## WE'RE CHANGING THE DYNAMICS IN TISSUE REPAIR & WOUND HEALING

Accelerating outcomes and decreasing costs with a cutting-edge, multi-dimensional wound healing solution for Acute and Chronic Wounds, and Burns.

# PHOENIX<sup>™</sup> WOUND MATRIX

Powered by Electrospun Synthetic Polymer Technology

↑ OUTCOMES.  $\downarrow$  COSTS.







### **Mission Statement**

RenovoDerm is a regenerative medicine company focused on the development and manufacture of scientifically engineered 3D electrospun synthetic polymer technology to help advance clinical practice, improve patient outcomes and reduce the overall cost of care.

Our mission is to change the dynamics in wound healing to make a profound impact on the clinical and economic burden of wound care with PHOENIX Wound Matrix – a cost-effective, sophisticated 3D electrospun synthetic matrix for tissue regeneration and repair of acute and chronic wounds, and burns.



### **Base Technology Developed by Nanofiber Solutions**

- Cutting-edge technology supported by over 50 issued and pending patents
- Over 12 years of research in tissue regeneration (soft tissue, trachea, esophagus, intestine, vascular, heart)
- Over \$10M dollars of non-dilutive funding (NIH/NSF/State of Ohio)
- Engineered to mimic cellular structure and encourage the bodies natural restorative process
- Acidic degradants accelerate pro-regenerative cellular function
- NFS manufactures and supplies products to Renovoderm

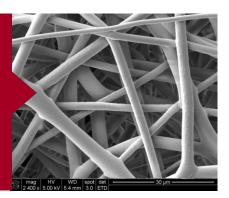




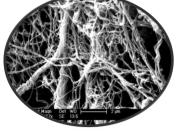








**RenovoDerm** 

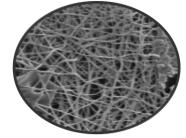


The 3D structure of the scaffold permits the

incorporation of cells and can be engineered to meet

specific parameters, making it ideal for a range of

applications.



Decellularized Tissue

Nanofabricated Matrix

## **The Problem: Chronicity and Persistent Inflammation**

### **Normal Wound Healing**

- Acidic milieu low pH
- A balance of macrophage phenotypes M1 & M2 allow for normal wound healing
- All wounds have the opportunity to become chronic

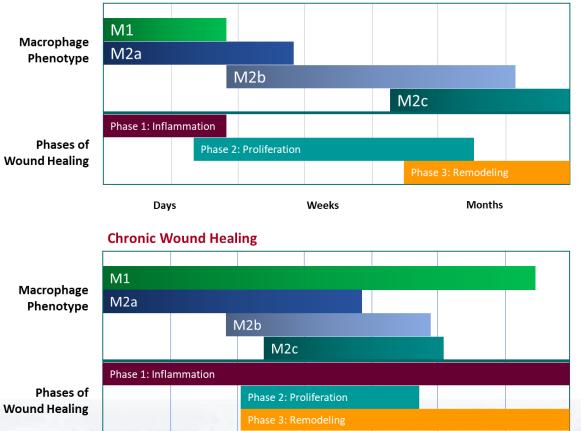
**GOAL:** Mitigate risk of chronicity and decrease time to wound closure.

### **Chronic Wound Healing**

- Alkaline milieu high pH
- Up-regulation of pro-inflammatory M1 down-regulates pro-regenerative M2 capability
- Causes **sustained inflammatory response** leads to skin breakdown, infection, **chronicity and delayed wound healing**

**GOAL:** Address chronicity and sustained inflammation to accelerate the wound healing process.

### Normal Wound Healing



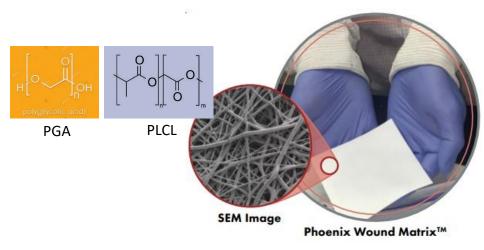
Weeks

Days

Months







### A cutting-edge, multi-dimensional wound healing solution

Phoenix Wound Matrix is a sophisticated, 3D electrospun synthetic polymer matrix designed to improve wound healing outcomes by addressing chronicity and persistent inflammation.



Scientifically engineered to mimic native extracellular matrix (ECM) morphology providing a multi-dimensional, microporous scaffold stimulus to facilitate natural cellular adhesion, infiltration and proliferation.



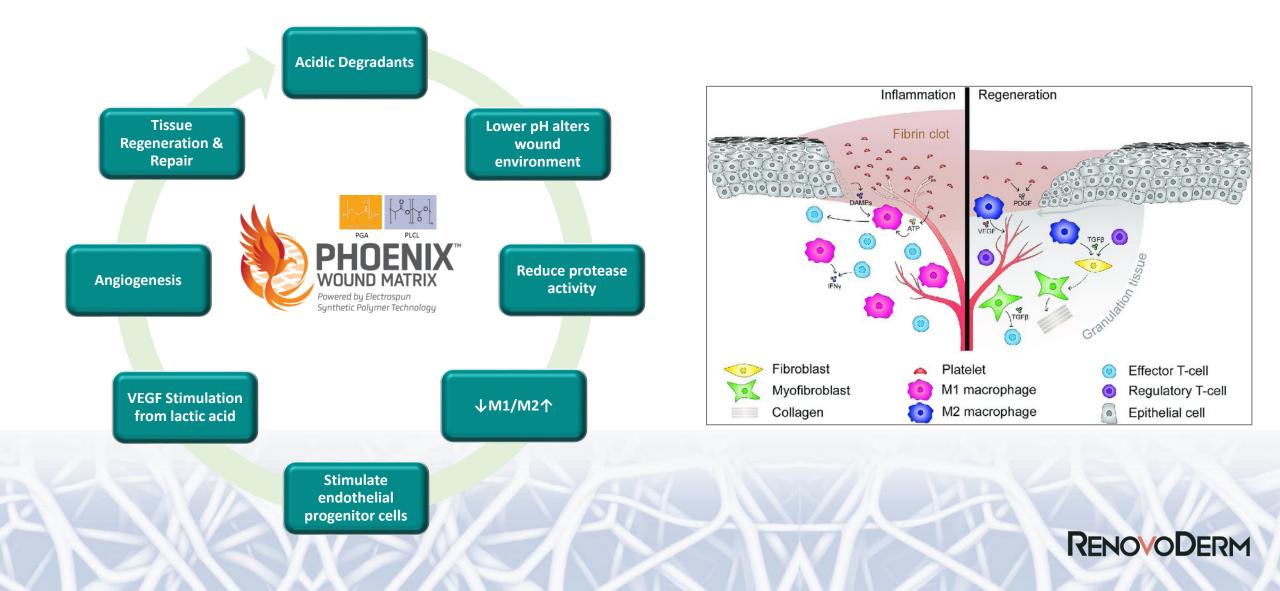
Comprised of **polymers which naturally biodegrade to α-hydroxy acids and fatty acid**, PHOENIX Wound Matrix acts as a **protective barrier to quickly inspire a pro-healing wound environment**.



Supports low pH and lactate expression that address chronicity and persistent inflammation to accelerate the wound healing process of acute and chronic wounds, and burns<sup>1-3</sup>.



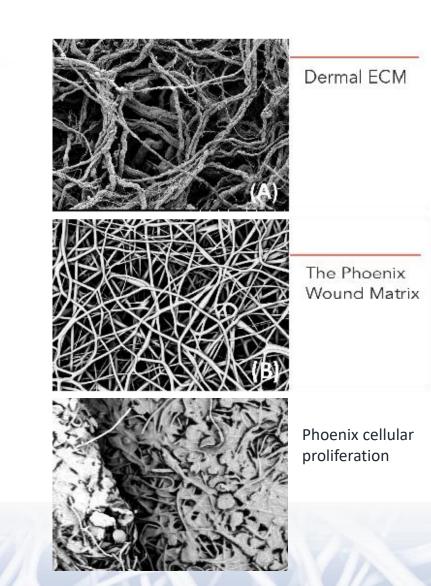
### **Scaffold Degradants Facilitate Wound Healing**



## **Sophisticated ECM Design**

### Supports pro-regenerative cellular activity

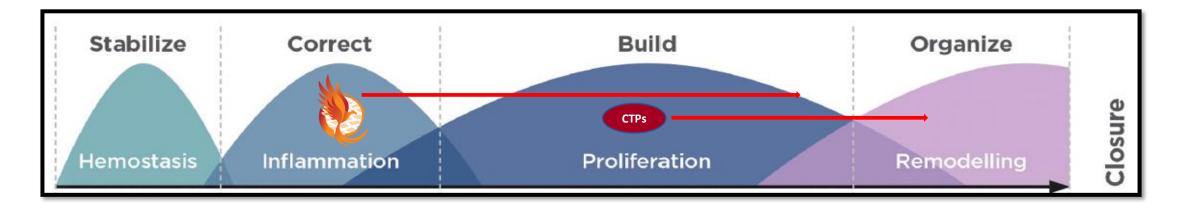
- Pore size and structure promotes cellular adhesion, **infiltration** and proliferation
  - **1 μm** (micron) = 1 millionth meter
  - 1 nm (nanometer) = 1 billionth meter = 1/1000 micron
  - **Fibroblast** average dia.: 10-15 μm (10,000-15,000 nm)
  - Phoenix fibers dia. range: 600 1000 nm
- Supports appropriate macrophage phenotype balance (M1/M2) to enable a pro-healing activity
- Offers a consistent and predictable ECM structure versus human/animal derivatives





## **Positioning as a 1<sup>st</sup> Line Treatment**

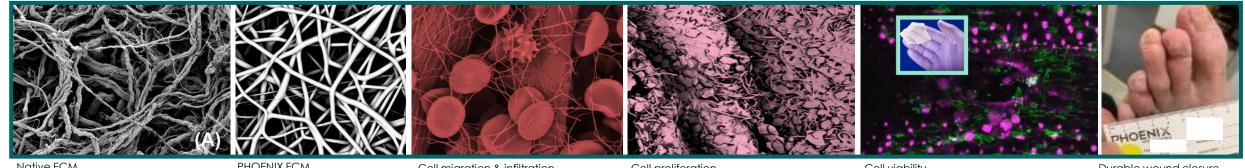
- **Complex Acute Wounds** mitigate the risk of chronic activity
- Chronic Wounds disrupt chronic activity to accelerate wound healing





### Fulfilling the Promise of Regenerative Medicine







<u>Goal</u>

PHOENIX ECM

#### Cell migration & infiltration

Cell proliferation

Cell viability

Durable wound closure

Sophisticated microporous electrospun polymer scaffold mimics native ECM

Acidic degradants address chronicity & persistent inflammation

Accelerated wound healing & cost effective durable tissue repair

↑ Graft Success Rates

↑ M2 **↓** M1 рH

 $\uparrow$  OUTCOMES  $\downarrow$  COSTS



## **Changing the dynamics in Wound Healing**

### Addressing chronicity and persistent inflammation.



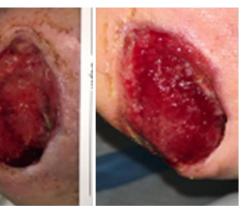
#### **Necrotizing Fasciitis**



Visible change in tissue within 11 days

within 11 days

DFU Pressure Injury - 4 months in duration



Healthy granulation tissue within 7 days

### within 7 days

2-year Complex Ulceration of the Left Foot



Healthy granulation tissue within 14 days -Neovascularization within 28 days

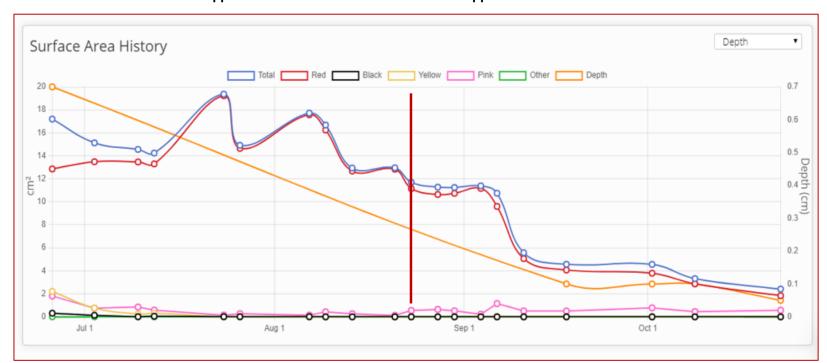
within 28 days



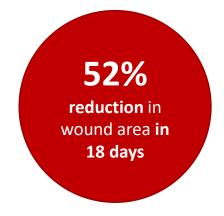
Please see full case data at www.renovoderm.tech

# **Changing the Healing Trajectory**

Wound healing trajectory prior to application of PHOENIX Wound healing trajectory post application of PHOENIX







Treatment Period	Day	Wound Area Reduction (%)
Prior to Phoenix	45	3%
Prior to Phoenix	59	32%
PHOENIX	18	52%
PHOENIX	46	72%
PHOENIX	59	79%



# **Clinical and Economic Value**

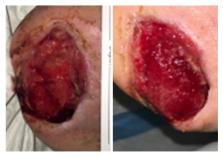
### Improves outcomes by addressing the primary problem, wound chronicity and inflammation

- CTPs are designed to combat chronic wounds. Approximately 45% 50% of cases do not heal in 12 weeks\*
- PHOENIX demonstrates consistent healing outcomes with decreased time to wound closure
  - Rapid reduction in inflammation observed in 100% of wounds treated with PHOENIX Wound Matrix
  - Increased healing rate with ≈ 88% wound area reduction in first 4 weeks
  - Median time to wound closure 5 weeks
  - Median application 2 PHOENIX Wound Matrix

### **Reduce expenses and improve profitability**

- PHOENIX is typically 40-50% less the cost of CTP's
- Encourages a pro-healing wound environment to help decrease the utilization of more expensive, cellular tissue products
- Potential to significantly impact throughput by reducing patient return visits

DFU Pressure Injury - 4 months in duration



Healthy granulation tissue within 7 days within 7 days

2-year Complex Ulceration of the Left Foot



Healthy granulation tissue within 14 days -Neovascularization within 28 days

within 28 days



Private and Confidential—Not for Distribution

# **Compelling Clinical Outcomes – Median Data**

**100%** 

Demonstrated rapid improvement in tissue appearance and reduced inflammation **88%** Median wound area reduction within

4 weeks

Median number of product applications

~5 weeks

Median time to wound closure











RENOVODERM

#### PHOENIX WOUND MATRIX Post Market Surveillance Median Case Data Summary

	All Cases	Pressure Injury	DFU	Chronic Lower Extremity	Complex Chronic	Surgical Wound	Trauma Wound	Complex Acute	Burn
Patients	47	5	18	16	2	1	3	1	1
Wounds	65	5	20	32	2	1	3	1	1
Significantly improved tissue appearance after 1 <sup>st</sup> application	100%	100%	100%	100%	100%	100%	100%	100%	100%
% area reduction within 4 weeks	88%	95%	89%	90%	87%	61%	63%	97%	100%
% area reduction within 8 weeks	97%	100%	98%	86%	92%	80%	97%	100%	

\*National average for CTP applications: 5-8

## **Necrotizing Fasciitis**

Noted and the second seco	Price	PHOEMX			77% reduction in wound area at 4.5 weeks
Day 0 1 <sup>st</sup> PHOENIX application Planimetric area: 256.9 cm <sup>2</sup>	Day 11 2 <sup>nd</sup> PHOENIX application Planimetric area: 115.7 cm <sup>2</sup> Plan. area reduction: 55%	Day 32 3 <sup>rd</sup> PHOENIX application Planimetric area: 58.4 cm <sup>2</sup> Plan. area reduction: 77%	Day 67 Planimetric area: 11.4 cm <sup>2</sup> Plan. area reduction: <b>96%</b>	Day 121 17.3 weeks Planimetric area: 0.96 cm <sup>2</sup> Plan. area reduction: > <b>99.9%</b>	

Images courtesy of Frank Aviles, Jr., PT CWS FACCWS CLT AWCC

#### Case Brief:

**57-year-old male** with **type 2 diabetes** and **hypertension**, presented 3-weeks after sustaining a fall to the sacral area. Patient was diagnosed with **necrotizing fasciitis**, requiring **extensive surgical debridement**, antibiotics, and hyperbaric oxygen therapy (HBOT). The resulting wound extended from upper right inguinal region, through perineum, to perianal area. Patient reported significant wound pain requiring pain medication for dressing changes. PHOENIX Wound Matrix was applied to anterior aspect of wound, and negative pressure wound therapy (NPWT) was also applied in combination with PHOENIX. By Day 7, patient reported considerable decrease in pain, no longer required pain medication, and healthy granulation tissue was observed. By Day 32, planimetric area of anterior wound decreased 77%. By Day 67, 96% reduction in planimetric area was achieved. Wound closure was achieved on Day 125.

#### Summary:

57-year-old male with diabetes and large open wound, resulting from extensive surgical debridement of necrotizing fasciitis tissue, closed in 18 weeks with 3 PHOENIX applications, combined with wound care best practices, including HBO and NPWT.

### **RENOVODERM**

### **Diabetic Foot Ulcer – 7 months in duration**



**Case Brief:** Case Brief: 51 y/o DM male with neuropathy. Pedal pulses were 2/4 bilateral with hair growth presented with a diabetic ulcer of left toe. **Ulcer was present for 7 months without resolution prior to PHOENIX application.** The area has been off-loaded in cam boot for over 6 months. Previous treatments include lodosorb, Medihoney, amniotic membrane. Treatment strategy switched to utilize Phoenix Wound Matrix. Patient RTC after one week with 83% reduction in wound volume, Phoenix applied 2X. Wound closure in two weeks.



# **5 Complex Arterial Ulcers**

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Day 0 1 <sup>st</sup> PHOENIX application Hallux:0.5cm x0.8cm x 0.2cm 2 <sup>rd</sup> toe: 3.5cm x 2.0cm x 0.1cm 3 <sup>rd</sup> toe: 3.6cm x 4.5cm x 0.1cm 5 <sup>rd</sup> toe: 0.3cm x 0.2cm x 0.1cm	Day 7 2 <sup>nd</sup> PHOENIX application Hollos: Epithelialized 2 <sup>nd</sup> toe: 1.8cm x 1.1cm x 0.2cm 3 <sup>nd</sup> toe: 3.7cm x 1.2cm x 0.1cm 4 <sup>nd</sup> toe: 3.5cm x 2.7cm x 0.2cm 5 <sup>nd</sup> toe: Epithelialized	Day 36 6 <sup>th</sup> PHOENIX application Hallux: Epithelialized 2 <sup>rd</sup> toe: 2.8cm x 2.0cm x0.2cm 3 <sup>rd</sup> toe: 0.8cm x0.5cm x 0.1cm 4 <sup>ch</sup> toe: 1.8cm x 1.9cm x0.3cm 5 <sup>th</sup> toe: Epithelialized	Day 49 8 <sup>th</sup> PHOENIX application Halloo: Epithelialized 2 <sup>th</sup> toe: Epithelialized 3 <sup>th</sup> toe: Epithelialized 4 <sup>th</sup> toe: L4cm 2.0cm x 0.3cm 5 <sup>th</sup> toe: Epithelialized	Day 84 Hallux: Epithelialized 2 <sup>16</sup> toe: 1.5cm x 1.2cm x 0.2cm 3 <sup>14</sup> toe: Epithelialized 4 <sup>16</sup> toe: 1.3cm 1.7cm x 0.3cm 5 <sup>th</sup> toe: Epithelialized	Day 155 Wound Closure Hallus: Epithelialized 2 <sup>rd</sup> toe: Epithelialized 4 <sup>rd</sup> toe: Epithelialized 4 <sup>rd</sup> toe: Epithelialized
Combined area: 26.180m <sup>2</sup>	Combined area: 26.18cm <sup>2</sup> Area reduction: 44%	Combined area; 26.18cm <sup>2</sup> Area reduction: 64%	Combined area: 26.18cm <sup>3</sup> Area reduction: 69%	Combined area: 26.18om <sup>2</sup> Area reduction: 85%	5 <sup>m</sup> met: Epithelialized

Images courtesy of Dan Davis, DMP and Denise Riera, DPM

#### Case Brief:

74-year-old male with type 2 diabetes, severe peripheral artery disease resulting in markedly inadequate perfusion status, and peripheral neuropathy presented with 5 ischemic diabetic toe ulcers of the left foot, after having failed SOC for 4 weeks. Prior consult recommended amputation of the gangrenous 2<sup>nd</sup> and 4<sup>th</sup> toes. Collectively, wound areas measured 26.18cm<sup>2</sup>. On Day 0, sharp debridement was performed and treatment with PHOENIX Wound Matrix initiated. By Day 7, epithelialization of Hallux and 5<sup>th</sup> toe wounds was achieved, along with a 44% reduction in combined wound area. By Day 36, the Hallux and 5<sup>th</sup> toe remained epithelialized and a combined wound area reduction of 64% noted. Patient continued to respond well to treatment with PHOENIX achieving an 85% reduction in combined wound area in 12 weeks. 100% reduction in combined wound area was achieved in 22 weeks with closure of the 2 initially gangrenous toes.

#### Summary:

74-year-old complex male patient severely compromised perfusion status and 5 ischemic diabetic ulcers achieved closure of all wounds in 22 weeks with 8 applications of PHOENIX, avoiding the loss of 2 gangrenous toes. Patient wears shoes and is ambulatory, adding friction to the challenge of healing the ischemic, diabetic wounds.

### RENOVODERM

Complete wound closure

Amputation

avoided

## **Diabetic Foot Ulcer**



Images courtesy of Dan Davis, DPM

#### Case Brief:

**66-year-old male** with **Charcot-Marie-Tooth** (CMT) disease, **peripheral neuropathy** and **neurological issues** presented on Day 0 with a plantar pressure ulcer over the left 5<sup>th</sup> metatarsal. Wound measured 3.3cm x 3.3cm x 0.2cm. Sharp debridement was performed, followed by application of becaplermin gel (recombinant PDGF) and PHOENIX Wound Matrix. Patient was not a candidate for total contact casting; bolstered padding was utilized to offload. By Day 10, a 28% reduction in total wound size was noted with wound measuring 2.8cm x 2.8cm x 0.2cm. **By Day 35, complete wound closure was achieved**. On further evaluation at Day 50, the wound remained closed and continued healthy tissue remodeling was noted.

#### Summary:

PHOENIX was selected as **first-line treatment option**, and wound closure of pressure ulcer in **66-year-old male** with **CMT** was achieved in **5 weeks** with **3 PHOENIX applications**, combined with wound care best practices.



## **Diabetic Foot Ulcer**



Images courtesy of Richard Schilling, DPM

#### Case Brief:

51-year-old male with chronic diabetic foot ulcer (DFU), of over 2 months duration, due traumatic puncture wound to the lateral left foot plantar surface. Patient has a history of peripheral neuropathy, hypertension, BMI 40, osteomyelitis, and is status post resection of 5<sup>th</sup> metatarsal head followed by 6 weeks IV antibiotics. Treatment with PHOENIX began 8 weeks post surgery. Wound healed in 6 weeks with 3 applications of PHOENIX Wound Matrix.

#### Summary:

**51-year-old male** with **DFU**, secondary to trauma and subsequent osteomyelitis necessitating amputation of the 5<sup>th</sup> metatarsal head, healed in 6 weeks with 3 PHOENIX applications.



# **Diabetic Ulcer/Trauma**





### **Case Brief:**

40-year-old female with history of type 1 diabetes, multiple sclerosis, and Raynaud's disease, presented to the wound care clinic status post a fall 4 weeks earlier. Following thorough debridement, PHOENIX was applied. Wound depth was visibly reduced within 1 week of treatment. **The planimetric area decreased by 43% after 2 weeks of treatment and 2 applications of PHOENIX.** The wound closed following 49 days of treatment.



## **Pressure Injury**



Images courtesy of Frank Aviles, Jr., PT CWS FACCWS CLT AWCC

#### **Case Report:**

90-year old male with **paraplegia** presented with right heel **pressure ulcer of over 4 months duration**. Additionally, at presentation, a **2.2 cm tunnel** was observed superomedially. Despite receiving best practice standard of care plus other advanced modalities, patient developed osteomyelitis and required surgical debridement. Following surgical debridement, the 1<sup>st</sup> PHOENIX Wound Matrix was applied on Day 0. Robust granulation tissue was noted within days; second PHOENIX was applied on Day 7, and accelerated progress continued. On Day 42, 70% decrease in planimetric area was observed. **Full wound closure was achieved on Day 77.** 

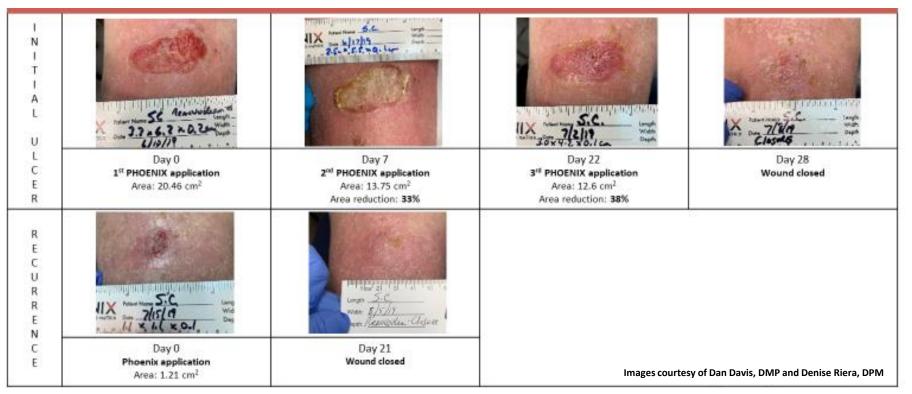
#### Summary:

**90-year-old male** with **paraplegia** and **heel pressure ulcer** achieved **wound closure** in **11 weeks** with **2 PHOENIX applications**, combined with wound care best practices, including NPWT and offloading.





## **Venous Leg Ulcer**





#### Case Brief:

66-year-old male with history of recurrent leg ulcers and multiple comorbidities including type 2 diabetes, congestive heart failure, peripheral artery disease, peripheral neuropathy, and hypertension, presented with a right, lower leg venous ulcer. PHOENIX Wound Matrix treatment was initiated as first-line therapy on Day 0, along with Regranex Gel for moisture. By Day 7, a 33% reduction in wound size was noted. Wound closure was achieved in 28 days with 3 applications of PHOENIX. One-week post closure, patient presented with a recurrence measuring. PHOENIX was applied once and wound closure was achieved in 3 weeks.

#### Summary:

66-year-old male with extremely poor vascular status and history of recurrent leg ulcers responded well to treatment with PHOENIX Wound Matrix. PHOENIX was selected as 1<sup>st</sup> line therapy to facilitate rapid wound healing in this complex patient. Initial wound closed in 4 weeks with 3 PHOENIX applications. Recurrence closed in 3 weeks with 1 PHOENIX application.



## **Arterial Leg Ulcer**



Images courtesy of Dan Davis, DMP and Denise Riera, DPM

#### Case Brief:

**84-year-old male** with **peripheral artery disease**, **coronary artery disease**, and **peripheral neuropathy** presented with a left lower leg ischemic ulcer measuring 3.7 x 3.6 x 0.1 cm. Treatment with PHOENIX Wound Matrix was initiated on Day 0. On Day 4, a 24% reduction in wound area was noted. The matrix was still visible on the wound bed, therefore, no new graft was applied. On Day 11, accelerated wound healing was noted with an 97% reduction in wound area. Remarkably, wound closure was achieved on Day 25.

#### Summary:

**84-year-old patient** with an **arterial leg wound** achieved **wound closure in 4 weeks** of treatment and **2 applications of PHOENIX Wound Matrix**. Ischemic wounds are challenging to manage and often exceed 6 months in duration.

### **RENOVODERM**

# 2nd degree burn - forearm



Images courtesy of L. Horn, MD

#### Case Brief:

50-year-old female with acute 2<sup>nd</sup> degree burn, of 6 days duration, to anterior forearm. PHOENIX Wound Matrix<sup>®</sup> was applied 6 days post trauma. Telfa pad was placed on PHOENIX and secured with Ace bandage wrap. Per patient, pain was alleviated immediately following application of PHOENIX on the wound. Seven days post application, wound was observed to be healing well. Wound healed in 18 days.

#### Summary:

**50-year-old female** with **2**<sup>nd</sup> **degree burn** to anterior forearm **healed in 18 days** with **1 PHOENIX application**. Patient reported immediate alleviation of pain following PHOENIX application.



Tissue achieved closure within

18 days

# **Summary**

### **Changing the dynamics in wound healing with PHOENIX**

- PHOENIX Wound Matrix is a cutting-edge, 3D electrospun synthetic polymer technology that addresses **two unmet needs in wound care**:
  - Improved outcomes
  - A lower cost to the healthcare
- Data demonstrates 60% of PHOENIX wounds achieved complete wound closure within 5 weeks versus industry standard of 50% of wounds treated with a CTP are not healed at 12 weeks
- Reduce expenses and improve profitability
  - PHOENIX demonstrates consistent healing outcomes with decreased time to wound closure
  - PHOENIX is typically 35% less the cost of CTP's
  - Encourages a pro-healing wound environment to help decrease the utilization of more expensive, cellular tissue products
  - Potential to significantly impact throughput by reducing patient return visits





**Renovo**, Derm

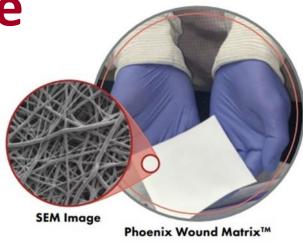


## **PHOEINX Wound Matrix Product Line**



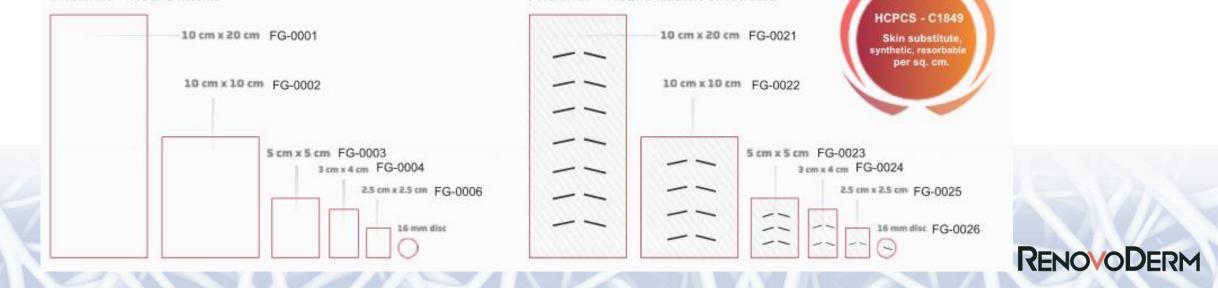


PHOENIX<sup>™</sup> Wound Matrix Fenestrated



### SIZING AND REIMBURSEMENT

PHOENIX™ Wound Matrix



### References

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- 6. Data on file, DOC-3487
- 7. Clinical case documentation. Data on file.
- \*Advanced wound care device, also known as cellular and/or tissue-based product (CTP) or skin substitute.
- + All claims supported by human use studies, Good Lab Practice (GLP), porcine animal study and veterinary case studies

