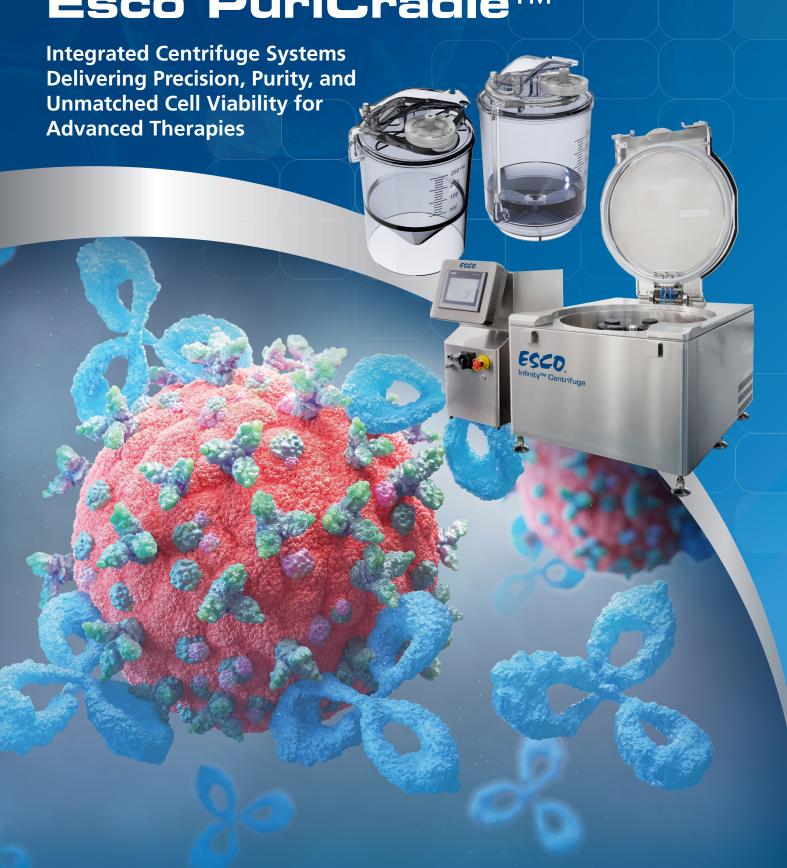


Esco InfinityTM & Esco PuriCradleTM



Esco Infinity™

cGMP Centrifuge for Cell Therapy Manufacturing

Introduction

The **Esco Infinity™ cGMP Centrifuge** is engineered to support a wide range of cell therapy unit operations, providing a seamless transition from traditional laboratory centrifugation into **fully closed**, **single-use processing systems**. It enables manufacturers to scale up with confidence while maintaining sterility, consistency, and regulatory compliance.

At the core of the Infinity™ platform is its **closed-system architecture**. The standalone design incorporates primary containment through **Puricradle™ closed single-use consumables**, which are housed within a sealed centrifuge bucket. The centrifuge chamber itself is **pressure-tested**, ensuring that particulates or aerosols cannot escape into the cleanroom environment. This significantly reduces crosscontamination risks and supports stringent GMP cleanroom requirements.



Key Advantages

• Full 21 CFR Part 11 Compliance

The Infinity™ cGMP Centrifuge operates on a validated **Siemens HMI/PLC platform**, ensuring electronic record integrity, audit trails, and secure user control in regulated manufacturing environments.

• Seamless Digital Integration

Optional connectivity with electronic batch record (EBR) systems and MES platforms—such as **DeltaV**[®], **PCS7**[®], **and other chain-of-identity/chain-of-custody systems**—supports data integrity, traceability, and end-to-end digital automation.

• Flexible Operation Modes

Designed for operational versatility, Infinity™ can function as a standalone centrifuge or be integrated directly with the **Infinity™ Cell Processing Workstation or Esco Cell Processing Isolators** for fully closed, GMP-compliant workflows.

• Open Platform for Customization

As an open centrifuge platform, Infinity™ supports customizable rotor, adapter, and bucket configurations, enabling users to tailor the system to specific process needs and vessel formats.

• Broad Consumable Compatibility

The system supports a broad selection of closed single-use consumables, including Esco Puricradle™ sets and qualified third-party options, enabling flexible operation across diverse cell processing workflows and volumes.



RUO to cGMP Product Evolution



Versati™ Centrifuge (RUO)

Designed for research laboratories requiring adaptability and ease of use.



Infinity™ cGMP Centrifuge

Purpose-built for GMP manufacturing with full regulatory compliance, closed-system capability, and integration readiness.

Applications

1. Mononuclear Cell Isolation

• Peripheral blood mononuclear cells from whole blood, bone marrow

2. Cell Enrichment for Specific Target Cells

- T Lymphocytes / T Cells are a type of white blood cells that play a key role in the immune system, particularly in the adaptive immune response. Subtypes include: helper T cells, cytotoxic T cells and regulatory T cells.
- **Dendritic Cells** are antigen-presenting cells (APCs) that are essential for initiating and regulating the adaptive immune response. They capture and process antigens, then present them on their surface to T cells, thereby activating them.
- Natural Killer Cells (NK Cells) are a type of lymphocyte that is part of the innate immune system. They provide rapid responses to viral infections and tumor formation. NK cells kill infected or transformed (cancerous) cells by detecting abnormal levels of major histocompatibility complex (MHC) molecules and recognizing stress signals on infected cells.

- Natural Killer T Cells (NKT cells) are a hybrid between T cells and NK cells, sharing properties of both. They recognize lipid antigens presented by the CD1d molecule, which is distinct from the usual MHC molecule involved in antigen presentation.
- **Gamma Delta T Cells (GDT Cells)** are a subset of T cells that have a unique T cell receptor (TCR) made of gamma and delta chains instead of the more common alpha and beta chains. These T cells recognize a broader range of antigens, including non-peptide antigens, and play a critical role in both the innate and adaptive immune responses.
- Cytokine-Induced Killer Cells (CIK Cells) are a subset of T cells that are expanded in vitro (outside the body) in the presence of cytokines like interleukin-2 (IL-2) and interferon-gamma (IFN-.) to enhance their cytotoxic activity.

These cells are capable of killing tumor cells and infected cells.

3. Cell Washing

- Cell washing prior to addition of cryopreservation
- Removal of cryopreservation media before infusion





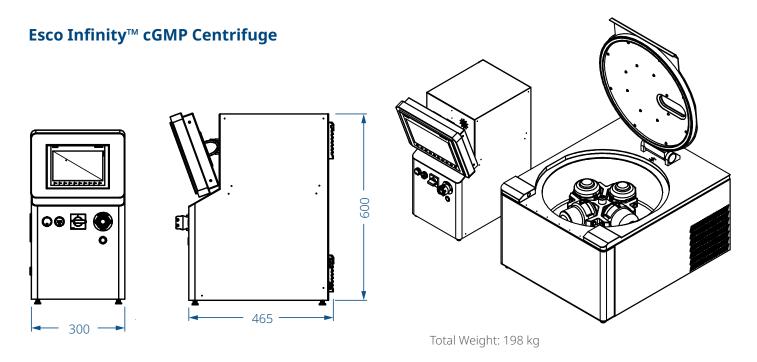






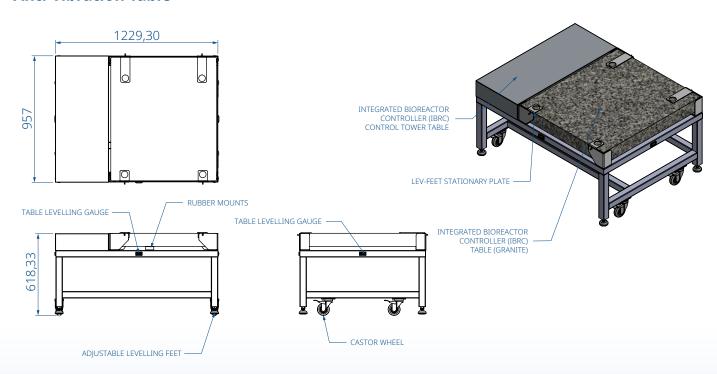


Equipment Footprint



Note: **Compressed Air Source:** The system is equipped with inflatable seal on the lid and pressure decay test feature.

Anti-vibration Table



A motorised trolley version can also be configured for ease of moving within cell processing facility.



Esco PuriCradle™

Streamlining Cell Therapy Workflow: Keeping Cells Viable in Every Spin



Esco PuriCradle™ is an open / closed system approach to cell isolation and purification in the field of cell therapy, reducing sample contamination risk from R&D to manufacturing. These cutting-edge instruments optimize processes while guaranteeing adherence to relevant regulatory requirements. Their versatility includes the ability to isolate and purify a variety of cell lines. Notably, they can also be used to separate peripheral blood mononuclear cells (PBMC) from whole blood, which is essential for the applications of CAR-T cell therapy.

The conventional methods for cell separation and washing pose challenges due to their labor-intensive nature and the increased risk of contamination associated with open system operations. Moreover, the intricate procedures often lead to decreased cell recovery and survival rates. In contrast, Esco PuriCradle™ provides a solution by facilitating the precise separation, washing, resuspension, and concentration of target cells within a sterile environment. This innovative system offers customizable process flows tailored to meet user requirements, thereby ensuring consistently high recovery rates.

Spinning blood in special tubes with a layered solution (density gradient centrifugation) allows for the separation and collection of PBMCs. This method keeps the cells sterile and yields a large

number of viable cells.

Features



Can be utilized across open and closed system options



Equipped with 0.22µm filter, ensuring no pressure differential is achieved



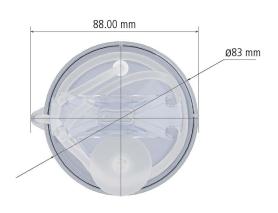
Upper and lower chambers for easier isolation of target cells



Top butterfly clamp design guarantees secure tubing fixation, preventing detachment even under centrifugation

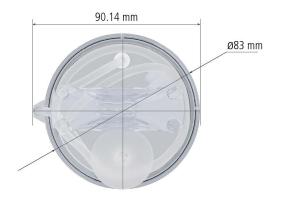
Separation Cup





Washing Cup





Applications

- Cell Isolation/ Enrichment (e.g. T Cells, NK Cells, M2 Macrophages, etc.)
- Isolation of PBMCs from whole blood/peripheral blood
- Isolation of bone marrow mesenchymal stromal cells (BM-MSCs) from bone marrow aspirate
- Cell concentration

- Cell washing
- Dimethylsulfoxide (DMSO) removal from cryopreserved cells
- Red blood cell separation
- Protein-based therapy from PBMCs
- Hematopoietic stem cell (HSC) therapy



Cell Processing Isolator (CPI) Integration

The Cell Processing Isolator (CPI) integrated with Infinity™ centrifuge enables seamless operation throughout the entire cell therapy process, from initial cell collection to final product preparation. It facilitates the isolation of products or processes while ensuring the necessary sterile or aseptic conditions required for cell therapy applications.



With the Esco CPI, procedures such as cell density gradient separation, washing, centrifugation, cell activation, harvesting, and preparation of the final product can be efficiently carried out. Moreover, it offers comprehensive protection for personnel, the product, and the environment, ensuring optimal safety and efficacy throughout the cGMP manufacturing process.

Features

- Easily customizable, depending on client's requirements
- Designed for cGMP Manufacturing of Cell, Tissue, and Gene Therapy Products (CTGTP)
- Modular and adaptable solutions for cell and gene therapy, tissue engineering, seed banking, and cell processing
- Integrates Esco PuriCradle™ cell centrifuge, separation, and washing cups
- Option of docking/undocking capabilites for CO₂ incubator or bioreactor (e.g. static bags/WAVE/Tide)
- Applicable for both autologous and allogeneic cell therapy applications

Esco Infinity™ Cell Processing Workstation

The Esco Infinity™ Cell Processing Workstation is designed based on Esco's certified biological safety cabinets. Integrated with Infinity™ centrifuge, this can support the entire cell therapy workflow. It offers unmatched convenience and safety, ideal for laboratory facilities, featuring an Ultra-Low Penetration Air filter (ULPA) filtration system with 10x the efficiency of HEPA filters. In addition, the technology is equipped with energy-efficient DC ECM that allows up to 70% energy savings versus AC motor.

Features

- Incorporates Siemens HMI/PLC technology
- Includes a shaking incubator for cell culture applications
- With viable and non-viable particle counter which offers monitoring capabilities for both living and non-living particles
- Option for docking/undocking feature of CO₂ incubator/bioreactor (e.g. static bags/WAVE/Tide)





Custom Adapter Solutions

These tools are meticulously engineered to ensure precise compatibility with Esco PuriCradle™ cups, catering particularly to clients utilizing centrifuges outside the Esco Infinity™.

Production of Mesenchymal Stromal/Stem cells and other adherent cell theraphy (E.g. Fibroblasts/Trophoblasts, etc..)

Infinity Centrifuge™ with PuriCradle™ is used in the cell-washing unit operation following automated cell harvesting of Mesenchymal Stromal Cells (MSCs) from Esco adherent Tide-Motion™ bioreactors.



Starting Cell Source

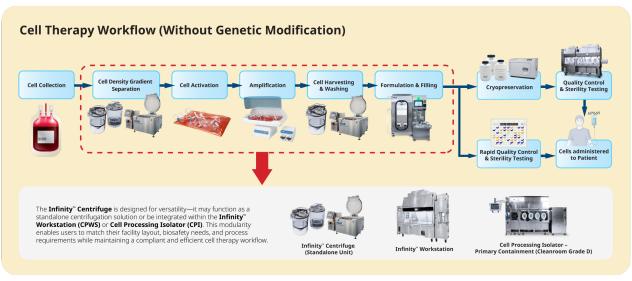
This table presents a comparative analysis between the two primary cell sources used in the manufacturing process of CAR-T Cell Therapy.

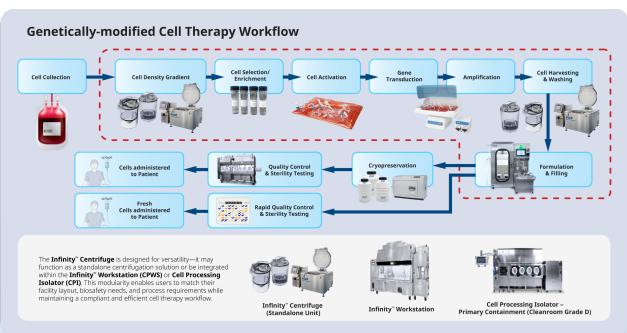
FEATURES	PBMCs	LEUKAPHERESIS
VOLUME	Lower volume/small quantity of highly potent CAR-X cells can be obtained App. 60 ml* * in a regular 450ml blood donation (buffy coat)	Larger volume can be obtained as it follows a selective collection process. App. 100 ml* * depending on absolute lymphocyte count and total blood volume to process per patient.
VASCULAR ACCESS	Requires standard phlebotomy procedures	Requires standard phlebotomy procedures but may also involve accessing large veins (e.g. internal jugular) for specialized collection tools such as central venous catheters.
INVASIVENESS AND COMPLEXITY	Less invasive procedure	Quite invasive and complex procedure
AVAILABILITY	More readily available as it can be obtained from routine blood donations	Requires scheduling and specialized equipment, making it less immediately available.
PLATELET/RBC CONTAMINATION	Potentially higher risk of platelet and RBC contamination due to standard phlebotomy procedures	Reduced RBC and platelet contamination due to selective collection via leukapheresis.
MATERIAL HANDLING	Easier to handle and process due to the smaller volume of blood collected.	Requires more complex handling and processing, including the use of apheresis machines for cell isolation/separation.
DONOR ATTRITION	Less invasive procedure, potentially leading to higher donor retention rates.	Quite invasive procedure which may result in donor attritions, especially if the donors find the process uncomfortable or inconvenient.
EXPERTISE REQUIREMENT	Requires highly skilled phlebotomist	Requires highly skilled phlebotomist and proficient in operating apheresis machines.
FACILITY REQUIREMENT	Requires facilities equipped for standard blood draw procedures and suitable for smaller-scale manufacturing processes, hence may not require highly specialized facilities.	Facilities need specialized equipment for leukapheresis procedures and typically performed in specialized centers with apheresis machines and trained personnel.
ADVERSE EVENTS	Mild, infrequent adverse reactions	Potentially more frequent, slightly severe adverse reactions
HEALTHCARE SERVICES	Out-patient setting which can lower overall cost	In-patient setting which may contribute to higher overall cost



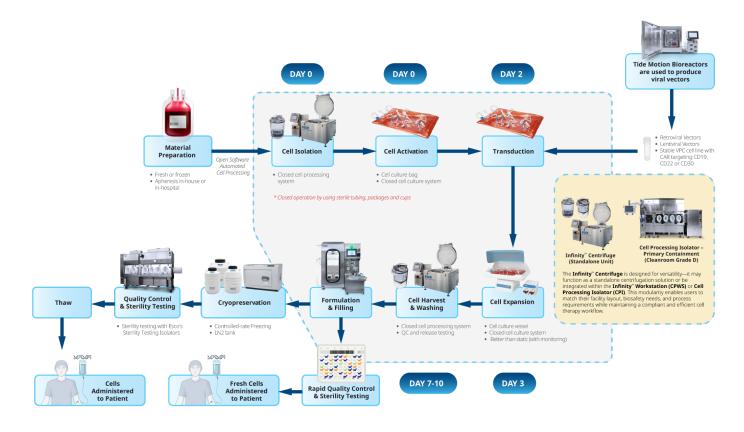
Autologous or Allogeneic Cell Therapy PBMC Separation **Cell therapy starting material from PBMCs:** Dendritic Primed Cell Therapy (E.g provenge), T Cell Reactivation (E.g. Tatmyctofusp-T, Krysaygio) PBMCs Centrifugation LSM Peripheral Blood Density **Gradient Centrifugation** Gene-Modified Cell Therapies (via gene-editing & gene-delivery platforms): CAR-T, CAR-NK, GDT, Tregs **Cell Therapies:** Cell Therapies: DC (Dendritic Cells), NK (Natural Killer Cells), NKT, CIK (Cytokine-Induced Killer Cells), LAK (Lymphokine-Activated Killer Cells), GDT (Gamma Delta T Cells), Tregs (Regulatory T Cells) Gene editing methods: CRISPR, TALEN, ZFN **Delivery methods:** mRNA, viral vectors, non-viral vectors (including plasmids, nanoparticles, electroporation, etc.) Cell Selection/Enrichment

Cell Centrifuge, Separation, and Washing Cup Closed System Applications: Immune Cell Therapy Products

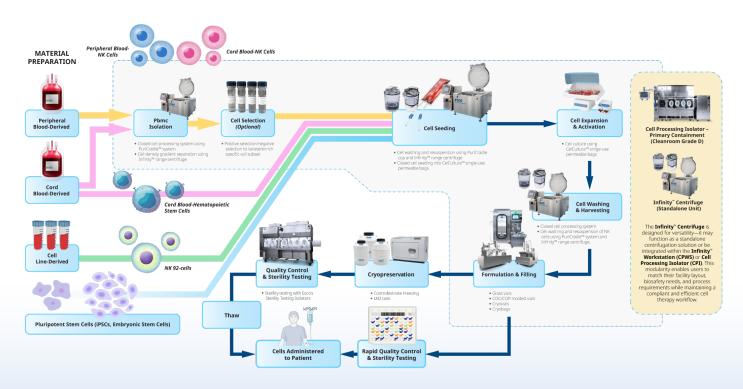




Esco Aster's cGMP CAR-X Cell Therapy Manufacturing Process



Esco Aster's NK Cell Therapy Workflow





Ordering Information

Item Code	Description
2220009	Infinity™, Benchtop Refrigerated Centrifuge (With Siemens HMI/PLC)
5220002	1 x Rotor Swing for PuriCradle™ Cups
5220003	1 x Rotor Swing for NanChac Tubes
5220004	1 x 250 ml x 4 Closed Buckets for PuriCradle™
5220005	1 x 500 ml x 4 Closed Buckets for NanChac
5220006	1 x 500 ml x 4 Standard Bucket
5220010	1 x 250 ml x 4 Standard Bucket
5220011	5 x 50 ml x 4 Standard Bucket
5220012	10 x 15 ml x 4 Standard Bucket
5220007	PuriCradle™ Separation Cup
5220008	PuriCradle™ Washing Cup
5220009	PuriCradle™ Custom Adapters
5220013	NanChac Cell Separation Tubes
5260120	Anti-vibration table

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- 6. Zanna, M. Y., Yasmin, A. R., Omar, A. R., Arshad, S. S., Mariatulqabtiah, A. R., Nur-Fazila, S. H., & Mahiza, M. I. N. (2021). Review of dendritic cells, their role in clinical immunology, and distribution in various animal species. International Journal of Molecular Sciences, 22(15), 8044. https://doi.org/10.3390/ijms22158044

Technical Specification

Item	Specification	
Whole System		
Weight	198 kg	
Dimension	1. Centrifuge (W x H x D) 649 x 461 x 790 mm 2. HMI Box (W x H x D) 300 x 600 x 465) mm	
Power Requirement	Single phase, AC, 220-240 V, 50/60 Hz	
Materials	SS316 and SS304 all with full welding	
Centrifuge		
Temperature	4°C to 40°C	
Speed	3000 rpm	
Speed Accuracy	2%	
Capacity	Up to 1 L total volume (4 x 250 ml) for PuriCradle Up to 0.4 L total (8 x 50 ml) for Nanchac	
Control Panel Box		
Touchscreen	Input interface: Siemens 7' color HMI Operating module: Siemens PLC	
Data Record	Data: datalogs, alarmlogs, audit trail	
Post Data Processing	csv file, pdf file	





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

Air Shower

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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