

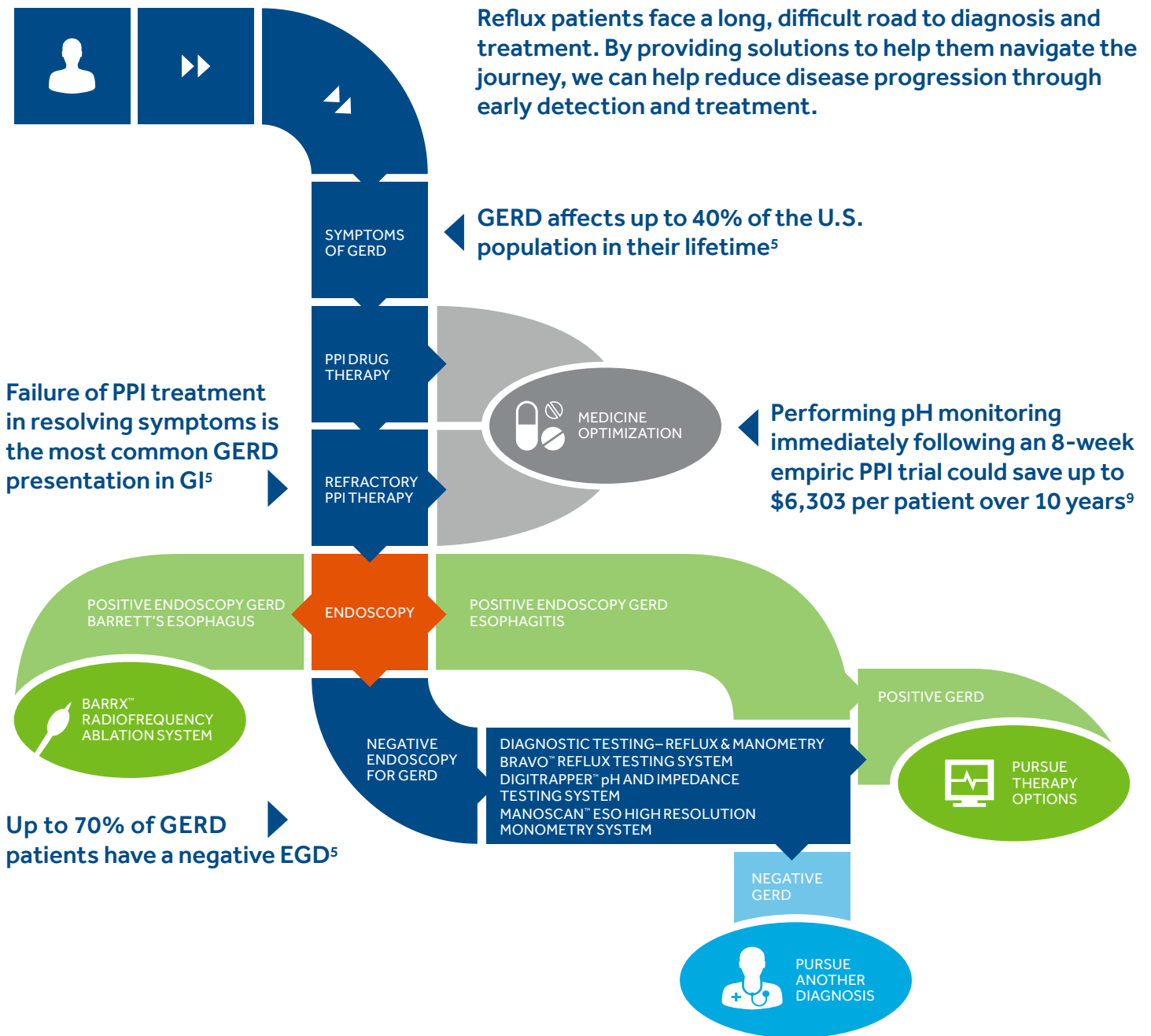


# ADVANCING PATIENTS ALONG THE REFLUX CARE CONTINUUM

DETECT EARLY. TREAT EARLY.

**Medtronic**  
Further. Together

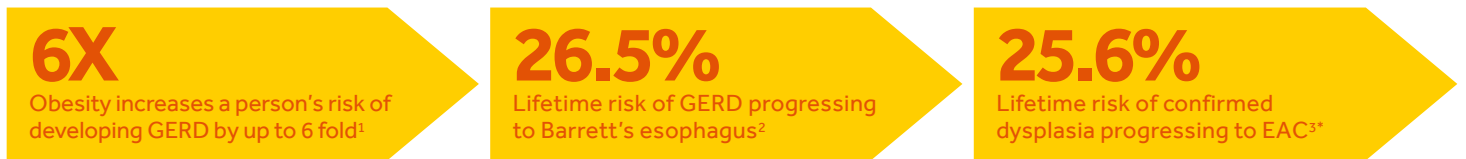
# THE PATIENT JOURNEY



# CONFRONTING CHALLENGES IN CARE

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).



**1 in 3**  
Amount of U.S. adults who are obese<sup>4</sup>

**~30%**  
Percentage of patients who fail to respond symptomatically to standard dose PPIs<sup>5</sup>

**12.5%**  
The rate of diagnosis for Barrett's esophagus in the U.S.<sup>3</sup>

**18%**  
Five-year survival rate of esophageal cancer<sup>7</sup>



**\$10 billion+**  
Annual burden of PPIs in the U.S.<sup>6</sup>



**6X**  
Increase in incidence of esophageal adenocarcinoma from 1973 to 2001<sup>8</sup>

\*As a weighted average of confirmed low-grade dysplasia and high-grade dysplasia

# COMPREHENSIVE SOLUTIONS

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.



## REFLUX SOLUTIONS



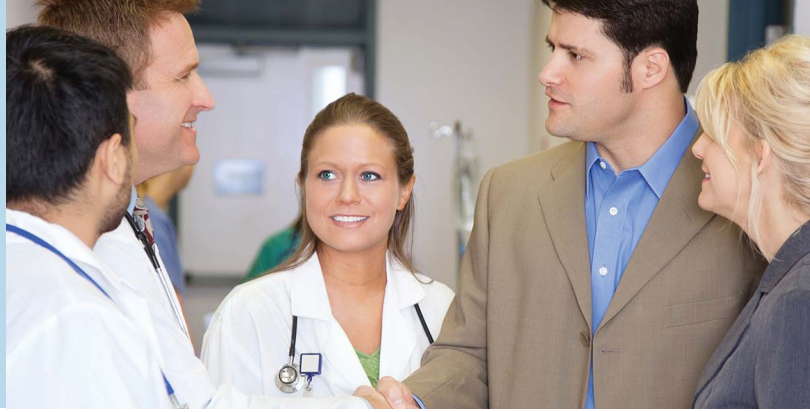
### Bravo™ Reflux Testing System

- 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<sup>10</sup>
- Allows physician to document relationships between symptoms and acid reflux events

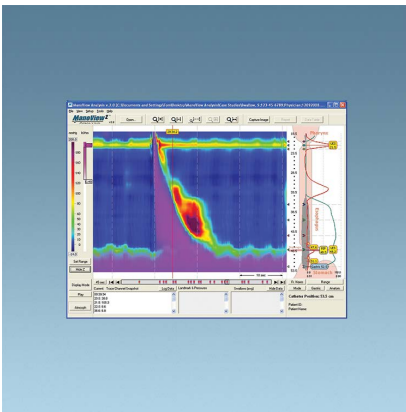


### Digitrapper™ pH and Impedance Testing System

- 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

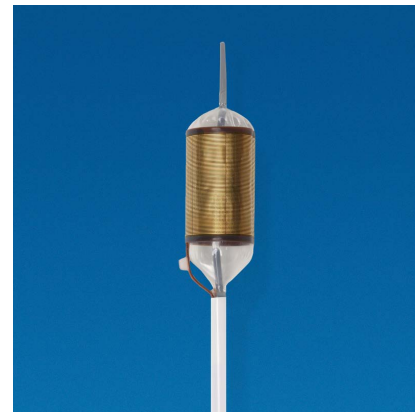


## BARRETT'S ESOPHAGUS SOLUTIONS



### 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<sup>11,12</sup>
- Over 216,000 procedures performed on over 70,000 patients worldwide<sup>13</sup>
- Over 100 peer-reviewed articles support the effectiveness of radiofrequency ablation (RFA)

# FURTHER, TOGETHER

Medtronic is proud to partner with physicians, hospitals and institutions in the GI community who share our focus on advancing GI care and improving patients' lives. Together, we can work toward early detection and treatment of GI diseases.



**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:** 1. Nilsson M, Johnsen R, Ye W, Hveem K, Lagergren J. Obesity and estrogen as risk factors for gastroesophageal reflux symptoms. *JAMA*. 2003;290:66-72. 2. Dymedex Market Development Consulting. GERD Sizing and Segmentation for pH Testing. February 13 2015. 3. Dymedex Market Development Consulting. Strategic Market Assessment: Barrx-GI. October 30, 2014. 4. "Overweight and Obesity Statistics." NIH National Institute of Diabetes and Digestive and Kidney Diseases. 5. Vaezi M, Zehrai A, Yuksel E. Testing for refractory gastroesophageal reflux disease. *ASGE Leading Edge*. 2012;2(2):1-13. 6. Shaheen N, Hansen, Morgan D, Gangarosa L, Ringel Y, Thiny M, Russo M, Sandler R. The burden of gastrointestinal and liver diseases. *American Journal of Gastroenterology*. 2006;101:2128-2138. 7. SEER Cancer Statistics Factsheets: Esophageal Cancer. National Cancer Institute. Bethesda, MD. <http://seer.cancer.gov/statfacts/html/esoph.html>. 8. Pohl H, Welch G. The role of over diagnosis and reclassification in the marked increase of esophageal adenocarcinoma incidence. *J Natl Cancer Inst*. 2005;97:142-6. 9. Kleiman DA, Beninato BP. Early Referral for Esophageal pH Monitoring is More Cost-Effective than Prolonged Empiric Trial of Proton Pump Inhibitors for Suspected Gastroesophageal Reflux Disease. *J Gastrointest Surg*. 2014;18:26-34. 10. Garrean CP, et al. Acid Reflux Detection and Symptom-Reflux Association using 4-Day Wireless pH Recording Combining 48-Hour Periods Off and On PPI Therapy. *Am J Gastroenterol*. 2008;103:1631-1637. Page 1636, Col 2. 11. Phoa KN, van Vilsteren FG, Pouw RE, et al. Radiofrequency Ablation in Barrett's Esophagus with Confirmed Low-Grade Dysplasia: Interim Results of a European Multicenter Randomized Controlled Trial (SURF). *Gastroenterology*. 2013;144:S-187. Page S-187, Col 1. 12. Shaheen NJ, Sharma P, Overholt BF, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. *N Engl J Med*. 2009;360:2277-88. Page 2277. 13. Internal Sales Data.