

# PENTAX Medical Introduces Next-Generation C2 CryoBalloon™ Ablation System for Treatment of Barrett's Esophagus

Endoscopic Device Uses Extreme Cold to Eradicate Precancerous Lesions and Minimize Post-Procedural Pain in 30-Minute Procedure

<https://www.prnewswire.com/news-releases/pentax-medical-introduces-next-generation-c2-cryoballoon-ablation-system-for-treatment-of-barretts-esophagus-300658152.html>

MONTVALE, N.J., June 1, 2018 /PRNewswire/ -- PENTAX Medical Company, a healthcare industry leader in diagnostic and therapeutic endoscopy, announces the introduction of the C2 CryoBalloon™ Ablation System for the treatment of Barrett's esophagus, a condition in which the lining of the esophagus develops abnormal lesions primarily as a result of chronic gastroesophageal reflux disease (GERD).<sup>1</sup> An estimated 3.3 million people in the U.S. are living with Barrett's esophagus,<sup>2</sup> which makes an individual 30 to 40 times more likely to develop esophageal cancer – a disease with, unfortunately, a 19.2% five-year survival rate.<sup>3</sup>

C2 CryoBalloon Ablation System for the treatment of Barrett's esophagus

PENTAX Medical will feature the next-generation endoscopic cryoablation device at Digestive Disease Week® (DDW) in Washington, DC from June 2–5. DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Separately, the company announced that beginning June 1, the developer of the C2 CryoBalloon, C2 Therapeutics, which it acquired last year, will operate under the PENTAX Medical name.

The C2 CryoBalloon Ablation System is used to destroy unwanted tissue by application of extreme cold. A balloon probe, which is connected to a catheter, comes in contact with the wall of the target tissue. Upon activation by a physician, the balloon probe is simultaneously cooled and inflated with nitrous oxide. The extreme cold eradicates the targeted precancerous or abnormal lesions along the esophageal lining while sparing healthy tissue. The system allows physicians complete control of the procedure under direct visualization of the treatment area during the procedure, which lasts between 15 to 30 minutes.<sup>4,5</sup>

The new C2 CryoBalloon Ablation System offers several key advantages including the ability to ablate a wide range of patients, enhanced visualization and control, and a new level of efficiency. "With the C2 Cryoballoon, you can promote your practice as a more comprehensive Barrett's center with the latest and best treatment options," said Harshit S. Khara, MD, FACG, FASGE, Clinical Associate Professor of Medicine, Geisinger Medical Center.

According to clinical studies, 95 percent of patients treated with the C2 CryoBalloon achieve complete eradication of dysplasia (CED) and 90 percent have complete eradication of intestinal metaplasia (CEIM) through two years.<sup>6</sup> Additionally, one week following treatment, no patients required narcotic pain medication.<sup>7</sup>

"We are committed to advancing the treatment of Barrett's esophagus with a new generation of ablation devices that are easy to use and improve clinical outcomes and patient satisfaction," said David Woods, Global Chief Marketing Officer, PENTAX Medical. "The C2 CryoBalloon strengthens our therapeutic endoscopy portfolio and is an important technology that enables endoscopists to improve the quality of care they provide to their patients."

### **Indications**

US ONLY: The C2 CryoBalloon Ablation System is intended for use as a cryosurgical tool in the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's esophagus with dysplasia.<sup>8</sup>

### **About PENTAX Medical**

PENTAX Medical is a division of Hoya Group. Its mission is to improve the standard of patient care and quality of healthcare delivery by providing the best endoscopy, informatics, speech, voice, and swallowing assessment products and services with a focus on QUALITY, CLINICALLY RELEVANT INNOVATION, and SIMPLICITY. Through leading edge R&D and manufacturing, PENTAX Medical provides endoscopic imaging devices and solutions to the global medical community. Headquartered in Japan, PENTAX Medical has a worldwide focus and presence with R&D, regional sales, service, and in-country facilities around the globe. PENTAX Medical employees represent the diverse countries where we do business, allowing us to provide innovative solutions tailored to meet local needs. For more information, visit [www.pentaxmedical.com](http://www.pentaxmedical.com).

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<sup>1</sup> <https://www.asge.org/home/for-patients/patient-information/understanding-barrett-39-s-esophagus>

<sup>2</sup> Stuart J Spechler, MD, Berta M and Cecil O Patterson - *Barrett's esophagus: Epidemiology, clinical manifestations, and diagnosis* <http://www.uptodate.com/contents/barretts-esophagus-epidemiology-clinical-manifestations-and-diagnosis>

<sup>3</sup> SEER stat fact sheets: Esophageal cancer. National Cancer Institute Web site. <http://seer.cancer.gov/statfacts/html/esoph.html> Published date unknown. Accessed March 1, 2016.

<sup>4</sup> Canto MI, Shaheen NJ, Almario JA, Voltaggio L, Montgomery E, Lightdale CJ. Multifocal Nitrous Oxide Cryoballoon Ablation with or without EMR for Treatment of Neoplastic Barrett's Esophagus. *Gastrointest Endosc*. 2018 Apr 4; pii: S0016-5107(18)30259-1. doi: 10.1016/j.gie.2018.03.024. PMID: 29626424

<sup>5</sup> Künzli HT, Schölvinck 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 Feb;49(2): 169-175. doi: 10.1055/s-0042-120117. Epub 2016 Dec 20. PMID: 27997963

<sup>6</sup> Canto MI. Safety, Efficacy, and Durability of Endoscopic Nitrous Oxide CryoBalloon Ablation for Eradication of Barrett's Neoplasia. To be presented via poster presentation during DDW 2018.

<sup>7</sup> Canto MI, Shaheen NJ, Almario JA, Voltaggio L, Montgomery E, Lightdale CJ. Multifocal Nitrous Oxide Cryoballoon Ablation with or without EMR for Treatment of Neoplastic Barrett's Esophagus. *Gastrointest Endosc*. 2018 Apr 4; pii: S0016-5107(18)30259-1. doi: 10.1016/j.gie.2018.03.024. PMID: 29626424

<sup>8</sup> In the European Union, The CryoBalloon Ablation System is indicated to ablate unwanted tissue in the gastrointestinal tract, including treatment of Barrett's Esophagus and squamous dysplasia with application of extreme cold. In the United States, the device is indicated for the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's Esophagus with dysplasia. SOURCE PENTAX Medical Company