

510(k) Summary

I. Submitter

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Date Submitted: 11/23/2020

II. Device

Name of Devices: AtriCure® cryoICE® cryoablation probe (Cryo2)
AtriCure® cryoICE® cryoSPHERE™ cryoablation probe (CryoS, CryoS-L)

Common Name: Cryosurgical Probe

Classification Name: Cryogenic Surgical Device (21 CFR 878.4250)

Regulatory Class: Class II

Product Code: GXH

III. Predicate Device

Predicate Device:
K180138 AtriCure® cryoICE® cryoablation probe (Cryo2)
K182565 AtriCure® cryoICE® cryoSPHERE™ cryoablation probe (CryoS, CryoS-L)

IV. Device Description

Cryo2

The cryosurgical handpiece, or cryo-ablation probe, utilized in the AtriCure Cryosurgical System is a hand held, single use, cryosurgical instrument intended for the cryosurgical treatment of cardiac arrhythmias during cardiac surgery; it is also intended for use in blocking pain by temporarily ablating peripheral nerves. The cryosurgical handpiece utilizes a high-pressure cryogen (nitrous oxide, N₂O) to freeze target tissues, creating an inflammatory response, and ultimately, cryonecrosis. The cryosurgical handpiece provides probe temperatures below -40°C, the temperature at which intracellular ice formation occurs which is considered lethal to cells. When high pressure nitrous oxide is supplied to the cryoprobe via the AtriCure Cryo Module, rapid cooling is achieved via the Joule-Thompson effect. The end effector, or cryotip, of the probe is malleable to allow access to varying anatomy and anatomical sites.

The cryo-ablation probes are comprised of a cryotip end effector, shaft, handle, thermocouple, inlet tube, and exhaust tube. The cryotip consists of an aluminum boiler and three internal inlet orifices distributed throughout the cryotip internally to provide uniform cooling. The 4-mm diameter, cryotip is malleable throughout its 10-cm length. A supplied forming tool can be used to bend the cryotip into the desired form. The cryotip is attached to an insulated rigid shaft that allows the surgeon to adjust the length of the exposed cryotip up to 10 cm in therapeutic length. A thermocouple is affixed to the proximal external surface of the shaft to display real time temperatures on the console. The handle is attached to the shaft. Inlet and exhaust tubes and thermocouple wire pass through the handle and connect to the AtriCure Cryo Module (ACM).

The cryoICE PROBE is a sterile, single-use cryosurgical instrument.

The form tool facilitates bending of the malleable tip.

This PROBE was designed for treatment of cardiac arrhythmias by achieving controlled temperatures down to -50° to -70°C; it can also be used to temporarily block pain by ablating peripheral nerves, and also intercostal nerves in adolescent patients of at least 12 years of age.

CryoS, CryoS-L

The cryoICE cryoSPHERE cryoablation (CRYOS/CRYOS-L) probe is a single use device that achieves cryoablation of peripheral nerves by allowing a surgeon to insert the probe through an incision to reach the target tissue, place the probe tip on the target site, and in conjunction with an AtriCure Cryo Module (ACM), temporarily freeze the tissue in contact with the probe tip by circulating a cryogenic agent, nitrous oxide, through the device. The CRYOS probe is offered in two probe length configurations: approximately 11" and 18" long. The probe is malleable and is capable of being bent by the end user. At the distal end, the CRYOS device features an 8 mm diameter ball tip shaped probe.

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.

V. Indications for Use

Cryo2

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 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 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.

CryoS, CryoS-L

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.

VI. Comparison of Technological Characteristics with the Predicate Device

AtriCure's cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) have no changes in technological characteristics as compared to the predicate.

Modifications included in the cryoICE cryoablation probes include the expanded indication for use in adolescent patients to temporarily block pain by ablating intercostal nerves under direct visualization.

Summary of Technical Characteristics		
	CRYO2	CRYOS/CRYOS-L
Market Product Name	cryoICE cryoablation probe	cryoICE cryoSPHERE cryoablation probe
Intended Use	<p>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 cryoICE cryo-ablation probes are also intended for use to temporarily block pain by ablating peripheral nerves.</p> <p>For Adolescent Patients The Cryo2 cryoICE 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</p>	<p>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.</p> <p>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.</p>
Operating Principle	Joule-Thompson Effect	Joule-Thompson Effect
Technology	The system consists of cryoprobes that are used for freezing target tissue. A console is used to control the supply of gas to the cryoprobe.	The system consists of cryoprobes that are used for freezing target tissue. A console is used to control the supply of gas to the cryoprobe.
Energy Used	Nitrous Oxide	Nitrous Oxide
Operating Temperature	-50°C to 70°C	-50°C to 70°C
Human Factors	Hand-held device containing cryogen with activation button on console or footswitch.	Hand-held device containing cryogen with activation button on console or footswitch.
Cryotip	<p>Material: aluminum alloy</p> <p>Construction: smooth malleable cylindrical linear probe</p> <p>Diameter: 4 mm</p> <p>Length: 10cm</p>	<p>Material: aluminum alloy</p> <p>Construction: smooth spherical ball welded to a malleable cylindrical aluminum shaft.</p> <p>Diameter: ball - 8mm; aluminum shaft – 5mm</p> <p>Length: reference the "end-effector" length</p>
End-effector Length – Shaft and Cryotip	28 cm	28cm (CRYOS) 46cm (CRYOS-L)
Biocompatibility	Biocompatible patient contacting materials.	Biocompatible patient contacting materials.
Probe Packaging	Sterile – Single Use disposable device	Sterile – Single Use disposable device
Sterilization	Gamma Irradiation	Gamma Irradiation
Power Source	Mains Powered	Mains Powered

VII. Performance Data

Clinical Evidence

AtriCure partnered with UCSF Stanford Pediatric Device Consortium (PDC) to evaluate Clinical Evidence in support of the cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) Indication for Use. The clinical evidence, including clinical publications demonstrated that use of the cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) in intercostal nerve ablation for temporarily pain block was as safe and effective when used in patients aged ≥ 12 years as compared to use of the cryoICE cryoablation probes (Cryo2, CryoS and CryoS-L) for equivalent procedures in adults, based on the following endpoints:

- Intraoperative or post-operative complications for patients receiving cryoanalgesia during Nuss procedure
- Adverse events observed for patients receiving cryoanalgesia
- Cryoablation associated numbness
- Neuropathic pain
- Chest wall numbness
- Post-operative pneumothorax

VIII. Conclusions

The Clinical Evidence reviewed in the 510(k) submission demonstrates that AtriCure's cryoICE cryoablation probes (Cryo2, CryoS, CryoS-L), as labeled per the Indication for Use do not present any new or additional questions of safety and effectiveness.