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Active Electrode Monitoring: Electrosurgical Safety During Monopolar Minimally Invasive Surgery

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Minimally invasive laparoscopic surgery with monopolar electrosurgical instruments is used increasingly in a wide array of surgical specialties because of its versatility and effectiveness. This versatility includes precise cutting and reliable hemostasis (coagulation). With the expanded use of such surgery, a significant patient population is at risk for unintended burns to nontargeted tissues. These unintended burns can result from insulation failure or capacitive coupling of electrical current into nontargeted tissue. The potential consequences of such burns to patients are significant and include emergency surgery, extended hospital stays, long-term convalescence, and severe and sometimes fatal infections. Failure to adequately address the underlying etiology with appropriate safety protocols and technology incurs heavy direct and indirect financial penalties for the surgeons involved, the institutions where they practice, and the health care system at large.

Many physicians and organizations have recommended a technologic solution using a continuously monitored electrical shielding of the instrument's active electrode shaft. This is known in the literature as active electrode monitoring. The active electrode monitor checks for proper instrument setup and then continuously monitors current flowing in the electrosurgical system. This technique offers a comprehensive solution to unintended burns with an overall cost similar to that of conventional premier instruments.

This article presents a summary of monopolar laparoscopic instruments, their alternatives, and the results of past studies into the issue of unintended burns. Some example case histories are presented, and the efficacy of the active electrode monitoring technology is explained (Fig. 1).

Minimally invasive surgery

Since its introduction in the early 1970s, minimally invasive surgery (MIS) has revolutionized surgical diagnosis and intervention. MIS offers patients the significant benefits of faster healing and less postoperative pain. Patients can often leave the hospital sooner, and in many cases can even have their surgery performed at an outpatient center. Convalescence is usually shorter, allowing patients to return to work and resume other activities earlier. Moreover, MIS is generally less expensive than open surgical procedures.

Until the late 1980s, laparoscopic surgery—one of the most common forms of MIS—was mainly limited to gynecologic procedures such as tubal ligation and the lysis of pelvic adhesions. The development of the endoscopic camera, however, opened the door to MIS surgical procedures in a large number of other specialties, including urologic, general, gastrointestinal, thoracic, and orthopedic surgery (Fig. 2).

Monopolar electrosurgery—the use of radio frequency (RF) current to cut tissue and control bleeding—has been used effectively in open operative procedures for more than 75 years. Partly because of its long history of use in open surgery, it has become the most widely used cutting and coagulation technique in MIS and is used by most surgeons who perform laparoscopic procedures.

Electrosurgery in general and monopolar in particular is expected to continue in popularity

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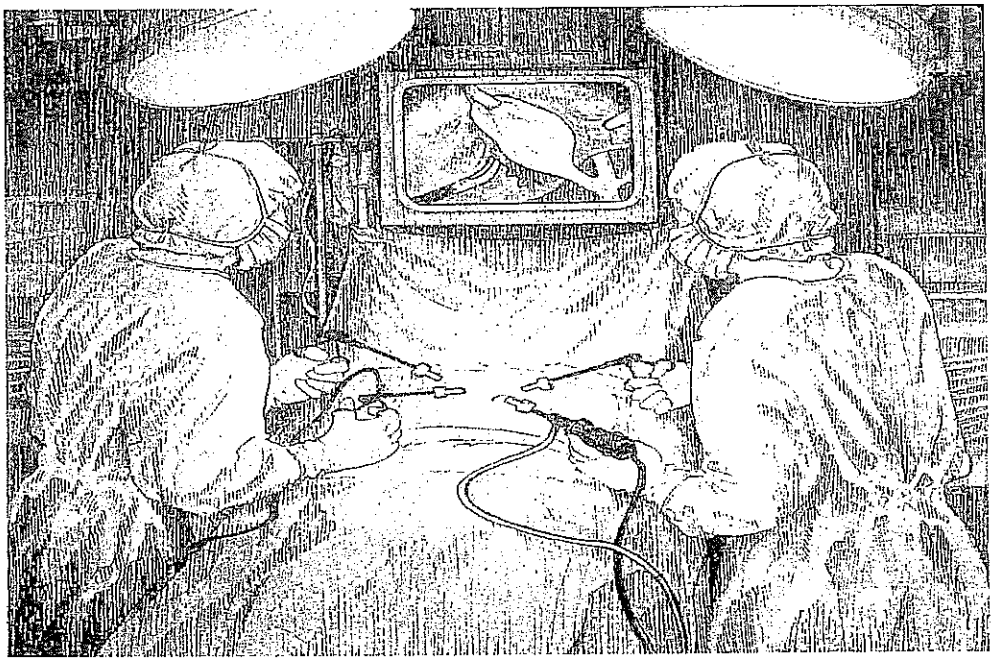

Fig. 1. Surgery scene. (*Courtesy of* Encision, Boulder, CO; with permission.)

and to be the fastest growing energy segment in laparoscopic surgery, at least through 2009 [1]. Its popularity, however, is not simply attributable to its long availability (since the 1930's).

The versatility of monopolar techniques has been demonstrated in a wide range of surgical settings [2]. Monopolar electrosurgery has traditionally been used to cut soft tissues and to provide hemostasis during surgery. The technique gets its name from the single electrode used to apply surgical energy to the patient. In most cases the monopolar energy modality allows the two functions to be performed optimally with a single electrode. A high-frequency electrical current is delivered from the tip of the active electrode to targeted tissues. The concentration of current near the tip causes complete vaporization of tissue in the case of electrosurgical cutting. For hemostasis, a different current waveform and different handling of the electrode produce heating without

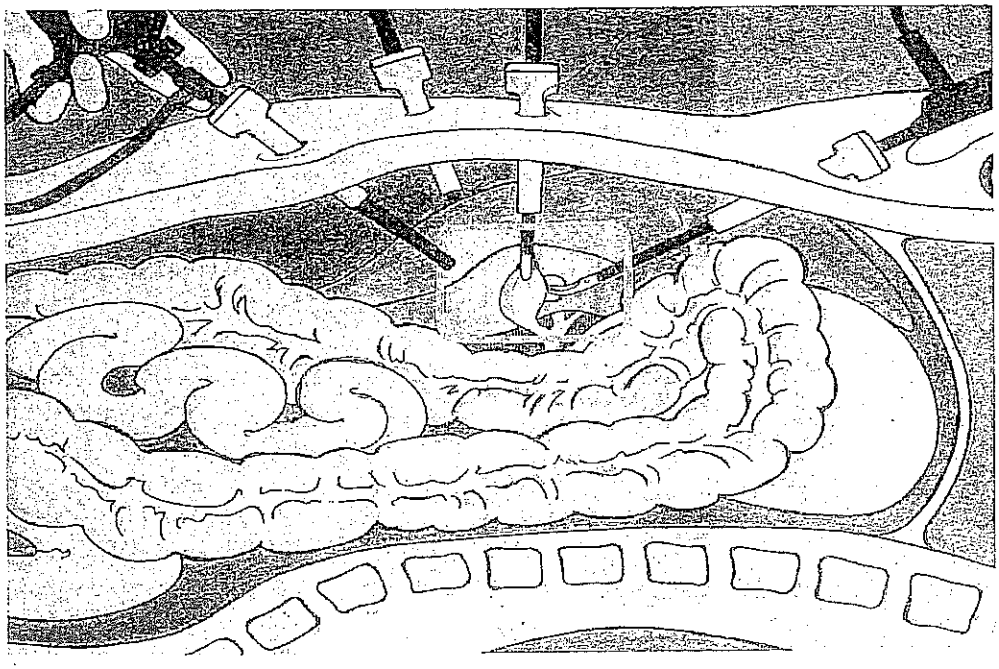

Fig. 2. Cross section of abdominal region. (*Courtesy of* Encision, Boulder, CO; with permission.)

complete tissue vaporization that stops bleeding. In monopolar electrosurgery, the current is concentrated only in the immediate vicinity of the active electrode and then it disperses and flows harmlessly through the patient, to return to the electrosurgical unit (ESU) at a distant site by way of a large return electrode pad attached to the patient's skin.

In addition to basic cutting and coagulation, there are several other surgical effects that can be obtained with most monopolar electrosurgery systems. By optimizing the application technique and the mode of generator operation, surgeons can

1. Produce a cut/coagulation blend that cuts and leaves a heat-affected tissue adjacent to the cut, providing immediate hemostasis.
2. Arc fulguration of tissue by providing a spark to the tissue through a small air gap. This allows superficial coagulation of diffuse bleeding across a significant area of tissue.
3. Achieve coaptive coagulation of grasped tissue. Excellent desiccation occurs and produces a "collagen weld" [3].

The versatility represented by the range of surgical effects and efficacy of coagulation have made monopolar electrosurgery the most popular energy source for MIS.

Alternative energy sources

Other MIS energy sources, such as bipolar electrosurgery, laser surgery, and the ultrasonic scalpel, are also available for tissue dissection and hemostasis. Each has its own set of merits and limitations and inherent risks.

Bipolar electrosurgery uses an instrument on which the active and return electrodes are included, and delivers energy to tissue between the two electrodes. Although bipolar electrosurgery can be superior to monopolar electrosurgery for certain neurosurgical and ophthalmic applications involving wet surgical fields, it is limited in the range of effects possible [4]. Bipolar electrosurgery is not as effective as monopolar for cutting. Furthermore, the bipolar technique cannot be used to stop bleeding over a large area. With most bipolar instruments, hemostasis requires tissue to be grasped between both the electrodes, which may be difficult with dense tissues [5,6].

Laser energy instruments have limited laparoscopic surgical applications. Lasers, however, do not coagulate as well as electrosurgical instruments [7]. Although lasers can be used with some degree of success for superficial hemostasis, they are ineffective for deep hemostasis. The contact neodymium Nd:YAG laser, in particular, has been shown to be less efficient in tissue excision and to cause more tissue damage and blood loss than monopolar electrosurgery [8,9].

Ultrasonic surgical energy sources have somewhat broader applications in laparoscopic surgery. The range of effects has increased with the recently improved ultrasonic systems. Ultrasonic sources, however, may be slower than monopolar electrosurgery.

Alternative energy sources are often significantly more expensive than monopolar systems. Also, each source has its own set of specialized training requirements.

A key advantage of monopolar electrosurgery is that it generally presents the shortest and most straightforward learning curve for most surgeons [2]. With the advantages of versatility, speed, cost, and a short learning curve, monopolar electrosurgery is clearly the dominant energy source for MIS.

Risk factors in monopolar laparoscopic electrosurgery: unintended tissue burns

> "The risk of inadvertent burns has been recognized since the invention of the first electrical surgical tools in the late 1920's. But the accident rate soared in the 1980's [and 1990's] as laparoscopic versions of the devices became widely used in gynecology, gall bladder removal, and gastric bypass surgery." [10]

Though highly versatile, cost effective, and popular, monopolar laparoscopic electrosurgery can compromise patient safety under certain circumstances. For example, the surgeon may directly burn nontargeted internal organs or tissue with the tip of the active electrode through imprecise mechanical operation of a laparoscopic instrument (ie, "pilot error"). Perhaps more alarming, stray electrical currents emanating from the shafts of laparoscopic instruments can inadvertently burn nontargeted tissues outside the surgeon's limited field of vision, leading to grave complications. Such stray energy burns can occur regardless of the surgeon's skill and judgment. Published clinical studies and case histories have documented the real risk of inadvertent tissue injury during

laparoscopic monopolar electrosurgery, even though prevalence of the problem is currently not well defined. Compounding the problem is the gross underreporting of medical device surgical misadventures to the Food and Drug Administration (FDA) Medical Device Report (MDR) Database. In April 2001, Chandler and colleagues [11] introduced an article pertaining to laparoscopic entry access injuries, stating, "Although unable to contribute a true incidence figure, the findings suggest, that considerable MDR underreporting exists because only 8% (5 of 64) of US PIAA cases were identifiable as the subject of MDRs in the overlapping time period" [11]. Only approximately 8% of incidents are therefore reported to the FDA.

During open surgery the surgeon operates in an unrestricted space and generally has a full view of the active electrode and surrounding tissues at all times. In this situation, the surgeon is usually immediately aware of an unintended burn and can apply treatment to avoid serious complications. During laparoscopic electrosurgery, however, the view of the surgical field is constricted. The surgeon operates from the exterior of the patient's body using long instruments. Visualization is by way of a camera connected to the laparoscope with the image displayed on a video monitor, which often results in only a 2-in diameter field of view. Although the laparoscope provides a detailed view of the tip of the active electrode, the shaft of the instrument, including the presumably insulated part of the instrument, may not be in the surgeon's view [12]. Unknown coupling could be occurring from the part of the instrument outside the field of view, and there might be no indication that a thermal injury is taking place, so the surgeon is not aware of the injury and cannot prevent or repair the injury [13].

The stray currents that can cause patient injury outside the laparoscope's view may come from any of three sources: insulation failure, capacitive coupling, or direct coupling.

1. Insulation failure occurs when the insulated shaft of the electrode that is intended to protect against the release of electrical energy becomes damaged by electrical stress, general wear and tear, or mechanical accident. Insulation degradation can occur cumulatively over time, during a single laparoscopic procedure, or during disinfection and sterilization procedures [4,14]. The breakdown along the unseen shaft of an activated electrode can allow electrical energy to flow to surrounding nontargeted tissues, causing unobserved damage. Testing and maintenance are resource-intensive and typically uncertain in their results. The consequence is that insulation failures are common and often unnoticed. Given the potential for stray energy to escape from these instruments through insulation failure, the question is: *If these instruments fail, will they fail safely or in a manner that injures a patient?*
2. Electrosurgical burns can also result from the phenomenon of capacitive coupling, which occurs when electrical current is induced from the active electrode to nearby conductive material, despite intact insulation. This occurs because of the transfer of charge brought about by high voltages and frequencies used during electrosurgery. The movement of electrically charged ions in tissue, coupled capacitively to the electrode, can heat tissue sufficiently to produce a burn [4,12,15].
3. Injury can occur by way of direct coupling when the active electrode touches another metal instrument within the abdomen and transfers energy to the second instrument, possibly injuring tissue with the second instrument. For example, the active electrode touches the laparoscope, which then touches and burns the bowel or other organs. The chance of direct coupling may be minimized through the use of an adjustable sheath to insulate as much of the active electrode as possible.

Because of the well-recognized phenomena of direct coupling, insulation failure, and capacitive coupling, surgeons performing laparoscopic monopolar electrosurgery can seriously burn nontargeted tissues outside the surgical field, despite their best skills and efforts. Patients who suffer such unintended electrosurgical injuries can develop painful and costly complications, resulting in subsequent emergency surgery, extended hospital stays, long-term convalescence, and potentially life-threatening infection.

Unfortunately symptoms of injury often do not show up for several days, thereby helping to obscure the underlying causes. The complications resulting from internal electrosurgical burn injuries compounded by delay in diagnosis and treatment can have a profound medical and economic impact on patients.

Complications resulting from unintentional tissue burns

Complications resulting from accidental, unsuspected thermal injuries can have significant adverse medical impacts on patients, including organ damage and vessel hemorrhage, perforation, and peritonitis. If not detected expeditiously, any of these conditions can result in significant morbidity or even death. Fecal peritonitis, resulting from the contamination of the abdominal cavity by bacteria from a bowel perforation, is the most feared complication of thermal injury, with a mortality rate estimated at 25% [16,17].

In a problematic scenario, a postoperative patient who has a severe but undetected thermal injury to the bowel leaves the hospital asymptomatic. The patient returns to the local emergency department or outpatient clinic a few days later with a low-grade fever, complaining of increasingly severe abdominal pain. Abdominal radiograph films are negative for free air (a pathognomonic sign of gastrointestinal tract perforation), and laboratory tests may show a moderate increase in white blood cells suggesting inflammation or infection. The patient is placed on antibiotics but does not respond. Instead, the signs of advanced peritonitis—high-grade fever and severe abdominal pain—develop in due course, and emergency exploratory surgery is performed. The surgery reveals extensive necrosis of the bowel with perforation and seepage of fecal contents into the abdominal cavity. Extensive areas of severe infection and inflammation—diffuse purulent peritonitis—are observed in the abdominal cavity. Wide debridement and resection of the intestine are performed with a colostomy. The patient is placed on aggressive intravenous antibiotic therapy, only to die in 7 days from septicemia (blood poisoning).

Although death is, of course, the most catastrophic complication of undetected burns to the bowel during laparoscopy, significant morbidity is associated with undetected burns and can present health care providers with extremely difficult patient management challenges. Patients recovering from the reparative resection of the intestine may require stents or colostomies to maintain gastrointestinal continuity. Parenteral nutrition is frequently necessary for up to 10 days after surgery while awaiting the return of bowel function. Oral intake of solid nutrients may be impossible for up to 20 days [18].

The morbidity associated with undetected burns can also have serious long-term financial and psychologic impacts on patients and their families. Recurrent infections and painful adhesions requiring additional hospitalizations and surgery are common long-term complications for these patients. Prolonged treatment can be expensive, and convalescence may be extended for many months, requiring long periods of time away from work or normal activities [4,19–22].

The seriousness and long-term impact of complications arising from unintended tissue burns during laparoscopy are further illustrated in the following case histories.

Case 1

A 38-year-old nurse was seen by a gynecologist for lower resection of the left ovary for endometriosis. The gynecologist made a diagnosis of pelvic adhesions of the ovary and performed diagnostic laparoscopy. Monopolar electrosurgery was used to cauterize adhesions from the ovary to the pelvic side wall. The electrosurgical generator power setting was 30 W and the electrode was activated for approximately 5 seconds. The patient was considered sufficiently well to be discharged from the hospital on the same day of the surgery. On the seventh postoperative day, however, the patient became ill and was admitted to the emergency department with a low-grade fever and slightly elevated white blood count. Free air was found in the abdomen by CT scan and the consulting gastroenterologist suggested that the patient was suffering a possible complication of laparoscopy. An exploratory laparotomy revealed "multiple necrotic areas" in the distal ileum that resembled "burns." Several areas of the colon appeared "compromised" and one area showed perforation. Peritonitis was localized to the right lower quadrant. Microscopic examination of the small bowel showed "focal full-thickness necrosis." Examination of the large intestine revealed "areas of mucosal ulceration and full-thickness wall necrosis." Forty centimeters—almost 16 in—of the ileum was removed during surgery and a temporary colostomy was performed. After the laparotomy, the patient developed a wound infection requiring treatment. The patient subsequently underwent surgery to close the colostomy and was sufficiently well to return to normal activities 6 months after the initial laparoscopy [19,20].

Case 2

A 79-year-old woman underwent laparoscopic surgery for gall bladder removal. No bowel injury was noted during the surgery. The colon was, in fact, not observed by the surgeon at any time during the procedure. The patient was discharged from the hospital 2 days postoperatively, asymptomatic. She collapsed and died, however, 4 days after discharge. On autopsy, examination of the abdominal cavity revealed extensive soiling of the peritoneal cavity with fecal material and generalized peritoneal inflammation. The source of the leakage of bowel contents was found to be two perforations in the transverse colon. Diffuse peritonitis was determined to be the cause of death. The pathologist concluded that the histologic appearance of the perforated tissue suggested "coagulative necrosis consistent with thermal injury" [23].

Case 3

In September 2003, a 26-year-old mother of three was admitted to an Oregon hospital to have a cyst removed. During the procedure (the patient maintains), her surgeon accidentally burned a hole in her lower intestine. Seepage of fecal material from the undetected perforation led to infection. When she was readmitted to the hospital, she fell into a life-threatening coma that lingered for 56 days. In 2005, her attorney filed a lawsuit against the hospital and the surgeon seeking $1.6 million in damages. This is the second suit her attorney has filed over accidental electrosurgical burns suffered during laparoscopic surgery. He argued in that case, and re-alleges in the new one, that the electrosurgical equipment used in the procedures lacked capacity for active electrode monitoring to protect patients from accidental burns [24].

Case 4

An earlier case involved a female patient who had laparoscopy in 1998 to relieve a painful gynecologic condition. No one suspected when the patient was sent home that a wayward spark might have seared a tiny hole in her colon. The patient, now 33 years of age, ended up with a malfunctioning bladder and disabling pain that despite frequent follow-up treatment (13 operations so far) prevent her from working or bearing children. She has a lawsuit pending against the device makers, the hospital, and the doctor involved [10].

Electrosurgical burns involve a high risk for tissue necrosis and abscess formation. This can lead to perforation of internal organs, such as the bowel, which could result in bacterial contamination of the abdominal cavity (fecal peritonitis), necessitating immediate and aggressive treatment. Even in this advanced age of antibiotics, the mortality rate from fecal peritonitis is reported to be as high as 25%.

In patients who survive such burns, the morbidity associated with the resulting complications can have serious and long-lasting physical, emotional, and financial implications. The necrosis of gastrointestinal tissue at a burn site, for example, can create a need for surgical resection of variable lengths of bowel and a temporary or a permanent colostomy. Treatment is expensive and convalescence may be extended for many months, requiring long periods of time away from work.

Medicolegal and economic impacts

The medicolegal and economic consequences of inadvertent and undetected burns that can occur outside the surgeon's field of view are considerable, and they divert health care resources and increase the costs of procedures and services. As evidenced by numerous legal cases, internal thermal injuries during laparoscopic surgery can be costly to the surgeons who perform these surgeries and the institutions at which they are performed.

As with any form of health care delivery, surgeons, biomedical engineers, risk managers, and health care provider organizations have a responsibility to protect patients from the potentially devastating injuries that can occur during MIS electrosurgery. Several precautionary procedures and techniques have been introduced over the years by operating room staff in an attempt to reduce the incidence of stray energy release. By their nature, however, these measures are limited in their ability to reduce the risk. Given the design of the instruments, the limited field of vision during laparoscopy, and the nature of the electrosurgical environment, "Some defects can reduce the safety of laparoscopy even in the hands of an expert" [25].

Hospital risk managers, hospital insurers, physician insurers, and surgeons have strong incentives to protect themselves and their institutions from the financial and legal risks associated with such injuries. Not surprisingly, the increasing number

and scope of malpractice claims citing injury during laparoscopic surgery has prompted the formation of a special Laparoscopic Litigation Group within the Association of Trial Lawyers of America [26]. This group has taken the position that injury resulting from stray electrosurgical current during electrosurgery provides a strong case for malpractice suits. According to one of the group's founders, surgeons and hospitals may be targeted for specific surgical errors and for simply using electrosurgery tools and instruments that allow stray current to injure a patient [26].

These examples represent just a small cross section of the legal cases filed as a result of electrosurgical burns. The number of cases that have actually gone to trial is likely dwarfed by the number of cases in which surgeons or insurance companies have settled claims out of court.

A study report published in 2000 by the Physician Insurers Association of America (PIAA) revealed that at that time there were 173,343 malpractice claims and suits, 48,936 of which were closed with total indemnity payments of more that $8 billion, and that the average indemnity payment was $163,732. In 1999, 2195 closed claims reported an average indemnity of $260,215 with a total indemnity of $571,172,105. Twenty-two domestic PIAA member companies participated in the studies. These companies collectively insure more than 95,000 physicians in the United States.

The most common injuries reported were to the bile duct; other injury claims were attributable to perforation of the bowel, small intestine, and liver and to injuries to hepatic duct, arteries, and veins. Additional surgeries commonly followed but were generally delayed, because the injuries were not detected during the initial laparoscopic procedures [27].

Case histories and survey results suggest that the problem is prevalent enough to cause substantial concern, especially given the severity of the complications when it does arise [28].

Professional and public awareness

The medicolegal problems associated with stray energy burns during laparoscopic monopolar electrosurgery are likely to escalate, considering the trend toward using these types of surgical procedures more often and the increased attention paid to this issue by trial lawyers, insurance companies, professional organizations, and the popular press.

Healthcare professionals are becoming increasingly aware of the issue of unintentional burns during minimally invasive monopolar electrosurgery. In 2005, the Emergency Care Research Institute (ECRI), a nonprofit research agency that reviews and tests medical devices, sponsored a patient safety conference and estimated that an audience of up to 1500 health care professionals attended the conference online. An interactive question, "Have any electrosurgical burns occurred at your facility in the past year?" was asked of the attendees. The results as listed in the materials provided post-conference are found in Table 1 [29].

A total of 50% of the respondents thus knew of electrosurgical burns in their facilities. The Association of periOperative Registered Nurses (AORN) has recognized the danger of tissue burns during laparoscopic electrosurgery since 1995 and has addressed them in its annual *Standards, Recommended Practices, and Guidelines* publication. Through 2006, among its Recommended Practices for Electrosurgery, AORN has stated the "use of active electrode shielding and monitoring minimizes the risks of insulation failure and capacitive-coupling injuries" [30].

Newer publications directed at the growing patient safety movement and a growing number of outpatient surgery centers have featured articles on safer laparoscopic electrosurgery. The May/June 2005 issue of *Patient Safety & Quality Healthcare* featured an article, "Advancing Patient Safety in Laparoscopy: The Active Electrode Monitoring System," which describes the problem of stray electrosurgical burns and the potential solutions [31]. A supplement to the March 2006 issue of *Outpatient Surgery* featured an article in its Patient Safety section that presented "smart, simple ways to protect you and your patients from ESU burns" [32].

The nonclinical press has recently begun to bring the possibility of serious injury during

Table 1
Electrosurgical burns over a 1-year period

Category	Response	Number of burns	% of responders
1	Yes	3 or more	2.7
2	Yes	1 or 2	47.3
3	No	0	41.8
4	Unsure	N/A	8.2

Data from ECRI Audio Conference. Electrosurgery and patient safety: critical measures for minimizing risk. March 16, 2005, 90-minute program.

minimally invasive electrosurgery to wider attention. An article in the March 17, 2006 business section of *The New York Times* discusses complications from stray energy burns during laparoscopy. The article is entitled, "Surgical Device Poses a Rare but Serious Peril" [10]. In the article, Dr. Alan Johns, a Fort Worth gynecologist who frequently teaches courses on the complications of laparoscopy states, "It wouldn't surprise me in the least if it [laparoscopy complications] causes more than 100 deaths and 10,000 injuries annually." Since that publication, a syndicated television story on stray energy burns during laparoscopy has appeared in 22 markets nationwide (as of this writing) [33].

Limitations of traditional methods used to minimize patient injuries

Historically, health care facilities have used several methods to reduce the risk for electrosurgical injury. Avoiding monopolar electrosurgery altogether is a solution that is often considered. Alternative energy sources, however, such as bipolar electrosurgery, ultrasonic equipment, and lasers, each tend to have their own efficacy limitations and safety problems. Also, each alternative tends to increase cost. Training medical personnel in the use of electrosurgical equipment can reduce the rate of electrosurgical complications. One study found that 22% of laparoscopic surgeons who had completed a 2-day introductory laparoscopy training seminar—but received no additional training—reported complications during minimal access electrosurgery. Only 5% of surgeons who received additional training in laparoscopy, however, reported complications [34]. The 2004 AORN document, *Recommended Practices for Electrosurgery*, lists training as a key element in safety (Recommended Practice II) [30]. In August 2005, ECRI's *Health Devices* suggests that "Appropriately training and credentialing medical and technical personnel be a part of hospital policies" [35].

Although improved training and credentialing can reduce electrosurgical complications relating to poor practices, these efforts alone cannot fully address the safety risks associated with stray electrical current. This is because the risks associated with insulation failure and capacitive coupling are strongly dependent on the instruments themselves and are only weakly related to user practices.

It has been suggested that frequent instrument inspection can reduce the risk for insulation failure [35]. Normal wear, handling, and electrical stress can damage insulation, but detecting cracks in insulation before surgery can be problematic, because the cracks can be difficult to see. In fact, one study showed that even with visual inspections, 18% of the instruments in use had defects [25]. High-voltage testers are now available to assist in the tasks of inspection, and the ability to find cracks has improved because of them. They cannot be effective, however, against cracks that occur during a procedure that are caused by electrical stress and contact with other instruments. The use of disposable electrodes eliminates the need for presurgical instrument inspection, but again, these offer no protection against capacitive coupling or intra-procedure insulation damage. Another remedy that has been proposed and is much discussed by the electrosurgical generator manufacturers is the use of lower voltages [36]. This can help, particularly with capacitive coupling, but it has limited success against the threat of insulation failure, because insulation failure can result in direct conductive contact between the instrument shaft and nontarget tissues. Also, lower voltages tend to reduce efficacy, particularly in the technique of spray coagulation. Another standard precaution is the avoidance of hybrid (plastic–metal) cannulae or plastic anchors with all-metal cannulae [3]. This is a good practice that somewhat reduces the possibility that current will capacitively couple from conventional instruments through a trocar cannula to nontarget tissue. It improves conditions only for zone 3, however, and does not address potential problems in zone 2 (Fig. 3).

The several traditional methods can each help reduce the likelihood of stray energy burns. To provide a comprehensive solution for the possibility of stray energy burns, however, a remedy is needed that addresses the frailties of the instruments themselves.

The active electrode monitoring solution

The encouraging news is that the problem of stray energy burns can be significantly reduced or eliminated if the proper safety protocols or technologic advancements are incorporated into clinical practice. A comprehensive and effective solution to stray energy risks is a technology known as active electrode monitoring. This patient protection device addresses the insulation failure and capacitive coupling phenomena

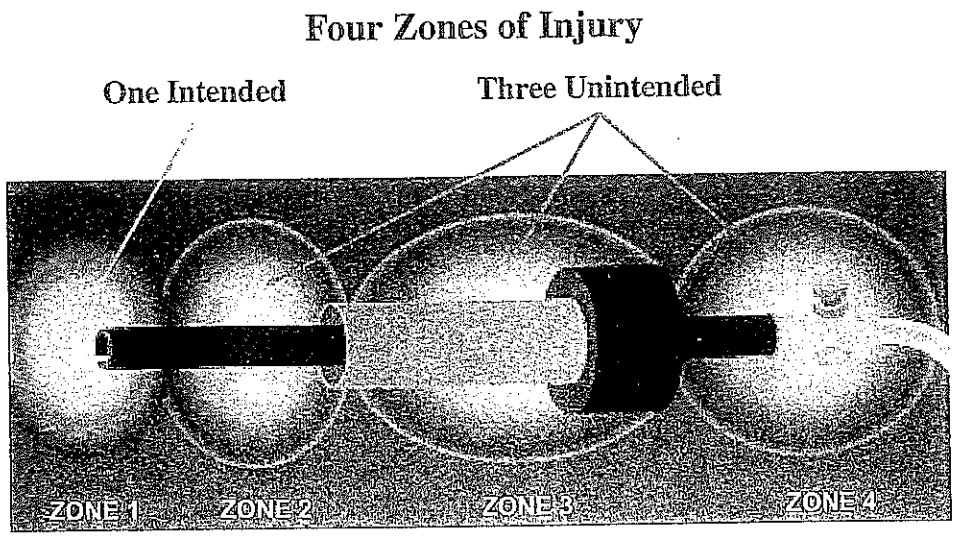

Fig. 3. Zone chart. (*Courtesy of* Encision, Boulder, CO; with permission.)

(Figs. 4 and 5) by casting a virtual safety net around the unpredictable electrical environment present during laparoscopic electrosurgery. By eliminating stray energy risks—which are, to a large extent, beyond the surgeon's immediate control—surgeons can concentrate instead on mastering their laparoscopic surgery techniques. Through better training and the use of simple, cost-effective safety protocols such as active electrode monitoring, surgeons and their patients can continue to reap the benefits of laparoscopic electrosurgery while avoiding some of its more serious complications.

The need for an improved, safer instrument system is addressed by the Encision (Boulder, Colorado) AEM products. These consist of specialized shielded instruments and AEM monitors, which are connected to standard ESU and standard monitored return electrodes (Figs. 4 and 5).

The AEM instruments are distinguished from conventional instruments in that they are constructed with multilayer insulation systems that include conductive shielding conductors that ensure the electrosurgical energy is contained within the instruments.

The result is that any failure of the instrument insulation is prevented from conducting energy to the patient or user. Also, the electric fields caused by the energy are blocked away from the patient and cannot result in capacitive coupling of energy. The AEM monitor is connected to the instruments to ensure that the appropriate connections have been made and that the internal instrument insulation is in good condition. If either condition is not met, the monitor inhibits the electrosurgical energy.

The instruments, monitor, ESU, and return electrode must work together as a system; thus all

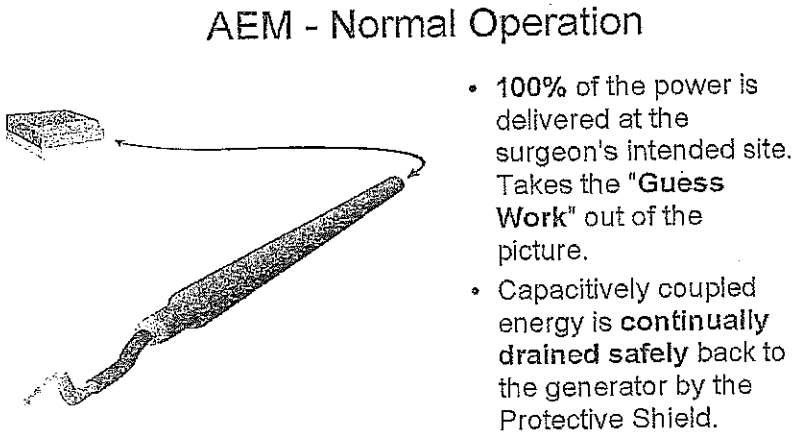

Fig. 4. AEM normal operation. (*Courtesy of* Encision, Boulder, CO; with permission.)

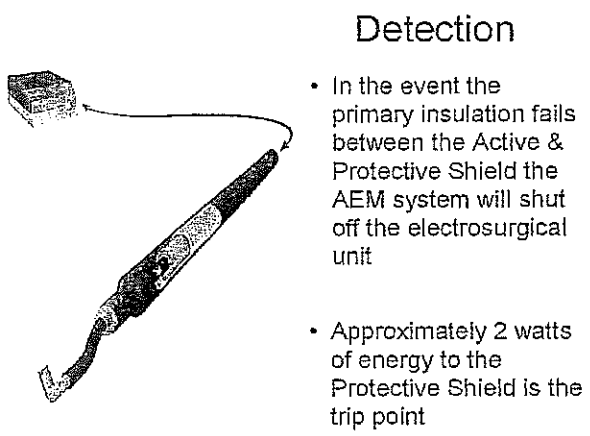

Fig. 5. Detection. (*Courtesy of* Encision, Boulder, CO; with permission.)

components must be compatible. Specialized procedures ensure compatibility among the key system components so that almost all ESUs in common use may be a part of the system. Return electrodes used in the AEM system must be of a low impedance conductive type compatible with ESU contact quality monitoring systems. This insures the instrument shield components are appropriately referenced to the patient's potential. Capacitive electrodes tested (as of the date of this writing) are not compatible, because their contacts with the patient are not made with adequately low impedance.

Active electrode monitoring instruments

Electrosurgical energy is conducted to the patient by cords, connectors, and instruments that must withstand the high voltages needed to perform the cutting and hemostasis objectives safely. Every AEM instrument has a multilayered insulation structure that is fundamentally different from conventional laparoscopic instruments. The active conductor is the central core of the instrument. Around that is the primary insulation that withstands the high voltages mentioned. The shielding conductor is a tube that surrounds the primary insulation. Finally, there is an outer insulation that is similar to the insulation used on a conventional instrument. This structure ensures energy containment within the shield component even under failure conditions. AEM instruments are available in several types and tip styles that suit most surgical preferences (Fig. 6).

The active electrode monitoring monitor

Every AEM instrument is connected to the ESU power source through a monitor hardware device that has three key functions: setup confirmation, coupling of the AEM instrument shield to ESU return, and insulation failure detection. The monitor provides visual and audio indications to inform users of the system status. The green "ready" indicator is the key to enabling power so that the surgery can proceed safely. Alerts that signal a disabling of power include

- AEM cord (instrument not appropriately connected)
- Return electrode (wrong type of electrode connected)
- Insulation (the detection of a failure of the instrument's primary insulation)

A key to successful use of the AEM system is the understanding of these alerts and the appropriate resolutions (Fig. 7).

Active electrode monitoring performance: handling unintentional capacitive coupling

Capacitive coupling is the projection of electrosurgical energy through intact insulation of conventional instruments. It occurs because of the high voltages and high frequencies used by

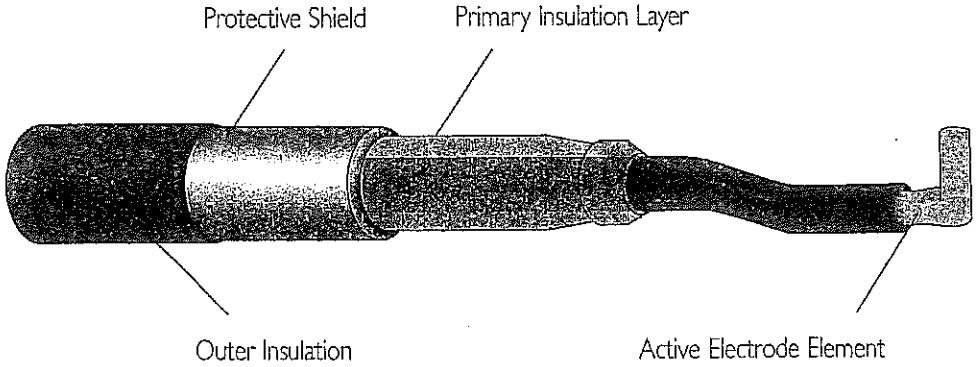

Fig. 6. AEM instrument. (*Courtesy of* Encision, Boulder, CO; with permission.)

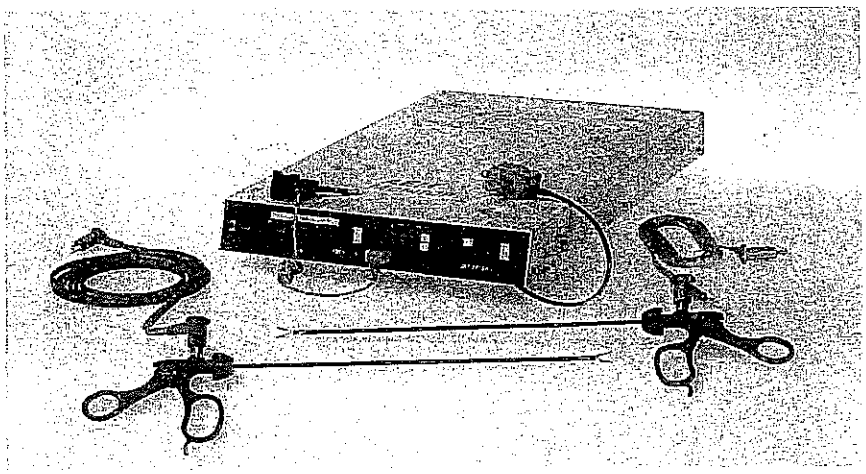

Fig. 7. AEM Monitor. (*Courtesy of* Encision, Boulder, CO; with permission.)

electrosurgery. The lower voltages of some newer generators can reduce but not eliminate capacitive coupling. An AEM instrument has a shield that is connected to the ESU return interposed between the primary insulation and the instrument exterior. Capacitively coupled energy is thus safely returned to the ESU and not transmitted to the patient (Fig. 8).

Active electrode monitoring performance: handling insulation failure

The failure of the primary insulation inside an AEM instrument is a rare occurrence. If such a failure occurs, an electric energy discharge takes place inside the instrument. This carries no direct risk for the patient or user, because the energy discharge is completely inside the instrument and the shield conductive component carries the electricity harmlessly back to the generator. Electrosurgical powers, however, are typically high enough to heat the instrument and present a thermal risk for the patient. This risk is mitigated with the AEM Monitor, which has the capability of detecting insulation failures and controlling the source so that the power is terminated before the heating becomes significant. The AEM Monitor also provides alerts and indicates the source of the problem on its front panel. The result is a system that is internally protected against stray energy discharges along the instrument shaft. It is monitored to detect the unsafe conditions of insulation failure. Detection of an unsafe condition produces the inhibition of power and an alert, resulting in a fail-safe condition (Fig. 9).

Third party analysis of active electrode monitoring

In 1995 and again in 2005, the ECRI conducted studies of the potential dangers of monopolar laparoscopic electrosurgery and the safety

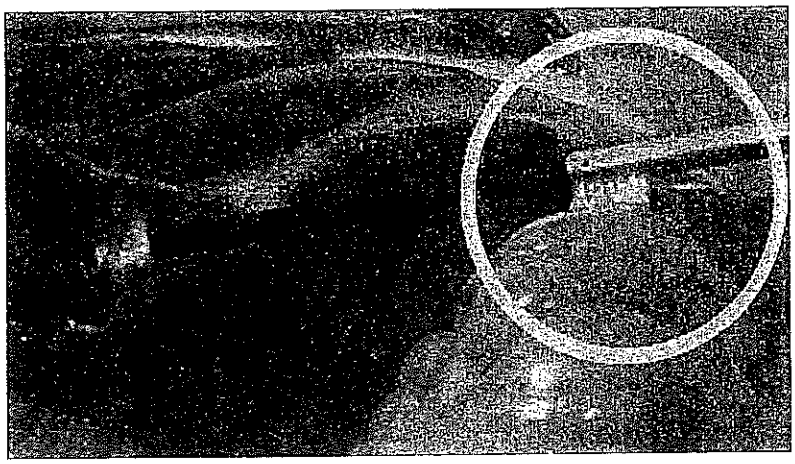

Fig. 8. Capacitive coupling on layered instrument sparking. (*Courtesy of* Encision, Boulder, CO; with permission.)

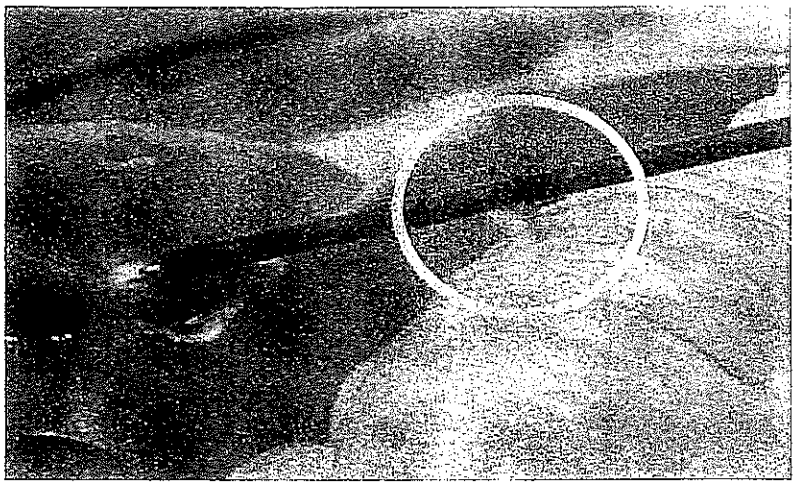

Fig. 9. Insulation image of layered instrument sparking. (*Courtesy of* Encision, Boulder, CO; with permission.)

precautions that could be taken to control those risks. ECRI found that the AEM system successfully and safely prevents stray energy leakage and tissue injury at unintended sites [35,37]. After comparing this technique with other suggested protective measures such as electrode inspection and the avoidance of high electrosurgical power settings, ECRI's 1995 report concluded that active electrode monitoring offers the highest available level of protection against patient injury caused by insulation failure and capacitive coupling, and recommended that this system be used as the best means to promote electrosurgical safety [37]. In 2005, another ECRI study also compared AEM with other means of control, including "appropriately training and credentialing medical and technical personnel" [35]. The article discusses four measures that they say "must be rigorously adhered to," and which are similar to some of the AORN recommended practices. Among the equipment options, ECRI gives the AEM system the highest rating of "preferred." The ECRI rates other options, such as insulation testing, as "acceptable" [35].

Cost of active electrode monitoring

AEM instruments are approximately equal in cost to equally-functioning premium conventional instruments.

Incorporation of the active electrode monitoring system

Conventional laparoscopic instrumentation, which has only a single coating of insulation, does not allow the perioperative staff assurance that stray energy is being monitored and controlled throughout the procedure. In contrast, AEM instrumentation does provide a high level of assurance. In many institutions this assurance is considered a key safety factor and merits being recorded in the patient charts (Fig. 10).

When so recorded, AEM meets the medicolegal requirement of positive documentation. In a way that is similar to the records for needle count, sponge count, and pulse oximetry, AEM records can be a part of the documented safe practices experienced by every patient.

Active electrode monitoring has also been recognized in leading medical journals, such as the *Journal of Reproductive Medicine and Gynecological Endoscopy*, and by professional societies for its contributions to the safe and effective application of monopolar laparoscopic electrosurgery [13,38]. In its recommendations on methods of preventing possible complications of minimally invasive electrosurgery, the American Association of Gynecological Laparoscopists has urged surgeons to consider using active electrode monitoring [39].

Summary

Minimally invasive monopolar electrosurgery is being used in a greater number of procedures in a wider array of surgical specialties because of its versatility and effectiveness. With this expanded use, a significant population of patients is currently and will continue to be at risk for unintended burns to nontargeted tissues caused by stray energy release from direct coupling, insulation failure, or capacitive coupling.

The potential consequences of such burns to patients—including emergency surgery, extended

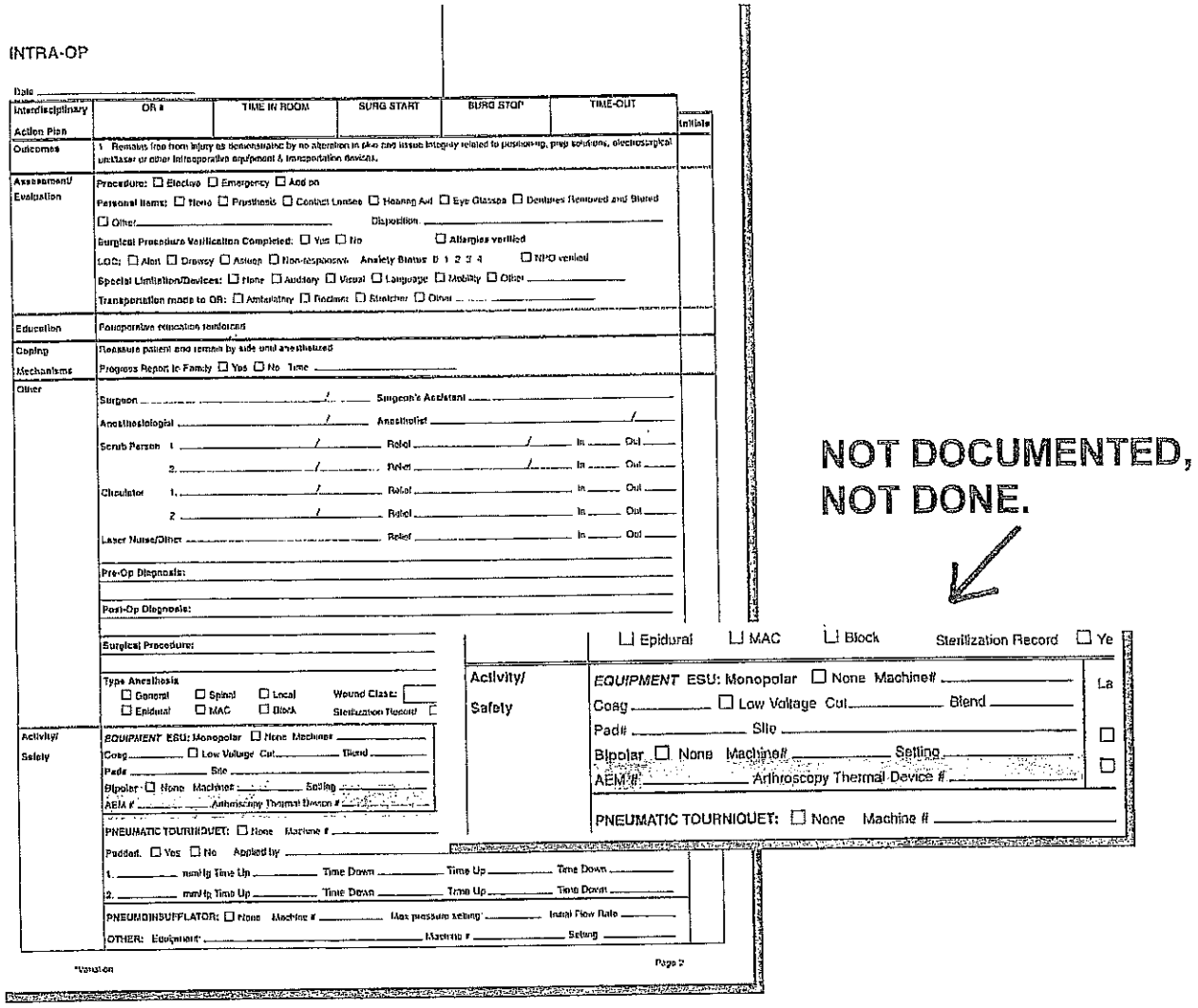

Fig. 10. Patient's perioperative chart accommodating AEM use. Patient perioperative chart. A common usage document used in many medical facilities. This chart reflects what technologies are used on patients and when. (*Courtesy of* Encision, Boulder, CO; with permission.)

hospital stays, long-term convalescence, and severe and sometimes fatal infections—are significant. Failure to adequately address the underlying etiology with appropriate safety protocols and technology incurs heavy direct and indirect financial penalties for the health care system at large, for the surgeons who perform these surgeries, and for the institutions where they practice.

This failure is all the more remarkable given the recent solution of an allied problem, skin burns at the site of the return electrode pad during open monopolar electrosurgery, which is caused by high currents flowing through the skin with inadequately attached return electrodes. As awareness increases, education and improved vigilance greatly reduce the frequency of skin burns, as do the introduction and adoption of innovative technology—contact quality monitoring—to the point at which these injuries are now virtually obsolete.

Even if one postulates that the incidence of stray energy burns is low, the severity of the injuries when the problem does occur is significant. Reasonable prudence and economics dictate that cost-effective and easy-to-implement safety technologies, such as active electrode monitoring, improved clinical training and credentialing practices, and biomedical engineering safety protocols, be adopted sooner rather than later. Surgeons, nurses, operating room managers, biomedical engineering directors, hospital risk managers, and health care insurers all share the responsibility for patient well-being and safety. As such, they all have ethical obligations to protect patients

from potential injury by continuously evaluating and adopting new practices and technologies.

By implementing active electrode monitoring, the following benefits are attained by the hospital:

- Optimized patient outcomes
- Compliance with AORN Recommended Practices for Endoscopic Minimally Invasive Surgery [30].
- Compliance with new Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards on Advancing Patient Safety [40]
- Loss prevention measure in all laparoscopic surgery—from the *PIAA (Physician Insurers Association of America) 2000 Report* [27]
- Enhanced surgeon confidence in the delivery of electrosurgical energy by providing fail-safe systems

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Further reading

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