

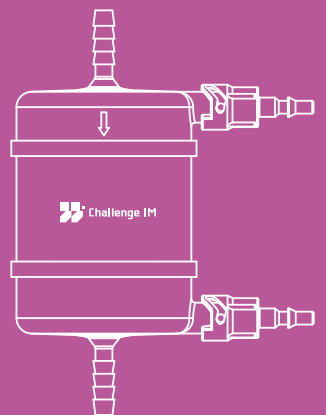


Challenge IM

WWW.CHALLENGETFF.COM



Capsule Filter





Company Profile

Industry Leader , Global Presence Focused on Biopharmaceutical Membrane Filtration Solutions

Challenge IM —A Global Leader in Biopharmaceutical Membrane Filtration Solutions

At the forefront of technology, we integrate R&D, manufacturing, sales, and service to build an efficient global network. Our core offerings include highly automated intelligent filtration systems and a full range of high-performance filtration membranes and consumables. Widely applied across critical processes in the biopharmaceutical industry, our solutions support antibodies and antibody-drug conjugates (ADCs), cell and gene therapies (CGT), vaccines, nucleic acid therapeutics, recombinant proteins, blood products, exosomes, and diagnostic reagents, serving customers worldwide. Our self-developed “fully automated, unmanned” Tangential Flow Filtration (TFF) system has successfully filled a gap in the global market and continues to drive technological innovation across the industry. The company has been recognized as a National High-Tech Enterprise and strictly adheres to the ISO 9001:2015.

Technology-Driven · Global Presence

Led by world-class membrane science experts, our R&D team brings together core members with over 10 years of experience in biopharmaceutical process development and materials science, holding 30+ invention patents. Supported by a 2,000 m² standard production facility compliant with international industry regulations and a 2,000 m² Class C cleanroom, and equipped with fully automated production lines and state-of-the-art testing instruments, we have established a full-lifecycle quality management system in line with FDA, EMA and GMP standards. Through our global R&D collaboration network, we continuously provide high-consistency, high-capacity and low-extractables membrane filtration products to the world’s Top 20 biopharmaceutical and innovative drug companies. Our products meet the requirements of the international pharmacopeias USP <661> and EP 3.1.5. With innovative technology and superior quality empowering the biopharmaceutical industry, we have become a core strategic partner to leading companies in various niche segments in China and successfully expanded our business footprint to international markets.

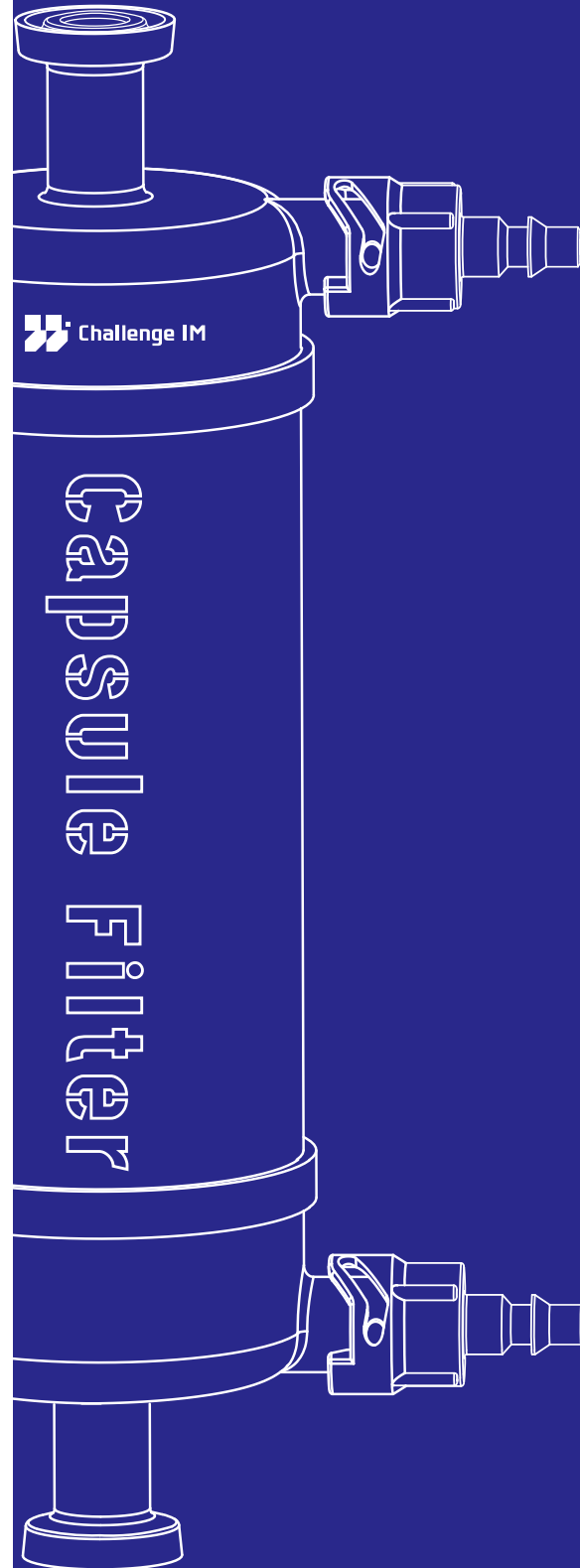
Customer Value · Industry Commitment

Guided by the corporate philosophy of “Challenge IM, Destined for Greatness,” we are dedicated to overcoming critical “bottleneck” technologies in bioprocessing. Through our three service systems—targeted development, process optimization, and joint validation—we support our customers in achieving domestic substitution of key processes.

Looking ahead, Challenge Intelligent Manufacturing (Challenge IM) will continue to deepen its integrated “Materials–Process–Equipment” solutions strategy, striving to become a trusted partner of the global biopharmaceutical industry and to promote technological self-reliance and sustainable development across the biopharmaceutical value chain.

Contents

01	Clarification Filtration Series	
	Challenge Pore® PP High-Performance Clarification Filter	05
02	Pre-Filtration & Sterilizing-Grade Filtration Series	
	Challenge Pore® PES Low-Protein- Binding Hydrophilic Filter	06
	Challenge Pore® PES High-Flow Hydrophilic Filter	07
03	Sterile Filtration Series	
	Challenge Pore® PES Low-Protein-Binding Hydrophilic Sterile Filter	08
04	Mycoplasma Removal Filtration Series	
	Challenge Pore® PES Hydrophilic Filter with High Mycoplasma Retention	09
05	Gas Filtration Series	
	Challenge Filair® PTFE Hydrophobic Sterile Filter with High Retention and High Throughput	10
06	Ordering Information	
	Challenge Pore® PP Filter Ordering Information	11
	Challenge Pore® PES Filter Ordering Information	11
	Challenge Filair® PTFE Filter Ordering Information	12



Why?

Take Challenge IM



**Exceptional
Compatibility**



Colorant-Free



Integrity



**Comprehensive
Quality System**



**Authoritative
Validation**

The Challenge IM capsule filters cover five major series: clarification filtration series, pre-filtration and sterilizing-grade filtration, sterile filtration series, mycoplasma removal filtration series, and gas filtration. With a particle retention range of 0.1 µm to 30 µm, they meet the full process requirements from cell culture clarification to final product sterilization.

- Suitable for both high-temperature steam sterilization and gamma irradiation;
- Compatible with a wide range of commonly used biopharmaceutical solvents.

- All molded components, seals and other accessories are free of colorants, comply with Class VI and ISO 10993 biocompatibility standards, minimize extractables and leachables risk, and ensure a more hygienic process.

- Each product is subjected to two integrity tests during manufacturing; the second test must pass two different integrity test methods before release, guaranteeing a 100% qualified rate at shipment.

- ISO 9001 quality system compliant and GMP-aligned; certified for USP <85> endotoxins, USP <87>/<88> biocompatibility and USP <665> extractables — with zero animal-derived TSE/BSE risk.

- Validated by leading international authorities including SGS and NF — every product released meets stringent validation standards.

Which?

International Authoritative Validation



Challenge IM capsule filters, designed for the biopharmaceutical industry, are ideal for buffer, intermediate, bulk, and final product filtration. Tested and validated by internationally recognized authorities such as SGS.

Standards Compliance:

ASTM F838–Standard Test Method for Determining Bacterial Retention of Membrane Filters for Liquids

USP <665> –United States Pharmacopeia: Extractables and Leachables (E&L) Testing in Biopharmaceutical Production

USP <87> –United States Pharmacopeia: Biological Reactivity Tests – In Vitro

USP <88> –United States Pharmacopeia: Biological Reactivity Tests – In Vivo



Physical Testing

Pressure burst testing, integrity testing



Functional Testing

Flow rate and pressure drop testing, maximum allowable differential pressure, thermal stability, accelerated shelf-life testing, fiber release assessment, particulate testing, bacterial retention testing



Chemical Testing

Chemical compatibility, physicochemical testing, extractables analysis, oxidizable substances, conductivity, pH, total organic carbon (TOC), chlorine, sulfur, ammonia



Biological Testing

Endotoxin testing, biocompatibility testing

01

Clarification Filtration Series

Challenge Pore® PP High-Performance Clarification Filter

[Product Features]

Constructed with multiple layers of polypropylene membranes of varying pore sizes, scientifically combined to provide high retention, high throughput, and excellent fouling capacity.

[Typical Applications]

- Prefiltration of cell culture media
- Clarification of fermentation broth or cell culture fluids
- Prefiltration of serum and blood products
- Prefiltration of colloidal or viscous liquids

[Operating Conditions]

Maximum operating temperature	80°C
Maximum differential pressure	0.55MPa/25°C 0.1MPa/80°C

[Biosafety]

Endotoxin	<0.25 EU/mL
Biocompatibility	Compliant with USP <87> Non-cytotoxic Meets USP <88> Class VI plastic biocompatibility requirements

[Filter Dimensions]

01: 0.04m ²	05: 0.2m ²
02: 0.08m ²	10: 0.4m ²
04: 0.15m ²	

[Material Construction]

Filter Membrane	Polypropylene (PP)
Inner Cage, Outer Cage, End Caps	Polypropylene (PP)
Capsule Housing	Polypropylene (PP)
Capsule Vent O-Ring	Silicone Rubber
Filtration Accuracy	0.2/0.5/0.65/1.0/ 3.0/5.0/10/20/30µm

[Sterilization]

Challenge Pore® PP capsule filter cable of up to 25 cycles of high-temperature steam sterilization.

02

Pre-Filtration & sterilizing-grade filtration Series

Challenge Pore® PES

Low Protein-Binding Hydrophilic Filter

[Product Features]

- Unique dual-layer design
- Reliable bacteria and particle retention
- Broad chemical compatibility (pH1-14)
- Extremely low extractables
- Low protein binding

[Typical Applications]

- Prefiltration of cell culture media
- Buffer filtration
- Pre-column / Pre-ultrafiltration protective filtration

[Operating Conditions]

Maximum operating temperature	80°C
Maximum differential pressure	0.55MPa/25°C 0.1MPa/80°C

[Biosafety]

Endotoxin	<0.25 EU/mL
Biocompatibility	Compliant with USP <87> Non-cytotoxic Meets USP <88> Class VI plastic biocompatibility requirements

[Filter Dimensions]

01: 0.05m ²	05: 0.28m ²
02: 0.10m ²	10: 0.55m ²
04: 0.20m ²	

[Material Construction]

Filter Membrane	Hydrophilic Polyethersulfone (PES)
Inner Cage, Outer Cage, End Caps	Polypropylene (PP)
Capsule Housing	Polypropylene (PP)
Capsule Vent O-Ring	Silicone Rubber
Filtration Accuracy	0.8+0.45µm /1.0+0.65µm/1.0+0.8µm

[Sterilization]

Challenge Pore® PES capsule filter cable of be sterilized by high-temperature steam (121 °C for 30 minutes, up to 5 cycles) or by gamma irradiation (25–40 kGy).

02

Pre-Filtration & sterilizing-grade filtration Series

Challenge Pore® PES High-Flow Hydrophilic Filter

[Product Features]

- Reliable bacteria and particle retention
- Broad chemical compatibility
- High flow rate
- High throughput

[Operating Conditions]

Maximum operating temperature	80°C
Maximum differential pressure	0.55MPa/25°C 0.1MPa/80°C

[Filter Dimensions]

01: 0.06m ²	05: 0.33m ²
02: 0.12m ²	10: 0.66m ²
04: 0.23m ²	

[Biosafety]

Endotoxin	<0.25 EU/mL
Biocompatibility	<ul style="list-style-type: none"> ● Compliant with USP <87> Non-cytotoxic ● Meets USP <88> Class VI plastic biocompatibility requirements

[Sterilization]

Challenge Pore® PES capsule filter cable of be sterilized by high-temperature steam (121 °C for 30 minutes, up to 5 cycles) or by gamma irradiation (25–40 kGy).

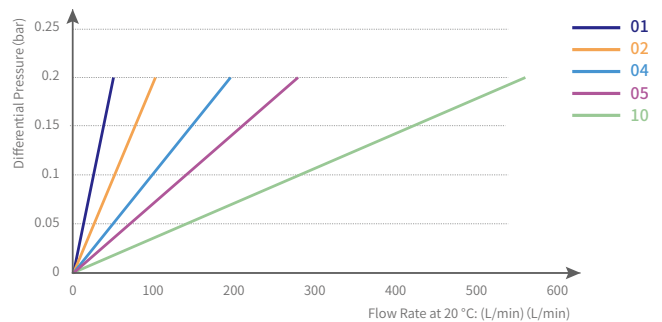
[Typical Applications]

- Prefiltration of cell culture media
- Buffer filtration

[Material Construction]

Filter Membrane	Hydrophilic Polyethersulfone (PES)
Inner Cage, Outer Cage, End Caps	Polypropylene (PP)
Capsule Housing	Polypropylene (PP)
Capsule Vent O-Ring	Silicone Rubber
Filtration Accuracy	0.45µm /0.65µm/0.8µm

[0.45µm Pre-Filtration Capsule Filter Flow Rate]



03

Sterile Filtration Series

Challenge Pore® PES

Low-Protein-Binding Hydrophilic Sterile Filter

[Product Features]

- Reliable bacteria and particle retention
- Broad chemical compatibility (pH1-14)
- Extremely low leachables
- Low protein binding

[Operating Conditions]

Maximum operating temperature	80°C
Maximum differential pressure	0.55MPa/25°C 0.1MPa/80°C

[Filter Dimensions]

01: 0.05m ²	05: 0.28m ²
02: 0.10m ²	10: 0.55m ²
04: 0.20m ²	

[Biosafety]

Endotoxin	<0.25 EU/mL
Biocompatibility	<ul style="list-style-type: none"> ● Compliant with USP <87> Non-cytotoxic ● Meets USP <88> Class VI plastic biocompatibility requirements
Integrity test	Bubble point and diffusive flow

[Sterilization]

Challenge Pore® PES capsule filter cable of be sterilized by high-temperature steam (121 °C for 30 minutes, up to 5 cycles) or by gamma irradiation (25–40 kGy).

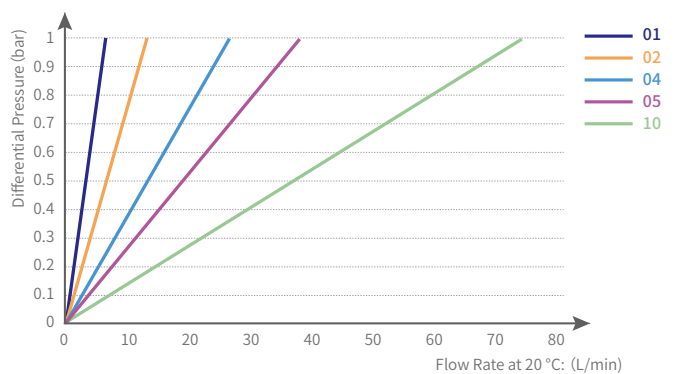
[Typical Applications]

- Sterile filtration of cell culture media
- Buffer filtration
- Pre-column / Pre-ultrafiltration protective filtration
- Filtration of serum and blood products
- Sterile filtration of final products
- Filtration of colloidal or viscous liquids

[Material Construction]

Filter Membrane	Hydrophilic Polyethersulfone (PES)
Inner Cage, Outer Cage, End Caps	Polypropylene (PP)
Capsule Housing	Polypropylene (PP)
Capsule Vent O-Ring	Silicone Rubber
Filtration Accuracy	0.2+0.45µm

[0.2+0.45µm Sterile Filtration Capsule Filter Flow Rate]



04

Mycoplasma Removal Filtration Series

Challenge Pore® PES Hydrophilic Filter with High Mycoplasma Retention

[Product Features]

- Unique dual-layer design
- Reliable bacteria and particle retention
- Broad chemical compatibility (pH1-14)
- Extremely low extractables

[Typical Applications]

- Sterile filtration of cell culture media
- Filtration of intermediate, bulk
- Filtration of serum and blood products
- Sterile filtration of final products

[Operating Conditions]

Maximum operating temperature	80°C
Maximum differential pressure	0.55MPa/25°C 0.1MPa/80°C

[Biosafety]

Endotoxin	<0.25 EU/mL
Biocompatibility	<ul style="list-style-type: none"> ● Compliant with USP <87> Non-cytotoxic ● Meets USP <88> Class VI plastic biocompatibility requirements
Integrity test	Bubble point and diffusive flow

[Filter Dimensions]

01: 0.05m ²	05: 0.28m ²
02: 0.10m ²	10: 0.55m ²
04: 0.20m ²	

[Material Construction]

Filter Membrane	Hydrophilic Polyethersulfone (PES)
Inner Cage, Outer Cage, End Caps	Polypropylene (PP)
Capsule Housing	Polypropylene (PP)
Capsule Vent O-Ring	Silicone Rubber
Filtration Accuracy	0.2+0.1µm

[Sterilization]

Challenge Pore® PES capsule filter cable of be sterilized by high-temperature steam (121 °C for 30 minutes, up to 5 cycles) or by gamma irradiation (25–40 kGy).

05

Gas Filtration Series

Challenge Filair® PTFE

Hydrophobic Sterile Filter with High Retention and High Throughput

[Product Features]

- Natural hydrophobicity
- High retention rate
- High throughput with low pressure drop
- Reliable bacteria and particle retention

[Operating Conditions]

Maximum operating temperature	80°C
Maximum differential pressure	0.55MPa/25°C 0.1MPa/80°C

[Biosafety]

Endotoxin	<0.25 EU/mL
Biocompatibility	<ul style="list-style-type: none"> • Compliant with USP <87> Non-cytotoxic • Meets USP <88> Class VI plastic biocompatibility requirements

[Filter Dimensions]

Disc Filter	D50: 20cm ²
	01: 0.075m ² 02: 0.14m ²
Capsule Filter	04: 0.25m ² 05: 0.34m ²
	10: 0.68m ²

[Sterilization]

Challenge Filair® PTFE filter cable of up to 50 cycles of high-temperature steam sterilization .

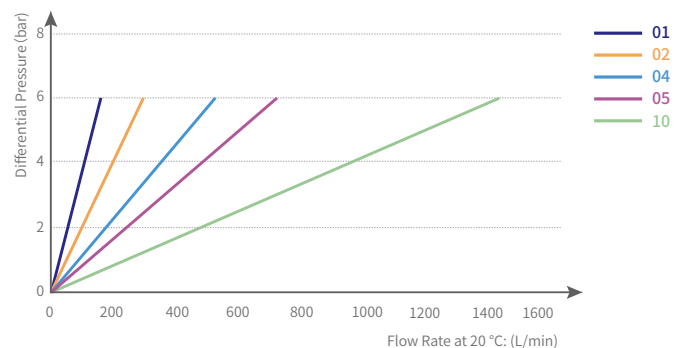
[Typical Applications]

- Vents for Fermenters, Storage Tanks, etc.
- Sterile Filtration for Compressed Air, O₂, N₂, etc.

[Material Construction]

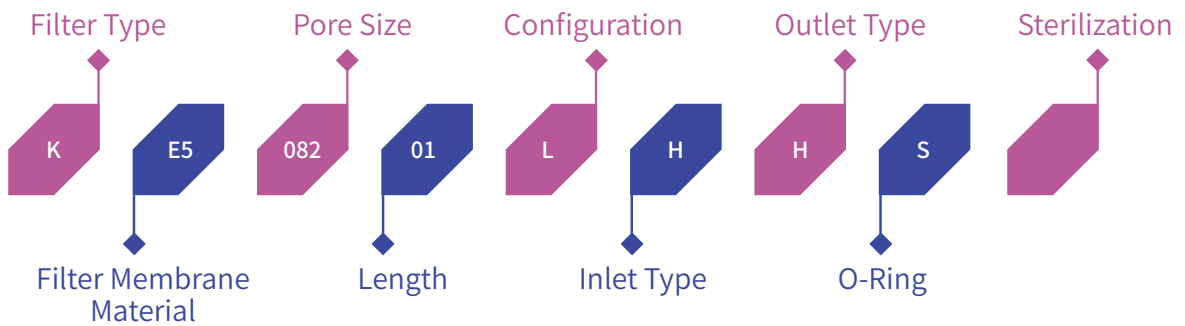
Filter Membrane	Hydrophobic Polytetrafluoroethylene (PTFE)
Inner Cage, Outer Cage, End Caps	Polypropylene (PP)
Capsule Housing	Polypropylene (PP)
Capsule Vent O-Ring	Silicone Rubber
Filtration Accuracy	0.2µm

[0.2µm Gas Capsule Filter Flow Rate]



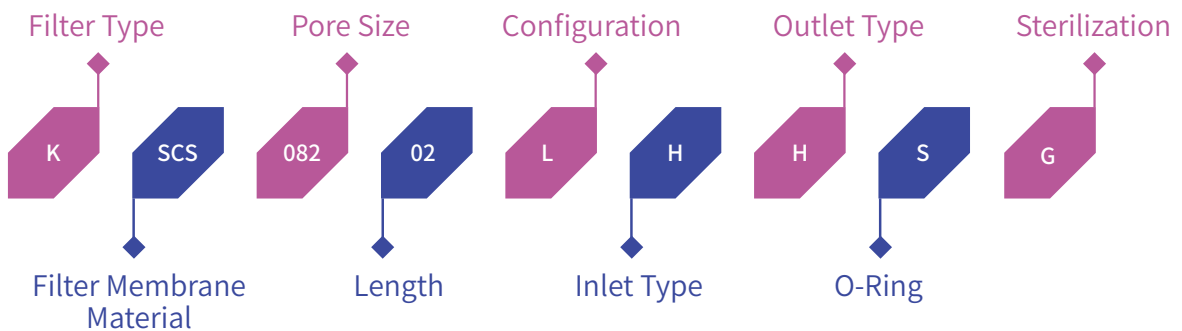
06 Ordering Information

ChallengePore® PP Series Filter



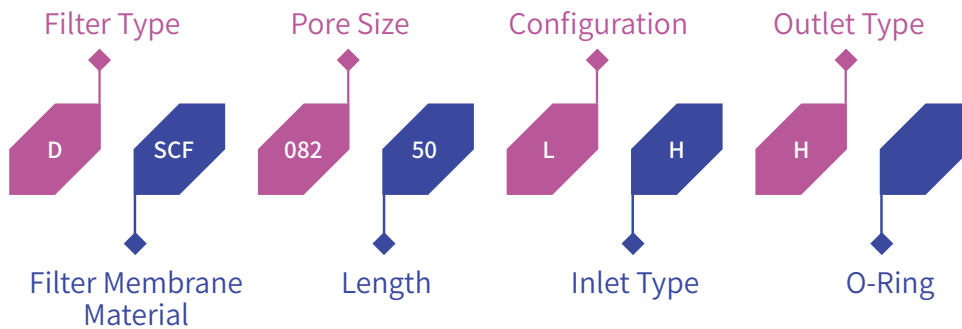
Filter Type	Filter Membrane Material	Pore Size (µm)	Length (")	Configuration	Inlet Type/Outlet Type	O-Ring	Sterilization
K=capsule filter	E5= Polypropylene (PP)	081=0.1	01=1 02=2 04=4	L= Top Inlet – Bottom Outlet	D=1/4" Barbed Fitting	S=Silicone E=Ethylene-Propylene-Diene Monomer (EPDM) V=FKM	Default = Only withstands wet heat sterilization, not sterilized
		082=0.2			E=3/8" Barbed Fitting		
		085=0.5			F=1/2" Barbed Fitting		
		086=0.65			G=1/2" Quick Coupling		
		088=0.85	H=1-1.5" Quick Coupling				
		001=1.0	J=1/4-1/2" Barbed Fitting				
		003=3.0	H=1"-1.5" Quick Coupling				
		005=5.0	F=1/2" Barbed Fitting				
		010=10					
		020=20					
		030=30					

ChallengePore® PES Series Filter



Filter Type	Filter Membrane Material	Pore Size (µm)	Length(")	Configuration	Inlet Type/Outlet Type	O-Ring	Sterilization
K=capsule filter	Polyethersulfone (PES)	081=0.1	01=1	L= Top Inlet – Bottom Outlet	D=1/4" Barbed Fitting	S=Silicone	G = Gamma-sterilized; can't withstand wet heat sterilization
		082=0.2			E=3/8" Barbed Fitting		
		084=0.45	02=2		F=1/2" Barbed Fitting	E=Ethylene-Propylene-Diene Monomer (EPDM)	F = Non-sterile; can be sterilized by gamma irradiation or wet heat sterilization
		086=0.65	04=4		G=1/2" Quick Coupling		
		088=0.85			H=1-1.5" Quick Coupling	V=FKM	
		001=1.0			J=1/4-1/2" Barbed Fitting		
		812=0.1+0.2	05=5		H=1"-1.5" Quick Coupling		
		824=0.2+0.45		10=10			F=1/2" Barbed Fitting
		846=0.45+0.65					
		861=0.65+1.0					
		881=0.85+1.0					

Challenge Filair® PTFE Series Filter



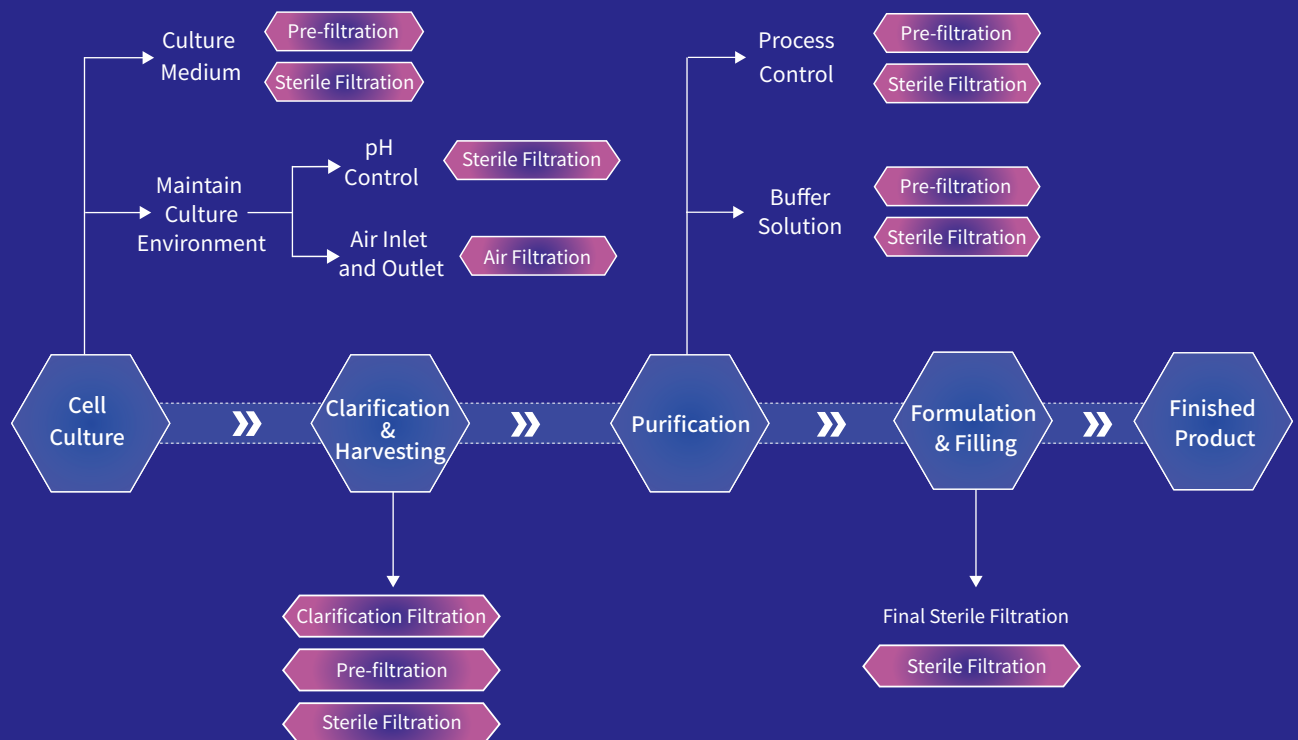
Filter Type	Filter Membrane Material	Pore Size (µm)	Length(")	Configuration	Inlet Type/Outlet Type	O-Ring	Sterilization
D=Disc Filter	SCF= Hydrophobic Polytetrafluoroethylene (PTFE)	081=0.1 082=0.2 084=0.45 001=1 005=5	50= Membrane diameter 50mm	N/A	H=6~13mm(1/4"-1/2") Multi-level Barbs	N/A	Default = Only withstands wet heat sterilization ,not sterilized
K=capsule filter	SCF= Hydrophobic Polytetrafluoroethylene (PTFE)	081=0.1 082=0.2 084=0.45 001=1 005=5	01=1	L= Top Inlet – Bottom Outlet	D=1/4" Barbed Fitting	S=Silicone	Default = Only withstands wet heat sterilization ,not sterilized
			02=2		E=3/8" Barbed Fitting		
			04=4		F=1/2" Barbed Fitting	E=Ethylene-Propylene-Diene Monomer (EPDM)	
					G=1/2" Quick Coupling		
					H=1-1.5" Quick Coupling	V=FKM	
					J=1/4-1/2" Barbed Fitting		
			05=5		H=1"-1.5" Quick Coupling		
			10=10			F=1/2" Barbed Fitting	



Application



Capsule Filter





Comprehensive, Professional Technical Support

Model Selection

Provide professional selection services based on process requirements (such as sterile filtration, virus removal, clarification filtration, etc.).

Free Trial

- Provide free sample trial services;
- conduct sample testing according to process requirements.

Process Validation

With every purchase, enjoy professional process validation services and end-to-end support to make your experiments more efficient.



Challenge IM, Destined for Greatness

Building Exceptional Products · Developing Exceptional Talent · Enabling Customers to Lead the Industry



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