Tofflon Life Science



Filtration Product

Tofflon Life Science

Address: No.139,Duhui Road,Shanghai,China 201108

Tel: 021-64909996-338

Mail:lifescience.info@tofflon.com

Web site:www.tofflon-lifescience.com

Website

LinkedIn

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Filter Plant Introduction

The filter manufacturing plant of Tofflon Life Science located in Hangzhou, and is one of the core production site in the field of filtration and separation technology of Tofflon Group. The plant is dedicated to providing stable and high-quality filter consumables for biopharmaceutical industry.

The plant has 12,000 m² in space and has a validation center which has passed CNAS certificate (ISO17025). The plant can not only provide filters to customer but also provide related validation service at the same time. It has four kinds of major filter consumables include virus filter, TFF cassette, depth filer and sterile filter which cover all downstream filtration process in biopharma production, makes its capability to provide one-stop solutions for downstream protein separation and purification.

The existing products include:

Valpha® virus removal filter, Vshell® virus removal prefilter, Vshell® Pod virus prefilter, TanFlux® II TFF cassette, TanFlux® Capsule, SaiClear® depth filter,SaiClear® Pod depth filter, SaiPress® sterilization-grade hydrophilic filter, SaiPress® HF sterilization-grade hydrophilic filter, SaiPress® HF Pro sterilization-grade hydrophilic filter, SaiPress® PVDF hydrophilic sterile filter, Filgiant® sterilization-grade hydrophobic filter, Filgiant® L series hydrophobic filter, Filgiant® PES sterilization-grade hydrophobic filter, Felix 6KP integrity tester,Saiflow™ pharmaceutical-grade stainless steel housing, PolySai™ polypropylene prefilter, peristaltic pump and torque wrench.

Company honor



Zhejiang Provincial Innovative Small and Medium-sized Enterprise Certificate



Zhejiang Provincial Specialized and Sophisticated Small and Medium-sized Enterprise Certificate



Zhejiang Provincial Enterprise Research Institute Certificate



High-tech Enterprise Certificate



Zhejiang Provincial Sci-Tech Small and Medium-sized Enterprise Certificate



CNAS Certificate



ISO 9001 Certificate

Technical invention



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Valpha® Virus Retention Membrane

Biosafety Security for Your Virus Removal Process

Tofflon Valpha® family of virus removal filters are designed to efficiently remove virus particles from biological products (plasma products, antibody drugs, etc.). The Valpha® family of virus removal filters are validated to provide you reliable virus retention even at higher levels of virus challenge.

Key to virus security

Valpha® virus removal filters use membrane filtration technology to remove virus particles based on size exclusion. It uses an innovative high-performance polymer membrane to trap the virus on the membrane surface and in the membrane pores. Key performance parameters are usually logarithmic removal rate (LRV), flux, and load. These parameters are infiuenced by many interacting factors, such as virus loading, protein concentration, impurity concentration, pressure, process flow rate, ion strength, and process interruption. Therefore, it is very important to select and validate the appropriate virus removal filter under the established process conditions.

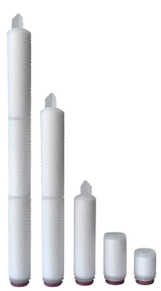
Valpha® family virus removal filters provide you two choices of membrane: Valpha RC(Regenerated Cellulose) and Valpha PES（Modified PolyEtherSulfone).

Valpha® RC HP uses regenerated cellulose membrane. Cellulose is a high hydrophilic material and is widely used as a basic polymer in the preparation of filtration membranes. The natural hydrophilic properties of cellulose maximize protein recovery by reducing protein adsorption. In addition, cellulose membrane can maintain high LRV value and filtration flow rate in long time filtration. Moreover, it has broad applicability and is suitable for virus removal process of multiple biological products.

Valpha® PES uses modified polyethersulfone material, and its unique asymmetric structure provides more possibilities for high process flux. At the same time, tofflon unique modification and membrane preparation process provides Valpha PES membrane very low protein adsorption and high flow rate. It really achieves the target of high flux, high load and high flow rate.It is truly characterized by high throughput, high loading and high retention.

Requirements for virus clearance

- ✓ Effective retention
- ✓ High yield
- ✓ Easy to use
- ✓ Shorter filtration time
- ✓ High capacity
- ✓ Can be validated
- ✓ Process robust





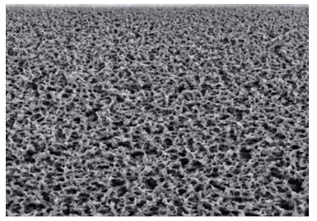
Valpha® features

Meet your needs for virus removal

- Reliable virus removal ability
- Mice Minute Virus（MMV） reduction rate LRV≥4
- Antibody protein (150kD) recover rate≥99%
- High efficient virus filtering unit
- Water based integrity testing, easy to test
- Single-use design, no cleaning validation required
- Sterility
- High pressure resistance
- High capability
- High flux, shorten the lot filtration time
- No additional filtration systems such as stainless steel clamps and accessories are required

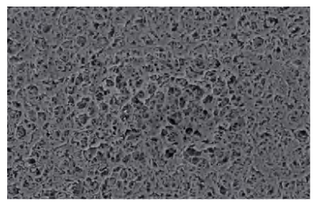
Unique virus retention membrane technology

Valpha® PES



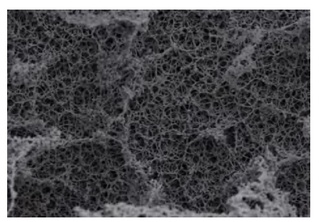
- High flux
- High retention
- Suitable for mab and clean drug luquid

Valpha® RC



- High retention
- High capacity
- Stable flux, suitable for polyclonal antibody, plasma products,biochemical extracts and other complex feed liquid

Valpha® RC HP



- High retention
- High capacity
- Designed for high concentration plasma products

Virus solutions from process development to production

Process development scale Syringe filter	Pilot scale 2.5”/5”/10” filter	Process scale 20”/30” filter
		
√ Unique vent design √ Effective membrane area of 2.8cm² √Suitable for process development, virus removal study and small scale process √ 100% in manufacture integrity test	√ Suitable for pilot scale √ Pleated cartridge and capsule design, easy to use. √ Gamma resistance (PES), Autoclavable and SIP tolerance (RC/RC HP) √ 100% in manufacture integrity test	√ Production scale √ Pleated cartridge and capsule design, easy to use. √ Gamma resistance (PES), Autoclavable and SIP tolerance (RC/RC HP) √ 100% in manufacture integrity test

Technical specification

PP7 phage retention capability

Figure 1. Retention ability of different batches of Valpha® RC membranes for PP7 phage

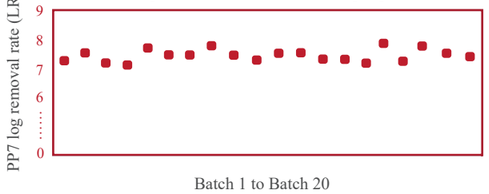
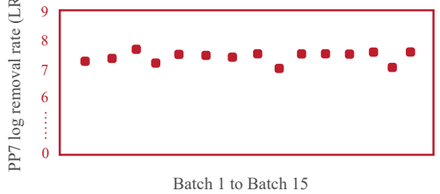


Figure 2. Retention ability of different batches of Valpha® RC HP membranes for PP7 phage



Figure 3. Retention ability of different batches of Valpha® PES membranes for PP7 phage



The photo shows the performance of Valpha® virus removal filter membrane on PP7 phage retention. It can be seen from the results that the three virus removal filter membranes, Valpha® PES, Valpha® RC and RC HP, have a strong virus removal performance as evidenced by the fact that for PP7 phage LRV≥7.

Valpha® Virus Removal Filter

Product parameters

Membrane material	PES						RC						RC HP					
Specification(inch)	1	2.5	5	10	20	30	1	2.5	5	10	20	30	1	2.5	5	10	20	30
Effective filtration area(m^2)	0.04	0.12	0.25	0.5	1	1.5	0.04	0.16	0.4	0.8	1.6	2.4	0.04	0.16	0.4	0.8	1.6	2.4
Component form	Capsule						Capsule, Cartridge											
Connection	TC connector at both ends(Capsule)；226(Cartridge)																	
Material	PP(Polypropylene)																	
ISO®9001 quality standard	The R&D, production and delivery process of the products follows the requirements of quality management system of ISO9001:2015																	
Membrane PP7 retention testing	Valpha® membrane - Phage PP7 retention test result indicates thatat the challenge level of 10^7 pfu/cm^2, LRV> 4.0																	
Device PP7 retention testing	Valpha® filter - Phage PP7 retention test result indicates that at the challenge level of 10^7 pfu/cm^2, LRV> 4.0																	
Fiber releasing	In compliance with the none fiber release standard of 21CFR 21.3 (b)(6)																	
USP <87> cytotoxicity test	The compenent of Valpha® filter have been tested to meet the standards of class VI plastics(according to USP<87> cytotoxicity test)																	
USP <88> biological reactivity	The compenent of Valpha® filter have been tested to meet the standards of class VI plastics(according to USP<88> biological reactivity test)																	
Sterilization method	Gamma resistance						Autoclavable(Capsule)； SIP(Cartridge)											
Maximum operation pressure	Forward: 4.1bar(60psi)@4~30°C																	
Bacterial endotoxin	According to Chinese Pharmacopoeia 2025 edition (1143), the water extract was tested for endotoxin and the endotoxin content was less than 0.25 EU/ml																	

Technical index

PP7 phage retention performance data

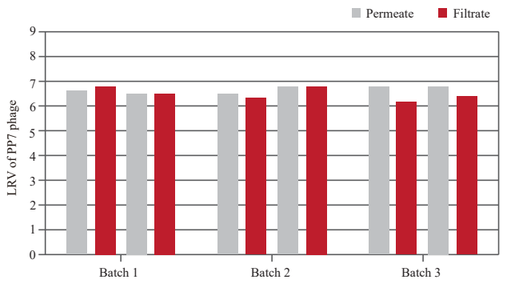


Figure 1. Removal ability of Valpha® PES syringe filter for PP7 phage

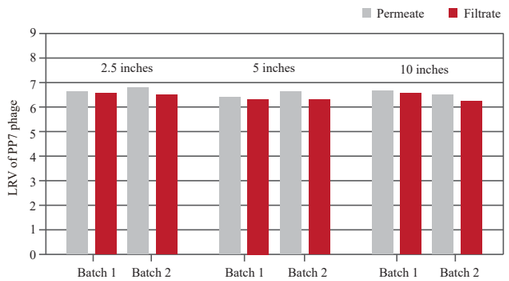


Figure 2. Removal ability of Valpha® Kapsule PES filter for PP7 phage

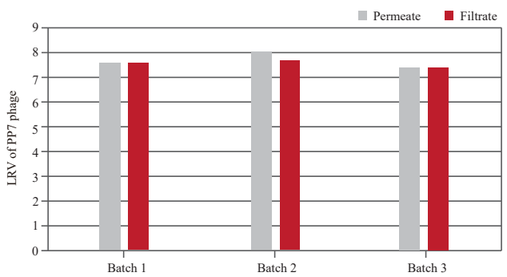


Figure 3. Removal ability of Valpha® RC syringe filter for PP7 phage

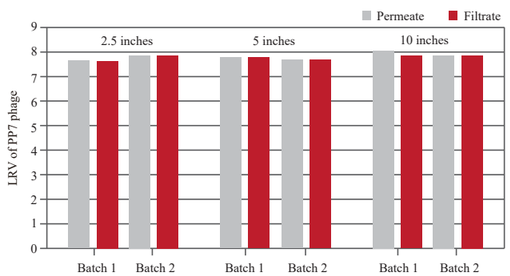


Figure 4. Removal ability of Valpha® Kapsule RC filter for PP7 phage

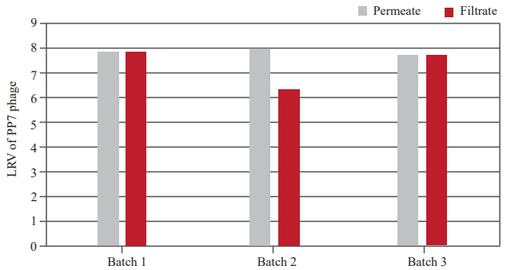


Figure 5. Removal ability of Valpha® RC HP syringe filter for PP7 phage

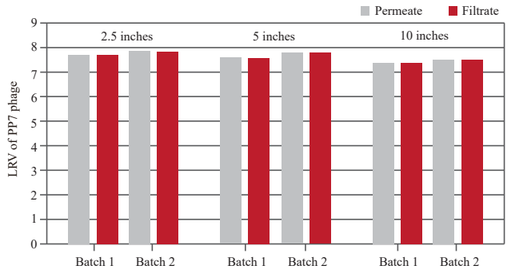


Figure 6. Removal ability of Valpha® Kapsule RC HP filter for PP7 phage

Water flux test data

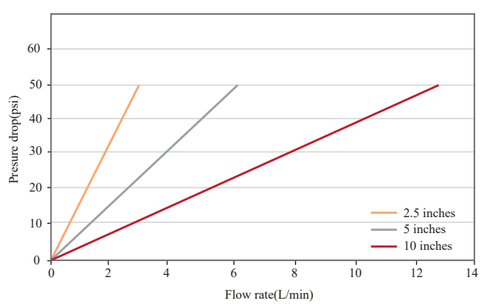


Figure 1. Valpha® Kapsule PES filter - Pressure drop and liquid flow rate

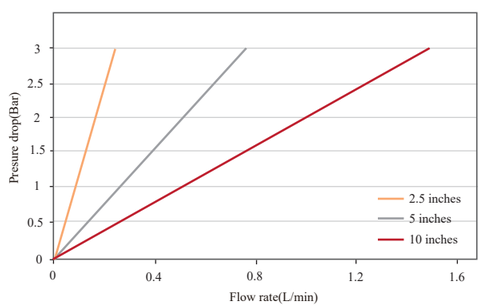


Figure 2. Valpha® Kapsule RC filter - Pressure drop and liquid flow rate

Water flux test data

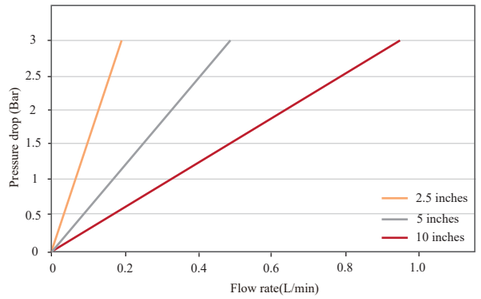


Figure 3. Valpha® Kapsule RC HP filter - Pressure drop and liquid

Order information

Valpha® Syringe filter

V	1

V1=Virus syringe

R	H

Product Type:
VR=Valpha RC
RH=Valpha RC HP
VP=Valpha PES

P	D

Product Scale:
PD=Process development scale

S	2	8

Membrane Area:
S28=2.8cm²

Valpha® Capsule filter

V

Product Code:
V=Valpha

K

Component form:
K=Kapsule

H

Membrane
P=PES
R=RC
H=RC HP

C	0	5	0

Specification:
F005=1 inch(only PES)
A012=2.5 inches
B025=5 inches
C050=10 inches
D100=20 inches
E150=30 inches

T	T

Connector type:
SH=inlet TC25, outlet 1/2 to 1/4 HB(1 inch)
HH=1/2 to 1/4HB(1 inch)
SS=TC25, In line(1/2.5/5 inches)
TT=TC50, In line(10/20/30 inches)
LL=TC50, T line(10/20/30 inches)

Valpha® Cartridge filter

V

Product Code:
V=Valpha

C

Component form:
C=Cartridge

H

Membrane
R=RC
H=RC HP

C	0	5	0

Specification:
A012=2.5 inches
B025=5 inches
C050=10 inches
D100=20 inches
E150=30 inches

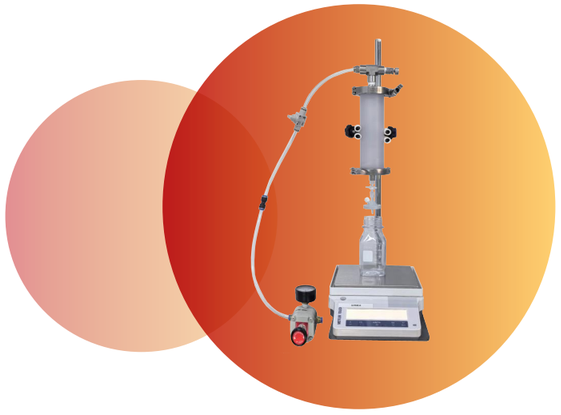
7

Connector type:
7=226

Vmax Equipment Set For Virus Filter

Filtration Experimental Equipment Set (Model:VHPDKIT)

Support for process development



Parts list

Number	Product description	Quantity	Picture
1	Iron support	1	
2	Relief valve (with pressure gauge)	1	
	No.6 trachea	3	
	Gas valve switch	1	
3	Diameter 64 fast-fit clamp (TC64)	2	
	Silicone gasket	2	
	Three-way valve	1	
	NPT1/4 pagoda turn 64 quick connecter	1	
	Two-way luer connector	1	
	Translucent storage tank	1	

NOTE: Syringe virus removal filter, balance and collection bottles are not included in the set.

Vshell® Virus Pre-filter

Effectively improve the capacity of the virus pre-filter

Virus filteration step is often resulting in low filtration capacity, increased cost, increased process time and other problems due to various reasons. Without changing the state of the sample, adding a pre-filter is the most effective solution increase the capacity.

Vshell® Pre-filter is specially designed by Tofflon which can work together with Valpha Virus retention filter to provide a reliable virus safety garantee for the virus fitration process.

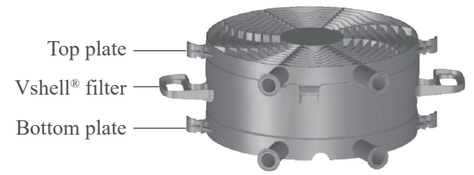
Selection of virus pre-filter

The purpose of virus pre-filter is to remove various impurities or contaminants such as protein aggregates, DNA, and other trace substances. The size of the pre-filter also has a significant impact on the viral filter capacity.

Tofflon provides a variety of specifications of pre-filter filters, according to different process requirements, to achieve robust virus removal purposes.

Product features

- Easy-to-use
- High flow rate, high capacity, high flow
- Improve the economic efficiency of virus removal filtration





Product parameters

Specification		5cm²	100cm²	250cm²	500cm²	1000cm²	0.5m²	1m²
Picture								
Type		Syringe filter	Capsule filter	Capsule filter	Capsule filter	Capsule filter	Plate filter	Plate filter
Size	Diameter(mm)	36	94	94	94	94	442	442
	Height(mm)	16.2	143	203	331	578	106	147
Connection		Luer	TC25		TC50			
Application		R&D	R&D	Pilot scale	Pilot scale	Pilot scale	Process Scale	Process Scale
Capacity		0-1L	1-20L	1-20L	1-100L	1-100L	100-500L	100-2000L
Material	Membrane	Diatomite, cellulose, perlite, positive charge resin						
	Housing	Polypropylene						
Pressure test		25℃ water bath, maintain 50 psi for 24 hours, filter no gas leakage 40℃ water bath, maintain 40 psi for 24 hours, filter no gas leakage						
Hydraulic stress test		40psi，30min，4cycles						
TOC		After flushing 100 L/m² , TOC was < 4mg/L						
Conductivity		After flushing 100 L/m² , conductivity was 10 μS/cm						
Bacterial endotoxins		After flushing 100 L/m² , endotoxin was <0.25 EU/ml						
Biosafety test		The material used meet the requirements of USP <87> and USP <88> biosafety test						

Vshell® Holder and Accessories: See "Depth Filter Holder and Accessories".

Ordering information

P	R	T	2	0	0	5	L	1

Product Code:
PR=Vshell

Membrane Code:
T2=Vshell series code
L6= Vshell R series code

Filtration Area:
005=5cm²
100=100cm²
250=250cm²
500=0.05m²
01K=0.1m²
05K=0.5m²
10K=1m²

Connection Type:
S=TC25 (100cm² and 250cm²)
T=TC50 (500cm²/1000cm²/0.5m²/1m²)
L=Inlet female luer Outlet male luer(only for 5cm²)

Packing Specification:
1= 1 per package

Vshell® POD Virus Pre-filter

Virus filteration step is often resulting in low filtration capacity, increased cost, increased process time and other problems due to various reasons. Without changing the state of the sample, adding a pre-filter is the most effective solution increase the capacity.

Vshell® Pre-filter is specially designed by Tofflon which can work together with Valpha Virus retention filter to provide a reliable virus safety garantee for the virus fitration process.



Product parameters

Specification		0.11m², 0.55m², 1.1m²
Material	Membrane	Diatomite, cellulose, perlite, cationic resin
	Housing	Polypropylene
Pressure test		25℃ water bath, maintain 50 psi for 24 hours, filter no gas leakage 40℃ water bath, maintain 40 psi for 24 hours, filter no gas leakage
Hydraulic stress test		40psi, 30min, 4cycles
TOC		After flushing 100 L/m² , TOC was < 4mg/L
Conductivity		After flushing 100 L/m² , conductivity was 10 μS/cm
Bacterial endotoxins		After flushing 100 L/m² , endotoxin was <0.25 EU/ml
Biosafety test		The material used meet the requirements of USP <87> and USP <88> biosafety test

Ordering information

P	R	R	T	2	0	5	5	N	1

Product Code:
PRR=Vshell Pod

Membrane Code:
T2=Vshell series code
L6= Vshell R series code

Filtration Area:
011=0.11m²
055=0.55m²
110=1.1m²

Connection Type:
N=Normal

Packing Specification:
1= 1 per package

TanFlux® Series TFF Membrane

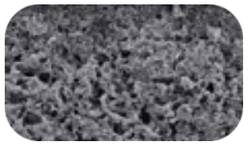
In order to meet the needs of different applications, we offer two defferent kinds of membrane：

Modified PES Polyethersulfone



PES membrane can tolerate the irritant chemical substances used in cleaning, decontamination and disinfection. The modified PES membrane improves on the basis of the traditional PES membrane to reduce nonspecific protein binding. The technique also makes the modified membrane tougher for withstanding process disturbances and extreme operating conditions. High flux and retention performance make processing faster and ensure higher yield, thus reducing the processing time.

Composite Flawless RC Regenerated cellulose



The high anti-fouling and anti-blocking performance and low protein adsorption of compositeflawless RC membrane ensure excellent product retention, recovery and higher yield. Flawless RC membrane is a flawless membrane made with RC membrane on microporous substrate. Compared with traditional membrane, it has excellent toughness. Composite material technology offers excellent mechanical strength, enabling it to withstand process disturbances and extreme operating conditions.

Product parameters

Membrane Material	Modified PES(polyethersulfone)		CompositeFlawless RC (regenerated cellulose)
Filtration Type	Ultrafiltration	Microfiltration	Ultrafiltration
Molecular weight cutoff	5/8/10/30/50/100/300/500KD	0.1/0.22/0.45μm	1/2/3/5/10/30/100/300KD
Relative flow rate	Fast		Medium
Protein adsorption	Low		Very low
pH range	1-14		2-13
Characteristics	High flux, good chemical compatibility		Very low protein adsorption, hard to block, resistant to organic solvents

Quality assurance

The same equipment, process and quality standards are adopted for all TanFlux® TFF membrane cassettes in production. 100% integrity test and visual inspection are conducted for each manufacturing batch of membrane cassettes in production to ensure that each membrane cassette is integral, intact in appearance and is up to the delivery quality standards. Each membrane cassette has a unique serial number in the batch number and a separate quality certificate.

The consistent performance of membrane's material guaranteed in the automatic manufacturing process ensures the consistency and high repeatability from scale expansion to scale reduction and between batches. All TanFlux® membrane cassettes are produced under the quality system that that refer to GMP requirements.

TanFlux® II TFF Cassette

TanFlux® II TFF Cassette are produced automatically to ensure the consistency of performance and linear scalability among the cassettes of different lots. The simplified design enables users to install and operate quickly and easily.

With excellent chemical compatibility, TanFlux® II TFF Cassette can be compatible with various chemical cleaning agents to ensure safe and effective cleaning and disinfection of the TFF system.

Product features

- From membrane to finished cassettes fully indepentent and localized.
- Robust and reliable design of the housing which can withstand high pressures and temperature.
- Easy to install and clean to ensure the reliability of the yield
- Multiple flow channel options
- Fast and reliable linear scale-up from lab to production scale
- Exllent chemical compatibility
- Extrem Low E&L level
- High separation efficiency

Process upgrading

1 Thermal welding sealing process

The unique thermal welding sealing process replaces the traditional glue injection process. Significantly improve the alkali resistance and chemical compatibility.

2 New resin formulation

The molding process adopts a new resin formula, while retaining the traditional silicone packaging process, which has higher hardness and better process stability.

3 More channel options

On the basis of the existing D channel, the new V (open) channel is compatible with different application scenarios.

4 More uniform pore size distribution

The optimized membrane process makes the membrane pore size distribution more uniform, the sieving effect is strong, and the protein separation efficiency is higher.

Reliable scale up from R&D to production

TanFlux® II has four sizes: 80 cm², 0.1 m² , 0.5 m² and 2.5 m². All TanFlux® II TFF Cassette membrane are made from the same materials and have the same channel structure, length and height, which enables TanFlux® II TFF Cassette membrane of various specifications to maintain the same performance, and truly achieve scale up from 100ml to thousands of liters.TanFlux® II TFF Cassette membrane is designed with a strong resin and silicone housing to protect the membrane's surface against the impact and potential damage.

Product specification

Membrane area	80cm²	0.1m²	0.5m²	2.5m²
Resin housing				
Silicone housing				
Procesing volume	100mL-1L	200mL-10L	2L or large-scale production	10L or large-scale production
Cassette length (mm)	207	207	205	205
Cassette width (mm)	56	56	178	178
Cassette thickness (mm)	4	15-16	15-16	70-75

Silicone housing



Resin housing



Product parameters

Cassette		TanFlux® II
Product Material	Channel	Polypropylene (PP)
	Preservation solution	RC(20% Glycerol + 0.1% Benzalkonium chloride); PES(20% glycerol + 0.05M sodium hydroxide)
	Membrane	Modified PES (polyethersulfone); Composite flawless RC (regenerated cellulose)
	Housing	Silicone/Resin
Operating Condition	Maximum inlet pressure	5.5bar(80psi)@25°C 5bar(72.5psi)@50°C
	Operating pH range	2~13
Regulatory Information	Biosafety	The product meet the requirements of USP <87> and USP <88> biosafety test
	Regulatory Conformity	Produced under the quality system that meets GMP requirements. Certified to ISO 9001(2015) quality management system
	Integrity test	Each unit must pass our integrity test before release
Transportation and Storage Condition		This product should be stored in an environment of 0 to 30°C, avoiding freezing and high temperature (>40°C) conditions. Internal packaging bag should remain intact.

Ordering information

T	2	P	0	1	0	D	2	5	R
Product series:		Membrane material:	Standard molecular weight cutoff:			Channel type:	Membrane area:		Housing material:
T2=TanFlux®II		R=RC P=PES	001~500=1~500kD			D=Channel D V=Channel V	S1=80cm² 01=0.1m² 05=0.5m² 25=2.5m²		S=Silicone R=Resin

T	2	P	M	2	2	D	2	5	R
Product series:		Membrane material:	Standard molecular weight cutoff:			Channel type:	Membrane area:		Housing material:
T2=TanFlux®II		P=PES	M22=0.22um M45=0.45um M10=0.10um			D=Channel D	S1=80cm² 01=0.1m² 05=0.5m² 25=2.5m²		S=Silicone R=Resin

TFF Holder & Accessory

Suitable for different specifications of membrane cassette, to meet different process requirements

Product features

- The holder body is made of stainless steel 316L
- The structural design complies with the cGMP medical grade standard. The diaphragm valve and pressure gauge with sanitary dead corners
- Stable filtration effect

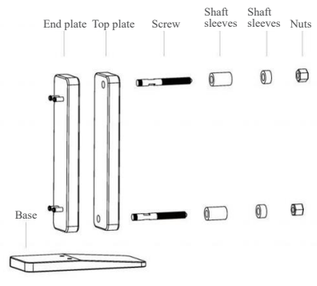
Mini TFF Holder

TFH100 (Including accessories)

Max. Holding Capacity: 80cm² cassttes*

The minimum working volume of the mini TFF holder can reach 20mL

Holder assembly diagram





Accessories information

Product picture						
Product series	Pressure tap	Sanitary grade 0-0.6 MPa pressure gauge	10-32UNF threaded to Luer connection	1/8 "Luer male connection	Luer Plug	Two-way value or Luer connection
Quantity	2	2	4	3	1	2

0.1m² Stainless Steel Holder

TFH01 (Including accessories)

Max. Holding Capacity: 0.1m² cassttes *3

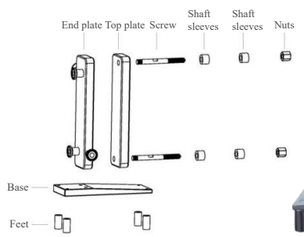
(Optional extension screw)

extension screw

TFH01R

Max. Holding Capacity: 0.1m² cassttes *5

Holder assembly diagram





0.5m² Stainless Steel Holder

TFH05 (Including accessories)

Max. Holding Capacity:

0.5m² cassttes *5, 2.5m² cassttes *1

(Optional extension screw)

extension screw

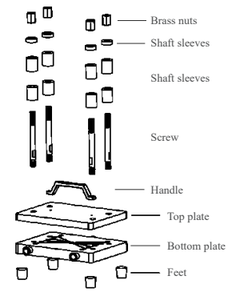
TFH05R

Max. Holding Capacity: 2.5m² cassttes *2

TFH05R3

Max. Holding Capacity: 2.5m² cassttes *3

Holder assembly diagram





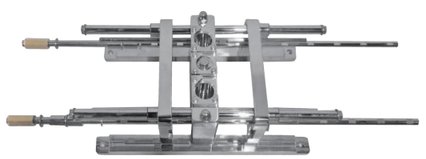
0.1m² / 0.5m² Stainless Steel Holder Accessories information

Product picture										
Product series	φ9.8mm three-way pipe	Sanitary grade 0-0.6 MPa pressure gauge	TC25 clamp	TC50 clamp	φ8-12mm hose clamp	0.5 " clamp gasket	1.5" clamp gasket	12.7*1.5mm manual diaphragm valve	φ25.4mm nausea board	φ6-25mm hose connection
Quantity	2	2	11	2	5	11	2	2	1	3

Pilot-scale and production-scale Holder

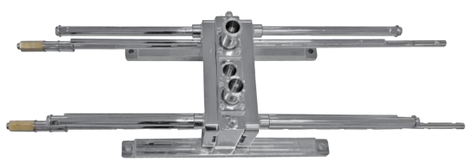
TFH10M

Max. Holding Capacity: 2.5m² cassttes *4



TFH20M

Max. Holding Capacity: 2.5m² cassttes *8



* Use pilot-scale and production-scale holder, the TFF cassette should be placed symmetrically. TFH10M/TFH20M only includes the holder itself. If you need a complete manual system including valves, pressure gauges, workbenches, pumps, etc., please consult the regional sales representative.

TanFlux® Capsule

Suitable for small scale and pilot scale process development.

Product parameters

Cassette		TanFlux® Capsule
Material	Channel	Polypropylene (PP)
	Preservation solution	RC(20% Glycerol + 0.1% Benzalkonium chloride); PES(20% glycerol + 0.05M sodium hydroxide)
	Membrane	Modified PES (polyethersulfone); RC (regenerated cellulose)
	Housing	Acrylic + Silicone + 304 Stainless Steel
Operating Condition	Maximum inlet pressure	3.0bar (80psi)@25℃
	pH range	2~13
Regulatory Information	Biosafety	The product meet the requirements of USP <87> and USP <88> biosafety test
	Regulatory Conformity	Produced under the quality system that meets GMP requirements. Certified to ISO 9001(2015) quality
	Integrity test	100% release test
Transportation and Storage Condition		This product should be stored in an environment of 0 to 30°C, avoiding freezing and high temperature (>40°C) conditions. Original internal packaging bag should remain intact.

Product Specification

Membrane area	80 cm²
Throughput	200mL-10L
Length (mm)	234
Width (mm)	88
Thickness (mm)	40

Ordering information

T	K	P	0	1	0	D	S	1
Product series:		Membrane:	Molecular cut off:			Channel type:	Membrane area:	
TK=TanFlux® Capsule		R=RC P=PES	001~500=1~500kD			D=Channel D	S1=80cm²	

Product Picture





SaiClear® Depth Filter

Multiple grades of depth filters provide suitable solutions for different application scenarios.

Used in clarification and downstream filtration processes

Depth Filter is commonly used for pre-filtration, such as fermentation fluid clarification, removal of cell debris and DNA, preconditioning in plasma products and other biological products.
SaiClear® Depth Filter, developed for demanding clarification applications in the biotechnology and pharmaceutical industries, significantly reduce the difficulty of downstream purification.

Product features

- With diatomaceous earth and cellulose as membrane materials, it has a high contaminant capacity
- Higher impurity removal capacity through mechanical interception and electrostatic adsorption
- Combine multiple clarification steps into one device to optimize the clarification process
- A full line of products is available for process reduction and scale-up

Filter application

- Clarification filtration of fermentation and cell culture fluids
- Filtration of plasma products
- Chemical medicine impurity removal, decarbonization filtration
- Remove particles and glue from process intermediates

Clarification filtration

The purpose of clarification is to effectively separate the cells, cell fragments and other colloidal substances in the harvest solution to provide an impurity-free feed solution for downstream purification. Clarification of cell harvest solution is the first step in middle and downstream purification of biopharmaceutical processes, usually using a combination of centrifugation, tangential flow filtration, flocculation, and depth filtration. Depth filters technology, because it can improve product quality, simplify operation, and more and more respected by the industry. The harvested clarification filtration usually uses two grades of depth filters: the first grade uses a filter medium with a large aperture to remove cells or cell debris; The second grade uses a filter medium with a tight aperture to remove colloidal impurities.

Depth Filter

SaiClear® P Series and S Series depth filters have been developed to meet different process requirements. The filter medium inside the filter is the same as the filter medium in the traditional depth filter system, and there are many choices of accuracy and models. In addition, SaiClear® has a small footprint, saving clean room space. Compared to traditional depth filtration systems, the SaiClear® installation position is flexible and easy to operate for process development.

Product picture

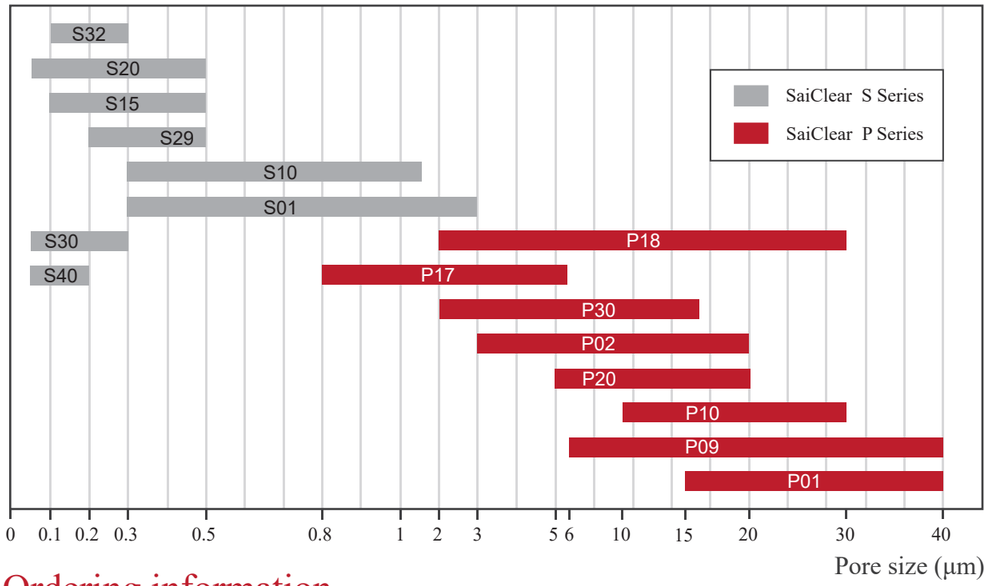
23cm²	100cm²	250cm²	480cm²	1000cm²	0.45m²	0.9m²
						

Product parameters

From process development to mass production, we provide you with the right solution

Specification		23cm²	100cm²	250cm²	480cm²	1000cm²	0.45m²	0.9m²
Filter type		Capsule	Capsule	Capsule	Capsule	Capsule	Plate	Plate
Equipment size	Diameter mm	63.8	94	94	94	94	442	442
	Height mm	51	143	203	331	578	90	139
Connection		Luer	TC25		TC50			
Application		R&D		Pilot scale		Production		
Processing volume		0-5L		1-20L		20-2000L		
Material	Membrane material	Diatomaceous earth, cellulose						
	Housing	Polypropylene						
Integrity test		No gas leakage, aerosol permeability meets the requirements						
Pressure test		25℃ water bath, maintain 50psi pressure for 24 hours, filter no gas leakage 40℃ water bath, maintain 40psi pressure for 24 hours, filter no gas leakage						
Hydraulic stress test		Rinse the filter at 40psi for 30 minutes and repeat this cycle four times before the filter passes the integrity test						
TOC		After rinsing with 100L/m² volume of purified water, sample the filtrate. TOC value ≤6mg/L						
Conductivity		After rinsing with 100L/m² volume of purified water, sample the filtrate. Conductivity value ≤15μS/cm						
Bacterial endotoxin		The content of endotoxin in the filtrate was less than 0.25EU/mL						
Biosafety testing		The materials used meet USP <87> and USP <88> biosafety requirements						

Filtration accuracy



Ordering information

S	C	P	2	0	5	0	0	T		1

Product series:
SC = SaiClear

Filter material code:

P01	S01
P02	S10
P09	S15
P10	S20
P17	S29
P18	S30
P20	S32
P30	S40

Filtration area:
023=23cm²
100=100cm²
250=250cm²
500=480cm²
01K=1000cm²
05K=0.45m²
01M=0.9m²

Connection type:
S= TC25 at both ends
T= TC50 at both ends
L= Luer at both ends (only 23cm²)

Packing quantity:
1=1 pack

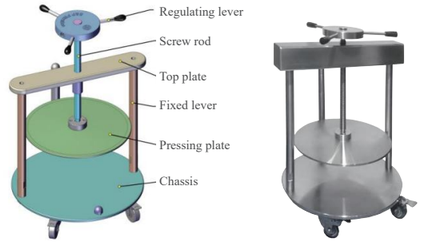
Product Name	SaiClear upper cover	SaiClear lower cover
Material	Polypropylene	
Pressure test	25°C water bath, maintain 50psi pressure for 24 hours, filter no gas leakage 40°C water bath, maintain 40psi pressure for 24 hours, filter no gas leakage	
Specification	0.45m²/0.9m² general	
Product Art.No	SCCP015TT	SCCP015BT

Holder and Accessories

Various specifications of depth holder, suitable for different specifications of filter packaging, to meet different process requirements

Product features

Compared to similar products on the market,
the provided holder can precisely adjust the pressure level.





Product parameters

Specification	3m² Holder	6m² Holder	9m² Holder
Length*Width*Height(mm)	580*530*920mm	750mm*560mm*1450mm	750mm*560mm*2000mm
Weight	80kg	190kg	200kg
Max. Holding Capacity	0.9m²*3	0.9m²*6	0.9m²*10
Min.Holding Capacity	0.45m²*1	0.45m²*1	0.45m²*1
Surface finishment	ra3.2	ra3.2	ra3.2
Adjustable torque	5-35N·m	5-35N·m	5-35N·m
Product Art.No	SCFH03M	SCFH06M	SCFH10M

Ordering information

Item	Product name	Specification	Unit
SCCP015MT	SaiClear Partition	0.45m², 0.9m² general	piece





SaiClear® POD Depth Filter

Depth Filter is commonly used for pre-filtration, such as fermentation fluid clarification, removal of cell debris and DNA, preconditioning in plasma products and other biological products.

SaiClear® Pod Depth Filter, developed for demanding clarification applications in the biotechnology and pharmaceutical industries, significantly reduce the difficulty of downstream purification.



Product parameters

Specification		0.11m², 0.55m², 1.1m²
Material	Membrane material	Diatomaceous earth, cellulose
	Housing	Polypropylene
Integrity test		No gas leakage, aerosol permeability meets the requirements
Pressure test		25°C water bath, maintain 50psi pressure for 24 hours, filter no gas leakage 40°C water bath, maintain 40psi pressure for 24 hours, filter no gas leakage
Hydraulic stress test		Rinse the filter at 40psi for 30 minutes and repeat this cycle four times before the filter passes the integrity test
TOC		After rinsing with 100L/m² volume of purified water, sample the filtrate. TOC value ≤6mg/L
Conductivity		After rinsing with 100L/m2 volume of purified water, sample the filtrate. Conductivity value ≤15μS/cm
Bacterial endotoxin		The content of endotoxin in the filtrate was less than 0.25EU/mL
Biosafety testing		The materials used meet USP <87> and USP <88> biosafety requirements

Ordering information

S	C	R	P	2	0	0	5	5	N	1

Product series:
SCR = SaiClear POD

Filter material code:

P01	P17	S15
P02	P20	S20
P03	P30	S29
P09	P31	S30
P10	P41	S32
P13	S01	S33
P14	S10	S38
		S40

Filtration area:
28C=280cm²
56C=560cm²
011=0.11m²
055=0.55m²
110=1.1m²

Connection type:
N=None connector

Packing quantity:
1= 1 per package

Felix 6KP Integrity Tester

Product features

- Portable, easy to use, automated
- Complete integrity test of filter and process equipment accurately and reliably
- Simple and intuitive user experience
- Flexible custom optional Settings



Product parameters

Technical index		6KP
Input voltage		(100-240)V AC
Input frequency		50/60Hz
Input power		160W
Audit trail		Y
Screen material		Resistive screen
Dimensions (L × W × H /mm)		360×280×280
Detection range	Diffusion flow	(0.1—600)ml/min
	Water intrusion	(0.01—100)ml/min
	Bubble point	(100—8000)mbar
	Pressure maintenance	(100—8000)mbar
Sensitivity	Diffusion flow	0.01ml/min
	Water intrusion	0.01ml/min
	Bubble point	50mbar
	Pressure maintenance	1mbar
Precision	Diffusion flow	±4% or 0.1ml/min
	Water intrusion	±4% or 0.02ml/min
	Bubble point	±50mbar
	Pressure maintenance	1mbar

Product compliance

- Support multi-level user access Settings
- Ensure data integrity
- Audit trail function

Ordering information

F	L	X

Felix Integrity Tester

6	K	P

6KP=Felix 6K Premium



SaiPress® Sterilizing-grade Hydrophilic Filter

High flow rate sterilizing-grade polyether sulfone (PES) filter

Product features

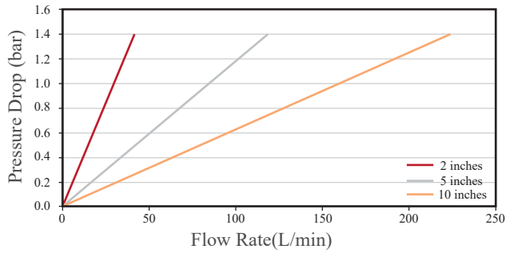
- Sterilizing-grade polyether sulfone (PES) material, can withstand multiple autoclaves
- Higher flow rates at the same level, thus reducing the process footprint and maximizing benefits
- Ready-to-use models for gamma irradiation
- Good chemical compatibility for pH1-14
- A full line of products is available for process reduction and scale-up

Filter application

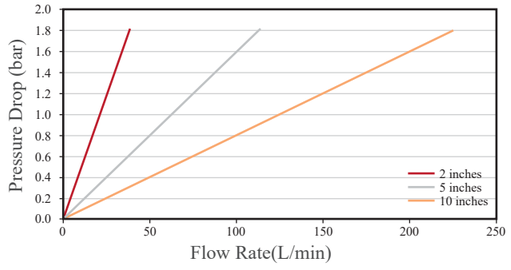
- Buffer, pH regulator filtration
- Process additives and intermediates filtration
- Chemical synthetic medium filtration
- Water-based feed filtration

Water flux test data

Relationship between pressure drop and flow rate of 0.22μm sterilizing-grade liquid filter



Relationship between pressure drop and flow rate of 0.45+0.22μm sterilizing-grade liquid filter

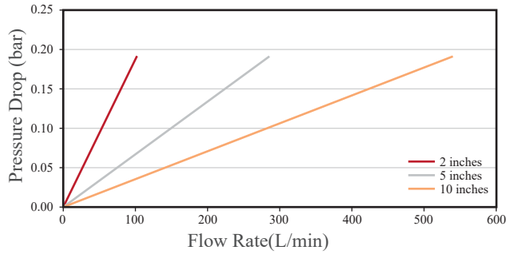


Filter type

- Ready-to-use capsule filters
- Cartridge filter
- Capsule filters sterilized by gamma irradiation
- Disk filters and customized filters



0.45μm liquid filter pressure drop and flow rate relationship



Product parameters

Filter type		Syringe	Disk filter	Capsule filter						Cartridge filter				
Nominal size (inch)		--	Φ50mm	1	2.5	5	10	20	30	2.5	5	10	20	30
Effective filtration area (m^2)	Single layer	2.8cm^2	13.8cm^2	380cm^2	0.16	0.33	0.66	1.32	1.98	0.16	0.33	0.66	1.32	1.98
	Double layer	2.8cm^2	13.8cm^2	350cm^2	0.14	0.28	0.57	1.14	1.71	0.14	0.28	0.57	1.14	1.71
Filter membrane pore size		0.1μm/0.22μm/0.22+0.1μm/0.22+0.22μm/0.45+0.1μm/ 0.45+0.22μm/0.65+0.22μm/0.8+0.22μm/1.2+0.22μm												
Material	Filter membrane	Hydrophilic polyether sulfone (PES)												
	Supporting layer/Housing structural components	Polypropylene (PP)												
	Vent O-ring	--	--	Silicone						--				
	O-ring	--	--	--						Silicone/EPDM/FKM				
Maximum operating pressure difference		--	--	Forward: 5.5bar(80psi)@25°C; 1.7bar(25psi)@80°C						Forward: 5.5bar(80psi)@25°C; 1.7bar(25psi)@80°C				
				Reverse: 2.1bar(30psi)@25°C						Reverse: 2.1bar(30psi)@25°C				
Bubble point (100% IPA @ 25°C)		0.1μm:≥2500mbar												
Bubble point (pure water @ 25°C)		0.22μm:≥3400mbar												
0.1μm filter diffusion flow (ml/min) (Pure water @ 25°C@2800mbar)		--	--	≤2.5	≤7.5	≤15	≤30	≤60	≤90	≤7.5	≤15	≤30	≤60	≤90
0.22μm filter diffusion flow (ml/min) (Pure water @ 25°C@2800mbar)		--	--	≤2.5	≤7.5	≤15	≤30	≤60	≤90	≤7.5	≤15	≤30	≤60	≤90
Sterilization method		--	Gamma not applicable	SIP not applicable						Gamma not applicable				
		--	Offline: 126°C / 60 minutes	Code R: Tolerance 40KGy gamma irradiation, autoclave not allowed Code A: Offline: 126°C/60min, 3 times, Gamma irradiation not allowed						Offline :126°C / 60min, 25 times SIP :126°C / 60min, 25 times (In the sterilization process, the upstream and downstream pressure difference of the cartridge is ≤300mbar)				
Pressure test		--	--	No leakage detected under 0.65MPa pressure						--				
TOC and conductivity		According to the determination method of total organic carbon in pharmaceutical water according to the General Rule of China Pharmacopoeia 2025 Edition (0682) and the determination method of electrical conductivity of pharmaceutical water according to the general rule (0681), the detected TOC value is ≤0.5mg/L, and the electrical conductivity value is ≤1.3us/cm												
Cleanliness		Meets the "no fiber release" filter standard as defined in 21 FR210.3 (b) (6)												
Bacterial endotoxin		According to the bacterial endotoxin test method stipulated in the General Rule of China Pharmacopoeia 2025 Edition (1143), the endotoxin content of the filter solution was determined, and the content of endotoxin in the filter solution was lower than 0.25EU/ml												
Biosafety testing		All materials of the filter cartridge conform to USP < 88 >, in vivo biosafety evaluation of ClassVI plastic products and in vitro biosafety test of USP < 87 >												
Bacterial retention		The test method of ASTMF838 and defective Pseudomonas (ATCC19146) were used for bacterial retention of this product. The results showed that the minimum retention rate was 10^7cfu/cm^2												
Regulatory compliance		Product production and quality management in accordance with ISO: 9001 (2015)												
Shelf life		3 years		Gamma irradiated(Sterilized packaging) Capsule: 2 years Autoclavable / Gamma sterilizable Capsule: 3 years						3 years				
Storage and transportation		This product should be stored in an environment of 0 to 30°C, avoiding freezing and high temperature (>40°C) conditions. The internal bag should be kept intact to prevent external particles or moisture from entering												

Ordering information

SaiPress® Capsule

K	S	F	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: S= PES	Filter Size: F=1inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out	Interface type (in/out) : SS= TC25 at both ends HH= 1/2 to 1/4 hose SH=inlet TC25, outlet 1/2 to 1/4 hose HS=inlet 1/2 to 1/4 hose, outlet TC25	Packing Specification: 1= 1 per package

K	S	A	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: S= PES	Filter Size: A= 2.5inch B= 5inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out	Interface type (in/out) : SS= TC25 at both ends TT= TC50 at both ends NN= 1/2 hose on both ends FF= 5/8 hose at both ends SN= inlet TC25, outlet 1/2 hose TF= inlet TC50, outlet 5/8 hose	Packing Specification: 1= 1 per package

K	S	C	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: S= PES	Filter Size: C=10inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out T=Left-in and right-out (Only TC50)	Interface type (in/out) : TT= TC50 at both ends FF= 5/8 hose at both ends TF= inlet TC50, outlet 5/8 hose	Packing Specification: 1= 1 per package

K	S	D	4 2	G	T	T T	1
Filter Type: K=Capsule	Membrane Material: S= PES	Filter Size: D=20inch E=30inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out T=Left-in and right-out	Interface type (in/out) : TT=TC50 at both ends	Packing Specification: 1= 1 per package

Pore size code table

Membrane pore size	Single layer	01=0.1μm/02=0.22μm
	Double layer	21=0.22+0.1μm/22=0.22+0.22μm/41=0.45+0.1μm/ 42=0.45+0.22μm/62=0.65+0.22μm/82=0.8+0.22μm/A2=1.2+0.22μm

Ordering information

SaiPress® Cartridge type

C	S	C	4 2	S	7	1
Cartridge Type: C= cartridge filter	Membrane Material: S= PES	Filter Size: A=2.5inch B=5inch C=10inch D=20inch E=30inch	Membrane Pore Size: In the following membrane pore size table	Sealing ring: S=Silicone E=EPDM F=FKM	Interface type: 7=226 connectors 5=215 connectors 2=222 connectors	Packing Specification: 1= 1 per package

SaiPress® Syringe filter

F	S	C 3	0 2	M L	1
Cartridge Type: F = Disk Cartridge	Membrane Material: S=PES	Filter Size: C3=Membrane area 2.8cm²	Membrane Pore Size: In the following membrane pore size table (without 22/A2)	Connector Type(In/Out): ML=Luer(female)in Luer(male)out	Packing Specification: 1= 1 per package

SaiPress® Disk type

F	S	5 0	0 2	H H	1
Cartridge Type: F = Disk Cartridge	Membrane Material: S=PES	Filter Size: 50=dia. 50mm	Membrane Pore Size: 01=0.1μm 02=0.22μm 04=0.45μm 41=0.45+0.1μm 42=0.45+0.22μm 62=0.65+0.22μm	Interface type (in/out) : HH= 1/2 to 1/4 hose	Packing Specification: 1= 1 per package

SaiPress® HF Sterilizing-grade Hydrophilic Filter

High flux sterilizing-grade hydrophilic polyether sulfone (PES) filter membrane

Product features

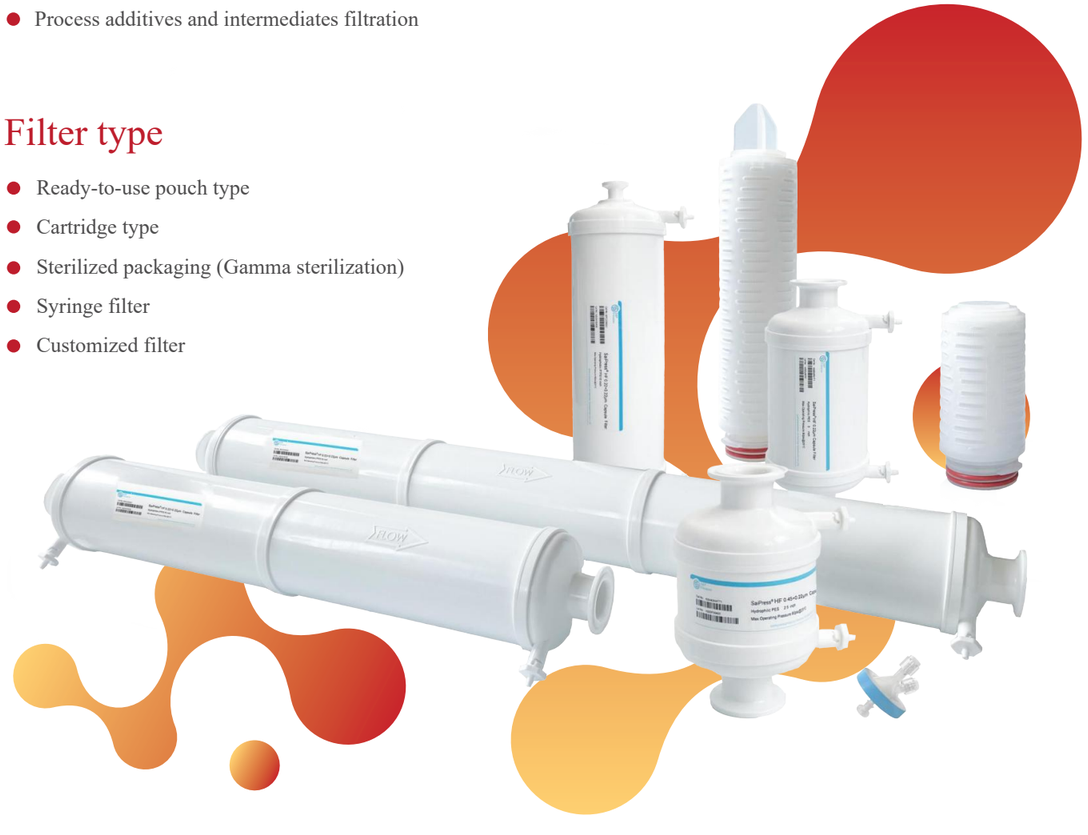
- **High flux** — The flow rate is more than 2.5 times that of the same type of sterilizing-grade filter membrane
- **High capacity** — High capacity, the same filtration area, larger processing capacity
- **pH 1-14** — Good chemical compatibility, suitable for various solutions of pH 1-14, including NaOH solutions
- **Low cost** — Process improvements increase efficiency and reduce costs

Filter application

- Buffer, pH regulator filtration
- Process additives and intermediates filtration

Filter type

- Ready-to-use pouch type
- Cartridge type
- Sterilized packaging (Gamma sterilization)
- Syringe filter
- Customized filter



Product parameters

Filter type		Syringe filter	Capsule filter						Cartridge filter				
Nominal size (inch)		--	1	2.5	5	10	20	30	2.5	5	10	20	30
Effective filtration area (m^2)	Single layer	2.8cm^2	380cm^2	0.16	0.33	0.65	1.3	1.95	0.16	0.33	0.65	1.3	1.95
	Double layer	2.8cm^2	350cm^2	0.14	0.28	0.55	1.1	1.65	0.14	0.28	0.55	1.1	1.65
Filter membrane pore size		0.22μm/0.45μm/0.65μm/0.8μm/1.2μm/0.22+0.22μm/ 0.45+0.22μm/0.65+0.45μm/0.8+0.22μm/0.8+0.45μm/1.2+0.45μm											
Material	Filter membrane	Hydrophilic polyether sulfone (PES)											
	Supporting layer	Polypropylene (PP)											
	Housing/structural components	Polypropylene (PP)											
	Vent O-ring	--	Silicone						--				
	O-ring	--	--						Silicone/EPDM/FKM				
Maximum operating pressure difference		--	Forward：5.5bar(80psi)@25℃； 1.7bar(25psi)@80℃						Forward：5.5bar(80psi)@25℃； 1.7bar(25psi)@80℃				
			Reverse：2.1bar(30psi)@25℃						Reverse：2.1bar(30psi)@25℃				
Bubble point（water@25℃）		0.22μm:≥3400mbar/0.45μm:≥2000mbar/0.65μm:≥1500mbar/0.8μm:≥1100mbar/1.2μm:≥500mbar											
Sterilization method		--	SIP not applicable						Gamma not applicable				
		--	Tolerance 40KGy gamma irradiation, autoclave not allowed Offline: 126℃/60min, 5 times, Gamma irradiation not allowed						SIP :126℃ / 60min, 25 times Offline :126℃ / 60min, 25 times				
Pressure test		--	No leakage detected under 0.65MPa within 24h						--				
TOC and conductivity		According to the determination method of total organic carbon in pharmaceutical water according to the General Rule of China Pharmacopoeia 2025 Edition (0682) and the determination method of electrical conductivity of pharmaceutical water according to the general rule (0681), the detected TOC value is ≤0.5mg/L, and the electrical conductivity value is ≤1.3us/cm											
Cleanliness		Meets the "no fiber release" filter standard as defined in 21 FR210.3 (b) (6)											
Bacterial endotoxin		According to the bacterial endotoxin test method stipulated in the General Rule of China Pharmacopoeia 2025 Edition (1143), the endotoxin content of the filter solution was determined, and the content of endotoxin in the filter solution was lower than 0.25EU/ml											
Biosafety testing		All materials of the filter cartridge meet the biosafety assessment of USP < 88 >, ClassVI-70℃ grade plastic materials											
Bacterial retention		The test method of ASTMF838 and defective Pseudomonas (ATCC19146) were used for bacterial retention of this product. The results showed that the minimum retention rate was 10^7cfu/cm^2											
Regulatory compliance		Product production and quality management inaccordance with ISO:9001 (2015)											
Shelf life		3 years	Gamma irradiated(Sterilized packaging) Capsule: 2 years Autoclavable / Gamma sterilizable Capsule: 3 years						3 years				
Storage and transportation		This product should be stored in an environment of 0 to 30℃, avoiding freezing and high temperature (>40℃) conditions. The internal bag should be kept intact to prevent external particles or moisture from entering											
Insoluble particles		Unless otherwise specified, the number of particles containing 10μm and more than 10μm in each 1ml filter rinse solution shall not exceed 25 particles, and the number of particles containing 25μm and more than 25μm shall not exceed 3 particles											

Ordering information

SaiPress® HF Capsule filter

K	H	F	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: H=HF	Filter Size: F=1inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out	Interface type (in/out) : SS= TC25 at both ends HH= 1/2 to 1/4 hose SH=inlet TC25, outlet 1/2 to 1/4 hose HS=inlet 1/2 to 1/4 hose, outlet TC25	Packing Specification: 1= 1 per package

K	H	B	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: H=HF	Filter Size: A=2.5inch B=5inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out	Interface type (in/out) : SS= TC25 at both ends TT= TC50 at both ends NN= 1/2 hose on both ends FF= 5/8 hose at both ends SN= inlet TC25, outlet 1/2 hose TF= inlet TC50, outlet 5/8 hose	Packing Specification: 1= 1 per package

K	H	C	2 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: H=HF	Filter Size: C=10inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out T=Left-in and right-out	Interface type (in/out) : TT= TC50 at both ends FF= 5/8 hose at both ends TF= inlet TC50, outlet 5/8 hose	Packing Specification: 1= 1 per package

K	H	D	2 2	G	T	T T	1
Filter Type: K=Capsule	Membrane Material: H=HF	Filter Size: D=20inch E 30inch	Membrane Pore Size: See below table	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out T=Left-in and right-out	Interface type (in/out) : TT= TC50 at both ends	Packing Specification: 1= 1 per package

Pore size code table

Membrane pore size	Single layer	02=0.22μm/04=0.45μm/06=0.65μm/08=0.8μm/12=1.2μm
	Double layer	22=0.22+0.22μm/42=0.45+0.22μm/64=0.65+0.45μm/ 82=0.8+0.22μm/84=0.8+0.45μm/A2=1.2+0.45μm

SaiPress® HF Cartridge filter

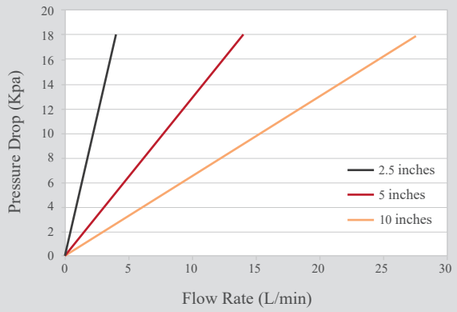
C	H	C	2 2	S	7	1
Filter type: C= cartridge filter	Membrane material: H=HF	Filter Size: A=2.5inch B=5inch C=10inch D=20inch E=30inch	Membrane Pore Size: See below table	Sealing ring: S=Silicone E=EPDM F=FKM	Connector Type: 7=226 connector	Packing Specification: 1= 1 per package

SaiPress® HF Syringe filter

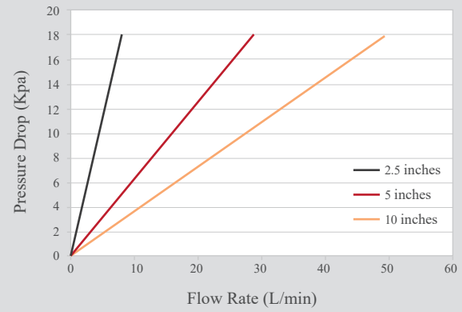
F	H	C 3	4 2	M L	1
Filter type: F=Disk filter	Membrane Material: H=HF	Filter Size: C3=Membrane area 2.8cm²	Membrane Pore Size: See below table	Connector Type(In/Out): ML=Luer(female)in Luer(male)out	Packing Specification: 1= 1 per package

Test data

0.45+0.22μm SaiPress® HF pressure drop and flow rate diagram



0.22μm SaiPress® HF pressure drop and flow rate diagram





SaiPress® HF Pro Sterilizing-grade Hydrophilic Filter

Ultra-high Flux Sterilizing-grade Polyether sulfone (PES) Filter

Product features

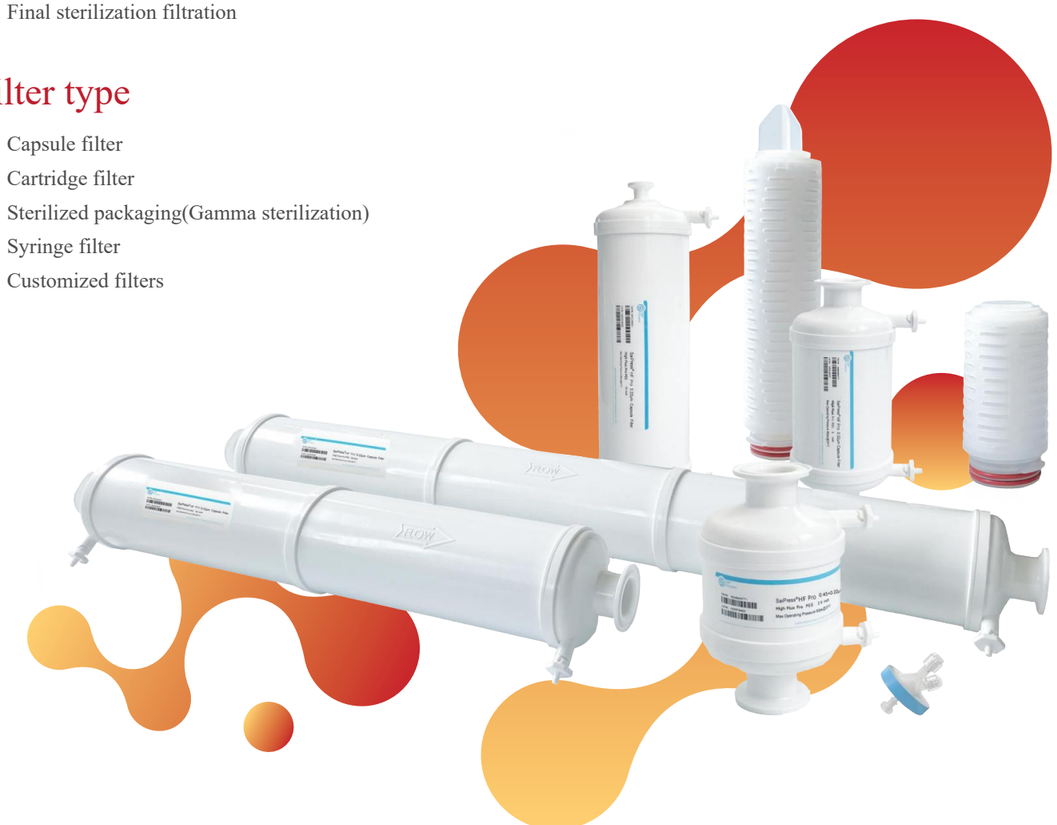
- **High flux** — The flow rate is more than 2.5 times that of the same type of sterilizing-grade filter membrane
- **High capacity** — High capatity, the same filtration area, larger processing capacity
- **High retention** — Higher retention rates
- **Low dissolution precipitation** — Low dissolution and precipitation to ensure filtrate purity
- **Low adsorption** — Low adsorption, reduce filtrate loss

Filter application

- Chemical synthetic media filtration
- Final sterilization filtration

Filter type

- Capsule filter
- Cartridge filter
- Sterilized packaging(Gamma sterilization)
- Syringe filter
- Customized filters



Product parameters

Filter type		Syringe filter	Capsule filter						Cartridge filter				
Nominal size (inch)		--	1	2.5	5	10	20	30	2.5	5	10	20	30
Effective filtration area (m^2)	Double layer	2.8cm^2	350cm^2	0.14	0.28	0.57	1.14	1.71	0.14	0.28	0.57	1.14	1.71
Filter membrane pore size		0.22+0.1μm/0.45+0.1μm/0.45+0.22μm											
Material	Filter membrane	Hydrophilic polysthersulfone (PES)											
	Supporting layer	Polypropylene (PP)											
	Housing/structural components	Polypropylene (PP)											
	Vent O-ring	--	Silicone						--				
	O-ring	--	--						Silicone / EPDM / FKM				
Maximum operating pressure difference		--	Forward: 5.5bar(80psi)@25°C; 1.7bar(25psi)@80°C						Forward: 5.5bar(80psi)@25°C; 1.7bar(25psi)@80°C				
			Reverse: 2.1bar(30psi)@25°C						Reverse: 2.1bar(30psi)@25°C				
Bubble point		0.22μm: ≥3400mbar(water@25°C); 0.1μm≥2500mbar (100%IPA@25°C)											
0.1μm/0.22μm filter diffusion flow (ml/min) (Pure water @ 25°C@2800mbar)		--	≤2.5	≤7.5	≤15	≤30	≤60	≤90	≤7.5	≤15	≤30	≤60	≤90
Sterilization method		--	SIP not applicable						Gamma not applicable				
		--	Code R: Tolerance 40KGy gamma irradiation, autoclave not allowed Code A: Off-line: 126°C/60min, 3 times, Gamma not allowed						Offline :135°C* 30min, 25 times SIP :135°C* 30min, 25 times (In the sterilization process, the upstream and downstream pressure difference of cartridge is ≤300mbar)				
Pressure test		--	No leakage detected under 0.65MPa within 24h						--				
TOC and conductivity		According to the determination method of total organic carbon in pharmaceutical water according to the General Rule of China Pharmacopoeia 2025 Edition (0682) and the determination method of electrical conductivity of pharmaceutical water according to the general rule (0681), the detected TOC value is ≤0.5mg/L, and the electrical conductivity value is ≤1.3us/cm											
Cleanliness		Meets the "no fiber release" filter standard as defined in 21 FR210.3 (b) (6)											
Bacterial endotoxin		According to the bacterial endotoxin test method stipulated in the General Rule of China Pharmacopoeia 2025 Edition (1143), the endotoxin content of the filter solution was determined, and the content of endotoxin in the filter solution was lower than 0.25EU/ml											
Biosafety testing		All materials of the filter cartridge comply with the biosafety assessment of USP < 87 >, USP < 88 >, ClassVI-70°C plastic materials											
Bacterial retention		The test method of ASTMF838 and defective Pseudomonas (ATCC19146) were used for bacterial retention of this product. The results showed that the minimum retention rate was 10^7cfu/cm^2											
Regulatory compliance		Product production and quality management in accordance with ISO:9001 (2015)											
Shelf life		3 years	Gamma irradiated(Sterilized packaging) Capsule: 2 years Autoclavable / Gamma sterilizable Capsule: 3 years						3 years				
Storage and transportation		This product should be stored in an environment of 0 to 30°C, avoiding freezing and high temperature (>40°C) conditions. The internal bag should be kept intact to prevent external particles or moisture from entering											
Insoluble particles		Unless otherwise specified, the number of particles containing 10μm and more than 10μm in each 1ml filter rinse solution shall not exceed 25 particles, and the number of particles containing 25μm and more than 25μm shall not exceed 3 particles											

Ordering information

SaiPress® HF Pro Capsule filter

K	F	F	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: F=HF Pro	Filter Size： F=1inch	Membrane Pore Size: 42=0.45+0.22μm 41=0.45+0.1μm 21=0.22+0.1μm	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out	Interface type (in/out) : SS= TC25 at both ends HH= 1/2 to 1/4 hose SH=inlet TC25, outlet 1/2 to 1/4 hose HS=inlet 1/2 to 1/4 hose, outlet TC25	Packing Specification: 1= 1 per package

K	F	B	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: F=HF Pro	Filter Size： A=2.5inch B=5inch	Membrane Pore Size: 42=0.45+0.22μm 41=0.45+0.1μm 21=0.22+0.1μm	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out	Interface type (in/out) : SS= TC25 at both ends TT= TC50 at both ends NN= 1/2 hose on both ends FF= 5/8 hose at both ends SN= inlet TC25, outlet 1/2 hose TF= inlet TC50, outlet 5/8 hose	Packing Specification: 1= 1 per package

K	F	C	2 1	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: F=HF Pro	Filter Size： C=10inch	Membrane Pore Size: 42=0.45+0.22μm 41=0.45+0.1μm 21=0.22+0.1μm	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out T=Left-in and right-out	Interface type (in/out) : TT= TC50 at both ends FF= 5/8 hose at both ends TF= inlet TC50, outlet 5/8 hose	Packing Specification: 1= 1 per package

K	F	D	2 1	G	T	T T	1
Filter Type: K=Capsule	Membrane Material: F=HF Pro	Filter Size: D=20inch E 30inch	Membrane Pore Size:: 42=0.45+0.22μm 41=0.45+0.1μm 21=0.22+0.1μm	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out T=Left-in and right-out	Interface type (in/out) : TT= TC50 at both ends	Packing Specification: 1= 1 per package

SaiPress® HF Pro Cartridge filter

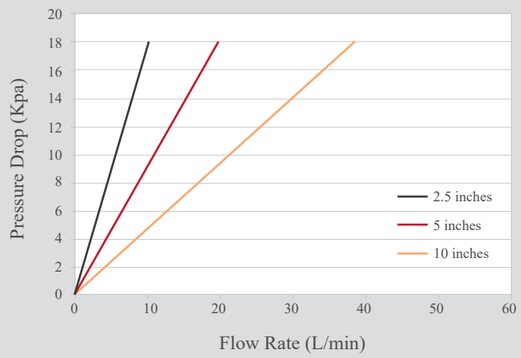
C	F	C	2 1	S	7	1
Filter Type: C= cartridge filter	Membrane Material: F=HF Pro	Filter Size: A=2.5 inches B=5 inches C=10 inches D=20 inches E=30inches	Membrane Pore Size: 42=0.45+0.22μm 41=0.45+0.1μm 21=0.22+0.1μm	Sealing ring: S=Silicone E=EPDM F=FKM	Connector Type: 7=226 connector	Packing Specification: 1= 1 per package

SaiPress® HF Pro Syringe filter

F	F	C 3	4 2	M L	1
Filter Type: F=Disk filter	Membrane Material: F=HF Pro	Filter Size: C3=Membrane area 2.8cm²	Membrane Pore Size: 42=0.45+0.22μm 41=0.45+0.1μm 21=0.22+0.1μm	Connector Type(In/Out): ML=Luer(female)in Luer(male)out	Packing Specification: 1= 1 per package

Test data

0.45+0.22μm SaiPress® HF Pro pressure drop and flow rate diagram





SaiPress® PVDF Hydrophilic Sterile Filter

SaiPress® PVDF hydrophilic sterile filter is suitable for sterile filtration of various biopharmaceutical products. It is made of PVDF membrane with symmetric pore structure, uniform hydrophilicity, high porosity, and extremely low protein adsorption.

Product Features

- High porosity, extremely low protein adsorption
- Low extractables and good chemical compatibility for pH1-14
- Sterilizing-grade (0.22μm) PVDF material, can withstand multiple autoclaves
- Higher flow rates at the same level, thus reducing the process footprint and maximizing benefits
- 100% integrity testing ensures sterilization effectiveness

Product applications

- Filtration of colloidal
- Filtration of cell culture medium
- Filtration of High-viscosity liquid filtration and high-concentration liquid
- Filtration of sterile APIs and ophthalmic preparations
- Filtration of high-purity chemicals, intermediates, strong acid and oxidizing liquids
- Filtration of vaccines, biologics, blood products

Filter type

- Ready-to-use capsule filters
- Cartridge filter
- Capsule filters sterilized by gamma irradiation
- Customized filters



Product parameters

Filter type		Syringe Filter	Capsule Filter				Cartridge Filter			
Nominal size (inch)		--	5	10	20	30	5	10	20	30
Effective filtration area (m^2)	Single layer	2.8cm^2	0.33	0.65	1.3	1.95	0.33	0.65	1.3	1.95
	Double layer	2.8cm^2	0.28	0.55	1.1	1.65	0.28	0.55	1.1	1.65
Filter membrane pore size		0.45μm、0.45+0.22μm								
Material	Filter membrane	PVDF								
	Supporting layer	Polypropylene(PP)								
	Housing/structural components	Polypropylene(PP)								
	Vent O-ring	--	Silicone				--			
	O-ring	--	--				Silicone/EPDM/FKM			
Maximum operating pressure difference		--	Forward：5.5bar(80psi)@25℃; 1.7bar(25psi)@80℃ Reverse：2.1bar(30psi)@25℃				Forward：5.5bar(80psi)@25℃ 1.7bar(25psi)@80℃ Reverse：2.1bar(30psi)@25℃			
Bubble point (pure water @ 25℃)		0.45+0.22μm:≥3400mbar 0.45μm:≥2000mbar								
0.45+0.22μm filter diffusion flow (ml/min) (Pure water @ 25℃@2700mbar)		--	≤6.3	≤12.6	≤25.2	≤37.8	≤6.3	≤12.6	≤25.2	≤37.8
0.45μm filter diffusion flow (ml/min) (Pure water@25℃@1600mbar)		--	≤10	≤20	≤40	≤60	≤10	≤20	≤40	≤60
Sterilization method		--	Offline:124℃ / 30min， 5times; 134℃ / 20min， 5times; 126℃ / 60min， 5times;				SIP:124℃ / 30min， 30times; 134℃ / 20min， 30times;			
TOC and conductivity		According to the determination method of total organic carbon in pharmaceutical water according to the General Rule of China Pharmacopoeia 2025 Edition (0682) and the determination method of electrical conductivity of pharmaceutical water according to the general rule (0681), the detected TOC value is ≤0.5mg/L, and the electrical conductivity value is ≤1.3us/cm								
Cleanliness		Meets the "no fiber release" filter standard as defined in 21 FR210.3 (b) (6)								
Bacterial endotoxin		According to the bacterial endotoxin test method stipulated in the General Rule of China Pharmacopoeia 2025 Edition (1143), the endotoxin content of the filter solution was determined, and the content of endotoxin in the filter solution was lower than 0.25EU/ml								
Biosafety testing		All materials of the filter cartridge meet the biosafety assessment of USP < 88 >, ClassVI grade plastic materials								
Bacterial retention		0.45+0.22μm: The test method of ASTMF838 and defective Pseudomonas (ATCC19146) were used for bacterial retention of this product. The results showed that the minimum retention rate was 10^7cfu/cm^2								
Regulatory compliance		Product production and quality management inaccordance with ISO:9001 (2015)								
Shelf life		3 years								
Insoluble particles		Unless otherwise specified, the number of particles containing 10μm and more than 10μm in each 1ml filter rinse solution shall not exceed 25 particles, and the number of particles containing 25μm and more than 25μm shall not exceed 3 particles								

Ordering information

SaiPress® PVDF Capsule Filter

K	V	B	4 2	G	N	T T	1
Filter Type: K=Capsule	Membrane: V= PVDF	Filter Size: B= 5inch C=10inch D=20inch E=30inch	Membrane Pore Size: 04=0.45μm 42=0.45+0.22μm	Sterilization Form: G=Gamma irradiated (Sterilized packaging) A=Autoclavable R=Gamma sterilizable	In & Out Type: N=Up-in and down-out (In line)	Interface type (in/out) : TT= TC50 at both ends	Packing Specification: 1= 1 per package

SaiPress® PVDF Cartridge Filter

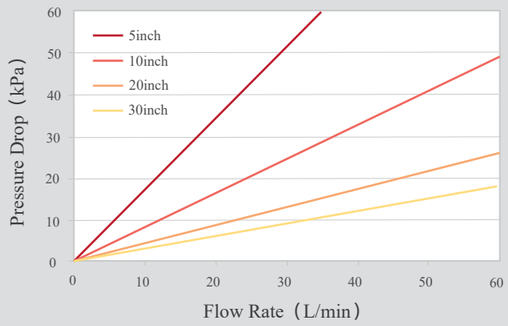
C	V	C	4 2	S	7	1
Filter Type: C=Cartridge	Membrane: V= PVDF	Filter Size: B= 5inch C=10inch D=20inch E=30inch	Membrane Pore Size: 04=0.45μm 42=0.45+0.22μm	Sealing ring: S=Silicone E=EPDM F=FKM	Connector type: 7=226 connectors 2=222 connectors	Packing Specification: 1= 1 per package

SaiPress® PVDF Syringe filter

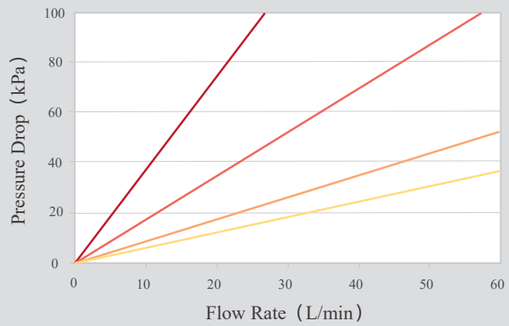
F	V	C 3	4 2	M L	1
Filter Type: F=Disk filter	Membrane: V=PVDF	Filter Size: C3=Membrane area 2.8cm²	Membrane Pore Size: 04=0.45μm 42=0.45+0.22μm	Connector Type(In/Out): ML=Luer(female)in Luer(male)out	Packing Specification: 1= 1 per package

Test data

0.45μm SaiPress® PVDF pressure drop and flow rate diagram



0.45+0.22μm SaiPress® PVDF pressure drop and flow rate diagram



Filgiant® Sterilizing-grade Hydrophobic Filter

Ideal for gas and non-aqueous liquid filtration

As a sterilizing-grade gas filter composed of single-layer/double-layer polytetrafluoroethylene (PTFE) membrane and polypropylene components, the Filgiant® sterilizing-grade hydrophobic filter has good chemical compatibility and boasts its characteristics of high flow rate, high flux and no shedding of fibers, providing all kinds of filter sizes and connectors to meet your wide application needs.

Product features

- Made of the sterilizing-grade polytetrafluoroethylene (PTFE) materials, it can withstand multiple sterilization cycles;
- By physical retentionand charge adsorption, it can retent particles of size down to 0.01μm;
- High-temperature and high-pressure tolerance;
- With good chemical compatibility, pH1-14 tolerance;
- Provide all scales products to meet your needs from R&D to manufacture.

Filter application

- Vent filter for storage tanks, fermentation tanks/WFI tanks;
- Gas sterile filtration of compressed air/clean pipelines;
- Input/output gases for bioreactors;
- Sterile filtration of non-aqueous liquids

Filter types

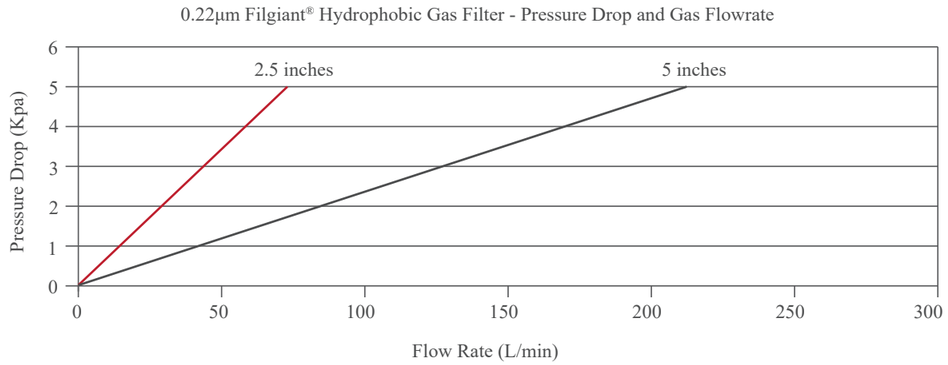
- Ready-to-use capsule filter
- Cartridge filter
- Disk filter and customized filters



Connector types

TC25	TC50	1/4-1/2HB	215 Connector	internal insert Connector	222 Connector	226 Connector
						

Pressure drop and gas flowrate



Product parameters

Filter type		Disk filter	Capsule filter	Cartridge filter
		Single layer/Double layer		
Nominal size		Φ50mm	1/2.5/5/10/20/30 inches	2.5/5/10/20/30 inches
Membrane pore size		0.22μm/0.22+0.22μm		
Effective filtration area		13.8cm²	0.04/0.16/0.33/0.65/1.3/1.95m²	0.16/0.33/0.65/1.3/1.95m²
Material	Filter membrane	Hydrophobic Polytetrafluoroethylene (PTFE)		
	Support layer	Polypropylene (PP)		
	Housing/structural components	Polypropylene (PP)		
	Vent O-ring	--	Silicone	--
	O-ring	--	--	Silicone/EPDM/FKM
Maximum operating differential pressure		Forward:5.5bar(80psi)@25℃ 1.7 bar(25psi)@80℃ Reverse:2.1bar(30psi)@25℃		Forward:5.5bar(80psi)@25℃ 1.7 bar(25psi)@80℃ Reverse:2.1bar(30psi)@25℃
Maximum inlet pressure		--	0.65Mpa	--
Bubble point		≥1100mbar (100%, IPA bubble point@25℃)		
Water intrusion (@2500mbar)		2.5 inches:≤0.2ml/min 5 inches:≤0.4ml/min 10 inches:≤0.8ml/min 20 inches:≤1.6ml/min 30 inches:≤2.4ml/min		
Sterilization resistance		Offline :126 ℃ /60 minutes	Offline :126℃/30 minutes, 30 times (SIP not allowed)	Offline :126℃/60 minutes, 50 times SIP: Forward :142℃/30 minutes, 200 times Reverse :126℃/60 minutes, 25 times (not exceeding the maximum operating pressure difference of cartridge)
Cleanliness		Meet 21CFR21 0.3(b)(6) of “None fiber release”		
Bacterial endotoxin		The endotoxin in the filtrate was determined according to the bacterial endotoxin test method specified in the General Principles (1143) of the "2025 Chinese Pharmacopoeia". Bacterial endotoxin ≤ 0.25 EU/ml		
Biosafety test		All materials of the filter element meet USP <88> , Class VI-70℃ biosafety evaluation of plastic materials		
Bacteria retention		This product was tested for retention of Brevundimonas diminuta (ATCC 19146) by the ASTM F838 test method, and it's shown that the minimum retention rate was 10^7cfu/cm²		
Aerosol test		This product was tested for retention of Brevundimonas diminuta (ATCC 19146) aerosol referring to the requirements of PDA TR40, and it's shown that the minimum retention rate was 10^7cfu/cm²		

Ordering information

Filgiant® Capsule filter

K	P	F	2 2	N	H H	1
Filter Type: K=Capsule	Membrane Material: P=PTFE	Filter Size: F=1inch	Membrane Pore Size: 02= 0.22μm 22= 0.22+ 0.22μm	In & Out Type: N=Up-in and down-out (In line)	Connector Type(In/Out): HH=1/2 to 1/4 hose at both end SS=TC25 at both end SH=inlet TC25，outlet 1/2 to 1/4 hose HS=inlet 1/2 to 1/4 hose，outlet TC25	Packing Specification: 1= 1 per package

K	P	C	2 2	N	T T	1
Filter Type: K=Capsule	Membrane Material: P=PTFE	Filter Size: A=2.5inch B=5inch C=10inch	Membrane Pore Size: 02=0.22μm 22=0.22+0.22μm	In & Out Type: N=Up-in and down-out (In line)	Connector Type(In/Out): SS=TC25 at both end TT=TC50 at both end FF=5/8 hose at both end NN=1/2 hose at both end SN=inlet TC25，outlet 1/2 hose TF=inlet TC50，outlet 5/8 hose	Packing Specification: 1= 1 per package

K	P	D	2 2	N	T T	1
Filter Type: K=Capsule	Membrane Material: P=PTFE	Filter Size: D=20inch E=30inch	Membrane Pore Size: 02=0.22μm 22=0.22+0.22μm	In & Out Type: N=Up-in and down-out(In line) T=Left-in and right-out(T line)	Connector Type(In/Out): TT=TC50 at both end	Packing Specification: 1= 1 per package

Filgiant® Cartridge filter

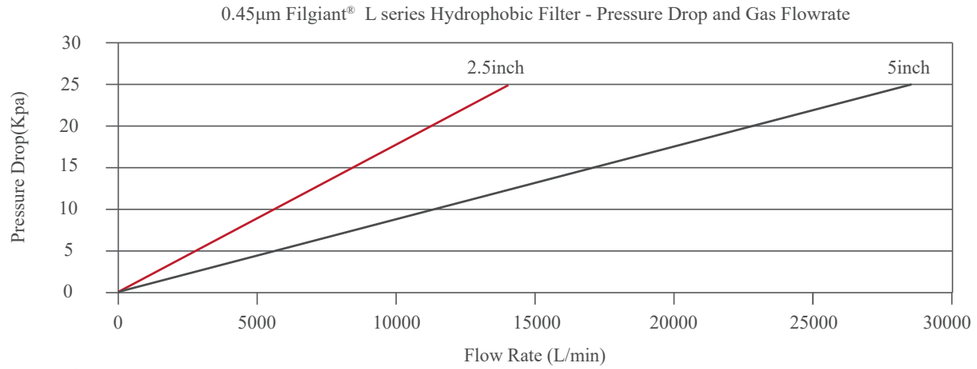
C	P	C	2 2	S	7	1
Filter Type: C=Cartridge	Membrane Material: P=PTFE	Filter Size: A=2.5inch B= 5inch C= 10inch D = 20inch E= 30inch	Membrane Pore Size: 02= 0.22μm 22= 0.22+ 0.22μm	Sealing ring: S=Silicone E=EPDM F=FKM	Connector Type: 7=226 connector 5=215 connector 2=222 connector 1=internal insert connector	Packing Specification: 1= 1 per package

Filgiant® Disk filter

F	P	5 0	2 2	H H	1
Filter Type: F=Disk	Membrane Material: P=PTFE	Filter Size: 50=dia. 50mm	Membrane Pore Size: 02= 0.22μm 22= 0.22+ 0.22μm	Connector Type(In/Out): HH=1/2 to 1/4 hose at both end	Packing Specification: 1= 1 per package

Filgiant® L series Hydrophobic Filter

Pressure drop and gas flowrate



Product parameters

Filter type		Capsule filter	Cartridge filter
Nominal size		1/2.5/5/10/20/30inch	2.5/5/10/20/30inch
Effective filtration area		0.04/0.16/0.33/0.65/1.3/1.95m²	0.16/0.33/0.65/1.3/1.95m²
Membrane pore size		0.22μm/0.22+0.22μm/0.45μm/0.01μm	
Material	Filter membrane	Hydrophobic Polytetrafluoroethylene (PTFE)	
	Support layer	Polypropylene (PP)	
	Housing/structural components	Polypropylene (PP)	
	Vent O-ring	Silicone	--
	O-ring	--	Silicone/EPDM/FKM
Maximum operating differential pressure		Forward:5.5bar(80psi)@25℃ 1.7 bar(25psi)@80℃ Reverse:2.1bar(30psi)@25℃	Forward:5.5bar(80psi)@25℃ 1.7 bar(25psi)@80℃ Reverse:2.1bar(30psi)@25℃
Bubble point		0.22μm:≥1100mbar (100%IPA) ; 0.45μm:≥600mbar (70%IPA)	
0.22μm Water intrusion pure water @25℃@2500mbar		2.5inch:≤0.2ml/min 5inch:≤0.4ml/min 10inch:≤0.8ml/min 20inch:≤1.6ml/min 30inch:≤2.4ml/min	
Sterilization resistance		0.22μm SIP: Forward:142℃/30min, 200 times 0.22μm Offline:126℃/30min, 200 times 0.45μm Offline:135℃/30min, 5 times	
Cleanliness		Meet 21CFR21 0.3(b)(6) of “None fiber release”	
Bacterial endotoxin		The endotoxin in the filtrate was determined according to the bacterial endotoxin test method specified in the General Principles (1143) of the "2025 Chinese Pharmacopoeia". Bacterial endotoxin ≤ 0.25 EU/ml	
Biosafety test		All materials of the filter element meet USP <88> , Class VI-70℃ biosafety evaluation of plastic materials	
Bacteria retention		0.22μm: This product was tested for retention of Brevundimonas diminuta (ATCC 19146) by the ASTM F838 test method, and it's shown that the minimum retention rate was 10^7cfu/cm²	
Insoluble particles		Unless otherwise specified, the number of particles containing 10μm and more than 10μm in each 1ml filter rinse solution shall not exceed 25 particles, and the number of particles containing 25μm and more than 25μm shall not exceed 3 particles	

Ordering information

Filgiant® L Capsule filter

K	L	F	0 2	N	H H	1
Filter Type: K=Capsule	Membrane Material: L=PTFE L	Filter Size: F=1inch	Membrane Pore Size: 02=0.22μm 22=0.22+0.22μm 04=0.45μm 0A=0.01μm	In & Out Type: N=Up-in and down-out (In line)	Connector Type(In/Out): SS=TC25 at both end HH= 1/2 to 1/4 hose connector SH=inlet TC25，outlet 1/2-1/4hose HS=inlet 1/2-1/4 hose，outlet TC25	Packing Specification: 1= 1 per package

K	L	C	0 2	N	T T	1
Filter Type: K=Capsule	Membrane Material: L=PTFE L	Filter Size: A=2.5inch B=5inch C=10inch	Membrane Pore Size: 02=0.22μm 22=0.22+0.22μm 04=0.45μm 0A=0.01μm	In & Out Type: N=Up-in and down-out (In line)	Connector Type(In/Out): SS=TC25 at both end TT=TC50 at both end FF=5/8 hose at both end NN=1/2hose at both end SN=inlet TC25, outlet 1/2 hose TF=inlet TC50, outlet 5/8 hose	Packing Specification: 1= 1 per package

K	L	D	0 2	N	T T	1
Filter Type: K=Capsule	Membrane Material: L=PTFE L	Filter Size: D=20inch E=30inch	Membrane Pore Size: 02=0.22μm 22=0.22+0.22μm 04=0.45μm 0A=0.01μm	In & Out Type: N=Up-in and down-out (In line) T=Left-in and right-out (T line)	Connector Type(In/Out): TT=TC50 at both end	Packing Specification: 1= 1 per package

Filgiant® L Cartridge filter

C	L	C	0 2	S	7	1
Filter Type: C= cartridge filter	Membrane Material: L=PTFE L	Filter Size: A=2.5inch B=5inch C=10inch D=20inch E=30icnh	Membrane Pore Size: 02=0.22μm 22=0.22+0.22μm 04=0.45μm 0A=0.01μm	Sealing ring: S=Silicone E=EPDM F=FKM	Connector Type: 7=226 connector 5=215 connector	Packing Specification: 1= 1 per package

Filgiant® PES Sterile Hydrophobic Capsule Filter

Ideal for gas and non-aqueous liquid filtration

As a sterilizing-grade gas filter composed of double-layer Hydrophobic polyether sulfone(PES) membrane and polypropylene components, the Filgiant® PES sterilizing-grade hydrophobic filter has good chemical compatibility and boasts its characteristics of high flow rate, high mechanical tolerance and tolerance 25~40KGy gamma irradiation.

Product features

- Made of the sterilizing-grade Hydrophobic polyether sulfone (PES) materials, it can tolerant 25~40KGy gamma irradiation;
- High flow rate, high mechanical tolerance
- With good chemical compatibility, pH1-14 tolerance;

Filter application

- Vent filter for fermentation tanks;
- Gas sterile filtration;
- cell culture flasks/bioreactors;
- Sterile filtration of non-aqueous liquids



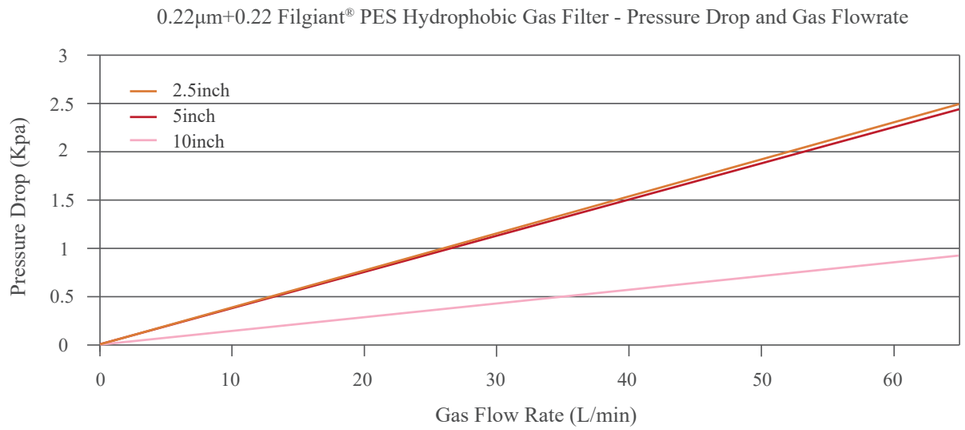
Filter types

- Ready-to-use capsule filter;
- Customized filters

Ordering information

K	M	B	2 2	G	N	T T	1
Filter Type: K=Capsule	Membrane Material: M=Hydrophobic PES	Filter Size: A=2.5inch B=5inch C=10inch	Membrane Pore Size: 22= 0.22+ 0.22μm	Sterilization Form: G=Gamma irradiated (Sterilized packaging) R=Gamma sterilizable	In & Out Type: N=Up-in and down-out (In line)	Connector Type(In/Out): TT=TC50 at both end	Packing Specification: 1= 1 per package

Pressure drop and gas flowrate



Product parameters

Filter type		Capsule filter
Nominal size		2.5/5/10inches
Membrane pore size		0.22+0.22μm
Effective filtration area		0.13/0.17/0.55m²
Material	Filter membrane	Hydrophobic polyether sulfone (PES)
	Support layer	Polypropylene (PP)
	Housing/structural components	Polypropylene (PP)
	Vent O-ring	Silicone
Maximum operating differential pressure		Forward:5.5bar(80psi)@25℃ 1.7 bar(25psi)@80℃ Reverse:2.1bar(30psi)@25℃
Maximum inlet pressure		0.65Mpa
Bubble point		≥2000mbar (60%, IPA bubble point@25℃)
Water intrusion (pure water @25℃)		≤0.1ml/min/2.5 inch @1200mbar ≤0.13ml/min/5 inch @1200mbar ≤0.4ml/min/10 inch @1200mbar
Sterilization resistance		Tolerance 25~40KGy gamma irradiation, autoclave not allowed
Cleanliness		Meet 21CFR21 0.3(b)(6) of “None fiber release”
Bacterial endotoxin		The endotoxin in the filtrate was determined according to the bacterial endotoxin test method specified in the General Principles (1143) of the "2025 Chinese Pharmacopoeia". Bacterial endotoxin ≤ 0.25 EU/ml
Biosafety test		All materials of the filter element meet USP <88> , Class VI biosafety evaluation of plastic materials
Bacteria retention		This product was tested for retention of Brevundimonas diminuta (ATCC 19146) by the ASTM F838 test method, and it's shown that the minimum retention rate was 10^7cfu/cm²
Insoluble particles		Unless otherwise specified, the number of particles containing 10μm and more than 10μm in each 1ml filter rinse solution shall not exceed 25 particles, and the number of particles containing 25μm and more than 25μm shall not exceed 3 particles

PolySai™ Polypropylene (PP) Filter

Designed to remove particles from liquids and gases



Product features

- The PP filter pore size is calibrated with the real pore size, the wide range of pore sizes provides various choices for large and small particles retention
- PP is widely applied in liquid and gas filtration
- Wide pH tolerance from pH 1-14
- Strong particle-removing capacity, resistance to clogging
- No integrity test required

List of nominal pore size

- 0.05μm
- 0.075μm
- 0.1μm
- 0.22μm
- 0.45μm
- 1.0μm
- 3.0μm
- 5.0μm
- 13.0μm
- 15.0μm
- 18.0μm
- 20.0μm
- 30.0μm
- 40.0μm
- 50.0μm
- 150.0μm

Filter types

- Capsule filter
- Cartridge filter
- Disk filter and customized filters



Product parameters

Filter type		Capsule filter						Cartridge filter				
Nominal size		1	2.5	5	10	20	30	2.5	5	10	20	30
Effective filtration area(m^2)	Single layer	0.038	0.16	0.33	0.65	1.3	1.98	0.16	0.33	0.65	1.3	1.98
	Double layer	0.035	0.14	0.28	0.55	1.1	1.65	0.14	0.28	0.55	1.1	1.65
Membrane pore size		0.1-100μm										
Filter membrane/ Support layer/ Housing/structural components		Polypropylene (PP)										
Vent O-ring		Silicone						--				
O-ring		--						Silicone/EPDM/FKM				
Maximum operating pressure		5.5bar(80psi)@25°C/1.7bar(25psi)@80°C										
Biosafety test		All materials of the filter element meet the biosafety evaluation of USP <88> class tests and Class VI-70°C plastic materials										

Ordering information

K	B	D	0	0	0	1	N	T	T		1
Filter Type: K=Capsule	Membrane Material: B=PP	Filter Size: F=1 inches	Membrane Pore Size: P1-P9=0.1-0.9μm 01-90=1-90μm 1H=100μm A2=1.2μm				In & Out Type: N=Up-in and down-out	Connector Type(In/Out): SS=TC25 at both end HH=1/2-1/4HB at both end SH=Inlet TC25, outlet1/2-1/4HB HS=Inlet 1/2-1/4HB, outlet TC25			Packing Specification: 1= 1 per package

K	B	D	0	0	0	1	N	T	T		1
Filter Type: K=Capsule	Membrane Material: B=PP	Filter Size: A=2.5 inches B=5 inches C=10 inches D=20 inches E=30inches	Membrane Pore Size: P1-P9=0.1-0.9μm 01-90=1-90μm 1H=100μm A2=1.2μm				In & Out Type: N=Up-in and down-out	Connector Type(In/Out): TT=TC50 at both end FF=5/8 HB at both end TF=Inlet TC50, outlet 5/8HB			Packing Specification: 1= 1 per package

C	B	C	0	0	1	0	S	7		1
Filter Type: C=Cartridge	Membrane Material: B=PP	Filter Size: A=2.5 inches B=5 inches C=10 inches D=20 inches E=30 inches	Membrane Pore Size: P1-P9=0.1-0.9μm 01-90=1-90μm 100=1H				Sealing ring: S=Silicone E=EPDM F=FKM	Connector Type: 7=226 connector 5=215 connector 2=222 connector		Packing Specification: 1= 1 per package

F	B	5	0	0	0	0	1	H	H		1
Filter Type: F=Disk	Membrane Material: B=PP	Filter Size: 50=dia.50mm	Membrane Pore Size: P1-P9=0.1-0.9μm 01-90=1-90μm 100=1H					Connector Type(In/Out): HH=1/2-1/4 hose at both end			Packing Specification: 1= 1 per package

* Membrane Pore Size e.g: Single layer 0.1μm=00P1; Double layer 20+20μm=2020

Peristaltic Pump

Peristaltic pump for 0.1m² TFF holder

Suitable for laboratory R&D and small batch production.

Uses brushless DC motor, suitable for pump head in series.

The upgrade model can realize the automatic allocation function of timing and quantity.

Product description

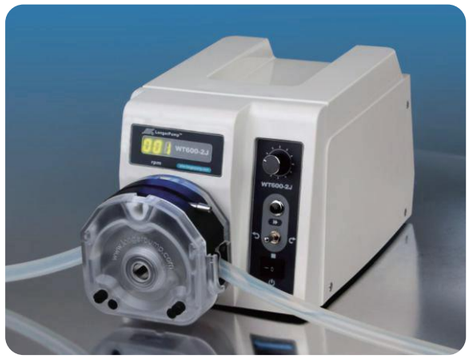
Dimensions: 285*207*180(MM)

Suitable hose specifications: 15# 24# 35# 36#

Maximum reference flow (ML/MIN): 6000(single pump head)

Basic version

Speed range (RPM): 60rpm-600rpm, reversible



Upgraded version

Speed range (RPM): 10rpm-600rpm, reversible





Fitting pump head

Torque wrench (10-50NM)

Suitable for 0.1m² tangential flow filtration



Torque range (NM)	10-50
Driving head	3/8″
Length (MM)	426
Index value (N·m)	0.5

Hexagonal long sleeve

(10 MM)



Φ(MM)	17
L(MM)	63.5

Peristaltic pump for 0.5m² TFF holder

With stainless steel housing, high protection level. Suitable for industrial production, using DC motor, suitable for pump head series. The upgrade model can realize the automatic allocation function of timing and quantity.



Product description

Dimensions: 380*326*214(MM)

Suitable hose specifications: 73# 82#

Maximum reference flow (ML/MIN):116000(single pump head)

Speed range (RPM): 60rpm-600rpm, reversible



Adapter pump head (Basic version)

Pump head housing material:

PSU



Adapter pump head (upgraded version)

Pump head housing material:

stainless steel

Ordering information

TFH01TW	10-50NM torque wrench
TFH05TW	20-100NM torque wrench
TFP01E	0.1m² peristaltic pump for fixture (economical)
TFP01F	0.1m² peristaltic pump for fixture (sub-assembly function)
TFP05E	Peristaltic pump for 0.5m² fixture (economical)
TFP05F	Peristaltic pump for 0.5m² fixture (sub-assembly function)

Torque wrench (20-100NM)

Suitable for tangential flow filtration of 0.5m² and above



Torque range (NM)	20-100
Driving head	1/2″
Length (MM)	473
Index value (N·m)	0.5

Hexagonal long sleeve

(12.5 MM)



Φ(MM)	24
L(MM)	77

Validation Center

1.Product integrity test

In the production process, since most product/drug liquid contains materials or components which influences the surface interaction between filter membrane and the wetting liquid, the integrity test results can be depends on the cleanliness of those components. The product integrity test make it possible and validated to test the filter integrity based on the product liquid, since the the product liquid based integrity test and standard liquid based integrity test are data-associated.



2.Chemical compatibility test

Chemical compatibility test can be used to evaluate the chemical impact of the medium to be filtered on the filter under specific process conditions.

Product components



Membrane
Appearance, tensile strength, flux, thickness, SEM scan



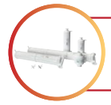
Filter
Integrity, flux, appearance



Seal ring
Appearanece, weight, wire diameter



Support components
Appearanece, weight



Subassembly
Appearanece, weight

Product components	Test Project					
	Appearance	Weight	Wire diameter	Tensile strengh	Flux	Integrity
Menbrane	✓	✓	✓	✓	✓	✓
Filter	✓				✓	✓
Support components	✓					
Seal ring	✓	✓	✓			
TFF&NF	✓				✓	✓

3.Extractables and leachtable test

Extractables

Extractables refer to compounds that can be extracted from packaging or production component materials (plastics, elastomers and their coatings) under harsh experimental conditions (such as solvent, temperature and time) with solvents of different physical and chemical properties (solvents of different polarity or solutions similar to product liquid).

Leachables

Leachable refers to compounds that migrate into a drug product from manufacturing parts, packaging parts, or delivery devices under normal manufacturing process, storage, and use conditions.

Basic testing process

- Carry out simulated extraction/simulated migration according to different component samples
- Speculate on potential extracts according to the results of simulated extraction
- Determine the risk substances according to the results of the extraction
- Carry out safety assessment according to risk substance content

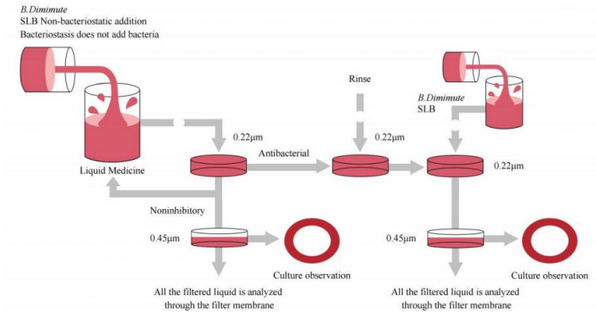
4.Bacterial retention test

Sterilizing filter

The sterilizing filter should be able to trap 1.0×10^7cfu of *Btrevundimonas diminuta* (ATCC 19146) by the ASTM F838 at a specific flow rate or pressure per square centimeter of effective filtration area.

Validation of bacterial retention process

To test the retention ability of sterilizing-grade filter with specific process fluid under specific filtration conditions , the bacterial retentation test is carried out on a laboratory scale under process conditions of scaling down.



Bacterial retention verification process

The purpose of the bacterial retention test is to simulate the worst conditions in the actual production filtration process, filter the product fluids containing a certain amount of challenging microorganisms or product substitute fluids, so as to confirm the microbial interception ability of the filter.

To test the retention ability of sterilizing-grade filter with specific process fluid under specific filtration conditions, the bacterial retentation test is carried out on a laboratory scale under process conditions of scaling down.

5.Validation service

S	V	C

SVC=validation center code

M	L

Laboratory Classification
ML=Microbiological Laboratory
VL=Virus Laboratory
EL=Chemical Laboratory
IL=Performance Laboratory

0	0	1

Test Project
002=Validation of bacterial retention process
004=Virus removal test
005=Extractables test and safety assessment
006=Leachable test and safety assessment
007=Chemical compatibility test
008=Product integrity test
009= Number of uses/lifetime verification

Saiflow™ Pharmaceutical-grade Stainless Steel Filter Housing

Adopt the latest sanitary design and the advanced polishing technology in the industry, and compatible with various types and brands of cartridge filter, so that it can be widely used in pharmaceutical, chemical, Bioengineering, food and beverage industries. The no-dead angle design inside the housing makes it more suitable for the use of high value-added feed liquid with very low residue.

Product features

- Manufacture in full compliance with cGMP standards and provide standard quality certificates
- Sanitary Design - to meet regulatory requirements of the pharmaceutical industry
- Equipped with high point exhaust valve - to ensure gas vent, prevent the formation of internal pressure or vacuum
- Equipped with low point exhaust valve - to ensure liquid discharge, prevent the formation of residual and the condensed water discharge when the SIP
- Very low residue - maximum recovery of product
- Provide customized design and manufacturing services





Product specification

Housing body	316L Stainless steel
Gasket and sealing ring	Silicone/ EPDM/ FKM/ PTFE
Clamp and feet	304 Stainless steel
Connection type	Code 7 connection(2-226); Code 2 connection(2-222)
In & Out Type	In line and T-line
Sterilization form	SIP or autoclave
Surface finish	Internal: Ra≤0.4μm; External: Ra≤0.6μm
Housing size	1-cartridge housing: 2.5inch/ 5inch/ 10inch/ 20inch/ 30inch 2-cartridges housing: 2.5inch/ 5inch/ 10inch/ 20inch/ 30inch 3-cartridges housing: 2.5inch/ 5inch/ 10inch/ 20inch/ 30inch Other sizes can be customized
Operating conditions	Pressure: -1 to 10 bar; Temperature: -10 to 150°C

Ordering information

S	L	1	0	5	A	K	2	5	W	L	S	7

Stainless steel Shell code

Type:
L:Left in right out type
U:Top-in, bottom-out type
C:C type
T:Ipsilateral access type

Number of filter:
1=1-cartridge
2=2-cartridge
3=3-cartridge

Size:
25:2.5 inches
05:5 inches
10:10 inches
20:20 inches
30:30 inches

Material:
A:304 SS
B:316L SS

Inlet and outlet pipe OD & Connection type:
K05=OD 1/2", TC12.5 connection
K20=OD 3/4"(DN20), TC25
K21=OD 3/4"(DN20), TC50
K25=OD 1"(DN25), TC50
K38=OD 1.5"(DN38), TC50
K50=OD 2"(DN50), TC63
F32=OD 32(DN25), Flange connection
F38=OD 38(DN32), Flange connection
F45=OD 45(DN40), Flange connection

Air bleed valve
L=screw thread
K=Quick-open
W=None

Drain outlet:
L=screw thread
K=Quick-open
W=None

Sealing ring:
S=Silicone
E=EPDM
F=FKM
T=PTFE

Filter connection:
7:226 connection
2:222 connection

Accessories

Product Name	Product Art.No	Product Picture
Relief valve	PRV01	
Pressure gauge(TC50/TC25)	PG6BT50 PG6BT25	
Translucent storage tank	VHPDKIT-T	
NPT1/4 pagoda turn 64 quick connecter	HBTC641	
Diameter 64 fast-fit clamp (TC64/TC50/TC25)	SHTC64C SHTC50C SHTC25C	
Gasket for depth filter	SCG1K10	
Gasket for TFF Cassette (80cm²/0.1m²)	TFHG01	
Gasket for TFF Cassette (0.5m²/2.5m²)	TFHG05	
Silicone gasket	TC64GSK	