SI-BONE, Inc. Announces FDA Clearance for Expanded Rod Compatibility with the iFuse Bedrock Granite® Implant System

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New Indications Include Use with a Broad Class of Commercially Available Rods



SANTA CLARA, Calif., Dec. 27, 2022 (GLOBE NEWSWIRE) -- SI-BONE, Inc., (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to solving musculoskeletal disorders of the sacropelvic anatomy, today announced an additional FDA clearance for iFuse Bedrock Granite®. New cleared indications include use with a wide variety of commercially available pedicle screw system rods.

Adult spinal deformity is a complex clinical problem to treat, with lumbopelvic fixation failure rates reported at 24%.[1] Surgeons have adopted different strategies involving preoperative planning to improve spinal alignment, biologics, and next-generation pelvic fixation implants to help improve surgical outcomes. SI-BONE introduced iFuse Bedrock Granite in May 2022 to address some of these issues. The implant is typically used both to immobilize and fuse the sacroiliac (SI) joint and to serve as foundational support at the base of a spine fusion construct. The initial clearance included an indication for use with a single manufacturer's pedicle screw system. The expanded indications include use with a wide range of rods that are commonly used in multilevel spine fusion surgeries. The expanded indications will allow surgeons to use their preferred techniques and implant systems with confidence in conjunction with iFuse Bedrock Granite as the foundation for their construct.

"Many patients with spinal deformity require a thorough surgical plan and a variety of implant solutions to help provide the best outcome," said Robert Eastlack, MD, Orthopedic Surgeon, Scripps Hospital. "By using iFuse Bedrock Granite at the base of my spinal constructs, I am providing my patients with the most advanced technology available."

"Since launch, Granite has become the preferred implant for surgeons as they incorporate SI joint fusion into their pelvic fixation constructs" said Laura Francis, CEO of SI-BONE. "We believe that this expanded clearance will help increase the number of surgeons who treat their patients with this breakthrough device."

References

1. Eastlack RK, et al. Spine. 2022 Jul 15;47(14):986-994.

SI-BONE, Inc. (NASDAQ: SIBN) is a global leader in technology 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, nearly 3,000 surgeons have performed a combined total of more than 75,000 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 minimally invasive SI joint fusion, including many payors that cover the 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 additional information on the company or the products including risks and benefits, please visit www.si-bone.com.

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Forward Looking Statements

The statements in this press release regarding expectations of future events or results, including SI-BONE's expectations of continued expansion of the market for its iFuse Bedrock Granite product, contained in this press release are "forward-looking" statements. These forward-looking statements are based on SI-BONE's current expectations and inherently involve significant risks and uncertainties. These risks include SI-BONE's ability to expand the market for and user-base of iFuse Bedrock Granite, its ability to introduce and commercialize new products and indications, its ability to

maintain favorable reimbursement for procedures using its products, its ability to manage risks to its supply chain, and the future impact the COVID-19 pandemic will have on the ability and desire of patients and physicians to undergo procedures using the iFuse Bedrock Granite Implant System. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these and other risks and uncertainties, many of which are described in the company's most recent filings on Form 10-K and Form 10-Q, and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov), especially under the caption "Risk Factors". SI-BONE does not undertake any obligation to update forward-looking statements and expressly disclaims any obligations or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein, except as required by law.

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/205d4347-afa8-4370-a248-490e0e0c50fb

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iFuse Bedrock Granite®



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