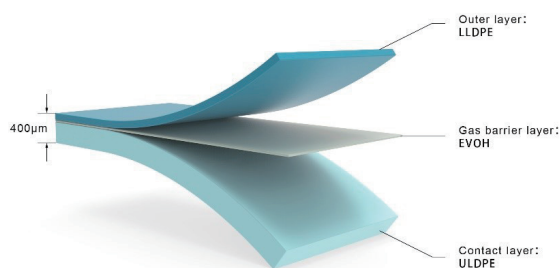


LeKrius® Single-use Bioreactor Bag

LePhenix® single use bioreactor bags are made using LePure's own LeKrius® film with excellent biosafety, chemical compatibility and physical properties to provide a suitable growth environment for upstream cell cultures, while the disposable technology reduces the risk of contamination during production. The LePhenix® single-use bioreactor provides precise control of the process parameters during the culture process. It can be adapted to other manufacturers' disposable reactors according to customer needs.



Film material information



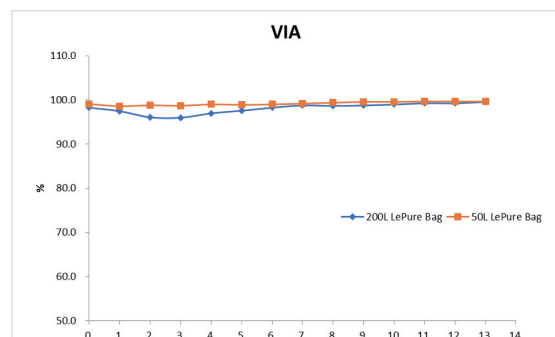
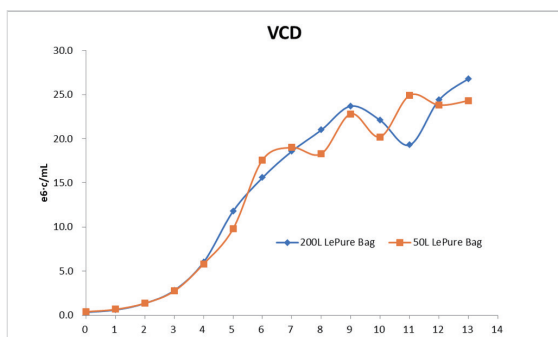
The film material is three-layer structure. LDPE is the outer layer, EVOH is the gas barrier layer. ULDPE is the liquid contact layer. The total thickness of 400µm. In order to fully guarantee good cell culture performance, the antioxidant Irgafos®168 was not used in the selection of LeKrius® film resins and formulations, and the film formulation was optimized to improve the physical properties of the film, including tensile strength, weldability, puncture resistance, and rubbing resistance.

Advantages

- ◎The amplification effect is excellent, and there are mature cases of 2000L amplification process.
- ◎The single use bioreactor bag adopts the classic stirring design, which greatly simplifies the process amplification process, reduces the risk of process transfer, and facilitates process transfer between different bioreactors.
- ◎The sealed design of the single use bioreactor bag prevents cross-contamination of the product and saves time during assembly, validation, in-situ cleaning and online sterilization operations.
- ◎Efficient oxygen supply, mixing, and CO₂ removal are possible, and these combined features ensure excellent cell culture performance and stable, high-density growth even for sensitive cell lines.
- ◎Disposable electrode solutions are available to reduce the risk of contamination during electrode installation.
- ◎Custom services are available.

Application

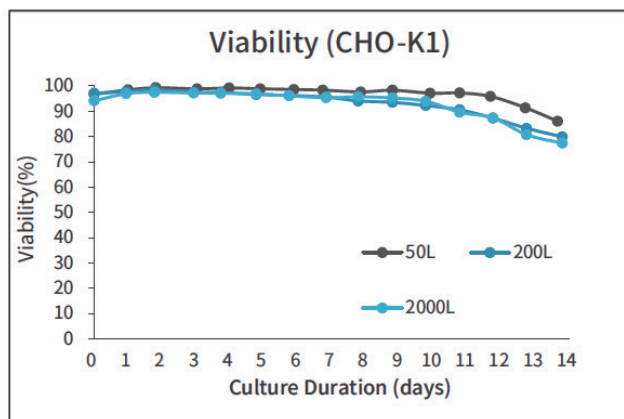
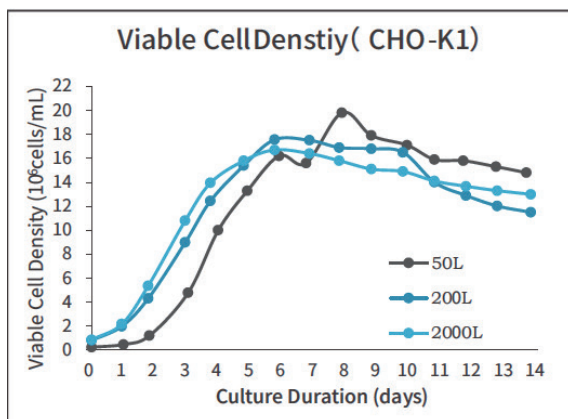
The LePhinix® single use bioreactor bag has been extensively studied, from cell culture testing to batch to batch stability of membrane materials. The experimental results showed that the LePhinix® disposable bioreaction bag could fully meet the cell culture of HEK293, CHO, SF9 and other cells with excellent performance.



Application case

The 50L and 200L Fed-Batch culture experiments of LePhinix® single-use bioreactor and single-use bioreactor bag proved that LePhinix® single-use reaction bag had good batch to batch consistency.

LePhinix®50-2000L CHO Cell Culture Experiment



LePhinix® single use bioreactor (50,200,2000 L) and LePhinix® single use bioreactor bag (50,200,2000 L) were used in this experiment.



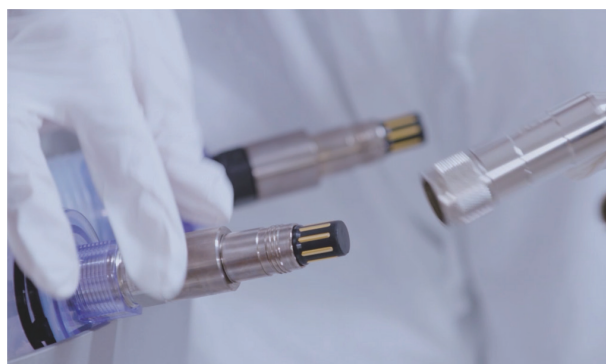
Quality Assurance

- ☑ **Manufacture:**The production site of LePhinix® single use bioreactor bags was certified by SGS, and obtained ISO9001 Jin2015 and ISO13485 Jin2016 quality management system certification
- ☑ **Packaging:**Proven packaging ensures product sterility and is designed to prevent collision and breakage
- ☑ **Install:**The bag body is designed for easy installation, with specialized sterile connectors to simplify sampling operations, and the relevant operating instructions are available for your reference
- ☑ **Disassembly:**The whole bag body can be easily disassembled by means of aseptic disconnection

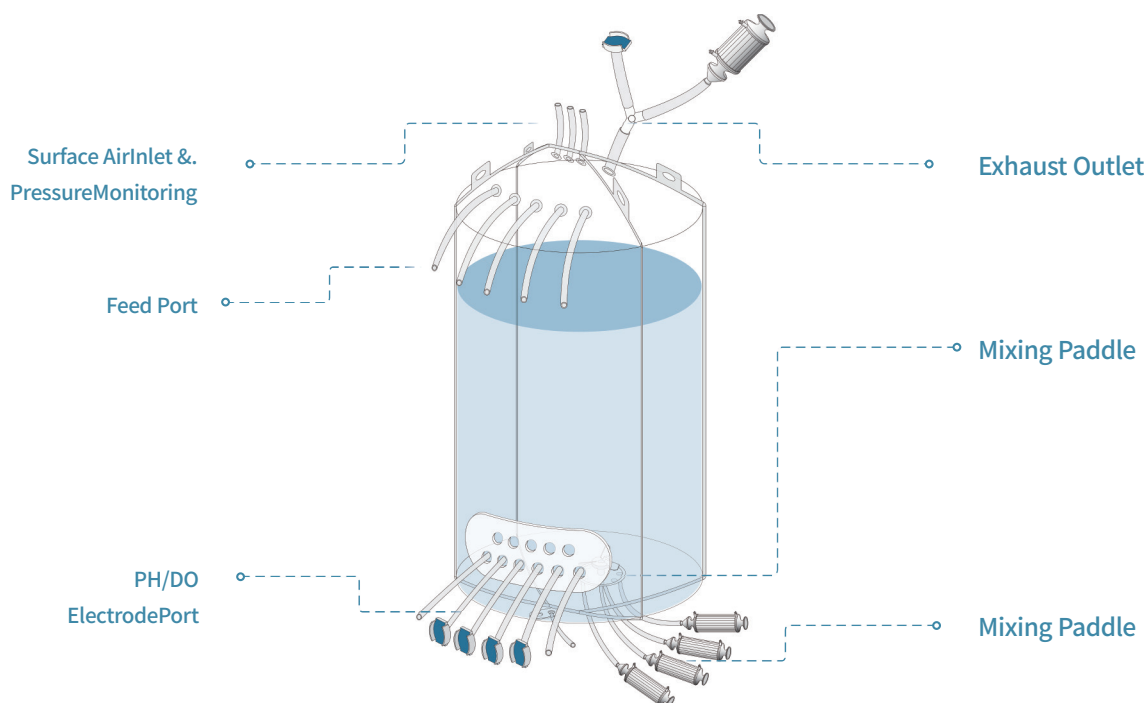
Leak detection of the bioreactor bag

LePhinix® Single-use bioreactor bags are 100% pre-factory leak tested to ensure the integrity of each product.

We provide special operating instructions for your reference, in addition, there are specialized technicians to support on-site installation testing.



Products Configuration



Composition of bioreactor bag	
Coupling assembly	KPC or CPC sterile connectors
pH/DO	Traditional or disposable electrodes from Hamilton, Mettler and other brands are available
Gas filter	PES or PVDF Gas filters (gamma irradiation sterilization. 0.2µm aperture)
Sparger	Ventilation disc :PE material; The ventilation line is equipped with a check valve to prevent liquid backflow and wet the air filter Vent plate :316 stainless steel, optional 2µm, 5µm, 20µm, 0.5mm, 1mm aperture The 1000L&2000L is available with the T-Sparger option for pCO2 reduction
Agitator	PP material
Tube	TPE and platinum vulcanized silicone tube

Product					
Art.No.	BL050-2K	BL200-2K	BL500-2K	BL1000-2K	BL2000-2K
Specification	50 L	200 L	500 L	1000 L	2000 L
Minimum culture volume	22	40	100	200	400
Max culture volume	50	200	500	1000	2000
Operating temperature	5-52°C				
Working pressure	0-50 mbar				
Diameter of paddle	240.8mm	240.8mm	260.8mm	315.5mm	420.8mm
Maximum stirring speed	200 rpm	200 rpm	150 rpm	140 rpm	120 rpm*

*Stirring direction up flow condition

Files/Tests

The LeKrius® single-use process bag product line has completed DMF registration and its (DMF) drug Master file.

FDA number: 037284

Validation Guide

The LeKrius® single-use bioreactor bags come with detailed validation guidelines to provide you with all the relevant information you need to support regulatory compliance.

Extractable guidelines

guidelines separately establish protocols for extractable testing and conduct extractable testing studies according to these protocols. USP<1665> and USP<665> single use bioreactor bags are provided with detailed extractable guidelines in combination with the categories and concentrations that can be extracted, and no high-risk substances were detected according to LeKrius® single-use bioreactor bags.

Operating manual

LeKrius® single-use bioreactor bags come with operating instructions for your installation.

Compliance testing

Pharmacopoeia compound

Test criteria	Test item	Result
USP<661>	Physico-chemical tests	Pass
E.P.3.1.5	Contact layer polyethylene	Pass

Biocompatibility

Test criteria	Test item	Result
ISO 10993-4	Hemolysis	Pass
ISO 10993-5	Cytotoxicity	Pass
ISO 10993-6	Implantation tests	Pass
ISO 10993-10	Irritation and Sensitization tests	Pass
ISO 10993-11	Acute Systemic Toxicity tests	Pass
USP<85>	Bactivity endotoxins-LAL tests	Pass
USP<87>	Biological reactivity tests, in vitro(Cytotoxicity)	Pass
USP<88>	Biological reactivity tests, in vivo, class VI	Pass
E.P.5.2.8	TSE/BES risk	Pass

Compliance testing

Test criteria	Test item	Result
ASTM F2095-07	Leak tests	Pass
ISO11137	Gamma irradiation	Pass
USP<788>	Insoluble Particles tests	$\geq 10 \mu\text{m} : \leq 10 \uparrow / \text{mL}$
		$\geq 25 \mu\text{m} : \leq 1 \uparrow / \text{mL}$
ASTM F1980-2016	Expiration Date	2 Years