



Sartolon 0.2 μm

Sterilizing Grade Filter Elements

Product Information

- Unique hydrophilic nylon (polyamide) membrane provides broadest chemical compatibility for solvents
- Heterogeneous double layer design provides outstanding throughput and exceptional flowrates



Perfectly Suited for Filtration of Aggressive Solvents

Featuring a unique hydrophilic nylon (polyamide) membrane, Sartolon 0.2 μm filters provide a broad chemical compatibility especially for aggressive solvent solutions.

Exceptional Filtration Performances

In addition to its wide-ranging areas of application, Sartolon 0.2 μm filters provide an outstanding total throughput and flow rate performance in the target applications. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Highest Safety and Absolute Reliability

Sartolon 0.2 μm filter elements are fully validated as sterilizing grade filter elements according to HIMA and current ASTM F-838 guidelines. Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability. Sartolon filter elements are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation and Extractable Guide are available for compliance with regulatory requirements.

Scalability

Sartolon 0.2 μm filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale. The wide range of membrane areas from 2,000 cm^2 to 1.8 m^2 per filter element guarantees greatest flexibility and most economic filter sizing.

Applications

- Solvents
- Antibiotics
- Large Volume Parenterals
- Bulk Pharmaceutical Chemicals
- ADCs

Technical Data

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar 36 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges MaxiCaps®			
Size 1	0.6 m ² 6.5 ft ²	13	3.0 43.5
Size 2	1.2 m ² 12.9 ft ²	26	3.0 43.5
Size 3	1.8 m ² 19.4 ft ²	39	3.0 43.5
Size 4 (only Cartridge)	2.4 m ² 25.9 ft ²	52	3.0 43.5
Mini Cartridge MidiCaps®			
Size 9	0.2 m ² 2.2 ft ²	4	3.0 43.5

Max. Allowable Differential Pressure

Cartridges | Mini Cartridges

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

MaxiCaps® | MidiCaps®

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

Max. Allowable Back Pressure

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

Materials

Prefilter Membrane
Nylon

Endfilter Membrane
Nylon

Support Fleece
Polypropylene

Core
Polypropylene

End Caps
Polypropylene

O-Rings
Silicone
(other materials on request)

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 ASTM current 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
- USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR

Sterilization

Cartridges, Mini Cartridges

In-Line Steam Sterilization

134 °C, 0.3 bar, 20 min.

Min. 25 Sterilization Cycles

or

Autoclaving

134°C, 2 bar, 30 min

Min. 25 Sterilization Cycles

MaxiCaps®, MidiCaps®

Autoclaving

134°C, 2 bar, 30 min

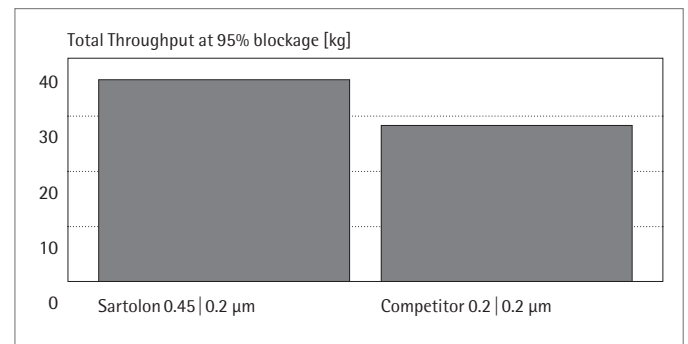
Min. 25 Sterilization Cycles

Technical References

Validation Guide SPK5716-e
Extractables Guide SPK5729-e

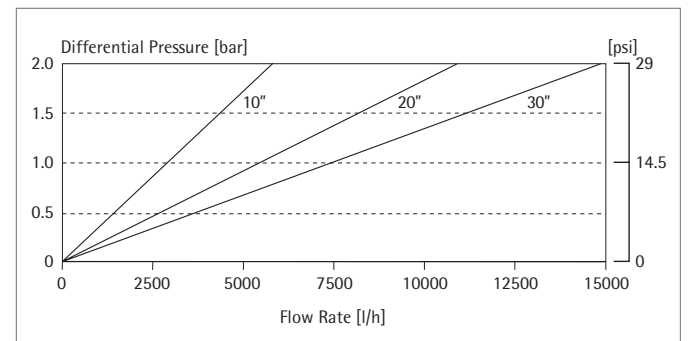
Performance

Total Throughput Comparison



10" Cartridge format

Water Flow Rates for Sartolon MaxiCaps®

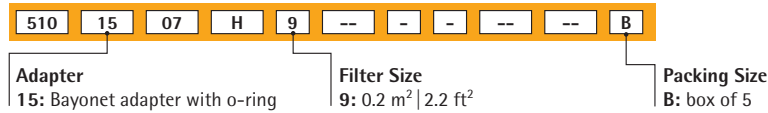


Standardized at 20°C

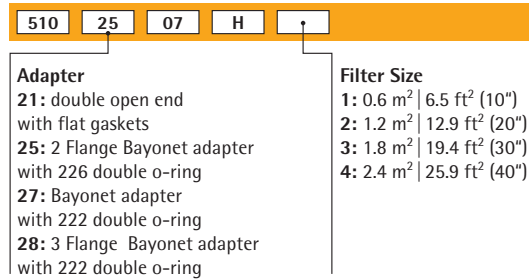
Ordering Information



Mini Cartridge



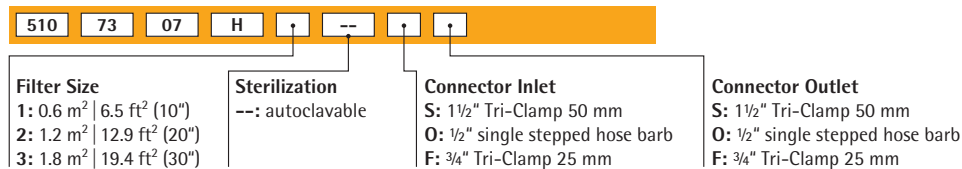
Cartridge



(Standard with silicone o-ring optional with EPDM o-ring. Example: 5102507H1)



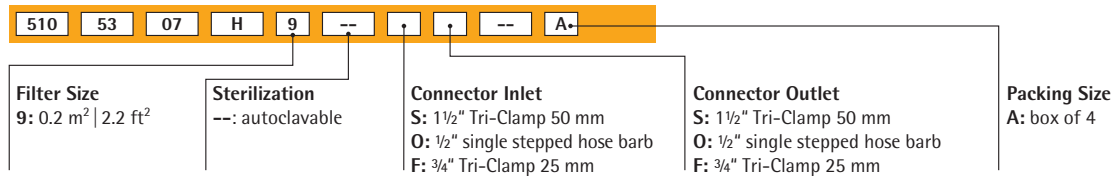
MaxiCaps®



(Optional with vent valve design for connection of integrity tester. Example: 5107307H1--SSIT)



MidiCaps®



Check the availability of your desired configuration with your Sartorius sales representative or online at:



www.sartorius-stedim.com

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany
Phone +49.551.308.0
Fax +49.551.308.3289
www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178
Argentina +54.11.4721.0505
Brazil +55.11.4362.8900
Mexico +52.55.5562.1102
UK +44.1372.737159
France +33.442.845600
Italy +39.055.63.40.41
Spain +34.913.586.098
Russian Federation +7.812.327.53.27
Japan +81.3.4331.4300
China +86.21.6878.2300