

ENCISION[®]

AEM[®] SAFETY - PERFORMANCE - VALUE

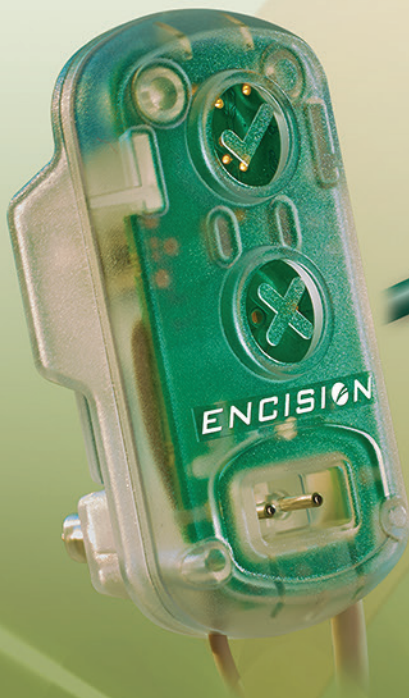
the Encision AEM[®] Solution

NEW!

AEM
ENDOSHIELD™
BURN PROTECTION SYSTEM

AEM
e.Edge™
SCISSORS

AEM
en.Touch™
INSTRUMENT PLATFORM



www.encision.com

The AEM EndoShield is currently undergoing premarket review by the FDA.

Why Encision?

Encision develops and manufactures innovative surgical devices that optimize patient safety and surgeon technique through AEM technology and design expertise.

To reduce the chance of patient injury during minimally invasive surgery, Encision® pioneered the development of patented Active Electrode Monitoring (AEM®) technology. Traditional monopolar laparoscopic instruments have an inherent design flaw, making them prone to insulation failure and capacitive coupling, which causes damaging stray energy burns to patients. AEM eliminates the chance of stray energy burns by electrically shielding the laparoscopic surgical instrument shaft. Encision's broad portfolio of state-of-the-art laparoscopic AEM instruments provides high performance as well as obvious safety advantages.

The Encision Solution high-performance, laparoscopic AEM instruments deliver exceptional value with guaranteed patient safety from stray energy burns.

The new disposable AEM EndoShield™ Burn Protection System utilizes advanced AEM monopolar energy, allowing surgeons a safe energy choice for higher power settings. A convenient add-on, compatible with widely used electrosurgical generators, AEM EndoShield has an intuitive interface that minimizes the need for staff training. It is designed to work with state-of-the-art AEM instruments, helping physicians quickly achieve optimal results and minimize complications.

One-of-a-kind indemnity guarantee.

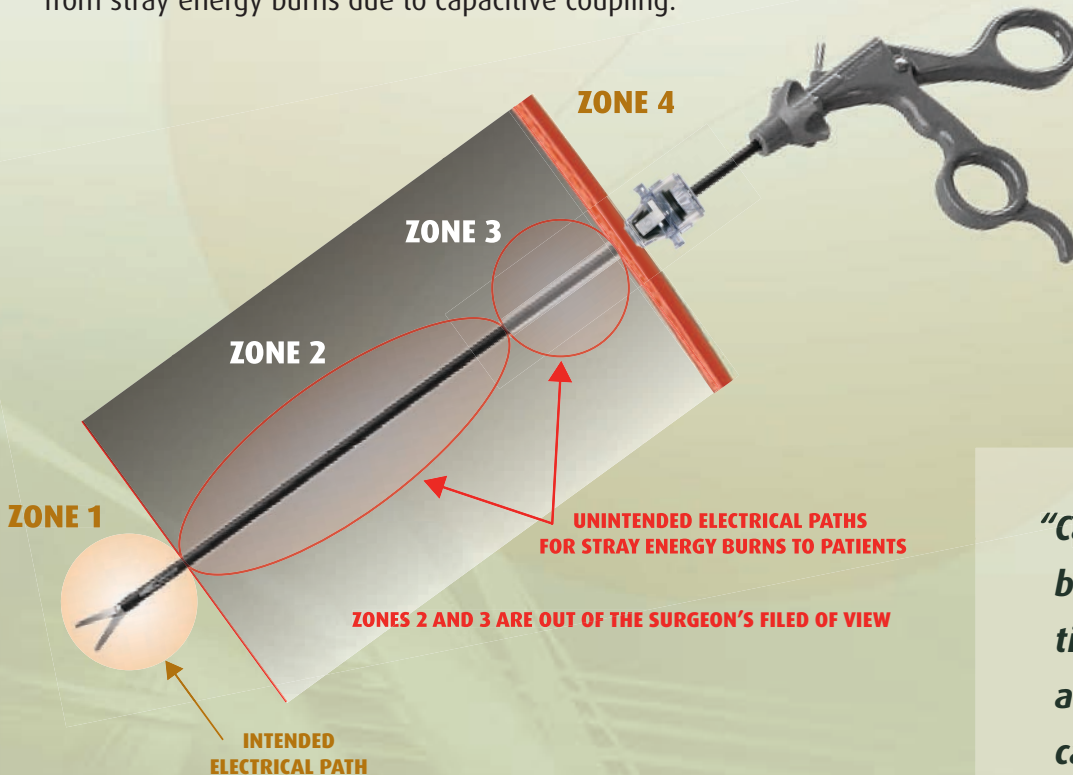
Confident of AEM technology's ability to eliminate stray energy burns, Encision offers customers its **Hold Harmless Guarantee**—a legal contract offering full indemnity to any physician or hospital using AEM monopolar instrumentation to eliminate stray energy burns. No other company in the world offers this type of guarantee because no other technology eliminates stray energy burns.



Why AEM?

It's not the technique, it's the technology!

- **Inherent design flaw:** Non-shielded monopolar laparoscopic instruments have a single layer of insulation, making them more prone to [insulation failure](#) and [capacitive coupling](#), which cause patient burns.
- **Low power settings are no guarantee:** Some ESU technologies claim to have a reduced level of capacitively coupled energy when used in specialized modes and low power settings. However, the level of reduction is not clearly defined and may still lead to patient burns. Additionally, none of these technologies claim to prevent patient burns from insulation failure. [Click here to see a comparative study of AEM and non-AEM instruments.](#)
- **Unobserved and undiagnosed:** Stray energy burns frequently occur in zones two and three, outside the surgeon's field of view. Compounding the issue is the fact that patient burn complications often present similarly to typical postoperative symptoms, "... low-grade fever, abdominal pain, and moderately elevated white blood count."² As a result, stray energy burns typically go undiagnosed causing treatment delay, [allowing severe complications to further manifest.](#)
- **Single Port Access (SPA) surgery:** With [advanced surgical techniques such as SPA](#), there is an increased opportunity for capacitive coupling. During these procedures, instruments are in close proximity to one another, which leads to a significantly increased risk of burning a patient.
- **Inadequate standard safety protocols:** Hospitals commonly employ visual inspection and/or electrical "wandering" of laparoscopic instrumentation as a precaution against insulation failure. Studies have shown that the rate of potential stray energy burns, from insulation failure, is no better, despite these precautionary measures. What's more, there are no precautionary measures that can protect patients from stray energy burns due to capacitive coupling.²



"Categorized as unintended burns to non-targeted tissue, stray energy burns are often undetected and can result in serious and even lethal outcomes."¹

Why AEM? *(continued)*

Patient burns can lead to poor patient outcomes, erode surgeon confidence, and substantially drain hospital resources.

- Over a 10-year period in the USA alone, patient burns resulting in thermal bowel injury have led to **more than 16,500 patient complications and 4,000 preventable patient deaths.**³
- Over that same period, more than 62,000 preventable patient injuries have occurred due to stray energy burns from laparoscopic surgery; if left untreated, the injuries can lead to peritonitis and possibly death.⁴
- Under the **Hospital Acquired Condition (HAC)** Reduction program, an initiative put forth by the Center for Medicare and Medicaid Services (CMS), hospitals are penalized 1% of all CMS funding for high rates of HAC, of which stray energy burns to patients are one of the key metrics. For some larger facilities, this could add up to millions of dollars a year.¹¹
- In addition to the CMS penalties assessed by the HAC reduction program, it is estimated that the direct cost of readmission and medico-legal expenses associated with **patient burns is \$249 per procedure.**

4, 6-8,13-15, 17-18

- It is thought that many complications from stray energy burns go unreported and unpublished. Such adverse events can negatively impact a surgeon's reputation and significantly handicap the future business of the hospital.
- Reported adverse events associated with stray energy burns can be a drain on hospital resources, as substantial time and money may be spent on lawsuits, litigation and settlements.

An emerging standard of care, AEM Burn Protection technology continuously shields and monitors the active electrode to eliminate stray energy burns resulting from insulation failure and capacitive coupling.

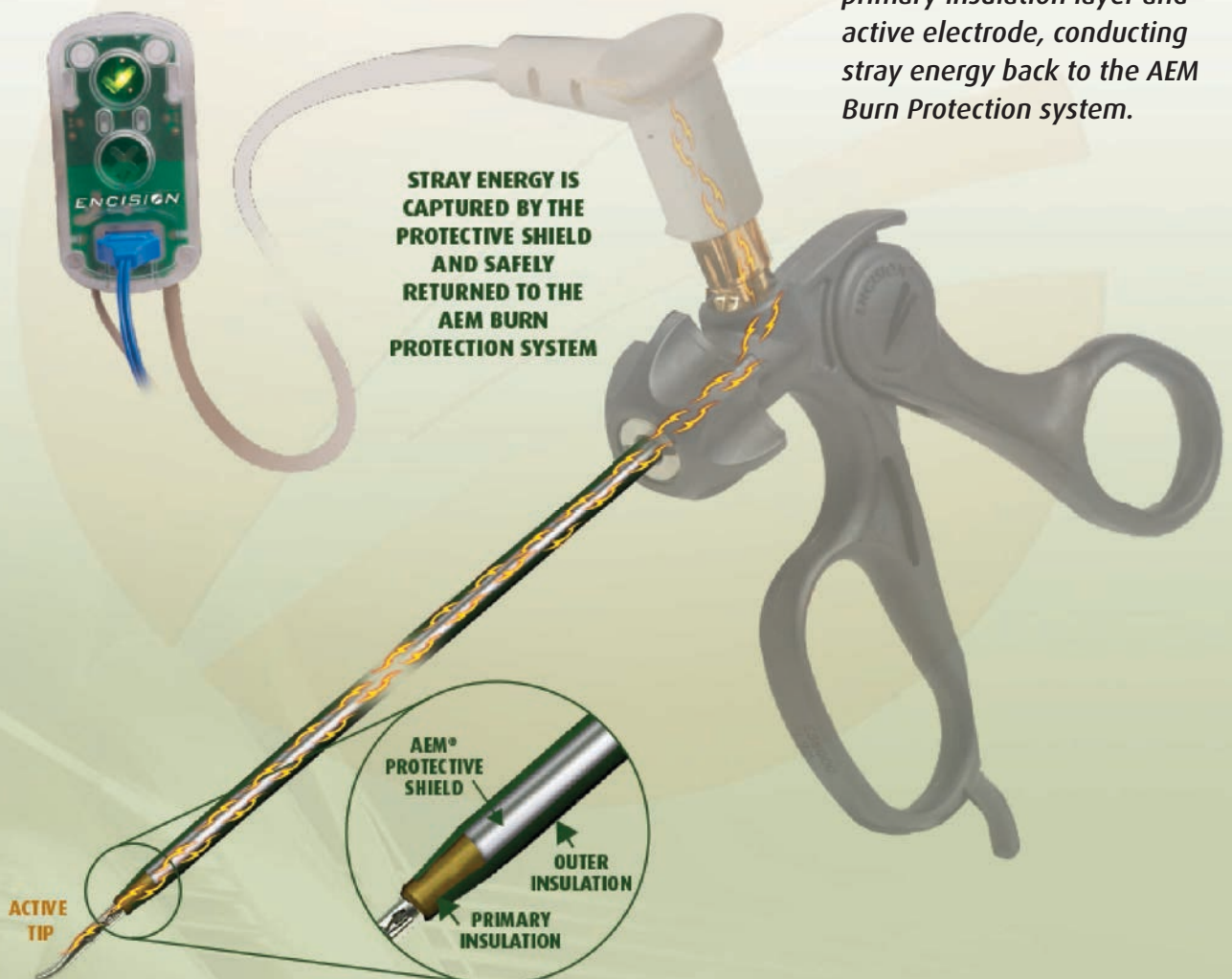


How AEM works...

Every AEM instrument has a protective shield that is actively monitored by the AEM Burn Protection system throughout a procedure. The protective shield conducts stray energy back to the generator, ensuring there is no chance of a stray energy burn to the patient. Additionally, when the AEM system detects an insulation failure, power to the instrument is immediately shut down—similar to a circuit breaker (GFCI) in the electrical wiring of a house.

Other electrosurgical energy forms can be an effective alternative to monopolar energy. However, these technologies have limited application and significantly higher instrumentation cost. Only Encision's AEM technology guarantees patient safety from stray energy burns, while providing the benefits of advanced AEM monopolar energy.

AEM instrument's actively shielded protection



Active electrode monitoring is a recommended practice by several organizations, including the Society of Laparoendoscopic Surgeons and the Association of Operating Room Nurses (AORN).¹⁶⁻¹⁹

To withstand the high voltages of electrosurgery, the primary insulation layer surrounds the active electrode. Next, the protective shield surrounds the primary insulation layer and active electrode, conducting stray energy back to the AEM Burn Protection system.

How AEM works... *(continued)*



At Encision, we understand that patient safety, quality, and affordability are all extremely important to our customers.

The new **AEM EndoShield Burn Protection System** is a convenient add-on that guarantees safety from stray energy burns.

- Compatible with widely used electro-surgical generators, in all modes
- Uses advanced AEM monopolar energy, allowing surgeons a safe energy choice for higher power settings
- Intuitive interface requires minimal staff training
- Plug-and-play capability provides always-ready-to-use convenience
- Eliminates capital budget requirements
- Eliminates costly cleaning and maintenance of reusable AEM monitors
- Substantial time savings over reusable AEM monitor setup



AEM EM3 monitor



For customers requiring hand-control instrumentation, we offer our AEM EM3 monitor. A reusable device, the EM3 provides the same best-in-class instruments and AEM protection from stray energy burns. Consignment is an option for the cost-sensitive customer, providing on-demand product delivery throughout the budget cycle.

AEM Instruments allow masterful control



Machined from a solid block of high-density, heat-treated, alloy steel using advanced EDM technology, state-of-the-art AEM instruments help physicians quickly achieve optimal results and minimize complications.



enTouch™ Instruments—the 7-1 mechanical advantage

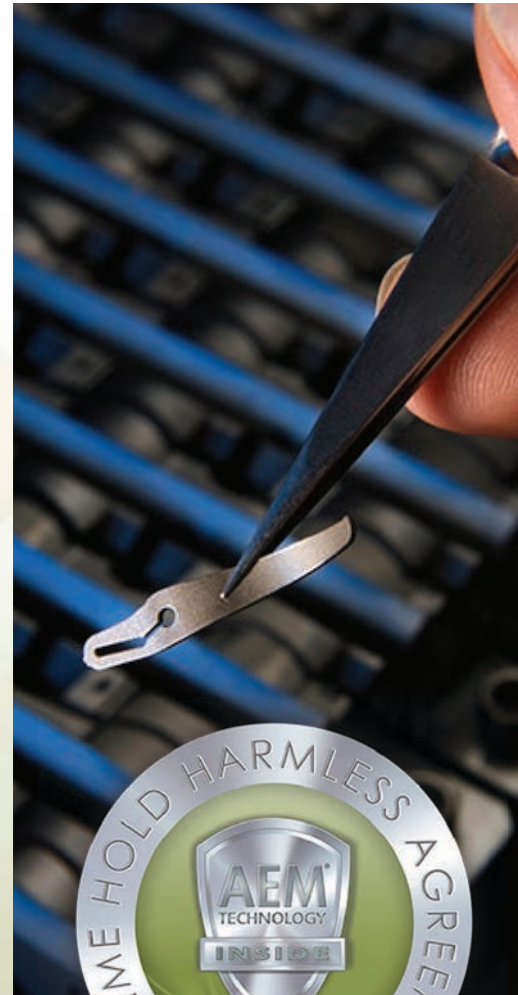
- Force applied at the trigger is amplified and directly transferred to the tip, which may reduce hand fatigue for the surgeon.
- Direct-drive trigger and a stiff shaft provide tactile feedback to the surgeon for enhanced stability and power, ensuring optimal tissue manipulation with AEM graspers.
- Indexing, locking rotation knob prevents the grasper from rotating, allowing precision tissue manipulation.
- Modular handle allows surgeons to quickly change tip styles on the go.
- Pairs with a wide portfolio of AEM enTouch graspers and dissectors (60+ tip styles) to satisfy surgeon preference and ensure the right instrument for the most demanding surgical procedures.

AEM Instruments allow masterful control



Super sharp, precisely edged scissors

- Out-of-the-box sharpness avoids the dulling that comes from continued use of reusable and reprocessed scissors.
- Micro-serrations on the blade "grip" tissue, helping physicians quickly achieve optimal results and minimize complications from tissue extrusion.
- Disposable sheath accessory allows ultra-precise concentration of the energy delivery to the tip.



Rotatable precision

- Stiff shaft and rotatable electrode enable precise positioning of the active tip.
- Ergonomically designed hand piece provides enhanced stability and power ensuring optimal tissue manipulation.
- Available in a wide variety of styles (tips, lengths, foot/hand control, suction and irrigation designs) to satisfy surgeon preference and ensure the right instrument for the most demanding surgical procedures.

Encision's AEM Burn Protection system provides exceptional value with guaranteed patient safety from stray energy burns.



The Encision Solution *abates the financial risk* related to stray energy burns produced by insulation failure and capacitive coupling:

- Significant financial penalties under the [Centers for Medicare & Medicaid Services \(CMS\) Hospital Acquired Condition \(HAC\) Reduction program](#)—1% of all CMS inpatient revenue, approximately 0.4% of all revenue.
- Direct cost of patient readmission
- Potential costly events such as lawsuits, litigation, and settlements
- Tarnished hospital and surgeon reputation can handicap future business

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With an intuitive interface, plug-and-play capability and wide ESU compatibility, the AEM EndoShield provides always-ready-to-use convenience. And it's disposable, eliminating capital budget requirements.

When combined with the obvious safety advantages of the AEM EndoShield, Encision's state-of-the-art laparoscopic AEM instrument portfolio provides surgeons and hospitals the high-performing solution they require. Disposable instruments eliminate the cost and effort expenditure of reusable instrument maintenance, while the robust design of reusables promotes maximum ROI. The comprehensive AEM instrument portfolio improves the overall cost-per-procedure value and promotes optimal inventory management.

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ENCISION INC.

6797 Winchester Circle • Boulder, CO USA 80301 • T: 800.998.0986 • F: 303.444.2693 • www.encision.com