



# Sartopore® 2 XLG

Sterilizing Grade MaxiCaps®, MidiCaps® and Capsules



## Description

Sartopore® 2 XLG MaxiCaps®, MidiCaps® & Capsules are self contained filter units that 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 MaxiCaps®, MidiCaps® & Capsules 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 MaxiCaps®, MidiCaps® & Capsules 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 built-in 0.8 µm pre-filter in front of a 0.2 µm final filter together with the 30% enlarged effective filtration area per XLG filter element provide an 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 MaxiCaps®, MidiCaps® & Capsules provide broad chemical compatibility from pH 1 to pH 14 and low extractable levels. They are compatible with multiple autoclaving 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.

## Cost Saving

The use of the capsule design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

## Microbiological Retention

Sartopore® 2 XLG MaxiCaps®, MidiCaps® & Capsules 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 Bubble Point and Diffusion test prior to being released assuring absolute reliability.

## Documentation

Sartopore® 2 XLG MaxiCaps®, MidiCaps® & Capsules 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

Pre-filter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support Fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

### Pore Size Combination

0.8 µm + 0.2 µm

### Available Sizes | Filtration Area

#### MaxiCaps®

Size 1	0.8 m <sup>2</sup>   8.6 ft <sup>2</sup>
Size 2	1.6 m <sup>2</sup>   17.2 ft <sup>2</sup>
Size 3	2.4 m <sup>2</sup>   25.8 ft <sup>2</sup>

#### MidiCaps®

Size 7	0.065 m <sup>2</sup>   0.7 ft <sup>2</sup>
Size 8	0.13 m <sup>2</sup>   1.4 ft <sup>2</sup>
Size 9	0.26 m <sup>2</sup>   2.8 ft <sup>2</sup>
Size 0	0.52 m <sup>2</sup>   5.6 ft <sup>2</sup>

#### Capsules

Size 4	0.021 m <sup>2</sup>   0.22 ft <sup>2</sup>
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### Available Connectors MaxiCaps®, MidiCaps®

S:	Tri-Clamp 50 mm (1 1/2")
O:	1/2" single stepped hose barb
F:	Tri-Clamp 25 mm (3/4")
H:	1/4" multiple stepped hose barb (only MidiCaps® size 7 with filling bell)

### Available Connectors Capsules

S:	Tri-Clamp 25 mm (3/4")
O:	1/4" multiple stepped hose barb

### Operating Parameters

Max. Allowable Differential Pressure	4 bar   58 psi at 20°C (MaxiCaps®, Capsules) 5 bar   72.5 psi at 20°C (MidiCaps®) 3 bar   43.5 psi at 50°C (MaxiCaps®) 2 bar   29 psi at 80°C (MidiCaps®, Capsules)
Max. Allowable Back Pressure	2 bar   29 psi at 20°C

## Specifications

### Extractables

Sartopore® 2 XLG 0.2 µm rated MaxiCaps®, MidiCaps® & Capsules 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

#### Autoclaving:

134°C, 2 bar, 30 min

#### Sterilization Cycles

Autoclaving: Min. 25

No In-Line Steam Sterilization

### Technical References

#### Validation Guide

SPK5772-e

### Order Information

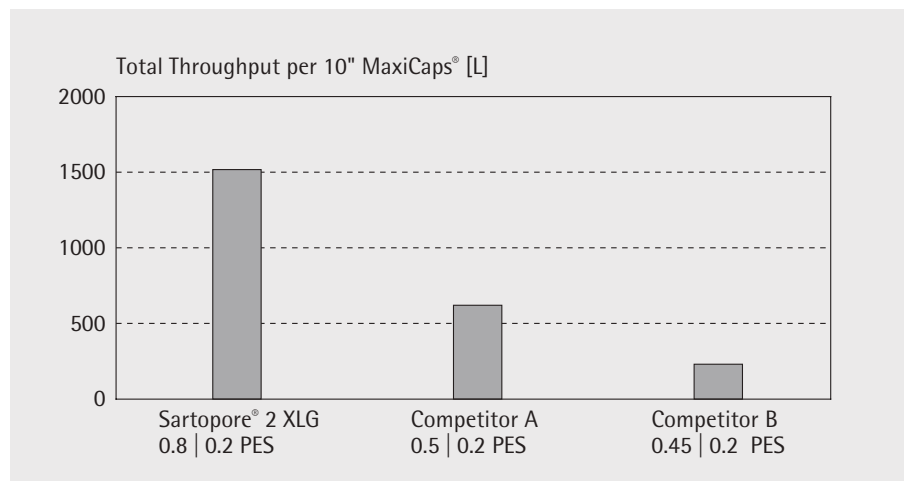
#### Order Code

	Pore Size [µm]	Pack Size [pieces]	Test Pressure [bar   psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar   psi]
<b>XLG MaxiCaps®</b>					
5441307G1--**	0.8 + 0.2	1	2.5   36	23	3.2   46
5441307G2--**	0.8 + 0.2	1	2.5   36	46	3.2   46
5441307G3--**	0.8 + 0.2	1	2.5   36	69	3.2   46
<b>XLG MidiCaps®</b>					
5445307G7--**--A	0.8 + 0.2	4	2.5   36	5	3.2   46
5445307G8--**--A	0.8 + 0.2	4	2.5   36	6	3.2   46
5445307G9--**--A	0.8 + 0.2	4	2.5   36	9	3.2   46
5445307G0--**--V	0.8 + 0.2	2	2.5   36	18	3.2   46
<b>XLG Capsules</b>					
5441307G4--**--B	0.8 + 0.2	5	2.5   36	1.1	3.2   46

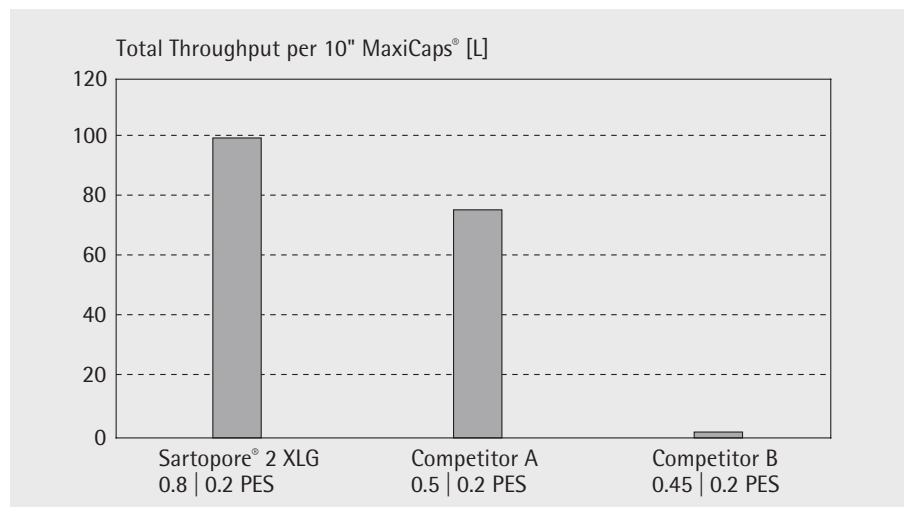
\*\* Connector Styles

(first code letter represents the inlet, the second the outlet)

## Soy Peptone Supplemented Cell Culture Media



## Monoclonal Antibody Pool



Antibody Concentration: 47.5 mg/ml

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