SI-BONE Awarded Significant "Across Bones" Patent Allowance

The Associated Press

SI-BONE, Inc. (San Jose, California), a medical device company that is pioneering the use of a minimally invasive surgical (MIS) device to treat the sacroiliac (SI) joint announced today that it has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for broad method claims related to the iFuse Implant System. SI-BONE currently markets the iFuse in the United States and European Union under the iFuse name.

Of considerable significance for SI-BONE, was the breadth of the method claims. These claims include placing an elongated device across a joint from one bone to another, using a guide wire to place the implant, using a device that is rectilinear in cross-section, and a device having an exterior surface to provide bony in-growth.

"Because the market for minimally invasive surgical treatment of the SI joint is potentially so significant, this allowance provides SI-BONE with a strong competitive barrier. Additionally, the Company has three dependent claims that further claim square, rectangular, and triangular cross-sections," according to Scott Yerby, Ph.D., Chief Technology Officer, SI-BONE.

This allowance reinforces the strength of SI-BONE's position regarding proper diagnosis and treatment of degenerative sacroiliitis and sacroiliac disruption and further secures its dominant market position as the leader in the MIS treatment space for the SI joint.

Increasingly, there is growing acceptance by surgeons that the SI joint is a significant source of unresolved low back pain (LBP) that requires an accurate diagnosis.

Jeff Dunn, CEO of SI-BONE, stated, "We are pleased that this allowance provides our company with additional support for our clinical and commercial efforts. It is a major competitive advantage to have the position of iFuse reinforced as the definitive MIS therapy and market leader for LBP patients with degenerative sacroiliitis. We continue to pursue and will achieve strong intellectual property claims and expand our portfolio related to iFuse technology. As arguably the fastest growing spine or orthopedic company in the world that is truly dedicated to both appropriate diagnosis and treatment, we will accomplish our mission of helping SI joint patients worldwide." The Company further noted that it has filed several additional US and foreign patent application in the past year that are focused on minimally invasive surgical technique, implantable devices, and supporting instrumentation related to the iFuse technology.

SI-BONE received clearance in November 2008 from the Food and Drug

Administration (FDA) to market its iFuse Implant System. The CE mark for European commercialization was obtained in November 2010. The iFuse provides immediate post-operative stabilization and accomplishes the goal of traditional SI joint fusion through an MIS approach.

Clinical publications have identified the SI joint as a pain generator for up to 22 percent of low back pain patients. In addition, DePalma, Pain Medicine 2011, identified the SI joint as a pain generator in low back pain in 40 to 61% of post-lumbar fusion patients, so-called 'failed back surgery' patients.(1) Effective treatment of the SI joint is a significant unmet clinical need and, when conservative therapy fails, iFuse may provide an option.

In response to increasing awareness of SI joint disruption and degenerative sacroiliitis as debilitating symptom generators, SI-BONE, Inc. developed an innovative, patented implant to treat the SI joint.

The company is also embarking on a prospective multicenter study to document acute and long-term clinical outcomes in patients who are proven to be refractory to prior therapies.

The iFuse Implant System is a commercially available device in the U.S. intended for treatment of conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The iFuse procedure uses a minimal incision for delivery and implantation of small, titanium implants. The implants are coated with a porous plasma spray that acts as an interference surface, designed to help decrease implant motion. These implants have substantial thickness and sophisticated metallurgy and are able to produce a much stronger construct than that of conventional pins or screws used to surgically fix boney structures. The SI-BONE implant technology has been used successfully in over 2,000 MIS SI joint cases to-date.

About SI-BONE, Inc. SI-BONE, Inc. (San Jose, California) is the leading sacroiliac joint medical device company dedicated to the development of tools and products for diagnosing and treating patients with low back issues related to SI joint pathology. The company has developed, and is manufacturing and marketing, less invasive approaches using implants for the treatment of SI joint disorders.

SI-BONE has an experienced management team with extensive experience in orthopedic and spine medical devices.

(1)DePalma, M. Etiology of chronic LBP patients having undergone lumbar fusion. Pain Medicine, 2011;12:732-39.

SOURCE SI-BONE, INC.

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