



PRP® & CELL THERAPY SPECIALISTS

RegenLab® A-PRP® technology

**SWISS R&D AND MANUFACTURER
IN BIOTECHNOLOGY**

RegenLab® is recognized as a leading provider of a patented technology to produce autologous platelet rich plasma. The technology processes the patient's own blood and isolates concentrated platelets and proteins for indications in various medical disciplines.

The RegenKit®-BCT product family is indicated by the U.S. FDA for the safe and rapid preparation of autologous platelet rich plasma from a small sample of blood at the patient's point of care. The platelet rich plasma is mixed with autograft and/or allograft bone prior to application to a bony defect for improved handling characteristics. The RegenKit®-BCT product family is for single use only.

Medical Devices class II



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WHAT IS A-PRP[®] ?

The patient's platelet concentrate prepared with RegenKit[®]

Platelets are key factors in hard and soft tissue repair mechanisms. They provide the essential growth factors FGF, PDGF, TGF- β , EGF, VEGF, and IGF that are involved in stem cell migration, differentiation and proliferation. The stimulation of fibroblasts and endothelial cells induces new extracellular matrix deposition and neo-vascularization.

Plasma is essential for cell survival as it contains nutrients, vitamins, hormones, electrolytes and proteins. Proteins are key molecules for the coagulation process and the formation of the fibrin polymer that will serve as a scaffold for cell migration, differentiation and proliferation.

IDEAL PLATELET CONCENTRATION

The Regen[™]-BCT tube prepares 5 to 6 ml of autologous platelet rich plasma with a platelet recovery greater than 80% and a concentration factor of 1.6-fold. Although the system is technically capable of producing significantly higher platelet concentrations, it is not what some research shows to be the most beneficial for clinical use. More and more studies demonstrate that concentrations of platelets 1 to 3 times over the baseline show more robust healing rates than those with concentrations of 3 to 8 times the baseline¹.

Some studies even showed that too high platelet concentrations may actually have negative effects. In an in vivo study², it was shown that highly concentrated platelet preparations had an inhibitory influence on osteoblast activity, probably due to unwanted inhibitory and cytotoxic effects of growth factors at such high concentrations. Similarly, an in vitro study³ demonstrated that platelet concentrations over 2.5-fold resulted in a reduction in proliferation and a suboptimal effect on osteoblast function.

WHITE BLOOD CELLS IN TISSUE REGENERATION

White blood cells are strongly reduced (> 85% depletion) with the Regen[™] PRP[®] system.

The role of white blood cells (WBC) in healing is controversially discussed among physicians. To address this concern scientifically, WBC subsets, granulocytes and mononuclear cells, need to be looked at individually. Granulocytes, and more specifically neutrophils, are the front-line defenders against invading pathogens and are associated with the inflammatory response. They release a large variety of highly active antimicrobial substances and proteases. Uncontrolled release of these factors can cause severe damage to the tissue, delay healing rates and increase the risk of scarring⁴. Thanks to the Regen[™] PRP[®] system, more than 96% of the granulocytes are removed from autologous platelet rich plasma. The few white blood cells still present in autologous platelet rich plasma are mostly mononuclear cells (lymphocytes and monocytes). These two cell types are also involved in the immune response, but have also been shown to support the healing process^{5,6}.

REFERENCES:

- 1- Rappl LM et al. Effect of platelet-rich plasma gel in a physiologically relevant platelet concentration on wounds in persons with spinal cord injury. *Int Wound J* 2011; 8:18.7–195.
- 2- Weibrich G. et al., Effect of platelet concentration in platelet-rich plasma on peri-implant bone regeneration. *Bone* 2004; 34:665-671.
- 3- Graziani F. et al., The in vitro effect of different PRP concentrations on osteoblasts and fibroblasts. *Clin. Oral. Impl. Res.* 17, 2006; 212–219.
- 4- Brubaker A.L. et al. Neutrophils and natural killer T cells as negative regulators of wound healing. *Expert Rev. Dermatol.* 2011; 6(1), 5–8
- 5- Barbul, A. et al. Wound healing in nude mice: a study on the regulatory role of lymphocytes in fibroplasia. *Surgery* 1989;105(6): 764-769.
- 6- Brancato S.K. and Albina J. E. Wound Macrophages as Key Regulators of Repair. *Am J Pathol* 2011, Vol. 178, No. 1, 19-25

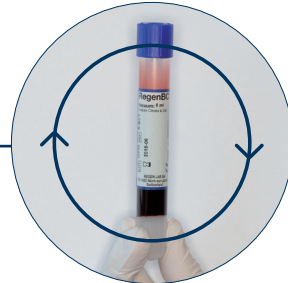
RegenPlasma®

REGENKIT®-BCT & REGENKIT®-THT TECHNOLOGIES

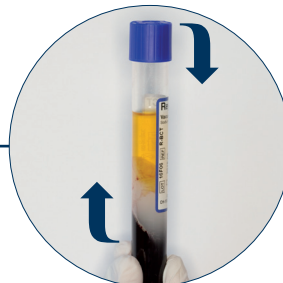
The simple, safe and efficient point of care preparation of autologous platelet rich plasma.



Blood Collection



Centrifugation



Platelet Resuspension



Ready to Use

• • •

SYSTEM SPECIFICATIONS

Properties

| | Cellular element recovery (%) and concentration factor (x) compared to baseline values in peripheral blood | | | | | | |
|-----------------|--|-----------------|-------------------|-------------------|----------------|----------------|----------------|
| | Platelets | Red blood cells | White blood cells | Mononuclear cells | Lymphocyte | Monocyte | Granulocyte |
| RegenBCT | ~ 80% 1.6x | <0.3% 0.007x | 10-13% 0.2x | 20-30% 0.5x | 25-35% 0.6x | ~ 10% 0.2x | 3.5% 0.06x |
| RegenTHT | ~95% 1.7-1.8x | <1% 0.011x | 30-40% 0.6x | 70-80% 1.3x | 70-75% 1.4x | 50-55% 0.9x | 10-15% 0.3x |

The performance tests were carried out according to the U.S. FDA requirements for platelet rich plasma medical devices. Platelet rich plasma samples were prepared and tested using the blood of 60 volunteers (33 women and 27 men, between 18 to 67 years old).

Performance Characteristics

The Regen BCT tubes collect 10mL of blood and prepare an average of 5.5mL of leukocyte poor PRP.

The RegenTHT tubes collect 8mL of blood and prepare an average of 4.5mL of a PRP enriched in MNC (lymphocytes and monocytes) but poor in granulocytes.

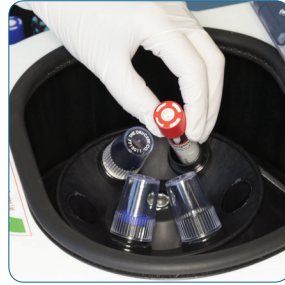


REGENKIT®- BCT PLUS FAMILY KITS TECHNOLOGY

The simple, safe and efficient point of care preparation of autologous thrombin serum.



Blood Collection



Centrifugation



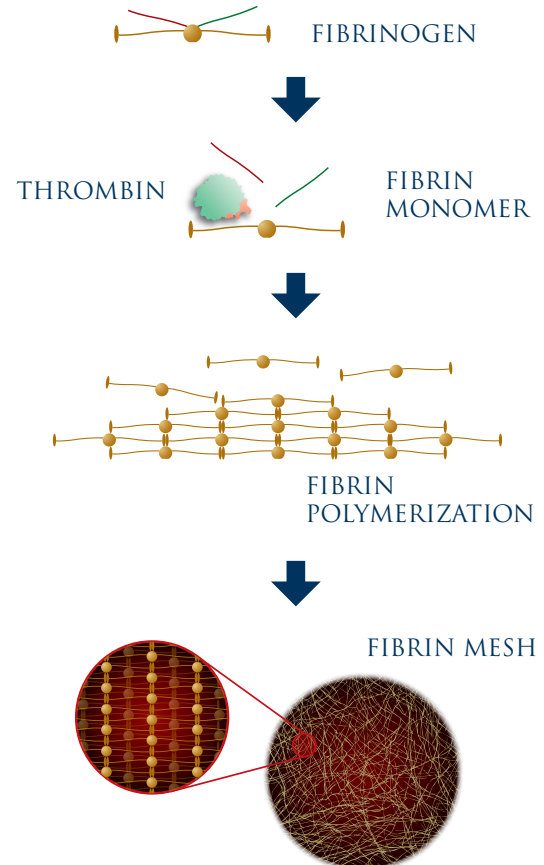
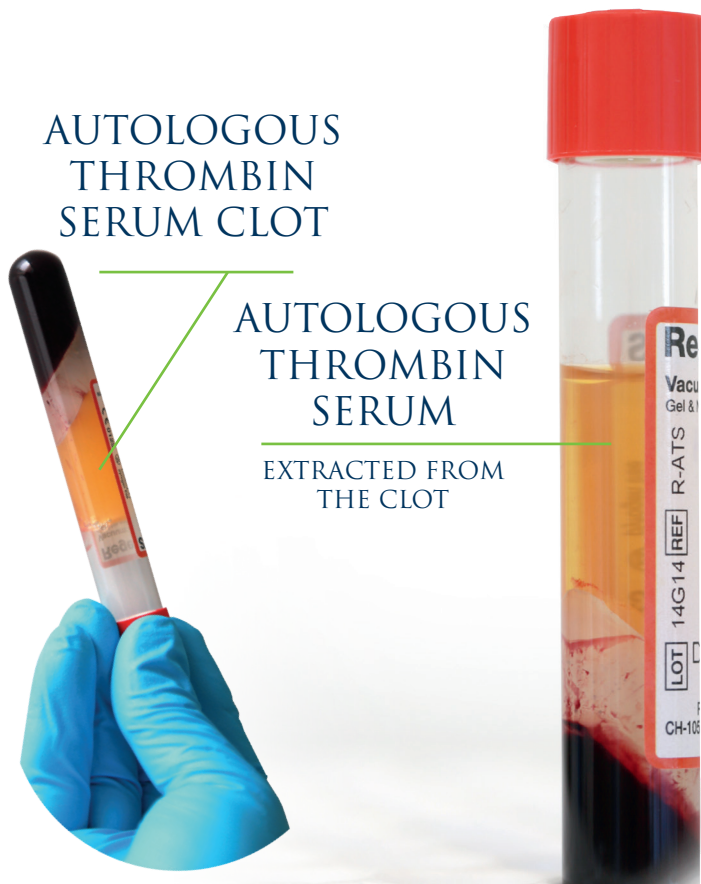
Autologous Thrombin Serum



Autologous Thrombin Serum Extraction

The Regen™-ATS tube supplied in the RegenKit®-BCT Plus product family is used for the preparation of autologous thrombin serum. The coagulation process is 100% natural and does not require any exogenous chemical activation. Thrombin is the enzyme that converts soluble fibrinogen to fibrin monomers which polymerize to form the clot.

Addition of autologous thrombin serum to autologous platelet rich plasma restarts the coagulation process in a physiological manner. This natural process induces the formation of three-dimensional fibrin matrix in which the platelets are entrapped. This allows a long-lasting growth factor delivery at the treatment site and the matrix serves as scaffold for new tissue reconstruction.



REGENKIT®- BCT PLUS FAMILY KITS TECHNOLOGY



The RegenKit®-BCT Plus Family Kits contain devices (Regen™-BCT and Regen™-ATS tubes) for the preparation of autologous platelet rich plasma and its natural activator, the thrombin serum. Both products are 100% autologous and prepared in a three step, sterile, and closed system. The preparation process is safe, reliable and efficient for patient use.

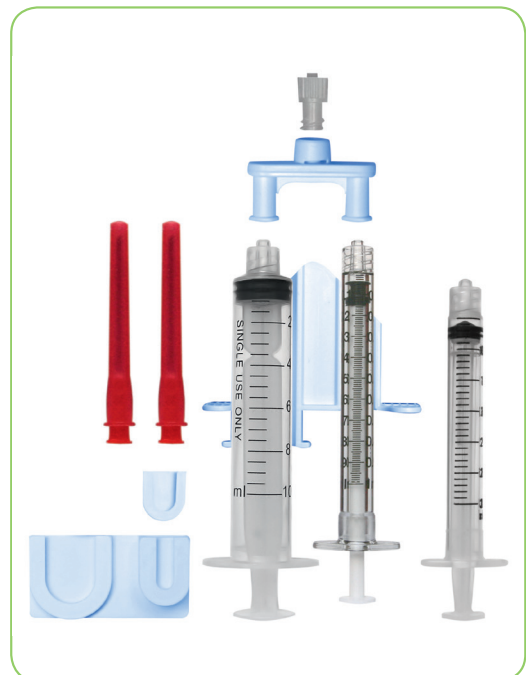


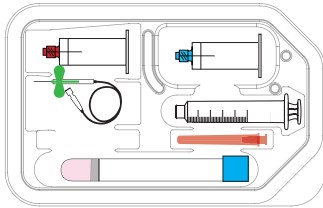
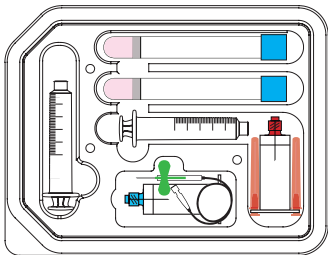
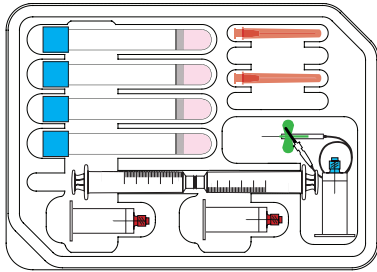
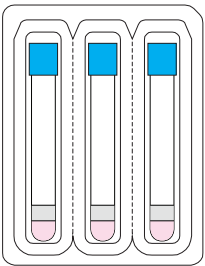
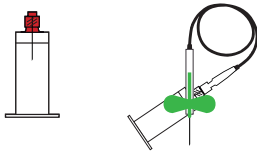
REGEN™ SPRAY APPLICATOR

The Regen™ Spray Applicator enables the application of autologous platelet rich plasma combined with its natural activator, the autologous thrombin serum. The spray applicator is a dual syringe system, allowing the mixing of the two solutions to be applied in a 10:1 or 10:3 ratio.



REF: R-A/NAC1



| Regen™ Product Line | Reference | Description | Set/Component |
|---|-----------------|---|---|
| RegenKit®-BCT-1 1 Safety-Lok™ Butterfly needle 1 Collection holder 1 Regen®BCT tube 1 Transfer device 1 Transfer needle 1 x 5 ml Luer-Lok™ syringe | RK-BCT-1 | RegenKit®-BCT-1 is designed to prepare 5-6 ml of autologous platelet rich plasma. |  |
| RegenKit®-BCT-2 1 Safety-Lok™ Butterfly needle 1 Collection holder 2 Regen®BCT tubes 1 Transfer device 2 Transfer needles 2 x 5 ml Luer-Lok™ syringes | RK-BCT-2 | RegenKit®-BCT-2 is designed to prepare 10-12 ml of autologous platelet rich plasma. |  |
| RegenKit®-BCT-4 1 Safety-Lok™ Butterfly needle 1 Collection holder 4 Regen®BCT tubes 2 Transfer devices 2 Transfer needles 2 x 5 ml Luer-Lok™ syringes | RK-BCT-4 | RegenKit®-BCT-4 is designed to prepare 20-24 ml of autologous platelet rich plasma. |  |
| RegenKit®-BCT-3 3 Regen®BCT Tubes | RK-BCT-3 | The RegenKit®-BCT-3 contains three individually packaged Regen®BCT tubes. Each tube is designed for the preparation of 5-6 ml of autologous platelet rich plasma. |  |
| Accessories Set 3 Safety-Lok™ Butterfly needles 3 Transfer devices | BCA-SET3 | Blood collection set for Regen Lab tubes. |  |

The RegenKit®-BCT Family Kit is designed to be used for the safe and rapid preparation of autologous platelet rich plasma from a small sample of blood at the patient's point of care. The platelet rich plasma is mixed with autograft and/or allograft bone prior to application to a bony defect for improved handling characteristics. The RegenKit®-BCT Family Kit are for single use only.

FDA clearance number BK 110061, comply with 21CFR820

Manufactured in accordance with Quality System Regulations and ISO 13485, CE0086

RegenKit®-BCT-1 (RK-BCT-1)

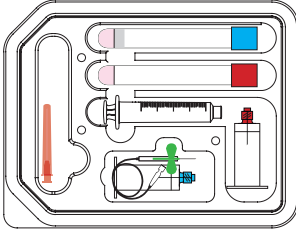
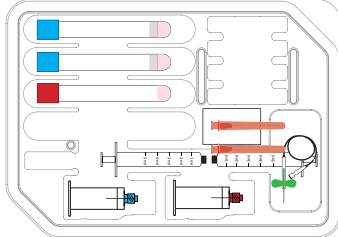
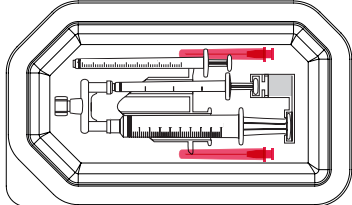
RegenKit®-BCT-2 (RK-BCT-2)

RegenKit®-BCT-3 (RK-BCT-3)

RegenKit®-BCT-4 (RK-BCT-4)

RegenLab® Intellectual Property Rights as Core Assets: www.regenlab.com/patents

U.S. patents US9833478 and US8529957

| Regen™ Product Line | Reference | Description | Set/Component |
|--|-------------------------|---|---|
| <p>RegenKit®-BCT-1 Plus</p> <p>1 Safety-Lok™ Butterfly needle 1 Collection holder 1 Regen®BCT tube 1 Regen®ATS tube 1 Transfer device 1 Transfer needle 1 x 5 ml Luer-Lok™ syringe</p> | <p>RK-BCT-1A</p> | <p>RegenKit®-BCT-1 Plus is designed for the preparation of autologous platelet rich plasma and autologous thrombin serum.</p> |  |
| <p>RegenKit®-BCT-2 Plus</p> <p>1 Safety-Lok™ Butterfly needle 1 Collection holder 2 Regen®BCT tubes 1 Regen®ATS tube 1 Transfer device 2 Transfer needles 2 x 5 ml Luer-Lok™ syringes</p> | <p>RK-BCT-2A</p> | <p>RegenKit®-BCT-2 Plus is designed for the preparation of autologous platelet rich plasma and autologous thrombin serum.</p> |  |
| <p>Regen™ Spray Applicator Ratio 10:1 or 10:3</p> <p>2 transfer needles 1 10 ml Luer lock syringe 1 1ml Luer lock syringe 1 3ml Luer lock syringe 1 Nozzle for spray application 1 Double piston stopper 1 Applicator syringe holder 1 Luer lock connector 1 10:3 ratio adapter</p> | <p>R-A/NAC-1</p> | <p>Regen™ Spray Applicator 10:1 & 10:3 is designed to obtain an autologous biological glue by combination of autologous platelet rich plasma and autologous thrombin serum.</p> |  |

Drucker 642 VFD Plus

The Drucker 642 VFD Plus is a continuous-duty, electrically controlled, fixed-angle centrifuge with a lid safety interlock system. The unit is controlled by two electronic push-button timers that have been preset for five (5) minutes 1,500RCF and nine (9) minutes 1,500RCF, for precise spin times and ease of use.



The RegenKit®-BCT Plus Family Kits are designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) and autologous serum from a small sample of blood at the patient's point of care. The combined PRP and autologous serum are mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics. The RegenKit®-BCT Plus Family Kits are for single use only.

FDA clearance number BK 120066, comply with 21CFR820

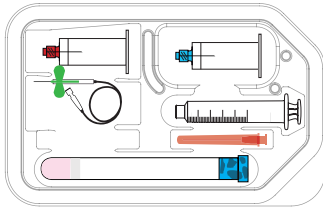
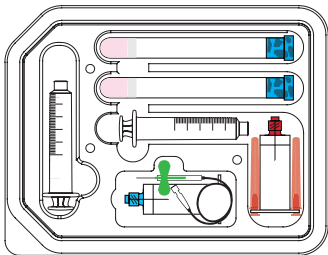
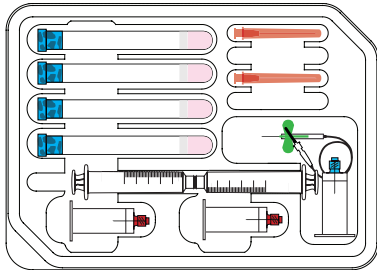
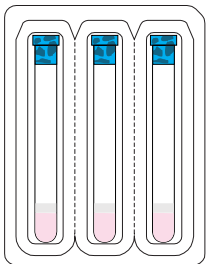
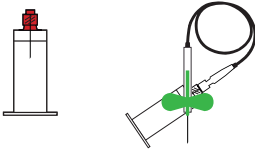
Manufactured in accordance with Quality System Regulations and ISO 13485, CE0086

RegenKit®-BCT-1 Plus (RK-BCT-1A)

RegenKit®-BCT-2 Plus (RK-BCT-2A)

Regen™ Spray Applicator is a sterile, single use device for application of two non-homogeneous fluids or liquids to a treatment site as deemed necessary by the clinical use requirements. Ref: R-A/NAC1 / FDA clearance number K122122

RegenLab® Intellectual Property Rights as Core Assets: www.regenlab.com/patents
 U.S. patents US9833478 and US8529957

| Regen™ Product Line | Reference | Description | Set/Component |
|---|-----------------|---|---|
| RegenKit®-THT-1 1 Safety-Lok™ Butterfly needle 1 Collection holder 1 Regen®THT tube 1 Transfer device 1 Transfer needle 1 x 5 ml Luer-Lok™ syringe | RK-THT-1 | RegenKit®-THT-1 is designed to prepare 4-5 ml of autologous platelet rich plasma. |  |
| RegenKit®-THT-2 1 Safety-Lok™ Butterfly needle 1 Collection holder 2 Regen®THT tubes 1 Transfer device 2 Transfer needles 2 x 5 ml Luer-Lok™ syringes | RK-THT-2 | RegenKit®-THT-2 is designed to prepare 8-10 ml of autologous platelet rich plasma. |  |
| RegenKit®-THT-4 1 Safety-Lok™ Butterfly needle 1 Collection holder 4 Regen®THT tubes 2 Transfer devices 2 Transfer needles 2 x 5 ml Luer-Lok™ syringes | RK-THT-4 | RegenKit®-THT-4 is designed to prepare 16-20 ml of autologous platelet rich plasma. |  |
| RegenKit®-THT-3 3 Regen® THT Tubes | RK-THT-3 | The RegenKit®-THT-3 contains three individually packaged Regen®THT tubes. Each tube is designed for the preparation of 4-5 ml of autologous platelet rich plasma. |  |
| Accessories Set 3 Safety-Lok™ Butterfly needles 3 Transfer devices | BCA-SET3 | Blood collection set for Regen Lab tubes. |  |

The RegenKit®-THT is designed to be used for the safe and rapid preparation of autologous platelet rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to an orthopaedic surgical site as deemed necessary by the clinical use requirements. The RegenKit®-THT is for single use only.

FDA clearance number BK 090048, comply with 21CFR820

Manufactured in accordance with Quality System Regulations and ISO 13485, CE0086

RegenKit®-THT-1 (RK-THT-1)

RegenKit®-THT-2 (RK-THT-2)

RegenKit®-THT-3 (RK-THT-3)


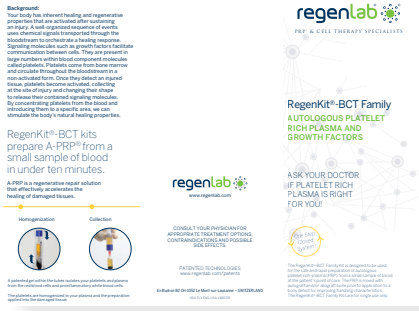


RegenKit®-THT-4 (RK-THT-4)

GOOD PRACTICES WITH REGEN LAB A-PRP[®] KITS

- Users must be **trained in the preparation of PRP** before starting to use Regen Lab kits.
- **Patient must be informed** of the general risks associated with the treatment and of possible adverse effects.
- **Integrity of the packaging** must be checked before opening the kit.
- Treatments are registered in the patient file, using the removable stickers to **record reference and lot number** of the kit used.
- Document **any undesired events** and report them to our quality affairs department.
- Use **surgical aseptic technique throughout the procedure** (blood draw, A-PRP collection, injection).
- Use **appropriate safety precautions** to protect yourself from needles and beveled cannulas.
- Throw away the entire kit after use, using the appropriate method of elimination for **potentially contaminated blood products**.
- Use a **Regen Lab centrifuge**. Centrifuges from other manufacturers can be used only if they have a **centrifugation angle of 45° or spin the tubes horizontally**.
- Tube holders must **correctly fit** Regen Lab tubes.
- Speed in round per minutes (RPM) should be set to reach the desired relative centrifugal force (**RCF**) of **1500 x g**. Use manufacturer instructions and RCF to RPM converter **to calculate the appropriate speed in RPM**.
- Tubes must be correctly **balanced**. If necessary, fill a **counterbalance tube** with water until it reaches the same volume as the blood filled tube.
- Respect the **centrifugation protocol** (time, centrifugal force). Any modifications will lead to lowering the device performances.
- Regen PRP is prepared and kept until used at **room temperature**. Never refrigerate. Use **within four hours** after blood collection.
- **Take time to resuspend the platelets in the plasma before PRP collection**. Always perform a **visual control** that platelets are well detached from the separating gel.
- If a cell and platelet count is desired, dedicate a full tube for this evaluation. Ensure that **all aggregates, even the microscopic ones, are well disrupted** before performing the automated cell counting.
- Respect injection or application protocol. **Avoid injecting too high volumes** that would distend tissues.

RegenLab USA marketing materials are available to all customers. Please reference our order form or ask your local representative for more details.



| | Name | Quantity (min) |
|---|--|----------------|
|  | Syringe pen | 100 |
|  | Patient Flyer | 50 |
|  | PRP Book | 1 |
|  | Patient Banner (white or blue) | 1 |
| <p>Bundle Option</p> | <p>100 pens 50 Flyers 1 Patient Banner</p> | 1 |



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