



Sartopore® 2 XLG 0.2 µm

Sterilizing Grade Filter Cartridges



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 m²/10" 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.

Specifications

Materials

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

Pore Size Combination

0.8 µm + 0.2 µm

Available Sizes | Filtration Area

Size 1	10"	0.8 m ²	8.6 ft ²
Size 2	20"	1.6 m ²	17.2 ft ²
Size 3	30"	2.4 m ²	25.8 ft ²

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

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

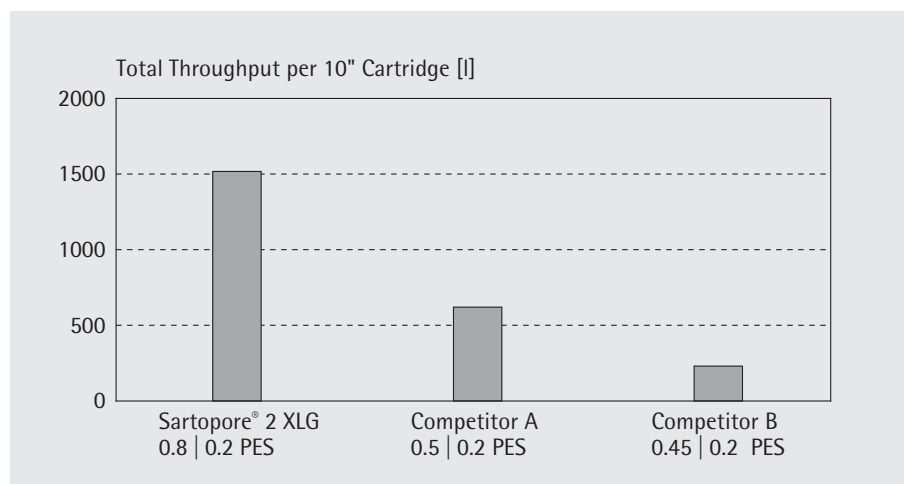
Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

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

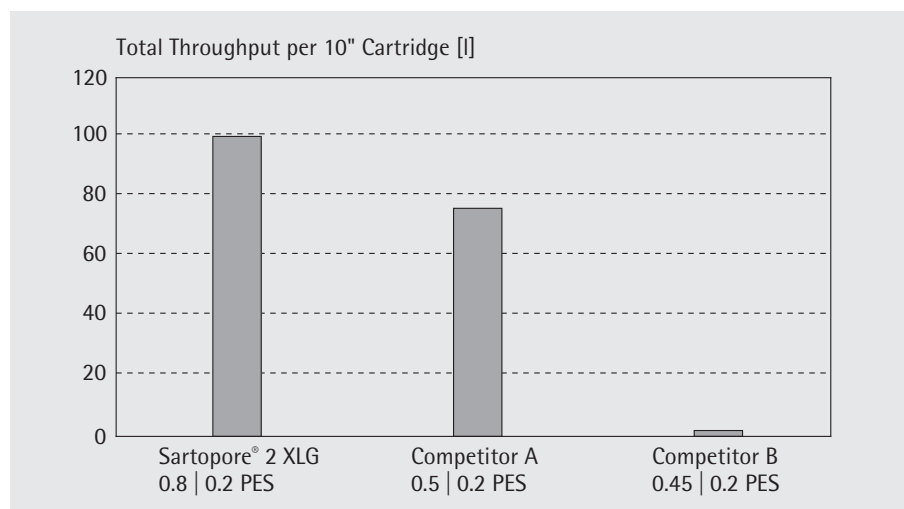
Validation Guide:

SPK5772-e

Extractables Guide:

SPK5775-e

Monoclonal Antibody Pool



Antibody Concentration: 47.5 mg/ml

Order Codes

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

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