

National Coverage Determination

RegenKit[®]-Wound Gel-1

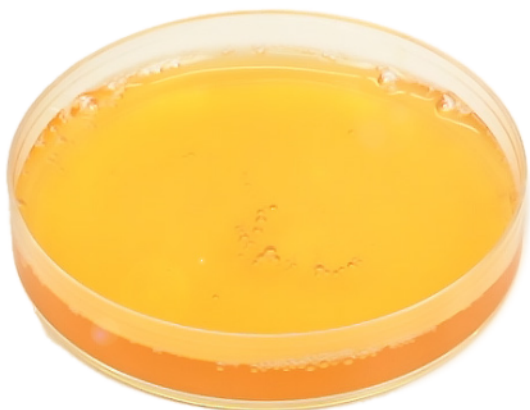
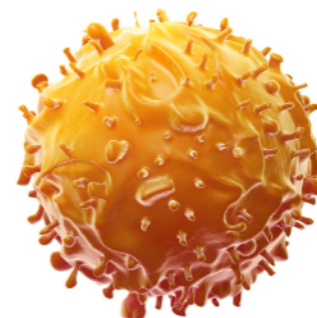
Autologous RegenPRP[™] + ATS

Rapid Healing, Your Blood, Our Expertise



What is RegenWound® Gel?

RegenKit®-Wound Gel-1 derives a **~6.5 mL autologous wound gel from your patient's own blood**, removing iron-laden red blood cells, while concentrating essential growth factors, functional platelets, plasma proteins, and cellular nutrients in a natural fibrin scaffold.



CONCENTRATED PLATELETS:

Delivery of live, functional platelets and growth factors directly to the wound bed.

FLEXIBLE FIBRIN MATRIX:

Manipulable gel to fit any shape of wound and provide sustained release of healing factors.

SAFE & EFFECTIVE:

Autologous platelet-rich plasma naturally activated with the patient's own thrombin serum.

CMS NATIONAL COVERAGE

Eligible for reimbursement under G0465 for the treatment of chronic diabetic wounds and G0460 for the non-diabetic population.*

EVIDENCE BASED MEDICINE

RegenLab® technology has over 200 scientific and clinical publications in academic journals.

PREMIUM TECHNOLOGY

RegenLab® has a long history in regenerative medicine, providing worldwide cutting-edge technologies for wound care.

EASE OF USE

RegenWound® Gel is prepared at the patient's point-of-care from a small sample of their blood.

MAXIMIZED PURITY, OPTIMAL RECOVERY

RegenPRP™ provides 99.7% elimination of red blood cells and over 80% recovery of live platelets.

DRAW, SPIN, APPLY

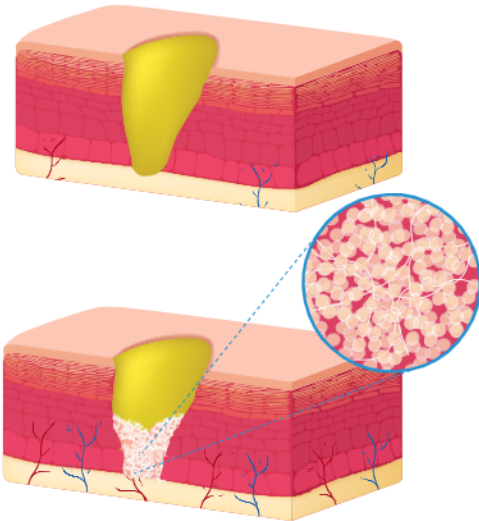
20mL blood draw, with a single 5 minute spin, 10 minute set, and then tailored to fit the size and shape of the wound.

RegenWound Gel Intended Use - FDA Clearance BK210661

The RegenKit®-Wound Gel-1 is designed to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel (RegenWound® Gel) from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the **RegenWound® Gel is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers and diabetic ulcers, and mechanically or surgically debrided wounds.**

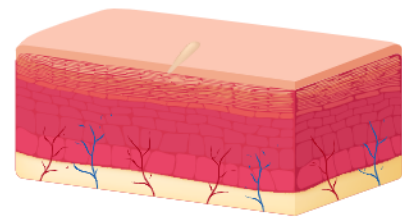
* G0460 is determined on a case by case basis by the regional MACs, based upon a standard of "reasonable and necessary."

State of the art wound healing technology:



1) PRP + ATS Coagulum - fully autologous PRP-based gel rich in Nutrients, Platelets, & Growth Factors, **rapidly prepared at point-of-care** then directly applied to a properly debrided wound bed.

2) Faster Healing - recruitment of local biological resources (e.g. fibroblasts, cytokines, additional growth-factor-rich platelets) **facilitating granulation tissue formation and fortifying the healing process.**

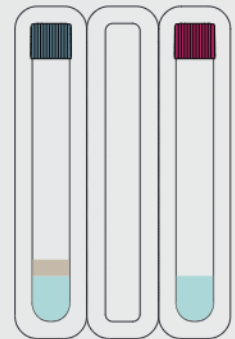


3) Re-Epithalization & Vascularization - orchestrated cellular signaling (via polyphosphate expression & Growth Factor release) to **stimulate collagen production, revascularization, and epithelialization.**



Ordering Code: RK-WG-1

Designed to meet the needs of today's high volume wound care industry, RegenWound® Gel offers healthcare professionals a premium wound healing solution prepared with a simple and efficient procedure.



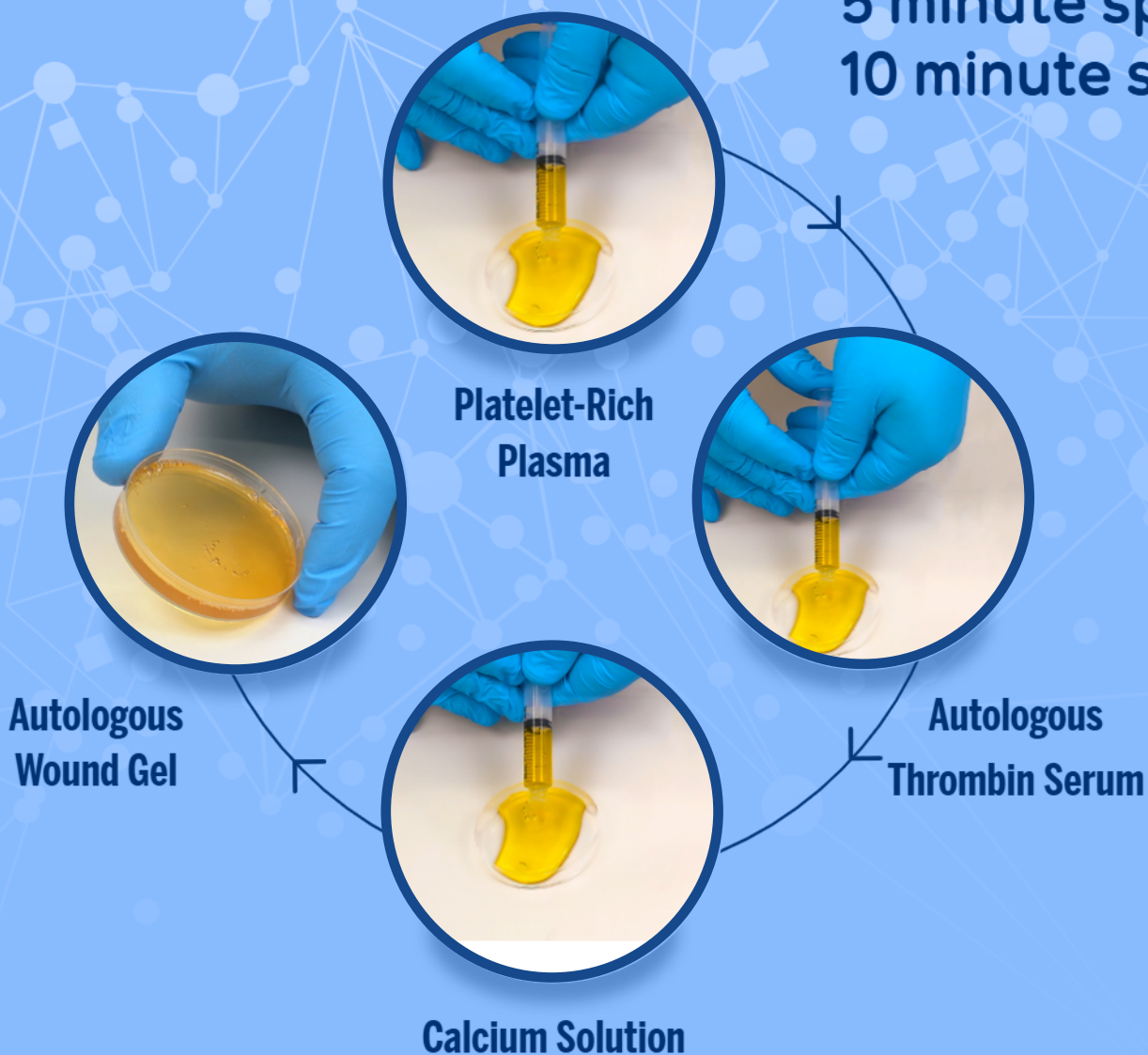
Kit Composition & Accessibility

The **RegenKit®-Wound Gel-1** is a single package containing one (1) RegenWound® PRP tubes and one (1) RegenWound® ATS (Autologous Thrombin Serum) tube for the preparation of approximately 6.5 mL of RegenWound® Gel. Additionally, the RegenKit®-Wound Gel-1 is encompassed by NCD 270.3 as a blood-derived product for **chronic, non-healing diabetic wounds and is eligible for reimbursement under G0465.**

RegenWound[®] Gel

Rapid Preparation at Point-of-Care

**5 minute spin
10 minute set**



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regenlab[®]  **TISSUE
ENGINEERING
SPECIALISTS**

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