

Medtronic

Engineering the extraordinary

Barrx™ radiofrequency ablation system

Help reduce risk of progression¹⁻³

Progression of Barrett's esophagus (BE) to esophageal adenocarcinoma (EAC) can be deadly. Surveillance may not be enough for some patients with risk factors that contribute to disease progression.



Progression can be deadly. Think beyond surveillance.

It has been published in literature that several risk factors contribute to disease progression:

- Dysplasia is the best-known precursor of disease progression.^{1,2}
- Barrett's esophagus patients with a first-degree family history of EAC are 5.5x more likely to progress to EAC.⁴
- Long segment disease: there is a 28 percent increase in risk of progression to HGD/EAC per 1 cm increase in BE length.⁵
- Smoking tobacco increases the risk of progression to cancer or high-grade dysplasia 2-fold among patients with BE, compared with patients with BE that have never smoked.⁶

In the future, the use of a risk scoring system to predict progression and guide treatment decisions might have value in clinical practice.⁷

†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)].

94%

RFA can eradicate Barrett's esophagus and reduce the relative risk of disease progression to HGD/EAC by up to 94 percent^{1-3,†}

5.5x

Barrett's esophagus patients with a first-degree family history of EAC are 5.5x more likely to progress to EAC⁴

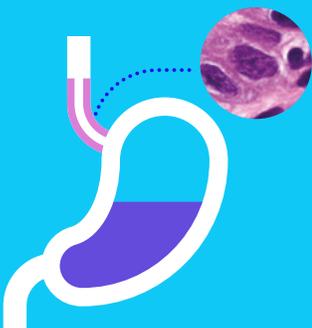
28%

Increase in risk of progression to HGD/EAC per 1 cm increase in BE length⁵

NNT=4

Prevent one case of confirmed low-grade dysplasia (LGD) from progression to HGD or EAC with every 4 patients treated with RFA²

Dysplasia



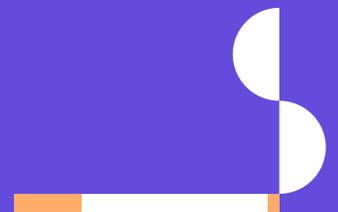
Family history



Long segment disease



Smoking



The power to make a difference.

The Barrx™ radiofrequency ablation system can eradicate BE and reduce the relative risk of disease progression to HGD/EAC by up to 94 percent^{1-3,†}

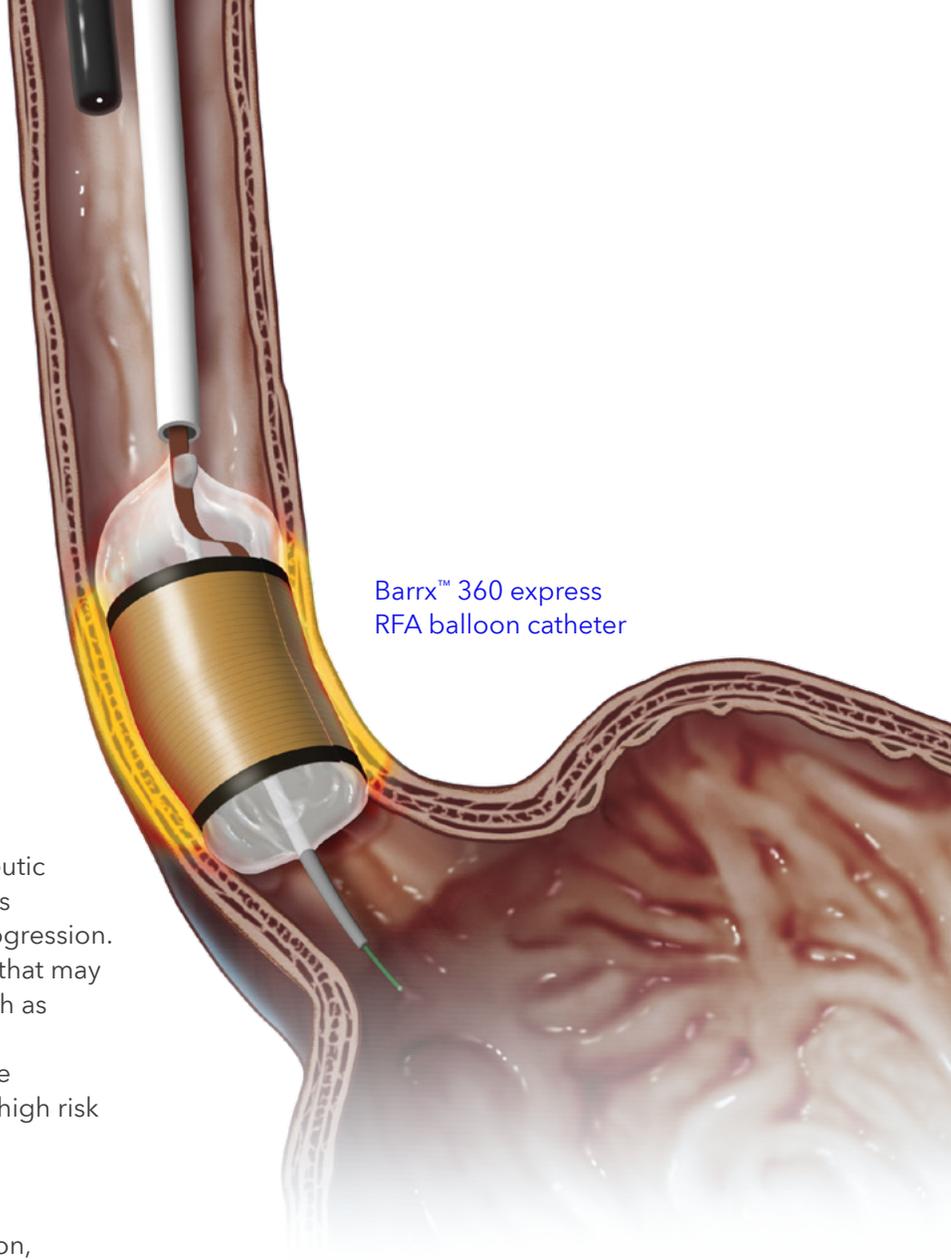
In addition, risk factors that contribute to disease progression are mentioned in all three guidelines:

- AGA 2011 states that RFA should be a therapeutic option for patients with non-dysplastic Barrett's esophagus (NDBE) carrying higher risks of progression.
- ACG 2015 also recognizes several risk factors that may impart a higher lifetime risk of EAC cancer such as family history and long segment disease.
- ASGE 2018 states that risk stratification and the development of predictive models to identify high risk patients is a critical future area of research.

Radiofrequency ablation can eradicate Barrett's esophagus and reduce risk of disease progression, regardless of histological grade.^{1-3,8}

Barrx™ 360 express
RFA balloon catheter

When risk of progression is high, consider proactive treatment with Barrx™ radiofrequency ablation system



Trusted partner

We are committed to providing training materials and resources to help healthcare professionals and staff deepen their expertise.

We provide educational courses, comprehensive reimbursement support, and other information to help our partners connect with patients and referring physicians.

We collaborate with public and private payers, governments, and hospital systems interested in working together to shape and deploy value-based business models.



Barrx™ radiofrequency ablation system

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

Indications for Use:

- The catheters are indicated for use in the coagulation of bleeding and nonbleeding sites in the gastrointestinal tract including, but not limited to, the esophagus.
- Indications for the circumferential catheters include esophageal ulcers, Mallory-Weiss tears, arteriovenous malformations, angiomata, Barrett's esophagus, Dieulafoy lesions, and angiodysplasia.
- Indications for the focal catheters 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:

Contraindications include pregnancy, prior radiation therapy to the esophagus, esophageal varices at risk for bleeding, prior Heller myotomy, and eosinophilic esophagitis.

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 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, and death.

References

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4. Tofani C, Gandhi K, Spataro J, et al. Esophageal adenocarcinoma in a first degree relative increases risk for progression to esophageal adenocarcinoma in patients with Barrett's Esophagus. *Am J Gastroenterol.* 2017; Abstract 309:112(1).
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6. Helen G. Coleman, Shivaram Bhat, Brian T. Johnston, Damian Mcmanus, Anna T. Gavin, and Liam J. Murray. Tobacco Smoking Increases the Risk of High-Grade Dysplasia and Cancer Among Patients With Barrett's Esophagus. *Gastroenterology Vol. 142, No. 2.* 2012.
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