

Virosart® HF

High-Speed Virus Filtration for MAbs and Recombinant Proteins



Product Information

Virosart® HF combines exceptional virus retention with excellent capacities. This high-speed virus filter is especially designed for easy implementation into single-use processes. The smart capsule design with low footprint and minimal flushing volumes can be easily implemented into pre-sterilized, ready-to-use assemblies.

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 comprises four different virus retentive membranes to find the best solution for every application. Virosart® HF 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 biopharmaceutical feed streams.

Application & Positioning

The main applications for Virosart® HF for virus retentive filtration are monoclonal antibodies (mAb), antibody fragments (Fab) and small recombinant proteins (< 150 kDa). Virosart® HF 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 the 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® HF membrane.

Product Benefits

Virosart® HF provides efficient virus removal for the biopharmaceutical product. Based on a uniquely modified PES membrane, Virosart® HF provides highest flow rates and excellent capacity. The high packing density of the elements combines extremely low hold up and flushing volumes with low footprint requirements.

The sterile delivery secures ease of use as well as fast installation of the filter elements. Virosart® HF retains $\geq 4 \log_{10}$ of small non-enveloped viruses (e.g. PPV, MVM) and $\geq 6 \log_{10}$ 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® HF are tested for integrity using a water-based diffusion test, e.g. based on the Sartocheck® technology of Sartorius Stedim Biotech. Virosart® HF filters have been validated for logarithmic reduction values of $\geq 4 \log_{10}$ for small non-enveloped viruses using bacteriophage PP7 as the model virus. Validation data is shown in the validation guide of Virosart® HF.

* 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



	Lab Module	Mid-Scale Module	Process Module
Nominal filtration area	1.7 cm ² & 5.0 cm ²	200 cm ² & 0.2 m ² 0.22 ft ² & 2.15 ft ²	0.8 m ² & 2.4 m ² 8.6 ft ² & 25.8 ft ²
To be used for	<ul style="list-style-type: none"> Scale-down work Flow & capacity studies Optimization of pre-filter- final-filter-ratio GLP spiking studies (IT tested version) 	<ul style="list-style-type: none"> Scale-up studies Small scale production 	<ul style="list-style-type: none"> Large scale manufacturing
Typical filtration volume	< 500 mL	< 50 L	> 50 L
Delivery status	<ul style="list-style-type: none"> Sterile (γ-irradiated) 	<ul style="list-style-type: none"> Sterile (γ-irradiated) Non-sterile (γ-irradiated in single-use assembly) 	<ul style="list-style-type: none"> Sterile (γ-irradiated) Non-sterile (γ-irradiated in single-use assembly)
Available connectors	<ul style="list-style-type: none"> Inlet, outlet & vent: Luer lock 	<ul style="list-style-type: none"> Inlet & vent: 3/4" sanitary connector Outlet: Hose barb 	<ul style="list-style-type: none"> Inlet & vent: 1 1/2" sanitary connector Outlet: 3/4" sanitary connector
Operating parameters	<ul style="list-style-type: none"> In the direction of filtration: max. 5.0 bar 73 psi at 20 °C In the reversed direction of filtration: max. 2.5 bar 36.3 psi at 20 °C 		

Materials

Process & Mid-Scale Module

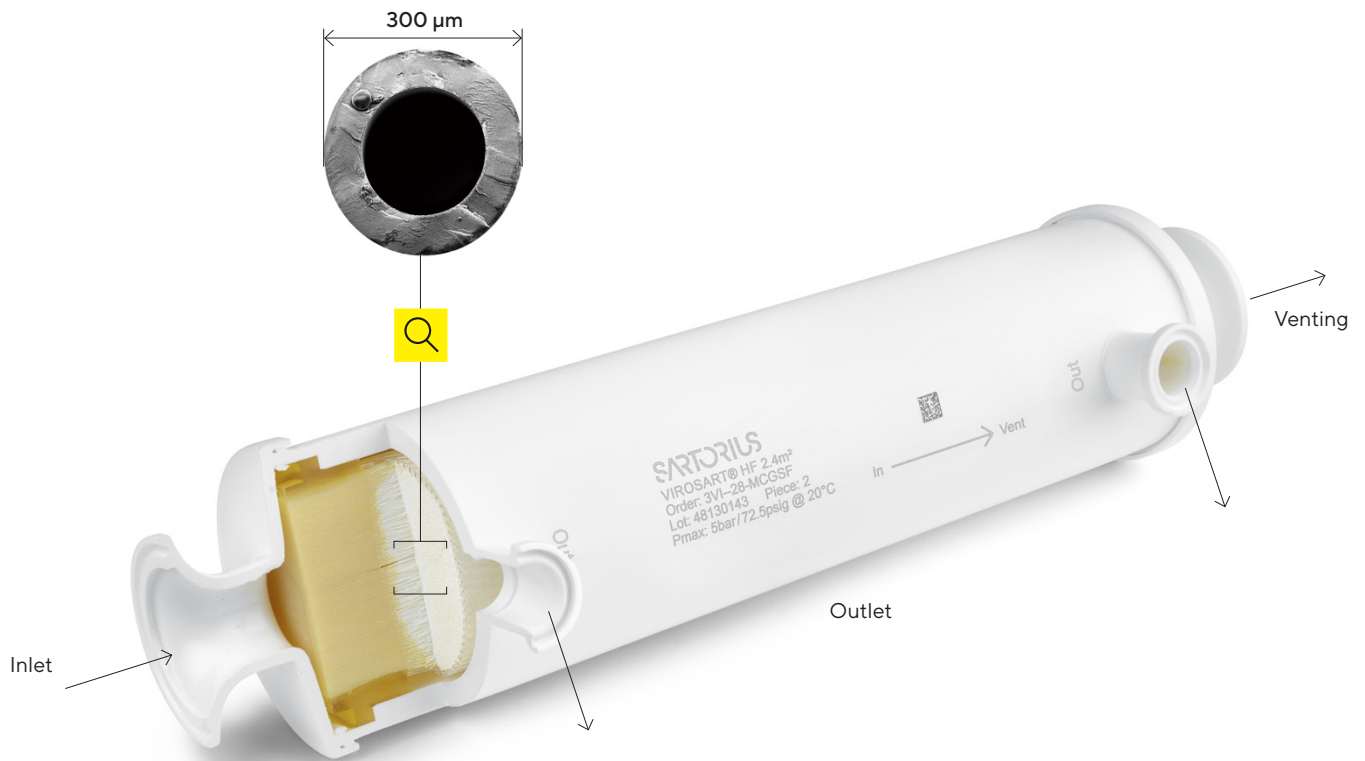
Resin	Polyurethane
Housing	Polypropylene
Protective sleeving	Polyamid
End caps	Polypropylene

Membrane

Material	Polyetersulfone
Pore size	20 nm nominal
Format	Hollow fiber

Lab Module

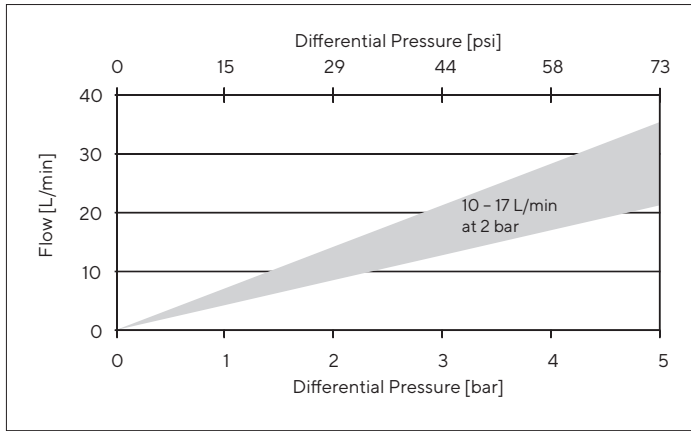
Resin	Polyurethane
Housing	Polycarbonate
Protective sleeving	Non



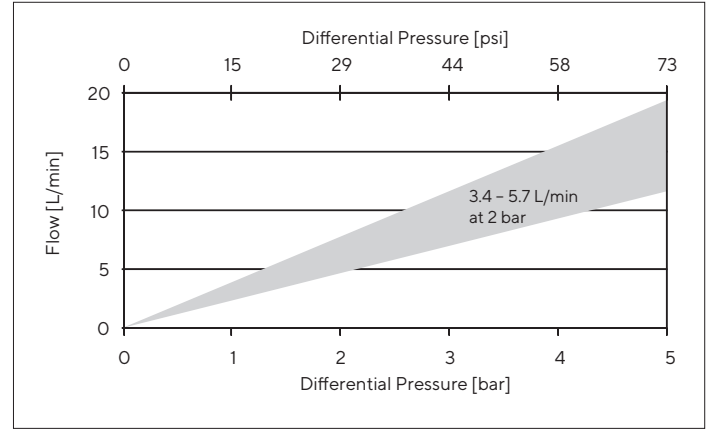
Performance

Characteristic Water Flow Rates

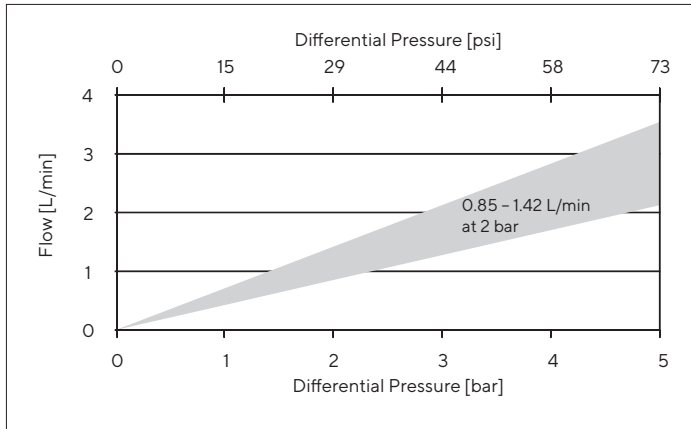
Virosart® HF Process Module (2.4 m² | 25.8 ft²)



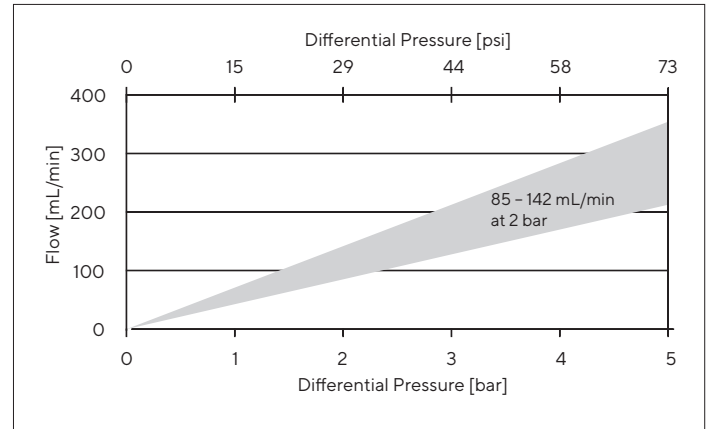
Virosart® HF Process Module (0.8 m² | 8.6 ft²)



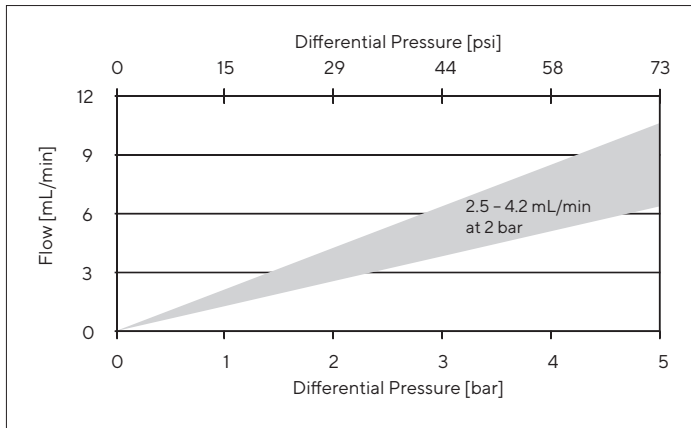
Virosart® HF Mid-Scale Module (0.2 m² | 2.15 ft²)



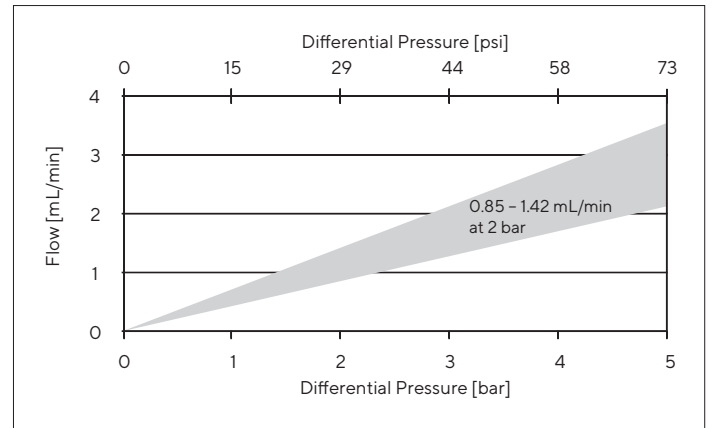
Virosart® HF Mid-Scale Module (200 cm² | 0.22 ft²)



Virosart® HF Lab Module (5.0 cm²)



Virosart® HF Lab Module (1.7 cm²)



Regulatory Compliance

- Each individual filter is tested for integrity (except 3VI--28-TCGML--V & 3VI--28-BCGML--V) and for water flux during manufacturing
- Validated for $\geq 4 \log_{10}$ 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

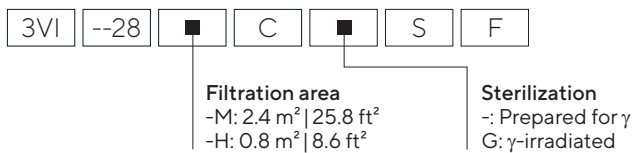
References

Technical References	Publication No.
Validation Guide	SPK5801-e
Extractables Guide	SPK5804-e
Virus Information Guide	SPK5752-e
Application Note	Publication No.
Autoclaving Virosart® Minisart® devices	(SPK4110-e)
Impact of Pressure Release and Multiple Pressure Fluctuations on Virus Retention Performance	SPK4112-e
Risk Mitigation for Calcium Chloride Solution	SPK4114-e
Publication	
Virus Filtration Using a High Throughput Parvovirus Retentive Membrane; Roederstein/Thom, BioPharm International, Aug 2013	

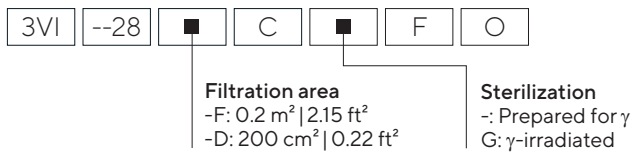
Ordering Information



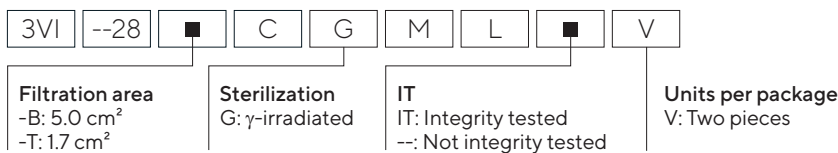
Process Module



Mid-Scale Module



Lab Module



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 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

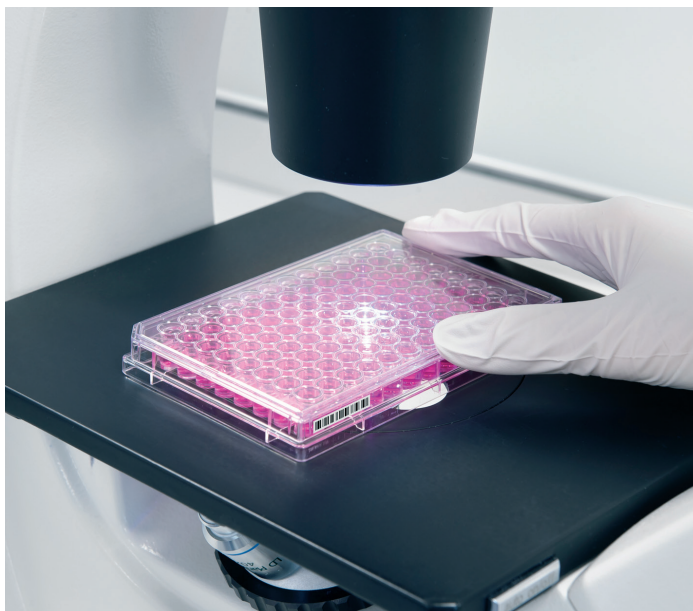
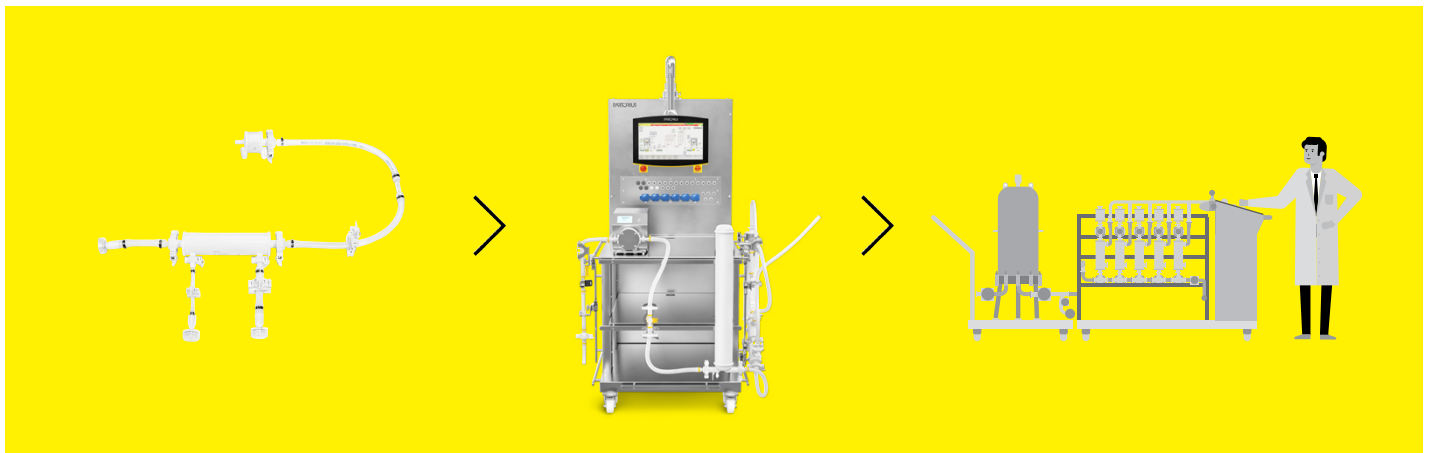
Simplify your daily routine work by using modular filter assembly.

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® HF 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 an effective virus clearance strategy for your process by MCB | WCB characterization and 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