SI-BONE, Inc. Announces First-In-Patient Procedures with FDA Breakthrough Device for Pelvic Fracture Fixation

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SANTA CLARA, Calif., Oct. 10, 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 first-in-patient procedures with the FDA-designated breakthrough device, iFuse TORQ TNT™ Implant System (TNT). Designed to address the anatomic and biomechanical challenges of pelvic fragility fractures, particularly in patients with poor bone quality, TNT offers a significant advancement over traditional cannulated screws.

TNT, which received 510(k) clearance in August 2024 and was awarded Breakthrough Device Designation by the FDA, is the first 3D-printed transiliac-transsacral screw cleared for market use in the U.S. It features a pelvis-specific design to improve initial fixation and reduce the risk of screw backout. Among the first surgeons to perform procedures with TNT were Edward Westrick, MD, at Allegheny General Hospital in Pittsburgh, PA, Reza Firoozabadi, MD, at Harborview Medical Center in Seattle, WA, J.D. Black, MD, at Kadlec Regional Medical Center in Richland, WA, and Brian Cunningham, MD, at Methodist Hospital – HealthPartners in St. Louis Park, MN.

“TNT went beyond my expectations,” said Dr. Black. “The streamlined instrumentation and implant design not only provided excellent fixation but also allowed for quick, precise implantation. This efficiency is critical when treating patients with fragile bones, as it reduces operating time, minimizes risks, and leads to faster recovery.”

“TNT’s 3D-printed porous surface facilitates osseointegration, which I believe will lead to better long-term outcomes for my older, osteoporotic patients,” said Dr. Cunningham, Vice Chair and Director of Orthopedics at Methodist Hospital – HealthPartners.

“We are thrilled with the successful completion of these initial procedures using our iFuse TORQ TNT system,” said Laura Francis, Chief Executive Officer of SI-BONE. “This breakthrough technology marks a significant step forward in addressing the unmet clinical needs of complex pelvic fragility fractures. By providing a solution that improves both surgical efficiency and patient recovery, we are further expanding our leadership in the sacropelvic space.”

About SI-BONE, Inc.

SI-BONE (NASDAQ: SIBN) is a global leader in technology for the 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 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 its products, including risks and benefits, please visit www.si-bone.com.

 Edward Westrick, MD, Reza Firoozabadi, MD, and J.D. Black, MD, are paid consultants for SI-BONE, Inc. Brian Cunningham, MD, is not a paid consultant for SI-BONE, Inc.

Investor Contact: Saqib Iqbal investors@si-bone.com

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