

Sartoguard PES

Bioburden Retention With Membrane Prefiltration



Product Information

- High total throughput for economic processing
- Onside integrity testable by Diffusion and Bubble
- Point Test
- Highly economic sizing for intermediate steps in downstream processing
- Excellent clarification capability and protection of subsequent final filters or other processing equipment

Bacteria Retention Capability

Sartoguard PES filters are available with 0.1 μm and 0.2 μm nominal retention rating. The 0.1 μm rated filters typically provide a LRV of 6 per cm^2 filtration area for *Brevundimonas Diminuta*. The 0.2 μm rated filters typically provide a LVR of 6 per cm^2 filtration area for *Serratia Marcescens*.

Scalability

Sartoguard PES 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 210 cm² to 2.4 m² per filter element provides exceptional flexibility and economic filter sizing.

Applications

Typical applications of Sartoguard PES filter elements include prefiltration of:

- Cell Culture Media
- Downstream Intermediates
(before and after UF | DF and chromatography steps)
- Clarified cell culture harvest
- Buffers
- Aseptically filled Small Volume Parenteral
- Protection of final filters

Technical Data

Available Sizes	Filtration Area	Max. Diffusion [mL/min]		Min. Bubble Point [bar psi]	
		0.1 µm (nom.) at 1.5 bar 22 psi	0.2 µm (nom.) at 1.2 bar 17.5 psi	0.1 µm (nom.)	0.2 µm (nom.)
Cartridges, Maxicaps® Gamma Maxicaps® and T-Style Maxicaps®					
Size 1 (10")	0.8 m ² 8.6 ft ²	25	18	2.8 40.5	1.8 26
Size 2 (20")	1.6 m ² 17.2 ft ²	50	36	2.8 40.5	1.8 26
Size 3 (30")	2.4 m ² 25.8 ft ²	75	54	2.8 40.5	1.8 26
Midicaps® Gamma Midicaps®					
Size 7	0.065 m ² 0.7 ft ²	3	3	2.8 40.5	1.8 26
Size 8	0.13 m ² 1.4 ft ²	6	4	2.8 40.5	1.8 26
Size 9	0.26 m ² 2.8 ft ²	9	6	2.8 40.5	1.8 26
Size 0	0.52 m ² 5.6 ft ²	18	12	2.8 40.5	1.8 26
Capsules Gamma Capsules					
Size 4	0.021 m ² 0.22 ft ²	1.1	1.1	2.8 40.5	1.8 26

Max. Allowable Differential Pressure

Cartridges

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

T-Style Maxicaps®, Maxicaps® | Gamma Maxicaps®, Midicaps® | Gamma Midicaps®

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

Capsules | Gamma Capsules Size 4

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

Max. Allowable Back Pressure

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

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartoguard PES filters.

Our services provide

- Extractables and leachables service
- 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.

Materials

Prefilter Membrane

Polyethersulfone, asymmetric

Endfilter Membrane

Polyethersulfone, asymmetric

Support Fleece

Polypropylene
(In-Line Steam sterilizable and autoclavable)
Polyester
(γ -irradiatable or γ -irradiatable | autoclavable)

Pore Size Combination

0.8 + 0.1 μm (nom.)
1.2 + 0.2 μm (nom.)

Regulatory Compliance

- Each individual element is tested for integrity by Diffusion and Bubble Point Test
- 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

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 (Midicaps® and Maxicaps®)
 Min. 5 Sterilization Cycles (Capsules)

Gamma Maxicaps®, Gamma Midicaps® & Gamma Capsules

Gamma Irradiation
 ≤ 50 kGy
 1 Sterilization Cycle

T-Style Maxicaps®

Autoclaving
 Max. 134 °C, 2 bar, 30 min
 Min. 5 Sterilization Cycles

or

Gamma Irradiation
 ≤ 50 kGy
 1 Sterilization Cycle

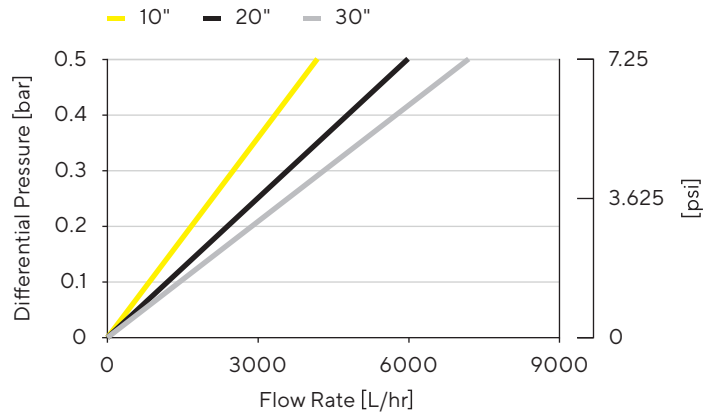
Technical References

Validation Guide

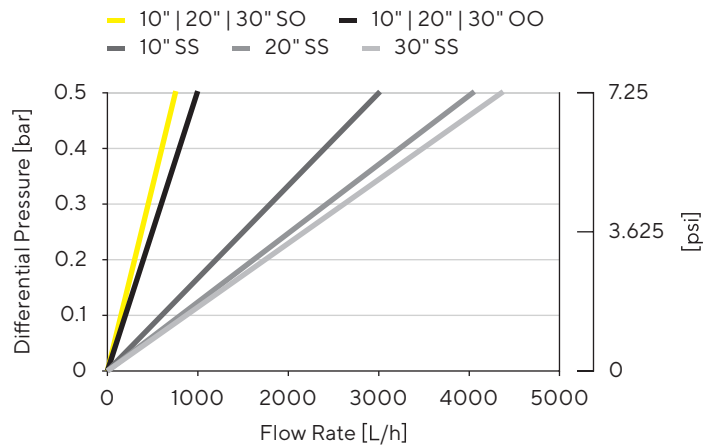
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Performance

Sartoguard PES 0.2 µm (nom.) Water Flow Rates for Standard Cartridges



Water Flow Rates for T-Style Maxicaps®



Ordering Information



Cartridges

547	25	■	■	■			
Retention Rates		Pore Size Filter		Filter Size			
58: 0.1 µm (nom.) 07: 0.2 µm (nom.)		G: 0.8 µm F: 1.2 µm		1: 0.8 m ² 8.6 ft ² (10") 2: 1.6 m ² 17.2 ft ² (20") 3: 2.4 m ² 25.8 ft ² (30")			



T-Style Maxicaps®

547	83	■	■	■	G-	■	■				
Retention Rates		Pore Size Filter		Filter Size		Sterilization		Connector Inlet		Connector Outlet	
58: 0.1 µm (nom.) 07: 0.2 µm (nom.)		G: 0.8 µm F: 1.2 µm		1: 0.8 m ² 8.6 ft ² (10") 2: 1.6 m ² 17.2 ft ² (20") 3: 2.4 m ² 25.8 ft ² (30")		G-: γ-irradiatable and autoclavable		S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb Y: 1" single stepped hose barb		S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb Y: 1" single stepped hose barb	



Maxicaps® | Gamma Maxicaps®

547	73	■	■	■	■	■	■				
Retention Rates		Pore Size Filter		Filter Size		Sterilization		Connector Inlet		Connector Outlet	
58: 0.1 µm (nom.) 07: 0.2 µm (nom.)		G: 0.8 µm F: 1.2 µm		1: 0.8 m ² 8.6 ft ² (10") 2: 1.6 m ² 17.2 ft ² (20") 3: 2.4 m ² 25.8 ft ² (30")		G-: γ-irradiatable --: autoclavable		S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb F: ¾" tri-clamp 25 mm		S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb F: ¾" tri-clamp 25 mm	



Midicaps® | Gamma Midicaps®

547	53	■	■	■	■	■	■	--	■		
Retention Rates		Pore Size Filter		Filter Size		Sterilization		Connector Inlet		Packing Size	
58: 0.1 µm (nom.) 07: 0.2 µm (nom.)		G: 0.8 µm F: 1.2 µm		7: 0.065 m ² 0.7 ft ² 8: 0.13 m ² 1.4 ft ² 9: 0.26 m ² 2.8 ft ² O: 0.52 m ² 5.6 ft ²		G-: γ-irradiatable --: autoclavable		S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb F: ¾" tri-clamp 25 mm H: ¼" multiple stepped hose barb (only size 7 with filling bell)		A: box of 4 (size 7, 8, 9) V: box of 2 (size 0)	
										Connector Outlet	
										S: 1½" Tri-Clamp 50.5 mm O: ½" single stepped hose barb F: ¾" tri-clamp 25 mm H: ¼" multiple stepped hose barb (only size 7 with filling bell)	



Capsules | Gamma Capsules


547	13	■	■	4	■	■	■	--	B	
Retention Rates		Pore Size Filter		Sterilization		Connector Inlet		Connector Outlet		Packing Size
58: 0.1 µm (nom.) 07: 0.2 µm (nom.)		G: 0.8 µm F: 1.2 µm		G-: γ-irradiatable --: autoclavable		S: ¾" Tri-Clamp 25 mm O: ¼" multiple stepped hose barb		S: ¾" Tri-Clamp 25 mm O: ¼" multiple stepped hose barb		B: box of 5

Germany

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Specifications subject to change without notice.

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