ADVANCING PATIENTS ALONG THE REFLUX CARE CONTINUUM

DETECT EARLY. TREAT EARLY.
GERD affects up to 40% of the U.S. population in their lifetime. Failure of PPI treatment in resolving symptoms is the most common GERD presentation in GI. Up to 70% of GERD patients have a negative EGD. Reflux patients face a long, difficult road to diagnosis and treatment. By providing solutions to help them navigate the journey, we can help reduce disease progression through early detection and treatment. Performing pH monitoring immediately following an 8-week empiric PPI trial could save up to $6,303 per patient over 10 years.
Reflux patients face many obstacles on the path to diagnosis and treatment. The current model of care does not effectively guide this large, heterogeneous patient population along the continuum.

The challenge of improving care is complicated by a number of public health trends, especially increasing obesity rates. It is further complicated by the limited diagnostic workup most patients receive. Even more concerning, reflux is part of a potentially serious disease progression that includes esophageal adenocarcinoma (EAC).

**CONFRONTING CHALLENGES IN CARE**

- **OBESITY**
  - 6X: Obesity increases a person’s risk of developing GERD by up to 6 fold

- **REFLUX**
  - ~30%: Percentage of patients who fail to respond symptomatically to standard dose PPIs

- **BARRETT’S ESOPHAGUS**
  - 12.5%: The rate of diagnosis for Barrett’s esophagus in the U.S.

- **EAC**
  - 25.6%: Lifetime risk of confirmed dysplasia progressing to EAC

- **1 in 3**
  - Amount of U.S. adults who are obese

- **$10 billion +**
  - Annual burden of PPIs in the U.S.

- **SAE%**
  - Five-year survival rate of esophageal cancer

- **6X**
  - Increase in incidence of esophageal adenocarcinoma from 1973 to 2001

*As a weighted average of confirmed low-grade dysplasia and high-grade dysplasia*
Medtronic offers a complete portfolio of products to empower GIs to provide a full continuum of care. With comprehensive diagnostic tools and reliable treatments, our solutions support patients through every step of the way.

**COMPREHENSIVE SOLUTIONS**

**REFLUX SOLUTIONS**

**Bravo™ Reflux Testing System**
- Capsule-based pH monitoring system
- Catheter-free design is less invasive and allows patients to resume regular activities during testing
- Extended recording time (up to 96 hours) significantly improves diagnostic yield
- Allows physician to document relationships between symptoms and acid reflux events

**Digitrapper™ pH and Impedance Testing System**
- Catheter-based test uses pH and impedance sensors to identify reflux events
- Assesses the presence of non-acidic reflux that may be contributing to PPI refractory disease
- Helps determine cause of extra-esophageal symptoms
- Identifies all types of reflux events and measures their duration and acid content
Barrett’s Esophagus Solutions

ManoScan™ ESO High Resolution Manometry System
- High-resolution manometry provides complete physiological mapping of esophageal motor function
- Helps HCPs better diagnose conditions such as dysphagia, achalasia, hiatal hernia and more
- Offers clinical value before anti-reflux surgery by providing insights that may alter surgical decisions
- Provides correlation of motor function with hypermotility and GERD

Barrx™ Radiofrequency Ablation System
- Proprietary technology helps maximize clinical outcomes
- Two randomized control trials demonstrated that RFA significantly reduces neoplastic progression in patients with dysplastic BE\textsuperscript{11,12}
- Over 216,000 procedures performed on over 70,000 patients worldwide\textsuperscript{13}
- Over 100 peer-reviewed articles support the effectiveness of radiofrequency ablation (RFA)
Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk Information: The risks of catheter insertion into the nasal passage associated with ManoScan™ esophageal high resolution manometry system 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, or the catheter may shift up or down causing false results.

The risks of the Bravo™ reflux testing system include: premature detachment, discomfort, failure to detach, failure to attach, capsule aspiration, capsule retention, tears in the mucosa, bleeding, and perforation. Endoscopic placement may present additional risks. Because the capsule contains a small magnet, patients should not have an MRI study within 30 days of undergoing Bravo™ reflux testing.

The risks of catheter insertion into the nasal passage associated with the Digitrapper™ pH and impedance testing system 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, or the catheter may shift up or down causing false results.

The following are transient side effects that may be expected after treatment with the Barrx™ radiofrequency ablation system catheters: chest pain, difficulty swallowing, painful swallowing, throat pain and/or fever. Complications observed at a very low frequency include: mucosal laceration, minor and major acute bleeding, stricture, perforation, cardiac arrhythmia, pleural effusion, aspiration, and infection. Potential complications that have not been observed include: death. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. These systems are not compatible for use in an MRI magnetic field. Please refer to the respective product user manuals, barrx.com, or givenimaging.com for detailed information.

References: