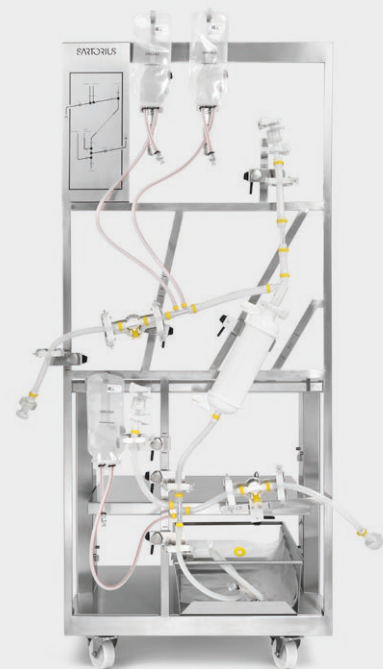


# Filter Transfer Set Final Filling

Streamlined. Standardized.  
Simplified.



## Product Introduction

By providing an industry-first, pre-designed solution for filtration in final filling, Sartorius filter transfer sets can reduce lead times by up to 80%. Standardized product design offers identical operating procedures to facilitate handling and mitigate the risk of operation errors, regardless of filter type and size. Further, the qualified, sterile filter transfer set for final filling is regulatory compliant and optimized for PUPSIT.

## Key Features & Benefits

- 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

## Relevant Applications

- Filtration of bulk drug substance into the bag (e.g., Celsius) or stainless steel cryovessel
- Filtration of drug products into a header bag of a filling machine

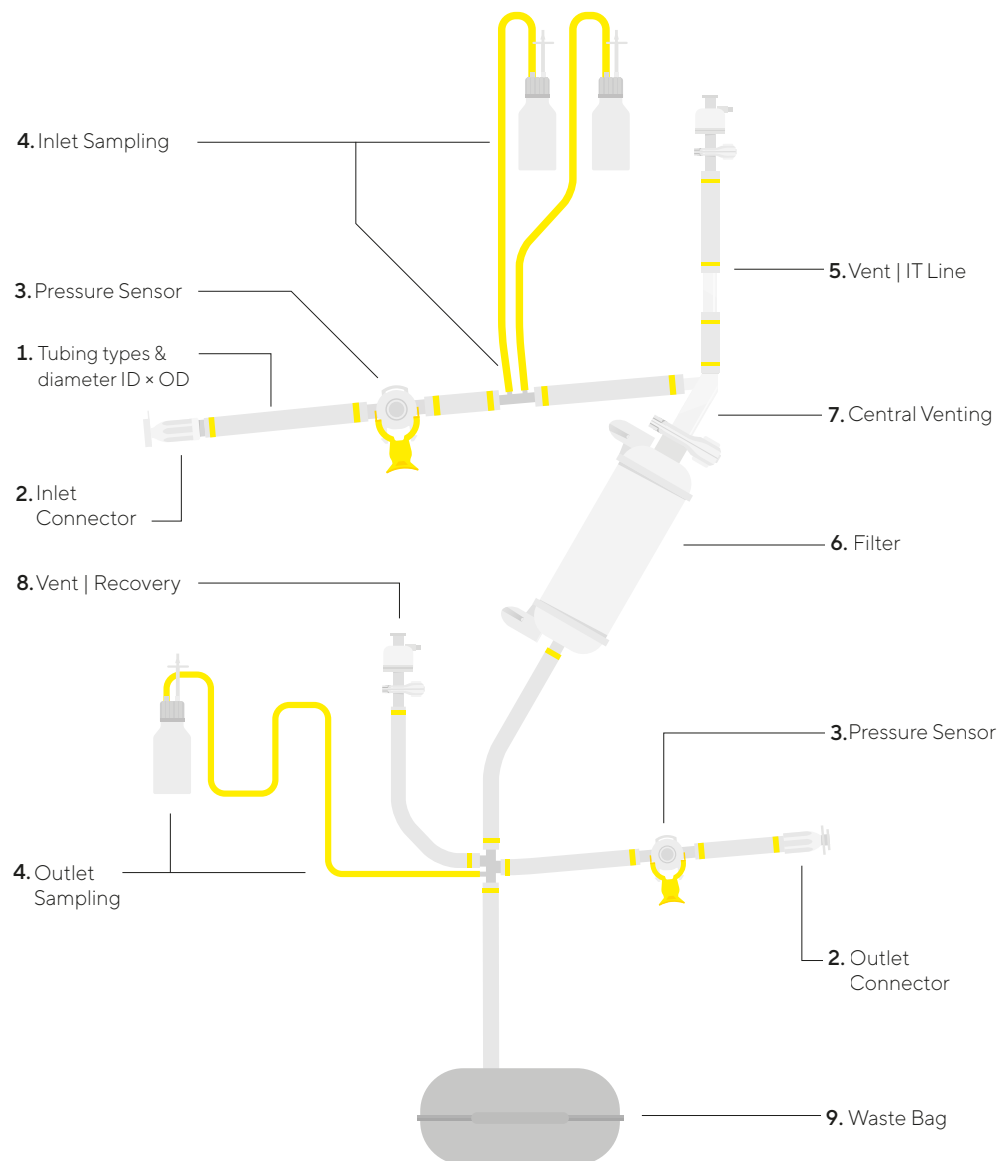
## Relevant Process Steps

- Sterile Filtration
- Fill & Finish



# Technical Specifications

## Single-Use Assembly



	Inlet	Outlet	Comment
<b>1. Tubing types   Tube diameter ID×OD</b>	<ul style="list-style-type: none"> <li>TuFlux® Sil   ½" × ¾"</li> <li>TuFlux® TPE   ½" × ¾"</li> <li>C-Flex® 374   ½" × ¾"</li> <li>Sani-Tech® STHT®-R   ½" × ⅞" (Filter integrity test area only)</li> </ul>	<ul style="list-style-type: none"> <li>TuFlux® Sil   ½" × ¾"</li> <li>TuFlux® TPE   ½" × ¾"</li> <li>C-Flex® 374   ½" × ¾"</li> </ul>	
<b>2. Connector</b>	<ul style="list-style-type: none"> <li>OPTA® SFT</li> <li>AseptiQuik® G</li> <li>TPE tube with plug for sterile weld</li> </ul>	<ul style="list-style-type: none"> <li>OPTA® SFT</li> <li>AseptiQuik® G</li> <li>TPE tube with plug for sterile weld</li> </ul>	
<b>3. Pressure Sensor</b>	BioPAT® Pressure	BioPAT® Pressure	Optional
<b>4. Sampling</b>	0 or 1 or 2	0 or 1	Optional
<b>Vessel   Volume Tubing type   ID   length</b>	Flexsafe® 2D bag   150 or 250 [mL] TuFlux® TPE   ¼"   770 mm or Mycap® botte 125 or 250 [mL] C-Flex® 374   ¼"   770 mm	Flexsafe® 2D bag   150 or 250 [mL] TuFlux® TPE   ¼"   770 mm or Mycap® botte 125 or 250 [mL] C-Flex® 374   ¼"   770 mm	<ul style="list-style-type: none"> <li>Flexsafe® 2D bag with outlet TuFlux® TPE   ¼"   150 mm, MPC female with sealing cap</li> <li>MyCap® with Quickseal and Minisart® vent filter</li> </ul>
<b>5. Vent   IT Line</b>			Mandatory
<b>Filter Type   Filter Size</b>	Sartopore® Air 0.2 µm   size 4		
<b>Tubing types   Tube diameter ID×OD</b>	½" × ⅞"		
<b>Sight glass</b>	Transparent medical grade Copolyester ½" inner diameter		
<b>6. Filter</b>	<b>Filter Type</b>	<b>Filter Size</b>	<b>Comment</b>
	<ul style="list-style-type: none"> <li>Sartopore® Platinum 0.2 µm</li> <li>Sartopore® Platinum HB 0.2 µm</li> <li>Sartopore® 2 0.2 µm</li> <li>Sartopore® 2 XLG 0.2 µm</li> <li>Sartopore® 2 XLI 0.2 µm</li> <li>Sartopore® 2 XLM 0.1 µm</li> </ul>	Midicaps® size 7, 8, 9, 0 Maxicaps® 10"	
	Sartobran® P 0.2 µm	Midicaps® size 7, 8, 9	Filter Tansfer Set required
<b>7. Central venting</b>	Gamma variant	HD-Variant	
	<ul style="list-style-type: none"> <li>Transparent Copolyester</li> <li>TC 1.5" × ½" × ½"</li> </ul>	TEE-Connector Polypropylene ½" × ½" × ½"	
<b>8. Vent   Recovery</b>			Optional
<b>Filter type   filter size</b>	Sartopore® Air 0.2 µm   size 4		
<b>Tubing types   tube diameter ID×OD</b>	<ul style="list-style-type: none"> <li>TuFlux® Sil   ½" × ¾"</li> <li>TuFlux® TPE   ½" × ¾"</li> <li>C-Flex® 374   ½" × ¾"</li> </ul>		
<b>9. Waste bag</b>	Flexsafe® 2 D 10 L or 20 L Inlet: TuFlux® TPE   ⅜ × ⅝"   1,000 mm Outlet: TuFlux® TPE   ¼ × ⅞"   150 mm   MPC female with sealing cap		

C-Flex® is a registered trademark of Saint-Gobain Performance.  
 Sani-Tech® and STHT®-R are registered trademarks of St. Gobain Performance Plastic Coporation.  
 AseptiQuik® is a registered trademark of the Colder Products Company.

# General Product Specifications

## Filter Assembly

Manufacturing environment	ISO 7 cleanroom
Sterilization method	Gamma irradiation
Max. operation pressure   Filter integrity test pressure (Depending on filter, sensor, tubing, connector combination)	1, 2   5 [barg] 14.5   72.5   [psig]
Weight	
Filter Transfer Set (Single use assembly)	3 kg 6.6 lbs
Including packaging (max.)	5 kg 11 lbs
Minimum order quantity	4 and multiples of 4
Total length Filter Transfer Set, provided by customer	535 mm 21.1"
Total shelf life	3 Years
Storage conditions	<ul style="list-style-type: none"><li>Storage in a closed, dry area</li><li>No direct solar radiation</li><li>No direct contact with moisture</li></ul>
Temperature	5°C – 40°C
Relative humidity	10% – 75%

Packaging	Type	Material	Size
Primary packaging	Packaging blister	Transparent PET-G	1050 × 650 × 115 [mm] 41.3 × 25.5 × 4.5 ["]
	Double bags	PA   PE bags	N   A
Secondary packaging	Cardboard box	Double wall carton	1182 × 762 × 250 [mm] 46.5 × 30 × 9.9 ["]
	Cushion set	LDPE	N   A

## Filter Holder

Main construction material	316 or 304
Surface finishing	Ra 1.2 µm
Dimension (W × D × H)	Single: 810 × 970 × 1,900 [mm]   32 × 38 × 75 ["] Redundant: 1,050 × 940 × 1,900 [mm]   41 × 37 × 75 ["]
Total weight	Single: 110 kg   243 lbs Redundant: 125 kg   276 lbs

## Certificate of Release

<b>Statements</b>	
Biological safety (USP Class VI)	USP <87> & USP <88>
Physicochemical	Flexsafe® bags pass current USP <661> for plastic Containers. The contact layer of the S80 film passes current EP 3.1.5 (Polyethylene with additives) and complies with U.S. FDA 21CFR177.1520..
TSE-BSE	Compliance with EMA/410/01 and EP 5.2.8
<b>Monitoring</b>	
Endotoxin	USP <85> and EP 2.6.14
Sub visible particles	USP <788> and EP 2.9.19
Bioburden	ISO 11737
Sterility	ISO 11737 Sterilization of medical devices
<b>Batch testing</b>	
Visual inspection	100% inspection
Leak test	100% of bags are leak tested
Product conformity	Technical drawing compliance and batch record review
Gamma irradiation	25 kGy minimum, Gamma irradiation certificate enclosed
<b>Particles prevention program</b>	
Visible particles	Representative product analyzed for particles with sizes $\geq 100 \mu\text{m}$

## Product Validation, Qualification & Tests

Pre-Use Post Sterilization Integrity Test (PUPSIT)	According to product wetting protocol, post gamma and after 3 years shelf life
Connection qualification	Tightness according to Sartorius test protocol, after 3 years shelf life
Microbial immersion test	According to ASTM standard E3251-20
Packaging validation	Based on ASTM D7386, enhanced by pre-conditioning at a tropical climate (ASTM D4332)
Seal seam of pouches	Based on EN ISO 11607
Box compression	DIN 55441-1
Others	REACH and RoHs compliance
Extractables	<ul style="list-style-type: none"> <li>Extractable data for components available</li> <li>Product specific extractable data available via extractables simulator</li> </ul>

# Peripherals and Accessories

Item	Order No.	Single Filtration	Redundant Filtration	Comment
Pressure sensor w/ holder ½" 0–4 bar	4ZF---0119	2	2	Required for each pressure measurement
Tube holder for system rail ½"	4ZF---0039	8	16	Single: 8× required (-1 per pressure sensor) Redundant: 16× required (-1 per pressure sensor)
System Rack PUPSIT, single	FIA500001	1	-	Required for single filtration & redundant
System Rack PUPSIT, redundant	FIA500002	-	1	Required for redundant filtration
Capsule clamp D100	4ZF---0016	2	2	Clamp for Maxicaps®
Capsule clamp D72	BB-34164020	2	2	Clamp for Midicaps®
Flexboy® Tray + Lid 10 L	FFA102715	1	1	
Flexboy® Tray + Lid 20 L	FFA102716	1	1	
Laboratory cart	4ZF---0021	1	1	Required for System rack PUPSIT single   redundant
Sampling holder bottle and bag	FIA500003	1	1	Required for each sampling
Digital Indicator for BioPAT® Pressure Transmitter	BPD0101	2	2	Required for each pressure measurement

## Used | Recommended Tube Clamps

Item	Manufacturer	Manufacturer Part Number	Manufacturer Product Name	Comment
Tube Clamp (Large)	Saint-Gobain Performance Plastics	PFTCL250	Pure-Fit® TCL	2× required, for high-pressure area (part of supply or separate purchase at manufacturer)
Tube Clamp	W. L. Gore & Associates, Inc.	AMS-4232	AME-CLAMP	Up to 7× required, depending on configuration (part of supply or separate purchase at manufacturer)

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