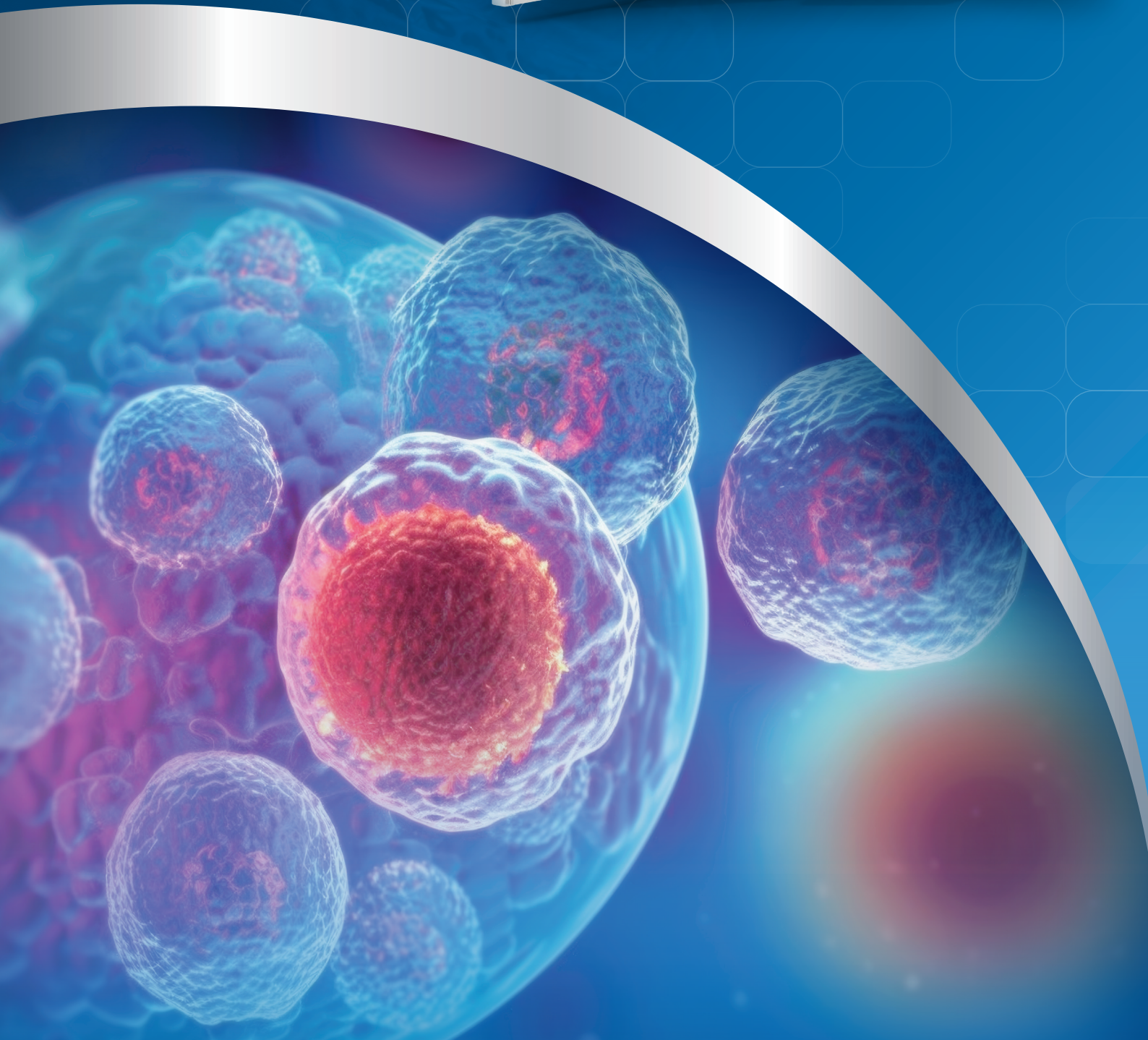


ESCO
HEALTHCARE



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

**design and specifications subject to change*

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

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

Control Tower

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)

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

The CelCradle X® Automated Cell Harvesting System (CCX-ACHS) is used to automatically harvest live whole cells in a closed horizontal manner, from the CelCradle X® matrix vessel through setting up culture harvest parameters. It can also be used for small scale process development for TideXcell® Automated Cell Harvesting System (TXC-ACHS).

The automated harvesting run involves set up from washing to harvesting live whole cells, with an efficiency of more than 90%. All major harvesting processes are standardized for increased cell harvest and viability, enabling the production of GMP-compliant cell products.

**harvesting efficiency may vary based on cell line, media, enzyme used, and etc.*



Applications

- Closed, automated process from rinsing to harvesting
- Mammalian cell harvest
- Biomass harvest for seed train, bioprinting, or cellular agriculture
- Intracellular virus harvest

Features

- Single-use harvest assembly kit for closed, automated harvesting
- Harvest viable cells within 1-3 hours
- Heating incubator for harvest procedures that requires 37°C
- Achieve >90% harvesting efficiency

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

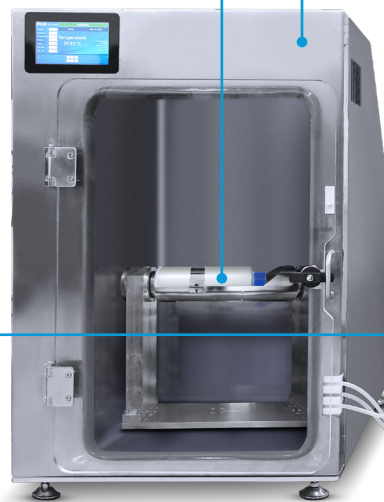
How Does It Work?

CCX-ACHS - Shaking Incubator Chamber

CCX Matrix Vessel

Placed within the incubator in a horizontal manner for efficient shaking during cell detachment step

Pinch Valve



**design and specifications subject to change*

Pinch Light Valve Indicator

Peristaltic Pump

Responsible for pumping media into and out of the bags as tubes are connected into a manifold to the CCX matrix

CCXACHS Assembly Kit

Includes the bag that will hold the rinse solution, enzyme, media, inhibitor, harvest, and waste, inhibitor bags into place

**the size of the bags will vary based on packed-bed volume used.*

Bag Hanger Rod

Emergency Stop Button

Stops operation at once when pressed

CCX-ACHS Controller

Controls parameters for the CCX-ACHS harvest run

Auxiliary Peristaltic Pump

(additional pump for back-up)

Harvesting Procedure

1. **Install.** Connect the tubing manifold to the CCX matrix vessel and input your parameters into the CCXACHS controller.
2. **Removal of Culture Medium/Waste.** Existing media or waste is pumped out of the vessel to initiate the harvest process.
3. **Rinse.** Cells are washed by adding **phosphate buffered saline (PBS) or ethylenediaminetetraacetic acid (EDTA)**. The system's rotary arms will rotate the bottle from left to right to distribute the PBS equally and slowly rinse the surface. The wash solution will be pumped out afterward.
4. **Enzyme.** Trypsin/EDTA (or other dissociating solution) is pumped into the vessel and will be gently distributed throughout the vessel via the rotating mechanism.
5. **Incubate and Inhibitor Addition** (Optional). After 15 minutes of incubation, an enzyme inhibitor will be pumped into the vessel.
6. **Mechanical Agitation.** Automatic vertical shaking of the vessel is performed to further detach the cells from the carriers.
7. **Add Medium.** Culture medium containing serum or trypsin inhibitor is pumped in to flush the cells.
8. **Collect.** Gather the solution with suspended cells into the harvest bag.
9. **Repeat steps 5-6 approximately 5 times.** Obtain cell pellet through centrifugation.

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

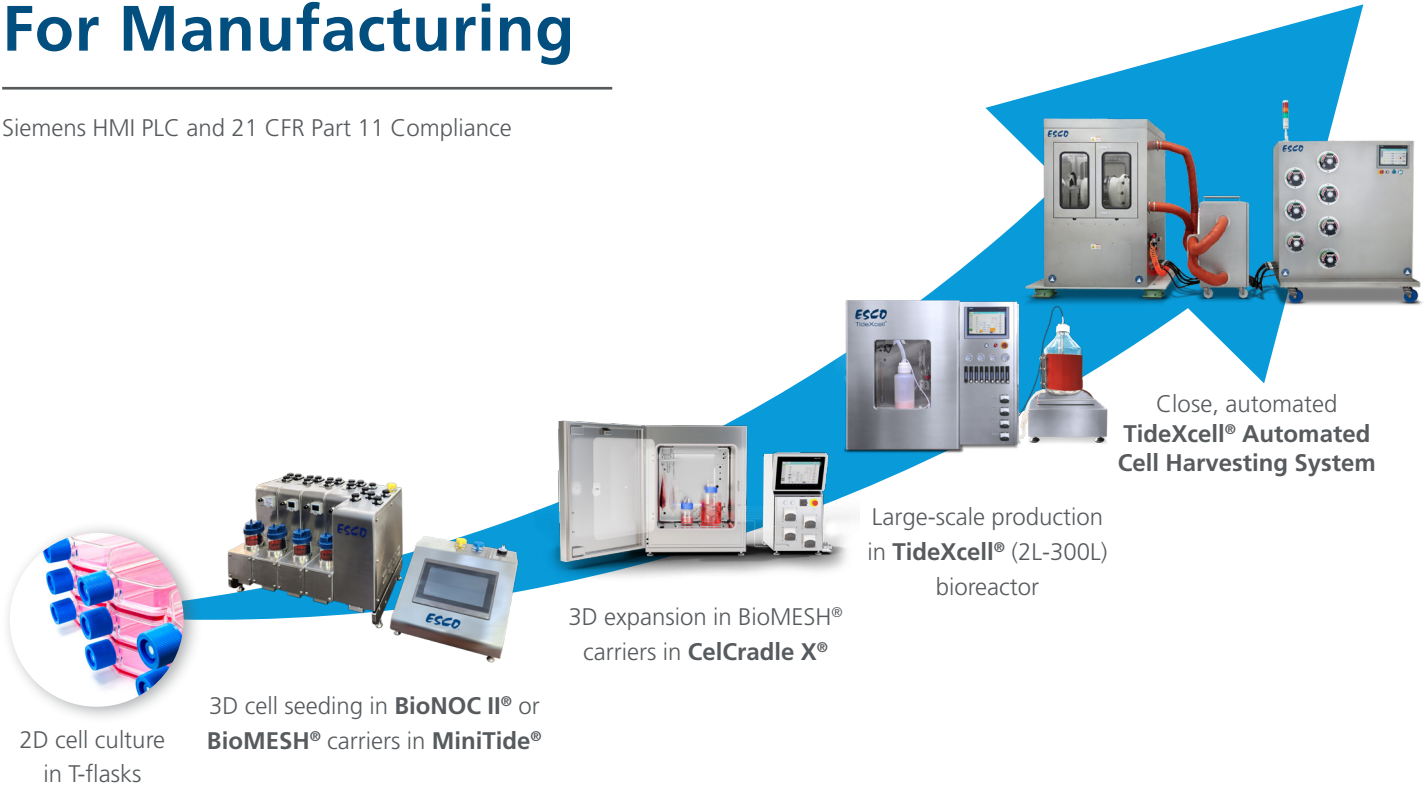
CelCradle X® Harvesting System (CCX-ACHS)	
External Dimension (W x D x H)	Chamber: 543 x 640 x 759 mm (21.38 x 25.20 x 29.88 in.) Harvest System: 928 x 380 x 822 mm (21.38 x 25.20 x 29.88 in.)
Power	Single phase 220 V, 50 Hz
Motor	Shaker motor
Capacity	CCX Matrix Vessel
Control	HMI 7" color

*specifications subject to change



Scale Up Strategy For Manufacturing

Siemens HMI PLC and 21 CFR Part 11 Compliance



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

ESCO LIFESCIENCES GROUP NETWORK

42 Locations in 21 Countries All Over the World



- Air Shower
- Aseptic Containment Isolator (ACTI)
- Ceiling Laminar Airflow Units
- Cleanroom Transfer Hatch
- Containment Barrier Isolator (CBI)
- Downflow Booth (DFB)
- Dynamic Floor Laminar Hatch
- Dynamic Pass Box
- Evidence Drying Cabinet
- Garment Storage Cabinet
- General Processing Platform Isolator (GPPI)
- Laminar Flow Horizontal Trolley
- 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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