



Cell therapy

The CTS Rotea Counterflow Centrifugation System

Close your system, free your process

Meet the CTS Rotea system

The award-winning Gibco™ CTS™ Rotea™ Counterflow Centrifugation System by Thermo Fisher Scientific is helping streamline the cell therapy manufacturing path from process development to commercialization.

Ideal for cell separation, concentration, and washing, the CTS Rotea system was recognized as a 2021–2022 winner of the following four industry awards:

- 2022 Asia Pacific Cell and Gene Therapy Excellence Awards Best Cell and Gene Therapy Supplier—Cell Processing Systems
- 2022 Edison Awards Best New Product
- 2021 Australian International Good Design Award
- 2021 R&D 100 Award

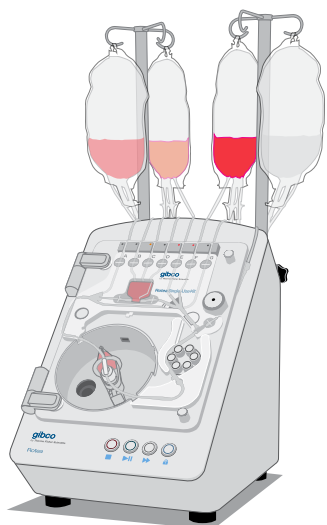


The CTS Rotea system offers key benefits when used for cell processing:

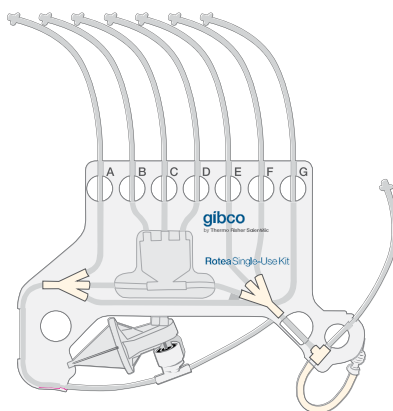
- **Seamlessly scale from process development through commercial manufacturing**—the closed, single-use kit enables sterile processing, and multiple software options are available to enable 21 CFR Part 11 compliance
- **Process flexibility**—user-programmable software enables customers to develop and optimize protocols for a range of applications
- **Low output volumes**—proprietary technology can deliver as little as 5 mL of concentrate
- **High cell recovery and viability**—gentle processing enables >95% cell recovery while maintaining cell viability



Scale from process development to commercial manufacturing



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Instrument

- Compact
- Multipurpose
- Easy integration into workflow

Single-use kit

- Sterile
- Closed
- Flexible input and output ports

Software

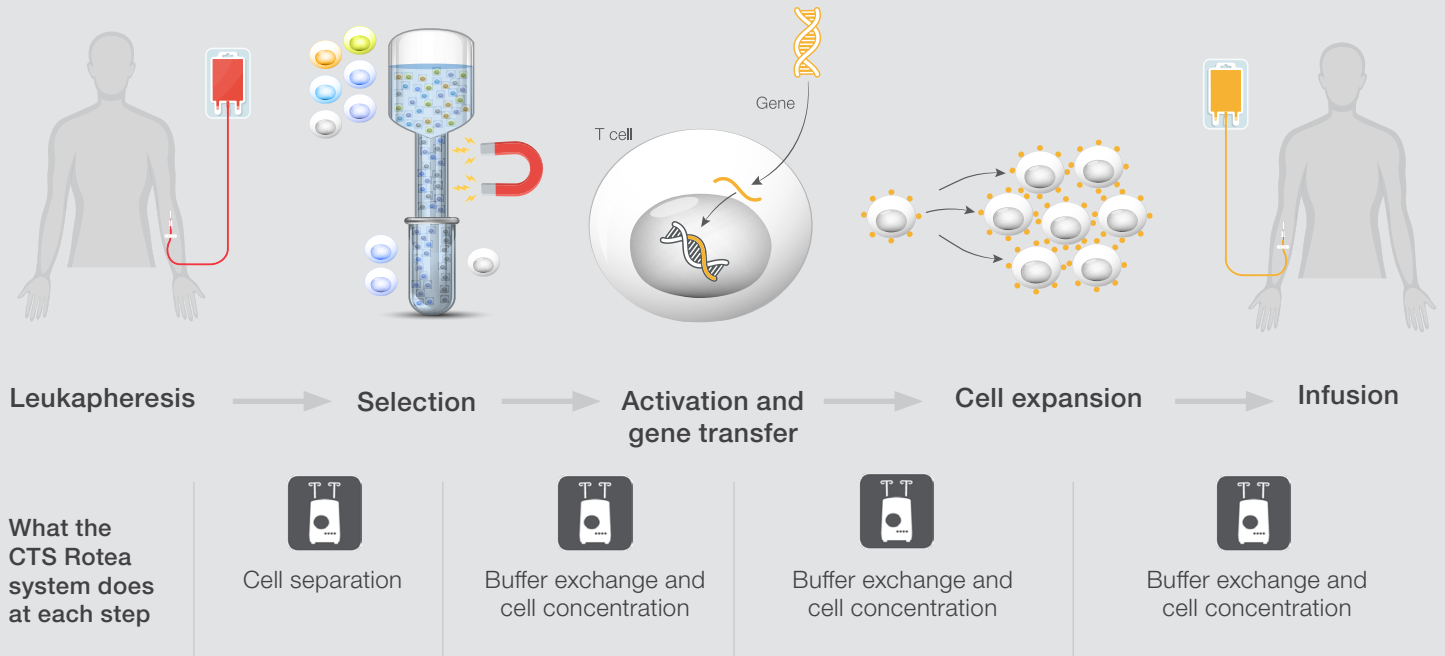
- Intuitive user-programmable interface
- Standard protocols available and customers can create their own protocols
- Suitable for GMP manufacturing

Explore the functionality of counterflow centrifugation throughout the cell therapy workflow

Low-volume recovery	Customer-controlled protocol development
Small- to mid-scale cell processing	T cell and MSC wash and concentration
Cell wash/buffer exchange	iPSC aggregate processing
Cell concentration	PBMC/monocyte separation
Elutriation/cell separation	RBC depletion
Cell isolation and selection	QC sample prep and isolation

Cell therapy processing

The CTS Rotea Counterflow Centrifugation System is a highly versatile tool that is suitable for cell separation, concentration, washing, and buffer exchange between cell therapy processing steps.



Features



Instrument

- **Counterflow centrifugation (CFC)**—helps improve cell therapy workflow from process development to manufacturing by using powerful, scalable technology; the system suspends cells in a fluidized bed by exerting a constant flow force, which is opposing centrifugal forces, to provide capabilities impossible for traditional centrifuges; fluid-suspended cells are gently concentrated without forming a pellet in the cone and washed quickly for high recovery rates; due to their reduced cell density, dead cells can be removed to optimize viability before delivery; cell types of different sizes can be separated by tuning centrifugal speed and flow rate to create an imbalance of forces
- **Gibco™ CellCam™ video technology**—visualizes cells live in a fluidized bed through color camera, enabling CFC parameter optimization; this allows users to easily fine-tune protocols for each application
- **Gibco™ DirectDraw™ extraction technology**—allows extremely low-volume output at up to 3×10^6 cells/mL
- **Process monitoring**—actively monitors and prompts users for interaction during runs as necessary
- **Compact footprint**—fits on a benchtop



Processing times and instrument specifications

T cell wash and concentrate (1 x 10⁶ cells/mL)

Input volume (L)	Processing time (min)	Cell recovery
0.5	11	>90%
1	18	
3	38	
5	58	
10	114	
20	226	

PBMC isolation

Diluted input volume (L)	Processing time (min)
1/4 leukopak bag	25
1/2 leukopak bag	45
Full leukopak bag	85*

* Optimal processing time assuming no lysis in process.

Specifications

Instrument

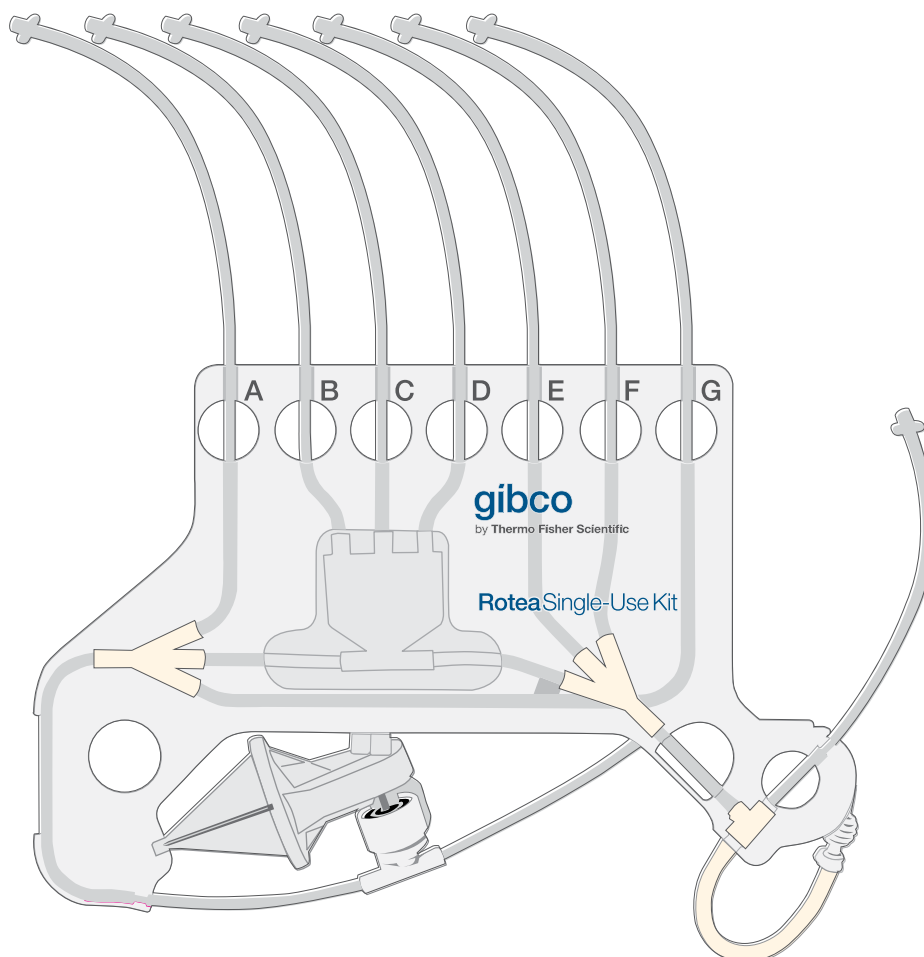
Centrifugal force	3,000 x g
Peristaltic pump flow rate	5–110 mL/min (CTS Rotea standard kit) 30–160 mL/min (CTS Rotea Hi-Flow kit)
Centrifuge chamber volume	10 mL
Cell count per chamber load	5 x 10 ⁷ –5 x 10 ⁹ cells*
Output cell concentration	5 x 10 ⁶ –500 x 10 ⁶ cells/mL
Recommended input volume range	50 mL–20 L
Minimum output volume	5 mL
Maximum fluid density	1.10 g/mL
Operating noise level	<70 dBA
Dimensions (H x W x D)	16 x 11.4 x 20 in. (body only), 30 x 11.4 x 20 in. (with bag poles) 40 x 29 x 50.8 cm (body only), 76.2 x 29 x 50.8 cm (with bag poles)
Weight	44 lb (20 kg)
Computer	Dell™ system, validated by Thermo Fisher Scientific for use with the CTS Rotea system

* Dependent upon cell type. Centrifuge can be filled multiple times to process larger batches.

Note: Instrument and Consumable Regulatory Support File available upon request at thermofisher.com/regulatory.

Consumable kits

- Single-use kits are simple to use, provide flexibility for process development, and can be configured to meet process needs
- Enable multiple batches to be processed in a shared, Class C clean room leading to cost-effective transfer and scale-out
- Compatible with Luer connectors and sterile welding
- Gamma-sterilized
- Tube material: DEHP-free PVC
- Standard kit: flow rates of 5–110 mL/min
- Hi-Flow kit: flow rates of 30–160 mL/min



Intuitive software

CTS Rotea system software interface

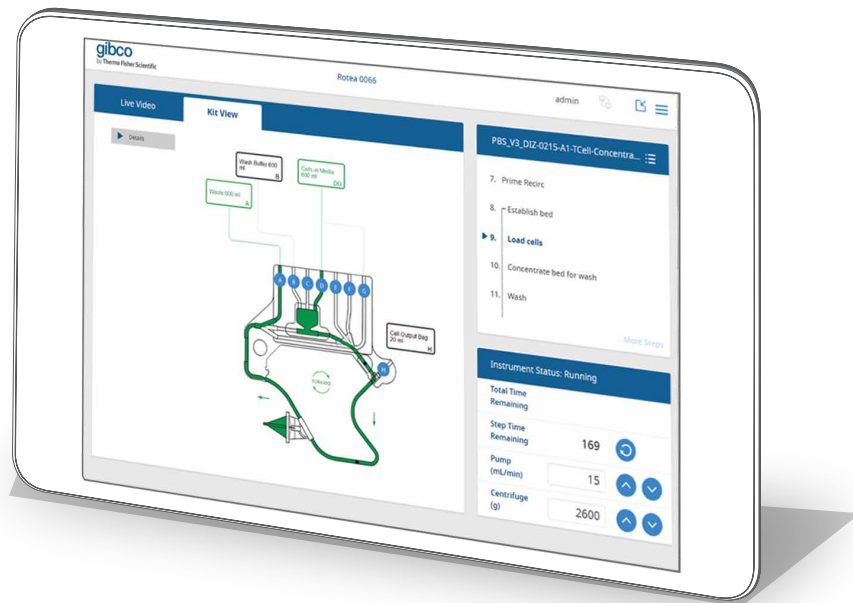
- User-friendly graphical user interface (GUI) is capable of fine-tuning protocol parameters for each application
- Easily switches between process development and manufacturing operator modes
- CTS Rotea system software and firmware updates are customer-installable

Gibco™ CTS™ Rotea™ Protocol Builder*

- Create, modify, save, and upload protocols
- Customizable settings provide flexibility to suit each unique application

Gibco™ CTS™ Rotea™ Software options

- **Standard software is available with the instrument**—the OPC-UA interface allows for connection to a DCS, MES, or 21 CFR Part 11–compliant system
- **Gibco™ CTS™ Rotea™ SAE Software**—ideal for customers who require GMP manufacturing; the off-the-shelf solution helps enable 21 CFR Part 11 compliance for stand-alone CTS Rotea systems
- **Gibco™ CTS™ Cellmation™ Software**—ideal for customers who require GMP manufacturing and already have a DeltaV™ system to control workflows across multiple instruments in a 21 CFR Part 11–compliant environment



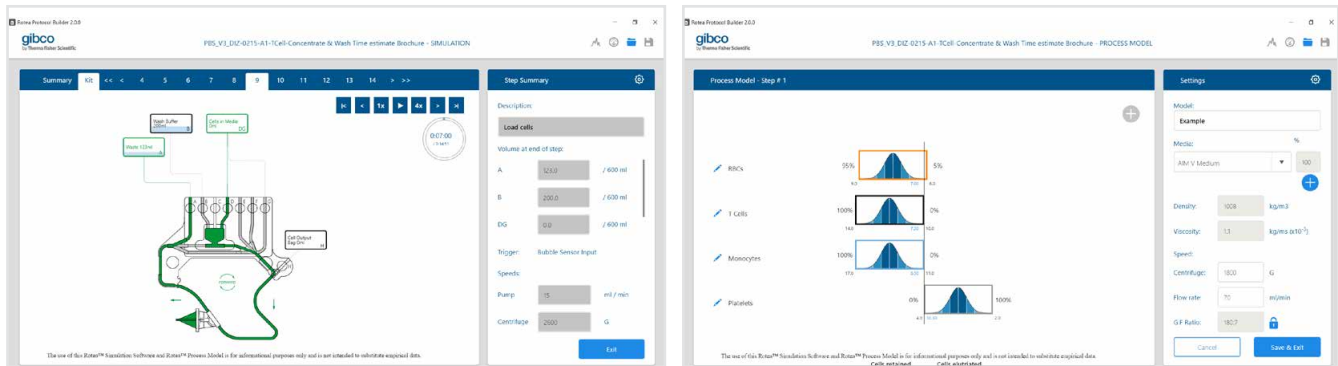
* CTS Rotea system users must validate protocols developed on the CTS Rotea system to ensure compliance with regulatory requirements within their own manufacturing (or laboratory) environment according to their own standard operating procedures (SOPs)/quality system.

Simulation software

- Simulates a protocol in the absence of a physical system and allows the user to troubleshoot protocols
- Helps user determine what bag volumes and run times are required to complete a specific protocol
- Facilitates protocol functionality assessment prior to running the protocol on instrument

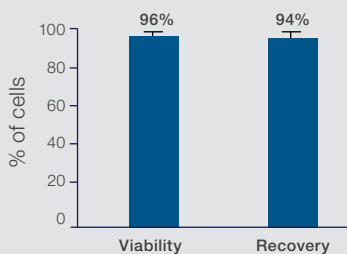
Process model

- Advanced fluid dynamics model helps users determine, based on their cells and media/buffer, which counterflow centrifuge and pump parameters to start with
- Commonly used reagents, buffer, and media are preinstalled in the model
- A library of cell types is preinstalled in the model, including RBCs, lymphocytes, lymphocytes (small), monocytes, granulocytes, platelets, CHO, amnion, aggregates, T cells, B cells, NK cells, magnetic beads, and more



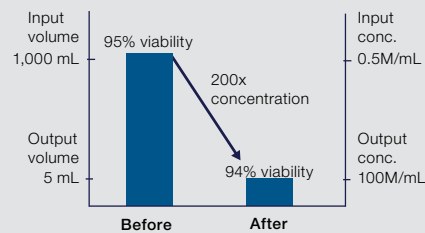
Performance data

Viability and recovery after T cell washing and concentration



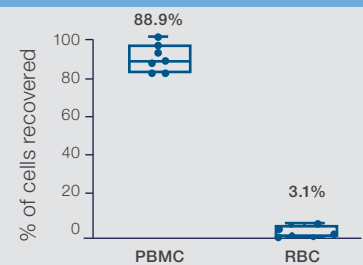
Gentle processing enables >90% cell recovery while maintaining cell viability through T cell washing and concentration. High reproducibility was demonstrated over 10 runs.

200x T cell concentration



The CTS Rotea system was used to concentrate 500 million T cells in a starting volume of 1,000 mL down to 5 mL, achieving 97% cell recovery while maintaining viability of 94%.

High PBMC recovery from a leukopak bag



The CTS Rotea system can achieve approximately 90% PBMC recovery from a leukopak bag in combination with a red blood cell lysis buffer across multiple donors (n=7).

For more data, visit thermofisher.com/rotea

Enabling GMP compliance

Gibco™ Cell Therapy Systems (CTS™) products are specifically designed to enable clinical and commercial cell and gene therapy manufacturing and are backed by testing and regulatory support.

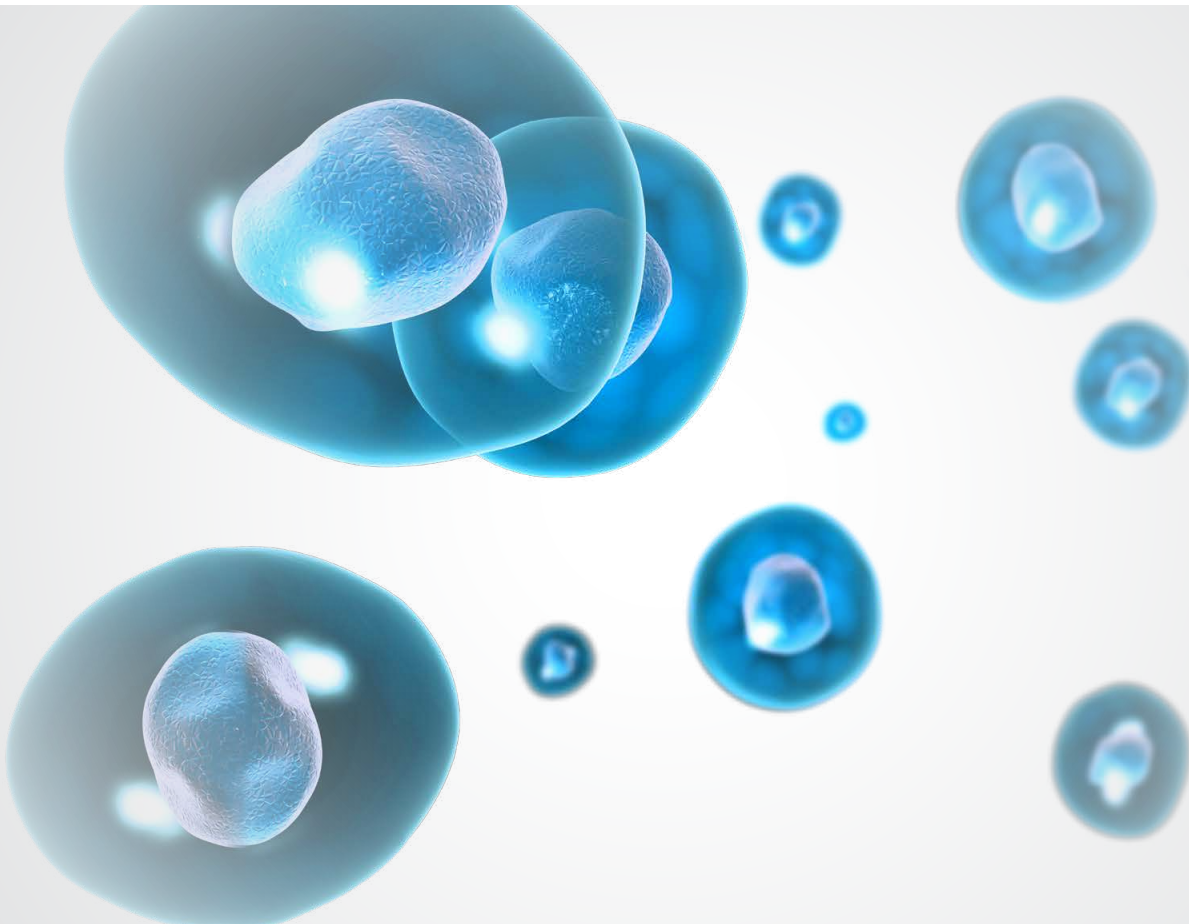
- The CTS Rotea Single-Use Kit Regulatory Support File (RSF) is available by request at [thermofisher.com/regulatory](https://www.thermofisher.com/regulatory)
- The RSF includes detailed information about the single-use consumable, including materials of construction, biocompatibility, extractable testing summaries, integrity of consumable sterility, stability testing, and instrument safety compliance standards
- The CTS Rotea Counterflow Centrifuge and CTS Rotea Single-Use Kit are manufactured at an ISO 13485 facility
- The CTS Rotea GUI software can be locked for operator manufacturing mode
- CTS Rotea SAE (security, audit, and e-signature) Software is available to help enable 21 CFR Part 11 compliance
- For customers with a DeltaV system, CTS Cellmation Software is available to allow for connection of the Rotea system to a DeltaV network to control workflows across multiple instruments in a 21 CFR Part 11–compliant manner

Cost-effectiveness of closed modular systems

The CTS Rotea system is a modular, closed cell therapy instrument that can be utilized from process development through commercial manufacturing, enabling efficiency and cost savings.

- **Closed systems help reduce the cost of clean room space**—a closed system that operates in a Class C manufacturing facility can reduce the size of Class A and Class B lab space required for open processing systems by up to 90%*
- **Modular designs enable increased instrument efficiency and utility**—manufacturing processes can be optimized using technologies that are ideally suited to each process step; time-consuming processes such as cell expansion can be decoupled from rapid processes such as buffer change and concentration, reducing the investment in facilities and capital equipment by up to 70%*
- **Avoid process development delays**—utilizing the same system from process development through 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
(Source: <https://pdfs.semanticscholar.org/1589/c6e2b45417f03f1014ed189c77dd0da8676a.pdf>).



Getting started with the CTS Rotea system

Customer experience and support

SmartStart Orientation includes:

- Introduction to the CTS Rotea system
- CTS Rotea system software training, which covers GUI, protocol builder, and counterflow centrifugation process model features
- CTS Rotea system protocol development best practices
- Qualification services
- Instrument service and support available through the Global Service and Support Team



Closed system-compatible media and reagents

Cell therapy workflows are varied and complex. To meet the demand for media and reagents suitable for closed systems, the design of our bioprocess container is flexible and adaptable. Gibco™ CTS™ off-the-shelf bagged media support closed cell and gene therapy manufacturing from process development through commercial manufacturing. Moving from open systems to closed systems may reduce the risk of cross-contamination, alleviating events impacting quality and increasing clinical and commercial manufacturing success. Gibco™ CTS™ AIM-V™ Medium, without phenol red and without antibiotics; Gibco™ CTS™ DPBS, without calcium chloride and without magnesium chloride; Gibco™ CTS™ DPBS, with calcium chloride and magnesium chloride; and Gibco™ CTS™ NK-Xpander™ Medium will help scale up or scale out the manufacturing process. Each formulation is available in flexible bioprocess container formats suitable for aseptic integration into the workflow through sterile welding, MPC quick-connect, or Luer lock connections.

- **Compatible with closed systems**—tubing polymers are compatible with market-leading sterile welding equipment to enable use in upstream and downstream applications
- **Seamless translation**—CTS reagents are now offered in closed packaging to help reduce lead times and to scale and close the process
- **Quality testing and regulatory documentation**—reagents and single-use technologies comply with industry standards and are backed by regulatory documentation and support (Drug Master File and/or a Regulatory Support File, Certificate of Analysis, and Certificate of Origin)



Products that meet needs at every step of the workflow, from process development through commercial manufacturing



Cell collection and tracking

- Clinical trial kit production
- Clinical packaging, labeling, and distribution
- Cold-chain logistics and cryogenic storage



Cell isolation, activation, and separation

- **CTS Rotea Counterflow Centrifugation System**
- Gibco™ CTS™ DynaCollect™ Magnetic Separation System
- CTS media and reagents
- Custom media and reagents



Cell engineering

- Gibco™ CTS™ Xenon™ Electroporation System
- Lentiviral production and purification solutions
- Gene editing solutions
- Invitrogen™ Neon™ Transfection System
- Adeno-associated virus solutions
- Invitrogen™ Lipofectamine™ transfection reagents



Cell expansion

- CTS media and reagents
- CTS culture supplement
- Gibco™ growth factors
- Single-use technologies and bioreactors



Cell wash and cryopreservation












- **CTS Rotea Counterflow Centrifugation System (for cell wash)**
- CTS wash and cryopreservation reagents
- Qualification and validation services
- Clinical trial kit production
- Clinical packaging, labeling, and distribution
- Cold-chain logistics and cryogenic storage



Cell characterization and quality control

- Invitrogen™ Attune™ NxT Flow Cytometer
- Invitrogen™ Countess™ 3 Automated Cell Counter
- Invitrogen™ EVOS™ M7000 Imaging System
- qPCR instruments and next-generation sequencing
- Identity and purity assays
- Potency assays
- Cell line authentication and HLA typing
- Genomic, proteomic, and cellular analytical tools
- Applied Biosystems™ MycoSEQ™ Mycoplasma Detection Kit

Additional resources

-  See the CTS Rotea system in action. Check out how-to videos and virtual demos at thermofisher.com/rotea
-  To learn more about how to use the CTS Rotea system in different applications, go to thermofisher.com/rotea-resources
-  For more information, or to request a quote, go to thermofisher.com/rotea
-  **SmartStart Orientation training** enables your success. Every CTS Rotea Counterflow Centrifugation System comes with SmartStart Orientation training to help your lab quickly become efficient at using your new CTS Rotea system. Led by field application specialists (FASs), the orientation provides interactive education that includes theoretical and hands-on training. FASs train in your lab or remotely and cover a variety of topics around the instrument, software, and applications.
-  View recent webinars, application notes, handbooks, posters, and more in our Cell and Gene Therapy Learning Center at thermofisher.com/cgtlearningcenter
-  For technical support or help, contact us at thermofisher.com/contactus
-  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
-  Services and support are 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
-  **Learn about our solutions** to help achieve cell therapy goals from research to commercialization at thermofisher.com/cellandgenetherapy
-  To request more information about our latest technology offerings, go to thermofisher.com/cgtask

Ordering information

Product	Cat. No.
Instrument	
CTS Rotea Counterflow Centrifugation System, 2-year service, and IQ/OQ	A50757
CTS Rotea Counterflow Centrifugation System and 2-year service	A50760
Software	
Rotea GUI Software and Rotea Protocol Builder	Included with system
Rotea SAE Software (security, auditing, and electronic signature module)	A52220
CTS Cellmation Software for DeltaV Systems	A55962
Consumables	
CTS Rotea Single-Use Kit (10 pk)	A49585
CTS Rotea Single-Use Kit (5 pk)	A49313
CTS Rotea Hi-Flow Single-Use Kit (10 pk)	A46575
CTS Rotea Hi-Flow Single-Use Kit (5 pk)	A49239
Closed system-compatible media and reagents	
CTS AIM-V Medium, without phenol red, without antibiotics (2 L)	A4672701
CTS DPBS, without calcium chloride, without magnesium chloride (2 L)	A1285602
CTS DPBS, with calcium chloride and magnesium chloride (2 L)	A4737901
CTS NK-Xpander Medium (5 L)	A5019002
Accessories	
Rotea Kit Tube Clamps (100 pk)	A49127
Rotea Kit Sterile Connectors (10 pk)	A50110
Rotea Kit Sterile Sample Ports (10 pk)	A50111



Learn more at thermofisher.com/rotea

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