



# 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 virus media filtration. Highest safety for your process is guaranteed by  $\geq 4$  LRV for small non-enveloped viruses. Easy implementation into single-use processes is given by gamma irradiatable capsules designs.



### Description

Sartorius is your partner to assure virus safety for the entire production process. Summarizing MCB | WCB (Master cell bank | Working cell bank) characterization, virus retention of chemically defined media, bulk harvest testing and spiking study service for the orthogonal virus clearance platform from Sartorius consisting of virus filtration, virus inactivation and virus adsorption. 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 vesivirus 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 – 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 high virus safety to the bioreactor as it is qualified for  $\geq 4$  LRV ( $\text{Log}_{10}$  reduction value) of small non-enveloped viruses (e.g. MVM) and  $\geq 6$  LRV for large enveloped viruses. 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 Test

Virosart® Media is tested for integrity using a water-based integrity test, e.g. the Sartocheck® technology of Sartorius. Virosart® Media filters have been validated for 4  $\text{log}_{10}$  removal of 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
			
<b>Nominal filtration area</b>	5.0 cm <sup>2</sup>	0.3 m <sup>2</sup>   3.2 ft <sup>2</sup>	1.0 m <sup>2</sup>   10.8 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 version)</li> </ul>	<ul style="list-style-type: none"> <li>– Scale-up studies</li> <li>– Growth 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>	≤ 1 L	< 500 L	< 1000 L
<b>Delivery status</b>	<ul style="list-style-type: none"> <li>– Sterile (γ-irradiated)</li> </ul>	<ul style="list-style-type: none"> <li>– Sterile (γ-irradiated)</li> <li>– Non-sterile (γ-irradiated in single-use assembly)</li> </ul>	<ul style="list-style-type: none"> <li>– Non-sterile (γ-irradiated in single-use assembly)</li> </ul>
<b>Available connectors</b>	<ul style="list-style-type: none"> <li>– Inlet, outlet &amp; vent: Luer lock</li> </ul>	<ul style="list-style-type: none"> <li>– Inlet &amp; vent: 3/4" sanitary connector</li> <li>– Outlet: Hose-barb</li> </ul>	<ul style="list-style-type: none"> <li>– Inlet &amp; vent: 1 1/2" sanitary connector</li> <li>– Outlet: 3/4" sanitary connector</li> </ul>
<b>Operating parameters</b>	<ul style="list-style-type: none"> <li>– In the direction of filtration: max. 5.0 bar   73 psi, 20°C</li> <li>– In the reversed direction of filtration: max. 1.0 bar   14.6 psi, 20°C</li> </ul>		
<b>Water based diffusion test at 4.5 bar   65.25 psi</b>	N   A	– 10 mL/min	– 30 mL/min

## Materials

### Process & Mid-Scale Module

**Resin**  
Polyurethane

**Housing**  
Polypropylene

**Protective sleeving**  
Polyamide

**End caps**  
Polypropylene

### Lab Module

**Resin**  
Polyurethane

**Housing**  
Polycarbonate

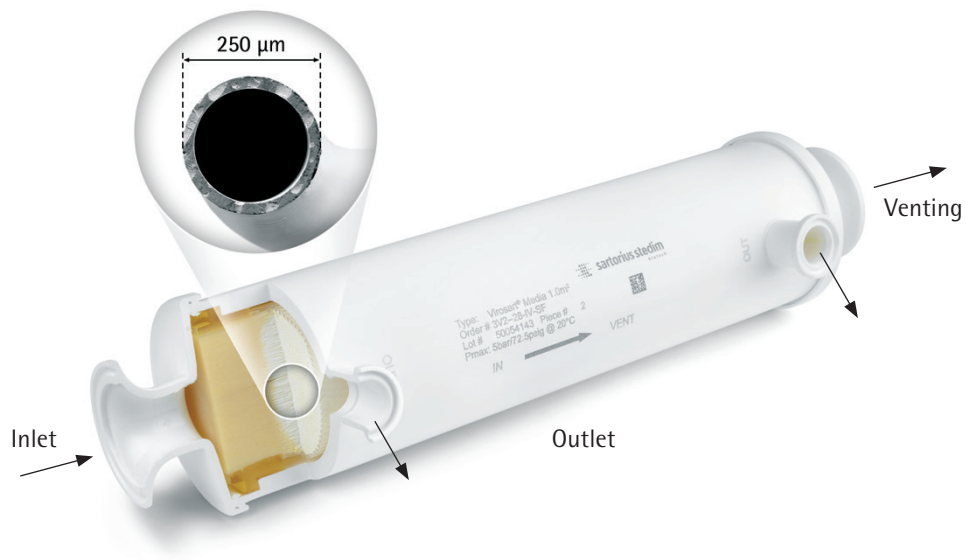
**Protective sleeving**  
Non

### Membrane

**Material**  
Polyethersulfone

**Pore size**  
20 nm nominal

**Format**  
Hollow fiber



# Performance

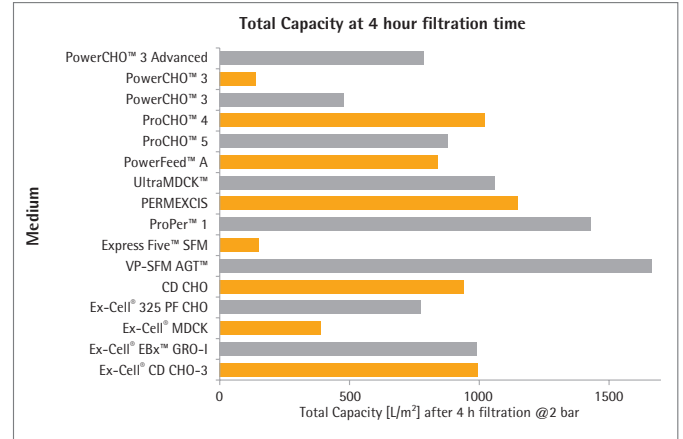
## Retention

Retention of small non-enveloped viruses e.g. MVM exceeds 4 LRV. Duplicate runs were performed at 2.0 bar | 30 psi constant pressure with 5.0 cm<sup>2</sup> 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
		SAFC EXCell® CD CHO-3	≥ 5.04	≥ 4.98

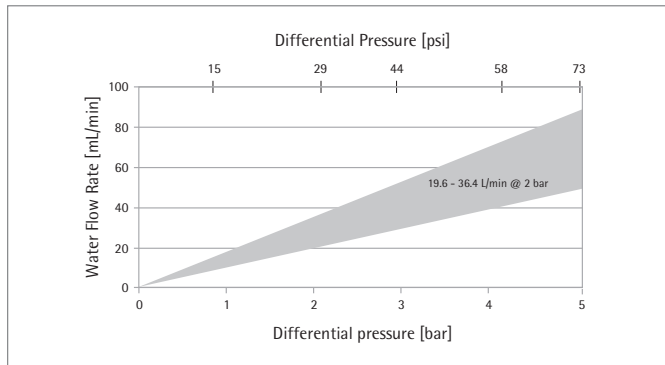
## Capacity with CCM

The total capacity within 4 hours filtration time tested with 16 cell culture media at constant pressure of 2.0 bar | 30 psi with 5.0 cm<sup>2</sup> lab module, reaching average capacities of 800 – 1000 L/m<sup>2</sup> in 4 h.



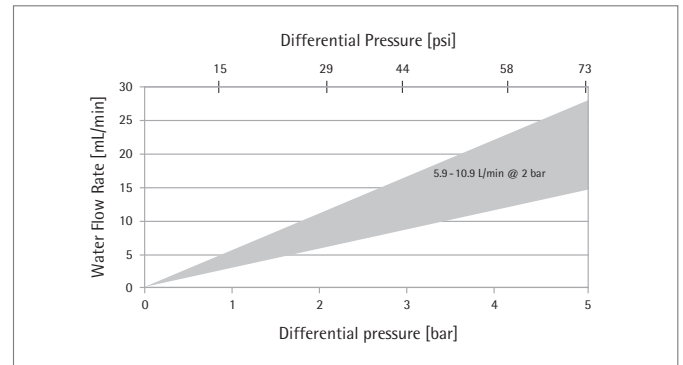
## Water Flow Rate

### Virosart® Media Process Module (1.0 m<sup>2</sup> | 10.8 ft<sup>2</sup>)



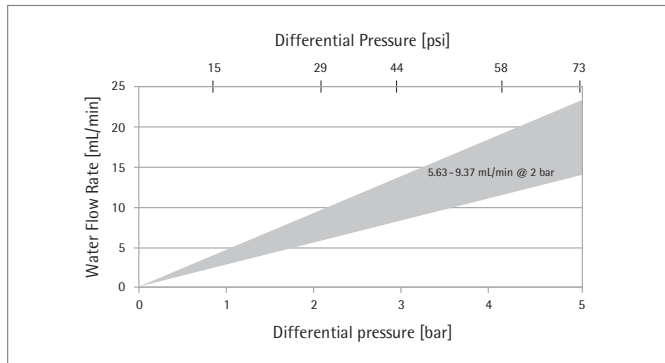
The water flow rate for the Virosart® Media process modules 1.0 m<sup>2</sup> is 420 LMH/bar ± 30%, 25°C.

### Virosart® Media Mid-Scale Module (0.3 m<sup>2</sup> | 3.2 ft<sup>2</sup>)



The water flow rate for the Virosart® Media mid-scale modules 0.3 m<sup>2</sup> is 420 LMH/bar ± 30%, 25°C.

### Virosart® Media Lab Module (5.0 cm<sup>2</sup>)



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  $\geq 4$  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	SPK5812-e
Extractables Guide	tbd
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)

## Ordering Information



### Process Module

3V2 --28 -I V - S F

Filtration area  
-I: 1.0 m<sup>2</sup>

Sterilization  
-: Prepared for  $\gamma$



### Mid-Scale Module

3V2 --28 -G V F O

Filtration area  
G: 0.3 m<sup>2</sup>

Sterilization  
-: Prepared for  $\gamma$   
G:  $\gamma$ -irradiated



### Lab Module

3V2 --28 -B V G M L V

Filtration area  
B: 5.0 cm<sup>2</sup>

Sterilization  
G:  $\gamma$ -irradiated

IT  
IT: Integrity tested  
--: Not integrity tested

Units per package  
V: Two pieces

## Accessories & Services

### Pre-Filtration

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



### Ready-to use Filter Transfer Sets

Simplify your daily routine work by using modular filter assembly.



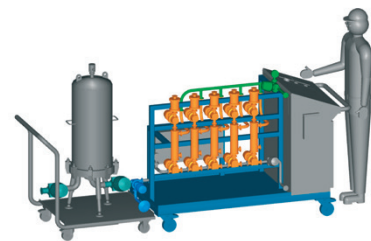
### Single-use Systems

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 relegated by customized single-use or hybrid solutions.



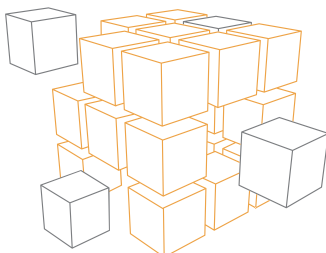
### Testing Service

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.



Sartorius Stedim Biotech GmbH  
August-Spindler-Strasse 11  
37079 Goettingen, Germany  
Phone +49.551.308.0  
www.sartorius-stedim.com

USA Toll-Free +1.800.368.7178  
Argentina +54.11.4721.0505  
Brazil +55.11.4362.8900  
Mexico +52.55.5562.1102  
UK +44.1372.737159  
France +33.442.845600  
Italy +39.055.63.40.41  
Spain +34.913.586.098  
Russian Federation +7.812.327.53.27  
Japan +81.3.4331.4300  
China +86.21.6878.2300

Specifications subject to change without notice.  
Copyright Sartorius Stedim Biotech GmbH. Printed  
in the EU on paper bleached without chlorine.  
Publication No.: SPK2171-e180102  
Order No.: 85037-559-36  
Ver. 01 | 2018