

# FREQUENTLY ASKED QUESTIONS

## Barrett's esophagus is a precancerous disease



### What is Barrett's esophagus?

Barrett's esophagus is a precancerous disease that affects the lining of the esophagus. It occurs when stomach acids and enzymes leak back into the esophagus over time and cause the cells to change. This transformation is also known as intestinal metaplasia.<sup>1</sup>

### What are the symptoms?

There are no symptoms specific to Barrett's esophagus, other than the typical symptoms of gastroesophageal reflux disease (or GERD). These include heartburn, chest pain, and regurgitation.<sup>1</sup>

### Who is at risk?

Patients with GERD are at an increased risk for developing Barrett's esophagus.<sup>15</sup> Caucasian males over the age of 50 with chronic reflux symptoms or heartburn have a higher risk for the disease.<sup>2</sup> Receiving a diagnosis at a young age or having a family history of Barrett's esophagus also contribute to one's risk.<sup>3-8</sup> Being overweight and obese (body mass index 25-30) increases a person's risk of developing cancer of the esophagus by almost two times.<sup>2,3</sup>

### How many people have Barrett's esophagus?

Barrett's esophagus is estimated to affect approximately 12.5 million adults in the United States.<sup>9</sup>

### How is Barrett's esophagus diagnosed?

Barrett's esophagus cannot be diagnosed by symptoms.<sup>9</sup> A diagnosis of Barrett's esophagus is currently dependent on an upper endoscopy performed by a gastroenterologist. This procedure enables the doctor to directly visualize the esophagus and take tissue samples of the esophageal tissue.

### Are treatment options available?

Yes, treatment with the Barrx™ radiofrequency ablation system has been shown to reduce disease progression by removing precancerous tissue from the esophagus.<sup>5,10,11,14</sup> Barrett's esophagus patients treated with radiofrequency ablation are less likely to progress to esophageal cancer compared to patients who undergo surveillance.<sup>5,11</sup> The Barrx™ radiofrequency ablation system can reduce the relative risk of disease progression to cancer by up to 94 percent.<sup>10,11,16,17</sup>

### What happens if Barrett's esophagus goes untreated?

Patients with Barrett's esophagus have up to 60x higher risk of developing esophageal cancer (EAC).<sup>12</sup> EAC has a 5-year survival rate of only 18%.<sup>15</sup> Barrett's esophagus patients with any of the above risk factors should speak to their physician about the most effective treatment to reduce their risk.

## For more information about Barrett's esophagus, visit [learnaboutbarretts.com](http://learnaboutbarretts.com)

**References:** 1. Spechler SJ. Barrett's esophagus. *N Engl J Med*. 2002;346(11):836-42. 2. Spechler SJ, Souza RF. Barrett's Esophagus. *N Engl J Med*. 2014;371(9):836-45. 3. Turati F, Tramacere I, La Vecchia C, Negri E. A meta-analysis of body mass index and esophageal and gastric cardia adenocarcinoma. *Ann Oncol*. 2013;24(3):609-17. 4. Evans JA, Early DS, Fukami N, et al. The role of endoscopy in Barrett's esophagus and other premalignant conditions of the esophagus. *Gastrointest Endosc*. 2012;76(6):1087-94. 5. Shaheen NJ, Sharma P, Overholt BF, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. *N Engl J Med*. 2009;360(22):2277-88. 6. Chak A, Lee T, Kinna rd MF, et al. Familial aggregation of Barrett's esophagus, esophageal adenocarcinoma, and esophagogastric junctional adenocarcinoma in Caucasian adults. *GUT*. 2002;51(3):323-8. 7. Anaparthi R, Gaddam S, Kanakadandi V, et al. Association Between Length of Barrett's Esophagus and Risk of High-Grade Dysplasia or Adenocarcinoma in Patients Without Dysplasia. *Clin Gastroenterol Hepatol*. 2013;11(11):1430-6. 8. Coleman HG, Bhat S, Murray LJ, McManus D, Gavin AT, Johnston BT. Increasing incidence of Barrett's esophagus: a population-based study. *Eur J Epidemiol*. 2011;26(9):739-45. 9. Dyrmedex Market Development Consulting. Strategic Market Assessment, Barrx. October 30, 2014. References 1, 4, 5, 10, 11, 13, 20, 23, 25, 27, 28, 54-57, 80, 87, and 97 from the full citation list, access at <http://www.medtronic.com/gic/claim>. 10. Wolf WA, Pasricha S, Cotton C, et al. Incidence of esophageal adenocarcinoma and causes of mortality after radiofrequency ablation of Barrett's esophagus. *Gastroenterology*. 2015;149:1752-61. 11. Phoa KN, van Vilsteren FG, Pouw RE, Weusten BL, et al. Radiofrequency ablation vs endoscopic surveillance for patients with Barrett esophagus and low-grade dysplasia: a randomized clinical trial. *JAMA*. 2014 Mar 26;311(12):1209-17. 12. Gilbert EW, Luna RA, Harrison VL, Hunter JG. Barrett's esophagus: a review of the literature. *J Gastrointest Surg*. 2011;15:708-13. 13. Vaezi M, Zehrai A, Yuksel E. Testing for refractory gastroesophageal reflux disease. *ASGE Leading Edge*. 2012 Vol 2, No 2, 1-13. American Society Gastroenterology Endoscopy, Page 1 14. Fleischer DE, O'dze R, Overholt BF et al. The case for endoscopic treatment of non-dysplastic and low-grade dysplastic Barrett's esophagus. *Dig Dis Sci*. 2010;55(7):1918-31. 15. SEER Cancer Statistics Factsheets: Esophageal Cancer. National Cancer Institute, Bethesda, MD. <http://seer.cancer.gov/statfacts/html/esoph.html>. 16. Orman ES, Li N, Shaheen NJ. Efficacy and durability of radiofrequency ablation for Barrett's esophagus: systematic review and meta-analysis. *Clin Gastroenterol Hepatol*. 2013;11:1245-55. 17. Shaheen NJ, Sharma P, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. *N Engl J Med*. 2009 May 28;360(22):2277-2288

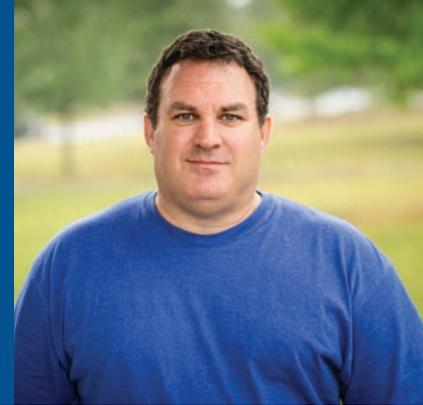
As you read this please keep in mind that all treatment and outcome results are specific to the individual patient. Results may vary. Complications, such as: chest pain, difficulty swallowing, painful swallowing, throat pain and/or fever. Complications observed at a very low frequency include: mucosal laceration, minor and major acute bleeding, stricture, perforation, cardiac arrhythmia, pleural effusion, aspiration, and infection. Please consult with your physician for a complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

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# FREQUENTLY ASKED QUESTIONS

## GERD is more than just heartburn



### What is gastroesophageal reflux disease (GERD)?

GERD causes stomach contents (food or liquid) to leak backwards into the esophagus (the tube from the mouth to the stomach). The backwash can irritate the esophagus, causing heartburn and other symptoms.

### What are the symptoms?

The common symptoms of GERD include chronic heartburn (burning pain in the chest) and regurgitation.<sup>5</sup> Less common symptoms include chronic cough, sore throat, and a hoarse voice.<sup>5</sup>

### Who is at risk?

Those at risk for GERD include males and people with a family history of gastrointestinal symptoms. Obesity can increase the risk of GERD up to six-fold.<sup>1-4</sup> Hiatal hernia, smoking, pregnancy, scleroderma, and excessive alcohol consumption are also risk factors.<sup>9</sup>

### How many people have GERD?

GERD affects up to 40% of the U.S. population in their lifetime.<sup>4</sup>

### How is GERD diagnosed?

GERD is often diagnosed based upon symptoms and response to anti-reflux medication.<sup>5</sup> Yet, symptoms alone are not enough to diagnose GERD, and testing is required for conclusive diagnosis.<sup>5</sup> Clinical studies reveal that as many as one in three patients taking proton pump inhibitors (PPIs) do not have GERD.<sup>6</sup>

If you have a diagnosis of GERD based upon symptoms, take PPIs regularly, and still have reflux symptoms, speak to a GI about a reflux test. The Bravo™ reflux testing system provides accurate information, so your doctor can tailor therapy to your needs.

### Are treatment options available?

GERD can be treated with lifestyle changes, such as weight loss, healthier, smaller meals, and not eating just before bed time. Prescription and over-the-counter medicines, like proton pump inhibitors, can lower the amount of acid released in your stomach. For patients who do not respond to lifestyle changes and medication, anti-reflux procedures may also be an option.

### What happens if GERD goes untreated?

In addition to its negative impact on health-related quality of life, GERD may lead to serious diseases, including Barrett's esophagus.<sup>4</sup> Over a quarter of GERD patients may progress to Barrett's esophagus in their lifetime.<sup>7</sup> If untreated, Barrett's esophagus may progress to esophageal cancer.<sup>5</sup> Esophageal cancer may not be curable depending on the stage at diagnosis. It has a low five-year survival rate of 18%.<sup>5,8</sup>

## For more information about GERD, visit [learnaboutgerd.com](http://learnaboutgerd.com)

**References:** 1. El-Serag HB, Sweet S, Winchester CC, Dent J. Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. *Gut* 2014; 63(6):871-880. 2. Voutilainen M, Sipponen P, Mecklin JP, Juhola M, Färkkilä M.I. GERD: prevalence, clinical, endoscopic and histopathological findings in 1,128 consecutive patients referred for endoscopy due to dyspeptic and reflux symptoms. *Digestion* 2000;61:6-13. 3. Vaezi M, Zehrai A, Yuksel E. Testing for refractory gastroesophageal reflux disease. *ASGE Leading Edge*. 2012;2(2):1-13. 4. 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. 5. Richter J, Pandolfino J, Vela M, et al. Utilization of wireless pH monitoring technologies: a summary of the proceedings from the esophageal diagnostic working group. *Dis Esophagus*. 2013;26(8):755-65. 6. Herregods TV, Troelstra M, Weijnenborg PW, Bredenoord AJ, Smout AJ. Patients with refractory reflux symptoms often do not have GERD. *Neurogastroenterol Motil*. 2015;27(9): 1267-1273. 7. Dymedex Market Development Consulting. Strategic Market Assessment, GERD, October 30, 2014. References 1-3, 6-15, 22, 23, 25, and 34 from the full citation list, access at <http://www.medtronic.com/gicclaims> 8. SEER Cancer Statistics Factsheets: Esophageal Cancer. National Cancer Institute. Bethesda, MD. <<http://seer.cancer.gov/statfacts/html/esoph.html>> Accessed December 2015. 9. Spechler S, et al. Barrett's Esophagus. *N Engl J Med* 2014; 371:836-45.

**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 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. Medical, endoscopic, or surgical intervention may be necessary to address any of these complications, should they occur. Because the capsule contains a small magnet, patients should not have an MRI study within 30 days of undergoing the Bravo™ reflux test. Please refer to the product user manual or [www.medtronic.com/GI](http://www.medtronic.com/GI) for detailed information.

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