Spinal Implant System Hits Milestone

/PRNewswire/ -- 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 achieved another significant milestone exceeding 4,000 patients implanted with the iFuse Implant System®. In 2013, the company expects to treat over 5,000 additional patients. SI-BONE has received dozens of emails from patients from all walks of life including US Army Soldiers involved in the Afghan war, Firefighters, Oil Rig Workers, Farmers, Writers, Navy Doctors, Professional Soccer Players and many others who have shared their stories with SI-BONE. 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 surgical option for treating these SI joint disorders.

To illustrate the impact of this new treatment option for patients suffering from chronic SI joint related back pain, here are some excerpts of the many letters and emails that patients have sent to the company describing their iFuse experience:

From a case manager in the US Army: "This soldier was deployed to Afghanistan 2009 and involved in an IED blast Oct 2009—conservative treatment then in 4 Oct 2011 had multilevel lumbar fusion but continued with SI pain. 17 May 2012—Right SI joint fusion with iFUSE implants—he is very pleased with the results. I can tell just over the phone (I do long distance case management) his voice now has a lift to it and is looking forward to physical therapy He returns today to light duty—desk job for 4 hrs/day."

"the iFuse Surgery it was a Godsend. Thank you I had the surgery in Indianapolis on August 14th this is the first time in 38 years that my back feels GOOD"

Oil Rig worker. " I just wanted to let you know how much better my life has improved since the surgery. I just wanted to touch base with you and say THANK YOU for the amazing product as it saved my life."

"My day consisted of painfully getting out of bed and moving to a Lazyboy recliner after taking anti-inflammatory pills and then waiting until my husband and children were home from school so I could safely take narcotics to get some real relief. Not much of a life. It has now been 6 months since having the SI Joint Fusion surgery on October 18, 2011. I could tell the next day that there was improvement because I could sit in a chair. My improvement has only continued. Every month I am amazed at things that seem so easy to do and yet a few months ago were impossible."

"I had my right SI Joint done back on 9-12. It has done wonders for me. I am so happy with the results I am having the left side done this month on the 22nd."

"All I can say is WOW! What an immediate difference this has made for me. After a two-night hospital stay I returned home with a new lease on life. My horrible pain (due to constant irritation of the sacral nerves) was eliminated, leg pain gone, SI pain gone. All I can say is thank you. This new procedure gave me my life back."

"I feel like humpty dumpty…except you did put me back together again and the purpose of this email is to thank you for all you all did to fix my back so can have my life back."

"We'll I did it! Three weeks ago the surgeon did the fusion and so far the results are wonderful. At this time, however, no more pain down the leg!"

"The SI-Bone system is also something I'd recommend without hesitation. I've read accounts of this procedure without the iFuse implant, and the recoveries seem to be much, much longer, without the same reductions in pain. It's a great product, and there are a lot of people out there that could benefit from this amazing procedure!"

US Navy person: "I'm 31 year old 7 month post-op bilateral I-Fuse patient who is doing extremely well. I've gone from being in pain all day long to being able to do anything I want pain free……Thank you for your product that has changed my life!"

"I had my IFuse on May 2 I experienced immediate relief from the left leg pain"

"I had both sides done with Ifuse, one in Nov, one in Jan. It has been a big success. I spent 12 yrs sitting in a recliner or a wheelchair so my muscles suck. I am getting my strength back quickly and the pain is nothing compared to what it was…….this is the happiest Easter I've ever had in my life."

"I'd recommend to maybe looking into this. It could help give your life back to you"

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.

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.

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. 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. and Europe. 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 and increase bony ingrowth. 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.

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