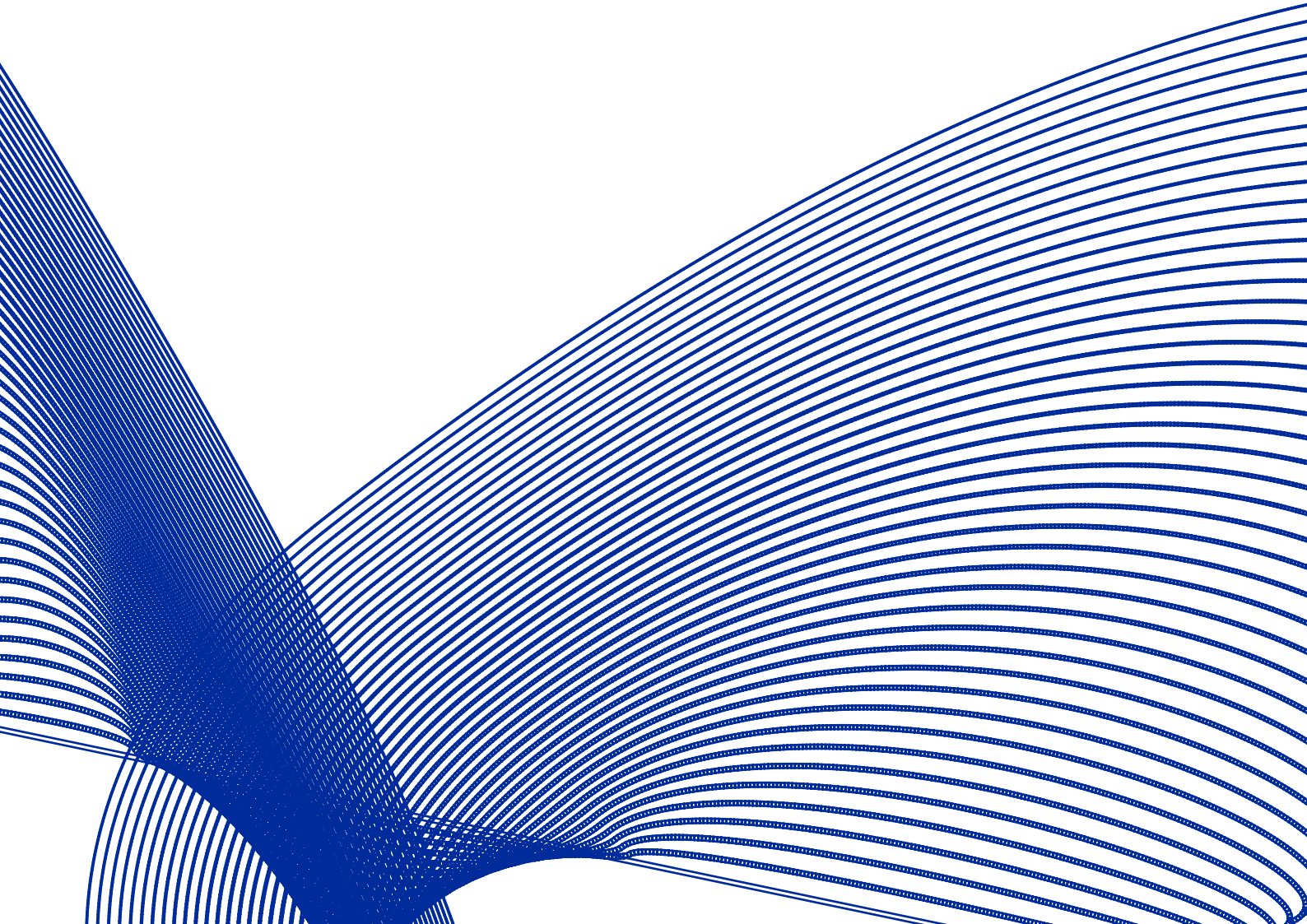




## **Evaluation of endotoxin retention efficiency of Pall NEO96 IV filters with 0.2 $\mu\text{m}$ Posidyne<sup>®</sup> membrane over a 96-hour period**

Smruti Rangunath, Sam Spiers (SLS Medical)

*Report Date: 20<sup>th</sup> September 2021*



## 1 Summary

The Pall NEO96 filter is an air eliminating filter with a 0.2 µm Posidyne® membrane for up to 96 hours use, with any administration set, for removal of inadvertent particulate debris, microbial contaminants and their associated endotoxins and entrained air# which may be found in solutions intended for intravenous or subcutaneous administration.

Intravenous (IV) therapy is an integral and major component of modern-day patient care systems. Inadvertent microbial contamination of IV administration systems from improper handling of the infusion set could however result in microbial contamination and potential shedding of endotoxin (lipopolysaccharide or LPS) if the bacteria are gram-negative.

Endotoxins consist of a fat (lipid A), core oligosaccharide and O-antigen<sup>1</sup>. The partially phosphorylated LPS group contributes to a net negative charge. Infusion of liquids contaminated with endotoxins may have serious effects on patients inflammatory and coagulation systems. There have been many reports of gram-negative bacterial contamination of IV infusion fluids leading to septicemia and the cause of endotoxic shock<sup>2-7</sup>.

The purpose of this study was to test the ability of Pall NEO96 filters to retain endotoxin produced from *Escherichia coli* (*E. coli*). The endotoxin challenge test was performed at the Pall Scientific and Laboratory Services facilities in Portsmouth, UK. Pall NEO96 accelerated aged to at least 5 years and unaged filters were challenged with endotoxin solution produced from  $1 \times 10^8$  colony forming units (cfu) *E. coli* in 1 liter of 0.9 % saline. at a flow rate of 10 mL/hour for a period of 96 hours. The effluent collected from each of the filters were analyzed for endotoxin concentration in EU/mL using a Limulus Amoebocyte Lysate (LAL) method using a Kinetic QCL endotoxin assay kit.

All Pall NEO96 filters (aged and unaged) retained > 99.9999 % of the endotoxin challenge produced from the  $1 \times 10^8$  *E. coli* challenge with an effluent concentration of < 0.1 EU/mL (this was the limit of detection of the test) from an average challenge level of  $> 1 \times 10^4$  EU/cm<sup>2</sup>.

#CE mark products have additional nano-particle reduction claim.

## 2 Materials and Method

The endotoxin challenge solution was prepared by reconstituting *E. coli* Bioball™ (Biomerieux, UK) with 1.1 mL of Bioball re-hydration fluid to produce a stock solution of  $1 \times 10^8$  cfu/mL. 1 mL of the reconstituted bacterial stock solution was added to 1 L of sterile 0.9 % saline solution and thoroughly mixed.

The endotoxin challenge solution was infused at 10 mL/hour for over a 96-hour period. Samples were collected in pyrogen free containers from the influent infusion bag and the effluent at 24, 48, 72 and 96 hours. All collected samples were analyzed for endotoxin levels by the Limulus Amoebocyte Lysate (LAL) method using a Kinetic QCL endotoxin assay kit with a limit of detection of 0.1 EU/mL for the test.

## 3 Results

Table 1 shows the total endotoxin challenge concentration and endotoxin challenge concentration per EFA for 96-hour period, total percent retention and calculated percent retention at 24-hour interval for all the test filters.

**Table 1. Endotoxin Challenge Results**

Filter	Total Challenge over 96 hours (EU/mL)	Total Challenge over 96 hours (EU/cm <sup>2</sup> )	Total Retention (%)	Average concentration of endotoxin in effluent at 24 hr interval (EU/mL)			
				24 hr	48 hr	72 hr	96 hr
Aged 1	$3.11 \times 10^4$	$1.85 \times 10^4$	> 99.9999	<0.100	<0.100	<0.100	<0.100
Aged 2	$3.45 \times 10^4$	$1.75 \times 10^4$	> 99.9999	<0.100	<0.100	<0.100	<0.100
Aged 3	$3.16 \times 10^4$	$1.66 \times 10^4$	> 99.9999	<0.100	<0.100	<0.100	<0.100
Unaged 1	$2.86 \times 10^4$	$2.45 \times 10^4$	> 99.9999	<0.100	<0.100	<0.100	<0.100
Unaged 2	$3.25 \times 10^4$	$2.19 \times 10^4$	> 99.9999	<0.100	<0.100	<0.100	<0.100
Unaged 3	$3.71 \times 10^4$	$2.22 \times 10^4$	> 99.9999	<0.100	<0.100	<0.100	<0.100
Average	$3.3 \times 10^4$	$1.9 \times 10^4$	> 99.9999	<0.100	<0.100	<0.100	<0.100

## 4 Conclusion

All Pall NEO96 filters (aged and unaged) retained > 99.9999 % of the endotoxin challenge produced from the  $1 \times 10^8$  *E. coli* challenge with an effluent concentration of < 0.1 EU/mL from an average challenge level of  $> 1 \times 10^4$  EU/cm<sup>2</sup>.

## References

1. Balatti IB et al., Applied Environmental Microbiology, 2008; 74(20): 6470-6472.
2. Merry AF et al., Anaesth Intensive Care, 2017; 45 (5): 539-542.
3. Denise O. Garrett et al. The Journal of Infectious Diseases, 2002; 186:81-86.
4. Isabel HR et al. The Pediatric Infectious Disease Journal, 2000; 19:888-890.
5. Kelly M et al., The Pediatric Infectious Disease Journal, 2005; 24:590-594.
6. Bernards AT et al. J Hospital Infection, 1997; 35:129-140.
7. Garland SM et al. J Hospital Infection, 1996; 33:145-151.
8. Fernandez C et al. Clinical Infectious Diseases, 1996; 22:1092-1095.



**Corporate Headquarters**  
Port Washington, NY, USA

**European Headquarters**  
Fribourg, Switzerland

**Asia-Pacific Headquarters**  
Singapore

Visit us on the Web at [www.pall.com/medical](http://www.pall.com/medical)  
Contact us at [www.pall.com/contact](http://www.pall.com/contact)

Pall Corporation has offices and plants throughout the world. To locate the Pall office or distributor nearest you, visit [www.pall.com/contact](http://www.pall.com/contact).

The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.

© Copyright 2021, Pall Corporation. Pall, , and Posidyne are trademarks of Pall Corporation. ® Indicates a trademark registered in the USA. Bioball™ is a trademark of Biomerieux in the UK.

210920.4GL  
10/2021