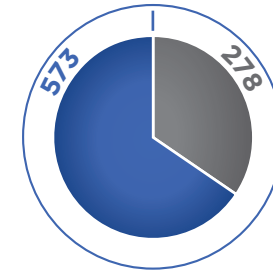


# C2 CryoBalloon® Ablation System

## CLINICAL DATA SUMMARY



The C2 CryoBalloon® Ablation System is used to ablate unwanted tissue by application of extreme cold. The balloon catheter is passed through the 3.7mm working channel of a therapeutic endoscope and inflated at a position such that the targeted tissue can be seen through the wall of the balloon. The nitrous oxide is fully contained within the balloon and exits through the controller at the proximal end of the catheter. The C2 CryoBalloon® Ablation System is designed for single patient use.



**Lifetime Procedure Volume**  
as of April 2017

- Clinical Studies
- Commercial

Authors	Title with Hyperlink	Where Presented or Published	NCT Number*	Patient Population	Results
<b>EFFICACY - PRIMARY THERAPY FOR BARRETT'S ESOPHAGUS</b>					
Canto, et al.	<a href="#">Multifocal Nitrous Oxide Cryoballoon Ablation with or without EMR for Treatment of Neoplastic Barrett's Esophagus</a>	Poster presentation at the <i>24th UEG Week</i> , Vienna, Austria, 2016.	NCT02534233	BE (HGD, LGD) 37 Enrolled	<ul style="list-style-type: none"> <li>• 92% CRD, 84% CRIM</li> <li>• 3% SAE</li> <li>• 0% Narcotics at 48 Hours</li> </ul>
<b>EFFICACY - SECONDARY FOR BARRETT'S ESOPHAGUS (OTHER THERAPY ATTEMPTED FIRST)</b>					
Canto, et al.	<a href="#">Multifocal Nitrous Oxide Cryoballoon Ablation with or without EMR for Treatment of Neoplastic Barrett's Esophagus</a>	Poster presentation at the <i>24th UEG Week</i> , Vienna, Austria, 2016.	NCT02534233	BE (HGD, LGD) 37 Enrolled	<ul style="list-style-type: none"> <li>• 92% CRD, 84% CRIM</li> <li>• 3% SAE</li> <li>• 0% Narcotics at 48 Hours</li> </ul>
Künzli, et al.	<a href="#">Efficacy of the CbFAS for the Eradication of Dysplastic Barrett's Esophagus Islands</a>	<i>Endoscopy</i> . 2017; 49(02): 169-175.	NCT02249975	BE (HGD, LGD) 30 Enrolled	<ul style="list-style-type: none"> <li>• 100% CRD, 100% CRIM</li> <li>• 0% SAE</li> <li>• 90% Pain Free at 48 Hours</li> </ul>
Sitaraman, et al.	<a href="#">Use of the CbFAS for the Eradication of Esophageal Neoplasia: A Single-Center Experience</a>	<i>Gastroenterology</i> . 2016 April; Volume 150, Issue 4, Supplement 1, Page S266.	---	BE 19 Enrolled	<ul style="list-style-type: none"> <li>• CbFAS Feasible, Safe for Patients with Treatment-Resistant Neoplasia</li> </ul>

Authors	Title with Hyperlink	Where Presented or Published	NCT Number*	Patient Population	Results
Wang, et al.	<a href="#">Multi-Center Experience with the CbFAS for Esophageal Dysplasia</a>	<i>Gastrointestinal Endoscopy</i> . 2015 May; Volume 81, Issue 5, Supplement, Page AB522.	NCT02230410	BE, ESCN, IMC 7 Enrolled	<ul style="list-style-type: none"> <li>• 86% CRD</li> <li>• 0% SAE</li> </ul>
<b>LEARNING CURVE AND PROCEDURE EFFICIENCY</b>					
John, et al.	<a href="#">Cryoballoon Ablation for Barrett's Esophagus: A Prospective Single Operator Learning Curve and Time-Efficiency Study</a>	<i>Gastrointestinal Endoscopy</i> . 2017 May; Volume 85, Issue 5, Supplement, Page AB560.	---	74 Enrolled	<ul style="list-style-type: none"> <li>• Learning Curve for CryoBalloon Ablation is 18 Procedures, After Which Efficiency Plateaus</li> </ul>
<b>PATIENT TOLERABILITY, COMPLICATION RATES</b>					
Van Munster, et al.	<a href="#">Post-Procedural Pain After Endoscopic Ablation Therapy of Barrett's Esophagus: Is Cryo Ablation Less Painful Compared with Radiofrequency Ablation?</a>	<i>Gastrointestinal Endoscopy</i> . 2017 May; Volume 85, Issue 5, Supplement, Page AB568.	---	BE 17 Enrolled	<ul style="list-style-type: none"> <li>• Pain Reported at 48 Hours: <ul style="list-style-type: none"> <li>o 18% Severe Pain for Cryo</li> <li>o 46% Severe Pain for RFA</li> </ul> </li> </ul>
Künzli, et al.	<a href="#">Efficacy of the CbFAS for the Eradication of Dysplastic Barrett's Esophagus Islands</a>	<i>Endoscopy</i> . 2017; 49(02): 169-175.	NCT02249975	BE 30 Enrolled	<ul style="list-style-type: none"> <li>• 100% CRD, 100% CRIM</li> <li>• 0% SAE</li> <li>• 90% Pain Free at 48 Hours</li> </ul>
Canto, et al.	<a href="#">Multifocal Nitrous Oxide Cryoballoon Ablation with or without EMR for Treatment of Neoplastic Barrett's Esophagus</a>	Poster presentation at the <i>24th UEG Week</i> , Vienna, Austria, 2016.	NCT02534233	BE (HGD, LGD) 37 Enrolled	<ul style="list-style-type: none"> <li>• 92% CRD, 84% CRIM</li> <li>• 3% SAE</li> <li>• 0% Narcotics at 48 Hours</li> </ul>
Schölvinck, et al.	<a href="#">Treatment of Barrett's Esophagus with a Novel Focal Cryoablation Device: a Safety and Feasibility Study</a>	<i>Endoscopy</i> . 2015 Dec; 47(12):1106-12.	NCT01633411	39 Enrolled	<ul style="list-style-type: none"> <li>• 100% Complete Response at 10 Seconds</li> <li>• 0% SAE</li> <li>• 86% Pain-Free at 48 Hours</li> </ul>

Authors	Title with Hyperlink	Where Presented or Published	NCT Number*	Patient Population	Results
Wang, et al.	<a href="#">Multi-Center Experience with the CbFAS for Esophageal Dysplasia</a>	<i>Gastrointestinal Endoscopy</i> . 2015 May; Volume 81, Issue 5, Supplement, Page AB522.	NCT02230410	BE, ESCN, IMC 7 Enrolled	<ul style="list-style-type: none"> <li>• 86% CRD</li> <li>• 0% SAE</li> </ul>
<b>DOSING, FEASIBILITY AND DEPTH OF INJURY FOR BARRETT'S ESOPHAGUS</b>					
Louie, et al.	<a href="#">Evaluation of a Novel Swipe CryoBalloon Ablation System in Bench, Porcine, and Human Esophagus Models</a>	<i>Gastrointestinal Endoscopy</i> . 2017 May; Volume 85, Issue 5, Supplement, Page AB513.	---	6 Enrolled	<ul style="list-style-type: none"> <li>• Uniform 3cm-Long Mucosal Ablation Confirmed</li> <li>• 0% Adverse Events</li> </ul>
Schölvinck, et al.	<a href="#">Treatment of Barrett's Esophagus with a Novel Focal Cryoablation Device: a Safety and Feasibility Study</a>	<i>Endoscopy</i> . 2015 Dec; 47(12):1106-12.	NCT01633411	39 Enrolled	<ul style="list-style-type: none"> <li>• 100% Complete Response at 10 Seconds</li> <li>• 0% SAE</li> <li>• 86% Pain-Free at 48 Hours</li> </ul>
Schölvinck, et al.	<a href="#">Deep Tissue Ablation with Little or No Late Fibrosis: Animal and Human Data on Esophageal Cryoablation Using the New CbFAS</a>	<i>Gastrointestinal Endoscopy</i> . 2014 May; Volume 79, Issue 5, Supplement, Page AB520.	---	8 Enrolled	<ul style="list-style-type: none"> <li>• Mucosal Ablation Confirmed</li> </ul>
DeMeester, et al.	<a href="#">Initial Human Experience with a Novel Through-the-Scope Cryoballoon Device for Mucosal Ablation</a>	<i>Gastroenterology</i> . 2012 May; Volume 142, Issue 5, Supplement 1, Page S-1038.	NCT01293448	13 Enrolled	<ul style="list-style-type: none"> <li>• Mucosal Ablation Confirmed</li> <li>• Necrosis Reached the Submucosa or Muscularis Propria in All Patients</li> </ul>
Friedland, et al.	<a href="#">A Novel Device for Ablation of Abnormal Esophageal Mucosa</a>	<i>Gastrointestinal Endoscopy</i> . 2011 Jul;74(1):182-8.	---	---	<ul style="list-style-type: none"> <li>• Device Determined Simple-To-Use</li> <li>• Maximal Effect for Animal Esophagus Achieved at 12 Seconds</li> </ul>

Authors	Title with Hyperlink	Where Presented or Published	NCT Number*	Patient Population	Results
<b>EFFICACY FOR OTHER APPLICATIONS BEYOND BARRETT'S ESOPHAGUS</b>					
Ke, et al.	<a href="#">Focal Cryoballoon Ablation for Eradication of Esophageal Squamous Cell Neoplasia: A Prospective Trial, Interim-Results for 43 Patients</a>	<i>Gastrointestinal Endoscopy</i> . 2017 May; Volume 85, Issue 5, Supplement, Page AB507.	NCT02605759	Squamous (HGIN, MGIN) 43 Enrolled	<ul style="list-style-type: none"> <li>• 88% CR</li> <li>• 0% SAE</li> </ul>
Canto, et al.	<a href="#">Nitrous Oxide Cryotherapy for (ESCN)</a>	<i>Gastrointestinal Endoscopy</i> . 2016 May; Volume 83, Issue 5, Supplement, Page AB567.	---	9 Enrolled	<ul style="list-style-type: none"> <li>• 100% CR</li> <li>• 0% SAE</li> </ul>
Patel, et al.	<a href="#">Endoscopic Management of Refractory GAVE with Cryoballoon Therapy: A Case Series</a>	<i>Gastrointestinal Endoscopy</i> . 2017 May; Volume 85, Issue 5, Supplement, Page AB501.	---	Refractory APC 10 Enrolled	<ul style="list-style-type: none"> <li>• 0% Adverse Events</li> <li>• 0% Requiring Transfusion 4-Weeks Post-Treatment</li> </ul>

\* CLINICALTRIALS.GOV IDENTIFIER (NCT NUMBER) - A unique identification code is given to each clinical study [registered](#) on ClinicalTrials.gov. Because the format is "NCT" followed by an 8-digit number (for example, NCT00000419), this identifier is also known as the NCT Number.

#### Acronyms:

BE	Barrett's Esophagus
CbFAS	CryoBalloon Focal Ablation System
CR	Complete Response
CRD	Complete Response, Dysplasia
CRIM	Complete Response, Intestinal Metaplasia
EMR	Endoscopic Mucosal Resection

ESCN	Esophageal Squamous Cell Neoplasia
GAVE	Gastric Antral Vascular Ectasia
HGD	High Grade Dysplasia
IMC	Intramucosal Cancer
LGD	Low Grade Dysplasia
SAE	Severe Adverse Event

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