



A SOLUTION
FOR EVERY
PROCEDURE

The Barrx™ RFA System

Medtronic
Further, Together

BARRX™ RFA SYSTEM



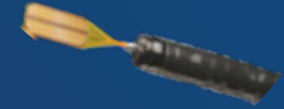
U.S. rollout of Halo³⁶⁰ ablation system



Worldwide rollout of Halo^{Flex} energy generator



Worldwide rollout of Halo⁶⁰ ablation catheter



EU rollout of first "through-the-scope" Barrx™ RFA catheter

'01

Halo³⁶⁰ ablation system receives FDA clearance

'05

Worldwide rollout of Halo⁹⁰ endoscope-mounted catheter

'06

'07

First randomized, controlled AIM-dysplasia study using RFA¹

'08

'09

Medtronic acquires BARRX Medical

'10

'11

Worldwide rollout of Halo⁹⁰ ultra ablation catheter

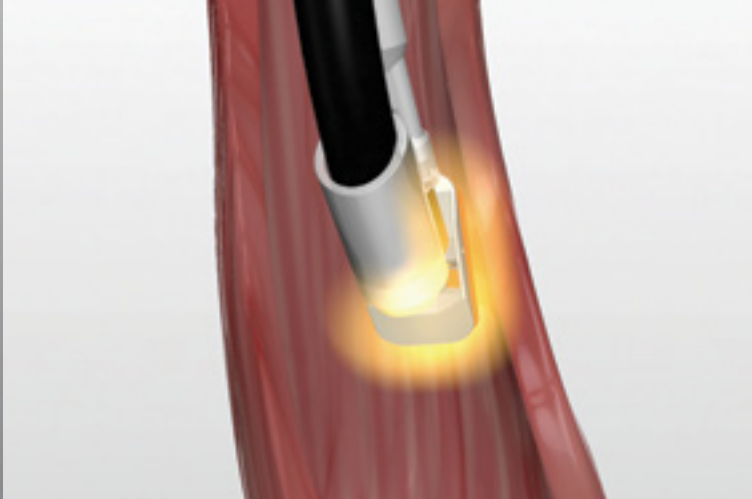
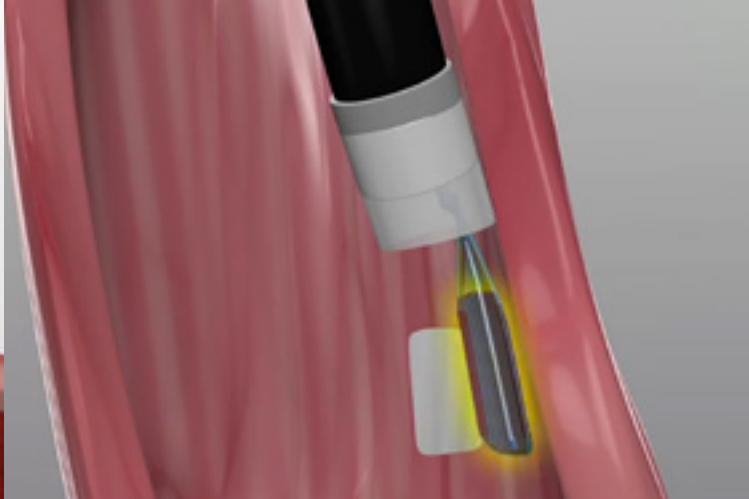
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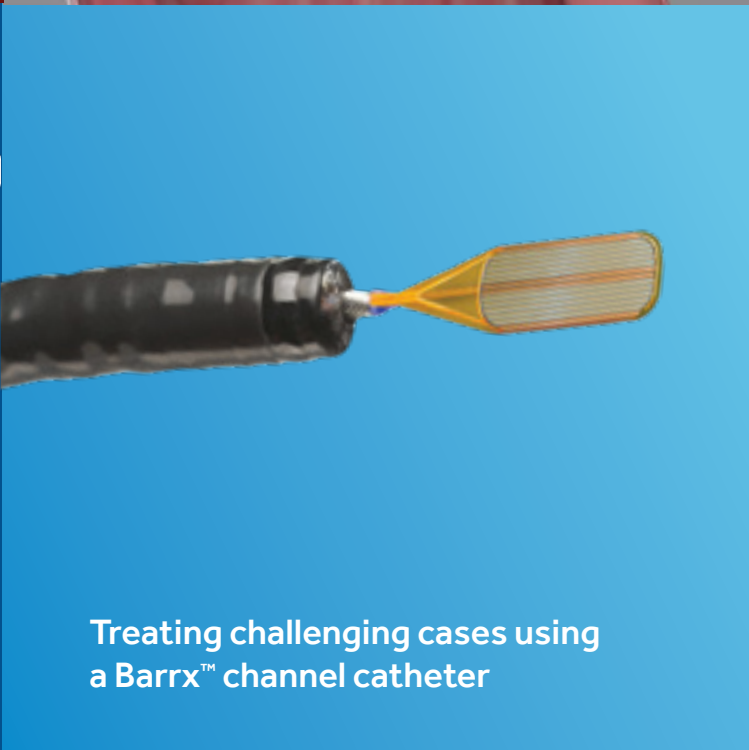
Barrx™ RF Ablation System
An Ever-Evolving Platform

First European randomized, controlled SURF trial in LGD using RFA²

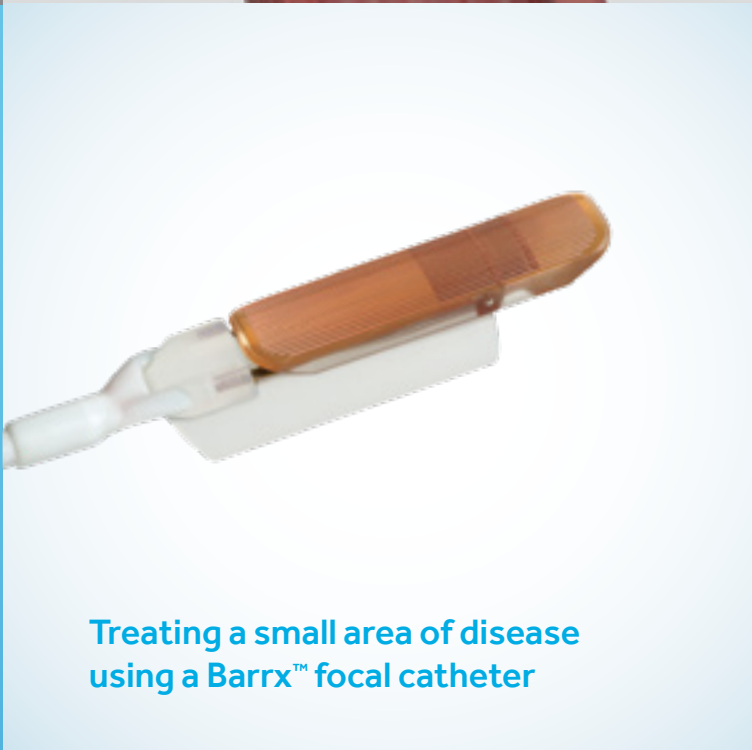




Treating circumferential and/or long Barrett's using a Barrx™ balloon catheter



Treating challenging cases using a Barrx™ channel catheter

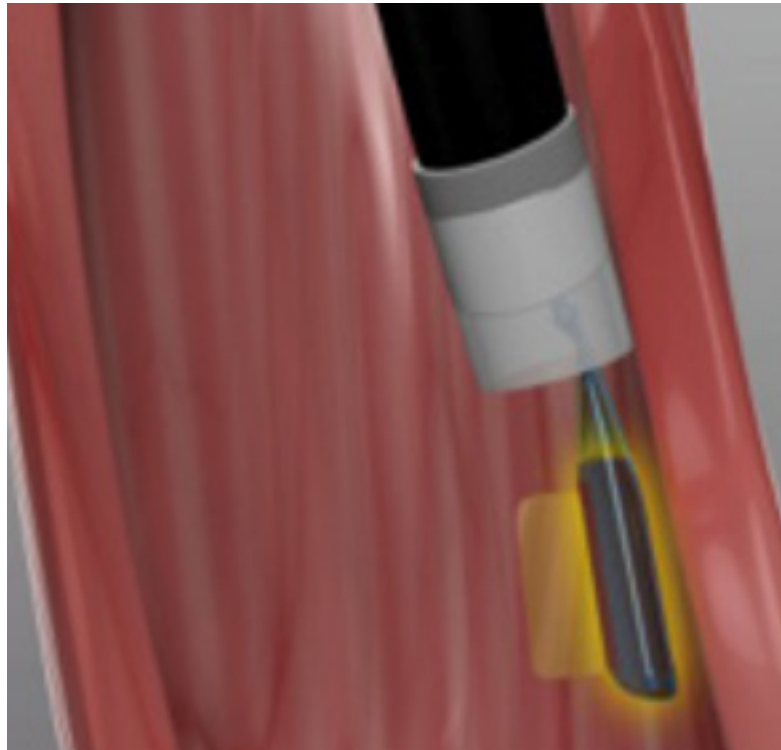


Treating a small area of disease using a Barrx™ focal catheter

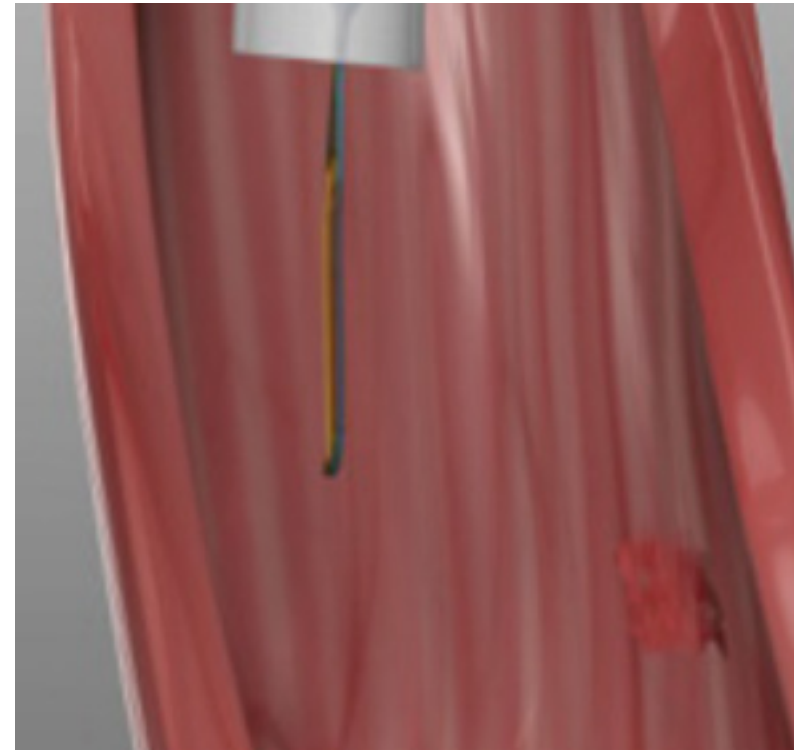
- More than 120,000 procedures have been performed using the revolutionary Barrx™ technology in 7 years, and adoption is growing rapidly.³
- Clinical evaluations and more than 100 peer-reviewed manuscripts reported safety and efficacy of the Barrx™ RF ablation technology for the treatment of all grades of Barrett's esophagus.
- Barrx™ RFA catheters come in a variety of configurations to treat diseased areas of different sizes and shapes.

DESIGNED TO TREAT CHALLENGING CASES WITH LESS TIME AND EFFORT

The “through-the-scope” design and fine electrode profile (> 89%⁴ thinner compared to that of focal catheters) are designed to allow more flexibility in catheter access and positioning to ablate targeted Barrett’s esophagus.



The “through-the-scope” feature is designed to facilitate treatment in patients with difficult access by decreasing the number of endoscope introductions.⁴



The thin profile of the electrode is designed to treat Barrett’s foci that are difficult to access with less time and effort.⁵

BUILDING ON PROVEN BARRX™ RF ABLATION SYSTEM PLATFORM

The Barrx™ channel RFA endoscopic catheter offers the same ablation capabilities as the widely accepted focal and balloon catheters, delivering controlled depth of coagulation for Barrett's esophagus and other bleeding and non-bleeding conditions of the GI tract.⁴⁻⁶

PRECISE ABLATION

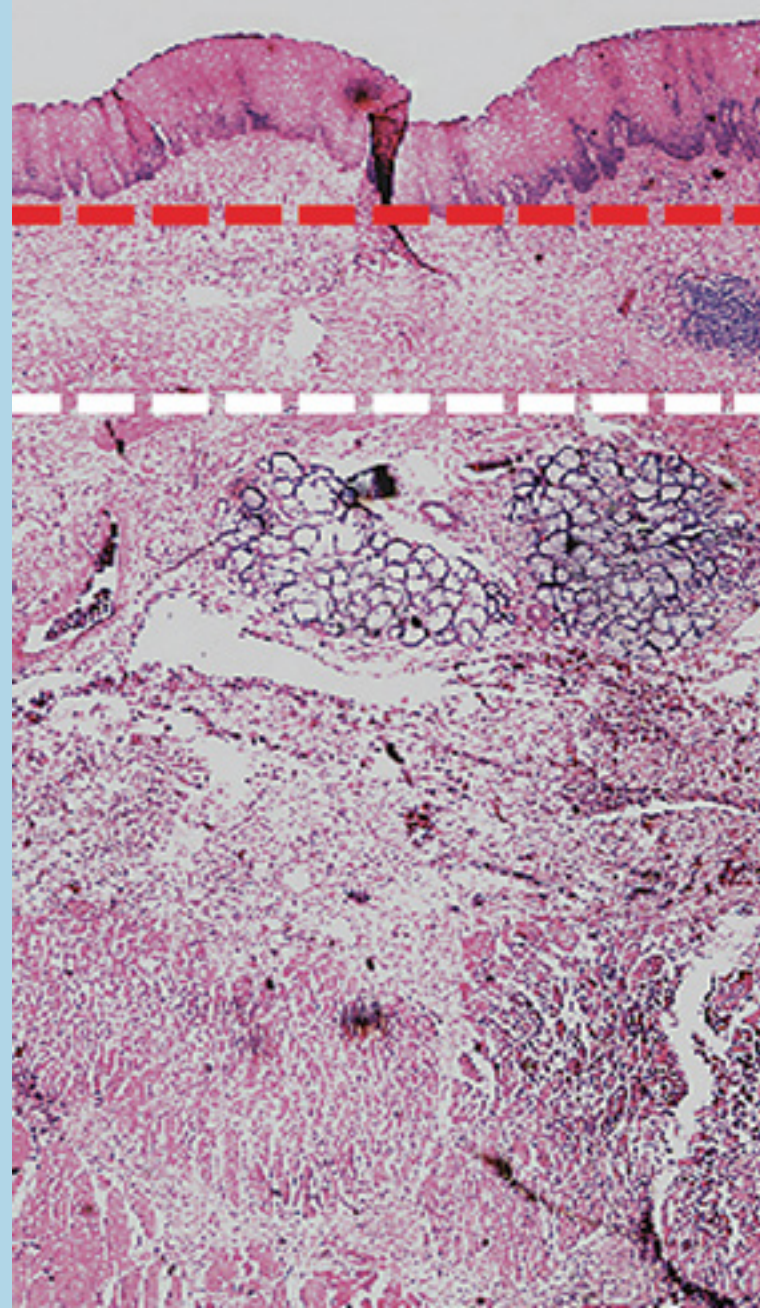
The ability to provide a controlled amount of ablative therapy to diseased tissue significantly reduces the risk of complications. The Barrett's epithelium is approximately 500 µm thick. The energy generator and the Barrx™ RF ablation catheter electrode arrays are designed to work in concert to achieve a uniform, superficial depth of ablation between approximately 500 µm and 1,000 µm.⁷⁻¹⁰

Human Esophagus Specimen

Targeted
Tissue

Barrx™ System
Ablation Depth

Approximate
EMR Depth



Epithelium

Lamina propria

Muscularis mucosae

Submucosa

Muscularis
propria

A COMPLETE BARRX™ RFA SYSTEM



360¹¹

Channel⁶

90¹²

Ultra Long¹³

60¹⁴

Treatment Area	Esophageal circumference of 3 cm in length	117 mm ²	260 mm ²	520 mm ²	150 mm ²
Treatment Length (cm)	3	1.57	2	4	1.5
WATTS	300 W (245 W for 18 mm balloon)	48 W	104 W	208 W	57 W
Power Density (W/cm ²)	40	40	40	40	40
Energy (J/cm ²)	10/12	12	12	12	12
Ablation Protocol (for BE)	1 Ablation, Clean, 1 Ablation	2 Ablations, Clean, 2 Ablations	2 Ablations, Clean, 2 Ablations	1 Ablation, Clean, 1 Ablation	2 Ablations, Clean, 2 Ablations
Through the Scope	No	Yes	No	No	No
Number of Ablations	16	120	80	80	80

The Barrx™ RFA catheters leverage the proven Barrx™ technology powered by the Flex generator, designed to enable physicians to effectively treat BE patients with predictable results.

REFERENCES

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3. Based on internal test report, GI Solutions, data on file.
4. Based on internal test report P/N V-0234-02 (A), Channel design verification testing. GI Solutions, data on file.
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6. Barrx™ channel RFA endoscopic catheter Instructions for Use (IFU).
7. Dunkin BJ, Martinez J, Bejarano PA, et al. Thin-layer ablation of human esophageal epithelium using a bipolar radiofrequency balloon device. *Surg Endosc*. 2006;20:125-130.
8. Ganz RA, Utley DS, Stern RA, et al. Complete ablation of esophageal epithelium with a balloon-based bipolar electrode: a phased evaluation in the porcine and in the human esophagus. *Gastrointest Endosc*. 2004;60:1002-1010.
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11. Barrx™ 360 RFA balloon catheter Instructions for Use (IFU).
12. Barrx™ 90 RFA focal catheter Instructions for Use (IFU).
13. Barrx™ ultra long RFA focal catheter Instructions for Use (IFU).
14. Barrx™ 60 RFA focal catheter Instructions for Use (IFU).

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IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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[medtronic.com/covidien/en-gb/index.html](https://www.medtronic.com/covidien/en-gb/index.html)

BRIEF STATEMENT

Indications

The Barrx™ 360 RFA balloon catheter, Barrx™ ultra long RFA focal catheter, Barrx™ 90 RFA focal catheter, Barrx™ 60 RFA focal catheter and Barrx™ channel RFA endoscopic catheter are indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including, but not limited to, Barrett's esophagus.

Contraindications

- Pregnancy
- Prior radiation therapy to the esophagus
- Esophageal varices at risk for bleeding
- Prior Heller myotomy
- Eosinophilic esophagitis

Refer to the device Instructions for Use for detailed information regarding the procedure, indications, contraindications, warnings and precautions.