PHOENIX
WOUND MATRIX

PHOENIX WOUND MATRIX™

Supporting Healthy Tissue Growth
Promoting Faster, Definitive Wound Healing*

Designed to Mimic Extracellular Matrix

Synthetic, Bioabsorbable

Native Tissue Regeneration*

Eliminates Painful Dressing Changes

Reduces Scarring*

BY: RENOVODERM

Who We Are

Nanofiber Solutions (NFS) – The Parent Company

NFS is redefining tissue engineering by addressing the problems associated with both synthetic and biologic devices while incorporating their respective advantages. Following over a decade of research and development, including numerous (and still ongoing) human and animal studies, NFS has launched four medical device companies, each tailoring NFS's proprietary and patented technology to meet the specific requirements of their respective clinical area:

RenovoDerm
Wound management

Atreon Orthopedics
Joint Repair

Vascular Genesis
Cardiovascular and peripheral vascular repair

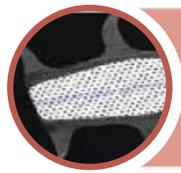
Tarian Medical
Hernia repair

We have over a decade of experience crafting polymer scaffolds that allow individual cells, cell clusters, and cellular systems to express phenotypes favorable for regeneration of healthy tissue. Our extensive experience working with cancer cells and stem cells and our ongoing work with researchers addressing other adherent cell diseases gives us a solid understanding of the properties our scaffolds must possess to complete their tasks.

Electrospun Devices

RenovoDerm was established to address the current performance gaps with yesterday's synthetics and biologics.

Biomimetic, synthetic, electrospun scaffolds provide the starting point for in situ tissue engineering (TE).



Synthetics
Biointegration, Infection, Fibrosis...

Performance Gap

Biologics
Degradation, Safety Sourcing, Cost...

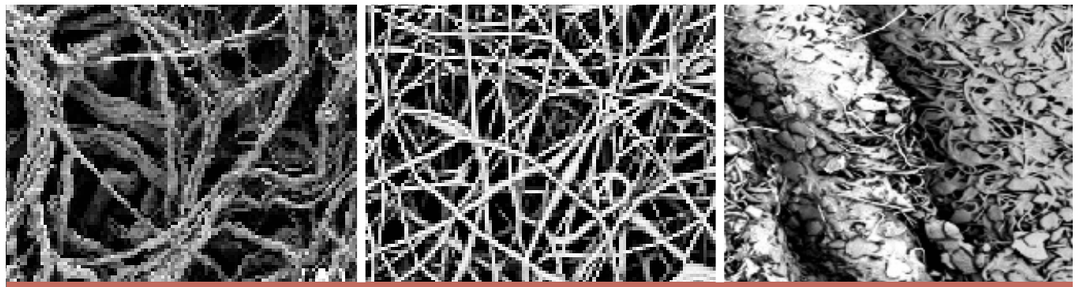
What Are Electrospun Devices?

- 1 µm = 0.000001 m
- Typical Fibroblast is 10- 15 µm across
- Fibers comprising traditional dressings have 50+ µm diameters – far too large for a fibroblast to adhere to
- *RenovoDerm's Phoenix Wound Matrix fibers are only 5 µm*

- Comprised of synthetic polymers – more cost effective and more consistent than human/animal derivatives

Designed To

- Replicate the structure of the native dermal ECM.
- Promote cell adherence and proliferation



Dermal ECM | The Phoenix Wound Matrix | The Phoenix Wound Matrix with Fibroblast

Phoenix Wound Matrix® is a fully bioabsorbable advanced wound care device (CTP) designed to harness and support the wound healing process, allowing for the regeneration of functional, native tissue in the wound bed. *

Using proprietary technology, the Phoenix is designed to:

- **Mimic** native ECM morphology
- **Promote** wound healing through all phases without stalling in the inflammatory phase
- **Facilitate** cellular adherence and infiltration
- **Support** capillary growth, cellular proliferation, and native mechanochemical behavior, including intercellular communication
- **Regenerate** fully-functional tissue

Other Advantages of the Phoenix Wound Matrix:

Easy to handle and apply, no re-hydration

Anchor with physician's/QHP's preferred method

Re-apply q7 days prn

No contraindications

Readily available off-the-shelf

Degradation within 14 days via hydrolysis

Convenient sizes 16 mm disc, 1.5 x 2 cm^2, 2.5 x 2.5 cm^2, 3 x 4 cm^2, 5 x 5 cm^2, 7 x 7 cm^2, 10 x 10 cm^2, 10 x 20 cm^2

The Phoenix Wound Matrix has FDA clearance for use in the treatment of both acute and chronic, partial and full-thickness wounds, including: diabetic ulcers, venous stasis ulcers, arterial insufficiency ulcers, pressure ulcers, tunneled/undermined wounds, trauma wounds, second degree burns, and surgical wounds (e.g., post-Mohs, post-laser, wound dehiscence, donor sites/grafts)

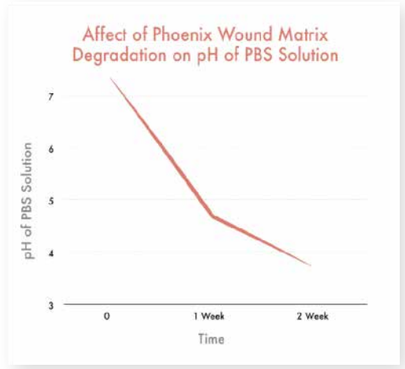
Why Phoenix?

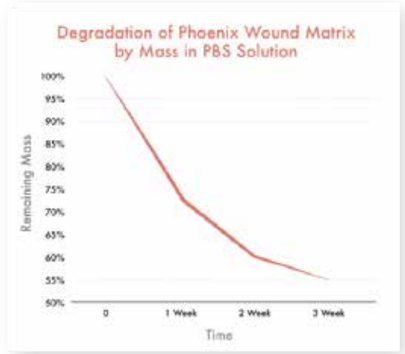
Acid Environment & Wound Healing

As the Phoenix Wound Matrix degrades, the weakly acidic monomers comprising it are gradually released into the wound bed. This acidic degradation is designed to lower the pH of the local wound environment.

In vitro degradation tests on the Phoenix Wound Matrix demonstrate a drop in the pH of PBS from 7.4 to 4.75 over the course of one week.

In wounds, an acidic pH inhibits destructive protease enzymes, increases available oxygen via the Bohr effect, promotes angiogenesis, reduces toxicity of bacterial enzymes and metabolites, enhances destruction of abnormal collagen, and increases macrophage and fibroblast activity [1] [2].





Controlled Degradation

In vitro testing of the Phoenix Wound Matrix demonstrates that it allows for cellular adhesion and proliferation [3]. The device slowly degrades after it is placed, with in vitro degradation tests displaying a 40 percent mass loss over two weeks in isotonic PBS solution. This degradation profile is designed to clear out space within the matrix so that it can be replaced by native ECM and provide a gradual transition from the Phoenix Wound Matrix to native ECM and healthy tissue over the wound bed.

Conclusions

The Phoenix Wound Matrix gradually degrades in the wound bed after it is placed. This degradation is designed to acidify the wound bed and to allow for gradual regrowth of native ECM structures to promote regeneration of healthy tissue.

Promoting Cellular Attachment

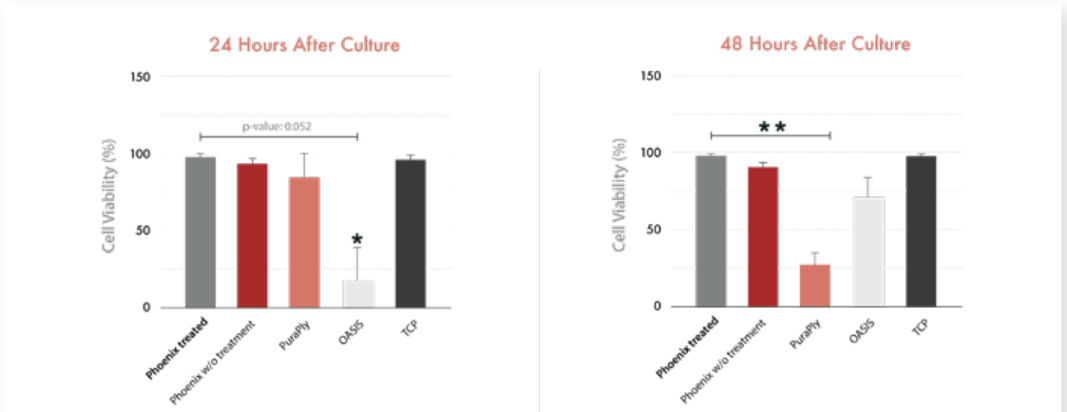
The Extracellular Matrix (ECM) is a three-dimensional network of collagen, enzymes, and glycoproteins [4]. Cells adhere to the ECM via specialized molecules on the cell surface. The ECM can act as a support when organizing cells into tissues and can also facilitate cell-to-cell signaling [5].

During the normal healing process, fibroblasts migrate over the wound bed and deposit new extracellular matrix, which contributes to the formation of vascularized granulation tissue. This process is critical to wound healing; however, it may be interrupted and impeded due to various co-morbidities and other factors. This interruption of the normal healing process results in a non-healing wound [6][7].

The Phoenix Wound Matrix was designed to replicate the structure of native ECM, with the intent of promoting cellular adhesion and proliferation and restarting the normal healing process.

Phoenix vs. Puraply and Oasis

Primary Human Dermal Fibroblasts (HDFa) were cultured on Phoenix Wound Matrix, Puraply, Oasis, and a Tissue Culture Polystyrene control at a density of 2.6 x 10^4 cells/cm2. Cell adhesion and viability was assessed via fluorescent imaging at 24 and 48 hours after seeding using a co-stain of green-fluorescent calcein-AM to indicate live cells, and redfluorescent ethidium homodimer-1 to indicate dead cells. The cell adherence and viability results (live cells/total cell count) are presented in the following figure:



**Indicates significant difference compared to other dresings. p-value <0.001*

***p-value: 0.014*

Cell viability results showed significantly higher numbers of HDFa cells attached to the Phoenix Wound Matrix after 24 and 48 hours of culture compared to competitors. Cell viability on the Phoenix Wound Matrix was comparable to that of Tissue Culture Polystyrene. This demonstrates the potential of the Phoenix Wound Matrix to provide support for cell adhesion and proliferation, and thus favor tissue regeneration.

Product Summary

The **Phoenix Wound Matrix** is a sterile, single-use device intended for the management of wounds. The Phoenix Wound Matrix is a conformable, non-woven, fibrous, three-dimensional matrix that is bio absorbed after degrading through hydrolysis.

Indications

- Partial and full thickness wounds
- Pressure ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcer
- Tunneled/undermined wounds
- Surgical wounds (donor sites/grafts, post-Moh's surgery, post laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions lacerations, second degree burns, skin tears)
- Draining wounds

Case Study: 1

Stalled Diabetic Foot Ulcer

Patient is a 61 y/o male with DM, lumbar radiculopathy, HTN, MRSA, Neuropathy, Osteomyelitis.

Just removed from pic line, currently on Doxycycline. Positive drainage, negative probe to bone. Pulses 2/4 bilateral. Wound has been open for 2 months.

After 3 applications of PHOENIX, achieving 83% reduction in wound size, treatment transitioned to an amniotic for closure.

Application Photos

Day 0 first Phoenix applied (pre-application image)

Day 7 29% reduction in wound size

Day 7 second Phoenix applied

Day 14 83% reduction in wound size third Phoenix applied

Day 21 continued closure transitioned to an amniotic

83% Wound Area Reduction in 14 Days

Case Study: 2

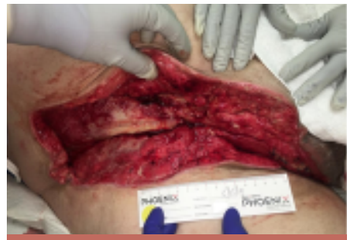
Necrotizing Fasciitis

57-year-old male with diabetes, hypertension and large open wound.

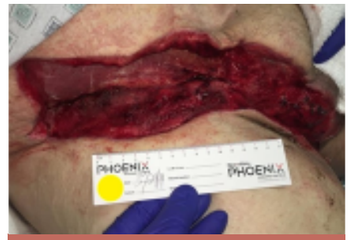
Patient was diagnosed with necrotizing fasciitis, requiring extensive surgical debridement, antibiotics, and hyperbaric oxygen therapy.

After 3 applications of PHOENIX, combined with wound care best practices, complete wound closure was achieved in 18 weeks.

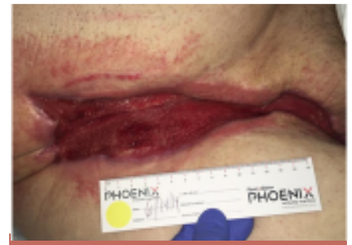
Application Photos



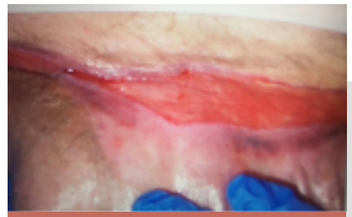
Day 0 first Phoenix applied (pre-application image)



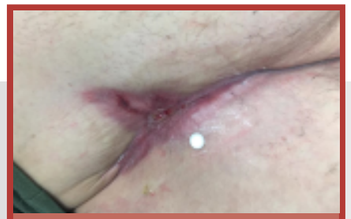
Day 11 second Phoenix applied (pre-application image)



Day 32 third Phoenix applied (pre-application image)



Day 67 96% reduction in planimetric area was achieved



Day 121 wound closure was achieved on Day 125.

77% Wound Area Reduction at 4 Weeks

Histology

GLP Porcine Wound Study

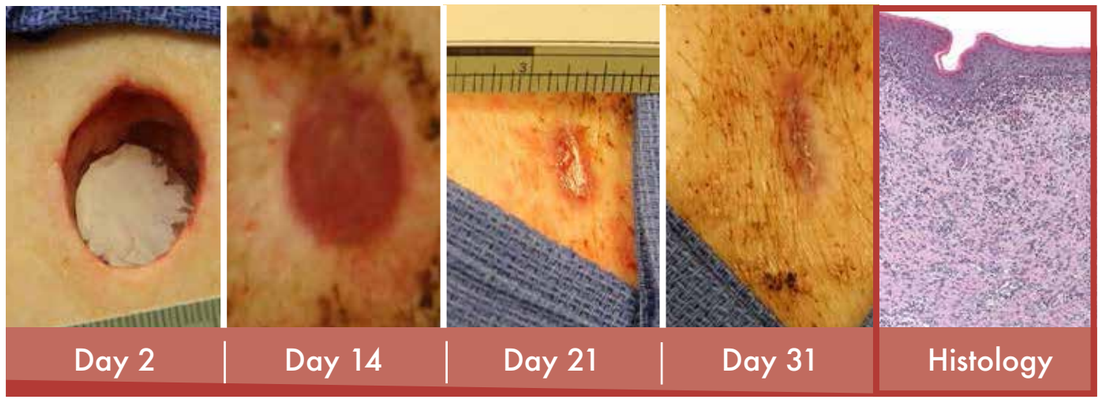
Full thickness wounds of 2.0 cm in diameter were created in the backs of Yucatan miniature swine. Wounds were dressed with a non-adherent dressing (TelfaClear), gauze moistened in sterile saline, and an adherent dressing (Tegaderm). The dressings were removed 48 hours after wounding and a Phoenix Wound Matrix was placed in direct contact with the wound bed.

A non-adherent dressing was placed over the Phoenix Wound Matrix, followed by moistened gauze, adherent dressing, and bandaging. The Phoenix Wound Matrix was left undisturbed for the duration of the study after placement and no additional Phoenix Wound Matrices were applied. Dressings were changed twice weekly during the in-life portion of the study. Animals were survived to 14, 21, and 31 days. Wounds were excised after euthanasia and evaluated by a pathologist after H&E staining.

Results

After 31 days, wounds demonstrated complete re-epithelialization under gross observation and histopathological evaluation. A panel of representative images at each time point and a histology slide from Day 31 is provided below:

Histology at Day 31



Application Guide

1. Trim the Matrix (Optional)

Trim the Phoenix Wound Matrix to-size such that the edges match the edges of the wound bed.

2. Anchor Matrix

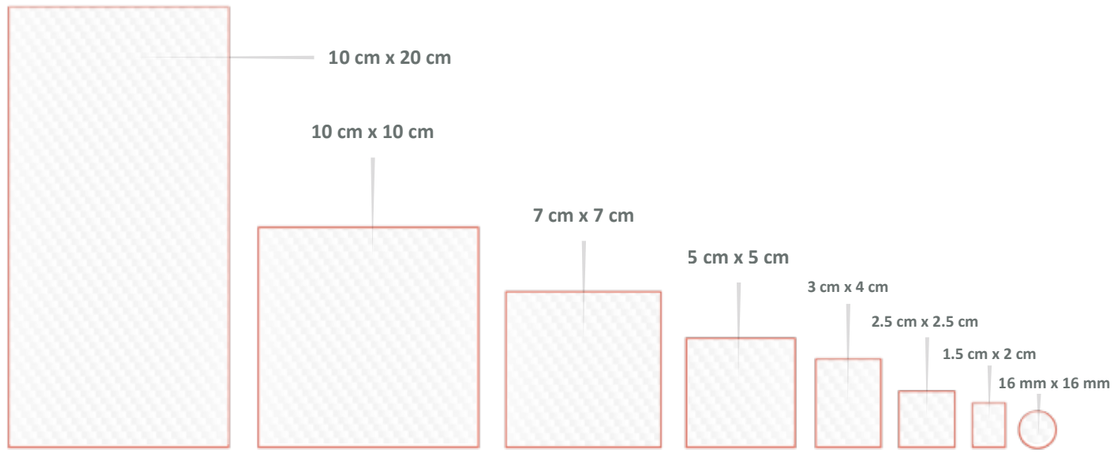
Place the matrix in the wound and gently smooth it onto the wound bed to ensure direct contact. Anchor with physician's/QHP's preferred method of fixation: staples, sutures, surgical glue, or reinforced adhesive skin closures (e.g., Steri-Strip™). Gently rinse the matrix and wound bed with sterile saline.

3. Non-Adherent Dressing

Apply an appropriate non-adherent dressing over the Phoenix Wound Matrix to bolster it firmly in contact with the wound bed.

Phoenix Sizes & Ordering Data

(5 sheets per box)



References:

1. Nagoba BS, Suryawanshi NM, Wadher B, Selkar S. Acidic Environment and Wound Healing: A Review. Wounds. 2015;27(1):5-11.
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3. Manufacturer-Sponsored White Paper – "Phoenix Wound Matrix: Cell Adherence and Proliferation".
4. Theocharis, A. D.; Skandalis, S. S.; Gialeli, C.; Karamanos, N. K. (2016). "Extracellular matrix structure". Advanced Drug Delivery Reviews. 97: 4–27.
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9. Nagoba BS, Suryawanshi NM, Wadher B, Selkar S. Acidic Environment and Wound Healing: A Review. Wounds. 2015;27(1):5-11.
10. Porporato PE, Payen VL, Saedeleer CJD, et al. Lactate stimulates angiogenesis and accelerates the healing of superficial and ischemic wounds in mice. Angiogenesis. 2012;15(4):581-592. doi:10.1007/s10456-012-9282-0.

RenovoDerm is dedicated to building an advanced line of wound care products that enhance tissue regeneration and promote rapid and definitive wound healing.

For product information and technical, medical or reimbursement questions, please call **(614) 602-1852** or visit **www.phoenixmatrix.tech**

**All claims are supported by clinical case studies, a GLP porcine animal study, and/or veterinary case studies.*

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