AtriCure®

Rx ONLY

# EPi-Sense® RF Cable ("RF Cable")

## # CSK-2000

## Instructions for Use

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

**INDICATIONS FOR USE:**

For use only with Compatible AtriCure RF Generator (CS-3000 or MAG) , Coagulation Device, and Sensing Cable.

**DEVICE DESCRIPTION:**

**Components of the EPi-Sense RF Cable:**

- One (1) CSK-2000 EPi-Sense RF Cable (STERILE in unopened, undamaged package. For single use only. Do not re-sterilize. Do Not Re-Use)
- One (1) Instructions for Use (IFU) Brochure.

**PROVIDED SEPARATELY BY ATRICURE:**

- CDK-1413 EPi-Sense 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 $cm^2$) minimum

**INSTRUCTIONS FOR USE:**

The RF Cable CSK-2000 is not made with natural rubber latex and does not contain PVC or phthalates.

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

⚠ **WARNING** ⚠

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 end of cable to BLUE port on EPi-Sense Coagulation Device
4. Connect BLACK end of cable to
   a) BLACK port on AtriCure Compatible RF Generator (CS-3000 or MAG) 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 wire.
7. After use this device should be treated as medical waste and disposed of following hospital protocol.

**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 55C (-20 to 131F) | 30% to 85% humidity | N/A |
| **Storage** | -29 to 55C (-20 to 131F) | 30% to 85% humidity | N/A |

⚠ **WARNINGS** ⚠

For information concerning all warnings, precautions, and troubleshooting see nContact Coagulation System Radiofrequency (RF) Generator Unit Model CS-3000 Operators Manual and EPi-Sense Coagulation Device (CDK- 1413) IFU. Failure to follow the instructions contained in the CS-3000 manual and EPi-Sense IFU may lead to an inability to complete the procedure.

For single use only. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing or re-sterilization 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 re-sterilization 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.

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

The EPi-Sense 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.

Cables are sterile in unopened, undamaged, outer package. For single use ONLY to avoid infection. Do NOT re-sterilize. Do NOT re-use. If opened and unused, discard immediately.

⚠ **CAUTION:** For Use only with compatible AtriCure RF Generator (CS-3000 or MAG)

**NOMENCLATURE:**

[1] RF=Radiofrequency [2] 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.

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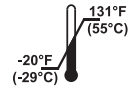
## EXPLANATION OF SYMBOLS ON PACKAGE LABELING

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

| | | | |
|---|---|---|---|
|  | Manufacturer |   | Country and Date of Manufacture |
|   | Catalog Number |  | Caution |
|   | Batch code |   | Model Number |
|   | Unique device identifier |   | Prescription Use Only |
|  | 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 |  | Single Sterile Barrier System with protective packaging outside |
|   | Sterilized Using Irradiation |  | 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 |
|   Transit/Storage Humidity limit | |   Transit/Storage Temperature limit | |

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