

ActiGraft^{PRO}

Blood Derived Wound Care System



Manufactured by RedDress, Ltd
Distributed by Alliant Biotech, LLC



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ActiGraft^{PRO} Overview

A PERSONALIZED APPROACH TO WOUND HEALING



ActiGraft^{PRO} system is an innovative wound solution that uses a patient's own blood to create an autologous whole blood clot. Once applied, the blood clot serves as a protective covering and supports wound healing processes which naturally occur in the patient's body.

IS **ACTIGRAFT^{PRO}** THE RIGHT SOLUTION FOR YOUR FACILITY?

Designed to meet the needs of today's high-volume practices and centers, ActiGraft^{PRO} offers practitioners a premium wound healing solution that delivers a quick, easy, and clean procedure.

RELIABLE OUTCOMES

173% more patients healed in the intervention arm compared to standard of care using Intent to treat (ITT) population, giving **odds ratio of 2.73.¹**

EASILY ADAPTABLE

Single application of the 28 sq. cm. whole blood clot can be applied up to **56 sq. cm.** wound.

STREAMLINED PROCEDURE

Seamless process with **no centrifuge, 5-minute coagulation**, and the flexibility to draw and store blood up to 24 hours prior to the procedure

ASSURED CONFIDENCE

Described by NCD 270.3 as a blood derived product, ActiGraft+ is **eligible for reimbursement under G0465**

NATURAL HEALING

Created from a patient's own blood, **even in the presence of blood thinners**, to provide the wound with an optimal, natural healing environment

AUTOLOGOUS

A personalized solution for patients with religious constraints, **immediately available at point of care.**

Challenges in Wound & Healthcare

LIFETIME RISK

25%

People with diabetes have a 25% lifetime risk of developing diabetic foot ulcers.²

CHRONIC

60%

Approximately 60% of all patients with diabetic foot ulcers develop wounds that become chronic.³

AMPUTATION

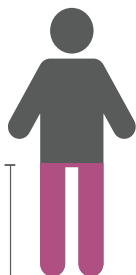
20%

For about 20% of patients, usual standard of care treatment ends with a devastating amputation within one year.⁴



INFECTION RATES

More than 10 million patients undergo surgical procedures as inpatients each year, accounting for over one-fourth of all hospital stays. Surgical site infection (SSI) occurs in 2-4% of all patients undergoing inpatient surgical procedures.⁵



21.3% - 25%
Readmission
Risk

READMISSION RATES

Lower extremity amputation has the highest readmission rate, surpassing 25% among Medicare patients greater than 65 years of age. Patients with diagnoses of “chronic ulceration” and “diabetes mellitus with complications” reportedly average readmission rates of 21.3 and 20.3%.⁶



COST & DISTRESS

Treating chronic wounds also has a substantial impact on the cost of care. If the severity of a wound progresses to grade 4 or 5, the cost of treatment is eight times higher than treating a grade 1 or 2 wound.⁷ For most patients, the experience is debilitating. The longer the wound takes to heal, the greater the social isolation, and emotional and physical distress for the patient and their caregivers.⁸

ActiGraft^{PRO} Clinical Trials

183% more patients healed in the intervention arm compared to standard of care using Per Protocol (PP) population, giving odds ratio of 2.83

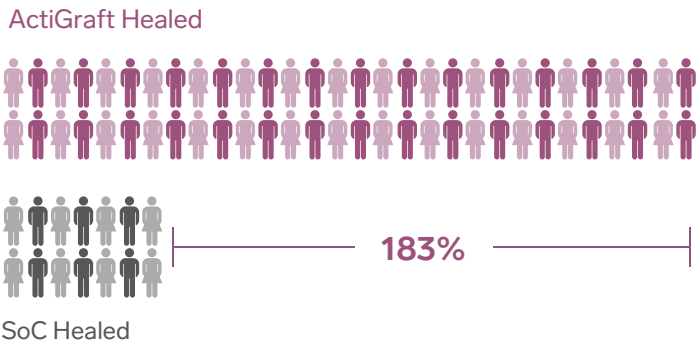
ActiGraft
Arm Healed

2.83X

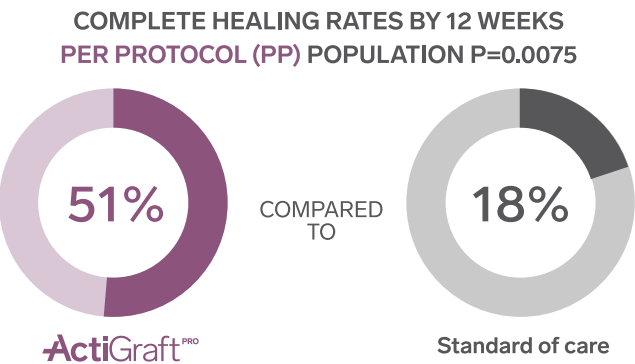
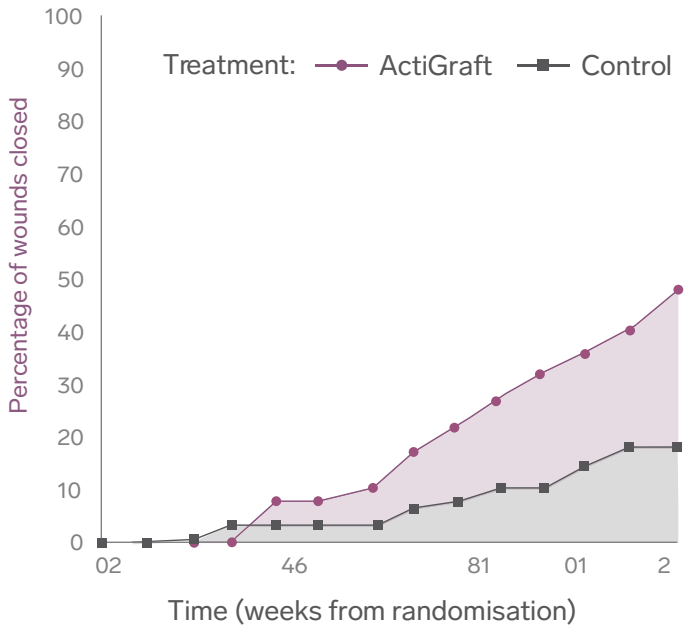
More than standard of care,
with **faster and more**
durable healing outcomes

*per protocol (PP)

Complete Wound Closure (PP)



Weekly Percentage of Wounds Closed (PP)

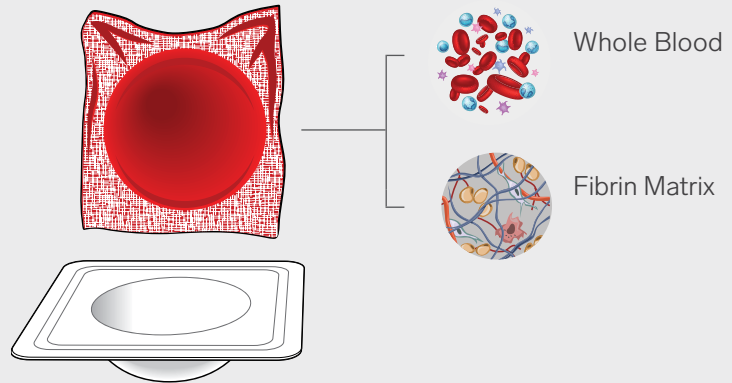


ActiGraft^{PRO} Mechanism of Action

RECREATING THE NATURAL WOUND HEALING ENVIRONMENT

ActiGraft^{PRO} Whole Blood Clot

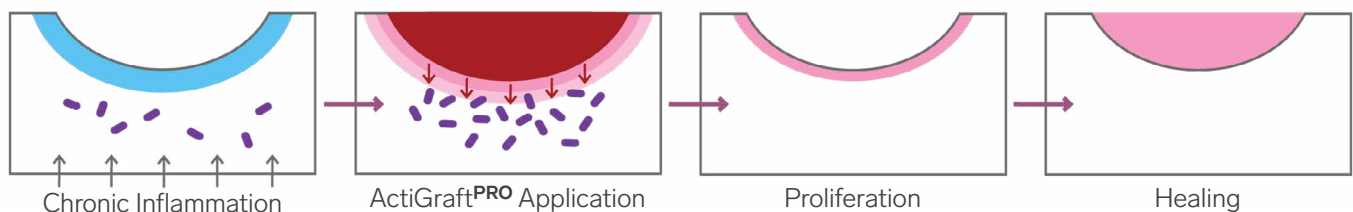
Derived from your patient's own blood, the ActiGraft^{PRO} Whole Blood Clot is embedded with essential wound healing elements, such as red blood cells, macrophages, platelets, proteins, clotting factors, minerals, electrolytes and dissolved gases, bound within a natural fibrin scaffold.



HOW ACTIGRAFT^{PRO} WORKS

ActiGraft^{PRO} is topically applied to your patient's wound site every 5-7 days. Once applied, it delivers biologically active elements to the wound bed and replaces the dysfunctional extracellular matrix - a leading culprit of stalled healing - with a provisional, functional fibrin matrix.

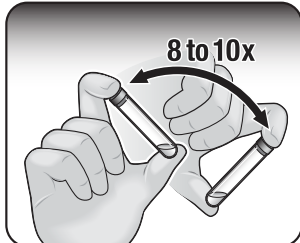
ActiGraft^{PRO} reactivates the body's natural healing cascade and serves as a protective covering that supports the wound healing process, accelerating your patient's road to recovery.



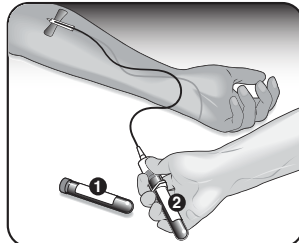
ActiGraft^{PRO} Instructions For Use

QUICK, SIMPLE AND SEAMLESSLY INTEGRATION INTO CURRENT TREATMENT PRACTICES

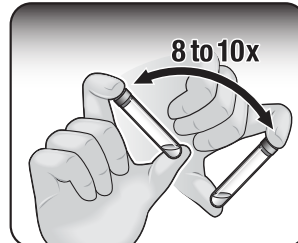
1. Agitate the tube to coat tube with anticoagulant



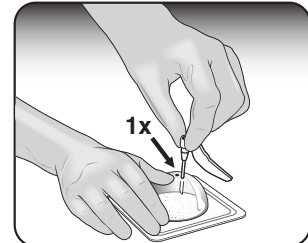
2. Draw blood



3. Gently shake immediately after blood draw to mix well



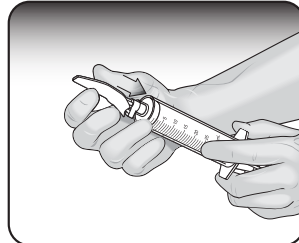
4. Pierce blister once for air outlet



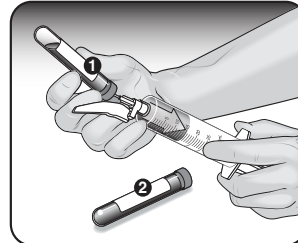
5. Dispose of needle



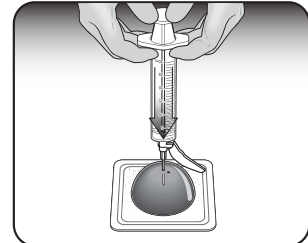
6. Attach 2nd safety needle



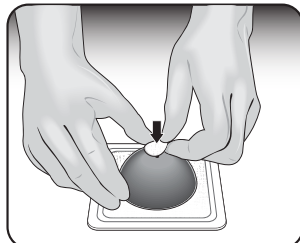
7. Draw 20ml of blood to safety needle



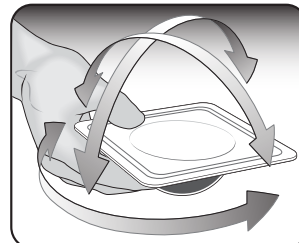
8. Inject blood through blister hole



9. Clean and seal hubs



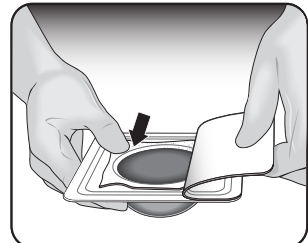
10. Mix contents



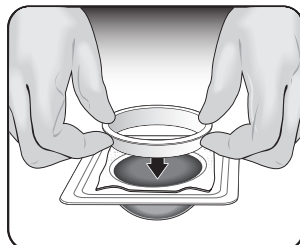
11. Allow at least 5 minutes for coagulation



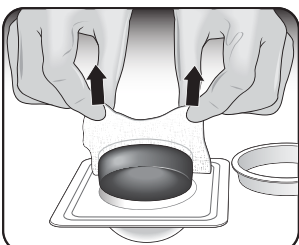
12. Secure gauze while removing backing



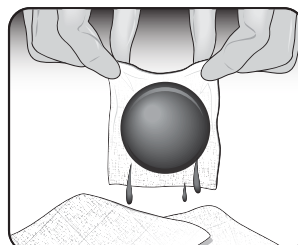
13. Loosen clot with ring



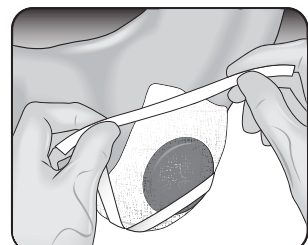
14. Lift clot holding gauze corners



15. Drain excess solution



16. Apply clot directly to wound



17. Complete all required documentation

REF: LBL-QG-0003 Rev.2

To view the ActiGraft^{PRO} Procedure Video, visit: reddressmedical.com/actigraftpro

Physician Coding and Payment

Starting in 2025, Physician payment rates have been established by CMS for HCPCS code G0465. Please note that CMS Wage Index may effect MPFS published rates. Medicare Administrative Contractors (MAC's) may choose to publish rates on their website.

HCPCS Code	HCPCS Description	MPFS Status Code	Medicare National Payment (Facility)	Medicare National Payment (Office)
G0465	Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (Includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)	A	\$87.33	\$890.18

Hospital Outpatient Procedure Coding and Payment

HCPCS Code	HCPCS Description	Status Indicator	APC	Medicare National Average Payment
G0465	Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (Includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)	T	5054	\$1,829.23

Status Indicator: T: Significant procedure, multiple reduction applies.

APPENDIX A: ActiGraft^{PRO} System Components



The ActiGraft^{PRO} System provides single-use components needed for the safe and rapid preparation of Whole Blood Clot (WBC) gel from a small sample of a patient's own peripheral blood. Each system is comprised of an individual box that contains all the components needed to prepare an ActiGraft^{PRO} whole blood clot.

SKU: RD2301

Patient Phlebotomy System:

- Gauze pad
- ACD-A tube
- Bandage
- 18" Tourniquet
- Needleless blood transfer set
- Alcohol Pad
- Blood draw needle

Coagulation & Accelerator System:

- Clotting blister containing kaolin powder and calcium gluconate powder
- Syringe and adapter

System Accessories:

- Gloves
- Drape
- Gauze
- Steri-strip
- Non adherent dressing
- Hydrophilic Foam Dressing
- Face mask with eye protection
- Tape, Ø .5" circle band-aid
- Puncture tool