

Sepax® system – the essential choice



Sepax is a fully-automated, mobile, closed system for the efficient and consistent processing of umbilical cord blood, bone marrow, peripheral blood or other cell based products.

Its advanced technology fulfills the core needs of the cell processor:

- highly efficient and consistent cell recoveries
- easy handling and safety of processing
- full traceability and GMP compliance

The Sepax system comprises:

- main processing unit
- application-specific software protocols
- single-use cell separation kit



The Sepax system is turn-key, no other equipment is required.

The Sepax system can be further enhanced for specific applications by addition of:

- Coolmix, for automated and controlled cryopreparation
- cryopreparation accessories and CryoSC-cryobags
- SepaxNet, for fully integrated data traceability



The versatility of the technology and associated products has made Sepax the reference in automated adult stem cell banking cell processing and regenerative medicine applications.

Adult Stem Cell Banking

The Sepax device offers multiple solutions for volume reduction and concentration of a cellular product prior to storage. Thanks to the specifically designed application software, the user is able to choose his preferred strategy for an optimal quality of the end-product. Additional flexibility is provided through a wide range of Sepax single-use kits.

Following volume reduction by the Sepax system, the Smart-Max is an automated device used to cryo-prepare or thaw cellular products, as well as infuse reagents for the controlled preparation of cells in cellular therapy or cryopreservation. Other cryopreparation accessories offered by Biosafe include proprietary cryobags, overwrap bags, overwrap bag sealers and canisters for cryo-storage.



Adult stem cell banking protocols

	UCB - HES	UCB	PlasmaFree	PeriCell
Input product	UCB	UCB	UCB	PBSC
Processable initial volume	35 - 320 ml	35 - 290 ml	35 - 440 ml	100 - 840 ml
Selectable final volume	20 - 50 ml	10 - 50 ml	adapted based on input product	30 - 600 ml
Processing time	~ 35 min	~ 35 min	~ 25 min	~ 20 min
TNC recovery	> 85 %	> 80 %	> 90 %	> 90 %

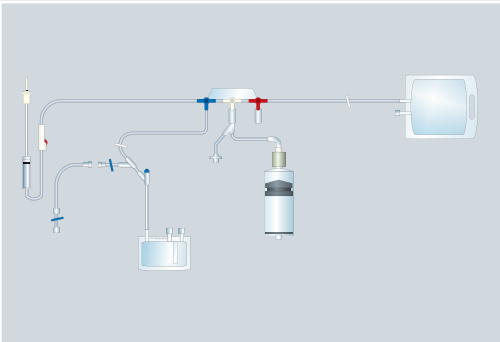
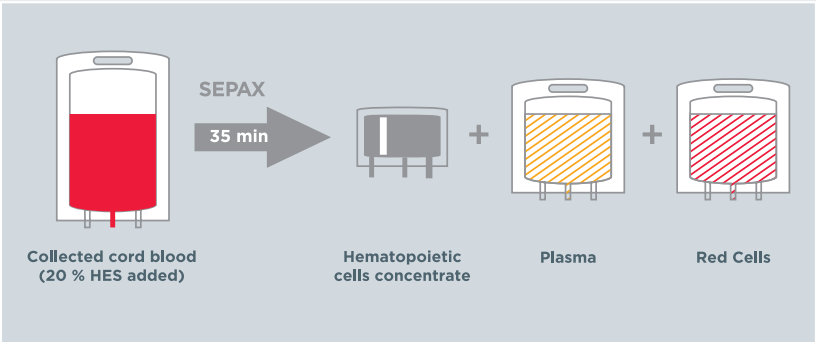
UCB: umbilical cord blood
HES: hydroxyl ethyl starch
PBSC: peripheral blood stem cells
TNC: total nucleated cells

UCB-HES: Concentration of the nucleated cells using HES sedimentation agent which is added to the cord blood unit before starting the procedure.

UCB: Concentration of the nucleated cells without any additive.

PlasmaFree: Plasma depletion of umbilical cord blood.

PeriCell: Concentration of the nucleated cells from aphaeresis product by plasma depletion.



Regenerative Medicine

Sepax is a true platform technology, allowing the volume reduction, concentration and washing of various cellular products in a fully closed and user independent manner.

Compliant with GMP- and GLP regulations as well as at the point-of-care, Sepax is a true enabling tool for the cell researcher, clinician and developer of new biological therapies.

Regenerative medicine and cell therapy protocols

	NeatCell	SmartRedux	ReadyCell	CordWash	SmartWash	CultureWash	Dilution	Adipose
Input product	BM - UCB - PBSC	BM - UCB - WB	BM	thawed UCB	thawed PBSC	cell cultured	cellular products	SVF
Processable initial volume	30 - 120 ml	30 - 3300 ml	30 - 220 ml	10 - 100 ml	50 - 880 ml	30 - 880 ml	0 - 220 ml	30 - 420 ml
Selectable final volume	8-20 ml or 50 ml	up to 1500 ml	7 - 20 ml	50 - 150 ml	50 - 200 ml	8 - 220 ml	(split up to 5 bags)	8 - 150 ml
Processing time	~ 1h15	20 min	~ 15 min	~ 30 min	~ 40 min	~ 40 min	~ 10 min	~ 45 min

BM: bone marrow
UCB: umbilical cord blood
PBSC: peripheral blood stem cells
WB: whole blood
SVF: stromal vascular fraction

NeatCell: Isolation of highly purified mononuclear cells (MNC) with high red blood cell and granulocyte depletion by means of a density gradient medium.

SmartRedux: Concentration of the nucleated cells mainly for bone marrow.

ReadyCell: Concentration of the nucleated cells into a small final volume of 7-20 ml.

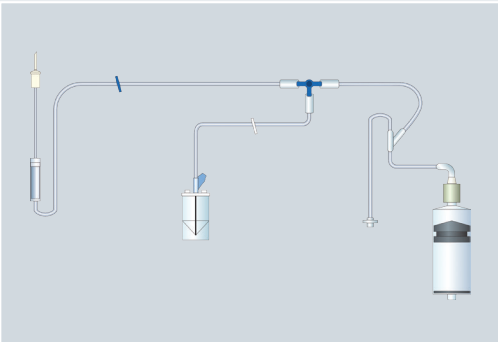
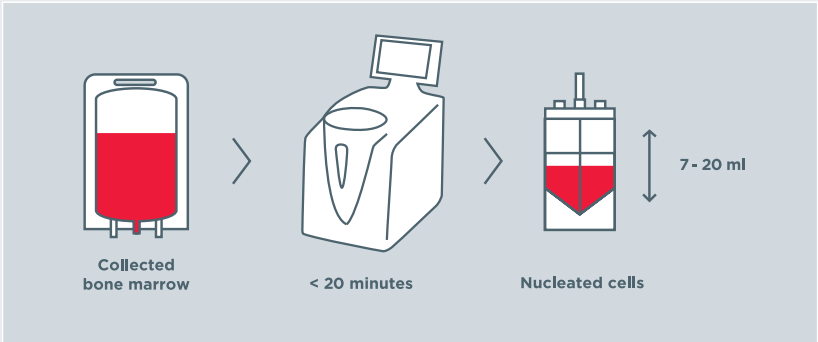
CordWash: Removal of cell debris, cryo-protectant and free hemoglobin from thawed UCB.

SmartWash: Removal of cell debris, cryo-protectant and free hemoglobin from thawed PBSC.

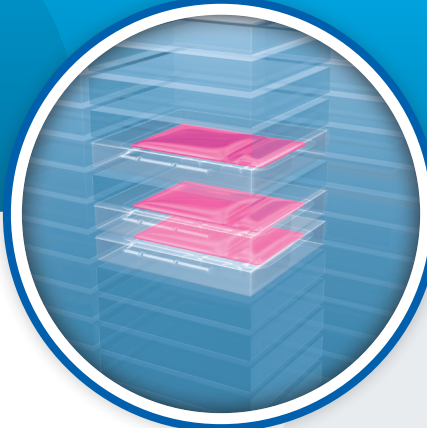
CultureWash: Removal of cell debris, cryo-protectant and free hemoglobin, exchange of media or volume reduction of cultured cells.

Dilution: Dilution of cellular products and possibility to split product homogeneously into multiple bags.

Adipose: Isolation of the nucleated cell fraction from digested lipoaspirate.



A versatile cell processing platform



To date, over 800 Sepax systems have been installed in stem cell laboratories and hospitals in more than 50 countries worldwide.

For adult stem cell banking

Sepax was the first automated cell processing technology to be specifically developed for use in cord blood banks. With its complete range of accessories it allows the safe and individual preparation of a child's stem cells for long-term storage. It is today the industry standard in public and private cord blood banks and is used by a majority of the world's leading public banks that form the NetCord organization.

For regenerative medicine

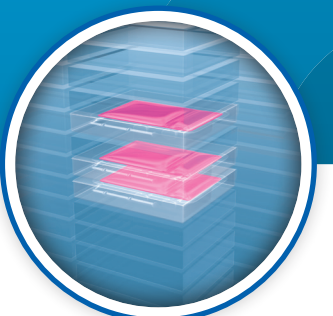
A safe and reliable system, Sepax has long found its place in the transplantation of hematopoietic stem cells.

More recently, the development and manufacture of innovative cell-based and gene therapy products require cutting-edge technologies like Sepax.

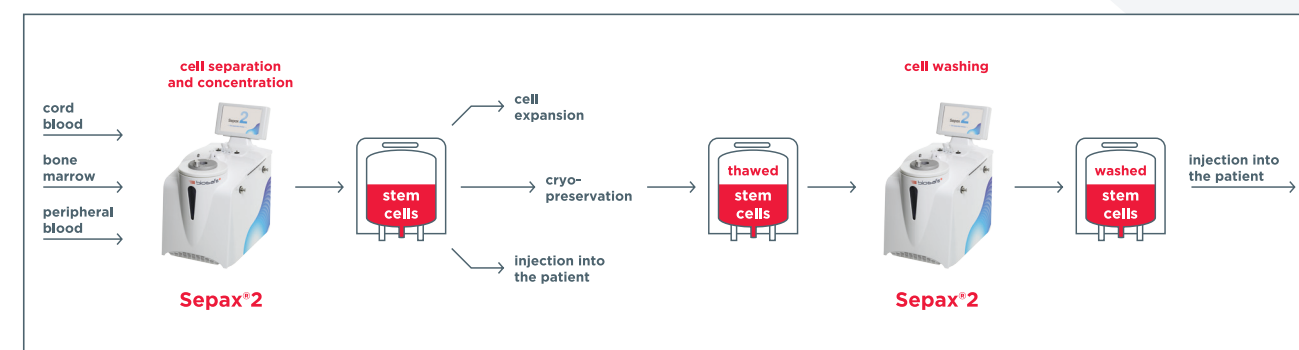
With a proven track-record of more than 15 years, Sepax has been adopted in leading clinical studies and products in a multitude of new emerging biological therapies.



Sepax® platform technology



The Biosafe Group is an internationally active medical technology company with its roots in the Lake Geneva region of Switzerland. Since it was established in 1997, the company has grown to become the industry standard in cord blood banking and in the fast developing field of adult stem cell therapy, serving its customers with innovative cell processing solutions. Biosafe markets its solutions worldwide through its own direct sales force and a growing network of distribution partners. Biosafe SA is a US FDA-registered establishment as well as an ISO 9001:2008 and ISO 13485:2003/AC:2007 certified company, working under the European Medical Devices Directive 93/42/EEC annex II.3. The Sepax has been cleared by the FDA and was approved in China by the SFDA.



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