



PATIENT INFORMATION

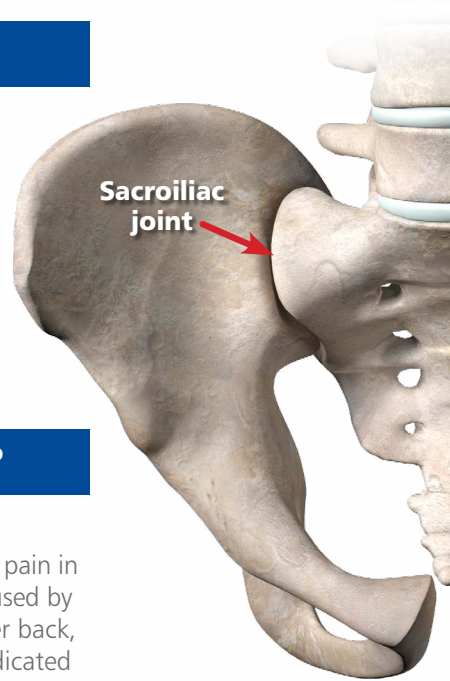
Lower Back Pain and the Sacroiliac Joint



ORTHOFIX[®]

What is the Sacroiliac Joint?

Your Sacroiliac (SI) joint is formed by the connection of the sacrum and iliac bones. These two large bones are part of the pelvis and are held together by a collection of ligaments. The SI joint supports the weight of your upper body which places a large amount of stress across your SI joint.

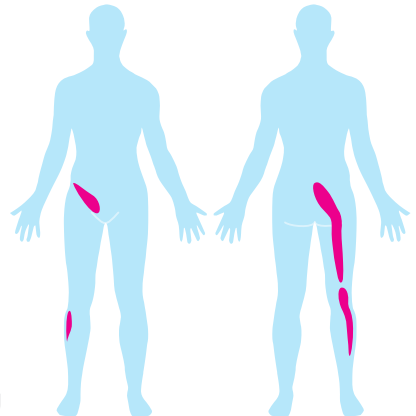


What is Sacroiliac Joint Disorder?

The SI joint is a documented source of lower back pain. The joint is the most likely source of pain in 30% of patients with lower back pain. Pain caused by sacroiliac joint disorder can be felt in the lower back, buttocks, or legs. Sacroiliac joint fixation is indicated in patients with severe, chronic sacroiliac joint pain who have failed extensive conservative measures, or in acute cases of trauma.

What are potential symptoms?

- Lower back pain
- Lower extremity pain (numbness, tingling, weakness)
- Pelvis/buttock pain
- Hip/groin pain
- Unilateral leg instability (buckling, giving away)
- Disturbed sleep patterns
- Disturbed sitting patterns (unable to sit for long periods of time on one side)
- Pain going away from sitting to standing

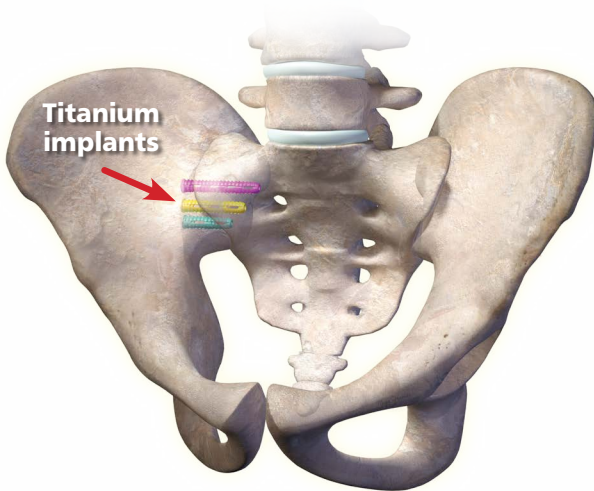


How is Sacroiliac Joint Disorder diagnosed?

Sacroiliac joint disorder is diagnosed by the patient's history, physical findings, radiological investigations and SI joint injections. Sacroiliac injection, which is the gold standard for confirming SI joint disorder will be delivered with fluoroscopic or CT guidance to validate accurate placement of the needle in the SI joint.

What is the Orthofix SambaScrew®?

Your surgeon has chosen the SambaScrew because it utilizes a minimally invasive surgical technique to sacroiliac fixation. The SambaScrew fixation system works to promote fixation by inserting titanium screws across the SI Joint. These titanium implants are intended to stabilize the joint. The system also has a low profile screw head that is designed to prevent soft tissue irritation.



Description:

The SambaScrew SI Fixation System is a temporary, multiple component system consisting of non-sterile instruments and non-sterile, medical-grade titanium (Ti-6Al-4V ELI) implants. The system consists of a 9mm diameter, cannulated screw with multiple orifices on its shaft. The Steinmann Pins, Variable Drill Bit, and Packing Tube are single use devices and should be discarded after use.

Indications for Use:

The SambaScrew SI Fixation System is intended for fixation of sacroiliac joint disruptions. This fixation device is to only be used in skeletally mature patients.

Contraindications:

The SambaScrew SI Fixation System is contraindicated for use in patients with:

1. Open wounds, infection, presence of tumor, pregnancy, osteoporosis, certain metabolic disorders affecting osteogenesis, certain inflammatory/neuromuscular conditions, and certain neuromuscular deficits which would place an unusually heavy load on the device during the healing period.
2. The implant is made from Ti-6Al-4V ELI (medical-grade titanium alloy). The fixation implant is contraindicated in any individual with a known or suspected allergy, sensitivity or intolerance to metal.

Potential Adverse Events:

Potential adverse events include, but are not limited to:

1. Allergic reaction or metal sensitivity to foreign body.
2. Cardiovascular system compromise.
3. Death.
4. Decrease in bone density due to stress shielding.
5. Device bending, disassembly, fracture, loosening, migration and/or retropulsion, or subsidence.
6. Dural tears, neural structure injury.
7. Fixation implant migration with or without bone fracture.
8. Fracture of pelvis or sacrum.
9. Gastrointestinal complications (i.e., ileus or bowel perforation).
10. Hemorrhage.
11. Incisional complications (i.e., dehiscence, hematoma).
12. Infection (Incisional or implant site).
13. Loss of spinal mobility or function.
14. Loosening or fracture of fixation implant.
15. Malfunction of fixation device and/or instruments.
16. Malposition of the fixation device.
17. Migration of fixation implant.
18. Neurological injury/deficit which may range from paresthesias to muscle paralysis, loss of rectal or bladder sphincter control, radiculopathies.
19. Organ, connective tissue or nerve damage.
20. Osteoarthritis.
21. Pain, discomfort or abnormal sensation due to device presence.
22. Persistent low back pain.
23. Reproductive system compromise.
24. Screw back-out or breakage possibly leading to local pain, perforation or irritation of adjacent structures.
25. Sepsis.
26. Urological compromise (i.e., infection/retention).
27. Vascular injury.
28. Wound hematoma.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings and Precautions:

1. The SambaScrew device should only be used by surgeons who have been trained in the use of this device. Information on laboratory and clinical training, as well as additional brochures with a detailed description of proper surgical technique, may be obtained from Orthofix. See the SambaScrew SI Fixation System Surgical Manual for instructions on the implant procedure.
2. Infection may occur immediately following implant fixation or a long time afterwards due to transient bacteremia such as caused by dental treatment(s), endoscopic examination or any other minor surgical procedure. To avoid infection at the implant fixation site, it may be advisable to use antibiotic prophylaxis before and/or after such procedures.

References:

Schwarzer AC, April CN, Bogduk N: The Sacroiliac Joint in Chronic Low Back Pain in Spine 1995;20:31-37.
Dreyfuss P, Dreyer SJ, Cole A, Mayo K: Sacroiliac Joint Pain. J Am Acad Orthop Surg 2004; 12:255-265
Van der Wurff P, Hagmeijer RH, Meyne W: Clinical Tests of the Sacroiliac Joint. A Systemic Methodological Review. Part 2: Validity. Man Ther 2000; 5:89-96.

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