Summary of Safety and Clinical Performance (SSCP)

AtriCure EPi-Sense Coagulation System

05 May 2023

CEM-265 Revision D

OVERVIEW

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions for Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

INFORMATION INTENDED FOR USERS/ HEALTHCARE PROFESSIONALS:

1. Device identification and general information

Product name	EPi-Sense® Coagulation Device (product code CDK-1413) EPi-Sense ST™ Coagulation Device (product code EPiST): Cannula with Guide (product code CSK-6131)
Product group/family Basic UDI-DI	EPi-Sense Coagulation Device (CDK-1413): 084014390000000000000010ZC EPi-Sense ST Coagulation Device (EPiST): 084014390000000000000010ZC Cannula with Guide (CSK-6131): 084014390000000000000012ZG
Manufacturer legal name, address, and Single Registration Number (SRN)	AtriCure 7555 Innovation Way Mason, OH 45040 USA SRN: US-MF-000002974
EU Authorised Representative name, address, and Single Registration Number (SRN)	AtriCure Europe B.V. De entree 260 1101 EE Amsterdam NL SRN: NL-AR-000000165
European Medical Device Nomenclature (EMDN) code and description	EPi-Sense Coagulation Device: C020301 – Cardiac Tissue Ablation Electrocatheters, Radiofrequency EPi-Sense ST Coagulation Device: C020301 – Cardiac Tissue Ablation Electrocatheters, Radiofrequency Cannula with Guide: V9012 – Surgical Instruments, Not Specialist Surgery, Single-Use
Product classification and rule (per MDR)	EPi-Sense Coagulation Device: Class III, Rule 7 EPi-Sense ST Coagulation Device: Class III, Rule 7 Cannula with Guide: Class III, Rule 7
Year when the first certificate (CE) was issued covering the device	EPi-Sense Coagulation Device: 2011 EPi-Sense ST Coagulation Device: Under review for initial CE marking Cannula with Guide: 2006

Notified Body name, address, and number	BSI Say Building John M. Keynesplein 9 1066 EP Amsterdam NL +31 20 346 0780 CE 2797

2. Intended use of the device

2.1 Intended Purpose

EPi-Sense Coagulation Device: The EPi-Sense Coagulation Device is intended for the ablation of cardiac tissue using radiofrequency (RF) energy.

EPi-Sense ST Coagulation Device: The EPi-Sense ST Coagulation Device is intended for the ablation of cardiac tissue using radiofrequency (RF) energy.

Cannula with Guide: The Cannula with Guide is intended for endoscopic use to provide cardiothoracic surgical access.

2.2 Indication(s) and target populations

EPi-Sense Coagulation Device:

- Indication: Epicardial treatment of atrial fibrillation, including when augmented with an endocardial ablation, with the aim to restore normal sinus rhythm (i.e., freedom from AF/AFL/AT), reduce AF symptoms, and improve quality of life.
- Target Population: Patients with arrhythmias including atrial fibrillation

EPi-Sense ST Coagulation Device:

- Indication: Epicardial treatment of atrial fibrillation, including when augmented with an endocardial ablation, with the aim to restore normal sinus rhythm (i.e., freedom from AF/AFL/AT), reduce AF symptoms, and improve quality of life.
- Target Population: Patients with arrhythmias including atrial fibrillation

Cannula with Guide:

- Indication: Endoscopic use to provide cardiothoracic surgical access during minimally invasive procedures for the treatment of arrhythmia.
- Target population: Patients who are undergoing epicardial ablation for the treatment of arrhythmia.

2.3 Contraindications and/or Limitations

EPi-Sense and EPi-Sense ST Coagulation Devices: Patients with presence of left atrial thrombus, a systemic infection, active endocarditis, or another infection local to the surgical site at the time of surgery. Patients with Barrett's Esophagitis.

Cannula with Guide: There are no known contraindications.

3. Device description

3.1 Description of the device

EPi-Sense Coagulation Device and EPi-Sense ST Coagulation Device

The EPi-Sense Coagulation Device (**Figure 1**) and EPi-Sense ST Coagulation Device (**Figure 2**) are sterile, single-use coagulation probes with electrodes at the distal end. The probes have a flexible, multi-lumen silicone shaft that provides separate paths for vacuum, perfusion, and a guidewire. The handles at the proximal end of the probes incorporate a connector for the compatible AtriCure RF generator, a port for connection to a commercially available vacuum pump, a connection for saline for perfusion, and a port for a guidewire to exit.

The probes integrate a 3 cm coagulation electrode and sensing electrodes at the distal end. A flexible, multi-lumen shaft provides a path for vacuum (suction), saline perfusion, and a guidewire. Once the probe is inserted and placed on the epicardial surface of the heart, vacuum is applied, and suction at the distal end of the probe brings the tissue into direct engagement with the coagulation electrode. When connected, a compatible AtriCure RF generator transmits energy to the coagulation device and into the contacted tissue, causing necrosis and creating lesions originating on the epicardium. Throughout the process, saline is perfused through the probe when the vacuum is applied and the saline stopcock provided with the device is open.

The EPi-Sense Coagulation Device is gamma sterilised, and the EPi-Sense ST is sterilised using ethylene oxide. These devices are not made with natural rubber latex or polyvinyl chloride (PVC). They do not contain phthalates. They are not made with animal tissue-derived materials. These devices include stainless steel, which contains nickel and cobalt. Nickel is a known allergen, and cobalt is registered in the European Union as a CMR[i] substance of concern. The Coagulation Devices contain small amounts of nickel and cobalt; thus, the devices should not be used if the patient has sensitivity to nickel or cobalt, as this may result in an adverse patient reaction.

Figure 1: EPi-Sense Coagulation Device

Figure 2: EPi-Sense ST Coagulation Device

[i] *CMR refers to Carcinogenic, Mutagenic, or Toxic for Reproduction*.

Cannula with Guide

The Cannula is a sterile, single-use access tool used to introduce the EPi-Sense or EPi-Sense ST Coagulation Device into the chest cavity. The Cannula is 30 cm long with a large, central, flexible lumen to accommodate both the probe and a commercially available endoscope for visualization. Access to the pericardial space and the epicardial surface of the heart is accomplished using standard surgical techniques such as a sub-xiphoid approach.

The Cannula (**Figure 3**) is comprised of a distal tip, a shaft with a textured grip at the proximal end, a vacuum line, and an integrated guidewire.

The Cannula incorporates a vacuum port at the proximal end that attaches to a commercially available vacuum pump. Suction is used to remove fluids for better visualization in the pericardial space. The device also incorporates an integrated guidewire. The Coagulation Devices can be placed over the guidewire through the Cannula.

The Cannula is gamma sterilised. The Cannula is not made with natural rubber latex and does not contain PVC or phthalates. It does not contain animal-derived tissues. The Cannula includes Nitinol and thus contains nickel, which is an allergen. The Cannula contains small amounts of nickel and thus should not be used if the patient has sensitivity to nickel, as this may result in an adverse patient reaction.

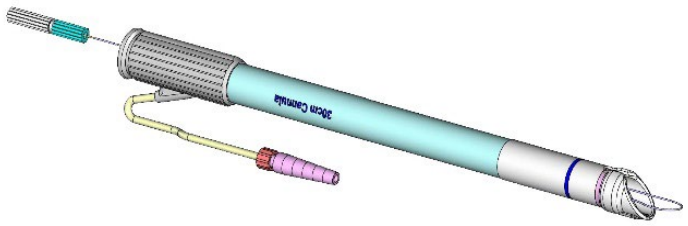

Figure 3: Cannula with Guide

Principles of Operation

The EPi-Sense Coagulation System utilizes the well-established technologies of RF coagulation, suction, and perfusion.

The Cannula is an access tool to insert the probe into the patient's chest cavity. The coagulation probe and a commercially available endoscope are inserted through the main lumen of the Cannula. The probe may also be inserted directly through the lumen or over the incorporated guide wire which is then fed back through the lumen. A vacuum line in the Cannula provides for fluid removal using suction.

The coagulation probe is inserted into a body cavity under visualization using endoscopic surgical techniques. The distal end of the probe is placed in contact with the epicardial surface of the heart.

Vacuum is applied through the probe during coagulation to ensure solid tissue engagement

for consistent lesions. As vacuum is applied via the vacuum lumen of the probe, tissue is brought into direct engagement with the coil electrode.

RF energy from the generator is transmitted to the coil electrode of the ablation probe. The application of RF energy into the tissue causes coagulation necrosis and creates lesions on the epicardial surface of the heart.

Throughout the coagulation process, saline is perfused through the probe. Applied vacuum pulls saline through the probe. During coagulation, the saline cools the non-tissue-contacting surface of the coagulation device and inhibits excessive heating at the probe and tissue interface.

3.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

EPi-Sense Coagulation Device (CDK-1413)[ii]

- Change of sterile barrier packaging to tray within a pouch
- Extension of shelf life from 1 to 3 years
- Interface increased between PEEK tubing and molded plug for guidewire (distal end)
- Addition of 6 visual dots on external device shaft due to market feedback
- Addition of polycarbonate Tuohy borst valve due to market feedback

EPi-Sense ST Coagulation Device (EPiST)[iii]

- Shaft length increased for ease of use
- Addition of thermistor, temperature control circuit board, and LED light to alert user to suboptimal device perfusion
- Addition of distal tip bidirectional deflection due to market feedback
- Addition of deflection and locking capability to handle due to market feedback
- Distal tip changed to anchor bidirectional deflection capability
- New RF cable to accommodate battery for temperature control circuit and LED light
- Change to main body tubing to accommodate thermistor wires
- Addition of grey polyolefin over-jacket to maintain rigidity of additional length
- Addition of 5 additional reference dots due to market feedback
- Change to ethylene oxide sterilization due to added components for thermistor functionality

[ii] The listed changes have been introduced to CDK-1413 since its introduction to market, with no change to the product code.
[iii] The listed changes appear in EPiST and reflect changes from its predicate device, CDK-1413.

Cannula with Guide (CSK-6131)[iv]

- Shortening the shaft and internal spring to prevent user damage to spring and encapsulant during use with endoscope
- Lengthening the molded tip to maintain device length
- Additional lumens in the molded tip to add Nitinol (NiTi) wires with polyimide tubes
- Shortening of the stainless steel distal wire

3.3 Description of any accessories which are intended to be used in combination with the device

For use with the EPi-Sense Coagulation Device:

Required

- CSK-2000 (Basic UDI-DI: 08401439000000000000011ZE) is a required accessory for use with the EPi-Sense Coagulation Device. CSK-2000 is a sterile, single-use radiofrequency cable manufactured by AtriCure, Inc., which is required to transmit RF energy from the compatible AtriCure RF Generator to the attached EPi-Sense Coagulation Device.

Recommended/Optional

- The External Graphics Display Software (LPK-302; Basic UDI-DI: 08401439000000000000009ZT) is an optional accessory manufactured by AtriCure, Inc., which is intended to be used in conjunction with the CSK-310 AtriCure RF Generator System and the Coagulation Device to display the energy delivered during each ablation.

For use with the EPi-Sense ST Coagulation Device:

Required

- CSK-2060 (Basic UDI-DI: 08401439000000000000011ZE) is a required accessory for use with the EPi-Sense ST Coagulation Device. CSK-2060 is a sterile, single-use radiofrequency cable manufactured by AtriCure, Inc., which is required to transmit RF energy from the compatible AtriCure RF Generator to the attached EPi-Sense ST Coagulation Device.

Recommended/Optional

- The External Graphics Display Software (LPK-302; Basic UDI-DI: 08401439000000000000009ZT) is an optional accessory manufactured by AtriCure, Inc., which is intended to be used in conjunction with the CSK-310 AtriCure RF Generator System and the Coagulation Device to display the energy delivered during each ablation.

For use with the Cannula with Guide:

Required

- None; refer to Section 3.4.

Recommended/Optional

[iv] The listed changes indicate design changes in CSK-6130, which is now given the product code CSK-6131 under EU MDR.

- None; refer to Section 3.4.

3.4 Description of any other devices and products which are intended to be used in combination with the device

For use with the EPi-Sense Coagulation Device:

Required

- Compatible AtriCure RF Generator System[v] (CSK-310; Basic UDI-DI: 08401439000000000000008ZR), Non-Sterile, Reusable
- Indifferent Patient Return Electrode (Ground Pad) – surface area of 21 square inches (136 cm^2) minimum
- CSK-6131 – Cannula with Guide – Sterile, Single Use
- 0.9% Normal Saline Solution (250 mL bag recommended)
- Sterile Perfusion/IV Tubing Set (10 Drops/mL)
- Sterile Vacuum Tubing Set
- Vacuum regulated to -400 mmHg (-7.7 psi; -53 kPa)

Recommended/Optional

- 0.035 in (0.89 mm) x 39.4 in (100 cm) “J” Guide Wire
- Sterile Water (For cannula flooding only)
- Endoscope - see Cannula IFU scope recommendations
- Temporary external electrogram recording device that meets the following specifications: Complies with IEC 60601-1 and system accepts shielded 2mm (0.08 in) pin connectors

For use with the EPi-Sense ST Coagulation Device:

Required

- Compatible AtriCure RF Generator System (CSK-310; Basic UDI-DI: 08401439000000000000008ZR), Non-Sterile, Reusable
- Indifferent Patient Return Electrode (Ground Pad) – surface area of 21 square inches (136 cm^2) minimum
- CSK-6131 – Cannula with Guide – Sterile, Single Use
- 0.9% Normal Room Temperature Saline Solution (250 mL bag recommended)
- Sterile Perfusion/IV Tubing Set (10 Drops/mL)
- Sterile Vacuum Tubing Set
- Vacuum regulated to -400 mmHg (-7.7 psi; -53 kPa)

[v] A pneumatic footswitch and the CSK-2030 non-sterile, reusable sensing cable are optional components included with the CSK-310 RF Generator System.

Recommended/Optional

- 0.035 in (0.89 mm) x 39.4 in (100 cm) Guide Wire
- 5 mm (0.2 in) Endoscope
- Temporary external electrogram recording device that meets the following specifications: Complies with IEC 60601-1 and system accepts shielded 2mm (0.08 in) pin connectors

For use with the Cannula with Guide:

Required

- Vacuum Tubing Set (Sterile)
- Vacuum regulated at -250 mmHg (-4.8 psi, -33 kPa)

Recommended/Optional

- 35 or 45 cm (13.8 or 17.7 in) long, 5 or 10 mm (0.2 or 0.4 in) diameter Scope, depending on Cannula use
- 1000 mL 0.9% Normal Saline or Sterile Water
- Coagulation Device – Refer to Instructions for Use for the Coagulation Device when being used with the Cannula with Guide.

4. Risks and warnings

4.1 Residual risks and undesirable effects

Coagulation Devices (CDK-1413 and EPiST)	
Potential complications	**Probability of occurrence – 30 days**
Infection	<0.1%, less than 1 in 1,000 patients[a]
Cardiac tamponade/perforation	3.9%[b]
Pulmonary vein stenosis	<0.1%, less than 1 in 1,000 patients[a,c]
Vessel injury	<0.1%, less than 1 in 1,000 patients[a]
Pericardial effusion	3.9%[b]
Tissue perforation	<0.1%, less than 1 in 1,000 patients[a,c]
Excessive bleeding	1%[d]
Phrenic nerve injury	1%[e]
Left atrial rupture/perforation	<0.1%, less than 1 in 1,000 patients[a]
Mediastinitis	<0.1%, less than 1 in 1,000 patients[a]
Pulmonary edema	<0.1%, less than 1 in 1,000 patients[a]
Vascular access complication	0.2-1.5%[f]
Stroke/TIA	2%[g]
Incisional herniation	1.5%[h]
Esophageal injury	<0.1%, less than 1 in 1,000 patients[a]
Pleural effusion	<0.1%, less than 1 in 1,000 patients[a]
Atrio-Esophageal fistula	<0.1%, less than 1 in 1,000 patients[a,c]
Cardiac arrest/Myocardial infarction	0%[c]
New arrhythmias	<0.1%, less than 1 in 1,000 patients[a]
Thromboembolic complication	2%[g]
Neurologic complication	2%[g]
Death	<0.1%, less than 1 in 1,000 patients[a,c,i]

Complete heart block requiring pacemaker implantation	<0.1%, less than 1 in 1,000 patients[a]
Pericarditis	0.3%[j]
Serious skin burn	<0.1%, less than 1 in 1,000 patients[a]
Transdiaphragmatic herniation	1.5%[h]
Damage (e.g., burn, puncture) to other adjacent structures	<0.1%, less than 1 in 1,000 patients[a]

[a] Estimated rate based on complaints/commercial rate. These data may be underreported.
[b] Occurrence rate of pericardial effusions with tamponade physiology from CONVERGE trial: 3.9% (4/102).
[c] Occurrence rate from CONVERGE clinical trial: 0%.
[d] Occurrence rate from CONVERGE clinical trial: 1% (n=1/102); one additional patient had excessive bleeding with late pericardial effusion and is included in the pericardial effusion event rate.
[e] Occurrence rate of phrenic nerve injury from CONVERGE trial: 1% (n=1/102).
[f] Estimated rate from 2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation (Calkins et al. 2017. Heart Rhythm. 14(10), e275-e444).
[g] Occurrence rate from CONVERGE clinical trial: 1% (n=1/102) stroke; 1% (n=1/102) transient ischemic attack.
[h] Based on systematic literature review results for Cannula used with EPi-Sense Coagulation System. The incidence of incisional hernias has been associated with trans-diaphragmatic pericardial access; sub-xiphoid access is more commonly used in contemporary best practice.
[i] Deaths reported as complaints were not related to device malfunction or attributable to the use of the device.
[j] Based on systematic literature review results for EPi-Sense Coagulation System.

Note: EPi-Sense was used commercially and in the CONVERGE trial. It is considered equivalent to the EPi-Sense ST.

Cannula with Guide (CSK-6131)	
Potential complications	**Probability of occurrence – 30 days**
Blunt trauma to adjacent organs	<1%[a]
Infection	<0.1%, less than 1 in 1,000 patients[b]
Pericardial effusion	3.9%[c]
Vessel injury	<0.1%, less than 1 in 1,000 patients[a]
Tissue perforation	0.2%[a]
Hemodynamic instabilities	<0.1%, less than 1 in 1,000 patients[b]
Arrhythmias	<0.1%, less than 1 in 1,000 patients[b]
Thromboembolic complication	2%[d]
Hernia	1.5%[a,e]
Pneumothorax	<0.1%, less than 1 in 1,000 patients[f]
Conversion to Sternotomy	<0.1%, less than 1 in 1,000 patients[b]

[a] Based on systematic literature review results for Cannula used with EPi-Sense Coagulation System.
[b] Estimated rate based on complaints/commercial rate. These data may be underreported.
[c] Occurrence rate of pericardial effusions with tamponade physiology from CONVERGE trial: 3.9% (4/102).
[d] Occurrence rate from CONVERGE clinical trial: 1% (n=1/102) stroke; 1% (n=1/102) transient ischemic attack

[e] The incidence of incisional hernias has been associated with trans-diaphragmatic pericardial access; sub-xiphoid access is more commonly used in contemporary best practice.
[f] Pneumothorax not reported in post-market surveillance data, CONVERGE trial, or literature but remains a potential risk.

4.2 Warnings and precautions

EPi-Sense Coagulation Device

Warnings

- Care should be taken to ensure that the device is not in contact with tissue that is not going to be coagulated (e.g. vascular and nerve tissue), in order to avoid inadvertent tissue damage.
- To avoid unintentional coagulation, always ensure the device or device combined with optional guidewire is oriented toward the desired coagulation location.
- Avoid contact with other surgical instruments, scopes, staples, or other objects while coagulating. Inadvertent contact with objects while coagulating could lead to conduction of RF energy or heat and unintentional coagulation of tissues in contact with those objects.
- The device is provided sterile and is intended for single patient use only. Do not reprocess or reuse. Reuse can cause damage to device, patient injury, and/or the communication of infectious disease(s) from one patient to another.
- Do not scrape or scratch off the gold surface of the sensing electrodes when cleaning the RF coagulation electrode to avoid an adverse reaction due to copper exposure to the patient.
- Inspect all devices and packaging prior to use. If any breach of the packaging is found the sterility of the product cannot be ensured which poses a risk of patient injury. Do not use product if breach is found.
- The risk of igniting flammable gases or other materials is inherent in the application of RF energy. Precautions must be taken to restrict flammable materials from the area where tissue coagulation is performed.
- Care should be taken to ensure device is not moved during RF power delivery. Device movement may cause loss of suction and tissue tear and/or unintentional ablation.
- Care should be taken to ensure no vessels (or other structures) are restricted during device manipulation. Vessel restriction could cause hemodynamic instabilities or patient harm.
- Care should be taken to confirm device placement before power application to avoid collateral tissue damage.
- Care should be taken to fill distal end of cannula within the pericardial space with room temperature saline during ablation to avoid collateral tissue damage.
- Care should be taken to ensure device is perfused during ablation to avoid unintentional tissue damage.
- Physicians should implement a comprehensive anti-coagulation protocol including pre-operative, intra-operative and post-operative anti-coagulation management to prevent potential thromboemboli.

- Physicians should use esophageal temperature monitoring as was conducted during the clinical investigation of the device to monitor for potential collateral tissue damage. Throughout the procedure ensure the probe is located directly behind the ablation probe to ensure an accurate reading.
- Physicians should consider post-operative anti-inflammatory medication to decrease the potential for post-operative pericarditis and/or delayed post-procedure inflammatory pericardial effusions.
- The coagulation device utilizes preset power and time settings; adjustment of these settings may result in excess or inadequate energy transmission.
- Physicians should consider post-operative proton pump inhibitors (PPIs) to decrease the potential for post-operative esophageal irritations.
- When inserting or retracting cannula from body, ablation device and standard 0.035 in (0.89 mm) guidewire should NOT be extended beyond tip of cannula.
- Excessive flexing and/or improper manipulation of the EPi-Sense with surgical tools can result in damage to the device.
- Ensure overlapping structures are separated and thermally isolated when anatomy allows. If the overlapping structures cannot be separated, ablation should not be performed.
- Reuse of the ground pad utilized in the epicardial portion of the procedure for the endocardial portion may result in patient harm.
- Simultaneous epicardial and endocardial mapping or ablation may result in cardiac injury.
- To avoid patient harm, care should be taken to assure the ablation electrode is oriented towards the heart and away from the pericardium using visual cues, i.e. Reference Dots, Locator Arrows, and black stripe.
- The coil on the distal end of the device must be kept clean of coagulum during surgery to avoid loss of power. Do not clean coagulum off the electrode of the device with an abrasive cleaner or electrosurgical tip cleaner. The electrodes could be damaged resulting in device failure.
- Implantable cardioverter/defibrillators can be adversely affected by RF signals.
- The use and proper placement of an Indifferent Electrode is a key element in the safe and effective use of electrosurgery, particularly in the prevention of patient burns. Ensure entire area of electrode is reliably attached to the patient’s body.
- While the distal portion of the device is designed to be malleable to conform to the anatomy of the area to be ablated, excessive manipulation, torquing, rough shaping, or forcing the movement of the device may damage or deform the distal end and cause potential patient harm. This may also cause the sensing electrodes to become detached and or break off the device.
- Care should be taken when handling the distal end of the device near the electrode with surgical instruments to prevent fragments from breaking off of the device – do not squeeze or clamp the electrode. Do not cut or tear silicone.
- The coagulation device is only suitable for use with the compatible AtriCure RF generator, cables, and accessories. Use of another manufacturer’s accessories may cause damage to the device and/or injury to the patient.

- Care should be taken to ensure the path to position the device is large enough to advance the device easily – forcing the device may damage the device, cause tissue damage or patient harm.
- Care should be taken to ensure device is not twisted or over manipulated during procedure. Twisting/torquing/over manipulating device can cause damage to the device, the lumen to collapse, fracture of electrodes or vacuum lumen spring, separation of electrodes from device, kinking of PEEK guide tube, loss of suction, disconnection of perfusion/IV tubing, kinked perfusion/IV tubing, or patient harm.
- Connection of multiple devices to one vacuum unit may reduce vacuum functionality.
- Care should be taken to ensure optional guidewire stays in the sterile field during manipulation to prevent infection.
- Care should be taken to visualize the devices and/or guidewire components when in the body, during introduction and/or removal from the Cannula. Always fully retract devices and components prior to insertion and removal in order to avoid inadvertent tissue damage with the devices and or guidewire.
- Before ablation of tissue, ensure guidewire and/or scope are not between tissue and coagulation device electrode to avoid ablation of unintended tissue.
- If a guidewire is used with coagulation device, ensure that insulative covering is intact along the exposed Guidewire to prevent ablation of unintended tissue.
- The coagulation devices should be used by physicians trained in the techniques of minimally invasive endoscopic surgical procedures and in the specific approach to be used to prevent patient harm.
- If using a TEE probe, care should be taken to withdraw the TEE probe prior to ablation to avoid compressing the esophagus against the left atrium during ablation.
- If the coagulation device is used near a pacemaker/AICD, a potential hazard exists due to possible interference with the action of the pacemaker and potential damage to the pacemaker. Consider placing a magnet on the pacemaker/AICD or programming the pacemaker/AICD per the manufacturer's instructions for use before applying RF energy.
- Physicians should obtain post-procedural imaging (i.e. 1-3 weeks post-procedure) for detection of post-procedure inflammatory pericardial effusions.
- This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- Additional warnings and precautions can be found in the compatible AtriCure RF Generator Operators Manual. Failure to follow the instructions contained in the RF generator manual may lead to an inability to complete the procedure.
- Using excess force to remove the device from the tray may result in damage to the device.
- Do not set vacuum to pressures outside of -375 to -425 mmHg (-7.25 to -8.22 psi; -50.0 to -56.7 kPa) - deviating from this pressure range may reduce suction capabilities, reduce tissue contact, or cause tissue damage
- Verify that IV line is fully open. Do not pressurize saline bag; that is, do not use an infusion pump for delivery or a pressure bag. Pressurizing saline or partially open

perfusion tubing can vary perfusion rate causing loss of suction and the coagulation dimensions to vary from values listed, and cause tissue perforations from excess heating.

- Ensure device is primed prior to first RF power delivery to prevent unintended tissue damage.
- Use ONLY 0.9% normal saline to prevent unintended tissue damage.
- Ensure perfusion/IV tubing is connected to the handle at the “droplet” symbol to avoid unintended tissue damage – do not connect perfusion tubing to stopcock or “Guide Wire Exit”.
- Ensure arrows on cable and handle are aligned and cable is completely connected. Device will not register on generator if cable is incorrectly connected.
- Ensure inputs from the ECG recorder are isolated from earth ground, if not, there is an increased possibility of fibrillation.
- Esophageal temperature monitoring should be utilized during epicardial and endocardial ablation to prevent damage to the esophagus. If esophageal temperature increases more than 0.5 ºC (0.9 ºF) during each ablation or above an absolute maximum of 38.0 ºC (100.4 ºF), RF energy should be terminated until temperature reduces to baseline or under 37 ºC (98.6 ºF).
- Care should be taken to ensure lesions overlap in order to achieve exit block.
- Ensure that fluid in pericardial space is aspirated during manipulation. Failure to do so may compromise visibility and device placement, leading to patient harm.
- The EPi-Sense Coagulation Device has a limited functional life; if greater than 30 ablation cycles are completed and additional ablations cannot be performed, replace device.
- Ensure device is disposed of following local governing ordinances and recycling plans to prevent biohazard exposure.
- To avoid interruption of vacuum or perfusion flow, do not leave device tubing clamped during coagulation of tissue.
- Large blood clots and tissue particles may clog vacuum lumen and impair suction.
- To avoid tissue or device damage: Do not move the device if vacuum is engaged.
- Do not torque coagulation device if distal end is curved as damage to device may occur and the electrodes may separate and/or break off from the device.
- Visualize the distal end of the device, to ensure it is not pinching/entrapping tissue with other devices, such as the Cannula.
- Care should be taken when handling the distal end of the device near the electrode with surgical instruments – do not squeeze or clamp the electrode. Do not use tools on the electrode coil, place tools on silicone only as the electrodes may separate and/or break off from the device.
- Temporarily unused active electrodes should be stored in a location isolated from the patient. Failure to do so may lead to patient burns

Cautions

- Interference produced by the operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems. Rearrange monitoring device cables so they do not overlap the Coagulation System cables.
- Coagulation devices have pre-set power and time settings for optimal ablation. Changing these settings may cause ablation dimension to vary from the values given in this document.
- Precautionary measures should be taken prior to considering treatment of patients:
  - Deemed to be high risk and who may not tolerate a potential delayed post-procedure inflammatory pericardial effusion.
  - Who may not be compliant with needed follow-ups to identify potential safety risks.
- To ensure patients undergoing treatment with the EPi-Sense device are well informed, the benefits, potential risks and procedural outcomes associated with the EPi-Sense Hybrid Convergent procedure should be discussed with the patient. Physicians should document accordingly in the medical record.
- Qualified operators are physicians authorized by their institution to perform surgical subxiphoid pericardial access.
- Operators should complete training on the use of EPi-Sense device before performing the procedure.
- Safety and effectiveness of concomitant left atrial appendage closure was not evaluated in the CONVERGE study.
- Cables to surgical electrodes should be positioned to prevent contact with patient or other leads
- Positioning and manipulation of the coagulation device without a guide wire inserted into the guide tube may cause the guide tube to kink. Avoid inserting guidewire into kinked guide tube.
- Ensure device is properly connected – switching connections may cause inadequate tissue contact and reduced functionality.

EPi-Sense ST Coagulation Device

Warnings

- Physicians should consider post-operative anti-inflammatory medication to decrease the potential for post-operative pericarditis and/or delayed post-procedure inflammatory pericardial effusions.
- Physicians should obtain post-procedural imaging (i.e. 1-3 weeks post-procedure) for detection of post-procedure inflammatory pericardial effusions.
- The coagulation device utilizes preset power and time settings; adjustment of these settings may result in excess or inadequate energy transmission.
- Physicians should consider post-operative proton pump inhibitors (PPIs) to decrease the potential for post-operative esophageal irritations.
- The EPi-Sense ST Coagulation Device should only be used under direct visualization.

Care should be taken to visualize the devices and/or guidewire components when in the body, during introduction and/or removal from the Cannula. Always fully retract devices and components prior to insertion and removal in order to avoid inadvertent tissue damage with the devices and or guidewire.

- When inserting or retracting Cannula from body, ablation device and standard 0.035 in (0.89 mm) guidewire should NOT be extended beyond tip of Cannula.
- Care should be taken to ensure the path to position the device is large enough to advance the device easily – forcing the device may damage the device, cause tissue damage or patient harm.
- Excessive flexing and/or improper manipulation of the EPi-Sense ST Coagulation Device with surgical tools can result in damage to the device.
- Care should be taken to ensure that the device is not in contact with tissue that is not going to be ablated (e.g. vascular and nerve tissue), in order to avoid inadvertent tissue damage.
- To avoid unintentional ablation, always ensure the device or device combined with optional guidewire is oriented toward the desired ablation location.
- Avoid contact with other surgical instruments, scopes, staples, or other objects while coagulating. Inadvertent contact with objects while coagulating could lead to conduction of RF energy or heat and unintentional ablation of tissues in contact with those objects.
- The device is provided sterile and is intended for single patient use only. Do not reprocess or reuse. Reuse can cause damage to device, patient injury, and/or the communication of infectious disease(s) from one patient to another.
- Do not scrape or scratch off the gold surface of the sensing electrodes when cleaning the RF ablation electrode to avoid an adverse reaction due to copper exposure to the patient.
- Inspect all devices and packaging prior to use. If any breach of the packaging is found the sterility of the product cannot be ensured which poses a risk of patient injury. Do not use product if breach is found.
- The risk of igniting flammable gases or other materials is inherent in the application of RF energy. Precautions must be taken to restrict flammable materials from the area where tissue ablation is performed.
- Care should be taken to ensure device is not moved during RF power delivery. Device movement may cause loss of suction and tissue tear and/or unintentional ablation.
- Ensure overlapping structures are separated and thermally isolated when anatomy allows. If the overlapping structures cannot be separated and thermally isolated, ablation should not be performed.
- Care should be taken to ensure no vessels (or other structures) are restricted during device manipulation. Vessel restriction could cause hemodynamic instabilities or patient harm.
- Care should be taken to confirm device placement before power application to avoid collateral tissue damage.
- Physicians should implement a comprehensive anti-coagulation protocol including pre-operative, intra-operative and post-operative anticoagulation management to prevent

potential thromboemboli.

- Physicians should use esophageal temperature monitoring as was conducted during the clinical investigation of the device to monitor for potential collateral tissue damage. Throughout the procedure ensure the probe is located directly behind the ablation probe to ensure an accurate reading.
- Reuse of the ground pad utilized in the epicardial portion of the procedure for the endocardial portion may result in patient harm.
- Simultaneous epicardial and endocardial mapping or ablation may result in cardiac injury.
- The coil on the distal end of the device must be kept clean of coagulum during surgery to avoid loss of power. Do not clean coagulum off the electrode of the device with an abrasive cleaner or electrosurgical tip cleaner. The electrodes could be damaged resulting in device failure.
- Implantable cardioverter/defibrillators can be adversely affected by RF signals.
- The use and proper placement of an Indifferent Electrode a key element in the safe and effective use of electrosurgery, particularly in the prevention of patient burns. Ensure entire area of electrode is reliably attached to the patient's body.
- While the distal portion of the device is designed to conform to the anatomy of the area to be ablated, excessive manipulation, torquing, rough shaping, or forcing the movement of the device may damage or deform the distal end and cause potential patient harm. This may also cause the sensing electrodes to become detached and or break off the device.
- Care should be taken when handling the distal end of the device near the electrode with surgical instruments to prevent fragments from breaking off of the device – do not squeeze or clamp the electrode. Do not cut or tear silicone.
- The coagulation device is only suitable for use with the compatible AtriCure RF generator, cables, and accessories. Use of another manufacturer's accessories may cause damage to the device and/or injury to the patient.
- Care should be taken to ensure device is not twisted or over manipulated during procedure. Twisting/torquing/over manipulating device can cause damage to the device, the lumen to collapse, fracture of electrodes or vacuum lumen spring, separation of electrodes from device, kinking of PEEK guide tube, loss of suction, disconnection of perfusion/IV tubing, kinked perfusion/IV tubing, or patient harm.
- To avoid patient harm, care should be taken to assure the ablation electrode is oriented towards the heart and away from the pericardium using visual cues, i.e., Reference Dots, Locator Arrows, and white stripe.
- Connection of multiple devices to one vacuum unit may reduce vacuum functionality.
- Care should be taken to ensure optional guidewire stays in the sterile field during manipulation to prevent infection.
- Before ablation of tissue, ensure guidewire and/or scope are not between tissue and ablation device electrode to avoid ablation of unintended tissue.
- If a guidewire is used with coagulation device, ensure that insulative covering is intact along the exposed guidewire to prevent ablation of unintended tissue.

- The coagulation device should be used by physicians trained in the techniques of minimally invasive endoscopic surgical procedures and in the specific approach to be used to prevent patient harm.
- If using a TEE probe, care should be taken to withdraw the TEE probe prior to ablation to avoid compressing the esophagus against the left atrium during ablation.
- If the coagulation device is used near a pacemaker/AICD, a potential hazard exists due to possible interference with the action of the pacemaker and potential damage to the pacemaker. Consider placing a magnet on the pacemaker/AICD or programming the pacemaker/AICD per the manufacturer's instructions for use before applying RF energy.
- Low battery will trigger the indicator light on the handle to Yellow and stop the application of RF energy. Reference troubleshooting table in IFU.
- High temperature of distal pod will trigger the indicator light on the handle to Red and stop the application of RF energy. Reference troubleshooting table in IFU.
- This device contains small amounts of Nickel (CAS# 7440-02-0) and Cobalt (CAS #7440-48-4). Do not use the device if the patient has sensitivity to Nickel or Cobalt as this may result in an adverse patient reaction.
- Additional warnings and precautions can be found in the compatible AtriCure RF Generator Operators Manual. Failure to follow the instructions contained in the RF generator manual may lead to an inability to complete the procedure.
- Using excess force to remove the device from the tray may result in damage to the device.
- Do not set vacuum to pressures outside of -375 to -425 mmHg (-7.25 to -8.22 psi; -50.0 to -56.7 kPa) – deviating from this pressure range may reduce suction capabilities, reduce tissue contact, or cause tissue damage.
- Verify that IV line is fully open. Do not pressurize saline bag; that is, do not use an infusion pump for delivery or a pressure bag. Pressurizing saline or partially open perfusion tubing can vary perfusion rate causing loss of suction and the ablation dimensions to vary from values listed, and cause tissue perforations from excess heating.
- Ensure perfusion/IV tubing is connected to perfusion tubing with luer connector (IRRIG) to avoid unintended tissue damage – do not connect perfusion tubing to stopcock or "Guidewire Port."
- Ensure arrows on cable and handle are aligned and cable is completely connected. Device will not register on generator if cable is incorrectly connected.
- Ensure inputs from the ECG recorder are isolated from earth ground, if not, there is an increased possibility of fibrillation.
- Ensure that fluid in pericardial space is aspirated during manipulation. Failure to do so may compromise visibility and device placement, leading to patient harm.
- The EPi-Sense ST Coagulation Device has a limited functional life; if greater than 30 ablation cycles are completed and additional ablations cannot be performed, replace device.
- Ensure device is disposed of following local governing ordinances and recycling plans to prevent biohazard exposure.

- To avoid interruption of vacuum or perfusion flow, do not leave device tubing clamped during coagulation of tissue.
- Large blood clots and tissue particles may clog vacuum lumen and impair suction.
- To avoid tissue or device damage: Do not move the device if vacuum is engaged.
- Do not torque coagulation device if distal end is deflected as damage to device may occur and the electrodes may separate and/or break off from the device.
- Visualize the distal end of the device, to ensure it is not pinching/entrapping tissue with other devices, such as the Cannula.
- Care should be taken when handling the distal end of the device near the electrode with surgical instruments – do not squeeze or clamp the electrode. Do not use tools on the electrode coil, place tools on silicone only as the electrodes may separate and/or break off from the device.
- Temporarily unused active electrodes should be stored in a location isolated from the patient. Failure to do so may lead to patient burns.
- Esophageal temperature monitoring should be utilized during epicardial and endocardial ablation to prevent damage to the esophagus. If esophageal temperature increases more than 0.5 ºC (0.9 ºF) during each ablation or above an absolute maximum of 38.0 ºC (100.4 ºF), RF energy should be terminated until temperature reduces to baseline or under 37 ºC (98.6 ºF).
- Care should be taken to ensure lesions overlap in order to achieve exit block.
- Esophageal temperature monitoring should be utilized during endocardial ablation to prevent damage to the esophagus. If esophageal temperature increases more than 0.5 ºC (0.9 ºF) during each ablation or above an absolute maximum of 38.0 ºC (100.4 ºF), RF energy should be terminated until temperature reduces to baseline or under 37 ºC (98.6 ºF).

Cautions

- Care should be taken to fill distal end of Cannula within the pericardial space with room temperature saline during ablation to avoid collateral tissue damage.
- Care should be taken to ensure device is perfused during ablation to avoid unintentional tissue damage.
- Precautionary measures should be taken prior to considering treatment of patients:
    - Deemed to be high risk and who may not tolerate a potential delayed post-procedure inflammatory pericardial effusion.
    - Who may not be compliant with needed follow-ups to identify potential safety risks.
- To ensure patients undergoing treatment with the EPi-Sense ST Coagulation Device are well informed, the benefits, potential risks and procedural outcomes associated with the EPi-Sense ST Coagulation Device Hybrid Convergent procedure should be discussed with the patient. Physicians should document accordingly in the medical record.
- Qualified operators are physicians authorized by their institution to perform surgical subxiphoid pericardial access.

- Operators should complete training on the use of EPi-Sense ST Coagulation Device before performing the procedure.
- Interference produced by the operation of high-frequency surgical equipment may adversely affect the operation of other electronic medical equipment such as monitors and imaging systems. Rearrange monitoring device cables so they do not overlap the Coagulation System cables.
- Coagulation devices have pre-set power and time settings for optimal ablation. Changing these settings may cause ablation dimension to vary from the values given in this document.
- Safety and effectiveness of concomitant left atrial appendage closure was not evaluated in the CONVERGE study.
- Ensure device is primed prior to first RF power delivery.
- Use ONLY 0.9% normal saline.
- Cables to surgical electrodes should be positioned to prevent contact with patient or other leads.
- Ensure device is properly connected – switching connections may cause inadequate tissue contact and reduced functionality.
- Positioning and manipulation of the coagulation device without a guide wire inserted into the guide tube may cause the guide tube to kink. Avoid inserting guidewire into a kinked guide tube.

Cannula with Guide

Warnings

- The Cannula is provided sterile and is intended for single use only. Do not reprocess or reuse. Reuse can cause patient injury and/or the communication of infectious disease(s) from one patient to another.
- Inspect the device packaging prior to use. If any breach of the packaging is found, the sterility of the product cannot be assured, and the product should not be used
- Inspect the Cannula and guidewire prior to use. Ensure Cannula distal end and guidewire are smooth with no sharp edges. Sharp edge can cause potential patient harm. If sharp edge is found, device should not be used.
- Care should be taken when inserting or removing the Cannula with Guide. Applying excess force could cause potential patient harm. To reduce friction during insertion, lubricate the Cannula with sterile saline.
- Care should be taken when manipulating the Cannula or guidewire. Always ensure no tissue is caught by the guidewire and brought into the Cannula with Guide lumen as this may cause altered hemodynamics or unintended tissue damage.
- Care should be taken when manipulating the guidewire, scope, and any over-the-wire devices. Excessive forces may damage the Cannula and/or guidewire or cause unintended tissue damage. The Cannula with Guide has a limited functional life; if greater than 18 bend cycles of the Cannula, guidewire, or scope are intended, it is recommended to monitor for damage. If damage is observed, replace the device.
- Avoid excessive pulling on the torquer. Excessive pulling on torquer may damage the

Cannula and/or guidewire or cause patient injury.

- This device contains small amounts of Nickel (CAS# 7440-02-0). Do not use the device if the patient has sensitivity to Nickel as this may result in an adverse patient reaction.
- When removing Cannula from packaging, care should be taken to ensure guidewire, Cannula cap, and stopcock remain inside sterile field to reduce risk of infection.
- Insertion or removal of the Cannula with Guide while guidewire is extended may cause potential patient harm. Always fully retract the guidewire into the Cannula with Guide lumen.
- Cannula cap and torquer should be removed prior to insertion and removal of any over-the-wire devices – failure to remove cap prior to insertion may result in damage to the Cannula cap and/or the over-the-wire devices preventing application of the intended therapy.
- Do not modify Cannula – modification could produce sharp edges resulting in unintended tissue damage.
- Care should be taken when handling surgical instruments near the distal end of the Cannula – do not clamp the distal end of the guidewire with surgical instruments or allow surgical instruments to stay outside the Cannula lumen during manipulation. Doing so may cut or break Cannula and cause tissue perforation or unintended damage.
- Ensure device is disposed of following local governing ordinances and recycling plans to prevent biohazard exposure.

Precautions

- Avoid over-rotating the Cannula with Guide. Over-rotation can cause the vacuum tubing of the Cannula to kink, reducing the Cannula suction, thus causing reduced visibility.
- Avoid over-inserting the Cannula with Guide into patient body. Over insertion may reduce Cannula suction.
- Inspect the device prior to use. If any damage is found, the function of the product cannot be assured, and the product should not be used.

Cautions

- Failure to place guidewire through hole in center of cap (puncturing cap or placing outside cap entirely) may reduce cap functionality.
- Failure to replace torquer exposes the sharp proximal end of the guidewire and may cause injury to patient and/or user.
- Ensure Cannula cap is fully attached to the Cannula grip – failure to fully attach cap my reduce functionality of the Cannula cap.
- Do not manipulate Cannula by grasping the tab of the Cannula cap. Doing so may loosen or remove Cannula cap from Cannula causing reduced functionality.
- Do not set vacuum pressure outside the range of -225 to -275 mmHg (-4.35 to -5.32 psi; -30.0 to -36.7 kPa).

- Large blood clots and tissue particles may clog vacuum lumen and impair suction to Cannula with Guide.
- To avoid interruption of vacuum or perfusion flow, ensure tubing is not clamped or kinked during coagulation of tissue.

4.3 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

The field action 3011706110-05.18.19-005-R was conducted. The sterile package seal for the EPi-Sense Coagulation System (CDK-1413) was potentially compromised and had a worst-case reasonable harm of an infection. A Field Safety Notice was issued for a recall of affected lots in the US, Netherlands, and Germany on 29 May 2019. All actions have been conducted to close the field action. The recall was terminated on 04 May 2020.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

This section is intended to summarise, in a comprehensive manner, the clinical evaluation results and the clinical data forming the clinical evidence for the confirmation of conformity with relevant general safety and performance requirements, the evaluation of undesirable side-effects and the acceptability of the benefit-risk ratio. It shall be an objective and balanced summary of the clinical evaluation results of all the available clinical data related to the device in question, whether favourable, unfavourable, and/or inconclusive.

5.1 Summary of clinical data related to equivalent device, if applicable

The EPi-Sense ST Coagulation Device (EPiST) was assessed and endorsed by the Notified Body on the basis of equivalence. Equivalence was demonstrated to the EPi-Sense Coagulation Device (CDK-1413; AtriCure, Inc.; Basic UDI-DI: 08401439000000000000010ZC). The EPi-Sense Coagulation Device and clinical data to support its safety and performance are included in this SSCP.

The Cannula with Guide (CSK-6131) was assessed and endorsed by the Notified Body on the basis of equivalence. Equivalence was demonstrated to the predicate design of the Cannula with Guide (AtriCure, Inc.) which was used in the CONVERGE trial and other observation studies. The Cannula with Guide and the clinical data to support its safety and performance are included in this SSCP.

5.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Identity of the investigation/study	CONVERGE Trial Clinicaltrials.gov: NCT01984346 DeLurgio et al. 2020[1]
Identity of the device	EPi-Sense Coagulation Device (CDK-1413) Cannula with Guide (CSK-6130) AtriCure RF Generator System (CSK-310) Sterile RF Cable (CSK-2000)
Intended use of the device in the investigation	Treatment of symptomatic persistent atrial fibrillation that is refractory or intolerant to at least one class I and/or III antiarrhythmic drug (AAD) when used with an open irrigated RF ablation catheter to complete pulmonary vein (PV) isolation by ablating breakthroughs between the epicardial lesions.

Objectives of the study	To demonstrate superiority of the convergent procedure (experimental) compared to the standalone endocardial catheter ablation (control) on overall success, defined as freedom from AF/AFL/AT absent class I and III AADs except for a previously failed class I or III AAD with no increase in dosage following the 3-month blanking period through the 12 months post procedure follow-up visit. The incidence rate of Major Adverse Events (MAEs) in the treatment arm will demonstrate an acceptable risk profile.
Study design and duration of follow-up	Randomised controlled trial Primary endpoint follow-up: 12-months post-index procedure Long-term follow-up: 5-years post-index procedure
Primary and secondary endpoint(s)	Primary effectiveness endpoint: Success or failure to be AF/AFL/AT free absent class I and III AADs except for a previously failed or intolerant class I or III AAD with no increase in dosage following the 3-month blanking period through the 12 months post procedure follow-up visit. Primary safety endpoint: The primary safety endpoint for the study will be defined as the incidence of major adverse events (MAEs) listed below for subjects undergoing the convergent procedure for the procedural to 30-day post procedure time period. • Cardiac tamponade/perforation • Severe pulmonary stenosis • Excessive bleeding • Myocardial infarction • Stroke • Transient ischemic attack (TIA) • Atrioesophageal fistula • Phrenic nerve injury • Death Secondary effectiveness endpoints: • Success or failure to achieve a 90% reduction from baseline AF burden and off all class I and III AADs at 12 months post procedure • Success or failure to achieve a 90% reduction from baseline AF burden regardless of their class I and III AAD status at 12 months post procedure • Change in quality of life (QOL) measures at 12 months post procedure from baseline values • Change in 6-minute walk test score from baseline score • Success or failure to be AF free and off all class I and III AADs except a previously failed or intolerant class I or III AAD with no increase in dosage following the 3-month blanking period through the 12 months post procedure follow-up visit • Success or failure to be AF free regardless of class I and III AAD status following the 3-month blanking

	period through the 12-months post procedure follow-up visit Secondary safety endpoint: • Incidence of serious adverse events (SAEs) in the study through the 12-month post procedure visit, in each arm of the study.	
Inclusion/exclusion criteria for subject selection	Inclusion criteria: • Age > 18 years; < 80 years • Left atrium < 6.0 cm (Trans Thoracic Echo [TTE] parasternal 4 chamber view) • Refractory or intolerant to one AAD (class I and/or III) • Documentation of persistent AF • Provided written informed consent Exclusion criteria: • Patients requiring concomitant surgery such as valvular repair or replacement, coronary artery bypass graft (CABG) surgery and atrial septal defect closure. • Left ventricular ejection fraction < 40% • Pregnant or planning to become pregnant during study • Co-morbid medical conditions that limit one year life expectancy • Previous cardiac surgery • History of pericarditis • Previous cerebrovascular accident (CVA), excluding fully resolved TIA • Patients who have active infection or sepsis • Patients with oesophageal ulcers strictures and varices • Patients with renal dysfunction who are not on dialysis (defined as glomerular filtration rate [GFR] ≤ 40) • Patients who are contraindicated for anticoagulants such as heparin and coumadin • Patients who are being treated for ventricular arrhythmias • Patients who have had a previous left atrial catheter ablation for AF (does not include ablation for AFL or other supraventricular arrhythmias) • Patients with existing implantable cardioverter defibrillators (ICDs).	
Number of enrolled studies	Hybrid convergent arm: 102 patients Endocardial ablation arm (control): 51 patients	
Study population	**EPi-Sense (Hybrid Convergent Arm)**	**Catheter Ablation (Endocardial Ablation Arm)**

Age (years), Mean ± SD	63.7 ± 9.64	65.1 ± 6.66
Male	78% (80/102)	53% (27/51)
Caucasian	94% (96/102)	98% (50/51)
Height (cm), Mean ± SD	177.7 ± 8.43	173.9 ± 11.64
Weight (kg), Mean ± SD	104.3 ± 19.98	106.3 ± 23.90
Body mass index (kg/m^2), Mean ± SD	33.0 ± 5.86	35.1 ± 7.13
Number of years in atrial fibrillation (years since persistent AF diagnosis)	4.4 ± 4.8	4.5 ± 4.7
Persistent AF	63% (64/102)	47% (24/51)
Longstanding Persistent AF	37% (38/102)	53% (27/51)
Summary of study methods	This was a prospective, open-label, 2:1 randomized, multi-centre, pivotal clinical study. Subjects were randomized to one of two procedures: convergent procedure utilizing the EPi-Sense or standalone endocardial catheter ablation procedure. Subjects with symptomatic persistent AF meeting all inclusion/exclusion criteria were eligible for this study. Subjects in both arms of the study were evaluated post-procedure at 1-, 3-, 6-, and 12-months. Subject participation in this study was 12-months from the procedure with additional, long-term follow-up visits at: 18-months, 2-, 3-, 4- and 5-years post-procedure.	

Summary of results

Safety and Effectiveness Endpoints – All Patients

Endpoint	EPi-Sense	Catheter Ablation	Treatment Difference, p-value
Primary Effectiveness	65.7% (67/102) [95% CI: 56.5%, 74.9%]	49.0% (25/51) [95% CI: 35.3%, 62.7%]	16.7% [95% CI: 0.1%, 33.2%], p=0.0472
Primary Safety	7.84% (8/102) [95% UCL: 13.7%]	-	-
Achieved ≥90% Burden Reduction at 12 Months, without New/Increased Class I/III AADs	80.0% (60/75) [95% CI: 70.9 – 89.1%]	56.8% (25/44) [95% CI: 42.2 – 71.5%]	23.2% [95% CI: 6.0%, 40.4%], p=0.0069
AF Free at 12 Months, without New/Increased Class I/III AADs	70.6% (72/102) [95% CI: 61.7 – 79.4%]	51.0% (26/51) [95% CI: 37.3 – 64.7%]	19.6% [95% CI: 3.3%, 35.9%], p=0.0172
Change in AFSS Composite Score at 12 Months: n, Mean ± SD	60, -11.7 ± 7.71	37, -10.3 ± 7.16	-
Change in SF-36 Physical Health	97, 7.3 ± 10.67	50, 5.7 ± 10.49	-

Composite Score at 12 Months: n, Mean ± SD			
Change in SF-36 Mental Health Composite Score at 12 Months: n, Mean ± SD	97, 5.7 ± 10.51	50, 7.7 ± 12.78	-
Change in 6-Minute Walk Score at 12 Months: n, Mean ± SD	94, 9.2 ± 120.59	48, -12.4 ± 190.09	-
Secondary Safety	32.4% (33/102)	35.3% (18/51)	-
Post-hoc Additional Effectiveness Endpoints – All Patients*			
Endpoint	**EPi-Sense**	**Catheter Ablation**	**Treatment Difference**
Freedom from Arrhythmia off AADs (12 Months)	52.0% (53/102)	31.4 (16/51)	20.6% (4.6 – 36.6%)
Freedom from Arrhythmia Regardless of AADs (12 Months)	74.5% (76/102)	58.8% (30/51)	15.7% (-0.25 – 31.6%)
Freedom from Arrhythmia off AADs (18 Months)	43.1% (44/102)	23.5% (12/51)	19.6% (4.5 – 34.7%)
Freedom from Arrhythmia Regardless of AADs (18 Months)	63.7% (65/102)	47.1% (24/51)	16.7% (0.0 – 33.2%)
Post-hoc Effectiveness and Safety Endpoints – Longstanding Persistent AF*			
Endpoint	**EPi-Sense**	**Catheter Ablation**	**Treatment Difference**
Primary Effectiveness	65.8% (25/38) [95% CI: 50.7 - 80.9%]	37.0% (10/27) [95% CI: 18.8 - 55.3%]	28.8% [95% CI: 5.1 - 52.4%]
Primary Safety	7.9% (3/38) [19.2% UCL]	-	-
Achieved ≥90% Burden Reduction at 12 Months, without New/Increased Class I/III AADs	78.9% (30/38) [95% CI: 66.0 – 91.9%]	46.2% (12/26) [95% CI: 27.0 – 65.3%]	-
AF Free at 12 Months, without New/Increased Class I/III AADs	71.1% (27/38) [95% CI: 56.6 – 85.5%]	37.0% (10/27) [95% CI: 18.8 – 55.3%]	-
Change in AFSS Composite Score at 12 Months: n, Mean ± SD	23, -12.9 ± 7.79	22, -9.8 ± 7.93	-
Change in SF-36 Physical Health Composite Score at 12 Months: n, Mean ± SD	38, 7.9 ± 9.27	27, 3.0 ± 10.40	-
Change in SF-36 Mental Health Composite Score at 12 Months: n, Mean ± SD	38, 5.6 ± 13.49	27, 6.5 ± 14.61	-

Freedom from Arrhythmia off AADs (12 Months)	52.6% (20/38)	25.9% (7/27)	26.7% [95% CI 3.8 – 49.6%]
Freedom from Arrhythmia Regardless of AADs (12 Months)	73.7% (28/38)	44.4% (12/27)	29.2% [95% CI: 5.8 – 52.6%]
Freedom from Arrhythmia off AADs (18 Months)	47.4% (18/38)	22.2% (6/27)	25.2% [95% CI: 2.8 – 47.5%]
Freedom from Arrhythmia Regardless of AADs (18 Months)	68.4% (26/38)	33.3% (9/27)	35.1% [95% CI: 12.0 – 58.2%]
Secondary Safety	26.3% (10/38)	33.3% (9/27)	-
Study Limitations	• Absence of empirical endocardial posterior wall ablation in catheter arm, though there are challenges with obtaining safe transmural posterior wall ablation. • Cryoballoon was not included for endocardial ablation. • Electrical isolation/exclusion of left atrial appendage not performed.		
Any device deficiency or device replacements related to safety or performance during the study	There were two (2) device malfunctions. In both cases, the impedance was too high, and the devices were replaced.		
*Confidence intervals in post-hoc analyses not adjusted for multiplicity.			

5.3 Summary of clinical data from other sources, if applicable

Systematic literature searches are performed as part of the Clinical Evaluation for the subject devices. From these searches, the following publications were identified that reported clinical data from use of the EPi-Sense Coagulation Device and Cannula with Guide[2-8]. Additional clinical data have been published on the Cannula using earlier generations of the coagulation device; these studies are listed in the bibliography[9-24].

Study, design, N	Performance outcomes	Safety outcomes
Larson et al. 2020[2] Prospective, single centre N=113	Survival free from any AF/AT episode > 30 seconds at 12-months after the blanking period: 53%. At one-year post-blanking, 94% of the cohort was free from an arrhythmia burden > 5%. Mean AF burden among the cohort at 12 months was 2.8%.	Total procedural complications were 16/113 (14%). MAEs were reported for 5/113 patients (4.4%): 3 cardiac tamponade 2 excessive bleedings Procedural complications decreased significantly following the transition from trans-diaphragmatic to sub-xiphoid surgical access (23% vs. 3.8%; p=0.005).

Study, design, N	Performance outcomes	Safety outcomes
Maclean et al. 2020[3] Retrospective, propensity-matched, single centre N=43 treated with EPi-Sense/Cannula in hybrid procedure; N=43 treated with endocardial catheter ablation only	<u>Hybrid versus endocardial:</u> AF-free at 1 year (single procedure, on AADs): 60.5% vs. 25.6%, p=0.002 AF-free at 1 year (single procedure, off AADs): 37.2% vs. 13.9%, p=0.025 Arrhythmia-free survival long term (multiple procedures, on AADs; mean follow-up 30.5 ± 13.3 months): 58.1% vs. 30.2%, p=0.036 Arrhythmia-free survival long term (multiple procedures, off AADs; mean follow up 30.5 ± 13.3 months): 32.5% vs. 11.6%, p=0.82	<u>Hybrid versus endocardial:</u> Complications: 11.6% vs. 2.3%, p=0.2 MAEs were reported for 3/43 patients (6.98%): 2 cardiac tamponade 1 phrenic nerve injury
Makati et al. 2020[4] Retrospective, registry analysis N=226	Freedom from AF/AFL/AT: 75% at 15.4 ± 6.5 months follow-up Mean Residual AF Burden: 1.10% with 7.30 ± 3.00 months follow-up 8.5% with 19.05 ± 3.86 months follow-up Proportion of patients with ≤5% AF burden: 94% at 7.30 ± 3.00 months follow-up 88% with 19.05 ± 3.86 months follow-up Proportion of patients with ≤1% AF burden: 90% at 7.30 ± 3.00 months follow-up 80% with 19.05 ± 3.86 months follow-up	Periprocedural complications: 6% There were five (5) additional pericardial effusions occurring 2-4 weeks post-procedure. These were managed medically or via pericardiocentesis with no long-term sequelae. MAEs were reported for 6/226 patients (2.65%): 3 excessive bleeding 1 stroke 2 phrenic nerve injury
Ellis et al. 2020[5] Prospective, observational registry N=33	Freedom from AF/AT: 91% (20 of 22 patients) at 6 months 90% (18 of 20 patients) at 12 months 92% (11 of 12 patients) at 18 months	There were no (0) acute periprocedural complications (<7 days). MAE rate was 0%.

Study, design, N	Performance outcomes	Safety outcomes
	92% (11 of 12) at 24 months	Thirty-day adverse events included two (2) patients with pericardial effusion requiring pericardiocentesis and one (1) incisional hernia repair. There were no (0) long-term complications, strokes, or deaths.
Tonks et al. 2020[6] Retrospective, single centre N=36	12-month freedom from atrial arrythmias was 78%.	No (0) periprocedural deaths, re-operations, strokes, or major complications occurred. One (1) patient had phrenic nerve palsy, two (2) patients had severe pericarditis, and three (3) patients had significant pericardial effusion. MAEs were reported for 2/36 patients (5.56%): 1 cardiac tamponade 1 phrenic nerve injury
Gulkarov et al. 2019[7] Retrospective, single centre N=31	Free from AF/AFL at 1 year: 71% Free from AF at 1 year: 87% Free from AF/AFL at 2 years: 52% Free from AF at 2 years: 71%	There were four (4) peri-procedural complications. Two (2) patients suffered minor cerebrovascular accidents immediately after the procedure, which resolved over time without any residual deficit. Two (2) patients developed pericardial effusion with cardiac tamponade that required emergent pericardial drainage about two (2) weeks after discharge. MAEs were reported for 4/31 patients (12.90%): 2 cardiac tamponade 2 stroke
Jan et al. 2018[8] Prospective, randomised N=24 treated with EPi-Sense or	Free from AF/AT/AFL without AAD: 58.3% with Hybrid vs. 34.6% with catheter-only ablation group were free of AF/AT/AFL without AAD treatment during mean 30.5 ± 6.9 months follow-up.	Complication rates: Hybrid arm: 12.5% Catheter ablation arm: 0% MAEs were reported for 1/24 patients (4.17%): 1 excessive bleeding

Study, design, N	Performance outcomes	Safety outcomes
Numeris Coagulation Device[vi] and Cannula in hybrid procedure N=26 treated with endocardial catheter ablation only	Recurrence of AF/AT/AFL was more likely in the catheter-only arm compared to the hybrid arm (OR 3.78 (95% CI (1.17, 12.19), p=0.048)).	

5.4 An overall summary of the clinical performance and safety

The clinical benefits of the EPi-Sense and EPi-Sense ST Coagulation devices are to return to normal sinus rhythm (i.e., freedom from AF/AFL/AT), reduce AF symptoms (palpitations, shortness of breath at rest, shortness of breath during physical activity, exercise intolerance, fatigue at rest, lightheadedness/dizziness, and chest pain or pressure), and improve quality of life. The clinical benefit of the Cannula is to gain access to the pericardial space to permit epicardial ablation for the treatment of arrhythmias. Based on the Clinical Evaluation, these clinical benefits are supported by sufficient clinical data, including results from the CONVERGE trial and published clinical studies. The clinical evidence for EPi-Sense (CDK-1413) applies to EPi-Sense ST (EPiST) based on equivalency.

The performance objective of the Clinical Evaluation was a pooled success rate (defined as return to normal sinus rhythm or freedom from AF/AFL/AT) at 12-months post-procedure of 65% with a lower confidence limit of 55%. The combined success rate from the CONVERGE trial and published literature identified in the Clinical Evaluation systematic literature review met this performance objective, with a pooled success rate of >65%.

The safety objective of the Clinical Evaluation was a major adverse event (MAE) rate of ≤12% with an upper confidence limit of 20%. Major adverse events include cardiac tamponade/perforation, severe pulmonary stenosis (≥70% reduction in diameter), excessive bleeding (requiring transfusion or ≥20% fall in hematocrit), myocardial infarction, stroke, transient ischemic attack, atrioesophageal fistula, phrenic nerve injury, and death. The combined MAE rate from the CONVERGE trial and published literature identified in the Clinical Evaluation systematic literature met this safety objective, with a pooled rate of <12%.

Based on the Clinical Evaluation, the benefits of the use of the subject devices outweigh the risks when the subject devices are used as intended, and the subject devices have a favourable risk-benefit ratio. The results from the clinical data did not identify any new or unexpected risks. Risk management activities have been performed and found the risk control measures in place continue to be effective, and all risks have been reduced as far as possible as required by AtriCure's risk management program and BS EN ISO 14971.

5.5 Ongoing or planned post-market clinical follow-up

AtriCure continues to follow long-term outcomes of the CONVERGE trial (described in Section 5.2). Patients are follow-up by phone at 2-, 3-, 4-, and 5-years post-convergent procedure. At each follow-up, data is collected on the patients' health status, rhythm status,

[vi] Jan et al. describes using a combination of EPi-Sense and Numeris Coagulation Devices to treat the cohort of patients. Numeris is a previous generation of the Coagulation Device that is not CE-marked under EU MDR. It is unknown how many patients were treated with the EPi-Sense Coagulation Device in this study.

medication use (including class I and III AADs and anticoagulants), and adverse events.

There were no unanswered questions that emerged from the CONVERGE trial; however, AtriCure continues to collect data on the safety and performance of the EPi-Sense Coagulation System via post-market clinical follow-up (PMCF). Ongoing PMCF studies include investigator-sponsored research studies, the TRAC-AF registry (clinicaltrials.gov NCT05111015), and the CONVERGE post-approval study (CONVERGE PAS, clinicaltrials.gov NCT05393180).

Investigator-sponsored research using the EPi-Sense Coagulation System is (1) collecting additional real-world evidence on the use of the subject devices and procedures at the investigating center, (2) comparing outcomes from patients treated with the subject devices or procedures to outcomes from historical controls treated at the investigating center or in published literature, and (3) evaluating additional or new endpoints in patients treated with the subject devices or procedures.

TRAC-AF is a multicentre, retrospective/prospective registry that records outcomes from adult patients undergoing ablations for the treatment of AF. This includes outcomes from patients treated with the EPi-Sense Coagulation System. The goal of TRAC-AF is to improve the understanding of the efficacy of ablation interventions in the treatment of AF. This registry tracks outcomes related to AF recurrence, freedom from AF, AF burden, AAD use, adverse events, and procedure- or device-related complications.

CONVERGE PAS is a prospective, multicentre, open-label, single arm study to evaluate clinical outcomes (peri-procedural and long-term) in a cohort of patients treated during commercial use of the EPi-Sense Coagulation System to treat symptomatic long-standing persistent atrial fibrillation patients who are refractory or intolerant to at least one class I and/or III AAD.

6. Possible diagnostic or therapeutic alternatives

Management of Atrial Fibrillation: Rate Control

Rate control drugs, such as beta blockers, calcium channel blockers, and cardiac glycosides, can be used to slow the heart rate in atrial fibrillation. While these drugs do not cure AF, they may offer a lower side effect profile than rhythm control drugs. A recent meta-analysis, which included results from the AFFIRM clinical trial, found that rate and rhythm control drugs did not result in significantly different clinical outcomes, including mortality, bleeding, and thromboembolic rate, but that rhythm control drugs were associated with higher rehospitalization rates[25].

Management of Atrial Fibrillation: Rhythm Control

Currently, the main indications for rhythm control are for patients with paroxysmal or persistent atrial fibrillation who have hemodynamic compromise associated with episodes of atrial fibrillation or who have bothersome symptoms despite adequate rate control[26]. A rhythm control strategy involves initial pharmacologic or electronic cardioversion, followed by pharmacologic treatment to maintain normal sinus rhythm.

Management of Thromboembolic Events

First-line management for stroke prevention is typically oral anticoagulation agents[27]. Traditional anticoagulants include heparins and coumarins (Vitamin K antagonists) of which warfarin is the most common[28] in clinical use due to its proven efficacy.

A number of newer anticoagulant medications, including dabigatran, rivaroxaban, and apixaban[29], have received U.S. Food and Drug Administration (FDA) approval for stroke prevention in nonvalvular AF and have demonstrated noninferiority to warfarin in clinical trials.

While oral anticoagulation medicine can be effective for stroke prevention, there is an increased risk of bleeding in patients as these types of medications prevent the blood from clotting. Additionally, many patients avoid this type of treatment because of adverse side effects and drug interaction.

Ablation Procedures

Pharmaceutical options are solely limited to management of atrial fibrillation and/or risks associated with the condition; they are not treatment of the arrhythmia itself.

A variety of ablative procedures have been investigated as potentially curative approaches or perhaps modifying the arrhythmia such that drug therapy becomes more effective. Ablative approaches focus on interruption of the electrical pathways that contribute to atrial fibrillation, through modifying the triggers of atrial fibrillation and/or the myocardial substrate that maintains the aberrant rhythm[30].

Understanding of the pathophysiological mechanism(s) underlying atrial fibrillation (AF) is the foundation on which current ablation strategies are built. A seminal finding in the 1990s was that the myocardial sleeves of the pulmonary veins (PVs) are a major site of AF triggers[31]. As a result, in most patients with paroxysmal AF, the ablation procedure should target the pulmonary veins[32]. In patients with non-paroxysmal AF, however, PV isolation alone seems to be insufficient to prevent the arrhythmia[33,34]. Over the years, using advanced mapping technologies, additional potential ablation targets outside of the PVs have been identified and tested, in particular for patients with persistent forms of AF. In addition to AF drivers, atrial substrate may be critical to sustained and progressive disease[31]. Substrate that may contribute to AF include atrial fibrosis, epicardial fat, and anatomical heterogeneity leading to endo/epicardial dissociation.

Lesions may be created via sequential incisions, or with use of a device that uses an energy source to burn or freeze the cardiac tissue. The most common types of energy for ablation include radiofrequency and cryothermal energy. These energy sources ablate the cardiac tissue by scarring or destroying the tissue to disrupt the electrical signals. Of these, RF energy is the one most commonly applied to ablate cardiac tissue that is determined to be the source of arrhythmia[35,36]. An emerging ablative method called pulsed field ablation (PFA), which involves irreversible electroporation of cells, is being explored as a cardiac ablation technique, but data is primarily preclinical[37]. PFA has the potential advantage of not carrying the risk of thermal injuries, but longer-term safety is currently unknown.

Surgical Ablation

The Cox-Maze surgical ablation procedure was initially introduced in 1987. It involved complicated “maze” incisions to the atria as well as to the sinus node to disrupt erratic signals that interfered with normal sinus rhythm[30]. The Maze (‘cut and sew’) procedure, an open surgical procedure often combined with other cardiac surgeries (e.g., valve repair, coronary artery bypass grafting), is an ablative procedure involving sequential atriotomy incisions designed to create electrical barriers that prevent the maintenance of AF.

Contemporary Cox-Maze approaches employ radiofrequency or cryothermal energy in lieu of incisions to disrupt the electrical signal creates the arrythmia with similar lesion patterns, such as Cox-Maze III and Cox-Maze IV. Advantages of using cryoenergy to ablate the cardiac tissue include the preservation of collagen and maintenance of the structural integrity of the tissue[38]. Despite the advantages of using cryoablation probes, there are limitations or conditions which may impact the efficacy of this technology. Limitations on the efficacy of cryoablation include the thickness of the tissue being ablated; thick cardiac tissue may require multiple applications of the cryoprobe.

Because of the highly invasive nature of open-heart surgical ablation, it is currently reserved mainly for patients who are undergoing open heart surgery for other reasons, such as valve repair or coronary artery bypass grafting. However, thoracoscopic approaches using RF ablation clamps or pens to create epicardial lesions to approximate the "maze" lesions have been described for use in patients who are not undergoing concomitant open cardiac surgery[39,40]. Additionally, hybrid techniques that combine minimally invasive epicardial ablation with endocardial ablation have also been described that can create the Cox-Maze IV[41] or similar but reduced lesion sets.

Catheter Ablation

Percutaneous catheter-based ablation is a well-established interventional approach for treating a variety of arrhythmias[35], in which intracardiac mapping identifies a discrete arrhythmogenic focus that is the target of ablation. The situation is more complex for AF, since there is not a single arrhythmogenic focus and there may be additional drivers of AF that are sustaining rather than initating[42]. Since the inception of ablation techniques in the early 1990s, there has been a progressive understanding of the underlying electrical pathways in the heart that are associated with AF. In the late 1990s, it was recognized that AF most frequently arose from an abnormal focus at or near the junction of the pulmonary veins and the left atrium, leading to the feasibility of more focused, percutaneous ablation techniques. The basic strategies that have emerged for focal ablation within the pulmonary veins, as identified by electrophysiologic mapping, are segmental ostial ablation guided by pulmonary vein potential (electrical approach), or circumferential pulmonary vein ablation (anatomic approach). Circumferential pulmonary vein ablation currently is the most commonly used approach.

Catheter ablation procedure uses endocardial catheter-based techniques via a transvenous approach[43]. There has been some evolution in catheter-based technology over time, including improvements to irrigation to reduce volume load and steam pops, as well as real-time contact force-sensing between the catheter and cardiac tissue to potentially improve clinical outcomes. Despite such efforts to improve catheter ablation success, improved efficacy as assessed through randomized clinical trials, observational studies, and meta-analyses has not been consistently demonstrated[44-47].

Several endocardial catheters are intra-cardiac electrophysiology diagnostic catheters; these devices enable the physician to monitor (i.e., by sensing, pacing, and recording) the success of the lesions in treating atrial fibrillation. High density mapping with circular catheters can help guide and optimize additional lesions, and may be useful to identify non-pulmonary vein targets[48].

Minimally Invasive Devices

More recently, minimally invasive devices to ablate cardiac tissue have been created. Aiming to preserve efficacy while reducing complication rates and recovery time, several minimally invasive surgical techniques have been described which vary in access site, ablation energy source, and lesion set[49,50]. These devices are introduced to the epicardial tissue via laparoscopic, thoracoscopic, and/or endoscopic procedures to create lesions of the cardiac tissue. These procedures involve small incisions (i.e., keyholes) to access the cardiac tissue. The devices that are the subject of this SSCP are minimally invasive devices which use RF energy to ablate the cardiac tissue resulting in the creation of lesions which interrupt the errant signals generated by the arrhythmia. For the subject devices in this SSCP, lesions are created to the beating heart under direct visualization from a guide wire.

7. Suggested profile and training for users

Cardiac and thoracic surgeons are qualified by training and education to use the AtriCure EPi-Sense, EPi-Sense ST, and Cannula devices. AtriCure offers additional comprehensive education and training on the use of these AtriCure devices per the device instructions for use. This training will be available to the clinicians using the AtriCure EPi-Sense, EPi-Sense ST, and Cannula devices.

8. Reference to any harmonized standards and CS applied

Standard	Devices	Compliance (full/partial/no)	Rationale if partial/no
BS EN ISO 13485:2016+A11: 2021 Medical devices – Quality management systems – Requirements for regulatory purposes	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 14971:2019 +A11:2021 Medical devices – Application of risk management to medical devices	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 14155:2020 Clinical investigation of medical devices for human subjects – Good clinical practice	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 10993-4:2017 Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 10993-11:2018 Biological evaluation of medical devices – Part 11: Test for systemic toxicity	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 10993-12:2021 Biological evaluation of medical devices – Part 12: Sample Preparation and reference materials	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN 60601-1:2006+A2:2021 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	EPi-Sense EPi-Sense ST	Full	N/A

Standard	Devices	Compliance (full/partial/no)	Rationale if partial/no
BS EN 60601-1-6:2010+A2:2021 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability	EPi-Sense EPi-Sense ST	Full	N/A
BS EN 60601-1-2:2015+A1:2021 Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests	EPi-Sense EPi-Sense ST	Full	N/A
BS EN 60601-2-2:2018 Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EPi-Sense EPi-Sense ST Cannula	Full	N/A
ISTA 3A:2018 Performance testing of Shipping Containers and Systems	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 11135:2014+A1+2019: Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices	EPi-Sense ST	Full	N/A
BS EN ISO 11137-1:2015+A2:2019 Sterilization of health care products. Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	EPi-Sense Cannula	Full	N/A
BS EN ISO 11137-2:2015 Sterilization of health care products. Radiation – Part 2: Establishing the sterilization dose	EPi-Sense Cannula	Full	N/A
BS EN ISO 11737-1:2018/A1:2021 Sterilization of health care products. Microbiological methods	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 11737-2:2020: Sterilization of health care products. Microbiological methods	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 11607-2:2020 Packaging for terminally sterilized medical	EPi-Sense EPi-Sense ST	Full	N/A

Standard	Devices	Compliance (full/partial/no)	Rationale if partial/no
devices - Part 2: Validation requirements for forming, sealing and assembly processes	Cannula		
ASTM F1980:2021 Standard Guide for Accelerated Aging of Sterile Barrier	EPi-Sense EPi-Sense ST	Full	N/A
ASTM F1929:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye	Cannula	Full	N/A
BS EN ISO 15223-1:2021 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 20417:2021 Medical Devices – Information to be supplied by the manufacturer	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN IEC 62366-1:2015+A1:2020 Medical devices – Application of usability engineering to medical devices	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN IEC 63000:2018 Technical documentation for the assessment for electrical and electronic products for the restriction of hazardous substances	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 14644-1:2015 Cleanrooms and Associated Controlled Environments – Classification	EPi-Sense EPi-Sense ST Cannula	Full	N/A
BS EN ISO 14644-2:2015 Cleanrooms and Associated Controlled Environments – Monitoring	EPi-Sense EPi-Sense ST Cannula	Full	N/A

9. Revision history

SSCP Revision Number	Date Issued	Change Description	Validated by Notified Body (Yes or No)	Validation Language
A	See AtriCure MasterControl	Initial Release	No	English
B	See AtriCure MasterControl	Corrected Cannula classification rule in Section 1. Added product codes and footnotes to Section 3.2. Added description of cannula equivalency to Section 5.1. Added footnote (vi) to Section 5.3. Added descriptions of PMCF activities to Section 5.5.	No	English
C	See AtriCure MasterControl	Updated Clinical Benefits statement to list out the 7 AF symptoms. Added Basic UDI-DI for CSK-2000. Aligned Warnings for EPi-Sense and EPi-Sense ST to IFU-0296 and IFU-0297 by correcting a typographical error and a missing word.	No	English
D	See AtriCure MasterControl	Corrected EU Authorised Representative address and Notified Body address from “The Netherlands” to “NL” in Section 1. Updated Section 9 Revision History table to state “Yes” for “Validated by Notified Body”.	Yes	English

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