ENCISION®

AEM® SAFETY – PERFORMANCE – VALUE

the Encision AEM® Solution

NEW!

AEM® ENDOSHIELD™ BURN PROTECTION SYSTEM

AEM® e-Edge™ SCISSORS

AEM® en-Touch® INSTRUMENT PLATFORM

The AEM EndoShield is currently undergoing premarket review by the FDA

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EXECUTIVE SUMMARY

At Encision®...we recognize that today's healthcare professionals are faced with providing safe, high-quality clinical outcomes while containing costs. As a solution, we offer our AEM® Burn Protection system—high-performance, laparoscopic AEM instruments that deliver exceptional value while guaranteeing patient safety from stray energy burns.

Stray energy burns are a real hazard in monopolar laparoscopy. Traditional monopolar laparoscopic instruments are inherently flawed. They cannot contain the electrosurgical energy they transmit, which may escape through insulation failure or capacitive coupling, resulting in inadvertent stray energy burns to patients.

To reduce the chance of patient injury during minimally invasive surgery, we have pioneered the development of patented Active Electrode Monitoring (AEM) technology. AEM eliminates the chance of stray energy burns by electrically shielding the laparoscopic surgical instrument shaft.

Our 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 our state-of-the-art AEM instruments, helping physicians quickly achieve optimal results and minimize complications.

While guaranteeing patient safety from stray energy burns, the ***Encision Solution*** also provides protection against avoidable expenditures such as CMS HAC reduction penalties. A new Centers for Medicare and Medicaid Services (CMS) initiative, hospitals with high rates of hospital acquired conditions (HAC) are penalized 1% of all CMS funding—for some facilities this could mean millions of dollars a year.

This Value Analysis Brief will define the problem of stray energy burns during laparoscopic surgery, describe how the AEM Burn Protection System resolves the issue, and categorize the many advantages gained from using this system.

The AEM Burn Protection system is the only technology that eliminates the risk of stray energy burns during laparoscopy. In fact, we believe in our AEM technology so much, we offer full indemnity to any physician or hospital using AEM monopolar instrumentation to eliminate stray energy burns.

Once you've reviewed the information in this document, we encourage you to contact us to learn how you can get the AEM guarantee for you and your patients.

Sincerely,

Gregory J. Trudel

Encision President and CEO

The implications of stray energy burns

Over a 10-year period in the USA patient burns resulting in thermal bowel injury have led to more than 16,500 patient complications and 4,000 preventable patient deaths.[1-6]

CMS analyzes U.S. hospital data annually, assessing a HAC score for each facility. Accidental Punctures and Lacerations (APLs) account for 15% of the total HAC score; stray energy burns to patients are estimated to be up to half of all laparoscopic APLs.[1,7]

INTRODUCTION

Healthcare professionals today wrestle with cost-containment pressures as they continue focusing on their priority to deliver optimal patient care and positive clinical outcomes.

For more than two decades, Encision has worked to create innovative surgical devices that optimize patient safety and surgeon technique, as well as economical value.

Recognizing the challenge today's healthcare professionals face, Encision has a solution—high-performance, laparoscopic AEM instruments that deliver exceptional value while guaranteeing patient safety from stray energy burns.

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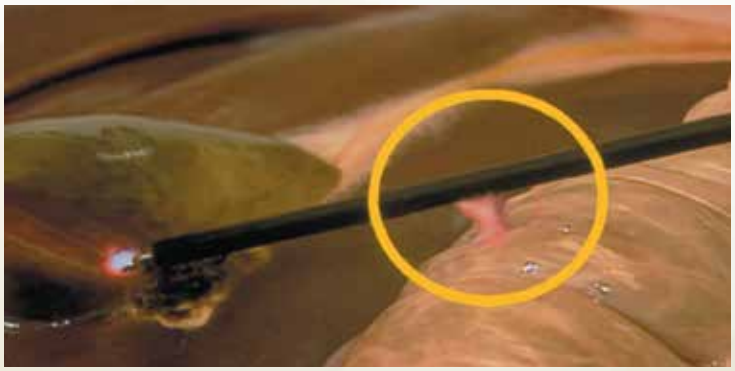
STRAY ENERGY BURNS—A REAL HAZARD IN MONOPOLAR LAPAROSCOPY—ARE THE RESULT OF INSULATION FAILURE AND CAPACITIVE COUPLING

Traditional monopolar laparoscopic instruments have an inherent design flaw. Un-shielded, these instruments are not able to contain the electrosurgical energy transmitted down their shafts. Inevitably, stray energy escapes, either through an insulation failure or through intact insulation by capacitive coupling, potentially burning non-targeted areas on a patient

To reduce the chance of patient injury during minimally invasive surgery, Encision pioneered the development of patented Active Electrode Monitoring (AEM) technology. AEM eliminates the chance of stray energy burns by electrically shielding the laparoscopic surgical instrument shaft.

Insulation Failure–When an instrument's outer insulation is compromised (either from mechanical or electrical breakdown) a hole is formed from which the full power of the electrosurgical generator (ESU) can be delivered to non-target tissue inside the patient.[2]

- Insulation failure occurs in approximately 1 in 5 reusable instruments and 1 in 33 new disposable instruments.[9-12]
- Insulation failures can be microscopic—Frei (2005) found that, "57% of holes could not be seen with the naked eye."



Capacitive Coupling–Regardless of insulation integrity, coupling occurs when there are two conductors (the instrument and the patient's body), separated by an insulator (the instrument's outer insulation). Energy from the ESU is coupled to the patient's tissue; this capacitive coupling can occur on any instrument activation.[2]

- Non-shielded monopolar instruments are not able to prevent this stray energy and therefore may burn patients.
- While some newer ESU technologies offer specialized modes or suggest use at lower power settings as a means to reduce the level of capacitively coupled energy, a safe level is not readily defined, and none of these ESUs claim to prevent patient burns from capacitive coupling.

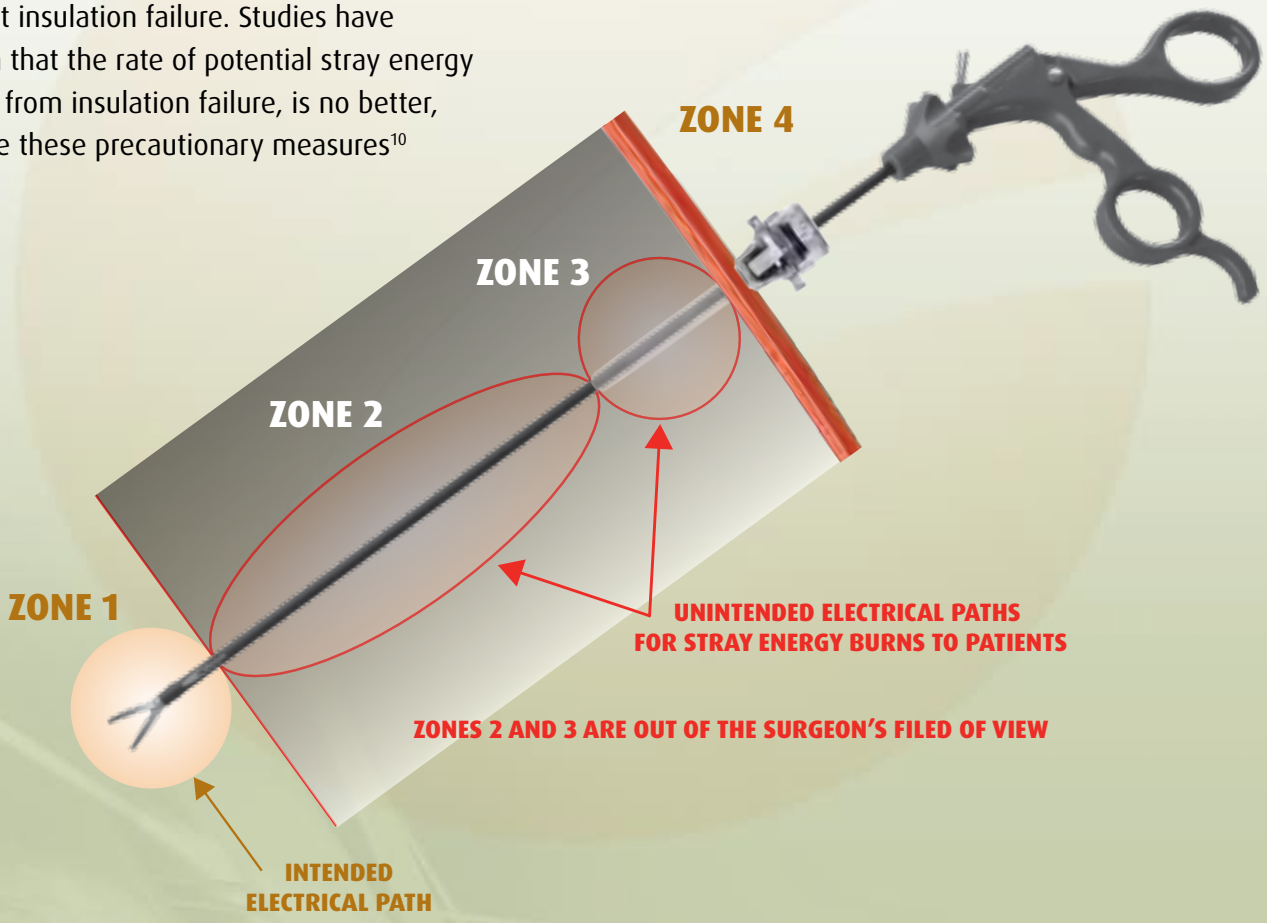
STRAY ENERGY BURNS—A REAL HAZARD IN MONOPOLAR LAPAROSCOPY—ARE THE RESULT OF INSULATION FAILURE AND CAPACITIVE COUPLING

Other factors compound the issue of inherent design flaw:

- Stray energy burns frequently occur, outside the surgeon's field of view
- During advanced surgical techniques such Single Port Access, there is an increased opportunity for capacitive coupling as the instruments are in close proximity to one another
- Inadequate standard safety protocols: Hospitals commonly employ visual inspection and/or electrical "wanding" 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[10]

Did you know?

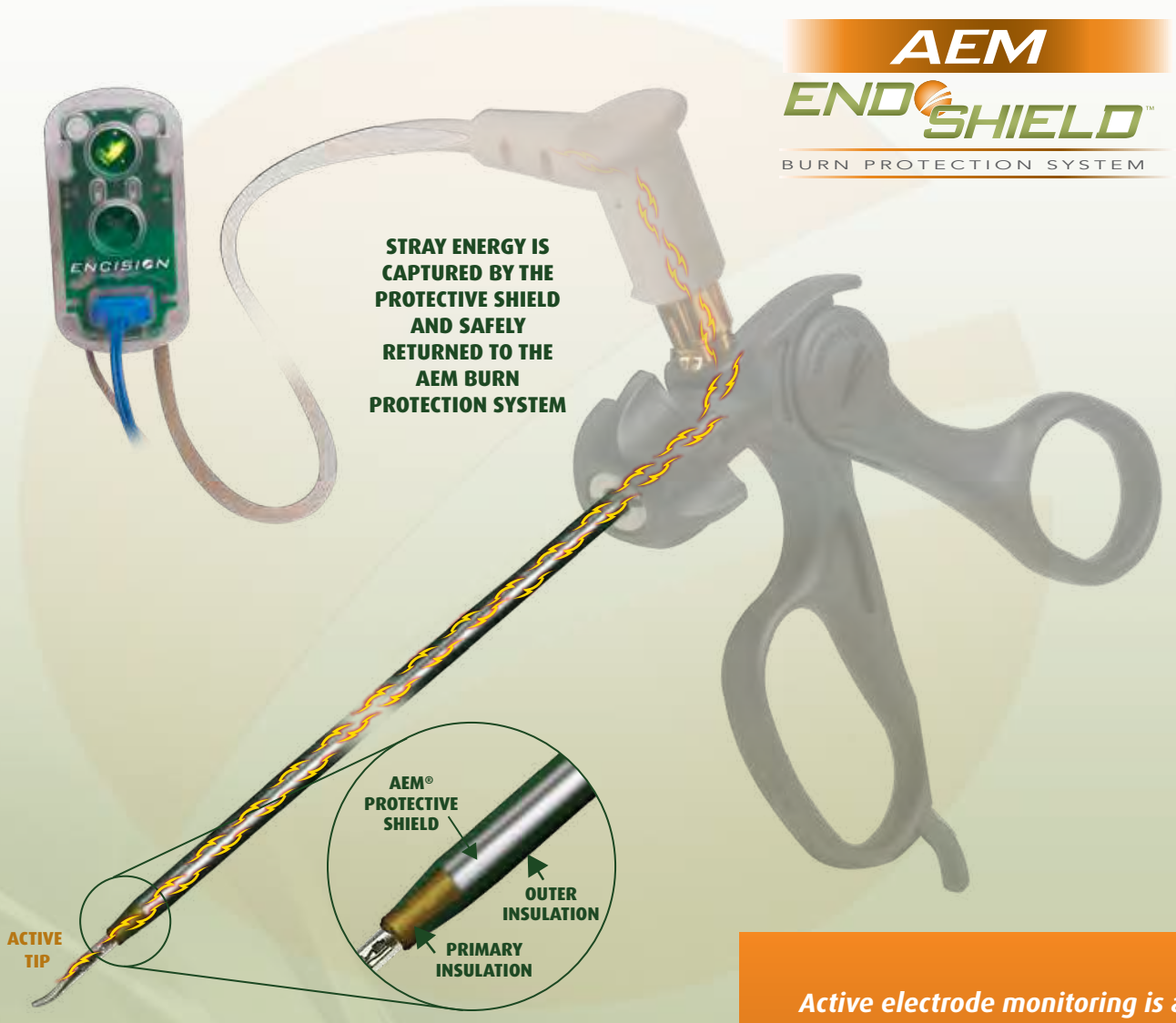
- *Over a 10-year period in the USA alone, patient burns resulting in thermal bowel injury have led to more than 16,500 patient complications and 4,000 preventable patient deaths.[1-6]*
- *50% of all reported laparoscopic bowel injuries are from stray energy burns. Fecal peritonitis following intestinal perforation has a mortality rate of 25%.[1,6]*
- *The incidence of stray energy burns to patients from monopolar energy in laparoscopic procedures is estimated to be between 1 and 3 per 1,000 procedures.[1,13]*



CONVENIENT NEW AEM ENDOSHIELD BURN PROTECTION SYSTEM

The disposable AEM Endoshield Burn Protection System is a convenient add-on, compatible with widely used electrosurgical generators, in all modes.

- Uses advanced AEM monopolar energy, allowing surgeons a safe energy choice for optimal monopolar performance
- Eliminates stray energy burns produced by insulation failure and capacitive coupling
- Intuitive interface requires minimal staff training



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). [8, 18]

AEM INSTRUMENTS ALLOW MASTERFUL CONTROL

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

AEM enTouch INSTRUMENT PLATFORM

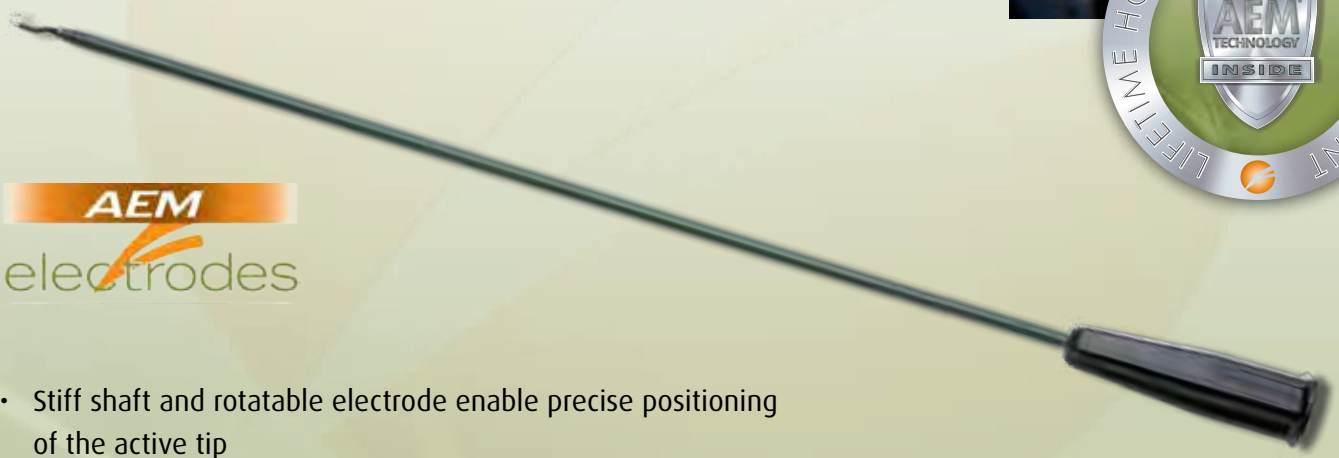
Reusable enTouch™ Instruments

- Enhanced stability and power with direct-drive trigger and stiff shaft
- Force applied at the trigger is amplified through 7 to 1 mechanical advantage and directly transferred to the tip, which may reduce hand fatigue for the surgeon
- Indexing, locking rotation knob enables precision tissue manipulation
- Pairs with a wide portfolio of AEM enTouch graspers and dissectors (60+ tip styles) to satisfy surgeon preference

AEM INSTRUMENTS ALLOW MASTERFUL CONTROL

Disposable eEdge™ 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



- Stiff shaft and rotatable electrode enable precise positioning of the active tip
- Enhanced stability and power through ergonomically designed hand piece
- Available in a wide variety of styles (tips, lengths, foot/hand control, suction-irrigation designs) to satisfy surgeon preference

ENHANCED ECONOMICAL VALUE

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

Hospitals with high rates of HAC will be penalized 1% of all CMS funding.

The Hospital Acquired Condition (HAC) Reduction program is a new initiative from The Center for Medicare and Medicaid Services (CMS). Hospitals will be penalized 1% of their CMS inpatient prospective payment system (IPPS) reimbursements for high rates of HAC.

- 1% of CMS funding is approximately 0.4% of all hospital revenue, and for some larger facilities, this could add up to millions of dollars a year.
  - As an example, [using data from www.ahd.com] a hospital with revenue in the upper $3+ billion range, could potentially lose $15+ million each year.
- Avoiding CMS penalties for the HAC program can be difficult for a number of reasons.
  - The HAC reduction program is competitive in nature. An annual comparison of U.S. hospital data will identify the worst performing 25% of all U.S. subsection (d) hospitals.[14] A hospital may significantly improve its HAC score and still be penalized by CMS if other hospitals show greater improvement. Also, hospitals are given a new score each year, regardless of improvements from the prior year.
  - Most HAC measures do not have a definitive solution, for example, hospital acquired infections. However, one measure—Accidental Punctures and Lacerations (APLs)—does have a definite solution through AEM technology.
- APLs are endoscopic surgical complications from mechanical and thermal injury. Stray energy burns to patients are estimated to be up to half of all laparoscopic APLs.[1]
  - APLs are one of the key metrics of the HAC program, accounting for 43% of the Domain 1 score, or 15% of the total HAC score.[7] Reducing a hospital's APL rate can help drastically improve its overall HAC score, which in turn could avoid the new CMS HAC reimbursement penalties.

The direct cost of readmission

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. [1,3-5,15-17,19-20]

A burden on resources and future business

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. And, it's likely that the problem is even worse, as 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.

ENHANCED ECONOMICAL VALUE

We understand that patient safety, quality outcomes, and affordability are all extremely important to our customers.

Abating the financial risk related to stray energy burns produced by insulation failure and capacitive coupling, the Encision Solution . . .

- Helps you avoid significant financial penalties under the CMS HAC program as well as the direct cost of patient readmission
- Allows you to shield hospital resources from the drain of time consuming, costly events such as lawsuits, litigation, and settlements resulting from stray energy burn complications
- Safeguards your hospital's reputation and protects your surgeon's confidence

In addition to eliminating the risks associated with stray energy burns to patients, the AEM Burn Protection System affords hospitals other economic advantages.

Disposable AEM EndoShield is an economical choice

- Eliminates capital budget requirements
- Eliminates costly cleaning and maintenance of reusable AEM monitors
- Provides substantial time savings over reusable monitor setup
- Easily remove and recycle battery to promote environmentally sound practices

AEM Instruments are designed with maximum ROI in mind

- Disposable e-Edge Scissors eliminate the cost and effort expenditure of reusable maintenance (sharpening, cleaning, and sterilization)
- Clear, see-through en-Touch handle enables fast and effective instrument cleaning and sterilization
- Reposable instruments (disposable e-Edge Scissors fitted to the reusable en-Touch handles) optimize inventory and improve your cost-per-procedure value
- SKU reduction through kitting optimizes inventory management, creating new efficiencies
- Robust design prolongs instrument life to maximize your ROI
- Warranty Service Program provides handle refurbishment for a nominal fee

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