Neox®

# The Most Human Form of Wound Healing

# We provide Mother Nature’s most natural gift of healing. At BioTissue, science meets nature.

# Meeting the Clinical and Financial Challenges of Wound Healing

## Time heals wounds. Diabetes doesn't know time.

In the United States, every 17 seconds someone is diagnosed with diabetes, and every day 230 Americans with diabetes will suffer an amputation.[1]

## Diabetic Foot Health

Up to **25%** of those with diabetes will develop a foot ulcer[2-3]

Annual incremental payer burden ranges from **$9.1 - $15 Billion.**[4]

More than half of diabetic foot ulcers (DFU) develop infection, often with osteomyelitis, and up to 20% of infected DFUs require major or minor amputations. One recent study demonstrated that excess health care costs of DFUs are approximately twice that attributable to the treatment of diabetes alone, with annual incremental per-patient medical costs ranging from $11,710 to $16,883[4]

**$1 Million** are spent on diabetic foot complications in the USA every 30 minutes[7]

## Wound Epidemiology

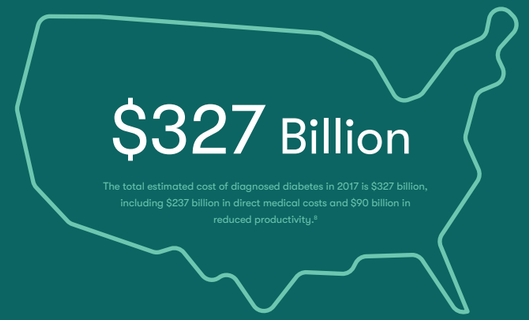
**14.5%** of Medicare beneficiaries in 2014 (8.2 million patients) were diagnosed with at least one type of wound or wound-related infection.[6]

Listed by prevalence:

1. Surgical wound infections, the largest category, at 4%
2. Diabetic wound infections 3.4%
3. Non-healing surgical wounds 3%



## Cost of Diabetes in the U.S.




**$237 Billion** direct medical costs

**$90 Billion** indirect medical costs (disability, reduced productivity, premature death)

## Outsmart Diabetes

Podiatric medical care can reduce amputation rates up to **80%**[10]

The use of Advanced Treatments improved outcomes in lower extremity diabetic ulcers as demonstrated in a recent clinical study. In the clinical use of Neox as an advanced treatment, 79% of patients with Wagner 3-4 DFUs achieved closure in an average of 16 weeks with an average of 1.24 graft applications.[11]

The inclusion of care provided by podiatrists for those with diabetes alone will save the healthcare system **$3.5 Billion** per year.[12]

# Managing the Complexities of Human Healing

## Together we are on a journey to solve unmet patient needs by helping to improve healing and reducing patient suffering.

We share your dedication to knowing more about the disease process and trying to understand if there is a better way to treat difficult diseases.

Our goal has been and always will be solving patients' unmet clinical needs through the relentless pursuit of new solutions to complex problems. Everything we do to discover, develop, and bring to market products and applications is centered on helping you as healers and improving the lives of patients.

## Built on a foundation of relentless clinical pursuit, discovery and cost-effective solutions

**36 Years**
of National Institute of Health (NIH) funding

**680,000+**
human clinical applications

**380+**
peer-reviewed publications studying our technology

**1st**
to establish Level 1 CPT Codes or reimbursement of amniotic membrane used on the ocular surface

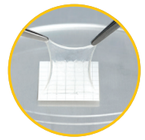
**6 IND**
(Investigational New Drug) products with three in Phase 2 & 3 Clinical trials for BLA approvals



# Biological Tissue Provides the Most Human Form of Healing

We are in a race against time to heal chronic wounds. BioTissue Surgical products provide the natural healing properties of human birth tissue to the wound.

**Neox 1K** is a cryopreserved ultra-thick human amniotic membrane derived from umbilical cord used as an adjunct treatment for chronic and acute, partial and full-thickness wounds.[11,13-15] This allograft helps promote healing in complex diabetic foot ulcers complicated with osteomyelitis, comparing favorably to the Standard of Care.[11,15,16] It's up to 10 times thicker than amniotic membrane alone,[17] which may increase longevity in the wound bed, potentially reducing applications and cost of care.



**Neox 100** is a thinner cryopreserved version of our human amniotic membrane allograft, ideal for shallow wounds or for larger wound areas. The allograft is delivered on a non-implantable, gridded paper backing for easier handling and application.

**Neox RT** is a sterile, ultra-thick human amniotic membrane allograft derived from umbilical cord, for chronic and acute partial and full thickness wounds. Neox RT delivers the benefits of human amniotic allograft in a shelf stable product with room temperature storage. It is manufactured, using the SteriTek® preservation process, stored in saline (0.9% w/v NaCl) and terminally sterilized via gamma irradiation yielding a hydrated shelf stable product.

## Preserving as Much of Nature as Possible

For over 36 years, our pioneering scientists have focused on understanding the regenerative features of human birth tissue—ultimately identifying HC-HA/PTX3 as a key orchestrator in human birth tissue regenerative healing.[18-22]

The BioTissue CryoTek cryopreservation process is the only tissue processing method shown to produce a matrix comparable to the native tissue.[17,23] In conventional dehydration processing, critical biological components—including the majority of HC-HA/PTX3 naturally found in birth tissue—are degraded, which may limit the processed tissue's healing capabilities.[17]

CryoTek cryopreservation technology utilizes controlled deep freezing to effectively preserve the functional and structural integrity of the birth tissue.[17,23]

CryoTek preserves the functional components of the extracellular matrix.

BioTissue Surgical human birth tissue products are aseptically processed, devascularized and cell devitalized to deliver the innate properties of human birth tissue to the wound environment.

# The Proof is in the Evidence

The number of non-healing wounds is dramatically increasing, this poses extreme challenges to the U.S. healthcare system. Diabetic wound healing is one of the most prevalent complications. Healing in the diabetic patient is more crucial than ever, as the 5-year mortality rate is 31% - the same rate as all reported cancer.

## Healing complex wounds in less time with fewer applications:

| | Neox UC[11] Caputo DPM 2016 | Neox UC[14] Raphael DPM 2016 | Neox UC[15] Raphael DPM 2017 | AM+Chorion[25] | Placenta[26] | AM+Chorion[27] |
|---|---|---|---|---|---|---|
| #Patients/ #Wounds | 31/33 | 29/32 | 13/14 | 63/63 | 31/31 | 13/13 |
| Indications | **Complex DFU with Osteomyelitis** | DFU | **Complex DFU with Osteomyelitis** | DFU | Complex DFU **without** Osteomyelitis | DFU |
| Avg Wound Area | 15.6 $cm^2$ | 10.6 $cm^2$ | 33.2 $cm^2$ | 5.2 $cm^2$ | 14.6 $cm^2$ | 2.6$cm^2$ |
| Healing Rate | **78.8%** Avg: 16 weeks | **87.5%** Avg: 13.8 weeks | **100% (+NPWT*)** Avg: 24 weeks | Week 24: 47% | Week 16: 59.7% | Week 6: 92% |
| Avg # Applications | **1.24** | **1.68** | **3.2** | **3.5** | **9.0** | N/A |
| Wagner Grade | Wagner 3-4 | Wagner 1-4 | Wagner 3-4 | N/A | Wagner 2 | Wagner 1 |

**Negative Pressure Wound Therapy*



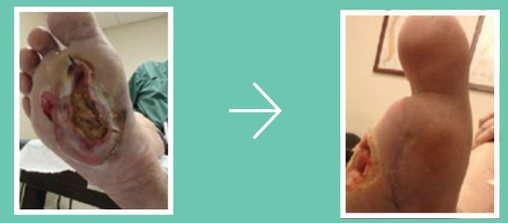
# Proven Outcomes

### Clinical Use of Neox 1K as an Adjunct Therapy In Promoting Healing of A Complex Wound Resulting from Necrotizing Fasciitis

Thomas Fusco, DPM, FACFAS - Orthopedic Associates, Fort Walton Beach, FL

**Wound closure in 10 weeks**

2 Neox 1K graft applications

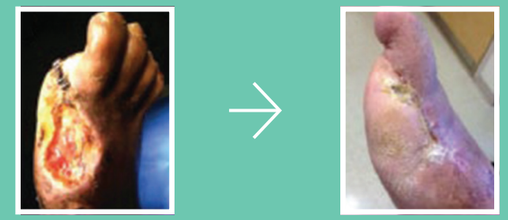


### Clinical Use of Neox 1K as an Adjunct Therapy in Promoting Healing of a Complex Wound

Wayne Caputo, DPM Clara Maass Medical Center, Newark, NJ

**Wound closure in 28 weeks**

2 Neox 1K graft applications



### Clinical Use of Neox 1K as an Adjunct Therapy in Transmetatarsal Amputation with Recurrent Ulceration of the Lateral Column

Allen Raphael, DPM, Village Podiatry Center, Smyrna, GA

**Wound closure in 13 weeks**

2 Neox 1K graft applications



# The time is now to achieve a new standard of care. Together we can make a difference in complex wound management.

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