



# Sartopore® 2 HF 0.2 µm

Sterilizing Grade Filter Cartridges



## Specifications

### Materials

Filter Membrane:	Polyethersulfone, asymmetric
Support fleece:	Polypropylene
Core:	Polypropylene
End caps:	Polypropylene
O-Rings:	Silicone

### Pore Size

0.2 µm

### Available Sizes | Filtration Area

Size 1	10"	0.7 m <sup>2</sup>	7.5 ft <sup>2</sup>
Size 2	20"	1.4 m <sup>2</sup>	15.1 ft <sup>2</sup>
Size 3	30"	2.1 m <sup>2</sup>	22.6 ft <sup>2</sup>

### Available Adapters

25

### Operating Parameters

Max. allowable	5 bar	72.5 psi at 20 °C
Differential pressure:	2 bar	29 psi at 80 °C
Max. allowable back Pressure:	2 bar	29 psi at 20 °C

### Description

Sartopore® 2 High Flow sterilizing grade filter cartridges are developed for filtration of water based pharmaceutical formulations. Sartopore® 2 HF cartridges feature a unique single layer, hydrophilic polyethersulfone membrane. This membrane is characterized by broadest chemical compatibility, highest thermal resistance, increased mechanical stability and higher flow-rates than any other sterilizing grade filter cartridge offers.

### Applications

Typical applications include sterilizing grade filtration of:

- Large Volume Parenterals (LVP)
- Buffers
- WFI
- Cleaning and sanitizing agents
- Bulk pharmaceutical products
- Each application requiring exceptional high flow rates

### Compatibility

The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 and to multiple steam sterilization cycles making Sartopore® 2 HF cartridges ideal for filtration of solutions with high | low pH and for SIP/CIP-cycles.

### Performance

The increased effective filtration area of Sartopore® 2 HF filter cartridges allows for highest flow rates and assures thereby most economic design of filtration systems.

### Wettability

Sartopore® 2 HF cartridges can be easily wetted out for integrity testing even after drying cycles with 80 °C for 12 hours.

### Microbiological Retention

Sartopore® 2 HF filter cartridges 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 guidelines.

### Quality Control

Each individual element is tested for integrity by B.-P. and Diffusion-Test prior to be released assuring absolute reliability.

### Documentation

Sartopore® 2 HF cartridges are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide and an Extractables Guide are available for compliance with regulatory requirements.

## По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,  
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,  
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,  
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

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## Specifications

### Extractables

Sartopore® 2 HF 0.2 µm rated filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

### Regulatory Compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

## Sterilization

### In-Line Steam Sterilization

134 °C, 20 min. at max differential pressure of 0.5 bar | 7 psi

### Autoclaving:

134 °C, 2 bar, 30 min

### Sterilization Cycles

In-Line Sterilization: Min. 25

Autoclaving: Min. 25

## Technical References

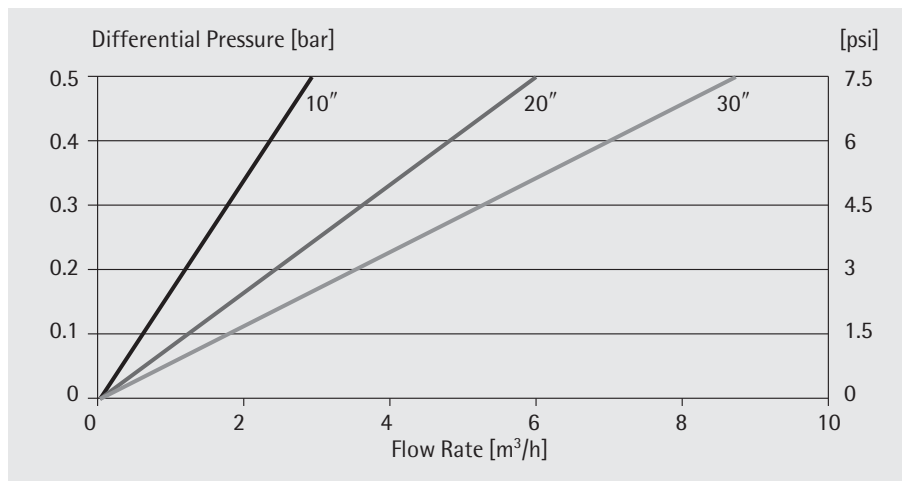
### Validation Guide:

SPK 5741-e

### Extractables Guide:

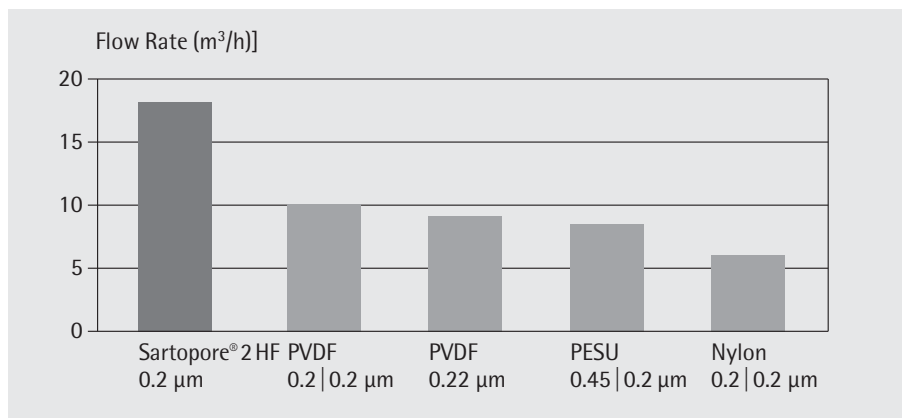
SPK 5742-e

Water Flow Rates for 10", 20" and 30" Cartridges



Standardized at 20 °C

Flow Rate Comparison



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

## Ordering Information

Order Code	Pore size [µm]	Pack Size [Pieces]
5442507A1----HF	0.2	1
5442507A2----HF	0.2	1
5442507A3----HF	0.2	1

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