

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 blood-like material.

Its advanced technology fulfills the core needs of the stem 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 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 cryobag mixing and cooling
- cryopreparation accessories
- SepaxNet, for fully integrated 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 of various cellular products prior to storage. Thanks to the specifically designed application software, the user is able to choose the optimal processing strategy for maximum quality of the end-product. Depending on the protocol used, a wide range of single-use kits is also provided, meeting all the user's needs.

Following volume reduction by the Sepax system, the Coolmix is an automated mixing and cooling device for the controlled preparation of stem cells prior to cryopreservation. Other cryopreparation accessories offered by Biosafe include proprietary cryobags, overwrap bags, overwrap bag sealers and canisters for cryo-storage.

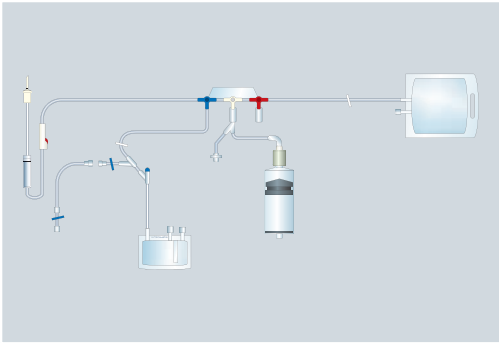
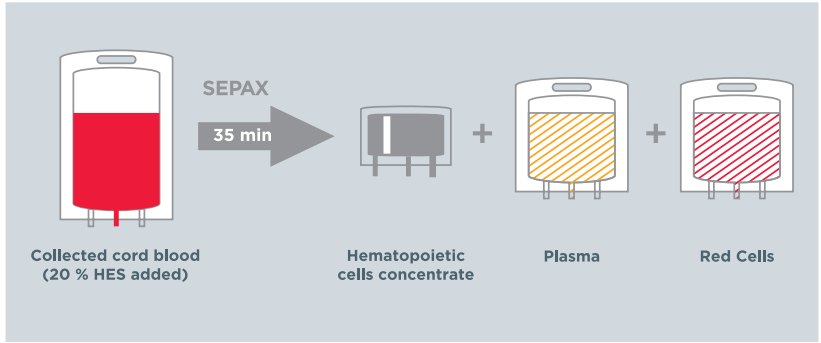


Stem cell banking protocols

	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 cell / TNC: total nucleated cell

- 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

The Sepax system provides a GMP-compliant processing package for regenerative medicine applications allowing a safe and user independent nucleated cell concentration. The isolation of purified mononuclear cells with optimal red blood cell and granulocyte depletion can also be performed by means of a density gradient medium.

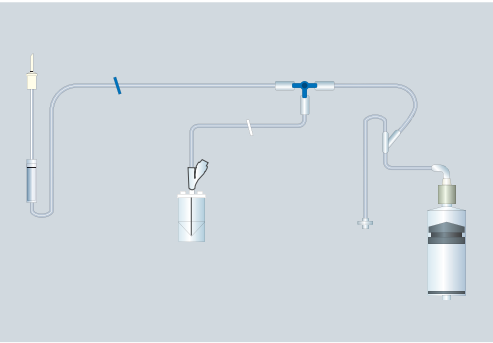
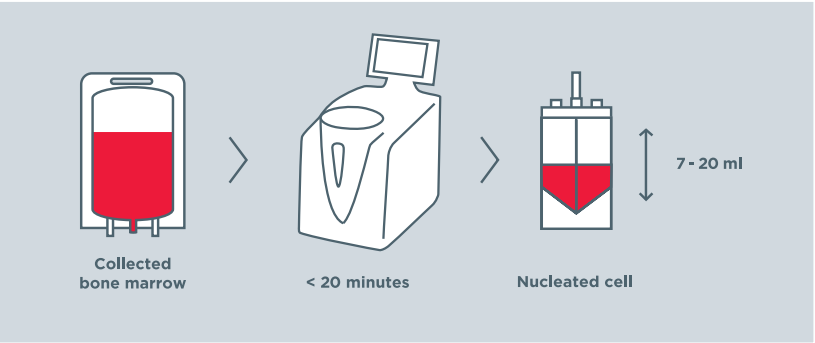
Other cell therapy protocols offer an automated and safe solution for cell washing after thawing: stem cells are then ready for transplantation.

Regenerative medicine and cell therapy protocols

	NeatCell	GVR	ReadyCell	CordWash	SmartWash
Input product	BM - UCB - PBSC	BM - UCB - WB	BM	thawed UCB	thawed PBSC
Processable initial volume	30 - 120 ml	30 - 880 ml	30 - 220 ml	10 - 100 ml	50 - 880 ml
Selectable final volume	8-20 ml	up to 400 ml	7 - 20 ml	50 - 150 ml	50 - 200 ml
Processing time	~ 1h15	~ 45 min	~ 15 min	~ 30 min	~ 40 min

BM: bone marrow / UCB: umbilical cord blood / PBSC: peripheral blood stem cell /  
WB: whole blood / GVR: generic volume reduction

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



## 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.

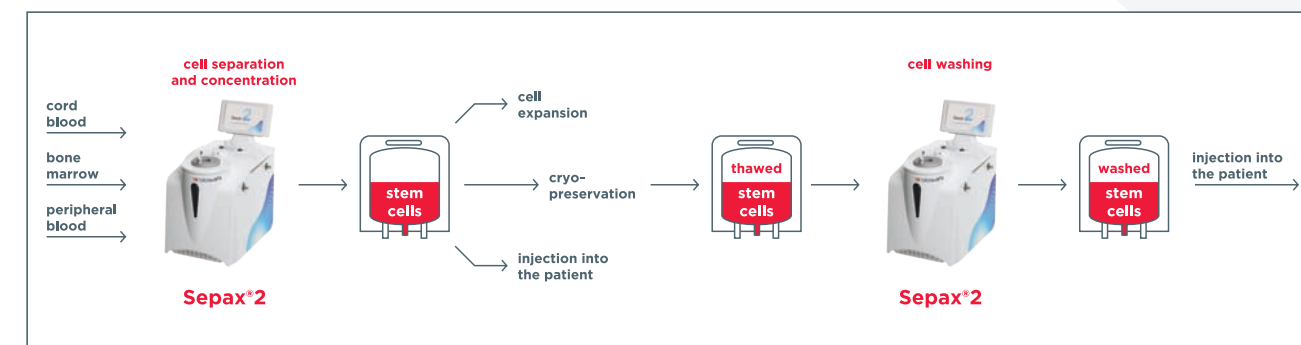
### For stem cell banking

Sepax was the first automated technology to be specifically developed for use in stem cell banks allowing processing of various cellular products with a wide range of input product volumes. 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

The Sepax system extends beyond stem cell banking and offers a true enabling solution for processing various cellular products such as cord blood, bone marrow and peripheral blood in regenerative medicine applications.

The Sepax cell processing technology has been adopted for leading clinical research studies, particularly for cardio-vascular and orthopaedic applications. Its fully integrated design and compact size makes it especially suitable for use at the point-of-care or in a confined laboratory space close to the operating environment.



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 the growing field of adult stem cell therapy, serving stem cell banks, hospitals and research institutes alike 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.

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## Sepax® technology