

Xuri W25 CellBag

Instructions for Use

Introduction

Important

Read these instructions carefully before using the products.

Intended use

The products are intended for research use only, and shall not be used in any clinical or in vitro procedures for diagnostic purposes. Xuri™ Cellbags are single-use bioreactors designed to function with Wave 2/10, Xuri Cell Expansion Systems W5 and W25 and support the in vitro expansion of cells. Optical sensors are only enabled on the Xuri Cell Expansion System W25.

Precautions and Disclaimer

1. Do not use if visible defects or foreign particulates are observed in the CellBag™
2. Do not use Xuri Cellbag beyond the expiration date indicated on the product label.
3. All claims of Xuri Cellbag W25 in regards to performance were validated in combination with the Xuri W25 Cell Expansion System.
4. For further manufacturing use only. Not intended for any therapeutic or diagnostic use in human or animals.
5. Do not use internally or externally in humans or animals.

Safety warnings and precautions

For use and handling of the products in a safe way, refer to the Safety Data Sheets.

All cell culture solutions should be disposed of according to local requirements.

We therefore recommend this product is handled only by those persons who have been trained in laboratory techniques and that are used in accordance with the principles of good laboratory practise. Wear suitable protective clothing such as safety glasses and gloves.

These products are not suitable for "direct" animal or human diagnostic or therapeutic applications as the products supplied are neither IVDs nor medicinal products. Customers using the products in a formulation or cell culture procedure can use the material under "For Further Manufacture" claim of the intended use statement.

The product meets USP<1043> 'ancillary materials for cell, gene, and tissue-engineered products', within the responsibilities applicable to a supplier. Cytiva cannot fulfil USP<1043> in regards of application and therapy specific aspects (e.g. use in finished therapeutic, assessment of removal from a finished therapeutic and possibly biocompatibility, cytotoxicity or adventitious agent testing)

Storage

Upon receipt Cellbags should be stored at 10°C to 50°C. Handle and store unopened bags with care. Avoid rough handling and store them in a cool dry location where the products will be protected from direct sun and physical damage. For Cellbags containing pH and DO sensors; do not remove Cellbag from the original packing until ready to use. The black outer packaging will protect the sensors from degradation by UV light.

Product Description

Xuri Cellbags are single use bioreactors supplied in a protective outer plastic packaging. The entire contents of the Cellbag have been sterilized by gamma irradiation. No sterilization or cleaning of the Cellbag is required prior to use. The cell contact surface is an FDA approved ethylene vinyl acetate (EVA)/low density polyethylene copolymer of the type routinely used for blood collection and handling of biological fluids. Outer layers are made of proprietary composites that provide strength and extremely low gas permeability.

Please take a few moments to familiarize yourself with the features of Cellbags, shown in [The Cellbag bioreactor, on page 1](#). The final format will have all or some of the described features, depending on the product ordered.

The Cellbag bioreactor

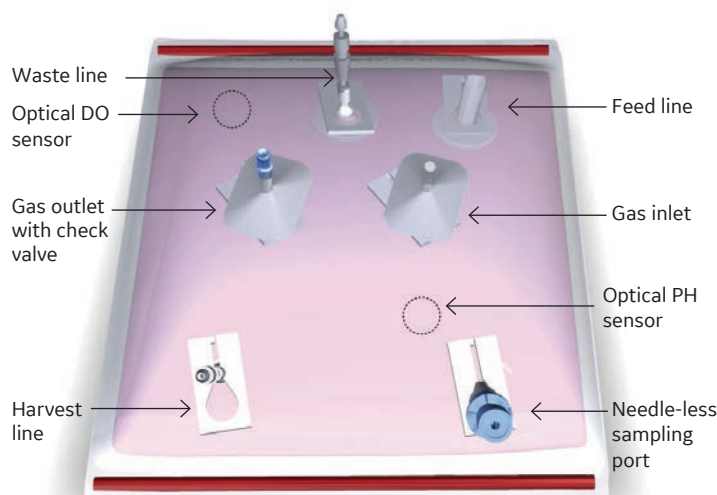


Fig 1. Standard Cellbag layout

Features

Port	Description
Needle-less Sampling Port	This port is equipped with a self-sealing Luer fitting for easy sampling using a conventional sterile syringe. The syringe is attached directly to the port for simple and effective removal of the cell sample.
Gas Inlet Filter	The hydrophobic gas inlet filter has a pore size of 0.2 microns. The filters are rated to remove airborne particulates of 0.2 microns or larger. Gas is required to inflate the Cellbag and to provide gas exchange with growth medium during cell expansion.
Gas outlet filter with pressure control valve	The pressure release valve is attached to the gas outlet filter. The purpose of the release valve is to maintain pressure inside the Cellbag bioreactor regardless of inlet gas flow rate.
Feed, waste and harvest lines	Silicone tubing is provided attached to the feed, waste and harvest lines for direct connection to the peristaltic pumps. PVC tubing is supplied with a direct connection to the silicone tubing. PVC tubing has been added for easy sterile connection to waste and medium supply bags. To ensure sterility is maintained, the PVC tubing is terminated with a standard Luer connector.
pH and DO sensors	The Cellbag bioreactor may be equipped with optical sensors for monitoring of pH and dissolved oxygen (DO). The sensors are light sensitive and should therefore be protected from excessive light. The sensors are located in the center of the sensor port on the Cellbag bioreactor and must be coupled to a sensor adapter.

Preparing the system for Use

This section describes how to attach the Cellbag to the bioreactor and prepare for cell cultivation. For detailed instructions and illustrations on preparing the Xuri Cell Expansion System W25, refer to User Manual.

Select Tray and Cellbag bioreactor

Select the appropriate combination of tray and Cellbag bioreactor depending on experimental demands and system configuration. The below table provides a guide on tray and Cellbag selection.

Table 1. Selection of Tray and Cellbag

Cell culture volumes (L)	Recommended Cellbag bioreactor size (L)	Tray
0.3 to 1	2	Tray 10, Tray 20
0.5 to 5	10	Tray 10, Tray 20

Note: To achieve optimum temperature control at low liquid volumes it is critical to keep the lowest rocking angle possible that is sufficient to attain adequate mixing of nutrients/waste and aeration of the culture.

Preparing pH and DO sensors (if required)

Follow the instructions below to connect the sensor adapters to the pH and Dissolved Oxygen (DO) sensor ports located on the underside of the Cellbag.

Step

Action

1

Carefully remove the Cellbag bioreactor from its protective outer packaging.



NOTICE
Intense light will deteriorate the optical sensors on the Cellbag bioreactor. To avoid unnecessary light exposure, remove the protective black bag just prior to use.

2

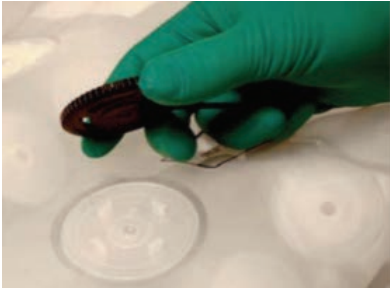
Place the Cellbag bioreactor on a steady, clean surface, free from particulates or sharp objects and with the bag sensor ports facing upwards.



NOTICE
The optical sensor spots have different colors. The spot on the pH sensor bag port is WHITE and the spot on the DO sensor port is PINK/BLACK. If both pH and DO sensors are used, a separate fiber-optic cable is needed for each sensor.

3

Attach the sensor adapter, with the optical lens facing the sensor port located on the Cellbag, by inserting the four pins of the port into the corresponding four holes of the adapter.



The sensor adapter can be fastened in any of four orthogonal directions. Select the most convenient direction aligned to the direction the fiber optic cables will run.

Step Action

- 4 Rotate the sensor adapter clockwise to fix the pins on the sensor port to the sensor adapter. A distinct "click" will indicate that the adapter is securely fastened. Check the sensor adapter does not rotate freely.



NOTICE

When rotating the sensor adapter, make sure not to place any force on the fiber cable. Avoid introducing kinks into the fiber optic cables.

- 5 Place the Cellbag bioreactor on the tray with the optical sensors facing downwards.



NOTICE

Make sure that the optical fiber cables are not placed between the Cellbag bioreactor and the temperature sensor on the tray. This could lead to erroneous temperature reading and control, resulting in overheating.

- 6 To keep track of the optical fiber cables, mark the cables with the supplied labels.
- 7 Bundle the optical fiber cables together and place them in the tubing exit. Refer to User Manual.
- 8 Connect the fibre optic cable from the pH sensor to the pH port on the front panel of the Cellbag control unit CBCU, see below.



- 9 Connect the fibre optic cable from the DO sensor to the DO port on the front panel of the CBCU.



Attaching the Cellbag bioreactor to the Tray

Follow the instructions below to attach the Cellbag bioreactor directly to the tray.

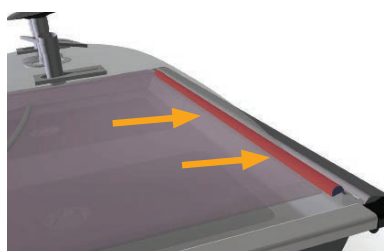
Ensure the Cellbag is oriented so that the feed and waste lines are situated at the top end of the tray.

Step Action

- 1 Remove the Cellbag from the outer packaging. Do not pierce the packaging with a sharp object.
- 2 Place the Cellbag on the tray. Orientate the Cellbag so the feed and waste lines are situated at the top end of the tray.
- 3 Push down the Cellbag clamp release in one upper corner of the tray. This opens the upper Cellbag clamp.



- 4 Insert the upper Cellbag rod into the open Cellbag clamp.



- 5 Push the Cellbag clamp release upwards to secure the upper end of the Cellbag bioreactor into the clamp, securing the Cellbag onto the tray.



NOTICE

If the Cellbag is not secure, it will be difficult to clamp once inflated and will move on the tray during rocking.

Note:

Check the Cellbag is secured by gently pulling on the Cellbag.

- 6 Repeat steps 1–3 on the lower half on the tray and Cellbag. Confirm the Cellbag is securely attached to the tray.

Attaching the filter heater and gas system

- Step

Action
- 1

Attach the filter heater to the outlet gas filter of the Cellbag bioreactor.



The image below shows the filter heater mounted on the stand on the Cellbag bioreactor.



- 2

Connect tubing from the GAS MIX OUT on the CBCU front panel to the inlet gas filter of the Cellbag.



Load silicone tubing

Follow the instructions below to load the silicone tubing in the pumphead.

All silicone tubing recommended for use on the Xuri W25 should have a wall thickness 1.6 mm (1/16"). The table below specifies the appropriate tubing inner diameters (ID) for the two pump head positions.

Refer to user manual for instructions on how to change the tubing holder position.

Tubing ID (mm)	Tubing ID (inches)	Tubing holder position	Use this position for Cellbags
0.5	1/50	Inner	
0.8	1/32	Inner	
1.6	1/16	Inner	29105492 29105494 29105498 29108442
2.4	3/32	Inner	
3.2	1/8	Inner	29105493 29105495 29105499

Tubing ID (mm)	Tubing ID (inches)	Tubing holder position	Use this position for Cellbags
			29108443
4.0	5/32	Outer	
4.8	3/16	Outer	



NOTICE

If the tubing holder is set for smaller ID tubing (inner position) when larger ID tubing is connected, flow rate and tubing life will decrease. If the tubing holder is set for larger ID tubing (outer position) when smaller ID tubing is connected, there is a risk of rupture and wandering of the tubing.

Insert the silicone tubing with the red label into the feed pump. Insert the silicone tubing with the yellow label into the waste pump. Use the silicone tubing with the blue label to harvest the culture.

- Step

Action
- 1

Make sure that the pump is switched off.
- 2

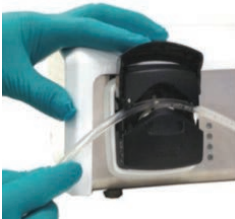
Open the flip top of the pumphead.



- 3

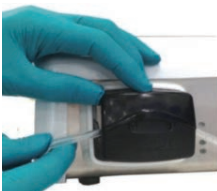
Adjust the tubing holder to the correct position for your size of tubing.
- 4

Place the tubing over the rotor rollers between the tubing guides located at either side of the pumphead.



- 5

Lower the flip top until it clicks into its fully closed position.



Note:

The pumping direction is clockwise.

Step	Action
6	Place the lid on top of the tray.
	 NOTICE Ensure that the liquid lines and fibre optic cables are correctly located to avoid pinching or trapping.
	 NOTICE Keep the Cellbag bioreactor covered with the lid throughout the duration of cultivation to protect the optical sensors from excessive light exposure.

Filling the Cellbag

It is strongly recommended that the medium is allowed to reach room temperature before filling the Cellbag fitted with pH and DO sensors.

How to avoid and remove bubbles

Set the tray to an angle of 12 degrees and fill with room temperature medium. If air bubbles form around either or both of the sensors, they can be removed by firmly flicking or shaking (sometimes rather harshly) the sensor from the underside. This requires that the Cellbag is released from the attaching mechanism of the tray, and the fiber cable should be disconnected.

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