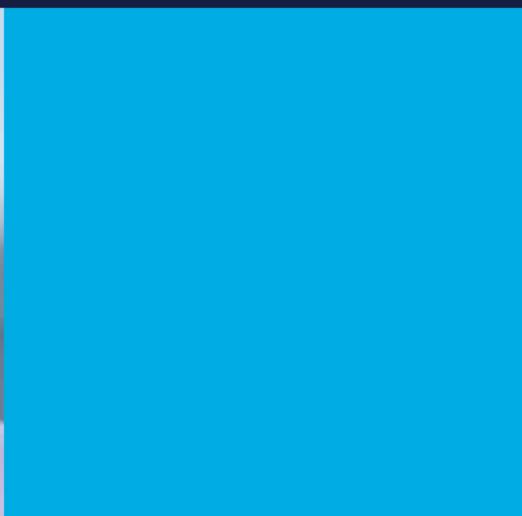


SACROILIAC JOINT DYSFUNCTION



Patient Information

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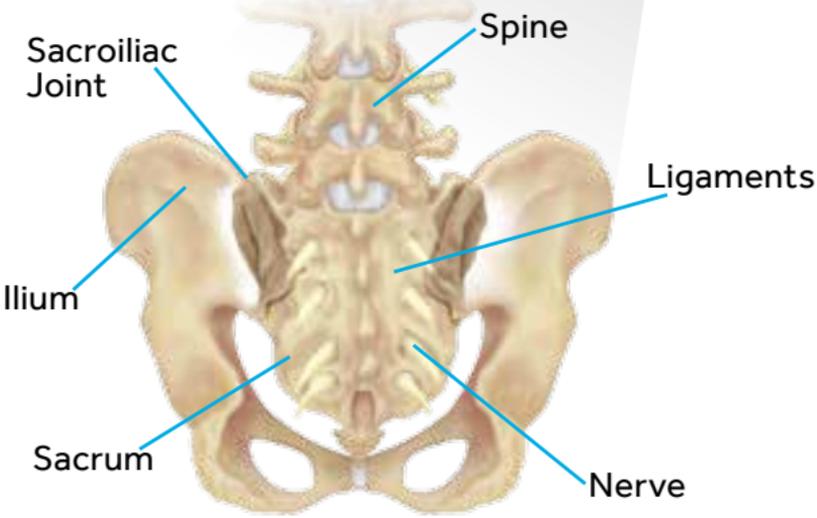
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SACROILIAC JOINT ANATOMY

The sacroiliac joint or SI joint (SIJ) is the joint in the lower portion of the spine. It is located in the bony pelvis between the sacrum and the ilium of the pelvis, which are joined by strong ligaments. The sacrum supports the spine. The sacrum is supported by an ilium on each side.

The pelvis is held together by a series of ligaments and muscles and the SI Joint acts as a shock absorber, transmitting the body's load from the upper body to the legs.



Back view of hip (pelvis)

WHAT CAUSES SACROILIAC JOINT PAIN?

Sacroiliac joint pain can be categorized as pain from the leg, buttocks, groin, and lower spine. Normal wear and tear of the joint (degenerative), traumatic events, and inflammation can lead to painful walking, sitting, sleeping, getting in and out of a car, and other activities. Although it is not always clear what causes sacroiliac joint pain, it is estimated that 15%-25% of patients with axial low back pain can attribute their pain to the SI Joint.¹

This patient information brochure is designed to help you understand one potential treatment option for your sacroiliac joint diagnosis. After reviewing your medical history, x-rays, and the results of other tests you have completed, your doctor may recommend that you consider surgery. This patient brochure explains one option, surgery using Rialto SI Fusion System.

The purpose of this brochure is to give you background information about SI joint surgery and the Rialto SI Fusion System. Please read this entire brochure and ask your doctor any questions you may have before your procedure.

CONDITIONS ASSOCIATED WITH SACROILIAC JOINT PAIN

(Definitions can be found in the Glossary of terms section)

- Adjacent segment disease (prior spine fusion)
- Ankylosing spondylitis
- Degenerative osteoarthritis
- Degenerative sacroiliitis
- Infection
- Inflammation
- Leg length discrepancy
- Ligamentous laxity (pregnancy/post pregnancy)
- Sacral disruption
- Sacroiliac Joint disruption (post trauma)
- Structural pelvic asymmetry
- Trauma
- Tumor

¹ Cohen, Steven P. Sacroiliac Joint Pain: A Comprehensive Review of Anatomy, Diagnosis, and Treatment. *Anesth Analg* 2005; 101:1440-1453.

WHAT IS SACROILIAC JOINT DISEASE?

Sacroiliac Joint Disease typically comes from one of two conditions:

Degenerative Sacroiliitis. In medicine, the term “itis” refers to inflammation, and sacroiliitis describes inflammation of the sacroiliac joint. The inflammation may, or may not, be caused by sacroiliac joint dysfunction.

Sacroiliac Joint Disruption. This condition generally refers to abnormal motion in the sacroiliac joint, either too much motion or too little motion.

WHY MAY I NEED SURGERY?

You may be a candidate for surgery if you have tried, with no lasting relief, other conservative care options such as physical therapy, chiropractic, medications, and/or injections for at least 6 months. After consulting with your surgeon, it may be determined that surgery might be an option to limit the amount of movement of the SI Joint in an effort to treat your diagnosis.

WHAT IS THE RIALTO SI FUSION SYSTEM?

The Rialto SI Fusion System is intended to stabilize your sacroiliac joint and provide an environment for fusion (joining bones together into one solid structure) to occur.

The Rialto SI Fusion System consists of cylindrical threaded devices designed to enhance sacroiliac joint fusion. The threaded devices are offered in various lengths to accommodate your anatomy. For fusion of the SI joint, one, two, or three devices may be placed at your surgeon’s discretion.

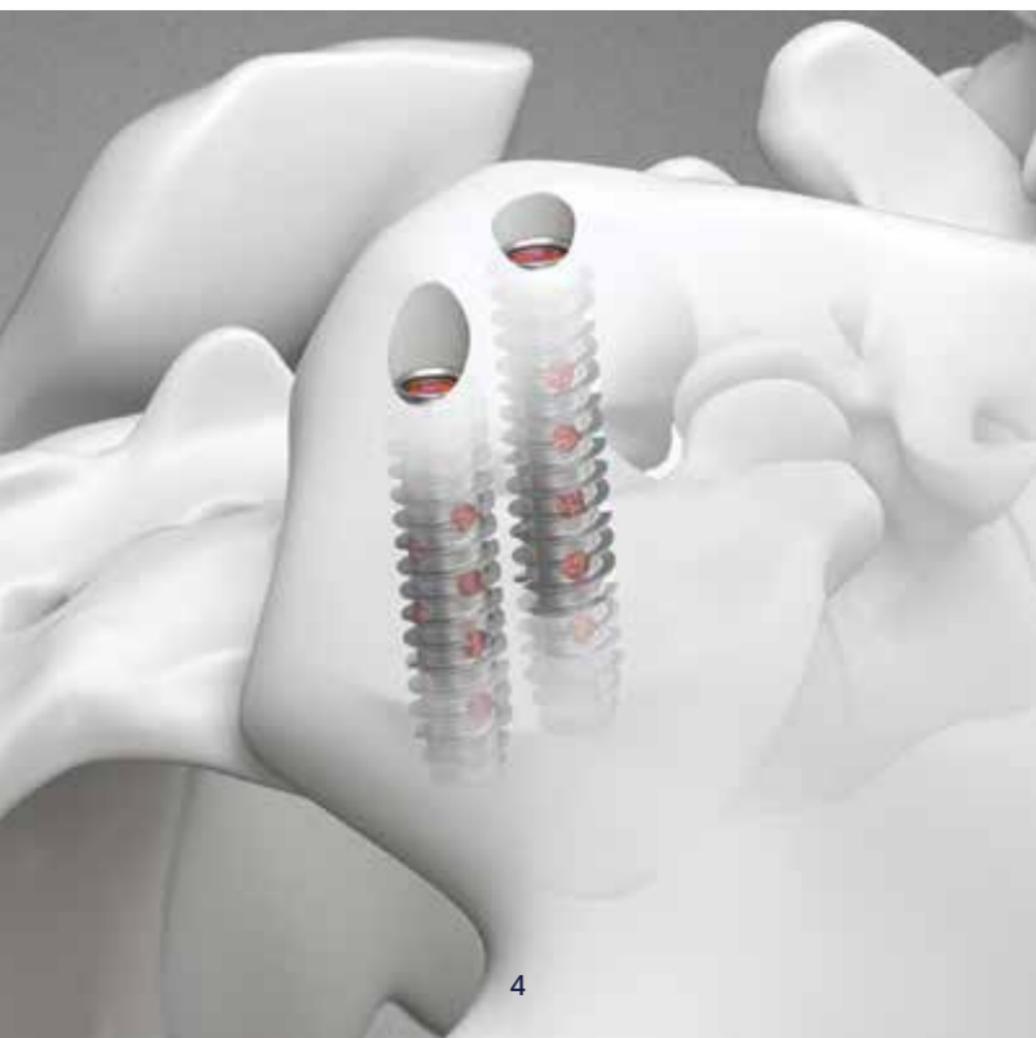
POSSIBLE DIAGNOSES FOR SURGERY CANDIDATES

- Degenerative Sacroiliitis
- SI Joint disruption
- You have undergone failed non-surgical treatment (physical therapy, chiropractic, physiatry, etc.)
- You have a positive response to SI Joint injection(s)

WHO IS NOT A CANDIDATE FOR THE RIALTO SI FUSION SYSTEM?

The Rialto SI Fusion System should not be used in patients with the following conditions:

- Deformities
- Tumor resection
- Infection near the operative site and/or signs of local inflammation
- Failed previous fusion
- Suspected or documented allergy or intolerance to the component materials





WHAT ARE THE POTENTIAL BENEFITS?

- Physicians can use a minimally invasive approach through a small incision
- Insertion of the device causes minimal tissue disruption
- Bone graft can be delivered within the device to promote a fusion

HOW IS THE SURGERY PERFORMED?

The Rialto SI Fusion procedure is performed under general anesthesia, in a minimally invasive fashion. Your surgeon will make a small incision above the buttock, just below your waist. The incision will be slightly to the left or right of your spine, depending on the area to be treated. Through a series of steps, a cylindrical threaded device will be placed and packed with a material to promote bone growth. Typically, but not always, two devices are placed to provide stability and promote fusion.

WHAT CAN I EXPECT AFTER SURGERY?

Ask your doctor about your specific recovery plan following surgery. It is important to follow your doctor's instructions carefully to recover from surgery as quickly as possible and increase your chance of a successful outcome. Recovering from back pain and surgery is an ongoing process. How fast you recover depends on the type of surgery you had, your commitment to working closely with your physical therapist, and moving and exercising correctly, as recommended by your surgeon. In most cases, immediately after surgery your heart and lung function will continue to be monitored and your doctor may prescribe medication to control pain and nausea.

A nurse will show you how to care for your incisions before you are sent home and your doctor will discuss a program to gradually increase your activity. You may be required to wear a back brace after surgery and you may be told to avoid repetitive bending, lifting, twisting and athletic activities while you recover. You may also be cautioned to avoid vibrations, such as those you might experience when driving a car, for a period of time after your surgery. Your doctor will schedule office visits to check on how you are doing and see if anything else needs to be done.

Contact your doctor immediately if:

- you get a fever
- the incision starts leaking fluids
- you have trouble swallowing or breathing
- you have trouble urinating
- you have new or increased back or leg pain or numbness

After surgery, your surgeon may refer you to a physical therapist who will teach you exercises to improve your strength and increase your mobility. The goal of physical therapy is to help you become active as soon as possible, using safe body movements that protect your spine and your sacroiliac joint. This often includes abdominal strengthening exercises. You may also be taught different ways of standing, sitting, or lifting to avoid reinjuring your spine.

WHAT POSSIBLE COMPLICATIONS COULD OCCUR?

Potential risks to any surgical procedure include unforeseeable complications caused by anesthesia, blood clots, undiagnosed medical problems, such as silent heart disease, and rare allergic reactions. Some risks of SI joint surgery include incomplete pain relief, damage to the nerve roots, infection, and complications with the hardware. Most of these complications can be treated once they are detected, but sometimes they require a longer period of hospitalization or recovery, additional medications, and sometimes even additional surgery.

These risks will be explained by the primary surgeon. In general, these complications happen very infrequently, but it is important to remember that surgery is a difficult process, and, therefore, unforeseeable complications do occur. As a patient, it is important to understand and follow your doctor's advice so that the best possible outcome can be achieved.

TALK TO YOUR DOCTOR

While this brochure is meant to provide you with information you need to make an informed decision about your treatment options, it is not intended to replace professional medical care or provide medical advice.

If you have any questions about the Rialto SI Fusion System, please call or see your doctor, who is the only one qualified to diagnose and treat your spinal and/or sacroiliac condition. As with any surgical procedure, you should find a surgeon who is experienced in performing the specific surgery that you are considering.

GLOSSARY OF TERMS

(As related to the Sacroiliac Joint)

Adjacent segment disease – A patient may experience recurrent pain many years after a spine fusion surgery. This can happen because the level above or below a segment that has been successfully fused can break down and become a new source of pain.

Ankylosing spondylitis – Classified as a rheumatologic disorder of the spine. It is considered one of the so-called sero-negative arthropathies. This inflammation can eventually lead the joints to become fused, leading to stiffness and reduced range of motion (known as ankylosis.) It also frequently affects the hips and other peripheral joints.

Degenerative osteoarthritis – The most common form of arthritis, affecting millions of people around the world. It is sometimes known as “wear and tear” arthritis as it worsens with time and age. Osteoarthritis can affect any joint in your body, including the spine.

Degenerative Sacroiliitis – Inflammation of one or both sacroiliac joint(s) caused by changes over time.

Infection – The condition in which the SI joint is invaded by a bacteria or virus, causing inflammation and potentially tissue damage.

Injection – Introduction of an analgesic (or other substance) used either to diagnose or treat low back and/or leg pain associated with sacroiliac joint dysfunction.

Leg length discrepancy – Differences between the length of each leg.

Ligamentous laxity – Loosening of the ligaments that may lead to excess motion.

Sacroiliac joint – Located in the lower back between the spine and hip joint, and normally does not move much. Inflammatory arthritis (such as ankylosing spondylitis), degeneration of the sacroiliac joint, or misalignment of this joint can cause pain associated with sacroiliac dysfunction.

Sacroiliac Joint disruption – This condition generally refers to abnormal motion in the sacroiliac joint, either too much motion or too little motion.

Sacroiliac joint dysfunction – Abnormal or impaired function of the sacroiliac joint.

Structural pelvic asymmetry – Asymmetric (uneven) positioning of bony landmarks on the two sides of the pelvis.

Trauma – An event such as a motor vehicle accident or fall which causes damage to the SI joint.

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PMD016386-3.0 UC 201702352a EN

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.



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