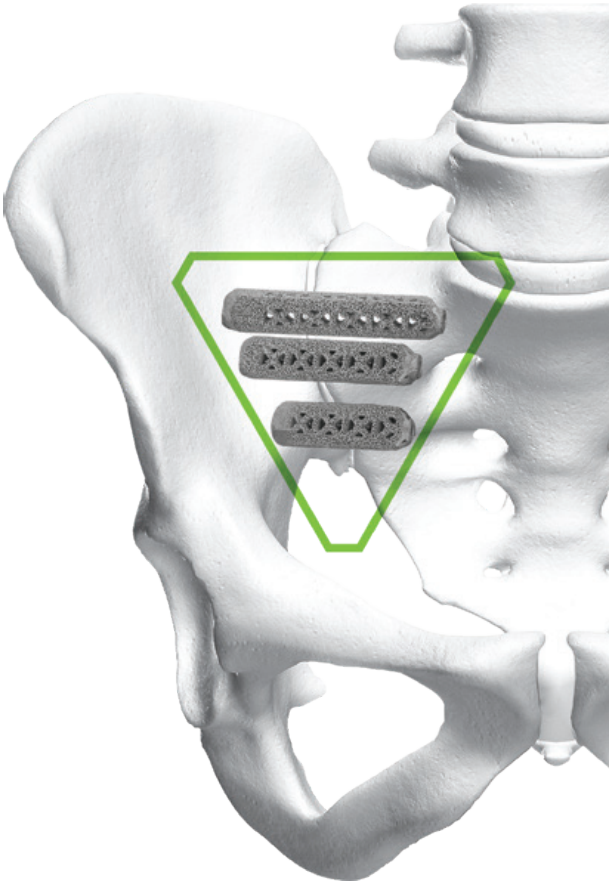
SI-BONE®

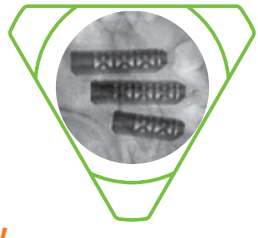
Sacropelvic Solutions™



The clinically proven SI Joint Fusion System

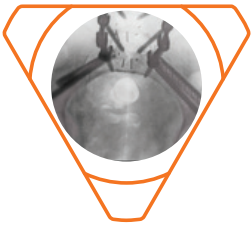
Degenerative

100+ clinical publications, >90% patient satisfaction, low revision and complication rate[10-12,15,16]



Deformity

FIXATION. FUSION. FOUNDATION.™ reduces SI Joint ROM & Stress on S2AI Screw [19]

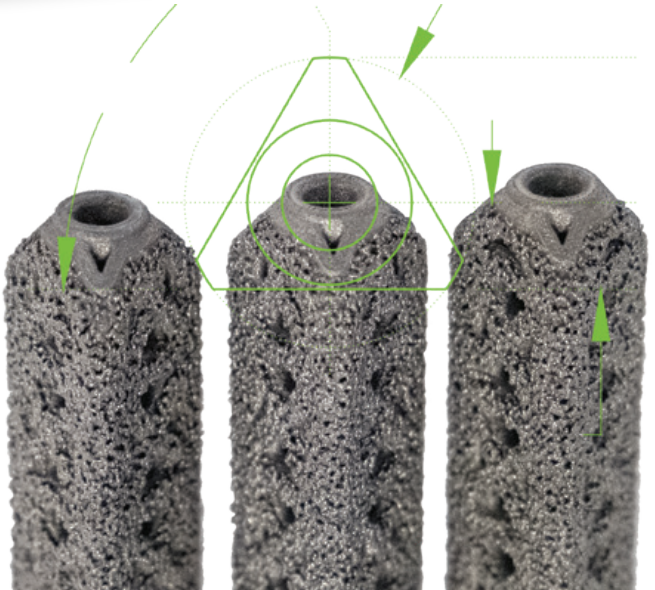


Trauma

FIX. FUSE. FORTIFY.™

8 Reasons to use the triangle

- The only clinically-proven SI joint fusion system with multiple RCTs and Prospective studies.
  - 100+ publications (*www.sibone.com/OUS/results*)
- 80.000+ cases performed worldwide (February 2023)
- Clinical outcomes[10-12,15,16]
  - Rapid pain relief
  - High patient satisfaction
  - Low revision rate
  - Superior to non-surgical management[10,11]
- MIS procedure
  - Radiolucent instruments
  - Cannulated insruments & implants
  - Less invasive
  - Navigation options available
- SI University® dedicated training
  - Primary Surgeon Trainings
  - Advanced Training courses
  - Surgical case support by trained sales people
  - SI-BONE SImulator™ – radiation free
- Triangular design to stabilise and fuse the heavily loaded SI joint
- Interference press fit between the implant and the adjacent osseous walls
- Lateral approach for optimal implant positioning[70]
  - UK NICE Guidance[46,47]
  - Exclusive coverage in France[48]

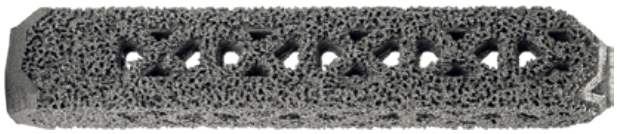


A Minimally Invasive Surgical Approach to the Management of SI Joint Dysfunction

SI Joint and Lower Back Pain

The sacroiliac (SI) joint has long been recognised as a source of lower back pain and several reports of surgical treatment date back to the 1920s. Numerous publications have studied the prevalence of SI joint pain as a component of lower back pain[1-5] as well as in patients with prior lumbar fusion.[6-9]

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



About SI-BONE

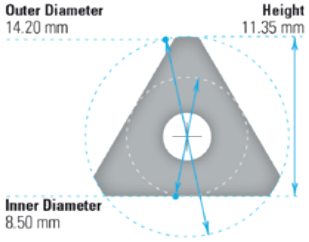
SI-BONE is a medical device company that developed the iFuse Implant System®, a proprietary minimally invasive surgical implant system to fuse the sacroiliac (SI) joint. The innovative and patented iFuse Implant System® provides a less invasive alternative to traditional open SI joint fusion surgery. The company is focused on and dedicated to educating surgeons on the diagnosis of lower back issues related to the SI joint. Therefore, a unique training program was developed to effectively train surgeons to perfom surgeries with the goal of obtaining outstanding patient results.

Treatment with the iFuse Implant System® may potentially minimise complications, often seen with open surgery, such as blood loss and average length of hospital stay.

2 RCTs[10,11] and a 5-year prospective follow-up study[12] prove the safety and efficacy of the sytem. As of February 2023, more than 80,000 minimally invasive surgical SI joint fusions have been performed with the iFuse Implant System® by 3,000 surgeons worldwide.

SI-BONE | iFuse 3D™ Implant System

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

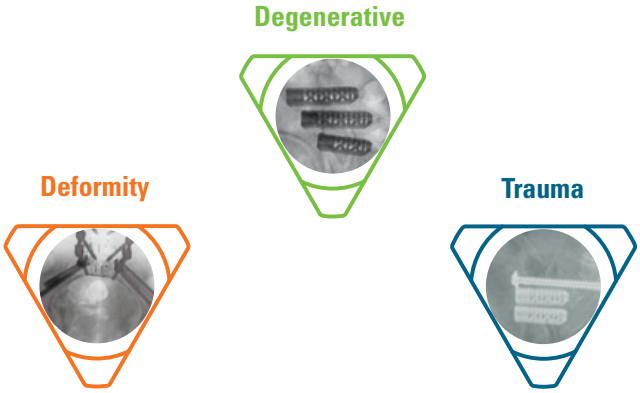


Implant Length (mm)	Graft Vol (cc)	Product Code
35	1.2	7035M-90
40	1.4	7040M-90
45	1.6	7045M-90
50	1.8	7050M-90
55	2.0	7055M-90
60	2.2	7060M-90
65	2.4	7065M-90
70	2.6	7070M-90
75	2.8	7075M-90
80	3.0	7080M-90
85	3.2	7085M-90
90	3.4	7090M-90

The Shape of Relief®

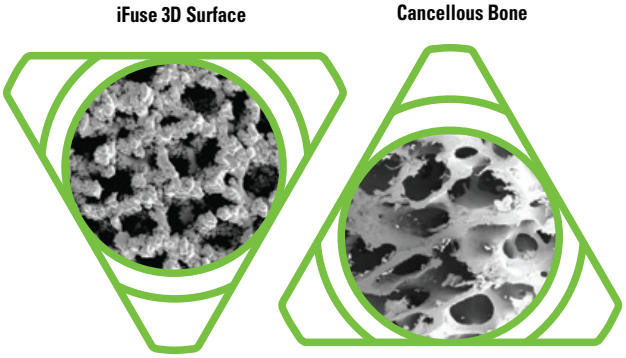
The iFuse Implant System®

Minimally invasive SI joint fusion is a surgical solution for SI joint pain when non-surgical methods have failed to provide sustained relief. The iFuse Implant System®, available since 2009, is a minimally invasive surgical (MIS) option designed to provide immediate SI joint stabilisation and allow long-term fusion.



iFuse 3D™ Implant System

- Minimally invasive surgery
- Patented triangular design
- 3D printed
- Self-harvesting technology[13]
- 6x greater rotational resistance vs. a 12mm screw[14]
- Demonstrated clinical outcomes[10-12,15,16]
  - Rapid pain relief
  - Improvement of back function
  - High patient satisfaction
  - Superior outcome to non-surgical management[10,11]
- Low revision rate[10-12,15,16]
- 3D printed trabecular surface mimics native cancellous bone and enhances osteointegration[13]



SI Joint Dysfunction

Causes of SI Joint Dysfunction

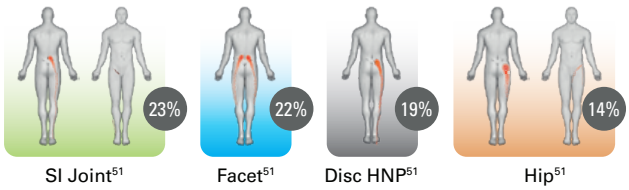
- SI Joint Degeneration
- Previous Lumbar Fusion
- Trauma
- Post Partum

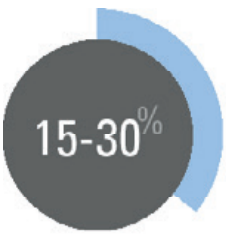
Burden of Disease and Prevalence

The impact on quality of life or health burden of patients with SI joint pain is similar or higher than many surgically treated musculoskeletal conditions or other health conditions.[17]

Ha[18] demonstrated in a 2008 SPINE article that 75% of post-lumbar fusion patients showed SI joint degenerative changes on CT scans after 5 years.

The symptoms and pain patterns of SI joint pain are very similar to other lumbar pathologies (facet, disc herniation, hip), and thus the SI joint is often overlooked during diagnosis.



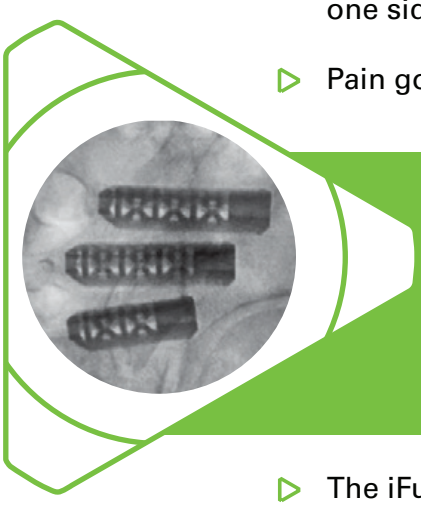


The prevalence of SI joint dysfunction as a cause of chronic lower back pain has been shown to be 15-30%.[1-5] The largest of these studies, Bernard[1] (n=1293 patients), showed over 22% of individuals with lower back pain complaints actually had problems in their SI joint.

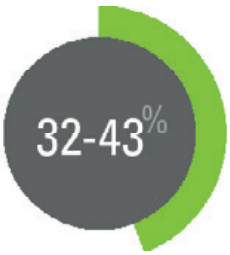
SI Joint in Lower Back Pain

Typical Patient Complaints:

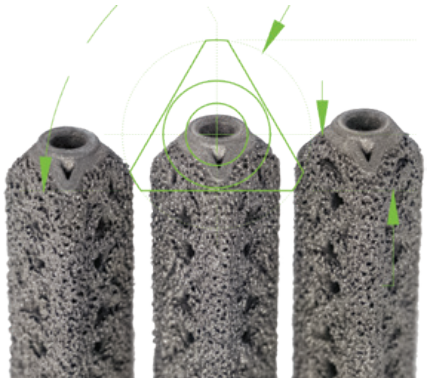
- Lower back pain (below L5)
- Sensation of lower extremity: pain, numbness, tingling, weakness
- Pelvis/ buttock pain
- Hip/ groin pain
- Feeling of leg instability
- Disturbed sleeping patterns
- Disturbed sitting patterns (unable to sit for long periods, sitting on one side)
- Pain going from sitting to standing



- The iFuse Implant System® is intended for sacroiliac joint fusion including use in high and low energy fractures of the pelvic ring



SI joint pain prevalence is higher in post-lumbar fusion patients (32-43%).[6-9] De Palma[8] studied lumbar fusion patients who experienced persistent or new onset 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.



iFuse Bedrock®
FIXATION. FUSION. FOUNDATION.™

FIXATION.

- Rigid titanium construction and triangular implant geometry provide immediate stabilisation
- Unique design provides interference fit between the implant and the surrounding bone (cortical and cancellous bone)
- 6x greater rotational resistance vs. 12 mm screw[14]

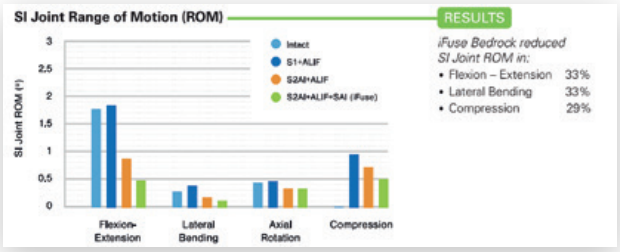
FUSION.

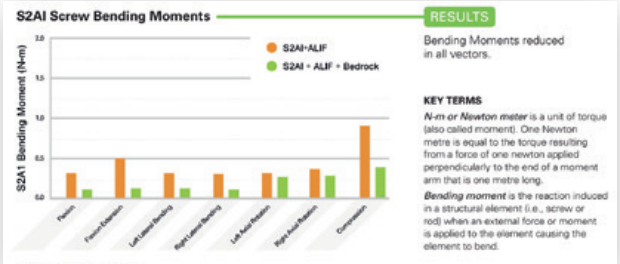
- 3D printed implant trabecular surface enhances osteointegration[13]
- Fenestrated structure allows through growth and accommodates bone graft[13]
- Porous surface self-harvests bone during insertion[13]

FOUNDATION.

- Immobilisation and stabilisation of the SI joint provides a foundation for long constructs that includes spinopelvic fixation.
- 30% reduction in SI joint motion by adding iFuse Bedrock to sacral-alar iliac (S2AI) screws.[19]

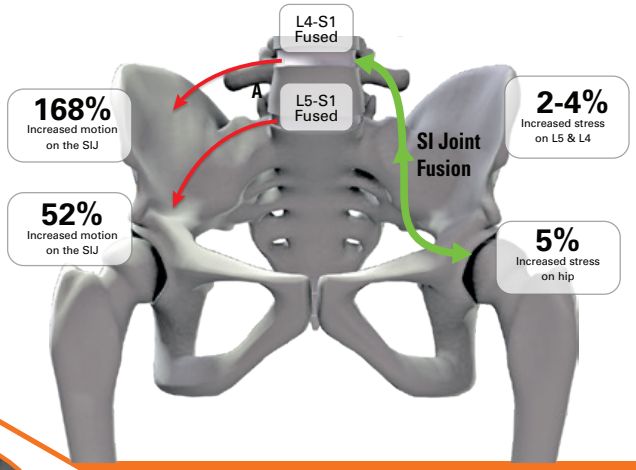
Effect of long construct fusion on the SI Joint[19]
Barrows Neurological Institute





FEA showed that fusing L5-S1 and L4-S1 increased the motion (stress) of the SI joint by 54% and 168% respectively.[20]

Conversely, there is little increase in motion of the lumbar spine (2-4%)[21] and little increase in hip stess (5%) after fusing the SI joint.[22]



30% reduction in SI joint motion
by adding iFuse Bedrock to Sacral alar iliac (S2AI Screw)[19]

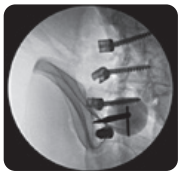
50% reduction of S2AI bending moments
by adding iFuse Bedrock to Sacral alar iliac (S2AI Screw)[19]

More levels fused, increased incidence of SI joint pain

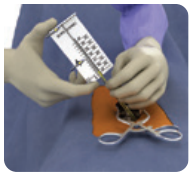
Unoki 2016[23] showed in a study of 262 patients that the more levels are fused, the greater the incidence of SI pain. In his paper, he proved that 1 level fusion led to 6%, 2 levels fusion to 10%, 3 levels fusion to 20% and >4 levels fusion to 23% of SI joint pain post lumbar fusion.

iFuse Bedrock® Surgical Technique

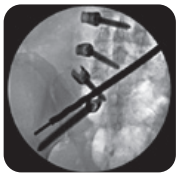
Pin



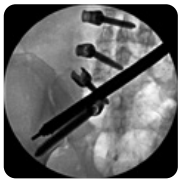
Measure



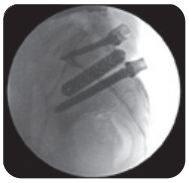
Drill (optional)



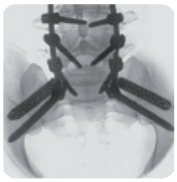
Broach



Implant



Repeat



FIX.

- Triangular implant geometry provides immediate SI joint stabilisation
- Unique design provides press fit fixation between the implant and adjacent osseous walls
- 31x greater rotational resistance vs. 7,3mm screw[24]

FUSE.

- 3D printed trabecular surface facilitates osteointegration[13]
- Fenestrated structure allows for bone through growth and accommodates bone graft[13]
- Porous surface self-harvests bone during insertion[13]

FORTIFY.

- Rigid titanium construction provides an implant that is 18x stronger than worst-case physiologic load, thus fortifying the SI joint[25]

CLINICAL NEED

Acute fractures and post-acute SI joint dysfunction

- Patient outcomes after traumatic disruption of the SI joint are directly correlated to the quality of SI reduction[27-29]
- Up to 85% of SI trauma patients develop SI joint pain and poor function due to post-traumatic arthritis or malreduction[30-38]

Non-traumatic fractures

Complications with non-surgical management:

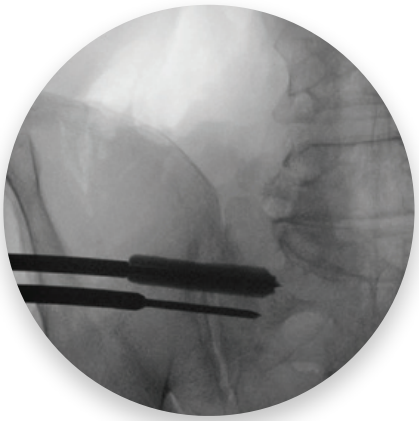
- 14-45 day average hospital stay[39-41]
- 29-61% risk of thromboembolic disorder[42, 43]
- 14-27% mortality rate at 1 year[39, 41]

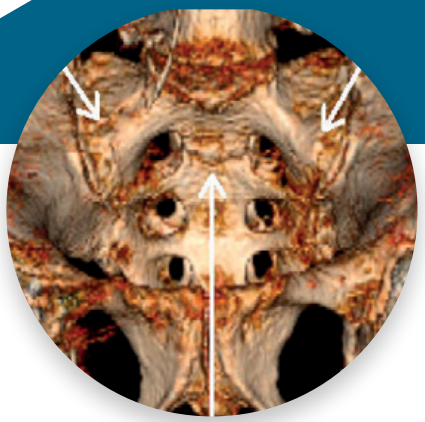
Complications with surgical management:

- 20% risk of iliosacral screw backout[44]
- 32% risk of extravasation in sacroplasty procedures[45]

LOW ENERGY FRACTURES

- Break of weakened bone
- Without identifiable trauma/ following a minor injury

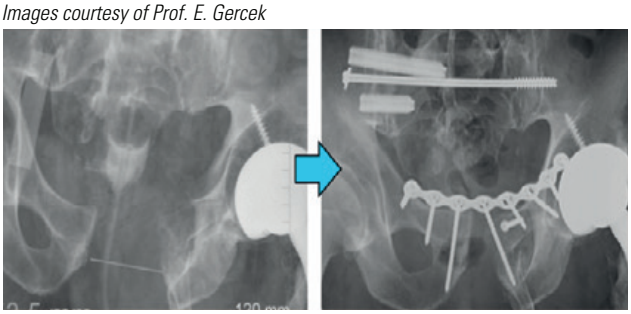




HIGH ENERGY FRACTURES

- Traumatic fractures
- Caused by a recent direct blow or impact

Images courtesy of Prof. E. Gercek



Motorcycle vs. Van

Pelvic Fixation and SI Joint Fusion

iFuse Implant System® – Publications

The only clinically-proven SI joint fusion system with multiple RCTs and Prospective studies.

- Improvement in pain and function durable to 5 years[12]
- Low complication rate[10-12,15,16]
- Low revision rate[10-12,15,16]
- High patient satisfaction[10-12, 15, 16, 49-55]
- Significant improvement in patient function[10-12,15,16,51,52,56-61]
- Improvement in quality of life[10-12,15,16,51,52]

FRANCE exclusive[48]

NICE Recommended[46,47]

NICE GUIDANCE

Interventional Procedures Guidance [IPG578][46]
Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.

This technically challenging procedure should only be done by surgeons who regularly use image-guided surgery for implant placement. The surgeons should also have had specific training and expertise in minimally invasive SI joint fusion surgery for chronic SI pain.

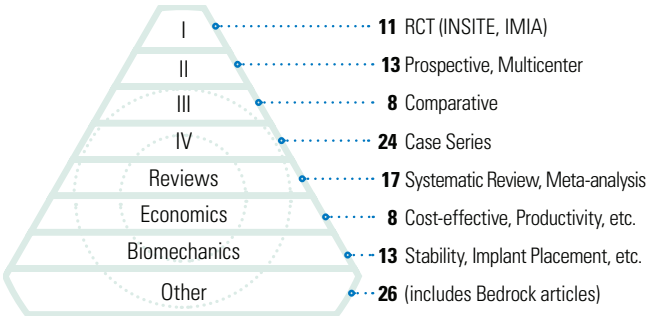
Medical Technologies Guidance [MTG39][47]
iFuse Implant System is recommended as an option for treating chronic SI joint pain.

iFuse should be considered for use in people with a confirmed diagnosis of chronic SI joint pain (based on clinical assessment and a positive response to a diagnostic injection of local anaesthetic in the SI joint) and whose pain is inadequately controlled by non-surgical management.

NOTE: This guidance was amended in 2022 to include the iFuse 3D implant, which evidence suggests may be clinically equivalent to the original iFuse implant.

SI-BONE has supported numerous clinical studies and is dedicated to training and educating healthcare professionals.

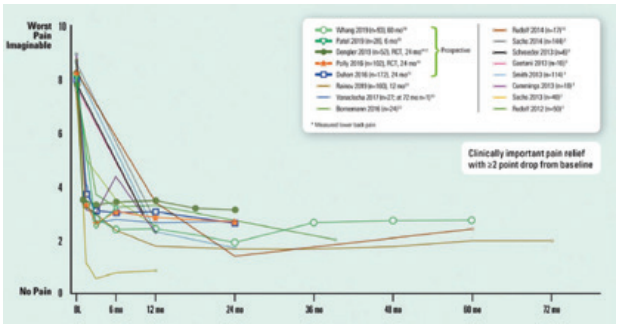
More than 100 published articles report on the safety, effectiveness, biomechanics, lasting pain relief and economic benefits of the iFuse Implant System®.



A complete and frequently updated list of all publications on the iFuse Implant System is available at *www.sibone.com/OUS/results*

Available since 2009, iFuse is the only SI joint fusion device for treatment of SI joint dysfunction supported with published results from randomised controlled trials[10,11] and the only one with multiple[15,16] and also long-term - up to 5 years[12] - prospective clinical studies that show iFuse significantly improved pain, patient function and quality of life.

High Patient Satisfaction 91% Average[10-12,15,16,49-55]

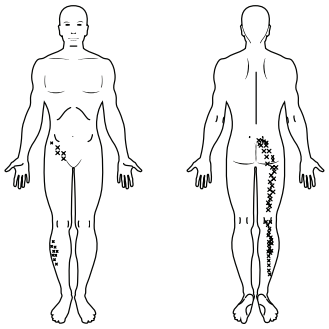


The graph above shows durable pain relief outcomes from multiple studies.[10-12,15,16,49-54,56,59-62]

Important Information
The iFuse Implant System is a class IIb medical device and intended for sacroiliac joint fusion, including use in high and low energy fractures of the pelvic ring. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. All information about risks and contra indications can be found at *https://si-bone.com/label*

Prevalence and Diagnosis of SI Joint Pain

- It is common for pain from the SI joint to mimic discogenic or radicular low back pain[63]
- The radiographic-incidence of SI joint degeneration in post-lumbar fusion surgery is 75% at 5 years post-surgery[18]
- The anti-inflammatory effect of SI joint corticosteroid injections may not be permanent and does not offer an opportunity to stabilise an incompetent SI joint[64,65]



Fortin Finger & Provocative Tests

The Fortin Finger test[66], where the patient points with one finger to their posterior superior iliac spine (PSIS) as the source of pain, and provocation tests (see below, with at least 3 out of 5 positive results)[67, 68], followed by a diagnostic injection, are recommended to confirm the SI joint as a pain generator.[69]

Fortin Finger Test

Distraction

Thigh Thrust

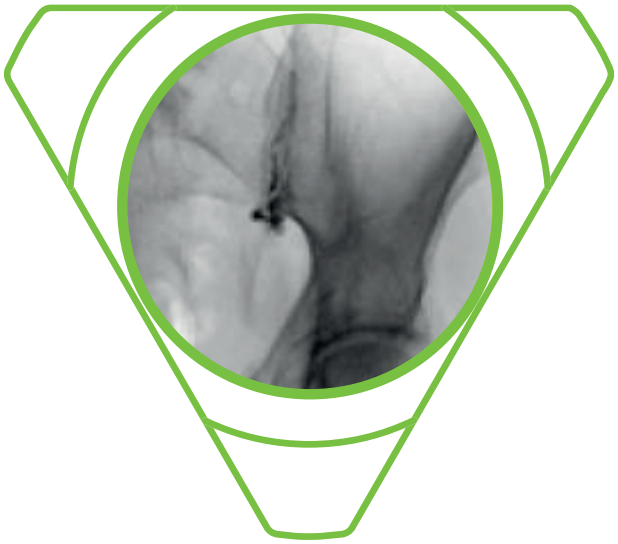
FABER

Compression

Gaenslen's

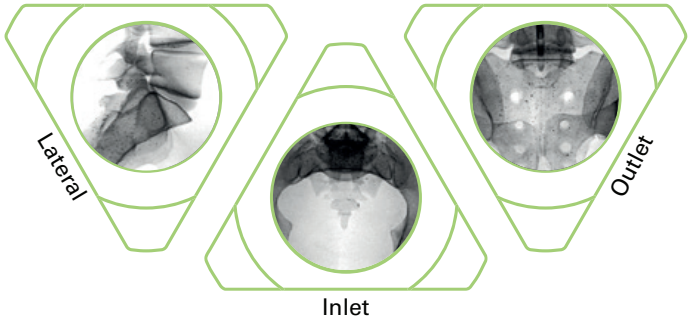
Diagnostic Injection, Fluroscopic Guided

Intra articular injection of 0,25ml contrast medium and less than 2.0 ml of local anesthetic into the inferior third of the joint under fluroscopic or CT guidance. Look for at least 50% reduction in SI Joint pain within 15-30 minutes.



iFuse Surgical Technique

For the best clinical result, correct C-Arm imaging is necessary. Landmarks in all fluroscopic views Lateral, Inlet and Outlet must be visible.



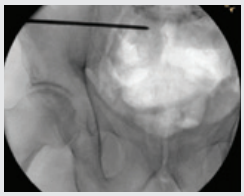
SI-BONE, Inc. has developed an innovative, patented minimally invasive surgical (MIS) implant system for sacroiliac (SI) joint fusion.

The iFuse Implant System® consists of triangular shaped titanium implants as well as associated radiolucent surgical instruments. Available implant lengths range from 35mm to 90mm in 5mm increments. The surgery is performed through a 2-3cm incision. Typically, patients receive three iFuse implants. The procedure usually takes less than 1 hour and has low complication and revision rates.

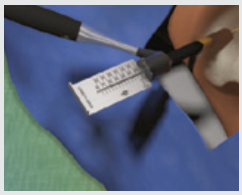
Studies have proven faster recovery compared to open procedures[57,58,62] as well as lower/less opioid use.[10-12,60]

All information about instruction for use and risks can be found at *https://si-bone.com/label*

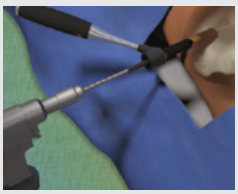
RADIOLUCENT. EFFICIENT. SIMPLE.



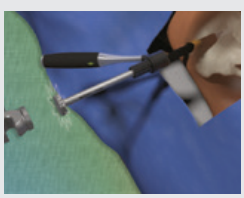
Pin insertion



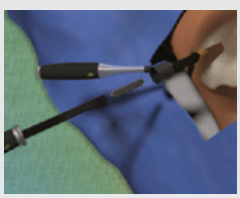
Measure depth



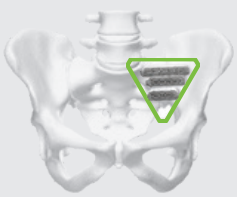
Drill



Broach



Insert implant



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Important Information
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