



Life Sciences

Pall *Kleenpak* Water Filtration in Dialysis Applications

Features

- Rugged, compact, self contained, sanitary filters
- Sterilising grade membrane
- 100% integrity and pressure tested
- Low filter extractables

Quality Bio-Safety Tests

Integrity

- Every filter tested during manufacture. Test correlated to microbial retention

Biological

- Meets USP Biological Reactivity Test, *in vivo*, for Class VI-121 °C Plastics

Effluent

- Non-fibre-releasing as per CFR 211.72 and CFR 210.3(b)(6)
- Non-pyrogenic per USP bacterial endotoxins (<0.25 EU/mL)



Easy to use
Efficient
Measurable

Filtration. Separation. Solution.SM



Pall Kleenpak

Water Filtration in Dialysis Applications

Water Quality and Dialysis in Intensive Care

Every week approximately 400 L water, used for dialysate production, comes into contact through the semi-permeable membrane of the dialyser with each dialysis patients' blood stream¹. Therefore, submitting municipal water to a purification process before use for dialysis is a necessity.

Intensive Care Units usually have their own dialysis machines, fed by reverse osmosis (RO) water supplied from a central production source, or from small portable RO generators. The optimal water treatment system for dialysis supply should include tap water pre-treatment². However, production of water by RO does not necessarily mean microorganism free water. Every component of the dialysis system, including the delivery of the treated water to the dialysis machines, should prevent microbial contamination of the fluid.

High microbiological purity of dialysis fluid, regularly verified, is a fundamental pre-requisite for dialysis quality (every dialysis unit should aim to obtain 'ultra-pure' dialysate microbial count <0.1 CFU/mL, endotoxins <0.03 IU/mL).³ However, dead spaces, multiple connections, influent water quality, plumbing maintenance and/or water stagnation during intermittent use, are a continuous opportunity for micro-organism growth, biofilm generation and endotoxin release, leading to contamination of the machine and potentially the upstream water supply^{4,5}. Even routine disinfection of the dialysis component system has varying success, with fast microorganism recovery (<48 hours) and growth⁶. These complexities lead to units often failing to meet the European Pharmacopoeia expectations for water produced for dialysis purposes, which states total microbial counts <100 CFU/mL and pyrogenic endotoxins <0.25 IU/mL⁸.

Product Information

Part Code	Membrane	Nominal Filter Area	Max. Dia. of Bowl (inc. Valves)	Length (inc. Sanitary Connection)	Inlet and Outlet Connections	Max. Pressure	Delta P at 500 mL/min	Sterilisation
KA2DJLP1S	Fluorodyne II Polyvinylidenedifluoride (PVDF), double layer 0.1 micron sterilising grade*	0.08 m ² (0.8 ft ²)	94 mm (3.2 ins)	117 mm (4.6 ins)	38 mm 1 1/2 ins Sanitary Flange	5.2 bar (75 psi)	83 mbar	Gamma irradiation, double bagged
KA3NTZP1	Ultipor N ₆₆ Nylon 6,6; double layer 0.1 micron sterilising grade**	0.2 m ² (2 ft ²)	109 mm (4.2 ins)	174 mm (6.8 ins)	38 mm 1 1/2 ins Sanitary Flange	5.2 bar (75 psi)	166 mbar	Non Sterile, single bagged

Accessories

Description	Part code
Sanitary flange connectors (2 pairs of connectors with silicon seal)	SANITC23H4
Sampling port	FA00474
6 mm adaptor	FFA1TC23
11 mm adaptor	FA-ACDC11

Water Filtration in Dialysis Applications

Pall Life Sciences have designed an easy to use and efficient solution to reduce contamination and improve water quality for dialysis applications: a **Pall Kleenpak** filter placed in the water pipeline, upstream of the dialysis machine.

Suitable **Pall Kleenpak** filters have 0.1 µm, sterilising grade membranes, and there are two types of membrane available for this application:

- * **Fluorodyne II** membrane, which has a high chemical compatibility
- * **Nylon 6,6 Posidyne** membrane, which carries a charged membrane surface

Pall Kleenpak filters may be connected to different diameter tubings via the autoclavable sanitary flange inlet and outlet connectors (see accessories table), and a sampling port is available (on request) to control water quality upstream of the dialysis machine.

A recent study, found that **Pall Kleenpak** filters (containing nylon membrane) were able to significantly reduce the bacteria and endotoxins present in influent dialysis water¹⁰. These authors found varying levels of bacterial (0-100 CFU/mL) and endotoxin (1.62±1.17 IU/mL) contamination of the influent water over time. The filter was considered effective in the reduction of bacteria and endotoxin, over a 30 day period resulting from the synergistic effect of pore size and the adsorbant properties of the positively charged membrane.

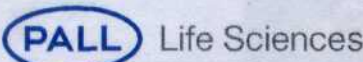
Pall work alongside hospitals to validate conditions and duration of filter use, specific to the hospital site. Please contact your local Pall sales office for further information.

* High removal efficiency for diminutive organisms (eg. typical titre reductions for *Acholeplasma laidlawii* is >10⁷).

** High removal efficiency for diminutive organisms (eg. typically retains >10⁷ cfu/cm² *Brevundimonas diminuta*, >10⁷ /cm² *Acholeplasma laidlawii*).

References

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