AtriCure®

cryoICE cryoFORM® cryoablation probe

INSTRUCTIONS FOR USE

 # CRYOF

MD

Rx ONLY

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

FIGURE 1: CRYOICE CRYOFORM CRYOABLATION PROBE

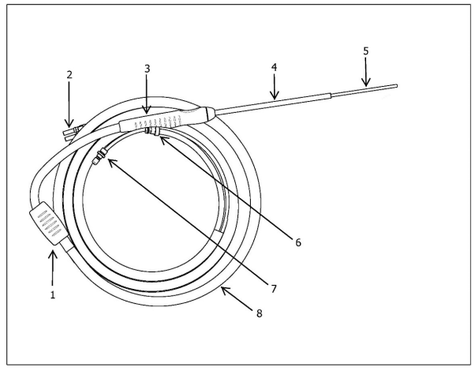


FIGURE 2: HANDLE AND RIGID SHAFT RETRACTION

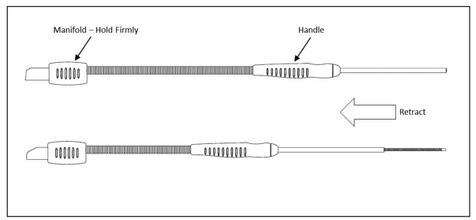


FIGURE 3: PROBE CONNECTIONS TO ACM

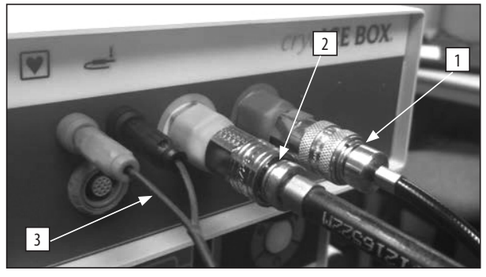
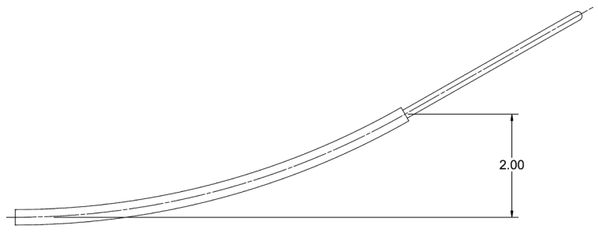


FIGURE 4: RECOMMENDED RIGID PROBE SHAFT BENDING



INSTRUCTIONS FOR USE (en)

cryoICE cryoFORM® cryoablation probe

DEVICE 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).

The system is comprised of the following components:

1. Single-use cryoICE cryoFORM cryoablation probe (referred to hereafter as PROBE).
2. AtriCure cryoICE BOX (referred to hereafter as CONSOLE).
3. AtriCure cryoICE BOX components and N_2O gas cylinder (not provided).

PROBE NOMENCLATURE (SEE FIGURE 1)

PROBE FEATURES

[1] Manifold
[2] Temperature Connectors
[3] Retractable Handle
[4] Rigid Shaft
[5] Malleable Tip
[6] Gas Inlet Connector
[7] Gas Exhaust Connector
[8] Tubing

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.

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

INDICATIONS 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 ⚠

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.

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

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.

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.

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

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

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

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.

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.

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.

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

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.

The distal end of the Rigid PROBE Shaft should not be bent more than 5 cm (2.0 in.) from straight, as illustrated in Figure 4.

⚠ **CAUTION:**

- The PROBE is only compatible with the AtriCure cryoICE BOX. Do not use the PROBE with any other system, to prevent injury and/or equipment damage.
- Do not use the PROBE if damaged as it may result in device malfunction. The PROBE has a limited functional life; if greater than 7 Freeze/Defrost cycles are intended, it is recommended to use a second probe.
- 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.
- Nitrous oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels.
- Ensure the CONSOLE is in Ready Mode before attempting to connect/disconnect the PROBE. The sudden release of pressurized gas may cause the PROBE to recoil, which may injure the operator or patient.
- Discontinue use immediately if a breach in the PROBE is suspected, to avoid the release of pressurized N_2O gas and injury to the patient or user.
- Follow standard guidelines for the safe handling and storage of high-pressure gas tanks.
- The Malleable Section of PROBE has a limited functional life; if greater than 4 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. Repetitive bends in the same location could cause damage to the Rigid PROBE Shaft. The PROBE has a limited functional life; if greater than 7 Rigid Probe Shaft bend cycles are intended, it is recommended to use a second probe.
- Use care while the CONSOLE is in Defrost Mode, as during N_2O gas venting, the PROBE may cool sufficiently to cause cryoadhesion.

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 1 provides a list of the connections to the ACM.

Table 1. 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. 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.

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

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.

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

⚠ **CAUTION:** Ensure the CONSOLE is in Ready Mode before attempting to connect/disconnect the PROBE. The sudden release of pressurized gas may cause the PROBE to recoil, which may injure the operator or patient.

DISCONNECTING AND DISPOSING OF THE PROBE

15. Close N_2O Cylinder by turning the Valve fully clockwise.

16. Pull the red N_2O Manual Exhaust Knob or press the N_2O Exhaust Switch on the back of the CONSOLE to fully depressurize the system.

17. Disconnect the PROBE from the CONSOLE and discard.

DISPOSAL

After use this device should be treated as medical waste and disposed of following hospital protocol.

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	2	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
-20°F -29°C 140°F 60°C	Transit/Storage Temperature limit	30% 85%	Transit/Storage Humidity limit

AtriCure Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 866 349 2342
+1 513 755 4100

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