

Virosart® Media

Upstream Virus Retentive Filter



Product Information

Virosart® Media is especially designed for virus filtration of chemically defined cell culture media. This high speed virus filter provides you with an economical solution suitable for upstream media virus filtration. Effective and reliable virus removal is guaranteed by logarithmic reduction values of $\geq 4 \log_{10}$ for small non-enveloped viruses. Easy implementation into single-use processes is given by gamma irradiatable capsule designs.

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® Media targets the removal of small non-enveloped adventitious viruses (20 nm) e.g. MVM or VSV from chemically defined cell culture media.

Application & Positioning of

Virosart® Media

The main application for Virosart® Media is virus retentive filtration of chemically defined cell culture media.

Virosart® Media is used after the media preparation step itself before transferring the media into the bioreactor.

This can be operated either as in-line filtration (e.g. perfusion) or batch filtration. Performance of the Virosart® Media is independent of the use of powder or liquid media but could be strongly impacted by the media itself.

Virosart® Media is optimized for chemically defined media. Protein transmission for mAbs and recombinant proteins is not given for this filter.

Additives like poloxamere can have an impact on the filter performance. An efficient pre-filtration step, such as the Sartopore® 2 XLM, could increase the capacity of the final virus filter. The optimum pre-filter to final filter ratio has to be identified during development of the process step as this strongly depends on the specific media used.

Product Benefits

Virosart® Media provides effective viral risk mitigation to the process as it is qualified for logarithmic reduction values of $\geq 4 \log_{10}$ for small non-enveloped viruses (e.g. MVM) and $\geq 6 \log_{10}$ for large enveloped viruses (e.g. MuLV). Based on the optimized Polyethersulfone membrane, Virosart® Media provides highest flow rates and excellent capacity for cell culture media (e.g. $\geq 1000 \text{ L/m}^2$ in 4 h).

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.

Integrity Testing

Virosart® Media is tested for integrity using a water-based diffusion test, e.g. the Sartocheck® technology of Sartorius. Virosart® Media 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® Media.

Technical Data



	Lab & IT-Tested Lab Module	Mid-Scale Module	Process Module
Nominal filtration area	5.0 cm ²	0.3 m ² 3.2 ft ²	1.0 m ² 10.8 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 Growth studies Small scale production 	<ul style="list-style-type: none"> Large scale manufacturing
Typical filtration volume	≤ 1 L	< 500 L	< 1000 L
Delivery status	<ul style="list-style-type: none"> Sterile (g-irradiated) 	<ul style="list-style-type: none"> Sterile (γ-irradiated) Non-sterile (γ-irradiatable) 	<ul style="list-style-type: none"> Sterile (γ-irradiated) Non-sterile (γ-irradiatable)
Available connectors	<ul style="list-style-type: none"> Inlet, outlet & vent: Luer lock 	<ul style="list-style-type: none"> Inlet & vent: ¾" sanitary connector Outlet: ¾" hose barb 	<ul style="list-style-type: none"> Inlet & vent: 1½" sanitary connector Outlet: ¾" 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. 1.0 bar 14.6 psi, 20 °C 		
Water based diffusion test at 4.5 bar 65.25 psi	N A	<ul style="list-style-type: none"> 10 mL/min 	<ul style="list-style-type: none"> 30 mL/min

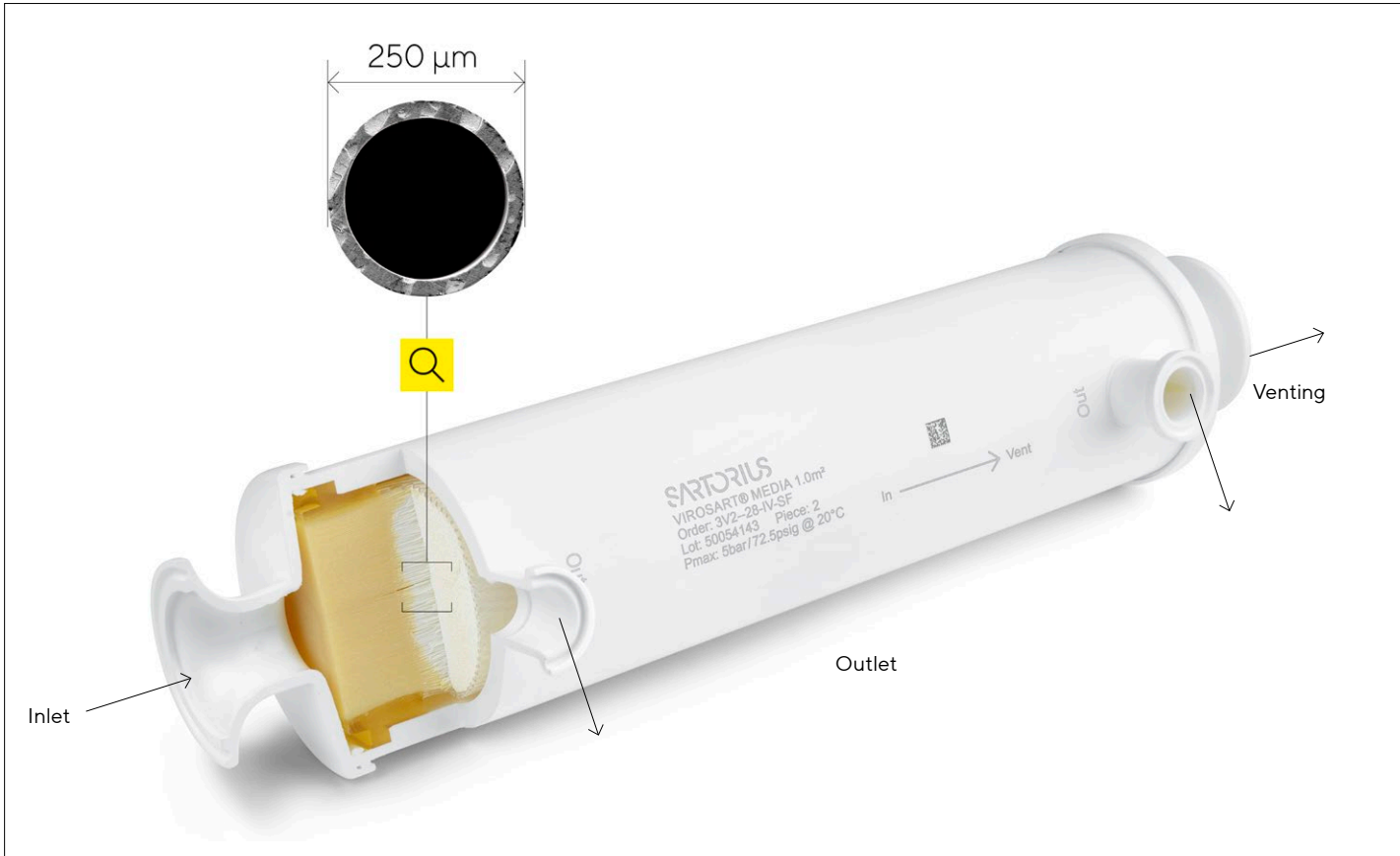
Note. Mid-scale and process-scale modules are additionally also available as virus filter transfer units. They are delivered pre-assembled and sterile (γ-irradiated). Learn more about Virus Filter Transfer Units in the [datasheet](#).

Materials

Process & Mid-Scale Module	
Resin	Polyurethane
Housing	Polypropylene
Protective sleeving	Polyamide
End caps	Polypropylene

Lab Module	
Resin	Polyurethane
Housing	Polycarbonate
Protective sleeving	Non

Membrane	
Material	Polyethersulfone
Pore size	20 nm nominal
Format	Hollow fiber



Performance

Retention

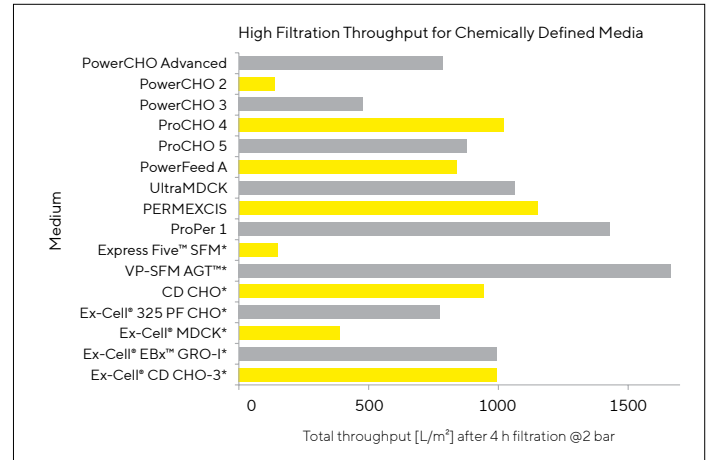
Retention of small non-enveloped viruses e.g. MVM exceeds 4 log₁₀. Duplicate runs were performed at 2.0 bar | 30 psi constant pressure with 5.0 cm² lab modules for 3 different media.

Organism	Description	Media	LRV Run 1	LRV Run 2
MVM	Model virus for small non-enveloped virus	KPI buffer	≥ 5.22	≥ 4.22
		ProCHO 5	≥ 4.98	≥ 4.98
		EXCell® CD CHO-3*	≥ 5.04	≥ 4.98

* EXCell® is a trademark of Merck KGaA; Express Five™ SFM, Gibco™ CD CHO and VP SFM AGT™ are trademarks of Life Technologies Corporation

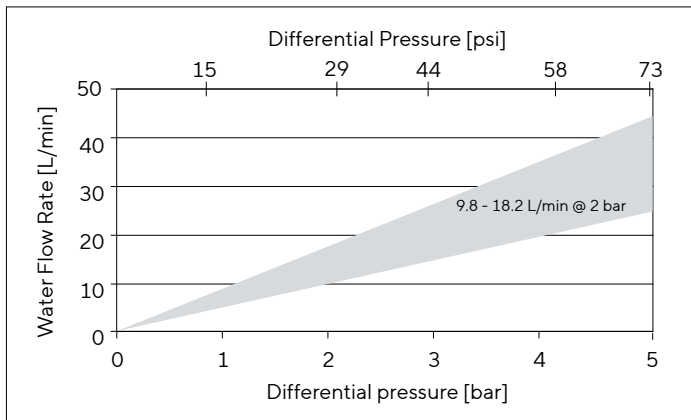
Throughput with Cell Culture Media

The total throughput within 4 hours filtration time tested with 16 cell culture media at constant pressure of 2.0 bar | 30 psi with 5.0 cm² lab module, reaching average capacities of 800 - 1000 L/m² in 4 h.



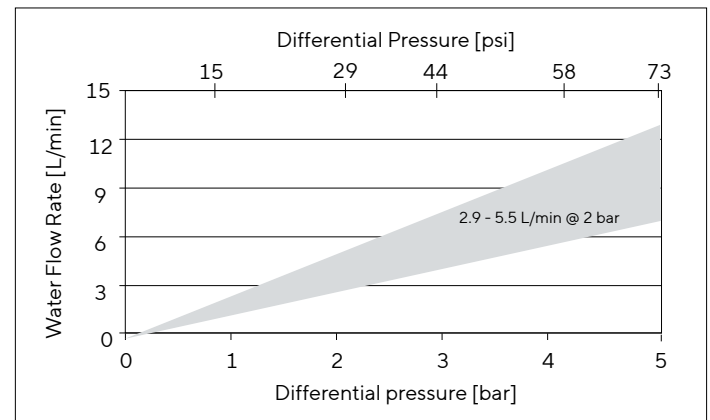
Water Flow Rate

Virosart® Media Process Module (1.0 m² | 10.8 ft²)



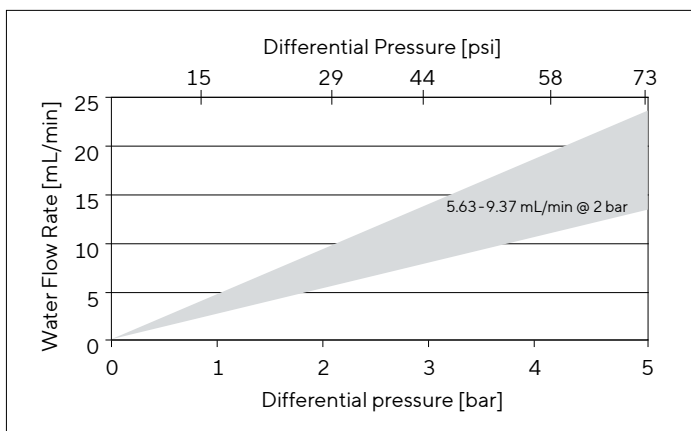
The water flow rate for the Virosart® Media process modules 1.0 m² is 420 LMH/bar ±30%, 25 °C.

Virosart® Media Mid-Scale Module (0.3 m² | 3.2 ft²)



The water flow rate for the Virosart® Media mid-scale modules 0.3 m² is 420 LMH/bar ±30%, 25 °C.

Virosart® Media Lab Module (5.0 cm²)



Due to the shorter fiber length in the Virosart® Media lab module, the water flow rate is 450 LMH/bar ±25%, 25 °C.

Regulatory Compliance

- Each individual module is tested for integrity (except 3V2--28-BVGML--V) and for water flow rate 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
- USP Plastic Class Test VI

Technical References

Validation Guide	SPK5812-e
Extractables Guide	1000053210
Publication	Virus Risk Mitigation in Cell Culture Media, Manzke/Kleindienst, BioPharm International, October 2016

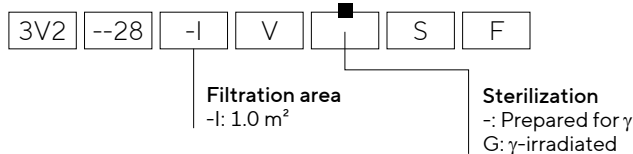
Application Notes

- Evaluating the Filterability of Chemically Defined Cell Culture Media (SPK4115-e)
- Retention Characteristics when filtering Chemically Defined Cell Culture Media (SPK4116-e)
- Influence of Cell Culture Media Components on the Filtration Characteristics (SPK4118-e)
- Evaluation of Impact on Cell Growth using Chemically defined Cell Culture Media (SPK4117-e)
- Risk Mitigation for Calcium Chloride Solution (SPK4114-e)
- Evaluating Lot-to-Lot Performance Consistency of Chemically Defined Cell Culture Media during filtration with the Virosart® Media Filter (1000053370)
- Evaluating the Robustness of Virus Clearance under Challenging Filtration Conditions using the Virosart® Media Filter (1000053359)

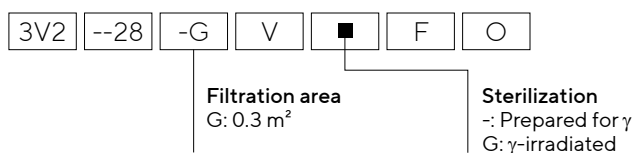
Ordering Information



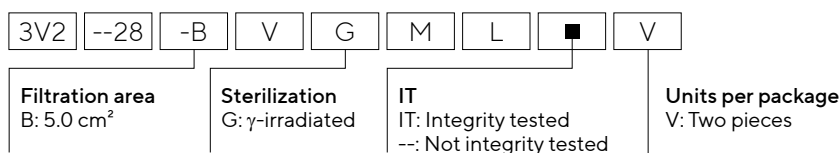
Process Module



Mid-Scale Module



Lab Module



Accessories & Services

Pre-Filtration

Sartopore® 2 XLM increases the capacity on the Virosart® Media. In addition it is providing sterile filtrate from Brev. Dim. and Mycoplasma. The filter 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

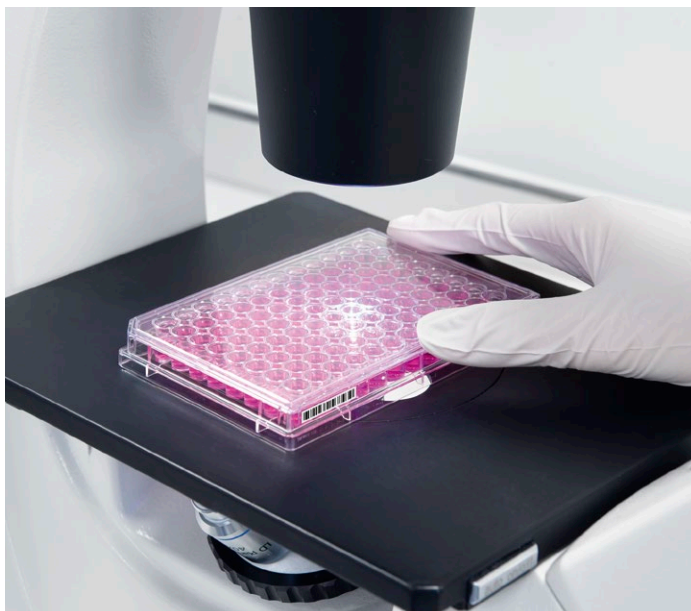
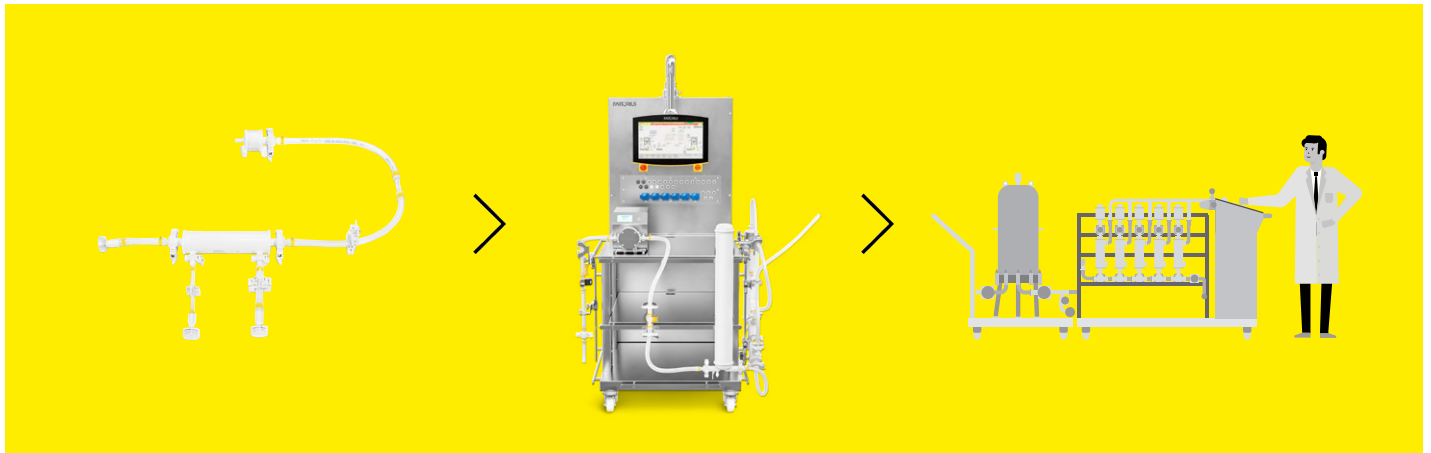
Simplify your daily routine work by using modular filter assembly.

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

Our virus clearance service is the perfect complement to Virosart® HF filters, providing:

- GLP virus clearance studies
- Process design support
- Optimization support

We use a variety of different relevant and model viruses including MVM, MuLV, Reo-3 and PRV. 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 process by MCB | WCB characterization and bulk harvest testing.

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