Xuri™ Cellbag™ bioreactor

Xuri Cellbag bioreactors are single-use, functionally closed bags that provide a suitable environment for the rapid expansion of cells during cultivation while minimizing the risk of cross contamination. They are manufactured from multilayer, laminated, clear USP class VI plastics and require no sterilization or cleaning steps. Xuri Cellbag bioreactors are suitable for the manufacture of cellular immunotherapies using Xuri Cell Expansion Systems. They are available in a range of working volumes from 300 mL to 25 L and are supplied with the required tubing pre-attached to simplify set up.

Functionally closed environment

A functionally closed environment removes the need to open cultures during the expansion phase and minimizes the risk of contamination from operator intervention, adventitious agents, or between patient samples.

Automatable

Operations such as inoculation, harvesting, and media changes can be automated thus significantly reducing hands-on time and simplifying the culturing process.

Ready-to-use

Xuri Cellbag 2L and 10L are supplied with the required tubing pre-attached so they can be loaded onto your Xuri Cell Expansion System as soon as they are unpacked.

Designed for use in a regulated environment

Xuri Cellbag bioreactors are supplied with a detailed validation guide providing you with all the relevant information you need to support regulatory compliance.

Fig 1. Xuri Cellbag bioreactors are designed for use with Xuri Cell Expansion Systems.

Principles of operation

The Xuri Cellbag bioreactor is mounted onto a rocking platform attached to the base of a Xuri Cell Expansion System and inflated. Culture medium and cells are then loaded into the Xuri Cellbag bioreactor via ports on the bag surface. An electric motor in the base creates a rocking motion that induces waves in the cell culture fluid to provide efficient mixing and gas transfer (Fig 2). The motion, speed, and angle of the rocking platform can be adjusted to suit different cell types and culture conditions.

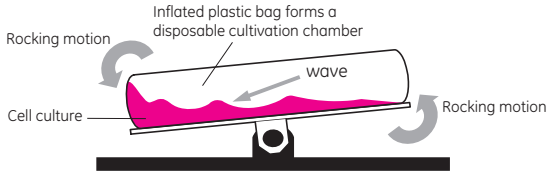

Fig 2. The wave action created by the rocking motion of the Xuri Cell Expansion Systems keeps the cells in motion and prevents settling in the Xuri Cellbag bioreactor.

If using the Xuri Cell Expansion System W25, process parameters such as temperature, pH, gas transfer, and flow rates are monitored by a range of optical sensors and controlled via UNICORN™ software. The resulting environment within the Xuri Cellbag bioreactor can easily support cell concentrations of 1×10^7 cells/mL, thereby producing enough cells for use in clinical manufacture as well as commercial production of cell therapies.

Components and materials of construction

Xuri Cellbag bioreactors are manufactured from multilayered USP Class VI plastics. The cell contact surface is an ethylene vinyl acetate (EVA)/low density polyethylene (LDPE) copolymer of the type routinely used for blood collection and handling of biological fluids. The outer layers are made of proprietary composites that provide flexibility, strength, and extremely low gas permeability (Table 1). Data are available to demonstrate biocompatibility. However, validation is recommended for specific applications.

Table 1. Standard Xuri Cellbag bioreactor components and materials

Component	Material
Film	EVA/LDPE fluid contact surface provides biological compatibility; external layers provide strength and low gas permeability
Barbed ports	Polyethylene
Luer-Lok™ connections	Polypropylene
Tubing adapters	Polypropylene
C-Flex™ tubing	Thermoplastic elastomer (medical grade)
Silicone tubing	Platinum-cured silicone
PVC tubing	PVC for sterile welding of feed and waste bags
Internal perfusion filter	Polyethylene, polyester, polypropylene, EVA
pHOPT sensor	Luminophore dye attached to a polycarbonate backing
DOOPT II sensor	Luminophore disc attached to a polycarbonate backing with silicone adhesive
Vent filter	0.2 µm acrylic housing
CLAVE™ connector	Polycarbonate, polyester housing, silicon

Optical sensing technologies

Optical pH (pHOPT) and Dissolved Oxygen (DOOPT II) sensors (Fig 3) are single-use "spot" sensors embedded into the Xuri Cellbag bioreactor for the highly accurate measurement of pH and DO. These sensors are supplied preinstalled and provide optimal process control when used with the Xuri Cell Expansion System, Xuri Cellbag Control Unit (CBCU), UNICORN software, and dedicated fiber-optic cables.

- Highly accurate measurements with minimal drift over time
- Single-use formats reduce setup time
- Optimized for minimum and maximum Xuri Cellbag working volumes
- Compatible with internal perfusion filter

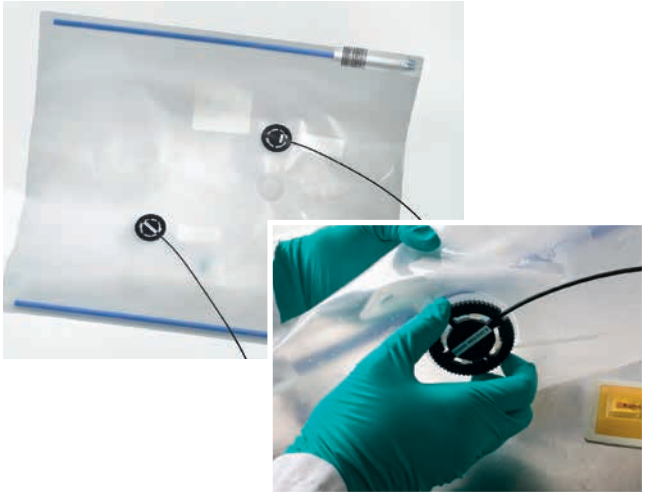

Fig 3. Xuri Cellbag adapter/optical fiber cables are attached to ports embedded in to the Xuri Cellbag bioreactor surface.

Table 2. Optical sensor specifications

pH measurement range	pH 4.5 to 8.5
pH control range	pH 6 to 8
pH accuracy within control range	±0.05 pH within 0.25 pH from offset calibration pH*
	±0.10 pH within 0.25 to 0.5 pH from offset calibration pH*

* Offset calibration should be done at the set point pH

Table 3. Optical dissolved oxygen sensor specifications

Dissolved oxygen measurement range	0% to 250% air saturation
Dissolved oxygen accuracy within control range	±3% air saturation after calibration at 100% air saturation

Operating specifications

The Xuri Cellbag bioreactor is designed to meet the following specifications:

- Operating temperature range: +10°C to +50°C
- Maximum operating pressure: 1.5 psig (0.1 bar)

Table 4. Xuri Cellbag working volumes

Bag size (L)	Minimum working volume	Maximum working volume (L)	System
2	300 mL	1	Xuri Cell Expansion Systems W5 and W25
10	500 mL	5	Xuri Cell Expansion Systems W5 and W25
20	1 L	10	Xuri Cell Expansion Systems W25
50	5 L	25	Xuri Cell Expansion Systems W25

Regulatory conformance

Xuri Cellbag bioreactors comply with USP <1043> "ancillary materials for cell, gene, and tissue-engineered products", within the responsibilities applicable to the supplier. Other aspects of USP <1043> will be the responsibility of the end-user to assess. GE Healthcare cannot fulfill USP <1043> in regards to 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).

Sterility and endotoxin

- Xuri Cellbag bioreactors are sterilized by gamma irradiation at 27.5 -40 kGy.
- Lot release requires < 0.125 EU endotoxin/mL detected per bag.

Ordering information

Product	Code number
Xuri Cell Expansion System Cellbag Basic 2L	29-1054-92
Xuri Cell Expansion System Cellbag Basic 10L	29-1054-93
Xuri Cell Expansion System Cellbag 2L pH and DO	29-1054-94
Xuri Cell Expansion System Cellbag 10L pH and DO	29-1054-95
Xuri Cell Expansion System Cellbag 20L pH and DO	29-1054-96
Xuri Cell Expansion System Cellbag 50L pH and DO	29-1054-97
Xuri Cell Expansion System Cellbag 2L Perfusion	29-1084-42
Xuri Cell Expansion System Cellbag 10L Perfusion	29-1084-43
Xuri Cell Expansion System Cellbag 2L Perfusion pH and DO	29-1054-98
Xuri Cell Expansion System Cellbag 10L Perfusion pH and DO	29-1054-99
Xuri Cell Expansion System Cellbag 20L Perfusion pH and DO	29-1055-00
Xuri Cell Expansion System Cellbag 50L Perfusion pH and DO	29-1055-01

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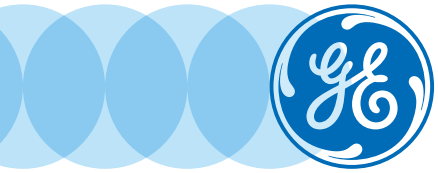

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