I. Indication For Use

LCCS Reusable Radiofrequency Electrode is used to conduct radiofrequency current for radiofrequency lesioning on peripheral nerve tissue to treat chronic pain.

II. General Description

LCCS Reusable RF Electrode is available in eight models as listed in following table. These electrodes have been designed for use with LCCS disposable RF cannula. However, the Radiofrequency Electrode may be used with RF generators made by other manufacturers by attaching an appropriate adapter cable.

Туре	Major Size	Gauge	Gauge Color Code	Compatible RF Cannula Gauge and Length		Length Color Code
RE-R	27G×50mm	27G	Medium Gray	22G 20G 18G	50mm	Green
	27G×100mm				100mm	Blue
	27G×150mm				150mm	Yellow
	27G×200mm				200mm	Brown
	25G×50mm	25G	Orange	20G 18G	50mm	Green
	25G×100mm				100mm	Blue
	25G×150mm				150mm	Yellow
	25G×200mm				200mm	Brown

Each Electrode size is designed to function with a corresponding length of cannula. Electrode hub color indicates the gauge of RF Electrode. The color-coded silicone tube connected with Electrode hub indicates compatible RF Cannula length. (e.g., RE-R 27G x 50mm Electrode compatible with 50mm RF Cannula, color-coded silicone tube color is Green, Electrode hub color is gray). Other disposable RF cannula can be used with the electrode, but the Electrode tip position must be checked for proper seating.

The Radiofrequency Electrode may be used with RF generators made by other manufacturers by attaching an appropriate adapter cable if necessary.

III. Directions for Use

LCCS Reusable RF Electrode can connect directly to RF generator with Lemo connector.

- Assemble all required equipment for the intended procedure and position the patient as necessary.
- Attach LCCS Disposable Grounding Pad.
- Obtain LCCS RF Electrode of correct length indicated by the part number of the electrode that should match the length of the RF cannula.
- With the stylet in LCCS RF Cannula, insert the RF Cannula into the patient using fluoroscopic guidance to place the active tip at the desired lesion location.
- Once the cannula is properly placed, carefully remove the stylet from the LCCS RF Cannula and insert the full length of the (Pre-sized) RF Electrode down the shaft of the LCCS RF Cannula.
- Plug the Electrode to Generator with Lemo connector.
- If proper connection is made, then the RF generator should read correct impedance and body temperature. Otherwise check all connections listed above.
- Stimulate to verify correct placement.
- Lesion as necessary.
- Upon completion of procedure remove the LCCS RF Electrode and LCCS RF Cannula.
- Dispose of single use products properly.
- Clean and sterilize reusable LCCS RF Electrode.

IV. Electrode Tip Position

The tip of the electrode, when in the cannula, should be within the cannula's exposed tip. This should always be checked with each cannula before use.

If the tip cannot be seen directly by the eye, then carefully introduce the cannula's stylet into the beveled end of the cannula until it contracts the thermocouple and note the distance when the stylet is withdrawn.

V. Cleaning and Decontamination

- Ensure that blood and other contaminates do not dry on LCCS RF Electrode.
- Rinse all parts with de-ionized water until colorless run-off water occurs. Once the water runs clear soak the parts (except for the LCCS RF Electrode cable connector) in de-ionized water at 22°C-48°C for 1 minute. Remove the Electrode from the water and scrub them with a soft bristle brush until electrode are visually clean.

Note: Do not let the connectors soak. Wipe cable and connector as necessary until they are visually clean.

- Soak the Electrode (except for the LCCS RF Electrode cable connector) in an enzymatic cleaning solution (such as Terg-A-Zyme®) for 20 minutes. Ensure that the temperature of the solution is below 55°C. Scrub again with a soft bristle brush, and rinse thoroughly using de-ionized water until all traces of detergent residue is removed.
- Visually inspect the electrode again for debris, if any is present repeat last two steps.
- Dry the device on the outside with a clean, dry towel. Put the clean protective tube back onto the probe and place all parts back in the Sterilization and Storage Tray.

VI. Sterilization

The Electrode is provided non-sterile. The Electrode always should be cleaned before sterilization.

CAUTION: After sterilization but before each use, connect the electrode to the lesion generator and ensure the readings of the temperature and impedance are within normal range.

NOTE: Before sterilization, inspect the product for any signs of damage or corrosion. Do not use such damage observed. The sterilizer manufacturer should be consulted for recommendation of loading instructions and drying times. Sterilization equipment should have validated certification and performance qualification tests of their process cycles for efficient processing.

Steam (Moist Heat) Sterilization

The Quality of Steam should be in accordance with the requirements of HTM2031 steam for Sterilization.

Wrapped Sterilization

For (Porous Load) fractionated and pulse cycles, sterilization temperature should be pre-vacuum 134-137°C for a minimum of 3 minutes.

CAUTION: Ensure the product does not contact the metal housing of the autoclave or other metal instruments during the autoclave cycle, as this may reduce the effective life of the product.

VII. Contraindications

For patients with cardiac pacemakers, a variety of changes can occur during and after the treatment. In sensing mode the pacemaker may interpret the RF signal as a heartbeat and may fail to pace the heart. Contact the pacemaker company to determine if the pacemaker should be converted to a fixed-rate pacing during the radio frequency procedure. Evaluate the patients pacing system after the procedure.

Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the radio frequency lesion generator. If the patient has a spinal cord stimulator, contact the manufacturer to determine if the stimulator needs to be in the bipolar stimulation mode or in the OFF position.

VIII. Warnings:

- This device should only be used by physicians trained in the use of the device.
- This device should be cleaned and sterilized before each use. Failure to properly clean and sterilize the device can cause patient injury and/or the communication of infectious diseases from one patient to another.
- During treatment with this device, the patient should continuously be monitored and evaluated for any unexpected symptoms.
- · Before starting any thermal treatment with this device, ensure no motor nerves are in the vicinity of the probe.
- Do not modify device. Any modifications may compromise the safety and efficacy of the device.
- Do not move this device while it is activated.
- Do not use this device if any damage is observed.
- Do not bend or reshape the device, this can cause permanent mechanical damage.
- Discontinue use if inaccurate, erratic or sluggish temperature readings are observed on RF Generator. Use of damaged equipment may cause patient injury.
- Stop if heat is felt at site of the grounding pad.
- Always ensure that the correct length RF Cannula is used with the device.
- Please operate the device between 5~30°C ambient temperature.

IX. Handling & Storage

Electrodes should not be bent or folded, as this may cause damage. Electrodes should be stored in a cool dry place; avoid exposure to extreme temperatures.

X. Symbols



Attention, See Instructions For Use!



Batch Code



Non-Sterile



REF

Catalogue Number / Part Number



For or By Order of a Physician



Temperature Range

Authorized Representative in the European Community

XI. For Further Information

If further information on this product is needed, please contact LCCS customer service or authorized representative.



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EC REP

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