SI-BONE Expands Portfolio with the Launch of New Offering for the iFuse Bedrock Granite Implant System and Completes Inaugural Surgical Procedures

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SANTA CLARA, Calif., May 07, 2024 (GLOBE NEWSWIRE) -- SI-BONE, Inc., (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to solving musculoskeletal disorders of the sacropelvic anatomy, announced the first cases completed with the smaller, 9.5 mm diameter, iFuse Bedrock Granite® Implant (Granite 9.5). When placed across the SI joint, the Granite implant provides sacroiliac fusion and spinopelvic fixation as a foundational element for multi-segment spinal fusion.

This milestone for Granite 9.5 comes after 510(k) clearance in January 2024. The iFuse Bedrock Granite Implant System was awarded a Breakthrough Device Designation by the Food & Drug Administration and a New Technology Add-on Payment by the Centers for Medicare and Medicaid Services. Granite 9.5 may be more suitable for patients with smaller anatomy and may allow easier placement of stacked implants in the sacroalar-iliac trajectory. Moreover, the recent FDA clearance also includes use in the S1 body of the sacrum and pediatric deformity.

“The technology delivered in the Granite implants is improving traditional iliac fixation. More importantly, even with complex reconstructions, as in my experience for my first Granite 9.5 case, the implant did not change my surgical workflow. An implant that has the potential for improved patient outcomes through enhanced fixation without requiring a change in workflow will be extremely beneficial to surgeons and our patients,” said Ronald Lehman, Jr., MD, an orthopedic surgeon at New York Presbyterian Allen / Och Spine Hospital at Columbia University (New York, NY). Dr. Lehman is not a paid Consultant for SI-BONE, Inc.

C.J. Kleck, MD, an orthopedic surgeon at the University of Colorado (Denver, CO) said, “The new Granite 9.5 will enable me to fit dual sacroalar-iliac Granite implants more easily into the pelvis at the base of my spine fusions. This four-implant Granite construct reduces range of motion at the SI joints and L5-S1 segment, while reducing stress on the S1 pedicles screws[1]. This provides a stable foundation for my spine fusion patients.”

“Granite 9.5 provided outstanding tactile feedback upon insertion, equivalent to what I've experienced using the 10.5 mm Granite implants”, Ali Mesiwala, MD, FAANS, a neurosurgeon at the Los Angeles-based DISC Sports & Spine Center, stated. “This new diameter gives the Granite system even greater optionality to help me utilize this breakthrough technology in treating more of my patients.”

According to Victor Chang, MD, a neurosurgeon at Henry Ford Health in West Bloomfield, MI, “The addition of Granite 9.5 and shorter lengths worked seamlessly in helping me revise failed S1 screws. The S1 Granite 9.5 implants were a welcome addition to the 10.5 mm Granite implants I use for sacroalar-iliac fixation in my constructs. I’m very excited to have the additional sizes available as it will allow more opportunities to incorporate robust fixation with Granite into my cases.”

“Granite has been a resounding success for us since the product was launched in 2022. It allowed us to target an exciting billion-dollar market by addressing a significant unmet clinical need at the foundation of multi-segment spinal fusion procedures,” said Laura Francis, Chief Executive Officer. “Given the surgeon enthusiasm around the smaller diameter implant, we are poised to accelerate the adoption of Granite across the nearly 130,000 annual adult deformity and degenerative spine target procedures.”

About SI-BONE, Inc.

SI-BONE (NASDAQ: SIBN) is a global leader in technology for surgical treatment of musculoskeletal disorders of the sacropelvic anatomy. Since pioneering minimally invasive surgery of the SI joint in 2009, SI-BONE has supported over 3,700 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 135 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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[1] Panico, M., et al. Stability and Instrumentation Stresses Among Sacropelvic Fixation Techniques With Novel Porous Fusion/Fixation Implants: A Finite Element Study International Journal of Spine Surgery (July 2023)



Source: SI-BONE, Inc.