

Sartopore 2 0.1 μm

Sterilizing Grade and Mycoplasma Retentive γ-Irradiatable Filter Capsules



Description

Sartopore 2 0.1 μm rated γ-irradiatable filter capsules are designed for sterilizing grade filtration and Mycoplasma removal in bag filtration processes. Prior or after connection to flexible-bag-container-systems they can be sterilized by γ-irradiation ≤ 50 kGy.

Applications

Typical applications for Sartopore 2-γ-Capsules include combined sterilizing grade filtration and mycoplasma removal from

- Cell Culture Media
- Culture Media Components
- Serum

They are ideally suited for bioprocessed pharmaceuticals and any other applications requiring sub 0.2 μm filtration for enhanced sterility assurance.

Compatibility

Sartopore 2-γ-Capsules are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore 2-γ-Capsules offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for a broad range of applications in the Pharma | Biotech field.

Performance

Due to the superior construction including a "built-in" prefiltration by a heterogeneous double layer membrane Sartopore 2-γ-Capsules achieve outstanding total throughputs and excellent flow rates.

Flexibility

Sartopore 2-γ-Capsules are available with filtration areas from 0.03 m² | 0.3 ft² up to 0.45 m² | 5 ft² for easy adaption to any bag-filtration process independent from the batch size.

Microbiological Retention

Sartopore 2-γ-Capsules 0.1 μm rated are validated as sterilizing grade filters according to ASTM F 838-83 standard and for Mycoplasma removal with a Log Reduction Value (LRV) of 7 for *Acholeplasma laidlawii*.

Quality Control

Each individual element is tested for integrity by Diffusion-Test prior to release, assuring absolute reliability.

Documentation

Sartopore 2 Gamma capsules are designed, developed and manufactured in accordance with a ISO 9001 certified Quality Management System. A Validation Guide is available for compliance with regulatory requirements.

Specifications

Materials

Prefilter Membrane:	Polyethersulfone, asymmetric
Endfilter Membrane:	Polyethersulfone, asymmetric
Support Fleece:	Polypropylene
Core:	Polypropylene
End Caps:	Polypropylene
Capsule Housing:	Polypropylene

Pore Size

0.2 μm + 0.1 μm

Available Sizes | Filtration Area

Size 7	0.05 m ² 0.5 ft ²
Size 8	0.1 m ² 1 ft ²
Size 9	0.2 m ² 2 ft ²
Size 0	0.45 m ² 5 ft ²

Available Connectors

SS, SO, OO

Operating Parameters

Max. Allowable Differential Pressure:	4 bar 58 psi at 20 °C	2 bar 29 psi at 80 °C
Max. Allowable Back Pressure:	2 bar 29 psi at 20 °C	

Integrity Test Limits

Maximum Allowable Diffusion at 4.0 bar / 58 psi Et 20 °C

Capsule Size	Maximum Diffusion
Size 7	4 ml/min
Size 8	6 ml/min
Size 9	9 ml/min
Size 0	18 ml/min

Membrane Filter Capsules

Specifications

Extractables

Sartopore- γ -Capsules meet, or exceed the requirements for WFI quality standards set by the current USP.

Regulatory Compliance

Individually integrity tested

Integrity test correlated to HIMA/ASTM F 838-83 Bacteria Challenge Test

Non pyrogenic according to USP Bacterial Endotoxins

Pass USP Plastic Class VI Test

Non fiber releasing according to 21 CFR

Sterilization

γ -irradiation \leq 50 kGy irradiation dosage

Autoclaving:

134 °C, 2 bar | 29 psi, 30 min

No In-Line Steam Sterilization

Sterilization Cycles

γ -Irradiation: Max. 1
Autoclaving: Max. 3

Technical References

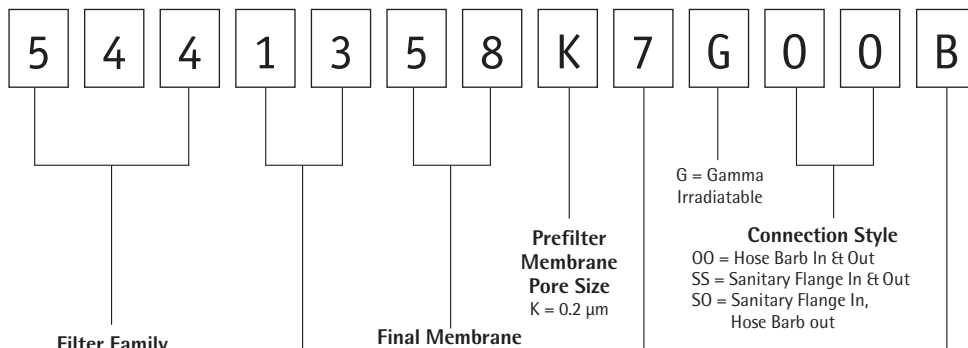
Validation Guide:

SPK5734-e

Extractables Guide:

SPK5740-e

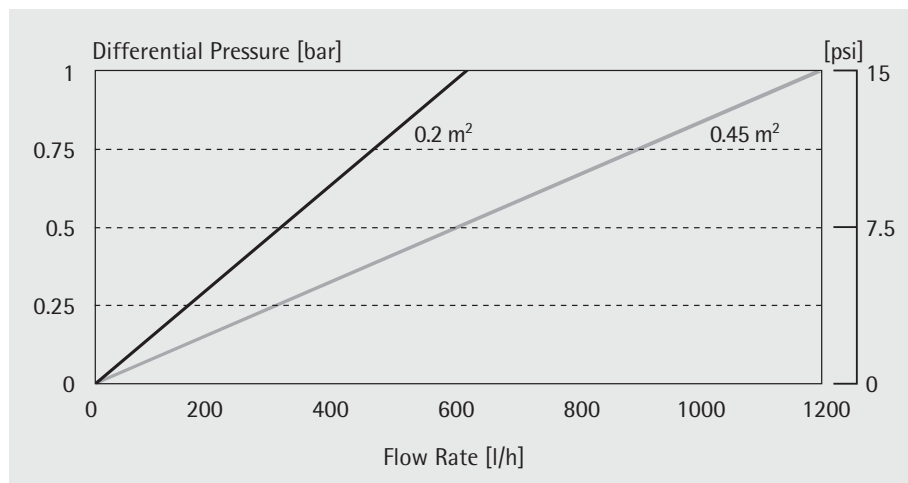
Ordering Guide:



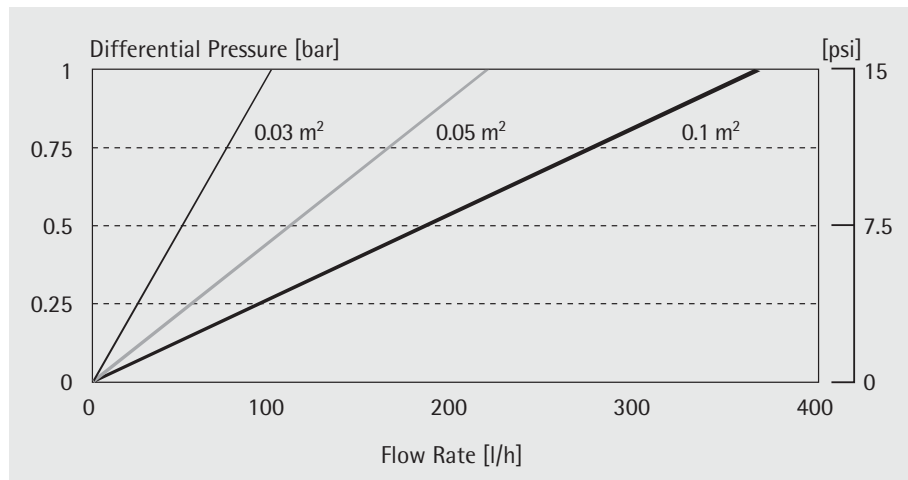
Capsule Size | Package Quantity (XX = Connection Style)

7GXXB = 500 cm² / .5 ft² Capsule, Pack of 5
8GXXB = 0.1 m² / 1 ft² Capsule, Pack of 5
9GXXA = 0.2 m² / 2 ft² Capsule, Pack of 4
0GXX_ = 0.45 m² / 5 ft² Capsule, Single Unit

Water Flow Rates for 0.2 m² and 0.45 m² Capsules



Water Flow Rates for 0.03 m², 0.05 m² and 0.1 m² Capsules



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