

Use with the following cryo-ablation probe models: CRY02

1. The AtriCure® cryoICE cryo-ablation system is comprised of:
 - a) cryoICE cryo-ablation probe, CRYO2, (also referred to as PROBE) with Cryo probe form tool
 - b) AtriCure® CryoICE Box (ACM) or the AtriCure® ACC2 Cardiac Cryosurgical System (also referred to as ACC2)
 - c) AtriCure® Cryo Accessory Kit (also referred to as Accessory Kit) if utilizing the ACC2
2. The Accessory Kit is comprised of:
 - a) Pressure Regulator Unit
 - b) Temperature Display Unit

FIGURE 1: CRYOICE CRYO-ABLATION PROBE AND FORM TOOL

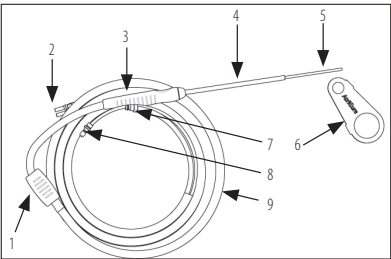


Table 1. PROBE Nomenclature

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

1. Turn the **Freeze/Defrost Control Valve** to the "Freeze" position.
2. Turn the **On/Off Control Valve** to the "Off" position.
3. Plug in and turn "On" the **Nitrous Oxide Tank Heater** to ensure adequate tank pressure. Please refer to the cryo1 Accessory Kit Installation Instructions for Nitrous Oxide Tank Heater.
4. Turn the **Nitrous Oxide Cylinder (Tank) Valve** fully counter-clockwise to open.
5. 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.
6. Connect the PROBE **Gas Inlet Connector** to the **Pressure Regulator**. See **Figure 2**.

FIGURE 2: PROBE CONNECTIONS TO ACC2

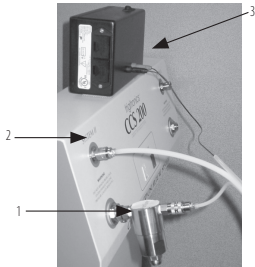
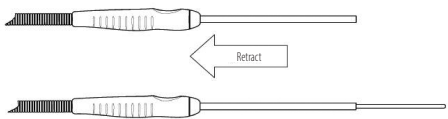
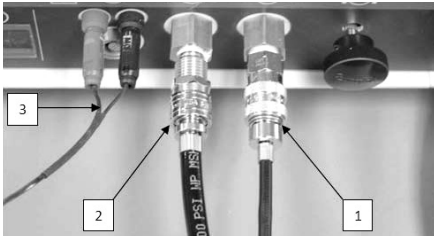


FIGURE 3: HANDLE AND RIGID SHAFT RETRACTION.



29. Follow the setup installation instructions for proper setup of the CryoCE BOX per the User's Manual.

FIGURE 4: PROBE CONNECTIONS TO CRYOICE BOX



- Turn the Nitrous Oxide Cylinder (Tank) Valve fully clockwise to close.
- Pull the red pressure relief knob on the rear panel of the CryoICE BOX to depressurize the CryoICE BOX.
- 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.
- Switch "Off" the CryoICE BOX.



BENDING

Bending PROBE Malleable Tip

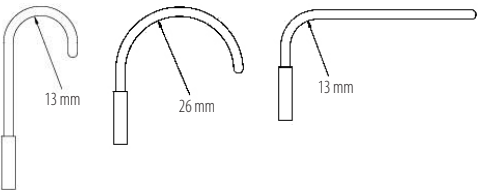
CAUTION: Repetitive bends in the same location could damage the Malleable Section of PROBE causing device malfunction.

- The PROBE malleable tip 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 Cryo1 form tool to create desired bends. The Cryo1 form tool has two ends, the smaller end radius is 13 mm and the larger end radius is 26 mm. See Table 1, located in the section labeled: "PROBE Nomenclature".

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

- Typical procedures may require the following bend profiles created with the use of the Cryo1 form tool:
See Figure 5: Form Tool Usage.

FIGURE 5



FORM TOOL USAGE



BENDING PROBE SHAFT

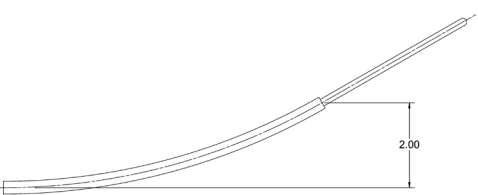
CAUTION: Repetitive bends in the same location could cause damage to the Rigid PROBE shaft.

- The probe shaft has limited functional life.

CAUTION: The distal end of the PROBE shaft should not be bent more than 5 cm (2.0 inches) from straight

- Typical procedures may require the following bend profile: **See Figure 6.**

FIGURE 6



FREQUENTLY ASKED QUESTIONS FOR USE WITH THE ACC2

Question	Answer	Solution
1. Why is the PROBE not reaching the proper temperature?	a. Inadequate inlet pressure	Turn on Nitrous Oxide Tank Heater Replace low or empty nitrous oxide tank
	b. Gas not flowing/Tubing is restricted	Verify tubing is not pinched
	c. Freeze/Defrost valve not turned completely to "Freeze" position	Turn Freeze/Defrost valve completely to "Freeze" position
	d. Maximum Freeze control valve not set to "Maximum Freeze" position	Turn Maximum Freeze control valve to "Maximum Freeze" position
	e. Leak in malleable tip or tubing	Replace with new probe
	f. Nitrous oxide cylinder (tank) valve closed	Fully open nitrous oxide cylinder (tank) valve
2. Why does the Temperature Display Unit stay at the setup screen or not turn on	g. Malleable tip is bent to radius less than 13 mm	Form malleable tip to radius of 13 mm or larger
	a. Batteries are low	Replace both 9 volt batteries
3. Why does the Temperature Display Unit read "OPEN"?	a. The PROBE connectors are partially, or not plugged into the Unit	Plug the PROBE connectors all the way into the Temperature Display Unit
	b. PROBE Temperature Connector wires are broken	Replace PROBE

4. Why does the Temperature Display Unit read a positive number during cryo-ablation?	a. The PROBE connectors are plugged into the Temperature Display Unit, but they are reversed	Reverse the PROBE connectors to match the appropriate color coded connectors on the Temperature Display Unit
5. What are the SEL and RST buttons on the Temperature Display Unit used for?	a. Not used, both buttons are disabled	Not used, both buttons are disabled
6. Why does the Nitrous Oxide Tank Heater power light not turn on?	a. Nitrous Oxide Tank Heater not receiving power	Ensure unit is plugged in

FREQUENTLY ASKED QUESTIONS FOR USE WITH THE ATRICURE CRYOICE BOX

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.
	N2O 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.	

HOW SUPPLIED

The PROBE is supplied as a sterile instrument and is for single patient use only. Sterility is guaranteed unless the package is opened or damaged.

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.

CLINICAL STUDY REFERENCES FOR NERVE BLOCK INDICATION

- 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.
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- 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.
- 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.
- 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.
- 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.
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- 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.
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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	Lot Number		Manufacturer
	Do Not Re-Use		Not made with Natural Rubber Latex	REF	Catalogue Number
	Expiration Date		Follow instructions for use		Model



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