

BIO-TISSUE AT A GLANCE

Redefining the standard of care with cryopreserved human birth tissue products

OVERVIEW

Bio-Tissue, Inc. (Bio-Tissue), a TissueTech company, offers amniotic membrane and umbilical cord human birth tissue-based products to facilitate recovery from a host of ocular surface diseases and injuries.

The Bio-Tissue product portfolio is comprised of four products. PROKERA[®] biologic corneal bandages have been cleared by the FDA as 510(k) devices for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred. AmnioGraft[®] cryopreserved amniotic membrane matrix is a biologic ocular transplantation graft used by eye surgeons around the world as an adjunct therapy to treat ocular surface indications such as corneal ulcers, pterygium, mechanical dry eye (also known as conjunctivochalasis), excision of tumors, chemical burns, and Stevens-Johnson syndrome. The cryopreserved amniotic membrane used in PROKERA and AmnioGraft has also been designated by the FDA as having anti-inflammatory, anti-scarring, and anti-angiogenic properties when used on the ocular surface.

AmnioGuard[®] is for use as tectonic support (e.g. protection of a glaucoma drainage device tube) to strengthen the cornea, conjunctiva, tenon's capsule, or sclera due to its thickness and tensile strength.

Bio-Tissue's fourth product is Cliradex[®]. This product contains 4-terpineol – an ingredient found in tea tree oil. Cliradex is available as a towelette or foam cleanser for lid, lash, and facial cleansing to provide symptomatic relief from Demodex, blepharitis, dry eye disease, and rosacea.

SURGICAL INDICATIONS

Bio-Tissue's customers are eye care professionals who treat numerous ocular conditions. These conditions include pterygium, Conjunctivochalasis, Stevens-Johnson syndrome, Sjögren's syndrome, glaucoma, blepharitis, lid margin irregularities, and corneal ulcers. In addition to treating these conditions, Bio-Tissue products treat chemical or thermal burns that have affected the ocular surface and provide tectonic support and better host tissue integration. One example of this is the protection of glaucoma drainage device tubes following tube-shunt surgery.

BIO-TISSUE'S ADVANTAGE

Although there are many human birth tissue products available in the marketplace, each product differs 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 Bio-Tissue's platform technology, the HC-HA/PTX3 complex inherent in human birth tissue, is a key component responsible for the tissue's therapeutic mode of action. Furthermore, based on scientific research, cryopreservation using the company's proprietary CryoTek[®] process has shown to preserve the HC-HA/PTX3 complex component significantly better than dehydration preservation processes.¹

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



SCIENTIFIC RESEARCH

Bio-Tissue is committed to solving unmet clinical needs and empowering healthcare professionals to deliver optimal outcomes through scientifically researched products. The company 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

Bio-Tissue was co-founded by 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 by 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, parent company TissueTech, Inc., and Amniox Medical, to bring together the scientists and resources needed to learn more about the healing power of human birth tissues. This team developed and brought to market TissueTech's current product line. Today, the company continues to be 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-based products for the ophthalmic market utilizing its proprietary cryopreservation process. After realizing the patient-driven 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 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 Bio-Tissue and Amniox are vertically integrated within TissueTech to optimize cross-functional collaboration in research and development.

OUR FACILITY

Parent company TissueTech adheres to stringent regulatory guidelines at our facility 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 manufacturing facility is located at:

- **TTI cGMP Manufacturing Facility**
8305 NW 27th Street Suite 101
Doral, FL 33122

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.