



# Sartopore® 2 XLG 0.2 µm

Sterilizing Grade Filter Cartridges



## Specifications

### Materials

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

### Pore Size Combination

0.8 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 XLG filter cartridges are especially designed for sterilizing grade filtration in special applications of cell culture processes. The unique heterogeneous double layer PES membrane combination of Sartopore® 2 XLG cartridges is specifically developed to deal with the broad variety of contaminants in up- and downstream processing of biotech applications. They provide consistently high total throughput performance for biological fluid streams independent from media and process variations.

## Applications

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

- Plant peptone or yeast supplemented cell culture media
- Serum containing cell culture media
- Other cell culture media used in biotech manufacturing
- Clarified cell culture harvest
- Downstream Intermediates (before and after UF | DF and chromatography steps)

## Economy

The combination of the build in 0.8 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 XLG 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 XLG 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 XLG 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 XLG 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.

## 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 XLG 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

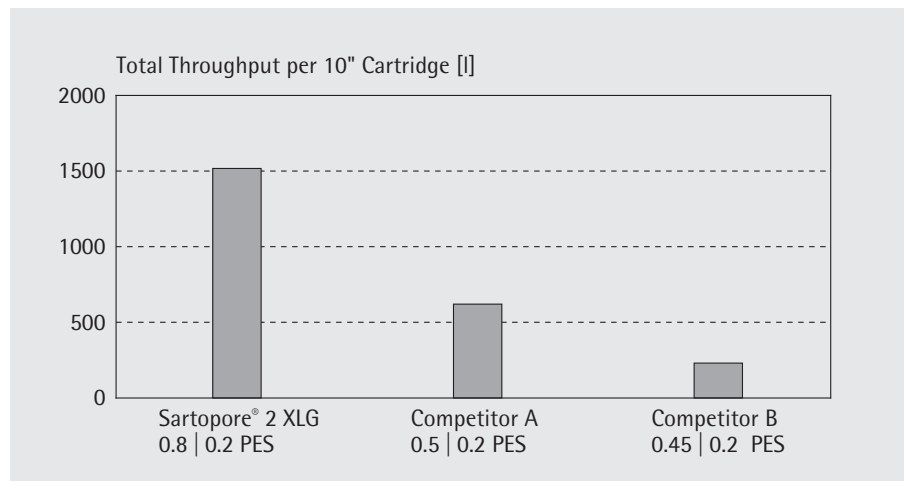
Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

## Soy Peptone Supplemented Cell Culture Media



## 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

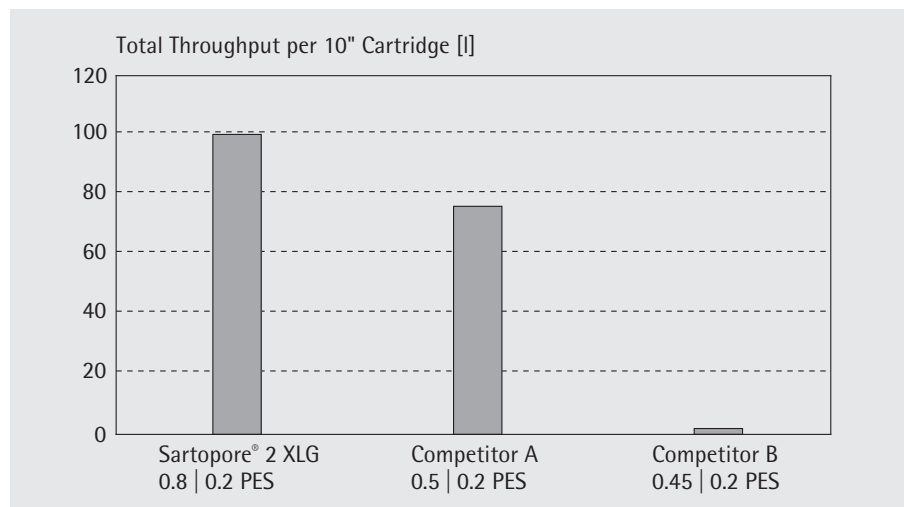
### Validation Guide:

SPK5772-e

### Extractables Guide:

SPK5775-e

## Monoclonal Antibody Pool



Antibody Concentration: 47.5 mg/ml

## Order Codes

| Cartridges | Pore Size [µm] | Pack Size [Pieces] | Test Pressure [bar   psi] | Max. Diffusion [ml/min] | Min. Bubble Point [bar   psi] |
|------------|----------------|--------------------|---------------------------|-------------------------|-------------------------------|
| 5442507G1  | 0.8 + 0.2      | 1                  | 2.5   36                  | 23                      | 3.2   46                      |
| 5442507G2  | 0.8 + 0.2      | 1                  | 2.5   36                  | 46                      | 3.2   46                      |
| 5442507G3  | 0.8 + 0.2      | 1                  | 2.5   36                  | 69                      | 3.2   46                      |

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