## Figure 2: PROBE Connections to ACC2 **AtriCure**® cryolCE™ cryo−ablation probe Instructions for Use Use with the following cryo−ablation probe models: CRYO2 DESCRIPTION The AtriCure® cryolCE cryo—ablation system is comprised of: a. cryolCE cryo—ablation probe, CRYO2, (also referred to as PROBE) with Cryo1 probe form tool b. AtriCure® Cryo Module (ACM) or the AtriCure® ACC2 Cardiac Cryosurgical System (also referred to as ACC2) c. AtriCure® Cryo1 Accessory Kit (also referred to as Accessory Kit) if utilizing the ACC2 The Accessory Kit is comprised of: a. Nitrous Oxide Tank Heater b. Pressure Regulator Unit c. Temperature Display Unit CAUTION 1. The PROBE must be used with the AtriCure Cryo1 Accessory Kit if utilizing the ACC2. The DROBE was designed for treatment of cardiac arrhythmias by achieving controller to the property of the p Figure 3: Handle and Rigid Shaft Retraction. 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 cryolCE cryo—ablation probe, form tool, and the Accessory Kit. The cryofCE cryo—ablation probe is a sterile, single-use cryosurgical instrument designed for use with the ACM or the ACC2 and the Accessory Kit. The Cryo1 form tool facilitates bending of the malleable tip. NOTE: Users should be aware of known radio frequency (RF) sources and consider them when using a medical device. The AtriCure® cryoICE cryo—ablation system can be sensitive to electrostatic discharge (ESD) and RF emissions, which may temporarily reduce system performance. cryoICE™ cryo-ablation probe ILLUSTRATION AND NOMENCLATURE Table 1. PROBE Nomenclature 1. Manifold 4. Rigid Shaft 7. Gas Inlet Connector 8. Gas Exhaust Connector BEFORE USING PRODUCT READ THE FOLLOWING INFORMATION THOROUGHLY IMPORTANT! This booklet is designed to assist in using this product. It is not a reference to surgical techniques. AtriCure's cryolCE™ cryo-ablation 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 probe is also 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 WARNINGS 1. Please refer to the ACM User's Manual or the ACC2 Operation and Maintenance Manual for Console warnings, cautions, product description and features. The PROBE is only compatible with the ACM or ACC2 Cardiac Cryosurgical System. Use of the PROBE with another manufacturer's system may damage the device and result in patient injury. The PROBE must be used with the AtriCure Cryo1 Accessory Kit if utilizing the ACC2. 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. 5. Crvo—ablation involving coronary vessels has been associated with subsequent clinically significant arterial stenosis It is unknown whether cryo—ablation 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 cryo—ablation. 6. Do not pull on the PROBE or console while the malleable tip is frozen to tissue as this could lead to inadvertent tissue damage. 7. Do not use excessive force when using the PROBE in order to avoid tissue damage. Cardiac surgical procedures may mechanically induce arrhythmias. The PROBE should be positioned correctly and the placement of the malleable tip confirmed prior to cryo—ablation. Ensure there is no undesired tissue contact with the malleable tip or shaft during freezing, in order to avoid 10. The PROBE contains pressurized gas during operation. Discontinue use immediately if a breach in the PROBE is suspected, as this may result in release of pressurized gas and injury to the patient or the user. 11. Do not attempt to disconnect the PROBE during operation. The sudden release of pressure may cause the PROBE to recoil, which may figure the operator or patient. 12. Do not reprocess or reuse the PROBE. Reuse can cause patient injury and/or the communication of infectious Bending 13mm disease(s) from one patient to another. 13. The Accessory Kit is not suitable for use in the presence of a flammable anesthetic mixture. CAUTIONS 1. Read all instructions carefully for the PROBE prior to using the device. Failure to properly follow instructions may lead to injury and may result in improper functioning of the device. 2. Use of the PROBE should be limited to properly trained and qualified medical personnel. To avoid damage to the device, do not drop or toss the PROBE. If the PROBE is dropped, do not use. Replace with a new PROBE. Do not re-sterilize or reuse the PROBE. Resterilization may cause loss of function or injury to patient. Do not use he PROBE if damaged in any way. I bo not use the PROBE if damaged in any way. If the sterile package is damaged and/or the sterile barrier is breached, discard device and DO NOT USE. Follow standard guidelines for the safe handling and storage of high-pressure gas tanks. Do not remove or install PROBE unless the line and exhaust pressure gauge read "Or psi if utilizing the ACC2. Do not remove or install PROBE from console unless the ACM is in the Stand-By Mode. Bending 26mm 10. Nitrous oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels. 12. Do not restrict, kink, bend, clamp or otherwise damage PROBE tubing. 13. 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 With the ACC2 and Accessory Kit: NOTE: Please refer to the ACC2 Operation and Maintenance Manual for Console instructions, product description and features. NOTE: If the Accessory kit has not been installed on the ACC2 please call ArtiCure before proceeding. 1. Turn the Freeze/Defrost Control Valve to the "Freeze" position. Turn the On/Off Control Valve to the "Off" position. Plug in and turn "On" the Nitrous Oxide Tank Heater to ensure adequate tank pressure. Please refer to the *cryo1* Turn the Nitrous Oxide Cylinder (Tank) Valve fully counter-dockwise to open. 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. Table 2. PROBE Connections to ACC2 Connect ACC2 Item To Probe: Pressure Regulator PROBE Gas Inlet Connector PROBE Gas Exhaust Connector Exhaust Probe Socket NOTE: Use the Exhaust Probe Socket located above the Pressure Regulator Temperature Display Unit Connectors Match Color coded Temperature connecto . Connect PROBE Gas Exhaust Connector to the appropriate ACC2 Exhaust Probe Socket. To engage Exhaust Probe Socket, slide retainer ring back on quick disconnect while inserting plug, then release. Confirm PROBE connectors are fully engaged by lightly pulling on connections. **RETURN OF USED PRODUCT**If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required Display Unit. See Figure 2: PROBE Connections to ACC2. NoTE: When connected correctly, the Temperature Display Unit will now display the PROBE temperature. NOTE: When connected correctly, the Temperature Display Unit will display current PROBE temperature. 11. For a cryoICE device, retract handle and rigid shaft to expose malleable aluminum probe. See Figure 3: Handle and 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. If the product has been in crimact with brood or body futures, it must be throughly be deathed and uslimite the british part if 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. Rigid Shaft Retraction. IMPORTANT: Do not use the PROBE in the Temperature Control mode. The Maximum Freeze Control Valve must be Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc. DISCLAIMER STATEMENTS 12. Turn the Maximum Freeze Control Valve to the "Maximum Freeze" position. CAUTION 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 manner described in these instructions for use, including, but not limited to, ensuring During the Pre-Freeze, if there are leaks in the Pressure Regulator Unit the sound of gas leaking will be heard, and/or frost will appear on the connections. Replace the Pressure Regulator before continuing with the procedure. 13. Perform a "Pre-Freeze" by turning the On/Off Control Valve to the "On" position while the probe is in air. that product is not re-used. Under no circumstances will Attricure, Inc. be responsible for any incidental, special or consiguential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense IMPORTANT: The PROBE must be operated at a pressure of 700 psi or higher. 14. Thirty seconds after frost appears on the malleable probe tip: a. Turn the Freeze/Defrost Control Valve to the "Defrost" position. EXPLANATION OF SYMBOLS ON PACKAGE LABELING Refer to the outer package label to see which symbols apply to this produce b. Turn the **On/Off Control Valve** to the "Off" position. Prior to bending the malleable tip or shaft always ensure the On/Off Control Valve is in the "Off" position. 15. With the **On/Off Control Valve** set to the "Off" position, turn the Freeze/Defrost Control Valve to the "Freeze". Caution: Federal Law (US) restricts this device to sale by or on the order of a Rx ONLY Non-Pyrogenic NOTE: Ensure the Line Pressure Gage and Exhaust Pressure Gage read 0 psi prior to bending the PROBE. 16. If bending of the malleable tip is required always use the form tool. Refer to the section labeled: "Bending PROBE terilized by Gamma Radiation STERILE R LOT Malleable Tip". If bending of the shaft is required refer to the section labeled: "Bending PROBE Shaft". 17. Identify and expose the sites to be cryoablated using standard surgical techniques. 18. Place the malleable tip against the targeted tissue under direct visualization by the surgeon. 2 **NOTE:** Ensure the malleable tip temperature is above 0°C before contacting tissue. Single Use Only **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. Use-By Date 19. Turn the On/Off Control Valve to the "On" position. a. Check the Line Pressure Gauge to ensure line pressure of 700 psi or greater has been maintained. NOTE: Movement of PROBE prior to tissue adhesion may affect freezing. Cryoadhesion occurs when malleable tip Follow instruction for use NOTE: Failure for PROBE to reach desired temperature is discussed further under the section labeled: "FREQUENTLY ASKED STEPRIZE 21. Turn the Freeze/Defrost Control Valve to the "Defrost" position until PROBE temperature warms to greater than Do Not Resterilize NOTE: If PROBE does not reach desired Defrost temperature, apply warm sterile saline to the tissue and probe area as 22. Remove PROBE from targeted tissue. Electronic Equipment (WEEE) CAUTION Turning the On/Off Control Valve to the "Off" position followed by turning the Freeze/Defrost Valve to the "Freeze" position can cause sufficient cooling to cause cryo-adhesion. 23. Turn the **On/Off Control Valve** to the "Off" position. 24. Turn the Freeze/Defrost Valve to the "Freeze" position to vent the PROBE. Manufactured by: Wipe the malleable tip clean. 26. Repeat steps 14 thru 23 as desired to create additional cryo lesions. AtriCure Incorporated CAUTION 7555 Innovation Way Mason, Ohio 45040 USA Do not remove or install PROBE from console unless the line and exhaust pressure gauge read "0" psi. 27. Upon completion of the surgical procedure: Customer Service: 1-866-349-2342 (toll free) 1-513-755-4100 (phone) a. Switch "Off" the Temperature Display Unit. b. Turn the Nitrous Oxide Cylinder (Tank) Valve fully clockwise to close. c. Turn On/Off valves "On" and "Off" repeatedly to relieve system pressure until all pressure gauges read "O" psi. d. Disconnect the PROBE from the ACC2 and discard the PROBE after use. Follow local governing ordinances and recycling plans regarding disposal or recycling of device component. e. Switch "Off" and unplug the Nitrous Oxide Tank Heater from the wall outlet.

physician

Lot Number

Caution

Manufacturer

Not made with natural rubber latex

Do Not Use if Package is Damaged

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

28. Follow the setup installation instructions for proper setup of the ACM per the User's Manual.

29. Turn the Nitrous Oxide Cylinder (Tank) Valve fully counter-clockwise to open. 30. 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.

31. Connect the PROBE Gas Inlet Connector to the Gas inlet Connection Port. See Figure 4. Table 3. PROBE Connections to ACM Item Number Connect ACM 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 32. 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. 33. Confirm PROBE connectors are fully engaged by lightly pulling on connections.

34. Connect Temperature Connectors of the PROBE to the corresponding colored connectors on the ACM. See Figure 35. Switch the ACM unit ON.  $\textbf{NOTE:} \ \text{When connected correctly, the ACM will display current PROBE temperature. If not connected, the ACM will display current PROBE temperature.}$ 

36. For a cryolCE device, retract handle and rigid shaft to expose malleable aluminum probe. See Figure 3: Handle and To a crystee characteristic and injud stant to expose management processes a Figure 3. Institute and Rigid Shaff Refraction.

IMPORTANT: Do not use the PROBE in the Temperature Control mode. The Handpiece Probe Temperature Control must be set full open (turn counterclockwise until it stops).

37. Perform a "Pre-Freeze" by cycling the ACM using the activation button or footswitch while the probe is in air.

IMPORTANT: The PROBE must be operated at a pressure of 700 psi or higher.

 Thirty seconds after frost appears on the malleable probe tip:
 a. Cycle the ACM to defrost.
 b. Cycle the ACM to vent the probe. 39. Identify and expose the sites to be cryoablated using standard surgical techniques

 If bending of the mallabel big 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". 41. 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.
42. Press the activation button of ofcostwich to begin freezing.

NOTE: Movement of PROBE prior to tissue adhesion may affect freezing. Cryoadhesion occurs when malleable tip NOTE: Failure for PROBE to reach desired temperature is discussed further under the section labeled: "FREQUENTLY ASKED QUESTIONS".

43. Freeze for desired length of time.

44. Defrost the probe by either

a. Allowing the ACM to automatically enter the Defrost mode
b. Or by cycling the activation button or foot pedal.

d. 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.

46. Cycle the activation button or foot pedal to vent the probe. CAUTION Venting the probe can cause sufficient cooling to cause cryo-adhesion.
47. Wipe the malleable tip clean.
48. Repeat steps 38 thru 46 as desired to create additional cryo lesions.

Do not remove or install PROBE from console unless the ACM is in the Stand-By Mode.

49. 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 on the rear panel of the ACM to depressurize the ACM. c. Disconnect the PROBE from the ACM and discard the PROBE after use. Follow local governing ordinances and
recycling plans regarding disposal or recycling of device component. d. Switch "Off" the ACM. BENDING
Bending PROBE Malleable Tip CAUTION

Repetitive bends in the same location could cause damage to the malleable tip. After each bend re-straighten the PROBE malleable tip prior to creating the next bend. If the same bend is desired in a different plane, do not rotate the PROBE malleable tip; re-straighten the PROBE malleable tip; re-straighten the PROBE malleable tip; and create the same bend in the desired plane.

1. The PROBE malleable tip has a limited functional life; if greater than 8 bends are intended, it is recommended to use a second profile it is always recommended to use the Cryo1 form tool to create desired, the 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).

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

Repetitive bends in the same location could cause damage to the shaft.

1. 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.

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

	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
		g.	Malleable tip is bent to radius less than 13 mm	Form malleable tip to radius of 13 mm or larger
	Why does the Temperature Display Unit stay at the setup screen or not turn on	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
	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
	What are the <b>SEL</b> and <b>RST</b> buttons on the Temperature Display Unit used for?	a.	Not used, both buttons are disabled	Not used, both buttons are disabled
-	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
E	QUENTLY ASKED QUESTIONS FO	R US	E WITH THE ACM	
_	Question		Answer	Solution
	Why is the PROBE not reaching	a.	Inadequate inlet pressure	Replace low or empty nitrous

oxide tank the proper temperature? o. Gas not flowing/Tubing is Verify tubing is not pinched Handpiece probe temperature adjust knob is not completely turned counter-clockwise Iurn Handpiece probe temperature adjust knob completely counter-clockwise d. Leak in malleable tip or tubing Replace with new probe Nitrous oxide cylinder (tank) valve closed Fully open nitrous oxide cylinder (tank) valve Malleable tip is bent to radius less than 13 mm Form malleable tip to radius of 13 mm or larger

The PROBE Temperature connectors are partially, or not plugged into the Unit Thermocouple port

Thermocouple port PROBE Temperature Connector Replace PROBE wires are broken Reverse the PROBETemperature Why does the ACM read The PROBE Temperature a positive number during cryo-ablation? connectors are plugged into connectors to match the appropr the ACM, but they are reversed color coded connectors on the ACM

See ACM User's Manual for See ACM User's Manual for Trouble Why does the ACM display a fault code, error code, Trouble Shooting 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.

WARNING Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one

