

RF 3000[®] Radiofrequency Ablation System

- **RF 3000 Generator**

- Impedance-based feedback system is designed to...
 - Accurately monitor extent of tissue desiccation
 - Permit continued delivery of RF energy until complete ablation is achieved
 - 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 use to reduce risk of complications
- Easy-to-read, backlit displays and audible signal allow constant assessment of procedure progress

- **LeVeen[®] Needle Electrodes**

- Patented umbrella-shaped array is designed to efficiently deliver high frequency RF energy to targeted tissue
- 1cm tine spacing facilitates creation of complete, predictable, spherical thermal lesions
- Range of designs allows use in a variety of clinical applications

RF 3000[®] GENERATOR

| UPN | Order Number | Description |
|------------------|---------------------|----------------------------|
| M001262200 | 26-220 | RF 3000 200 Watt Generator |

LEVEEN[®] NEEDLE ELECTRODES

| UPN | Order Number | Description |
|------------------|---------------------|--------------------------------|
| M001262170 | 26-217 | LeVeen Needle Electrode 5.0/25 |
| M001262160 | 26-216 | LeVeen Needle Electrode 5.0/15 |
| M001262310 | 26-231 | LeVeen Needle Electrode 4.0/25 |
| M001262130 | 26-213 | LeVeen Needle Electrode 4.0/15 |
| M001262150 | 26-215 | LeVeen Needle Electrode 3.5/25 |
| M001262030 | 26-203 | LeVeen Needle Electrode 3.5/15 |
| M001262020 | 26-202 | LeVeen Needle Electrode 3.5/12 |
| M001262050 | 26-205 | LeVeen Needle Electrode 3.0/15 |
| M001262040 | 26-204 | LeVeen Needle Electrode 3.0/12 |
| M001262070 | 26-207 | LeVeen Needle Electrode 2.0/15 |
| M001262060 | 26-206 | LeVeen Needle Electrode 2.0/12 |

Key: Array Diameter (cm)/Length (cm)

LEVEEN COACCESS[™] ELECTRODE SYSTEMS

| UPN | Order Number | Description |
|------------------|---------------------|----------------------------------|
| M001262240 | 26-224 | CoAccess Electrode System 4.0/15 |
| M001262230 | 26-223 | CoAccess Electrode System 3.5/15 |
| M001262220 | 26-222 | CoAccess Electrode System 3.0/15 |
| M001262250 | 26-225 | CoAccess Introducer Set |

Key: Array Diameter (cm)/Length (cm)

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LEVEEN SUPERSLIM[™] NEEDLE ELECTRODES

| UPN | Order Number | Description |
|------------------|---------------------|--|
| M001262290 | 26-229 | LeVeen SuperSlim Needle Electrode 3.0/25 |
| M001262280 | 26-228 | LeVeen SuperSlim Needle Electrode 3.0/15 |
| M001262270 | 26-227 | LeVeen SuperSlim Needle Electrode 2.0/25 |
| M001262260 | 26-226 | LeVeen SuperSlim Needle Electrode 2.0/15 |

Key: Array Diameter (cm)/Length (cm)

SOLOIST[™] SINGLE NEEDLE ELECTRODE

| UPN | Order Number | Description |
|------------------|---------------------|--|
| M001262500 | 26-250 | Soloist Single Needle Electrode 0.9/18 |

Key: Active Electrode (cm)/Length (cm)

Note: Soloist Single Needle Electrode may also be used in conjunction with the LeVeen CoAccess[™] Introducer Set.

Caution: Federal (USA) law restricts this device to sale, distribution and use by or on the order of a physician.

Indications:

The RF 3000 Radiofrequency (RF) Generator is intended for thermal coagulation of soft tissue with electrodes separately cleared by the United States FDA.

Contraindications:

None known.

Warnings:

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 accessories be read, understood, and followed in order to ensure safety and effectiveness.

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.

When not in use, the active electrodes should never touch the patient.

Potential Adverse Effects:

Use of this device with laparoscopic instruments may result in a gas embolism. When this generator is used with a laparoscopic electrode, activation of the electrode, when it is not in contact with or in position to deliver energy to the target tissue, may cause capacitive coupling and result in patient burns.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

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. Whenever practical, the patient should not be allowed to come into contact with electrically conductive parts that are earth grounded.
3. 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.

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4. CAUTION FOR MAGNETIC RESONANCE (MR) IMAGING! The RF 3000 Generator is not MR compatible and should be kept outside the shielded MR scan room. In addition, the RF Generator emits signals that may interfere with MR imaging. Therefore, the Generator should be “OFF” when the MR scanner is acquiring image data.
5. Ensure that the Voltage Selector and the fuse block on the rear panel are set to the appropriate main voltage before turning the main power switch on.
6. Use of this device with laparoscopic instruments may result in a gas embolism. When this generator is used with a laparoscopic electrode, activation of the electrode, when it is not in contact with or in position to deliver energy to the target tissue, may cause capacitive coupling and result in patient burns.
7. Electrosurgical leads (active and return) should be positioned so that they cannot come into contact with the patient or other leads, except during ablation.
8. Electrodes and probes of monitoring, stimulating, and imaging devices can provide paths of high-frequency currents even if these devices are battery-powered, insulated, or isolated at 60Hz (or 50Hz). The risk of burns can be reduced, but not eliminated, by placing the respective electrodes or probes as far away as possible from the electrosurgical site and from the dispersive electrode.
9. The power applied to any electrode should be kept to the minimum necessary to achieve the desired surgical effect.
10. To protect the test equipment, ensure that the electrosurgical analyzer can dissipate 200W at 100% duty cycle.



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Ordering Information
1.800.225.3238

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