

EPI-Sense® ST RF Cable (“RF Cable”)

CSK-2060

INSTRUCTIONS FOR USE

CAUTION: Federal law (US) restricts this device to sale by or on the order of a physician.

For Use only with the AtriCure EPI-Sense® ST Coagulation System

DEVICE DESCRIPTION:

Sterile cable for connection of compatible EPI-Sense family coagulation device (EPI-Sense ST Coagulation Device) and compatible AtriCure(R) RF generator (CS-3000 or MAG) or Sensing Cable. STERILE in unopened, undamaged package. For single use only. Do not re-sterilize. Do Not Re-Use.

CONTENTS:

CSK-2060 RF Cable contains:

- 1 each CS-2060 RF extension cable in sterile packaging
- 1 each Instructions for Use (IFU) brochure.

PROVIDED SEPARATELY BY ATRICURE:

- EPIST Coagulation Device, Sterile, Single Use (under separate IFU).
- Compatible AtriCure® RF Generator (CS-3000 or MAG), plus accessories, Non-Sterile, Reusable (under separate IFU).
- CSK-2030 Sensing Cable, Non-Sterile, Reusable (under generator IFU).
- CSK-6131 Cannula with Guide, Sterile, Single Use (under separate IFU).

COMPONENTS REQUIRED FOR USE BUT NOT OFFERED BY ATRICURE:

- Indifferent patient return electrode – surface area of 21 square inches (136 cm²) minimum.

INDICATIONS FOR USE:

For use only with compatible AtriCure RF Generator (CS-3000 or MAG), EPI-Sense ST Coagulation Device (EPIST), and Sensing Cable (CSK-2030).

⚠️ WARNINGS ⚠️

For information concerning all warnings, precautions, and troubleshooting, see nContact Coagulation System Radiofrequency (RF) Generator Unit Model CS-3000 or MAG Operators Manual and EPI-Sense ST Coagulation Device (EPIST) IFU. Failure to follow the instructions contained in the CS-3000 or MAG manual and EPIST IFU may lead to an inability to complete the procedure.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure, which in turn may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

⚠️ WARNINGS ⚠️

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.

Do not use if cable is damaged as the procedure may not be able to be completed. Replace cable.

Do not use cable if yellow LED on EPI-Sense family coagulation device is illuminated. This indicates low battery and RF ablation energy will not be delivered. Replace cable. The RF cable has a limited functional life; if greater than 4 hours of use are required, it is recommended to use a second cable.

The Coagulation Device, RF Generator, Cables and Accessories have been tested as a system and comply with the limits for medical devices to IEC 60601-1-2. Use of another manufacturer's accessories may cause damage to the equipment or injury to the patient.

Replace device if additional ablations cannot be performed after 30 ablations.

CAUTION: Only use with Atricure RF generator (CS-3000 or MAG).

INSTRUCTIONS FOR USE:

1. Inspect package and RF cable for damage. If either RF cable or package is damaged, discard without using.
2. Remove RF cable from sterile package.

⚠️ WARNING ⚠️

Arrow indicators and color coded ends on connectors should be used to aid in correct alignment to avoid damage to cable ends.

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

3. Connect BLUE strain relief end of cable to BLUE strain relief end of the EPI-Sense ST Coagulation Device.
4. Connect BLACK end of cable to:
 - a) BLACK port on RF Generator or
 - b) BLACK port on the sensing cable
5. Follow instructions for use of generator, coagulation device, and sensing cable.
6. To disconnect cable, grasp by connector cover and pull back. Do NOT pull on cable.

⚠️ WARNING ⚠️

RF Cable contains a Lithium disposable battery. Do not recharge, disassemble, heat above 60°C, incinerate, or expose the battery directly to water to avoid injury to user or damage to device.

Ensure device is disposed of following local governing ordinances and recycling plans to prevent biohazard exposure.

7. After use, this device should be treated as medical waste and disposed of following hospital procedure
 - a) To remove battery, unscrew the cover, using a #1 Phillips screwdriver, to access the battery.

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	-20 to 55°C (-4 to 131°F)	30% to 85% humidity	N/A
Storage	-20 to 55°C (-4 to 131°F)	30% to 85% humidity	N/A

NOMENCLATURE:

1. RF = Radiofrequency
2. IFU = Instructions For Use
3. LT = Label

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.

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.

DISPOSAL






















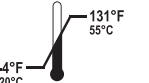
After use this device should be treated as medical waste and disposed of following hospital protocol.

RETURN OF USED PRODUCT

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.

EXPLANATION OF SYMBOLS ON PACKAGE LABELING

Refer to the outer package label to see which symbols apply to this product.

	Manufacturer		Country and Date of Manufacture
	Caution		Catalog Number
	Batch Code		Model Number
	Unique device identifier		Use-by Date
	Do not resterilize		Do not re-use
	Do Not Use if Package is Damaged		Single sterile barrier system with protective packaging inside
	Sterilized Using Irradiation		Single sterile barrier system with protective packaging outside
	Follow instructions for use		Waste Electrical and Electronic Equipment
	Not made with natural rubber latex		Does not contain Phthalates
	Defibrillation Proof Type CF Applied Part		Prescription Use Only
 30% 85% Transit/Storage Humidity limit		 -4°F 131°F -20°C 55°C Transit/Storage Temperature limit	



AtriCure Inc.
7555 Innovation Way
Mason, Ohio 45040 USA
+1 866 349 2342
+1 513 755 4100