

# MEGA 2000® Patient Return Electrode System

## Theory of Operation and Product Description

### Theory of Operation:

The Mega 2000 Patient Return Electrode System is designed to safely exit current from the patient, and return it back to the generator to complete the electrosurgical circuit.

Mega2000 is a unique product which provides benefits to both the clinical users and the economic managers without compromise to either group. Mega2000 provides benefits in “ease of use” to the clinician in the operating room setting as well as improved patient outcomes through greater safety and efficacy, without compromise. It provides between a 30% and 70% reduction in cost per use when compared to the current disposable gel pad technology. Most new medical device offerings provide benefits to either the economic or clinical user, but very few, such as the Mega2000, provide both, making it a true “win win” situation.

Mega2000 works on the principle of capacitive coupling utilizing materials with a much higher impedance per area which adds a level of safety equal to or exceeding that of monitoring style gel pads. Capacitive coupling can be defined as the flow of current through a capacitor. A capacitor is essentially two metal plates separated by an insulator. During monopolar electrosurgery the patient is very conductive and can be viewed as one plate in the circuit. The Mega2000 Reusable Patient Return Electrode pad is essentially a single conductive material sandwiched by two sheets of flexible urethane. The conductive portion of the Mega2000 pad is the other plate of the capacitor. The insulating materials between the conductor are the flexible urethane sheet, the protective sheath, O.R. table linen, and draw sheet. The pad DOES NOT make direct contact with the patient. Due to the oscillating, high frequency nature of the current flow, current flow is INDUCED from the patient to the pad, safely exiting current from the patient.

The ability for current flow to be INDUCED into the Mega2000 pad is directly proportional to the amount of patient area in “contact” known as the weight bearing area of the patient placed over the pad. In other words, when the patient has little “contact” with the pad, the pad’s ability to conduct an adequate amount of current becomes diminished.

When the “contact” area the patient has with the pad decreases to a minimal level, the relatively high impedance per area limits current flow from the patient to the pad. By limiting, or regulating the current flow, the current density is ALWAYS kept sufficiently low to prevent heat buildup under the pad and a subsequent burn. This current limiting feature is built in to the pad and requires no special circuitry to function. Mega2000 achieves a significantly higher impedance per area due to the materials of construction e.g. the polyurethane plastic. The term used to describe this material property is “bulk resistivity” which is selected to maintain the desired impedance. The Mega2000 is designed using materials with a higher impedance per area which WILL NOT ALLOW CURRENT TO FLOW at dangerous levels when the “contact” area becomes too small. The nature of the material properties prevents current densities from reaching unsafe levels. Standard patient return electrodes are manufactured using materials with a lower bulk resistivity or a lower impedance per contact area which will allow the current to still flow even while the contact area is reduced. This constant current flow through a reduced contact area results in higher current densities, which can lead to a patient burn at the return electrode site.

The relatively large size of the Mega 2000 pad in concert with the safer high bulk resistivity material selection enables safe and efficacious electrosurgery. Adequate “contact” area between the patient and the pad, which shows no compromise in surgical effect / power setting, has been easily achieved in many surgical positions including: supine, prone, lateral, lithotomy, and modified beach chair.

**Product Description:**

The materials of construction include two layers of flexible urethane. A flexible conductive layer is sandwiched and bonded between the two layers of urethane which is hermetically sealed around the perimeter. A jacketed, copper conductor cable is attached at one corner of the conductive layer which is then over-molded to provide a suitable strain relief. At the other end of the cable is a female plug designed to be compatible with common electrosurgical generators. The protective sheath that the pad is placed into is made from polyethylene resin. Latex is not contained in any of the materials used in fabrication of this system.

- FDA 510(k) number K982826
- Meets or exceeds applicable AAMI (U.S.) Electrosurgical Standards
- Meets or exceeds applicable IEC (International) Electrosurgical Standards
- Compatible with isolated electrosurgical generators