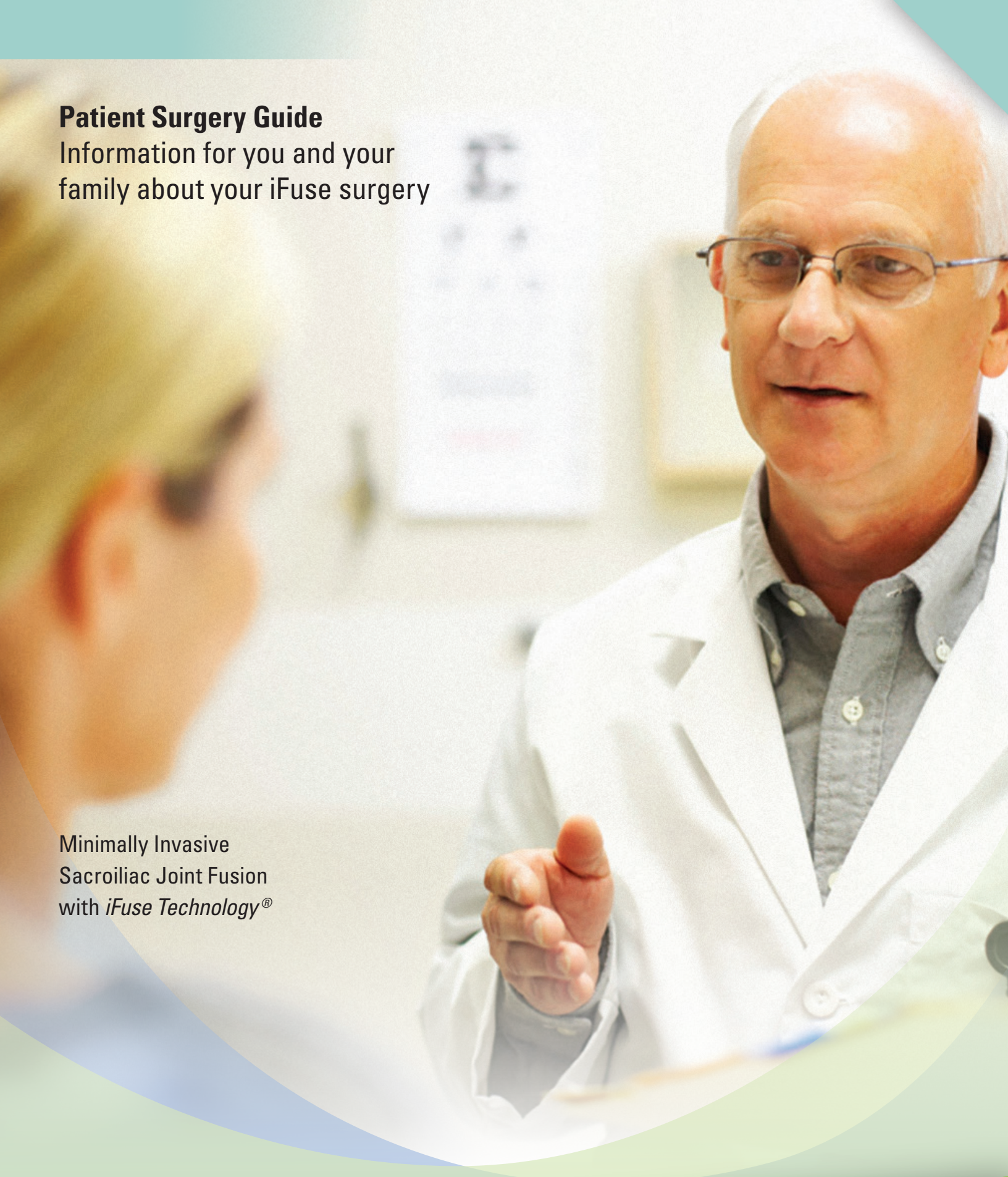
Patient Surgery Guide

Information for you and your family about your iFuse surgery



Minimally Invasive Sacroiliac Joint Fusion with *iFuse Technology®*

SI-BONE®

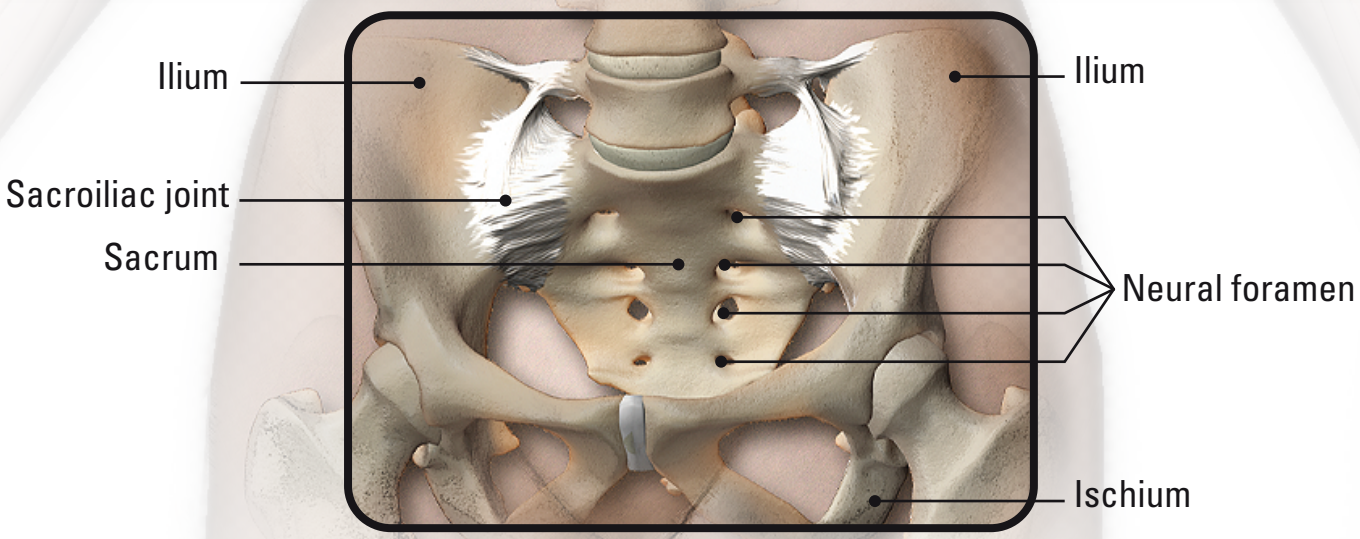
Lower Back Pain and SI Joint Dysfunction

The **sacroiliac (SI) joint** is located in the pelvis; it links the iliac bones (pelvis) to the sacrum (lowest part of the spine above the tailbone).

The SI joint is the largest joint in the body and like other joints it can degenerate, or its supporting ligaments may be injured, causing **SI joint dysfunction.** When this happens, people can feel pain in their buttocks, lower back, groin and even their legs. This is especially true with lifting, running, walking, or lying 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, the spine or any combination of these three interrelated potential pain generators.

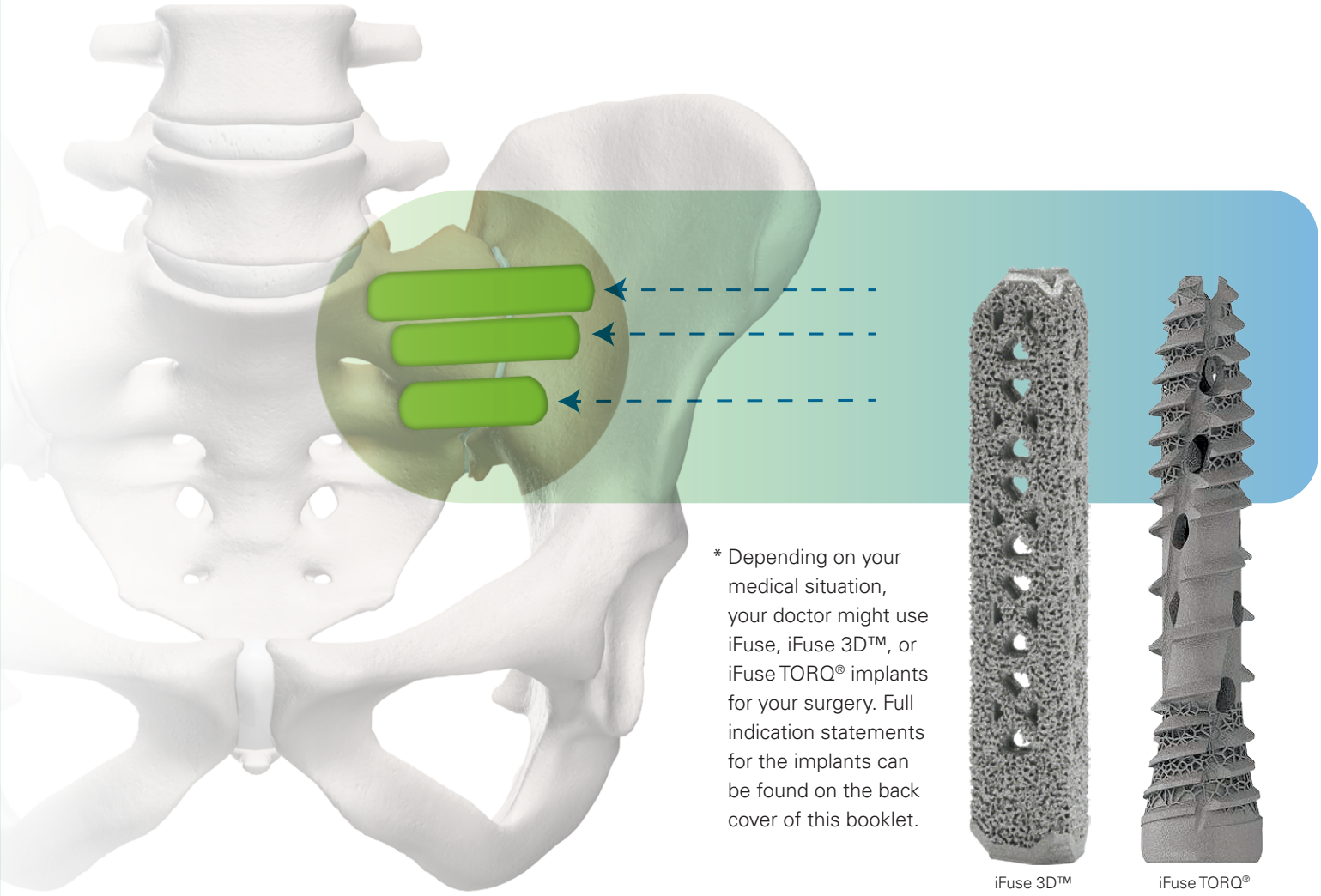
Getting the correct diagnosis is a very important step in your treatment path. Appropriate diagnosis of lower back pain should include assessment of the SI joint. Accurate diagnosis includes a complete patient history, physical exam of the lumbar spine-SI joint-hip complex, and a series of SI joint provocative tests. Positive pain response to these tests, confirmed by pain relief from diagnostic injections of local anesthetic into the joint, provides strong evidence the SI joint is causing some pain.



Minimally Invasive SI Joint Fusion with iFuse Technology®

Procedures using iFuse implants* are minimally invasive and take about an hour. The implants are designed specifically to stabilize and fuse the heavily loaded SI joint. The rigid titanium construction provides immediate stabilization, and the porous surface is similar to cancellous bone which supports bone growth and integration.[1]

Tens of thousands of patients have been treated with iFuse procedures around the world and the highest level clinical evidence has demonstrated improvement in pain, patient function, and quality of life.[2,3]



* Depending on your medical situation, your doctor might use iFuse, iFuse 3D™, or iFuse TORQ® implants for your surgery. Full indication statements for the implants can be found on the back cover of this booklet.

iFuse 3D™ iFuse TORQ®

This document does not contain medical advice. If you have any questions about the information in this educational brochure, talk to your doctor.

1. MacBarb RF, Lindsey DP, Woods SA, Lalor PA, Gundanna MI, Yerby SA. Fortifying the Bone-implant Interface Part 2: An In Vivo Evaluation of 3D-Printed and TPS-Coated Triangular Implants. *Int J Spine Surg.* 2017;11(3):16. DOI: 10.14444/4016.
2. 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: 42T10.14444/3028
3. 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.

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 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. Typically, you will be positioned lying face down.

Your doctor will use 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 protect the surrounding tissues.

The entire procedure is performed through a small incision (approximately 3 cm long) along the side of your buttock. During the procedure, fluoroscopy provides your doctor with live imaging to enable proper placement of the implants. Typically, three implants are used, but the type, number, and length of implants may vary depending on your size and anatomy.

The procedure takes approximately one hour. You may feel comfortable enough to return home the same day of surgery or perhaps the morning after. Your doctor will make this decision based on your medical history and post-surgical status.

After Surgery

At discharge, your doctor will arrange follow-up visits to assess your incision, and how you are progressing. Your doctor will make decisions about your post-surgical care based on your medical health.

You may experience some post-operative buttock swelling, which can be helped by icing the region after surgery, as directed by your doctor. You may be advised to temporarily bear only partial weight using crutches or a walker. Your progress will be assessed by your healthcare providers, and they will decide when you can return to full weight bearing and will provide you with post-operative guidelines.

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 sacroiliac (SI) joint can also 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 posterior pelvis, linking the iliac bones (pelvis) to the sacrum (lowest part of the spine above the tailbone).

3. What is SI joint dysfunction?

SI joint dysfunction is a term used to describe the pain and the physical impairment associated with a disrupted/degenerated SI joint. Pain from SI 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 body weight and forces 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 activity from reaching the spine.

The primary role of the SI joint is to provide stability for the pelvis and to bear the load of the upper body.

5. Why does the SI joint hurt?

As with other joints in the body, the SI joint can become damaged, can suffer from wear and tear, or the ligaments supporting the joint may be stretched or injured. This may result in altered function of the SI joint (SI joint dysfunction) which may result in pain in the buttocks, lower back, groin and even legs. SI joint dysfunction and associated pain can be caused by a specific traumatic event (disruption) or can develop over time (degeneration). Common traumatic events include a motor vehicle accident, fall on buttock, lifting and/or twisting, and natural childbirth. SI joint degeneration may be due to previous lumbar surgery, stresses to the joint due to leg length differences or scoliosis, pregnancy (chronic lower back pain during pregnancy or after giving birth, post-partum pelvic girdle pain), osteoarthritis, previous iliac crest bone graft (ICBG), and prior infection of the SI joint.

6. How does the SI joint cause pain?

The SI joint is a synovial joint. This type of joint is supplied by nerves that transmit pain signals if the joint degenerates, does not move properly, or does not properly 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 supporting ligaments may be injured. When this happens, people can feel pain in their back, especially when sitting, 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 will my doctor determine whether I am a candidate for the iFuse procedure?

If you have been diagnosed with SI joint dysfunction and have failed appropriate non-surgical treatment, your doctor may determine that you are a candidate for minimally invasive SI joint fusion using the iFuse Implant System.

Frequently Asked Questions

To confirm your diagnosis, your doctor may administer a fluoroscopic or CT-guided injection of local anesthetic to your SI joint and verify that you experience significant pain relief from it. Some doctors repeat the injection to be sure.

8. 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.

9. What are some of the risks associated with the iFuse procedure?

As with all surgeries, the risks associated with the iFuse procedure include, but are not limited to:

- Adverse reactions to anesthesia;
- Hemorrhaging or bleeding which is difficult to control and may become dangerous;
- Muscle and/or nerve damage;
- Localized bruising or swelling;
- Dangerous blood clots;
- Wound site infections, wound re-opening and damage to the tissues surrounding the surgical site;
- Excessive radiation exposure;
- Lung damage; and
- Death.

Potential risks specific to the iFuse implant include, but are not limited to:

- Local injury to the pelvis;
- Increased pain in the SI joint or surrounding tissues and joints;
- Allergic reaction to or rejection of the implants;
- Migration, loosening, breakage or failure of the implant;
- Muscle pain due to the change in function of the SI joint;
- Stress to and fracture of the bones in the pelvis surrounding the implants; and
- Need for additional surgery to remove or adjust the positioning of one or more implants.

10. What can I do to help healing after my 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 doctor's post-operative weight bearing and activity instructions. Avoid smoking, which is thought to impair bone fusion.

Discuss your current medications with your doctor; 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.

11. 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.

12. If I have already had one or more spinal surgeries, does this affect my ability to have minimally invasive SI joint fusion?

iFuse implants are not anticipated to affect the ability to have other surgeries of the spine, hip, or pelvis. Your doctor will determine whether your health, including any impact from previous surgeries, influences you being a candidate for minimally invasive SI joint fusion.

13. Can the iFuse implants 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 doctor's best judgment.

FIND MORE FAQs ONLINE

Patient Stories (results vary)

"Two and a half months later, I was out hiking, back to being me, back to being fun"

Andel

"To get the relief I have is beyond my wildest dreams, and I'm so glad that we did it"

Suzanne

"If I had to do it over again, I wouldn't hesitate"

Bill

"I basically have my life back"

Lacey

iFuse Implant System® *The Method of Choice for SI Joint Fusion®*

READ OTHER PATIENT SUCCESS STORIES ONLINE

The **iFuse Implant System®** (iFuse or iFuse 3D™) is intended for sacroiliac fusion for the following conditions:

- 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.
- To augment stabilization and immobilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

If present, a pelvic fracture should be stabilized prior to the use of iFuse implants.

The **iFuse TORQ® Implant System** is indicated for:

- Fusion of the sacroiliac joint for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute, and non-traumatic fractures.

The iFuse TORQ Navigation instruments are intended to be used with the iFuse TORQ Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse TORQ Navigation instruments are intended to be used with the Medtronic® StealthStation® System.

There are potential risks associated with iFuse procedures. 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

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