SMARTER CHOICES, SAFER PATIENTS
VOL. 38 NO. 10 | OCTOBER 2009

# health. DEVICES

## SURGICAL FIRE PREVENTION GUIDE

Includes New Recommendations for Controlling Oxygen Delivery during Surgery

## O.R. INTEGRATION

6 Cost-Saving Tips

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## HAZARD REPORTS

Submitting Power Cord Hazard Information

Foreign Material Inside Flow Sensors Can Ignite

Overlapping Surgical Light Beams Can Burn Patients

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# table of CONTENTS

OCTOBER 2009 | VOLUME 38, NUMBER 10

# A LOOK AT OCTOBER

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## FIRE IN THE O.R.!

Fires that break out inside or on a patient during surgery are rare. Nevertheless, ECRI Institute estimates that 550 to 650 surgical fires occur each year in the United States alone. Of these, 20 to 30 are serious fires—and one or two are fatal. What steps can your facility take to prevent surgical fires from happening—and how should your staff react if one occurs?

In this month's Guidance Article (page 314), we present our latest recommendations on the prevention of surgical fires. They include important new changes in clinical practice regarding the control of oxygen delivery during surgery of the head, face, neck, and upper chest. The key change in the recommendations is that, with certain limited exceptions, the traditional practice of open delivery of 100% oxygen should be discontinued. These new recommendations, which are being supported not only by ECRI Institute but also by other professional medical societies and experts, are described in detail starting on page 321.

The article also describes the causes of surgical fires, explains the measures healthcare personnel should follow to prevent them, and reviews how your staff should respond in the event of a surgical fire.

## O.R. INTEGRATION FOR LESS

Investing in an integrated OR system can provide some notable benefits to your facility, but it can also be expensive. OR integration systems allow centralized management of a number of capabilities, and though some of these capabilities may seem intriguing, several can be achieved much more cheaply—and some may not be worth doing at all.

In the Money Matters feature on page 333, we outline six cost-saving tips that can help your facility save thousands of dollars while planning an OR integration system.

## WE'VE GOT A WINNER!

ECRI Institute would like to congratulate the recipient of the 2009 Health Devices Achievement Award, Dartmouth-Hitchcock Medical Center of Lebanon, New Hampshire. For details, see page 335.

## PROBLEM REPORTS

In this month's articles from our Problem Reporting System, we explain when it's important to include power-cord-specific information in some device incident reports (page 337).

We also describe how foreign material that enters Spirolog or SpiroLife flow sensors used with Draeger ventilators and anesthesia systems can ignite, potentially causing patient injury and damage to the system (page 339).

And on page 341, we describe how using more than one surgical lighthead during a procedure can sometimes present the risk of patient burns. HD

### Web Conferences: We Want to Hear from You!

What topics would you like to discuss with ECRI Institute's expert staff in upcoming Web conferences? This is your chance to tell us what matters most to you. Recent topics have included surgical fire prevention, alarm safety, and benchmarking best practices. Share your thoughts with us at education@ecri.org.

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guidance
ARTICLE

# NEW CLINICAL GUIDE TO SURGICAL FIRE PREVENTION

SURGICAL FIRES, THOUGH RARE, CAN HAVE DEVASTATING CONSEQUENCES FOR PATIENTS, STAFF, AND THE HEALTHCARE FACILITY AS A WHOLE. IT'S IMPORTANT TO KNOW HOW SUCH FIRES CAN BE PREVENTED—AND HOW TO HANDLE THEM IF THEY OCCUR. THIS ARTICLE INCLUDES NEW CLINICAL PRACTICE RECOMMENDATIONS FOR OXYGEN DELIVERY THAT ARE DESIGNED TO REDUCE THE LIKELIHOOD OF FIRES.

Fires that ignite in or around a patient during surgery continue to be a real danger, whether in an operating room (OR), a physician's office, or an outpatient clinic. Such fires are especially devastating if open oxygen sources are present during surgery of the head, face, neck, and upper chest. The consequences can be grave: Patients can be killed, staff can be injured, and critical equipment can be damaged.

Fortunately, surgical fires are rare: They occur in only an extremely small percentage of the approximately 65 million surgical cases each year. Nevertheless, the actual number of incidents that occur annually may surprise many healthcare providers. Extrapolating from data published by the Pennsylvania Patient Safety Authority in 2007 (see the box on page 317), we estimate that 550 to 650 surgical fires occur nationally each year, making the frequency of their occurrence comparable to that of other surgical mishaps (e.g., wrong-site surgery).

In recent years, the medical, healthcare risk management, and surgical communities have experienced a growing awareness of this continuing patient safety risk, along with realization of the need for an OR team approach to prevent surgical fires. And an increasing number of organizations are incorporating surgical fire safety into formal patient safety initiatives (AORN 2005, APSF 2009, ASA 2008, Mathias 2006). Such endeavors help to spread surgical fire prevention information and help put policy into practice at the front lines of patient care.

Through awareness of the hazards—and with an emphasis on following safe practices—virtually all surgical fires can be prevented.

## Surgical Fire Safety Initiatives

A number of healthcare-related groups have taken steps to prevent surgical fires. Below, we discuss some of these initiatives.

### HOSPITAL-BASED INITIATIVES

Some healthcare facilities are currently educating staff on the dangers of surgical fires. One health system, for example, has recently heightened its clinicians' awareness of the risks of surgical fires by adding a "Surgical Fire Risk Assessment Score" to its perioperative forms for verifying

*Patients Can Catch Fire—Here's How to Keep Them Safer*

the surgical site and patient identification (Mathias 2006). Before surgery, the surgical team is required to identify and assess several fire risk potentials—including, for example, the use of alcohol-based skin prep solutions and the use of open oxygen sources on the face. The initiative at this healthcare system has served to stimulate collaborative communication among surgical team members.

ECRI Institute staff have also participated in numerous educational programs aimed at preventing surgical fires. Each program typically includes a lecture on surgical fire causes, prevention, and extinguishment, sometimes followed by an OR fire drill immediately afterward. Attendance by surgeons, anesthesia providers, and OR nurses and technicians is mandatory, and a written postdrill quiz must be completed.

## THE JOINT COMMISSION'S INITIATIVES

In 2003, the Joint Commission published a Sentinel Event Alert called "Preventing Surgical Fires," which stimulated considerable action within the medical community. The alert described the risks of surgical fires and cited the importance of surgical fire prevention and education. It noted the root causes of surgical fires and described risk-reduction strategies.

The Joint Commission has further emphasized the issue with its ongoing National Patient Safety Goals related to surgical fire prevention. These goals, which were retained for ambulatory care and office-based surgery from 2006 to 2009, largely mirror the recommendations put forth in the 2003 Sentinel Event Alert. They specify education for all surgical staff on "how to control heat sources and manage fuels," and require establishing "guidelines to minimize oxygen concentrations under [surgical] drapes." Although these goals are specifically applied only to ambulatory care programs and office-based settings, hospitals are encouraged to implement the recommendations as well (Joint Commission 2008).

Accreditation-based initiatives like the Joint Commission's National Patient Safety Goals may ultimately prove to be the most effective means of communicating the lessons of surgical fire prevention to hospitals.

## NEW CLINICAL GUIDANCE ON CONTROLLING OXYGEN DELIVERY

From APSF and ECRI Institute

This Guidance Article includes new clinical practice recommendations for delivering oxygen during surgery of the head, face, neck, and upper chest. Developed by the Anesthesia Patient Safety Foundation (APSF) in collaboration with ECRI Institute, these new recommendations are intended to prevent the formation of oxygen-enriched atmospheres near the surgical site and, thus, reduce the likelihood of fires.

The key change in the recommendations is that, with certain limited exceptions, *the traditional practice of open delivery of 100% oxygen should be discontinued.* If supplemental oxygen is needed, the airway should be secured through intubation or the use of a laryngeal mask airway to prevent oxygen-enriched gases from venting under the surgical drapes.

These new recommendations, which represent significant changes to clinical practice for anesthesia professionals, are described in detail on page 321. They are also the focus of a new educational video on surgical fire prevention, which is described in the box on page 322.

### PROFESSIONAL SOCIETIES

Professional societies have begun to seriously address surgical fire risks at annual conferences and, in some cases, have also undertaken dedicated initiatives to educate their members. In 2006, the American Society of Anesthesiologists (ASA) established its Task Force on Operating Room Fires. The task force, which included ECRI Institute staff, produced an advisory titled "Practice Advisory for the Prevention and Management of Operating Room Fires," which was adopted in the fall of 2007 and published in May 2008. Of note, it contains an Operating Room Fires Algorithm flowchart for assessing the potential fire risks of a surgical procedure and for fire management.

The American College of Surgeons has included surgical fire prevention as a session topic at its annual conference on several occasions. And in 2007, the American Academy of Otolaryngology-Head and Neck Surgery sponsored a session on preventing and managing surgical fires at its annual Quality in Otolaryngology Conference. Safety and quality committees in both organizations have endorsed the 2008 ASA practice advisory.

Furthermore, the 2008 ASA recommendations were expanded upon in 2009 by the Anesthesia Patient Safety Foundation (APSF) in its development of a surgical fire prevention educational video and an online course (see the box article on page 322). It is the new APSF expanded clinical practice recommendations on controlling oxygen delivery during surgery that are most significant; they are addressed later in this article.

For many years, the Association of periOperative Registered Nurses (AORN) has promoted recommended practices for electrosurgery and lasers—the two most common ignition sources (AORN 2005). In regard to surgical fire prevention educational initiatives, AORN produced the Fire Safety Tool Kit in 2006 to raise awareness among OR staff. The tool kit contains training videos, interviews of clinicians and surgical fire researchers, slide presentations, and session evaluation forms for acquiring clinical contact hours of credit. Recognize, however, that its recommendations regarding open delivery of supplemental oxygen are superseded by those of APSF and ASA.

### OTHER U.S. INITIATIVES

At the national level, the National Guideline Clearinghouse (NGC) accepted the January 2003 *Health Devices* Guidance Article, "A Clinician's Guide to Surgical Fires," as a national guideline. NGC, which was initiated by the U.S. Agency for Healthcare Research and Quality, is a comprehensive database of evidence-based clinical practice guidelines and related documents. (For details, refer to the NGC Web site at www.guideline.gov.) The present article is being used to update the 2003 NGC guidance.

At the state level, Massachusetts and Pennsylvania have developed and continue to promote patient safety initiatives for prevention of surgical fires (see the

### KEY POINTS IN THIS ARTICLE

- Based on data released by the Pennsylvania Patient Safety Authority, we now estimate that approximately 550 to 650 surgical fires occur each year in the United States. This frequency is generally comparable to that of other low-incidence, but highly notorious, surgical mishaps, such as wrong-site surgery or retained instruments. Surgical fires are worthy of no less attention by hospitals than these incidents.
- A major change in the recommendations regarding the control of oxygen delivery during surgery of the head, face, neck, and upper chest is being promoted by the Anesthesia Patient Safety Foundation and ECRI Institute. This recommendation puts forth that, with certain limited exceptions, the traditional practice of open delivery of 100% oxygen should be discontinued for these surgeries. If supplemental oxygen is needed, the airway should be secured through intubation or the use of a laryngeal mask airway to prevent oxygen-enriched gases from venting under the surgical drapes.
- The fire triangle includes the three basic elements of surgical fires—an oxidizer, an ignition source, and a fuel. Keeping the elements of the fire triangle from coming together in ways that could lead to a fire requires that all surgical team members be aware of the risks and that they consistently follow practices that can minimize those risks.

selected bibliography at the end of this article). The initiatives undertaken by the Pennsylvania Patient Safety Authority are particularly detailed. Their publications have addressed the risks of airway fires, electrosurgical units (ESUs) and fires, and alcohol-based surgical fires. (For information on the Pennsylvania Patient Safety Authority's 2007 data on surgical fires, see the box on this page.)

And in 2003, the Army Medical Command adopted policies and recommendations "that will help ensure minimal risk of fires associated with the performance of surgical procedures in any health care setting to include, but not limited to, the following: operating room (OR), office-based, ambulatory surgery, and intensive care unit type" (Department of the Army 2003).

## SURGICAL FIRE DATA: PREVIOUS ESTIMATES WERE LOW

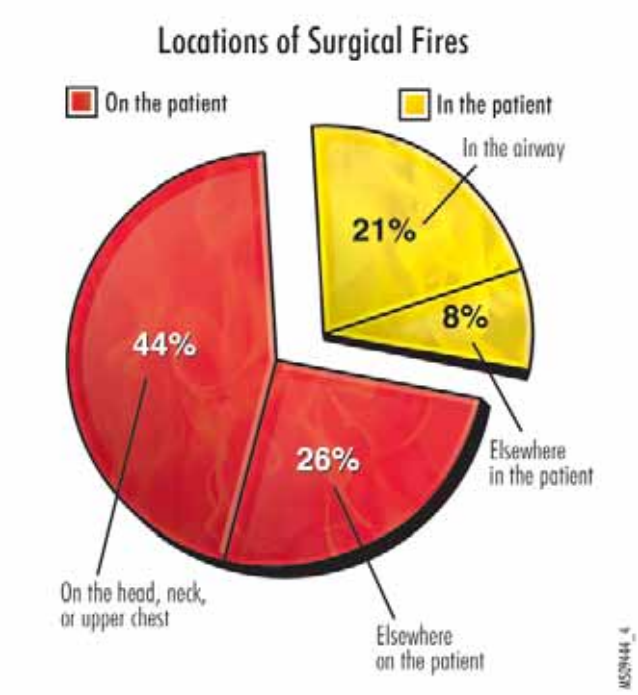
There is no national repository for statistics on the incidence of surgical fires, and no agency, center, or comprehensive database provides complete information on their occurrence. This makes reliable data on surgical fires hard to obtain. As a case in point, we have recently determined that our own estimates of the incidence of these fires were far too low.

Based on published accounts, reported incidents, and data from the U.S. Food and Drug Administration, ECRI Institute had previously estimated that at least 100 surgical fires occur each year in the United States. We continue to receive, on average, one or two reports of surgical fires each week, which fits with this estimate. However, we were well aware that many fires are not reported because of embarrassment, potential adverse publicity, or the fear of investigation and possible litigation, and that the overall incidence was probably much higher. But we had no way to obtain more accurate numbers.

In 2007, however, the Pennsylvania Patient Safety Authority published the first hard data on the incidence of surgical fires in Pennsylvania facilities (Pennsylvania Patient Safety Authority 2007). According to the statistics, the chances of a surgical fire in Pennsylvania are 1 in 87,646 operations—an average of 28 surgical fires per year in Pennsylvania alone.

We have scaled the Pennsylvania statistics to the United States in two ways: based on population and on the number of surgical procedures. From that analysis, and from ECRI Institute's ongoing research and investigations of surgical fires, we offer the following estimates about surgical fires in the United States:

- **Number of fires.** The number of surgical fires in the United States each year ranges from 550 to 650 per year. Of these, about 20 to 30 are serious, with disfiguring or disabling injuries. One or two fatal fires occur each year, most of which are airway fires. We judge that the frequency of surgical fires is generally comparable to that of other rare surgical misadventures, such as retained instruments or wrong-site/side/patient surgery. (It is important to understand, however, that about 95% of these fires, by our estimate, are minor and result in no injury.)
- **Type of equipment involved.** About 70% of surgical fires involve electrosurgical equipment as the ignition source. Another 10% involve lasers. The remainder are ignited by a variety of other heat sources, including electrocautery (hot-wire cauterization) equipment and fiberoptic light sources. More rarely, other ignition sources include defibrillators and high-speed burs (which can produce sparks), but only if an oxygen-enriched atmosphere is present.
- **Oxidizers and fuels.** Oxygen-enriched atmospheres are reportedly involved in about 75% of surgical fires. Alcohol-based surgical preps are involved in about 4% of reported fires.
- **Location.** About 21% of reported fires occur in the airway (involving oxygen-enriched or nitrous-oxide-enriched atmospheres); 44% occur on the head, face, neck, or upper chest; 26% occur elsewhere on the patient; and 8% occur elsewhere *in* the patient (see the chart below).




The figures represented here are ECRI Institute's estimates based on accounts of fires—including published accounts and incidents described to ECRI Institute by involved parties—and on analyses of data in the U.S. Food and Drug Administration's medical device reporting databases.

# THE TEAM APPROACH TO SURGICAL FIRE PREVENTION

## The Fire Triangle in the Clinical Setting

A fire will occur when an *oxidizer*, an *ignition source*, and a *fuel* come together in the proper proportions and under the right conditions. These three basic elements of surgical fires—and all other types of fires—constitute the traditional "fire triangle." Keeping the elements of the fire triangle from coming together in ways that could lead to a fire requires that all surgical team members be aware of the risks and that they consistently follow practices that can minimize those risks.

During surgery, these three elements are typically present in a number of forms, including breathing gases, surgical instruments, and associated equipment. Consequently, each member of the surgical team is associated with—and should be concerned with—one or more sides of the triangle:

- Surgeons are involved mainly with ignition sources, such as ESUs, lasers, electrocautery units, and fiberoptic light sources.
- Anesthesia providers are involved mainly with oxidizers, such as oxygen, nitrous oxide ($N_2O$), and medical compressed air.
- Nurses are involved mainly with fuels, such as surgical drapes and prepping agents.

Of course, the above areas frequently overlap. For example, tracheal tubes, breathing circuits, and masks, which are all fuels, fall within the purview of anesthesia providers during surgery. Similarly, preps, drapes, and ointments applied by surgeons intraoperatively are also fuels, and nurses often handle ignition sources such as lasers and ESUs.

Each member of the surgical team should understand the fire hazards presented by each side of the fire triangle and endeavor to keep the triangle's elements apart. This concept supports the preoperative surgical fire risk assessment now in use at some institutions (Mathias 2006). In addition, each team member should not only understand the basics of surgical fires and how to extinguish them, but also make a point of communicating information on the risks to the other team members—intraoperatively or in seminars, for example.

In the following sections, we discuss each of the elements of the fire triangle—oxidizers, ignition sources, and fuels—as they relate to the surgical setting. Particular attention is given to the new guidance on the delivery of oxygen during surgery around the head, face, neck, and upper chest. We then describe steps that can be taken to manage or control each element of the fire triangle.


The fire triangle and its components. Different members of the surgical team are primarily involved with different sides of the triangle.

**THE SURGICAL TEAM NEEDS TO UNDERSTAND AND EFFECTIVELY COMMUNICATE FIRE RISKS.**

# ONLY *YOU* CAN PREVENT SURGICAL FIRES

## Surgical Team Communication Is Essential

The applicability of these recommendations must be considered individually for each patient.

### At the Start of Each Surgery:

- Enriched $O_2$ and $N_2O$ atmospheres can vastly increase flammability of drapes, plastics, and hair. Be aware of possible $O_2$ enrichment under the drapes near the surgical site and in the fenestration, especially during head/face/neck/upper-chest surgery.
- Do not apply drapes until all flammable preps have fully dried; soak up spilled or pooled agent.
- Fiberoptic light sources can start fires: Complete all cable connections before activating the source. Place the source in standby mode when disconnecting cables.
- Moisten sponges to make them ignition resistant in oropharyngeal and pulmonary surgery.

### During Head, Face, Neck, and Upper-Chest Surgery:

- Use only air for open delivery to the face if the patient can maintain a safe blood $O_2$ saturation without supplemental $O_2$.
- If the patient cannot maintain a safe blood $O_2$ saturation without extra $O_2$, secure the airway with a laryngeal mask airway or tracheal tube.
  Exceptions: Where patient verbal responses may be required during surgery (e.g., carotid artery surgery, neurosurgery, pacemaker insertion) and where open $O_2$ delivery is required to keep the patient safe:
  - At all times, deliver the minimum $O_2$ concentration necessary for adequate oxygenation.
  - Begin with a 30% delivered $O_2$ concentration and increase as necessary.
  - For unavoidable open $O_2$ delivery above 30%, deliver 5 to 10 L/min of air under drapes to wash out excess $O_2$.
  - Stop supplemental $O_2$ at least one minute before and during use of electrosurgery, electrocautery, or laser, if possible. Surgical team communication is essential for this recommendation.
  - Use an adherent incise drape, if possible, to help isolate the incision from possible $O_2$-enriched atmospheres beneath the drapes.
  - Keep fenestration towel edges as far from the incision as possible.
  - Arrange drapes to minimize $O_2$ buildup underneath.
  - Coat head hair and facial hair (e.g., eyebrows, beard, moustache) within the fenestration with water-soluble surgical lubricating jelly to make it nonflammable.
  - For coagulation, use bipolar electrosurgery, not monopolar electrosurgery.

### During Oropharyngeal Surgery (e.g., tonsillectomy):

- Scavenge deep within the oropharynx with a metal suction cannula to catch leaking $O_2$ and $N_2O$.
- Moisten gauze or sponges and keep them moist, including those used with uncuffed tracheal tubes.

### During Tracheostomy:

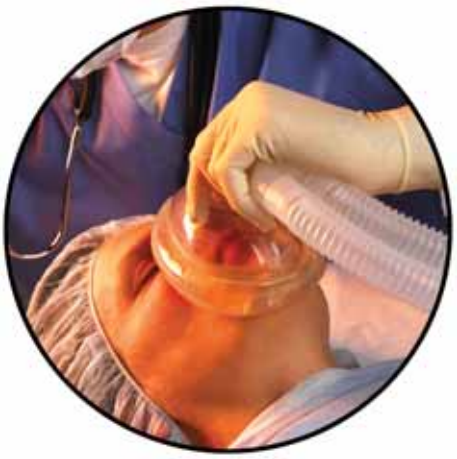
- Do not use electrosurgery to cut into the trachea.

### During Bronchoscopic Surgery:

- If the patient requires supplemental $O_2$, keep the delivered $O_2$ below 30%. Use inhalation/exhalation gas monitoring (e.g., with an $O_2$ analyzer) to confirm the proper concentration.

### When Using Electrosurgery, Electrocautery, or Laser:

- The surgeon should be made aware of open $O_2$ use. Surgical team discussion about preventive measures before use of electrosurgery, electrocautery, and laser is indicated.
- Activate the unit only when the active tip is in view (especially if looking through a microscope or endoscope).
- Deactivate the unit before the tip leaves the surgical site.
- Place electrosurgical electrodes in a holster or another location off the patient when not in active use (i.e., when not needed within the next few moments).
- Place lasers in standby mode when not in active use.
- Do not place rubber catheter sleeves over electrosurgical electrodes.



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**Source:** New Clinical Guide to Surgical Fire Prevention. *Health Devices* 2009 Oct;38(10):319. 

## Controlling Oxidizers

### OXIDIZERS IN THE O.R.

Oxidizers are gases that can support combustion; examples include air, oxygen, and nitrous oxide. Oxygen at concentrations above that of ambient air is often provided to patients by means of tracheal tubes, face masks, nasal cannulae, or hyperbaric chambers. This can create oxidizer-enriched atmospheres—most often *oxygen*-enriched ones—which can enhance ignition and combustion.

#### Oxygen-Enriched Atmospheres

Oxygen-enriched atmospheres are an often-unsuspected fire risk during surgery in the airway or around the head, face, neck, or upper chest. Such atmospheres are involved in the majority of reported surgical fires. They are typically defined as atmospheres in which the oxygen concentration exceeds 21% by volume.

Oxygen-enriched atmospheres lower the temperature at which a fuel will ignite; as the oxygen concentration increases, so typically does the risk of fire. Many materials that will not burn or sustain a flame in ambient air will do so in oxygen-enriched environments. For instance, polyvinyl chloride (PVC) plastic, a component of tracheal tubes and many other medical devices, requires 26% oxygen to maintain burning. (See the photo on this page for an illustration of a tracheal tube fire.)

Also, fires involving oxygen-enriched atmospheres are hotter, more vigorous, and more intense than those in ambient air, and they spread more rapidly.

#### Nitrous Oxide

Nitrous oxide, or $N_2O$, is an analgesic gas often mixed with oxygen and administered to surgical patients. It supports combustion by exothermally dissociating, thereby releasing heat and oxygen. In addition to the fire hazards of oxygen-enriched atmospheres, fires involving oxygen/$N_2O$ mixtures can be as easily ignited, and as severe, as fires involving 100% oxygen.

For all intents and purposes, the fire hazards during surgery in $N_2O$-enriched atmospheres should be considered as equal to those of oxygen-enriched atmospheres.

#### Medical Air

Medical air is air produced in a healthcare facility by compressing ambient air or by combining nitrogen and oxygen in the proper proportion. At the pressures present within medical gas piping systems, medical air is slightly oxygen enriched in that the partial pressure of oxygen is higher than that of ambient air. However, medical air is *not* oxygen enriched at ambient pressure when it is delivered to the patient.

#### Ambient Air

Ambient air has about 21% oxygen, about 78% nitrogen, and fractional percentages of argon, carbon dioxide, and other gases. Ambient air can support the combustion of many potential fuels. And some materials are flammable in atmospheres of less than 21% oxygen. For example, the red rubber used in medical equipment will ignite and burn in just 17% oxygen.

### OROPHARYNGEAL, TRACHEAL, AND BRONCHOSCOPIC FIRE PROCEDURES

There are several surgical procedures that are considered high risk for fire because an ignition source may be used in close proximity to or within an oxidizer-enriched atmosphere (ASA 2008). Such procedures include, but are not limited to, tonsillectomy, tracheostomy, and removal of laryngeal papillomas. Fires during these surgical procedures occur inside the trachea or bronchial tree even though the airway is secured. Airway fires are frequently oxygen or $N_2O$ enriched and put the patient at serious risk. They require quick removal of burning materials to minimize injury. These fires are, however, preventable.

#### Tonsillectomy

Fires during tonsillectomy can occur when the oropharynx is enriched with oxygen and/or $N_2O$ that has passed through the tracheal tube. Potential fuels—for example, the tracheal tube, a disposable plastic suction cannula, rubber catheters used to elevate the soft palate, or dry gauze—may be ignited if oxygen or $N_2O$ is allowed to

### POSTERS AVAILABLE

Downloadable copies of this article's posters on prevention and extinguishment of surgical fires are available online at www.ecri.org/surgical_fires. Additionally, glossy 11 × 17-inch copies of the poster "Only *You* Can Prevent Surgical Fires" can be purchased from ECRI Institute; for details, contact ECRI Institute's Client Management Services by telephone at +1 (610) 825-6000, ext. 5891, or by e-mail at clientservices@ecri.org.

Demonstration of a burning tracheal tube with oxygen flowing through it. Note the flame and smoke being emitted from the tube, as well as the fire progressing inside the tube against the flow of oxygen.

## MISINFORMATION IN THE LITERATURE

Although there have been many articles published that present reliable and cogent information on surgical fires, there are also several that have presented incorrect information, particularly regarding the flammability of common fuels in the surgical setting and the appropriate actions that should be taken to extinguish a surgical fire. One prominent example (Podnos and Williams 1997) has been frequently cited in subsequent literature, which unfortunately only perpetuates the errors the article contains. Here are the errors presented in that article, and the reasons why they're wrong:

- **What the article says:** In regard to extinguishment, the article suggests that the best course of action for staff when a surgical fire occurs is to get a fire extinguisher, pull fire alarms, and evacuate the area through emergency exits.

  **Why it's wrong:** There is no time to get a fire extinguisher (or fire blanket) when the patient is on fire; physically removing the burning materials from the patient is the first priority (and is typically done instinctively by the staff).

- **What the article says:** "Use only appropriately protected endotracheal tubes when operating near the trachea."

  **Why it's wrong:** This vague recommendation ignores differing ignition sources. Even laser-resistant tubes will combust under certain circumstances, depending on oxygen concentration, laser wavelength, and tube materials. In addition, laser-ignition-resistant tubes are not resistant to electrosurgical ignition.

- **What the article says:** "Use fire-retardant surgical drapes."

  **Why it's wrong:** There *are* no fire-retardant surgical drapes, given the potential presence of oxygen-enriched atmospheres and the high energy delivery of lasers (as *Health Devices* reported in its January 1992 Evaluation, in which we tested how well surgical drapes resist laser ignition, and in its May 1986 Evaluation of surgical drapes). No surgical drapes are fire-retardant treated, though some disposable drapes do have a degree of ignition resistance in air.

- **What the article says:** The article suggests that both Betadine and iodine are flammable.

  **Why it's wrong:** Only *tinctures* (i.e., alcohol-containing solutions) of Betadine or iodine are flammable. Standard Betadine scrub and paint are water-based solutions and are not flammable.

build up in the oropharynx. The enriched atmosphere can cause a flame flare-up of desiccated tissue or blood on the electrosurgical probe tip, with resulting ignition of these materials.

Some styles of mouth gags used during tonsillectomy have a metal channel designed to separate and protect the tracheal tube from the areas at the tonsillar beds where electrosurgical cutting and coagulation are performed. Although this can protect the tracheal tube from ignition, the other materials present are still vulnerable. Thoroughly moistening sponges and keeping them moist will render them nonflammable during the surgery.

The risk of fire during tonsillectomy can be reduced by using an oxygen concentration less than 30% without $N_2O$, and by using an endotracheal tube that does not leak. If an oxygen concentration greater than 30% or $N_2O$ is used, suctioning with a metal cannula before using electrosurgery is recommended.

### Tracheostomy

Fires during tracheostomy can occur if an active electrosurgical or electrocautery instrument enters the oxygen-enriched trachea with the tracheal tube still in place. The tracheal tube or its cuff may then be easily ignited since they are present below the incision made through the trachea. Instead, use a scalpel or scissors to enter the trachea itself. Initial cauterization of the skin incision when gaining access to the trachea does not pose a fire risk since the trachea has not been opened. However, cauterization after entering the trachea may ignite the underlying tracheal tube or the tracheostomy tube if oxygen is flowing.

## NEW CLINICAL GUIDANCE ON CONTROLLING OXYGEN DELIVERY

Traditionally, 100% oxygen has been used when delivering open oxygen to spontaneously breathing patients via nasal cannula or disposable oxygen mask. However, this can foster the development of oxygen-enriched atmospheres during head, face, neck, and upper-chest surgery. Oxygen-enriched atmospheres can be dangerous in the vicinity of ESU, laser, or electrocautery activation or other sources of ignition.

To address the risks created by the use of 100% oxygen, below we list new recommendations for oxygen delivery during those types of surgery. These new recommendations are now being promoted by APSF and were developed in collaboration with ECRI Institute. They were devised with careful consideration of the realities of the surgical setting, patient physiology during monitored anesthesia care, the medical devices and equipment used for surgery and anesthesia, and the inherent limitations of prior recommendations for minimizing oxygen concentrations under surgical drapes.

### Recommendations

Briefly, the major changes in clinical practice that are being advised for head, face, neck, and upper-chest surgery are:

- As long as a spontaneously breathing sedated patient can maintain his or her blood oxygen saturation without extra

oxygen, use only air for open delivery to the face (ASA 2008, APSF 2009).

- If the patient cannot maintain a safe blood oxygen saturation without supplemental oxygen, then the airway must be secured by using a laryngeal mask airway or tracheal tube, so that oxygen-enriched gases do not vent under the surgical drapes.
- The traditional practice of open delivery of 100% oxygen should be discontinued (with limited exceptions, which are discussed below).

It's important to remember that, for surgery in locations not in proximity to an oxygen source, such as the abdomen, groin, legs, and hands, open delivery of oxygen can be used; however, the risk of fire is *always* present.

### Exceptions

**General.** There are, of course, some surgical procedures around the head, face, neck, and upper chest wherein conscious sedation is required and oxygen delivered by nasal cannula or mask may be necessary to maintain adequate blood oxygen saturation. These may include carotid artery surgery, neurosurgery, and some pacemaker implantations in which the sedated patient needs to be able to speak during the procedure. In such cases, certain fire prevention measures and techniques must be considered.

When delivering oxygen by nasal cannula or mask in exceptional cases, staff should *not* use an auxiliary oxygen flowmeter (as may be attached to an anesthesia machine), which is only capable of delivering 100% oxygen. The goal is to deliver the minimum concentration of oxygen necessary to maintain adequate blood oxygen saturation.

For cases in which open oxygen delivery is essential, it is particularly vital to delivery only the *minimum concentration of oxygen necessary* at all times to maintain an adequate blood oxygen saturation. Keep oxygen concentrations below 30% if this can be safely accomplished. Ideally, a method for blending air and oxygen should be used and the oxygen concentration gradually increased (e.g., from 21% [air only] or 30%) to the minimum clinically acceptable oxygen concentration to keep the patient safe. Delivery of 100% oxygen should be avoided unless clearly required to maintain adequate oxygen saturation. In addition, if the patient can tolerate it, lower the oxygen concentration, preferably to 21% (air), at least one minute before activating the ESU or other potential ignition source.

Using a lower delivered oxygen concentration (e.g., 30%), along with following the additional recommendations regarding blending air and oxygen that are outlined below, will help minimize fire risks. However, these measures are not a substitute for using air whenever possible.

**Blending air and oxygen.** Three options are recommended for blending oxygen with air during exceptional surgical cases in which open oxygen delivery is essential.

The first option is to use an oxygen-air blender independent of the anesthesia machine to provide gas to the nasal cannula or mask. This option is the most reliable one, since oxygen-air blenders can precisely and reliably control the oxygen concentration and the gas mixture flow rate for delivery through a standard oxygen mask or nasal cannula. Another advantage is that the user can select the oxygen concentration directly.

However, there are a few logistical considerations with this option. For one thing, although oxygen-air blenders may be commonly available in certain areas of the hospital, they may not be present in locations where anesthesia is administered. Additionally, even oxygen-air blenders can have some performance limitations in delivering accurate oxygen concentrations. Staff must ensure that the appropriate high-flow or low-flow type of blender is used and that the correct high-flow or low-flow port is selected (ECRI Institute 2009 Jan). Space can also be an issue: Although most blenders are mounted on IV poles, they still require an oxygen source and a compressed air source that can further clutter an already crowded OR workspace. Despite these issues, blenders are the best alternative for delivering oxygen-air mixtures when this is essential to keep the patient safe during surgery.

The second option is for staff to take the blended gas directly from a common gas outlet (CGO) on a three-gas (air, oxygen, and $N_2O$) anesthesia machine. Anesthesia professionals must, however, be mindful of the oxygen-to-air ratio, since a very small amount of oxygen can enrich the oxygen concentration beyond 30%. For example, adding only 200 mL/min of oxygen to 1.8 L/min of air creates an oxygen concentration of 29%.

A limitation of this option is that many new three-gas anesthesia machines that allow air mixtures do not provide a classic CGO for access to the gas mixture by the anesthesia professional. But there is a third option available: Blended air and oxygen can be delivered to the patient via the patient wye on the anesthesia breath-

## COMING SOON: NEW SURGICAL FIRE VIDEO AND ONLINE COURSE

In 2008, the Anesthesia Patient Safety Foundation (APSF), supported by funding from the American Society of Anesthesiologists (ASA), set out to develop a new educational video on surgical fire prevention and management. APSF chose ECRI Institute to produce the video and an accompanying online course containing more details on surgical fires. The video is due to be released in late 2009, and the accompanying online course will be released soon afterward. Continuing medical education credits will be available upon completion of the online training.

APSF's video and online course expand upon ASA's 2008 practice advisory recommendations, as described in our updated recommendations beginning on page 321. All clinicians and OR staff are encouraged to view the APSF video and online course.

ing circuit. This technique allows staff to measure the concentration of oxygen delivered by the flowmeters using the anesthesia unit's oxygen concentration monitor. The primary disadvantage of this approach is that it can take a long time for the oxygen concentration to change. Faster changes in delivered oxygen concentration can be achieved by closing the adjustable pressure-limiting (APL) valve on the absorber; however, even with the APL valve closed, it still may take minutes for the oxygen concentration at the patient end to change.

For some exceptional surgeries, the anesthesia professional might judge that it is clinically necessary to openly deliver 100% oxygen on the patient's face under the drapes at the beginning of the case and then reduce the delivered oxygen concentration to 30% or lower only before activation of the ESU (or similar device). Regardless of which open oxygen delivery method is used, if 100% oxygen is first delivered, several minutes may be needed to reduce the oxygen concentration under the drapes. A further safety consideration is that this technique does not ensure reliable reduction of oxygen concentration in all locations under the drapes. The oxygen concentration in these areas is not knowable during surgery. Prior delivery of 100% oxygen to the patient, along with potentially incomplete dilution of the under-drape space due to high oxygen-enriched volumes and variable washout characteristics, may allow pockets of oxygen to remain under the drapes. That oxygen may waft into the fenestration, presenting a fire risk.

When the open delivery of 100% oxygen under the drapes is unavoidable, the delivery of 5 to 10 L/min of air under the drapes can help wash out excess oxygen. This technique should be used with other recommendations presented below, including lowering the oxygen concentration, preferably to 21% (air) at least one minute before activating the ESU or other potential ignition source.

Venturi blenders have been suggested for providing lower oxygen concentrations, but have not yet been vetted for use during surgery in regard to fire prevention. While the operation of a venturi blender appears simple, its ability to deliver consistent gas mixture concentrations is affected by nozzle size, oxygen flow rate, downstream back pressure, location under the drapes, and other factors. Also, these blenders are apparently not usable with nasal cannulae because of the low gas delivery pressure. We therefore do not recommend their use for delivering supplemental oxygen during surgery.

In summary, three options are recommended for blending oxygen during exceptional surgical cases in which open oxygen delivery is essential:

- Use an oxygen-air blender. This is the preferred and most reliable approach since it is the simplest.
- Use a three-gas (air, oxygen, $N_2O$) anesthesia machine that has a CGO and take the blended gas from the CGO.
- Use the breathing circuit wye on an anesthesia machine that does not have an available CGO. Close the APL valve on the absorber for faster changes in the delivered oxygen concentration.

Regardless of how the oxygen-air mixture is obtained, monitoring the delivered oxygen is recommended to ensure that the gas mixture is as desired.

## RECOMMENDATIONS: MINIMIZING OXIDIZER RISKS

*Note:* The applicability of the following recommendations must be considered individually for each patient.

### During Head, Face, Neck, and Upper-Chest Surgery

- Use only air for open delivery to the face if the patient can maintain a safe blood oxygen saturation without supplemental oxygen.
- If the patient *cannot* maintain a safe blood oxygen saturation without extra oxygen, secure the airway with a laryngeal mask airway or tracheal tube.

## THE DEVASTATION OF SURGICAL FIRES

The adverse effects surgical fires can have on both patients *and* staff should be considered when reviewing this hazard.

For patients, such fires are frequently disfiguring or disabling and can seriously impact quality of life. Burn injuries to the head, face, neck, upper chest, or airway present especially significant concerns given the potential for disfigurement and the possible loss of sense of smell or taste if flames are inhaled. A surgical fire can be especially horrific in that many patients undergo surgery around the head and upper chest with only local anesthesia and are therefore somewhat conscious when the fire erupts. They understandably may recall their fear when the fire broke out, the smell and feel of the flames, and the resulting pain—all of which would obviously have an effect on their lives. The patient's families may also be affected; in fact, one incident led the daughter of a seriously burned patient to initiate a Web site dedicated to surgical fire education and prevention (www.surgicalfire.org).

Surgical fires can also take an emotional toll on the clinical staff involved. In addition, they can have a negative effect on the hospital as a whole, since increased public attention on errors in medicine over the past decade has resulted in greater media awareness of surgical fires. There are typically two or three publicized incidents in the news each year, with resulting adverse publicity for the incident hospital or surgical clinic.

Surgical fires are a very real problem, and staff should be instructed on how to reduce their risk to help avoid these devastating consequences.

*Exceptions*: The following recommendations are for surgery in which the patient's verbal responses may be required—such as carotid artery surgery, neurosurgery, and pacemaker insertion—*and* where open oxygen delivery is required to keep the patient safe.

- — At all times, deliver the minimum oxygen concentration necessary for adequate oxygenation.
- — Begin with a 30% delivered oxygen concentration and increase as necessary.
- — For unavoidable open oxygen delivery above 30%, deliver 5 to 10 L/min of air under drapes to wash out excess oxygen.
- — Stop supplemental oxygen at least one minute before and during use of electrosurgery, electrocautery, or laser, if possible. Surgical team communication is *essential* for this recommendation.
- — Use an adherent incise drape, if possible, to help isolate head, face, neck, and upper-chest incisions from oxygen-enriched atmospheres and from flammable vapors beneath the drapes. The incise drape can help prevent gas communication channels between the under-drape space and the surgical site.
- — Keep fenestration towel edges as far from the incision as possible to prevent their ignition from electrosurgical flames or sparks.
- — Arrange drapes to minimize oxygen buildup underneath (such as from an uncuffed tracheal tube or a laryngeal mask airway) and to direct gases away from the operative site. This recommendation has limited potential effect in minimizing an oxygen-enriched surgical fire but nonetheless remains as a complement to the other recommendations for controlling open oxygen delivery.
- — Coat head hair and facial hair (e.g., eyebrows, beard, moustache) within the fenestration with water-soluble surgical lubricating jelly to make it nonflammable.
- — For coagulation, use bipolar electrosurgery, not monopolar electrosurgery.

### During Oropharyngeal Surgery

- ▷ Use suction with a metal cannula deep within the oropharynx to scavenge the gases from an intubated patient. Do not use plastic suction cannulae. Do not rely on electrosurgical suction coagulators for scavenging of oropharyngeal gases; their suction at the tip is not continuous.
- ▷ Keep all moistened sponges, gauze, pledgets, and their strings thoroughly moist throughout the procedure to render them ignition resistant.

### During Tracheostomy

- ▷ Do not use electrosurgery or electrocautery to cut into the trachea. Instead, use a scalpel or scissors to enter the trachea itself.

### During Bronchoscopic Surgery

- ▷ If the patient requires supplemental oxygen, minimize the risk of fire by keeping the delivered oxygen below 30% and using inhalation and exhalation oxygen monitoring. This can be done with an oxygen analyzer to confirm the proper concentration.

### In General

- ▷ Recognize that oxygen- and $N_2O$-enriched atmospheres can vastly increase flammability of drapes, plastic, and hair.
- ▷ Be aware of possible oxygen- and oxygen/$N_2O$-enriched atmospheres near the surgical site, under the drapes, and in the fenestration, especially during head, face, neck, and upper-chest surgery.
- ▷ Use a pulse oximeter to monitor the patient's blood oxygen saturation.
- ▷ Avoid the use of $N_2O$ during bowel surgery. (During $N_2O$ anesthesia delivery, the gas can diffuse into the bowel and enrich the intestinal gas mixture, making it even more flammable.)
- ▷ Make the surgeon aware of open oxygen use.

## Controlling Ignition Sources

### IGNITION SOURCES IN THE O.R.

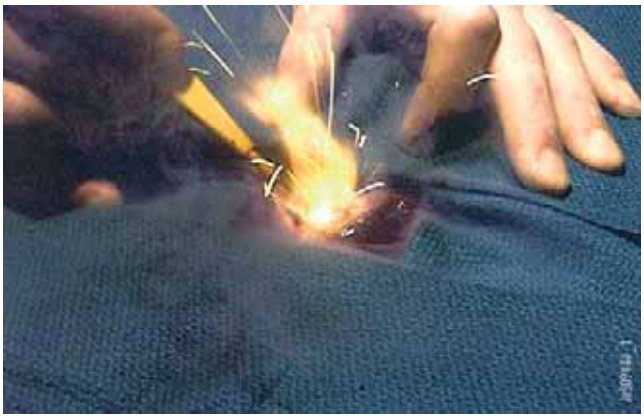
Ignition sources provide the heat energy that can start a fire should the energy be directed onto or come in contact with some fuel, either in ambient air or in an oxidizer-enriched atmosphere.

### Electrosurgical Units and Cables

Electrosurgery is a widely used surgical technology that employs a high-frequency electric current to cut or cauterize tissue. ESUs are the most common ignition source in surgical fires. By its very nature, electrosurgery can produce a high-temperature electric arc, incandescence at the probe tip, "sputtering" (ejection of tissue embers from the surgical site), a flaring flame of organic gases from desiccated tissue, or combinations thereof, as seen in the photo on page 325. Note, however, that to our knowledge, there has never been a report of a fire with bipolar electrosurgery. This is likely due to the low power used across the forceps tips and the general lack of arcing that can occur with the tips grasping the target tissue.

Surgical fires can be started if electrosurgical electrode cables spark during a procedure. The problem usually occurs with reusable monopolar cables that connect to an active electrode, such as those used in laparoscopy. Sparking typically results from cable failure at the active electrode connector or at its strain relief.

The cable's internal conductor strands can also become severed over time from use and handling during sterilization processing. When the electrosurgical current is activated, the resulting electrical arcing at the internal break can quickly burn through the insulation and ignite surgical drapes or a surgeon's gown. Internal damage can be difficult for OR staff to detect, but pre-use inspection of the cables is nonetheless essential. A program of periodic cable replacement based on usage is one way to avoid the problem. (For more information on this problem, see our July 2009 Hazard Report "Internal Wire Breakage in Reusable Electrosurgical Active Electrode Cables May Cause Sparking and Surgical Fires.")



Enhanced flames and sparks from electrosurgery can occur in oxygen-enriched atmospheres within the surgical site and ignite nearby materials.

### Surgical Lasers

Surgical lasers are the second most frequently cited ignition source in surgical fires, but the fires they cause are often more serious because of the methods by which the energy is delivered and applied. Lasers use a collimated, coherent, monochromatic, directed, intense beam of electromagnetic radiation to cut, coagulate, or vaporize tissue. The wavelengths used include ultraviolet, visible, and infrared. The radiation is transmitted from the laser to the tissue through an array of mirrors, optical fibers, or waveguides. Delivered power is typically in the tens of watts and can be as high as 120 W in some lasers. However, the power density can be in the tens of thousands of $W/cm^2$ and can vary depending on the spot diameter. The spot diameter in turn can vary from a fraction of a millimeter to a few centimeters; it also varies with the distance from the laser aperture or focal point of the laser beam to the target tissue.

Laser energy can penetrate drapes and ignite underlying towels and linens that may burn for some time before a fire is recognized. Laser fibers can, if broken (by a drape clamp, for example), ignite materials around the break. When used in the airway, the sheath on a laser fiber can sometimes ignite and spread a fire to other instruments and bronchoscopes.

### Electrocautery

Electrocautery is the use of an electric current to heat a wire or scalpel blade to a high temperature. The hot wire or blade is used to cauterize tissue or vessels. In some cases, the electrocautery probe is also used to cut tissue. Unlike electrosurgery, electrocautery does not make the tissue part of the electric circuit, and no electrical arcs are generated.

Wire-type electrocautery probes have been involved in surgical fires. With these probes, wire temperatures are typically at or above incandescence (500°C [932°F]). Blade-style probes, in comparison, are more limited in their operating temperatures, and no incidents of surgical fires have been reported with their use.

### Fiberoptic Light Sources

Fiberoptic light sources collect incandescent light energy and direct it into an optical fiber to illuminate specific areas during surgery. While often called "cold light," these light sources can provide several hundred watts of visible, infrared, and ultraviolet light—enough energy to melt, scorch, or ignite materials. Although some of these wavelengths can be filtered out, this power is typically focused into a fiberoptic cable of small diameter, which can deliver a power density of up to several hundred $W/cm^2$.

### Other Surgical Ignition Sources

Other ignition sources, albeit rare, include defibrillators, argon beam coagulators, and dental and orthopedic burs. There are also instances in which an electrical component of a medical device fails, emitting smoke and sometimes flames; these are best handled by disconnecting the device from its electric power supply and removing the device from the room.

### Trash Fires

Some ignition sources can cause fires even when they are not in use. For example, there have been several reports of trash fires involving disposable battery-operated electrocautery pencils discarded contrary to the device's instructions. Instructions typically call for measures such as breaking off the cauterizing wire and capping the device before discarding it.

## RECOMMENDATIONS: MINIMIZING IGNITION SOURCE RISKS

*Note:* The applicability of the following recommendations must be considered individually for each patient.

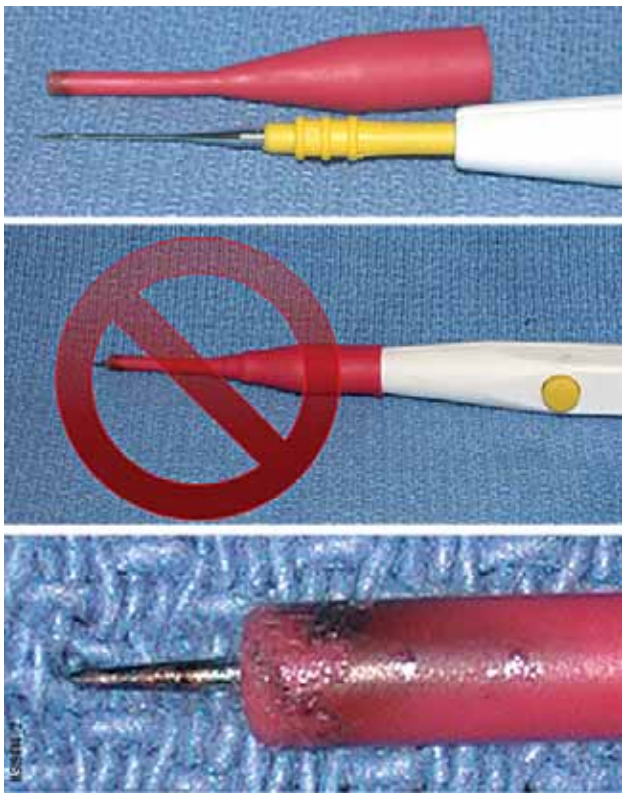
### During Electrosurgery

- Place the electrosurgical active electrode in a holster or another location off the patient when it is not in active use—that is, when it won't be needed within the next few moments.

- Allow the electrosurgical active electrode to be activated *only* by the person wielding it.
- The surgeon should activate the unit *only* when the active electrode tip is in direct view, especially if looking through a microscope or endoscope.
- Deactivate the unit *before* the active electrode tip leaves the surgical site.
- If open oxygen sources are employed, use bipolar electrosurgery whenever possible and clinically appropriate (such as for cauterization during head, face, neck, and upper-chest surgery). Bipolar electrosurgery creates little or no sparking or arcing and, to our knowledge, has not been involved in starting any surgical fires.
- Never use insulating sleeves cut from catheters or packing material and placed over electrosurgical active electrode tips. Such materials are not designed as insulators for the voltages present during electrosurgery (several thousand volts) and can cause flame flare-ups, especially in oxygen- or $N_2O$-enriched atmospheres. The image to the right shows a rubber urinary catheter that had been placed over an electrosurgical pencil tip. The rubber flared during oropharyngeal surgery and ignited nearby gauze and the tracheal tube. Use only active electrode tips that are manufactured with appropriate insulation.
- Never use electrosurgery to enter the trachea, such as during a tracheostomy.
- Never use electrosurgery in close proximity to flammable materials in oxidizer-enriched atmospheres.
- Disconnect contaminated electrosurgical active electrodes, and remove them from the surgical field.

### During Laser Surgery (Including Use in the Trachea or Bronchus)

- Limit the laser output to the lowest clinically acceptable power density and pulse duration.
- Test-fire the laser onto a safe surface (such as a laser firebrick) before starting the surgical procedure to ensure that the aiming and therapeutic beams are properly aligned.
- Place the laser in standby mode whenever it is not in active use.
- The surgeon should activate the laser *only* when the tip is in direct view.
- Allow the laser to be activated *only* by the person wielding it.
- Deactivate the laser and place it in standby mode *before* removing it from the surgical site.
- Use surgical devices designed to minimize laser reflectance.
- Never clamp laser fibers to drapes; clamping can break the fibers.
- When performing laser surgery through an endoscope, pass the laser fiber through the endoscope before introducing the scope into the patient. Before inserting the scope in the patient, verify the fiber's functionality. This will minimize the risk of using a damaged fiber that could cause a fire.
- During lower-airway surgery, keep the laser fiber tip in view and make sure it is clear of the end of the bronchoscope or tracheal tube before laser emission.
- Use a laser backstop, if possible, to reduce the likelihood of tissue injury distal to the surgical site.
- Use appropriate laser-resistant tracheal tubes during upper-airway surgery. Follow the directions in the product literature and on the labels, which typically include information regarding the tube's laser resistance, use of dyes in the cuff to indicate a puncture, use of a saline-filled cuff to prevent



Do not cover electrosurgical probe tips with rubber catheters. The rubber can flare up and easily burn (bottom photo) in an oxygen- or $N_2O$-enriched atmosphere and ignite the tracheal tube or gauze.

cuff ignition, and immediate replacement of the tube if the cuff becomes punctured.

- Place wetted gauze or sponges adjacent to the tracheal tube cuff to protect the tube from laser damage, and keep them wet.
- Moisten, and keep moist, any gauze or sponges used with uncuffed tracheal tubes to minimize leakage of gases into the oropharynx.
- Keep all moistened sponges, gauze, pledgets, and their strings moist throughout the procedure to render them ignition resistant.
- Consider the use of towels soaked in saline or sterile water around the operative site to minimize the risk of igniting the towels. Note, however, that this should be done only if it will not compromise aseptic technique for the procedure.

### Additional Recommendations

- Remove unneeded footswitches so that they are not accidentally activated. (Do this only after the attached device has been placed in standby mode.)
- Dispose of electrocautery pencils properly—for example, break off the cauterizing wire and cap the pencil.
- Be aware that fiberoptic light sources can start fires. Complete all cable connections before activating the light source.
- Never place active fiberoptic cables on drapes or other flammable materials.
- Place the fiberoptic light source in standby mode or turn the light source off when disconnecting cables.

## Managing Fuels

### FUELS IN THE O.R.

Potential fuels in the surgical setting include most of the materials that come into contact with the patient or that are used on or in the patient. Most of the fuels discussed below can ignite and burn in air, and all of them can easily ignite and burn in oxygen-enriched atmospheres. Also, the individual flammability characteristics of these fuels can be affected by interaction among the fuels. For example, alcohol can be absorbed into a towel, making the towel more flammable, or a fiberoptic light cable can penetrate a surgical drape and ignite underlying materials.

### Common OR Materials

Common OR materials make up the largest fuel load in the OR. The table below lists the flammable items typically present on the patient or in the OR.

Many of these materials are composed of cellulose or polymeric fibers, such as rubber, nylon, polyethylene, and polypropylene. While fire retardants are used in some of these materials, they cannot be relied on to prevent surgical fires under all conditions. (And, notably, no surgical drapes are made with fire retardants.)

In oxygen concentrations above about 50%, the fine nap fibers on cotton surgical towels, drapes, and OR table linens can serve as a fuel that rapidly spreads a fire across the fabric surface throughout spaces of high oxygen concentration. This is a phenomenon known as surface-fiber flame propagation.

### Alcohol and Other Volatile Organic Chemicals

Volatile organic chemicals include alcohol, acetone, and ether used in liquids such as skin preps, tinctures, degreasers, dressings, and some suture pack solutions and liquid wound dressings. These materials can be present during surgery in volumes from a few milliliters to about a liter.

Prepping agent fires are caused by the ignition of flammable vapors at the surgi-

### FUELS COMMONLY ENCOUNTERED IN SURGERY

| | |
|---|---|
| **Patient** | Hair (face, scalp, body) |
| **Prepping agents** | Aerosol adhesives<br>Alcohol (also in suture packets)<br>Alcohol-based prepping agents (DuraPrep, ChloraPrep, Prevail, Hibitane) (all are >70% alcohol)<br>Degreasers (ether, acetone)<br>Merthiolate (thimerosal)<br>Tinctures |
| **Linens** | Drapes (woven, nonwoven disposable, adherent)<br>Egg-crate mattresses<br>Gowns (reusable, nonwoven disposable)<br>Instrument and equipment drapes and covers<br>Masks, hoods and caps, shoe covers<br>Mattresses, pillows, blankets |
| **Dressings** | Adhesive tape (cloth, plastic, paper)<br>Gauze, sponges, pledgets |
| **Ointments** | Aerosols (e.g., Aeroplast)<br>Collodion<br>Petrolatum (petroleum jelly)<br>Tincture of benzoin (74% to 80% alcohol)<br>White wax |
| **Equipment/supplies** | Anesthesia components (e.g., breathing circuits, masks, nasal cannulae, airways, tracheal tubes, suction catheters)<br>Coverings of fiberoptic cables and wires (e.g., ESU leads, electrocardiogram leads)<br>Flexible endoscopes<br>Gloves<br>Smoke evacuator hoses |

cal site. Prep solutions can wick (or be absorbed) into hair and linens or can pool on or under the body. Spilled or pooled agent should be soaked up and removed from the patient. Even when properly applied, solutions that are not allowed time to fully evaporate before draping can result in patient-warmed prep vapors diffusing throughout the space beneath the drapes and rising out of the fenestration, thereby presenting a fire hazard. Alcohol fires can be particularly difficult to detect because they burn with a flame that can be invisible under bright surgical lights.

### Tracheal Tubes

Tracheal tubes are typically made from PVC, latex rubber, or silicone elastomer, all of which are flammable. Laser-resistant tracheal tubes often contain one or more of these materials; while they are resistant to certain laser wavelengths, these tubes may be flammable under other conditions—for example, if exposed to different laser wavelengths or to other heat sources such as an electrocautery pencil—or may have parts that are not laser resistant, such as the cuff or inflation tube.

Combustion of a tracheal tube, as demonstrated in the photo on page 320, delivers flames, smoke, and hot gases into the airway and lungs. Tracheal tube fires typically produce an intraluminal fire that can then produce an extraluminal flame that exits the distal opening.

### Body Tissue and Hair

Body tissue is flammable if it has been fully desiccated by therapeutic heat, such as that from an ESU or laser at the small target area of its application. The organic materials that remain after desiccation can ignite and become incandescent embers or flares of gas.

Hair of varying density and fineness is found on all people. As with the nap on cotton fabrics, body hair—especially the fine sublayer of hair called vellus—can easily ignite and fuel a fire that rapidly spreads across the skin in areas of high oxygen concentration (e.g., above 50%). This is another example of surface-fiber flame propagation. In ambient air, on the other hand, vellus will shrivel from heat but will not propagate a fire. Similarly, other types of body hair do not tend to be easily ignited in ambient air during surgery.

Questions about the role of hair spray in surgical fires have been occasionally raised. Dried hair spray does not enhance the ease with which hair may ignite, but may promote burning after ignition.

### Intestinal Gases

Intestinal gases are composed of varying concentrations of oxygen, nitrogen, carbon dioxide, hydrogen, and methane, a mixture that can vary widely in volume. In certain proportions, this mixture is flammable. Furthermore, during $N_2O$ anesthesia delivery, the gas can diffuse into the bowel and enrich the intestinal gas mixture, making it even more flammable.

### Other Fuels

Other fuels include flexible bronchoscopes, face masks, breathing system components, adhesives, surgical instrument coverings and drapes, smoke evacuator hoses, blood pressure cuffs, and laser fiber sheaths. Petroleum jelly can also be a fuel, but only if it comes in contact with other burning materials.

## RECOMMENDATIONS: MINIMIZING FUEL RISKS

*Note:* The applicability of the following recommendations must be considered individually for each patient.

### During Prep

- Be aware that alcohol-based preps are flammable.
- Avoid pooling, spilling, or wicking of flammable liquid preps. Spilled or pooled agent should be soaked up and removed from the patient.
- Allow flammable liquid preps to dry fully before draping.
- Remove towels used to catch dripped flammable prep before draping.
- Keep fenestration towel edges as far from the incision as possible.

### In General

- For surgery around the head, face, neck, and upper chest, consider coating hair within the fenestration with water-soluble surgical lubricating jelly to make the hair nonflammable if an oxidizer-enriched atmosphere may be present under the drapes.
- Be aware of the flammability of tinctures, solutions, and dressings (such as benzoin and collodion) used during surgery, and take steps to avoid igniting their vapors.
- Moisten sponges to make them ignition resistant in oropharyngeal and pulmonary surgery.

### FIRES ARE CURRENTLY OUR #3 HAZARD

Surgical fires are currently ranked third in ECRI Institute's list of Top 10 Technology Hazards, behind endoscope cross-contamination and alarm hazards. Look for the complete Top 10 list in our November issue.

# EXTINGUISHING A FIRE ON THE PATIENT

*The initial response to a surgical fire on a patient should be to stop the flow of gases to the patient and to remove the burning materials.* This is especially true for fires around the head, neck, and face. Immediately announcing that there is a fire to the OR team members is also critical. The first response should *not* be to retrieve a fire extinguisher or other firefighting equipment. Surgical fires can spread so rapidly that they will be out of control before an extinguisher can be used. In the 30 years that ECRI Institute has been investigating and collecting reports on hundreds of surgical fires, there have only been a few cases that we know of in which an extinguisher was needed and used. An extinguisher should be employed, if needed, only after other steps are taken, as described below. (The recommended actions for extinguishing a surgical fire—either on the patient or in the patient's airway—are also summarized in the poster on page 330.) For all fires, save involved materials and devices for later investigation.

Fires on or in the patient require an immediate comprehensive team response:

- **Stop the flow of all airway gases to the patient.** In many fires, removing the oxidizer (oxygen and $N_2O$) sources—for example, by disconnecting the breathing circuit—will cause the fire to go out or at least become less intense. Some materials burn only in oxygen-enriched atmospheres, and all materials burn more vigorously in them. Disconnection of the breathing circuit can also facilitate moving the patient rapidly (for example, to another OR).
- **Immediately remove the burning materials from the patient, and have another team member extinguish them. If needed, use a carbon dioxide fire extinguisher to put out the fire on the patient.** Removing the burning and burned materials is the only way to protect the patient from the heat of these materials. This applies regardless of whether the fire is burning *on* the patient or *in* the patient (as in the case of an airway fire). If this is not done, the heat can continue to cause thermal injury even after the fire is put out. Furthermore, the fire may reignite if oxidizers are reintroduced to hot or molten materials. Also, removing these materials will allow clinicians to view all the areas of the patient that were near the fire, aiding their assessment of the injury. It will be very unlikely that a fire extinguisher will need to be used, especially on the patient. Nonetheless, know the location of the fire extinguisher in your OR.
- **Care for the patient.** The patient must be cared for swiftly. He or she may not be spontaneously breathing, may be severely bleeding, and may still be in contact with other burning materials. The anesthesia staff should restore breathing, if needed, with air initially (never oxygen) until all possible sources of fire, or of reignition, are suppressed. The surgeon should deal with the patient's injuries. The nursing staff should extinguish any remaining burning materials on the patient, or that were removed from the patient. Evacuate the patient if the room is dangerous from smoke or fire.

Note that there is no step specifying removal of the ignition source. In the vast majority of cases, this will not be a consideration because the surgeon almost always has the ignition source in hand and will dispose of it to deal with the fire. Since the typical ignition sources for surgical fires deactivate when not in use, this step generally takes care of itself.

## FOR VERY SMALL FIRES

Very small fires that are not on the head, face, or neck, and whose extent is easily seen—such as those caused when a hot electrosurgical pencil ignites drapes on a patient, or when an electrocautery pencil ignites a blotting sponge—can be extinguished by patting out the fire with a gloved hand or towel. If using a towel or sheet to smother the flames, pat out the fire in a direction away from your body.

## IF A FIRE IS NOT QUICKLY CONTROLLED

It is extraordinarily rare for a surgical fire not to be quickly controlled by the staff present. Nonetheless, in such a case:

- **Notify the OR desk and call the fire department.** Inform other operating suite staff that a fire has occurred, and call the fire department.
- **Isolate the room to contain smoke and fire.** After evacuating the patient, close the door to the room and shut off power and medical gases to the room.

## FOR AIRWAY FIRES

At the first sign of fire in the airway, tracheal tube, or breathing circuit—whether during a tracheotomy or during internal tracheal/bronchial surgery—immediately and simultaneously disconnect the breathing circuit from the tracheal tube and remove the tube. Have another team member extinguish it. Also, immediately remove cuff-protective devices and any segments of burned tube that may remain smoldering in the airway. Pour saline or water into the airway to ensure that any remaining embers are extinguished and to cool the tissues.

Care for the patient by reestablishing the airway, and resume ventilating with air until you are certain that nothing is left burning in the airway, then switch to 100% oxygen. Don't use oxygen before ensuring that no burning or smoldering material is present; doing so will likely reignite the fire.

Examine the airway to determine the extent of damage, and treat the patient accordingly.

EMERGENCY PROCEDURE

# EXTINGUISHING A SURGICAL FIRE

## Fighting Fires ON the Surgical Patient

### Review before every surgical procedure.

In the Event of Fire on the Patient:

1. Stop the flow of all airway gases to the patient.
2. Immediately remove the burning materials and have another team member extinguish them. If needed, use a $CO_2$ fire extinguisher to put out a fire on the patient.
3. Care for the patient:
   - —Resume patient ventilation.
   - —Control bleeding.
   - —Evacuate the patient if the room is dangerous from smoke or fire.
   - —Examine the patient for injuries and treat accordingly.
4. If the fire is not quickly controlled:
   - —Notify other operating room staff and the fire department that a fire has occurred.
   - —Isolate the room to contain smoke and fire.

Save involved materials and devices for later investigation.

## Extinguishing Airway Fires

### Review before every surgical intubation.

At the First Sign of an Airway or Breathing Circuit Fire, Immediately and Rapidly:

1. Remove the tracheal tube, and have another team member extinguish it. Remove cuff-protective devices and any segments of burned tube that may remain smoldering in the airway.
2. Stop the flow of all gases to the airway.
3. Pour saline or water into the airway.
4. Care for the patient:
   - —Reestablish the airway, and resume ventilating with air until you are certain that nothing is left burning in the airway, then switch to 100% oxygen.
   - —Examine the airway to determine the extent of damage, and treat the patient accordingly.

Save involved materials and devices for later investigation.

ECRI Institute
The Discipline of Science. The Integrity of Independence.

MS09444_7

**Source:** New Clinical Guide to Surgical Fire Prevention. *Health Devices* 2009 Oct;38(10):330. 

## PRACTICING FOR DISASTER

Quick and effective response to a surgical fire—or any other fire that occurs in the OR or OR suite—requires a combination of planning and practice. A fire response plan provides a detailed description of who will do what in the event of a fire (Flowers 2004). A thorough plan will account for the various kinds of OR fires that can occur—from the small, quickly extinguished fire with no injury to the large, smoky, potentially catastrophic fire requiring evacuation of the OR or possibly the whole OR suite.

For fire safety initiatives, practice usually takes the form of fire drills. After staff are educated about the fire response plan, drills should be conducted to help staff learn the plan and to help the facility test the effectiveness of the plan and identify areas that need improvement. When planning a fire drill, be sure to consider the following elements:

- The proper response of each surgical team member and the OR suite staff. For example, the surgeon should remove the burning material, the anesthesia professional should initially disconnect the breathing circuit and assess the patient's respiratory status, nursing personnel should extinguish the burning material that may be on the floor and alert suite staff, and the suite staff should provide assistance as needed.
- When, how, and what to communicate within the OR, within the OR suite, with the rest of the facility, and with the local authorities (e.g., fire department, state department of health).
- How the patient can easily and safely be moved, if needed, to another OR or to another safe area.
- How the spread of smoke should be prevented—for example, by closing doors or using smoke doors and air duct dampers.
- The location and operation of fire extinguishers, fire alarm pull stations, and exits.
- The location, operation, and coverage area of medical gas zone (shutoff) valves.
- The location, operation, and coverage area of electrical supply panels.
- What the response of additional firefighting personnel (such as the fire response team and local fire department) should be.

After completing the drill, be sure to follow up with a review to learn how to improve the fire response plan and thus improve OR safety.

### Further Reading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## ALTERNATIVE FIREFIGHTING METHODS

**Aqueous solutions.** Aqueous solutions—such as bottled saline solution, bottled water, and tap water—can be used to help put out a fire (in combination with removal of the burning materials from the patient). Some hospitals keep a saline bottle, labeled "FOR FIRE," on the back table just for this purpose. Recognize, however, that surgical drapes are waterproof, and applied water may not contact the underlying burning materials. While basins of water or saline are also sometimes used to extinguish surgical fires, bottled solutions should be preferred, since they make it easier to accurately apply the solution to the area of burning.

**Carbon-dioxide-based fire extinguishers.** Although they should not be the first choice when dealing with a surgical fire, fire extinguishers may be needed in the extremely rare instance in which a fire engulfs the patient, has migrated off the patient, involves materials that continue to burn after being removed from the patient, or involves equipment in the OR. Surgical staff should know why, when, and how to use fire extinguishers.

ECRI Institute and APSF recommend carbon dioxide ($CO_2$) extinguishers for use in the OR. Specifically, we recommend that a 5 lb $CO_2$ extinguisher be mounted just inside the entrance of each OR in the hospital (ECRI Institute 2006, ASA 2008). In addition, we recommend that a 20 lb dry-powder fire extinguisher be available outside the OR, but within the OR suite, for use as a last resort for fighting catastrophic fires. See "Selecting Fire Extinguishers for the Operating Room" on page 62 of the February 2006 *Health Devices* for additional discussion.

## *NOT* APPROPRIATE FOR THE O.R.!

**Fire blankets.** Fire blankets—typically wool blankets that are treated with fire retardants and are placed over a fire to smother it—should never be located in an OR and should never be used for surgical patient fires (see "Fire Blankets in the OR?" on page 63 of our February 2006 issue). Such blankets could trap the fire next to or under the patient or could displace surgical instruments, leading to further injury. In addition, for cases in which a fire is sustained by oxygen delivered to the patient, a fire blanket would be ineffective at extinguishing the fire; in fact, the blanket itself could burn if it is used in an oxygen-enriched atmosphere.

**Water-based and halon-replacement fire extinguishers.** Fire extinguishers that use water-based agents, whether delivered as a stream or a "water mist," are not suitable for use on a burning patient in the OR

and are not recommended. Similarly, we do not recommend extinguishers that use halon-replacement agents for OR use.

### IF EVACUATION IS NECESSARY . . .

In very rare cases, extreme smoke and fire conditions may force the evacuation of the specific OR in which the fire occurs. ECRI Institute is aware of only one case in the past 35 years in which the surgical team had to evacuate the OR and temporarily leave the burning patient behind. Further, we know of only one other incident in which the entire OR suite needed to be evacuated. Nonetheless, we present the following guidance for OR evacuation.

When evacuation is necessary, the acronym RACE defines the actions that should take place: **R**escue, **A**lert, **C**onfine, and **E**vacuate.

**Rescue.** Reasonable attempts to rescue the surgical patient from the fire and the OR should be made. Several rescuers will likely be needed to deal with disconnecting the patient from any devices (such as an anesthesia machine or ESU) and, possibly, to move the operating table. The rescuers should not place themselves at severe risk, though each individual will have to decide what level of risk he or she considers to be severe.

**Alert.** The staff in nearby ORs should be alerted to the fire and kept informed in case they need to evacuate their patients from the area. In addition, fire alarm systems should be activated. Often, these systems summon assistance from within the facility to the area of the alert; some systems also call the local fire department.

**Confine.** Staff should contain the smoke and fire in the OR by closing all the doors. The medical gas zone (shutoff) valves for the affected OR should be shut to prevent piped gas and vacuum systems from sustaining the fire. Many facilities have automatic dampers in the air-conditioning ducts to prevent smoke migration. Some facilities have central smoke evacuator systems that are similar to vacuum systems; these should also be shut off. In addition, electric power to the involved OR should be turned off at the circuit-breaker panel outside the room; this will prevent it from sustaining electrical fires and will prevent an electric shock hazard for firefighters who are using water from extinguishers or hoses.

**Evacuate.** Though very unlikely, the incident OR—and, if necessary, the surgical suite—should be evacuated in an orderly manner to preplanned areas capable of handling the needs of the surgical patients.

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# INTEGRATING YOUR O.R. FOR LESS

## Six Cost-Saving Tips That Can Save You Thousands

You've decided to take the plunge and invest in an integrated operating room (OR) system to route video signals within and possibly outside the OR. Great—there are a number of systems out there that can do this well. But what about those other capabilities you're hearing about—things like centralized control of room lighting, surgical lights, the heating/ventilating/air-conditioning (HVAC) system, and even clinical devices?

These possibilities may sound intriguing, but the fact is, there are cheaper ways to accomplish some of these objectives—and others may just not be worth doing.

In this article, we present six cost-saving tips that could have a significant impact on your bottom line when you're acquiring an integrated OR system. In each item, we have provided a broad estimate of the possible cost savings based on implementing the measure in eight ORs.

Keep in mind that each OR integration system supplier implements its system differently, and all six points presented here may not apply to every system. Additionally, the cost figures presented here are derived from prices quoted in requests for proposal that we've reviewed and may differ from the price quotes that you receive. The savings we describe are for illustration only; your actual savings may be significantly different.

### 1. PURCHASE YOUR WALL-MOUNTED DISPLAYS FROM A LOCAL VIDEO EQUIPMENT RETAILER

The large displays that will be mounted onto the walls of the OR do not need to be medical-grade displays obtained from your OR integration system supplier. (For more on this, see the Guidance Article "Using Off-the-Shelf Computer Equipment" in the July 2008 *Health Devices*.) A similar non-medical-grade display can be purchased from a local video equipment retailer (e.g., Best Buy) for much less, with no sacrifice in image quality. All you'll need the OR integration system supplier to do is install the cabling to the display.

**Savings:**

- Cost of 52-inch LCD from OR integration vendor ($8,000) *minus* cost of 52-inch LCD from local video equipment retailer ($2,000)
- Total: $6,000 per OR × 8 = $48,000

### 2. KEEP ROOM-STATUS MONITORING SEPARATE FROM THE O.R. INTEGRATION SYSTEM

You don't need high-quality pan/tilt/zoom (PTZ) cameras to monitor room status (e.g., to find out whether the surgery has been completed). Simple, fixed network cameras (no PTZ capability) are sufficient to allow the coordinating nurse to observe rooms from any PC. And rather than having the cameras connect through the OR integration system, you can have your information technology (IT) department install the network cabling and assign IP addresses for the network cameras.

**Savings:**

- Cost of room-status monitoring with PTZ cameras using the OR integration system for 8 ORs ($21,000) *minus* cost of 8 fixed network cameras ($3,000)
- Total: $18,000

### 3. DON'T USE THE INTEGRATION SYSTEM TO CONTROL ROOM LIGHTING

Controlling room lighting through the OR integration system may not seem like a major project, but it actually is. Adding this capability often requires major expansion of a basic OR integration audio/video (AV) system. Much more cost-effective is to install the lighting controls on the wall close to the in-room nurse's station—so that they're still just an arm's length away—without going through the OR integration system.

**Savings:**

- Cost of implementing lighting control by OR integration vendor for 8 ORs ($60,000) *minus* cost of installing controls on the wall near the in-room nurse's station (negligible cost)
- Total: $60,000

### 4. DON'T USE THE INTEGRATION SYSTEM TO CONTROL SURGICAL LIGHTING EITHER

Like room lighting control, controlling surgical lights via the OR integration system adds a significant cost (one that is separate from that for room lighting control) that isn't justified by the benefits.

**Savings:**

- Cost of having the OR integration vendor implement surgical lighting control for 8 ORs ($60,000)
- Total: $60,000

### 5. DON'T USE THE INTEGRATION SYSTEM TO CONTROL HVAC

The quotes you receive may include a line item for control of HVAC, but you can save a lot of money by omitting this option. Keep it simple—have the HVAC contractor install the HVAC controls on the wall close to the in-room nurse's station, and avoid going through the OR integration system at all.

**Savings:**

- Cost of implementing HVAC control by OR integration vendor for 8 ORs ($60,000) *minus* cost of having HVAC contractor install controls on the wall near the in-room nurse's station (negligible cost)
- Total: $60,000

### 6. DON'T USE THE INTEGRATION SYSTEM FOR AUDIO COMMUNICATION

Unlike bidirectional video routing, audio routing between ORs via the OR integration system doesn't add enough value or convenience to be worth the price. Unless this capability is already included in the cost of the system, use the cheaper method: Just pick up the phone.

**Savings:**

- Cost of adding audio communication to the OR integration system for 8 ORs ($30,000)
- Total: $30,000

## SAVINGS FROM ALL SIX TIPS: $276,000

And don't forget about the cost of the extended warranty, which could be as much as 10% of the capital cost per year—meaning that if you chose *not* to follow the six tips above, the price of the extended warranty would increase by $27,600 per year. Assuming the extended warranty covers years two through five, that's another $110,400.

## GRAND TOTAL SAVINGS INCLUDING EXTENDED WARRANTY: $386,400

### OTHER THOUGHTS

You may also have considered controlling non-AV medical devices (e.g., insufflators, electrosurgical units) via the integrated OR system. In most cases, it won't be worth it. Such control is usually possible only if the medical devices are provided by the integrated OR system vendor. If you have clinical devices from a different vendor, then control of these devices from the integrated OR system probably won't be possible. Even if your devices are all from the same vendor, the actual features on a medical device that can be controlled through the integrated OR system can be quite minimal (e.g., power on/off) and probably don't justify the cost.

One last item to keep in mind is that it is not necessary to purchase an OR integration system from the same vendor that supplies your endoscopic cameras. All manufacturers' video output signals are standard formats, which can be handled by any OR integration system. So don't feel tied to purchasing an OR integration system from a vendor just because you have their endoscopic cameras. Go out and get competitive quotes and choose the system that will best meet your needs. hd

### WANT TO KNOW MORE ABOUT O.R. INTEGRATION?

ECRI Institute has done extensive work on the topic of integrated OR systems. There are several relevant *Health Devices* articles that will help you make sure you spend your money wisely, including:

- "Integrating Your OR: Equipment and Construction Needs," March 2008
- "Medical Video: Bringing Your Equipment Needs into Focus," January 2008
- "OR Integration: What It Is—and What It Isn't," September 2007

We've also worked with a number of healthcare facilities that have installed integrated OR systems. These experiences are the basis of the cost-saving measures we describe in this article.

health. DEVICES ACHIEVEMENT AWARD

# DARTMOUTH-HITCHCOCK MEDICAL CENTER WINS HEALTH DEVICES ACHIEVEMENT AWARD

## INNOVATIVE APPLICATION OF PULSE OXIMETRY MONITORING REDUCES FAILURE-TO-RESCUE EVENTS

Dartmouth-Hitchcock Medical Center (DHMC) of Lebanon, New Hampshire, has won the fourth annual Health Devices Achievement Award for excellence in health technology management.

The submission from the Dartmouth-Hitchcock team is titled "A Multidisciplinary Approach to Improving Patient Safety in the Adult Medical/Surgical Population through Earlier Detection of Patient Deterioration Using Surveillance Monitoring." It describes an initiative designed to decrease failure-to-rescue (FTR) events—instances of severe patient harm (such as death or disability) that occur because a serious deterioration in the patient's condition is not detected in time.

The project was designed to reduce FTR events through a new application of pulse oximetry monitoring: using it continuously from admission to discharge. The primary goal was to enhance nurse surveillance in the postoperative setting. A secondary goal was to reduce the number of nuisance alarms, which tend to desensitize nurses to alarms.

Monitoring patients continuously allows nurses to better detect "drift"—a downward trend in a patient's condition—and therefore intervene before the patient deteriorates to the point of requiring a rescue team. Nurse satisfaction with the new surveillance tool was reported to be very high, and preliminary analysis indicates that the initiative has contributed to decreases in annual rescue calls and transfers to critical care.

"ECRI Institute has identified clinical alarm hazards as the number one device-related risk on its list of top 10 health technology hazards," says James P. Keller, Jr., ECRI Institute's vice president for health technology evaluation and safety. "Any effort to improve this problem can have a huge impact on patient safety. Dartmouth-Hitchcock Medical Center should be commended for recognizing the problems that alarm 'overload' can cause and for taking on a project to improve the way clinicians monitor for and respond to serious changes in patient conditions."

George Blike, MD, quality and patient safety officer for Dartmouth-Hitchcock Medical Center, said, "The award from ECRI Institute is a tremendous honor and a great recognition for the many people who have played a role in the deployment of this new technology." He added, "Creating excellence in patient care is a matter of finding and training the right people, enabling them with the right tools, and doing it all within the right environment of care. This tremendous group effort and innovative technology have combined to save lives, which is incredibly rewarding for everyone involved."

A formal presentation will be made by Jim Keller at DHMC later this year.

The Health Devices Achievement Award recognizes an outstanding initiative undertaken by an ECRI Institute member healthcare facility that improves patient safety, reduces costs, or otherwise facilitates better strategic management of health technology.

For more information, call ECRI Institute at +1 (610) 825-6000, ext. 5377; visit www.ecri.org; send an e-mail to communications@ecri.org; or write to us at ECRI Institute, 5200 Butler Pike, Plymouth Meeting, PA 19462-1298, USA. HD

# FREE CONSULTATIONS ARE PART OF YOUR MEMBERSHIP

Your membership in the Health Devices System entitles **your entire facility** to free consultations with ECRI Institute's healthcare technology experts. **Often, the information you receive from a single consultation will more than justify the annual cost of membership.** You can ask for advice on topics of general interest or take advantage of one of these specialized consultation services:

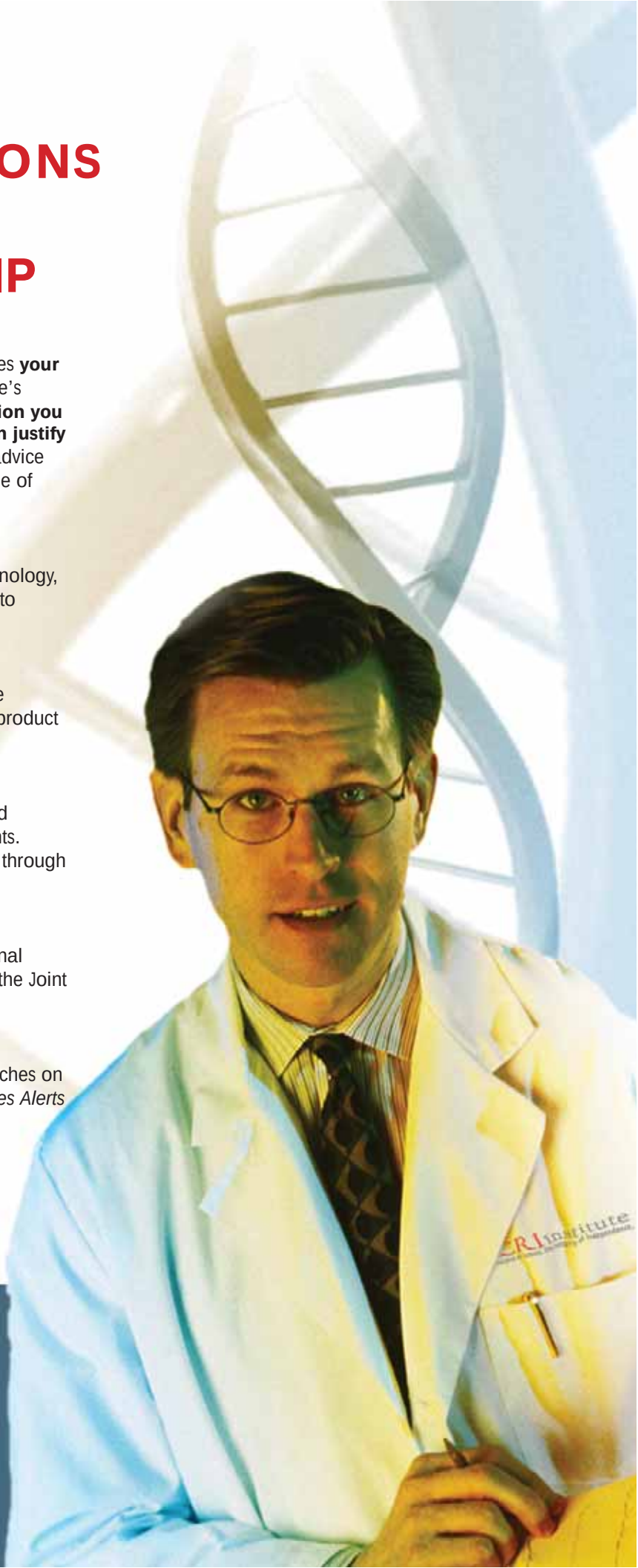
**Safety Consultations**
Ask us about the safety of a particular device or technology, your safety-related policies and procedures, or ways to handle device-related incidents.

**Technology Dispute Resolution**
Are departments in your facility at odds over a device purchase? Call us for unbiased advice about which product is likely to meet your needs.

**Service and Maintenance Analyses**
We'll assess your hospital's policies covering IPM and repairs, and we'll review individual service agreements. (More extensive service contract analysis is available through our SELECTplus program.)

**Regulatory Analyses**
We can offer guidance in applying current international standards, help interpreting specific requirements of the Joint Commission, and much more.

**Custom Database Searches**
Each membership year, you can request custom searches on up to three specific device topics in the *Health Devices Alerts* database at no charge.



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# HAZARD REPORT

## ECRI Institute Recommends Providing Power-Cord-Specific Data when Reporting Device Incidents

**SUMMARY**

When power cord defects or damage contributes to device-related incidents, crucial information about the cord and/or plug (e.g., manufacturer, details of damage) is often not included in incident reports. To facilitate the investigation of these events—which frequently pose a risk of shock or fire—ECRI Institute is asking hospitals to include cord and plug details when reporting the incidents to us, to device manufacturers, and to regulatory agencies.

**DISCUSSION**

Although power cords are used in a vast array of medical devices, they are supplied by a comparatively small number of manufacturers and purchased by device suppliers for use with their products. Many device users, unaware of this fact, understandably tend to think of the cord as part of the device rather than as a distinct item that was manufactured separately.

Consequently, when a device-related incident occurs in which a power cord is implicated or is suspected to be involved, users who report the incident to regulatory agencies (e.g., the U.S. Food and Drug Administration [FDA], Health Canada) and to other parties (including ECRI Institute) often fail to include information about the cord, providing information only about the device. As a result, their reports frequently lack the information necessary to determine the make and model of the cord or, in some cases, exactly what role the cord may have played in the incident. The lack of power-cord-specific information in incident reports may make it difficult to identify failure trends in that cord model.

Compounding the problem is the fact that multiple device manufacturers may provide the same power cord (or substantially similar cords) for their products, either at initial shipment or as a replacement for damaged or broken cords. Thus, a problem with one model or type of cord could potentially affect a number of manufacturers, and what appears to be a small number of unrelated reports scattered across a few device models may actually be a more widespread issue affecting a wide array of equipment supplied by a number of companies. We discussed an instance of this situation—in which broken ground pins on a cord supplied by a single manufacturer posed a shock hazard in devices from at least four medical device suppliers—in a July 2003 Hazard Report.

Cord-related problems pose a variety of risks, including smoke, shocks, burns, and fire. Medical device and power cord manufacturers often attribute power cord failures to abuse, which may in some cases be a legitimate contributing factor. But problems can also result from product defects. Without a sufficient quantity of reports (each with detailed information on the cord), there may be no way to determine whether a

flaw is associated with a particular cord model or design or to assess how many medical devices may be affected.

To address the lack of power-cord-specific information, we are asking that, when a cord is known or suspected to have contributed to an incident, healthcare facilities include details about the cord when reporting the problem to us, to the medical device manufacturer, and to the appropriate regulatory agencies (e.g., FDA). Submit reports as you typically would for medical device problems (i.e., identify the parent device as you normally would), but also include the following to identify power cords:

- Power cord manufacturer (typically printed on the male plug).
- Part/catalog number (if provided on the cord).
- Method of connection (i.e., crimped, soldered) between plug blades and conductor wires, if known (e.g., if the plug is translucent and allows easy viewing of the connections).
- Documentation of any notable damage to the cord or male or female plugs.
- Photos of the incident power cord, as well as photos of a sample cord in good condition. The photos should include shots of the male and female plugs placed in various orientations to provide a comprehensive set of views. (Note that some organizations' reporting systems may be unable to accept photos or other attachments with the original report and may require that they be submitted separately. You may need to contact the organization to arrange the submission of these files.*)

While cord-specific information may sometimes be difficult to obtain, especially if the cord is damaged, the effort is worthwhile and may prove useful in investigating and identifying causes of the problem.

## RECOMMENDATIONS

1. Alert biomedical engineering, facilities engineering, and risk management personnel to our report.
2. Report all power cord problems, such as sparking, charring, and associated smoke/fire, to ECRI Institute, the medical device manufacturer involved, and the appropriate regulatory agencies (e.g., FDA, Health Canada). Ensure that cord-specific identifying information and photos are included in your report, as specified in the list above.

* Hospitals submitting incident reports to ECRI Institute's Problem Reporting System can send their photos (or other attachments) to problemreport@ecri.org.

problem reporting SYSTEM

### REPORTING PROBLEMS TO ECRI INSTITUTE

ECRI Institute encourages members, healthcare providers, patients, and suppliers to report all medical-device-related incidents and deficiencies to us so that we can determine whether a report reflects a random failure or one that is likely to recur and cause harm. Reports can be generic or model specific. We add all reports to our internal confidential databases to track trends of device failure or lot-specific defects. Although many reports do not result in a published article, we inform the reporting party of our findings or opinions when appropriate. As soon as we become aware of device hazards and problems, we inform the suppliers and invite them to respond constructively.

If our investigations yield information that should be communicated to the healthcare community, we publish the information in *Health Devices* as either a Hazard Report or a User Experience Network™ (UEN™) article, depending on the level of risk associated with the problem. Member hospitals may reproduce these reports for internal distribution only. This policy does not apply to other articles in *Health Devices,* unless otherwise noted.

Please report problems to us by sending us a letter, by completing the online form available at www.ecri.org/problemreport, or by calling +1 (610) 825-6000. The identity of the reporting individual or institution is never revealed without permission.

### ABOUT HAZARD REPORTS

A Hazard Report describes a possible source of danger or difficulty involving medical devices. We publish reports about those units concerning which we have identified a fault, design feature, or user practice that might, under certain circumstances, place patients or users at risk. These reports describe the problem and our recommendations on how to correct or avoid it. Publication of a report on a specific brand name and model of device in no way implies that competitive devices lack hazardous characteristics.

When deciding whether to discontinue using a device that ECRI Institute believes poses a risk, staff should balance the needs of individual patients, the clinical priorities, and the availability of safer or superior products against the information we provide. Clinical judgment is more significant than an administrative, engineering, or liability decision. Users can often take precautions to reduce the possibility of injury while waiting for equipment to be modified or replaced.

# HAZARD REPORT

## Flammable Material Introduced into Draeger Ventilator and Anesthesia Unit Flow Sensors Could Ignite, Posing Risks to Patients


### SUMMARY

In rare cases, when flammable material is introduced into the Spirolog or SpiroLife flow sensor used with Draeger Medical ventilators and anesthesia units, the material could ignite, posing the risk of patient injury or device damage. Users can reduce this risk by carefully inspecting circuit components before use, by not introducing flammable products into the circuit during use, and by strictly complying with the company's instructions to allow the sensors to dry completely following alcohol disinfection.


### PROBLEM

A member facility reports that, while using a Draeger Medical anesthesia unit during surgery, an anesthesiologist manually initiated calibration of the machine's flow sensor to correct a suspected sensor error. Shortly after, the unit began making "popping" noises, and the breathing system began emitting smoke. Clinicians discontinued ventilation, and the patient (who, at this point, was able to breathe spontaneously) was not harmed. Following the incident, hospital staff inspected the unit and found that its Spirolog flow sensor was blackened and partially melted. Draeger subsequently found that a piece of foreign plastic material, likely a piece of packaging or mold flash from the breathing circuit mask, had entered the sensor and ignited during flow-sensor calibration.

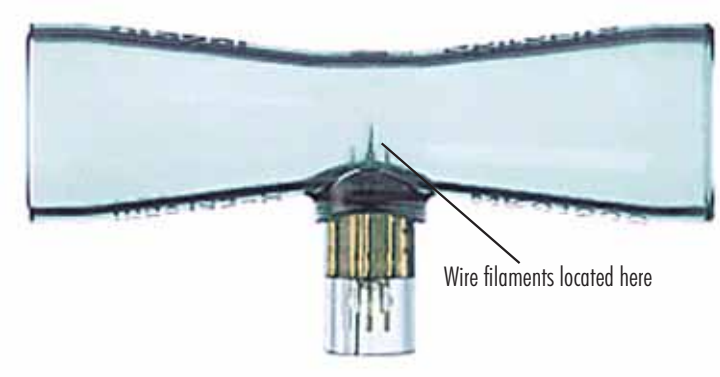
ECRI Institute is aware of a handful of additional reports of smoke and/or flames involving Spirolog and SpiroLife flow sensors, which are used with many of Draeger's ventilators and anesthesia systems. It appears that each of these incidents resulted from the presence of flammable material in the flow sensor during calibration, a process in which components of the sensor are briefly heated to very high temperatures. ECRI Institute believes that the potential for severe clinical impact—smoke inhalation, interruption of ventilation resulting from device damage, or burns—merits strict adherence to precautions, despite the relatively small number of reported incidents.

### DISCUSSION

The Spirolog and the autoclavable SpiroLife are hot-wire-anemometer flow sensors used with several models of Draeger ventilators (the Evita Series and Savina) and anesthesia systems (Apollo, Primus, Fabius GS and Tiro, Julian, Cato, Cicero, and Sulla). Ventilators and anesthesia units that use these flow sensors apply electrical current to thin wire filaments within the sensor housing to heat them to a specific temperature and to maintain that temperature as cooler gas flows through the sensor. There is a direct correlation between the current applied to maintain the filaments' temperature and the gas flow through the sensor. Ventilators and anesthesia units use this relationship to calculate and

display both flow and volume information for the user, and, in some cases, to adjust the unit's delivered volume.

The Draeger sensors are periodically calibrated by the anesthesia unit or ventilator; this process can be initiated either automatically (at device start-up and following delivery of nebulized medications) or manually (e.g., if the user suspects flow-monitoring inaccuracy). As part of this brief process, gas delivery is interrupted, and the wires are heated to temperatures as high as 800ºC to clean them.




MS09444_6

Side image of the Spirolog flow sensor.

While calibration normally occurs without a problem, the presence of any flammable material within the sensor presents the risk of ignition. This is particularly true if the oxygen concentration within the sensor is high; depending on the delivery settings in use at the time, oxygen concentrations can range from 21% to 100%. In the reported incident, Draeger found that a small amount of plastic material—likely a piece of packaging or mold flash from the breathing circuit or the mask—had adhered to the wire filaments and ignited during cleaning; this damaged the sensor and ignited other components within the breathing system, producing smoke.

Additionally, we know of a few other cases involving both anesthesia units and ventilators in which Draeger suspects that alcohol or other flammable solutions within the sensor led to ignition during sensor calibration. (Sensors may be soaked in alcohol periodically for disinfection.)

## SUPPLIER'S RESPONSE

According to Draeger, the risk of ignition exists only when flammable material is present in the sensor; based on our review of the sensor design, we agree with the company's assessment. The various operator manuals address the importance of not introducing flammable solutions into the breathing circuits and of allowing alcohol to evaporate completely after disinfection before installing the sensor. (The company recommends a minimum of 30 minutes of air drying.)

Additionally, the company indicates that if ignition occurs in its Evita Series ventilators, the risk of smoke inhalation is very low because a check valve and wire mesh separate the sensor from the patient and the rest of the breathing system. However, the resulting damage to the sensor could still impact ventilation.

## RECOMMENDATIONS

Based on ECRI Institute's review of the available information, we believe that the likelihood of ignition within the Spirolog or SpiroLife sensors is low. However, given the potential for severe clinical impact should ignition occur, we recommend that facilities using ventilators or anesthesia units equipped with Spirolog or SpiroLife sensors do the following:

1. Alert users and support staff—including the respiratory therapy, pulmonology, anesthesiology, and clinical engineering departments—to this report.
2. Remind users not to introduce flammable solutions or medications into breathing circuits when using the Spirolog or SpiroLife flow sensors.
3. Instruct users that, before using the system, they should check for any foreign material within the breathing circuit or within associated components (e.g., breathing mask). This can be done through visual inspection and by shaking the breathing circuits to help dislodge any unseen material.
4. Follow Draeger's published instructions for cleaning and disinfecting Spirolog and SpiroLife sensors. These instructions are typically included in the appropriate operator manuals; contact the company if you can't locate this information. Pay particular attention to the instruction that stipulates at least a 30-minute wait after disinfecting the unit with alcohol before reinstalling the sensors.

**UMDNS terms.** Anesthesia Units [10-134] ■ Ventilators, Intensive Care [17-429]

**Supplier.** Draeger Medical Inc. [371341], Telford, PA (USA); +1 (800) 437-2437, +1 (215) 721-5400; www.draeger.com

# HAZARD REPORT

## Overlap of Surgical Lighthead Beams May Present Burn Risk


### SUMMARY

The heat created when the beams from multiple surgical lightheads overlap can sometimes present the risk of patient burns during a procedure. Safe use of multiple heads requires limiting the total light intensity to acceptable levels.


### PROBLEM

ECRI Institute has investigated a small number of patient burns that appear to have resulted from the overlapping of the light from two or more high-intensity surgical lightheads. We have also reviewed a handful of similar reports available in the U.S. Food and Drug Administration's (FDA) MAUDE (Manufacturer and User Facility Device Experience) database. In each case, the multiple lightheads—which were found to be in proper working order following the incidents—were focused on a single surgical site and operated at or near maximum intensity.* Although incidents of this sort appear to be rare, our review of the cases suggests that many clinicians may not be sufficiently aware of the risk.

### DISCUSSION

As a by-product of illumination, surgical lighting systems deliver heat to the surgical site, raising the temperature of objects and tissue located there. As the user increases the light intensity and reduces the beam pattern (focusing it to concentrate the light over a smaller area), the heating effect increases. To control the risk of excessive heating, the governing design standard (the International Electrotechnical Commission's IEC 60601-2-41) limits the peak irradiance—the rate at which energy is delivered to the illuminated area—of a single lighthead to 1,000 W/$m^2$. We have reviewed the specifications for a number of models, including those involved in the incidents that we investigated, and all of them fall well below this limit.

While adherence to the IEC standard means that a single lighthead should not raise temperatures to dangerous levels, common clinical practice is to use two or three lightheads at once. When the heads are operated at moderate intensity, this seldom presents a risk. However, when more than one light is operated at or near maximum intensity—and particularly when more than one head is focused to deliver the tightest beam possible—the total irradiance may easily exceed the IEC value and raise temperatures in the surgical field to unsafe levels.

In one of our investigations, we found that focusing two of the incident lightheads at maximum intensity resulted in a total irradiance of approximately 1,200 W/$m^2$ within the simulated surgical field and quickly raised the temperature to 47°C (117°F), a temperature that could cause patient burns in less than 30 minutes. Adding a third light further increased irradiance and temperature, exacerbating the burn risk.

* Patient burns can also occasionally occur because of problems with the lighting system itself, such as missing heat filters or improper wiring at installation.

All the incidents we've reviewed involved incandescent light technology, but newer LED designs may also present a risk of excessive heating. Although these systems typically generate lower irradiance levels than similar non-LED designs, the cumulative effect of multiple LED lightheads overlapping at very high intensity might still be a concern.

The IEC standard recognizes the risk presented by overlapped lightheads and requires that manufacturers warn users of this risk in each lighting system's operating instructions. Unfortunately, while such warnings are typically present in operator manuals, they are sometimes presented vaguely and may not convey the appropriate urgency to the reader. Furthermore, most users will not have read the manual or may not recall such details. For these reasons, it's important that hospitals impress on surgical staff the rare but serious risk presented by the simultaneous use of multiple lightheads and train them to control that risk.

## RECOMMENDATIONS

1. Alert users of surgical lights to this problem and to our report.
2. Direct users to do the following when employing more than one lighthead on a surgical site:
   a. Set all lightheads at the minimum operating intensity required to adequately illuminate the site. If very high intensity is required only temporarily, reduce intensity as soon as that need passes.
   b. If maximum or near-maximum intensity is required from one lighthead, ensure that other lightheads are set at lower levels and are not focused on the site.
3. Report injuries involving the use of surgical lights to ECRI Institute, to the supplier, and to the appropriate regulatory body (e.g., FDA, Health Canada).

**UMDNS term.** Lights, Surgical [12-282]

**Suppliers.** Surgical lightheads are available from a variety of suppliers. Consult ECRI Institute's Health Devices International Sourcebase for a list of companies.

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## OBJECTIVES

To improve the effectiveness, safety, and economy of health services by:

- Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.
- Functioning as an information clearinghouse for hazards and deficiencies in medical devices.
- Encouraging the improvement of medical devices through an informed marketplace.


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