SI-BONE, Inc. Announces FDA Clearance for Expanded Indication of the iFuse-TORQ® Implant System

June 13, 2022

Use Includes Pelvic Fragility Fractures

SANTA CLARA, Calif., June 13, 2022 (GLOBE NEWSWIRE) -- SI-BONE, Inc. (SIBN), (Nasdaq: SIBN), a Silicon Valley-based medical device company dedicated to solving musculoskeletal disorders of the sacropelvic anatomy, today announced an FDA clearance for iFuse-TORQ® for pelvic fracture fixation, including acute, non-acute and non-traumatic fractures.* Fractures covered in this clearance include pelvic fragility fractures (fractures related to low-energy traumatic events) and pelvic insufficiency fractures. Together, these constitute an approximately $300 million market opportunity.

Sacral fragility and insufficiency fractures are common and often devastating for patients and healthcare systems, where:

- 120,000 sacral fragility or insufficiency fractures occur annually in the US[1]
- 78% of patients are treated with bedrest leading to 14- to 45-day hospital stays[2-6]
- 27% 1-year mortality results from bedrest-associated complications[5,6]

“Many elderly patients with sacral fragility fractures require long periods of immobility while their fracture heals, often leading to complications associated with bedrest,” said Michael Gardner, MD, Chief of Orthopedic Trauma at Stanford University Hospital. “A paradigm shift is required. The strength and osseointegrative features of iFuse-TORQ make it the most attractive implant on the market to remobilize these osteoporotic patients.”

“Since its launch in 2021, iFuse-TORQ has been used to treat many patients suffering from a pelvic fracture or sacroiliac joint dysfunction,” said Laura Francis, CEO of SI-BONE. “This pelvic fracture fixation indication expansion comes on the coattails of the iFuse Bedrock Granite launch and expands SI-BONE’s position as the market leader in the sacropelvic space.”

References

1. Burge R, et al. J Bone Miner Res. 2007 Mar; 22(3):465-75.
2. Per Medicare ICD-10 Code Search includes patients >65 y/o by Watson Policy Analysis. June 2020.
3. Alnaib et al J Orthop Traumatol. 2012 Jun; 13(2): 97–103
4. Breuil V, et al. Joint Bone Spine. 2008;75:585–8.
5. Taillandier J, et al. Joint Bone Spine. 2003;70 (4):287–289.
6. Morris R, et al. Postgrad Med J. 2000;76 (900):646.

About SI-BONE, Inc.
SI-BONE is a global technological leader 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, more than 2,700 surgeons have performed a combined total of more than 65,000 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 the SI joint fusion 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 more information or to join our team, please visit us at www.si-bone.com.

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

* The newly cleared indication statement is:

The iFuse-TORQ Implant System is indicated for:

- Fusion of the sacroiliac joint for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis
- Fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures

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A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/36baeebe-01cb-430d-bb1e-1d23d65e3e5c

Source: SI-BONE, Inc.

iFuse-TORQ® Implant System

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