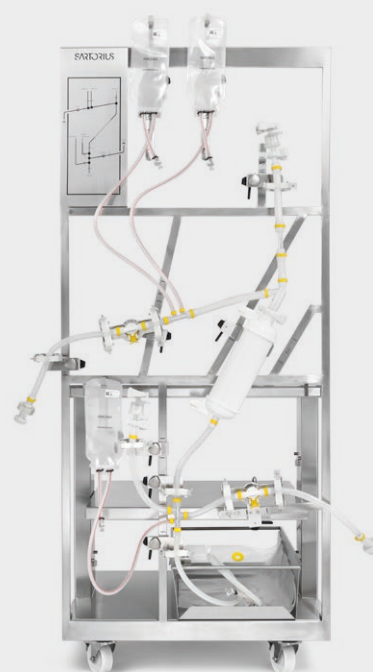


Filter Transfer Set Final Filling

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

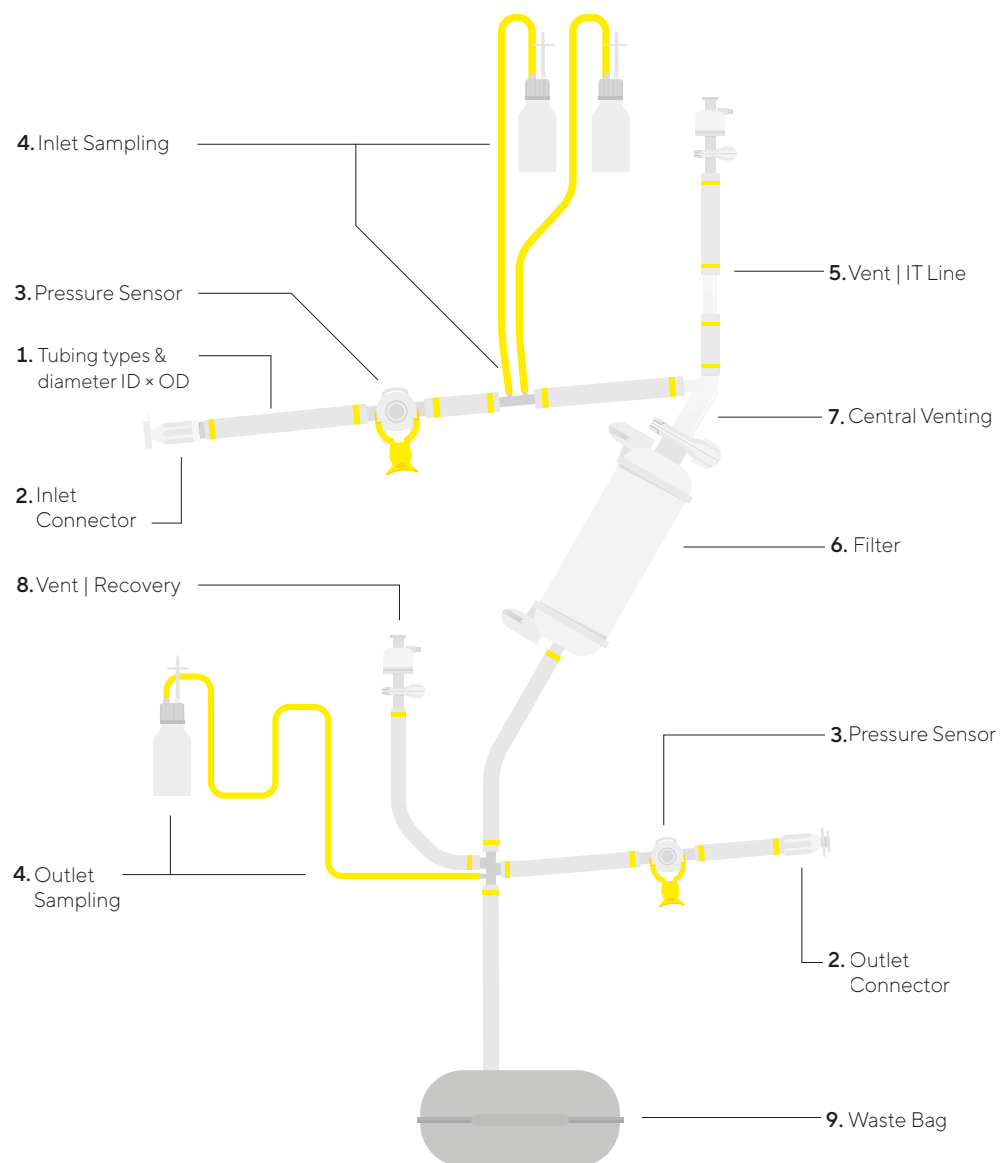
Relevant Process Steps

- Sterile Filtration
- Fill & Finish



Technical Specifications

Single-Use Assembly



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

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 (Sartopore® Platinum, Sartopore® Platinum HB, Sartopore® 2, Sartopore® 2 XLG, Sartopore® 2 XLI, Sartopore® 2 XLM) 2 Years (Sartopore Evo®)
Storage conditions	<ul style="list-style-type: none"> ▪ Storage in a closed, dry area ▪ No direct solar radiation ▪ No direct contact with moisture
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

Statements	
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
Monitoring	
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
Batch testing	
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
Particles prevention program	
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"> ▪ Extractable data for components available ▪ Product specific extractable data available via extractables simulator

Peripherals and Accessories

Item	Order No.	Single Filtration	Redundant Filtration	Comment
Pressure sensor w holder ½" 0–4 bar	4ZF---0119	up to 2	up to 4	Required for each pressure measurement (Pressure Transmitter BPD0005 included)
Tube holder for system rail ½"	4ZF---0039	up to 8	up to 16	Single: 8× required (-1 per pressure sensor) Redundant: 16× required (-1 per pressure sensor)
System Rack PUPSIT, single	FIA500001	1	1	Required for single filtration & redundant
System Rack PUPSIT, redundant	FIA500002	-	1	Required additionally for redundant filtration
Capsule clamp D100	4ZF---0016	1	2	Clamp for Maxicaps®
Capsule clamp D72	BB-34164020	1	2	Clamp for Midicaps®
Flexboy® Tray + Lid 10 L	FFA102715	1	2	For waste bag 10 L
Flexboy® Tray + Lid 20 L	FFA102716	1	2	For waste bag 20 L
Laboratory cart	4ZF---0021	1	1	Required for System rack PUPSIT single redundant
Sampling holder bottle and bag	FIA500003	up to 3	up to 6	Required for each sampling
Digital Indicator for BioPAT® Pressure Transmitter	BPD0101	up to 2	up to 4	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)
	Nordson MEDICAL	CPT110-U71	PharmaLok™ Large Tube Clamp	
Tube Clamp	W. L. Gore & Associates, Inc.	AMS-4232	AME-CLAMP	2× required, for high-pressure area (part of supply or separate purchase at manufacturer)

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