

Virosart® Max

Maximize your virus filter performance with adsorptive pre-filtration



Product Information

Virosart® Max* is a specially optimized virus pre-filter designed to significantly enhance the performance of downstream virus filters. It combines a size exclusion mechanism with efficient adsorptive capacities to boost the robustness of subsequent virus filters. Consequently, Virosart® Max provides exceptional protection for your final virus retentive membrane, greatly increasing its robustness and capacity.

Description

Choose your perfect fit from the Sartorius virus clearance strategy summarizing orthogonal technologies, manufacturing solutions, validation support and consultancy.

The orthogonal technologies from Sartorius consist of virus inactivation as well as virus removal by chromatography and virus filtration. The Virosart® product range includes four

different virus retentive membranes, in order to provide the best solution for every application. The performance of the final virus filter mainly depends on the feed stream properties. Therefore, appropriate feed stream conditioning i.e. through efficient pre-filtration is a major aspect within the development of a virus filtration step.

Application & Positioning

The main application for Virosart® Max is the protection of the final virus retentive membrane. For that purpose this filter is used at the end of the purification process in-line with the final virus filtration step of the biopharmaceutical product.

The optimized pre-filter to final-filter ratio should be determined during development of the virus filtration step.

Product Benefits

Virosart® Max provides efficient protection of the virus retentive membrane with significant increase in robustness and capacity of the final virus filter. The most challenging molecules for the final virus retentive membrane are aggregates and | or small hydrophobic molecules. Virosart® Max binds aggregates very efficiently through hydrophobic interactions, independently of process conditions such as conductivity. The clean triple layer membrane material provides exceptional adsorptive capacities optimized for this process step.

With the T-Style design the Virosart® Max Maxicaps® is ideal for easy installation of multiple filters in series or parallel.

Integrity Testing

Virosart® Max filters are tested for integrity using a water-based integrity test with the Sartocheck® technology of Sartorius Stedim Biotech.

* 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).

Technical Data



| | Minisart® & Sartolab® | Capsule & Micapacs® | T-Style Maxicaps® & Cartridge |
|---|---|---|---|
| Nominal filtration area | 5 & 21 cm ² | 220 cm ² 0.24 ft ² 0.21 m ² 2.3 ft ² | 0.7 m ² , 1.4 m ² , 2.1 m ² 7.5 ft ² , 15 ft ² , 22.6 ft ² |
| To be used for | <ul style="list-style-type: none"> Scale-down work Filtration work for capacity studies Optimizing the pre-filter final-filter-ratio of the final virus filtration step | <ul style="list-style-type: none"> Scale-up studies | <ul style="list-style-type: none"> Large scale manufacturing |
| Typical filtration volume | < 200 mL | < 80 L | > 80 L |
| Delivery status | Non-sterile | Sterile (autoclaved) | <ul style="list-style-type: none"> Maxicaps[®]: Sterile (autoclaved) Cartridges: Non-sterile |
| Available connectors | <ul style="list-style-type: none"> Female luer lock inlet & male luer lock outlet | <ul style="list-style-type: none"> Micapacs[®] & Capsule: ¾" triclamp (sanitary) connector inlet & outlet | <ul style="list-style-type: none"> Maxicaps[®]: Sanitary inlet & outlet adapter Cartridges: S-adapter top, 2 flange bayonet adapter with double o-ring bottom |
| Sterilization | <ul style="list-style-type: none"> Autoclaving: 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles <p>⚠ No inline steaming of Minisart[®]</p> | <ul style="list-style-type: none"> Autoclaving: 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles <p>⚠ No inline steaming of Capsule & Micapacs[®]</p> | <ul style="list-style-type: none"> Maxicaps[®] Cartridges: Autoclaving 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles <p>⚠ No inline steaming of Maxicaps[®]</p> <ul style="list-style-type: none"> Cartridges: Steaming 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles |
| Operating parameters | <ul style="list-style-type: none"> In the direction of filtration: max. 5.0 bar 72.5 psi at 20°C; max. 0.5 bar 7.3 psi at 121°C In the reversed direction of filtration: max. 0.5 bar 7.3 psi at 20°C | | |
| Water based diffusion test at 2.0 bar 29 psi | N/A | <ul style="list-style-type: none"> 1 mL/min (220 cm²) 3 mL/min (0.21 m²) | <ul style="list-style-type: none"> 8 mL/min (0.7 m²) 16 mL/min (1.4 m²) 24 mL/min (2.1 m²) |

Note: Micapacs[®] and T-Style Maxicaps[®] are additionally also available as filter transfer sets. Configurable filter assemblies are composed of filter capsules connected with tubing and connectors, allowing for immediate integration with both single-use and stainless-steel systems.

Materials

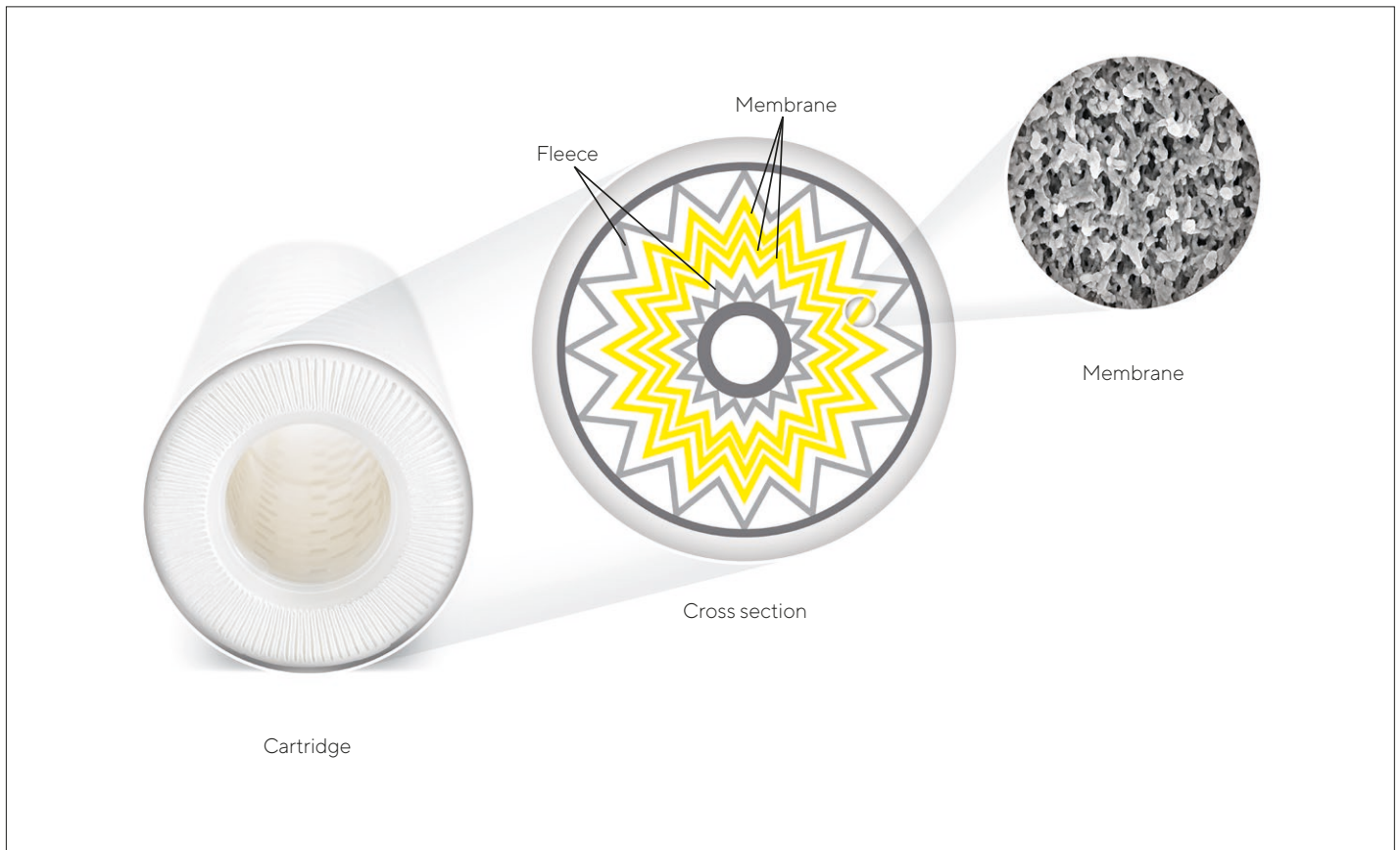
Device

| Cartridge, T-Style Maxicaps®, Midicaps® & Capsule | |
|---|---------------|
| Supportive Fleece | Polypropylene |
| Core (not capsule) | Polypropylene |
| End Caps | Polypropylene |
| Capsule Housing | Polypropylene |

| Minisart® | |
|-----------|---------------|
| Housing | Polypropylene |

| Sartolab | |
|----------|---------------|
| Housing | Polycarbonate |

| Membrane | |
|-----------|---------------------|
| Material | Optimized polyamide |
| Pore size | 0.1 µm (nominal) |
| Format | Triple layer |



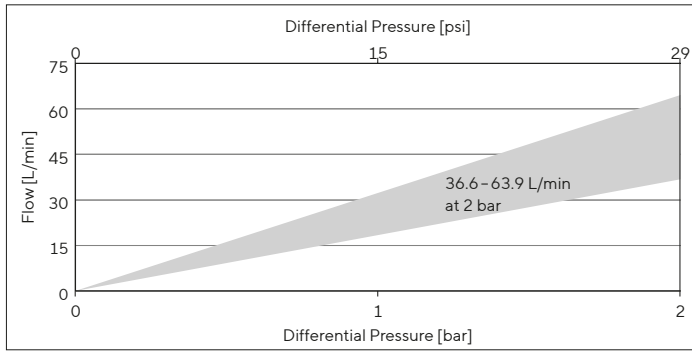
Construction of Virosart® Max cartridge and capsule with zoom on cross section and membrane.

Performance

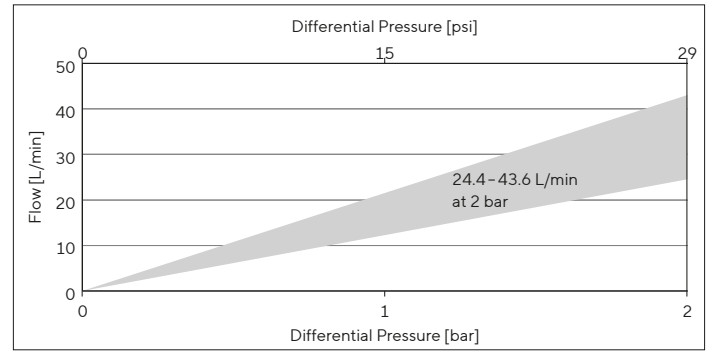
Characteristic Water Flow Rates

The flow rate achieved through the Virosart® Max, in-line with the final virus filter, is determined by the flow rate of the final virus filter.

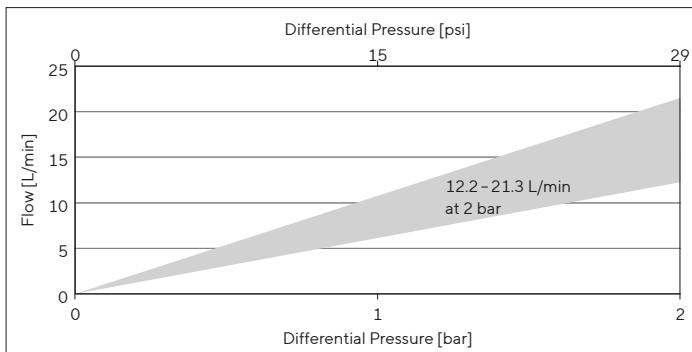
Virosart® Max 30" Cartridges & 30" T-Style Maxicaps®
(2.1 m² | 22.6 ft²)



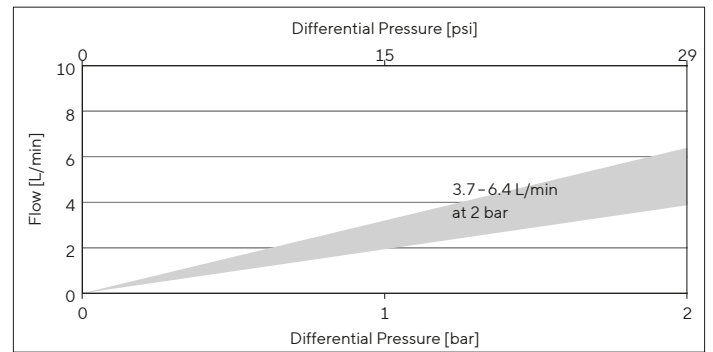
Virosart® Max 20" Cartridges & 20" T-Style Maxicaps®
(1.4 m² | 15 ft²)



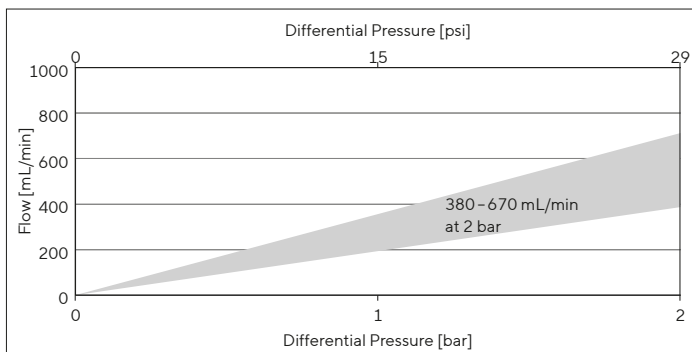
Virosart® Max 10" Cartridges & 10" T-Style Maxicaps®
(0.7 m² | 7.5 ft²)



Virosart® Max Midicaps®
(0.21 m² | 2.3 ft²)



Virosart® Max Capsules
(220 cm² | 0.24 ft²)



Regulatory Compliance

- Each individual filter is tested for integrity (except 54AMI-----B and 54ASA-----V)
- 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 Test VI

Technical References

| | |
|--------------------|-------------|
| Validation Guide | 2650008-000 |
| Extractables Guide | 2654263-000 |

Ordering Information



Cartridge

54A 25 58 ■

Adapter
25: S-adapter top,
1 flange bayonet
adapter with double
O-ring bottom

Filter size
N1: 10" 0.7 m² | 7.5 ft²
N2: 20" 1.4 m² | 15 ft²
N3: 30" 2.1 m² | 22.6 ft²



T-Style Maxicaps®

54A 83 58 ■ -- SS

Filter size
N1: 10" 0.7 m² | 7.5 ft²
N2: 20" 1.4 m² | 15 ft²
N3: 30" 2.1 m² | 22.6 ft²

Adapter
SS: 1 ½" Tri-Clamp (sanitary)
inlet & outlet adapter



Midicaps® & Capsules

54A ■ 58 ■ -- FF -- ■

13: Capsules
53: Midicaps®

Filter size
N4: 220 cm² | 0.24 ft²
N9: 0.21 m² | 2.3 ft²

Connector
FF: ¾" Tri-Clamp (sanitary)
inlet & outlet adapter

Units per package
B: Five pieces
V: Two pieces



Minisart®

54A ■ -- -- -- -- -- ■

Filter size
M1: Minisart®
SA: Sartolab

Units per package
B: Five pieces
V: Two pieces

Accessories & Services

Virus Filtration

Virosart® HF is a high speed virus filter for mAbs and recombinant proteins. The filter combines exceptional virus retention with superior capacities.



Integrity Testing using Sartocheck®

Fully automated Virosart® integrity testing to guarantee intactness of the Virosart® filter applying pre- and post-use diffusion tests.



Ready-to-use Filter Transfer Sets

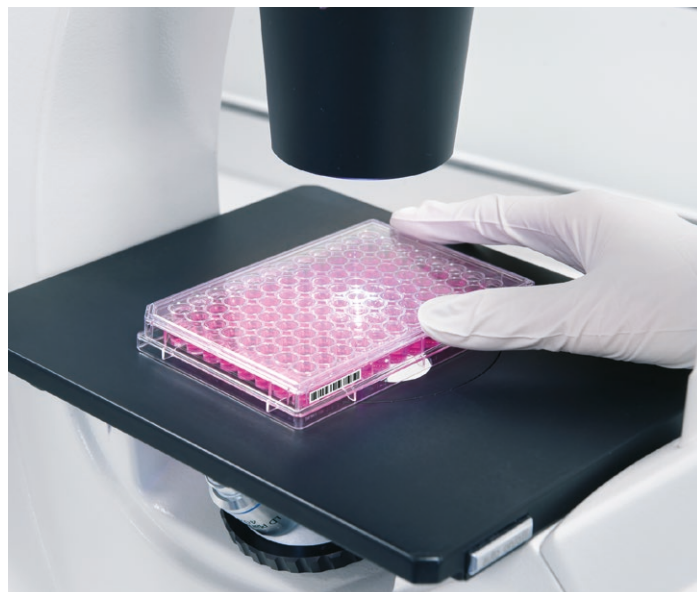
Simplify your daily routine work by using modular filter assembly.

Single-use Systems

Flexible processing with FlexAct® VR system for production from pilot plants up to commercial processing.

Customized Systems

High level of automation and individual requirements can be realized by customized single-use or hybrid solutions.



Sartorius Confidence® Virus Clearance Services

Our virus clearance service is the perfect complement to Virosart® Max filters, providing:

- GLP virus clearance studies
- Process feasibility studies
- Regulatory guidance

We use a variety of different relevant and model viruses including MVM, MuLV, Reo-3 and PRV. The combination of product and services provides you with a comprehensive virus clearance solution that gives you the confidence you need to proceed.

Sartorius Biologics Testing Services

Your partner to assure an effective virus clearance strategy for your process by MCB | WCB characterization, bulk harvest testing and lot release testing.

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