



Sartopore[®] 2 0.45 µm

Bioburden & Particle Retentive Filter Elements

Product Information

- Extremely high flow rates and total throughputs
- Number one choice for bioburden reduction & particle removal
- Broad compatibility and easy scalability
- Outstanding filtration performance of aqueous solutions that are highly viscous & difficult to filter



No. 1 choice for bioburden reduction & particle removal
Due to the "built-in prefiltration" by a 0.8 µm membrane, Sartopore[®] 2 0.45 µm rated filter systems are ideally suited for bioburden reduction and particle removal of highly viscous and difficult to filter pharmaceutical solutions. Due to its hydrophilic Polyethersulfone membrane Sartopore[®] 2 0.45 µm filter elements offer outstanding total throughputs and flow rate performances. Thus ensuring highest process efficiency, minimized filtration costs and short filtration cycle times.

Broad compatibility and highest reliability

The unique Polyethersulfone membrane gives Sartopore[®] 2 0.45 µm broad chemical compatibility, including a pH-range from pH 1 to pH 14, and a high thermal resistance, making it suitable for a broad range of filtration liquids. To assure absolute reliability, each individual Sartopore[®] 2 0.45 µm filter element is integrity tested by Diffusion Point and Bubble Point Test prior to release.

Scalability

Sartopore[®] 2 0.45 µm filter elements are available in a broad range of sizes and formats to provide linear scale-up from R&D to process scale. The wide range of membrane areas from 300 cm² to 1.8 m² per filter element guarantees greatest flexibility and most economic filter sizing.

Applications

- Therapeutics
- Buffers
- Injectables
- Ophthalmics
- Large volume parenterals
- Antibiotics
- Biological Fluids
- Tissue Culture Media
- Bulk pharmaceutical products
- Acetic and basic solutions

Technical Data

Available Sizes	Filtration Area	Max. Diffusion at 1.7 bar 25 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges MaxiCaps®			
Size 0.5 (Only Cartridge)	0.3 m ² 3.2 ft ²	7	2.2 32
Size 1	0.6 m ² 6.5 ft ²	12	2.2 32
Size 2	1.2 m ² 12.9 ft ²	24	2.2 32
Size 3	1.8 m ² 19.4 ft ²	36	2.2 32
MidiCaps® Mini Cartridges			
Size 7	0.05 m ² 0.5 ft ²	3	2.2 32
Size 8	0.1 m ² 1.1 ft ²	4	2.2 32
Size 9	0.2 m ² 2.2 ft ²	6	2.2 32
Size 0 (Only MidiCaps®)	0.45 m ² 4.8 ft ²	12	2.2 32
Capsules			
Size 5	0.03 m ² 0.32 ft ²	2	2.2 32

Max. Allowable Differential Pressure

Cartridges | Mini Cartridges

5 bar | 72.5 psi at 20°C
2 bar | 29 psi at 80°C

MaxiCaps®

5 bar | 72.5 psi at 20°C
3 bar | 43.5 psi at 50°C

MidiCaps®

5 bar | 72.5 psi at 20°C
2 bar | 29 psi at 80°C

Capsules

4 bar | 58 psi at 20°C
2 bar | 29 psi at 50°C

Max. Allowable Back Pressure

2 bar | 29 psi at 20°C
(for all elements)

Materials

Prefilter Membrane
Polyethersulfone, asymmetric

Endfilter Membrane
Polyethersulfone, asymmetric

Support Fleece
Polypropylene
(In-Line Steam sterilizable & autoclavable)

Core
Polypropylene

End Caps
Polypropylene

Capsule Housing
Polypropylene

O-Ring
Silicone
(other materials on request)

Filling Bell
Polycarbonate

Pore Size Combination

0.8 µm + 0.45 µm



Regulatory Compliance

- Each individual element is tested for integrity by Bubble Point and Diffusion test
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- Meet or exceed the requirements for WFI quality standards set by the current USP
- Non pyrogenic according to USP Bacterial Endotoxins
- USP Plastic Class VI Test
- Non fiber releasing according to 21 CFR

Sterilization

Cartridges, Mini Cartridges

In-Line Steam Sterilization

134 °C, 0.5 bar, 20 min.

Min. 25 Sterilization Cycles

or

Autoclaving

134°C, 2 bar, 30 min

Min. 25 Sterilization Cycles

MaxiCaps®, MidiCaps® & Capsules

Autoclaving

134°C, 2 bar, 30 min

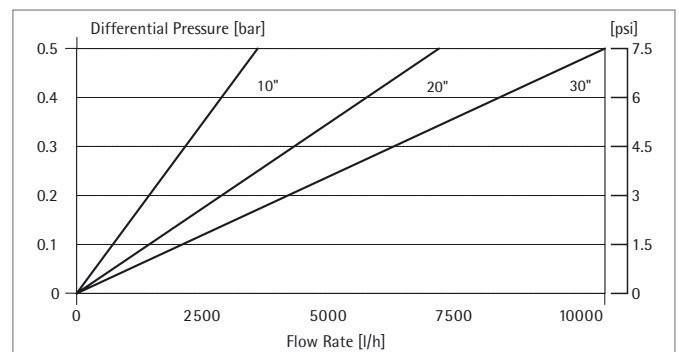
Min. 25 Sterilization Cycles (MidiCaps® & MaxiCaps®)

Technical References

Validation Guide	SPK5732-e
Extractables Guide	SPK5731-e

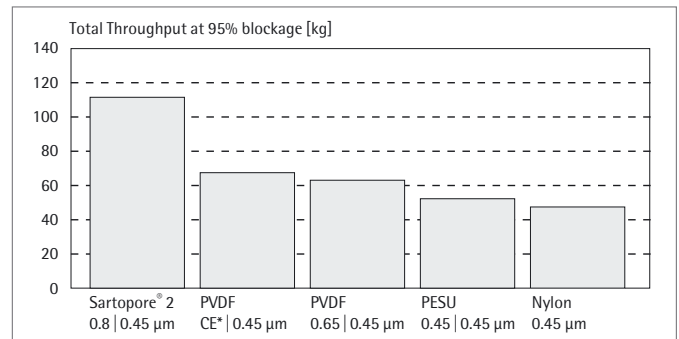
Performance

Water Flow Rate for MaxiCaps® and Standard Cartridges



Standardized at 20°C

Total Throughput Comparison



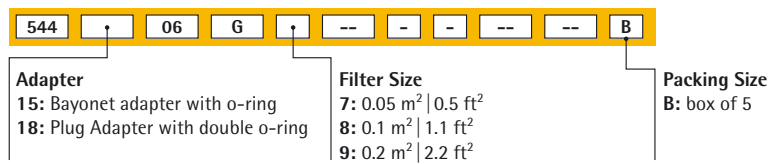
10" Cartridges

* Cellulose Ester prefilter

Ordering Information



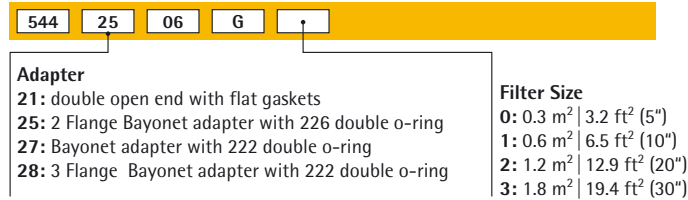
Mini Cartridge



(Standard with silicone o-ring optional with EPDM o-ring. Example: 5441506G1---E--B)



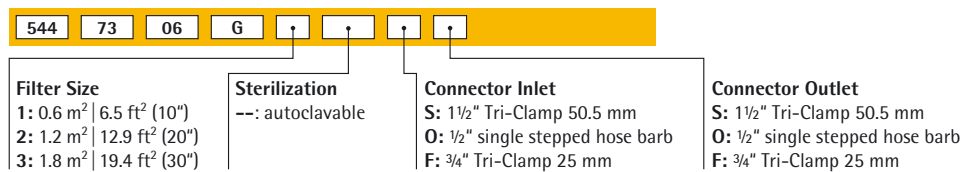
Cartridge



(Standard with silicone o-ring optional with EPDM o-ring. Example: 5442506G1---E)



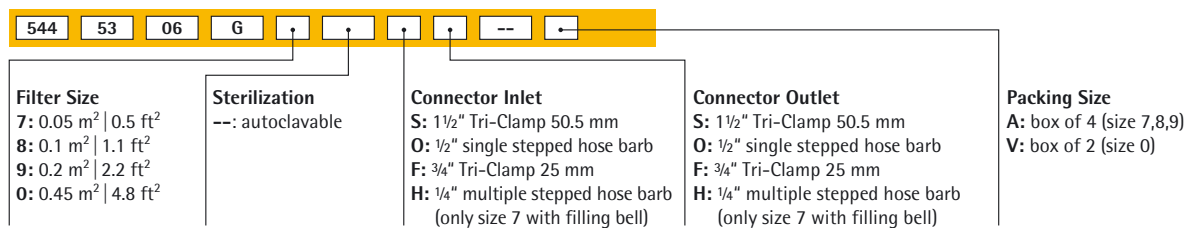
MaxiCaps[®]



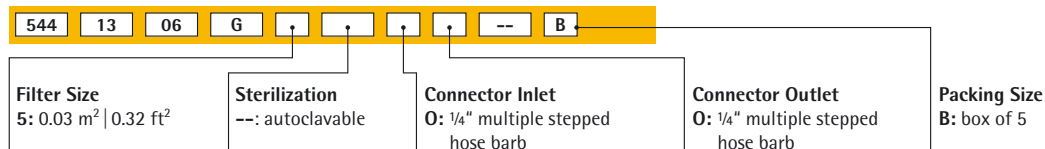
(Optional with vent valve design for connection of integrity tester. Example: 5447307H1--SSIT)



MidiCaps[®]



Capsules



Check the availability of your desired configuration with your Sartorius sales representative or online at www.sartorius-stedim.com

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