SARTORIUS

Product Datasheet

Virosart® Max*

Maximize your virus filter performance with adsorptive pre-filtration

Product Information

Virosart® Max is a specifically optimized virus pre-filter significantly increasing downstream virus filter performance. This filter combines size exclusion mechanism with efficient adsorptive capacities to increase the robustness of the following virus filter. As a result, Virosart® Max ensures the highest protection of your final virus retentive membrane, significantly 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 highest 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 highest 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 & Midicaps®	T-Style Maxicaps® & Cartridge
Nominal filtration area	5 & 21 cm^2	220 cm^2 0.21 m^2 0.24 ft^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	▪ Scale-down work ▪ Filtration work for capacity studies ▪ Optimizing the pre-filter final-filter-ratio of the final virus filtration step	▪ Scale-up studies	▪ Large scale manufacturing
Typical filtration volume	< 200 mL	< 80 L	> 80 L
Available connectors	▪ Female luer lock inlet & male luer lock outlet	▪ **Midicaps® & Capsule:** ¾" triclamp (sanitary) connector inlet & outlet	▪ **Maxicaps®:** Sanitary inlet & outlet adapter ▪ Cartridges: S-adapter top, 2 flange bayonet adapter with double o-ring bottom
Sterilization	▪ Autoclaving: 121°C @ 2.0 bar | 29 psi for 30 min up to 2 cycles ⚠ No inline steaming of Minisart®	▪ Autoclaving: 121°C @ 2.0 bar | 29 psi for 30 min up to 2 cycles ⚠ No inline steaming of Capsule & Midicaps®	▪ **Maxicaps®:** Autoclaving 121°C @ 2.0 bar | 29 psi for 30 min up to 2 cycles ⚠ No inline steaming of Maxicaps® ▪ **Cartridges:** Steaming 121°C @ 2.0 bar | 29 psi for 30 min up to 2 cycles
Operating parameters	▪ 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	▪ 2 mL/min (220 cm^2) ▪ 10 mL/min (0.27 m^2)	▪ 8 mL/min (0.7 m^2) ▪ 16 mL/min (1.4 m^2) ▪ 24 mL/min (2.1 m^2)

Materials

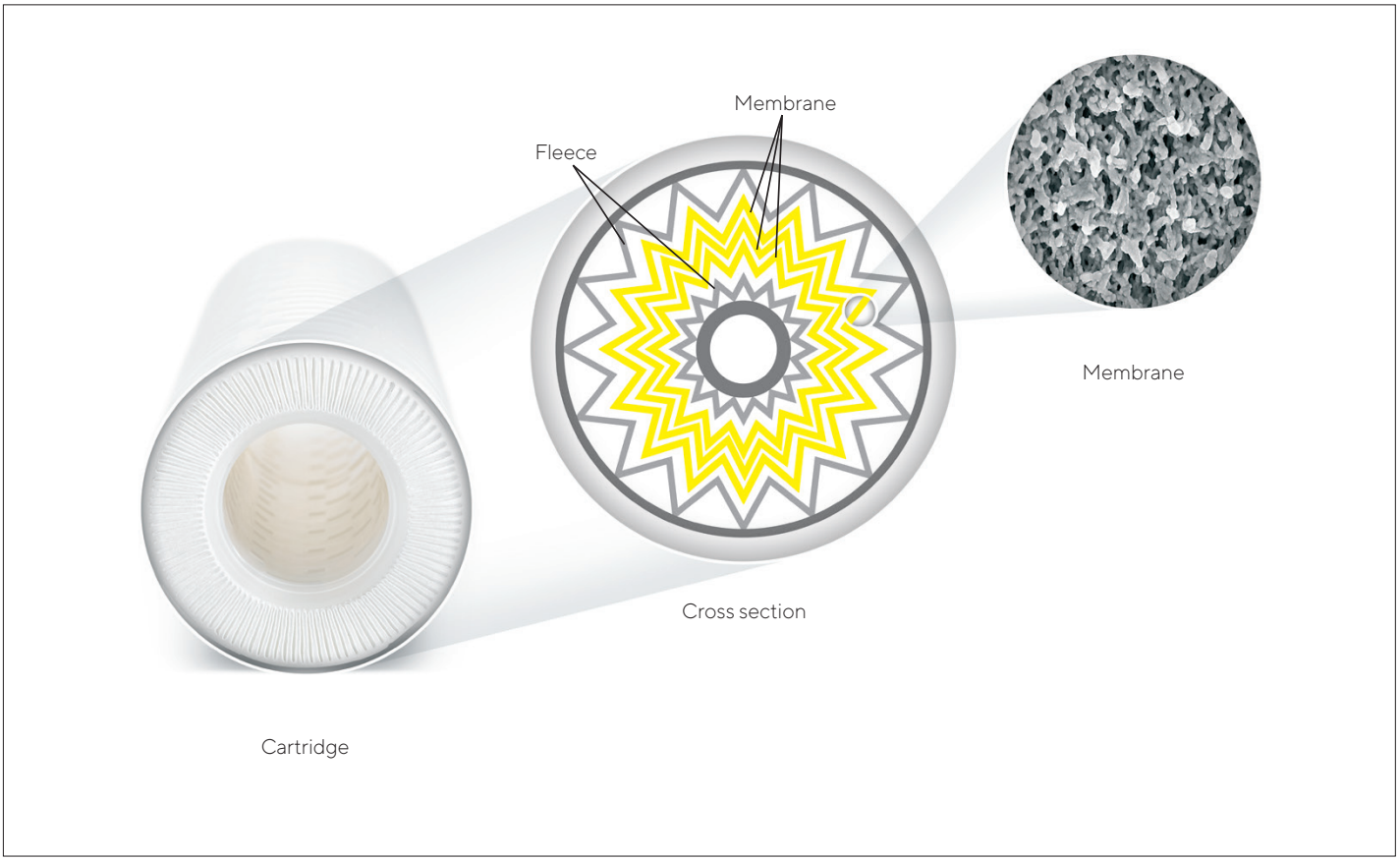
Device

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



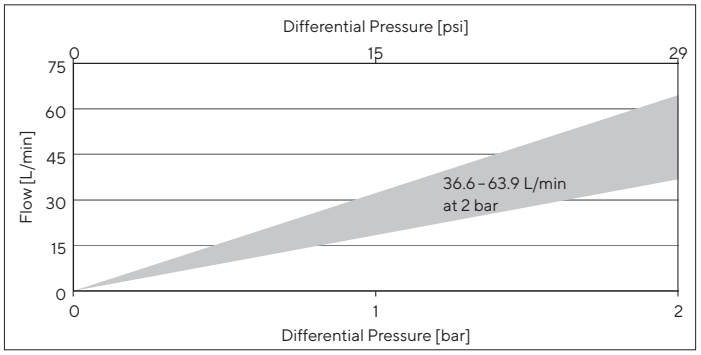
Construction of Virosart® Max cartridge and capsule with zoom on cross section and membrane.

Performance

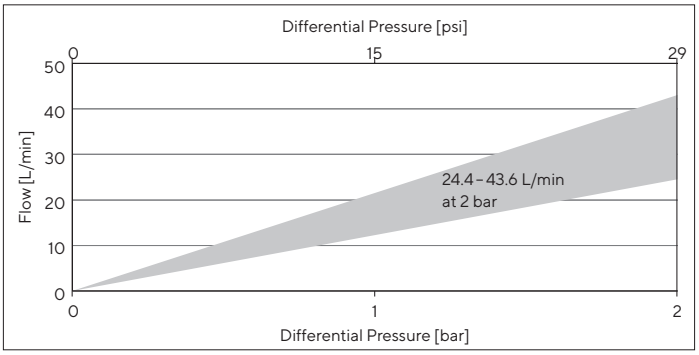
Characteristic Water Flow Rates

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!

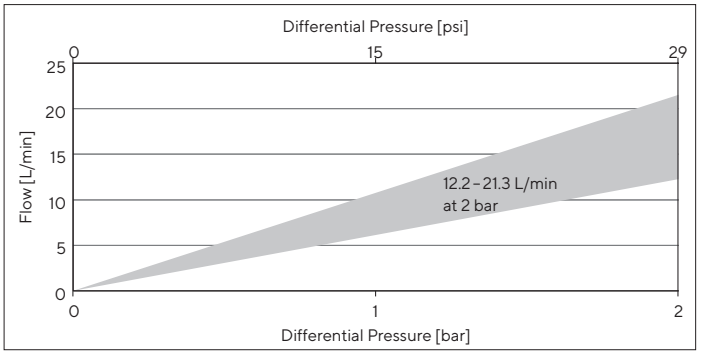
Virosart® Max 30″ Cartridges & 30″ T-Style Maxicaps®
(2.1 m^2 | 22.6 ft^2)



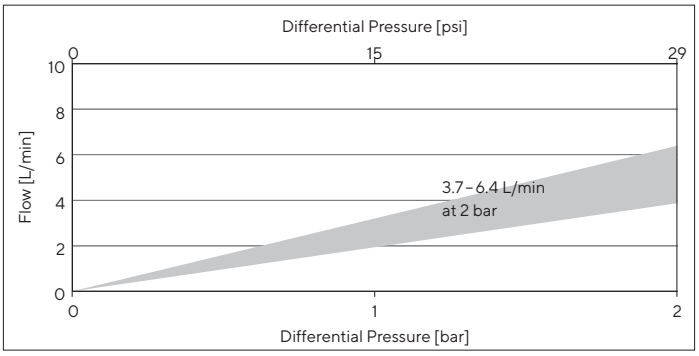
Virosart® Max 20″ Cartridges & 20″ T-Style Maxicaps®
(1.4 m^2 | 15 ft^2)



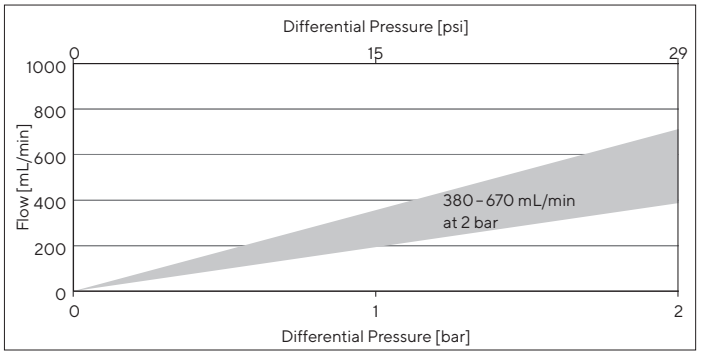
Virosart® Max 10″ Cartridges & 10″ T-Style Maxicaps®
(0.7 m^2 | 7.5 ft^2)



Virosart® Max Midicaps®
(0.21 m^2 | 2.3 ft^2)



Virosart® Max Capsules
(220 cm^2 | 0.24 ft^2)



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	2650008-000-00
Extractables Guide	SPK5803-e

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 m^2 | 7.5 ft^2
N2: 20″ 1.4 m^2 | 15 ft^2
N3: 30″ 2.1 m^2 | 22.6 ft^2

T-Style Maxicaps®

54A	83	58	■	--	SS

Filter size
N1: 10″ 0.7 m^2 | 7.5 ft^2
N2: 20″ 1.4 m^2 | 15 ft^2
N3: 30″ 2.1 m^2 | 22.6 ft^2

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

Midicaps® & Capsules

54A	■	58	■	--	FF	--	■

13: Capsules
53: Midicaps®

Filter size
N4: 220 cm^2 | 0.24 ft^2
N9: 0.21 m^2 | 2.3 ft^2

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

Units per package
B: Five pieces
V: Two pieces

Minisart®

54A	■	--	--	--	--	--	■

Filter size
MI: Minisart®
SA: Sartolab

Units per package
B: Five pieces
V: Two pieces

Accessories & Services

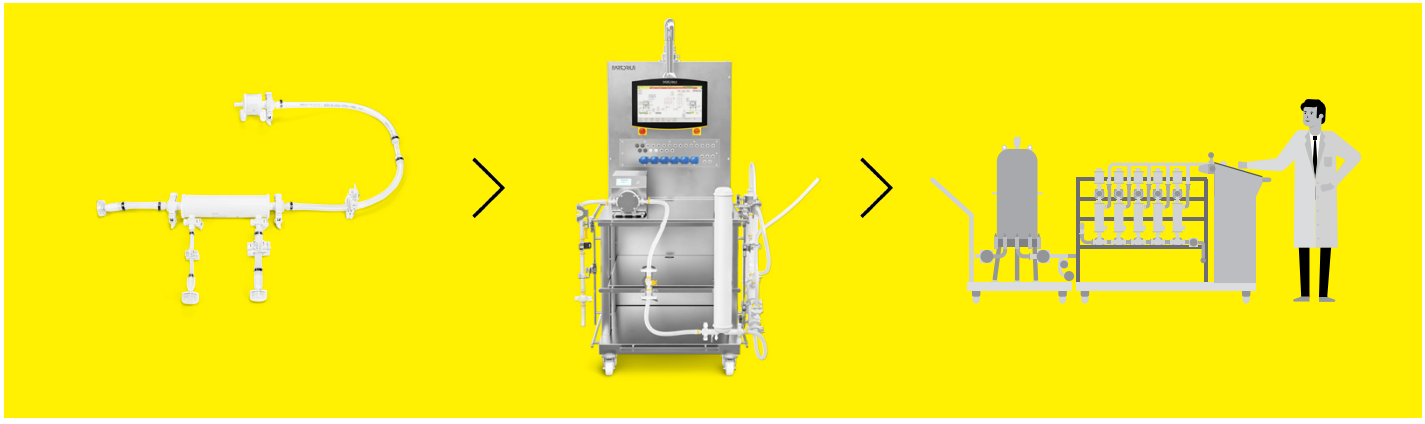
Virus Filtration
Virosart® HF is a high speed virus filter for mAbs and recombinant proteins. The filter combines highest virus safety with superior capacities.

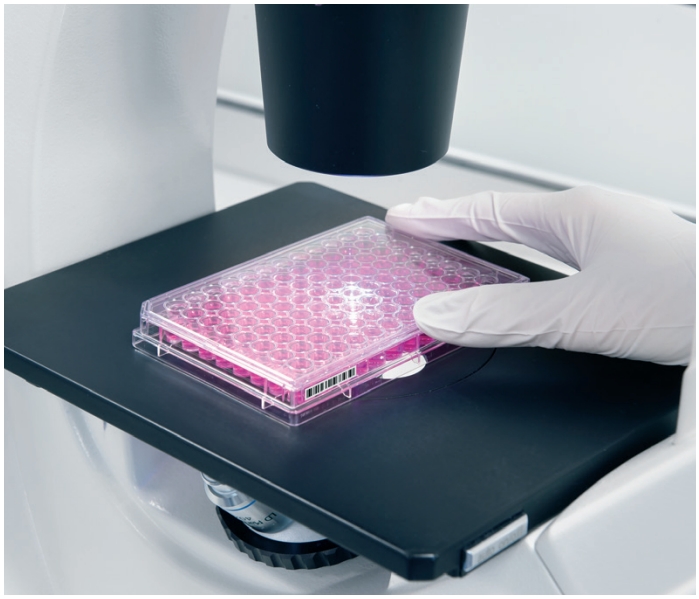
Integrity Testing using Sartocheck®
Fully automated Virosart® integrity testing to guarantee intactness of the Virosart® filter applying pre- and post-use diffusion tests.

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 are the perfect complement to Virosart® virus filters.
Our services provide:

- Virus clearance studies
- Process design support
- Optimization support

We use a variety of different relevant and model viruses including MVM, MuLV, Reo-3 and HSV-1. The combination of product and services provides you with a comprehensive virus clearance solution that gives you the confidence you need to proceed.

BioOutsource Testing Services
Your partner to assure virus safety for your process by MCB | WCB characterization, bulk harvest testing.

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For further contacts, visit
www.sartorius.com

DIR: 2650739-000-00
Material-No.: 85037-561-70
Status: 11 | 2020