amniox®
A TissueTech Company

# FREQUENTLY ASKED QUESTIONS

## WHAT IS REGENERATIVE MEDICINE?

Regenerative medicine is an interdisciplinary field that applies engineering and life science principles to promote human tissue regeneration. Regenerative medicine is defined as the process of replacing or "regenerating" human cells, tissues or organs to restore or establish normal function. This field holds the promise of regenerating damaged tissues and organs in the body by replacing damaged tissue or by stimulating the body's own repair mechanisms to heal tissues or organs.

Regenerative medicine has grown over the last two decades to encompass a host of treatment options. These include:

- **Tissue Engineering.** Tissue engineering is a strategy where biologically compatible scaffolds are implanted in the body at the site where new tissue will form to repair or replace damaged, diseased, or dysfunctional cells, tissues, and organs.
- **Cellular Therapies.** The human body uses stem cells as one way of repairing itself. This is a strategy whereby adult stem cells are harvested and then injected at the site of diseased or damaged tissue to facilitate reconstruction.
- **Gene Therapies.** There are three ways a genetic material can be introduced to a patient's cell or organ. First, replacing a mutated gene that causes disease with a healthy copy of the gene. Second, inactivating a mutated gene that is functioning improperly. Third, introducing a new gene into the body to help fight a disease.

## WHAT ARE AMNIOX PRODUCTS USED FOR?

Amniox products are amniotic membrane and umbilical cord human birth tissue products used by physicians and surgeons to treat complex wounds, reduce perioperative complication rates, and promote healing following reconstructive surgical procedures. These membrane grafts are either surgically placed or injected into the surgical or wound site to support a structured and nurturing healing environment. Amniox products are used to help with:

- The treatment of chronic and advanced wounds for diabetic and venous ulcers with or without osteomyelitis, plantar foot ulcers, and wound dehiscence that does not respond to traditional treatment options.
- The prevention of adhesions after surgeries in degenerative conditions resulted from tendinosis and tendinitis, osteoarthritis, plantar fasciitis, or ligament damage.
- Surgical incisions and burns as a covering, wrap, or barrier to facilitate faster recovery.

## WHAT MAKES AMNIOX PRODUCTS UNIQUE?

Although there are many tissue processing methods available in the marketplace, each produces different clinical results depending on the tissue source, the processing method applied, the product's storage and delivery, and the manufacturer. A study has shown that the cornerstone of Amniox's platform technology, the HC-HA/PTX3 matrix inherent in human birth tissue, is a key component responsible for the tissue's therapeutic mode of action. Furthermore, based on scientific research and according to the same study, cryopreservation using parent company TissueTech's proprietary CryoTek® process has been shown to preserve the HC-HA/PTX3 matrix component significantly better than dehydration preservation processes.[1]

## WHY IS HUMAN BIRTH TISSUE USED TO MANUFACTURE AMNIOX PRODUCTS?

Research has shown that human birth tissues, particularly the umbilical cord and amniotic membrane, have innate healing properties in the fetal environment. And since Amniox human birth tissue products don't contain living cells, this supports an environment that allows patients' own stem cells to repair and regenerate.

## HOW ARE AMNIOX PRODUCTS ADMINISTERED?

Amniox offers products in two forms – umbilical cord and amniotic membrane grafts that are surgically placed over the wound matrix and particulate product stored in vials formulated for use as an injectable.

## HOW WERE AMNIOX PRODUCTS INVENTED?

In March 1997, Bio-Tissue, Inc., became the first company to commercialize human birth tissue products processed through the CryoTek platform technology for the ophthalmic market using its proprietary cryopreservation process. After realizing the commercial success of Bio-Tissue's PROKERA®, AmnioGraft®, and AmnioGuard® human birth tissue products, TissueTech moved into orthopedic and wound care markets with the launch of Amniox Medical, Inc. in April 2011. Shortly after, Amniox launched the CLARIX® line of products for surgical applications and the NEOX® product line for the management of chronic and complex wounds. Today, both Amniox and Bio-Tissue are vertically integrated within TissueTech to optimize cross-functional collaboration in research and development.

*1. Cooke M, Tan EK, Mandrycky C, He H, O'Connell J, Tseng SC. Comparison of cryopreserved amniotic membrane and umbilical cord tissue with dehydrated amniotic membrane/chorion tissue. J Wound Care 2014; 23: 465—76.*



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