

# GRAFTJACKET®

REGENERATIVE TISSUE MATRIX  
FOR WOUNDS

Thin, fenestrated acellular  
human dermal matrix  
designed for single  
application that supports  
**regeneration of host tissue**



# NON-HEALING DIABETIC FOOT ULCERS MAY LEAD TO VARIOUS MEDICAL COMPLICATIONS

- ▶ DFU-related complications can result in a reduced quality of life for the patient and are a significant cost burden to the healthcare system.
- ▶ Approximately 85% of all non-traumatic amputations are preceded by a non-healing foot ulcer.<sup>1</sup>
- ▶ Within five years following an initial amputation, up to 51% of diabetic amputees undergo a second leg amputation.<sup>2</sup>
- ▶ 69% of diabetic amputees will not survive past five years.<sup>3</sup>

Examples of non-healing diabetic foot ulcers. Case images courtesy of Lee C. Rogers, DPM; used by permission.



▲ **Patient 1**  
Patient presents with an infected diabetic foot ulcer under the right fifth metatarsal head.



▲ **Patient 2**  
Patient with previous foot surgery, including an incomplete transmetatarsal amputation on the right foot, presents with a new ulcer under the first metatarsal head.

# KCI PRESENTS GRAFTJACKET® REGENERATIVE TISSUE MATRIX (RTM) FOR DIABETIC FOOT ULCERS

## A Structured Wound-Healing Therapy From A Leader In Wound Care

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GRAFTJACKET® RTM is an intact, human acellular dermal matrix for DFUs, including superficial and deep wounds:

- ▶ In a 12-week prospective, randomized, controlled study, beginning at the 3-week follow-up evaluation, the proportion of healed ulcers in the study group (received GRAFTJACKET® RTM) was at least 15% higher than the control group (received Moist Wound Therapy) ( $p = 0.0289$ , Odds Ratio = 2.7).<sup>4</sup>
- ▶ Requires only one application, in most cases, and can be placed in the operating room or outpatient setting.
- ▶ KCI V.A.C.® Therapy can be used to prepare the wound bed for grafting and as a bolster following GRAFTJACKET® RTM application.
- ▶ Replaces damaged or missing tissue with 'like' tissue by supporting cellular repopulation and revascularization by host tissue.
- ▶ Provided in a thin sheet for conformability to the wound, maintaining surface area contact when sutured or stapled in place.
- ▶ Fenestrated to allow for wound fluid to escape.



\*A 12-week prospective, randomized, controlled, multicenter study using GRAFTJACKET® RTM in the treatment of UT Grade 1 & 2 diabetic foot ulcers, N = 46 received GRAFTJACKET® RTM (4 x 4cm). N = 39 received standard of care wound management (Moist Wound Therapy with alginates, foams, hydrocolloids or hydrogels).

# Positive healing trend demonstrated at Week 3.<sup>4</sup>

## 12-week prospective, randomized, controlled, multicenter study using GRAFTJACKET® regenerative tissue matrix in the treatment of UT Grade 1 & 2 diabetic foot ulcers

Authors: Dr. Alexander Reyzelman and Dr. David Armstrong, DPM Journal: International Wound Journal. 2009;6(3):196-208.

### Objective

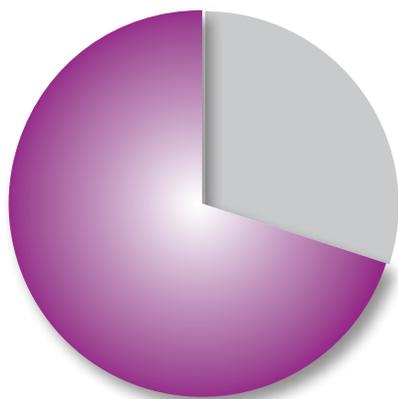
To evaluate the healing rates at 12 weeks of patients with UT Grade 1 & 2 diabetic foot ulcers when applying GRAFTJACKET® RTM (N = 46) compared with Moist Wound Therapy (N = 39) for the treatment of diabetic foot ulcers.

Complete healing was defined as 100% re-epithelialization without drainage.

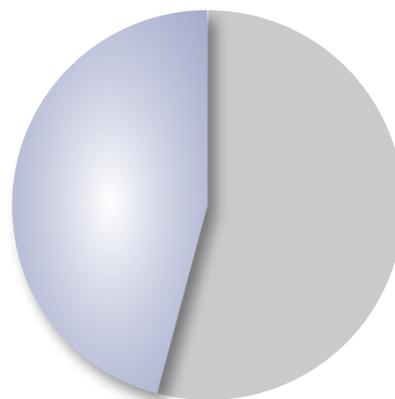
UT Grade = University of Texas Wound Classification System

### Results and conclusions

- ▶ Wounds treated with a single GRAFTJACKET® RTM application were approximately **2.7 times more likely to heal** at 12 weeks versus standard wound management ( $p = 0.0289$ , Odds Ratio = 2.7).



GRAFTJACKET® RTM (69.6%)



Control group (46.2%)

- ▶ Beginning at the 3-week follow-up evaluation, the proportion of healed ulcers in the study group (received GRAFTJACKET® RTM) was at least 15% higher than the control group (received Moist Wound Therapy).
- ▶ 69.6% of patients treated with GRAFTJACKET® RTM achieved complete healing. Mean time to healing was less than 6 weeks.

# Positive healing outcomes demonstrated in chronic full-thickness wounds.<sup>11</sup>

## A multicenter study involving the use of a human acellular dermal regenerative tissue matrix (GRAFTJACKET® regenerative tissue matrix) for the treatment of diabetic lower extremity wounds.

Author: Christopher Winters, DPM

Journal: Advances in Skin & Wound Care. August 2008. (21)8:375–381.

### Objective

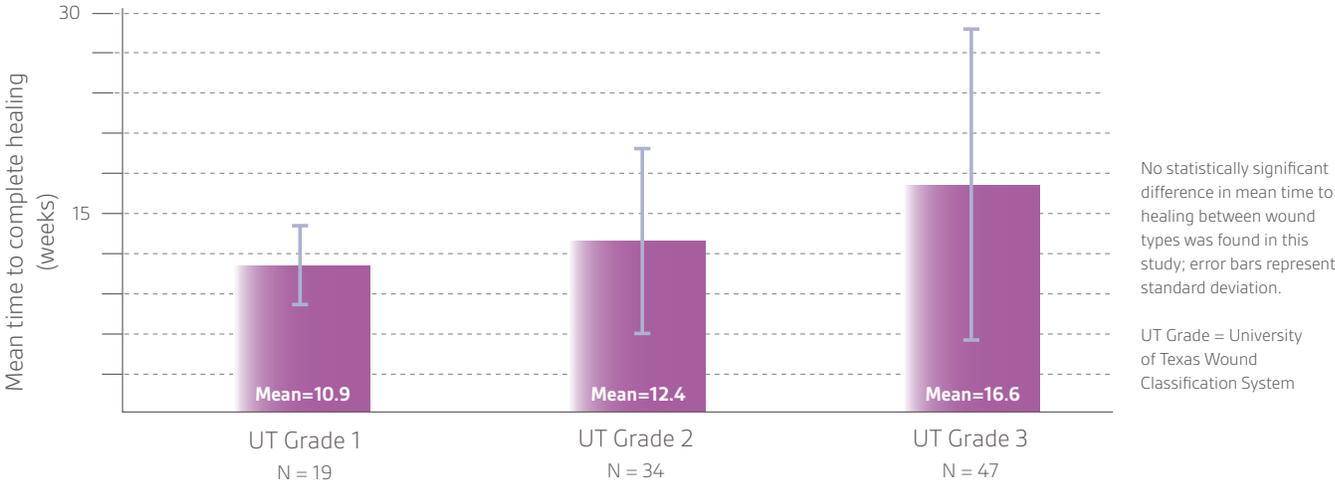
A multicenter, retrospective study to evaluate the time to complete healing of chronic full-thickness wounds using GRAFTJACKET® RTM (N = 100 wounds, N = 75 patients).

Healing was considered complete when the basement membrane of the matrix was released and full epithelialization was present across the wound.

### Results and conclusions

- ▶ GRAFTJACKET® RTM healed 91 wounds in 75 patients
- ▶ Mean time for incorporation of matrix for Grade 3 wounds: 1.5 weeks
- ▶ Overall healing rate: 91.0%
- ▶ Mean time to complete healing: 13.8 weeks
- ▶ Authors conclude: “Absence of matrix-related complications and high rates of closure in a wide array of diabetic wounds suggest that this matrix is a viable treatment for complex lower extremity wounds...”

### Mean time to complete healing



# CASE STUDY

## V.A.C.® Negative Pressure Wound Therapy Used To Prepare Wound Bed For GRAFTJACKET® RTM

### Situation



▲ Figure 1

47 year-old male with Type 2 diabetes, HIV and peripheral neuropathy presented with an infected diabetic foot ulcer under the right fifth metatarsal head. (Figure 1)

The ulcer was debrided in the OR and the patient was admitted to the hospital on IV antibiotics.

### Treatment



▲ Figure 2

Osteomyelitis was ruled out by bone biopsy and x-ray. After the infection was controlled, V.A.C.® Therapy was initiated. After 12 days, it was determined that V.A.C.® Therapy met its goal; the wound bed was granular and therefore ready for GRAFTJACKET® RTM application. (Figure 2)



▲ Figure 3

GRAFTJACKET® RTM was sutured into the wound and covered with a non-adherent dressing. Offloading was prescribed. (Figure 3)

### Outcome



▲ Figure 4

GRAFTJACKET® RTM absorbed in the center of the wound. (Figure 4)



▲ Figure 5

The wound epithelialized with healthy plantar skin within 6 weeks. (Figure 5)

Case images courtesy of Lee C. Rogers, DPM; used by permission.

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

# CASE STUDY

## Patient With Incomplete Transmetatarsal Amputation Presents With New Ulcer

### Situation



▲ Figure 1

60 year-old male with Type 2 diabetes and previous foot surgery, including an incomplete transmetatarsal amputation on the right foot, presents with a new ulcer under the first metatarsal head. Infection, including osteomyelitis, was ruled out.

### Treatment



▲ Figure 2

The wound was debrided to healthy bleeding tissue. (Figure 1)

GRAFTJACKET® RTM was applied in the clinic and sutured in place. (Figure 2)



▲ Figure 3

GRAFTJACKET® RTM incorporated over 4 weeks and the superficial layer desiccated and sloughed at that time. (Figure 3)

### Outcome



▲ Figure 4

The wound was 90% closed and best practices for wound care were followed until complete closure 2 weeks later. (Figure 4)



▲ Figure 5

After 6 months, the healed wound had remodeled and healthy plantar skin was noted at this location. (Figure 5)

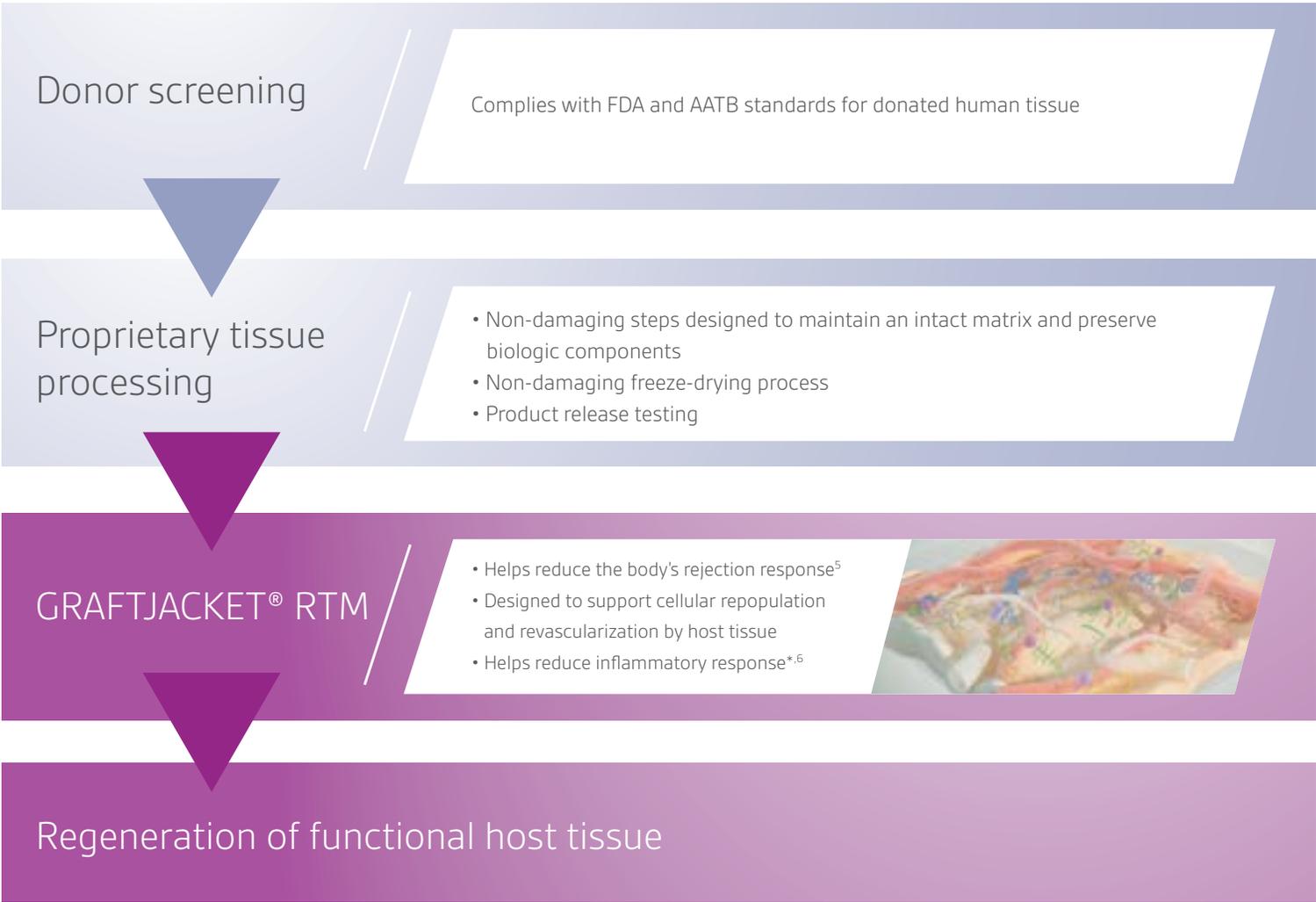
*Case images courtesy of Lee C. Rogers, DPM; used by permission.*

As with any case study, the results and outcomes should not be interpreted as a guarantee or warranty of similar results. Individual results may vary depending on the patient's circumstances and condition.

# PROPRIETARY PROCESS PROVIDES A FOUNDATION FOR TISSUE REGENERATION

## Natural Biological Components And Structure Of The Dermal Matrix Are Preserved

Our proprietary process leaves an intact, acellular matrix that allows the body to initiate its own tissue regeneration process.



\*Data based on non-human primate studies; correlation of these results in humans have not yet been established.

# UNDERSTANDING YOUR OPTIONS

## Acellular Scaffolds Differ From Cellular-Based Products

### Acellular Scaffold Products

Cells are removed leaving only the extra cellular matrix

Provides architecture to support cell in-growth

May be incorporated (positive recognition) or resorbed (negative recognition)

### Cellular Based Products

Release growth factors that stimulate wound healing

May contain multiple cell types

Cells do not persist and may require multiple applications<sup>9,10</sup>

## Different Biologic Scaffolds May Produce Different Results

### Positive Recognition<sup>5</sup>

Cellular infiltration of the scaffold with minimal inflammation; results in like-for-like replacement of missing tissue.<sup>5</sup>

Tissue that has similar structure, function and physiology as surrounding host tissue

### Negative Recognition<sup>6</sup>

A prolonged inflammatory response occurs, resulting in destruction of the scaffold as well as scar tissue formation as demonstrated in primate studies.<sup>6</sup>

Tissue that has a different structure, cellularity, vascular pattern from the surrounding host tissue<sup>6</sup>

# REIMBURSEMENT CODES

HCPCS Code <sup>2</sup>	Description
Q4107	GRAFTJACKET® Skin Substitute

CPT® Code <sup>3</sup>	Description
<b>Wound Location : Trunk, arms and legs</b>	
15271	Application of skin substitute graft to trunk, arms, legs, total surface area up to <b>100sqcm</b> ; first <b>25sqcm</b> or less wound surface area
+15272	Each additional <b>25sqcm</b> wound surface area, or part thereof (List separately in addition to code for primary procedure)
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100sqcm; first <b>100sqcm</b> wound surface area, or 1% of body area of infants and children
+15274	Each additional <b>100sqcm</b> wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)
<b>Wound Location : Face, Scalp, Eyelids, Mouth, Neck, Ears, Orbits Genitalia, Hands, Feet and/or multiple digits</b>	
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to <b>100sqcm</b> ; first <b>25sqcm</b> or less wound surface area
+15276	Each additional <b>2sqcm</b> wound surface area, or part thereof (List separately in addition to code for primary procedure)
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to <b>100sqcm</b> ; first <b>100sqcm</b> wound surface area , or 1% of body area of infants and children
+15278	Each additional <b>100sqcm</b> wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)

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13. CPT codes and descriptions only are copyright © 2011 American Medical Association. All rights reserved. No fee schedules are included in CPT. The American Medical Association assumes no liability for data contained, or not contained, herein.

# GRAFTJACKET® REGENERATIVE TISSUE MATRIX FOR DIABETIC FOOT ULCERS

## GRAFTJACKET® RTM Is A Preferred Regenerative Treatment For Challenging Wounds Such As DFUs

- ▶ In a 12-week prospective, randomized, controlled study, beginning at the 3-week follow-up evaluation, the proportion of healed ulcers in the study group (received GRAFTJACKET® RTM) was at least 15% higher than the control group (received Moist Wound Therapy) ( $p = 0.0289$ , Odds Ratio = 2.7).<sup>4</sup>
- ▶ A single application of GRAFTJACKET® RTM may help reduce cost of care.<sup>4</sup>
- ▶ KCI V.A.C.® Therapy can be used to prepare the wound bed for grafting and as a bolster following GRAFTJACKET® RTM application.
- ▶ Replaces damaged or missing tissue with 'like' tissue by supporting cellular repopulation and revascularization by host tissue.
- ▶ Provided in a thin sheet for conformability to the wound, maintaining surface area contact when sutured or stapled in place.
- ▶ Fenestrated to allow for wound fluid to escape.

## ORDERING INFORMATION

GRAFTJACKET® regenerative tissue matrix			
Product code	HRI Number	Product Size	Thickness
GJ44	9978251644	4 x 4cm	Thin (0.38 - 1.02mm)
GJ48	9978253248	4 x 8cm	Thin (0.38 - 1.02mm)

GRAFTJACKET® Xpress flowable soft tissue scaffold		
Product code	HRI Number	Product Size
GJX	9979300202	2cc

\* A 12-week prospective, randomized, controlled, multicenter study using GRAFTJACKET® RTM in the treatment of UT Grade 1 & 2 diabetic foot ulcers, N = 46 received GRAFTJACKET® RTM (4 x 4cm). N = 39 received standard of care wound management (Moist Wound Therapy with alginates, foams, hydrocolloids or hydrogels).

To order call **800-275-4524**, or visit **acelity.com**

**NOTE: Every patient is different and patient results may vary. Before use, physicians must review all risk information and essential prescribing information which can be found in the GRAFTJACKET® regenerative tissue matrix *Instructions for Use*. Rx only.**

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