

# Sartofluor GA

## The Pharmaceutical Grade Hydrophobic PTFE Membrane Filter Cartridge

### Major Applications

Sartofluor GA pharmaceutical grade cartridges are for sterile venting applications and the critical filtration of gases, solvents and oil-based pharmaceuticals where adherence to cGMPs is a must. Applications include:

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

Sartofluor GA filter cartridges are available as 0.2  $\mu\text{m}$  or 0.45  $\mu\text{m}$  PTFE membranes.

### Product Profile

Sartofluor GA 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 cartridges to be integrity tested without the use of alcohol or solvents. This water based integrity test method makes it possible to test a filter *in-situ* without downstream manipulations. The Water Intrusion Test (WIT) has been correlated to the ASTM Bacterial Challenge test, F-838-83, for the retention of *B. diminuta* at a minimum concentration of  $1 \times 10^7$  organisms per  $\text{cm}^2$  effective filtration area.

All materials have passed the current USP Class VI Plastics Test and all filtrates exceed the requirements for Water for Injection with respect to total solids, oxidizable substances, particulate matter, ammonia, chloride, nitrate, sulfate and heavy metals. All materials comply with cGMP requirements for non-fiber releasing filters and are filed under the Drug Master File Number DMF 5967 by the FDA, Washington, D.C.

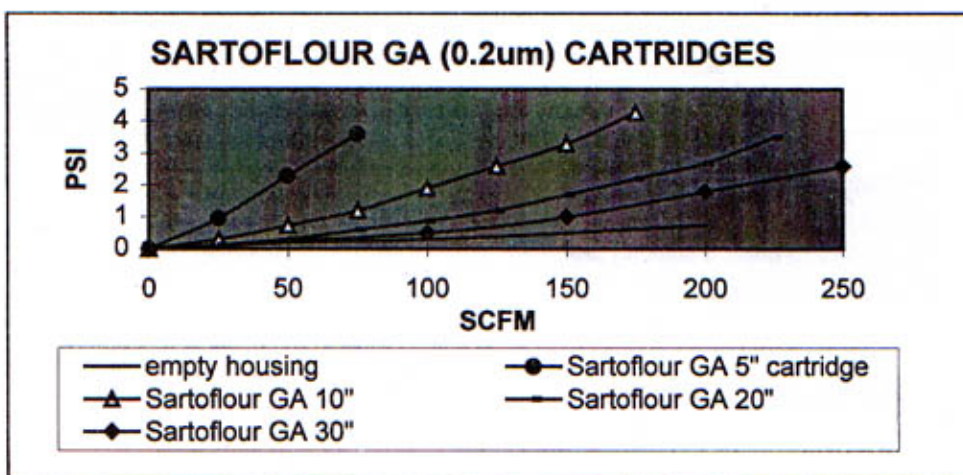
### 100% Integrity Tested

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

### Maximum Hydrophobicity

PTFE is a naturally hydrophobic material that will not lose its hydrophobicity with use. Sartofluor GA membranes have been tested for retention efficiency 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 alcohol contamination. |
| Low differential pressures at high air flow rates   | Allows for smaller air filtration system sizing with high air flow requirements.                                       |
| Integrity tests, such as alcohol based Bubble Point and Diffusion Testing are correlated to the ASTM F-838-83 Bacterial Challenge Test. | Sartofluor GA filter cartridges can be used in processes where vent filters are currently tested with alcohol.         |
| Available in a standard 5" filter cartridge.  | Can be used in systems where filter capsules are too small and 10" would be oversized.                                 |
| Chemical Resistance is extremely broad due to only two materials of construction; PTFE and Polypropylene.                               | Sartofluor GA 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 Cage                 | Polypropylene | O-Rings  | Silicone*     |

\*EPDM and Viton O-rings are also available. Add an E or V to the part number

**Technical Data**

|  |  |
|--|--|
| Filtration area, Standard cartridges   | 8 ft <sup>2</sup> /10"   |
| Maximum differential pressure          | 75 psi at 20°C    7 psi at 134°C<br>22 psi at 121°C  |
| Maximum back pressure                  | 45 psi at 20°C    7 psi at 134°C<br>22 psi at 121°C  |
| Sterilization:                         | Autoclaving (121°C, 15 psi, 30 min.),<br>In-line Steaming (up to 30 psi inlet with max. differential pressure of 7 psi, 30 min.) |
| Maximum Number of Sterilization Cycles | 150 forward<br>20 reverse  |
| Chemical compatibility:                | See table in 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   |

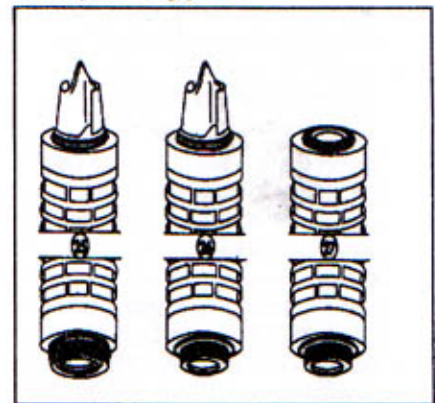
| Pore Size | Max. Allowable Air Diffusion at Test Pressure of 10 psi<br><u>Wetted with 60 % IPA</u> |
|-----------|--|
| 0.2 µm    | 5" - 6 ml/min.<br>10" - 11 ml/min.<br>20" - 22 ml/min.<br>30" - 33 ml/min.             |

| Pore Size | Maximum Allowable WIT Value at 36 psi   |
|-----------|---|
| 0.2 µm    | 5" - 7 ml/min.<br>10" - 13 ml/10 min.<br>20" - 26 ml/10 min.<br>30" - 36 ml/10 min. |

**Available types and Order Number: Sartofluor GA Standard Cartridges**

| (End cap/ adapter type) | Final Pore Size | CONFIGURATION |              |              |              |
|-------------------------|-----------------|---------------|--------------|--------------|--------------|
|                         |                 | 1/2-HIGH      | 1-HIGH       | 2-HIGH       | 3-HIGH       |
| Number                  | (µm)            | (5")          | (10")        | (20")        | (30")        |
| 25                      | 0.2             | 5182507T0-GA  | 5182507T1-GA | 5182507T2-GA | 5182507T3-GA |
|                         | 0.45            | 5182506T0-GA  | 5182506T1-GA | 5182506T2-GA | 5182506T3-GA |
| 26                      | 0.2             | N/A           | 5182607T1-GA | 5182607T2-GA | 5182607T3-GA |
|                         | 0.45            |               | 5182606T1-GA | 5182606T2-GA | 5182606T3-GA |
| 27                      | 0.2             | N/A           | 5182707T1-GA | 5182707T2-GA | 5182707T3-GA |
|                         | 0.45            |               | 5182706T1-GA | 5182706T2-GA | 5182706T3-GA |

**Adapter Types**



**Cartridge Adapter Types**

- 25 - (2) 226 O-rings, lock in tabs, S-adapter top
- 26 - (2) 222 O-rings, S-adapter top
- 27 - (2) 222 O-rings, flat top

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