

**SI JOINT
FIXATION**

Sacroiliac
Joint Fixation

LifeSpine®

IT'S TIME TO GET **YOUR LIFE BACK.**

SI Joint Dysfunction relief is possible with
Life Spine's SImpact SI Joint Fixation System.



PATIENT INFORMATION

It is important that you understand the diagnostic and treatment options that your doctor will recommend. In this brochure you will find information pertaining to SI Joint Dysfunction and various treatment options. This brochure will help you understand more about:

- Anatomical features and conditions of the spine
- SI Joint Fixation surgical approach
- What to expect before and after surgery

Receiving medical treatment is individualized to the patient's anatomy and symptoms. Information in this booklet may not apply to your condition, treatment, or outcome as surgical technique vary with surgeon preference. It is important to discuss all options before you and your physician decid which treatment option is right for you.

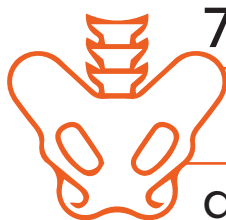
This booklet is not intended as a replacement for professional medical care and is meant only as an educational resource. Please consult your physician for clinical results and all other important medical information that pertains to this procedure.



Lower back pain affects

90% OF ADULTS

at some point in their lives¹



75% OF FUSION PATIENTS

DEVELOP SI JOINT

degeneration after 5 years²

Low back pain can hold you back from doing the things you love. Apart from the common cold, low back pain is the most common reason for visits to the primary care doctor. Common symptoms of SI joint pain are sensations of lower extremity pain, numbness, tingling or weakness. Other symptoms are pelvis, buttocks, hip and/or groin pain, leg instability, and more.^{3,4,5}

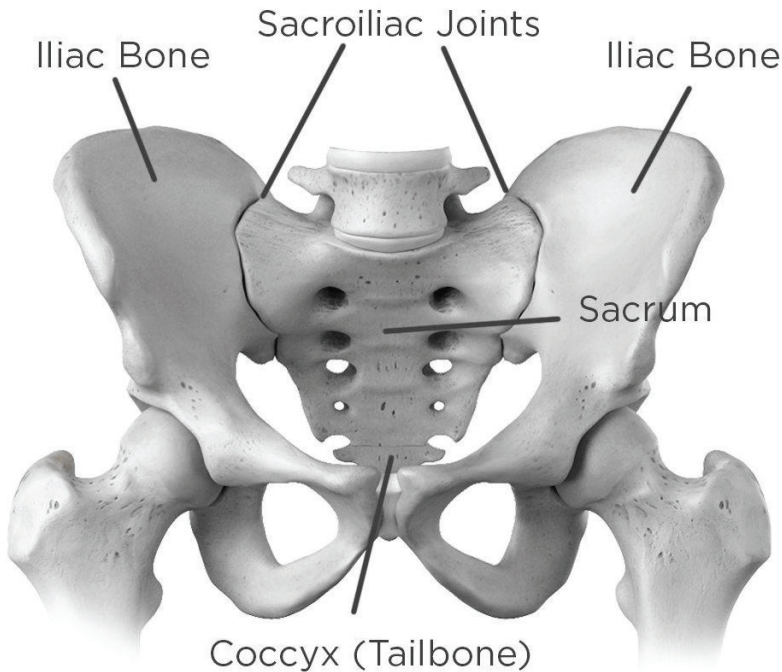
MICRO-INVASIVE PROCEDURAL SOLUTIONS

Our goal is to provide innovative surgical solutions that are designed to save time, save money, and accelerate patient recovery.

Find out how SImpact™ can help with your low back pain at www.sijointfixation.com

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SPINE AND PELVIC ANATOMY.

The sacroiliac joint (SI joint) connects the sacrum, or the lowest part of the spine, with the pelvis (iliac bone that is part of the hip joint). The SI joint provides stability and bears the load of the upper body by transferring its weight and forces through the pelvis to the legs. This joint is essentially the shock absorber of the body when activities are being performed. Typically this joint does not have much movement.

Your SI Joints

The SI Joints have numerous nerve endings and when degeneration or inflammation affect their ability to move properly it can be very painful.

WHY IS THE SI JOINT CAUSING PAIN?

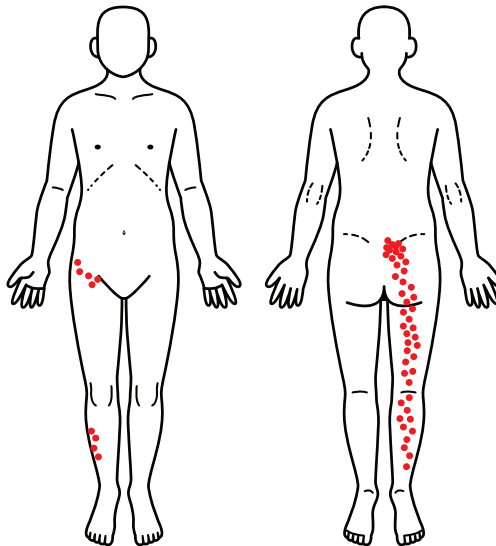
Lower Back Pain and the SI Joint

There are several reasons why the SI joint can start causing pain. As with other joints in the body, the SI joint can become degenerated, damaged, or the supporting ligaments can become injured. Other causes that contribute to SI joint pain include but are not limited to: Rheumatoid Arthritis (RA), trauma such as a motor vehicle accident or childbirth, deformity such as pelvic tilt and obliquity, limb length inequality, or instability with motion of the pelvis.

Pain originating from the SI joint can include pain in the buttocks, lower back, groin and the legs during activities such as lifting, walking, lying on the injured side, and many more.

It is important to know that pain may come from a combination of the spine, the hips, or the SI joint. It is possible that patients with prior lumbar spine surgery, who did not receive relief, may have had other undiagnosed issues.

**If the following conditions are present a
diagnostic SIJ Injection(s) should be ordered.**



● Pain Indicator

SI JOINT FIXATION



As previously stated, pain may come from a combination of the spine, the hips, or this SI joint. Your surgeon is trained on effective ways to determine whether or not your pain is originating from your SI joint. One of the simplest ways of determining SI joint pain is seen in the Fortin Finger Test (see image above). After that, a number of other tests will be performed by the doctor in their office. The provocative tests can be an effective way to pinpoint the pain that you are experiencing. X-rays and CT-scans can be helpful in determining your pain, as it could be possible that other conditions can coexist with SI joint dysfunction.

A common step to determine whether the SI joint is the source of your pain is with an SI joint injection. These injections will be delivered with fluoroscopic or CT guidance with the goal of decreasing your pain. If the injection gives you at least 50% relief, then the SI joint is likely the source of your pain or a major contributor to it. (subnote 15). If the injection does not give you at least 50% relief, then the SI joint is less likely the source of your pain.



FORTIN FINGER TEST.

If your pain is coming from below your belt line, it may be the right time to ask your physician about your SI Joint.

Painful Activities



Sitting

- Weight on unaffected side



Sit to Stand

- Pain from sitting to standing
- Midrise catch
- Use of hands/arms to help stand



Stepping Up

- Pain going up/down stairs
- Pain with loading affected side

It Hurts Here

Fortin Finger Test

**Simple,
Reliable**

Diagnostic Aid

Ask Patient to Point to Pain Location:

Below L5: Consider SI Joint

Above L5: Consider Lumbar Spine

TREATMENT OPTIONS

NON-SURGICAL OPTIONS

Treatment of the SI joint begins once the pain you are experiencing is properly confirmed as the source of symptoms. Treatments include physical therapy, oral medications, therapeutic injections and diagnostic injections. Symptom improvements may be temporary and are often times used repeatedly. If these treatment options do not provide lasting relief, your surgeon may consider other options, including surgery.

SI Joint Fixation with the SImpact System

SI joint fixation is a surgical procedure intended to immediately stabilize the joint and permanently eliminate motion by fusing the bones together. The system utilizes orthopedic screws placed across the joint to stabilize and fuse the ilium to the sacrum.

The SImpact Sacroiliac Joint Fixation System consists of fully threaded and partially threaded cannulated screws in various diameters and lengths to enhance sacroiliac joint fusion. The system is intended for SI joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. All components are fabricated and manufactured from titanium alloy.

There are potential risks associated with the SImpact system. It may not be appropriate for all patients and all patients may not benefit. For more information about risks, see page___

SImpact Benefits

- Minimally invasive surgical (MIS) approach
- Self-Drilling implant design for less intra-operative impact
- Osseo-Loc Surface technology to promote boney on-growth (subnote)
- Fenestrated design to allow bone growth through implant aiding fusion
- Multiple implant sizes for varying patient anatomies

YOUR SURGERY

This booklet is not intended as a replacement for professional medical care and is meant only as an educational resource. Please consult your physician for clinical results and all other important medical information that pertains to this procedure.

Before Surgery

It is possible that your surgeon will ask you to obtain crutches or a walker to use after surgery. You will be told when to stop eating and drinking before surgery. If you take 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 fixation is a surgical procedure performed in an operating room under general or spinal anesthesia. The surgery is performed with you lying prone or lying on your stomach. The SImpact system is specially designed to accommodate every patient's anatomy with both its instruments and implants. The procedure is minimally invasive, and a small 3cm incision will be made along your buttock. Under X-ray guidance, your surgeon will insert the implants (typically three) across your SI joint.

A typical SI joint fixation procedure takes one hour. Your surgeon will decide whether you can return home the same day of surgery or the morning after.

After Surgery

Your surgeon will schedule follow-up visits to check on your recovery. Your surgeon will determine when you can return to full weight bearing, and you may temporarily use crutches or a walker depending on your progress.



FREQUENTLY ASKED QUESTIONS

What is SI joint dysfunction?

SI joint dysfunction is the pain and the physical impairment associated with a disrupted or degenerated SI joint.

Why does the SI joint cause pain?

There are several reasons why the SI joint can start causing pain. As with other joints in the body, the SI joint can become degenerated, damaged, or the supporting ligaments can become injured. Other causes that contribute to SI joint pain include but are not limited to: Rheumatoid Arthritis (RA), trauma such as a motor vehicle accident or childbirth, deformity such as pelvic tilt and obliquity, limb length inequality, or instability with motion of the pelvis.

Pain originating from the SI joint can include pain in the buttocks, lower back, groin and the legs during activities such as lifting, walking, lying on the injured side, and many more.

It is important to know that pain may come from a combination of the spine, the hips, or the SI joint. It is possible that patients with prior lumbar spine surgery, who did not receive relief, may have had other undiagnosed issues.

Who is most prone to SI joint pain?

Although men and women can have SI joint pain, women are at a higher risk because of their broader pelvises and greater lumbar spine curve. Pregnancy is also a contributing factor to SI joint pain. Lastly, women have elastin in their ligaments, which allows increased movement in the joint.

FREQUENTLY ASKED QUESTIONS

How would I know that my SI joint is the source of my pain?

Your SI joint may be a source of your pain if you answer yes to many of the following questions:

- Do you have trouble sitting for long period of time with pain?
- Do you have to shift from side to side while sitting?
- Do you have trouble sleeping comfortably at night?
- Do you have pain in your buttocks when climbing stairs?
- Does your pain get worse when getting in and out of a car?
- Does driving over a bump in the road increase back and/or buttocks pain?
- Do you have trouble and is it painful standing on one leg for a period of time?
- Does your leg feel like it wants to give out when stepping?
- Do you have pain in your groin area?
- Will my doctor check for SI joint 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 match what your doctor can see on an image (X-ray, CT-scan, and/or 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 the other sources of pain as well as running specific tests that stress the SI joint.

What should I tell my doctor about my pain?

One simple way to tell your doctor about your back or buttock pain is to point precisely at where it hurts. Refer to the Fortin Finger Test shown earlier in this booklet. It is also important to discuss any prior injuries you have had that may be affecting your pelvic region.

FREQUENTLY ASKED QUESTIONS

Are there non-surgical treatments of SI problems?

Non-surgical treatments include physical therapy, oral medications, therapeutic injections and diagnostic injections. Symptom improvements may be temporary and are often times used repeatedly. If these treatment options do not provide lasting relief, your surgeon may consider other options, including surgery.

What are the SIm pact implants made of?

The SIm pact implants are small orthopedic screws that can be as long as a small finger. Titanium is a very strong but lightweight material, commonly used for medical device implants.

How do the SIm pact implants work?

The SIm pact implant has a sleeve that is press fit into your ilium to prevent screw rotation. The implant also has large fenestrations, or holes, to allow bone to grow through the implant, securely fixating and stabilizing the joint.

What is the procedure for SIm pact?

SI joint fixation is a surgical procedure performed in an operating room under general or spinal anesthesia. The surgery is performed with you lying prone or lying on your stomach. The SIm pact system is specially designed to accommodate every patient's anatomy with both its instruments and implants. The procedure is minimally invasive, and a small 3cm incision will be made along your buttock. Under X-ray guidance, your surgeon will insert the implants (typically three) across your SI joint.

A typical SI joint fixation procedure takes one hour. Your surgeon will decide whether you can return home the same day of surgery or the morning after.

FREQUENTLY ASKED QUESTIONS

What happens after my Slmpact Procedure?

Your surgeon will schedule follow-up visits to check on your recovery. Your surgeon will determine when you can return to full weight bearing, and you may temporarily use crutches or a walker depending on your progress.

What can I do to avoid problems healing after Slmpact surgery?

Your doctor may provide you with post-operative instructions. In general, you should avoid strenuous activities in the first six weeks.

When can I expect to get back to my normal daily activities?

Individual recovery time will vary from patient to patient. You can expect to have activities limited in a period usually reaching 6 months post-operation. Consult your physician for specific recommendations.

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

Slmpact implants are not anticipated to affect the ability to have other surgeries of the spine, hip, or pelvis. Please ask your doctor for additional information.

Can I have an MRI after the Slmpact procedure?


After the Slmpact procedure you are safe to have an MRI. Please ask your doctor for additional information.

Can the Slmpact implant be removed or revised?

Even though it is uncommon, there may be a reason (such as loosening, trauma, improper placement, etc.) a Slmpact implant may need to be repositioned or removed. Please ask your doctor for additional information.

What are some of the risks associated with the Slmpact procedure?

For risks associated with the Slmpact procedure, please turn to page ___.



"SIm pact has streamlined the SI joint fixation procedure for me and my patients. The screw is designed to reduce surgical steps, resulting in a shorter and less invasive surgery. I continue to see excellent results in treating sacroiliac joint disruptions and degenerative sacroiliitis."

Keith Maxwell, MD, North Carolina

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2 J. N. Sembrano and D.W. Polly, "How often is low back pain not coming from the back?" Spine, vol. 34, no. 1, pp. E27-E32, 2009.

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Sacroiliac
Joint Fixation

SI JOINT FIXATION



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