

The ***iFuse TORQ® Implant System*** is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute, and non-traumatic fractures.

The iFuse TORQ Navigation instruments are intended to be used with the iFuse TORQ Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse TORQ Navigation instruments are intended to be used with the Medtronic® StealthStation® System.

The TORQ iGPS instruments and iGPS Drill Bits are compatible with Globus ExcelsiusGPS® Instrument Trackers and intended to be used with the iFuse TORQ Implant System and the Globus ExcelsiusGPS® Robotic Navigation System (including the Globus Excelsius3D® Imaging System), which is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy. Use of the iGPS instruments is limited to use only with 10.0 mm and 11.5 mm fully threaded iFuse TORQ implants.

Healthcare professionals please refer to the Instructions For Use for indications, contraindications, warnings, and precautions at si-bone.com/label.

There are potential risks associated with iFuse procedures. They may not be appropriate for all patients, and all patients may not benefit.

For information about the risks, visit: si-bone.com/risks.

REFERENCES

Prevalence of SI Joint Pain (15-30% of chronic Low Back Pain)

¹Bernard TN Jr, Kirkaldy-Willis WH. Recognizing specific characteristics of nonspecific low back pain. *Clin Orthop Relat Res.* 1987 Apr;(217):266-80. PMID: 2951048.

Schwarzer AC. The Sacroiliac Joint in Chronic Low Back Pain. *Spine.* 1995;20(1):31-7.

²Maigne JY, Aivaliklis A, Pfefer F. Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain. *Spine.* 1996;21:1889-92.

³Irwin RW, Watson T, Minick RP, Ambrosius WT. Age, body mass index, and gender differences in sacroiliac joint pathology. *Am J Phys Med Rehabil.* 2007 Jan;86(1):37-44. doi: 10.1097/phm.0b013e31802b8554. PMID: 17304687.

⁴Sembrano JN, Polly DW Jr. How Often is Low Back Pain Not Coming From the Back? *Spine.* 2009 Jan;34(1):E27-32.

Prevalence of SI Joint Pain (32-43% symptomatic post-lumbar fusion)

⁵Katz V, Schofferman J, Reynolds J. The sacroiliac joint: a potential cause of pain after lumbar fusion to the sacrum. *J Spinal Disord Tech.* 2003 Feb;16(1):96-9. doi: 10.1097/00024720-200302000-00015. PMID: 12571491.

⁶Maigne JY, Planchon CA. Sacroiliac joint pain after lumbar fusion. A study with anesthetic blocks. *Eur Spine J.* 2005 Sep;14(7):654-8. doi: 10.1007/s00586-004-0692-6. Epub 2005 Mar 11. PMID: 15761709; PMCID: PMC3489225.

⁷DePalma MJ, Ketchum JM, Saullo TR. Etiology of Chronic Low Back Pain in Patients Having Undergone Lumbar Fusion. *Pain Med.* 2011;12(5):732-739.

⁸Liliang P-C, Lu K, Liang C-L, Tsai Y-D, Wang K-W, Chen H-J. Sacroiliac joint pain after lumbar and lumbosacral fusion: findings using dual sacroiliac joint blocks. *Pain Med.* 2011;12:565-70.

Diagnosis of SI Joint Dysfunction

⁹Szadek KM, et al. Diagnostic Criteria for Sacroiliac Pain, a Systemic Review. *J Pain.* 2009;Apr;10(4):354-68.

¹⁰Laslett M. Evidence-based diagnosis and treatment of the painful sacroiliac joint. *J Man Manip Ther.* 2008;16(3):142-52.

¹¹Petersen T, Laslett M, Juhl C. Clinical classification in low back pain: best-evidence diagnostic rules based on systematic reviews. *BMC Musculoskelet Disord.* 2017 May 12;18(1):188. doi: 10.1186/s12891-017-1549-6. PMID: 28499364; PMCID: PMC5429540.

iFuse Implant System® – Clinical Outcomes (<https://si-bone.com/results>)

¹²[iMIA 2yr] Dengler J, Kools D, Pflugmacher R, Gasbarrini A, Prestamburgo D, Gaetani P, Cher D, Van Eeckhoven E, Annertz M, Stuesson B. Randomized Trial of Sacroiliac Joint Fusion vs. Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. *J Bone Joint Surg.* 2019;101(5):400-411. DOI: 10.2106/JBJS.18.00022.

¹³[INSITE 2yr] Polly DW, Swofford J, Whang PG, Frank CJ, Glaser JA, Limoni RP, Cher DJ, Wine KD, Sembrano JN, and the INSITE Study Group. Two-Year Outcomes from a Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion vs. Non-Surgical Management for Sacroiliac Joint Dysfunction. *Int J Spine Surg.* 2016;10:Article 28. DOI: 10.14444/3028.

¹⁴[SALLY 5yr] Patel V, Meyer SC, Kovalsky D, Lockstadt H, Farris J, Limoni R, Chowdhary A, Yuan P, Langel C, Kranenburg A, Tender G. Prospective Trial of Sacroiliac Joint Fusion Using 3D-Printed Triangular Titanium Implants: 5-Year Follow-Up. *Spine (Phila Pa 1976).* 2024 Sep 30. doi: 10.1097/BRS.0000000000005170. Epub ahead of print. PMID: 39344079.

¹⁵Whang PG, Patel V, Duhon B, Stuesson B, Cher D, Carlton Reckling W, Capobianco R, Polly D. Minimally Invasive SI Joint Fusion Procedures for Chronic SI Joint Pain: Systematic Review and Meta-Analysis of Safety and Efficacy. *Int J Spine Surg.* 2023 Oct 5:8543. doi: 10.14444/8543. Epub ahead of print. PMID: 37798076.