AtriCure®

cryoICE™ cryo–ablation probe
Instructions for Use
Use with the following cryo–ablation probe models: CRYO2

DESCRIPTION

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

This Instructions for Use will cover the use of the cryoICE PROBE, form tool, and Accessory kit. The cryoICE PROBE is a sterile, single-use cryosurgical instrument designed for use with the cryoICE Box or the ACC2 and the Accessory Kit. The form tool facilitates bending of the malleable tip. The PROBE must be used with the AtriCure Cryo Accessory Kit if utilizing the ACC2. 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

The PROBE must be used with the AtriCure Cryo1 Accessory Kit if utilizing the ACC2.

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 cryo–ablation probe, form tool, and the Accessory Kit. The cryoICE cryo–ablation probe is a sterile, single-use cryosurgical instrument designed for use with the CryoICE BOX or the ACC2 and the Accessory Kit. The Cryo1 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.

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.

FIGURE 1: CRYOICE CRYO–ABLATION PROBE AND FORM TOOL

CRYOICE™ CRYO-ABLATION PROBE ILLUSTRATION AND NOMENCLATURE

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

⚠ **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.

INDICATION 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 cryo-ablation 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

1. Read all instructions carefully prior to using the device.
2. Please refer to the CryoICE Box (ACM) Instructions for Use for Console Warnings, Cautions, product description and features.
3. Use of the PROBE should be limited to properly trained and qualified medical personnel.
4. Improper use of this device may lead to device malfunction, failure to provide intended therapy, and/or serious injury.
5. Do not re-sterilize or reuse the PROBE. Resterilization may cause loss of function or injury to patient.
6. 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.
7. Use care to avoid PROBE movement while cryoadhesion is present, to prevent inadvertent tissue damage.
8. Do not use excessive force when using the PROBE in order to avoid tissue damage.
9. The Accessory Kit is 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.
10. Avoid direct contact of PROBE with lung to prevent potential risk of pneumothorax.
11. Cardiac surgical procedures may mechanically induce arrhythmias.
12. 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.
13. 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.
14. 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. 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.
16. 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.
17. Intercostal nerve ablations should be performed 2-4cm lateral to the internal mammary artery (IMA), to prevent potential damage to the IMA.
18. 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.
19. 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.
20. 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.
21. Ensure the CONSOLE is in READY Mode and the PROBE temperature is above 0°C before contacting tissue, to avoid unintended cryoadhesion.

⚠ CAUTIONS

1. The PROBE uses 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 user.
2. Follow standard guidelines for the storage and safe handling of high-pressure gas tanks.
3. Nitrous Oxide gas must be safely exhausted. Follow standard hospital guidelines for allowable concentration levels.
4. 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.
5. Do not use the PROBE if damaged in any way as it may result in device malfunction.
6. The PROBE is only compatible with the AtriCure cryoICE BOX or ACC2 Cardiac Cryosurgical System. Use of the PROBE with another manufacturer's system may damage the device and result in patient injury.
7. Do not remove or install PROBE from ACC2 unless the line and exhaust pressure gauge read "0" psi. The sudden release of pressurized gas may cause the PROBE to recoil, which may injure the operator or patient.
8. 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 patient.
9. 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

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 AtriCure before proceeding.

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

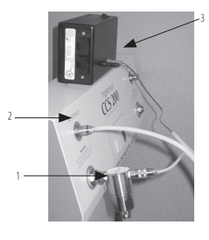


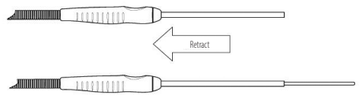
Table 2. PROBE Connections to ACC2		
Item Number	**Connect ACC2 Item**	**To Probe:**
1	Pressure Regulator	PROBE Gas Inlet Connector
2	Exhaust Probe Socket **NOTE:** Use the Exhaust Probe Socket located above the Pressure Regulator	PROBE Gas Exhaust Connector
3	Temperature Display Unit Connectors	Match Color coded Temperature connectors to the matching colored PROBE connectors

7. 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.
8. Confirm PROBE connectors are fully engaged by lightly pulling on connections.
9. Connect **Temperature Connectors** of the PROBE to the corresponding colored connectors on the Temperature Display Unit. **See Figure 2**: PROBE Connections to ACC2.
10. Switch the Temperature Display Unit "On". 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 Rigid Shaft Retraction.

FIGURE 3: HANDLE AND RIGID SHAFT RETRACTION.



IMPORTANT: Do not use the PROBE in the Temperature Control mode. The **Maximum Freeze Control Valve** must be set to "Maximum Freeze".

12. Turn the **Maximum Freeze Control Valve** to the "Maximum Freeze" position.
13. During the FREEZE cycle, if there are leaks in the blue inlet/orange exhaust connector, the sound of gas leaking will be heard and/or frost will appear on the connections. Replace the device before continuing with the procedure.
14. Perform a "Pre-Freeze" by turning the **On/Off Control Valve** to the "On" position while the probe is in air.

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

15. Thirty seconds after frost appears on the malleable probe tip:
    a) Turn the **Freeze/Defrost Control Valve** to the "Defrost" position.
    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.
16. With the **On/Off Control Valve** set to the "Off" position, turn the Freeze/Defrost Control Valve to the "Freeze" position.

NOTE: Ensure the Line Pressure Gage and Exhaust Pressure Gage read 0 psi prior to bending the PROBE.

17. 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".
18. Identify and expose the sites to be cryoablated using standard surgical techniques.
19. 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.

20. 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 temperature is below 0°C.

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

21. Freeze for desired length of time.
22. Turn the **Freeze/Defrost Control Valve** to the "Defrost" position until PROBE temperature warms to greater than 0°C.

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

23. Remove PROBE from targeted tissue.

⚠ **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.

24. Turn the **On/Off Control Valve** to the "Off" position.
25. Turn the Freeze/Defrost Valve to the "Freeze" position to vent the PROBE.
26. Wipe the malleable tip clean.
27. Repeat steps 14 thru 23 as desired to create additional cryo lesions.
28. Upon completion of the surgical procedure:
    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 "0" 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.

With the CryoICE BOX:

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

29. Follow the setup installation instructions for proper setup of the CryoICE BOX per the User's Manual.
30. Turn the Nitrous Oxide Cylinder (Tank) Valve fully counter-clockwise to open.
31. 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.
32. Connect the PROBE Gas Inlet Connector to the Gas inlet Connection Port. **See Figure 4**.

FIGURE 4: PROBE CONNECTIONS TO CRYOICE BOX

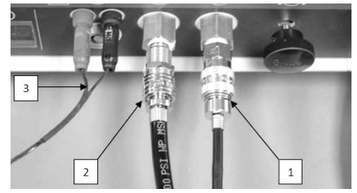


Table 3. PROBE Connections to CryoICE BOX		
Item Number	**Connect CryoICE BOX Item**	**To Probe:**
1	Gas Inlet Connection Port	PROBE Gas Inlet Connector
2	**Gas** Exhaust Connection Port	PROBE Gas Exhaust Connector
3	Thermocouple Port	Match Color coded Temperature connectors to the matching colored PROBE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

33. 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.
34. Confirm PROBE connectors are fully engaged by lightly pulling on connections.
35. Connect **Temperature Connectors** of the PROBE to the corresponding colored connectors on the CryoICE BOX. See Figure 4: PROBE Connections to CryoICE BOX.
36. **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 E-H.

37. For a cryoICE device, retract handle and rigid shaft to expose malleable aluminum probe. **See Figure 3**: Handle and Rigid Shaft Retraction.

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).

38. Perform a "Pre-Freeze" by cycling the CryoICE BOX 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.

39. 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.
40. Identify and expose the sites to be cryoablated using standard surgical techniques.
41. 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".
42. 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.

43. 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".

44. Freeze for desired length of time.
45. 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.
46. 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.

47. 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 cyroadhesion.

48. Wipe the malleable tip clean.
49. Repeat steps 38 thru 46 as desired to create additional cryo lesions.

⚠ **CAUTION:** Do not remove or install PROBE from CONSOLE unless the line and exhaust pressure gauge read "0" PSI. The sudden release of pressurized gas may cause the PROBE to recoil, which may injure the operator or patient.

50. 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 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.

AtriCure®

BENDING

Bending PROBE Malleable Tip

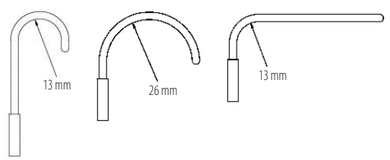
⚠ **CAUTION:** Repetitive bends in the same location could damage the Malleable Section of PROBE causing device malfunction.

1. 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).

2. 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 13mm

Bending 26mm

Straightening

BENDING PROBE SHAFT

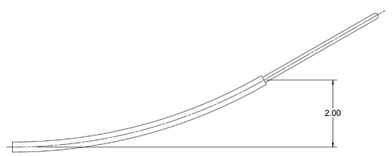
⚠ **CAUTION:** Repetitive bends in the same location could cause damage to the Rigid PROBE shaft.

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**.

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
	g. Malleable tip is bent to radius less than 13 mm	Form malleable tip to radius of 13 mm or larger
2. 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
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_2O cylinder.	Replace low or empty N_2O 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_2O 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

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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.
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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.
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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	2 STERILIZE	Do Not Re-Sterilize
	Non-Pyrogenic		Waste Electrical and Electronic Equipment		Do Not Use if Package is Damaged
STERILE R	Sterilized by Gamma Radiation	LOT	Lot Number		Manufacturer
2	Do Not Re-Use		Not made with Natural Rubber Latex	REF	Catalogue Number
	Expiration Date		Follow instructions for use	#	Model

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