

Sartopore[®] Air Midicaps[®] and Maxicaps[®]

The Single-Use Venting Filter
for Critical Applications



Product Information

The Sartopore[®] Air with its revolutionary hydrophobic 0.2 µm PES membrane completely addresses the rigorous demands of single-use venting applications. Sartopore[®] Air ensures sterility with an outstanding flow rate performance.

This filter delivers a high level of performance and process security.

Introduction

This filter raises the bar and sets the standards when it comes to the requirements needed for single-use applications.

Particle retention, phage retention and of course bacterial retention in air and liquid are specifications that prove the quality of Sartopore[®] Air. 100% factory integrity testing ensures inherent quality in every filter prior to use. Superior and steady flow rates over long duration imply high efficient processes.

Applications

- Single Use Bioreactors
(Sparge | Overlay filter assemblies | Exhaust filter assemblies)
- Single-Use Mixing and Storage bag vents
- Single-Use Liquid filter assemblies requiring PUPSIT
(Post Sterilization Pre-Use Integrity Testing)
- Fill-finish

Inherent Quality Provides Full Confidence

The 0.2 µm single-layer hydrophobic polyethersulfone (PES) membrane is self-dewetting and therefore provides high air flow rates at low differential pressures over an extended process time. All components were developed and are produced under full control of Sartorius. Furthermore, the following indispensable requirements are fulfilled:

- Retention of $\geq 10^7$ B. diminuta/cm² in aerosol and liquid
- Retention of $\geq 10^7$ MS2 coliphage/cm² in aerosol
- Retention of particles sizes 0.005 µm | 0.3 µm
- 100% integrity tested prior to release
- Clear labelling with Lot. number and individual unit number. All information lasered on each filter housing.

Technical Specifications

Available Sizes	Filtration Area [m ² ft ²]	Max. Diffusion @ 0.7 bar 10.2 psi [mL/min]	Min. Bubble Point [bar psi]
Maxicaps®			
Size 1	0.53 5.7	10	1 14.5
Size 2	1.06 11.4	20	1 14.5
Midicaps®			
Size 7	0.06 0.54	2	1 14.5
Size 8	0.1 1.1	3	1 14.5
Size 9	0.17 1.83	4	1 14.5
Size 0	0.34 3.66	8	1 14.5
Capsules			
Size 4	0.016 0.17	1.2	1 14.5

Max. Differential Pressure (in Direction of Flow)

Midicaps®, Maxicaps® and Capsules

5 bar | 72.5 psi at 5–30°C for max. 12h

1 bar | 14.5 psi at 5–40°C for max. 3 months

1 bar | 14.5 psi at 40–50°C* for max. 1 month

* 65°C Heating Jacket for max. 1 month
(Operating Bioreactor Conditions max. 100 mbar)

Max. Back Pressure (in Reverse Direction of Flow)

Midicaps® and Maxicaps®

1 bar | 14.5 psi at 5–40°C for max. 3 month

Materials

Filter Membrane

Hydrophobic Polyethersulfone (PES)

Drainage Fleece

Nonwoven Polypropylene (PP) | Polyethylene (PE) Fleece

Outer Cage

Polypropylene

Inner Core

Polypropylene

End Caps

Polypropylene

Housing

Polypropylene

O-Rings

Silicone

Available Pore Size

0.2 µm

Sterilization

Gamma Irradiation < 50 kGy
1 Sterilization Cycle

Sartopore® Air Midicaps®, Maxicaps® and Capsules
cannot be in-line steam sterilized or autoclaved

Technical References

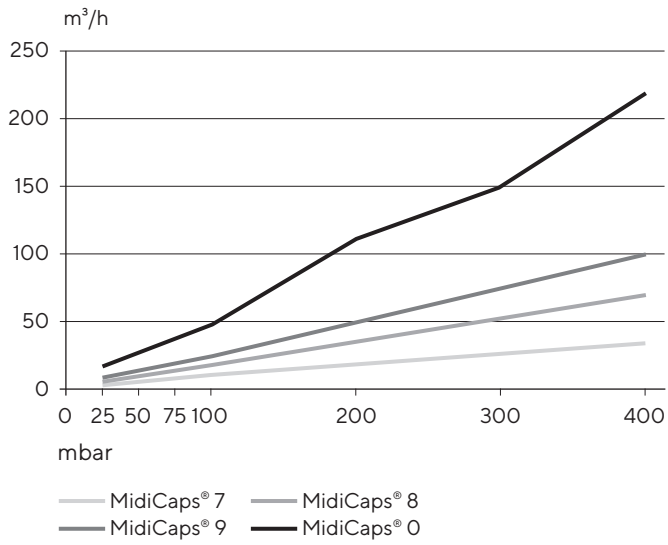
Validation Guide SPK5819-e

Regulatory Compliance

- Each individual element is tested for integrity by Bubble Point and Diffusion test
- Fully validated as sterilizing grade filters according to current ASTM F-838 guidelines
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System
- USP Plastic Class VI Test
- Non-fiber releasing: This product was manufactured with a membrane which meets the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6) and 211.72.
- Oxidizable Substances: The filtrate of these filter elements shows a negative reaction when tested according to the current USP

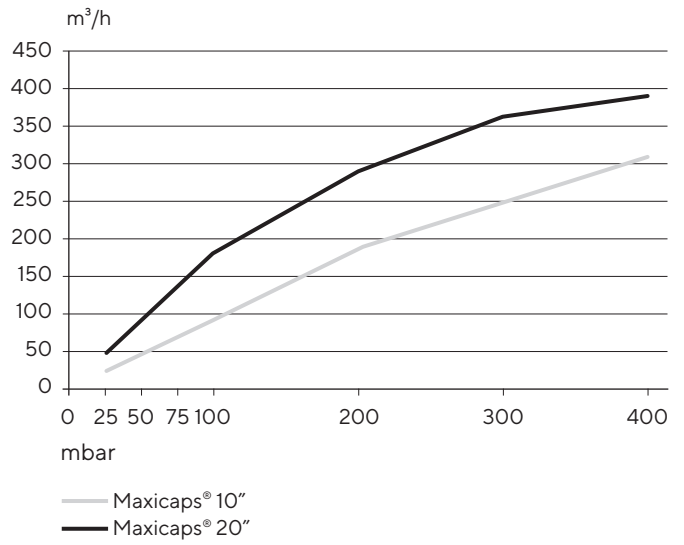
Performance

Air Flow Rate Midicaps®



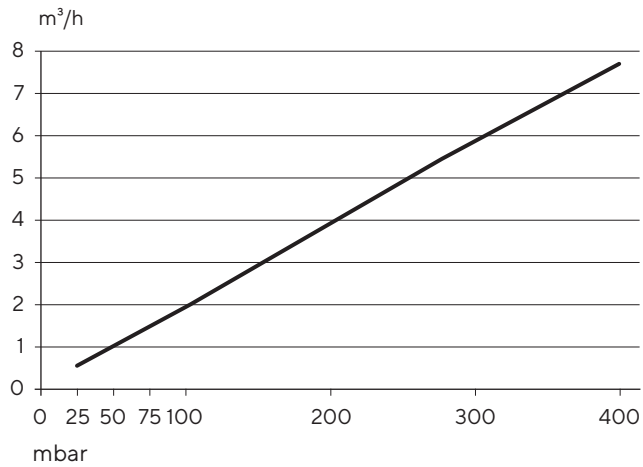
Valid for SS-Connector

Air Flow Rate Maxicaps®



Valid for SS-Connector

Air Flow Rate Capsule



Valid for SS-Connector

Ordering Information



Maxicaps®

519 73 07 A ■ G- ■ IT

Filter Size
 1: 0.53 m² | 5.7 ft² (10")
 2: 1.06 m² | 11.4 ft² (20")

Connector Inlet | Outlet
 S: 1½" tri-clamp 50.5 mm
 O: ½" single stepped hose barb

Packing Size
 Box of 1



Midicaps®

519 53 07 A ■ G- ■ -- ■

Filter Size
 7: 0.05 m² | 0.54 ft²
 8: 0.1 m² | 1.1 ft²
 9: 0.17 m² | 1.83 ft²
 0: 0.34 m² | 3.66 ft²

Connector Inlet | Outlet
 S: 1½" tri-clamp 50.5 mm
 O: ½" single stepped hose barb
 F: ¾" tri-clamp 25 mm

Packing Size
 A: box of 4 (size 7, 8, 9)
 V: box of 2 (size 0)



Capsules

519 13 07 A 4 G- ■ -- B

Connector Inlet
 S: ¾" tri-clamp 25 mm
 O: ¼" multiple stepped hose barb

Packing Size
 B: box of 5

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