AtriCure CRYO2 cryoICE System CRYO Ablation Probe and Form Tool Instruction Manual

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AtriCure

AtriCure CRYO2 cryoICE System CRYO Ablation Probe and Form Tool

INTENDED PURPOSE

The cryoICE system cryoablation probe, was designed for treatment of cardiac arrhythmias by achieving controlled temperatures ranging from -50°C (-58°F) to -70°C (-94°F). The PROBE is a sterile, single-use cryosurgical instrument designed for use with the AtriCure Cryo Module (ACM).

INDICATIONS FOR USE

The cryoICE system 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.

SYSTEM DESCRIPTION

The AtriCure cryoICE system cryoablation probe creates cryoablation lesions in tissue by delivering a cryogenic Nitrous Oxide (N2O) energy source from the console to the tip of the connected probe. The system provides controlled lesion forming temperature that is below –40°C (–40°F).

The system is comprised of the following components:

1. Single-use cryoICE system cryoablation probe (referred to hereafter as PROBE) and forming tool (referred to hereafter as TOOL).
2. AtriCure cryoICE BOX (referred to hereafter as CONSOLE)
3. AtriCure cryoICE BOX components and N2O gas cylinder (not provided).

PRODUCT DESCRIPTION

The PROBE is a single-use device. The probe shaft is malleable and supports forming by the user via the supplied TOOL.

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: 15% to 85%	Relative Humidity: 30% to 85%
Atmospheric Pressure: 980 to 1050kPA (142 to 152 psi)	Atmospheric Pressure: 980 to 1050kPA (142 to 152 psi)	N/A

PACKAGE CONTENTS

1. One (1) PROBE
2. One (1) TOOL

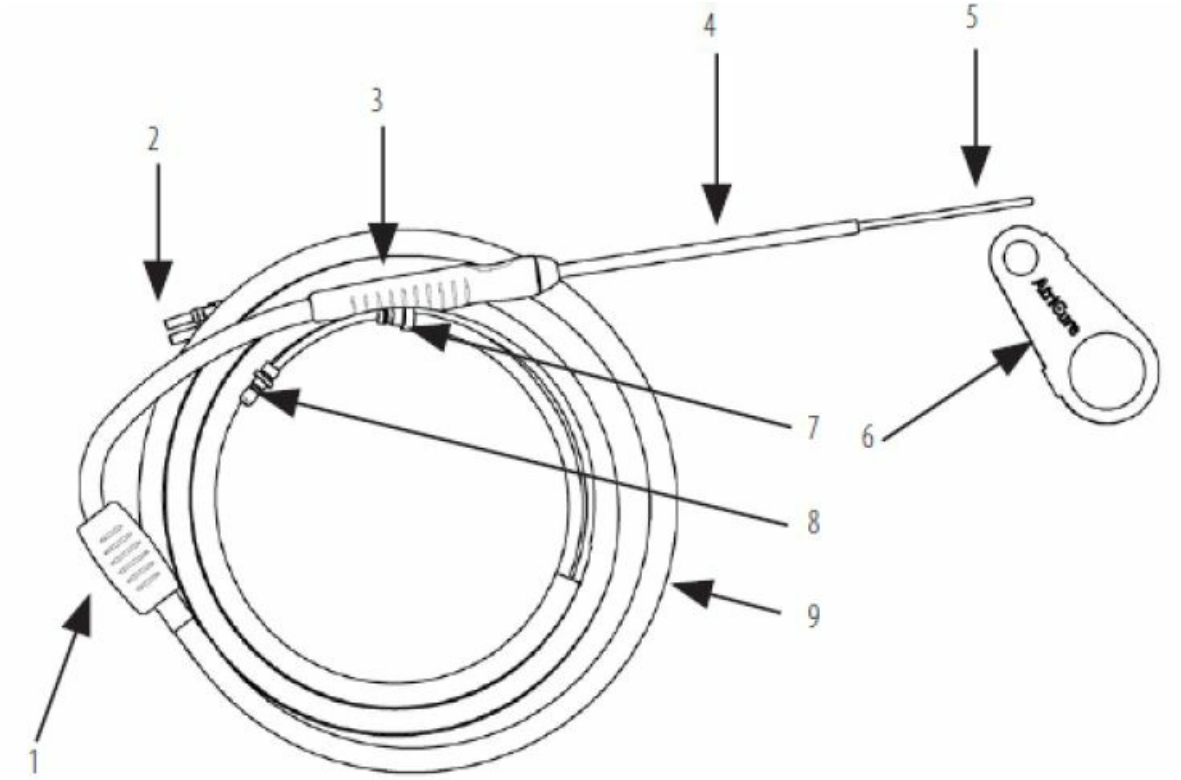
The PROBE is supplied STERILE and is NON-PYROGENIC in unopened, undamaged package. For single use only, Do not re-sterilize. Do Not Re-Use.

INTENDED USER AND TARGET POPULATION
The AtriCure's cryoICE system cryoablation probe is a medical device for use by certified/licensed medical doctors who perform cardiothoracic surgical procedures using AtriCure instrumentation for treatment of adult patients with cardiac arrhythmias.

INTENDED CLINICAL BENEFITS
The clinical benefit of the cryoICE probes with the ACM is the restoration of normal sinus rhythm and freedom from atrial arrhythmia (atrial fibrillation, atrial flutter, and atrial tachycardia). The detailed safety and performance information can be found in the Cryo Summary of Safety and Clinical Performance (SSCP) in the European database on medical devices (Eudamed) at **https://ec.europa.eu/tools/eudamed** by using the following Basic UDI-DI search key: "0840143900000000000007ZP".

NOMENCLATURE
This instruction refers to features of the PROBE as follows

PROBE FEATURES



1. Manifold
2. Temperature Connectors
3. Retractable Handle
4. Rigid PROBE Shaft
5. Malleable Section of PROBE
6. TOOL
7. Gas Inlet Connector
8. Gas Exhaust Connector
9. Tubing

WARNING
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. 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.

DEVICE USE INSTRUCTIONS

SETTING UP THE SYSTEM

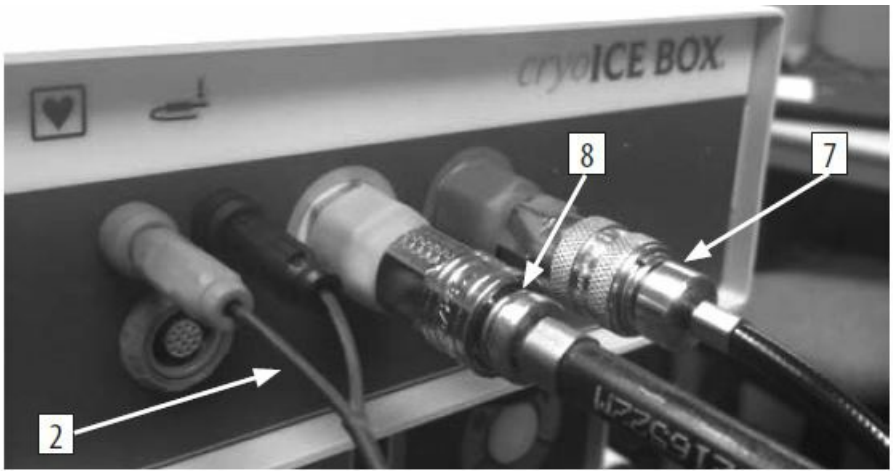
- **CAUTION**: The PROBE is only compatible with the AtriCure cryoICE BOX. Do not use the PROBE with any other system, to prevent injury and/or equipment damage.
- **CAUTION**: Do not restrict, kink, clamp, or otherwise damage the Malleable Section of PROBE or Tubing, as this may interrupt the gas supply path, preventing the PROBE from properly freezing and/or defrosting.
- **CAUTION**: Follow standard guidelines for the safe handling and storage of high-pressure gas tanks.
- **CAUTION**: Nitrous Oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels.

1. Install and power on the CONSOLE and required components. The instructions for installing and operating the CONSOLE, as well as a technical description of the system, are detailed in the cryoICE BOX™ User's Manual.
2. Turn the N2O Cylinder tank valve fully counter-clockwise to open. Verify pressure is at least 4826 kPa (700 psi) after the appropriate warming period.
3. Examine the device packaging to ensure the sterility of the product has not been compromised. Remove the PROBE and TOOL from the package per standard sterile technique.

   WARNING

   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.

   CAUTION: Ensure the CONSOLE is in Ready Mode before attempting to connect the PROBE. The sudden release of pressurized gas may cause the PROBE to recoil, which may injure the operator or patient.
4. With the CONSOLE in Ready Mode (see Figure 6), connect the PROBE Connectors to the CONSOLE Ports as follows (see Figure 2):



1. **a**) Insert the blue Gas Inlet Connector into the blue Inlet Port.
2. **b**) While pushing back the locking sleeve on the orange Exhaust Port, insert the orange Gas Exhaust Connector, then release the locking sleeve.
3. **c**) Verify the Gas Inlet and Exhaust connectors are engaged by gently tugging on the hoses connectors. Insert the red and black Temperature Connectors into the same-colored Thermocouple Ports.

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

   FORMING THE MALLEABLE SECTION OF THE PROBE TO THE DESIRED SHAPE

   NOTE: The Malleable Section of PROBE should only be formed using the TOOL, which maintains a safe bending radius of 13 mm (0.5 inches) or greater.

   NOTE: Use steady, firm pressure while forming rather than quick, intense force.

   NOTE: If the same bend is desired in a different plane, do not twist the Malleable Section of PROBE; re-straighten the Malleable Section of PROBE and create the same bend in the desired plane.

   WARNING

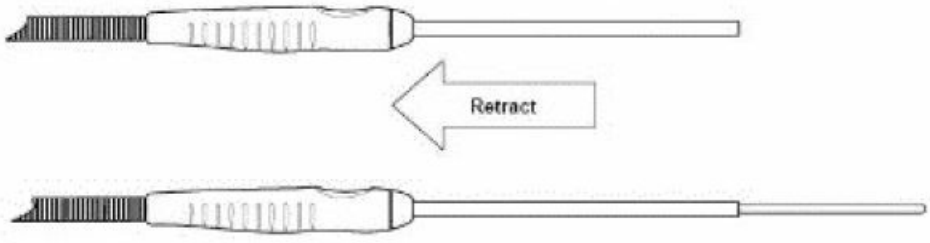
   Forming the Malleable Section of PROBE in any way other than indicated in the following instructions can damage the PROBE and potentially cause tissue damage. Do not bend Malleable Section of the PROBE during FREEZE or DEFROST mode. It can cause a high pressurized gas leak that can potentially lead to tissue perforation, unintended damage, or injury to user.

   CAUTION: Repetitive bends in the same location could damage the Malleable Section of PROBE causing device malfunction.

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

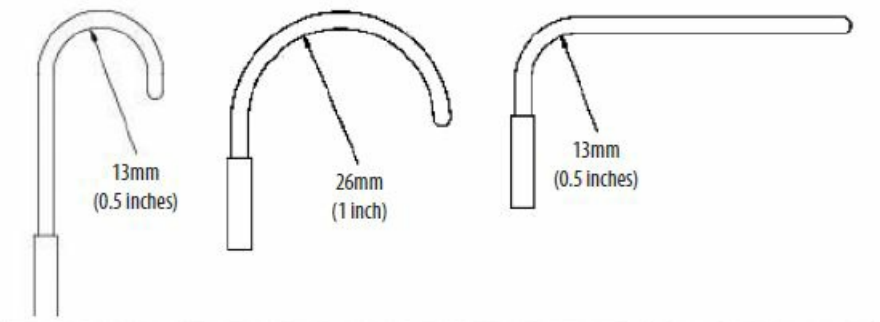
   CAUTION: Discontinue use immediately if a breach in the PROBE is suspected, to avoid the release of pressurized N2O gas and injury to the patient or user.
5. Prior to forming, ensure the CONSOLE is in READY Mode per Figure 6.
6. Retract the PROBE handle and rigid PROBE shaft to expose Malleable Section of PROBE. See Figure 3: Handle and Rigid PROBE Shaft Retraction.

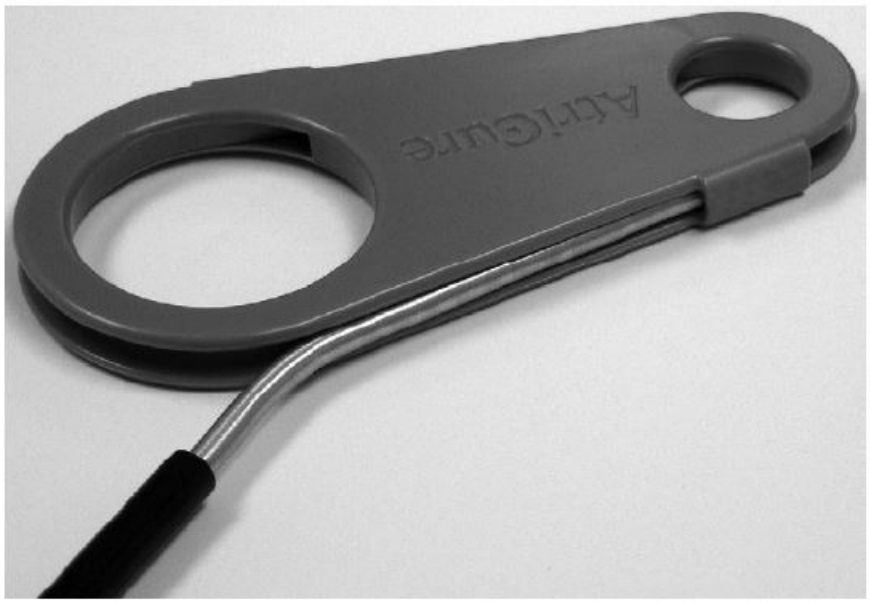
   CAUTION: The Malleable Section of PROBE has a limited functional life; if greater than 8 bends are intended, it is recommended to use a second probe.



7. It is always recommended to use the TOOL to create desired bends. The TOOL has two ends, the smaller end radius is 13 mm (0.5 inches) and the larger end radius is 26 mm (1.0 inch).
8. Typical procedures may require the following bend profiles created with the use of the TOOL, as illustrated in Figure 4.

   FORMING THE RIGID PROBE SHAFT





CAUTION: 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.

CAUTION: 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.

USING THE PROBE TO PERFORM CRYOABLATION

NOTE: The PROBE ablates tissue via cryogenic energy delivered to the Malleable Section of PROBE. Cryoadhesion of the Malleable Section of PROBE to tissue can occur when the PROBE reaches a temperature of 0°C (32°F) or below. Other portions of the PROBE, including the Rigid PROBE Shaft, can become cold, and should be handled with appropriate care.

CAUTION: 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.

9. With the PROBE in air, prime the system with a Pre-Freeze cycle: Set the CONSOLE Ablation Timer to 30 seconds and press the Activation Button to engage FREEZE Mode. Wait for the system to cycle through FREEZE and DEFROST, or manually advance via the Activation Button.
10. During the FREEZE cycle, if there are leaks in the blue inlet/orange exhaust connector, the sound of gas leaking will be heard and/or frost will appear on the connections. Replace the device before continuing with the procedure.

    WARNING

    Ensure the CONSOLE is in READY Mode and the PROBE temperature is above 0°C (32°F) before contacting tissue, to avoid unintended cryoadhesion.
11. Set the Ablation Timer to the desired ablation time. The timer is preset to a default of 120 seconds.
12. Navigate the PROBE to the target ablation site:
    1. **a**) Identify the target site.
    2. **b**) Reach the Malleable Section of PROBE through an appropriate-sized incision to the target.
    3. **c**) Under direct visualization, place the Malleable Section of PROBE against the target tissue.

       WARNING

       Do not use excessive force when using the PROBE to prevent tissue damage. 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. Cardiac surgical procedures may mechanically induce arrhythmias. 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.
13. Using the Retractable Handle, apply gentle pressure to the Malleable Section of PROBE, and avoid any PROBE movement until after the freeze cycle completes.
14. Under direct visualization ensure that the PROBE Malleable Section of PROBE and Rigid PROBE Shaft are not in contact with other anatomical structures not intended for ablation.

    WARNING

    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.
15. Press the activation button or use the optional ACM footswitch to engage FREEZE Mode for the desired length of time. The system will automatically cycle from FREEZE to DEFROST after the Ablation Timer has expired.

    WARNING

    Use care to avoid PROBE movement while cryoadhesion is present, to prevent inadvertent tissue damage.
16. Wait until the PROBE temperature has warmed to above 0°C (32°F) before attempting to remove the Malleable Section of PROBE from the ablation site or moving the Rigid PROBE Shaft. CAUTION: Use care while the CONSOLE is in Defrost Mode, as during N2O gas venting, the PROBE may cool sufficiently to cause

cryoadhesion.

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

17. After the CONSOLE is in Ready Mode and the PROBE temperature is above 0°C (32°F), repeat steps (11) to (16) to create additional cryoablation lesions.

DISCONNECTING AND DISPOSING OF THE PROBE

18. Close N2O Cylinder by turning the Valve fully clockwise.
19. Pull the red N2O Manual Exhaust Knob or press the N2O Exhaust Switch on the back of the CONSOLE to fully depressurize the system.

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

20. Disconnect the PROBE from the CONSOLE and discard.

WARNING
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.

DISPOSAL

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

SSCP
A summary of the safety and clinical performance of the device can be found in the European database on medical devices (Eudamed) at **https://ec.europa.eu/tools/eudamed** by using the following Basic UDI-DI search key: “0840143900000000000007ZP”

SERIOUS INCIDENT
Any serious incident that has occurred in relation to this device should be reported to AtriCure and the competent authority of the Member State in which the user and/or patient is located.

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.

TROUBLESHOOTING

PROBLEM	POTENTIAL CAUSE	SOLUTION
PROBE does not reach desired def rost temperature after freeze.	Plugged gas supply path.	Manually defrost by applying warm salin e to tissue and probe as necessary.
PROBE does not reach the proper temperature.	Empty or low N_2O cylinder.	Replace low or empty N_2O cylinder.
	Gas not flowing, tubing is restri cted.	Verify PROBE tubing is not pinched.
	Gas leak in PROBE Shaft or tu bing.	Replace PROBE.
	N_2O tank valve closed.	Fully open N_2O tank valve.
CONSOLE displays “—”.	Thermocouple Connectors not fully plugged into the CONSOL E.	Plug Thermocouple Connectors all the w ay into the CONSOLE ports.
	PROBE internal wires are brok en.	Replace PROBE.
CONSOLE reads positive temperat ure during ablation.	Thermocouple Connectors are plugged in reversed (red-to-bla ck).	Plug Thermocouple Connectors into the matching colored CONSOLE Ports.

CONSOLE displays fault code, err or code, maintenance needed, or l ow cylinder pressure light.	See CONSOLE User’s Manual.

Documents / Resources

	**AtriCure CRYO2 cryoICE System CRYO Ablation Probe and Form Tool** [pdf] Instruction Ma nual CRYO2 cryoICE System CRYO Ablation Probe and Form Tool, CRYO2, cryoICE System CRYO Ablation Probe and Form Tool, CRYO Ablation Probe, Ablation Probe, Probe