

TriCor[®]

Sacroiliac Joint Fusion System

Patient Education



HIGHRIDGE

Sacroiliac Joint

This patient education booklet explains sacroiliac joint anatomy and dysfunction in the sacroiliac joint (also called the SI joint). It also describes treatment options for your SI joint pain and related problems. Your doctor may recommend fusion surgery to relieve your pain and discomfort using cannulated implants. This booklet will help answer questions in preparation for, during, and after surgery.

This material does not comprise medical advice or recommendations. Please consult with your healthcare provider to determine the medical treatment that makes the most sense for you.



About the Sacroiliac Joint

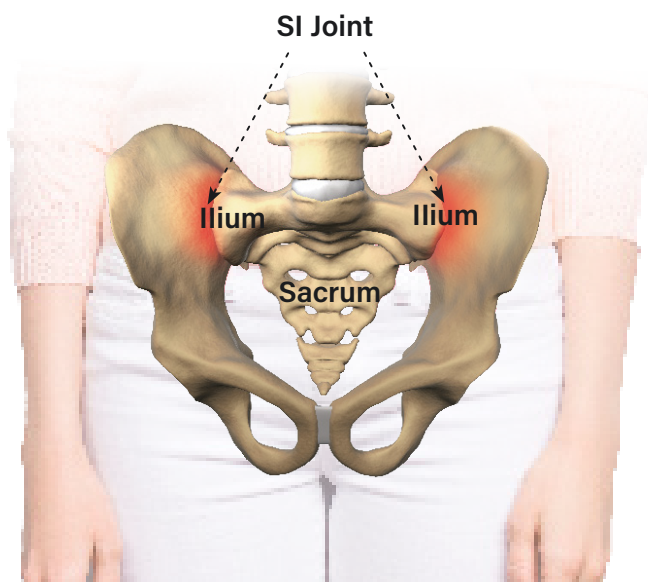
The sacroiliac joint is located where the pelvis, lower spine, and the sacrum, connect. It acts as a shock absorber between the upper and lower halves of the body. SI joint pain can happen if the SI joint becomes injured or degenerates over time.

Sacroiliitis

A person with sacroiliitis has inflammation of one or both of their sacroiliac joints, which can cause pain in the buttocks, lower back, and even extend down the leg.

Symptoms of sacroiliitis include:

- Pain radiating into the lower back, buttocks, and/or groin
- Referred pain in the legs
- Leg pain when getting in and out of the car
- Difficulty rolling over in bed
- Difficulty putting shoes on
- Stiffness or aching in the lower back



Sacroiliac Joint Pain

Some causes of sacroiliac joint pain may include:

- Sacroiliitis (inflammation of the joint)
- Sacral disruption
- Ankylosing spondylitis (arthritis of the spine)
- Post-traumatic SI joint disruption
- Leg length discrepancy
- Pelvic asymmetry
- A tumor (pituitary or metastatic)
- Infection
- Inflammation
- Osteoarthritis
- Ligamentous laxity (loose ligaments)
- Trauma
- Adjacent segment disease

Diagnosing SI joint pain:

In 25% of lower back pain cases, the sacroiliac joint is the culprit. Diagnosis can be difficult because SI joint symptoms overlap with other back problems, but there are varieties of tests to confirm the pain is from the SI joint. Some of these tests include:

- **Medical history:** past injuries, when the pain began, description of symptoms, and information on sleep habits, diet, and exercise
- **Physical exam:** movement tests designed to either improve or provoke symptoms
- **Diagnostic imaging tests:** X-ray, CT, and MRI to rule out other types of back pain
- **Injection tests:** anesthetic injection to determine if pain is reduced at the injection site

About Fusion Surgery and Non-Surgical Options

Joint fusion surgery can reduce pain from sacroiliac joint inflammation and dysfunction. With joint fusion, bone grafts can encourage bone growth around the SI joint to solidify the fusion. Although, in most cases of sacroiliac joint pain, surgery is not always necessary.

Nonsurgical treatments may include:

- Exercise and physical therapy
- Chiropractic adjustment
- Pain medication
- A pelvic belt for enhanced stability
- Osteopathic manipulation
- Injections into the SI joint

Nonsurgical treatments of SI joint dysfunction are helpful, but SI joint fusion surgery can help treat the root cause of the problem when conservative treatments are no longer effective. Consider the effectiveness of non-surgical treatments and your doctor's recommendations before deciding to get SI joint fusion surgery.



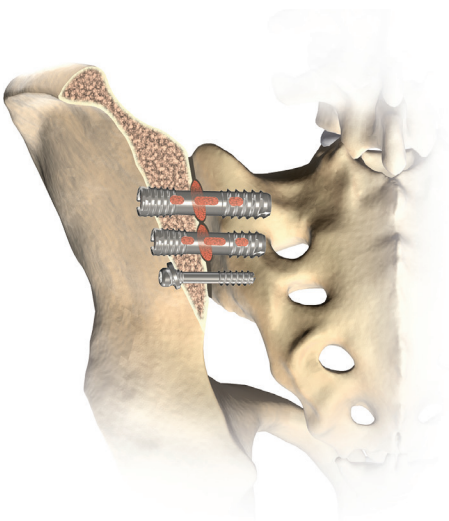
When is SI Joint Fusion an Option?

Sacroiliac Joint Fusion may be an option if any of the following symptoms persist for several weeks or months:

- Lower back, hip, and/or groin pain to the point where it is difficult to function
- Pain from instability of the lower back and pelvis
- Stiffness in the lower back, hips, legs, and/or groin
- Pain after standing or sitting for long periods

Common Traits for Patient Selection Include:

- Failed non-surgical treatments
- Chronic acute pain
- Failed diagnostic exams
- Capable of post-surgical recovery and rehabilitation



The TriCor Sacroiliac Joint Fusion System

The TriCor Sacroiliac Joint Fusion System provides stabilization and fusion of the SI joint in eligible patients where non-surgical treatments have failed. Surgery with the TriCor system may be performed in a less invasive way than traditional sacroiliac fusions, allowing for less blood loss and the potential for a quicker recovery time. The TriCor system can treat conditions like degenerative sacroiliitis and sacroiliac joint disruption.

Features:

- Two unique diameter cannulated implants
- Various implant lengths
- Full and partially threaded configurations to accommodate different patient anatomies
- Titanium plasma-coated to help with friction resistance and provide a bioactive template

Benefits:

- The device stabilizes the SI joint through a combination of proprietary dual-pitch compression-thread design and titanium plasma coating
- The implant design allows for the insertion of the bone graft along with the implant to achieve solid fusion
- The instrumentation and implant allow for the preparation of the SI joint, placement of the bone graft under direct visualization, and placement of the bone graft within the TriCor implant



Minimally Invasive Sacroiliac Joint Fusion

The development of minimally invasive implant systems for SI joint fusion has increased in recent years. Most SI joint fusion surgeries are minimally invasive by going through a small incision in the buttock. These systems have been shown to cause fewer complications and have a shorter recovery process than open fusion surgeries.^{1, 2}

During surgery, fluoroscopic imaging helps prepare the joint and confirm implant placement and if needed, bone graft placement. This minimally invasive procedure has been shown to reduce pain following surgery when compared to open SI joint fusion procedures.²

Open SI Joint Fusion: A Rarely Used Procedure

Open SI joint fusion surgery is rare now because it is at risk for more complications and longer recovery time. A study comparing open SI fusion and minimally invasive fusion found that while both surgeries improved pain scores and disability, minimally invasive surgery had greater improvement in all measures.²

Potential Risks and Complications

As with all surgeries, there are risks and possible complications from SI joint fusion. There can be excessive blood loss or complications from anesthesia, but with advancements in technology, the minimally invasive SI joint fusion procedure has significantly reduced these risks and complications.

Sacroiliac Joint Fusion Recovery

Recovery from SI joint fusion varies from patient to patient and some discomfort after surgery is common. Pain could take a few weeks to reduce and full recovery could take up to 6 months. Consult with your doctor and specialists for an appropriate recovery plan and timeline.

The following can help manage pain after fusion surgery:

- A walker or cane to reduce joint stress
- A sacral belt to provide stability
- Pain medication for post-op pain and sensitivity
- Ice and heat therapy

Physical therapy can help rehabilitate function to the lower back while minimizing pain. Physical therapy can include:

- **Passive Range of Motion Stretches:** These stretches help loosen tight muscles and relieve lingering pain.
- **Active Stretching Exercises:** These stretches help regain full range of motion in the lower back, hips, and legs.
- **Strengthening Exercises:** Bodyweight resistance training of the core, lower back, and legs can build up the strength of the muscles around the SI joint.
- **Aerobic Exercise:** Using an elliptical, stationary bike, or swimming will help increase muscle activity and circulation.
- **Water Therapy:** Water will provide natural resistance while reducing pressure on the SI joint and will help relax tense muscles.

Commonly Asked Questions

What is the post-op recovery period?

Post-op recovery usually includes one day in the ICU and four days in the hospital. Pain medication is prescribed when you leave the hospital but is usually only needed for a couple weeks. Recovery times vary depending on how well the patient does during surgery. Your doctor will let you know about an appropriate recovery period for you.

How active can I be after surgery?

It is possible to go back to physical activity as soon as four weeks with your doctor's permission. Consult with your doctor to make sure this kind of activity is appropriate for you. They will let you know when and what types of exercise you can do. Take it slow and refrain from strenuous activity until your doctor clears you.

How soon can I return to work?

Your doctor will let you know when it is safe to go back to work, but most patients go back after two weeks.

What if I have pain after surgery?

If you have pain, first tell your doctor, but realize that recovery can be uncomfortable immediately after surgery.

Can I walk through metal detectors of security with the TriCor Sacroiliac Joint Fusion System?

Yes, you may walk through metal detectors or security scanners. Implants made from Titanium alloy like the TriCor Sacroiliac Joint Fusion System do not typically set off airport security although TSA rules state that, "TSA security officers will need to resolve all alarms associated with metal implants". Always refer to the medical advice of your doctor.

Indications For Use

The TriCor Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.

1. Kube RA, Muir JM. Sacroiliac Joint Fusion: One Year Clinical and Radiographic Results Following Minimally Invasive Sacroiliac Joint Fusion Surgery. *Open Orthop J.* 2016;10:679-689.
2. Ledonio CG, Polly DW, Swiontkowski MF, Cummings JT. Comparative effectiveness of open versus minimally invasive sacroiliac joint fusion. *Med Devices (Auckl).* 2014;7:187-93.

Reference sites:

<https://www.spine-health.com/treatmentspinal-fusion/what-know-about-sacroiliac-joint-fusion>

<https://www.mayoclinic.org/diseases-conditions/sacroiliitis/symptoms-causes/syc-20350747>



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