SI-BONE, Inc. Announces FDA Clearance of iFuse Bedrock™ Novel Spinopelvic Fixation Technology

April 15, 2019

SANTA CLARA, Calif., April 15, 2019 (GLOBE NEWSWIRE) -- SI-BONE, Inc. (Nasdaq: SIBN), a Silicon Valley based medical device company dedicated to solving musculoskeletal disorders of the spinopelvic anatomy, today announced that it received an additional 510(k) clearance from the U.S. Food and Drug Administration (FDA) for use of its iFuse Bedrock technology in fusion of the sacroiliac (SI) joint during long construct procedures.

iFuse Bedrock is a technology designed to provide greater stabilization of the joint at the base of long spinal constructs. iFuse was previously cleared by the FDA for sacroiliac fusion using a dorsal, or posterior, implantation approach to treat SI joint dysfunction in patients also undergoing long fusion procedures involving a posterior approach. With this new broader indication, iFuse Bedrock can now be placed across the SI joint as an adjunct to long fusion procedures with the intent of gaining fusion to augment immobilization and stabilization of the SI joint.

“iFuse Bedrock potentially represents an important advancement in how we treat adult deformity patients,” said Dr. Chris Shaffrey, MD, Chief of the Duke Spine Division at Duke University.

Adult spinal deformity surgery represents one of the fastest growing segments of the spine market with an estimated 50,000 procedures per year. Pelvic stabilization of the sacroiliac joint is a well understood clinical need in spinal deformity patients who undergo long fusions to the sacrum.

“The iFuse technology provides spine surgeons with a novel spinopelvic fixation solution for their long construct cases,” said Jeffrey Dunn, President, Chief Executive Officer, and Chairman at SI-BONE. “As we enter the adult deformity market, we remain focused on our commitment to education and clinical evidence that has been the cornerstone of our company, as demonstrated by our 68 peer-reviewed publications including two randomized clinical trials and published long-term data out to six years involving use of iFuse to treat sacroiliac joint dysfunction.”

About SI-BONE
SI-BONE is a medical device company that pioneered the iFuse Implant System, a minimally invasive surgical system for fusion of the sacroiliac joint to treat sacroiliac joint dysfunction. The SI joint is the last major joint with a clinically proven surgical treatment. The iFuse Implant, commercially available since 2009, is the only SI joint fusion device supported by multiple prospective clinical studies showing improved pain, patient function and quality of life resulting from treatment. There are over 65 peer-reviewed publications supporting 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.

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Source: SI-BONE, Inc.