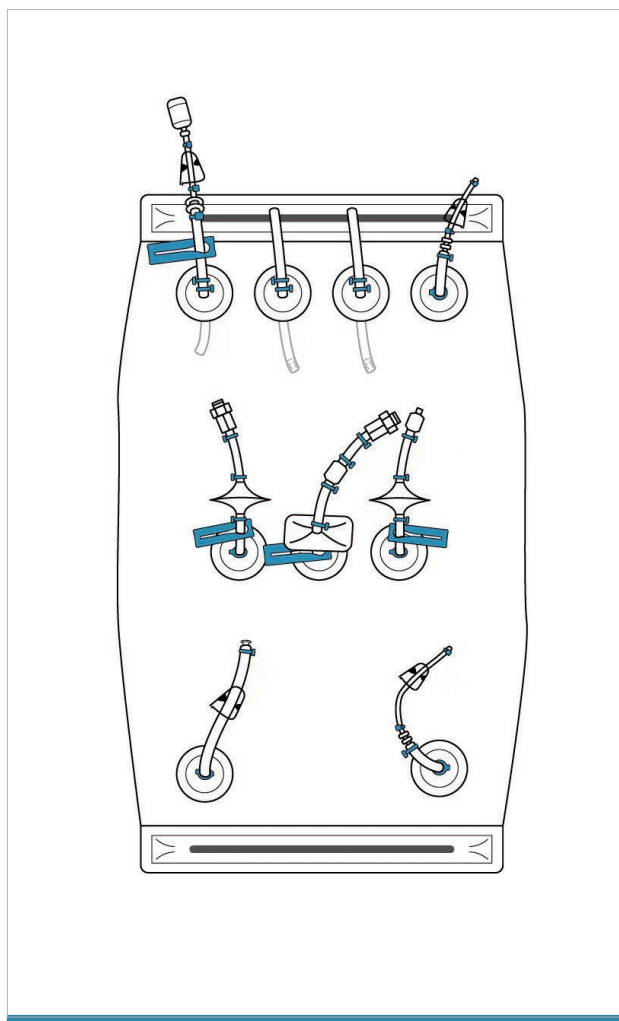


LeKrius® Rocking bioreactor Bag

The LeKrius® Single use Rocking Bioreactor Bag is designed to integrate seamlessly with the LePhinix® CCS Rocking Bioreactor. It delivers superior mixing and gas exchange performance for suspension and adherent cell cultures. Constructed from the high-performance LeKrius® Bioprocess film, it ensures exceptional biosafety and mechanical integrity, meeting the stringent demands of bioprocessing applications.



Advantage

- Enhanced cell culture performance
- Enables high-density perfusion culture with cell densities up to 100×10^6 cells/mL.
- Supports adherent cell culture with micro-carrier compatibility.
- Secured through a reliable and consistent supply chain.

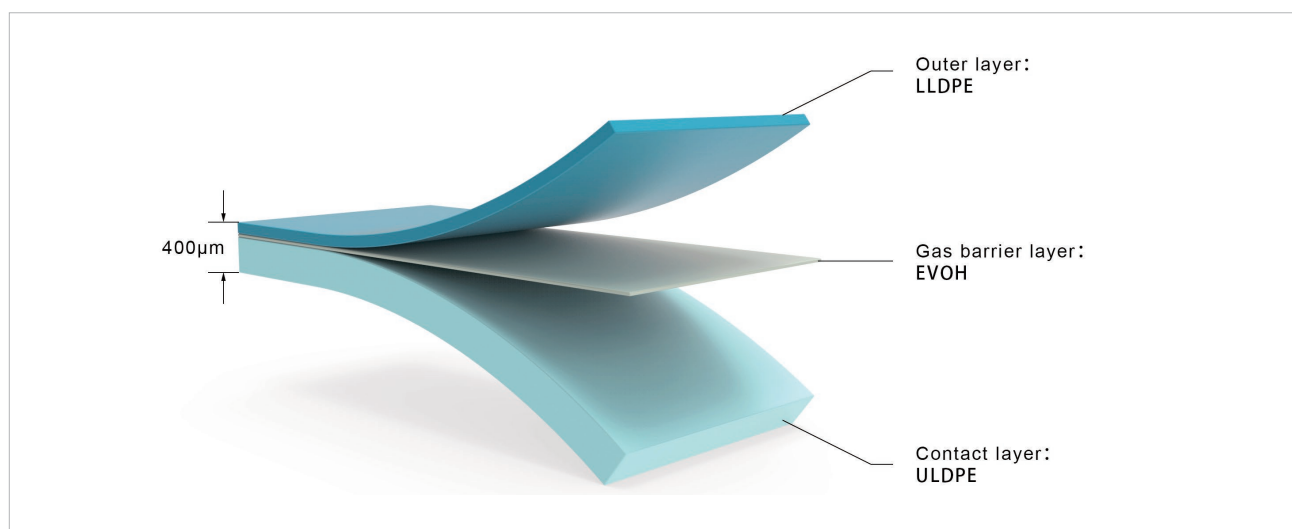
Typical applications

- Seed passage
- N-1 high cell density seed
- Construction of high density cell bank
- Perfusion manufacture

Cell type:

CHO, 293F, SF9 and other suspended cells
VERO, 293T, MSC and other adherent cells
(with LePure carrier)

Film material



Proven co-extrusion manufacturing process



Exceptional cell culture performance with extremely low levels of extractables / leachables.



Stringent biocompatibility tests.



Comprehensive and stable supply chain assurance with rigorous quality control.



Robust, bending resistance, anti-twisting, ensuring superior physical properties.



Compatible with bioreactors for linear, stepwise scale-up

TheLeKrius® Single use Rocking Bioreactor Bag, developed by LePure Biotech, features a proprietary three-layer construction tailored for advanced bioprocessing applications. The outer layer is composed of low-density polyethylene (LDPE), providing structural integrity; the middle layer incorporates ethylene vinyl alcohol (EVOH) for superior gas barrier properties; and the inner layer utilizes ultra-low-density polyethylene (ULDPE) to ensure biocompatibility at the liquid interface. With an overall thickness of 400 µm, this design optimizes cell culture performance.

To enhance biocompatibility, the formulation deliberately excludes the antioxidant Irgafos® 168, which has been associated with cytotoxic degradation products that can adversely affect cell growth. Additionally, the film's formulation has been refined to improve critical physical properties, including tensile strength, heat-seal integrity, puncture resistance, and abrasion resistance, thereby meeting the stringent demands of biopharmaceutical manufacturing processes.

Technical specification

Specification	Min.working	Max.working	Fitted tray
2L	200mL	1L	Tray10L or tray 20L
10L	1L	5L	Tray 10L or tray 20L
20L	2L	10L	Tray 20L
50L	5L	25L	Tray 50L

Pharmacopoeia compound

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

Biocompatibility

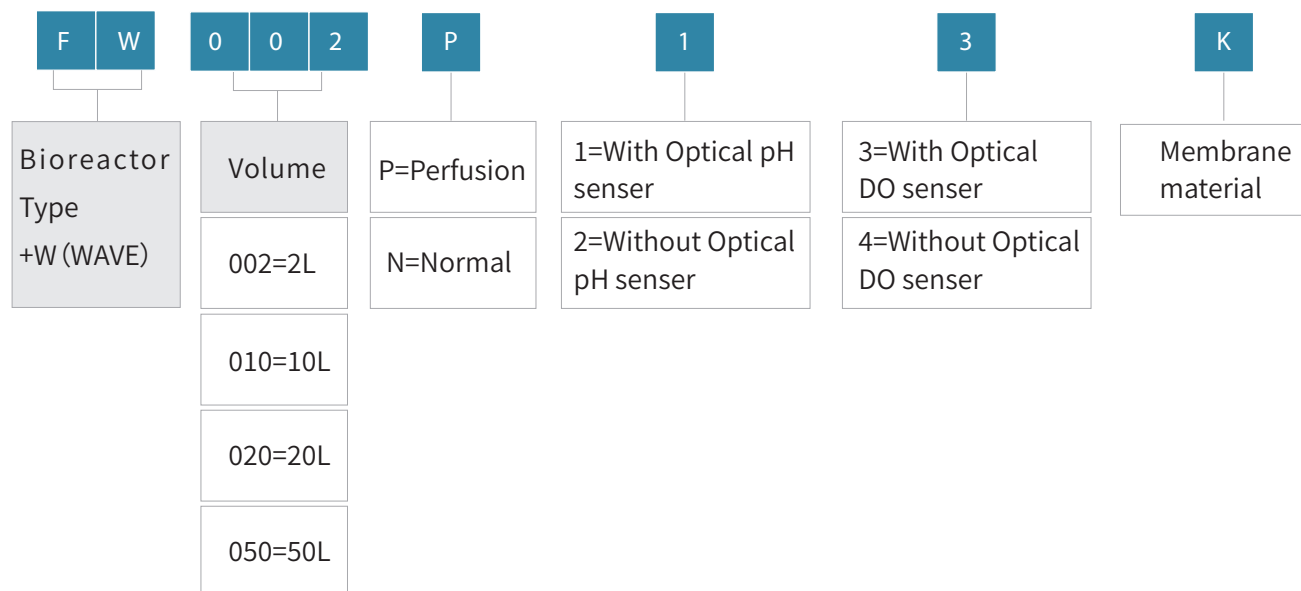
Test criteria	Test item	Result
ISO 10993-4	Hemolysis	Pass
ISO 10993-5	Cytotoxicity	Pass
ISO 10993-6	Implantation tests	Pass
ISO 10993-10	Irritation and Sensitization tests	Pass
ISO 10993-11	Acute Systemic Toxicity tests	Pass
USP<85>	Bactivity endotoxins-LAL tests	Pass
USP<87>	Biological reactivity tests, 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
ISO 11137	Gamma irradiation	Pass
USP<788>	Insoluble Particles tests	$\geq 10 \mu\text{m} : \leq 10 / \text{mL}$ $\geq 25 \mu\text{m} : \leq 1 / \text{mL}$
ASTM F1980-2016	Expiration Date	2 Years

Ordering information

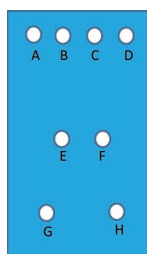
Pro NO.



2L BAG

Basic&With Optical Sensor	Basic	A+D+E+F+G
	With Optical Sensor	A+B+C+D+E+F+G
	Perfusion	A+B+C+D+E+F+G+H
	A	Sampling: 1/4*3/8 silicone tube+ needleless sampling
Perfusion	B	pH Optical Sensor
	C	DO Optical Sensor
	D	"Harvest: 1/8*1/4 C-Flex 100 cm"
	E	Air inlet filter
	F	Air outlet filter with check valve
	G	"Feed: 1/8*1/4 C-Flex 100 cm"
	H	"Perfusion (Interception plate) : 1/8*1/4 C-Flex 30 cm +1/8*1/4 BTPump tube 20cm 1/8*1/4 C-Flex 50cm"

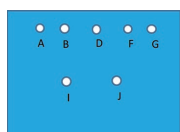
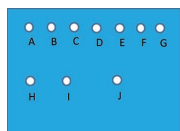
10L BAG



Basic	A+D+E+F+G
With Optical Sensor	A+B+C+D+E+F+G
Perfusion	A+B+C+D+E+F+G+H
A	Sampling: 1/4*3/8 silicone tube+needleless sampling
B	pH Optical Sensor
C	DO Optical Sensor
D	"Harvest: 1/8*1/4 C-Flex 100 cm"
E	Air inlet filter
F	Air outlet filter with check valve
G	"Feed: 1/8*1/4 C-Flex 100 cm"
H	"Perfusion (Interception plate) : 1/8*1/4 C-Flex 30 cm +1/8*1/4 BPT pump tube 20cm 1/8*1/4 C-Flex 50cm"

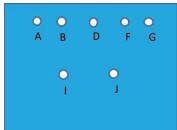
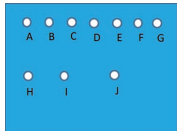
20L BAG

BASIC

Perfusion&With
Optical Sensor

Basic	A+D+E+F+G
With Optical Sensor	A+B+C+D+E+F+G
Perfusion	A+B+C+D+E+F+G+H
A	"Harvest: 3/8*5/8 C-Flex 100 cm"
B	"Feed: 1/8*1/4 C-Flex 100 cm"
C	pH Optical Sensor Sampling: 1/4*3/8 silicone tube+needleless sampling
D	DO Optical Sensor
E	"Feed: 1/8*1/4 C-Flex 100 cm"
F	"Harvest: 3/8*5/8 C-Flex 100 cm"
G	"Perfusion (Interception plate) :
H	1/8*1/4 C-Flex 100 cm (With needleless sampling) +1/8*1/4 BPT pump tube 20cm 1/8*1/4 C-Flex 40cm"
I	Air inlet filter
J	Air outlet filter with check valve

50L BAG

BASIC  Perfusion&With Optical Sensor 	Basic	A+D+E+F+G
	With Optical Sensor	A+B+C+D+E+F+G
	Perfusion	A+B+C+D+E+F+G+H
	A	"Harvest:3/8*5/8 C-Flex 100 cm"
	B	"Feed:1/8*1/4 C-Flex 100 cm"
	C	pH Optical Sensor
	D	Sampling:1/4*3/8 silicone tube+needleless sampling
	E	DO Optical Sensor
	F	"Feed:1/8*1/4 C-Flex 100 cm"
	G	"Harvest:3/8*5/8 C-Flex 100 cm"
	H	"Perfusion (Interception plate) : 1/8*1/4 C-Flex 100 cm (needleless sampling) +1/8*1/4 BPT pump tube 20cm 3/8*5/8 C-Flex 40cm"
	I	Air inlet filter
	J	Air outlet filter with check valve

Accessory Products

The LeKrius® Single use Rocking Bioreactor Bag can be equipped with an optional cell interception plate to support perfusion culture. This interception plate, made from polyethylene (PE) with a precise 7 µm pore size, effectively retains cells within the bioreaction bag while allowing the seamless passage of expressed products and metabolites.