

LeVeen CoAccess™ Electrode System

Designed for Complete, Predictable Thermal Ablation

- **Introducer Set with Insulated Cannula Facilitates:**
 - Pre-procedural planning and lesion mapping
- **Sharp Echogenic Stylet Tip Facilitates Tissue Penetration and Visualization**
- **Short, Lightweight Handle Allows Gantry Clearance During CT-Monitored Ablation**
- **Patented LeVeen Needle Electrode Design**
 - Sharp, polished array tips facilitate tissue penetration
 - Umbrella-shaped array design promotes stable, accurate deployment
 - 1cm tine spacing is designed to help create a complete predictable, spherical thermal lesion
 - Continuous impedance feedback facilitates accurate assessment of complete thermal lesion formation

Product Information

LeVeen CoAccess Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001262220.....	26-222	3.0.....	15
M001262230.....	26-223	3.5.....	15
M001262240.....	26-224	4.0.....	15

RF 3000® Generator

UPN	Order Number	Description
M001262200.....	26-220	200 Watt Radiofrequency Generator

Accessories

UPN	Order Number	Description
M001262250.....	26-225	CoAccess™ Introducer Set

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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Indications:

The LeVeen® Needle Electrode Family is intended to be used in conjunction with a Boston Scientific radiofrequency (RF) generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions. These procedures should only be performed by physicians and staff familiar with the equipment and techniques involved.

Contraindications:

None known.

Warnings:

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Warnings for all LeVeen and LeVeen CoAccess Electrodes

1. When not in use, the active electrodes should never touch the patient.
2. Use of this device may result in elevated core body temperature. Patient's temperature should be monitored and appropriate clinical precautions taken to maintain normothermia.
3. Use of this device during laparoscopic insufflation may result in a gas embolism.
4. Use of this device results in localized elevated temperatures that can cause thermal injury to the skin if the electrode is deployed in a shallow position. In addition, tissue or organs adjacent to the tissue being ablated may be injured thermally. To reduce the potential for thermal injury to the skin or adjacent tissues, temperature-modifying measures can be initiated at the physician's discretion. These may include applying a sterile ice pack or saline-moistened gauze to cool and/or separate tissues.
5. The electrode is fabricated from materials that are not compatible with Magnetic Resonance (MR) imaging magnets. Do not use in MR suite.
6. Do not use in main biliary ducts, gallbladder or during pregnancy.

LeVeen CoAccess Electrode System Specific Warnings

1. The colored insulated cannula must be used at all times when accessing tissue. Use of the electrode without the colored insulated cannula may result in serious burns to the patient and/or user.
2. The skin must be incised prior to insertion of the introducer to prevent damage to the insulation. Damage to the insulation of the introducer may result in serious burns to the patient and/or user.

Cautions:

1. The safety of electrosurgery will be greatly enhanced by a thorough knowledge of the medical literature on the subject. Study of specific information on the hazards and complications of the procedure in question is especially recommended.
2. As necessary, clean the array between deployments by rinsing the array in sterile solution by gently wiping the tines to remove excess tissue. Accumulation of excess tissue on the tines may make array retraction difficult.

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3. Never use electro-surgical devices in the presence of flammable liquids, gases or oxidizing agents. The risk of igniting flammable gases or other materials is inherent in electro-surgery and cannot be eliminated by device design. Precautions must be taken to avoid contact of flammable materials and substances with electro-surgical electrodes.
4. When using the device in situations where vision may be limited, burns may result if the device is activated outside the field of view.
5. Do not insert the cannula at an angle such that the surrounding tissue is compressed. This may result in reduced perfusion and localized heating.
6. Localized burns to the patient or physician may result from electrical currents being carried through conductive objects, such as metal cannulae or scopes, or from metal objects in close proximity to the electrode array or cannula.
7. Safe use of the device requires adequate separation between the thermal lesion and adjacent anatomical structures.
8. If the device is used in laparoscopic procedures, activation when not in direct contact with the target tissues, or in position to deliver energy to the target tissues (fulguration), may cause capacitive coupling with a metal trocar. This may result in patient burns.
9. Electrodes and probes of monitoring, stimulating and imaging devices can provide paths for high-frequency currents even if these devices are battery operated, insulated, or isolated at 60 Hz (or 50 Hz). The risk of burns can be reduced, but not eliminated, by placing these electrodes or probes as far as possible from the electro-surgical site and the return electrode.
10. The LeVeen and LeVeen CoAccess Electrodes are intended only for use with Boston Scientific radiofrequency (RF) generators (peak voltage up to 200V max.). The power applied by the radiofrequency (RF) generator should be kept to the minimum necessary to achieve the desired clinical effect. Electrodes with array diameters of 3.0 cm (30 mm) or greater should be used only with the RF 3000® Radiofrequency Generator.
11. If a needle guide is used, such as with the LeVeen SuperSlim™ Needle Electrode, note that needle guides may have sharp edges that can cause damage to or removal of portions of the insulation on the electrode. Do not bend the electrode while in the needle guide. When moving the electrode or making other placement adjustments, ensure that needle guide edges do not scrape or otherwise damage the insulation. Damage to the insulation may result in skin burns or tissue burns at points along the length of the electrode.
12. The disposable patient return electrodes should be placed on intact skin over muscle tissue with good perfusion. There is a potential for superheating if the return electrodes are placed over implanted metal prostheses. Return electrodes should not be placed over superficial metal implants.
13. For patients with permanent pacemakers and Implantable Cardiac Defibrillators (ICD) additional precautions should be taken. These precautions include, but are not limited to:
 - checking with the manufacturer of the pacemaker and the patient's cardiologist regarding functioning of the pacemaker during Radiofrequency Ablation (RFA).
 - ensuring that the current path from the Radiofrequency Ablation (RFA) site to the disposable patient return electrodes does not pass through the vicinity of the patient's heart, the implanted pacemaker or the Implantable Cardiac Defibrillators (ICD).
 - keeping all Radiofrequency Ablation (RFA) cords and cables away from patient's pacemaker and leads.
 - continuous evaluation of the patient's cardiac rhythm and pacemaker function.
 - having a magnet available and a pacemaker programmer present.
 - having an external pacemaker available and ready to be activated in the event of prolonged inhibition of the permanent pacemaker.
14. The effectiveness of this device for use in the treatment of liver cancer or liver disease (i.e., improved clinical outcomes) has not been established.

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Warning

The use, placement, and proper monitoring of dispersive electrodes (return pads) is a key element in the safe and effective use of monopolar electrosurgery, particularly in the prevention of burns. For extended ablations (ablations lasting greater than 30 minutes), frequent monitoring of the dispersive electrode for excessive temperature increase is recommended.



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