

AURIX SYSTEM®



THE AURIX SYSTEM®

The Aurix System is intended to be used at the point-of-care for the safe and rapid preparation of platelet rich plasma (PRP) gel from a small sample of the patient's own blood. The PRP gel produced by the Aurix System is suitable for exuding wounds, such as leg ulcers, pressure injuries, diabetic ulcers, and for the management of mechanically and surgically debrided wounds.

Aurix is indicated for the following:

- Stalled or difficult-to-manage wounds
- Full or partial thickness wounds
- Exposed bone or tendon
- Undermining, sinus tracks, or tunnels
- Diabetic ulcers, venous ulcers, stage III – IV pressure injuries



FEATURES AND BENEFITS

- The Aurix system allows for the safe and rapid preparation of a biodynamic hematogel at the point of care from a small amount of the patients on blood and is indicated for the treatment of all chronic wounds.
- The Aurix system has a proprietary **1-minute spin** and is easy to use compared to other PRP devices.
- The Aurix system kit comes with all the components necessary from the blood draw equipment to the wound dressing.
- The Aurix System is reimbursed under an NCD (National Coverage Determination) for chronic diabetic wounds.



Product Description	Item Number
Aurix System Combination Kit	AUSP-01
Aurix System Combination Kit (case of 5)	AUSP-05
Aurix System Combination Kit (case of 10)	AGWR-04
Aurix XL Expansion Kit	AUXP-2T
Aurix EZ-FLY Needle (4 pack)	AUXP-001
Aurix System Centrifuge	AGSC-04



	Aurix®	3C Patch®
Blood volume required	5-20ml	18ml
Spin time	1 minute	20 minutes
Wound size treated	Any	Up to 5cm ²
Flowable	Yes	No
Total process time	5-10 minutes	20-40 minutes
Clinical Study Experience	81% DFU closure rate	59% DFU closure rate

AURIX SYSTEM KITS

The Aurix System Kit

The Aurix system kits contain everything that is required for the preparation and application of the Aurix product. The Aurix system is comprised of two components, the wound dressing kit and the reagent kit. The wound dressing kit contains all the necessary items to draw the patient's blood and prepare the Aurix product for application.

Wound Dressing Kit

Phlebotomy

6 - Aurix S-Monovette tubes
2 - Safety MultiFLY needles
1 - Tourniquet
2 - Alcohol Prep pads
2 - Gauze sponges
1 - Adhesive bandage

Process and Application

1 - Drape & N-Terface dressing
2 - Alcohol and skin protectant Pads
2 - Gauze Sponges
1 - 3ml & 5ml syringe with needle
1 - 20ml mixing chamber
1 - 3-way stopcock and blunt needle

Reagent Kit

1 - vial of 10% Calcium Chloride Solution - 10ml
1 - vial of Thrombin - 5,000 IU
1 - vial of Ascorbic Acid - 30ml

AURIX SYSTEM - THE GOLD STANDARD

The Aurix® system is one of the products approved by the FDA to treat chronic wounds with platelet-rich plasma (PRP). These products all have the same indication statement, "The Aurix System is to be used at point-of-care for the safe and rapid preparation of platelet-rich plasma (PRP) gel from a small sample of a patient's own peripheral blood. Under the supervision of a healthcare professional, the Aurix System 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."

The major differentiator between the Aurix System and other products is, the Aurix System is the culmination of 20 years of research and development. While competitor products seek to leverage the healing power of platelets in isolation, the Aurix System unleashes the power of platelets by creating a biodynamic hematogel. This is achieved by combining the Aurix System reagents with the patient's own platelets that are collected after centrifugation. The reagents are combined with the platelets to activate them, cross-link fibrin strands, and prepare the wound bed for healing. These critical elements are essential for wound healing.

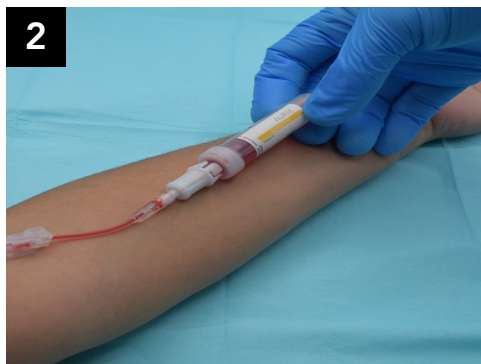
Key Differentiators

- Blood volume required
- Platelet concentration
- Spin time
- Treatment size
- Handling characteristics
- Processing time
- Complete kit
- Ascorbic acid
- Data

AURIX SYSTEM PROCESS



1 Prepare the Aurix collection tubes by pulling back on the plunger until it clicks. Once the plunger is pulled back into locked position, gently snap off the plunger. Repeat as necessary. The Aurix collection tube(s) are now ready for use.



2 Once the Aurix tubes are prepared for blood collection, draw the patient's blood utilizing the multi-fly needle and tube adapter. The multi-fly needle is recommended for the blood draw.



3 Place the Aurix tubes in the centrifuge with the label facing away from the operator. Ensure that tubes are placed across from one another to balance the centrifuge.



4 Close the centrifuge lid. Press the green button to "start" the centrifuge. The total processing time is 60 seconds.



5 An audible alert is sounded at completion of the spin. Open the centrifuge lid, remove samples and place in the foam tube holder. Connect stopcock and blunt needle to the 20ml syringe.



6 Withdraw the platelet rich plasma (yellow blood fraction) from each tube. Assess volume of PRP. Consult Aurix application chart for volume of reagents. For example: 8ml of PRP = 1ml of Ascorbic Acid + 1ml of Thrombin.



7 Open stopcock to side port. Inject Ascorbic Acid into side port and close stop port. Mix by gently inverting. Next open side port, inject thrombin solution into the side port. Gently invert.



8 If a flowable product is desired, the product is now ready for use. If a gel is desired continue to gently invert the syringe while observing for gel formation.



9 Once the gel formation has completed, Aurix gel may now be applied to the prepared wound bed surface.

PROVEN CLINICAL OUTCOMES

The Aurix System is a bio-dynamic hematogel that harnesses a patient's innate healing mechanisms to jumpstart the natural healing process for **any wound at any stage**. Platelet Rich Plasma products are not all the same. The Aurix System utilizes a patented formulation to unleash the healing power of platelets.

Gude W, Hagan D, Abood F, et al. Aurix Gel is an effective intervention for chronic diabetic foot ulcers: A pragmatic randomized controlled trial. Adv Skin Wound Care. 2019 Sep; 32(9):416-426.

- Higher rate of healing across all wound severities (Wagner grade 1-4)
- Significant time to heal advantage
- Significant healing advantage for smokers and patients with PAD
- The control group included advanced wound dressings and skin substitutes.

Driver V.R., Hanft J., Fylling, C.P., Beriou J.M., & AutoloGel Diabetic Foot Ulcer Study Group. (2006). A Prospective, randomized, controlled trial of autologous platelet rich plasma gel for the treatment of diabetic foot ulcers. Ostomy Wound Manage, 52(6),68-87.

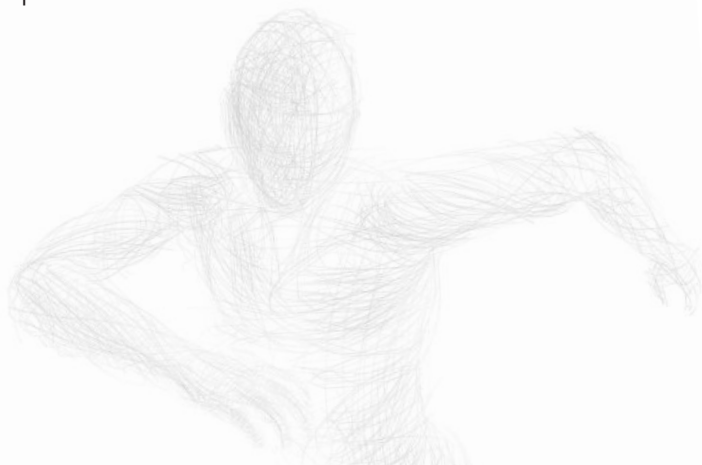
- Safety and efficacy confirmed, no serious adverse events or complications.
- Statistically significant improvement in time to healing versus control
- 81% of Aurix treated wounds healed versus 42% of control group

Carter, M., Fylling, C, Li, W., De Leon, J., Driver, V., Serena, T., et al. (2011). A statistical analysis of a wound outcomes' registry using run-in data: clinical impact of platelet rich plasma gel on healing trajectory. Int Wound J. 2011; 8:638-650.

- Statistically significant differences in wound area and depth between Aurix and run-in treatments
- Demonstrated that Aurix can heal wounds at any stage
- Demonstrated non-healing, stalled wounds responded to Aurix

Sakata, J., Sasaki S., Handa K., Uchino T., Sasaki T., Higashita R, Tsuno N., Hiyoshi T., Imakado S., Morimoto S., Rinoie C., Saito N. A retrospective, longitudinal study to evaluate healing in lower extremity wounds in patients with diabetes mellitus and ischemia using standard protocols of care and platelet-rich plasma gel in a Japanese wound care program. Ostomy Wound Management 2012;58(4):36-49.

- 39 patients with an average wound age of 99.7 days
- Infection was present in all wounds
- 83% of wounds healed following topical treatment of Aurix
- Only 1 patient required LEA





Frykberg, R.G., Driver, V.R., Carman, D., Lucero, B., Borris-Hale, C., Fylling, C.P., et al. (2010). Chronic wounds treated with a physiologically relevant concentration of platelet-rich plasma gel: a prospective case series. *Ostomy Wound Manage*, 56(6), 36-44.

- 49 patients, 65 non-healing wounds
- Mean duration of wounds 47.8 weeks
- Results of mean treatment time of 2.8 weeks and 3.2 treatments decreased:
 - » Wound volume – 51%
 - » Wound area – 39%
 - » Undermining – 77%
 - » Sinus tract – 45%
- 97% of patients showed wound improvement

Rappi LM. (2011) Effect of platelet-rich plasma gel in a physiologically relevant platelet concentration on wounds in persons with spinal cord injury. *Int Wound Journal*. 8(2), 187-195.

- 90% of subjects responded positively
 - » Wound area > 53% reduction
 - » Wound volume > 67% reduction
- Aurix progresses non-healing wounds

DeLeon J., Driver V.R., Fylling C.P., Carter M.J., Anderson C., Wilson J., et al (2011). The clinical relevance of treating chronic wounds with an enhanced near physiological concentration of platelet rich plasma (PRP) gel. *Advances in Skin and Wound Care*, 24(8), 357-368.

- Positive response occurred in 96% of patients
- > 60% reduction in wound volume
- 50% in area of undermining and sinus tract tunneling

Carter, M.J., Fylling, C.P., Parnell, LKS. (2011) Use of Platelet Rich Plasma Gel on Wound Healing: A Systemic Review and Meta-Analysis. www.eplasty.com, Open Access Journal of Plastic Surgery. September 15, 2011.

- Systematic review of PRP literature for cutaneous wounds
- Presence of infection reduced in PRP group
- Complete and partial wound healing was enhanced in the PRP groups

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