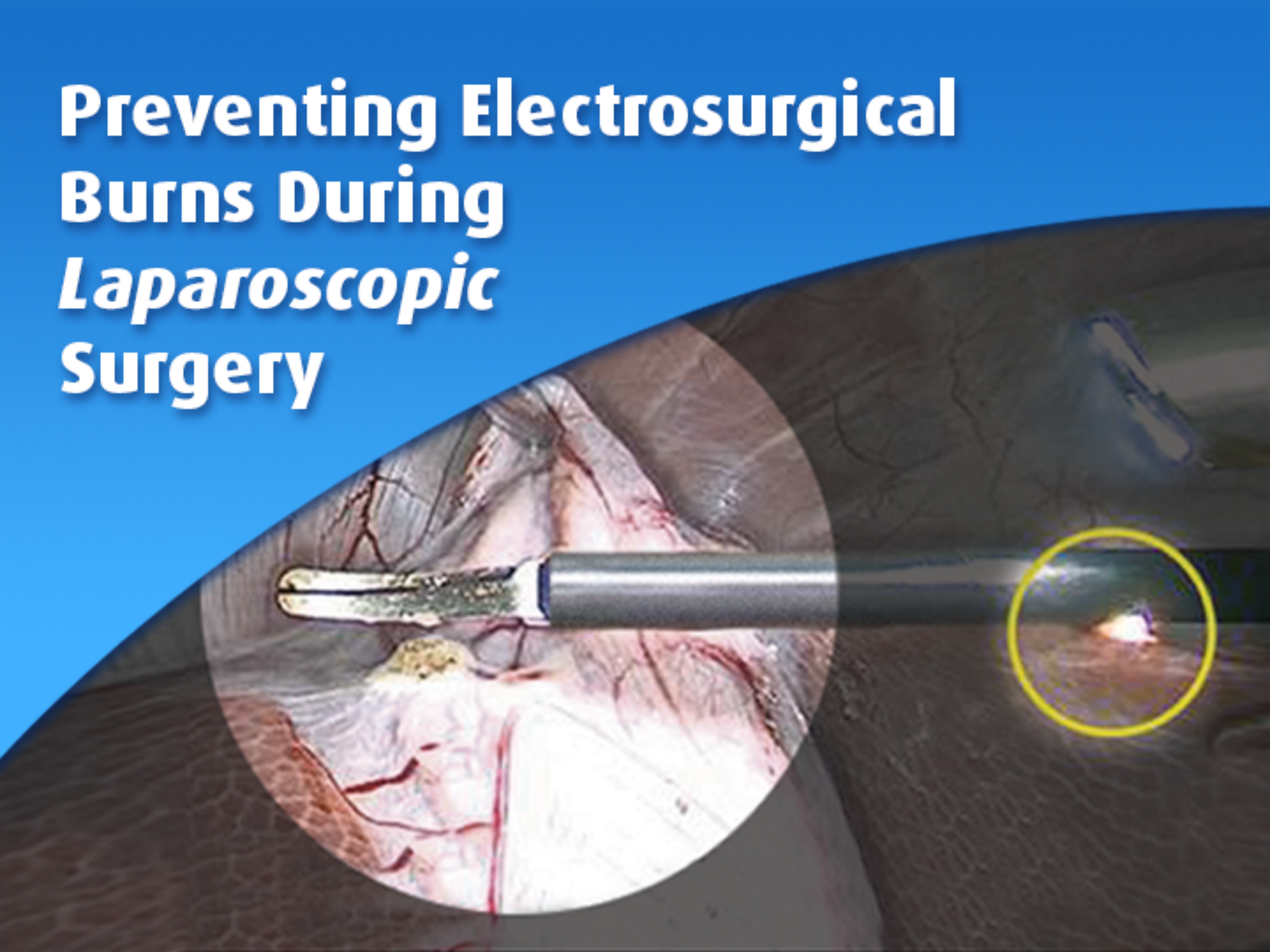
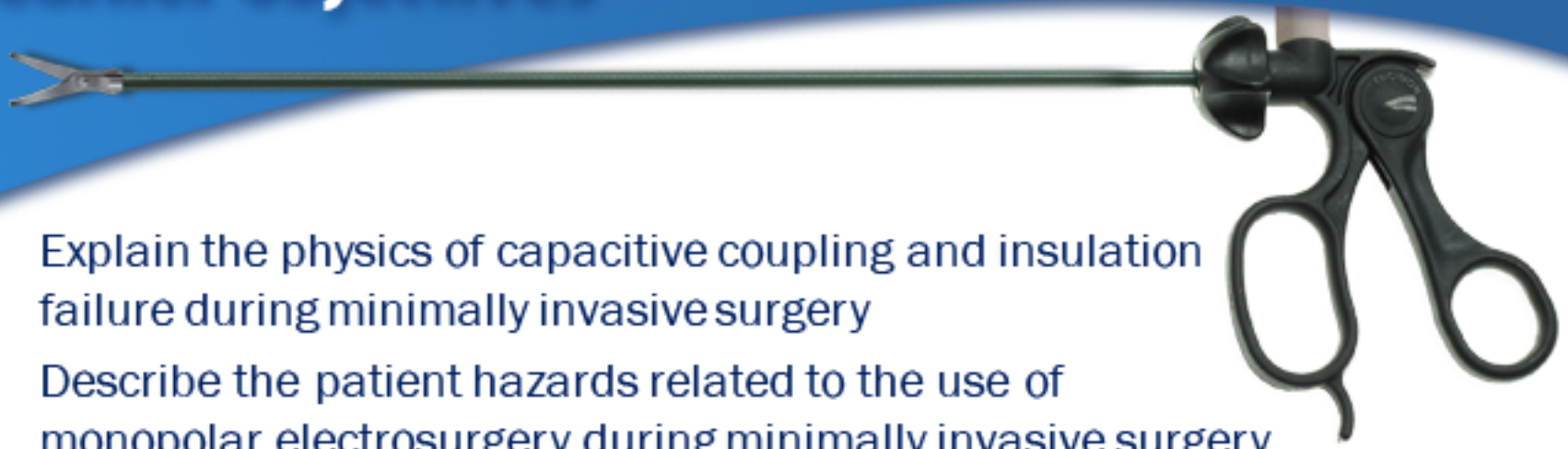
Preventing Electrosurgical Burns During *Laparoscopic* Surgery



Learner Objectives

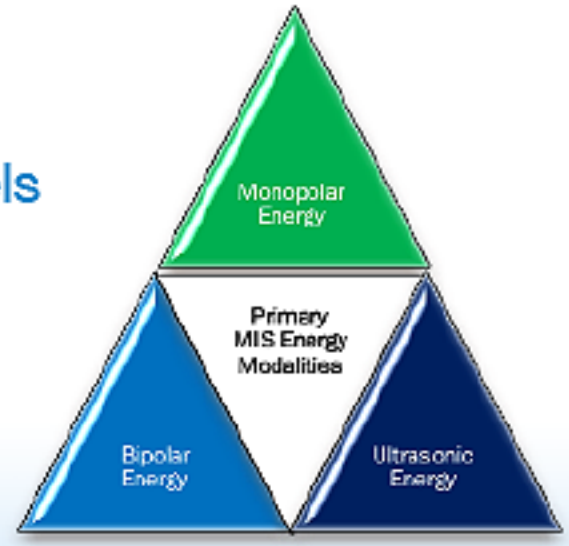


- Explain the physics of capacitive coupling and insulation failure during minimally invasive surgery
- Describe the patient hazards related to the use of monopolar electrosurgery during minimally invasive surgery
- Describe the economic impact of electrosurgery injuries in today's dynamic health care environment
- Explain the new CMS position and penalties for accidental lacerations, punctures, and burns during laparoscopic surgery
- Identify technologies that prevent monopolar injury during minimally invasive surgery
- Outline the recommended practices related to patient safety during laparoscopic procedures
- Discuss the responsibilities of the perioperative team related to patient safety during minimally invasive surgery

Electrosurgical Fundementals

Energy Modalities

- **Monopolar Energy:**
  - Used in 75% - 85% of all laparoscopic procedures
  - Provides efficient dissection and controls bleeding well
  - Cost effective
- **Bipolar Energy:**
  - Used primarily for sealing larger vessels
- **Ultrasonic Energy:**
  - Good for sealing larger vessels as well as dissection

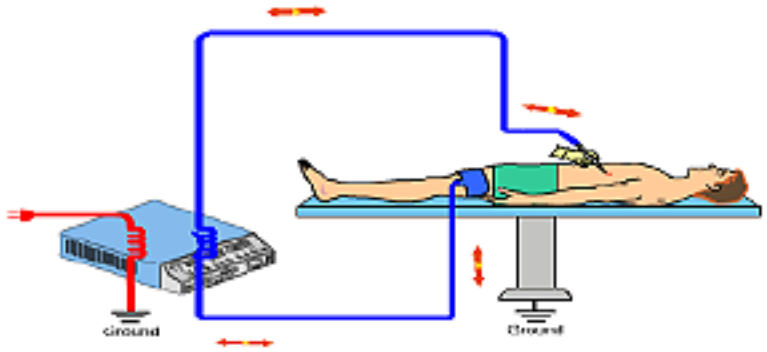


Monopolar Energy
in Laparoscopy

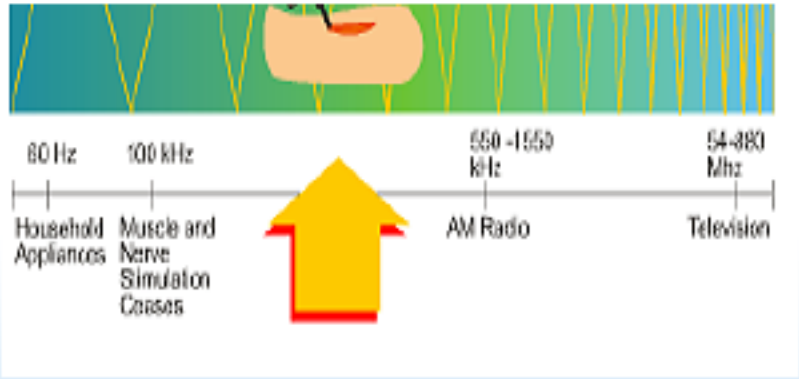
- Popular surgical tool since the 1990s
  - Preferred surgical device for controlling bleeding (non-contact fulguration)
  - Excellent tool for dissection including cutting, coagulating and ablating tissue
- 2,250,000 monopolar laparoscopic procedures per year in the USA

Basics of Monopolar Energy

- Electrical circuit = generator, instrument, patient return pad, and the patient

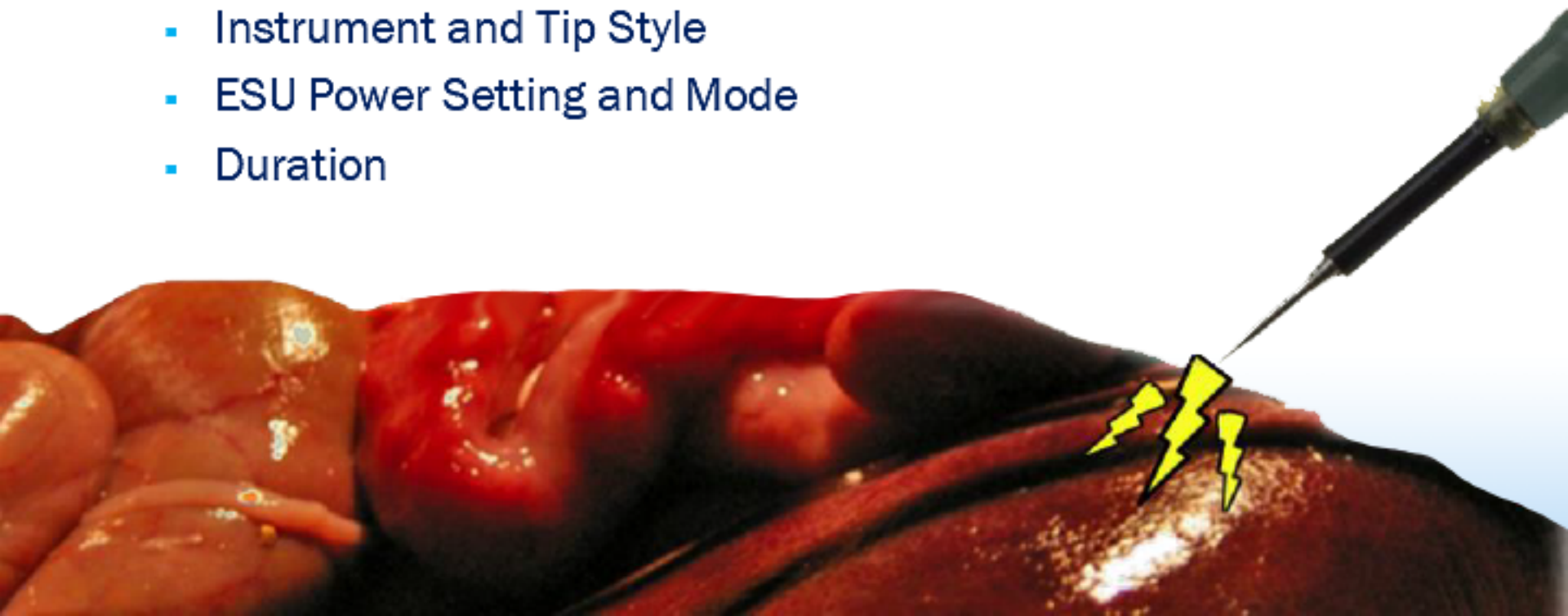


- Monopolar Energy is delivered at an electrical frequency appropriate for cutting, coagulation, and ablation of tissue

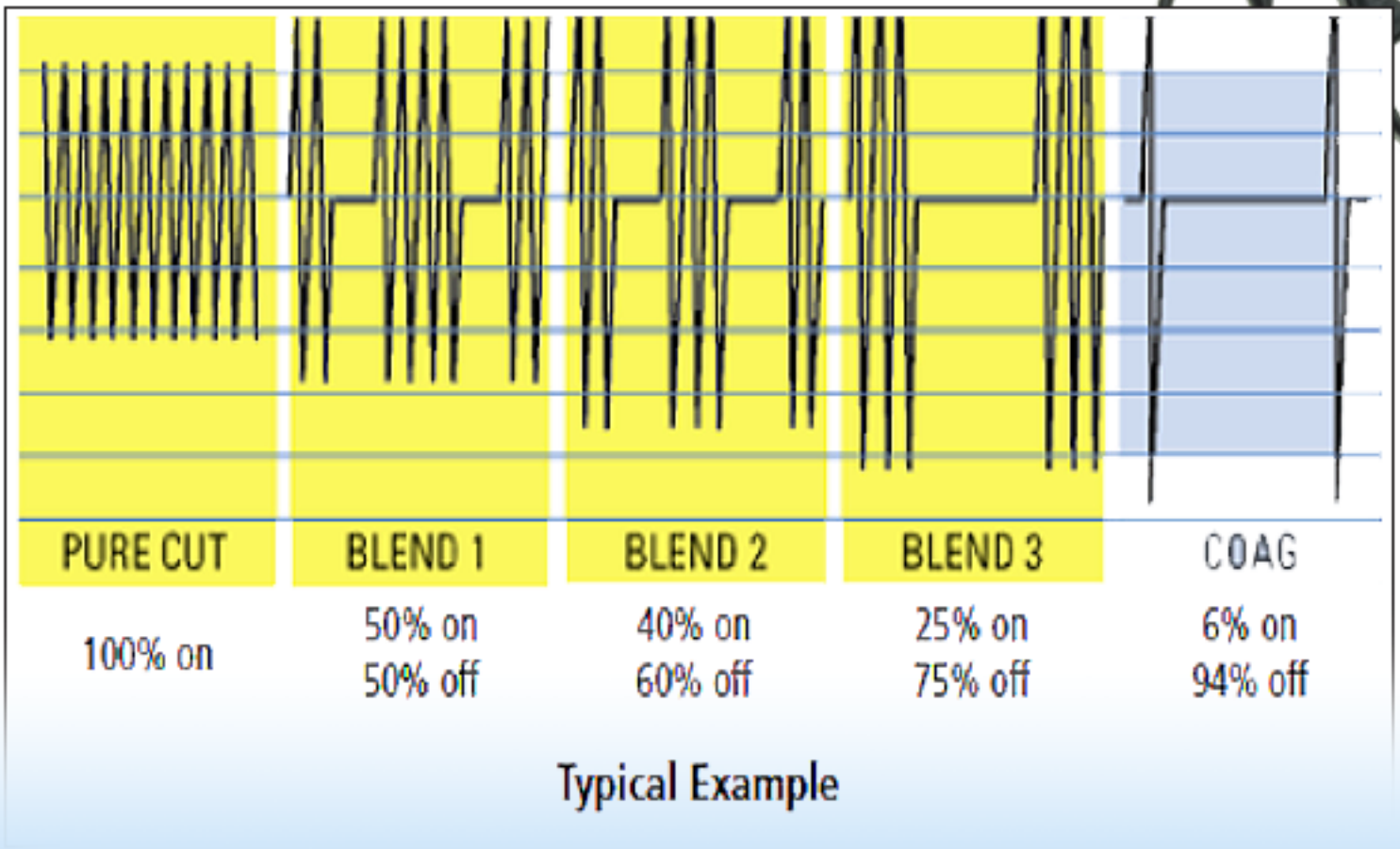


Basics of Monopolar Energy

- The electrical circuit and tissue effects are also affected by many other factors including:
  - Tissue Type
  - Instrument and Tip Style
  - ESU Power Setting and Mode
  - Duration



Monopolar Energy Modes



Monopolar Energy Modes

- **Tissue Effect:**
  - Tissue vaporization
  - High current density
  - Minimizes charring tissue destruction and lateral thermal spread
  - Current penetrates deeply (may damage underlying vessels/structures)
- **Common Uses:**
  - Desiccating deeper lesions
  - Penetrating high-impedance fatty/scar tissue

Monopolar Energy Modes

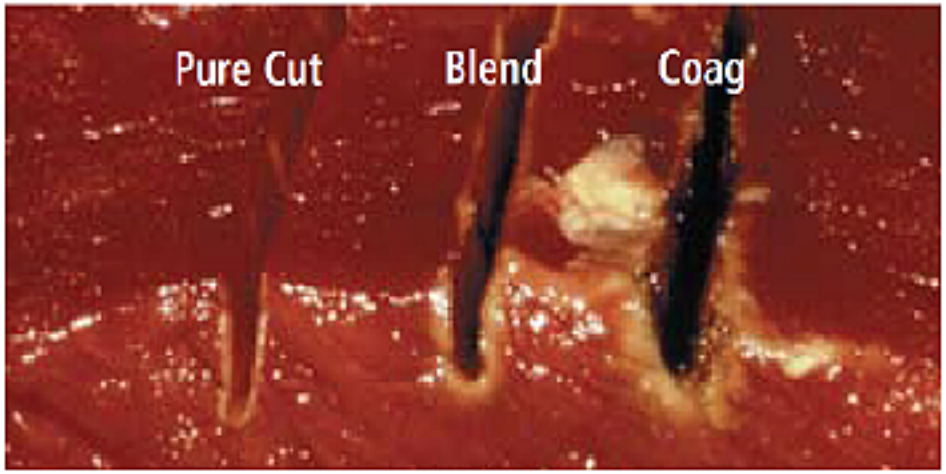
- **Tissue Effect:**
  - Tissue coagulates
    (essential for hemostasis, to control bleeding)
  - Non-contact fulguration (a spark to tissue through a small air gap) achieves coagulation over a larger surface area without penetrating deep into tissue

- **Common Uses:**
  - Controlling bleeding during dissection
  - Prevents superficial bleeders (liver surface for instance)
  - Seal smaller vessels (≤2mm diameter)

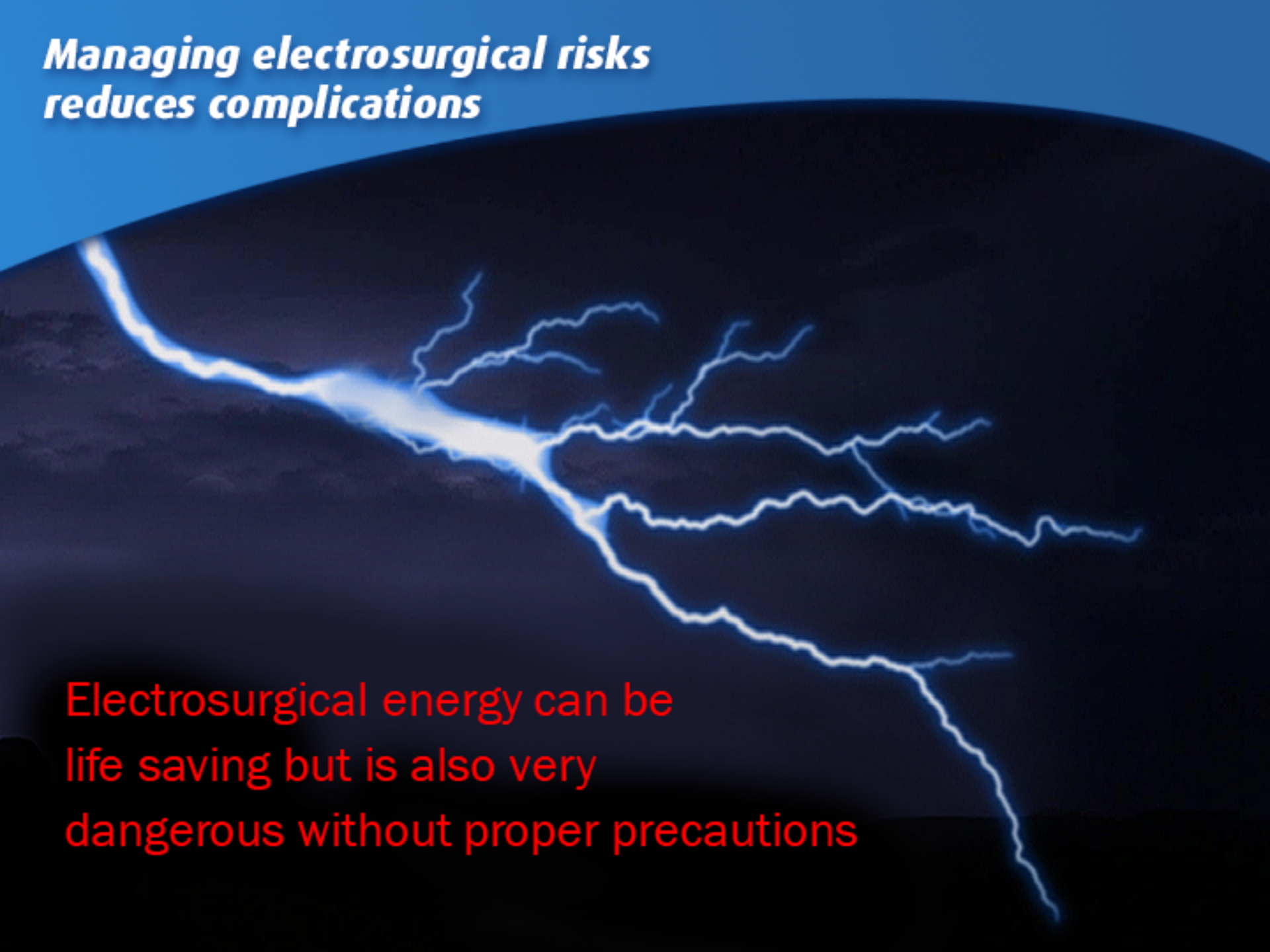
Monopolar Energy Modes

BLEND

- Mix of cut and coag (based on surgeon's experience, tissue characteristics, and procedure)



Managing electrosurgical risks reduces complications

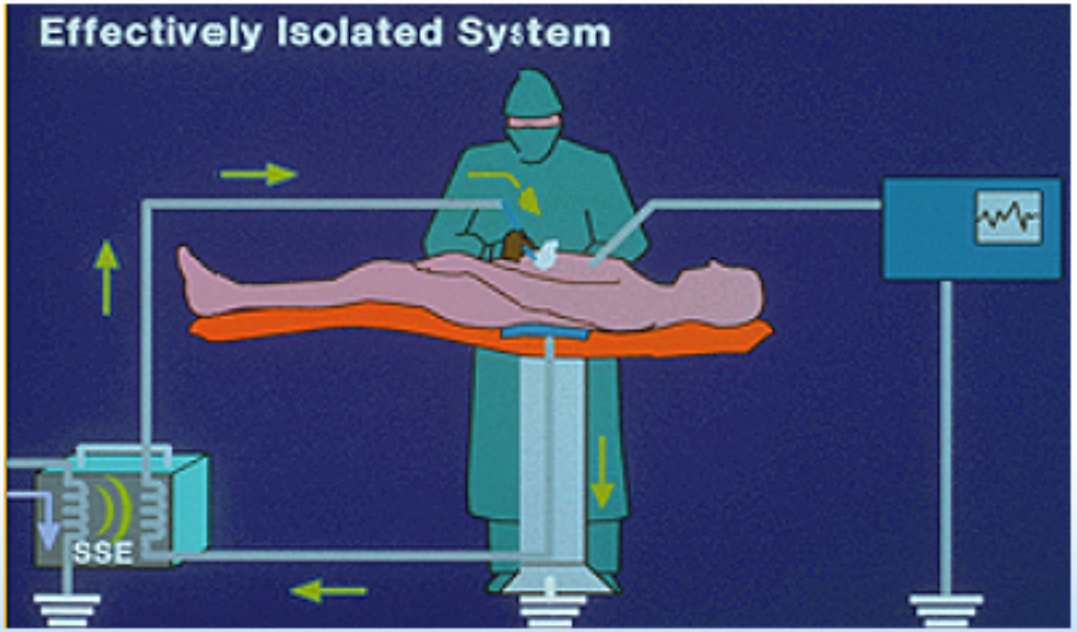


Electrosurgical energy can be life saving but is also very dangerous without proper precautions

Advances in patient safety: Monopolar Isolated Circuitry

- **Prior to the 1970s:** Electrosurgical procedures had multiple return paths for energy which led to patient burns at contact sites (ECG electrode, Stirrups, Retractors)

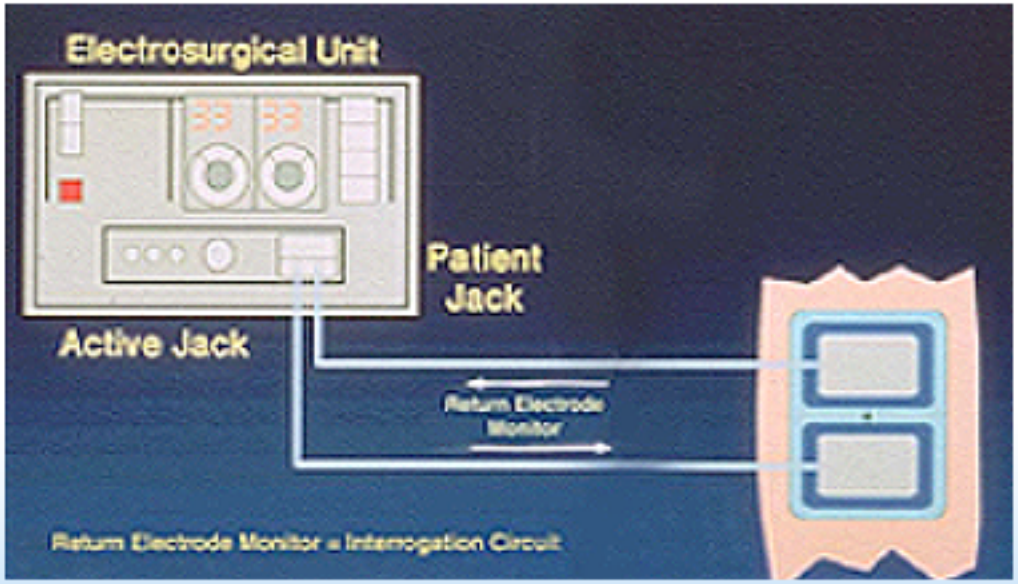
- **1970s:** A new standard of care established with isolated circuitry
- ***Patient Safety Improved!***



Advances in patient safety: Monopolar Isolated Circuitry

- **Prior to the 1980s**: All electrosurgical patient return electrodes were not "monitored" which led to patient burns at return electrode site

- **1980s:** Return electrode monitoring systems prevented burns. Fail-safe and not user dependent
- ***Patient Safety Improved!***

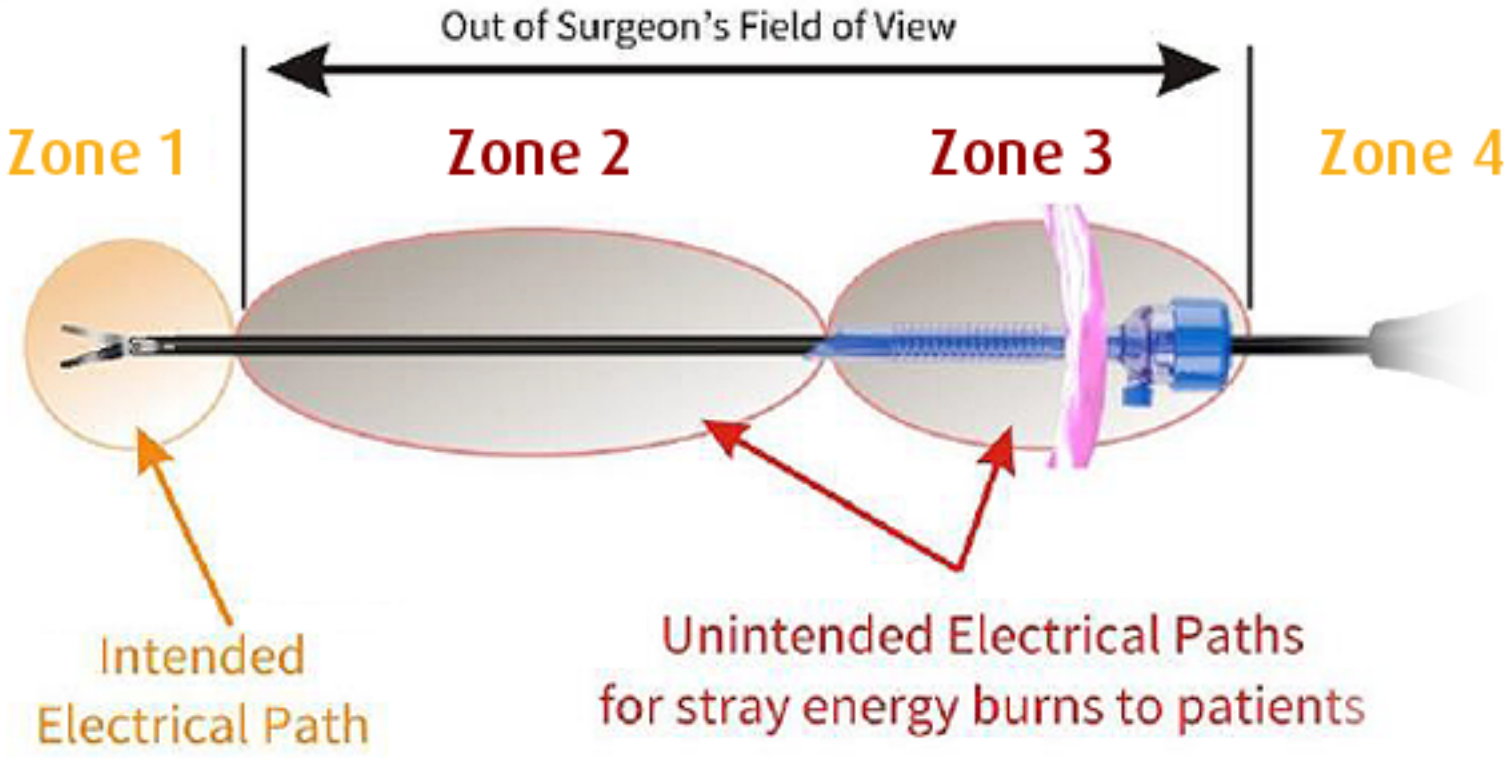


Areas to improve patient safety: internal stray energy burns

How do internal patient burns to delicate tissue and organs occur?

1. Pilot Error: Direct coupling, inadvertent activation of electrode, latent heat
2. System Error: Insulation failure and capacitive coupling

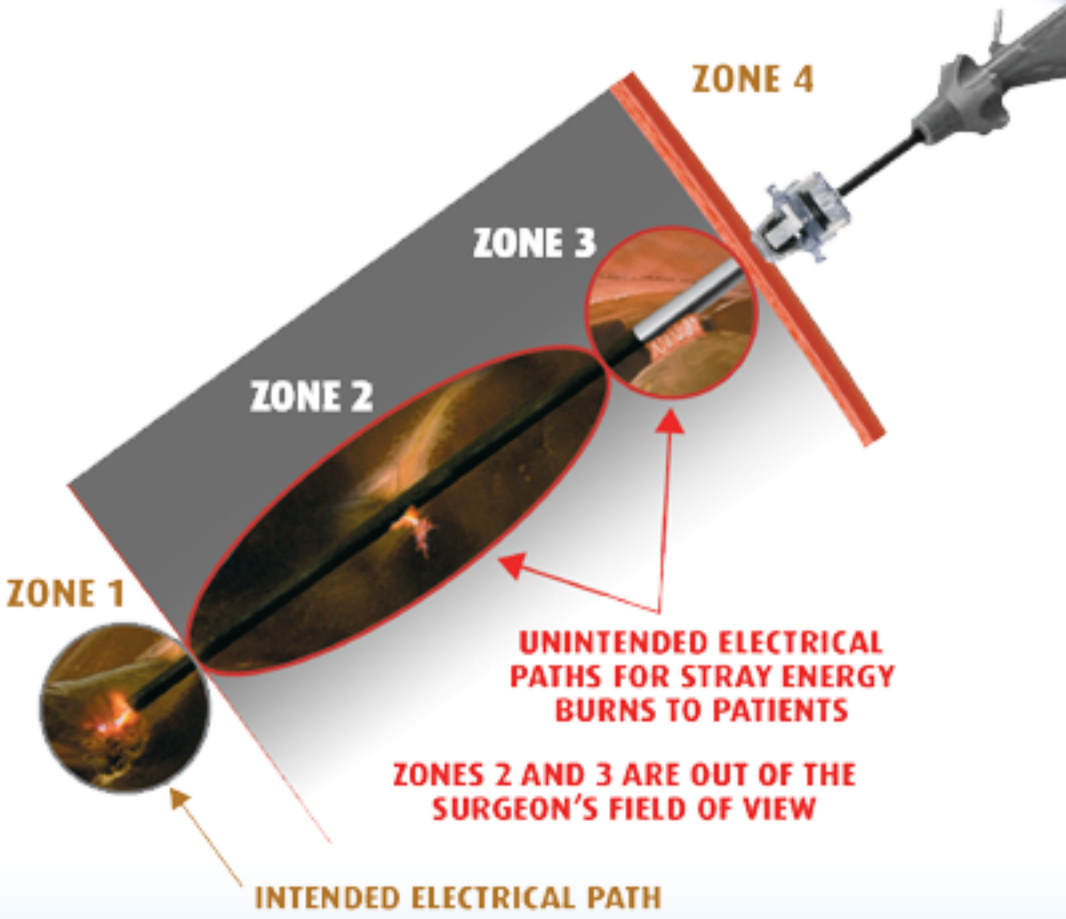
Areas to improve patient safety: internal stray energy burns



There are 4 zones of potential injury for laparoscopic instruments

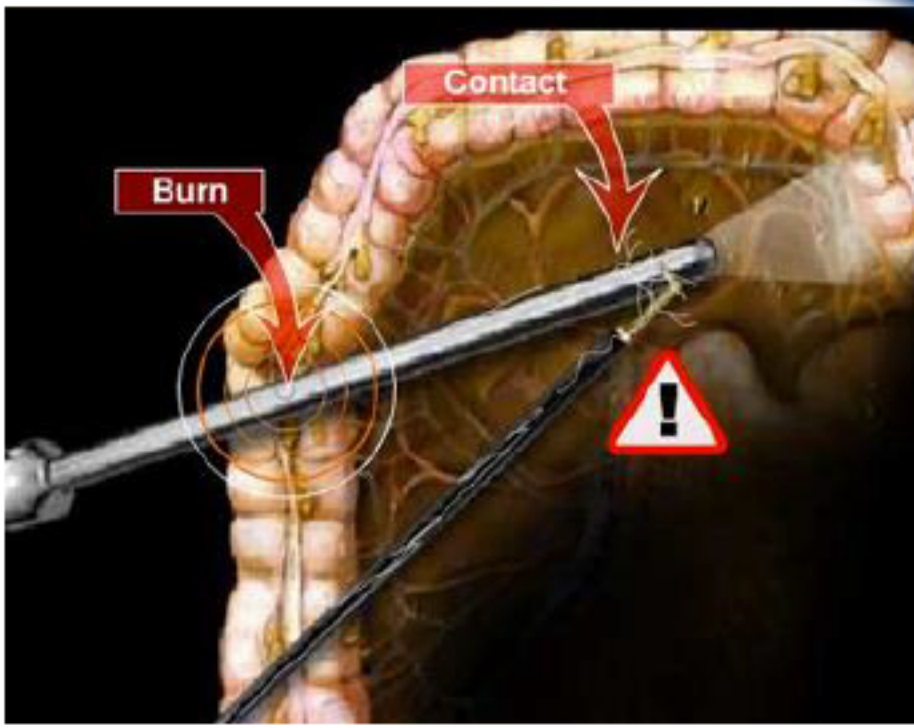
Areas to improve patient safety: internal stray energy burns

- Surgeon's field of view is often limited to 1 to 2 inches
- Stray energy outside field of view may cause unintended burns which are invisible to the user
- Resulting complications can be severe

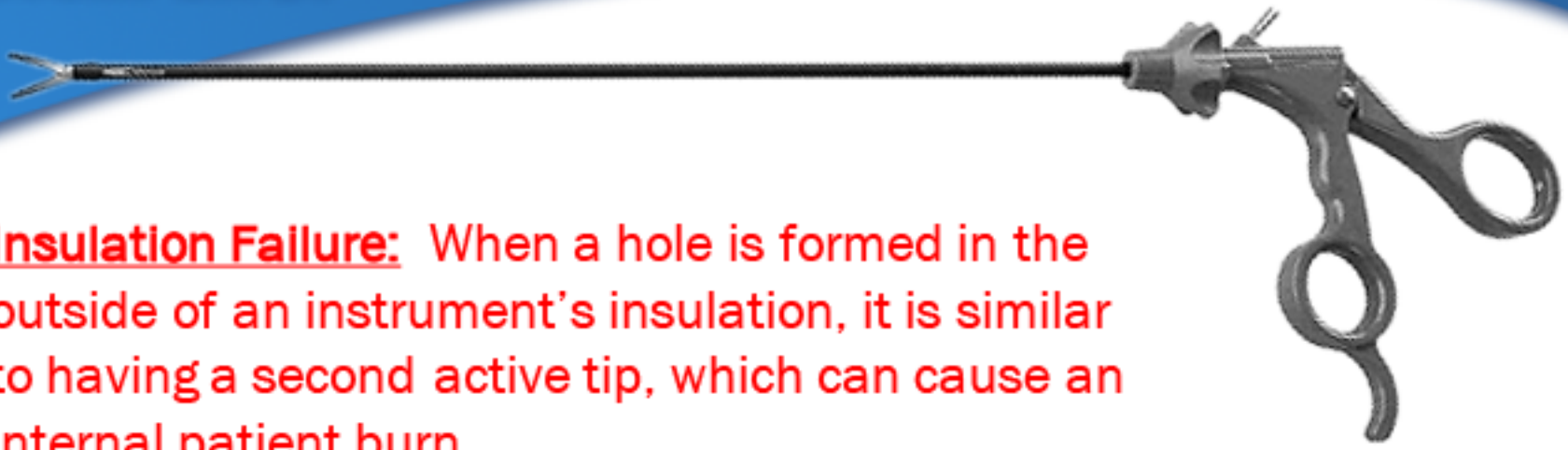


Monopolar stray energy burns:
Pilot Error

- **Inadvertent Activation:** Accidental activation of the electrode, causing a burn
- **Direct Coupling:** Activated instrument inadvertently couples to the metal of another instrument, causing a burn
- **Latent Heat:** Instrument is hot from a previous activation and is touched to tissue, causing a burn



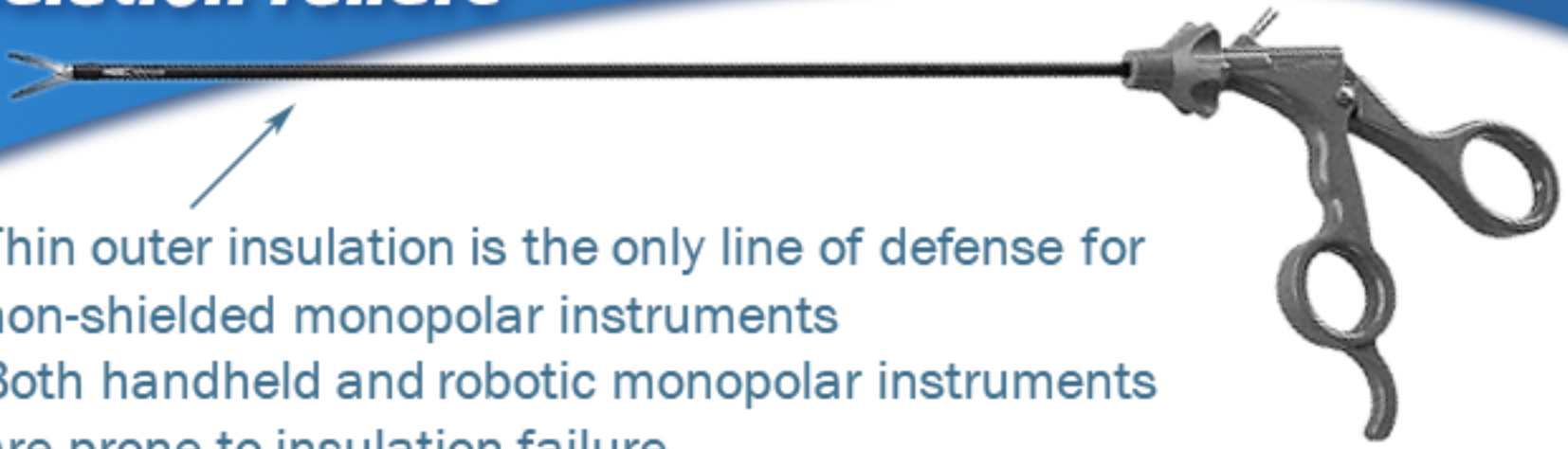
Monopolar stray energy burns:
System Error



- **Insulation Failure:** When a hole is formed in the outside of an instrument's insulation, it is similar to having a second active tip, which can cause an internal patient burn.

- **Capacitive Coupling:** Activation of monopolar instrument generates an RF field that can induce current in a nearby instrument or the patient, which can cause an internal patient burn.

Monopolar stray energy burns:
Insulation Failure



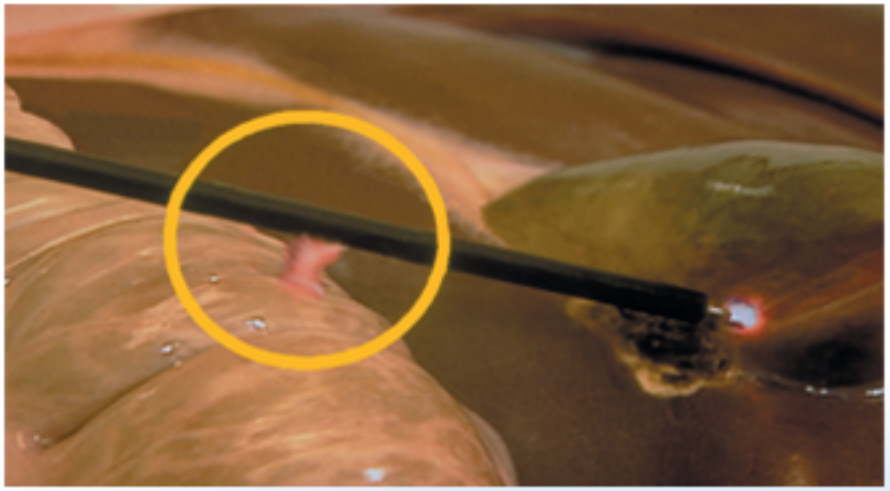
- Thin outer insulation is the only line of defense for non-shielded monopolar instruments
- Both handheld and robotic monopolar instruments are prone to insulation failure

INSULATION FAILURE

A hole in the instrument's outer insulation, from which the full power of the ESU is delivered to unintended tissue. 57% cannot be seen!

Instrumentation insulation-failure rates*

- **1 in 5 reusables**
- **1 in 33 disposables**



Monopolar stray energy burns:
Insulation Failure

- Insulation can break down anytime, including during the procedure
- Defects in insulation can allow stray energy to burn non-intended tissue

Surgical team will likely not notice a change in output at surgical site

Monopolar stray energy burns: Incidence of Insulation Failure

	Study I SAGES 2005	**Study II** 2007	**Study III** Mayo Clinic 2008	**Study IV** Univ. Colorado 2010	**Total**
Instruments Tested	1,438	98	299	165	**2,000**
Insulation Failures	267	28	105	31	**431**
Incidence of Failures	18.6%	28.6%	35.1%	18.8%	**21.6% or 1 in 5!**

*Current **hospital-based detection programs do not alter** the incidence of insulation failures in laparoscopic instruments and the U. of Colorado study further noted a* ***3% failure rate with disposables straight from the package***

Monopolar stray energy burns: Capacitive Coupling

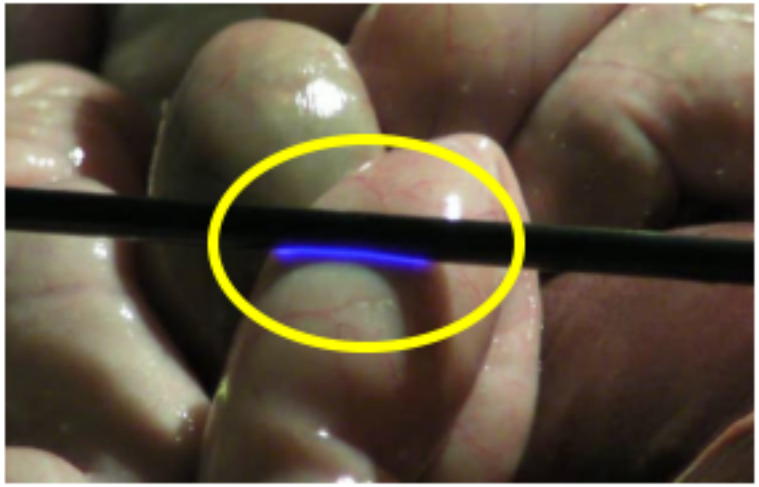
Activation of electrode generates RF field

↓

Inducing electrosurgical energy in a nearby conductor

↓

Unintended Patient Burn

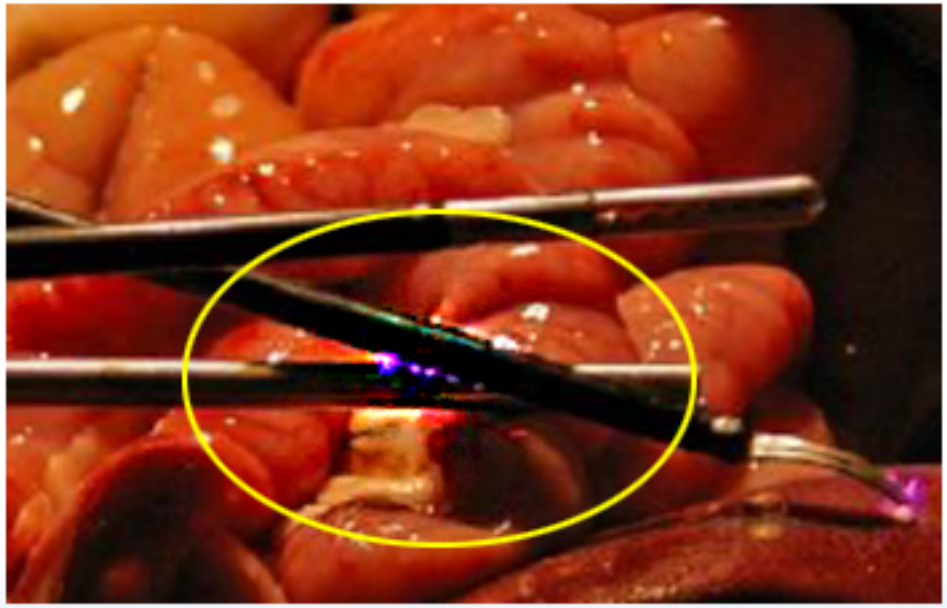


Capacitive Coupling through Intact Insulation

Monopolar stray energy burns: Capacitive Coupling

- Capacitive Coupling can occur on any activation

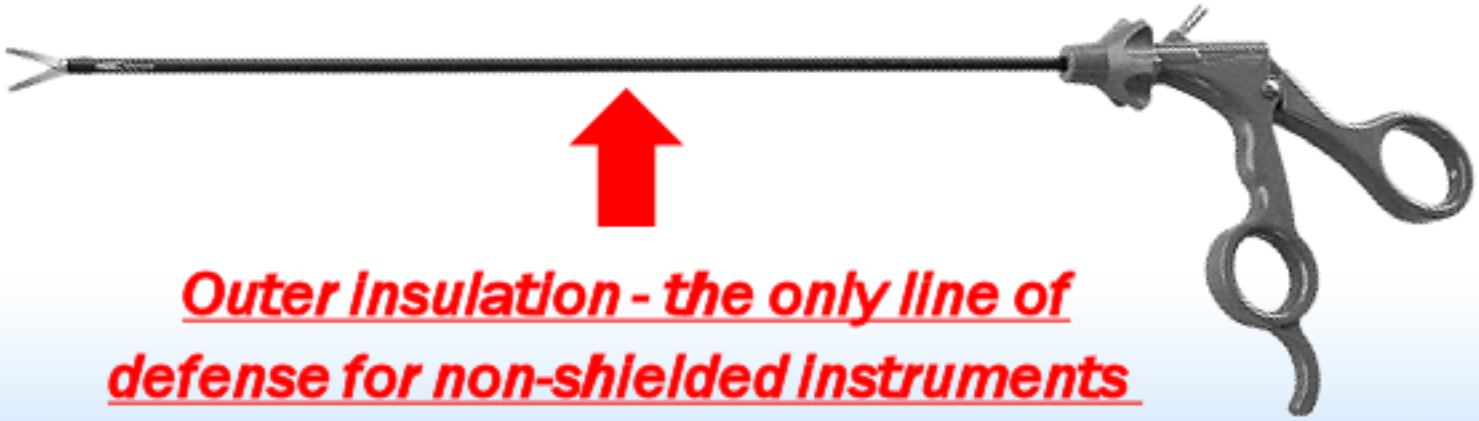
- A 2015 study from Annals of Surgery showed that capacitive coupling thermal injury occurred at the skin adjacent to the active electrode trocar in 19% - 26% of laparoscopic cholecystectomies



Monopolar stray energy burns:

it's not the Technique, it's the Technology

- Traditional laparoscopic instruments can burn patients from insulation failure and capacitive coupling
- Inherent design flaw: There is no way to detect or prevent stray energy with unshielded monopolar laparoscopic instruments



Outer Insulation - the only line of defense for non-shielded instruments

Monopolar stray energy burns:

it's not the Technique, it's the Technology

Insulation Failure

Monopolar stray energy burns:

it's not the Technique, it's the Technology

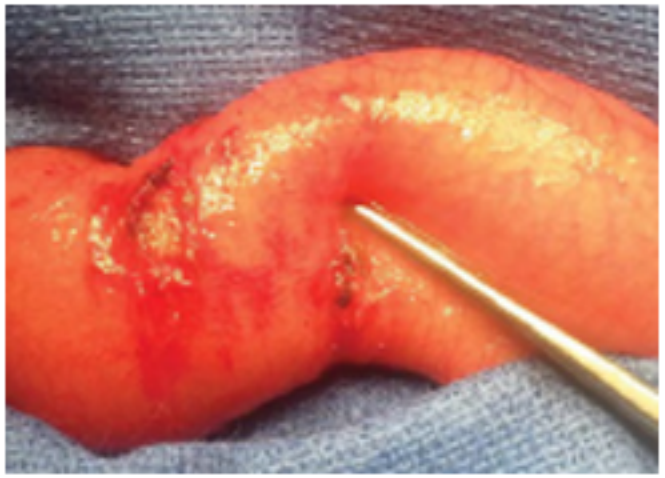
Monopolar stray energy burns: Patient Complications

- Unrecognized at the time of surgery
- Underreported
- Complications manifested 3-10 days later
- Catastrophic and potentially fatal complications in otherwise healthy patients

Monopolar stray energy burns: Patient Complications

"The negative impact of inadvertent bowel injury is hard to understate.

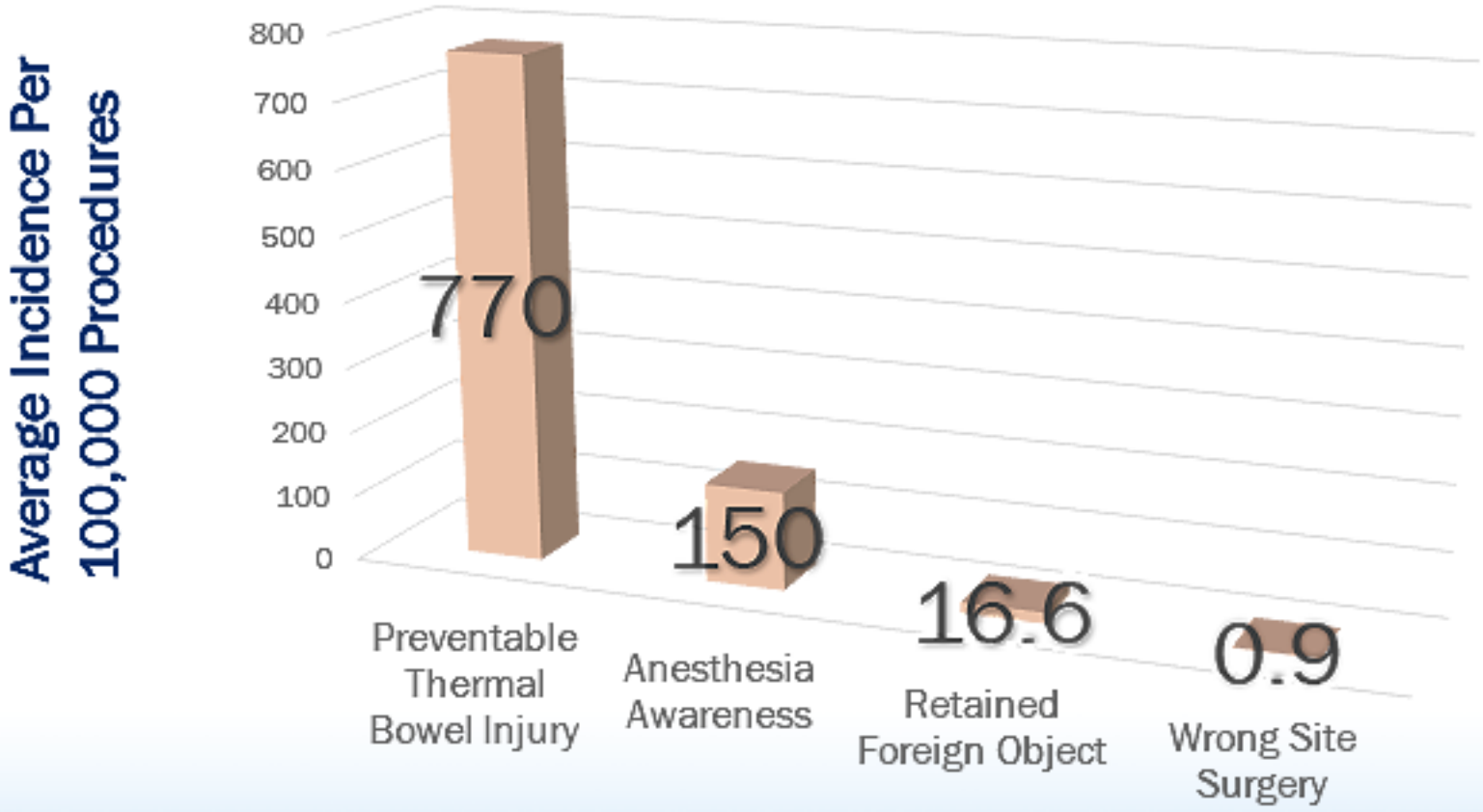
The consequences of a missed bowel injury are even more devastating"



1 in 130 (0.77%) Advanced Lap Procedures Have a Preventable Thermal Bowel Injury

1 in 3 bowel injuries are not caught at the time of the initial procedure

Monopolar stray energy burns: Patient Complications



Monopolar stray energy burns: Patient Complications

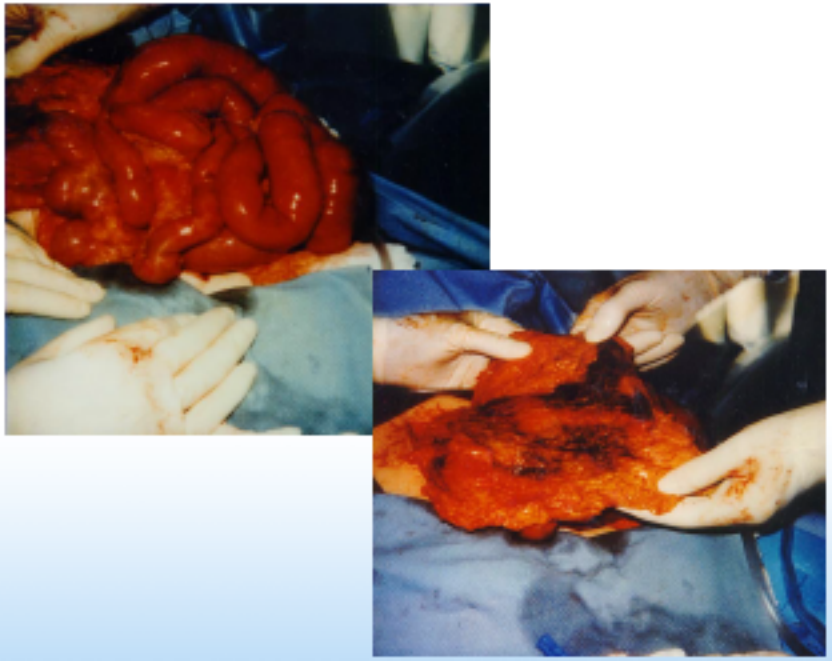
Patient Complication Rates for bowel injuries not caught at the time of the initial procedure:

- 100% Manifest into Fecal Peritonitis
- 56% Require an Extended ICU Admission
- 50% Have a Surgical Site Infection
- 31% Go into Multi-Symptom Organ Failure
- 25% Die from This Often Preventable Complication

Monopolar stray energy burns: Patient Complications

- **Complications (occur every ~90 minutes in the USA)**
  - Many go unrecognized at the time of the initial surgery and require readmissions and additional surgeries

- **Mortality (1 - 2 deaths per day)**
  - Stray energy burns account for half of laparoscopic bowel injuries
  - **Extremely severe: Fecal peritonitis following intestinal perforation has 25% mortality rate**



Monopolar stray energy burns: Patient Complications

CNN Politics

SEARCH

POWERED BY Google

Justice | Entertainment | Tech | Health | Living | Travel | Opinion | iReport | Money › | Sports ›

SURGERY

Rep. John Murtha dies after surgery complications

February 08, 2010

Share | Twitter | Email

Recommend | 80 recommendations. Sign Up to see what your friends recommend.

Rep. John Murtha of Pennsylvania, a longtime fixture on the House subcommittee that oversees Pentagon spending, died after complications from gallbladder surgery, according to his office. He was 77.

The Democratic congressman recently underwent scheduled laparoscopic surgery at National Naval Medical Center in Bethesda, Maryland, to remove his gallbladder. The procedure was "routine minimally invasive surgery," but doctors "hit his intestines," a source close to the late congressman told CNN.

Rep. John Murtha, D-Pennsylvania, recently underwent laparoscopic surgery to remove his gallbladder.

Murtha was initially hospitalized in December and had to postpone a hearing with Defense Secretary Robert Gates on the administration's strategy in Afghanistan. The congressman returned to work after a few days in the hospital and helped oversee final passage of the 2010 defense appropriations bill.

Monopolar stray energy burns: Patient Complications

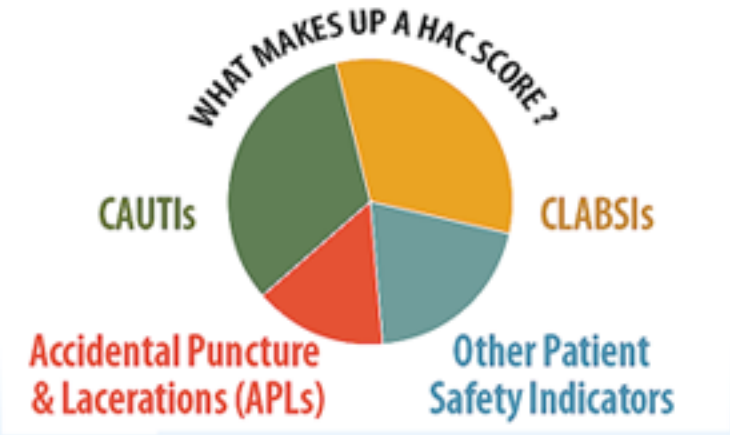
specific to GYN

Injury Type	Overall Injury Rate	Estimated Prevalence from Preventable Stray Energy Burns
Ureter	1.7% - 3.0%	1 per 120 procedures - 1 per 70 procedures
Bladder	0.2% - 8.3%	1 per 1000 procedures - 1 per 25 procedures
Bowel	0.5% - 3.6%	1 per 400 procedures – 1 per 60 procedures

- Gynecologic procedures generally have higher complication rates than general surgery procedures, due to close proximity of tissues to instrumentation.

Medicare and Medicaid (CMS) fines for preventable complications

- The Hospital Acquired Condition (HAC) Reduction Program Penalizes 1% of CMS reimbursements, from the worst performing 25% of hospitals
- In 2015, 721 hospitals lost a combined $371 Million (any hospital scoring above a 7.0 out of 10). HAC scores are self-reported by hospitals
- In 2016, 758 hospitals penalized $364 M (score of 6.75+ out of 10)



- APLs are the third largest part of the HAC score
- Half of all Laparoscopic APLs are from stray energy burns to patients

CMS hac reduction program definition of an APL

"Accidental puncture or laceration (APL) is a health outcome measure. This measure captures an injury to an organ (eg, bowel, bladder, liver, diaphragm) or blood vessel that was entirely unintended and was NOT due to an underlying disease process. This definition would be met if (for example) placement of a retractor underneath the symphysis pubis accidentally enters the bladder.

Another example would be use of a **cautery device or scissors** to dissect a tissue plane **that errantly causes an injury to underlying bowel.** The rationale for this measure is that **these injuries** have adverse consequences for patients, and **are often preventable**."

-The National Quality Forum on Defining APLs for the CMS HAC Reduction Program

CMS HAC reduction program

- Avoiding CMS HAC penalties can be difficult:
  - Most HAC measures do not have a definitive solution (such as hospital acquired infections)
  - The HAC reduction program is competitive (hospitals are given a new score each year)
  - A hospital may significantly improve on their HAC score and still be penalized by CMS

New CMS HAC reduction program

- Nearly every hospital has a plan in place for infection control
- However, many do not have a plan to reduce APLs
- Reducing the APL rate (43% of Domain 1 score) will substantially increase a hospital's score
  - 50% of laparoscopic APLs are from stray energy burns
- Hospitals that eliminate stray energy burns have a distinct advantage over the competition, by providing better patient outcomes

Medico-legal and Economic Consequences

Additional costs of complications are staggering:

- Readmission costs approximately $30k+
- Additional surgical procedure $20k - $30k+

Malpractice costs:

- Low end: $260k
- High End: $19 Million

Medico-legal and Economic Consequences

Plaintiff alleged laparoscopic instrument caused perforation due to “stray electricity”

Andrea P. Huber vs. a Healthcare Corporation
Gary O'Hara, M.D., Endoscopy Corporation
Medical Instruments Corporation and Electrosurgical Company

Verdict: $2,201,283 in favor of plaintiff

Jury found the device manufacturer negligent and liable for the plaintiff’s injuries because of the instrument design

Monopolar stray energy burns:

it's not the Technique, it's the Technology

Insulation Failure:

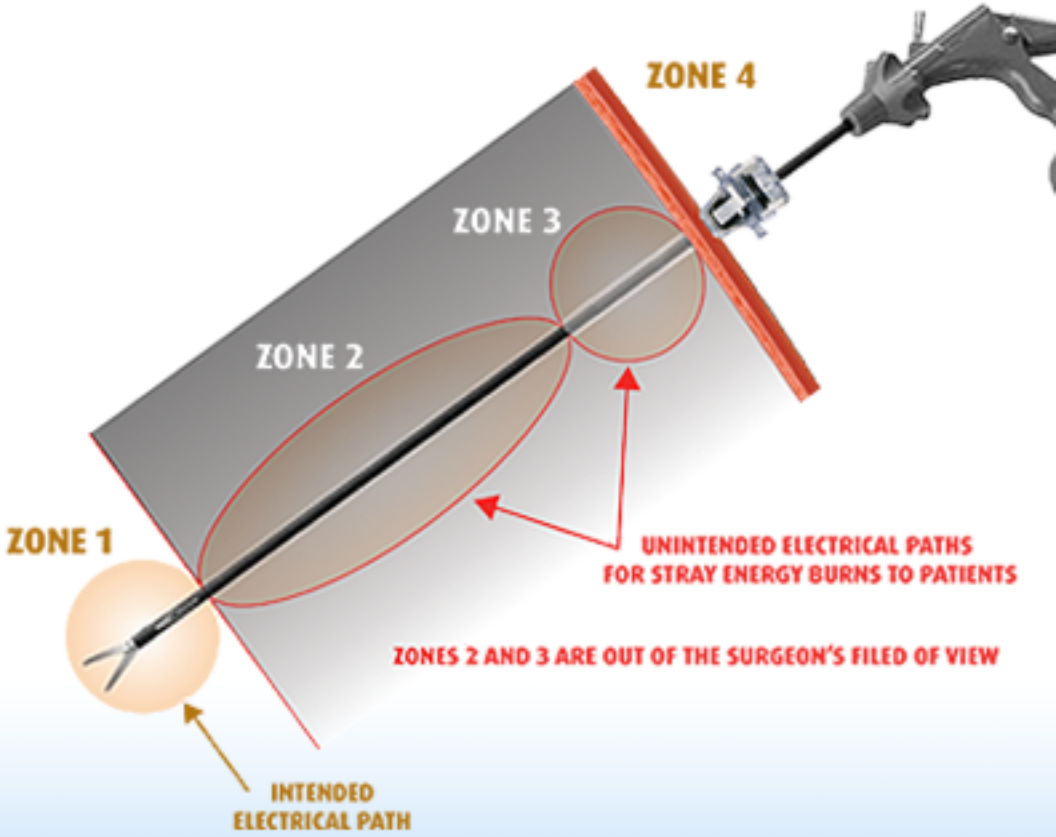
- Frequency: 1 in 5 reusables
  1 in 33 disposables

Capacitive Coupling:

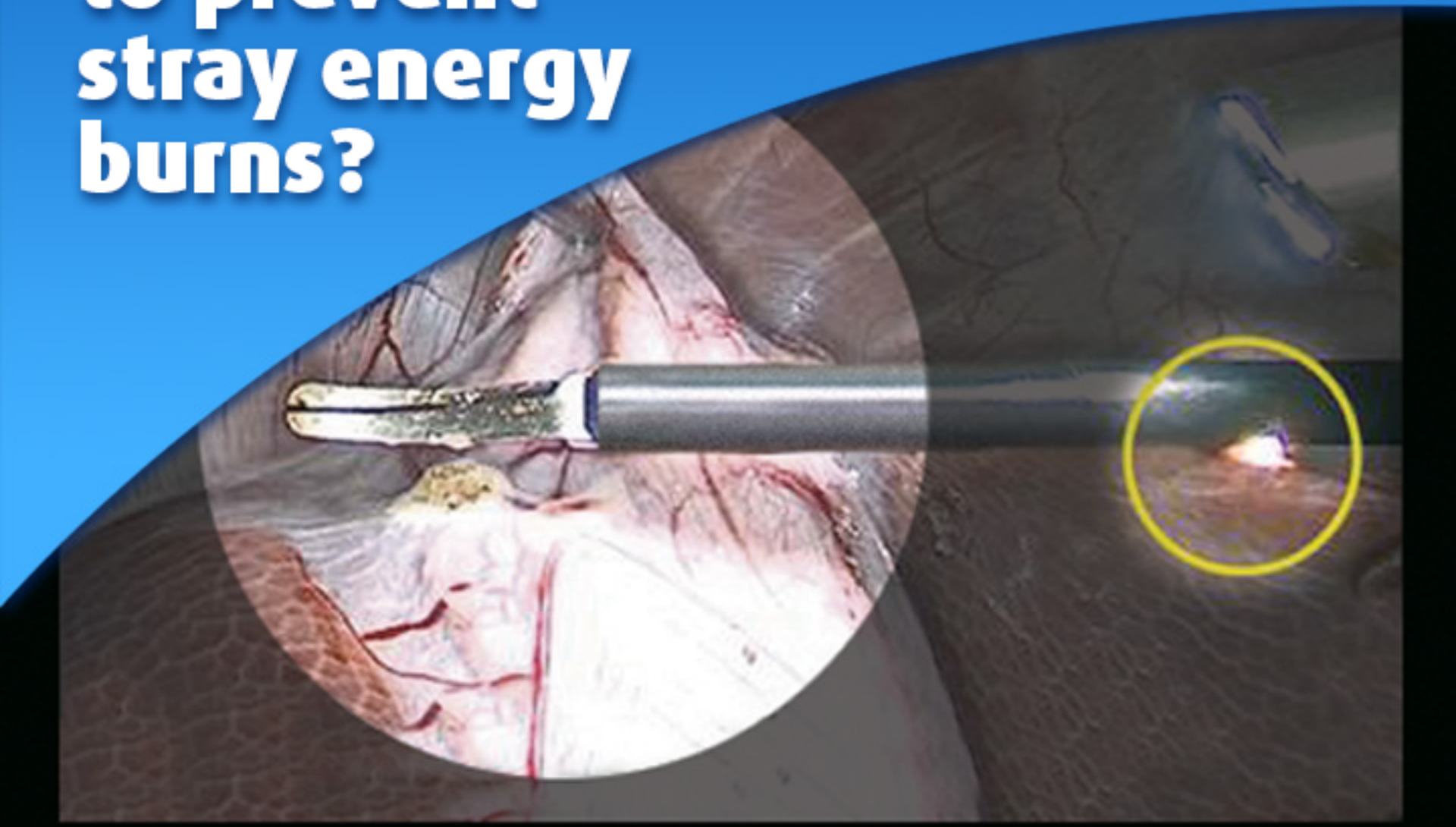
- Frequency: Can occur anytime monopolar energy is used

Implications of Stray Burns:

- Readmissions (every 90 minutes in the USA; $30k+)
- Mortality (1 - 2 deaths per day)
- Lawsuits ($260k - $19M)
- CMS Penalties (Millions each year)

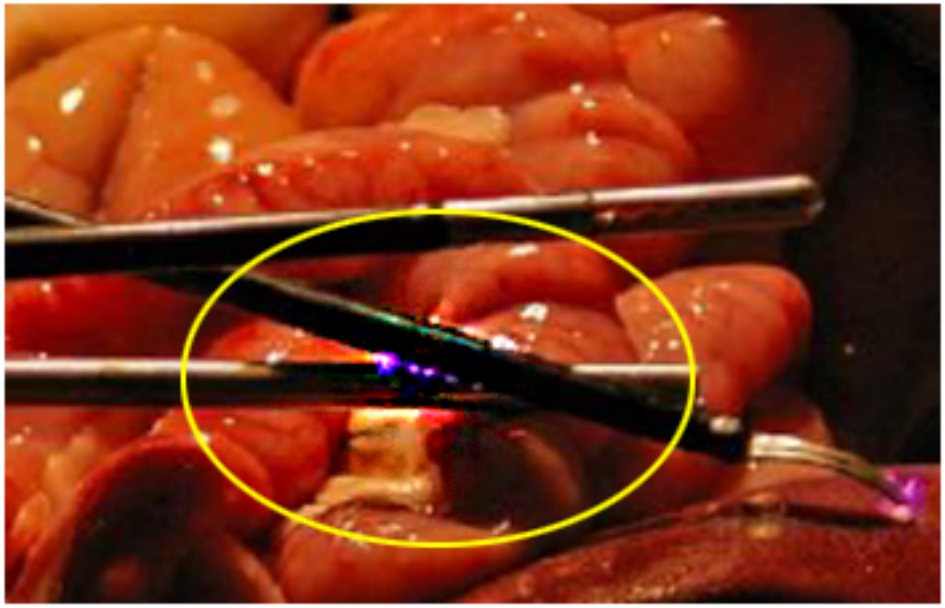


Are there ways to prevent stray energy burns?



Common techniques that attempt to reduce capacitive coupling injuries

- Use lower ESU power settings and “cut” modes
- Avoid hybrid cannulas (plastic and metal)
- Neither of these guidelines reduce the problem to a safe level or eliminate patient injuries



Common techniques that attempt to reduce insulation failure injuries

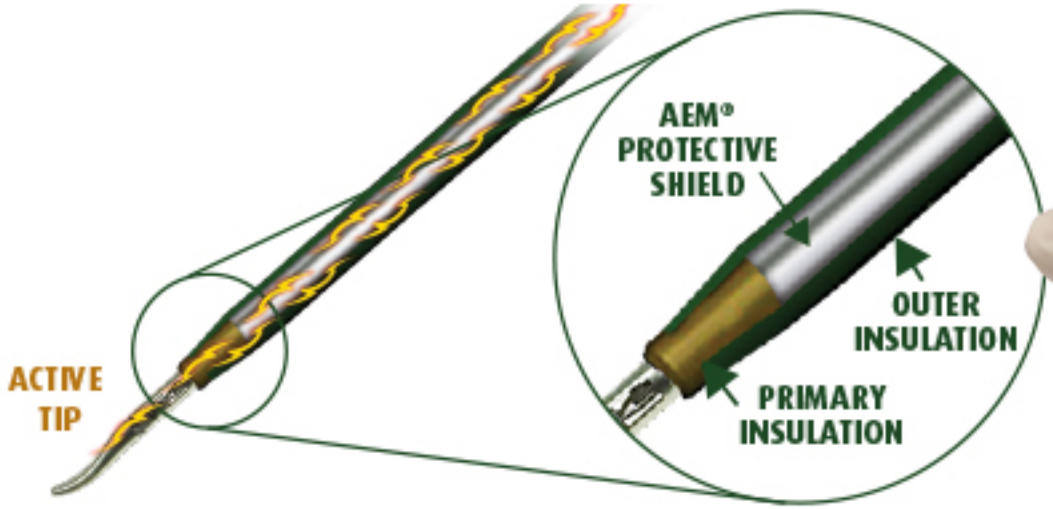
- **Use high potential instrument wanding:**
  - From the IFU: "A quick check of the insulated instruments… immediately prior to the case will expose any defective instruments so they can be removed and reinsulated. *One last scan post-operatively will confirm for the patient's surgical chart that no defects occurred during surgery."*
  - *What if the insulation breaks down during the surgery?*
  - *Are these technologies protecting the instrument or the patient?*
- ***Visually Inspect the Instruments:***
  - *57% of insulation defects can not be seen with the naked eye*
- ***Use disposable monopolar instruments:***
  - *Reduce rate of insulation failure from 20% to 3%*
  - *However typically higher cost*

Solution to eliminate stray energy burns: Active Electrode Monitoring (AEM)

The AEM Burn Protection System is the *only* technology that eliminates stray energy burns due to insulation failure and capacitive coupling *during* laparoscopy

Solution to eliminate stray energy burns: Active Electrode Monitoring (AEM)

- Shielded and monitored AEM Instruments



- Constantly drains capacitive coupled energy
- Shuts down power to instrument in the event of an insulation failure

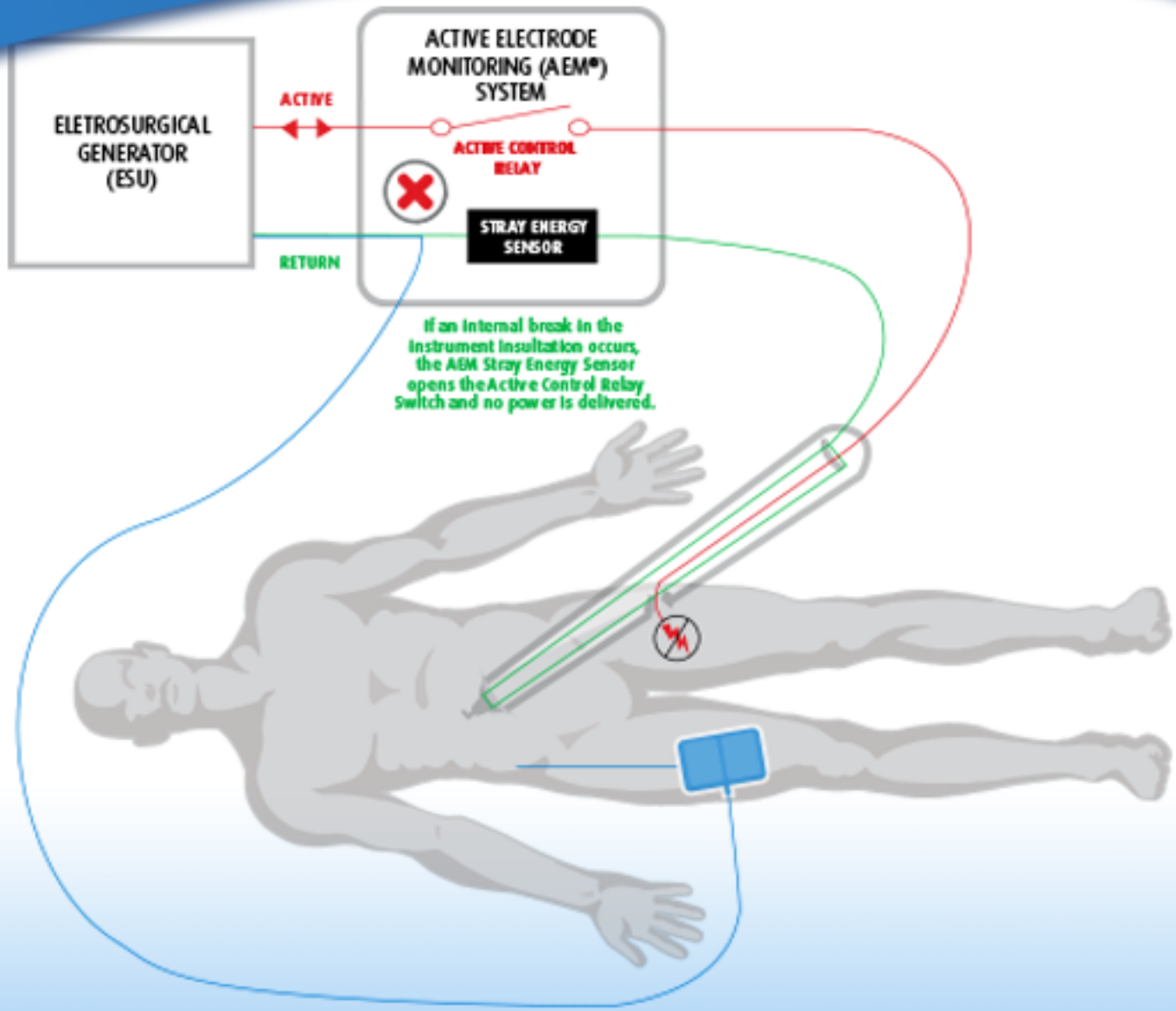
Solution to eliminate stray energy burns from Insulation Failure

- For Insulation Failures: AEM Technology works similarly to the Ground Fault Interrupt (GFCI) Circuit in your house

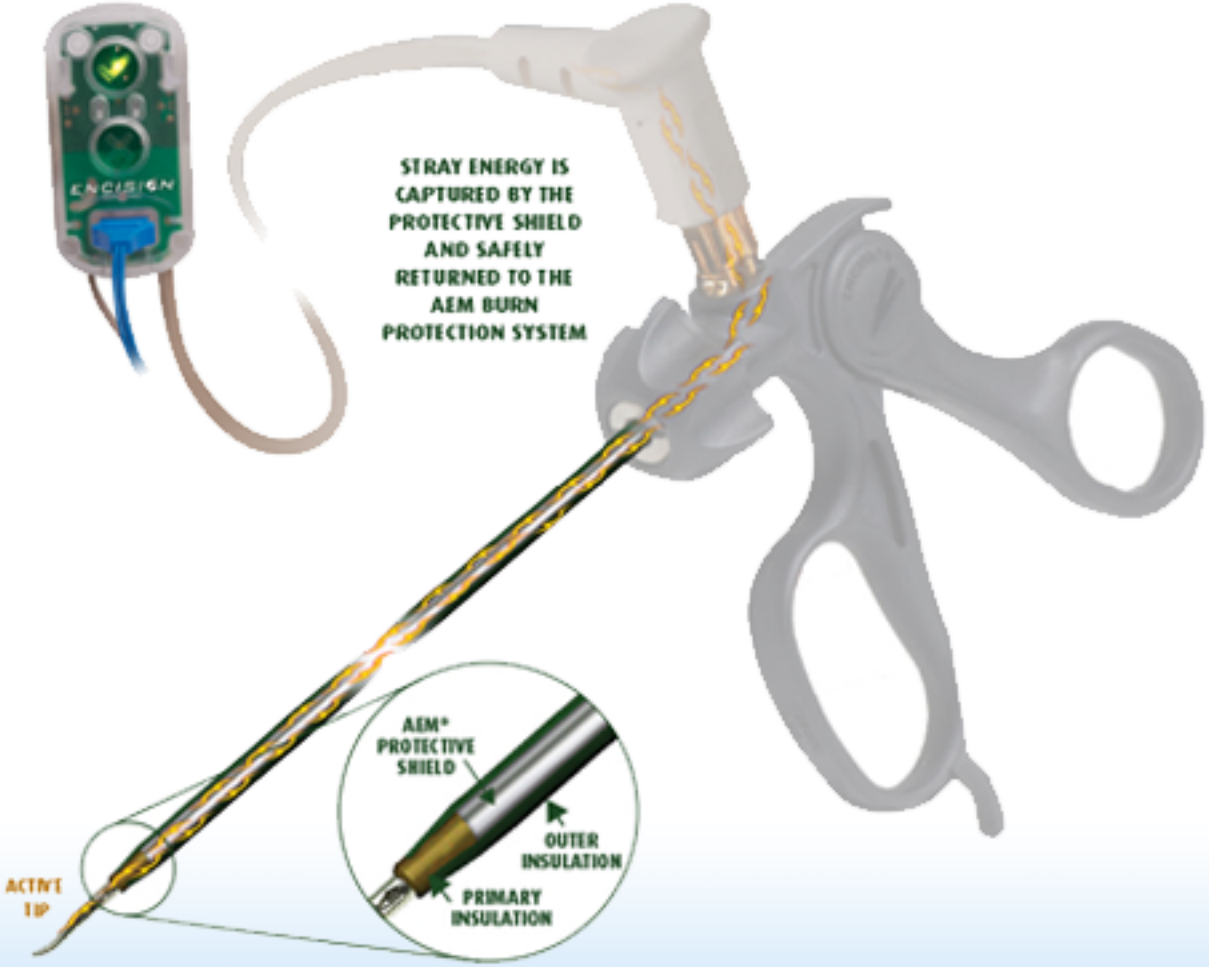
GFCI

AEM Burn Protection System

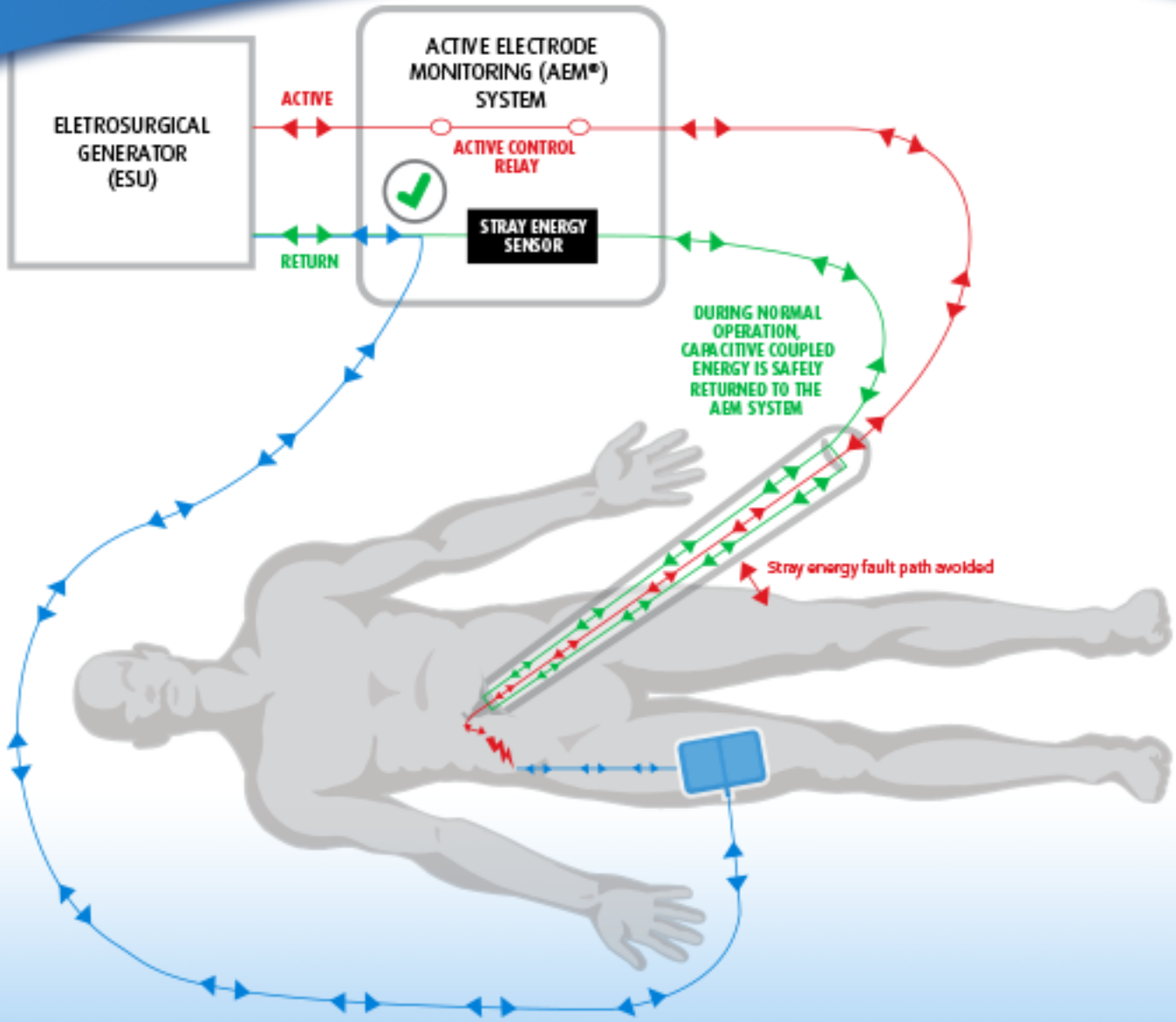
Solution to eliminate stray energy burns from Insulation Failure



Solution to eliminate stray energy burns from Capacitive Coupling

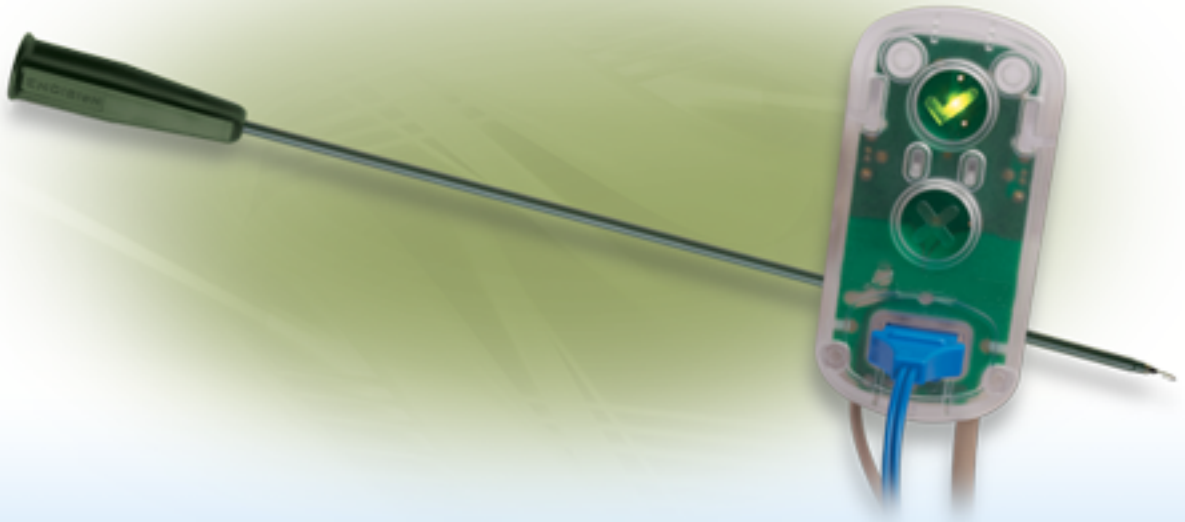


Solution to eliminate stray energy burns from Capacitive Coupling



Benefits of the AEM burn protection system and instruments

- Eliminates the chance of patient injury from stray electrosurgical energy
- Efficacious and fail-safe
- Cost effective
- No change in surgical technique



AEM Recommendations for Standards of Practice

- Association of periOperative Registered Nurses
- ECRI/Health Devices- Biomedical Safety Group
- Society of Laparoendoscopic Surgeons
- American Association of Gynecologic Laparoscopists
- International Society for Gynecologic Endoscopy

AORN

AAGL

JSLS Journal of the Society of Laparoendoscopic Surgeons

ECRI A NONPROFIT AGENCY

ISGE INTERNATIONAL SOCIETY OF GYNECOLOGICAL ENDOCRINOLOGY

AEM guidelines for perioperative practice from AORN

Methods should be used to detect insulation failure including, but not limited to:

- Active Electrode Monitoring (AEM)
- Active Electrode indicators shafts of different colors
- Using active electrode insulation integrity testers that use high DC voltage to detect full thickness insulation breaks

AORN

AEM Recommendations for Standards of Practice

ECRI rating of “preferred”

Responsibilities of the Perioperative Team during MIS

- Have adequate training in laparoscopic monopolar electrosurgery
- Encourage professional societies to establish standards
- Collect data and conduct studies related to laparoscopic monopolar electrosurgery
- Keep power source as low as possible
- Have product education
- Mandate preventative maintenance and inspection program
- Consider Active Electrode Monitoring (AEM) burn protection if monopolar electrosurgery is being used

Questions?

Thank you for attending this
continuing education presentation.

Please be sure to return your registration
and evaluation forms to your presenter.

Certificates of Attendance for this course
are available in your course booklets.

Please keep this for your records.

Replace slide 56 w/ HealthTrust
“Questions” slide since info on
theirs does not apply to this webinar

Add HealthTrust end slide with CE information