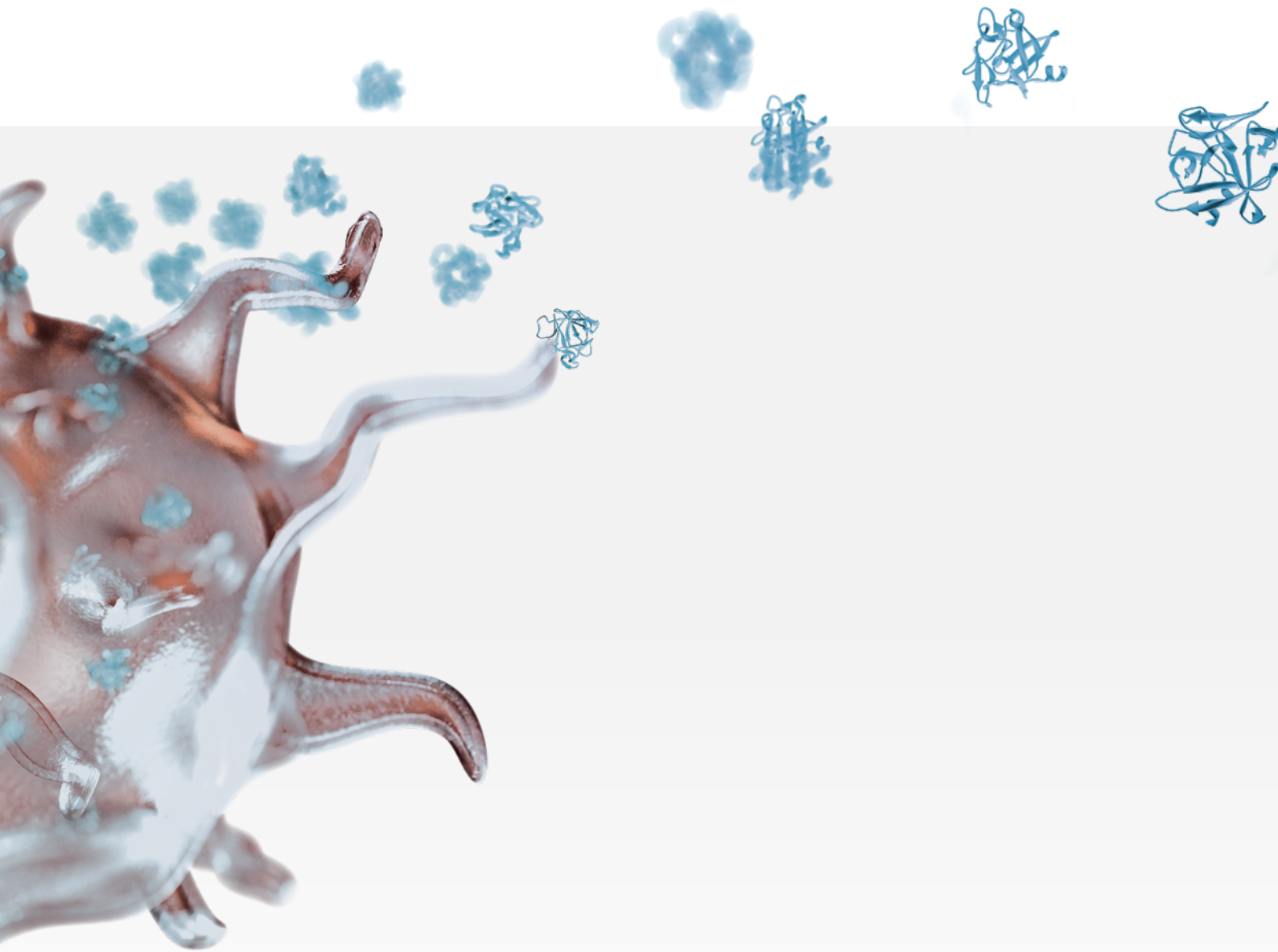


Personalized Injection Therapies

Regenerative Treatment Options



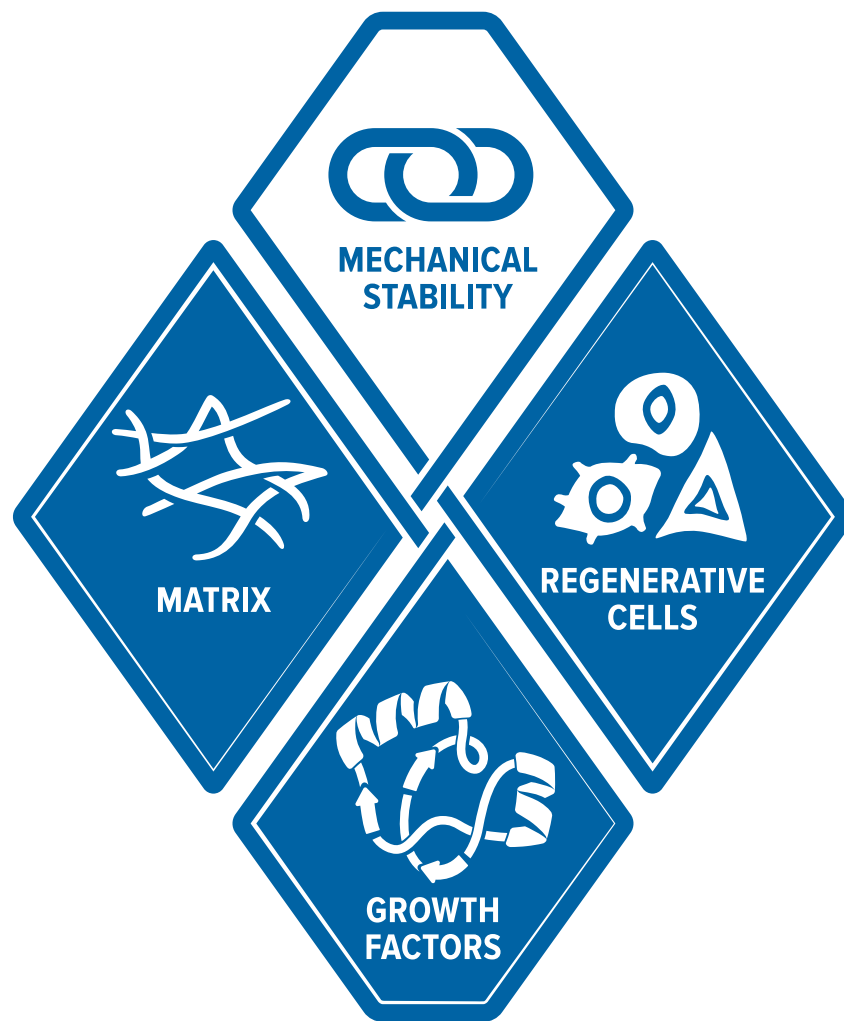
Helping Surgeons Treat Their Patients Better®

Since its inception, Arthrex has been committed to one mission: Helping Surgeons Treat Their Patients Better. We are strategically focused on constant product innovation through scientific research, surgeon collaboration, and medical education to make less invasive surgical procedures simple, safer, and more reproducible. Each year, we develop more than 1000 new innovative products and procedures to advance minimally invasive orthopedics worldwide.

Arthrex has always remained a privately held company, which allows for the rapid evaluation of new technologies and ideas and the freedom to develop products and techniques that truly make a difference. Our experienced team of dedicated professionals represents a shared passion and commitment to delivering uncompromising quality to the health care providers who use our products and the millions of patients whose lives we impact.

The medical significance of our contributions serves as our primary benchmark of success and will continue into the future as the legacy of Arthrex.

04	The Healing Diamond
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28	References



The Healing Diamond: A Comprehensive Approach to Tissue Regeneration

Tissue regeneration is an important process that allows damaged tissue to be reformed into its native state to perform its dedicated function. This rebuilding process requires the collaboration of different tissue components. From small molecules to cells and overall tissue integrity, every part must contribute to ultimately restore tissue health and function. The concept of the “Healing Diamond” summarizes the importance of each cornerstone in contributing to the overall regenerative process.

- › **Mechanical stability** is a necessity for every regeneration process, as it provides the physical integrity that supports cellular and molecular growth and reorganization.
- › **Regenerative active cells** are essential for tissue regrowth through proliferation, differentiation, or the production of dedicated extracellular matrix components.
- › **Growth factors** are bioactive signaling molecules that serve as major communication vessels within tissue, promoting cellular regeneration processes and counteracting catabolic inflammatory reactions that may hinder regeneration.
- › **Matrix components** provide a three-dimensional structural network that not only regulates the diffusion of molecular components such as growth factors but also acts as a scaffold for regenerative cells to adhere to and for new tissue to grow within.

Tissue regeneration is impaired as soon as one or more components of the Healing Diamond are missing or cannot perform their intended function. Arthrex orthobiologic solutions are designed to provide or augment missing or impaired cellular and molecular components of the Healing Diamond to enable regeneration. Our portfolio of autologous injectable treatment options, paired with synthetic molecular products, enables practitioners to offer their patients a highly personalized treatment regime.

Tailored Regenerative Treatment Options for Optimal Patient Outcomes



Arthrex ACP®
Simple and safe PRP preparation with the well-proven double syringe



ACP Max™ System
Safe preparation of highest platelet concentrations



Arthrex SVF
Provides the regenerative potential of the stromal vascular fraction



SYNOZ
Multi-injection hyaluronic acid, supporting the restoration of synovial fluid viscoelasticity



SYNOZ ULTRA
Single-injection linear hyaluronic acid, to combat pain and mobility in all synovial joints



Thrombinator™ System
For the preparation of autologous thrombin serum



Angel® System
For customized cellular concentrations of PRP



Angel® System Bone Marrow Aspiration
Indication-specific PRP preparations from bone marrow aspirate

Arthrex ACP® Double Syringe



ACP – Autologous Conditioned Plasma



Introduction

The interest in autologous blood products such as blood plasma has grown for use in a number of orthopedic therapies. The healing effect of plasma is supported by growth factors released by thrombocytes. The Arthrex ACP double-syringe system is used for the sterile separation of non-homogeneous liquids. This device allows the withdrawal of blood from the human body using a commercially available cannula with a Luer lock connection.

Features and Benefits

- › 2-in-1: A unique system for the preparation of autologous conditioned plasma (ACP)
- › ACP preparation with the Arthrex ACP double syringe can be performed within minutes
- › The Arthrex ACP double syringe is a closed, sterile system for use in the doctor's office and operating room
- › The double-syringe design allows for easy, convenient, and safe handling

Indications

As different studies have shown, white blood cells are not concentrated in ACP.¹⁻³ The supernatant should not contain red blood cells.^{3,4} A significant increase in the cell proliferation of muscle, tendon, and bone cells has been documented in vitro.⁴

Studies have confirmed the effectiveness of ACP therapy for the following indications:

- › Mild to moderate osteoarthritis (grade I-III)⁵⁻⁷
- › Epicondylitis^{8,9}
- › Plantar fasciitis¹⁰
- › Patellar tip syndrome¹¹

Mechanism of Action

Using the described method with the Arthrex ACP double syringe to prepare blood, the plasma contains a platelet concentration increased by about 2-3 times.³ Outside the bloodstream, platelets become activated and release proteins (eg, growth factors). These growth factors are known to be relevant for healing in a variety of tissue types and they appear to work synergistically.¹²⁻¹⁴

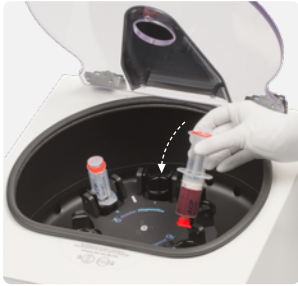
Major Effects of Growth Factors

- › Induced proliferation and differentiation of various cell types (eg, osteoblasts, chondroblasts)¹⁵
- › Improved matrix formation (eg, collagen and proteoglycan production)¹⁶
- › Stimulation of angiogenesis and chemotaxis¹⁷

Preparation



Blood withdrawal



Centrifugation



Separation



Ready for injection

Ordering Information

Arthrex ACP® Double-Syringe System	
Arthrex ACP® double syringe (a)	ABS-10014
Arthrex ACP® kit, series I	ABS-10011
Centrifuge Options	
Drucker Centrifuges	
Centrifuge, general purpose, horizontal, incl. 4 buckets, spacers and counterweights (b)	HORIZON 24-AH
Horizon 24 FLEX-AH centrifuge, general purpose, horizontal, 2 buckets	00389-129-000K
Bucket	03-1-0001-0123HK
Bucket spacer, for Arthrex ACP® double syringe	03-1-0001-0098K
Blood counterbalance	03-1-0001-0070K
Hettich Centrifuge	
Centrifuge, Hettich Rotofix 32 A, with swing-out rotor, 220 V	1206-Art
Centrifuge, Hettich Rotofix 32 A, with swing-out rotor, 110 V	1206-01-Art
Bucket, for Hettich Rotofix 32 A	1491-2
Screw cap, for Hettich bucket	1492-2
Counterweight, for centrifugation of Arthrex ACP® double syringe, 15 mL	ABS-10027
Accessories	
Cart, for centrifuge, 45 cm	KU.1079.800

An anticoagulant can be ordered on request.
Please note that not all products advertised in this brochure may be available in all countries.



ACP Max™ System



Maximum Yield Platelet-Rich Plasma (PRP) Preparation System



Introduction

The regenerative capacity of platelet-rich plasma (PRP) lies in the highly concentrated variety of biologically active growth factors encapsulated in thrombocytes.¹ Ever since its first documented clinical applications, the indicative field of PRP has been expanding rapidly. The ACP Max system has been made to accommodate these applications as well as the growing demands for a PRP preparation device. The system is made for the sterile separation of non-homogenous liquids and can be used to prepare PRP formulations highly or very highly concentrated in thrombocytes paired with or without leukocytes. The ACP Max system can process 30 mL, 60 mL, or 90 mL of whole blood to produce a final output with platelet concentrations up to 12× over baseline while significantly reducing neutrophil content.²⁻⁴

Features and Benefits

- › Always-closed system to collect and prepare PRP with swabable valves for sterile liquid transfer to injection syringe
- › Large-volume collection syringe allows for the preparation of ACP Max, a PRP with a unique cellular composition
- › Building on the success of the double-syringe design, this system is compatible with existing ACP preparation material

Indications

Blood withdrawal may be done either with supplied syringes or directly into the ACP Max syringe container. This container can be centrifuged up to 2000 × g in order to separate non-homogenous liquids such as venous blood directly at the point of care. The closed design of the ACP Max syringe enables the surgeon to withdraw the products of the centrifugation in a safe and sterile manner via the swabable Luer lock connector on top of the device. ACP as well as ACP Max PRP prepared with the ACP Max system can be used to treat osteoarthritis of the knee, rotator cuff repairs, and tendinosis of the elbow.

Key Points

- › Up to 90 mL processing volume
- › Compatible with ACP centrifuges and rotors
- › Preparation of hyperconcentrated ACP
- › Preparation of large ACP volumes

Preparation



01

Push the plunger of the ACP Max syringe down to the syringe bottom and attach one of the red caps to the syringe's Luer lock connector.



02

Transfer anticoagulated whole blood into the syringe via the swabbable back valve of the syringe plunger.



03

Remove the syringe guide. Do not discard.



04

Prepare counterweight by adding tap water to at least the same filling line as the patient syringe containing whole blood. Place ACP Max syringe and counterweight into opposite buckets of the centrifuge.



05

After centrifugation, withdraw PPP until ACP Max plunger is 2 gradations above the red phase.



06

Transfer the following 15 mL containing PPP and the buffy coat into the ACP double syringe. **Gently invert the double syringe for 15-30 seconds to ensure proper mixing before proceeding to the next step.**



07

Place ACP syringe and ACP counterweight into opposite buckets of the centrifuge.



08

Carefully transfer yellow phase into the inner syringe by pressing on the red wings and pulling on the inner syringe plunger.



09

See next page for protocols and tips.

Ordering Information

ACP Max™ System

ACP Max™ system	ABS-10013-B
ACP Max™ system kit	ABS-10013
Anticoagulant, ACD-A, 20 mL	SAAV222.G00
ACP Max™ counterweight	ABS-10017

Centrifuge Options

Drucker Centrifuges

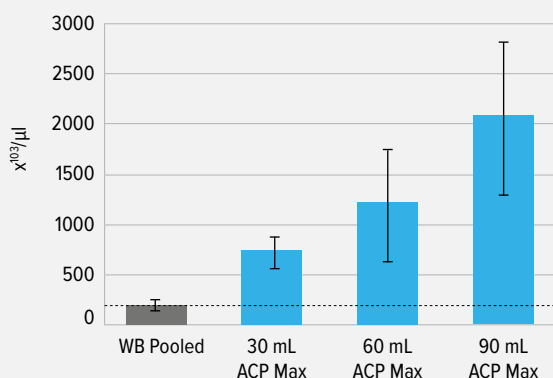
Horizon 24 FLEX-AH centrifuge, general purpose, horizontal, 2 buckets	00389-129-000K
Bucket	03-1-0001-0123HK
Bucket spacer, for Arthrex ACP® double syringe	03-1-0001-0098K
Blood counterbalance	03-1-0001-0070K

Hettich Centrifuge

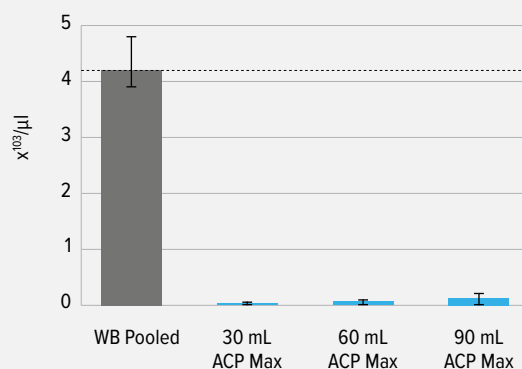
Hettich Rotofix 32A centrifuge, with swing-out rotor, 220 V	1206-Art
Hettich Rotofix 32A centrifuge, with swing-out rotor, 110 V	1206-01-Art
Hettich ACP Max™ bucket	1490
Hettich ACP bucket	1491-2
Screw cap, for Hettich buckets	1492-2
Counterweight, for centrifugation of Arthrex ACP® double syringe, 15 mL	ABS-10027

Cellular Characterization of ACP Max™ PRP Preparation

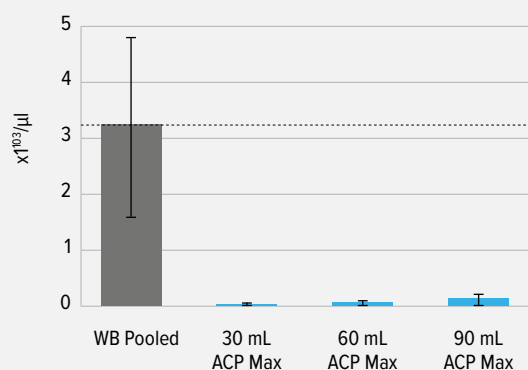
PLT Concentrations in PRP vs WB2-4*



RBC Concentrations in PRP vs WB2-4*



Neutrophil Concentrations in PPRP vs WB2-4*

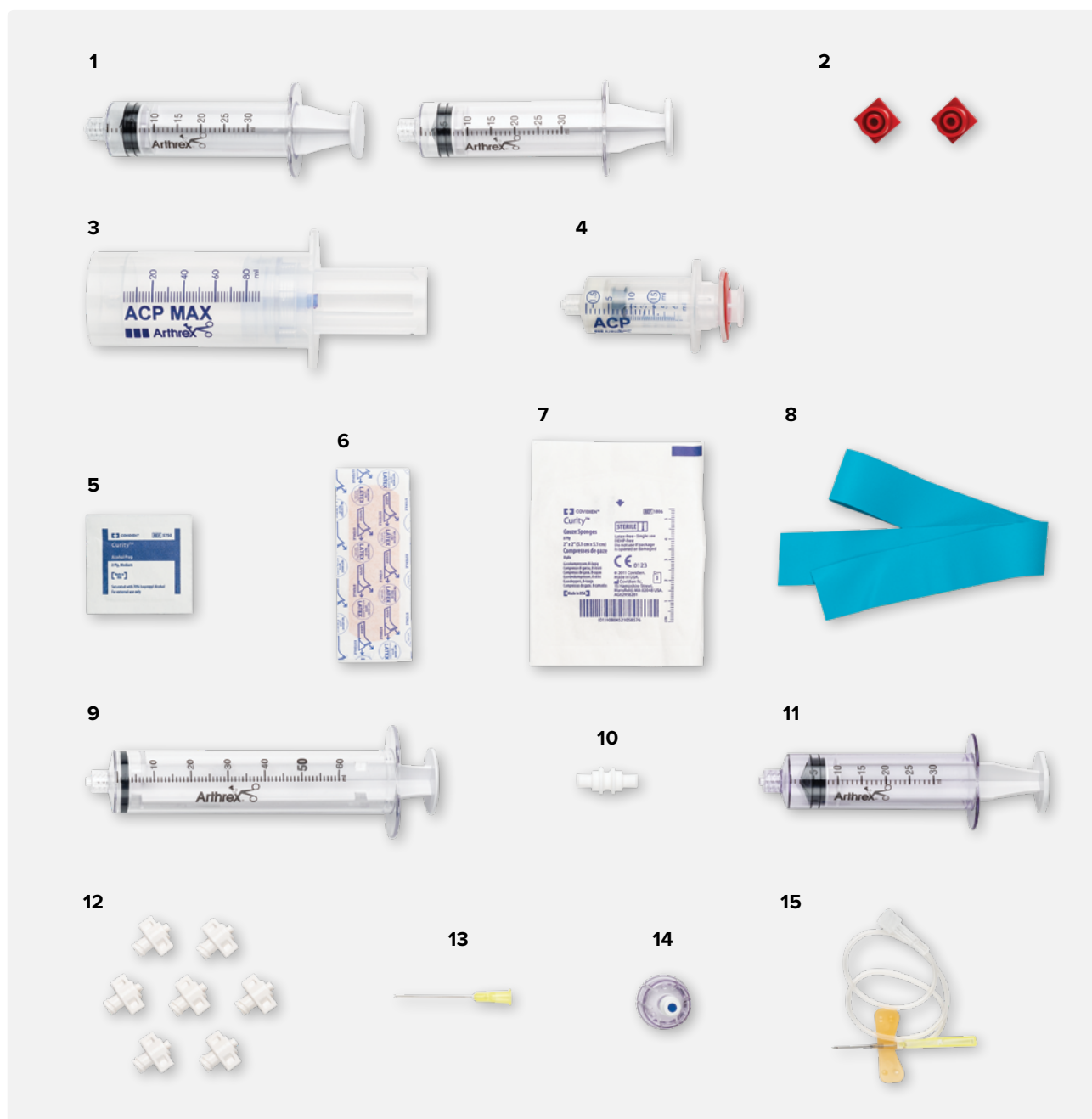


The ACP Max system produces an average of 5 mL PRP, containing approximately 3×, 7×, and 12× platelet concentrations over baseline for 30 mL, 60 mL, and 90 mL processing volumes of WB, respectively. This concludes that PRP produced from the ACP Max system is depleted of red blood cells and neutrophils, resulting in a 95% to 99% reduction in red blood cells and a 97% to 99% reduction of neutrophils, depending on processing volume. Overall, the ACP Max system can produce PRP with up to 12× concentration of platelets over baseline, while depleting inflammatory cells.

PLT = platelets; PRP = platelet-rich plasma; WB = whole blood; RBC = red blood cells

*Data on file APT-5368, APT-5535, APT-5756

ACP Max™ Kit Components



Inner Blister Tray (sterile)

Contents of ABS-10013-B

Pic.	Qty.	Description
1	2	Syringe, 30 mL, for PPP withdrawal
2	2	Luer caps, red
3	1	ACP Max™ container
4	1	Arthrex ACP® double syringe

Outer Blister Tray

Additional contents of ABS-10013

Pic.	Qty.	Description
5	1	Alcohol pad
6	1	Bandage, latex-free
7	1	Gauze sponge
8	1	Tourniquet
9	1	Blood draw syringe, 60 mL
10	1	Female-to-female Luer
11	1	Blood draw syringe, 30 mL
12	7	Male-to-female Luer caps, white
13	1	Hypodermic needle for ACD-A withdrawal, 20 ga
14	1	Vial adapter for ACD-A
15	1	Butterfly phlebotomy cannula, 19 ga

Arthrex SVF

Regenerative Cells



Introduction

Stem cells from adipose tissue (AdSC), which are located in the stromal vascular fraction (SVF), share similar properties with bone-marrow-derived stem cells. They can differentiate into different cell lines such as bone, fat, cartilage, and muscle and secrete a large number of cytokines and growth factors,¹⁻⁴ but in comparison to bone-marrow-derived stem cells, they are easier to collect for clinical application and show higher isolation yields.⁵

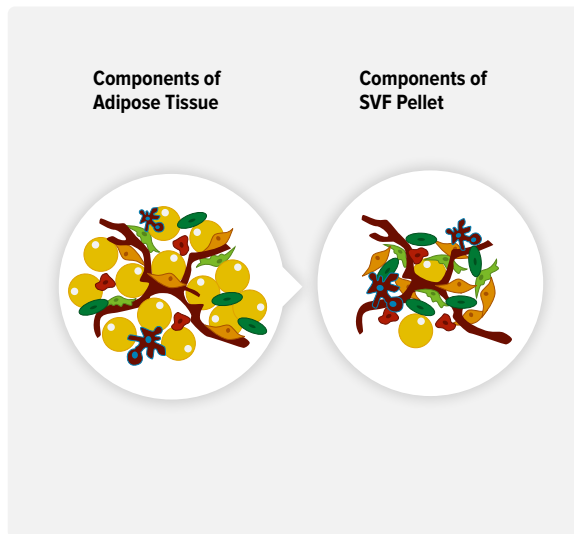
Features and Benefits

- › The SVF technique offers a fast and easy solution for harvesting and processing nonhomogenous liquids such as adipose tissue
- › No enzymes: Purely mechanical processing whereby the SVF can be collected as a pellet⁶
- › Proven synergistic effect: PRP promotes cell proliferation and differentiation of AdSC⁷⁻¹³
- › Supports tissue regeneration^{14,15}

AdSCs in Osteoarthritis

The first promising preclinical and clinical results to treat osteoarthritis with autologous SVF and the combination of SVF and ACP have been published, assuming the possible regenerative potential of this new biological treatment option.¹⁶⁻¹⁸

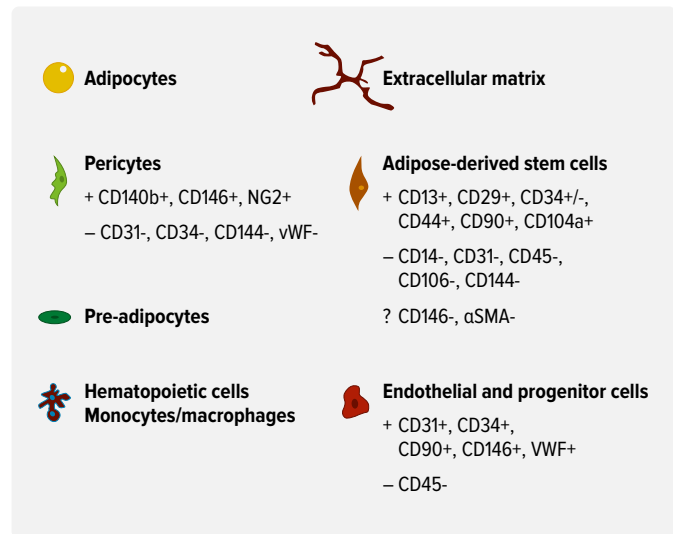
Mechanism of Action



Modified picture from Shukla et al (2015)²⁷

Composition of SVF

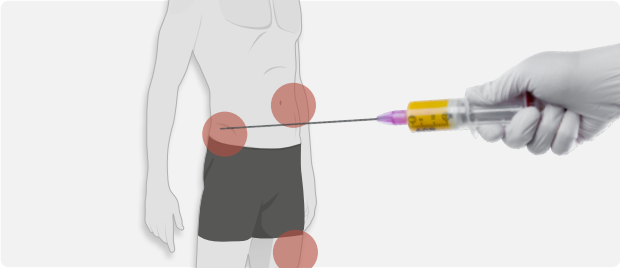
In addition to their multipotent differentiation potential, adipose-derived stem cells also secrete a large number of cytokines and growth factors, such as hepatocyte growth factor (HGF), interleukin-6 (IL-6), or transforming growth factor beta 1 (TGF- β^1), that support tissue regeneration.^{2-4,19} The SVF also comprises some endothelial cells, smooth muscle cells, erythrocytes, leukocytes, adipocytes, and the extracellular matrix, which can act as a temporary scaffold that also contains matrix remodeling enzymes.^{20,21}



Major Effects of SVF

- > Reduction of local inflammation²²⁻²⁶
- > Prevention of tissue fibrosis²⁶
- > Anti-apoptotic^{2-4,19}
- > Supports angiogenesis and tissue remodeling^{2-4,19}
- > Enhancement of endogenous stem cell recruitment and proliferation¹⁹
- > Reduction of osteophyte formation and synovial inflammation¹⁹
- > Reduction of cartilage degradation¹⁹

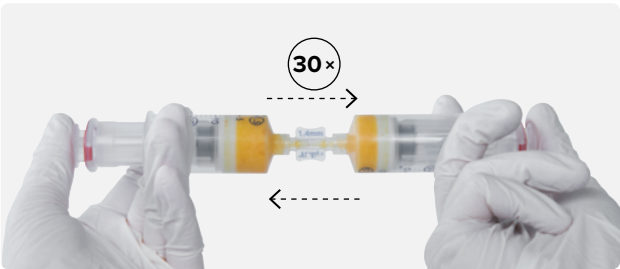
Preparation



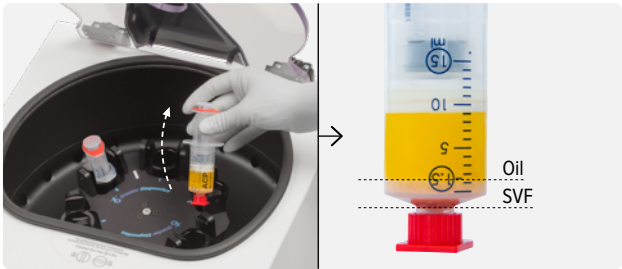
Fat tissue harvesting from an appropriate donor site (eg, belly, waist, or thigh)



Isolation of fat graft



Processing



Isolation of SVF



Ordering Information

Adipose Tissue Harvesting Kit (a) Includes:

ABS-10056

Syringe, 3 cc **(b)**
 Syringe, 10 cc, qty. 2 **(c)**
 Syringe, 20 cc, qty. 2 **(d)**
 Syringe, 60 cc, qty. 2 **(e)**
 VacLok harvesting syringe, 30 cc **(f)**
 Transfer device, 2.4 mm, qty. 2 **(g)**
 Transfer device, 1.4 mm, qty. 2 **(h)**
 Transfer device, 1.2 mm, qty. 2 **(i)**
 Anaesthesia cannula, 25 ga x 16 mm **(j)**
 Injection cannula, 14 ga x 40 mm **(k)**
 Syringe, 1 cc, qty. 5 **(l)**
 Infiltration cannula **(m)**
 Carraway harvester **(n)**

Arthrex ACP® Double-Syringe System

Arthrex ACP® double syringe **(o)**
 Arthrex ACP® kit, series I

ABS-10014
 ABS-10011

Centrifuge Options

Drucker Centrifuges

Centrifuge, general purpose, horizontal, incl. 4 buckets, spacers and counterweights
 Horizon 24 FLEX-AH centrifuge, general purpose, horizontal, 2 buckets
 Bucket
 Bucket spacer, for Arthrex ACP® double syringe
 Blood counterbalance

HORIZON 24-AH
 00389-129-000K
 03-1-0001-0123HK
 03-1-0001-0098K
 03-1-0001-0070K

Hettich Centrifuge

Hettich Rotofix 32A centrifuge, with swing-out rotor, 220 V
 Hettich Rotofix 32A centrifuge, with swing-out rotor, 110 V
 Hettich ACP Max™ bucket
 Hettich ACP bucket
 Screw cap, for Hettich buckets
 Counterweight, for centrifugation of Arthrex ACP® double syringe, 15 mL

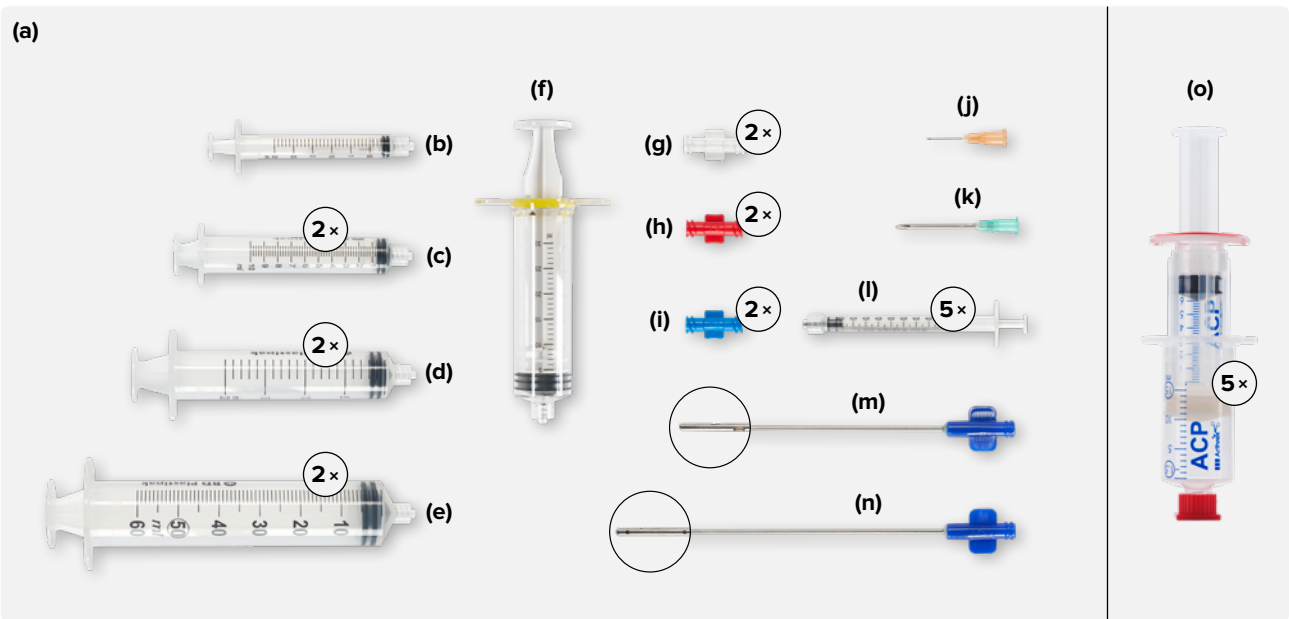
1206-Art
 1206-01-Art
 1490
 1491-2
 1492-2
 ABS-10027

Accessories

Cart, for centrifuge, 45 cm

KU.1079.800

An anticoagulant can be ordered on request.
 Please note that not all products advertised in this brochure may be available in all countries.





Introduction

In patients with degenerative joint disease (osteoarthritis), the viscoelasticity of the synovial fluid is significantly affected. This leads to mechanical stress of the joint and the degradation of articular cartilage, which results in limited joint mobility and pain. The lubricating and shock-absorbing properties of SYNOZ contributes to pain reduction and improved joint mobility. This effect can last for several months after a treatment cycle of 3 intra-articular injections.¹

Key Facts

- > 1% (10 mg/mL) sodium hyaluronate
- > 1.6 MDa, linear
- > 2 mL injection volume
- > Low allergenicity due to biofermentative origin (no materials of animal origin)
- > Superior quality and extraordinary safety

Mode of Action

- > **Inflammatory Processes – Anti-inflammatory Action**
Inhibits the expression of Interleukin-1 β and the associated synthesis of metalloproteinases and reactive oxygen species.²
- > **Cartilage Degradation – Chondroprotection**
Reduces chondrocyte apoptosis while simultaneously increasing chondrocyte proliferation and the synthesis of proteoglycans and glycosaminoglycans.²
- > **Compromised Synovial Fluid – Improvement of Synovial Fluid**
Promotes the intrinsic production of hyaluronic acid (HA), reduces friction, and provides protection through shock-absorbing effects.²

Indications

The device is used in humans for injection into knee joints in order to restore the natural viscoelastic properties of the synovial fluid (viscosupplementation). The device is indicated for treatment of pain and restricted movement as a consequence of degenerative or traumatic changes to the knee joint area.

Ordering Information

SYNOZ	4941101
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SYNOZ ULTRA



Single Injection Hyaluronic Acid



Introduction

Hyaluronic acid injections aim to restore the natural properties of the synovial fluid. Long-chain hyaluronic acid closely mimics the structure of endogenous, physiological hyaluronic acid, resulting in prolonged residence time within the joint. This enhanced biocompatibility enables a new generation of treatment options: a single injection can deliver sustained symptom relief, reducing the need for repeated interventions, which is efficient for physicians and highly convenient for patients.

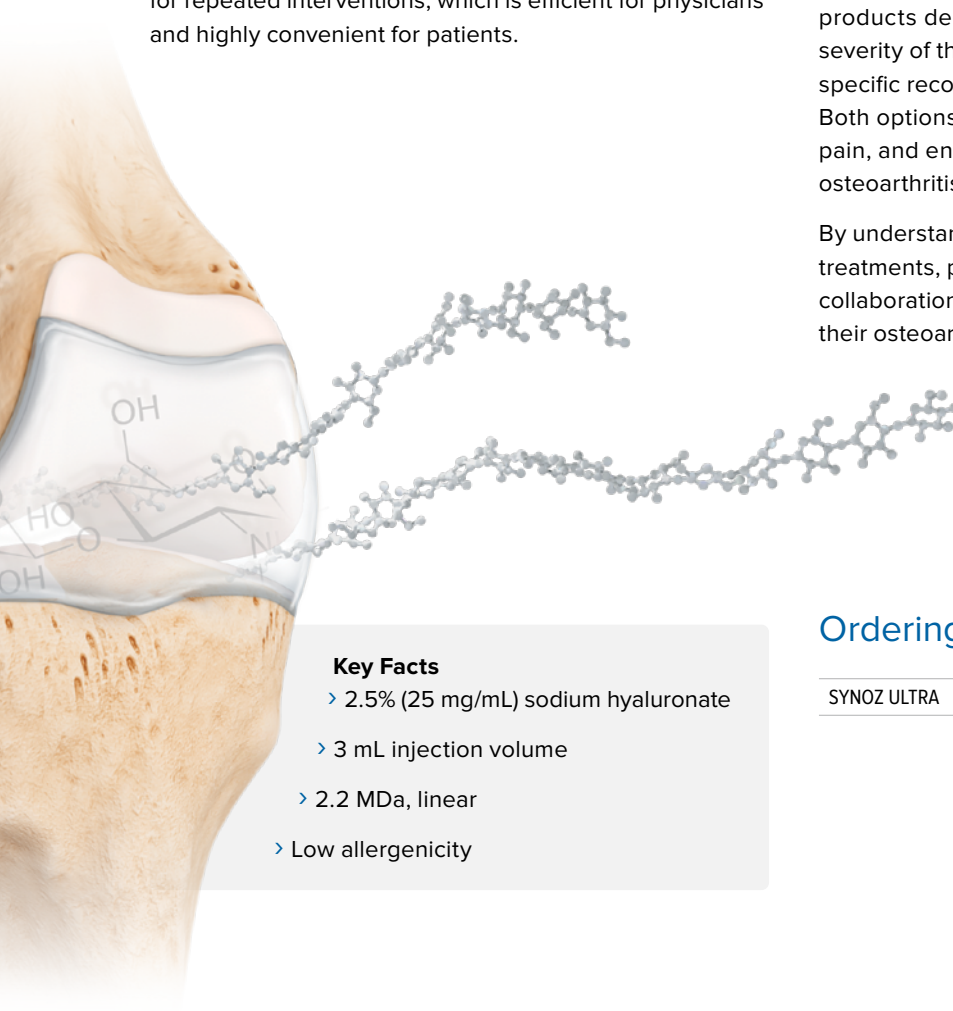
Indications

SYNOZ ULTRA is used to accommodate pain and reduced mobility associated with degenerative deformities of the knee joint and other synovial joints. It is administered via a single intra-articular injection using an aseptic technique.

Choosing the Right Treatment

The choice between single-injection and multi-injection products depends on various factors, including the severity of the osteoarthritis, patient preference, and the specific recommendations of the health care provider. Both options aim to improve joint function, reduce pain, and enhance the quality of life for patients with osteoarthritis.

By understanding the benefits and differences of these treatments, patients can make informed decisions in collaboration with their health care providers to manage their osteoarthritis effectively.



Key Facts

- > 2.5% (25 mg/mL) sodium hyaluronate
- > 3 mL injection volume
- > 2.2 MDa, linear
- > Low allergenicity

Ordering Information

SYNOZ ULTRA

4941201

References are listed on Page 29

Angel® System

Indication-Specific PRP Preparation



Introduction

The Angel system utilizes a proprietary platelet sensor and 1-button automation to prepare customized platelet-rich plasma (PRP) formulations. It is the only PRP device that can deliver platelet concentrations up to 18x above baseline, with adjustable leukocyte concentrations.

Features and Benefits

- › Proprietary platelet sensor system
- › Adjustable platelet concentrations
- › Adjustable white blood cell (WBC) concentrations
- › Flexible processing volume 40-180 mL
- › Each processing kit can process 3 cycles up to 180 mL on the same patient
- › Programmable: Can store up to 30 custom processing protocols
- › Closed system, delivers PRP, PPP, and red blood cells (RBCs) into separate, sterile compartments

Applications for PRP Include:

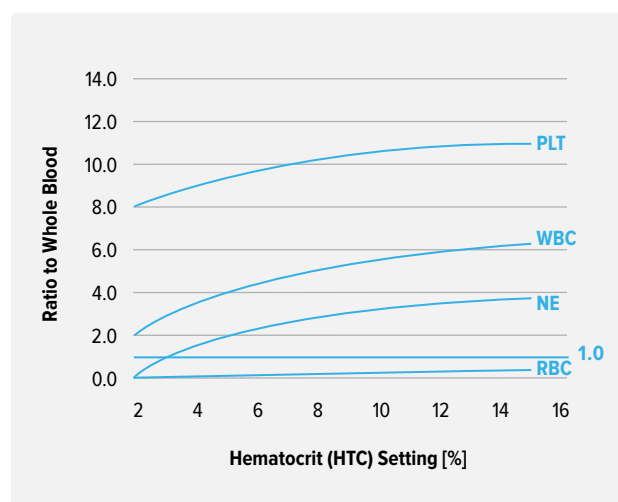
- › Rotator cuff repair
- › Hip labral repair
- › Meniscal repair
- › Microfractures

Mechanism of Action

Outside the bloodstream, platelets become activated and release proliferative and morphogenic proteins. These proteins appear to work synergistically to invoke the following benefits:¹⁻³

- › Induce proliferation and differentiation of various cell types (eg, progenitor cells, osteoblasts, epidermal cells)
- › Enhance/modulate production of collagen, proteoglycan and tissue inhibitor metalloproteinases (TIMP)
- › Stimulate angiogenesis and chemotaxis

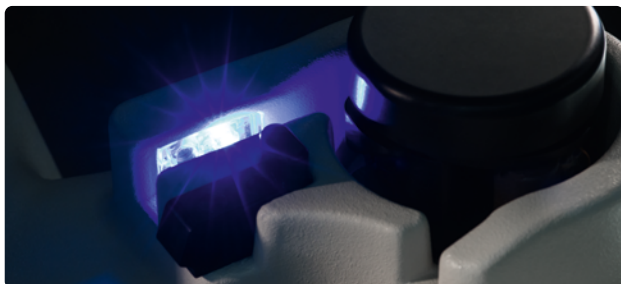
Angel® System PRP Output



In order to evaluate the difference between the Angel system PRP output and whole blood, the Angel system PRP was prepared from the venous blood of 6 healthy donors at hematocrit settings of 2%, 5%, 7%, 10%, and 15%. The concentration of platelets, white blood cells (WBC), and neutrophils (NE) were measured with a standard complete blood count (CBC).

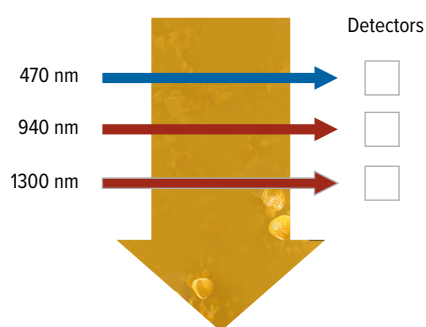
Precision Separation With 3-Sensor Technology

The Angel system incorporates 3 sensors to accurately separate blood components using cell-specific wavelengths of light to increase cellular yields. Absorption of 470 nm light detects platelets and leukocytes, 940 nm detects erythrocytes, and the 1300 nm wavelength corrects for ambient light and the presence of air bubbles.



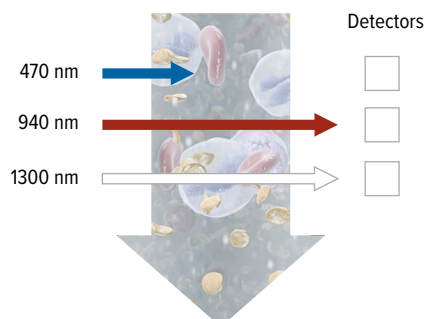
Advantages

- › No syringe switching
- › No manual steps to prepare PRP
- › Delivers PRP, PPP, and RBCs into separate, sterile compartments
- › Ability to modulate platelet, leukocyte, and RBC content
- › Consistent PRP output



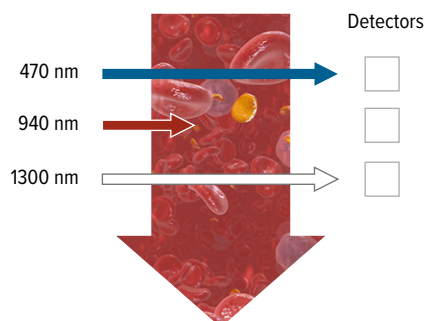
Plasma

When plasma is present, all 3 light beams pass through and contact the detector. The Angel device recognizes the presence of plasma and turns the valve to collect PPP. The PPP is deposited in the PPP collection reservoir.



Platelet and WBC

When platelets and WBCs are present, the 470 nm wavelength of light is absorbed. The absence of the 470 nm beam on the detector alerts the Angel system to stop collecting PPP. The Angel device will then actuate the valve to collect PRP. The PRP is directed into the collection syringe on top of the unit.



RBC

The 940 nm wavelength is absorbed by RBCs. When the detector no longer detects the 940 nm beam, the Angel system will allow a percentage of RBCs to pass through into the PRP collection syringe. The percentage of RBCs collected in the PRP syringe is determined by the HCT setting selected by the operator.

Preparation



Loading



Centrifugation

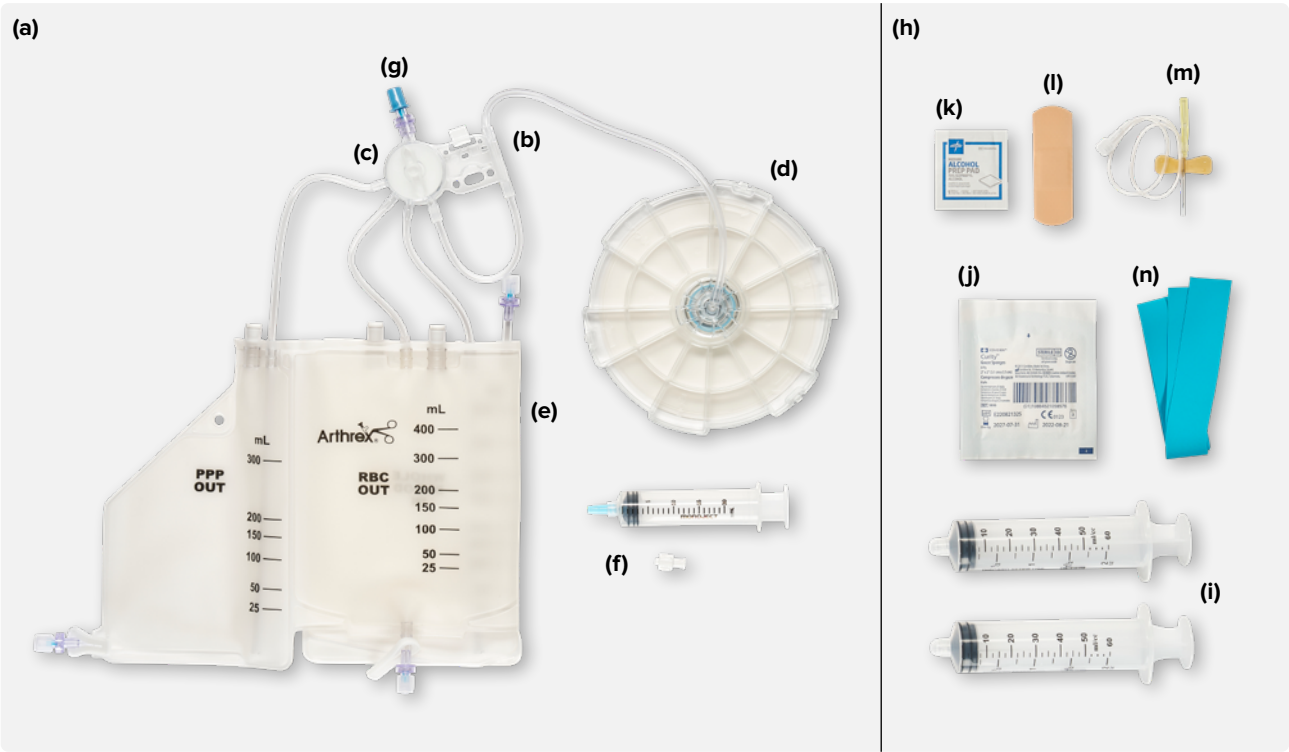


Fully automated separation

Ordering Information

Angel® System Centrifuge		
Angel® system		ABS-10066
Angel® System Consumables		
Anticoagulant, ACD-A, 20 mL		SAAV222.G00
Angel® cPRP Processing Set (a) Includes:		
Platelet cuvette (b)		
Valve, rotating (c)		
Separation chamber, variable volume (d)		ABS-10064
Reservoir bag, 3-compartment (e)		
Luer lock plugs, male-female (f)		
PRP valve, syringe-activated (g)		
Angel® PRP Kit (h) Includes:		
Angel® processing set (a)		
Luer lock syringes, 60 mL (i)		
Gauze (j)		ABS-10071
Alcohol pad (k)		
Bandage (l)		
Butterfly phlebotomy cannula (m)		
Tourniquet (n)		
Accessories		
Delivery needle, fenestrated		ABS-20000
Delivery needle, epidural, Tuohy		ABS-21000
Cannula bending tool		AR-6650
Cart, for centrifuge, 50 cm		KU.5157.800

Please note that not all products advertised in this brochure may be available in all countries.



Angel® System Bone Marrow Aspiration



Indication-Specific PRP Preparations From Bone Marrow Aspirate



Introduction

Technology is what sets the Angel system apart from the competition. The Angel cPRP and bone marrow processing system utilizes a proprietary platelet sensor and 1-button automation to prepare customized PRP concentrate from bone marrow aspirate (BMA). Bone marrow is a rich source of platelets, nucleated cells, and progenitor cells. The Angel device is the only one to provide PRP concentrate from BMA with adjustable cellular levels.

Features and Benefits

- › Proprietary platelet sensor system
- › Adjustable platelet concentrations
- › Adjustable white blood cell (WBC) concentrations
- › Flexible processing volume 40-180 mL
- › Each processing kit can process 3 cycles up to 180 mL on the same patient
- › Programmable: Can store up to 30 custom processing protocols
- › Closed system delivers PRP, PPP, and red blood cells (RBCs) into separate, sterile compartments

Mechanism of Action

Bone marrow-stimulating techniques, such as abrasion and microfracturing, have been advocated for over 20 years.¹ Bone marrow is a source of stem cells and progenitor cells that:

- › Differentiate into a variety of tissues (bone, cartilage, tendon, ligament, fat, muscle, nerve)
- › Have a role in the maintenance and repair of several other tissues²

The Angel BMA kit for the Angel system is a convenient and rapid means of concentrating the cellular contents and growth factors in bone marrow aspirate.

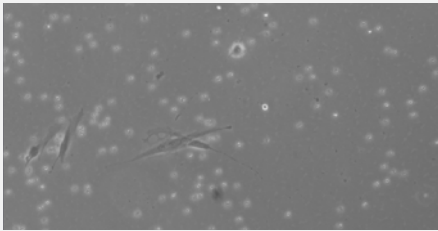
	Platelets ($\times 10^3 / \mu\text{l}$)	Nucleated Cells ($\times 10^3 / \mu\text{l}$)	Hematopoietic Cells ($\times 10^3 / \mu\text{l}$)	Mesenchymal Stem Cells (per mL)*	Neutrophils ($\times 10^3 / \mu\text{l}$) (Total Neutrophils ($\times 10^6$))
BMA**	87.7 $\pm$ 6.4	24.5 $\pm$ 15.6	0.002 $\pm$ 0.001	24.3 $\pm$ 49.4	612.1
Concentrate from BMA**	787.0 $\pm$ 317.6	240.5 $\pm$ 186.6	0.081 $\pm$ 0.056	910.7 $\pm$ 223.5	132.9
Fold Increase**	$\sim 9\times$	$\sim 10\times$	$\sim 33\times$	$\sim 38\times$	$\downarrow 80\%$

* Mesenchymal stem cell counts measured in colony-forming units – fibroblasts in vitro.

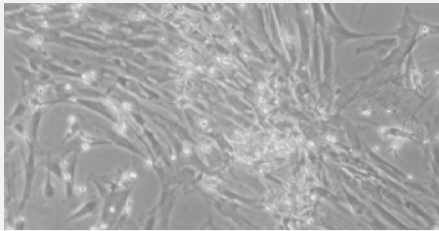
These values are mean values with standard deviation (n = 5) that may differ in some cases.
Starting volume: 40 mL anticoagulated BMA from iliac crest, HCT 15%.
Average concentrate output: 4 mL

** Data on file APT-2569

CFUs After 96 Hours of Incubation Time



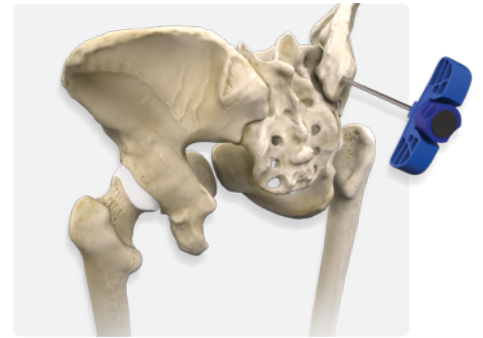
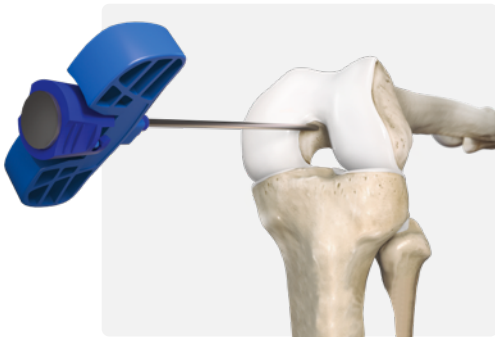
BMA



Concentrate

Harvesting

Bone marrow aspirate (BMA) provides a cell suspension that can be readily processed intraoperatively for immediate implantation. BMA is commonly withdrawn from the iliac crest, but can also be aspirated from the femur, humerus, and the calcaneus.



Preparation



Loading



Centrifugation



Fully automated separation

Application

Concentrated bone marrow aspirate is a bioactive fluid that can be injected directly to a repair site, localizing a specific volume of concentrated bone marrow aspirate to support and facilitate healing. Autograft and allograft, as well as synthetic material, can be mixed with concentrated bone marrow aspirate prior to application to an orthopedic site in order to support ingrowth and resorption.³⁻⁶



Cubes



Chips

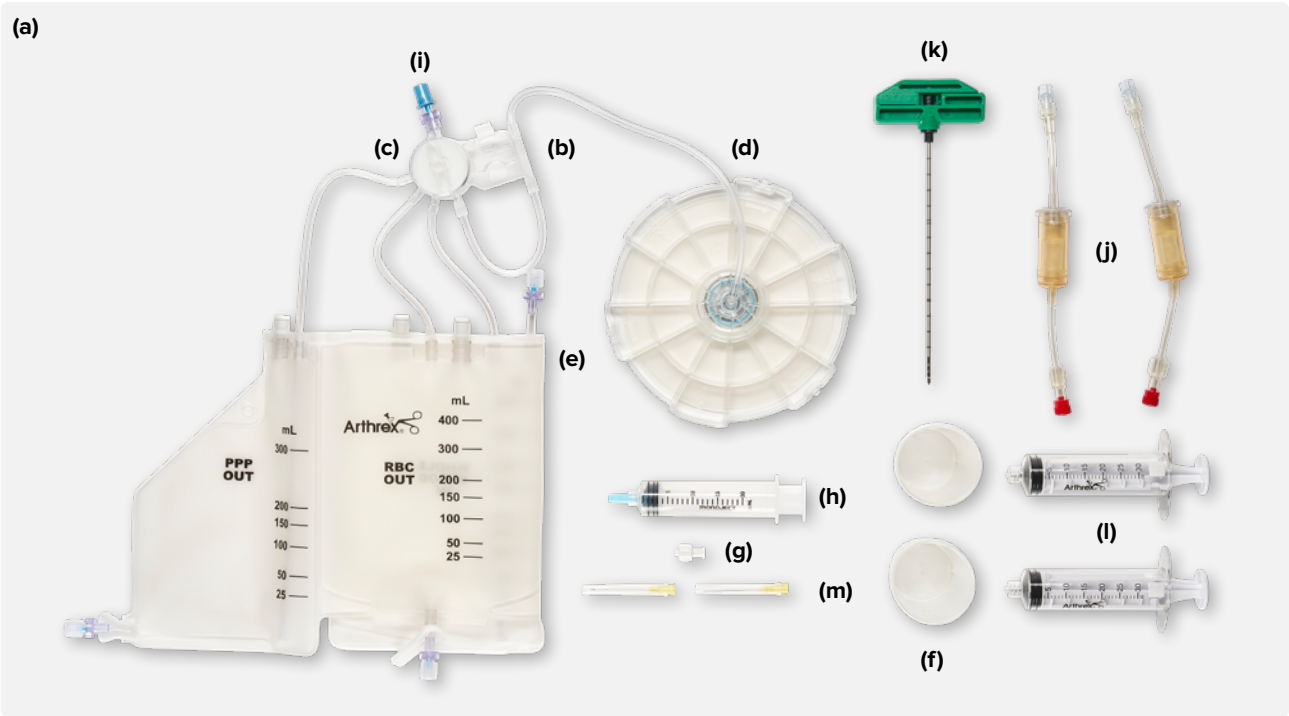


INNOTERE 3D wedges

Ordering Information

Angel® System Centrifuge	
Angel® system	ABS-10066
Angel® System Consumables	
Anticoagulant, ACD-A, 20 mL	SAAV222.G00
Angel® BMA Kit (a) Includes:	ABS-10072
Platelet cuvette (b)	
Valve, rotating (c)	
Separation chamber, variable volume (d)	
Reservoir bag, 3 compartments (e)	
Specimen cup, wrapped, 60 mL (f)	
Luer lock plugs, male-female (g)	
Luer lock syringe, 20 mL (h)	
PRP valve, syringe-activated (i)	
BMA clot filter (j)	
Bone marrow needle, fenestrated (k)	
VacLok syringe, 30 mL (l)	
Needle, hypodermic, 20 ga (m)	
Accessories	
Cart, for centrifuge, 50 cm	KU.5157.800

Please note that not all products advertised in this brochure may be available in all countries.



Thrombinator™ System

For Use With the Angel® cPRP System



Introduction

The Thrombinator system for use with the Angel concentrated platelet-rich plasma (cPRP) system is designed to produce an autologous activation serum at the point of care. Activation serum produced by the Thrombinator system can be used to improve the handling of bone grafts hydrated with platelet-rich plasma. Autologous activation serum improves handling by activating platelets to produce a gel that serves as a binding agent for bone graft material.

The Thrombinator process uses the principles of the clotting cascade to produce an activation serum without the use of harsh chemical reagents such as ethanol. The Thrombinator device design eliminates the need for lengthy incubation times and heating requirements. Autologous activation serum can be produced in as little as 10 minutes from whole blood or platelet-poor plasma at the point of care.

Features and Benefits

- › Rapid preparation, 10-15 minutes
- › Prepare from whole blood (WB) or platelet-poor plasma (PPP)
- › Produces clot in as little as 15 seconds
- › Centrifugation not required
- › Heating step not required

Indications

The Thrombinator system for use with the Angel cPRP system is designed for the preparation of autologous serum from anticoagulated peripheral blood or platelet-poor plasma. This is to be mixed with the PRP and autograft or allograft bone prior to application to a bony defect to improve handling characteristics.

Preparation



Addition of CaCl² and WB or PPP



Incubation at room temperature



Harvesting of autologous thrombin serum

Ordering Information

Thrombinator™ System for Use With the Angel® cPRP System (a)		ABS-10080
Angel® System		
Angel® system		ABS-10066
Angel® processing set		ABS-10064
Anticoagulant, ACD-A, 20 mL		SAAV222.G00
Angel® PRP kit, incl. Angel® processing set		ABS-10071
Angel® BMC kit		ABS-10072
Cart, for centrifuge, 50 cm		KU.5157.800
Accessories		
Delivery needle, fenestrated		ABS-20000
Delivery needle, epidural, Tuohy		ABS-21000
Cannula bending tool		AR-6650
Applicator assembly, 10 cc, 1:1 ratio		SA-3310
Dual spray tip		SA-3660
Blending connector, with single flexible cannula		SA-3673
Blending connector, with mixer		SA-3678

Please note that not all products advertised in this brochure may be available in all countries.



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In-vitro study quantifying various growth factor concentrations of ACP and a competitor product. This study also demonstrates the decrease of leukocytes in ACP and the subsequently low concentration of catabolic growth factors.
- Kisiday JD, McIlwraith CW, Rodkey WG, Frisbie DD, Steadman JR. Effects of Platelet-Rich Plasma Composition on Anabolic and Catabolic Activities in Equine Cartilage and Meniscal Explants. *Cartilage.* 2012;3(3):245-254. doi:10.1177/1947603511433181
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In-vitro study comparing the composition and growth factor concentration of a double-spin and 2 single-spin protocols of PRP preparations, including Arthrex ACP. This study shows that plasma preparations of ACP increase the platelet concentrations $\sim 2.5 \times$ and decrease the concentration of white blood cells by $\sim 9 \times$, which is comparable to an established double-spin protocol.
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- Cerza F, Carni S, Carcangiu A, et al. Comparison between hyaluronic acid and platelet-rich plasma, intra-articular infiltration in the treatment of gonarthrosis. *Am J Sports Med.* 2012;40(12):2822-2827. doi:10.1177/036354651246190
Randomized clinical study to compare the treatment of 4 subsequent intra-articular injections of ACP or hyaluronic acid (HA) on 120 Kellgren-Lawrence grade I - III OA patients. Over the course of 6 months, the WOMAC score of ACP-treated patients improved significantly compared to HA treatment, independent of the OA severity.
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This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes.

A medical professional must always refer to and comply with the relevant product labels and directions for use, including cleaning and sterilization instructions, before using an Arthrex product. This information provided is intended for medical professionals only. Arthrex, as the creator and distributor of its products, does not practice medicine, is not rendering medical or professional advice, and does not recommend any surgical techniques for use on a particular patient. Arthrex strongly recommends that medical professionals are trained in the use of an Arthrex product before using it in a procedure or surgery. The medical professional who performs any surgical procedure is responsible for determining and using the appropriate techniques for surgical procedures on each individual patient.



Arthrex manufacturer, authorized representative, and importer information (Arthrex eIFUs)



US patent information