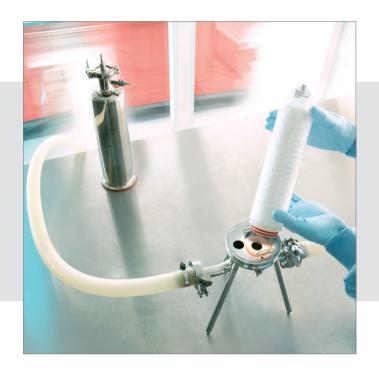


Sartopore® 2 HF 0.2 μm

Sterilizing Grade Filter Cartridges

Product Information

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



Maximum flowrate performance

Due to its enlarged effective filtration area, the single layer hydrophilic polyethersulfone membrane gives Sartopore® 2 HF higher flowrate rate performance in the target applications than any other sterilizing grade filtration cartridge. 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 cartridges can be easily wetted for integrity testing even after drying at 80°C for 12 hours.

Highest safety and reliability

Sartopore® 2 HF filter cartridges 0.2 µm 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 be released assuring absolute reliability.

Applications

- Buffers
- Large volume parenterals
- WFI
- Cleaning and sanitizing agents
- Bulk pharmaceutical products
- Any application that requires exceptional flow rates

Technical Data

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar 36 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges			
Size 1	$0.7 \text{ m}^2 7.5 \text{ ft}^2$	21	3.2 46
Size 2	1.4 m ² 15.1 ft ²	42	3.2 46
Size 3	$2.1 \text{ m}^2 \mid 22.6 \text{ ft}^2$	63	3.2 46

Max. Allowable Differential Pressure

Cartridges

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

Max. Allowable Back Pressure

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

Materials

Prefilter Membrane

Polyethersulfone, asymmetric

Endfilter Membrane

Polyethersulfone, asymmetric

Support Fleece

Polypropylene

Core

Polypropylene

End Caps

Polypropylene

Outer Support

Polypropylene

O-Ring

Silicone

Pore Size Combination

0.2 µm



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 guidelines
- 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

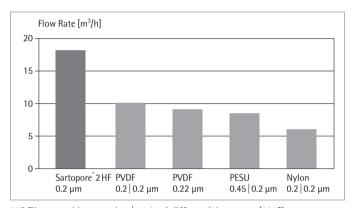
Cartridges

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

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

Performance

Flow Rate Comparison

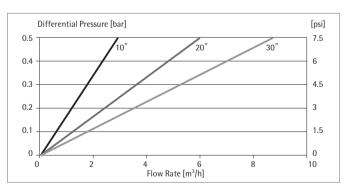


30" Filter cartridges at 1 bar | 14.5 psi differential pressure (20°C)

Technical References

Validation Guide SPK5741-e Extractables Guide SPK5742-e

Water Flow Rates for Standard Cartridges

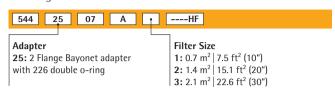


Standardized at 20°C

Ordering Information



Cartridge



(Standard with silicone o-ring optional with EPDM o-ring. Example: 5442507A1---EHF)

Check the availability of your desired configuration with your Sartorius sales representative or online at:



Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen, Germany Phone +49.551.308.0 Fax +49.551.308.3289 www.sartorius-stedim.com