# SARTURIUS

# Sartobran® P 0.2 µm

Sterilizing-Grade Filter Elements



# Product Information

- Highest product yield due to extremely low unspecific adsorption
- Ideally suited for sterile filtration of vaccines and blood & plasma products
- Best solution for sterile filtration of large & shear-sensitive proteins and high-value biological solutions

# Highest Product Yield

Sartobran® P's cellulose acetate membranes provide the lowest unspecific adsorption of any membrane material available, ensuring high product recovery rates without alteration of excipient levels. Additionally, large and shear-sensitive proteins do not lose their structure and function when filtered through this special membrane.

# Flexibility and Scalability

All Sartobran® P 0.2  $\mu$ m filters are produced with the same type of membrane and identical materials of construction. The filter elements are available with various filtration areas from 0.015 m² | 0.54 ft² up to 1.8 m² | 19.4 ft² for simple and predictable scale-up as well as great process flexibility.

# Compatibility

Sartobran® P 0.2 µm filter elements can be used over pH range 4 – 8 thereby covering the vast majority of biopharmaceutical applications.

# **Applications**

- Coagulation factors, Albumin, IgG
- Bacterial, viral & mRNA-based vaccines
- Bioprocessed pharmaceuticals
- Ophthalmics
- Purified protein solutions
- Biological fluids
- Fluids containing preservatives

### Services

Sartorius Confidence® Validation Services is the perfect complement to Sartobran® P.

Our services provide

- Extractables and leachables services
- Microbiological testing
- Physicochemical testing

in compliance with regulatory requirements. Our local teams of validation experts support you with our tailored and consultative approach to determine the most cost-effective solution and give you the confidence you need to succeed.

# Technical Specifications

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar   36 psi [ml/min]	Min. Bubble Point [bar   psi]
Cartridges   Maxicaps®   T-Style	• Maxicaps®		
Size 0.5 (Only Cartridges)	0.3 m²   3.2 ft²	10	3.2   46
Size 1	0.6 m²   6.5 ft²	15	3.2   46
Size 2	1.2 m²   12.9 ft²	30	3.2   46
Size 3	1.8 m²   19.4 ft²	45	3.2   46
Mini Cartridge   Midicaps®			
Size 7	0.05 m²   0.54 ft²	3	3.2   46
Size 8	0.1 m <sup>2</sup>   1.1 ft <sup>2</sup>	4	3.2   46
Size 9	0.2 m <sup>2</sup>   2.2 ft <sup>2</sup>	5	3.2   46
Size 0 (Only Midicaps®)	0.45 m²   4.8 ft²	10	3.2   46
Capsules			
Size 4	0.015 m²   0.16 ft²	1	3.2   46
Size 5	0.03 m²   0.32 ft²	2	3.2   46

### Max. Allowable Differential Pressure

#### Cartridges | Mini Cartridges

5 bar | 72.5 psi at 20 °C 2 bar | 29 psi at 80 °C

#### T-Style Maxicaps® | Maxicaps® | Midicaps®

5 bar | 72.5 psi at 20 °C 3 bar | 43.5 psi at 50 °C

#### Capsules

4 bar | 58 psi at 20 °C 2 bar | 29 psi at 50 °C

# Max. Operating Pressure

# Cartridges | T-Style Maxicaps® | Maxicaps® | Midicaps® | Mini Cartridges

5 bar | 72.5 psi at 20 °C

#### Capsules

4 bar | 58 psi at 20 °C

#### Materials

#### Prefilter Membrane

Cellulose Acetate

#### **Endfilter Membrane**

Cellulose Acetate

#### Support Fleece

Polypropylene

#### Core

Polypropylene

#### **End Caps**

Polypropylene

#### Capsule Housing

Polypropylene

#### O-Ring

Silicone (optional EPDM or Fluoroelastomer)

#### Filling Bell

Polycarbonate

#### Max Allowable Back Pressure

2 bar | 29 psi at 20 °C (for all elements)

## Pore Size Combination

 $0.45 \, \mu m + 0.2 \, \mu m$ 

# Regulatory Compliance

- Each individual element is tested for integrity by Bubble Point and Diffusion test
- Fully validated as sterilizing-grade filters according to current ASTM F-838 guidelines
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- Meet or exceed the requirements for WFI quality standards set by the current USP
- Non-pyrogenic according to USP Bacterial Endotoxins
- Pass USP Plastic Class VI Test
- Non-fiber releasing according to 21 CFR



### Sterilization

#### Cartridges | Mini Cartridges

In-Line Steam Sterilization Max. 134 °C, 0.3 bar, 20 min

Min. 25 Sterilization Cycles

or

#### Autoclaving

Max. 134 °C, 2 bar, 30 min Min. 25 Sterilization Cycles

#### Maxicaps® | Midicaps® | Capsules

#### Autoclaving

Max. 134 °C, 2 bar, 30 min

Min. 25 Sterilization Cycles (Maxicaps® | Midicaps®)

Min. 3 Sterilization Cylcles (Capsules)

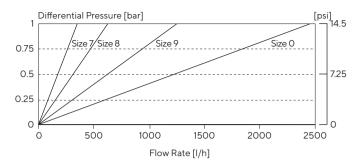
#### T-Style Maxicaps®

Autoclaving

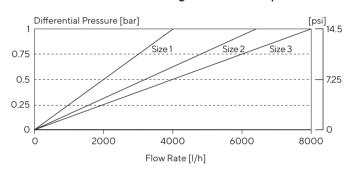
Max. 134 °C, 2 bar, 30 min Min. 25 Sterilization Cycles

### Performance

#### Water Flow Rates of Midicaps® with SS Adapter

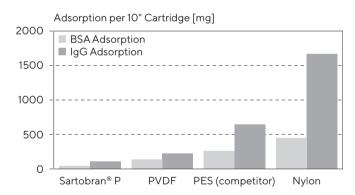


#### Water Flow Rates of Cartridges and Maxicaps®



Standardized at 20°C

#### **Protein Binding**



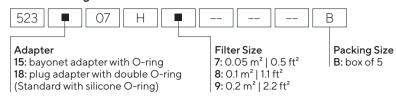
# **Technical References**

Validation Guide SPK5726-e Extractables Guide 100002449247

# Ordering Information

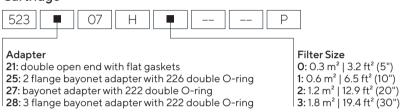


#### Mini Cartridge

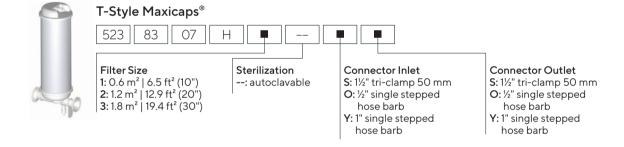




#### Cartridge

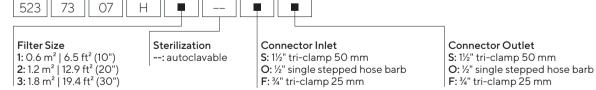


(Standard with silicone O-ring, optionally with EPDM O-ring. Example 5232507H2---EP)





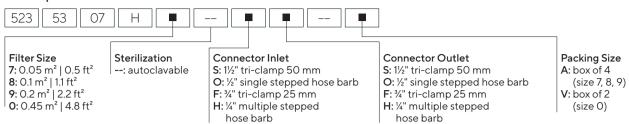
#### Maxicaps®



(Optionally with vent valve design for connection to integrity tester. Example: 5237307H1--OOIT)



#### Midicaps®





#### Capsules 523 13 07 Filter Size Sterilization Connector Outlet Packing Size Connector Inlet 4: 0.015 m<sup>2</sup> | 0.16 ft<sup>2</sup> --: autoclavable **S**: ¾" tri-clamp 25 mm S: ¾" tri-clamp 25 mm **B**: box of 5 5: 0.03 m<sup>2</sup> | 0.32 ft<sup>2</sup> O: ¼" multiple stepped O: ¼" multiple stepped hose barb hose barb (with filling bell)

Check the availability of your desired configuration with your Sartorius sales representative or online at www.sartorius.com

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www.sartorius.com