TISSUETECH AT A GLANCE

Wholly Owned Subsidiaries: Amniox Medical, Inc. and Bio-Tissue, Inc.

FOUNDED

biotissue — 1997

TISSUETECH — 2001

amniox MEDICAL — 2011

MIAMI, FL
CORPORATE HQ

~300
EMPLOYEES

40
PATENTS

34 YEARS
National Institutes of Health (NIH)-funded research

500K+
Human-Use Cases

360+
Peer-reviewed Publications

TissueTech, Inc. is a pioneer in harnessing the regenerative properties of human birth tissue through the development and clinical application of products marketed through its subsidiaries Bio-Tissue, Inc. and Amniox Medical, Inc. Bio-Tissue is focused on the Eye Care space, while Amniox Medical focuses on Surgical Applications of our technology. The company's umbilical cord and amniotic membrane products are used to treat ocular surface disease and disorders, diabetic foot ulcers and other complex wounds, surgical wounds, and musculoskeletal indications.

TissueTech is committed to solving unmet clinical needs and empowering healthcare professionals to deliver optimal outcomes through scientific research. 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.

UPDATED FDA REGULATIONS

The products TissueTech manufactures are classified as 361 Human Cell, Tissues, and Cellular and Tissue-based Products (HCT/Ps) regulated by the FDA under Title 21 Part 1271 of the U.S. Code of Federal Regulations. Examples of HCT/Ps include bone, skin, amniotic membrane and umbilical cord, blood vessels, adipose tissue, cartilage, tendon and ligament. Per Section 361 of the Public Health Service Act (PHSA), Congress authorized the FDA to issue these regulations in order to prevent the introduction, transmission, or spread of communicable disease.

In November/December 2017, the FDA issued its final Guidance entitled, “Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue Based Products: Minimal Manipulation and Homologous Use.” The Guidance contains the FDA’s nonbinding recommendations regarding its current thinking and does not change the laws cited above. In the Guidance, the FDA confirmed that HCT/Ps may only be applied for “homologous use.” The FDA defines “homologous use” as the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. In the Guidance, the FDA recognized application of amniotic membrane to cover or offer protection from the surrounding environment as homologous use. The FDA also stated that they do not currently consider application of amniotic membrane to support bone tissue replacement, wound healing or reduction of scarring and inflammation as homologous use.

The FDA considers HCT/Ps that are applied other than for homologous use to be “biological products,” requiring a Biologics License Application (BLA) approval to be marketed lawfully. In the Guidance, the FDA stated that over the following 36 months, they intended to exercise enforcement discretion as to BLA requirements for HCT/Ps not applied for homologous use. These 36 months will end in December 2020.

TISSUETECH RESPONSE

Taking the FDA’s cue, TissueTech has been preparing by initiating three BLAs. The process involved entails transitioning to rigorous Chemistry, Manufacturing, and Controls (CMC) with Good Manufacturing Practice (GMP) manufacturing and multi-phased clinical trials to obtain approval for specific products and indications. As of March 2020, the FDA has granted TissueTech three Investigational New Drug Approvals (INDs) to predicate to a BLA to heal Chronic and Complex Wounds, to end pain and restore functionality with osteoarthritis, and heal serious spine conditions including Spina Bifida (a congenital defect of the spine often causing paralysis of the lower limbs and sometimes mental handicaps). The FDA has also granted our Spina Bifida program RMAT (Regenerative Medicine Advanced Therapy) status and our Chronic and Complex Wounds Fast Track Status. Additionally, TissueTech is already in Phase 3 clinical trials towards our BLA approval for Chronic and Complex Wounds, and Phase 3 for TissueTech’s human umbilical cord spine product.

Bio-Tissue’s Prokera® corneal contact bandages have been cleared by the FDA as a 510(k) device for use in eyes in which the ocular surface cells have been damaged, or underlying stroma is inflamed and scarred. The cryopreserved amniotic membrane contained in this product – along with our AmnioGraft® and AmnioGuard® products – has been designated by the FDA as acting as an anti-inflammatory agent, an anti-scarring agent, and an anti-angiogenic agent and for supporting epithelial adhesion and differentiation on the ocular surface.

Progress in the company’s efforts to pursue BLA approval for its products demonstrates TissueTech’s leadership role in the regenerative medicine industry. TissueTech will continue to provide sustainable health economic value, solve unmet clinical needs, and lead in technological innovation in seeking to deliver the promise of regenerative healing for our physician and patient customers. During this time, we will continue to offer our HCT/Ps for uses consistent with those described as allowed above.

OPHTHALMIC AND SURGICAL APPLICATIONS

Bio-Tissue’s customers are eye care professionals who treat numerous severe 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 are also used to treat chemical or thermal burns that have affected the ocular surface and to provide tectonic support and better host tissue integration, e.g., protection of a glaucoma drainage device tube following tube-shunt surgery. Amniox customers are a wide variety of medical professionals who specialize in wound care, orthopedics, podiatry, rheumatology, pain management, sports medicine, urology, trauma, gynecology, and plastic surgery.

THE TISSUETECH 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 TissueTech'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 TissueTech's proprietary CryoTek® process has been shown to preserve the HC-HA/PTX3 matrix component significantly better than dehydration preservation processes.[1] TissueTech products provide a versatile solution that enable cool storage with minimal thawing and the ability to return the product to storage unopened.

FACILITIES

TissueTech adheres to stringent regulatory guidelines within each of 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 state tissue bank requirements. Our advanced manufacturing facility is located at:

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

HISTORY

In 1997, TissueTech's (now) subsidiary Bio-Tissue became the first company to commercialize human birth tissue products for the ophthalmic market utilizing its proprietary cryopreservation process. After realizing commercial success with 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.

EXECUTIVE LEADERSHIP

TissueTech was co-founded by Scheffer C.G. Tseng, a John Hopkins Hospital and Massachusetts Eye & Ear Infirmary, Harvard Medical School-trained ophthalmologist and University of California PhD, 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 for these patients. 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 tissues and to develop and bring to market TissueTech's current product line.

Today, the company is still focused on helping physicians with unmet patient needs and improving patient outcomes. TissueTech's Executive Leadership team includes:

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

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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