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INSTRUCTIONS FOR USE

EPI-Sense® ST RF Cable

DEVICE DESCRIPTION:

This device is a combination of compatible EPI-Sense® family coagulation device (EPI-Sense® ST) Coagulation Device and compatible EPI-Sense® RF generator (CSK-310 or MAG) or Sensor Cable. STERILE in unopened, undamaged package. For single use only. Do not reuse.

CONTENTS:

• One (1) EPI-Sense® ST RF Cable (STERILE in unopened, undamaged package. For single use only. Do not reuse).

• One (1) Instructions for Use (IFU) brochure

COMPONENTS REQUIRED FOR USE NOT PROVIDED BY ATCURE:

The EPI-Sense® ST RF Cable is a medical device for users licensed medical doctors perform coagulation and/or thoracic procedures using the EPI-Sense® family of coagulation devices for treatment of patients with amyloidosis, renal fibrillation, and atrial fibrillation.

INDICATIONS FOR USE:

The EPI-Sense® ST RF Cable is designed to transmit RF energy from the compatible EPI-Sense® RF Generator (CSK-310 or MAG) to the attached EPI-Sense® family coagulation device to achieve its intended purpose.

INTENDED PURPOSE:

The EPI-Sense® ST RF Cable is a medical device for users licensed medical doctors perform coagulation and/or thoracic procedures using the EPI-Sense® family of coagulation devices for treatment of patients with amyloidosis, renal fibrillation, and atrial fibrillation.

THE CLINICAL BENEFIT:

To achieve the clinical benefit of the attached EPI-Sense® family of coagulation devices.

WARNING! □

For information concerning all warnings, precautions, and troubleshooting, see compatible EPI-Sense® RF Generator Operator Manual and EPI-Sense® family coagulation device IFU (Information for Use).

However, see the attached EPI-Sense® ST RF Cable IFU for specific instructions and troubleshooting steps to take if you experience any adverse reactions or problems with your device.

NOTICE:

For safety, only use the device for its intended purpose. Do not reuse, reprocess, or sterilize. Reuse, reprocessing or sterilization may compromise the structural integrity of the device and lead to device failure, which is most likely in patient injury, illness, or death, or result in 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.

NOTICE:

Inspect and clean the device prior to use. This device has a limited lifetime; do not use after the expiration date.

NOTICE:

The Coagulation Device, RF Generator, Cables, and Accessories have been tested as a system and comply with the limits for devices in IEC 60011-1, -2, and -3 of another manufacturer's accessories may cause damage to the equipment or injury to the patient.

NOTICE:

Replace device if additional cleaning cannot be performed after 30 absorptions.

INSTRUCTIONS FOR USE:

1. Insert package and bag for device. If either RF cable or package is damaged, discard without using.

2. Remove device from sterile package.

WARNING! □

Arrow indicates and color coded red on connectors should be used to aid in correct alignment to avoid damage to cables ends.

NOTICE:

Do not use the device if yellow end of the cable is visible.

NOTICE:

Follow instructions for use of generator, coagulation device, and sensing.

NOTICE:

Do not use the device if yellow end of the cable is visible.

NOTICE:

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

NOTICE:

To remove battery, unscrew the cover using a Phillips screwdriver, to access the battery.

ENVIRONMENTAL SPECIFICATIONS:

Temperature: 10 to 40°C (50 to 104°F)

Humidity: 30%–75% relative humidity (10 to 15 psi)

Atmospheric Pressure: 760 to 1060 millibars (10 to 15 psi)

Transit: -20 to 55°C (-4 to 131°F)

Storage: -20 to 55°C (-4 to 131°F)

NOTICE:

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

NOTICE:

After removal of the device, it is recommended to store the device in its original packaging.

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NOTICE:

An illustration of a person sitting cross-legged, facing right, and holding a book or document open with both hands as if reading it.

en Waste electrical and electronic equipment^{bz} bg Отпадъци от електрическо и електронно оборудване^{da} cs Odpadní elektronická a elektronická zářivka^{de} Afval af elektrisk og elektronisk udstyr^{de} Elektro- und Elektronik-Altergäte^{el} El Ämbožtja láptektrikai ja läketeknolojikou eziplišojo^{es} Residuos de aparatos eléctricos y electrónicos^{fr} et Elektri- ja elektronikkalaitomeru^{fi} Déchets d'équipements électriques et électroniques^{hr} I/O Odpadna električna v elektronička oprema^{hu} hu Elektromos és elektronikus berendezések hulladéka^{it} Úrgangar raf- og rafeindattaja^{ja} I/Rifiuti di apparecchiature elettriche ed elettroniche^{lt} Elektros ir elektroninės įrangos atliekos^{lv} Elektrisko un elektronisko iekārtu atkritumi^{nl} Afgedankte elektrische en elektronische apparatuur^{no} Avfall fra elektrisk og elektronisk utstyr^{pl} Zużyty sprzęt elektryczny i elektroniczny^{pt} Resíduos de equipamentos elétricos e eletrônicos^{ro} Deseur de echipamente electrice și electronice^{sk} Odpad z elektrických a elektronických zariadení^{sl} Odпадna električna v elektronska oprema^{sq} Mbjetje nga pajisjet elektrike dhe elektronike^{sv} Avfall från elektrisk och elektronisk utrustning



en Does not contain Phthalates^{bz} bg Не съдържа фталати^{ca} Neobsahuje ftalát^{da} Indeholder ikke phthalater^{de} Enthält keine Phthalate^{el} Δεν περιέχει φθαλικές εύνοιες^{es} No contiene ftalatos^{fr} Et Ei sisalda ftalate^{fi} Ei sisalja ftalateja^{ja} fr Ne contient pas de phthalates^{hr} Ne sadrži ftalate^{hu} Nem tartalmaz ftalátokat^{it} Inniheldur ekki phthalat^{lv} Non contiente ftalati^{lt} Sudetyne nera ftalatu^{lv} Nesarut ftalatus^{nl} Bevat geen ftalaten^{no} Innehelder ikke ftalater^{pl} Nie zawiera ftalanów^{pt} Não contém ftalatos^{ro} Nu confine ftalati^{sk} Neobsahuje ftaláty^{sl} Ne vsebuje ftalato^{sv} Nu är påbemann ftalat^{sv} Inte ftalater

en Transit/Storag Temperature limit^{1/bg Ограничение на температурата при транспорт/съхранение\}

cs Mezní teplota při přepravě/skladování/da Transit/

opbevaringstemperaturgrænse/de Temperaturrengrenzwert für Transport/Lagerung/el Ορος θερμοκρασίας κατό τη μεταφορά/αποθήκευση/les Limite de température durante el transporte/almacenamiento/et Temperaturuiuring transportimisiel/hoiustamisel/v Kuljetusken/säilytyksen lämpötilarajat/

fr Limite de température lors du transport/stockage\

hr Granična vrijednost temperature za transport/skladištenje\

hu Szállítási/tárolási hőmérséklet korlát/is Hitatakmörkün flutnings/gemysl/it Limite di temperatura di trasporto/ stoccaggio/lt Gabenimo / laikymo temperatūros riba\

lv Pārvadāšanas/glabāšanas temperatūras ierobežojums/ nl Temperatuurlimiet transport/opslag/nl Temperaturgrense for transport/lagring/pj Wartości graniczne temperatury podczas transportu/zbawczowywania/pj Limite de temperatura de transporte/armazenamento/oj Limite de temperatura pentru transport/depozitare/sk Limit teploty počas pravovy/skladovania/sk Omejitev temperature pri transportu/shranjevanju/sq Temperatura maksimale e transportit/ua/jtejs/

sv Temperaturgräns för lagring/transport

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