

Maxicaps® MR for Virus Filtration

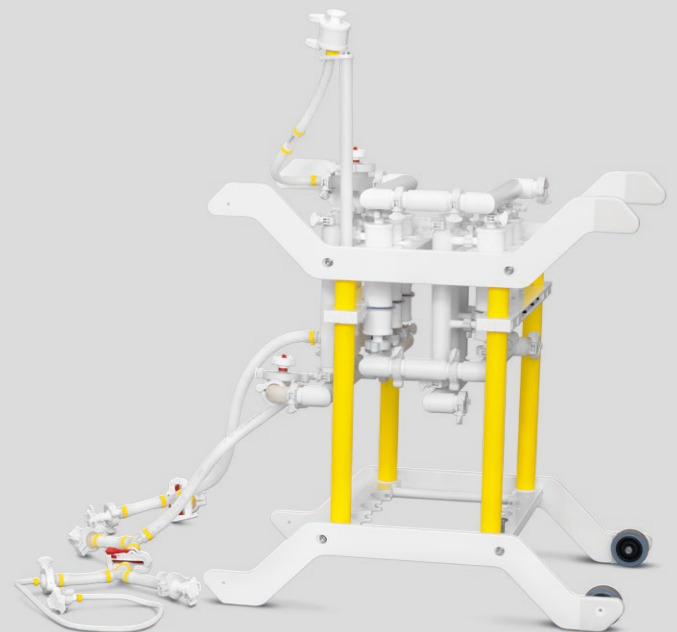
Unique Large Scale Single-Use Filter Device

Product Information

Maxicaps® MR Virosart® is a fully contained single-use assembly with up to 14.4 m² | 155 ft² 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 offers the most cost-effective solution for large-scale single-use processes, ensuring the lowest total cost of ownership.

Benefits

- **Ready-to-use:** Pre-sterilized and pre-assembled
- **Certified quality:** Sterile and sanitary delivery option
- **Risk mitigation:** 90% less tubings and 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 the biopharmaceutical 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.

Traditional multi-round filter housings have transformed into single-use Maxicaps® MR systems to address modern advanced requirements. Before Maxicaps® MR, there was no single-use alternative to the large-scale, multi-round filter configurations typically employed 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 cell culture media. This can be operated either as in-line filtration (e.g. perfusion) or batch filtration. An efficient pre-filtration step, for example with Sartopore® 2XLM, 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**

Utilizing Virosart® Max ensures the protection of the final virus filter in all process conditions. It enhances process efficiency by increasing the robustness and capacity of the virus filter, ultimately lowering overall virus filtration costs.

Delivery Conditions

Sterile

- Applicable for all gamma stable filter materials (Virosart® HF, Virosart® Media)
- Assembled in a classified clean room
- Complete device gamma irradiated in a validated sterilization process

Sanitary

- Applicable for non-gamma stable filter materials (Virosart® Max)
- 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 10⁶ 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
- GLP virus clearance 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.

Technical Specifications

Maxicaps® MR Configuration	Filtration Area	Material	Alarm Values	Delivery Condition
Virosart® HF Pore Size: 20 nm nominal				
MR2	4.8 m ² 51.7 ft ²	Polyethersulfone surface modified	≤ 41 mL/min at 2.5 bar 36 psi	Gamma Irradiation
MR3	7.2 m ² 77.5 ft ²	Polyethersulfone surface modified	≤ 60 mL/min at 2.5 bar 36 psi	Gamma Irradiation
MR4	9.6 m ² 103.3 ft ²	Polyethersulfone surface modified	≤ 79 mL/min at 2.5 bar 36 psi	Gamma Irradiation
MR5	12 m ² 129.2 ft ²	Polyethersulfone surface modified	≤ 99 mL/min at 2.5 bar 36 psi	Gamma Irradiation
MR6	14.4 m ² 155 ft ²	Polyethersulfone surface modified	≤ 117 mL/min at 2.5 bar 36 psi	Gamma Irradiation

Virosart® Media
Pore Size: 20 nm nominal

MR3	3 m ² 32.3 ft ²	Polyethersulfone surface modified	≤ 48 mL/min at 2.5 bar 36 psi	Gamma Irradiation
MR6	6 m ² 64.6 ft ²	Polyethersulfone surface modified	≤ 97 mL/min at 2.5 bar 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 m ² 45.2 ft ²	Polyamide	48 mL/min at 2 bar 29 psi	Sanitary
MR3	6.3 m ² 67.8 ft ²	Polyamide	72 mL/min at 2 bar 29 psi	Sanitary
MR4	8.4 m ² 90.4 ft ²	Polyamide	96 mL/min at 2 bar 29 psi	Sanitary
MR5	10.5 m ² 113 ft ²	Polyamide	120 mL/min at 2 bar 29 psi	Sanitary
MR6	12.6 m ² 135.6 ft ²	Polyamide	144 mL/min at 2 bar 29 psi	Sanitary
MR7	14.7 m ² 158.2 ft ²	Polyamide	168 mL/min at 2 bar 29 psi	Sanitary
MR8	16.8 m ² 180.8 ft ²	Polyamide	192 mL/min at 2 bar 29 psi	Sanitary
MR9	18.9 m ² 203.4 ft ²	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.

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

** The patented technology (DE 10 2011 105 525 B4) binds aggregates efficiently through hydrophobic interactions with polyamide, independently of process conditions such as conductivity from biological feed streams (mAbs, plasma derivatives or recombinant proteins).

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)

*** Please Note: Maxicaps® MR Virosart® HF and Media are delivered with a new optimized venting line, including a translucent empty filter housing, similar as you can see on page 5 Maxicaps® MR Virosart® Max, since February 2024.

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



Maxicaps® MR6 Virosart® HF

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

For further configuration options of Maxicaps® MR Virosart® Max or quotation, please contact your Sartorius Sales Representative or Application Specialist.



Maxicaps® MR9 Virosart® Max

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Specifications subject to change without notice.

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