Medtronic
Engineering the extraordinary

Transform esophageal care

Delivering meaningful innovation and comprehensive solutions from diagnosis to treatment.

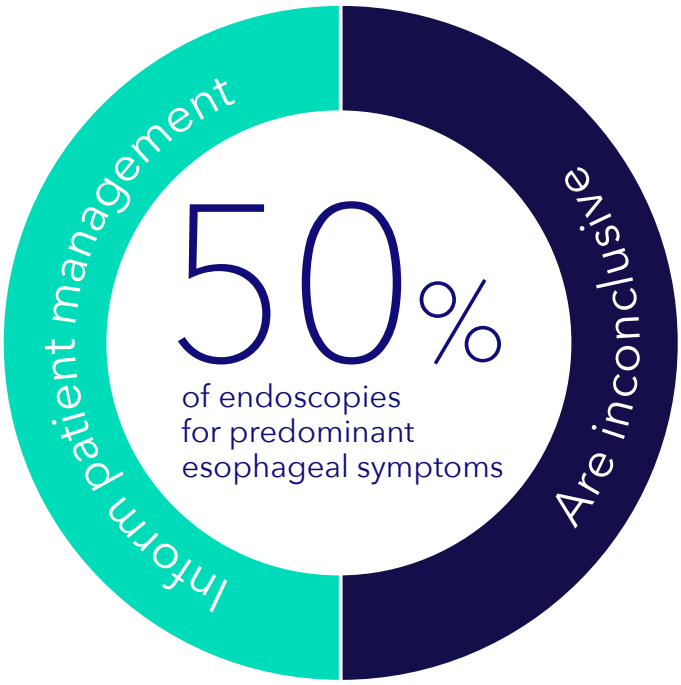
All-in-one detection and treatment portfolio for esophageal care

Endoscopy is not enough.

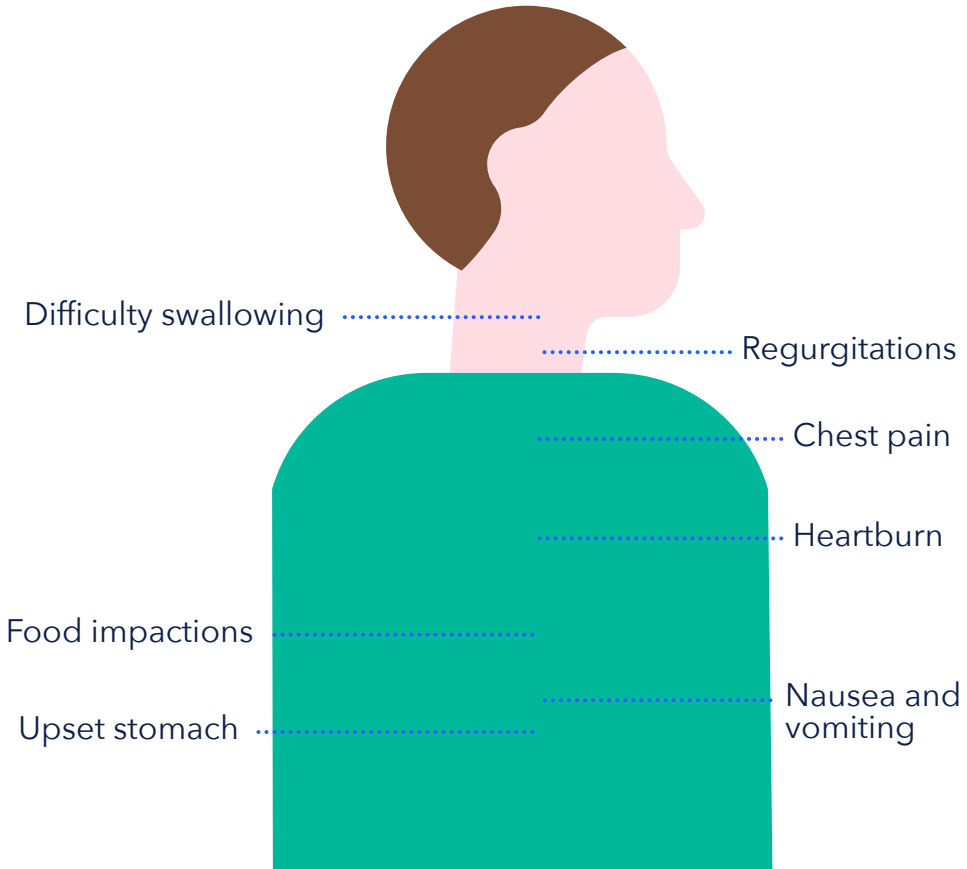
It's time to transform the standard of esophageal care for your patients. In the US, 50 percent of endoscopies for predominant esophageal symptoms are inconclusive.[1] This can lead to a continual cycle of tests and a long road to diagnosis.

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

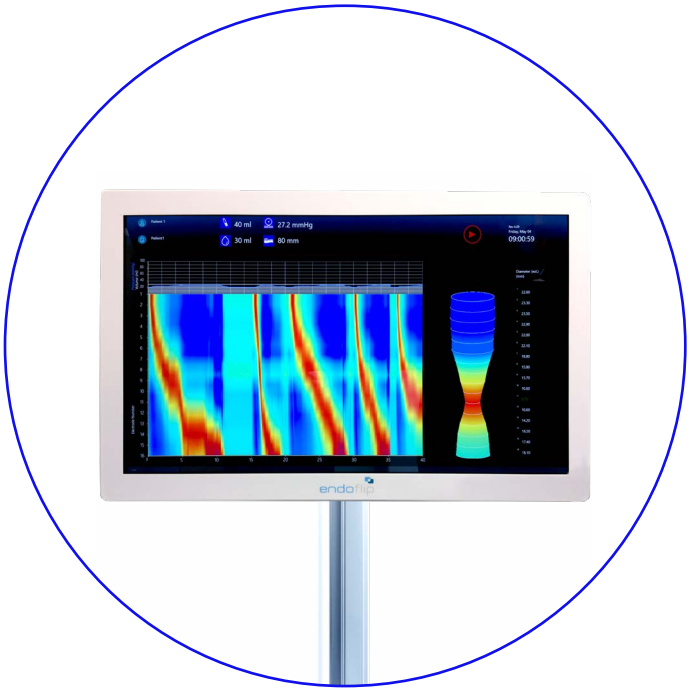
- Determine the root cause of symptoms – all in one single encounter
- Diagnose esophageal disorders objectively
- Personalize your approach to patient management



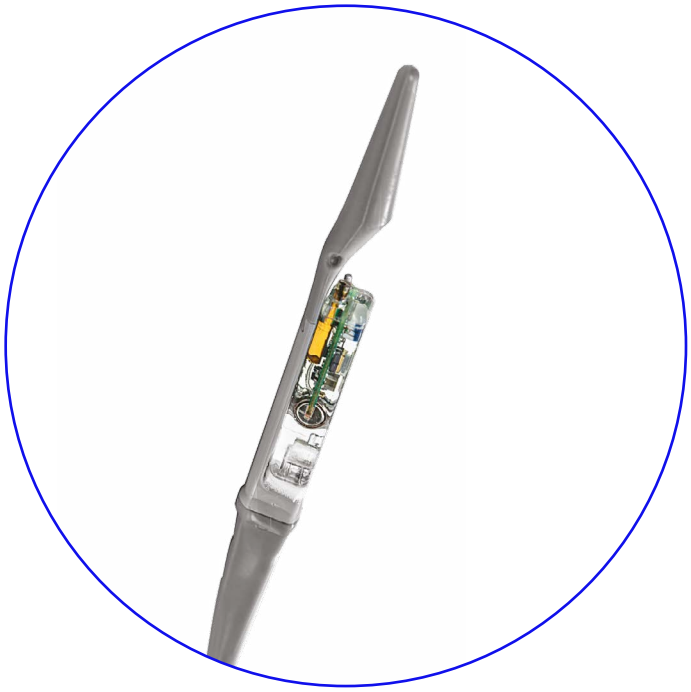
Comprehensive esophageal care – for a targeted approach



Diagnosis portfolio

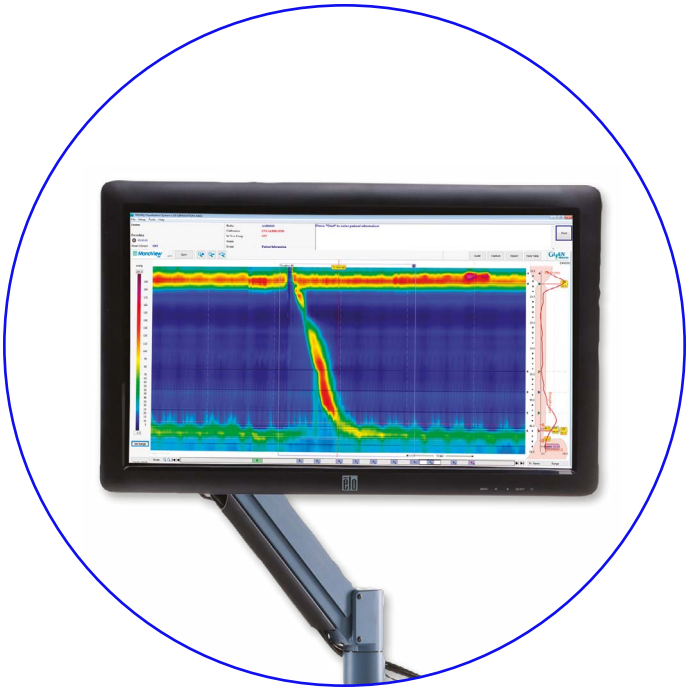


Endoflip™
impedance planimetry system



Bravo™
calibration-free reflux testing system

SmartPill™
motility testing system



ManoScan™
ESO high-resolution manometry system

Treatment portfolio

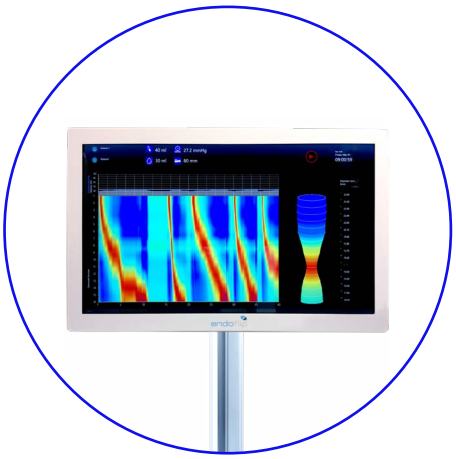
Eleview®*
submucosal injectable composition

Barrx™
radiofrequency ablation system

Digitrapper™
ph-Z testing system

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

Diagnosis portfolio



Endoflip™

impedance planimetry system

Evaluate motility – minimize discomfort

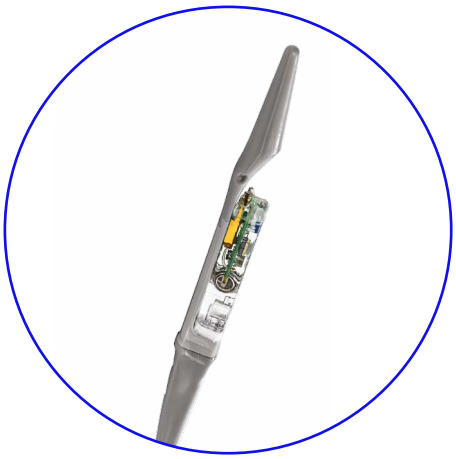
- Flip™ topography is a well-tolerated method for esophageal motility assessment during endoscopy and may provide a complementary method to HRM for evaluation of non-obstructive dysphagia.[2]
- Normal motility on functional lumen imaging probe (FLIP) topography was predictive of a normal HRM. Thus, real-time 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]

Digitrapper™

ph-Z testing system

Understand the root cause of reflux symptoms

- Esophageal pH testing may avert Proton Pump Inhibitor (PPIs) use in 50 percent of patients with gastroesophageal reflux symptoms.[4]
- Using combined esophageal pH-impedance monitoring it has been shown that refractory symptoms are often associated with weakly acidic reflux events.[5]
- Catheter-based monitoring allows for the addition of impedance and detection of weakly acidic or non-acidic reflux.[6]

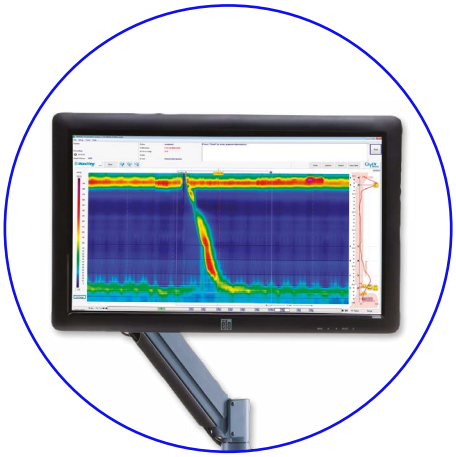


Bravo™

calibration-free reflux testing system

An objective means of diagnosing GERD[7]

- Up to 70 percent of patients with GERD do not have evidence of erosive changes on endoscopy.[8]
- The system provides greater sensitivity than endoscopy and higher specificity than therapeutic trials with PPIs.[9]
- Patients maintain regular diet and activities so testing is done under normal physiologic conditions.[7]
- Tolerance and satisfaction with catheter-free pH monitoring are high in patients who had previously failed catheter based pH; catheter-free pH monitoring assists the definitive diagnosis of GERD in this group.[10]



ManoScan™

ESO high-resolution manometry system

Manometry with greater clarity

- High-resolution manometry (HRM) has made esophageal manometry easier for the technician due to shorter procedure time and in turn is more tolerable for the patient.[11]
- 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]

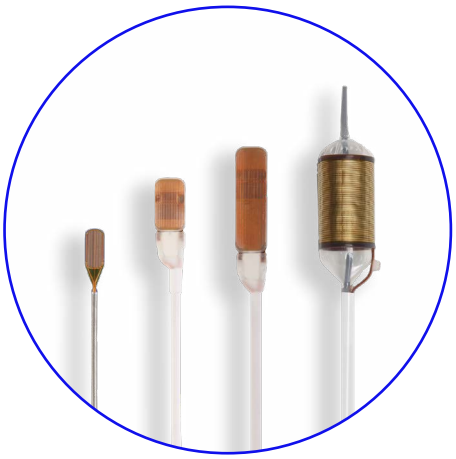
SmartPill™

motility testing system

Full GI tract evaluation with a single test

- The SmartPill™ monitoring system includes an non-digestible oral ingested capsule. It measures gastric empting time, and small bowel transit time all in a single study.[13]
- SmartPill™ motility monitoring systems' Gastric Emptying Test correlates with Gastric Emptying Scintigraphy (r = 0.73). It discriminates between healthy and gastroparetic subjects offering a nonradioactive, standardized ambulatory alternative to scintigraphy.[14]

Treatment portfolio



Barrx™

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.[15]
- Clinical studies have demonstrated the safety and efficacy of RFA for treating dysplastic Barrett's esophagus.[16]
- RFA can eradicate Barrett's esophagus and reduce the relative risk of disease progression to HGD/EAC by up to 94%*[17]

*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

Shown to help deliver complete resection

- Provides an immediate and long-lasting cushion, that holds for up to 45 minutes.[18]
- Submucosal injection helps you to completely remove the target lesions – safely – and decrease the risk of perforation.[19]

Indications and risks

Endoflip™ impedance planimetry system

Indications:
The Endoflip™ system is indicated for use in a clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters in adults and to measure pressure and dimensions in the esophagus, in patients from 5 years of age. 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 re-sterilize. Reuse, reprocessing or re-sterilization can: compromise the structural integrity of the device; impair performance accuracy due to residual fluid in the balloon and degrade the catheter markings.
- Federal law (U.S.) restricts this catheter to sale by, or on the order of, a physician.
- 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/gi for detailed information.

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

SmartPill™ motility testing system

Indications:

- The SmartPill™ motility testing system measures whole gut and regional gut (stomach, small bowel, and colon) transit times. Measurements of gastrointestinal tract transit times are used for evaluating motility disorders.
- Gastric transit time (or gastric emptying time, GET) is indicated for the evaluation of patients with suspected gastroparesis. Delayed gastric emptying is implicated in such disorders as idiopathic and diabetic gastroparesis and functional non-ulcer dyspepsia.
- Colonic transit time (CTT) is indicated for the evaluation of colonic transit in patients with chronic constipation and used to aid in differentiating slow and normal transit constipation. Combined small and large bowel transit time (SLBTT) is used as a surrogate measure of colonic transit in patients with chronic constipation when colonic transit time alone cannot be determined.
- The system measures pH, pressure, and temperature throughout the GI tract. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.
- Not for use in pediatric patients.

Contraindications for the SmartPill™ motility testing system include patients with these diseases or conditions:

- History of gastric bezoar
- Swallowing disorders
- Suspected or known strictures, fistulas, or physiological/mechanical GI obstruction
- Gastrointestinal surgery within the past 3 months.
- Severe dysphagia to food or pills
- Crohn's disease or diverticulitis
- Implanted or portable electro-mechanical medical device such as a cardiac pacemaker, defibrillator, or infusion pump
- Patients younger than 18 years of age
- Data transmission from the capsule to the data receiver is influenced by patient BMI. Significant data dropout can occur in severely obese patients (> 40 BMI)

Risks:

- Risks associated with capsule ingestion and transit is minimal The primary hazard is capsule retention.
- Retention incidence, as determined by a review of published studies of capsule endoscopy in adults, is estimated as 0.75% in patients without known stenosis and 21% in patients with known stenosis. Stenosis and strictures can be complications in inflammatory bowel disease. If you suspect a delay in passage and the capsule is located in the stomach, a pro-motility drug could be administered to assist in emptying the capsule from the stomach. Alternatively, endoscopy could be performed in order to retrieve the capsule. If located in the colon, laxative therapy could be administered to facilitate capsule movement, or a colonoscopy could be performed.

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.
- The ManoScan™ CLT module provides conventional line tracing mapping of the pressure data and can be used as a stand-alone system or as a module of the ManoScan™ high resolution manometry system.

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™ RFA circumferential catheters are indicated for use in the coagulation of bleeding and non bleeding sites in the gastrointestinal tract including, but not limited to, the esophagus. Indications include esophageal ulcers, Mallory-Weiss tears, arteriovenous malformations, angiomata, Barrett's esophagus, Dieulafoy lesions, and angiodysplasia.
- Barrx™ 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, the esophagus. Indications include esophageal ulcers, Mallory-Weiss tears, arteriovenous malformations, angiomata, Barrett's esophagus, Dieulafoy lesions, and angiodysplasia, gastric antral vascular ectasia (GAVE) and radiation proctitis (RP).

Contraindications for Barrett's esophagus:

- Contraindication 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, irritation or injury to the esophagus or anal canal, gastric or colorectal stricture or perforation, and 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.

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