

LEVEEN[™] Needle Electrodes

THE CHOICE FOR OPEN AND PERCUTANEOUS

RADIOFREQUENCY ABLATION



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DESIGNED FOR USE WITH RF 3000™ RADIOFREQUENCY GENERATOR

CANNULA DESIGN

- **LeVeen SuperSlim™ Electrode cannula** design options provide an excellent choice for patients who are at risk of bleeding
- Short, lightweight LeVeen SuperSlim Electrode handle facilitates gantry clearance during CT-monitored ablations
- 1cm shaft markers and echogenic tip help to guide insertion
- Choice of lengths facilitates lesion access

INNOVATIVE LEVEEN NEEDLE ELECTRODE DESIGN

- 5 cm array is designed to create larger thermal lesions and reduce the need for overlapping ablations, potentially decreasing the overall risk of local tumor recurrence
- Expanded portfolio of array diameters from 2 cm to 5 cm – enhances ability to treat lesions of variable dimensions
- Sharp, polished array tips facilitate tissue penetration
- **Umbrella-shaped array design** promotes stable, accurate deployment
- 1 cm tine spacing is designed to help create a complete, predictable, spherical thermal lesion
- Continuous impedance feedback facilitates accurate assessment of complete thermal lesion formation

ORDERING INFORMATION

LeVeen SuperSlim™ Needle Electrodes					
UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)		
M001 26229 0	26-229	3.0	25		
M001 26228 0	26-228	3.0	15		
M001 26227 0	26-227	2.0	25		
M001 26226 0	26-226	2.0	15		
LeVeen CoAccess™ Needle Electrode Systems					
UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)		
UPN M001 26222 0	0.40.		• • • • • • • • • • • • • • • • • • • •		
J	Number	Diameter (cm)	Length (cm)		
M001 26222 0	Number 26-222	Diameter (cm) 3.0	Length (cm)		
M001 26222 0 M001 26223 0	Number 26-222 26-223 26-224	Diameter (cm) 3.0 3.5	Length (cm) 15 15		
M001 26222 0 M001 26223 0 M001 26224 0	Number 26-222 26-223 26-224	Diameter (cm) 3.0 3.5	Length (cm) 15 15		

LeVeen Needle Electrodes				
UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)	
M001 26216 0	26-216	5.0	15	
M001 26213 0	26-213	4.0	15	
M001 26202 0	26-202	3.5	12	
M001 26203 0	26-203	3.5	15	
M001 26215 0	26-215	3.5	25	
M001 26204 0	26-204	3.0	12	
M001 26205 0	26-205	3.0	15	
RF 3000® Generator				
UPN	Order Number	Description		
M001 26220 0	26-220	200 Watt Radiofrequency Generator		

LEVEEN NEEDLE ELECTRODE FAMILY CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use"

for more information on Indications, Contraindications, Warnings, Precautions. Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The LeVeen Needle Electrode Family is intended to be used in conjunction with the RF 3000 Generator for the thermal coagulation necrosis of soft tissues, including partial or complete ablation of nornessectable liver lesions. These procedures should only be performed by physicians and staff familiar with the equipment and techniques involved. PRECAUTION: Before using, inspect the package for any breach to the sterile barrier and inspect product for any damage. If package is broken or product is damaged D0 NOT USE. Immediately return package and product to Boston Scientific. WARNINGS: ◆ 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. Damage to the insulation of the introducer may result in serious burns to the patient and/or user. Precaution: The LeVeen Needle Electrode Family must be used in conjunction with the Boston Scientific RF 3000 ™ Generator. For patients with permanent pacemakers and Implantable Cardiac Defibrillators (ICD) additional precautions should be taken. ADVERSE EVENTS: Reported complications associated with radiofrequency (RF) ablation of liver tissue include, but are not limited to: ◆ Abscess ◆ ARDS (Acute Respiratory Distress Syndrome) ◆ Arrhythmia ◆ Ascites ◆ Biloma ◆ Burn ◆ Death ◆ Delayed hemorrhage into ablated tissue ◆ Diarrhea ◆ Electric Shock ◆ Fistula, including biliary fistula ◆ Hematorma ◆ Hemorrhage • Infection ◆ Liver Failure ◆ Liver Insufficiency ◆ Pain ◆ Perforation ◆ Peritonitis ◆ Persistent Fever > 39° C ◆ Pleural Effusion ◆ Renal Failure ◆ Tumor Recurrence ◆ Tumor Seeding

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Peripheral Interventions

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