AtriCure®

cryoICE® cryoFORM™ cryoablation probe

Instructions for Use

Use with the following cryoablation probe models: CRYOF

DESCRIPTION

The cryoICE cryoFORM cryoablation probe, CRYOF, (also referred to as PROBE) was designed for treatment of cardiac arrhythmias by achieving controlled temperatures ranging from-50° C to -70° C. The PROBE is a sterile, single-use cryosurgical instrument designed for use with the AtriCure Cryo Module (ACM) V5 or V6.

cryoICE cryoFORM cryoablation probe
ILLUSTRATION AND NOMENCLATURE

See Figure 1: cryoICE cryoablation probe

Table 1. PROBE Nomenclature		
1. Manifold	4. Rigid Shaft	7. Gas Exhaust Connector
2. Temperature Connectors	5. Malleable Tip	8. Tubing
3. Retractable Handle	6. Gas Inlet Connector	

⚠ BEFORE USING THIS PRODUCT READ THE FOLLOWING INFORMATION THOROUGHLY

IMPORTANT!
This booklet is designed to assist in using this product. It is not a reference to surgical techniques.

INDICATION FOR USE

The cryoICE cryoFORM cryoablation probe is indicated for use in the cryosurgical treatment of cardiac arrhythmias by freezing target tissues, creating an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

CONTRAINDICATIONS

There are no known contraindications.

⚠ WARNINGS

1. Please refer to the ACM User's Manual for Console warnings, cautions, product description and features.
2. The PROBE is only compatible with the ACM. Use of the PROBE with another manufacturer's system may damage the device and result in patient injury.
3. Do not use the PROBE to freeze tissue inside the beating heart. Use of the PROBE to freeze tissue inside the beating heart may result in severe injury to the patient.
4. Cryoablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether cryoablation with the PROBE will have such an effect, but as in all such procedures, care should be taken to minimize unnecessary contact with coronary vessels during cryoablation.
5. Do not pull on the PROBE or console while the malleable tip is frozen to tissue as this could lead to inadvertent tissue damage.
6. Do not use excessive force when using the PROBE in order to avoid tissue damage.
7. Cardiac surgical procedures may mechanically induce arrhythmias.
8. The PROBE should be positioned correctly and the placement of the malleable tip confirmed prior to cryoablation. Ensure there is no undesired tissue contact with the malleable tip or shaft during freezing, in order to avoid inadvertent tissue freezing.
9. The PROBE contains pressurized gas during operation. Discontinue use immediately if a breach in the PROBE is suspected, as this may result in release of pressurized gas and injury to the patient or the user.
10. Do not attempt to disconnect the PROBE during operation. The sudden release of pressure may cause the PROBE to recoil, which may injure the operator or patient.
11. Do not reprocess or reuse the PROBE. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

⚠ CAUTIONS

1. Read all CRYOF instructions as well as the ACM user manual carefully prior to using the device. Failure to properly follow instructions may lead to injury and may result in improper functioning of the device.
2. Use of the PROBE should be limited to properly trained and qualified medical personnel.
3. To avoid damage to the device, do not drop or toss the PROBE. If the PROBE is dropped, do not use. Replace with a new PROBE.
4. Do not resterilize or reuse the PROBE.
5. Do not use the PROBE if damaged in any way.
6. If the sterile package is damaged and/or the sterile barrier is breached, discard device and DO NOT USE.
7. Do not remove or install PROBE from console unless the ACM is in the Stand-By Mode and is fully vented (ACM V5).
8. Do not restrict, kink, clamp, or otherwise damage PROBE malleable tip, rigid shaft, or tubing.
9. Nitrous oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels.
10. Users should be aware of known radio frequency (RF) sources and consider them when using a medical device. The AtriCure cryoICE cryoablation system can be sensitive to electrostatic discharge (ESD) and RF emissions, which may temporarily reduce system performance.

INSTRUCTIONS FOR USE

NOTE: Reference the ACM User Manual for additional instructions on use of the ACM.

1. Connect PROBE to the ACM. See Figure 3. Table 2 provides a list of the connections to the ACM.

Table 2. PROBE Connections to ACM	
Item Number	**Item Description**
1	PROBE Gas Inlet Connector (blue)
2	PROBE Gas Exhaust Connector (orange)
3	PROBE Temperature Connectors (black and red)

2. Retract retractable handle and rigid shaft to expose malleable tip. See Figure 2: Handle and Rigid Shaft Retraction.

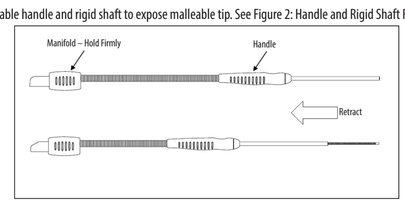


Figure 2: Handle and Rigid Shaft Retraction – Hold handle and manifold firmly while retracting rigid shaft.

3. Perform a "Pre-Freeze" by cycling the ACM using the activation button or footswitch while the PROBE is in air.

IMPORTANT: The PROBE must be operated at a pressure of 700 psi or higher.

4. Thirty seconds after frost appears on the PROBE malleable tip, cycle the ACM to defrost mode and vent the probe.
5. Identify and expose the sites to be cryoablated using standard surgical techniques.
6. Bend the malleable tip to the required shape.

NOTE: Take care not to restrict, kink, clamp, or otherwise damage PROBE malleable tip during bending.
NOTE: Only the malleable tip should be bent. Do not bend the PROBE rigid shaft.

7. Place the malleable tip against the targeted tissue under direct visualization by the surgeon.

NOTE: Ensure the malleable tip temperature is above 0°C before contacting tissue.
NOTE: Ensure there is no undesired tissue contact with the malleable tip or rigid shaft.
NOTE: Do not use excessive force when using the PROBE in order to avoid tissue damage.

8. Press the ACM activation button or footswitch to begin freezing.

NOTE: Movement of PROBE prior to tissue adhesion may affect freezing. Cryoadhesion occurs when malleable tip temperature is below 0°C.

9. Freeze for desired length of time.
10. Defrost the probe by either:
    a. Allowing the ACM to automatically enter the Defrost mode;
    b. Or by cycling the activation button or foot pedal.
11. Once the PROBE temperature warms to greater than 0°C remove PROBE from targeted tissue.

NOTE: If PROBE does not reach desired Defrost temperature, apply warm sterile saline to the tissue and probe area as necessary.

12. For the ACM V5 only, cycle the ACM activation button or foot pedal to vent the PROBE (the ACM V6 automatically vents the probe).

⚠ CAUTION
Venting the probe can cause sufficient cooling to cause cryoadhesion.

13. Ensure the probe tip is clean before creating the next lesion.
14. Repeat steps 6 through 13 as desired to create additional cryo lesions.

⚠ CAUTION
Do not remove or install PROBE from console unless the ACM is in the Stand-By Mode (ACM V6) and fully vented (ACM V5).

HOW SUPPLIED

The PROBE is supplied as a sterile instrument and is for single patient use only. Sterility is guaranteed unless the package is opened or damaged.

RETURN OF USED PRODUCT

If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping. If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER STATEMENTS

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in manner described in these instructions for use, including, but not limited to, ensuring that product is not re-used.
Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consiquential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

Explanation of symbols on package labeling

Refer to the outer package label to see which symbols apply to this product.

	Non-Pyrogenic	**Rx ONLY**	Caution: Federal Law (US) restricts this device to sale by or on the order of a physician		Follow instructions for use
STERILE R	Sterilized by Gamma Radiation	LOT	Lot Number		Manufacturer
	Single Use Only		Caution		Not made with natural rubber latex
	Use-By Date		Do Not Resterilize		Do not use if the package is damaged
	Waste Electrical and Electronic Equipment (WEEE)				

Figure 1. cryoFORM cryoICE cryoablation PROBE

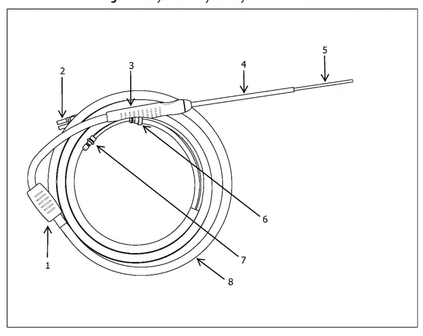
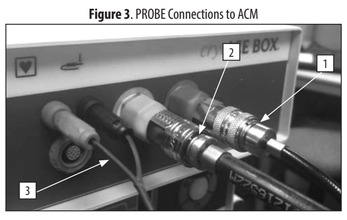


Figure 3. PROBE Connections to ACM



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