



## Sartofluor® PTFE Filter Cartridges Scalable and secure performance in sterile venting



# Choose Sartofluor® PTFE for optimum air filtration

## The optimum means

The air filter as a barrier needs to be highly reliable under all circumstances, i.e. pressure pulses, high steaming cycles, elevated moisture content etc. That's why we optimized our Sartofluor air filter cartridges to meet all the requirements with highest assurance levels.

Sartofluor filter cartridges fulfill all demands placed on an air filter, such as:

- Highest hydrophobicity
- High flow rates at low differential pressures
- High steam cycle lifetimes
- High mechanical and thermal strength
- Reliable and validated separation of microorganisms and bacteriophage

## User-Optimized

The development of this extremely reliable, secure, "last chance" barrier filter included the experiences of our Research and Development, engineering groups, suppliers, and especially our customers. Their input was and is our most valuable resource to find the optimum performance.

The optimum includes:

- Optimized, durable construction
- PTFE membrane
- High void volume
- Optimized selection of prefilter and support fleece
- Maximized filtration area
- Optimal pleat density

## Optimum choice for sterile venting and gas applications

Specify Sartofluor cartridge systems to optimize filtration performance in sterile venting and gas applications such as:

- Sterile gas filtration of fermentor inlets
- Off-gas filters downstream of fermentors or bioreactors
- Sterilizing vent filters on autoclaves and lyophilizers (freeze dryer)
- Sterile vent filters on product and WFI tanks
- Sterile air supply for service gases, such as filling lines in blow-fill-seal machines

Sartofluor cartridges are available in the optimum range of pore sizes – 0.45 µm, 0.2 µm and 0.1 µm.



# Scale up with a complete product line for air filtration

## Dependable performance at every scale

Our scale-up philosophy does not stop at liquid filtration. Especially in air filtration, with its variety of applications and demands, different filter sizes are essential. Sartofluor filter cartridges are available from 300 m<sup>2</sup> to 2.3 cm<sup>2</sup> for single filter elements, which means you can effectively filter air from small volume bioreactor to seed and large scale fermentor venting, as well as tank venting.

## The right hydrophobicity

If the filter membrane is not hydrophobic enough, moisture can accumulate and microorganisms may grow. A highly hydrophobic membrane can eliminate this danger along with any risk of water logging. Sartofluor membranes are constructed of PTFE. It provides more than twice the hydrophobicity of polypropylene or PVDF.

## Optimized construction adds savings

Experience, testing and customer feedback have guided the evolution of Sartofluor cartridges. For example, membrane pleatings and layers of filter fleece have been chosen to avoid water logging. Attention to detail at this level means you realize added savings in low blow down times.

## Materials of construction

Prefilter Layer	Polypropylene
Membrane Filter	PTFE
Drainage Layer	Polypropylene
Outercage	Polypropylene
Inner Core	Polypropylene
Endcaps	Polypropylene
O-Rings	Silicone*

\* EPDM and Viton are available



|1



|2



|3



|4



|5



|6

- |1 Capsules 150
- |2 Mini cartridges
- |3 Standard cartridges
- |4 MaxiCaps
- |5 MidiCaps
- |6 Sartofluor Junior

# Top Performance... even after 150 steam sterilization cycles

## Mechanical strength and optimized construction

We've tested Sartofluor cartridges to 134°C and they all withstood 150 steam cycles. No loss in integrity or performance. Or in PTFE hydrophobicity. No loss in flow rate. Plus, optimized Sartofluor cartridge construction allows differential pressures up to 0.5 bar at 134°C. This exceptional performance has been confirmed by Bacterial Challenge testing.

## Differential Pressure Limits at given temperatures

In the Direction of Filtration

°C	20	121	134	140
bar	5	1.5	0.5	0.5

Opposite the Direction of Filtration

°C	20	12	34	140
bar	3	1.0	0.5	0.5

## No water blockage. High flow rates. Maximum savings.

In air filtration applications, high flow rates result in lower energy costs and help to maximize safety – for example, for tank, venting. Sartofluor cartridges are optimized to maintain high flow rates, even in challenging process conditions like condensate build-up in steam-venting or elevated moisture content. No cartridge does more to control life-cycle costs. No cartridge system is more cost-effective.

The Reason: Sartofluor PTFE membrane and support fleece are extremely hydrophobic and feature optimized pleat density.

The Result: effective drainage of condensate and no water blockage.

## Validated performance for assured security

Sartofluor cartridges fulfill all known current regulatory requirements, for example USP, cGMP and FDA. This is documented in our Validation Guidelines for Sartofluor filter cartridges. Besides the validation, Sartofluor cartridges undergo a stringent performance qualification procedure:

- They're pressure-pulsation tested for 5000 cycles at 5 bar differential pressure.
- They're steam-cycle evaluated for 150 cycles at 134°C for 30 min; then 11 additional cycles over 7 hours.
- Their flow rate and water penetration are measured only after defined steam cycling.
- They're tested at maximum allowable differential pressure at a full range of temperatures.
- Their blow-down time is measured after steam sterilization and Water Intrusion Testing.
- They pass extractables tests done using RP-HPLC, GC-MS and FTIR.
- They pass phage challenge tests that last as long as 7 days.



# Integrity Testing

## Why the biopharmaceutical industry chose the Sartorius Water Intrusion Test (WIT).

Sartorius Stedim Biotech was the first to develop and validate an in-place integrity test for hydrophobic air filter cartridges—the WIT.

It surpasses other integrity tests because:

- It utilizes water as a test medium instead of a solvent water mixture.
- It can be performed in place, after steam sterilization.
- The WIT tests the complete system housing, O-rings, valves and filter elements including filter integrity and hydrophobicity.
- No downstream manipulations are required.
- Contamination by solvents or oil aerosols is avoided. The WIT can be fully automated, or it may be performed manually or semi-automatically.
- It is directly correlated to the ASTM Bacteria Challenge Test.

The test pressure for the WIT, at 2.5 bar (36 psi), is far lower than the Water Penetration Pressure, which is around 4.5 bar (67 psi) for a Sartofluor (Sartofluor 0.2  $\mu\text{m}$ ) PTFE filter cartridge.

## The Simplicity of the WIT Procedure.

The upstream side of the filter housing is filled with water and the air volume above the water column is measured. Afterwards a test pressure of 2.5 bar is applied and the system stabilized for 10 min. During the 10 min test time, the pressure drop is measured, which happens due to the intrusion of water into the first layers of the membrane. With the measured volume and pressure drop and the known test time, the intrusion is calculated and compared to the maximum allowable intrusion quoted in the validation guides.



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