AtriCure®

Rx ONLY

Instructions for Use

cryoICE® cryoXT™ Cryoablation Probe, Exposed Nerves

CRYOXT

MD

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

INDICATION FOR USE

AtriCure's cryoICE cryoXT cryoablation probes are intended for use to temporarily block pain by ablating peripheral nerves performed by freezing target tissues, creating an inflammatory response (cryonecrosis).

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 cryoXT cryoablation probe (referred to hereafter as PROBE)
2. AtriCure cryoICE BOX (referred to hereafter as CONSOLE) and an optional footswitch
3. AtriCure cryoICE BOX components and N_2O gas cylinder (not provided).

PRODUCT DESCRIPTION

The PROBE is a single-use device offered in one configuration (cryoXT). The PROBE features a prong-shaped cryoablation tip.

NOTE: The PROBE has been designed to engage nerves in a variety of fashions including both in-situ or exposed applications.

PACKAGE CONTENTS

1. One (1) PROBE

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

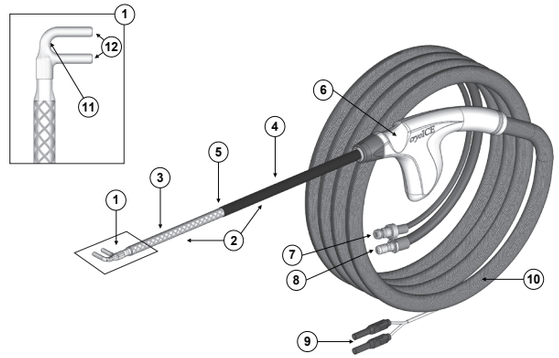
NOMENCLATURE

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

PROBE FEATURES:

[1]	Distal Tip	[5]	Shaft Transition	[9]	Thermocouple Connectors
[2]	Shaft	[6]	Handle	[10]	Tubing
[3]	Flexible Region	[7]	Inlet Connector (blue)	[11]	Base
[4]	Rigid Region	[8]	Exhaust Connector (orange)	[12]	Prongs

FIGURE 1: PROBE



⚠ **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.

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

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 Flexible Region 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 counterclockwise 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 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 Inlet/Exhaust 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 associated hoses connectors.

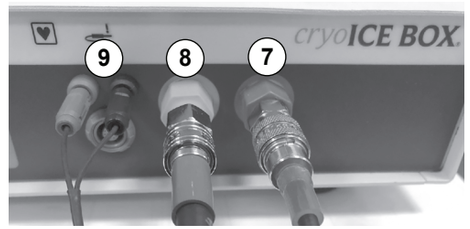
   d) Insert the red and black Thermocouple Connectors into the same-colored Thermocouple Ports.

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

FIGURE 2: CONSOLE ABLATION STATUS INDICATOR

a) Ready Mode (green) b) Freeze Mode (blue) c) Defrost Mode (orange)

FIGURE 3: CONSOLE CONNECTIONS



FORMING THE FLEXIBLE REGION OF THE SHAFT TO THE DESIRED SHAPE

NOTE: The Flexible Region of the Shaft can be formed by hand and supports bending one time.

NOTE: The Flexible Region of the Shaft supports bending up to 90° in one direction.

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

NOTE: Do not twist the Flexible Region of the Shaft.

⚠ **CAUTION:** Forming the Flexible Region of the Shaft in any way other than indicated in the following instructions can damage the PROBE.

⚠ **CAUTION:** Do not bend the Flexible Region of the Shaft during FREEZE or DEFROST mode. It can cause a high pressurized gas leak.

⚠ **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 the Shaft has a limited functional life; if greater than 1 bend is intended, it is recommended to use a second PROBE.

⚠ **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.

5. Prior to forming, ensure the CONSOLE is in Ready Mode per Figure 2.
6. Grasp the Shaft with both hands, as illustrated in Figure 4. Avoid grasping the Distal Tip of the device and avoid applying load in area of the Shaft Transition.

NOTE: Do not grasp the Distal Tip of the device or apply pressure to the Distal Tip of the device when bending the Flexible Region of the Shaft.

NOTE: Do not attempt to bend or reshape the Distal Tip of the device in any way.

7. Bend the Flexible Region of the Shaft until the desired deflection is achieved, up to the maximum deflections illustrated in Figure 4.

FIGURE 4: FORMING THE FLEXIBLE REGION OF THE SHAFT

USING THE PROBE TO PERFORM CRYOABLATION

NOTE: The PROBE ablates tissue via cryogenic energy delivered to the Distal Tip. Cryoadhesion of the Distal 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.

8. 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.

⚠ **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.

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⚠ **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 7 Freeze/Defrost cycles are intended, it is recommended to use a second probe.

9. Set the Ablation Timer to the desired ablation time. The timer is generally set to a default of 120 seconds.

10. Navigate the PROBE to the target ablation site:

a) Identify the target peripheral nerve.

b) Under direct visualization[1], position the target peripheral nerve within the Prongs, with the nerve contacting the Base and both Prongs to maximize surface contact.

[1]Direct visualization, in this context, requires that the surgeon is able to see the targeted tissue for cryoablation directly or with assistance from a camera or other similar optical technology.

> ⚠ **WARNING** ⚠
>
> Do not use excessive force when using the PROBE to avoid tissue damage.
>
> Before entering Freeze Mode, always confirm the placement of the Distal Tip is as desired and there is no undesired tissue contact with the Distal Tip or cold zone of the Shaft, to prevent unintended cryoadhesion and/or cryoablation.

11. Under direct visualization ensure that the Distal Tip and Shaft are not in contact with other anatomical structures not intended for ablation. An insulative barrier may be used to avoid unintended cryoadhesion and/or cryoablation.

⚠ **CAUTION:** The cryoXT device is designed to freeze peripheral nerve tissue positioned between the Prongs of the Distal Tip. Nerve tissue which extends beyond the Prongs may not receive adequate cryogenic energy to achieve the desired therapeutic effect.

12. 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.

⚠ **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.

13. Wait until the PROBE temperature has warmed to above 0°C (32°F) before attempting to remove the Distal 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.

14. After the CONSOLE is in Ready Mode and the PROBE temperature is above 0°C (32°F), repeat steps (9) to (13) to create additional cryoablation lesions.

⚠ **CAUTION:** Following cryogenic ablation, transecting the nerve proximal to the ablation site may negate the therapeutic effect of the ablation.

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.

⚠ **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.

17. 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.

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.	

SYMBOLS GLOSSARY

	Manufacturer	US	Country and date of manufacture
	Keep Dry		Fragile, handle with care
	Caution	REF	Catalogue number
UDI	Unique device identifier	LOT	Batch code
#	Model number	MD	Medical device
Rx ONLY	Prescription Use Only		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 outside
	Single sterile barrier system with protective packaging inside	STERILE R	Sterilized using irradiation
	Refer to instruction manual		Waste electrical and electronic equipment
LATEX	Not made with natural rubber or dry rubber latex		Non-pyrogenic
PHT	Does not contain phthalates		
85% % 30%	Transit/Storage Humidity limitation	140°F 60°C -20°F -29°C	Transit/Storage Temperature limit

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