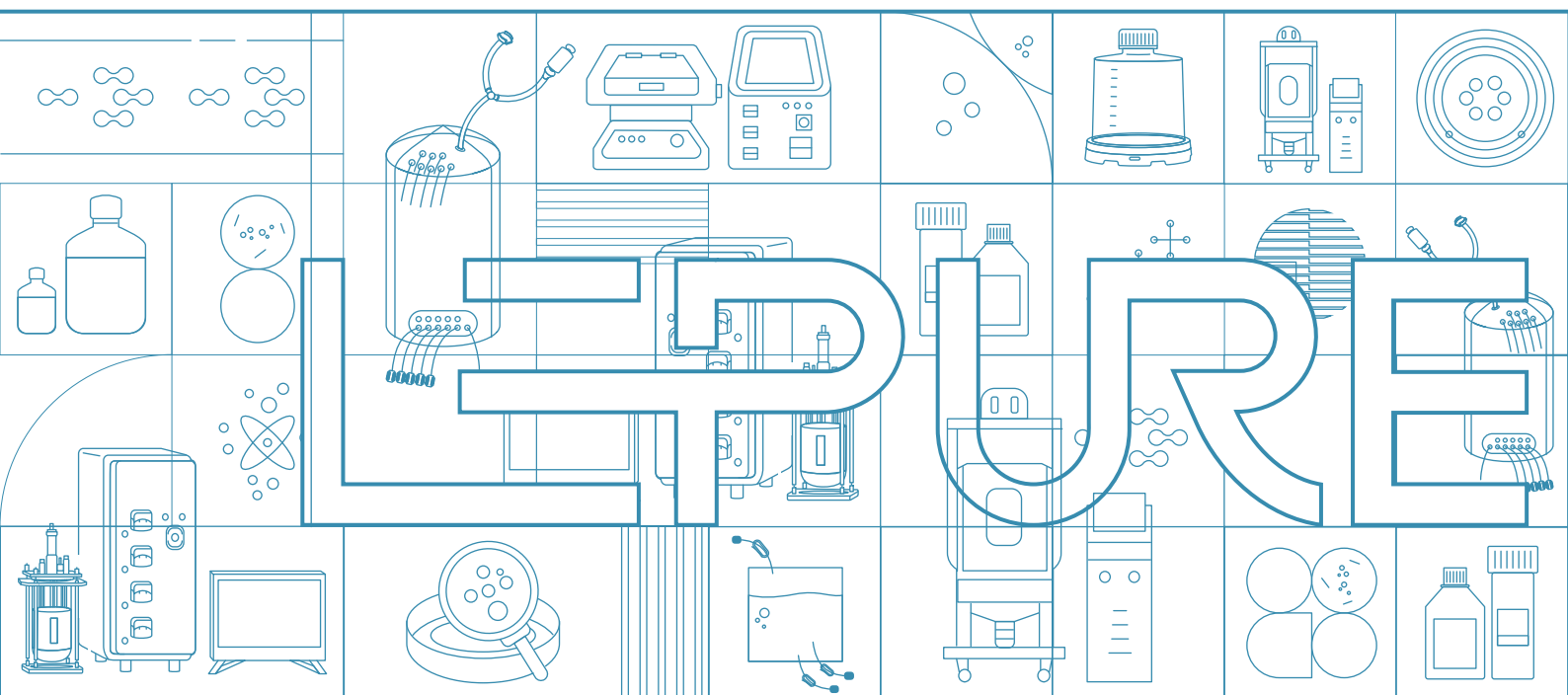


Gene & Cell Therapy Solutions

Specialized Solutions for the Gene and Cell Therapy Industry



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Company Introduction

LePure Biotech delivers a comprehensive, end-to-end portfolio of single-use bioprocess solutions engineered to empower biopharmaceutical development, scale-up, and commercial GMP manufacturing. Spanning bioprocess bags / films, fluid management components, filtration systems, and process equipment, our offerings are unified by three core strengths that drive bioprocess excellence worldwide:

① Proprietary Technology

Our LeKrius® film sets the standard with ultra-low extractables, high mechanical strength, and proven biocompatibility. This foundational technology ensures consistent performance across our storage bags, mixing bags, and freeze-thaw consumables, throughout bioprocess workflows. Complementing this, our dedicated filtration product line leverages specialized, application-optimized membrane technologies, choose UniPore PES (high flux, sterile-grade) or LeSiever® multi- membrane filters (PES / PTFE / PP / Nylon) for diverse clarification needs.

② Full Process Coverage & Flexibility

From upstream cell culture to downstream purification and final fill. Volume ranges from 0.5 mL to 4000 L, scalable equipment (from benchtop mixers to 4000 L systems). Seamless scale up from R&D to production.

③ Global Compliance, Reliable Supply

DMF filings, full validation packages, and a closed loop traceable supply chain with in house film extrusion. Batch to batch consistency, short lead times, and uninterrupted availability for clinical and commercial manufacturing.

With a focus on safety, efficiency, and regulatory confidence, LePure Biotech is your trusted partner for advancing bioprocess excellence worldwide.

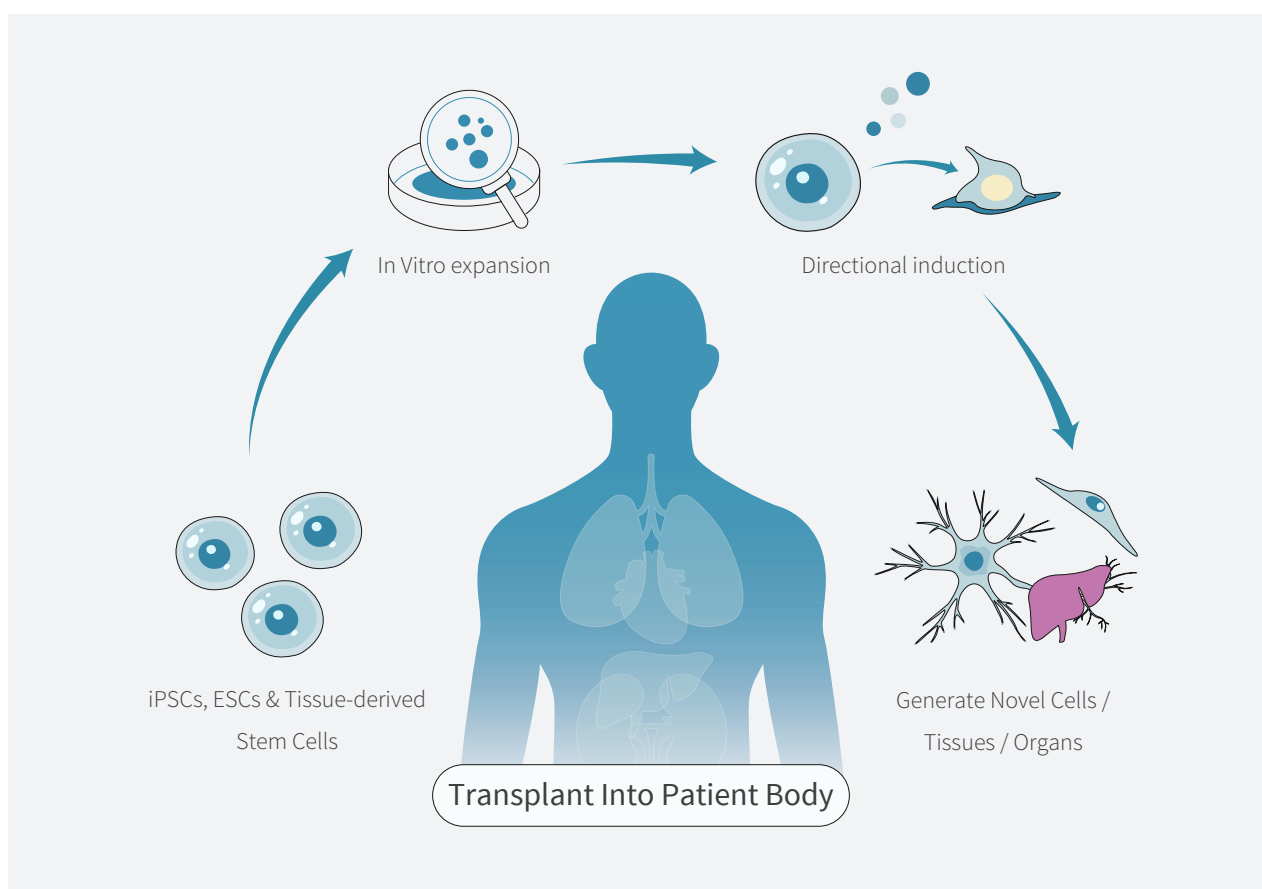


Enabling Scalable and Compliant CGT Manufacturing

Cell and Gene Therapy (CGT) is redefining the future of medicine. Innovative modalities such as CAR-T cell therapy, stem cell therapy, and viral vector-based gene therapy are accelerating the development of next-generation treatments for cancer, rare diseases, and other serious conditions.

As these therapies move from discovery to commercialization, manufacturers face increasing challenges in process scalability, sterility assurance, regulatory compliance, and cost efficiency. Reliable and integrated bioprocess solutions have become essential to support successful CGT manufacturing.

Stem Cell Therapy



Process



Product Introduction

■ Cell Expansion



ELAREM Perform-FD PLUS X-RUO (For Asian Market)

Serves as an alternative to fetal bovine serum, supplying rich natural cytokines and growth factors to support cell adhesion and proliferation.

- Compatible with multiple cell types, including MSCs, NK cells and endothelial cells etc.
 - Features a fully xeno-free formulation derived from EU-origin human platelets, ensuring a safe supply chain and complete traceability.
 - Delivers high consistency in large-scale manufacturing with reliable batch-to-batch stability.
-



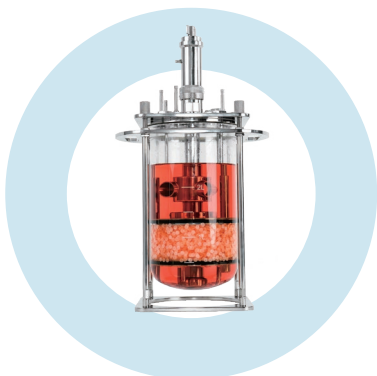
LeProlif[®] Sphere Microcarrier

- High specific surface area enables efficient stem cell expansion, supporting both stem cell and exosome production
 - Suitable for 3D suspension culture, compatible with stirred bioreactors.
 - Enables linear scale-up via sphere-to-sphere process effectively reducing process costs and improving operational efficiency for large-scale stem cell expansion.
-



LeProlif[®] Disk Microcarrier

- Large-scale product of exosomes, offering cost-effective raw materials for clinical use.
- Sufficient specific surface area for rapid cell growth with patented surface treatment
- Perfusion system for highly efficient nutrients exchange in fixed-bed reactor or rocking bioreactor



LePhinix® EZG Fixed-bed Bioreactor

- Leverage fixed-bed perfusion design to optimize nutrient mass transfer efficiency.
- Enhance viable cell density and enables harvesting of high-activity, high-concentration exosomes.
- Feature a compact stable structure with operation friendly.



LePhinix® EZG Benchtop Bioreactor

- Designed for spherical microcarriers, equipped with special impellers to ensure uniform suspension of microcarriers and stable cell proliferation.
- Built-in cylindrical filters enable efficient separation of microcarriers and cells after digestion.
- Optimized impeller design ensures uniform mixing of culture medium and stable dissolved oxygen supply.
- High porosity membrane contributes to high flux and efficient operation.



LePhinix® CCS Single-use Rocking Bioreactor

- Pre-sterilized single-use rocking bags are pre-packed with LeProlif® Disc, ready for direct use without pretreatment.
- Compatible with perfusion culture ranging from 200 mL to 100 L, covering laboratory to commercial scale.
- Enables long-term continuous perfusion for high-yield exosome manufacturing.

■ Filtration and Purification for Exosomes



LeClafine® Depth Filters

- Delivers excellent clarification performance via physical retention and electrostatic adsorption (Van der Waals forces) for effective turbidity and particulate removal.
- Offers high loading capacity while maintaining efficient clarification and contaminant retention.
- Ensures high protein recovery, typically exceeding 95 % for monoclonal antibody processes.
- Endotoxin level is controlled below 0.25 EU/mL, fully complying with regulatory requirements.
- Specially optimized for exosome clarification to efficiently remove residual cell debris.



LeFiber® TFF

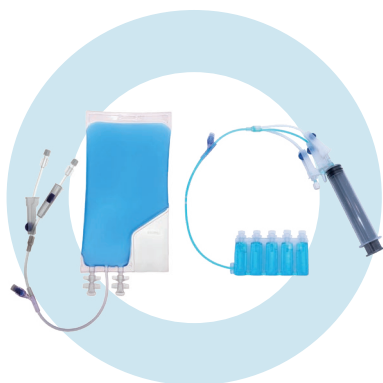
- Modified polyethersulfone (mPES) hollow fiber membrane with low protein adsorption.
- Narrow pore size distribution provides superior molecular separation performance.
- High hydrophilicity enhances anti-fouling properties.
- High porosity delivers high flux and shorter process duration.
- Gradient membrane structure enables convenient CIP cleaning and regeneration.
- Defect-free membrane fibers ensure outstanding stability and linear scalability.
- Optimized for high-purity exosome harvesting, efficiently removing hormones and other impurities

■ Cryopreservation and Recovery



QuaCell® Powerful Cryopreservation Medium

- DMSO-free and animal-origin-free.
- Supports clinical-grade and pharmaceutical-grade mesenchymal stem cell , cell recovery viability over 90 %.
- Ready-to-use cryopreservation medium, convenient to operate with outstanding stability.

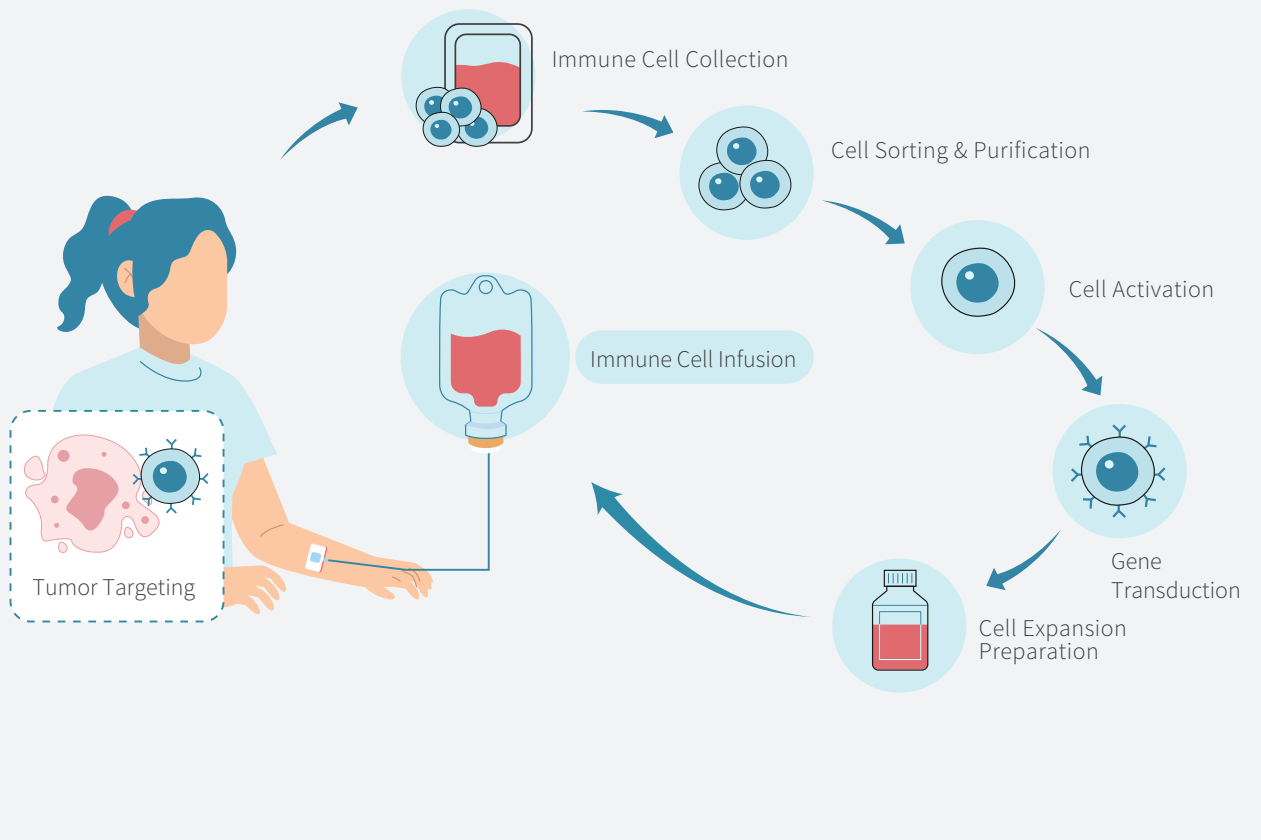


LeThenea® Single-use Freezing Bag

- Applicable for cell storage, low-temperature preservation of intermediates and other applications
- Fully validated for extractables and leachables safety, with 100 % integrity testing completed.
- Available in single-chamber and multi-chamber designs to meet customized process requirements.
- Fully qualified and CDE-filed, offering a safe and reliable long-term cell storage solution.

Immune Cell Therapy

Therapeutic Mechanism



Process

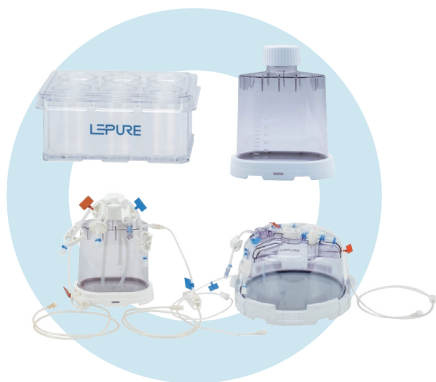


■ Cell Expansion



ELAREM Perform-FD PLUS X-RUO (For Asian Market)

- Serves as an alternative to fetal bovine serum, supplying rich natural cytokines and growth factors to support cell adhesion and proliferation.
- Compatible with multiple cell types, including MSCs, NK cells and endothelial cells etc.
- Features a fully xeno-free formulation derived from EU-origin human platelets, ensuring a safe supply chain and complete traceability.
- Delivers high consistency in large-scale manufacturing with reliable batch-to-batch stability.



LeCulti® Permeable Cell Culture Vessel Series

- Designed for immune cell expansion (T-cell, NK, CIK) in adoptive immunotherapies.
- Unique gas-permeable membrane enables efficient O₂ & CO₂ exchange and homogeneous gas distribution for optimal cell growth.
- Streamlined operation reduces medium/consumable usage; closed-system design fully complies with GMP standards.
- Working volumes: 40 mL to 5 L, covering R&D to clinical-scale workflows.



LeCulti® Single Use Cell Culture Bag

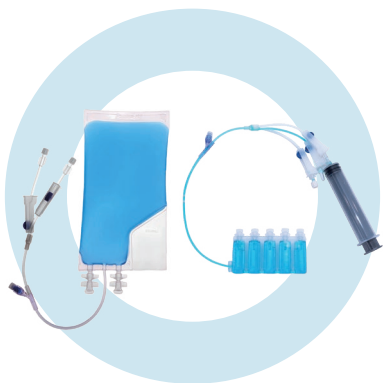
- Premium gas-permeable material modulates gas exchange, simulates in vivo conditions for T/NK cells, supporting growth.
- High flexibility and transparency for easy handling, transport and real-time cell observation.

■ Cryopreservation and thawing



QuaCell® Powerful Cryopreservation Medium

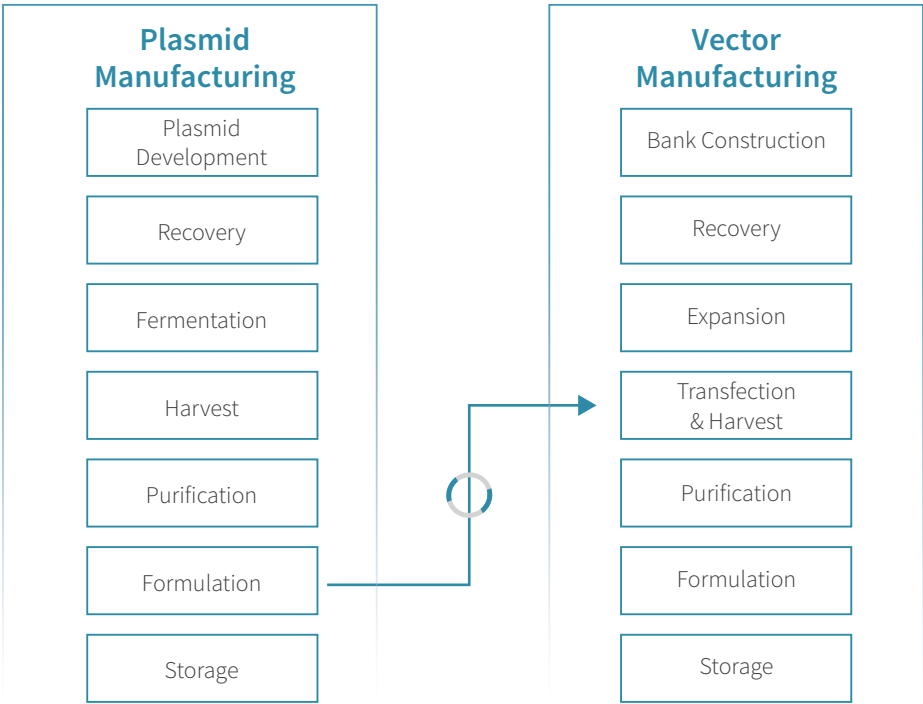
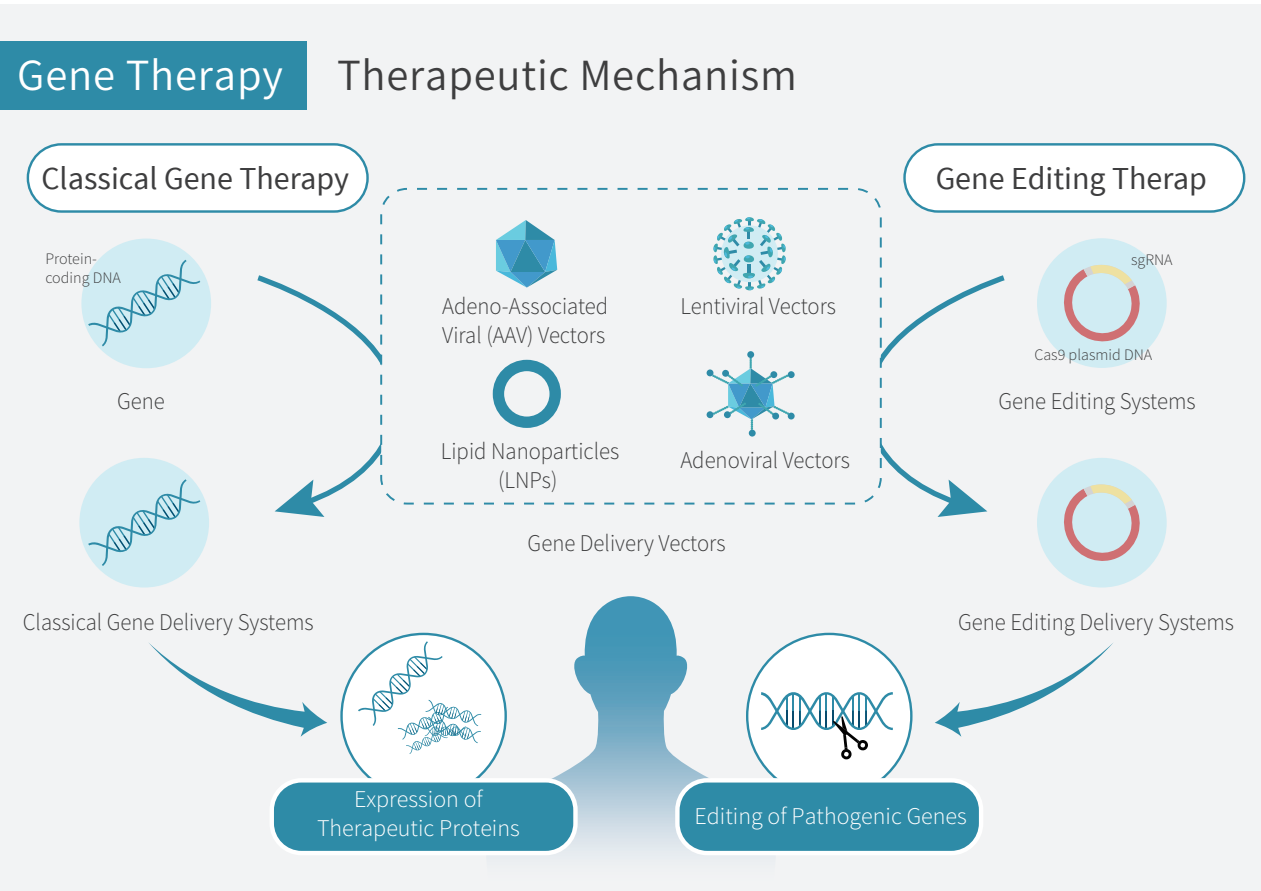
- DMSO-free and animal-origin-free
- Supports clinical-grade and pharmaceutical-grade mesenchymal stem cell , cell recovery viability over 90 %
- Ready-to-use cryopreservation medium, convenient to operate with outstanding stability



LeThenea® Single-use Freezing Bag

- Applicable for cell storage, low-temperature preservation of intermediates and other applications
- Fully validated for extractables and leachables safety, with 100% integrity testing completed.
- Available in single-chamber and multi-chamber designs to meet customized process requirements.
- Fully qualified and CDE-filed, offering a safe and reliable long-term cell storage solution.

Plasmid and Virus Preparation Platform



Product Introduction

■ Virus Production



WayneLVPro™ HEK293 Cell Line

- High cell density up to 1×10^7 cells/mL, compatible with multiple commercial culture media.
 - High titer for different products, with the lentivirus infection titer up to 1.3×10^7 TU/mL.
 - High transient transfection efficiency, reaching up to 85 %.
 - Clear traceability with complete IND and BLA documentation support.
 - True Freedom to Operate (FTO) with flexible global commercial licensing solutions.
-



HEK 293 Medium

- Supports high density proliferation of suspended HEK293 cells, max density up to 1×10^7 cells/L.
 - High transfection efficiency and high yield, max yield up to 255 mg/L.
-



LePhinix® EZG Benchtop Bioreactor

- Intelligent process management and data analysis software.
- Comply with 21 CFR PRAT 11, GAMP5 and cGMP.
- Open configuration platform to provide customization solutions.
- Multi tank controllable, comes with integrity test function.



LePhinix® CCS Single-use Rocking Bioreactor

- Single-use rocking bags pre-packed with LeProlif® lamellar carriers, gamma sterilized and ready to use without extra pretreatment.
- Compatible with perfusion culture from 200 mL to 100 L, covering lab-scale to large-scale production.
- Supports long-term continuous perfusion to achieve high-yield exosome production.



LePhinix® Single-use bioreactor

- Suitable for cell culture processes in antibodies, cell & gene therapy, vaccines and other biopharmaceutical applications.
- Customizable configurations to accommodate diverse technological requirements.
- High-performance hardware and modular design. Dual database architecture ensures enhanced data security and stable system operation.
- Three-level authority management, compliant with audit trail regulations and supporting signal interconnection with third-party systems.
- Effectively reduces cross-contamination risks and facilitates convenient process management.
- Multiple optional probes including pH, DO, temperature and pressure, paired with flowmeters for precise gas regulation.



LeKrius® Single use bioreactor bag

- Extensive experimental studies have been conducted on cell culture exploration and inter-batch membrane stability. Results demonstrate excellent performance, fully meeting the culture requirements of HEK293, CHO-K1, CHO-DG44, SF9 and other cell lines.
- LeKrius® membrane boasts outstanding biosafety, chemical compatibility and physical properties, providing biopharmaceutical companies with safe and reliable single-use products.
- Compatible with LePhinix® bioreactors, enabling precise control of process parameters during culture.
- Supports direct linear scale-up, improving bioprocess development efficiency and reducing costs.

■ Virus Filtration & Purification



LeClafine® Depth Filters

- **Significant clarification effect:** Significant turbidity reduction and foreign matter interception are achieved through physical interception and positive charge adsorption (Van der Waals forces) in the interior.
- **High Capacity:** high capacity, while achieving turbidity reduction and foreign matter interception.
- **High Protein Recovery Rate:** Generally, monoclonal antibody customers require a protein recovery rate greater than 95 %.
- It has been determined that the endotoxin levels in the filter fully meet the regulatory content requirements (i.e., less than 0.25 EU/mL).
- Specialized for exosome filtration purification, effectively eliminating residual cell debris.



LeFiber® TFF

- Modified polyethersulfone (mPES) membrane fibers, lower protein adsorption.
- Narrow pore size distribution, superior separation performance.
- High hydrophilicity, stronger anti-fouling capability.
- High porosity and high flux, shorter process time.
- Gradient-distributed membrane structure, easier CIP cleaning and regeneration.
- Defect-free membrane fibers, more reliable stability and linear scalability.
- Optimized for high-purity exosome harvesting, effectively removing hormones and other impurities.

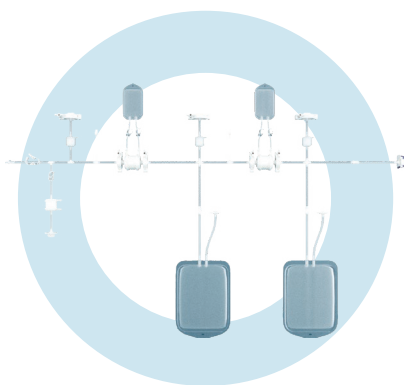
General Use

Product Introduction



LeKrius® Bioprocess Bags & Solution Preparation & Storage Equipment

- Paired with LeMagmixer® series disposable magnetic stirring system, it offers multiple customized options to adapt to various stirrer impeller types, with round and square tanks available.
- Flexibly customizable sensor functions meet online monitoring needs during preparation. The integrated control system ensures data integrity.
- Satisfies the preparation, storage and transportation requirements of various feed solutions in biopharmaceutical processes.



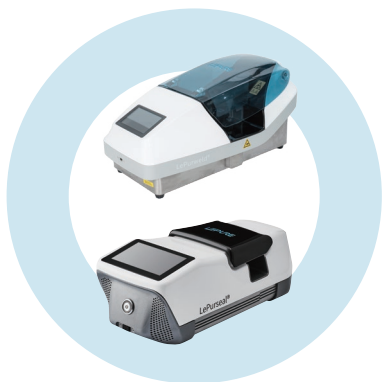
LeBrider® Tubing Assembly & Components

- A comprehensive component library provides a complete ‘full-process connection’ tubing solution.
- Professional technical and regulatory teams design customized assembly products to meet end-users’ specific needs.
- 100 % batch leak testing ensures process safety and reliability.



LePurseal® / LePurweld® PVC Tube Sealer & Welder

- Applied to sealing and connection of PVC & EVA tubing, enabling sterile production workflows for customers.
- Widely adopted in CGT biopharmaceuticals, blood stations, hospitals etc.
- Domestic manufacturing with premium after-sales services, helping customers achieve cost reduction and efficiency improvement rapidly.



LePurseal® / LePurweld® TPE Tube Sealer & Welder

- Supports aseptic connection of thermoplastic TPE tubing and heat-weldable pump tubing (including PharMed® BPT, PureWeldXL).
- Fully automatic equipment for cross-connection of various pipeline tubing.
- Comprehensive validation protocols guarantee the aseptic integrity of all welded connections.



QuaCell® Ready to Use Antifoam

- **Convenient and Reliable:** ready to use, excellent defoaming ability.
- The product is sterilized by gamma irradiation.
- This product can be directly connected to bioreactor by aseptic tubing welding.



LeSeidon® Ready to Use WFI

- **Reliable Quality:** Compliant with WFI standards of Chinese Pharmacopoeia and USP.
- **Complete Validation:** Full set of qualification documents to eliminate customer concerns.
- **Stable Supply:** Independent production, controllable lead time and fast delivery.



LeSeidon® Ready to Use PBS

- Pre-filled bag design eliminates tedious manual preparation and enables immediate experimental operation.
- Seamlessly compatible with cell processing systems, easy to mount and rapidly connect with various tubing as required.
- Precise liquid inflow & outflow control matching supporting equipment, achieving efficient washing and medium exchange for blood and cell products with smooth, user-friendly operation.



LeSiever® LFT-1010

- Applicable to filtration of biological preparations including culture media, serum and buffer solutions.
- Excellent chemical compatibility (pH range: 1-14).
- Outstanding performance in treating easily-clogged feed liquids.
- Ideal solution for reducing bioburden and removing particulate impurities.



Microbial Contamination Control for Pharmaceutical Cleanrooms

- Full-range product portfolio for microbial control in cleanroom environments.
- Disinfection & sterilization product series, including ready-to-use alcohols, compound quaternary ammonium salts, 3 % hydrogen peroxide, 6 % hydrogen peroxide and compound peroxide disinfectants.
- Full technical documentation available, covering CoA, MSDS, microbial efficacy validation reports, radiation validation and safety assessment.
- Complete supporting disinfection equipment lineup.
- Matched pharmaceutical industrial protective supplies and cleanroom cleaning products.

Service & Support System

1. Technical Support

- Provide customized process development support to adapt to diverse enterprise technological applications.
- Equipped with a professional technical team, offering on-site training and technical guidance to rapidly resolve practical production challenges.

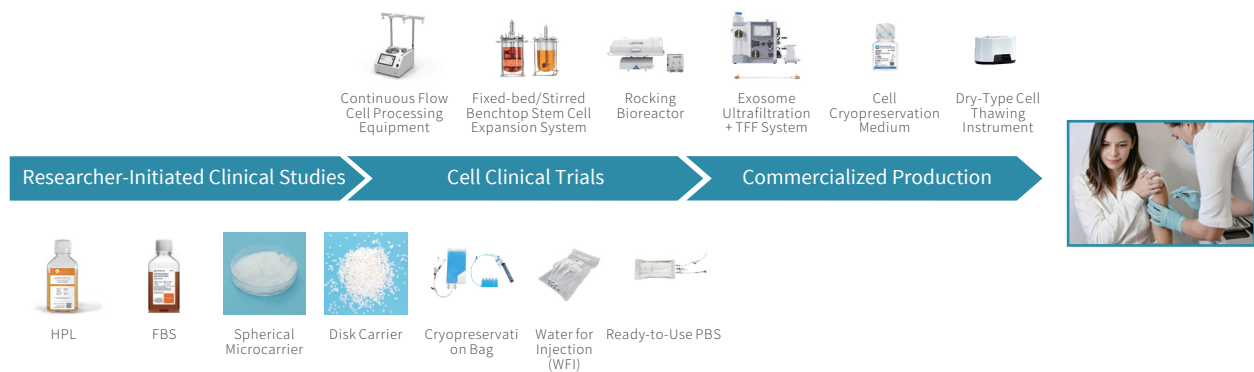
2. Medium Development & Manufacturing Platform

- Deliver customized powder & liquid medium, process scale-up and full-range technology transfer services.
- Support matched quality inspection and cell culture validation, with GMP-compliant seamless supply solutions to meet industrial-scale production demands.

3. Supply ChainSysteme

- Multi-base production layout with sufficient core product inventory, ensuring stable and predictable delivery lead times.
- Guarantee continuous commercial production and eliminate risks of supply chain disruptions.

Cell to Vial/Bag Cell Therapy Process Solution



Ordering Information

	Product Name	Cat. No.	Description
01	QuaCell® UltraFD HPL-GMP	C61302-01	100 mL GMP
02	QuaCell® UltraFD HPL-GMP	C61302-05	500 mL GMP
03	ELAREM Perform-FD PLUS X	PE71011-1-CN	500 mL RUO
04	LeCulti® Permeable Cell Culture Vessel Series	AADC0040	Six well plate GMP
05	LeCulti® Permeable Cell Culture Vessel Series	AADC001	1L open bottle GMP
06	LeCulti® Permeable Cell Culture Vessel Series	AADC001C	1L Closed bottle GMP
07	LeCulti® Permeable Cell Culture Vessel Series	AADC005C	5L Closed bottle GMP
08	LeCulti® Permeable Cell Culture Vessel Series	AA001	1L open bottle RUO
09	LeCulti® Single Use Cell Culture Bag	CEA-01X	100-800 mL; 330cm ²
10	LeCulti® Single Use Cell Culture Bag	CEB-01X	300-1800 mL; 640cm ²
11	LeCulti® Single Use Cell Culture Bag	CEC-01X	200-2900 mL; 825cm ²
12	LeThenea® Single-use Freezing Bag	CR0050-1E	130 × 120mm, 50 mL(work volume 10-20 mL), 5 set / pouch / 20 pouch / carton
13	LeThenea® Single-use Freezing Bag	CR0250-1E	150 × 120 mm, 250 mL(work volume 30-70 mL), 5 set / pouch / 20 pouch / carton
14	LeThenea® Single-use Freezing Bag	CR0500-1E	200 × 120 mm, 500 mL(work volume 55-100 mL), 5 set / pouch / 20 pouch / carton
15	LeThenea® Single-use Freezing Bag	CR0750-1E	230 × 120mm, 750 mL(work volume 80-190 mL), 5 set / pouch / 20 pouch / carton
16	LeThenea® Single-use Freezing Bag	CR001-1E	300 × 120 mm, 1000 mL(work volume 125-270 mL), 5 set / pouch / 20 pouch / carton
17	LeThenea® Single-use Freezing Bag	CR0050-3E	130 × 120 mm, 50 mL(work volume 10-20 mL), 5 set / pouch / 20 pouch / carton
18	LeThenea® Single-use Freezing Bag	CR0250-3E	150 × 120 mm, 250 mL(work volume 30-70 mL), 5 set / pouch / 20 pouch / carton
19	LeThenea® Single-use Freezing Bag	CR0500-3E	200 × 120 mm, 500 mL(work volume 55-100 mL), 5 set / pouch / 20 pouch / carton
20	LeThenea® Single-use Freezing Bag	CR0750-3E	230 × 120 mm, 750 mL(work volume 80-190 mL), 5 set / pouch / 20 pouch / carton
21	LeThenea® Single-use Freezing Bag	CR001-3E	300 × 120mm, 1000 mL(work volume 125-270 mL), 5 set / pouch / 20 pouch / carton
22	Dry-Type Cell Recovery Instrument	LPThaw002-2	2-position thawing system, for 2 mL cryovials, volume 0.3–2 mL
23	Dry-Type Cell Recovery Instrument	LPThaw002-5	2-position thawing system, for 5 mL cryovials, volume 3.4–5 mL
24	Dry-Type Cell Recovery Instrument	LPThaw004-2	4-position thawing system, for 2 mL cryovials, filling volume 0.3–2 mL
25	Dry-Type Cell Recovery Instrument	LPThaw006-2	6-position thawing system, for 2 mL cryovials, filling volume 0.3–2 mL
26	Dry-Type Cell Recovery Instrument	LPThawBAG	Bag thawing system, for 25–1000 mL cryo bags, volume N/A
27	WayneLVPro™ HEK293 Cell line	A23109	1.5x10 ⁷ /Vial, Suspension HEK293 cells
28	WayneLVPro™ HEK293T Cell line	A23110	1.5x10 ⁷ /Vial, Suspension HEK293T cells
29	WayneLVPro™ HEK293 Cell line(GMP Banked)	A23111	1.5x10 ⁷ /Vial, Suspension HEK293 cells(GMP bank)
30	Wayne293® transfection medium	A21501	Liquid, 1000ml, animal component-free, applicable cell lines: HEK293 / HEK293T / HEK293A / HEK293FT
31	Wayne293® transfection medium Part A	A22501A	Powder, 10L, 100L, animal component-free, applicable cell lines: HEK293 / HEK293T / HEK293A / HEK293FT

	Product Name	Cat. No.	Description
32	Wayne293® transfection medium Part B	A22501B	Powderc 10 L, 100 L, animal component-free, applicable cell lines: HEK293 / HEK293T / HEK293A / HEK293FT
33	Wayne293® LeTrans Medium	A21503	Liquid, 1000 mL, animal component-free, chemically defined medium, applicable cell lines: HEK293 / HEK293T / HEK293A / HEK293FT
34	Wayne293® LeTrans Medium	A22503	Powder, 10 L, 100 L, animal component-free, chemically defined medium, applicable cell lines: HEK293 / HEK293T / HEK293A / HEK293FT
35	Wayne293® LeTrans Feed Medium	A21901	Liquid, 1000mL, animal component-free, chemically defined medium, use with Wayne293® LeTrans Medium
36	Wayne293® LeTrans Feed Medium	A22901-10	Powder, 10L, animal component-free, chemically defined medium, use with Wayne293® LeTrans Medium
37	PVC Aseptic Sealer	BDPSZ000	1/ unit
38	PVC Aseptic Welder	BDQSZ000	1/ unit
39	CO ₂ Shaker	BWWSA003	Stacked constant temperature shaker
40	CO ₂ Shaker	BWWSS001	Benchtop constant temperature shaker
41	CO ₂ Incubator	BWPSA001	Air-jacketed, 150 L, dry heat, touch screen
42	CO ₂ Incubator	BWPSA002	Air-jacketed, 150 L, moist heat, touch screen
43	QuaCell® Ready to Use Antifoam	P11001-05	0.5 L/bag
44	QuaCell® Ready to Use Antifoam	P11001-10	1 L/bag
45	LePurseal® Automatic Aseptic Sealer II	BDASZ000	1 / unit
46	LePurweld® Automatic Aseptic Welder II	BDBSZ000	1 / unit
47	QuaCell® Powerful Cryopreservation Medium	B31002	Liquid, 100 mL/bottle
48	LeProlif® Sphere microcarrier	LPS0025	25 g
49	LeProlif® Sphere microcarrier	LPS0100	100 g
50	LeProlif® Sphere microcarrier	LPS0500	500 g
51	LeProlif® Sphere microcarrier	LPS1000	1000 g
52	LeProlif® Disk microcarrier	LPD0050	50 g, Non-sterile
53	LeProlif® Disk microcarrier	LPD0250	250 g, Non-sterile
54	LeProlif® Disk microcarrier	LPD1000	1000 g, Non-sterile
55	LeProlif® Disk microcarrier	LPD0050G	50g, Gamma Pre-sterilized
56	LeProlif® Disk microcarrier	LPD0250G	250g, Gamma Pre-sterilized
57	LeProlif® Disk microcarrier	LPD1000G	1000g, Gamma Pre-sterilized
58	QuaCell® Ready to Use Antifoam	P11001-02	0.2 L / bag
59	QuaCell® Ready to Use Antifoam	P11001-05	0.5 L / bag
60	QuaCell® Ready to Use Antifoam	P11001-10	1 L / bag
61	QuaCell® Ready to Use Antifoam	P11001-25	2.5 L / bag
62	LeSeidon® Ready to use WFI	RW001-01	1 L, 4 bag/carton
63	LeSeidon® Ready to use WFI	RW002-01	2 L, 2 bag/carton
64	LeSeidon® Ready to use WFI	RW005-02	5 L, 1 bag/carton
65	LeSeidon® Ready to use WFI	RW010-02	10 L, 2 bag/carton
66	LeSeidon® Ready to use WFI	RW020-02	20 L, 1 bag/carton
67	LeSeidon® Ready to use WFI	RW250-03	250 L (recyclable cubic container), 1 bag/carton
68	LeSeidon® Ready to use WFI	RW250-03-1	250 L (non-recyclable cubic container), 1 bag/carton



LePure Biotech

Building 1-3, No.269, Rongxin Road, Songjiang District, Shanghai, China
Email: support@lepurebiotech.com

 www.lepurebiotech.com

LePure Biotech LLC

2200 West Park Drive, Suite 300, Westborough, MA 01581, USA
Email: contacts@lepurebiotech.com

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