SARTORIUS

Product Datasheet

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^2 to 1.8 m^2 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]
Cartridges, T-Style Maxicaps®, Maxicaps® | Gamma Maxicaps®			
Size 0.5 (Only Cartridge)	0.3 m^2 | 3.2 ft^2	10	3.2 | 46
Size 1	0.6 m^2 | 6.5 ft^2	18	3.2 | 46
Size 2	1.2 m^2 | 12.9 ft^2	36	3.2 | 46
Size 3	1.8 m^2 | 19.4 ft^2	54	3.2 | 46
Mini Cartridges, Midicaps® | Gamma Midicaps®			
Size 7	0.05 m^2 | 0.5 ft^2	4	3.2 | 46
Size 8	0.1 m^2 | 1.1 ft^2	5	3.2 | 46
Size 9	0.2 m^2 | 2.2 ft^2	7	3.2 | 46
Size 0 (Only Midicaps® & Gamma Midicaps®)	0.45 m^2 | 4.8 ft^2	14	3.2 | 46
Capsules | Gamma Capsules			
Size 4	0.015 m^2 | 0.16 ft^2	1	3.2 | 46
Size 5	0.03 m^2 | 0.32 ft^2	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, symmetric

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

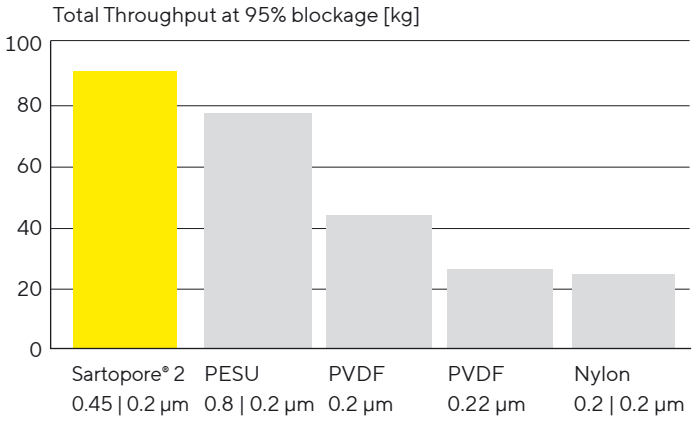
Gamma Irradiation
< 50 kGy
1 Sterilization Cycle

Technical References

Validation Guide	2665239
Extractables Guide	2396283

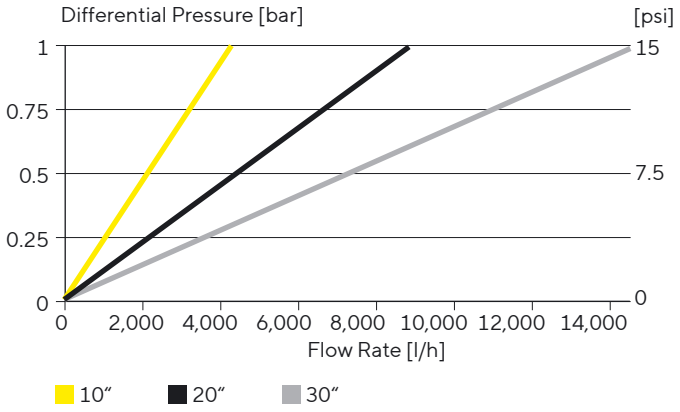
Performance

Total Throughput Comparison



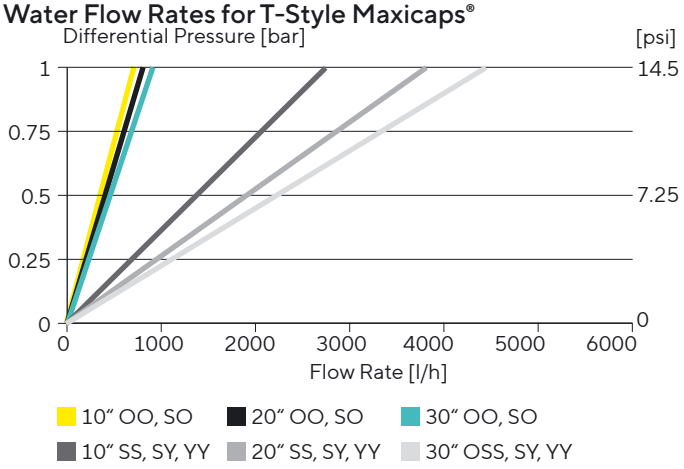
10" Cartridges format

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 m² | 0.5 ft²
8: 0.1 m² | 1.1 ft²
9: 0.2 m² | 2.2 ft²

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 m² | 3.2 ft² (5")
1: 0.6 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (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 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (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 m² | 6.5 ft² (10")
2: 1.2 m² | 12.9 ft² (20")
3: 1.8 m² | 19.4 ft² (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 m² | 0.5 ft²
8: 0.1 m² | 1.1 ft²
9: 0.2 m² | 2.2 ft²
0: 0.45 m² | 4.8 ft²

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 m² | 0.16 ft²
5: 0.03 m² | 0.32 ft²

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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