Regen BCT
technology

regenlab® TISSUE ENGINEERING SPECIALISTS

1/ What is RegenPRP™ ?

RegenPRP™: the standardised leucocyte-reduced platelet concentrate prepared with RegenLab® technology that provides an autologous reservoir of growth factors.

1.1 - PLATELETS

In addition to their role in haemostasis, platelets are key factors in tissue repair mechanisms.[1] They provide essential growth factors, such as FGF, PDGF, TGF-β, EGF, VEGF, IGF, which are involved in stem cell migration, differentiation, and proliferation. Platelet growth factors also stimulate fibroblasts and endothelial cells to induce the deposition of new extracellular matrix and neo-vascularisation, respectively.

1.2 - PLASMA

Plasma contains many factors essential for cell survival including nutrients, vitamins, hormones, electrolytes, growth factors (such as IGF and HGF), and proteins. Among the plasma proteins, the molecules involved in the coagulation process allow the formation of the fibrin polymer that serves as a scaffold for cell migration and new tissue generation.[2]

1.3 - PLATELET-RICH PLASMA (PRP)

- Proven efficacy in tissue healing, with key roles in cell migration, proliferation, and differentiation
- Mechanism of action comprises anti-inflammatory activity and activation of cell-signalling cascades
- Key role in the synthesis of new extracellular matrix for tissue regeneration

1.4 - REGENKIT® TECHNOLOGY

RegenKit®-BCT* are medical devices intended for the preparation of RegenPRP™ in closed circuit. Their main component is the Regen BCT device, a pharmaceutical grade glass tube with vacuum for automated blood collection. Regen BCT contains a sodium citrate anticoagulant solution and a separator gel to isolate the plasma and platelets from the blood cells, producing a PRP with a standardised composition: RegenPRP™.

Regen BCT devices properties	Blood sample vol	RegenPRP™ vol	Platelet recovery	Red blood cell depletion	Platelet concentration factor (native)§
	10 ml	5 to 6 ml	> 80 %	> 99.7 %	1.6 x
	20 ml	10 to 12 ml			

§ If considered necessary, the platelet concentration factor can be increased up to 5 x by discarding acellular plasma before the resuspension step.

Summary of new Regen BCT and A-CP tube performance tests-2017, data on file

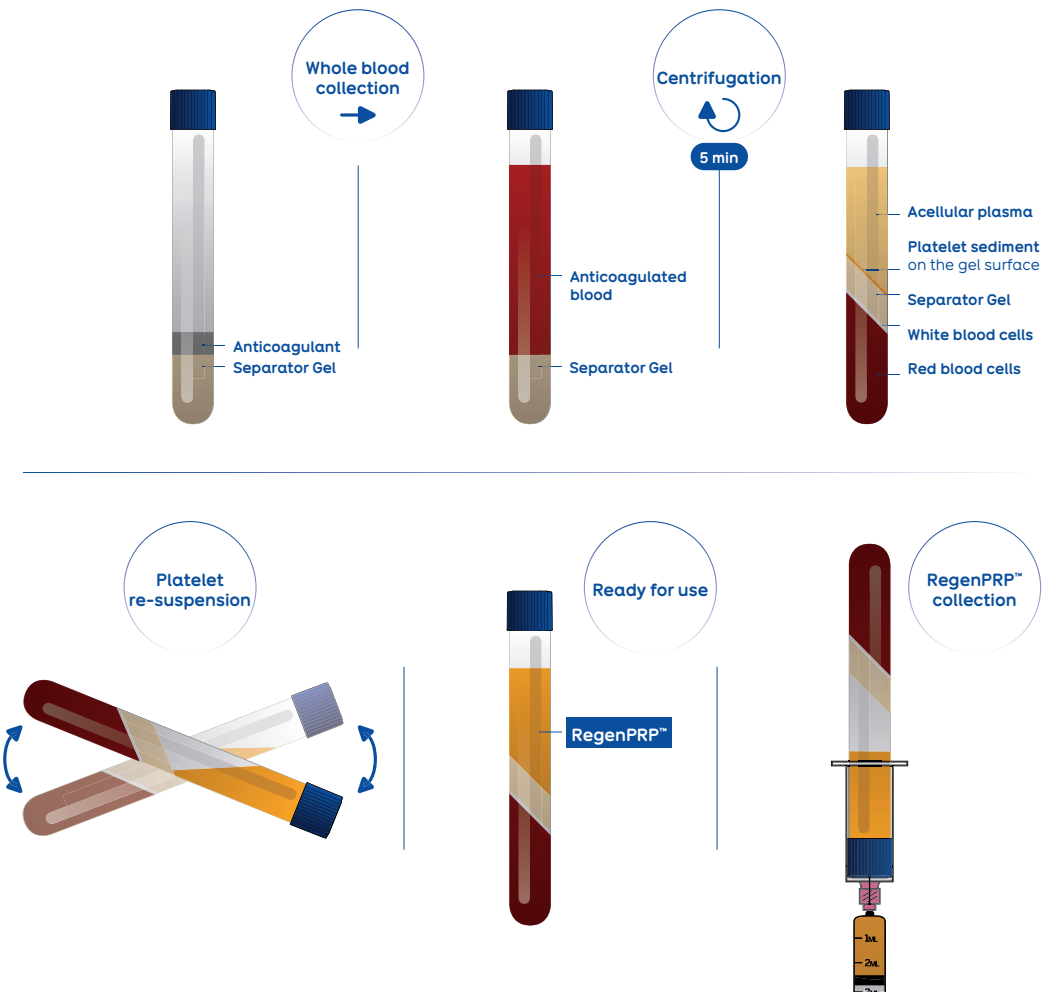
*** "BCT" stands for "blood collection tube"**

RegenKit®-BCT are CE certified medical devices. For related information, consult the specific brochure. Before use, read the instructions provided with the medical device.

1. Fountain, J. H. and S. L. Lappin (2019). Physiology, Platelet, StatPearls Publishing, Treasure Island (FL).
2. Mathew, J. and M. Varacallo (2019). Physiology, Blood Plasma, StatPearls Publishing, Treasure Island (FL).

2/ Technology Platform for Standardised Autologous Regenerative Medicine

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



2.1 - TECHNOLOGY ADVANTAGES

- User-independent standardised preparation
- Minimum volume of blood required
- Safe closed-circuit system
- Mechanical separation of PRP using a chemically inert separator gel with a single centrifugation at a relative centrifugal force of 1500 x g
- Pharmaceutical grade solution of sodium citrate allowing a reversible anticoagulation
- Addition of Autologous Thrombin Serum (ATS prepared with RegenATS™ device), either alone or combined with a calcium solution, allows to obtain RegenPRP™ in different jellified forms
- Minimal learning curve and ease of use
- Operationally and clinically efficient process
- Facilitates and streamlines routine practice

2.2 - BIOLOGICAL ADVANTAGES

- RegenPRP™ is standardised, leucocyte-reduced and easily reproducible
- RegenLab® specific separator gel technology guarantees minimal variability
- Platelet recovery > 80%
- High platelet quality. Viable & functional platelets
- Full plasma recovery. No loss of plasma growth factors and fibrinogen
- Leucocyte-reduced PRP. Depletion of ~ 96% of pro-inflammatory granulocytes, leaving mainly lymphocytes and monocytes
- Virtually no red blood cells. Depletion of ~ 99.7% of erythrocytes

2.3 - SCIENTIFIC ADVANTAGES

- Demonstrated safety and efficacy
- Evidence-based outcomes for numerous therapeutic indications
- Large number of clinical studies, with over 200 publications

Regen Lab SA is an ISO13485 : 2016 and MDSAP certified medical device manufacturer

This brochure is provided as an educational tool for Regen Lab's product users. The preparation of RegenPRP™ must be performed by a physician (or a qualified person under the supervision of the physician) trained on the equipment and procedure, and according to the instructions for use.

The treatment with RegenPRP™ must be performed by a qualified physician. Therapeutic outcomes are patient-specific. The physician should assess, based on his personal experience and data from the literature, whether the treatment is suitable for the patient. The contents of this brochure do not constitute a recommendation for specific treatment.

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