



Sartopore® 2 0.2 µm & 0.1 µm

Sterilizing Grade & Mycoplasma Retentive γ-Irradiatable MidiCaps® and Capsules



Description

Sartopore® 2-γ-MidiCaps® and Capsules are designed for connection to flexible-bag-container-systems prior to sterilization by gamma-irradiation. They are available with 0.2 µm & 0.1 µm final membranes for sterilizing grade filtration and Mycoplasma removal.

Applications

Typical applications include sterilizing grade filtration and Mycoplasma removal of:

- Biologicals
- Pharmaceuticals
- Cell Culture Media (serum free or serum containing)
- Culture Media Components
- Serum
- Buffers

Compatibility

Sartopore® 2-γ-MidiCaps® and Capsules are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore® 2-γ-MidiCaps® and Capsules offers a broad chemical compatibility from pH 1 to pH 10 making them ideally suited for filtration of high and low pH-buffers in the Pharma | Biotech field.

Performance

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

Flexibility

Sartopore® 2-γ-MidiCaps® and Capsules are available with various filtration areas from 150 cm² | 0.16 ft² up to 0.45 m² | 4.8 ft² and a broad range of different connector styles to allow an easy integration into any bag-container system.

Microbiological Retention

Sartopore® 2-γ-MidiCaps® and Capsules 0.2 µm & 0.1 µm rated elements are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-05 guidelines. In addition Sartopore® 2-γ-MidiCaps® with 0.1 µm final membranes are validated for Mycoplasma removal with a LRV of 7 for *Acholeplasma Laidlawii*.

Quality Control

Each individual element is tested for integrity by B.-P. (0.2 µm only) and Diffusion-Test prior to be released assuring absolute reliability.

Specifications

Materials

Prefilter Membrane	Polyethersulfone, asymmetric
Endfilter Membrane	Polyethersulfone, asymmetric
Support fleece	Polyester
Core	Polypropylene
End caps	Polypropylene
Capsule Housing	Polypropylene
O-Ring	Silicone

Pore Size Combinations

0.2 µm + 0.1 µm
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Capsules

Size 4 0.015 m² | 0.16 ft²
Size 5 0.03 m² | 0.32 ft²

MidiCaps®

Size 7 0.05 m² | 0.5 ft²
Size 8 0.1 m² | 1.1 ft²
Size 9 0.2 m² | 2.2 ft²
Size 0 0.45 m² | 4.8 ft²

Available Connectors Capsules

SS, SO, OO

Available Connectors MidiCaps®

SS, SO, OO, FO, FO, HH (only Size 7)

S: 1½" Tri-Clamp (Sanitary)
O: ½" Single stepped hose barb
F: ¾" Tri-Clamp (Sanitary)
H: ¼" Multiple stepped hose barb (with filling bell at the outlet)
B: ¾" - 1" Multiple stepped hose barb

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	2 bar 29 psi at 20°C

По вопросам продаж и поддержки обращайтесь:

Астана+7(7172)727-132, Волгоград(844)278-03-48, Воронеж(473)204-51-73, Екатеринбург(343)384-55-89,
Казань(843)206-01-48, Краснодар(861)203-40-90, Красноярск(391)204-63-61, Москва(495)268-04-70,
Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
Санкт-Петербург(812)309-46-40, Саратов(845)249-38-78, Уфа(347)229-48-12

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Specifications

Extractables

Sartopore® 2-γ-MidiCaps® and Capsules meet, or exceed the requirements for WFI quality standards set by the current USP after γ-irradiation with ≤ 50 kGy.

Regulatory Compliance

Individually integrity tested

Integrity test correlated to HIMA | ASTM F 838-05 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 ≤ 50 kGy irradiation dosage

Sartopore® 2-γ-MidiCaps® and Capsules cannot be autoclaved or in-line steam sterilized

Sterilization Cycles

γ-Irradiation: 1 Cycle

Technical References

Validation Guide

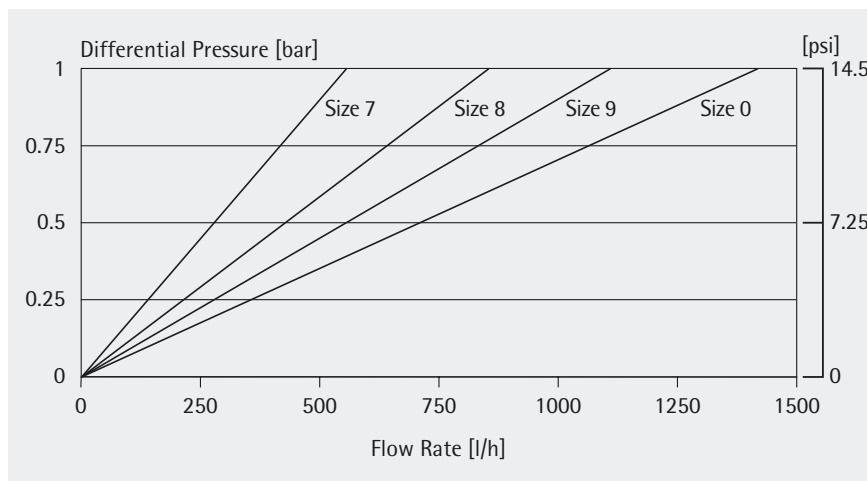
SPK5734-e

Order Information

Order Code	Pore size [µm]	Pack size [Pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
Capsules:					
5441307H4G-**-B	0.2	5	2.5 36	1	3.2 46
5441307H5G-00--B	0.2	5	2.5 36	2	3.2 46
5441358K4G-**-B	0.1	5	4.0 58	1	not applicable
MidiCaps®:					
5445307H7G-**-A	0.2	4	2.5 36	4	3.2 46
5445307H8G-**-A	0.2	4	2.5 36	5	3.2 46
5445307H9G-**-A	0.2	4	2.5 36	7	3.2 46
5445307H0G-**-V	0.2	2	2.5 36	14	3.2 46
5445358K7G-**-A	0.1	4	4.0 58	4	not applicable
5445358K8G-**-A	0.1	4	4.0 58	6	not applicable
5445358K9G-**-A	0.1	4	4.0 58	9	not applicable
5445358K0G-**-V	0.1	2	4.0 58	18	not applicable

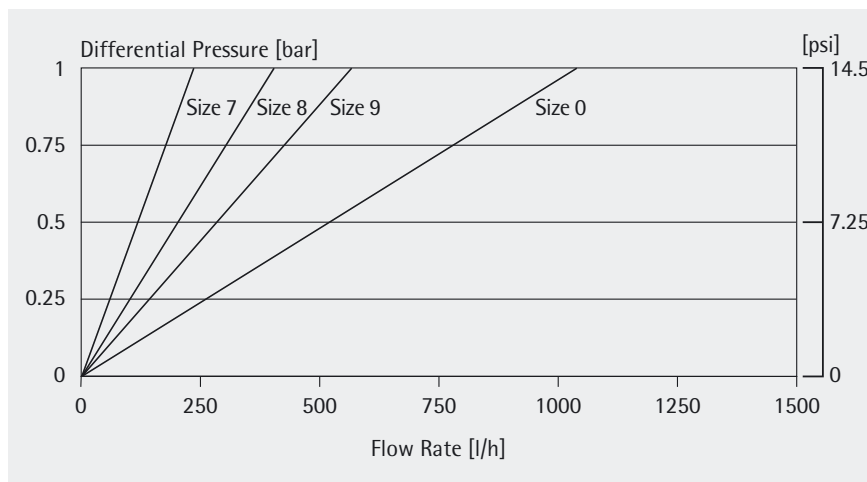
** : Connector Style

Sartopore® 2 0.2 µm. Water Flow Rates for γ-MidiCaps®



Standardized at 20°C

Sartopore® 2 0.1 µm. Water Flow Rates for γ-MidiCaps®





Sartopore[®] 2 0.2 µm & 0.1 µm

Sterilizing Grade & Mycoplasma Retentive γ-Irradiatable MaxiCaps[®]



Description

Sartopore[®] 2-γ-MaxiCaps[®] are designed for connection to flexible-bag-container-systems prior to sterilization by gamma-irradiation. They are available with 0.2 µm & 0.1 µm final membranes for sterilizing grade filtration and Mycoplasma removal.

Applications

Typical applications include sterilizing grade filtration and Mycoplasma removal of:

- Biologicals
- Pharmaceuticals
- Cell Culture Media (serum free or serum containing)
- Culture Media Components
- Serum
- Buffers

Compatibility

Sartopore[®] 2-γ-MaxiCaps[®] are designed for sterilization by gamma irradiation ≤ 50 kGy irradiation dosage. The Polyethersulfone membrane of the Sartopore[®] 2-γ-MaxiCaps[®] offers a broad chemical compatibility from pH 1 to pH 14 making them ideally suited for filtration of high and low pH-buffers in the Pharma | Biotech field.

Performance

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

Flexibility

Sartopore[®] 2-γ-MaxiCaps[®] are ideally suited to be used in large scale filtration applications in combination with flexible bag containers due to their superior effective filtration area of up to 1.8 m²/18 ft² per 30" element.

Microbiological Retention

Sartopore[®] 2-γ-MaxiCaps[®] 0.2 µm & 0.1 µm rated are fully validated as sterilizing grade filters according to HIMA and ASTM F-838-83 guidelines. In addition Sartopore[®] 2-γ-MaxiCaps[®] are validated for Mycoplasma removal with a LRV of 7 for *Acholeplasma Laidlawii*.

Quality Control

Each individual element is tested for integrity by B.-P. (0.2 µm only) and Diffusion-Test prior to be released assuring absolute reliability.

Documentation

Sartopore[®] 2-γ-MaxiCaps[®] 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
O-Ring:	Silicone

Pore Size Combinations

0.2 µm + 0.1 µm
0.45 µm + 0.2 µm

Available Sizes | Filtration Area

Size 1	0.6 m ² 6.5 ft ²
Size 2	1.2 m ² 12.9 ft ²
Size 3	1.8 m ² 19.4 ft ²

Available Connectors

SS, SO, OO, FF, BB

S:	1½" Tri-Clamp (Sanitary)
O:	½" Single stepped hose barb
F:	¾" Tri-Clamp (Sanitary)
B:	¾" - 1" Multiple stepped hose barb

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

Specifications

Extractables

Sartopore® 2-γ-MaxiCaps® meet, or exceed the requirements for WFI quality standards set by the current USP after γ-irradiation with ≤ 50 kGy.

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 ≤ 50 kGy irradiation dosage

Sartopore® 2-γ-MaxiCaps® cannot be autoclaved or in-line steam sterilized

Sterilization Cycles

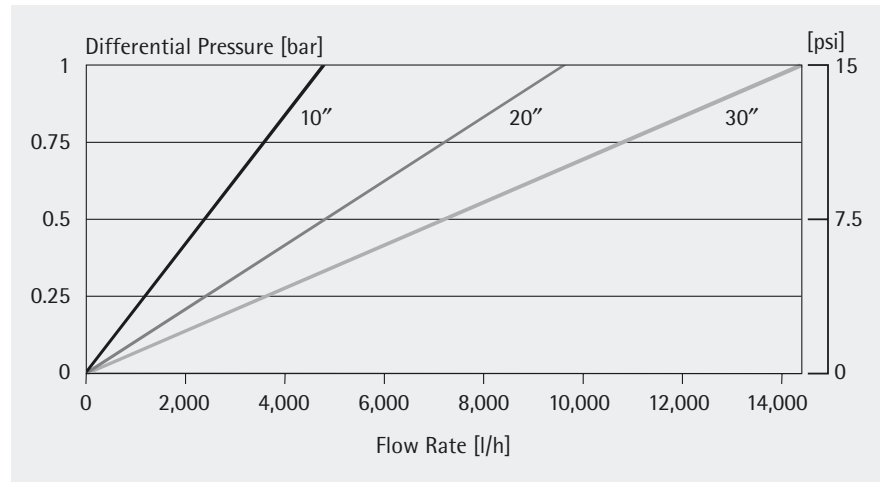
γ-Irradiation: 1 Cycle

Technical References

Validation Guide:

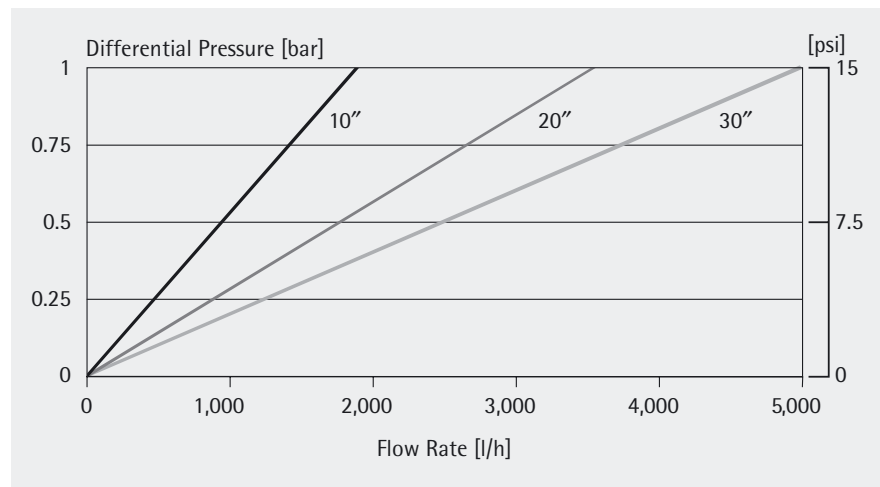
SPK5734-e

Sartopore® 2 0.2 μm. Water Flow Rates for γ-MaxiCaps®



Standardized at 20°C

Sartopore® 2 0.1 μm. Water Flow Rates for γ-MaxiCaps®



Order Information

Order Code	Pore size [μm]	Pack size [pieces]	Test Pressure [bar psi]	Max. Diffusion [ml/min]	Min. Bubble Point [bar psi]
5441307H1G-**-	0.2	1	2.5 36	18	3.2 46
5441307H2G-**-	0.2	1	2.5 36	36	3.2 46
5441307H3G-**-	0.2	1	2.5 36	54	3.2 46
5441358K1G-**-	0.1	1	4.0 58	24	not applicable
5441358K2G-**-	0.1	1	4.0 58	48	not applicable
5441358K3G-**-	0.1	1	4.0 58	72	not applicable

** : Connector Styles

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 Нижний Новгород(831)429-08-12, Новосибирск(383)227-86-73, Ростов-на-Дону(863)308-18-15, Самара(846)206-03-16,
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