

Virosart® HF

High Speed
Virus Filtration for Mabs and
Recombinant Proteins



Product Information

Virosart® HF combines highest virus safety 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 easily be implemented into pre-sterilized ready to use assemblies.

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 range includes four different virus retentive membranes, in order to provide 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) or 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 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® HF membrane.

Product Benefits

Virosart® HF provides high virus safety to the biopharmaceutical product. Based on a unique 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 ≥ 4 LRV of small non-enveloped viruses (e.g. PPV, MVM) and ≥ 6 LRV of large enveloped viruses (e.g. MuLV). This filter offers high virus safety over the entire flow decay profile independently of operating pressure.

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 ≥ 4 LRV removal of 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



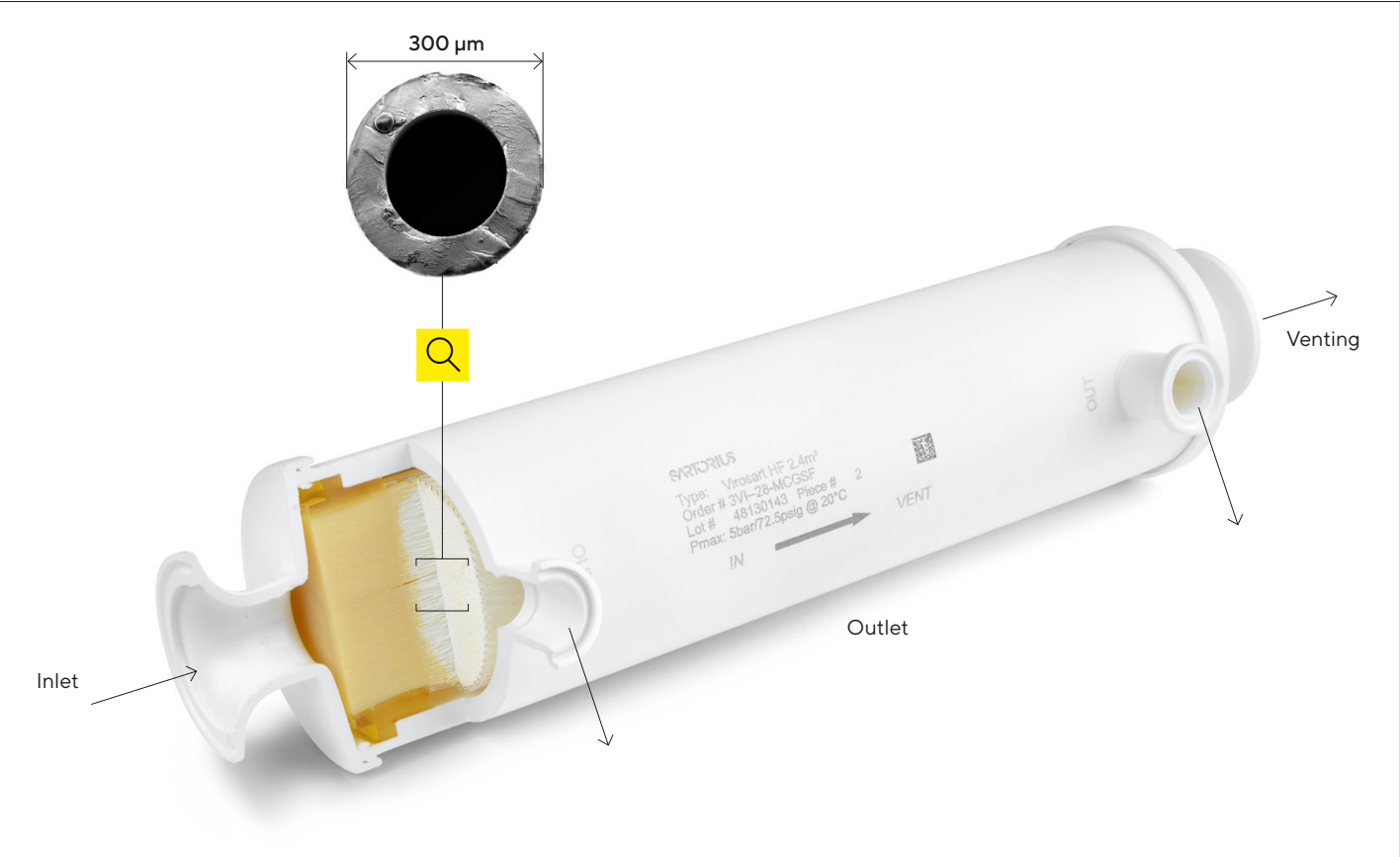
| | Lab Module | Mid-Scale Module | Process Module |
|----------------------------------|---|---|--|
| Nominal filtration area | 1.7 cm ² & 5.0 cm ² | 200 cm ² & 0.2 m ² 0.22 ft ² & 2.15 ft ² | 0.8 m ² & 2.4 m ² 8.6 ft ² & 25.8 ft ² |
| To be used for | <ul style="list-style-type: none"> Scale-down work 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 |

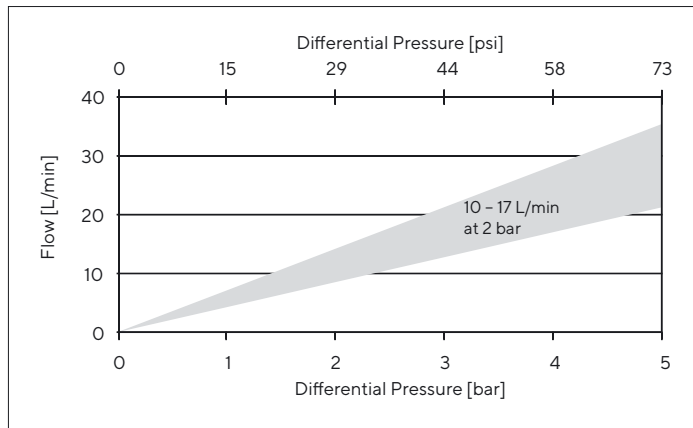
| Lab Module | |
|---------------------|---------------|
| Resin | Polyurethane |
| Housing | Polycarbonate |
| Protective sleeving | Non |



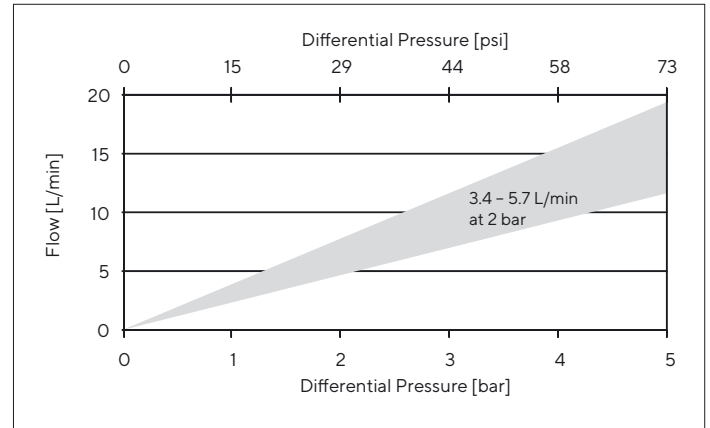
Performance

Characteristic Water Flow Rates

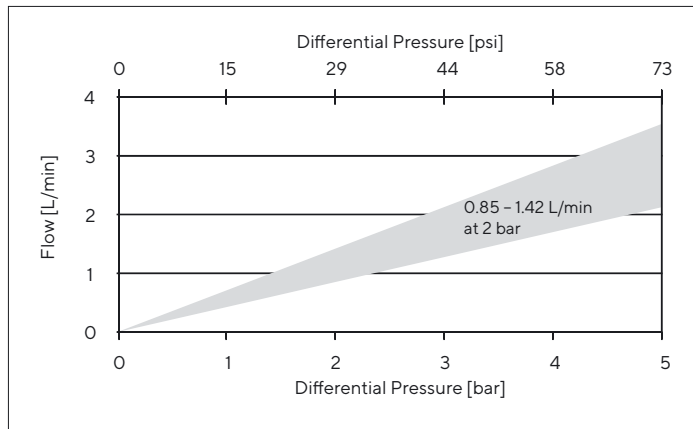
Virosart® HF Process module (2.4 m² | 25.8 ft²)



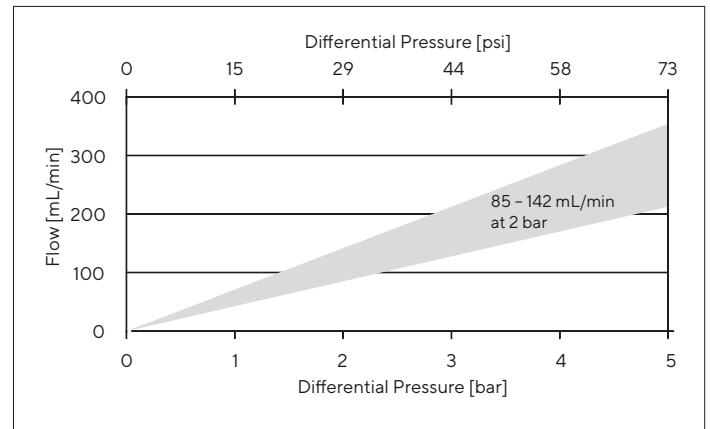
Virosart® HF Process module (0.8 m² | 8.6 ft²)



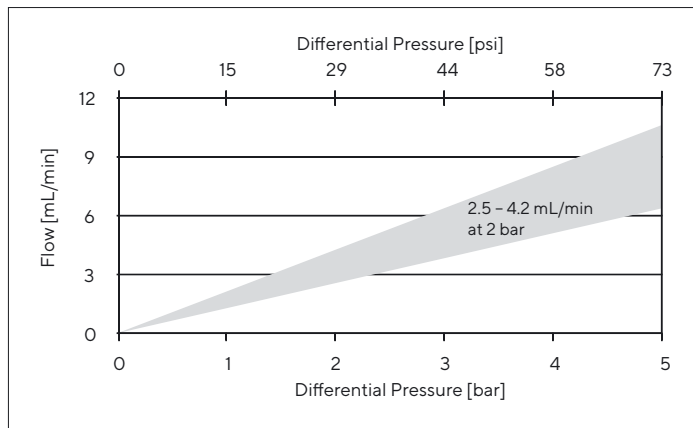
Virosart® HF Mid-Scale Module (0.2 m² | 2.15 ft²)



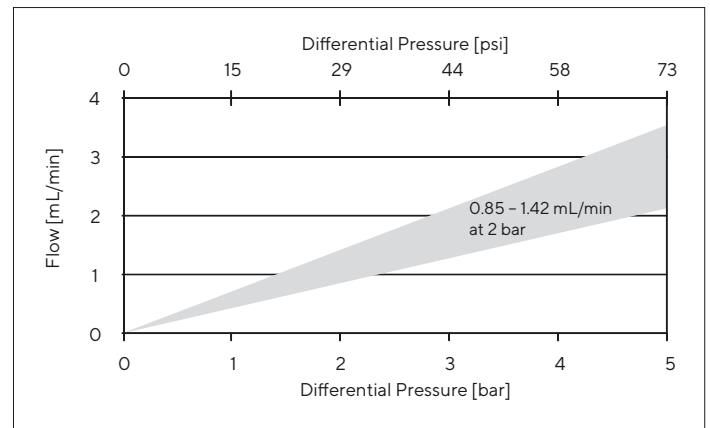
Virosart® HF Mid-Scale Module (200 cm² | 0.22 ft²)



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 ≥ 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

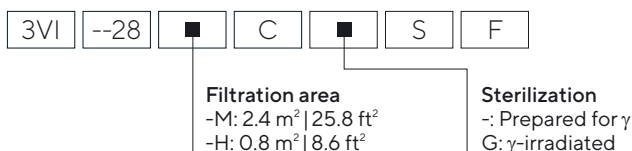
Technical References

| | |
|-------------------------|--|
| Validation Guide | SPK5801-e |
| Extractables Guide | SPK5804-e |
| Virus Information Guide | SPK5752-e |
| Application Note | 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 |

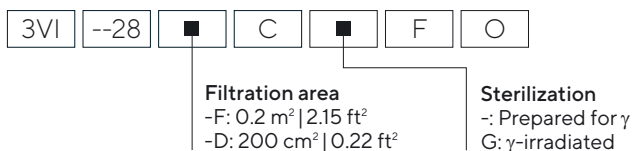
Ordering Information



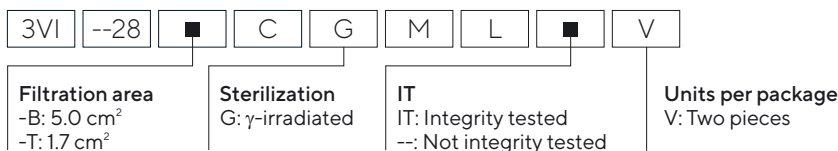
Process Module



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

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 relegalized by customized single-use or hybrid solutions.



BioOutsource Testing Services

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

CONFIDENCE® Virus Clearance Services

Trust our comprehensive range of services for your virus filtration process:

- Process validation
- Virus spiking feasibility study and design of experiment
- Process optimization

Our service team gladly assists you with any inquiries.

Sales and Service Contacts

For further contacts, visit
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