

# Sartopore 2 0.1 µm

## Sterilizing Grade and Mycoplasma Retentive Filter Capsules & MaxiCaps



### Description

Sartopore 2 0.1 µm rated filter capsules and MaxiCaps 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
- Biological Fluids

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 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 0.1 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 from the batch size.

### Scalability

Consistent and predictable scale-up and scale-down trials can reliably be performed as all Sartopore 2 capsules and MaxiCaps 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 0.1 µm filter capsules and MaxiCaps are validated as sterilizing grade filters according to ASTM F 838-83 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 release assuring absolute reliability.

### Documentation

Sartopore 2 capsules and MaxiCaps are designed, developed and manufactured in accordance with a 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

0.2 µm + 0.1 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, S0, 00

#### 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 |
|-------------------------------|-------------------------|

#### Integrity Test Limits

Maximum Allowable Diffusion at 4.0 bar /58 psi & 20°C

| Capsule Size | Maximum Diffusion |
|--------------|-------------------|
| Size 1       | 24 ml/min         |
| Size 2       | 48 ml/min         |
| Size 3       | 72 ml/min         |
| Size 4       | 1 ml/min          |
| Size 5       | 2 ml/min          |
| Size 7       | 4 ml/min          |
| Size 8       | 6 ml/min          |
| Size 9       | 9 ml/min          |
| Size 0       | 18 ml/min         |

# Membrane Filter Capsules & MaxiCaps

## Specifications

### Extractables

Sartopore 2 0.1 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 and Mycoplasma removal

Non-pyrogenic according to USP Bacterial Endotoxins

Passes USP Plastics Class VI Test

Non-fiber releasing according to 21 CFR

### Sterilization

#### Autoclaving:

134 °C, 2 bar | 29 psi, 30 min

No In-Line Steam Sterilization

#### Sterilization Cycles

Autoclaving: Min. 25

### Technical References

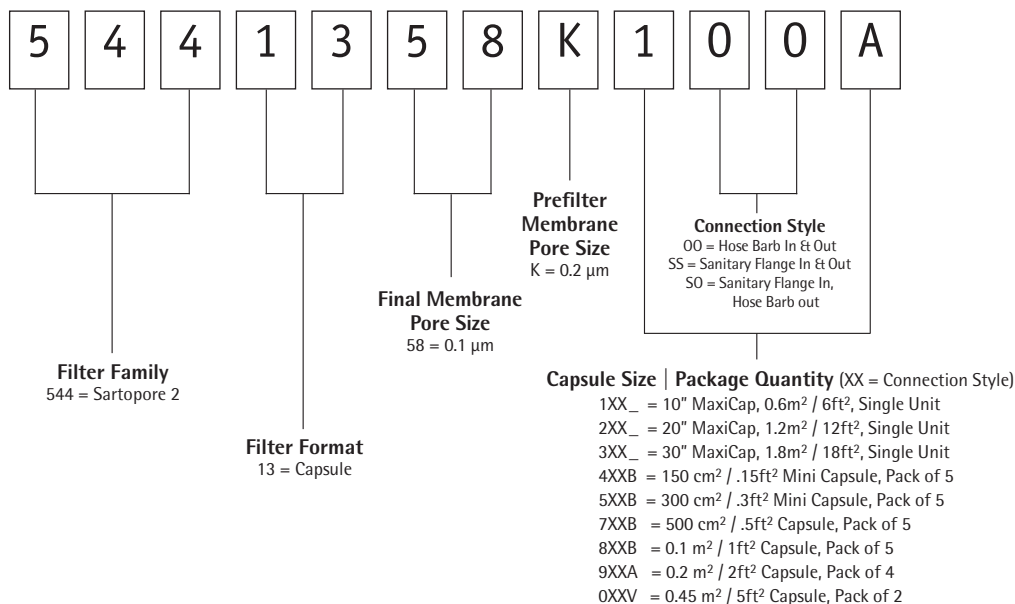
#### Validation Guide:

SPK5735-e

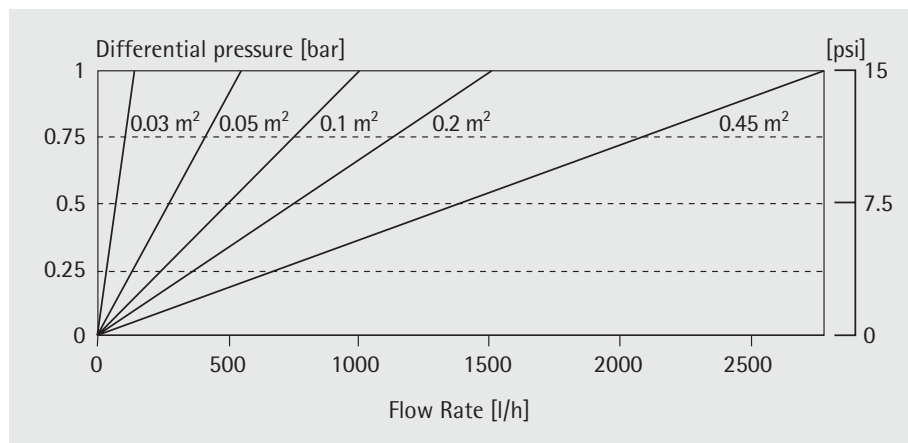
#### Extractables Guide:

SPK5731-e

### Ordering Guide:

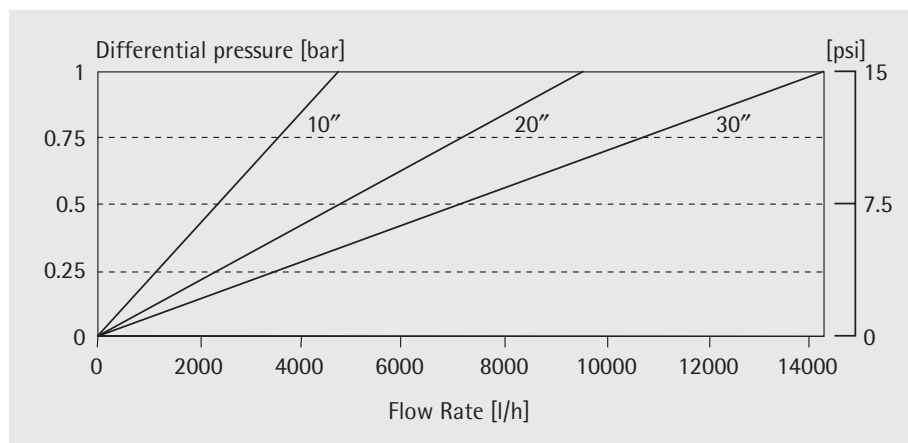


Water Flow Rates for Capsules



Standardized at 20 °C

Water Flow Rates for MaxiCaps



Standardized at 20 °C

Sartorius AG  
 Weender Landstrasse 94-108  
 37075 Goettingen, Germany  
 Phone +49.551.308.0  
 Fax +49.551.308.3289  
 www.sartorius.com  
 USA +1.631.254.4249  
 UK +44.1372.737100  
 France +33.1.69192100  
 Italy +39.055.634041  
 Spain +34.91.3586100  
 Japan +81.3.33293366

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