

## INDICATIONS

The iFuse INTRA X® Allograft is intended for homologous use.

The iFuse INTRA X® Allograft Implant System instruments are intended for placement of the iFuse INTRA X allograft.

Healthcare professionals please refer to the Instructions For Use for indications, contraindications, warnings, and

precautions at [si-bone.com/label](http://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](http://si-bone.com/risks).

## REFERENCES

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

<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>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. doi: 10.1097/phm.0b013e31802b8554. PMID: 17304687.

<sup>4</sup>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)**

<sup>5</sup>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. doi: 10.1097/00024720-200302000-00015. PMID: 12571491.

<sup>6</sup>Maigne 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.

<sup>7</sup>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.

<sup>8</sup>Liliang 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**

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

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

<sup>11</sup>Petersen 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>)**

<sup>12</sup>[iMIA 2yr] Dengler J, Kools D, Pflugmacher R, Gasbarrini A, Prestamburgo D, Gaetani P, Cher D, Van Eeckhoven E, Annertz M, Stuessen 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.

<sup>13</sup>[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.

<sup>14</sup>[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.

<sup>15</sup>Whang PG, Patel V, Duhon B, Stuessen 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.