

SI-BONE Receives Transitional Pass-Through Payment Status for iFuse Bedrock Granite™

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The iFuse Bedrock Granite™ system is a Breakthrough Device Designation technology that provides pelvic fixation and sacroiliac joint fusion, in conjunction with lumbar spinal fusion procedures

SANTA CLARA, Calif., Nov. 05, 2024 (GLOBE NEWSWIRE) -- SI-BONE, Inc., (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to providing surgical solutions for sacropelvic disorders, today announced that the Centers for Medicare & Medicaid Services (CMS) has granted Transitional Pass-Through (TPT) payment status for the iFuse Bedrock GraniteTM (Granite) system, used for pelvic fixation and sacroiliac joint fusion in conjunction with lumbar spinal fusion procedures, under the Medicare Hospital Outpatient Prospective Payment System. TPT payment status, which will be effective up to three years beginning January 1, 2025, allows patient access to new and innovative technology like Granite by providing an add-on payment to hospitals and ambulatory surgery centers supporting it.

As part of the TPT determination, CMS confirmed that a customary deduction from the add-on payment, known as a device offset, will not be applied to lumbar spinal fusion procedures involving pelvic fixation with Granite. This decision recognizes that Granite costs are not currently included in the existing facility payment amount for the procedures using this technology.

"We are pleased that CMS has acknowledged the importance of providing outpatient-based Granite procedures with TPT payment status and no device offset, allowing hospitals to maintain their usual facility payment rates for lumbar fusion procedures, while receiving TPT payment for Granite implants they report as part of the Medicare cases they support," said Laura Francis, CEO of SI-BONE. "With a growing number of specialty degenerative spine procedures moving to the outpatient setting, the additional reimbursement for Granite ensures that patients and surgeons can access new technology and procedures without regard to the site of service in which they are performed."

According to CMS, a "Transitional Pass-Through" payment is a temporary, additional payment provided to healthcare providers for new, innovative technologies like Granite, allowing patients better access while CMS supports hospitals and gathers data to accurately incorporate their cost into standard facility payment rates. Its intent is to provide an incentive for the use of new medical advances by supplying a higher reimbursement to the facility in which they are used for up to three years.

Granted BDD in November 2021 and cleared by the U.S. Food and Drug Administration (FDA) in May 2022, Granite is intended to provide fusion and fixation to the pelvis when used in conjunction with certain pedicle screw fixation systems as a foundational element for segmental spinal fusion. In finalizing its decision, CMS noted the uniqueness of the device's porous surface and interstices, and that fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection. Every year, approximately 130,000 lumbar spinal fusion procedures that end at the pelvis are performed in the United States to treat adult deformity and degenerative spine conditions.

About SI-BONE, Inc.

SI-BONE (NASDAQ: SIBN) is a global leader in technology for surgical treatment of sacropelvic disorders. Since pioneering minimally invasive surgery of the SI joint in 2009, SI-BONE has supported over 3,900 surgeons in performing a total of more than 100,000 sacropelvic procedures. A unique body of clinical evidence supports the use of SI-BONE's technologies, including two randomized controlled trials and over 140 peer reviewed publications. SI-BONE has leveraged its leadership in minimally invasive SI joint fusion to commercialize novel solutions for adjacent markets, including adult deformity, spinopelvic fixation, and pelvic trauma.

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

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