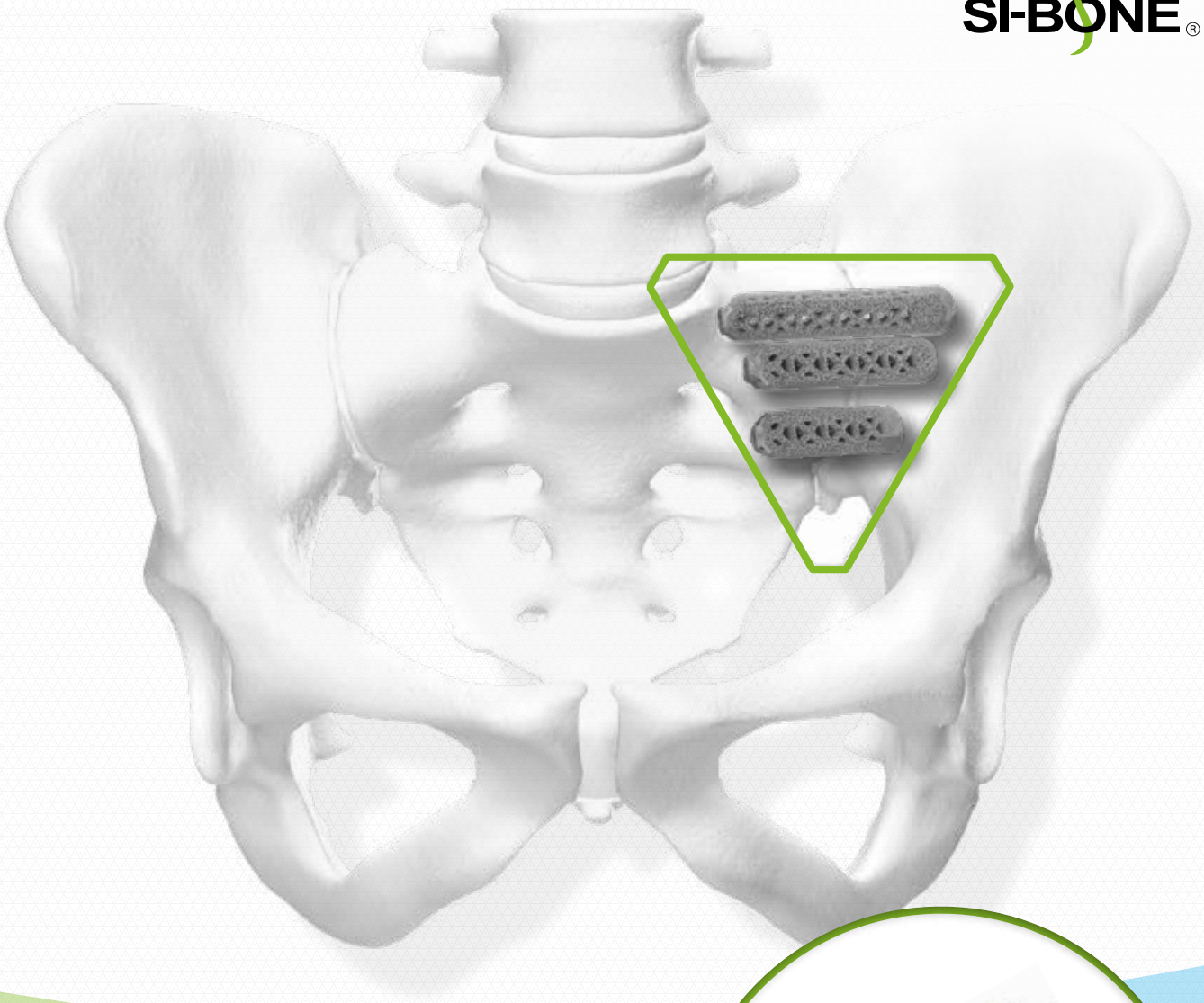
SI-BONE®



iFuse-3D™

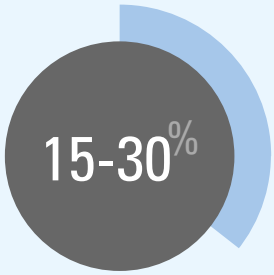
Product Brochure

A Minimally Invasive Surgical Approach to the Management of SI Joint Dysfunction

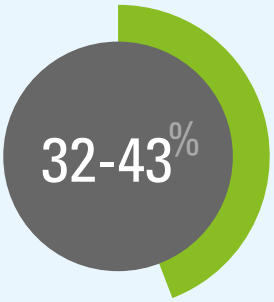
SI Joint in Low Back Pain

The Sacroiliac (SI) joint has long been recognized as a source of low back pain and several reports of surgical treatment date back to the 1920s.[1-3] Numerous publications have studied the prevalence of SI joint pain as a component of low back pain[4-8] as well as in patients with prior lumbar fusion.[9-12]

Since sympotoms are very similar to other lumbar pathologies, the SI joint is often overlooked during diagnosis.

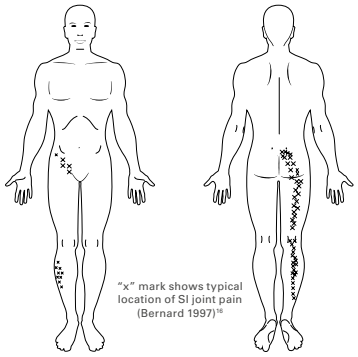


*According to a study by **Bernard**[4], (n=1293 patients) over **22% of individuals with lower back pain complaints** actually had problems in their sacroiliac (SI) joint.*



***DePalma**[11] studied lumbar fusion patients who were experiencing persistent or new lower back pain (LBP) post-operatively. The results demonstrated that **43% of post-lumbar fusion patients** were symptomatic for SI joint disorders based on diagnostic blocks.*

- It is common for pain from the SI joint to mimic discogenic or radicular low back pain.[13]
- The radiographic-incidence of SI joint degeneration in post-lumbar fusion surgery is **75% at 5 years post-surgery**.[14]
- The anti-inflammatory effect of SI joint injections is not permanent and does not offer an opportunity to stabilize an incompetent SI joint.[15]



"x" mark shows typical location of SI joint pain (Bernard 1997)[16]

Diagnosis of SI Joint Disorders

Understanding sacroliliac joint symptoms

An evidence-based diagnostic algorithm can help determine if the sacroiliac (SI) joint is a component of low back pain. Proper diagnosis of SI joint dysfunction includes a complete patient history, clinical exam and imaging studies to rule out other sources of pain. It is important to note, hip pathology and/or lumbar pathology can often coexist and symptoms can be similar to that of SI joint disorders.

- The Fortin Finger test[17], where the patient points with one finger to their PSIS as the source of pain and provocation tests (see below, with at least 3 out of 5 positive results)[18,19], followed by a diagnostic injection, are recommended to confirm the SI joint as a pain generator[20].

Fortin Finger & Provocative Tests

Fortin Finger Test

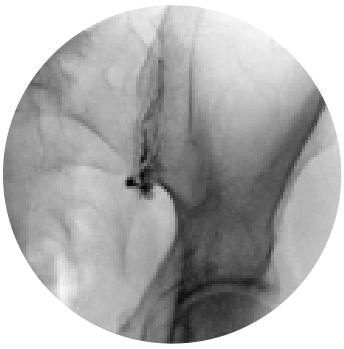
Distraction

Thigh Thrust

FABER

Compression

Gaenslen's



Diagnostic Injection

Intra-articular Diagnostic SI Joint Injections

Fluoroscopic-guided SI joint injection with:

- contrast medium
- local anesthetic

Post-injection pain reduction:

- ≥ 50% SI joint is likely the source of pain
- < 50% Should consider other pain sources, but SI joint may be a component

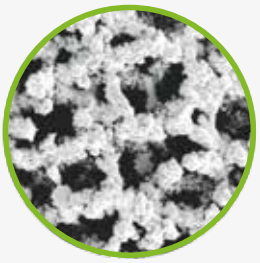
iFuse Product Benefits

The **iFuse-3D™** is intended for sacroiliac joint fusion.

- The iFuse-3D implant is specifically designed to stabilize and fuse the SI joint.
- The titanium implant provides an interferene fit between the implant and the adjacent osseous walls.
- The unique triangular-shaped implant profile minimizes rotation (more than 6X the rotational resistance of a screw[21]) and stabilizes the joint while the porous surface area supports long-term fusion.
- 3D-Printed Trabecular Surface mimics native cancellous bone and enhances osteointegration.[22-24] (Fig. 1a, 1b)
- iFuse-3D is designed to allow for ongrowth, ingrowth and through growth.[25] (Fig. 2a, 2b)
- Self-Harvesting Technology: iFuse-3D™ captures bone during implantation.[25]
- Fenestrated structure may be pre-packed with autograft or allograft, 1-3cc depending on implant size.

Fig. 1a

iFuse-3D™ Surface



Porosity	Pore Size
65%	300 µm

Fig. 1b

Cancellous Bone

Porosity	Pore Size
60-70%	200-400 µm

Fig. 2a

Top view

Fig. 2b

Cross-section view

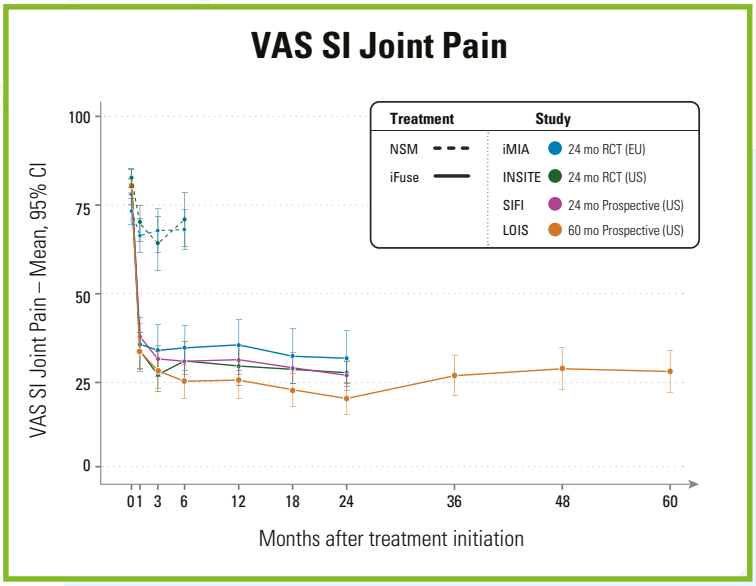
Sheep study results at 12 weeks post-implantation[26]

Consistent Prospective Study Results (iMIA[26], INSITE[27], SIFI[17], LOIS[28], SALLY[29])

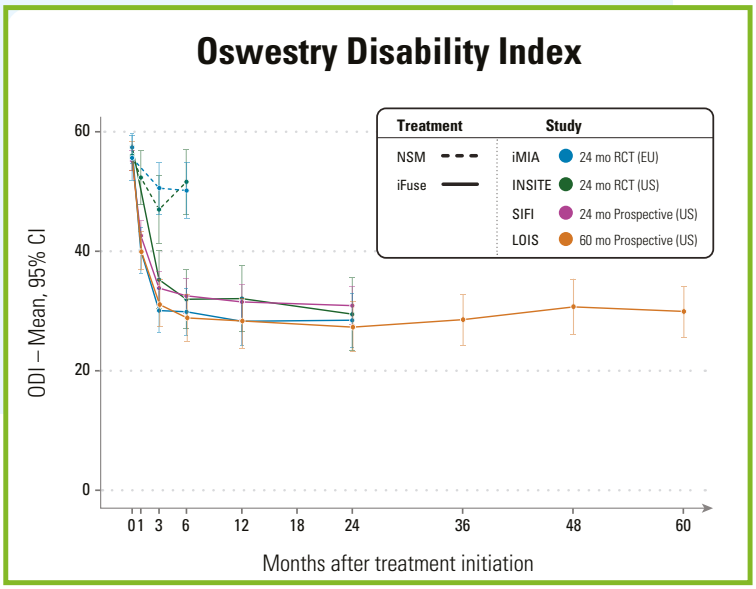
More than **80 published articles** have reported on the safety, effectiveness, biomechanics and economic benefits of the iFuse Implant System.®

Available since 2009, iFuse is the only SI joint fusion device with published results from randomized controlled trials[26,27] and **the only one** with multiple[26-29] and also long-term - up to **5 years**[30] - prospective clinical studies that show iFuse improved pain, patient function and quality of life significantly[15-18].

The prospective multicenter SALLY[30] study confirms similar clinical outcomes for the 3D-printed triangular titanium iFuse-3D™ implant to the above-mentioned trials, with improved physical function and decreased opioid use.



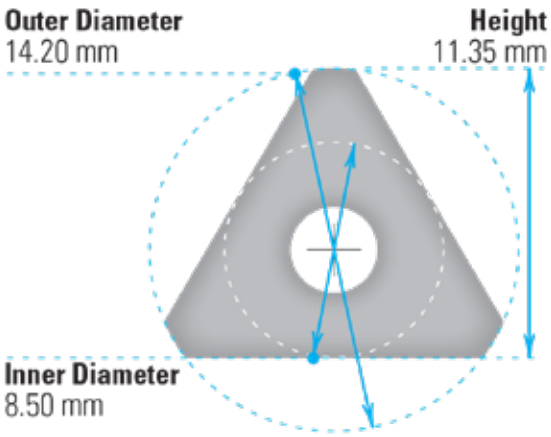
VAS and ODI results from a 5 year prospective multicenter study.



A complete list of all publications on the **iFuse Implant System®** is available at **www.si-bone.com/results**

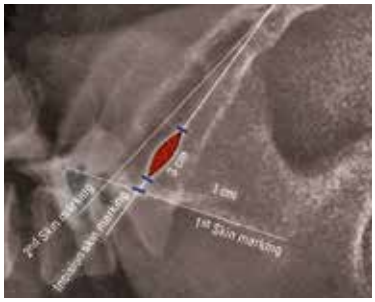
iFuse-3D™

Implant	Height	Inner Diameter	Outer Diameter
iFuse-3D™	11.35	8.50	14.20

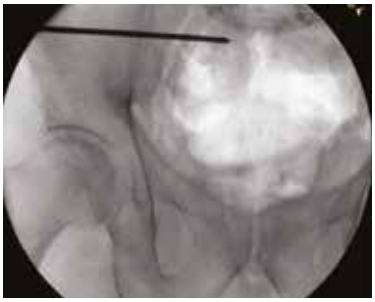


Implant Length	Graft Vol (cc)
35	1.2
40	1.4
45	1.6
50	1.8
55	2.0
60	2.2
65	2.4
70	2.6
75	2.8
80	3.0
85	3.2
90	3.4

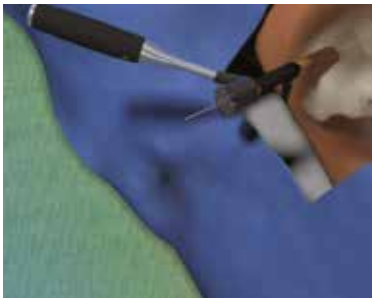
iFuse Surgical Technique



1. Skin Mark & Incision



2. Pin Insertion



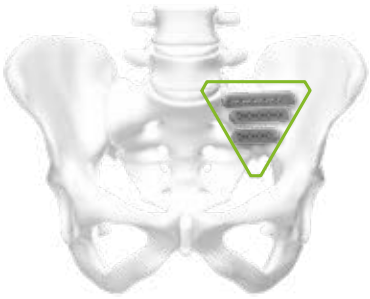
3. Place Soft Tissue Protector

4. Measure Depth

5. Drill

6. Broach

7. Insert Implant

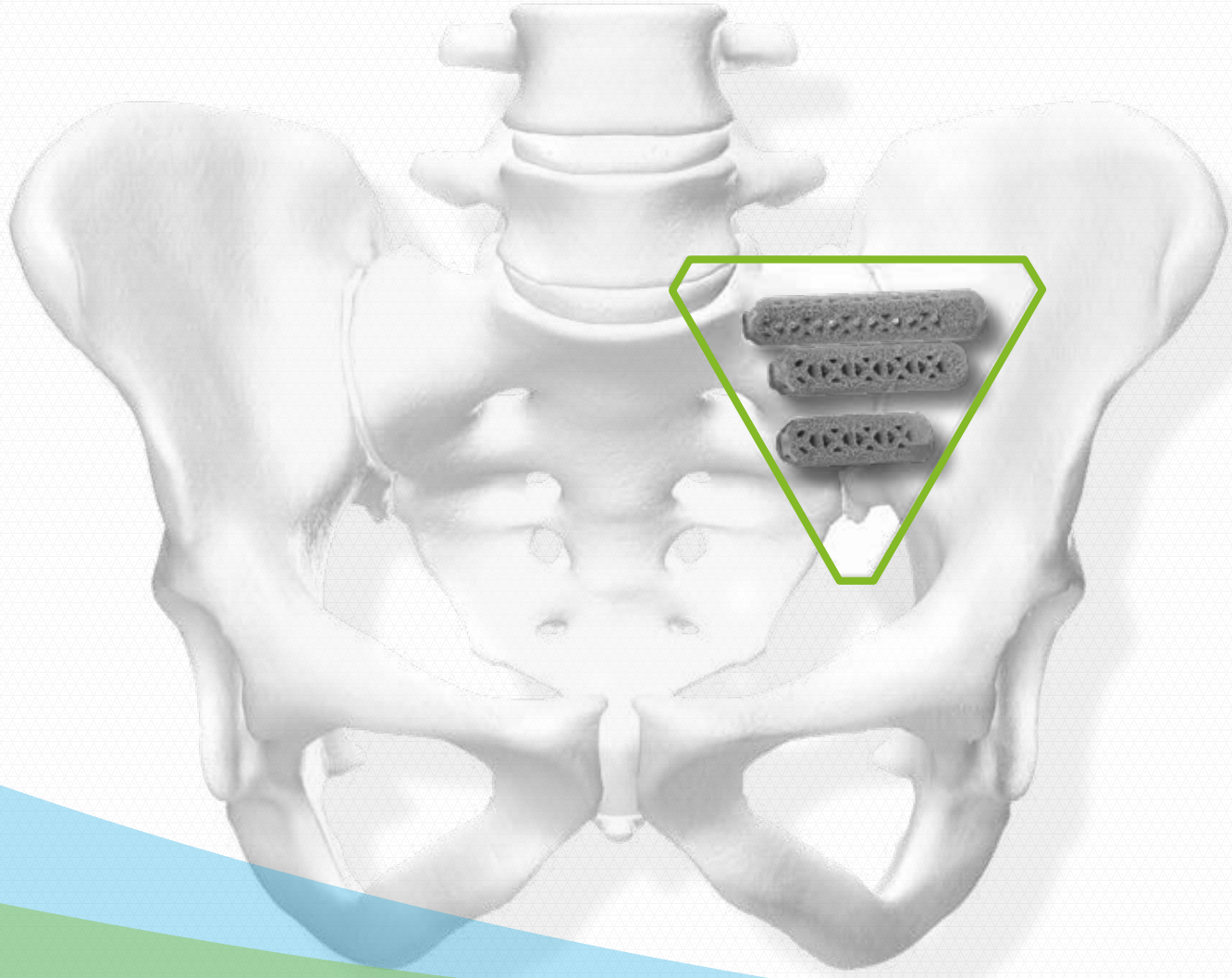


8. Repeat

SI-Bone Educational Program

SI-BONE is focused on educating providers on one of the most under-served, under-diagnosed and under-treated areas in the spine, the sacroiliac (SI) joint.

For further information regarding the iFuse Implant System® and our broad educational program on SI joint diagnosis and treatment at the SI University ® please contact your local SI-BONE sales representative or email SI-BONE at **training_EMEA@si-bone.com**



References

1. Goldthwait JE, Osgood RB. Boston Med Surg J. 1905;152(21):593-601.
2. Camp bell WC. Surg Gynecol Obstet. 1927;45:218-9.
3. Smith-Petersen MN, Rogers WA. J Bone Joint Surg. 1926;8(1):118-36.
4. Bernard TN, Kirkaldy-Willis WH. Clin Orthop. 1987;Apr(217):266-280. doi:10.1097/00003086-198704000-00029
5. Schwarzer AC, Aprill CN, Bogduk N. Spine. 1995;20(1):31-37. doi:10.1097/00007632-199501000-00007
6. Maigne JY, Aivaliklis A, Pfefer F. Spine. 1996;21(16):1889-1892. doi:10.1097/00007632-199608150-00012
7. Irwin RW, et al. Am J Phys Med Rehabil. 2007;86(1):37-44. doi:10.1097/PHM.0b013e31802b8554
8. Sembrano JN, Polly DW. Spine. 2009;34(1):E27-32. doi:10.1097/BRS.0b013e31818b8882
9. Katz V, Schofferman J, Reynolds J. J Spinal Disord Tech. 2003;16(1):96-99.
10. Maigne JY, Planchon CA. Eur Spine J. 2005;14(7):654-658. doi:10.1007/s00586-004-0692-6
11. DePalma MJ, et al. Pain Med. 2011;12(5):732-739. doi:10.1111/j.1526-4637.2011.01098.x
12. Liliang P-C, et al. Pain Med. 2011;12(4):565-570. doi:10.1111/j.1526-4637.2011.01087.x
13. Weksler N, et al. Arch Orthop Trauma Surg. 2007;127(10):885-8.
14. Ha KY, et al. Spine. 2008;33(11):1192-8.
15. Zelle BA, et al. Clin J Pain. 2005;21(5):446-55.43-66.
16. SI-BONE Technical Study 3000610-TS.
16. Bernard TN Jr, Cassidy JD. The sacroiliac joint syndrome: Pathophysiology, Diagnosis, and Management. In: Frymoyer JW, ed. The Adult Spine: Principles and Practice. 2nd Edition. Lippincott-Raven Publishers, Philadelphia, 1997; Chapter 109, pp 2343-66.
17. Fortin JD, Falco FJ. Am J Orthop Belle Mead NJ. 1997;26(7):477-480.
18. Laslett M. J Man Manip Ther. 2008;16(3):142-52.
19. Szadek KM, et al. J Pain. 2009;Apr:10(4):354-68.
20. Petersen T, Laslett M, Juhl C. BMC Musculoskelet Disord. 2017;18(1):188. DOI: 10.1186/s12891-017-1549-6.
21. SI-BONE Technical Study 3000610-TS.
22. MacBarb RF, et al. Int J Spine Surg. 2017;11(3):15. DOI: 10.14444/4015.
23. Karageorgiou V, Kaplan D. Biomaterials. 2005;26:5474-91.
24. Hutmacher DW. Biomaterials. 2000;21(24):2529-43.
25. MacBarb RF, et al. Int J Spine Surg. 2017;11(3):16. DOI: 10.14444/4016.
26. Dengler J, et al. J Bone Joint Surg Am. 2019;101(5):400-411. [Epub 2019 Mar 6]. PMID: 30845034. DOI: 10.2106/JBJS.18.00022.
27. Polly DW, et al. Int J Spine Surg. 2016;10:28. DOI: 10.14444/3028.
28. Duhon BS, et al. Int J Spine Surg. 2016;10:13. DOI: 10.14444/3013.
29. Whang PG, et al. Med Devices (Auckl). 2019;12:411-422.
30. Patel V, et al. Med Devices (Auckl). 2019;12:203-214. DOI: 10.2147/MDER.S205812.

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Important Information
The iFuse Implant System® is intended for sacroiliac joint fusion. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *www.si-bone.com/risks*

OUS Providers

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