SARTURIUS

Sartopore® 2 XLG

Sterilizing-Grade Filter Elements



Product Information

- Outstanding capacity and flow performance
- Lowest filter consumption for filtration of cell culture media
- Highly economic sizing for intermediate steps in downstream processing
- Optimization of conventional and single-use processes

Reducing 50 - 90% of Filtration Costs

Sartopore® 2 XLG uses a coarser pre-filter layer (0.8 μ m) in front of the sterilizing-grade rated final membrane (0.2 μ m). The coarser pre-filter layer avoids early blocking in many biological liquids. The enhanced filtration capacity can reduce filtration costs by 50 – 90% for many processes.

Scalability

Sartopore® 2 XLG 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 210 cm² to 2.4 m² per filter element guarantees greatest flexibility and economic filter sizing.

Applications

- Filtration of cell culture media such as:
- Plant peptone or yeast supplemented cell culture media
- Serum containing cell culture media
- Other cell culture media used in biotech manufacturing
- Post cell harvest filtration
- Downstream intermediates
 (before and after UF | DF and chromatography steps)

Services

Sartorius Confidence® Validation Services is the perfect complement to Sartopore® 2 XLG filters.

Our services provide

- Extractables and leachables services
- Microbiological testing
- Physicochemical testing

in compliance with regulatory requirements. Our local teams of validation experts support you with our tailored and consultative approach to determine the most costeffective solution and give you the confidence you need to succeed.

Technical Specifications

Available Sizes	Filtration Area	Max. Diffusion at 2.5 bar 36 psi [ml/min]	Min. Bubble Point [bar psi]
Cartridges, T-Style Maxica	aps®, Maxicaps® Gamma Maxicaps®		
Size 1	0.8 m² 8.6 ft²	23	3.2 46
Size 2	1.6 m² 17.2 ft²	46	3.2 46
Size 3	2.4 m² 25.8 ft²	69	3.2 46
Midicaps® Gamma Midic	caps [®]		
Size 7	0.065 m² 0.7 ft²	5	3.2 46
Size 8	0.13 m² 1.4 ft²	6	3.2 46
Size 9	0.26 m² 2.8 ft²	9	3.2 46
Size 0	0.52 m² 5.6 ft²	18	3.2 46
Capsules Gamma Capsu	les		
Size 4	0.021 m² 0.22 ft²	1.1	3.2 46

Max Allowable Differential Pressure

Cartridges

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

T-Style Maxicaps®, Maxicaps® | Gamma Maxicaps®, Midicaps® | Gamma Midicaps®

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

Capsules | Gamma Capsules Size 4

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

Materials

Prefilter Membrane

Polyethersulfone, asymmetric

Endfilter Membrane

Polyethersulfone, asymmetric

Support Fleece

Polypropylene (In-line steam sterilizable & autoclavable) Polyester (Y-irradiatable or γ-irradiatable | autoclavable)

Core

Polypropylene

End Caps

Polypropylene

Capsule Housing

Polypropylene

O-Ring

Silicone

(other materials on request)

Filling Bell

Polycarboate

Max Allowable Back Pressure

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

Pore Size Combination

 $0.8 \, \mu m + 0.2 \, \mu m$

Regulatory Compliance

- For release, each individual element is tested for integrity by bubble point and diffusion test
- Fully validated as sterilizing-grade filters according to ASTM current F-838 guidelines
- 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

In-Line Steam Sterilization

Max. 134 °C, 0.3 bar, 20 min. Min. 25 Sterilization Cycles

or

Autoclaving

Max. 134°C, 2 bar, 30 min Min. 25 Sterilization Cycles

Maxicaps®, Midicaps® & Capsules

Autoclaving

Max. 134°C, 2 bar, 30 min

Min. 25 Sterilization Cycles (Midicaps® & Maxicaps®)

Min. 5 Sterilization Cycles (Capsules)

Gamma Maxicaps®, Gamma Midicaps® & Gamma Capsules

Gamma Irradiation

≤ 50 kGv

1 Sterilization Cycle

T-Style Maxicaps®

Autoclaving

Max. 134°C, 2 bar, 30 min Min. 5 Sterilization Cycles

or

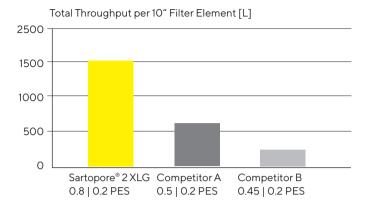
Gamma Irradiation

≤50 kGy

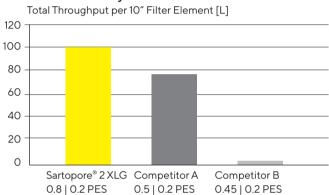
1 Sterilization Cycle

Performance

Soy Peptone Supplemented Cell Culture Media



Monoclonal Antibody Pool¹



¹Antibody Concentration: 47.5 mg/ml

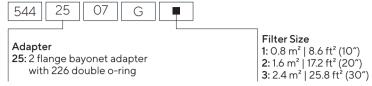
Technical References

Validation Guide 2665242 Extractables Guide SPK5775-e

Ordering Information



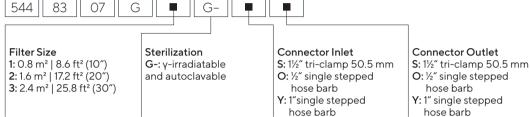
Cartridge



(Standard with silicone o-ring optional with EPDM or Fluoroelastomer o-ring).

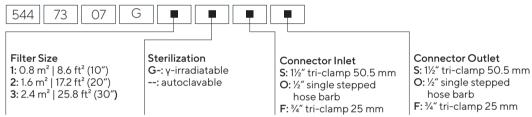


T-Style Maxicaps®





Maxicaps® | Gamma Maxicaps®



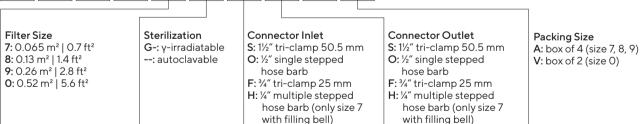
(Optional with vent valve design for connection of integrity tester. Example: 5447307G1--SOIT)



544

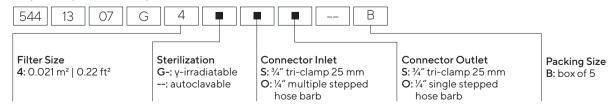
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Midicaps® | Gamma Midicaps®





Capsules | Gamma Capsules



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