SARTORIUS

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.

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	▪ Scale-down work ▪ Flow & capacity studies ▪ Optimization of pre-filter- | final-filter-ratio ▪ GLP spiking studies (IT tested version)	▪ Scale-up studies ▪ Small scale production	▪ Large scale manufacturing
Typical filtration volume	< 500 mL	< 50 L	> 50 L
Delivery status	▪ Sterile (γ-irradiated)	▪ Sterile (γ-irradiated) ▪ Non-sterile (γ-irradiated in single-use assembly)	▪ Sterile (γ-irradiated) ▪ Non-sterile (γ-irradiated in single-use assembly)
Available connectors	▪ Inlet, outlet & vent: Luer lock	▪ Inlet & vent: ¾" sanitary connector ▪ Outlet: Hose barb	▪ Inlet & vent: 1½" sanitary connector ▪ Outlet: ¾" sanitary connector
Operating parameters	▪ 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

Lab Module	
Resin	Polyurethane
Housing	Polycarbonate
Protective sleeving	Non

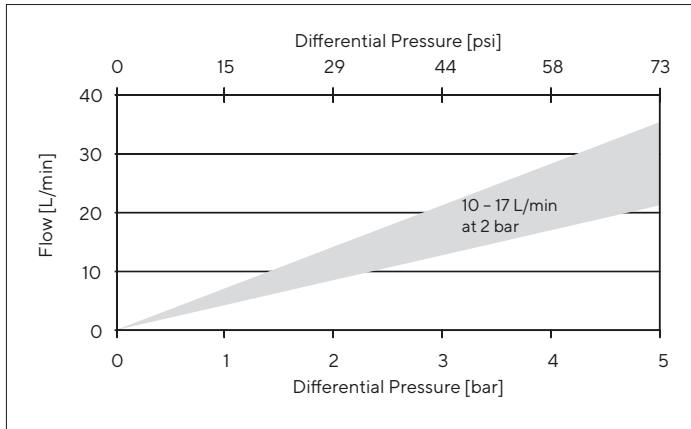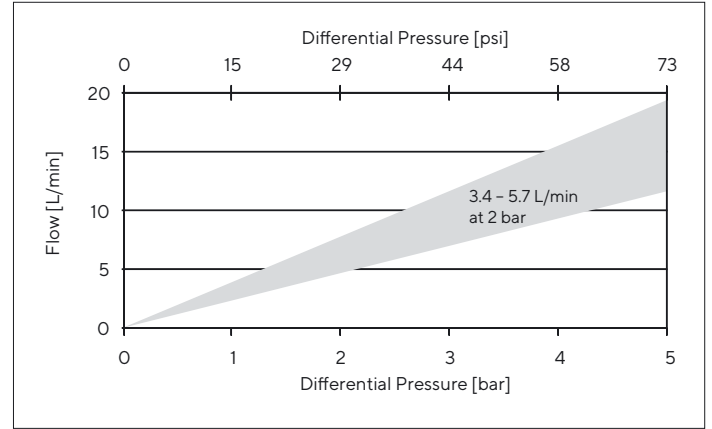| Membrane	
Material	Polyetersulfone
Pore size	20 nm nominal
Format	Hollow fiber
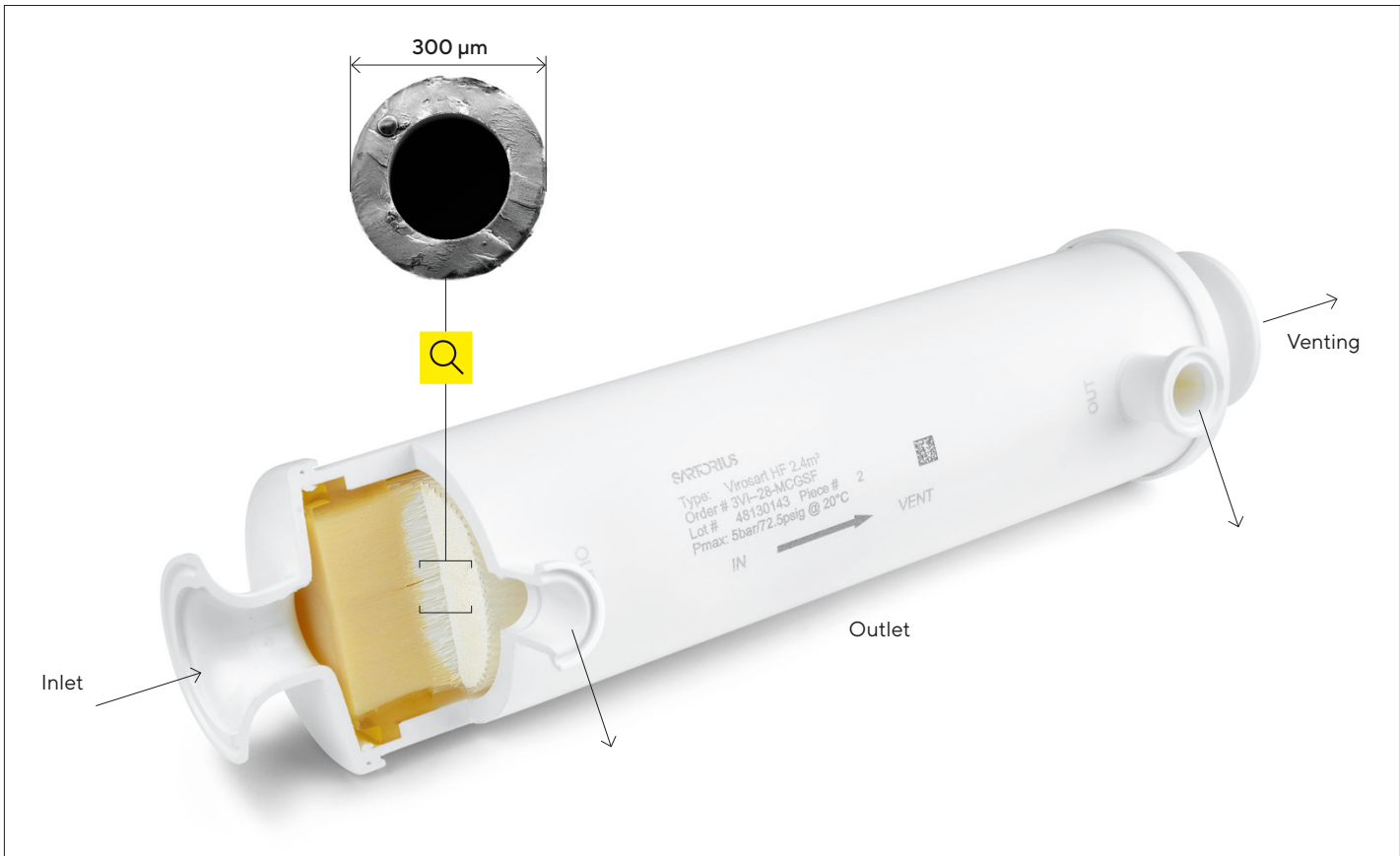
Performance

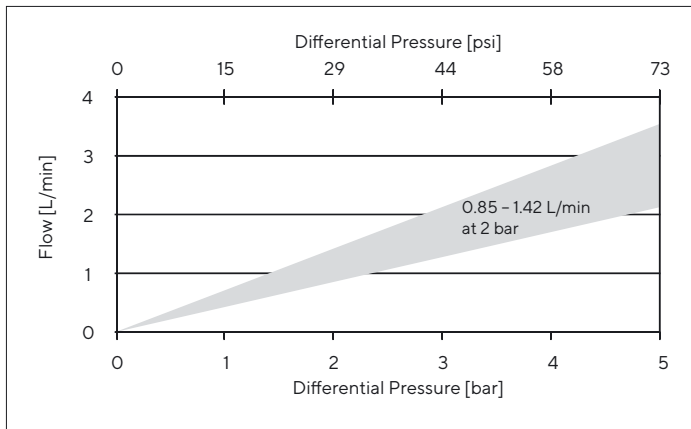## Characteristic Water Flow Rates

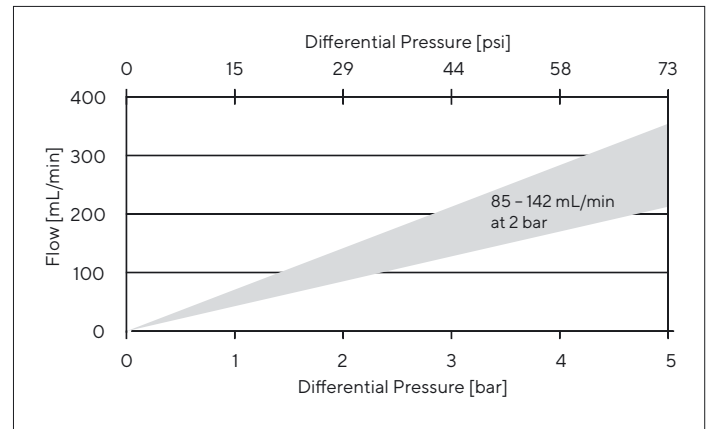Virosart® HF Process module (2.4 m² | 25.8 ft²)

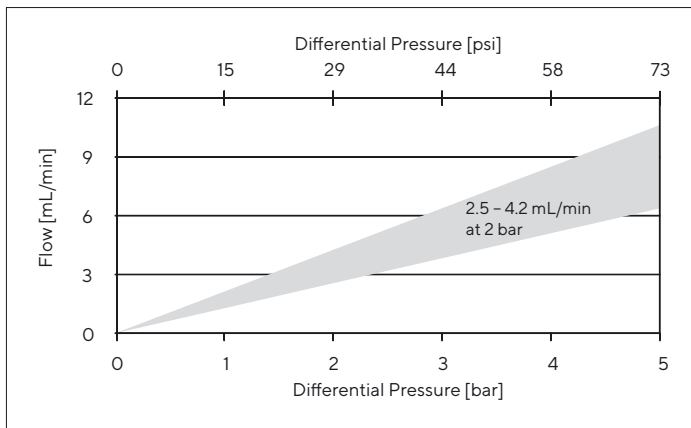Virosart® HF Process module (0.8 m² | 8.6 ft²)
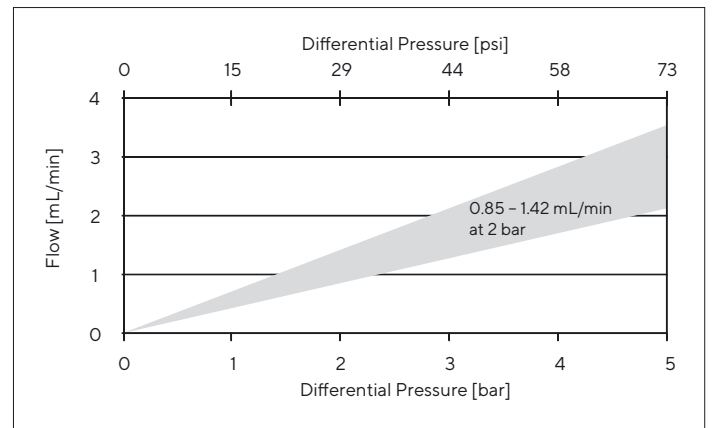

Virosart® HF Mid-Scale Module (0.2 m² | 2.15 ft²)

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
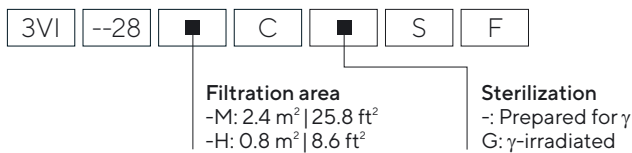- Non pyrogenic according to USP Bacterial Endotoxins

Technical References

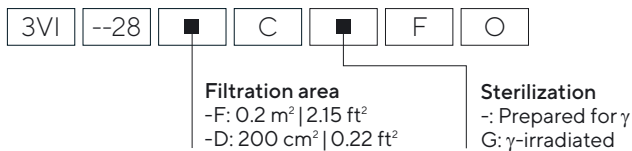|	
Validation Guide	SPK5801-e
Extractables Guide	SPK5804-e
Virus Information Guide	SPK5752-e
Application Note	Autoclaving Virosart® Minisart® devices (SPK4110-e)
	Impact of Pressure Release and Multiple Pressure Fluctuations on Virus Retention Performance, SPK4112-e
	Risk Mitigation for Calcium Chloride Solution, SPK4114-e
Publication	Virus Filtration Using a High Throughput Parvovirus Retentive Membrane; Roederstein/Thom, BioPharm International, Aug 2013

Ordering Information

Process Module

3VI	--28	■	C	■	S	F

Filtration area
-M: 2.4 m² | 25.8 ft²
-H: 0.8 m² | 8.6 ft²

Sterilization
-: Prepared for γ
G: γ-irradiated

Mid-Scale Module

3VI	--28	■	C	■	F	O

Filtration area
-F: 0.2 m² | 2.15 ft²
-D: 200 cm² | 0.22 ft²

Sterilization
-: Prepared for γ
G: γ-irradiated

Lab Module

3VI	--28	■	C	G	M	L	■	V

Filtration area
-B: 5.0 cm²
-T: 1.7 cm²

Sterilization
G: γ-irradiated

IT
IT: Integrity tested
--: Not integrity tested

Units per package
V: Two pieces
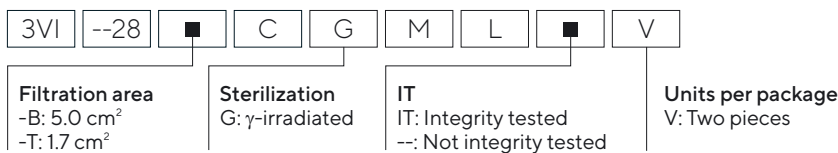
Accessories & Services

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
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

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