AtriCure®

Rx ONLY

cryoICE® system cryoablation probe

INSTRUCTIONS FOR USE

**CRYO2**

MD

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

FIGURE 1: CRYOICE SYSTEM CRYOABLATION PROBE AND FORM TOOL

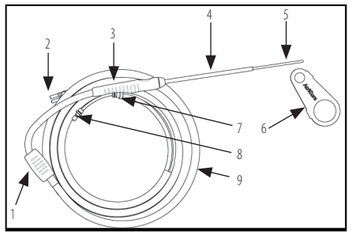


FIGURE 2: PROBE CONNECTIONS TO CRYOICE BOX

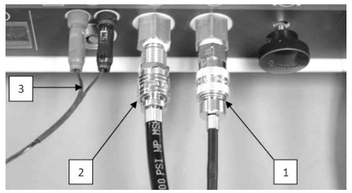


FIGURE 3: HANDLE AND RIGID SHAFT RETRACTION

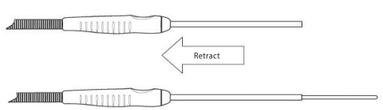


FIGURE 4: FORM TOOL USAGE

Bending 13mm (0.5 in)	Bending 26mm (1.0 in)	Straightening

FIGURE 5: BEND PROFILE

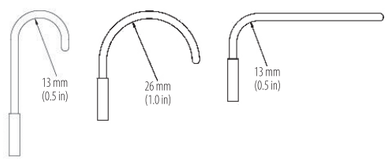
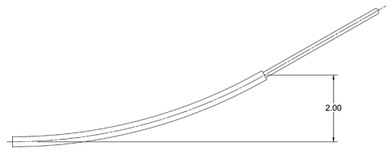


FIGURE 6: RECOMMENDED RIGID PROBE SHAFT BENDING



INSTRUCTIONS FOR USE

en

cryoICE® system cryoablation probe

DEVICE DESCRIPTION

1. The AtriCure cryoICE cryoablation system is comprised of:

   a) cryoICE cryoablation probe, CRYO2, (also referred to as PROBE) with Cryo probe form tool

   b) AtriCure CryoICE BOX (ACM), Components and N_2O gas cylinder (not provided)

This Instructions for Use will cover the use of the cryoICE PROBE and form tool. The cryoICE PROBE is a sterile, single-use cryosurgical instrument designed for use with the cryoICE BOX. The form tool facilitates bending of the malleable tip. This PROBE was designed for treatment of cardiac arrythmias by achieving controlled temperatures down to -50° to -70°C; it can also be used to block pain by temporarily ablating the peripheral nerves and by ablating intercostal nerves under direct visualization in adolescent patients of at least 12 years of age.

IMPORTANT

This PROBE was designed for treatment of cardiac arrhythmias by achieving controlled temperatures down to -50° C to -70° C; it can also be used to block pain by temporarily ablating the peripheral nerves.

This Instructions for Use document will cover use of the cryoICE cryoablation probe, and form tool. The cryoICE cryoablation probe is a sterile, single-use cryosurgical instrument designed for use with the CryoICE BOX. The form tool facilitates bending of the malleable tip. It can also be used to block pain by temporarily ablating the peripheral nerves in patients of at least 12 years of age.

DEVICE NOMENCLATURE (SEE FIGURE 1)

PROBE FEATURES

[1]	Manifold	[4]	Rigid Shaft	[7]	Gas Inlet Connector
[2]	Temperature Connectors	[5]	Malleable Tip	[8]	Gas Exhaust Connector
[3]	Retractable Handle	[6]	Form Tool	[9]	Tubing

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

⚠ **CAUTION:** Before using product read the following information thoroughly.

INDICATIONS FOR USE

FOR ADULT PATIENTS

AtriCure's Cryo2 cryoICE cryoablation probes are sterile, single use devices intended for use in the cryosurgical treatment of cardiac arrhythmias by freezing target tissues, creating an inflammatory response (cryonecrosis) that blocks the electrical conduction pathway. The Cryo2 cryoICE cryo-ablation probes are also intended for use to temporarily block pain by ablating peripheral nerves.

FOR ADOLESCENT PATIENTS

The Cryo2 cryoICE cryoablation probes are intended for use to temporarily block pain by ablating intercostal nerves under direct visualization[1] in adolescent patients of at least 12 years of age.

[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, endoscope or other similar optical technology.

CONTRAINDICATIONS

There are no known contraindications.

⚠ 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.

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.

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.

⚠ WARNINGS ⚠

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

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

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.

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

Cardiac surgical procedures may mechanically induce arrhythmias.

Do not use the PROBE to freeze tissue inside the beating heart. Use of the PROBE to freeze tissue inside the beating heart may result in severe injury to the patient.

Cryoablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis. It is unknown whether cryoablation with the PROBE will have such an effect, but as in all such procedures, care should be taken to minimize unnecessary contact with coronary vessels during cryoablation.

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.

Intercostal nerve ablations should be at least 2 cm (0.79in) from the dorsal root ganglia or 4 cm (1.58in) from the base of the spine to prevent damage to the sympathetic chain.

Intercostal nerve ablations should be performed 2-4 cm (0.79-1.58in) 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.

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.

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

⚠ **CAUTIONS:**

- 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.
- Follow standard guidelines for the storage and safe handling of high-pressure gas tanks.
- Nitrous Oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels.
- When using a standard off-the-shelf nerve stimulator, read all of the manufacturer's instructions carefully prior to using the device. Failure to follow instructions may lead to injury and may result in improper functioning of the device.
- 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.
- The PROBE is only compatible with the AtriCure cryoICE BOX. Use of the PROBE with another manufacturer's system may damage the device and result in patient injury.
- Ensure the CONSOLE is in Ready Mode before attempting to connect or disconnect the PROBE. The sudden release of pressurized gas may cause the PROBE to recoil, which may injure the operator or the patient.
- 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.

INSTRUCTIONS FOR USE

NOTE: PLEASE REFER TO THE CRYOICE BOX USER'S MANUAL FOR CONSOLE INSTRUCTIONS, PRODUCT DESCRIPTION AND FEATURES.

WITH THE CRYOICE BOX:

NOTE: Please refer to the CryoICE BOX User's Manual for Console instructions, product description and features.

1. Follow the setup installation instructions for proper setup of the CryoICE BOX per the User's Manual.
2. Turn the Nitrous Oxide Cylinder (Tank) Valve fully counter-clockwise to open.
3. Examine the packaging of the device to ensure the sterility of the product has not been breached. Remove the sterilized instrument from its package per standard sterile technique.
4. Connect the PROBE Gas Inlet Connector to the Gas inlet Connection Port. **See Figure 2**.

Table 1. PROBE Connections to CryoICE BOX

Item Number	Connect CryoICE BOX Item	To Probe:
1	Gas Inlet Connection Port	PROBE Gas Inlet Connector
2	Gas Exhaust Connection Port	PROBE Gas Exhaust Connector
3	Thermocouple Port	Match Color coded Temperature connectors to the matching colored PROBE connectors

5. Connect PROBE **Gas Exhaust Connector** to the Gas Exhaust Connection Port. To engage **Exhaust Probe Socket**, slide retainer ring back on quick disconnect while inserting plug, then release.
6. Confirm PROBE connectors are fully engaged by lightly pulling on connections.
7. Connect **Temperature Connectors** of the PROBE to the corresponding colored connectors on the CryoICE BOX. See Figure 2: PROBE Connections to CryoICE BOX.
8. **Switch** the CryoICE BOX unit ON.

NOTE: When connected correctly, the CryoICE BOX will display current PROBE temperature. If not connected, the CryoICE BOX will display "- - -".

9. For a cryoICE device, retract handle and rigid shaft to expose malleable aluminum probe. **See Figure 3**: Handle and Rigid Shaft Retraction.
10. Perform a "Pre-Freeze" by cycling the CryoICE BOX using the activation button or footswitch while the probe is in air.

NOTE: Verify pressure is at least 4826 kPa (700 psi) after the appropriate warning period.

11. Thirty seconds after frost appears on the malleable probe tip:

    a) Cycle the CryoICE BOX to defrost.

    b) Cycle the CryoICE BOX to vent the probe.

12. Identify and expose the sites to be cryoablated using standard surgical techniques.
13. If bending of the malleable tip is required always use the form tool. Refer to the section labeled: "Bending PROBE Malleable Tip". If bending of the shaft is required refer to the section labeled: "Bending PROBE Shaft".
14. Place the malleable tip against the targeted tissue under direct visualization by the surgeon.

NOTE: Ensure the malleable tip temperature is above 0°C before contacting tissue.

NOTE: Ensure targeted tissue is in contact with the malleable tip prior to freezing.

NOTE: Ensure there is no undesired tissue contact with the malleable tip or shaft.

NOTE: Do not use excessive force when using the PROBE in order to avoid tissue damage.

15. Press the activation button or footswitch to begin freezing.

NOTE: Movement of PROBE prior to tissue adhesion may affect freezing. Cryoadhesion occurs when malleable tip temperature is below 0°C.

NOTE: Failure for PROBE to reach desired temperature is discussed further under the section labeled: "FREQUENTLY ASKED QUESTIONS".

16. Freeze for desired length of time.
17. Defrost the probe by either

    a) Allowing the CryoICE BOX to automatically enter the Defrost mode

    b) Or by cycling the activation button or foot pedal.

18. Once the PROBE temperature warms greater than 0°C remove PROBE from targeted tissue.

NOTE: If PROBE does not reach desired Defrost temperature, apply warm sterile saline to the tissue and probe area as necessary.

19. Cycle the activation button or foot pedal to vent the probe.

⚠ **CAUTION:** Use care while the CONSOLE is in Defrost Mode, as during N_2O gas venting, the PROBE may cool sufficiently to cause cryoadhesion.

20. Wipe the malleable tip clean.
21. Repeat steps 12-20 as desired to create additional cryo lesions.
22. Upon completion of the surgical procedure:

    a) Turn the Nitrous Oxide Cylinder (Tank) Valve fully clockwise to close.

    b) Pull the red pressure relief knob or press the N_2O exhaust switch on the rear panel of the CryoICE BOX to depressurize the CryoICE BOX.

    c) Disconnect the PROBE from the CryoICE BOX and discard the PROBE after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device component.

    d) Switch "Off" the CryoICE BOX.

BENDING

Bending PROBE Malleable Tip

⚠ **CAUTION:** Do not use the PROBE if damaged as it may result in device malfunction. Repetitive bends in the same location could damage the Malleable Section of PROBE causing device malfunction. 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.

23. The PROBE malleable tip has a limited functional life. It is always recommended to use the form tool to create desired bends. The form tool has two ends, the smaller end radius is 13 mm (0.5 in) and the larger end radius is 26 mm (1.0 in), **see Figure 4.**

⚠ **CAUTION:** The PROBE malleable tip should not be bent into a radius of less than 13 mm (0.5 in).

24. Typical procedures may require the following bend profiles created with the use of the form tool: **See Figure 4**: Form Tool Usage.
25. Typical procedures may require the following bend profile: **See Figure 5**.

Bending PROBE Shaft

⚠ **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 PROBE Shaft.

⚠ **CAUTION:** The PROBE has limited functional life; if greater than 7 Rigid Probe Shaft bend cycles are intended, it is recommended to use a second probe.

⚠ **CAUTION:** The distal end of the PROBE shaft should not be bent more than 5 cm (2.0 in) from straight , as illustrated in **Figure 6.**

HOW SUPPLIED

The PROBE and Form Tool are supplied STERILE and NON-PYROGENIC in unopened, undamaged packaging. For single use only, do not re-sterilize and do not re-use.

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.

AtriCure®

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.

	Manufacturer	US	Country And Date of Manufacture
	Keep dry		Caution
REF	Catalogue Number	LOT	Batch Code
#	Model Number	UDI	Unique Device Identifier
Rx ONLY	Prescription use only	MD	Medical Device
	Use-by date	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 using irradiation		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	

AtriCure Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 866 349 2342
+1 513 755 4100