Brief Summary Document

Overview

Product	Endo-SPONGE® – IFU 506570

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 or Hartmann's stump leakages following colorectal surgery in the lower pelvic area (extraperitoneal position) by means of negative pressure.

The leak must have created a drainable cavity with or without a local infection. Endo-SPONGE® is intended for use in adults. Since limited clinical evidence is available in the paediatric population, Endo-SPONGE® is not indicated for the paediatric population.

Moreover, since there is no clinical evidence for the use of Endo-SPONGE® in pregnant and breastfeeding women either, Endo-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 interventional treatment of the lower gastrointestinal tract using flexible endoscopy and in negative pressure wound therapy in general.

CONTRAINDICATIONS

- Contraindications derived from the device's intended purpose
    - Malignant tumour wound
    - Necrotic tissue/gangrene
    - Untreated osteomyelitis
    - Sponge position directly adjacent to vessels, urinary bladder or small intestinal loops
    - Non-drainable septic focus
    - Clotting disorders

    - Treatment with a therapeutic dose of anticoagulant or platelets aggregation inhibitor drugs
    - Generalised peritonitis or sepsis

- Contraindications derived from the residual risks
    - Patients with known sensitivities or allergies to its components (refer to Materials used section of IFU for details about the components).
    - The dimensions of the device should be taken into consideration for its use in specific patient groups (e.g., small-framed persons).

WARNINGS

- Do not use suction power 2 or 3 of the Redyrob® Trans Plus bottle.
- Do not use conventional high vacuum or medium vacuum wound drainage bottles, as they produce too much suction.
- For more information on using the Endo-SPONGE® Pump, please refer to its IFU.
- Sponge residue left in patients could result in foreign body reactions, surgical intervention and increased operating times.
- The Endo-SPONGE® drain sponge is made of plastic materials and is MRI compatible. See Precautions.
- The sponge may generate residual sponge particles when reshaping and/or removing.
- The residual sponge particles could cause fistula formation or foreign body reactions. Possible need for endoscopic removal.
- Endo-SPONGE® must not be used in body openings other than that indicated.
- Due to the underlying disease, most patients have a localised infection that can lead to sepsis (i.e. peritonitis, necrosis, etc.).
- Due to the underlying disease, some patients may develop chronification of sinus.
- Endo-SPONGE® can only be used in combination with the vacuum sources mentioned below:
    - Redyrob® Trans Plus bottle, Ref. 5526604 (not included).
    - Endo-SPONGE® Pump, Ref. 5526650 (not included) in combination with the Endo-SPONGE® Pump Disposable canister, Ref. 5526653 (not included).

PRECAUTIONS

- It must be ensured that the drain sponge is not connected to the pump during the MRI exploration, and also that there is no metal clip or metal piece used to stick or fix the drain tube to the patient.
- 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, which must be 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 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.
- If using the Endo-SPONGE® Pump, the prescribed negative pressure (125 to 200 mmHg) must be ensured.
- If using the Redyrob® Trans Plus bottle, set the control knob to position 1.
- The dwell time depends on the local clinical situation. If applicable, it is recommended to adjust the sponge change time according to the amount of debris and growth of granulation tissue.
- 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, and, as a result, the sponge possibly breaking during removal, leaving part of it in the application area and embedded in granulation tissue. If this occurs, 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 90 days.

- Prior to application, an appropriate imaging procedure must be performed to rule out an abscess in the wound area, which can only be treated by a surgical or interventional procedure and not with Endo-SPONGE®.
- 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 the Endo-SPONGE® and the vacuum source must be checked, as well as its settings.
- Do not use items if the packaging is not intact.
- Be careful not to damage the endoscope sheath.
- Damage to endoscope cables can occur in the case of excess bending of the flexible distal end within the overtube.
- Do not re-use the Endo-SPONGE®. All items are for single use except the variable speed medical pump (Endo-SPONGE® Pump).
- After each replacement, the sponge must be disposed of due to the risk of clogging or obstruction of the sponge, because as a result of this, the soaking and draining capacity of the sponge may be affected.
- The Endo-SPONGE® device must not be used after the expiry date indicated on the label.

POTENTIAL ADVERSE EVENTS

- Erosion of structures adjacent to sponge (vessels, urinary bladder, small intestine, colon, etc.)
- Injury to intestinal wall and perforation has been reported in some cases
- Fistula formation
- Abscess has been reported in patients undergoing Endo-SPONGE treatment
- Scarring
- Bleeding, which depending on patient condition could lead to severe bleeding
- Sponge dislocation
- Post-interventional stricture / stenosis
- Pain