Over 3,000 Patients Treated with iFuse@ for Minimally Invasive Surgical Sacroiliac Joint Fusion

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 fuse the sacroiliac (SI) joint announced today that it has reached a significant milestone for its iFuse Implant System@ with over 3,000 patients implanted.

Based on the increasing use of minimally invasive or mini-open fusion for SI joint conditions including degenerative sacroiliitis and SI joint disruptions, the U.S. and EU medical communities are embracing iFuse as a widely accepted treatment option for treating these SI joint disorders.

SI-BONE works with spine surgeons to address the unmet clinical need for treatment of SI joint pain due to conditions including degenerative sacroiliitis and SI joint disruptions that are unresponsive to conservative therapy. SI-BONE has accelerated innovation in a clinical area that has not seen new treatments for many years. SI-BONE also announced that it has trained over 950 spine surgeons to date, and the company expects to train an additional 500-700 surgeons in U.S. and EU markets over the next twelve months.

Training includes didactic lectures followed by hands-on cadaveric procedures.

Jeff Dunn, President and CEO of SI-BONE, commented, "We are pleased with the significant surgeon adoption of the iFuse in the U.S. and EU.

To the best of our knowledge, a majority of all SI joint fusions are performed with iFuse. Surgeons using iFuse are interested in improving patient care by offering SI joint fusion and we are especially encouraged by data on 168 patients presented in six different studies over the last 18 months indicating significant improvements in pain and function scores as a result of treatment with iFuse." The iFuse is a titanium implant coated with a porous plasma spray acting as an interference surface fit, to decrease implant motion. By providing initial post-operative stabilization with fusion occurring over a number of months, iFuse accomplishes the goal of open SI joint fusion through an MIS or mini-open approach, without compromising structural integrity of the surrounding sacroiliac bones.

The iFuse does not require special SI joint preparation, which can be very difficult for surgeons to perform on a multi-planar, irregular shaped joint.

SI-BONE received original clearance in November 2008 from the Food and Drug Administration (FDA) to market its iFuse Implant System and an updated clearance in April 2011 for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The CE mark for European

commercialization was obtained in November 2010.

Clinical publications have identified the SI joint as a pain generator for up to 22 percent of low back pain patients.[1] 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.[2] Effective treatment of the SI joint has been identified as a significant unmet clinical need and, when non-surgical care fails, iFuse may provide an option.

SI-BONE, Inc. developed an innovative, patented implant to treat the SI joint in response to increasing awareness of SI joint disruption and degenerative sacroiliitis as debilitating symptom generators. As part of SI-BONE's commitment to ongoing scientific clinical research, SI-BONE is also embarking on U.S. and EU multicenter prospective randomized and non-randomized clinical studies to further document acute and long-term clinical outcomes in patients who have failed non-surgical care.

The iFuse Implant System is a commercially available device in the U.S. The iFuse procedure uses a minimal incision for delivery and implantation of small, titanium implants. 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 bony structures. The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Implant.

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

[1]Bernard TN, Kirkaldy-Willis WH. Recognizing specific characteristics of nonspecific low back pain. Clinical Orthopedics 1987;217:266-80.

[2]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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ST: California IN: HEA MEQ SU: PDT PRN -- SF37302 -- 0000 07/10/2012 13:00:00

EDT http://www.prnewswire.c

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