

CHANGE HOW YOU TREAT BARRETT'S ESOPHAGUS



Exceeding expectations^{1),2)}

A vital part of your comprehensive offering for patients with dysplastic Barrett's Esophagus



Ablation Range

Ready to ablate a wide range of patients²⁾



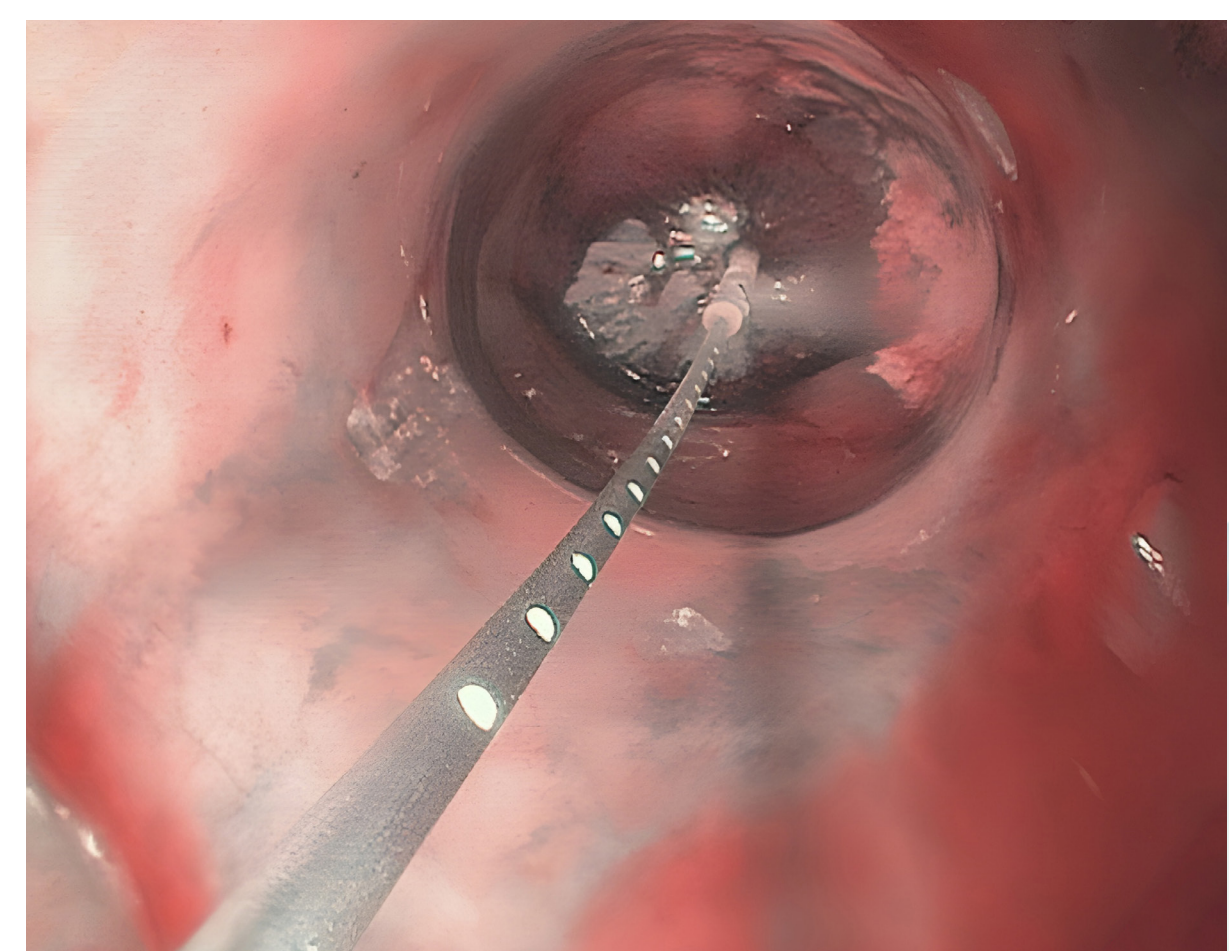
Highly safe and effective in both naïve and refractory patients with Barrett's esophagus. New catheter designs reach tubular structures, gastroesophageal junction (GEJ), and lesions big and small.



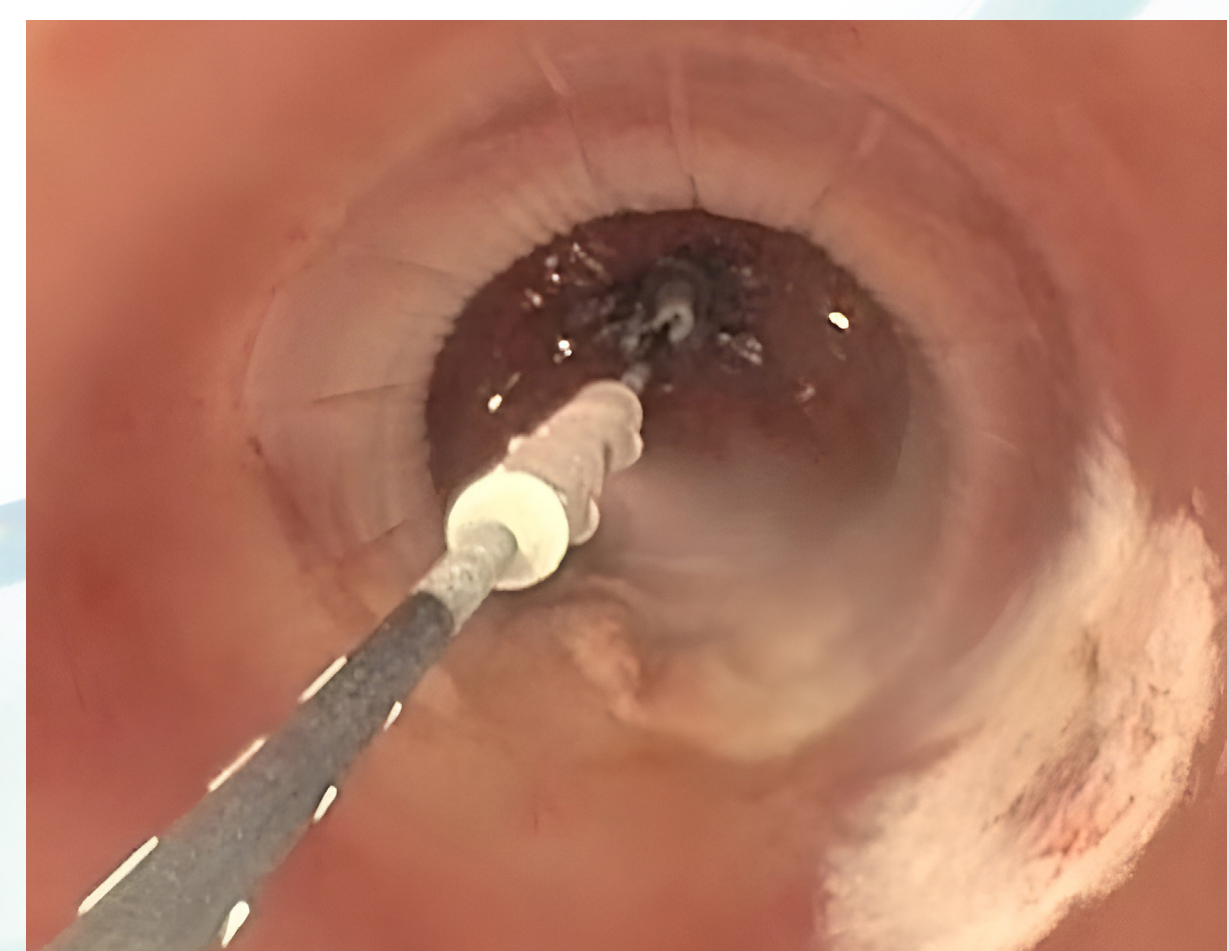
Focal Standard Catheter

Pear Catheter

This device changes how you see Barrett's esophagus²⁾



C2 CryoBalloon Pear Catheter at the GEJ



C2 CryoBalloon Focal Standard Catheter ablating treatment naïve tissue

Enhanced Visualisation and Control

Target and ablate tissue selectively^{2),4),5)}

Transparent compliant balloon pushes tissue flat for better apposition and controlled therapeutic delivery. Physicians can selectively target and ablate diseased tissue while sparing healthy tissue using advanced rotational and translational reach of diffuser mechanism. Intuitive controls give physicians total control of balloon inflation, deflation, diffuser positioning, and ablation.

With C2, I can offer my patients the latest and most effective treatment options and develop a more comprehensive Barrett's center.

Harshit S. Khara, MD. FACG, FASGE
Clinical Associate Professor of Medicine
Director of Endoscopy
Geisinger Medical Center



Clinical Data Pipeline

Highly effective and durable response through 2 years^{2),3)}

Generating a robust clinical data pipeline in Barrett's esophagus and beyond. A clinical study showed convincing results (median number of ablation procedures was 3).



Complete eradication of dysplasia (CED)



Complete eradication of intestinal metaplasia (CEIM)

No disease progression noted in a single patient at 2 years (N=41)

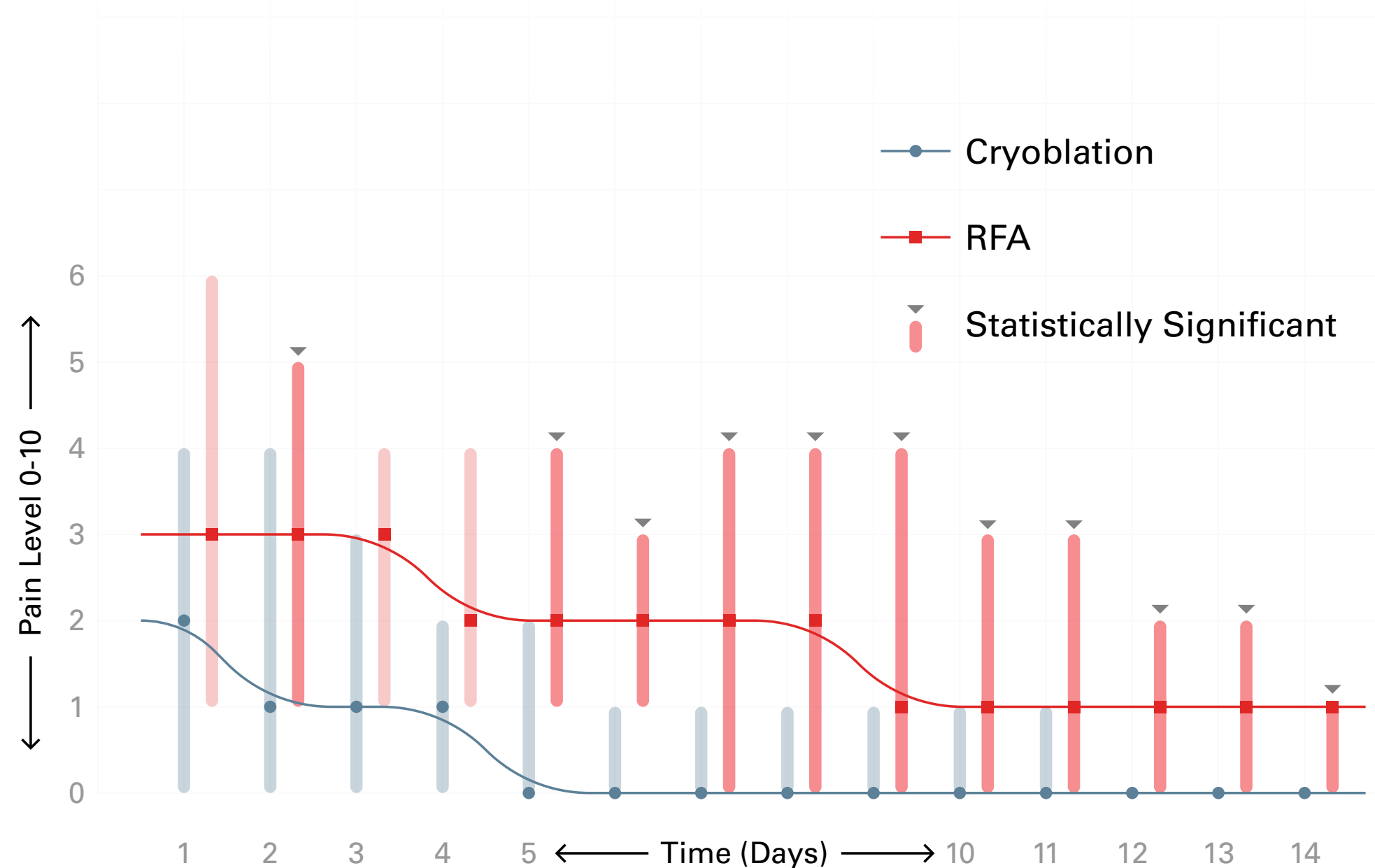


Clinical Data Pipeline

Patients experience less post-procedure pain and need for narcotic medication^{2),4)}



Cryoablation is significantly less painful than radiofrequency ablation (RFA)



- Peak pain was lower after CryoBalloon ablation (median VAS 2 vs, 4, P< 0.01)
- Duration of pain was shorter after CryoBalloon ablation (median 2 vs. 4 days, P< 0.01)
- Mild pain was reported by 27% of patients immediately after cryoablation and by 14% after 2 days²⁾
- No patient required narcotic medication after Day 7 following treatment

Integration Made Easy

Experience a new level of efficiency^{2),6),7),8)}



Practice integration made easy with simplicity and speed^{2),3),8)}

Fast and easy-to-use

Streamlined procedure takes approximately 15 to 30 minutes, depending on the amount of BE present.

On-demand with simple storage

- Minimal set-up time
- Compact, lightweight, portable system can be moved throughout care setting
- Disposable cartridges allow for easy storage

Smart, intuitive interface

Hand-held touchscreen controller provides system feedback to the user.



System Components

The simplicity of C2 CryoBalloon



FG-1028 / FG-1024
C2 CryoBalloon™ Standard and Pear Catheters



FG-1018
C2 CryoBalloon™ Foot Pedal



FG-1013
C2 CryoBalloon™ Cartridge (Box of 5)

	PART NUMBER	PRODUCT CODE	DESCRIPTION
Catheters	FG-1028	300613	Focal Standard Catheter
	FG-1024	300617	Focal Pear Catheter
Controller & Foot Pedal	FG-1017	300610	Controller
	FG-1018	300611	Foot Pedal
Cartridge	FG-1013	300612	Cartridge (Box of 5)



FG-1017
C2 CryoBalloon™ Controller

References



- 1) Wani S, Muthusamy VR, Shaheen NJ, Yadiapeti R, Wilson R, Abrams JA, et al. Development of quality indicators for endoscopic eradication therapies in Barrett’s esophagus: the TREAT-BE (Treatment with Resection and Endoscopic Ablation Techniques for Barrett’s Esophagus) Consortium. Am J Gastroenterol 2017; 112(7): 1032-1048.
- 2) Canto MI, Shaheen NJ, Almario JA, Voltaggio L, Montgomery E, Lightdale CJ. Multifocal nitrous oxide C2 CryoBalloon ablation with or without EMR for treatment of neoplastic Barrett’s esophagus. Gastrointestinal Endoscopy Volume 88, No. 3 2018
- 3) Canto MI. Safety , efficacy and durability of endoscopic nitrous oxide CryoBalloon ablation for eradication of Barrett’s neoplasia. Poster presented at: Digestive Disease Week, June 2-5, 2018. Washington DC.
- 4) Van Munster SN, Overwater A, Haidry R, Bisschops R, Bergman J, Weusten BL. Focal CryoBalloon verses radiofrequency ablation of dysplastic Barrett’s esophagus: impact on treatment response and postprocedural pain. Clinical Endoscopy. 2018 Volume 88 No. 5 795-803.
- 5) Dumot JA. The little engine that could. Gastrointestinal Endoscopy. 2018; 87(2): 582-583.
- 6) PENTAX Medical C2 CryoBalloon Ablation System Instructions for Use (IFU). LBL 1028 Master Document Rev. M
- 7) Kunzli HT, Scholvinck DW, Meijer SL, Seldenrijk KA, Bergman JGHM, Weusten BLAM. Efficacy of the CryoBalloon Focal Ablation System for the eradication of dysplastic Barrett’s esophagus islands. Endoscopy. 2017; 49(2): 169-175.
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Contact us if you have any questions

See how C2 CryoBalloon™ can help you treat more patients

Request a demo. Talk to your Territory Manager to schedule a visit.

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TÜV Rheinland CE0197. Medical device class IIa

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