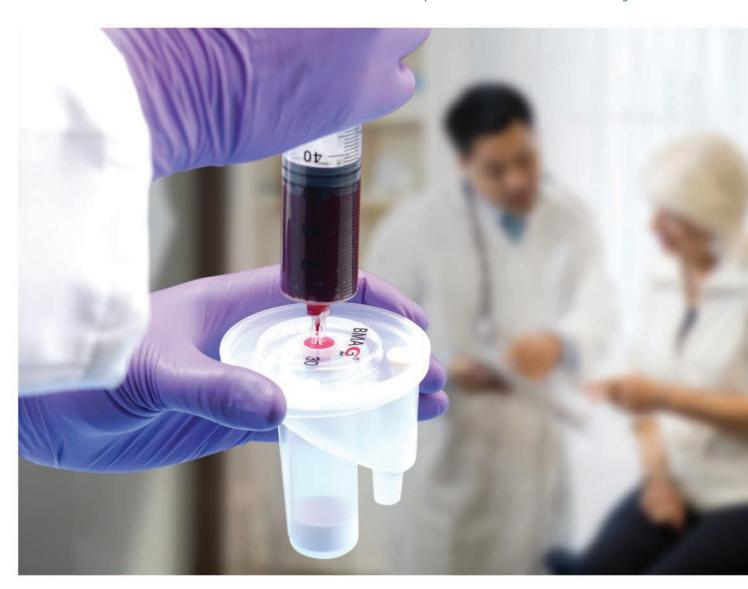


HARVEST® BONE MARROW ASPIRATE CONCENTRATE (BMAC®) SYSTEM

Delivering the Highest Concentration and Yield of Stem Cells When Compared to Four 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 four other systems.*

*Compare the numbers. View the mean nucleated cell count and yield for the four 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 Autograft¹⁰

lliac Crest Autograft	
53 × 10 ⁶	

Harvest BMAC System: Cell Concentration Versus BMA

ВМА	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}

Average Concentration	
MSCs (CFU)	3,526/mL
HSCs (CD34+)	800 x 10 ³ /mL
Platelets	752 x 10 ⁶ /mL

 $\label{eq:cfus} CFUs = colony-forming \ units\\ --- the \ gold \ standard \ assay \ for \ measuring \ MSC \ concentration \ MSCs = mesenchymal \ stem \ cells$

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 clinical applications

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 time¹⁴
- 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.

Scientific References

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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.

Terumo BCT, Inc.

10811 West Collins Ave. Lakewood, Colorado 80215-4440 USA

USA Phone: 1.877.339.4228 Phone: +1.303.231.4357 Fax: +1.303.542.5215

Terumo BCT Europe N.V.

Europe, Middle East and Africa Ikaroslaan 41 1930 Zaventem Belgium

Phone: +32.2.715.05.90 Fax: +32.2.721.07.70

Terumo BCT Asia Pte. Ltd.

89 Science Park Drive #04-25 (Lobby B) The Rutherford Singapore 118261

Phone: +65.6715.3778 Fax: +65.6774.1419

Terumo BCT Latin America S.A.

La Pampa 1517–12th Floor C1428DZE Buenos Aires Argentina

Phone: +54.11.5530.5200 Fax: +54.11.5530.5201

Terumo BCT Japan, Inc.

Tokyo Opera City Tower 49F, 3-20-2, Nishi-Shinjuku, Shinjuku-ku, Tokyo 163-1450, Japan

Phone: +81.3.6743.7890 Fax: +81.3.6743.9800

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