# Sepax<sup>™</sup> 2 S-100 and RM instrument

SEPAX<sup>™</sup> CELL SEPARATION SYSTEM

The Sepax<sup>™</sup> 2 is a mobile, closed capability system that efficiently processes umbilical cord blood, bone marrow, peripheral blood or other blood derivatives, as permitted by applicable regulatory requirements.

### Note for US market:

The Sepax<sup>™</sup> 2 S-100 is available in the US for umbilical cord blood banking application only. The Sepax<sup>™</sup> 2 RM is a variant of Sepax<sup>™</sup> 2 S-100, available only for the US market for the separation of nucleated cells from various cellular products.

The system, which is comprised of Sepax<sup>™</sup> 2 Cell Separation instrument, software applications, and single-use kits, allows you to combine multiple processing steps in a versatile manner. These steps include cell concentration, enrichment, washing, and resuspension.

• Support your requirements and system implementation with an automated and functionally closed system

• Simplify your operations. Compact design and user-friendly interface to minimize your space and resource requirements

- Maintain flexibility. Sepax<sup>™</sup> 2 is a multipurpose solution allowing you to perform diverse and dedicated applications
- Simplify record-keeping. Track specific identification criteria and print out a PDF report



Fig 1. Sepax<sup>™</sup> 2 instrument.

# Applications and related products

Application software	Single-Use Kit(s)	Intended Use
CordWash	CS-600.1	The CordWash application is intended for concentration of total nucleated cells (TNC) and hematopoietic stem cells (HSC) from thawed umbilical cord blood (UCB), and to wash out a maximum quantity cryoprotectant solution and cellular debris.
NeatCell	CS-900.2	The NeatCell application is intended for enrichment of the mononucleated cells (MNC) by depletion of granulocytes as well as red blood cells by use of a density gradient (DG) medium from bone marrow, whole blood, fresh apheresis or umbilical cord blood.



PeriCell	CS-430.1 or CS-490.1	The PeriCell application is intended for partial plasma removal to achieve concentration of the total nucleated cells (TNC) or hematopoietic stem cells (HSC) from fresh apheresis.
SmartRedux	CS-490.1	The SmartRedux application is intended for concentration of the total nucleated cell (TNC) from bone marrow.
SmartWash	CS-600.1	The SmartWash application is intended for concentration of total nucleated cells (TNC) and hematopoietic stem cells (HSC) from thawed apheresis, and to wash out a maximum quantity cryoprotectant solution and cellular debris.
UCB	CS-430.1, CS-530.1, CS-530.4b or CS-540.4b	The UCB application is intended for concentration of the total nucleated cell (TNC) fraction from umbilical cord blood (UCB) without the use of a sedimentation agent.
UCB-HES	CS-430.1, CS-530.1, CS-530.4b or CS-540.4b	The UCB-HES application is intended for concentration of the total nucleated cell (TNC) fraction from umbilical cord blood (UCB) using hydroxy-ethyl starch (HES) as sedimentation agent.

### **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
User interface	Color touchscreen with an intuitive graphical user interface (GUI)
Software	Compatible with Sepax <sup>™</sup> 2 applications only
	Windows® Operating System embedded and proprietary GMAP application software
Unified digital platform	Chronicle automation software connects Cytiva cell therapy instruments and third-party instruments
Connectivity	Four USB ports and two ethernet ports
Dimension	W: 27 cm, L: 40 cm, H: 46 cm (10.6" × 14.7" × 18.1"), 16.3 kg (35.9 lb)
Power	200 VA, 100–240 VAC, 50/60 Hz

### Safety and compliance

The Sepax<sup>™</sup> 2 is CE marked and complies with the applicable European Regulatory framework requirements for medical devices, including the electrical safety standard IEC 60601-1. Design control activities have been performed to ensure its safety and performance. Confirm with your local regulatory authority for compliance with other regulations.

# Operation and storage conditions

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

	Operation	Storage and transport
Temperature	7 to 27°C	0 to 50°C
Relative humidity	30 to 75 %,	20 to 75 %,
	non-condensing	non-condensing

# Ordering information

Product	Product code	
Sepax™ 2 S-100 Cell Separation Instrument	14000	
Sepax <sup>™</sup> 2 RM Cell Separation Instrument	14100	

Related products	Product code
CS-430.1 Sepax™ cell separation kit - Box of 6 Units	10017
CS-490.1 Sepax™ cell separation kit - Box of 6 Units	10001
CS-530.1 Sepax™ cell separation kit - Box of 6 Units	10015
CS-530.4b Sepax™ cell separation kit - Box of 6 Units	10036
CS-540.4b Sepax™ cell separation kit - Box of 6 Units	10037
CS-600.1 Sepax™ cell separation kit - Box of 6 Units	10006
CS-900.2 Sepax™ cell separation kit - Box of 6 Units	10008
CordWash Sepax™ 2 protocol softwar	14304
NeatCell Sepax™ 2 protocol software	14300
PeriCell Sepax <sup>™</sup> 2 protocol software	14203
SmartRedux Sepax™ 2 protocol software	14301
SmartWash Sepax™ 2 protocol software	14305
UCB Sepax™ 2 protocol software	14201
UCB-HES Sepax <sup>™</sup> 2 protocol software	14200

Not all products are available in all countries. Please contact your sales representative about the product availability in your region.

# Manufacturer information

Biosafe S.A., Route du Petit-Eysins 1, 1262 Eysins, Switzerland

Contact us at: www.cytivalifesciences.com/en/us/support/ contact-us

### cytiva.com

Cytiva and the Drop logo are trademarks of Global Life Sciences IP Holdco LLC or an affiliate. Sepax, is a trademark of Global Life Sciences Solutions USA LLC or an affiliate doing business as Cytiva.

© 2021 Cytiva

All goods and services are sold subject to the terms and conditions of sale of the supplying company operating within the Cytiva business. A copy of those terms and conditions is available on request. Contact your local Cytiva representative for the most current information.

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

