

# Sartopore 2 0.2 µm

## Sterilizing Grade Filter Capsules and MaxiCaps



### Description

Sartopore 2 membrane filter capsules and MaxiCaps are self contained, ready to use, filter units for sterilizing grade filtration in the pharma | biotech industry. Made of a unique hydrophilic heterogeneous double layer Polyethersulfone membrane, Sartopore 2 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 capsules and MaxiCaps ideal for filtration of solutions with high | low pH.

### Easy to use

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

### Flexibility

Sartopore 2 0.2 µm capsules and MaxiCaps are available with various filtration areas

from 150 cm<sup>2</sup> | 0.15 ft<sup>2</sup> up to 1.8 m<sup>2</sup> | 18 ft<sup>2</sup> for easy use in any filtration process independent of the batch size.

### Scalability

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

### Cost Saving

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

### Microbiological Retention

Sartopore 2 0.2 µm rated filter capsules and MaxiCaps are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 guidelines.

### Quality Control

Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability.

### Documentation

Sartopore 2 capsules and MaxiCaps 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

Prefilter Membrane:	Polyethersulfone, asymmetric
Endfilter Membrane:	Polyethersulfone, asymmetric
Support Fleece:	Polypropylene
Core:	Polypropylene
End Caps:	Polypropylene
Capsule Housing:	Polypropylene

#### Pore Size

0.45 µm + 0.2 µm

#### Available Sizes | Filtration Area

#### Capsules

Size 4	0.015 m <sup>2</sup>   0.15 ft <sup>2</sup>
Size 5	0.03 m <sup>2</sup>   0.3 ft <sup>2</sup>
Size 7	0.05 m <sup>2</sup>   0.5 ft <sup>2</sup>
Size 8	0.1 m <sup>2</sup>   1 ft <sup>2</sup>
Size 9	0.2 m <sup>2</sup>   2 ft <sup>2</sup>
Size 0	0.45 m <sup>2</sup>   5 ft <sup>2</sup>

#### MaxiCaps

Size 1	0.6 m <sup>2</sup>   6 ft <sup>2</sup>
Size 2	1.2 m <sup>2</sup>   12 ft <sup>2</sup>
Size 3	1.8 m <sup>2</sup>   18 ft <sup>2</sup>

#### Available Connectors

SS, SO, OO

#### Operating Parameters

Max. Allowable Differential Pressure:	4 bar   58 psi at 20 °C
	3 bar   43.5 psi at 50 °C (MaxiCaps)
	2 bar   29 psi at 80 °C

Max. Allowable Back Pressure:	2 bar   29 psi at 20 °C
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#### Integrity Test Limits

Maximum Allowable Diffusion at 2.5 bar / 36 psi @ 20 °C

Cartridge Size	Maximum Diffusion	Minimum Bubble Point
Size 1	18 ml / min	3.2 bar   46 psi
Size 2	36 ml / min	3.2 bar   46 psi
Size 3	54 ml / min	3.2 bar   46 psi
Size 4	1 ml / min	3.2 bar   46 psi
Size 5	2 ml / min	3.2 bar   46 psi
Size 7	4 ml / min	3.2 bar   46 psi
Size 8	5 ml / min	3.2 bar   46 psi
Size 9	7 ml / min	3.2 bar   46 psi
Size 0	14 ml / min	3.2 bar   46 psi

# Membrane Filter Capsules & MaxiCaps

## Specifications

### Extractables

Sartopore 2 0.2 µm rated filter capsules and MaxiCaps meet, or exceed the requirements for WFI quality standards set by the current USP.

### Regulatory Compliance

100% Individually integrity tested

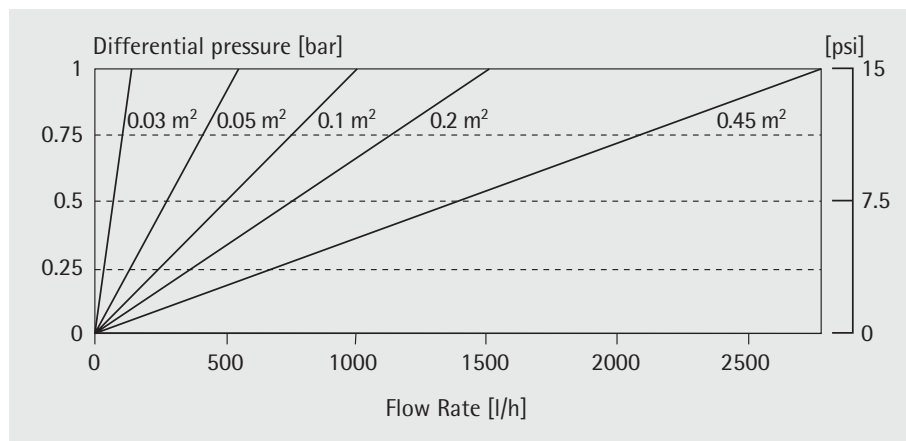
Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

Water Flow Rates for Capsules



Standardized at 20 °C

## Sterilization

### Autoclaving:

134 °C, 2 bar | 29 psi, 30 min

No In-Line Steam Sterilization

### Sterilization Cycles

Autoclaving: Min. 25

## Technical References

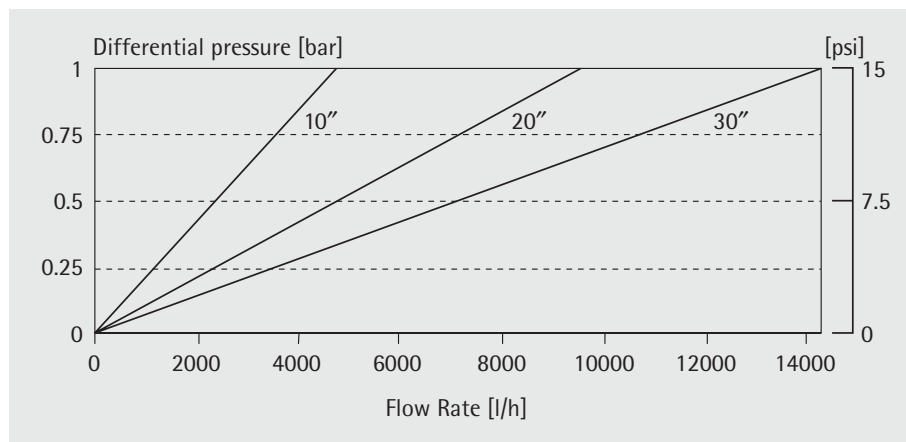
### Validation Guide:

SPK5732-e

### Extractables Guide:

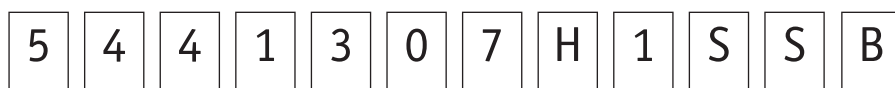
SPK5731-e

Water Flow Rates for MaxiCaps



Standardized at 20 °C

## Ordering Guide:



**Filter Family**  
544 = Sartopore 2

**Filter Format**  
13 = Capsule

**Final Membrane Pore Size**  
07 = 0.2 µm

**Prefilter Membrane Pore Size**  
H = .45 µm

**Connection Style**  
OO = Hose Barb In & Out  
SS = Sanitary Flange In & Out  
SO = Sanitary Flange In, Hose Barb out

### Capsule Size | Package Quantity (XX = Connection Style)

- 1XX\_ = 10" MaxiCap, 0.6m<sup>2</sup> / 6ft<sup>2</sup>, Single Unit
- 2XX\_ = 20" MaxiCap, 1.2m<sup>2</sup> / 12ft<sup>2</sup>, Single Unit
- 3XX\_ = 30" MaxiCap, 1.8m<sup>2</sup> / 18ft<sup>2</sup>, Single Unit
- 4XXB = 150 cm<sup>2</sup> / .15ft<sup>2</sup> Mini Capsule, Pack of 5
- 5XXB = 300 cm<sup>2</sup> / .3ft<sup>2</sup> Mini Capsule, Pack of 5
- 7XXB = 500 cm<sup>2</sup> / .5ft<sup>2</sup> Capsule, Pack of 5
- 8XXB = 0.1 m<sup>2</sup> / 1ft<sup>2</sup> Capsule, Pack of 5
- 9XXA = 0.2 m<sup>2</sup> / 2ft<sup>2</sup> Capsule, Pack of 4
- 0XXV = 0.45 m<sup>2</sup> / 5ft<sup>2</sup> Capsule, Pack of 2

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