

RTI Biologics Announces Positive Clinical Results for BioCleanse®-Processed BTB Allografts Used in ACL Reconstruction

The Associated Press

ALACHUA, Fla.--(BUSINESS WIRE)--Mar 20, 2013--RTI Biologics Inc. (RTI) (Nasdaq: RTIX), a leading provider of orthopedic and other biologic implants, is pleased to announce the results of a recent randomized prospective clinical study of BioCleanse® -processed bone-patellar tendon-bone (BTB) allografts used in anterior cruciate ligament (ACL) reconstruction surgery. The study was published in the peer reviewed journal, *Knee Surgery, Sports Traumatology, Arthroscopy*, in December 2012.

The article compares the clinical outcomes of BTB allografts processed using RTI's patented BioCleanse Tissue Sterilization Process with a control group consisting of aseptically-processed allografts from the three U.S. tissue banks that provide this type of allograft. According to the American Association of Tissue Banks' 13th edition of Standards for Tissue Banking, aseptic processing refers to the processing of tissue using methods to prevent, restrict or minimize contamination with microorganisms from the environment, processing personnel, and/or equipment. A total of 67 patients undergoing ACL reconstruction at six independent investigation sites were evaluated at six, 12 and 24 months. After randomization, 24 patients received aseptic BTB allografts and 43 patients received BioCleanse-sterilized allografts.

"These results indicate that the sterilization process, BioCleanse, did not demonstrate a statistical difference in clinical outcomes for the BTB allograft at two years," authors find. "The BioCleanse process may provide surgeons with allografts clinically similar to aseptically-processed allograft tissue with the benefit of addressing donor-to-recipient disease." According to Millennium Research Group's "U.S. Markets for Orthopedic Soft Tissue Solutions 2011" report, more than 457,400 ACL reconstructions are performed annually in the U.S., with 21 percent of those using allograft implants. According to the authors, the use of allograft tissue in ACL reconstruction has been noted to decrease operating time, eliminate donor site morbidity and increase the tissue available for multi-ligament cases. The one disadvantage compared with autografts (the use of one's own tissue) or metal and synthetic implants, is that disease can be transmitted as a result of an aseptically-processed allograft.

However, RTI's BioCleanse Tissue Sterilization Process, a patented, validated, automated process provides surgeons with a safe option for allografts. The system sterilizes tissue to SAL 10⁻⁶ using a complex, proprietary combination of mechanical and chemical processes, working in conjunction with each other. The mechanical component applies oscillating positive and negative pressure in the presence of the chemical agents (including detergents and sterilants), which gently

perfuse the tissue. This combination removes blood and lipids, and inactivates or removes pathogenic microorganisms. Repeated water rinses throughout the process remove debris, and final water rinses remove residual chemicals, leaving the tissue biocompatible. The BioCleanse process does not use excessive heat or irradiation to sterilize tissue.

“This study provides further evidence that BioCleanse-processed implants are a safe alternative to autografts,” said Roger Rose, RTI’s executive vice president and chief commercial officer. “BioCleanse sterilizes tissue without the potentially harmful side effects of other methods.” The safety of allograft tissue is contingent on three stages: donor screening, laboratory testing and tissue preparation validated to address potential disease transmission. Some companies rely only on donor screening, laboratory testing and aseptic processing for the safety of their implants.

“When we launched BioCleanse in March 2000 it was the first of its kind in terms of allograft tissue sterilization for our industry,” said Brian K. Hutchison, president and CEO. “The low-temperature chemical sterilization process inactivates or removes bacteria, fungi, spores and viruses from tissue without compromising the biocompatibility or structural integrity of the tissue. The positive results of this clinical study prove just that. Surgeons and patients can rest assured knowing that RTI provides allografts that will maintain their biomechanical integrity the same as aseptically-processed implants, while addressing the risk of donor-to-recipient infection.” Where possible, RTI has advanced beyond the use of aseptic processing, which does not ensure the removal or inactivation of microorganisms inherent to the donor or tissue, to better protect recipients from the risk of donor-to-recipient disease transmission. RTI’s proprietary, validated sterilization processes have a proven track record of more than four million implants distributed with zero incidence of implant-associated infection. To learn more, visit www.rtibiologics.com/safety/sterilization-processes.

The article entitled, “Aseptically processed and chemically sterilized BTB allografts for anterior cruciate ligament reconstruction: a prospective randomized study,” can be downloaded for free at

<http://link.springer.com/article/10.1007%2Fs00167-012-2309-7>. Authors are: Peter A. Indelicato, University of Florida, Gainesville, Fla.; Michael G. Ciccotti, Thomas Jefferson University, Philadelphia, Pa.; Joel Boyd, TRIA Orthopaedic Center, Minneapolis, Minn.; Laurence D. Higgins, Brigham and Women’s Hospital-Ortho, Boston, Mass.; Benjamin S. Shaffer, George Washington University, Washington, D.C.; and C. Thomas Vangsness Jr., University of Southern California, Los Angeles.

To learn more about RTI’s BioCleanse-processed BTB allografts, as well as the company’s full biologic portfolio, visit the RTI Biologics booth, #3823, at the American Academy of Orthopaedic Surgeons’ 2013 Annual Meeting in Chicago, Ill., March 19-23.

About RTI Biologics Inc.

RTI Biologics Inc. is a leading provider of sterile biologic implants for surgeries around the world with a commitment to advancing science, safety and innovation.

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RTI prepares human donated tissue and xenograft tissue for transplantation through extensive testing and screening, precision shaping and using proprietary, validated processes. These allograft and xenograft implants are used in orthopedic, dental and other specialty surgeries.

RTI's innovations continuously raise the bar of science and safety for biologics – from being the first company to offer precision-tooled bone implants and assembled technology to maximize each gift of donation, to inventing validated sterilization processes that include viral inactivation steps. These processes — BioCleanse®, Tutoplast® and Cancell® SP DBM — have a combined record of more than four million implants distributed with zero incidence of implant-associated infection. These processes have been validated by tissue type to inactivate or remove viruses, bacteria, fungi and spores from the tissue while maintaining biocompatibility and functionality.

RTI's worldwide corporate headquarters are located in Alachua, Fla., with international locations in Germany and France. The company is accredited by the American Association of Tissue Banks in the United States and is a member of AdvaMed.

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