AtriCure®

cryoSPHERE® cryoablation probe

INSTRUCTIONS FOR USE

[#] CRYOS; CRYOS-L

MD

FIGURE 1

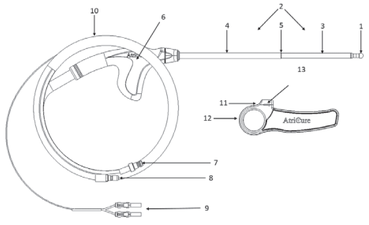


FIGURE 2

Ready Mode (green) Freeze Mode (blue) Defrost Mode (orange)

FIGURE 3

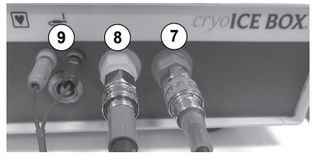


FIGURE 4

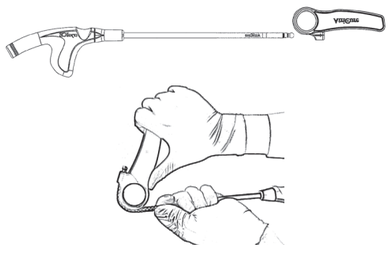
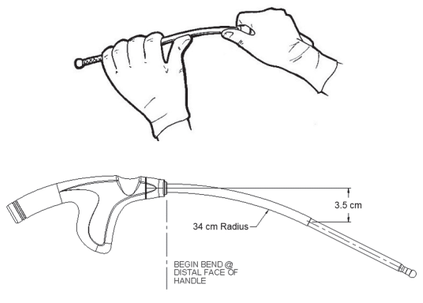
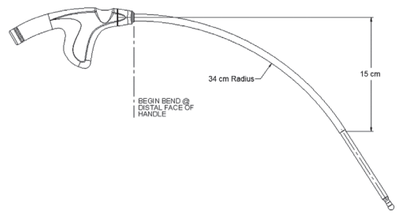


FIGURE 5





INSTRUCTIONS FOR USE (en)

cryoSPHERE® cryoablation probe

INTENDED PURPOSE

The cryoSPHERE probes are sterile, single use devices intended for use in blocking pain by temporarily ablating intercostal peripheral nerves.

INDICATIONS FOR USE

The cryoSPHERE probes are indicated for blocking pain associated with cardiac and/or thoracic procedures, by temporarily ablating intercostal peripheral nerves.

CONTRAINDICATIONS

There are no known contraindications.

SYSTEM DESCRIPTION

The AtriCure cryoSPHERE cryoablation probe creates cryoablation lesions in tissue by delivering a cryogenic Nitrous Oxide (N_2O) 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 cryoSPHERE 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 N_2O gas cylinder (not provided).

PRODUCT DESCRIPTION

The PROBE is a single-use device offered in two configurations: standard length probe shaft (CRYOS), and extended length probe shaft (CRYOS-L). The flexible region of the shaft supports forming by the user via the supplied TOOL. The PROBE features a spherical 8mm cryoablation tip.

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

PACKAGE CONTENTS

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

The PROBE and TOOL are supplied STERILE and 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 cryoSPHERE cryoablation probe is a medical device for use by licensed medical doctors who perform cardiac and/or thoracic procedures for treatment of patients aged 18 years to 85 years with potential to experience pain after cardiac and/or thoracic procedures.

INTENDED CLINICAL BENEFITS

The clinical benefit of the cryoSPHERE probes with the ACM is to safely manage pain after cardiac and/or thoracic procedures.

NOMENCLATURE

This instruction refers to features of the PROBE and TOOL as follows (see Figure 1):

PROBE FEATURES				TOOL FEATURES	
[1]	Ball Tip	[6]	Handle	[11]	Barrel
[2]	Shaft	[7]	Gas Inlet Connector	[12]	Bending Channel
[3]	Flexible Region	[8]	Gas Exhaust Connector	[13]	Insertion Arrow
[4]	Rigid Region	[9]	Thermocouple Connectors		
[5]	Shaft Transition	[10]	Tubing		

⚠ 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.

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 N_2O 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.

⚠ WARNINGS ⚠

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 2), connect the PROBE Connectors to the CONSOLE Ports as follows (see Figure 3):
   a) Insert the blue Gas Inlet Connector into the blue Inlet Port.
   b) While pushing back the locking sleeve on the orange Exhaust Port, insert the orange Gas Exhaust Connector, then release the locking sleeve.
   c) Verify the Gas Inlet and Exhaust connectors are engaged by gently tugging on the hoses connectors.
   d) 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 FLEXIBLE REGION OF THE SHAFT TO THE DESIRED SHAPE

NOTE: The Flexible Region of the Shaft should only be formed using the TOOL, which maintains a safe bending radius (>1.9 cm) for the Shaft.

NOTE: The Flexible Region of the Shaft supports bending up to 180° in one direction. Successive bends will result in increased bend resistance.

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

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

⚠ WARNINGS ⚠

Forming the Flexible Region of the Shaft in any way other than indicated in the following instructions can damage the PROBE and potentially cause tissue damage.

Do not bend Flexible Region of the Shaft 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:** 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.

⚠ **CAUTION:** Do not use the PROBE if damaged as it may result in device malfunction. Repetitive bends in the same location could damage the Flexible Region of the Shaft causing device malfunction. The Flexible Region of PROBE has a limited functional life; if greater than 5 bends are intended, it is recommended to use a second PROBE.

5. Prior to forming, ensure the CONSOLE is in READY Mode per Figure 2.
6. Insert the PROBE Ball Tip through the TOOL Barrel in the direction of the Insertion Arrow, as illustrated in Figure 4.
7. Rotate the TOOL so the Shaft is rolled into the Bending Channel, as illustrated in Figure 4, until the desired bend angle is achieved.

FORMING THE RIGID REGION OF THE SHAFT TO THE DESIRED SHAPE

⚠ **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 Section of the Shaft causing device malfunction. The PROBE has a limited functional life; if greater than 2 Rigid Probe Shaft bend cycles are intended, it is recommended to use a second probe.

NOTE: The Rigid Region of the Shaft can be formed by hand and supports a maximum of two bends in the same plane, per the illustrated shaft deflections shown in Figure 5.

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

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

8. Grasp the Rigid Region of the Shaft with both hands, as illustrated in Figure 5. Avoid applying load in area of the Shaft Transition.
9. Bend until the desired deflection is achieved, up to the maximum deflections illustrated in Figure 5.

USING THE PROBE TO PERFORM CRYOABLATION

NOTE: The PROBE is designed to reach peripheral nerves through an incision sized for an 8mm or larger trocar, after the trocar has been removed.

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

10. 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, DEFROST, and Vent, or manually advance via the Activation Button.
    a) 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.

⚠ WARNINGS ⚠

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

⚠ **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.

11. Set the Ablation Timer to the desired ablation time. The timer is generally set to a default of 120 seconds.
12. Navigate the PROBE to the target ablation site:
    a) Identify the target peripheral nerve site.
    b) Reach the Ball Tip through an appropriate-sized incision to the target. The probe is designed to fit through the incision for an 8mm trocar or larger.
    c) Under direct visualization, place the Ball Tip against the target tissue.

⚠ WARNINGS ⚠

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

13. Using the Handle, apply gentle pressure to the Ball Tip, and avoid any PROBE movement until after the FREEZE cycle completes.
14. Under direct visualization ensure that the probe ball and shaft are not in contact with other anatomical structures not intended for ablation. An insulative barrier, such as a trocar indicated for thoracic use, may be used at the incision site to avoid unintended cryoadhesion and/or cryoablation.

⚠ WARNINGS ⚠

Before entering Freeze Mode, always confirm the placement of the Ball Tip is as intended, to avoid unintended tissue contact with the Ball Tip or Shaft, to prevent unintended cryoadhesion and/or cryoablation.

Avoid direct contact of PROBE with lung to prevent potential risk of pneumothorax.

Intercostal nerve ablations should be performed 2-4cm lateral to the internal mammary artery (IMA), to prevent potential damage to the IMA.

If ablating the intercostal nerve for chest wall surgery posterior to mid-axillary line, it is not recommended to ablate above the 3rd intercostal space due to the proximity of the sympathetic trunk or below the 9th intercostal space due to risk of abdominal muscle bulging.

Intercostal nerve ablations should be at least 2 cm from the dorsal root ganglia or 4 cm from the base of the spine to prevent damage to the sympathetic chain.

AtriCure®

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.

⚠ WARNINGS ⚠

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

⚠**CAUTION:** When using a standard off-the-shelf nerve stimulator, read all of the manufacturers instructions carefully prior to using the device. Failure to follow instructions may lead to injury and may result in improper functioning of the device.

16. Wait until the PROBE temperature has warmed to above 0°C (32°F) before attempting to remove the Ball Tip from the ablation site or moving the Shaft.

⚠**CAUTION:** Use care while the CONSOLE is in Defrost Mode, as during N_2O 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.

    a) Cryoablations are recommended to be performed 2 levels above the incision(s), at incision(s), and 2 levels below the incision(s).

DISCONNECTING AND DISPOSING OF THE PROBE

18. Close N_2O Cylinder by turning the Valve fully clockwise.
19. 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.

⚠**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.

⚠ WARNINGS ⚠

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.

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 defrost temperature after freeze.	Obstructed gas supply path.	Manually defrost by applying warm saline 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 restricted.	Verify PROBE tubing is not pinched.
	Gas leak in PROBE Shaft or tubing.	Replace PROBE.
	N_2O tank valve closed.	Fully open N_2O tank valve.
CONSOLE displays "---".	Thermocouple Connectors not fully plugged into the CONSOLE.	Plug Thermocouple Connectors all the way into the CONSOLE ports.
	PROBE internal wires are broken.	Replace PROBE.
CONSOLE reads positive temperature during ablation.	Thermocouple Connectors are plugged in reversed (red-to-black).	Plug Thermocouple Connectors into the matching colored CONSOLE Ports.
CONSOLE displays fault code, error code, maintenance needed, or low cylinder pressure light.	See CONSOLE User's Manual.	

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
	Caution	REF	Catalogue Number
LOT	Batch Code	#	Model Number
UDI	Unique Device Identifier	MD	Medical Device
	Use-by date	2 STERILIZE	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 by Gamma Radiation		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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