AtriCure®

Instructions for Use

cryoICE® cryoA cryoablation probe

REF CAT. **CRYOA**

INDICATION FOR USE

AtriCure's cryoICE cryoablation probe is a sterile, single use device intended for use in blocking pain by temporarily ablating peripheral nerves.

CONTRAINDICATIONS

There are no known contraindications.

SYSTEM DESCRIPTION

The AtriCure cryoICE system 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.

The system is comprised of the following components:

1. Single-use cryoablation probe (referred to hereafter as PROBE) and forming tool (referred to hereafter as TOOL)
2. AtriCure cryoICE BOX (referred to hereafter as CONSOLE) and an optional footswitch
3. N_2O gas cylinder (not provided), gas line hose, exhaust hose, and cylinder heater band.

PRODUCT DESCRIPTION

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

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 Profile: Board-certified MDs (notably cardiac surgeons, thoracic surgeons, general surgeons, trauma surgeons, vascular surgeons, pediatric surgeons. *This is not a comprehensive list of all specialties applicable for this device's indicated use.)

NOMENCLATURE

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

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

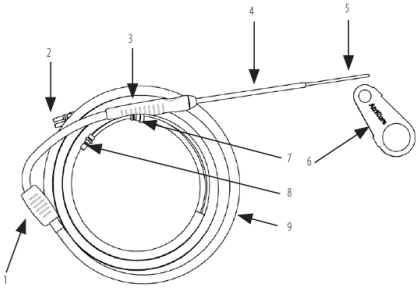


FIGURE 1: PROBE FEATURES

WARNING

Read all instructions carefully prior to using the device.

Please refer to the CryoICE Box (ACM) for Console Warnings, Cautions, product description and features.

Use of the PROBE should be limited to properly trained and qualified medical personnel.

Improper use of this device may lead to device malfunction, failure to provide intended therapy, and/or serious injury.

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 space 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 accessories. 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 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 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.

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.

FIGURE 2: CONSOLE CONNECTIONS

▶ 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 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: 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 2.
6) For a cryoICE device, retract handle and rigid PROBE shaft to expose Malleable Section of PROBE. See figure 3: Handle and Rigid PROBE Shaft Retraction.

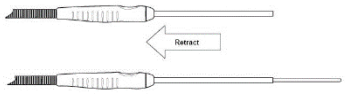
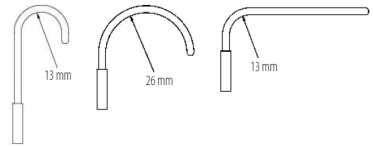


FIGURE 3: HANDLE AND RIGID SHAFT RETRACTION.

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



Bending 13mm

Bending 26mm

Straightening

FIGURE 3: FORMING THE MALLEABLE SECTION OF THE PROBE

▶ 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: Repetitive bends in the same location could cause damage to the Rigid PROBE Shaft.

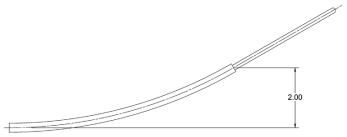


FIGURE 4: PROBE RIGID PROBE SHAFT

▶ 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 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.

READY Mode (green) | FREEZE Mode (blue) | DEFROST Mode (orange)

FIGURE 5: CONSOLE ABLATION STATUS INDICATOR

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 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:
   a) Identify the target peripheral nerve site.
   b) Reach the Malleable Section of PROBE through an appropriate-sized incision to the target.
   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 avoid tissue damage.

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

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.

If ablating the intercostal nerve, 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.

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. 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.

⚠ 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 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.

⚠ 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 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 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, repeat steps (9) to (13) 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.

⚠ WARNING ⚠
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.

DISPOSAL

Upon completion of the surgical procedure, after the PROBE has been disconnected from the CONSOLE discard the PROBE. Follow local governing ordinances and recycling plans regarding disposal or recycling of the PROBE.

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.	Plugged 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.	

SYMBOLS GLOSSARY

SYMBOL	MEANING
	Manufacturer
	Do not re-use
	Do not use if package is damaged
	Not made with natural rubber latex
REF CAT.	Catalog number
Rx ONLY	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
LOT	Batch code
STERILE R	Sterilized using irradiation
	Refer to instruction manual
	Non-pyrogenic
	Use-by date
	Caution
	Temperature limit
85% 20%	Humidity limit
	Waste Electrical and Electronic Equipment

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