

Neox® 1K for Non-Healing Venous Ulcer

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Why this Study is Relevant

Venous Leg Ulcers (VLUs) are late indicators of Chronic Venous Insufficiency (CVI) and Venous Hypertension. Venous leg ulcers are difficult to treat and are likely to have a longer term impact on the patient's quality of life once they develop. Treating patients with VLUs can also be costly as a result of frequent hospital and clinic visits associated with the condition.1

For Medicare and commercial insurance, VLUs are a costly chronic condition, the total annual cost burden has been estimated at \$14.9 billion in the US.2

Case Example

A 70-year-old wheelchair/bed bound male with a 50 pack/year history of cigarette abuse, combinatorial venous & diabetes disease, Peripheral Vascular Disease (PVD) and joint contracture presented with a two year non-healing VLU & diabetic foot ulcer on the medial right ankle, despite peripheral bypass surgery. The patient refused smoking cessation, and failed local wound care and antibiotic therapy.

Treatment Procedure

The wound underwent sharp debridement with opening of the bone cortex prior to a Neox® 1K application. Neox 1K was stapled in place completely covering the wound, and dressed with a petrolatum gauze. Weekly dressing changes applying silver sulfadiazine without disturbing the birth tissue allograft were utilized.

Outcomes

80% reduction in size and depth of wound at week 15 with full healing noted at week 23 (with single application of Neox 1K).



APPLICATION



2 WEEKS



3 WEEKS



Controlled inflammation

Expedited closure with one application

Expedited wound healing





23 WEEKS

32 WEEKS

Neox 1K

Neox 1K cryopreserved ultra-thick human amniotic membrane allograft derived from umbilical cord is an adjunct treatment for chronic and acute, partial and full-thickness wounds.



Up to 10x thicker than amniotic membrane,³ which may increase longevity in the wound bed for **fewer applications and lower cost of care.**

| % Patients Achieving Complex Wound Closure with: | | | |
|--|-------------------------------------|--|--|
| Neox 1K | Standard of Care | | |
| 70% at 16 weeks ⁴ | 32.6% at 20 weeks ⁵ | | |
| 79% at 1 year ⁴ | 45% regardless of time ⁶ | | |

Neox RT

Neox RT is a hydrated, shelf stable, ultra-thick human amniotic membrane allograft derived from umbilical cord, for chronic and acute partial and full thickness wounds. Neox RT is manufactured, using the proprietary SteriTek® preservation process, stored in saline (0.9% w/v NaCl) and terminally sterilized via gamma irradiation.

Neox 100

Cryopreserved amniotic membrane allograft for wound applications, a thinner alternative to Neox 1K. The allograft is delivered on a non-implantable, gridded paper backing for easier handling and application.

The BioTissue Difference

| Over-38-year commitment to understanding the science behind fetal regenerative healing. The leader in the transformation to becoming a biologics provider. | Manufacturer | Processing | Proprietary CryoTek® cryopress shown to preserve more of the components and structural intetissue. |
|---|---------------|------------|--|
| Focused on delivering quality amniotic membrane-based allografts, we are the only company with FDA-designation for its unique anti-inflammatory, anti-scarring, and anti-angiogenic properties on the ocular surface. | Tissue Source | Storage | Versatile solution enables cool minimal thawing and the abilit product to storage unopened. |

- 1. Health Quality Ontario. Ont Health Technol Assess Ser. 2019;19(2):1-86. Published 2019 Feb 19.
- Rice JB, Desai U, Cummings AK, Birnbaum HG, Skornicki M, Parsons N. Burden of venous leg ulcers in the United States. J Med Econ. 2014;17(5):347-356.
- 3. Cooke M, Tan EK, Mandrycky C, He H, O'Connell J, Tseng SC. J Wound Care. 2014;23(10):465-476.
- 4. Caputo WJ, Vaquero C, Monterosa A, et al. Wound Repair Regen. 2016;24(5):885-893.

Neox 1K

Cryopreserved Ultra-Thick Amniotic Membrane Allograft

Neox RT
Room Temperature Amniotic Membrane Allograft

Neox 100

Cryopreserved Amniotic Membrane Allograft

Size

2.0 x 1.0 cm

20 x 20 cm

3.0 x 2.0 cm

3.0 x 3.0 cm

4.0 x 3.0 cm

6.0 x 3.0 cm

8.0 x 3.0 cm

2.0 x 1.0 cm

2.0 x 2.0 cm

3.0 x 2.0 cm

 $3.0 \times 3.0 \text{ cm}$

4.0 x 3.0 cm

6.0 x 3.0 cm

8.0 x 3.0 cm

Size

20 x 20 cm

3.0 x 3.0 cm

4.0 x 4.0 cm

7.0 x 7.0 cm

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Product Code

NX-10-2010

NX-10-2020

NX-10-3020

NX-10-3030

NX-10-4030

NX-10-6030

NX-10-8030

Product Code NX-UR-2010

NX-UR-2020

NX-UR-3020

NX-UR-3030

NX-UR-4030

NX-UR-6030

NX-UR-8030

Product Code

NX-02-2020

NX-02-3030

NX-02-4040

NX-02-7070

- 5. Margolis DJ, Allen-Taylor L, Hoffstad O, Berlin JA. Diabetes Care. 2002;25:1835–9.
- 6. Fife CE, Eckert KA, Carter MJ. Adv Wound Care 2018; 7: 77-94.

BioTissue Surgical products are authorized under the regulations of the U.S. Food and Drug Administration (FDA) governing the manufacture and distribution of Human Tissue Products. They are marketed as structural tissue products for homologous use and are used by physicians as barriers, wound coverings, conduits, and/or cushions in the treatment of their patients.

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