

Cell Processing Isolator (CPI)



Cell Processing Isolator

The Esco Cell Processing Isolator (CPI) is an advanced aseptic containment system that combines several types of equipment into one isolation technology.

As a cGMP-compliant isolator, it is designed to isolate the process to ensure operator safety without compromising product quality. It provides a sterile ISO Class 5/Grade A environment that is required in carrying out sterile/aseptic cell processing.



Features:

- Customizable, adaptable design as per client's process flow and requirements
- The ULPA (U15) supply filters with measured efficiency of >99.9995% at 0.1 microns as per EN1822; provide superior ISO Class 5 air cleanliness as per ISO 14644-1
- Capable of automated pressure hold testing (APHT)
- Fully integrated BioVap™ Hydrogen peroxide (H₂O₂) based Biodecontamination System
- Laminar (Unidirectional) airflow (0.45 m/s air velocity) within work zone and pass chamber.
- Airlock pass chamber ensures work zone remains sterile during ingress and egress of items.
- The electromagnetic interlocking door mechanism with time-delayed ingress/egress control allows sufficient time for air purging to minimize transfer of contamination.
- Improved safe-change cuff rings enable glove change with zero risk of contamination.

Applications:

- Aseptic Processing
- Allogenic Cell Therapy
- Autologous Cell Therapy
- Biosafety/Animal Biosafety Level 3/4 Containment
- Cell Banking
- Cell and Gene Therapy

- cGMP Manufacturing
- Monoclonal Antibody Production
- Phase III Clinical Trial
- Protein Production
- Quality Control
- Vaccine Research
- Virus Production



Incubation System

Integration of Tide Motion
Bioreactors
(may vary based on customer requirements)



How does it work?

The CPI's design and configuration are highly dependent on the process flow described by each client. Every CPI unit is carefully designed upon consultations with the client and Esco's multi-versed team. This is a critical process in order for Esco to provide the optimal solution specific for the application, product, and requirements of each client. Overall, the goal is to optimize the delivery of high-quality biologics.

Our technical and application support team will be with you from design stage of the preferred cell processing containment technology, up to actual equipment production.



Unidirectional Process Workflow



Cell Processing Area

Integration of cell processing laboratory tools and equipment



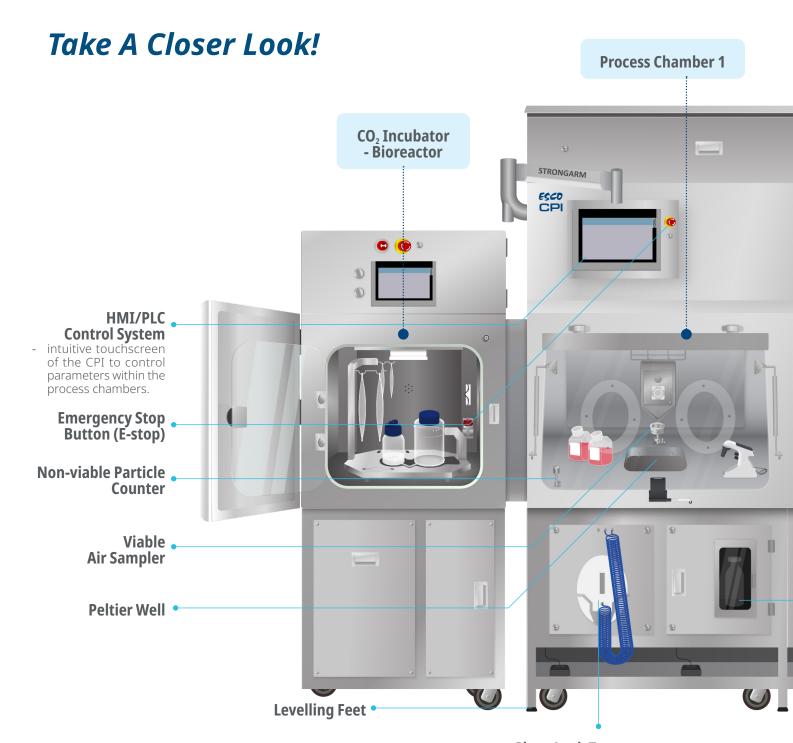
Monitoring and Harvest

Monitoring devices such as microscope and harvest systems are placed in this area



Final Product

Pass-through chamber for final product harvest and/or removal from the containment system



Note: Customizations may apply based on end user's requirement. This pre-set is for general culture process only. Contact Esco Sales Representative for more information

Glove Leak Tester

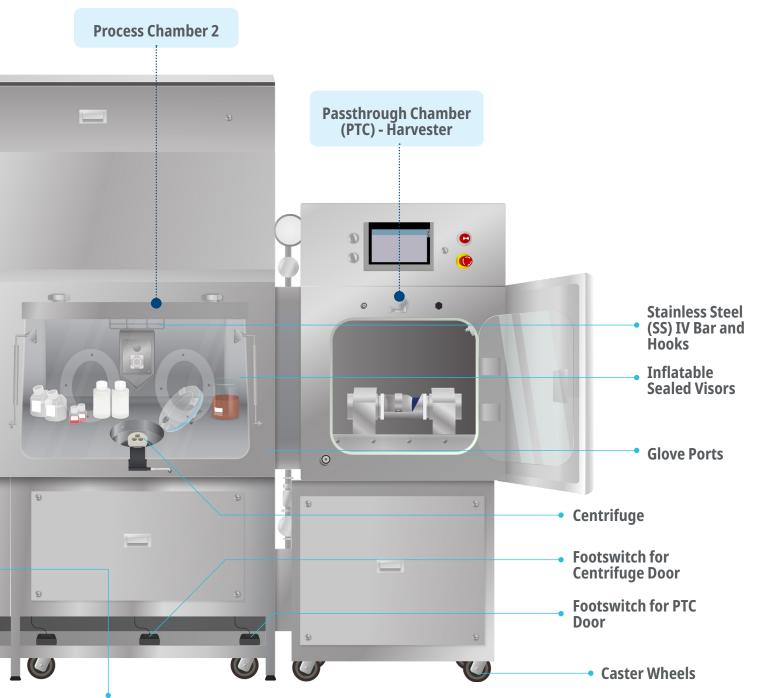
- an accessory that detects a leak in the glove under pressure test to check its integrity.

Optional Equipment Integration:

- Benchtop Freeze Dryer
- Benchtop Shaker
- Biobank
- Bioreactor

- Biosafety Cabinet
- Centrifuge
- CO₂ Incubator (with Docking/Undocking Capability)
- Cooling/Heating Well





BioVap™ Biodecontamination System

- a system that utilizes H₂O₂ sterilant as it is injected into the chamber space for decontamination for 6-log reduction of bioburden
- Laminar Airflow Cabinet
- Microscope
- Sieve
- Rapid Transfer Port (RTP)

- Rapid Decontamination System
- Refrigerator/Freezer
- Sterile Liquid Transfer Port

	Ge	neral Specifications
Cell Processing Isolator (CPI)		Specifications
External dimensions		The dimensions of the CPI are fully customizable based on the selected features; contact
Internal dimensions		Esco for more information.
Process Chamber Environment		ISO Class 5/ Grade A Environment for all chambers
Chamber Airflow Velocity		0.45 ± 20% m/s measured at 150mm below the entry plane
Airflow Regime		Unidirectional/laminar Airflow
Filtration	Pre-filter	M6 (as per EN 779:2012)
	Supply Filter	U15 with 99.9995% efficiency at Most Penetrating Particle Size (MPPS) as per EN1822:2009
	First Stage Exhaust Filters Second Stage Exhaust Filters	H14 with 99.995% at Most Penetrating Particle Size (MPPS) as per EN1822:2009
Lighting Level		≥500 Lux
Sound Level		≤ 80 dBA *
Chamber Pressure		Positive Pressure (+60 Pa ± 20% for Process Chamber and +60 Pa ± 20% for Passthrough Chamber) for Product Protection Application
		Positive Pressure (depending on client's requirement) for Operator Protection Application
Filtration	Glove Port	Oval, 200 x 300 mm as Standard.
		Circular 200 x 200 mm available as Optional
	Glove Sleeve System	Single-piece system, CSM/Hypalon, 0.4mm thickness
Control System		HMI 12" with PLC
Isolator Construction	External	2.0 mm SS304
	Internal	4.0 mm SS316 L
	Operating Panel	In-house SS304 (IP-20), 1.5mm thickness
	Chamber Glass Outer Door	10 mm (0.39") Tempered Glass
	Pass Chamber Inner Door	25 mm (0.98") Acrylic
	Door Seals	Silicone, Inflatable Seals, 21 CFR 177.2600 Compliant
Isolator Finish	External	≤ 0.4 Ra
	Internal	≤0.6 Ra
Electrical Requirement		110-120V, AC, 50Hz/60Hz, 1Ø
		220-240V, AC, 50Hz/60Hz, 1Ø
		480V, AC, 50Hz/60Hz, 3Ø
		Please contact Esco for other Electrical Requirement
Compressed Air Requirement		Minimum 6 Bar, Maximum 12 Bar, ≥ 200L/min
Optional Accessories		RTP Beta Container or Liner
		Gas Ports
		Non-viable Particle Counter
		Viable Air Sampler
		Sterility Test Pump Integration
		Balance Integration with Terminal/Display
		Integrated Refrigerated or non-Refrigerated Centrifuge
		Integrated CO2 Incubator (Permanently Docked or Dock-Undock)
		Integration of Liquid Waste Container
		Integration of Microscope
		Integration of Cell Counter
		Integration of Automated Drain Valve
		Aseptic Liquid Transfer Port
		Integration for Height Adjustable Local Operating Panel
		Upgrade for Industrial PC
		SCADA Integration to send isolator's sensor reading to client's BMS/EMS
		Integration with Peristaltic Pump
		IV-Bar or Hanging Rails
		Biosafety Cabinet
		Laminar Airflow Hood
		Latiniai Annow Hood



CUSTOMIZATION CAPABILITIES Cell Processing Isolator (CPI)

The Esco Cell Processing Isolator is designed around the evolving needs of advanced cell therapy manufacturing and cutting-edge research.

Built to support complex workflows, it delivers ISO Class 5 clean air protection, ensuring full product and operator safety during every critical step.

At the heart of the system is a clever closed-loop airflow and pressure control design, maintaining stable environmental conditions even during intensive processing. Every unit is built to comply with 21 CFR Part 11 requirements, featuring integrated audit trails, alarm logs, user authorization levels, secure data storage, and robust electronic record management





Constructed to meet full GMP standards, the isolator features a 4 mm SS316L internal liner with coved corners, creating a durable, easy-to-clean work zone that supports long-term use in demanding facilities.

What sets the Esco Cell Processing Isolator apart is its high level of customization, allowing clients to configure the system around their specific process steps and workflow needs. Available integration options include:

• CO₂ Incubator Integration

With or without bioreactor capability, fully controlled and seamlessly integrated for uninterrupted cell culture processes.

• Refrigerated Centrifuge Accommodation

Configurable for various bucket volumes, operating temperatures, and maximum speed requirements to meet diverse cell processing protocols.

• Microscope Integration

Ideal for real-time observation, colony assessment, morphological checks, and workflow efficiency.

• Weighing Balance Integration

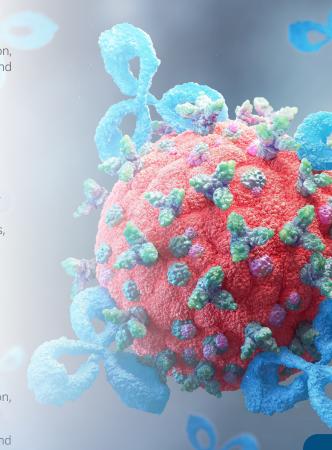
Ensures precise material measurement without compromising aseptic conditions.

• Docked and Undocked CO₂ Incubators

Compatible with interstitial transfer systems, with an option to include Esco's Rapid Decontamination System (RDS) for fast, validated biodecontamination cycles.

Every Esco Cell Processing Isolator can be tailored to fit your unique application, from research laboratories to clinical and commercial manufacturing suites.

Connect with Esco today to explore the ideal configuration for your process and transform your cell therapy workflow with confidence.





42 Locations in 24 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)

Since 1978, Esco has emerged as a leader in the development of controlled environment, laboratory and pharmaceutical equipment solutions. Products sold in more than 100 countries include biological safety cabinets, fume hoods, ductless fume hoods, laminar flow clean benches, animal containment workstations, cytotoxic cabinets, hospital pharmacy isolators, and PCR cabinets and instrumentation. With the most extensive product line in the industry, Esco has passed more tests, in more languages, for more certifications, throughout more countries than any biosafety cabinet manufacturer in the world. Esco remains dedicated to delivering innovative solutions for the clinical, life science, research and industrial laboratory community.







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