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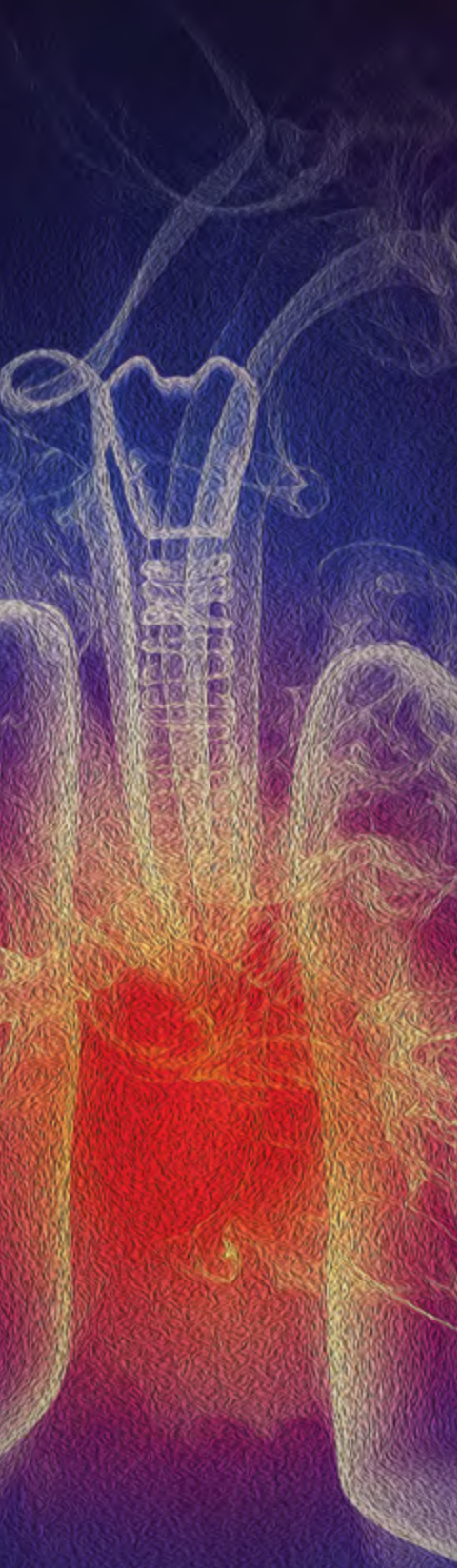
A SELF STUDY GUIDE

RESPIRATORY PROTECTION IN SURGERY

Registered Nurses



RESPIRATORY PROTECTION IN SURGERY

OVERVIEW

Exposure to surgical smoke is an anticipated risk for perioperative team members in all operating room (OR) practice settings. The hazards of surgical smoke in the OR have received increased attention due to the escalating use of various energy modalities, such as electrosurgery, lasers, and ultrasonic devices, all of which generate smoke plume. Moreover, the smoke generated from these devices has been found to contain toxic gases and vapors, bioaerosols, and viruses, which in high concentrations can lead to adverse health conditions. Therefore, all members of the perioperative team should be aware of the concerns related to surgical smoke in the OR and the need to implement effective strategies to minimize the associated hazards; respiratory protection is one measure to protect OR personnel. This continuing education activity will present a review of the risks associated with exposure to surgical smoke. The contents of surgical smoke, as well as the potential respiratory hazards, will be discussed. Surgical masks and surgical respirators will be differentiated in terms of respiratory protection. The recommendations for appropriate use of a surgical respirator for respiratory protection will be outlined.

LEARNER OBJECTIVES

Upon completion of this continuing education activity, the participant should be able to:

1. Discuss the risks associated with surgical smoke.
2. Discuss the airborne contaminates and respiratory hazards of surgical smoke.
3. Explain the differences between surgical masks and surgical respirators.
4. Identify when the use of a surgical respirator is recommended.

INTENDED AUDIENCE

The information contained in this self-study guidebook is intended for use by healthcare professionals who are responsible for or involved in the following activities related to this topic:

- Educating healthcare personnel
- Establishing institutional or departmental policies and procedures
- Decision-making responsibilities for safety and infection prevention products
- Maintaining regulatory compliance
- Managing employee health and infection prevention services

INSTRUCTIONS

Ansell is a Recognized Provider of continuing education by the California Board of Registered Nursing, provider #CEP 15538 and the Australian College of Perioperative Nurses (ACORN). This course has been accredited for 2 (two) contact hours. Obtaining full credit for this offering depends on completion of the self-study materials on-line as directed below. Approval refers to recognition of educational activities only and does not imply endorsement of any product or company displayed in any form during the educational activity.

To receive contact hours for this program, please go to the "Program Tests" area and complete the post-test. You will receive your certificate via email.

AN 85% PASSING SCORE IS REQUIRED FOR SUCCESSFUL COMPLETION. Any learner who does not successfully complete the post-test will be notified and given an opportunity to resubmit for certification.

For more information about our educational programs or perioperative safety solution topics, please contact Ansell Healthcare Educational Services by e-mail at edu@ansellhealthcare.com.

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As employees of Ansell Mrs. Ouellet, Mrs. Richardson, Mrs. Taylor and Ms. Werner have declared an affiliation that could be perceived as posing a potential conflict of interest with development of this self-study module. As a consultant for Ansell Dr Huckfeldt has declared an affiliation that could be perceived as posing a potential conflict of interest with development of this study guide.

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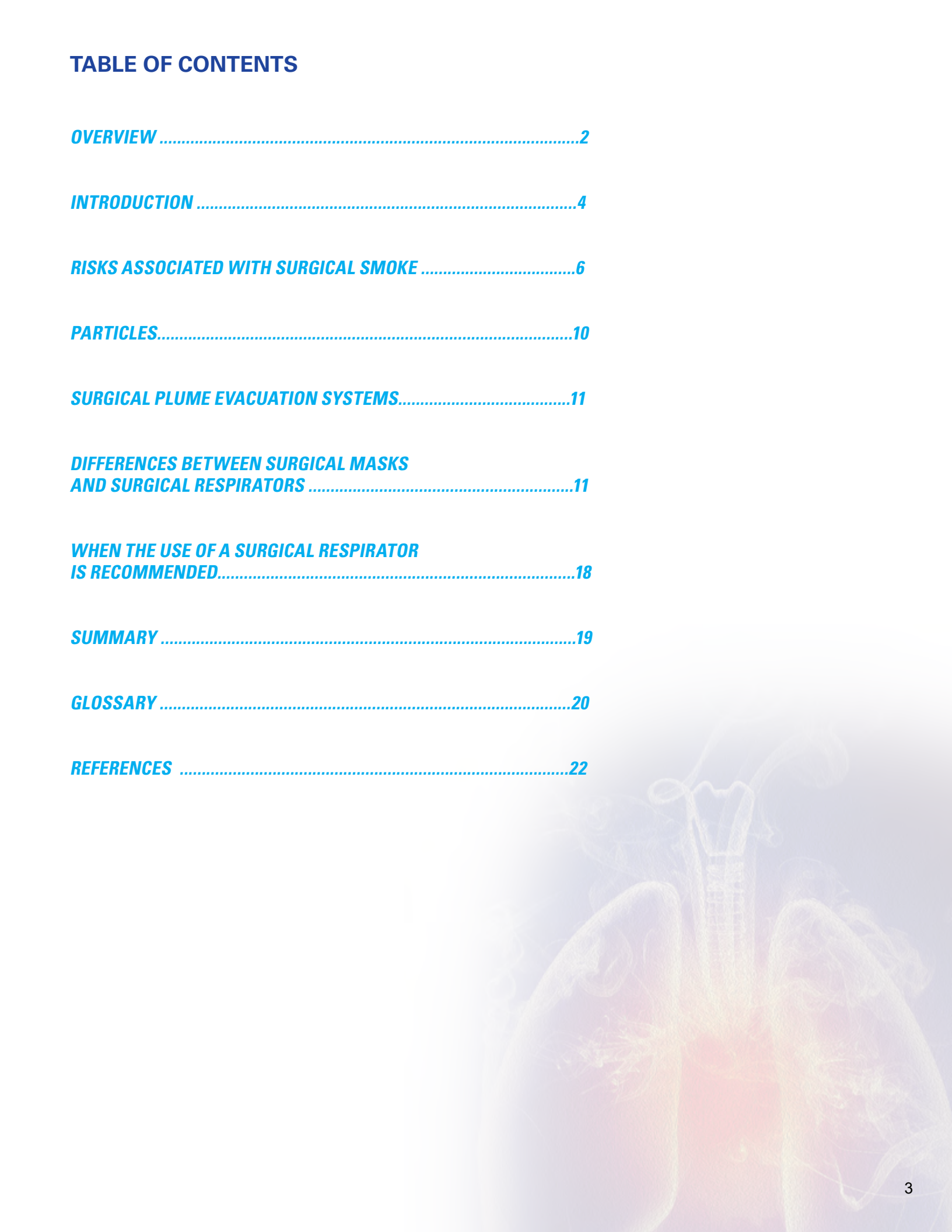
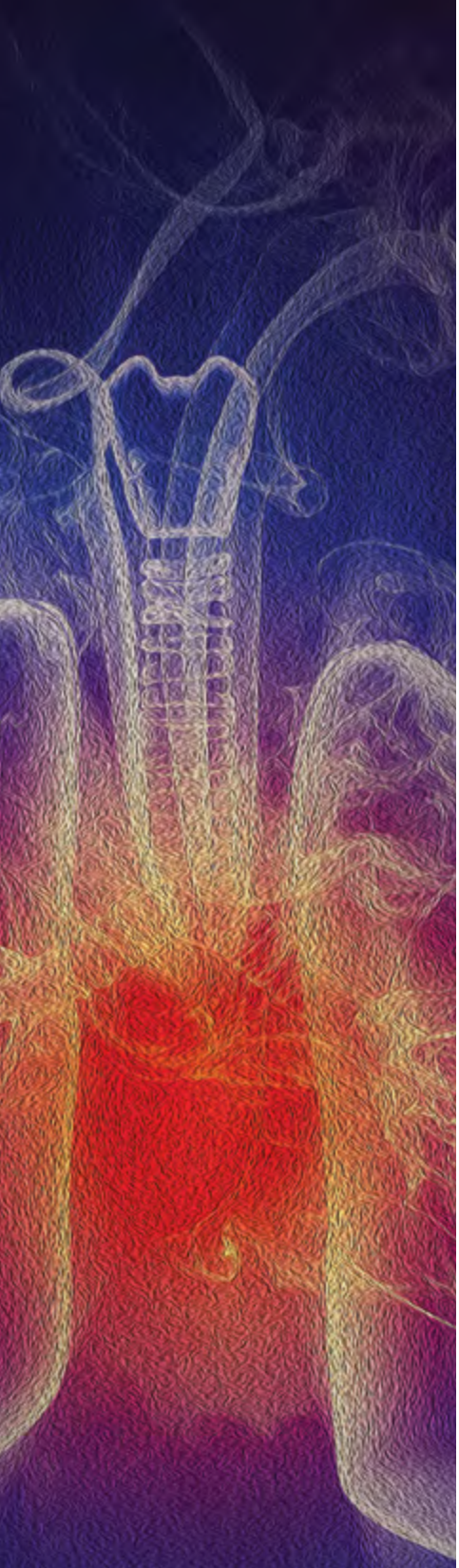


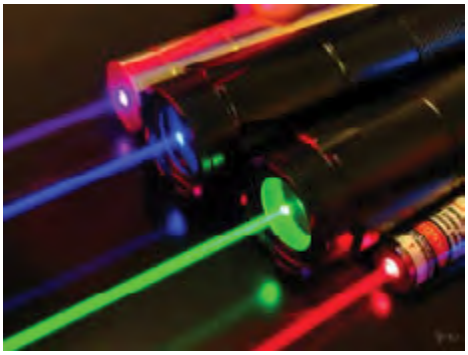


RESPIRATORY PROTECTION IN SURGERY

INTRODUCTION

The inherent nature of the surgical practice setting places staff members at greater risk for occupational exposure to infectious agents. The number of surgical procedures performed continues to rise, as invasive procedures are being performed in clinics and physician offices, in addition to hospitals and ambulatory surgery centers.[1] Smoke is present in any operating room (OR) environment where procedures are performed with the use of heat-producing devices (eg, electrosurgery units, lasers, ultrasonic devices, and high-speed drills, burrs, and saws) to achieve a desired tissue effect (ie, hemostasis or tissue dissection).[2] As the use of these devices continues to increase to support contemporary surgical techniques, there is a corresponding increase in exposure to the smoke generated during these procedures, which poses certain health risks. Approximately 90% of both open and endoscopic procedures generate some level of surgical smoke.[3]

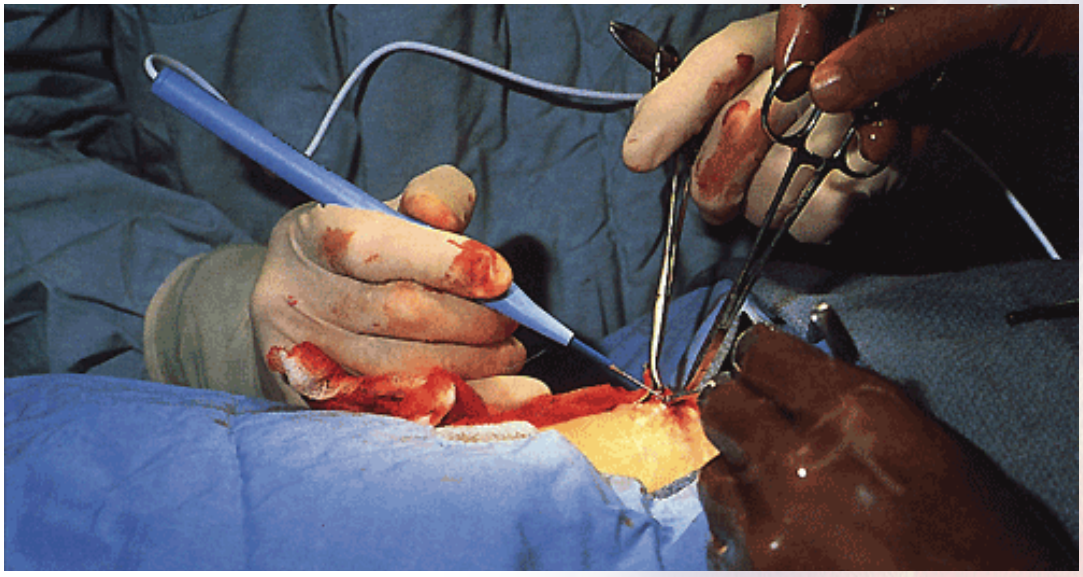
Surgical smoke use has been found to contain toxic gases and vapors, bioaerosols, and viruses, all of which in high concentrations can cause adverse health conditions. In today's dynamic healthcare environment, reducing the risk for transmission of infectious agents and other adverse events remains a primary focus for the perioperative team, especially in the face of newly recognized pathogens and microorganisms that have become resistant to current treatment modalities.[4]

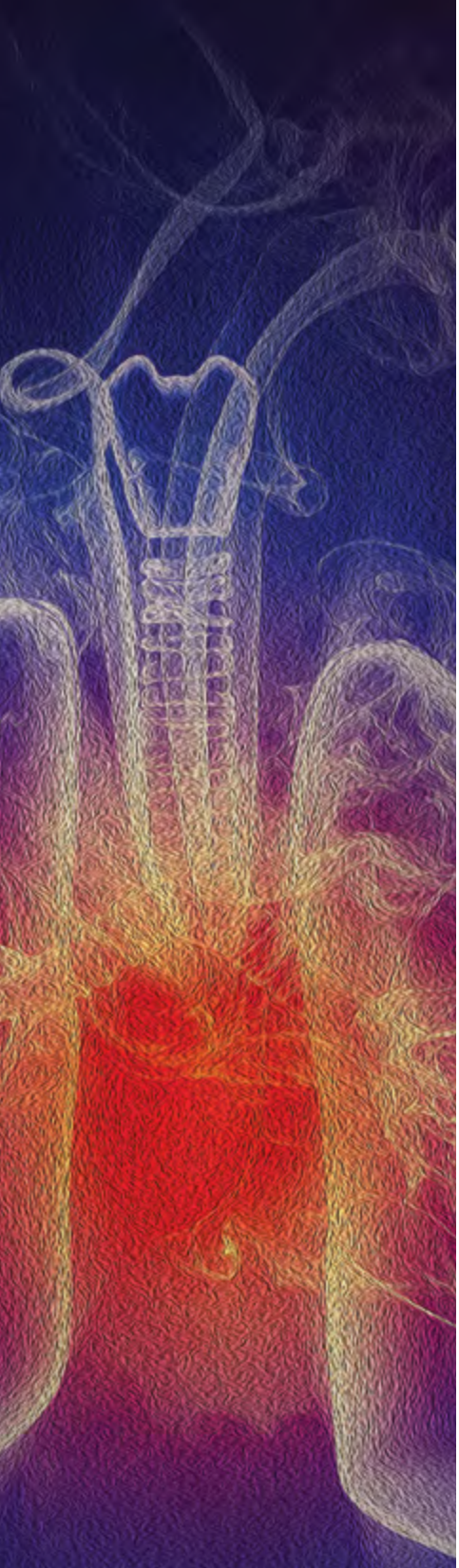


The term surgical smoke is used to describe any gaseous by-product that contains bioaerosols, including viable and non-viable cellular material; however, in the medical literature, the terms plume and aerosol are also used to describe this gaseous by-product.[5,6] The qualities of surgical smoke produced by electrosurgery and laser energy modalities are very similar. Furthermore, both electrosurgery and laser systems generate smoke by the same mechanism: during the procedure (ie, cutting, coagulating, vaporizing or ablating tissue), the targeted cells are heated to the point of boiling, which causes the membranes to rupture and disperse fine particles into the air or pneumoperitoneum (during laparoscopic procedures). The by-product that results from the use of ultrasonic scalpels is often referred to as plume, aerosol, or vapor. The use of ultrasonic energy produces aerosols without a heating (ie, burning) process, which is generally referred to as low-temperature vaporization; however, this low-temperature vapor generally has a greater chance of carrying viable and infectious particles than higher temperature aerosols.

Healthcare workers (HCWs) in the OR, including surgeons, anesthesia providers, nurses, and surgical technologists are exposed to electrosurgery or laser smoke. It is estimated that each year in the United States approximatively 500,000 surgical personnel are exposed. [7]

According to the Association of periOperative Registered Nurses (AORN) and the Australian College of Perioperative Nurses (ACORN), the most effective measure to prevent contaminants found in airborne surgical smoke from reaching the breaching zones of surgical staff is to use effective evacuation equipment. Effective respiratory protection is a second measure to reduce the risk of occupational exposure to surgical smoke and its associated hazards. [8,9]





RESPIRATORY PROTECTION IN SURGERY

RISKS ASSOCIATED WITH SURGICAL SMOKE

OVERVIEW

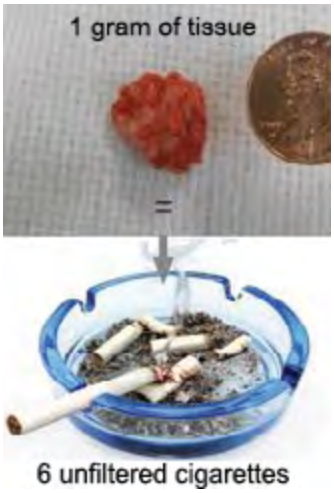
Research conducted over the past several decades demonstrates that surgical smoke can transmit disease. A study that quantified the toxic compounds present in surgical smoke found the presence of irritant, carcinogenic, and neurotoxic compounds in electrosurgical smoke, which may have significant implications for the health and safety of personnel involved in surgical procedures.[10]

In a research study designed to evaluate the potential for disease transmission through plume released from virally infected tissue exposed to a carbon dioxide laser, the collected laser plume was shown to contain papillomavirus DNA is all tested laser settings.[11] The results of an earlier study, conducted to determine if viable malignant cells are present in suspension within the electrocautery plume, confirmed that the application of electrocautery to a pellet of melanoma cells releases these cells into the plume; furthermore, these cells are viable and may be grown in culture.[12] This release of malignant cells may explain the appearance of port metastases at sites that are remote from the surgical dissection or that were never in direct contact with the tumor.

Generally, within five minutes of using electrosurgery during a procedure, particulate matter in the immediate area increases from a baseline measurement of approximately 60,000 particles per cubic foot to over one million particles per cubic foot.[13] In addition, it takes the typical OR air handling system approximately 20 minutes to return particle concentrations to normal after the procedure has been completed.

An early study comparing smoke condensates induced by the use of CO_2-laser and electrosurgery demonstrated that the total mutagenic potency observed was comparable to that of cigarette smoke:

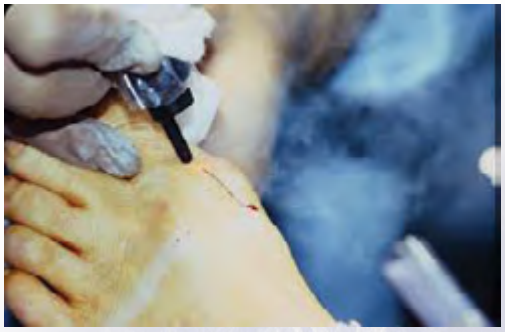
- Using the CO_2 laser on one gram of tissue is like inhaling the smoke from three unfiltered cigarettes in 15 minutes.[14]
- Using electrosurgery on one gram of tissue is like inhaling smoke from six unfiltered cigarettes in 15 minutes.

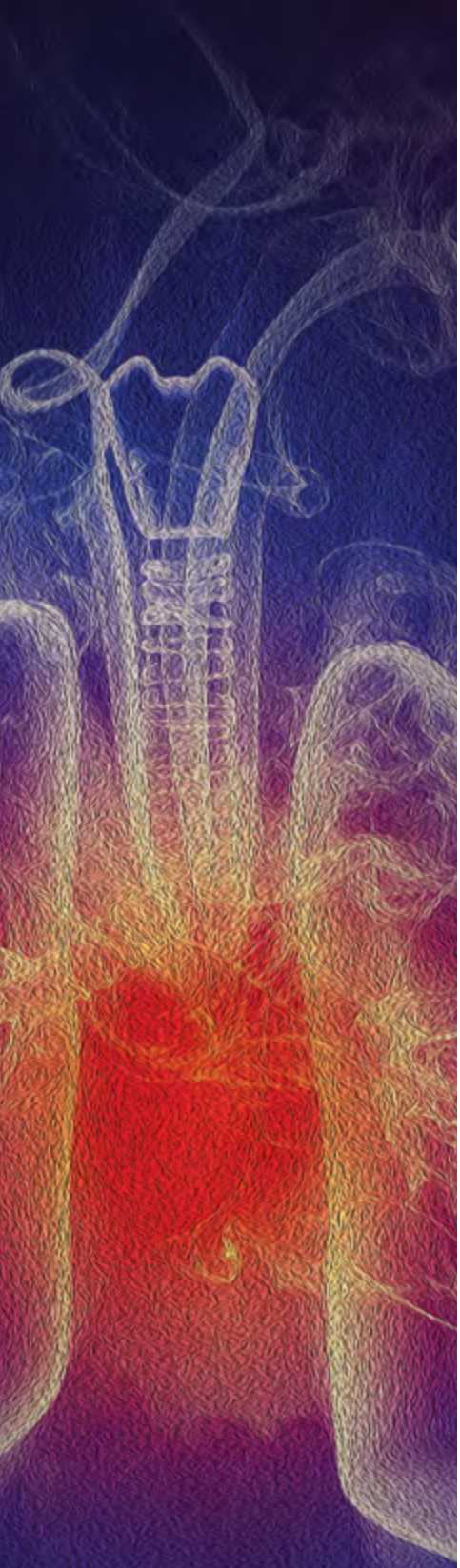


AIRBORNE CONTAMINATES OF SURGICAL SMOKE

Surgical smoke can be seen and also smelled; both the visible and the odorous components of surgical smoke are the gaseous by-products of the disruption and vaporization of tissue protein and fat.[15] Surgical smoke is comprised of 95% water or steam and 5% cellular debris in the form of particulate matter, which contains chemicals, blood and tissue particles, intact viruses, and intact bacteria. The water itself is not harmful; however it acts as a carrier for particulate matter contained in surgical smoke. The concentration of these by-products produced during pyrolysis depends on the type of tissue, power density, and length of time the energy is used on the tissue.

Since the mid-1970s, as the body of evidence documenting the hazardous components of surgical smoke has continued to grow, the chemical composition of surgical smoke has also been well documented (see Table 1).[16] As noted above, surgical smoke contains chemicals and chemical by-products similar to other smoke plumes (eg, cigarette smoke), including benzene, carbon monoxide (CO), formaldehyde, hydrogen cyanide, methane, phenol, styrene, and toluene; these by-products also are known to be carcinogenic.





RESPIRATORY PROTECTION IN SURGERY

Table 1. Chemical Contents of Surgical Smoke[17]

Acetonitrile	1-Decene	4-Methly phenol
Acetylene	2,3-Dihydro indene	2-Methyl propanol
Acroloin	Ethane	Methyl pyrazine
Acrylonitrile	Ethyl benzene	Phenol
Alkyl benzene	Ethylene	Propene
Benzaldehyde	Formaldehyde	2-Propylene nitrile
Benzene	Furfural	Pyridine
Benzonitrile	Hexadecanoic acid	Pyrrole
Butadiene Styrene	Hydrogen cyanide	Styrene
Butene	Indole	Toluene
3-Butenenitrile	Methane	1-Undecene
Carbon dioxide	2-Methyl butenal	Xylene
Creosol	6-Methyl indole	

The most prominent chemicals found in electrosurgery smoke are hydrocarbons, phenols, nitriles and fatty acids.[18] Of these chemicals, acrylonitrile, hydrogen cyanide, and benzene are of great concern, as follows: [19,20]

- Acrylonitrile is a volatile, colorless chemical which can be absorbed through the skin and lungs; it also releases hydrogencyanide.
- Hydrogen cyanide is toxic and colorless and can also be absorbed into the lungs, and through the skin and gastrointestinal tract.
- Benzene is documented as being a trigger for leukemia; therefore, the Occupational Safety and Health Administration (OSHA) mandates permissible exposure limits (PELs) to protect workers from the hazards associated with inhaling benzene.

RESPIRATORY AND HEALTH HAZARDS ASSOCIATED WITH SURGICAL SMOKE

In the past, perioperative personnel may have believed that surgical smoke is not dangerous; however, over the years, there has been greater interest in defining the specific hazards associate with surgical smoke.[21] While there are no known mandatory regulations for evacuation of surgical smoke, the voluntary standards from professional organizations and other studies clearly indicate that a potential danger exists if personnel continuously inhale the substances contained in surgical smoke.

As early as 1996, the United States National Institute for Occupational Safety and Health (NIOSH) recognized the hazards of surgical smoke when it released a hazard control report outlining that at high concentrations, smoke generated by electrosurgical or laser systems causes ocular and upper respiratory tract irritation in healthcare personnel and also creates visual problems for the surgeon; furthermore, the smoke has unpleasant odors and has been shown to have mutagenic potential.[22]

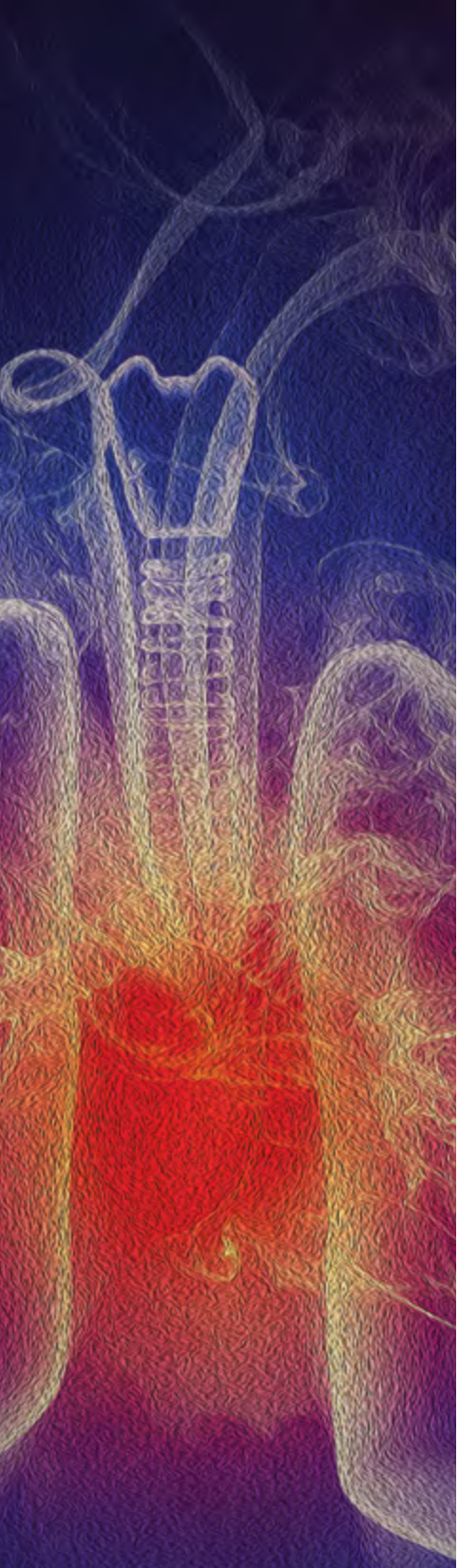
Surgical smoke and aerosols are potentially dangerous to OR personnel; the potential risks include pulmonary irritation and inflammation, transmission of infection, and genotoxicity. Many of the by-products that result from pyrolysis of tissue are respiratory irritants. It has been shown that when laboratory rats were exposed to a relatively large quantity of surgical smoke, they developed pulmonary congestion and lung abnormalities; it has also been shown that surgical smoke can induce both acute and chronic inflammatory changes, such as alveolar congestion, interstitial pneumonia, bronchiolitis, and emphysematous changes in the respiratory tract. Smoke is also mutagenic and therefore genotoxic; the specific mechanism of genotoxicity is most likely multifactorial and may include chemical and biologic modalities.[23]

In addition to respiratory problems, after repeated exposures to surgical smoke, perioperative staff members have reported signs and symptoms that include burning and watery eyes, nausea, and headaches.[24]

Table 2 lists the potential health hazards associated with exposure to surgical smoke.

Table 2. Potential Health Hazards of Surgical Smoke[25]

Acute and chronic inflammatory respiratory changes (ie, asthma, chronic bronchitis, emphysema)
Anemia
Anxiety
Carcinoma
Cardiovascular dysfunction
Colic
Dermatitis
Eye irritation
Headache
Hepatitis
Human Immunodeficiency Virus (HIV)
Hypoxia or dizziness
Lacrimation
Leukemia
Lightheadedness
Nasopharyngeal lesions
Nausea or vomiting
Sneezing
Throat irritation
Weakness



RESPIRATORY PROTECTION IN SURGERY

PARTICLES [26, 27]

NIOSH defines aerosols as a suspension of tiny particles or droplets in the air. Person-to-person transmission of pathogens through the air by means of inhalation of infectious particles is a concern.

Particles 1 – 5 microns in diameter can enter upper airways, while particles 0.1 – 1 microns in diameter may enter lower lungs and alveolar ducts. Examples of particle size:

- Tobacco smoke 0.01 to 3 microns
- Surgical smoke 0.1 to 5 microns
- Viruses 0.02 to 0.3 microns
- Bacteria 0.5 to 10 microns
- Mold spores 1 to 70 microns
- Fungi 2 to >200 microns

Aerosols are emitted whenever an infected person coughs, sneezes, talks, or exhales and by aerosol-generating procedures such as electrosurgery. Pathogens transmitted by aerosols can travel short or long range from the source depending on the size and shape of the particles, the initial velocity, and environmental conditions (e.g., humidity, airflow).

The size of the particles in surgical smoke is also an important consideration in assessing the respiratory hazards of surgical smoke. The different types of heat-producing modalities and devices used during surgery produce different size particles; the smaller the particle size, the farther it can travel to affect the nonscrubbed surgical team members, in addition to those who are scrubbed.[28]

A study that directly measured the speed and distance that smoke particles were ejected from lasered animal skin by laser Doppler velocimetry (LDV) reported speeds recorded just above animal skin were in the range of 9 to 18 meters (29.52 to 59.05 feet) per second.[29] However, when the particles were set in motion, the residual kinetic energy sent the particles up to about 0.87 meter (2.85 feet) from the skin surface.

It is important for perioperative nurses to remain aware of the tools available today to minimize exposure to surgical smoke; this includes implementation of a smoke evacuation system and knowing the differences between surgical masks and surgical respirators in regards to effective respiratory protection.

SURGICAL PLUME EVACUATION SYSTEMS [30,31]

Surgical plume should be removed by the use of a smoke evacuation system to prevent occupational exposure to airborne contaminates generated by energy-based devices such as electrosurgery equipment, radio-frequently units, ultrasonic devices and lasers. Local exhaust ventilation (LEV) is the primary means to protect surgical staff.

Policies, procedures and training should be developed, implemented, reviewed and revised in facilities that use energy-based devices to provide staff with guidance for limiting exposure to surgical smoke. Such polices and procedures may include but are not limited to the following:

1. Surgical smoke shall be confined and contained at the time generated.
2. A smoke evacuation system with a 0.1 micron filter {e.g. ultra-low particulate air (ULPA) with an efficiency rating of not less then 99.999 percent} or higher efficiency particulate air (HEPA) should be used to remove surgical smoke.
3. The capture drive (e.g. wand) of the smoke evacuation system should be placed as close as possible to the smoke source. Generally no greater than two (2) inches away is considered best practice.
4. Evaluators should be used according to the manufacturer's directions.
5. Personnel should receive education and competency validation on all equipment.
6. Periodic monitoring of staff compliance to determine areas of deficiency and recommendation of practice improvements should be initiated.
7. Filters, tubing and wands should be considered as biohazardous waste and handled as such according to local regulations.
8. Personnel should wear respiratory protection masks during the procedure.

DIFFERENCES BETWEEN SURGICAL MASKS AND SURGICAL RESPIRATORS

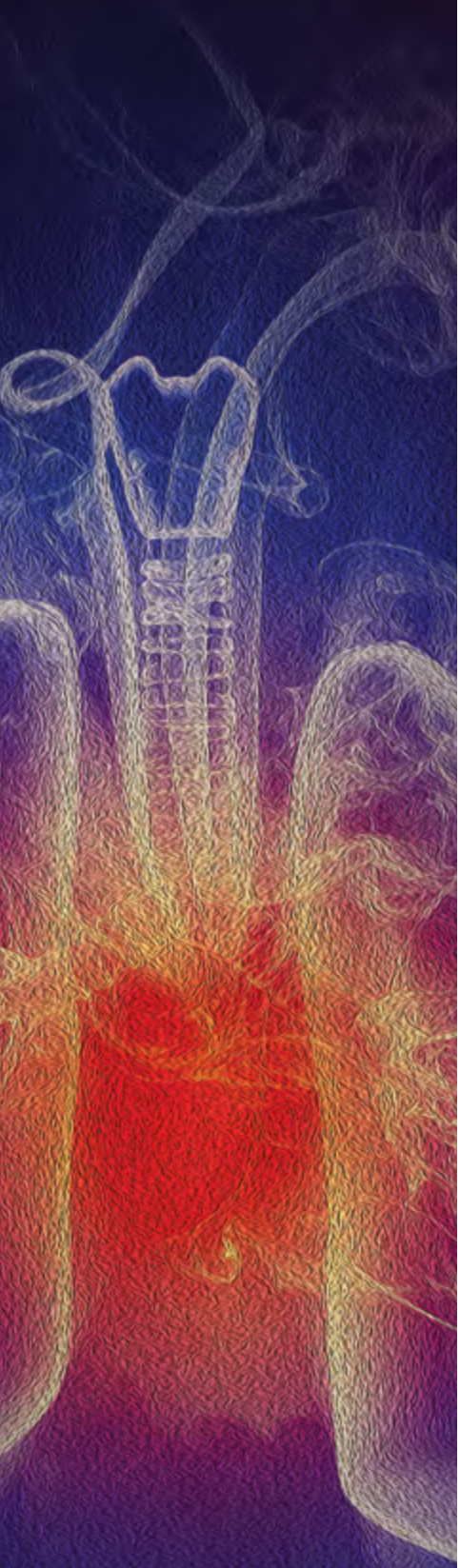
OVERVIEW [32]

Surgical masks are the most commonly used protective facemask in perioperative practice settings. While surgical/medical face masks are intended first to protect the patient and/or working environment from droplets coming from the nose and mouth of the wearer's face, masks to some extent are also worn as a barrier to protect the wearer's face from large droplets and splashes of blood and other body fluids. In certain clinical situations where the potential for exposure to airborne contaminants and infectious agents exists, the use of respiratory personal protective equipment (PPE), such as a surgical respirator, is needed. Surgical masks and surgical respirators vary in intended use, fit against the face, required testing and approval standards. It is important that employers and healthcare workers understand the significant differences between these two types of personal protective equipment. The decision whether or not to require workers to use either a surgical mask or a surgical respirator must be based upon a hazard analysis of the workers' specific work environments and the different protective properties of each type of personal protective equipment.

SURGICAL MASKS [33]

The most important thing to remember about surgical masks is that they are designed to cover the mouth and nose loosely but are not sized for individual fit and therefore will not pass a fit test. Their purpose is to help protect the environment and nearby persons from the wearer's contaminants. The surgical mask provides a barrier preventing contamination of the sterile field or environment from large particles (e.g. spit, mucous) generated by the surgical member wearing the mask. Surgical masks also provide protection to the wearer by reducing the risk of splashes of blood, body fluids, and other secretions from reaching their mouth and nose. While a surgical facemask may be effective in blocking splashes and large-particle droplets, a surgical facemask, by design, does not filter or block very small particles in the air that may be transmitted by coughs, sneezes or certain medical procedures. Surgical masks also do not provide complete protection from germs and other contaminants because of the loose fit between the surface of the facemask and your face. The fitting and filtering attributes of surgical masks are inadequate to provide respiratory protection for the wearer. During inhalation, much of the air passes through gaps between the face and the surgical mask.

Unfortunately, at times surgical masks are used to protect healthcare workers from the aerosols released into the atmosphere from surgical smoke.[34] It is important to note that the filtration efficiency of surgical masks varies; however, in general, surgical masks filter particles to approximately **5 microns in size**.



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Approximately 77% of the particulate matter in surgical smoke is 1.1 microns and smaller.[35] While each facility has its own policy, surgical masks in general are discarded after each procedure. Surgical masks are disposable, single-use devices that should be worn during a single patient encounter by one person; they should not be shared among HCWs.[36]

SURGICAL RESPIRATOR MASKS

Several types of respirators are available today; however, the ones most commonly used by HCWs generally fall into the category of air-purifying filtering facepiece respirators (FFRs).[37]

These personal protective devices seal the face of the wearer (nose and mouth) and are composed of a filter that prevents the passage of a wide size range of hazardous airborne particulate matter, including very small (**0.3 microns or larger in diameter**) dust particles and infectious agents from entering the wearer's breathing space.[38,39] To determine proper fit, wearers must be fit tested to make sure they have selected the appropriate size. The wearer must also perform a "user seal check" each time the respirator is worn to check the respirator-to-face seal.

As with surgical masks, surgical respirators are disposable, single-use devices that should be worn during a single patient encounter by one person; they should not be shared among HCWs.

United States Regulations [40]

The approval process for surgical masks and respirators are substantially different.

Surgical Mask

Fluid Resistant Specialty Surgical Mask with Eye Shield

Surgical Masks[41]

The U.S. Food and Drug Administration (FDA) clears surgical masks for sale in the United States. Surgical masks are not tested by the FDA. The FDA clears the mask for sale after reviewing the manufacturer's test data and proposed claims. The US standard **ASTM F2100-11 "Standard specification for performance of material used in medical face masks"** describes the tests and requirements with which the materials have to comply that are used to produce the masks. The manufacturer performs and submits the results from several tests, including particle filtration efficiency (PFE), bacterial filter efficiency, fluid resistance, flammability, etc. The particulate filter efficiency gives an indication of the quality of the healthcare surgical mask. However, this rating is completely different and far less rigorous than the NIOSH N95 filter efficiency rating and should not be used as a comparison between the two. The filter media of a surgical mask with a PFE greater than 95% may be less than 70% efficient when tested with the NIOSH N95 test method. The bacterial filtration efficiency and fluid resistance tests measure the mask's ability to capture large particles expelled by the wearer and to help reduce the wearer's exposure to splashes respectively.

Surgical masks do not require NIOSH (National Institute for Occupational Safety and Health) approval.

Surgical N95 Respirators[42, 43]

N95 respirators that are cleared by the FDA for use in healthcare settings are called Surgical N95 Respirators. The clearance of these respirators involves the evaluation of safety data from biocompatibility testing and performance testing from fluid resistance and flammability testing. In addition, the Surgical N95 Respirators are NIOSH-certified, which includes filtration efficiency and differential pressure testing to demonstrate that the device meets the N95 respirator performance requirements.

Respirators must be tested and certified by the National Institute for Occupational Safety and Health. NIOSH tests particulate respirators under "worst case" conditions to help ensure adequate performance in the work place. The test protocol includes high flow rate, most penetrating particle size, aerosols that may degrade filter material, etc. Filtering facepiece respirators that are approved under these tests must have "NIOSH" and the filter classification printed on them.

Under NIOSH criteria levels of filter efficiency are 95%, 99%, and 99.97%. Filter materials are tested at a flow rate of 85 lpm for penetration by particles with a mass median diameter of 0.3 micrometers and if certified are placed in one of the following three categories:

- Type 100 (99.7% efficient)
- Type 99 (99% efficient)
- Type 95 (95% efficient)

Ninety-five percent is the minimal level of filtration that will be approved by NIOSH.

Surgeon with N95 Mask

European Regulations [44, 45, 46]

European regulations for testing and certifying respirators and surgical masks are substantially different.

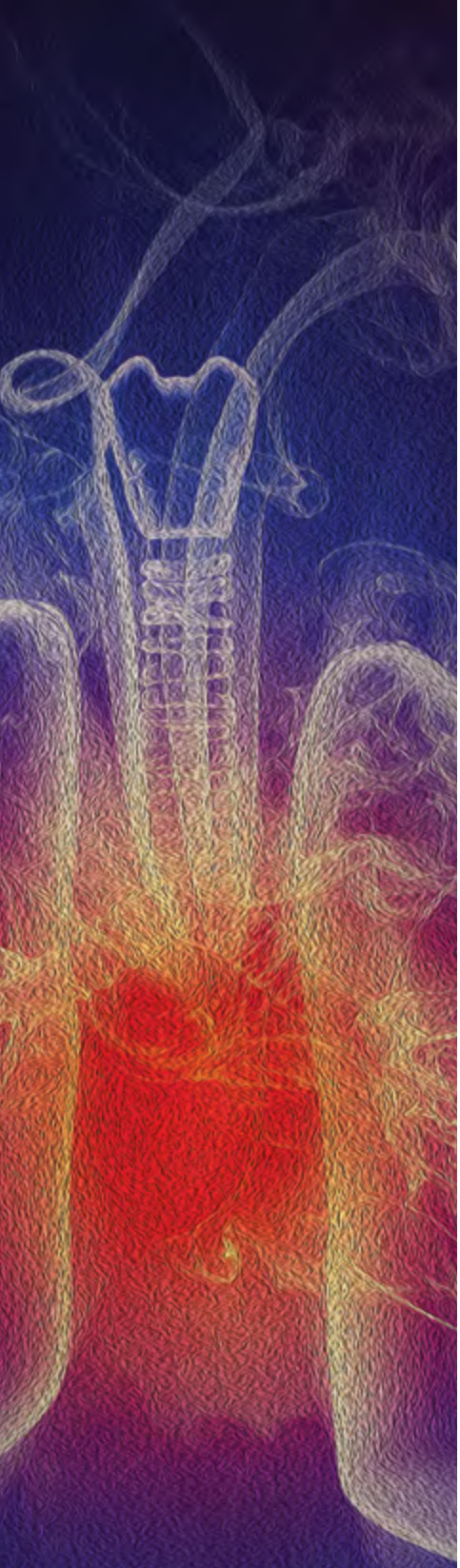
Surgical Masks or Medical Face Masks

Surgical masks or medical face masks are classified as class 1 Medical Devices under the Medical Devices Directive 93/42/EEC. They are intended to be used in operating theaters and healthcare settings with similar requirements and are designed to protect the patients and environment from infective agents from the noses and mouths of the staff and, in certain situations, to protect the wearer against splashes of potentially contaminated liquids.

In Europe, surgical masks must wear a CE-mark and comply with the requirements defined in EN 14683. These requirements concern the construction, design and technical performances as described in **EN 14683 "Medical face masks – requirements and test methods."**

The standard defines surgical masks as: medical devices, covering the mouth, nose and chin ensuring a barrier that limits the transmission of an infective agent between the hospital staff and the patient.

In respect of the performances, the mask is tested as a final product and must comply with different requirements. Based on the test results, the mask is classified in a certain class. The required performance level depends on the end use.



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EN14683 – THE EUROPEAN STANDARD MEDICAL FACE MASKS – REQUIREMENTS AND TEST METHODS

EN 14683 is intended to help facilitate the choice of medical face masks in the European market by standardizing the information and performance data required for the masks.

The present version of EN 14683:2014 includes 4 tests to classify the masks in 3 types:

1. **Bacterial Filtration Efficiency (BFE)**
   The BFE measures the percent efficiency at which the face mask filters bacteria passing through the mask.

2. **Breathing Resistance**
   The Delta P is the pressure drop across a face mask, expressed in Pascal/cm2. The higher the Delta P, the more difficult the mask is to breathe through.

3. **Splash Resistance (ISO 22609)**
   The splash test measures the fluid resistance of the mask.

4. **Microbial Cleanliness (EN ISO 11737)**
   BS EN ISO 11737 Part 1 specifies the requirements to be met in the determination of bioburden.

THE CLASSIFICATION OF MEDICAL FACE MASKS BASED ON THE TEST RESULTS

PERFORMANCE REQUIREMENTS FOR MEDICAL FACE MASK

Test	Type I	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	< 29,4	< 29,4	< 49,0
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

Respiratory Masks (EN 149:2001+A1:2009)

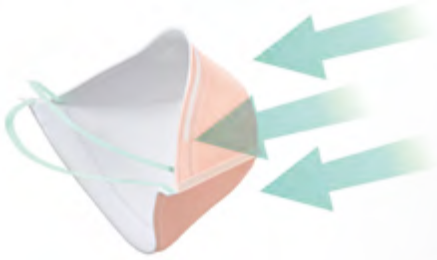
The European Standard addresses respiratory protective devices. Respirators which meet the requirements of EN 149:2001+A1:2009 are designed to protect against solids, water based aerosols and oil based aerosols. There are three classes of protection detailed in EN 149:2001+A1:2009 – FFP1, FFP2 & FFP3 and filtering facepieces are classified according to filter efficiency.

FILTRATION EFFICIENCY

The higher the FFP number, the more protection the respirator can provide if it is used properly.

Class	Max. permitted total inward leakage	Max. permitted filter penetration*	Min. filter efficiency
FFP1	22%	20%	80%
FFP2	8%	6%	94%
FFP3	2%	1%	99%

*Maximum penetration of test aerosol: Sodium chloride test 95 l/min – % max & Paraffin oil test 95 l/min – % max.



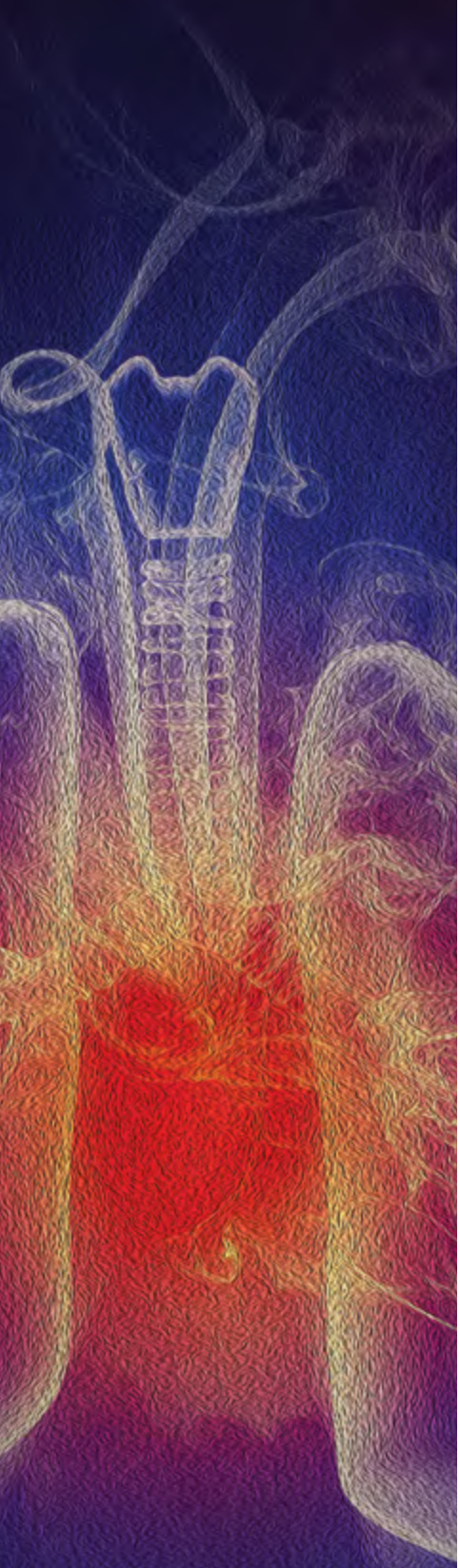
TOTAL INWARD LEAKAGE

Total inward leakage is the leakage through the filter and through the face seal.

BREATHING RESISTANCE

	Inhalation 30 l/min	Inhalation 95 l/min	Exhalation 160 l/min
FFP1	0.6 mbar	2.1 mbar	3 mbar
FFP2	0.7 mbar	2.4 mbar	3 mbar
FFP3	1.0 mbar	3.0 mbar	3 mbar

Note: Delta P of respiratory masks is 10 times higher than surgical masks. (1 mbar = 100 Pascal)



RESPIRATORY PROTECTION IN SURGERY

THE SEAL CHECK

A user seal check is a quick check performed by the wearer each time the respirator is put on. It determines whether the respirator is properly seated on the user's face or needs to be adjusted.

THE FIT TEST

There are two types of fit tests: qualitative and quantitative fit test.

QUALITATIVE FIT TESTING

Qualitative fit testing is a pass-fail test that uses the sense of taste or smell and the user's reaction to an irritant in order to detect leakage into the respirator's face piece.

QUANTITATIVE FIT TESTING

Quantitative fit testing uses a machine to measure the actual amount of leakage into the face piece.

- FFP1 reduces the wearer's exposure to airborne particles by a factor of 4
- FFP2 reduces the wearer's exposure to airborne particles by a factor of 10
- FFP3 reduces the wearer's exposure to airborne particles by a factor of 20

ISO 22609 – SPLASH RESISTANCE

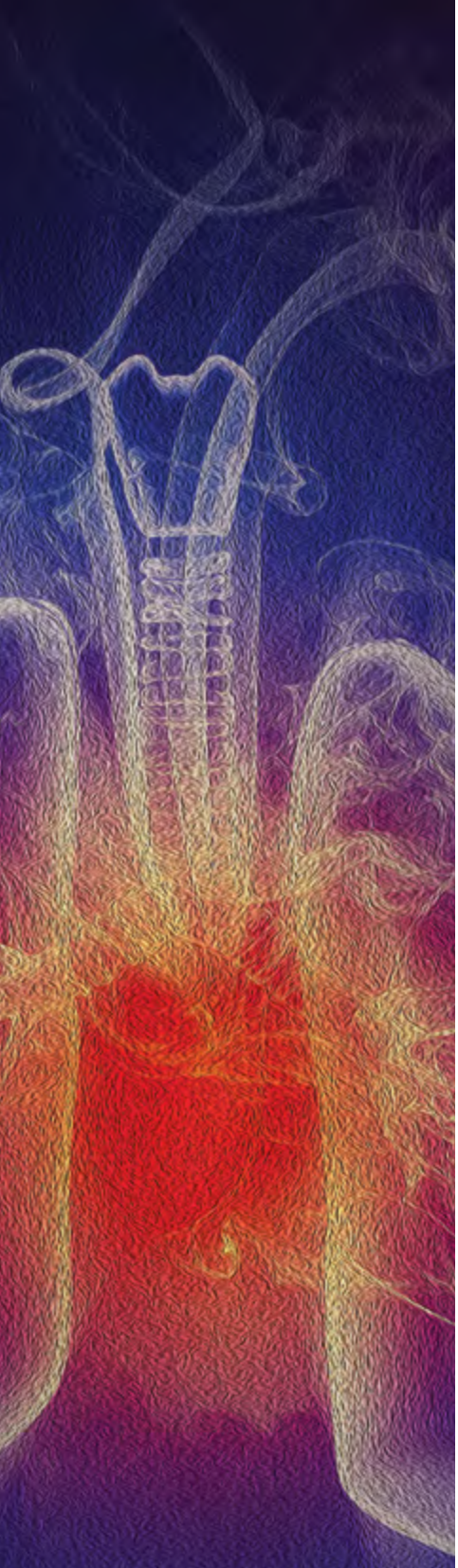
Workers, primarily those in healthcare profession, involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. Respiratory masks which meet the splash resistance protocol test defined by the ISO 22609 standard, fulfill the World Health Organization requirement for protection against Ebola. The mask does not collapse against the mouth and protects efficiently against airborne contaminants as well as liquid splashes.

An in-depth comparison of surgical masks and respirators is outlined on the following page in Table 3.[47,48,49]

Table 3.

Characteristic/ Quality	Surgical Mask	Respirator (e.g. Surgical N95; FFP1; FFP2; FFP3)
Purpose	• To protect the patient and/or working environment from droplets coming from the nose and mouth of the staff, and to some extent, used as a barrier to protect the wearer's face from large droplets and splashes of blood and other body fluids	• To protect from exposure to airborne particles and barrier to splashes*, droplets and sprays • In a healthcare setting, to protect from exposure to biohazards, including bacteria and viruses
Face Seal Fit	• Not designed to fit tightly on the face	• Designed to fit tight to the face, creating a seal around the perimeter of the respirator to improve protection
User Seal Check Requirements	• Not designed for seal check	• Required every time a respirator is donned
Filtration	• Does not effectively filter small particles from the air	• Effectively filters both large and small particles from the air
Leakage	• Leakage occurs around the edge of the mask when the user inhales	• Minimal leakage occurs around the edges of the respirator when the user inhales, when it is properly fitted and donned
Evaluation, Testing and Certification	• U.S. FDA reviews data on filter efficiency (bacterial filtration efficiency and particle filtration efficiency), breathing resistance, fluid resistance, and flammability • Mask demonstrate filtration efficiency no less than another surgical mask already cleared by the U.S. FDA (the minimum filtration level is unspecified) • EU Standard reviews data on filter efficiency (bacterial filtration efficiency only), breathing resistance, fluid resistance, and bioburden (microbial cleanliness)	• Evaluated, tested and certified by NIOSH and per the minimum performance requirements as an N95 FFR • U.S. FDA accepts filter efficiency and breathing resistance based on NIOSH test results from the NIOSH approval evaluation • EU standard reviews filter efficiency and breathing resistance to categorize respirators in 3 groups: - FFP1 (minimum 80% filtration) - FFP2 (minimum 94% filtration) equivalent to N95 - FFP3 (minimum 99% filtration) equivalent to N100 • EU standard also reviews flammability data • EU: Respirators are classified as Personal Protective Equipment only
Intended Use	• Prevent the release of potential contaminants from the users nose and mouth into their immediate environment • Protect the wearer from large droplets, sprays and splashes of body fluids	• Any occupational setting where a respirator is appropriate • Medical use where a sterile field needs to be maintained • To reduce the wearer's exposure to certain airborne particles (all non-oil aresols) and provide a barrier to splashes and sprays
Use Limitations	• One time use i.e., one patient encounter • Wear maximum 3 hours • Should be discarded when it become contaminated with blood or other bodily fluids	• Single use; should be discarded when it: - Becomes wet or visibly dirty; - Damaged or deformed; - No longer forms an effective seal to the face; - Breathing through it becomes more difficult; or - It becomes contaminated with blood, respiratory or nasal secretions, or other bodily fluids
Available Sizes	• Typically available in only one size • Available in various shapes	• Available in multiple size configurations; however, sizing is not standardized among approved models • Some of the sizing options are small, small/medium, medium, medium/large, and large • Variations in shapes of masks as well

* https://ohsonline.com/Articles/2014/05/01/Comparison-Respiratory.aspx



RESPIRATORY PROTECTION IN SURGERY

WHEN THE USE OF A SURGICAL RESPIRATOR IS RECOMMENDED

In addition to the intended uses noted above, there are other clinical scenarios for which the use of a surgical N95 respirator is recommended, as outlined below.

A study conducted by Huckfeldt, et al recommended that the use of an N95 surgical mask/respirator should be considered during the use of electrocautery and laser and also during the care of isolation patients to protect the HCW; it should also be considered when providing care to immunocompromised patients, including those with open wounds, in order to protect those patients.[50] Their study compared the protection provided for the patient from microorganism transfer from the wearer when an N95 surgical mask/respirator or a standard surgical mask was worn. In this study, 10 healthy volunteers were recruited to evaluate the amount of live organisms transmitted from the wearer's oral cavity through either an N95 surgical mask/respirator or surgical mask over a two hour wear period. A square box was fitted with contact blood agar plates secured in a pattern previously tested to provide best microorganism collection (see Figure 3).

Figure 3 – Breathing Box and Agar Plate

Each test subject placed his head in the box with the chin comfortably resting on a chin rest for a two hour period breathing normally. The plates were incubated at 37° Celsius (98.6° Fahrenheit) for 48 hours; colony forming units were then counted and recorded. The two hour period was performed three times by each test subject; without a mask, with a standard surgical mask, and with an N95 surgical mask/respirator. In this study, fit testing was not performed with the N95 mask to represent the realistic pattern of use in a healthcare setting. The results demonstrated that during the 2 hour period during which the N95 surgical mask/respirator was worn, there was a reduction of 80.4% of collected microorganisms in comparison to the unmasked period; the standard surgical mask only provided a 50.4% reduction. Therefore, an N95 surgical mask/respirator provides improved protection for the wearer and may provide improved patient protection from transfer of microorganisms that could lead to healthcare associated infections.

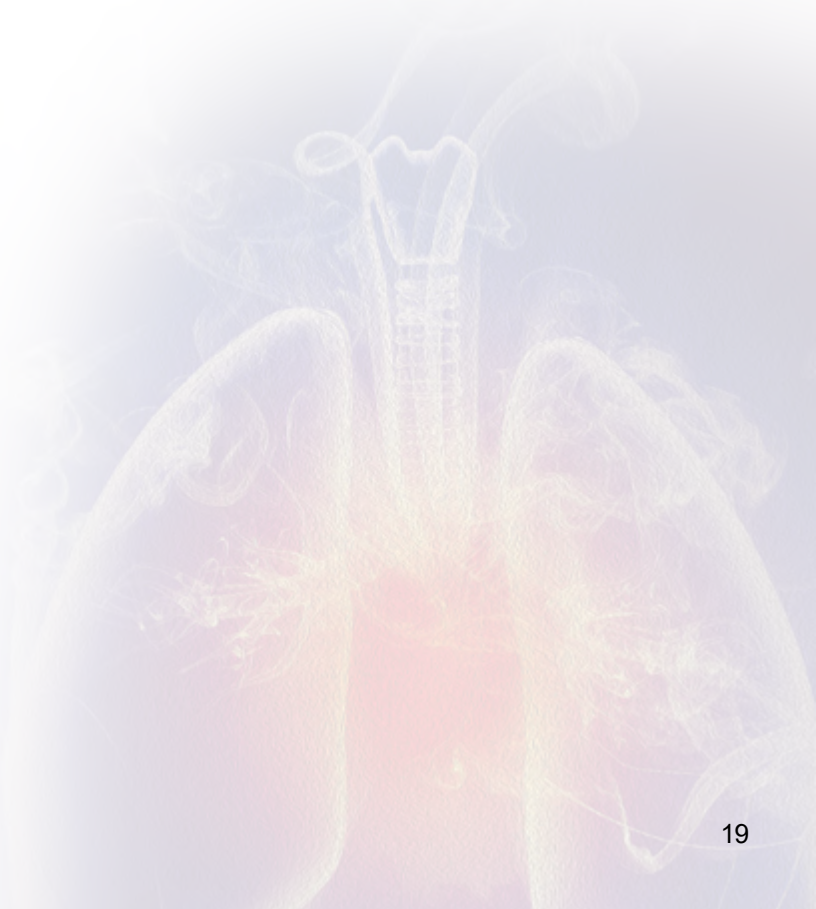
Recommendation X of the AORN Recommended Practices for Electrosurgery states, "Potential hazards associated with surgical smoke generated in the practice setting should be identified, and safe practices established."[51] In regards to respiratory protection, the recommendations include that perioperative personnel should wear a fit-tested surgical N95 FFR or high-filtration surgical mask during any procedure that generates surgical smoke as secondary protection against residual smoke or plume that has escaped capture by a local exhaust ventilation (LEV), which is the primary method of protection. Respiratory protection that is at least as protective as a fit-tested N95 FFR should also be considered in combination with LEV in disease transmissible procedures (eg, human papilloma virus) and also during high-risk or aerosol transmissible disease procedures (eg, tuberculosis, rubeola, varicella). As noted above, high-filtration surgical face masks should not be used as the first line of protection against the inhalation of surgical smoke or as protection from the particulate or chemical contaminants that are present in surgical smoke.

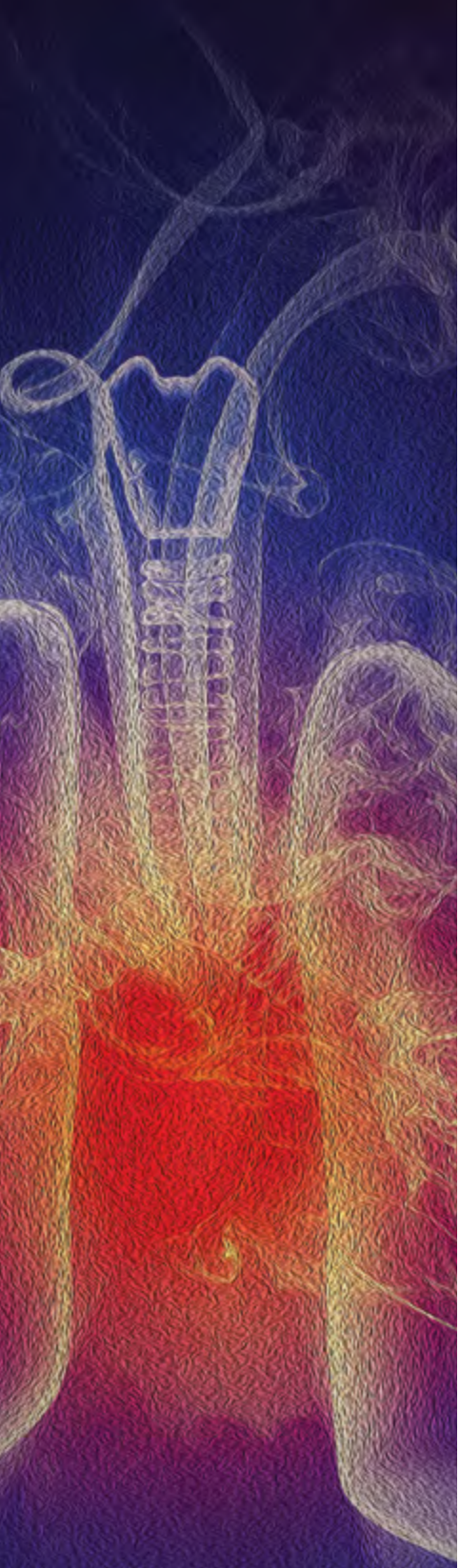
Recommendation V of the AORN Recommended Practices for Laser Safety in Perioperative Practice Settings also states, "Potential hazards associated with surgical smoke generated in the laser practice setting should be identified, and safe practices established."[52] While LEV is noted to be the first line of protection against surgical smoke, respiratory protection (ie, a fit tested surgical N95 FFR or high-filtration surgical mask) should be worn during procedures that generate surgical smoke as a secondary protection measure against residual smoke that escapes capture by LEV. This recommendation also includes that respiratory protection, at least as protective as a fit-tested N95 FFR, should also be considered for use in combination with LEV in disease transmissible procedures and also during high-risk or aerosol transmissible disease procedures, as noted in the Recommended Practices for Electrosurgery.

The Australian College of Perioperative Nurses standard on surgical plume (16, November 2012) recommends the use of 0.1 micron filtration masks as secondary protection against exposure to surgical plume. The primary protection being the plume evacuation system.[53]

SUMMARY

Surgical smoke has been found to be a toxin similar to cigarette smoke; in addition, it is well documented that surgical smoke contains potentially harmful, mutagenic biological materials, gases, and particulates. Members of the surgical team continue to be exposed to the hazards of surgical smoke, especially as the use of various energy modalities to support today's surgical techniques continues to increase. As safety advocates, perioperative nurses must remain aware of the potential risks and hazards of occupational exposure to surgical smoke, as well as the various types of respiratory protection devices available. All members of the perioperative team know that wearing appropriate respiratory protection devices is a key component in minimizing the spread of potentially infectious diseases, especially in the face of today's drug resistant organisms, newly recognized pathogens, and knowledge of the health risks associated with surgical smoke. To reduce occupational exposure to certain airborne particles contained in surgical smoke, LEV and a surgical respirator is needed. The appropriate use of respiratory protection in surgery is a critical component in effective personal protection in order to reduce the hazards of occupational exposure to the airborne pathogens and harmful particulates contained in surgical smoke.





RESPIRATORY PROTECTION IN SURGERY

GLOSSARY

ACRYLONITRILE
A volatile, colorless chemical which can be absorbed through the skin and lungs; it releases hydrogen cyanide.

AEROSOL
A liquid or solution dispersed in air in the form of a fine mist.

AIRBORNE CONTAMINANT
A substance carried by or through the air that contaminates (infects, pollutes, defiles) another substance.

BENZENE
A colorless, volatile liquid hydrocarbon; it is a by-product in the destruction of coal and coal tar.

BIOAEROSOL
An aerosol containing biologically active bacteria, spores, viruses, toxins, and other similar material.

ELECTROSURGERY
The cutting and coagulation of body tissue with high-frequency (ie, radio frequency) current.

EMPLOYEE EXPOSURE
In regards to respiratory protection, exposure to a concentration of an airborne contaminant that would occur if the employee were not wearing respiratory protection.

FIT FACTOR
The quantitative estimate of the fit of a particular respirator to a specific person; it generally estimates the ratio of the concentration of a substance in the ambient air to its concentration inside the respirator when it is worn.

FIT TEST
The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual HCW.

GENOTOXIC
Damaging to DNA and therefore capable of causing mutations or cancer.

HIGH-FILTRATION SURGICAL MASK
A mask that has the filtering capacity of particulate matter at 0.3 microns to 0.1 microns in size.

HYDROGEN CYANIDE
An extremely poisonous and colorless liquid or gas.

LASER
An acronym for light amplification by stimulated emission of radiation; a surgical modality/device that produces an intense, coherent, directional beam of light by stimulating electronic or molecular transitions to lower energy levels .

LASER-GENERATED AIRBORNE CONTAMINANTS
Particles, steam, and toxins produced by the vaporization of target tissues.

MUTAGEN
A substance that causes the occurrence of a sudden variation in some inheritable characteristic in a germ cell of an individual animal or plant.

PARTICULATE
A formed element or discrete body within a surrounding liquid or semi-liquid material.

PERMISSIBLE EXPOSURE LIMIT (PEL)
The permissible exposure limit of a hazardous substance, which is enforceable by OSHA.

PERSONAL PROTECTIVE EQUIPMENT (PPE)
Protective equipment (eg, masks, gloves, fluid-resistant gowns, goggles, and face shields) for eyes, face, head, and extremities; protective clothing; respiratory devices; and protective shields and barriers designed to protect the wearer from injury.

PYROLYSIS
Decomposition or transformation of a chemical compound caused by heat.

RESPIRATOR
A personal protective device that is worn on the face and covers at least the nose and mouth; it is worn to reduce the wearer's risk of inhaling hazardous airborne particles (including infectious agents and dust particles), gases, or vapors. A surgical N95 respirator prevents at least 95% of particles from passing through the filter.

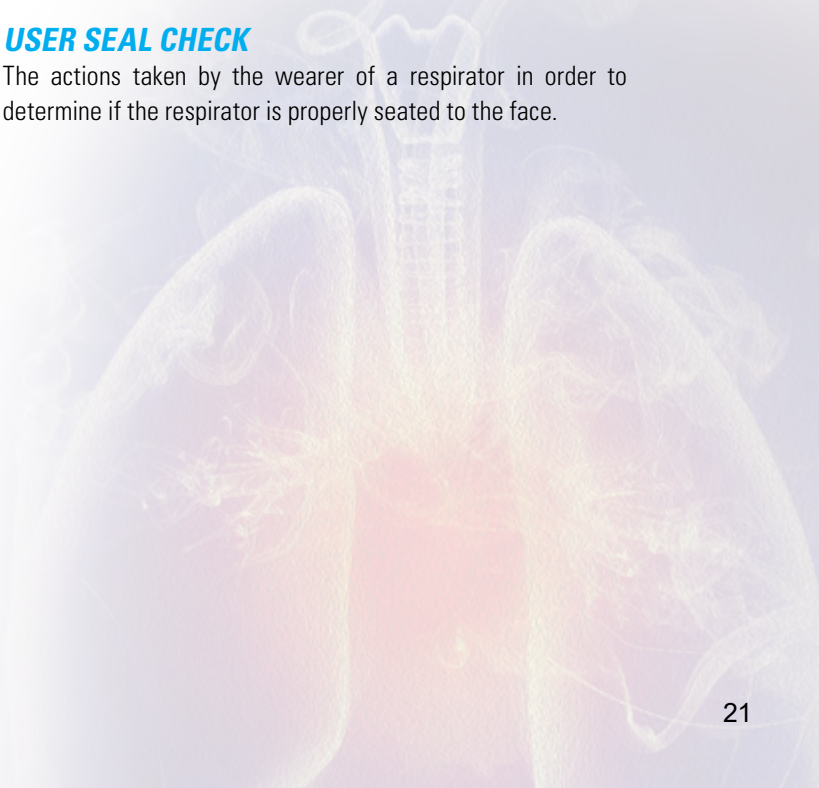
QUALITATIVE FIT TEST
A pass/fail test to assess the adequacy of N95 respirator fit, as determined by an individual's response to the certain aerosolized test solutions.

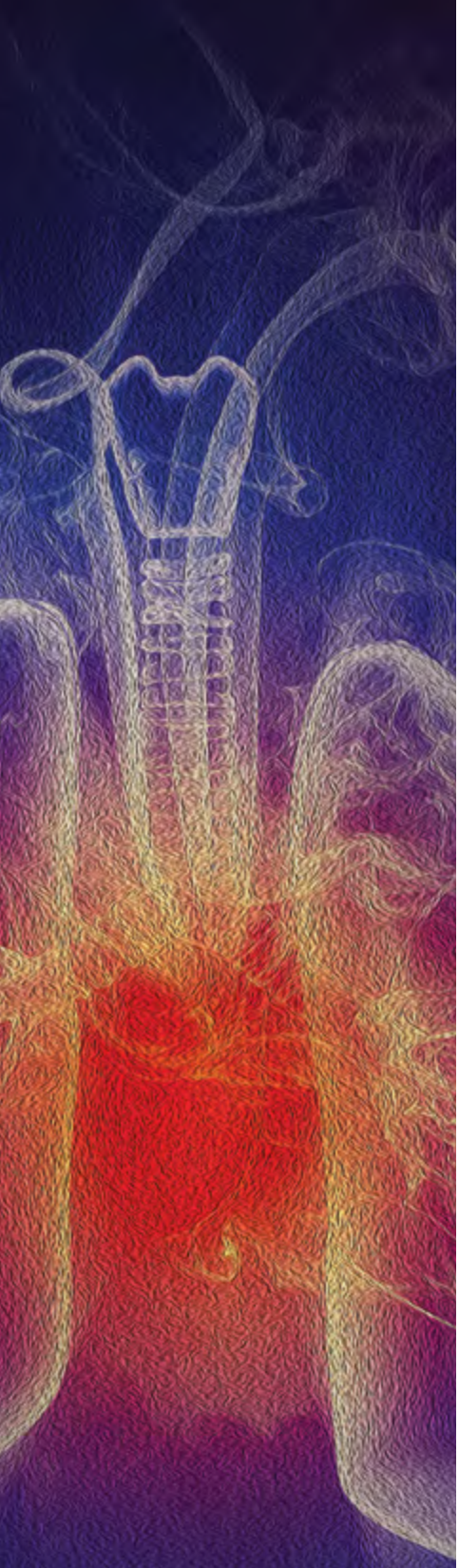
QUANTITATIVE FIT TEST
The test assessing the adequacy of N95 respirator fit by numerically measuring the amount of leakage into the respirator.

SURGICAL FACE MASK
A device worn over the mouth and nose by members of the perioperative team during a surgical procedure to protect both the HCW and patient from the transfer of microorganisms and body fluids; it also protects the HCW from contact with large infectious droplets up to approximately 5 microns in size.

SURGICAL SMOKE
Smoke that is generated when tissue is heated and cellular fluid is vaporized by the thermal action of an energy source.

USER SEAL CHECK
The actions taken by the wearer of a respirator in order to determine if the respirator is properly seated to the face.





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