



For Immediate Release

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**AMNIOX Highlights Study Demonstrating Improved Outcomes in Patients Treated with CLARIX® Regenerative Matrix as an Adjunct to Lumbar Discectomy**  
Company is Introducing its Proprietary Technology at North American Spine Society (NASS) Annual Meeting

ATLANTA – October 26, 2016—AMNIOX Medical, Inc., a TissueTech™, Inc., company, announced the results of a prospective randomized clinical study of its proprietary cryopreserved Amniotic Membrane (AM) as an adjunct to lumbar discectomy. The findings will be presented at the North American Spine Society 2016 Annual Meeting, by the study’s lead investigator, D. Greg Anderson, M.D. of the Rothman Institute in Philadelphia, PA.

The study included 80 patients, with half of the patients receiving CLARIX 100 in the disc space following removal of the disc herniation and half receiving the standard of care which involved removal of the herniation alone. Patients treated with CLARIX saw statistically significant improvement in Oswestry Disability Index (ODI) scores and SF-12 (Physical Composite Scale) at six weeks and two years. The ODI quantifies disability due to low back pain and the SF-12 assesses the patients’ physical and mental well-being. The study also reports that there were no recurrent herniations in the CLARIX treatment group during the 2-year follow-up period, compared to a 7.5 percent recurrence rate in the control group.

“Degenerative disc disease is the most common source of back pain and lumbar discectomy is the most common surgical intervention to treat this condition. However, residual back pain and recurrent herniations can be as high as 20%” said Dr. Anderson, Professor in the Departments of Orthopaedic and Neurological Surgery at Thomas Jefferson University and Clinical Director of the Spine Section of the Orthopaedic Research Laboratory. “These results indicate that the application of CLARIX can influence the healing response to significantly improve post-surgical outcomes. Patients experience reduced pain and a faster and sustained return to activities of daily living. Additionally, although it was not an endpoint identified in the study protocol, we observed a reduction in the use of narcotics in the patients treated with CLARIX.”

“This Level 1 study is the first one to evaluate the benefits of placental tissue in conjunction with discectomy and is clear evidence that the benefits of CLARIX that have been observed in other orthopedic procedures can be brought to patients undergoing spinal surgery” said Tom Dugan, Chief Executive Officer of AmnioX Medical. “Equally important to the clinical benefits observed are the enormous health economic implications of this study. Reductions in the rate of rehospitalization and in the number of future operations for reherniation make this a technology that will be embraced by payers as well as providers.”

AmnioX parent TissueTech pioneered the commercialization and clinical application of human umbilical cord and amniotic membrane to promote regenerative healing. This restorative ability is innate to these placental tissues and can be preserved and transplanted to adults. Heavy chain hyaluronic acid/pentraxin-3 (HC-HA/PTX3) is the key protein complex present in these tissues to orchestrate that regenerative healing process. AmnioX utilizes its proprietary CryoTek® process, a cryopreservation technology, to preserve the biological and structural integrity of these tissues more effectively than other available technologies. Since the company’s inception, clinicians have performed more than 250,000

human transplants of its products and published more than 300 peer-reviewed studies supporting its technology platform.

#### **About Amniox Medical, Inc.**

Founded in 2011 to serve the orthopedic and wound care markets, Amniox Medical is dedicated to developing and marketing regenerative therapies processed from umbilical cord and amniotic membrane utilizing its proprietary CryoTek technology. This process has been proven to preserve the innate biological and structural properties of the matrix, which can then be transplanted to adult wound and surgical environments. Amniox Medical procures its tissue through elective donation following healthy live birth via Cesarean section. Thorough donor screening is performed to ensure safety of its products. For additional information, please visit <http://www.amnioxmedical.com>.

#### **About TissueTech, Inc.**

TissueTech, Inc., the parent company of Amniox Medical, Inc. and BioTissue®, Inc., pioneered the development and clinical application of regenerative, amniotic tissue-based products. Amniox Medical develops and markets products for use in the musculoskeletal and wound care markets; BioTissue develops and markets products for the ophthalmology and optometry markets. The National Institutes of Health (NIH) has supported TissueTech's research with more than 25 continuous years of research grants. Since the company's inception, clinicians have performed more than 250,000 human implants of the company's products and published more than 300 peer-reviewed studies supporting its technology platform. The Company's first product, AmnioGraft®, is the only tissue graft designated by the FDA as homologous for promoting ophthalmic wound healing while suppressing scarring and inflammation.

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