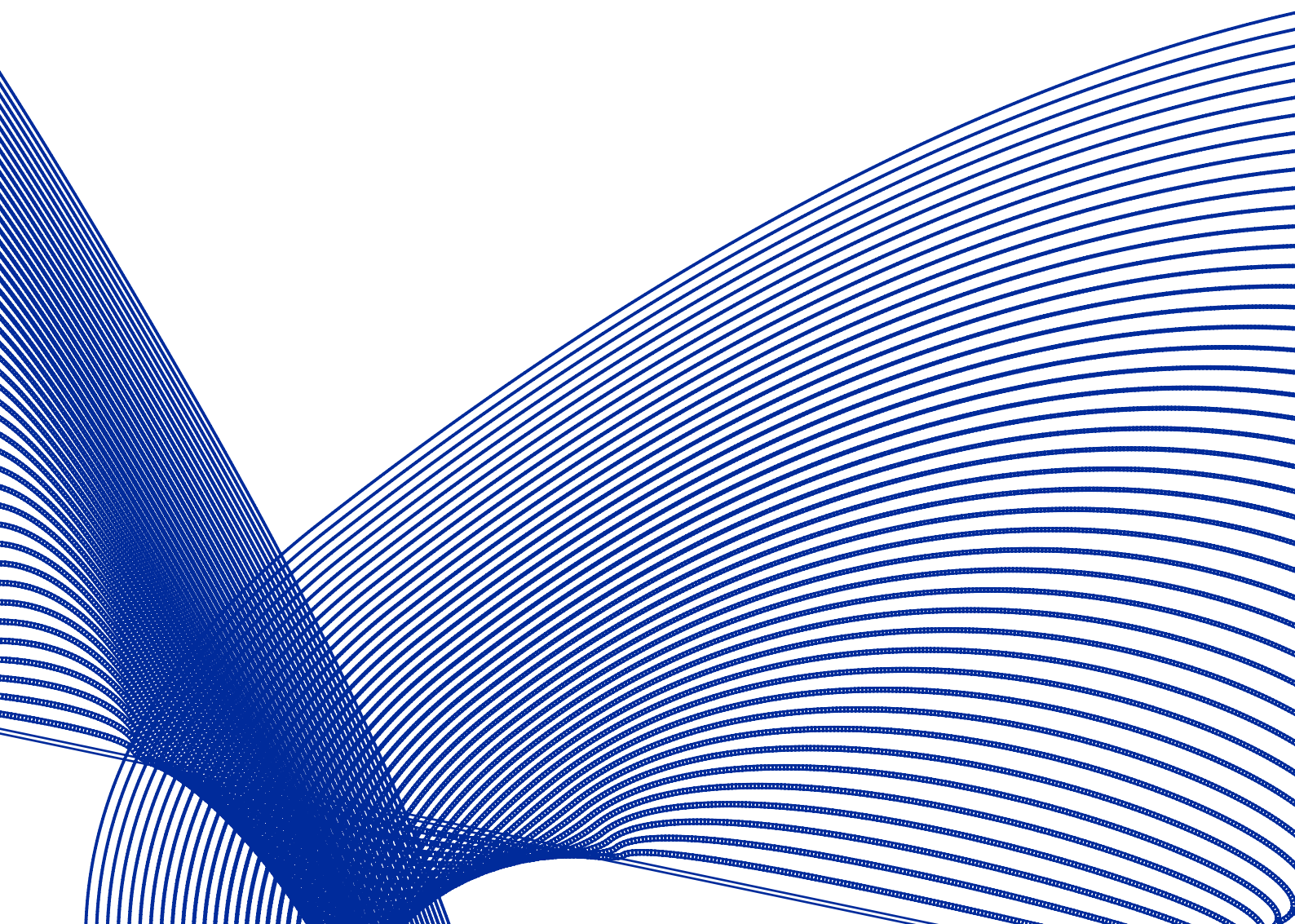




Evaluation of bacterial retention efficiency of Pall NEO96 IV filters with 0.2 μm Posidyne[®] membrane over a 96-hour period

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1 Summary

The Pall NEO96 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. Microbial contamination of IV administration systems could inadvertently arise from handling of the infusion set¹⁻³.

The purpose of this study was to test the Pall NEO96 filters ability to retain *Brevundimonas diminuta*, a small bacterium recognized as the industry standard used for qualifying sterilizing grade filters. The bacterial challenge test was performed at the Pall Scientific and Laboratory Services facilities in Portsmouth, UK, in accordance with a modified ASTM F838-15ae methodology and both aged (naturally aged to 5 years) and unaged Pall NEO96 filters were challenged at a flow rate of 10 mL/hour for a period of 96 hours using buffered saline inoculated with *B. diminuta* to give a challenge of > 1 x 10⁷ colony forming units (cfu) per cm² of effective filtration area (EFA).

The naturally aged and unaged Pall NEO96 filters challenged with at least > 1 x 10⁷ cfu/cm² EFA. *B. diminuta* demonstrated ≥ 99.99 % retention over the 96 hour usage. The results of this testing show that Pall NEO96 filters can retain *B. diminuta* and acts as a barrier to any inadvertent microbial contaminants.

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

2 Materials and Method

The bacterial challenge was carried out using *Brevundimonas diminuta* (*B. diminuta*) as the test organism as described in ASTM F838-15ae standard. The *B. diminuta* cell paste was re-suspended and diluted in buffered saline to produce a stock solution of 5 x 10⁹ cfu/mL. 1 mL of stock solution was aseptically added to 1 L of buffered 0.9 % saline and thoroughly mixed by inversion.

The Pall NEO96 filters were tested for bacterial retention over their lifetime of 96 hours using at least 1 x 10⁷ CFU/cm² effective filtration area as defined by ASTM F838-15ae standard, these filters are not designed to be sterilizing grade but this method gives a standard concentration to use for analysis. The *B. diminuta* challenge was infused at 10 mL/hour for over a 96-hour period to simulate clinical usage. The influent infusion bag was sampled, and the entire filter effluent was analyzed for the presence of *B. diminuta* at 24, 48, 72 and 96 hours. The bacterial load of the challenge solution and the filter effluent was determined by filtration through 0.2 µm Supor analysis membranes and incubation on Tryptone Soy Agar at 30 °C for 48 hours and any colonies were enumerated.

3 Results

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

Table 1. *Brevundimonas diminuta* Challenge Results

Filter	Total Challenge over 96 hours (CFU)	Total Challenge over 96 hours (CFU/cm ²)	Percent Retention of <i>B. diminuta</i> at 24 hr interval			
			24 hr	48 hr	72 hr	96 hr
Unaged 1	1.56 x 10 ⁷	9.47 x 10 ⁶	100.0000	100.0000	100.0000	100.0000
Unaged 2	1.40 x 10 ⁷	8.54 x 10 ⁶	100.0000	100.0000	100.0000	99.9997
Unaged 3	1.62 x 10 ⁷	9.80 x 10 ⁶	100.0000	100.0000	100.0000	99.9999
Unaged 4	1.64 x 10 ⁷	9.94 x 10 ⁶	100.0000	100.0000	99.9999	100.0000
Aged 1	1.93 x 10 ⁷	1.17 x 10 ⁶	100.0000	100.0000	99.9999	99.9997
Aged 2	2.05 x 10 ⁷	1.24 x 10 ⁶	100.0000	100.0000	99.9998	99.9991
Aged 3	2.19 x 10 ⁷	1.33 x 10 ⁶	100.0000	100.0000	100.0000	99.9999
Aged 4	1.89 x 10 ⁷	1.14 x 10 ⁶	100.0000	100.0000	99.9982	99.9938
Average	1.8 x 10 ⁷	1.1 x 10 ⁶	100.0000	100.0000	99.9997*	99.9990*

*The Pall NEO96 is not a sterilizing grade filter device; it is intended to remove inadvertent microbial contamination and therefore would not be expected to completely retain microbial contamination at the elevated challenge levels applied in this study.

5 Conclusion

The naturally aged and unaged Pall NEO96 filters when challenged with at least $> 1 \times 10^7$ cfu/cm² EFA *B. diminuta* demonstrated ≥ 99.99 % retention for up to 96-hour use. The results of this testing show that Pall NEO96 filters can retain *B. diminuta* and acts as a barrier to any inadvertent microbial contaminants.

References

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