Sepax C-Pro Cell Processing Instrument

SEPAX C-PRO CELL PROCESSING SYSTEM

The Sepax™ C-Pro Cell Processing System is an automated and functionally closed technology for cell processing when developing and manufacturing cell therapy products. The system, which is comprised of the instrument, Sepax C-Pro protocol software, and kits, allows you to combine multiple processing steps in a versatile manner. These steps include but are not limited to enrichment, magnetic bead incubation, spinoculation, concentration, washing, dilution, and splitting. Using Chronicle™ automation software, Sepax C-Pro can be integrated with other cell therapy instruments from Cytiva and third-party instruments.

- **Support your requirements and system implementation.** Automated and functionally closed system to support GMP compliance
- **Simplify your operations.** Compact design and user-friendly interface to minimize your space and resource requirements
- **Maintain flexibility.** Sepax C-Pro is a multipurpose solution allowing you to perform diverse and dedicated applications
- **Simplify record-keeping.** Sepax C-Pro can transmit instrument data and alarms for remote monitoring or for incorporation into a Chronicle eSOP
- **Keep operations running smoothly.** Integrate with Chronicle to monitor all connected instruments (Sepax C-Pro and others) and manage service records

Fig 1. Sepax C-Pro instrument. The centrifugation chamber is in the middle, and the touchscreen is at the top.

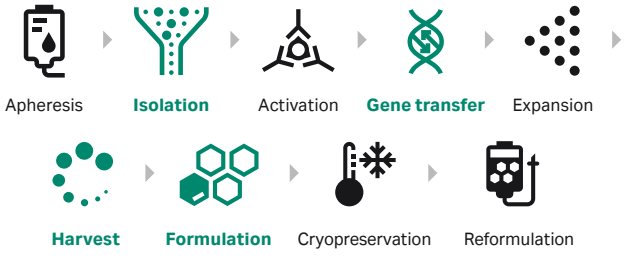

Fig 2. General workflow for cell therapy manufacturing. The Sepax C-Pro Cell Processing System provides solutions for the steps highlighted in green.

Applications and related products

Protocol software	Kit	Application
PeriCell C-Pro	CT-49.1	Concentrate cells from fresh apheresis product via plasma depletion
PlateletFree C-Pro	CT-60.1	Concentrate cells and remove platelets from fresh apheresis units
BeadWash C-Pro	CT-60.1 or CT-90.1	Incubate magnetic beads onto the cell fractions obtained from apheresis units – sequence concentration, platelet depletion, bead incubation, and washing
NeatCell C-Pro	CT-90.1	Enrich mononuclear cell fraction via a density gradient medium
SpinOculation C-Pro	CT-60.1	Concentrate, wash, and transduce isolated cells by spinoculation
CultureWash C-Pro	CT-60.1 or CT-90.1	Dilute, concentrate, and wash fresh or frozen cellular products
Dilution C-Pro	CT-49.1, CT-60.1, or CT-90.1	Dilute and split cellular products into multiple bags for accurate dosing

Product specifications

Feature	Description
Core technology	Electric centrifugation motor and pneumatic circuitry for piston drive
	Pressure monitoring sensor
	Optical line sensor
Traceability	Barcode reader
	Data management with PDF reports and procedural graphs – data saving capacity on the instrument 32 log files, 50 PAT files, and 50 report files (PDF)
User interface	Color touchscreen with an intuitive graphical user interface (GUI)
Software	Compatible with Sepax C-Pro protocol software only
	Windows® XP embedded and proprietary GMAP application software
Unified digital platform	Chronicle automation software connects Cytiva cell therapy instruments and third-party instruments
Connectivity	Four USB slots and two ethernet ports
Dimensions	W: 27 cm, L: 40 cm, H: 46 cm (10.6" × 14.7" × 18.1"), 16.3 kg (35.9 lb)
Power	1000 W, 100–240 VAC, 50/60 Hz

Safety and compliance

Sepax C-Pro is manufacturing equipment with the CE mark (Machinery Directive 2006/42/EC) intended for cell therapy manufacturing in good automated manufacturing practice (GAMP™) compliant environments. It is compliant with IEC-61010, IEC-61326, and IEC-62304 standards.

Sepax C-Pro is not intended for any therapeutic or diagnostic use in humans. Only for use with Sepax C-Pro software protocols and kits.

Country	Compliance
China	Instrument complies with specific Chinese standard labeling (SJ/T11364-2014) and China ROHS 2 (Order 32- 01 JUL 2016)
USA	Instrument complies with UL 61010-1 :2012-05/R :2015-07
	UL 61010-2-020 :2016-12
	47 FCC part 15 Subpart B
Canada	Instrument complies with Canadian ICES-001
	CAN/CSA-C22.2 NO. 61010-1 :2012
Japan	PSE mark (Electrical safety): Electrical Appliance and Material Safety Law (Denan Law): Not applicable
	EMC (VCCI Mark (voluntary mark): Not applicable
	J-MOSS (JIS C 0950 The marking for presence of the specific chemical substances for electrical and electronic equipment): Not applicable here as Sepax C-Pro is not in the scope of JIS C0950 standard
South Korea	Sepax C-Pro is registered in South Korea (registration number: r-r-bsa-29264741) under the clause 3, article 58-2 of Radio Waves Act. Certificate 374a-ad20-b2a8-b37e. Registration date: 31.10.2018
	EMC test report e42830-01-01mk issued on 13.11.2018

Storage requirements

Only operate the Sepax C-Pro instrument on a flat, stable, horizontal, and clean surface. Use it in an open environment to allow sufficient ventilation. Operate and store within the following conditions:

	Operation	Storage and transport
Temperature	7°C to 27°C	0°C to 50°C
Relative humidity	30% to 75% non-condensing	20% to 75% non-condensing
Altitude	2000 m, 80 kPa	N/A

Ordering information

Product	Product code
Sepax C-Pro Cell Processing Instrument	29264741

Related products	Product code
PeriCell C-Pro Protocol Software	29264735
PlateletFree C-Pro Protocol Software	29329538
NeatCell C-Pro Protocol Software	29264734
BeadWash C-Pro Protocol Software	29286433
SpinOculation C-Pro Protocol Software	29367187
CultureWash C-Pro Protocol Software	29264736
Dilution C-Pro Protocol Software	29264737
CT-49.1 Sepax C-Pro Cell Processing Kit	29264738
CT-60.1 Sepax C-Pro Cell Processing Kit	29264739
CT-90.1 Sepax C-Pro Cell Processing Kit	29264740
CPAK-100 Sampling Line	29275109
CPAK-101 Sampling Line	29275108
Chronicle Pre-GMP Automation Software	MYC_30001
Chronicle GMP Automation Software	MYC_60001
Chronicle Enterprise Automation Software	MYC_90001

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