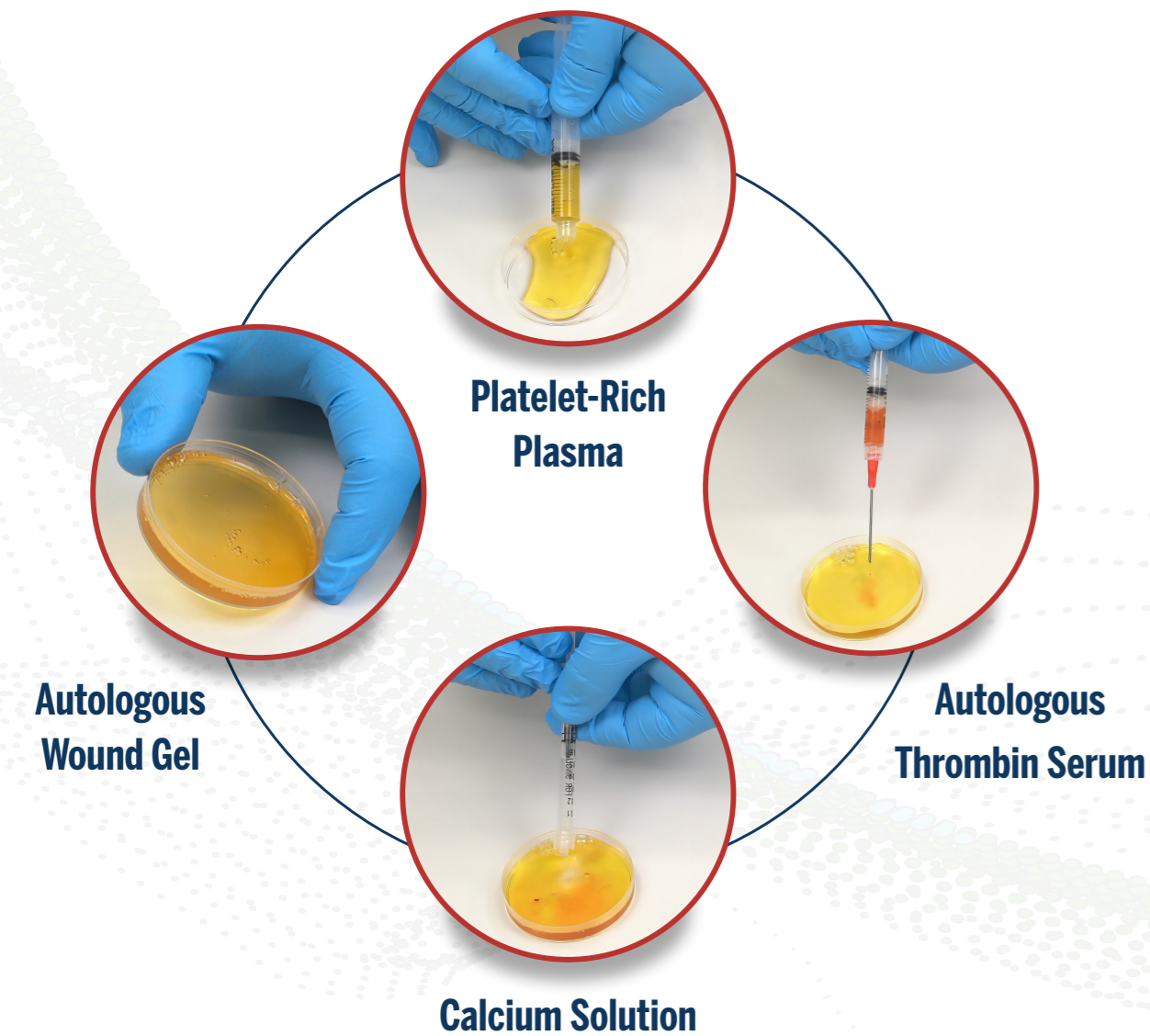


RegenWound™ Gel Technology

Safe, Efficient & Evidence-Based Medicine

Prepared in Four Easy Steps
After Blood Draw & Centrifugation



RegenLab® USA works in partnership with renowned experts to develop medical devices aimed at preparing Autologous Platelet-Rich Plasma.



Developed & Manufactured in the USA

Order Now:

1-800-220-9082 | info@regenlabusa.com

(Contact your Local Representative Today)

RegenLab® USA LLC

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RegenLab® Intellectual Property Rights as Core Assets:

www.regenlab.com/patents U.S. patents US9833478 and US8529957

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PRP® & CELL THERAPY SPECIALISTS

RegenWound™



AUTOLOGOUS WOUND GEL



Autologous Wound Care

In addition to being autologous by design, RegenWound™ Gel boasts an impressive healing time:

Made **from** Your Patient,
for Your Patient!



**30ml Blood Draw,
5 minute spin**

2 tubes of RegenWound™ PRP
&
1 tube of RegenWound™ ATS

Safe.
Flexible.
Effective.

One 10 ml blood draws yield an average
5.5 ml of RegenWound™ PRP

RegenWound™ ATS tube generates a highly
bioactive autologous thrombin serum

Comparisons of Efficacy with Analogous Competitors			
Product	Cellular Origin	Application Frequency	Healing Time
RegenWound™ Gel	Autologous	Every 2 to 3 weeks	6 weeks ³
PRP + Bovine Thrombin	Autologous + Bovine	Twice per Week	12 weeks ¹
Leukocyte-Rich Fibrin Patch	Autologous	Weekly	20 weeks ²

(Based upon comparative analysis of three studies, with analogous wound assessment and SOC.)

RegenWound™

An Autologous Answer to a Chronic Question

What is RegenWound™?

RegenWound™ Gel is an autologous platelet-rich plasma gel, produced by the Regenkit®-Wound Gel kit. From a 30 ml blood draw, approximately 10-12 ml of autologous PRP are produced. The system offers significant flexibility, with an initial platelet concentration factor of 1.6x, in addition to producing an Autologous Thrombin Serum (ATS). Used in conjunction with a calcium solution (calcium gluconate or calcium chloride in differing amounts), this will form a stable autologous gel which can be topically applied to a properly prepared wound bed.

The preparation produces roughly 13 ml of RegenWound™ Gel, for the treatment of wounds classified up to 3A (University of Texas Classification).

RegenWound™ Gel has been shown to strongly support the granulation and re-epithelialization of tissue in wounds classified as difficult-to-heal, boasting substantially reduced healing times, as well as complete closures in times as little as 6 weeks.³

What can it do for patients?

With an average reapplication period of 2 to 3 weeks (in the absence of recurrent infection), this helps to improve patient compliance, decrease patient discomfort, and improve healing times due to minimal disturbance of the wound bed.

Regenkit®-Wound Gel should be used in conjunction with standard of care (SOC) procedures for comprehensive wound management such as:

removal of necrotic or infected tissue, off-loading, compression therapy for venous stasis ulcers, establishment of adequate blood circulation, management of wound infection, wound cleansing, nutritional support (blood glucose control for patients with DFUs), bowel/bladder care for patients with pressure ulcers at risk for contamination, and management of underlying disease as well as other accepted standards of care.

Currently, there are two listed reimbursement codes under Federal Coverage: one specifically for DFU's, and a second for non-diabetic Chronic Wounds, under the definition of wounds which persist beyond 30 days.

(Please consult the IFU for any exclusionary protocols or standards.)

REFERENCES:

- 1- Driver VR, Hanft J, Fylling CP, Beriou JM; Autogel Diabetic Foot Ulcer Study Group. A prospective, randomized, controlled trial of autologous platelet-rich plasma gel for the treatment of diabetic foot ulcers. *Ostomy Wound Manage.* 2006 Jun;52(6):68-70, 72, 74 passim. PMID: 16799184.
- 2- Game F, Jeffcoate W, Tarnow L, Jacobsen JL, Whitham DJ, Harrison EF, Ellender SJ, Fitzsimmons D, Löndahl M; LeucoPatch II trial team. LeucoPatch system for the management of hard-to-heal diabetic foot ulcers in the UK, Denmark, and Sweden: an observer-masked, randomized controlled trial. *Lancet Diabetes Endocrinol.* 2018 Nov;6(11):870-878. doi: 10.1016/S2213-8587(18)30240-7. Epub 2018 Sep 19. PMID: 30243803.
- 3- Clavel S, Denizot C, Boëzennec B, Turzi A, Albache N.A randomized, controlled, clinical study comparing the efficacy of an autologous standardized leucocyte-poor platelet gel with standard care for the treatment of chronic neuropathic diabetic foot ulcers.
- 4- Rappi 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; 8:187-195.
- 5- Weibrich G. et al., Effect of platelet concentration in platelet-rich plasma on peri-implant bone regeneration. *Bone* 2004; 34:665-671.
- 6- Graziani F. et al., The in vitro effect of different PRP concentrations on osteoblasts and fibroblasts. *Clin. Oral. Impl. Res.* 17, 2006; 212-219.



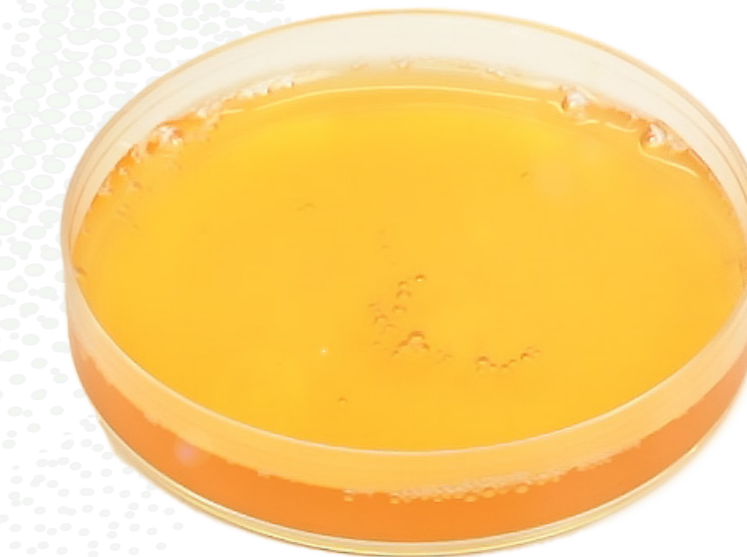
Regenkit®-Wound Gel

A Brief Overview

Regenkit®-Wound Gel is the newest addition to the RegenLab® USA portfolio of medical devices that are developed and manufactured in the USA. Our New York facility is certified compliant to the highest quality management system, ISO 13485 and Medical Device Single Audit Program (MDSAP), to produce RegenKit® containing proprietary and patented gel-based technology systems.

RegenLab® devices have demonstrated safety and efficacy in evidence-based outcomes for numerous therapeutic indications through a large number of clinical studies in over 200 publications to date.

This number continues to grow, as we pride ourselves upon being a leader of research in the field.



Under the supervision of a healthcare professional, RegenWound™ Gel is topically applied to manage exuding cutaneous wounds, such as leg ulcers, pressure ulcers and diabetic ulcers, and mechanically or surgically debrided wounds.

The preparation of RegenWound™ Gel capitalizes upon a dual-mechanism synergistic process, which achieves a stable coagulated gel, capable of retaining its shape and dimensions while still conforming well to a properly prepared wound bed.



Regenkit®-Wound Gel is designed to be used at point-of-care for the safe and rapid preparations of A-PRP gel from a small sample of a patient's peripheral blood.