



LCCS Disposable RF Electrode Instructions For Use

I. Indication For Use

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

II. General Description

LCCS Disposable RF Electrode is available in eight models as listed in following table. These electrodes have been designed for use with LCCS disposable RF cannula.

Type	Major Size	Gauge	Gauge Color Code	Compatible RF Cannula Gauge and Length	Length Color Code
RE-D	27G X 50mm	27G	Gray	50mm	Green
	27G X 100mm			100mm	Blue
	27G X 150mm			150mm	Yellow
	27G X 200mm			200mm	Brown
	25G X 50mm	25G	Orange	50mm	Green
	25G X 100mm			100mm	Blue
	25G X 150mm			150mm	Yellow
	25G X 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-D 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 Disposable 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.

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. 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.

VI. 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.



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VII. Warnings:

- This device should only be used by physicians trained in the use of the device.
- 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 reuse, re-sterilize or modify Disposable RF Electrode. Any reusage, re-sterilization or modifications may compromise patient 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°C~30°C ambient temperature.

VIII. Symbols

	Attention, See Instructions For Use!		Sterilized Using Ethylene Oxide
	Do Not Reuse		Catalogue Number / Part Number
	Batch Code		Use By
	Do Not Use If Package Is Damaged		Do Not Resterilize
	Temperature Range		For or By Order of a Physician
	Usable Length		Latex Free
	Manufacturer Information		Authorized Representative in the European Community

IX. For Further Information

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



LCCS Products Limited

Address (HK): Office 3A-7, Kaiser Center, No.18 Center Street, Sai Ying Pun, Hong Kong

Address (US): 16661 N. 84th Avenue, Suite 110, Peoria, AZ 85382 USA

Tel: +1 (844)743-6449

Email: info@lccsmedical.com

Web: www.lccsmedical.com



Wellkang Ltd (www.CE-marking.eu)
29 Harley St., London W1G 9QR, UK