

A Guide for
PATIENTS RECEIVING NEOX



neox[®]

WHAT IS A CHRONIC WOUND?

A chronic wound is one that experiences a delay in the normal phases of healing. From an insurance perspective, these are wounds that do not heal completely after receiving the standard medical treatment for 30 days.

Your chronic wound may be one of seven primary types:

Diabetic Foot Ulcer (DFU)—a non-healing wound below the ankle in an individual with diabetes caused by repetitive injury to a numb foot (patients often have a loss of sensation in the area), restricted blood supply, or a combination of both. DFUs most commonly occur on the bottom of the foot or between or at the tip of the toes.

Venous Leg Ulcer—venous leg ulcers are caused when the veins in the lower part of the leg don't circulate blood well, and the leg swells in response. This extreme swelling can put so much pressure on the skin that ulcers form. The swelling is also called edema.

Arterial Ulcer—a wound that results from inadequate arterial blood supply or flow, typically located in the lower part of the leg. It is typically caused by Peripheral Artery Disease (PAD).

Pressure Ulcer—also called a bed sore, a pressure ulcer is the result of injury to the skin or underlying tissue resulting from prolonged pressure on the skin. They most often develop on skin that covers bony areas of the body like the tailbone, hips, and heels.

Surgical Wound—a wound that occurs at the surgical site and doesn't heal in the expected time frame.

Traumatic Wound—a traumatic wound is caused by an external force and includes skin tears, cuts, punctures and wounds caused by fractures or foreign bodies.

Burn or Radiation Wound—a thermal or chemical burn, or a wound from the effects of radiation therapy for cancer treatment

WHAT IS NEOX® AND WHY IS YOUR PHYSICIAN USING IT TO TREAT YOUR CHRONIC WOUND?

Amniotic tissue, which includes the umbilical cord and amniotic membrane surrounding the unborn baby, has been designed by nature to allow the fetus to develop in a healthy, protected manner.

Unlike any other tissue in the body, amniotic tissue has regenerative properties that promote healing with minimal evidence of scarring. These reparative abilities come from innate biological factors that promote tissue growth and healing.

The properties of amniotic tissue can be preserved and transplanted into environments outside the womb. These tissues have been used in medicine for more than 100 years. NEOX is donated human umbilical cord/amniotic membrane used to aid in wound healing.

Non-resolving inflammation is a key contributor to the development of chronic wounds. The biological content of NEOX umbilical cord/amniotic membrane has been shown to manage inflammation, inhibit or reduce scarring of normal tissue. **Essentially, it acts like a conductor of a symphony, directing the different cells and molecules of your body in a coordinated manner so it can heal itself.**



NEOX acts like a conductor, directing cells and molecules so that they can heal the wound.

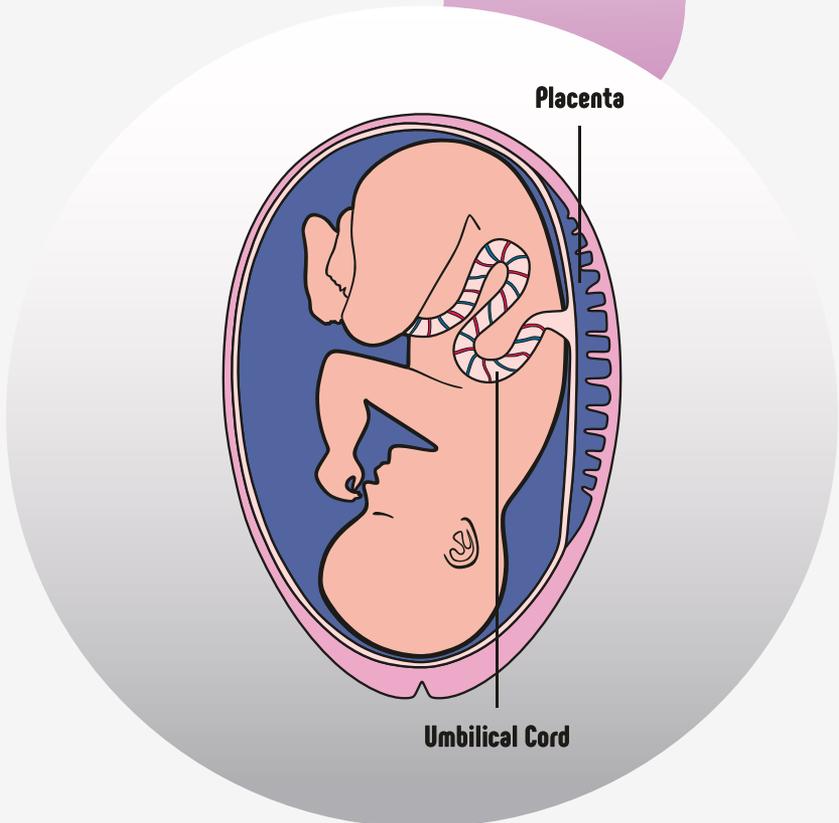


THE NEOX DIFFERENCE: PRODUCT SOURCE AND PROCESS

While both the amniotic membrane and the umbilical cord promote healing of chronic wounds, the **umbilical cord is a more potent source** of the healing properties than amniotic membrane alone.¹⁻³

NEOX CORD 1K was the first umbilical cord/amniotic membrane tissue on the market used for treatment of chronic wounds, and is the leading brand today.

The **process** used to preserve NEOX is called Cryotek®—a patented process where the tissue is kept at very low temperatures to prevent damage to the vital biology that makes it effective. The tissue is stored in a freezer or refrigerator until use.



LET'S TALK SAFETY

NEOX's parent company, Tissue Tech, has more than 20 years of clinical experience and over 300,000 umbilical cord/amniotic membrane transplants supporting its safety record. It won highly competitive research grants continuously over the past 30 years from the National Institutes of Health (NIH).

Tissue Donation—The Ultimate “Green” Product

Amniox Medical obtains the tissue used in all its products through a voluntary donation program across the US.

Donor mothers provide full consent prior to delivery of a full-term, live newborn baby via a scheduled Cesarean section.

The amniotic membrane and umbilical cord, which are typically discarded after a delivery, are instead processed and preserved at Amniox Medical's state-of-the-art US-based facility before being shipped to hospitals and wound care clinics across the US to be utilized by clinicians to effectively treat wounds.

Safety Information

Prior to donation, all mothers are carefully screened to ensure safety based on requirements established by the United States Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB).

Additionally, the donated tissue is thoroughly screened for infectious diseases, including HIV, Hepatitis B & C, Syphilis, West Nile Virus, and Zika, among others.

Finally, the donated tissue is thoroughly cleaned and processed to preserve the tissue's regenerative properties. To date, after more than 300,000 procedures, there have been no reports of disease transmission or tissue rejection from use of these tissues.



WHAT TO EXPECT DURING YOUR VISIT TO THE DOCTOR

Initial NEOX Application

1. Prior to applying NEOX to your wound, your doctor will clean and debride (remove damaged or unhealthy tissue) the wound to ensure the optimal conditions for NEOX to work.
2. He or she will then apply the correct size of NEOX to your wound and may use adhesive strips or another method to attach the tissue to the wound bed.
3. Your NEOX tissue will be covered by a non-adherent dressing (the primary dressing) to protect it and keep it close to the wound.
4. The protective layer (primary dressing) will be wrapped with an absorptive pad or gauze layer to secure NEOX and absorb any excess fluid from the wound.

Subsequent Visits

Because NEOX is made of umbilical cord and is more potent than amniotic membrane alone, it may keep working in your wound for up to 3-4 weeks. During this time your body will begin to break down the tissue, releasing the biology that modulates the wound environment. During these follow-up visits, the doctor will change the dressings and may debride around the edges of the wound.

It is common for the graft to turn yellow and then black while it is being incorporated into the wound. It may become red or pink as it begins to heal. Contact your doctor if you have any concerns.



Once NEOX is fully incorporated into your wound, your doctor will evaluate whether your wound has healed or requires an additional application of the tissue.

TAKING CARE OF YOUR WOUND BETWEEN VISITS

For best results, always follow your physician's directions regarding your dressing and weight-bearing restrictions (if applicable). Return for all scheduled doctor's visits.

HOW LONG WILL IT TAKE FOR MY WOUND TO CLOSE?

Each wound is different; in general, the larger the wound, the longer it will take to close. With NEOX, you can generally expect to see changes within the first 1-2 weeks after application.

Recent studies have shown varying degrees of healing rates for chronic wounds receiving standard of care only, ranging from 21%⁴ to 51%⁵ at 12 weeks. A larger study of 586 patients with neuropathic diabetic ulcers found that only 23% had healed at 20 weeks.⁶

In contrast, recently published studies have shown NEOX has a healing rate ranging from 78%-87% in large and complex wounds.⁷⁻⁸



¹ He et al., (2009) J Biol Chem, 284:20136-46

² Zhang et al., (2012) J Biol Chem, 287: 12433-44

³ He et al., (2013) J. Biol Chem, 288: 25792-803 Lavery, LA et al. Int Wound J, 11: 554-560, July 2014.

⁴ Lavery, LA et al. Int Wound J, 11: 554-560, July 2014.

⁵ Zelen CM et al. Int Wound J, 12(6): 724-32, Dec. 2015.

⁶ Kantor, J and Margolis, D. Wounds 12 (6):155-158 Dec. 2000.

⁷ Caputo, WJ et al. Wound Rep Reg (2016) 24 885-893.

⁸ Raphael, A. JoWC, Vol. 25. Number 7, July 2016

This information brought to you by your wound care provider:



For more information, ask your doctor,
or visit www.amnioxmedical.com

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