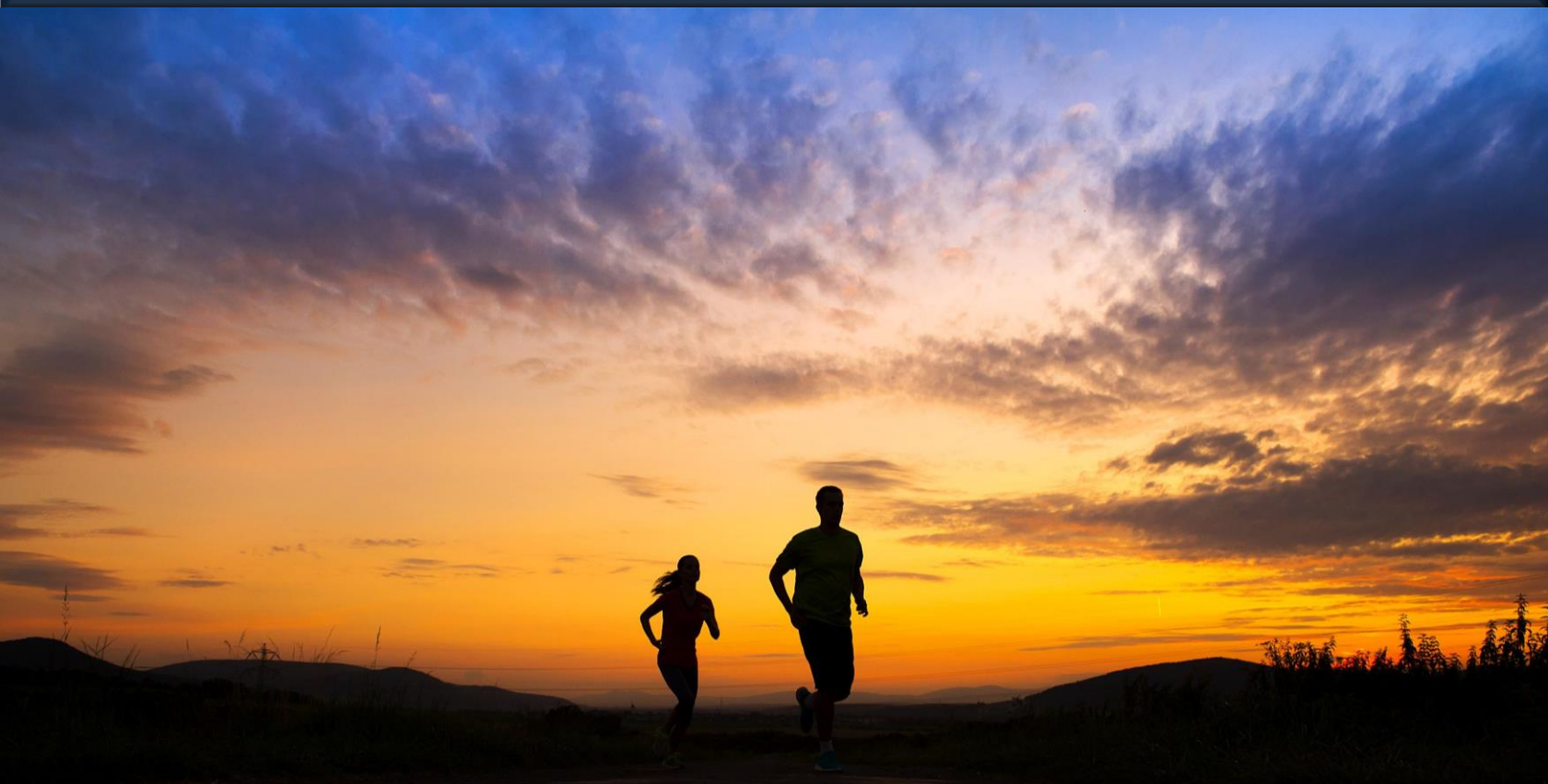
ACCELLERATED BIOLOGICS

5th Year Anniversary
CATALOG **2017**



TRUSTED to deliver the TOTAL BIOLOGIC

ACCELLERATED BIOLOGICS

2017 Catalog

1-800-367-0844
WWW.ACCELLERATEDBIOLOGICS.COM
304 Tequesta Dr. Suite 400 Tequesta, FL 33469

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START HEALING AND GET BACK TO LIVING





TESTIMONIALS

"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'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*

"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**

"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. " -**Dr. Jon Swift,** *Desert Orthopedics, Bend, OR*

"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**

DELIVERING THE TOTAL BIOLOGIC

ABOUT:

ACCELLERATED BIOLOGICS

Welcome to Ac**CELL**erated Biologics. We are uniquely positioned within the field of biologics. We are an independent medical distribution company focused on consulting and providing the physician, their staff and community with quality information and products related to Platelet Rich Plasma, Stem Cells, Bone Marrow Concentrate and other products that support the use of biologics.

Our customers receive our ongoing commitment of supplying them with the most up to date information, technologies and equipment. We do this because we firmly believe that not all PRP is created equal. As a result, 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.

We could choose any PRP system to distribute. However basic engineering designs with some systems simply cannot match platelet yields. Some cannot adjust for hematocrit or leukocyte percentages as other systems can and do consistently. Some automated systems have design flaws which 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.

In addition many companies do not offer independent laboratory analysis of their final product. That is an important factor into why all PRP and stem cell products are not created equal even though the manufacturers make statistical claims showing equal numbers.

Fortunately, Ac**CELL**erated Biologics saw this need for a reliable and trustworthy partner for physicians that 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.

Sincerely,

Steve

Steve Whyte
CEO Ac**CELL**erated Biologics

PRP:

PLATELET RICH PLASMA (PRP)

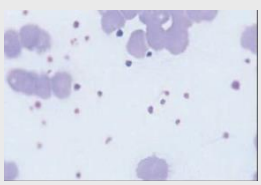
Platelet Rich Plasma (PRP) is concentrated from your own blood which contains healing factors, such as white blood cells and bioactive proteins, called growth factors and stem cell markers. These cells are vital for tissue regeneration and repair. Platelets, once thought of being responsible for only 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.

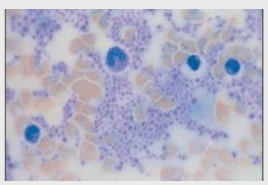
Patients can expect to see significant improvement in symptoms over the course of healing time. This procedure may eliminate the need for further invasive treatments, such as surgery or prolonged use of medications. While other treatments such as corticosteroid injections may provide temporary relief 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

PRP:

ACCELLERATED BIOLOGICS' Preferred Biologic System:

Genesis CS Component Concentrating System by EmCyte

TOTAL BIOLOGIC CAPABLE WITH ACTIVE DISPLACEMENT DISC TECHNOLOGY (ADDT)

Direct access to the platelet buffycoat layer/bone marrow aspirate/A2M concentrate/Adipose graft in a closed system environment. This is done in minimal sterile barrier entries designed to reduce handling and improve sterility maintenance.

FULL SWINGING BUCKET CENTRIFUGATION

Optimizes separation & enhances the buffycoat concentrate. The Executive Series Centrifuge II provides full vertical to horizontal separation in a smooth and unhindered motion. There is no platelet slip phenomenon.

SOFT BRAKING TECHNOLOGY

With soft braking technology the acceleration and deceleration are both controlled to prevent the buffycoat from re-suspending into the plasma after separation.

CONSISTENT OUTCOME REGARDLESS OF HEMATOCRIT

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.

CLOSED SYSTEM PROCESSING

GenesisCS is a closed system throughout. Trapping blood within a watertight sealed environment maximizes the safety of the contents and ensures sterility throughout processing.

PRP:

PRP Concentrating Systems:

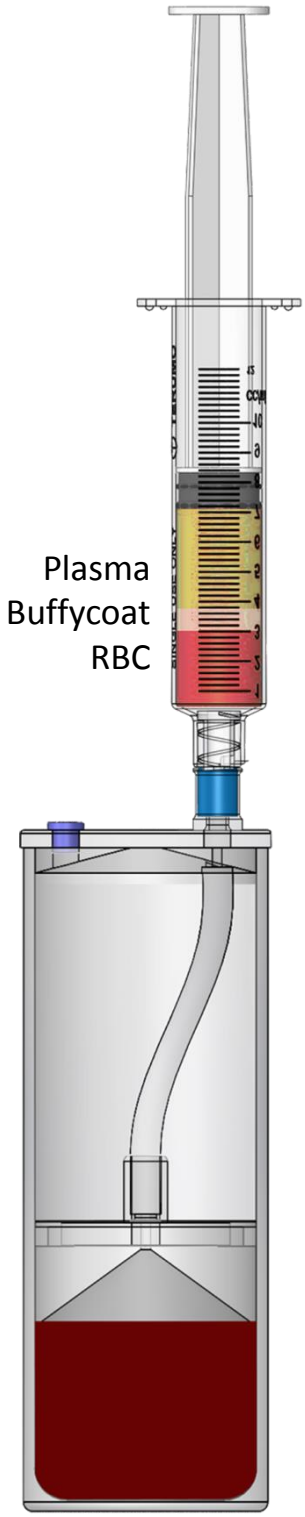
GS30 Absolute PRP - Platelet Concentrating system 30mL
GS60 Absolute PRP- Platelet Concentrating System 60mL
GS120 Absolute PRP- Platelet Concentrating System 120mL

Absolute kits offer a **5 minute spin**.
Quickest standard spin time in the market space.

The Absolute/544E Concentrating Systems

The GenesisCS Platelet and Bone Marrow Concentrating Systems has been greatly improved. They are now the fastest and most efficient 6omL concentrating systems available. Prepare 7mL of PRP or BMC, 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 544E Concentrating System is the new 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.



Pure PRP®:

The NEW Ac**CELL**erated Biologics 60mL 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].

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

AB60-Pure

GS120-Pure II

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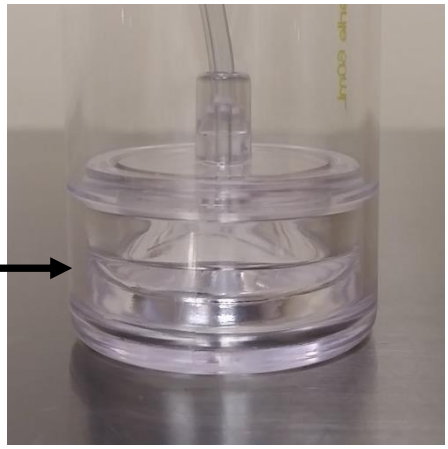
AB60 Pure:

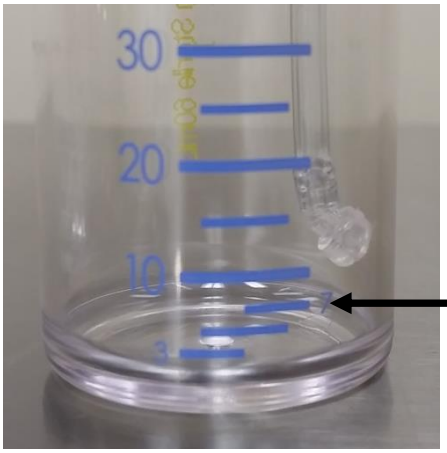
Vertical Side Port with Self Sealing Swabbable Valve Port

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



Rounded Interior Base

Improves buffycoat re-suspension

16X Platelet Concentrations in 7mL
Over 16 billion Platelets Delivered in 7mL
No Red Blood Cells

The most powerful tabletop system available

A therapeutic treatment with resounding capabilities

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Pure PRP®:

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®:

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%

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FC120-Pure:

A2M and Fibrinogen Protein Concentrator

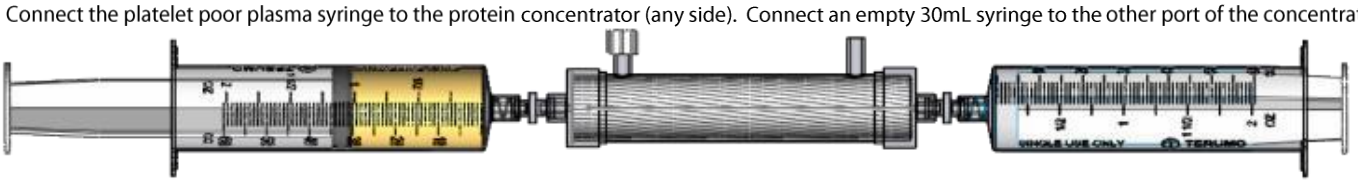
ACCELLERATED BIOLOGICS is proud to offer the FC120-Pure Concentrating System. This kit is designed to provide at least 6x concentration of A2M and Fibrinogen Proteins.

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.

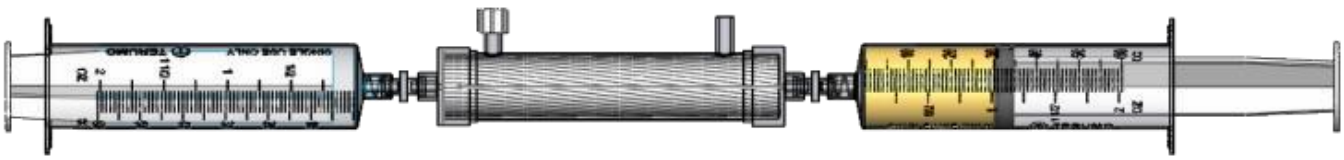
A2M and Fibrinogen Concentrating Systems:

FC120-Pure - A2M and Fibrinogen Concentrating system 120mL

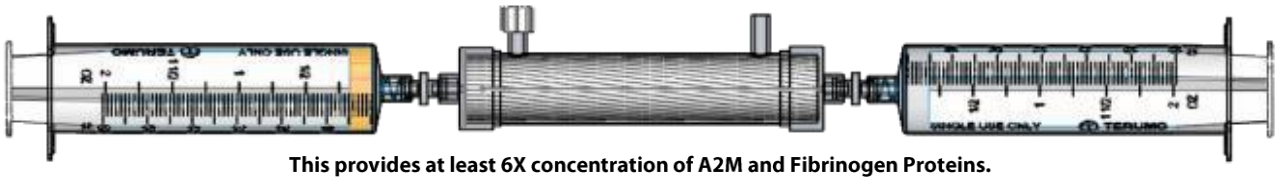
Connect the platelet poor plasma syringe to the protein concentrator (any side). Connect an empty 30mL syringe to the other port of the concentrator.



Transfer the plasma back and forth from syringe to syringe



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



This provides at least 6X concentration of A2M and Fibrinogen Proteins.

Platelet Sample Analysis:

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

Platelet Sample Validation:

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.

PureBMC®:

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.

Table 1. BMC Total Nucleated Cell (TNC) Concentration Factor & Total Cell Count

System	BMA Baseline (TNC x 10^6/mL)	BMC (TNC x 10^6/mL)	Concentration Factor	BMC Total Cell Count (TNC/BMC Sample)
BMC	17	70.4	4.1	457,600,000
PureBMC®	17	155	9.1	1,162,500,000

Table 2. BMC Hematopoietic Stem/Progenitor Cells (HSC) Concentration Factor & Total Cell Count

System	BMA Baseline (HSC/mL)	BMC (HSC/mL)	Concentration Factor	HSC Total Cell Count (HSC/BMC Sample)
BMC	92,332	342,844	3.7	2,228,486
PureBMC®	92,332	1,230,172	13.3	9,226,290

Table 3. BMC Platelet Concentration Factor & Total Cell Count

System	BMA Baseline (PLT x 10^6/mL)	BMC (PLT x 10^6/mL)	Concentration Factor	PLT Total Cell Count (PLT/BMC Sample)
BMC	96	326	3.4	2,119,000,000
PureBMC®	96	534	5.6	4,005,000,000

An Independent Review of EmCyte PureBMC® vs Standard BMC

Principle Investigator(s): Dr. Robert Mandle Ph.D.

BioSciences Research Associates, Inc

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PureBMC®:

PureBMC®

PureBMC®

PureBMC® also contain concentrating devices that have been upgraded to improve performance outcomes. Beyond the device upgrade, PureBMC® has upgraded the aspirating accessory consisting of a 3mL syringe, 3 way stopcock, and a 60mL syringe. This allows the end user to more accurately collect the cell concentrate after the first centrifugation.

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® (2015) 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

PureBMC® Sample Size: 7 mL
Total Nucleated Cell Concentrations: 9.1 X Baseline or Greater
Hematopoietic Stem/Progenitor Cells: 13.3 X Baseline or Greater
Platelet Concentrations: 5.6 X Baseline
Hemotocrit: Less than 15% on Average

Independently Reviewed at the Bioscience Research Associates Cambridge MA

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PureBMC®:

PureBMC® Concentrating Systems:

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

HCT < 15% on Average

Normal pH (7.5)

Low viscosity

The highest cell concentrations and volume of deliverable

Hematopoietic Stem Cells

Total Nucleated Cells

Mesenchymal Stem Cells

Platelets

PureBMC®

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

Ongoing Performance Analysis Report Campaign

See the Ongoing Performance Analysis Report Campaign, for PureBMC® at http://www.emcyte.com for the "always current" and up-to-date analysis of the performance of the PureBMC® system. This system was developed to provide objectivity and transparency in the clinical performance of the EmCyte systems. To be a participant in a sample submission, call 239-481-7725, or visit the website for more information.

The data provided in the Ongoing Performance Analysis Report Campaign is independently reviewed at a reputable laboratory.

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BMC:

BMC Concentrating Systems:

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

EmStyle:

ASC Rejuvenation:

- **ES35-ASC** - Concentrating System ASC 35mL
- **CANSUP** - Cannula Supplement Set

Equipment:

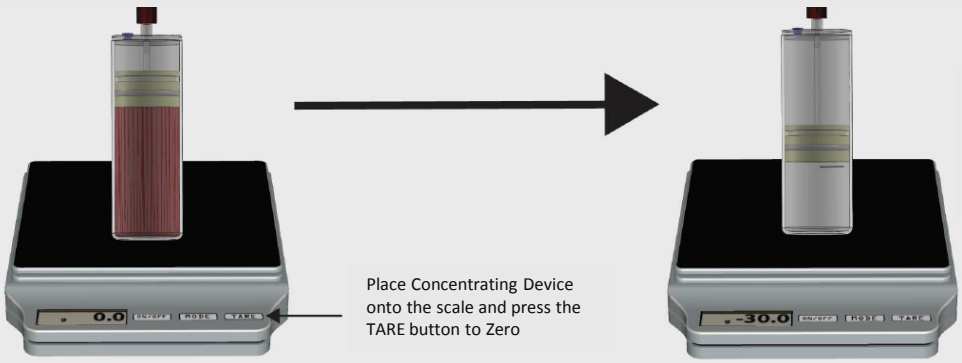
Executive Series Centrifuge II:

GS-022624340-ACB - AcCELLerated Biologics Executive Series Centrifuge II

Additional Equipment:

One Step Counterbalance with Tare Counterweight Scale

Eliminate the guess work and time spent counterbalancing Pure PRP® Concentrating Devices. With the new EmCyte Tare Counterweight Scale you are told exactly how much volume to add or remove from the counterbalance device, all in one easy step.



Place Concentrating Device onto the scale and press the TARE button to Zero

Place the counterbalance device onto the scale and get a digital read-out of exactly how much volume to add or remove for a perfect counterbalance.

For Example:

-30 g means add 30mL to balance

3 g means remove 3mL to balance

PRP and Stem Cell Workstation

Easily store, move, and use the EmCyte PRP and Stem Cell kits with this steel workstation cart. With pullout worktable. The cart is rated to hold over 300lbs and the rubber wheels and braking system ensure a quiet and reliable spin for all kits. The pullout work table is a perfect place to process each kit.

ADI LIGHT 2:

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 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.

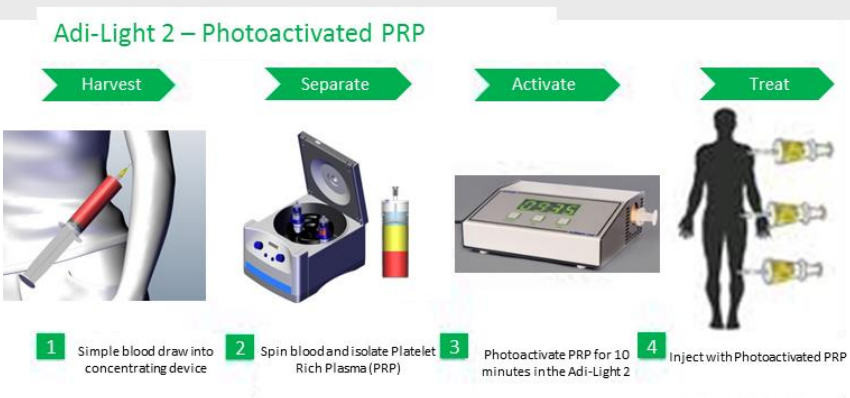
AdiStem Ltd. has researched the effect of different monochromatic light intensities and frequencies in the colored spectrum on various human and animal cell populations such as mesenchyme stem cells and white blood cells. The company has found that low-level light photoactivation or photomodulation can 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.

Benefits to Doctors Using PhotoActivation:

- 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 Kit.
- Used for both Orthopedic or Cosmetic PRP Applications.
- Protocol: One Injection per Week for 3 Weeks.



MiMedx:

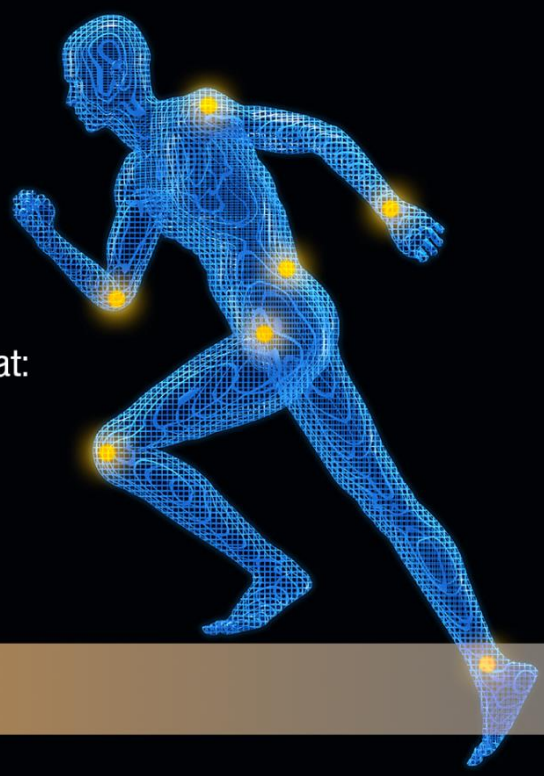
INTRODUCING

OrthoFlo SPORT

A regenerative boost to protect, cushion and enhance mobility

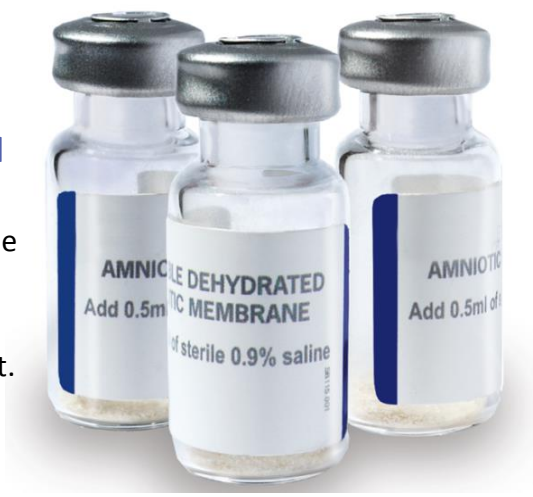
OrthoFlo Sport is a human amniotic fluid derived allograft that:

- Protects & cushions
- Provides lubrication
- Reduces inflammation



GET YOUR PATIENTS BACK ON THE GO

AmnioFix® SPORTS MED



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 inflamed. Scar tissue may form and impede a full recovery. Conservative treatments of oral or topical anti-inflammatories and rest usually will help heal the injury. If additional treatment is needed, AmnioFix might be an option for your patient.

How can AmnioFix help the injury?

AmnioFix contains more than 57 different growth factors, cytokines, and chemokines including interleukins (IL-1ra, IL-4, and IL-10) to modulate inflammation. AmnioFix contains these natural growth factors and collagens, which are core building blocks to help enhance healing.

MiMedx

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.

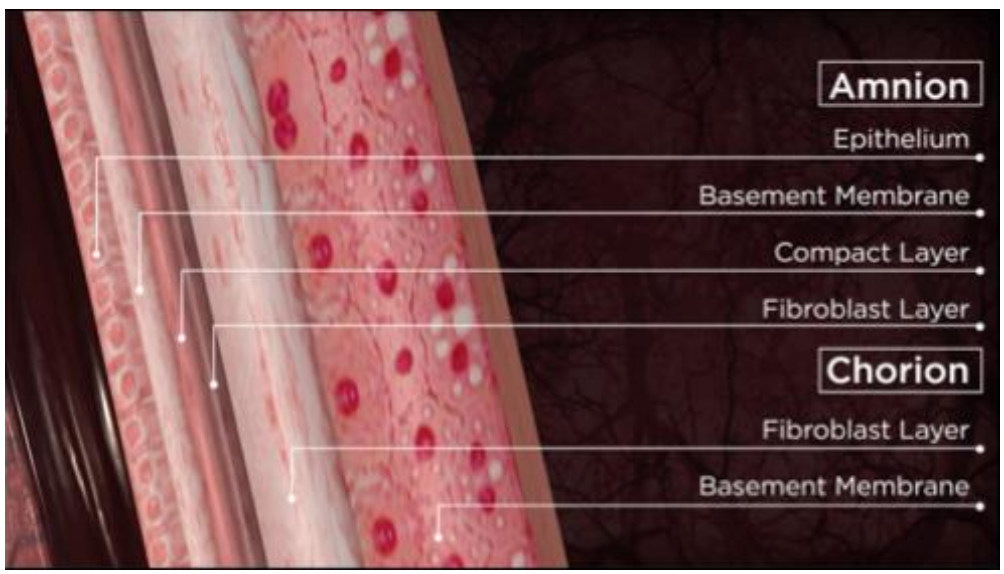
Regulatory Factors

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.



AmnioFix Sizes:

20mg – single dose vial
40mg – single dose vial
100mg – single dose vial

OrthoFlo Sizes:

.5 mL – single dose vial
1 mL – single dose vial
2 mL – single dose vial
4 mL – single dose vial

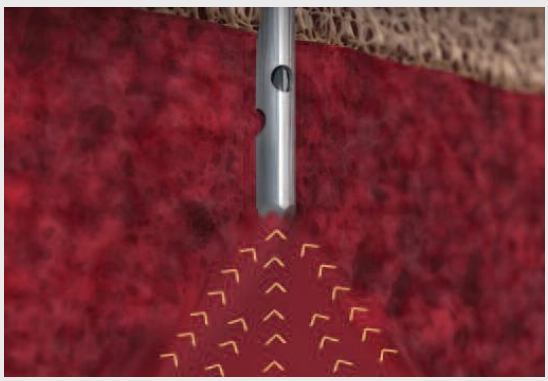
MARROW CELLUTION™

"A QUANTUM LEAP IN BONE MARROW ASPIRATION"

The patent pending Marrow Cellution™ systems maximize the yield of stem and progenitor cells by giving the clinician the ability to efficiently harvest bone marrow from multiple levels within the medullary space, while restricting dilution caused by peripheral blood.

What are the Limitations of a Traditional Needle?

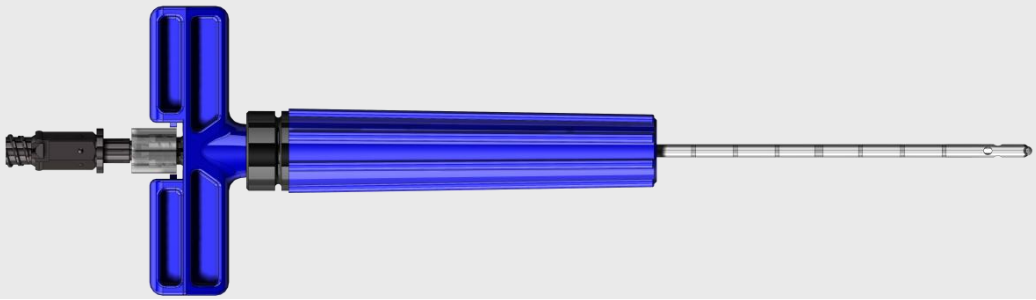
Traditional bone marrow aspiration needles aspirate primarily through an open-ended cannula, which leads to excess peripheral blood dilution and inadequate collection of key stem and progenitor cells. For this reason a high volume of bone marrow aspirate must be collected and then manipulated (i.e. centrifuged) 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.



Marrow Cellution™ :

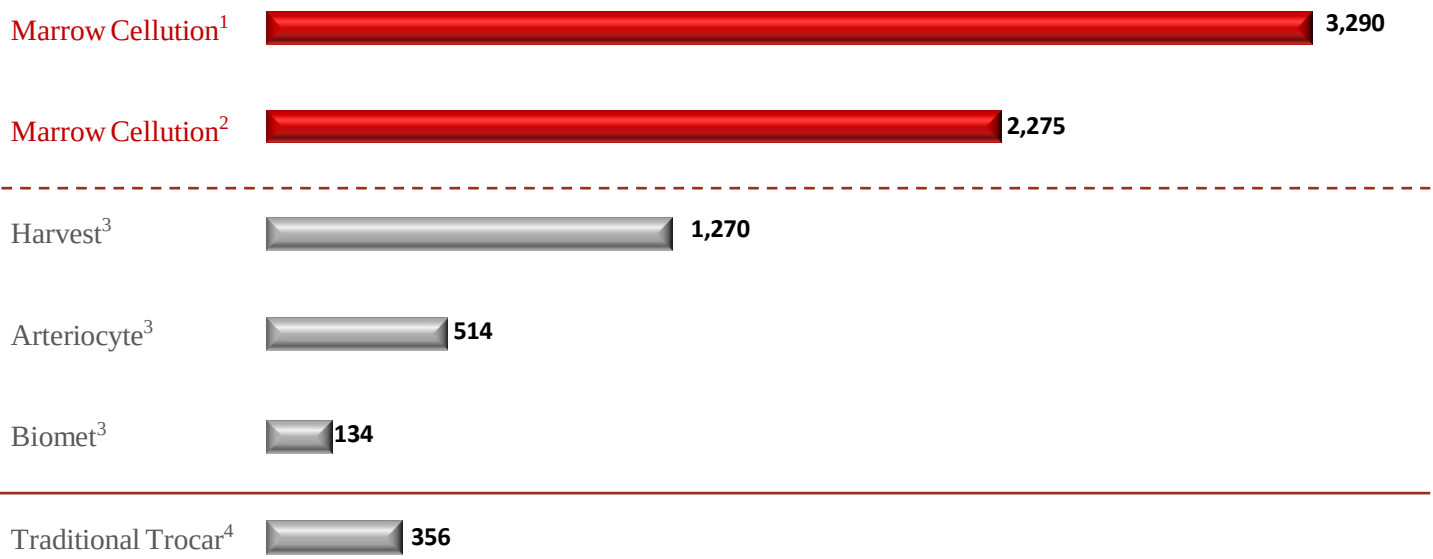
MC-Ran-11C
MC-Ran-11CSTS
MC-Ran-11CT

MC-Ran-8
MC-Ran-8T

Marrow Cellution

Marrow Cellution™ vs. Centrifugation Systems & Traditional Aspiration Needle

CFU-f per mL



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Product Details

Article Code	Description	Introducer	Components
MC-RAN-11C	**Marrow Cellution™** Bone Marrow Aspiration System – Intended for use for aspiration of bone in a measured and controlled manner over a large geography within the marrow space.	11 Gauge, effective length: 2.5”	11 Gauge Introducer Cannula & Sharp Stylet 11 Gauge Introducer Blunt Stylet 14 Gauge Aspiration Cannula & Blunt Stylet 10 mL Syringe
MC-RAN-11CSTS	**Marrow Cellution™** Bone Marrow Aspiration System – Same as MC-RAN-11 but with longer introducer for obese patients	11 Gauge, effective length: 3.5”	11 Gauge Introducer Cannula & Sharp Stylet 11 Gauge Introducer Blunt Stylet 14 Gauge Aspiration Cannula & Blunt Stylet 10 mL Syringe
MC-RAN-8	**Marrow Cellution™** Bone Marrow Aspiration System & Bone Dowel Harvesting System – Same as MC-RAN-11 but with added ability to harvest bone dowels for grafting procedures	8 Gauge, effective length: 3.5”	8 Gauge Introducer Cannula & Sharp Stylet 8 Gauge Introducer Blunt Stylet 14 Gauge Aspiration Cannula & Blunt Stylet 8 Gauge Bone Dowel Extraction Cannula 10 mL Syringe

Ranfac

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

VisionScope:

What is the VisionScope system?

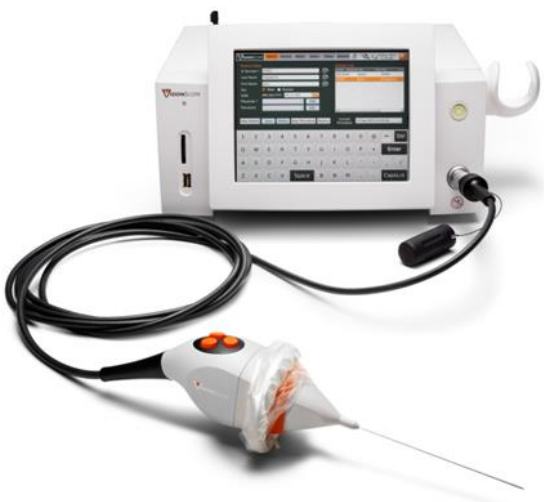
A: The VisionScope system provides similar information to surgical diagnostic arthroscopy – using a minimally-invasive technique. The exam takes place in the office exam room and requires only a local anesthetic (Lidocaine). The system's small needle endoscope houses a miniature camera and when it is 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/procedures and followup visits may be eliminated.

Q: What are the benefits?

A: A VSI exam can accurately diagnose and confirm meniscus, tendon and labral tears, chondral defects, loose bodies, arthritis, partial tears and any joint trauma that is not always clear on MRI scans. The VisionScope system provides an accurate and efficient way to confirm a clinical diagnosis and to provide an appropriate, immediate treatment plan during the same visit.

Q: What are the risks?

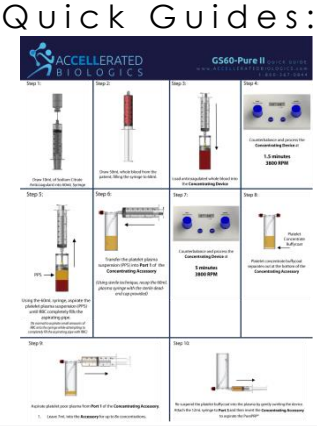
A: Complications associated with a VSI exam are minimal. The most common discomfort is a slight pressure from needle insertion. The least common is mild bleeding in and around the joint area. And although rare, there is always a risk of infection from the introduction of a foreign object into the body.

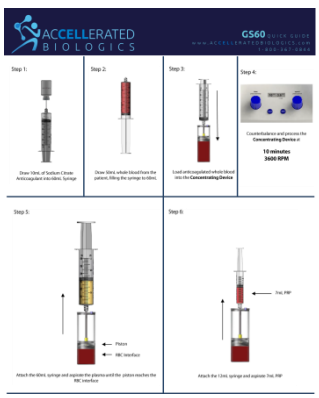


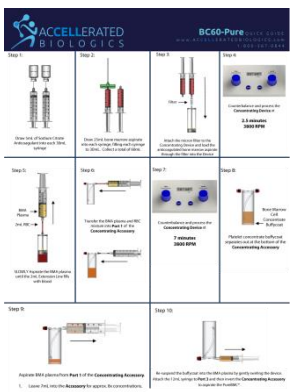
MARKETING SUPPORT:

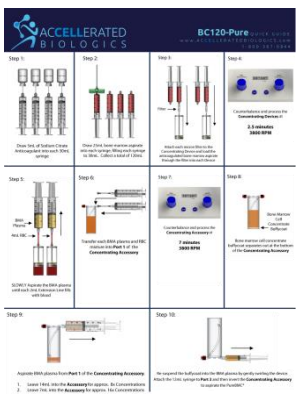
Patient Education Brochures:

Quick Guides:





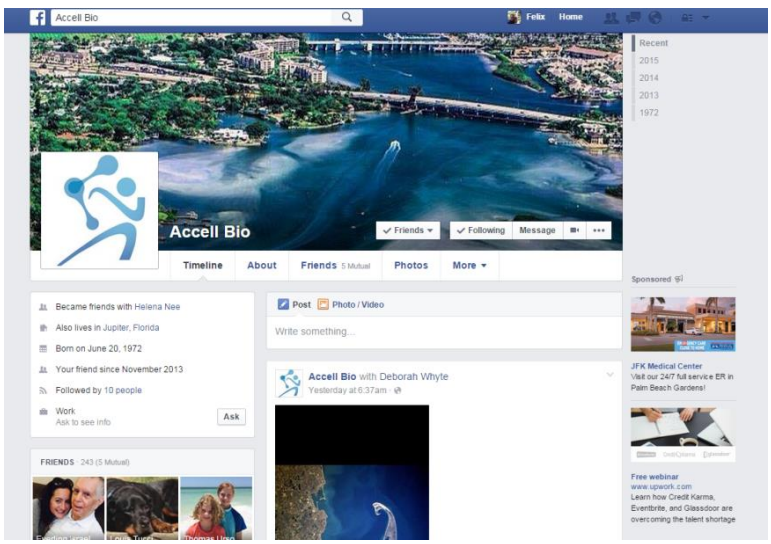


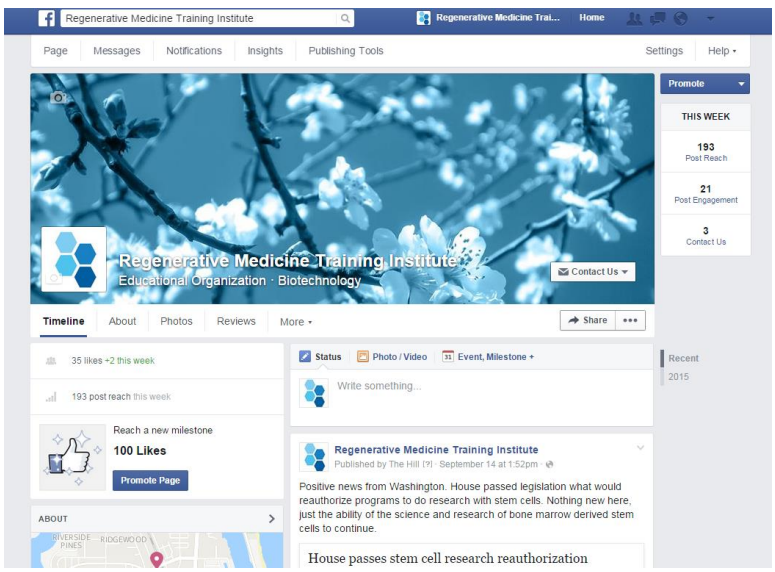


MARKETING SUPPORT:

A revolutionary approach for patient care, outreach, surveys, ASAP Texts, E-Newsletters to patients and other customizable marketing concepts.

AcCELLerated Biologics' Marketing programs include ways to enhance your online reputation, boost your search ranking, and educate existing and prospective patients about Stem Cells, PRP, or any other specialty you want to promote. These customized programs will increase your marketing and efficiency efforts and will show measurable results over the next 4 quarters.





Regenerative Medicine Training Institute:

The Regenerative Medicine Training Institute is proud to offer a continuing educational series of workshops, courses, webinars, and training conferences to provide the practitioner comprehensive training for Stem Cell aspiration, PRP and other autologous biologic products.

Our Educational Series has courses all throughout the United States. The facilities and training centers we use are all first class medical centers with a wide array of options for the doctors to learn in.

Our staff physicians are leaders in regenerative medicine and other autologous biologic practices. These world renown physicians take great pride and passion in improving the methods of helping patients.

RMTInstitute is located in Tequesta, FL. This world class facility offers hands on training, prestigious faculty, CME hours, marketing and networking strategies all based on Regenerative Medicine, stem cells, prp, and other autologous therapies.

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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

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7. List of Summary Tables

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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**

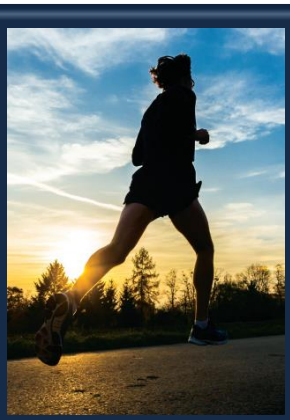
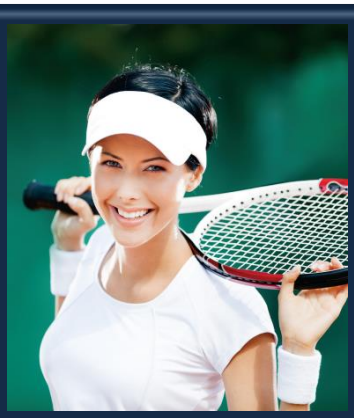
Table 6.15. Growth Factor: SDF-1α (pg/ml PLT Releaseate)

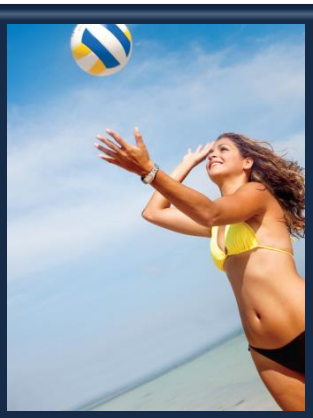
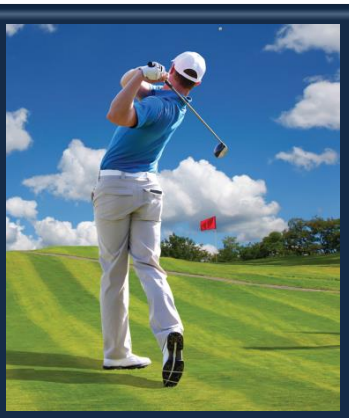
Sample Number	EmCyte PurePRP® II 2015	Harvest Clear PRP	Arthrex Angel
603	3,708	2,941	3,184
604	3,824	3,590	3,380
605	3,480	3,204	2,475
606	4,127	4,162	3,981
607	3,778	3,367	2,862
608	3,289	2,528	2,207
609	2,633	2,354	2,027
MEAN	**3,418**	**3,113**	**2,771**
STDEV	**537**	**610**	**661**

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

Notes

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