Single-Use Filtration and Sensor Solutions

Simplify and Control Your Filtration Processes

Simplifying Progress

SARTORIUS

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Standardized basic Transfer Sets that are quickly available: Pre-Designed Solutions (PDS)

→ Sartopore® Platinum, Sartopore® 2, XLM and XLG

→ 500 mm TPE tubing

→ Opta®
→ MPX Connector

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

→ Sartorius Filters
→ BioPAT® Flow
→ BioPAT® Pressure

→ Configure

The Final Filling Solution
Streamlined.
Standardized.
Simplified.

Filter Transfer Set Final Filling

→ Single or Redundant Sartorius Filters
Tubings
BioPAT® Pressure
Sampling
Connectors
Holder

→ Configure

The Special Solution
Customized solutions for complex assemblies that need to be designed from scratch: Engineer-To-Order (ETO)

→ Learn more on page 23.

The Large Solution
Large-Scale Single-Use Filtration Device: Maxicaps® MR

Ready-to-use, pre-assembled, pre-sterilized

→ Learn more on page 24.

Standard vs. Customized Solutions

Standardization and Harmonization
Whether you need simple (PDS) transfer sets or very complex assemblies, such as a PUPSIT (Pre-Use-Post-Sterilization-Integrity-Test) configuration, Sartorius will help you find the perfect design. Our experts can help you standardize and harmonize your single-use world, no matter how complex it seems today.

Your Options:
Simple off-the-shelf standardized options (PDS: Pre-Designed-Solutions)

Customizable assemblies that come within a few weeks (CTO: Configure-To-Order)

Complex solutions according to your needs (ETO: Engineer-To-Order)

Oetiker®* Metal Clamp vs. Plastic Cable Tie
All gamma irradiated & autoclaved Filter and Sensor Transfer Sets use Oetiker® clamps.

The metal clamps are wrapped with an innovative silicone rubber band to protect the user and the packaging.

* Oetiker® is a registered trademark of the Oetiker Group.

	The Fast Solution	The Flexible Solution	The Special Solution
	Pre-Designed Solutions (PDS)	**Configure-To-Order (CTO)**	**Engineer-To-Order (ETO)**
Filter Elements 100% Tested	■	■	-
100% Visual Inspection and Batch Record Review	■	■	■
Biocompatibility USP 87 or 88 Class VI	■	■	■
TSE|BSE EMA/410/01 & Reach	■	■	■
Pre-Qualified Connections	■	■	▪
Extractables Profile	■	■	▪
Assurance of Supply (AoS)	■	■	▪**
ASTM Transport Validation	■	■	-
Approx. Lead Time	4 weeks	6 weeks	-

■ Yes ▪ Case by case - On request ** Best AoS with Sartorius Components

Filter and Sensor Transfer Sets

Filter and Sensor Transfer Sets are pre-assembled, pre-sterilized and fully pre-qualified ready to use filtration units for connection to single-use processing solutions. Transfer Sets consist of filters or pressure | flow sensors pre-assembled with tubing and connectors for immediate connection to single use or hybrid stainless steel systems.

Important Considerations for Process Optimization with Single-Use Transfer Sets

Verification of the Right Components

- Which component to use? Ask for a demo!

Implementation

- How to integrate your transfer set
- How to control your parameters
- Extractables | Leachables

Routine Operation

- Assurance of supply
- Lead times
- Integrity testing
- Calibration

Easy Integration

Pre-sterilized Filter and Sensor Transfer Sets allow an easy integration of Sartorius filters and pressure or flow measurement in a single-use set-up.

A secure connection of the Transfer Set can be carried out in the following ways:

- Sterile connectors, such as Opta®, AseptiQuik® and others
- Connection to stainless steel equipment using Steam-Thru® Connectors
- Aseptic connection (under laminar flow) using a Tri-Clamp or MPX & MPC Quick Coupler connectors
- Sterile welding of TPE Tubing (C-Flex®) using the Biowelder TC®

Sterile Transfer Sets are intended for single-use. Additional multi-use components like the pressure transmitter and the clamp-on for flow pipes can be connected to any control devices.

Complete Process Control

Both sensor systems can be connected to a controlling unit, e.g. programmable logic control or local control platforms. By combining the sterile sensor Transfer Sets with Sartorius sterile Filter Transfer Sets, you can monitor for example the pressure upstream of the filter and enable immediate shut-off of the pumps in the event of critical pressure increase.

Flexibility and Ease of Use

Whether designing a new single-use process facility or integrating disposable technology step-by-step to your existing equipment, sterile Filter and Sensor Transfer Sets provide:

- Various tubing types & lengths
- Broad choice of connectors
- Ready to use solutions

Safety

- The filter elements are 100% integrity tested
- The sensor pipes are 100% tested during manufacturing (leak, offset, particles)
- 100% visual inspection and batch record review
- All connections are pre-qualified according to Sartorius Stedim Biotech quality standards

Read more in our **Data Sheet Filter & Sensor Transfer Sets**

Read more in our **Data Sheet Virus Filter Transfer Units Gamma**

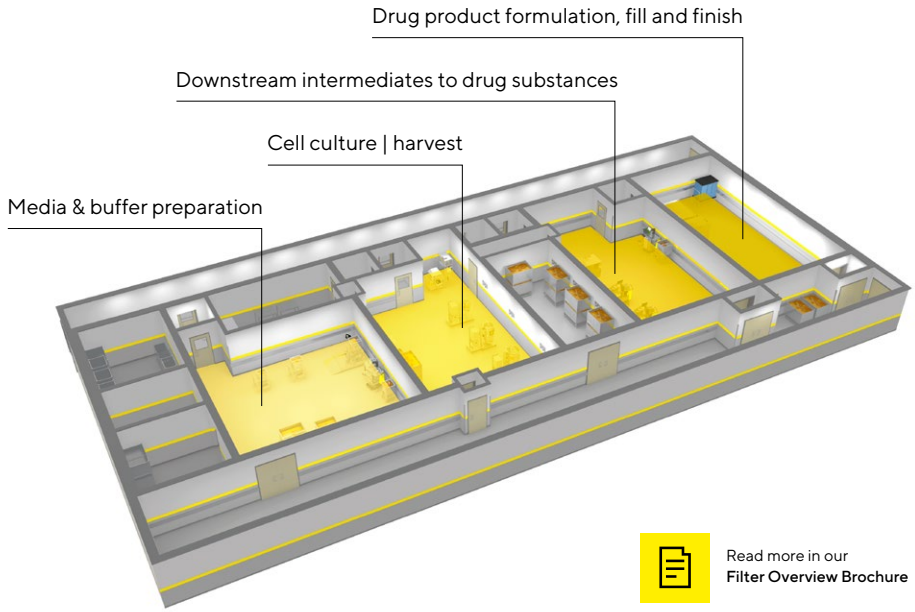
Read more in our **Data Sheet BioPAT® Pressure**

Read more in our **Data Sheet BioPAT® Single Use Flow Family**

Unprecedented Performance and Assurance of Supply

Sterile Filter and Sensor Transfer Sets for All Process Steps
Building on more than 20 years of experience in designing single-use solutions, we have established solutions for every media, buffer, harvest & downstream intermediates, drug substance and drug product process step.

The performance and assurance of supply of Sartorius Transfer Sets are based on the complete control of our manufacturing process for filters, sensors and the resins and extrusion of Tuflux® SIL tubes. Other fluid-contact components are secured by strategic partnerships, long term contracts and quality agreements and are available off-the-shelf to provide best delivery reliability.



Read more in our **Filter Overview Brochure**

Media
Solutions for media storage, shipping and feeding of bioreactors

Buffer
Solutions for storage and shipping of buffers used for purification or final formulation

Drug Substance
Solutions for storage and shipping of drug substance post virus filtration after the last cross-flow step

Cell Harvest & Downstream Intermediates
Solutions for harvesting cell cultures and for handling all the process intermediates before the last cross-flow step

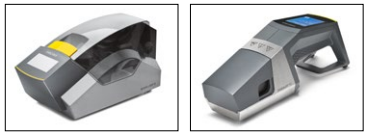
Drug Product
Solutions for sterile filtration, hold and transfer of drug products

Pre-Designed Solutions: Standard Filter Transfer Sets

Filter

Outlet Connections

C-Flex® 374 tubing allows for sterile weld connection with Biowelder® TC and sterile seal disconnection with Biosealer®



Oetiker® Metal Clamp

Passed ASTM Shipping Test

Connectors
- Opta® SFT enables sterile connections to other single-use systems
- CPC Quick Couplers (MPX) are used for either sanitary connection or aseptic connection under ISO5 laminar air flow

Filters
- Sartopore® Platinum 0.45 | 0.2 µm
- Sartopore® 2 0.45 | 0.2 µm
- Sartopore® 2 XLG 0.8 | 0.2 µm
- Sartopore® 2 XLM 0.2 | 0.1 µm

For these PES (polyethersulfone) membrane filters a broad range of sizes | filtration areas are available.

Tubing Materials

C-Flex® 374
Specifically designed for welding connections and sealing disconnections, Thermoplastic Elastomer Tubing is the ideal choice.

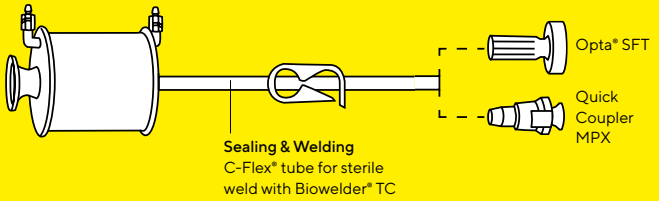
Pre-Designed Solutions: Standard Filter Transfer Sets

The Fast Solution
Standardized basic Transfer Sets that are quickly available: Pre-Designed Solutions (PDS)

Sartopore® Platinum
Sartopore® 2, XLM and XLG

500 mm TPE tubing

Opta®
MPX Connector



Overview

Filter Type	Filter	Tubing & Outlet Connector	Part Number	Lot size
Sartopore® 2 0.45 | 0.2 µm	Midicaps® size 7	½" ID Clear C-Flex® 500 mm	FFU500214	4
	Midicaps® size 8		FFU500215	4
	Midicaps® size 9	**Opta® male ½"**	FFU500216	4
	Midicaps® size 0		FFU500217	4
	Maxicaps® T-Style 10"		FFU500249	4
	Maxicaps® T-Style 20"		FFU500250	4
	Maxicaps® T-Style 30"		FFU500251	4
	Midicaps® size 7	½" ID Clear C-Flex® 500 mm	FFU500252	4
	Midicaps® size 8		FFU500253	4
	Midicaps® size 9	**MPX male + sealing cap**	FFU500254	4
	Midicaps® size 0		FFU500255	4
	Maxicaps® T-Style 10"		FFU500256	4
	Maxicaps® T-Style 20"		FFU500257	4
	Maxicaps® T-Style 30"		FFU500258	4

Filter Type	Filter	Tubing & Outlet Connector	Part Number	Lot size
Sartopore® 2 XLM 0.2 | 0.1 µm	Midicaps® size 7	½" ID Clear C-Flex® 500 mm	FFU500268	4
	Midicaps® size 8		FFU500269	4
	Midicaps® size 9	**Opta® male ½"**	FFU500270	4
	Midicaps® size 0		FFU500271	4
	Maxicaps® T-Style 10"		FFU500272	4
	Maxicaps® T-Style 20"		FFU500273	4
	Maxicaps® T-Style 30"		FFU500274	4
	Midicaps® size 7	½" ID Clear C-Flex® 500 mm	FFU500275	4
	Midicaps® size 8		FFU500276	4
	Midicaps® size 9	**MPX male + sealing cap**	FFU500277	4
	Midicaps® size 0		FFU500278	4
	Maxicaps® T-Style 10"		FFU500226	4
	Maxicaps® T-Style 20"		FFU500279	4
	Maxicaps® T-Style 30"		FFU500225	4

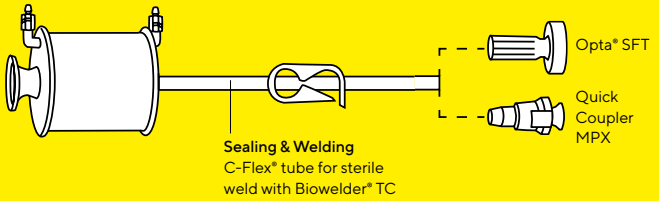
Pre-Designed Solutions: Standard Filter Transfer Sets

The Fast Solution
Standardized basic Transfer Sets that are quickly available: Pre-Designed Solutions (PDS)

Sartopore® Platinum
Sartopore® 2, XLM and XLG

500 mm TPE tubing

Opta®
MPX Connector

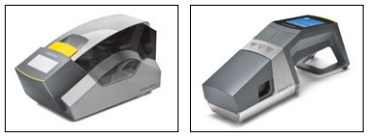


Overview

Filter Type	Filter	Tubing & Outlet Connector	Part Number	Lot size
Sartopore® Platinum 0.45 | 0.2 µm	Midicaps® size 7	½" ID Clear C-Flex® 500 mm **Opta® male ½"**	FFU500235	4
	Midicaps® size 8		FFU500236	4
	Midicaps® size 9		FFU500237	4
	Midicaps® size 0		FFU500238	4
	Maxicaps® T-Style 10"		FFU500239	4
	Maxicaps® T-Style 20"		FFU500240	4
	Maxicaps® T-Style 30"		FFU500241	4
	Midicaps® size 7	½" ID Clear C-Flex® 500 mm **MPX male + sealing cap**	FFU500242	4
	Midicaps® size 8		FFU500243	4
	Midicaps® size 9		FFU500244	4
	Midicaps® size 0		FFU500245	4
	Maxicaps® T-Style 10"		FFU500246	4
	Maxicaps® T-Style 20"		FFU500247	4
	Maxicaps® T-Style 30"		FFU500248	4

Filter Type	Filter	Tubing & Outlet Connector	Part Number	Lot size
Sartopore® 2 XLG 0.8 | 0.2 µm	Midicaps® size 7	½" ID Clear C-Flex® 500 mm **Opta® male ½"**	FFU500220	4
	Midicaps® size 8		FFU500221	4
	Midicaps® size 9		FFU500222	4
	Midicaps® size 0		FFU500223	4
	Maxicaps® T-Style 10"		FFU500259	4
	Maxicaps® T-Style 20"		FFU500260	4
	Maxicaps® T-Style 30"		FFU500261	4
	Midicaps® size 7	½" ID Clear C-Flex® 500 mm **MPX male + sealing cap**	FFU500262	4
	Midicaps® size 8		FFU500263	4
	Midicaps® size 9		FFU500264	4
	Midicaps® size 0		FFU500172	4
	Maxicaps® T-Style 10"		FFU500265	4
	Maxicaps® T-Style 20"		FFU500266	4
	Maxicaps® T-Style 30"		FFU500267	4

Configure-To-Order Filter Transfer Sets



Passed ASTM Shipping Test

Connectors
- Opta® SFT, AseptiQuik® and Kleenpak™ enable sterile connections to other single-use systems
- Tri-Clamp 1½" and ¾" sanitary flanges are used for either sanitary connection or aseptic connection under ISO5 laminar air flow to stainless steel systems
- CPC Quick Couplers are used for either sanitary connection or aseptic connection under a laminar air flow to single-use systems
- Stream-Thru® (STCII) valve allows for steaming and sterile transfer to stainless steel systems

Filters
The complete Sartorius filter range is available in a configurable transfer set. Pre-filters, sterile filters, virus filters and air filters.

Sensors
Single-use BioPAT® Pressure and Flow Sensors are also available in CTO Transfer Sets **(see page 18)**.

Tubing Materials

Tuflux® SIL
Platinum cured Silicone Si(Pt)

C-Flex® 374
Thermoplastic Elastomer TPE

Pharma-50 & Pharma-80
Platinum cured Silicone

Advanced Pump Tubing (APT)
Platinum cured Silicone (for peristaltic pump applications)

Sani-Tech® STHT®-R
Reinforced tubing for virus filter applications

Configure-To-Order Filter Transfer Sets

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

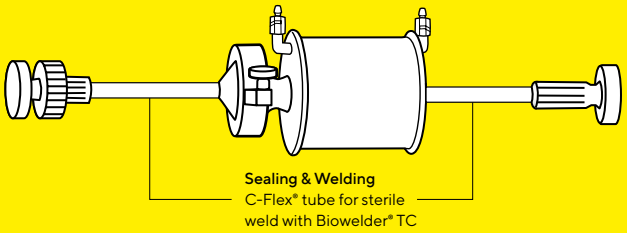
Configuration

Sartorius Filter
BioPAT® Sensors

Tube type
Tube length

Connectors

Inlet | Outlet Connectors
Opta® SFT
AseptiQuik® G
Stream-Thru® (STCII)
Kleenpak™ HT
Kleenpak™ Presto
Silicone Tuflux® tube for sterile disconnection with Clipster®
Tri-Clamp 1½" sanitary flange
Tri-Clamp mini sanitary flange
Quick Coupler (MPC, MPX)
Plug-in



Filter Options

Filter	Pore Size(s) [µm] | Retention Rate	Filter | Membrane Material	Sterilization Method
Sartopore® Platinum	0.45 | 0.2	Polyethersulfone, asymmetric Surface modified	Gamma
Sartopore® 2	0.45 | 0.2	Polyethersulfone, asymmetric	Gamma
Sartopore® 2 XLG	0.8 | 0.2	Polyethersulfone, asymmetric	Gamma
Sartopore® XLM	0.2 | 0.1	Polyethersulfone, asymmetric	Gamma
Sartopore® XLI	0.35 | 0.2	Polyethersulfone, asymmetric	Gamma
Sartopore® Air	0.2	Hydrophobic Polyethersulfone	Gamma
Sartoguard® PES	1.2 | 0.2 or 0.8 | 0.1	Polyethersulfone, asymmetric	Gamma
Sartoguard® GF	0.8 | 0.2 or 0.2 | 0.1	Polyethersulfone, Filter active Fleece: Glass Fiber	Autoclave
Sartofluor®	0.2	Hydrophobic PTFE	Autoclave
Sartolon®	0.45 | 0.2	Polyamide	Autoclave
Sartobran® P	0.45 | 0.2 or 0.65 | 0.45	Cellulose Acetate	Autoclave
Sartoclean® CA	0.8 | 0.65, 3.0 | 0.8	Cellulose Acetate	Autoclave
Sartoclean® GF	3 | 0.8 or 0.8 | 0.65	Cellulose Acetate, Filter Active Fleece: Glass Fiber	Autoclave
Sartopure® GF Plus	0.65 or 1.2	Glass Fiber	Autoclave
Sartopure® PP3	0.45, 0.65, 1.2, 3, 5, 8, 20, 50, 100	Polypropylene	Autoclave
Virosart® Max	0.1	Polyamid	Autoclave

Configure-To-Order Filter Transfer Sets, Gamma

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

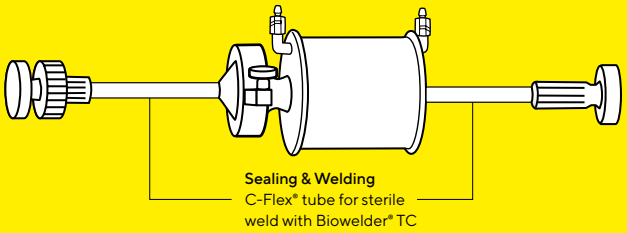
Configuration

Sartorius Filter
BioPAT® Sensors

Tube type
Tube length

Connectors

Inlet | Outlet Connectors
Opta® SFT
AseptiQuik® G
Stream-Thru® (STCII)
Kleenpak™ HT
Kleenpak™ Presto
Silicone Tuflux® tube for sterile disconnection with Clipster®
Tri-Clamp 1½" sanitary flange
Tri-Clamp mini sanitary flange
Quick Coupler (MPC, MPX)
Plug-in



Sealing & Welding
C-Flex® tube for sterile weld with Biowelder® TC

Connector & Tubing Options

Filter size	Connector	Tubing Type	Tubing Length Inlet [mm]	Tubing Length Outlet [mm]	Tubing Diameter (ID – OD)
Midicaps® size 7	Opta® SFT	C-Flex® 374	150	150	⅜" – ⅝"
Midicaps® size 8	Plug-in	Tuflux® Silicone	300	300	½" – ¾"
Midicaps® size 9	Tri-Clamp 1½"	Pharma-50	500	500	
Midicaps® size 0	Tri-Clamp ¾"		1,000	1,000	
Maxicaps® Size 10"	AseptiQuik® G			1,500	
Maxicaps® Size 20"	Quick Coupler MPC			3,000	
Maxicaps® Size 30"	Quick Coupler MPX			5,000	
	Stream-Thru® (STCII)				
	Kleenpak™ HT				

Configure-To-Order Filter Transfer Sets, Autoclave

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

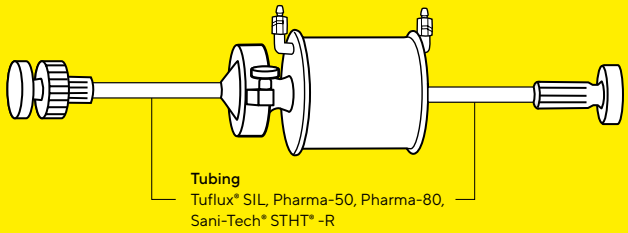
Configuration

Sartorius Filter
BioPAT® Sensors

Tube type
Tube length

Connectors

Inlet | Outlet Connectors
Opta® SFT
AseptiQuik® G
Stream-Thru® (STCII)
Kleenpak™ HT
Silicone Tuflux® tube for sterile disconnection with Clipster®
Tri-Clamp 1½" sanitary flange
Tri-Clamp mini sanitary flange
Quick Coupler (MPC, MPX)
Kleenpak™ Presto



Connector & Tubing Options

Filter size	Connector	Tubing Type	Tubing Length Inlet [mm]	Tubing Length Outlet [mm]	Tubing Diameter (ID – OD)
Midicaps® size 7	Opta® SFT	Tuflux® Silicone	100	100	⅜" – ⅝"
Midicaps® size 8	Tri-Clamp 1½"	Pharma-50	300	300	½" – ¾"
Midicaps® size 9	Tri-Clamp ¾"	Pharma-80			½" – ⅞"
Midicaps® size 0	AseptiQuik® G	Sani-Tech® STHT® -R			
Maxicaps® Size 10"	Quick Coupler MPC				
Maxicaps® Size 20"	Quick Coupler MPX				
Maxicaps® Size 30"	Stream-Thru® (STCII)				
	Kleenpak™ HT				
	Kleenpak™ Presto				

Configure-To-Order Filter Transfer Sets, Closed Design, Autoclave

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

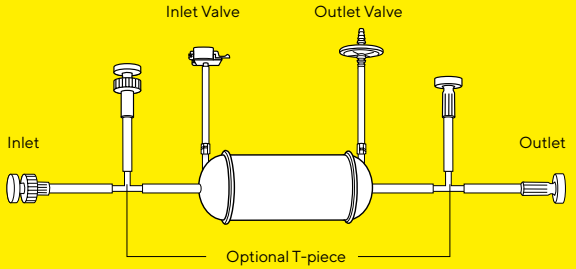
Configuration

Sartorius Filter
BioPAT® Sensors

Tube type
Tube length

Connectors

Inlet | Outlet Connectors
Opta® SFT
AseptiQuik® G
Stream-Thru® (STCII)
Kleenpak™ HT
Tri-Clamp 1½" sanitary flange
Tri-Clamp mini sanitary flange
Quick Coupler MPX
Kleenpak™ Presto



Connector & Tubing Options

Filter size	Connector	Tubing Type	Tubing Length Inlet [mm]	Tubing Length Outlet [mm]
Maxicaps® Size 10"	Opta® SFT	Tuflux® Silicone	100	100
Maxicaps® Size 20"	Tri-Clamp 1½"	Pharma-50	250 (with T-piece)	250 (with T-piece)
Maxicaps® Size 30"	AseptiQuik® G	Pharma-80	300	300
	Quick Coupler MPX	Sani-Tech® STHT® -R		
	Stream-Thru® (STCII)			
	Kleenpak™ HT			
	Kleenpak™ Presto			

Inlet Valve Connector	Outlet Valve Filter
Opta® SFT	Midisart® 2000
AseptiQuik® G	

Tubing Diameter (ID – OD)
¼" – 7⁄16" (valve lines only)
½" – ¾"
½" – ⅞"

Configure-To-Order Virus Filter Transfer Sets

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

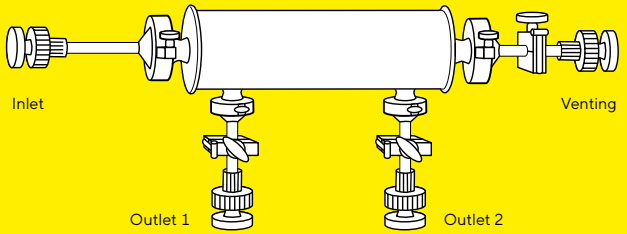
Configuration

Sartorius Filter
BioPAT® Sensors

Tube type
Tube length

Connectors

Inlet | Outlet Connectors
Opta® SFT
AseptiQuik® G
Tri-Clamp
Sani-Tech® STHT®-R



Downstream – Virosart® HF

- Pore Size: 20 nm nom.
- Membrane Material: Asymmetric Polyethersulfone
- Sterilization Method: Gamma



Filter Area	2.4 m^2 | 25.8 ft^2	0.8 m^2 | 8.6 ft^2	0.2 m^2 | 2.15 ft^2
Tubing types	Sani-Tech® STHT®-R		
Tubing diameters (ID × OD)			
Inlet	½" × ⅞"	⅜" × ⅝"	¼" × ½"
Outlet 1	¼" × ½"*	¼" × ½"*	¼" × ½"
Outlet 2	½" × ⅞"	⅜" × ⅝"	¼" × ½"
Venting	½" × ⅞"	½" × ⅞"	½" × ⅞"
	* IT Wetting Kit for Virosart® HF process modules is integrated to ensure a defined back pressure without the need for manual or automated valve control and thus optimal wetting conditions.		
Tubing lengths (Outlet 1 & 2 have the same tubing length; Venting line is fixed)	150 mm, 300 mm, 500 mm, 1,000 mm		
Connectors (Identical connector is used for one configuration)	Opta® SFT AseptiQuik® G Tri-Clamp 1½"	Opta® SFT AseptiQuik® G Tri-Clamp 1½"	Opta® SFT AseptiQuik® G Tri-Clamp 1½"

Configure-To-Order Virus Filter Transfer Sets

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

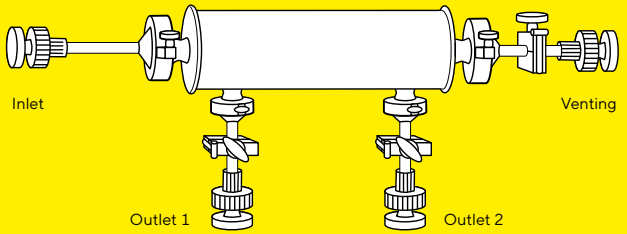
Configuration

Sartorius Filter
BioPAT® Sensors

Tube type
Tube length

Connectors

Inlet | Outlet Connectors
Opta® SFT
AseptiQuik® G
Tri-Clamp
Sani-Tech® STHT®-R (reinforced)



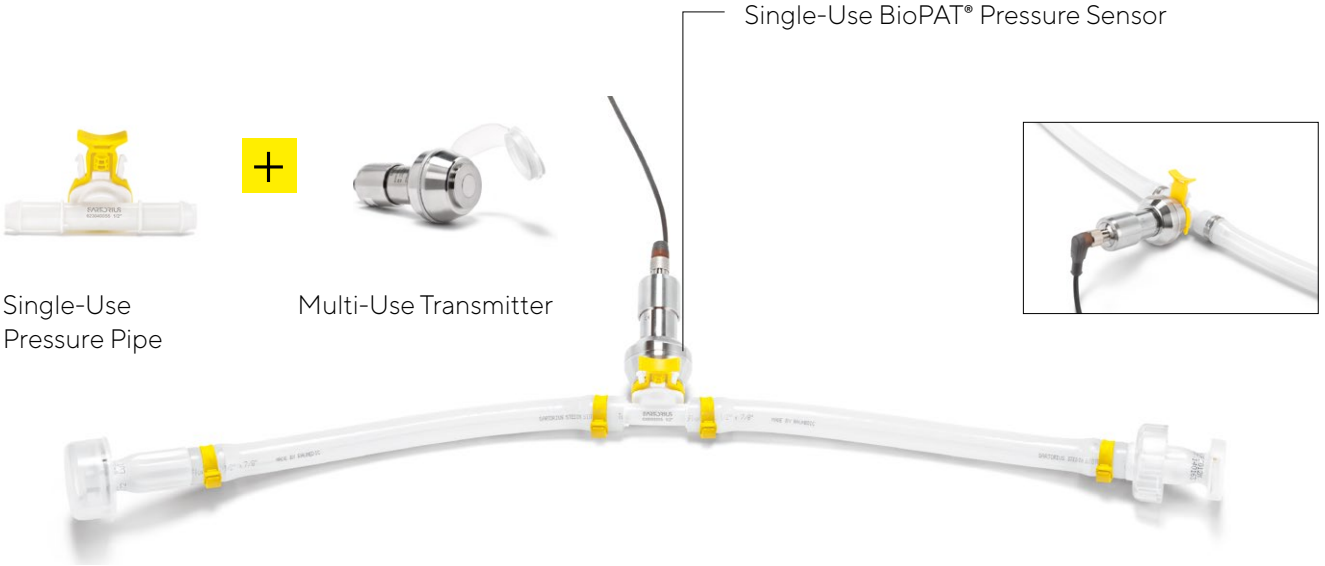
Upstream – Virosart® Media

- Pore Size: 20 nm nom.
- Membrane Material: Asymmetric Polyethersulfone
- Sterilization Method: Gamma

Passed ASTM Shipping Test

Filter Area	1 m^2 | 10.8 ft^2	0.3 m^2 | 3.2 ft^2
Tubing types	Sani-Tech® STHT®-R (reinforced)	
Tubing diameters (ID × OD)		
Inlet	½" × ⅞"	⅜" × ⅝"
Outlet 1	½" × ⅞"	¼" × ½"
Outlet 2	½" × ⅞"	¼" × ½"
Venting	½" × ⅞"	⅜" × ⅝"
Tubing lengths (Outlet 1 & 2 have the same tubing length; Venting line is fixed)	150 mm, 300 mm, 500 mm, 1,000 mm	
Connectors (Identical connector is used for one configuration)	Opta® SFT AseptiQuik® G	Opta® SFT AseptiQuik® G

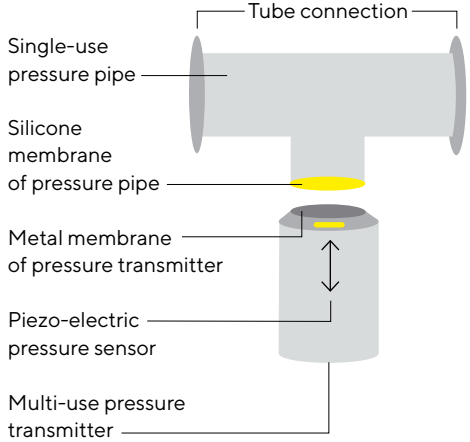
Pressure Sensor Transfer Sets



- Detect pressure increase due to filter blockage
- Process monitoring | control

Measurement Principle: Piezo-resistive pressure measurement

- The silicone membrane of the pipe and the metal membrane of the transmitter get tightly connected through an integrated fixing mechanism (not shown)
- The pressure in the pipe bends the silicone membrane, which bends the metal membrane
- The exerted force is detected by a pressure sensor within the transmitter



Sensor Read-out | Options


Flexact®

Sartorius Flexact®

- 5 pressure sensor inputs available
- sensor is readily integrated in the process control software
- plug-and-play fashion
- automation, alarm function and documentation


Open-ends cable

Do-it-yourself connection to any control unit

- use open-ends cable as power supply and data read-out
- signal is sent as an analogue 4 – 20 mA signal via blue and brown cable

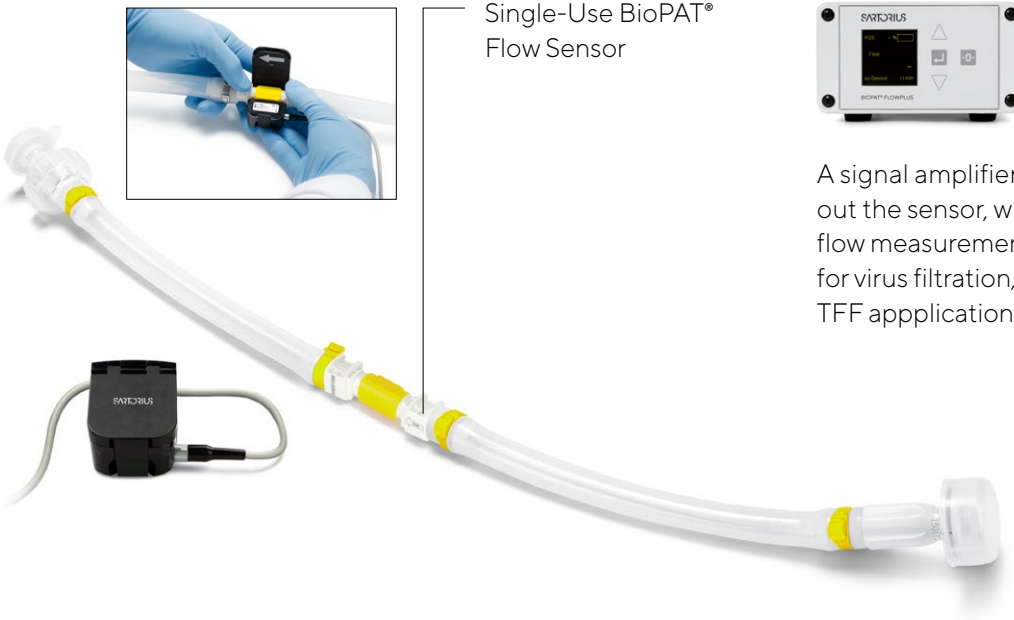
Bench-top indicator for direct read-out

For at-line reading and simple applications without need for automation or documentation.

Flow Sensor Transfer Sets

Single-Use
Flow Pipe

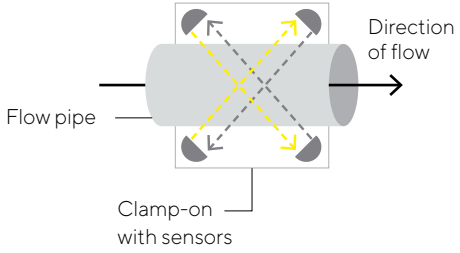
Multi-Use Clamp-On
Transmitter



A signal amplifier box is used to read out the sensor, with an option to have flow measurement in Flexact® Modular for virus filtration, cell clarification and TFF appplications.

Measurement Principle
Two pairs of sensors are fitted in one clamp-on:

- The upstream sensor sends sound waves in the direction of flow
- The downstream sensor sends sound waves against the direction of flow
- The flow accelerates the upstream sound waves and decelerates the downstream sound waves
- The detected transit time difference between the two signals is proportional to the flow velocity



High accuracy through optimized coupling, rigid material, straight flow path

Precalibrated
The sensor is precalibrated and the measurement can start immediately

High flexibility of tubing sizes and material
Any tubes can be connected to the pipes, even tissue-enhanced pipes. Other clamp-ons that measure on tubes can only be calibrated for one tube type.

Highly chemically resistant

ADC compatible

High pressure applications
The pipe can withstand a pressure of 5 bar*. The rigid material doesn't expand or collapse with changing pressure.

Note: BioPAT® Flow is the world's only ultrasonic clamp-on flowmeter with a flow pipe.

* The maximal operating pressure of an assembly is always limited to the pressure resistance of the weakest component. CTO sets are currently limited to 2 bar.

Configure-To-Order Filter Transfer Sets

The Flexible Solution
Configurable Filter and Sensor Transfer Sets with a broad range of tubing and connector options: Configure-To-Order (CTO)

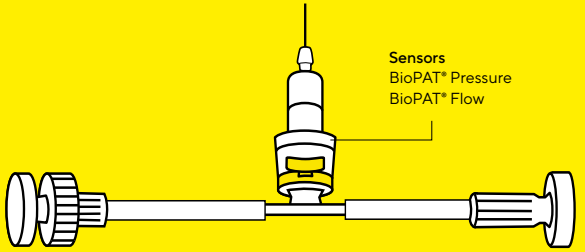
Configuration

Sartorius Filter
BioPAT® Sensors

Tube type
Tube length

Connectors

Inlet | Outlet Connectors
Opta® SFT
AseptiQuik® G
Stream-Thru® (STCII)
Kleenpak™ HT
Silicone Tuflux® tube for sterile disconnection with Clipster®
Tri-Clamp 1½" sanitary flange
Tri-Clamp mini sanitary flange
Quick Coupler (MPC, MPX)
Plug-in



Overview

Sensor	Connector	Tubing Type	Tubing Length Inlet [mm]	Tubing Length Outlet [mm]	Tubing Diameter (ID – OD)
BioPAT® Pressure	Opta® SFT	Tuflux® Silicone	150	150	½" – ¾"
BioPAT® Flow	Plug-in	C-Flex®	300	300	⅜" – ⅝"
	Tri-Clamp 1–½"	Pharma-50	500	500	½" – ⅞"
	Tri-Clamp ¾"	APT	750	1,000	
	AseptiQuik® G		1,000	1,500	
	Quick Coupler MPC		1,500	2,000	
	Quick Coupler MPX			2,500	
	Stream-Thru® (STCII)				
	Kleenpak™ HT				

Passed ASTM Shipping Test

Sensor Transfer Sets Implementation

Typical Applications for Pressure Measurement

- Use of a peristaltic pump, for example when filling a single-use bag
- Overpressure from one tank to another
- Pressure measurement in front of a filter
- Process monitoring | control

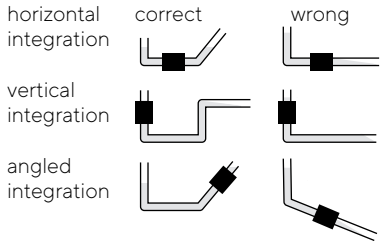
Why to use Single-Use Sensors

Currently often used autoclavable manometers with a T-piece bring a lot of disadvantages. Leakages, calibration and the risk of oil spilling into the filling line can be avoided by using single-use solutions.

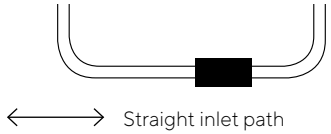
Sartorius BioPAT® Pressure and Flow sensors are available in quickly configurable standard solutions with a pressure resistance of 2 bar, which covers most applications. Customized configurations can be designed as well. For example transfer sets with braided tubing can be designed to resist up to 4 bar.

The pressure transducer only needs calibration once a year. For the Flow Pipe clamp-on Sartorius recommends to validate the correct performance every two years.

Recommended Installation of the BioPAT® Flow Sensors



To ensure proper functionality, it is important to position the sensor such that the pipe is always filled with liquid.



10 × inner diameter for systems < 3" inner diameter
15 × inner diameter for systems > 3" inner diameter

To reach highest accuracy, it is important to provide a straight inlet path in front of the sensor.

Combine Sensor and Filter Transfer Sets

Whether you prefer sterile connectors or weldable tubing the standard PDS | CTO transfer set range offers compatible options.

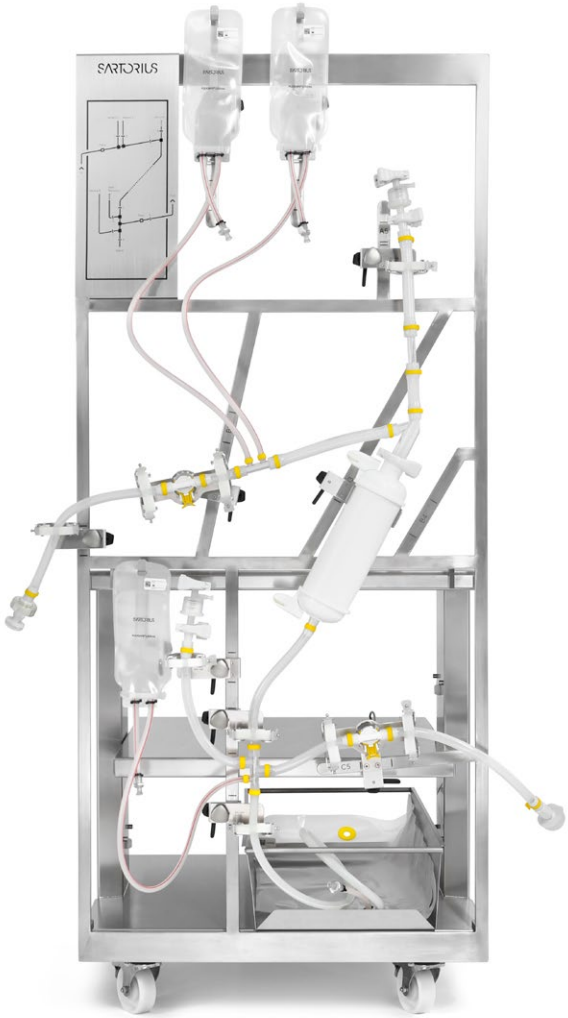
Single-Use Filter Transfer Set for Final Filling

Streamlined. Standardized. Simplified.

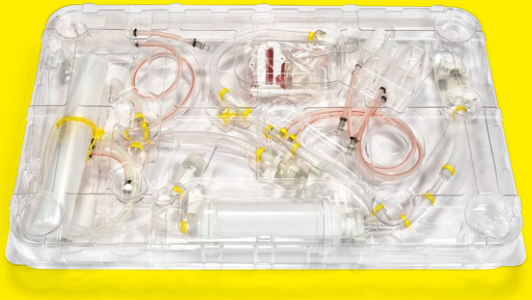
Introduction
Single-Use Filter Transfer Sets for Final Filling are an industry-first configured to order solution for filtration in final filling applications.

High standardization mitigates our customers risks while operating the system, it ensures lowest residual volume due to optimal component placing and saves up to 80% delivery time. The whole set up is PUPSIT optimized, qualified, sterile and ready to use.

Pre-designed	Fast Availability
Regulatory Compliant	PUPSIT Optimized
High Standardization	Promotes Usability and Mitigates Risks
Stainless Steel Holder	Engineered to Limit Product Loss
Full Flexibility	Various Filter Types and Sizes, Single and Redundant Filtration



ASTM transport validated blister packaging
- Excellent protection also for internal transfer
- Over pouch sealing validation
- Double bagged
- Product easily removable from blister



Filter Transfer Set Final Filling

Connectors
- Opta® SFT and AseptiQuik® enable sterile connections to other single-use systems
- TPE tube with plug for sterile weld

Filters
Various types and sizes of the complete Sartopore® filter family for gamma irradiatable filter transfer sets and Sartobran P for autoclavable filter tranfer sets are available.

Sensors
Single-use BioPAT® Pressure Sensors are available for our CTO filtration solution in final filling.

Tubing Materials

Tuflux® SIL | ½" × ¾"
Platinum cured Silicone Si(Pt)

Tuflux® TPE | ½" × ¾"
Thermoplastic Elastomer Tubing

C-Flex® 374 | ½" × ¾"
Thermoplastic Elastomer TPE

Sani-Tech® STHT®-R | ½" × ⅞
Reinforced tubing for filter integrity test area only

Sampling

Flexsafe® 2D Bag
150 ml or 250 ml with Tuflux® TPE ¼"

Mycap® Bottle
125 ml or 250 ml with C-Flex® 374 ¼"

Vent | IT line
- Sartopore® Air 0.2 µm size 4
- Sani-Tech® STHT®-R | ½" × ⅞"
- Sight glass ½" inner diameter

Central Venting

Gamma Variant:
Transparent Capolyester
TC 1.5" × ½" × ½"

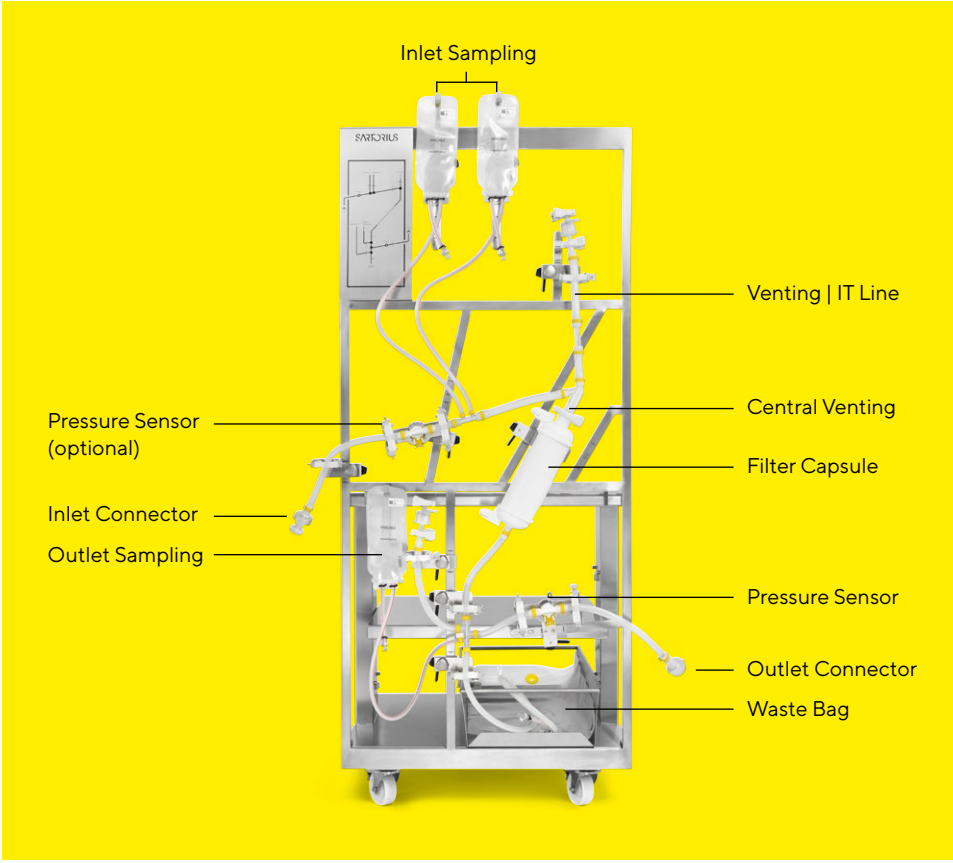
HD Variant:
TEE-Connector Polypropylene
½" × ½" × ½"

Vent | Recovery
Sartopore® Air 0.2 µm | size 4
- Tuflux® SIL | ½" × ¾"
- Tuflux® TPE | ½" × ¾"
- C-Flex® 374 | ½" × ¾"

Waste Bag

Flexsafe® 2 D Bag
- 10 L or 20 L
- Tuflux® TPE | ⅜ × ⅝" | 1,000 mm
- Tuflux® TPE | ¼ × 7/16" | 150 mm | MPC female with sealing cap

Read more in our
Data Sheet
Filter Transfer Set Final Filling



Configure-To-Order Filter Transfer Set Final Filling

The Final Fill Solution
Streamlined.
Standardized.
Simplified.

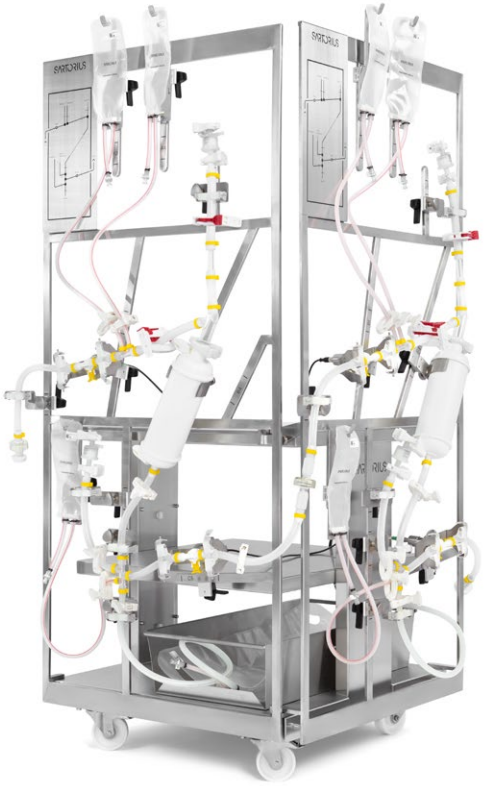
Filter Transfer Set
Final Filling

Configuration

Single or Redundant	Sartorius Filter	Sampling	Stainless steel Holder
Tube type	BioPAT® Pressure	Connector	

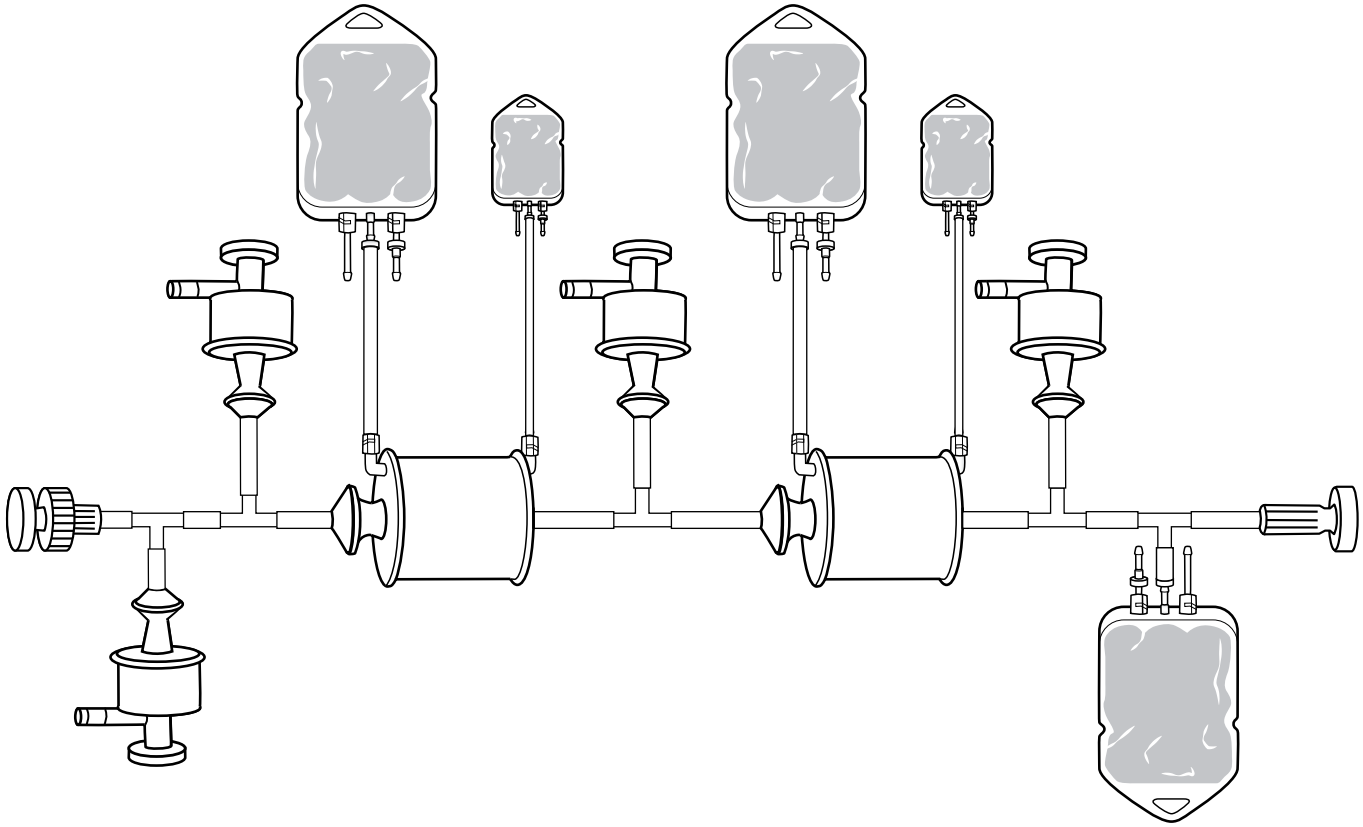
Filter Options

Filter Type	Pore Size	Filter Sizes	Sterilization Method
Sartopore® Platinum	0.45 | 0.2	Midicaps® Size 7, 8, 9, 0 | Maxicaps 10"	Gamma
Sartopore® Platinum HB	0.45 | 0.2	Midicaps® Size 7, 8, 9, 0 | Maxicaps 10"	Gamma
Sartopore® 2	0.45 | 0.2	Midicaps® Size 7, 8, 9, 0 | Maxicaps 10"	Gamma
Sartopore® 2 XLG	0.8 | 0.2	Midicaps® Size 7, 8, 9, 0 | Maxicaps 10"	Gamma
Sartopore® 2 XLI	0.35 | 0.2	Midicaps® Size 7, 8, 9, 0 | Maxicaps 10"	Gamma
Sartopore® 2 XLM	0.2 | 0.1	Midicaps® Size 7, 8, 9, 0 | Maxicaps 10"	Gamma
Sartobran® P	0.45 | 0.2	Midicaps® Size 7, 8, 9	Autoclaved separate FTS



Engineer-To-Order Filter and Sensor Transfer Sets

While Pre-Designed Solutions (PDS) and Configure-To-Order (CTO) Transfer Sets offer a broad design space that covers many needs, Sartorius is aware that there are specific needs that require special single-use assemblies. The Engineer-To-Order (ETO) process enables the development of customized solutions with the support of a team of application specialists. Personal assistance in finding the right single-use solution is indispensable when it comes to critical applications.



Speed and Flexibility for the Design and Delivery of Prototypes

- Dedicated Project Management Team across all regions (EU, US, Asia) to deliver quote in 3 – 5 days.
- ETO prototypes assembled on dedicated lines for 4 – 5 week delivery time.
- High flexibility obtained through our extensive base of components (>1,500) and qualifications integrated into a reliable and qualified custom solution.
- For new components we provide specific qualifications & studies in line with the User Requirement Specification (URS).

Large Scale Single-Use Filtration: Maxicaps® MR

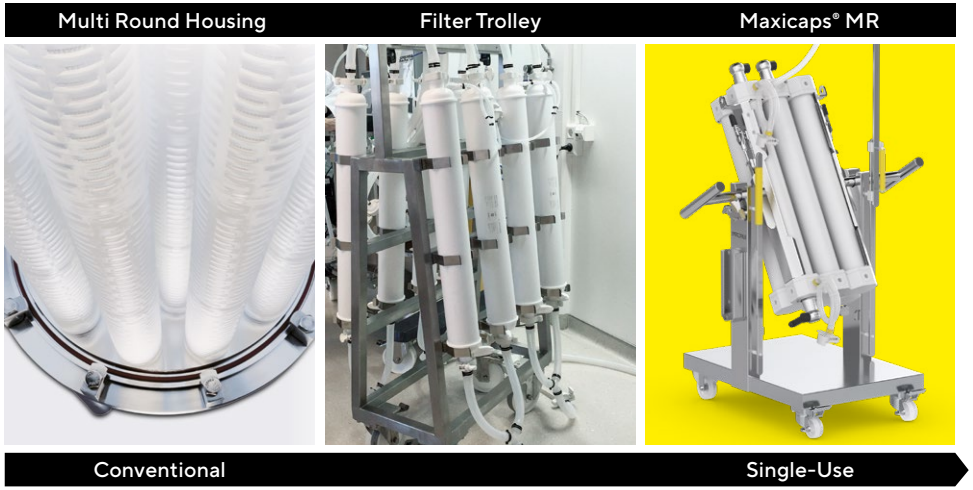
Introduction
Maxicaps® MR is a unique, pre-assembled, single-use, large-scale filtration unit that reduces connections and complexity while allowing for multiple configuration options for seamless process integration.

The novel design provides integrated fluid distribution, while using 80% less tubing and only two process connections. This decreases the risk of faulty connections by up to 90% and shortens installation, test, and dismantling time by up to 87%.

Background
Single-use filter capsules have been systematically replacing stainless steel housings and filter cartridges as a highly economical and risk-adverse choice for the biopharmaceutical industry. From capsules to complex custom assemblies, implementation of single-use filter systems reduces the time it takes for equipment setup and virtually eliminates the need for cleaning.

Conventional multi-round filter housings have now evolved into single-use Maxicaps® MR systems to meet today's advanced requirements.

Large Scale Filtration — Adaptation to Single-Use



C-Flex® is a registered trademark of Saint-Gobain Performance Plastics Corporation.

Maxicaps® MR

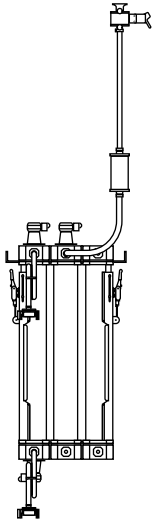
Overview Particle Reduction & Prefilter Options

Large-Scale Single-Use Filtration Device: Maxicaps® MR

Ready-to-use, pre-assembled, pre-sterilized

Configuration

Filter > **Venting** > **Inlet | Outlet Tubing** > **Inlet | Outlet Connectors**



Configuration Options

Filter	Retention Rate | Pore Size	Material	Delivery Condition	Number of 30" Cartriges	Filtration Area (Min.)	Filtration Area (Max.)
Sartoguard PES	0.1 µm | 0.2 µm	Polyetersulfone	Sterile	2 – 9	4.8 m² | 51.6 ft²	21.6 m² | 232.2 ft²
Sartoguard GF	0.1 µm | 0.2 µm	Polyetersulfone	Non-Sterile	2 – 9	2.7 m² | 29 ft²	12.15 m² | 130.5 ft²
Sartopure® GF Plus	0.65 µm | 1.2 µm	Glass Fiber	Non-Sterile | Sanitary	2 – 9	2.4 m² | 25.8 ft²	10.8 m² | 116.1 ft²
Sartopure® PP3	0.45 µm | 0.65 µm | 1.2 µm | 3 µm | 5 µm | 8 µm | 20 µm | 50 µm | 100 µm	Polypropylene	Non-Sterile | Sanitary	2 – 9	2.4 m² | 25.8 ft²	17.55 m² | 189 ft²
Sartoclean® CA	0.65 µm | 0.8 µm	Cellulose Acetate	Sanitary	2 – 9	3.6 m² | 38.8 ft²	16.2 m² | 174.6 ft²
Sartoclean® GF	0.65 µm | 0.8 µm	Cellulose Acetate	Sanitary	2 – 9	2.82 m² | 30.6 ft²	12.69 m² | 137.7 ft²

Venting
Basic
Advanced

Inlet | Outlet Tubing
Tuflux® SIL |750 mm
Sani-Tech® STHT-R® | 750 mm
Pharma-50 | 750 mm
Tuflux® TPE | 1,500 mm
C-Flex® 374 | 1,500 mm

Inlet | Outlet Connectors
AseptiQuik® G
AseptiQuik® L
Opta® SFT Female
Opta® SFT Male
Presto HB
1.5" Sanitary Clamp
Plug for TPE tubing

Read more in our **Data Sheet Maxicaps® MR**

Passed ASTM Shipping Test

All Maxicaps® MR with gamma stable filter are delivered sterile. Non-gamma stable filters are delivered in the sanitary delivery condition, that means autoclaved filter capsules, irradiated lids and tub sets finally assembles in a controlled environment by trained operators for lowest possible bioburden. C-Flex® and Sani-Tech® STHT®-R are registered trademarks of Saint-Gobain Performance Plastics Corporation. AseptiQuik® is a registered trademark of Colder Products Company.

Maxicaps® MR

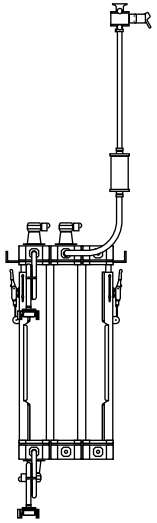
Overview Sterilizing Grade Filter Options

Large-Scale Single-Use Filtration Device: Maxicaps® MR

Ready-to-use, pre-assembled, pre-sterilized

Configuration

Filter > **Venting** > **Inlet | Outlet Tubing** > **Inlet | Outlet Connectors**



Configuration Options

Filter	Pore Size	Material	Delivery Condition	Number of 30" Cartriges	Filtration Area (Min.)	Filtration Area (Max.)
Sartopore® Platinum	0.2 µm	Modified Polyethersulfone	Sterile	2 – 9	6 m² | 64.6 ft²	27 m² | 290.7 ft²
Sartopore® 2	0.2 µm | 0.45 µm	Polyetersulfone	Sterile	2 – 9	3.6 m² | 38.8 ft²	16.2 m² | 174.6 ft²
Sartopore® 2 XLG	0.2 µm	Polyetersulfone	Sterile	2 – 9	4.8 m² | 51.6 ft²	21.6 m² | 232.2 ft²
Sartopore® 2 XLI	0.2 µm	Polyetersulfone	Sterile	2 – 9	4.8 m² | 51.6 ft²	21.6 m² | 232.2 ft²
Sartopore® 2 XLM	0.1 µm	Polyetersulfone	Sterile	2 – 9	4.8 m² | 51.6 ft²	21.6 m² | 232.2 ft²
Sartobran® P	0.2 µm | 0.45 µm	Cellulose Acetate	Sanitary	2 – 9	3.6 m² | 38.8 ft²	16.2 m² | 174.6 ft²

Venting
Basic
Advanced

Inlet | Outlet Tubing
Tuflux® SIL |750 mm
Sani-Tech® STHT-R® | 750 mm
Pharma-50 | 750 mm
Tuflux® TPE | 1,500 mm
C-Flex® 374 | 1,500 mm

Inlet | Outlet Connectors
AseptiQuik® G
AseptiQuik® L
Opta® SFT Female
Opta® SFT Male
Presto HB
1.5" Sanitary Clamp
Plug for TPE tubing

Read more in our **Data Sheet Maxicaps® MR**

Passed ASTM Shipping Test

All Maxicaps® MR with gamma stable filter are delivered sterile. Non-gamma stable filters are delivered in the sanitary delivery condition, that means autoclaved filter capsules, irradiated lids and tub sets finally assembles in a controlled environment by trained operators for lowest possible bioburden. C-Flex® and Sani-Tech® STHT®-R are registered trademarks of Saint-Gobain Performance Plastics Corporation. AseptiQuik® is a registered trademark of Colder Products Company.

Maxicaps® MR Virosart® Max

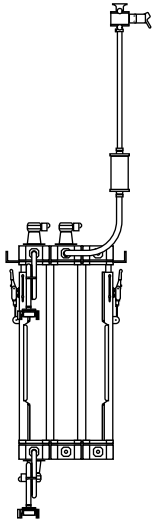
Overview Virus Pre-Filter Options

Large-Scale Single-Use Filtration Device: Maxicaps® MR Virosart®

Ready-to-use, pre-assembled, pre-sterilized

Configuration

Filter > **Venting** > **Inlet | Outlet Tubing** > **Inlet | Outlet Connectors**



Configuration Options

Filter	Pore Size	Material	Delivery Condition	Number of 30" Cartriges	Filtration Area (Min.)	Filtration Area (Max.)
Virosart® Max	0.1 µm	Polyamide	Sanitary	2 – 9	4.2 m² | 45.2 ft²	18.9 m² | 203.4 ft²

Venting
Basic
Advanced

Inlet | Outlet Tubing
Tuflux® SIL |750 mm
Sani-Tech® STHT-R® | 750 mm
Pharma-50 | 750 mm
Tuflux® TPE | 1,500 mm
C-Flex® 374 | 1,500 mm

Inlet | Outlet Connectors
AseptiQuik® G
AseptiQuik® L
Opta® SFT Female
Opta® SFT Male
Presto HB
1.5" Sanitary Clamp
Plug for TPE tubing

Read more in our **Data Sheet Maxicaps® MR**

Passed ASTM Shipping Test

Maxicaps® MR Virosart® Max is available only in the sanitary delivery condition, that means autoclaved filter capsules, irradiated lids and tub sets finally assembles in a controlled environment by trained operators for lowest possible bioburden. C-Flex® and Sani-Tech® STHT®-R are registered trademarks of Saint-Gobain Performance Plastics Corporation. AseptiQuik® is a registered trademark of Colder Products Company.

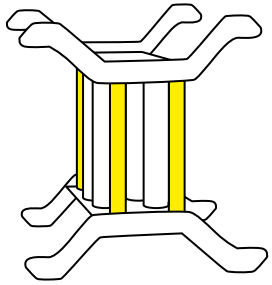
Maxicaps® MR Virosart® Media and HF

Overview Virusfilter Options

Large-Scale Single-Use Filtration Device: Maxicaps® MR Virosart®

Ready-to-use, pre-assembled, pre-sterilized

- Inlet Tubing
- Inlet Connectors
- Virosart® Media
- Virosart® HF
- Outlet Tubing
- Outlet Connectors



Maxicaps® MR Virosart® Media and HF is available in various pre-defined configurations.

Filter	Pore Size	Material	Delivery Condition	Number of Process Modules	Filtration Area (Min.)	Filtration Area (Max.)	Inlet Tubing	Inlet Connectors	Outlet Tubing	Outlet Connectors
Virosart® Media	20 nm	Polyethersulfone Surface modified	Gamma Irradiated	3 or 6	3 m² | 32.3 ft²	6 m² | 64.6 ft²	Reinforced silicon tubing	2 × AseptiQuik® G on Tri-Clamp 1½"	Reinforced silicon tubing	2 × AseptiQuik® G on Tri-Clamp 1½"
Virosart® HF	20 nm	Polyethersulfone Surface modified	Gamma Irradiated	2 – 6	4.8 m² | 51.7 ft²	14.4 m² | 155 ft²	Reinforced silicon tubing	2 × AseptiQuik® G on Tri-Clamp 1½"	Reinforced silicon tubing	2 × AseptiQuik® G on Tri-Clamp 1½" 1 × AseptiQuik® G on Tri-Clamp ¾", Tri-Clamp 1½", and flow restrictor

Read more in our Data Sheet Maxicaps® MR

Passed ASTM Shipping Test

Validation and Quality Assurance

Component Quality, Change Control and Business Continuity
Critical fluid-contact components used for Transfer Sets are secured by long term contracts and quality agreements to offer the best assurance of supply. Many designs are also available off-the-shelf to offer the best delivery reliability.

Components are selected to meet the most stringent quality requirements and all engagements with tubings are extensively qualified to ensure consistent robustness.

Our supply contracts ensure at least a 2-year change notification thus providing robust change control and business continuity.

Material Qualification
Filter and Sensor Transfer Set components are evaluated for conformity against the EP and USP standards after reviewing technical documentation and certificates of quality available from our suppliers.

Additional internal qualification tests are performed to establish extractable profiles, post gamma sterilization shelf life and consistent functional properties.

Criteria for Component Selection	Reference
Biological safety (USP Class VI)	USP<87> or USP<88>
TSE-BSE questionnaire	Compliance with EMA/410/01
Endotoxin	USP<85> or EP 2.6.14
Bioburden	ISO 11737
Sub visible particles	USP<788> or EP 2.9.19
Others	Bisphenol A free, REACH compliance

Our core expertise in plastics and polymers enables the selection of the cleanest and most inert materials to minimize chemical interactions with biopharmaceutical fluids to provide consistent cell growth.

Design Qualification
Component designs are selected to maximize tubing engagement tensile strength and tightness. All engagements with tubings are qualified for at least 2 years shelf life*. Test samples are visually inspected for absence of defect and tested for leak and traction.

* Virus Filter Transfer Sets have 1 year shelf life

Transfer Sets with Tuflux®
Tuflux® SIL (Pt) tubing in all your process steps ensures best performance and assurance of supply.

Filter and Sensor Transfer Sets

Components	Biological compatibility (USP Class VI)	Endotoxin Sub visible particles bioburden	TSE | BSE EMA/410/01 & REACH	Change Control Notification
Tuflux® tubes	Yes	Yes	Yes	24 months
Opta® sterile connectors	Yes	Yes	Yes	24 months
Fittings	Yes	Yes	Yes	24 months
Connectors	Yes	Yes	Yes	24 months
Filters	Yes	Yes	Yes	24 months**
Sensor Pipes	Yes	Yes	Yes	24 months**

** Minor changes might have a shorter notification time. Changes will be evaluated according to the Sartorius Change Matrix.

Validation and Quality Assurance

Transfer Sets are qualified using extensive biological, chemical, physical, extractable and cell growth testing to provide reliable data for validation purposes applicable to a wide range of process conditions.

Sartorius Stedim Biotech Quality
Systems for single-use products follow applicable ISO 9001 and FDA regulations. Because single-use systems replace traditional stainless steel equipment, suppliers own a more important part of the drug manufacturing process. Design, manufacture, quality control and sterilization of Filter and Sensor Transfer Sets are conducted under conditions that mirror biopharmaceutical operations like requirements to ensure they are supplied clean, pure, endotoxin free and sterile.

Filter and Sensor Transfer Sets
are qualified and routinely controlled to provide consistent performance.

Additional tubing materials, components and pressure ratings are available for customized assemblies upon request.

Biocompatibility and Chemical Compatibility
- ISO 10993:
  Biological reactivity tests, in Vitro
  Not available for all components
  see SD152370
- USP<87>: Biological reactivity tests, in Vitro
- USP<88>: Biological reactivity tests, in Vivo
- Internal standardized methods for cell growth compatibility evaluation

Purity, Extractable & Potential Leachable
- Extractable data based on knowledge and control of resins and film manufacturing process
- TSE/BSE: EP 5.2.8

Cleanliness, Particles
- USP<788> and EP 2.9.19:
  Particulate Matter in Injections
  Endotoxin
- USP<85> and E P 2.6.14:
  Bacterial endotoxins Sterility
- ISO 11737 Sterilization of medical devices – Microbiological methods:
  Bioburden
- ISO 11137 Sterilization by irradiation of Medical Devices: Sterilization of Medical Devices
- ISO 17665 Steam Sterilization
- ISO 14644: Cleanroom environmental controls

Quality Assurance Certificate (PDS & CTO)

Statement	Monitoring	Batch Testing
Biosafety USP 87 or 88 Class VI	Bacterial Endotoxins USP 85 and EP 2.6.14.	**Bacterial Retention** Each 0.2 and 0.1 µm membrane lot according to ASTM 838
TSE-BSE EMA/410/01	Bioburden	**Virus Retention** Each 20 nm membrane lot is tested for PP7 retention
	Particulate Matter USP "Large Volume Injections for Single Dose Infusion"	**Integrity Test** Each integrity testable membrane filter element was tested by means of diffusion and bubble point testing
		Visual Inspection 100% of the products
		Product Conformity Technical drawing and batch record review
		Sterilization

Sartorius Extractables & Leachables Approach

Sartorius developed a new extractables matrix based on over 20 years of experience, know-how and results of recent internal studies and consideration of BPOG, USP and ASTM. It provides worst case and consistent extractables data for Sartorius components and products.

For single-use Transfer Sets Sartorius is following a component approach.

Four levels of support are provided depending on the criticality of their intended use in the manufacturing process:

1. Extractables guides per major component or product family.
2. Extractables reports:
   Data extrapolated from the component tested to a multi-component assembly (data selected from Opta® connector, tubing and filter extractables guide).
3. Process related extractables reports: Data extrapolated from the component tested to a multi-component assembly and related to specific end user process conditions (surface | volume ratio, contacting fluid and contact conditions based on the application).
4. Leachables studies: Extraction and study conditions with specific pharmaceutical solutions | product and process conditions.

The extensive data provided in our Validation Guides and Extractables Guides builds a comprehensive basis for the risk assessment of your respective process and product.

We work in partnership with you to develop the appropriate Extractables & Leachables approach – risk-based and adapted to your specific production environment.

Legal requirements, rapid time-to-market, high cost efficiency:
We understand the daily challenges in the biopharmaceutical industry and know what is important in your business.

Implementation and Validation Services

Application Support
Our expert Application Specialists provide global support for:

- Single-use process URS definitions and application development
- Process design with standard and custom solutions
- Filter selection and sizing optimization study
- SOP development, process validation and operator training
- Technology transfer and process optimization

Instrument Services
- Installation start up, FAT, IQ & OQ, calibration and maintenance

Validation Services
Our global validation services network offers consultancy service as well as product and process specific validation studies including a comprehensive test portfolio:

- Risk assessment support
- Grouping | Bracketing support
- Microbiological tests
- Chemical | Physical tests
- Extractables | Leachables tests

Find out more
For more information, please visit www.sartorius.com

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