SARTURIUS

Sartolon

Sterilizing-Grade Filter Elements

- Sterile filtration of solvents and oily formulations
- Unique hydrophilic nylon membrane with broad chemical compatibility
- Heterogeneous double layer design provides outstanding throughput and exceptional flow rates



Perfectly Suited for Filtration of Solvents

Featuring a unique hydrophilic nylon (polyamide) membrane, Sartolon filters offer mechanical strength and broad chemical compatibility. They are the ideal choice for sterile filtration of solvents and oily formulations where chemical stability is needed.

Exceptional Filtration Performance

In addition to its wide range of applications, Sartolon filters provide outstanding total throughput and flow rates due to their heterogeneous double-nylon layer. The enhanced filtration performance guarantees process efficiency, reduces filtration costs and leads to short filtration cycles.

Scalability

Sartolon filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale. Membrane areas from 0.2 to 1.8 m² per filter element guarantee a high degree of flexibility and economic filter sizing.

Applications

- Solvents & Oily Formulations
- Antibiotics
- Large Volume Parenterals
- Bulk Pharmaceutical Chemicals
- ADCs



Services

Sartorius Confidence® Validation Services is the perfect complement to Sartolon.

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 Data

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar 36 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges Max	cicaps [®]		
Size 1	0.6 m² 6.5 ft²	13	3.0 43.5
Size 2	1.2 m ² 12.9 ft ²	26	3.0 43.5
Size 3	1.8 m² 19.4 ft²	39	3.0 43.5
Size 4 (only cartridge)	2.4 m ² 25.9 ft ²	52	3.0 43.5
	A4. I. @		
Mini Cartridge	Midicaps [®]		
Size 9	$0.2 m^2 2.2 ft^2$	4	3.0 43.5

Materials

Prefilter Membrane Nylon (Polyamide), reinforced with PET fleece
Endfilter Membrane Nylon (Polyamide)
Support Fleece Polypropylene
Core Polypropylene
End Caps Polypropylene
O-Rings Silicone (optional EPDM)

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	

Pore Size Combination

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

Max. Allowable Back Pressure

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

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
- 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

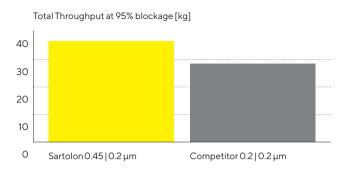
Maxicaps® | Midicaps®

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

Technical References		
Validation Guide	SPK5716-e	
Extractables Guide	SPK5729-e	

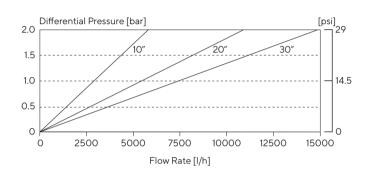
Performance

Total Throughput Comparison



10" Cartridge

Water Flow Rates Sartolon Maxicaps®

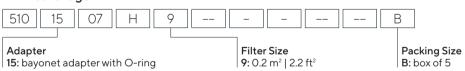


Standardized at 20°C

Ordering Information

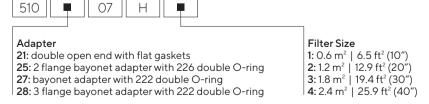


Mini Cartridge





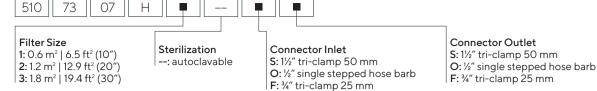
Cartridge



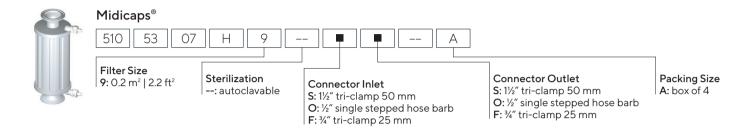
(Standard with silicone O-ring, optionally with EPDM O-ring. Example 5102507H1---E)



Maxicaps®



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





For further contacts, visit sartorius.com

Germany USA

Sartorius Stedim Biotech GmbH Sartorius Stedim North America Inc. August-Spindler-Strasse 11 565 Johnson Avenue

37079 Goettingen Bohemia, NY 11716
Phone +49 551 308 0 Toll-Free +1 800 368 7178

Representaciones de Centroamérica, S.A.

GUATEMALA

(502) 2461-2727 mercadeo@recasa.net **EL SALVADOR**

(503) 2522-0638 (503) 2522-1926 infosv@recasa.net **COSTA RICA**

(506) 4001-2965 infocr@recasa.net





