AtriCure

EPi-Sense ST™ RF Cable ("RF Cable")

 # CSK-2060

Instructions for Use

Rx ONLY

⚠ ***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 EPi-Sense ST™ Coagulation Device and nContact™ RF Generator 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.

INDICATIONS FOR USE:

For use only nContact RF Generator (CS-3000), EPi-Sense ST Coagulation Device (EPIST), and Sensing Cable (CSK-2030).

⚠ WARNING ⚠

For information concerning all warnings, precautions, and troubleshooting, see nContact Coagulation System Radiofrequency (RF) Generator Unit Model CS-3000 Operators Manual and EPi-Sense ST Coagulation Device (EPiST) IFU. Failure to follow the instructions contained in the CS-3000 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.

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 ST Coagulation Device is illuminated. This indicates low battery and RF ablation energy will not be delivered. Replace cable.

⚠ **CAUTION**: Only use with nContact RF generator.

INSTRUCTIONS FOR USE:

CSK-2060

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.

⚠ **CAUTION**: Arrow indicators 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.

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 60°C (-4 to140°F)	30-85% relative humidity	
Storage	-29 to 55 C (-20 to 131 F)	0-90% relative humidity (90% for <500 hr)	

EXPLANATION OF SYMBOLS FROM PACKAGE LABEL:

	Caution	LOT	Lot Number
#	Model Number	REF	Catalog Number
	Single Use Only	2 STERILIZE	Do not resterilize
	Use by Date		Do Not Use if Package is Damaged
Rx ONLY	Caution: Federal (US) law restricts this device to sale by or on the order of a physician or other licensed practitioner.		Follow instructions for use
			Manufacturer
LATEX	Not made with natural rubber or dry rubber latex	US	Date & Country of Manufacture
85% % 30%	Transit Humidity Range	60°C 140°F -20°C -4°F	Transit Temperature Range
	Waste Electrical Electronic Equipment	STERILE R	Sterilized Using Irradiation
	Defibrillation Proof Type CF Applied Part		

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.

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