

# HALO<sup>360+</sup> Ablation Catheter

## Model 32041-XX

### INSTRUCTIONS FOR USE

**CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a Physician.**

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#### INDICATED USE

The HALO<sup>360+</sup> Ablation Catheter is 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, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

**EU, Canada:** The HALO<sup>360+</sup> Ablation Catheter is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including, but not limited to, Barrett's Esophagus.




The HALO<sup>360+</sup> Ablation Catheters are referred to in this Instructions For Use as the "Ablation Catheter". The HALO<sup>360+</sup> Sizing Balloon is referred to as the "Sizing Balloon". The HALO<sup>FLEX</sup> or HALO<sup>360</sup> Energy Generator is referred to as the "Energy Generator". The HALO<sup>FLEX</sup> or HALO<sup>360</sup> Output Cable is referred to as the "Output Cable". The HALO<sup>FLEX</sup> or HALO<sup>360</sup> Footswitch is referred to as the "Footswitch".

#### ABLATION CATHETER: AVAILABLE SIZES

The Ablation Catheter is available in the following balloon diameter sizes: 18 mm, 22 mm, 25 mm, 28 mm, and 31 mm.

#### GENERAL WARNINGS AND PRECAUTIONS

 The safe and effective use of radiofrequency (RF) energy is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained medical staff. It is important that the operating instructions supplied with the HALO<sup>360+</sup> Ablation Catheters as well as the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Energy Generators be read, understood and followed before use.

#### GENERAL WARNINGS

- Do not use this device for any purpose other than the indicated uses.
- Inspect the device packaging before use and do not use device if any damage to inner pouch or device is observed.
- Do not advance or retract the Ablation Catheter if resistance is met.
- Prior to repositioning or removal, ensure complete deflation of the Ablation Catheter.
- Always reposition or remove Ablation Catheter under direct endoscopic visualization.
- Place the supplied filter (included in the catheter packaging or provided separately) between the pneumatic connector located at the proximal end of the Sizing Balloon or Ablation Catheter and the pneumatic connector on the Output Cable to ensure fluids are not aspirated into the Output Cable in the event of a balloon leak. Each catheter is packaged with a filter to be used specifically with the product, which may vary for each catheter. Only the supplied filter should be used. If any catheter is used without the filter, and a balloon leak occurs, inspect the clear tubing portion of the connecting cable for fluid. If fluid is detected, discontinue the use of the cable and order a replacement.
- If the generator displays an E95 or C56 Operational Code, this is most likely caused by an air leak in the system. If the E95 or C56 Operational Codes are observed, under endoscopic visualization, manually deflate the balloon using a syringe and remove and replace the Ablation Catheter.
- Do not store the Ablation Catheter near flame or temperatures in excess of 35°C.
- Do not deliver RF energy in areas containing surgical staples. The presence of metallic staples can disturb the treatment pattern and may lead to complications.

## GENERAL PRECAUTIONS

- The HALO<sup>360+</sup> Ablation Catheters are for use with the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Energy Generators only.
  - The HALO<sup>360+</sup> Ablation Catheters should be used only by a physician trained in advanced therapeutic endoscopy.
  - The HALO<sup>360+</sup> Ablation Catheters should be used under direct endoscopic visualization using a HALO Guidewire or other stiff guidewire (0.035-0.039") indicated for gastrointestinal procedures.
  - The HALO<sup>360+</sup> Ablation Catheter should be used with caution in patients who present with anatomic variations of the targeted portion of the esophagus, such as a diameter that may be too large or too small to accommodate the device. Such disorders may include stricture, achalasia, history of endoscopic mucosal resection, and scleroderma.
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## CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS

### SPECIFIC TO THE USE OF THE HALO<sup>360+</sup> ABLATION CATHETER FOR THE SUB-INDICATION OF BARRETT'S ESOPHAGUS

#### CONTRAINDICATIONS

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

#### WARNINGS

- The following are transient side effects that may be expected after treatment: chest pain, difficulty swallowing, painful swallowing, throat pain, and/or fever. Side effects should be managed by the physician at their discretion.
- Complications observed at very low frequency include:
  - mucosal laceration;
  - minor acute 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;
  - major bleeding;
  - transfusion secondary to major bleeding;
  - cardiac arrhythmia;
  - and aspiration.
- Potential complications that have not been observed include:
  - infection;
  - and death.
- A patient should report any vomiting post-treatment to their physician so that proper management can be instituted to avoid subsequent serious injury; such as esophageal perforation, aspiration and possibly death.
- Previous stricture formation within the esophagus, dilation procedures within the esophagus, erosions of the esophagus, ulceration of the esophagus, other ablative procedures of the esophagus, and/or resective procedures of the esophagus may predispose patient to acute esophageal injury (laceration and perforation) and subsequent esophageal stricture formation after treatment with this device given the altered anatomy, physiology and wound healing characteristics inherent to these disease states and therapies.
- Anti-secretory medication should be provided in a dosing regimen that fully controls GERD symptoms and heals esophageal inflammation, erosions and ulcerations prior to use of this device and thereafter. In the AIM clinical trials, high-dose proton pump inhibition (esomeprazole 40 mg bid) was provided for at least 7 days prior to and for at least one month after use of this device. Esomeprazole was reduced to 40 mg qd after healing of coagulated tissue was confirmed, although drug treatment was continued indefinitely as underlying GERD remains in these patients.
- Failure to provide adequate anti-secretory therapy at least 7 days before and then in a long-term regimen after the use of this device may lead to a higher rate of stricture formation than expected and/or persistence/recurrence of Barrett's esophagus.
- Use of this device in a patient with active esophagitis, erosions, or ulceration may lead to a higher rate of complications and should not be undertaken until such abnormalities are treated to resolution.

- Failure to follow the instructions for use regarding the positioning, inflation and energy delivery related to the Ablation Catheter may result in a higher than expected rate of stricture formation after use of the device. Specifically, failure to reposition the device adequately after delivering energy (move catheter linearly) before delivering the next treatment, may result in a deeper ablation effect than intended, thus resulting in a higher than expected rate of stricture formation. The physician is warned to confirm adequate repositioning of the Ablation Catheter after each treatment is delivered, using endoscopic visualization, prior to initiating the next treatment cycle. Minimize the overlap of each treatment zone when moving the Ablation Catheter linearly.
- Failure to follow the recommended discharge instructions regarding anti-secretory medications, antacid/lidocaine, and narcotics may result in higher incidence of complications and patient pain.
- Selecting a larger than recommended Ablation Catheter size can result in trauma to the esophagus (laceration and perforation), excessive energy delivery, and stricture formation.
- Treating more than 6 cm of Barrett's length in one treatment session may result in a higher than expected rate of stricture formation, pain, difficulty swallowing, and other complications.
- Failure to clean the Ablation Catheter electrode and the lumen of treated esophagus after the first treatment pass may result in areas of under-treatment and/or over-treatment, and could reduce effectiveness and increase risk of complications.
- Failure to recognize information on Energy Generator LCD (display) after an operational code occurs indicating that partial treatment had occurred, then repeating the treatment in the same area, could result in excessive treatment to one region (stacking of ablation) and could lead to a higher than expected rate of stricture formation. If the generator indicates an Operational Code, inspect the display to determine if energy was delivered. Then inspect the treatment zone for treatment effect. If any energy was delivered, move on to the next treatment area. Do not retreat at the same location.
- Failure to discontinue platelet inhibiting agents (i.e., aspirin, clopidogrel, non-steroidal anti-inflammatory agents) and anti-thrombotic agents (i.e., heparin, warfarin) 7 days before and after treatment may lead to higher rates of intra and post-treatment bleeding, and may possibly lead to transfusion therapy, endoscopic therapy for hemostasis, surgery, or even death.
- Do not remove the Ablation Catheter while leaving the endoscope in place in the esophagus, as this may result in patient injury.
- Do not introduce any Ablation Catheter or Sizing Balloon with the endoscope already in place in the esophagus, as this may result in patient injury. Always introduce the endoscope after the catheter and guidewire are in place.

#### PRECAUTIONS

Use of this device has not been studied in or may be more difficult, less effective, or less well-tolerated in patients with:

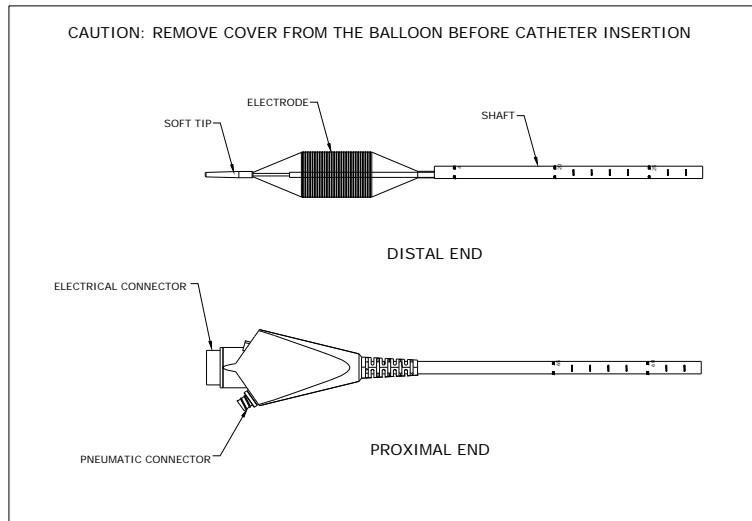
- Barrett's esophagus length greater than 6 cm;
- age under 18 years;
- esophageal stricture preventing passage of endoscope or catheter;
- active esophagitis (Hetzl-Dent Grade III or IV) described as erosions or ulcerations encompassing more than 10% of distal esophagus;
- history or current diagnosis of malignancy of the esophagus;
- any previous ablative therapy within the esophagus (photodynamic therapy, multipolar electrical coagulation, argon plasma coagulation, laser treatment, or other);
- any previous endoscopic mucosal resection within the esophagus (recent studies have allowed 2 months after EMR prior to use of this device to allow complete healing, and have limited the extent of prior EMR to less than 2 cm length and less than 50% of esophageal lumen circumference);
- any previous esophageal surgery, including fundoplication (users are cautioned regarding inflation of a balloon in the fundoplication zone as this could potentially disrupt the fundoplication). Staples from previous esophageal surgery may interfere with the performance of this device and may lead to complications;
- an implantable pacing device unless permission given by the specialist responsible for the pacing device;
- dysplasia;
- cancer;
- nodularity of the esophageal mucosa.

Specifically, use of this device for treatment of longer circumferential segments of Barrett's esophagus, in patients with a history of stricture, or in patients with scarring from previous therapies may result in a further increased risk of stricture or more pain as compared with the rate in patients without these findings.



**Instructions For Use for the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Energy Generators are supplied with the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Energy Generators and must be read and understood prior to use of the HALO<sup>360+</sup> Ablation Catheter.**

## HALO<sup>360+</sup> ABLATION CATHETERS: DEVICE OVERVIEW



- The Ablation Catheter consists of an electrode that is concentric to a deployment balloon, a shaft, a thru lumen, and electrical and pneumatic (inflation) connectors.
- The pneumatic port connector is a female luer-lock fitting. The Energy Generator incorporates an inflation system that connects to the Ablation Catheter via the male luer-lock fitting on the Output Cable. The Energy Generator is the only device that should be used to inflate the Ablation Catheter. When connected to the Energy Generator, the inflation system will provide a preset inflation pressure. Refer to the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Energy Generator User's Manuals for complete instructions on the use of the inflation system.
- Note that the electrode and deployment balloon will not be visible upon removal from packaging, since they are contained within a cover. Remove cover before use.
- If any abnormalities exist that would affect the functionality of the Ablation Catheter such as breaks, tears, bends or kinks, do not use.

### INSTRUCTIONS FOR USE: SPECIFIC TO THE USE OF THE HALO<sup>360+</sup> ABLATION CATHETER FOR THE SUB-INDICATION OF BARRETT'S ESOPHAGUS

*The following is a representation of the procedural steps used in prospective clinical trials for this device. This guide is not meant to replace physician judgment. Procedural steps may vary by patient according to patient tolerability, anatomy, motility, characteristics of the Barrett's esophagus, and underlying health condition.*

1. Turn power switch to the "on" position on the back panel of the Energy Generator. Upon "power on," the Energy Generator LCD screen will display:

**Ready  
Connect Catheter**

2. Connect the Footswitch cable to the back panel of the Energy Generator and place the Footswitch on the floor in a position accessible to the physician.
3. Connect the Output Cable to the front panel of the Energy Generator. Connect the pneumatic connector.
4. Connect a Sizing Balloon to the Output Cable (ensuring proper connection of the electrical and pneumatic connectors). See Sizing Balloon Instructions for Use for more information.
5. Connect the supplied FL-200C filter between the pneumatic connector located at the proximal end of the Sizing Balloon and the pneumatic connector on the Output Cable.
6. Upon connection of the Sizing Balloon, the Energy Generator LCD screen will display:

**Sizing Balloon  
Ready to Calibrate**

**Before Introduction  
Calibrate Balloon**

7. Remove the balloon cover. The calibration pouch should remain centered over the balloon.

- With the Sizing Balloon held by the catheter shaft, position the balloon in the center of the supplied calibration pouch and singly depress the "Calibrate" button on the front of the Energy Generator. The Energy Generator LCD screen will display:

**Calibrating System  
Standby**

- During calibration, the Energy Generator will inflate-deflate-inflate-deflate the Sizing Balloon to calibrate its volume and outer dimension. Upon completion of calibration, the Energy Generator Balloon Diameter LED will read 33.7 mm and the Energy Generator LCD screen will display:

**Calibration Complete  
Ready to Auto-size**

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**Introduce Balloon  
Inflate Balloon**

- Upon completion of successful calibration, remove and discard the calibration pouch. The Sizing Balloon is now ready for use in the auto-sizing steps. The Sizing Balloon should be disconnected from the Energy Generator in order to facilitate introduction into the esophagus in a later step. Calibration is performed only once, therefore, re-calibration upon reconnection is not necessary.
- Perform esophagoscopy.
- Irrigate the esophageal lining with N-acetylcysteine (Mucomyst) (1%) mixed in plain water. Do not use saline. Evacuate the stomach and esophagus of all instilled irrigation. Deflate stomach.
- Measure and record distance (cm) from the incisors (biteblock) to the most proximal (top) of the Barrett's esophagus/intestinal metaplasia (TIM) as well as the top of the gastric folds (TGF).
- Introduce the HALO Guidewire or other stiff, coated guidewire (0.035-0.039"), remove endoscope, leaving guidewire in place.
- The Sizing Balloon shaft markings are provided in 1 cm increments and are referenced to the proximal end of the 4 cm long flat portion of the balloon. The balloon extends 4 cm beyond that of the referenced mark (the zero mark) should be considered when interpreting sizing results and selecting an Ablation Catheter.
- Prior to introduction of the Sizing Balloon, ensure that the balloon is fully deflated and folded upon itself in a low profile configuration. Apply a small amount of gel lubrication to the shaft of the Sizing Balloon and introduce into the esophagus over the guidewire, using proper guidewire management techniques (stationary guidewire while moving catheter). Do not apply gel lubrication to the balloon or catheter tip. Position the Sizing Balloon (using shaft markings) 12 cm above the gastric folds (TGF). Optionally, the endoscope may be reintroduced in a side-by-side manner and sizing may be performed under direct vision. Further, if the user is treating more proximally than 12 cm above the TGF, beginning measurements more proximally may be advisable.
- Singly depress the Auto Inflation (left) pedal on the Footswitch or singly depress the Automatic Inflate Button (Up) on the Energy Generator. The balloon will automatically inflate and then automatically deflate. During this measurement step, the Energy Generator LCD screen will display:

**Inflating  
Measuring**

- If at any time, the operator wishes to interrupt the automatic sizing process, they may do so by singly depressing the Auto Inflation (left) pedal on the Footswitch or singly depressing the Automatic Deflate Button (Down) on the Energy Generator.
- After a complete measurement cycle, the diameter estimate (mm) will be displayed in the "Balloon Diameter" LED window. Upon attaining the measurement, a recommended size (mm) for the Ablation Catheter is displayed in the LCD window:

**XX mm Recommended  
Ready**

- See appropriate Energy Generator User Manual for a table of computed balloon diameter versus recommended catheter size. Note the esophageal inner diameter estimate in mm (for example, XX.X mm) displayed in the LED and then record this value according to the linear position where the measurement was obtained utilizing the Sizing Worksheet.

NOTE: If the user observes an E97 Operational Code during sizing, this may indicate that there is patient movement, esophageal motility pushing on the balloon, or balloon migration due to esophageal narrowing. If this occurs, it is recommended to repeat the sizing under direct endoscopic visualization. Caution should be used in this situation as migration of the balloon may prevent the user from noting a narrowed area on the measurements, and a subsequent esophageal injury can occur if an overly large Ablation Catheter is selected.

- Move the balloon distally by 1 cm and repeat Steps 16-19. As the catheter moves closer to the TGF, the user should expect the balloon to migrate into the stomach and display an abruptly larger inner diameter from that point distally. This increase in size is noted approximately when the catheter shaft markings register a location of 4 to 7 cm above the TGF (due to the length of the balloon and motility of the gastroesophageal junction). Therefore, typically no more than 5 sizing

steps are required to accurately measure the esophageal body above the TGF (i.e., the treatment area.) Misinterpreting the proximal stomach measurements as esophageal measurements and subsequently selecting an overly large Ablation Catheter can result in patient injury.

NOTE: If using the Sizing Balloon in conjunction with the HALO<sup>FLEX</sup> Energy Generator and a measurement of 37mm or greater is received the Energy Generator LCD screen will display:

**Sizing Balloon  
Unconstrained  
Repeat Sizing  
Check Position**

This may be an indicator the balloon has migrated into the stomach.

22. After obtaining an adequate number of Sizing Balloon measurements, disconnect the Sizing Balloon and filter from the Output Cable, and remove the Sizing Balloon from the esophagus leaving the guidewire in place. If performing sizing with the endoscope in place, remove the Sizing Balloon and endoscope together while observing the balloon to avoid injury.

NOTE: If any blood is seen on the Sizing Balloon after removal, the user may perform endoscopy to rule out esophageal injury prior to introducing the Ablation Catheter. If esophageal injury is noted, ablation should be delayed to allow healing.

NOTE: If using the Sizing Balloon in conjunction with the HALO<sup>FLEX</sup> Energy Generator, upon completion of sizing and after disconnecting the Sizing Balloon, the Energy Generator will display the smallest esophagus diameter measured, and the final recommended Ablation Catheter balloon size.

23. Review all esophageal inner diameter values recorded on the sizing worksheet. Select an appropriately sized Ablation Catheter according to these measurements based on the smallest single size obtained during sizing, regardless of the location of that sizing measurement. If it appears that two different sizes are recommended or recorded, always choose the smaller of the two sizes. Selecting a larger than recommended Ablation Catheter can result in excessive delivery of energy, increase the risk for stricture formation, and increase the risk for mucosal laceration and esophageal perforation.

NOTE:

- If during sizing, RFA Not Recommended or Balloon Ablation Not Recommended was displayed, ablation should not be performed with a HALO<sup>360+</sup> Ablation Catheter.
- If all measurements are greater than 37mm, ablation should not be performed with a HALO<sup>360+</sup> Ablation Catheter and the sizing process should be repeated.
- If a HALO<sup>360+</sup> Ablation Catheter is connected after the HALO<sup>FLEX</sup> Energy Generator recommended that the smallest size was less than 18mm, then the following message will display on the LCD screen:

**Balloon Ablation  
Not Recommended  
Esophagus Too Small**

The message can be over ridden by pressing RESET. It is not recommended to proceed if the Energy Generator states this warning.

- If a larger HALO<sup>360+</sup> Ablation Catheter is connected to the HALO<sup>FLEX</sup> Energy Generator, other than the recommended size, the following message will display on the LCD screen:

**Catheter is Too Big  
Review Sizing Result  
Smallest Size XXmm**

The message can be over ridden by pressing RESET. It is not recommended to proceed using the selected Ablation Catheter if the Energy Generator states this warning.

- If all sizing measurements were greater than 37 mm and a HALO<sup>360+</sup> Ablation Catheter is connected to the HALO<sup>FLEX</sup> Energy Generator, the following message will display on the LCD screen:

**Catheter Not  
Recommended  
Repeat Sizing**

The message can be over ridden by pressing RESET. It is not recommended to proceed if the Energy Generator states this warning. Sizing should be repeated as all sizings were likely in the stomach.

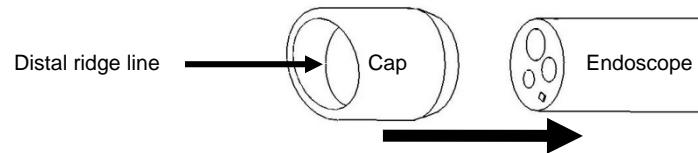
24. Apply a small amount of gel lubrication to the shaft of the Ablation Catheter (do not apply gel to the electrode or balloon) and introduce the Ablation Catheter over the guidewire so that it is ~1 cm proximal to the TIM by catheter shaft measurements. Use proper guidewire management technique.
25. Connect the supplied filter to the pneumatic connector located at the proximal end of the Ablation Catheter.

26. Connect the Ablation Catheter to the Output Cable and connect the pneumatic connector to the filter. Upon successful connection, the Energy Generator LCD will indicate the ablation catheter is ready.
27. Confirm the default energy density setting displayed on the Energy Generator LED (10 J/cm<sup>2</sup>.) (In the AIM clinical trials, investigators studied these default settings for the treatment of Barrett's esophagus without dysplasia. Additional studies have been conducted for the treatment of Barrett's esophagus with dysplasia using 12 J/cm<sup>2</sup>. Physicians are advised to use clinical judgment in determining the most appropriate energy density setting for any given patient.)
28. Apply a small amount of gel lubrication to the endoscope and introduce the endoscope in a side-by-side manner with the Ablation Catheter. Limited lubrication on the endoscope may minimize friction between the endoscope and catheter shaft, allowing easier positioning and visualization. Position the electrode under direct endoscopic visualization so that its proximal edge is 1 cm above the top of the intestinal metaplasia (TIM). The catheter shaft may be rotated so as to rotate the electrical connector between shaft and electrode out of the visual field, thus providing optimal visualization of the balloon and electrode.
29. Singly depress the Auto Inflation (left) pedal on the Footswitch or singly depress the Automatic Inflate Button (Up) on the Energy Generator. The balloon will automatically inflate to a pre-set pressure. During the inflation process and after the ablation balloon is fully inflated, do not apply traction to the Ablation Catheter in an attempt to stabilize or prevent migration, and do not attempt to move the Ablation Catheter, as this can lead to serious patient injury.
30. If at any time, the operator wishes to interrupt the inflation process, they may do so by singly depressing the LEFT pedal on the Footswitch or singly depressing the Automatic Deflation button (down arrow) on the Energy Generator.
31. The Energy Generator "arms" the system when the pressure in the Ablation Catheter balloon is within the preset pressure range, enabling the delivery of energy when activated by the user. The inflation pump is an active system that will attempt to maintain the pressure in the balloon within this preset range. When "armed", the blue "RF Power Control" button on the Energy Generator will be illuminated and the Energy Generator LCD screen will indicate the system is ready to deliver energy.
32. Prior to delivering energy, apply suction via the endoscope. Then, singly depress the RIGHT pedal on the Footswitch or singly depress the illuminated "RF Power Control" button on the Energy Generator. During energy delivery, the Energy Generator LCD screen will be blank. Energy delivery should be initiated as soon as the balloon reaches the preset pressure and the generator "arms", as this minimizes the likelihood of balloon migration and peristalsis.
33. After energy delivery, the Ablation Catheter balloon is immediately and automatically deflated. If energy was delivered completely to all segments of the electrode, the Energy Generator LCD screen will indicate the catheter is ready for the next energy delivery and will display the percent energy delivered to each electrode.
34. If energy delivery is incomplete (for example, high or low tissue resistance, poor tissue contact, debris on electrode, etc.) an "Operational Code" may be displayed on the Energy Generator LCD screen, along with an explanation and instruction to the user. (Refer to the User's Manual for a full list of Operational Codes.)

Do not repeat treatment in the same region if at least 50% of the energy was delivered to any of the electrodes. Move on to the next treatment zone. Repeatedly treating an area may result in complications.

35. If the Ablation Catheter size is too large for the esophagus, certain behaviors may be observed by the user. An Operational Code (E92) may display immediately upon attempting to deliver energy, indicating that energy was not delivered and that the esophagus is too narrow for the selected Ablation Catheter. If an E92 occurs, the user should remove the Ablation Catheter, reconsider the Sizing Worksheet, consider repeating the sizing steps, and select an appropriately sized Ablation Catheter. Also, migration of the Ablation Catheter during inflation may occur, blood may be observed on the catheter, and mucosal injury may occur, which are all indications that the Ablation Catheter size is too large for the esophagus. In all such cases, remove the Ablation Catheter, reconsider the Sizing Worksheet, consider repeating the sizing steps, and select an appropriately sized Ablation Catheter.
36. If the Ablation Catheter migrates distally during inflation and ablation, it is possible that treatment of a rim of proximal Barrett's tissue will be incomplete. Such migration is due to a narrowed portion of the esophagus or too large an Ablation Catheter. In this case, do not hold the Ablation Catheter in place to prevent migration nor should repeated attempts be made to treat the missed area, as these can lead to patient injury. Rather, the Sizing Worksheet should be reconsidered and the user may select a smaller Ablation Catheter for this area.
37. After energy is delivered, confirm that the Ablation Catheter balloon is fully deflated, then advance the Ablation Catheter by 3 cm and visualize the treatment zone. Keep the endoscope approximately 1 cm proximal to the balloon electrode for optimal visualization. By advancing 3 cm, the electrode is now aligned with the distal margin of the first treatment zone, which should be confirmed visually by the user. Repeat inflation, ablation, and repositioning until the distal end of the treatment zone overlaps the TGF. Do not permit excessive overlap between treatment zones, as this may predispose to stricture formation.
38. After confirming that the entire length of Barrett's esophagus is treated, position the endoscope immediately proximal to the Ablation Catheter electrode and balloon, ensure that the balloon and electrode are completely collapsed, then withdraw the endoscope and Ablation Catheter and guidewire together as a unit. During withdrawal, observe the balloon and electrode for any interaction with the esophageal tissue so as to ensure atraumatic removal. Do not remove the Ablation Catheter while leaving the endoscope in place, as this may result in patient injury, including perforation or laceration.

39. With the Ablation Catheter removed from the esophagus, inflate the balloon and clean the electrode surface in a circumferential direction with a clean moist 4x4 pad in the direction of the electrode rings, then deflate and prepare for reintroduction. Ensure that the Ablation Catheter is folded in a low profile before reintroduction.
40. Prior to the second set of ablations, it is recommended that the treatment zone be cleaned utilizing the HALO CAP or other soft distal endoscope attachment device. Insert the distal end of the endoscope into the proximal end of the HALO CAP, and then advance the endoscope into the cap until the tip of the endoscope is aligned with the distal ridge line inside the cap. The longest extent of the beveled edge should be positioned at the 12 o'clock position in the videoendoscopic view. Water may be used to lubricate the endoscope and cap to facilitate placement, but do not use alcohol or gel lubrication.



#### HALO CAP – SMALL (CP-001A)

- Recommended use for endoscopes with actual diameter between 8.8 mm – 9.7 mm. It is recommended to use the smaller HALO CAP (CP-001A) for the 9.5 mm endoscopes.
- Device compatibility was assessed for the following Olympus endoscope models: GIF-160, GIF-Q180, GIF-Q160.

#### HALO CAP – MEDIUM (CP-002A)

- Recommended use for endoscopes with actual diameter between 9.8 mm – 11.1 mm.
- Device compatibility was assessed for the following Olympus endoscope model GIF-H180.

41. Reintroduce the endoscope and inspect the treatment zone for completeness of treatment. Using the endoscope with irrigation and the HALO CAP, remove the coagulum from the coagulation zone. Irrigate with plain water. Evacuate all irrigation and air from the stomach and esophagus. Reinsert the guidewire. Remove endoscope.
42. Remove the HALO CAP from the endoscope and discard the CAP.
43. Reintroduce the Ablation Catheter over the guidewire, followed by the endoscope, as in Steps 24-28.
44. Visually reposition the Ablation Catheter so that the proximal margin is aligned with the most proximal treatment edge.
45. Repeat ablation steps [Steps 29-37] so that all areas are treated a second time.
46. Remove the Ablation Catheter and guidewire under direct visualization.
47. Repeat endoscopy to check for completeness of treatment and signs of unintended mucosal injury or bleeding.

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### REPRESENTATIVE DISCHARGE INSTRUCTIONS

#### SPECIFIC TO THE USE OF THIS DEVICE FOR THE SUB-INDICATION OF BARRETT'S ESOPHAGUS




***The following is a representation of the discharge instructions used for the Coagulation of Intestinal Metaplasia Trial (AIM-II). These instructions are not meant to replace physician judgment. Instructions provided to the patient are the responsibility of the physician.***

- Maximize anti-secretory regimen (for example, esomeprazole 40 mg twice per day for 1-3 months, followed by at least 40 mg per day thereafter).
- Antacid/lidocaine mixture per oral prn.
- Liquid acetaminophen with or without codeine per oral prn.
- Anti-emetic medication per rectum prn.
- Sucralfate oral suspension, one gram up to four times per day.
- Full liquid diet for 24 hours, then advancing to soft diet for 1 week.
- Avoid aspirin or non-steroidal anti-inflammatory medications for 7 days (per physicians' instructions).
- Patient instructed to contact treating physician immediately for significant chest pain, difficulty swallowing, fever, bleeding, abdominal pain, difficulty breathing, vomiting or other warning signs provided by the physician, so that the physician may complete the appropriate diagnostic work-up (contrast radiography, CT scan, or endoscopy) and/or provide the appropriate therapeutic intervention in order to avoid further complications.



- If the patient seeks care for a digestive issue from any healthcare personnel in the 6 months following the coagulation procedure, other than the treating physician, the treating physician should be consulted before any treatment is initiated.

**LABELING SYMBOLS**

<b>Attention: consult accompanying documents</b>	
<b>This product contains no detectable latex.</b>	
<b>This is a Single-Use device</b>	

**DISPOSAL OF USED PRODUCT**

Dispose of used catheters in accordance with all government regulations. The Ablation Catheter is a one-time use, disposable product.

**HALO<sup>360+</sup> Sizing Balloon**  
**Model 3441C**  
**INSTRUCTIONS FOR USE**

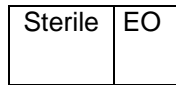
**CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a Physician.**

BÁRRX Medical, Inc.  
540 Oakmead Parkway, Sunnyvale, CA 94085 USA  
Telephone: 888-662-2779; 408-328-7310 Facsimile: 408-738-1741

**INDICATED USE**

The HALO<sup>FLEX</sup> and HALO<sup>360</sup> Energy Generators (inclusive of the HALO<sup>360+</sup> Sizing Balloon) is 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, Angiomata, Barrett's Esophagus, Dieulafoy Lesions, and Angiodysplasia.

**EU, Canada:** The HALO<sup>360</sup> System is indicated for use in the coagulation of bleeding and non-bleeding sites in the gastrointestinal tract including but not limited to Barrett's Esophagus.



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**HALO<sup>360+</sup> SIZING BALLOON: AVAILABLE SIZES**

The HALO<sup>360+</sup> Sizing Balloon has a nominal diameter of 47.5 mm and is used to size esophageal diameters from 18 mm-34 mm.

The HALO<sup>360+</sup> Ablation Catheters are referred to in this Instructions For Use as the "Ablation Catheter". The HALO<sup>360+</sup> Sizing Balloon is referred to as the "Sizing Balloon". The HALO<sup>FLEX</sup> or HALO<sup>360</sup> Energy Generator is referred to as the "Energy Generator". The HALO<sup>FLEX</sup> or HALO<sup>360</sup> Output Cable is referred to as the "Output Cable". The HALO<sup>FLEX</sup> or HALO<sup>360</sup> Footswitch is referred to as the "Footswitch".

**GENERAL WARNINGS AND PRECAUTIONS**



The safe and effective use of the HALO<sup>360+</sup> Sizing Balloon is highly dependent upon factors under the control of the operator. There is no substitute for a properly trained medical staff. It is important that the operating instructions supplied with the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Systems and Sizing Balloon be read, understood and followed before use.

**GENERAL WARNINGS**

- Do not use this device for any purpose other than the indicated use.
- Inspect the device packaging before use and do not use device if any damage to inner pouch or device is observed.
- Do not advance or retract the Sizing Balloon if resistance is met.
- Prior to repositioning or removal, ensure complete deflation of the Sizing Balloon.
- It is necessary to use the supplied FL-200C filter, placed between the pneumatic connector located at the proximal end of the Sizing Balloon or Ablation Catheter and the pneumatic connector on the Output Cable to ensure fluids are not aspirated into the Output Cable in the event of a catheter leak. If the catheter is used without the filter, and a balloon leak occur, inspect the clear tubing portion of the connecting cable for traces of fluid. If fluid is detected, discontinue the use of the cable and order a replacement. The Sizing Balloon should only be used with the FL-200C filter. Use of another filter may cause restricted air flow and lead to errors during use.
- If the Generator displays an E95 Operational Code, this is most likely caused by an air leak in the catheter. If the E95 Operational Code is observed, under endoscopic visualization, manually deflate the balloon using a syringe and remove and replace the catheter.
- Calibration of the Sizing Balloon must be completed with the balloon centered within the supplied calibration sleeve. Failure to do so will lead to a calibration error. After successful calibration, the calibration sleeve should be discarded prior to insertion into the patient.
- Do not store the Sizing Balloon near flame or temperatures in excess of 35°C.

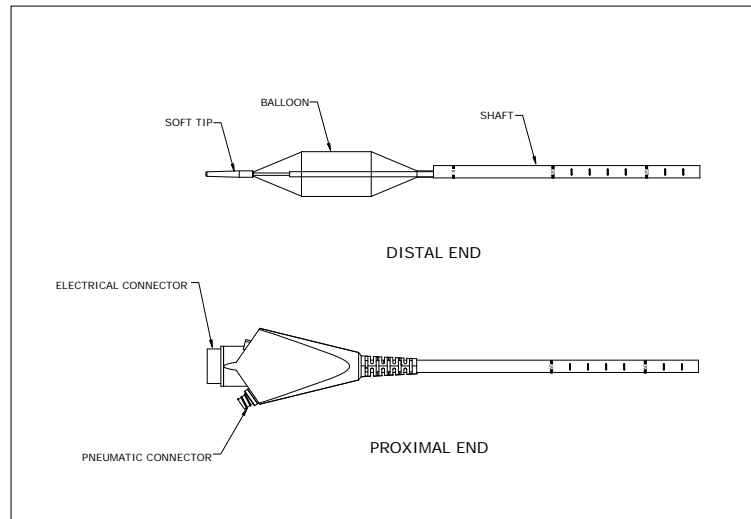
**GENERAL PRECAUTIONS**

- The Sizing Balloon is for use with the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Systems only.
- The Sizing Balloon should only be used by a physician trained in therapeutic endoscopy.
- Sizing Balloon may be used with endoscopic visualization.

**CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS FOR THE SUB-INDICATION OF BARRETT’S ESOPHAGUS**




See Instructions for Use for the HALO<sup>360+</sup> Ablation Catheter for Contraindications, Warnings and Precautions related to the use of the HALO<sup>FLEX</sup> and HALO<sup>360</sup> Systems (inclusive of the HALO<sup>360+</sup> Sizing Balloon) for the sub-indication of Barrett’s esophagus.

**SIZING BALLOON: DEVICE OVERVIEW**



- The Sizing Balloon consists of a balloon, a shaft, a thru lumen, pneumatic (inflation) connectors, electrical connectors, a calibration sleeve, a balloon cover, and a filter.
- The pneumatic port connector is a female luer-lock fitting. The Energy Generator incorporates an inflation system that connects to the Sizing Balloon via the male luer-lock fitting on the Output Cable. The HALO<sup>FLEX</sup> and HALO<sup>360</sup> Energy Generator are the only devices that should be used to inflate the Sizing Balloon. When connected to the Energy Generator, the inflation system will provide the correct inflation pressure. Refer to the HALO<sup>FLEX</sup> and HALO<sup>360</sup> System User’s Manuals for complete instructions on the use of the inflation system.
- Note that the balloon will not be visible since it is contained within a cover. The cover should be removed prior to calibration. During cover removal, ensure the calibration sleeve remains centered over the balloon. After successful calibration in the calibration sleeve, the sleeve should be removed before insertion into the patient.
- If any abnormalities exist that would affect the functionality of the Sizing Balloon, such as breaks, tears, bends or kinks, do not use.

**LABELING SYMBOLS**

<b>Attention: consult accompanying documents</b>	
<b>This product contains no detectable latex.</b>	
<b>This is a Single-Use device</b>	

**DISPOSAL OF USED PRODUCT**

Dispose of used sizing balloons in accordance with all government regulations. The Sizing Balloon is a one-time use, disposable product.



**AUTHORIZED EUROPEAN REPRESENTATIVE:**

WMDE  
Bergerweg 18  
6085 AT Horn  
The Netherlands