DELIVER YOUR ESSENTIAL
YOUR PROTOCOL HAS CHANGED

Targeted for use in a variety of clinical settings, the CellPoint™ Concentrated Bone Marrow Aspirate System rapidly provides clinicians with concentrated marrow-derived cells via a simple, automated process. With no operator intervention required, the closed-loop system dispenses concentrated bone marrow aspirate (cBMA) directly into a final collection vial, delivering consistent performance to meet your needs.

MUCH MORE THAN A SIMPLE SYSTEM

On the surface, you’ll see a smart touchscreen interface and simple pre-loaded protocols that allow for rapid cBMA preparation with minimal set-up. Optical sensors and a vertical elutriation mechanism are employed by the system to precisely separate cells, while a universal cell separation kit offers simplicity and value. But the benefits extend beyond technology.

Designed to improve how you operate, CellPoint enables clinicians to recover a high density of marrow-derived cells at the point-of-care. Think of it as efficiency, evolved. Think of it as your new protocol.

- Fully automated system: Enables consistent, repeatable performance
- Specifically designed to concentrate BMA: Delivers a high concentration of marrow-derived progenitor cells
- Minimal set-up and rapid prep times < 20 minutes: Allows for quick and easy cBMA recovery
- Universal cell separation kit for all processing volumes: Offers flexibility and cost-savings
- Vertical elutriation mechanism precisely separates cells: Extracts cBMA while maintaining high cell recovery and cell viability
Bone marrow aspirate provides a rich source of viable progenitor cells and other soluble factors, but the relative abundance of these elements within human bone marrow is low. CellPoint's precise cell separation process isolates these elements while removing the red blood cells and platelet poor plasma. cBMA contains high concentrations of total nucleated cells and growth factors, including:

- Multi-potent mesenchymal stromal cells (MSCs), which have the potential to differentiate into osteoblasts and chondrocytes¹
- CD34+ hematopoietic stem cells (HSCs), which give rise to endothelial progenitor cells²
- Platelets, which provide a rich source of essential growth and differentiation factors, such as PDGF, VEGF, TGF-b1 and EGF³

References
The CellPoint system enables clinicians to quickly recover concentrated, patient-derived nucleated cells, platelets, and other soluble factors in the form of cBMA. The relative concentration of nucleated cells in cBMA is dependent on many factors, including the input BMA volume and the desired cBMA output volume, which are both defined by the user for the CellPoint system. By providing reliable volume reduction, the CellPoint system achieves typical total nucleated cell (TNC) concentration factors that are 3–6 times the baseline TNC concentration in BMA.

**CELLPOINT CONCENTRATED BONE MARROW ASPIRATE SYSTEM PERFORMANCE***

<table>
<thead>
<tr>
<th>VOLUME REDUCTION FACTOR</th>
<th>TNC COUNT PER mL BMA</th>
<th>TNC COUNT PER mL cBMA</th>
<th>TNC CONCENTRATED FACTOR</th>
<th>CD34 + CELL RECOVERY</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.3</td>
<td>2.1x10^7</td>
<td>8.2x10^7</td>
<td>4.5</td>
<td>92.6%</td>
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* ISTO internal analysis of CellPoint System Performance in 263 clinical procedures
CellPoint utilizes the most cutting-edge technology available, the **Sepax 2 RM**, along with a disposable cell separation kit, to create a fully automated closed-loop system for separating nucleated cells from bone marrow. An advanced optical sensor detects the cell fractions and eliminates the need for operator intervention to separate the nucleated cell layer. Platelet-poor plasma and hematocrit are extracted, and volume-reduced cBMA is delivered into a sterile final collection vial. With the addition of pre-loaded protocols and minimal set-up, CellPoint makes cBMA preparation easy.

- Smart touchscreen interface is easy to use
- Pre-loaded protocols for rapid cBMA preparation with minimal set-up
- Selectable range of BMA input and cBMA output volumes allows users to customize the volume reduction factor achieved
- Universal cell separation kit is used for all processing volumes, providing flexibility and cost-savings
- Vertical elutriation mechanism precisely separates cells while maintaining high cell recovery and viability
- User-defined cBMA volume is output into closed final collection vial

**CONCENTRATED BONE MARROW ASPIRATE (cBMA)**

Automated extraction of buffy coat layer

Rich in Total Nucleated Cells
PRODUCT INFORMATION

CellPoint™ Procedure Pack (CLPT-PK-101)

- Includes cell separation kit and accessories required to aspirate and concentrate bone marrow
- Cell separation kit accommodates bone marrow input volumes of 30–220 mL and cBMA output volumes of 7–20 mL

SEPAX 2 RM INTENDED USE

The Sepax 2 RM system is a cell processing system intended for the separation of nucleated cells from various cellular products (e.g., bone marrow, apheresis, peripheral blood, diluted components of the same). The Sepax 2 RM is manufactured by Biosafe and is available through ISTO Technologies, Inc. for the CellPoint™ Concentrated Bone Marrow Aspirate System.

The cellular product to be processed (separated) is collected for medical use; the Sepax 2 RM system is not connected to the patient. Following collection, the cellular product is either processed bed-side, point-of-care, or transported to a processing laboratory.

The Sepax 2 RM system is not intended for use in transfusion applications where blood circulates directly between a patient and the Sepax 2 RM system. There is no claim of therapeutic benefit in the labeling. Safety and effectiveness of this device for in vivo indications has not been established.

The Sepax RM is a Class I device. The Sepax RM is registered with the FDA and is listed as follows:

- Listing Number — D079348
- Product Code — JQC

Biosafe is the FDA registered manufacturer of the Sepax 2 RM and associated products. Biosafe America is the FDA registered distribution arm of Biosafe in the U.S. FDA registrations are shown below.

- Biosafe FDA Registration Number — 3004728017
- Biosafe America FDA Registration Number — 3007508533

Biosafe is ISO 13485 certified. Biosafe certificate number — TUV SUD S 951 06 3563

Ordering information:
CellPoint is available through ISTO Technologies, Inc.
Sepax 2 RM is manufactured by Biosafe SA.

To order, call Customer Service at 1-888-705-ISTO (4786) | www.istotech.com
Cellpoint is a trademark of ISTO Technologies, Inc.