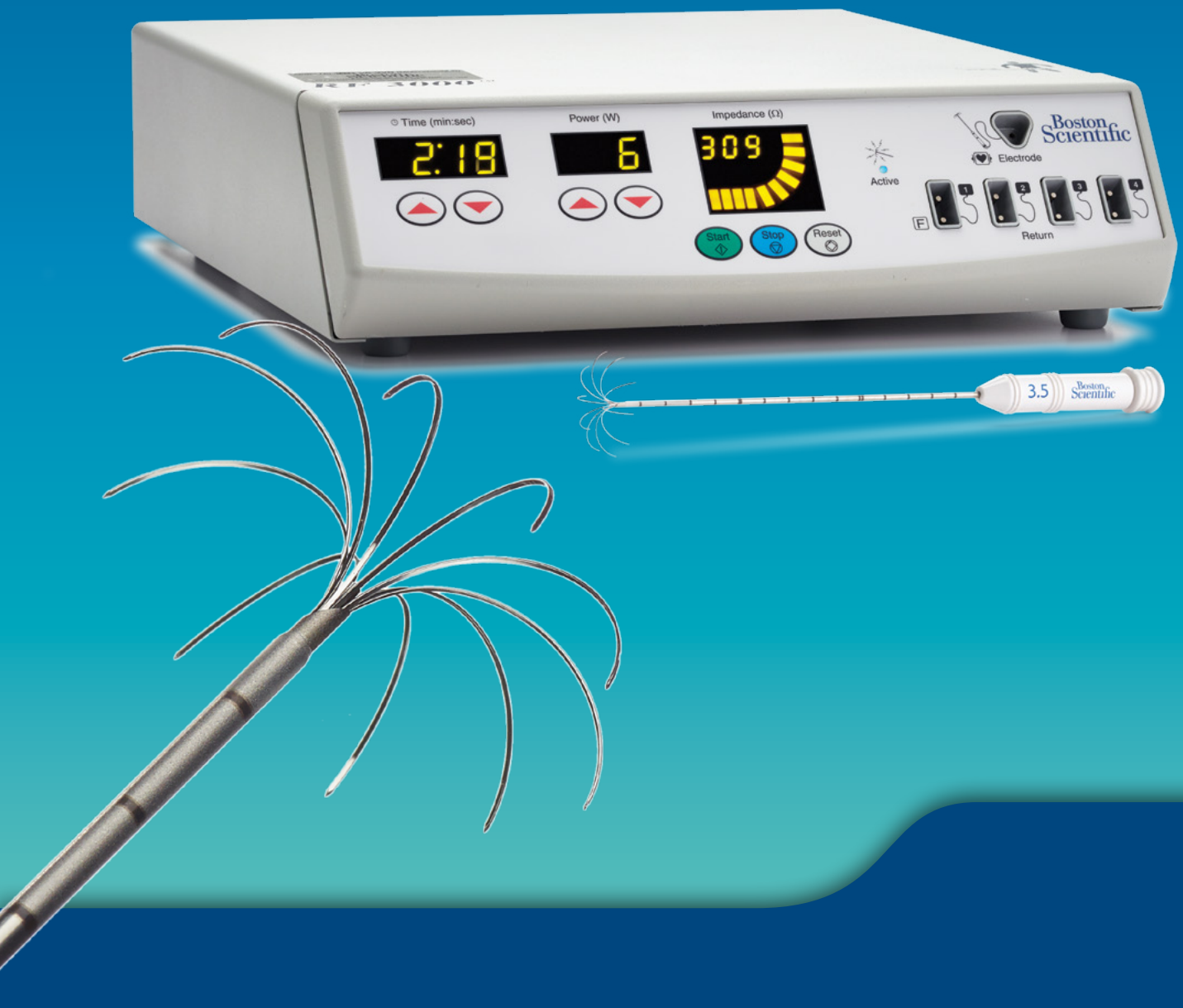
Boston Scientific
Advancing science for life™

RADIOFREQUENCY ABLATION

SIMPLICITY AND PREDICTABILITY IN SOFT TISSUE ABLATION



RF 3000™ Generator

Designed for complete predictable thermal ablation

- **200W capacity** promotes rapid, efficient ablation of large volumes of tissue.
- **Easy-to-read,** back lit displays and audible signal are designed to allow constant assessment of procedure progress.
- Because ablation algorithms and generator inputs are manual, there is **no need for generator software updates** if/when probe algorithms change.

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 and is typically within the range of 40 to 80 ohms (Ω), illumination three bars on the front panel of the RF 3000 Generator.

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

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

Boston Scientific is the choice for Percutaneous and Open Radiofrequency Ablation

- Utilizes **impedance as a procedural endpoint**. As proteins denature and tissue desiccates, the resistance to the passage of electrical current (impedance) increases.
- Probes **do not require the use of saline or cooling** mechanisms.
- Umbrella shaped tine arrays are designed for **secure anchoring** and intended to provide **accurate and predictable ablation profiles.**

Probe Family

Probe Selection Guide

Procedural Need/Intent	LeVeen™ Needle Electronics	LeVeen SuperSlim™ Electrodes	LeVeen CoAccess™ Electrodes	LeVeen Single Needle Electrodes
Stable probe array anchoring within tissue	✓	✓	✓	
Short, 12 cm cannula length for added CT Gantry Clearance	✓			
Less invasive, small diameter cannula		✓		
Coaxial access cannula for preprocedural planning and compound ablations			✓	
Ability to biopsy through the same introducer cannula			✓	
Single needle electrode for small diameter ablation zones				✓

LeVeen Needle and LeVeen SuperSlim Needle Electrodes

- **Variety of array sizes** (3.0-5.0 cm) **and cannula lengths** (12,15, 25 cm) to provide more flexibility to treat a variety of lesion sizes and depths.
- **Small diameter cannula** intended to minimize invasiveness and bleeding risks (available on LeVeen SuperSlim Needle Electrode).

LeVeen Needle Electrodes

UPN	Order Number	Diameter (cm)	Length (cm)
M001262160	26-216	5.0	15
M001262170	26-217	5.0	25
M001262130	26-213	4.0	15
M001262310	26-231	4.0	25
M001262020	26-202	3.5	12
M001262030	26-303	3.5	15
M001262150	26-215	3.5	25
M001262040	26-204	3.0	12
M001262050	26-205	3.0	15

LeVeen SuperSlim Needle Electrodes

UPN	Order Number	Diameter (cm)	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

5.0 cm LeVeen

2.0 cm LeVeen SuperSlim

LeVeen CoAccess Needle Electrodes

- **Coaxial system with insulated introducer set** for pre-procedural lesion mapping and cannula placement prior to ablation(s). Excellent choice for compound ablations.
- **Introducer set and cannula** compatible with most soft-tissue biopsy devices.
- **Umbrella shaped array with sharpened tines** to promote lesion penetration and stable probe positioning.

UPN	Order Number	Diameter (cm)	Length (cm)
M001262220	26-222	3.0	15
M001262230	26-223	3.5	15
M001262240	26-224	4.0	15
M001262250	26-225	CoAccess Introducer	

LeVeen CoAccess Introducer

3.0 cm LeVeen

LeVeen Soloist™ Single Needle Electrode

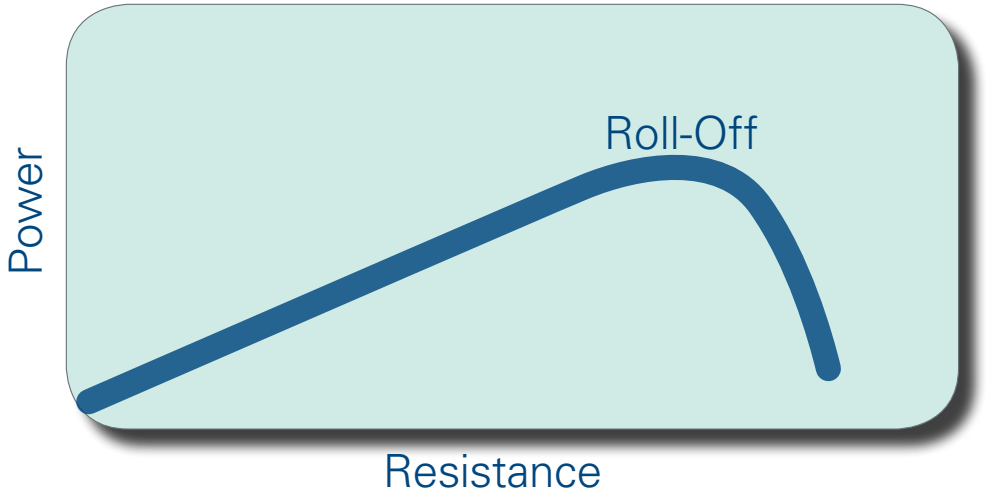
- **Single needle electrode** for small diameter ablations (approximately 1.5 x 1.0 cm).
- **Trocar tip** to access small and difficult-to-treat lesions.
- **1 cm shaft markings** intended to aid in accuracy of needle placement.

UPN	Order Number	Diameter (cm)	Length (cm)
M001262500	26-250	1.68	18

LeVeen Soloist

The Use of Impedance as a Procedural Endpoint

- **Impedance is a physical phenomenon** that is not dependent upon calculations or measurement systems.
- **Time and or temperature based ablation systems** may not fully account for variability in lesion composition.



- Application of electrical current results in tissue heating above 50°C.
- Proteins denature and tissue desiccates, increasing tissue's impedance *(resistance to conduct electrical current).*
- More power is applied to overcome the rise in electrical resistance.
- Once thermal coagulation and necrosis is achieved, the impedance will rise and a corresponding drop in delivered power results (Roll-Off Indication), indicating the completion of a thermal ablation.

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 nonresectable 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 DO 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 • Hematoma • Hemorrhage • Infection • Liver Failure • Liver Insufficiency • Pain • Perforation • Peritonitis • Persistent Fever > 39° C • Pleural Effusion • Renal Failure • Tumor Recurrence • Tumor Seeding
RF3000 RADIO FREQUENCY GENERATOR
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.
The RF 3000 Radio Frequency (RF) Generator is intended for thermal coagulation of soft tissue with electrodes separately cleared by the United States FDA. The generator delivers an isolated RF output of up to 200 watts to the electrode. Full power is available in the impedance range of 25Ω to 100Ω at a constant RF voltage; lower powers are available outside this range. Power can be adjusted manually; however, changes in load impedance will change the actual power delivered (a safety feature described more fully in "Passive Power Limitation"). When power is on, actual delivered RF power and impedance are displayed. The Operation and Service Manual is intended as an instructional guide only. **General Procedure Safety WARNING!** Safe and effective electrosurgery is dependent not only on equipment design, but also, to a large extent, on factors under the control of the operator. It is important that the instructions supplied, both with this equipment and the accessories, be read, understood, and followed in order to ensure safety and effectiveness. **WARNING!** No modification of this equipment is allowed **WARNING!** The use of RF energy can produce unintended neuromuscular stimulation. **Electromagnetic Interference WARNING!** The use of electrosurgical devices can cause electromagnetic interference (EMI) in other devices, particularly cardiac pacemakers. Precautions should be taken to ensure that the patient's well-being is maintained in the event of such interference. **WARNING!** The use and proper placement of dispersive electrodes (return pads) is a key element in the safe and effective use of monopolar electrosurgery, particularly in the prevention of burns. Follow the manufacturer's Instructions for Use.
SOLOIST SINGLE NEEDLE ELECTRODE
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 Soloist Single Needle Electrode 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 nonresectable liver lesions. **CONTRAINDICATIONS:** None known. **WARNINGS:** Damage to the insulation of the introducer or needle may result in serious burns to the patient and/or user. Precaution: The Soloist™ Single Needle Electrode 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 • Hematoma • 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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