sartorius stedim biotech

MidiCaps® and Capsules – 0.2 µm

The New Sterilizing Grade Filters

Membrane Filter Cartridges

Sartopore® platinum

A New Vision of Perfection.
A New Class of Sterile Filtration.

Description

Sartopore® Platinum sterilizing grade MidiCaps® and Capsules are self-contained ready-to-use, sterile filter units for sterilizing-grade filtration in the pharma | biotech industry. These filters contain a unique heterogeneous double layer of hydrophilized polyethersulfone membranes and are specially designed to meet the requirements for filtration of a broad range of pharmaceutical products.

The complete new and innovative technologies which are incorporated in these filters lead to outstanding and unique performance data. Using Sartopore® Platinum the critical step of sterilizing-grade filtration will reach a yet unmatched quality, performance and cost efficiency:

- outstanding total throughput and permeability
- unmet wettability
- broad chemical compatibility (pH 1-14)
- high thermal resistance
- exhibiting very low protein binding
- low extractables level
- reliable integrity testing

New Surface Modification
A new and patented membrane hydrophilization process is used to permanentely modify the membrane surface. In this process, a thermally exceptionally stable and hydrophilic polymer is directly grafted to the inner and outer surface of the membrane.

This new technology provides those membrane surface properties that are responsible for the outstanding wettability and low protein binding character of the Sartopore® Platinum membrane, even after thermal and chemical stress.

Excellent Wettability
Sartopore® Platinum MidiCaps® and Capsules can be easily wetted with lowest flushing volume needed. For reliable wetting you only need less than 1 liter for a size 9 MidiCaps® (0.26 m^2).

This excellent wetting behavior will thus directly reduce the filtration costs of your process.

Applications
Typical applications include sterilizing grade filtration of:

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

Reliable Integrity Testing
Imperfect wetting is the most frequent reason for failed integrity tests. In such cases filters have to be reliably re-wetted and tested again. Besides the cost factor for the additional test also a certain risk is present to loose a complete product batch when even repeated tests fail again.

The extraordinary wetting behavior of Sartopore® Platinum thus avoids this important risk factor. Using Sartopore® Platinum the process of integrity testing meets a yet unmet degree of reliability.

Compatibility
The polyethersulfone membrane can be used for the filtration of liquids with a pH range between 1 and 14. It is not affected even by multiple sterilizing cycles. Therefore, Sartopore® Platinum MidiCaps® and Capsules are suitable for most filtration applications in pharmaceutical and biotechnological processes.

Scalability
The flow rates and total thoughput per squaremeter membrane area are the same for the different filter sizes. Therefore, Sartopore® Platinum can be perfectly up-scaled from R&D to large process scale.

Microbial Retention
Sartopore® Platinum MidiCaps® and Capsules are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-05 guidelines.

Packaging
All MidiCaps® and Capsules are sterile and double wrapped for easy and safe clean-room transfer.

Quality Control
Each individual filter element is integrity tested by diffusion and bubble point prior to release, assuring highest quality and absolute reliability.

Documentation
Sartopore® Platinum MidiCaps® and Capsules are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.

Specifications

Materials of Construction

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polypropylene
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene
O-rings	Silicone

Pore Size
0.45 µm + 0.2 µm (double layer)

Available Sizes | Filtration Area

Capsules
Size 4 0.021 m² | 0.226 ft²

MidiCaps®
Size 7 0.065 m² | 0.67 ft²
Size 8 0.13 m² | 1.4 ft²
Size 9 0.26 m² | 2.8 ft²
Size 0 0.52 m² | 5.6 ft²

Available Connectors Capsule Size 4
SS, SO, OO, NO

S: TC Flange 25 mm (3/4 ")
O: multiple stepped hose barb
N: 1/4" NPT threat

Available Connectors MidiCaps®
SS, SO, OO, FF, FO, HH

S: TC Flange 50 mm (1½")
O: ½" Single-stepped hose barb
F: TC Flange 25 mm (¾")
H: ¼" Multiple stepped hose barb

Operating Parameters Capsule Size 4

Max. allowable differential pressure	4 bar | 58 psi at 20°C 2 bar | 29 psi at 50°C
Max. allowable back pressure	2 bar | 29 psi at 20°C 1.5 bar | 21.8 psi at 50°C

Operating Parameters MidiCaps®

Max. allowable differential pressure	5 bar | 72.5 psi at 20°C 3 bar | 29 psi at 50°C
Max. allowable back pressure	2 bar | 29 psi at 20°C 1.5 bar | 21.8 psi at 50°C

Extractables
Sartopore® Platinum 0.2 µm rated MidiCaps® and Capsules meet, or exceed the requirements for WFI quality standards set by the current USP. A detailed Extractables Guide is available on request.

Regulatory Compliance
100% individually integrity tested (Diffusion Test and Bubble Point Test).

Integrity test correlated with HIMA/ASTM F838-05 Bacterial Challenge Test.

Non pyrogenic according to USP Bacterial Endotoxins.

Passes USP Plastics Class VI Test.

Non-fibre releasing according to 21 CFR.

Sterilization

Autoclaving
134°C, 2 bar | 29 psi, 30 min

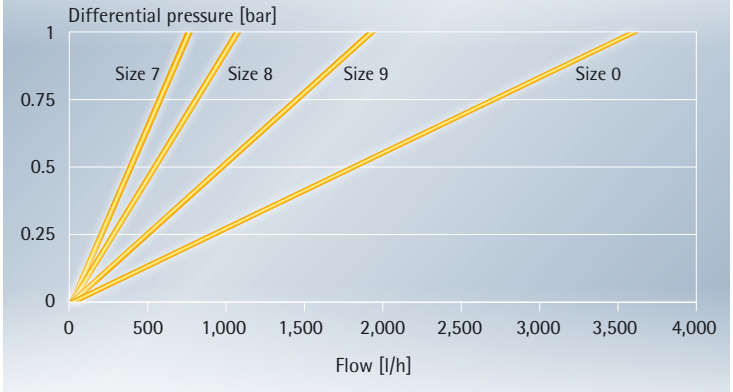
No in-line steam sterilization

Sterilization Cycles
Autoclaving: 25 (MidiCaps®)
3 (Capsules)

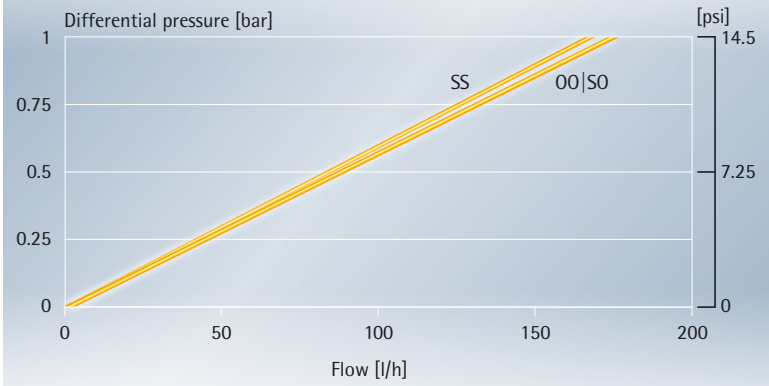
Technical References

Validation Guide
SPK5795-e

Water Flow Rates for MidiCaps®



Water Flow Rates for Capsules Size 4



Ordering Information

Order Code	Pore Size [µm]	Pack Size [pieces]	Test Pressure [bar | psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar | psi]
Capsules Size 4					
5491307H4--**--B	0.2 µm	5	2.5 | 36.25	1.1	3.5 | 50.7
MidiCaps®					
5495307H7—**—A	0.2 µm	4	2.5 | 36.25	4	3.5 | 50.7
5495307H8—**—A	0.2 µm	4	2.5 | 36.25	5	3.5 | 50.7
5495307H9—**—A	0.2 µm	4	2.5 | 36.25	7	3.5 | 50.7
5495307H0—**—V	0.2 µm	2	2.5 | 36.25	14	3.5 | 50.7

** Connector type