

Advanced Ablation Technology for Treating Bleeding and Non-bleeding Sites of the Gastrointestinal Tract.



# Barrx Flex RFA Energy Generator



# Barrx™ Flex RFA Energy Generator: 1190A-115A

The Barrx<sup>™</sup> Flex RFA Energy Generator encompasses "2 procedures in 1," providing the flexibility to choose either the balloon based circumferential Barrx<sup>™</sup> 360 Express or Barrx<sup>™</sup> 360 RFA Balloon Catheter for larger treatment areas or the Barrx<sup>™</sup> RFA Focal Catheters for smaller focal areas.

Barrx<sup>™</sup> Flex RFA Energy Generator Service Agreements:

2 YEAR (XWAR2-FL)

4 YEAR (XWAR4-FL)

5 YEAR (XWAR5-FL)

- Includes footswitch & output cable
- Parts & labor
- Software upgrades

#### **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  $\mathsf{Barrx}^\mathsf{TM}$ 

Flex RFA Energy Generator

#### Barrx™ RFA Cart: CART-100

A custom procedural cart specifically designed for the storage and easy transportation of the Barrx<sup>TM</sup> System. The cart provides a convenient and efficient working station for radiofrequency ablation procedures along with storage space designed specifically to hold Barrx<sup>TM</sup> Flex RFA Energy Generator, Barrx<sup>TM</sup> catheters and accessories.

#### **Specifications:**

#### **Overall Dimensions:**

Height: 42.5"

Width: 22.5" (34" w/trays)

Depth: 23"

# **Product Capacity:**

18 Barrx<sup>™</sup> 360 RFA Balloon Catheters 12 Barrx<sup>™</sup> 90 RFA Focal Catheters or Barrx<sup>™</sup> RFA Endoscopic Guidewires

Net Weight: 100 lbs.





Barrx<sup>™</sup> 360 Express RFA Balloon Catheter: 64082 Single, self-adjusting balloon catheter with a 4cm 360° electrode array that removes the need to perform the sizing step and to choose correct size ablation catheter.

**Specifications:** 

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

#### Barrx<sup>™</sup> 360 RFA Balloon Catheter:

Single-use catheter with a 3 cm long, 360° electrode array that delivers a short burst (<1 sec) of ablative energy circumferentially to the lining of the esophagus.

#### **Specifications**:

Balloon length: 6 cm Electrode length: 3 cm Catheter shaft diameter: 7 mm Catheter shaft working length: 85 cm

### **Available Diameter Sizes:**

18 mm: 32041-18 22 mm: 32041-22 25 mm: 32041-25 28 mm: 32041-28 31 mm: 32041-31





Barrx™ 360 Soft Sizing Balloon: 3441C

Compatible with the Flex RFA Energy Generator to measure the esophageal inner diameter.

## **Specifications:**

Balloon length: 4 cm

Balloon unconstrained nominal diameter: 47.5 mm (3 psi)

Catheter shaft diameter: 7 mm Catheter shaft working length: 85 cm

### **Accessories included:**

Barrx™ 360 Soft Balloon Filter: FL-200C

Disposable, single-use .45 µm hydrophobic filter.



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)

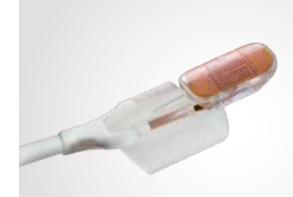
Barrx<sup>™</sup> 60 RFA Focal Catheter: 90-9300 Single-use catheter fits on the distal end of a flexible endoscope. This bipolar electrode array delivers energy to smaller areas of tissue.

#### **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<sup>™</sup> 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™ 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<sup>™</sup> RFA Endoscopic Guidewire:** 

Designed to facilitate the exchange of the Barrx™ 360 Express RFA Balloon Catheter, the Barrx™ 360 Soft Sizing Balloon, and the Barrx™ 360 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 in conjunction esophageal tissue with the Barrx™ 360 RFA Balloon Catheter. Each single-use cap mounts on the distal end of a flexible endoscope.

#### **Specifications:**

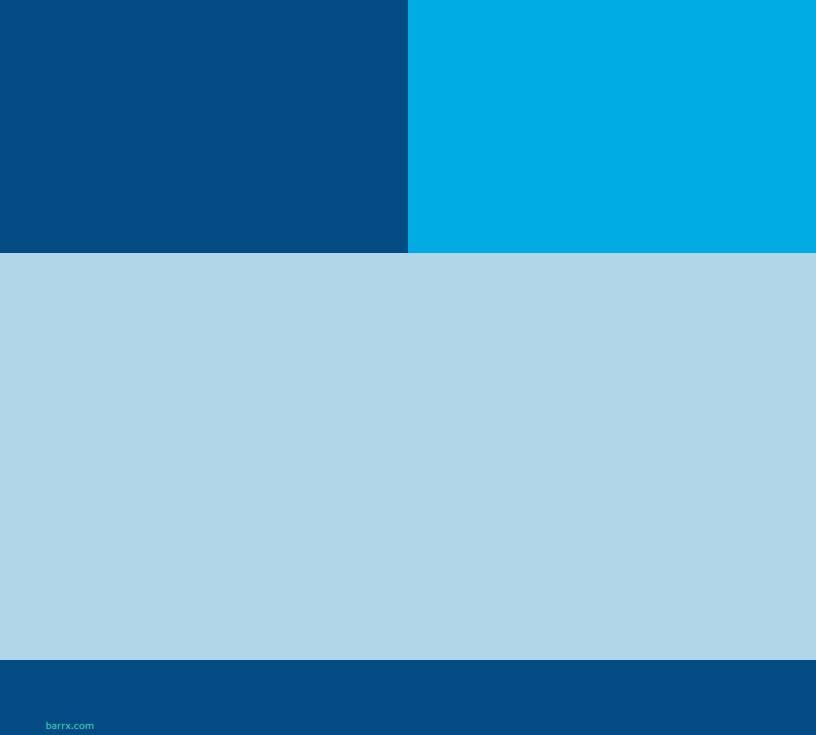
# Barrx™ RFA Cleaning Cap - Small: CP-001A

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

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

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