

RegenKit A-PRP Plus

Autologous Thrombin Serum

Platelet Activation via Physiological Pathway

Platelet gel is a simple, inexpensive and minimally invasive procedure that provides a concentrate of autologous growth factors which accelerates the physiological process of healing. ⁵



WHAT IS A-PRP® Plus Autologous Thrombin Serum

A-PRP : The patient's platelet concentrate prepared with RegenKit®

Platelets are key factors in hard and soft tissue repair mechanisms¹. They provide essential growth factors, such as FGF, PDGF, TGF-β, EGF, VEGF, which are involved in stem cell migration, differentiation and proliferation. They also stimulate fibroblasts and endothelial cells to induce respectively new extracellular matrix deposition and neo-vascularisation. The platelets are concentrated from the patient's own blood 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, there are vital molecules for the coagulation process and generation of the fibrin polymer that will serve as a scaffold for cell migration and new tissue generation.

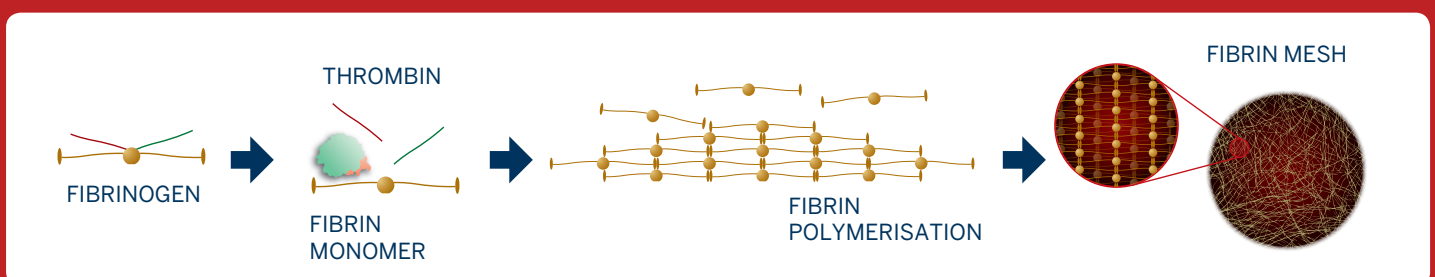
- The A-PRP prepared with the Regen BCT device has a very low level of contaminants.
- Red blood cells are removed at 99.7 %.
- The white blood cell level is drastically reduced, with a preferential depletion (96.7 %) of the pro- inflammatory granulocytes. The remaining white blood cells are mostly lymphocytes and monocytes.



RegenBCT® Tube Properties	BLOOD SAMPLE VOL PER TUBE	PRP VOL PER TUBE	PLATELET RECOVERY	RED BLOOD CELL DEPLETION	PLATELET CONCENTRATION FACTOR (NATIVE)
	10 ml	5 to 6 ml	> 80 %	> 99.7 %	1.6 X

*BCT stands for Blood Cell Therapy.

Autologous Thrombin Serum (ATS) converts soluble fibrinogen to fibrin monomers which polymerise to form the clot. Addition of ATS to the platelet patient concentrate 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.



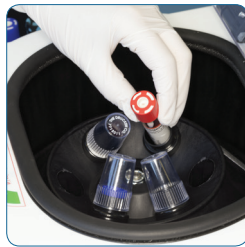
RegenKit® A-PRP® Plus

The RegenATS tube supplied in the RegenKit®-A-PRP Plus is used for the preparation of Autologous Thrombin Serum (ATS). 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 polymerise to form the clot.

Simultaneous preparation of PRP & ATS



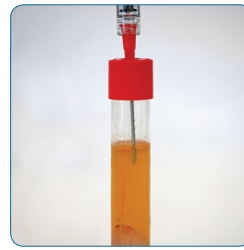
Blood Collection



Centrifugation



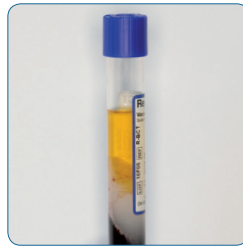
Autologous Thrombin Serum



Autologous Thrombin Serum Extraction



Blood Collection



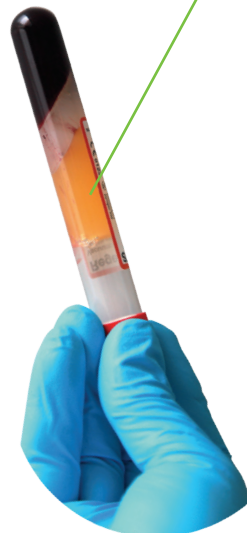
Platelet Resuspension



Ready to Use

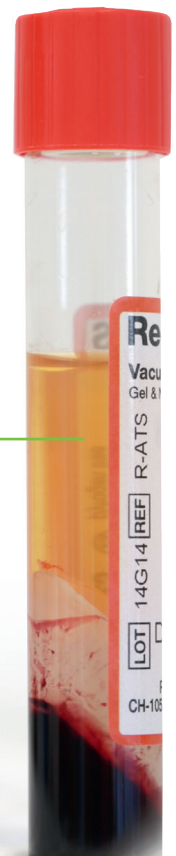
ATS PREPARATIONS

AUTOLOGOUS
THROMBIN
SERUM CLOT



AUTOLOGOUS
THROMBIN
SERUM

EXTRACTED FROM
THE CLOT



Diabetic Foot Ulcer

72 patients with diabetic foot ulcers and concomitant Peripheral Arterial Disease (PAD) were evaluated, 30 of which with Critical Limb Ischemia (CLI). Ulcer area reduction of >50% was observed in 58/72 patients while reduction of >90% was achieved in 52/72 patients, whereas the limb salvage rate was 89%.

Patients were divided into two groups based on the severity of PAD according to the Fountain Classification:

Group A, stages I, IIa and IIb: 42 patients

Group B, stages III and IV: 30 who suffered from CLI

Group A:

- 86% of ulcer reduction of >50%
- 83% of ulcer reduction of >90%
- 100% of limb salvage

Group B:

- 73% of ulcer reduction of >50%
- 56% of ulcer reduction of >90%
- 73% of limb salvage

In patients with diabetic foot ulcers and concomitant Peripheral Arterial Disease (PAD), RegenKit A-PRP Plus Autologous Thrombin Serum successfully reduces ulcers and contributes to avert amputation in 89% of limbs treated.²



Figure. A representative case of foot ulceration in a diabetic patient being assigned to group A (compromised arterial perfusion without CLI). (A) Initial presentation, (B) After session 6, (C) Complete wound healing after session 15.

© Kontopodis et al. - Int J Low Extrem Wounds 2015.

Hidradenitis Suppurativa

A patient in their thirties with severe cystic acne lesions on their face and back underwent a wide surgical excision of the nuchal area. The wound was left open to heal by secondary intention and the PRP gel (A-PRP + ATS) and Hyalomatrix were used as topical treatments.

At that time of the first wound dressing change, the floor of the wound was covered with pink granulation tissue without any slough. During the subsequent dressings, the granulation tissue was observed to be more stable and was gradually getting covered with thin layer of skin over it. The patient achieved complete wound healing after 2 months.

Application of PRP gel with Hyalomatrix is a new concept in the management of HS. Its application is easy, compatible and provides excellent results without additional morbidity.³



© Nicoli - Int Wound J. 2015.

REFERENCES

- 1- Marx RE. Platelet-rich plasma: evidence to support its use. *J Oral Maxillofac Surg* 2004;62:489-96.
- 2- Kontopodis et al. Effectiveness of Platelet-Rich Plasma to Enhance Healing of Diabetic Foot Ulcers in Patients With Concomitant Peripheral Arterial Disease and Critical Limb Ischemia. *Int J Low Extrem Wounds* 2015
- 3- Nicoli F. Severe hidradenitis suppurativa treatment using platelet-rich plasma gel and Hyalomatrix. *Int Wound J.* 2015 Jun;12(3):338-43
- 4-- Serraino GF, Dominijanni A, Jiritano F, et al. Platelet-rich plasma inside the sternotomy wound reduces the incidence of sternal wound infections. *Int Wound J* 2013.
- 5- Filomia D. et al. Treatment of pilonidal sinus disease with autologous platelet-rich plasma. *G Ital Dermatol Venereol* 2013;148:704-6.
- 6- Gumina S. et al. Use of platelet-leukocyte membrane in arthroscopic repair of large rotator cuff tears: a prospective randomized study. *J Bone Joint Surg Am* 2012;94:1345-52.

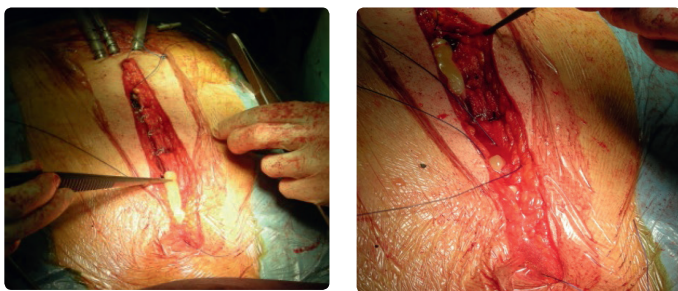
Sternotomy Wound

A study evaluated that the use of platelet-rich plasma (PRP) applied inside the sternotomy wound would reduce the effect of sternal wound infections, both superficial and deep.

Occurrence of Deep Sternal Wound Infection (DSWI) was significantly higher in group 1, who received a median sternotomy without the application of PRP, than in group 2, who received the PRP applied inside the sternotomy wound before closure [10 of 671 (1.5%) versus 1 of 422 (0.20%), $P = 0.043$].

Also, superficial sternal wound infections (SSWIs) were significantly higher in group 1 than in group 2 [19 of 671 (2.8%) versus 2 of 422 (0.5%), $P = 0.006$].

The use of PRP can significantly reduce the occurrence of DSWI and SSWI in cardiac surgery.⁴



© Serraino GF et al. - Int Wound J 2013.

Rotator Cuff Surgery

The use of A-PRP membrane improve repair integrity of large tears of the supraspinatus tendon compared to repair without membrane ⁶.

MRI results: Repair integrity of the tear (table II) according to Sugaya's classification

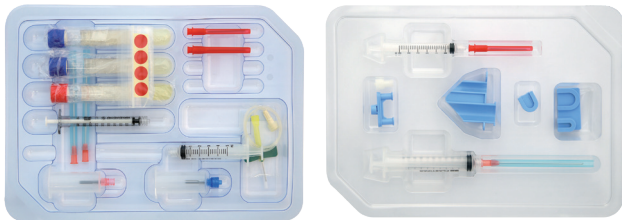
TABLE II Repair Integrity*		
Repair Integrity Type	Group I (no. [%])	Group II (no. [%])
I	23 (59)	13 (35)
II	11 (28)	11 (30)
III	5 (13)	10 (27)
IV, re-tear	0 (0)	1 (3)
V, re-tear	0 (0)	2 (5)

*The repair integrity differed significantly between the two groups (chi-square = 6.29 [degrees of freedom = 2], $p = 0.04$).

LEGEND

- Group I with PRP membrane
- Group II control group
- I - Repaired cuff, homogenous thickness
- II - Sufficient thickness
- III - Insufficient thickness, without discontinuity
- IV - Retear (small discontinuity)
- V - Retear, medium to large discontinuity

RegenKit A-PRP® Plus



INTENDED USE OF THE DEVICE

Preparation of Autologous Platelet Rich Plasma & other plasma-derived products

CE 0086

Intellectual Property Rights (IPRs) as Core Assets
www.regenlab.com/patents

ORDERING INFORMATION

RegenKit-BCT-1 Plus

Ref: RK-BCT-1A

- 1 Safety-Lok™ Butterfly needle
- 1 Collection holder
- 1 RegenBCT tube
- 1 RegenATS tube
- 1 Transfer device
- 1 transfer needle
- 1 x 5 ml Luer-Lok™ syringes

RegenKit-BCT-2 Plus

Ref: RK-BCT-2A

- 1 Safety-Lok™ Butterfly needle
- 1 Collection holder
- 2 RegenBCT tubes
- 1 RegenATS tube
- 1 Transfer device
- 2 transfer needles
- 2 x 5 ml Luer-Lok™ syringes

RegenKit® Surgery

Ref: RK-SRG-AZ/BA1

- 1 Safety-Lok™ Butterfly needle,
- 1 Collection holder,
- 1 Transfer device,
- 2 RegenBCT tubes,
- 1 RegenATS tube,
- 1 x 1 ml Luer-Lok™ syringe,
- 1 x 5 ml Luer-Lok™ syringe,
- 2 transfer needles,
- 2 x 80 mm transfer cannulas,
- Self-adhesive discs.

Regen Spray Applicator

Ref: R-A/NAC1

- 1 X 1 ml Luer lock syringe
- 2 Red transfer needles
- 1 3 ml Luer lock syringe
- 1 10 ml Luer lock syringe
- 1 Luer connector
- 1 Nozzle for spray application
- 1 double piston stopper
- 1 3:10 ratio adapter
- 1 Applicator syringe holder

Spray Applicator

- 1 x 10 ml Luer-Lok™ syringe,
- 1 Nozzle for spray application,
- 1 double piston stopper,
- 1 Applicator syringe holder,
- 1 x 3 ml Luer-Lok™ syringe,
- 1 Luer-lock connector (FM),
- 1 x 80 mm transfer cannula,
- 1 transfer needle.

One Step
Closed
System!

PRODUCT

Quality

- ISO 13485 Certified
- Patented Innovations
- +1 Million Patients treated
- CE Certified

PATIENT

Safety

- GMP Manufacturing
- Class IIb Medical Devices
- Non Pyrogenic - Sterile

A-PRP®

Efficacy

- Dedicated Kits for specific preparations**
- + 100 published studies**

Patented by Regen Lab SA - Platelet Rich Plasma

- U.S. patent US8529957,
- European patent EP2073862B,
- Swiss patent CH696752

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