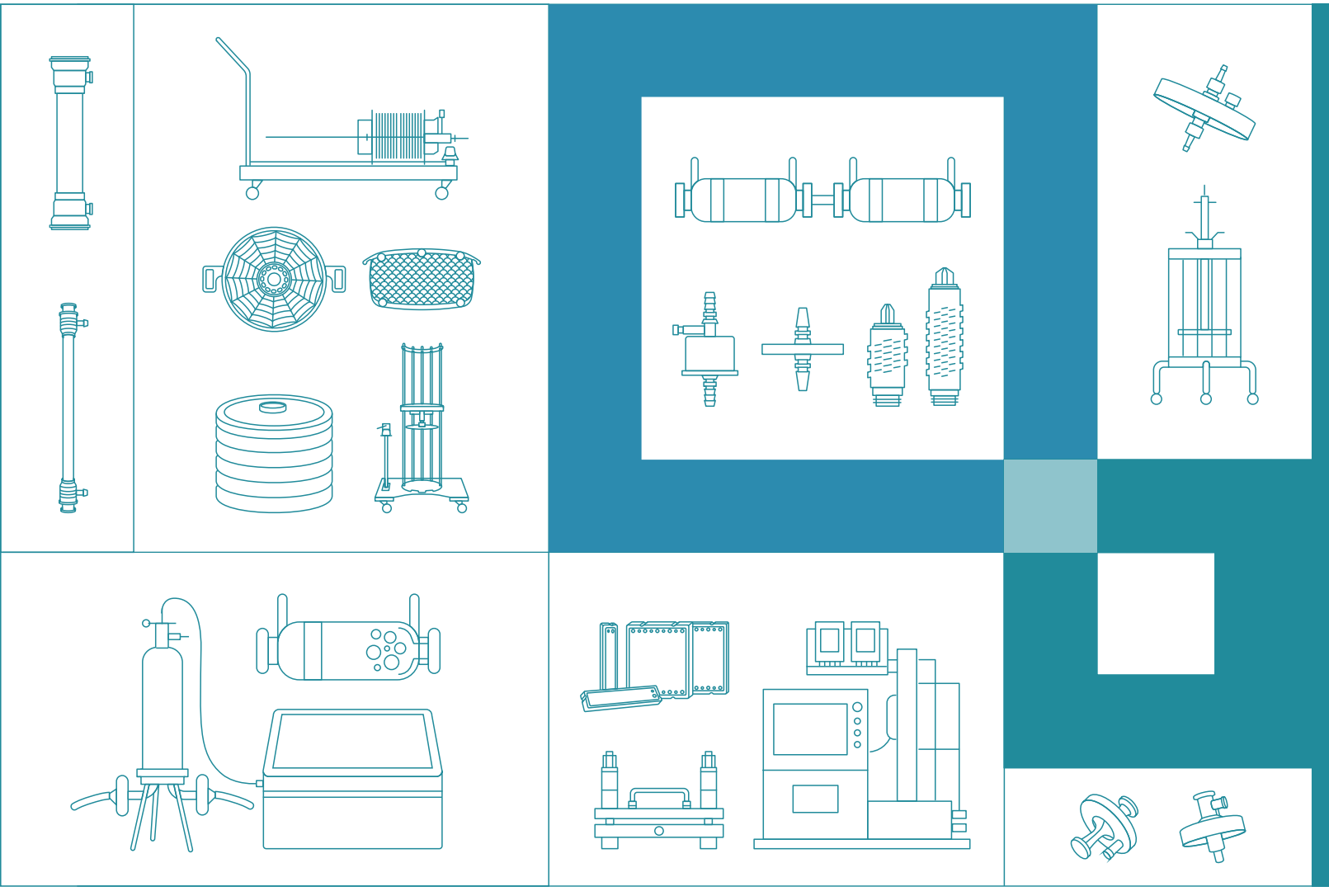
LEPURE

Process Solutions for Plasma-Derived Products

Empowering biopharma through high-quality bioprocess solutions



Granted patents
280+

Manufacturing sites
11

ISO Class 7 cleanrooms
23,600+ m²

Employees
1000+

LePure Biotech

Shanghai LePure Biotech Co., Ltd. is committed to providing the biopharmaceutical industry with high-quality, innovative bioprocess membrane materials and products, equipment, validation services and customized services. Its business covers early-stage drug research, single-use systems, filtration and purification, cell culture, GMP-compliant cleanroom contamination-control solutions. LePure is a high-tech enterprise integrating R&D, manufacturing, sales and technical services.

LePure Biotech has served more than 10,000 customers, with operations extending across more than 30 countries and regions. With technical expertise and sustained investment in R&D, LePure continually improves its products and services, supports the high-quality development of the global biopharmaceutical industry, and helps safeguard the development and implementation of every therapy that benefits patients

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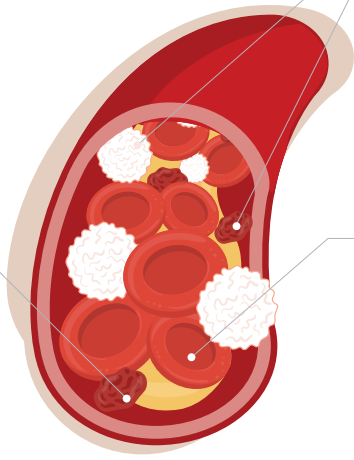
Overview of Plasma-Derived Products

Plasma-derived products are biological medicinal products manufactured from plasma collected from healthy human donors through processes such as fractionation, purification and virus inactivation. Manufacturing scale-up, safety and economics are subject to strict review and approval by domestic and international drug regulators, including the NMPA and FDA. As clinically irreplaceable medical supplies, plasma-derived products are widely used in surgical and emergency care, treatment of immunodeficiency diseases and correction of coagulation disorders. They also represent critical medical stockpiles for public-health emergency preparedness and are of major importance to medical treatment and public-health security.

Composition of whole blood and plasma

- White blood cells and platelets **3%**
- Red blood cells **42%**
- Plasma **55%**

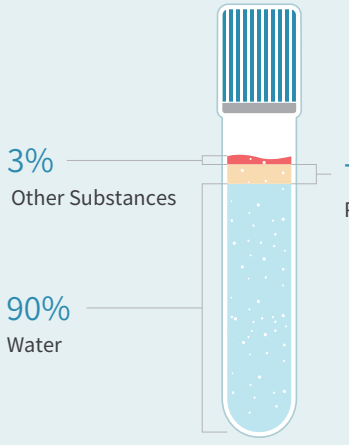


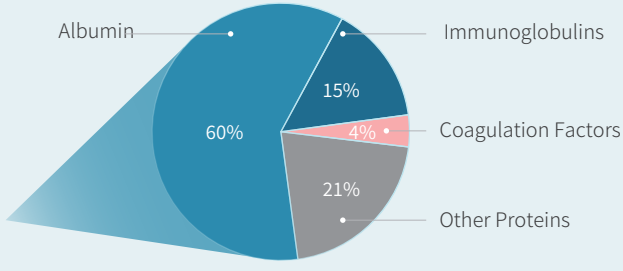
White blood cells and platelets
3%

Red blood cells
42%

Plasma
55%

Plasma Composition





Plasma Protein Composition

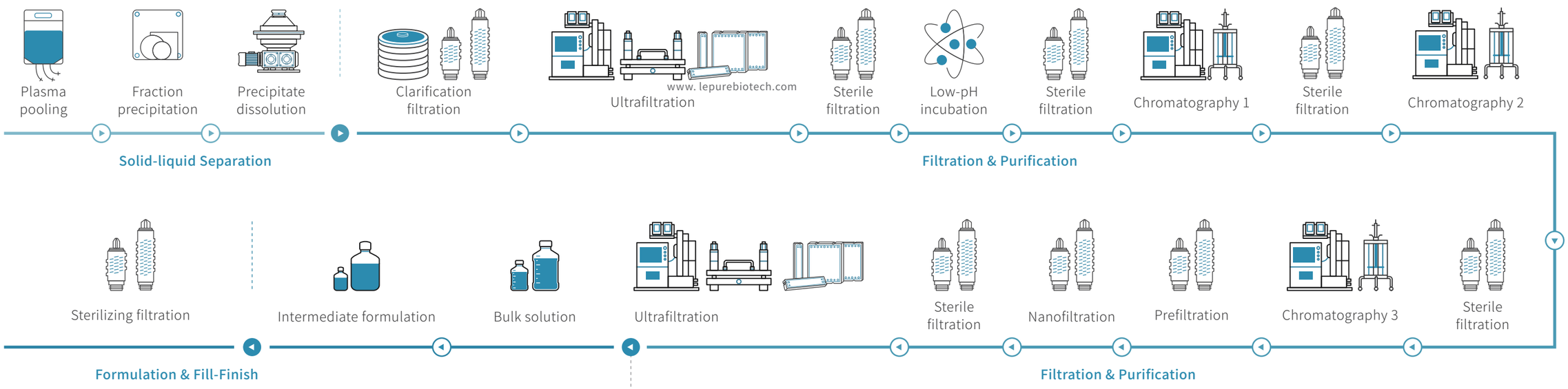
Plasma consists of approximately 90% water, 7% plasma proteins and 3% other substances. Of the plasma proteins, albumin accounts for approximately 60%, immunoglobulins for 15%, coagulation factors for 4%, and other proteins for 21%.

Classification and clinical value

By function and clinical use, plasma-derived products are mainly divided into three groups: albumin products, immunoglobulin products and coagulation-factor products. Their core functions and clinical value are summarized below.

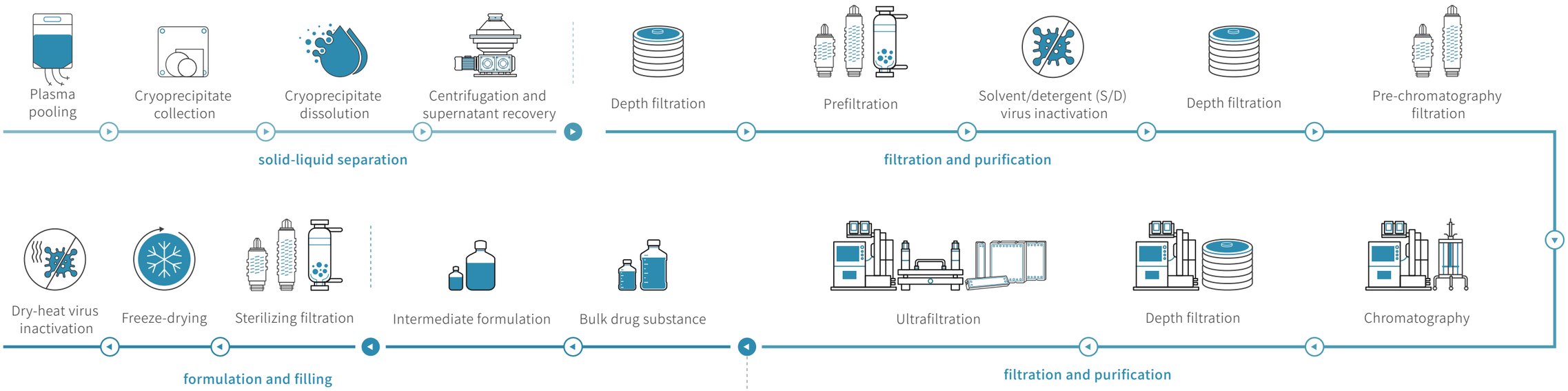
Category	Products	Core function	Clinical applications
Albumin	Human albumin; recombinant human albumin	Maintains colloid osmotic pressure, expands circulating volume, and supports transport and detoxification	Hypovolemic shock, hypoalbuminemia, liver cirrhosis
Immunoglobulins	Intravenous immunoglobulin (IVIG); specific immunoglobulins	Provides broad antibody activity, immune support and anti-infective protection	Primary immunodeficiency and severe infection
Coagulation factors	Human coagulation factor VIII; human prothrombin complex	Participates in the coagulation cascade and corrects coagulation dysfunction	Hemophilia and surgical or traumatic bleeding

Representative Manufacturing Workflow for Intravenous Immunoglobulin (IVIG)

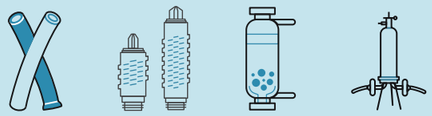


This process flow has been compiled from typical advanced industry practices. Because specific process routes vary among manufacturers, it is provided for reference only and actual manufacturing workflows shall be adapted per each manufacturer's validated process.

Typical Process Flow - Human Coagulation Factor VIII



Single-use systems



stainless-steel systems

Systems and full-process supporting applications

This process flow has been compiled from typical advanced industry practices. Because specific process routes vary among manufacturers, it is provided for reference only and should be adjusted to the actual process in practical applications.

Process stages: solid-liquid separation | filtration and purification | formulation and filling

Product Selection Guidance for Plasma-Derived Product Manufacturing

Plasma-derived-product manufacturing is complex and the feed stream changes significantly from step to step. Common pain points across solid-liquid separation, filtration and purification, and fill-finish directly affect yield, safety and manufacturing efficiency.

Process step	Core challenge	Recommended product	Material	Product advantages	Product type
Solid-liquid separation	High solids cause rapid flux decay; metal-ion leaching; target-protein loss through adsorption	LeClafine™ depth filters	Cellulose	High filtration capacity; high impurity-removal efficiency; high target-protein recovery	Depth-filter sheets; membrane stacks; capsules
Clarification filtration	High-viscosity feed; low flow and flux; high concentration	LeUniPore™ PES / LeSiever™ PES	PES	High flux; high loading; high impurity-removal efficiency	Pleated cartridges; capsule filters; super-pleated cartridges
Filtration before and after virus inactivation	Resistance to extreme pH and organic reagents	LeUniPore™ PES / LeSiever™ PES	PES	Broad pH tolerance; strong impurity removal	Pleated cartridges; capsule filters; super-pleated cartridges
Buffer filtration	Repeated sterilization of filters; heat resistance	LeUniPore™ PES / LeSiever™ PES	PES	Heat resistant; stable filtration capacity	Pleated cartridges; capsule filters; super-pleated cartridges
UF concentration / TFF	Concentration polarization reduces flow; protein adsorption impacting product recovery; membrane fouling complicating cleaning regimes	LeUltra™ PES ultrafiltration cassettes	PES	High water-flux recovery; high flow at specified pressure; broad MWCO range suited to plasma-derived products	Ultrafiltration membrane cassettes
Virus prefiltration	Remove particles and aggregates; protect the virus-removal membrane	BetPore™ PVDF / Extreme™ PVDF	PVDF	High flow and loading; low adsorption	Pleated cartridges; capsule filters; super-pleated cartridges
Core virus filtration	Fluctuating virus-removal efficiency; membrane blockage; batch-to-batch variation in aggregate removal	LeEndurance™ virus-removal filter	PVDF	High loading; effective aggregate removal; robust virus clearance	Pleated cartridges; capsule filters
Fill-finish filtration	Low-extractables and high-sterility requirements; severe flux attenuation; insufficient protection of protein activity	LeUniPore™ PES / Extreme™ PVDF	PES / PVDF	Extremely low surface adsorption; high flow; clean membrane; high loading	Pleated cartridges; capsule filters; super-pleated cartridges

Process Solutions

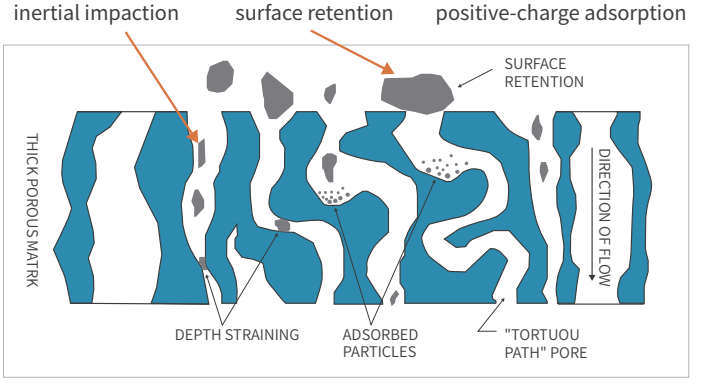
LePure Biotech provides customized, integrated solutions to meet filtration and separation requirements throughout the entire plasma-derived product manufacturing process, from raw material handling to final drug product production. The portfolio includes key products such as depth filter sheets, tangential flow filtration (TFF) cassettes, virus removal filters, and sterilizing-grade filters, complemented by single-use technologies and cleanroom cleaning and disinfection solutions. Together, these solutions help ensure product yield, safety, and manufacturing consistency throughout the process.

Solid-liquid separation stage

Process background: In plasma-derived-product manufacturing, low-temperature ethanol processing is used to precipitate plasma-protein fractions, followed by depth-filter sheets to separate the fractions. This is a classic industrial method for plasma-protein separation. The central requirement at this stage is efficient separation of high-solids feed while preventing metal-ion contamination and protein loss.
Key considerations: high solids can cause the filtration rate to decline rapidly; metal ions such as aluminum must not leach into the process and affect product safety; target-protein retention must be maximized while adsorption losses are minimized.
Depth-filtration mechanisms: inertial impaction; surface retention; positive-charge adsorption; depth straining; adsorbed particles; tortuous-path pores; direction of flow; thick porous matrix.

Key considerations

- high solids can cause the filtration rate to decline rapidly
- metal ions such as aluminum must not leach into the process and affect product safety
- target-protein retention must be maximized while adsorption losses are minimized.



Recommended product	Core applications and advantages
LeClafine™ BP-series depth filters	Filtration of precipitates from plasma-derived products; clarification before chromatography or virus filtration; removal of contaminating proteins
LeClafine™ F-series depth-filter sheets	Gradient structure increases filter throughput; large specific surface area strengthens impurity-retention capacity; proprietary pretreatment delivers low metal-ion content, especially low aluminum; relieves bottlenecks at prefilters, virus-removal membranes and chromatography columns, extending service life and reducing clogging; high efficiency, high throughput and low cost; good wet strength and pressure resistance

Filtration and purification

01 Process Intermediate, Buffers and Bulk-Solution Filtration

Process background

Solvent/detergent (S/D) inactivation and low-pH incubation are core virus-inactivation steps. Before and after these operations, feed properties change significantly because of extreme pH conditions and the presence of surfactants or organic reagents. Filtration must remove microorganisms and protein aggregates. Buffer solutions used before chromatography or ultrafiltration must reduce bioburden. Together, these duties impose exceptionally high requirements for chemical compatibility, heat resistance and flux stability.

Key considerations

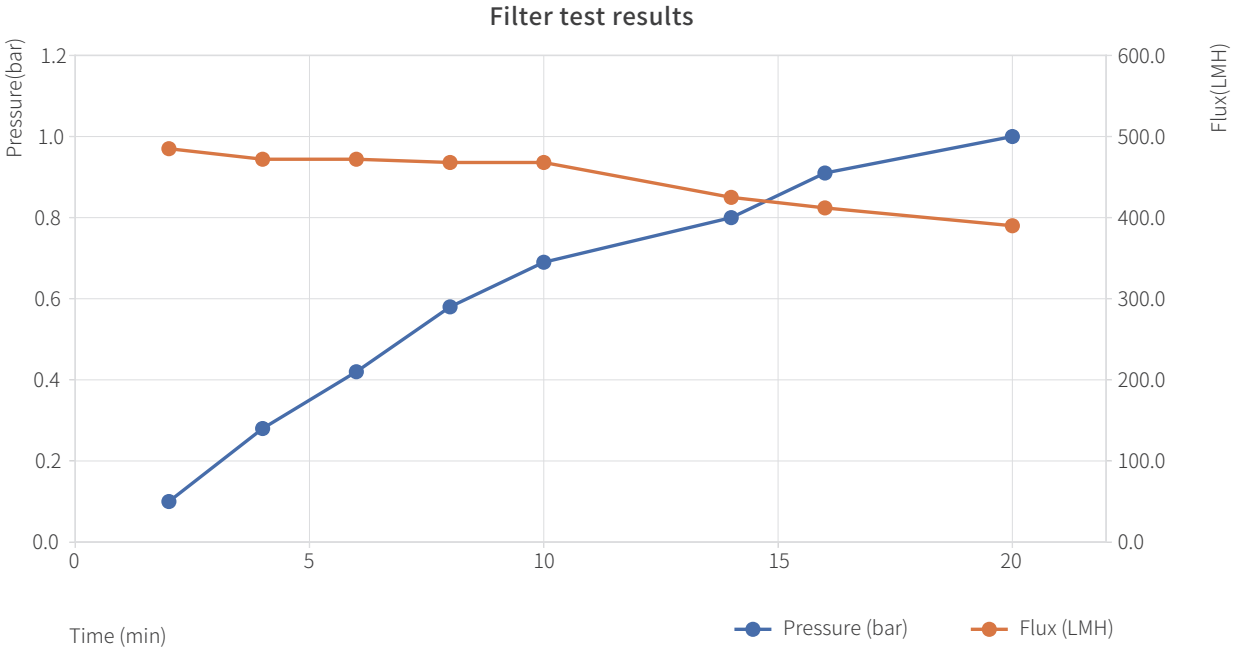
- Resistance to organic reagents used in S/D inactivation and to the strongly acidic environment of low-pH incubation.
- Stable flux and loading across different viscosities and concentrations.
- Excellent thermal stability for filter elements used in repeated sterilization cycles.

Recommended solutions

Product	Advantages
LeUniPore™ PES	0.45/0.2 µm options; high flux and loading; strong performance with viscous feed; reduced blockage and longer service life
LeSiever™ PES	Super-pleated format provides a larger filtration area; stable upon repeated steam-sterilization exposure (134 °C, 30 min, up to 30 cycles) - and well suited to buffer applications

Case study

This experiment used PES filter material with a 0.45/0.2 μm retention rating. Pressure increased gradually while flux remained high throughout the test. The data below come from an actual customer application involving sterilizing filtration of a human coagulation factor VIII intermediate.



sterilizing filter for a factor VIII intermediate

Time (min)	Pressure (bar)	Filtrate (mL)	Loading (L/m²)	Flux (LMH)
2	0.10	4.5	16.1	482.1
4	0.28	8.8	31.4	471.4
6	0.42	13.2	47.1	471.4
8	0.58	17.4	62.1	466.1
10	0.69	21.8	77.9	467.1
14	0.80	27.7	98.9	424.0
16	0.91	30.7	109.6	411.2
20	1.00	36.3	129.6	388.9

（数据源自典型客户应用案例）

02 Ultrafiltration / Tangential Flow Filtration

Process background

Tangential flow filtration (TFF) is a core technology used for protein concentration, washing, desalting and molecular-weight fractionation. Throughout this stage, the target protein's activity must be protected, membrane fouling must be reduced, and the process must support linear scale-up from laboratory development to industrial production.

Key considerations

- Match the membrane MWCO precisely to the molecular weight of the target protein.
- Mitigate flux decline caused by concentration polarization in high-viscosity feed.
- Maximize product recovery and reduce protein loss through adsorption.

LeUltra® PES ultrafiltration cassettes

产品	特性
LeUltra™ PES ultrafiltration cassettes	in-house membrane technology, high efficiency, high flux, low protein adsorption, high loading and easy cleaning.

03 Virus prefiltration and virus filtration

Process background

Virus clearance is a core step for ensuring product safety and regulatory compliance, and it is directly related to marketing approval and clinical safety. Actual manufacturing frequently encounters rapid virus-filter blockage, unstable membrane flux and loading, and batch failure; filter selection and process scale-up are therefore critical.

Key considerations

- validated virus-clearance performance
- Filter loading normalized to nominal filter membrane area

Recommended solutions

Virus prefiltration and virus filtration

Product	Features
BetPore™ hydrophilic PVDF prefilter	High loading; low protein adsorption; protects the downstream virus filter
Extreme™ hydrophilic PVDF prefilter	High porosity and flux; low protein adsorption; protects the downstream virus filter

Virus prefiltration and virus filtration

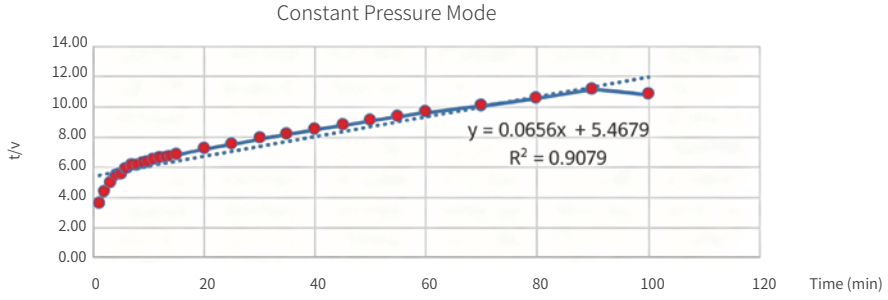
Product	Features
LeEndurance™ virus-clearance filter	Stable, validated clearance with LRV >4 for small viruses; stable constant-pressure flux; aggregate removal; low adsorption and extractables; optimized pleats and automated-system compatibility

Case study

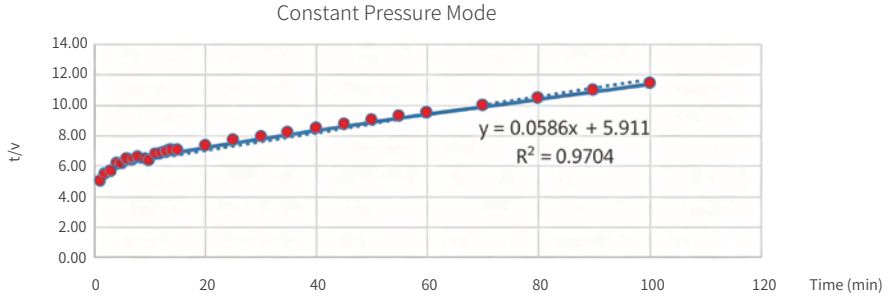
Virus-Prefilter Performance

A permeability test performed at a constant pressure of 43.5 psi investigated how different protein concentrations affected the loading and flux of a virus prefilter.

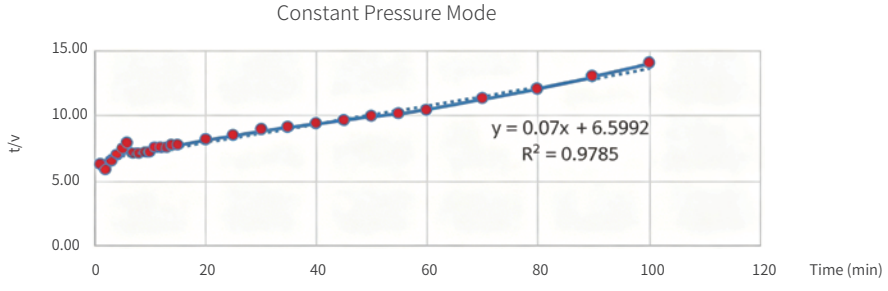
Virus prefilter result using a BetPore™ PVDF prefilter after loading 1kg/m² protein.



Virus prefilter result using a BetPore™ PVDF prefilter after loading 2kg/m² protein.



Virus prefilter result using a BetPore™ PVDF prefilter after loading 4kg/m² protein.



(Data from representative customer application case studies)

Final drug-product sterilizing filtration

Process background

Final sterilizing filtration is the last microbial barrier in the manufacture of plasma-derived products and directly affects product sterility and patient safety. Because the feed at this stage is the final drug product, filters must meet the highest process requirements for low extractables, sterility assurance, chemical compatibility and protein protection.

Key considerations

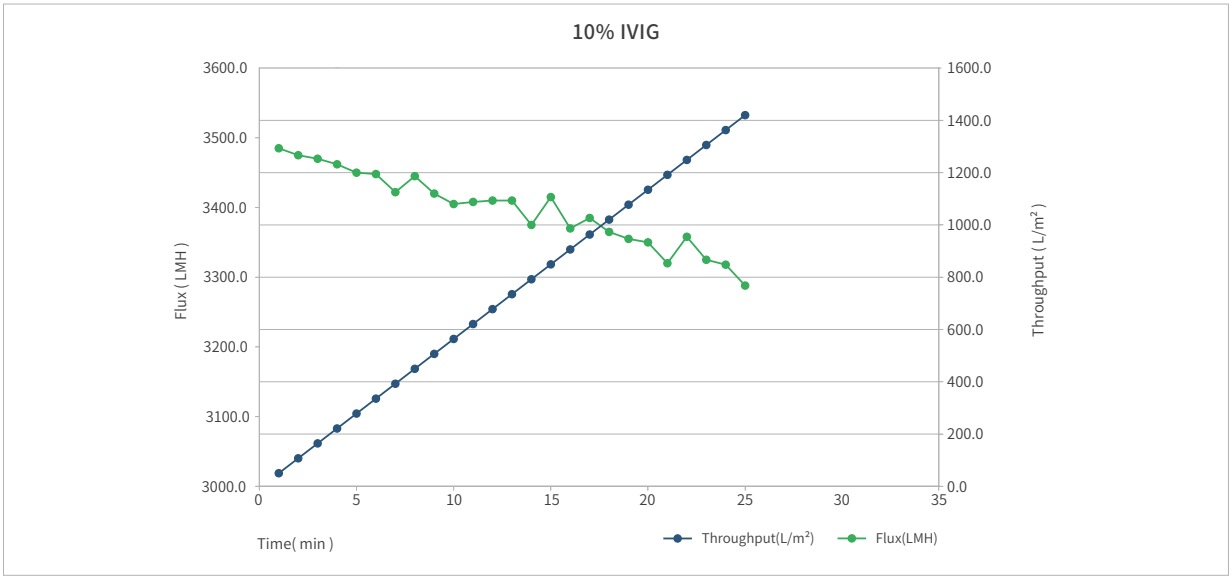
- Low extractables
- High sterility assurance
- Chemical compatibility

Recommended solutions

Product	Features
UniPore™ PES	Good solvent and oxidation resistance; improved heat resistance; low extractables; high flux; high sterility assurance; low protein adsorption
Extreme™ PVDF	Broad chemical compatibility; high throughput; high sterility assurance; low protein adsorption

Case study

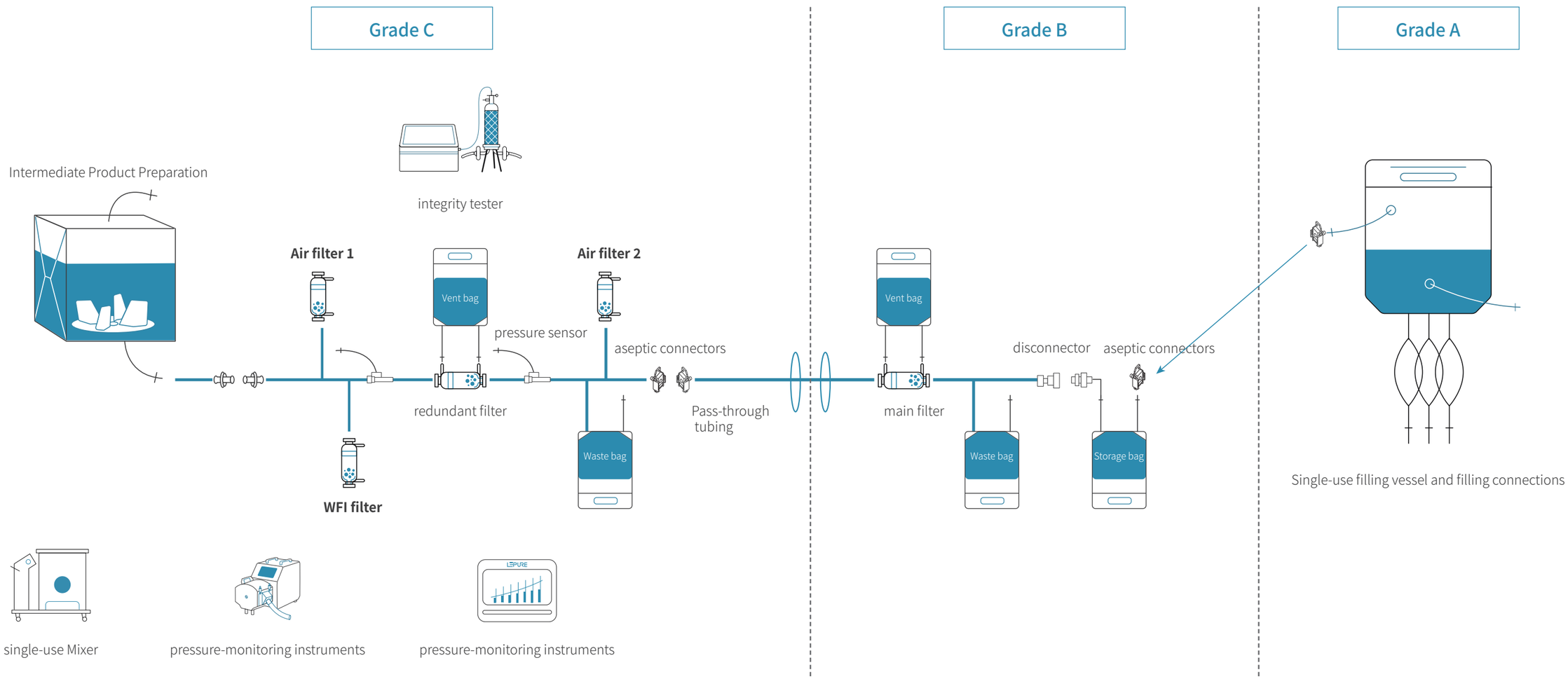
At a constant pressure of 43.5 psi, testing investigated the loading and throughput of UniPore® PES.



Integrated Small-Batch Formulation and Fill-Finish Solution

To enable one-stop procurement and full-process coordination, LePure Biotech provides a supporting product portfolio for plasma-derived-product manufacturing that integrates seamlessly with the core filtration train.

The configuration can be adapted to the user's batch size, facility zoning, process controls and validation strategy.



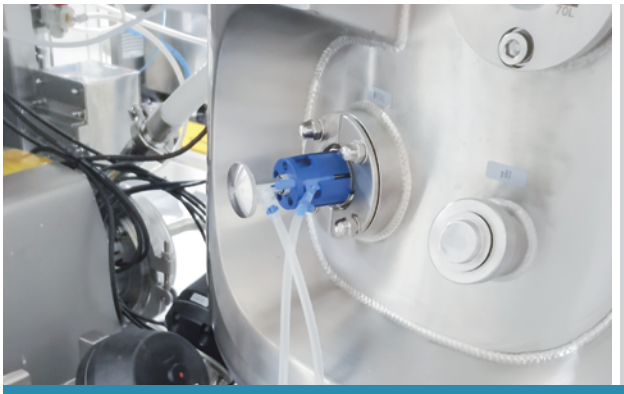
Supporting Product Portfolio

- Selectable single-use products

Pre-use post-sterilization integrity testing (PUPSIT) assemblies

Single-use bag portfolio

- Aseptic sampling



LeCouple KY sampling system

silicone puncture septum

Fluid management

Tubing

additional clamp fittings

straight-through connectors

multi-way, multi-port connectors

cradle-type clamps

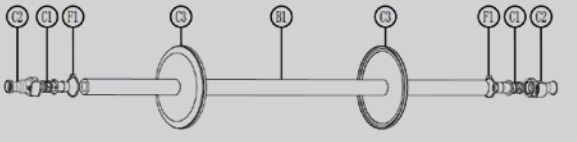
tube plugs

valve plates

Pass-through systems

LePurport® pass-through system

semicircular silicone plates



configured tubing assemblies

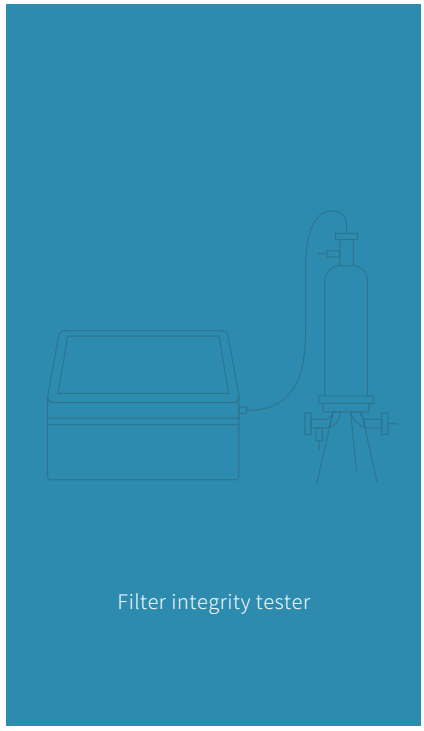
Cleaning, Disinfection and Stainless-Steel Housings

Disinfectants

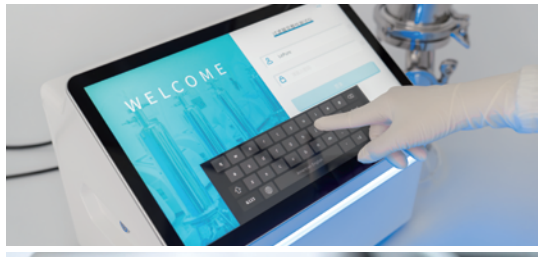
Supporting stainless-steel housings

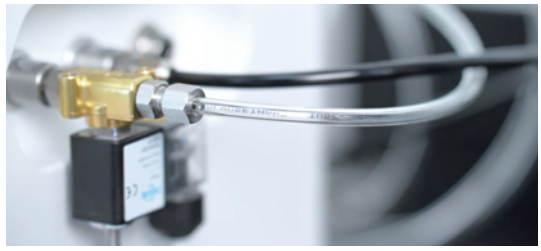
Integrity-testing solutions

Glove integrity tester



Filter integrity tester





Regulatory Consulting and Validation Services

LePure's Validation Center Laboratory (LePurValid®), part of LePure Biotech, is an efficient, collaborative and interdisciplinary technical team composed of materials scientists, chemists, toxicologists and chemical analysts. It is committed to serving as an R&D and technical-service partner to biopharmaceutical companies worldwide. The center provides one-stop R&D, validation, testing and safety-assessment services, fully supporting technical-service needs across product development, registration submissions, manufacturing, post-marketing changes and quality maintenance.

Two service platforms

01 Services related to upstream and downstream process consumables

Focuses on the safety of consumables used in upstream and downstream biopharmaceutical processing, providing related R&D, validation, testing and safety-assessment services.

- **Disinfectant efficacy validation: neutralizer toxicity testing and efficacy testing; in-use shelf-life validation after opening; disinfectant efficacy validation.**
- **Filter validation: risk assessment; extractables and leachables studies; bacterial-retention testing; chemical-compatibility testing; product-wetted integrity testing; adsorption testing; safety assessment.**
- **Single-use systems and/or components: extractables and leachables studies.**

02 Services related to final drug products

Focuses on the safety of packaging materials used with finished biopharmaceutical products, providing related R&D, validation, testing and safety-assessment services.

- **Compatibility studies: drug-packaging materials, drug-delivery devices and medical devices.**
- **Container-closure integrity studies: microbial challenge, vacuum decay, helium mass-spectrometry leak detection and laser-based headspace analysis.**
- **Preparation of positive-control samples for closure-integrity studies: laser drilling, micropipette insertion and capillary insertion.**
- **Impurity studies: particulate and foreign-matter analysis, elemental impurities and related investigations.**

Our advantages

10+ years	2000+	500+	3000+
Biopharma experience	Toxicology database	Methods database	Extractables database

Qualifications and analytical capabilities

- ☑ CNAS-accredited laboratory and ISO 9001-certified quality management system.
- ☑ The microbiology laboratory has passed P2 certification.
- ☑ Advanced analytical instrumentation, including UPLC-MS/MS, GC-MS, ICP-MS, laser headspace analyzers, helium leak detectors and micro-FTIR systems.

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