



## Recommendations - USA

### ECRI

- The filter should be used during all laparoscopic procedures to protect the patient from exposure to particulates originating in the external CO<sub>2</sub> gas cylinder and to potentially pathogenic micro-organisms contained in a contaminated laparoscopic insufflator
- Filter should be compatible with the insufflator
- Discard filter after each procedure



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## Recommendations - UK

Medical Devices Agency (Now Medicines and Healthcare products Regulatory Agency -MHRA)

- The MDA has received reports that ‘...laparoscopic insufflators became contaminated with patient fluids.’
- ‘ACTION: ..ensure that any bacterial/viral filter recommended...is fitted appropriately.’

MDA Safety Notice 1996 SN9602. Medical Devices Agency

## Recommendations - Canada

### Canadian Health Protection Board

- Reports on contamination of laparoscopic insufflators with patient fluids:
  - “The Health Protection Board consider these failures as having occurred under normal working conditions”
  - “Most brands of insufflators will allow backflow under single fault conditions”
- ‘Several recent incidents in which the internal gas circuit of the insufflator was contaminated with patient fluids.’
- ‘Always use a **hydrophobic** bacterial filter...and change it after each procedure.’

## Recommendations - Australia

Health Department of Western Australia

- Laparoscopic insufflator – patient filters:
- ‘Theatre staff should use a **hydrophobic** bacterial filter to prevent backflow of fluids.’ ‘Replace...filter after each procedure.’
- ‘Use of insufflators without a **hydrophobic** bacterial filter in a circuit creates a potential hazard of patient cross contamination.’

## Recommendations -Germany

German Association of Surgeons

„... If gases are being insufflated to sterile body compartments, a filter must be used“



## Recommendations -France

Centre de Coordination de la Lutte contre les Infections nosocomiales de l'Interrégion Paris-Nord, 2000

**“At every intervention the use of the disposable, sterile, hydrophobic, bacterial filter is indispensable.**

**This is to prevent:**

- Contamination by the insufflation gas
- Passage of micro-organisms (aerosolized and in the smoke)
- Liquid backflow

**Requirements for the filter**

- Sterile
- Adapted to the ward's requirements
- Adequate resistance at the flow rates needed
- Adequate connectors and tubing fitments“



## Recommendations

**AORN – 2008** (American Association of periOperative Registered Nurses)

- AORN recommends the following risk reduction strategies:
  - Use local exhaust ventilation (.1 micron filtration at 99.999% efficiency)
    - ...
    - Laparoscopic evacuation/filtration systems
  - ...

## Recommendations

### EU-Guideline 98/24/EWG Art.6,1. - 1998

- The employer has to ensure that the risk imposed on health and safety of an employee by a dangerous chemical substance at work is reduced to a minimum.



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## Recommendations

OSHA - USA

Recommendations for Laser and ESU Smoke Hazards

- Provide Safe Work Environment:  
“The primary objective is to control occupational diseases caused by breathing air contaminated with harmful substances.”
- Surgical Masks Are Inadequate Protection

## Recommendations

AORN - USA

“Exposure to smoke plume...should be reduced.  
(It) ...exposes the surgical team to blood products,  
fluid and cellular debris.”

“Patients and peri-operative personnel should be  
protected from inhaling the smoke generated from  
electrosurgery. “



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## Recommendations

MHRA – UK

Guidance on the safe use of lasers in Medical & Dental Practice  
(1994)

“ A properly designed, dedicated smoke evacuator should feature a primary filter which removes airborne particles down to sub-cellular size, and a secondary carbon filter which removes odours”

## Recommendations

E. Alp *et al.*, University Hospital Nijmegen, Netherlands:  
**Surgical smoke and infection control**

“Recently, filters have become available that can be attached to the Luer-Lock valve on the cannula and can be set to allow continuous ventilation and filtration of the peritoneum at a rate that does not exceed the inflow rate of the insufflator. These add-on filters have been shown to reduce operative time by practically eliminating the need to interrupt the procedure and release the accumulated smoke that obstructs the surgeon's view. These filters remove most of the harmful chemicals and nearly all biological material that might be present and eliminate most of the smoke's odour.”