

# Sartopore® 2 0.2 µm

## Sterilizing-Grade Filter Elements



### Product Information

- Industry standard of high-performance liquid sterile filters
- Unique hydrophilic heterogeneous double layer Polyethersulfone membrane
- Exceptionally high throughput and excellent flow rates at low pressure drops
- High thermal resistance and broad chemical compatibility

### High-Performance and broad compatibility

Sartopore® 2 filter elements feature a unique hydrophilic heterogeneous double layer design of a 0.45 µm pre-filter and 0.2 µm final filter membrane with an exceptionally high throughput and flow rate. In addition to its outstanding performance, the Polyethersulfone membrane gives Sartopore® 2 0.2 µm broad chemical compatibility, including a pH-range from pH 1 to pH 14, and a high thermal resistance.

## Industry standard for sterile-grade liquid filters

Sartopore® 2 0.2 µm filters are fully validated as sterilizing grade filter elements according to current ASTM F-838 guidelines. Each individual element is integrity tested by diffusion and bubble point test prior to release, assuring absolute reliability. Sartopore® 2 filter elements are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. The Validation and Extractables Guide are available for compliance with regulatory requirements.

## Scalability

Sartopore® 2 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 150 cm<sup>2</sup> to 1.8 m<sup>2</sup> per filter element guarantees greatest flexibility and most economic filter sizing.

## Applications

- Therapeutics
- Biological Fluids
- Ophthalmic solutions
- Injectables
- Media
- SVPs, LVPs
- Antibiotics
- WFI
- Buffers
- Chemicals
- Cleaning and sanitizing agents
- Bulk pharmaceutical products

## Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 0.2 µm 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 costeffective 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 0.5 (Only Cartridge)	0.3 m <sup>2</sup>   3.2 ft <sup>2</sup>	10	3.2   46
Size 1	0.6 m <sup>2</sup>   6.5 ft <sup>2</sup>	18	3.2   46
Size 2	1.2 m <sup>2</sup>   12.9 ft <sup>2</sup>	36	3.2   46
Size 3	1.8 m <sup>2</sup>   19.4 ft <sup>2</sup>	54	3.2   46
<b>Mini Cartridges, Midicaps®   Gamma Midicaps®</b>			
Size 7	0.05 m <sup>2</sup>   0.5 ft <sup>2</sup>	4	3.2   46
Size 8	0.1 m <sup>2</sup>   1.1 ft <sup>2</sup>	5	3.2   46
Size 9	0.2 m <sup>2</sup>   2.2 ft <sup>2</sup>	7	3.2   46
Size 0 (Only Midicaps® & Gamma Midicaps®)	0.45 m <sup>2</sup>   4.8 ft <sup>2</sup>	14	3.2   46
<b>Capsules   Gamma Capsules</b>			
Size 4	0.015 m <sup>2</sup>   0.16 ft <sup>2</sup>	1	3.2   46
Size 5	0.03 m <sup>2</sup>   0.32 ft <sup>2</sup>	2	3.2   46

## Max. Allowable Differential Pressure

### Mini Cartridges | 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

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 (γ-irradiatable or γ-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

0.45 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

## Mini Cartridges, 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® & 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

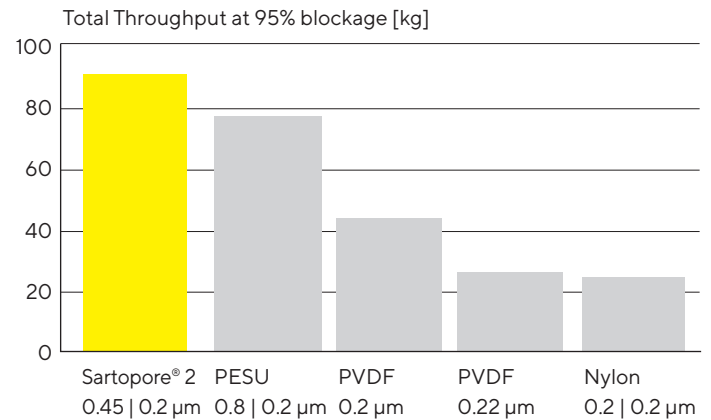
Gamma Irradiation  
 < 50 kGy  
 1 Sterilization Cycle

# Technical References

Validation Guide            2665239  
 Extractables Guide        2396283

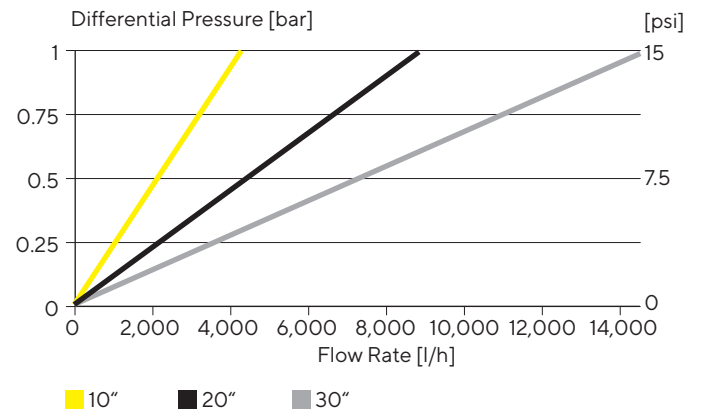
# Performance

## Total Throughput Comparison



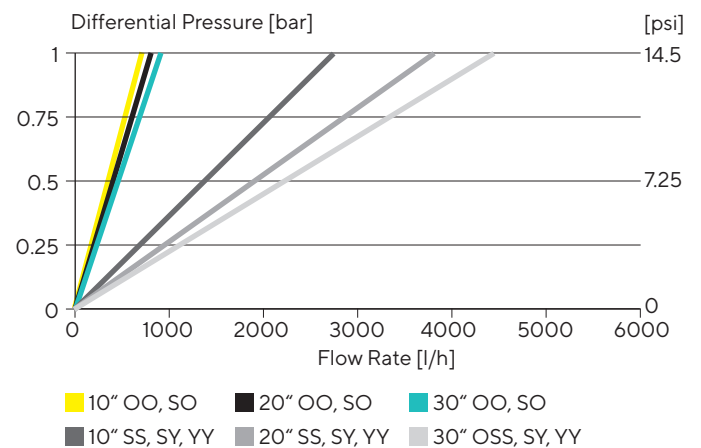
10" Cartridges format

## Water Flow Rates for Standard Cartridges



Standardized at 20°C

## Water Flow Rates for T-Style Maxicaps®



# Ordering Information



## Mini Cartridge

544 15 07 H ■ -- - - -- -- B

### Adapter

**15:** Bayonet adapter with o-ring  
**18:** Plug Adapter with double o-ring

### Filter Size

**7:** 0.05 m<sup>2</sup> | 0.5 ft<sup>2</sup>  
**8:** 0.1 m<sup>2</sup> | 1.1 ft<sup>2</sup>  
**9:** 0.2 m<sup>2</sup> | 2.2 ft<sup>2</sup>

### Packing Size

**B:** box of 5

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



## Cartridge

544 25 07 H ■

### Adapter

**21:** double open end with flat gaskets  
**25:** 2 flange bayonet adapter with 226 double o-ring  
**27:** Bayonet adapter with 222 double o-ring  
**28:** 3 Flange bayonet adapter with 222 double o-ring

### Filter Size

**0:** 0.3 m<sup>2</sup> | 3.2 ft<sup>2</sup> (5")  
**1:** 0.6 m<sup>2</sup> | 6.5 ft<sup>2</sup> (10")  
**2:** 1.2 m<sup>2</sup> | 12.9 ft<sup>2</sup> (20")  
**3:** 1.8 m<sup>2</sup> | 19.4 ft<sup>2</sup> (30")

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



## T-Style Maxicaps®

544 83 07 H ■ G- ■ ■

### Filter Size

**1:** 0.6 m<sup>2</sup> | 6.5 ft<sup>2</sup> (10")  
**2:** 1.2 m<sup>2</sup> | 12.9 ft<sup>2</sup> (20")  
**3:** 1.8 m<sup>2</sup> | 19.4 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 H ■ ■ ■ ■

### Filter Size

**1:** 0.6 m<sup>2</sup> | 6.5 ft<sup>2</sup> (10")  
**2:** 1.2 m<sup>2</sup> | 12.9 ft<sup>2</sup> (20")  
**3:** 1.8 m<sup>2</sup> | 19.4 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: 5447307H1--SSIT)



### Midicaps® | Gamma Midicaps®

544 53 07 H ■ ■ ■ ■ -- ■

**Filter Size**  
 7: 0.05 m<sup>2</sup> | 0.5 ft<sup>2</sup>  
 8: 0.1 m<sup>2</sup> | 1.1 ft<sup>2</sup>  
 9: 0.2 m<sup>2</sup> | 2.2 ft<sup>2</sup>  
 0: 0.45 m<sup>2</sup> | 4.8 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  
 H: ¼" multiple stepped  
 hose barb (only size 7  
 with filling bell)

**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)

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



### Capsules | Gamma Capsules

544 13 07 H ■ ■ ■ ■ -- B

**Filter Size**  
 4: 0.015 m<sup>2</sup> | 0.16 ft<sup>2</sup>  
 5: 0.03 m<sup>2</sup> | 0.32 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" single stepped  
 hose barb

**Packing Size**  
 B: box of 5

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