



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 cm² | 0.32 ft² up to 1.8 m² | 19.4 ft² 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 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 5 | 0.03 m ² 0.32 ft ² |
|--------|--|

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 |
|----|---------------------------------|

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

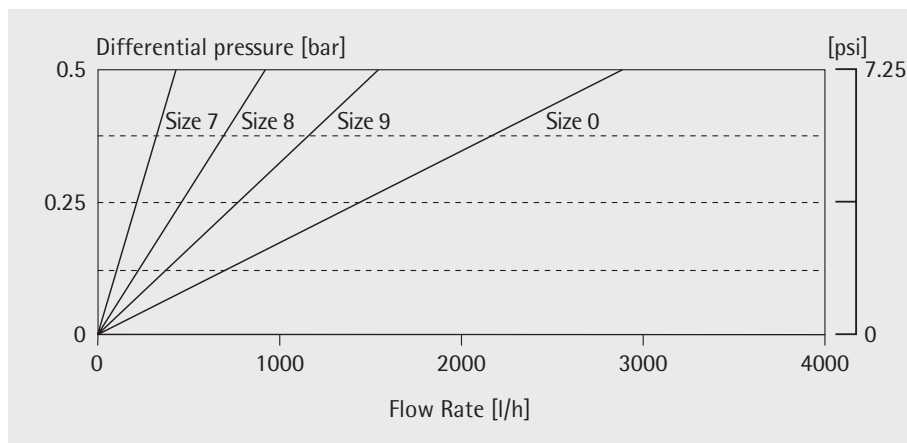
Autoclaving: Min. 25

Technical References

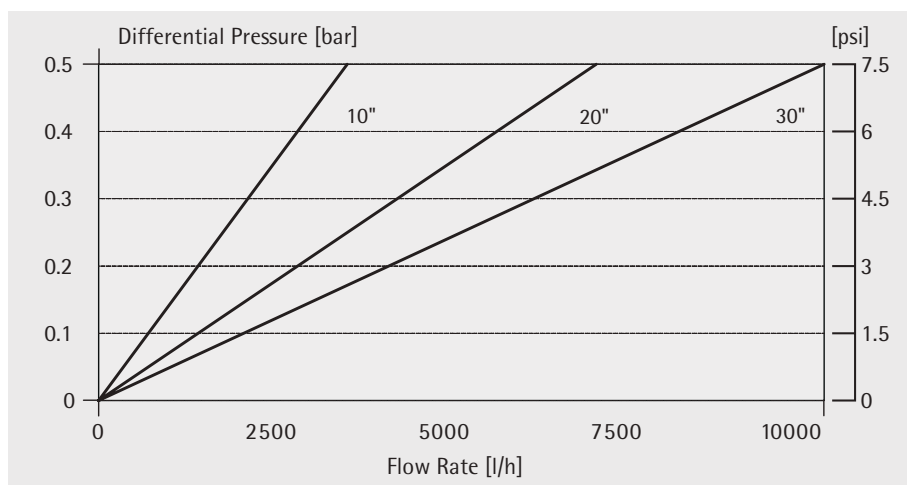
Validation Guide

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] |
|------------------|----------------|--------------------|---------------------------|-------------------------|-------------------------------|
| MaxiCaps® | | | | | |
| 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 |
| MidiCaps® | | | | | |
| 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 |
| Capsules | | | | | |
| 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)

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

Specifications subject to change without notice. Printed and copyrighted by Sartorius Stedim Biotech GmbH. | W
Publication No.: SPK2061-e13057
Order No.: 85030-521-82
Ver. 05 | 2013