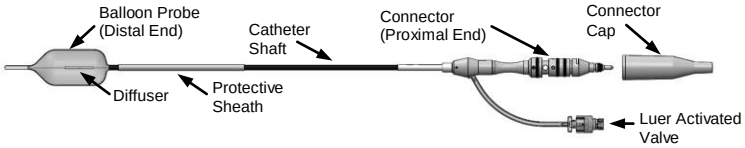
C2 CryoBalloon™ Ablation System

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 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, 100 cm maximum working length). The System is comprised of the following main components:

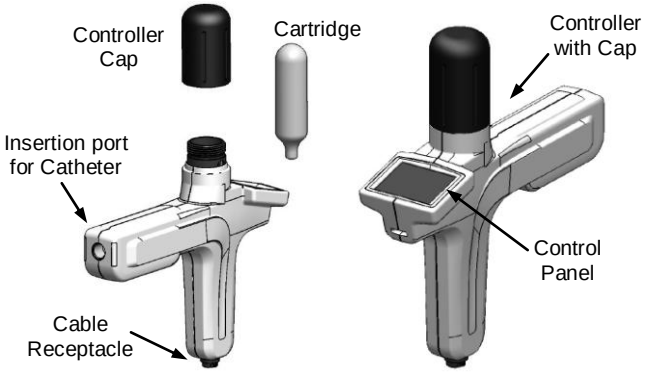
- C2 CryoBalloon™ Catheter (see Figure 1) connects to the Controller, which controls the operation of the Catheter such as diffuser (sprayer) positioning and ablation (nitrous oxide release). C2 CryoBalloon Catheter consists of proximal Connector, Catheter Connector Cap, Catheter Shaft, balloon probe,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

Figure 1 – C2 CryoBalloon™ Catheter



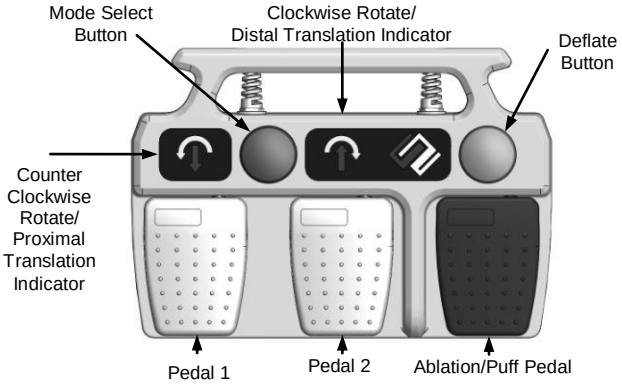
- C2 CryoBalloon™ Controller (see Figure 2) contains the cartridge heater and the cryogen delivery valve, which is controlled with the Foot Pedal. The Controller contains diffuser radial and axial positioning features that are controlled by the Foot Pedal. The Controller is powered by 12VDC through the Foot Pedal and is supplied non-sterile and is reusable. An LCD touch screen on the Controller communicates system status and allows dosimetry input.
- C2 CryoBalloon™ Cartridge (see Figure 2) 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 2 – C2 CryoBalloon™ Controller & C2 CryoBalloon™ Cartridge



- C2 CryoBalloon™ Foot Pedal 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 3 – C2 CryoBalloon™ Foot Pedal



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.

Prescription Use

Caution: USA federal law restricts this device to sale by or on the order of a physician.

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 lumen that precludes advancing the C2 CryoBalloon Catheter to the site of ablation
- Target tissue varices 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 cryogenic fluid may freeze the skin.
- Do not inhale nitrous oxide from the cryogen cartridge. Inhalation may be dangerous to your health.
- WARNING: No modification of this equipment is allowed.
- WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

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 diameters measuring 20 mm to 30 mm. Ablation in larger or smaller lumens 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 0^{o}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.

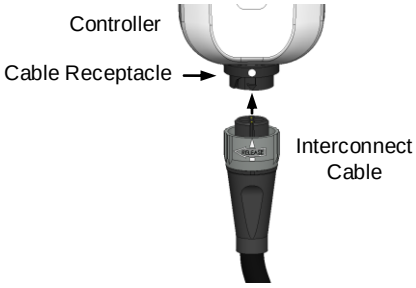
Foot Pedal Preparation

1. Open the Foot Pedal package and remove the Power Cable and Foot Pedal.
2. Plug the Power Cable into the Foot Pedal power supply.
3. Plug the Power Cable plug into the mains power source.
4. Position the Foot Pedal at the desired location.

Controller Preparation

5. Open the Controller package and remove the Controller and Controller Cap. Open the Cartridge package and remove a Cartridge.
6. Plug the Interconnect Cable of the Foot Pedal into the Controller to power it on. Confirm the cable is securely attached. (**Figure 4**)

Figure 4 – Interconnect Cable to Controller



7. Insert the round end of the Cartridge into the Controller Cap (press firmly).

Caution: Use only C2 CryoBalloon™ Cartridges.

8. Insert the Controller Cap and Cartridge into the Controller and rotate the Controller Cap clockwise until it stops. This action breaks the seal on the Cartridge.

Catheter Insertion

9. Open the package and remove the Catheter.

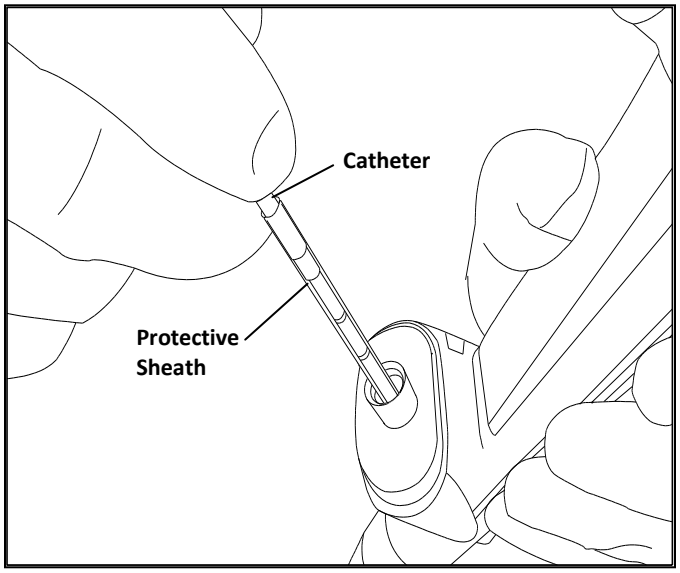
Caution: Do not remove the Catheter Connector Cap (proximal) or Protective Sheath (distal) until instructed.

10. Remove the biopsy valve cap and insert the Catheter Balloon Probe constrained within the Protective Sheath into the biopsy valve of the endoscope (3.7 mm ID minimum; 100 cm length maximum).

Caution: Do not pre-inflate or pre-test the balloon. Do not attempt to refold the balloon into the Protective Sheath. If the balloon is not constrained within the Protective Sheath prior to use, discard and replace the Catheter.

11. Grasp the Catheter close to the endoscope and advance the Catheter through the Protective Sheath and through the biopsy valve (**Figure 5**).

Figure 5 – Insert Catheter into the Biopsy Valve

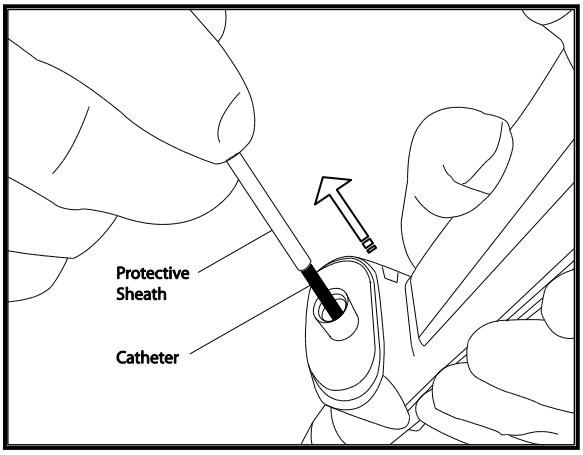


12. Continue advancing the Catheter until the balloon exits the endoscope.

Caution: Visualize the Catheter tip as it exits the endoscope.

13. Withdraw the Protective Sheath from of the biopsy valve and slide proximally onto the Catheter shaft (**Figure 6**).

Figure 6 – Slide the Protective Sheath Proximally



Catheter Positioning

14. Position the distal end of the endoscope approximately 2 to 3 cm proximal to the ablation site.

15. Advance the Catheter out of the endoscope until the black Catheter shaft (proximal to the balloon) is visible. Retract the Catheter into the endoscope until there is slight resistance (balloon contacting endoscope).

16. Remove and discard the Catheter Connector Cap.

17. Insert the Catheter Connector into the Controller. An audible "click" will be heard. Lightly tug on the Connector and Controller to confirm a secure connection.

18. After the Catheter has been connected, press 

to verify that a Catheter has been connected.

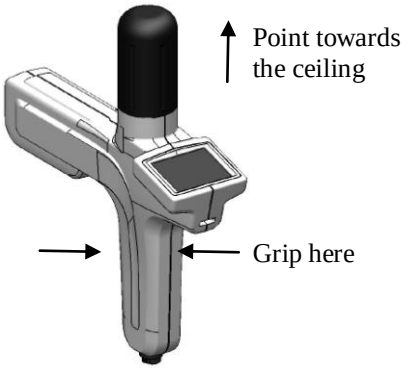
Ablation Dosimetry Selection

19. Using the Controller Control Panel, select the desired ablation dosimetry. Refer to specific dosimetry information in the Catheter Instructions For Use (IFU). The System is ready for ablation after the ablation dosimetry has been selected.

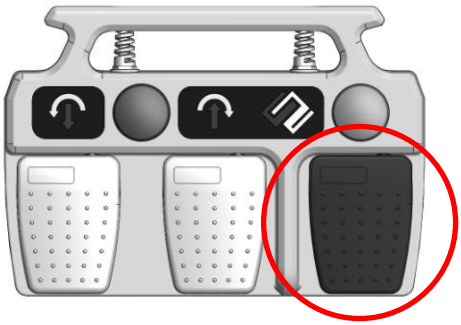
Balloon Pre-Inflation and Ablation

20. When the Cartridge is at operational pressure, the orange **Standby Icon** will change to a blue **Ready Icon**, and an audible beep will sound.

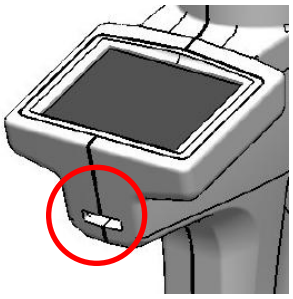
21. Hold the Controller upright with the Controller Cap pointing vertically (towards the ceiling). Ablation will be disabled if the Controller orientation is incorrect.

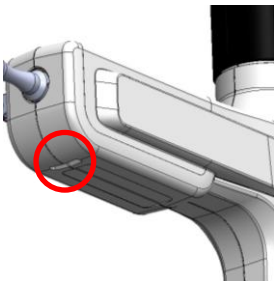


22. Depress and quickly release the Foot Pedal Ablation pedal (circled below) to pre-inflate the balloon.



Note: This will deliver a small amount of cryogen that inflates the balloon so that it is in contact with the tissue.



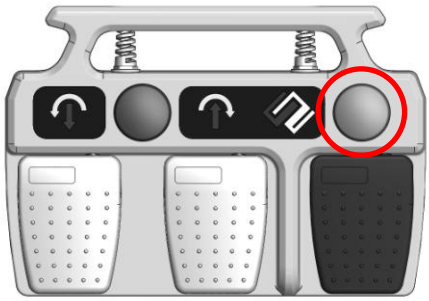


Caution: Do not occlude the exhaust ports during ablation.

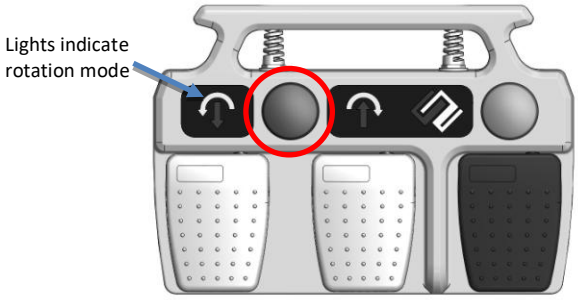
23. Visualize the ablation site through the balloon. Retract or advance the Catheter for optimal positioning.

24. To visualize the target tissue area, press and quickly release the Ablation pedal (puff). This will deliver a small amount of cryogen to the targeted tissue area. The tissue will turn white due to momentary freezing.

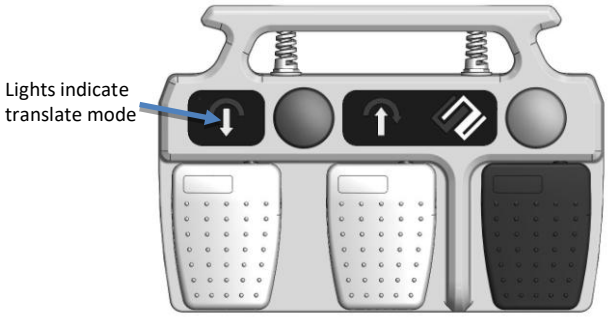
25. To reposition the balloon proximally or distally press the Deflate button on the Foot Pedal (circled below), or deflate the balloon by attaching a 30 mL syringe to the Luer Activated Valve on the Catheter Connector and drawing vacuum to deflate the balloon. Reposition the balloon and repeat step 22 through step 24 to confirm the position.



26. To **Rotate** the diffuser, select the Rotation mode with the Mode Select Button on the Foot Pedal (circled below), and use the grey pedals to rotate the diffuser clockwise or counter -clockwise. The rotational arrows will illuminate to indicate to user that Foot Pedal is in Rotation mode.



27. To adjust the **Axial** position of the diffuser, select the Translate mode on the Foot Pedal with the Mode Select Button, and use the grey pedals to move the diffuser distally or proximally. The axial arrows will illuminate to indicate to user that Foot Pedal is in Translate mode.



28. Repeat Step 24 to verify position.

Note: During ablation, the inflated balloon remains stationary.

Note: During ablation, the Focal catheter diffuser remains stationary for the duration of the selected dosimetry time. The diffuser for all other catheter configurations travels proximally at the selected dosimetry rate.

29. To perform ablation, press and hold the Ablation pedal on the Foot Pedal. Cryogen is continuously delivered from the diffuser for the entire ablation duration. During ablation, the Control Panel will indicate that **Treating** is in process, and a beep sounds every second.

Caution: To stop the flow of cryogen during ablation prior to the full ablation duration, release the Ablation pedal.

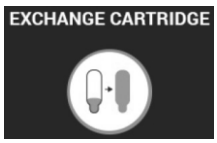
30. Cryogen flow will automatically stop after the user selected duration has elapsed.

31. An extended audible sound signals when ablation is complete. Release the ablation pedal.

Note: The balloon inflates to approximately 4.5 psig (0.3 ATM). The balloon pressure cannot be altered by the user.

Exchange Cartridge

32. Additional Ablations can be performed with the current cartridge until the **Exchange Cartridge** prompt appears.



33. To exchange the Cartridge, by slowly rotate the Controller Cap counterclockwise. Any remaining nitrous will exhaust. Dispose of the used Cartridge.

34. Install a new Cartridge by following Steps 7 to 8.

35. Perform additional ablation by following Steps 20 to 31.

Catheter Withdrawal

36. Prior to withdrawal, return the diffuser to the distal most position and straighten the distal end of the endoscope as much as possible. Any excess bend on the endoscope will increase the resistance during withdrawal of the catheter.

37. Follow one of the two techniques to withdraw the Catheter into the endoscope:

a) Press and hold the Deflate button on the Foot Pedal and withdraw the Catheter into the endoscope.

Release the button when the Catheter has been fully withdrawn into the endoscope. Or,

b) Attach a 30mL syringe to the luer-activated valve that is attached to the Catheter. Draw a vacuum to fully deflate the balloon. Maintain the vacuum and slowly retract the Catheter into the endoscope.

Caution: If there is excessive resistance, remove the endoscope and Catheter as a unit.

38. Press ⏏ on the Control Panel, to detach the Catheter from the Controller. Dispose of the Catheter according to standard hospital guidelines for the disposal of medical waste.

39. When the procedure has been completed, remove the Cartridge from the Controller and dispose of the Cartridge.

40. Clean/disinfect Controller and clean Foot Pedal and store according to Operation, Storage and Disposal instructions.

Troubleshooting

If a fault condition occurs, the LCD touch screen on the Controller will display an Error Description with recommended Corrective Action. If the Corrective Action displayed does not resolve the fault condition, do not use the system. Contact C2 Therapeutics, Inc.

Cleaning and Disinfection

The reprocessing instructions are based on recommendations found in the "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008" by the Centers for Disease Control (CDC).

This section provides guidelines for cleaning and disinfecting the C2 CryoBalloon™ Controller. The Controller has a reuse life of 1 year. Use EPA-registered disinfectant wipes and the provided brushes/swabs wetted by EPA-registered disinfectant spray.

Caution: The Controller is rated for IPX0 (it has no protection against ingress of liquids) – do not allow any fluid to enter the Controller.

1. Remove the Controller Cap and soak it in warm water for at least 5 minutes.
2. Wipe all accessible surfaces on the Controller and the Cap. Repeat until visible soils are removed.
3. Spray the Controller to adequately wet the external surfaces. Brush all the external surfaces and swab the inner exhaust ports.

Caution: Do not spray liquid disinfectant directly into the catheter insertion port, the receptacle for the cartridge, and the cable receptacle.

4. Leave the Controller undisturbed for at least 4 minutes.
5. Wipe the Cap and all accessible surfaces on the Controller. Use multiple wipes.
6. Allow the Controller assembly to dry prior to use.

This section provides guidelines to clean the C2 CryoBalloon™ Foot Pedal. The Foot Pedal has a reuse life of 3 years.

Caution: The Foot Pedal is rated for IPX6 (protection against splashing of liquids; no protection against submersion) – do not fully submerge the Foot Pedal.

1. Clean any visible soils with a mild soap and water solution if necessary. Wipe clean.
2. Allow the Foot Pedal to dry prior to use.

Operation, Storage and Disposal

Operate and 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™ System components in accordance with standard hospital guidelines and local codes for the disposal of medical waste and electronic waste.

EMC Compliance and Warning Statement

This equipment has been tested and found to comply with the limits of the standard for medical devices, IEC 60601-1-2. The limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radiofrequency energy, and, if not installed and used in accordance with the manufacturer's instructions may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes interference with other devices, which may be determined by turning the equipment off and on, the user should notify the hospital safety personnel and try to correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between the equipment.
- Consult the manufacturer for help.

FCC Compliance and Warning Statement

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

EMC Guidance and Declaration

The CryoBalloon Ablation System is intended for use in the electromagnetic environments described in the tables below. The customer or user of the system should assure that is used in such an environment

ELECTROMAGNETIC IMMUNITY			
Immunity Test	**Test Level**	**Compliance Level**	**Electromagnetic environment guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial hospital environment
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the CryoBalloon Ablation Controller, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. The recommended separation distances calculations can be calculated as follows: $d = 1.2\sqrt{P}$ ($P < 800$Mhz) $d = 2.3\sqrt{P}$ ($P \geq 800$Mhz) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of the equipment marked with the following symbol:

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed for normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Controller.

[b] Over the frequency range 150kHz to 79MHz, field strength should be less than 3 V/m.

ELECTROMAGNETIC EMISSION		
Emission Test	**Compliance**	**Electromagnetic environment guidance**
RF Emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
	Class B	The system is suitable for use in all establishments, domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

The C2 CryoBalloon™ Ablation System is intended for use in an electromagnet environment in which radiated radiofrequency (RF) disturbances are controlled. The Controller part of the system is the only electronic component of the system; therefore, the distances described below only apply to the Controller. The customer or user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Controller as recommended below, according to the maximum output power of the communications equipment.

Recommended separation distances between portable and mobile communications systems and the CryoBalloon Ablation Controller			
Rated Max Output of Transmitter (watts)	**Separation distance according to frequency of the transmitter (meters)**		
	150kHz-79Mhz $d=1.2\sqrt{P}$	**80MHz-799Mhz $d=1.2\sqrt{P}$**	**800MHz-2.5GHz $d=2.3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Labeling Symbol Key

REF	Catalog number	1 Contents	1 unit
LOT	Lot number	5 Contents	5 units
	Single patient use	STERILIZE	Do not resterilize
	Expiration date		Date of Manufacturer
STERILE EO	Sterilized by ethylene oxide gas	LATEX	This product is not manufactured with natural rubber latex
	Type BF applied part		Keep dry
	Consult instructions for use		Caution See Warnings
	Manufacturer	EC REP	Authorized European Representative
	Do not use if package is opened or damaged	75% 30%	Store at 30% to 75% RH (relative humidity)
1060 hPa 700 hPa	Store at 700 to 1060 hPa (hectopascals) atmospheric pressure	+40°C +10°C	Store at +10°C to +40°C
Rx Only	Caution: USA Federal law restricts this device to sale by or on the order of a physician	1060 hPa 700 hPa	Store at 700 to 1060 hPa (hectopascals) atmospheric pressure

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