sartorius stedim biotech

# Sartopore® 2 0.1 µm

**Sterilizing Grade and Mycoplasma Retentive MaxiCaps®, MidiCaps® and Capsules**

MidiCaps® & MaxiCaps®

## Description
Sartopore® 2 0.1 µm rated MaxiCaps®, MidiCaps® and Capsules are self-contained, ready-to-use membrane filter units for validated sterile filtration and reliable Mycoplasma removal in the pharma | biotech industry.

## Applications
Typical applications include sterilizing grade filtration and Mycoplasma removal from:
- Animal Sera
- Cell Culture Media
- Media Components
- Bioprocessed Pharmaceuticals
- Prefiltration infront of virus filters
- Biological Fluids

and any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.

## 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 0.1 µm MaxiCaps®, MidiCaps® and Capsules are available with various filtration areas from 150 $cm^2$ | 0.16 $ft^2$ up to 1.8 $m^2$ | 19.4 $ft^2$ 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 0.1 µm MaxiCaps®, MidiCaps® and Capsules are validated as sterilizing grade filters according to ASTM F-838-05 standard and for Mycoplasma removal with a Log Reduction Value (LRV) of 7 for Acholeplasma laidlawii.

## Quality Control
Each individual element is tested for integrity by 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
0.2 µm + 0.1 µm

### Available Sizes | Filtration Area

**MaxiCaps®**

| | |
|---|---|
| Size 1 | 0.6 $m^2$ \| 6.5 $ft^2$ |
| Size 2 | 1.2 $m^2$ \| 12.9 $ft^2$ |
| Size 3 | 1.8 $m^2$ \| 19.4 $ft^2$ |

**MidiCaps®**

| | |
|---|---|
| Size 7 | 0.05 $m^2$ \| 0.5 $ft^2$ |
| Size 8 | 0.1 $m^2$ \| 1.1 $ft^2$ |
| Size 9 | 0.2 $m^2$ \| 2.2 $ft^2$ |
| Size 0 | 0.45 $m^2$ \| 4.8 $ft^2$ |

**Capsules**

| | |
|---|---|
| Size 4 | 0.015 $m^2$ \| 0.16 $ft^2$ |
| Size 5 | 0.03 $m^2$ \| 0.32 $ft^2$ |

### Available Connectors MaxiCaps®, MidiCaps®

| | |
|---|---|
| S: | Tri-Clamp 50 mm (1 ½") |
| O: | ½" single stepped hose barb |
| F: | Tri-Clamp 25 mm (¾") |
| H: | ¼" multiple stepped hose barb (only MidiCaps® Size 7 with filling bell) |

### Available Connectors Capsules

| | |
|---|---|
| S: | Tri-Clamp 25 mm (¾") |
| O: | ¼" multiple stepped hose barb |

### Operating Parameters

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

## Specifications

**Extractables**
Sartopore® 2 0.1 µm 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 HIMA/ASTM F-838-05 Bacteria Challenge Test and Mycoplasma removal.

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

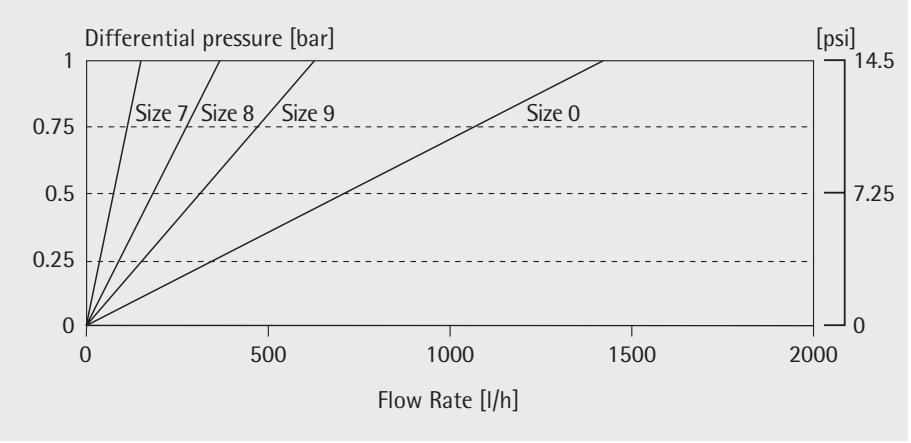
No In-Line Steam Sterilization

**Sterilization Cycles**
Autoclaving: Min. 25

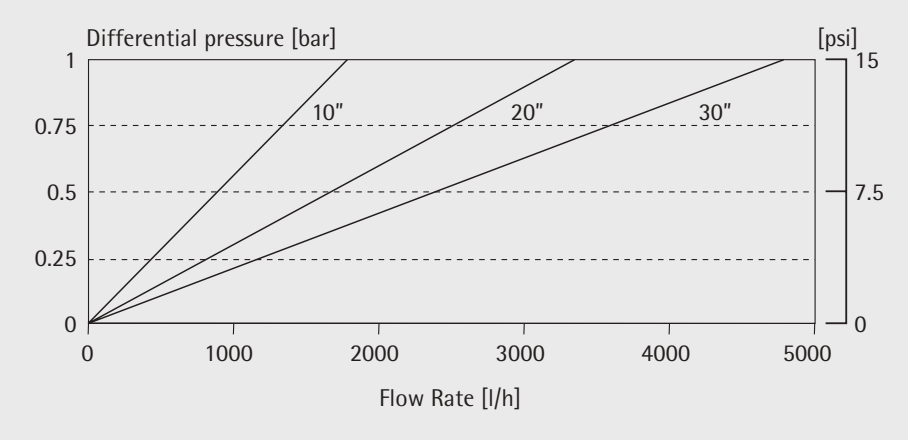
**Technical References**

**Validation Guide**
SPK5732-e

Water Flow Rates for MidiCaps® with SS Connector




Water Flow Rates for MaxiCaps®




Standardized at 20 °C

## Order Information

| Order Code | Pore size [µm] | Pack size [Pieces] | Test Pressure [bar \| psi] | Max. Diffusion [ml/min] |
|---|---|---|---|---|
| **MaxiCaps®** | | | | |
| 5441358K1--** | 0.1 | 1 | 4.0 \| 58 | 24 |
| 5441358K2--** | 0.1 | 1 | 4.0 \| 58 | 48 |
| 5441358K3--** | 0.1 | 1 | 4.0 \| 58 | 72 |
| **MidiCaps®** | | | | |
| 5445358K7--**--A | 0.1 | 4 | 4.0 \| 58 | 4 |
| 5445358K8--**--A | 0.1 | 4 | 4.0 \| 58 | 6 |
| 5445358K9--**--A | 0.1 | 4 | 4.0 \| 58 | 9 |
| 5445358K0--**--V | 0.1 | 2 | 4.0 \| 58 | 18 |
| **Capsules** | | | | |
| 5441358K4--**--B | 0.1 | 5 | 4.0 \| 58 | 1 |
| 5441358K5--**--B | 0.1 | 5 | 4.0 \| 58 | 2 |

** Connector Styles
(first code letter represents the inlet, the second the outlet)


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 +34.90.2110935
Russian Federation +7.812.327.5.327
Japan +81.3.4331.4300

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