



Sartopore® 2 0.2 µm

Sterilizing Grade MaxiCaps®, MidiCaps® and Capsules

MidiCaps® & MaxiCaps®



Description

Sartopore® 2 0.2 µm MaxiCaps®, MidiCaps® and Capsules are self contained, ready to use, sterile filter units for sterilizing grade filtration in the pharma | biotech industry. Made of a unique hydrophilic heterogeneous double layer Polyethersulfone membrane, Sartopore® 2 MaxiCaps®, MidiCaps® and Capsules are designed for convenient sterile filtration of a broad range of pharmaceutical products.

Applications

Typical applications include sterilizing grade filtration of:

- Therapeutics
- Biological Fluids
- Injectables
- Media
- Buffers
- Chemicals
- Cleaning and sanitizing agents

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 0.2 µm MaxiCaps®, MidiCaps® and Capsules are available with various

filtration areas from 150 cm² | 0.16 ft² up to 1.8 m² | 19.4 ft² 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 MaxiCaps®, MidiCaps® and 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 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

0.45 µm + 0.2 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 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 0.2 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

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

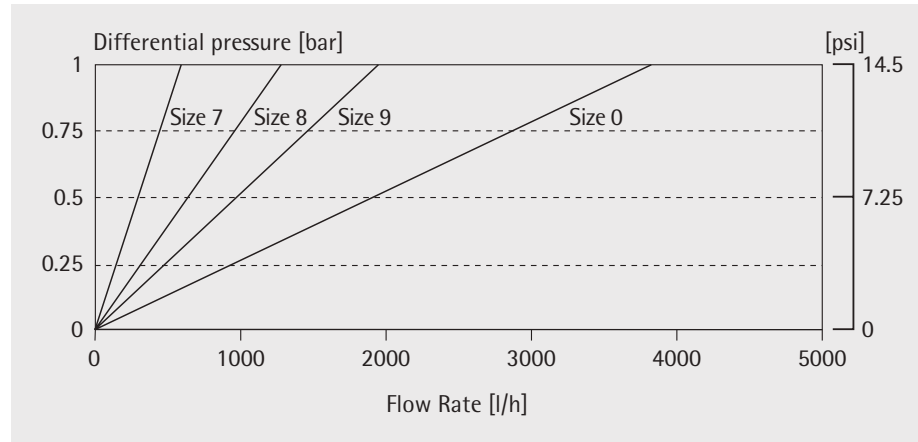
Autoclaving: Min. 25

Technical References

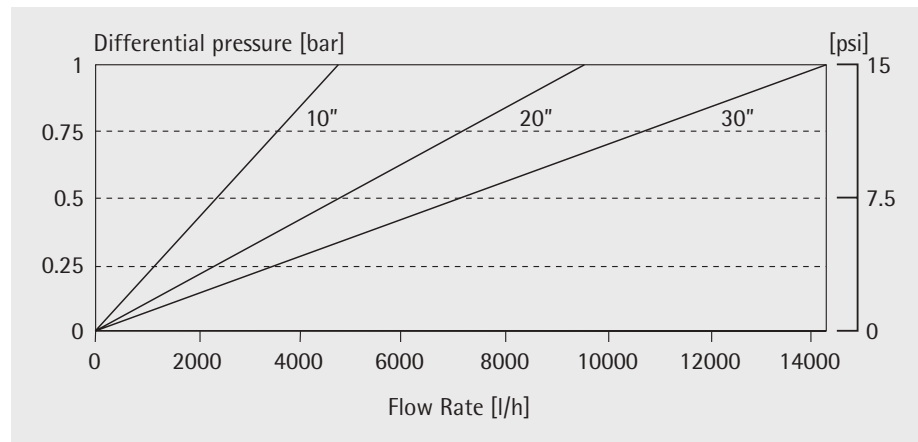
Validation Guide

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]	Min. Bubble Point [bar psi]
MaxiCaps®					
5441307H1--**	0.2	1	2.5 36	18	3.2 46
5441307H2--**	0.2	1	2.5 36	36	3.2 46
5441307H3--**	0.2	1	2.5 36	54	3.2 46
MidiCaps®					
5445307H7--***-A	0.2	4	2.5 36	4	3.2 46
5445307H8--***-A	0.2	4	2.5 36	5	3.2 46
5445307H9--***-A	0.2	4	2.5 36	7	3.2 46
5445307H0--***-V	0.2	2	2.5 36	14	3.2 46
Capsules					
5441307H4--***-B	0.2	5	2.5 36	1	3.2 46
5441307H5--***-B	0.2	5	2.5 36	2	3.2 46

** Connector Styles

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

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