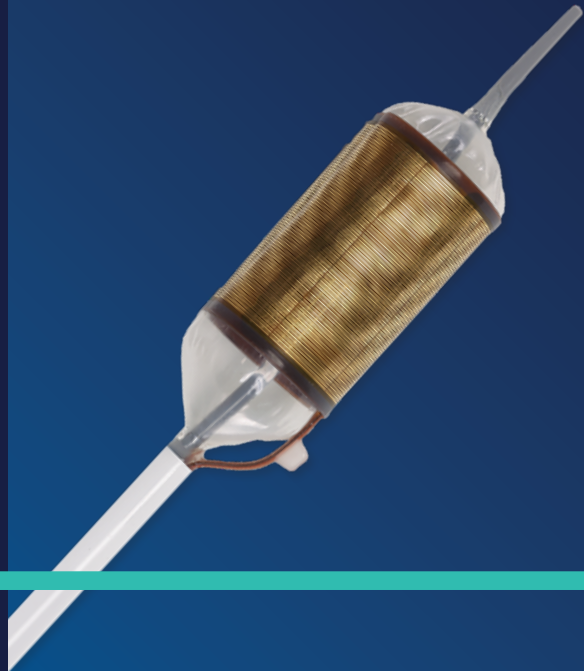




**THE BARRX™
ABLATION
SYSTEM
PRODUCT
CATALOG**



Barrx™

Flex RFA energy generator



Barrx™ flex RFA energy generator (1190A-115A)

The Barrx™ flex RFA energy generator is a bipolar radiofrequency generator designed to precisely control depth and uniformity of tissue ablation in the GI tract. It provides the flexibility to choose either the Barrx™ 360 express RFA balloon catheter for larger treatment areas or the 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"

Product Capacity:

- 18 Barrx™ 360 express RFA balloon catheters.
- 12 Barrx™ 90 RFA focal catheters or Barrx™ RFA endoscopic guidewires

Net Weight: 100 lbs.

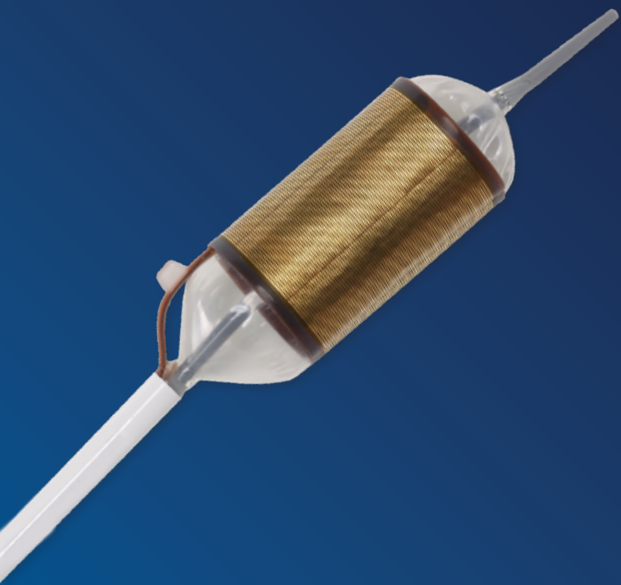
Barrx™

RFA cart



Barrx™

360 express RFA balloon catheter



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 %.^{1,2}

Specifications:

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

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:

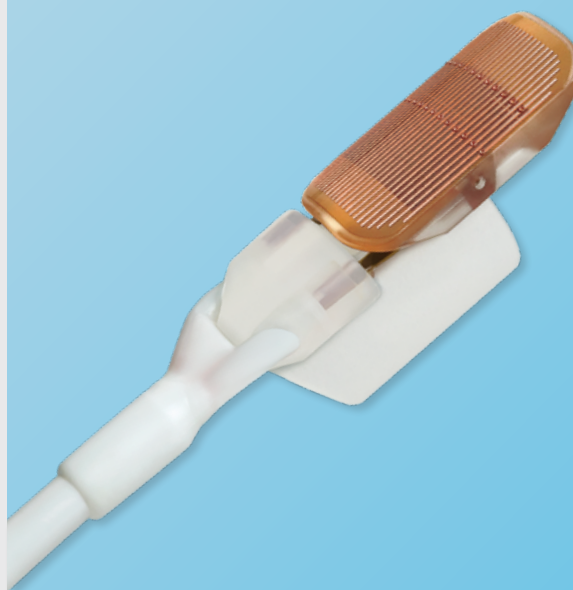
- Recommended scope sizes: 8,6 mm to 12,8 mm
- Catheter shaft diameter: 4 mm
- Catheter shaft length: 160 cm

Electrode:

- 20 mm length – 13 mm width

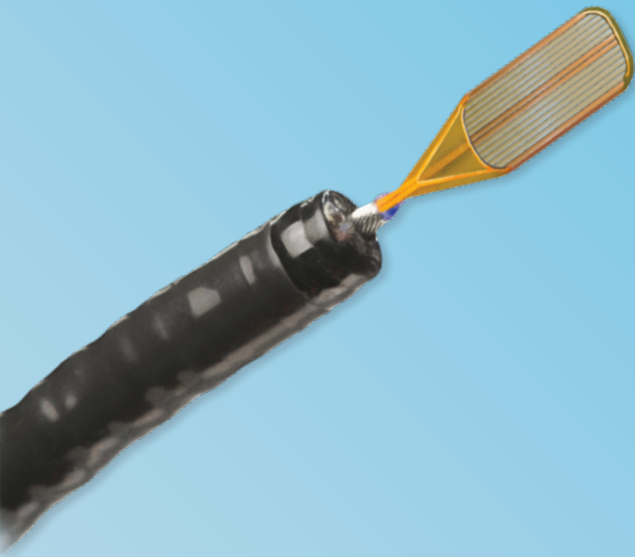
Barrx™

90 RFA focal catheter



Barrx™

Channel RFA endoscopic catheter



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 larger
- Catheter shaft diameter: 2,5 mm
- Catheter shaft length: 135 cm

Electrode:

- 15,7 mm length – 7,5 mm width (when “wings” are unfolded)

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:

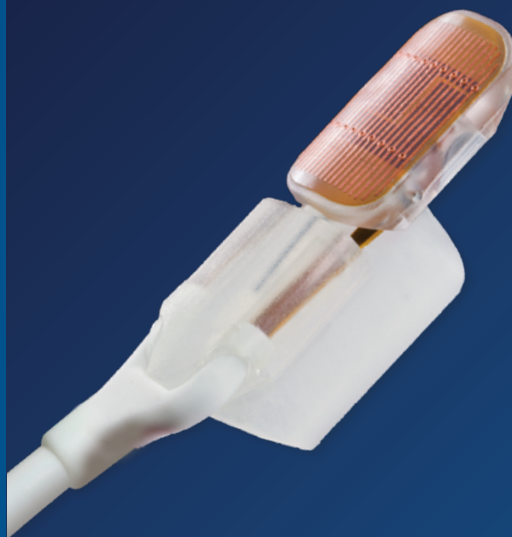
- Recommended scope sizes: 8,6 mm to 9,8 mm
- Catheter shaft diameter: 4 mm
- Catheter shaft length: 160 cm

Electrode:

- 15 mm length – 10 mm width

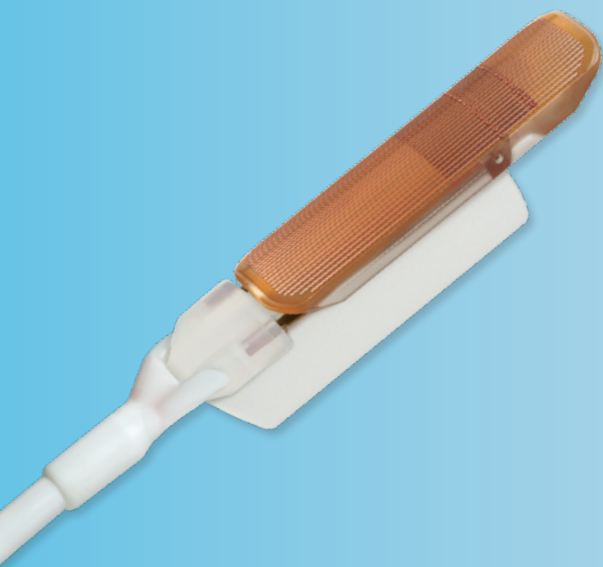
Barrx™

60 RFA focal catheter



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: 160 cm

Electrode:

- 40 mm length – 13 mm width

ACCESSORIES

Barrx™

RFA endoscopic guidewire



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.

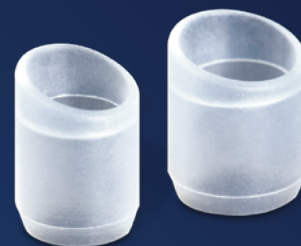
Specifications:

Barrx™ RFA endoscopic guidewire, marked: GW-005M

- Outer diameter: 0,038"
- Length: 230 cm
- Coated, marked, straight, flexible distal tip

Barrx™

RFA cleaning cap



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

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. Complications observed at very low frequency include: mucosal laceration, minor and major acute bleeding, esophageal stricture, perforation, cardiac arrhythmia, pleural effusion, aspiration, and infection. Potential complications that have not been observed include: death. Please refer to the product user manual for additional detailed information.

References:

1. Bergman JJ, Weusten BL, Schoon EJ, Koch AD. Safety and Efficacy of the Self Sizing RFA balloon: an uncontrolled multicenter feasibility study (B-550). 2014 Oct-Dec.
2. Phoa KN, van Vilsteren FG, Weusten BL, et al. Radiofrequency Ablation vs. Endoscopic Surveillance for Patients With Barrett's Esophagus and Low-Grade Dysplasia: A Randomized Clinical Trial. JAMA. 2014; 311(12): 1209-17

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

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