PALL Medical

Technical Report

Bacterial and Viral Retention of the Pall *LaparoShield*® Laparoscopic Smoke Filtration System

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Introduction

Use of lasers and electrocautery equipment during laparoscopic surgery leads to the generation of surgical smoke, a complex mixture which contains potentially hazardous chemicals, particles of the size range considered to have lung damaging effects[1-6] and viable cells and viruses. The **Pall** *LaparoShield* Laparoscopic Smoke Filtration System removes harmful chemicals and particulate matter and allows for a safe and rapid evacuation of smoke, leading to a better view of the surgical site.

This report provides data to confirm that the **Pall** *LaparoShield* Laparoscopic Smoke Filtration System significantly reduces odour and organic volatiles, and has an airborne bacterial and viral removal efficiency of >99.999%.

Materials and Methods

Bacterial and Viral Removal

The two test microorganisms used in this study were *Brevundimonas diminuta* (ATCC 19146) and Bacteriophage MS-2 (ATCC 15597).

The test rig consisted of a nebuliser, mixing chamber and microorganism sampling system. A DeVilbiss # 40 (De Vilbiss Co, Somerset, P.A.) nebuliser generated aerosols of the test microorganism into the mixing chamber with a controlled nebulisation pressure of 0.61 – 0.65 bar. 5 mL suspension of microorganism was placed into the nebuliser and the residual volume was measured after each challenge test. Dry air (-40°C dew point) was simultaneously introduced to the mixing chamber at a flow rate of 28.3 L/min. A vertical evaporator column was then used to ensure drying of the aerosol droplets and the presentation of a mono-dispersed aerosol challenge to the test filters. A specially designed housing was made to contain the test filter, with an empty housing used as a control. Each of the housings was then connected to a 14 L/min impinger (Ace Glass Inc, New Jersey) containing 20 mL phosphate buffer for capturing microorganisms. An electronic vacuum-switcher box controlled alternate sampling between the test and control housings at 5-second intervals, drawing the aerosol through either the test or control impingers.

The total challenge test time was 6 minutes followed by 2 minutes dry airflow to flush out residual aerosol in the apparatus.

Bacterial or viral concentrations in the upstream and downstream impingers were determined by colony or plaque forming unit counts on recovery agar plates, made from varying dilutions of the impinger fluid immediately after the challenge.

The calculations used to obtain titre reduction (TR) value are shown in Appendix 1.

B. diminuta is a standard challenge organism within the filtration industry and is rated as 0.3 μm in size[7]. For filter challenge, a *B. diminuta* suspension of approximately 10^7 Colony Forming Units (CFU/ mL) was prepared and nebulised, presenting a dry monodispersed aerosol challenge of 0.3 μm particles to the test filters. An Andersen sampler was used to validate particle distribution, where greater than 95% *B. diminuta* were found on stage 6, indicating monodispersed particles[8].

Bacteriophage MS-2 is a polyhedral virus approximately 0.02 μm in size[9]. An MS-2 suspension of approximately 10^7 Plaque Forming Units (PFU/mL) was prepared and nebulised as above.

Odour and Organic Volatile Reduction

A carbon dioxide canister was connected to an insufflator (Surgiflator-40, WOM, GmbH) which in turn was connected to a testing chamber containing a sample of beef liver. Two trocar sleeve access ports were present, one to allow a cautery scalpel (Surgistat ValleyLab, CO) to be inserted into the chamber and the other to allow sampling of the gases. The chamber was sealed and the insufflator was set for 15 mmHg at a fill rate of 40 L/min. A filter was then attached to one trocar followed by a prepared Tenax TA absorbent tube (Matrix Environmental Group, Inc, Ann Arbor, MI) to collect the generated gases. With the trocar ports in the on position, 10-second cautery bursts on the liver at level 5 setting clouded the chamber and the gas was collected in the Tenax tube using a vacuum connected downstream (set at 127 mmHg). Chemicals were identified by thermal desorption GC/MS, specifically those that are suspected of causing odour, are present in high concentrations or suspected or known to be the most toxic. Results were obtained for 60 and 180 seconds of cautery with a filter and for 60 seconds of cautery with no filter.

Results

The airborne bacterial retention efficiency (*B. diminuta*) is shown in Table 1 where the average is >99.999996%. The airborne viral retention efficiency (MS-2 bacteriophage) is shown in Table 2 where the average is >99.9999964%.

TABLE 1: *LaparoShield* Filter Airborne Bacterial Retention Efficiency (*B. diminuta*)

Filter Lot No.	Total Challenge (CFU)	Total Recovery (CFU)	Titre Reduction	% Efficiency
6677	$2.5x10^7$	0	$>2.5x10^7$	>99.999996
6677	$2.0x10^7$	0	$>2.0x10^7$	>99.999995
6677	$2.2x10^7$	0	$>2.2x10^7$	>99.999995
6677	$2.0x10^7$	0	$>2.0x10^7$	>99.999995
6677	$1.9x10^7$	0	$>1.9x10^7$	>99.999995
6677	$1.9x10^7$	0	$>1.9x10^7$	>99.999995
6677	$2.2x10^7$	0	$>2.2x10^7$	>99.999995
6677	$2.1x10^7$	0	$>2.1x10^7$	>99.999995
6678	$2.5x10^7$	0	$>2.5x10^7$	>99.999996
6678	$3.0x10^7$	0	$>3.0x10^7$	>99.999997
6678	$3.0x10^7$	0	$>3.0x10^7$	>99.999997
6678	$4.1x10^7$	0	$>4.1x10^7$	>99.999998
6678	$2.5x10^7$	0	$>2.5x10^7$	>99.999996
6678	$2.9x10^7$	0	$>2.9x10^7$	>99.999997
6678	$2.5x10^7$	0	$>2.5x10^7$	>99.999996
6678	$2.2x10^7$	0	$>2.2x10^7$	>99.999995
6679	$2.8x10^7$	0	$>2.8x10^7$	>99.999996
6679	$2.9x10^7$	0	$>2.9x10^7$	>99.999997
6679	$2.2x10^7$	0	$>2.2x10^7$	>99.999995
6679	$2.2x10^7$	0	$>2.2x10^7$	>99.999995
6679	$4.6x10^7$	0	$>4.6x10^7$	>99.999998
6679	$1.4x10^7$	0	$>1.4x10^7$	>99.999993
6679	$8.1x10^7$	0	$>8.1x10^7$	>99.9999988
6679	$3.6x10^7$	0	$>3.6x10^7$	>99.999997

Mean efficiency: >99.999996% **Standard deviation:** $1.22x10^{-8}$

No bacteria were recovered downstream

Results

TABLE 2: *LaparoShield* Filter Airborne Viral Retention Efficiency (MS-2 bacteriophage)

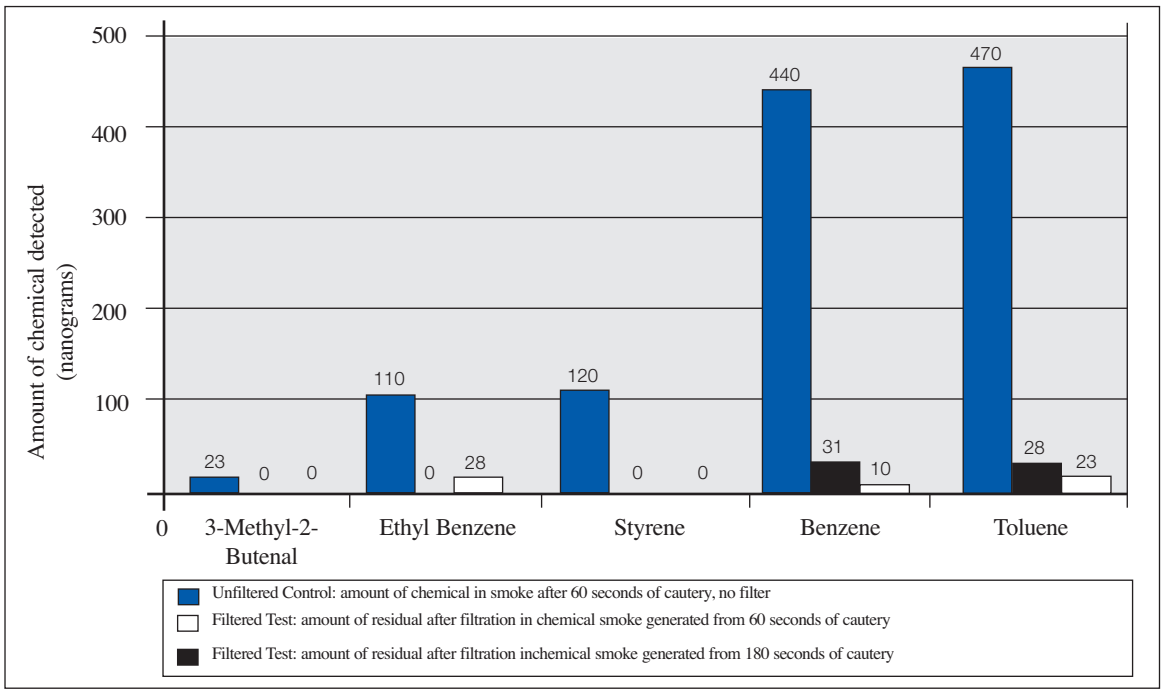
Filter Lot No.	Total Challenge (PFU)	Total Recovery (PFU)	Titre Reduction	% Efficiency
6677	$1.6x10^8$	0	$>1.6x10^8$	>99.9999994
6677	$1.7x10^8$	0	$>1.7x10^8$	>99.9999994
6677	$1.6x10^8$	0	$>1.6x10^8$	>99.9999994
6677	$1.7x10^8$	0	$>1.7x10^8$	>99.9999994
6677	$4.4x10^7$	0	$>4.4x10^7$	>99.999998
6677	$3.2x10^7$	0	$>3.2x10^7$	>99.999997
6677	$4.4x10^7$	0	$>4.4x10^7$	>99.999998
6677	$4.9x10^7$	0	$>4.9x10^7$	>99.999998
6678	$3.2x10^6$	0	$>3.2x10^6$	>99.99997
6678	$6.4x10^6$	0	$>6.4x10^6$	>99.99998
6678	$2.0x10^7$	0	$>2.0x10^7$	>99.999995
6678	$3.9x10^7$	0	$>3.9x10^7$	>99.999997
6678	$2.7x10^7$	0	$>2.7x10^7$	>99.999996
6678	$3.5x10^7$	0	$>3.5x10^7$	>99.999997
6678	$3.8x10^7$	0	$>3.8x10^7$	>99.999997
6678	$4.7x10^7$	0	$>4.7x10^7$	>99.999998
6679	$3.7x10^7$	0	$>3.7x10^7$	>99.999997
6679	$7.0x10^7$	0	$>7.0x10^7$	>99.9999986
6679	$9.9x10^7$	0	$>9.9x10^7$	>99.99999899
6679	$9.2x10^7$	0	$>9.2x10^7$	>99.9999989
6679	$1.7x10^8$	0	$>1.7x10^8$	>99.9999994
6679	$3.6x10^8$	0	$>3.6x10^8$	>99.9999997
6679	$3.5x10^8$	0	$>3.5x10^8$	>99.9999997
6679	$4.5x10^8$	0	$>4.5x10^8$	>99.9999998

Mean efficiency: 99.9999964% **Standard deviation:** $6.77x10^{-8}$

No virus was recovered downstream

Odour and Organic Voltatile Reduction

Testing showed a significant reduction in some of the chemicals suspected of causing odour, with known or suspected toxicity or those present in high concentrations.



Discussion & Conclusion

There are numerous examples of viable virus being identified in laser and electrocautery smoke[10-14], it has been reported that HIV RNA contained in smoke generated by a CO_2 laser may remain intact for up to 14 days[10]. As surgeons using CO_2 laser have a high incidence of nasopharyngeal lesions, their risk of acquiring nasopharyngeal warts is increased through inhalation of laser plume containing viable Human Papilloma Virus (HPV)[15]. Mucous laryngeal papillomatosis in a laser surgeon has been directly linked to virus particles in laser plume from a patient[16].

Research has also demonstrated that intact cells and blood components are aerosolised by lasers and ultrasonic scalpels[2-4,17-20]. Liberation of cells during laparoscopic procedures has been considered as the cause for tumour growth at the port sites (port-site metastasis). Metastases have been documented at port sites remote to the removal area of the cancerous tissue[4-6, 21-26].

The smoke generated during laparoscopic procedures is a by-product of burning proteins and lipids[27,28] and the odour present is an indication of the chemical content of the smoke. The chemical composition of surgical smoke is not yet fully understood, but substances that have been identified so far are known to have a potential for being toxic, mutagenic, carcinogenic or teratogenic. As well as having possible long term-term effects, surgical smoke may cause headaches and irritation in the eyes, nose and throat[27-30].

The results of our tests show that the **Pall** *LaparoShield* Laparoscopic Smoke Filtration System is an effective filtration barrier, with air-borne bacterial and viral retention efficiencies of >99.999% and significant reductions in odour and organic volatiles. In addition to removing chemical contaminants from the evacuated smoke, it provides a high degree of protection against particulate and microbiological contaminants.

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Appendix 1

Titre Reduction (TR) is calculated by dividing the number of microorganisms used to challenge the filter by the number of microorganisms collected downstream of the filter.

$$TR = \frac{\text{Average Total Challenge}}{\text{Average Total Recovery}}$$

Bacterial/viral removal efficiency is calculated for each filter as follows:

$$\text{Removal Efficiency } (\%) = \left(\frac{\text{Average Total Challenge - Average Total Recovery}}{\text{Average Total Challenge}}\right) \times 100$$

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