Instructions for Use

for the

EPi-Sense® Guided Coagulation System with VisiTrax®

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Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

IFU for Coagulation Kit
LBL-1819-US Rev. G

INSTRUCTIONS FOR USE

Product Description

Components of the Guided Coagulation System:

(1) EPi-Sense® Guided Coagulation System with VisiTrax® Device (sterile, for single-use only) – multiple formats include:

- o **CDK-1411** Coagulation Device, 1cm,
- o **CDK-1412** Coagulation Device, 2cm
- o **CDK-1413** Coagulation Device, 3cm,

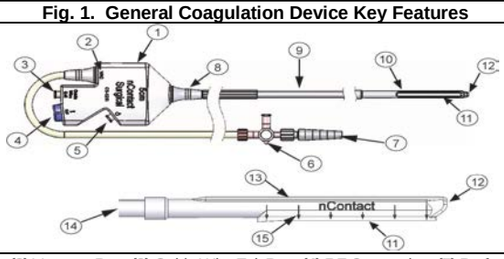
ACCESSORIES PROVIDED SEPARATELY:

(2) **CS-3000** RF Generator plus accessories, Non-Sterile, Reusable (under separate IFU)
(3) **CSK-2030** Sensing Cable, Non-Sterile, Reusable (under separate IFU)
(4) **CSK-2000** RF Cable, Sterile, Single Use (under separate IFU)
(5) nContact Cannula– multiple formats, Sterile, Single Use (under separate IFUs)
(6) Stylet –multiple formats, Sterile, Single Use (under separate IFUs)

The EPi-Sense Guided Coagulation Devices with VisiTrax are manufactured of latex-free materials and are PVC-free.

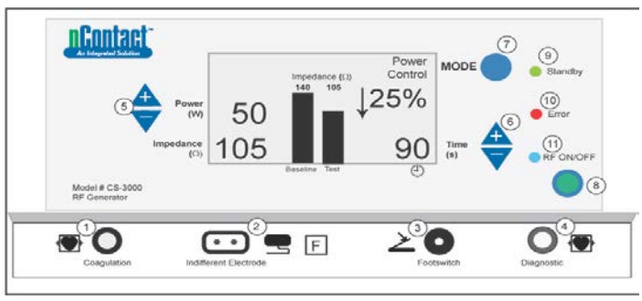
Product Features

Fig. 1. General Coagulation Device Key Features



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

Fig. 2. Generator Key Features



(1) CSK-2030 Cable Connection; **(2)** Indifferent, Dispersive Electrode Connection; **(3)** Footswitch Connection; **(4)** Diagnostic Device Connection; **(5)** Power Adjustment; **(6)** Time Adjustments; **(7)** Mode button; **(8)** RF ON/OFF Button; **(9)** Standby Mode ED; **(10)** Error LED; **(11)** RF LED;

Indications:

The EPi-Sense Guided Coagulation System with VisiTrax is intended for the coagulation of cardiac tissue using Radiofrequency (RF) energy using thoracoscopic, endoscopic, and laparoscopic surgical techniques.

The EPi-Sense Guided Coagulation System with VisiTrax may be used for temporary cardiac signal sensing and recording during surgery when connected to an external recording device.

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.

⚠ Warnings and Precautions:

- 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 nContact Stylet or 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.
- The coils 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.
- Do not scrape or scratch off the gold surface of the sensing electrodes when cleaning the RF coagulation electrode.
- If the device is used near a pacemaker, a potential hazard exists due to possible interference with the action of the pacemaker and potential damage to the pacemaker. A pacemaker in a patient undergoing any surgery with RF energy must be turned off before applying RF energy.
- Implantable cardioverter/defibrillators can also be adversely affected by RF signals.
- 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. This can be minimized or resolved by rearranging monitoring device cables so they do not overlap the Coagulation System cables.
- 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.
- To avoid unintentional coagulation, care should be taken to ensure overlapping structures are separated and thermally isolated when anatomy allows.
- Inspect all devices and packaging prior to use. If any breach of the packaging is found the sterility of the product cannot be ensured. Do not use product if breach is found.
- While the distal portion of the device is designed to be malleable to conform to the anatomy of the area to be coagulated, excessive manipulation, torqueing, 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 – do not squeeze or clamp the electrode. Do not cut or tear silicone.
- 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.
- The coagulation device is only compatible with the nContact generator, cables, and accessories. Use of another manufacturer's accessories may cause damage to the device and/or injury to the patient.
- Coagulation devices have been tested and have pre-set power and time settings for optimal coagulation. Changing these settings may cause coagulation dimension to vary from the values given in this document.
- Care should be taken to ensure device is not moved during RF power delivery. Device movement may cause loss of suction and unintentional coagulation.
- 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 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/torqueing/over manipulating device can cause the lumen to collapse, 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 on the sterile field during manipulation.
- Care should be taken to visualize the devices and optional Stylet 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 coagulation of tissue, ensure guidewire and/or scope are not between tissue and coagulation device electrode.
- If a guidewire is used with guided device, ensure that insulative covering is intact along the exposed Guidewire.
- 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.

Additional warnings and precautions can be found in the nContact Coagulation System Radiofrequency (RF) Generator Unit Model **CS-3000** Operators Manual (LBL-1095).

Potential Complications of the Coagulation Procedure

- Infection
- Cardiac tamponade
- Pulmonary vein stenosis
- Vessel injury
- Pericardial effusion
- Tissue perforation
- Excessive bleeding
- Phrenic nerve injury
- Left atrial rupture
- Esophageal Fistula
- Myocardial infarction
- New arrhythmias
- Thromboembolic complication
- Neurologic complication
- Death
- Complete heart block requiring permanent pacemaker implantation

Required Equipment/Supplies

- Only 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 (-533 mbar; -15.75 inHg; -40 cmHg; -7.73 psi; -400 torr; -53 kPa)
- Valleylab PolyHesive Patient Return Electrode (REF E7506)

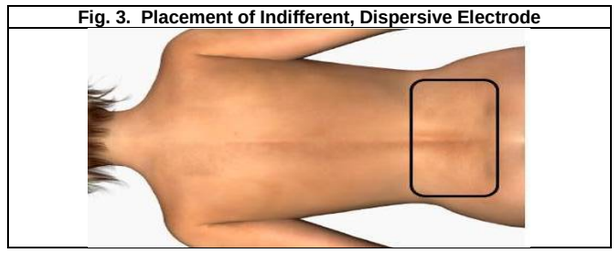
Recommended Optional Equipment/Supplies

- .035" Guidewire100cm
- nContact Cannula Kit (multiple formats)
- nContact Stylet Kit (multiple formats)
- nContact Sensing Cable Assembly Kit (non-sterile)
- Endoscope - see nContact Cannula IFU scope recommendations
- Temporary external electrogram recording device that meets the following specifications; Complies with IEC 60601-1 and system accepts shielded 2mm pin connectors

Device Set Up

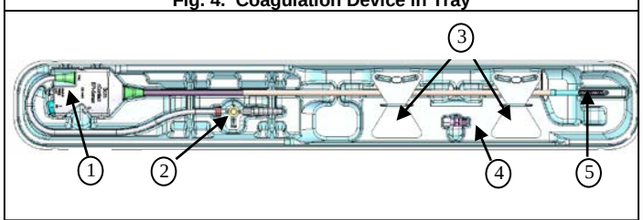
1. Place the indifferent, dispersive electrode on patient, per Fig. 3, and connect cable to front of generator (Fig. 2, #2). Ensure entire area of electrode is reliably attached to the patient's body.

Fig. 3. Placement of Indifferent, Dispersive Electrode



2. Place generator footswitch near the surgeon and connect the footswitch cable to front of generator. Refer to Fig. 2, #3.
3. Inspect all trays, pouches, 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.
      ii. Remove the Touhy Borst fitting from the tray and attach to guide wire exit port on the handle.

Fig. 4. Coagulation Device in Tray



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

⚠ **CAUTION**: Using excess force to remove the device from the tray may result in damage to the device.

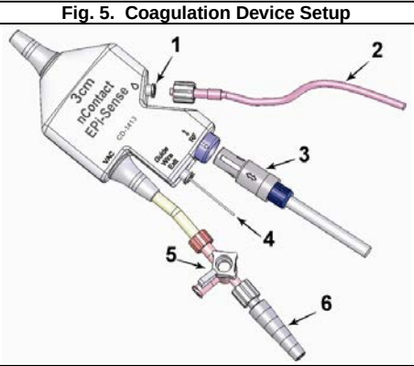
4. Prepare the Vacuum

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 (Fig 5 & 6). Use the stopcock to apply and release the vacuum to the distal assembly.

b) Ensure the vacuum unit pressure is set to -400 mmHg.

⚠ **CAUTION**: Do not exceed -550 mmHg for vacuum use – exceeding this pressure may reduce suction capabilities, reduce tissue contact, or cause tissue damage.

Fig. 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, Fig. 5, #1. Verify IV line is fully open.
   c) Insert IV tubing set into 0.9% normal saline bag.
   d) Turn on vacuum pressure and prime device by engaging the suction with a sterile surface (gloved hand).
      i. Ensure perfusion flow is functioning by observing drops in IV tubing. 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.

⚠ **CAUTION**: 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.

⚠ **CAUTION**: Ensure device is primed prior to first RF power delivery.

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

⚠ **CAUTION**: Ensure perfusion/IV tubing is connected to the handle at the "droplet" symbol – do not connect perfusion tubing to stopcock or "Guide Wire Exit".

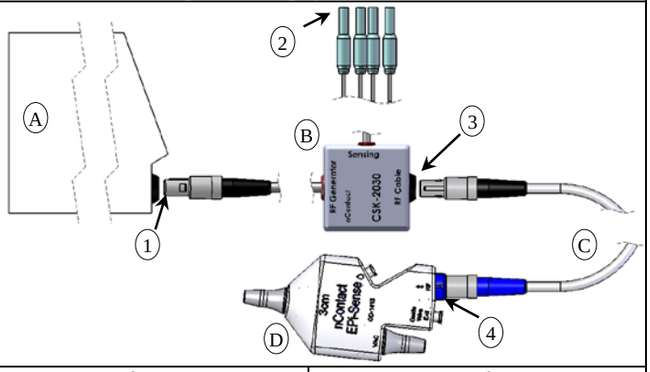
6. Connect nContact RF cable **CSK-2000** to device handle where indicated by the 'RF' symbol - blue connection to blue connection, Fig. 5, #3 & Fig.6, #4.

⚠ **CAUTION**: Ensure arrows on cable and handle are aligned and cable is completely connected. Device will not register on generator if cable is incorrectly connected.

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

   a) Connect the black end of the Sensing Cable **CSK-2030** to the generator front panel connector (Fig. 2, & Fig 6, #1).
   b) Connect the black end of the RF cable **CSK-2000** to the black Bessel receptacle of the Sensing Cable **CSK-2030** per the Fig. 6, #3.

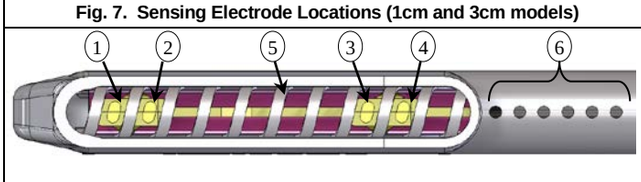
Fig. 6. Sensing System Connection



Equipment	Connections
(A) Generator **CS-3000**;	**(1)** CSK-2030 to CS-3000
(B) Sensing Cable **CSK-2030**;	**(2)** CSK-2030 to Sensing
(C) RF Cable **CSK-2000;**	**(3)** CSK-2000 to CSK-2030
(D) Device **CDK-14XX**	**(4)** CSK-2000 to CDK-14XX

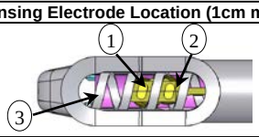
7. When connecting the shrouded pins from Cable **CSK-2030** (Fig 6, #2) to the ECG recorder equipment refer to Fig 7 below.

Fig. 7. Sensing Electrode Locations (1cm and 3cm models)



(1) Distal #1 Sensing Electrode = CSK-2030 Shrouded Pin **#1**
(2) Distal #2 Sensing Electrode = CSK-2030 Shrouded Pin **#2**
(3) Proximal #3 Sensing Electrode = CSK-2030 Shrouded Pin **#3**
(4) Proximal #4 Sensing Electrode = CSK-2030 Shrouded Pin **#4**
(5) Coagulation Electrode
(6) Reference Dots

Sensing Electrode Location (1cm model)

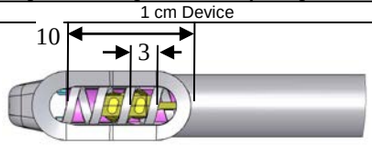


(1) Distal #1 Sensing Electrode = CSK-2030 Shrouded Pin **#1**
(2) Distal #2 Sensing Electrode = CSK-2030 Shrouded Pin **#2**
(3) Coagulation Electrode

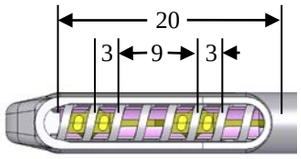
⚠ **CAUTION**: Ensure inputs from the ECG recorder are isolated from earth ground, if not, there is an increased possibility of fibrillation.

Fig. 8. Sensing Electrode Spacing in mm

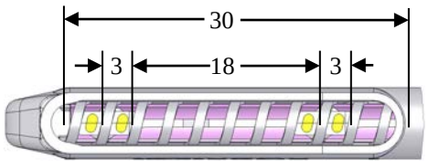
1 cm Device



2 cm Device

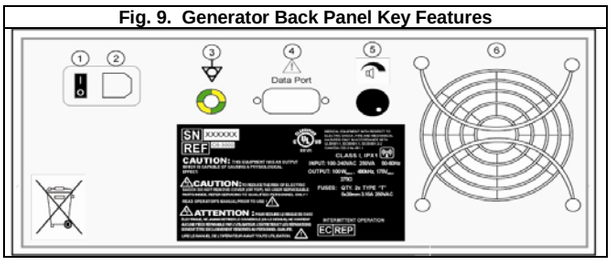


3 cm Device



8. Connect power cable to generator back panel connector (Fig. 9, #2) then power on the generator via the Power ON/OFF rocker switch (Fig. 9, #1). Refer to the Operator Manual for complete generator instructions.

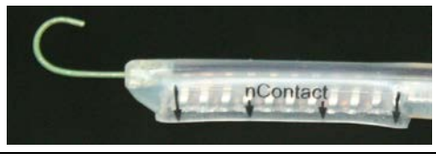
Fig. 9. Generator Back Panel Key Features



Manipulation of Guided 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 guided coagulation device. Ensuring that the floppy end of the guide wire is at the distal end of the coagulation device (Fig. 10).

Fig. 10. Accessory Guide Wire and Distal End of Coagulation Device

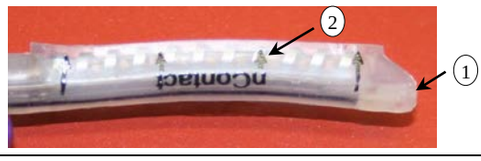


2. Secure the rigid end of the accessory guide wire with a Touhy Borst or stopcock such that the floppy end of the guide wire is in the desired position relative to the distal end of the coagulation device.
3. Advance the guided coagulation device through the cannula until positioned at desired coagulation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

Manipulation of Guided Coagulation Device Over Cannula Guidewire

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

Fig. 11. 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 guided coagulation device (Fig. 11, #1).
5. Slide guided coagulation device until guidewire protrudes from handle of guided coagulation device. If available, attach torquer to the end of guidewire protruding from handle of device.
6. Advance the guided coagulation device along the guidewire until positioned at desired coagulation location using guidewire to assist in placement.

Tissue Coagulation

1. Ensure all steps of device set-up are performed.
2. Select the power mode of operation on the generator.
   Ensure contact between the electrode and cardiac tissue by;
   i. Using locator arrows (Fig 11, #2) to visualize the direction and location of the coagulation electrode

ii. Reference dots designate the exposed ablative area of the coagulation coil.

iii. Direct visualization of the device against cardiac tissue after initiation of vacuum;

iv. 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.

4. 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.
5. 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.
6. Coagulate tissue for pre-determined cycle.

			Average Lesion Dimensions			
Device Code and Size	Power Watts	Time Sec	Depth mm	Length mm	Width Mm	Volume mm^3
CDK-1411, 1cm	10*	120*	7	18	10	803
CDK-1412, 2cm	25*	60*	6	28	9	1085
CDK-1413, 3cm	30*	90*	7	35	10	1691

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

7. When the generator completes a cycle, RF energy turns off automatically, and an audible completion beep sounds for 1 second.
8. After the cycle is complete, disengage vacuum from the distal end of the device by turning the stopcock lever.
9. Remove the distal end of coagulation device from tissue and observe completeness of lesion.
10. Place device electrode in next desired location using guidewire if desired.
11. **Repeat steps 3-10 from above as needed until desired lesions have been completed.**
12. 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.

⚠ **CAUTION**: Positioning and manipulation of the coagulation device without a guide wire inserted into the guide tube may cause the guide tube to kink.

⚠ **CAUTION**: To avoid interruption of vacuum or perfusion flow, do not leave device tubing clamped during coagulation of tissue.

⚠ **CAUTION**: Large blood clots and tissue particles may clog vacuum lumen and impair suction.

⚠ **CAUTION**: To avoid tissue damage: Do not move the device if vacuum is engaged.

⚠ **CAUTION**: Bending device without guidewire in guide tube may kink the guide tube. Avoid inserting guidewire into a kinked guide tube.

⚠ **CAUTION**: Do not torque guided 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.

⚠ **CAUTION**: Visualize the distal end of the device, to ensure it is not pinching/entrapping tissue with other devices, such as the optional nContact Cannula.

⚠ **CAUTION**: 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.

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

⚠ **CAUTION**: Temporarily unused active electrodes should be stored in a location isolated from the patient.

Maintenance and Troubleshooting

(See LBL-1095 nContact Coagulation System Radiofrequency (RF) Generator Unit Model CS-3000 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 -400 to -550 mmHg • 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 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 figures 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

Troubleshooting	
Situation	**Action(s)**
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 generator Operator Manual LBL-1095
Guidewire will not insert into device	• Ensure guidewire 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 nContact Cannula	• Ensure guide tube is not kinked • Flush "Guide Wire Exit" port on the handle with saline • Lubricate lumen of nContact Cannula with sterile water or 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 or thigh, the indifferent, dispersive electrode is connected to the generator at the Indifferent Connector.

Abbreviations

RF	Radiofrequency	**IFU**	Instructions for Use
VAC	Vacuum	**LBL**	Label

Symbols

	Manufacturer		Catalog Number
VAC	Vacuum	RF	Radiofrequency
OC	Open Circuit		Perfusion
	Equipotential		Footswitch Connection
	Indifferent, Dispersive Electrode		Attention, Consult Accompanying Documents
	Caution: Electrical Shock Hazard		Defibrillation Proof Type CF Applied Part
W	Watts	**Ω**	Ohms
	Time	**s**	Seconds
	Follow instructions for use		Non-ionizing Radiation
	Lot Number		Sterile by gamma irradiation
	Expiry Date		Single Use Only
	Latex Free		CE Mark and Identification number of Notified body

Manufacturer:

AtriCure Incorporated
7555 Innovation Way
Mason, Ohio 45040 USA
Customer Service:
1-866-349-2342 (toll free)
1-513-755-4100 (phone)

Customer Service

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. 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 control directly affect the instrument and the result obtained from its use. AtriCure's obligation under this warranty is limited to the repair or replacement of this instrument and AtriCure shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use 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. AtriCure assumes no liability with respect to instruments 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 instrument.

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