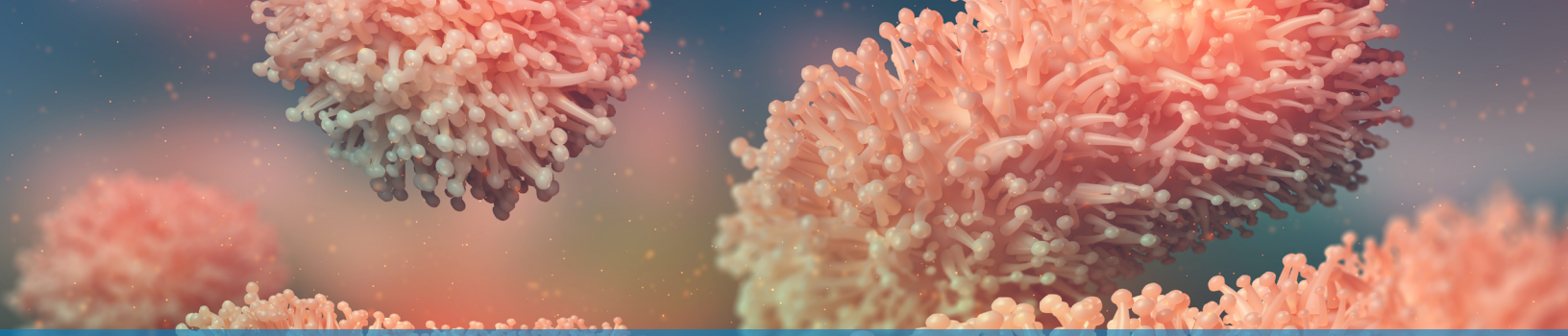

GLOBAL FILTER

BRHNY+ SERIES

APPLICATION BRIEF

Filter Elements For Endotoxin & Microbe Removal In Medical Device Reprocessing

BRHNY+ Series Bio-Burden Reduction Grade filter cartridges feature nylon 6,6 membrane with an advanced positively-charged surface modification that is highly effective in capturing submicronic particulate and microbial matter much finer than the stated mechanical rating.

Based on well-documented field use, industry journals, and laboratory data, these characteristics make the BRHNY+ ideally suited for medical device reprocessing applications, where effective removal of microbes and pyrogenic endotoxins is critical to system performance and patient health. Furthermore, the BRHNY+ series presents a more cost-effective alternative to hollow-fiber cartridges commonly used for endotoxin/microbe removal, while also serving other demanding high-purity applications.

Significant Application in Medical Device Reprocessing

- Reusable medical devices for patient use become soiled, fouled, and contaminated with body tissue and fluids, cellular debris, and microorganisms. To avoid risk of infection by a contaminated device, reusable devices undergo "reprocessing", a highly specific, multi-step process to clean, disinfect, and/or sterilize them.

- The Association for the Advancement of Medical Instrumentation (AAMI) develops standards & documents for enhancing the safety, performance, and management of medical devices and health technologies. AAMI is an ANSI accredited organization and publishes a comprehensive Technical Information Report, #TIR34 – *Water for the Reprocessing of Medical Devices.*

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Water Quality Levels of Criticality

Distinctions are made between levels of water quality used in medical device reprocessing.

First, we distinguish between **Critical Water** and **Utility Water**.

> Critical Water undergoes processing designed to ensure removal of microorganisms, bio-load, inorganic, and organic substances. Critical Water is used for final rinsing of devices and for steam generation for sterilization.
>
> Utility Water is used for less demanding general cleaning, flushing, rinsing.

Second, water quality required for re-processing within each group is specified with regard to its composition and the processing it undergoes.

Medical Device Classifications

Medical devices are divided into three groups.

Non-Critical Medical Devices

- contact intact skin but not mucous membranes
- e.g. stethoscopes, blood pressure cuffs, and stretchers
- must be cleaned, and if shared between patients, low- or intermediate-level disinfection

Semi-Critical Medical Devices

- may encounter mucous membranes or non-intact skin
- e.g. cystoscopes, anesthesia equipment, laryngoscopes and some endoscopes
- should be free from microorganisms, but some bacterial spores may remain
- must be cleaned, and sterilization is recommended (high-level disinfection is acceptable for devices unable to be sterilized)

Critical Medical Devices

- enter sterile areas of the body, including contact with the vascular system
- e.g. surgical forceps, scalpels, implants, biopsy instruments, and urinary catheters
- require cleaning followed by sterilization

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BRHNY+ Filter Elements for AAMI Standard TIR34 Compliance

The BRHNY+ is a key component of water systems required to be compliant to AAMI Standard #TIR34 – *Water for the Reprocessing of Medical Devices*.

The BRHNY+ delivers highly efficient scavenging of microbes and endotoxin when used in a properly-designed system maintained to TIR34 recommended practices. This assures continued compliance of the system to meet the highest standards of cleanliness, patient protection, and operator confidence.

Endotoxin Removal Performance

Bacterial endotoxin is the pyrogen of greatest concern in the pharmaceutical and medical device industries. BRHNY+ filter elements have been proven in independent laboratory testing to remove endotoxins by 100% to non-detectible levels with a challenge concentration of 6.25 Endotoxin Units per milliliter (EU/ml) and a sensitivity of 0.005 EU/ml.

Endotoxin Test Study Summary

A BRHNY+0.05A10C4S filter was challenged with a solution of pyrogen-free water dosed with 6.25 EU/ml. Twenty liters of challenge solution were pushed through the filter at a flow rate of 4 L/min for 20 total cycles. Influent and effluent samples were collected at defined time points.

The test filters were effective in retaining bacterial endotoxin at a total challenge of approximately 1.57×10^6 EU as demonstrated by all effluent samples being free of endotoxin below the detection limit of 0.005 EU/ml after cycles #1, #5, #10, #15, and #20.

Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211, and 820.

Microbial Retention Performance

Data presented below describes representative results of testing in accordance with the protocol for the evaluation of bacterial retention characteristics of membrane filters. Per the ASTM F858-15a test methodology, each test filter is challenged with a suspension of the referenced microbe, containing at least 1×10^7 colony forming units (CFU) per cm^2 of effective filtration area. The sterility of the complete apparatus is tested before the challenge. Each filter is challenged at a pressure of 30 psi. The collected effluent is quantified using 0.45µm assay membranes. Integrity testing is conducted pre-sterilization, post-sterilization, and post-challenge. Testing is performed in compliance with US FDA Good Manufacturing Practice (GMP) regulations 21 CFR Parts 210, 211, and 820.

MICROBE RETENTION EFFICIENCY

Filter Grade	Challenge, Typical, CFU/cm^2	Total Challenge, Typical, CFU	Log Reduction Value, LRV
BRHNY+0.1	1.35×10^7	9.7×10^{10}	>9.1
BRHNY+0.05			>10.1

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APPLICATION BRIEF

Filter Elements For Endotoxin & Microbe Removal In Medical Device Reprocessing

Assurance of Product Purity & Performance

Cartridges are manufactured in a cleanroom environment and are extensively flushed with 18 megaohm ultra-high purity water. This ensures cleanliness, low extractables, and quick rinse-up for service use. Tolerant of repeated hot water sanitization and *in-situ* steam sterilization cycles for maximum service life. Each element is diffusion tested to Global Filter standards of integrity to assure consistent and optimal performance.

Why Partner With Global Filter?

Global Filter is a leading producer of high purity filtration products for food & beverage, high purity water & chemicals, consumer products, pharmaceutical/bio-tech, and general industrial applications. We pride ourselves in our focus on the customer while striving to deliver superior value in all industries. Our solutions improve product quality and safety while optimizing processes, protecting equipment, and reducing total operating costs.

Advantages To Working With Global Filter:

- Access to an extensive network of filtration professionals from all over the world who have experience with thousands of unique processes and applications
- Manufacturing facilities in North America, Europe and Japan
- Products designed to maximize your productivity, product quality and bottom line
- Built to grow with you and help navigate the challenges and changing landscapes of your industry
- Technical support from initial conversations to implementation and beyond
- Shortest lead times and industry-leading value

Our Solutions Are:

Safer

Our products meet US and EU standards for purity and safe use with food and beverages.

Healthier

We develop products that improve the quality of life for humans and animals.

More Productive

Our solutions allow you to produce more product at a lower cost, improving your bottom line.

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