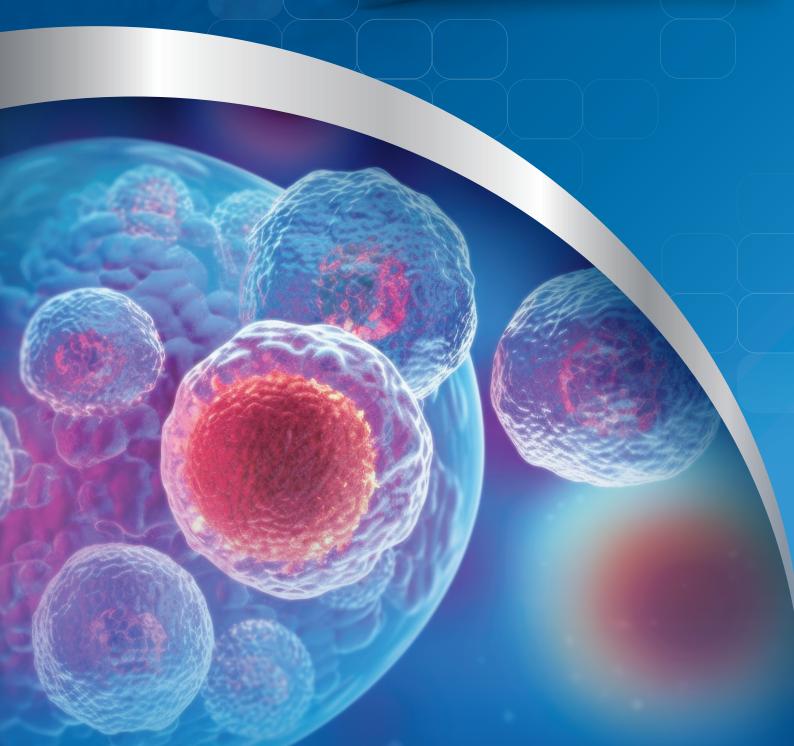


CelCradle X®

The Closed Automated Benchtop Cradle Bioreactor





CelCradle X®

The CelCradle X® (CCX) is a closed, automated single-use benchtop bioreactor that comes with its own fully automated harvesting system. Its design features an external Siemens HMI PLC control tower, automated parameter controls for pH and DO, and separation of the matrix (where packed-bed resides) and mixing vessel making it ideal for adherent cultures especially for autologous cell therapy applications.

The matrix vessel can accommodate packed-bed volumes from 0.1 – 0.3 L to achieve higher cell density yields. Choose from different Tide Motion macroporous carriers or your own for your next adherent cell expansion.

*cell yield may vary based on cell type, media used, process efficiency, and more.



CelCradle X® - Standalone Bioreactor (CCX-SB)

Features:

- Touchscreen Siemens HMI (Human-Machine Interface) control tower
- Single-use optical pH and DO sensor dots for parameter control and monitoring
- Culture in batch, fed-batch, perfusion, and 100% media exchange
- Culture in normal or hypoxic conditions
- Partnered with CelCradle® X Automated Cell Harvesting System (CCX-ACHS) for closed-system live whole cell harvest

CelCradle X® – **Isolator Integration** (CCX-ISIN)

Features:

- Dockable CelCradle X® unit with integrated Siemens HMI controller
- Customizable, adaptable design as per client's process flow requirements
- Work in an ISO Class 5 environment
- Integrated with independent hydrogen peroxide (H₂O₂) biodecontamination system
- Fully enclosed cell processing via third-party or Esco adherent cell-processing equipment integration





What's In It?

Main Chamber

Acts as a large CO₂ incubator that houses the matrix vessel, mixing vessel, feed/harvest-, glucose/alkali bags.

Glucose/Alkali Bags

Contains glucose/alkali solution for pH control

Main Chamber

Runs in 21 CFR Part 11-compliant software via an intuitive HMI. It controls the parameters needed to run the CCX unit.

Integrated with:

- Emergency stop button
- On/Off switch
- Four peristaltic pumps (feed, harvest)



Feed/Harvest Bags

Contains culture medium for the feed process as well as harvest bag for harvesting waste/conditioned media.

Run in:

- » fed-batch
- » perfusion mode

Matrix Vessel

Used to house the macroporous carrier/client's own carrier where cells reside

Mixing Vessel

Equipped with magnetic impeller for mixing. This is where the pH and DO optical sensors are located for pH and DO level monitoring and where tubings are connected for running a specific process mode.

Load Cell

- 1. Matrix Vessel Responsible for detecting the weight of the matrix vessel for the TideMotion® control.
- 2. Mixing Vessel Responsible for detecting the weight of the mixing vessel for perfusion process

Applications

- Autologous Adherent Cell Therapy
- cGMP Stem Cell Manufacturing
- Intracellular, Secreted Viral Vector or Virus Production
- Monoclonal Antibody/Secreted Proteins
- Exosome Production
- Adherent Cell Master Cell bank (MCB) or Working Cell Bank (WCB) Generation



CelCradle X® Automated Cell Harvesting System

Bridging the Gap to Scalable Cell Therapy with Automated Harvesting

The demand for manufacturing adherent mammalian cells such as Mesenchymal Stem Cells/Mesenchymal Stromal Cells/Medicinal Signalling Cells (MSCs), induced pluripotent stem cells (iPSCs), embryonic stem cells (ESCs), differentiated cells from pluripotent cells, fibroblast cells and others. This transition requires a shift from small-scale lab work to pilot-scale production and beyond accelerating as cell therapies rapidly advance toward commercial approval.

To achieve this essential increase in volume, automation is required across the entire workflow. However, most available solutions focus narrowly on upstream expansion, leaving a significant bottleneck in the downstream process, especially cell harvest. The **CelCradle® X-Automated Cell Harvesting System (CelCradle X® ACHS)** was designed to close this gap in cell manufacturing. Built for agility, ACHS provides a closed, automated solution that compatibly integrates with **CelCradle®X** and **CelCradle®** and capable of interfacing with various existing upstream platforms. It replaces inconsistent and labour-intensive manual methods with a standardized, closed, and efficient process.

The **CelCradle X® ACHS** is optimized to ensure gentle and efficient cell recovery from the TideMotion bioreactors, maximizing your yield and ensuring the viability of your final product.

Beyond Tide Motion bioreactors, the patented cell harvesting system can also be configured for adherent microcarriers in suspension bioreactors or potentially other packed bed bioreactors and cultureware working with Esco Aster Manufacturing Science and Technology department to perform the bio engineering and process development and validation.



Features:

- Single-use harvest assembly kit for closed, automated harvesting
- Harvest viable cells within 1-3 hours
- Heating incubator for harvest procedures that requires 20°C to 40°C
- Achieve >90% harvesting efficiency

Note: Harvesting efficiency will be dependent on the cell line used, media or enzyme used, process, etc.

Applications:

The **CelCradle X® ACHS** supports a wide range of applications across research, development, and industrial manufacturing, including:

- **Adherent Cell Therapy Manufacturing** Automated harvesting of autologous and allogeneic MSCs and other adherent cell types; harvesting adherent cells for cell derivatives such as cell derived nanovesicles, mitochondria, etc.
- **Seed Train Expansion** Biomass production for larger packed-bed or suspension bioreactors.
- **Process Development and Scale-Up** Ideal for optimizing harvest parameters, reducing variability, and validating GMP-ready processes.
- Ability to be configured for harvesting cells from microcarriers

The **CelCradle X**® **ACHS** leverages automation, flexibility, and process integrity to **streamline downstream workflows**. This reduces manual labour and provides a faster, more reliable path to **commercial biomanufacturing scale**.



How Does It Work?



Workflow:

- $1. \ \ \ Set the \ harvesting \ conditions \ (e.g., \ chamber \ temperature).$
- 2. Configure the harvesting recipe (washing, enzyme incubation, shaking, harvest,etc.)
- 3. Prepare reagents and buffers and fill them into single-use bags.
- 4. Install the consumables kit onto the system.
- 5. Place the **CelCradle**[®] or **CelCradle X**[®] vessel onto the holder.
- 6. Start the automated harvesting process.

Harvesting Recipe:

1. Removal of Culture Medium/Waste

• Existing medium or waste is pumped out of the vessel to initiate the harvest process.

2. Washing

- Add phosphate-buffered saline (PBS) or ethylenediaminetetraacetic acid (EDTA).
- The shaking motor generates a gentle vertical oscillation on the bottle.
- The wash solution is then pumped out.

3. Enzyme Incubation

- A dissociating reagent is pumped into the vessel.
- The rotating mechanism distributes it evenly.
- Incubation time is set according to optimized conditions.

4. Inhibitor Addition (Optional)

• An enzyme inhibitor may be pumped into the vessel if required.

5. Mechanical Shaking

• The system automatically performs vertical shaking of the vessel to further detach cells from the carriers.

6. Medium Addition

 Culture medium containing serum or trypsin inhibitor is pumped in to flush the cells.

7. Collection

• The suspension containing cells is collected into the harvest bag.

8. Repetition

- Steps 5–6 are repeated approximately five times to maximize yield.
- Cells are fully harvested from carriers then obtained via centrifuge.

Product Specifications

CelCradle X [®]	
Base Units	CelCradle X® Standalone Bioreactor (CCX-SB) Inclusive of: - CelCradle X incubator chamber - Siemens HMI control tower - Integrated load cell, pumps
	CelCradle X® - Isolator Integration (CCX-ISIN) Inclusive of: - Dockable CCX unit - Integrated control
Standard Consumables	
CCX-SUMAV-BN_	Matrix vessel pre-packed with BioNOC carriers
CCX-SUMAV-BM_	Matrix vessel pre-packed with BioMESH carriers
CCX-SUMIV	Single use mixing vessel inclusive of magnetic impeller
pH sensor	Single use optical pH sensor
DO sensor	Single use optical DO sensor
CCX-FHB-AC	Feed/harvest bag with sterile tubing connections
CCX-BG-AC	100 mL glucose or alkali bag

^{*}specifications subject to change

CelCradle X® Harvesting System (CCX-ACHS)	
External Dimension (W x D x H)	Chamber: 543 x 640 x 759 mm (21.38 x 25.20 x 29.88 in.) Harvest System: 928 x 380 x 822 mm (21.38 x 25.20 x 29.88 in.)
Power	Single phase 220 V, 50 Hz
Motor	Shaker motor
Capacity	CCX Matrix Vessel
Control	HMI 7" color



Scale Up Strategy For Manufacturing



Small Scale Autologous Production

Large Scale Allogenic Production



CelCradle X® Automated Cell Harvesting System (CCX-ACHS)



CelCradle X® and **TideXcell®** bioreactors can be integrated with Cell Processing Isolators

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Laminar Flow Straddle Units, Single and Double Laminar Flow Vertical Trolley

Pass Box Soft Wall Cleanroom Sputum Booth

Ventilated Balance Enclosure (VBE)

Weighing and Dispensing Containment Isolator (WDCI)

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