ACCELLERATED BIOLOGICS

DELIVERING THE TOTAL BIOLOGIC™

SPRING 2018 CATALOG

PLATELET RICH PLASMA | BONE MARROW ASPIRATE | ADIPOSE | AMNIOTIC TISSUE | A2M AND FIBRINOGEN | TOPICAL GEAR | ARTHROSCOPY | ADILIGHT | SUPPORT | TRAINING | RESEARCH | PATIENT ACQUISITION

1-800-367-0844 | www.AcCELLeratedBiologics.com
304 Tequesta Dr. Suite 400, Tequesta, FL 33469

TESTIMONIALS

"We've been using Accelerated Biologics' products with tremendous success for the past few years. We appreciate the collaborative nature and the service they provide for our patients at the Regenerative SportsCare Institute. We look forward to a long, successful collaboration with Accelerated Biologics, as we continue to help patients with orthopedic injuries heal with regenerative treatments."
-**Dr. Gregory Lutz**, *Founder of the Regenerative SportsCare Insitute.*

"The team at AcCELLerated Biologics back their business model with a wealth of knowledge and experience that is reliable and easy to access.. Whether you are new to the field or an expert seeking a consultation on the latest technology, you will find they truly care about enhancing your expertise in this emerging field."
-Joseph J Ruane, DO. *Medical Director Spine, Sport and Joint Physicians. Head Team Physician NHL Columbus Blue Jackets*

"I have worked with AcCELLerated Biologics and Steve Whyte for over seven years. This organization has been an incredible resource for our orthobiologics, research and education programs at the Andrews Institute. I highly recommend them."
Josh Hackel, MD, *The Andrews Institute, Gulf Breeze, FL*

"I've used Accelerated Biologics since the company opened and have found amazing customer support from Steve and everyone who works there. I also am a big believer in their products and am seeing great results in my orthobiologics practice."
-**Dr. Ken Mautner** *Emory Sports Medicine Center*

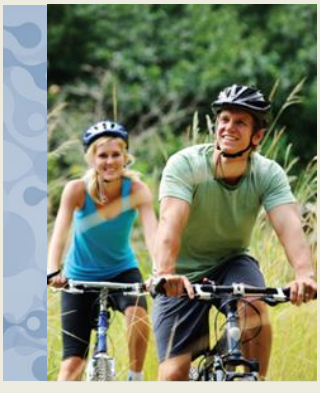
TESTIMONIALS

"Accellerated Biologics had been an invaluable resource for my regenerative medicine practice. They are on top of the latest products and research in the orthobiologic arena. Steve and his staff are always readily available to address any need I that have, form shooting to new product/process information they go above and beyond with customer service."
-R. Amadeus Mason MD, *Emory Orthopaedics, Sports & Spine*

"The AcCELLerated Biologics team is an invaluable asset to our company, providing excellent products and consistently superior service."
-Christoper J. Rogers, M.D., RMSK *XCELL Sports and Regenerative Medicine, San Diego CA*

"Accelerated Biologics has always been ahead of the curve in the field of Regenerative Medicine. They offer the full spectrum of Regenerative agents at a competitive price and offer customer service that is both better informed and more available than other dealers who I've worked with in the past."
-Jake Wardwell, D.O., ABIHM, RMSK

"I have worked with Accelerated Biologics for many years. The owner and staff work with utmost respect and professionalism. Steve Whyte has tremendous experience in the field of regenerative medicine and has given me important insight to the effectiveness and differences of different biologic treatments, in particular, platelet rich plasma. My regenerative medicine practice has thrived with the use of products from Accelerated Biologics. Not only does this company provide excellent service but provides knowledge and support in the field of biologic treatments." -**Kristopher Goddard, DO**



We are an independent medical distribution company focused on consulting and providing the physician, their staff and community with superior customer service and products related to platelet rich plasma, bone marrow aspirate and concentrate, Adipose, Amniotic tissue/fluid and other products that support the use of biologics.

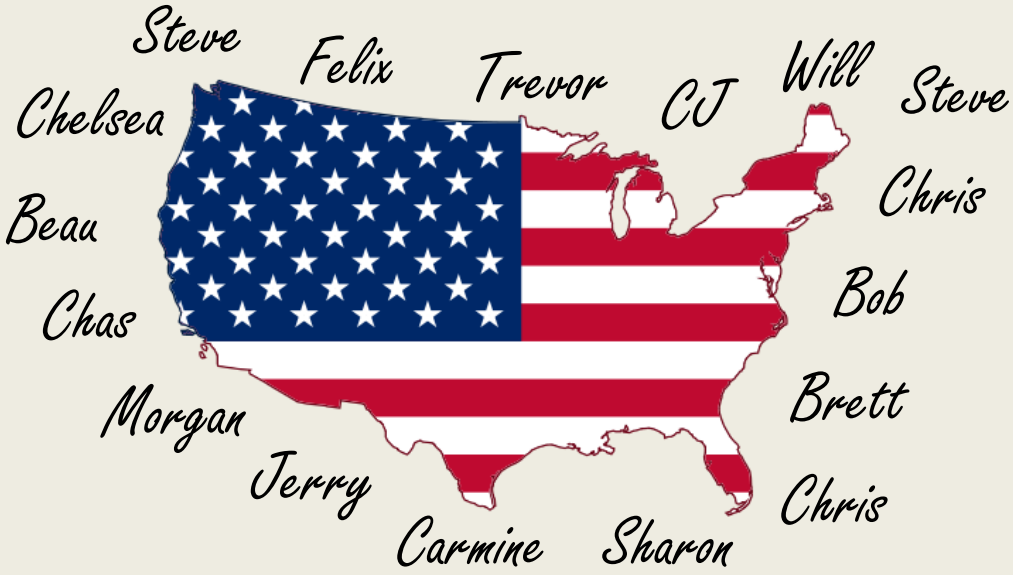
AcCELLerated Biologics continues to be the first to market with innovative new products. We were the first distributor for the Marrow Cellution Bone Marrow Aspiration needle by Ranfac, and T:25 Technology from Topical Gear CEP. Our customers receive our ongoing commitment of supplying them with the most up to date information, technologies and equipment.

In 2015 we introduced the Regenerative Medicine Training Institute (RMTI) as a sister company. Adding the educational component of RMTI gives our customers a chance to learn from their colleagues. We have a series of on site educational training sessions throughout the year with CME approved didactic presentations, live patient procedures and cadaver trainings at our facility.

Since 1999, the people of AcCELLerated Biologics have gained a great deal of knowledge through tests and first hand use of many of the prp systems and cell harvesting platforms on the market. Some require a large capital investment and therefore, cost prohibitive. Some have basic engineering design flaws, others simply cannot match platelet yields. Some cannot adjust for hematocrit or leukocyte percentages as other systems can and do consistently. Some automated systems cause laminar flow/turbulent flow problems that prematurely activate the platelets and create an early release of growth factors. These systems inherent to their design, disrupt the buffy coat and consistently have platelet counts that don't measure up to competing systems during testing.

Ac**CELL**erated Biologics is here to provide a reliable and trustworthy partner for physicians who want to introduce or use biologics in their practice. Please feel free to look at our catalog, or our website www.accelleratedbiologics.com for more information. We look forward to any and all opportunities to work with you.

THE ACCELLERATED BIOLOGICS TEAM



Platelet Rich Plasma (PRP)

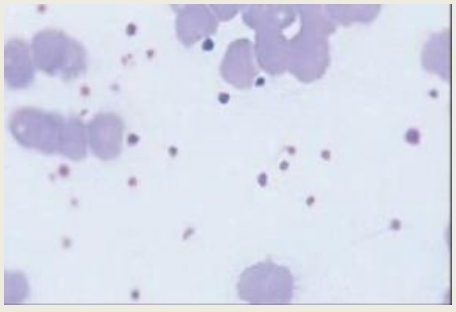
Platelet Rich Plasma (PRP) is concentrated from your own blood which contains healing factors, such as white blood cells and bioactive proteins, called growth factors and stem cell markers. These cells are vital for tissue regeneration and repair. Platelets, once thought of being responsible for only clotting, have been scientifically proven to be a reservoir of these vital healing components. With advanced techniques we are able to concentrate these regenerative healing cells in a simple outpatient setting.

PRP is from your own blood, autologous, so there is little to no risk when conducted by a trained professional. Since the cells are autologous there is no risk for an allergic or immune reaction. Side effects or complications with PRP are extremely rare.

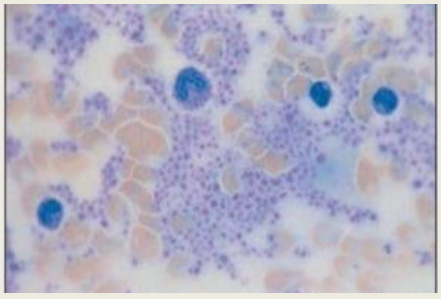
Patients can expect to see significant improvement in symptoms over the course of healing time. This procedure may eliminate the need for further invasive treatments, such as surgery or prolonged use of medications. While other treatments such as corticosteroid injections may provide temporary relief and stop inflammation, PRP injections stimulate healing of the injury over a shorter time period with less side effects. Patients usually report a gradual improvement in symptoms and return of function. Many patients require two to three treatments to obtain optimal results and may even experience a dramatic return of function and relief within 2-3 months.

Not All PRP Is The Same

PRP products differ both qualitatively & quantitatively. It is well documented that not all PRP is the same. Patients may experience varying outcomes with PRP applications. This can be attributed to the system used to prepare the PRP. To get the best results, the PRP system must significantly concentrate the platelet growth factors in the treatment sample. The better the concentration, the better the chances for recovery.



Normal Platelet Count



Concentrated Platelet Count

EmCyte – AcCELLerated Biologics' AB60 Pure PRP

PRP Concentrating Systems:

GS30 Absolute PRP - Platelet Concentrating system 30mL
GS60 Absolute PRP- Platelet Concentrating System 60mL
GS120 Absolute PRP- Platelet Concentrating System 120mL

5 minute spin.

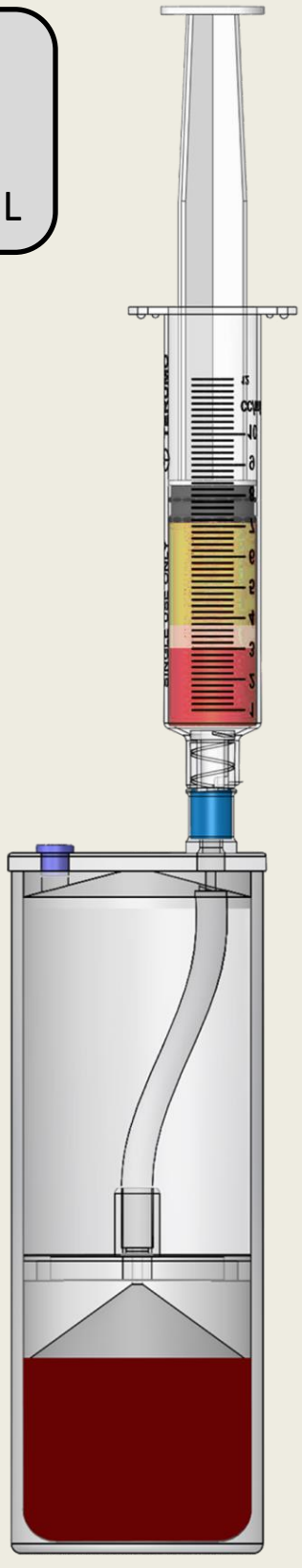
Quickest standard spin time in the market space.

The Absolute Concentrating Systems

The AbsolutePRP Concentrating Systems has been greatly improved. AbsolutePRP provides the complete PRP composition. Therapeutically high concentrations of platelets and growth factors along with very high concentrations of neutrophils, monocytes and other cell mediating cytokines. AbsolutePRP is the fastest and most efficient single spin 60mL concentrating systems available. Prepare 7mL of PRP, with high concentrations of regenerative cells, in a SINGLE 5 MINUTE SPIN. These systems were designed to accommodate physicians that run a busy practice and mandate superior performance outcomes that is consistent and reliable.

The key to the Absolute Concentrating System is the ClearVUE Conical Piston. The piston is specially designed to greatly improve the collection of the cell concentrate buffycoat layer. The primary feature of the new ClearVUE Conical Piston is it's the deep conical shape. The deep conical design perfectly directs the collection of the cell concentrate buffycoat with minimal red cell integration. This provides quality platelet rich plasma and bone marrow concentrate with near perfect collection yields. The ClearVUE Conical Piston also features enhanced handling of the concentrating device with frictionless motion and a CLEAR VIEW of the buffycoat while its being aspirated, further instilling confidence in the quality of the end product.

With Active Displacement Disc Technology the operator has the flexibility to access the buffycoat concentrate at any point of separation. The GenesisCS System is not volume dependent or hematocrit dependent. Physicians adore the versatility of GenesisCS and enjoy using a system that can respond to their specific needs.



Soft Braking Technology acceleration and deceleration are both controlled for optimal buffycoat

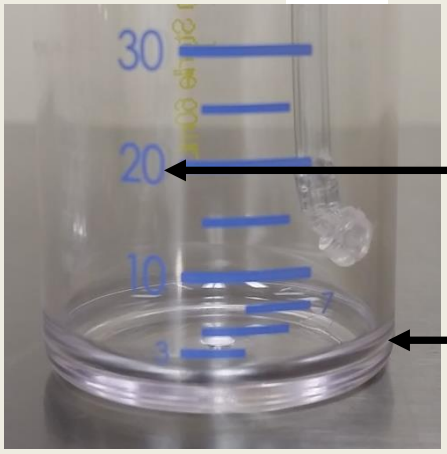
Active Displacement Disc Technology (ADDT)

Closed system throughout. Maximizes safety of the contents and ensures sterility throughout processing

CENTRIFUGE AND EMCYTE KIT TECHNOLOGY

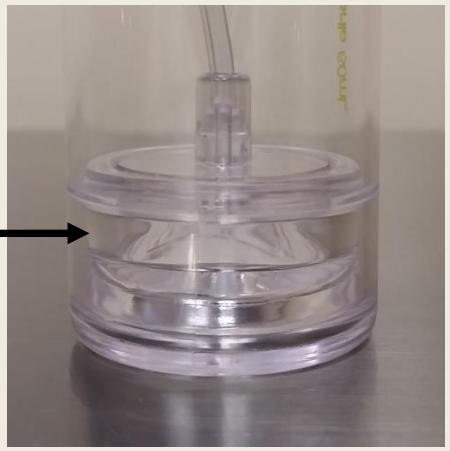
Vertical Side Port with Self Sealing Swabbable Valve Port

Closed and sterile enclosure during all steps of processing
Requires no caps to maintain sterility
No centrifugal aerosolization, eliminating bucket caps
Improved device handling



Conical Aspirating Disc

Reduce RBC contamination during aspiration



Precise Volume Doses

mL marks enables custom and precise dose for final solution

Rounded Interior Base

Improves buffycoat re-suspension

Executive Series II Centrifuge

The New Executive Series Centrifuge II (ESC II) has the most advanced technology setting it apart from all predecessors. With a new elegant design, the ESC II is crafted to perfection and universability while maintaining its affordable cost.

Kits Are Available To Process:

Prp
Pure Prp
Bmc Pure Bmc
Adipose
A2M
Fibrinogen

Minimal sterile barrier entries designed to reduce handling and improve sterility maintenance.

Total biologic capable with direct access to the platelet buffycoat

Full swinging bucket centrifugation optimizes separation & enhances the buffycoat concentrate

Pure PRP® Concentrating Systems:

GS30-Pure II – Pure Platelet Concentrating System 30mL
AB-60 Pure - **AcCELLerated Biologics** Pure Platelet Concentrating System 60mL
GS120-Pure II - Pure Platelet Concentrating System 120mL

The NEW Ac**CELL**erated Biologics 30mL, 60mL, or 120mL Pure PRP® system is revolutionary. PurePRP® II is an autologous cellular biologic that has become standard of care for many treatment modalities. In today's world of regenerative medicine, clinicians are requiring products that are not only clinically effective but also have the versatility to provide for specific treatment requirements. This may include therapeutic strength PRP with low neutrophils and no red blood cells. Or it may include therapeutic strength PRP with high neutrophils and nominal red blood cells. Some physicians may require a bioregenerative fibrinogen matrix scaffold to support PRP retention and sustain growth factor release. Others may require protein compositions to help mitigate cellular degradation. Whatever the need, PurePRP® II has the biologic versatility to be an integral part of the treatment modality.

The Cellular Physiology of PurePRP® II / Deliverable Platelets in PurePRP® II
Deliverable platelets are the actual volume of viable platelets contained in a PRP sample. PurePRP® II provide upwards of 9.5 billion platelets in a 7mL treatment sample (approximately 1.4 million platelets per microliter). High volumes of deliverable platelets enhances the volumetric activity of platelet growth factors and cytokines in active tissue repair. Platelet alpha granules contain various platelet growth factors that promote tissue repair through cell proliferation, chemotaxis, differentiation, and angiogenesis. Platelet cytokines provide the chemical stimulus needed to mediate cell signaling and migration. The amount of deliverable platelets are clinically significant if you are to attain active tissue repair. It is imperative that your deliverable platelet count be more than 1 million platelets per microliter [1].

Neutrophils in PurePRP® II
Neutrophils are the most abundant leukocyte and one of the first-responders to migrate towards a site of injury or infection (chemotaxis). Neutrophils are also the hallmark of acute inflammation. This is an aggressive response of chemical signals from cytokines such as interleukins (IL-1, IL-8) and tumor necrosis factor alpha (TNF-α) along with many others. The primary function of the neutrophil is to engulf and destroy foreign material through phagocytosis. Under normal circumstances, neutrophils are short lived (1-2 days) and are cleared by tissue macrophages. In conditions where the neutrophils cannot be cleared, for a lack of macrophages, they undergo a process called necrosis resulting in the release of all of the intracellular contents. This causes the amplification and prolonging of the inflammatory response. This prolonged amplified inflammatory response potential, is a concern of many physicians. This is why physicians are not encouraged by a PRP product containing high concentrations of neutrophils.



Monocytes in PurePRP® II

Monocytes are the largest of all leukocytes and are characteristically non-inflammatory phagocytic cells. Monocytes migrate to sites of injury and infection and differentiate into macrophages and dendritic cells to elicit an immune response which last for longer periods of time (months rather than days when compared to neutrophils). Monocytes illicit the immune response through phagocytosis, antigen presentation, and cytokine production each of which has a specific and deliberate function in enhancing the immune response through both protective prophylaxis and active phagocytosis.

PurePRP® II is unique in that it greatly enhances monocyte concentrations, while giving the end user control over the amount of neutrophils they would like to add to their PRP preparation. PurePRP® II takes advantage of the long term phagocytic and protective properties of the monocytes while avoiding the potential harmful inflammation incurred by large concentrations of neutrophils that go through cellular necrosis. This is another differentiating factor that help to explain the natural success of PurePRP® II in patient outcomes.

PURE PRP® II ONE SYSTEM TWO PROTOCOLS

Protocol A

Protocol A processes Pure PRP® without red blood cells or neutrophil granulocytes. This protocol is used when powerful healing without inflammatory activity is required at the application site. This protocol is also the low viscosity solution to a viable PRP product, providing very high concentrations of platelets in a bath of non-viscous plasma. This protocol has also been reported to reduce the potential for pain at the application site. It is the most frequently used protocol.

Low Inflammatory PRP

Higher Platelet Count
Low Granulocyte
Low Viscosity
Less than 1% HCT

Protocol B

Protocol B processes Pure PRP® with low red blood cell counts and very high cytokine activity and neutrophil cell recoveries. This protocol is used when the phagocytic powers of neutrophils are needed to help fight infectious processes at the application site. This protocol produces the highest chemoattractant activity and significantly increases regeneration potential. Once the neutrophils have completed phagocytosis, they become apoptic cells and are subsequently removed, thereby also eliminating the inflammatory activity.

Infection Fighting PRP with Increased Cytokines

Higher Platelet Count
High Neutrophil Granulocytes
Moderate Viscosity
HCT Less than 20%

ANALYZING PLATELET SAMPLES

Concentrated platelet samples prepared with the GenesisCS concentrating System tend to have higher platelet concentrations when compared to other systems. High concentrations of platelets suspended in low plasma volumes may clump together. When analyzing platelet samples attained with the GenesisCS Concentrating Systems the following procedures are recommended for accurate results.

Blood Analyzer

1. Platelet counts are best measured in the Beckman Coulter ACT 5, or any approved blood analyzer of similar or better quality.
2. The PRP test sample must be placed in an empty red top PLASTIC tube containing no anticoagulant. Glass tubes may activate platelets causing an inaccurate reading.

De-Clumping

3. To help remove platelet clumping prior to testing, the PRP sample **MUST** be placed on a rocker for a minimum of 1 hour. The PRP sample must mix with at least 1mL of air inside the sample tube or syringe. GenesisCS PRP samples are stable for up to 4 hours after collection.

Pre Testing Preparation

4. After the 1 hour de-clumping period is completed, the test sample **MUST** be diluted to 50% using an approved isotonic solution.

Analyzing the Results

5. Once the sample results are attained, the CBC (WBC, RBC, HGB, HCT, PLT) results will represent 50% of the sample and then must be multiplied by 2 to attain the final results.
6. The WBC differentials (NE, LY, MO, EO, BA) percentages reflect the correct results without multiplying by 2 because the percentages remain constant throughout the dilution procedure.

Formulation

7. The Platelet yield is calculated using the following formulation

8. **Yield =** $\frac{PLT_{PRP} \times PRP\ volume}{PLT_{start} \times Process\ volume}$

    a. PLT_{PRP} = Platelet count in PRP sample
    b. PRP_{volume} = Total volume of the PRP collected (not just the volume used for testing
    c. PLT_{start} = Baseline platelet count of the blood sample with anticoagulant
    d. $Process_{volume}$ = Total volume of collected whole blood with anticoagulant

Marrow Cellution™ :

MC-Ran-11C - Marrow Cellution™ 11G x 3.5” (9cm)
MC-Ran-11CSTS - Marrow Cellution™ 11G x 4.5” (11.4cm)
MC-Ran-13C - Marrow Cellution™ 13G x 3.5” (9cm)
MC-Ran-13FA - Marrow Cellution™ 13G x 2” (5cm) designed for use in foot and ankle surgery and feature a closed tip, sharp introducer needle. No blunt stylet or aspiration cannula is included.

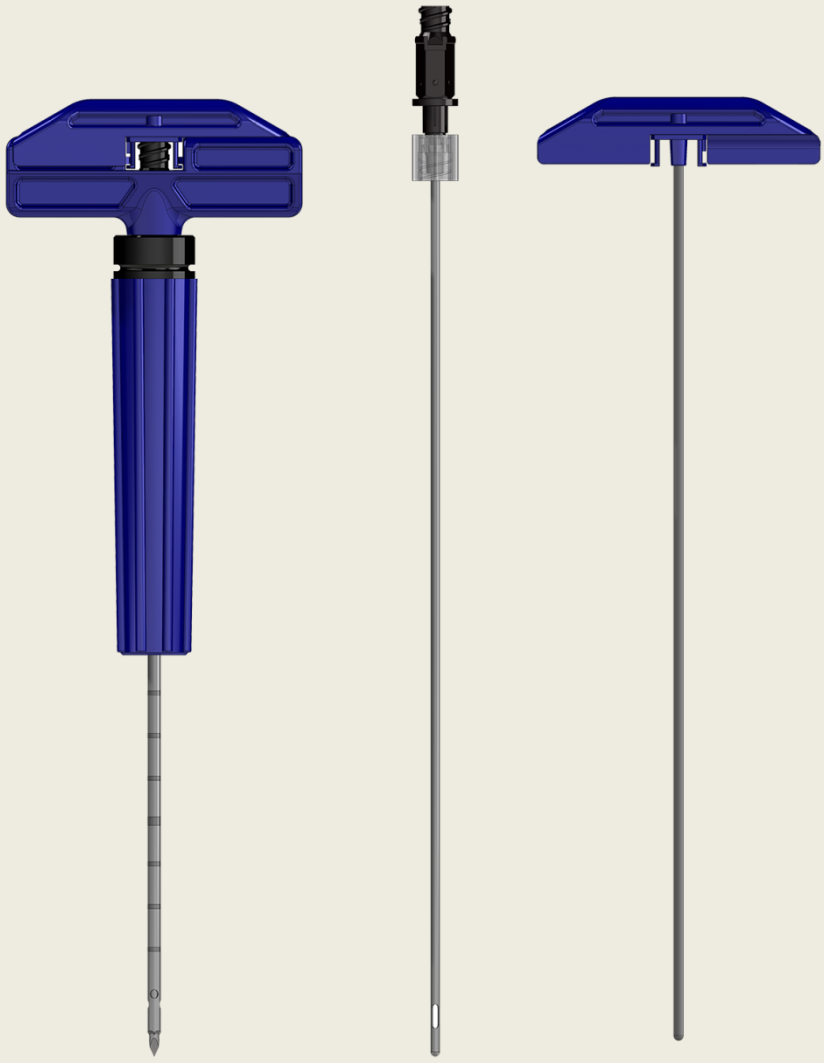
Autologous Bone Marrow Aspiration & Bone Graft Harvesting

The Marrow Cellution™ Bone Marrow Aspiration & Cancellous Bone Graft Harvesting System is a novel bone marrow access and retrieval device that incorporates features designed to minimize limitations of traditional trocar needles.

Marrow Cellution™ maximizes stem and progenitor cell recovery while minimizing peripheral blood infiltration. Because fluid under force follows the path of least resistance, trocar needles with side ports aspirate primarily through the distal end of the cannula. This leads to excessive blood collection, requiring additional manipulation, i.e. centrifugation or chemical separation in a laboratory.

Marrow Cellution™ accesses aspirate flow collected exclusively laterally as the tip of the aspiration cannula is closed allowing marrow collection perpendicular to and around the channel created by the device. It incorporates technology to precisely reposition the retrieval cannula within the marrow space after each aspiration. These features achieve a clinicians‘ desire for a single entry point.

A single puncture with Marrow Cellution™ provides high quality bone marrow aspirate and cancellous bone graft, collected from numerous sites within the marrow geography.

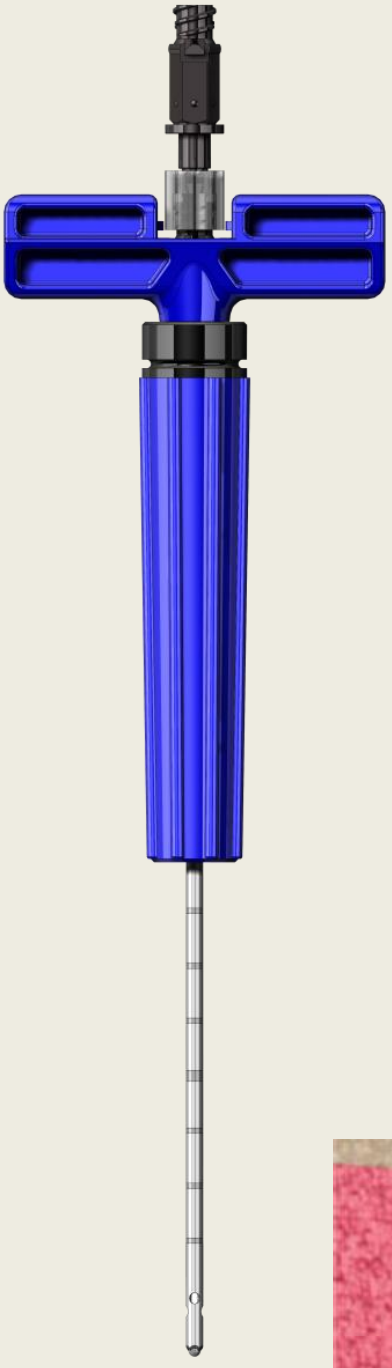


Overcome Aspiration Limitations & Maximize Cell Yield

510(k) – Marrow Cellution™ Bone Marrow Aspiration Needle #K150563

Hematopoietic component of bone marrow produces approximately 500 billion blood cells per day

Marrow Aspiration , Minimal Manipulation

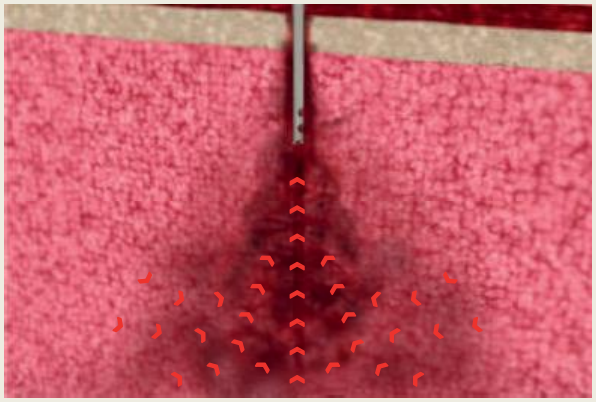


The Marrow Cellution™ Bone Marrow Aspiration System is intended for use for aspiration of bone marrow or autologous blood. It allows the user to aspirate in a measured and controlled manner over a large geography within the marrow space. Marrow Cellution™ is available in 11 Gauge and 13 Gauge diameters and includes an introducer needle, sharp and blunt stylet, aspiration cannula and 10ml syringe. Marrow Cellution™ also comes in multiple lengths and is designed for use in the Iliac Crest, Pedicle, Calcaneous or Tibia.

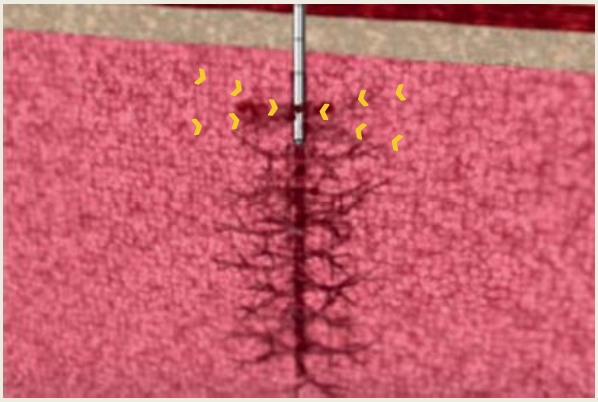
What are the Limitations of a Traditional Needle?
Traditional bone marrow aspiration needles aspirate primarily through an open-ended cannula, which leads to excess peripheral blood dilution and inadequate collection of key stem and progenitor cells. For this reason a high volume of bone marrow aspirate must be collected and then manipulated (i.e. centrifuged) before being applied for regenerative therapies.

How Does the Marrow Cellution™ System Overcome These Limitations?
The unique design of the Marrow Cellution™ system offers two key features that are not capable with a traditional needle:

- Closed-tip aspiration cannula that restricts aspiration through the side holes of the cannula and away from the channel caused by the tip of the needle, avoiding excess peripheral blood infiltration.
- A mechanical means for measured controlled retraction of the aspiration cannula to collect bone marrow aspirate from multiple geographies inside the medullary space with a single puncture.



Traditional Needle



Marrow Cellution™

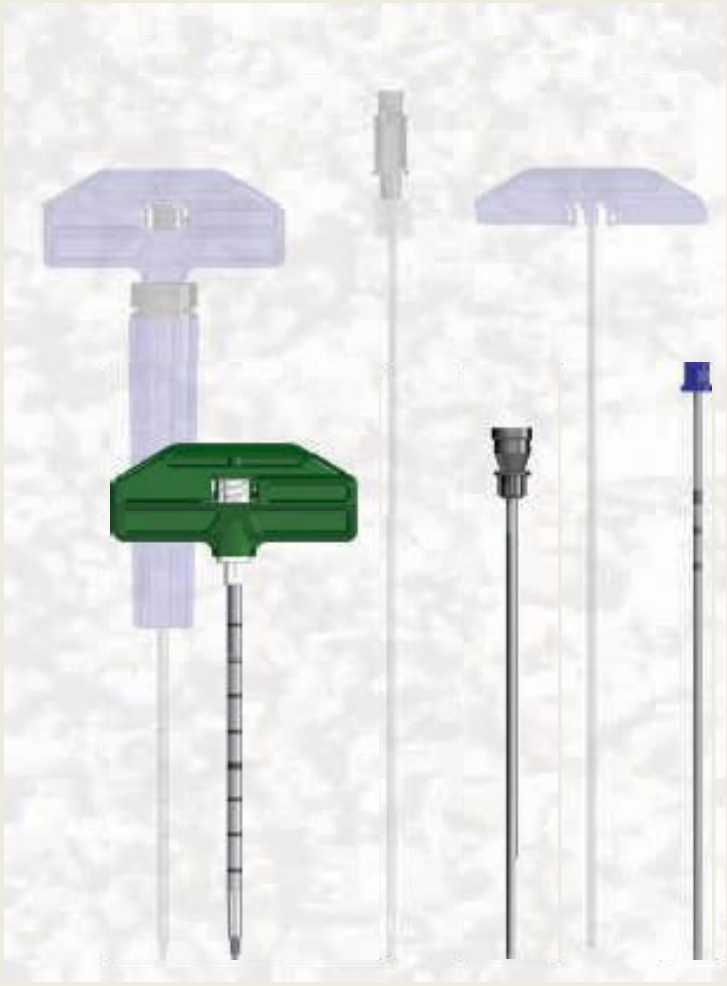
Marrow Cellution™ Percutaneous Bone Graft Collection :

MC-Ran-8C - Marrow Cellution™ 11G x 3.5" (9cm) with 8G x 4" Trephine Needle
MC-Ran-8CSTS - Marrow Cellution™ 11G x 4.5" (11.4cm) with 8G x 6" Trephine Needle
MC-Ran-13FAB - Marrow Cellution™ 13G x 2" (5cm) designed for use in foot and ankle surgery and feature a closed tip, sharp introducer needle. No blunt stylet or aspiration cannula is included.

Marrow Cellution™ Autologous Bone Marrow Aspiration & Bone Graft Harvesting

Intact Bone Cores vs. Morselized Bone

- Harvesting intact cancelleous bone cores without disrupting the highly-organized living tissue is superior to transplanting pieces of bone. Intact grafts maintain the micro-vascular network within the graft promoting bone callus formation/ remodeling and do not exhibit extensive resorption.[1 2]
- Intact bone exploits the biology of normal fracture healing rather than through slow creeping substitution associated with the slow incorporation of a non-vascularized graft.[1]
- Research demonstrates the enhanced survival of a bone graft as long as its primary blood supply is preserved. A living bone graft will shorten the time for boney union because the reconstructed bone is comparable to a bone with a double fracture. [1 2]
- Allogenic or synthetic bone chips hydrated with marrow can be packed around the living bone graft/core to accelerate anastomosis into the graft and minimize morbidity.[1 2]

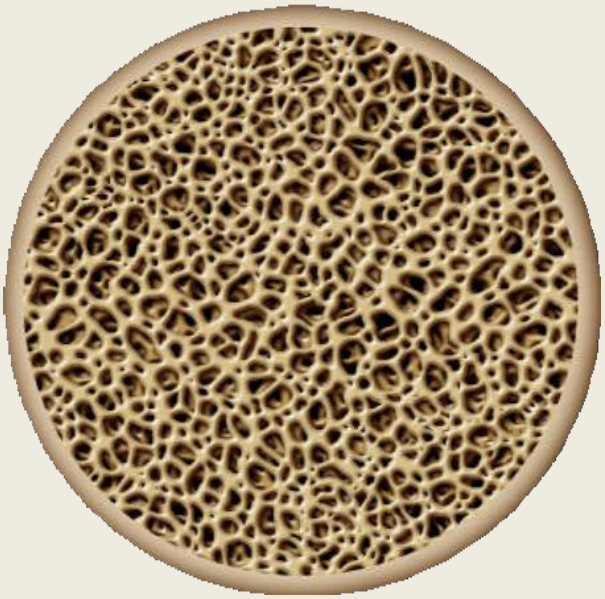


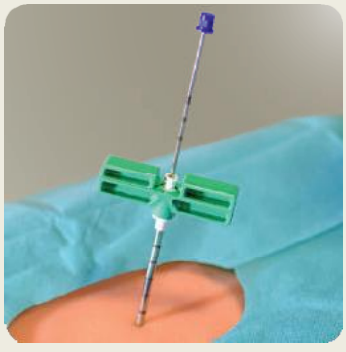
(1) Bleuming SA, et al. Bone morphogenetic protein signaling suppresses tumorigenesis at gastric epithelial transition zones in mice. Cancer Res. 2007 Sep 1;67(17):8149-55.
(2) Ostrup LT, et al. Distant transfer of a free, living bone graft by microvascular anastomoses. An experimental study. Plast Reconstr Surg. 1974 Sep;54(3):274-85.
(3) Taylor GI, et al. The free vascularized bone graft. A clinical extension of microvascular techniques. Plast Reconstr Surg. 1975 May; 55(5):533-544.

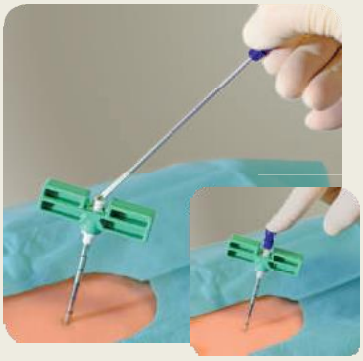
Marrow Cellution™ Autologous Bone Marrow Aspiration & Bone Graft Harvesting

Minimally Invasive Bone Grafts

- Vascularized and cancellous autograft shows optimal skeletal incorporation but is limited by morbidity concerns.[3]
- Using the Marrow Cellution™ Graft Delivery Syringe and the Marrow Cellution™ Bone Core Harvest Device, the clinician can create a combination graft of a vascularized intact bone core in the center of the graft surrounded by allogeneic, autologous or synthetic bone chips hydrated with cellular marrow aspirate.
- Higher quality, less quantity, delivered appropriately minimizes host morbidity







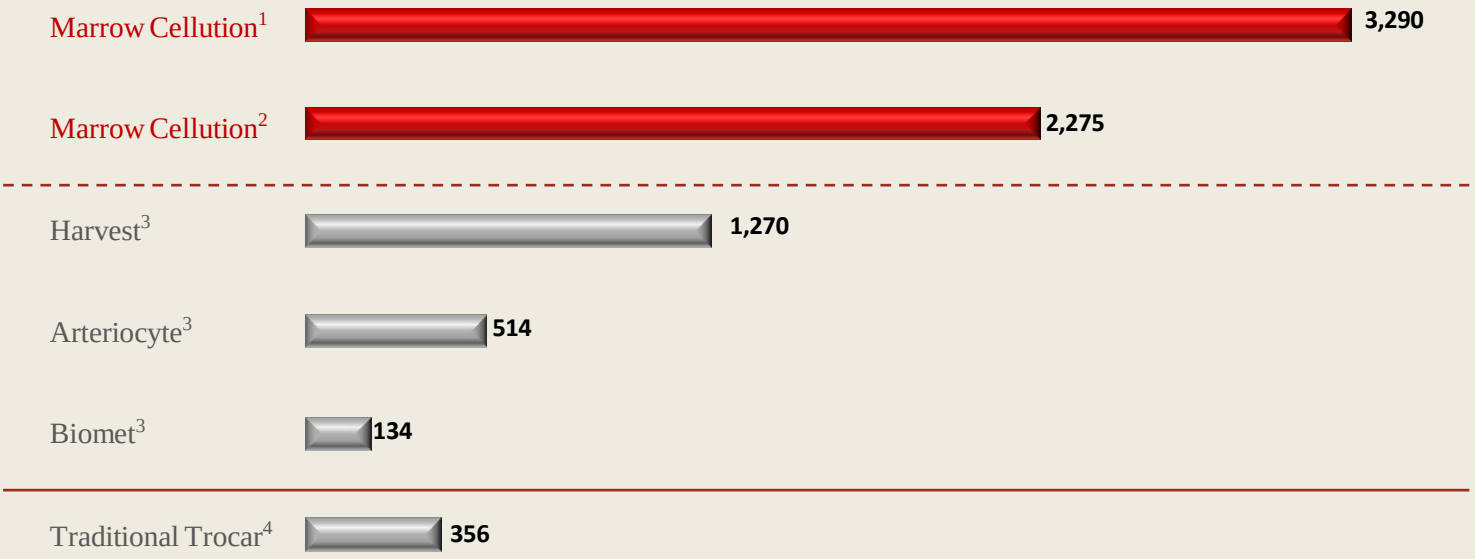
Produces Autologous Cancellous Graft Material with Osteoconductive, Osteoinductive & Osteogenic Properties

Minimally Invasive Cancellous Bone Core Extraction Technique

Combine with Allogeneic, Autologous or Synthetic Bone Chips Hydrated with Marrow Cellution™ Aspirate

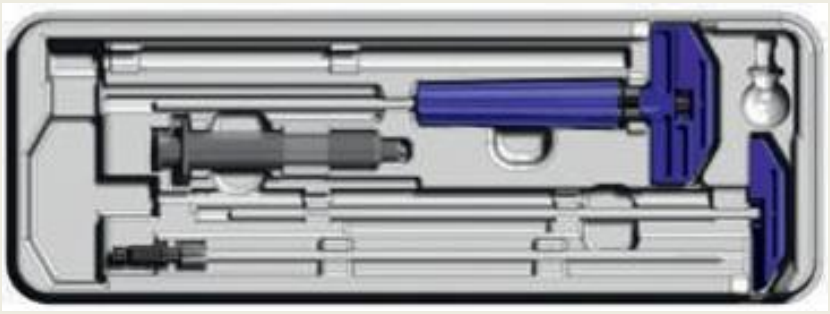
Marrow Cellution™ vs. Centrifugation Systems & Traditional Aspiration Needle

CFU-f per mL

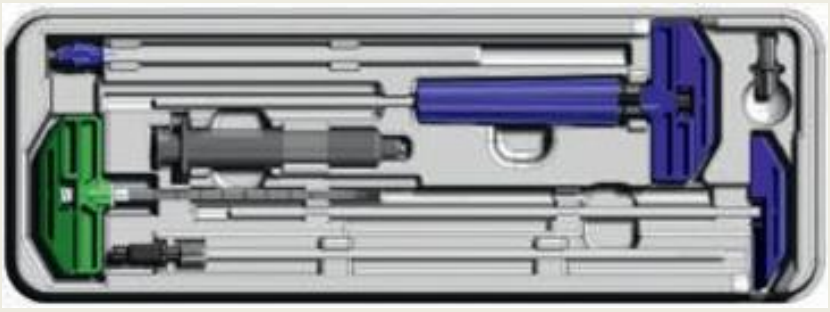


1. *Scarpone M, et al. Marrow Cellution Bone Marrow Aspiration System and Related Concentrations of Stem and Progenitor Cells. White Paper 2015.*
2. *Harrell DB, et al. Novel Technology to Increase Concentrations of Stem and Progenitor Cells from Marrow Aspiration. White Paper 2015.*
3. *Hegde V, et al. A prospective Comparison of Three Approved Systems for Autologous Bone Marrow Concentration Demonstrated Non-Equivalency in Progenitor Cell Number and Concentration. J Orthop Trauma. 2014 Oct; 28(10):591-8*
4. *McLain R, et al. Aspiration of Osteoprogenitor Cells for Augmenting Spinal Fusion: Comparison of Progenitor Cell Concentrations from the Vertebral Body and Iliac Crest. J Bone Joint Surg Am. 2005 Dec; 87(12): 2655-2661.*

MC Ran 11C



MC Ran 8C



USA pat pending and international patent pending
Manufactured by RANFAC, Avon, MA USA

BMC Concentrating Systems:

GSBMA-30 - Absolute Bone Marrow Concentrating System 30mL (544E)
GSBMA-60 - Absolute Bone Marrow Concentrating System 60mL (544E)
GSBMA-120 - Absolute Bone Marrow Concentrating System 120mL (544E)

The *Absolute*BMC Concentrating System

The AbsoluteBMC Concentrating System has been rebranded from the former 544e. AbsoluteBMC provides significant concentrations of CFU-F, CD34+, and total nucleated cell counts. CD34+ are cell markers for hematopoietic stem cells. These are the primary multipotent cells that replenishes all blood cell types. These cells are crucial for the regenerative processes needed for active tissue repair. In addition to these cells are CFU-F, which are representative of mesenchymal stem cells.

Mesenchymal stem cells (MSC) are multipotent stromal cells that can differentiate into a variety of cell types, including cartilage, bone and adipose cells. AbsoluteBMC provide therapeutic concentrations of these cell types which is the key to desirable patient outcomes. AbsolutePRP is the fastest and most efficient single spin 60mL concentrating systems available. Prepare 7mL of BMC, in a SINGLE 5 MINUTE SPIN.

Bone marrow cells reside deep inside bone cavities in the most protected part of the body and are redundant throughout the organism. This preferential status reflects the primary role these cells play in the survival of the organism. Tissue repair is a dynamic self-organizing process that relies on cell mobility and growth factor production from cells within a biologic scaffold. Platelets and Cells from Peripheral Blood Initiate the Inflammatory Process of the Healing Cascade and release cytokines to cause marrow cells to mobilize and home to the injury site (vasculogenesis). Marrow stem cell and marrow complimentary cell mediated vasculogenesis and cell-to-cell contact with immune system stem cells transition the Healing Cascade from the inflammatory phase to the proliferation and remodeling phase.

5 Minute spin time. Fastest spin time in the market.	Concentrate hematopoietic stem cells (HSC), & mesenchymal stem cells (MSC) in a bath of plasma	AbsoluteBMC delivers the excellence and reliability physicians depend on

PureBMC® Concentrating Systems:

BC30-Pure - PureBMC® Concentrating System 30mL
BC60-Pure - PureBMC® Concentrating System 60mL
BC120-Pure - PureBMC® Concentrating System 120mL

PureBMC®

Pure BMC® is Better Than Ever
Pure BMC® is better than ever and remains the flawless solution to Bone Marrow Cell Concentrate. PureBMC® processes BMC in a system that remains closed and sterile throughout all steps of processing. This is especially important when processing in a surgical suite. It is also proven to concentrate viable platelets, hematopoietic stem cells (HSC), total nucleated cells (TNC) and mesenchymal stem cells (MSC) in a bath of plasma with a low hematocrit. PureBMC® can be prepared with or without Heparin, either way it provides viable platelet concentrates that further add to the strength of the cell composition. PureBMC® delivers the excellence and reliability physicians can depend on.

Higher HSC Concentrations
Hematopoietic stem cells (HSCs) are the blood cells that have the ability to replenish all blood cell types (Multipotency) and the ability to self-renew. This include monocytes, macrophages, erythrocytes, megakaryocytes, platelets, neutrophils, basophils, eosinophils, dendritic cells and lymphoid lineage cells.

Higher MSC Concentrations
Mesenchymal stem cells (MSC) are multipotent stromal cells that can differentiate into a variety of cell types. These cell types primarily include cartilage, bone and adipose cells. Mesenchymal stem cells are found in very small quantities in bone marrow aspirate, making the concentrating capabilities of PureBMC® more vital to the physician.

Higher TNC Concentrations
Total nucleated cell count by any method is a count of cells with nuclei. In order to properly represent the TNC cell count a correction calculation that removes nucleated red blood cells (nRBCs) is performed. It is understood, as in other therapies, that more cells = better outcomes.

PureBMC®

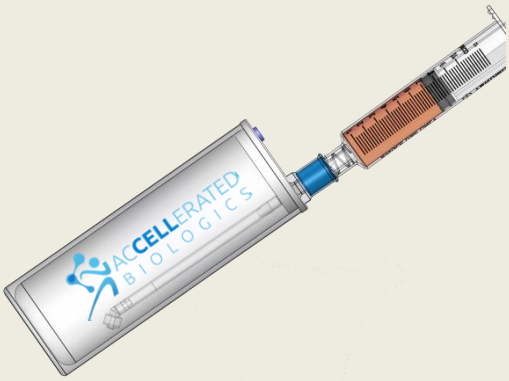
PureBMC® has been designed to improve performance outcomes. The design details allows the end user to more accurately collect high therapeutic cell concentrates with low red blood cell content.

Same Great Outcomes

Hematopoietic stem cells (CD34+), total nucleated cell (TNC), mesenchymal stem cell (CFU-F) and platelet isolation is perfected in the PureBMC® system. Similar to the Pure PRP®, PureBMC® is designed to retain high concentrations of these multiple cell concentrates with the lowest concentrations of red blood cells in a bone marrow concentrate product. Using a specialized cell isolation technique, PureBMC® provides more than 9X cell concentration in 7ml of PureBMC®. Preparation times are less than 10 minutes at the point of care. With careful attention to the details of gradient cell isolation, PureBMC® is a viable choice for a low hematocrit and high yielding bone marrow cell concentrate product.

Cell Concentrate
Plasma Suspension

Platelet, HSC, TNC, MSC
Cell Concentrate



Selectable Volumes & Concentrations

PureBMC® provide selectable sample volumes ranging from 3mL to 14mL. No matter what the sample size, PureBMC® provide therapeutic cell counts that exceed industry standards.

PureBMC Sample Size: 7mL, Independently Reviewed at the Bioscience Research Associates, Cambridge, MA

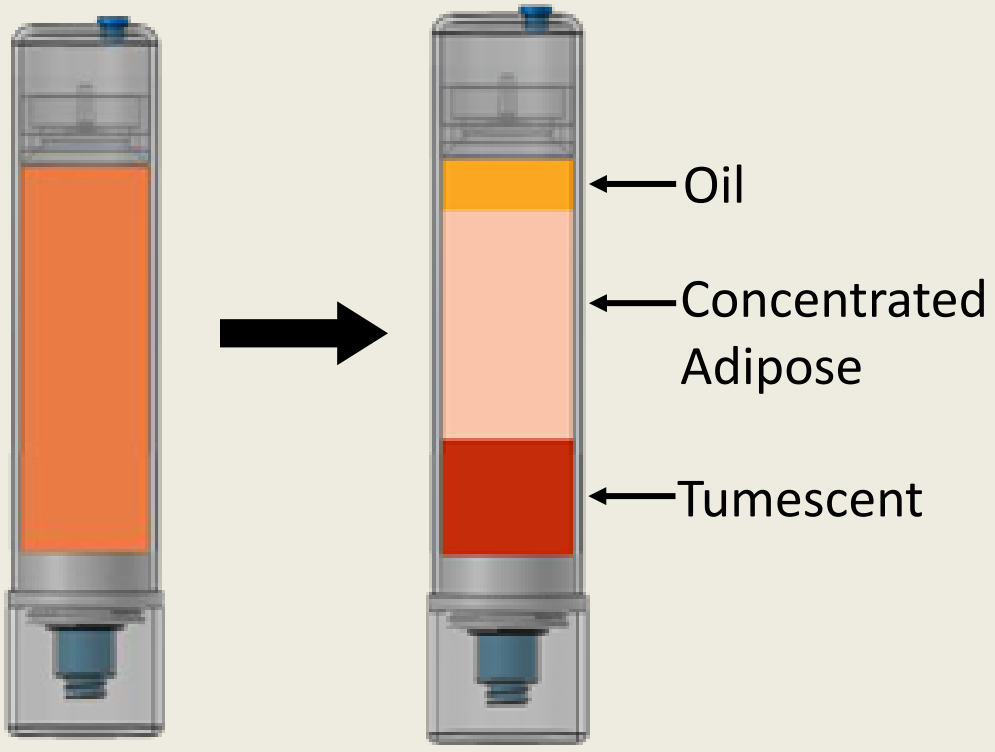
Total nucleated cell concentrations: 9.1 x Baseline or greater	Hematopoietic stem cells / Progenitor Cells: 13.3 x Baseline or Greater	Hematocrit: Less than 15% on Average

Adipose Systems:

ES35-ASC - EmStyle ASC Rejuvenation Concentrating System 35mL
CANSUP - Tulip Medical Harvester and Infiltrator Canula Set
DSLCAR1410 - Single Use Carraway SuperLuerLok 2.11mm OD(1.70mm ID) x 10cm
DSLINF1412 - Single Use Infiltrator SuperLuerLok 2.11mm OD(1.70mm ID) x 12cm
VPH - Vacuum Pressure Handle 30cc and (2) 30mL Syringes

Adipose is used in regenerative medicine procedures because mesenchymal stem cells can be isolated from almost every tissue in the human body. The central connecting aspect to explain this fact is that all of these tissues are vascularized and that every blood vessel in the body has mesenchymal cells in abluminal locations. These perivascular cells can be summarily called Pericytes.
Adipose-Derived MSCs are being used therapeutically because they undergo homing to sites of inflammation or tissue injury and they secrete massive levels of bioactive agents that are both immunomodulatory and trophic.

ES35-ASC



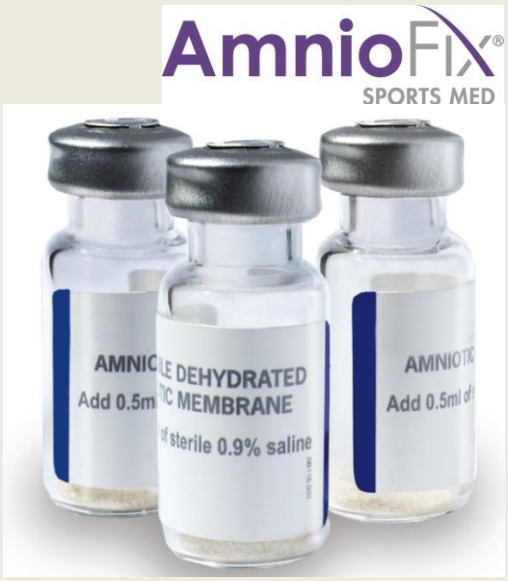
DSLCAR1410
Carraway Harvester

DSLINF1412
Tumescent Infiltrator

MIMEDX AMNIOFIX

AmnioFix Sports Medicine:

ASM-5050 - AmnioFix Sports Medicine 20mg
ASM-5040 - AmnioFix Sports Medicine 40mg
ASM-5100 - AmnioFix Sports Medicine 100mg



Growth Factors

Over 57 different growth factors, specialized cytokines, and enzyme inhibitors have been identified in AmnioFix®, including the following which are some of the most notable growth factors that help modulate infammation and enhance soft tissue healing:[4-6]

- Transforming Growth Factor Beta (TGF-ß1) - Promotes normal soft tissue healing and reduced scar formation
- Fibroblast Growth Factor (FGF) - Promotes cellular proliferation and important for collagen matrix formation
- Platelet Derived Growth Factors (PDGF AA & BB) - Promote cell proliferation in connective tissue and enhance soft tissue healing

AmnioFix is a bioactive tissue matrix composed of human amnion/chorion membrane for homologous use to:

- Modulate inflammation
- Reduce scar tissue formation
- Enhance healing of soft tissue

Treats soft tissue injuries even when conventional treatments fail

Soft tissue injuries are often caused by either trauma or overuse of the affected area. Micro-tears in the tissue form and become infamed. Scar tissue may form and impede a full recovery. Conservative treatments of oral or topical anti-infammatories and rest usually will help heal the injury. If additional treatment is needed, AmnioFix might be an option for your patient.

Is AmnioFix right for my patient?

You may consider AmnioFix as an option for your patient if:

- Your patient has been diagnosed with a tendon or soft tissue injury
- Conservative treatment such as anti-infammatories, physical therapy, and bracing have not provided symptomatic relief of infammation
- Your patient wants a non-steroidal option or has reached the limit of steroid injections

Proprietary PURION Process
AmnioFix is processed using the PURION Process

Dehydrated for ease of use and application. 5 year shelf life at ambient conditions

Over 400,000 allografts distributed with ZERO FDA reportable adverse reactions

MIMEDX ORTHOFLO

OrthoFlo Sport:

LS-0050 - OrthoFlo Sport 0.5 mL
LS-0100 - OrthoFlo Sport 1.0 mL
LS-0200 - OrthoFlo Sport 2.0 mL
LS-0400 - OrthoFlo Sport 4.0 mL

What is OrthoFlo Sport?

Amniotic fluid, *in utero*, naturally functions to protect, cushion and lubricate.1 Key elements of amniotic fluid include growth factors, carbohydrates, proteins, lipids, electrolytes, and other nutrients, as well as hyaluronic acid (HA), a principle component that provides viscosity and lubrication in the synovial fluid that surrounds joints.1,2

OrthoFlo Sport is an amniotic fluid allograft for homologous use to protect and cushion, provide lubrication for enhanced mobility, and reduce inflammation.

Regulatory Factors

OrthoFlo Sport contains an array of well-known regulatory proteins, growth factors, cytokines, and chemokines that are naturally occurring in amniotic fluid and the fluid surrounding many joints. Some of the bioactive factors contained within OrthoFlo Sport include:

- **Interleukin 1 Receptor Antagonist (IL-1ra):** Antagonist of IL-1 signaling which is known to be involved in cartilage degeneration
- **Tissue Inhibitor of Metalloproteinases (TIMPs):** Inactivates a number of matrix metalloproteinases responsible for cartilage degradation

Biological Activity

Proliferation and hyaluronic acid production by cells in response to OrthoFlo Sport were measured in normal human synoviocytes. Normal human synoviocytes from healthy donors were cultured in the presence of OrthoFlo Sport, either at 0.2 or 0.8 mg/mL. OrthoFlo Sport significantly increased cell number after 3 days compared to basal medium, indicating that OrthoFlo Sport promoted proliferation of human synoviocytes.

Protein composition of OrthoFlo Sport compared to fresh amniotic fluid

OrthoFlo Sport Maintains Amniotic Fluid Profile

The SDS-PAGE gel left illustrates the composition and relative abundance of proteins, separated by molecular weight, for OrthoFlo Sport compared to fresh amniotic fluid. The protein composition of OrthoFlo Sport appears very similar to fresh amniotic fluid with a nearly identical pattern of protein bands.

Dried for ease of use and application

Five year shelf life at ambient conditions; no special storage required

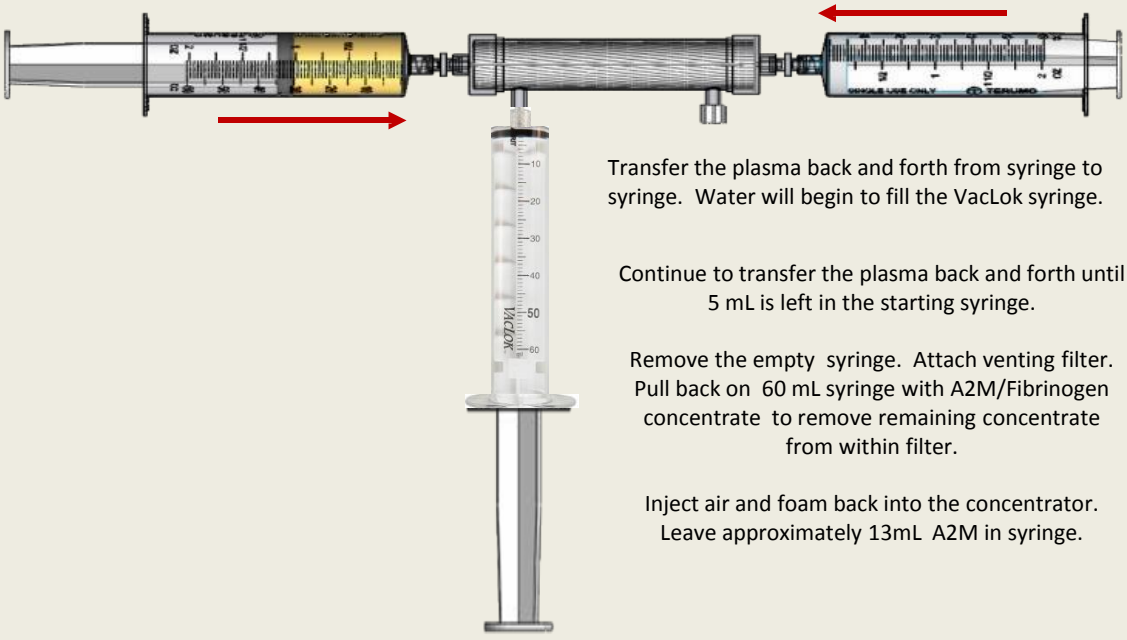
Human amniotic fluid allograft, donated by mothers delivering healthy babies by scheduled Caesarean section

A2M and Fibrinogen Protein Concentrator:

FC-120 PURE - A2M Pure PRP with Protein Concentrator 120mL
CUST1000 - Fibrin and A2M Plasma Concentrator

This kit is designed to provide at least 6x concentration of A2M and Fibrinogen Proteins.

Alpha-2-Macroglobulin is the largest major nonimmunoglobulin protein in plasma. The alpha-2-macroglobulin molecule is synthesized mainly in liver, but also locally by macrophages, fibroblasts, and adrenocortical cells. Alpha 2 macroglobulin acts as an antiprotease and is able to inactivate an enormous variety of proteinases. It functions as an inhibitor of fibrinolysis by inhibiting plasmin and kallikrein. It functions as an inhibitor of coagulation by inhibiting thrombin. Alpha-2-macroglobulin may act as a carrier protein because it also binds to numerous growth factors and cytokines, such as platelet-derived growth factor, basic fibroblast growth factor, TGF-β, insulin, and IL-1β.
The plasma protease inhibitor A2M is not present in sufficient concentrations to inactivate the high concentrations of catabolic factors found in OA synovial fluid. Findings suggest that supplemental intra-articular A2M provides chondral protection in posttraumatic OA.



Transfer the plasma back and forth from syringe to syringe. Water will begin to fill the VacLok syringe.

Continue to transfer the plasma back and forth until 5 mL is left in the starting syringe.

Remove the empty syringe. Attach venting filter. Pull back on 60 mL syringe with A2M/Fibrinogen concentrate to remove remaining concentrate from within filter.

Inject air and foam back into the concentrator. Leave approximately 13mL A2M in syringe.

Provides at least 6 x concentration of A2M and Fibrinogen proteins

Protects the joint space from destructive proteins

Powerful inhibitor of cartilage catabolic factors

Topical Gear:

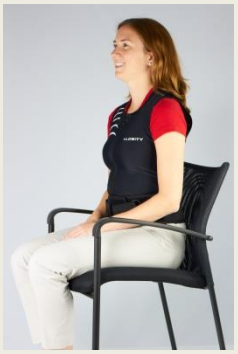
T:25 Knee
T:25 Pro Taco Ankle
T:25 Vlosity Shoulder

AcCELLerated Biologics and Topical Gear is changing the way athletes and patients are cared for pre and post injection. T:25 technology applies topical compression on specific muscles in order to stimulate neuromuscular communication and enhance proprioception. This naturally enhances performance while reducing risk of injury.

- Thin and light– only 2 oz.
- Easy to apply and remove
- Indications: post-op ACL reconstruction, patella femoral and patella tendonitis issues and Osgood-Schlatter disease
- Use: Wear 1.5 hours/day for 10 days in motion. Then 1.5 hours/every other day for 6 weeks in motion. After initial training of the key muscles are complete, this can be worn as desired.

By applying Topical Gear's patented technology of 25mmHg to muscles or ligaments with T:25 pads incorporated into the products, it will enhance proprioception and neuromuscular communication, reducing risk of injury and enhancing performance. T:25 pads to the medial quadriceps and medial hamstring (agonist and antagonist), proprioception and neuromuscular communication are enhanced, causing the femur to be externally rotated improving knee alignment.

T:25 Knee



T:25 Vlosity Shoulder

T:25 Pro Taco Ankle

Based on Thomas Kuhn's The Structure of Scientific Revolutions (1962), Topical Gear is creating a pre-paradigm shift in the standard care of athletes and patients.

Applying T:25 Technology to the medial quadriceps and hamstrings enhances proprioception and neuromuscular communication with the tendons and ligaments in the knee, training those muscles to respond faster, giving the athlete more time to get out of the vulnerable position, ultimately reducing the risk of injury.

RESEARCH

Based on Thomas Kuhn's The Structure of Scientific Revolutions (1962), Topical Gear is creating a pre-paradigm shift in the standard care of athletes and patients.

Ortho T:25 Knee

Applying T:25 Technology to the medial quadriceps and hamstrings enhances proprioception and neuromuscular communication with the tendons and ligaments in the knee, training those muscles to respond faster, giving the athlete more time to get out of the vulnerable position, ultimately reducing the risk of injury.
Decker, "The Effectiveness of the ACL Tube on ACL Injury Risk Reduction and Performance in Female Soccer Athletes"
Decker, M. Shaw, C. Madden, C. Byers,"Postural Control Enhancement in Female Collegiate Soccer Players"
M. Palmieri-Smith, S.G. McLean, J.A. Ashton-Miller, E.M. Wojtys, "Association of Quadriceps and Hamstrings Cocontraction Patterns With Knee Joint Loading", Journal of Athletic Traning, No. 44 (2009), 256-263
M. Stearns, C.D. Pollard, "Abnormal Frontal Plane Knee Mechanics During Sidestep Cutting in Female Soccer Athletes After Anterior Cruciate Ligament Reconstruction and Return to Sport",The American Journal of Sports Medicine, Vol. 41, No. 4 (2013), 918-923
Ortiz, S. Olson, C.L. Libby, E. Trudelle-Jackson, "" Landing Mechanics Between Noninjured Women and Women With Anterior Cruciate Ligament Reconstruction During 2 Jump Tasks,The American Journal of Sports Medicine, Vol. 36, No. 1 (2008)

Pro Taco Ankle

Applying T:25 Technology to the ATFL and CFL speed up proprioception through the central nervous system to the peroneals. The T:25 pads that rest on both sides of the Achilles tendon train the peroneal muscles to shorten their latency period, giving the athlete more time to get out of the vulnerable position, reducing the risk of injury.

2011 SIMS Report, Penn State—reports positive results with the Pro Taco in preventing ankle sprains
Pro Taco Youth Female Volleyball Survey—in 86 ankles of youth female volleyball players, a 90% reduction in ankle injury is suggested.
Myers, B. Rieman, J. Hwang, F. Fu, S. Lephart,"Effect of Peripheral Afferent Alteration of the Lateral Ankle Ligaments on Dynamic Stability," American Journal of Sports Medicine 31, no. 4 (2003): 498-506.
A. Ashton-Miller JA, R.A. Ottaviani, C. Hutchinson, E.M. Wojtys,"What Best Protects the Inverted Weightbearing Ankle Against Further Inversion? Evertor Muscle Strength Compares Favorably with Shoe Height, Athletic Tape, and Three Orthoses," American Journal of Sports Medicine 24, no. 6 (Nov–Dec 1996): 800–809.

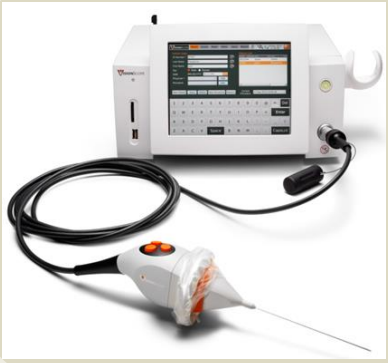
Vlosity Shoulder

The tensioning system in our Vlosity garment draws the shoulders back as the scapula goes into a posterior tilt. Capturing the upper torso in this position retrains the trapezoids, rhomboids and the mind as to where an athlete or patient should carry themselves. This allows the humeral head to function properly, enhancing performance and reducing the risk of injury.

Vlosity Shoulder Study in Female Division I Volleyball Players, Stanford University
Kebaetse, P. McClure, N. A. Pratt, "Thoracic Position Effect on Shoulder Range of Motion, Strength and Three-Dimensional Scapular Kinematics", Arch Phys Med Rehabil, Vol. 80 (1999)

What is the VisionScope system?

The VisionScope system provides similar information to surgical diagnostic arthroscopy – using a minimally-invasive technique. The exam takes place in the office exam room and requires only a local anesthetic (Lidocaine). The system's small needle endoscope houses a miniature camera and when it is inserted into a joint it captures real-time images and video – providing a thorough evaluation with higher quality information and improved reliability compared to static MRI images. Patients are able to get a clear diagnosis during the same office visit and the need for additional diagnostic tests or procedures and follow up visits may be eliminated.



For patients who may not benefit from standard diagnostic modalities, VisionScope® Imaging (VSI™) can enrich the clinical exam and diagnostic discussion in real time.

Exam room set up takes no time at all with the VSI™ PrepPak™. Just add sterile gloves and local anesthesia and you're ready to go.

Reusable endoscopes, come in a variety of lengths and house premium optics, delivering the highest quality images.

VSI™ components that come in contact with a patient are packaged in a sterile, single-use procedure kit.

Bringing Diagnostic Arthroscopy Power Into The Office

Choose the right tool for the right reason

- Inconclusive MRI
- Articular Surface Assessments
- Meniscal or Cuff Tears
- Post-operative evaluation
- Surgical Planning
- MRI Contradictions
- Pacemaker
- Implants
- Claustrophobia
- Obesity
- Accurate
- Immediate
- Convenient
- Patient-centric
- Cost-effective
- Office-based
- Safe

VSI™ combines durable and disposable Components to maximize workflow efficiency!

Direct visualization adds clarity to the conversation

In-office convenience with uncompromising quality and accuracy

AdiLight2:

AdiLight 2 - LED Photoactivation System

AdiLight-2 is available from AcCELLerated Biologics for use in activating mesenchyme stem cells and modulating cytokine release by white blood cells.

How PhotoActivation Works
As a concentrated source of platelets, PRP contains several different growth factors and other cytokines that accelerate and enhance the healing of bone and soft tissue. The PRP is then activated under AdiLight-2 for 10 minutes since this has been shown to significantly reduce pain and further accelerate healing.

While PRP treatment (without photoactivation) is fast becoming a popular new treatment for muscular and skeletal injuries, it is also known to cause aggravated pain in the affected area for 2-10 days after injection.

AdiStem Ltd. has researched the effect of different monochromatic light intensities and frequencies in the colored spectrum on various human and animal cell populations such as mesenchyme stem cells and white blood cells. The company has found that low-level light photoactivation or photomodulation can be utilized for significant benefit in stimulating the proliferation, differentiation, and inhibition/induction release of growth factors/cytokines of cells from any living organism.

Healing is Accelerated and Post-Treatment Pain for PRP Patients Reduced:
Once the PRP is prepared, it is activated briefly using AdiLight-2 before being injected back into the affected area. In most cases, photoactivation using AdiLight-2 increases Interleukin-1 Receptor Antagonist (IL-1RA) which decreases the pain and inflammation associated with PRP injections. In other cases, the duration of any pain is significantly reduced.

The PhotoActivation Process Takes Only 10 Minutes

AdiLight-2 is Simple to use. No Monitoring Required. No Training Necessary

Can be Used with Any High Quality PRP / BMA / Adipose

REGENERATIVE MEDICINE TRAINING INSTITUTE

Stem Cell Training, Hands on PRP Training, Highly Accredited Faculty

The Regenerative Medicine Training Institute offers peer to peer courses in a comfortable setting offering classrooms, procedure rooms, a lounge and lab space. Our PRP training classes help you advance your practice to better serve your patients. Class sizes are relatively small, up to 40 attendees. Our training courses encompass lectures on history, current studies and literature relating to platelet rich plasma and stem cell therapy from bone marrow, adipose and other biologic modalities. Additional elements of a course could also include live patient procedures, cadaver labs, patient protocols, product specific training, and marketing sessions. Point blank, our regenerative medicine conferences are just different. Our concierge approach to our student interactions ensures all attendees are happy from their initial enrollment, to transportation and travel, hotel accommodations to the day of the course and beyond.

The Regenerative Medicine Training Institute is committed to provide quality hands on training you won't receive anywhere else. We strive to empower you to change the lives in your practice and your community. Our cutting-edge technology accompanied with an expert teaching staff is the premier choice for earning your CME credits or just to advance your biologics knowledge and capabilities. Our courses encompass platelet rich plasma training, stem cell therapy utilizing bone marrow aspirate, bone marrow concentrate and adipose.

Success

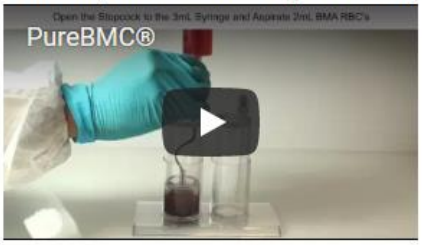
Our graduates upon completion of their respective course are able to competently introduce regenerative medicine techniques and applications to their staff, patients, and community. The platelet rich plasma courses and stem cell courses offered can easily be transitioned from the class room to the office. The success of our graduates is evident by their practices initial implementation, growth stage, new technologies and effective operations of a cellular therapy and biologics based practice.

VIDEOS, WEBINARS, QUICKGUIDES

AcCELLerated Biologics is proud to offer training programs to best meet the physicians schedule and preferences. Our training opportunities include day long training courses at the RMT Institute, live one-on-one webinars, training videos, quick guides and clinical visits. Please call customer service 1-800-367-0844 for training opportunities.

AB60 Pure PRP Processing instructions

BC60-Pure, PureBMC Processing instructions



QuickDRAW Delivery System

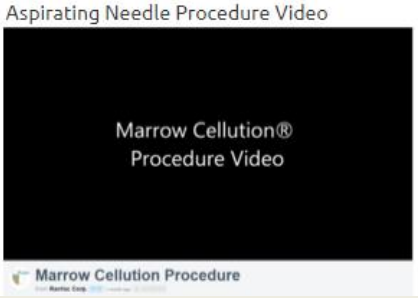
GS60 Absolute PRP Processing instructions

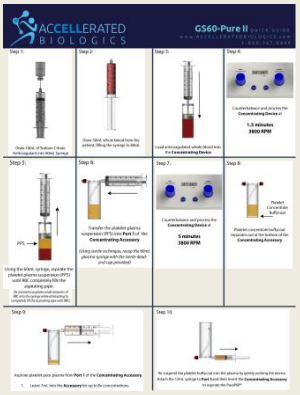
GSBMA60 Absolute instructions

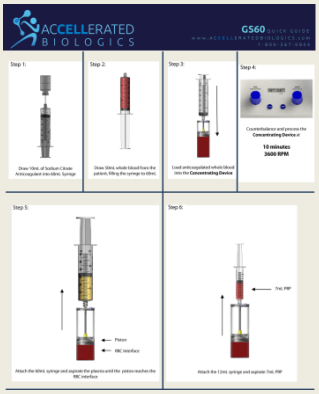
Executive Series Centrifuge

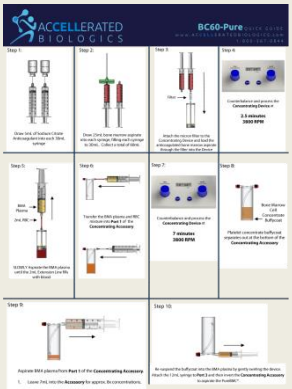
BC60-Pure 2014 instructions

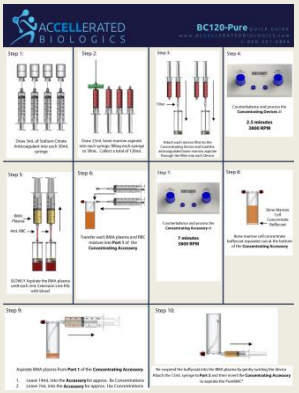
Marrow Cellution Bone Marrow Aspirating Needle Procedure Video











FREE training webinars and in-service visits

Receive access to AcCELLerated Biologics library of learning tools

Training opportunities offer one-on-one learning for staff and physicicans

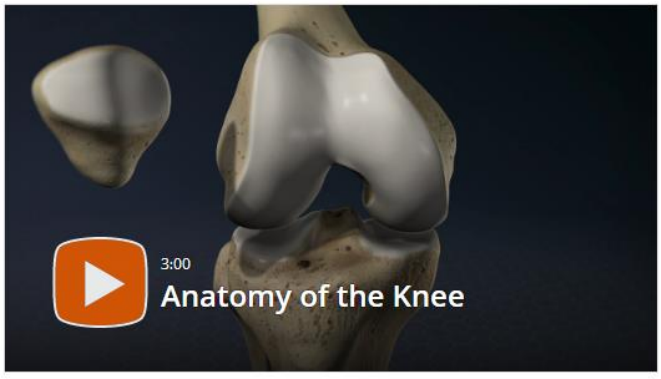
PATIENT EDUCATION VIDEOS, PATIENT EDUCATION BROCHURES, TOTAL BIOLOGIC PARTNERSHIP

AcCELLerated Biologics - Business Development through Website, Email, and Social Media Marketing Programs

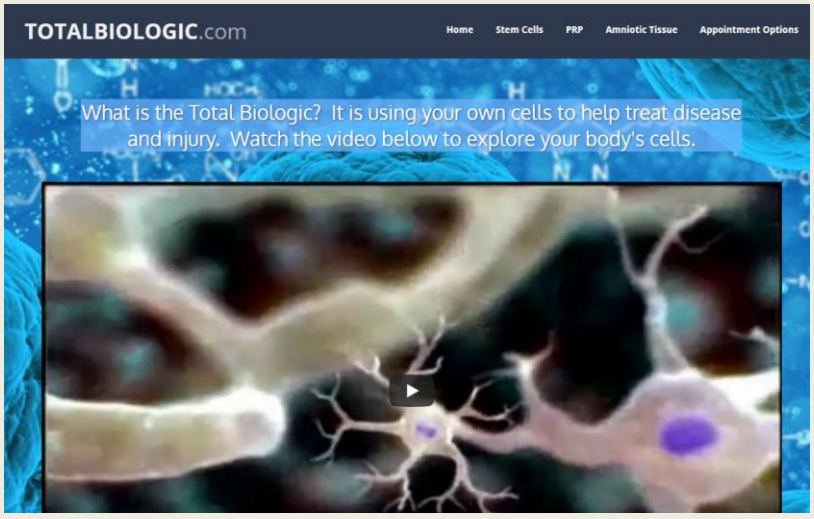
We provide programs and guidance on how to develop your practice through the most effective and efficient vehicles in your specific community. We will help you get the word out, let your community know what you are doing. The scope of the program is extensive. You choose the range and support needed. We offer a free Strategic Planning worksheet to everyone who wants to see where they are before starting any program.

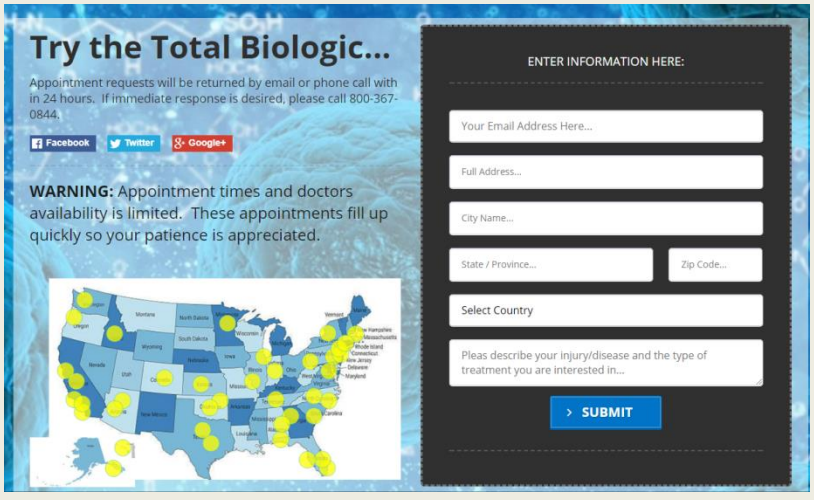
Pain and injury can occur at anytime to any part of your body. The natural make up of your anatomy is designed to be pain free.

PRP and Platelet Rich Plasma is used by physicians to treat many types of injuries. Orthopedic, Musculoskeletal, Sports Medicine, Pain Management, Physiatry, Family Practice, Interventional Radiology are some of the physicians that use biologics in their practice.



Website Help, Patient Acquisition Funnel Management, SEO Instruction
The most successful doctors have implemented a regenerative medicine specific page on their existing website or make a brand new regenerative medicine specific site. Use the words that best describe services offered. Use good SEO techniques so the page title lists items that are in the page description and throughout that page. Title each page with 2-3 key words such as: **PRP | Regenerative Medicine | City I practice in** or **Knee Pain | Platelet Rich Plasma | Biologic Therapy**.





•Yetsa A. Tuakli-Wosornu, MD, MPH, Alon Terry, MD, Kwadwo Boachie-Adjei, BS, CPH, Julian R. Harrison, BS, Caitlin K. Gribbin, BA, Elizabeth E. LaSalle, BS, Joseph T. Nguyen, MPH, Jennifer L. Solomon, MD, Gregory E. Lutz, MD **Lumbar Intradiskal Platelet-Rich Plasma (PRP) Injections: A Prospective, Double-Blind, Randomized Controlled Study.** *FLA 5.4.0 DTD PMRJ1567_proof 18 September 2015*

•Anz A, Hackel J, Nilssen E, Andrews J. **Application of Biologics in the Treatment of the Rotator Cuff, Meiscus, Cartilage, and Osteoarthritis**. *J Am Acad Orthop Surg 2014;22:68-69*

• Mautner K, Malanga G, Smith J, Shiple B, Ibrahim V, Sampson S, Bowen J. **A Call for a Standard Classification System for Future Biologic Research: The Rationale forNew PRP Nomenclature**. *PM R 7 (2015) 553-559*

•Pettine K, Murphy M, Suzuki R, Sand T. **Percutaneous Injection of Autologous Bone Marrow Concentrate Cells Significantly Reduces Lumbar Discogenic Pain Through 12 Months.** *Stem Cells 2015; 33:146-156*

•Foster, TE, Puskas, BL, Mandelbaum, BR, Gerhardt MB, Rodeo SA. **Platelet-rich plasma: from basic science to clinical applications.***Am. J. Sports Med. 37, 2259–2272 (2009).*

•Gosens T, Peerbooms JC, van Laar W, den Oudsten BL. **Ongoing positive effect of platelet-rich plasma versus corticosteroidinjection in lateral epicondylitis: a double-blind randomized controlled trial with 2-year follow-up.***Am. J. Sports Med. 39(6),1200–1208 (2011).*

•Mishra A, Woodall J Jr, Vieira A. T**reatment of tendon and muscle using platelet-rich plasma.***Clin. Sports Med. 28(1), 113–125 (2009).*

•de Vos RJ, Weir A, van Schie HTM et al. **Platelet-rich plasma injection for chronic achilles tendinopathy: a randomized controlled trial.***JAMA 303(2), 144–149 (2010).*

•Nguyen RT, Borg-Stein J, McInnis K. **Applications of platelet-rich plasma in musculoskeletal and sports medicine: an evidence-based approach.** *PM R. 3(3), 226–250 (2011)*

•Giusti I, Rughetti A, D'Ascenzo S et al. **Identification of an optimal concentration of platelet gel for promoting angiogenesis in human endothelial cells.***Transfusion 49(4), 771–778 (2009).*

•Lisa A. Fortier, Hollis G. Potter, Ellen J. Rickey, Lauren V. Schnabel, Li Foong Foo, Leroy R. Chong, Tracy Stokol, Jon Cheetham and Alan J. Nixon**Concentrated Bone Marrow Aspirate Improves Full-Thickness Cartilage Repair Compared with Microfracture in the Equine Model** *J Bone Joint Surg Am. 2010;92:1927-1937. doi:10.2106/JBJS.I.01284*

•Kenneth Mautner, Gerard Malanga & Ricardo Colberg **Optimization of ingredients, procedures and rehabilitation for platelet-rich plasma injections for chronic tendinopathy** *10.2217/PMT.11.56 © 2011 Future Medicine Ltd Pain Manage. (2011) 1(6), 523–532 ISSN 1758-1869*

•Donna D. Alderman, DO, Robert W. Alexander, MD, DMD, FICS, Gerald R. Harris, DO, Patrick C. Astourian, MS, PA-C S**tem Cell Prolotherapy in Regenerative Medicine Background, Theory and Protocols** *JOURNAL of PROLOTHERAPY | VOLUME 3, ISSUE 3 | AUGUST 2011*

•Kevin S. Sadati, DO; Anthony C. Corrado, DO; Robert W. Alexander, MD, DMD **Platelet-Rich Plasma (PRP) Utilized To Promote Greater Graft Volume Retention in Autologous Fat Grafting***The American Journal of Cosmetic Surgery Vol. 23, No. 4, 2006*

•Julien Ben Freitag,1 Adele Barnard **CASE REPORT To evaluate the effect of combining photo-activation therapy with platelet-rich plasma injections for the novel treatment of osteoarthritis** *BMJ Case Rep 2013. doi:10.1136/bcr-2012-007463*

•Feng Lin, Steven F Josephs, Doru T Alexandrescu, Famela Ramos, Vladimir Bogin, Vincent Gammill, Constantin A Dasanu, Rosalia De Necochea-Campion, Amit N Patel, Ewa Carrier, David R Koos **Lasers, stem cells, and COPD** *Journal of Translational Medicine 2010, 8:16*

•Hernigou, et al, **"Percutaneous Autologous Bone-Marrow Grafting for Nonunions: Influence of the Number and Concentration of Progenitor Cells"**, *Journal of Bone and Joint Surgery, 87:1430-1437, 2005*

•Yaokai Gan a, b, Kerong Dai, Pu Zhang, Tingting Tang, Zhenan Zhu, Jianxi Lu a **The clinical use of enriched bone marrow stem cells combined with porous beta-tricalcium phosphate in posterior spinal fusion Biomaterials** *29 (2008) 3973–3982*

•Witko-Sarsat, V; Rieu P, Descamps-Latscha B, Lesavre P, Halbwachs-Mecarelli L (2000). **"Neutrophils: molecules, functions and pathophysiological aspects".***Lab Invest 80 (5): 617–53. doi:10.1038/labinvest.3780067. PMID 10830774.*

•Klebano , SJ; Clark, RA (1978). **The Neutrophil: Function and Clinical Disorders.***Elsevier/North-Holland Amsterdam. ISBN 0444800204.*

•Nathan, C (Mar 2006). **"Neutrophils and immunity: challenges and opportunities".** *Nature Reviews Immunology 6 (March): 173–82. doi:10.1038/nri1785. ISSN 1474-1733.PMID 16498448*

•Ear T, McDonald PP (2008). **"Cytokine generation, promoter activation, and oxidant-independent NF-kappaB activation in a transfectable human neutrophilic cellular model".***BMC Immunol. 9: 14. doi:10.1186/1471-2172-9-14. PMC 2322942. PMID 18405381*

Ongoing Performance Analysis Report Campaign

EmCyte stands behind the performance of its concentrating systems. It is the only company that offers free independently reviewed onsite product validation . A representative will assist in the preparation of test a sample at your facility using any EmCyte 2015 PRP or BMC product. Then EmCyte will pay to have it independently validated at a reputable laboratory. This provides the physician with the documentation that confirms and validates the product performance, assuring that the clinical demand is met according to the standards of the physician.

Avoid Biased Comparison Studies by Competitors

Avoid biased white papers and comparison performance data provided by competitors. It is simply better to rely on your own data. EmCyte understands that your motivation is not to sell products but rather to provide the best care to your patients. It is EmCyte's mission to help physicians achieve this goal. Onsite performance validation is the simple and unadulterated truth about real-time product performance at your facility.

Tests Performed

EmCyte provides the sample preparation kit with simple instructions. The following test results are provided free of charge for the respective sample types

Tests Performed	Platelet Rich Plasma Sample	Bone Marrow Concentrate Sample
	Platelet Count	Platelet Count
	WBC	Total Nucleated cell count
	Granulocytes	Hematopoietic stem cell count (CD34+)

Additional tests can be performed at nominal fees.

Performance Results

The performance results will be posted online, viewable to the public. So get up-to-date validation data from end users like yourself or add to the database by providing information of your own.

Schedule Validation

Simply call 239-481-7725 to schedule product validation. The product validation program is only available to customers located within the US.

Case Study

Bone marrow aspirate concentrates produced with the EmCyte GSBMA-544E system and the Harvest/Terumo BMAC2 system

Prepared for:
Patrick Pennie
Chairman & CEO
EmCyte Corporation

Sample analysis by:
Biosciences Research Associates
Cambridge, MA

Prepared by: R J Mandle

Robert J. Mandle, PhD
Laboratory Director

Date: 10 June 2015

Case Study: Bone marrow aspirate concentrates produced with the EmCyte GSBMA-544E system and the Harvest/Terumo BMAC2 system

Data of processing: 14 May 2015 Date of Testing: 15 May 2015

Objective: to compare bone marrow concentrates produced with two commercial systems, the EmCyte GSBMA-544E and the Harvest/Terumo BMAC2.

Approximately 120mL of bone marrow aspirate was drawn from each of two donors prior to surgical procedure. For each donor, 50 mL of aspirate plus 5mL of Na Heparin (1000 U/mL) and 5mL of NaCitrate was processed with the EmCyte system according to manufacturer's instructions for use. For each donor, 60mL of aspirate was added to the Harvest MarrowPREP Filter Bag along with 8mL of Anticoagulant Citrate Dextrose formula A and processed with the Harvest/Terumo SmartPREP 2 system according to manufacturer's instructions for use.
One mL samples of bone marrow concentrates aspirates were sent to the Testing Laboratory for the following analysis:

Total Nucleated Cell Counts (TNC): determined with a Coulter AcT Diff2 hematology analyzer.
Platelet Counts (PLT): determined with the Coulter analyzer
CD34 Pos. Cells: CD34 Positive cells were measured using an Accuri C6 flow cytometer.

Results:

Donor 1: Hematology parameters for marrow concentrates

Platform	TNC x 10^6/mL	PLT x 10^6/mL	Htc %	CD34 Pos./mL	Volume(mL)
EmCyte	75	767	56	286,697	8
Harvest	60	576	47	209,871	7

Donor 2: Hematology parameters for marrow concentrates

Platform	TNC x 10^6/mL	PLT x 10^6/mL	Htc %	CD34 Pos./mL	Volume(mL)
EmCyte	125	548	36	956,597	8
Harvest	132	406	39	726,264	7

Number of cells delivered

Platform	Nucleated Cells	Platelets	CD34 Positive Cells
EmCyte Donor 1	599 x 10^6	6,136 x 10^6	2,293,576
Harvest Donor 1	423 x 10^6	4,032 x 10^6	1,469,097
EmCyte Donor 2	998 x 10^6	4,384 x 10^6	7,652,776
Harvest Donor 2	925 x 10^6	2,842 x 10^6	5,083,848

Report 515

Research Study

Comparisons of and EmCyte PurePRP® II 2015, Harvest/Terumo APC60,/Clear PRP, and Arthrex Angel PRP Products.

Principle Investigator
Robert Mandle, PhD
Biosciences Research Associates
Cambridge, MA

Prepared for:
Patrick Pennie
Chairman & CEO
EmCyte Corporation

Prepared by: R J Mandle **Date:** 04, June 2015
Robert J. Mandle, PhD
Laboratory Director

Approved by: Patrick Pennie **Date:** June 4, 2015
Patrick Pennie
Chairman & CEO

Executive Summary

There is market pressure for a PRP product with reduced red blood cell contamination, especially in aesthetic and cosmetic procedures and in sports medicine to reduce potential complications in joint treatment. Reduced granulocyte levels may also be desirable. While granulocytes are helpful in wound debridement and preventing infection, high granulocyte levels may be inflammatory.

This study evaluated the PRP products from three platforms: PurePRP® II 2015 (EmCyte Corporation), Clear PRP (Harvest/Terumo bct) and Angel system (Arthrex). PurePRP® II 2015 and Clear PRP are red cell reduction methods while Angel has a programmable setting to control RBC level in the product. The study is a paired sample design, with each donor tested on all three platforms.

Results: The PurePRP® II 2015 device produced a reduced Red Blood Cells PRP product with, on average, to 100 x 10^6 RCB/ml and an average hematocrit of 1.1%. Only 2% of the granulocytes were retained, a reduction of 84% from the baseline whole blood values. The PurePRP® II 2015 products had higher cell concentration and calculated cell metrics including platelet yield and concentration, RBC, mononuclear and granulocyte cell recoveries than either the Clear PRP or Angel products. The average concentrations for all growth factors measured were higher in PurePRP® II 2015 products compared to Clear PRP and Angel products; however, The difference between TGF-β and VEGF was not significantly different between the PurePRP® II 2015 and Clear PRP products.
Both red cell reduction platforms had similar processing times (24 min) and the number of aseptic entries (6).
Only the PurePRP® II 2015 platform was capable of providing a PRP product with an optimum platelet concentration of > 1 x 10^6 platelets per µL (Giusti I, Rughetti A, D'Ascenzo S, et al. Identification of an optimal concentration of platelet gel for promoting angiogenesis in human endothelial cells. Transfusion 2009;49:771-8. Marx R, Garg A. Dental and craniofacial applications of platelet rich plasma. Carol Stream: Quintessence Publishing Co, Inc.; 2005)

Table of Contents

1. Introduction

The objective of this study was to evaluate parameters associated with the platelet concentrates (PRP) produced by three commercially successful PRP systems. The Emcyte PurePRP® II 2015 system, Harvest/Terumo Clear PRP device, and the Arthrex Angel system were evaluated with paired samples from seven normal donors.

2. Study Design

This was a single center study conducted by BioSciences Research Associates, Inc. (BSR). BSR provides custom contract research and laboratory services for product development, medical device testing and clinical trials support to Pharmaceutical and Biotechnology companies. All studies were conducted within BSR's cGXP Quality Systems. BSR has extensive experience with development and evaluation of platelet concentration devices and product evaluation, including support for FDA CBER and CDRH filings.

Up to 160 ml of human whole blood was obtained from each of 7 donors following informed consent. The informed consent forms, as well as blood collection protocols were approved by the New England Institutional Review Board Protocol number 04-144 "The Collection of Whole Blood for Research Purposes". Donors met the requirements of the American Association of Blood Banks (AABB) and the FDA CBER. There were no specific exclusion specifications, other that the donor be healthy. There was no selection for age, sex or ethnicity. Donors were referenced only by assigned code numbers. Blood was drawn into a 60cc syringe that had been preloaded with anticoagulant according to Table I. An ETDA tube was drawn for baseline comparison.

Table I. Anticoagulant Protocol

Platform	Anticoagulant	Blood
Emcyte PurePRP® II 2015	10 ml Na Citrate	50 ml
Harvest Clear PRP	6 ml ACD-A	54 ml
Arthrex Angel	8 ml ACD-A	52 ml

PurePRP® II 2015 product was produced from 60 ml of Na Citrate anticoagulated blood samples according to manufacturer's instructions for use with a modified "Protocol A": Following the first centrifugation, the platelet plasma layer was withdrawn until the aspiration tubing filled with RBC. The recovered platelet plasma was transferred to the concentration disposable along with 5ml of ACD-A. After centrifugation, all but 7 ml of the plasma was removed, and approximately 7 ml of PRP recovered. For the Harvest/Terumo APC60 devices, 60 ml ACD-Blood samples were processed according to manufacturer's instructions for use to produce approximately 10 ml of platelet concentrate, which was further processed with the LP-10 Clear PRP Procedure Kit, to produce approximately 7 ml of product. The reduced red cell PRP was harvested without disturbing the RBC/Buffy interface. The Angel system processed 60 ml of anticoagulated blood with a Hct setting of 7% and the product adjusted with PPP to a volume of 7 ml.

3. Study Objectives and Outcome Measures

The analytical parameters chosen to identify differences or similarities among the three platelet concentrating platforms were:

1. Platelet Concentration Factor

Complete blood counts (CBCs) were performed using a 3-part differential hematology analyzer to quantify the platelets contained within the start sample and platelet concentrates. The platelet concentration factor, which is the ratio of the concentration of platelets in the platelet concentrate product to the concentration of platelets in the start sample (adjusted for dilution with anticoagulant), was determined for each device. CBC was tested according to BSR TM-076 Coulter Ac-T diff 2 Hematology Analyzer.

2. Platelet Yield

CBC were performed using a hematology analyzer to quantify the platelets contained within start sample and platelet concentrates. The platelet yield, which is the ratio of the number of platelets in the platelet concentrate product to the number of platelets in the start sample, was determined for each device.

3. pH

Sample pH was measured in platelet concentrates. The testing was conducted on a blood gas analyzer according to SOP: TM-018 Blood pH.

4. Leukocyte, Erythrocyte and Platelet Counts

CBC was performed using a hematology analyzer for start sample and platelet concentrates. The Leukocyte, Platelet counts, Erythrocyte (RBC), and calculated hematocrit (hct) were recorded for each sample. CBC was tested according to BSR TM- 076 Coulter Ac-T diff 2 Hematology Analyzer.

3.5 *Growth Factors*

PRP samples were treated with bovine thrombin reconstituted in 10% $CaCl_2$. The serum is collected by centrifugation. Growth factors (PDGF AB, TGF-β, SDF-1α, and VEGF) were measured by ELISA (R&D Systems)

5. Statistical Methods

Data tables and descriptive statistics are shown for each parameter.

5.1 Platelet Concentration Factor

The platelet concentration factor (PCF) was derived as the ratio of the platelet count in the platelet concentrate (PC) to the platelet count in baseline sample (adjusted for dilution with anticoagulant) (BL) :

PCF = PC/BL

Results are summarized in tables showing observations by donor, mean platelet concentration factor and standard deviation for each device.

2. Platelet Yield

The platelet yield (PY) was derived as the ratio of the platelet count in the platelet concentrate (PC) times the volume of the platelet concentrate (VPC) to the platelet count in the baseline sample (adjusted for dilution with anticoagulant) (BL) times the volume of the sample processed (VBL):

$$PY = (PC*VPC) / (BL*VBL)$$

Results are summarized in tables showing observations per donor, mean platelet yield and standard deviation for each device.
A two tailed, paired t-Test was used to compare the mean PLT yield for Clear PRP and PurePRP® II 2015.

3. pH of Platelet Concentrate

Product pH observations, per donor, from each device are shown in tables along with means and standard deviations.

4. Leukocyte, Erythrocyte and Platelet Counts

Results are summarized in tables showing data by donor, with calculated mean and standard deviation. A two tailed, paired t-Test was used to compare the for Clear PRP and PurePRP® II 2015 products mean yields for Mononuclear Cells, Granulocytes, and RBC.

5. Growth Factors

Results are summarized in tables showing data by donor, with calculated mean and standard deviation. A two tailed, paired t-Test was used to compare the Clear PRP and PurePRP® II 2015 products means.

6. List of Tables: Data Analysis

1. Hematology data: EDTA Baseline anticoagulated blood
2. Hematology data: Hematology data: EmCyte PurePRP® II 2015
3. Hematology data: Harvest Clear PRP
4. Hematology data: Arthrex Angel
5. Platelet Yield (% recovery)
6. Mononuclear Cell Yield (%recovery)
7. Granulocyte Yield (% recovery)
8. Platelet Concentration (times baseline)
9. pH
10. Platelet Activation
11. Platelet Function
12. Growth Factors: PDGF AB
13. Growth Factors: TGF-β
14. Growth Factors: VEGF
15. Growth Factors: SDF-1α

7. List of Summary Tables

1. Process Time and Number of Aseptic Entries
2. Hematology of Products
3. Cell Yield

7.4 Growth Factors

8. Conclusions.

Two red cell reduction platforms, PurePRP® II 2015 (EmCyte) and Clear PRP (Harvest/ Terumo) were compared along with the Angel (Arthrex) system, in a paired sample design. Mean platelet recoveries were 81% for PurePRP® II 2015, 62% for the Clear PRP platform and 49% for the Angel system. The average platelet concentration factor was 7.0 times baseline in an average product volume of 6.9 ml for PurePRP® II 2015, 5.0 times baseline in an average volume of 7.4 ml for the Clear PRP product and 4.1 times baseline in an average volume of 7.0 ml for Angel. The PurePRP® II 2015 had a mean hematocrit of 1.1% compared with 0.1% for the Clear PRP product and 2.8% for Angel. The mean recovery of mononuclear cells was 70% with the PurePRP® II 2015 system and 7% and 33% for Clear PRP and Angel platform, respectively. The granulocyte recoveries were low in all three platforms: 2%, 0% and 3% for PurePRP® II 2015, Clear PRP and Angel, respectively. The mean pH of Platelet Concentrates from the PurePRP® II 2015, Clear PRP and Angel products were 6.9, 7.0 and 7.1. The average concentrations for all growth factors measured were higher in PurePRP® II 2015 products compared to Clear PRP and Angel products. Samples collected in Na Citrate vs. ACD-A prior to processing in the PurePRP® II 2015 device showed slightly elevated platelet activation by p-Selecting staining, however the differences observed were not clinically significant.

Table 6.1. Hematology data: EDTA Baseline anticoagulated blood

Sample Number	WBC x 10^6/ml	MC x 10^6/ml	Granulocytes x 10^6/ml	PLT x 10^6/ml	HCT %	RBC x 10^9/ml
603	5.6	1.4	4.2	192	38.1	12.40
604	7.5	2.1	5.3	210	37.4	3.98
605	4.5	1.4	3.0	170	37.5	4.26
606	8.0	1.7	6.3	240	37.6	3.95
607	11.3	2.9	8.5	335	35.8	3.98
608	7.2	1.8	5.4	261	35.8	4.25
609	10.4	3.0	7.4	142	36.1	4.19
MEAN	**7.8**	**2.0**	**5.7**	**221**	**36.9**	**5.3**
STDEV	**2.4**	**0.7**	**1.9**	**64**	**1.0**	**3.1**

Table 6.2. Hematology data: EmCyte PurePRP® II 2015

Sample Number	WBC x 10^6/ml	MC x 10^6/ml	Granulocytes x 10^6/ml	PLT x 10^6/ml	HCT %	RBC x 10^9/ml
603	7.1	6.6	0.5	1136	0.8	0.08
604	12.5	11.6	0.8	1202	1.1	0.14
605	13.7	12.4	1.3	1072	1.9	0.21
606	7.7	6.9	0.8	1524	0.9	0.10
607	15.3	14.1	1.2	1866	1.1	0.11
608	10.1	9.5	0.5	1494	1.2	0.14
609	8.5	7.3	1.3	760	0.8	0.10
MEAN	**10.7**	**9.8**	**0.9**	**1293**	**1.1**	**0.1**
STDEV	**3.2**	**3.0**	**0.4**	**362**	**0.4**	**0.0**

Table 6.3. Hematology data: Harvest Clear PRP

Sample Number	WBC x 10^6/ml	MC x 10^6/ml	Granulocytes x 10^6/ml	PLT x 10^6/ml	HCT %	RBC x 10^9/ml
603	3.0	2.7	0.3	741	0.3	0.08
604	0.8	0	0	914	0	0.02
605	0.7	0	0	810	0	0.02
606	0.2	0	0	1170	0	0.10
607	1.7	1.6	0	1548	0	0.02
608	0.2	0	0	1158	0	0.01
609	3.0	2.6	0.3	682	0.2	0.04
MEAN	**1.4**	**1.0**	**0.1**	**1003**	**0.1**	**0.0**
STDEV	**1.2**	**1.3**	**0.1**	**307**	**0.1**	**0.0**

Table 6.4. Hematology data: Arthrex Angel

Sample Number	WBC x 10^6/ml	MC x 10^6/ml	Granulocytes x 10^6/ml	PLT x 10^6/ml	HCT %	RBC x 10^9/ml
603	4.0	3.2	0.8	673	2.7	0.29
604	5	4.5	0.6	755	3.0	0.33
605	5.9	3.4	2.5	691	2.8	0.32
606	7.2	6.4	0.8	964	2.8	0.31
607	7.8	7.4	0.4	1304	2.3	0.28
608	4.6	4.4	0.2	942	2.6	0.33
609	7.0	4.2	2.8	682	3.2	0.38
MEAN	**5.9**	**4.8**	**1.2**	**859**	**2.8**	**0.3**
STDEV	**1.4**	**1.6**	**1.0**	**231**	**0.3**	**0.0**

Table 6.5. Platelet Yield (% recovery)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	82%	57%	47%
604	86%	60%	47%
605	82%	64%	55%
606	83%	68%	54%
607	67%	56%	56%
608	83%	62%	48%
609	82%	67%	34%
MEAN	**81%**	**62%**	**49%**
STDEV	**6%**	**5%**	**8%**

Table 6.6. Mononuclear Cell Yield (% recovery)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	65%	29%	31%
604	83%	0%	28%
605	116%	0%	33%
606	53%	0%	50%
607	59%	7%	37%
608	76%	0%	33%
609	37%	12%	19%
MEAN	**70%**	**7%**	**33%**
STDEV	**25%**	**11%**	**10%**

Table 6.7. Granulocyte Yield (% recovery)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	2%	1%	3%
604	2%	0%	1%
605	6%	0%	11%
606	2%	0%	2%
607	2%	0%	1%
608	1%	0%	0%
609	3%	1%	5%
MEAN	**2%**	**0%**	**3%**
STDEV	**1%**	**0%**	**4%**

Table 6.8. Platelet Concentration (times baseline)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	7.1	4.3	4.0
604	6.9	4.8	4.1
605	7.6	5.3	4.7
606	7.7	5.4	4.6
607	6.7	5.1	4.5
608	6.9	4.9	4.1
609	6.4	5.3	2.9
MEAN	**7.0**	**5.0**	**4.1**
STDEV	**0.4**	**0.4**	**0.6**

Table 6.9. pH

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	6.8	7.0	7.1
604	6.8	6.9	7.2
605	6.7	7.0	7.1
606	6.9	7.0	7.2
607	7.0	7.1	7.1
608	6.9	7.1	7.2
609	6.9	7.1	7.2
MEAN	**6.9**	**7.0**	**7.1**
STDEV	**0.1**	**0.1**	**0.0**

Table 6.10 Platelet Activation:

Sample Number	Na Citrate	ACD-A
610	1.8%	0.8%
611	4.4%	1.7%

Two Blood samples from each of 2 donors were drawn. One blood sample was anticoagulated with 13% Na Citrate. One sample was anticoagulated with 10% ACD-A. Resting p-Selectin values (% of positive PLT) reflect the degree of platelet activation after processing in the PurePRP® II 2015 device. Two ml of ACD-A was added to the concentration device irrespective of anticoagulant. However the differences observed were not clinically significant.

Table 6.11 Platelet Function

Sample Number	Na Citrate	ACD-A
610	95%	96%
611	92%	94%

Two Blood samples from each of 2 donors were drawn. One blood sample was anticoagulated with 13% Na Citrate. One sample was anticoagulated with 10% ACD-A. P-Selectin values (% of positive PLT) following platelet stimulation with ADP reflect the degree of platelet response to agonist after processing in the PurePRP® II 2015 device. Two ml of ACD-A was added to the concentration device irrespective of anticoagulant. However the differences observed were not clinically significant.

Table 6.12. Growth Factor: PDGF(pg/ml PLT Releaseate)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	53,474	34,669	35,807
604	65,312	45,871	39,289
605	50,308	32,391	26,270
606	76,886	59,154	49,693
607	87,233	64,260	53,658
608	82,483	60,745	51,745
609	61,843	50,721	25,993
MEAN	**68,194**	**55,860**	**39,714**
STDEV	**12,398**	**18,013**	**11,248**

Table 6.13. Growth Factor: TGF-β (pg/ml PLT Releaseate)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	66,679	40,311	44,807
604	79,517	52,584	43,292
605	ND	38,759	29,661
606	56,745	78,611	55,254
607	124,924	69,838	57,448
608	77,057	51,209	45,886
609	60,490	42,608	22,274
MEAN	**75,546**	**58,505**	**41,886**
STDEV	**21,491**	**18,048**	**12,794**

Table 6.14. Growth Factor: VEGF(pg/ml PLT Releaseate)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	609	386	374
604	210	151	119
605	633	504	300
606	1,725	1,408	808
607	918	702	562
608	251	313	183
609	2,529	2,186	861
MEAN	**813**	**689**	**387**
STDEV	**811**	**679**	**293**

Table 6.15. Growth Factor: SDF-1α (pg/ml PLT Releaseate)

Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	3,708	2,941	3,184
604	3,824	3,590	3,380
605	3,480	3,204	2,475
606	4,127	4,162	3,981
607	3,778	3,367	2,862
608	3,289	2,528	2,207
609	2,633	2,354	2,027
MEAN	**3,418**	**3,113**	**2,771**
STDEV	**537**	**610**	**661**

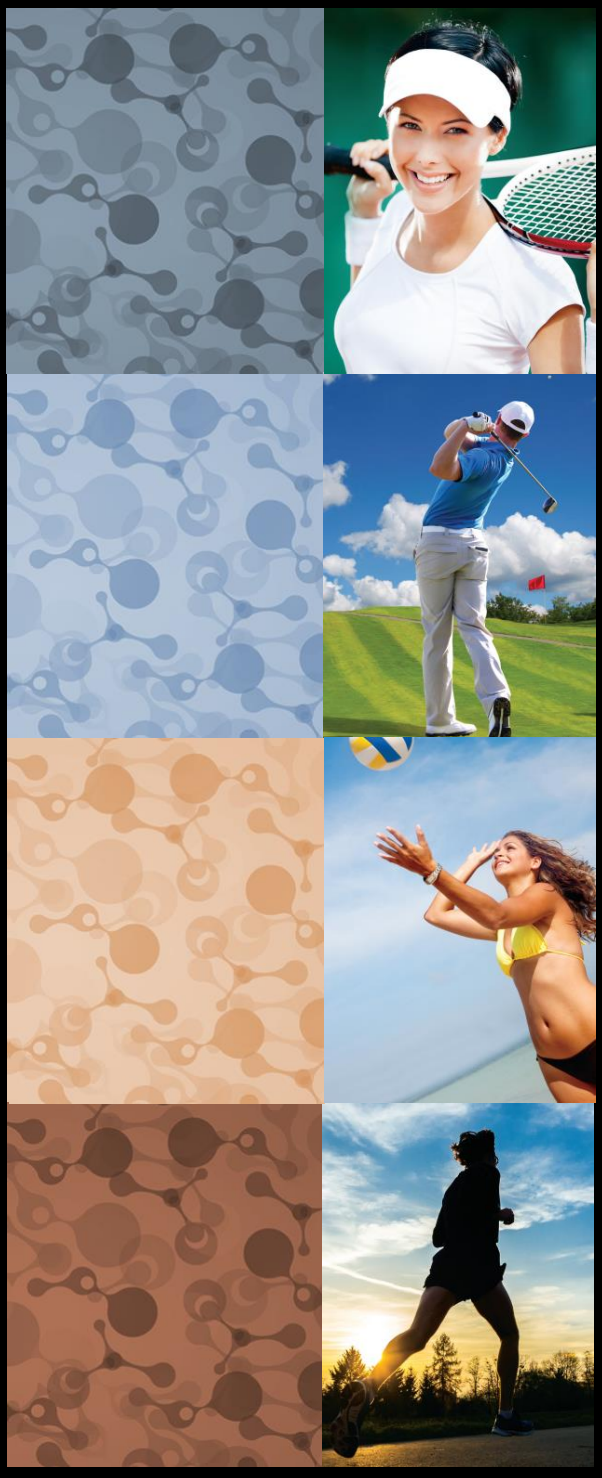
Table 7.1. Process Time and Number of Aseptic Entries

	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
Nominal Centrifuge Time 1st Spin	1.5 min.	4 min.	18 min.
Nominal Centrifuge Time 2nd Spin	5 min.	10 min.	-
BSR Overall Process Time	19 min.	24 min.	23 min.
Aseptic Entries	6	6	3

ACCELLERATED BIOLOGICS

DELIVERING THE TOTAL BIOLOGIC™

SPRING 2018 CATALOG



PLATELET RICH PLASMA

BONE MARROW ASPIRATE

ADIPOSE

AMNIOTIC TISSUE

A2M AND FIBRINOGEN

TOPICAL GEAR

VISIONSCOPE ARTHROSCOPY

SUPPORT

TRAINING

RESEARCH

PATIENT ACQUISITION

1-800-367-0844 | WWW.ACCELLERATEDBIOLOGICS.COM
304 TEQUESTA DR. SUITE 400, TEQUESTA, FL 33469

AccBioCat01.15.18.12