



Arthrex Angel System[™]

Indication-specific PRP and PRF gel preparations





Arthrex Angel System[™]

The Arthrex Angel System[™] is a revolutionary production system for platelet-rich plasma (PRP) formulations which can be exactly tailored to the specific treatment needs of the patient. The Arthrex Angel System satisfies the three most important requirements for a modern PRP system: Maximum flexibility, easy handling, and a high level of safety.

Maximum flexibility – one system for all PRP applications

No matter which condition needs to be treated with PRP, with the Arthrex Angel System it is possible to tailor the PRP composition to the patient in question. The Arthrex Angel System gives the user control over the platelet, neutrophil and erythrocyte (RBC) levels in the PRP, thereby making it possible to match them to the indication and needs of the patient. So, no more compromises have to be made in PRP therapy, and the patients get the best solution possible - with just one system!

When the Arthrex Angel System is combined with Arthrex activAT it is also possible to prepare platelet-rich fibrin (PRF) gel, thereby expanding the range of applications.

Easy handling – PRP preparation with just the push of a button

No more cumbersome manual separation and transfer of the platelet-rich plasma fraction, where both the composition and yield of the PRP depended on the skill of the user. The Arthrex Angel System allows automatic push-button separation processing!

High level of safety - "Closed" PRP preparation

Needles and open containers have no place in PRP preparation. The dangers of needlestick injury and microbial contamination are just too high! After automatic and fully closed separation in the Arthrex Angel System the various fractions of the blood are collected in separate sterile containers and may be used directly or withdrawn through valves.

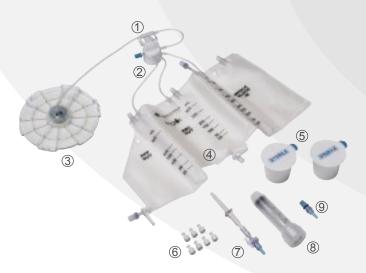


Arthrex Angel System

- (4) Sensor
- 2 Pump rotor

(1)

- 3 Centrifuge well
- Valve assembly driver
- (5) Touch screen display



Angel processing set

- Platelet cuvette
- 2 Rotating valve
- 3 Variable volume separation chamber
- ④ Three-compartment reservoir bag
- 60 ml wrapped (5) specimen cup

- 6Male-female luer lock plugs
- ⑦ Whole blood spike adapter
- (8) 20 ml luer lock syringe
- (9) Svringe-activated PRP valve

Maximum flexibility

The Arthrex Angel System[™] allows the preparation of patientspecific PRP formulations. The user can choose between various platelet, leukocyte (WBC), and RBC concentrations and thereby tailor the PRP treatment to the specific needs of the patient. This is made possible by the proprietary 3-sensor technology which utilizes the differences in light absorption of the various cell types.

Once the two-step centrifuge process fully automatically fractionates the whole blood into RBCs, platelet-poor plasma (PPP), and an intermediate layer (buffy coat) rich in platelets and leukocytes, the various phases pass by the sensor. Since the blood components differ in their light absorption characteristics, the sensor can not only differentiate between the individual phases but can also collect various subfractions in a precise and reproducible fashion. Since the elements of the buffy coat are distributed nonhomogeneously at the transition to the RBC-enriched fraction, it is possible to vary the PRP composition by altering the preset hematocrit*:

Hematocrit	2%	7 %
PRP volume	3 ml	3 ml
Platelet level versus whole blood	4.6x	6.8 x
Neutrophil level versus whole blood	0.3x	1.2x

* These values are averages, which may differ in some cases. Starting volume was always 60 ml of anticoagulated whole blood.

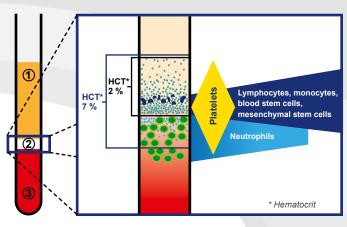
The Arthrex Angel System can handle volumes from 40 ml to 180 ml in a single cycle. Because the Angel processing set may be used up to three times in a row on the same patient, a maximum of 540 ml of patient blood may be processed with one processing set. The combination with Arthrex activAT offers the opportunity to prepare autologous thrombin. With the use of thrombin, the user can process the PRP into platelet-rich fibrin gel (PRF gel) ready for injection or spraying.

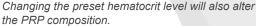
PRP – mechanism of action

Platelets are activated outside the blood stream and release proteins such as growth factors. These growth factors appear to act synergistically and support the healing process.^{1, 2, 3}

- Initiation of the proliferation and differentiation of different cell types (e.g., osteoblasts and chondrocytes)⁴
- Improved matrix formation (e.g., collagen and proteoglycan production)
- · Stimulation of angiogenesis and chemotaxis

- Adjustable platelet (~1 18x whole blood) and neutrophil levels
- Processing volume: 40 180 ml
- Platelet-rich gel (together with Arthrex activAT)





- ① Platelet-poor plasma (PPP)
- ② Buffy Coat
- ③ Erythrocyte-enriched (RBC) fraction

The applications for PRP and PRF gels include:

Orthopedics

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

Plastic, Reconstructive & Cosmetic Surgery

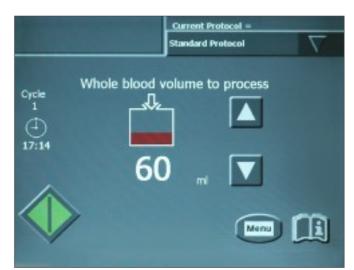
- · Facial, neck, and eyebrow lifts
- Breast reconstruction
- Abdominoplasty
- Facial reconstruction
- Fat transfer

Easy handling

The Arthrex Angel System[™] has an intuitive user interface which allows the operator to prepare the desired PRP formulation at the push of a button. Unlike other systems, where syringes have to be replaced or buffy coats suspended, the Arthrex Angel System is fully automatic. Once the volume to be processed and the hematocrit have been entered, the Arthrex Angel System takes over the processing. The user may store up to 30 customized processing protocols, which can be retrieved at the push of a button. A built-in algorithm automatically matches both the duration and speed of centrifuge rotation to the preset conditions, without the operator having to perform complex calculations.

The Arthrex Angel System comes with a tutorial which familiarizes the operator with the setup process of the Angel processing set. This animated step-by-step tutorial guides the user through the setup of the Angel processing set and illustrates the necessary maneuvers. In addition, once an error message has been activated the help pages built into the system support the user in solving the problem at hand. The user can, of course, choose between numerous languages.

- Fully automatic PRP preparation (at the push of a button)
- Programmable, can store up to 30 customizable processing protocols
- · Preassembled processing set



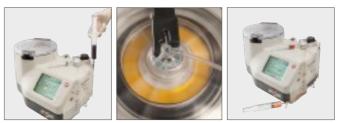
Intuitive user interface

High level of safety

Since the Angel processing set comes sterile and preassembled, the patient is protected against the risks of possible microbial contamination and the operator against any contact with the patient's blood. Mounting of the set requires only a few easy and simple steps. Once the set has been loaded with the patient's blood, the closed processing cycle runs automatically. The various fractions are collected in separate containers, which are equipped with syringe-activated valves (PPP and RBC chambers) or may be used directly (PRP Luer syringe).

The patient data from each processing cycle can be saved. Subsequently, these data can be transferred quite easily since the Arthrex Angel System is equipped with both a USB as well as a LAN port.

- Separate sterile containers for PRP, PPP and RBC collection
- USB and LAN connection for easy transfer of patient data



PRP preparation from whole blood

activAT

For PRF Gel Production

Combined with the Arthrex Angel System[™], Arthrex activAT allows the preparation of platelet-rich gel. Arthrex activAT enables the extraction of autologous thrombin from the platelet-poor plasma (PPP) "byproduct" obtained during whole blood processing. When added to the harvested PRP, thrombin activates the platelets and initiates the formation of the fibrin matrix.

Use of the platelet-rich gel may facilitate the release of growth factors at the application site over a period of several days.

With Arthrex activAT the preparation of autologous thrombin is fast and easy. In less than 30 minutes, 5-7 ml of autologous thrombin will be extracted from 12 ml of PPP. Due to the high level of thrombin activity, 1 ml of thrombin will suffice for about 10 ml of PRP (ratio approx. 1:10). Therefore, when combined with the Arthrex Angel System a single Arthrex activAT kit will yield about 50-70 ml of platelet rich gel. The short coagulation period (10-20 seconds) markedly reduces waiting time and ensures that the PRP will adhere to the application site.

Just as with the PRP prepared with the Arthrex Angel System, the thrombin prepared with Arthrex activAT is tolerated very well by the patients since it has been prepared from their own blood.

You will find the details on both the Arthrex Angel System and Arthrex activAT in the respective Instructions for Use.

Additional Applications

- Tissue sealing
- Tissue adherence
- Oozing blood
- Tissue transplant augmentation



- ① Processing syringe
- ② Transfer syringe
- ③ Reagent syringe
- ④ Female connector
- 5 Wrapped 60 ml cup

Arthrex offers various applicators and needles for PRF gel application:



Viscous-Gel high viscosity ratio applicator with 10 cm mixing tip



Viscous-Spray II applicator with non-clogging mixing/ spray tip



Viscous-Spray applicator with 3 cm mixing/spray tip





Fenestrated delivery needle, 17 G

Ordering Information

Arthrex Angel System [™] Angel processing set Arthrex activAT (thrombin processing kit) Anticoagulant ACD-A 20 ml Angel blood access kit (incl. ACD-A) Viscous-Gel high viscosity ratio applicator with 10 cm mixing tip Viscous-Spray low viscosity ratio applicator with 3 cm mixing/spray tip Viscous-Spray II applicator with non-clogging mixing/spray tip Fenestrated delivery needle Tuohy delivery needle (epidural needle) Cannula bending tool

ABS-10066 ABS-10064 ABS-10069 SAAV222.G00 ABS-10068 ABS-10050 ABS-10051 ABS-10052 ABS-20000 ABS-21000 AR-6650

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- 4. Graziani F, et al: The In Vitro Effect of Different PRP Concentrations on Osteoblasts and Fibroblasts. Clin Oral Implants Res. 2006; 17(2): 212-219.





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This brochure is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. The contents of this brochure do not constitute a recommendation for specific treatment. As part of this professional usage, the medical professionals must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professionals 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. Within the framework of medical freedom and based on the risk-benefit analysis for the patient in question, the treating physician bears sole responsibility for the appropriateness of treating the patient with the Arthrex Angel System[™]. A manufacturing authorization is not required, but notification of state agency (might differ from country to country).