



STEM CELL LABORATORY (STCL)



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Sepax 2 Product Data Sheet CS-490.1

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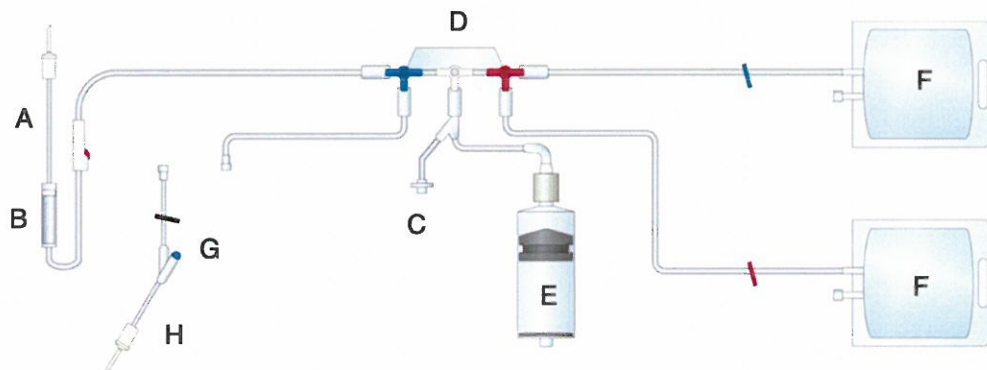
Sepax single-use kit – Regenerative Medicine



Product data sheet CS-490.1

The Sepax single-use kit is an integral part of the Sepax system and provides a sterile, functionally-closed environment in which the cellular product is separated into its components.

The CS-490.1 single-use kit is designed for processing of various cellular products, especially bone marrow, in order to obtain the Total Nucleated Cell (TNC) fraction in a user selectable final bag.



Facts & figures

In order of procedure steps:		
A	Input line	Spike (non-vented) or Sterile Connection Device (SCD) connection of collection bag.
B	Bubble chamber	Traps air bubbles; Equipped with 200 µm filter to block blood clots.
C	Line pressure monitor luer	Connected to the Sepax line pressure sensor; equipped with 0.2 µm bacterial filter.
D	Stopcock manifold	Set of 3 stopcock rotational valves automatically triggered by the Sepax.
E	Separation chamber	Operates as a spinning syringe enabling centrifugation and transfer of the blood unit in a closed and sterile environment ; 220 ml volume capacity.
F	By-product bags	500 ml standard PVC blood product bags intended to collect plasma and red blood cells.
G	Output line	Female luer or Sterile Connection Device (SCD) connection of output (buffy-coat) bag.
H	Extension line with spike	Allows connection of output bag using the pre-installed spike. Equipped with a silicon injection port.



Single-use kit x Protocol software compatibility

Kit/ protocol	ReadyCell	GVR	NeatCell	CordWash	SmartWash
CS-470.1	X				
CS-490.1		X			
CS-600.1				X	X
CS-900.2			X		

Storage requirements:

The separation kit must be stored in a clean and dry place, free from biological contaminants and chemical vapors. The separation kit must only be used/ stored under the following environmental conditions:

	Operation	During Transport
Temperature	+7°C to +27°C	4°C to 40°C
Relative humidity	30% to 75%, non-condensing	20% to 75%, non-condensing

- **Shelf life** 2 years from manufacturing
- **Sterility** Guarantee 2 years (EtO), pyrogen free
- **Material** Standard medical grade PVC, PP; All material are latex free

Order information:

CS-490.1	Product #10001
Packaging	Individual sterile blisters sealed with a Tyvek® cover
Minimum order quantity	Box of 6 kits (box dimension: 33x35x26 cm/ 13x14x10 in)

CS-490.1 is CE marked.

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Signature Manifest**Document Number:** STCL-PROC-046 JA1**Revision:** 01**Title:** Sepax 2 Product Data Sheet CS-490.1

All dates and times are in Eastern Time.

STCL-PROC-046 JA1 Sepax 2 Product Data Sheet CS-490.1**Author Approval**

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