

HALO⁹⁰ System

Advanced Ablation Technology for Treating
Barrett's Esophagus

See it,

Treat it



The HALO⁹⁰ System

Advanced Ablation Technology for Barrett's Esophagus



The HALO⁹⁰ System is designed to remove Barrett's epithelium in a short, well-tolerated endoscopic procedure and offers an alternative to "watchful waiting" for patients with intestinal metaplasia, low-grade dysplasia, and high-grade dysplasia.

The HALO⁹⁰ System enables physicians to provide primary treatment for short segments of Barrett's esophagus, or provide secondary treatment after ablation with the HALO³⁶⁰ System, or other therapeutic devices.

Advanced HALO Technology, Clinically Tested¹

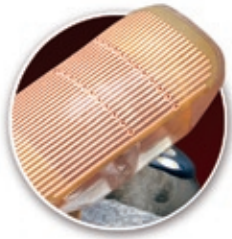
- Tightly controlled, uniform ablation of the epithelium
- Clinical evaluations completed for all types of Barrett's tissue: intestinal metaplasia, low-grade dysplasia, and high-grade dysplasia
- Treatment of the gastroesophageal junction and "Z" line
- No strictures, perforations, or serious adverse events reported in any clinical studies
- Retreatment is possible, if required
- Leading-edge-technology results in fast, straightforward, consistent treatment

Designed for the Endoscopist



Streamlined Profile

- Provides easy introduction into upper GI tract
- Allows positioning within the esophagus and gastroesophageal junction



Optimal Electrode Size

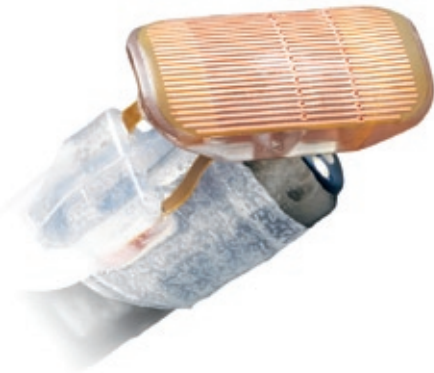
- Treatment for short segment Barrett's including focal areas such as islands and small tongues
- Leaves a definitive, identifiable ablation zone
- Allows complete treatment of gastroesophageal junction



Identifiable ablation zone

Endoscope-Mounted

- Provides for direct visualization of electrode during procedure
- Utilizes standard endoscopic technique
- Articulated electrode platform moves in 2-D, left to right & front to back, to assure tissue contact



Optimal Electrode Surface Area
(20mm x 13mm)

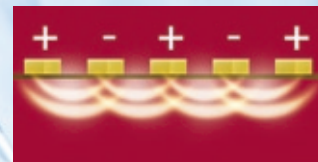
Revolutionary Electrode Array Technology

- Controls depth of energy delivery (<1mm), reducing risk of stricture formation^{16,7}
- Maximizes clinical outcomes without significant injury to the underlying tissue and allows for the re-growth of healthy tissue^{4,5}
- Consistent application of energy uniformly removes the epithelium, reducing potential for buried glands and improving patient tolerability



Normal Epithelium After Ablation

No strictures reported in any clinical study using the HALO⁹⁰ System.⁵



HALO⁹⁰ Ablation Catheter Electrode

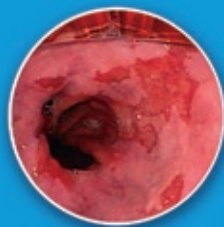
Tight bipolar electrode array spacing and very short ablation "on time" controls depth of ablation to < 1mm.^{2,3}

Using standard endoscopic techniques the HALO System facilitates rapid ablation of Barrett's in 3 simple steps:



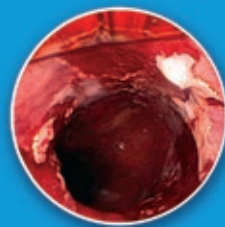
STEP 1: MOUNT

Mount ablation catheter onto endoscope.



STEP 2: IDENTIFY

Deploy HALO⁹⁰ Ablation Catheter and endoscope. Identify the anatomic landmarks and the Barrett's epithelium.



STEP 3: ABLATE

Move the HALO⁹⁰ Ablation Catheter to cover the targeted tissue and deflect the endoscope upward confirming good contact. The catheter ablates a 20mm x 13mm area of Barrett's epithelium in less than 1 second.



ELIMINATE

The HALO⁹⁰ System



1. HALO⁹⁰ Energy Generator — 90-9000

Proprietary high-power energy generator supplies power to the ablation catheter to control tissue ablation.

Accessories included with energy generator:

- **Footswitch 90-9020**
Hands-free activation of energy delivery function
- **Output Cable 90-9010**
Connection cable for the ablation catheter to the energy generator

2. HALO⁹⁰ Ablation Catheter — 90-9100

Proprietary bipolar electrode array delivers energy to the targeted tissue.

- Single use HALO⁹⁰ catheter fits on distal end of a flexible endoscope
- Recommended scope sizes: 8.6mm to 12.8mm
- Electrode dimensions:
20.62mm length x 13.21mm width
- Active Electrode dimensions:
20mm length x 13mm width
- Catheter shaft length: 160cm
- Catheter shaft diameter: 4mm

To find out more about the HALO⁹⁰ System or to place an order, contact BARRX Medical.

INDICATED USE: The HALO⁹⁰ Ablation System (inclusive of the HALO⁹⁰ 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.

NOTE: Consult Instructions for Use for full contraindications, warnings, and precautions.

References:

- 1 Data are referenced elsewhere in this document. Refer to subsequent footnotes for specific references. (2-5 back up the use of the technology in all types of BE as well as the other statements in that section)
- 2 Sharma et al. Successful circumferential ablation of Barrett's esophagus (BE) with low-grade dysplasia (LGD): one-year follow-up of the AIM-LGD pilot trial. DDW abstract, 2006.
- 3 Wells et al. Ablation of Barrett's esophagus (BE) with LGD using the HALO360 Ablation System: a single center experience. DDW abstract, 2006.
- 4 Ganz et al. Treatment of Barrett's esophagus with high-grade dysplasia using the HALO360 Ablation System: a multi-center experience. DDW abstract, 2006.
- 5 Sharma VK, Overholt B, Wang K, et al. A randomized, multi-center evaluation of ablation of nondysplastic short segment Barrett esophagus using BARRX bipolar balloon device: extended follow-up of the Ablation of Intestinal Metaplasia (AIM)-I Trial. Gastrointest Endosc. 2005;61(special issue):AB239.
- 6 Ganz RA, Utley DS, Stern RA, Jackson J, Batts KP, Termin P. 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.
- 7 Dunkin BJ, Martinez J, Bejarano PA, et al. Thin-layer ablation of human esophageal epithelium using a bipolar radiofrequency device. Surg Endosc. 2006;20:125-130.
- 8 Sharma VK, et al. Circumferential endoscopic ablation of Barrett's esophagus by using a balloon-based system: 1-year follow-up of 100 patients. Gastrointest Endosc. 2007.
- 9 Bergman et al. Balloon-based radiofrequency ablation of Barrett's esophagus in patients with low-grade dysplasia or high-grade dysplasia with and without prior endoscopic resection using the HALO360 Ablation System. DDW abstract, 2006.
- 10 Chang K, et al. Focal ablation of Barrett's Esophagus using a novel endoscopic device. DDW abstract, 2006



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