3M™ Universal Electrosurgical Pad
with Safety Ring
Product Profile
### Ordering Information

**9100 Series 3M™ Universal Electrosurgical Pads with Proprietary Safety Ring**

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Description</th>
<th>Conductive Area</th>
<th>Shipper</th>
</tr>
</thead>
<tbody>
<tr>
<td>9130</td>
<td>Standard (non-split) Uncorded</td>
<td>15 sq. in.</td>
<td>100</td>
</tr>
<tr>
<td>9135</td>
<td>Standard (non-split) with Pre-attached Cord</td>
<td>15 sq. in.</td>
<td>40</td>
</tr>
<tr>
<td>9160</td>
<td>Split (CQMS Compatible) Uncorded</td>
<td>15 sq. in.</td>
<td>100</td>
</tr>
<tr>
<td>9165</td>
<td>Split (CQMS Compatible) with Pre-attached Cord</td>
<td>15 sq. in.</td>
<td>40</td>
</tr>
</tbody>
</table>

Also Available:

3M Electrosurgical Multiple-use Cables, Catalog numbers: 21150-21156, 21158, 21170-21174.

Consult 3M Cable Guide 70-2008-9825-5 for compatibility information.
3M™ Universal Electrosurgical Pad Features and Specifications

3M Universal Electrosurgical Pads are disposable, single use patient, dispersive return electrodes. This new type pad utilizes the 3M proprietary current dispersing technology to reduce corner and leading edge effect, thus permitting a more efficient design and a smaller size. The hydrophilic conductive adhesive has excellent performance characteristics but leaves no mess upon removal.

3M Universal Electrosurgical Pads, split style, are for use with generators equipped with a functioning Contact Quality Control Monitoring System (CQMS).

Features
- Soft gel-like conductive adhesive, a technology invented by 3M.
- The pad’s hydrophilic qualities maximize good adhesion and conductivity.
- Balanced adhesive approach.
- Small size for ease of application.
- No pad orientation worries.
- Compatible with all major CQMS systems (REM®, ARM™, NESSY®, PSS™, etc.) available today.
- Green Safety Ring technology permits more efficient collection of surgical current.

Specifications

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
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<tbody>
<tr>
<td>Pad Type</td>
<td>Lossy dielectric and resistive combination, similar in function to larger conventional resistive pads.</td>
</tr>
<tr>
<td>Overall Dimensions</td>
<td>4.75 x 5.25 in./12.1 x 13.3cm.</td>
</tr>
<tr>
<td>Conductive Surface Area</td>
<td>15 in²/96.8cm².</td>
</tr>
<tr>
<td>Border Adhesive</td>
<td>3M™ Micropore™ Pressure Sensitive Adhesive.</td>
</tr>
<tr>
<td>Conductive Adhesive</td>
<td>Proprietary, hydrophilic formula invented by 3M.</td>
</tr>
<tr>
<td>Contact Impedance</td>
<td>Less than 1 ohm.</td>
</tr>
<tr>
<td>CQMS Compatible</td>
<td>Split design allows for use with all major CQMS systems (REM®, ARM™, NESSY®, PSS™, etc.) available today.</td>
</tr>
<tr>
<td>Pad Backing Material</td>
<td>Polypropylene non-woven combined with a polyethylene extruded film.</td>
</tr>
<tr>
<td>Weight or Age Restrictions</td>
<td>None, as long as full pad-to-skin contact is obtained in a site recommended for placement.</td>
</tr>
<tr>
<td>Shelf Life</td>
<td>3 years from date of manufacture if kept in sealed pouch.</td>
</tr>
<tr>
<td>Latex Indication</td>
<td>Neither natural rubber latex nor dry natural rubber are components in 9100 Series Electrosurgical Pads or their packaging.</td>
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</table>
# Table of Contents

Background ........................................... 2

Lossy Dielectric (Green *Safety Ring*) .... 3

Generator Compatibility ......................... 4

Curved Split Design .............................. 5

3M™ Conductive Adhesive ....................... 6

Low R-Value, Non-foam Backing Material .... 7

Electrical and Thermographic Performance ... 7

Measurement Methods ............................ 8

Summary of Thermographic Studies ............ 8

Universal Orientation ............................ 9

Moisture Protection .............................. 11

Electrode-Skin Impedance ....................... 11

Cable Attachment ............................... 11

Biocompatibility ................................. 12

Biocompatibility Summary ....................... 12

Application and In-service Checklist .......... 13

Guarantee and Indemnification .................. 15

3M™ Universal Electrosurgical Pad Features and Specifications .............. 16

Ordering Information ............................ 17
Background

This publication is written for physicians, nursing professionals, and biomedical engineers to provide technical information on the new 3M™ Universal Electrosurgical Pad with Safety Ring. It is intended to aid those who are evaluating electrosurgical dispersive electrodes or those who are preparing in-service programs.

The information contained in this document addresses the safety and efficacy requirements such as thermal performance testing, biocompatibility testing, and adhesion-to-skin testing. In addition, this publication also provides information for best practices and use of the 3M Universal Electrosurgical Pad in the operating room for best performance and patient safety.

The electrosurgical dispersive electrode, also called the patient plate, return electrode, grounding pad, Bovie Pad, etc., has been an integral part of monopolar electrosurgery since its introduction by Christian Otto Erbe in 1923. The dispersive electrode has undergone modifications from its original inception as a metal plate placed under some portion of the patient’s anatomy. 3M’s invention of the disposable, dispersive electrode with hydrophilic conductive adhesive addressed issues related to suitable placement sites and ease of use. Until now, however, no non-capacitive electrode design had overcome the technological issue referred to as “corner and edge effect.” Corner and edge effect is the tendency for electrosurgical current to cluster around the leading corners and edges of any resistive dispersive electrode.

3M has now invented a method of reducing corner and edge effect. By doing so, 3M has been able to reduce the size of the electrosurgical pad without compromising patient safety. Smaller pad size will improve the ease of use required in today’s patient care environment. This new technology utilizes a lossy dielectric coating to increase the uniformity of RF current distribution over the entire conductive surface of the dispersive electrode. This proprietary technology allows for a subsequent reduction in overall size of an electrode.
**During Surgery**

**Excessive Power Required:**
When “constant current” generators are used, unusual requests for higher settings on the electrosurgical unit are one of the most common indications of a burn in progress. First, ensure that the pad is in good contact with the patient. If it appears that the pad is not in good contact, repeat the application process as directed, utilizing a new pad. Second, check the cord and connections. Finally, check the active accessories and the electrosurgical unit.

**Patient Repositioning:**
If the patient is repositioned, check pad contact and cable connections.

**After Surgery**

**Pad Removal and Site Inspection:**
Remove 3M Universal Electrosurgical Pads slowly. Rapid removal is more likely to cause skin trauma. Assess the skin condition upon removal of pad.

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**Guarantee and Indemnification**

*We offer the broadest, split-pad indemnification in the industry.*

Use the 3M split-pad with any brand of electrosurgical generator equipped with a CQMS (REM* or NESSY* style) safety system, and 3M will indemnify your hospital, and its employees, medical and professional staff.

If your hospital is like most, it has multiple brands of generators. Our broad indemnification allows your hospital to standardize on one brand of electrosurgical pad.

**Guarantee...**
3M fully recognizes its responsibilities as a manufacturer of health care products and warrants that reasonable care was used in the manufacture of its electrosurgical patient pads, cables and adapters.

**3M’s Technical Organization...**
offers biomedical engineering, clinical and professional support to address any product or product application concerns.

**Key features of 3M’s Split-Pad Indemnification Agreement...**

- Offered to the hospital and its employees, medical and professional staff (hereafter referred to as HOSPITAL).
- Provides that 3M will defend litigation, not just pay back HOSPITAL later if HOSPITAL is found liable.
- Applies regardless of which brand of CQMS type generator is used.
- Applies even if HOSPITAL is found to be liable and 3M not liable.
- Applies so long as claim is promptly reported to 3M.

For additional information about this policy, please contact your local 3M Surgical Products Account Representative or call 3M Technical Service at 1 800 563-2921.
**Application:**

Open the package just prior to use. Then visually inspect the pad for obvious damage. Avoid contact with the adhesive surface. Apply 3M Universal Electrosurgical Pad beginning at one edge and progress to the opposite edge, pressing firmly to ensure good contact of the entire adhesive surface. This technique will avoid entrapment of air pockets. By far the most important aspect of pad application is to assure that the entire conductive area of the pad is in good contact with the patient’s skin, and that it remains so throughout the procedure.

Connect the pad to the electrosurgical unit. Once the pad is applied, do not reuse or reapply it. Good pad adhesion is essential for preventing burns.

**Figure 12  Suggested Application Sites**

<table>
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<tr>
<th>Position</th>
<th>Best Pad Location for the Adjacent Position</th>
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Lossy Dielectric  
(Green Safety Ring)

The 3M Universal Electrosurgical Pad with Safety Ring is an entirely new class of dispersive electrode. Using a lossy dielectric material coated on an aluminum foil substrate at the corners and edges, the electrosurgical RF current is more uniformly distributed over the entire surface of the dispersive electrode. This uniform distribution reduces the potentially harmful “corner/edge effect.” 3M refers to this lossy dielectric coating as the “Safety Ring.”

Thermographic studies confirm that the lossy dielectric coating (Safety Ring) significantly improves the current distribution on dispersive electrodes. The adjacent 3-dimensional thermogram on a human volunteer shows the difference between 20 square inch dispersive electrodes with and without the Safety Ring. In Figure 2 the vertical Z-axis is the Maximum Safe Temperature Rise seen after a test conducted according to the AAMI HF-18 standard. The electrode in the background is one with a bare aluminum foil conductor (similar to all other brands of dispersive electrodes sold today) and the electrode in the foreground is one with aluminum foil and the lossy dielectric coating (Safety Ring). Note that the temperature for the plain Al foil electrode without Safety Ring is much higher, and that the heat is concentrated at the corners of the electrode. In the case of the electrode with Safety Ring, however, the heat is evenly distributed around the entire periphery of the electrode in a broad band.

In addition to the presence of the dark green lossy dielectric coating on the corners and edges of the aluminum foil conductor, there are rings of lighter green color nearer the center of the pad. The purpose of this concentric shading is to create a transition zone between the lossy dielectric at the edge of the conductor, and the bare aluminum foil in the middle of the pad. It is this shading that allows the 3M Universal Pad to work well with both high and low tissue impedance patients.
Generator Compatibility

A Contact Quality Monitoring System (CQMS), i.e., REM®, NESSY®, ARM™, PSS™, etc., uses a split conductor style dispersive electrode and a monitoring circuit within the generator to evaluate dispersive electrode-to-patient contact. This is done by imposing a small AC voltage across the two halves of the split conductor electrode attached to a patient. This voltage is monitored by the generator and must remain within specified limits, or an alarm will sound warning of poor or no electrode-to-skin contact.

A very high impedance may indicate poor contact to the skin. A very low impedance could mean the pad is in contact with a very conductive surface, such as a metal table top.

It is difficult to set impedance limits to ensure the detection of all pad contact failures while eliminating false alarms. This is because the electrode-to-skin impedance varies from patient to patient. Patients with thick layers of adipose tissue generally have a higher impedance than thin patients. A high impedance could indicate either that the patient has an abnormally high tissue impedance, or that pad contact has been compromised. This problem is solved by the use of a second voltage monitor in the CQMS circuit that keeps track of the impedance after the dispersive electrode has been applied to the patient. If CQMS impedance increases by a certain percentage of the initial value, an alarm will sound indicating that the pad is starting to come loose.

Different generator manufacturers have different specifications and methods for measuring dispersive electrode contact impedance, and maintaining compatibility can be a problem. The 3M™ Universal Electrosurgical Pad has been specifically designed to be compatible with all major brands of generators manufactured today.

The chart in Figure 3 shows the CQMS impedance of the Universal Pad on a very broad tissue impedance range of human test subjects. The upper and lower CQMS limits for all of the major brands of generators is also shown. Note how all of the data is centered between the upper and lower limits for each brand, and that there is a comfortable margin between the data and the limits on both sides.

For information on ERBE electrosurgical hardware and pencils dial 1 800 668-5236.
Application and In-service Checklist:

Before Surgery

Primary Considerations for Pad Application Sites:

The site should be well-vascularized, smooth, and muscular. Common placement sites include the anterior thigh or upper arm. This will help to ensure that all of the pad’s conductive area is in contact with the skin. See the Chart of Pad Application Sites. (Figure 12)

Adipose tissue, scars and bony areas are poorly perfused and they have a high electrical resistance. This means that they are more likely to experience a dangerous temperature rise and they have less of a blood supply to remove excess heat. When possible, avoid extremely adipose areas and never apply a pad over bony areas, such as the ribs or scapula.

3M Universal Electrosurgical Pads can be placed on any surface where complete pad-to-skin contact can be obtained. If the patient has a pacemaker, implanted neuro-stimulator, or other conductive implant, the pad should be placed so the electrosurgical current does not flow across the implanted device. Do not apply the pad where fluids may pool. This could compromise electrical isolation of the electrosurgical unit.

Secondary Considerations for Pad Application Sites:

Choose the best application site that is closest to the surgical site. However, it is more important to have a good application site as described above, than it is to place the pad close to the operative site. ECG electrodes should also be placed as far from the operative site and 3M Universal Electrosurgical Pads as reasonable. This will reduce the possibility of burns under the ECG electrodes. It may also reduce ECG artifact and the amount of time that the ECG trace is off the screen.

Site Preparation:

Hair at the application site should be removed as necessary. (If a solid style plate is being applied, all hair must be removed prior to pad application.) The skin must be clean and dry prior to applying the pad.
Biocompatibility

Chemical skin irritation and local allergic skin reaction are often similar in appearance and can be very annoying to the patient and worrisome to the staff. For this reason, materials that are placed in extended contact with patients should undergo biocompatibility testing. Since human skin varies considerably from person to person, several standard tests are required. The material present in the 3M™ Universal Electrosurgical Pad remains within normally accepted parameters for the tests outlined below.

Cell Culture Toxicity Screening:
The test materials are placed on an agar overlay covering a monolayer of cells. Toxic materials will cause death in the thin layer of cells.

Primary Skin Irritation (Modified Draize Test):
The test materials are applied by a patch-test technique to both intact and abraded skin. The skin is examined after one or two days for evidence erythema and edema.

Cumulative Irritation:
The test materials are applied to human subjects for 21 days. Each day the application sites are examined for evidence of irritation.

Modified Draize Predictive Patch Test:
This test is used to evaluate whether the test materials could cause allergic contact sensitization or delayed hypersensitivity. Test material is applied to human subjects (of varying age, sex, and weight) for three weeks in order to induce allergic sensitization. After a two week rest period, a challenge patch is applied for 24 hours and the skin is examined at 48 hours and 72 hours for reaction.

Biocompatibility Summary:
The optimization of dispersive electrode design requires that all of the factors affecting safety be considered. This was the goal in the design of the 3M Universal Electrosurgical Pad. It has been carefully designed and thoroughly tested to provide a true margin of safety for allergic skin reaction and chemical skin irritation.
Curved Split Design

Unlike all other split pad designs which utilize a parallel split between the two halves of the dispersive electrode, the 3M Universal Pad has a curved split between the halves of the conductor surface. The purpose of this curved split is to increase the sensitivity of the CQMS circuits in all major brands of generators, so that the alarm will sound with less of the pad peeled off the patient. The electrical theory of this curved split is explained below.

With a split pad in place on a patient, the pad’s CQMS impedance can be thought of as the total impedance of a group of resistors wired together in parallel. The total impedance of such a circuit is calculated by the formula:

$$\frac{1}{R_{total}} = \frac{1}{R_1} + \frac{1}{R_2} + \frac{1}{R_3} + \frac{1}{R_4} + ... + \frac{1}{R_n}$$

For a traditional split with parallel sides, the resistors all have the same value, while for the new 3M Universal Pad’s curved split, the resistors in the middle have a larger value, since the edges of the split are further apart from each other. As the calculations in the following theoretical example show, the CQMS impedance for the parallel split increases 25% as the pad is peeled back 20% (1/5th of its length), while the CQMS impedance for the 3M curved split increases 35% with the same peel back distance. For any split pad which is peeled back in a direction that is perpendicular to the split, a curved split will cause the CQMS alarm on an ESU generator to sound with less peel back than with the same design utilizing a parallel split.
In 1981, 3M invented and patented the first hydrophilic conductive adhesive to be used on a dispersive electrode. Since then, this adhesive has been improved to provide the softness, thickness, and adhesion level desired by the majority of nurses in extensive preference testing.

The 3M Universal Pad’s conductive adhesive is hydrophilic, so it can absorb perspiration that may be generated by the skin of the patient at the pad placement site. This can be an important consideration in long surgical procedures where posterior placements and the use of heating blankets may be involved. When this conductive adhesive is exposed to perspiration, its already high level of conductivity is increased even further, so that excellent adhesive-to-skin electrical contact is assured.

The smaller conductor surface area and thickness of the 3M Universal Pad’s conductive adhesive also minimizes the cold sensation associated with initial pad placement. Thicker gel layers have a larger thermal mass that can draw more heat from underlying tissues. In addition, these thicker pads feel much colder to patients who are undergoing outpatient surgery and are not anesthetized when the dispersive electrode is placed on them.

Finally, since the conductive adhesive of the 3M Universal Pad has been specifically designed to provide a secure level of adhesion to the patient’s skin in its own right, it does not require the use of an overly aggressive border adhesive to hold it safely in place. Thus, the possibility of skin stripping is minimized. The pressure sensitive adhesive on the border of the 3M Universal Pad is the same adhesive that is used on 3M™ Micropore™ Tape, which has 30+ years of history providing gentle, but secure adhesion.
Moisture Protection:
An electrosurgical pad should not allow liquids to come in contact with its conductive surface. Water or body fluids can form conductive bridges with the grounded O.R. table and possibly compromise electrical isolation. It can also adversely affect most gels and adhesives.

The 3M Universal Electrosurgical Pad keeps out moisture in two ways. First, the pad’s backing has a non-woven polypropylene material combined with a thin polyethylene extruded film which forms a barrier to moisture. Second, the pad has a narrow nonconductive isolation border, coated with 3M’s Micropore™ pressure sensitive adhesive, surrounding the conductive adhesive to resist moisture from all sides.

Electrode-Skin Impedance:
Alternate current path burns may result when ground referenced current seeks low impedance paths to ground through ECG electrodes or other grounded objects. A low impedance between the electrosurgical pad and the skin reduces this possibility of alternate current path burns.

The hydrophilic conductive adhesive establishes a very low electrode-skin impedance at electrosurgical frequencies. Upon application, the conductive adhesive conforms to the minute surface irregularities of the skin in a matter of seconds. The contact impedance of both the split and solid 3M Universal Pads, as measured under AAMI section 5.2.3.2, is less than 1 ohm.

Cable Attachment:
Cable connections should be designed so they will not compromise pad adhesion or cause pressure injuries. Strong mechanical tension on the cable can dislodge the pad from the patient. On 3M Universal Electrosurgical Pads, the cable attachment is near the end to prevent tenting, but stress relief tabs on both sides of the connection distribute cable forces that could otherwise cause the pad to peel off the skin.

Figure 10 3M 21100 Series Clamp and Cable
In viewing these thermograms, it can be seen that the 3M Universal Pad has more yellow around the edge of the conductor than the conventional resistive pad. This is not, however, an indication that the heat under the 3M Universal Pad is greater than the heat under the larger conventional resistive pad. The 3-dimensional thermogram’s side view in Figure 9 shows that the maximum height (or temperature) of both pads is identical, indicating that they have the same maximum temperature rise. The fact that the 3M Universal Pad has more surface area operating at the same maximum temperature as the plain resistive pad shows the efficiency of its design.

In summary, the thermal performance of the 3M Universal Pad is similar to conventional pads that are up to 33% larger in surface area. The lossy dielectric coating (green Safety Ring) on the 3M Universal Pad makes it more efficient, allowing its size to be reduced and making it more convenient to handle and place.

Figure 9  Side View of a
Low R-Value Non-foam Backing Material

Our low thermal backing is a composite of non-woven polypropylene covered with a fluid resistant, non-conductive, low-density polyethylene film. In addition to being much more tear resistant than a traditional foam backing, this backing material is thinner, which enhances its conformability and ability to stick to uneven body contours. Most importantly, the R-value (its resistance to heat transmission) for this new backing is 25% lower than the value for foam backings that are commonly used today on dispersive electrodes. Since heat is generated in the skin under dispersive electrodes, and foam is an insulating material which tends to block the flow of this heat, the use of a material which permits heat to escape faster is appropriate.

Electrical and Thermographic Performance

Since burns can result from heating under the pad, verification of thermal performance is essential. The Association for the Advancement of Medical Instrumentation (AAMI) has defined thermal test methodology and performance criteria for electrosurgical pads.

Test methodology consists of passing electrosurgical current through a pad (0.7 amperes of current through the test pad for 60 seconds) and measuring the resulting temperature rise of the skin, under and around the pad.

The temperature rise under a pad is a good indicator of its thermal safety. Given sufficient time, a temperature of 45 °C will burn the skin. Since human skin is usually 30 °C to 33 °C, a burn will not occur until the pad causes a temperature rise of about 12 °C. In order to provide a thermal safety margin, the skin under a pad should remain much cooler than this during electrosurgery. J.A. Pearce et al. recommend a thermal safety factor of two—that is, the temperature rise should not exceed 6 °C, a value that AAMI has adopted as a standard for dispersive electrodes.

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**Measurement Methods:**

The thermographic camera is currently the most accurate instrument for measuring skin temperature. Other temperature sensing techniques either provide poor resolution or affect the test pad’s thermal characteristics. For example, thermocouples may interfere with electric fields or they may be directly heated by the current. Also, local hot spots, which are often smaller than one centimeter, could easily escape detection by widely spaced thermocouples.

3M’s Agema thermographic camera produces high resolution color images of the thermal patterns, accurate to 0.1 °C.

3M validated the performance of its Universal Pad using the thermal test methodology defined by the Association for the Advancement of Medical Instrumentation (AAMI). Results have been verified with extensive testing on human volunteers.

A number of precautions were taken to ensure accurate, reproducible test results. The test environment was free of artifact producing heat sources. A baseline picture of the test subject was taken before the pads were applied. Small reference dots were placed on the test subject to allow precise alignment of this image (with later test images). After the pads were placed on the test subject, they were allowed to equilibrate to normal skin temperature for 30 minutes. When the tests were performed, the thermograms were taken within 10 seconds after the end of the test to avoid inaccuracies from cooling due to evaporation of gel or perspiration. Finally, the baseline skin temperature picture was “subtracted” from the thermal image, to remove any error from the measurement due to uneven temperatures on the subject’s skin at the start of the test. All of these steps are necessary to produce accurate and reproducible thermal data.

**Summary of Thermographic Studies:**

Both the split and solid versions of the 3M™ Universal Pad pass the 1993 AAMI HF-18 Maximum Safe Temperature Rise test, section 5.2.3.1. In addition, the split (CQMS compatible) 3M Universal Pad with Safety Ring passes the more demanding section 5.2.8.2.2, which requires that the pad pass the Maximum Safe Temperature Rise test after the pad has been peeled back to the point of alarm with a CQMS equipped generator. This test must be passed twice, with the pad peeled back once in the direction perpendicular to the split, and once in the direction parallel to the split.
The thermogram in Figure 7 shows the 3M Universal Pad on the right anterior thigh of a human test subject, and a 20 square inch commercially available conventional pad on the left thigh. Note that there is very little current concentration on the bottom 3/4 of the conventional pad, indicating the relative inefficiency of this pad, while with the 3M Universal Pad current is being collected all the way around the periphery of the conductor in a broad band.

A 3-dimensional perspective plot of the previous thermogram is shown in Figure 8. The AAMI 6 °C temperature rise limit and the burn threshold limit of 12 °C have been added to the plot. Note that both the 3M Universal Pad and the larger conventional pad are well under both limits, indicating that they both meet the AAMI requirement for Maximum Safe Temperature Rise.

**Universal Orientation**

It should also be noted that with the 3M Universal Pad, the orientation has a negligible effect on the thermal performance of the pad. The pad may be placed so that a single corner of the pad is closest to the surgical site, without significant change in thermal performance. This is made possible by the use of the Safety Ring (lossy dielectric coating) on the Universal Pad, which prevents heat-producing current concentrating on the corners of the pad, regardless of orientation.