

Virus Filter Transfer Units (Gamma)

Pre-Assembled,
Sterile & Ready to Use,
Single-use
Virosart® Filtration Units



Product Information

Virus Filter Transfer Units (Gamma) are pre-assembled, pre-sterilized and fully pre-qualified ready to use filtration units for connection to single-use processing solutions. The smart Virosart® capsule design with low footprint, minimal flushing volumes and sterile delivery secures ease of use as well as fast installation of the filtration units.

What?

Virus Filter Transfer Units (Gamma) allow an easy integration of any gamma-stable Sartorius virus filter (Virosart® HF and Virosart® Media) into a single-use setup.

A secure connection of the Virus Filter Transfer Unit can be realized in the following ways:

- Sterile connection using sterile connectors, such as Opta® and AseptiQuik®
- Aseptic connection (under laminar flow) using a TriClamp

How?

Through years of experience with single-use technologies, Sartorius Stedim Biotech has qualified a wide range of components and connections commonly used for Virus Filter Transfer Units. With this portfolio (see details on p. 3 and 4) a Virus Filter Transfer Unit can be configured easily by our team. Contact your local sales representative or application specialist for an instant quote and technical drawing of a configurable Virus Filter Transfer Unit.

Why?

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 Virus Filter Transfer Sets provide:

- Various tubing diameters & lengths
- Broad choice of connectors
- Sterilization by gamma-irradiation
- Ready to use solutions

Modularity

By splitting your assemblies into modules, e.g. Filter Transfer Sets, bags, Sensor Transfer Sets you can:

- Produce several products with the same pool of equipment
- Reduce the total amount of part numbers
- Optimize the warehousing footprint

Safety

- Sartorius Stedim Biotech follows strict regulatory compliance standards.
- The filter elements are 100% integrity tested.
- 100% visual inspection and batch record review.
- All connections are pre-qualified according to Sartorius Stedim Biotech quality standards.

Technical Data

Virosart® HF – Downstream Virus Filter

Available virus filter



2.4 m² | 25.8 ft²

0.8 m² | 8.6 ft²

0.2 m² | 2.15 ft²

Tubing types Sani-Tech® STHT® -R (reinforced)

Tubing diameters (ID × OD)

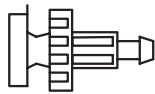
Inlet 1/2" × 7/8"
Outlet 1 1/4" × 1/2"*
Outlet 2 1/2" × 7/8"
Venting 1/2" × 7/8"

3/8" × 5/8"
 1/4" × 1/2"*
 3/8" × 5/8"
 1/2" × 7/8"

1/4" × 1/2"
 1/4" × 1/2"
 1/4" × 1/2"
 1/2" × 7/8"

Tubing lengths** 150 mm, 300 mm, 500 mm, 1000 mm

Connectors***



Opta®



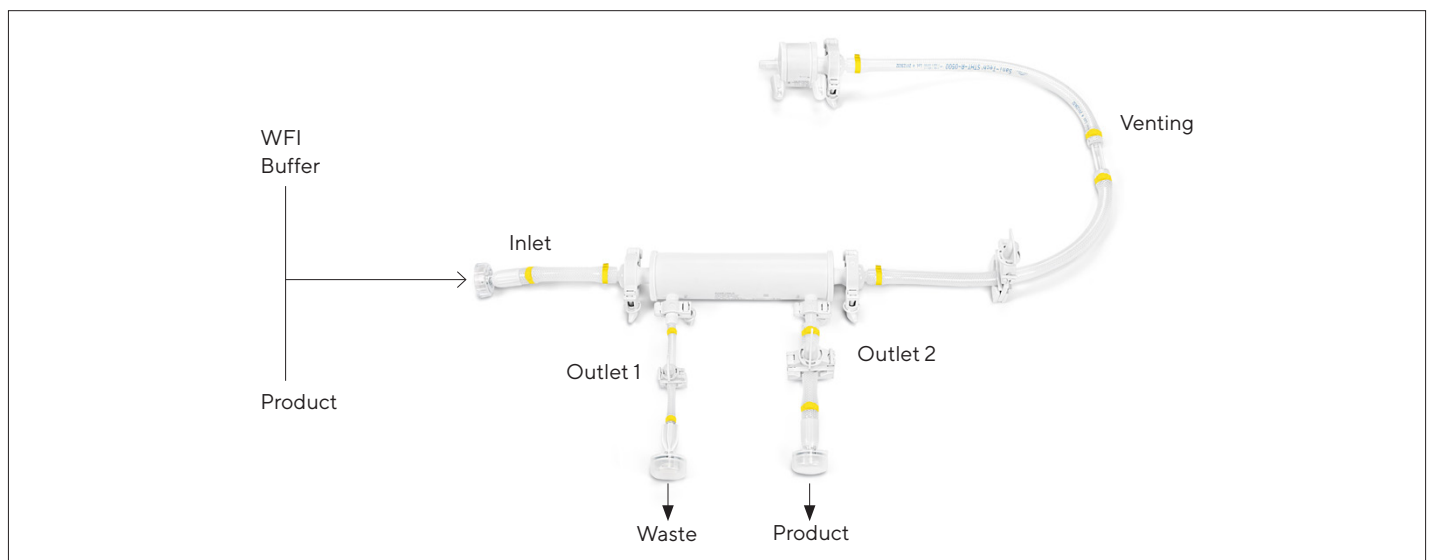
AseptiQuik®



TriClamp

Technical parameters

- Max. allowable operating pressure: 3.0 bar | 43.5 psi
- Sterilization method: Gamma irradiation. Re-sterilization is not permitted!



* 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.

** Outlet 1 & 2 have the same tubing length

** Venting line is fixed

*** Identical connector is used for one configuration

Virosart® Media – Upstream Virus Filter

Available virus filter



1 m² | 10.8 ft²

0.3 m² | 3.2 ft²

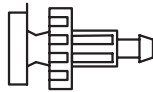
Tubing types Sani-Tech® STHT® -R (reinforced)

Tubing diameters (ID × OD)

Inlet	1/2" × 7/8"	3/8" × 5/8"
Outlet 1	1/2" × 7/8"	1/4" × 1/2"
Outlet 2	1/2" × 7/8"	1/4" × 1/2"
Venting	1/2" × 7/8"	3/8" × 5/8"

Tubing lengths** 150 mm, 300 mm, 500 mm, 1000 mm

Connectors***



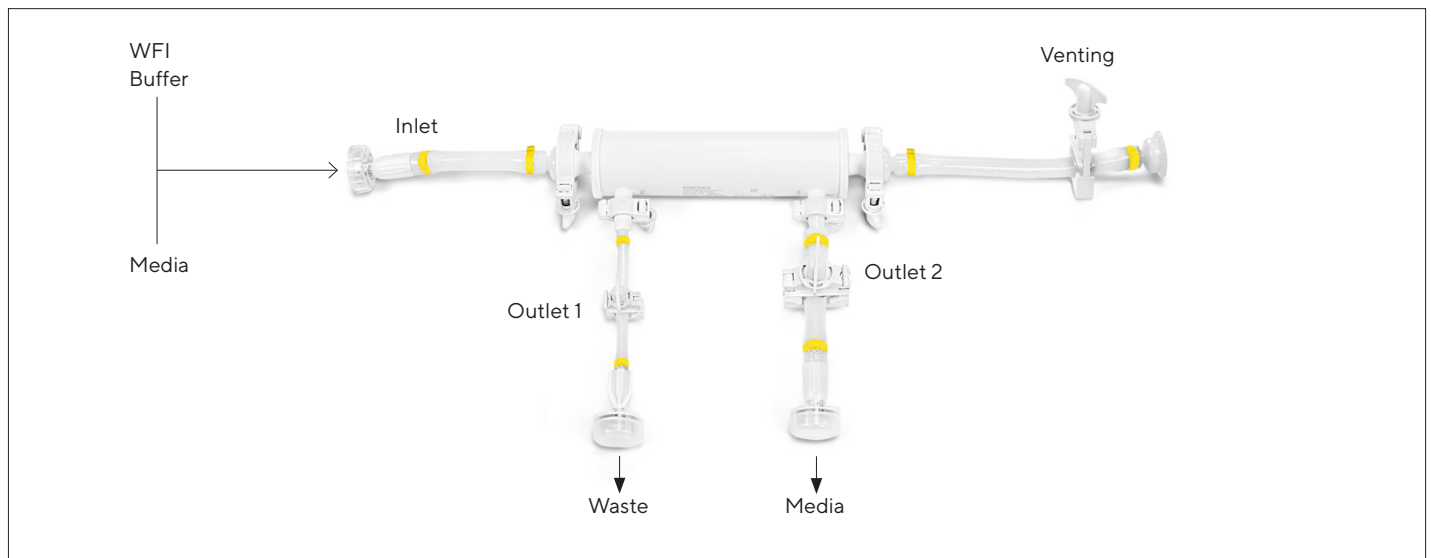
Opta®



AseptiQuik®

Technical parameters

- Max. allowable operating pressure: 3.0 bar | 43.5 psi
- Sterilization method: Gamma irradiation. Re-sterilization is not permitted!



** Outlet 1 & 2 have the same tubing length
 ** Venting line is fixed
 *** Identical connector is used for one configuration

Materials

Component	Material
Product Contact	
Connectors:	
Opta®	Acrylate/PC/PP/PSU/TPV
AseptiQuik®	PC/SI/PES/PTFE
TriClamp	PEHD
Tube:	
Sani-Tech® STHT® -R	Silicon (Reinforced)
Connecting pieces:	
Flow Reducer	PP
Sight glass	PET
Non-Product Contact	
Oetiker® clamp	Stainless Steel
Gasket	Silicon
Clamp	PA GLASS REINFORCED
Valve	PSU

Regulatory Compliance

- All filters and tubing meet the requirements of the current USP Biological Reactivity tests <88> and all other product contact materials have passed USP <87> or ISO10993 as a minimum requirement.
- The Virus Filter Transfer Sets are in compliance with the European guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary products (EMA/410/01).
- The Virus Filter Transfer Sets are subject to bioburden, endotoxin and particulate matter control on a regular basis.
- Meet or exceed the requirements for WFI quality standards set by the current USP.
- USP Plastic Class Test VI.
- Designed, developed and manufactured in accordance with an ISO 9001 certified Quality Management System.
- The Virus Filter Transfer sets are produced in a cleanroom class ISO 7.
- The Virus Filter Transfer Sets (Gamma) are sterilized using a validated process in accordance with DIN EN ISO 11137 regulations.
- 100% of the products undergo visual inspection and are subject to batch record.

Technical References

Validation Guide Filter Transfer Set	2630981-000
Validation Guide Virosart® HF	2841203-000
Validation Guide Virosart® Media	2827073-000
Extractable Guide Virosart® HF	2641986-000
Extractable Guide Virosart® Media	2494649-000

AseptiQuik® is a registered trademark of the Colder Product Company.

Accessories & Services

Adsoptive Pre-Filtration

Virosart® Max protects your virus filter irrespective of the process conditions. Virosart® Max will downsize your process and reduce your total virus filtration costs. Virosart® Max is available as ready-to-use filter transfer set as well as stand-alone capsules and cartridges.



Integrity Testing using Sartocheck®

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



Ready-to-use Filter Transfer Sets

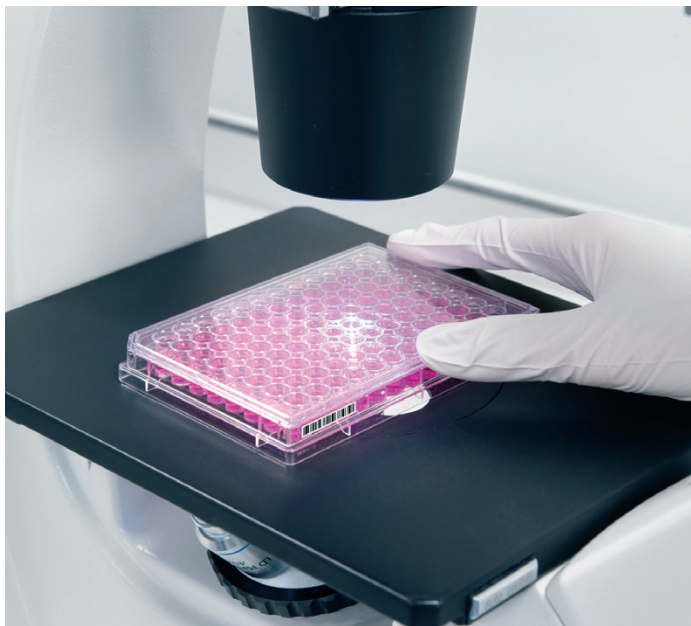
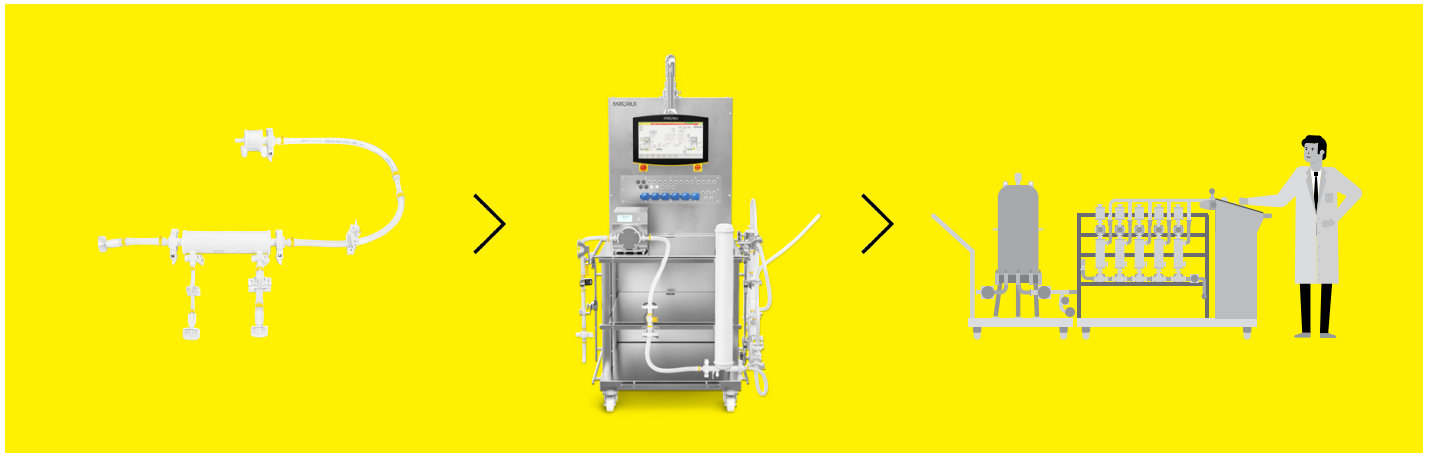
Simplify your daily routine work by using modular filter assembly.

Single-use Systems

Flexible processing with Flexact® VR system for production from pilot plants up to commercial processing.

Customized Systems

High level of automation and individual requirements can be realized by customized single-use or hybrid solutions.



Sartorius Confidence® Virus Clearance Services are the perfect complement to Virosart® filters.

Our services provide:

- Virus clearance studies
- Process design support
- Optimization support

We use a variety of different relevant and model viruses including MVM, MuLV, Reo-3 and HSV-1. The combination of product and services provides you with a comprehensive virus clearance solution that gives you the confidence you need to proceed.

BioOutsource Testing Services


Your partner to assure an effective virus clearance strategy for your process by MCB | WCB characterization and bulk harvest testing.

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

 For further contacts, visit
www.sartorius.com