SARTORIUS

Product Datasheet

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. Highest safety for your process is guaranteed by logarithmic reduction values of ≥ 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 high virus safety to the bioreactor as it is qualified for logarithmic reduction values of ≥ 4 $\log_{10}$ for small non-enveloped viruses (e.g. MVM) and ≥ 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. ≥ 1000 L/m² 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 ≥ 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

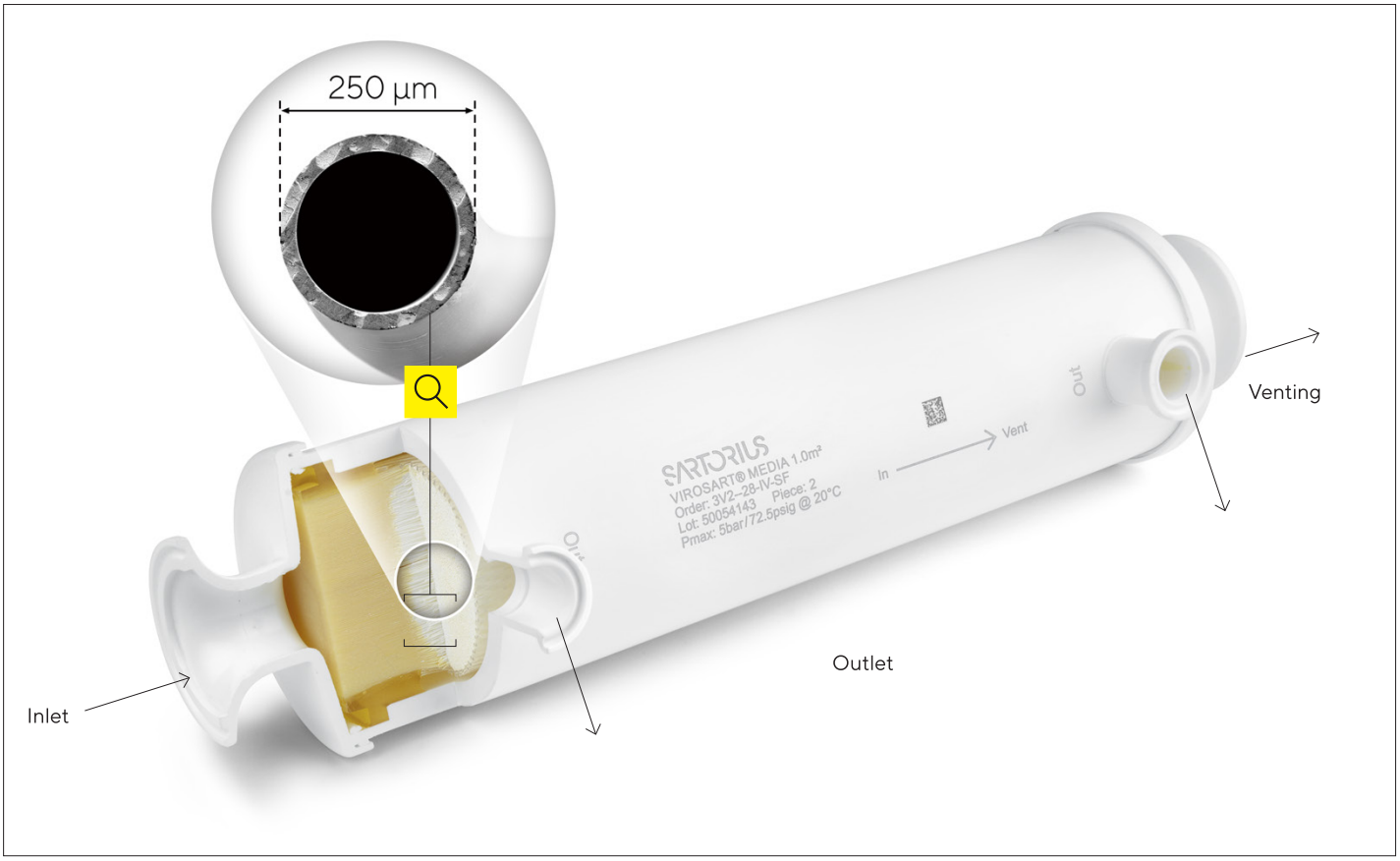
	Lab & IT-Tested Lab Module	Mid-Scale Module	Process Module
Nominal filtration area	5.0 cm^2	0.3 m^2 | 3.2 ft^2	1.0 m^2 | 10.8 ft^2
To be used for	▪ Scale-down work ▪ Flow & capacity studies ▪ Optimization of pre-filter- | final-filter-ratio ▪ GLP spiking studies (IT tested version)	▪ Scale-up studies ▪ Growth studies ▪ Small scale production	▪ Large scale manufacturing
Typical filtration volume	≤ 1 L	< 500 L	< 1000 L
Delivery status	▪ Sterile (γ-irradiated)	▪ Sterile (γ-irradiated) ▪ Non-sterile (γ-irradiated in single-use assembly)	▪ 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. 1.0 bar | 14.6 psi, 20°C		
Water based diffusion test at 4.5 bar | 65.25 psi	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	Polyetersulfone
Pore size	20 nm nominal
Format	Hollow fiber

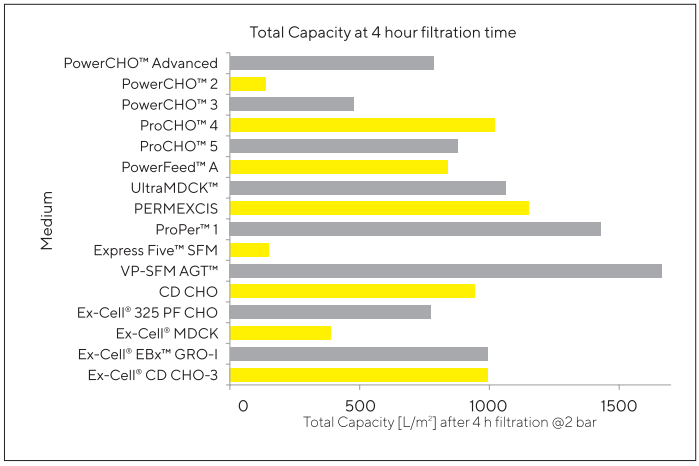


Performance

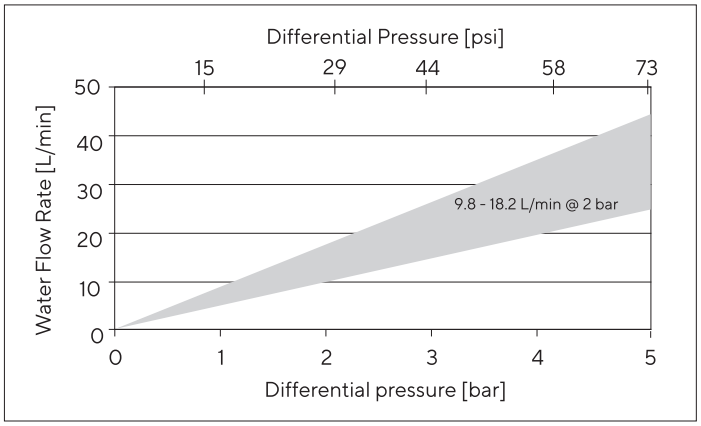
Retention
Retention of small non-enveloped viruses e.g. MVM exceeds 4 $\log_{10}$. Duplicate runs were performed at 2.0 bar | 30 psi constant pressure with 5.0 cm^2 lab modules for 3 different media.

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^2 lab module, reaching average capacities of 800 – 1000 L/m^2 in 4 h.

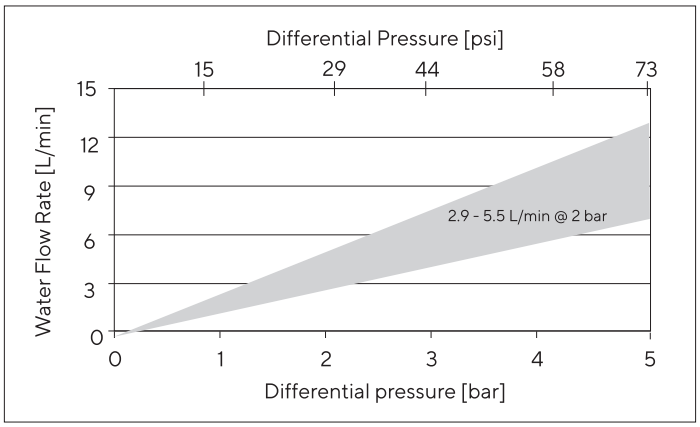


Water Flow Rate
Virosart® Media Process Module (1.0 m^2 | 10.8 ft^2)



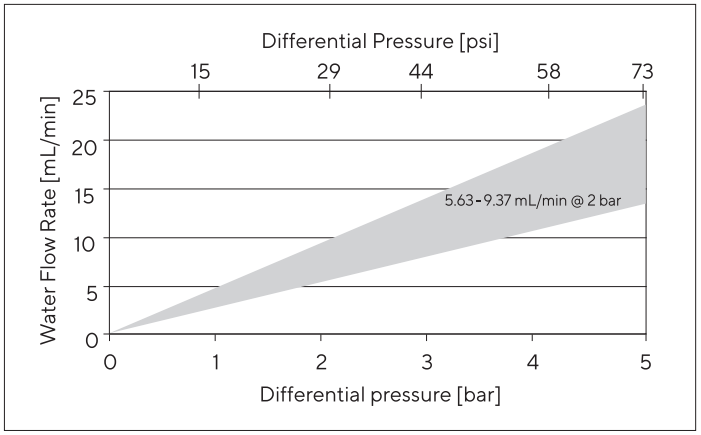
The water flow rate for the Virosart® Media process modules 1.0 m^2 is 420 LMH/bar ± 30%, 25°C.

Virosart® Media Mid-Scale Module (0.3 m^2 | 3.2 ft^2)



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

Virosart® Media Lab Module (5.0 cm^2)



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 ≥ 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

3V2	--28	-I	V	-	S	F

Filtration area
-I: 1.0 m^2

Sterilization
-: Prepared for γ

Mid-Scale Module

3V2	--28	-G	V	■	F	O

Filtration area
G: 0.3 m^2

Sterilization
-: Prepared for γ
G: γ-irradiated

Lab Module

3V2	--28	-B	V	G	M	L	■	V

Filtration area
B: 5.0 cm^2

Sterilization
G: γ-irradiated

IT
IT: Integrity tested
--: Not integrity tested

Units per package
V: Two pieces

Accessories & Services

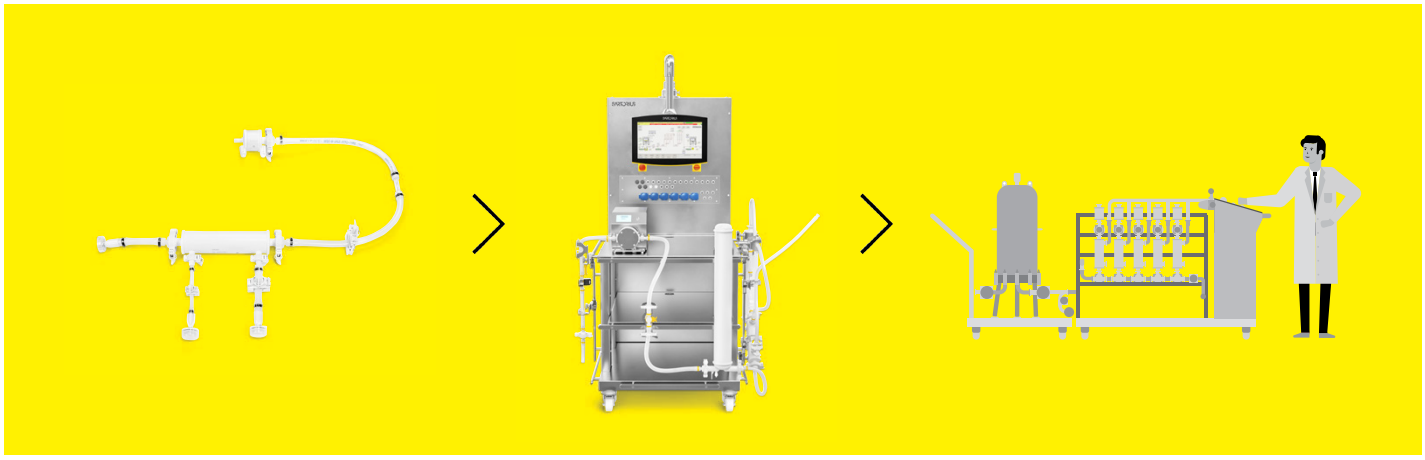
Pre-Filtration
Sartopore® 2 XLM increases the capacity on the Virosart® Media. In addition it is providing sterile filtrate from Brev. Dim. and Mycoplasma. The filter will downsize your process and reduce your total virus filtration costs.

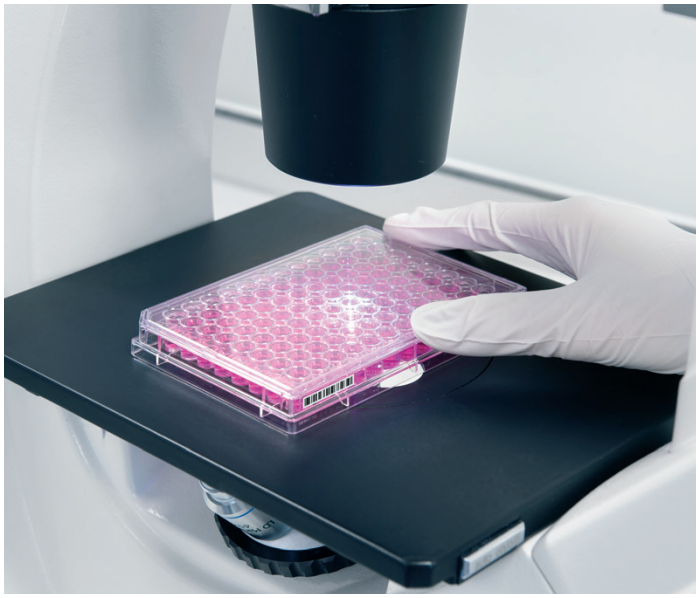
Integrity Testing using Sartocheck®
Fully automated Virosart® integrity testing to guarantee intactness of the Virosart® filter applying pre- and post-use diffusion tests.

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 are the perfect complement to Virosart® Media 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 virus safety for your process by MCB | WCB characterization, bulk harvest testing.

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