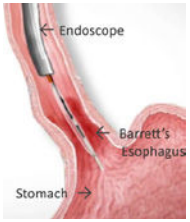
The C2 CryoBalloon Procedure

BEFORE TREATMENT

Your doctor will give you instructions about what you can and cannot eat before your treatment. Your doctor will likely tell you to stop eating altogether for some time before the procedure. It is important that you follow these instructions and any other instructions your doctor gives you.

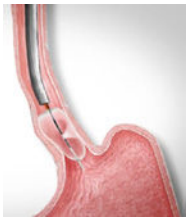
STEP 1: POSITION THE C2 CryoBalloon



Your doctor will insert the C2 CryoBalloon through the endoscope to overlay the abnormal tissue.

Next, your doctor will inflate the C2 CryoBalloon with nitrous oxide until it touches the sides of your esophagus.

STEP 2: ABLATE UNWANTED TISSUE



Your doctor will spray the nitrous oxide onto the area of diseased tissue. While the nitrous oxide stays inside the balloon, any abnormal cell tissue touching the balloon will freeze and die.

STEP 3: REMOVE THE C2 CryoBalloon

Your doctor will deflate the C2 CryoBalloon and remove it from the endoscope.

Note: This photo shows how cryoablation targets abnormal tissue. Your doctor will likely ablate most of the abnormal tissue before removing the C2 CryoBalloon.

AFTER TREATMENT

In clinical studies, patients reported less pain and using less pain medicine after Cryoablation procedure compared to heat based treatments.[3] Nevertheless, it is possible you may experience one or more of the following symptoms after your treatment: mild pain with swallowing, fever, sore throat, chest discomfort, nausea or vomiting. If you experience any of these symptoms, you should expect that they will continuously improve each day after your treatment. At home, please use the medicine prescribed by your doctor as directed and follow the discharge instructions provided by your doctor.

If you are experiencing any severe symptoms please contact your doctor or call 911 in case of emergencies.

1. Study provides first estimate of US population affeced by Barrett's esophagus. Science Daily [webpage]. www.sciencedaily.com/ releases/2005/12/051202084834.htm. Published December 2, 2015. Accessed March 1, 2016.
2. Scholvinck DW, Wuesten BL, Triadafilopoulos G, et al. Deep tissue ablation with little or no late fibrosis: Animal and human data on esophageal cryoablation using a new cryoballoon focal ablation system. Gastrointest Endosc. 2014; 79(5S).
3. van Munster SN, Overwater A, Haidry R, Bisschops R, Bergman JJGHM, Weusten BLAM, Focal cryoballoon versus radiofrequency ablation of dysplastic Barrett's esophagus: impact on treatment response and postprocedural pain, Gastrointestinal Endoscopy (2018), doi: 10.1016/j.gie.2018.06.015.
4. Friedland S, Triadafilopoulos G. A novel device for ablation of abnormal esophageal mucosa. Gastrointest Endosc. 2011 Jul; 74(10):182-8.
5. DeMeester SR, Awas O, Bergman JJ, et al. Initial human experience with a novel through-the-scope cryoballoon device for mucosal ablation. Gastroenterology. 2012 May; 142(5): Supplement 1, Page S-1038.

C_2 CryoBalloon®
Ablation System

To learn more about the C2 CryoBalloon Ablation System, scan the QR code or visit us at merit.com/c2-cryoballoon-ablation-system

Before using, refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

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C_2 CryoBalloon®
Ablation System
PATIENT GUIDE

Treating Barrett's Esophagus with C2 CryoBalloon® Ablation System

MERIT MEDICAL

What is Barrett's Esophagus?

Barrett's esophagus (BE) is a pre-cancerous condition that affects more than 3.3 million adults and is the leading cause of esophageal cancer in the United States[1]. The esophagus is the tube that carries food from the mouth to the stomach. BE occurs when long-term acid reflux causes the lining of the esophagus to change from healthy squamous cells to abnormal cells (ie, Intestinal Metaplasia, Dsyplasia). Doctors monitor these changes in your esophagus by taking a small tissue sample during an endoscopy. The tissue is examined under a microscope to identify the stage of your disease. Doctors monitor your disease because over many years they can sometimes lead to esophageal cancer. Cancer may be prevented if the abnormal cells are removed before they become cancerous.

Barrett's esophagus is classified into three distinct levels of cellular disease. In each stage, the new cells that appear in the esophagus are not cancer, but are different from normal esophageal cells. Doctors may recommend treatment to remove or destroy the abnormal tissue, which can often prevent cancer from developing in the esophagus.

Intestinal Metaplasia (IM) – This is the earliest change seen in the lining of the esophagus. The normal cells lining the esophagus are replaced by abnormal cells that look more like the lining of the intestine. These cells appear because the body is trying to protect itself from the repeated acid exposure from the stomach.

Low-grade Dysplasia (LGD) – Some of the cells in the lining start to have a mildly abnormal pattern but have not invaded deeper tissue. The abnormal growth in the cells is not cancer, but they have started to change in ways that may increase the risk of cancer over time. This is considered a precancerous stage because of the change in the esophagus.

High-grade Dysplasia (HGD) – The cells in the lining of the esophagus look increasingly abnormal and are growing in a disorganized multi-layered pattern. They are still confined to the top layer of the tissue but have a high chance of progressing into cancer without treatment.

What is Cryoablation?

Cryoablation is a procedure that removes abnormal, diseased or damaged tissue by freezing it. For this procedure, the doctor will access the esophagus with a thin, flexible tube with a small camera on the end called an endoscope. The endoscope is passed through your mouth to your esophagus to treat the abnormal tissue.

Once the endoscope is in place, the doctor guides a small balloon into your esophagus. The balloon expands to touch the abnormal tissue areas that need treatment. A very cold gas (Nitrous Oxide, N20) is released inside the balloon. The cold temperature travels through the balloon wall to freeze the targeted tissues. The targeted abnormal cells are destroyed while the area surrounding healthy tissue is preserved.

Peer-reviewed research on Cryoablation using the C2 CryoBalloon Ablation System has shown that:

- Cryoablation is safe.[2, 3, 4]
- Patients report they have less pain and require less pain medication after cryoablation.[3]
- Cryoablation is effective at removing abnormal or diseased cells.[4,5]

ALTERNATIVE TREATMENT OPTIONS FOR BARRETT'S ESOPHAGUS

There are other treatment options your doctor may have considered, including radiofrequency ablation (RFA) and endoscopic mucosal resection (EMR), which differ from Cryoablation. RFA uses heat to burn the diseased tissue, whereas EMR cuts out the diseased tissue from the lining of the esophagus. You should discuss with your doctor which procedure is the best option for treating your disease. In some cases, your doctor may recommend a combination of treatments.

The C2 CryoBalloon Ablation System

The C2 CryoBalloon Ablation System is designed to work with the endoscope your doctor is already using for your care. With the CryoBalloon Ablation System, your doctor can target nitrous oxide spray directly at the abnormal esophageal tissue.

Before the cryoablation procedure, your doctor will choose the C2 CryoBalloon catheter that is the appropriate shape and spray pattern, based on where the abnormal tissue is located in your esophagus.

The C2 CryoBalloon Ablation System allows the doctor to target the nitrous oxide spray to treat specific areas of diseased tissue.