



BARRETT'S ESOPHAGUS

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WHAT IS BARRETT'S ESOPHAGUS?

Barrett's esophagus is a precancerous disease that affects the lining of the esophagus, the swallowing tube that carries foods and liquids from the mouth to the stomach. **Roughly 12 million Americans could have Barrett's esophagus, but only 1.5 million have been diagnosed to actually suffer from the disease.**¹

HOW DOES BARRETT'S ESOPHAGUS DEVELOP?

Gastroesophageal reflux disease (GERD) is a disorder in which stomach acid and enzymes cause injury to the esophageal lining, producing symptoms such as heartburn, regurgitation, and chest pain.² In some patients with GERD, the normal esophagus cells are damaged. Over time, this damage can result in inflammation and genetic changes that cause the cells to become altered. The tissue takes on different characteristics, becoming more like the intestine rather than the esophagus. This is called "intestinal metaplasia" or Barrett's esophagus.^{17,18} If a patient has troubling GERD-related symptoms, they should consult their physician. **It is estimated that 26.5% of Americans who suffer from GERD could develop Barrett's esophagus.**¹



HOW IS BARRETT'S ESOPHAGUS DIAGNOSED?

A diagnosis of Barrett's esophagus requires that the patient undergo an upper endoscopy procedure by their physician, typically a gastroenterologist or surgeon endoscopist. Endoscopy is a non-surgical procedure. Barrett's esophagus tissue appears as a different color on examination, which directs a biopsy of the tissue for pathology evaluation. Biopsies which show intestinal-like cells in the esophagus (intestinal metaplasia) confirm the diagnosis of Barrett's esophagus.

What are the different types of Barrett's esophagus?

There are different types, or "grades," of Barrett's esophagus, according to biopsy and microscopic findings. These grades include: intestinal metaplasia (IM) without dysplasia, IM with low-grade dysplasia, and IM with high-grade dysplasia. "Dysplasia" refers to inherent abnormalities of a tissue or cell that make it more cancer-like and disorganized.

What are the risks to the patient who has Barrett's esophagus?

Barrett's esophagus is the primary risk factor for the development of esophageal adenocarcinoma (EAC).³⁻⁵ Clinical data has identified several risk factors that contribute to progression of Barrett's esophagus. These risk factors include: dysplasia, family history of Barrett's esophagus or esophageal adenocarcinoma, long-segment disease and early disease onset.⁶⁻⁹

HOW IS BARRETT'S ESOPHAGUS MANAGED?

Medical societies recommend a surveillance approach for patients diagnosed with Barrett's esophagus. Patients should undergo an upper endoscopy procedure with biopsies on a regular basis for the remainder of their lifetime. The frequency of endoscopy is determined by the grade of the Barrett's esophagus.¹⁰⁻¹²

In addition to surveillance endoscopy approaches for Barrett's esophagus, there are treatment options that include endoscopic and surgical therapy to eliminate the Barrett's esophagus tissue completely. Patients should consult with their physician to determine what the optimal approach is for their particular disease state.

WHAT IS ABLATION?

"Ablation" is a technique where tissue is either heated or frozen until it is no longer viable or alive. Physicians have used various forms of ablation for nearly a century to treat a number of cancerous and precancerous conditions, as well as to control bleeding.¹³

What is the treatment option using the Barrx™ radiofrequency ablation system?

The Barrx™ radiofrequency ablation system is a very specific type of ablation, in which thermal (heat) energy is delivered in a precise and highly controlled manner.

Barrett's esophagus tissue is very thin and, therefore, a good candidate for removal with ablative energy. Delivery of ablative energy with the Barrx™ radiofrequency ablation system can achieve complete removal of the diseased tissue without damage to the normal underlying structures.^{6,16}

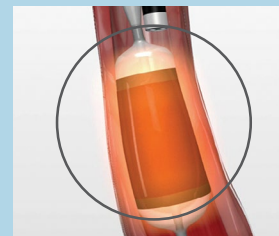
Clinical studies have demonstrated the safety and efficacy of the Barrx™ radiofrequency ablation system for treating all grades of Barrett's esophagus.^{6,14,15} Controlled trials have reported complete eradication of dysplasia in over 90% of patients.^{6,16}

What happens during treatment with the Barrx™ radiofrequency ablation system?

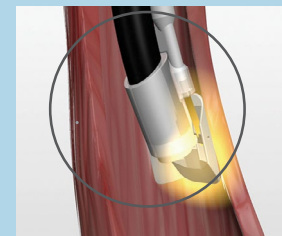
Ablation therapy is performed in conjunction with upper endoscopy. The treatment is performed in an outpatient setting and no incisions are involved. The Barrx™ radiofrequency ablation system consists of a generator,

and two different device types: a radiofrequency (RFA) balloon catheter and a series of radiofrequency (RFA) focal catheters. The Barrx™ 360 express RFA balloon catheter is capable of treating larger areas of circumferential Barrett's esophagus, while the Barrx™ RFA focal catheters can be used to treat smaller areas.

Barrx™ 360 express RFA balloon catheter



Barrx™ 90 RFA focal catheter



Depending on the extent of the Barrett's esophagus, the Barrx™ 360 express RFA balloon catheter or one of the Barrx™ RFA focal catheters is introduced into the esophagus and used to deliver energy to the targeted areas.

WHAT TO EXPECT AFTER TREATMENT?

Please refer to the back of this brochure for a detailed list of risks associated with this procedure.

Patients may experience some chest discomfort and difficulty swallowing for several days after the procedure, both of which are managed with medications provided by the physician. In clinical trials, these symptoms typically resolved within 3-4 days.^{17,18} Patients are provided with anti-acid medications to promote healing of the treated esophagus and replacement of the diseased Barrett's esophagus tissue with a normal, healthy esophagus lining.^{6,17}

A follow-up appointment is scheduled within 2-3 months to assess the response to treatment. If any Barrett's esophagus tissue remains, additional therapy may be recommended.

How is GERD managed after a successful ablation?

Successful elimination of the Barrett's esophagus tissue does not treat pre-existing GERD or the associated symptoms. The physician will guide the patient regarding long-term GERD therapy.



To learn more about Barrett's esophagus go to:
learnaboutbarretts.com

Ask your physician about treating your Barrett's esophagus with the Barrx™ radiofrequency ablation system.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk Information: 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 and major acute bleeding, stricture, perforation, cardiac arrhythmia, pleural effusion, aspiration, and infection. Potential complications that have not been observed include: death. Please consult a physician for further information.

Important Reminder: This information is intended only to provide general information and not as a definitive basis for diagnosis or treatment in any particular case. Please consult your physician for a complete list of indications, warnings, precautions, adverse events, clinical results, and other important medical information.

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