Soft Tissue Regeneration Receives FDA Clearance To Market Breakthrough Rotator Cuff Repair Device

The Associated Press

Soft Tissue Regeneration, an early stage orthopedic device company that has developed a breakthrough tissue engineering platform used to regenerate ligaments and tendons, announced today that it has received FDA clearance to market its STR GRAFT, a biodegradable scaffold used for soft tissue augmentation and rotator cuff repair.

Developed by Cato T. Laurencin, M.D., Ph.D., an orthopedic surgeon and the company's founder, the STR GRAFT is a three-dimensional braided engineered matrix that Laurencin likens to a patch. During surgery, surgeons can drape this biodegradable patch over the tendon that sits on the shoulder bone, anchoring it with sutures to keep it in place while the tendon, bones and nearby tissues heal. Unlike currently available devices, which are made of weaker cadaver or animal tissue that can cause sutures to pull, the STR GRAFT is thinner-about 1 millimeter-and stronger, which lessens pain, speeds recovery time and drastically reduces surgical failure rates.

Rotator cuff tears are a common cause of pain and disability among adults. According to the American Academy of Orthopaedic Surgeons, in 2008, close to 2 million people in the U.S. saw their doctor because of a rotator cuff problem. But surgeries aren't always successful.

According to Dr. Laurencin, depending on the size of the tear, the degree of muscle atrophy, the quality of the tendon and the post-op rehabilitation protocol, repeat surgeries are necessary 20 to 70 percent of the time. "There are several products available to augment rotator cuff repair, but they suffer from strength, suture pull-through and surgical deployment issues, all of which the STR GRAFT addresses," said Dr. Laurencin.

In development for two and a half years, STR's device has undergone several successful pre-clinical studies and extensive mechanical and other testing. The company expects the STR GRAFT to be on the market by 2014.

About Soft Tissue Regeneration Soft Tissue Regeneration Inc. (STR), based in New Haven, CT, was established to develop a breakthrough technology for soft tissue regeneration of the anterior cruciate ligament (ACL) of the knee. The company's patented, proprietary technology uses an FDA-approved polymer, already widely used in biomedical devices, that allows STR to address a tremendous unmet need in the repair of musculoskeletal soft tissue injuries. In 2012, National Geographic named regenerative medicine as one of the "Top 100 Scientific Discoveries That Changed the World," highlighting STR's technology to regenerate the ACL. In

addition to its new rotator cuff repair device, the company is developing a surgical mesh and hernia repair mesh product line. The company has successfully raised a series A of $4 million, and is currently raising a $10 million series B.

Connecticut Innovations is an investor and advisor. For more information, visit http://softtissueregeneration.com.

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