



# **AMNIOX AT A GLANCE**

Advancing regenerative medicine using human birth tissue products to facilitate optimal clinical outcomes

### **OVERVIEW**

Amniox Medical, Inc. (Amniox), a TissueTech company, offers umbilical cord and amniotic membrane human birth tissue products to manage diabetic foot ulcers and other complex wounds, surgical wounds, and musculoskeletal indications. Our customers are comprised of a wide variety of medical professionals who specialize in orthopedics, podiatry, rheumatology, pain management, sports medicine, urology, trauma, wound care, gynecology, and plastic surgery.

The Amniox product portfolio is comprised of two brands. CLARIX® cryopreserved umbilical cord and amniotic membrane human birth tissue products are used for a range of surgical and injectable procedures. These include soft tissue repair, bone and joint reconstruction, nerve decompression and repair, orthopedic trauma, arthroscopic repair, and joint arthroscopy. In addition to orthopedic procedures, CLARIX has been used in reconstructive plastic surgery, urology and other surgical indications. NEOX® cryopreserved umbilical cord and amniotic membrane human birth tissue products are used to facilitate regenerative healing of chronic or complex wounds. NEOX products share many of the biologic and handling benefits of its CLARIX counterparts.

### **AMNIOX ADVANTAGE**

Although there are many human birth tissue products 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.<sup>1</sup>

Amniox products provide a versatile solution that enable cool storage with minimal thawing and the ability to return the product to storage unopened.

## SCIENTIFIC RESEARCH

Amniox is committed to solving unmet clinical needs and empowering healthcare professionals to deliver optimal outcomes through scientific research. Amniox's parent company, TissueTech, holds a long history of innovation as evidenced by more than 34 years of National Institutes of Health (NIH)-sponsored research. Since the company's inception, clinicians have performed over 500,000 human implants using the company's human birth tissue products and more than 360 peer-reviewed studies have been published.



### **EXECUTIVE LEADERSHIP**

Amniox was launched by parent company TissueTech in 2011 with the goal of solving unmet patient needs for orthopedic and wound care indications. These unmet needs were identified by TissueTech Co-founder and Chief Technology Officer Scheffer C.G. Tseng, MD, PhD, a Johns Hopkins Hospital and Massachusetts Eye & Ear Infirmary, Harvard Medical School-trained ophthalmologist and University of California PhD. His goal was to solve an unmet patient need he identified while serving as Charlotte Breyer Rodgers Chair Professor at Bascom Palmer Eye Institute University of Miami Miller School of Medicine. Dr. Tseng would often see patients with chemical eye burns and other severe ocular surface diseases and set out to find something that would help promote regenerative healing while minimizing scarring and inflammation. He experimented with and was impressed with how human birth tissue seemed to help promote an improved healing environment for his patients. Dr. Tseng and his wife, Amy Tseng, established Bio-Tissue, and then TissueTech and Amniox, to bring together the scientists and resources needed to learn more about the healing power of human birth tissue. This team developed and brought to market TissueTech's current product line. Today, the company is still focused on helping physicians with unmet patient needs and improving patient outcomes.

- Scheffer C.G. Tseng, MD, PhD, Co-Founder, Chief Technology Officer
- Amy Tseng, MBA, Co-Founder, President and Chief Executive Officer
- Thomas Williamson, Chief Commercial Officer
- Michael Cornelius, Chief Financial Officer
- Devin Buckley, General Counsel and Chief Compliance Officer

# **HISTORY**

In 1997, TissueTech subsidiary Bio-Tissue became the first company to commercialize human birth tissue products for the ophthalmic market utilizing its proprietary cryopreservation process. After realizing the commercial success of Bio-Tissue's PROKERA®, AmnioGraft®, and AmnioGuard® human birth tissue products, TissueTech moved into the orthopedic and wound care markets with the launch of Amniox Medical, Inc., in 2011. Shortly thereafter, 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.

# **OUR FACILITIES**

Parent company TissueTech adheres to stringent regulatory guidelines within each of the company's facilities to ensure patient safety. These guidelines include maintaining compliance with all U.S. Food and Drug Administration, American Association of Tissue Banks, and many state tissue bank guidelines. Our advanced facility sites include:

- TTI cGMP Manufacturing Facility (Doral) 8305 NW 27th Street Suite 101 Doral, FL 33122
- TTI Distribution Center (San Diego)
  11315 Rancho Bernardo Road Suites 140 and 141
  San Diego, CA 92127

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.

