



Sartopore® 2 0.2 µm T-Style MaxiCaps

Sterilizing Grade γ -Irradiatable or Autoclavable T-Style MaxiCaps

T-Style MaxiCaps Membrane Filter



Description

Sartopore® 2 0.2 µm - γ irradiatable or autoclavable T-Style MaxiCaps feature a new and innovative capsule housing design. The T-Style design is ideal for easy installation of multiple filters in series or parallel configurations to reduce overall footprint and hold-up volumes. Sartopore® 2 0.2 µm T-Style MaxiCaps can be sterilized by autoclaving or gamma-irradiation. The opportunity to sterilize by gamma irradiation allows the use of these filters in flexible-bag-container-systems.

Applications

Typical applications include sterilizing grade filtration of:

- Biologicals
- Pharmaceuticals
- Cell Culture Media
- Culture Media Components
- Serum
- Buffer

Compatibility

Sartopore® 2 T-Style MaxiCaps are designed for sterilizing by gamma irradiation at a maximum dosage of \leq 50kGy or by autoclaving at 134°C and 2 bar. The PES membrane offers a broad chemical compatibility from pH 1 – pH 10 and 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 combination of a built-in 0.45 µm pre-filter in front of the a 0.2 µm final filter and the asymmetric membrane structure provide outstanding total throughput performance.

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 0.2 µm T-Style MaxiCaps rated are fully validated as sterilizing grade filters according to ASTM F-838-05 guidelines.

Quality Control

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

Documentation

Sartopore® 2 0.2 µm T-Style MaxiCaps are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation 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

0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Size 1	0.6 m ² 6 ft ²
Size 2	1.2 m ² 12 ft ²
Size 3	1.8 m ² 18 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	5 bar 72.5 psi at 20°C
Differential pressure	2 bar 29 psi at 80°C
Max. allowable back Pressure	2 bar 29 psi at 20°C

Specifications

Extractables

Sartopore® 2 0,2 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.

Regulatory Compliance

Individually integrity tested

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

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 0.2 µm T-Style MaxiCaps can not be In-line steam sterilized!

Sterilization Cycles

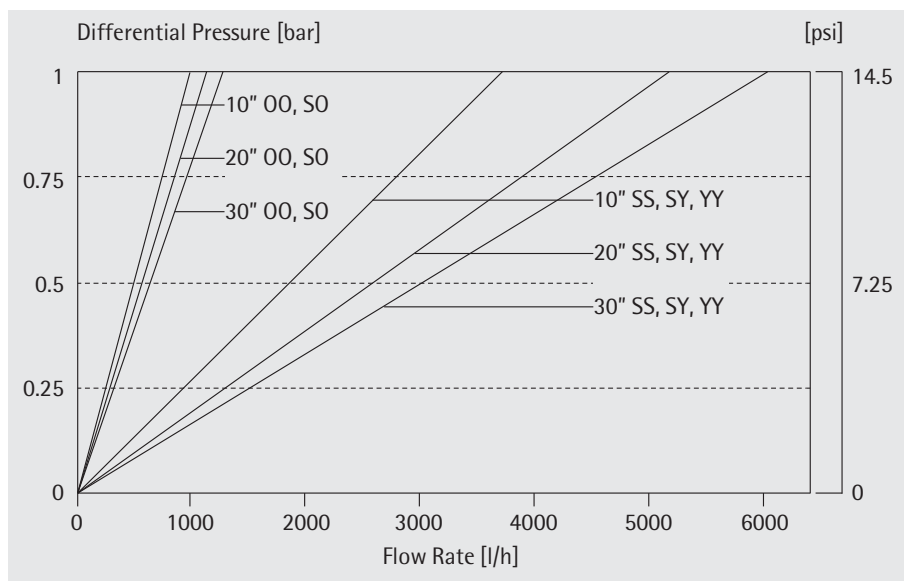
γ-irradiation 1 Cycle
or
autoclaving 3 Cycles

Technical References

Validation Guide

Order Code	Pore size [µm]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
5448307H1G-**	0.2	2.5 36	18	3.2 46
5448307H2G-**	0.2	2.5 36	36	3.2 46
5448307H3G-**	0.2	2.5 36	54	3.2 46

** : Connector Style



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