Instructions for Use

Sartobind Convec® SC and D

Void Volume Optimized Capsules
With 8 mm Bed Height

1000136931

SARTORIUS

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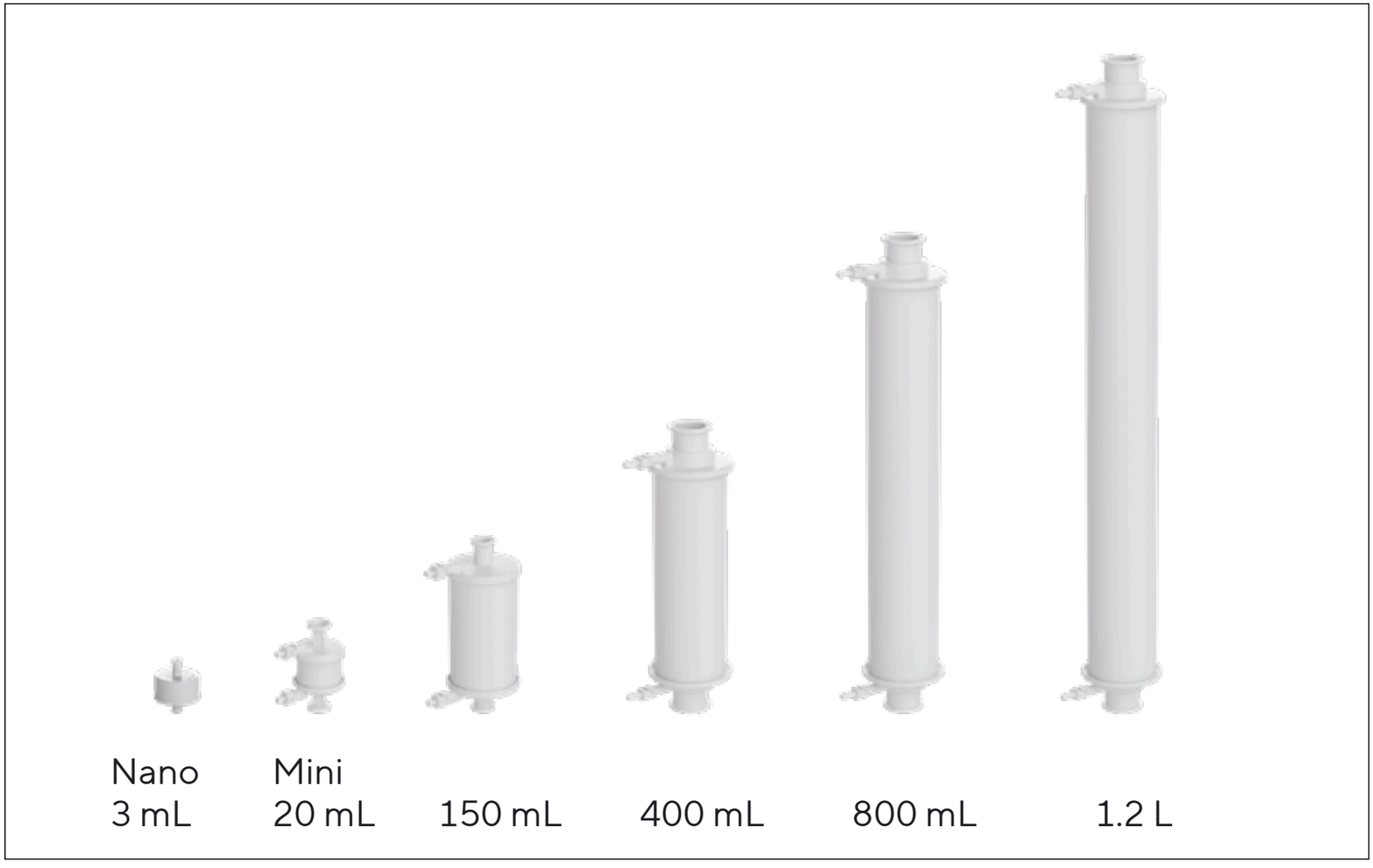
1 About these Instructions

1.1 Validity

These instructions are part of the product; they must be read in full and retained. These instructions apply to the following versions of the product:



1.2 Related Documents

In addition to these instructions, please observe the following documents:

- Operating instructions of the device in which the product is used
- Validation Guide of the respective product

1.3 Target Groups

These instructions are addressed to the following target groups. The target groups must possess the knowledge specified below.

Target Group	Knowledge and Qualifications
Operator	The operator is familiar with the product and the associated work processes. The operator understands the hazards which may arise when working with the product, and knows how to prevent them.

1.4 Symbols Used

1.4.1 Warnings in Operation Descriptions

⚠ CAUTION

Denotes a hazard that may result in moderate or minor injury if it is **not** avoided.

NOTICE

Denotes a hazard that may result in property damage if it is **not** avoided.

1.4.2 Other Symbols

▶ Required action: Describes activities that must be carried out. The actions in the sequence must be carried out in succession.

▷ Result: Describes the result of the activities carried out.

2 Safety

⚠ **Use of the products in applications not specified or not described in this manual, may result in improper function, personal injury, or damage of the product or material. The products are supplied as non-irradiated unless otherwise explicitly described. The membrane is dried from glycerol.**

2.1 Intended Use

The product is intended exclusively for use in accordance with these instructions. Any other use is considered improper.

The membrane chromatography products also described as membrane adsorbers are intended and validated for single use to avoid carryover as well as tedious and costly cleaning validation procedure. However, it is technically possible to reuse after cleaning in place depending on application, character of sample and process. Additional cleaning and validation steps will be needed to assure constant binding capacity and flow rate after each cycle.
The product is used when bind & elute applications or the highest possible binding capacity is needed.

Sartobind Convec® Nano capsules (3 mL) have been developed for working with small sample volumes. They are perfect for small scale applications, and also for screening purposes and laboratory-scale bind & elute and flow-through purifications.

Sartobind Convec® Mini capsules (20 mL) have been developed for first scale up trials and preclinical production. This product size closes the gap between the Nano and the 150 mL size.

Sartobind Convec® capsules (**150 mL**) have been developed for intermediate and pilot scale.

Sartobind Convec® capsules (**400 mL up to 1.2 L)** have been developed for production purposes in the biopharmaceutical industry.

2.2 Modifications to the Product

If the product is modified: Personnel may be put at risk. Product-specific documents and product approvals may lose their validity. If you have any queries regarding modifications to the product, contact Sartorius.

2.3 Qualifications of Personnel

Personnel who do **not** possess adequate knowledge about how to use the product safely may injure themselves and other personnel.

2.4 Personal Protective Equipment

Personal protective equipment protects against risks arising from the product. If the personal protective equipment is missing or is unsuitable for the work processes on the product: Personnel may be injured. The following personal protective equipment must be worn:

- Protective work clothing
- Safety gloves
- Safety glasses

2.5 Leaking Liquids from the Product

If the product is damaged or incorrectly installed: Liquids can leak from the product.

- ▶ Do **not** exceed the maximum pressure (see chapter “8 Technical Data”, page 43).
- ▶ Perform a visual inspection before use.
- ▶ Ensure correct installation.

2.6 Components under Pressure

Operating above the maximum operating pressure can lead to the bursting of pipes and plastic components. This can result in leakage of media and injuries due to bursting components. Escaping medium can lead to infections.

- ▶ Wear appropriate personal protective equipment.
- ▶ Do **not** exceed the maximum operating pressure (see chapter “8 Technical Data”, page 43).

2.7 Product Weight

The product may be heavy. There is a risk of injury when lifting and transporting the product, e.g. from the product being dropped.

- ▶ Wear appropriate personal protective equipment.
- ▶ If required get help from others when lifting and transporting the product.

3 Product Overview

3.1 Operating Principle

The capsules are pseudo affinity and ion exchange chromatography products based on macroporous membranes. They can be used for chromatographic separation in downstream processing of large molecules such as viruses or virus-like particles (VLPs). The pseudo affinity and ion exchange ligands are coupled to a membrane which is fitted into a plastic housing ready to use. The products are constructed with optimized fluid channels.
The capsules contain a central core. These products are intended for single use to avoid carryover as well as tedious and costly cleaning validation procedures. However, it is technically possible to reuse after cleaning in place (see also section “8.4 Chemical Stability”, page 48).

The potential target for Sartobind Convec® SC are viruses or VLPs which have Heparin-like binding affinity such as Japanese encephalitis, Feline leukemia, Calicivirus, Respiratory syncytial virus, Human herpes simplex, Human measles, Human parainfluenza.

Similarly, potential target for Sartobind Convec® D could be Lentivirus and Adenovirus. Furthermore, viruses and VLPs which can be captured using weak anion exchange chromatography.

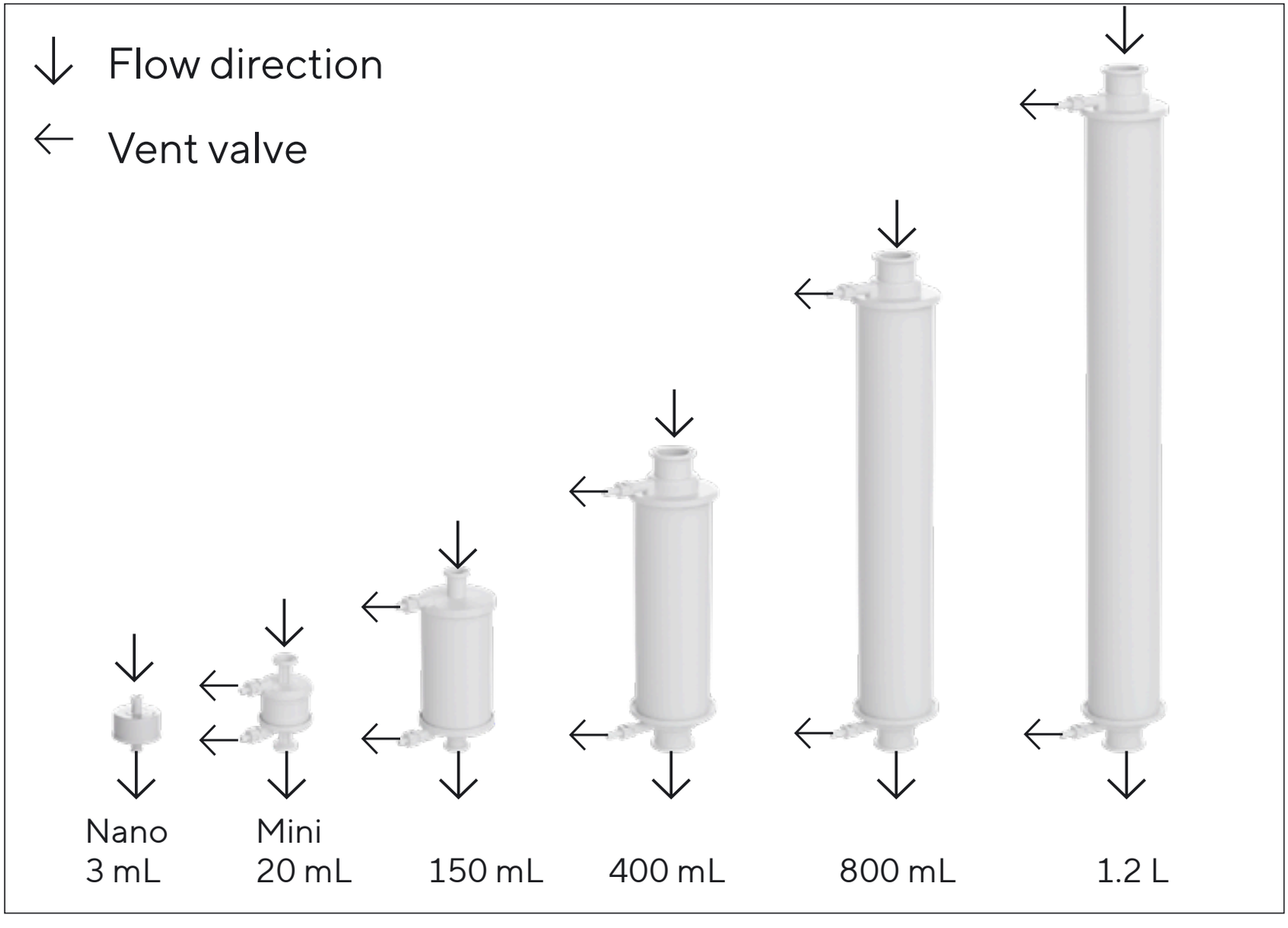


Fig. 1: Flow direction and position of vent valves of capsules

For Mini and 150 mL products the central core is made from a solid polypropylene cylinder.
For the larger capsules it is made from a self-contained air filled polypropylene cylinder.
The interior of the core is inaccessible for gases and fluids.

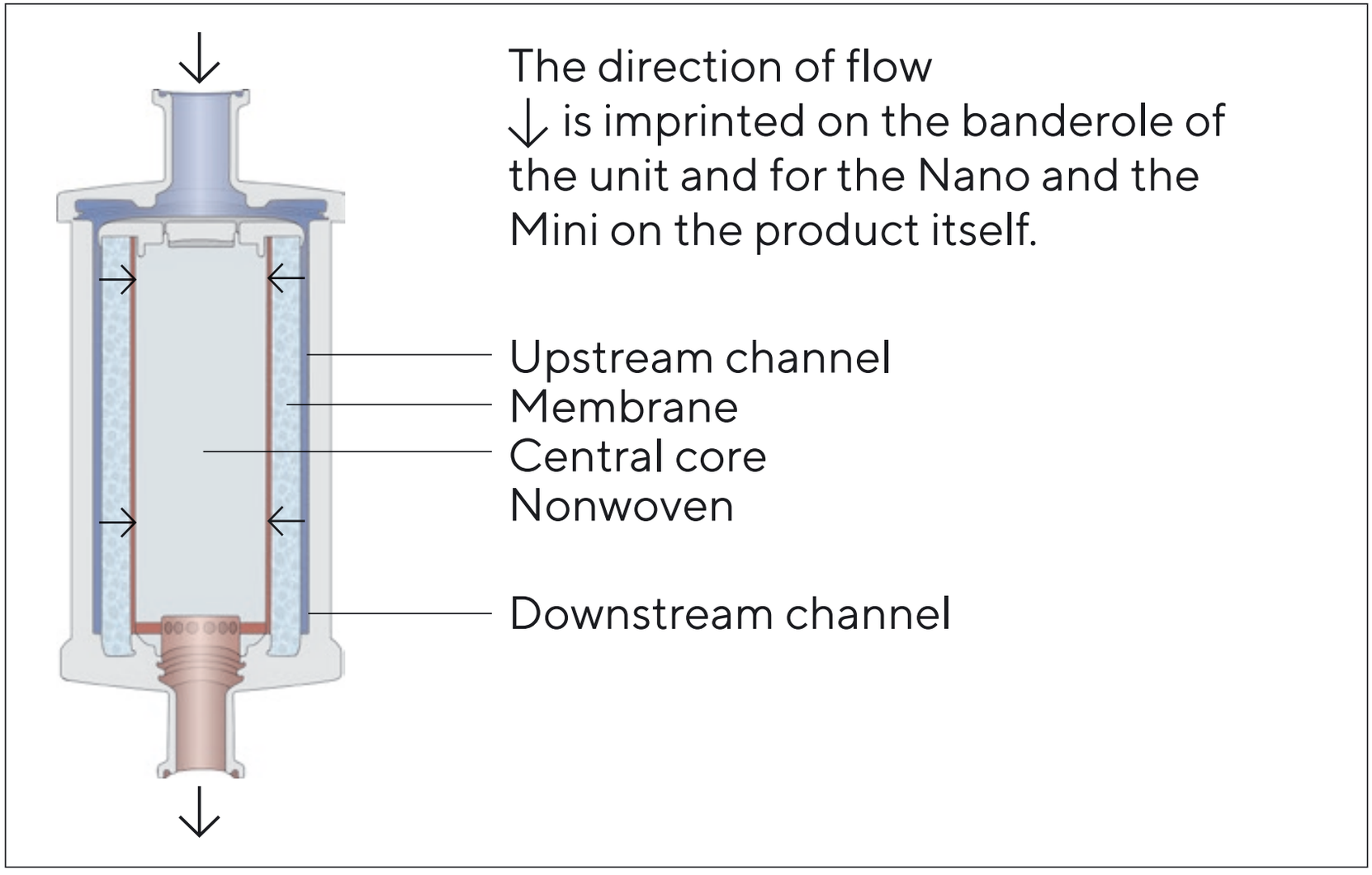


Fig. 2: Construction and flow path inside the capsules

4 Installation

NOTICE

Malfunctions due to damaged products. A damaged product can cause malfunctions.

- ▶ Visually inspect the product before use.
- ▶ Close vent valve before use by screwing the valve clockwise.
- ▶ Do **not** keep or place the products with the connector directly on the floor.
- ▶ In case of damage: Replace the product.

Sartobind Convec® SC and D Capsules

- ▶ Protect inlet and outlet connectors when unpacking.
- ▶ Install the product in an upright position according to the process flow.
- ▷ The inlet is up.
- ▷ The flow is guided to the upstream channel (i.e. the solution enters the product) passing through the membrane layers to the downstream channel and to the outlet of the product (see Fig. 2).

5 Operation

5.1 Venting the Capsule

All capsules except Nano have vent valves (see Fig. 1).

Procedure

- ▶ Remove the entire air from the unit before use.
- ▷ The vent valves are equipped with hose barb connectors for the fluid spilled out during venting.
- ▶ Check vent valve position.
- ▷ When turning anticlockwise, the valve is open, when turning clockwise, the valve is closed.
- ▶ Before opening the vent valve, connect the valves with flexible tubing (inner diameter 6 mm) to waste.
- ▶ **NOTICE** Insufficient closing of the valve due to excessive pressure! During venting of capsules do **not** exceed 0.05 MPa (0.5 bar | 7.3 psig).
- ▶ Open the vent valve screw ⅓ turn to left until all air is replaced by fluid.
- ▶ For venting the cassettes, tubes with quick connectors are attached to the inlet and outlet manifolds and closed with a pinch clamp.

5.2 Venting the Nano Capsule

- ▶ Fill a 10 – 20 mL Luer syringe with equilibration buffer and connect to the capsule. Hold capsule upright (outlet is up) and expel air as shown in Fig. 3.
- ▶ If you still detect any air in the filled unit, close the outlet, hold the syringe up and move the plunger slightly up and down that air bubbles can ascend into the syringe.
- ▶ Alternatively, connect a second empty syringe to the top of the Nano and expel air and buffer into that syringe, disconnect the upper syringe to push out air and reconnect to the Nano, turn it and purge the solvent back and forth.
- ▷ Very small air bubbles observed directly below the inlet of the Nano do **not** disturb performance.
- ▷ The capsule function will **not** be influenced as long as the small air bubbles remain outside of the membrane bed.

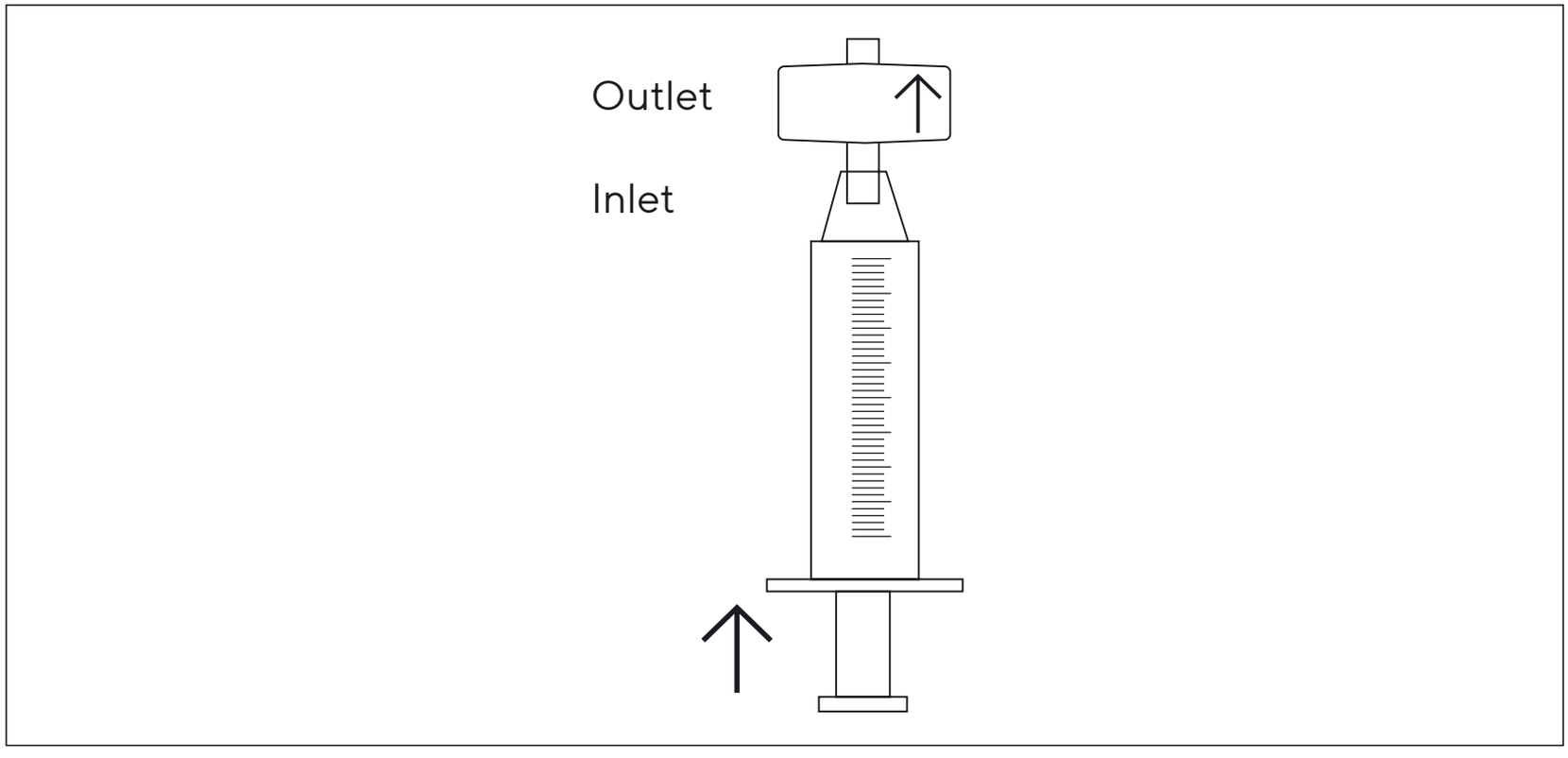


Fig. 3: Filling the Sartobind Convec® SC and D Nano with a Luer syringe for air removal

5.3 Cleaning and Equilibration

Non-gamma-irradiated Sartobind products have to be sanitized in-place directly before use.
For **gamma-irradiated** Sartobind products sanitization is optional.

▶ For sanitization use 30 membrane volumes (MV) of 1 N NaOH solution at the flow rate of 1 MV/min. Preferentially, work at

room temperature as low temperature increases viscosity of solvents. Also cold NaOH can cause swelling of the cellulose matrix significantly which will result in pressure increase.

- ▶ Flush with 5 MV of 1 N NaCl at 3 MV/min (Sartobind Convec® SC) or 5 MV/min (Sartobind Convec® D).
- ▶ Flush with 20 MV of equilibration buffer at 3 MV/min (Sartobind Convec® SC) or 5 MV/min (Sartobind Convec® D).

5.4 Autoclaving

NOTICE

Risk of damage to the product from improper handling!

- ▶ Do **not** perform autoclaving for capsules.
- ▶ Do **not** perform in-line steam sterilization for the product.

5.5 Gamma Irradiation

NOTICE

Damage to the product due to repeated gamma irradiation!

▶ Gamma irradiation may only be performed once.

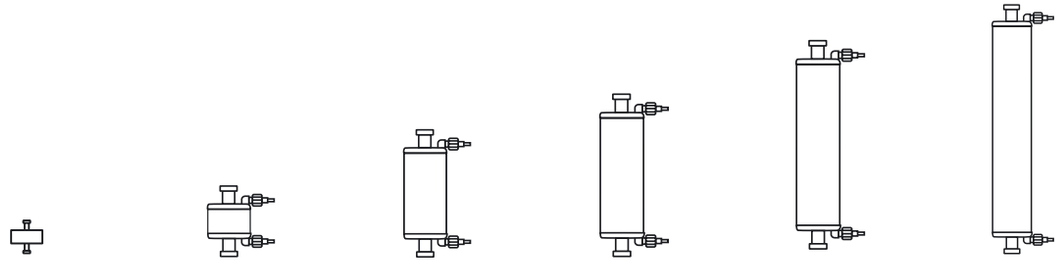
Sartobind Convec® SC and D are also available in gamma irradiated product format. If customer choose non-gamma irradiated devices for Sartobind Convec® SC and D, these devices can be gamma-irradiatable. The recommended dose for gamma irradiation is 25 kGy and the maximum dose is 50 kGy.
Products that are gamma irradiated can be identified by a colored indicator:
red indicator: gamma irradiated
orange indicator: **not** gamma irradiated
Once Sartobind Convec® SC and D was irradiated, further autoclaving steps are prohibited.

5.6 Recommended Flow Rates and Equilibration Buffer Volumes

Membrane adsorbers can be run at much higher flow rate per volume than resin columns. As a rule of thumb, the following flow rates are recommended (see section “8 Technical Data”, page 43).

This recommendation is only a guideline as buffers and samples have different compositions and viscosities. Please test your respective flow rates with a small scale product to ensure that the flow rate fits with your pump capacities and the pressure limits.

Lower flow rates than the recommended ones can also be used but will typically **not** improve binding capacity or overall performance. Cold room temperature increases buffer viscosity and possibly back pressure.
The equilibration buffer volume is typically 20 membrane volumes depending on the type of buffer.



Membrane volume (MV)	3 mL	20 mL	150 mL	400 mL	800 mL	1.2 L
Rec. flow rate (L/min)						
Sartobind Convec® SC	0.009	0.06	0.45	1.2	2.4	3.6
Sartobind Convec® D	0.015	0.1	0.75	2	4	6
Rec. equilibration volume* (L)	0.06	0.4	3.0	8	16	24

* Refer to 5.3 Cleaning and equilibration

5.7 Buffer Conditions

In the majority of applications an equilibration buffer concentration of 10 mM provides sufficient buffering capacity and prevents the molecule (Viruses or VLPs) of interest from precipitation. The ionic strength should be kept as low as possible to avoid reduction of binding capacity.
The buffer should have a pKa within 0.5 pH units of the pH used. It should be filtered with 0.45 µm filters before use and the quality of water and chemicals should be of high purity.

NOTICE

Risk of reversible swelling and decreased permeability of the Sartobind Convec® SC membrane due to use of pure water!

▶ Do not apply pure water for Sartobind Convec® SC.

For Sartobind Convec® SC:
Affinity mode
Buffer: 10 mM Tris, pH 7.4 or 10 mM phosphate, pH 7.4
Load conductivity: < 5 mS/cm
Elution: 0.25 - 2.0 M NaCl in buffer

CEX mode
Buffer: 10 mM Acetate, Tris or PB pH < [pI(virus) - 1]
Load conductivity: < 5 mS/cm
Elution: 0.25 - 2.0 M NaCl in buffer

For Sartobind Convec® D:
AEX mode
Buffer: 20 mM Tris, pH 7.2 or 50 mM HEPES, pH 7.5
Load conductivity: < 10 mS/cm
Elution: 0 - 1.0 M NaCl in buffer

5.8 Selection of pH Conditions

In ion exchange chromatography, a molecule carrying a charge adheres to groups with opposite charges connected to the insoluble matrix. This attachment is reversible and triggered by elevating the salt concentration in the elution buffer.

5.9 Use of Sartobind Convec® SC and D for Capturing of Viruses and Virus Particles (VP)

Sartobind Convec® SC

Concentrations of Influenza viruses in typical feed streams fall in the range of 9.0 – 14.0 x 10^3 HAU/mL. Clarified and nuclease treated cell-supernatants are to be diluted to 4 mS/cm (higher conductivities also applicable) using a suitable low salt buffer (e.g. 10 mM Tris/HCl pH 7.4). Under these conditions, the binding capacity has been estimated to 1.0 – 2.5 x 10^6 HAU/mL membrane.

For initial screening approaches we recommend the following separation procedure:

— Flow rate: 3 MV/min
— Equilibration 20 MV in low salt buffer

- Sample application 20 MV
- Wash 10 MV in low salt buffer
- Step elution 1 over 10 MV in elution buffer consisting of e.g., 10 mM Tris/HCl pH 7.4, 200 - 1000 mM NaCl (depending on target)
- Step elution 2 over 10 MV in elution buffer consisting of e.g., 10 mM Tris/HCl pH 7.4, 2 M NaCl

Please note that these values are recommended starting conditions for screening and may require individual optimization.

Sartobind Convec® D

Concentrations of Lentivirus in typical feed streams fall in the range of 2 x 10^{10} VP/mL. Clarified and nuclease treated cell-supernatants are to be diluted to 7 mS/cm using a suitable low salt buffer (e.g. 20 mM Tris/HCl pH 7.2). Under these conditions, the binding capacity has been estimated to 2 x 10^{12} VP/mL membrane.

For initial screening approaches we recommend the following separation procedure based on a linear salt gradient:

- Flow rate: 5 MV/min
- Equilibration 20 MV in low salt buffer
- Sample application 40 MV

- Wash 20 MV in low salt buffer
- Gradient elution over 20 MV to 75% elution buffer consisting of e.g. 20 mM Tris/HCl pH 7.2, 1 M NaCl (750 mM NaCl final concentration)
- Step elution in 75% elution buffer 20 MV (750 mM NaCl final concentration)
- Step elution in 100% elution buffer 20 MV (1 M NaCl final concentration)

For runs with stepwise elution, we recommend performing the wash step with 100 mM NaCl, a first elution step with 650 mM NaCl and a final second elution step at 1 M NaCl after loading (each 20 MV, e.g., 20 mM Tris/HCl pH 7.2).

We recommend diluting the virus-containing fractions with 4 volumes of storage buffer (50 mM HEPES pH 7.5, 20 mM $MgCl_2$, 5% sucrose) immediately after finishing the run (A.J. Valkama, I. Oruetxebarria, E. M. Lipponen, N. R. Parker, S. Ylä-Herttuala, H. P. Lesch; Development of Large-Scale Downstream Processing for Lentiviral Vector; https://doi.org/10.1016/j.omtm.2020.03.025).

Please note that these values are recommended starting conditions for screening and may require individual optimization.

5.10 Sample Preparation

Procedure

- ▶ Adjust the sample to the starting buffer conditions and prefilter sequentually through
  1. Sartopure® PP3 20 µm
  2. Sartopure® PP3 0.65 µm
  3. Sartopore® 2 0.45 µm
- ▶ For small volumes in the mL range, use a 0.45 µm Sartopore® 2 filter with Luer outlet (e.g. order number 5445306GS--HH--M (hose barb 1/4") or order number 5445306GS--FF--M (santitary 3/4")).

NOTICE

Unfiltered feed will block the Membrane Adsorber and lead to capacity loss and increased back pressure!

- ▶ We recommend filtering prior to chromatography.

5.11 Washing

Procedure

▶ When using capsules in bind & elute mode, wash with equilibration buffer after sample loading.

5.12 Elution

Procedure

▶ To elute target virus or virus like particle (VLP) use buffers with appropriate salt concentration.

5.13 Draining

A dual air regulator system is recommended to prevent over-pressure of the Sartobind Convec® products. The first regulator should reduce line air pressure to 2 bar.
The second regulator, positioned immediately upstream of the Sartobind Convec® SC and D, should reduce the 2 bar regulated supply pressure to <1 bar (14.5 psig) for a capsule.

Procedure

- You may drain the capsule by application of air or nitrogen pressure (<1 bar | 14.5 psig) to the inlet of the product.

5.14 Regeneration and Storage

After elution wash with equilibration buffer. If necessary, use 1 N NaOH or 70% ethanol for 1 hour for regeneration and store in 20% ethanol in equilibration buffer.

5.15 Operation of the Sartobind Convec® SC and D Nano with Peristaltic Pumps or Liquid Chromatography (LC) Systems

Procedure

- After the unit is filled completely with equilibration buffer, close the outlet of the Sartobind Convec® Nano and remove the syringe.
- Start your LC system or peristaltic pump at a low flow rate.
- When fluid emerges, stop the pump, connect the tubing to the inlet of the Sartobind Convec® Nano.
- Make sure that no air is introduced.

- ▶ Remove the cap from outlet.
- ▶ Run the pump until fluid emerges from the outlet of the unit and stop it.
- ▶ Connect the outlet of the unit via Luer adapter to the LC detector and proceed with loading.
- ▶ If your system pressure is too high, refer to your LC system manual to remove any flow restrictor after the UV cell, as the system may generate a pressure above the allowed maximum pressure.
- ▷ As membrane adsorbers are typically run at much higher flow rates than columns, there is no risk of bubble formation in the UV cell when removing the flow restrictor.

5.16 Scaling Up

Run break through experiments for the target compound (contaminants) to be bound on the membrane matrix. After optimization of the binding conditions, the purification step can be scaled up to a larger capsule.

If gamma-irradiated capsules will be used in a larger scale, compare non-irradiated and irradiated capsules before scaling up.

Recommendations:
Maintain

- Linear flow (when using capsules with the same bed height), the flow rate will scale up linearly when keeping MV/min constant.
- Sample concentration
- Increase (see scaling factors in the following table)
- Sample load volume
- Volumetric flow rate
- Membrane volume

Scale up calculations are done by adjusting the membrane volume. This will make the calculation simple. Other methods for scale up via residence time will lead to same results. Residence time is calculated by the membrane volume divided by the flow rate.

When using Sartobind Convec® SC and D Nano 3 mL, the scale up factor for flow rate and binding capacity is equal to the multiplication factor of membrane volumes for the listed scale up products:

Size	Membrane Volume (mL)	Factor to increase* (from Nano)	Bed height (mm)
Nano	3	–	8
Mini	20	6.7	8
5″	150	50	8
10″	400	133	8
20″	800	266	8
30″	1,200	400	8

* Flow rate and binding capacity

Example: After breakthrough experiments with the Nano 3 mL, you realize that a 350-fold higher binding capacity is needed for a large scale run. Then you choose the 1.2 L capsule. To determine the running conditions of the 1.2 L capsule and to keep consistent upscaling, adjust the flow rate by a factor of ~400.
To assure the scale up, additional experiments with the 150 mL capsule (increase by a factor of 50) support this scale up calculation.

NOTICE

Keep sample concentration constant in lab and production scale.

- Adjustments might be required due to additional volumes from tubing and the system.

6 Integrity Test by Diffusion

The integrity of a membrane adsorber can be tested by a diffusion test.

The testing procedure describes the diffusion test for pre and post use. The test is intended to discriminate between defective and intact products and to detect major bypasses, large holes and faulty assembly.

6.1 Installation

Procedure

▶ Install adsorber as shown in Fig. 4.

The test procedure has been developed and checked with the Sartocheck® instrument family e. g. Sartocheck® 4 Plus (26288) or 4 (16288). The use of Sartocheck® instruments older than Sartocheck® 4 will generate faulty data.

▶ Note that the test procedure with other vendor's integrity testers can require a different set up.

6.2 Operation Procedure

6.2.1 Pre-washing of Device

Prior to integrity testing, the capsule needs to be prewashed, to remove any glycerol. The washing solution should have room temperature.

NOTICE

Risk of reversible swelling and decreased permeability of the Sartobind Convec® SC membrane due to use of pure water!

- ▶ Do not apply pure water for Sartobind Convec® SC.

Procedure

- ▶ Keep the unit in an upright position for proper venting and open the vent screw on top of the product until all air is replaced by the testing solvent.
- ▶ Pre-wash the product with 30 membrane volumes (MV) of buffer or 0.9% NaCl in water at recommended flow rate.

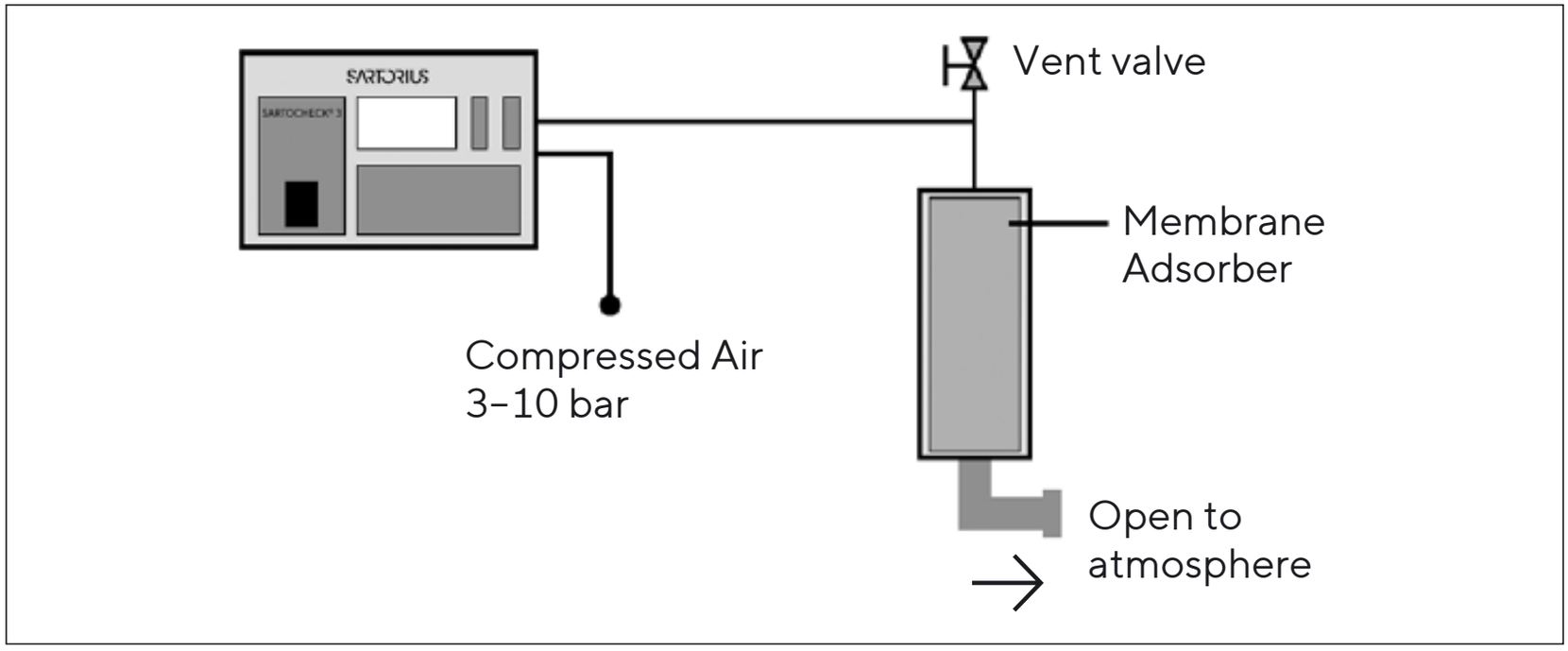


Fig. 4: Set up of diffusion test with Sartocheck®.

6.2.2 Diffusion Measurement With Sartocheck®

– Choose “Programming” in the main menu
– Choose “Diffusion Test”

Procedure

▶ Choose the test pressure, stabilization and testing time for your product from the table (next page).
▶ If you set the Net Volume to zero, Sartocheck® automatically measures the upstream void volume including tubing.

Test Parameters

Size	Membrane Volume (mL)	Test pressure mbar (psig)	Stabilisation time (min)	Testing time (min)	Diffusion max. (mL/min)
Nano	3	200 (2.9)	2	1	15
Mini	20	200 (2.9)	2	1	15
5″	150	200 (2.9)	2	1	15
10″	400	200 (2.9)	3	1	15
20″	800	200 (2.9)	3	1	15
30″	1,200	200 (2.9)	3	1	15

6.3 Results and Evaluation for One Device

— Diffusion ≤ Diffusion max.:
Test passed (diffusion value on the print out)
— Diffusion > Diffusion max.:
Test failed (red text on the print out)

The maximum allowed diffusion values are per product.

7 Troubleshooting

Problem	Possible cause	Action
Air bubbles can be seen	Incomplete air removal	Small air bubbles seen in the top of the unit do **not** interfere with the purification as long as they do **not** touch the membrane bed. If too much air is enclosed, repeat removal as described in chapter "5.1 Venting the Capsule", page 16.
I installed the capsule upside down	Installation of capsule may be easier in the process flow	Validation has been done with a process flow from top to bottom. Thus it is clearly recommended to use capsules in the described flow direction (Feed enters capsule on top and leaves it on bottom).
I deviated from the CIP and flushing equilibration procedure		The capsules have been qualified and validated according the given procedure. If a deviation is necessary, the results may also deviate from the given validation data.
High back pressure	Material has **not** been filtered	Prefilter with 0.45 µm filter before processing through the unit.

Problem	Possible cause	Action
High back pressure	Material has been filtered but was stored before purification	Contaminants can form aggregates within hours or during operation. We recommend a prefiltration step with a 0.45 µm filter device. When you observe again pressure built up, repeat the filtration step.
	LC system generates high pressure	Remove restrictor after the UV cell.
	The adsorber is clogged | membrane fouling	Replace unit. Perform a regeneration cycle. You may backflush within given flow and pressure limits.
	Viscosity | swelling effects	Work at room temperature, avoid lower temperatures
High back pressure	Pure water leads to swelling of membrane	Add sodium chloride or use ionic buffers
Target molecule is **not** bound	Conditions for binding are insufficient	Decrease conductivity, control other process parameters as type of buffer and pH.

Problem	Possible cause	Action
Binding capacity is **not** sufficient	Process conditions **not** optimized	Use larger adsorber product, or: connect two adsorbers (same size) in series (i.e connect outlet of first adsorber to inlet of second) to achieve higher binding capacity. As a rule of thumb the pressure doubles when the flow rate is kept constant and the number of membrane layers is doubled.
Reuse is needed	For economic or practical reasons	The major application of Sartobind Convec® capsules is the single use and they are constructed in plastic housing for this. Also they are validated and certified only for one use. Technically they can be reused. The durability of the unit depends on the nature of sample and sample preparation, prefiltration as well as proper regeneration and application. Plastic materials and membranes allow CIP and long term storage if carefully treated. For reuse validation we assist you with our Validation Service. Please ask your local representative.

Problem	Possible cause	Action
Binding capacity decreases after several uses	Improper filtration	Prefilter before processing through the unit.
	Some molecule species binds tightly and **cannot** be removed with 1 N NaOH 1 h	Use capsule only once.
Binding capacity decreases after several uses	Contaminants are still bound from last cycle	Run a 1 M NaCl buffer step to elute tightly bound proteins quantitatively. Then regenerate adsorber by loading with 1 N NaOH and keep it for 1 hour at room temperature (20°C).
	Wrong storage	Do **not** store in sodium hydroxide containing buffers. Store long term in 20% ethanol buffer (e. g. equilibration buffer) solution and do **not** use oxidative chemicals in buffers.
A vertical line is seen on one capsule side when filled	Membrane edge visible	No action necessary. It can be visible the edge of the nonwoven touching the inner tube.

Problem	Possible cause	Action
I purged with air or nitrogen and lost flow and binding capability.	Air has entered into the pores	See troubleshooting “Applied bubble point instead of diffusion test” below.
Accidentally a bubble point test instead of diffusion test has been run	Operation error	The membrane has then to be purged extensively to remove all the air which has been pressed into the pores. If properly purged, the diffusion test can be run successfully and the product works as expected.

8 Technical Data

8.1 Bed Height 8 mm

Membrane volume (MV)	3 mL	20 mL	150 mL
Nominal membrane area Sartobind Convec® SC | D	114 cm^2 | 135 cm^2	760 cm^2 | 900 cm^2	5,700 cm^2 | 6,750 cm^2
Design	Cylindrical	Cylindrical	Cylindrical
Maximum pressure bar (MPa, psig) at 20°C	4 (0.4, 58)	4 (0.4, 58)	4 (0.4, 58)
Maximum pressure during venting bar (MPa, psig) at 20°C	–	0.5 (0.05, 7)	0.5 (0.05, 7)
Nominal void volume (mL)	4	32	200
Nominal void volume (MV)	1.3	1.6	1.3
Recommended flow rate Sartobind Convec® SC | D	3 MV/min | 5 MV/min	3 MV/min | 5 MV/min	3 MV/min | 5 MV/min
Approximate weight	10 g	65 g	400 g

1 mL membrane = 38 cm^2 Sartobind Convec® SC and 45 cm^2 Sartobind Convec® D
Short term pH stability: 3–14 refers to cleaning in place and regeneration procedures during operation. Long term storage pH stability: 4–13 refers to overnight storage and longer. Preferably store units in 20% ethanol | buffer

Membrane volume (MV)	400 mL	800 mL	1.2 L
Nominal membrane area Sartobind Convec® SC | D	15,200 cm^2 | 18,000 cm^2	30,400 cm^2 | 36,000 cm^2	45,600 cm^2 | 54,000 cm^2
Design	Cylindrical	Cylindrical	Cylindrical
Maximum pressure bar (MPa, psig) at 20°C	4 (0.4, 58)	4 (0.4, 58)	4 (0.4, 58)
Maximum pressure during venting bar (MPa, psig) at 20°C	0.5 (0.05, 7)	0.5 (0.05, 7)	0.5 (0.05, 7)
Nominal void volume (mL)	540	1,080	1,600
Nominal void volume (MV)	1.4	1.4	1.3
Recommended flow rate Sartobind Convec® SC | D	3 MV/min | 5 MV/min	3 MV/min | 5 MV/min	3 MV/min | 5 MV/min
Approximate weight	760 g	1.3 kg	1.9 kg

1 mL membrane = 38 cm^2 Sartobind Convec® SC and 45 cm^2 Sartobind Convec® D
Short term pH stability: 3–14 refers to cleaning in place and regeneration procedures during operation. Long term storage pH stability: 4–13 refers to overnight storage and longer. Preferably store units in 20% ethanol | buffer

8.2 Materials

Membrane materials	
Matrix	Stabilized reinforced cellulose
Membrane thickness | membrane volume = membrane area Sartobind Convec® SC Sartobind Convec® D	 265 µm | 1 mL = 38 cm^2 220 µm | 1 mL = 45 cm^2
Nominal pore size	1.1 µm
Ligand Sartobind Convec® SC Sartobind Convec® D	 Pseudo affinity/strong cation: sulfate moiety ($-OSO_3^-$) Weak anion: diethyl amino moiety ($-NH(C_2H_5)_2$)
Ligand density Sartobind Convec® SC Sartobind Convec® D	 8 - 15 µmol/cm^2, 270 - 620 µmol/mL 0.11 - 0.31 µmol/cm^2, 6 - 12 µmol/mL

Capsule materials	
Outer cage, inner core, end caps, capsule housing	PP (polypropylene)
Nonwoven Non-gamma-irradiatable products Gamma-irradiatable | gamma-irradiated products	 PP (polypropylene) PET (polyethylene terephthalate)
O-ring in vent valve (except Nano)	EPDM (ethylene propylene diene monomer)

8.3 Binding Capacity

The DBC highly depends on the target molecules and has to be tested for each application.

	Typical dynamic binding capacity	Virus Strain
SC	>2.47 x 10^6 HAU/mL*	Influenza A / Puerto Rico / 8 / 1934 (H1N1)
	>1.11 x 10^6 HAU/mL*	Influenza B / Phuket / 3073 / 2013
	>1.64 x 10^6 HAU/mL*	Influenza A / Switzerland / 9715293 / 2013 (H3N2)
D	2 x 10^{12} VP/mL	Clarified Lentivirus cell culture supernatant

* A. Fortuna, S. Teeffelen, A. Leyb, L. Fischer, F. Taft, Y. Genzel, L. Villain, M. Wolff, U. Reichl, Use of sulfated cellulose membrane adsorbers for chromatographic purification of cell cultured-derived influenza A and B viruses https://doi.org/10.1016/j.seppur.2019.05.101

8.4 Chemical Stability

Stable for all commonly used buffers in chromatography

No oxidizing agents

8.5 Storage Conditions

Clean, dry place in closed bag and box at room temperature.

Protected from direct sunlight.

Store membrane samples enclosed in a safe place as they **cannot** be ordered again.

9 Quality Assurance

The final Sartobind Convec® products are tested for ligand density and flow rate. Sartobind Convec® membranes are tested for ligand density, flow rate, thickness, and eveness.

Capsules and membranes are manufactured in a controlled environment. The products meet all Sartorius standards for traceability, production and specifications as given here or exceeded them as certified in the quality assurance certificate enclosed. A validation and an extractables guide are available on request.

10 Trademark Information

Sartobind®, Sartobind Convec® and Sartocheck® are registered trademarks of Sartorius Stedim Biotech GmbH.
For details on the registrations please refer to our website:
www.sartorius.com (patents-and-trademarks)

11 Ordering Information

11.1 Products Sartobind Convec® SC

Order number	Description	Quantity
97SC--04E-C11	Sartobind Convec® SC Nano 3 mL, 8 mm, Luer female connectors, 2 PEEK adapters Luer male to UNF 10-32 female	1
97SC--04E-C11--A	Sartobind Convec® SC Nano 3 mL, 8 mm, Luer female connectors, 2 PEEK adapters Luer male to UNF 10-32 female	4
97SC--04E4J11	Sartobind Convec® SC Mini 20 mL, 8 mm, Luer female connectors, 2 PEEK adapters Luer male to UNF 10–32 female	1
97SC--04E4J11--A	Sartobind Convec® SC Mini 20 mL, 8 mm, Luer female connectors, 8 PEEK adapters Luer male to UNF 10–32 female	4
97SC--04E4JFF	Sartobind Convec® SC Mini 20 mL, 8 mm, ¾" sanitary clamp	1
97SC--04E4JFF--A	Sartobind Convec® SC Mini 20 mL, 8 mm ¾" sanitary clamp	4

Order number	Description	Quantity
97SC--04E4JOO	Sartobind Convec® SC Mini 20 mL, 8 mm hose barb connectors	1
97SC--04E4JOO--A	Sartobind Convec® SC Mini 20 mL 8 mm hose barb connectors	4
97SC--04E9BFF	Sartobind Convec®SC 150 mL, 8 mm, ¾" sanitary clamp	1
97SC--04E9BOO	Sartobind Convec® SC 150 mL, 8 mm, hose barb connectors	1
97SC--04E1HSS	Sartobind Convec® SC 400 mL, 8 mm, 1½" sanitary clamp	1
97SC--04E1HOO	Sartobind Convec® SC 400 mL, 8 mm, hose barb connectors	1
97SC--04E2LSS	Sartobind Convec® SC 800 mL, 8 mm, 1½" sanitary clamp	1
97SC--04E2LOO	Sartobind Convec® SC 800 mL, 8 mm, hose barb connectors	1
97SC--04E3FSS	Sartobind Convec® SC 1.2 L, 8 mm, 1½" sanitary clamp	1
97SC--04E3FOO	Sartobind Convec® SC 1.2 L, 8 mm, hose barb connectors	1

11.2 Products Sartobind Convec® D

Order number	Description	Quantity
97LV--04E-C11	Sartobind Convec® D Nano 3 mL, 8 mm, Luer female connectors, 2 PEEK adapters Luer male to UNF 10-32 female	1
97LV--04E-C11--A	Sartobind Convec® D Nano 3 mL, 8 mm, Luer female connectors, 2 PEEK adapters Luer male to UNF 10-32 female	4
97LV--04E4J11	Sartobind Convec® D Mini 20 mL, 8 mm, Luer female connectors, 2 PEEK adapters Luer male to UNF 10–32 female	1
97LV--04E4J11--A	Sartobind Convec® D Mini 20 mL, 8 mm Luer female connectors, 8 PEEK adapters Luer male to UNF 10–32 female	4
97LV--04E4JFF	Sartobind Convec® D Mini 20 mL, 8 mm, ¾" sanitary clamp	1
97LV--04E4JFF--A	Sartobind Convec® D Mini 20 mL, 8 mm, ¾" sanitary clamp	4
97LV--04E4JOO	Sartobind Convec® D Mini 20 mL, 8 mm, hose barb connectors	1

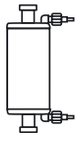
Order number	Description	Quantity
97LV--04E4JOO--A	Sartobind Convec® D Mini 20 mL 8 mm, hose barb connectors	4
97LV--04E9BFF	Sartobind Convec® D 150 mL, 8 mm, ¾" sanitary clamp	1
97LV--04E9BOO	Sartobind Convec® D 150 mL, 8 mm, hose barb connectors	1
97LV--04E1HSS	Sartobind Convec® D 400 mL, 8 mm, 1½" sanitary clamp	1
97LV--04E1HOO	Sartobind Convec® D 400 mL, 8 mm, hose barb connectors	1
97LV--04E2LSS	Sartobind Convec® D 800 mL, 8 mm, 1½" sanitary clamp	1
97LV--04E2LOO	Sartobind Convec® D 800 mL, 8 mm, hose barb connectors	1
97LV--04E3FSS	Sartobind Convec® D 1.2 L, 8 mm, 1½" sanitary clamp	1
97LV--04E3FOO	Sartobind Convec® D 1.2 L, 8 mm, hose barb connectors	1

For gamma irradiated capsules and assembly please contact your local Sartorius sales representative.

11.3 Accessories

Order number	Description	Quantity
1ZA---0004	Adapter Luer male to UNF 10 – 32 female, PEEK	1
1ZAOGV0003	Adapter UNF 10 – 32 female to sanitary ¾", 25 mm, polyoxymethylene	2
5ZGI--0001	Holder for 1 × 200 to 1,200 mL (10 – 30") capsule, stainless steel, 3 legs	1
5ZALB-0002	Distribution adapter for 3 × 200 (10 – 30") to 1200 mL capsules, 1 × 2", 3 × 1½", sanitary, stainless steel	1
7ZAL-V0013	Reducing adapter 1½" (50.5 mm) to ¾" (25 mm), sanitary	1
7ZAL-V0010	Reducing adapter 2" (64 mm) to 1½" (50.5 mm), sanitary	1
26787---FT	Sartocheck® 5 Filter Tester	1
26787---FT---P	Sartocheck® 5 Plus Filter Tester	1

12 Dimensions and Connections

			
Membrane volume	3 mL	20 mL	150 mL
Size	Nano	Mini	5″
Dimensions in mm	37 × 31 H × Ø	Luer: 70 × 55 Sanitary: 100 × 55 Hose barb: 110 × 55 H × Ø	Sanitary: 190 × 77 Hose barb: 204 × 77 H × Ø
Connectors	Luer female	– Luer female – Sanitary ¾″, 25 mm outer, 14 mm inner Ø – Hose barb ½″, 12.7 mm*	– Sanitary ¾″ 25 mm outer, 14 mm inner Ø – Hose barb ½″, 12.7 mm*
Gaskets	n.a.	¾″, inner Ø 16 mm	¾″, inner Ø 16 mm

n.a. = not available | * Recommended inner diameter of flexible tube: ½″, 12.7 mm

			
Membrane volume	400 mL	800 mL	1.2 L
Size	10″	20″	30″
Dimensions in mm	Sanitary: 347 × 100 Hose barb: 359 × 100 H × Ø	Sanitary: 579 × 100 Hose barb: 591 × 100 H × Ø	Sanitary: 807 × 100 Hose barb: 819 × 100 H × Ø
Connectors	- Sanitary 1½″ 50.5 mm outer, 36 mm inner Ø – Hose barb ½″, 12.7 mm*	- Sanitary 1½″ 50.5 mm outer, 36 mm inner Ø – Hose barb ½″, 12.7 mm*	- Sanitary 1½″ 50.5 mm outer, 36 mm inner Ø – Hose barb ½″, 12.7 mm*
Gaskets	1½″, inner Ø 35.8 mm	1½″, inner Ø 35.8 mm	1½″, inner Ø 35.8 mm
n.a. = not available | * Recommended internal diameter of flexible tube: ½″, 12.7 mm			

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Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

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List of Sartorius material numbers applying to EPA-FIFRA

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97SC--04E4JOO--A	97LV--04E4JFF	
97SC--04E9BFF	97LV--04E4JFF--A	
97SC--04E9BOO	97LV--04E4JOO	
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