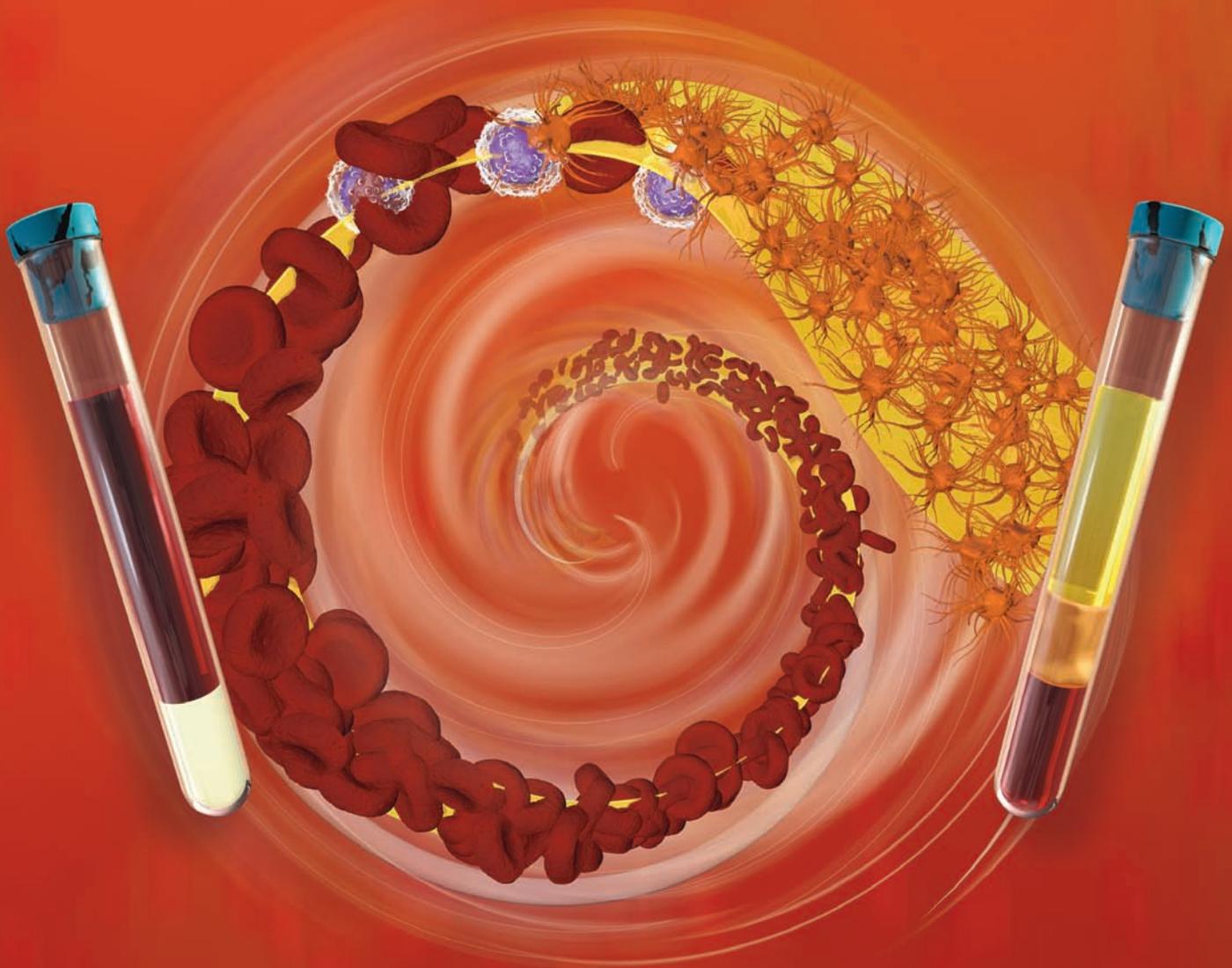


RegenKit® THT

Autologous Platelet Rich Plasma (A-PRP)

The Power in You.™



RegenKit THT

Autologous Platelet Rich Plasma (A-PRP)

The RegenKit THT is designed to be used for the safe and rapid preparation of autologous platelet-rich plasma (A-PRP) from a small sample of blood at the patient's point of care. After preparation, the A-PRP can be applied to an orthopaedic surgical site, as deemed necessary by clinical use requirements.



Features and Potential Benefits¹

Simplicity

Single tube preparation, in combination with a minimal 8 minute centrifuge spin time, helps maximize efficiency in the office and O.R. setting. A reduction in the number of steps for platelet preparation can provide simplicity for the medical staff.

Low Blood Volume Required

The RegenKit THT allows for a reduced blood draw volume of 8 cc.

Optimum Platelet Recovery

The RegenKit THT is designed to provide > 90% platelet recovery as per Regenlab 510 K data, while delivering 4-5cc of concentrated PRP. Platelet concentration in PRP is 1.7x greater than in whole blood.

Consistent Isolation of Platelet Concentrate and Plasma

The RegenKit THT uses a physical barrier (thixotropic gel) to separate red blood cells from whole blood to produce a platelet-rich plasma preparation and help minimize potential operator errors.

Leukocyte At Physiological Levels

The RegenKit THT allows the level of leukocytes to be maintained at physiological levels.

Red Cell Depletion

The level of Red Blood Cells is drastically reduced, with 95% of RBC's removed from whole blood.

Kit Components

- 1 Regen THT
- 1 Safety-Lok™ blood collection set
- 1 Vacutainer® holder
- 1 18 G red needle
- 1 27 G grey needle
- 1 5-ml Luer-Lok™ syringe
- 1 Vacutainer® blood transfer device



SAFETY-Lok™ blood collection set (luer adapter)



Vacutainer® Holder



27 G grey needle



Regen™ THT tube



Vacutainer® blood transfer device



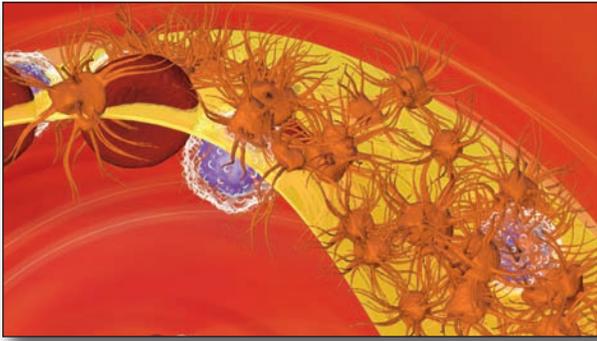
18 G red needle



5-ml Luer-Lok™ syringe



Platelet-Rich Plasma - Science Matters



Platelet-Rich Plasma - (PRP)^{2, 3, 4}

- Defined as plasma solution with a platelet concentration over whole blood baseline.
- PRP preparation systems have been designed to produce a plasma solution rich in platelets and proteins.
- Processes used to concentrate platelets may result in different recovery levels of platelets from whole blood, depletion levels of red blood cells, amounts of leukocytes (white blood cells), and different viability and potency of platelets.

Platelets (Thrombocytes)⁵

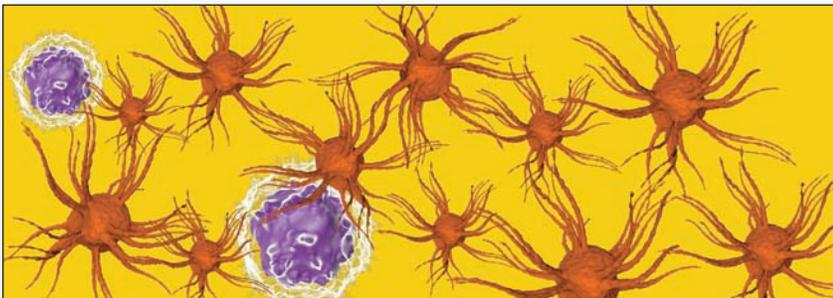
- Are the main component of PRPs and play a central role in hemostasis and tissue healing.
- Platelets are the architects of tissue healing as their presence to an injury site initiates and guides the healing process.
- When activated, platelets change shape and exhibit stickiness, while increasing their surface area to attach and spread over the injury site. Clot formation then occurs, providing a fibrin-based bioscaffold which sustains a healing environment.
- During the clot formation process, platelets degranulate and release growth factors (VEGF, PDGF, TGF- β , FGF, EGF) which participate in and enhance the healing process.
- In addition to releasing growth factors, platelet degranulation also produces a multitude of bioadhesive proteins and of bioactive factors, such as fibrinogen, fibronectin and vitronectin, which are all critical to the healing process and the recruitment of cells.

Plasma contains biological factors and proteins involved in healing, including growth factors (IGF, HGF). Leukocytes (white blood cells) are responsible primarily for defending the body against infection, but also serve other functions during tissue healing. These cells, when present in suitable concentrations, are key players during the initial inflammation phase of tissue healing, protect the body against infection, remove undesired organisms, produce antibodies, and/or are involved in allergic response.

Leukocytes^{3, 4, 6, 7} are nucleated cells and therefore can release growth factors which in turn may be beneficial to the healing process. The following factors present in PRP and their physiologic effects on healing have been identified.

PRP Factors and their Physiologic Effects

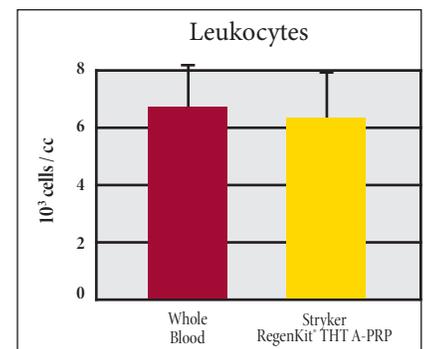
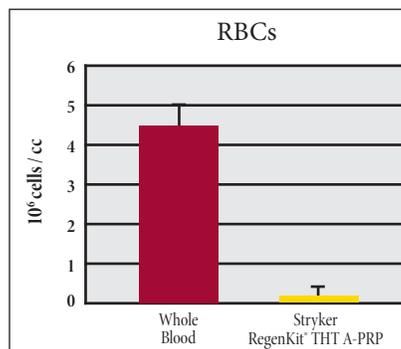
FACTOR	FULL NAME	FUNCTION	SOURCE
VEGF	Vascular Endothelial Growth Factor	Angiogenesis; Cell migration & proliferation	Platelet
PDGF	Platelet Derived Growth Factor	Angiogenesis; Cell migration & proliferation Tissue matrix formation	Platelet
TGF- β 1	Transforming Growth Factor	Key regulator in cell behavior; Collagen synthesis Cell differentiation	Platelet Leukocyte
FGF	Fibroblast Factor Growth	Angiogenesis Cell migration & proliferation	Platelet Leukocyte
EGF	Epidermal Growth Factor	Cell migration, proliferation & differentiation	Platelet Leukocyte
IGF	Insulin-like Growth Factor	Cell migration, proliferation & differentiation	Plasma Leukocyte
HGF	Hepatocyte Growth Factor	Angiogenesis; Antifibrosis Cell proliferation	Plasma Leukocyte
Fibrinogen Fibronectin Vitronectin	Bioadhesive Proteins	Fibrin clot formation; Chemotaxis Cell adhesion, migration, proliferation, & differentiation	Platelet



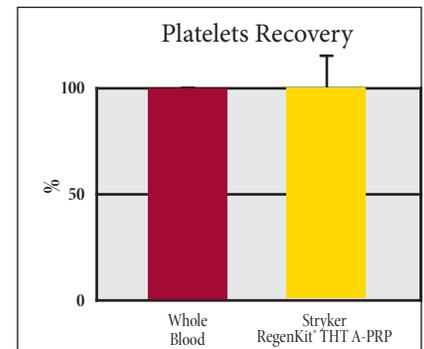
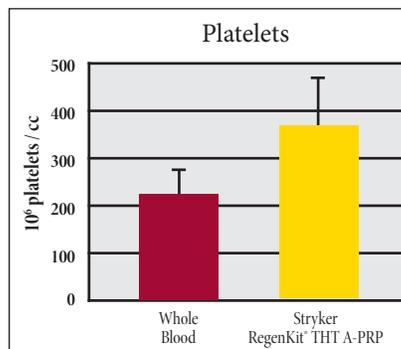
RegenKit THT - Autologous Platelet Rich Plasma (A-PRP)^{1, 7, 10}

- The RegenKit THT A-PRP preparation is designed to deliver an increased concentration of bioactive factors and proteins through the concentration of platelets from whole blood.
- The PRP prepared using the RegenKit THT is a platelet-rich plasma preparation with high platelet recovery and viability, a physiological level of leukocytes, and contains the entire plasma component of blood, which is rich in growth factors, such as IGF-1, and proteins, such as fibrinogen, critical in the healing process.
- The RegenKit THT A-PRP preparation is produced with one centrifugal “soft spin” (1500g).
- The characteristics and performance of the RegenKit THT A-PRP were measured from the venous blood of 60 healthy donors and was compared to whole blood. For each donor, 8 mL of venous blood was drawn and centrifuged in a Regen THT tube for 8 minutes at 1500g. The volume of PRP obtained was 4.9 cc, with a physiological pH of 7.60.

- The level of **RBCs** was drastically reduced, with 95% of RBCs removed from whole blood, while the level of **Leukocytes** was maintained at physiological levels of that of whole blood. RBC's have been shown to be pro-inflammatory in tissue healing, likely due to their high level of iron. Leukocytes positively influence the inflammatory phase during tissue healing and may modulate infection at the tissue site.



- **Platelet concentration** was 1.7x higher than in whole blood. **Platelet recovery** was total (100%), representative of the gentle, but efficient process parameters used during handling and centrifugation.



- **Platelet viability, integrity and stability** of the PRP after preparation from 12 healthy donors using the RegenKit THT product was demonstrated as measured by increase in P selectin levels after activation with ADP, minimal hypotonic stress response, and aggregation after activation with collagen. These results were achieved at zero times up to 4 hours after the A-PRP was prepared and further demonstrated the stability of the PRP preparation.

References

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Instructions For Use

For additional details please refer to the **RegenKit THT Instructions for Use and Centrifuge Manual**

1

Draw Blood

Using the butterfly needle and the blood collection set, draw 8cc of venous blood into the Regen THT tube. Invert the filled tube 5 times for mixing.



2

Load and Balance

Insert the Regen THT tubes into opposite sides of the centrifuge. If using an odd number of tubes then the balancing tube needs to be utilized.



3

Spin

Close the lid and select the appropriate centrifuge settings for 1,500 RCF (Stryker Universal Centrifuge = 3,400 RPM) and 8 minutes. Start centrifuge.



4

Platelet Preparation

After centrifugation, gently invert the Regen THT tube 5 to 10 times. Collect the supernatant fraction using the syringe equipped with the blood transfer device. The A-PRP is ready for use.



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EMS Equipment

PART NUMBER	DESCRIPTION
8495-9-001	RegenKit THT1
8495-9-010	Stryker Universal Centrifuge
8495-9-998	Balancing Tube 3-Pack

325 Corporate Drive
Mahwah, NJ 07430
t: 201 831 5000

www.stryker.com

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