

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. Flexibility is given by using either cartridges in existing stainless steel housings or disposable capsules.

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® 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) and small recombinant proteins (< 150 kDa).

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 probability of virus filter blockage due to contaminants (DNA, CHOP, aggregates and lipoproteins) is the lowest. Although 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 to final filter ratio has to be identified during development of the process step.

Product Benefits

Virosart® CPV provides efficient virus removal to the biopharmaceutical product. Based on the unique double layer 20 nm PES membrane, Virosart® CPV provides excellent flow rates and excellent capacity.

Virosart® CPV retains $\geq 4 \log_{10}$ of small non-enveloped viruses (e.g. PPV, MVM) and $\geq 6 \log_{10}$ of large enveloped viruses (e.g. MuLV). This filter offers excellent virus retention over the entire flow decay profile independently of operating pressure.

Customized process-specific virus LRV determination can be individually provided by our Confidence® Virus Clearance Services (see page 7 for details).

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 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® 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 & Micaps® | | 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"> Micaps® & Capsules: FF: ¾" triclamp (sanitary) connector inlet & outlet Capsules: OO: ½" 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 Capsule & Micaps®</p> | <ul style="list-style-type: none"> Maxicaps® Cartridges: 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, Maxicaps®, Capsules & Midicaps®

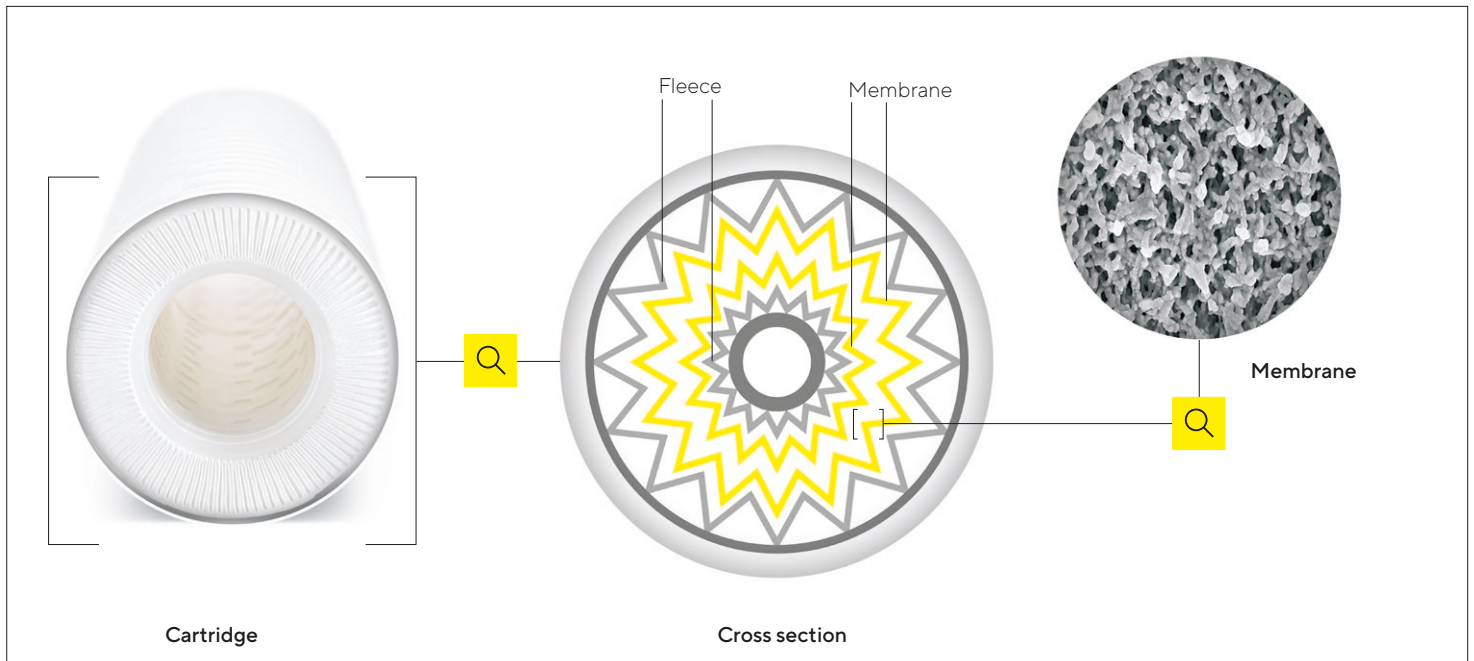
| | |
|--------------------|---------------|
| Supportive fleece | Polypropylene |
| Capsule housing | Polypropylene |
| End caps | Polypropylene |
| Core (not capsule) | Polypropylene |

Membrane

| | |
|-----------|------------------|
| Material | Polyethersulfone |
| Pore size | 20 nm nominal |
| Format | Double layer |

Minisart®

| | |
|-----------------|---------------|
| Capsule housing | Polycarbonate |
|-----------------|---------------|

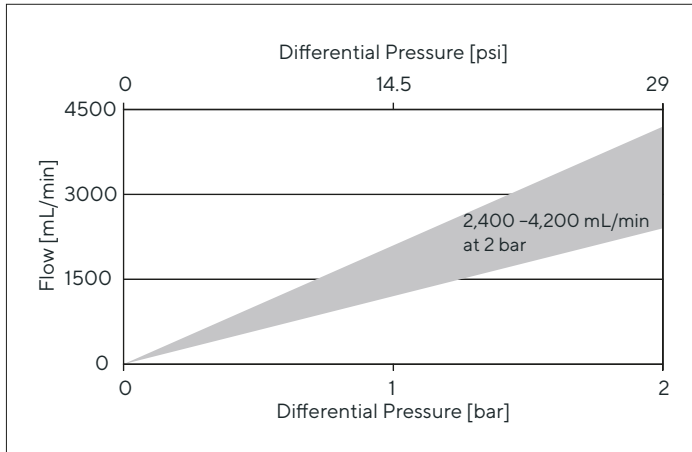


Construction of Virosart® CPV cartridge and capsule with zoom on cross section and membrane.

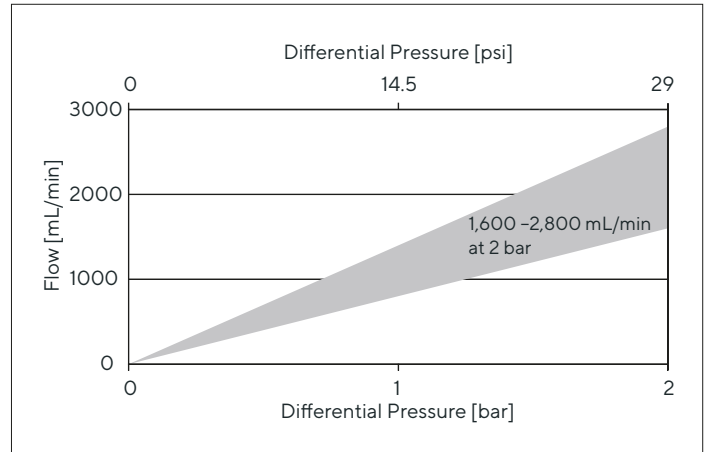
Performance

Characteristic Water Flow Rates

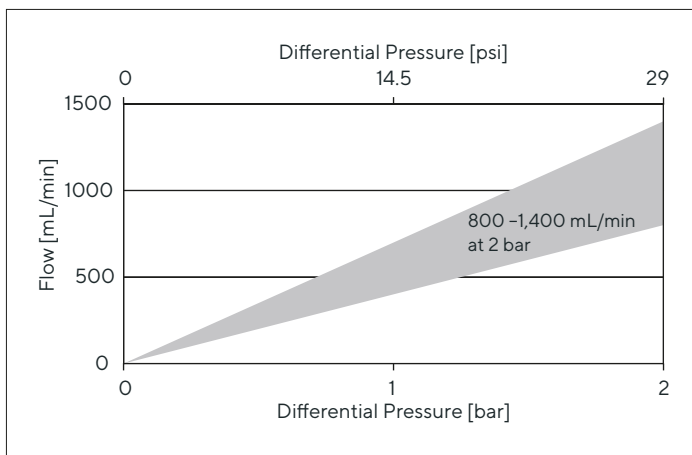
Virosart® CPV 30" Cartridge & 30" Maxicaps® (2.1 m² | 22.6 ft²)



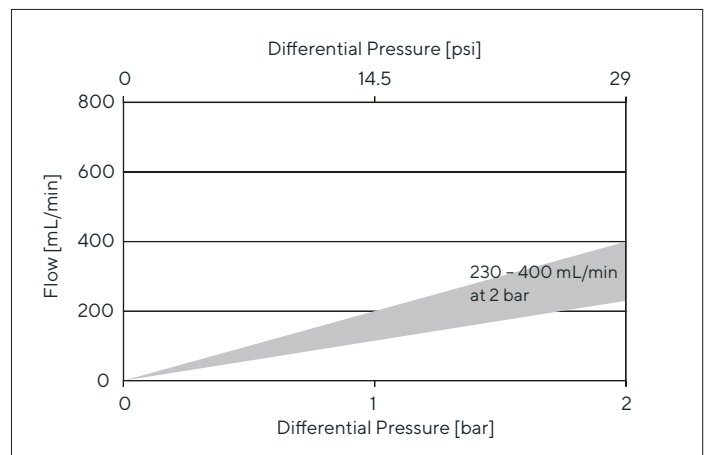
Virosart® CPV 20" Cartridge & 20" Maxicaps® (1.4 m² | 15 ft²)



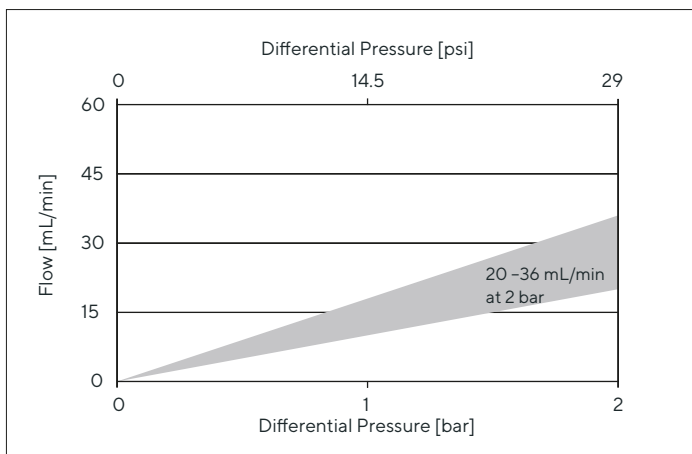
Virosart® CPV 10" Cartridge & 10" Maxicaps® (0.7 m² | 7.5 ft²)



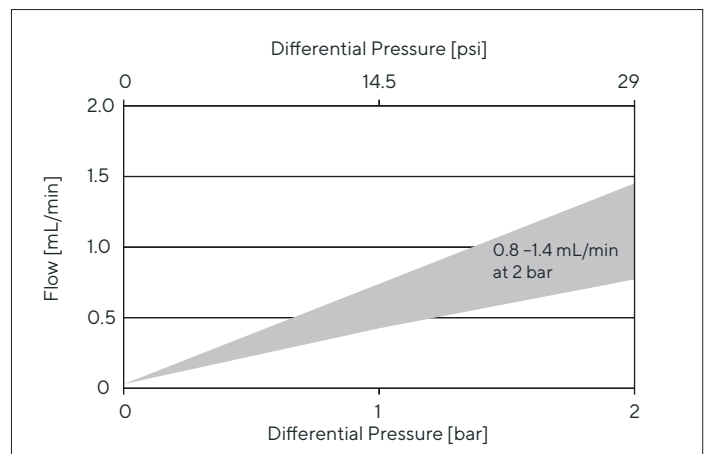
Virosart® CPV Midicaps® (0.2 m² | 2.1 ft²)



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 $\geq 4 \log_{10}$ 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 2845527-000
 Extractables Guide SPK5773-e
 Virus Information Guide SPK5752-e

Application Note

- 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 | 7.5 ft²
 V2: 20" 1.4 m² | 15 ft²
 V3: 30" 2.1 m² | 22.6 ft²



Maxicaps®

545 73 28 ■ -- SS

Filter size

V1: 10" 0.7 m² | 7.5 ft²
 V2: 20" 1.4 m² | 15 ft²
 V3: 30" 2.1 m² | 22.6 ft²

Adapter

SS: Sanitary inlet – and outlet adapter



Midicaps®

545 53 28 V9 -- FF -- V

Filter size

V9: Size 9
 0.2 m² | 2.1 ft²

Adapter

FF: ¾" 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: ¾" triclamp (sanitary) connector inlet & outlet
 OO: ½" hose barb connector inlet & outlet

Units per package

B: Five pieces



Minisart®

545 VM -- -- -- -- ■ ■

IT

IT: Integrity tested
 --: Not integrity tested

Units per package

A: Four pieces
 B: Five pieces

Accessories & Services

Adsoptive Pre-Filtration

Virosart® Max* protects whatever virus filter you choose irrespective of process conditions. Virosart® Max will down-size 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.



Filter Holders and Housing

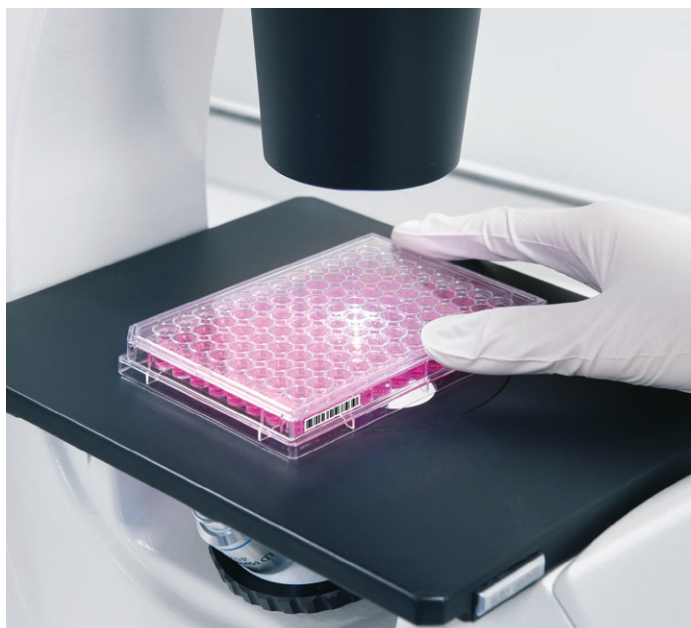
Filter holders are designed to accommodate all different Maxicaps® heights. Different standard designs of filter housings are available for cartridges from 10" to 30".

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 solutions.



Sartorius Confidence® Virus Clearance Services

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

- GLP Virus clearance studies
- Process feasibility studies
- Regulatory Guidance

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, bulk harvest testing and lot release testing.

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