

# AtriCure®

## Instructions for Use

### cryoICE® cryoSPHERE™ cryoablation probe

REF CRYOS; CRYOS-L

#### INDICATION FOR USE

AtriCure's cryoICE cryoSPHERE cryoablation probes are sterile, single use devices intended for use in blocking pain by temporarily ablating peripheral nerves.

The probe may be used in conjunction with a standard off-the-shelf nerve stimulator device in applications where precise peripheral nerve location is desired.

#### CONTRAINDICATIONS

There are no known contraindications.

#### SYSTEM DESCRIPTION

The AtriCure cryoICE system creates cryoablation lesions in tissue by delivering a cryogenic Nitrous Oxide (N<sub>2</sub>O) energy source from the console to the tip of the connected probe. The system provides controlled lesion forming temperature that is below -40°C, with typical operating ranges between -50°C to -70°C.

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) and an optional footswitch
3. N<sub>2</sub>O gas cylinder (not provided), gas line hose, exhaust hose, and cylinder heater band.

#### 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 probe shaft is malleable and supports forming by the user via the supplied TOOL. The PROBE features a spherical 8mm cryoablation tip.

#### 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.

#### NOMENCLATURE

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

##### PROBE FEATURES

- [1] Ball Tip
- [2] Shaft
- [3] Flexible Region
- [4] Rigid Region
- [5] Shaft Transition
- [6] Handle
- [7] Inlet Connector
- [8] Exhaust Connector
- [9] Thermocouple Connectors
- [10] Tubing

##### TOOL FEATURES

- [11] Barrel
- [12] Bending Channel
- [13] Insertion Arrow

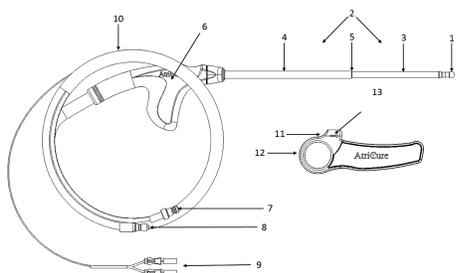


FIGURE 1: PROBE & TOOL FEATURES



**WARNING**

Read all instructions carefully prior to using the device. Failure to properly follow instructions may lead to injury and/or improper device function.

#### 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 Shaft or Tubing, as this may pinch or rupture the gas supply path, preventing the PROBE from properly freezing and/or defrosting.

- 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) Verify the N<sub>2</sub>O Cylinder 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**

Do not use the PROBE if the package sterile barrier has been breached, to prevent risk of infection.

**CAUTION:** Ensure the CONSOLE is in Ready Mode before attempting to connect the PROBE, to avoid the release of pressurized N<sub>2</sub>O gas.

- 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** Inlet Connector into the **blue** Inlet Port.
  - b) While pushing back the locking sleeve on the **orange** Exhaust Port, insert the **orange** Exhaust Connector, then release the locking sleeve.

- c) Verify the Inlet and Exhaust connectors are engaged by gently tugging on the hoses connectors.
- d) Insert the **red** and **black** Thermocouple Connectors into the same-colored Thermocouple Ports.



FIGURE 2: CONSOLE ABLATION STATUS INDICATOR



FIGURE 3: CONSOLE CONNECTIONS

##### FORMING THE FLEXIBLE REGION OF THE SHAFT TO THE DESIRED SHAPE

- i) 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.
- i) The Shaft supports bending up to 180° in one direction. Successive bends will result in increased bend resistance.



**WARNING**

Use steady, firm pressure while forming rather than quick, intense force, and discontinue use immediately if a breach in the PROBE is suspected, to avoid the release of pressurized N<sub>2</sub>O gas.

**CAUTION:** Forming the Shaft in any way other than indicated in the following instructions (e.g. using the forming tool incorrectly, bending to 180° more than once, bending at the Shaft Transition) can damage the PROBE.

**CAUTION:** Repetitive bends in the same location could damage the Shaft. 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.

- 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.

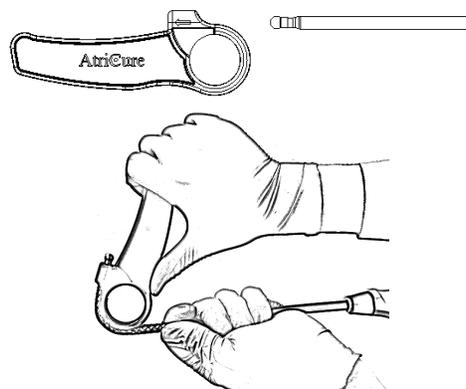


FIGURE 4: FORMING THE SHAFT FLEXIBLE PORTION

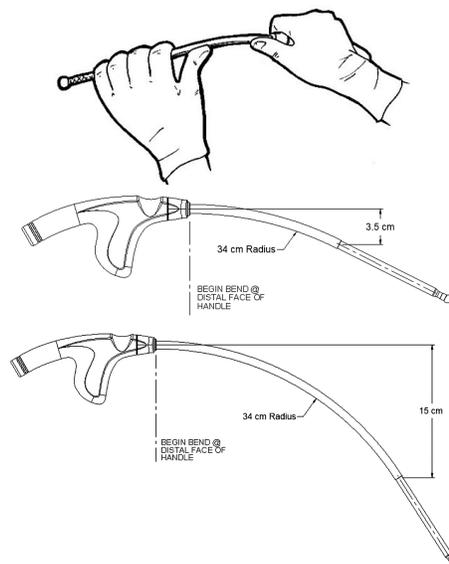


FIGURE 5: FORMING THE SHAFT RIGID REGION

**▶ FORMING THE RIGID REGION OF THE SHAFT TO THE DESIRED SHAPE**

- i The Rigid Region of the Shaft can be formed by hand and supports bending two times with up to the deflections illustrated in Figure 5.
- 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**

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

 **WARNING**   
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.

 **WARNING**   
Before entering Freeze Mode, always confirm the placement of the Ball Tip is as desired and there is no undesired tissue contact with the Ball Tip or Shaft, to prevent unintended cryoadhesion and/or cryoablation.

- 15) Engage Freeze Mode to freeze for the desired length of time. The system will automatically cycle from Freeze to Defrost after the Ablation Timer has expired.

 **WARNING**   
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.

CAUTION: 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 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<sub>2</sub>O gas venting, the PROBE may cool sufficiently to cause cryoadhesion.

- 17) After the CONSOLE is in Ready Mode and the PROBE temperature is above 0°C, repeat steps (11) to (15) 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).

 **WARNING**   
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.

**▶ DISCONNECTING AND DISPOSING OF THE PROBE**

- 18) Close N<sub>2</sub>O Cylinder by turning the Valve fully clockwise.
- 19) Pull the red N<sub>2</sub>O Manual Exhaust Knob or press the N<sub>2</sub>O 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, to avoid the release of pressurized N<sub>2</sub>O gas and possible sudden recoil of the PROBE.

- 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.

**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 <sub>2</sub> O cylinder.	Replace low or empty N <sub>2</sub> O cylinder.
	Gas not flowing, tubing is restricted.	Verify PROBE tubing is not pinched.
	Gas leak in PROBE Shaft or tubing.	Replace PROBE.
	N <sub>2</sub> O tank valve closed.	Fully open N <sub>2</sub> O 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
	Catalog number
	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician
	Batch code
	Sterilized using irradiation
	Refer to instruction manual
	Non-pyrogenic
	Use-by date
	Caution or Warning
	Informational note
	Temperature limit
	Humidity limit

 **ATRICURE, INC.**  
7555 Innovation Way  
Mason, Ohio 45040 USA  
+1 (513) 755-4100  
+1 (866) 349-2342  
CustomerService@AtriCure.com  
www.AtriCure.com