

# Maxicaps<sup>®</sup> MR

## Unique Large Scale Single-Use Filter Device



### Product Information

Maxicaps<sup>®</sup> MR is a fully contained single-use assembly with up to 27 m<sup>2</sup> filtration area, designed for large scale filtration in biopharmaceutical applications. The compact and ready-to-use Maxicaps<sup>®</sup> MR comes pre-sterilized and pre-assembled with 90% less tubing and connectors compared to standard multi-capsule assemblies. Maxicaps<sup>®</sup> 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

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 significantly.

## 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 downstream
- Adsorptive virus pre-filtration

## Features

- Filtration area of up to 27 m<sup>2</sup>
- 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

## 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<sup>-6</sup> 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.

## Services

Sartorius Confidence® Validation Services is the perfect complement to Maxicaps® MR.

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 cost-effective solution and give you the confidence you need to succeed.

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

# Technical Specifications

Filter Families	Filtration Area	Materials	Max. Diffusion	Delivery Condition
<b>Sartopore® Platinum</b>				
MR3	9 m <sup>2</sup>   96.9 ft <sup>2</sup>	Polyethersulfone, surface modified	225 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR6	18 m <sup>2</sup>   193.8 ft <sup>2</sup>	Polyethersulfone, surface modified	450 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR9	27 m <sup>2</sup>   290.7 ft <sup>2</sup>	Polyethersulfone, surface modified	675 ml/min at 2.5 bar   36 psi	Gamma Irradiated
<b>Sartopore® 2 0.2 µm</b>				
MR3	5.4 m <sup>2</sup>   58.2 ft <sup>2</sup>	Polyethersulfone	162 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR6	10.8 m <sup>2</sup>   116.4 ft <sup>2</sup>	Polyethersulfone	324 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR9	16.2 m <sup>2</sup>   174.6 ft <sup>2</sup>	Polyethersulfone	486 ml/min at 2.5 bar   36 psi	Gamma Irradiated
<b>Sartopore® 2 0.45µm</b>				
MR3	5.4 m <sup>2</sup>   58.2 ft <sup>2</sup>	Polyethersulfone	108 ml/min at 1.7 bar   25 psi	Gamma Irradiated
MR6	10.8 m <sup>2</sup>   116.4 ft <sup>2</sup>	Polyethersulfone	216 ml/min at 1.7 bar   25 psi	Gamma Irradiated
MR9	16.2 m <sup>2</sup>   174.6 ft <sup>2</sup>	Polyethersulfone	324 ml/min at 1.7 bar   25 psi	Gamma Irradiated
<b>Sartopore® 2 XLG</b>				
MR3	7.2 m <sup>2</sup>   77.4 ft <sup>2</sup>	Polyethersulfone	207 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR6	14.4 m <sup>2</sup>   154.8 ft <sup>2</sup>	Polyethersulfone	414 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR9	21.6 m <sup>2</sup>   232.2 ft <sup>2</sup>	Polyethersulfone	621 ml/min at 2.5 bar   36 psi	Gamma Irradiated
<b>Sartopore® 2 XLI</b>				
MR3	7.2 m <sup>2</sup>   77.4 ft <sup>2</sup>	Polyethersulfone	189 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR6	14.4 m <sup>2</sup>   154.8 ft <sup>2</sup>	Polyethersulfone	378 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR9	21.6 m <sup>2</sup>   232.2 ft <sup>2</sup>	Polyethersulfone	567 ml/min at 2.5 bar   36 psi	Gamma Irradiated
<b>Sartopore® 2 XLM</b>				
MR3	7.2 m <sup>2</sup>   77.4 ft <sup>2</sup>	Polyethersulfone	180 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR6	14.4 m <sup>2</sup>   154.8 ft <sup>2</sup>	Polyethersulfone	360 ml/min at 2.5 bar   36 psi	Gamma Irradiated
MR9	21.6 m <sup>2</sup>   232.2 ft <sup>2</sup>	Polyethersulfone	540 ml/min at 2.5 bar   36 psi	Gamma Irradiated

Filter Families	Filtration Area	Materials	Max. Diffusion	Delivery Condition
<b>Sartoguard PES 0.1 µm nom.</b>				
MR3	7.2 m <sup>2</sup>   77.4 ft <sup>2</sup>	Polyethersulfone	225 ml/min at 1.5 bar   22 psi	Gamma Irradiated
MR6	14.4 m <sup>2</sup>   154.8 ft <sup>2</sup>	Polyethersulfone	450 ml/min at 1.5 bar   22 psi	Gamma Irradiated
MR9	21.6 m <sup>2</sup>   232.2 ft <sup>2</sup>	Polyethersulfone	675 ml/min at 1.5 bar   22 psi	Gamma Irradiated
<b>Sartoguard PES 0.2 µm nom.</b>				
MR3	7.2 m <sup>2</sup>   77.4 ft <sup>2</sup>	Polyethersulfone	162 ml/min at 1.2 bar   17.5 psi	Gamma Irradiated
MR6	14.4 m <sup>2</sup>   154.8 ft <sup>2</sup>	Polyethersulfone	324 ml/min at 1.2 bar   17.5 psi	Gamma Irradiated
MR9	21.6 m <sup>2</sup>   232.2 ft <sup>2</sup>	Polyethersulfone	486 ml/min at 1.2 bar   17.5 psi	Gamma Irradiated
<b>Sartopure® GF Plus 0.65 &amp; 1.2 µm nom.</b>				
MR3	3.6 m <sup>2</sup>   38.7 ft <sup>2</sup>	Glass Fiber		Sanitary or Non-Sterile
MR6	7.2 m <sup>2</sup>   77.4 ft <sup>2</sup>	Glass Fiber		Sanitary or Non-Sterile
MR9	10.8 m <sup>2</sup>   116.1 ft <sup>2</sup>	Glass Fiber		Sanitary or Non-Sterile
<b>Sartopure® PP3 0.45 µm nom.</b>				
MR3	3.6 m <sup>2</sup>   38.7 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
MR6	7.2 m <sup>2</sup>   77.4 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
MR9	10.8 m <sup>2</sup>   116.1 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
<b>Sartopure® PP3 0.65, 1.2 &amp; 3 µm nom.</b>				
MR3	4.05 m <sup>2</sup>   43.5 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
MR6	8.1 m <sup>2</sup>   87 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
MR9	12.15 m <sup>2</sup>   130.5 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
<b>Sartopure® PP3 5, 8, 20 &amp; 50 µm nom.</b>				
MR3	5.85 m <sup>2</sup>   63 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
MR6	11.7 m <sup>2</sup>   126 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile
MR9	17.55 m <sup>2</sup>   189 ft <sup>2</sup>	Polypropylene		Sanitary or Non-Sterile

Filter Families	Filtration Area	Materials	Max. Diffusion	Delivery Condition
<b>Virosart® HF 20 nm nominal hollow fibre</b>				
MR2	4.8 m <sup>2</sup>   51.7 ft <sup>2</sup>	Polyethersulfone surface modified	≤ 41 ml/min at 2.5 bar   36 psi	Gamma Irradiation
MR3	7.2 m <sup>2</sup>   77.5 ft <sup>2</sup>	Polyethersulfone surface modified	≤ 60 ml/min at 2.5 bar   36 psi	Gamma Irradiation
MR4	9.6 m <sup>2</sup>   103.3 ft <sup>2</sup>	Polyethersulfone surface modified	≤ 79 ml/min at 2.5 bar   36 psi	Gamma Irradiation
MR5	12 m <sup>2</sup>   129.2 ft <sup>2</sup>	Polyethersulfone surface modified	≤ 99 ml/min at 2.5 bar   36 psi	Gamma Irradiation
MR6	14.4 m <sup>2</sup>   155 ft <sup>2</sup>	Polyethersulfone surface modified	≤ 117 ml/min at 2.5 bar   36 psi	Gamma Irradiation
<b>Virosart® Media 20 nm nominal hollow fibre</b>				
MR3	3 m <sup>2</sup>   32.3 ft <sup>2</sup>	Polyethersulfone surface modified	≤ 48 ml/min at 2.5 bar   36 psi	Gamma Irradiation
MR6	6 m <sup>2</sup>   64.6 ft <sup>2</sup>	Polyethersulfone surface modified	≤ 97 ml/min at 2.5 bar   36 psi	Gamma Irradiation
<b>Virosart® Max 0.1 µm</b>				
MR3	6.3 m <sup>2</sup>   68 ft <sup>2</sup>	Polyamide	≤ 16 ml/min at 2.0 bar   29 psi	Sanitary or Non-Sterile
MR6	12.6 m <sup>2</sup>   136 ft <sup>2</sup>	Polyamide	≤ 31 ml/min at 2.0 bar   29 psi	Sanitary or Non-Sterile
MR9	18.9 m <sup>2</sup>   203 ft <sup>2</sup>	Polyamide	≤ 46 ml/min at 2.0 bar   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

## T-Style Maxicaps®

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

## Sartopore® 2

544 73 ■ 3 G - ■

**Pore Size**  
06G: 0.8 µm + 0.45 µm  
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

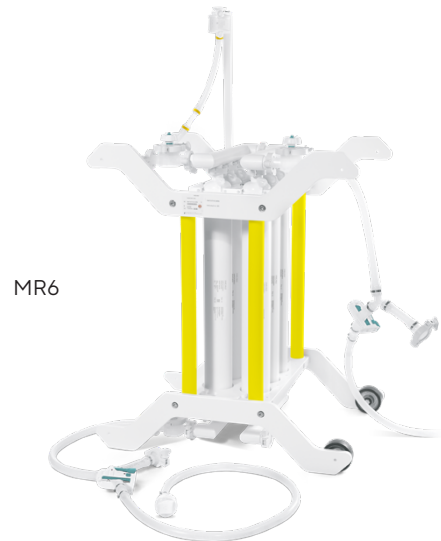
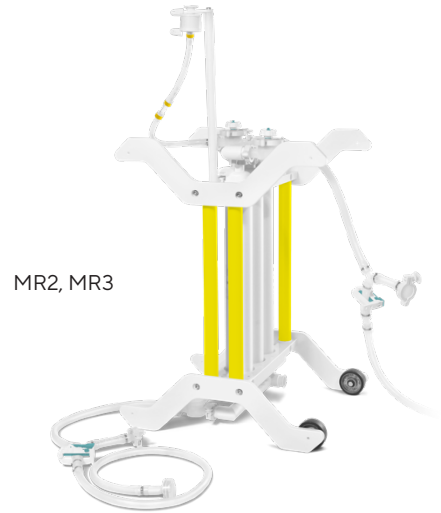
## Sartopure® GF Plus

555 73 ■ 3 -- ■

**Pore Size**  
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



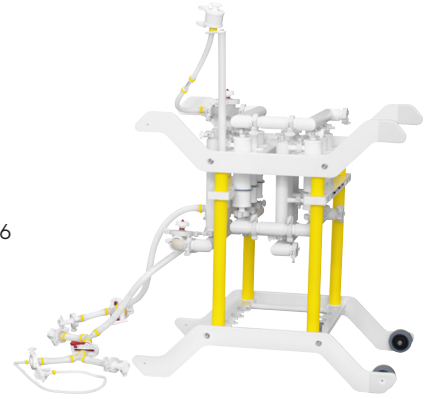
## Virosart® HF

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

-- Non-Sterile  
C- Sanitary

### Number of Filter Elements per Device

MR3: 3 Filter Elements  
MR6: 6 Filter Elements  
MR9: 9 Filter Elements

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