



FDA CLEARS REVOLUTIONARY TENDON REPAIR SYSTEM FOR UNITED STATES SALES

Ortheon Medical's Teno Fix® System Designed To Lower Costs, Speed Recovery and Reduce Need for Repeat Surgeries

Winter Park, Fla. - A new surgical system that could forever change the way orthopedic and plastic reconstructive surgeons repair torn and damaged tendons has received clearance for sales and marketing from the U.S. Food & Drug Administration (FDA).

The Teno Fix® system, introduced by Orlando-based Ortheon Medical, represents the first use of a surgical anchor system in soft tissue repair. Utilizing a patented technology, a small anchoring coil is inserted into a damaged tendon, gathering collagen fibers as it turns and harnessing the intrinsic strength of the tendon. Current tendon repair surgeries utilize standard suturing techniques, which require a slow, methodical post-surgery treatment period to avoid potential tears and/or scarring and adhesions. The Teno Fix® system is designed to allow patients to begin active motion therapy more quickly after surgery, leading to an earlier return to normal motion and greatly reducing the need for repeat surgeries caused by scarring and adhesions.

"Beginning active motion therapy - expansion and contraction of the tendon - as soon as possible is critical to a successful repair," said Dr. Melvin Rosenwasser, department chairman at the Columbia School of Medicine. "This new surgical system should allow such therapy to begin much sooner than ever before."

The Teno Fix® system is currently designed for repair of digital flexor tendons of the hand (with multiple digits repaired), a procedure that is performed approximately 145,000 times annually in the U.S. alone. Limitations of current suturing techniques, combined with the inherent delicate nature of tendon fibers, leads to an approximately 30 percent rate of failure, which is defined as the need for a repeat surgery. Hand surgeons face a delicate Catch-22 ... beginning therapy too soon can lead to "creep," when sutures pull through tendon fibers and create a gap that affects the healing process; but immobilizing the repair can lead to scarring and adhesions that won't allow normal, fluid motion of the tendon. Ortheon expects the benefits of the Teno Fix® system to decrease the occurrence of such problems and increase the success rate of delicate hand surgeries.

William J. Christy, Ortheon president, said, "Our goal is two-fold; Ortheon wants to dramatically improve the standard of care for patients, and reduce the overall costs and re-operation rates associated with the current techniques. We believe the Teno Fix® system will do both."



The system is already gaining attention in several worldwide markets, where Teno Fix® has been available since May 2002. "Teno Fix® has shown great promise in allowing patients to return to normal function faster than we've seen with traditional suture repair," said Dr. M.W. Solomons, head of the Martin Singer Hand Unit at Groote Schuur Hospital's Department of Orthopedic Surgery in Cape Town, South Africa. "The increased strength of repair combined with earlier initiation of therapy is contributing to a much higher success rate."

Early results in worldwide markets and "sneak peeks" at national and international trade shows have led to a great deal of excitement for the system among U.S. hand surgeons. "Hand trauma surgery has been caught in a time vacuum with only minimal advances in the last 30 years," said Dr. Rosenwasser. "Teno Fix® represents a revolutionary advance in surgical technique."

"The Teno Fix® technology platform represents a significant opportunity for Ortheon," said Christy. "We hold the exclusive license to a technology that promises to change the way surgeons perform tendon repair. It benefits patients and surgeons alike. It contributes to better outcomes and reduces cost. We are very excited about introducing this to the market."

About Ortheon Medical

Ortheon Medical is a privately held medical device company that develops innovative technologies to enable surgeons to perform safe and effective mechanical, repeatable tendon repairs. The Teno Fix® system has the potential to reduce costs and the need for repeat surgeries often associated with hand procedures. The company believes this may be applicable to other areas of the body including Achilles and Rotator Cuff repair. For more information about Ortheon or Teno Fix®, contact the company at 866-TENOFIX, or visit the company's Web site at www.ortheon.com.