



# Sartopore® 2 0.45 µm

Bioburden & Particle Retentive MaxiCaps®, MidiCaps® and Capsules

MidiCaps® & MaxiCaps®



## Description

Sartopore® 2 0.45 µm rated MaxiCaps®, MidiCaps® and Capsules are self contained, ready to use filter units for bioburden reduction and particle removal from a broad range of pharmaceutical products. Membrane prefiltration of aqueous solutions and highly viscous pharmaceutical products difficult to filter can effectively be accomplished due to the outstanding total throughput and flow rate performance of Sartopore® 2 0.45 µm MaxiCaps®, MidiCaps® and Capsules.

## Applications

Typical applications include bioburden reduction and particle removal from:

- Therapeutics
- Injectables
- Buffers
- Biological Fluids
- Tissue Culture Media
- Acetic and basic solutions

## Compatibility

The polyethersulfone membrane is compatible with a pH-range from pH 1 to pH 14 making Sartopore® 2 MaxiCaps®, MidiCaps® and Capsules ideal for filtration of solutions with high | low pH.

## Easy to use

Sartopore® 2 MidiCaps® and Capsules are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

## Flexibility

Sartopore® 2 0.45 µm MaxiCaps®, MidiCaps® and Capsules are available with various

filtration areas from 300 cm<sup>2</sup> | 0.32 ft<sup>2</sup> up to 1.8 m<sup>2</sup> | 19.4 ft<sup>2</sup> and various connector styles for easy adoption to any filtration process independent from the batch size.

## Scalability

Consistent and predictable scale-up and down trials can reliably be performed as all Sartopore® 2 MaxiCaps®, MidiCaps® and Capsules are produced with the same type of membrane and materials and identical construction.

## Cost Saving

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

## Microbiological Retention

Sartopore® 2 0.45 µm rated MaxiCaps®, MidiCaps® and Capsules are fully validated with a Log Reduction Value (LRV) of 7 for *Serratia Marcescens* according to HIMA and ASTM F-838-05 procedures.

## Quality Control

Each individual element is tested for integrity by Bubble Point and Diffusion test prior to be released assuring absolute reliability.

## Documentation

Sartopore® 2 MaxiCaps®, MidiCaps® and Capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

## Specifications

### Materials

Prefilter 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 + 0.45 µm

### Available Sizes | Filtration Area

#### MaxiCaps®

Size 1	0.6 m <sup>2</sup>   6.5 ft <sup>2</sup>
Size 2	1.2 m <sup>2</sup>   12.9 ft <sup>2</sup>
Size 3	1.8 m <sup>2</sup>   19.4 ft <sup>2</sup>

#### MidiCaps®

Size 7	0.05 m <sup>2</sup>   0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1.1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup>   2.2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup>   4.8 ft <sup>2</sup>

#### Capsules

Size 5	0.03 m <sup>2</sup>   0.32 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

O:	1/4" multiple stepped hose barb
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### 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 0.45 µm rated MaxiCaps®, MidiCaps® and Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

### Regulatory Compliance

Individually integrity tested

Integrity test correlated to Bacteria Challenge Test using *Serratia marcescens* following HIMA/ASTM methodologies.

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

No In-Line Steam Sterilization

#### Sterilization Cycles

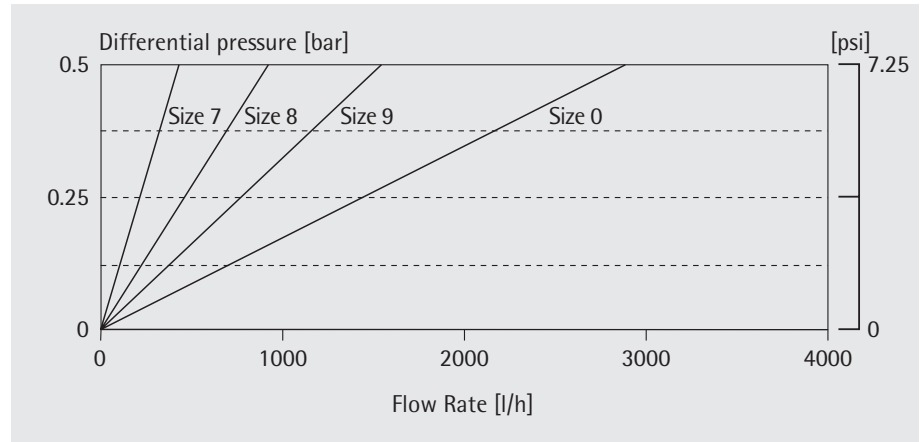
Autoclaving: Min. 25

### Technical References

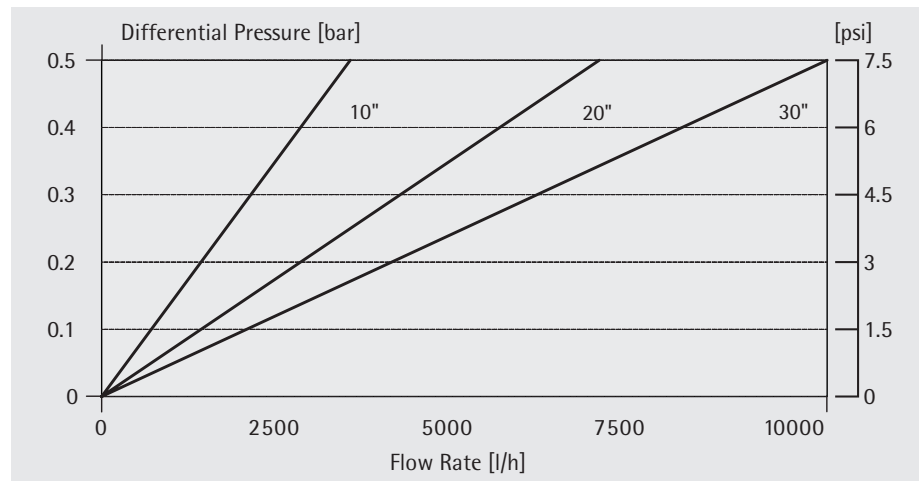
#### Validation Guide

SPK5732-e

Water Flow Rates for MidiCaps® with SS Connector



Water Flow Rates for Sartopore® 2 MaxiCaps®



Standardized at 20 °C

## Order Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar   psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar   psi]
<b>MaxiCaps®</b>					
5441306G1--**	0.45	1	1.7   25	12	2.2   32
5441306G2--**	0.45	1	1.7   25	24	2.2   32
5441306G3--**	0.45	1	1.7   25	36	2.2   32
<b>MidiCaps®</b>					
5445306G7--**--A	0.45	4	1.7   25	3	2.2   32
5445306G8--**--A	0.45	4	1.7   25	4	2.2   32
5445306G9--**--A	0.45	4	1.7   25	6	2.2   32
5445306G0--**--V	0.45	2	1.7   25	12	2.2   32
<b>Capsules</b>					
5441306G5--00--B	0.45	5	1.7   25	2	2.2   32

\*\* Connector Styles

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

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