LeVeen® CoAccess™ Electrode System

Boston Scientific

Coaxial Radiofrequency Ablation Device

LeVeen CoAccess Electrode System Design

- Introducer set with insulated cannula facilitates:
  - Pre-procedural planning and lesion mapping
  - Agent injection
- Sharp echogenic stylet tip facilitates tissue penetration and visualization
- Short, lightweight handle designed to allow gantry clearance during CT-monitored ablation

Patented LeVeen Needle Electrode Design

- Sharp, polished array tips are designed to 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

Designed for Use with RF 3000® Radiofrequency Generator

- Continuous impedance feedback facilitates accurate assessment of complete thermal lesion formation

LeVeen® CoAccess™ Electrode System

Ordering 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

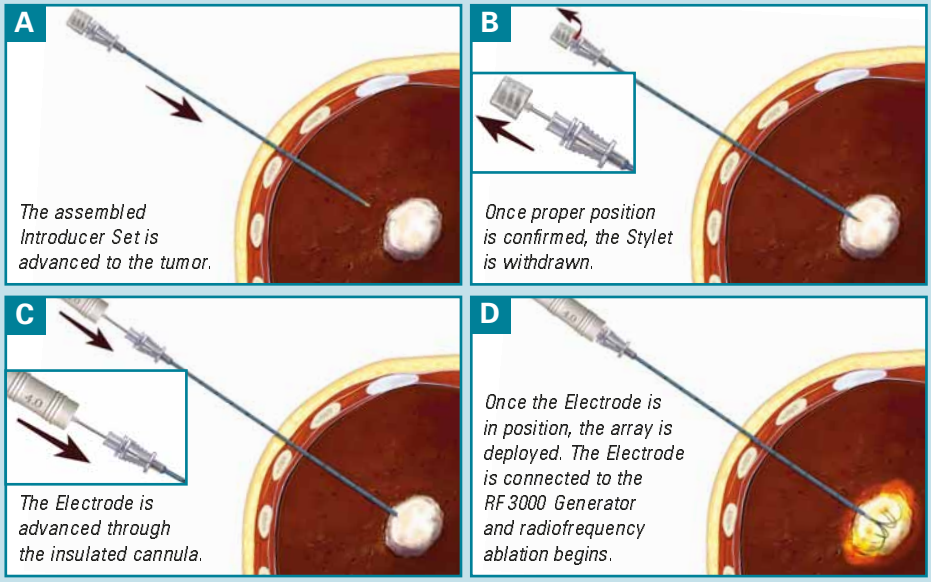
RF 3000® Generator

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

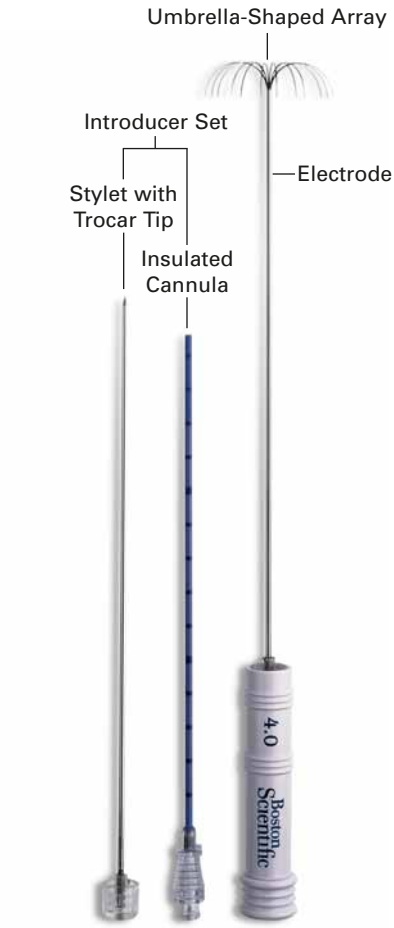
Accessory

UPN	Order Number	Description
M001262250	26-225	CoAccess Introducer Set

TO USE THE LEVEEN COACCESS ELECTRODE SYSTEM



NOTE: The LeVeen CoAccess Electrode System is a coaxial system. The Electrode must be used in conjunction with the insulated cannula.



Refer to full Directions for Use for complete instructions on how to use this medical device.

INDICATIONS
The LeVeen® CoAccess™ Electrode System 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.

WARNINGS
1. The colored insulated cannula must be used at all times when accessing tissue. **Use of the electrode without the blue-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.** 3. When not in use, the active electrodes should never touch the patient. 4. Use of this device during laparoscopic insufflation may result in a gas embolism. 5. 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 minimize 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.

CAUTIONS
1. 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. 2. 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. 3. As necessary, clean the array between deployments by rinsing the array in sterile solution or by gently wiping the tines to remove excess tissue. Accumulation of excess tissue on the tines may make array retraction difficult. 4. Never use electrosurgical devices in the presence of flammable liquids, gases or oxidizing agents. The risk of igniting flammable gases or other materials is inherent in electrosurgery and cannot be eliminated by device design. Precautions must be taken to avoid contact of flammable materials and substances with electrosurgical electrodes. 5. When using the device in situations where vision may be limited, burns may result if the device is activated outside the field of view. 6. Do not insert the cannula at an angle such that the surrounding tissue is compressed. This may result in reduced perfusion and localized heating. 7. 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. 8. Safe use of the device requires adequate separation between the thermal lesion and adjacent structures. 9. 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. 10. 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 60Hz (or 50Hz). The risk of burns can be reduced, but not eliminated, by placing these electrodes or probes as far as possible from the electrosurgical site and the return electrode. 11. The LeVeen® CoAccess™ Electrode System is intended only for use with Boston Scientific Radiofrequency Generators (peak voltage up to 200V max.). The power applied by the Radiofrequency Generator should be kept to the minimum necessary to achieve the desired clinical effect. Electrodes with array diameters of 4.0 cm or greater should be used only with the RF 3000® Radiofrequency Generator.
Federal (USA) law and governing law outside the USA restricts these devices to sale by or on the order of a physician.

Boston Scientific

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To order product or for more information, contact Customer Service at ***1.800.225.3238***

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