

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 highest 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 & Scalability

All Sartobran® P 0.2 µm 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

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 m ² 3.2 ft ²	10	3.2 46
Size 1	0.6 m ² 6.5 ft ²	15	3.2 46
Size 2	1.2 m ² 12.9 ft ²	30	3.2 46
Size 3	1.8 m ² 19.4 ft ²	45	3.2 46
Mini Cartridge Midicaps®			
Size 7	0.05 m ² 0.54 ft ²	3	3.2 46
Size 8	0.1 m ² 1.1 ft ²	4	3.2 46
Size 9	0.2 m ² 2.2 ft ²	5	3.2 46
Size 0 (Only Midicaps®)	0.45 m ² 4.8 ft ²	10	3.2 46
Capsules			
Size 4	0.015 m ² 0.16 ft ²	1	3.2 46
Size 5	0.03 m ² 0.32 ft ²	2	3.2 46

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.

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 µm + 0.2 µm

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 Cycles (Capsules)

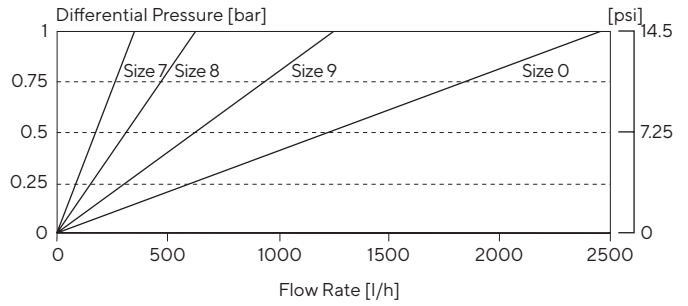
T-Style Maxicaps®

Autoclaving

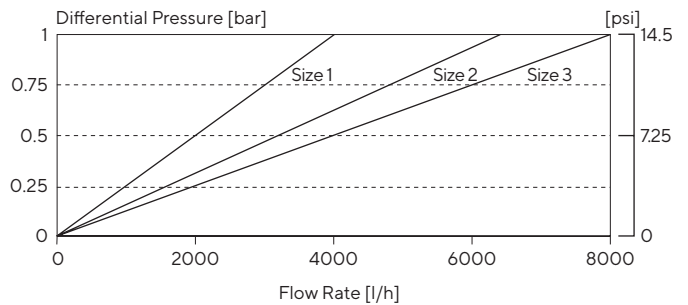
Max. 134°C, 2 bar, 30 min
 Min. 25 Sterilization Cycles

Performance

Water Flow Rates of Midicaps® with SS Adapter

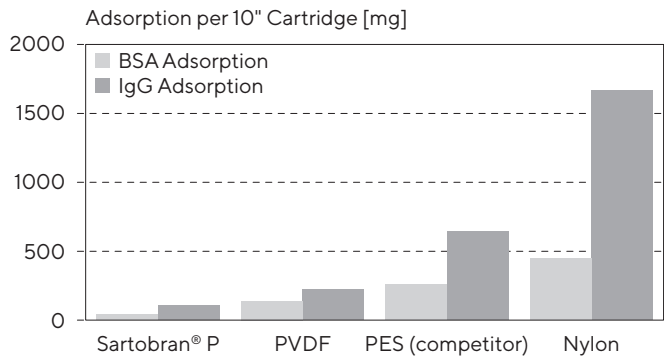


Water Flow Rates of Cartridges and Maxicaps®



Standardized at 20°C

Protein Binding



Technical References

Validation Guide SPK5726-e
 Extractables Guide 100002449247

Ordering Information



Mini Cartridge

523 ■ 07 H ■ -- -- -- B

Adapter

15: bayonet adapter with O-ring
18: plug adapter with double O-ring
(Standard with silicone O-ring)

Filter Size

7: 0.05 m² | 0.5 ft²
8: 0.1 m² | 1.1 ft²
9: 0.2 m² | 2.2 ft²

Packing Size

B: box of 5



Cartridge

523 ■ 07 H ■ -- -- P

Adapter

21: double open end with flat gaskets
25: 2 flange bayonet adapter with 226 double O-ring
27: bayonet adapter with 222 double O-ring
28: 3 flange bayonet adapter with 222 double O-ring

Filter Size

0: 0.3 m² | 3.2 ft² (5")
1: 0.6 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (30")

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



T-Style Maxicaps®

523 83 07 H ■ -- ■ ■

Filter Size

1: 0.6 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (30")

Sterilization

--: autoclavable

Connector Inlet

S: 1/2" tri-clamp 50 mm
O: 1/2" single stepped
hose barb
Y: 1" single stepped
hose barb

Connector Outlet

S: 1/2" tri-clamp 50 mm
O: 1/2" single stepped
hose barb
Y: 1" single stepped
hose barb



Maxicaps®

523 73 07 H ■ -- ■ ■

Filter Size

1: 0.6 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (30")

Sterilization

--: autoclavable

Connector Inlet

S: 1/2" tri-clamp 50 mm
O: 1/2" single stepped hose barb
F: 3/4" tri-clamp 25 mm

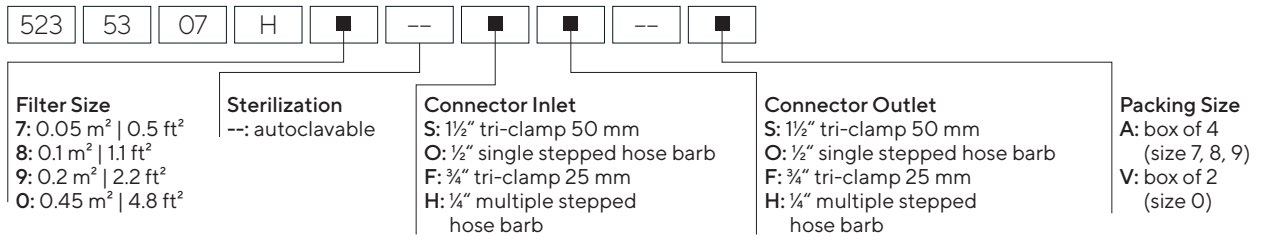
Connector Outlet

S: 1/2" tri-clamp 50 mm
O: 1/2" single stepped hose barb
F: 3/4" tri-clamp 25 mm

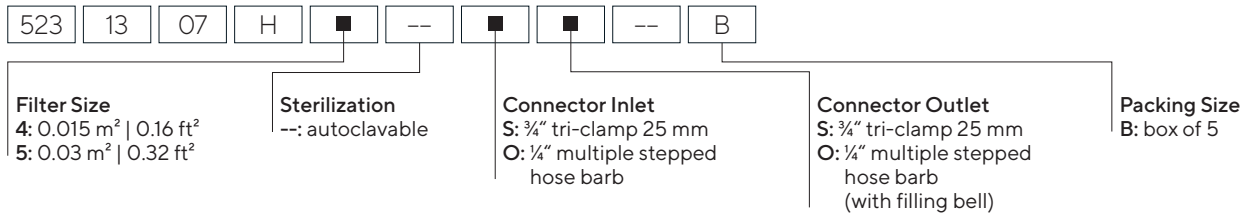
(Optionally with vent valve design for connection to integrity tester. Example: 5237307H1--OOIT)



Midicaps®



Capsules



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

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178



For more information, visit
www.sartorius.com