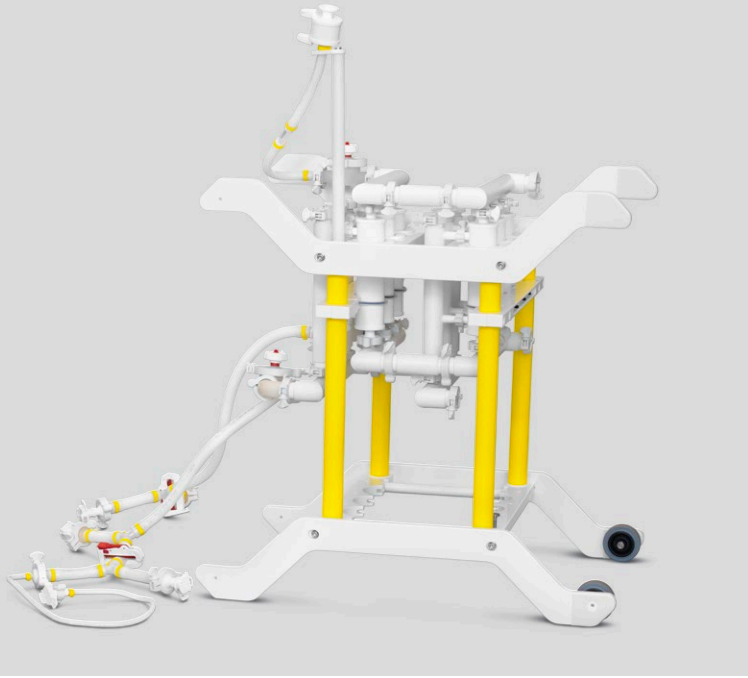
SARTORIUS

Product Datasheet

Maxicaps® MR for Virus Filtration

Unique Large Scale Single-Use Filter Device



Product Information

Maxicaps® MR Virosart® is a fully contained single-use assembly with up to 14.4 m^2 I 155 ft^2 filtration area, designed for large scale virus 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 choice for the lowest total cost of ownership in large-scale single-use processes.

Benefits

Ready-to-use	→	Pre-sterilized & pre-assembled
Certified quality	→	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

Introduction

Self-contained, single-use filter capsules have been systematically replacing stainless steel housings and filter cartridges as a highly economical and risk-adverse choice for thebiopharmaceutical industry. From individual capsules to complex customized assemblies, implementation of single-use filter systems reduces the time it takes for equipment setup and 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 used in 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 a significantly reduced number of connections, Maxicaps® MR minimizes the installation time and the risk of operating errors significantly.

Single-Use Applications

- Upstream virus filtration
- Downstream virus filtration
- Adsorptive virus pre-filtration

Features

- Filtration area of up to 18.9 m² | 203 ft²
- Complete device integrity testable as a single unit
- Pre- and final virus filters
- Flexible connections: Opta®, 1.5" Tri-Clamp, AseptiQuik®* or weldable tubing
- Single air filter for easy system venting

Application & Positioning

Upstream Virus Filtration with Virosart® Media
Virosart® Media is a dedicated virus-retentive filter optimized for chemically defined media. This can be operated either as in-line filtration (e.g. perfusion) or batch filtration. An efficient pre-filtration step, such as the Sartopore® 2 XLM, can further increase the capacity of the final virus filter.

Downstream Virus Filtration with Virosart® HF
Virosart® HF is used at the end of the purification process for virus retentive filtration of the biopharmaceutical product such as monoclonal antibodies (mAb), antibody fragments (Fab), and small recombinant proteins (< 150 kDa).

Adsorptive Pre-Filtration with Virosart® Max
The use of the pre-filter, Virosart® Max, provides efficient protection of the virus-retentive membrane with significant increase in robustness and capacity of the final virus filter. Virosart® Max protects your virus filter irrespective of the process conditions, downsizes your process, and reduces your total virus filtration costs.

Delivery Conditions

Sterile
- Applicable for all gamma stable filter materials
- Assembled in a classified clean room
- Complete device gamma irradiated in a validated sterilization process

Sanitary
- Applicable for non-gamma stable filter materials
- All fluid contact materials are sterilized in validated sterilization process
- Assembled in a classified clean room following specific hygienic measures and rules of conduct

Validation

Maxicaps® MR have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests are combined with extensive extractable testing. A sterilization validation in order to obtain a 10^6 Sterility Assurance Level (SAL) 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.

Services

Sartorius Confidence® Validation and Virus Clearance Services are the perfect complement to Maxicaps® MR.

Our services provide
- Extractables and leachables services
- Microbiological testing
- Physicochemical testing
- Virus spiking studies

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

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

Technical Specifications

Maxicaps® MR Configuration	Filtration Area	Material	Alarm Values	Delivery Condition
Virosart® HF Pore Size: 20 nm nominal				
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 Pore Size: 20 nm nominal				
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

Max. operating pressure 2.5 bar | 36 psi at 20°C

Maxicaps® MR Configuration	Filtration Area	Material	Max. Diffusion	Delivery Condition
Virosart® Max Pore Size: 0.1 µm				
MR2	4.2 m²	45.2 ft²	Polyamide	48 mL/min at 2 bar	29 psi	Sanitary
MR3	6.3 m² I 67.8 ft²	Polyamide	72 mL/min at 2 bar	29 psi	Sanitary
MR4	8.4 m²	90.4 ft²	Polyamide	96 mL/min at 2 bar	29 psi	Sanitary
MR5	10.5 m²	113 ft²	Polyamide	120 mL/min at 2 bar	29 psi	Sanitary
MR6	12.6 m² I 135.6 ft²	Polyamide	144 mL/min at 2 bar	29 psi	Sanitary
MR7	14.7 m²	158.2 ft²	Polyamide	168 mL/min at 2 bar	29 psi	Sanitary
MR8	16.8 m²	180.8 ft²	Polyamide	192 mL/min at 2 bar	29 psi	Sanitary
MR9	18.9 m² I 203.4 ft²	Polyamide	216 mL/min at 2 bar	29 psi	Sanitary

For further technical specifications on the Maxicaps® MR Virosart® Max, please see datasheet Maxicap® MR. DIR: 3175410 or contact your sales representative.

Regulatory Compliance

- Each individual Maxicaps® filter element is tested for integrity.
- 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.

Accessories for Maxicaps® MR Virosart® HF & Virosart® Media

Accessoires (Reusable – Need to Be Ordered Separately)

Item	Order No.
SU Valve Actuator*	BPR0202
Pressure Safety Device	26787- - -PS

* 3 reusable actuators are needed for each Maxicaps® MR

Materials

Filter Material
Polyethersulfone (PES)

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)

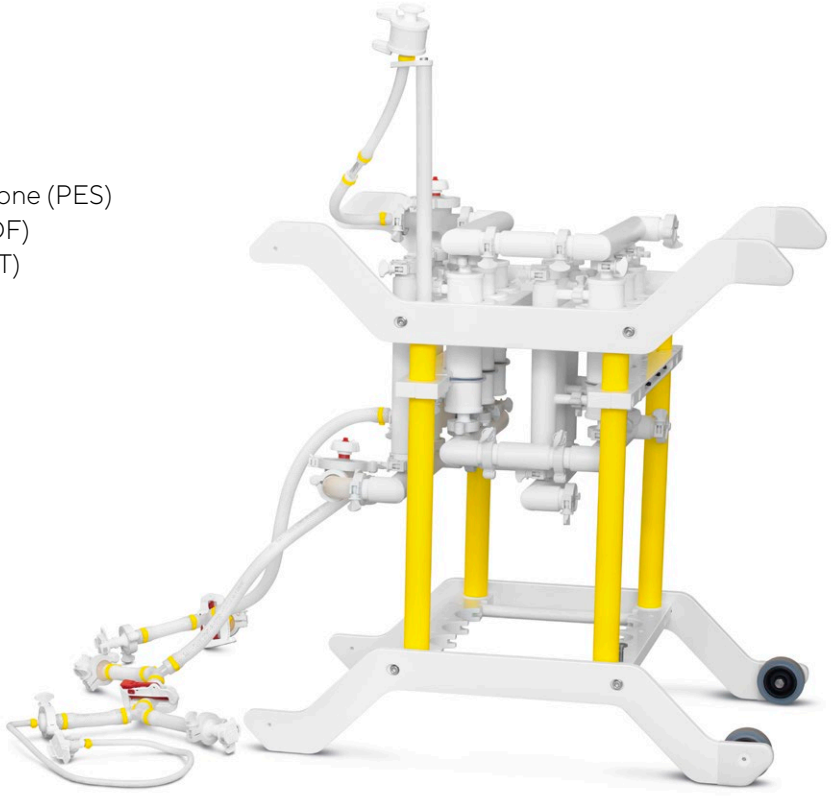
Technical References

For further information on Maxicaps® MR and Virosart® virus filters please see references below:

Maxicaps® MR Virosart® HF and Virosart® Media
Validation Guide Maxicaps® MR 2646224

Virosart® HF
Datasheet 2650723
Validation Guide 2841203

Virosart® Media
Datasheet 2650737
Validation Guide 2827073



Accessories for Maxicaps® MR Virosart® Max

Item	Order No.	Comment
Trolley Maxicaps® MR	FIA500010	
Lifting handles Maxicaps® MR	FIA500011	Package incl. 2 handles
Lifting gear Maxicaps® MR	FIA500012	Peripheral for Biostat STR® Lifting Device
Manual valve actuator Maxicaps®	FIA500013	Package incl. 1 piece–3 pieces required
Pressure safety device	26787---PS	Required for filter integrity test

Technical References

For further information on Maxicaps® MR & Virosart® virus filters please see references below:

Maxicaps® MR Virosart® Max

Validation Guide Maxicaps® MR	3151774
Datasheet Maxicaps® MR	3175410

Virosart® Max

Datasheet	2650739
Validation Guide	2650008

Ordering Information

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

Virosart® Media

3V2--	28-	I	V	G-	MR3

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

Virosart® Max

Number of Filter Elements per Device	Order No.
2	FMR500048
3	FMR500042
4	FMR500049
5	FMR500050
6	FMR500043
7	FMR500051
8	FMR500052
9	FMR500044

Maxicaps® MR6 Virosart® HF

Maxicaps® MR9 Virosart® Max

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DIR: 3176213-000-01
Status: 08 | 2023