AtriCure®

cryoICE™ cryo–ablation probe

Instructions for Use

Use with the following cryo–ablation probe models: CRYO2

CAUTION: Investigational Device. Limited by Federal (United States) Law to Investigational Use. Exclusively for Clinical Investigation.

Please refer to the Clinical Study Protocol (CP2018-1) for these Instructions.

DESCRIPTION

1. The AtriCure cryoICE cryo–ablation system is comprised of:
   a. cryoICE cryo–ablation probe, CRYO2, (also referred to as PROBE) with Cryo1 probe form tool
   b. AtriCure Cryo Module (ACM).

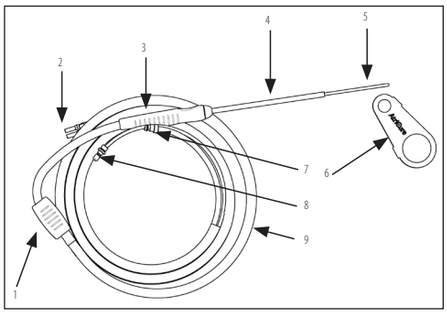
CAUTION

1. This PROBE was designed for treatment of cardiac arrhythmias by achieving controlled temperatures down to -50° C to -70° C; it can also be used to block pain by temporarily ablating the peripheral nerves.
2. This Instructions for Use document will cover use of the cryoICE cryo–ablation probe, form tool. The cryoICE cryo– ablation probe is a sterile, single-use cryosurgical instrument designed for use with the ACM. The Cryo1 form tool facilitates bending of the malleable tip.
   NOTE: Users should be aware of known radio frequency (RF) sources and consider them when using a medical device.The AtriCure cryoICE cryo–ablation system can be sensitive to electrostatic discharge (ESD) and RF emissions, which may temporarily reduce system performance.

cryoICE™ cryo-ablation probe
ILLUSTRATION AND NOMENCLATURE

Table 1. PROBE Nomenclature		
1. Manifold	4. Rigid Shaft	7. Gas Inlet Connector
2. Temperature Connectors	5. Malleable Tip	8. Gas Exhaust Connector
3. Retractable Handle	6. Form Tool	9. Tubing

Figure 1: cryoICE cryo–ablation probe and form tool



BEFORE USING 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
Please refer to the Clinical Study Protocol (CP2018-1)

CONTRAINDICATIONS
Please refer to the clinical study protocol (CP2018-1) for Exclusion Criteria

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. Cryo–ablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether cryo–ablation 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 cryo–ablation.
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 cryo–ablation. 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 instructions carefully for the PROBE 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 re-sterilize or reuse the PROBE. Re-sterilization may cause loss of function or injury to patient.
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. Follow standard guidelines for the safe handling and storage of high-pressure gas tanks.
8. Do not remove or install PROBE from console unless the ACM is in the Stand-By Mode.
9. Nitrous oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels.
10. Do not restrict, kink, bend, clamp or otherwise damage PROBE tubing.

NOTE: Please refer to the ACM User's Manual for Console instructions, product descriptionand features.

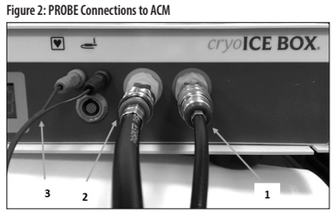
11. When using a standard off-the-shelf nerve stimulator, read all of the manufacturer's instructions carefully prior to using the device. Failure to follow instructions may lead to injury and may result in improper functioning of the device.

Instructions for Use

1. Follow the setup installation instructions for proper setup of the ACM per the User's Manual.
2. Turn the Nitrous Oxide Cylinder (Tank) Valve fully counter-clockwise to open.
3. Examine the packaging of the device to ensure the sterility of the product has not been breached.
4. Remove the sterilized instrument from its package per standard sterile technique.
5. Connect the PROBE Gas Inlet Connector to the Gas inlet Connection Port. **See Figure 2**.

Table 2. PROBE Connections to ACM		
Item Number	**Connect ACM Item**	**To Probe:**
1	Gas Inlet Connection Port	PROBE Gas Inlet Connector
2	Gas Exhaust Connection Port	PROBE Gas Exhaust Connector
3	Thermocouple Port	Match Color coded Temperature connectors to the matching colored PROBE connectors

Figure 2: PROBE Connections to ACM



6. Connect PROBE **Gas Exhaust Connector** to the Gas Exhaust Connection Port. To engage **Exhaust Probe Socket**, slide retainer ring back on quick disconnect while inserting plug, then release.
7. Confirm PROBE connectors are fully engaged by lightly pulling on connections.
8. Connect **Temperature Connectors** of the PROBE to the corresponding colored connectors on the ACM. See **Figure 2**: PROBE Connections to ACM.
9. Switch the ACM unit ON.

NOTE: When connected correctly, the ACM will display current PROBE temperature. If not connected, the ACM will display E-H.

10. For a cryoICE device, retract handle and rigid shaft to expose malleable aluminum probe. See **Figure 3**: Handle and Rigid Shaft Retraction.

IMPORTANT: Do not use the PROBE in the Temperature Control mode. The **Handpiece Probe Temperature Control** must be set full open (turn counterclockwise until it stops).

11. 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.

12. Thirty seconds after frost appears on the malleable probe tip:
    a. Cycle the ACM to defrost.
    b. Cycle the ACM to vent the probe.
13. Identify and expose the sites to be cryoablated using standard surgical techniques.
14. If bending of the malleable tip is required always use the form tool. Refer to the section labeled: "Bending PROBE Malleable Tip". If bending of the shaft is required refer to the section labeled: "Bending PROBE Shaft".
15. 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 targeted tissue is in contact with the malleable tip prior to freezing.

NOTE: Ensure there is no undesired tissue contact with the malleable tip or shaft.

NOTE: Do not use excessive force when using the PROBE in order to avoid tissue damage.

16. Press the 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.

NOTE: Failure for PROBE to reach desired temperature is discussed further under the section labeled: "FREQUENTLY ASKED QUESTIONS".

17. Freeze for desired length of time.
18. 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.
19. Once the PROBE temperature warms 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.

20. Cycle the activation button or foot pedal to vent the probe.

CAUTION

Venting the probe can cause sufficient cooling to cause cryo-adhesion.

21. Wipe the malleable tip clean.
22. Repeat steps 23 thru 31 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.

23. Upon completion of the surgical procedure:
    a. Turn the Nitrous Oxide Cylinder (Tank) Valve fully clockwise to close.
    b. Pull the red pressure relief knob on the rear panel of the ACM to depressurize the ACM.
    c. Disconnect the PROBE from the ACM and discard the PROBE after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device component.
    d. Switch "Off" the ACM.

BENDING
Bending PROBE Malleable Tip

CAUTION

Repetitive bends in the same location could cause damage to the malleable tip. After each bend re-straighten the PROBE malleable tip prior to creating the next bend. If the same bend is desired in a different plane, do not rotate the PROBE malleable tip; re-straighten the PROBE malleable tip and create the same bend in the desired plane.

1. The PROBE malleable tip has a limited functional life; if greater than 8 bends are intended, it is recommended to use a second probe. It is always recommended to use the Cryo1 form tool to create desired bends. The Cryo1 form tool has two ends, the smaller end radius is 13 mm and the larger end radius is 26 mm. See Table 1, located in the section labeled: "PROBE Nomenclature".

CAUTION

The PROBE malleable tip should not be bent into a radius of less than 13 mm (0.5 inches).

2. Typical procedures may require the following bend profiles created with the use of the Cryo1 form tool: See **Figure 4** Form Tool Usage.

Bending PROBE Shaft
CAUTION

Repetitive bends in the same location could cause damage to the shaft.

1. The probe shaft has limited functional life.

CAUTION

The distal end of the PROBE shaft should not be bent more than 5 cm (2.0 inches) from straight.

2. Typical procedures may require the following bend profile: see **Figure 5**.

FREQUENTLY ASKED QUESTIONS FOR USE WITH THE ACM			
Question		**Answer**	**Solution**
1. Why is the PROBE not reaching the proper temperature?	a.	Inadequate inlet pressure	Replace low or empty nitrous oxide tank
	b.	Gas not flowing/Tubing is restricted	Verify tubing is not pinched
	c.	Handpiece probe temperature adjust knob is not completely turned counter-clockwise	Turn Handpiece probe temperature adjust knob completely counterclockwise
	d.	Leak in malleable tip or tubing	Replace with new probe
	e.	Nitrous oxide cylinder (tank) valve closed	Fully open nitrous oxide cylinder (tank) valve
	f.	Malleable tip is bent to radius less than 13 mm	Form malleable tip to radius of 13 mm or larger
2. Why does the ACM unit display "E-H"?	a.	The PROBE Temperature connectors are partially, or not plugged into the Unit	Plug the PROBE Temperature connectors all the way into the Thermocouple port
	b.	PROBE Temperature Connector wires are broken	Replace PROBE
3. Why does the ACM read a positive number during cryo-ablation?	a.	The PROBE Temperature connectors are plugged into the ACM, but they are reversed	Reverse the PROBE Temperature connectors to match the appropriate color coded connectors on the ACM
4. Why does the ACM display a fault code, error code, maintenance needed, or low pressure cylinder light?	a.	See ACM User's Manual for Trouble Shooting	See ACM User's Manual for Trouble Shooting

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.

WARNING

Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.

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 the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential 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.

PYROGEN	Non-Pyrogenic	Rx ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
STERILE R	Sterilized using irradiation	LOT	Batch code
	Single Use Only		Caution
	Used by date		Manufacturer
	Follow instructions for use	LATEX	Not made with Natural Rubber Latex

Figure 3: Handle and Rigid Shaft Retraction.

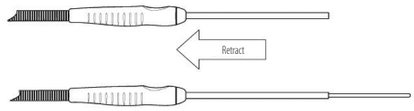
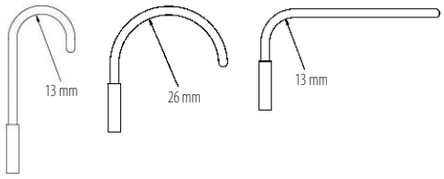


Figure 4



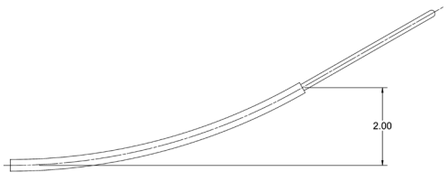
Form Tool Usage

Bending 13mm

Bending 26mm

Straightening

Figure 5



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