



**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.

**Caution:** Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

**Risk information:** 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. The sponge may detach from the string during removal of the device. Secondary intervention including endoscopy and/or surgery may be required to treat any of the potential complications listed above.

**Contraindicated for:** Patients with any 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 agents (e.g., anticoagulants, antiplatelet agents) that cannot be temporarily discontinued.

Please consult your physician for a complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

**References:**

1. Assessment of a minimally invasive oesophageal cytology collection system (CE marked) in patients with Barrett's oesophagus (specimen adequacy, biomarker sensitivity for BO, and safety). Clinical Study Report - CASE I: COVB2700466-CSR, May 2015 (Data on file)
2. Kadri Sudarshan R, Lao-Sirieix Pierre, O'Donovan Maria, Debiram Irene, Das Madhumita, Blazeby Jane M et al. Acceptability and accuracy of a non-endoscopic screening test for Barrett's oesophagus in primary care: cohort study BMJ 2010; 341 :c4372

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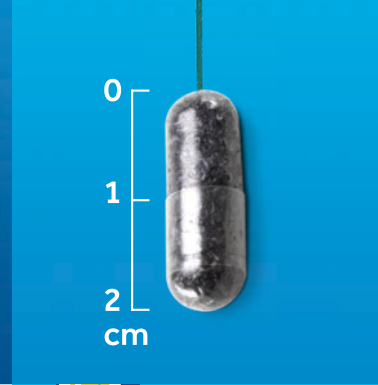
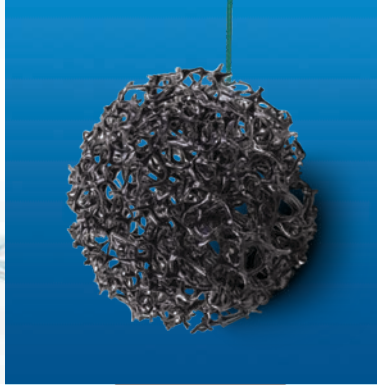
## A SIMPLE SOLUTION FOR COLLECTING ESOPHAGEAL CELLS

Cytosponge™ cell collection device

**Medtronic**

**Medtronic**  
Further, Together

SIMPLE,  
CONVENIENT,  
FAST

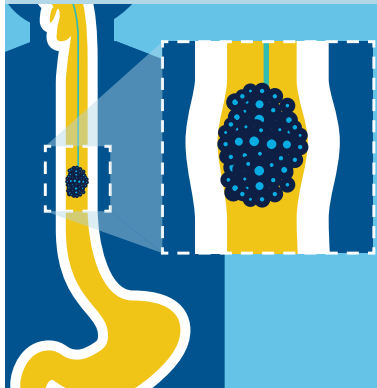


## How it works

Your health care professional can identify potentially significant health concerns related to your esophagus right in the office. The Cytosponge™ cell collection device collects tissue samples from the esophagus with one simple procedure.

This innovative solution uses a small capsule-shaped device the size of a multivitamin. A thin string is connected to a sponge inside the capsule. When you swallow it, the capsule dissolves and the sponge expands in your stomach. The string is then gently pulled to retract the sponge. As it's retracted, the sponge collects cells from the entire length of your esophagus.

In clinical testing, most patients found the capsule easy to swallow.<sup>1</sup> The entire process, including patient instruction, took less than 10 minutes.<sup>2</sup>



## What to expect

Here's how to prepare and what to expect during your procedure:

- You must fast for four hours prior to procedure.
- You swallow the capsule as you would any other pill. You will be given water to drink.
- A timer is set for seven and a half minutes. This period of time allows the capsule to dissolve in the stomach and the sponge to expand.
- Your health care professional will gently and continuously pull the string until the sponge is extracted.
- Once the sponge has been removed it will be placed in a preservative filled jar, packaged and sent to a pathologist for analysis.