (not included) in combination with bacterial filter, Ref. MTG18022 (not included) and collection bottle, Ref. MTG18032 (not included).
    - Endo-SPONGE® Pump, Ref. 5526650 (not included) in combination with Endo-SPONGE® Pump Disposable cannister, Ref. 5526653 (not included).

PRECAUTIONS

- Precaution needs to be taken that the drain-sponge is not connected to the pump during the MRI exploration, also that there is not any metallic clip or metallic piece used to stick or fix the drain tube to the patient.
- 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.

- The dwell time depends on the local clinical situation. If applicable, it is recommended to 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 clogging or granulation tissue overgrowing into the sponge, as a result the sponge could no longer provide effective treatment or 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.
- For 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 vacuum sources (MV1 low vacuum pump and Endo-SPONGE® Pump).
- 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.
- The device Eso-SPONGE shall not be employed after the expiry date indicated on the label.
- Do not re-use Eso-SPONGE, it is a single use device.

POTENTIAL ADVERSE EVENTS

- 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, heart)
- 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