

SI-BONE's iFuse Implant System Surpasses 40,000 Procedures

June 27, 2019

Long-term prospective study with 5-year follow-up submitted for publication

SANTA CLARA, Calif., June 27, 2019 (GLOBE NEWSWIRE) -- SI-BONE, Inc. (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to solving musculoskeletal disorders of the sacropelvic anatomy, announced today that the iFuse Implant System[®] has been used in more than 40,000 sacroiliac joint fusion procedures by more than 1,900 surgeons worldwide.

"It is incredibly gratifying that so many patients who've suffered for years with debilitating sacroiliac joint dysfunction are able to regain quality of life following minimally invasive sacroiliac joint fusion with the iFuse Implant System," said Jeffrey Dunn, President, CEO and Chairman of SI-BONE. "We are still at the beginning of this journey with an estimated 279,000 new patients in the United States each year who may become candidates for an iFuse procedure. We look forward to continuing to ramp our commercial efforts to provide an even broader patient benefit."

Since introducing the iFuse Implant System in 2009, SI-BONE has pioneered a proprietary minimally invasive surgical approach to fuse the sacroiliac joint to treat sacroiliac joint dysfunction. Today, the iFuse Implant System is supported by more than 70 peer-reviewed publications, including 2 randomized controlled trials that demonstrate the safety, effectiveness, durability, reduction in the number of patients using opioids, economic and biomechanical benefits. This clinical evidence has resulted in growing payer coverage among insurance plans that routinely approve minimally invasive sacroiliac joint fusion with iFuse for more than 260 million Americans.

"Superior clinical evidence is a foundational element of our organization. Last week, 5-year follow-up results from LOIS (Long Term Outcomes from INSITE and SIFI), a long-term prospective study, were submitted for publication. The follow-up at five years demonstrates durability of the clinical benefit related to the procedure. These results further support the benefits of minimally invasive sacroiliac fusion with iFuse," said Mr. Dunn.

About SI-BONE

SI-BONE is a medical device company that pioneered minimally invasive surgery of the SI joint with the iFuse Implant System. Studies have shown that the SI joint can be a source of pain in 15% to 30% of chronic low back pain. The iFuse Implant[™], commercially available since 2009, is the only SI joint fusion device supported by multiple prospective clinical studies, including two RCTs, showing improved pain, patient function and quality of life resulting from treatment. There are over 70 peer-reviewed publications demonstrating the safety, durable effectiveness, and biomechanical and economic benefits unique to the iFuse Implant (www.si-bone.com/results). This body of evidence has enabled multiple government and private insurance payors to establish coverage of the SI joint fusion procedure exclusively when performed with the iFuse Implant System.

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

The iFuse Implant System is also intended for sacroiliac fusion to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. Rx Only. For information about the risks, visit: www.si-bone.com/risks

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Source: SI-BONE, Inc.