Clarix®

The Most Human Form of Healing

We provide Mother Nature’s most natural gift of healing so patients can get back to the life they love.

Meeting the Challenges of Foot and Ankle

The best chance for better outcomes is at time of surgery.

Give that one chance, its best chance.

The Challenges of Foot & Ankle Surgery

A Surgical Site Infection (SSI) is an infection that occurs after surgery. SSIs can sometimes be superficial involving the skin only, while other times lead to more serious complications such as osteomyelitis.

Patient risk factors for SSI include age, tobacco use, diabetes, and malnutrition and procedure-specific risk factors.

The unique anatomy of the foot and ankle leads to a higher propensity of wound healing complications compared to other orthopedic surgeries due to:[1]

- Thin layer of soft tissue protection of underlying anatomy
- Deficient extremity blood flow around the ankle, especially in patients with comorbidities

SSIs occur in **2% to 4%** of all patients.[2,3]

Soft Tissue Tendon Repair

Common complications after tendon repair include delayed wound healing, soft tissue adhesions, tendon rupturing, and infections.

Achilles tendon repair is known to have a higher risk potential for complications such as delayed healing, dehiscence, scarring, and infection.[4]

The pooled rate of complications has been reported to be **27-33%** with an overall rate of 2%–4% specifically for wound infection.[5,6]

Foot Fracture Calcaneal Fractures

Calcaneal fracture repair is a procedure with high probability of complications.

The complication rate after open reduction and internal fixation of calcaneal fractures operated on by a lateral extensile approach range from 10% to 20%.[7]

One of the worst perioperative complications associated with calcaneal fractures can be tissue or bone infection, and/or wound complications.[8,9]

In a retrospective case review of 176 calcaneal fractures, 4% wound infection rate and 27% overall complication rate were noted.[10]

Calcaneal fractures have a wound infection rate of **4% and 27%** overall complication rate.[5,6]

Bone/Joint Total Ankle Arthroplasty (TAA)

Anterior approach TAA procedures have high wound healing complications of up to 34% due to the delicate skin around the ankle.[11] Patients with diabetes, tobacco use, and obesity can exacerbate post-operative wound complications.

A recent study showed that patients who received cryopreserved umbilical cord application as an adjunct at time of surgery, experienced an average of 11.5 day reduction in overall time to skin healing (28.5 days vs. 40 days) after TAA.[12]

High wound healing complications of up to **34%**

11.5 day reduction in overall time to skin healing[12]

Managing the Complexities of Human Healing

Together we are on a journey to solve unmet patient needs by improving healing and reducing patient suffering.

We share your dedication to knowing more about the disease process and trying to understand if there is a better way to treat difficult diseases.

Our goal has been and always will be solving patients' unmet clinical needs through the relentless pursuit of new solutions to complex problems. Everything we do to discover, develop, and bring to market products and applications is centered on helping you as healers and improving the lives of patients.

Built on a foundation of relentless clinical pursuit, discovery, and cost-effective solutions

36 Years
of National Institute of Health (NIH) funded research

680,000+
transplantations performed

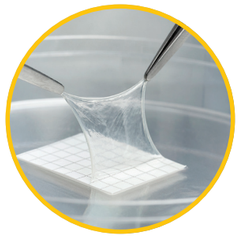
380+
peer-reviewed publications studying our technology

40+
issued patents

Biological Tissue Provides the Most Human Form of Healing

We are in a race against time to heal wounds. BioTissue products provide the natural healing properties of human birth tissue to the wound.

Clarix 1K is a cryopreserved ultra-thick human amniotic membrane derived from umbilical cord. Clarix 1K is used as a barrier or cushion to create a protective environment for healing in soft tissue repair and reconstruction as an adjunct. It's up to 10X thicker than amniotic membrane alone,[13] which may increase longevity in the surgical site.



Clarix 100 is a thinner cryopreserved version of our human amniotic membrane. Clarix 100 is ideal for surgical applications that favor a minimal approach/incision or where space is anatomically compromised. For easier handling and application, the allograft is delivered on a non-implantable, gridded paper backing which is removed at the time of application.

Preserving as Much of Nature as Possible

For over 36 years, our pioneering scientists have focused on understanding the regenerative features of human birth tissue—ultimately identifying HC-HA/PTX3 as a key orchestrator in human birth tissue regenerative healing.[14-18]

The BioTissue CryoTek® cryopreservation process is the only tissue processing method shown to produce a matrix comparable to the native tissue.[13,19] In conventional heat dehydration processing, critical biological components—including the majority of HC-HA/PTX3 naturally found in birth tissue—are degraded, which may limit the tissue's healing capabilities.[10]

CryoTek cryopreservation technology utilizes controlled deep freezing to effectively preserve the functional and structural integrity of the birth tissue.[13,19]

CryoTek minimizes the risk of an immune reaction and preserves the functional components of the extracellular matrix.

BioTissue human birth tissue products are aseptically processed, devascularized, and cell devitalized to deliver the innate properties of human birth tissue to the wound environment.

The Proof is in the Evidence

SSIs pose a challenge to elective and chronic foot and ankle soft tissue and bone/joint procedures. When there is an insult to the skin due to a surgical incision, evidence suggests the use cryopreserved human birth tissue allografts, as an adjunct during surgery, give your patients the best chance to heal.

Proven Outcomes

Clinical Use of Clarix 1K as an Adjunct Therapy in Promoting Healing of a Calcaneal Fracture

Christopher M. Stewart, MD, Orthopaedic Trauma Surgeon, Baptist Medical Center, Little Rock, AR

Wound closure in 16 weeks

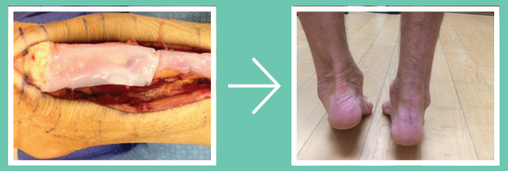
1 Clarix 1K application

Clinical Use of Clarix 1K as an Adjunct Therapy in Promoting Healing of a Chronic Achilles Rupture

Ryan Putman, MD, Carillion Clinic, Roanoke, VA

Wound closure in 10 weeks

1 Clarix 1K application

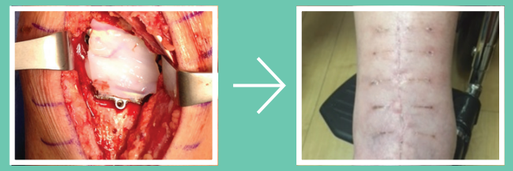


Clinical Use of Clarix 1K as an Adjunct Therapy in Promoting Healing in Total Ankle Arthroplasty

Ryan Putman, MD, Carillion Clinic, Roanoke, VA

Wound closure in 10 weeks

1 Clarix 1K application



The time is now to achieve a new standard of care. Together we can make a difference in surgical wound healing.

www.biotissue.com/surgical

References

1. Dalton GP, Wapner KL, Hecht PJ. Complications of achilles and posterior tibial tendon surgeries. Clin Orthop Relat Res. 2001 Oct;(391):133-9.
2. Mu, Y., Edwards, J., Horan, T., Berrios-Torres, S., & Fridkin, S. (2011). Improving Risk-Adjusted Measures of Surgical Site Infection for the National Healthcare Safely Network. Infection Control & Hospital Epidemiology, 32(10), 970-986. doi:10.1086/662016
3. McKibben, L., Horan, T., Tokars, J., Fowler, G., Cardo, D., Pearson, M., & Brennan, P. (2005). Guidance on Public Reporting of Healthcare-Associated Infections: Recommendations of the Healthcare Infection Control Practices Advisory Committee. Infection Control & Hospital Epidemiology, 26(6), 580-587. doi:10.1086/502585
4. Bruggeman, Nicholas B MD; Turner, Norman S MD; Dahm, Diane L MD; Voll, Anthony E RN; Hoskin, Tanya L MS; Jacofsky, David J MD; Haidukewych, George J MD Wound Complications after Open Achilles Tendon Repair, Clinical Orthopaedics and Related Research: October 2004 - Volume 427 - Issue - p 63-66 doi: 10.1097/01.blo.0000144475.05543.e7
5. Barfod KW, Sveen TM, Ganestam A, Ebskov LB, Troelsen A. Severe Functional Debilitations After Complications Associated With Acute Achilles Tendon Rupture With 9 Years of Follow-Up. J Foot Ankle Surg. 2017 May-Jun;56(3):440-444.
6. Khan RJ, Fick D, Keogh A, Crawford J, Brammar T, Parker M. Treatment of acute achilles tendon ruptures. A meta-analysis of randomized, controlled trials. J Bone Joint Surg Am. 2005 Oct;87(10):2202-10.
7. DiGiovanni, CW; Benirschke, SK; Hansen, ST. Foot Injuries. Skeletal Trauma Third Edition, 2003; 2375-2492.
8. Hansen, ST; Functional Reconstruction of the Foot and Ankle. Philadelphia, Lippincott Williams & Wilkins, 2000; 1-512.
9. Levin, LS, Nunley JA The management of soft-tissue problems associated with calcaneal fractures. Clin Orthop 1993; 290: 151-156.
10. Li Y, Bao RH, Jiang ZQ, Wu HY. Complications in operative fixation of calcaneal fractures. Pak J Med Sci. 2016;32(4):857-862.
11. Raikin SM, Kane J, Ciminiello ME. Risk factors for incision-healing complications following total ankle arthroplasty. J Bone Joint Surg Am. 2010 Sep 15;92(12):2150-5. doi: 10.2106/JBJS.I.00870. PMID: 20844156.
12. Bemenderfer TB, Anderson RB, Odum SM, Davis WH. Effects of Cryopreserved Amniotic Membrane-Umbilical Cord Allograft on Total Ankle Arthroplasty Wound Healing. J Foot Ankle Surg. 2019;58(1):97-102.
13. Cooke M, Tan EK, Mandrycky C, He H, O'Connell J, Tseng SC. J Wound Care. 2014;23(10):465-476.
14. Tseng SC. HC-HA/PTX3 Purified from Amniotic Membrane as Novel Regenerative Matrix: Insight Into Relationship Between Inflammation and Regeneration. Invest Ophthalmol Vis Sci. 2016;57(5):ORSFh1-ORSFh8.
15. He H, Li W, Tseng DY, et al. Biochemical characterization and function of complexes formed by hyaluronan and the heavy chains of inter-alpha-inhibitor (HC*HA) purified from extracts of human amniotic membrane. J Biol Chem. 2009;284:20136-46.
16. He H, Zhang S, Tighe S, Son J, Tseng SC. Immobilized Heavy Chain-Hyaluronic Acid Polarizes Lipopolysaccharide- activated Macrophages towards M2 Phenotype. J Biol Chem. 2013;288:25792-803.
17. Zhang S, He H, Day AJ, et al. Constitutive expression of inter-α-inhibitor (Ial) family proteins and tumor necrosis factor-stimulated gene-6 (TSG-6) by human amniotic membrane epithelial and stromal cells supporting formation of the heavy chain-hyaluronan (HC-HA) complex. J Biol Chem. 2012;287:12433-44.
18. Zhang S, Zhu YT, Chen SY, et al. Constitutive expression of pentraxin 3 (PTX3) protein by human amniotic membrane cells leads to formation of the heavy chain (HC)-hyaluronan (HA)-PTX3 complex. J Biol Chem. 2014;289:13531-42.
19. Tan EK, Cooke M, Mandrycky C, et al. Structural and biological comparison of cryopreserved and fresh amniotic membrane tissues. J Biomaterial T Eng. 2014;4:379-388.

www.biotissue.com
7300 Corporate Drive, Suite 700, Miami, FL 33126 | 888.296.8858

BioTissue® Surgical

www.biotissue.com/surgical