CRITICAL PROCESS FILTRATION, INC.

Application Summary

Filters for Medical Device Reprocessing

Bacteria Control in Desalination Systems

Heat-sensitive, semi-critical medical devices such as endoscopes are cleaned then disinfected using 'high level disinfectants' (HLD). The process is not called sterilization because the devices cannot be guaranteed sterile after removal from the process.

Most healthcare professionals realize how filters help prevent device re-contamination from bacteria in water. However, filter technologies and performance measures are not as commonly understood. This document provides information to help those unfamiliar with filters understand and evaluate their filter options.

What Are the Filtration Requirements for Semi-Critical Device Reprocessing?

There are some guidelines for water quality from standard setting organizations and device makers.

For endoscope reprocessing, the CDC, HICPAC, Society for Gastroenterology Nurses and Associates (SGNA), American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Healthcare Epidemiology of America (SHEA) have all made recommendations to use "sterile water, filtered water, or tapwater …." 1-4

There is a more specific standard for reprocessing dialyzers. The Association for the Advancement of Medical Instrumentation (AAMI) and the United States Pharmacopeia (USP) published standards for dialysis water that call for very low bacteria and endotoxin levels.

No dialyzer manufacturer's instructions contradict the AAMI and USP standards, however, endoscope manufacturers have water quality requirements written into their reprocessing directions that are more stringent than those in the guidelines from the CDC, SGNA and others.

Olympus states their preference for 'sterile water' in a 2010 letter, but allows "… fresh, potable tap water or water that has been processed (e.g., filtered, deionized or purified) …" if sterile water is unavailable.5

Pentax says in their instructions to "RINSE all internal channels with sterile water."6

In their device manual, FujiFilm Medical Systems (Fujinon) calls for "microbiologically clean drinking water or sterile water."7

All of the endoscopy organizations and endoscope makers agree that the final rinse of all endoscope channels should be followed by a 70% alcohol flush and an air purge to dry the channels.1-7 This helps with drying and reduces the chances of waterborne organisms growing in the devices and forming biofilm.

NOTE: Many healthcare professionals believe that alcohol will kill anything. But alcohol is not sporicidal4, so it will not kill spores like those from Bacillus and Clostridium species. Alcohol also does not kill cysts, such as the waterborne Cryptosporidium oocysts that caused an outbreak of illness in Milwaukee in 1993. Filtering is a cost-effective way to remove these organisms from water.

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Current Filtration Practices in Medical Device Reprocessing

Dialysis water must be produced using a system approved by the FDA under 510 (k) rules. [See our paper on filters used in dialysis water production.]

For water used in semi-critical device reprocessing, most facilities use filter systems to remove bacteria from the water. The systems should supply 'bacteria-free' water, so the final filter is often called a 'bacteria removal' filter. Common system configurations have two or three filters in series (see Figure 1 below). The first filter, a pre-filter, removes larger particles and protects the bacteria filter from being overloaded. A second filter may be installed to further protect the final filter from smaller particles or larger bacteria, if water supply conditions warrant. Finally the bacteria filter, usually rated at 0.22 or 0.10 micron, removes all bacteria.

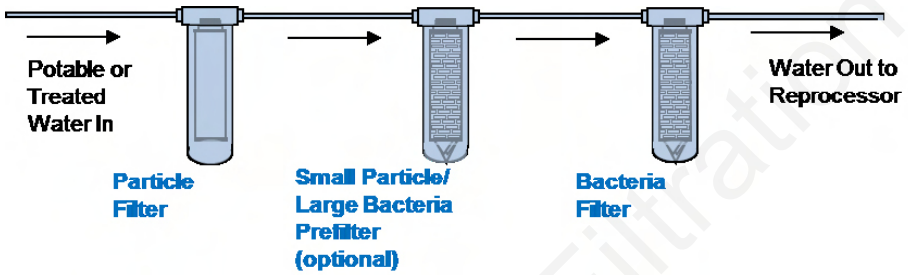

Figure 1: Common Medical Facility Potable Water Filter System

Choosing Your Filters

The most important factor in choosing your filters is the amount of bacteria you wish to remove. Most facilities desire 'bacteria-free' water, so the system needs to be designed to remove 'all' bacteria.

In all filter systems, the most important filter is the final filter. In this case, the filter is used to remove bacteria. In the pharmaceutical industry, this filter is called a 'sterilizing' filter and is tested to ensure it can remove all bacteria in water. The rest of the filters in the system protect the final (and most expensive) filter to maximize its useful life.

Important note: While AAMI and FDA have an accepted standard for filters used in dialysis water, there are no filters specifically approved by the FDA for semi-critical device reprocessing under 510(k) rules.

Understanding the "Sterilizing" Filters

Sterilizing filters must remove 'all' bacteria. This pharmaceutical industry term describes filters that remove all bacteria during packaging of injectable drugs. The performance of the filters must be proven to the FDA before any drug can be made and sold utilizing the filters.8, 9

Here is a short list of the major performance characteristics of sterilizing filters.

1. Depending on the filter pore size rating, remove all bacteria larger than 0.22 microns or mycoplasma larger than 0.10 microns.
    a. 0.22 micron filters are documented based on testing using Brevundimonas diminuta bacteria.
    b. 0.10 micron filters are documented based on testing using Acholeplasma laidlawii mycoplasma.

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2. Be “integrity testable” with test pass/fail values correlated to the retention of bacteria or mycoplasma.
3. Be proven safe for patients, meaning that all materials are at least FDA accepted. Some filter materials may also be tested according to USP standards for safe implantation in patients.
4. Be proven not to affect the liquid being filtered or have their performance affected by filtration process factors.

Filter Options for Medical Water Filtration Technology

Filter Media	Grade	Media Code	Cartridge	Capsule	Disc Filter	Recommended Pore Size (µm)	Features
Melt Blown Polypropylene Depth Media	General	GDMB	X	X	X	1, 3, 5	Continuously bonded polypropylene media for consistent 85% nominal performance
Nano-Spun Polypropylene Depth Media	General	NSPD	X	X	X	1, 3, 5	Very high retention efficiency (99%) and high load capacity to protect downstream processes
Activated Carbon Block	General	ACB	X			5	High efficiency removal of sediment, chlorine and organic chemicals
Pleated Polypropylene Depth Media	General	PD	X	X	X	0.22, 0.45, 1.0	100% polypropylene construction for high purity
High Capacity Polyvinylidene Fluoride (PVDF) Membrane	Biopharm	PVWL	X	X	X	0.22, 0.45, 0.65, 0.85, 1.0	Holds high levels of contaminants for long service life
Asymmetric Polyethersulfone (PES) Membrane	Biopharm	PS	X	X	X	0.10, 0.22, 0.45	Highly asymmetric, hydrophilic PES membrane in single- and double-layer configurations for high efficiency and high flow rates.

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