



Sartobran® P 0.2 µm

Sterilizing Grade (T-Style) MaxiCaps®, MidiCaps® and Capsules



Description

Sartobran® P 0.2 (T-Style) MaxiCaps®, MidiCaps® and Capsules are self contained, ready to use, sterile filter units for sterilizing grade filtration in the pharma | biotech industry. The extremely low unspecific adsorption of their cellulose acetate membranes assures highest protein yields and rapid preservative recovery.

Applications

Sartobran® P filter elements have proven throughout the years to be the first choice for all applications in the biopharmaceutical industry requiring low adsorption capabilities. They are typically used for sterilizing grade filtration of:

- Coagulation Factors, Albumin, IgG
- Bacterial & Viral Vaccines
- MAB
- Bio-processed Pharmaceuticals
- Diagnostics
- Purified Protein Solutions
- Biological Fluids
- Fluids containing preservatives

Easy to use

Sartobran® P (T-Style) MaxiCaps®, MidiCaps® and Capsules are delivered as individually packed sterile units. On site, pre-use sterilization can be eliminated.

Flexibility

Sartobran® P 0.2 (T-Style) MaxiCaps®, MidiCaps® and Capsules are available with various filtration areas from 150 cm² |

0.16 ft² up to 1.8 m² | 19.4 ft² for easy adoption to any filtration process independent from the batch size.

Scalability

Consistent and predictable scale-up and down trials can reliably be performed as all Sartobran® P (T-Style) MaxiCaps®, MidiCaps® and Capsules are produced with the same type of membrane and identical materials of construction.

Cost Saving

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.

Microbiological Retention

Sartobran® P (T-Style) MaxiCaps®, MidiCaps® and Capsules 0.2 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines.

Quality Control

Each individual element is tested for integrity by Bubble Point and Diffusion test prior to be released assuring absolute reliability.

Documentation

Sartobran® P (T-Style) MaxiCaps®, MidiCaps® and Capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Specifications

Materials

Prefilter Membrane	Cellulose Acetate
Endfilter Membrane	Cellulose Acetate
Support fleece	Polypropylene
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Rings	Silicone
Filling Bell	Polycarbonate

Pore Size Combination

0.45 µm + 0.2 µm

Available Sizes | Filtration Area

(T-Style) MaxiCaps®

Size 1	10"	0.6 m ² 6.5 ft ²
Size 2	20"	1.2 m ² 12.9 ft ²
Size 3	30"	1.8 m ² 19.4 ft ²

MidiCaps®

Size 7	0.05 m ² 0.54 ft ²
Size 8	0.1 m ² 1.1 ft ²
Size 9	0.2 m ² 2.2 ft ²
Size 0	0.45 m ² 4.8 ft ²

Capsules

Size 4	0.015 m ² 0.16 ft ²
Size 5	0.03 m ² 0.32 ft ²

Available Connectors (T-Style) MaxiCaps®, MidiCaps®

S:	Tri-Clamp 50 mm (1½")
O:	½" single stepped hose barb
F:	Tri-Clamp 25 mm (¾") (only MaxiCaps®)
Y:	1" single stepped hose barb (only T-Style MaxiCaps®)

Available Connectors Capsules

S:	Tri-Clamp 25 mm (¾")
O:	¼" multiple stepped hose barb

Operating Parameters

Specifications

Max. Allowable Differential Pressure	5 bar 72.5 psi at 20°C (T-Style MaxiCaps®, MidiCaps®) 4 bar 58 psi at 20°C (MaxiCaps®, Capsules) 2 bar 29 psi at 80°C (MidiCaps®, Capsules) 3 bar 43.5 psi at 50°C (T-Style MaxiCaps®, MaxiCaps®)
Max. Allowable Back Pressure	2 bar 29 psi at 20°C

Extractables

Sartobran® P 0.2 (T-Style) MaxiCaps®, MidiCaps® and Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-05 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non-fiber releasing according to 21 CFR

pH Compatibility

Sartobran® P filters have a limited pH compatibility in the range of pH 4–8.

This range covers most of the relevant bio-pharmaceutical applications.

Sterilization

Autoclaving:

134°C, 2 bar, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

T-Style MaxiCaps®

Autoclaving Min. 5

MaxiCaps® | MidiCaps® | Capsules

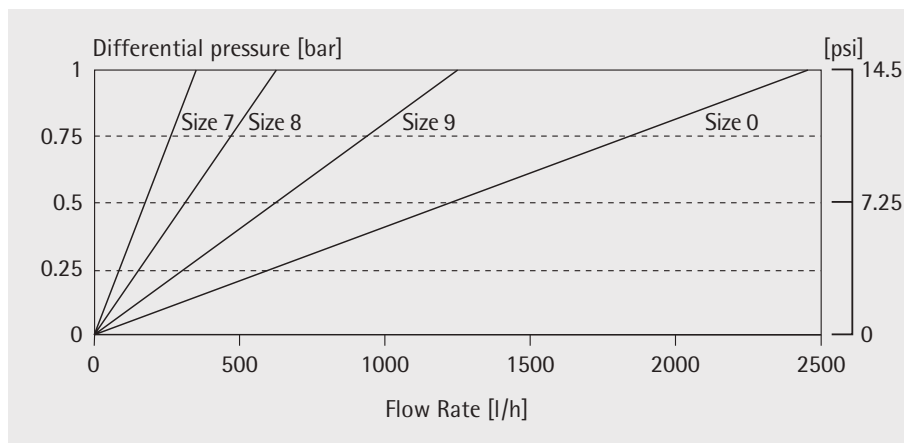
Autoclaving Min. 25

Technical References

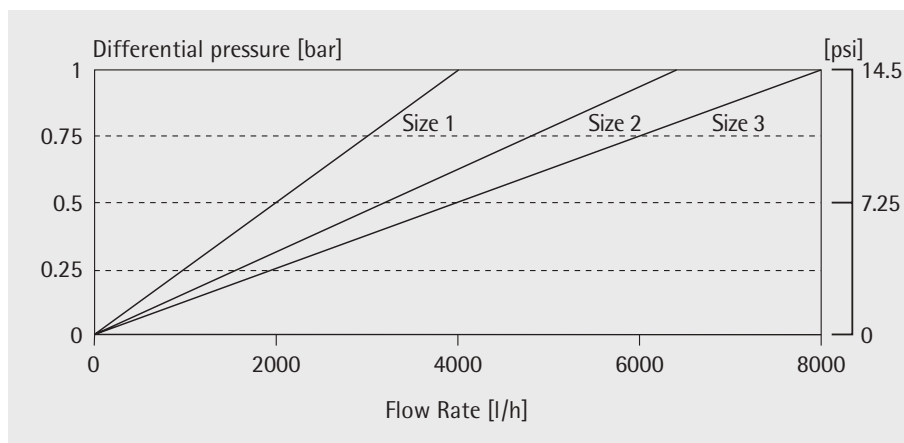
Validation Guide:

SPK5726-e

Water Flow Rates for MidiCaps® with SS adapter



Water Flow Rates for MaxiCaps®



Standardized at 20°C

Order Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
T-Style MaxiCaps®:					
5238307H1--**	0.2	1	2.5 36	15	3.2 46
5238307H2--**	0.2	1	2.5 36	30	3.2 46
5238307H3--**	0.2	1	2.5 36	45	3.2 46
MaxiCaps®:					
5231307H1--**	0.2	1	2.5 36	15	3.2 46
5231307H2--**	0.2	1	2.5 36	30	3.2 46
5231307H3--**	0.2	1	2.5 36	45	3.2 46
MidiCaps®:					
5235307H7--**--A	0.2	4	2.5 36	3	3.2 46
5235307H8--**--A	0.2	4	2.5 36	4	3.2 46
5235307H9--**--A	0.2	4	2.5 36	5	3.2 46
5235307H0--**--V	0.2	2	2.5 36	10	3.2 46
Capsules:					
5231307H4--**--B	0.2	5	2.5 36	1	3.2 46
5231307H5--**--B	0.2	5	2.5 36	2	3.2 46

** : Connector Styles (first code letter represents the inlet, the second the outlet)

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