



Barrx™ Radiofrequency Ablation Systems
Advanced RF Ablation Technology for Treating
Barrett's Esophagus



COVIDIEN

positive results for life™

Barrx™ RF Ablation Systems

ADVANCED RF ABLATION TECHNOLOGY FOR TREATING BARRETT'S ESOPHAGUS

The Barrx™ RF ablation system is designed to remove the Barrett's esophagus epithelium in a short endoscopic procedure that patients tolerate well. Recognizing the need to reduce risks of progression to cancer, many physicians searched for therapies that would replace the “watch and wait” Barrett's esophagus management protocol with a “diagnose and treat” standard of care.

The Barrx™ RF ablation system offered by Covidien GI Solutions provides a uniform and controlled ablative therapy at a consistent depth. It can remove the layer of diseased tissue while sparing healthy underlying tissue. This allows regrowth of new, healthy tissue within eight weeks.

Barrx™ RF ablation systems include a growing line of ablation catheters designed to treat circumferential disease as well as smaller areas such as islands and tongues. The single-use disposable catheters work together with an RFA energy generator to deliver the appropriate level of energy to the diseased tissue.



The Barrx™ Flex RFA Energy Generator (shown above on the Barrx™ RFA Cart) can be used with either circumferential or focal catheters



Barrx™ RF ablation systems include an ever-evolving family of balloon catheters for treating large areas of disease, and focal catheters for treating smaller areas such as islands and tongues, and for residual disease touch-up.

Shown, left to right: Barrx™ 360 RFA Balloon Catheter, Barrx™ Ultra Long RFA Focal Catheter, Barrx™ 90 RFA Focal Catheter, Barrx™ 60 RFA Focal Catheter, and Barrx™ Channel RFA Endoscopic Catheter

CLINICALLY TESTED

Clinical evaluations have been completed for the treatment of all grades of Barrett's esophagus with the Barrx™ RF ablation technology:

- Comprehensive results have been reported in more than 90 peer-reviewed publications, including the New England Journal of Medicine.
- The multi-center US RFA Patient Registry has allowed for treatment and follow-up of over 5,500 patients under a centralized IRB approved protocol.
- Robust level 1 evidence supports the Barrx™ technology with three randomized controlled trials published or interim results presented.¹⁻³



Barrx™ RFA catheters come in a variety of configurations to treat diseased areas of different sizes and shapes. Shown, left to right: Barrx™ Ultra Long RFA Focal Catheter, Barrx™ 90 RFA Focal Catheter, Barrx™ 60 RFA Focal Catheter, and Barrx™ Channel RFA Endoscopic Catheter

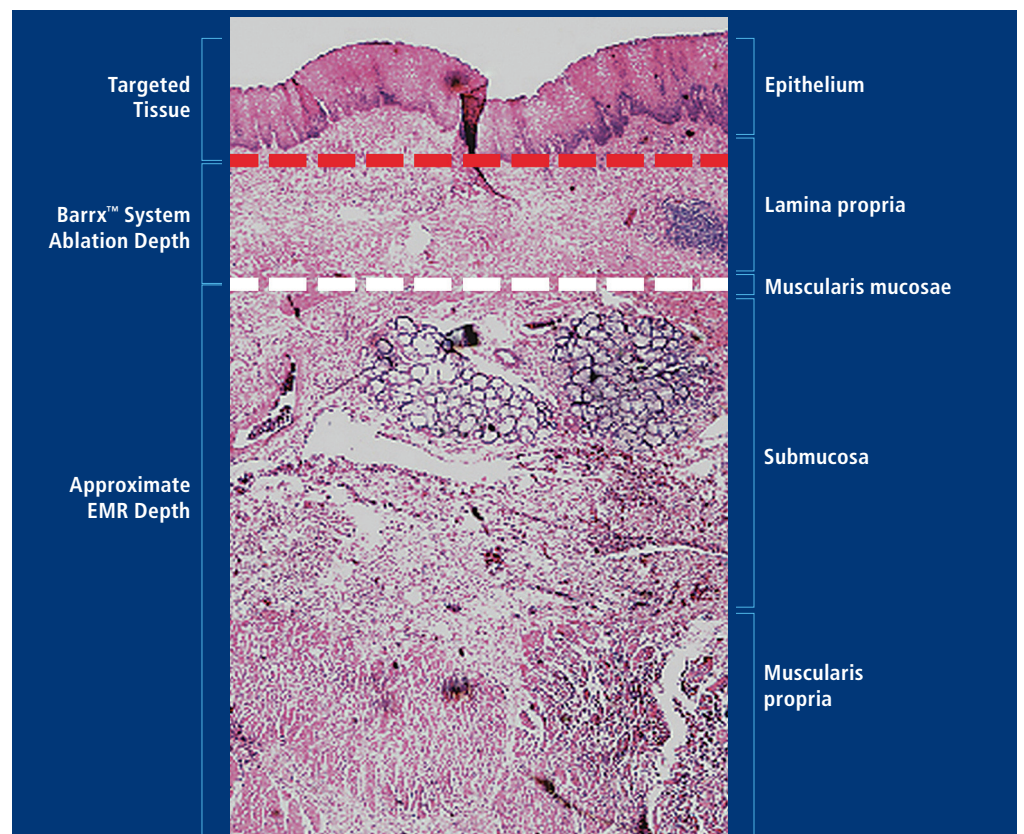
Precise Ablation, Predictable Results

PRECISE ABLATION

The ability to provide a controlled amount of ablative therapy to diseased tissue significantly reduces the risk of complications.

The Barrett's epithelium is approximately 500 μm thick. The energy generator and the Barrx™ RF ablation catheter electrode arrays are designed to work in concert to achieve a uniform, superficial depth of ablation between approximately 500 μm and 1,000 μm .

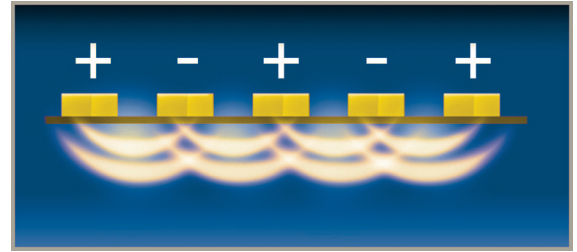
Human Esophagus Specimen



PREDICTABLE RESULTS

The proprietary technology in Barrx™ RF ablation systems is designed to maximize clinical outcomes and remove the Barrett's epithelium without significant injury to the underlying tissue.

- Delivery of ablative energy in less than one second allows long or short segments of Barrett's to be treated quickly.
- Consistent application of bipolar energy uniformly removes the esophageal epithelium, reducing potential for buried glands and helping patients tolerate the procedure.
- Controlled treatment depth of less than 1,000 µm reduces the risk of stricture formation.

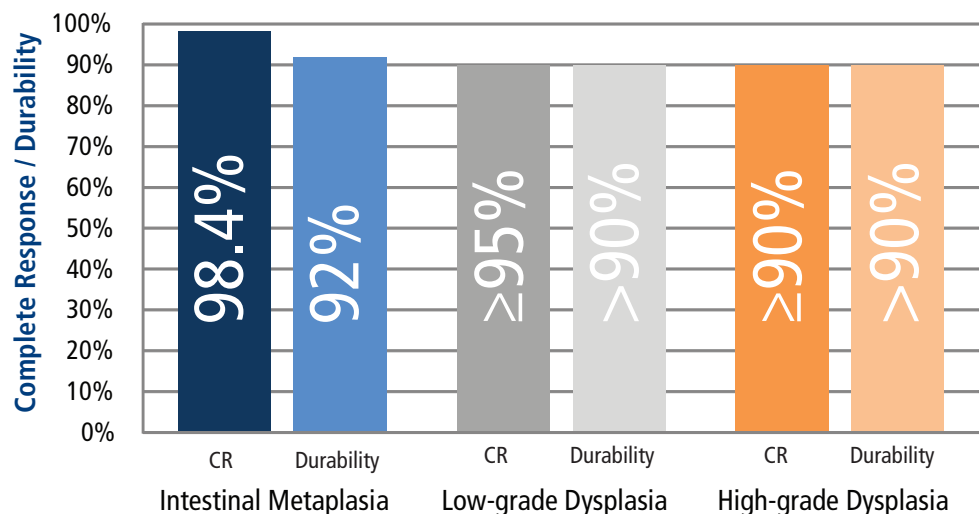


Barrx™ Ablation Catheter Electrode

The geometry of the bipolar electrode array helps to precisely control the depth of ablation to < 1000 µm

Clinical Results

Complete Response (CR) and Durability of RFA in Prospective Clinical Trials^{1-5,8*†}



* Eradication and durability rates based on initial diagnosis and one or more clinical trials.

† In clinical studies, most patients required one circumferential ablation procedure and one or two focal ablation procedures.

Complete response and durability defined per trial.

RESULTS

Clinical studies have been completed in the United States and Europe demonstrating the safety and efficacy of the Barrx™ technology for treating all grades of Barrett's esophagus.

- The Ablation of Intestinal Metaplasia (AIM) Trial showed that 98.4% of patients with baseline non-dysplastic IM were completely free of all Barrett's tissue after 2.5 years of follow-up.⁴
- The AIM-Dysplasia and SURF randomized controlled trials utilized RFA to treat LGD and reported complete eradication of dysplasia in $\geq 95\%$ of cases and IM in $\geq 85\%$ of cases.^{1,2}
- Several US and European trials have studied the use of RFA in HGD and reported complete eradication of dysplasia in $\geq 90\%$ of cases and IM in $\geq 82\%$ of cases.^{2,3,5}

The long-term durability of Barrett's eradication after treatment with RFA has also been studied.

- The AIM-II Trial found a durable complete response in 92% of non-dysplastic patients five years after RFA.⁴
- The AIM-Dysplasia Trial showed a durable complete response in $>90\%$ of dysplastic subjects at two and three years after treatment.⁶
- A European prospective trial for HGD and intramucosal cancer using RFA \pm endoscopic mucosal resection revealed durable eradication at five year follow-up in $>90\%$ of patients.⁵
- A meta-analysis evaluated six studies on the long-term outcomes after RFA with a total of 540 patients and showed an overall durability of 87%.⁷
- In most studies, recurrent Barrett's was primarily IM at the gastroesophageal junction (raising the possibility of cardia sampling), occupied a small surface area, and was managed endoscopically.

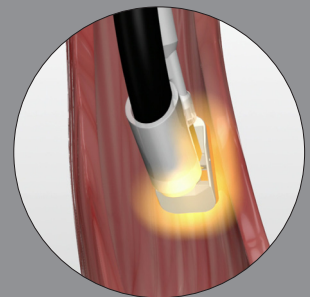
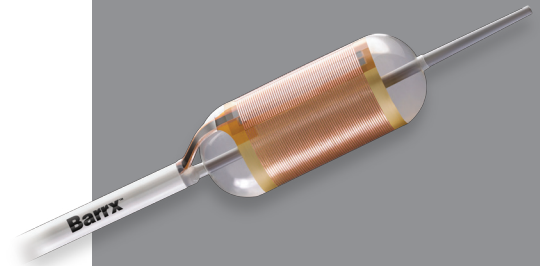
Two randomized controlled trials have demonstrated that RFA significantly reduces neoplastic progression in patients with dysplastic Barrett's esophagus.

- Interim results of the SURF Trial for confirmed LGD showed a fourteen fold decrease in progression to HGD or cancer after RFA as compared to surveillance.¹
- The AIM-Dysplasia Trial demonstrated an eight fold reduction in progression to cancer in patients with HGD after RFA as compared to surveillance.²

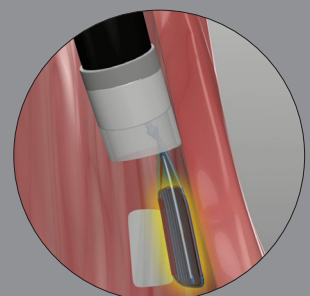
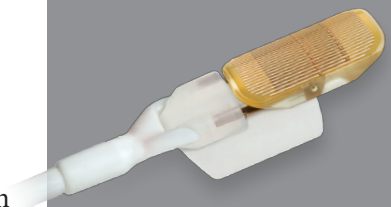
Subsquamous intestinal metaplasia (SSIM) occurs when Barrett's glands are buried beneath the squamous epithelium. Current evidence supports that SSIM is part of the natural history of BE, is uncommon after RFA, and that RFA actually treats this phenomenon.^{2,8,9}



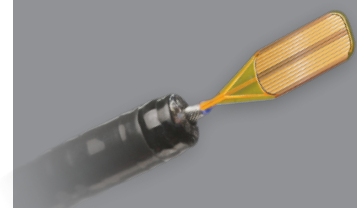
Treating circumferential disease with a Barrx™ balloon catheter.



Treating a small area of disease with a Barrx™ focal catheter.



Treating a small area of disease with a Barrx™ Channel RFA Endoscopic Catheter.

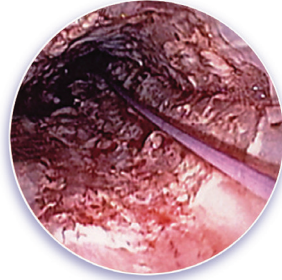


Complete Ablation. Rapid Healing.

Following treatment with the Barrx™ RF ablation system, a neosquamous epithelium appears within weeks. Complete healing occurs in approximately 8-12 weeks.²



SEE.



TREAT.



COMPLETE.

Product Support Services

In addition to high quality and clinical efficacy, Covidien GI Solutions backs your Barrett's program with these offerings:

- Reimbursement Services – Dictation tools, coding guides, and claims assistance through a third party resource are available for your RFA program
- Outreach Services – The Covidien REACH program offers many resources and templates to help you reach out effectively to patients, referring physicians and the broader community

Continuing Progress in Barrett's Esophagus Treatment

Treatment of Barrett's esophagus is a valuable technique for reducing progression to esophageal cancer^{1,2} and Covidien GI Solutions is committed to continuous improvement in RFA treatment technology. Our aim is to develop solutions that are progressively more effective, more affordable, and more comfortable for patients. For more information, visit www.barrx.com.



NOTE: The complication rate associated with radiofrequency ablation (RFA) using Barrx™ RF ablation catheters has been demonstrated to be low. However, as with most endoscopic and surgical procedures, there are risks associated with RFA, including serious complications. For complete information regarding indications for use, warnings, precautions, adverse events and methods of use, please reference the devices' Instructions for Use.

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540 OAKMEAD PARKWAY,
SUNNYVALE, CA
94085

888-662-2779 [T]
408-738-1741 [F]

WWW.BARRX.COM