



Instructions for Use

cryoICE® cryoSPHERE™ cryoablation probe

CRYOS; CRYOS-L

INDICATION FOR USE

FOR ADULT PATIENTS

AtriCure's cryoICE cryoSPHERE cryoablation probes are sterile, single use devices intended for use performed by freezing target tissues, creating an inflammatory response (cryonecrosis) for blocking pain by temporarily ablating peripheral nerves.

FOR ADOLESCENT PATIENTS

The cryoICE cryoSPHERE cryo-ablation probes are intended for use to temporarily block pain by ablating intercostal nerves under direct visualization¹ in adolescent patients of at least 12 years of age.

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

CONTRAINDICATIONS

There are no known contraindications.

SYSTEM DESCRIPTION

The AtriCure cryoICE system 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, 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. N₂O 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

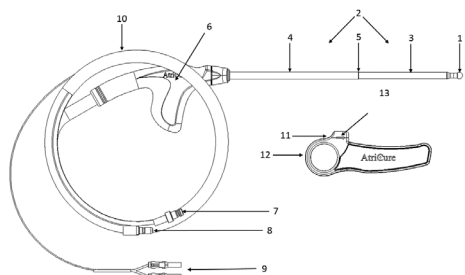
The PROBE and TOOL are supplied STERILE and NON-PYROGENIC in unopened, undamaged package. For single use only, Do not re-sterilize. Do Not Re-Use.

NOMENCLATURE

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

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

FIGURE 1: PROBE & TOOL 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 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 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 N₂O 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

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 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

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 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 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. 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

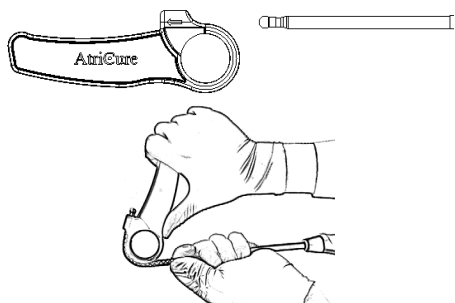
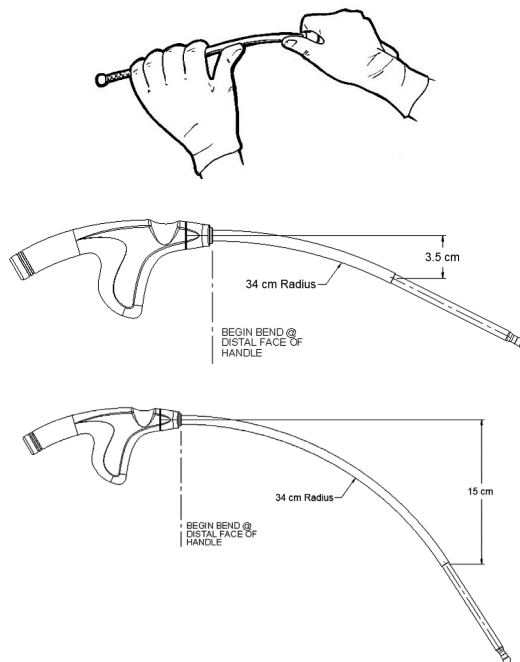


FIGURE 5: FORMING THE SHAFT RIGID REGION



FORMING THE RIGID REGION OF THE SHAFT TO THE DESIRED SHAPE

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

NOTE: The Rigid Region of the Shaft can be formed by hand and supports bending two times with up to the deflections as 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

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 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.

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 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.

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.

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.

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 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. 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

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 Ball Tip from the ablation site or moving the Shaft.

CAUTION: Use care while the CONSOLE is in Defrost Mode, as during N₂O 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).

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

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 ₂ O cylinder. | Replace low or empty N ₂ O cylinder. |
| | Gas not flowing, tubing is restricted. | Verify PROBE tubing is not pinched. |
| | Gas leak in PROBE Shaft or tubing. | Replace PROBE. |
| | N ₂ O tank valve closed. | Fully open N ₂ 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. | |



CLINICAL STUDY REFERENCES FOR NERVE BLOCK INDICATION

1. Graves C, Idowu O, Lee S, Padilla B and Kim S. Intraoperative cryoanalgesia for managing pain after the Nuss procedure. J Pediatr Surg. 2017;52:920-924.
2. Graves CE, Moyer J, Zobel MJ, Mora R, Smith D, O'Day M and Padilla BE. Intraoperative intercostal nerve cryoablation during the Nuss procedure reduces length of stay and opioid requirement: A randomized clinical trial. J Pediatr Surg. 2019.
3. Harbaugh CM, Johnson KN, Kein CE, Jarboe MD, Hirschl RB, Geiger JD and Gadepalli SK.vComparing outcomes with thoracic epidural and intercostal nerve cryoablation after Nuss procedure. J Surg Res. 2018;231:217-223.
4. Keller BA, Kabagambe SK, Becker JC, Chen YJ, Goodman LF, Clark-Wronski JM, Furukawa K, Stark RA, Rahm AL, Hirose S and Raff GW. Intercostal nerve cryoablation versus thoracic epidural catheters for postoperative analgesia following pectus excavatum repair: Preliminary outcomes in twenty-six cryoablation patients. J Pediatr Surg. 2016;51:2033-2038.
5. Kim S, Idowu O, Palmer B and Lee SH. Use of transthoracic cryoanalgesia during the Nuss procedure. J Thorac Cardiovasc Surg. 2016;151:887-888.
6. Morikawa N, Laferriere N, Koo S, Johnson S, Woo R and Puapong D. Cryoanalgesia in Patients Undergoing Nuss Repair of Pectus Excavatum: Technique Modification and Early Results. J Laparoendosc Adv Surg Tech A. 2018;28:1148-1151.
7. Parrado R, Lee J, McMahon LE, Clay C, Powell J, Kang P, Notrica DM, Ostlie DJ and Bae JO. The Use of Cryoanalgesia in Minimally Invasive Repair of Pectus Excavatum: Lessons Learned. J Laparoendosc Adv Surg Tech A. 2019;29:1244-1251.
8. Pilkington M, Harbaugh CM, Hirschl RB, Geiger JD and Gadepalli SK. Use of Cryoanalgesia for Pain Management for the Modified Ravitch Procedure in Children. J Pediatr Surg. 2019.
9. Sujka J, Benedict LA, Fraser JD, Aguayo P, Millspaugh DL and St Peter SD. Outcomes Using Cryoablation for Postoperative Pain Control in Children Following Minimally Invasive Pectus Excavatum Repair. J Laparoendosc Adv Surg Tech A. 2018;28:1383-1386.
10. Dekonenko C, Dorman RM, Duran Y, Juang D, Aguayo P, Fraser JD, Oyetunji TA, Snyder CL, Holcomb GW, Millspaugh DL and St Peter SD. Post-Operative Pain Control Modalities for Pectus Excavatum Repair: a Prospective Observational Study of Cryoablation Compared to Results of a Randomized Trial of Epidural Vs Patient-Controlled Analgesia. J Pediatr Surg. 2019.
11. Zobel MJ, Ewbank C, Mora R, Idowu O, Kim S and Padilla BE. The incidence of neuropathic pain after intercostal cryoablation during the Nuss procedure. Pediatr Surg Int. 2019.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

REFER TO THE OUTER PACKAGE LABEL TO SEE WHICH SYMBOLS APPLY TO THIS PRODUCT.

| | | | | | |
|----------------|-------------------------------|----------------|---|------------|----------------------------------|
| | Caution | Rx ONLY | Caution: Federal Law (US) restricts this device to sale by or on the order of a physician | | Do Not Re-Sterilize |
| | Non-Pyrogenic | | Waste Electrical and Electronic Equipment | | Do Not Use if Package is Damaged |
| STERILE | Sterilized by Gamma Radiation | LOT | Batch code | | Manufacturer |
| | Do Not Re-Use | | Not made with Natural Rubber Latex | REF | Catalogue Number |
| | Expiration Date | | Follow instructions for use | # | Model |