The CTS Rotea Counterflow Centrifugation System

Close your system, free your process
The CTS Rotea system—a closed cell processing system for cell therapy manufacturing

The multipurpose Gibco™ Cell Therapy Systems (CTS™) Rotea™ Counterflow Centrifugation System offers unparalleled flexibility. This highly versatile system features user-programmable software to enable a broad range of cell processing applications.

The CTS Rotea system offers exceptional cell recovery, flexible input and output volume capability, and high throughput, making it ideal for cell separation, concentration, washing, and more. The compact footprint, process flexibility, and closed single-use kit allow the system to seamlessly scale with your process, from research through commercial manufacturing.

Key benefits
• **Process flexibility**—user-programmable software enables you to create and optimize a broad range of protocols for cell separation, washing, and concentration
• **High cell recovery and viability**—gentle processing enables >95% cell recovery while maintaining cell viability
• **Low output volumes**—proprietary technology can deliver as little as 5 mL of concentrate
• **Research through commercial manufacturing**—the closed single-use kit enables sterile processing, and an Open Platform Communications Unified Architecture (OPC-UA) interface enables connectivity to a 21 CFR Part 11–compliant system
Highly flexible system that scales with you from research through commercial manufacturing

**Instrument**
- Compact
- Multipurpose
- Easily integrates into your process

**Single-use kit**
- Sterile
- Closed
- Flexible input and output ports

**Software**
- User-programmable
- Preset protocols available
- Suitable for GMP manufacturing

A versatile instrument with many possibilities for use throughout your workflow

<table>
<thead>
<tr>
<th>Task</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cell wash/buffer exchange</td>
<td>T cell and MSC wash and concentration</td>
</tr>
<tr>
<td>Cell concentration</td>
<td>iPSC aggregate processing</td>
</tr>
<tr>
<td>Elutriation/cell separation</td>
<td>PBMC/monocyte separation</td>
</tr>
<tr>
<td>Cell isolation and selection</td>
<td>RBC depletion</td>
</tr>
<tr>
<td>Low-volume recovery</td>
<td>QC sample prep and isolation</td>
</tr>
<tr>
<td>Small- to mid-scale cell processing</td>
<td>Formulation for cryopreservation</td>
</tr>
</tbody>
</table>
Cell therapy processing

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

Instrument

- Counterflow centrifugation (CFC) is a gentle-yet-powerful, scalable technology designed to improve your entire cell therapy workflow from research to manufacturing. The system suspends cells in a fluidized bed by exerting a constant flow force opposite centrifugal forces to provide capabilities impossible for traditional centrifuges. Fluid-suspended cells are gently concentrated without ever forming a pellet in the cone and washed quickly and efficiently at unmatched 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—color camera visualizes cells live in a fluidized bed, 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 300M cells/mL.

- Process monitoring to prevent and detect faults.

- Compact footprint—fits on a benchtop.
### Processing times and instrument specifications

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

<table>
<thead>
<tr>
<th>Input volume (L)</th>
<th>Processing time (min)</th>
<th>Cell recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>18</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>3</td>
<td>50</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>116</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>230</td>
<td></td>
</tr>
</tbody>
</table>

#### PBMC isolation

<table>
<thead>
<tr>
<th>Diluted input volume (L)</th>
<th>Processing time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/4 Leukopak bag</td>
<td>25</td>
</tr>
<tr>
<td>1/2 Leukopak bag</td>
<td>45</td>
</tr>
<tr>
<td>Full Leukopak bag</td>
<td>85</td>
</tr>
</tbody>
</table>

### Specifications

#### Instrument

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centrifugal force</td>
<td>3,000 x g</td>
</tr>
<tr>
<td>Peristaltic pump flow rate</td>
<td>5–110 mL/min (Standard Kit)</td>
</tr>
<tr>
<td></td>
<td>30–160 mL/min (Hi-Flow Kit)</td>
</tr>
<tr>
<td>Centrifuge chamber volume</td>
<td>10 mL</td>
</tr>
<tr>
<td>Cell count per chamber load</td>
<td>5 x 10⁷–5 x 10⁹ cells*</td>
</tr>
<tr>
<td>Output cell concentration</td>
<td>5 x 10⁶–300 x 10⁶ cells/mL</td>
</tr>
<tr>
<td>Recommended input volume range</td>
<td>50 mL–20 L</td>
</tr>
<tr>
<td>Minimum output volume</td>
<td>5 mL</td>
</tr>
<tr>
<td>Maximum fluid density</td>
<td>1.10 g/mL</td>
</tr>
<tr>
<td>Operating noise level</td>
<td>&lt;70 dBA</td>
</tr>
<tr>
<td>Dimensions (H x W x D)</td>
<td>16 x 11.4 x 20 in. (body only), 30 x 11.4 x 20 in. (with bag poles)</td>
</tr>
<tr>
<td></td>
<td>40 x 29 x 50.8 cm (body only), 76.2 x 29 x 50.8 cm (with bag poles)</td>
</tr>
<tr>
<td>Weight</td>
<td>44 lb (20 kg)</td>
</tr>
<tr>
<td>Tablet accessory model</td>
<td>2-in-1 Dell™ 5290 system (laptop and tablet)</td>
</tr>
</tbody>
</table>

* 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 kit provides flexibility for process development, is simple to use, and can be customized to support commercial-scale manufacturing
- 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
• This OPC-UA allows connectivity to 21 CFR Part 11–compliant system or MES/LIS software
• Easily switches between R&D and manufacturing operator modes
• CTS Rotea system software and firmware updates are customer-installable through the GUI
• Capability to connect to the Thermo Fisher Scientific cloud platform

Protocol Builder
• Create/modify/save/upload protocols
• A field application scientist from our global service and support team will guide you through each step to create a protocol that fits your application
• Customizable settings provide flexibility to suit each unique application
**Simulation software**
- Simulates a protocol in the absence of physical system; allows the user to troubleshoot a protocol
- 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 pre-installed in the model
- A library of cell types is pre-installed in the model; includes RBCs, lymphocytes, lymphocytes (small), monocytes, granulocytes, platelets, CHO, amnion, aggregates, T cells, B cells, NK cells, magnetic beads, and more

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**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, go to **thermofisher.com/rotea**
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.

- CTS Rotea Single-Use Kit Regulatory Support Files (RSF) are available by request at 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 under ISO 13485 regulations, adhering to all compliance guidelines
- The CTS Rotea GUI 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

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

- Closed systems reduce the cost of clean room space—a closed system that operates in a Class C manufacturing facility can reduce the size of Class B lab space required for open processing systems by 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 research through process development and commercial manufacturing can help you 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/c6e2b45417f0311014ed180c77dd0da8676a.pdf).
Getting started with the Rotea system

Customer experience and support

1. SmartStart orientation includes:
   - Rotea system software training—covers GUI, protocol builder, simulation software, and CFC process model
   - Rotea system protocol development training
   - Creation of one custom protocol to suit your cells and application
     - Step-by-step explanation of instrument and software available tools, using your custom protocol as an example
     - Detailed protocol builder training to enable you to customize off-the-shelf protocols or create new customized protocols
   - General instrument setup and operation
   - IQ/OQ package available with additional AB Qualification service that provides an on-site Field Service Engineer (FSE) visit within 2 years of installation.

2. Field application scientists will work together with you to provide ongoing protocol development support.

3. Annual preventative maintenance and instrument service will be available through the Instrument Services 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 clinical translation 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; and Gibco™ CTS™ DPBS, with calcium chloride and magnesium chloride will be ready when you are to help scale up or scale out your manufacturing process. Each formulation is available in flexible bioprocess container format suitable for aseptic integration into your workflow through sterile welding, MPC quick-connect, or Luer lock connections.

- **Closed system compatible**—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 your 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 your need at every step of the workflow, from research through commercial manufacturing

- **Cell collection and tracking**
  - Clinical trial kit production
  - Clinical packaging, labeling, and distribution
  - Cold-chain logistics and cryogenic storage

- **Cell isolation and activation**
  - CTS Rotea Counterflow Centrifugation System
  - CTS media and reagents
  - Gene editing solutions
  - Adeno-associated virus solutions

- **Cell engineering**
  - CTS Rotea Counterflow Centrifugation System
  - Lentiviral production and purification solutions
  - Gene editing solutions
  - Invitrogen™ Neon™ Transfection System

- **Cell expansion**
  - CTS media and reagents
  - CTS culture supplement
  - Gene editing solutions
  - Invitrogen™ Lipofectamine™ transfection reagents

- **Cell wash and cryopreservation**
  - CTS Rotea Counterflow Centrifugation System
  - CTS wash and cryopreservation reagents
  - Qualification and validation services
  - Clinical trial kit production

- **Cell characterization**
  - Invitrogen™ Attune™ NxT Flow Cytometer
  - Invitrogen™ Countess™ II Automated Cell Counter
  - Invitrogen™ EVOS™ M7000 Imaging System
  - qPCR instruments and next-generation sequencing
  - Identity, purity, and contamination assays
  - Potency assays
Additional resources

See the CTS Rotea system in action. Check out how-to videos and virtual demos at thermofisher.com/rotea

To view protocols and learn more about how to use the CTS Rotea system in different applications, go to thermofisher.com/rotea

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 professional trainers, the orientation provides interactive education that includes theoretical and hands-on training. Field application scientists 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/us/en/home/technical-resources.html

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 for 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 you achieve your cell therapy goals from research to commercialization at thermofisher.com/cellandgenetherapy

For more information about our latest technology offerings, go to thermofisher.com/cgtask

Ordering information

<table>
<thead>
<tr>
<th>Product</th>
<th>Cat. No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTS Rotea Counterflow Centrifugation System + 2 year warranty (including OQ after PM) + IQOQ</td>
<td>A50757*  A47695**</td>
</tr>
<tr>
<td>CTS Rotea Counterflow Centrifugation System + 2 year warranty (including PM)</td>
<td>A50760*  A47679**</td>
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<tr>
<td><strong>Consumables</strong></td>
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<tr>
<td>CTS Rotea Single-Use Kit (10 pk)</td>
<td>A49585</td>
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<tr>
<td>CTS Rotea Single-Use Kit (5 pk)</td>
<td>A49313</td>
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<tr>
<td>CTS Rotea Hi-Flow Single-Use Kit (10 pk)</td>
<td>A46575</td>
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<tr>
<td>CTS Rotea Hi-Flow Single-Use Kit (5 pk)</td>
<td>A49239</td>
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<tr>
<td><strong>Closed system–compatible media and reagents</strong></td>
<td></td>
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<tr>
<td>CTS AIM-V Medium, without phenol red, without antibiotics (2 L)</td>
<td>A4672701</td>
</tr>
<tr>
<td>CTS DPBS, without calcium chloride, without magnesium chloride (2 L)</td>
<td>A1285602</td>
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<tr>
<td>CTS DPBS, with calcium chloride and magnesium chloride (2 L)</td>
<td>A4737901</td>
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<tr>
<td><strong>Accessories</strong></td>
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<tr>
<td>Rotea Kit Tube Clamps (100 pk)</td>
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<td>Rotea Kit Sterile Connectors (10 pk)</td>
<td>A50110</td>
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<td>Rotea Kit Sterile Sample Ports (10 pk)</td>
<td>A50111</td>
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* North America, Europe.
** Rest of world.