Medtronic provides the following synopsis of a clinical publication related to the Cytosponge™ cell collection device.

**TITLE**
Cytosponge-trefoil factor 3 versus usual care to identify Barrett’s oesophagus in a primary care setting: a multicentre, pragmatic, randomised controlled trial

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**Objective:**
The objective of this study was to determine whether offering the Cytosponge-trefoil factor 3 (TFF3) test to patients on medication for gastro-oesophageal reflux would increase detection of Barrett’s oesophagus, compared to usual care.

**Study Design:**
This was a multicenter, pragmatic, randomised controlled trial in which randomisation was performed at the clinic level across 109 general practice clinics in England, and at the individual patient level. The usual care group underwent standard management of gastro-oesophageal reflux, with endoscopy only when required by the general practitioner. The intervention group received usual care and an offer of the Cytosponge-TFF3 procedure. Endoscopy was offered if the test identified TFF3-positive cells.

**Key Findings:**
- 13,222 participants were enrolled, including 6,388 participants in the usual care group and 6,834 participants in the intervention group.
- 2,679 (39%) participants in the intervention group expressed interest in the Cytosponge-TFF3 procedure.
- 1,750 participants (65%) in the intervention group provided consent and underwent the procedure, with 95% (N=1,654) successfully swallowing the Cytosponge and producing a sample.
  - 231 participants had TFF3-positive cells and were referred for endoscopy.
- 221 (13%) underwent endoscopy after a TFF3-positive test. The overall positive predictive value of the test was 59%.
  - 127 participants (8%, representing 57% of participants with an endoscopy) were diagnosed with Barrett’s oesophagus.
  - 4 participants (2%) were diagnosed with stage I oesophago-gastric cancer.
  - 33 participants (37%) not diagnosed with Barrett’s oesophagus, dysplasia, or cancer were found to have intestinal metaplasia.
- 127 diagnosed with dysplastic Barrett’s oesophagus
- 3 diagnosed with oesophago-gastric cancer
- 4 diagnosed with oesophago-gastric cancer
- 33 diagnosed with intestinal metaplasia
During an average 12 months of follow-up:
- In the intervention group, 140 participants (2%) were diagnosed with Barrett’s oesophagus.
- In the usual care group, 13 participants (<1%) were diagnosed with Barrett’s oesophagus.
- The cumulative rate of Barrett’s oesophagus in the intervention and usual care groups was 20.2/1000 person-years and 2.0/1000 person-years, respectively (RR 10.6, 95% CI 6.0 – 18.8, p<0.0001).

- 8 of the 9 cases of Barrett’s oesophagus in the intervention group were detected by the Cytosponge-TFF3 test, all of which underwent curative intervention.
- In the usual care group, 3 participants were diagnosed with cancer, 2 of which were palliative at presentation.
- Two participants in the intervention group who did not undergo the Cytosponge-TFF3 test were diagnosed with stage IV oesophago-gastric cancer during the trial.
- The median acceptability score among 1464 participants who underwent the Cytosponge-TFF3 procedure was 9 (IQR 8-10), with 10 representing ‘completely acceptable’.
  - 97% of participants (N=1427/1464) gave a score of 5 or higher.
- 63 participants (4%) who underwent the Cytosponge procedure reported having a sore throat that required medication or that interfered with eating.
- One participant experienced Cytosponge detachment requiring endoscopic removal.

Conclusion:
- An invitation to undergo a Cytosponge-TFF3 test led to an increased diagnosis of Barrett’s oesophagus.
- This real-world trial suggests that for patients with heartburn symptoms requiring acid-suppressant therapy for >6 months, the Cytosponge-TFF3 test is feasible, safe, and acceptable to administer in a general practice setting.
- The Cytosponge procedure improves detection of Barrett’s oesophagus and offers a proactive approach for identification and treatment of dysplasia and early cancer.

**THIS CONCLUDES THE CLINICAL SYNOPSIS OF THIS PUBLICATION**