

Sartofluor Mini Cartridges and Capsules

Pharmaceutical Grade Hydrophobic PTFE Membrane Filter

Major Applications

Sartofluor pharmaceutical grade mini-cartridges and capsules are ideal for sterile venting applications, and the critical filtration of gases and solvents where adherence to cGMPs is a must.

Applications include:

- Sterile venting of tanks
- Sterile air filtration for filling equipment
- Fermentation air filtration
- Bioreactor inlet gas and outlet streams.

Sartofluor mini-cartridges and capsule filters are available with 0.2 µm and 0.45 µm PTFE membranes.

Product Profile

Sartofluor PTFE membranes are extremely hydrophobic and are especially suited for applications where membrane blockage due to moisture can be a problem.

Sartofluor GA filters are the first filters to be integrity tested without the use of alcohol or solvents. This water based integrity test method, known as the Water Intrusion Test, makes it possible to test a filter *in-situ* on a vessel without downstream manipulations.

The Water Intrusion Test has been correlated to the ASTM Bacterial Challenge test for the retention of *B. diminuta* at a minimum concentration of 1×10^7 organisms per cm² of effective filtration area.

All materials have passed the current USP Class VI Plastics Test and all filtrates meet or exceed the requirement for Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals. Complies with cGMP requirements for non-fiber releasing filters and is filed under the Drug Master File 5967 by the Food and Drug Administration, Washington, D.C. Full validation information is available.

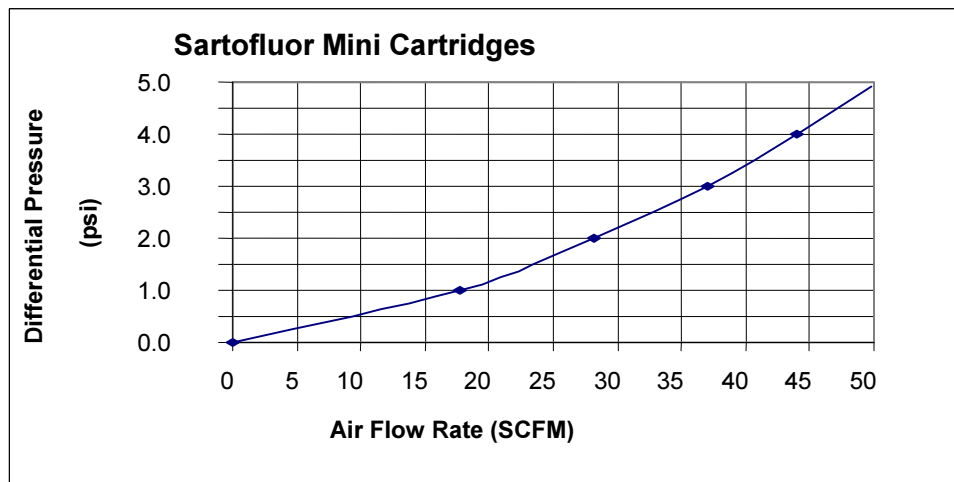
100% Integrity Tested

Each mini-cartridge or capsule is individually integrity tested prior to release by the Water Intrusion Test. The filters are user integrity testable at any time by this method or the standard alcohol based methods including the Bubble Point and Diffusion Testing.

Maximum Hydrophobicity

PTFE is a naturally hydrophobic material that will not lose its hydrophobicity after use. Sartofluor membranes have been tested for retention efficiencies as per the HIMA/ASTM guidelines, so as to provide the maximum user assurance.

Features	Benefits
PTFE requires a pressure of 65 psi to wet the membrane with water.	PTFE is twice as hydrophobic as either PVDF or Polypropylene.
Validated Water Intrusion Test does not require alcohol. WIT Test is correlated to the ASTM F-838-83 bacterial Challenge Test.	It is possible to <i>in-situ</i> test a filter without downstream manipulations nor the risk of downstream contamination.
Low differential pressures at high air flow rates	Allows for smaller air filtration systems sizing with high air flow requirements.
Integrity test, such as alcohol based Bubble Point and Diffusion Testing are correlated to the ASTM Bacterial Challenge Test	Sartofluor mini-cartridges and capsules can be used in processes where vent filters are currently tested with alcohol.
The PTFE membranes offer the widest range of chemical compatibility coupled with the high resistance of polypropylene.	Sartofluor capsules can be used for the filtration of aggressive chemicals and solvents.



Materials of Construction

Membrane Filter	PTFE	Core	Polypropylene
Up-and Downstream Support	Polypropylene	End Caps	Polypropylene
Outer Support	Polypropylene	O-Rings	Silicone*

*Silicone is standard for NA. EPDM and Viton O-rings are also available.

Technical Data

Filtration area, mini cartridges & capsules	0.3, 0.5, 1, 2, or 5 ft ² per element for capsules 2ft ² for mini-cartridges.	
Maximum differential pressure for mini - cartridges	75 psi at 20°C	7 psi at 134°C
	22 psi at 121°C	7 psi at 140°C
Maximum Operating Pressure for capsule filters	60 psi at 20°C	
Maximum back pressure for mini-cartridges	45 psi at 20°C	7 psi at 140°C
	7 psi at 134°C	
Sterilization:	Autoclaving (134°C, 30 min.)	
	Capsule Filters are not in-line steam sterilizable.	
	In-line Steaming (134°C, 30 psi inlet, max. differential pressure of 7 psi for 30 min.)	
Chemical compatibility:	See the Sartorius Validation Guide or contact Sartorius	

Integrity Test Values

Pore Size	Bubble Point - for filters wetted with 60% Isopropanol (IPA)
0.2 µm	≥ 15 psi

Pore Size	Max. Allowable Air Diffusion at Test Pressure of 10 psi Wetted with 60 % IPA
0.2 µm	1/2 ft ² ≤ 2 ml/min
	1ft ² ≤ 3 ml/min
	2 ft ² ≤ 4 ml/min

Pore Size	WIT Test Maximum Allowable Value at 36 psi
0.2 µm	2 ft ² ≤ 4 ml/10 min.

Available types and Order Number: Sartofluor Mini Cartridges (Order numbers for packs of 5)

Pore Size	1 ft ² Mini	2 ft ² Mini
0.2 µm	5181507T8B	5181507T9B

Available Types and Order Number: Sartofluor Capsules

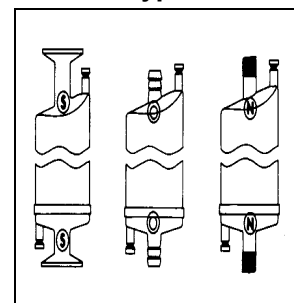
Final Membrane Pore Size	1/3 ft ² Capsules (Box of 10)	1/2 ft ² Capsules (Box of 5)	1 ft ² Capsules (Box of 5)	2 ft ² Capsules (Box of 4)	5 ft ² Capsules (Box of 2)
0.45 µm	-	5181306T7..B	5181306T8 .. B	5181306T9 .. A	5181306T0..V
0.2 µm	5181307T5OOD	5181307T7..B	5181307T8.. B	5181307T9 .. A	5181307T0..V

***Note - To complete the order number simply replace the two dots with the appropriate two letter combination (S,O,N) to indicate the type of end connectors you require.

S = 1-1/2" Sanitary Flange; O = 1/2" Hose Barb for 1/2, 1 and 2 ft² capsules; O = 1/8" Hose Barb for 1/3 ft²; N = 1/4" MNPT.

Example: 5181307T8..B would become 5181307T8SSB, signifying the selection of a Sartofluor, 0.2 µm, 1 ft², box of 5 capsules with a sanitary flange inlet and outlet connectors.

Connector Types



Lit# A-005, Rev. 03/02

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