TISSUETECH

biotissue | amniox

DISCOVER TISSUETECH

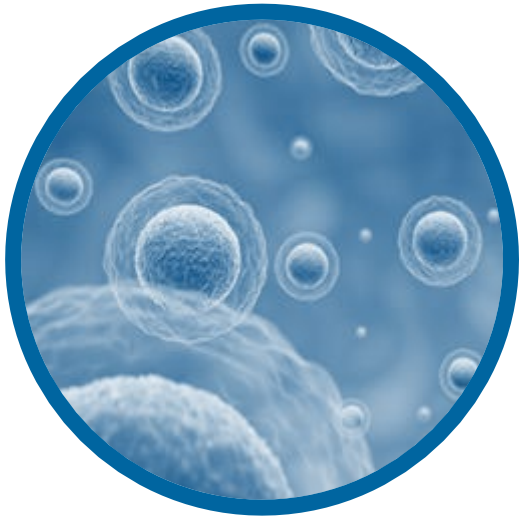
Pioneering the Future of Regenerative Medicine

www.tissuetech.com

OVERVIEW

Pioneer

TissueTech continues to pioneer the application of human birth tissue for regenerative medicine.



Category Leader

TissueTech is well positioned to be the leader with the new regulatory requirements for HCT/Ps.

Trusted Provider

TissueTech is a trusted provider with decades of scientific evidence and a clear health economic value.

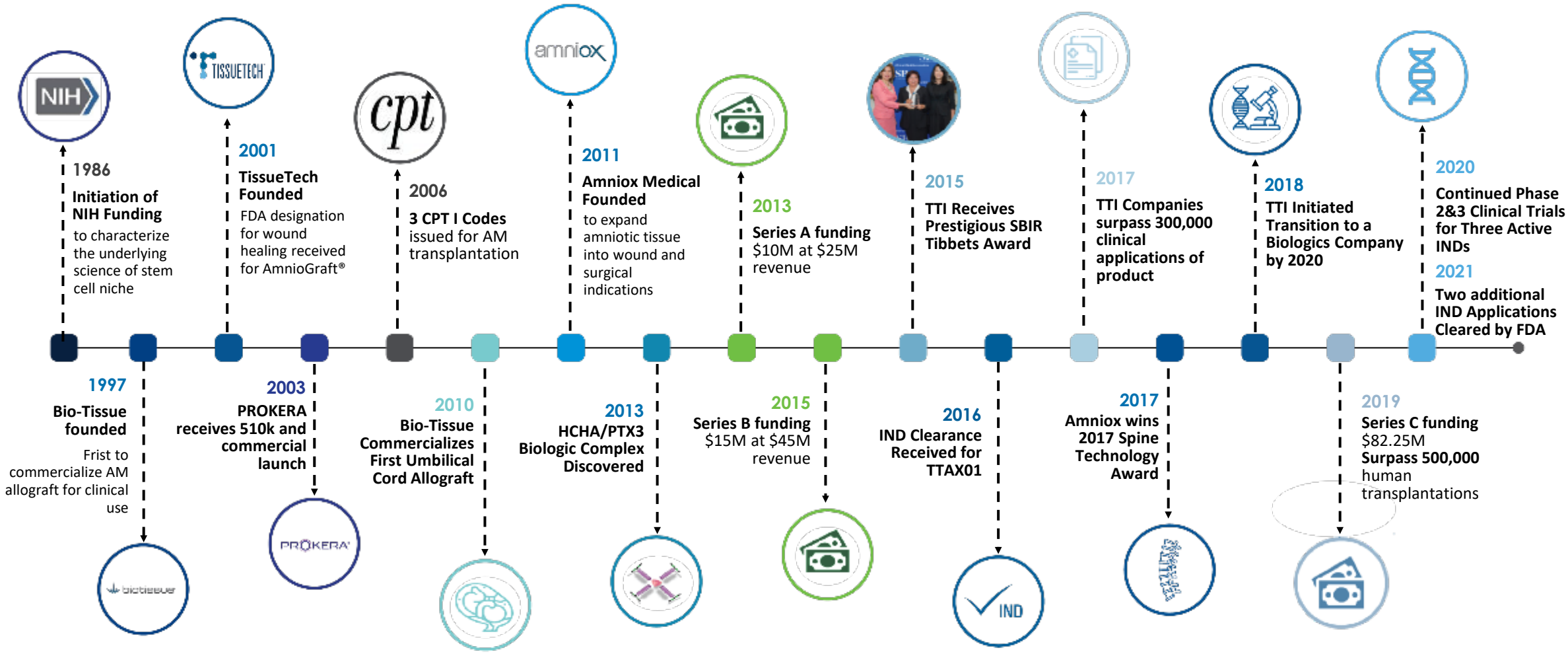
Partner

TissueTech is your partner for reimbursement support and professional education and training.

PIONEER

OF THE FUTURE OF REGENERATIVE MEDICINE

PIONEERING THE FUTURE OF REGENERATIVE MEDICINE



PIONEERING THE FUTURE OF REGENERATIVE MEDICINE

35 Years
National Institutes of Health (NIH) Funding

600,000+
Human Clinical Applications

380+
Peer-Reviewed Publications

1st
to establish Level 1 CPT Codes for Amniotic Membrane Transplantation

100+
Clinical Training Opportunities Each Year

5 IND
Products with Three in Phase 2 & 3 Clinical Trials for BLA Approval

OUR VISION AND MISSION

We **empower healthcare professionals** to deliver **optimal patient healing** outcomes, setting the standards that **define regenerative medicine**.

We do this by living our **MISSION**:

SOLVING UNMET NEEDS

as the PATIENT-FOCUSED PIONEER

FOSTERING TRUST

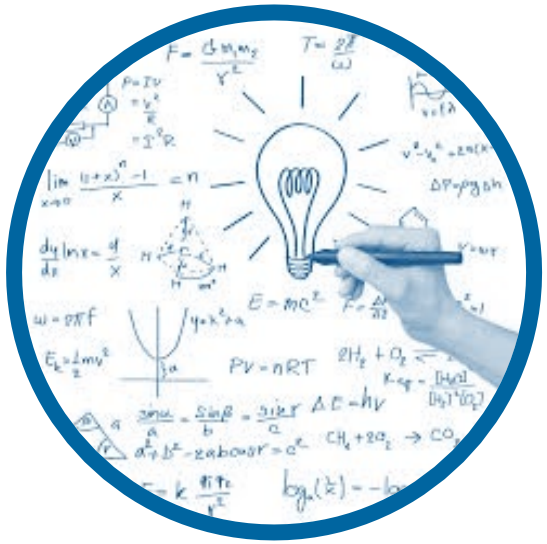
as the EVIDENCE-BASED LEADER

PROVIDING HEALTH ECONOMIC VALUE

OUR VALUES

Conduct all interactions with utmost level of **INTEGRITY AND ETHICS**

Deliver the **HIGHEST QUALITY** and most **COST-EFFECTIVE** therapies for the benefit of patients



Foster innovation through **PROVEN SCIENCE** and **STRONG CLINICAL EVIDENCE**

Provide a **HIGH-PERFORMANCE CULTURE** where people are accountable, respectful and enjoy what they do

CATEGORY LEADER

POSITIONED TO LEAD IN THE CHANGING REGULATORY ENVIRONMENT

CHANGING REGULATORY ENVIRONMENT

Current State: 361 HCT/P

Human Cell, Tissues, and Cellular & Tissue-Based Products (HCT/P) are regulated by FDA under Title 21 of the CFR Part 1271

Allowed marketing, sale and transplantation of human cells or tissues without premarket approval

To qualify, product must conform to criteria:

- *Minimally manipulated*
- *Homologous use*
- *Not combined with another article*
- *No systemic effect and/or not dependent on living cells*

Products and manufacturing facilities must be registered annually and adhere to GTP regulations

FDA Guidance Document Issued **November 2017**

Original 36-month FDA limited enforcement was extended six additional months

Future State: 351 Biologics BLA

Companies must file for Biologics License Application (BLA) in order to make biologic claims about products they previously sold as HCT/Ps

Requires transition to rigorous CMC with GMP manufacturing and multi-phased clinical trials to obtain BLA approval for specific products

Originally, Investigational New Drug (IND) applications needed to be submitted by **November 2020**

In July 2020, the FDA extended the start of their limited enforcement discretion policy six months to **May 2021**

BLA approvals provide company exclusivity to specific indications & provides evidence for future reimbursement

TissueTech is pursuing multiple Clinical Trials to obtain BLAs to ensure its portfolio is protected

CLINICAL TRIAL UPDATE

TTAX01

Diabetic Foot Ulcer

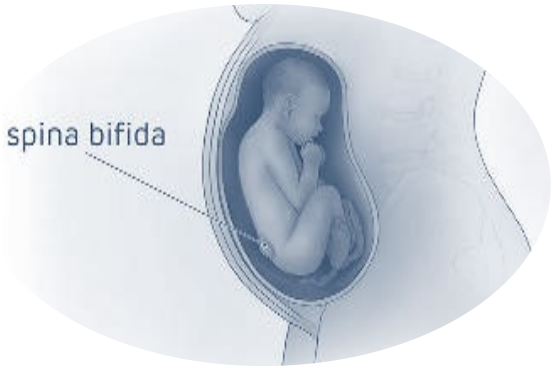
- The Phase 2 Pilot Clinical Trial was positive, along with a 1-year follow-up study, both completed
- AMBULATE DFU and AMBULATE DFU II Phase 3 confirmatory trials initiated in 2020, each conducted at 20 U.S. sites with 220 patients

TTBT01

Ocular Surface Disease

- FDA cleared IND in January 2021
- Phase 2 clinical dose-escalation study currently being finalized

TTAX02



Spina Bifida

- Single Phase 3 Multi-center, Randomized Controlled Trial with Study Activation planned for the second half of 2021
- Granted Regenerative Medicine Advanced Therapy (RMAT) and Orphan Therapy Designations from FDA

TTAX03

Osteoarthritis (OA)

- KL grade 3-4 knee OA Phase 2 multi-center Randomized Controlled Trial, 52-week study in 8-10 U.S. sites with 90 subjects, starts in Q3 2021
- Facet joint Phase 1 multi-center Randomized Controlled Trial in 3 U.S. sites with 36 subjects planned for Q3 2021

OUR FOCUS: UNMET PATIENT NEEDS

We are **focused** on giving healthcare providers **cost-effective solutions** to successfully address previously **unmet patient needs**

Ophthalmic and optometric indications – It is estimated that the **total economic burden** of eye disorders and vision loss in the U.S. is **$139 billion**[5]

Advanced wounds – A conservative estimate of the **cost of caring** for these wounds exceeds **$50 billion** per year in the U.S.[1,2,3,4]

Musculoskeletal applications – In 2011, the total **indirect and direct costs** for musculoskeletal disorders was estimated to be **$874 billion**, or 5.7 percent of U.S. Gross Domestic Product[6]

Non-opioid alternative to managing pain – the total **economic burden** of prescription **opioid misuse** in the U.S. is **$78.5 billion** annually with an estimated 128 people dying each day after overdosing on opioids[7]

1. Kuhn BA, Coulter SJ. Balancing ulcer cost and quality equation. Nurs Econ. 1992;10(5):353–359. 2. Hess CT. Putting the squeeze on venous ulcers. Nursing. 2004;34(Suppl Travel):8–13. 3. Driver VR, Fabbi M, Lavery LA, Gibbons G. The costs of diabetic foot: the economic case for the limb salvage team. J Am Podiatr Med Assoc. 2010;100(5):335–341. 4. Gordon MD, Gottschlich MM, Helvig EI, Marvin JA, Richard RL. Review of evidence-based practice for the prevention of pressure sores in burn patients. J Burn Care Rehabil. 2004;25(5):388–410. 5. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4664309/ 6. https://www.sciencedaily.com/releases/2016/03/160301114116.htm 7. https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis

TRUSTED PROVIDER

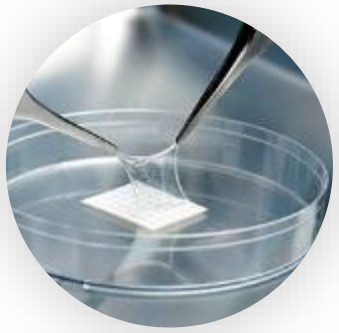
OF HUMAN BIRTH TISSUE PRODUCTS

OUR CURRENT PRODUCT PORTFOLIO

Focused on **solving unmet clinical needs** by **harnessing the regenerative properties** of human umbilical cord and amniotic membrane

biotissue
A TissueTech Company

PROKERA

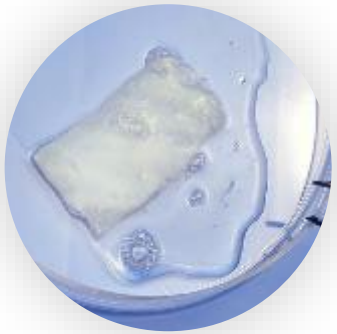


AMNIOGRAFT

AMNIOGUARD

Cliradex

amniox
A TissueTech Company



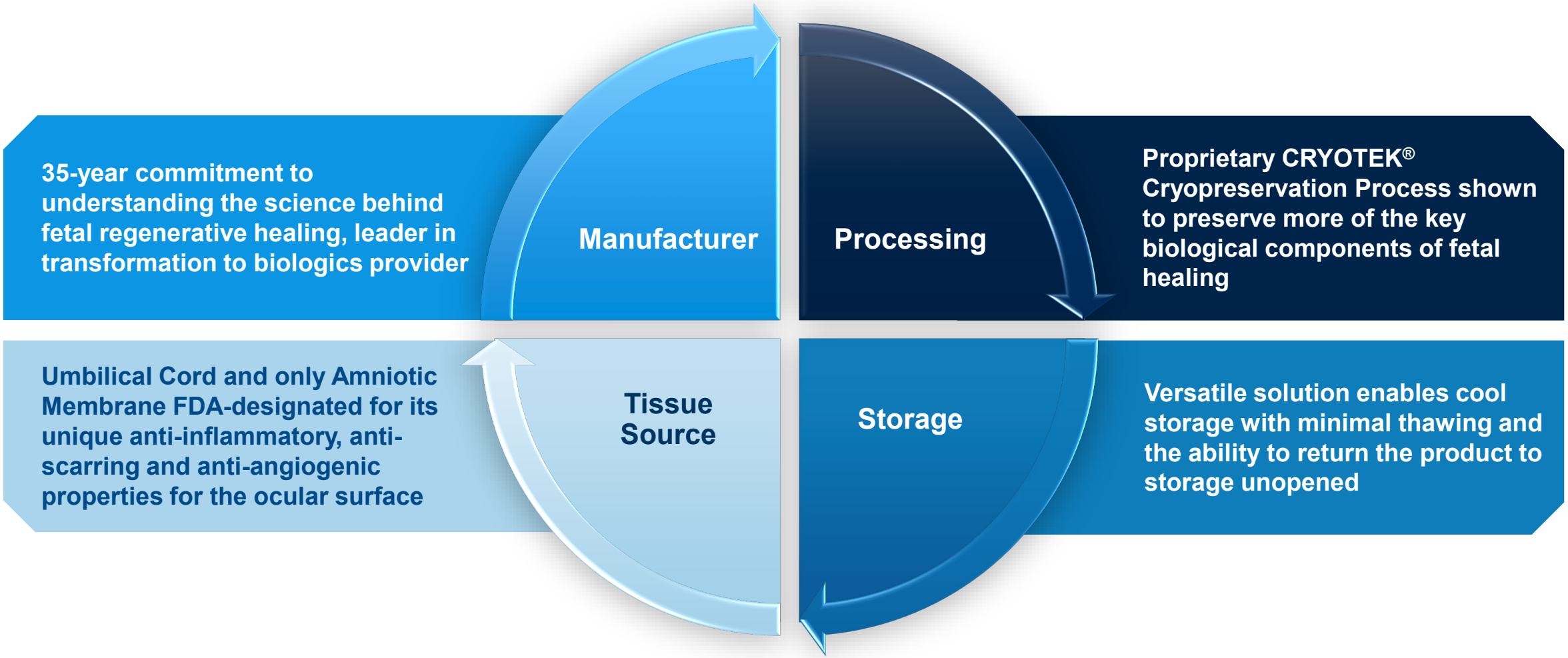
clarix
CORD BK

neox
CORD BK

clarix
FLO

neox
FLO

HUMAN BIRTH TISSUE PROVIDER CONSIDERATIONS



OUR PLATFORM SCIENCE

PARTNER

FOR REIMBURSEMENT SUPPORT, TRAINING & EDUCATION

DEMONSTRATED HEALTH ECONOMIC VALUE

NEOX & IND TTAX01
Faster Healing, Fewer Applications

STUDY	LEAD	OUTCOME
TTAX01 Phase 2	Marston[1]	**87.5% closure 13.8 weeks 1.68 applications**
NEOX CORD 1K	**Caputo[2]**	**96.3% closure 16.02 weeks (mean) 1.24 applications (average)**
Standard of Care	Multiple	31% closure 20 weeks 45% closure regardless of time

CLARIX
Faster Healing, Reduced Risk of Infection

STUDY	LEAD	OUTCOME
CLARIX CORD 1K	Bemen-derfer[3]	Reduced overall time to skin healing after TAA from **40 days** (traditional closure) to **28.5 days** (CLARIX)

Results **even more pronounced** in patients with **comorbidities** including diabetes, tobacco use and obesity

Delayed wound healing increase risk of infection, which significantly increases cost for treatment

PROKERA
Quick Application, Reduced Follow-Ups

STUDY	LEAD	OUTCOME
PROKERA	Desai[4]	**25 second PK treatment time** + 35 second SFK treatment time

Reliably healed, without haze or scar, at **7 days**

Improved clinical outcomes and **patient satisfaction** with ocular surface optimization prior to refractive cataract surgery

1. Marston WA, *et al*. An open-label trial of cryopreserved human umbilical cord in the treatment of complex diabetic foot ulcers complicated by osteomyelitis. *Wound Repair Regen* 2019;27:680-6. 2. Caputo, W.J., *et al*., A retrospective study of cryopreserved umbilical cord as an adjunctive therapy to promote the healing of chronic, complex foot ulcers with underlying osteomyelitis. *Wound Rep Reg*, 24: 885-893. doi:10.1111/wrr.12456 3. Bemenderfer TB, *et al.* Effects of cryopreserved amniotic membrane-umbilical cord allograft on total ankle arthroplasty wound healing. *J Foot Ankle Surg* 2019;58:97-102. 4. 1 Desai NR. A comparison of cryopreserved amniotic membrane and bandage contact lens in their ability to provide high-quality healing after superficial keractectomy. *Rev Ophthalmol*. September 2014:1-6

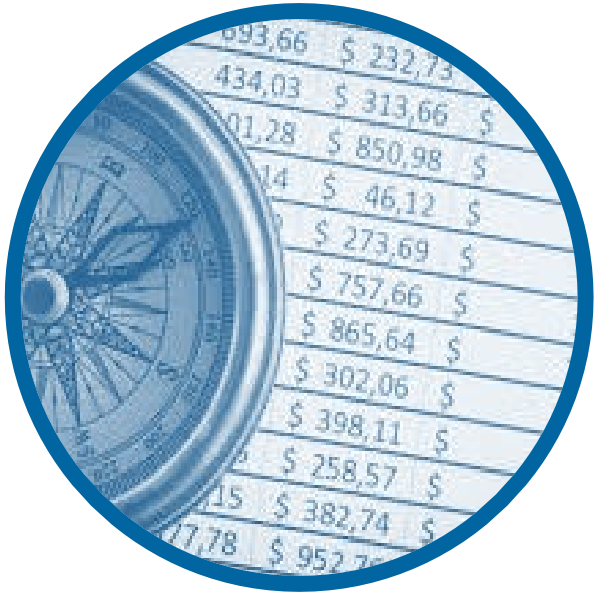
YOUR PARTNER IN REIMBURSEMENT

First to establish Level 1 CPT codes

for reimbursement for Amniotic Membrane Transplantation for the ocular surface

Reimbursement Pathway

being set up to do the same for BLA-approved indications



Dedicated support team of certified coding professionals

to help with billing, claim submission, and appeal services through

THE PINNACLE HEALTH GROUP

YOUR PARTNER IN EDUCATION & TRAINING

Partnering with you and your staff to provide seven unique training programs to best fit your needs:

- Ocular Surface Biologics Course (OSBC)
- Amniox National Pro Ed Events
- Pro Ed Webinar Series
- DocMatter Peer-to-Peer Online Resources
- Physician Portal One-Stop Clinical Resource
- Local Peer-to-Peer Events
- In-Clinic In-Services and Training

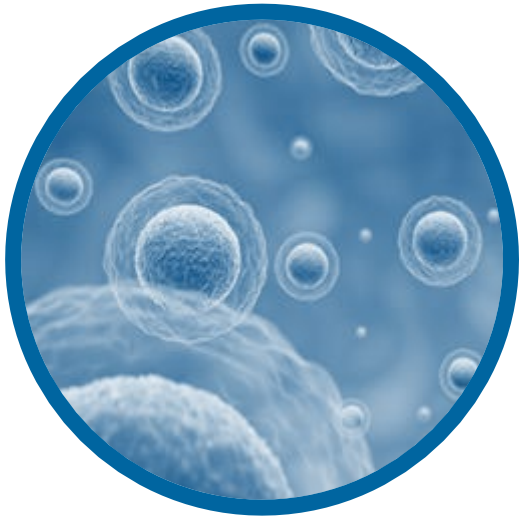
BROAD REACH

575K+	Video Views
3K+	Webinar Attendees
450+	Peer-to-Peer Events
150+	OSBC Attendees

SUMMARY

Pioneer

TissueTech continues to pioneer the application of human birth tissue for regenerative medicine.



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ARE YOUR READY TO PARTNER WITH TISSUETECH?

Where should we start?