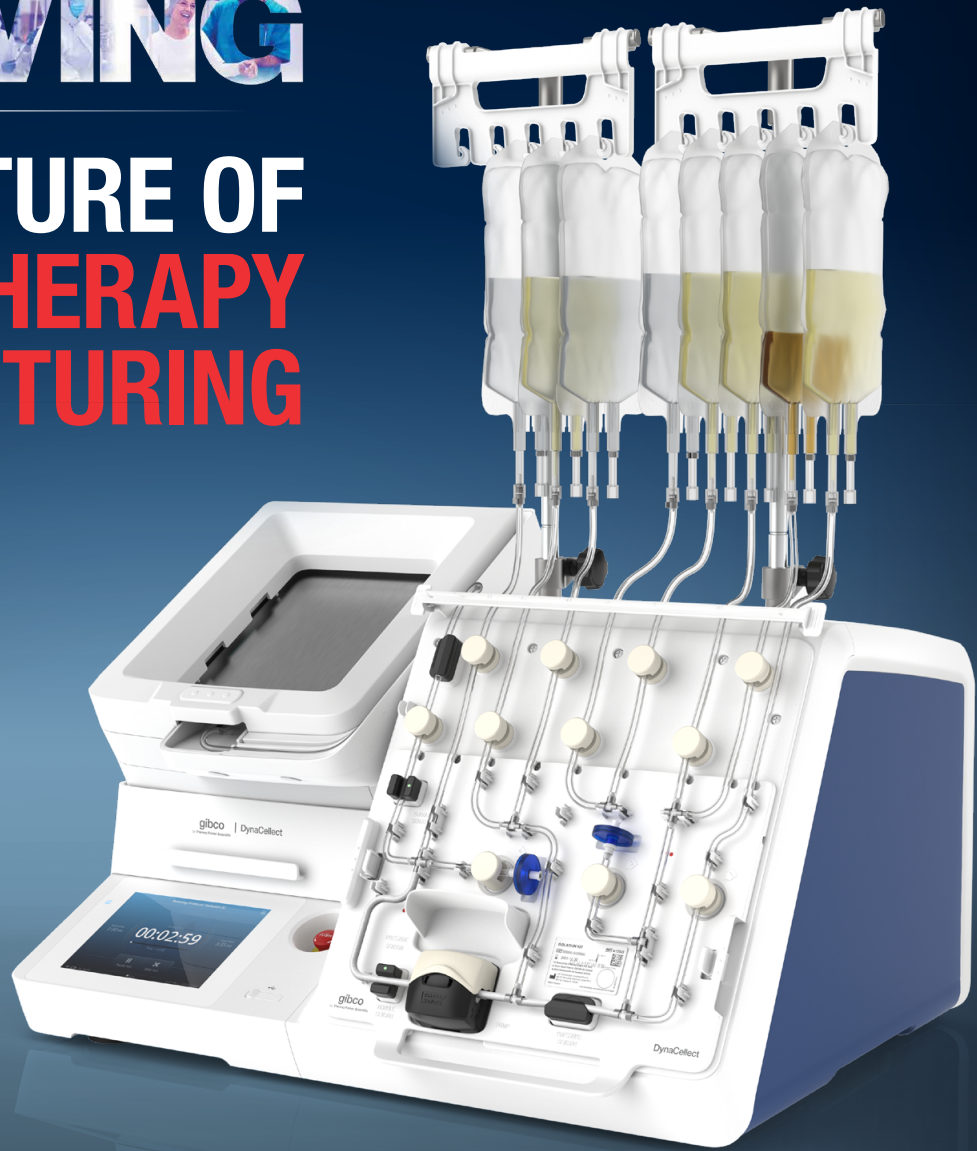


Cell therapy manufacturing

EVOLVING

THE FUTURE OF CELL THERAPY MANUFACTURING



CTS DynaCollect Magnetic Separation System

A closed, automated isolation and bead removal system
for cell therapy manufacturing

CTS DynaCollect Magnetic Separation System

Streamline and expedite your cell therapy development with the Gibco™ CTS™ DynaCollect™ Magnetic Separation System, a flexible, automated, and closed system that enables rapid isolation and bead removal for cell therapy manufacturing. As a stand-alone instrument or as part of a workflow, the operator-independent system will help you isolate the right cells and minimize failures in manufacturing while providing increased robustness and precision.

Designed to be used with magnetic beads, the CTS DynaCollect Magnetic Separation System delivers exceptional cell recovery, purity, high-throughput capability, and process flexibility. This system enables you to easily scale your process from research to clinical manufacturing without sacrificing cell viability.

Key benefits of the system include:

- **Isolation efficiency, purity, and viability**—enables >86% isolation efficiency of target cells with >96% purity and no effect on cell viability when used with Gibco™ CTS™ Dynabeads™ CD3/CD28
- **Speed**—a processing time of 70–100 minutes with CTS Dynabeads CD3/CD28
- **Process flexibility**—user-programmable software enables you to create and optimize a broad range of protocols
- **Modularity**—use independently or as part of your workflow
- **Research through commercial manufacturing**—the closed single-use kits enable sterile processing, and an Open Platform Communications Unified Architecture (OPC-UA) interface enables connectivity to a 21 CFR Part 11–compliant system

Performance data

The CTS DynaCollect Magnetic Separation System helps users easily scale from research to clinical and commercial manufacturing. This highly scalable system allows for 10 mL to 1 L of reaction volume (with an optimal density of 100 million to 10 billion target cells) for cell isolation. Since a continuous flow process is used for bead removal, the volume is potentially unlimited.

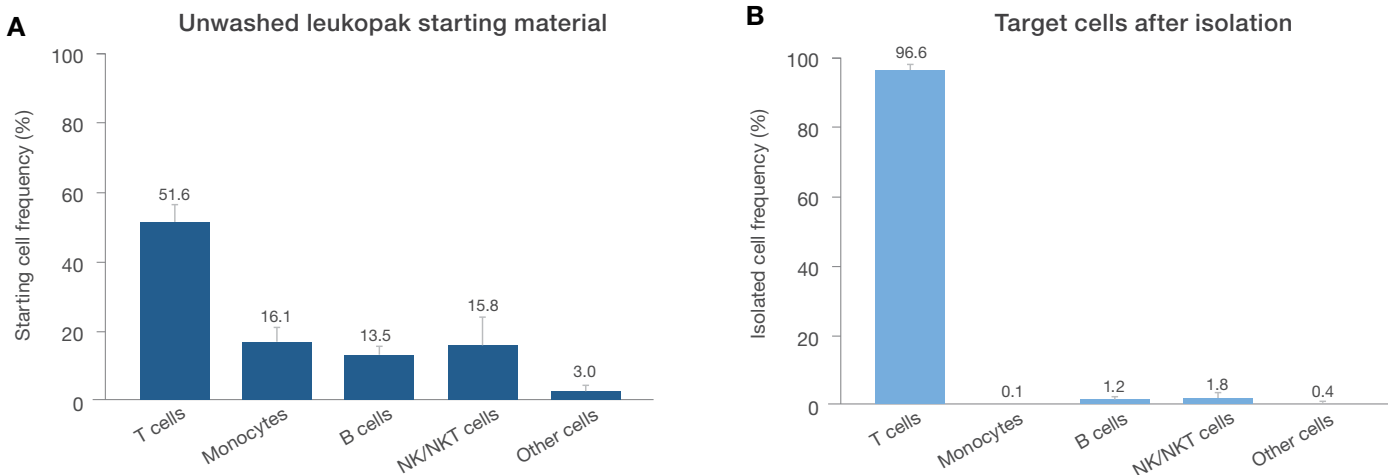


Figure 1. Cell phenotype of starting material and enriched target cells after isolation. (A) Purity of the target cells from unwashed starting material was ~52%. **(B)** After isolation using CTS Dynabeads CD3/CD28 and the CTS DynaCollect Magnetic Separation System, the purity of target cells CD4 and CD8 (positive and negative) was ~97% as measured by flow cytometry. Bars represent mean of frequency of parent population gated on viable cells from four independent experiments.

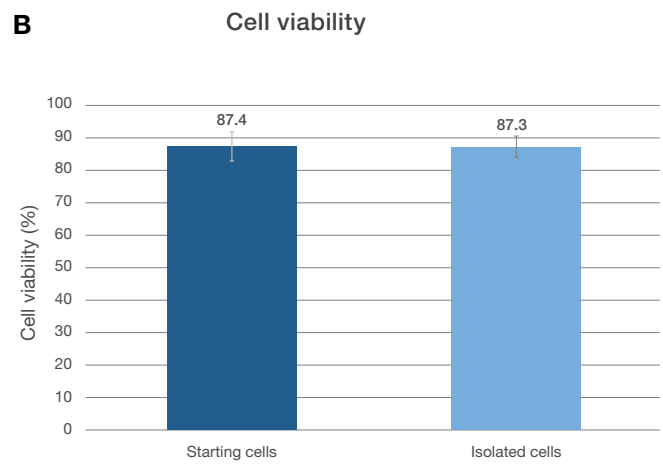
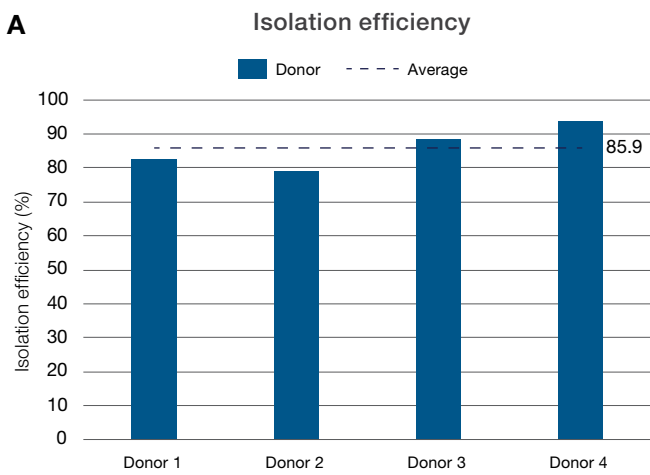


Figure 2. Strong isolation efficiency with no impact on cell viability. Using CTS Dynabeads CD3/CD28 and the CTS DynaCollect Magnetic Separation System, (A) isolation efficiency was greater than ~86% (N=4) while (B) cell viability was maintained at >87%, as determined by flow cytometry.

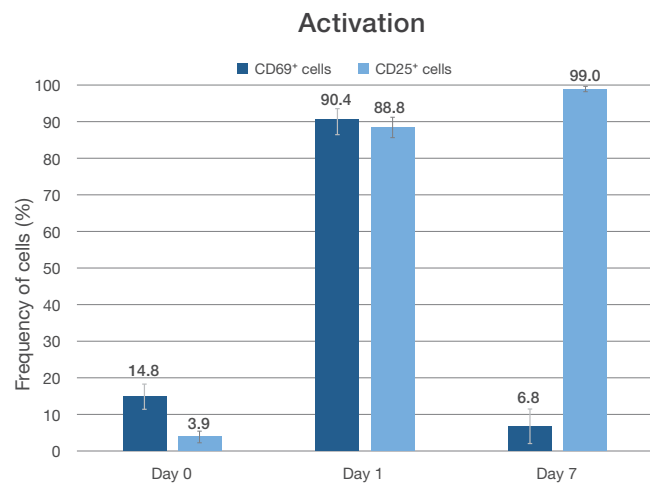


Figure 3. Activation of isolated target cells is confirmed. On day one, early activation marker CD69 is expressed on target cells and is downregulated by day seven. Late activation marker CD25 is expressed on day one and continues to be upregulated and expressed by day seven. The expression profile adheres to expected target cell kinetics (N=4).

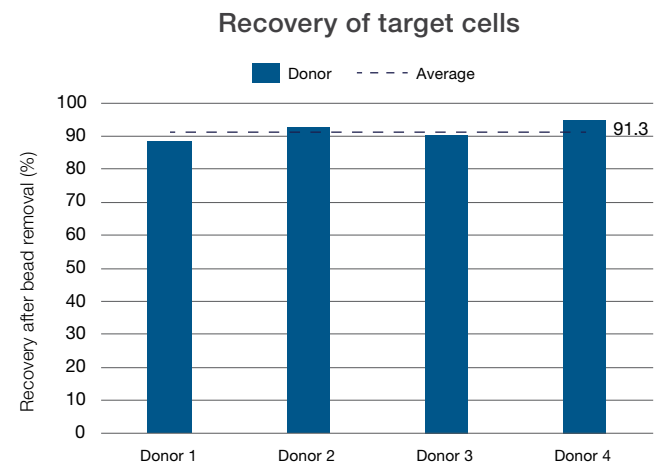


Figure 4. Bead removal process achieves high recovery of cells. Recovery after CTS Dynabeads CD3/CD28 removal was ~91% (N=4). Recovery was assessed by cell counting before and after bead removal at day seven.

System specifications

The CTS DynaCollect Magnetic Separation System is manufactured in a state-of-the-art, current Good Manufacturing Practice (cGMP), and ISO-certified facility to help ensure the highest quality and consistency for reproducible results.

Instrument specifications	
Processing time	70–100 minutes
Efficiency	>85% isolation (with CTS Dynabeads CD3/CD28)
DeltaV™ system compatibility (OPC-UA)	Yes
Reproducibility	CV of 3%
Purity	95% (with CTS Dynabeads CD3/CD28)
Viability	Unaffected
Isolation scale	Maximum 1,000 mL working volume (equivalent to ~10 billion T cells as input)
Bead removal scale	Unlimited, verified up to 10 L
Maximum cell input	~10 billion T cells (1,000 mL isolation volume)
Pump speed	1–150 mL/min
Rocker angle	–30° to 30°
Rocker speed	1–30 cpm
Air pressure	Max 2 bar
Enables compliance with 21 CFR Part 11	Yes, with upgrade
OPC-UA-compatible	Yes
Cloud connect utility	Yes
Touch display	20.32 cm
Voltage	100–240 V AC ±10%, 50/60 Hz, 600 W
Weight	50 kg
Depth	562 mm
Width	749.5 mm
Height	485 mm with pole

Consumables

The CTS DynaCollect Magnetic Separation System is designed for exceptional cell isolation and bead removal, ease of use, and to have a closed, integrated workflow. Together with the fit-for-purpose, sterile, and single-use consumables, it delivers high cell purity, recovery, and viability from process development to commercial manufacturing.

CTS DynaCollect Cell Isolation Kit

The Gibco™ CTS™ DynaCollect™ Cell Isolation Kit is specifically designed for the isolation and activation of immune cells in cell processing applications.

Key attributes of the kit include:

- Maximum capacity: 1,000 mL
- Enables isolation to be done in a Class C cleanroom
- Eight weldable lines for input and output bags: DEHP-free PVC connections (150 mm, 2.4 mm ID, 4.0 mm OD)
- Sterile air filters: 0.20 micron
- Gamma-sterilized



CTS DynaCollect Bead Removal Kit

The Gibco™ CTS™ DynaCollect™ Bead Removal Kit is specifically designed for bead removal from immune cells for cell processing applications.

Key attributes of the kit include:

- Continuous processing
- Enables bead removal to be done in a Class C cleanroom
- Four weldable lines for input and output bags: DEHP-free PVC connections (150 mm, 2.4 mm ID, 4.0 mm OD)
- Sterile air filter: 0.20 micron
- Gamma-sterilized



CTS DynaCollect Magnetic Separation System software

The CTS DynaCollect Magnetic Separation System comes with two protocols: isolation and bead removal. Protocols can be customized through the intuitive, user-programmable software interface to create and manage all instrument actions, including:

- Engage or disengage the magnet
- Open or close the pinched valves
- Change the pump speed from 10 to 150 mL/min
- Change the specified volume of the pump
- Change the rocker angle from -30° to 30°
- Change the rocker speed from 1 to 30 cpm
- Change the air pressure sensor (max 2 bar)

Additionally, the software is easily locked, so that when you are ready to move your optimized process to manufacturing, users can no longer adjust the process settings. The clinical manufacturing mode also includes an optional software module that enables:

- Compliance with 21 CFR Part 11
- Communication with the DeltaV system via OPC-UA
- Ability to provide a summary file (sample ID, run ID, SUT lot, bead lot, operator, and date)
- Barcoding through the USB port



Enabling GMP compliance

Gibco™ CTS™ products are specifically designed to enable clinical and commercial cell and gene therapy manufacturing and are backed by testing and regulatory support including:

- Regulatory support files (RSFs) for the CTS DynaCollect Magnetic Separation System, CTS DynaCollect Isolation Kit, and CTS DynaCollect Bead Removal Kit are available by request at [thermofisher.com/regulatory](https://www.thermofisher.com/regulatory)
- RSFs include detailed information about the instrument and the single-use consumables, including materials of construction, biocompatibility, extractable testing summaries, integrity of consumable sterility, stability testing, and instrument safety compliance standards
- The CTS DynaCollect Magnetic Separation System, CTS DynaCollect Isolation Kit, and CTS DynaCollect Bead Removal Kit are manufactured under ISO 13485 standards
- CTS DynaCollect Magnetic Separation System software can be locked for operator manufacturing mode
- The OPC-UA interface, the industry-standard machine communication language, enables connection to an MES/LIM or 21 CFR Part 11-compliant system

Cost-effectiveness of closed, modular systems

The CTS DynaCollect Magnetic Separation System is a modular, closed cell therapy instrument that can enable a path from research to commercial manufacturing, helping to deliver efficiency and cost savings.

Key benefits of the system include:

- **Helping reduce the cost of cleanroom spaces**—a closed system that operates in a Class C manufacturing facility can reduce the size of the Class B lab space required for open processing systems by up to 90%*
- **Enabling increased instrument efficiency and utility with modular designs**—manufacturing processes can be optimized using technologies that are ideally suited to each step; time-consuming processes such as cell expansion can be decoupled from rapid processes such as buffer exchanging and concentrating, reducing the investment in facilities and capital equipment by up to 70%*
- **Reducing process development delays**—using the same system or platform from research through process development and commercial manufacturing can help avoid process delays associated with changing systems

* Claims based on CAR T therapy, 7-day incubation, 2,000 patients per year, from: James D (2017) How short-term gain can lead to long-term pain. *Cell Gene Therapy Insights* 3(4): 271–284.

Getting started with the CTS DynaCollect Magnetic Separation System

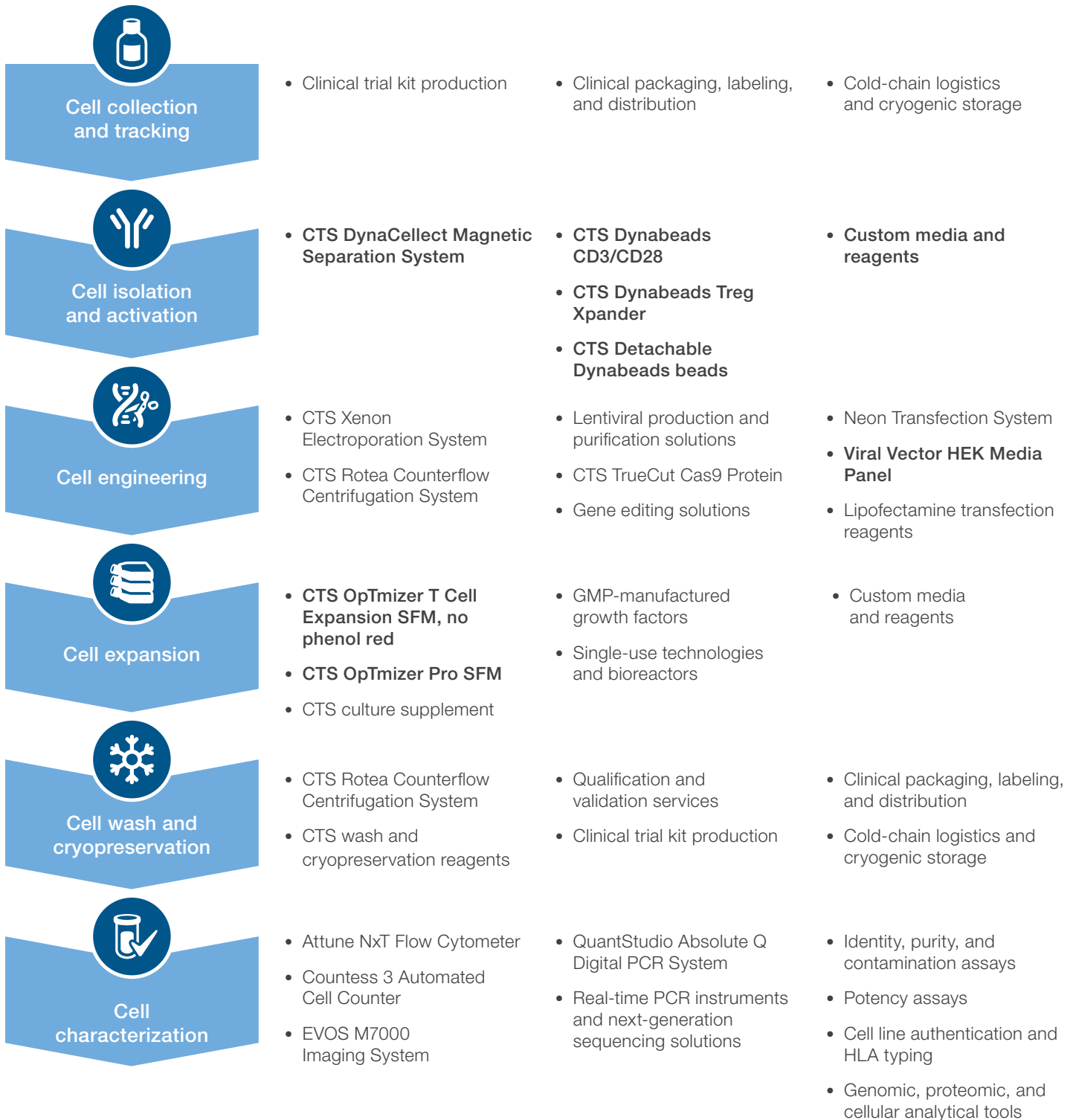
Customer experience and support

SmartStart Orientation training enables your success. Every CTS DynaCollect Magnetic Separation System comes with SmartStart Orientation training to help your lab quickly become efficient at using the system. Led by professional trainers, the orientation provides interactive education that includes theoretical and hands-on training.

1. SmartStart Orientation includes:
 - General instrument setup and operation
 - Training on the DynaCollect system software, covering eGUI and protocol optimization using DynaCollect system consumables
 - Discussion of custom protocols to suit your cells
 - Step-by-step explanation of available tools on the instrument and software using starting protocols as examples
 - Protocol creation training to enable you to customize starting protocols or create new customized protocols
2. Field application scientists will work together with you to support ongoing protocol development
3. Annual preventative maintenance and instrument service will be available through the instrument services team

Products that meet your needs at every step of the workflow, from research through commercial manufacturing

Thermo Fisher Scientific has built a fit-for-purpose portfolio of modular instrumentation platforms, consumables, reagents, and media designed to support closed, large-scale cell therapy manufacturing. Our goal is to enable automation of the end-to-end manufacturing workflow, from cell isolation and activation to gene modification and expansion.



Additional resources

Visit thermofisher.com/dynacollect to:

- See the CTS DynaCollect Magnetic Separation System in action with a virtual tour and how-to videos
- Request a demo or quote

Field application scientists can train in your lab or remotely and cover a variety of topics regarding the instrument, software, and applications.

- To request regulatory support files, contact us at thermofisher.com/regulatory
- See our product and service selection tool for a complete list of cell and gene therapy products and services at thermofisher.com/cellgenetherapytool
- High-quality materials, services, and support offered at every step of the journey, from discovery to clinical research to commercial cell and gene therapy manufacturing—learn more at thermofisher.com/ctssupport

Ordering information

Description	Quantity	Cat. No.
CTS DynaCollect Magnetic Separation System		
<ul style="list-style-type: none"> • SmartStart Orientation at installation • Two-year warranty with planned maintenance (PM) in second year 		A55867
CTS DynaCollect Magnetic Separation System	1	
<ul style="list-style-type: none"> • SmartStart Orientation at installation • IQ/OQ at installation • Two-year AB qualification with OQ post PM and/or repair 		A55868
CTS DynaCollect Cell Isolation Kit	5 pack	A52300
CTS DynaCollect Bead Removal Kit		A52301
Additional products		
CTS Xenon Electroporation System		A52727
CTS Rotea Counterflow Centrifugation System* (includes two-year warranty including OQ after PM and IQ/OQ services)		A50757** A47695†
CTS Dynabeads CD3/CD28		40203D
CTS Dynabeads Treg Xpander	1	46000D
CTS OpTmizer T Cell Expansion SFM, no phenol red, bottle format		A3705001
CTS OpTmizer T Cell Expansion SFM, no phenol red, bag format		A3705003
CTS OpTmizer Pro SFM, bottle format		A4966101
CTS OpTmizer Pro SFM, bag format		A4966103

* For Research Use or Manufacturing of Cell, Gene, or Tissue-Based Products. Caution: Not intended for direct administration into humans or animals.

** North America and Europe.

† Rest of the world.

 Learn more at thermofisher.com/dynacollect

gibco

Intended use of the products mentioned varies. For specific intended use statements, please refer to the Instructions for Use (IFU). © 2023, 2023 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. DeltaV is a trademark of Emerson Electric Inc. COL023980 0223