



Press Releases

ReGen Biologics Debuts FDA-Cleared Menaflex™ Collagen Meniscus Implant

February 24, 2009

Las Vegas (Feb. 24, 2009) – Orthopaedic surgeons have a new option for treating patients suffering from knee meniscus injuries following the recent marketing clearance of the ReGen Biologics (OTC: RGO) Menaflex™ collagen meniscus implant. “We are proud to be bringing to market this important technology,” said ReGen Chairman and Chief Executive Officer Gerald E. Bisbee, Jr., Ph.D. “The device provides a ground-breaking method to reinforce and repair the medial meniscus following surgery,” stated Dr. Bisbee at the 2009 Annual Meeting of the American Academy of Orthopaedic Surgeons.

The need for technology that improves the lives of active people with acute and chronic meniscus injuries seems clear. An estimated 1.3 million partial meniscectomy surgeries to remove damaged tissue take place world wide each year. These surgeries successfully treat the short-term symptoms of meniscal tears but the resulting tissue loss is linked to long-term degenerative knee joint changes. In turn, these degenerative changes are linked to osteoarthritis, reduced activity, and health risks associated with lower activity levels.

The Menaflex™ implant is a resorbable collagen scaffold that facilitates the growth of new tissue following surgery. Use of the device addresses the long-term goal of reinforcing and repairing the damaged meniscus. The Menaflex™ implant has been used safely and effectively in more than 2,500 patients in Europe with medial and lateral meniscus injuries. It was cleared to be marketed in the United States for use in surgery involving the medial meniscus after more than a decade of clinical experience.

“I believe the Menaflex implant represents an important innovation in the treatment of meniscus injuries, which are relatively common but can be debilitating,” said Dr. Kenneth E. DeHaven of the University of Rochester School of Medicine and Dentistry, a past president of the AAOS.

ReGen presented clinical data from 162 patients with a mean follow-up of almost five years in a multicenter trial involving 25 surgeons at 16 sites. On average, patients experienced a 70 percent increase in tissue over the tissue that remained after traditional meniscectomy surgery.

“I was particularly impressed that in many cases I could not tell, even when probing the tissue, where the native meniscal tissue ended and the newly formed tissue began,” said Dr. DeHaven, who participated in the clinical study. He has practiced sports medicine for more than 30 years and is a widely respected leader in meniscus surgery.

A feasibility study confirmed that in patients using the Menaflex™ implant, the new tissue detected maintains its volume through at least six years. The clinical benefits of the Menaflex™ device were documented in the July 2008 issue of *The Journal of Bone and Joint Surgery*, which can be viewed at <http://www.regionbio.com/usa/en/publications.php>.

ReGen received marketing clearance from the U.S. Food and Drug administration in December through a 510(k) submission that included review by the agency’s Orthopaedic and Rehabilitation Devices Advisory Panel, which concluded the device was as safe and effective as predicate devices.

Surgeon education and training is a key element of the marketing plan for the Menaflex™ implant and is scheduled to start in New York in early March.

About ReGen Biologics, Inc.:

ReGen Biologics is an orthopedic products company that develops, manufactures and markets innovative tissue growth and repair products for U.S. and global markets. ReGen’s Menaflex™ collagen meniscus implant employs proprietary biological collagen scaffold technology to facilitate tissue growth, thereby reinforcing and repairing the damaged meniscus of the knee. The Menaflex device has been cleared for sale in Europe and other countries, and is marketed through ReGen’s European subsidiary, ReGen Biologics AG. The FDA cleared the Menaflex device to be marketed in the United States in December 2008. Visit www.regenbio.com and www.menaflex.com for more information.

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