# The SAGES FUSE program: Bridging a patient safety gap

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by

## HIGHLIGHTS

- · Provides details on the increasing use of energy-based surgical devices
- Describes how a lack of familiarity with the proper use of energybased devices negatively affects patient safety and outcomes
- Explains why surgeons and other members of the operating team need to participate in training programs that teach the fundamental use of surgical energy
- Describes the FUSE program developed by SAGES

perating rooms (ORs) and procedure suites are host to millions of patient interventions every year in the U.S. It is now well understood that many invasive procedures carry substantial risk and may lead to potentially serious complications. The risks have increased in the modern operating theater, which is defined by human interaction, increasingly challenging patient cases, and dazzling technology. Extensive knowledge, training, and skill in all of these domains are required to optimize clinical outcomes and patient safety.

Heightened public awareness about safety in the OR has led many institutions to adopt a plethora of effective performance improvement programs and tools, such as team training and checklists.<sup>1</sup> Despite these efforts, many gaps in OR safety education and training remain. A striking example is a lack of inculcation in the safe application of energy-based devices commonly used by surgeons, anesthesiologists, gastroenterologists, and nurses. These instruments can cause serious harm and death in patients when applied by individuals lacking a fundamental understanding of their function, design, and application. This lack of knowledge contributes to an estimated 600 OR fires annually in the U.S., a large number of accidents due to interference with implantable cardiac devices, as well as unrecognized and, therefore, life-threatening internal injuries among patients undergoing abdominal operations.2-13

This article analyzes how energy-based surgical devices have contributed to complications and mortality in the OR. It also looks at how surgeons have been trained to use these devices. In addition, this article describes the curriculum developed by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) called the Fundamental Use of Surgical Energy (FUSE) program (*www.fuseprogram.org*). The FUSE program was established to ensure that surgeons have a more comprehensive understanding of how to use energy-based surgical devices safely.

## Scope of the problem

Surgeons have used devices that apply energy to tissue therapeutically for millennia. Cautery-the direct application of heat to tissue—has been used therapeutically since 3000 BC to destroy tumors and achieve hemostasis.<sup>14</sup> At the beginning of the 20th century, several engineers developed surgical instruments based on electrical energy. The best-known instrument was invented by William T. Bovie and applies high-frequency alternating current (radiofrequency electrosurgery) to tissues, combining the action of cutting and coagulation.<sup>15</sup> After introduction into surgical practice by Harvey W. Cushing, MD, FACS, the "bovie" is still the most widely used energy-based device today. In the 1940s, surgical energy devices started to slowly evolve. Bipolar devices were introduced, with innovations such as the incorporation of cutting blades and real-time impedance measurement.

Nurses and anesthesiologists long ago recognized the gap in knowledge about the safe use of surgical energy devices. In 1979, Chambers and Saha reported a cardiac arrest due to electrocution in a young patient undergoing laparotomy. The patient died because an electrocardiogram (EKG) monitor with a direct earth ground created an electrical circuit that included the patient. Because of a faulty electrical switch in the operating table, the patient was electrocuted.<sup>16</sup> Although this design has been abandoned and every OR electrical device must now comply with numerous safety requirements, injuries from electrical devices still occur. In 2010, Wills and colleagues reported a case of electroshock injury to a nurse in a state-of-the-art equipped OR.<sup>17</sup>

These reports of injuries related to electric monitoring devices have led to safer standards for common electronic devices used in ORs, including EKG machines, anesthesia monitors, operating tables, electrical outlets, and switches. Surgeons, however, were not involved in the development of these safety standards and remained largely unaware of the potential dangers associated with energy sources in the OR.

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A vast array of devices for tissue dissection and efficient control of larger vessels without suturing have emerged. Today's modern practicing surgeons use a range of devices that apply energy to tissues in many different ways, including electric current at radiofrequency wavelength, ultrasonic energy, and microwavebased, water jet-based, and plasma-based energy. This broad collection of energy sources allows the technology to be used in all forms of procedures—from open, laparoscopic, and robotic procedures to percutaneous interventions and endoscopic procedures. The advent of minimally invasive surgery has fueled the introduction of an exponentially greater number of surgical energy-based devices marketed to virtually every surgical specialty. In many ways it is because of these technical innovations that the advances in minimally invasive surgery, endoscopic interventional techniques, and percutaneous approaches to diseases have become possible. This technological boom has led to a multitude of energy device platforms, configurations, generators, cost points, and vendors.

Because of the increased complexity and number of energy devices used in surgical procedures, the susceptibility of surgeons to inadvertently harming patients has increased in the last two decades. The estimated prevalence of injuries related to electrosurgery during laparoscopic procedures is 1–2 per 1,000 patients.<sup>4</sup> These devastating complications are often unrecognized bowel injuries and major vascular injuries.<sup>4,18</sup> Unrecognized thermal injuries to the intestine dur-

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ing laparoscopic surgery are particularly dangerous because they are difficult to detect and carry a significant associated mortality.<sup>19,20</sup> With more than 2 million laparoscopic procedures performed annually in the U.S., these energy-based surgical devices represent a major patient safety issue.<sup>21</sup>

# Health care community's response

The widespread use of energy-based surgical devices carries an increased risk of adverse events, largely because the devices are not completely understood. A common practice is for a surgeon to use a new device after a short primer by a vendor without understanding the fundamental principles of its function and safety.

This gap in surgeon knowledge directly affects patient safety and must be addressed.

Individual surgeons, other health care professionals, and surgical societies both in the U.S. and abroad have tried to respond to this safety issue.<sup>22-26</sup> These pioneers have shown us the specific complications associated with electrosurgical devices and the risks involved in their use, particularly in laparoscopy. Their seminal work included a survey sponsored by the ACS to assess the complication rate associated with the use of electrosurgical devices. This study demonstrated for the first time that most surgeons reported inappropriately high-power settings when using electrosurgical instruments (n=508).<sup>27</sup> As early as 1998, the Society of Laparoendoscopic Surgeons proposed to educate A common practice is for a surgeon to use a new device after a short primer by a vendor without understanding the fundamental principles of its function and safety.

surgeons on the safe use of laparoscopic monopolar electrosurgical devices, and in 2005, the Association of periOperative Registered Nurses (AORN) published basic recommendations on the safe use of energy devices.<sup>28,29</sup> However, these efforts had a minimal impact on surgical practice.

Fundamental knowledge concerning the correct use and inherent dangers of energy-based devices remains incomplete. In contrast to textbooks written for anesthesiologists and nurses, surgical texts contain little relevant information regarding these instruments. Furthermore, surgeons are rarely required to train on the energy-based devices they use in the OR or to document their knowledge of device-related safety issues.

## Lack of fundamental knowledge

Although many surgeons believe they understand how to use energy-based devices properly and safely, their actual effectiveness in using the instruments had never been formally tested until 2011 at a SAGES postgraduate continuing medical education course on the optimal use, safety profile, and knowledge of surgical energy-based devices. The faculty developed an 11-item multiple-choice pretest to measure what they considered to be critical knowledge. This pretest was administered to all postgraduate course participants and experienced SAGES surgeons. Course participants also completed a 10-item posttest covering the same content at the end of the course.<sup>30</sup>

In all, 48 experienced SAGES surgeons completed the test. The median number of correct answers out of 11 was 6.5, or 59 percent. One-third of SAGES leaders did not know how to correctly handle a fire on the patient; 31 percent could not identify the device least likely to interfere with a pacemaker; 13 percent did not know that thermal injury can extend beyond the jaws of a bipolar instrument; and 10 percent thought a dispersive return electrode should be cut to fit a child. The 27 postgraduate course participants had similar scores, with a median six correct answers out of 11.<sup>30-31</sup> Similar results were seen for surgeons in training, revealing that knowledge regarding the safe use of energy devices does not seem to increase with experience and that surgical "experts" do not necessarily have greater understanding of energy devices compared with junior trainees.<sup>30-31</sup>

This issue is not specific to electrosurgery; it is evident in the use of newer energy technologies, as well. In April 2014, at the SAGES annual meeting, a short video of a laparoscopic superior mesenteric artery (SMA) dissection in a Whipple procedure was shown. Using ultrasonic shears, the uncinate process was separated from the SMA. One must stay very close to the vessel to remove all potentially involved lymphatic tissues. Laparoscopy, with its magnification and superior visualization, is particularly suited for this step of the procedure. As the surgeon dissected along the SMA with the ultrasonic shears, one could observe the development of an arterial pseudoaneurysm. The surgeon immediately recognized the potentially devastating complication and repaired the vascular injury. One key point gleaned from this video is that when energy devices with lateral thermal spread are used close to major arteries, injury from proximity to the instrument's jaw can occur.

This example highlights the importance of understanding the characteristics of surgical energy devices as more and more complex laparoscopic procedures are performed. Perhaps the knowledge of the different thermal spread characteristics and temperatures generated by different vessel sealers and dissectors may help prevent such injuries. This particular example emphasizes the potential for unintended injury from energy devices through collateral thermal damage. Surgeons must be knowledgeable and aware of the side effects and must ascertain good control of the effector tip of any energy device used near a vessel or other tissue.

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# EXAMPLE FROM THE FUSE ONLINE CURRICULUM



# **Need for training**

Clearly, a standardized training program on energybased devices is needed, particularly one that provides a rigorous framework for the introduction of these potentially harmful devices into routine clinical practice. Several key developments mentioned in this article support this conclusion.

#### Rapid expansion of new technologies

ORs have rapidly transformed from analog workrooms into sophisticated control centers of electronic health records, anesthetic delivery machines, high-definition screens, recording equipment, and a multitude of surgical energy devices.

#### **OR** fires

The estimated 600 OR fires that occur in the U.S. annually are preventable. In each case, the ingredients are a spark from an energy device, fuel, or oxidizer. Several professional societies have created videos, monographs, and posters highlighting the dangers of OR fires, but they still occur. The U.S. Food and Drug Administration recognizes this threat to patient safety and has organized a special task force to address this hazard, but few physician groups participate. There still is no common educational pathway to teach fire prevention by safely using surgical energy devices in the operative field.

Evolving industry ties to surgical education Today, introduction of new surgical devices for use by surgeons is left in the hands of industry representatives, and knowledge regarding new devices is largely disseminated through industry-sponsored courses. Although a certain logic underlies this approach, it is inherently problematic. The primary goal of device representatives is not to teach function and safety, and they have no standards for determining whether a surgeon is able to use a new device safely. With rising concern about the influence of industry on surgeons, boundaries have been created to keep these parties separate. As a result, it has become increasingly difficult for industry representatives to teach surgeons and nurses how to use new devices. And yet, no alternative instruction model is currently available, which raises several important questions:

- Where will the training to master new surgical energy devices originate?
- Who will create a curriculum covering their functionality and safety profiles?
- •How should we offer appropriate training and certification?

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- What is the standard procedure when a surgeon or nurse is suddenly faced with unfamiliar equipment?
- How will we mandate and pay for fire safety training?
- Should there be a standard approach for how energy devices are introduced into the hands of surgeons—and who will create these standards?

Perhaps the most obvious solution is a nationwide, non-industry sponsored, multidisciplinary educational program with validated assessment in surgical energy-based devices to address the knowledge gap and to ensure patient safety and the use of best practices.

## **FUSE program**

Educational programming can be based on either a topdown or bottom-up approach. The top-down approach would involve federally mandated programs, which is unappealing on many levels. It will be hard to create buy-in for yet another external mandate that will likely involve time away from patient care. Using the bottom-up approach, surgeons of all specialties, nurses, and anesthesia professionals would work together to create an educational program. The benefit of this approach, in which providers take responsibility for meeting stated goals, is that it is more likely to produce buy-in and meaningful change.

SAGES created the FUSE program using a bottom-up approach. Working in partnership with AORN, the American Association of Gynecologic Laparoscopists (AAGL), and the American Urologic Association, the FUSE team includes a variety of general and subspecialty surgeons, nurses, anesthesiologists, gynecologists, and engineers. Following in the tradition of two other SAGES educational programs—Fundamentals of Laparoscopic Surgery and Fundamentals of Endoscopic Surgery—FUSE has two central components: a standardized curriculum for surgeons and allied health care professionals of all specialties, and a high-stakes certification test that meets rigorous psychometric and accreditation standards. Test results will serve as verification that the surgeon has attained the basic knowledge necessary to safely use energy-based devices in the OR.

The FUSE curriculum was first presented at a SAGES postgraduate course in 2011 and 2012. The material was expanded into a textbook on surgical energy and safety. The SAGES *Fundamental Use of Surgical Energy Manual* was published in 2012 and as an online multimedia curriculum that same year.<sup>32</sup> The FUSE online curriculum is available from SAGES at *www.fundamentals-didactics.com*.

The FUSE curriculum includes 10 sections:

- 1. Fundamentals of Electrosurgery
- 2. Mechanisms and Prevention of Adverse Events with Electrosurgery
- 3. Monopolar Devices
- 4. Bipolar Devices
- 5. Radiofrequency for Soft Tissue Ablation
- 6. Endoscopic Devices
- 7. Ultrasonic Energy Devices
- 8. Microwave Energy Systems
- 9. Energy-Based Devices in Pediatric Surgery
- 10. Integration of Energy Systems with Other Devices

The content focuses on the key principles of safe and effective use of surgical and endoscopic energy devices. For example, Fundamentals of Electrosurgery (Section 1) covers the types of electric currents used; correct nomenclature; explanation of physics, such as Ohm's law as it is applied to electrosurgery; electrosurgical generators; differences in "coag" and "cut" waveforms; monopolar versus bipolar systems; isolated versus ground-referenced systems; active and dispersive electrodes; physical effects of temperature and alternating current on cells and tissue; resistive heating; and the different tissue effects (desiccation, coagulation, fulguration). Section 2 describes the safe use of electrosurgical devices, current diversion includ-

# EXAMPLE OF EDUCATIONAL OBJECTIVES USED TO DEVELOP ONLINE CURRICULUM AND CERTIFICATION EXAM

- 1 Fundamentals of electrosurgery
- 1.1 Define proper electrosurgery terms
- 1.2 Given a clinical situation, identify the application of Ohms law, power equation, and energy
- 1.3 Identify the function (input and output) of an electrosurgical (RF) generator
- 1.4 Identify the characteristics of monopolar and bipolar instruments and the differences between them
- 1.5 Identify the characteristics of the RF electromagnetic spectrum and why it is used for surgical applications
- 1.6 Identify how radiofrequency electrical energy causes effects in cells and tissue
- 1.7 Identify the different effects of ranges of temperature on cells and tissue
- 2 Mechanisms and prevention of adverse events with electrosurgery
- 2.1 Identify general patient protection measures for setup and settings for the electrosurgical unit
- 2.2 Identify various mechanisms whereby electrosurgical injuries may occur
- 2.3 Identify circumstances, mechanisms, and prevention of dispersive electrodes-related injury

ing direct and capacitive coupling, insulation failure, and prevention and response to OR fires. A similar emphasis on fundamental principles and safe application is used in the sections on specific devices that include monopolar, bipolar, ultrasonic, radiofrequency ablation, and microwave and endoscopic devices. Special considerations for use of energy devices in pediatric patients and in patients with other medical devices (cardiac implantable devices) are addressed in additional sections. The FUSE manual contains supplemental hands-on chapters describing how to set up "live" stations for demonstration and teaching surgical energy principles and safe practice.

The online curriculum provides multimedia content of the FUSE curriculum, including self-assessment test questions eligible for continuing medical education, maintenance of certification, and continuing education units. An example of a "page" from the online curriculum is shown in the figure on page 23.

The FUSE curriculum is designed to provide surgeons with the knowledge they need to pass the FUSE certifying exam, which has been developed to comply with the legal and technical requirements for professional certification. More specifically, psychometricians led 15 FUSE content experts through a systematic process to define the competencies required to use energy devices safely. For each section of the curriculum, two to 20 objectives were identified, for a total of 72 objectives. For example, see the table on this page for the

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The online curriculum provides multimedia content of the FUSE curriculum, including self-assessment test questions eligible for continuing medical education, maintenance of certification, and continuing education units.

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objectives set forth for Section 1: Fundamentals of Electrosurgery and Section 2: Mechanism and Prevention of Adverse Events with Electrosurgery. Leaders from SAGES, along with selected members of AORN and AAGL, participated in development of the test blueprint by ranking each objective and determining the number of test items for the written exam. They determined that the assessment should, most importantly, measure health care professionals' understanding of the fundamental principles of energy devices, their electrosurgical safety, and the integration of energy systems with other devices. Beta testing of the program and assessment was completed in April of this year. More than 170 surgeons and allied health professionals achieved a passing score in beta testing of the exam, making them the first cohort of FUSE-certified surgeons.

Further additions to the FUSE curriculum are currently under way, including a structured interactive bench-top simulation component. This goal-directed, hands-on, bench-top training session has been shown to improve learning and retention of vital knowledge on surgical energy-based devices at three months.<sup>33</sup> Simulation of surgical energy is currently being developed into a portable, virtual reality simulation-based educational tool for surgical trainees.<sup>34</sup>

## Conclusion

All members of the surgical team should be able to demonstrate and apply a fundamental understanding of the use of surgical energy in the OR in order to achieve optimal clinical results and create the safest possible environment for the patient and staff. The FUSE program bridges a gap in patient safety as it relates to best practice in the use of surgical and endoscopic energy devices. It addresses the most common types of energy devices, their impact on OR fire prevention, the safety of implantable electronic devices, and safe and appropriate use of energy devices within

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# FUSE CONTACT INFORMATION

FUSE program: www.fuseprogram.org FUSE didactics: www.fundamentals-didactics.com

the operative field. This program is the first educational tool of its kind to address patient and OR team safety for energy devices in the surgical theatre or the endoscopy suite.

Future developments in the FUSE program will include specific modules tailored to individual energy devices. These modules will be designed in collaboration with industry to provide standardized education for the safe and appropriate use of new and current energy devices. Industry involvement will ensure that the FUSE program will continue to fill the unmet curricular, regulatory, safety, and competency assessment needs that exist for the use of energy devices by surgeons, endoscopists, anesthesiologists, and nurses worldwide. ◆

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