SI-BONE, Inc. Receives 510(k) Clearance and FDA Breakthrough Device Designation for Pelvic Fracture Fixation System

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SANTA CLARA, Calif., Aug. 20, 2024 (GLOBE NEWSWIRE) -- SI-BONE, Inc., (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to providing surgical solutions for sacropelvic disorders, announces FDA 510(k) clearance of the iFuse TORQ TNT™ Implant System (TNT). The TNT implant system is designed to meet the specific anatomical and bone mineral density needs of the sacrum and ilium and will serve as the next generation technology for pelvic fragility fracture fixation and sacroiliac joint fusion.

TNT includes a porous threaded implant with lengths capable of spanning the posterior pelvis, passing through the ipsilateral ilium, sacrum, and into the contralateral ilium (through and through, “TNT”). TNT was awarded Breakthrough Device Designation (BDD) by the FDA. In designating TNT as a Breakthrough Device, the FDA determined that it has the potential to provide more effective treatment of pelvic fragility fractures than the current standard of care, cannulated screws. TNT is designed to improve early fixation and reduce the rate of screw backout, which may allow for early patient weight-bearing and mobilization.

According to Charles Moon, MD, Director of Orthopedic Trauma at Cedars-Sinai, “The current smooth stainless steel cannulated screws we are using in the pelvis were designed decades ago for fixing hip fractures. When trauma surgeons began modernizing their techniques for pelvic fracture fixation, they simply started using longer screws. Numerous clinical studies have shown significant issues with this strategy, especially in the geriatric population. Screw loosening can cause pain, which can slow a patient’s progress postoperatively and may require a second surgery. As surgeons we really want to avoid second surgeries in the elderly. With TNT, there is now a system designed specifically for the sacropelvic anatomy that may reduce the rate of screw backout in this patient population. The implant is accompanied by instrumentation to match modern surgical techniques. I am very excited for the many patients who will benefit from this new technology.”

“We are pleased the FDA recognized TNT as a Breakthrough Device. The number of people bedbound from pain related to pelvic fragility fractures is large and growing,” said Laura Francis, CEO of SI-BONE. “As the leader in the sacropelvic space we’re honored to be able to help surgeons get their frail and elderly patients back to mobility sooner, by providing the first anatomy-specific system designed to meet the biomechanical challenges presented by pelvic fragility fractures. After iFuse Bedrock Granite, which also was a Breakthrough Device, this is our second device to receive the designation. This highlights our ability to develop a platform of unique solutions that target large unmet clinical needs.”

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 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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