Indications for Use

The Cytosponge™ cell collection device is indicated for use in the collection and retrieval of surface cells in the esophagus for cytological and histological analyses.

Contraindications

- Patients with symptoms of dysphagia or history of swallowing disorders.
- Patients with known or suspected anatomical abnormalities of the esophagus or stomach.
- Patients that have undergone esophageal or gastric dilation, ablation, biopsy, mucosal resection or other invasive medical procedures within the previous two months.
- Pregnancy.
- Patients with known or suspected portal hypertension and/or gastric or esophageal varices.
- Patients taking anti-thrombotic drugs (e.g. anticoagulants, antiplatelet agents) that cannot be temporarily discontinued.

Warnings

- Use of this device has not been studied in, or may be more difficult, less effective, or less well tolerated in patients under 18 years of age.
- Use of this device in patients taking anti-thrombotic drugs which cannot be temporarily stopped before and after the procedure is contraindicated.
- Potential complications include: Mucosal laceration or perforation requiring secondary intervention, Major and minor bleeding, Airway obstruction, Infection, Aspiration, Intestinal obstruction, Tissue damage, Allergic reaction, Dysphagia, Pain.
- Secondary intervention including endoscopy and/or surgery may be required to treat any of the potential complications listed above.
- The sponge may detach from the string during removal of the device.
- In the event of the separation of the sponge and suture, an endoscopic retrieval procedure (e.g. use of a Roth Net™* retriever) may be necessary.
- In the event that a serious incident has occurred related to device use, immediately report the event to Medtronic, the competent authorities, and any other regulators as required.

Caution

UK laws restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.
Before procedure

- Patient must not eat or drink during the four hours prior to procedure as stated in the IFU.

Procedural steps

- **Precaution:** Inspect the device packaging before use. Do not use the device if the inner pouch or device is damaged. Remove the retaining card with the device from the outer pouch.
- Carefully remove the capsule from the plastic retainer, unwind the string from the retainer card ensuring it does not tangle, knot or kink.
- Fold the string back and forth in 2 cm lengths against the capsule, until 10 cm of string is left between your fingers and the plastic retainer card. Do not wrap the string around the capsule.
- Seat the patient in an upright position and ask them to open their mouth and extend their tongue.
- Gently place the capsule and bunched string on the back of the patient’s tongue.
  - **Note:** If it is easier for the patient, they can place the capsule and string in their own mouth. HCP to retain holding the plastic retainer close to the patient’s face.
- Hold the plastic retainer so that approximately 10 cm of string remain outside of the patient’s mouth.
- Ask the patient to swallow the capsule and bunched string with a cup of tepid water. Advise the patient to drink the water until the capsule and string have been swallowed.
- Instruct the patient to open his or her mouth. If excess or bunched string is detected, instruct the patient to drink additional water. Repeat until there is no evidence of any bunched suture at the back of the patient’s mouth.
- Set the timer for 7 and 1/2 minutes – only after the device has been completely swallowed.
- If the patient has requested throat spray, after 5 and 1/2 minutes, spray the back of the throat with xylocaine.
- After 7 and 1/2 minutes have elapsed, centre the string in the middle of the throat before pulling.
- Grip the retainer card and string, then gently and continuously pull on the string until the Cytosponge™ exits the patient’s mouth.
  - **There might be a need to apply slightly more force as the Cytosponge™ passes lower oesophageal sphincter and the upper oesophageal sphincter.**
  - Oesophageal spasm can result in increased resistance. If increased resistance is encountered, discontinue pulling on the string and allow the patient to relax for several minutes before resuming the retrieval process.
  - **Warning:** Do not continue pulling the string if increased resistance remains. Excessive force can result in harm to the patient or failure of the device.
- Immediately place the sponge portion of the device within a collection container with an alcohol-based fixative solution shown to preserve cells and small tissue fragments in suspension appropriate for cytological and histological examination and cut the string close to the sponge.
- Close the collection container and label it according to laboratory procedures.
- Discharge the patient as appropriate per standard procedures. Instruct patient to contact treating physician immediately for significant chest pain, throat pain, difficulty swallowing, fever, bleeding, abdominal pain, difficulty breathing, vomiting, or other warning signs provided by the physician.