

Method of Reducing Stray Energy Burns in Laparoscopic Surgery

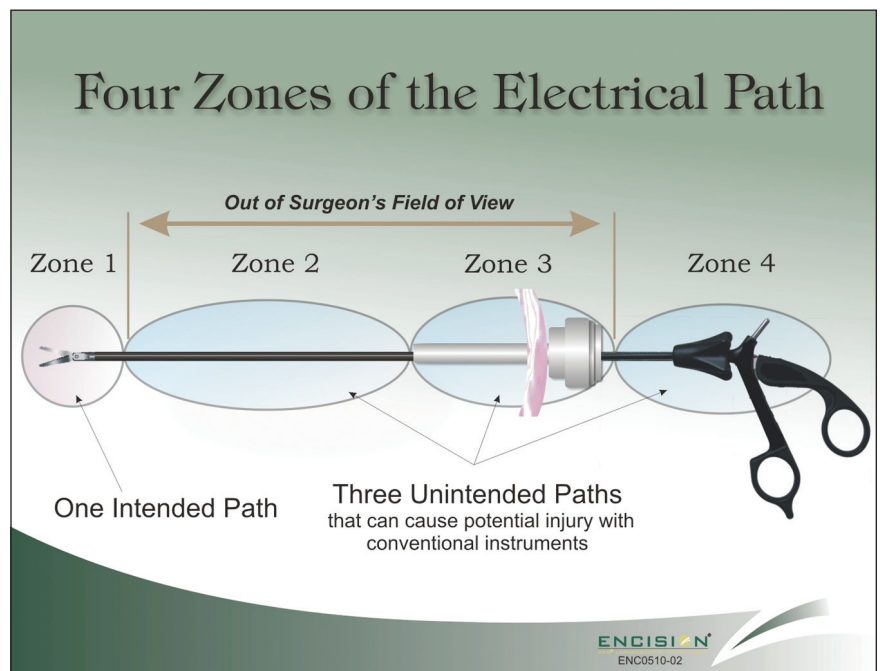
Active Electrode Monitoring (AEM) instruments incorporate a “shielded and monitored” design to lower risk of injury.

Encision Inc., Boulder, CO

Any surgery brings with it risk, both to the patient and the surgeon. However, laparoscopic surgery sometimes brings an additional invisible risk: stray energy burns. Electrosurgical devices and laparoscopic instruments can suffer insulation failures and capacitive coupling, potentially causing stray energy burns to the patient. Often these burns occur out of sight of the surgeon and may go unnoticed until the patient presents with symptoms like peritonitis or sepsis.

A recent jury award of \$2.2 million dollars in San Diego brings renewed light to the risk carried by medical device makers. The patient in the case suffered a perforated bowel during laparoscopic surgery, causing peritonitis. The jury found the surgical device maker liable under product liability and negligence causes of action. It is always in a device maker's best interest to provide the safest, most stable device possible to protect both the patient and the surgeon. Incorporating safeguard technology is imperative, especially when costs are comparable and surgeon technique is unaffected.

During laparoscopic surgery, as much as 90 percent of the active electrode is out of the view of the surgeon, where stray energy burns can affect non-targeted tissue. With the advent of emerging Single Port Access procedures, a new type of risk has occurred as the instruments in the access device, “sword fight” or contact each



Stray energy is any energy that is outside of the intended electrical path. In the diagram, Zone 1 is the area at the tip of the active electrode in view of the surgeon. Zone 2 encompasses the area just outside the field of view of the surgeon to the end of the cannula. Zone 3 is the area of the active electrode covered by the cannula system. Zone 4 is the portion of the electrode and cannula that is outside the patient's body. During laparoscopy, 90% or more of the active electrode may be outside the surgeon's field of view in Zones 2, 3, and 4, where stray energy burns can occur in non-targeted tissue.

other, presenting another opportunity for electrical coupling and unintended burns. There is a solution available, and the technology can be licensed for use by other device makers.

The risk of stray energy burns can be minimized and even eliminated

through patented AEM® (Active Electrode Monitoring) technology. AEM instruments incorporate a, “shielded and monitored” design to prevent the risk of stray energy burn injury from insulation failure and capacitive coupling.

AEM technology consists of two primary components: AEM laparoscopic instruments and the AEM monitor. Whereas conventional instruments are simply a conductive element with a layer of insulation coating, every AEM instrument has a multilayered insulation design with a built-in “shield,” a concept much like a third-wire ground in standard electrical cords. The components of the AEM technology are as follows:

- The **active electrode element** is the central core of the instrument.
- The **primary insulation layer** withstands the high voltages needed to perform cutting and maintain hemostasis.
- The **protective shield** is a tube that surrounds the primary insulation layer. The shield conducts stray current from the active electrode back to the generator and away from the patient during surgery.
- The **outer insulation**, similar to that used on a conventional instrument, ensures energy containment within the shield component, even under primary insulation failure conditions.
- The **monitor** is attached to the generator and to the laparoscopic instrument. The AEM monitor is compatible with commonly used electro-surgical

power sources. During electrode activation, the monitor continuously checks for primary insulation failure and prevents capacitive coupling. If the monitor detects a dangerous situation, it interrupts the power by shutting down the generator, alerts the surgeon and staff, and protects the patient from thermal burn injury.

Conventional monopolar instruments have two inherent design weaknesses. First, a conventional instrument consists of a conductor and a single layer of insulation. If any defects exist before surgery or occur during surgery in this primary layer of insulation, the patient is at risk for a stray electro-surgical burn.

Secondly, conventional monopolar instruments do not have a monitoring system that will continuously check for a dangerous electrical situation during electrode activation. Several peer-reviewed studies have examined the tendency of monopolar laparoscopic instruments to have an insulation failure that could lead to a burn. On average, these studies show that 21 percent of monopolar laparoscopic instruments involved in the studies had an insulation failure. That’s one in five instruments with the potential of causing a stray energy burn.

AEM technology is currently being licensed by Intuitive Surgical’s da Vinci® Surgical Systems to enable safer laparoscopy for the next generation of minimally invasive surgery. The AEM product line includes all of the standard shapes, sizes, and functionality as conventional instruments, but with patented “shielding and monitoring” technology integrated into the design. Broader utilization of AEM technology can result in improved surgical outcomes and advanced patient safety, at a comparable cost. It also does not require the surgeon to change his or her techniques. AEM is the only technology that continuously shields and monitors the instrument during surgery to prevent stray energy burns that can cause unintended injury to patients.

Limiting risk is important to the patient, the surgeon, and the hospital’s risk management team. The far-reaching consequences resulting from a stray energy burn can not only have precipitous impacts on the patient’s health, but also on the overall reputation of the surgeon, the instrument manufacturer, and the medical institution providing the care.

This technology was done by Encision Inc., Boulder, CO. For more information, visit <http://info.hotims.com/34453-193>.

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