SARTURIUS

Sartopore® 2 HF

Sterilizing-Grade Filter Elements



Product Information

- Highest flow rates due to increased effective filtration area
- Ideal solution for filtration of water-based pharmaceutical formulations
- Broadest chemical compatibility & highest thermal resistance

Maximum Flow Rate Performance

Due to its enlarged effective filtration area, the single layer hydrophilic polyethersulfone membrane gives Sartopore® 2 HF higher flow rate performance in the target applications than any other sterilizing-grade filter. Thus ensuring shortest filtration cycle times and minimized total costs.

Broadest Compatibility and Excellent Wettability

In addition to its outstanding performance, the single layer polyethersulfone membrane gives Sartopore® 2 HF broad chemical compatibility, including a pH-range from pH 1 to pH 14, and a high thermal resistance. Sartopore® 2 HF filter cartridges can be easily wetted for integrity testing even after drying at 80°C for 12 hours.

Safety & Reliability

Sartopore® 2 HF filter cartridges 0.2 μ m rated are fully validated as sterilizing-grade filters according to current ASTM F-838 guidelines. Each individual element is tested for integrity by bubble point and diffusion test prior to release assuring absolute reliability.

Applications

- Buffers
- Large volume parenterals
- WFI
- Cleaning and sanitizing agents
- Bulk pharmaceutical products
- Applications requiring high flow rates

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 HF filters.

Our services provide

- Extractables and leachables services
- Microbiological testing
- Physicochemical testing

in compliance with regulatory requirements. Our local teams of validation experts support you with our tailored and consultative approach to determine the most costeffective solution and give you the confidence you need to succeed.

Technical Specifications

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar 36 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges			
Size 1	0.7 m² 7.5 ft²	21	3.2 46
Size 2	1.4 m² 15.1 ft²	42	3.2 46
Size 3	2.1 m² 22.6 ft²	63	3.2 46

Max. Allowable Differential Pressure

Cartridges

5 bar | 72.5 psi at 20°C 2 bar | 29 psi at 80°C

Materials

Prefilter Membrane

Polyethersulfone, asymmetric

Endfilter Membrane

Polyethersulfone, asymmetric

Support Fleece

Polypropylene

Core

Polypropylene

End Caps

Polypropylene

Outer Support

Polypropylene

O-Ring Silicone

(other materials on request)

Max Allowable Back Pressure

2 bar | 29 psi at 20°C (for all elements)

Pore Size Combination

0.2 µm (single layer)

Regulatory Compliance

- Each individual element is tested for integrity by bubble point and diffusion test
- Fully validated as sterilizing-grade filters according to ASTM current F-838 quidelines
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- Meet or exceed the requirements for WFI quality standards set by the current USP
- Non pyrogenic according to USP Bacterial Endotoxins
- USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR



Sterilization

Cartridges

In-Line Steam Sterilization Max. 134 °C, 0.3 bar, 20 min. Min. 25 Sterilization Cycles

or

Autoclaving

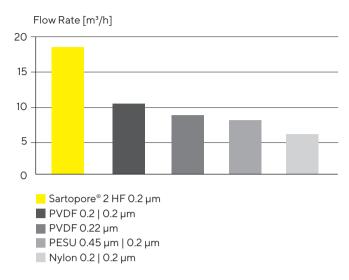
Max. 134°C, 2 bar, 30 min Min. 25 Sterilization Cycles

Technical References

Validation Guide 2665255 Extractables Guide SPK5742-e

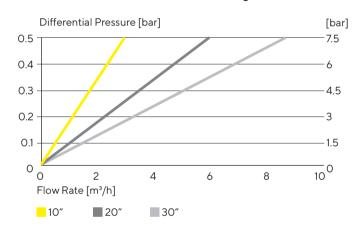
Performance

Flow Rate Comparison



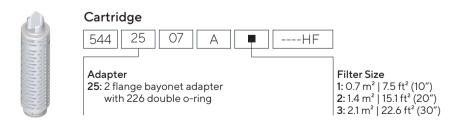
30" Filter cartridges at 1 bar | 14.5 psi differential pressure (20°C)

Water Flow Rates for Standard Cartridges



Standardized at 20°C

Ordering Information



(Standard with silicone o-ring optional with EPDM or fluoroelastomer o-ring.)

Germany

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0

USA

Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178



For more information, visit

www.sartorius.com