Patient Information



SI-LOK[™]

Sacroiliac Joint Fixation System



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SI-LOK[™] Sacroiliac Joint Fixation System

Patient Information

This brochure will help you understand more about:

- General conditions of the sacroiliac joint
- Information about surgical treatment
- SI-LOK[™] Sacroiliac Joint Fixation System
- What to expect from surgery

The decision to receive medical treatment is individual to the patient and the patient's symptoms. The information presented within this brochure may not apply to your condition, treatment or its outcome, as surgical techniques vary and complications may occur. It is important to discuss the viability of this procedure with your physician to decide whether this treatment option is right for you.

This brochure is intended to be an educational resource only and is not meant to be a warranty, or to replace a conversation between a patient and their physician or member of their health care team. Please consult your physician for a complete list of indications, contraindications, warnings, precautions, clinical results and other important medical information that pertains to this procedure.

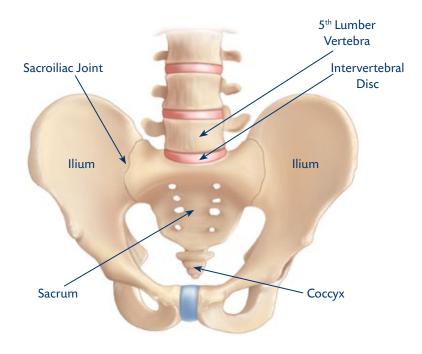
Anatomy of the Sacroiliac Joint

The sacroiliac (SI) joint connects the sacrum, which is the lowest bony segment of the spine, with the lower limbs on each side.

The SI joint transmits most of the weight loads from the upper body to the lower limbs, acting as a shock absorber, relieving forces on the spine. The SI joint is reinforced by strong ligaments, limiting motion in the joint.

The SI joint typically has the following characteristics:

- Reinforced by strong ligaments and muscles
- Limited in motion
- Transmits most of the forces of the upper body to the pelvis and legs
- Acts as a shock absorber



Possible Causes and Symptoms of SI Joint Dysfunction

Symptoms

The most common symptom of SI joint dysfunction is pain. Patients often experience pain in the area of the sacrum (tail bone), upper buttocks, upper thigh, or upper groin.

The pain can lead to issues with sleeping, sitting, and walking.

The pain typically worsens with standing and walking, while less severe when lying down. Swelling and arthritis in the SI joint can also cause pain and stiffness in the pelvis.

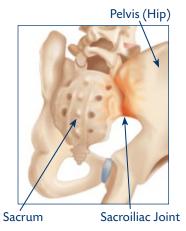


Causes

The cause of sacroiliac joint pain is unknown; however, it may occur with trauma or injury.

Typical causes of SI joint dysfunction include:

- Tissue loosening due to pregnancy
- Trauma due to injury or accident
- Arthritic conditions
- Previous lower back surgery



Chronic Sacroiliac Joint Dysfunction

SI joint dysfunction is a condition in which the patient has chronic pain associated with the SI joint. Sacroillitis is a condition in which one or both of the SI joints are swollen or inflamed.



The SI joint is a potential source of lower back and limb pain. SI joint problems can result in issues with surrounding ligaments and muscles.



How is the Procedure Performed?

A minimally invasive surgical approach is used to implant the $SI\text{-}LOK^{\mathsf{TM}}$ Sacroiliac Joint Fixation System, to help minimize disruption to the underlying muscles and tissues. A 2-4cm incision is made as indicated, using Xrays during surgery. Incision Site

The surfaces of the joint are prepared and screws are placed across the SI joint. Using titanium alloy implants helps to maintain fixation and may help with recovery (e.g. weight bearing). Your doctor will determine the appropriate implant type and size for your condition.



Speak to your doctor about surgical options for your specific condition and what is beneficial for you.



What Should I Expect with My Recovery?

Treatment with SI-LOK™ Sacroiliac Joint Fixation may help you return to normal activities. Recovery time for patients will vary and it is important that you talk to your doctor prior to returning to full weight bearing activities following surgery.

A positive attitude, reasonable expectations and compliance with your doctor's post-surgical instructions may all contribute to a satisfactory outcome.

Contraindications and Warnings

You may be contraindicated for this device if you have an infection, a congenital abnormality, are obese, pregnant, mentally ill, diabetic, suffer from rheumatoid arthritis, osteoporosis, or cancer.

As with any surgical procedure, complications may occur following the placement of this device. These can include but are not limited to early or late implant bending, failure, loosening, movement/migration, bone fracture, and allergic reaction to implant material.

Other general complications associated with any spinal procedure include non-union or delayed union, pseudarthrosis, pain, second surgery, bleeding, early or late infection, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, cardiovascular system compromise, respiratory problems, complications due to bone grafting, reactions to anesthesia, impotence, sexual dysfunction, paralysis, and death.

This list does not include all possible contraindications, complications, warnings, or precautions. Please consult with your surgeon for additional information on this topic and how it applies to your particular medical condition.

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