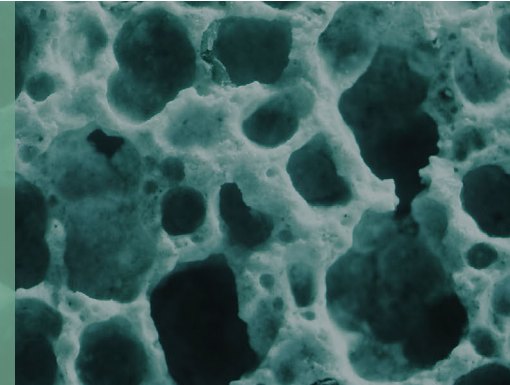




PureBMC[®]

FDA Cleared Bone Marrow Concentrate Kits

Increased cell yields through
technique & concentration



Bone Marrow Concentrate (BMC) consists of mesenchymal stromal cells also known as medicinal signaling cells (MSCs)¹, platelets, monocytes, lymphocytes, hematopoietic stem cells (HSCs) and various plasma proteins.²

MSCs are multipotent stromal cells that can differentiate into a variety of cell types to include cartilage, bone and adipose tissue.³ Mesenchymal stem cells are found in limited quantities in bone marrow aspirate⁴ meaning concentration is required to produce a therapeutic dose⁵, free from contaminants. MSCs have powerful proliferative and signaling capabilities allowing BMC to be an effective biologic for interventional orthopedics.

HOW DOES PureBMC[®] WORK?

When injury occurs or in the case of chronic joint or disc disease, the usual number of healing cells needed for tissue healing is often inadequate. With BMC, the concentrate of healing cells provides a more robust healing of the damaged tissue and aids in growth and repair by accelerating the body's natural healing mechanism.⁶

Additionally, BMC acts as a chemoattractant⁷: BMC signals additional healing factors and MSCs to the site of injury. BMC has been shown to reduce swelling, relieve pain, and enhance healing of articular cartilage, discs and bone.^{8,9}



PureBMC[®] CHARACTERISTICS¹⁰

Laboratory Determinations BMC Volume 8.5 mL	Aspire BMA (BL)	PureBMC Injectate	Concentrating Effect BMA vs PureBMC
TNC (-nRBCs) (x 10 ⁶ /mL)	28	143.7	5.1xBL
Platelet count (x 10 ⁶ /mL)	91	624	6.9xBL
Erythrocyte count (x 10 ⁹ /mL)	4.34	0.75	-83% BL
Hematocrit %	40.7	6.8	-83% BL
CD34+ (x 10 ⁵ /mL)	1.65	9.15	5.6xBL
CFU-F (MSCs) (x 10 ³ /mL)	1.025	5.679	5.5xBL
Cell Viability (%)	95.8	972	+0.6% BL
PFHb (mg/dL)	1690	505	-70% BL
Hemolysis (%)	7.1	1.8	-75% BL



PLYMOUTH
MEDICAL

EMCYTE[®]
CORPORATION



LESS FREE HEMOGLOBIN, HIGHER PRODUCT ACTIVITY

Excess free hemoglobin and red blood cells (RBCs) are known to trigger specific pathologies associated with adverse clinical outcomes such as pain and inflammation. PureBMC[®] collects and processes a pure sample of bone marrow with minimal hemolysis by virtue of its unique processing and collection technique. Furthermore, PureBMC[®] has a progenitor cell viability of 96%. This is the highest independently rated cell viability of any point of care bone marrow concentrating system.²

COMPETITIVE ADVANTAGE

1. Highest yield of cells compared to any other system on the market
2. Utilizes the same centrifuge platform as PRP and Adipose
3. FDA Cleared: The only 510K cleared BMC device that requires no dilution with peripheral blood
4. Variety of kit sizes (60mL, 120mL)
5. Sterile / Closed System
6. Short processing time < 15 minutes
7. Greatest reduction of hematocrit % of any system
8. Filtered prior to centrifugation to remove bone spicules / fatty deposits

PUBLICATIONS

¹Stem Cells Transl Med. 2017 Jun;6(6):1445-1451. 2017 Apr 28. Mesenchymal Stem Cells: Time to Change the Name! Caplan.

²Emcyte Corp. Data on File

³Concise Review: Mesenchymal Stem/Multipotent Stromal Cells: The State of Transdifferentiation and Modes of Tissue Repair—Current Views. Donald G. Phinney Ph.D. Darwin J. Prockop. 02 January 2009 <https://doi.org/10.1634/stemcells.2007-0637> Citations: 1047

⁴Stem Cell Yield after Bone Marrow Concentration. Jason L. Dragoo, MD¹ and Malcolm R. DeBaun. The Orthopaedic Journal of Sports Medicine, 5(7)(suppl 6)

⁵BSR Labs, March 2015. Comparison of BOM to BMA (Marrow Cellutions)

⁶Andrews Clinic overview of Bone Marrow treatments (web page)

⁷Stem Cells Int. 2015; 2015: 628767. 2015 Jul 26. Adult Mesenchymal Stem Cells: When, Where, and How

⁸Bone Marrow Aspirate in the Treatment of Chondral Injuries. James Holton,1,* Mohamed A. Imam,2,3 and Martin Snow2. Front Surg. 2016; 3: 33. 2016 Jun 16. 10.3389/fsurg.2016.00033

⁹American Journal of Stem Cell Research. 2018; 2(1): 1-4. Reducing Lumbar Discogenic Back Pain and Disability with Intradiscal Injection of Bone Marrow Concentrate: 5-year Follow-up. Kenneth Pettine M. D.1, Maxwell Dordevic1, Michael Hasz M. D.2

¹⁰Poster: The Need for Concentrating Bone Marrow Aspirate to Eliminate Detrimental Plasma Free Hemoglobin and Decrease the Hematocrit to Minimize Eryptosis in Orthobiologic Applications. Peter A. Everts, PhD Kenneth R. Mautner, MD

Regulatory: K183205

FDA Clearance for the safe and rapid preparation of platelet concentrate and cell concentrate from a small sample of bone marrow aspirate.

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