

# PROVEN EFFICACY **AND SAFETY**<sup>1-3</sup>

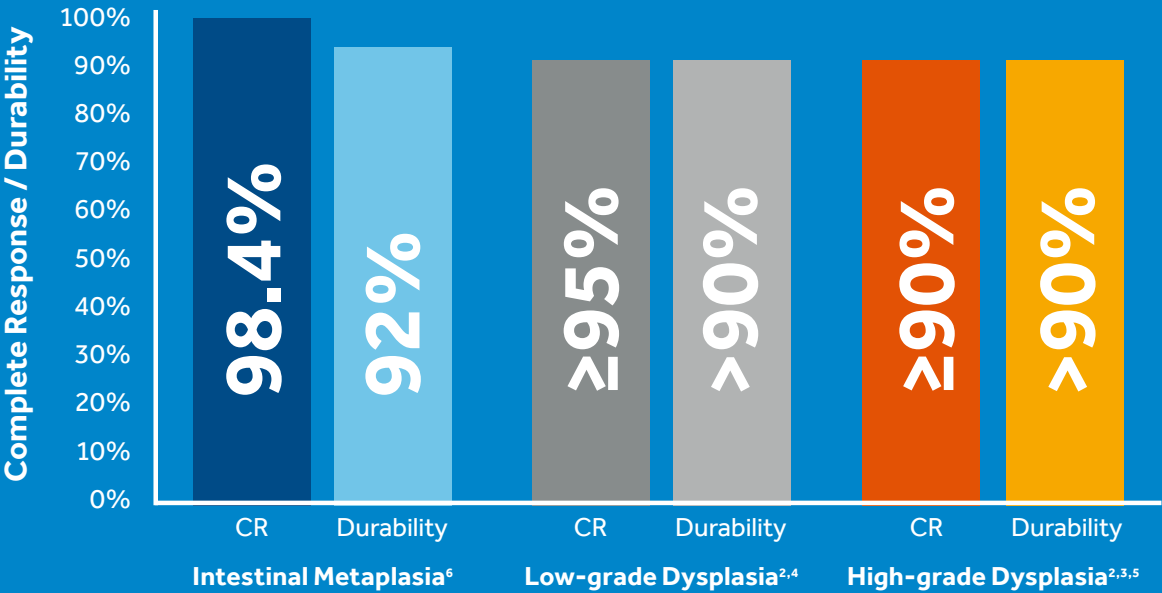
**Barrx™ radiofrequency ablation system**  
Advanced ablation technology for treating  
Barrett's esophagus



**Medtronic**  
Further. Together

# CLINICAL RESULTS

Complete response (CR) and durability of RFA in prospective clinical trials<sup>2-7†,‡</sup>



Treating circumferential disease with the Barrx™ 360 express RFA balloon catheter.

Treating a small area of disease with a Barrx™ focal catheter.

Treating a small area of disease with a Barrx™ channel RFA endoscopic catheter.

## Results

Clinical studies completed in the US and Europe demonstrated the safety and efficacy of Barrx™ technology to treat all grades of Barrett’s esophagus.

- The Ablation of Intestinal Metaplasia (AIMII) trial showed that 98.4% of patients with baseline non-dysplastic IM were completely free of all Barrett’s tissue after 2.5 years of follow-up.<sup>6\*</sup>
- The AIM-Dysplasia and SURF randomized controlled trials utilized RFA to treat low-grade dysplasia and reported complete eradication of dysplasia in ≥95% of cases and Intestinal metaplasia (IM) in ≥83% of cases.<sup>2,4</sup>
- Several US and European trials have studied the use of RFA in high-grade dysplasia and reported complete eradication of dysplasia in ≥90% of cases and IM in ≥82% of cases.<sup>2,3,5\*</sup>

The long-term durability of Barrett’s eradication after treatment with RFA has also been studied.

- The AIM-II trial found a durable complete response in 92% of non-dysplastic patients five years after RFA.<sup>6</sup>
- The AIM-Dysplasia trial showed a durable complete response in >90% of dysplastic subjects at two and three years after treatment.<sup>8</sup>
- A meta-analysis evaluated six studies on the long-term outcomes after RFA with a total of 540 patients and showed an overall durability of 87%.<sup>9</sup>

Two randomized controlled trials demonstrated that RFA significantly reduces neoplastic progression in patients with dysplastic Barrett’s esophagus.

- Results of the SURF trial for confirmed LGD showed a fourteen fold decrease in progression to HGD or cancer after RFA as compared to surveillance.<sup>4</sup>
- The AIM-Dysplasia trial demonstrated an eight fold reduction in progression to cancer in patients with HGD after RFA as compared to surveillance.<sup>2</sup>

†Eradication and durability rates based on initial diagnosis and one or more clinical trials.

‡In clinical studies, most patients required one circumferential ablation procedure and one or two focal ablation procedures.

Complete response and durability defined per trial.

\*per protocol analysis.

# COMPLETE ABLATION SOLUTIONS

## Barrx™ radiofrequency ablation system



### Indications

Barrx™ RFA circumferential catheters are indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including, but not limited to, the esophagus. Indications include esophageal ulcers, Mallory-Weiss tears, arteriovenous malformations, angiomas, Barrett's esophagus, Dieulafoy lesions, and angiodysplasia.

Barrx™ RFA focal catheters are indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to the esophagus. Indications include esophageal ulcers, Mallory-Weiss tears, arteriovenous malformations, angiomas, Barrett's esophagus, Dieulafoy lesions, 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.

### Risks

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, irritation or injury to the esophagus or anal canal, gastric or colorectal stricture or perforation, and death.

Please refer to the product user manual or [www.medtronic.com/gi](http://www.medtronic.com/gi) for detailed information.

### References

1. 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;149:1752-1761.
2. Shaheen NJ, Sharma P, Overholt BF, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. *N Engl J Med*. 2009;360:2277-88.
3. Phoa KN, Pouw RE, van Vilsteren FG, et al. Remission of Barrett's esophagus with early neoplasia 5 years after radiofrequency ablation with endoscopic resection: a Netherlands cohort study. *Gastroenterology*. 2013;145:96-104.
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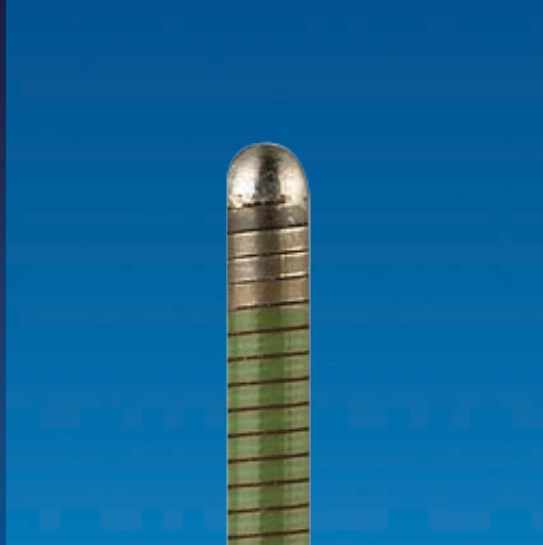
## Barrx™

Ultra long RFA focal catheter

**Barrx™ ultra long RFA focal catheter: 90-9200**  
Single-use catheter fits on the distal end of a flexible endoscope. This bipolar electrode array delivers energy to larger areas of tissue.

**Specifications:**  
Recommended scope sizes: 8.6 mm to 9.8 mm  
Catheter shaft diameter: 4 mm  
Catheter shaft length: 162 cm

**Electrode:**  
40 mm length – 13 mm width



## Barrx™

RFA endoscopic guidewire

Designed to facilitate the exchange of the Barrx™ 360 express RFA balloon catheter. Each single-use guidewire has a coated stainless steel core.

**Specifications:**  
**Barrx™ RFA endoscopic guidewire: GW-002B**  
Outer diameter: 0.038"  
Length: 260 cm  
Coated, straight, flexible distal tip

**Barrx™ RFA endoscopic guidewire, marked: GW-005M**  
Outer diameter: 0.038"  
Length: 230 cm  
Coated, marked, straight, flexible distal tip



## Barrx™

RFA cleaning cap

Designed to facilitate removal of ablated esophageal tissue. Each single-use cap mounts on the distal end of a flexible endoscope.

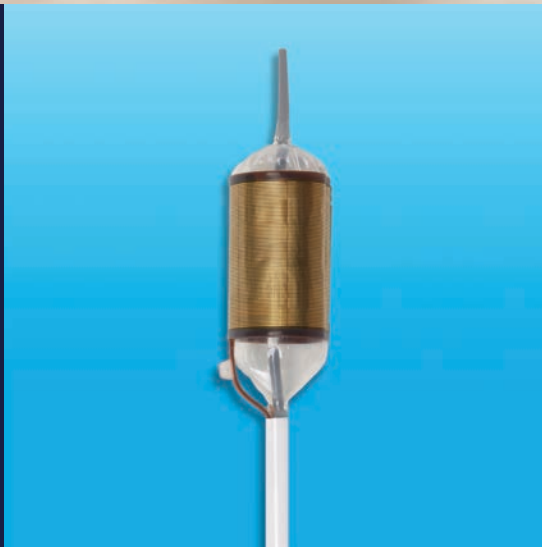
**Specifications:**  
**Barrx™ RFA cleaning cap – small: CP-001A**  
Recommended for endoscopes with diameters between 8.8 mm and 9.7 mm  
Compatibility assessed for the following Olympus endoscope models: GIF-160, GIF-Q180, and GIF-Q160

**Barrx™ RFA cleaning cap – medium: CP-002A**  
Recommended for endoscopes with diameters between 9.8 mm and 11.1 mm  
Compatibility assessed for Olympus endoscope model GIF-H180



Actor portrayal

# THE BARRX™ ABLATION SYSTEM PRODUCT CATALOG



[medtronic.com/gi](https://www.medtronic.com/gi)

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

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

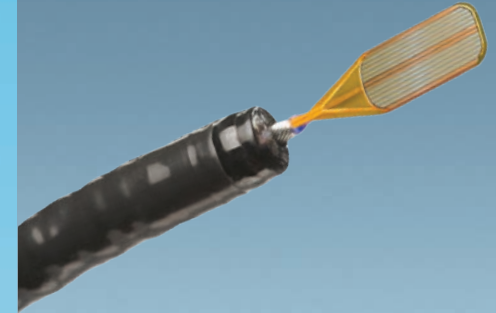
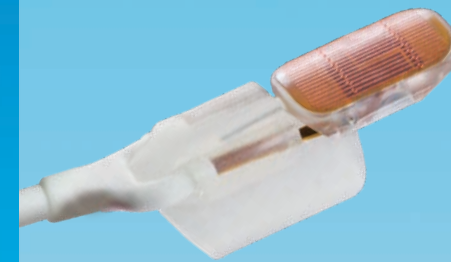
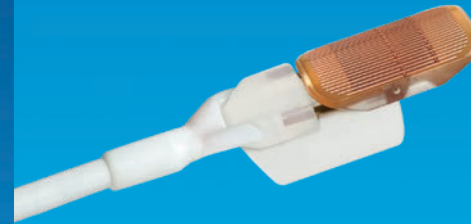
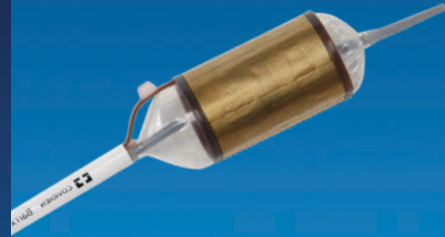
**Risk Information:** The following are transient side effects that may be expected after treatment: chest pain, difficulty swallowing, painful swallowing, throat pain, and/or fever. Potential complications include mucosal laceration, minor or major bleeding, endoscopic clipping to manage mucosal laceration 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, irritation or injury to the esophagus or anal canal, gastric or colorectal stricture or perforation, and death. Please see Instructions for Use document for each device for a complete review of all risks and contraindications.

**References:** 1. K Belghaz . A single-step sizing and radiofrequency ablation catheter for circumferential ablation of Barrett's esophagus: Results of a pilot study. United European Gastroenterology Journal 2018, Vol. 6(7) 990–999.

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## Barrx™

Flex RFA energy generator

**1190A-115A**  
The Barrx™ flex RFA energy generator is a bipolar radiofrequency generator provides the flexibility to chose either the Barrx™ 360 express RFA balloon catheter for larger treatment areas or Barrx™ RFA focal catheters for smaller focal areas.

- Accessories Included:**  
Flex RFA footswitch:  
FLEXFS-010A  
Footswitch for hands-free activation of ablative delivery system
- Flex RFA output cable:  
FLEXCC-020A  
Connection cable for the ablation catheter to the Barrx™ flex RFA energy generator

## Barrx™

RFA cart

**CART-100**  
A custom procedural cart specifically designed for the storage and easy transportation of the Barrx™ system. The cart provides a convenient and efficient working station for radiofrequency ablation procedures. It has storage space designed specifically to hold the Barrx™ flex RFA energy generator, Barrx™ catheters, and accessories.

**Specifications:**  
**Overall Dimensions:**  
Height: 42.5"  
Width: 22.5" (34" w/trays)  
Depth: 23"

## Barrx™

360 express RFA balloon catheter

**64082**  
Self adjusting balloon catheter with a 4 cm 360 electrode array that eliminates the need to perform sizing, reducing procedure time by up to 20%.<sup>1</sup>

**Specifications:**  
Balloon length: 8cm  
Electrode length: 4cm  
Diameter range: 18-31mm  
Catheter shaft diameter: 7mm  
Catheter shaft working length: 85cm

## Barrx™

90 RFA focal catheter

**90-9100**  
Single-use catheter fits on the distal end of a flexible endoscope. This bipolar electrode array delivers energy to smaller areas of tissue.

**Specifications:**  
Recommended scope sizes: 8.6 mm to 12.8 mm  
Catheter shaft diameter: 4 mm  
Catheter shaft length: 160 cm

**Electrode:**  
20 mm length – 13 mm width

## Barrx™

60 RFA focal catheter

**90-9300**  
Single-use catheter fits on the distal end of a flexible endoscope. This bipolar electrode array delivers energy to smaller areas of tissue.

**Specifications:**  
Recommended scope sizes: 8.6 mm to 9.8 mm  
Catheter shaft diameter: 4 mm  
Catheter shaft length: 160 cm

**Electrode:**  
15 mm length – 10 mm width

## Barrx™

Channel RFA endoscopic catheter

**TTS-1100**  
Single-use catheter fits through the working channel of a flexible endoscope. This bipolar electrode array delivers energy to smaller areas of tissue.

**Specifications:**  
Recommended scope sizes: endoscopes with working channel diameter of 2.8 mm or maximum working channel length of 126 cm  
Catheter shaft diameter: 2.5 mm  
Catheter shaft length: 135 cm

**Electrode:**  
15.7 mm length – 7.5 mm width (when "wings" are unfolded)







## 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.

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## 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.



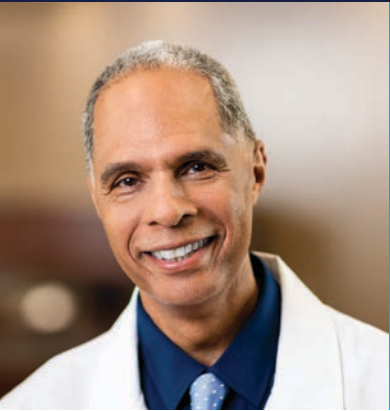
Actor portrayal

# HELP REDUCE RISK OF PROGRESSION<sup>1,2,3</sup>

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.



Barrx™  
radiofrequency  
ablation (RFA)  
system



### References

1. Shaheen NJ, Sharma P, Overholt BF, et al. Radiofrequency ablation in Barrett's esophagus with dysplasia. N Engl J Med. 2009; 28;360(22):2277-88.
2. Phoa KN, van Vilsteren FG, Pouw RE, et al. Radiofrequency ablation vs endoscopic surveillance for patients with Barrett esophagus and low-grade dysplasia: a randomized clinical trial. JAMA. 2014;26;311(12):1209-17.
3. 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(7):1752-1761.
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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13. 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.

\*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%<sup>1,2,3\*</sup>

**5.5x**

Barrett's esophagus patients with a first-degree family history of EAC are 5.5x more likely to progress to EAC<sup>4</sup>

**28%**

Increase in risk of progression to HGD/EAC per 1 cm increase in BE length<sup>5</sup>

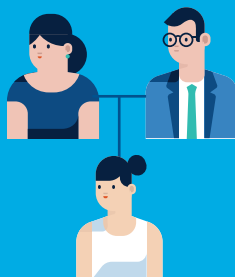
**NNT = 4**

Prevent one case of confirmed low-grade dysplasia (LGD) from progression to HGD or EAC with every 4 patients treated with RFA<sup>2</sup>

Dysplasia



Family history



Long segment disease



Smoking



## PROGRESSION CAN BE DEADLY. THINK BEYOND SURVEILLANCE.

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

- Dysplasia is the best-known precursor of disease progression.<sup>1,2</sup>
- Barrett's esophagus patients with a first-degree family history of EAC are 5.5x more likely to progress to EAC.<sup>4</sup>
- Long segment disease: there is a 28% increase in risk of progression to HGD/EAC per 1cm increase in BE length.<sup>5</sup>
- 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.<sup>13</sup>

In the future, the use of a risk scoring system to predict progression and guide treatment decisions might have value in clinical practice.<sup>8</sup>

## 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.<sup>\*1,2,3</sup>

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.<sup>1,2,3,12</sup>

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



Actor portrayal

Barrx™ 360  
express RFA  
balloon catheter

