SI-BONE, Inc. Receives FDA 510(k) Clearance for iFuse Bedrock Granite, a Breakthrough Pelvic Fixation and Fusion Technology

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SANTA CLARA, Calif., May 31, 2022 (GLOBE NEWSWIRE) -- SI-BONE, Inc., (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to solving musculoskeletal disorders of the sacropelvic anatomy, announces FDA 510(k) premarket clearance of the iFuse Bedrock Granite Implant System (Granite). The Granite implant provides sacroiliac fusion and sacropelvic fixation as a foundational element for segmental spinal fusion.

This clearance follows the earlier designation by the Food & Drug Administration (FDA) of Granite as a Breakthrough Device (BDD), and most recently, a proposal by the Centers for Medicare and Medicaid Services (CMS) for a New Technology Add-on Payment (NTAP). CMS has also issued new technology “Section X” ICD-10 unique procedure coding for hospitals to report NTAP eligible cases that use Granite as an Internal Fixation Device with Tulip Connector, for either open or percutaneous sacroiliac joint fusion and sacropelvic fixation.

According to Christopher Shaffrey, MD, Chief of the Spine Division at Duke University, “Pedicle screws were designed for pedicles. When spine surgeons began anchoring screws into the pelvis to strengthen the base of the spinal constructs, surgeons simply used longer and larger diameter pedicle screws in iliac and sacro-alar iliac trajectories. Numerous clinical studies have shown significant issues with this strategy; screw loosening, post-operative sacroiliac joint pain and hardware failure. With Granite, there is now a device designed for the specific demands of the sacropelvic anatomy. I am very excited for the many patients who will benefit from this new technology.”

“Reoperations following adult spinal deformity surgery occur in over 20% of all cases. That’s an expensive problem from a time, cost, and patient discomfort standpoint. It is refreshing to see that CMS recently proposed an NTAP for SI-BONE’s iFuse Bedrock Granite. The adoption of that product should lead to fewer reoperations, better patient outcomes, and less cost to the system,” said Scott Alexander, Former Vice-President of Innovation at Mercy Health System.

“We are thrilled to receive FDA 510(k) clearance to launch Granite to the market. The anticipation has been building ever since the FDA awarded BDD for its promise of providing more effective treatment than the current standard of care, and CMS’ recently proposed NTAP, recognizing it as a new technology that can provide substantial clinical improvement over already available therapies,” said Laura Francis, CEO of SI-BONE. “Based on the early pre-clinical data from *in vivo* animal studies suggesting significant bone ingrowth and superior mechanical stability, internal studies showing markedly improved biomechanics, and initial feedback from surgeons, we couldn’t be more enthusiastic about Granite’s clinical and commercial promise as a uniquely disruptive technology.”

About SI-BONE, Inc.
SI-BONE is a global technological leader for surgical treatment of musculoskeletal disorders of the sacropelvic anatomy. Since 2009, when SI-BONE introduced the iFuse Implant System for minimally invasive surgery of the SI joint, more than 2,700 surgeons have performed a combined total of more than 65,000 SI joint fusion procedures. A unique body of evidence, supporting the iFuse Implant System, including two randomized controlled trials and over 100 peer reviewed publications, has enabled multiple government and private insurance payors to establish near-universal coverage of the SI joint fusion procedure exclusively when performed with the iFuse Implant System. Supported by this proprietary reimbursement advantage, SI-BONE has actively leveraged its market leadership position in recent years to further clinical research, and evolve and commercialize novel surgical treatment solutions for SI-Joint pain, sacropelvic and pelvic fixation, and pelvic trauma. For more information or to join our team, please visit us at www.si-bone.com.

For additional information on the company or the products including risks and benefits, please visit www.si-bone.com.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/2cc5daff-cf85-455d-b19c-a2483b5675a4

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