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

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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*

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

Patient Surgery Guide

Information for you and your family about your surgery

You were provided this brochure because your physician believes you are a candidate for SI joint fusion with the iFuse Implant System®.

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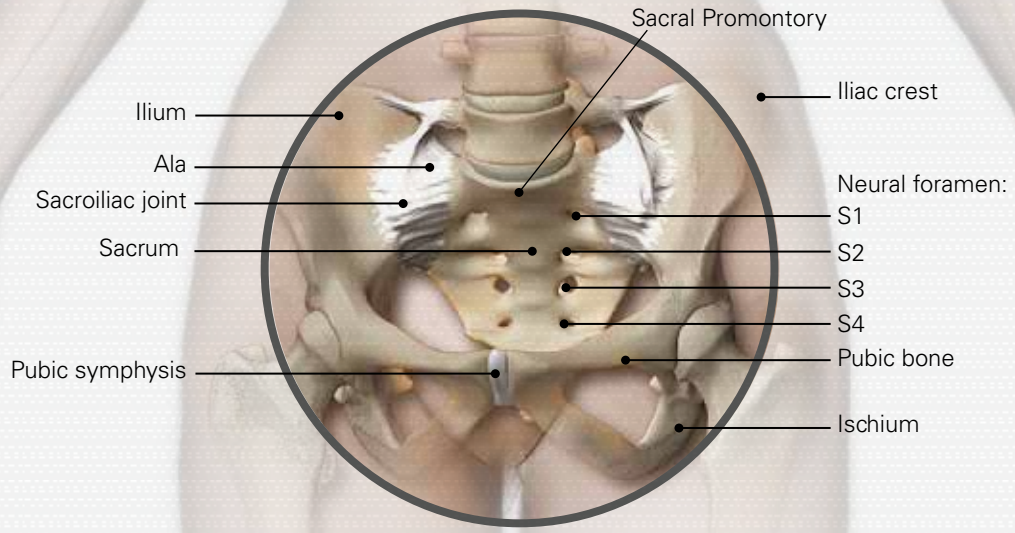
Sacroiliac Joint Anatomy



Introduction to the SI Joint

Studies show that sacroiliac (SI) joint disorders are a challenging condition affecting up to 25% of patients with lower back pain.[1]

Patient education is a critical component of healthcare today. It is important that you are informed of your diagnostic and treatment options that your doctor will recommend. You were provided this brochure because your physician believes you are a candidate for SI joint fusion with the iFuse Implant System®.

In this educational brochure, you will find information about lower back problems caused by SI joint disorders and various treatment options. We invite you to read on to learn about the diagnosis and treatment of SI joint disorders.

A HISTORY OF THE SI JOINT

SI joint disorders and associated symptoms have been well known for over a century. In fact, in the early 1900s symptoms which seemed to arise from the back were attributed to the SI joint, and many surgical treatments were directed at that joint.

In 1934, a paper was published that described the disc as a source of symptoms in the back. As a result, disc treatment became the most common surgery for lower back pain, and the SI joint was all but forgotten. Now, 70 years later, orthopedic and spine surgeons as well as pain specialists have recognized that the disc is not the only source of lower back symptoms.

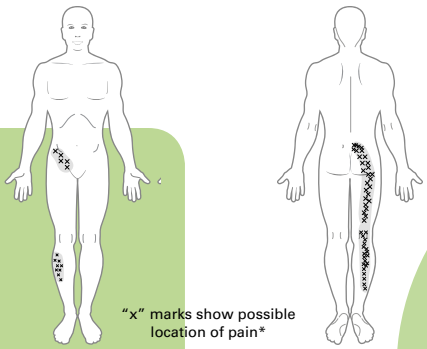
According to published scientific data, it's common for pain from the SI joint to feel like disc or lower back pain. For this reason, SI joint disorders should always be considered in lower back pain diagnosis.[2]

SI Joint Symptoms & Diagnosis

LOWER BACK PAIN AND THE SI JOINT

The SI joint is located in the pelvis; it links the iliac bones (pelvis) to the sacrum (lowest part of the spine above the tailbone). Like any other joint in the body, the sacroiliac (SI) joint can degenerate or its support ligaments can become loose or injured. When this happens, people can feel pain in their buttocks, lower back, groin and even in their legs. This is especially true with lifting, running, walking or even sleeping on the involved side. It is important to note that on occasion, patients who have not had symptomatic relief from lumbar spine surgery may actually have had other issues to begin with. Pain in the lower back and buttocks may come from the SI joint, the hip, or a combination of the two.

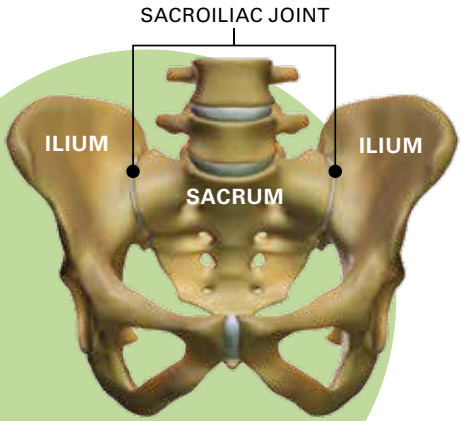
DIAGNOSIS OF THE SI JOINT AS A SOURCE OF SYMPTOMS



"x" marks show possible location of pain*

A variety of tests performed during physical examination may help determine whether the SI joint is a source of your symptoms. In addition, X-rays, CT-scans, and/or MRIs may be helpful in the diagnosis of SI joint-related problems. It is also important to remember that more than one condition (like a disc problem) can coexist with SI joint disorders.

An often relied upon method to accurately determine whether the SI joint is the cause of your lower back symptoms is to inject the SI joint with a local anesthetic. The injection will be delivered with either fluoroscopic or CT guidance to verify accurate placement of the needle in the SI joint. If your symptoms are decreased by at least 75%, it may be surmised that the SI joint is either the source, or a major contributor, to your lower back pain.[3] If your symptoms do not improve after SI joint injection, it is less likely that a problem with your SI joint is the cause of your lower back symptoms.



*Source: Frymoyer JW et al. Raven Press; The Adult Spine Principles and Practice 1991. Chapter 101, pp. 2115-16, "The Sacro Iliac Joint Syndrome"

Treatment Options

NON-SURGICAL OPTIONS

Once the SI joint is confirmed as a source of your symptoms, treatment can begin. Some patients respond to physical therapy, use of oral medications, as well as injection therapy. The anti-inflammatory effect of SI joint injections is not permanent and does not stabilize the SI joint.[4]

Intermittent use of a pelvic belt may provide symptom relief as well. Treatments such as injections or use of a belt are performed repetitively and frequently symptom improvement using these therapies is only temporary. Once non-surgical treatment options have been tried and do not provide relief, your surgeon may consider other options, including surgery.

SI JOINT FUSION WITH THE IFUSE IMPLANT SYSTEM®

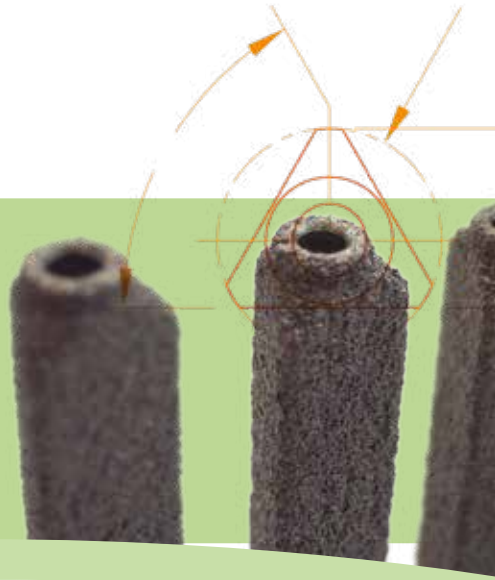
Sacroiliac joint fusion is a surgical procedure intended to stabilize the joint and eliminate motion.

The iFuse Implant System® is intended for sacroiliac joint fusion. This system uses small titanium implants placed across the sacroiliac joint to stabilize and fuse it.

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, read the "Important Safety Information" section of this guide.

IFUSE BENEFITS

- Minimally invasive surgical (MIS) approach.
- Triangular implant profile minimizes rotation and an interference fit minimizes micromotion.
- Porous titanium plasma spray (TPS) coating allows for biological fixation.
- Designed specifically to stabilize and fuse the heavily loaded SI joint.
- Rigid titanium construction and implant geometry provide immediate stabilization.
- No conflicts with lumbar fusion devices.



iFuse Implant System® Surgery

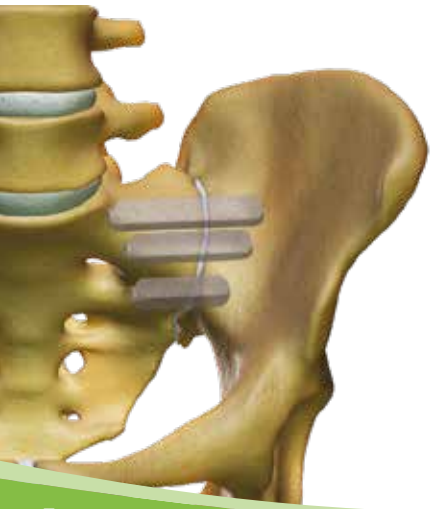
The information provided below is intended only as a guide and should not be mistaken for medical advice or treatment.

BEFORE SURGERY

You may need to obtain crutches or a walker for use after surgery. Your doctor will help you decide which type is best for you and tell you where to get them. You will be told when to stop eating and drinking before surgery. If you take a daily medication, ask if you should still take it the morning of the surgery. It is critical to inform your doctor if you are taking any blood thinning medication. At the hospital, your temperature, pulse, breathing and blood pressure will be checked. An IV (intravenous) line may be started to provide fluids and medications needed during surgery.

DURING SURGERY

SI joint fusion is performed in an operating room, with either general or spinal anesthesia. You will be lying down while your surgeon uses a specially designed system to guide the instruments that prepare the bone and insert the implants. Both the surgical technique and the iFuse Implant System are designed to offer the maximum protection to your surrounding tissues.



The entire procedure is performed through a small incision (approximately 2-3 cm long), along the side of your buttock. During the procedure, X-rays provide your surgeon with live imaging to enable proper placement of the implants. Normally, three implants are used, depending on your size The procedure typically takes less than one hour. You may feel comfortable enough to return home the same day of surgery or perhaps the morning after. Your surgeon will make this decision based on your post-surgical status.

AFTER SURGERY

At discharge, your surgeon will arrange follow-up visits to assess your progress, the status of your incision, and your health status. You may experience some post-op buttock swelling, which can be alleviated by icing the region after surgery, as directed by your surgeon. You may be partial-weight bearing for 3-6 weeks with use of crutches or a walker. Your progress will be assessed by your doctor and he/she will decide when you can return to full weight bearing. Your surgeon will make decisions about your post-surgical care based on your individual status.

Frequently Asked Questions

1. **WHAT ARE SOME CAUSES FOR PAIN IN THE LOWER BACK, BUTTOCKS OR PELVIC REGION?**
   Lower back pain is a common symptom that affects many people during their lifetime. For some, lower back pain can be an acute, short-term problem. Others experience chronic, long-term symptoms. There are many structures in the lower back and pelvic area that can cause pain. Most commonly, people think of a "slipped disc" as a cause of lower back pain. Occasionally, hip problems can be confused with lower back conditions. In fact, there are many causes of back pain, including arthritis of the back, and degeneration secondary to scoliosis. The SI joint can be a significant contributor to pain in the lower back, pelvic region, buttocks, or legs.

2. **WHERE IS MY SI JOINT?**
   The SI joint is located in the pelvis, linking the iliac bone (pelvis) to the sacrum (lowest part of the spine above the tailbone).

3. **WHAT IS SACROILIAC JOINT DYSFUNCTION?**
   Pain from sacroiliac joint dysfunction can be felt anywhere in the lower back, buttocks, or in the legs. Chronic SI joint pain or dysfunction can make it difficult to perform common daily tasks, and can affect many aspects of a patient's life.

4. **HOW DOES MY SI JOINT WORK?**
   The function of the SI joint is to transfer weight and forces due to movement from your upper body through the pelvis to your legs and vice versa. The SI joint is an essential component for shock absorption to prevent impact forces during walking from reaching the spine. The primary role of the sacroiliac joint is to provide stability for the pelvis and to bear the load of the upper body.

5. **WHY DOES THE SI JOINT START HAVING PROBLEMS?**
   Potential causes of SI joint problems include degenerative sacroiliitis or SI joint disruptions. If the motion in your pelvis is asymmetric, then problems can occur in your SI joint. You could have asymmetric motion if your legs are significantly different in length or one leg is weaker than the other. These biomechanical conditions, or even wearing inappropriate footwear, can alter your gait and cause repetitive stress to your sacroiliac joint and related structures.

6. **HOW DOES THE SI JOINT CAUSE PAIN?**
   The SI joint is a synovial joint. This type of joint has free nerve endings that can cause pain if the joint degenerates, does not move properly, or does not properly

Frequently Asked Questions

accommodate the forces that cross the joint. The SI joint has been long known to cause pain in the lower back and buttocks. Like any other joint in the body, the SI joint can become arthritic or its support ligaments can become loose or injured. When this happens, people can feel pain in their back, especially with lifting, running or even walking. In these cases, the pain is sometimes similar to the pain caused by a "disc" or spinal arthritis.

7. HOW COMMON ARE SI JOINT PROBLEMS?

It is commonly reported in clinical literature that up to 25% of lower back pain is caused by the SI joint. Risk factors associated with lower back pain may include: smoking, poor physical condition, positive family history, and occupational exposure to repetitive trauma to the SI joint.[5-7]

8. HOW IS LOWER BACK PAIN DUE TO THE SI JOINT MANIFESTED?

Many people have pain that worsens over time. However, over half the time SI joint pain can be related to a specific event, often an injury. It is difficult to directly relate any specific functional difficulty (including walking, sitting, standing, sleeping on the affected side, job activity, bowel movements, cough, sneeze, etc.) to the sacroiliac joint as a source of pain.

9. WHO IS AT RISK FOR SI JOINT PROBLEMS?

Women may be at increased risk for SI joint problems because of their broader pelvises, greater curvature of lumbar spine, and shorter limb lengths. Women also have more elastin in the collagen that makes up their ligaments. Elastin is a molecule that allows increased flexibility of ligaments. In addition, pregnancy often leads to stretching of the sacroiliac ligaments.

10. HOW WOULD I KNOW THAT MY SI JOINT IS NOT FUNCTIONING PROPERLY?

If you have trouble sleeping comfortably, or frequently experience your leg giving way, pain in certain lying or bending positions, or tenderness in your buttocks, you may have an SI joint disorder.

11. WILL MY DOCTOR CHECK FOR SI PROBLEMS?

Doctors do not always look for the SI joint as a source of lower back pain, although many articles have been written about it. Sometimes your lower back pain may have been previously diagnosed as originating from the lumbar spine. However, if your symptoms don't fit what the doctor can see on an MRI, this may indicate that your pain is coming from a place other than the lumbar spinal region. Your doctor may determine if your SI joint is the source of your pain by ruling out other sources of pain as well as running specific tests.

Frequently Asked Questions

12. WHAT MAKES THE IFUSE IMPLANTS DIFFERENT FROM OTHER FUSION DEVICES?

The iFuse implants have a unique triangular shaped design to maintain their implant position over time. The Implants allow for biologic fixation, and promote fusion of the SI joint over time.

13. WHAT ARE THE IFUSE IMPLANTS MADE OF?

The iFuse Implants are small titanium rods about the size of your little finger. Titanium is a very strong but lightweight material, commonly used for medical device implants.

14. HOW DO THE IFUSE IMPLANTS WORK?

The iFuse Implants have triangular cross-sections to keep them from rotating once they have been implanted. They are also coated with a titanium plasma spray that creates a rough surface to better secure the iFuse Implants. The Implants are strong and provide stability to the joint.

15. WHAT IS THE PROCEDURE FOR IFUSE?

The iFuse Implant System® is used in a surgical procedure that is performed in an operating room with either general or spinal anesthesia. You will be lying on a bed while your surgeon prepares the bone and inserts the implants. The surgical technique, iFuse Implant, and supporting instrumentation are designed to offer maximum protection to your tissues during the surgical procedure.

The entire procedure is performed through a small incision (approximately 2-3cm long), along the side of your buttock. During the procedure, X-ray guidance provides your surgeon with live imaging to facilitate proper placement of the implants. Typically three implants are placed, depending on your size.

16. WHAT HAPPENS AFTER MY IFUSE PROCEDURE?

Your surgeon will make decisions about your post-surgical care based on your individual status. Your doctor will most likely recommend using crutches, a cane or a walker for 3 or more weeks after surgery. Your surgeon will schedule a post-operative visit to evaluate the surgical incision and to assess your progress after surgery.

17. WHAT CAN I DO TO AVOID PROBLEMS HEALING AFTER IFUSE SURGERY?

Your doctor may provide you with post-operative instructions. In general, you should avoid strenuous activities in the first six weeks and follow your surgeon's post-operative weight bearing and activity instructions. Avoid smoking, which is

Frequently Asked Questions

thought to impair bone fusion. Discuss your current medications with your surgeon; some medications may impair bone growth (for example: steroids). If you have osteoporosis, ask your doctor what osteoporosis medications might be best for your bone health.

18. HOW SOON CAN I RESUME MY DAILY ACTIVITIES?

Your doctor will advise you on resuming your daily living activities and return to work as your healing and symptoms allow.

19. IF I HAVE ALREADY HAD ONE OR MORE SPINAL SURGERIES, DOES THIS AFFECT MY ABILITY TO HAVE MIS SACROILIAC JOINT SURGERY?

iFuse may be used in patients with prior spinal surgery(ies) and existing spinal implants. SI joint problems may coexist with lumbar spine or hip conditions. SI problems may appear after lumbar spine surgery or hip replacements. iFuse can be safely used after either lumbar or hip surgeries or both. Your doctor will determine whether your health, including any impact from previous surgeries, influences your being a candidate for MIS sacroiliac joint fusion.

20. CAN I HAVE AN MRI AFTER RECEIVING IFUSE IMPLANTS?

A patient with this device can be scanned safely, immediately after placement, with some conditions. Please ask your doctor for additional information.

21. CAN THE IFUSE IMPLANT BE REMOVED OR REVISED?

Although infrequent, there may be a reason (e.g. malpositioning, loosening, trauma, etc.) an iFuse Implant may need to be repositioned or removed. The determination to remove an implant will be based on the treating physician's best judgement.

Indications

The iFuse Implant System® is intended for sacroiliac joint fusion.

CONTRAINDICATIONS

1. Deformities or anatomic variations that prevent or interfere with iFuse placement
2. Tumor of sacral or ilial bone
3. Active infection at treatment site
4. Unstable fracture of sacrum and or ilium involving the sacroiliac joint
5. Allergy to metal components

WARNINGS

Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.

PRECAUTIONS

Patient adherence to post-operative physical activity instructions is important to support long-term service life of the implant.

RISKS

As with other surgical procedures used to treat SI joint conditions, the risks associated with the iFuse surgical procedure include, but are not limited to the following:

1. Adverse reactions to anesthesia
2. Hemorrhage (internal bleeding)
3. Muscle damage
4. Hematoma (blood pooled under the skin) or seroma (clear fluid under the skin) at the implant site
5. Neurological deficit, nerve root or peripheral nerve injury, irritation or damage (damage to nerves, permanent or temporary)
6. Vascular injury (damage to a blood vessel) or damage resulting in catastrophic or fatal bleeding
7. Neurovascular (blood vessel and nerve) injury
8. Damage to lymphatic vessels and or lymphatic fluid exudation (leakage)
9. Injury to intra-pelvic structures
10. Infection of the wound, deep infection, peritonitis (infection in the abdomen)
11. Wound dehiscence (the surgery incision opens up)
12. Pulmonary or systemic embolism (clot in lungs or blood vessel system)
13. Thrombosis, thrombophlebitis (blood clot and swelling of blood vessels)
14. Death
15. Bruising
16. Local swelling
17. Radiation exposure

Potential risks specifically associated with the iFuse Implants or Delivery System include, but are not limited to the following:

1. Infection
2. Pain, discomfort, or abnormal sensations due to presence of the implant
3. Instrument failure resulting in a complication

Indications

4. Migration (moving), loosening or fracture of the implant
5. Pain in muscle due to altered biomechanics (the positioning of your hip, leg and foot during normal daily activities)
6. Nerve root or peripheral nerve root irritation due to local swelling or altered biomechanics (changes in position of your hip, leg and foot during normal daily activities)
7. Loss of fixation / stabilization (implant becomes loose from the bones)
8. Metal sensitivity, or allergic reaction
9. Failure of device to improve symptoms and/or function
10. Increased pain at treated or adjacent levels (lumbar spine above and hips below)
11. Need for re-operation or removal of the implant(s)
12. Implant rejection
13. Response to wear debris (small metal particles that come loose from the device causing a tissue response)
14. Decrease in bone density due to stress shielding (loss of bone mass due to the implant assuming some of the normal daily load of the SI joint)
15. Failure of device to fuse your SI joint
16. Potential difficulty in delivering fetus vaginally due to device-related restriction of SI joint stretching

Notes