



## 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 consisting of virus adsorption by chromatography, virus inactivation and virus filtration. The Virosart® product ranges 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 derivatives as well as hydrophobic antibodies & recombinant proteins (< 150 kD). 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 virus filter blockage due to contaminants (DNA, CHOP, aggregates & lipoproteins) is the lowest. Even if these 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 – final filter ratio has to be identified during development of the process step.

### Product Benefits

Virosart® HC provides high virus safety 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. This filter retains  $\geq 4$  LRV ( $\log_{10}$  reduction value) of small non-enveloped viruses (e.g. PPV, MVM) and  $\geq 6$  LRV of large enveloped viruses (e.g. MuLV). This filter offers high virus safety over the entire flow decay profile independent of operating pressure or pressure pauses.

### 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  $\geq 4$  LRV removal of 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



<b>Nominal filtration area</b>	5.0 cm <sup>2</sup>	240 cm <sup>2</sup> 0.27 ft <sup>2</sup>	0.27 m <sup>2</sup> 2.9 ft <sup>2</sup>	0.9 m <sup>2</sup> , 1.8 m <sup>2</sup> , 2.7 m <sup>2</sup> 9.7 ft <sup>2</sup> , 19.4 ft <sup>2</sup> , 29 ft <sup>2</sup>
<b>To be used for</b>	<ul style="list-style-type: none"> <li>– Scale-down work</li> <li>– Flow &amp; capacity studies</li> <li>– Optimization of pre-filter-   final-filter-ratio</li> <li>– GLP spiking studies (IT tested Minisart®)</li> </ul>	<ul style="list-style-type: none"> <li>– Scale-up studies</li> <li>– Small scale production</li> </ul>		<ul style="list-style-type: none"> <li>– Large scale manufacturing</li> </ul>
<b>Typical filtration volume</b>	< 200 mL	< 5 L	< 80 L	≥ 80 L
<b>Available connectors</b>	<ul style="list-style-type: none"> <li>– Female luer lock inlet &amp; male luer lock outlet</li> </ul>	<ul style="list-style-type: none"> <li>– <b>MidiCaps® &amp; Capsules:</b> FF: 3/4" triclamp (sanitary) connector inlet &amp; outlet</li> </ul>		<ul style="list-style-type: none"> <li>– <b>MaxiCaps®:</b> Sanitary inlet &amp; outlet adapter</li> <li>– <b>Cartridges:</b> S-adapter top, 2 flange bayonet adapter with double o-ring bottom</li> </ul>
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>– Autoclaving: 121°C @ 2.0 bar   29 psi for 30 min up to 2 cycles</li> </ul> <p>⚠ No inline steaming of Minisart®</p>	<ul style="list-style-type: none"> <li>– Autoclaving: 121°C @ 2.0 bar   29 psi for 30 min up to 2 cycles</li> </ul> <p>⚠ No inline steaming of Capsule &amp; MidiCaps®</p>		<ul style="list-style-type: none"> <li>– <b>MaxiCaps®:</b> Autoclaving 121°C @ 2.0 bar   29 psi for 30 min up to 2 cycles</li> <li>– <b>Cartridges:</b> Steaming 130°C @ 2.7 bar   39.6 psi for 60 min up to 3 cycles</li> </ul> <p>⚠ No inline steaming of MaxiCaps®</p>
<b>Operating parameters</b>	<ul style="list-style-type: none"> <li>– In the direction of filtration: max. 5.0 bar   73 psi at 20°C, max. 0.2 bar   2.92 psi at 121°C</li> <li>– In the reversed direction of filtration: max. 0.05 bar   0.725 psi at 20°C</li> </ul>			
<b>Water based diffusion test at 4.5 bar   65.25 psi</b>	N/A	<ul style="list-style-type: none"> <li>– 2 mL/min (240 cm<sup>2</sup>)</li> <li>– 8 mL/min (0.27 m<sup>2</sup>)</li> </ul>		<ul style="list-style-type: none"> <li>– 24 mL/min (0.9 m<sup>2</sup>)</li> <li>– 48 mL/min (1.8 m<sup>2</sup>)</li> <li>– 72 mL/min (2.7 m<sup>2</sup>)</li> </ul>

## Materials

### Device

Cartridges, T-Style MaxiCaps®,  
Capsules & MidiCaps®

Supportive fleece  
Polypropylene

Capsule housing  
Polypropylene

End caps  
Polypropylene

Core (not capsule)  
Polypropylene

Minisart®

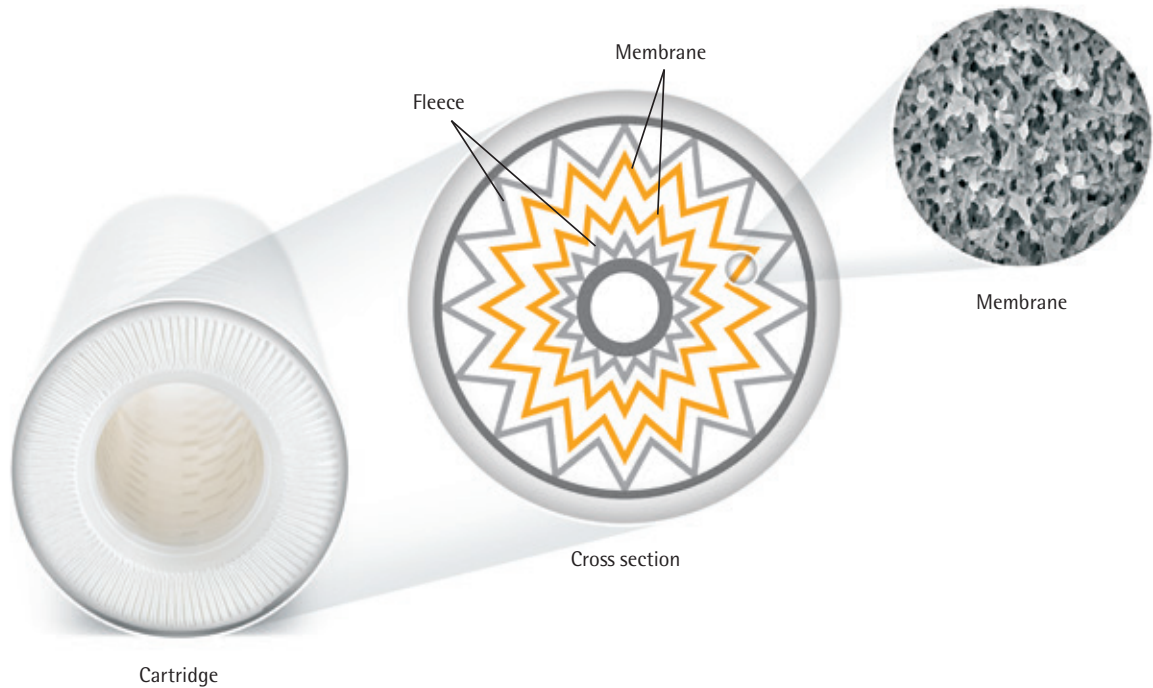
Capsule housing  
Polycarbonate

### Membrane

Material  
Surface modified polyethersulfone

Pore size  
20 nm nominal

Format  
Double layer

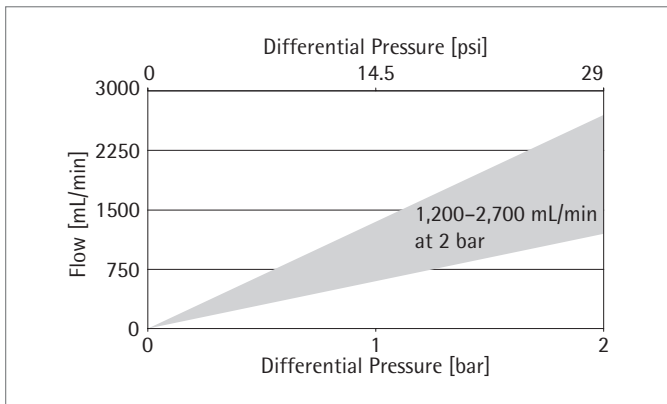


Construction of Virosart® HC cartridge and capsule with zoom on cross section and membrane

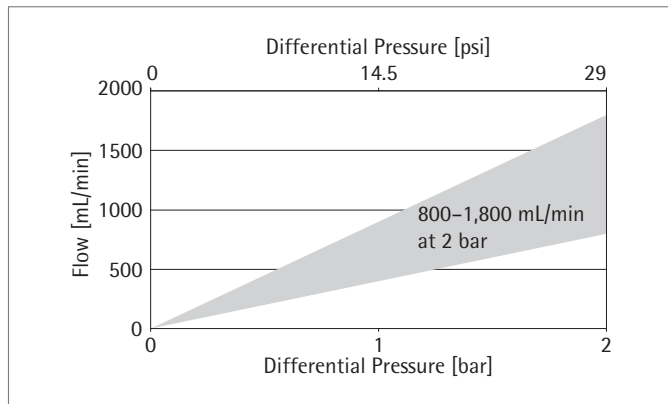
# Performance

## Characteristic Water Flow Rates

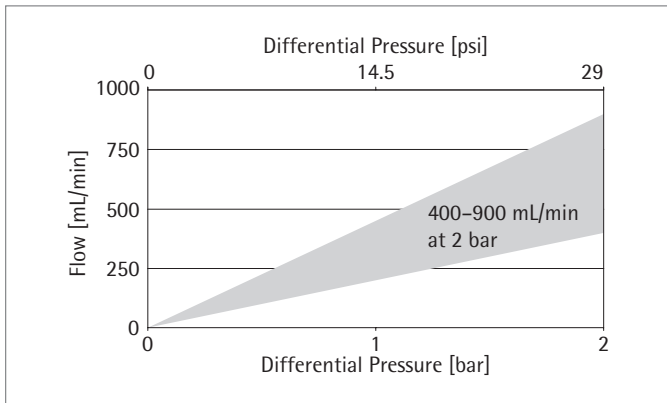
**Virosart® HC 30" Cartridge & 30" T-Style MaxiCaps®**  
(2.7 m<sup>2</sup> | 29 ft<sup>2</sup>)



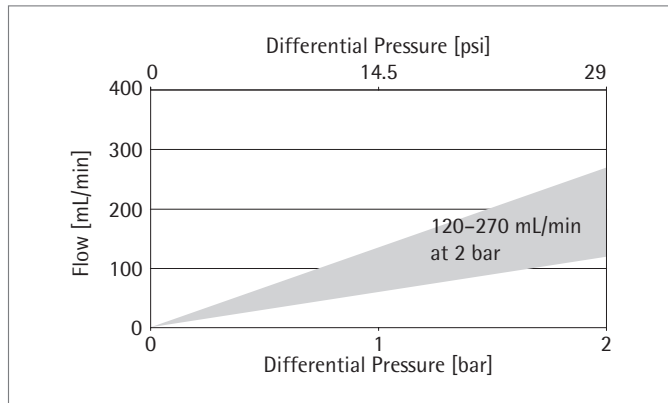
**Virosart® HC 20" Cartridge & 20" T-Style MaxiCaps®**  
(1.8 m<sup>2</sup> | 19.4 ft<sup>2</sup>)



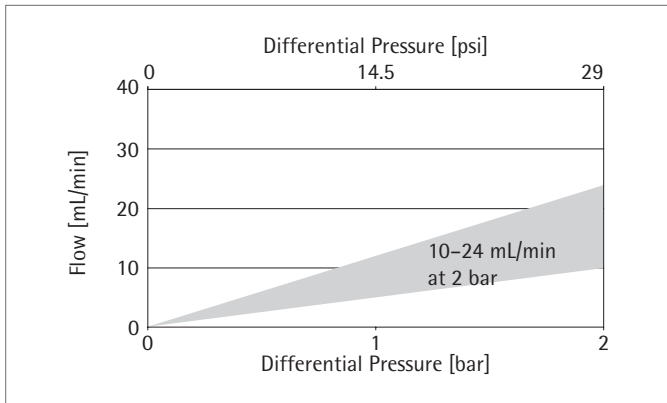
**Virosart® HC 10" Cartridge & 10" T-Style MaxiCaps®**  
(0.9 m<sup>2</sup> | 9.7 ft<sup>2</sup>)



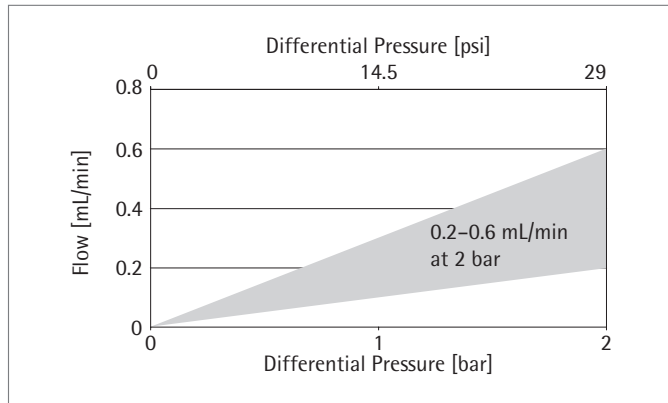
**Virosart® HC MidiCaps® (0.27 m<sup>2</sup> | 2.9 ft<sup>2</sup>)**



**Virosart® HC Capsule (240 cm<sup>2</sup> | 0.27 ft<sup>2</sup>)**



**Virosart® HC Minisart® (5 cm<sup>2</sup>)**




## Regulatory Compliance

- Each individual filter is tested for integrity (except 539VM-----B)
- Validated for  $\geq 4$  LRV 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	SPK5791-e
Extractables Guide	SPK5790-e
Virus Information Guide	SPK5752-e
Application Note	– Autoclaving Virosart® Minisart® devices (SPK4110-e)

## Ordering Information




### Cartridge

545	25	28	
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**Adapter**  
25: S-adapter top, 2 flange bayonet adapter with double o-ring bottom

**Filter size**  
V1: 10" 0.9 m<sup>2</sup> | 9.7 ft<sup>2</sup>  
V2: 20" 1.8 m<sup>2</sup> | 19.4 ft<sup>2</sup>  
V3: 30" 2.7 m<sup>2</sup> | 29 ft<sup>2</sup>




### T-Style MaxiCaps®

539	83	28		--	SS
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**Filter size**  
V1: 10" 0.9 m<sup>2</sup> | 9.7 ft<sup>2</sup>  
V2: 20" 1.8 m<sup>2</sup> | 19.4 ft<sup>2</sup>  
V3: 30" 2.7 m<sup>2</sup> | 29 ft<sup>2</sup>

**Adapter**  
SS: Sanitary inlet – and outlet adapter




### MidiCaps®

539	53	28	V9	--	FF	--	V
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**Filter size**  
V9: Size 9 0.27 m<sup>2</sup> | 2.9 ft<sup>2</sup>

**Adapter**  
FF: 3/4" triclamp (sanitary) connector inlet & outlet

**Units per package**  
V: Two pieces




### Capsule

539	13	28	V4	--	FF	--	B
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**Filter size**  
V4: Size 4 240 cm<sup>2</sup> | 0.26 ft<sup>2</sup>

**Adapter**  
FF: 3/4" triclamp (sanitary) connector inlet & outlet

**Units per package**  
B: Five pieces



### Minisart®

539	VM	--	--	--	--	--		
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**IT**  
IT: Integrity tested  
--: Not integrity tested

**Units per package**  
A: Four pieces  
B: Five pieces

## Accessories & Services

### Adoptive 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

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



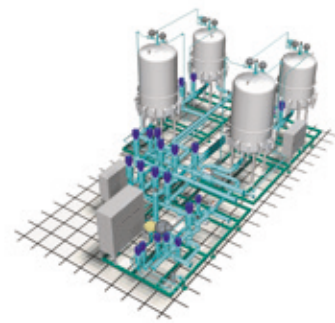
### Filter Holders and Housing

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



### Customized Systems

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



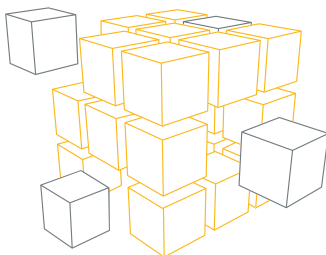
### Testing Service

Your partner to assure virus safety for your process by MCB | WCB characterization, bulk harvest testing and spiking studies.



### Services Worldwide

Trust our comprehensive range of services for your virus filtration processes: We gladly assist you with tasks like process validation, process optimization and many more.



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