

Sartopore® 2 XLM 0.1 µm T-Style MaxiCaps®

Mycoplasma Retentive γ-Irradiatable or Autoclavable T-Style MaxiCaps®

T-Style MaxiCaps® Membrane Filter



Description

Sartopore® 2 XLM 0.1 µm rated T-Style MaxiCaps® are especially designed for validated sterilizing grade filtration and reliable Mycoplasma removal for modern cell culture media. The unique, highly asymmetric, heterogeneous double layer PES membranes provide outstanding total throughput and flow rate performance reducing filter costs and footprint of filtration systems significantly.

Applications

Typical applications of Sartopore® 2 XLM filter include sterilizing grade filtration and Mycoplasma removal from:

- Plant peptone, soy or yeast supplemented cell culture media
- Serum containing cell culture media
- Cell culture media components
- All other cell culture media used in biotech manufacturing

Any other application requiring sub 0.2 µm filtration for enhanced sterility assurance.

Compatibility

Sartopore® 2 T-Style MaxiCaps® are designed for sterilizing by gamma irradiation at a maximum dosage of ≤ 50 kGy or by autoclaving at 134°C and 2 bar. The PES membrane offers a broad chemical compatibility make them ideally suited for processing in biopharmaceutical industry. The innovative design allows a maximum forward differential pressure of 5 bar | 72.5 psi at 20°C.

Flexible Integration

The variety of different connector styles, dimensions and filter sizes facilitates an easy integration into any process.

Economy

The build in prefilter layer is specifically designed to protect the final 0.1 µm membrane layer in cell culture media filtration applications. The optimized membrane combination together with the exceptionally high effective filtration of 0.8 m²/10" filter element allow for > 50% more performance compared to existing 0.1 µm rated filter elements, thus ensuring lowest filtration costs per liter, minimized filtration times and smallest footprint of the filtration system.

Cost Savings

The use of T-Style design concept avoids investment in stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation. They also avoid investment in additional tubing required to connect multiple filters in serie.

Microbiological Retention

Sartopore® 2 0.1 µm T-Style MaxiCaps® rated are fully validated as sterilizing grade filters according to ASTM F-838-05 guidelines and for Mycoplasma removal with a Log Reduction Value (LRV) fo 7 for Acheloplasma laidlawii.

Quality Control

Each individual filter is tested for integrity by Diffusion-Test prior to being released assuring absolute reliability.

Documentation

Sartopore® 2 0.1 µm T-Style MaxiCaps® are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Vailidation Guide is available for compliance with regulatory requirements.

Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support Fleece	Polyester
Core	Polypropylene
End Caps	Polypropylene
Capusle Housing	Polypropylene
O-Rings	Silicone

Pore Size Combinations

0.2 µm + 0.1 µm

Available Sizes | Filtration Area

Size 1	0.8 m ² 8.6 ft ²
Size 2	1.6 m ² 17.2 ft ²
Size 3	2.4 m ² 25.8 ft ²

Available Connectors

SS, SO, OO, YY, SY

S: 1 ½" Tri-Clamp (Sanitary)

O: ½" Single stepped hose barb

Y: 1" Single stepped hose barb

Operating Parameters

Max. allowable differential pressure	5 bar 72.5 psi at 20°C
	3 bar 43.5 psi at 50°C
Max. allowable back pressure	2 bar 29 psi at 20°C

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

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Specifications

Extractables

Sartopore® 2 XLM 0.1 µm T-Style MaxiCaps® meet, or exceed the requirements for WFI quality standards set by the current USP after γ-irradiation with < 50 kGy, or autoclaving by preflushing with 5 L WFI/10".

Regulatory Compliance

Individually integrity tested

Integrity test correlated to ASTM F 838-05 Bacterial Challenge Test and Mycoplasma removal

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

1 × γ-irradiation ≤ 50 kGy irradiational dosage
or
3 × autoclaving, 134°C, 2 bar, 30 min

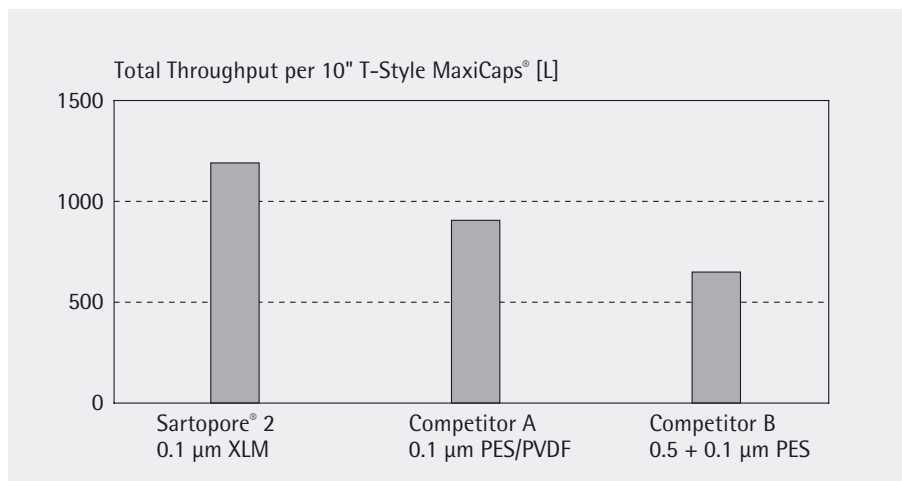
Sartopore® 2 T-Style MaxiCaps® can not be In-line steam sterilized!

Technical References

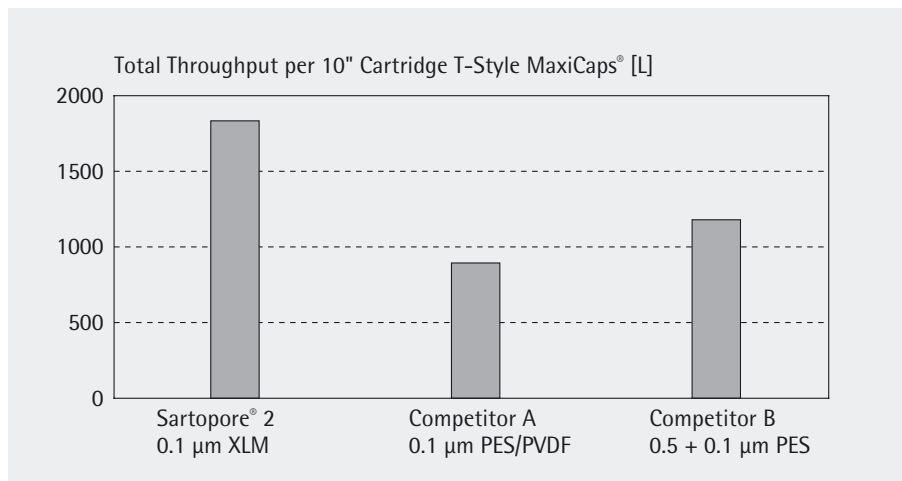
Validation Guide

SPK5793-e

Plant Peptone Supplemented Cell Culture Media



Soy Supplemented Cell Culture Media



Order Code	Pore Size [µm]	Test Pressure [bar psi]	Max. Diffusion [ml/min]
5448358M1G-**	0.1	4.0 58	39
5448358M2G-**	0.1	4.0 58	78
5448358M3G-**	0.1	4.0 58	117

** : Connector Style

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