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biotech

T-Style MaxiCaps[®] – 0.2 μm

Sterilizing Grade Filters with TwinPleat Technology

Membrane Filter Cartridges



Sartopore[®]

platinum

A New Vision of Perfection.
A New Class of Sterile Filtration.

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,
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Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
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Description

Sartopore® Platinum sterilizing grade T-Style MaxiCaps® are specially designed to meet the requirements for filtration of a broad range of pharmaceutical products within a cGMP environment.

The use of the disposable capsule design concept avoids investments into stainless steel filter housings and eliminates additional costs for cleaning of housings and cleaning validation.

The complete new and innovative technologies which are incorporated in these filters lead to outstanding and unique performance data. Using Sartopore® Platinum the critical step of sterilizing-grade filtration will reach a yet unmatched quality, performance and cost efficiency:

- outstanding total throughput and permeability
- unmet wettability
- broad chemical compatibility (pH 1-14)
- high thermal resistance
- exhibiting very low protein binding
- low extractables level
- reliable integrity testing

New Surface Modification

A new and patented membrane hydrophilization process is used to permanently modify the membrane surface. In this process, a thermally exceptionally stable and hydrophilic polymer is directly grafted to the inner and outer surface of the membrane.

This new technology provides those membrane surface properties that are responsible for the outstanding wettability and low protein binding character of the Sartopore® Platinum membrane, even after extreme thermal and chemical stress, without affecting wettability and integrity testing.

New Membrane Construction – TwinPleat

The new and innovative TwinPleat Technology (patent pending) is characterized by an alternating sequence of longer and shorter membrane pleats, positioned in a specific angle. This special design maximizes the effective filtration area (e.g. +66% compared to Sartopore® 2) without compromising the hydrodynamics during filtration. Thus, the cartridges are characterized by an outstanding total throughput by which the filtration process will be most efficient.

Excellent Wettability

Sartopore® Platinum T-Style MaxiCaps® can be easily wetted with lowest flushing volume needed. For reliable wetting you only need less than 5 liter for a size 1 T-Style MaxiCaps® (1 m² membrane area).

This excellent wetting behavior will thus directly reduce the filtration costs of your process.

Reliable Integrity Testing

Imperfect wetting is the most frequent reason for failed integrity tests. In such cases filters have to be reliably re-wetted and tested again. Besides the cost factor for the additional test also a certain risk is present to lose a complete product batch when even repeated tests fail again.

The extraordinary wetting behavior of Sartopore® Platinum thus helps to eliminate this important risk factor. Using Sartopore® Platinum the process of integrity testing meets a yet unmet degree of reliability.

Scalability

Due to the identical principal construction of the different sizes, and due to full product accessibility to the entire membrane even in the depth of the pleatings, Sartopore® Platinum filters are perfectly scalable from R&D to production scale.

Microbial Retention

Sartopore® Platinum T-Style MaxiCaps® are fully validated as sterilizing grade filter elements according to HIMA and ASTM F-838-05 guidelines.

Packaging

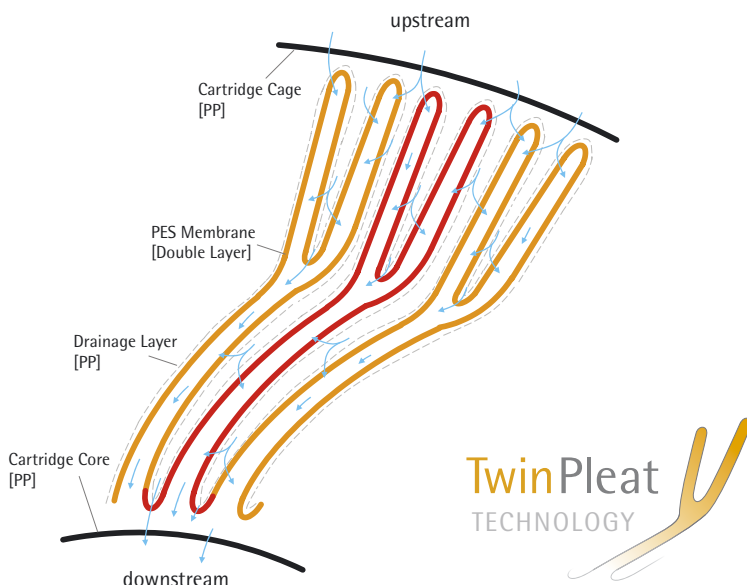
All filters are sterile and double wrapped for easy and safe clean-room transfer.

Quality Control

Each individual filter element is integrity tested by diffusion and bubble point prior to release, assuring highest quality and absolute reliability.

Documentation

Sartopore® Platinum T-Style MaxiCaps® are designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System. A Validation Guide and Extractables Guide are available for compliance with regulatory requirements.



Specifications

Materials of Construction

Prefilter membrane	Polyethersulfone, asymmetric
Endfilter membrane	Polyethersulfone, asymmetric
Support fleece	Polyester
Core	Polypropylene
End Caps	Polypropylene
Capsule Housing	Polypropylene
O-rings	Silicone

Pore Size

0.45 µm + 0.2 µm (double layer)

Available Sizes | Filtration Area

Size 1	1.0 m ² 10.8 ft ²
Size 2	2.0 m ² 21.5 ft ²
Size 3	3.0 m ² 32.3 ft ²

Available Connectors

SS, SO, OO, YY, SY

S: TC Flange 50 mm (1½")

O: ½" Single-stepped hose barb

Y: 1" single-step hose barb

Operating Parameters

Max. Allowable Differential Pressure	5 bar 72.5 psi at 20°C 3 bar 29 psi at 50°C
Max. Allowable Back Pressure	2 bar 29 psi at 20°C

Extractables

Sartopore® Platinum 0.2 µm rated 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. A detailed Extractables Guide is available on request.

Regulatory Compliance

100% individually integrity tested (Diffusion Test and Bubble Point Test).

Integrity test correlated with HIMA/ASTM F838-05 Bacterial Challenge Test.

Non pyrogenic according to USP Bacterial Endotoxins.

Passes USP Plastics Class VI Test.

Non-fibre releasing according to 21 CFR.

Sterilization

Autoclaving

134°C, 2 bar | 29 psi, 30 min

γ-Irradiation

≤50 kGy irradiation dosage

In-Line Steam Sterilization

T-Style MaxiCaps® must not be steam sterilized

Sterilization Cycles

Autoclaving: 3 cycles

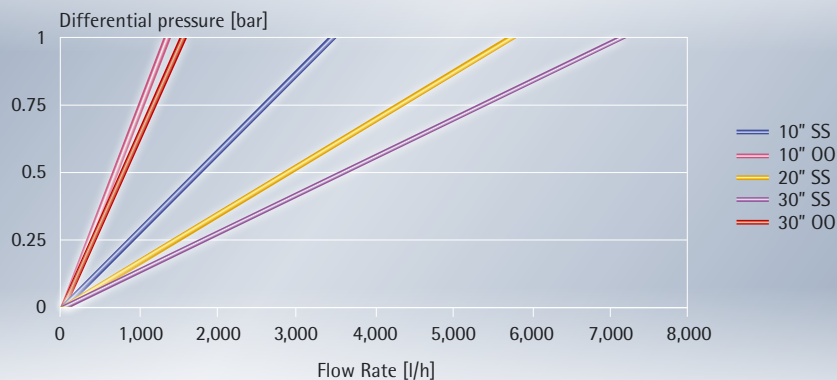
γ-Irradiation: 1 cycle

Technical References

Validation Guide

SPK5795-e

Water Flow Rates for T-Style MaxiCaps®



Ordering Information

Order Code	Pore Size [μm]	Pack Size [pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
5498307H1G-**	0.2 μm	1	2.5 36.25	25	3.5 50.7
5498307H2G-**	0.2 μm	1	2.5 36.25	50	3.5 50.7
5498307H3G-**	0.2 μm	1	2.5 36.25	75	3.5 50.7

** Connector type

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