English

C2 CryoBalloon®
Catheter

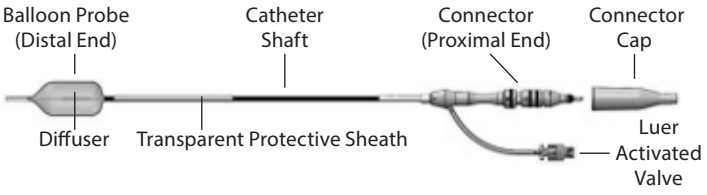
INSTRUCTIONS FOR USE

DESCRIPTION

The C2 CryoBalloon® Ablation System is used to destroy unwanted tissue by application of extreme cold. The balloon probe comes in contact with the wall of target tissue. Upon activation by a physician using the Foot Pedal, the balloon probe at the distal end of the Catheter is simultaneously cooled and inflated with nitrous oxide, which ablates the unwanted tissue. Nitrous oxide is fully contained within the balloon and the system. The nitrous oxide gas exits through the proximal end of the Catheter. The C2 CryoBalloon Ablation System is designed for use in conjunction with a therapeutic endoscope (3.7 mm working channel ID, 105 cm maximum working length). The System is comprised of the following main components:

- C2 CryoBalloon Catheter (see Figure 1) connects to the Controller (See Figure 3), which controls the operation of the Catheter such as diffuser (sprayer) positioning and ablation (nitrous oxide release). C2 CryoBalloon Catheter consists of proximal Connector, Catheter Connector Cap, Catheter Shaft, balloon probe, and protective sheath. The Catheter is supplied sterile and available in two balloon configurations and is disposable after single patient use.

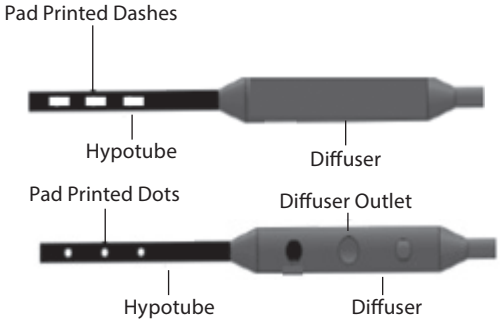
Figure 1. C2 CryoBalloon Catheter



NOTE: The balloon probe is the BF type applied part. It comes into contact with the wall of target tissue in the gastrointestinal tract and is made of "themoplastic polyuerthanes" material.

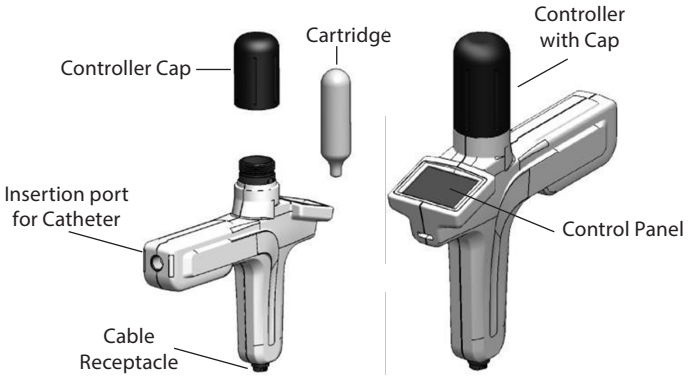
NOTE: The interior of catheter within the balloon utilizes a series of printed dots and dashes on the Hypotube for positioning (see Figure 2). Dots are aligned to the diffuser outlet and dashes are 180° on opposite side.

Figure 2. C2 CryoBalloon Catheter Hypotube



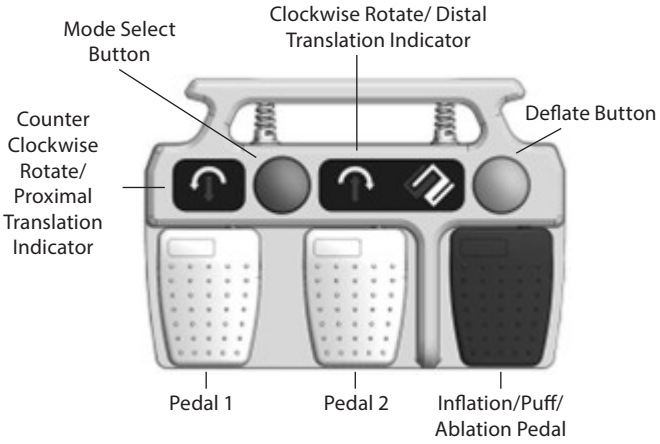
- C2 CryoBalloon Controller (see Figure 3) contains the cartridge heater and the cryogen delivery valve, which is controlled with the Foot Pedal. The Controller contains diffuser radial and axial positioning features that are controlled by the Foot Pedal. The Controller is powered by 12VDC through the Foot Pedal and is supplied non-sterile and is reusable. A LCD touch screen on the Controller communicates system status and allows dosimetry input.
- C2 CryoBalloon Cartridge (see Figure 3) containing 36 grams of nitrous oxide. The Cartridge is installed into the Controller and replaced as required per procedure. The Cartridge is supplied non-sterile for single patient use.

Figure 3. C2 CryoBalloon Controller & C2 CryoBalloon Cartridge



- C2 CryoBalloon Foot Pedal (see Figure 4) communicates the user input to the Controller such as diffuser positioning, ablation, and balloon deflation. The Foot Pedal is powered by mains with an input voltage of 90 to 264VAC, 50-60Hz at 2A. The Foot Pedal is supplied non-sterile and is reusable.

Figure 4. C2 CryoBalloon Foot Pedal



INTENDED USE/INDICATIONS FOR USE

The C2 CryoBalloon Ablation System is intended to be used as a cryosurgical tool in the field of general surgery, specifically for endoscopic applications, to include ablation of Barrett's Esophagus with dysplasia and treatment and management of Gastric Antral Vascular Ectasia (GAVE).

DIRECTIONS FOR USE

This device should only be used by a medical professional authorized to perform endoscopy and only at a medical facility.

This IFU provides vital information regarding operating procedures, handling precautions, and safe and effective use of the device. It does not, however, detail specific endoscopic procedures. Such procedures should be determined at the discretion of a medical professional.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professionals.

CONTRAINDICATIONS

There are no known contraindications for use of this device. Reported contraindications for endoscopic use of cryosurgical ablation devices include:

- Pregnancy
- Significant ulceration of the target tissue
- Narrowing of the access esophagus lumen that precludes advancing the C2 CryoBalloon Catheter to the site of ablation
- Varices in target tissue at risk for bleeding
- Prior Heller myotomy

WARNINGS:

- The C2 CryoBalloon Catheter is intended for single patient use only. Do not resterilize or reuse. Resterilization or reuse may compromise device performance and increase the risk of cross contamination due to inappropriate reprocessing, resulting in damage to the device or patient injury.
- If there is resistance during manipulation of the Catheter, determine the cause of the resistance before proceeding.
- Use the device prior to the Use By date specified on the package.
- If the Catheter shaft is bent or kinked, discard and replace the device. Do not use or attempt to straighten. This may result in damage to the device or patient injury.
- Use only the C2 CryoBalloon Cartridge. Device operation will be impaired if other refrigerants or gasses are used.
- The pressure inside the C2 CryoBalloon Cartridge is 50 atm. Carefully remove the Cartridge to avoid unintended release of residual cryogenic fluid from the Controller. The cryogen fluid may freeze the skin. Unused cartridges should not be exchanged in quick succession.
- Do not inhale nitrous oxide from the cryogen Cartridge. Inhalation may be dangerous to your health.
- If using the Pear balloon, do not ablate tissue adjacent to the larger balloon diameter that is not clearly visualized.
- WARNING: No modification of this equipment is allowed.

CAUTIONS

- The Controller must be operated by one individual and the Catheter must be operated by a separate individual.

PRECAUTIONS

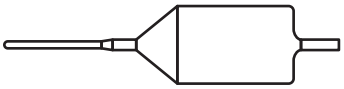
- A thorough understanding of the principles, clinical applications and risks associated with ablation of unwanted tissue is necessary before using this product.
- Use of the C2 CryoBalloon Ablation System for procedures other than those indicated in these instructions is not recommended.
- Multiple ablations at the same site may result in deeper than intended ablation. In the event that adjacent ablations are desired, wait until visible ice is no longer present near the adjacent ablation area.
- The C2 CryoBalloon Ablation System is designed to be used in patients with esophageal lumen diameters measuring 20 mm to 30 mm. Ablation in larger or smaller esophageal lumen is not recommended.
- Do not use if package is open or damaged.
- Prior to use, examine for defects such as breaks, tears, bends or kinks. Do not use if defects are found.
- Do not pre-inflate or pre-test balloon prior to introduction through endoscope or Sidecar.
- Do not attempt to refold balloon into the protective sheath.
- If the Control Panel on the C2 CryoBalloon Controller does not illuminate after it is plugged into the Foot Pedal interconnect cable, replace the Controller.
- After the procedure, straighten the distal end of the endoscope as much as possible prior to removing the C2 CryoBalloon Catheter from the endoscope. Any excess bends of the endoscope will increase the resistance during withdrawal. If there is excessive resistance, remove the endoscope and Catheter as a unit.
- Under normal use, the balloon probe is the only element of the C2 CryoBalloon Ablation System that will be zero degrees C or colder. If any of the user accessible components are excessively cold, discontinue use.
- The C2 CryoBalloon Controller heater assembly contains a thermal protector to protect against temperatures in excess of 100°C. If this temperature is reached, the thermal protector will render the Controller unusable.
- The C2 CryoBalloon Controller is considered IPX0 (no protection, do not immerse in liquids) for ingress protection against liquids.
- The C2 CryoBalloon Foot Pedal meets IPX6 (protection against water rinsing, do not immerse in liquids) for ingress protection against liquids.
- The C2 CryoBalloon Controller should not be used in the presence of flammable anesthetics.
- In the event that the C2 CryoBalloon Controller is dropped, discard and replace it.

CATHETER SELECTION

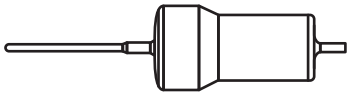
The C2 CryoBalloon Catheter is intended to work with upper endoscopes with a minimum 3.7 mm ID accessory channel (therapeutic) and maximum 105 cm working length.

Based on the ablation site, select an appropriate Catheter with either a straight balloon (same lumen diameter, nominal 23mm) or Pear balloon (different lumen diameters, nominal 20mm proximal and 30mm distal).

- Standard Balloon
  - Intended for esophagus lumens 20 to 30 mm inner diameter



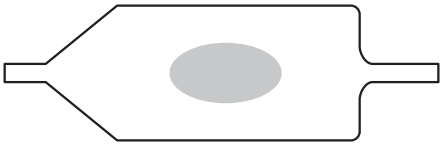
- Pear Balloon
  - Intended for gastroesophageal junction or the proximal margin of a hiatal hernia



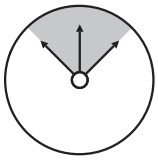
WARNING: If using the Pear balloon, do not ablate tissue adjacent to the larger balloon diameter that is not clearly visualized.
NOTE: The operational balloon pressure is approximately 4.5 psig (0.3 ATM). The balloon pressure cannot be altered by the user.

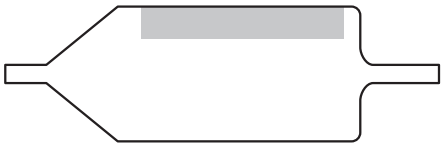
Select the appropriate ablation type based on ablation area. Two nitrous oxide spray types are available:

- Focal sprayer
  - Oval-shaped ablation size approximately 2.0 cm2

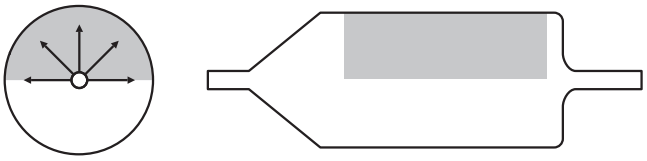


  - Nitrous oxide spray remains stationary for a fixed duration, selectable by user
- 90 °/180 °/360° sprayer
  - 90° sprayer ablates a quarter of the circumference

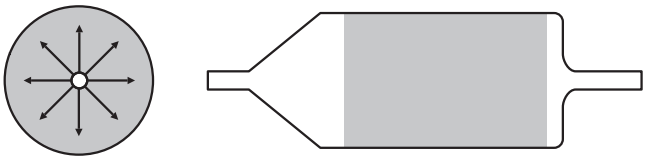




- 180° sprayer ablates half of the circumference



- 360° sprayer ablates fully circumferentially



- Nitrous oxide spray traverses distally to proximally for up to 30 mm

CONTROLLER & FOOT PEDAL PREPARATION
Refer to C2 CryoBalloon Ablation System Instructions For Use.

SYSTEM OPERATION
Refer to C2 CryoBalloon Ablation System Instructions For Use.

ABLATION DOSIMETRY SELECTION
Select the desired ablation Dosimetry based on Tables 1 through 4 and input the Dosimetry on the Controller Control Panel.

NOTE: For treatment of Barrett's Esophagus and GAVE, refer to tables 3 and 4.

NOTE: The CryoBalloon Ablation System 90, 180 and 360 catheters are designed to treat larger areas of disease (>2.5cm2), approximately 90, 180 and 360 degrees of the targeted treatment area. For these catheters, the diffuser of this balloon moves within the balloon longitudinally, spraying as it moves. The volume of gas that diffuses in the balloon and touches the inner balloon surface does not change for a fixed amount of time that the gas is being sprayed. However, the speed of the longitudinal movement of the diffuser affects the total diffuser traversal and the length of the cylinder (or half cylinder for the 180, and quarter cylinder for 90) and therefore the areas over which the cryogen is sprayed. Therefore, the faster the diffuser moves, for the same Esophageal canal length and diameter, the less tissue exposure time to the diffuser spray Higher speeds for the CryoBalloon Ablation System 90, 180 and 360 catheters result in lower dosing for the same targeted treatment area. e.g. A speed of 1.2 mm/s provides a lower dose than a speed of 1.0 mm/s dose. In addition, the depth of ablation for each catheter is correspondingly lower at higher speeds (see Table 2).

Table 1. General Focal Dosimetry

Desired Ablation Depth	Recommended Treatment Duration (sec)
< 0.5 mm	4, 5
0.5 mm to 1.0 mm	6, 8
1.0 mm to 1.5 mm	10, 12
1.5 mm to 2.0 mm	14

Table 2. General 90°/180°/360° Dosimetry

Desired Ablation Depth	Recommended Treatment Rate (mm/sec)		
	360°	180°	90°
0.025mm to 0.5mm	-	1.0 – 1.2	-
< 0.5 mm	0.5	0.7 – 0.8	0.9 – 1.0
0.5 mm to 1.0 mm	0.4	0.6 – 0.7	0.7 – 0.8
1.0 mm to 1.5 mm		0.5 – 0.6	0.6

Table 3. Barrett's Esophagus Treatment Dosimetry

Desired Ablation Depth	Recommended Treatment Rate (mm/sec)		
	360°	180°	90°
0.025mm to 0.5mm	-	1.0 – 1.2	-

Table 4. GAVE Treatment Dosimetry

Recommended Treatment Rate (sec)			
360°	180°	90°	Focal
-	-	-	12 to 14

STORAGE AND DISPOSAL
Store the C2 CryoBalloon Ablation System as follows:
- Controlled room temperature environment with ambient temperature from +10°C to +40°C
- Relative humidity from 30% to 75%
- Atmospheric pressure from 700 to 1060 hPa

Dispose of the C2 CryoBalloon Catheter and used cartridge in accordance with standard hospital guidelines and local codes for the disposal of medical waste and electronic waste.

CLINICAL DATA SUMMARY
Prospective clinical data for the C2 CryoBalloon Ablation System is included below.

Table 5. General Ablation Data

Clinical Data Characteristic	Schölvinck 2015[1]	Canto 2016[2]
Barrett's esophagus with LGD	9/39 (23%)	13/40 (33%)
Follow-up Duration (LGD)	64 days (median)	1 year
Device Used	Focal	Focal
Resolution at Follow-Up (LGD, 10 second ablation)	5/5 (100%)	12/13 (92%)
Serious Adverse Events (LGD, requiring treatment)		
Dysphagia	0/9 (0%)	0/13 (0%)
Stricture	0/9 (0%)	1/13 (8%)
Bleeding	0/9 (0%)	0/13 (0%)
Perforation	0/9 (0%)	0/13 (0%)
Pain requiring prolonged course of narcotics	0/9 (0%)	0/13 (0%)
Non-Serious Adverse Events (LGD)		
Dysphagia ≥ 24 hours	0/9 (0%)	2/13 (15%)
Stricture	0/9 (0%)	0/13 (0%)
Mucosal laceration	2/9 (22%)	0/13 (0%)
Pain requiring narcotics ≥ 24 hours	0/9 (0%)	1/13 (8%)

Table 6. Recent Clinical Ablation Summary for Barrett's Esophagus

Clinical Data Characteristic	Canto 2020[3]	Dbouk 2022[4]
Barrett's Esophagus Baseline pre-treatment highest neoplasia grade	IMC: 23/94 (25%) HGD: 50/94 (54%) LGD: 19/94 (21%)	IMC: 4/59 (6.8%) HGD: 33/59 (56%) LGD: 22/59 (37%)
Catheter Used	Focal	Focal
Dose	10 seconds	10 seconds
Resolution at Follow-Up (LGD, 10 second ablation)	n/a	n/a
Year 1 Follow-up	CE-D: 97% CE-IM: 91%	CE-D: 94.6% CE-IM: 75%
Year 2 Follow-up	n/a	CE-D: 100% 53/53) CE-IM: 98% 47/48)
Year 3 Follow-up	n/a	CE-D: 100% (45/45) CE-IM: 98% (40/41)
Year 4 Follow-up	n/a	CE-D: 100% (37/37) CE-IM: 97% (32/33)
Serious Adverse Events (LGD, requiring treatment)		
Upper GI Bleeding	1	1
Laceration after Dilation	1	None Reported
Perforation	1	None Reported
Non-Serious Adverse Events (LGD)		
Mucosal Laceration	1 (0.8%)	None Reported
Stricture	15 (12.5%)	5/59 (8.4%)
Pain requiring narcotics ≥ 24 hours	1(0.3%)	None Reported
Buried BE	1 (0.8%)	None Reported
Neoplastic progression to ImCA	1 (0.8%)	None Reported

Table 7. Clinical Data for GAVE

Clinical Data for GAVE Characteristic	Patel 2018[5]	Clinical Data[8]
Gastric Antral Vascular Ectasia patients	23	28
Follow-up Duration	6 months	6 months
Catheter Used	Focal	Focal
No acute or late adverse events reported		
Technical Success	23/23 (100%)	28/28 (100%)
Transfusion Independent @ 6 months	19/23 (83%)	16/26 (62%)
>75% GAVE eradicated @ 6 months	20/23 (87%)	22/32 68.8%)
Average Increase in mean Hemoglobin Level after treatment	2.55 g/dl	4.6 g/dl

Table 8. 180 Medical Research Data

Clinical Data for BE Characteristic	Medical Clinical Data[7]	Overwater 2021[6]
Barrett's Esophagus patients	23	25
Catheter Used	180	180
Dose	1.2mm/sec dose	1.0mm/sec dose
Barrett's Esophagus Baseline pre-treatment highest neoplasia grade	IMC: 4 (17%) HGD: 6 (25%) LGD: 14 (58%)	IMC: 10 (40%) HGD: 5 (20%) LGD: 10 (40%)
3-month follow-up	90% BE surface regression after 1 cm treatment	90%**
Serious Adverse Events (LGD, requiring treatment)		
Upper GI Bleed	1/23 (4%)	None Reported
Stricture requiring Dilation	1/23 (4%)	1/23 (4%)
Non-Serious Adverse Events (LGD)		
Stricture	None Reported	3/23 (13%)
Dysphagia without Endoscopic focus	1/23 (4%)	None Reported
Black stool without abnormalities in feces or blood in occult testing	1/23 (4%)	1/23 (4%)
Pain requiring narcotics < 24 hours	None Reported	1/23 (4%)

** Overall, the median BE regression as evaluated by the treating physicians was 90% (95%CI 70%–90 %).

	Caution
	Do not use if package is damaged and consult instruction for use
	Catalog number
	Lot number
	Medical Device
	Unique Device Identifier
	Single use
	Do not resterilize
	Consult Instructions for Use For electronic copy scan QR Code, or go to www.merit.com/ifu and enter IFU ID Number. For printed copy available within seven calendar days, call U.S.A. or EU Customer Service.
	Sterilized using ethylene oxide
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Single sterile barrier system
	Use by date: YYYY-MM-DD
	Date of manufacture: YYYY-MM-DD
	Manufacturer
	Authorized Representative in European Community
	Keep dry
	Type BF Applied Part
	Atmospheric pressure limitation. Store at 700 to 1060 hPa (hectopascals) atmospheric pressure.
	Humidity limitation. Store at 30% to 75% RH (relative humidity).
	Temperature limitation. Store at +10°C to +40°C.
	Electronic Equipment: Dispose of Properly
	No latex
	1 unit
	5 units
	Importer

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6. Overwater, A., Van Munster, S. N., Nagengast, W. B., Pouw, R. E., Bergman, J., Schoon, E. J., & Weusten, B. L. (2021). Novel cryoballoon 180° ablation system for treatment of Barrett's esophagus-related neoplasia: a first-in-human study. Endoscopy, 54(01), 64–70

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8. PENTAX Medical held clinical data final report- A multi-center retrospective series to assess the safety and efficacy of the C2 CryoBalloon Ablation System™ when used for the treatment and management of Gastric Antral Vascular Ectasia of the GI tract.

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