

C2 CryoBalloon™

FOCAL ABLATION SYSTEM

A better choice for patients with unwanted esophageal tissue

BETTER FOR PATIENTS

The C2 CryoBalloon™ Ablation System provides you with another option for treating unwanted tissue in the esophagus, while offering inherent patient benefits of cryotherapy:

- Reduced potential for stricture and scarring^{1,2}
- Less post-procedure pain^{1,3-5}
- Safe ablative approach^{4,6-8}
- Psychological preference to that of burning tissue³

BETTER FOR CLINICIANS

C2's patented design delivers nitrous oxide (N₂O) cryogen from the diffuser through a conformable balloon, providing controlled depth of ablation but with the versatility to address tortuous anatomy, advanced disease and other characteristics or conditions that would otherwise preclude ablative therapy.^{5,7,8}

Cryoablation reaches the submucosa without damaging underlying healthy tissue.⁷

Expanded patient use and a favorable safety and efficacy profile allows cryotherapy to be considered a first line therapy for esophageal disease.⁹

BETTER FOR HEALTH ECONOMICS

The C2 CryoBalloon™ Ablation System is a therapy enabled through a handheld controller in combination with self-sizing balloon catheters, without the need for large capital investment or substantial inventory of disposable items.⁷



C2 CryoBalloon™ Focal Catheter, Standard (FG-1009)

Insert through working channel

THE PROCEDURE*

- C2 CryoBalloon™ Focal Ablation System is inserted into the working channel of a 3.7mm therapeutic endoscope (diagnostic endoscopes may also be used with the addition of a C2 CryoBalloon™ Sidecar device).
- A pre-puff of N₂O is delivered to inflate the balloon and orient cryogen diffuser.
- Set dosing and hold trigger of the C2 CryoBalloon™ Controller to deliver cryotherapy.
- Reposition diffuser by tilting Controller left or right. Repeat energy delivery as needed.
- Deflate C2 CryoBalloon™ and withdraw catheter.



*See Instructions For Use (IFU) for complete procedural information.

PART NUMBER	DESCRIPTION
SYSTEMS (Includes Controller and Catheter)	
SYS-1035	C2 CryoBalloon™ Focal Ablation System
ACCESSORIES	
FG-1010	C2 CryoBalloon™ Nitrous Oxide Cartridges, Regular (Box of 5)
FG-1011	C2 CryoBalloon™ Sidecar (Box of 5)
FG-1016	C2 CryoBalloon™ Boa (Box of 5)

NOTE: The C2 CryoBalloon™ Focal Ablation System is intended to be used as a cryosurgical tool for the destruction of unwanted tissue in the field of general surgery, specifically for endoscopic applications.

REFERENCES

- 1 Schölvinc DW, Künzli HT, Kestens C, et al. Treatment of Barrett's esophagus with a novel focal cryoablation device: a safety and feasibility study. *Endoscopy*. 2015 Dec; 47(12):1106-12.
- 2 Vikingstad EM, de Ridder GG, Glisson RR, et al. Comparison of Acute Histologic and Biomechanical Effects of Radiofrequency Ablation and Cryoablation on Periarticular Structures in a Swine Model. *JVIR*. 26:1221-1228,2015.
- 3 Timmermans C, Ayers GM, Crijns HJ, Rodríguez LM. Randomized Study Comparing Radiofrequency Ablation with Cryoablation for the Treatment of Atrial Flutter with Emphasis on Pain Perception. *Circulation*. 107:1250-1252,2003.
- 4 Deisenhofer I, Zrenner B, Yin Y, et al. Cryoablation Versus Radiofrequency Energy for the Ablation of Atrioventricular Nodal Reentrant Tachycardia (the CYRANO Study). *Circulation*. 2010;122:2239-2245.
- 5 Johnston et al. Cryoablation of Barrett's esophagus: a pilot study. *Gastrointest Endosc* 2005; Vol. 62, p842-848.
- 6 Evonich RF, Nori DM, Haines DE. A Randomized Trial Comparing Effects of Radiofrequency and Cryoablation on the Structural Integrity of Esophageal Tissue. *J Interv Card Electrophysiol*. 2007 Aug;19(2):77-83.
- 7 Friedland S, Triadafilopoulos G. A novel device for ablation of abnormal esophageal mucosa. *Gastrointest Endosc*. 2011 Jul;74(1):182-8.
- 8 Sengupta, et al. Salvage cryotherapy after failed radiofrequency ablation for Barrett's esophagus-related dysplasia is safe and effective. *Gastrointest Endosc*. 2015 Apr 14.
- 9 Dumot J. The Use of Cryotherapy for Treatment of Barrett's Esophagus. *Gastro & Hep*. 2013; Vol. 9, Issue 12, p811-813.

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