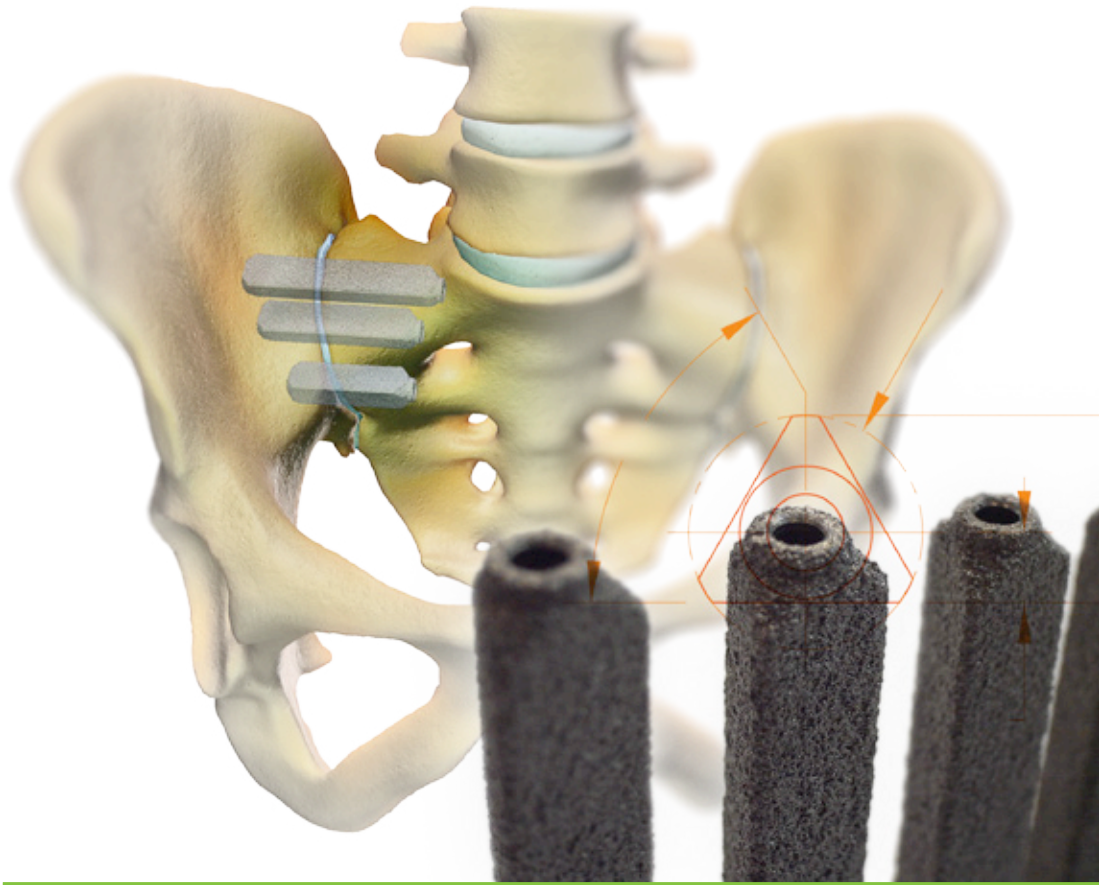
SI-BONE® | **iFuse** Implant System®

Minimally Invasive Sacroiliac Joint Surgery



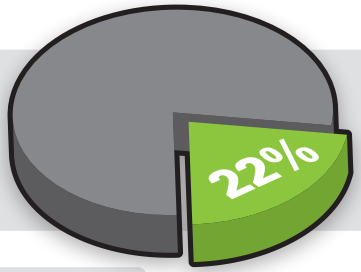
Unique Design | Strength of Experience | Clinical Results

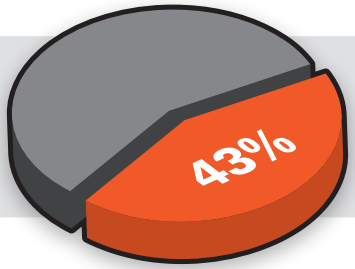
SI Joint in Low Back Pain

The SI joint has long been recognized as a source of low back pain and several reports of surgical treatment date back to the 1920's.[1,2,3] Numerous publications have studied the prevalence of the SI joint as a component of low back pain as well as in patients with prior lumbar fusion.

- It is common for pain from the SI joint to mimic discogenic or radicular low back pain. – *Weksler*[4]
- The prevalence of SI joint degeneration after lumbar fusion surgery is 75% at 5 years post-surgery. – *Ha*[5]
- The anti-inflammatory effect of SIJ injections is not permanent and does not offer an opportunity to stabilize an incompetent SI joint. – *Zelle*[6]

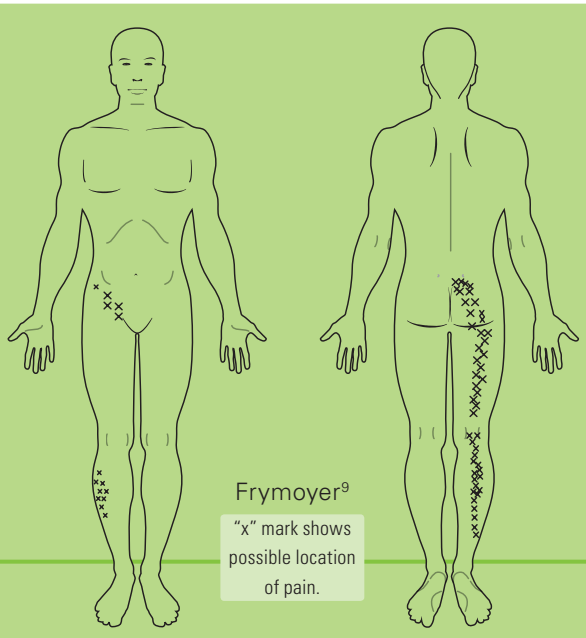
- According to a study by *Bernard*[7], over **22% of individuals with lower back pain complaints** actually had problems in their sacroiliac (SI) joint.





- *DePalma*[8] 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.

Diagnosis of SI Joint Disorders



Frymoyer[9]

"x" mark shows possible location of pain.

- Pain can be in the low back, buttocks,and/or legs.
- Pain complaints may be similar to those of other conditions of the lumbar spine, pelvis, and hip.
- Sacroiliac (SI) joint disorders require appropriate interpretation of a patient's history, clinical exam results, and imaging studies.
- A differential diagnosis is necessary to rule out other sources of pain such as the hip or spine.
- Provocative tests followed by diagnostic injections are recommended for confirmation of the SI joint as the pain generator.

Distraction

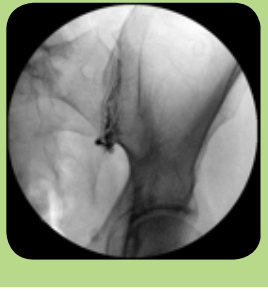
Thigh Thrust

FABER

Compression

Gaenslen's

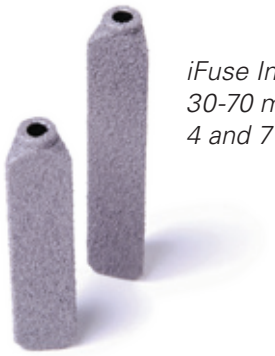
Diagnostic Injections



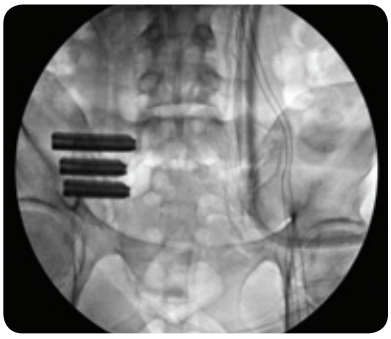
The Method of Choice for SI Joint Fusion℠

The **iFuse Implant System**® is intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis.

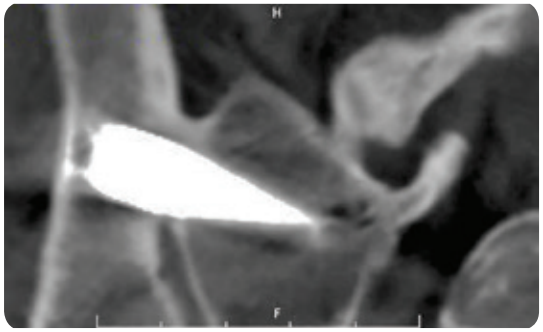
- Triangular implant profile minimizes rotation
- An interference fit between the implant and the adjacent osseous walls
- Porous titanium plasma spray (TPS) coating allows for biological fixation
- TPS technology used for decades in other medical applications such as orthopedics and dentistry
- Designed specifically to stabilize and fuse the heavily loaded SI joint
- Rigid titanium construction and implant geometry provide immediate stabilization



iFuse Implants:
30-70 mm length,
4 and 7 mm diameter



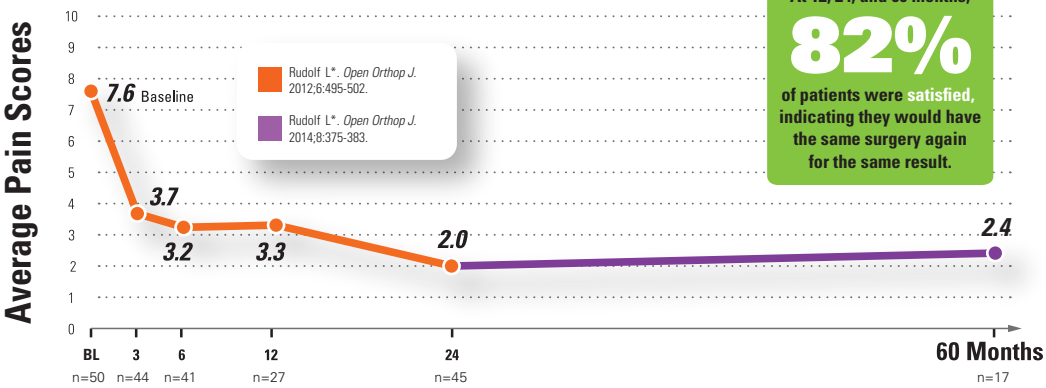
Post-op X-ray



Axial CT scan obtained at 5 years showing favorable placement of the implants and intra-articular osseous bridging

Rapid and Sustained Pain Relief[11]

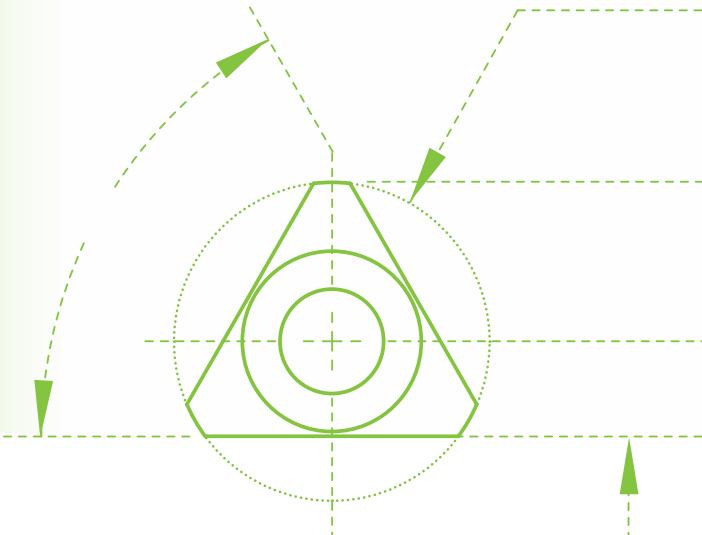
0=No Pain; 10=Worst pain imaginable



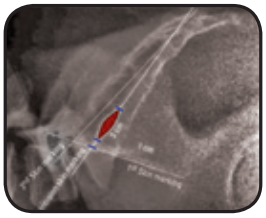
Several published articles including prospective and randomized controlled trials have reported on the clinical results for the iFuse Implant System. Outcome measures assessed include the visual analog scale (VAS), Oswestry Disability Index (ODI), quality of life (SF- 36), and patient satisfaction with the surgery. An independent review of the company complaints database with information on over 5,000 procedures documented a low complaint rate and a low revision rate.[10] A complete list of publications is available at **www.si-bone.com**

With the **iFuse Implant System**, there is no need for:

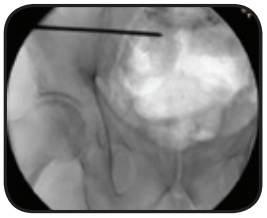
- Preparation of the joint prior to implant
- BMP or bone graft
- Additional fixation such as pedicle screws and rods
- Hollow modular anchorage screws
- Cannulated compression screws
- Threaded cages within the joint



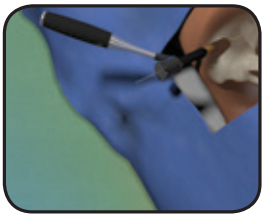
iFuse Surgical Technique



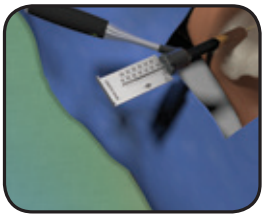
1. Skin Mark & Incision



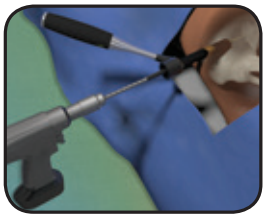
2. Pin Insertion



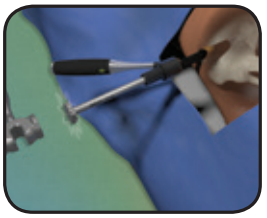
3. Place Soft Tissue Protector



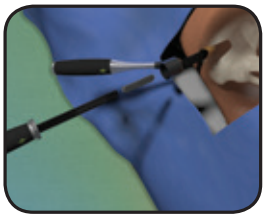
4. Measure Depth



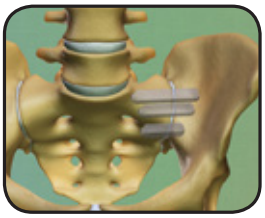
5. Drill



6. Broach



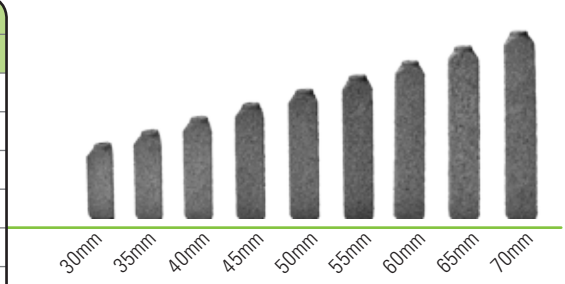
7. Insert Implant



8. Repeat

iFuse Implants

Implant Length (mm)	Diameter (mm) 4.0	Diameter (mm) 7.0
30	4030-90	7030-90
35	4035-90	7035-90
40	4040-90	7040-90
45	4045-90	7045-90
50	4050-90	7050-90
55	4055-90	7055-90
60	4060-90	7060-90
65	4065-90	7065-90
70	4070-90	7070-90



Ordering Information

To order your iFuse Implant System, please contact your local SI-BONE sales representative or call SI-BONE at **408.207.0700**

References

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10. Miller LE†, *et al.* Analysis of Postmarket Complaints Database for the iFuse SI Joint Fusion System: A Minimally Invasive Treatment for Degenerative Sacroiliitis and Sacroiliac Joint Disruption. *Med Devices* (Auckl). 2013;6:77-84.
11. Polly, D.W. *et al.,* 2015. Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs. Non-Surgical Management for Sacroiliac Joint Dysfunction. *Neurosurgery.* 2015. Epub 2015 Aug 19. Dr. Polly is an investigator on a clinical research study sponsored by SI-BONE. He has no financial interest in SI-BONE. Research was funded by SI-BONE, Inc. A list of additional published studies is available at *www.si-bone.com/results*

† Conducts clinical research for SI-BONE, Inc.

* Rudolf, Leonard is a paid consultant of, conducts clinical research for, and has an ownership interest in SI-BONE, Inc.

The iFuse Implant System® is intended for sacroiliac fusion for conditions including 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. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life at 12 months post-implantation. 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*

SI-BONE® | **iFuse** Implant System®
Minimally Invasive Sacroiliac Joint Surgery

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