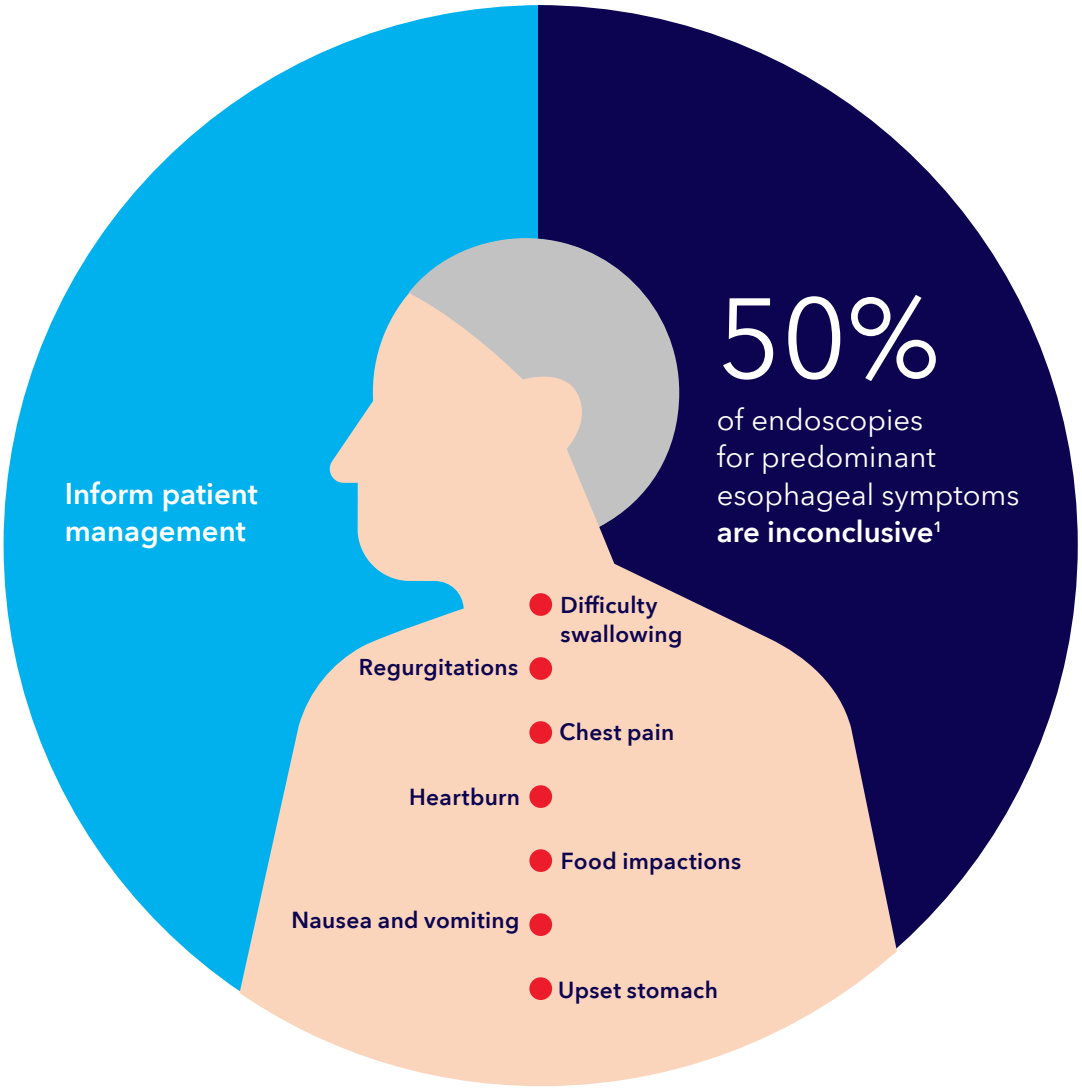
Medtronic

Transform esophageal care

Delivering meaningful innovation and comprehensive solutions from diagnosis to treatment.

All-in-one detection and treatment portfolio for esophageal care

Comprehensive esophageal care. For a targeted approach.



Endoscopy is not enough.

It's time to transform the standard of esophageal care for your patients.

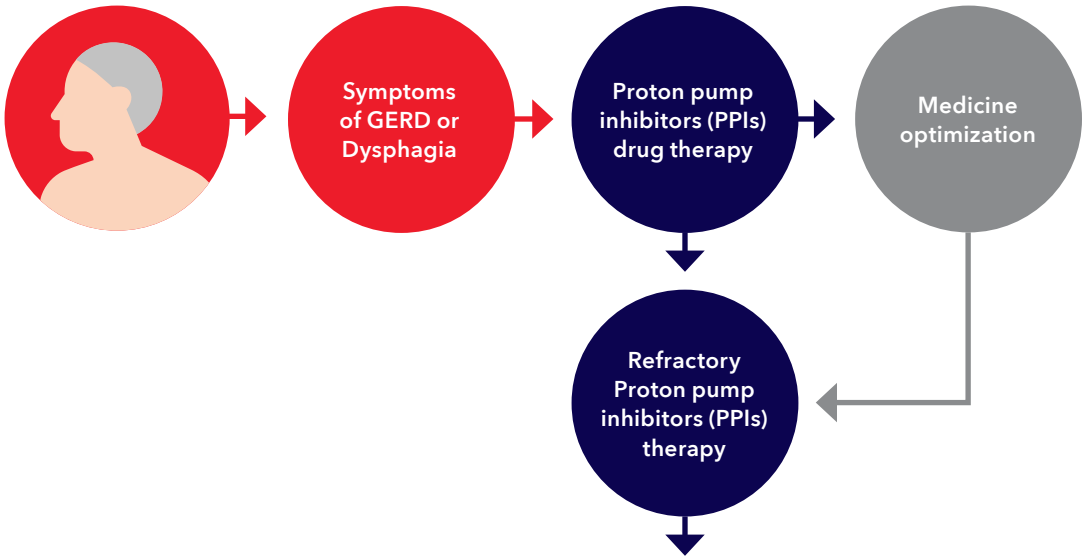
In the U.S., 50 percent of endoscopies for predominant esophageal symptoms are inconclusive.[1] This can lead to a continual cycle of tests and a long road to diagnosis.

Our comprehensive solutions can assist you in simplifying the assessment and treatment of esophageal patients by allowing you to:

- Determine the root cause of symptoms – all-in-one single encounter[2]
- Diagnose esophageal disorders objectively[3,4]

Helping to improve reflux care throughout the patient journey

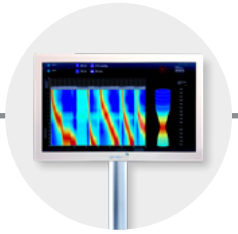
Join us in advancing the development of meaningful innovations in reflux and GI functional diagnostic care.



Barrx™ ablation system

Nexpowder™* endoscopic hemostatic system helps prevent bleeding, loss of body fluid and contamination

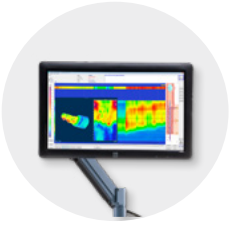
Negative Endoflip™ test* Helps to rule out motility disorders



Endoflip™ impedance planimetry system

Positive Endoflip™ test* May indicate motility disorder

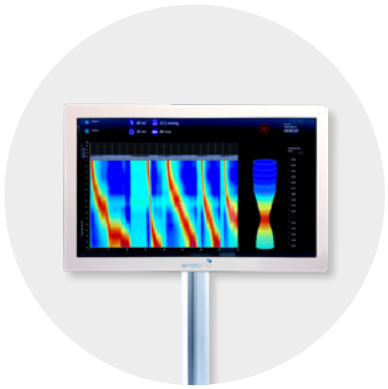
Bravo™ reflux testing system Helps to confirm or rule out GERD



Manoscan™ manometry system Confirm and classify the motility disorder

* As indicated by clinician based on Distensibility Index (DI) and topographic patterns.

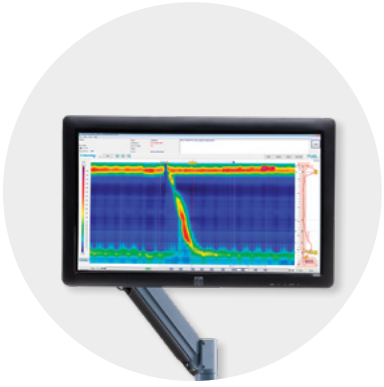
Diagnosis portfolio



Endoflip™
impedance planimetry system

Bravo™
calibration-free reflux testing system

Digitrapper™
pH-Z testing system



Manoscan™
ESO high-resolution manometry system

Treatment portfolio

Barrx™ RFA
radiofrequency ablation system

Eleview®*
submucosal injectable composition

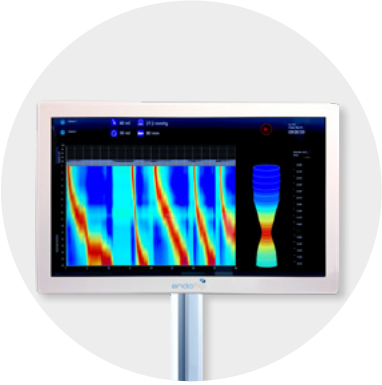
Nexpowder™*
endoscopic hemostatic system

It’s time to transform the standard of esophageal care for your patients

Diagnosis portfolio

Endoflip™

impedance planimetry system



Evaluate motility – minimize discomfort

- Flip™ topography is a well-tolerated method for esophageal motility assessment during endoscopy and may provide a complementary method to HRM for evaluation of non-obstructive dysphagia.[2]
- Normal motility on FLIP™ topography was predominantly predictive of a normal HRM.[2] Thus, real-time FLIP™ topography incorporated with endoscopy appears to provide a suitable and well-tolerated point-of-care esophageal motility assessment.[2]
- The Endoflip™ impedance planimetry system may be a useful tool to aid anti-reflux procedures, Heller myotomy and POEM.[3]

Bravo™

calibration-free reflux testing system

Ambulatory pH monitoring is considered an objective means of diagnosing GERD[4]

- Tolerance and satisfaction with catheter-free pH monitoring are high in patients who had previously failed catheter based pH monitoring; catheter-free pH monitoring assists the definitive diagnosis of GERD in this group.[7]
- Patients with Bravo™ wireless capsule pH monitoring reported higher satisfaction and were more likely to be able to eat and drink without difficulties and resume daily activities compared to catheter-based pH monitoring.[5,6]
- Up to 70% of patients with GERD do not have evidence of erosive changes on endoscopy.[8]

Digitrapper™

pH-Z testing system

Understand the root cause of reflux symptoms

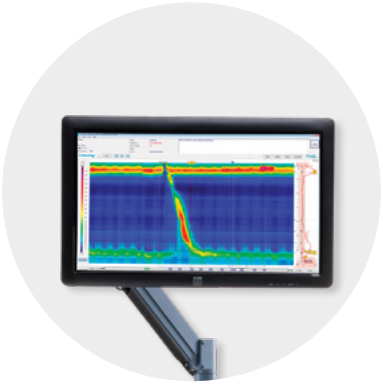
- Using combined esophageal pH-impedance monitoring showed that refractory symptoms are often associated with weakly acidic reflux events.[9]
- Catheter-based monitoring allows for the addition of impedance and detection of weakly acidic or non-acidic reflux.[10]
- Esophageal pH testing may avert Proton Pump Inhibitor use in 50% of patients with gastroesophageal reflux symptoms.[11]

Manoscan™

ESO high-resolution manometry system

Manometry with greater clarity

- High-resolution manometry (HRM) has provided a major advance in the evaluation of esophageal swallowing disorders. HRM color plots, known as Clouse plots, are easier to understand through pattern recognition.[12]
- HRM has made esophageal manometry easier for the technician due to shorter procedure time which is more tolerable for the patient.[13]



Delivering meaningful innovation and comprehensive solutions from diagnosis to treatment

Treatment portfolio

Barrx™ RFA

radiofrequency ablation system

Reduce risk of Barrett's esophagus progression with a proven treatment

- The Barrx™ radiofrequency ablation system enables the removal of Barrett's mucosa, while preserving the underlying submucosal tissue.[16]
- Clinical studies have demonstrated the safety and efficacy of RFA for treating dysplastic Barrett's esophagus.[17]
- RFA can eradicate Barrett's esophagus and reduce the relative risk of disease progression to HGD/EAC by up to 94%.*[18]

* 94% is the calculated relative risk reduction [(26-1.5)/26] = 25/26 *100.
From [25.0% (1.5% for ablation vs 26.5% for control; 95% CI, 14.1%–35.9%; P < .001]

Eleview®*

submucosal injectable composition

- Helps you to completely remove the target lesions safely and decrease the risk of perforation.[19]
- Provides an immediate and long-lasting cushion, that holds for up to 45 minutes.[20]

Nexpowder™*

endoscopic hemostatic system

A hemostatic powder that puts you in control

- Nexpowder™* is a novel hemostatic adhesive powder that provides an easy to use solution for the management of refractory and active upper GI bleeding sites.[21,23]
- The Nexpowder™* endoscopic hemostatic system is a non-contact, non-thermal and non-traumatic hemostatic powder sprayed through a catheter. Featuring a proprietary powder-coating technology, Nexpowder™* minimizes catheter clogging and particle scattering, giving you more control and better visibility.[22,23]
- Unique delivery system doesn't require CO_2.[21-24]

Indications and risks

Endoflip™ impedance planimetry system

Indications:

The Endoflip™ System is used in a clinical setting to obtain an estimation of the dimensions and balloon pressure within the alimentary canal.

The FLIP™ Topography System is an accessory to the Endoflip™ System. The FLIP™ Topography System is indicated for use with an Endoflip™ System in a clinical setting to measure pressure and dimensions in the esophagus, pylorus and anal sphincters. It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

Contraindications:

- Where endoscopy is contraindicated
- In patients with actively bleeding varices in the esophagus

Potential complications include:

- Allergic reaction
- Anaphylaxis
- Bleeding
- Cardio-respiratory complications
- Dental trauma
- Infection
- Pain
- Perforation
- Pulmonary aspiration
- Vasovagal response

Precautions:

- Do not reuse, reprocess, or sterilize the catheters. Reuse, reprocessing or sterilization can: compromise the structural integrity of the device; impair performance accuracy due to residual fluid in the balloon and degrade the catheter markings.
- All catheter components are intended for single patient use only: do not attempt to reuse. Follow all applicable Federal and local regulations for disposal or recycling.
- To ensure proper operation and to minimize the risk of patient injury, do not attempt to add or remove fluid from the supplied pre-filled syringes. Only use the pre-filled syringe supplied with the catheter.
- Do not use this device for any purpose other than the indicated use.
- Inspect the device packaging before use and do not use the device if any damage to inner pouch or device is observed.
- Do not use the catheter if excessive resistance is met during insertion or removal.
- Prior to repositioning or removal, ensure complete deflation of the balloon.

Bravo™ calibration-free reflux testing system

Indications:

- The Bravo™ monitoring system is intended to be used for gastroesophageal pH measurement and monitoring of gastric reflux in adults and children from 4 years of age.
- The Bravo™ capsule can be attached following either endoscopy or manometry.
- The Reflux/Accuview™ software application is intended to record, store, view, and analyze gastroesophageal pH data.

Contraindications:

- Patients with bleeding diathesis, strictures, severe esophagitis, varices or obstructions.
- Patients with pacemakers or implantable cardiac defibrillators.

Risks:

- Aspiration, tears or perforation in the mucosa, discomfort associated with the capsule, premature detachment, or failure to detach, which may necessitate endoscopic removal.
- The safety and efficacy has not been established for pediatric use on patients below the age of 4.
- Patients are restricted from undergoing an MRI study within 30 days of the start of a reflux study. Use of the Bravo™ reflux testing system in an MRI magnetic field will result in damage to the system and possible patient injury.
- Undergoing an MRI while the Bravo™ reflux capsule is inside the patient's body may result in serious damage to the patient's intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of any Bravo™ reflux capsule, the patient should contact the physician for evaluation and possible abdominal x-ray before undergoing an MRI examination.
- The Bravo™ reflux capsule contains a trocar needle that is made of stainless steel. Use caution in patients with known sensitivities to the metals that are contained including chromium, nickel, copper, cobalt, and iron. Tests last from 48 to 96 hours.
- Gastrointestinal endoscopy: Potential complications include, but are not limited to: perforation, hemorrhage, aspiration, fever or infection, hypertension, respiratory arrest, and cardiac arrhythmia or arrest.
- Nasal intubation: Potential complications include, but are not limited to: sore throat, discomfort, and nasopharyngeal damage resulting in bleeding and soft tissue damage.

Please refer to the product user manual or **medtronic.com/covidien/uk** for detailed information.

Indications and risks – continued

Digitrapper™ pH-Z testing system

Indications:

- The Digitrapper™ pH-Z system is intended to record, store, view, and analyze esophageal and gastric pH data (and optionally, impedance levels) to diagnose reflux disorders.

Contraindications:

- Patients with inability to tolerate nasal intubation.
- Patients with significant bleeding disorders for whom nasal intubation is contraindicated.
- Patients with a known esophageal obstruction preventing passage of the instrument.

Risks:

- Discomfort or pain (nasal and/or throat)
- Minor bleeding, perforation, or hemorrhage
- Aspiration
- Fever or infection
- Hypertension
- Respiratory arrest
- Cardiac arrhythmia or arrest
- In rare instances, the catheter can be misdirected into the trachea causing coughing or choking, or the catheter may shift up or down causing false results.
- The system is not compatible for use in an MRI magnetic field.

Manoscan™ high resolution manometry system

Indications:

The ManoScan™ system provides mapping of pressures and, optionally, impedance within organs of the human gastrointestinal tract. These include the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), stomach, sphincter of Oddi, small bowel, colon, duodenum, and anorectal organs.

- It is used in a medical clinical setting to acquire pressures and then store the corresponding data for visualization and analysis.
- The real-time data as well as the analysis information can be viewed by medically-trained personnel for diagnostic and analytic purposes.
- The ManoScan™ HRM modules provide high-resolution and/or 3D (three dimensional) display of the pressure and impedance data.

Contraindications:

The use of the ManoScan™ system for pharyngeal/esophageal motility study and proximal gut (gastric/duodenal) manometry is contraindicated for the following:

- Patients with inability to tolerate nasal intubation
- Patients with significant bleeding disorders for whom nasal intubation is contraindicated
- Patients with a known esophageal obstruction preventing passage "of the instrument
- The use of the ManoScan™ system for anorectal manometry is contraindicated for patients with known anal stricture/obstruction preventing insertion of the instrument

Adverse events:

Potential adverse events associated with the use of this system and catheter insertion into the nasal passage may include: discomfort, nasal pain, minor bleeding, runny nose, throat discomfort, irregular heartbeat with dizziness, and perforation.

In rare instances, the catheter may be misdirected into the trachea causing coughing or choking, the catheter may curl during intubation and catheter position may move during the procedure.

Potential adverse events associated with the use of this system and catheter insertion into the anorectum may include: discomfort, pain, minor bleeding, irregular heartbeat with dizziness, and perforation.

In rare instances, the catheter may curl during insertion and catheter position may move during the procedure.

Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur.

The system is not compatible for use in an MRI magnetic field.

Barrx™ radiofrequency ablation system

Indications:

- The Barrx™ 360 Express RFA Balloon Catheter is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract, including but not limited to, Barrett's esophagus and esophageal squamous cell neoplasia, defined as moderate grade intraepithelial neoplasia (MGIN), high grade intra-epithelial neoplasia (HGIN), and/or early squamous cell carcinoma (SCC) of the esophagus limited to the lamina propria (i.e., T1m2).
- The Barrx™ 90, Barrx™ Ultra Long, and Barrx™ 60 RFA Focal Catheters are indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to Barrett's Esophagus and Esophageal Squamous Cell Neoplasia, defined as moderate grade intraepithelial neoplasia (MGIN), high-grade intra-epithelial neoplasia (HGIN), and/or early squamous cell carcinoma (SCC) of the esophagus limited to the lamina propria (i.e. T1m2).

Contraindications for Barrett's esophagus:

- Contraindications include pregnancy, prior radiation therapy to the esophagus, esophageal varices at risk of bleeding, prior Heller myotomy, and eosinophilic esophagitis.

Risks:

- The following are transient side effects that may be expected after treatment: chest pain, difficulty swallowing, painful swallowing, throat pain, and/or fever.
- Potential complications include mucosal laceration, minor or major bleeding, endoscopic clipping to manage mucosal laceration or bleeding, perforation of the stomach, esophagus, or pharynx, surgery to manage perforation, esophageal stricture, endoscopic dilation to manage stricture, pleural effusion, transfusion secondary to major bleeding, cardiac arrhythmia, aspiration, infection, death.

Eleview®* submucosal injectable composition

Indications:

- Eleview®* submucosal injectable composition is intended for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers, or other gastrointestinal lesions, prior to excision with a snare or endoscopic device.

Contraindications:

- Patients with known sensitivity to any of the components contained in Eleview®* submucosal injectable composition.

Risks:

- The endoscopist injecting Eleview®* must be experienced in the administration technique.
- The safety of Eleview®* has not been established in pregnant or lactating women or in children under 18 years of age.
- Eleview®* is provided in single use ampoules. Eleview®* should not be reused after first opening. Any emulsion not injected during the procedure should be not reused for another endoscopic procedure.
- Do not use if the primary packaging (ampoule) or secondary packaging (aluminum pouch) is damaged.
- Do not use if the twist-off cap is damaged.
- Do not use if the emulsion is not clear, shows any signs of opalescence or contains floating or precipitated visible particles.
- The product compatibility with other substances has not been tested.
- Rarely, local bleeding and/or inflammatory reaction could occur which may or may not be associated with Eleview®* submucosal injection.
- During the procedure do not exceed a total dose of 50 mL per patient, either in single or in multiple administrations.

Please refer to the product user manual or **medtronic.com/covidien/uk** for detailed information.

Nexpowder™* endoscopic hemostatic system

Indications:

- Nexpowder™ is used for most GI bleeding. The device is applied during an endoscopic procedure and can cover ulcer or bleeding sites. The device is not intended for use in patients with variceal bleeding.
- Note: Do not use this device for any purpose other than stated intended use.

Contraindications:

- Because the Nexpowder™* system includes lactose, it is contraindicated in patients who have galactose intolerance, lapp lactase deficiency, or glucose-galactose malabsorption and they would be at risk of having nausea, bloating, and diarrhoea. Because the Nexpowder™* system includes Brilliant Blue FCF, it must not be used in patients with known hypersensitivity to brilliant blue FCF.

Potential complications:

- Those associated with gastrointestinal endoscopy include, but are not limited to: hemorrhage, perforation, aspiration, fever, infection, allergic reaction, and foreign body sensation in the digestive tract.

Please refer to the product user manual or **medtronic.com/covidien/uk** for detailed information.

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