Sefia Select™ system

CELL THERAPY MANUFACTURING

The Sefia Select™ system comprises two hardware components (Sefia™ S-2000 instrument and Sefia Select module, Fig 1.), specialized application software, and single-use kits to provide a comprehensive solution to your cell processing needs. The automated and functionally closed system covers cell isolation, cell harvesting, and formulation resulting in a standardized process for reliable autologous cell therapy manufacturing (Fig 2).

- **Confidence to manufacture.** Well-established technology already used for commercialized cell therapies.
- **Flexible system.** Adapts to your specific process and the variation in initial product by utilizing different application parameters.
- **Designed to ensure cellular product integrity.** Closed processing keeps contaminants out. Sensor monitoring and automation facilitate control of the process.
- **Designed to increase productivity.** Reduced operator touchpoints and labor hours optimize your resources and reduce the potential for human error.
- **Easy integration.** User-friendly design of applications and consumables. Centralized data traceability, consistent setup duplication and regulatory compliance thanks to Chronicle™ software connectivity.

Fig 1. Sefia S-2000 instrument and Sefia Select module. Sefia Select module is a new accessory designed specifically to work with Sefia S-2000 instrument; to increase its capabilities.

Fig 2. General workflow for cell therapy manufacturing. The Sefia Select system enables the steps highlighted in green to be performed.

cytiva

System overview

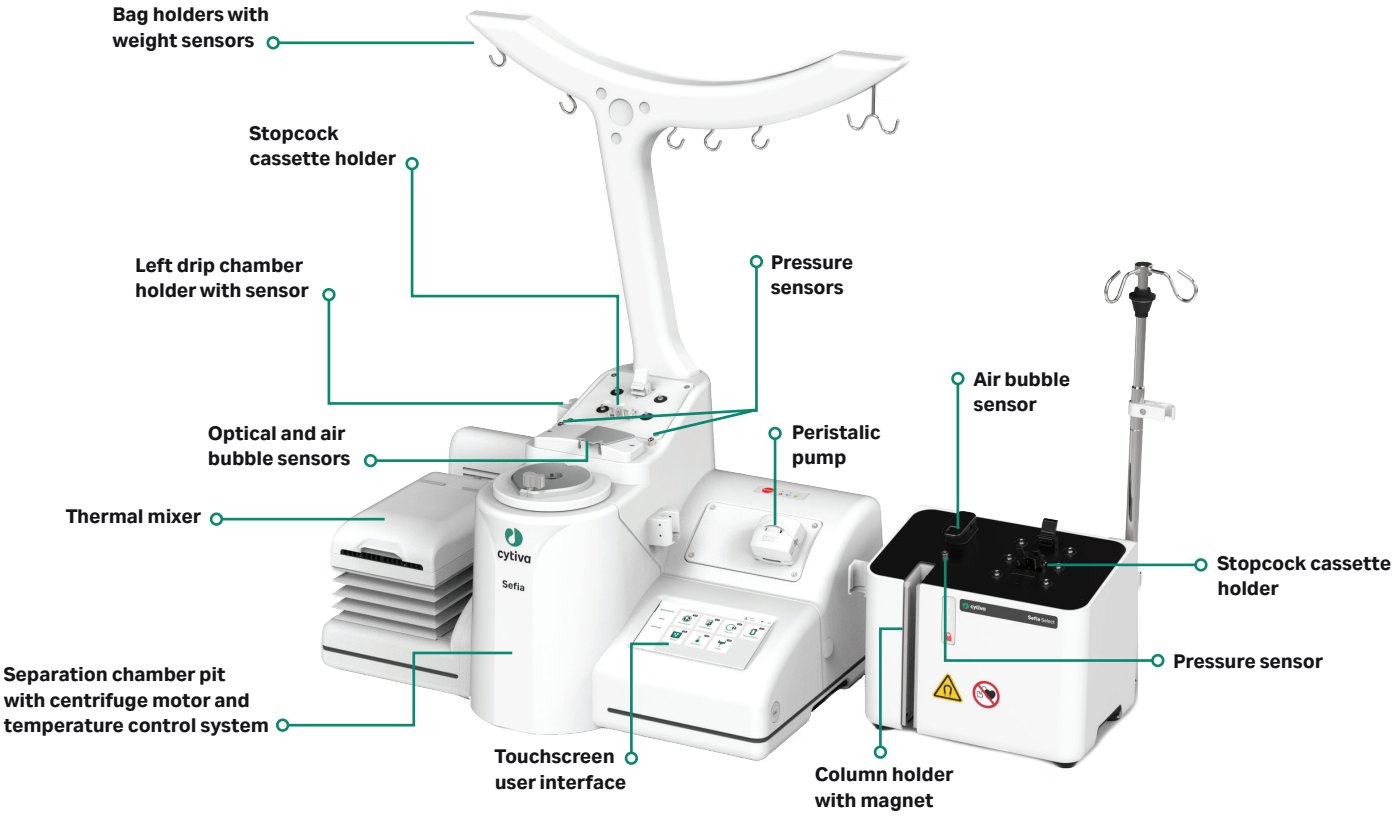


Fig 3. Core technologies of Sefia S-2000 instrument and Sefia Select module.

Hardware

The Sefia S-2000 instrument and the Sefia Select module support a variety of capabilities to automate several steps of cellular therapy manufacturing workflow (Fig 3). The separation chamber pit includes a centrifuge motor and pneumatic circuit to support centrifugation and fluid management in the separation chamber which is part of the single-use kit. The temperature within the separation chamber can be controlled during use. The stopcocks, also included within the single-use kit, allow automatic control of the liquid pathways between the different bags connected to the kit and the separation chamber. A peristaltic pump ensures large volume processing via continuous flow technology or can be used for specific and accurate liquid transfers. To monitor processes, both hardware pieces are equipped with several sensors such as pressure sensors, optical sensors, air bubble sensors, and weight sensors. The thermal mixer provides temperature-controlled mixing of cellular product or reagent solutions. The Sefia Select module includes a column holder with a magnet which can be activated and inactivated to support magnetic cell isolation.

Software

All the elements of the hardware are controlled by an embedded computer system with customized software (BPAS: BioProcessing Application Software) for process automation accessed via a touchscreen user interface.

The Sefia Select system can be connected to Chronicle software, a unified digital platform to monitor cell therapy manufacturing operations and supply chain logistics. Chronicle software enables the digitization of manufacturing documentation by generating electronic batch manufacturing records (eBMRs) through the use of electronic standard operating procedures (eSOPs). It also offers the ability to monitor instrument data in real-time and receive alert notifications via SMS and emails. Chronicle software centralizes the creation, approval, and deployment of parameter groups on connected Sefia Select systems. Chronicle software supports cell therapy process development and manufacturing in compliance with FDA 21 CFR Part 11 and EU Annex 11.

Applications

To support different steps in the cellular therapy manufacturing workflow, dedicated application software and single-use kits have been developed on the Sefia Select system. Each application enables user-definable parameters that provide flexibility to configure the relevant process steps and guide the user.

Consumables

The Sefia Select single-use kits are predominantly composed of a proprietary separation chamber, stopcock cassette(s), lines, filter(s) and pre-attached bag(s). The separation chamber is a syringe pump that enables centrifugation and transfer of liquid. To provide a closed and sterile environment, different bags can be connected to the kit lines with a sterile connection device. To facilitate the kit installation, user-friendly, color-coded lines show where to hang the bag on the Sefia S-2000 instrument (equipped with the same color-coded hook).

Application software	Workflow step	Description	Single-use kit	Module required
PremierCell	Isolation	Mononuclear cells enrichment via density gradient medium from fresh or thawed apheresis	CT-300.1	✗
MagnetSelect	Isolation	T cells isolation via magnetic nano beads from fresh or thawed aspheresis	CT-400.1 + PB-100.1	✓
S-Wash	Harvest	Concentration and washing of expanded cells up to 1.2 L or thawed cellular product	CT-200.1	✗
FlexCell	Harvest and formulation	Concentration and washing of cells up to 10 L and formulate up to 3 final bags	CT-800.1	✗
ReadySelect	Formulation	Preparation of cellular product ready to be used and/or cryopreparation of up to 4 final doses	CT-350.1	✓

PremierCell

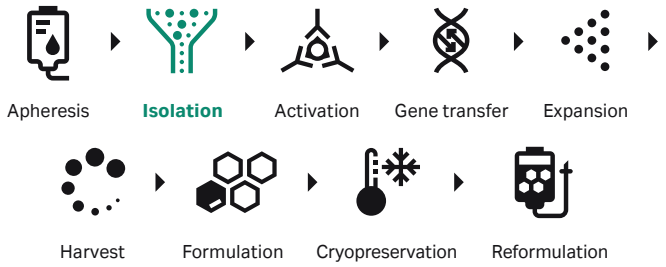


Fig 4. General workflow for cell therapy manufacturing. PremierCell application performs the step highlighted in green.

With the PremierCell application you can automate the mononuclear cell fraction enrichment of fresh or thawed apheresis. Designed for use with the Sefia instrument and CT-300.1 single-use kit (Fig 6), PremierCell offers the flexibility to customize your cell isolation (Fig 4). PremierCell uses centrifugation technology in a functionally closed system to concentrate cells, deplete platelets via washing, perform a density gradient-based isolation[1], and formulate your final cellular product (Fig 5).

- **Fully automated.** Perform all the steps you need to enrich the mononuclear cell fraction via an automated procedure without need for operator intervention during process.
- **Flexible.** Process either fresh or thawed units by activating an initial dilution from a wide range of starting volumes. Fully configure steps of your process via user-definable parameters.
- **Standardize.** Use washing to effectively remove excess platelets that could interfere with the density gradient-based isolation.

[1] Performance has been validated using media with 1.077 g/mL density, such as Ficoll-Paque™ PREMIUM density gradient medium (DGM). Medium of any other density must be validated by the user.

Feature	Description
Initial volume	20 to 880 mL
Initial dilution	
• Dilution volume	Up to 200 mL
• Injection rate	17 to 60 mL/min
• Temperature	4°C to 37°C
• Mixing time	Up to 20 min
Washing (pre- and post-isolation)	
• Number of cycles	Up to 4
• Centrifugation g-force	85 to 400 × g
• Centrifugation time	Up to 10 min
• Intermediate volume	5 to 20 mL
Density gradient medium isolation	
• Initial hematocrit	0% to 30%
• DGM retention volume	45 to 70 mL
Final formulation	
• Bag split	Up to 2 final bags
• Temperature range	4°C to 37°C
Final volume	20 to 200 mL

Performances	Value
Typical processing time[2]	2 h
Average cell recovery[3]	
• Lymphocytes	55%
• Monocytes	55%
Average platelet depletion[3]	92%
Average red blood cell (RBC) depletion[3]	86%
Average cell viability drop[3]	7%
Standard deviation for final volume[3]	+/- 4.3 mL

[2] For an initial volume of 300 mL and with default parameters
[3] Indication only as performances depend on user and cellular product configuration. Check with your local representative to get more details on these performances

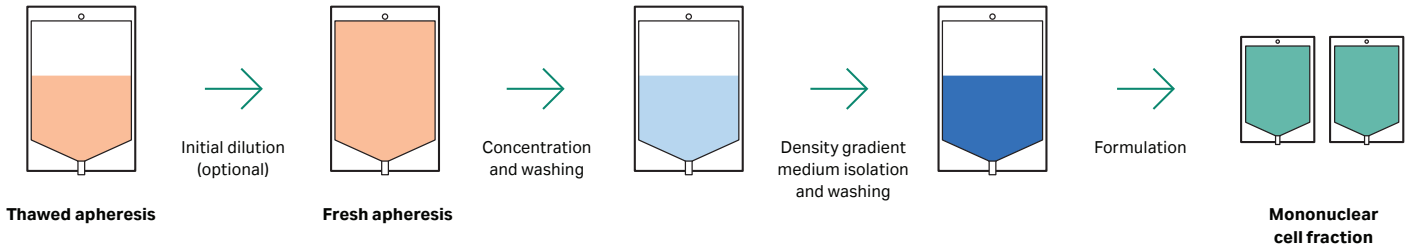


Fig 5. Diagram of steps performed by PremierCell application.

CT-300.1

CT-300.1 single-use kit (Fig 6) allows you to maintain a functionally closed fluid path during the mononuclear cell fraction enrichment of fresh or thawed apheresis.

Designed for use with Sefia S-2000 instrument and PremierCell application, CT-300.1 is ready for connection to your cellular product bag and other bags with reagents and solutions.

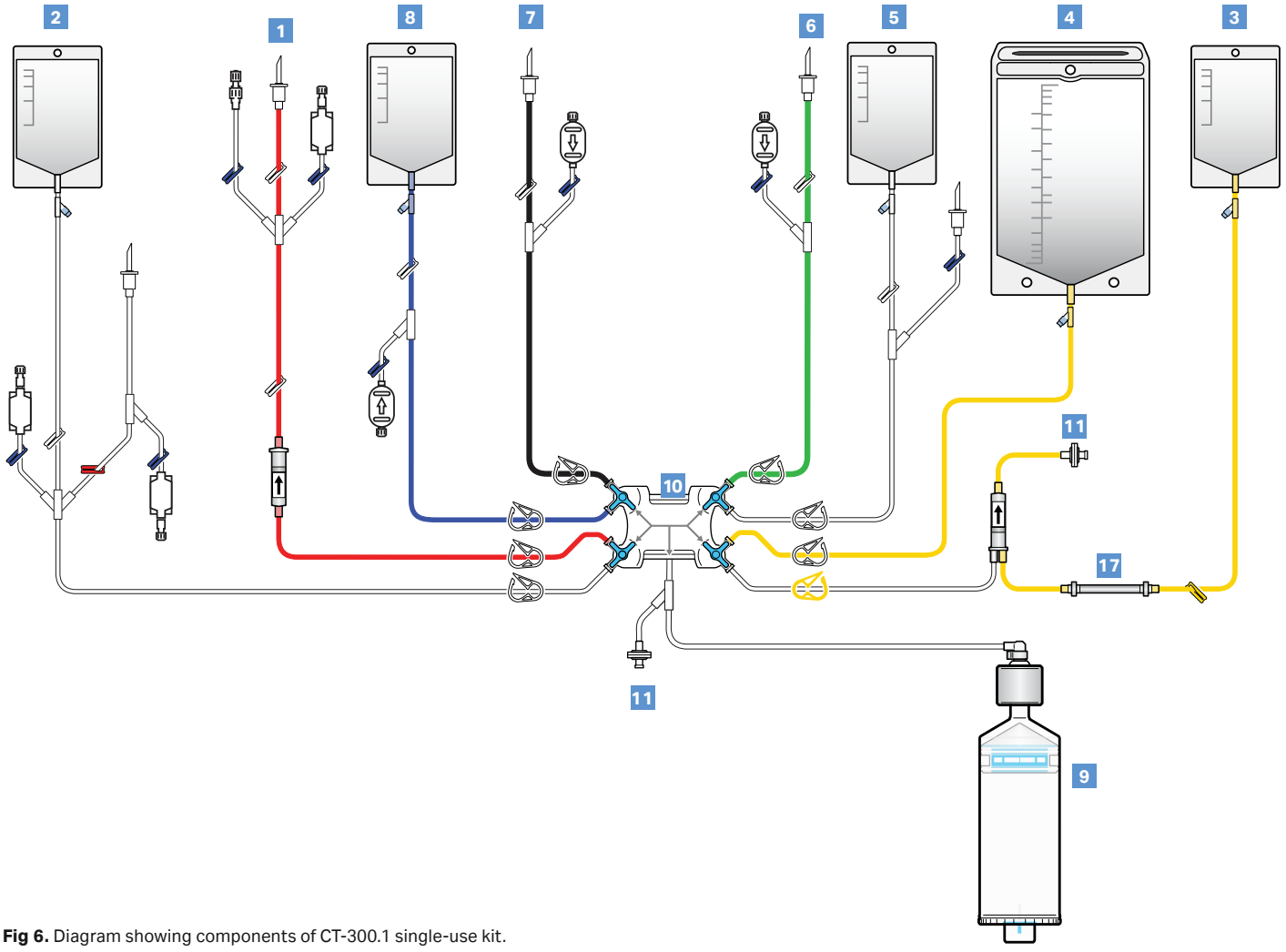


Fig 6. Diagram showing components of CT-300.1 single-use kit.

Part	Description
1	Initial line with a spike, a male luer connector, a sampling pillow and a drip chamber with 200 µm filter
2	Final line with a 250 mL bag, a second line with a spike (for second final bag) and two sampling pillows
3	Pre-isolation intermediate product line with a 250 mL bag, a drip chamber and a silicone tubing for the peristaltic pump
4	Waste line with a 5.5 L bag
5	Resupension line with a 250 mL bag and a spike
6	Post-isolation washing solution line with a spike and a 0.2 µm hydrophilic polyethersulfone (PES) filter
7	Pre-isolation washing solution line with a spike and a 0.2 µm PES filter
8	DGM/post-isolation intermediate product line with a 250 mL bag and a 0.2 µm PES filter
9	Separation chamber used for centrifugation with a capacity of 220 mL
10	Stopcock cassette with four stopcocks controlling up to eight fluid pathways
11	Pressure filters with a 0.2 µm hydrophobic filter

MagnetSelect

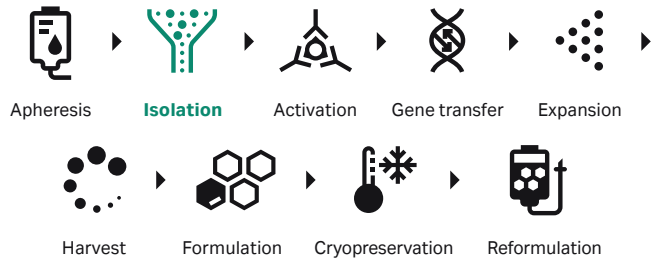


Fig 7. General workflow for cell therapy manufacturing. MagnetSelect application performs the step highlighted in green.

With the MagnetSelect application you can fully automate the T cell isolation of fresh or thawed apheresis (Fig 7). Designed for use in combination with Sefia S-2000 instrument, Sefia Select module, CT-400.1 single-use kit (Fig 9) and PB-100.1 processing bag (Fig 10). MagnetSelect uses centrifugation and magnetic cell separation technology in a functionally closed system to concentrate cells, deplete platelets via washing, incubate cells with magnetic beads, perform magnetic cell isolation[4], and resuspend your final cellular product (Fig 8).

- **Fully automated.** Perform all the steps you need to isolate T cells via an automated procedure without need for operator intervention during process.
- **Flexible.** Process either fresh or thawed units by activating an initial dilution from a wide range of starting volumes. Fully configure steps of your process via user-definable parameters.
- **Standardize.** Optimized application to provide comparable performances for a wide range of initial product scenarios (even with an extremely low percentage of T cells).

[4] Performance has been validated using CD4 and CD8 nanobeads from Miltenyi Biotec. Any other beads must be validated by the user.

Feature	Description
Initial volume	20 to 880 mL
Initial dilution	
• Dilution volume	Up to 440 mL
• Injection rate	17 to 60 mL/min
• Temperature	4°C to 37°C
• Mixing time	Up to 20 min
Washing (pre- and post-isolation)	
• Number of cycles	Up to 3
• Centrifugation g-force	85 to 800 × g
• Centrifugation time	Up to 10 min
• Intermediate volume	5 to 50 mL
Bead incubation	
• Bead solution volume	Up to 50 mL
• Incubation time	Up to 90 min
• Temperature	4°C to 37°C
Magnetic isolation	
• Isolation volume	Up to 300 mL
• Isolation and rinsing flow rate	Up to 60 mL/min
• Rinsing volume	Up to 150 mL
• Isolation serial capture	Enable multiple cell captures
Final formulation	
• Centrifugation g-force	85 to 800 × g
• Centrifugation time	Up to 10 min
• Intermediate volume	5 to 50 mL
• Final volume	20 to 250 mL

Performances	Fresh healthy donor	Frozen healthy donor	Patient model
Typical processing time[5]	2.5 h	3 h	3.5 h
Average T cell recovery[6]	76%	63%	72%
Average T cell purity[6]	90%	92%	89%
Average cell viability drop[6]	1%	3%	1%
Average platelet depletion[6]	99%	n/a	n/a
Average RBC depletion[6]	94%	n/a	n/a
Standard deviation for final volume[6]	+/- 3.2 mL	+/- 3.2 mL	+/- 3.2 mL

[5]For an initial volume between 65 and 150 mL and with parameters adapted to each input product.
[6]Indication only as performance depends on user and cellular product configuration.
Check with your local representative to get more details on these performances.

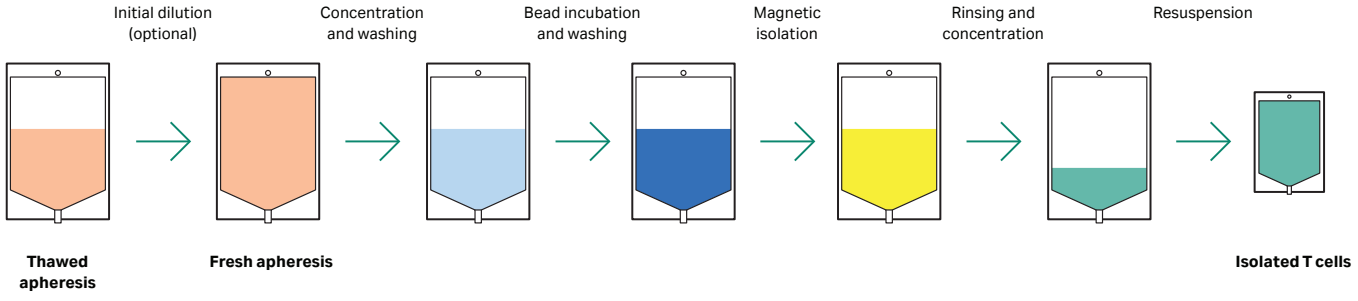


Fig 8. Diagram of steps performed by MagnetSelect application.

CT-400.1

CT-400.1 single-use kit (Fig 9) allows you to maintain a functionally closed fluid path during the magnetic T cell isolation of fresh or thawed apheresis.

Designed for use with Sefia Select system and MagnetSelect application, CT-400.1 is ready for connection to your cellular product bag and other bags with reagents and solutions.

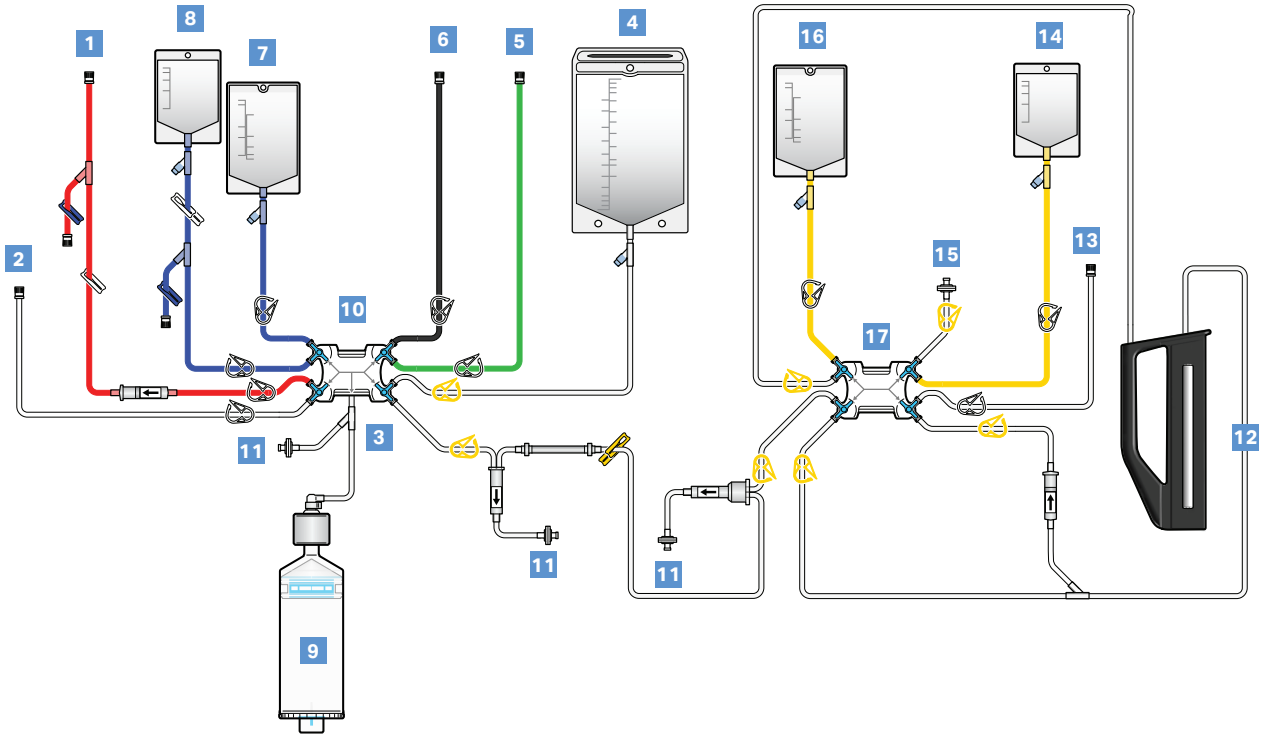


Fig 9. Diagram showing components of CT-400.1 single-use kit.

Part	Description
1	Initial line with an additional line for sampling and a drip chamber with 200 µm filter
2	Processing bag line for connecting the PB-100.1 bag containing the magnetic bead solution
3	Line with pressure filter, drip chamber and silicone tubing for the peristaltic pump
4	Waste line with a 5.5 mL bag
5	Isolation washing solution line
6	Pre-incubation washing solution line
7	Transfer bag 1 line with a 1000 mL bag
8	Final line with a 250 mL bag and an additional line for sampling
9	Separation chamber used for centrifugation with a capacity of 220 mL
10	Sefia stopcock cassette with four stopcocks controlling up to eight fluid pathways
11	Pressure filter with a 0.2 µm hydrophobic filter
12	Column holder with the magnetic isolation column
13	Resuspension solution line
14	Transfer bag 2 line with a 250 mL bag
15	Air inlet line with a 0.2 um hydrophobic filter
16	Negative fraction bag line with a 1000 mL bag
17	Module stopcock cassette with four stopcocks controlling up to eight fluid pathways

PB-100.1

The PB-100.1 (Fig 10) bag is a single-use processing bag allowing the user to fill the bag with magnetic bead solutions in a flexible manner, and connect the bag to the CT-400.1 kit.

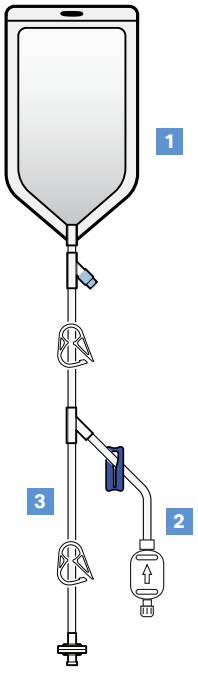


Fig 10. Diagram showing components of PB-100.1 processing bag.

Part	Description
1	Processing bag of 300 mL with a luer port
2	Line 2 with a 0.2 µm hydrophilic PES filter
3	Line 3 with a 0.2 µm hydrophobic filter

S-Wash

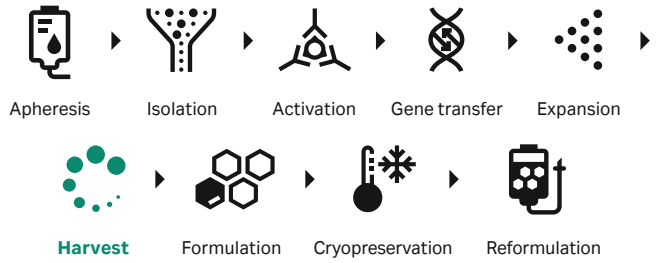


Fig 11. General workflow for cell therapy manufacturing. S-Wash application performs the step highlighted in green.

With the S-Wash application you can automate cell harvest (Fig 11). Designed for used with the Sefia S-2000 instrument and CT-200.1 single-use kit (Fig 13), S-Wash offers a simple and flexible washing application for downstream as well as upstream steps. S-Wash uses centrifugation technology to dilute, concentrate, and wash fresh or thawed cellular products (Fig 12).

The S-Wash application has been validated downstream to harvest cells post expansion and upstream to wash thawed isolated cells before activation. However, S-Wash can be used at any step you need to concentrate and/or wash cellular product.

- **Simple.** Choose the required parameters and your cells will automatically be concentrated and washed as requested.
- **Flexible.** Process either fresh units from starting volumes up to 1.2 L or thawed units by activating initial dilution. Then resuspend cells in the solution of your choice.
- **Standardize.** Effectively remove debris and reagents through a functionally closed system.

Feature	Description
Initial volume	20 to 1200 mL
Initial dilution	
• Dilution volume	Up to 440 mL
• Injection rate	17 to 60 mL/min
• Temperature	4 to 23°C
• Mixing time	Up to 20 min
Washing	
• Number of cycles	Up to 3
• Centrifugation g-force	100 to 600 × g
• Centrifugation time	Up to 10 min
Final volume	20 to 285 mL

Performances	Value
Typical processing time[7]	1.5 h
Washout efficiency[8]	4 log
Average cell recovery for expanded cells[8]	98%
Average cell recovery for thawed cells[8]	87%
Average cell viability drop[8]	3%
Standard deviation for final volume[8]	+/- 3.6 mL

[7] For an initial volume of 1000 mL and with default parameters
[8] Indication only as performance depends on user and cellular product configuration. Check with your local representative to get more details on these performances.

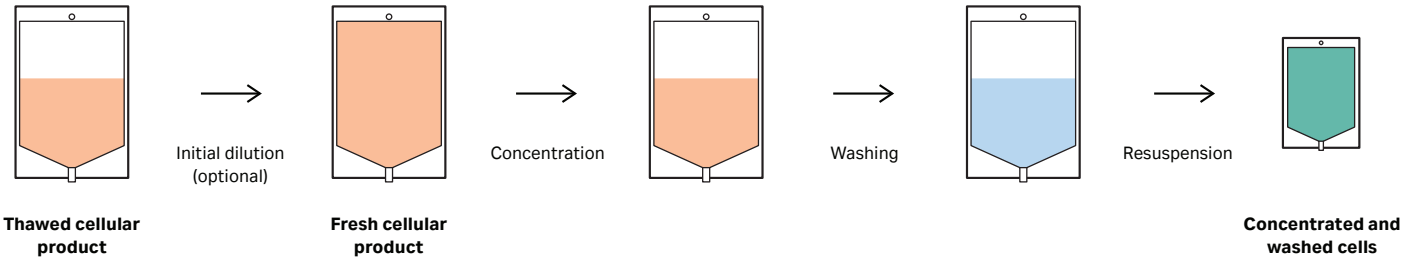


Fig 12. Diagram of steps performed by S-Wash application.

CT-200.1

CT-200.1 single-use kit (Fig 13) allows you to maintain a functionally closed fluid path during the concentration and washing step of fresh or thawed cellular products.

Designed for use with Sefia S-2000 instrument and S-Wash application, CT-200.1 is ready for connection to your cellular product bag and solution bags.

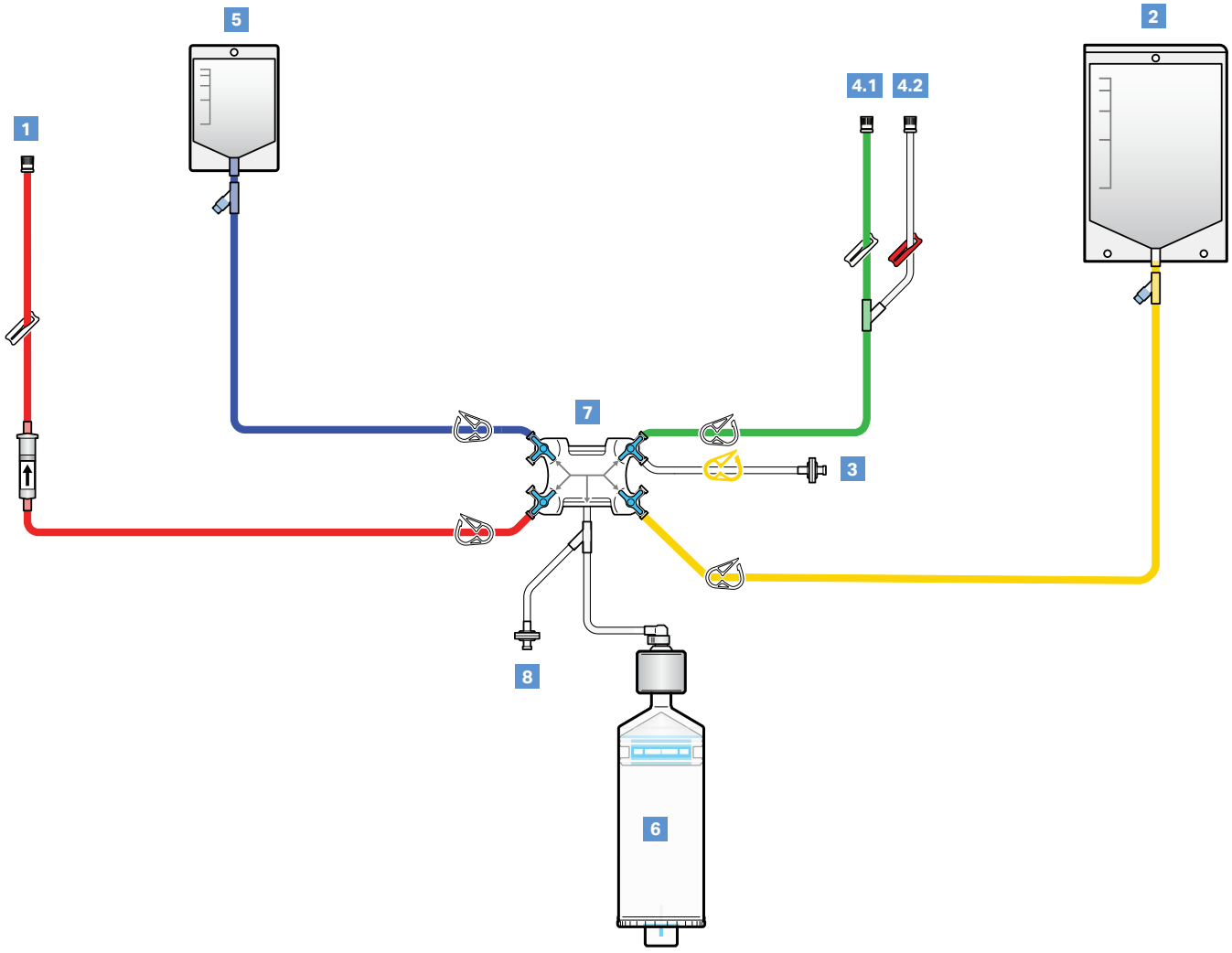


Fig 13. Diagram showing components of CT-200.1 single-use kit.

Part	Description
1	Initial line with a drip chamber with 200 µm filter
2	Waste line with a 5.5 L bag
3	Air inlet line with a 0.2 µm hydrophobic filter
4.1	Washing solution line
4.2	Resuspension solution line
5	Final line with a 250 mL bag
6	Separation chamber used for centrifugation with a capacity of 220 mL
7	Stopcock cassette with four stopcocks controlling up to eight fluid pathways
8	Pressure filters with a 0.2 µm hydrophobic filter

FlexCell

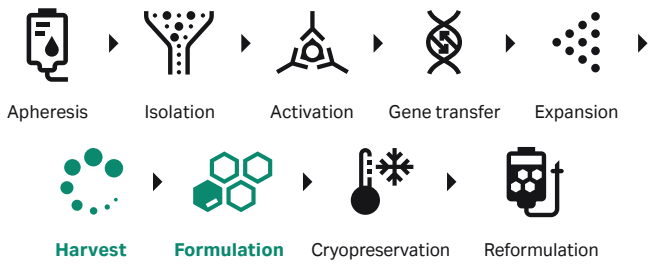


Fig 14. General workflow for cell therapy manufacturing. FlexCell application performs the steps highlighted in green.

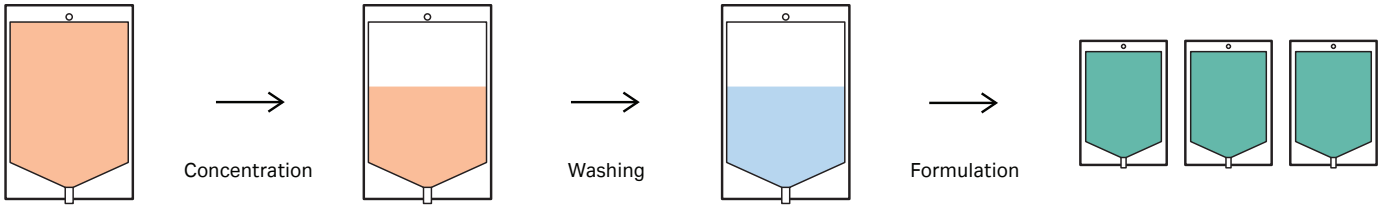
With the FlexCell application you can automate the harvest and formulation of expanded cells. Designed for use with Sefia S-2000 instrument and CT-800.1 single-use kit (Fig 16), FlexCell offers the flexibility to customize your downstream processing (Fig 14). FlexCell uses centrifugation and continuous flow technologies to concentrate volumes up to 10 L, wash and formulate your final cellular product (Fig 15).

- **Fast.** Concentrate up to 10 L per hour thanks to combination of peristaltic pump and separation chamber design.
- **Fully automated.** Perform all the steps you need to harvest and formulate your cells via an automated procedure without need for operator intervention during process.
- **Flexible.** Process a wide range of initial volumes and resuspend cells in the solution of your choice. Fully configure your process steps via user-definable parameters.

Feature	Description
Initial volume	0.1 to 10 L
Formulation • Harvest flow rate	 Up to 10 L/h
Washing • Number of cycles • Centrifugation g-force • Centrifugation time • Intermediate volume	 Up to 4 85 to 800 × g Up to 20 min Up to 150 mL
Formulation • Bag split • Temperature range	 Up to 3 final bags 4°C to 37°C
Final volume	15 to 300 mL

Performances	Value
Typical processing time[9]	2 h
Average cell recovery[10]	80%
Average cell viability drop[10]	3%
Standard deviation for final volume[10]	+/- 3.2 mL

[9] For an initial volume of 5 L and with default parameters
[10] Indication only as performance depends on user and cellular product configuration. Check with your local representative to get more details on these performances.



Expanded cellular product

Final cellular products

Fig 15. Diagram of steps performed by FlexCell application.

CT-800.1

CT-800.1 single-use kit (Fig 16) allows you to maintain a functionally closed fluid path during the concentration, washing and formulation of cultured cells.

Designed for use with Sefia S-2000 instrument and FlexCell application, CT-800.1 is ready for connection to your cellular product bag and other solution bags.

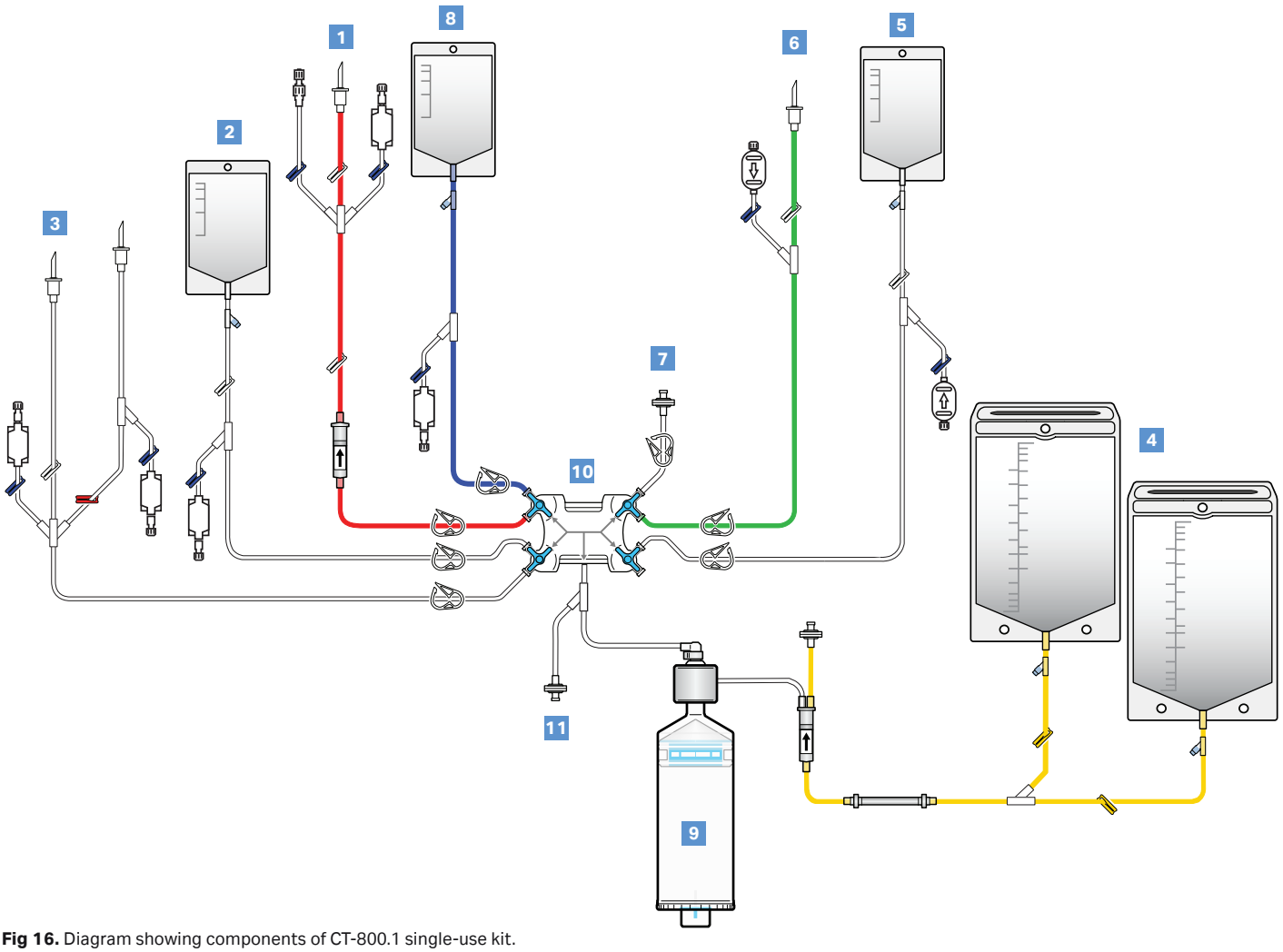


Fig 16. Diagram showing components of CT-800.1 single-use kit.

Part	Description
1	Initial line with a spike, a male luer connector, a sampling pillow and a drip chamber with 200 µm filter
2	Final line with a 250 mL bag and a sampling pillow
3	Final line with two spikes (for second and third final bags if applicable) and two sampling pillows
4	Waste line with two 5.5 L bags, a silicone tubing for the peristaltic pump, a drip chamber, and a pressure filter
5	Resupension line with a 250 mL bag and a 0.2 µm PES filter
6	Washing solution line with a spike and a 0.2 µm PES filter
7	Air inlet line with a 0.2 µm hydrophobic filter
8	Temporary line with a 250 mL bag and a sampling pillow
9	Separation chamber used for centrifugation and continuous-flow processing with a capacity of 210 mL
10	Stopcock cassette with four stopcocks controlling up to eight fluid pathways
11	Pressure filters with a 0.2 µm hydrophobic filter

ReadySelect

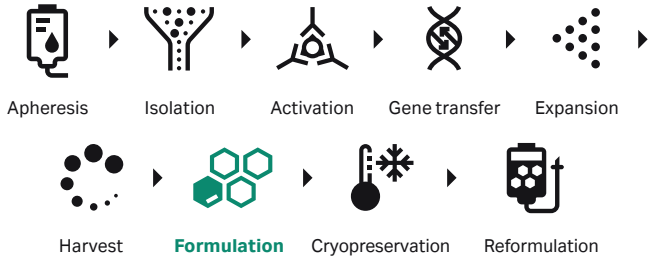


Fig 17. General workflow for cell therapy manufacturing. ReadySelect application performs the step in green.

With the ReadySelect application you can fully automate dilution, mixing, cryo preparation, and splitting of cellular products in a functionally closed system (Fig 18).

Designed for use with Sefia S-2000 instrument, Sefia Select module, and CT-350.1 single-use kit (Fig 19), ReadySelect offers multiple scenarios via open parameters to cover your upstream and downstream needs (Fig 17).

- **Flexible.** Dilute with your desired solution(s). Formulate a ready-to-use cellular product and/or cellular product ready to be cryopreserved. Split product in up to 4 doses using any model of standard cryobags
- **Efficient.** Attain a consistent formulation through accurate volumes and cell repartitions
- **Control:** Streamline comprehensive electronic data recording and reporting to ensure compliance with current good manufacturing practices (cGMP)

Feature	Description
Formulation	
• Initial cellular product	Up to 250 mL
• Mixing time	Up to 5 min
• Final volume	Up to 250 mL
Cryopreparation	
• Initial cellular product	Up to 300 mL
• Dilution	Up to 3 different solution including cryoprotectant
• Product condition before cryoprotectant addition	4°C to 22°C
• Mixing time	Up to 1 h
• Splitting	Up to 4 cryobags User-defined volumes in each final bag with an overall volume up to 300 mL
• Air removal in final bags	Minimized based on kit configuration

Performances	Value
Average final volume accuracy[11]	98%
Average cell repartition accuracy[11]	96%
Average cell recovery[11]	96%
Average cell viability drop[11]	2%

[11] Indication only as performance depends on user and cellular product configuration. Check with your local representative to get more details on these performances

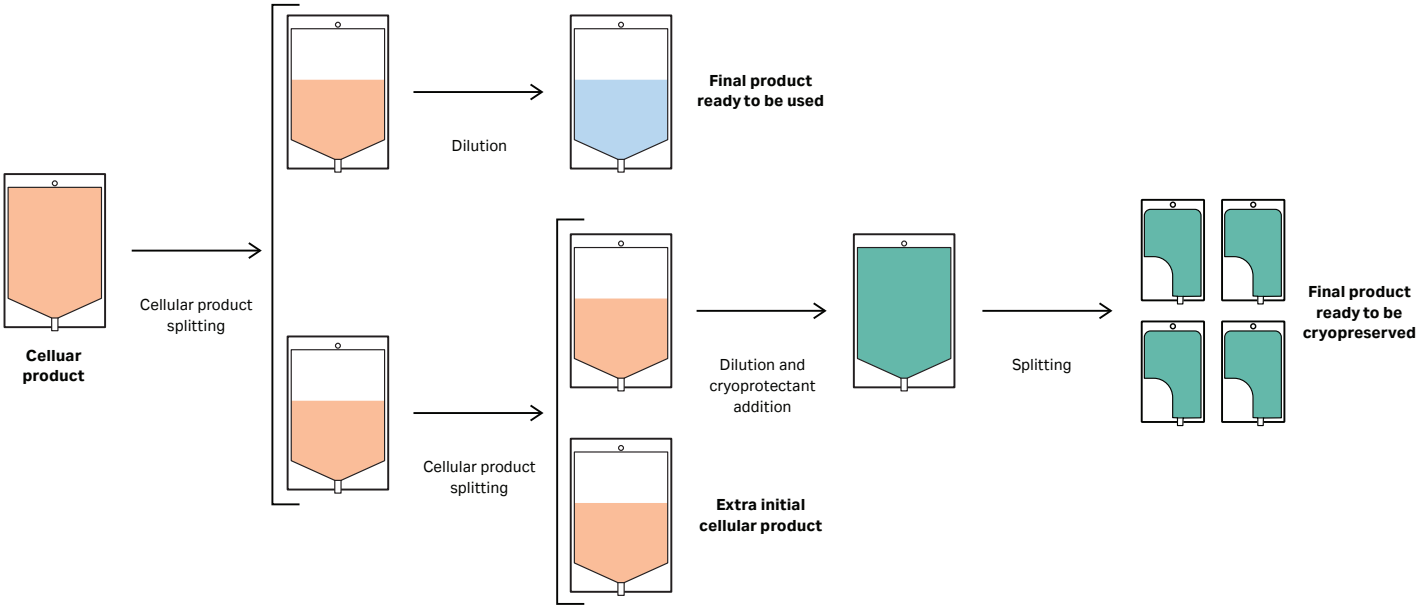


Fig 18. Diagram of steps and scenarios performed by ReadySelect application.

CT-350.1

CT-350.1 single-use kit (Fig 19) allows you to maintain a functionally closed fluid path during the formulation step of your cellular product at any stage of your cell therapy manufacturing.

Designed for use with Sefia Select system and ReadySelect application, CT-350.1 is ready for your cellular product bag and other solution bags.

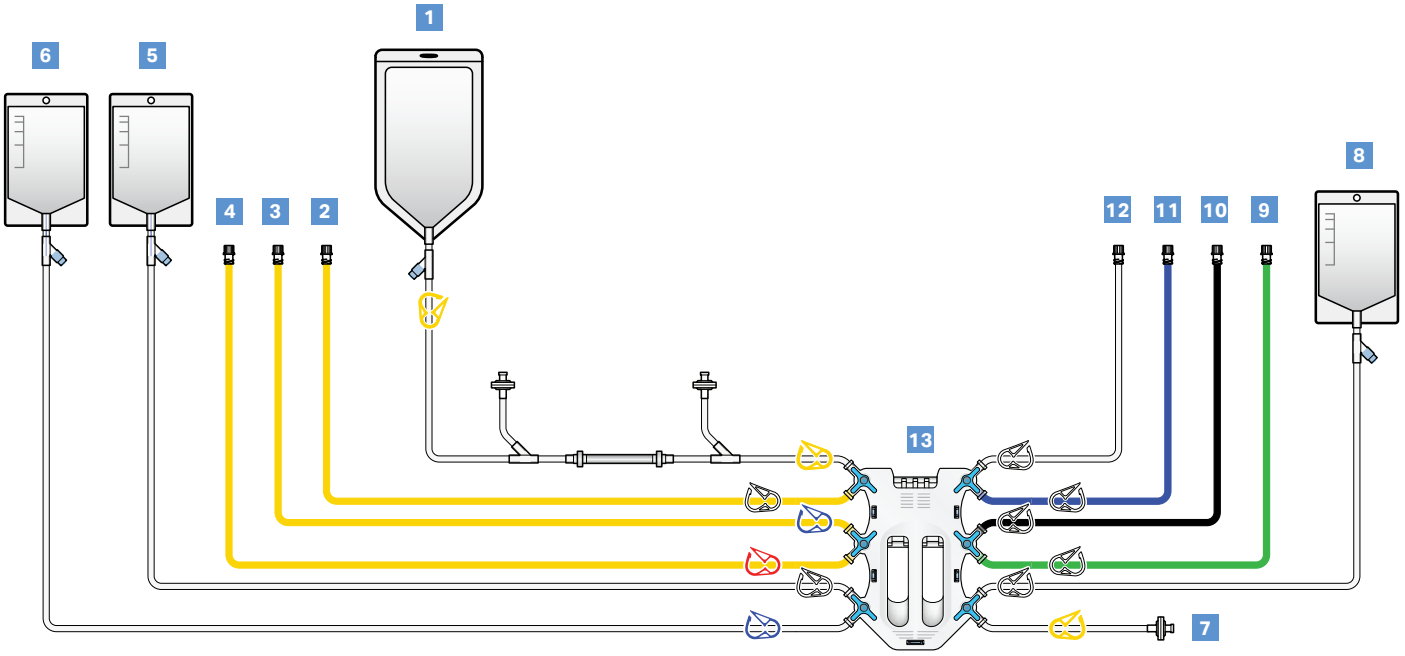


Fig 19. Diagram showing components of CT-350.1 single-use kit.

Part	Description
1	Processing bag line with a 300 mL bag, silicone tubing for the peristaltic pump and two pressure filters with a 0.2 µm hydrophobic filter
2-4	Solution lines
5	Formulation line with a 250 mL bag
6	Initial/intermediate line with a 250 mL bag
7	Air inlet line with a 0.2 µm hydrophobic filter
8	Waste line with a 250 mL bag
9-12	Cryobag lines
13	Stopcock cassette with six stopcocks controlling up to twelve fluid pathways

System specifications

Hardware

Feature	Sefia S-2000 instrument	Sefia Select module
Dimension	W: 74 cm, L: 51 cm, H: 91 cm (29 in./20 in./36 in.)	W: 37.5 cm, L: 27 cm, H: 30/90 cm (14.8 in./10.6 in./ 11.8/35 in.)
Weight	40 kg (88 lb)	25 kg (55 lbs)
Power consumption Input voltage Frequency	1000 W, 100-240 VAC 50/60 Hz	100 W 100-240 VAC 50/60 Hz
Core technology	Electric motor for centrifugation up to 1600 × g Four motorized axis for automated fluid flow management Thermal mixer for temperature control between +4°C and +40°C Temperature control of separation chamber between +4°C and +37°C Peristaltic pump: up to 405 mL/min Pressure sensors for kit lines: -800 to +2000 mbar Bag holders with weight sensors: each hook has a maximum load capacity of 15 kg. The total safe working load of the pole is 20 kg.	Permanent magnet Pressure sensors for kit lines: -800 to +2000 mbar Six motorized axis for automated fluid flow management
Connectivity	Five USB ports and two ethernet ports	Dedicated electronics controlled by the Sefia S-2000 instrument via USB connection.
Software	Compatible with Sefia application software only, Windows 10 and proprietary Bioprocessing Application Software (BPAS)	
User interface	Color touchscreen with an intuitive graphical user interface (GUI) Dynamic user guide to support operations	
Traceability	Barcode reader Data management with PDF reports	N/A
User authentication	Role based configuration Authentication and permission using a customer's ActiveDirectory (AD) server	
Electronic signature	Electronic signature is performed in Chronicle automation software only	
Data exchange	Encrypted and secured	
System log/audit trail	Every system action is recorded in the system log Data transfer populates associated equipment logs in Chronicle automation software	
Certification	The Sefia instrument is included in the validation support file (Certificate)	

Consumables

Feature	Sefia Select consumables
Shelf life	Two years from the date of manufacture[12]
Sterility	Ethylene oxide, minimum sterility assurance level (SAL) of 10^{-6} non-pyrogenic, < 20 EU/device endotoxin
Material	Lines are in polyvinyl chloride (PVC) and pre-attached bags are in ethylene-vinyl acetate (EVA). For additional information on material, refer to Sefia kit validation guide.
Lines	All the lines are compatible with sterile welding connections. External diameter is 4.1 mm and thickness is 0.75 mm.

[12] Two years validation are still pending for CT-400.1 and PB-100.1

Safety and compliance

Sefia S-2000 is a laboratory instrument with the CE mark (Machinery Directive 2006/42/EC). Sefia Select module is an accessory to Sefia S-2000. The system is intended for cell therapy manufacturing in good automated manufacturing practice (GAMP) compliant environments. Both hardware are compliant with IEC-61010, IEC-61326, and IEC-62304 standards.

Chronicle enables technical compatibility with ISPE GAMP 5, FDA 21 CFR Part 11 and EU GMP Annex 11 compliance.

Storage requirements

In addition to the environmental requirements outlined in the following table, installation of the Sefia S-2000 instrument and Sefia Select module must comply with the following general requirements:

- The room must have exhaust ventilation
- The instrument should not be exposed to sources of heat such as direct sunlight
- Dust in the atmosphere should be kept to a minimum
- The equipment must not be exposed to vibrations

Parameter	Requirement
Allowed location	Indoor use only
Ambient temperature, operation	7°C to 27°C
Ambient temperature, storage and transport	0°C to 45°C
Maximum relative humidity, operation	30% to 75%, non-condensing
Relative humidity, non-operating	20% to 75%, non-condensing
Ambient atmospheric pressure, operation	840 to 1060 mbar (12 to 15 psi)
Pollution degree of the intended environment	Pollution degree 2

The table below highlights the environmental requirements for storage, transport and operation of Sefia Select consumables. Sefia Select kits and bags must be stored in a clean and dry environment without chemical or biological contamination.

Mode	Operation	Storage
Temperature	7°C to 27°C	10°C to 30°C
Relative humidity	30% to 75% non-condensing	Not applicable

Service information

OptiRun™ Service Solutions

Regulatory authorities require systems to be qualified and maintained within specifications during use in process scale-up and GMP-manufacturing. Our OptiRun™ Service Solutions offer a comprehensive range of services throughout the product's life cycle to support your technology, processes, and people.

Services	Description
Equipment installation	Installation can be performed by trained Cytiva service engineers
Preventive maintenance	Replacement of wear-and-tear parts and functional testing to ensure continuous performance of your instrument
Installation/ operational qualification (IQ/OQ)and re-qualification	Standard and custom qualification services for Cytiva equipment throughpout its life cycle, including IQ/OQ, RQ, and continuous verification
Instruments upgrades	Hardware and software upgrades to keep your equipment state-of-the-art during its life cycle
Repairs	Field, remote and mail-in repairs are available depending on your instrument type and environment
Digital services	A range of digital solutions, from remote assistance to network installation and virtual support and trainings
Spare parts	High quality spare parts for use in GxP environment; parts security of supply consultancy
Relocation support	Preparing your equipment for move and re-installing it in its new location
Service plans	A range of plans to support your operations and instrument performance

Ordering information

Products	Product code
Sefia S-2000 instrument	29285527
Sefia Select module	29376725
PremierCell Sefia application software	29321902
MagnetSelect Sefia application software	29417852
S-Wash Sefia application software	29515521
FlexCell Sefia application software	16301
ReadySelect Sefia application software	29515518
Sefia Select applications package	29749704
CT-300.1 kit	29284866
CT-400.1 kit	29660968
CT-200.1 kit	29656477
CT-800.1 kit	20001
CT-350.1 kit	29660965
PB-100.1 bag	29660974
Chronicle Pre-GMP base annual subscription	29734890
Chronicle GMP base annual subscription	29734894
Ficoll-Paque PREMIUM (6× 100 mL)	17544202

cytiva.com/celltherapy

For local office contact information, visit cytiva.com/contact

CY39186-14May24-DF