SI-BONE Announces 1st Peer Reviewed Journal Publication of iFuse@ and 5,000 Patients Treated Milestone

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 the publication of the first peer-reviewed journal article on the iFuse Implant System for the treatment of sacroiliac joint disruptions or degenerative sacroiliitis. The article, entitled "Sacroiliac Joint Arthrodesis - MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes" is a retrospective study of the first 50 consecutive patients treated by a single surgeon in a single center. Patients were evaluated for pain and functional outcomes and showed early and sustained statistically significant improvement at all post-operative time points.

Complication rates were low and after an average of 40 months1, more than 80% of patients report that they would have the same surgery again.

In addition, the company also announced it has surpassed another significant milestone with over 5,000 patients treated with the iFuse Implant System since the product became commercially available in early 2009. In a recent analysis performed by Covance Market Access Services, Inc., overall SI joint fusion procedure growth has increased over ten-fold from 2008 to 2012 and minimally invasive SI joint fusion appears to account for almost all of that growth and now comprises 85% of all SI joint fusions. Jeffrey Dunn, President and CEO of SI-BONE stated: "We are delighted to have this first peer-reviewed publication available showing additional evidence of the safety and effectiveness of the iFuse Implant System for treating patients with degenerative sacroiliitis or sacroiliac joint disruption. It also is our understanding that a number of surgeons have submitted, or are in the process of submitting, manuscripts to peer reviewed journals describing their experience with the iFuse in SI joint fusion. We continue to believe that sacroiliac disease has been under-diagnosed and under-treated for many years, and that these results validate the effectiveness of iFuse in this patient population." The porous coated iFuse is intended to provide immediate post-operative stabilization, and allow for fusion to occur over the next several months. In addition, the iFuse is placed through a small incision intended to minimize disruption of the surrounding soft tissues.

SI-BONE received original clearance in November 2008 from the Food and Drug Administration (FDA) to market its iFuse Implant System for fracture fixation of long bones and large bone fragments of the pelvis and an additional 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.2 In addition, DePalma et al, 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.3 Initial treatment options for patients with SI joint disorders typically involve non-surgical management and, when non-surgical treatment of the SI joint fails, surgical treatments such as the iFuse may provide an option.

The iFuse Implant System is a commercially available device in the U.S. and Europe. The iFuse procedure uses a small incision for delivery and implantation of titanium implants. The implants are coated with a porous, titanium plasma spray that acts as an interference surface, designed to help decrease implant motion and provide immediate fixation and long term fusion. These implants have substantial thickness and sophisticated metallurgy and are able to produce a much stronger construct than that of conventional 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 disorders. 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. SI-BONE and iFuse Implant System are registered trademarks of SI-BONE, Inc. 5/82012 SI-BONE, Inc. All Rights Reserved.

1 Rudolf, L. Sacroiliac Joint Arthrodesis - MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes. The Open Orthopaedics Journal, 2012, 6, 492-499.

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

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

8384.121012 SOURCE SI-BONE, Inc.

-0- 12/11/2012 /CONTACT: Joe Powers, Senior Director of Marketing, SI-BONE, Inc., +1-408-207-0700, ext. 3209, jpowers@si-bone.com CO: SI-BONE, Inc.

IN: HEA MEQ PUB SU: TRI PRN -- SF27356 -- 0000 12/11/2012 15:00:00 EDT
http://www.prnewswire.c

Source URL (retrieved on *04/16/2014 - 8:12pm*):
http://www.mdtmag.com/news/2012/12/si-bone-announces-1st-peer-reviewed-journal-publication-ifuse-and-5000-patients-treated-milestone?qt-recent_content=0&qt-video_of_the_day=0