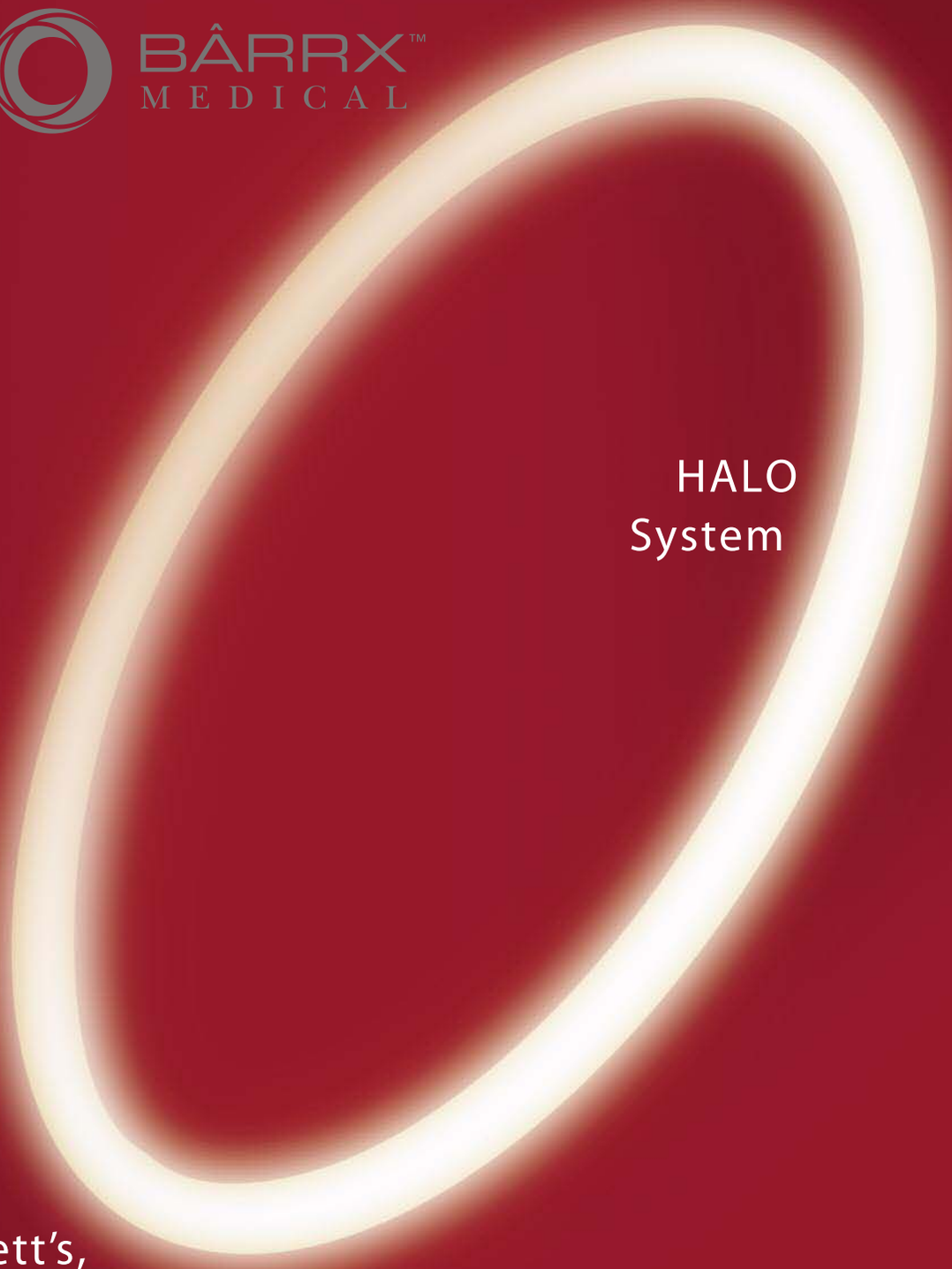
BÂRRX™
MEDICAL



HALO
System

Treat Barrett's,

Remove the Risk

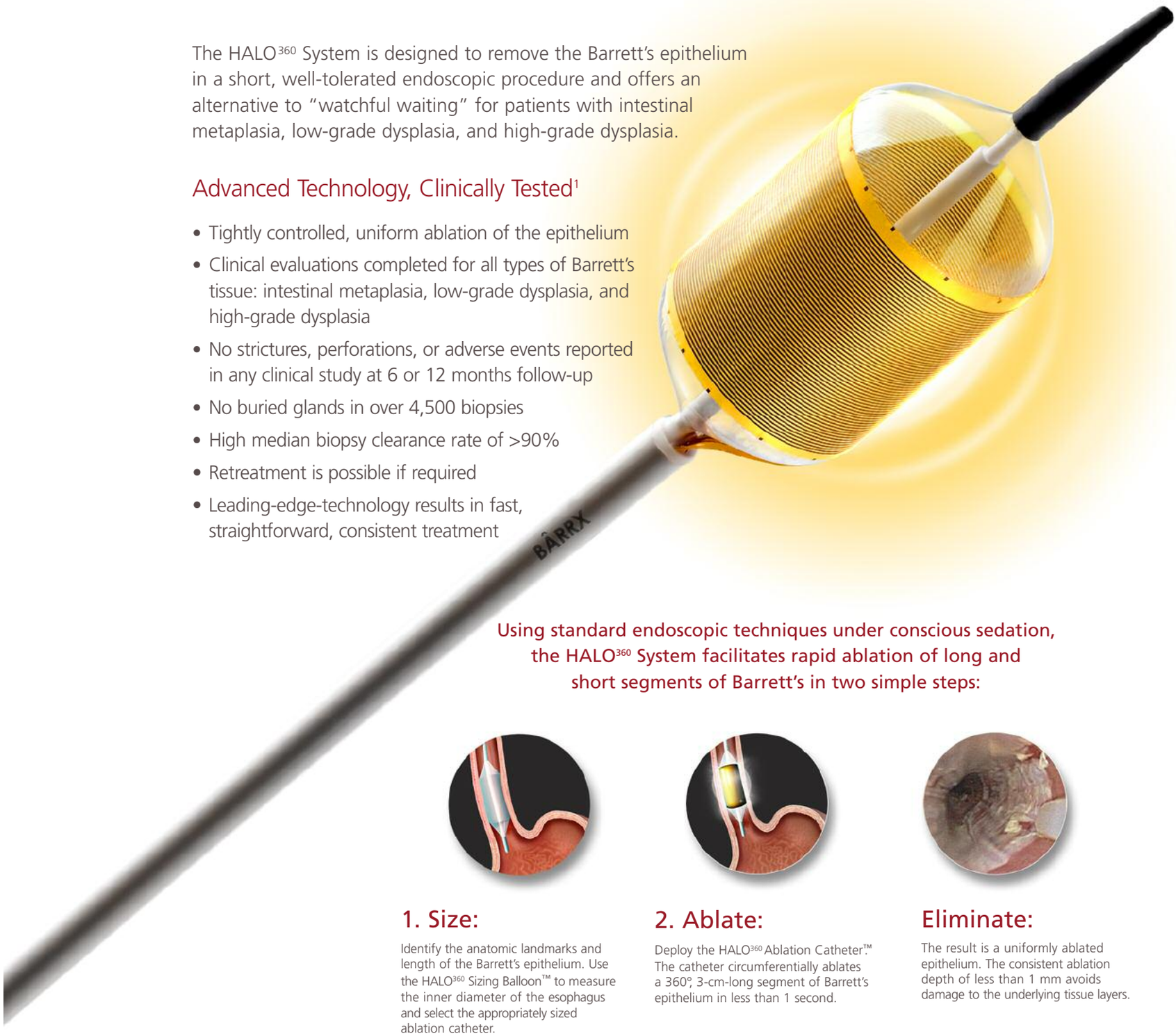
The HALO^{360} System™

Advanced Ablation Technology for Barrett's Esophagus

The HALO^{360} System is designed to remove the 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.

Advanced Technology, Clinically Tested[1]

- 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
- No strictures, perforations, or adverse events reported in any clinical study at 6 or 12 months follow-up
- No buried glands in over 4,500 biopsies
- High median biopsy clearance rate of >90%
- Retreatment is possible if required
- Leading-edge-technology results in fast, straightforward, consistent treatment



Using standard endoscopic techniques under conscious sedation, the HALO^{360} System facilitates rapid ablation of long and short segments of Barrett's in two simple steps:

1. Size:

Identify the anatomic landmarks and length of the Barrett's epithelium. Use the HALO^{360} Sizing Balloon™ to measure the inner diameter of the esophagus and select the appropriately sized ablation catheter.

2. Ablate:

Deploy the HALO^{360} Ablation Catheter™. The catheter circumferentially ablates a 360°, 3-cm-long segment of Barrett's epithelium in less than 1 second.

Eliminate:

The result is a uniformly ablated epithelium. The consistent ablation depth of less than 1 mm avoids damage to the underlying tissue layers.

Precise Ablation, Predictable Results.

The advanced, proprietary technology incorporated in the HALO360 System is designed to maximize clinical outcomes and completely remove the Barrett's esophageal epithelium without significant injury to the underlying tissue:

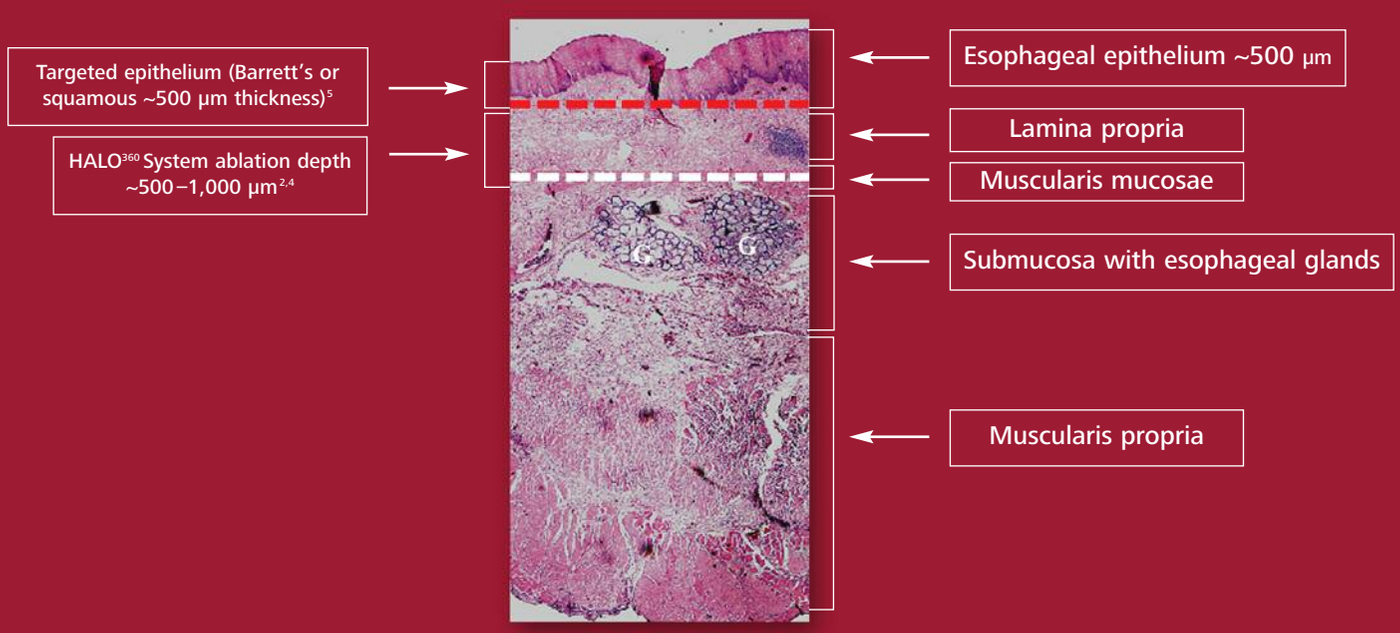
- Circumferential, 360°, 3-cm-long ablation in less than 1 second allows long segments of Barrett's to be treated quickly[2]
- Consistent application of bipolar energy uniformly removes the esophageal epithelium, reducing potential for buried glands and improving patient tolerability[2,3]
- Controlled treatment depth of less than 1,000 µm reduces risk of stricture formation, even after multiple energy applications[2,4,*]

*Current stricture rate including all patients (N=600) treated in clinical studies and post-clinical studies is ~1%.

Precise Depth Control

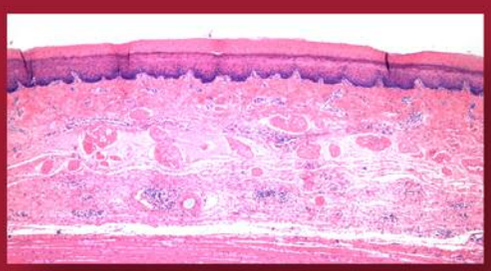
Barrett's epithelium is approximately 500 µm in thickness.[5] The HALO360 Energy Generator™ and the HALO360 Ablation Catheter electrode array are designed to work in concert to achieve a uniform, superficial depth of ablation of ~1,000 µm.[2,4]

Human Esophagus Specimen (H&E Stain)

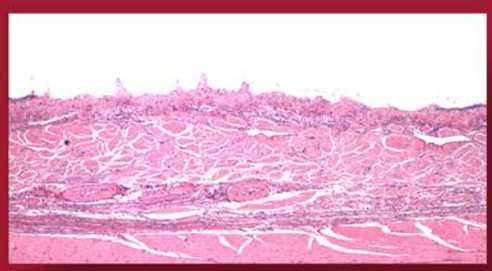


Predictable Outcome

In both porcine and human esophagectomy studies, the HALO360 System has demonstrated removal of the esophageal epithelium without significant injury to the submucosa when using the recommended treatment settings.



Non-ablated esophagus Epithelium intact



48 hours post-ablation Absence of epithelium with preservation of lamina propria and muscularis mucosae

HALO360 Ablation Catheter Electrode

Bipolar electrode array geometry precisely controls the depth of ablation to < 1 mm.[2,4]

HALO^{360} System™ Clinical Results.

Clinical Methods

The HALO^{360} System has been extensively studied in rigorous animal and human studies conducted since 2002:

- Human esophagectomy and animal studies defined the histological depth of ablation and uniform epithelium removal
- Dosimetry studies defined safe and effective energy dose and treatment parameters to minimize the risk of strictures
- Rigorous four-quadrant biopsy protocol every 1, 3, 6, and 12 months to obtain histological evidence of the resolution of intestinal metaplasia/dysplasia

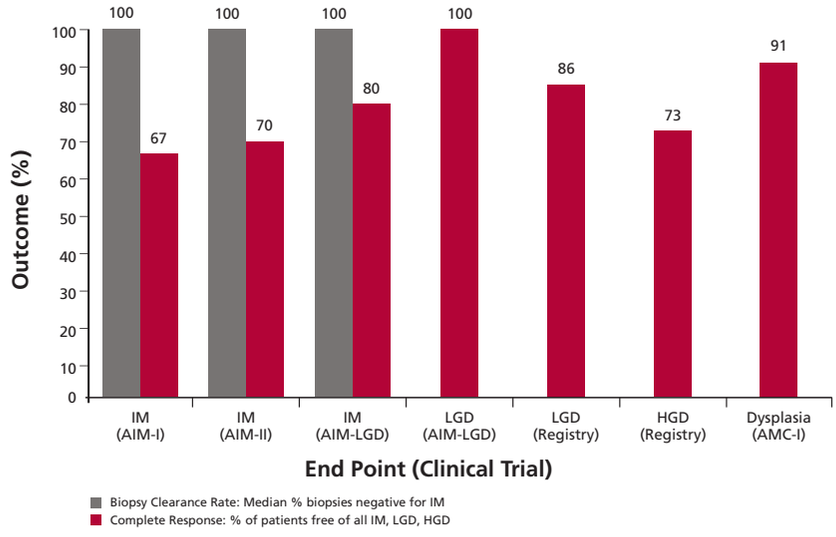
Data from several multicenter clinical trials show that ablation may completely cure many patients:

- 90% of biopsies free of Barrett's after ablation in clinical study patients*
- Majority of patients with intestinal metaplasia, low-grade dysplasia, and high-grade dysplasia were completely free of Barrett's following ablation†

* Biopsy clearance rate is defined as the percent of biopsies per patient per EGD that are negative for IM or dysplasia (as defined in the specific study primary end point).
† Cure is defined as complete absence upon biopsy of IM or dysplasia (as defined in the specific study primary end point).

Clinical Efficacy[6-9]

HALO^{360} Results for Ablation of Intestinal Metaplasia and Dysplasia



Clinical Safety

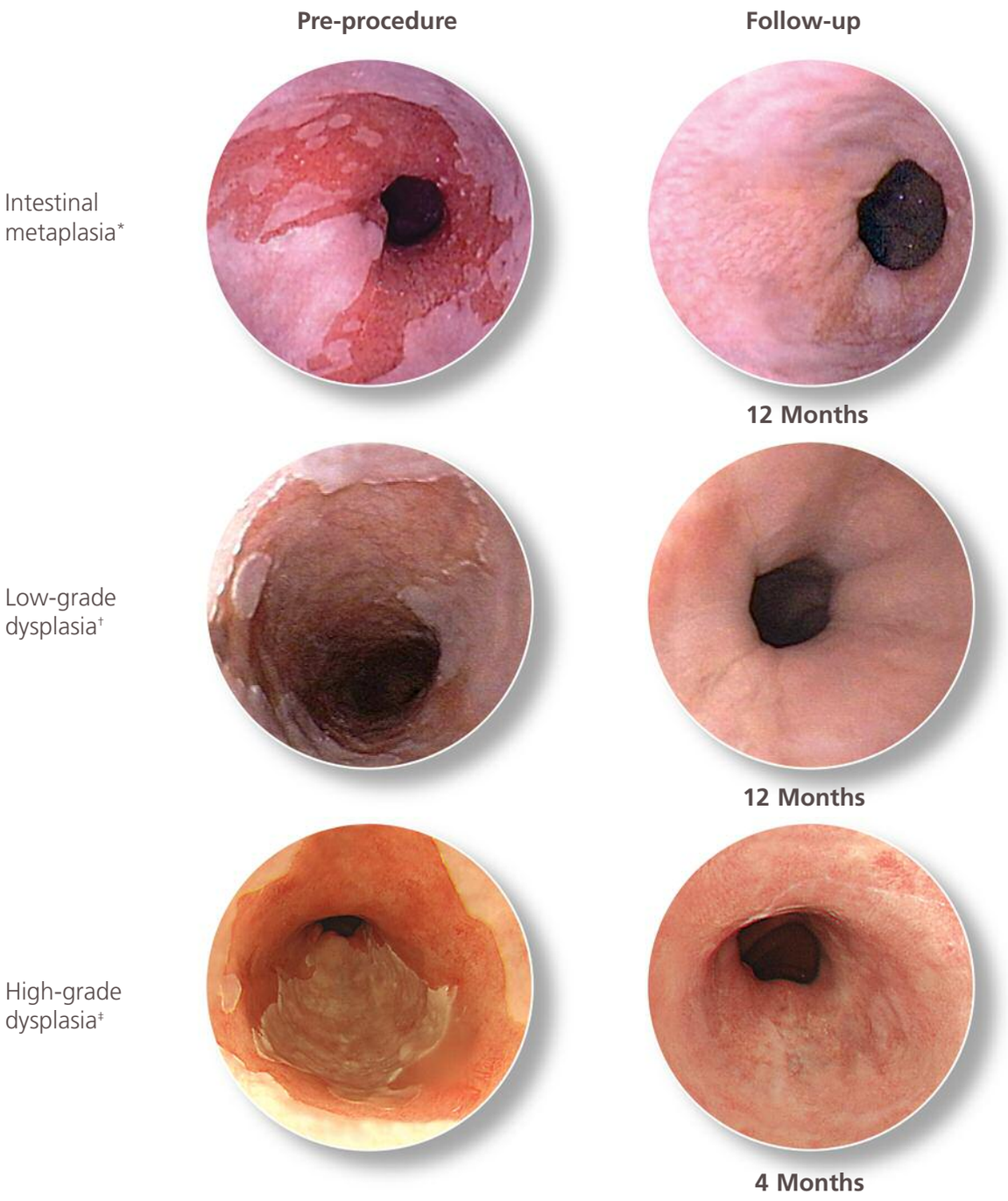
The HALO^{360} System has been shown to be safe. In clinical studies, no device-related serious adverse events have been reported.[10]

- No perforations
- No strictures reported in clinical studies at 6 or 12 months follow-up‡
- No buried glands in over 4,500 four-quadrant large-cup biopsies taken every 1–2 cm read by independent, blinded pathologist[3]
- Well-tolerated outpatient procedure; median procedure time <28 minutes[10]

‡ Current stricture rate including all patients (N=600) treated in clinical studies and post-clinical studies is ~1%.

360° Ablation—Complete Healing of Dysplastic and Non-Dysplastic Barrett's

Studies show that following treatment with the HALO360 System, neosquamous cells begin to grow immediately—with complete healing in approximately 8–12 weeks.[9–12] In areas free of Barrett's at follow-up, there have been no noted areas of Barrett's regrowth.



* Courtesy of A. Reymunde, N. Santiago, AIM-II Clinical Trial, Ponce, PR.
† Courtesy of V.K. Sharma, Mayo Scottsdale, AZ.
‡ Courtesy of Jacques Bergman, AMC Amsterdam.

Why Treat Barrett's Esophagus?

The Facts About Barrett's Esophagus

- Approximately 3 million Americans have Barrett's esophagus[13-15]
- Patients with Barrett's esophagus are 40–130 times more likely to develop adenocarcinoma than the general population[16]
- Adenocarcinoma is the fastest-rising cancer in the U.S.[17,18]
- Even with aggressive therapy, the 5-year survival rate from adenocarcinoma is only approximately 16%[19]

The fact is that Barrett's esophagus is a precancerous condition that can lead to adenocarcinoma.[16] Colon polyps advance to cancer at a rate of approximately 0.5% per year…a rate virtually identical to the rate Barrett's esophagus progresses to cancer.[20,21]

Progression of Intestinal Metaplasia to Low-Grade Dysplasia, High-Grade Dysplasia, and Cancer[20]

Diagnosis	% Risk in 4 Years	% Risk per Year
Intestinal metaplasia advancing to low-grade dysplasia	16.1%	4.3%
Intestinal metaplasia advancing to high-grade dysplasia	3.6%	0.9%
Cancer	2.0%	0.5%
Colon polyp advancing to cancer[21]	NA	0.5%

The standard of care for other precancerous conditions such as polyps is to remove the suspected lesion immediately. Yet the current standard of care of Barrett's esophagus is to survey patients on a periodic basis and to "watch and wait." Patients with intestinal metaplasia have a combined 1.4% risk per year of progressing to high-grade dysplasia or cancer—which may result in an esophagectomy procedure.

Ablation with the HALO360 System™ allows early intervention and treatment of intestinal metaplasia, low-grade dysplasia, and high-grade dysplasia and removal of this pre-malignant tissue.

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1 Data are referenced elsewhere in this document. Refer to subsequent footnotes for specific references.
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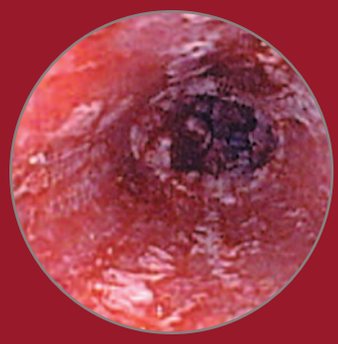
Complete Ablation. Rapid Healing.

Baseline
3 cm of Barrett's

Immediate post-ablation
Sloughing of Barrett's



Three-month follow-up
Healed esophageal lining
with no Barrett's

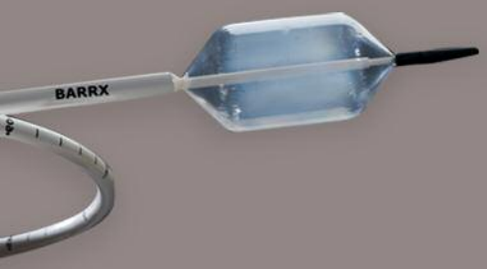
The HALO^{360} System™

1. The HALO^{360} Energy Generator™ — 1100C-115B

Proprietary 300-watt RF energy generator automates the sizing procedure, sets the ablation parameters, and supplies energy to the ablation catheter.

Accessories included with the purchase of the energy generator:

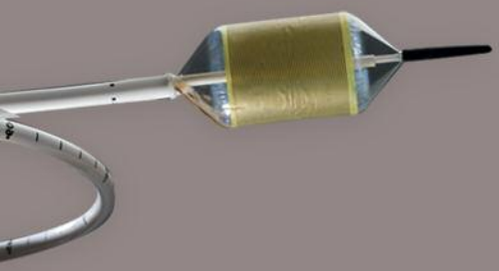
- **The HALO^{360} Footswitch™ — FS-100B**
  Hands-free activation of sizing and energy delivery functions
- **The HALO^{360} Output Cable™ — CCC-001B**
  Connection cable for the sizing balloon and the ablation catheter to the energy generator



2. The HALO^{360} Sizing Balloon™ — 3441B

Works with HALO^{360} Energy Generator to measure the esophageal inner diameter.

- Diameter of balloon: 33.7 mm
- Balloon length: 4 cm
- Catheter shaft length: 100 cm



3. The HALO^{360} Ablation Catheter™

360° electrode array delivers a short burst (< 1 sec) of ablative energy circumferentially to the esophagus.

- Balloon length: 4 cm
- Electrode length: 3 cm
- Catheter shaft length: 100 cm
- Available Diameter Sizes:

22 mm……..31041-22
25 mm……..31041-25
28 mm……..31041-28
31 mm……..31041-31
34 mm……..31041-34

4. The HALO^{360} Filter™ — FL-200B

Disposable and single-use .45-µm hydrophobic filter to be used with both the ablation catheter and the sizing balloon.

To find out more about the HALO^{360} System or to place an order, contact BÂRRX Medical.

The HALO^{360} System is indicated for use in the coagulation of bleeding and nonbleeding sites in the esophagus. Indications include esophageal ulcers, Mallory-Weiss tears, arteriovenous malformations, angiomata, Barrett's esophagus, Dieulafoy lesions, and angiodysplasia.

CONTRAINDICATIONS: Pregnancy, prior radiation therapy to the esophagus, esophageal varices at risk for bleeding, prior Heller myotomy.

WARNINGS: Complications that have been observed in U.S. clinical studies include: mucosal laceration and minor acute bleeding. The following are side effects that may be expected after treatment (all transient): chest pain, dysphagia, odynophagia, throat pain and/or fever after treatment. Side effects should be managed by the physician at their discretion.

- Potential complications not observed to date in U.S. clinical trials include: perforation of the stomach, esophagus, or pharynx; surgery to correct perforation; stricture formation requiring dilation; infection; pleural effusion; arrhythmia; major bleeding; transfusion secondary to major bleeding; aspiration; death.
- Vomiting post-treatment must be addressed by the physician, as it may result in more 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, ablative procedures of the esophagus, and/or respective procedures of the esophagus may predispose patient to esophageal stricture formation after treatment with this device given the altered anatomy, physiology, and wound-healing characteristics inherent to these disease states and therapies.

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

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