

# Sartoguard PES

## Bioburden Retention With Membrane Prefiltration



### Product Information

- High total throughput for economic processing
- Onsite 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  $\mu\text{m}$  and 0.2  $\mu\text{m}$  nominal retention rating. The 0.1  $\mu\text{m}$  rated filters typically provide a LRV of 6 per  $\text{cm}^2$  filtration area for *Brevundimonas Diminuta*. The 0.2  $\mu\text{m}$  rated filters typically provide a LRV of 6 per  $\text{cm}^2$  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 cm<sup>2</sup> to 2.4 m<sup>2</sup> per filter element guarantees greatest flexibility and most 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 at 1.5 bar   22 psi	0.2 µm at 1.2 bar   17.5 psi	0.1 µm	0.2 µm
<b>Cartridges, Maxicaps®   Gamma Maxicaps® and T-Style Maxicaps®</b>					
Size 1 (10")	0.8 m <sup>2</sup>   8.6 ft <sup>2</sup>	25	18	2.8   40.5	1.8   26
Size 2 (20")	1.6 m <sup>2</sup>   17.2 ft <sup>2</sup>	50	36	2.8   40.5	1.8   26
Size 3 (30")	2.4 m <sup>2</sup>   25.8 ft <sup>2</sup>	75	54	2.8   40.5	1.8   26
<b>Midicaps®   Gamma Midicaps®</b>					
Size 7	0.065 m <sup>2</sup>   0.7 ft <sup>2</sup>	3	3	2.8   40.5	1.8   26
Size 8	0.13 m <sup>2</sup>   1.4 ft <sup>2</sup>	6	4	2.8   40.5	1.8   26
Size 9	0.26 m <sup>2</sup>   2.8 ft <sup>2</sup>	9	6	2.8   40.5	1.8   26
Size 0	0.52 m <sup>2</sup>   5.6 ft <sup>2</sup>	18	12	2.8   40.5	1.8   26
<b>Capsules   Gamma Capsules</b>					
Size 4	0.021 m <sup>2</sup>   0.22 ft <sup>2</sup>	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  
( $\gamma$ -irradiatable or  $\gamma$ -irradiatable | autoclavable)

## Pore Size Combination

0.8 + 0.1  $\mu\text{m}$   
1.2 + 0.2  $\mu\text{m}$

## 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  
 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® & Capsules

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

or

Gamma Irradiation  
 ≤ 50 kGy  
 1 Sterilization Cycle

# Technical References

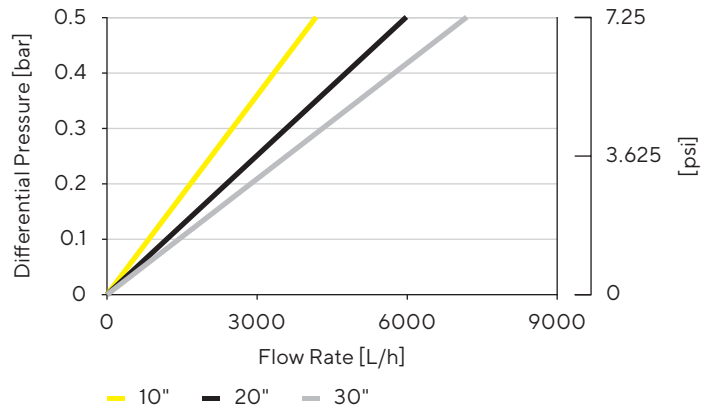
Validation Guide

DIR No.: 2670060

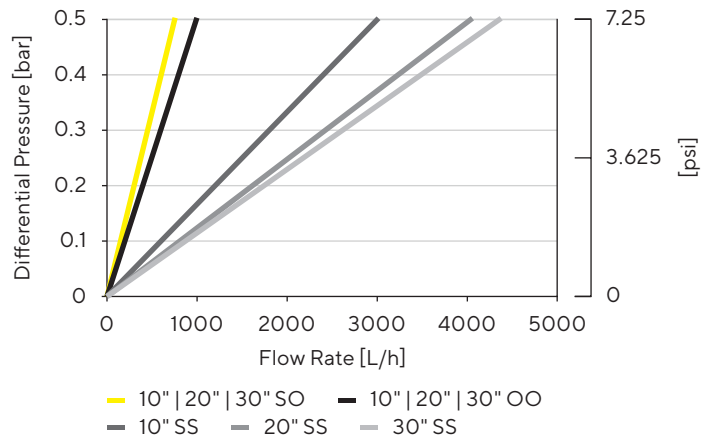
# Performance

## Sartoguard PES 0.2 µm Nominally

### Water Flow Rates for Standard Cartridges



### Water Flow Rates for T-Style Maxicaps®



# Ordering Information



## Cartridge

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



## T-Style Maxicaps®

547	83	■	■	■	G-	■	■
<b>Retention Rates</b> 58: 0.1 μm 07: 0.2 μm	<b>Pore Size Filter</b> G: 0.8 μm F: 1.2 μm	<b>Filter Size</b> 1: 0.8 m <sup>2</sup>   8.6 ft <sup>2</sup> (10") 2: 1.6 m <sup>2</sup>   17.2 ft <sup>2</sup> (20") 3: 2.4 m <sup>2</sup>   25.8 ft <sup>2</sup> (30")		<b>Sterilization</b> G-: γ-irradiatable and autoclavable	<b>Connector Inlet</b> S: 1½" Tri-Clamp 50 mm O: ½" single stepped hose barb	<b>Connector Outlet</b> S: 1½" Tri-Clamp 50 mm O: ½" single stepped hose barb	



## Maxicaps® | Gamma Maxicaps®

547	73	■	■	■	■	■	■
<b>Retention Rates</b> 58: 0.1 μm 07: 0.2 μm	<b>Pore Size Filter</b> G: 0.8 μm F: 1.2 μm	<b>Filter Size</b> 1: 0.8 m <sup>2</sup>   8.6 ft <sup>2</sup> (10") 2: 1.6 m <sup>2</sup>   17.2 ft <sup>2</sup> (20") 3: 2.4 m <sup>2</sup>   25.8 ft <sup>2</sup> (30")		<b>Sterilization</b> G-: γ-irradiatable --: autoclavable	<b>Connector Inlet</b> S: 1½" Tri-Clamp 50 mm O: ½" single stepped hose barb	<b>Connector Outlet</b> S: 1½" Tri-Clamp 50 mm O: ½" single stepped hose barb	



## Midicaps® | Gamma Midicaps®

547	53	■	■	■	■	■	■	--	■
<b>Retention Rates</b> 58: 0.1 μm 07: 0.2 μm	<b>Pore Size Filter</b> G: 0.8 μm F: 1.2 μm	<b>Filter Size</b> 7: 0.065 m <sup>2</sup>   0.7 ft <sup>2</sup> 8: 0.13 m <sup>2</sup>   1.4 ft <sup>2</sup> 9: 0.26 m <sup>2</sup>   2.8 ft <sup>2</sup> 0: 0.52 m <sup>2</sup>   5.6 ft <sup>2</sup>		<b>Sterilization</b> G-: γ-irradiatable --: autoclavable	<b>Connector Inlet</b> S: 1½" Tri-Clamp 50 mm O: ½" single stepped hose barb	<b>Connector Outlet</b> S: 1½" Tri-Clamp 50 mm O: ½" single stepped hose barb	<b>Packing Size</b> A: Box of 4 (size 7, 8, 9) V: Box of 2 (size 0)		



## Capsules | Gamma Capsules


547	13	■	■	4	■	■	■	--	B
<b>Retention Rates</b> 58: 0.1 μm 07: 0.2 μm	<b>Pore Size Filter</b> G: 0.8 μm F: 1.2 μm	<b>Sterilization</b> G-: γ-irradiatable --: autoclavable		<b>Connector Inlet</b> S: ¼" Tri-Clamp 25 mm O: ¼" multiple stepped hose barb		<b>Connector Outlet</b> S: ¼" Tri-Clamp 25 mm O: ¼" multiple stepped hose barb		<b>Packing Size</b> B: Box of 5	

**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 further contacts, visit  
[www.sartorius.com](http://www.sartorius.com)