iFuse Implant System® Indications

The iFuse Implant System® is intended for sacroiliac fusion for the following conditions:

• Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

• To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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)

1. Bernard 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.

2. Maigne 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.

3. Irwin 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.

4. Sembrano 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)

5. Katz 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.

6. Maigne JY, Planchon CA. Sacroiliac joint pain after lumbar fusion. Eur Spine J. 2005 Sep;14(7):654-8.

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

8. Liliang P-C et al. Sacroiliac joint pain after lumbar and lumbosacral fusion. Pain Med. 2011;12:565–70.

Diagnosis of SI Joint Dysfunction

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

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

11. Petersen T et al. Clinical classification in low back pain. BMC Musculoskelet Disord. 2017;18(1):188.

iFuse Implant System® – Clinical Outcomes

12. Dengler J et al. Randomized Trial of Sacroiliac Joint Fusion vs. Conservative Management. J Bone Joint Surg. 2019;101(5):400-411.

13. Polly DW et al. Two-Year Outcomes from a Randomized Controlled Trial. Int J Spine Surg. 2016;10:28.

14. Patel V et al. 5-Year Follow-Up. Spine. 2024.

15. Whang PG et al. Systematic Review and Meta-Analysis. Int J Spine Surg. 2023.