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

Patient Kit

Information for you and your family about your surgery

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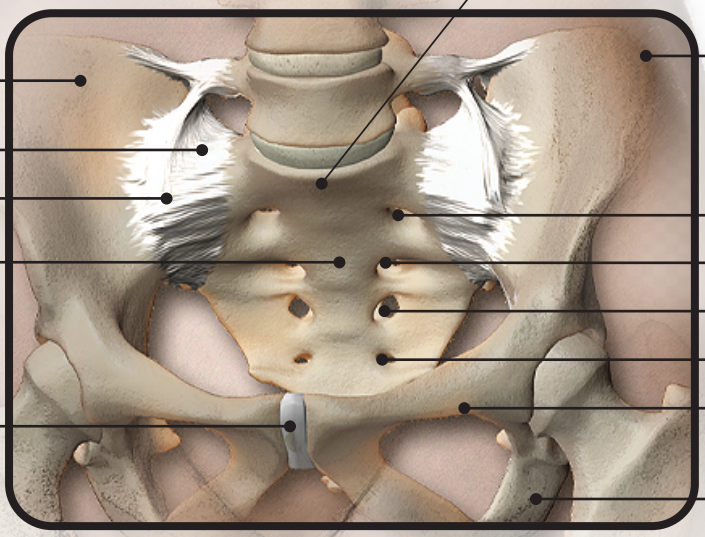
Sacroiliac Joint Anatomy



Introduction to the SI Joint

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

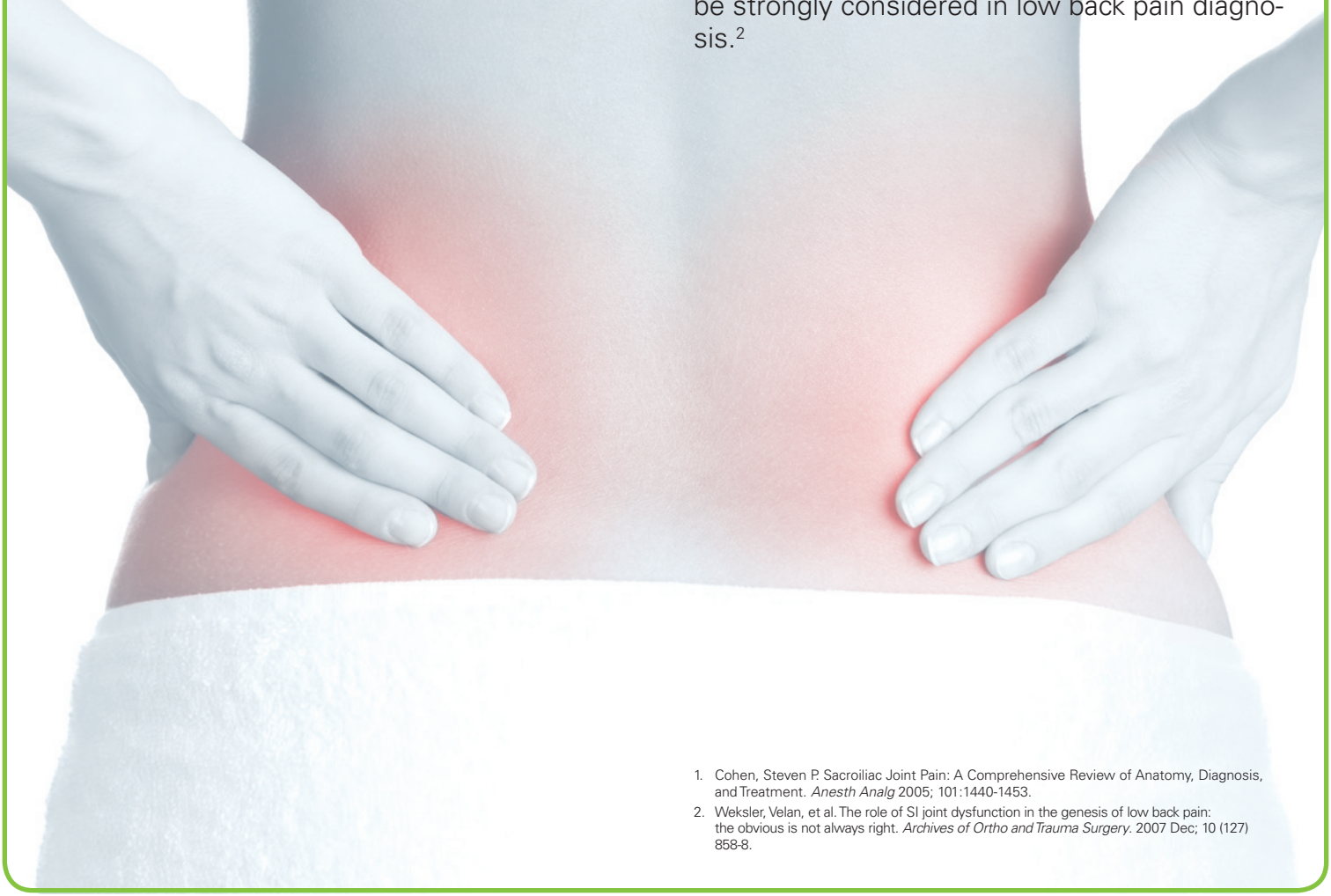
Patient education is a critical component of healthcare today. It is important that you are informed of your diagnostic and treatment options, including the type of device that your doctor will recommend. In this educational brochure, you will find information about low back problems caused by SI joint disorders and various treatment options for stabilizing the SI joint, including SI joint fusion using the iFuse Implant System®. 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 all 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 on the disc as a source of symptoms in the back. As a result, disc treatment became the most common surgery for low 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 low back symptoms.

According to published scientific data, it's common for pain from the SI joint to mimic disc or low back pain. To avoid unnecessary lumbar spine surgery, SI joint disorders should be strongly considered in low back pain diagnosis.[2]



1. Cohen, Steven P. Sacroiliac Joint Pain: A Comprehensive Review of Anatomy, Diagnosis, and Treatment. *Anesth Analg* 2005; 101:1440-1453.
2. Weksler, Velan, et al. The role of SI joint dysfunction in the genesis of low back pain: the obvious is not always right. *Archives of Ortho and Trauma Surgery*. 2007 Dec; 10 (127) 858-8.

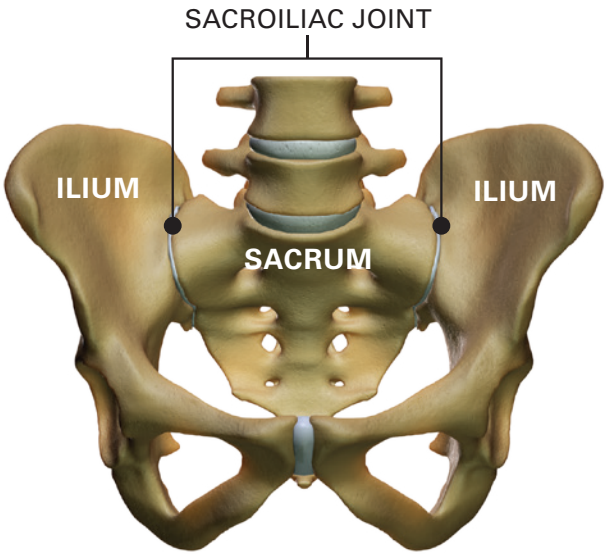
Low Back Pain and the SI Joint

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 SI joint can be injured and/or become degenerative.

When this happens, people can feel pain in their buttock and sometimes higher on the skeleton (bones forming the central axis of the body: the skull, the vertebral column, the ribs and the sternum). 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. This could include the SI joint, the hip, the spine, or any combination of these three pain generators.



Diagnosis of the SI Joint as a Source of Symptoms

The good news is that your surgeon can now distinguish between low back symptoms arising from the lumbar portion of the spine and the SI joint. 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-scan, and/or MRI are 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 low back symptoms is to inject the SI joint with painkillers. Your surgeon will deliver the injection 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 low 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 low back symptoms.

3. Katz, Victor, Jerome Schofferman, and James Reynolds. "The Sacroiliac Joint: a Potential Cause of Pain After Lumbar Fusion to the Sacrum." *Journal of Spinal Disorders & Techniques* 16, no. 1 (February 2003): 96–99

Treatment Options

Conservative Therapy

Once the SI joint is confirmed as a source of your symptoms, treatment can begin. Some patients respond to physical therapy, chiropractic manipulations, 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. These treatments 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

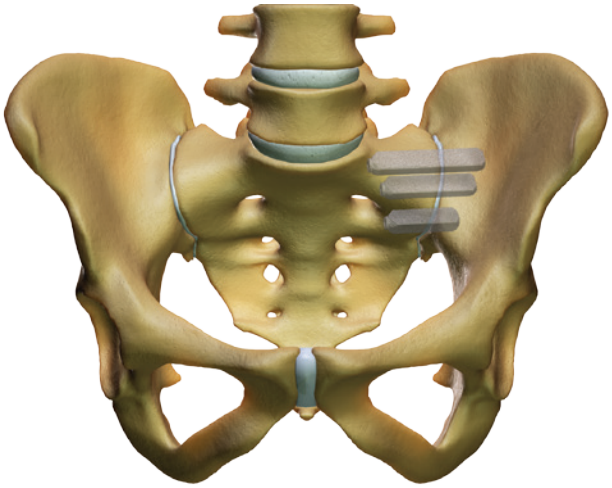
Sacroiliac joint fusion is a surgical procedure intended to stabilize the joint and eliminate motion.

The iFuse Implant System is intended for use in patients with certain SI joint disorders including sacroiliac joint disruptions and degenerative sacroiliitis. This system uses small titanium implants placed across the sacroiliac joint to stabilize and fuse it.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Implant. You should discuss these risks and considerations with your physician before deciding if this treatment option is right for you.

iFuse Benefits

- Minimally invasive surgical (MIS) approach
- Triangular implant profile minimizes rotation and an interference fit minimizes micromotion
- Porous plasma titanium spray coating
- Designed specifically to stabilize and fuse the heavily loaded SI joint
- Rigid titanium constructs and large implant surface area provide stability
- No conflicts with lumbar fusion devices



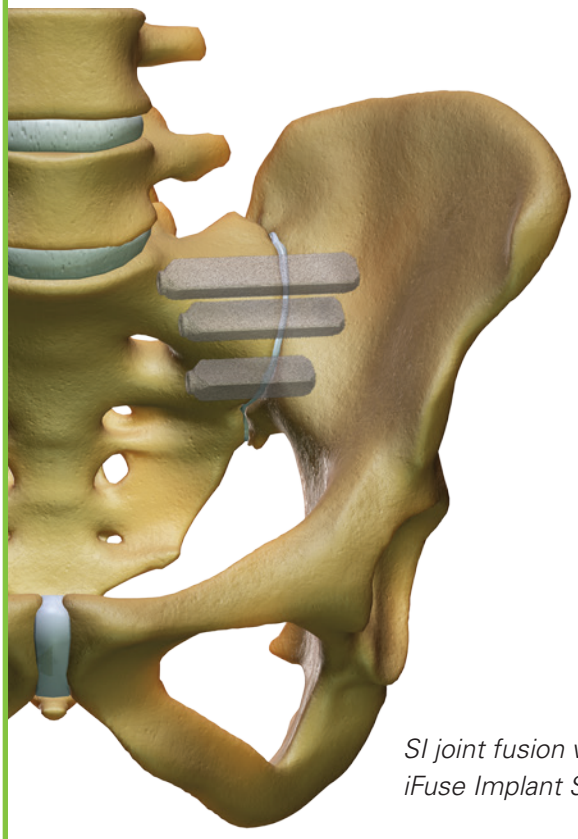
4. Zelle, Boris, et al. Sacroiliac Joint Dysfunction, Evaluation and Management. *Clinical Journal of Pain*, 2005 Sept/Oct 21(5): 446-455

Your Surgery

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

Before Surgery

You will 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. Depending on your surgeon's protocol, you may also receive an enema to clear out your bowels in preparation for surgery. An IV (intravenous) line may be started to provide fluids and medications needed during surgery.



SI joint fusion with the iFuse Implant System

During Surgery

SI joint fusion is performed in an operating room, with either general or spinal anesthesia. You will be lying face 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 will be partial-weight bearing for 3-6 weeks with use of crutches or a walker. At approximately 6 weeks, your progress will be assessed by your doctor and he/she will decide when you can return to full weight bearing. Your doctor will monitor the status of the SI joint fusion by taking additional images of your pelvis, likely at 3, 6 and 12 months after surgery.

1. What are some causes for pain in the lower back, buttocks or pelvic region?

Low back pain is a common symptom that affects many people during their lifetime. For some, low 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 low back pain. The word "sciatica" may be used when describing low back pain. Occasionally, hip problems can be confused with low back conditions. In fact, there are many causes of back pain, including arthritis of the back, osteoporosis, and a poorly aligned spine. 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. 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.

4. Why does the SI joint start having problems?

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. This can be congenital or caused due to an injury or illness such as polio or scoliosis. Other conditions that can predispose you to SI joint problems include having one leg that is weaker, such as seen with hip osteoarthritis. These biomechanical conditions, or even wearing inappropriate footwear, can alter your gait and cause repetitive stress to your sacroiliac joint and related structures. Other potential causes of SI joint problems include joint disruptions, degenerative sacroiliitis, history of trauma, pregnancy/childbirth, and other unknown reasons. Injury from accidents is another predisposing factor for SI joint pain.

5. 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 chronic pain if the joint degenerates or does not move properly. 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.

6. How common are SI joint problems?

It is commonly reported in clinical literature that up to 25% of all low 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 lifting.[5,6,7]

7. How is low 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 functioning 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.

8. Who is at risk for SI joint problems?

Women may be at increased risk for SI joint problems because of their broader pelvises, the greater curve of their necks, and shorter limb lengths. In addition, pregnancy often leads to stretching of the pelvis, specifically in the sacroiliac ligaments.

9. 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.

10. 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.

11. What should I tell my doctor about my back or buttock pain?

The most important information you can give your doctor is the exact location of your pain. Try to notice when the pain occurs and how intensely you feel it in various locations, including your low back, buttocks, and legs. Also, be sure to tell your doctor about any previous injury that may have either directly affected your pelvis, or caused you to walk asymmetrically.

5. Maigne, JY, et al. Sacroiliac joint pain after lumbar fusion: A study with anesthetic blocks, Eur. *Spine J* (2005) 14: 654-658.
6. Sembrano, JN et al. How often is Low Back Pain Not Coming from the back? *Spine*. 2009; 34 (1): E27-E32.
7. Cohen, SP, Sacroiliac Joint Pain: A Comprehensive Review of Anatomy, Dx, and Rx. *Anesth Analg*; 2005; 101:1440-53.

12. How will my doctor determine whether I have SI joint problems?

Your doctor will consider all the information you provide, including any history of injury, location of your pain, and problems standing or sleeping. Your doctor will also give you a physical examination. You may be asked to stand or move in different positions and point to where you feel pain. Your doctor may manipulate your joints or feel for tenderness over your SI joint.

In addition, X-rays, a CT scan, or MRI may be helpful in diagnosis of SI joint disorders. It is also important to remember that more than one condition (like a disc or hip problem) can coexist with SI joint problems and your doctor will need to check for other factors that may be causing your pain.

The most widely used method to determine the cause of SI joint pain is to inject the SI joint with a painkiller. Your doctor will deliver the injection with either fluoroscopic guidance or CT guidance to ensure that the needle is accurately placed in the SI joint. If, following the injection, your pain is decreased by more than 75%, then it can be concluded that the SI joint is either the source or a major contributor to your low back pain. If the level of pain does not change after the injection, it is unlikely that the SI joint is the cause of your low back pain.

13. How easy is it to diagnose SI joint problems?

It is not always easy to diagnose SI joint disorders, but provocative tests and injections are helpful for confirming the SI joint as the pain source. Sometimes your physical findings may indicate a SI joint condition, but chronic changes may also be seen in your lumbar spine. Your doctor may discuss the difficulty of making a correct diagnosis in the presence of multiple problems.

14. What are some options for treatment of SI problems?

There are several options for treating SI joint problems. Some people respond to physical therapy, chiropractic manipulations, and exercises. Others require more interventional treatments including various oral medications, or therapeutic injections. These treatments are performed repetitively, and frequently symptom improvement using these therapies is temporary. Once non-surgical treatment options have been tried and do not provide relief, your surgeon may consider other options, including surgery.

Sacroiliac joint fusion, is a surgical procedure intended to stabilize the joint and eliminate motion. SI joint fusion can relieve pain in many cases.[8]

8. Buchowski, et al. Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint. *The Spine Journal*: Official Journal of the North American Spine Society 5, no. 5 (October 2005): 520-528; discussion 529

15. How will my doctor determine whether I am a candidate for the iFuse Implant System?

Once the source of your low back pain has been diagnosed as SI joint in origin, your surgeon will discuss the iFuse Implant System procedure as a potential treatment option. You may be an iFuse surgical candidate if your low back symptoms are predominantly below your L5 vertebra, your doctor does not find any neurological problems, and is able to determine through maneuvering your joint that your pain originates in the SI joint. To confirm your diagnosis, your doctor may administer a CT guided injection of pain reducing medication to your SI joint and verify that you experience significant pain relief from it. Some doctors may repeat the injection to be sure.

16. What are 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.

17. 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 to bone. The stiffness of the implants holds the joint in place.

18. 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 face down while your surgeon uses the specially designed system to guide the instruments that prepare the bone and insert 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.

19. What happens after my iFuse procedure?

Your doctor will provide recommendations. These may include post-operatively using crutches, a cane or a walker for 3 to 6 weeks, depending upon what your doctor recommends. You should not travel by air for a minimum of 2 weeks after an iFuse surgery. This limitation on air travel is strictly a precaution, and has to do with decreasing what is already a low risk of clots forming in the veins of your legs.

At discharge, your doctor may arrange follow-up visits to assess the incision and take follow-up X-rays. It is recommended that you see your surgeon for a post-operative visit between 1 and 2 weeks following surgery. However each surgeon may have specific recommendations as patient situations may vary.

Based upon your doctor's recommendation, you will need to come back at or around 12 weeks for more X-rays and, barring any complications and your doctor's ok, you may resume full weight-bearing activities.

20. What can I do to avoid problems healing after iFuse surgery?

Your doctor will 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 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.[9,10]

21. How soon can I resume my normal daily activities?

Your doctor will advise you on resuming your daily living activities as your healing and symptoms allow. Depending on your occupation, you may be able to return to work at this time. You will need to have additional X-rays taken at 6 months and later at 1 year to assess your progress.

22. If I have an iFuse procedure, does it affect my ability to have other surgeries if I need them?

In some cases, a person may require other surgeries after having an iFuse procedure. The iFuse implants are not anticipated to affect the ability to have other surgeries.

23. If I have already had one or more spinal surgeries, does this affect my ability to have an MIS SI joint surgery?

The iFuse may be used in patients with previous orthopedic surgeries and spinal implants. SI joint problems may coexist with lumbar spine or hip conditions. SI joint problems may appear after lumbar spine surgery or hip replacements. The iFuse can be safely used after either lumber 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.

24. Could there be complications from the iFuse procedure?

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of the iFuse Implant. You should discuss these risks and considerations with your physician before deciding if this treatment option is right for you.

9. Fusion versus nonoperative management for chronic low back pain: do comorbid diseases or general health factors affect outcome? *http://www.ncbi.nlm.nih.gov/pubmed/21897346*

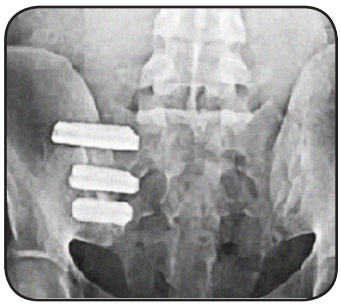
10. Dose-dependent inhibition of diclofenac sodium on posterior lumbar interbody fusion rates. *http://www.ncbi.nlm.nih.gov/pubmed/18790686*

Who is Eligible to Have SI Joint Fusion?

The following patients have graciously given permission to present their personal experiences regarding SI joint problems and subsequent surgery using the iFuse Implant System.

Case 1: SI joint pain limited my life.

This 36-year old experienced chronic low back



symptoms for 13 years after childbirth due to sacroiliac joint laxity. For many women after parturition, the sacroiliac joints normally revert to a tightened and locked position. But for 1-in-5 women, full tightening does not occur and these women develop varying intensities of chronic low back pain.[11]

As her symptoms increased, simple house work became challenging and her performance as an X-ray tech diminished.

After trying multiple therapies to relieve her symptoms, her surgeon recommended the iFuse Implant System. This minimally invasive procedure is designed to provide stabilization and fusion to the SI joint.

There was an equivalent reduction in symptoms eight weeks post-op compared to the two weeks following injection. The patient returned to full-time work at twelve weeks post-op. At 12 months there have been no recurrence of symptoms following surgery.

Case 2: *I suffered with back pain for 30 years before I got help.*

"I went to my doctor with persistent low back problems several years after undergoing hip replacement surgery. I was spending many hours in physical therapy without experiencing any relief."

"Due to the severity of the symptoms, my physician recommended sacroiliac (SI) joint fusion after he diagnosed it using CT guided injection, which provided temporary relief. Within three months following the surgery, I experienced significant relief and was able to resume my normal daily activities. In the subsequent months, I continued to improve, and at one year, the iFuse has returned me to a normal lifestyle."

Case 3: *I had been suffering from low-back pain for years.*

"It was absolutely depressing because if you hurt all the time, it's a cycle. You hurt; you sit; you don't do things; you don't get out. I was limited in my ability to stand for periods. I was limited in my ability to walk. I was limited in my ability to lift. It was difficult to do my job. It was difficult to play with my grandchildren. Stair climbing was almost impossible."

"I met with my doctor following my injection, which showed that the source of my pain was the SI joint, he explained the procedure, which would be an implanting of these implants in my SI joint. The procedure went very well. I was up and out of bed that same day, into physical therapy. I have no awareness of having the implants in my back at all. I gardened all summer, and it was no problem for me."

11. Badgley, L. Disordered Sacroiliac Joint. *Practical Pain Management*. 2009 Sept: 9(7)

For more information
please visit:
www.si-bone.com

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

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