



# Sartopore® 2 XLI 0.2 µm

Sterilizing Grade Filter Cartridges



## Specifications

### Materials

|                     |                 |
|---------------------|-----------------|
| Prefilter Membrane: | PES, asymmetric |
| Endfilter Membrane: | PES, asymmetric |
| Support Fleece:     | Polypropylene   |
| Core:               | Polypropylene   |
| End Caps:           | Polypropylene   |
| O-Rings:            | Silicone        |

### Pore Size Combination

0.35 µm + 0.2 µm

### Available Sizes | Filtration Area

|        |     |   |
|--------|-----|---|
| Size 1 | 10" | 0.8 m <sup>2</sup>   8.6 ft <sup>2</sup>  |
| Size 2 | 20" | 1.6 m <sup>2</sup>   17.2 ft <sup>2</sup> |
| Size 3 | 30" | 2.4 m <sup>2</sup>   25.8 ft <sup>2</sup> |

### Available Adapters

25

### Operating Parameters

|                                       |                          |
|---------------------------------------|--------------------------|
| Max. Allowable Differential Pressure: | 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   |

### Description

Sartopore® 2 XLI filter cartridges are especially designed for sterilizing grade filtration of pharmaceutical solutions with a homogenous particle spectrum. The unique heterogeneous double layer PES membrane combination of Sartopore® 2 XLI cartridges is specifically developed to provide exceptional high total throughputs and outstanding flow rates for totally chemically defined process fluids and other process fluids of biotech manufacturing processes with small particle spectrum.

### Applications

Typical applications of Sartopore® 2 XLI cartridges include sterilizing grade filtration of:

- Ophthalmic solutions
- Chemically defined cell culture media
- High viscous large volume parenterals
- Any fully chemically defined media

### Economy

The combination of the build in 0.35 µm pre-filter in front of a 0.2 µm final filter together with an exceptionally high effective filtration area of 0.8 m<sup>2</sup>/10" cartridge provide outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

### Compatibility

The PES membrane of Sartopore® 2 XLI cartridges provides broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple in line steam sterilization cycles up to 134°C.

### Scalability

Sartopore® 2 XLI filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale.

### Microbiological Retention

Sartopore® 2 XLI filter cartridges are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 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 XLI cartridges are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

## Specifications

### Extractables

Sartopore® 2 XLI 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 838-05 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

### Autoclaving:

134°C, 2 bar, 30 min

### Sterilization Cycles

In-Line Sterilization: Min. 25

Autoclaving: Min. 25

## Technical References

### Validation Guide:

SPK5768-e

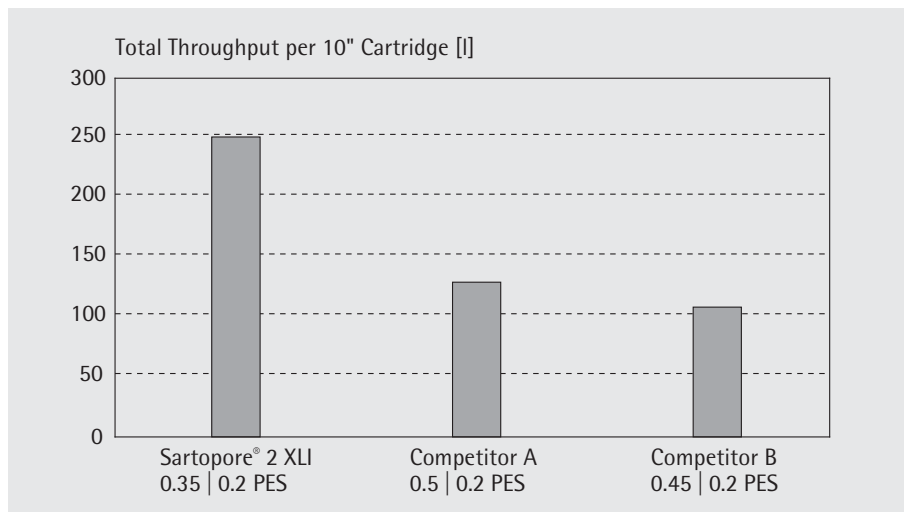
### Extractables Guide:

SPK5766-e

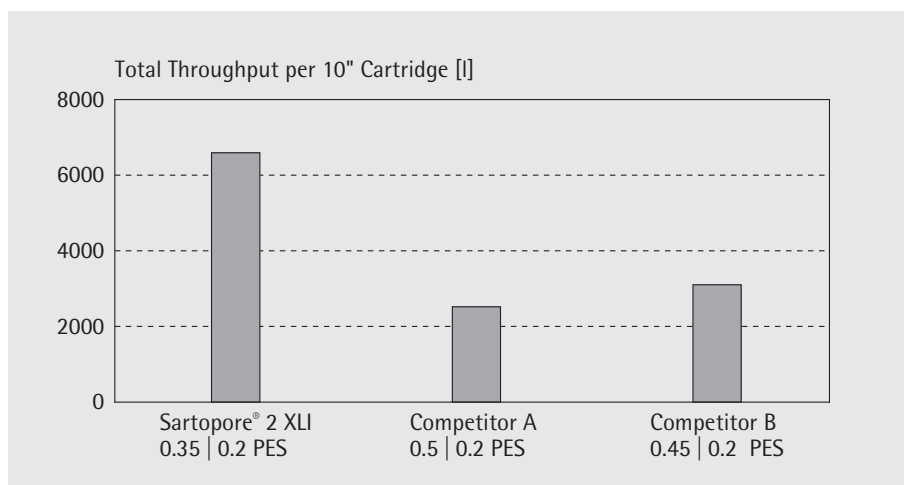
## Order Codes

| Cartridges | Pore Size [µm] | Test Pressure [bar   psig] | Max. Diffusion [ml/min] | Min. Bubble Point [bar   psig] |
|------------|----------------|----------------------------|-------------------------|--------------------------------|
| 544250711  | 0.35 + 0.2     | 2.5   36                   | 21                      | 3.2   46                       |
| 544250712  | 0.35 + 0.2     | 2.5   36                   | 42                      | 3.2   46                       |
| 544250713  | 0.35 + 0.2     | 2.5   36                   | 63                      | 3.2   46                       |

## Chemically Defined Cell Culture Media



## Ophthalmic Solution



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

USA Toll-Free +1.800.368.7178

UK +44.1372.737159

France +33.442.845600

Italy +39.055.63.40.41

Spain +34.91.3586102

Japan +81.3.3740.5407

Specifications subject to change without notice. Printed and copyrighted by Sartorius Stedim Biotech GmbH W/sart-000 - G  
Publication No.: SPK2084-e08062  
Order No.: 85030-534-89