

# LEPURE

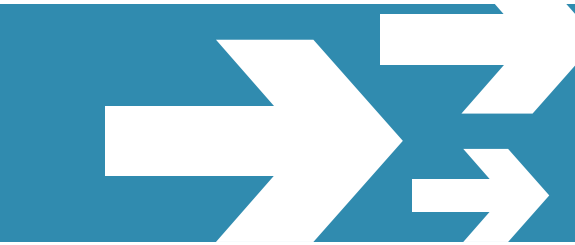
## LeKrius<sup>®</sup> Disposable Bioreaction Bag

### User Guide



上海乐纯生物技术有限公司





# Contents

◆	Description of the installation operation manual .....	2
◆	Unpack the LePhenix® Single-use Bag operation mode .....	2
◆	Equipment inspection .....	3
◆	Single-Use Bioreactors bags Installation .....	3
◆	Single-Use Bioreactors bags Inflatable operation .....	5
◆	Single-Use Bioreactors bags Installation test .....	8

## Description of the installation operation manual

We will take the LePhenix® Single-Use Bioreactors bags 200L as an example, explain the bag itself and how to install it into the tank container, and illustrate its function. This document takes the 200L Single-Use Bioreactors bag installation operation as an example, and basically the 50L-1000L is also suitable for these operation methods. If a model / specification requires a special operation, the difference is indicated accordingly. For more information, please contact [www.lepure-biotech.com](http://www.lepure-biotech.com).



- Especially when installing Single-Use Bioreactors bag sizes 500L and 1000L (for example using a live ladder).
- Incorrect unpacking poses a risk of damage to LePhenix® Single-Use Bioreactors bags. To avoid the risk of damage, functional / operational failures, or defects due to incorrect unpacking, please follow all of the instructions provided here. To ensure proper unpacking, ensure that the Single-Use Bioreactors bag is correctly installed and operated without failure in the LePhenix® Single-Use Bioreactors, Observe all warnings and security information listed in the LePhenix® Action Instructions.

## Unpack the LePhenix® Single-use Bag operation mode

LePhenix® Single-Use Bioreactors bag is the core key consumables. A standardized design was used, However, the connection can be customized according to the customer's request. All Single-Use Bioreactors bags were gamma-ray sterilized. All openings, connections, and pipes installed on the Single-Use Bioreactors bag are equipped with clips.

Perform the following checks before the operation:

### 1 Outer packaging and label inspection



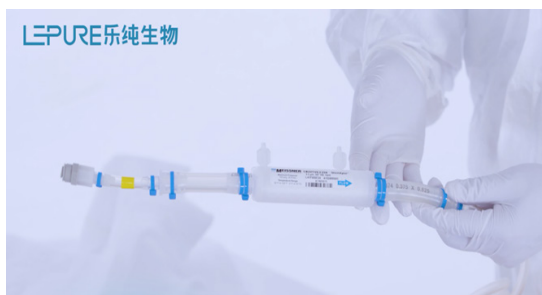
- Visually inspect the bag body for damage;
- Visually check the bag body for stains and clean it if necessary;
- Visual inspection of bag label is red (sterilized).

### 2 After removing the outer packaging



- Check all lines and hoses for damage and are properly installed;
- Remove the outer package and internal foam pad, and clamp the pipe clip on the pipe road in time.

### 3 Check the ventilation filter



- Check that all lines and intake filters are damaged and directed correctly;
- Check whether the air filter is damaged and remove the plastic packaging of the air filter.

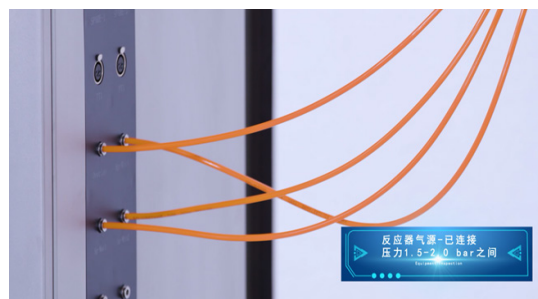
## Equipment inspection



- In the Single-Use Bioreactors, if the water pipe or trachea is not installed correctly, it may loosen accidentally !
- Note that the control cabinet power cord and other lines have high voltage !
- Only Lepure after-sales service technicians can install bioreactors and perform initial startup procedures !
- After upgrading maintenance or repair, always check the line connection to ensure safety and equipment installation and normal operation !
- Follow the instructions of Lepure service technicians, and according to the steps described here, all users can transport and install by themselves!

LeKrius® Disposable Bioreactor Bags are the core critical consumable in bioreactors. Standardized design, but its connections can be customized according to customer requirements. All reaction bags are gamma sterilized. Therefore, the openings, connections and pipes installed on the reaction bag are equipped with clips.

### 1 4 trachea (6mm) connections



- Check the air path for damage;
- Check whether the air path is connected to the intake unit and surface ventilation device at the bottom of the bioreactors bag and is correctly installed.

### 2 Inside the tank cleaning



- Check the tank for foreign matter;
- It can be cleaned with 75% alcohol and dust-free rags.

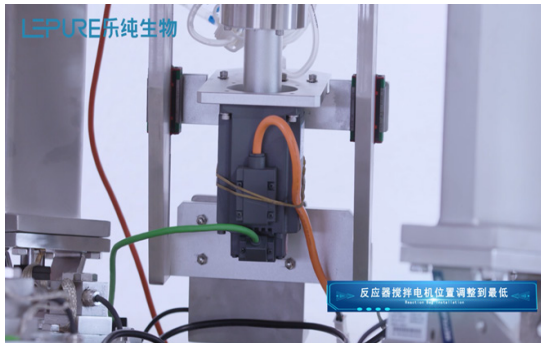
## Single-Use Bioreactors bags

### 1 4 trachea (6mm) connections

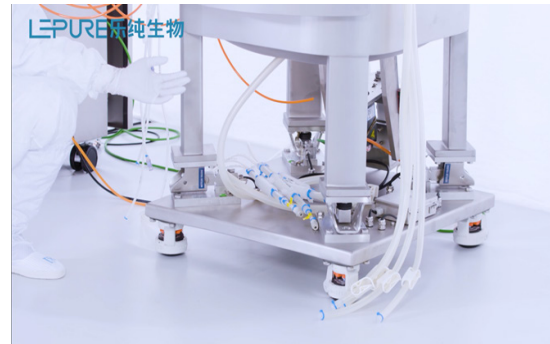


- The bag body can be tiled on the table or clean area, to arrange the pipe, to be installed.

2 Lower the motor position



- The upper and lower positions can be adjusted through the motor button;
- Adjust the motor to a minimum before installing the bioreactors bag.



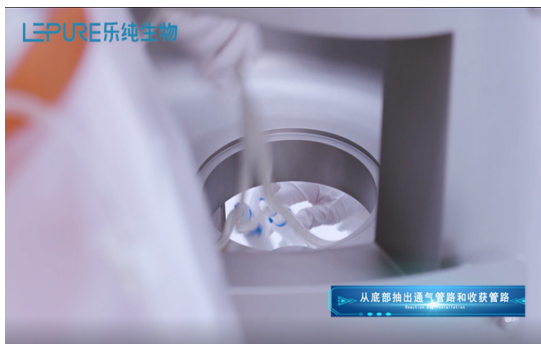
- Place the bottom ventilation filter on the bioreactors bag tray, bypass the motor section and place below;
- Place the bioreactors bag harvest line and baffle at the bottom of the tank;
- Keep the bioreactors bag tray as close as possible to the bottom of the round hole and coupled to the motor;

3 Open the front door



- Remove the plug pin on the bioreactors tank door and move the handle to open the front door.

4 Location of ventilation lines and harvest lines



5 Organize the bioreactors bag pipeline and its location



- After the bioreactors bag can be erected, the pipe can be attached to the bracket;
- Adjust the position of the bioreactors bag, try to correct, and adjust after inflation.

### 6 Adjust the position of the baffle and the electrode fast interface



- Adjust the baffle of the electrode port;
- Attach the sampling, electrode CPC \* 4, and temperature joint to the baffle.

### 7 Heating blanket communication interface



- Ensure that the interface for the heating blanket is installed;
- Cover the air filter on the bioreactors bag to a heating blanket;
- Attach the integral filter to the exhaust gas bracket.

### Single-Use Bioreactors bags Inflatable operation



- Incorrect inflation rate can damage the distributor and the bioreactors bag !
- To avoid damage to the distributor and bioreactors bag, the inflation rate (total gas flow) shall not exceed 0.1vvm !
- Incorrect use and inflation carries the risk of damaging the bioreactors bag !

### 1 Pressure Sensor



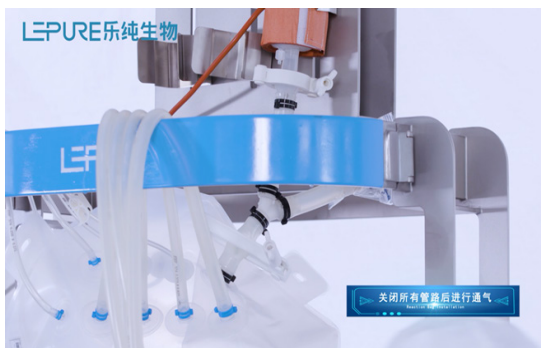
### 2 Tracheal pipe connecting overlay



### 3 Connecting sparge



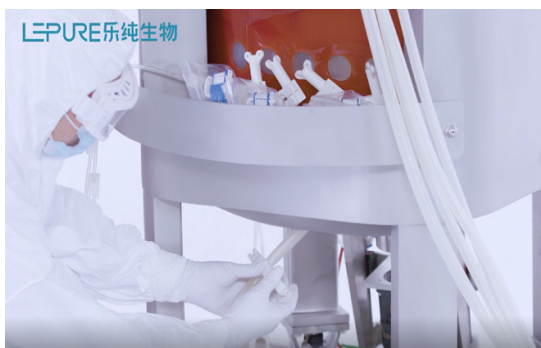
### 4 Clip and tightening of the tail gas pipe



### 5 Clip the CPC electrode



### 6 Clip the harvest

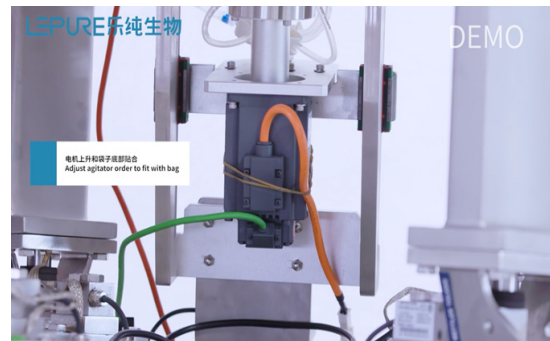


- Ensure that the pressure sensor connector is connected to the control cabinet and then connect the Overlay to the pressure monitoring line;
- Connect the sparge on the ventilation disc;
- Clip the exhaust line, and the CPC electrode silicone line and the harvest line, and open the Robert clip on the ventilation line to fill it up.

### 7 Clip the harvest tube



### 8 Slowly rising the motor



- Set the ventilation rate by using the touch screen and clicking on the ventilation module;
- Inflation by overlay and sparge;
- By observation, the bag body can be inflated to 40% of the total volume;
- Determine the position of the bioreactors bag, and finally couple the motor slowly rising to the bottom ventilation disk for the final fixed position. During the slow rise of the electrode, pay attention should be paid to the position of the bottom ventilation tubes and the magnetic stirring electrode to prevent friction.



- The lifting motor shall be operated slowly during installing the bioreactors bag !



9 Inflatable completion, the exhaust pipeline is opened



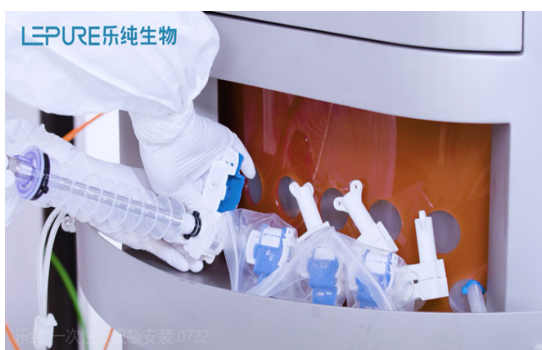
10 Inflatable completion, Open the clip on the CPC



11 Prepare the electrode sterile connection



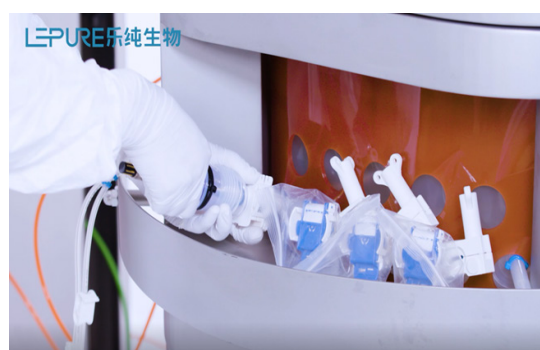
12 Electrode docking



13 Pull CPC diaphragm

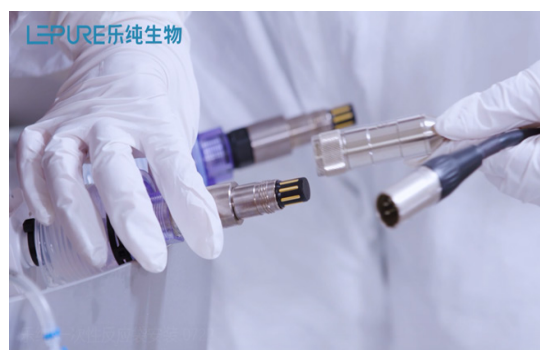


14 Electrode is inserted into the bioreactors bag

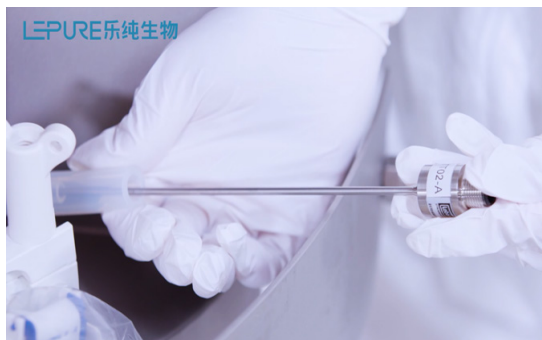


- Inflatable completion, Remove the clip on the exhaust end and CPC interface end;
- The bioreactors bag was prepared for sterile docking with the pH and DO electrodes;
- First, rotate the pull shield of the CPC and the bioreactors bag CPC upward, align the two joints, and slide them together;
- Independent squeeze on both sides of the joint, until the "CPC click" sound is heard, and simultaneously extract the CPC diaphragm at both ends, to complete the sterile docking;
- Then push the sterile electrode in the bellows slowly into the fixed position of the bioreactors bag.

15 Connecting the electrode signal line



## 16 Connecting the temperature electrodes



- Install the pH, DO, and temperature electrode communication signal lines;
- After the inflation and electrode installation are completed, the reaction bag can be safely used.

## 3 Setting of process parameters



- Add liquid or medium (liquid higher than electrode);
- Set and open process parameters such as temperature, stirring, ventilation through touch screen operation;

## Single-Use Bioreactors bags Installation test

### 1 Material and fluid test



### 2 Full load test





# LEPURE



Wechat

## LEPURE

**China Shanghai LePure Biotech Co., Ltd.**

Building 3, 410 Yunzhen Road, Songjiang, Shanghai, China 201600

Email: [marketing@lepure-bio.com](mailto:marketing@lepure-bio.com)

Website: [www.lepure-bio.com](http://www.lepure-bio.com)

Tel: 021-37635888

**United States LePure Biotech LLC**

300 Baker Ave. Suite 300, Concord, MA 01742, USA

Tel: +1 (415)755-7486 +1 (608)692-1988

Version No.:20220909