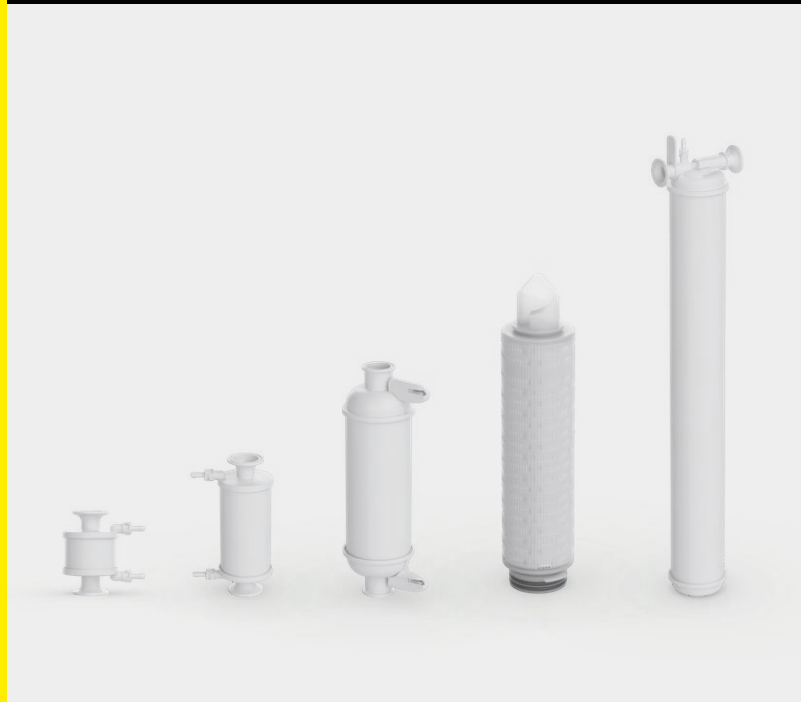


Sartopore Evo[®]

0.8 | 0.2 μm

Low Adsorptive
Sterilizing-Grade Filter



Product Information

Sartopore Evo[®] marks the next generation of high-performance, sterilizing-grade filters for pharmaceutical and biopharmaceutical fluids. An innovative modification of polyethersulfone (PES) membranes minimizes the adsorption of proteins and excipients, such as polysorbates, to ensure stable drug formulations and reduce the number of vials that must be discarded during form and fill operations. Unlike the polyvinylidene fluoride (PVDF) membrane filters, Sartopore Evo[®] does not intentionally use PFAS compounds in its construction material. In addition, Sartopore Evo[®] filters achieve much higher flow rates and throughputs than PVDF membrane filters, allowing the use of a smaller filter element, further reducing adsorption and disposable waste.

Features and Benefits

- Minimized adsorption of proteins and excipients, like polysorbate 20 and 80, to increase yield and ensure stable drug formulation, supporting compliance with specifications
- High filter capacity and flow rates for efficient process operations
- No intentional use of PFAS compounds, protecting the long-term supply security of critical components

Introduction

Relevant Applications

Sterilizing-grade filtration of biopharmaceuticals like monoclonal antibodies, adeno-associated virus (AAV)-based therapies, or lipid nanoparticles

Relevant Process Steps

- Sterilizing-grade filtration of bulk drug substance
- Final filtration of drug product

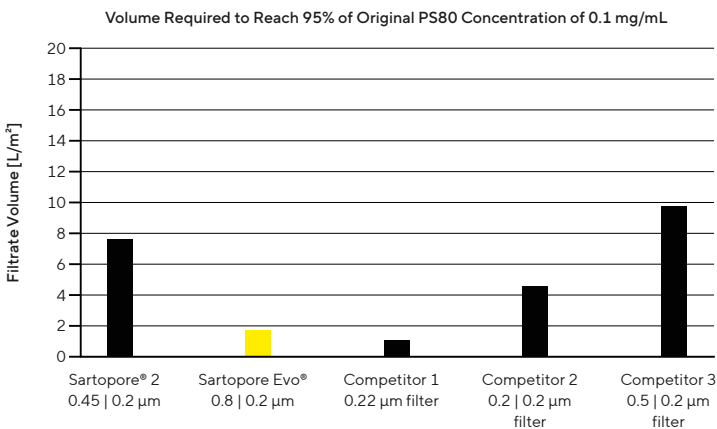
Performance

The Sartopore Evo® filter represents a significant advancement in filtration technology, characterized by its unique surface modification that minimizes protein and excipient adsorption during sterilizing-grade filtration. Coupled with high flow rates and throughput, these advances position the Sartopore Evo® as a high-performing alternative to PVDF filters, which potentially face increasing regulatory restrictions.

Unique Surface Modification

The Sartopore Evo® filter's unique surface modification is fundamental to its robust performance. This feature minimizes the adsorption of proteins and excipients, such as polysorbates, which are commonly used in drug formulations (Figure 1). The adsorption of these components can lead to significant challenges, including reduced drug efficacy and stability. By effectively reducing adsorption, the Sartopore Evo® filter ensures that the integrity and potency of the drug product are maintained throughout the filtration process and significantly reduces lost batches due to deviations from formulation specifications. This increases the process yield and reduces costs.

Figure 1: Customer Data Showing the Low Adsorption of Polysorbate 80 by the Sartopore Evo®

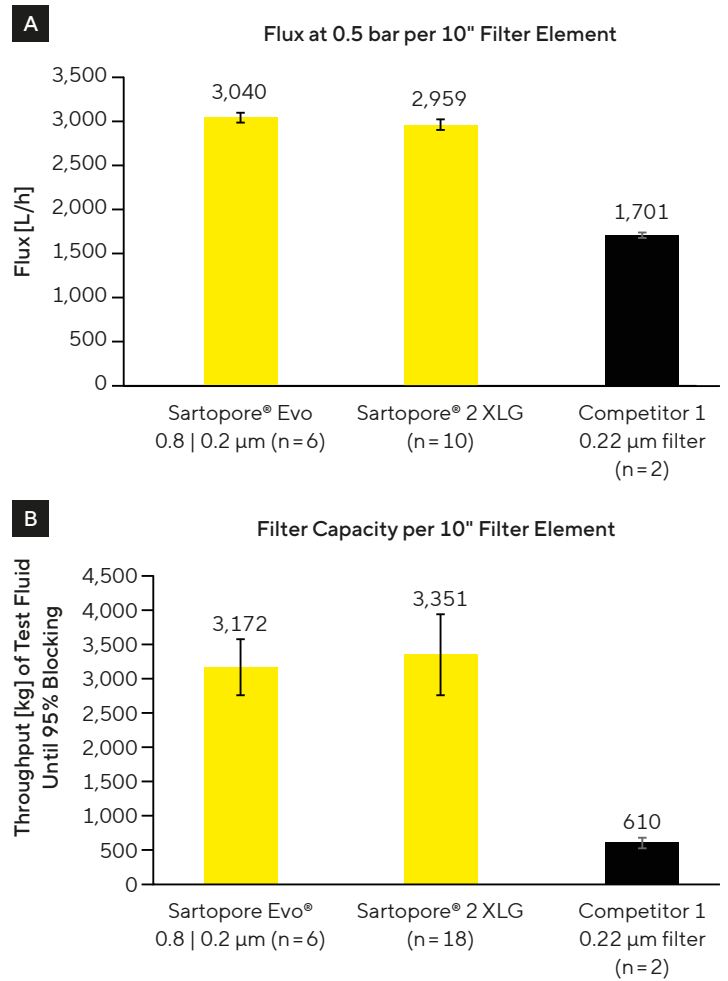


Note. Performed in dynamic mode (1 hour static, followed by filtration at a low flow rate)

High Filter Capacity & Flow Rate

The Sartopore Evo® outperforms PVDF membrane filters in terms of capacity (Figure 2A) and flow rate (Figure 2B). These improvements are achieved while still minimizing absorption, increasing efficiency during final formulation and filling.

Figure 2: Sartopore® Evo (A) Filter Capacity and (B) Initial Flow Rate With 5% IVIG at pH 7



Note. 1.8 cm² Minisart® syringe filters were used. IVIG = Intravenous immunoglobulin.

Reduced Environmental Impact and Supply Security

Unlike PVDF filters, the Sartopore Evo® is made without the intentional introduction of PFAS compounds. As regulatory pressures mount against PFAS due to their potential health and environmental risks, the Sartopore Evo® filter provides a future-proof solution that aligns with global sustainability goals. This ensures that manufacturers can confidently meet regulatory requirements and maintain a reliable supply chain while maintaining the highest standards of product safety and efficacy.

Technical Specifications

Filter Assemblies

Sartorius offers a range of filter assemblies, from simple configurations to complex setups like pre-use post-sterilization integrity test (PUPSIT) designs. Our team is equipped to assist in standardizing and harmonizing your single-use systems, regardless of complexity.

All filter assemblies are qualified, sterilized, and ready for integration with single-use processing solutions.

Services

Sartorius Confidence® Validation Services complement Sartopore® Evo filters by offering comprehensive support in compliance with regulatory requirements.

Our services provide:

- Filter validation studies
- Extractables and leachables services
- Microbiological testing
- Physicochemical testing

Our local teams of validation experts provide tailored and consultative support to determine the most cost-effective solution, ensuring you can make informed decisions about your process.



Available Sizes	Filtration Area [m ² ft ²]	Max. Diffusion at 2.5 bar 36 psi [mL/min]*	Min. Bubble Point [bar psi]*
Cartridges, T-Style Maxicaps®, Maxicaps®			
5" (only Cartridge)	0.4 4.3	11	3.3 47.9
10"	0.8 8.6	22	3.3 47.9
20"	1.6 17.2	44	3.3 47.9
30"	2.4 25.8	66	3.3 47.9
Mini Cartridges, Midicaps®			
Size 7	0.065 0.7	3	3.3 47.9
Size 8	0.13 1.4	5	3.3 47.9
Size 9	0.26 2.8	8	3.3 47.9
Size 0 (only Midicaps®)	0.52 5.6	16	3.3 47.9
Capsules**			
Size 4	0.021 0.22	1	3.3 47.9
Sartoscales			
25	0.00045 0.0048	–	3.3 47.9
47	0.00173 0.019	–	3.3 47.9

* Wetting fluid: Water; for more information on integrity testing and additional bubble point values or isopropyl alcohol | water mixtures, refer to the appropriate Validation Guide.

Max. Allowable Differential Pressure

Mini Cartridges, Cartridges, Sartoscales

5 bar | 72.5 psi at 20 °C

2 bar | 29 psi at 80 °C

Midicaps®, T-Style Maxicaps®, Maxicaps® (All Hybrid)

5 bar | 72.5 psi at 20 °C

3 bar | 43.5 psi at 50 °C

Capsules Size 4 (Hybrid)**

4 bar | 58 psi at 20 °C

2 bar | 29 psi at 50 °C

** Important information: Due to limited pressure resistance of single-use filter housings, the recommended integrity test method (pre- and post-use) at customers' site is a diffusion test. If a bubble point test is required, then the max. test pressure of the integrity tester must be limited according to the maximum allowable operating pressure of the respective single-use housing.

Max. Allowable Back Pressure

2 bar | 29 psi at 20 °C

(For all elements except Sartoscale 25 and 47.

Sartoscale filters cannot be used in reverse direction of filtration.)

Pore Size Combination

Prefilter layer 0.8 µm + final filter layer 0.2 µm
(sterilizing grade according to ASTM F 838-20)

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
- Meets or exceeds 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*

* Sartoscale 25, 47 and flat filters are disposable screening tools for process development and optimization. Sartoscale and flat filters are not designed for use in a GMP environment and have not been tested for all regulatory aspects that are met by the rest of the Sartorius filter portfolio.

Delivery Condition & Sterilization

Filter Design	Delivery Condition	Type of Packaging	Sterilization Method
Mini Cartridges Cartridges	Non-sterile	Double-pouched in PA PE bag	<ul style="list-style-type: none"> ■ In-Line Steam Sterilization (dry or wet steaming) Max. 134 °C, 0.3 bar (inlet pressure: max. 2.3 bar 34 psi, outlet pressure: 2 bar 29 psi), 20 min. Min. 3 Sterilization cycles or ■ Autoclaving Max. 134 °C, 2 bar, 30 min Min. 3 Sterilization cycles
Capsules Size 4 Midicaps® Maxicaps® T-Style Maxicaps® (all hybrid)	Sterile (autoclaved)	Double-pouched in Tyvek® bag	<ul style="list-style-type: none"> ■ Autoclaving** Max. 134 °C, 2 bar, 30 min Min. 3 Sterilization cycles or ■ Gamma X-ray Irradiation** ≤50 kGy 1 Sterilization Cycle
Sartoscales Flat Filters	Non-sterile	Blister (4.5 cm²) LDPE bag (17.3 cm²) Box (Flat Filter)	<ul style="list-style-type: none"> ■ Autoclaving Max. 134 °C, 2 bar, 30 min Min. 1 Sterilization cycle

** Once a filter capsule has undergone autoclaving, it may still be subjected to gamma or X-ray irradiation. Conversely, once a filter has been irradiated, subsequent autoclaving is prohibited.

Technical References

Validation Guide DIR no.: 3555457

Extractables Guide DIR no.: 3593828

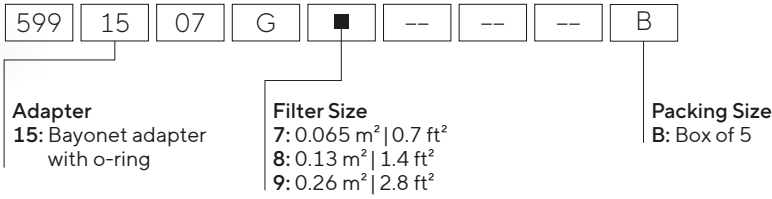
 **For more information about Sartopore Evo®, visit**
[sartorius.com/sartopore-evo](https://www.sartorius.com/sartopore-evo)

Ordering Information

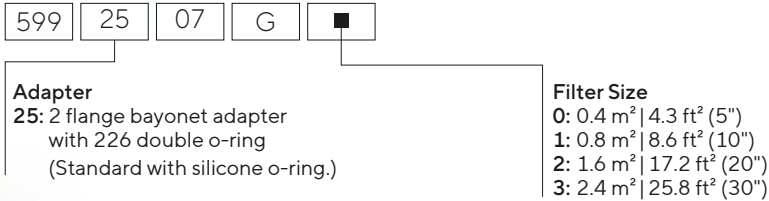
Flat Filter



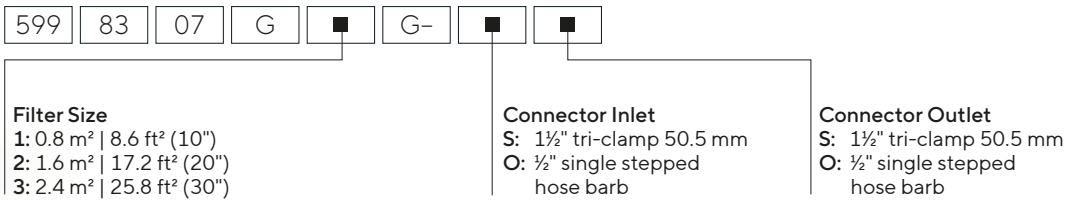
Mini Cartridge



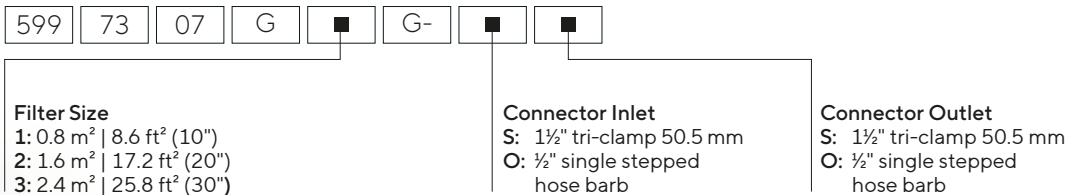
Cartridge



T-Style Maxicaps®



Inline Maxicaps®





Midicaps®

599 53 07 G ■ G- ■ ■ -- ■

Filter Size

7: 0.065 m² | 0.7 ft²
8: 0.13 m² | 1.4 ft²
9: 0.26 m² | 2.8 ft²
0: 0.52 m² | 5.6 ft²

Connector Inlet

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)

Connector Outlet

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



Capsules

599 13 07 G 4 G- ■ ■ -- B

Filter Size

4: 0.021 m² | 0.22 ft²

Connector Inlet

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

Packing Size

B: Box of 5

Connector Outlet

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



Sartoscales

599 53 07 G ■ -- ■ -- ■

Filter Size

V: 4.5 cm²
S: 17.3 cm²

Connectors

LX: In: Female Luer Lock
| Out: Male Luer Slip
(4.5 cm² only)
FF: In: ¾" tri-clamp |
Out: ¾" tri-clamp
(17.3 cm² only)
HH: In: ¾" multiple
stepped hose barb |
Out: ¾" multiple
stepped hose barb
(17.3 cm² only)

Packing Size

C: Box of 6 (4.5 cm² only)
M: Box of 3 (17.3 cm² only)

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