

# Sartopore® 2 XLG

## Sterilizing-Grade Filter Elements



### Product Information

- Outstanding capacity and flow performance
- Lowest filter consumption for filtration of cell culture media
- Highly economic sizing for intermediate steps in downstream processing
- Optimization of conventional and single-use processes

### Reducing 50 – 90% of Filtration Costs

Sartopore® 2 XLG uses a coarser pre-filter layer (0.8 µm) in front of the sterilizing-grade rated final membrane (0.2 µm). The coarser pre-filter layer avoids early blocking in many biological liquids. The enhanced filtration capacity can reduce filtration costs by 50 – 90% for many processes.

## Scalability

Sartopore® 2 XLG 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 economic filter sizing.

## Applications

- Filtration of cell culture media such as:
  - Plant peptone or yeast supplemented cell culture media
  - Serum containing cell culture media
  - Other cell culture media used in biotech manufacturing
- Post cell harvest filtration
- Downstream intermediates  
(before and after UF | DF and chromatography steps)

## Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 XLG filters.

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 Specifications

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar   36 psi [ml/min]	Min. Bubble Point [bar   psi]
<b>Cartridges, T-Style Maxicaps®, Maxicaps®   Gamma Maxicaps®</b>			
Size 1	0.8 m <sup>2</sup>   8.6 ft <sup>2</sup>	23	3.2   46
Size 2	1.6 m <sup>2</sup>   17.2 ft <sup>2</sup>	46	3.2   46
Size 3	2.4 m <sup>2</sup>   25.8 ft <sup>2</sup>	69	3.2   46
<b>Midicaps®   Gamma Midicaps®</b>			
Size 7	0.065 m <sup>2</sup>   0.7 ft <sup>2</sup>	5	3.2   46
Size 8	0.13 m <sup>2</sup>   1.4 ft <sup>2</sup>	6	3.2   46
Size 9	0.26 m <sup>2</sup>   2.8 ft <sup>2</sup>	9	3.2   46
Size 0	0.52 m <sup>2</sup>   5.6 ft <sup>2</sup>	18	3.2   46
<b>Capsules   Gamma Capsules</b>			
Size 4	0.021 m <sup>2</sup>   0.22 ft <sup>2</sup>	1.1	3.2   46

## 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

## Materials

### Prefilter Membrane

Polyethersulfone,  
asymmetric

### Endfilter Membrane

Polyethersulfone,  
asymmetric

### Support Fleece

Polypropylene (In-line steam sterilizable & autoclavable)  
Polyester (Y-irradiatable or  $\gamma$ -irradiatable | autoclavable)

### Core

Polypropylene

### End Caps

Polypropylene

### Capsule Housing

Polypropylene

### O-Ring

Silicone  
(other materials on request)

### Filling Bell

Polycarbonate

## Max. Allowable Back Pressure

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

## Pore Size Combination

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

## Regulatory Compliance

- For release, 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

**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® & Maxicaps®)  
Min. 5 Sterilization Cycles (Capsules)

## Gamma Maxicaps®, Gamma Midicaps® & Gamma Capsules

**Gamma Irradiation**  
≤ 50 kGy  
1 Sterilization Cycle

## T-Style Maxicaps®

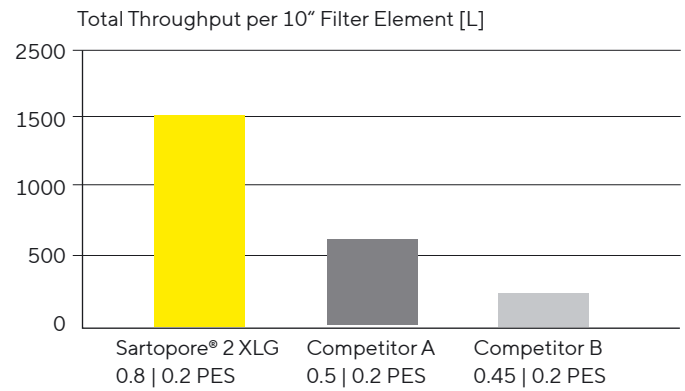
**Autoclaving**  
Max. 134°C, 2 bar, 30 min  
Min. 5 Sterilization Cycles

or

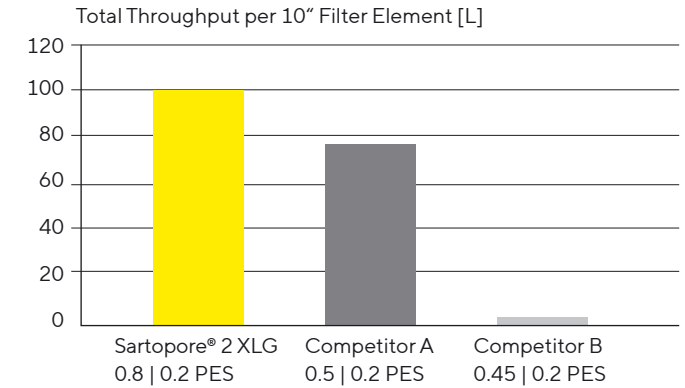
**Gamma Irradiation**  
≤ 50 kGy  
1 Sterilization Cycle

# Performance

## Soy Peptone Supplemented Cell Culture Media



## Monoclonal Antibody Pool<sup>1</sup>



<sup>1</sup>Antibody Concentration: 47.5 mg/ml

# Technical References

Validation Guide            2665242  
Extractables Guide        SPK5775-e

# Ordering Information



## Cartridge

544 25 07 G ■

### Adapter

25: 2 flange bayonet adapter with 226 double o-ring

### Filter Size

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")

(Standard with silicone o-ring optional with EPDM or Fluoroelastomer o-ring).



## T-Style Maxicaps®

544 83 07 G ■ G- ■ ■

### Filter Size

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")

### Sterilization

G-: γ-irradiatable and autoclavable

### Connector Inlet

S: 1½" tri-clamp 50.5 mm  
 O: ½" single stepped hose barb  
 Y: 1" single stepped hose barb

### Connector Outlet

S: 1½" tri-clamp 50.5 mm  
 O: ½" single stepped hose barb  
 Y: 1" single stepped hose barb



## Maxicaps® | Gamma Maxicaps®

544 73 07 G ■ ■ ■ ■

### Filter Size

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")

### Sterilization

G-: γ-irradiatable  
 --: autoclavable

### Connector Inlet

S: 1½" tri-clamp 50.5 mm  
 O: ½" single stepped hose barb  
 F: ¾" tri-clamp 25 mm

### Connector Outlet

S: 1½" tri-clamp 50.5 mm  
 O: ½" single stepped hose barb  
 F: ¾" tri-clamp 25 mm

(Optional with vent valve design for connection of integrity tester. Example: 5447307G1--SOIT)



## Midicaps® | Gamma Midicaps®

544 53 07 G ■ ■ ■ ■ -- ■

### Filter Size

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>

### Sterilization

G-: γ-irradiatable  
 --: autoclavable

### Connector Inlet

S: 1½" tri-clamp 50.5 mm  
 O: ½" single stepped hose barb  
 F: ¾" tri-clamp 25 mm

### Connector Outlet

S: 1½" tri-clamp 50.5 mm  
 O: ½" single stepped hose barb  
 F: ¾" tri-clamp 25 mm

### Packing Size

A: box of 4 (size 7, 8, 9)  
 V: box of 2 (size 0)



## Capsules | Gamma Capsules

544 13 07 G 4 ■ ■ ■ -- B

### Filter Size

4: 0.021 m<sup>2</sup> | 0.22 ft<sup>2</sup>

### Sterilization

G-: γ-irradiatable  
 --: autoclavable

### Connector Inlet

S: ¾" tri-clamp 25 mm  
 O: ¼" multiple stepped hose barb

### Connector Outlet

S: ¾" tri-clamp 25 mm  
 O: ¼" multiple stepped hose barb

### Packing Size

B: box of 5

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