

Recommendations to Reduce Surgical Fires and Related Patient Injury: FDA Safety Communication

Date Issued:

May 29, 2018

Audience:

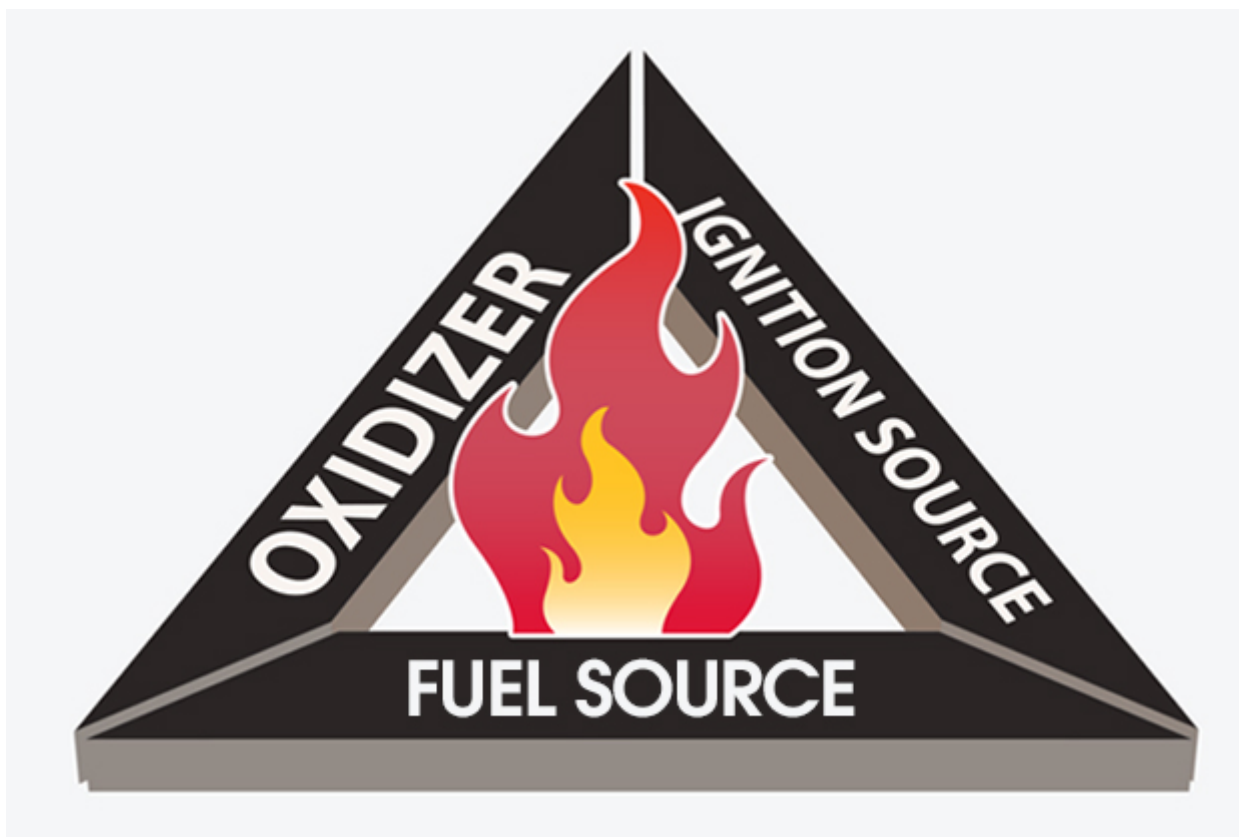
- All health care professionals involved in surgical procedures, including: surgeons, surgical technicians, anesthesiologists, anesthesiologist assistants, certified registered nurse anesthetists (CRNA), physician assistants, nurses, etc.
- Health care facility staff responsible for patient safety and risk management.

Purpose:

The FDA is reminding health care professionals and health care facility staff of factors that increase the risk of surgical fires on or near a patient. The FDA is also recommending practices to reduce these fires from occurring, including the safe use of medical devices and products commonly used during surgical procedures.

Summary of Problem and Scope:

Although surgical fires are preventable, the FDA continues to receive reports about these events. Surgical fires can result in patient burns and other serious injuries, disfigurement, and death. Deaths are less common and are typically associated with fires occurring in a patient's airway.



Surgical fires can occur at any time when all three elements of the fire triangle are present:

1. **Oxidizer** (e.g., oxygen, nitrous oxide)
2. **Ignition source** (e.g., electrosurgical units (ESUs), electrocautery devices, lasers, and fiber-optic illumination systems)
3. **Fuel source** (e.g., surgical drapes, alcohol-based skin preparation agents, the patient's tissue, hair, or skin)

Most surgical fires occur in oxygen-enriched environments, when the concentration of oxygen exceeds 30 percent. When supplemental oxygen is delivered to a patient in an operating room, an oxygen-enriched environment can be created. An open oxygen delivery system, such as nasal cannula or mask, presents a greater risk of fire than a closed delivery system, such as a laryngeal mask or endotracheal tube. In an oxygen-enriched environment, materials that may not normally burn in room air can ignite and burn.

Recommendations to Reduce Surgical Fires:

Health care professionals and staff who perform surgical procedures should be trained in practices to reduce surgical fires. Training should include factors that increase the risk of surgical fires, how to manage fires that do occur, periodic fire drills, how to use carbon dioxide (CO₂) fire extinguishers near or on patients, and evacuation procedures.

Specific recommendations to reduce surgical fires include:

- **A fire risk assessment at the beginning of each surgical procedure.**
 - Be aware the highest risk procedures involve an ignition source, delivery of supplemental oxygen, and use of an ignition source near the oxygen (e.g., head, neck, or upper chest surgery).
- **Encourage communication among surgical team members.**

- Ensure communication exists between the anesthesia professional delivering medical gases, the surgeon controlling the ignition source, and the operating room staff applying skin preparation agents and drapes.
- **Safe use and administration of oxidizers.**
 - Evaluate if supplemental oxygen is needed for your patient.
 - Any increase in oxygen concentration in the surgical field increases the chance of fire.
 - At concentrations of approximately 30 percent, a spark or heat can ignite a fuel source.
 - If supplemental oxygen is necessary, particularly for surgery in the head, neck, or upper chest area:
 - Titrate to the minimum concentration of oxygen needed to maintain adequate oxygen saturation for your patient.
 - When appropriate and possible, use a closed oxygen delivery system.
 - If using an open delivery system, take additional precautions to exclude oxygen and flammable/combustible gases from the operative field, such as draping techniques that avoid accumulation of oxygen in the surgical field.
- **Safe use of any devices that may serve as an ignition source.**
 - Consider alternatives to using an ignition source for surgery of the head, neck, and upper chest if high concentrations of supplemental oxygen (greater than 30 percent) are being delivered.
 - If an ignition source must be used, be aware that it is safer to do so after allowing time for the oxygen concentration in the room to decrease. It may take several minutes for a reduction of oxygen concentration in the area even after stopping the gas or lowering its concentration.
 - Inspect all instruments for evidence of insulation failure (device, wires, and connections) prior to use. Do not use if any defects are found.
 - In addition to serving as an ignition source, monopolar energy use can directly result in unintended patient burns from capacitive coupling and intra-operative insulation failure. If a monopolar electrosurgical units (ESU) is used:
 - Do not activate when near or in contact with other instruments.
 - Use a return electrode monitoring system.
 - Tips of cautery instruments should be kept clean and free of char and tissue.
 - When not in use, place ignition sources, such as ESUs, electrocautery devices, fiber-optic illumination light sources and lasers in a designated area away from the patient (e.g., in a holster or a safety cover) and **not** directly on the patient or surgical drapes.
 - Recognize that other items that generate heat, including drills and burrs, argon beam coagulators, and fiber-optic illuminators, can also serve as potential ignition sources.
- **Safe use of surgical suite items that may serve as a fuel source.**
 - Allow adequate drying time and prevent alcohol-based antiseptics from pooling during skin preparation and assess for pooling or other moisture to ensure dry conditions prior to draping.
 - Use the appropriate size applicator for the surgical site. For example, do not use large (e.g., 26mL) applicators for head and neck cases.
 - Be aware of other surgical suite items that may serve as a fuel source, including:
 - Products that may trap oxygen, such as surgical drapes, towels, sponges, and gauze – even those which claim to be "flame-resistant."

- Products made of plastics including some endotracheal tubes, laryngeal masks, and suction catheters.
- Patient-related sources such as hair and gastrointestinal gases.
- **Plan and practice how to manage a surgical fire.**
 - Stop the main source of ignition. Turn off the flow of flammable gas; unplug electrical devices that may be involved.
 - Extinguish the fire –Use a safe method to smother the fire such as, water or saline, and a CO2 or other extinguisher if the fire persists.
 - Remove all drapes and burning materials and assess for evidence of smoldering materials.
 - For airway fires, disconnect the patient from the breathing circuit, and remove the tracheal tube.
 - Move the patient to a safe environment. Reestablish the airway to resume respiratory care.
 - Review the fire scene and remove all possible sources of flammable materials.

FDA Activities:

The FDA is working with The Joint Commission (TJC), and other organizations, to inform health care professionals and health care facility staff of risks of surgical fires and provide recommendations to reduce them. The FDA also reviews product labeling for drugs and devices that are components of the fire triangle to ensure the appropriate warnings about the risk of fire are included.

Reporting Problems to the FDA:

Prompt reporting of adverse events will help the FDA identify and better understand the risks and adverse events associated with surgical fires. If you experience a surgical fire, we encourage you to file a voluntary report through **MedWatch, the FDA Safety Information and Adverse Event Reporting program** (<https://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>). Health care personnel employed by facilities that are subject to the **FDA's user facility reporting requirements** (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>) should follow the reporting procedures established by their facilities.

Additional Resources:

- **[Medscape - Recommendations to Prevent Surgical Fires and Patient Injury](https://www.medscape.com/viewarticle/897198)**
(<https://www.medscape.com/viewarticle/897198>)
- **[ECRI Institute: Surgical Fire Prevention](http://www.ecri.org/surgical_fires)** (http://www.ecri.org/surgical_fires)
- **[Council on Surgical & Perioperative Safety \(CSPS\): Safe Surgery Resources](http://www.cspsteam.org/7-fire-safety/)** (<http://www.cspsteam.org/7-fire-safety/>)
- **[Anesthesia Patient Safety Foundation \(APSF\): Resources – Fire Safety Video](https://www.apsf.org/resources/fire-safety/)**
(<https://www.apsf.org/resources/fire-safety/>)
- **[Association of Perioperative Registered Nurses \(AORN\): Fire Safety Tool Kit](https://www.aorn.org/guidelines/clinical-resources/tool-kits/fire-safety-tool-kit)**
(<https://www.aorn.org/guidelines/clinical-resources/tool-kits/fire-safety-tool-kit>)
- **[Society of American Gastrointestinal and Endoscopic Surgeons \(SAGES\) – The SAGES Manual on the Fundamental Use of Surgical Energy \(FUSE\)](https://www.sages.org/publications/sages-manuals/sages-manual-fundamental-use-surgical-energy-fuse/)** (<https://www.sages.org/publications/sages-manuals/sages-manual-fundamental-use-surgical-energy-fuse/>)

- **[Pennsylvania Patient Safety Authority – Surgical Fires: Decreasing Incidence Relies on Continued Prevention Efforts](http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SurgicalFires.aspx)** (http://patientsafety.pa.gov/ADVISORIES/Pages/201806_SurgicalFires.aspx)

Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041 or 301-796-7100.

More in Safety Communications

(<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/default.htm>)

2018 Safety Communications (<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm>)

2017 Safety Communications (<https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm>)