SARTORIUS

Product Datasheet

Virosart® HC

The High Capacity Virus Filter for Blood & Plasma Applications

Product Information

Virosart® HC is especially developed for plasma derivatives in cooperation with one of the market leaders within this industry. The unique surface modified hydrophilic PES membrane can be easily wetted and shows a constant flow even with hydrophobic feed streams e.g. IVIG. Flexibility is given by using either cartridges in existing stainless steel housings or disposable capsules.

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. Virosart® HC targets the removal of both small non-enveloped viruses (20 nm) e.g. PPV, MVM and larger enveloped viruses (> 50 nm) e.g. MuLV from a biopharmaceutical product, in particular from hydrophobic feed streams.

Application & Positioning

The main applications for Virosart® HC for virus filtration are hydrophobic feed streams such as IVIG or any other plasma derivative as well as hydrophobic antibodies and recombinant proteins (< 150 kDa). Virosart® HC is used at the end of the purification process for virus filtration of the biopharmaceutical product.

At this stage the purity of the biopharmaceutical product is the highest and probability of virus filter blockage due to contaminants (DNA, CHOP, aggregates and lipoproteins) is the lowest. Although contaminants should be removed during the polishing process of the target molecule, small amounts might be sufficient to cause premature blockage of the final virus filter.

To prevent this, an efficient pre-filtration step, such as the Virosart® Max*, might be required as protection for the Virosart® HC membrane. The optimum pre-filter to final filter ratio has to be identified during development of the process step.

Product Benefits

Virosart® HC provides efficient virus removal to the biopharmaceutical product. Based on the unique surface modified double layer 20 nm PES membrane, Virosart® HC provides excellent capacity even for hydrophobic, high blocking feed streams.

Virosart® HC retains ≥ 4 $\log_{10}$ of small non-enveloped viruses (e.g. PPV, MVM) and ≥ 6 $\log_{10}$ of large enveloped viruses (e.g. MuLV). This filter offers excellent virus retention over the entire flow decay profile independently of operating pressure.

Customized process-specific virus LRV determination can be individually provided by our Confidence® Virus Clearance Services (see page 7 for details).

Integrity Testing

Virosart® HC filters are tested for integrity using a water based diffusion test, e.g. based on the Sartocheck® technology of Sartorius Stedim Biotech. Virosart® HC filters have been validated for logarithmic reduction values of ≥ 4 $\log_{10}$ for small non-enveloped viruses using bacteriophage PP7 as the model virus.

* Virosart® Max is a specifically optimized virus pre-filter significantly increasing downstream virus filter performance. Virosart® Max is a patented technology (DE 10 2011 105 525 B4) binding 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®	Capsule & Midicaps®	T-Style Maxicaps® & Cartridge
Nominal filtration area	5.0 cm²	240 cm² 0.27 m² 0.27 ft² 2.9 ft²	0.9 m², 1.8 m², 2.7 m² 9.7 ft², 19.4 ft², 29 ft²
To be used for	▪ Scale-down work ▪ Flow & capacity studies ▪ Optimization of pre-filter- | final-filter-ratio ▪ GLP spiking studies (IT tested Minisart*)	▪ Scale-up studies ▪ Small scale production	▪ Large scale manufacturing
Typical filtration volume	< 200 mL	< 5 L < 80 L	> 80 L
Available connectors	▪ Female luer lock inlet & male luer lock outlet	▪ Midicaps® & Capsules: FF: 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® | Cartridges: Autoclaving 121 °C @ 2.0 bar | 29 psi for 30 min up to 2 cycles ⚠ No inline steaming of Maxicaps® ▪ Cartridges: Steaming 130 °C @ 2.7 bar | 39.6 psi for 60 min up to 3 cycles
Operating parameters	▪ In the direction of filtration: max. 5.0 bar | 73 psi at 20 °C, max. 0.2 bar | 2.92 psi at 121 °C ▪ In the reversed direction of filtration: max. 0.05 bar | 0.725 psi at 20 °C		
Water based diffusion test at 4.5 bar | 65.25 psi	N/A	▪ 2 mL/min (240 cm²) ▪ 8 mL/min (0.27 m²)	▪ 24 mL/min (0.9 m²) ▪ 48 mL/min (1.8 m²) ▪ 72 mL/min (2.7 m²)

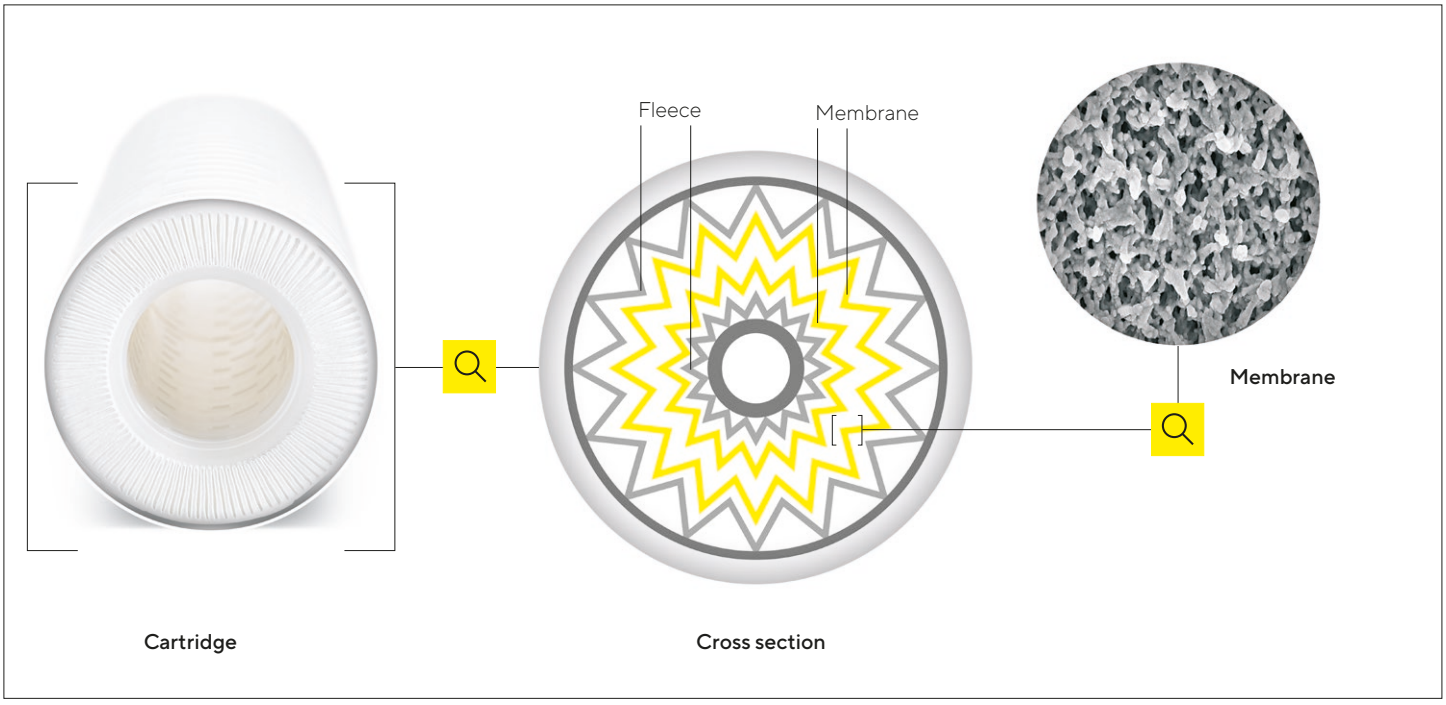
Materials

Device

Cartridges, T-Style Maxicaps®,Capsules & Midicaps	
Supportive fleece	Polypropylene
Capsule housing	Polypropylene
End caps	Polypropylene
Core (not capsule)	Polypropylene

Minisart®	
Capsule housing	Polycarbonate

Membrane	
Material	Surface modified polyethersulfone
Pore size	20 nm nominal
Format	Double layer

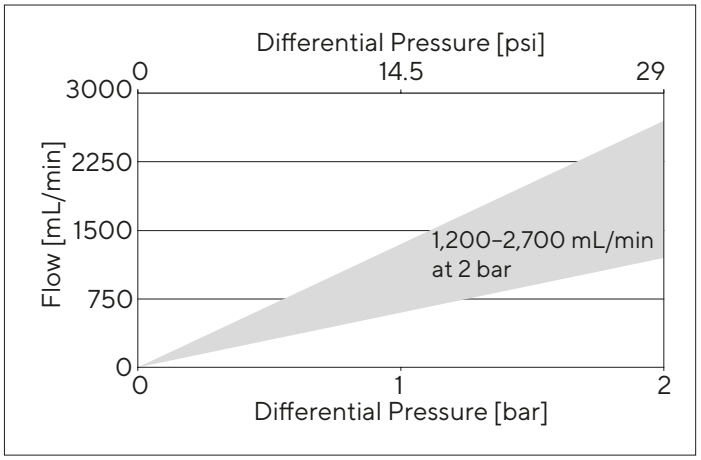


Construction of Virosart® HC cartridge and capsule with zoom on cross section and membrane.

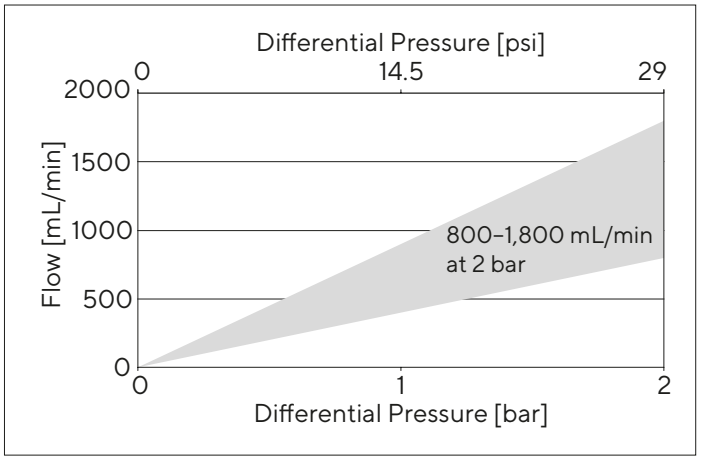
Performance

Characteristic Water Flow Rates

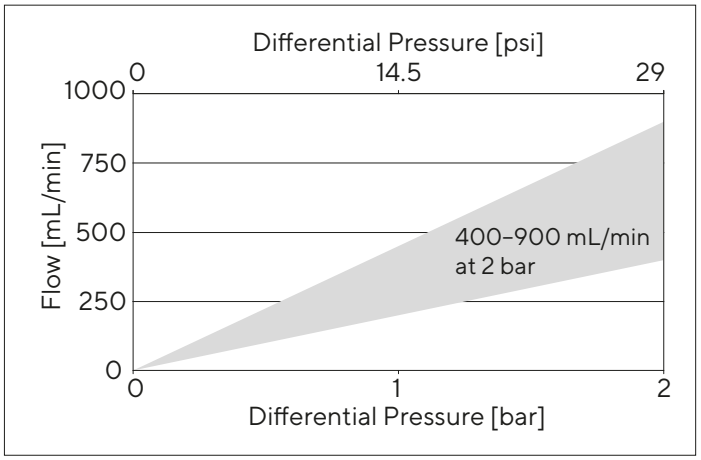
Virosart® HC 30" Cartridge & 30" T-Style Maxicaps®
(2.7 m² | 29 ft²)



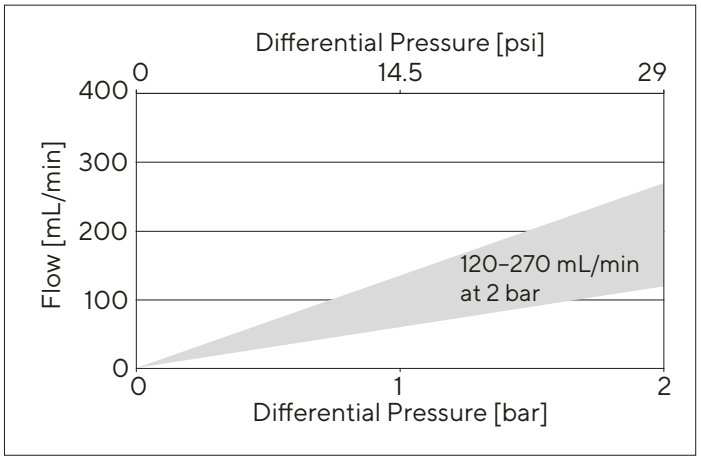
Virosart® HC 20" Cartridge & 20" T-Style Maxicaps®
(1.8 m² | 19.4 ft²)



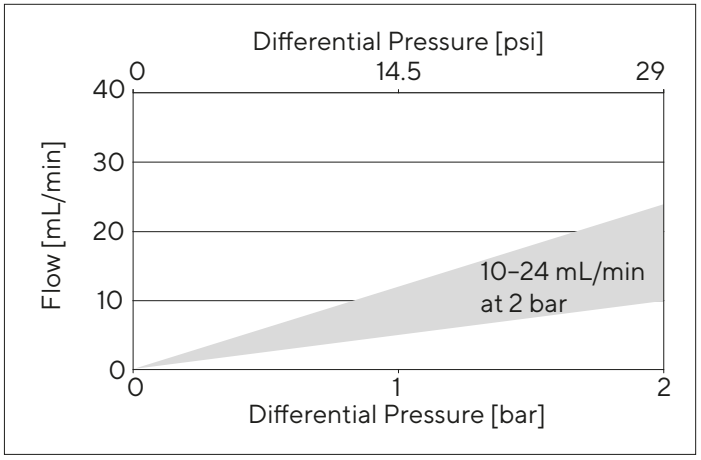
Virosart® HC 10" Cartridge & 10″ T-Style Maxicaps®
(0.9 m² | 9.7 ft²)



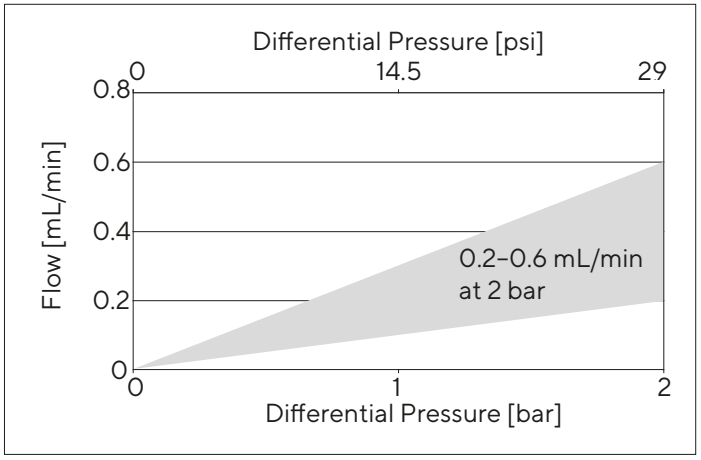
Virosart® HC Midicaps® (0.27 m² | 2.9 ft²)



Virosart® HC Capsule (240 cm² | 0.27 ft²)



Virosart® HC Minisart® (5 cm²)



Regulatory Compliance

Each individual filter is tested for integrity (except 539VM----------B)

- Validated for ≥ 4 $\log_{10}$ removal of small non-enveloped viruses using bacteriophage PP7
- 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	2838409-000
Extractables Guide	2889522-000
Virus Information Guide	SPK5752-e
Application Note	Autoclaving Virosart® Minisart® devices (SPK4110-e)

Ordering Information

Cartridge

539	25	28	■

Adapter
25: S-adapter top, 2 flange bayonet adapter with double o-ring bottom

Filter size
V1: 10" 0.9 m² | 9.7 ft²
V2: 20" 1.8 m² | 19.4 ft²
V3: 30" 2.7 m² | 29 ft²

T-Style Maxicaps®

539	83	28	■	--	SS

Filter size
V1: 10" 0.9 m² | 9.7 ft²
V2: 20" 1.8 m² | 19.4 ft²
V3: 30" 2.7 m² | 29 ft²

Adapter
SS: Sanitary inlet – and outlet adapter

Midicaps®

539	53	28	V9	--	FF	--	V

Filter size
V9: Size 9
0.27 m² | 2.9 ft²

Adapter
FF: ¾" triclamp (sanitary) connector inlet & outlet

Units per package
V: Two pieces

Capsule

539	13	28	V4	--	FF	--	B

Filter size
V4: Size 4
240 cm² | 0.26 ft²

Adapter
FF: ¾" triclamp (sanitary) connector inlet & outlet

Units per package
B: Five pieces

Minisart®

539	VM	--	--	--	--	--	■	■

IT
IT: Integrity tested
--: Not integrity tested

Units per package
A: Four pieces
B: Five pieces

Accessories & Services

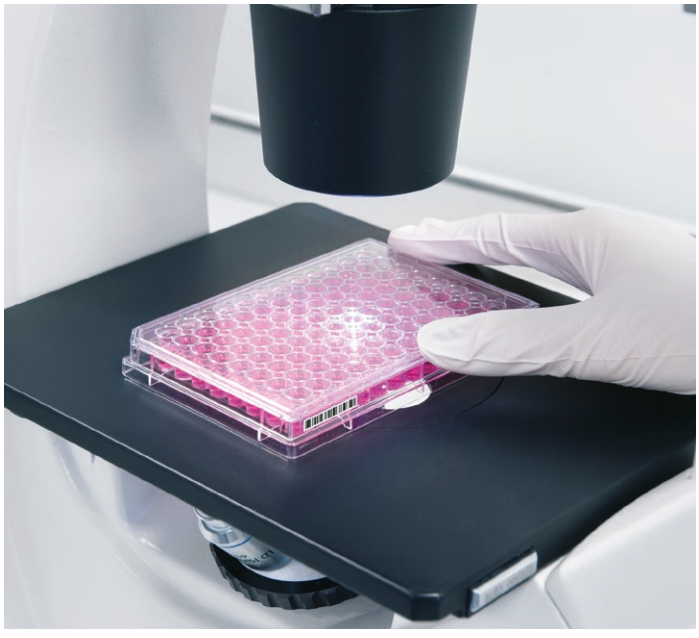
Adsoptive Pre-Filtration
Virosart® Max* protects your virus filter irrespective of the process conditions. Virosart® Max will downsize your process and reduce your total virus filtration costs.

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

Filter Holders and Housing
Filter holders are designed to accommodate all different Maxicaps® heights. Different standard designs of filter housings are available for cartridges from 10" to 30".

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® HC filters, providing:

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

We use a variety of different relevant and model viruses including BVDV, PRV, HAV and PPV. 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 blood | plasma product and manufacturing process.

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