

# Graft-In International Ltd.

## ActiGraft

### TREATMENT PROTOCOL

CAUTION: Federal law (US) restricts product sale only by or in the order of a physician

#### The kit includes:

##### 1. Blood draw kit:

- Gloves, nitrile, without powder
- 18-inch arterial blocker
- Sterile blood draw / infusion set, 21G with wing with 7-inch tube
- Sterile alcohol pad 2 inches X 2 inches
- Gauze
- Bandage

##### 2. Coagulation preparation kit & accelerator (WBC preparation kit):

- 5 ml sterile vial containing 3.6 ml of 10% calcium gluconate (RedDress Ltd.)
- 30 ml sterile syringe with 18g needle - to puncture coagulation mold
- 18 g. blood injection safety needle
- Coagulation mold. made of a sterile blister in one size (diameter 6 cm) of  $\mu$  PETG 400, Sealed with Tyvek cover and sterilized, containing: Kaolin powder 28 mg and Medical grade cotton gauze.
- A compatible 600- $\mu$ m sterile biological clot extraction ring
- Face mask

##### 3. Coagulation preparation kit & accelerator (WBC preparation kit) contains:

###### 3.1. single-use applicability kit for wound healing- local application (sterile):

- Powderless nitrile gloves.
- Treatment surface.
- Gauze.
- Pads.
- Wound measuring gauge.
- Optifoam (soft pad)
- Round stripe tape  $\varnothing$ . 5 "
- Steri-Strips

Please note: Use of the device requires sterile vacuum tubes containing anticoagulants (ACDA) that can hold 8.5-9.5 ml of collected blood.

Koronis 25-27, Limassol 3081, Cyprus.

Phone numbers: +972-54-5662669 ; +357-96848444 ; +357-99353959

e-mail: [info@graft-in.com](mailto:info@graft-in.com)

# Graft-In International Ltd.

## **4. Intended use / Indications for use**

ActiGraft is designed to be used in treatment points for the rapid and safe preparation of Whole Blood Clot (WBC) from a small sample taken from the patient's peripheral blood. Under the supervision of a healthcare professional, the WBC gel manufactured by ActiGraft is applied locally to treat skin wounds, such as leg ulcers, pressure ulcers, diabetic ulcers, and mechanical or surgical wounds.

## **User manual**

ActiGraft should be used in combination with standard treatment procedures for comprehensive wound care, such as:

- Removal of necrotic or infected tissue.
- Compression Treatment of venous ulcers.
- Establishment of adequate blood flow.
- Wound infection.
- Cleansing wounds.
- Nutritional support, blood glucose control for subjects with diabetic ulcers.
- Treatment of the bowel / bladder for subjects with pressure ulcers at risk of infection.
- Management of the latent disease.

## **1. Contraindication:**

ActiGraft should not be used in patients with the following types of wounds:

- Wounds due to malignant background (wounds due to malignancy).
- Wounds with clinically diagnosed active infection.

## **2. Precautions**

- Some of the blood-related components in ACTIGRAFT have been sterilized by ethylene oxide and can cause severe allergic reactions in susceptible individuals.
- Throughout the processing and application of ActiGraft use universal precautions as defined in the product policy and procedure guide.
- All parts of the procedure will be performed in a way that minimizes spraying and potential droplets.
- Calcium gluconate should only be used with the ACTIGRAFT kit
- Calcium gluconate (without preservative): Use only if the solution is clear and intact. Note on calcium gluconate: Saturated solutions are prone to precipitation, the precipitate, if present, can be dissolved by heating the vial to 60°C - 80°C, with occasional fermentation, until the solution clears. Shake vigorously. You can cool the room temperature before procedure.  
Use gluconate calcium only if clean immediately before use.

Koronis 25-27, Limassol 3081, Cyprus.

Phone numbers: +972-54-5662669 ; +357-96848444 ; +357-99353959

e-mail: [info@graft-in.com](mailto:info@graft-in.com)

# Graft-In International Ltd.

## 3. Preparation and application of ACTIGRAFT

Follow the below instructions:

- 3.1. Mark the patient's name in the kit.
- 3.2. Measure the total length (end to end) of the ulcer/wound using the tape.
- 3.3. Open the ActiGraft cardboard box
- 3.4. Using gloves, a skin blocker, a sterile alcohol pad, a sterile blood test/ infusion kit and an IV butterfly needle, pump the patient's blood into two 8.5-9.5 ml vacuum tubes provided in the kit and containing an anticoagulant (ACDA).  
After the blood was withdrawn, place a gauze pad and a bandage over the site of the phlebotomy on the patient's skin.  
Note - Blood drawback and treatment should be performed in accordance with normal blood drawback and careful instructions.
- 3.5. Insert the vacuum tubes back into the kit.
- 3.6. Make sure the ActiGraft Kit box is horizontal balanced on the table.
- 3.7. Puncture the blood clotting mold with the needle twice near the top center:  
The first hole will be used to inject blood and the second hole will be used as an outlet for air when you inject blood into the coagulation mold.



Figure 1: Creating a perforation near the top center of the coagulation pattern

- 3.8. Gently mix each of the two vacuum tubes containing blood.
- 3.9. Draw the blood from both tubes into a 30 ml syringe.
- 3.10. Insert all the contents of the calcium gluconate into the syringe containing the blood.
- 3.11. Insert the needle into one of the existing perforated holes in the top center of the blister

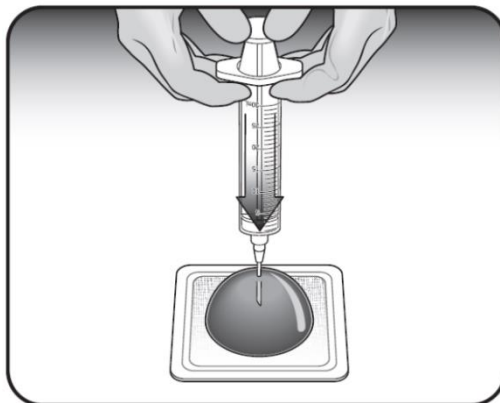


Figure 2: Inserting the needle into the perforated hole in the center to inject the blood

Koronis 25-27, Limassol 3081, Cyprus.

Phone numbers: +972-54-5662669 ; +357-96848444 ; +357-99353959

e-mail: [info@graft-in.com](mailto:info@graft-in.com)

# Graft-In International Ltd.

3.12. Slowly inject the blood into the coagulation mold.

**Note:** Make sure air comes out of the blister through the puncture hole when you inject blood to prevent rupture of the inner seal from pressure

3.13. After injecting blood, clean the perforated blister and stick the round sterile band over the perforation to prevent leakage.

3.14. Mix the blood with the kaolin by shaking and flipping the clotting mold.

3.15. Place the mold back in the kit, making sure it is horizontal.

3.16. Wait for 9 minutes for complete coagulation to occur.

3.17. Tilt the blister to ensure that the blood has clotted.

3.18. Turn the blister over to open it.

3.19. First open only the outer square seal around the blister - do not open the round seal with the gauze

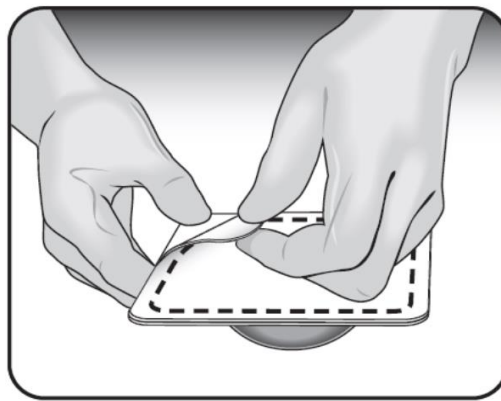


Figure 3: First open only the outer square seal - marked with a dashed line in the picture

3.20. After complete opening the outer square seal, begin to open the round seal.

3.21. Hold the gauze tightly to the blister while pulling the white paper around the seal.

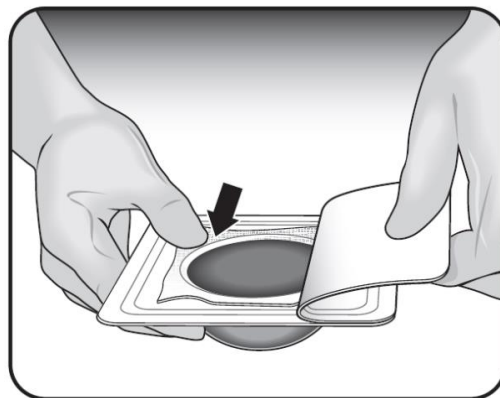


Figure 4: Pull the white paper around the inner round seal while holding the gauze tightly to the transparent blister

3.22. After the Tyvek paper is completely removed, the gauze should still be glued to the blister around the inner seal.

Koronis 25-27, Limassol 3081, Cyprus.

Phone numbers: +972-54-5662669 ; +357-96848444 ; +357-99353959

e-mail: [info@graft-in.com](mailto:info@graft-in.com)

# Graft-In International Ltd.

3.23. Use the clot extraction ring to release the clot. Press the clot extraction ring to ensure that all gauze edges are released from the blister seal

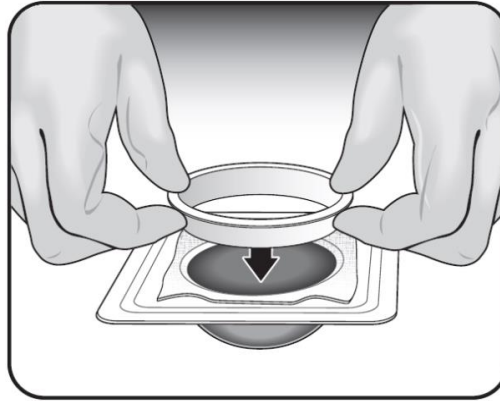


Figure 5: Press the extraction ring down around the WBC

3.24. The ActiGraft Full Blood Clot (WBC) is now in the blister, ready for application.

#### 4. **WBC application and treatment:**

- 4.1. Wear sterile gloves.
- 4.2. Gently remove the WBC from the coagulation tray by grasping it at its edges. Use both hands.
- 4.3. Place the WBC over the wound with the embedded gauze facing up (distal).
- 4.4. WBC may be shaped, if necessary, by cutting it with sterile scissors. Cutting or adjusting the WBC to the wound, should be done on the tray or when it is held in the hand with the gloves.

**Note:** Make sure the ActiGraft is large enough to cover the entire wound and extends over the wound edges.

#### Attaching / gluing WBC to the wound:

- 4.5. Place the WBC to the wound and anchor using sterile Curad Medi-Strips. You can place the straps over the WBC itself.

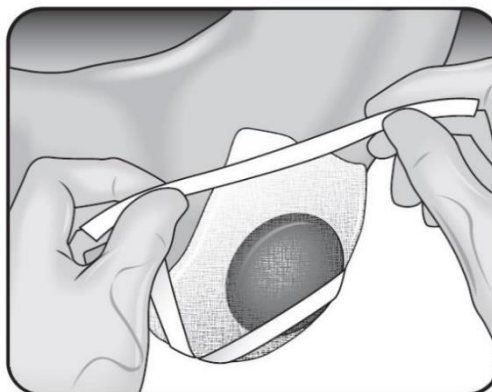


Figure 6: WBC attachment

Koronis 25-27, Limassol 3081, Cyprus.

Phone numbers: +972-54-5662669 ; +357-96848444 ; +357-99353959

e-mail: [info@graft-in.com](mailto:info@graft-in.com)

# Graft-In International Ltd.

- 4.6. Place a non-sticky bandage (supplied with the ACTIGRAFT kit) over the WBC and over the straps.
- 4.7. Place the Optofoam (foam-absorbing secondary bandage) provided in the ACTIGRAFT kit on top of the non-stick bandage.
- 4.8. Finish dressing with regular bandages to cover the wound.

## 5. **WBC removal (after approximately 7 days):**

- 5.1. Wear sterile gloves.
- 5.2. Remove the rest of the WBC by gently pulling from the wound.
- 5.3. In case of adhesions, moisten the WBC with salt water to facilitate and aid in gentle removal.
- 5.4. Remove WBC residue properly.

**Note:** if the clot is attached to the wound – leave it and dress the wound again.

## 6. **Storage conditions:**

- Keep in original container in a temperature-controlled room (15°C-25°C).
- Protect from freezing and avoid overheating.

7. **Validity (Shelf life):** One year from the date of production.

## 8. **Disposal / Disposal Instructions:**

Dispose of all blood, vessels, needles, and substances according to local requirements.

Koronis 25-27, Limassol 3081, Cyprus.




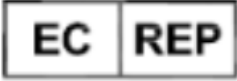













Phone numbers: +972-54-5662669 ; +357-96848444 ; +357-99353959

e-mail: [info@graft-in.com](mailto:info@graft-in.com)

# Graft-In International Ltd.

## 9. Terms & Symbols:

The following icons are used in labels / tagging for ActiGraft, according to: ISO 7000, graphic symbols for the use of equipment - registered symbols, and in accordance with: ISO 15223-1, Medical devices - Labels for use in medical devices - General requirements.

description	symbol	description	symbol
Do not use in case the packaging is damaged		Manufacturer	
Fragile, handle with care		Authorized representative of the European Community	
Keep away from sunlight		Manufacturing date	
Keep dry		Expiration date	
Temperature limit		LOT No.	
Do not reuse		Catalog No.	
Consult the instructions for use		Serial No.	
prescription Only		Sterile label	
Caution			

Koronis 25-27, Limassol 3081, Cyprus.

Phone numbers: +972-54-5662669 ; +357-96848444 ; +357-99353959

e-mail: [info@graft-in.com](mailto:info@graft-in.com)