SI-BONE®
Sacropelvic Solutions™

iFuse INTRA SUGGESTED WEBSITE COPY

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Do you have SI Joint Pain?

The sacroiliac (SI) joint can be a significant cause of lower back pain. Clinical publications have identified the SI joint as a pain generator in 15-30% of chronic lower back pain patients.[1-4] In addition, the SI joint is a pain generator in up to 43% of patients with continued or new onset lower back pain after a lumbar fusion.[5]

Sacroiliac Joint (SI Joint) Anatomy

The sacroiliac joint (SI joint) is located in the pelvis; it links the iliac bones (pelvis) to the sacrum (lowest part of the spine above the tailbone). It is an essential component for energy transfer between the legs and the torso.

IMAGE OPTION

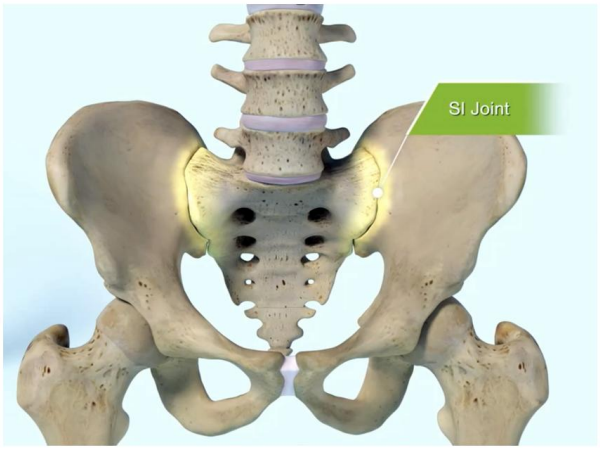

Image file name:
Sacroiliac_(SI)_joint.png

Image caption:
The SI joint is the link between the ilium in the pelvis and the sacrum, which is the lowest part of the spine above the tailbone.

Like any other joint in the body, the SI joint can be injured and/or undergo degeneration. When this happens, people can feel pain in their buttock and sometimes in their lower back, hips and legs. This is especially true while lifting, running, walking or even lying on the involved side.

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IMAGE OPTION

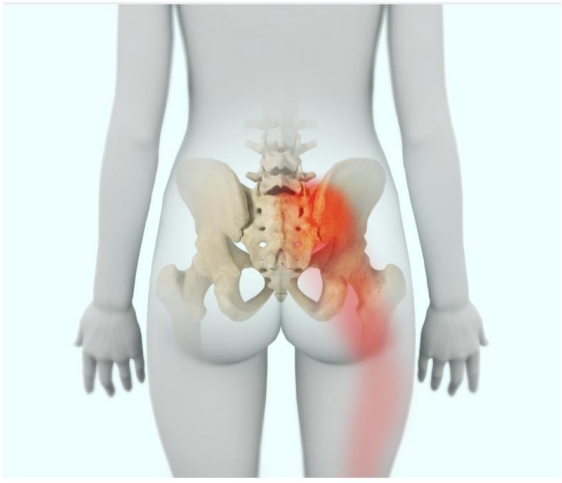

Image file name:
Pelvis_sij-pain.png

Image caption:
A dysfunctional sacroiliac (SI) joint can cause pain in the lower back, hip, groin, or pelvis.

It's common for pain from the SI joint to feel like disc or lower back pain, or sometimes hip or groin pain. For this reason, SI joint disorders should always be considered when being evaluated for lower back, hip, or pelvic pain.

Do you experience one or more of the symptoms listed below?

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

IMAGE OPTIONS

Image file name:
Stepping_up.png

Image caption:
SI joint pain can present as pain in the lower back, hip, groin, or pelvis.

Image file name:
Sit_to_stand.png

Image caption:
Patients who suffer from SI joint dysfunction can have severe pain when performing transitional movements like standing from a chair.

Image file name:
Painful_sitting.png

Image caption:
Patients who have SI joint pain usually find it difficult to sit for long periods of time, and usually try to alleviate the discomfort by sitting on the least effected side.

Making a Diagnosis
A variety of tests performed during physical examination may help reveal the SI joint as the cause of your symptoms. Sometimes, X-rays, CT-scan or MRI may be helpful in the diagnosis of SI joint-related problems because they can rule out other common sources of pain—such as your lumbar spine or hip joints. It is also important to remember that other conditions (like a disc problem) can co-exist with SI joint disorders.

The most relied upon method to accurately determine whether the SI joint is the cause of your lower back pain symptoms is to inject the SI joint with a local anesthetic. This diagnostic injection will be performed under either X-ray or CT guidance to verify accurate placement of the needle in the SI joint. If your symptoms decrease by at least 75%, it can be concluded that the SI joint is either the source of or a major contributor to your lower back, hip, or pelvic pain. If the level of pain does not change after the SI joint injection, it is less likely that the SI joint is the cause of your pain.

Treatment Options
Once the SI joint is confirmed as the cause of your symptoms, treatment can begin. Some patients respond well to physical therapy, use of oral medications, or injection therapy. These treatments are often performed repetitively, and frequently symptom improvement using these therapies is temporary. If non-surgical

treatment options have been tried and do not provide long-term relief, your doctor may consider other options, including minimally invasive treatment with iFuse implants.

iFuse INTRA™ Allograft Implant System
See note on indications statement when using iFuse INTRA-specific copy.

(Option #1 Treatment paragraph, non-physician specific copy)
iFuse INTRA™ Allograft is designed to provide SI joint stabilization and promote fusion in patients who have sacroiliac joint dysfunction. The minimally invasive iFuse INTRA allograft procedure is performed entirely through a small, two-centimeter incision in the lower back. Using a soft tissue protector, the small triangular allograft is implanted into the SI joint. The procedure typically takes less than an hour.

IMAGE OPTIONS

Image file name:
iFuse-INTRA-implant-01.png

Image caption:
The iFuse INTRA Implant is an innovative triangular bone allograft.

NEW IMAGE:

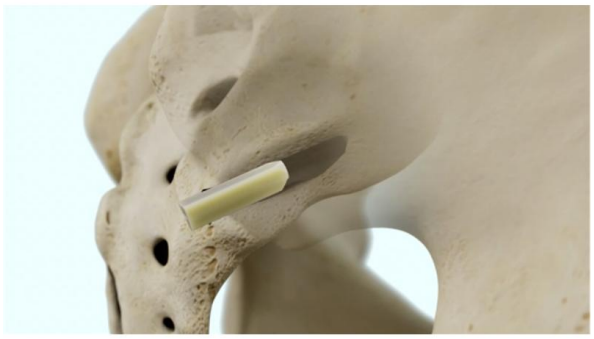

Image file name:
iFuse-INTRA-implant-into-pelvis.png

Image caption:
Through a small incision on the low back, iFuse INTRA is implanted into the SI joint to enhance sacroiliac joint stabilization and promote fusion.

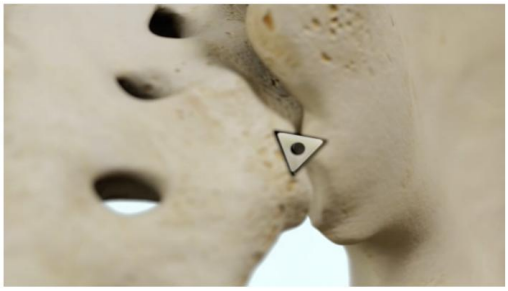

Image file name:
iFuse-INTRA-implants-in-pelvis_01.png

Image caption:
The iFuse INTRA Implant System is designed to provide sacroiliac joint stabilization and promote fusion for certain SI joint disorders.

Image file name:
iFuse-INTRA-implants-in-pelvis_02.png

Image caption:
The iFuse INTRA Implant System is designed to provide sacroiliac joint stabilization and promote fusion for certain SI joint disorders.

iFuse INTRA™ Allograft Implant System is one of the latest innovative solutions from SI-BONE, the creator of the original minimally-invasive SI joint fusion device—the triangular titanium iFuse implant. More than 130 peer-reviewed publications demonstrate the safety, durable effectiveness, and biomechanical and economic benefits of the iFuse implant (www.si-bone.com/results). The iFuse implant is the only SI joint fusion device with multiple prospective clinical studies, including two randomized controlled trials[7,8], demonstrating that treatment improved pain, patient function, and quality of life.[7-12] As with any minimally invasive surgical procedures, 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 www.si-bone.com/risks.

References

1. Bernard TN, et al. Recognizing specific characteristics of nonspecific low back pain. *Clin Orthop Relat Res*. 1987;217:266–80.
2. Schwarzer AC, et al. The Sacroiliac Joint in Chronic Low Back Pain. *Spine*. 1995;20:31–7.
3. Maigne JY, et al. 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.
4. Sembrano JN, et al. How Often is Low Back Pain Not Coming From The Back? *Spine*. 2009;34:E27–32.
5. DePalma MJ, et al. Etiology of Chronic Low Back Pain Patients Having Undergone Lumbar Fusion. *Pain Med*. 2011;12:732-9.
6. SI-BONE 300857-R.
7. Polly DW, et al., 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
8. Dengler J, et al. Randomized Trial of Sacroiliac Joint Fusion vs. Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. *J Bone Joint Surg Am*. 2019;101(5):400-11. DOI: 10.2106/JBJS.18.00022.
9. Duhon B, Bitan F, Lockstadt H, Kovalsky D, Cher D, Hillen T, on behalf of the SIFI Study Group. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. Int J Spine Surg. 2016;10:Article 13. DOI: 10.14444/3013
10. Dengler J, et al. on behalf of the INSITE, iMIA and SIFI study groups. Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating from the Sacroiliac Joint – a Pooled Analysis. *Spine*. 2017;42(21):1664-73. [Epub 2017 Mar 27]. DOI: 10.1097/BRS.0000000000002169
11. Whang PG, et al. Long-Term Prospective Clinical and Radiographic Outcomes After Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants. *Med Devices (Auckl)*. 2019;12:411-422. DOI: 10.2147/MDER.S219862

12. Patel V, et al. Prospective Trial of Sacroiliac Joint Fusion Using 3D-Printed Triangular Titanium Implants: 24-Month Follow-Up. *Med Devices (Auckl)*. 2021;14:211-216. DOI: 10.2147/MDER.S314828

(NOTE: If using the iFuse-specific information above, SI-BONE requests inclusion of the following indication and risk statement below.)

The iFuse INTRA™ Allograft Instruments are indicated for placement of the iFuse INTRA Allograft. The iFuse INTRA Allograft is indicated for homologous use. 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.

FOR TRAINED PHYSICIAN'S WEBSITES:
(Option #2 Treatment paragraph, with surgeon-specific copy)

Dr. XXXXXX is trained in current minimally invasive surgical (MIS) techniques, including use of the iFuse INTRA™ Allograft Implant System from SI-BONE®, a medical device company pioneering MIS sacroiliac (SI) joint treatment. The iFuse INTRA Allograft Implant System is designed for SI joint stabilization and intended to promote SI joint fusion to relieve pain caused by SI joint dysfunction. SI joint treatment using the iFuse INTRA Allograft implant takes less than an hour and is performed through a small incision in the lower back. The iFuse INTRA implant is inserted into the SI joint to stabilize it, with the aim of reducing or eliminating pain. As with all surgical procedure, 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 www.si-bone.com/risks.

References:

1. Polly DW, et al., 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
2. Dengler J, et al. Randomized Trial of Sacroiliac Joint Fusion vs. Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. *J Bone Joint Surg Am*. 2019;101(5):400-11. DOI: 10.2106/JBJS.18.00022.
3. Duhon B, Bitan F, Lockstadt H, Kovalsky D, Cher D, Hillen T, on behalf of the SIFI Study Group. Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicenter Trial. Int J Spine Surg. 2016;10:Article 13. DOI: 10.14444/3013
4. Dengler J, et al. on behalf of the INSITE, iMIA and SIFI study groups. Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating from the Sacroiliac Joint – a Pooled Analysis. *Spine*. 2017;42(21):1664-73. [Epub 2017 Mar 27]. DOI: 10.1097/BRS.0000000000002169
5. Whang PG, et al. Long-Term Prospective Clinical and Radiographic Outcomes After Minimally Invasive Lateral Transiliac Sacroiliac Joint Fusion Using Triangular Titanium Implants. *Med Devices (Auckl)*. 2019;12:411-422. DOI: 10.2147/MDER.S219862
6. Patel V, et al. Prospective Trial of Sacroiliac Joint Fusion Using 3D-Printed Triangular Titanium Implants: 24-Month Follow-Up. *Med Devices (Auckl)*. 2021;14:211-216. DOI: 10.2147/MDER.S314828

Indications
(NOTE: If using the iFuse-specific information above, SI-BONE requests inclusion of the following indication and risk statement below.)

SI-BONE®
Sacropelvic Solutions™

The iFuse INTRA™ Instruments are indicated for placement of the iFuse INTRA Allograft. The iFuse INTRA Allograft is indicated for homologous use.

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 www.si-bone.com/risks.

Explore whether iFuse is right for you
The first step to finding out if you're a candidate for the iFuse procedure is making an appointment with an iFuse-trained physician to discuss your options.

<Include specifics regarding the appointment and scheduling process>

For more information and to make an appointment, call <Hospital/Department/Practice Name> at <Phone Number> or email us at <email address>.

Additional available videos:
Visit SI-BONE's YouTube channel to view the latest videos https://www.youtube.com/user/thesacroiliacjoint

- iFuse INTRA Procedure Animation
  https://youtu.be/20Q-r2xw1Dk?si=8F91pcZiI0IYmspW
- SI Joint: Where is it and how does it work?
  https://youtu.be/lIPDM-z-hW8?si=0c0pTQg15QU6MR9n
- SI Joint Dysfunction: Prevalence and Causes
  https://youtu.be/EFlJVu4KW7k?si=6I5XsInruJRGrPRa

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By default YouTube videos embedded on other websites will display related or suggested videos after your video or playlist has completed. To disable this, add ?rel=0 to the end of the video URL, as shown in the example below: