



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.

Barrx™ flex RFA energy generator service agreements:

Service plans feature complete coverage of the Barrx™ flex RFA energy generator and accessories. There are two service plan options available: 2 year (XWAR2-FL) and 3 year (XWAR3-FL). Coverage includes:

- Barrx™ flex RFA footswitch & output cable
- Parts & labor
- Software enhancements
- Service loaner

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.

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RFA cart



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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: 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

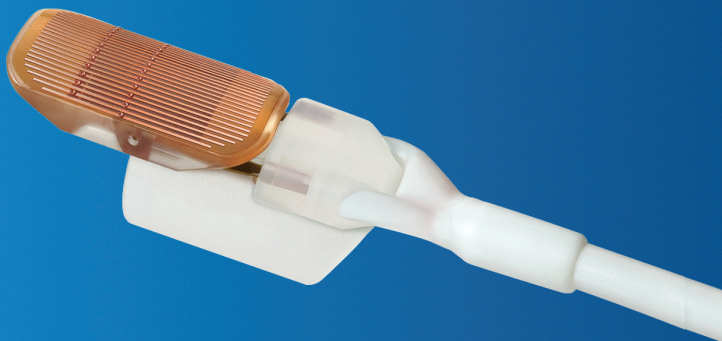
Catheter shaft length: 160 cm

Electrode:

20 mm length – 13 mm width

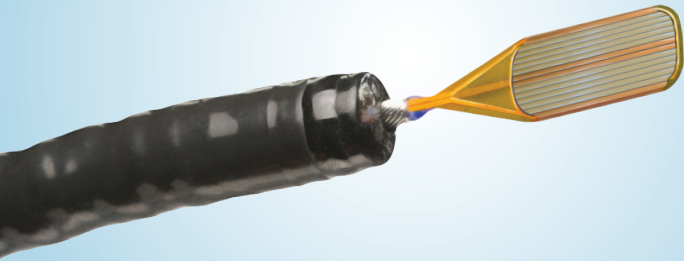
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90 RFA focal catheter



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Channel RFA endoscopic catheter



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:

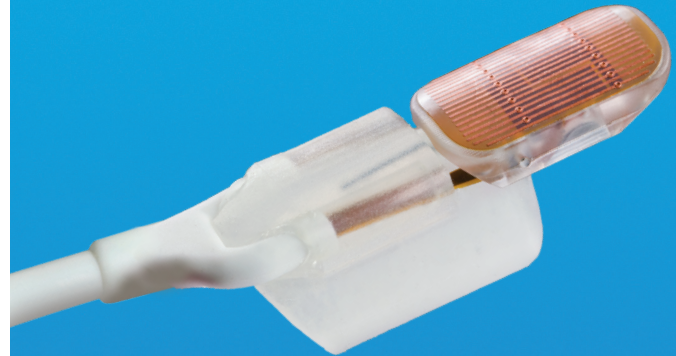
Recommended scope sizes: 8.6 mm to 9.8 mm

Catheter shaft diameter: 4 mm

Catheter shaft length: 160 cm

Electrode:

15 mm length – 10 mm width



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60 RFA focal catheter

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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:

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

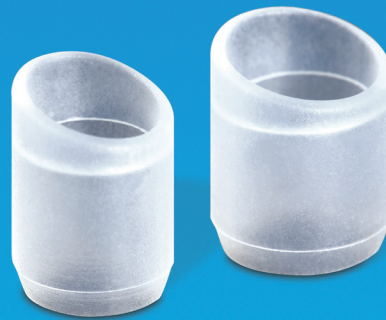


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RFA endoscopic guidewire

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.



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RFA cleaning cap

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

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

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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. 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