SARTORIUS

Product Datasheet

Maxicaps® MR

Unique Large Scale Single-Use Filter Device

Product Information

Maxicaps® MR is a fully contained single-use assembly with up to 27 m² filtration area, designed for large scale filtration in biopharmaceutical applications. The compact and ready-to-use Maxicaps® MR comes pre-sterilized and pre-assembled with 90 % less tubing and connectors compared to standard multi-capsule assemblies. Maxicaps® MR is the only logical choice for the lowest total cost of ownership in large-scale single-use processes.

Introduction

Single-use filter capsules have been systematically replacing stainless steel housings and filter cartridges as a highly economical and risk-adverse choice for the biopharmaceutical industry. From capsules to complex custom assemblies, implementation of single-use filter systems reduces the time it takes for equipment setup and virtually eliminates the need for cleaning.

Conventional multi-round filter housings have now evolved into single-use Maxicaps® MR systems to meet today's advanced requirements. Until Maxicaps® MR, there has been no single-use equivalent to large-scale, multi-round filter configurations provided by stainless steel systems. Maxicaps® MR is the first ready-to-use, fully self-contained, single-use filtration unit featuring a wide choice of configurations. With 90% less tubing and only two connections, Maxicaps® MR reduces the installation time and the risk of operating errors significant.

Single-Use Applications

- Media & feeds filtration
- Post cell harvest bioburden reduction for mAb's
- Clarification of vaccines
- Capture-column guard filtration
- Large-scale buffer preparation
- Virus filtration upstream and downwstream
- Adsorptive virus pre-filtration

Features

- Filtration area of up to 27 m^2
- Complete device integrity testable as a single unit
- Large variety of pre-, sterile- and virus filters
- Flexible connections: Opta®, 1.5" Tri-Clamp, AseptiQuik®* for virus filters or weldable tubing
- One single air filter for easy system venting

Benefits

Ready-to-use	→	pre-sterilized & pre-assembled
Certified safety	→	Sterile & Sanitary delivery option
Risk mitigation	→	90 % less tubings & connectors
Space saving	→	Compact and organized design
Time saving	→	90 % less test time – saves up to 4 hours

Delivery Conditions

Sterile
- For all gamma stable filter materials
- Assembled in a classified clean room, complete device gamma irradiated in a validated sterilization procedure

Sanitary
- For non-gamma stable filter materials
- All fluid contact materials are sterilized in validated sterilization procedures and assembled in a classified clean room following specific hygienic measures and rules of conduct

Non-Sterile
- For non-gamma stable filter materials
- Assembled in a classified clean room

Validation

Maxicaps® MR have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing. A sterilization validation in order to obtain a 10^{-6} Sterility Assurance Level was performed to demonstrate the effectiveness of the gamma sterilization method for configurations with gamma stable filter material. The Maxicaps® filter capsules of the Sanitary delivery option are sterilized by autoclaving using a validated process following DIN|EN ISO 17665-1 regulations.

*AseptiQuik® is a registered trademark of the Colder Products Company.

Technical Data

Filter Families	Filtration Area	Materials	Max. Diffusion	Delivery Condition
Sartopore® Platinum				
MR3	9 m² | 96.9 ft²	Polyethersulfone, surface modified	225 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR6	18 m² | 193.8 ft²	Polyethersulfone, surface modified	450 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR9	27 m² | 290.7 ft²	Polyethersulfone, surface modified	675 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
Sartopore® 2 0.2 µm				
MR3	5.4 m² | 58.2 ft²	Polyethersulfone	162 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR6	10.8 m² | 116.4 ft²	Polyethersulfone	324 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR9	16.2 m² | 174.6 ft²	Polyethersulfone	486 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
Sartopore® 2 XLG				
MR3	7.2 m² | 77.4ft²	Polyethersulfone	207 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR6	14.4 m² | 154.8 ft²	Polyethersulfone	414 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR9	21.6 m² | 232.2 ft²	Polyethersulfone	621 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
Sartopore® 2 XLI				
MR3	7.2 m² | 77.4ft²	Polyethersulfone	189 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR6	14.4 m² | 154.8 ft²	Polyethersulfone	378 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR9	21.6 m² | 232.2 ft²	Polyethersulfone	567 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
Sartopore® 2 XLM				
MR3	7.2 m² | 77.4ft²	Polyethersulfone	180 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR6	14.4 m² | 154.8 ft²	Polyethersulfone	360 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
MR9	21.6 m² | 232.2 ft²	Polyethersulfone	540 ml/min at 2.5 bar | 36 psi	Gamma Irradiated
Sartoguard PES 0.1 µm nom.				
MR3	7.2 m² | 77.4ft²	Polyethersulfone	225 ml/min at 1.5 bar | 22 psi	Gamma Irradiated
MR6	14.4 m² | 154.8 ft²	Polyethersulfone	450 ml/min at 1.5 bar | 22 psi	Gamma Irradiated
MR9	21.6 m² | 232.2 ft²	Polyethersulfone	675 ml/min at 1.5 bar | 22 psi	Gamma Irradiated
Sartoguard PES 0.2 µm nom.				
MR3	7.2 m² | 77.4ft²	Polyethersulfone	162 ml/min at 1.2 bar | 17.5 psi	Gamma Irradiated
MR6	14.4 m² | 154.8 ft²	Polyethersulfone	324 ml/min at 1.2 bar | 17.5 psi	Gamma Irradiated
MR9	21.6 m² | 232.2 ft²	Polyethersulfone	486 ml/min at 1.2 bar | 17.5 psi	Gamma Irradiated
Sartopure® GF Plus 0.65 & 1.2 µm nom.				
MR3	3.6 m² | 38.7 ft²	Glass Fiber		Sanitary or Non-Sterile
MR6	7.2 m² | 77.4 ft²	Glass Fiber		Sanitary or Non-Sterile
MR9	10.8 m² | 116.1 ft²	Glass Fiber		Sanitary or Non-Sterile

Filter Families	Filtration Area	Materials	Max. Diffusion	Delivery Condition
Sartopure® PP3 0.45 µm nom.				
MR3	3.6 m² | 38.7 ft²	Polypropylene		Sanitary or Non-Sterile
MR6	7.2 m² | 77.4 ft²	Polypropylene		Sanitary or Non-Sterile
MR9	10.8 m² | 116.1 ft²	Polypropylene		Sanitary or Non-Sterile
Sartopure® PP3 0.65, 1.2 & 3.0 µm nom.				
MR3	4.05 m² | 43.5 ft²	Polypropylene		Sanitary or Non-Sterile
MR6	8.1 m² | 87 ft²	Polypropylene		Sanitary or Non-Sterile
MR9	12.15 m² | 130.5 ft²	Polypropylene		Sanitary or Non-Sterile
Sartopure® PP3 5.0, 8.0, 20.0 & 50.0 µm nom.				
MR3	5.85 m² | 63 ft²	Polypropylene		Sanitary or Non-Sterile
MR6	11.7 m² | 126 ft²	Polypropylene		Sanitary or Non-Sterile
MR9	17.55 m² | 189 ft²	Polypropylene		Sanitary or Non-Sterile
Virosart® HF 20 nm nominal hollow fibre				
MR2	4.8 m² I 51.7 ft²	Polyethersulfone surface modified	≤ 41 ml/min at 2.5 bar I 36 psi	Gamma Irradiation
MR3	7.2 m² I 77.5 ft²	Polyethersulfone surface modified	≤ 60 ml/min at 2.5 bar I 36 psi	Gamma Irradiation
MR4	9.6 m² I 103.3 ft²	Polyethersulfone surface modified	≤ 79 ml/min at 2.5 bar I 36 psi	Gamma Irradiation
MR5	12 m² I 129.2 ft²	Polyethersulfone surface modified	≤ 99 ml/min at 2.5 bar I 36 psi	Gamma Irradiation
MR6	14.4 m² I 155 ft²	Polyethersulfone surface modified	≤ 117 ml/min at 2.5 bar I 36 psi	Gamma Irradiation
Virosart® Media 20 nm nominal hollow fibre				
MR3	3 m² I 32.3 ft²	Polyethersulfone surface modified	≤ 48 ml/min at 2.5 bar I 36 psi	Gamma Irradiation
MR6	6 m² I 64.6 ft²	Polyethersulfone surface modified	≤ 97 ml/min at 2.5 bar I 36 psi	Gamma Irradiation
Virosart® Max 0.1 µm				
MR3	6.3 m² I 68 ft²	Polyamide	≤ 16 ml/min at 2.0 bar I 29 psi	Sanitary or Non-Sterile
MR6	12.6 m² I 136 ft²	Polyamide	≤ 31 ml/min at 2.0 bar I 29 psi	Sanitary or Non-Sterile
MR9	18.9 m² I 203 ft²	Polyamide	≤ 46 ml/min at 2.0 bar I 29 psi	Sanitary or Non-Sterile

Max.Differential Pressure

2.5 bar | 36 psi at 20°C

Accessoires (Reusable – Need to Be Ordered Separately)

SU Valve Actuator*	Order Code: BPR0202
Pressure Safety Device	Order Code: 26787---PS

* 3 reusable actuators are needed for each Maxicaps® MR

Delivery Condition

Sterile, for gamma stable filter material
Sanitary, for non-gamma stable filter material
Non-Sterile, for non-gamma stable filter material

Materials

Filter Material
Refer to the technical reference of the respective filter.

Maxicaps® Housing and Distribution Manifold Pipes
Polypropylene (PP)

Inlet | Outlet Tubing
Silicone (reinforced)
Thermoplastic Elastomer (TPE)

Rack
Polypropylene (PP), Polyethylene (PE)

Mounting Parts
Screws, Washer, Threaded Rod: Stainless Steel
Gaskets: Silicone
Tri Clamp: Polyamide (PA)

Venting
Sartopore® Air with hydrophobic Polyethersulfone (PES)
Pure-Fit TCL Clamp: Polyvinylidenfluorid (PVDF)
Inspection Glass: Polyethylenterephthalat (PET)

Technical References

For further information regarding pre-, sterile- & virus filters please click here.

For further information on Maxicaps® MR & Virosart® Validation Guides, please see references below:

Maxicaps® MR

Validation Guide Maxicaps® MR	2646224

Virosart® HF

Datasheet	SPK2180-e
Validation Guide	SPK5801-e

Virosart® Media

Datasheet	DIR 2650737
Validation Guide	SPK5812-e

Virosart® Max

Datasheet	DIR 2650739
Validation Guide	DIR 2650008

Regulatory Compliance

- Each individual Maxicaps® element is tested for integrity (membrane filters only).
- Fully validated as sterilizing grade filters according to current ASTM F838 guideline for Sartopore® filter family.
- Designed, developed and manufactured in accordance with ISO 9001 certified Quality Management System.
- Non pyrogenic according to USP Bacterial Endotoxins.
- All assembled filters and tubing meet the requirements of the current USP Class VI Biological reactivity tests.
- Non-fiber releasing: This product is manufactured with membranes which meet the criteria for a “non-fiber releasing” filter as defined in 21 CFR 210.3 (b) (6) and 211.72.
- This product is conform to Pressure Equipment Directive 2014/68/EU.

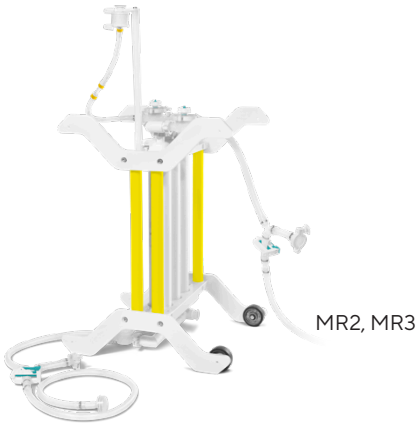
Ordering Information

Sartopore® Platinum

549	73	07H	3	G	-	.

Pore Size
07H: 0.45 µm + 0.2 µm

Number of Filter Elements per Device
MR3: 3 Filter Elements
MR6: 6 Filter Elements
MR9: 9 Filter Elements



MR2, MR3

Sartopore® 2

544	73	.	3	G	-	.

Pore Size
07H: 0.45 µm + 0.2 µm
07G: 0.8 µm + 0.2 µm (XLG)
07I: 0.35 µm + 0.2 µm (XLI)
58M: 0.2 µm + 0.1 µm (XLM)

Number of Filter Elements per Device
MR3: 3 Filter Elements
MR6: 6 Filter Elements
MR9: 9 Filter Elements

Sartoguard PES

547	73	.	3	G	-	.

Pore Size
07F: 0.2 µm nominally
58G: 0.1 µm nominally

Number of Filter Elements per Device
MR3: 3 Filter Elements
MR6: 6 Filter Elements
MR9: 9 Filter Elements

Sartopure® PP3

505	73	.	3	--	.

Retention Ratings
50P: 50 µm
20P: 20 µm
01P: 8 µm
42P: 5 µm
02P: 3 µm
03P: 1.2 µm
05P: 0.65 µm
06P: 0.45 µm

-- Non-Sterile
C- Sanitary

Number of Filter Elements per Device
MR3: 3 Filter Elements
MR6: 6 Filter Elements
MR9: 9 Filter Elements

MR6

Sartopure® GF Plus

555	73	.	3	--	.

Retention Ratings
03P: 1.2 µm
05P: 0.65 µm

-- Non-Sterile
C- Sanitary

Number of Filter Elements per Device
MR3: 3 Filter Elements
MR6: 6 Filter Elements
MR9: 9 Filter Elements

Virosart® HF

3VI--	28-	M	C	G-	MR2

Number of Filter Elements per Device
MR2: 2 Filter Elements
MR3: 3 Filter Elements
MR4: 4 Filter Elements
MR5: 5 Filter Elements
MR6: 6 Filter Elements

MR6

Virosart® Media

3V2--	28-	I	V	G-	MR3

Number of Filter Elements per Device
MR3: 3 Filter Elements
MR6: 6 Filter Elements

MR9

Virosart® Max

54A	73	58	N3	--	MR3

Number of Filter Elements per Device
MR3: 3 Filter Elements
MR6: 6 Filter Elements
MR9: 9 Filter Elements

-- Non-Sterile
C- Sanitary

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