

LeClafine® Depth Filters

LeClafine® series depth filters are cellulose-based filters developed for clarification applications in the biopharmaceutical and pharmaceutical industry.

LeClafine® depth filters consist of cellulose matrix, inorganic filter aid and binder resin, which have the advantages of high throughput and good removal efficiency.

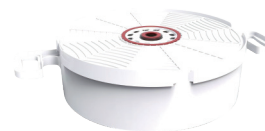
The contaminants of sufficient size can be removed by mechanical entrapment within the LeClafine® depth filter matrix. The binder resin provides positive charge which can remove negatively charged contaminants by electrostatic attraction.

LeClafine® depth filters provide a wide range of grades and formulation which can offers a solution for a variety of applications such as bioreactor harvest, low pH incubation or pre-filter for sterilizing filter.

Product Features

- ⦿ Asymmetrical structure media, high throughput & flux
- ⦿ Priority media formulation
- ⦿ High target product recovery
- ⦿ High particle and colloid removal efficiency
- ⦿ Low extractable, more clean
- ⦿ Unique capsule sealing design, no leakage risk
- ⦿ Linearly scale up from R&D to commercial production
- ⦿ Various filter area options to meet different request
- ⦿ Automation production line, strong quality stability

Procap-P



Procap-M



ST



Midcap



Minicap



Typical applications

- ⦿ Clarification of cell harvest solution
- ⦿ Clarification of bacterial lysate
- ⦿ Clarification of feed solution after low pH incubation
- ⦿ HCP/HCD reduction
- ⦿ Protein aggregates removal
- ⦿ Endotoxin removal
- ⦿ Pre-filtration before sterilization filter
- ⦿ Pre-filtration before virus clearance filter

LeClafine® Depth Filter Capsules Products

LeClafine® depth filter capsules can meet virtually any process flow requirement. LeClafine® depth filter capsules are designed to facilitate the scale-up of processes between the lab bench and the plant floor. Process-scale capsules come in a variety of sizes to accommodate a wide range of application conditions to handle the most critical clarification and depth filter applications in pharmaceutical manufacturing.

Minicap Capsules

Minicap Capsules configuration is used for laboratory evaluation and small volume filtration. The Minicap capsule is supplied with 20cm² of most LeClafine depth filter media offerings, for simple laboratory evaluation of the media in your application. The Minicap capsule is available in the connection of luer.

Midcap Capsules & Procap Capsules

The Midcap and Procap disposable depth filter capsules represent intermediate (or pilot) scale-up devices for most applications. The Midcap capsules have 300cm² filter media while Procap capsules offer maximum 1.1m² filter media which provide a flexible alternative during process development.

Technical specification

Product specification	Minicap	Midcap	Procap-P	12 inch	16 inch	
				Single Layer	Single Layer	Double Layer
Filtration Area(m ²)	0.002	0.03	0.25/0.5/1.0	1.0/1.4/1.6	2.1/3.4/3.8	2.3
Inlet/Outlet	Luer	¾" TC	1.5" TC	DOE		
O-ring	—	—	—	Silicone / EPDM / NBR/ Fluororubber		
High pressure steam sterilization	30 min@126°C, 1cycle			30 min@126°C, 3 cycles		
Max. operating temperature	40°C (104°F)			80°C (208°F)		
Max. operating ΔP	3.5 bar@40°C			—		
Max. positive ΔP				2.4 bar@40°C		
Biocompatibility				USP<88>		
Endotoxin				<0.25EU/ml, LAL test		

Ordering information

LeClafine® depth filter

Filter category	Specification	Filtration set	Media		Diameter	Version	Package
C=LeClafine® Depth Filter	MN=Minicap MD=Midcap	D01=Double layer 1set	C1=8~20µm C5=1~10µm F1=0.5~3µm F3=0.2~1µm F6=0.1~0.8µm F9=0.05~0.5µm	POB series: P1 P2 P3 P4 P1P2 P2P3 P3P4	A=12Inch (Single Layer Only) B=16Inch	G= Standard	1= 1pack/box
	PL=Procap-P*	D01=Double layer 1set D02=Double layer 2set D04=Double layer 4set	C1C5=5~20µm C1F1=1~20µm C5F1=1~10µm F1F3=0.5~1µm F1F6=0.2~1µm F3F6=0.2~0.5µm F3F9=0.1~0.5µm F6F9=0.05~0.2µm			T= Synthetic media	4= 4pack/box
	PK=Procap-M	D01=Double layer 1set D05=Double layer 5set D10=Double layer 10set				S= Functional	
	ST=Cartridge	S09=Single layer 9set S14=Single layer 14set S16=Single layer 16set D10=Double layer 10set					

*Please contact Lepure sales for the ordering information of manifold which should be used together with Procap-P.



LeClafine® Housing

Match LeClafine® ST series meets the requirements of process fluid and production environment from laboratory to production scale. Fully closed filtration system, no leakage risk, greatly reduced replacement labor costs and maintenance costs, and small floor area, LeClafine® ST filter cartridge is the ideal choice.

Product Advantage

- ◎ Fully closed, isolated from external pollution, safe operation, and prevent leakage and material loss
- ◎ Different number of stacks can be installed according to different volume and scale, which is easy for linear amplification
- ◎ Hygienic design, mirror polishing, minimize biological adhesion
- ◎ Sanitary pipe, valve, complete with exhaust valve and check valve
- ◎ Spring locking sealing system, safe and convenient operation
- ◎ Small floor area, light and flexible, simple and convenient disassembly and assembly



- ◎ **Fully enclosed system**
Protect the safety of operators while avoiding external pollution
- ◎ **System structure**
Reasonable structure design, 316L stainless steel material, mirror polishing
- ◎ **Filter Specification**
A single row can stack up to 4
- ◎ **Connection mode**
Bolt or clamp, quick loading and unloading

Technical specification

LeClafine® Housing technical parameter

Operating parameter	
Max. operating ΔP&Temp.	6bar(87psi)@142°C(287.6°F)
Material parameter	
Contact part with liquid	316L ss
Non-contact part with liquid	304 ss
O-ring/Gasket	Silicone
Connections and accessories	
Cylinder connection	Quick-opening clamp
pressure gage	Standard configuration

Number	Height h(mm)	Inlet & outlet pipe diameter d(mm)	Total Height H(mm)
12 inch			
1	300	25.4	850
2	580	32	1130
3	860	38.1	1410
4	1140	50.8	1690
16 inch			
1	300	25.4	870
2	580	32	1150
3	860	38.1	1430
4	1140	50.8	1710

LeClafine® Holder

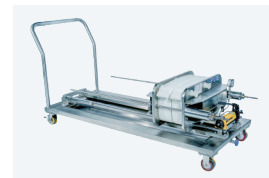
LeClafine® SU capsule uses holder to simplify the cleaning and verification process, and is the first choice of disposable depth filtration system. There are two forms, vertical and horizontal, which are applicable to all kinds of holder brands on the market.

Product Advantage

- ◎ With full consideration of ergonomics, the operation is intuitive and simple, and the hydraulic device can be provided, which is convenient, safe and reliable.
- ◎ Single-stage and two-stage depth filtration can be completed in one holder.
- ◎ The linear amplification from pilot test to GMP production can meet the requirements of different scale production through parallel connection.
- ◎ Fully disposable system, free from cleaning verification.
- ◎ All control devices are provided by the depth filtration system. No other external controls are required. All liquid connection parts (eg. valves, pipes and pipelines, etc.) are made of 316L stainless steel



Procap-P



Procap-M

Validation

According to the validation guidelines, the depth filter needs to be tested according to the validation guidelines. LeClafine® can only be used by customers after strict verification. LePure has a professional quality inspection team to control the product quality, ensure the high quality of the product and reduce the difference between batches.