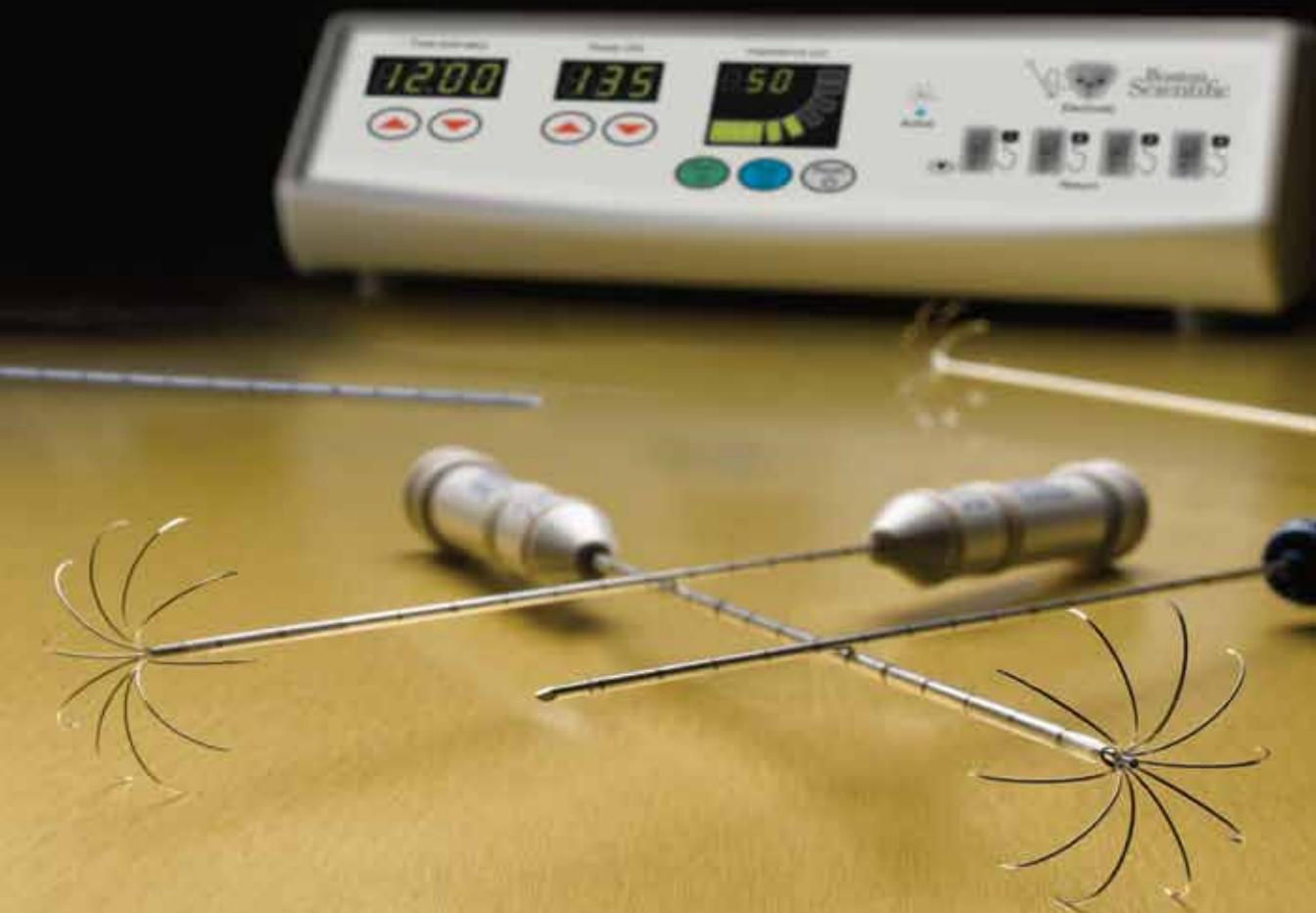


Radiofrequency Ablation

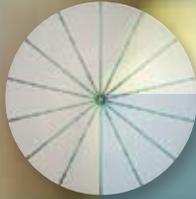
Boston
Scientific



Product Guide

- LeVeen™ Needle Electrodes
- LeVeen SuperSlim™ Needle Electrodes
- LeVeen CoAccess™ Electrode System
- Soloist™ Single Needle Electrodes
- RF 3000™ Radiofrequency Generator





Pages 2 – 3

- LeVeen™ Needle Electrodes
- LeVeen SuperSlim™ Needle Electrodes



Pages 4 – 5

- LeVeen CoAccess™ Electrode System
- Soloist™ Single Needle Electrode



Pages 6 – 7

- RF 3000™ Radiofrequency Ablation System Generator



LeVeen™ Needle Electrodes

LeVeen SuperSlim™ Needle Electrodes

The Choice for Percutaneous and Open Radiofrequency Ablation

Designed for Use with RF 3000™ Radiofrequency Generator

Innovative Electrode Design

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

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

Indicated for: Thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

ORDERING INFORMATION

LeVeen Standard Needle Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001262160	26-216	5.0	15
M001262170	26-217	5.0	25
M001262130	26-213	4.0	15
M001262310	26-217	4.0	25
M001262020	26-202	3.5	12
M001262030	26-203	3.5	15
M001262150	26-215	3.5	25
M001262040	26-204	3.0	12
M001262050	26-205	3.0	15



5.0cm



4.0cm



3.5cm



3.0cm

CHOICE OF ARRAYS

LeVeen SuperSlim Needle Electrode System

UPN	Order Number	Array Diameter (cm)	Cannula Length (cm)
M001262290	26-229	3.0	25
M001262280	26-228	3.0	15
M001262270	26-227	2.0	25
M001262260	26-226	2.0	15



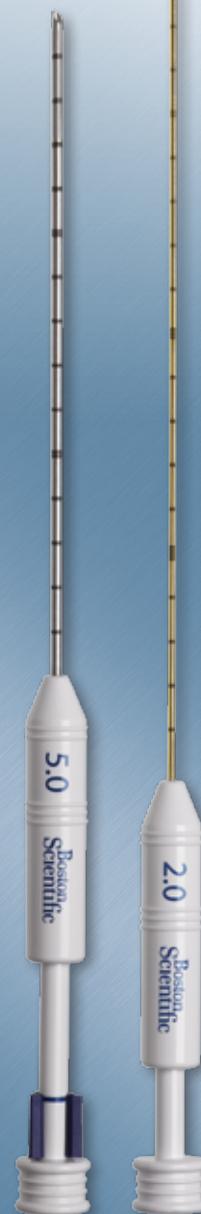
3.0cm



2.0cm

CHOICE OF ARRAYS

LeVeen
SuperSlim
Cannula
Design



LeVeen™ CoAccess™ Electrode System Soloist™ Single Needle Electrode

LeVeen CoAccess Electrode System

Electrode System Design

- **Introducer set** with insulated cannula facilitates pre-procedural planning and lesion mapping
- **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
- **Consistent tine spacing** is designed to help create a complete, predictable, spherical thermal lesion

Soloist Single Needle Electrode



The Choice for Small Lesions

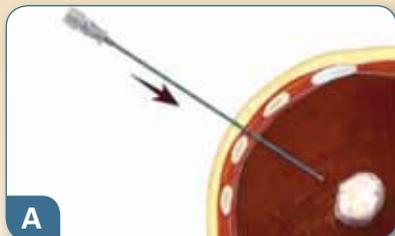
- **Small ablation zone** of approximately 1.5cm length and 1cm diameter for targeted tissue desiccation
- **Single-needle design** facilitates access to small and difficult-to-treat lesions
- **Tri-faceted needle tip** designed for echogenicity and ease of needle insertion into solid lesions
- **Depth markings** at 1cm intervals facilitate accurate positioning

Designed for Use with RF 3000™ Radiofrequency Generator

Indicated for: Thermal coagulation necrosis of soft tissues, including partial or complete ablation of nonresectable liver lesions.

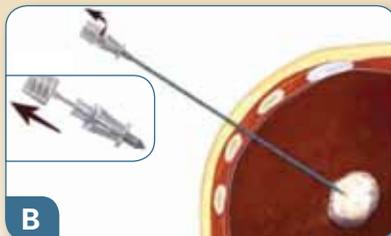


TO USE THE LEVEEN COACCESS NEEDLE ELECTRODE SYSTEM



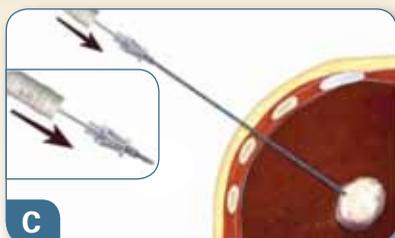
A

The assembled Introducer Set is advanced to the tumor.



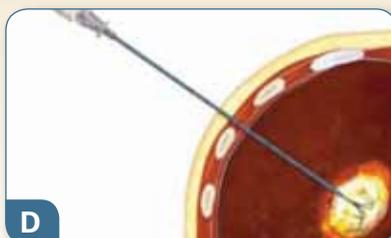
B

Once proper position is confirmed, the Stylet is withdrawn.



C

The Electrode is advanced through the insulated cannula.



D

Once the Electrode is in position, the array is deployed. The Electrode is connected to the RF 3000 Generator and radiofrequency ablation begins.



Umbrella-Shaped Array

Introducer Set
Stylet with Trocar Tip
Blue Portion Insulated Cannula

ORDERING INFORMATION

LeVeen CoAccess Needle 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

CoAccess Introducer Set

UPN	Order Number	Description
M001262250	26-225	CoAccess Introducer Set

Soloist Single Needle Electrode (16.5ga)

UPN	Order Number	Active Electrode Length (cm)	Cannula Length (cm)
M001262500	26-250	.9	18

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.



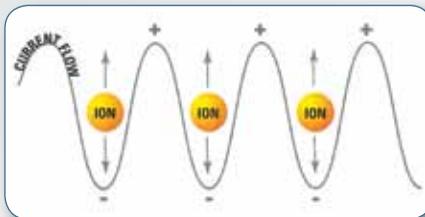
RF 3000™ Radiofrequency Ablation System Generator

Use of Impedance as a Procedural Endpoint

RF 3000 Generator

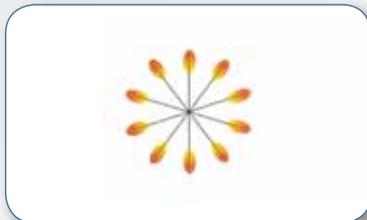
Designed for complete predictable thermal ablation

- **Impedance-based feedback system** is designed to...
 - Accurately monitor extent of tissue desiccation
 - Permit continued delivery of RF energy until achievement of complete ablation
 - Accommodate lesion and patient variability
 - Provide predictable, consistent clinical endpoints
- **200W capacity** promotes rapid, efficient ablation of large volumes of tissue
- **Pad-Guard™ Current Monitoring System** promotes proper grounding pad utilization to reduce risk of complications
- **Easy-to-read**, backlit displays and audible signal are designed to allow constant assessment of procedure progress

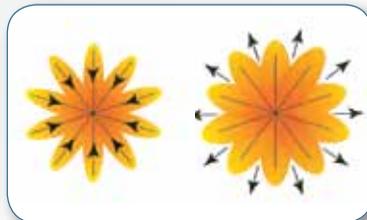


Ionic agitation from alternating current causes tissue coagulation through frictional heating. Tissue desiccation increases impedance which eventually decreases current flow.¹

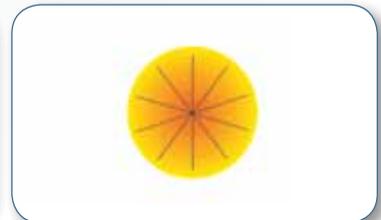
LEVEEN NEEDLE ELECTRODE THERMAL LESION CREATION



1. The thermal lesion developed by the LeVeen Needle electrode begins at the tips of the array tines. The multiplicity of tines in the electrode allow the RF energy to shift away from any given tine as the adjacent tissue desiccates and increases in impedance.²

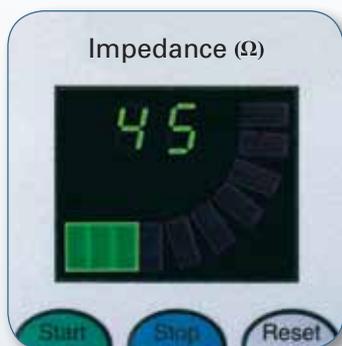


2. As the tissue near the tips of the tines desiccates, the zone of ablation travels back along the tines toward the center of the array. The thermal lesion then moves outward and begins to fill in the gaps between the tines.

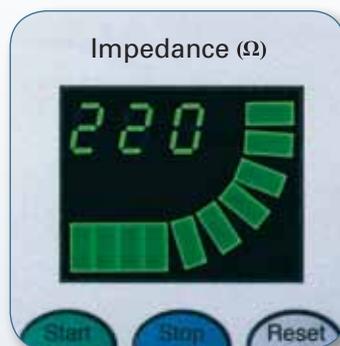


3. A complete thermal lesion is achieved once tissue desiccation has occurred throughout the target tissue. The RF 3000 Radiofrequency Generator is designed to receive feedback from the target tissue to reduce power and signal a complete thermal lesion.

THE RF 3000 GENERATOR USES A DIRECT MEASUREMENT OF IMPEDANCE FEEDBACK FROM THE TARGET TISSUE TO MONITOR THE COURSE OF TISSUE ABLATION.

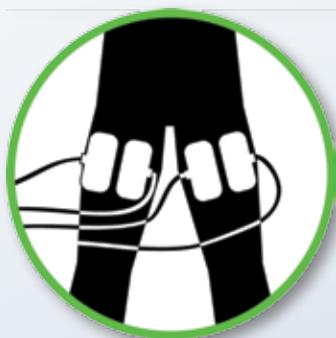


Initial tissue impedance is measured prior to application of RF energy and is typically within the range of 40 to 80 ohms, illuminating three bars on the front panel of the RF 3000 Generator.



Impedance rise is indicated by an increase in ohms and a sequential illumination of the bars on the front panel, signaling cellular destruction and the completion of a thermal lesion.

RF 3000 GROUNDING PAD PLACEMENT



Proper Orientation & Alignment
(Evenly Spaced)



Improper Orientation



Misalignment

RF 3000™ Radiofrequency Ablation System and Generator

Error Table: Hardware Self-Test Errors

Hxx: Recoverable errors due to problems with computer circuits or analog circuits

Measurement Errors

	Error Code	Description	Resettable Error	Recoverable Error
PROBE / PAD	E01	Low Impedance Measured (Displays "LO")	✓	
	E02	High Initial Impedance Measured	✓	
	E03	High Initial Impedance Measured (Displays "HI")	✓	
	P#	High Current in Pad # (P1, P2, P3, P4)	✓	
GENERATOR	E80	Pad Current Sum Error		✓
	E81	Hardware Shutdown: Over Voltage		✓
	E82	Hardware Shutdown: Over Current		✓
	E83	Hardware Shutdown: Over Power		✓
	E84	Hardware Shutdown: Multiple		✓
	E85	Reference Voltage Error		✓
	E86	Power Offset Error		✓
	E87	High Voltage Measured		✓
	E88	High Current Measured		✓
	E89	High Power Measured		✓
	E91	Software Shutdown		✓
	E92	PAD Current Offset Error		✓
	E93	V(rms) Offset Error		✓
E94	I (rms) Offset Error		✓	

Resettable Error

1. Press Reset Button
2. If Continues, Troubleshoot Probe/Pad

Recoverable Error

1. Power Down and Restart Unit
2. If Continues, Return For Inspection and/or Repair

ORDERING INFORMATION

RF 3000 Generator

UPN	Order Number	Description
M001 262200	26-220	200 Watt Radiofrequency Generator





Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.bostonscientific.com/endo-resources

Ordering Information
1.888.272.1001

© 2013 Boston Scientific Corporation
or its affiliates. All rights reserved.

ENDO-149636-AA 5M APRIL 2013

Bibliography

- 1 McGahan JP. Hepatic ablation using radiofrequency electrocautery. *Invest Radiol.* 1990;25:267-270.
- 2 LeVeen RF. Laser hyperthermia and radiofrequency ablation of hepatic lesions. *Sem Intervent Radiol.* 1997;14:313-324.

LeVeen, LeVeen SuperSlim, LeVeen CoAccess, CoAccess and RF 3000 are unregistered or registered trademarks of Boston Scientific Corporation or its affiliates.

Indications, Contraindications, Warnings and Instructions for Use can be found in the product labeling supplied with each device.

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