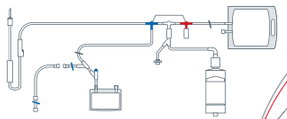
Sepax® system

Main processing unit
Fully automated
and integrated system

Single use kit
Closed, sterile processing
environment



Protocol
Cell separation
software

+ Cryopreparation accessories
overwrap bag, sealer and metal storage canister

+ Coolmix mixing/cooling during
cryopreservant injection

+ Sepaxnet fully integrated
traceability system

About Biosafe

Sepax® is present in over 40 countries

- Biosafe representatives
- Biosafe SA head office
- Biosafe America Inc.

Biosafe was founded in 1997 and has grown to become world leader in automated stem cell processing for **stem cell banking** and **regenerative medicine** applications.
Biosafe products are used in **hundreds of procedures every day** and significant **transplant outcome data** is a clear indication of product efficiency, safety and quality.
As an active participant in its fields of interest, Biosafe is notably a proud **Official Collaborator of the Netcord organisation** that groups leading cord blood banks around the world.
Biosafe SA is a US FDA registered establishment as well as an ISO 9001:2000 and ISO 13485:2003/AC:2007 certified company, working under the European Medical Devices Directive 93/42/EEC annex II.3.

Your Biosafe representative

Biosafe SA - Switzerland
t +41 22 365 27 27
f +41 22 365 27 37
info@Biosafe.ch I www.Biosafe.ch

Biosafe America Inc. - TX, USA
t +1 (713) 294 9029
info@Biosafeamerica.com

SEPAXINTRO 002

Sepax® system
introduction

Sepax® system
equipment and accessories

Sepax® system
single-use kits

Stem cell banking
protocols

Regenerative medicine
protocols

World leader in adult
stem cell processing

biosafe
innovation in cell processing

Sepax® system

Sepax, Biosafe's lead technology platform, is a versatile cell separation technology of which the unique proprietary separation chamber is core. The combination of the compact Sepax main processing unit and single-use kits allows the controlled separation of cellular products in a fully automated and closed environment - no other equipment is required.

Sepax is equipped with protocols that allow the processing of cord blood, bone marrow and peripheral blood using different separation methods, such as volume reduction, nucleated cell component (buffy-coat) concentration and density gradient separation. Each separation protocol has an associated single-use kit consumable specifically configured to optimize the efficacy of the separation protocol.

The Sepax system can be further enhanced for specific applications with addition of the Coolmix and the SepaxNet devices. Coolmix provides automated mixing and cooling of the cryobag following the stem cell separation procedure and prior to cryopreservation, a step referred to as cryopreparation. Other cryopreparation solutions provided by Biosafe include overwrap bags, overwrap bag sealer and canisters for cryo-storage.

SepaxNet is a fully integrated traceability system (ISBT 128) that allows up to 20 Sepax and Coolmix devices to be networked either by Ethernet or Wifi connections. Procedure data from the Sepax and Coolmix devices is automatically sent to the SepaxNet central database and printed. SepaxNet can be used as a stand-alone system or interfaced with a customer's existing network.

The versatility of the technology and associated products has allowed Sepax to become the industry standard in automated stem cell processing for adult stem cell banking and regenerative medicine.

Sepax® cell separation protocols

The Sepax system is equipped with a number of protocols or software programs each validated for a specific use. These protocols were specifically developed for adult stem cell banking and regenerative medicine applications. Biosafe is the world's leading supplier of automated cell processing technology to public and private stem cell banks. Sepax is the only fully automated cell processing system to be used in routine regenerative medicine applications.

Protocols for stem cell banking

UCB-HES Concentration of buffy coat using hydroxyl ethyl starch sedimentation agent

UCB Concentration of buffy coat with no requirement for hydroxyl ethyl starch or any other sedimentation agent

UCB-Washing (UCB-W) Removal of cryoprotectant solution and haemolysed plasma from thawed UCB. The cells are washed and re-suspended in fresh medium, ready for transplantation.

PBSC Concentration of buffy coat from aphaeresis product by plasma depletion.

PBSC-Washing (PBSC-W) Removal of cryoprotectant solution from thawed PBSC. The cells are washed and re-suspended in fresh medium, ready for transplantation.

UCB-LBC Protocol for concentration of the buffy-coat fraction in a very small volume without use of additives.

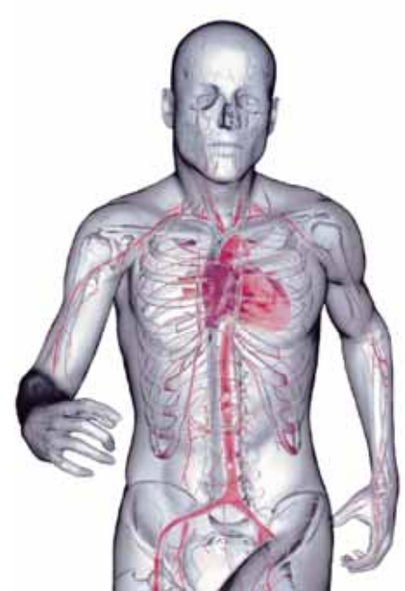
Stem cell banking	UCB-HES	UCB	UCB-LBC	UCB-W	PBSC	PBSC-W
Input product	UCB	UCB	UCB	thawed UCB	PBSC	thawed PBSC
Processed initial volume	35-310 ml	35-290 ml	35-220 ml	10-100 ml	100-600 ml	up to 440 ml
Selectable final volume	20-50 ml	10-50 ml	7-20 ml	50-150 ml	30-600 ml	50-200 ml

Protocols for regenerative medicine

Density Gradient Based Separation (DGBS) Isolation of highly purified mononuclear cell (MNC) component with high granulocyte and red blood cell depletion by means of a density gradient medium.

Generic Volume Reduction (GVR) Concentration of the buffy-coat fraction, mainly conceived for bone marrow volume reduction.

Regenerative medicine and cell therapy	DGBS	GVR	PBSC	PBSC-W
Input product	BM-UCB PBSC	BM-UCB-WB	PBSC	thawed PBSC
Processed initial volume	30-120 ml	30-880 ml	100-600 ml	up to 440 ml
Selectable final volume	~50 ml (not selectable)	up to 400 ml	30-600 ml	50-200 ml



UCB Umbilical cord blood
BM Bone marrow
PBSC Peripheral blood stem cell
WB Whole blood