AtriCure®

Rx ONLY

cryoICE® system cryoablation probe

INSTRUCTIONS FOR USE

 # CRY03

MD

⚠**CAUTION:** Federal law (US) restricts this device to sale by or on the order of a physician.

FIGURE 1: CRYOICE SYSTEM CRYOABLATION PROBE AND FORM TOOL

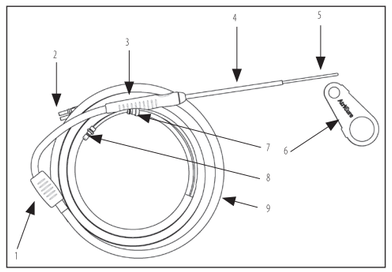


FIGURE 2: PROBE CONNECTIONS TO ACM

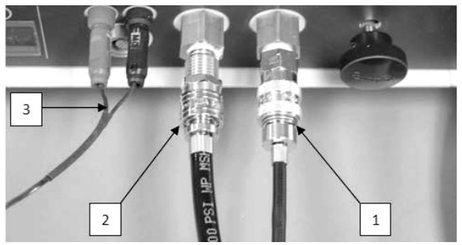


FIGURE 3: HANDLE AND RIGID SHAFT RETRACTION

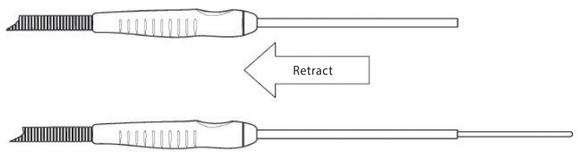
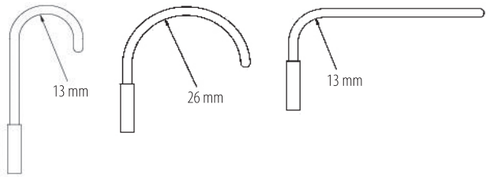


FIGURE 4: FORM TOOL USAGE

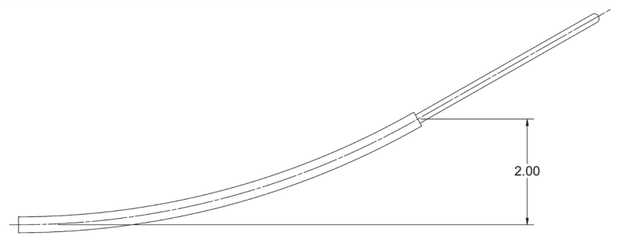


Bending 13mm

BENDING 26MM

Straightening

FIGURE 5: RECOMMENDED RIGID PROBE SHAFT BENDING



2.00 inches

INSTRUCTIONS FOR USE (en)

cryoICE® system cryoablation probe

DEVICE DESCRIPTION

1. The AtriCure cryoICE system is comprised of:
   a) cryoICE cryoablation probe, CRYO3, (also referred to as PROBE) with probe form tool
   b) AtriCure cryoICE BOX (ACM)
   c) AtriCure cryoICE BOX components and N_2O gas cylinder (not provided)

NOTE: This Instructions for Use document will cover use of the cryoICE cryoablation probe and form tool. The cryoICE cryoablation probe is a sterile, single-use cryosurgical instrument designed for use with the ACM. The form tool facilitates bending of the malleable tip.

PROBE NOMENCLATURE (SEE FIGURE 1)

PROBE FEATURES

[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

⚠**CAUTION:** Before using product read the following information thoroughly.

INDICATION FOR USE

AtriCure's cryoICE cryoablation probe is indicated for use in the cryosurgical treatment of cardiac arrhythmias. The PROBE freezes target tissues, creating an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway.

CONTRAINDICATIONS

There are no known contraindications.

⚠WARNINGS ⚠

Carefully read ALL instructions PRIOR to use. Failure to follow these instructions, warnings, and cautions may lead to device damage and/or patient injury.

Carefully read ALL instructions PRIOR to use. Failure to follow CryoICE Box (ACM) Console Warnings, Cautions, product description, flow rates, and features may lead to device damage and/or patient injury.

Use of the PROBE should be limited to properly trained and qualified medical personnel. Failure to provide intended therapy and/or serious injury could occur with improper use of this device.

FOR SINGLE USE ONLY. DO NOT reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

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.

If the sterile package is dropped and/or damaged or the sterile barrier is breached, discard device and DO NOT USE. Breach of sterile barrier can lead to infection.

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.

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

Use care to avoid PROBE movement while cryoadhesion is present, to prevent inadvertent tissue damage.

Cardiac surgical procedures may mechanically induce arrhythmias.

Before entering Freeze Mode, always confirm the placement of the Malleable Section of PROBE is as desired and there is no undesired tissue contact with the Malleable Section of PROBE or Rigid PROBE Shaft, to prevent unintended cryoadhesion and/or cryoablation.

The ACM components are not suitable for use in the presence of a flammable anesthetic mixture which can cause a fire or explosion, resulting in user and patient injury or death.

Ensure the CONSOLE is in READY Mode and the PROBE temperature is above 0°C (32°F) before contacting tissue, to avoid unintended cryoadhesion.

Do not bend Malleable Section of the PROBE during FREEZE or DEFROST mode. It can cause a high pressurized gas leak that can potentially lead to tissue perforation, unintended damage, or injury to user.

Forming the Malleable Section of PROBE in any way other than indicated in the following instructions can damage the PROBE and potentially cause tissue damage.

⚠**CAUTION:**

- The PROBE is only compatible with the ACM. Do not use the PROBE with any other manufacturer's system may damage the device and result in patient injury.
- Do not use the PROBE if damaged as it may result in device malfunction. Repetitive bends in the same location could damage the Malleable Section of PROBE causing device malfunction. The Malleable Section of PROBE has a limited functional life; if greater than 8 bends are intended, it is recommended to use a second probe.
- Do not use the PROBE if damaged as it may result in device malfunction. The PROBE has a limited functional life; if greater than 14 Freeze/Defrost cycles are intended, it is recommended to use a second probe.
- Do not use the PROBE if damaged as it may result in device malfunction. Repetitive bends in the same location could cause damage to the Rigid PROBE Shaft. The PROBE has limited functional life; if greater than 7 Rigid Probe Shaft bend cycles are intended, it is recommended to use a second probe.
- Follow standard guidelines for the safe handling and storage of high-pressure gas tanks.
- Ensure the CONSOLE is in Ready Mode before attempting to connect or disconnect the PROBE. The sudden release of pressurized gas may cause the PROBE to recoil, which may injure the operator or the patient.
- Nitrous oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels.
- Do not restrict, kink, clamp, or otherwise damage the Malleable Section of PROBE or Tubing, as this may interrupt the gas supply path, preventing the PROBE from properly freezing and/or defrosting.
- 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.
- The distal end of the rigid PROBE shaft should not be bent more than 5 cm (2.0 inches) from straight as illustrated in figure 5.

INSTRUCTIONS FOR USE

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

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. Remove the sterilized instrument from its package per standard sterile technique.
4. Connect the PROBE **Gas Inlet Connector** to the **Gas inlet Connection Port**.

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

5. 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.
6. Confirm PROBE connectors are fully engaged by lightly pulling on connections.
7. Connect **Temperature Connectors** of the PROBE to the corresponding colored connectors on the ACM. See Figure 2: PROBE Connections to ACM.
8. **Switch** the ACM unit ON.

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

9. Retract the PROBE handle and rigid PROBE shaft to expose malleable aluminum probe. See Figure 3: Handle and Rigid Shaft Retraction.
10. Perform a "Pre-Freeze" by cycling the ACM using the activation button or footswitch while the probe is in air.

NOTE: Verify pressure is at least 4826 kPa (700 psi) after the appropriate warning period.

11. Thirty seconds after frost appears on the malleable probe tip:
    a) Cycle the ACM to defrost.
    b) Cycle the ACM to vent the probe.
12. Identify and expose the sites to be cryoablated using standard surgical techniques.
13. 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".
14. 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.

15. 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".

16. Freeze for desired length of time.
17. 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.
18. 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.

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

⚠**CAUTION:** Use care while the CONSOLE is in Defrost Mode, as during N_2O gas venting, the PROBE may cool sufficiently to cause cryoadhesion.

20. Wipe the malleable tip clean. Repeat steps 12 thru 20 as desired to create additional cryo lesions.
21. 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 or press the N_2O Exhaust Switch 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:** Do not use the PROBE if damaged as it may result in device malfunction. Repetitive bends in the same location could damage the Malleable Section of PROBE causing device malfunction. The Malleable Section of PROBE has a limited functional life; if greater than 8 bends are intended, it is recommended to use a second probe.

1. The PROBE malleable tip has a limited functional life. It is always recommended to use the form tool to create desired bends. The form tool has two ends, the smaller end radius is 13 mm and the larger end radius is 26 mm. See Figure 4, 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 form tool

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BENDING PROBE SHAFT

⚠**CAUTION:** Repetitive bends in the same location could cause damage to the shaft.

1. The probe shaft has limited functional life ; if greater than 7 Rigid Probe Shaft bend cycles are intended, it is recommended to use a second probe.

⚠**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:

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 counter-clockwise
	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 "- - -"?	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 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 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.

ENVIRONMENTAL SPECIFICATIONS		
Operational	**Storage**	**Transit**
Temperature: 10°C/50°F to 40°C/104°F	Temperature: -29°C/-20°F to 60°C/140°F	Temperature: -29°C/-20°F to 60°C/140°F
Relative Humidity: 15% to 90%	Relative Humidity: 30% to 85%	Relative Humidity: 30% to 85%
Atmospheric Pressure: 98 to 105kPA (14.2 to 15.2 psi)	Atmospheric Pressure: 98 to 105kPa (14.2 to 15.2 psi)	N/A

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

REFER TO THE OUTER PACKAGE LABEL TO SEE WHICH SYMBOLS APPLY TO THIS PRODUCT.

	Manufacturer	US	Country And Date of Manufacture
	Keep dry		Caution
REF	Catalogue Number	LOT	Batch Code
#	Model Number	UDI	Unique Device Identifier
Rx ONLY	Prescription use only	MD	Medical Device
	Use-by date	STERILE	Do Not Resterilize
	Do Not Re-use		Do Not Use if Package is Damaged
	Single Sterile Barrier System with protective packaging inside		Single Sterile Barrier System with protective packaging outside
STERILE R	Sterilized using irradiation		Follow instructions for use
	Waste Electrical and Electronic Equipment	LATEX	Not made with natural rubber latex
	Non-pyrogenic	PHT	Does not contain Phthalates
140°F 60°C -20°F -29°C	Transit/Storage Temperature limit	85% % 30%	Transit/Storage Humidity limit

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