AtriCure®

CE 2797

EPi-Sense® Coagulation Device Instructions for Use

CDK-1413

MD

FIGURE 1

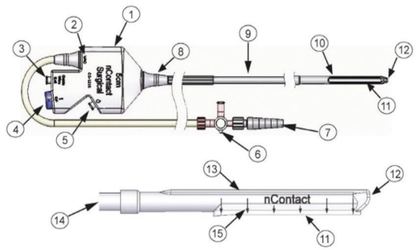


FIGURE 2.A

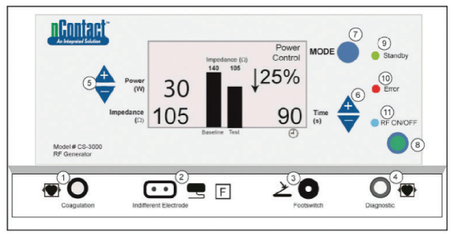


FIGURE 2.B

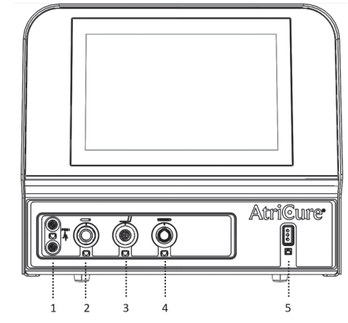
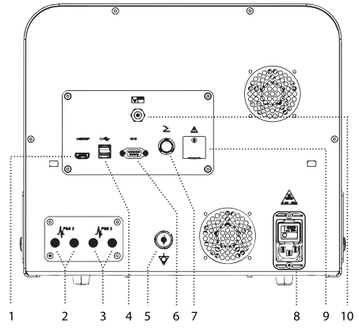


FIGURE 2.C



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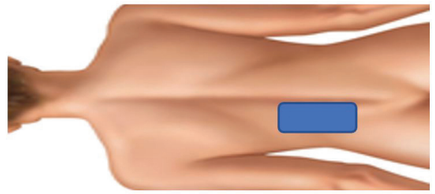


FIGURE 4

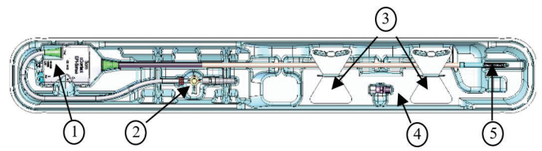
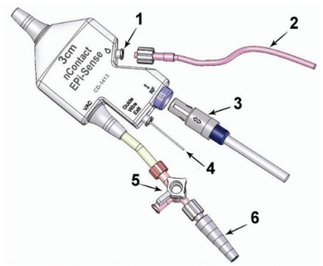


FIGURE 5



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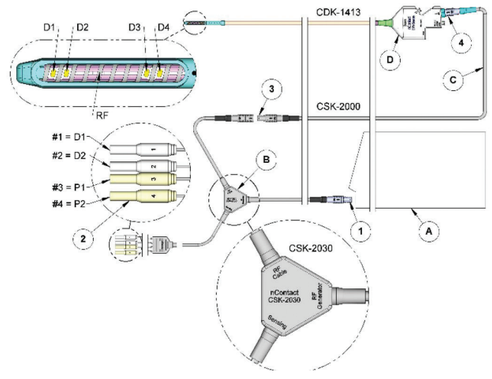
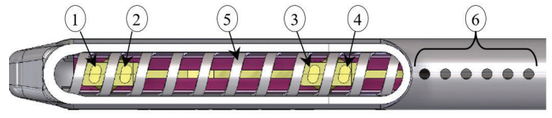


FIGURE 7



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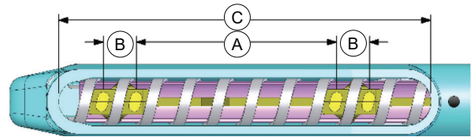
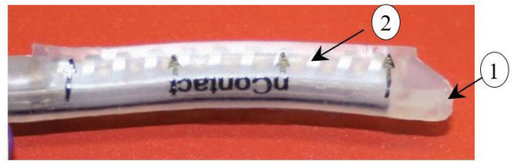


FIGURE 9

FIGURE 10



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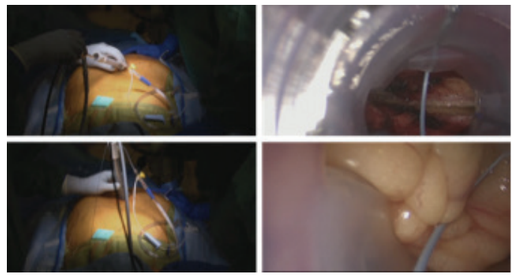


FIGURE 12

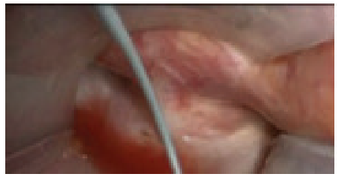


FIGURE 13

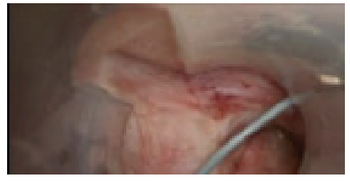


FIGURE 14

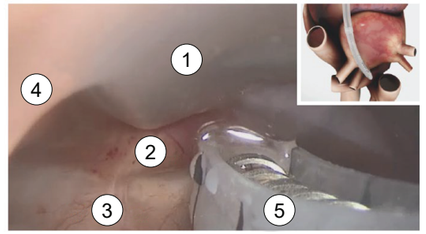


FIGURE 15

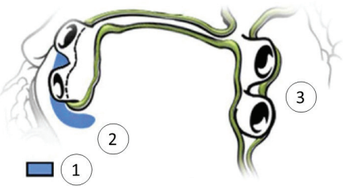


FIGURE 16

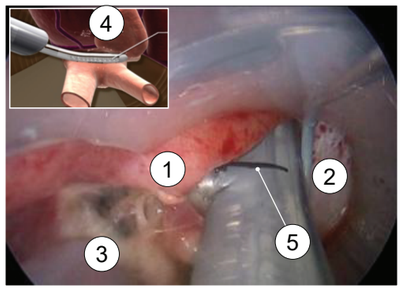


FIGURE 17

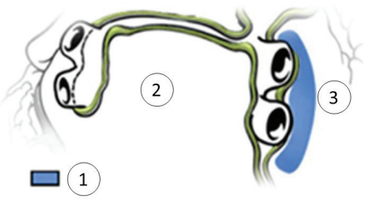
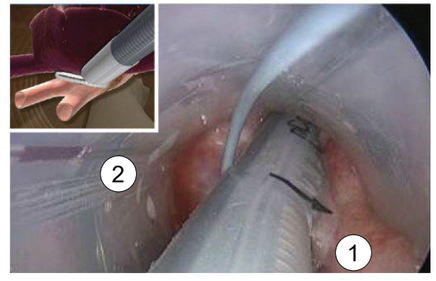


FIGURE 18



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INSTRUCTIONS FOR USE (en)

EPi-Sense® Coagulation Device

PRODUCT DESCRIPTION

Components of the Coagulation Device:

- One (1) CDK-1413 EPi-Sense Coagulation Device (STERILE in unopened, undamaged package. For single use only. Do not re-sterilize. Do Not Re-Use)

COMPONENTS NOT SUPPLIED WITH THE CDK-1413

- Compatible AtriCure® RF Generator (CSK-310 or MAG), plus accessories, Non-Sterile, Reusable (under separate IFU)
- CSK-2030 Sensing Cable, Non-Sterile, Reusable (under generator IFU)
- CSK-2000 RF Cable, Sterile, Single Use (under separate IFU)
- CSK-6131 Cannula with Guide, Sterile, Single Use (under separate IFU)

COMPONENTS REQUIRED FOR USE BUT NOT PROVIDED BY ATRICURE

- Indifferent Patient Return Electrode (Ground Pad) - surface area of 21 square inches (136 cm_2) minimum

The EPi-Sense® Coagulation Device is not made with natural rubber latex and does not contain PVC or phthalates.

PRODUCT FEATURES, FIGURE 1

[1]	Handle	[9]	Main Body
[2]	Vacuum Port	[10]	Distal Shell
[3]	Guide Wire Exit Port	[11]	Coagulation Electrode and Sensing Electrodes
[4]	RF Connection	[12]	Guide Tube Opening
[5]	Perfusion Port	[13]	Insulative Covering
[6]	Stopcock	[14]	Vacuum Lumen
[7]	Graduated Fitting to Vacuum Tubing	[15]	Locator arrows - 1 cm (0.4 in) spacing
[8]	Strain Relief		

PRODUCT FEATURES, FIGURE 2.A

[1]	Cable Connection	[6]	Time Adjustments
[2]	Indifferent, Dispersive Electrode (Ground Pad) Connection	[7]	Mode button
[3]	Footswitch Connection	[8]	RF ON/OFF Button
[4]	Diagnostic Device Connection	[9]	Standby Mode LED
[5]	Power Adjustment	[10]	Error LED
		[11]	RF LED

PRODUCT FEATURES, FIGURE 2.B

[1]	Sense-Pace Input (MLP)	[4]	EPi-Sense Receptacle
[2]	Pens Receptacle	[5]	Return Electrode Receptacle
[3]	Clamp Receptacle		

PRODUCT FEATURES, FIGURE 2.C

[1]	HDMI port	[6]	Serial Port
[2]	PSS pass-through	[7]	Footswitch Connector
[3]	PSS pass-through	[8]	Power Switch
[4]	USB ports	[9]	Service Port - AtriCure Only
[5]	Equipotential Connector	[10]	Vacuum Port

INDICATIONS FOR USE

The EPi-Sense Coagulation Device is indicated for 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.

INTENDED PURPOSE

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

INTENDED USER AND PATIENT POPULATION

The EPi-Sense Coagulation Device is a medical device for use by licensed medical doctors who perform cardiac and/or thoracic procedures for treatment of patients with arrhythmias including atrial fibrillation.

INTENDED CLINICAL BENEFIT

The clinical benefits of the EPi-Sense Coagulation System 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.

CONTRAINDICATIONS

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.

ENVIRONMENTAL SPECIFICATIONS

	Temperature	Humidity	Atmospheric Pressure
Operational	10 to 40°C (50 to 104°F)	30%-75% relative humidity non-condensing	700 to 1060 millibar (10 to 15 psi)
Transit	-29 to 55°C (-20 to131°F)	30-85% relative humidity	N/A
Storage	-29 to 55°C (-20 to131°F)	30-85% relative humidity	N/A

⚠ WARNING ⚠

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 or nickel 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.

⚠ WARNING ⚠

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 (CSK-310 or MAG), 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.

⚠ WARNING ⚠

This device contains small amounts of Cobalt (CAS# 7440-48-4). Do not use the device if the patient has sensitivity to Cobalt as this may result in an adverse patient reaction.

⚠ 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 followups 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.

⚠ WARNING ⚠

Additional warnings and precautions can be found in the compatible AtriCure RF Generator (CSK-310 or MAG) Operators Manual. Failure to follow the instructions contained in the RF generator manual may lead to an inability to complete the procedure.

POTENTIAL COMPLICATIONS OF THE COAGULATION PROCEDURE

- Infection
- Cardiac tamponade/perforation
- Pulmonary vein stenosis
- Vessel injury
- Pericardial effusion
- Tissue perforation
- Excessive bleeding
- Phrenic nerve injury
- Left atrial rupture/perforation
- Mediastinitis
- Pulmonary edema
- Vascular access complication
- Stroke/TIA
- Incisional herniation
- Esophageal injury
- Pleural effusion
- Atrio-Esophageal Fistula
- Cardiac arrest/Myocardial infarction
- New arrhythmias
- Thromboembolic complication
- Neurologic complication
- Death
- Complete heart block requiring permanent pacemaker implantation
- Pericarditis
- Serious skin burn
- Transdiaphragmatic herniation
- Damage (e.g., burn, puncture) to other adjacent structures

REQUIRED EQUIPMENT/SUPPLIES

- 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 EQUIPMENT/SUPPLIES

- 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 2 mm (0.08 in) pin connectors

DEVICE SET UP

1. Place the indifferent, dispersive (return) electrode on patient, per FIGURE 3, and connect cable to front of generator (CSK-310 or MAG, FIGURE 2.A or FIGURE 2.B, respectively). Ensure entire area of electrode is reliably attached to the patient's body.

See FIGURE 3. Placement of Indifferent, Dispersive Electrode

2. Place generator footswitch near the surgeon and connect the footswitch cable to generator (CSK-310 or MAG, FIGURE 2.A or FIGURE 2.B, respectively). Refer to the generator (CSK-310 or MAG) Operators Manual for complete generator instructions.
3. Inspect all trays, cartons and packaging to ensure there has been no package damage, which may result in product contamination. If package damage is discovered, do not use – replace the product.
   a) Outside the sterile field, remove the device and cable from cartons.
   b) Inside the sterile field, remove device from the tray and place near patient.
   i) Remove the device from the tray by releasing the tabs. (See FIGURE 4, #3)
   ii) Remove the Touhy Borst fitting (See FIGURE 4, #4) from the tray and attach to guide wire exit port on the handle.

See FIGURE 4. Coagulation device in tray

(1) Handle; (2) Stopcock; (3) Tabs; (4) Touhy Borst fitting (5) Distal End

⚠ WARNING ⚠

Using excess force to remove the device from the tray may result in damage to the device.

4. Prepare the Vacuum
   a) Attach one end of the sterile vacuum tubing to the graduated fitting where indicated on device handle by the vacuum symbol ('VAC') and the other to the vacuum trap (FIGURE 5). Use the stopcock to apply and release the vacuum to the distal assembly.
   b) Ensure the vacuum unit pressure is set to -400 +/- 25 mmHg (-7.7 +/- 0.5 psi; -53 +/- 3 kPa).

⚠ WARNING ⚠

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.

See FIGURE 5. Coagulation Device Setup

(1) Perfusion Port; (2) Line to Saline Bag; (3) RF Cable CSK-2000; (4) Guidewire Exit;(5) Stopcock; (6) Stepped Luer to Vacuum tube

5. Prepare the 0.9% Normal Saline Bag
   a) Place unpressurized saline IV bag at patient height or above.
   b) Connect perfusion tubing to female Luer connection where indicated on device handle by the perfusion "droplet" symbol, FIGURE 5, #1. Verify IV line is fully open.
   c) Insert IV tubing set into 0.9% normal saline bag.

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CE 2797

d) Turn on vacuum pressure and prime device by engaging the suction with a sterile surface (gloved hand).

e) Ensure perfusion flow is functioning by observing drops in IV tubing drip chamber. Make sure the device is primed by observing perfusion at distal end of coagulation device before starting operation of device. Ensure IV line is fully open.

⚠ WARNING ⚠

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.

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 (CSK-310 or MAG) if cable is incorrectly connected.

⚠ **CAUTION:** Cables to surgical electrodes should be positioned to prevent contact with patient or other leads

⚠ **CAUTION:** Use ONLY 0.9% normal saline.

6. Connect RF cable CSK-2000 to device handle where indicated by the 'RF' symbol - blue connection to blue connection, FIGURE 5, #3 & FIGURE 6, #4.

a) If using the CSK-2030: Connect the black end of the CSK-2030 Sensing Cable to the generator front panel connector (FIGURE 6, #1).

b) Connect the black end of the CSK-2000 RF Cable to the black Bessel receptacle of the CSK-2030 Sensing Cable per the FIGURE 6, #3.

See FIGURE 6. Sensing System Connection using CSK-2030 new style

Equipment	Connections
(A) Compatible AtriCure RF Generator (CSK-310 or MAG)	(1) CSK-2030 to Compatible AtriCure RF Generator (CSK-310 or MAG)
(B) CSK-2030 Sensing Cable	(2) CSK-2030 to Sensing Equipment
(C) CSK-2000 RF Cable	(3) CSK-2000 to CSK-2030
(D) CDK-1413-EU Device	(4) CSK-2000 to CDK-1413-EU

c) If not using the CSK-2030: Connect the black end of the CSK-2000 cable to the coagulation device connection on the generator front panel (Refer to the Operators Manual for complete generator (CSK-310 or MAG) instructions).

7. When connecting the shrouded pins from Cable CSK-2030 (FIGURE 6, #2) to the ECG recorder equipment refer to FIGURE 7.

a) Sensing electrodes provide the option to transmit signal directly from the probe to a commercially available electrogram recording system. This provides the option to sense, and record directly from the device to aid in lesion assessment.

See FIGURE 7. Sensing Electrode Locations

8. Distal #1 Sensing Electrode = CSK-2030 Shrouded Pin #1
9. Distal #2 Sensing Electrode = CSK-2030 Shrouded Pin #2
10. Proximal #3 Sensing Electrode = CSK-2030 Shrouded Pin #3
11. Proximal #4 Sensing Electrode = CSK-2030 Shrouded Pin #4
12. Coagulation Electrode
13. Reference Dots

⚠ WARNING ⚠

Ensure inputs from the ECG recorder are isolated from earth ground, if not, there is an increased possibility of fibrillation.

See FIGURE 8. Sensing Electrode Spacing

(A) 18 mm (0.71 in) (B) 3 mm (0.12 in) (C) 30 mm (1.2 in)

14. Connect power cable to generator back panel connector then power on the generator via the Power ON/OFF rocker switch. Refer to the Operators Manual for complete generator (CSK-310 or MAG) instructions.

MANIPULATION OF COAGULATION DEVICE OVER ACCESSORY GUIDE WIRE

1. Insert the rigid end of the accessory guide wire into the guide tube in the distal end of the coagulation device. Ensuring that the floppy end of the guide wire is at the distal end of the coagulation device (FIGURE 9).

See FIGURE 9. Accessory Guide Wire and Distal End of Coagulation Device

2. Secure the rigid end of the accessory guide wire with a Touhy Borst or stopcock such that the floppy end of the guide wire is in the desired position relative to the distal end of the coagulation device.
3. Advance the coagulation device through the cannula until positioned at desired coagulation location.

MANIPULATION OF COAGULATION DEVICE OVER GUIDEWIRE

1. Prepare distal end of device by pre-shaping to give distal tip a slight upward bend as shown in FIGURE 10.

See FIGURE 10. Pre-shaped Distal End Configuration

2. Place cannula guidewire in desired coagulation location.
3. If attached, remove torquer from end of guidewire.
4. Carefully feed one end of the guidewire into the guide tube in the distal end of coagulation device (FIGURE 10, #1).
5. Slide coagulation device until guidewire protrudes from handle of coagulation device. If available, attach torquer to the end of guidewire protruding from handle of device.
6. Advance the coagulation device along the guidewire until positioned at desired coagulation location using guidewire to assist in placement.

a) Use locator arrows (FIGURE 10, #2) to visualize the direction and location of the coagulation electrode during positioning.

b) Hold device on desired location until vacuum is engaged.

ENDOSCOPIC EPICARDIAL ACCESS VIA SUBXIPHOID APPROACH

1. Utilizing instructions below, access the epicardial space utilizing a Subxiphoid approach.

SUBXIPHOID ACCESS

1. Standard surgical subxiphoid access of the pericardial space should be performed by a physician authorized by his/her hospital to perform such surgical techniques.
2. Using standard surgical techniques for creating a pericardial window superior to the diaphragm, obtaining access to the posterior surface of the heart.
3. Create an incision immediately inferior to the xiphoid process. Direct visualization of the pericardium superior to the diaphragm can be achieved through the incision. The xiphoid process may be removed, dependent on patient anatomy.
4. A 2 cm (0.79 in) incision should be made in the pericardium to allow access for the cannula. The cannula provides direct access to the posterior surface of the heart and is sized to create space between the epicardium and the pericardium to visualize cardiac structures and manipulate the coagulation device alongside an endoscope, so all device manipulations are performed under direct visualization.
5. After obtaining subxiphoid access, the EPi-Sense Guided Coagulation Device, cannula, scopes and surgical instruments are used to create the epicardial lesion pattern.

CANNULA PLACEMENT AND MANIPULATION

1. The cannula should be positioned through the incision and into the pericardial space. As the cannula is advanced into the pericardial space, it should be directed towards the left of the patient, away from the IVC, as shown in FIGURE 11.

ENDOSCOPIC VISUALIZATION

1. Use the cannula to create space so that an endoscope can provide direct visualization of the posterior left atria. When the pericardium is intact and free of adhesions, the cannula will gently separate the heart from the pericardium and create a cavity into which the device may be advanced under endoscopic visualization.

The cannula may be manipulated along the posterior heart surface to visualize the left pulmonary veins (LPV) (FIGURE 12), the right pulmonary veins (RPV) (FIGURE 13), the inferior vena cava (IVC), the coronary sinus (CS), and the posterior left ventricle (LV). To manipulate the cannula, use the bevel end to lift the heart. Rotate the cannula during manipulations to separate the heart from the pericardium and facilitate delineation of anatomic structures. Use the cleft to visualize tissue structures and assist in creating space. It is best to have the tip of the cannula against the pericardium as opposed to the heart surface.

CARDIAC COAGULATION

⚠ WARNING ⚠

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 °C (0.9 °F) during each ablation or above an absolute maximum of 38.0 °C (100.4 °F), RF energy should be terminated until temperature reduces to baseline or under 37 °C (98.6 °F).

Care should be taken to ensure lesions overlap in order to achieve exit block.

1. Ensure all steps of device set-up are performed.
2. Select the power mode of operation on the generator (CSK-310 or MAG).
3. Place device in desired location by direct visualization. Engage vacuum by turning the stopcock.
4. Ensure contact between the electrode and cardiac tissue by:

a) Using locator arrows (FIGURE 10, #2) to visualize the direction and location of the coagulation electrode;

b) Reference dots designate the exposed ablative area of the coagulation coil;

c) Direct visualization of the device against cardiac tissue after initiation of vacuum;

d) Visual observation of saline perfusion from the unpressurized saline bag at a rate of approximately 1 drop per second through the drip chamber while vacuum is initiated.

5. Use the sensing electrodes as a secondary aid to confirm contact with cardiac tissue.

a) Pre-Coagulation with the vacuum engaged: check ECG recorder to visualize cardiac tissue waveforms.

6. Fill cannula with approximately 10 to 20 mL of room temperature saline or sterile water. Saline or sterile water may be administered via the cannula stopcock or directly through the cannula. See Cannula IFU for stopcock set-up.
7. Initiate power by pressing and releasing the footswitch or RF ON/OFF button on generator front panel. An audible signal will sound at the beginning of the RF cycle.
8. Coagulate tissue for pre-determined cycle.

			Average Lesion Dimensions		
#	Power Watts	Time Sec	Depth mm (in)	Length mm (in)	Width mm (in)
CDK-1413	30*	90*	7 (0.28)	35 (1.38)	10 (.39)

*Automatic cycles have been pre-determined for optimal tissue coagulation.

9. When the generator completes a cycle, RF energy turns off automatically, and an audible completion beep sounds for 1 second.
10. Suction saline or sterile water from pericardial space using cannula suction to improve visibility. Reference Cannula IFU for suction set-up.

⚠ WARNING ⚠

Ensure that fluid in pericardial space is aspirated during manipulation. Failure to do so may compromise visibility and device placement, leading to patient harm.

11. After the cycle is complete, disengage vacuum from the distal end of the device by turning the stopcock lever.
12. Remove the distal end of coagulation device from tissue and observe completeness of lesion.
13. Place device electrode in next desired location using guidewire if desired.

a) After reactivating the vacuum, ensure perfusion flow is functioning by observing drops in IV tubing drip chamber.

14. Check for cardiac signals from the sensing electrodes.
15. **Repeat steps 4-12 from above as needed until desired lesions have been completed.**

⚠ WARNING ⚠

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.

16. At completion of procedure, remove device from tissue, disconnect all cables and tubes and discard device, tubing sets, and cable following local governing ordinances and recycling plans for disposal or recycling of device components.

⚠ WARNING ⚠

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.

⚠ **CAUTION:** 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.

⚠ **CAUTION:** Ensure device is properly connected – switching connections may cause inadequate tissue contact and reduced functionality.

EPICARDIAL LESION CREATION

1. Prior to creating any lesions, retract the TEE probe (if used) and the NG/OG tube (if used) to the upper third of the esophagus; between 18 – 23 cm (7 to 9 in) from the incisors. At a minimum, retract the TEE probe relative to the esophagus, so that the probe is not near the atrium.
2. The upper alarm limit of the temperature probe should be set to 38.0°C (100.4°F). The preset power and time settings for ablation with the coagulation device are based on extensive testing; changing the settings may cause excessive heating and tissue damage.
3. Prior to ablation, connect a stopcock in-line between the vacuum port and the tapered adapter to control vacuum through the cannula.
4. During ablation, room temperature saline should be administered through the cannula to cool and hydrate the pericardium and underlying anatomy. Before injecting the saline, turn the cannula vacuum off by closing the in-line stopcock.

⚠ WARNING ⚠

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°C (0.9°F) during each ablation or above an absolute maximum of 38.0°C (100.4°F), RF energy should be terminated until temperature reduces to baseline or under 37°C (98.6°F).

***Note:** Baseline temperature should be taken prior to any lesion creation.

LESION LOCATION

1. Access the recommended anatomical locations endoscopically and create the epicardial lesions (see clinical study section for lesion map) based on patient anatomy and physician discretion.
   - Left Antral Posterior Pulmonary Vein Orifice Lesion
   - Right Antral Posterior Pulmonary Vein Orifice Lesion
   - Posterior Parallel Vertical Connecting Lesions
   - Left Antral Anterior Pulmonary Vein Orifice Lesion
   - Right Antral Anterior Pulmonary Vein Orifice Lesion
2. Completion of each lesion may require multiple device placements and applications of energy delivery.

POSTERIOR LEFT ATRIAL LESIONS

1. To create lesions along the posterior left atrium, medial to the RPVs or the LPVs, position the cannula under the left atrium. Once in the proper location, use the cannula to separate the pericardium to create space and allow visualization of the posterior anatomy. This is achieved with the tip of the cannula facing the pericardium (cleft facing the heart, shown in FIGURE 14). This maneuver will create a space for the device. Once the cannula is at the desired location, advance the device such that the ablating coil is in the appropriate location, with coils facing the heart.

DEVICE ORIENTATION (SEE FIGURE 14)

[1]	Cannula	[4]	Cleft
[2]	Atrium	[5]	Device
[3]	Pericardium		

1. Retract the cannula until the sensing and coagulation electrodes are distal to the cannula tip and in contact with the left atrium. This will allow the heart to better sit against the device. Always ensure proper orientation of the exposed ablation coil electrode under endoscopic visualization, utilizing the directional arrows and black stripe on back of device to confirm contact with atrial tissue only.
2. Continue to manipulate cannula and device such that lesions on the posterior LA are adjacent to one another. Repeat lesions until ablation of posterior LA is complete.
3. To avoid deformation of the pericardial reflections or the ablation device and the misdirection of RF energy delivery, do not use excessive force when advancing the device against the reflections. Retract the cannula until the sensing and coagulation electrodes are distal to the cannula tip and in contact with the LA Multiple applications of RF energy may be required to create the desired posterior left atrial lesion, with the 3 cm (1.2 in) device. Always confirm that the ablation coil arrows are directed toward the heart, away from the pericardium.
4. Epicardial lesions are visible and connection of discrete lesions provides confirmation of lesion continuity. Use the endoscope to facilitate manipulation of the cannula when confirming that the lesions intersect.

LEFT ANTRAL LESIONS

LEFT ANTRAL LESIONS (SEE FIGURE 15)

[1] Left Antral Lesion Area [2] Left Atrium [3] Right Atrium

To position the device along the antral aspect of the left pulmonary vein, (FIGURE 15), endoscopically identify the LPVs. Once in position, gently rotate the cannula clockwise to create space between the left atrium and the pericardium with the cleft toward the PVs and the tip toward the pericardium. When the desired cannula location is obtained, advance the device such that it passes anterior to the superior LPV and the exposed side of the RF coil (arrows pointing towards the left atrium, FIGURE 16), faces the left atrium. Remember that in most cases, the superior LPV is anterior to the inferior LPV. Use caution when advancing the device, to not exert excessive force. Engage the vacuum and retract the cannula until the sensing and coagulation electrodes are distal to the cannula tip and in contact with the left atrium.

DEVICE ORIENTATION TO THE SUPERIOR LPV (SEE FIGURE 16)

[1]	Left Atrium	[4]	Left Atrial Appendage
[2]	Pericardium	[5]	Locator Arrow
[3]	Left Pulmonary Vein		

RIGHT ANTRAL LESIONS

RIGHT ANTRAL LESIONS (SEE FIGURE 17)

[1] Right Antral Lesion Area [2] Left Atrium [3] Right Atrium

The anterior right atrium (FIGURE 17) can be accessed by rotating the cannula anterior to the IVC. To position the cannula anterior to the IVC, endoscopically identify the IVC and position the cannula adjacent to the IVC from the posterior left atrium. After visual conformation of the IVC, right atrium and pericardium, the cannula is rotated counterclockwise to position the cannula between the right atrium and pericardium with the cleft of the cannula directed toward the IVC and tip of the cannula toward the pericardium.

1. With the cannula positioned over the IVC, the ablation device may be advanced such that the coagulation electrode is located along the anterior orifice, between the RPV antrum and the right atrium (FIGURE 18). The cannula may be used to create space between the pericardium and the atria, allowing the coagulation electrode to seat against tissue. The cannula also helps separate the pericardium (and phrenic nerve) from the atrium, permitting the ablation device to be positioned along the Waterston's groove region that defines the interatrial junction. A lesion may be created at the left orifice to the RPV antrum.

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DEVICE LOCATION FOR RIGHT ANTRAL LESIONS (SEE FIGURE 18)

[1] Right Atrium [2] Cannula Tip

TRANSSEPTAL ACCESS AND CONVENTIONAL ENDOCARDIAL CATHETER ABLATION – (REFER TO CATHETER MANUFACTURER'S INSTRUCTIONS FOR USE):

1. Transseptal access and conventional endocardial catheter ablation should be performed by a physician authorized at his/her hospital to perform such procedures.
2. Obtain venous vascular access using appropriate introducers to insert diagnostic and ablation catheters into the right and left atria.
3. Use appropriate technique to obtain transseptal access to the left atrium after completion of the epicardial lesions. The patient should be heparinized before or after transseptal access is obtained to maintain a target ACT between 300 and 400 seconds to prevent thrombus formation.

⚠ WARNING ⚠

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°C (0.9°F) during each ablation or above an absolute maximum of 38.0°C (100.4°F), RF energy should be terminated until temperature reduces to baseline or under 37°C (98.6°F).

4. The esophageal temperature probe should be positioned under fluoroscopic guidance directly posterior to the LA at the same level as the tip of the ablation catheter during endocardial ablation.
5. Using standard mapping techniques and diagnostic catheters, the locations of breakthrough between discrete epicardial lesions are detected. The Ablation Catheter is then used to ablate these locations. If additional locations of breakthrough along an epicardial lesion are suspected the endocardial ablation catheter may be used to ensure lesion completeness. Complete the following as indicated by breakthrough locations;
   - Right Superior Pulmonary Vein Lesions
   - Right Inferior Pulmonary Vein Lesions
   - Left Superior Pulmonary Vein Ridge Lesions
   - Cavotricuspid Isthmus (Typical Atrial Flutter) Lesions
6. Once all endocardial lesions are created and confirmation of lesion completeness is achieved, including pulmonary vein isolation and bi-directional block, all catheters and sheaths are removed and vascular access sites closed using standard technique.

POST OPERATIVE CARE

Postoperative mitigations for Pericarditis and/or Inflammatory Pericardial Effusions

1. To mitigate the potential of pericarditis, pericardial effusion or delayed onset cardiac tamponade, the following postoperative care is recommended:
   - Drain management: Leave pericardial drain in the pericardial space (until drainage is less than 50 mL over at least 12 hours is preferable)
   - Prophylactic anti-inflammatory agents (e.g. NSAIDs or Colchicine). A three (3) week duration is recommended.
   - Use of diuretics as needed
   - Echocardiogram should be performed between 1-3 weeks post-procedure and whenever there are suggestive symptoms or signs to screen for late onset pericardial effusion
   - Patient education regarding symptoms of pericarditis, pericardial effusion and cardiac tamponade. Patients should be closely monitored for suspected symptoms, which should be further evaluated with appropriate imaging tests.
2. Follow-up should be conducted at approximately 30 days post-procedure to monitor for signs of delayed onset pericarditis or pericardial effusion.

ANTICOAGULATION AND ANTI-ARRHYTHMIC THERAPY MANAGEMENT

1. Anticoagulation management should be followed per the 2017 HRS Expert Consensus on Catheter and Surgical Ablation of Atrial Fibrillation, including:
   - Systemic anticoagulation therapy should be initiated for all patients post procedure through at least two months following the ablation procedure.
   - Decisions regarding the use of systemic anticoagulation more than two months following ablation should be based on the patient's risk factors for stroke and not on the presence or type of AF.
2. Anti-arrhythmic drug management post ablation should be per physician judgment.

TRAINING RECOMMENDATIONS

TRAINING PLAN FOR NEW OPERATORS

New operators are defined as de novo operators or those who have completed fewer than 5 cases with the EPi-Sense device. New operators should complete the following training:

1. Participate in a training and education module on the Instructions For Use and best practices with emphasis on the indication and risk mitigation strategies related to pericardial effusion, atrioesophageal fistula (AEF) and stroke.
2. Peer-to-peer education (in-person or online) with focus on the above areas.
3. Pre-lab didactic review covering the salient points from (1) followed by cadaver or comparable simulated models training with the EPi-Sense device.
4. Proctoring by a trained physician and /or a certified AtriCure training specialist for first 5 clinical (human) cases.

TRAINING PLAN FOR CURRENT OPERATORS

1. Current operators will be provided a training and education module on the instruction for use and best practices with emphasis on the indication and risk mitigation strategies related to pericardial effusion, atrioesophageal fistula (AEF) and stroke.
2. Supplemental in-person training course, including case presentation and hands-on training, will also be available for current users.

MAINTENANCE AND TROUBLESHOOTING

(See compatible AtriCure RF Generator (MAG or CSK-310) Operators Manual for additional system maintenance and trouble shooting)

Troubleshooting	
Situation	**Action(s)**
Device is not receiving perfusion flow	Check perfusion connections on device handle Check perfusion line connection at IV saline bag Ensure perfusion line is fully open Ensure saline bag is not empty Ensure that device perfusion line/IV tubing are not clamped/ obstructed/kinked
Device is connected but does not register pre-set power and time	Check all connections to the generator and to Cable CSK-2030 Check the connection of the patient return electrode to the patient Check the cable connection at the handle of the device; the arrows on the cable should be aligned with the arrow on the handle. If both arrows are not aligned, disconnect cable and rotate blue end 180° until aligned then reconnect.
Device does not engage with tissue	Check vacuum connections on device handle Ensure stopcock lever is in correct position Check vacuum line connection at trap and vacuum unit and ensure other lines are not open Check vacuum pressure – should be approximately -400mmHg (-7.7 psi; -53 kPa) Ensure that device and vacuum unit lines are not clamped/obstructed/ kinked Check that perfusion set-up is per IFU Ensure that device distal end is shaped to conform to tissue
Generator shuts down during cycle due to high impedance (High impedance warning will be indicated on Generator)	Check that device is still engaged with tissue (see above if not) Check for excessive material (e.g. fat, tissue) on device electrode, remove material as required Check all cable connections including indifferent electrode connection Re-start coagulation
No signals are registering on sensing equipment monitors	Check all cable connections. Ensure the cables and shrouded pins are connected per FIGURE 6 and 7 Ensure the shrouded pin numbers match the sensing electrodes on the sensing equipment
Unable to remove device from guidewire	Remove torquer from end of guidewire Flush "Guide Wire Exit" port on the handle with saline
Generator does not activate cycle (High impedance warning will be indicated on Generator as "OC" which means Open Circuit)	Ensure generator is plugged in and turned on Check all cable connections; check indifferent electrode connection for correct position and it is adhered to the patient Ensure device electrode is in direct contact with desired tissue Check for material on device electrode, remove material as required Check footswitch connection Ensure that generator is in "Power Control Mode" Ensure that Time is not set to "zero" Refer to the Instructions for Use for the compatible AtriCure RF generator (CSK-310 or MAG) for more information.
Guidewire will not insert into device	Ensure guide wire is being inserted into guide tube opening Ensure recommended guidewire is being used Ensure guide tube opening is not blocked Ensure device is not kinked
Device will not advance along Guidewire or through optional Cannula	Ensure guide tube is not kinked Flush "Guide Wire Exit" port on the handle with saline Lubricate lumen of Cannula with sterile saline

GLOSSARY OF TERMS

Electrocoagulation: Surgical procedures in which high-frequency electric current is used to coagulate tissues.

Coagulation Electrode: The metal conductor in the coagulation device used to transmit radiofrequency energy to tissue.

Sensing Electrodes: Metal conductors between the coagulation electrode used to sense cardiac voltages from the heart.

Indifferent, Dispersive Electrode: Commonly referred to as the "return electrode" or "patient electrode" or "ground pad." Large surface area indifferent ground used to complete the circuit of the electrical current. Usually placed on the patient's back, the indifferent, dispersive electrode is connected to the generator at the Indifferent Connector.

ABBREVIATIONS

RF: Radiofrequency
VAC: Vacuum
IFU: Instructions for Use

LIMITED WARRANTY

AtriCure warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular use. AtriCure's sole obligation under this warranty is limited to the repair or replacement of this instrument. AtriCure neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond AtriCure's control directly affect the instrument and the result obtained from its use. AtriCure assumes no liability with respect to instruments deliberately mis-used or those reused, reprocessed or re-sterilized and makes no warranties expressed or implied, including but not limited to merchantability or fitness for intended use, with respect to such mis-used or reused instruments. AtriCure shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the deliberate mis-use or re-use of this instrument.

DISPOSAL

After use this device should be treated as medical waste and disposed of following hospital protocol.

SSCP

A summary of the safety and clinical performance of the device can be found in the European database on medical devices (Eudamed) at https://ec.europa.eu/tools/eudamed by using the following Basic UDI-DI search key: 0840143900000000000010ZC

SERIOUS INCIDENT

Any serious incident that has occurred in relation to this device should be reported to AtriCure and the competent authority of the Member State in which the user and/or patient is located.

RETURN OF USED PRODUCT

If for any reason this product must be returned to AtriCure, Inc., a return goods authorization (RGA) number is required from AtriCure, Inc., prior to shipping. If the product has been in contact with blood or body fluids, it must be thoroughly cleaned and disinfected before packing. It should be shipped in either the original carton or an equivalent carton, to prevent damage during shipment; and it should be properly labeled with an RGA number and an indication of the biohazardous nature of the contents of shipment. Instructions for cleaning and materials, including appropriate shipping containers, proper labeling, and an RGA number may be obtained from AtriCure, Inc.

DISCLAIMER

Users assume responsibility for approving the acceptable condition of this product before it is used, and for ensuring that the product is only used in the manner described in these instructions for use, including, but not limited to, ensuring that the product is not re-used.

Under no circumstances will AtriCure, Inc. be responsible for any incidental, special or consequential loss, damage, or expense, which is the result of the deliberate misuse or re-use of this product, including any loss, damage, or expense which is related to personal injury or damage to property.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

REFER TO THE OUTER PACKAGE LABEL TO SEE WHICH SYMBOLS APPLY TO THIS PRODUCT.

VAC	Vacuum	RF	Radiofrequency
	Perfusion		Manufacturer
	Country And Date of Manufacture	REF	Catalog number
EC REP	Authorized representative in the European Community		Caution
LOT	Batch code	#	Model number
UDI	Unique device identifier	CE 2797	Meets the Medical Device Regulation (MDR) 2017/745
MD	Medical device		Importer
	Use-by date	STERILE	Do not resterilize
	Do not re-use		Do not use if package is damaged
	Single sterile barrier system with protective packaging inside		Single sterile barrier system with protective packaging outside
	Follow instructions for use	STERILE R	Sterilized using irradiation
	Waste electrical and electronic equipment	LATEX	Not made with natural rubber latex
PHT	Does not contain Phthalates		Non-pyrogenic
	Contains hazardous substances		Defibrillation Proof Type CF Applied Part
	Non-ionizing Radiation	85% 30%	Transit/Storage Humidity limit
-20°F (-29°C) 131°F (55°C)	Transit/Storage Temperature limit		

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