PALL Medical

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Laparoshield™ Laparoscopic Smoke Filter

Protect Patients and Staff

- Reduces exposure to harmful chemicals, bacteria, viruses, and viable cells
- Keeps field of view continually clear
- Eliminates odors
- Double peel-pouch for presentation to the sterile surgical field
- Single-use disposable

Outlaw Surgical Smoke!

*Filtration. Separation. Solution.*SM

Surgical Smoke Poses Risks

The destruction of human tissue by electrosurgical devices, lasers, and ultrasonic scalpels creates gaseous byproducts that are commonly referred to as surgical smoke or plume. Surgical smoke is produced by electrocautery devices and is characterized by smaller particles that pose a chemical hazard. Plume is produced by lasers and ultrasonic scalpels and generally contains larger particles that may contain viruses and viable cells that pose a biological hazard.[1,2]

In a position statement on surgical smoke issued in 2008, the Association of PeriOperative Registered Nurses (AORN) declared, "AORN believes that exposure to surgical smoke and bio-aerosols can and should be controlled. Health care professionals are responsible for learning about surgical smoke and bio-aerosols and taking steps to minimize the risks associated with these hazards.*"

Even a short exposure to laser plume during minimally invasive surgery has been reported to lead to changes in the biochemical conformation of hemoglobin in patients. The fact that operating room personnel are chronically exposed to these substances is cause for concern.[3]

Although the chemical and biological composition of surgical smoke has not yet been fully characterized, those components that have been identified to date clearly warrant the treatment of surgical smoke as potentially hazardous.

Odor and Mutagenic Chemicals

Enduring the noxious odor of surgical smoke has become accepted as a routine consequence of working in a modern operating room. However, instead of merely being regarded as unpleasant and annoying, this odor should be recognized as an indicator of the presence of chemical byproducts derived from the incineration of proteins and lipids by laser and electro-surgical instruments.[4,5] In addition to possible long term effects, these chemicals may cause headaches, as well as, irritation and soreness in the eyes, nose, and throat.[4-7]

A partial list of the chemicals contained in surgical smoke appears below.

*http://www.aorn.org/PracticeResources/AORNPositionStatements/SurgicalSmokeAndBioAerosols

Viable Viruses

There are many examples of viable viruses being identified in surgical smoke produced by laser (CO_2, ER:Yag, and ND:Yag) and electrocautery devices at a wide range of power settings.[8-14] HIV RNA contained in laser smoke generated by a CO_2 laser may remain intact for up to 14 days.[15]

Surgeons using CO_2 lasers have been shown to exhibit higher incidences of nasopharyngeal lesions, and the inhalation of laser plume that contains viable Human Papilloma Virus (HPV) increases their risk of acquiring nasopharyngeal warts.[16] The source of laryngeal papillomatosis diagnosed in a surgeon who used an ND:Yag laser has been traced to viral particles in the laser plume from one of his patients.[17] Furthermore, CO_2 laser plume from a cutaneous bovine papillomavirus-induced lesion was used to induce disease when reinoculated onto the skin of calves.[18]

Viable Cells

The scientific literature documents many studies that have demonstrated that intact cells and blood components are aerosolized by lasers and ultrasonic scalpels.[10,14-19]

The liberation of viable cells during the performance of laparoscopic surgery has been considered to be a possible cause of subsequent tumor growth at the port sites (port-site metastasis). Metastases have also been documented at port sites distant from the area of cancerous tissue removal.[10,20-27]

Small Particles

Particles in the size range of 0.5-5 microns are considered to be "lung damaging dust" because they are able to penetrate to the deepest regions of the lungs.

In CO_2 laser plume and electrocautery smoke, particles ranging in size from 0.07-25 microns have been observed.[15,16,28] In animal experiments the presence of these particles caused congestive interstitial pneumonia, bronchiolitis, and emphysema.[10,20,27]

Poor Visibility

A continually clear surgical field of view is critical to efficient surgical procedure turnover. Waiting for surgical smoke to spontaneously dissipate or having to resort to desufflating the pneumoperitoneum to clear the field of view unnecessarily lengthens procedures and exposes the patient and healthcare personnel to health risks. In addition, poor visibility can lead to surgical team distraction, frustration, and procedural errors.

Chemicals in Surgical Smoke

- Acrolein
- Acetonitrile
- Acrylonitrile
- Acetylene
- Alkyl benzenes
- Benzaldehyde
- Benzene
- Benzo nitrile
- Butadiene
- Butene
- 3-Butene nitrile
- Carbon disulfide
- Carbon monoxide
- Creosols
- 1-Decene
- 2,3-Dihydro indene
- Ethane
- Ethene
- Ethyl benzene
- Ethylene
- Ethynyl benzene
- Formaldehyde
- Furfural
- Hexadecanoic acid
- Hydrogen cyanide
- Indole
- Isobutene
- Methane
- 6-Methyl indole
- 2-Methyl propanol
- 3-Methyl butenal
- 2-Methyl furan
- 4-Methyl phenol
- Methyl pyrazine
- Phenol
- Polyaromatic Hydrocarbons
- Propene
- Propylene
- 2-Propylene nitrile
- Pyridine
- Pyrrole
- Styrene
- Toluene
- 1-Undecene
- Xylene

PALL Medical

The Pall Laparoshield™ Laparoscopic Smoke Filter

Patient and Staff Protection
The Pall Laparoshield smoke filter allows safe and rapid evacuation of surgical smoke throughout the surgical procedure. It minimizes the exposure of patients and staff to the harmful biological and chemical components of surgical smoke.

Removes Chemical Contamination
The Pall Laparoshield smoke filter contains an activated carbon absorbent that removes volatile compounds from surgical smoke and eliminates odor.

Removes Particulate Contamination
The Pall Laparoshield Smoke Filter is a highly efficient particulate filter that retains >99.999% of particles of 0.02 microns in diameter (MS-2 virus). These particles are not retained by surgical masks.[29-31]

Removes Viable Bacteria, Viruses and Cells
The Pall Laparoshield Smoke Filter removes >99.999% of bacteria, viruses, and cells from surgical smoke, reducing the risk of infection to surgical staff.

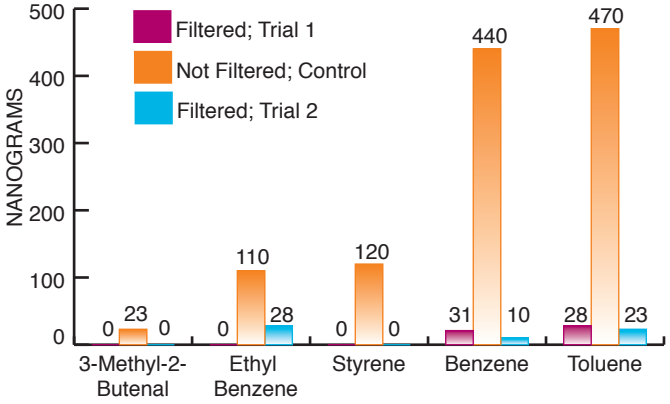
Easy and Safe to Attach
The universal luer lock connector allows for a leak-free connection to the trocar. The rotating hub of the luer lock prevents twisting of the tubing during connection.

Ready to Use
Double peel-pouch sterile packaging permits easy presentation to the sterile surgical field.

Convenient to Use
The Pall Laparoshield smoke filter is a passive filter that uses the continual flow of gas into and out of the pneumoperitoneum to eliminate surgical smoke. No additional equipment is required to use it.

Maintain Surgical Procedure Continuity
The Pall Laparoshield smoke filter is equipped with a roller clamp that enables continual gas flow to purge surgical smoke during procedures that require extensive use of electrocautery or lasers. Interruption of surgical procedures due to vision impairment is avoided, and overall procedure time is decreased.

Technical Performance

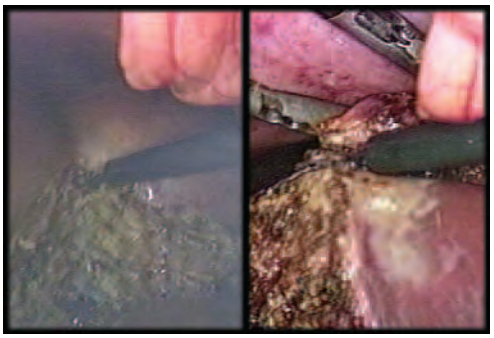


Results of internal Pall Medical testing. Smoke generated using electrocautery on beef liver.

Trial 1 represents the amount of chemical present after filtration of smoke generated in 60 seconds of cautery. Control represents amount of chemical present in smoke after 60 seconds of cautery and no filter.

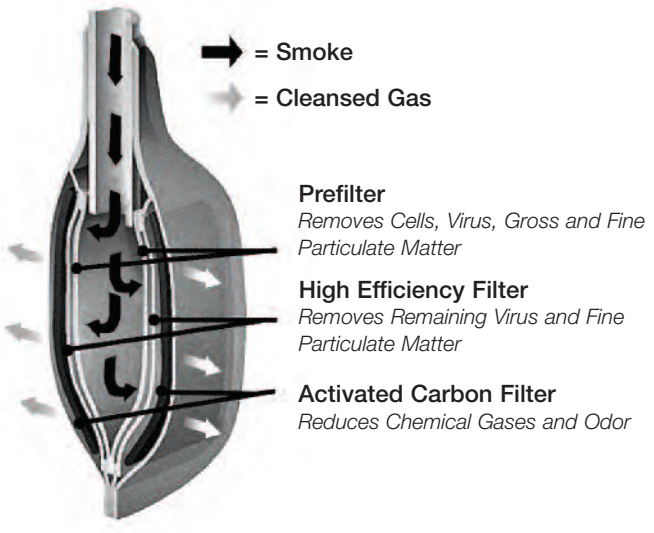
Trial 2 represents the amount of chemical present after filtration of smoke generated in 180 seconds of cautery.

Pall Laparoshield Smoke Filter Improves Visibility of Surgical Field



Without Filter *With Filter*

Pall Laparoshield Smoke Filter Cross Section



Specifications

Working Pressure
15 mm Hg

Flow Rate
Maximum 12 L/min at 15 mm Hg.
Can be adjusted down using roller clamp.

Service Period
One procedure (single patient)

Cellular/Bacterial Retention
99.999%

Reduction of Aerosolized Virus (MS-2)
99.999%

Inlet Fitting
Male luer with rotating hub, conforms to ISO594-2:1996

Package Type
Double peel-pouch

Sterilization Method
Ethylene oxide

Ordering Information

Part Number	Description	Pkg	Quantity
LSF1	Laparoshield™ Laparoscopic Smoke Filter	Individually packaged, sterile	10/case

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