

# C2 CRYOBALLOON™

**PENTAX®**  
MEDICAL

## A new way to treat Barrett's Esophagus

### Exceeding expectations<sup>1,2</sup>

A vital part of your comprehensive  
offering for patients with Barrett's  
esophagus with dysplasia



Home

Ablation  
Range

Enhanced  
Visualization  
and Control

Clinical Data  
Pipeline

Integration  
Made Easy

System  
Components



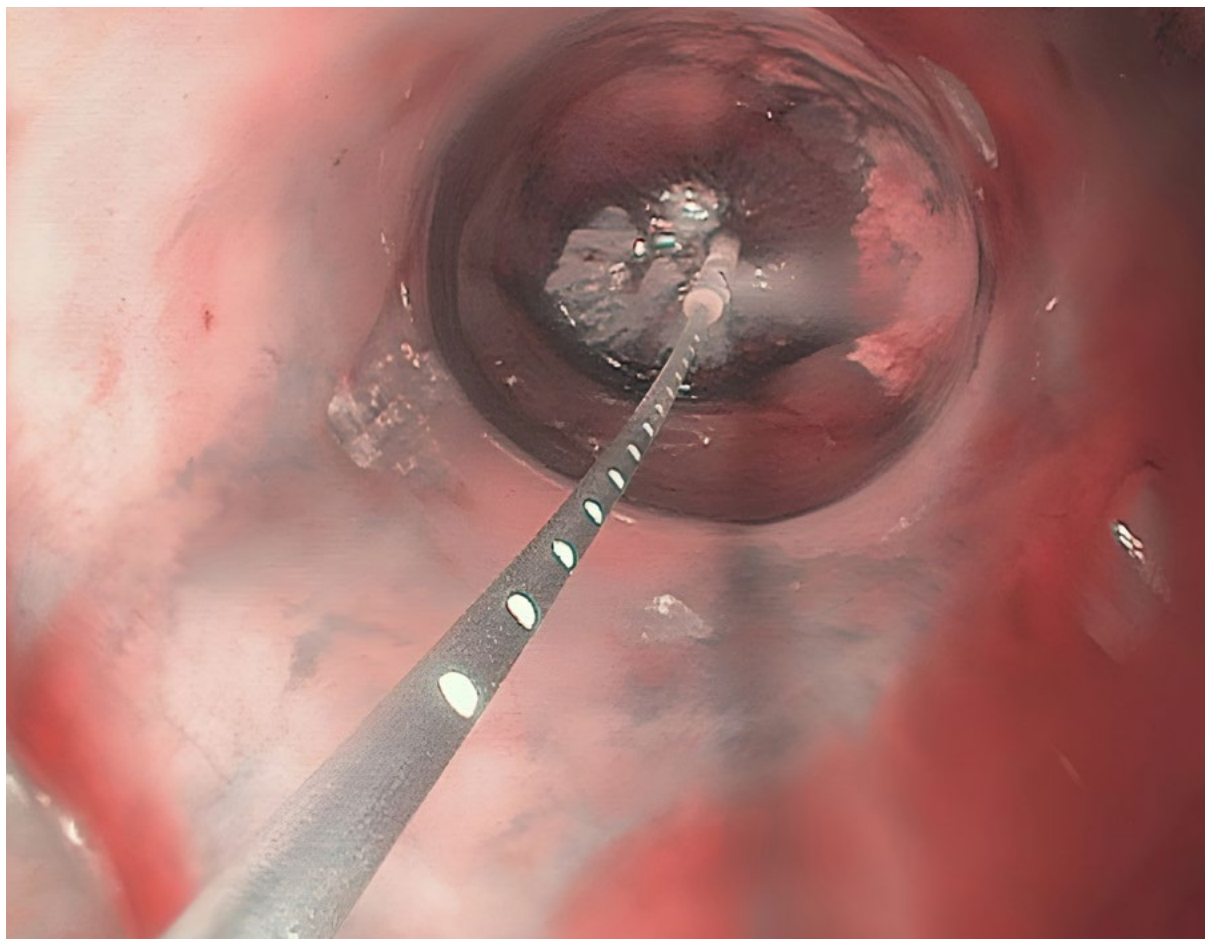
# Ready to ablate a wide range of patients<sup>2</sup>



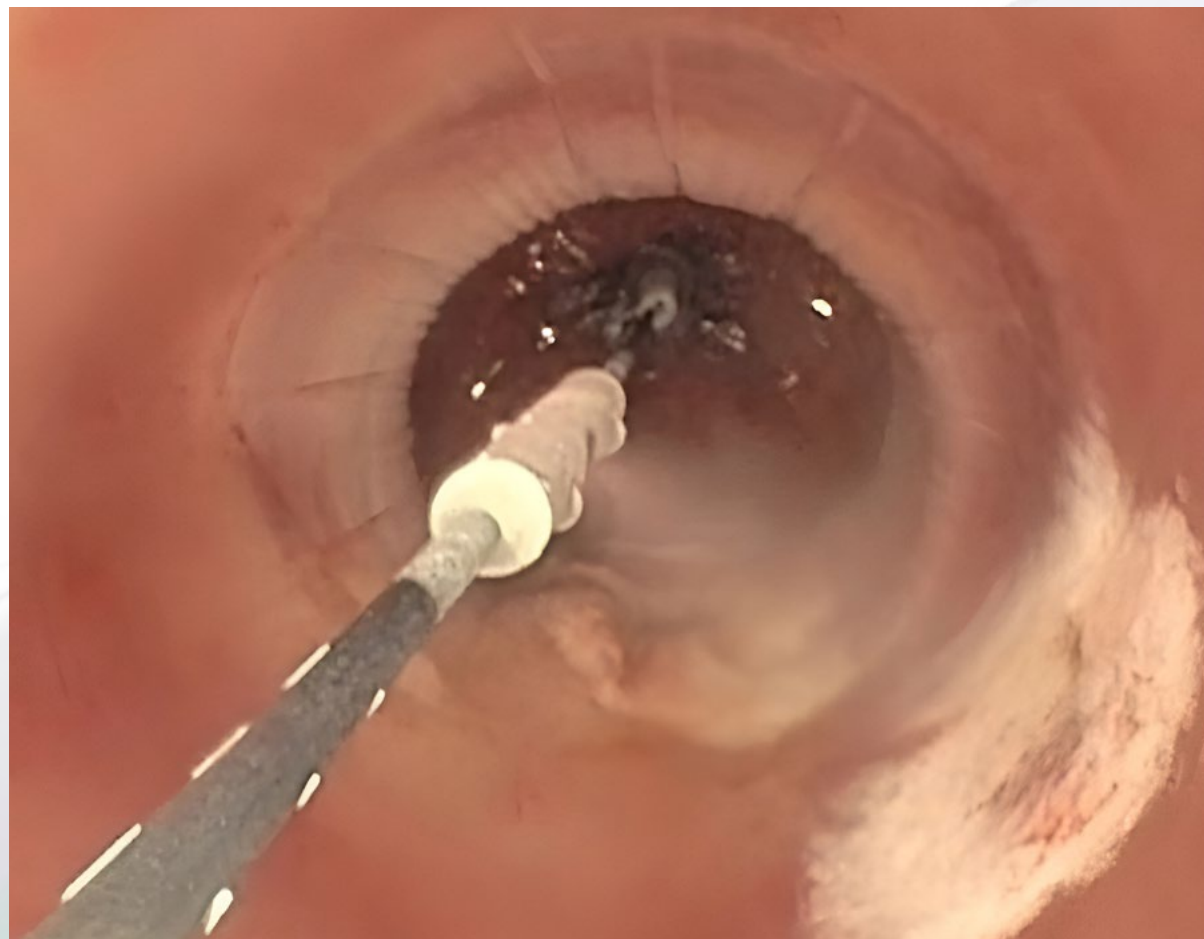
Highly safe and effective in both naïve and refractory patients with Barret’s esophagus. New catheter designs reach tubular structures, gastroesophageal junction (GEJ), and lesions big and small.



This device changes how you see Barrett’s esophagus<sup>2</sup>



C2 CryoBalloon Pear Catheter at the GEJ



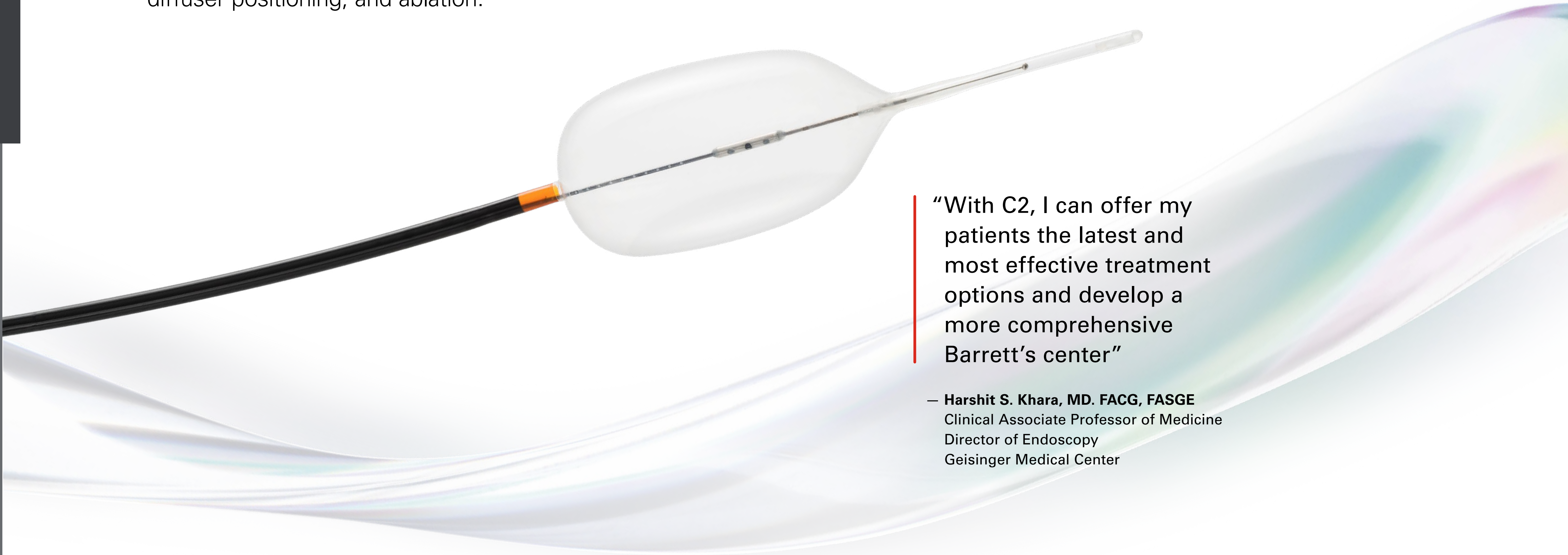
C2 CryoBalloon Focal Standard Catheter ablating treatment naïve tissue



# Enhanced visualization and control<sup>2,4,5</sup>



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



# Generating a robust clinical data pipeline in Barrett’s esophagus and beyond

Highly effective and durable response through 2 years<sup>2,3</sup>

**1-year results**

**95%**  
CED

**88%**  
CEIM

**2-year results**

**95%**  
CED

**90%**  
CEIM

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

No patient required narcotic medication after Day 7 following treatment

Median number of ablation procedures was 3

2. Canto MI, Shaheen NJ, Almario JA, Vologgi 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.

# Generating a robust clinical data pipeline in Barrett's esophagus and beyond

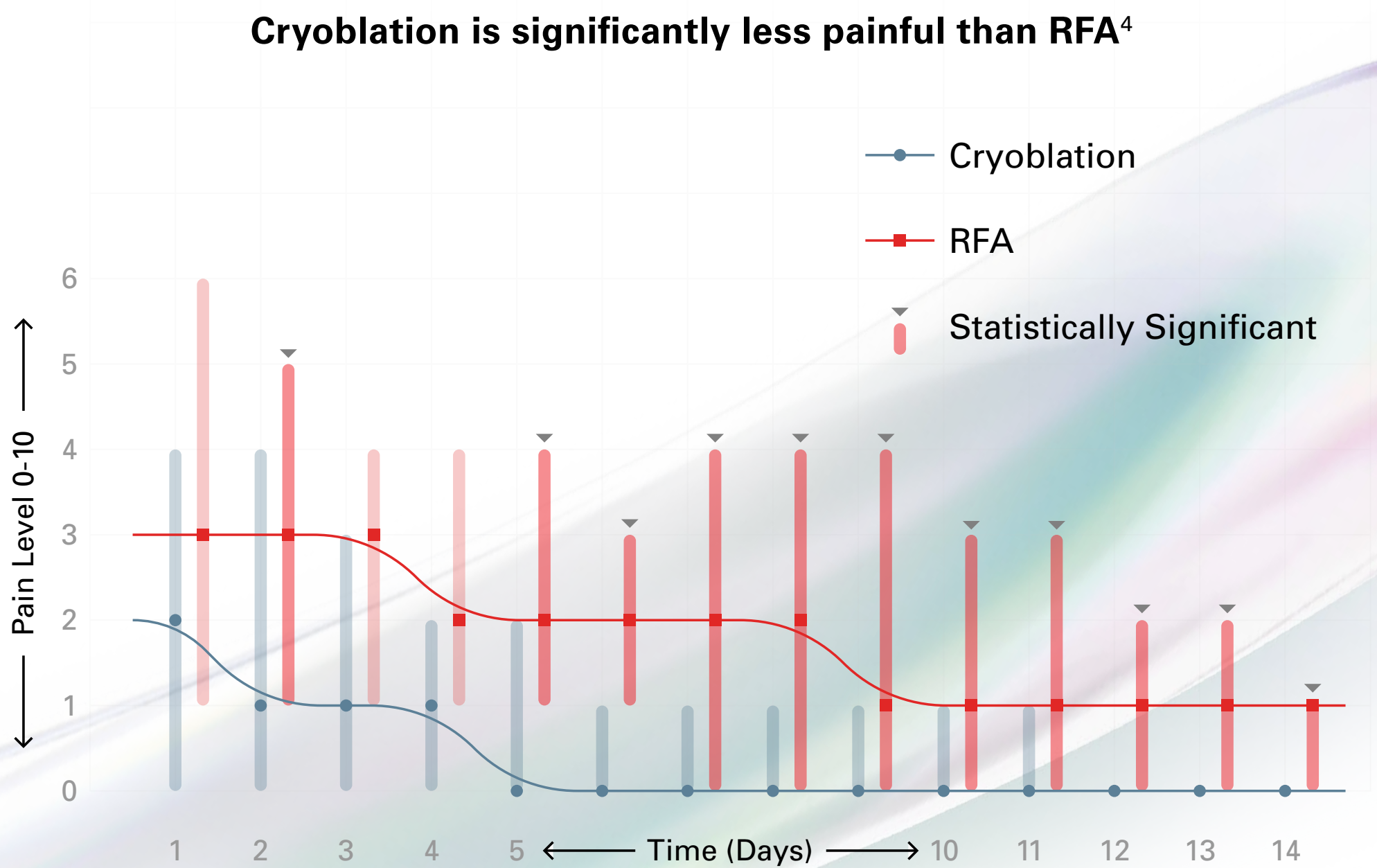


Patients experienced less post-procedure pain and need for narcotic medication<sup>2,4</sup>

Peak pain was lower after CryoBalloon ablation (median VAS 2 vs. 4, P < .01)

Duration of pain was shorter after CryoBalloon ablation (median 2 vs. 4 days, P < .01)

Mild pain was reported by 27% of patients immediately after cryoblation and by 14% after 2 days<sup>2</sup>





# Practice integration made easy with simplicity and speed<sup>2,3,8</sup>



## Experience a new level of efficiency in action<sup>2,6,7,8</sup>

### 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.



**See how C2 CryoBalloon™ can help you treat more patients**

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



# System Components



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



**FG-1018**  
C2 CryoBalloon™ Foot Pedal



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



**FG-1040**  
C2 CryoBalloon™  
EndoGrip



**FG-1040**  
C2 CryoBalloon™  
NitroClip



**FG-1054**  
C2 CryoBalloon™  
Storage Case

	Part Number	Description
Systems	SYS-2017	C2 CryoBalloon™ Ablation System (Controller and Foot Pedal)
Catheters	FG-1028	C2 CryoBalloon™ Focal Standard Catheter
	FG-1024	C2 CryoBalloon™ Focal Pear Catheter
Controller & Foot Petal	FG-1017	C2 CryoBalloon™ Controller
	FG-1018	C2 CryoBalloon™ Foot Petal
Other	FG-1013	C2 CryoBalloon™ Cartridge (Box of 5)
	FG-1011	C2 CryoBalloon™ SideCar
	FG-1040	C2 CryoBalloon™ EndoGrip (Box of 5)
	FG-1050	C2 CryoBalloon™ NitroClip
	FG-1054	C2 CryoBalloon™ Storage Case



**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, Vologgi 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.
- 8.Canto MI, Trindade AJ, Abrams J, Rosenblum M et al. Multifocal CryoBalloon Ablation for Eradication of Barrett’s Esophagus-Related Neoplasia: A Prospective Multicenter Clinical Trial. Am J Gastroenterol. 2020; 115:1879-1890.



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