



Virosart® CPV

The virus filter for robust and efficient removal of all viruses

Product Information

Virosart® CPV is a well established virus retentive filter within the monoclonal antibody market. The unique asymmetric PES membrane structure provides highest virus retention under all circumstances independent from operation pressure or pressure pauses.



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 ranges includes four different virus retentive membranes, in order to provide the best solution for every application. Virosart® CPV 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 a biopharmaceutical feed stream.

Application & Positioning

The main applications for Virosart® CPV for virus filtration are monoclonal antibodies (mAb), antibody fragments (Fab) or small recombinant proteins (< 150 kD). Virosart® CPV 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® CPV membrane. The optimum pre-filter – final filter ratio has to be identified during development of the process step.

Product Benefits

Virosart® CPV provides high virus safety to the biopharmaceutical product. Based on the unique double layer 20 nm PES membrane, Virosart® CPV provides excellent flow rates and excellent capacity. This filter retains ≥ 4 LRV (\log_{10} reduction value) 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 independent of operating pressure or pressure pauses.

Integrity Testing

Virosart® CPV filters are tested for integrity using a water based diffusion test, e.g. based on the Sartocheck® technology of Sartorius. Virosart® CPV filters have been validated for ≥ 4 LRV of small non-enveloped viruses using bacteriophage PP7 as the model virus. Validation data is shown in the validation guide of Virosart® CPV.

*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

Minisart®



Capsule & MidiCaps®



MaxiCaps® & Cartridge



Nominal filtration area	5.0 cm ²	180 cm ² 0.19 ft ²	0.2 m ² 2.15 ft ²	0.7 m ² , 1.4 m ² , 2.1 m ² 7.5 ft ² , 15 ft ² , 22.6 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 Minisart®) 	<ul style="list-style-type: none"> – Scale-up studies – Small scale production 	<ul style="list-style-type: none"> – Large scale manufacturing 	
Typical filtration volume	< 200 mL	< 5 L	< 80 L	≥ 80 L
Available connectors	<ul style="list-style-type: none"> – Female luer lock inlet & male luer lock outlet 	<ul style="list-style-type: none"> – MidiCaps® & Capsule: 3/4" triclamp (sanitary) connector inlet & outlet – Capsule: 1/2" hose barb connector inlet & outlet 	<ul style="list-style-type: none"> – MaxiCaps®: Sanitary inlet & outlet adapter – Cartridges: S-adapter top, 2 flange bayonet adapter with double o-ring bottom 	
Sterilization	<ul style="list-style-type: none"> – Autoclaving: 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles <p>⚠ No inline steaming of Minisart®</p>	<ul style="list-style-type: none"> – Autoclaving: 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles <p>⚠ No inline steaming of MidiCaps® & Capsule</p>	<ul style="list-style-type: none"> – MaxiCaps®: Autoclaving 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles <p>⚠ No inline steaming of MaxiCaps®</p> <ul style="list-style-type: none"> – Cartridges: Steaming 121°C @ 2.0 bar 29 psi for 30 min up to 2 cycles 	
Operating parameters	<ul style="list-style-type: none"> – In the direction of filtration: max. 5.0 bar 72.5 psi at 20°C, max. 0.2 bar 2.9 psi at 121°C – In the reversed direction of filtration: max. 0.2 bar 2.9 psi at 20°C, max. 0.05 bar 0.7 psi at 121°C 			
Water based diffusion test at 4.5 bar 65.25 psi	N/A	<ul style="list-style-type: none"> – 2 mL/min (180 cm²) – 10 mL/min (0.2 m²) 	<ul style="list-style-type: none"> – 22 mL/min (0.7 m²) – 44 mL/min (1.4 m²) – 66 mL/min (2.1 m²) 	

Materials

Device

Cartridges, T-Style MaxiCaps®,
Capsules & MidiCaps®

Supportive fleece
Polypropylene

Capsule housing
Polypropylene

End caps
Polypropylene

Core (not capsule)
Polypropylene

Minisart®

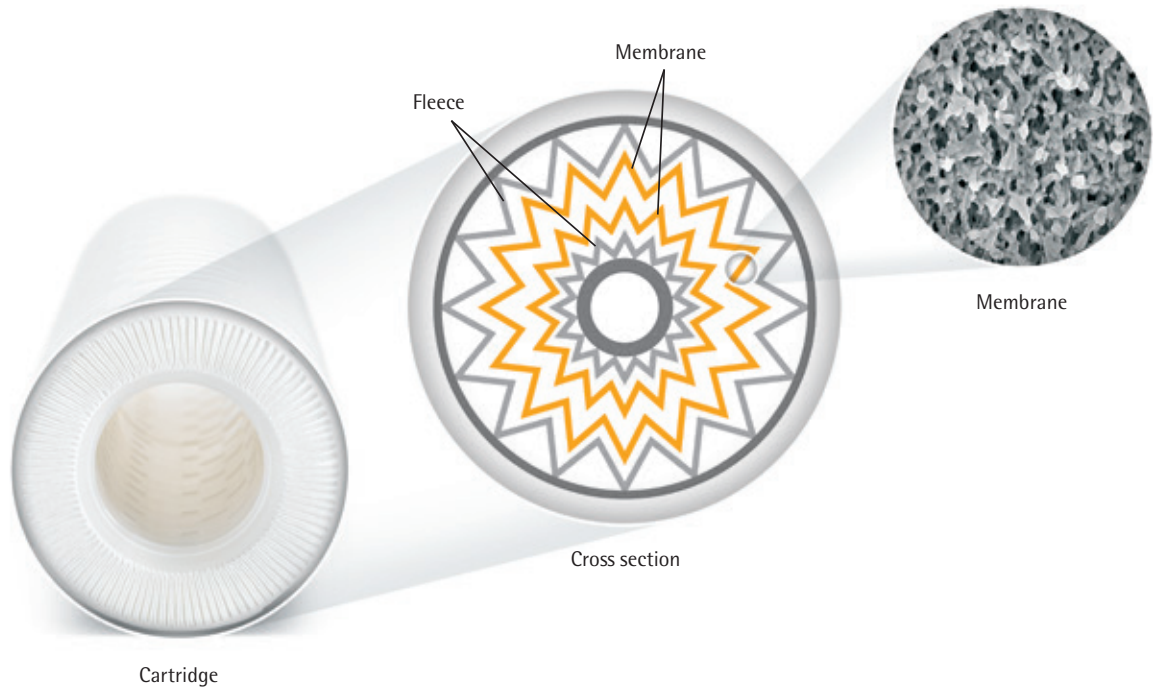
Capsule housing
Polycarbonate

Membrane

Material
Polyethersulfone

Pore size
20 nm nominal

Format
Double layer

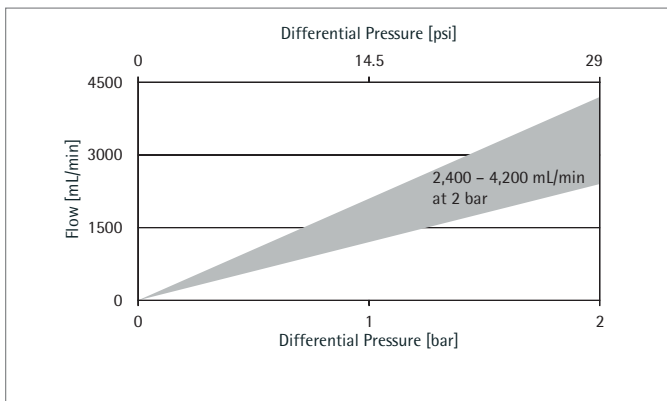


Construction of Virosart® CPV cartridge and capsule with zoom on cross section and membrane

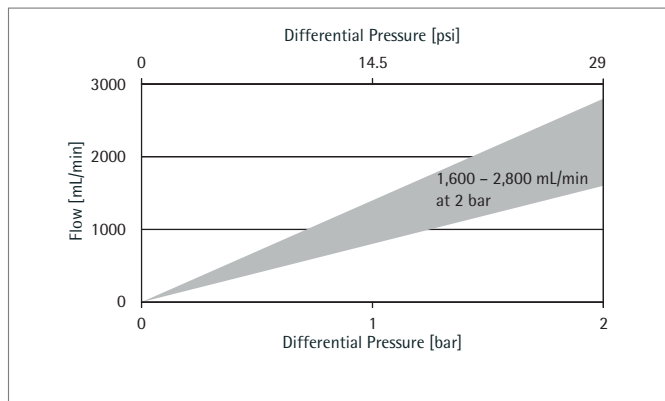
Performance

Characteristic Water Flow Rates

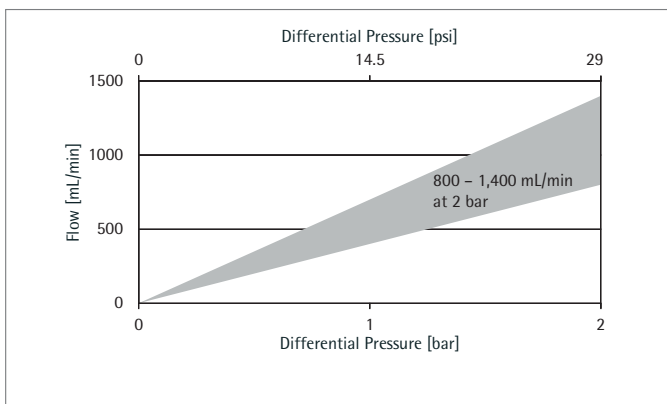
Virosart® CPV 30" Cartridge & 30" MaxiCaps® (2.1 m² | 22.5 ft²)



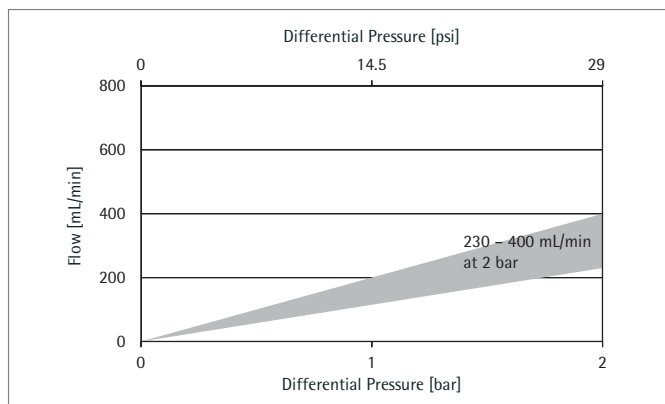
Virosart® CPV 20" Cartridge & 20" MaxiCaps® (1.4 m² | 15 ft²)



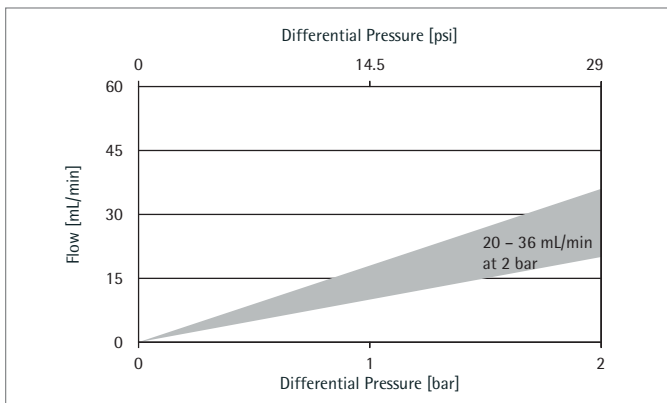
Virosart® CPV 10" Cartridge & 10" MaxiCaps® (0.7 m² | 7.5 ft²)



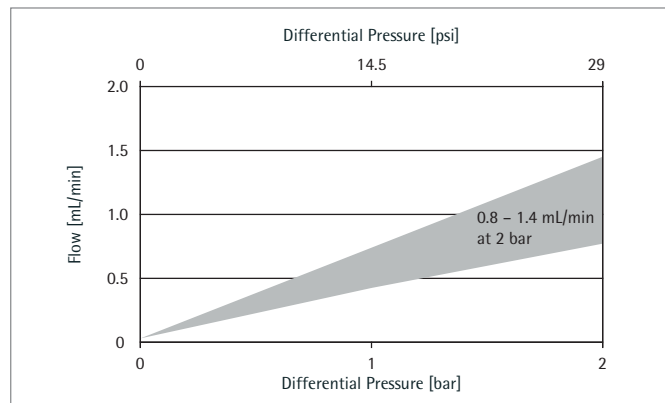
Virosart® CPV MidiCaps® (0.2 m² | 2.1 ft²)



Virosart® CPV Capsule (180 cm² | 0.19 ft²)



Virosart® CPV Minisart® (5 cm²)



Regulatory Compliance

- Each individual filter is tested for integrity (except 545VM-----B)
- 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
- USP Plastic Class Test VI

Technical References

Validation Guide	SPK5754-e
Extractables Guide	SPK5773-e
Virus Information Guide	SPK5752-e
Application Note	<ul style="list-style-type: none"> – Impact of Pressure Release on Virus Retention Performance (SPK4111-e) – Effect of Flux Decay on Virus Retention (SPK4109-e) – Autoclaving Virosart® Minisart® devices (SPK4110-e)

Ordering Information



Cartridge

545 25 28

Adapter
25: S-adapter top, 2 flange bayonet adapter with double o-ring bottom

Filter size
V1: 10" 0.7 m² | 7 ft²
V2: 20" 1.4 m² | 14 ft²
V3: 30" 2.1 m² | 21 ft²



MaxiCaps®

545 73 28 -- SS

Filter size
V1: 10" 0.7 m² | 7 ft²
V2: 20" 1.4 m² | 14 ft²
V3: 30" 2.1 m² | 21 ft²

Adapter
SS: Sanitary inlet – and outlet adapter



MidiCaps®

545 53 28 V9 -- FF -- V

Filter size
V9: Size 9 0.2 m² | 2 ft²

Adapter
FF: 3/4" triclamp (sanitary) connector inlet & outlet

Units per package
V: Two pieces



Capsule

545 13 28 V4 -- -- B

Filter size
V4: Size 4 180 cm² | 0.19 ft²

Adapter
FF: 3/4" triclamp (sanitary) connector inlet & outlet
OO: 1/2" hose barb connector inlet & outlet

Units per package
B: Five pieces



Minisart®

545 VM -- -- -- -- --

Units per package
A: Four pieces
B: Five pieces

IT: Integrity tested
--: Not integrity tested

Accessories & Services

Adaptive Pre-Filtration

Virosart® Max* protects whatever virus filter you choose irrespective of 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 pre- and post diffusion test.



Filter Holders and Housing

Filter holders are designed to accommodate all different MaxiCaps® heights. Different standard designs of filter housings are available for cartridges from 10" to 30".



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 systems.



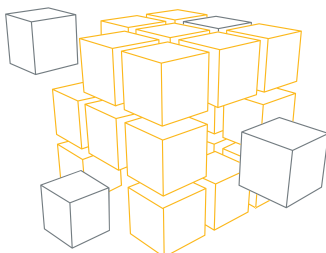
Testing Service

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.



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