



Sartofluor® GA

Air Filter Cartridges and Mini Cartridges for Bio-Pharmaceutical Applications



Specifications

Materials

| | |
|----------------|---|
| Membrane | PTFE |
| Support Fleece | Polypropylene |
| Core | Polypropylene |
| End Caps | Polypropylene |
| O-Rings | Silicone (EPDM or Fluoroelastomer optional) |

Pore Size

0.45 µm (only Mini Cartridges)
0.2 µm
0.1 µm

Available Sizes | Filtration Area

Cartridges:

| | | |
|--------|-----|---|
| Size 0 | 5" | 0.375 m ² 4.05 ft ² |
| Size 1 | 10" | 0.75 m ² 8.1 ft ² |
| Size 2 | 20" | 1.5 m ² 16.1 ft ² |
| Size 3 | 30" | 2.25 m ² 24.2 ft ² |

Mini Cartridges:

| | |
|--------|--|
| 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 |

Junior:

| | |
|--------|--|
| Size 7 | 0.05 m ² 0.54 ft ² |
|--------|--|

Available Adapters Cartridges

| | |
|-----|---|
| 25: | 2 Flange Bayonet adapter with 226 double o-ring |
|-----|---|

Available Adapter Mini Cartridges

| | |
|-------------|---|
| 12, 15, 18: | Bayonet adapter with o-ring (other adapters on request) |
|-------------|---|

Available Adapter Junior

| | |
|-----|---------------------------------|
| 14: | Plug adapter with double o-ring |
|-----|---------------------------------|

Operating Parameters

| | |
|--------------------------------------|--|
| Max. Allowable Differential Pressure | 5 bar 72.5 psi at 20°C 2 bar 29 psi at 80°C |
| Max. Allowable Back Pressure | 3 bar 43.5 psi at 20°C |

Description

Sartofluor® GA filter cartridges, manufactured with permanently hydrophobic PTFE membranes, are specially designed for sterile venting and gas applications where adherence to cGMP's is a must. Due to their permanent hydrophobicity, Sartofluor® GA cartridges offer the highest process security, even with high volume gas streams, extreme humidity and stringent in-line steam sterilizations.

Applications

Sartofluor® GA cartridges are ideally suited for application requiring a sterile, hydrophobic gas filter such as:

- Fermenter and bioreactor inlet gases
- Fermenter and bioreactor vents
- Autoclave vents
- Lyophilizer vents
- Purified water system storage tank vents
- In process storage tank vents
- Filling equipment process air

Performance

PTFE is the most hydrophobic of all membranes used in sterile filtration of gases. The inherent hydrophobicity of the PTFE membrane remains unaffected by repeated autoclaving or steaming. The sterile filtration of dry or moist gases is guaranteed. The unique single layer design is optimized for high flow rates at low differential pressures with short blow down times.

Stability

Sartofluor® GA can withstand high differential pressures in either the forward or reverse direction of flow. The mechanical stability and membrane structure are not affected by pulsation or high flow rates.

Water Intrusion Test (WIT) | Water Flow Test (WFT)

A Sartorius Stedim Biotech development, the WFT offers the first and only correlated in-situ integrity testing system for hydrophobic vent filters. WFT not only eliminates downstream intervention and preflushing, more importantly, it does not require a single drop of alcohol.

Quality Control

Each individual element is tested for integrity prior to released assuring absolute reliability.

Documentation

Sartofluor® GA cartridges 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

Extractables

Sartofluor® GA filter cartridges meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

100% Individually integrity tested

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

Non-pyrogenic according to USP Bacterial Endotoxins

Meets USP Plastics Class VI biological reactivity test, in vivo

Non-fiber releasing according to 21 CFR

Sterilization

In-Line Steam Sterilization

134°C, 20 min. at max differential pressure of 0.5 bar | 7.25 psi

Autoclaving

134°C, 2 bar | 29 psi, 30 min

Sterilization Cycles

In-Line Sterilization: min 150 (in direction and in reverse direction of filtration)

Technical References

Validation Guide:

SPK5711-e

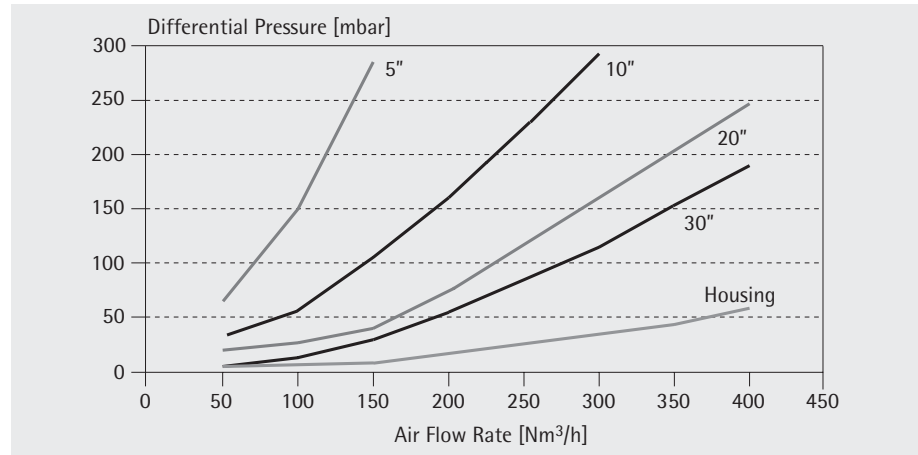
Extractables Guide:

SPK5749-e

Ordering Information

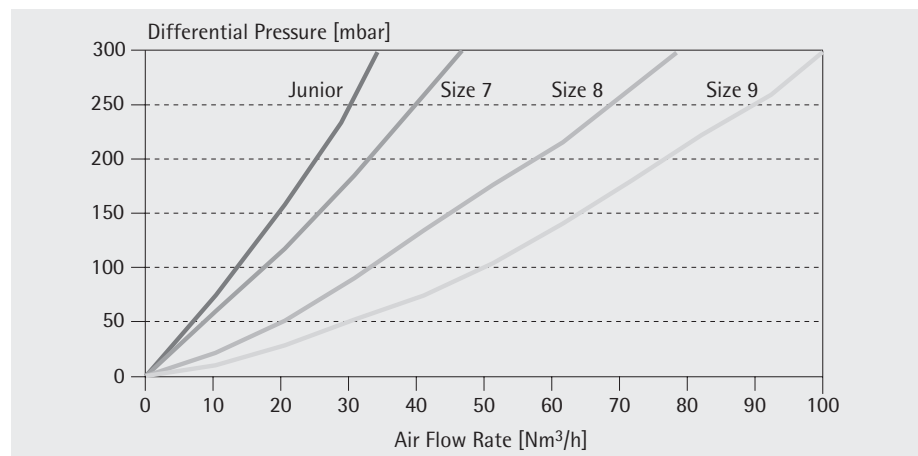
| Order Code | Pore Size [µm] | Pack Size [pieces] | Test Pressure [bar psi] | Max. Diffusion [ml/min] | Min. Bubble Point [bar psi] |
|------------------------|----------------|--------------------|---------------------------|-------------------------|-------------------------------|
| Cartridges | | | | | |
| 5182558T1----GA | 0.1 | 1 | 0.9 13 | 11 | 1.5 22 |
| 5182558T2----GA | 0.1 | 1 | 0.9 13 | 22 | 1.5 22 |
| 5182558T3----GA | 0.1 | 1 | 0.9 13 | 33 | 1.5 22 |
| 5182507T0----GA | 0.2 | 1 | 0.7 10 | 6 | 1.0 14.5 |
| 5182507T1----GA | 0.2 | 1 | 0.7 10 | 11 | 1.0 14.5 |
| 5182507T2----GA | 0.2 | 1 | 0.7 10 | 22 | 1.0 14.5 |
| 5182507T3----GA | 0.2 | 1 | 0.7 10 | 33 | 1.0 14.5 |
| Mini Cartridges | | | | | |
| 5181558T7-----B | 0.1 | 5 | - | - | 1.5 22 |
| 5181558T8-----B | 0.1 | 5 | - | - | 1.5 22 |
| 5181558T9-----B | 0.1 | 5 | 0.9 13.1 | 5 | 1.5 22 |
| 5181507T7-----B | 0.2 | 5 | 0.7 10.2 | 2 | 1.0 14.5 |
| 5181507T8-----B | 0.2 | 5 | 0.7 10.2 | 3 | 1.0 14.5 |
| 5181507T9-----B | 0.2 | 5 | 0.7 10.2 | 4 | 1.0 14.5 |
| 5181506T7-----B | 0.45 | 5 | 0.4 5.8 | 1 | 0.6 8.7 |
| 5181506T8-----B | 0.45 | 5 | 0.4 5.8 | 2 | 0.6 8.7 |
| 5181506T9-----B | 0.45 | 5 | 0.4 5.8 | 3 | 0.6 8.7 |
| Junior | | | | | |
| 5181407T7-----B | 0.2 | 5 | 0.7 10 | 2 | 1.0 14.5 |

Air Flow Chart Sartofluor® GA Cartridge 0.2 µm



Under atmospheric pressure conditions

Air Flow Chart Sartofluor® GA Mini Cartridges | Junior 0.2 µm



Under atmospheric pressure conditions

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany
Phone +49.551.308.0
Fax +49.551.308.3289
www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178
Argentina +54.11.4721.0505
Brazil +55.11.4451.6226
Mexico +52.5555.62.1102
UK +44.1372.737159
France +33.442.845600
Italy +39.055.63.40.41
Spain +34.913.586.098
Russian Federation +7.812.327.5.327
Japan +81.3.4331.4300
China +86.21.68782300

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