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HARVEST® BONE MARROW ASPIRATE CONCENTRATE (BMAC®) SYSTEM

Delivering the Highest Concentration and Yield of Stem Cells When Compared to Five Other Systems*

HARVESTING BONE MARROW ASPIRATE

Concentrated bone marrow aspirate (BMA) is an autologous biologic concentrate derived from a patient's own bone marrow. Concentrated BMA is high in hematopoietic stem cells (HSCs) and mesenchymal stem cells (MSCs), which are known to be vital to biological processes such as the regeneration of tissue—including cartilage, muscle, marrow, tendons, ligaments and connective tissue—as well as bone formation.[1,2,3,4]

The Harvest BMAC system is used to concentrate the stem cells found in bone marrow. To make concentrated bone marrow, a small (30 mL to 60 mL) sample of marrow is drawn from the iliac crest. The bone marrow is spun using the Harvest SmartPrep® Multicellular Processing System to concentrate the sample; processing takes less than 15 minutes.

For more than a decade, the Harvest BMAC system has delivered quality, flexibility and reliability—and the highest stem cell concentration and yield compared to five other systems.*

*Compare the numbers. View the mean nucleated cell count and yield for the five other systems at HARVESTTECH.COM/clinician.[5,6,7,8]

QUALITY: NEVER COMPROMISE

Higher cell concentration means that more cells with potential healing power are delivered to the application site. The Harvest BMAC system generates higher concentrations of nucleated cells than a traditional iliac crest autograft. In fact, the total nucleated cell count found in the product generated from the Harvest BMAC system is typically three to six times that of bone marrow aspirate.[9]

High Concentration of Nucleated Cells in the Product From the Harvest BMAC System as Compared With Alternatives *(measured in total nucleated cells (TNCs)/mL)*

Average Cell Capture of Iliac Crest Autograft[10]

Iliac Crest Autograft
53×10^6

Harvest BMAC System: Cell Concentration Versus BMA

BMA	Harvest BMAC Product
22×10^6	84×10^6

A standard 10 mL sample product from the Harvest BMAC system provides more than 850 million TNCs and over 5 billion platelets.[11] Compared with other concentrated BMA products, the product from the Harvest BMAC system delivers greater concentrations of TNCs and stem cells.[9,12] Results may vary.

A typical sample of the product from the Harvest BMAC system contains the following concentrations of stem cells and platelets:

Composition of Product From the Harvest BMAC System[5,13,14]

Cell Type	% of TNCs*	BMAC Concentration/mL
MSCs†	0.001%	1,500 to 3,000 CFUs** 3,526 CFUs**
HSCs‡	1%	0.8 to 1.5×10^6 800×10^6
Platelets	N/A	600 to 900×10^6 752×10^6

*TNCs = total nucleated cells; platelets do not contain a nucleus
**CFUs = colony-forming units—the gold standard assay for measuring MSC concentration
†MSCs = mesenchymal stem cells
‡HSCs = hematopoietic stem cells

FLEXIBILTY: EXPANDED TREATMENT OPTIONS

Flexibility helps limit your capital investment while broadening the number of treatment options you can offer patients. Our products are designed with that flexibility in mind. Harvest BMAC process disposables are used with the Harvest SmartPrep system, with 510(k) clearances to process all three major autologous biologics—platelet-rich plasma (PRP), concentrated BMA and concentrated adipose tissue—using a single platform.[12]

The Harvest BMAC process disposable incorporates a proprietary, self-calibrating floating shelf designed specifically for concentrating BMA. The density of the floating shelf is engineered to maximize the capture of the TNCs from the bone marrow.

Harvest SmartPrep System

The Harvest SmartPrep system is microprocessor-controlled to provide a reproducible process for concentrating BMA. No user interaction is required beyond loading and starting the device.

Not all biologic processing systems are created equal. The Harvest SmartPrep system is the only system cleared by the U.S. Food and Drug Administration (FDA) to process the three major autologous biologic solutions. This unique capability affords you the freedom to select the type of biologic treatment that may benefit your patients most.

Processes All Three Autologous Biologics

Harvest® Platelet Concentrate System

Harvest® Bone Marrow Aspirate Concentrate (BMAC®) System

Harvest® AdiPrep® Adipose Concentration System

RELIABILITY: PROVEN RESULTS

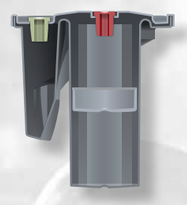
In addition to generating a purified, stem-cell-rich product in as little as 15 minutes, the biologic concentration technology used in the Harvest BMAC system also provides clinicians and physicians with key advantages:

- Automated processing means the Harvest SmartPrep centrifuge can deliver quality biologic treatment products regardless of patient variability
- Concentrated, high-quality autologous biologics are ready for immediate injection

Automated Processing

The Harvest SmartPrep system combined with the Harvest BMAC Procedure Pack automates point-of-care processing of autologous biologics:

- Produces concentrated autologous biologics in less than 15 minutes of processing time[15]
- Reduces the number of steps compared to a manual method
- Simplifies training among multiple users



Reduce Risk of Contamination

The disposables used with some other BMA systems have design features that can increase the risk of contamination. Our process disposables incorporate resealable injection ports that can be aseptically disinfected prior to entry. This design reduces the opportunity for contamination of the final product.

To arrange an evaluation or for more information, call 877.8.HARVEST (toll-free) or visit HARVESTTECH.COM.

Harvest Technologies, a Terumo BCT company, has long been a leader in point-of-care cell therapy products.

Harvest Terumo BCT is a global leader in blood component, therapeutic apheresis and cellular technologies, offering more than 30 years of cell processing expertise and a comprehensive range of solutions that cover the continuum of cell therapy—from point-of-care to cell therapy manufacturing.

As a leader in innovation with established global reach, we are shaping the future of cell therapy.

INDICATIONS FOR USE

The Harvest BMAC system is intended to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet-poor plasma and platelet concentrate from a small sample of blood and for preparation of a cell concentrate from bone marrow.

RISK INFORMATION

For bone marrow aspirate processing, the safety and effectiveness of this device for in vivo indications for use has not been established. This information does not take the place of discussing your medical condition with your doctor. These procedures require needle access, possibly resulting in apprehension, discomfort, tenderness, bruising, swelling, bleeding or pain at the access site, at which there is a small risk of infection. Lightheadedness, fainting, nausea or vomiting may occur. Before any medical procedure: Tell your doctor about prescription and nonprescription medicines and any natural or herbal remedies you are taking or plan to take; and consult your insurance company to verify coverage.

Scientific References

1. Matsumoto T, et al., "Therapeutic Potential of Vasculogenesis and Osteogenesis Promoted by Peripheral Blood CD34-Positive Cells for Functional Bone Healing." *The American Journal of Pathology* 2006; 169 (4): 1440–1457.
2. Matsumoto T, et al., "Fracture Induced Mobilization and Incorporation of Bone Marrow-Derived Endothelial Progenitor Cells for Bone Healing." *Journal of Cellular Physiology* 2008; 215 (1): 234–242.
3. Mifune Y, et al., "Local Delivery of Granulocyte Colony Stimulating Factor-Mobilized CD34-Positive Progenitor Cells Using Bioscaffold for Modality of Unhealing Bone Fracture." *Stem Cells* 2008; 26 (6): 1395–1405.
4. Tondreau T, et al., "Mesenchymal Stem Cells Derived From CD133-Positive Cells in Mobilized Peripheral Blood and Cord Blood: Proliferation, Oct4 Expression, and Plasticity." *Stem Cells* 2005; 23 (8): 1105–1112.
5. Kevy S and MS Jacobson, "Comparative Analysis of Bone Marrow Concentrates Prepared by the Harvest Terumo SmartPrep System and the Cytomedix Angel System." 2014, unpublished raw data.
6. Kevy SV and MS Jacobson, "Comparison of Bone Marrow Concentrates Prepared by the Harvest/Terumo BMAC® System and the Thermogenesis Res-Q™ 60 System." 2012, unpublished raw data.
7. Hegde V, et al., "A Prospective Comparison of Three Approved Systems for Autologous Bone Marrow Concentration Demonstrated Nonequivalency in Progenitor Cell Number and Concentration." *Journal of Orthopaedic Trauma* 2014; 28 (10): 591–598.
8. Kevy SV and MS Jacobson, "Comparative Analysis of Bone Marrow Concentrate and Platelet Rich Plasma Prepared by the SmartPRep 2 System and the EmCyte Elite System." 2014, unpublished raw data.
9. Muschler G, et al., "Comparison of Bone Marrow Aspiration and Bone Core Biopsy as Methods for Harvest and Assay of Human Connective Tissue Progenitor." Scientific paper 41; 2006, presented at 58th Association of Bone and Joint Surgeons Meeting.
10. *Ibid.*
11. Tidwell L, et al., "Harvest Technologies BMAC Data Summary." 2014, unpublished raw data.
12. Kevy SV and MS Jacobson, "Platelet Concentrate Preparation: A Comparison of the Harvest SmartPReP® 2 with the Biomet GPS® III." Immune Disease Institute 2008.
13. Bourin P, et al., "Stromal Cells From the Adipose Tissue-Derived Stromal Vascular Fraction and Culture Expanded Adipose Tissue-Derived Stromal/Stem Cells: A Joint Statement of the International Federation for Adipose Therapeutics and Science (IFATS) and the International Society for Cellular Therapy (ISCT)." *Cytotherapy* 2013; 15 (6): 641–648.
14. Kon E, et al., "Platelet-Rich Plasma Intra-Articular Injection Versus Hyaluronic Acid Viscosupplementation as Treatments for Cartilage Pathology: From Early Degeneration to Osteoarthritis." *Arthroscopy* 2011; 27 (11): 1490–1501.
15. Data on file.

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