PATIENT INFORMATION

SACROILIAC JOINT FIXATION

SI-LOK®

Life moves us

Outside the US Only

GLOBUS MEDICAL

SI-LOK®
Sacroiliac Joint Fixation

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 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 healthcare 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.

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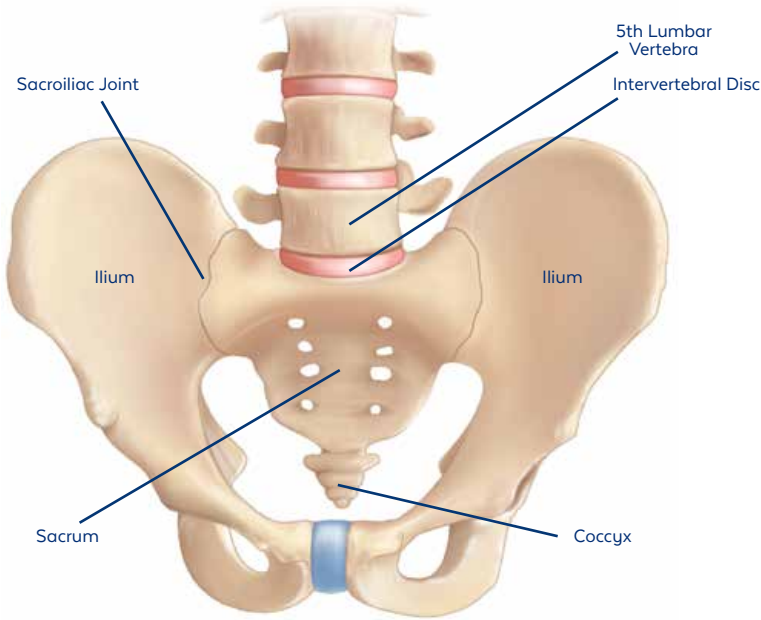
Anatomy of the Sacroiliac Joint

The sacroiliac (SI) joint connects the sacrum, which is the second lowest bony portion of the spine, with the hip bones (ilium) on each side.

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

The SI joint typically has the following characteristics:

- Reinforced by strong ligaments and muscles
- Limited in motion
- Transfers most of the weight loads from the upper body to the pelvis (area where your hips and groin are located) 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.

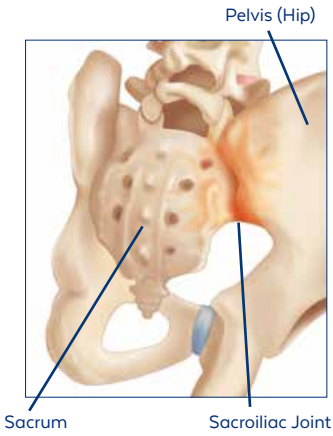
The pain typically worsens with standing and walking, and can be less severe when lying down. Swelling and arthritis in the SI joint can also cause pain and stiffness in the pelvis.

Causes

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

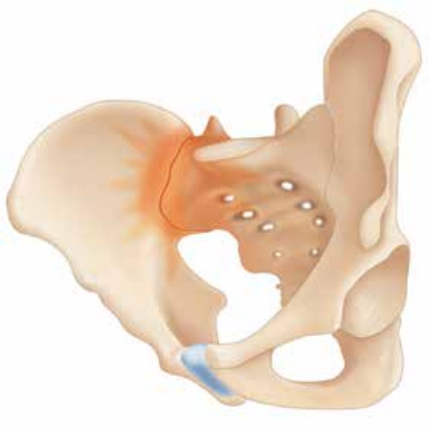
Typical causes of SI joint dysfunction include:

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

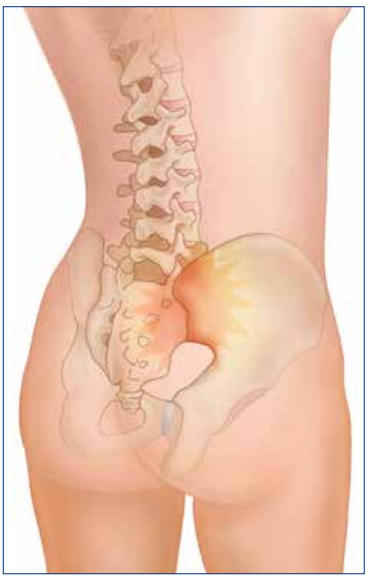


Chronic Sacroiliac Joint Dysfunction

SI joint dysfunction is a condition in which the patient has chronic pain associated with the SI joint. Sacroiliitis 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, groin, and limb pain. SI joint problems can result in issues with surrounding ligaments and muscles.

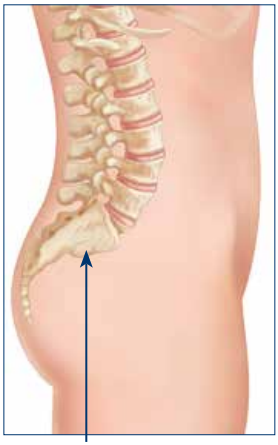


How Is the Procedure Performed?

The SI-LOK® Sacroiliac Joint Fixation System is used for SI joint fusion (joining of two bones) to treat SI joint dysfunction and sacroiliitis.

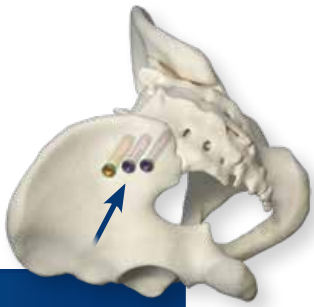
A standard or a minimally invasive (using small incisions) surgical approach (direction of surgery) may be used to implant SI-LOK®.

A small incision is made, using X-rays to view your anatomy during surgery.



Incision Site

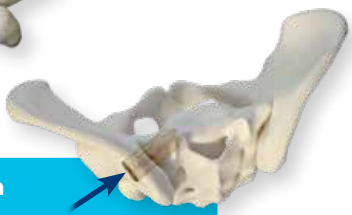
SI-LOK® or SI-LOK® SELECT screws may be used for treatment. SI-LOK® can be placed through a posterior surgical approach, while SI-LOK® SELECT can be placed in three different approaches, as shown below. The surgeon selects an approach based on your anatomy and their preferred technique.



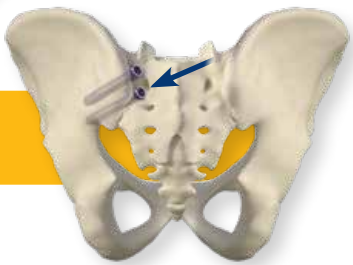
Lateral Approach

Three approach options:

- Lateral
- Posterior (back)—lateral to medial (middle)
- Posterior (back)—medial to lateral



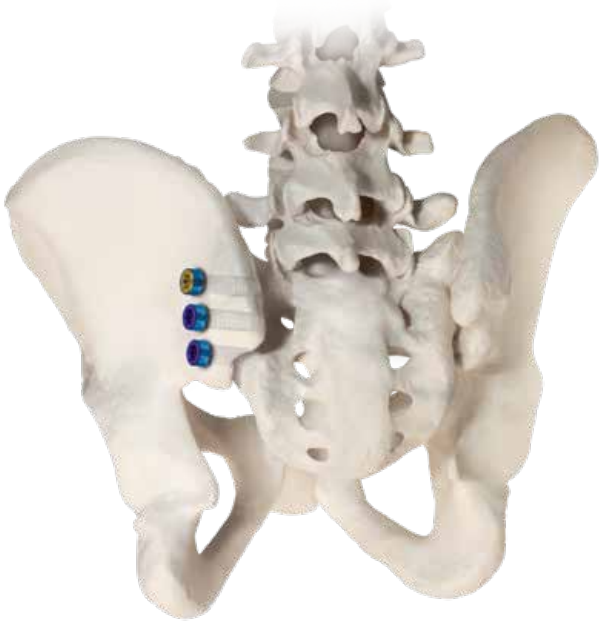
Posterior Approach
Lateral to Medial



Posterior Approach
Medial to Lateral

How Is the Procedure Performed? (Cont'd)

The surfaces of the SI joint are prepared and screws are then placed across the joint space. These implants may also be coated with hydroxyapatite (a mineral found in bone). 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.

Frequently Asked Questions

What Should I Expect with My Recovery?

Treatment with SI-LOK® SI 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.

How Long Will My Implant Last?

The device lifetime for these implants is one year, in which it is expected that the devices will achieve their intended purpose (to support fusion) and maintain performance until fusion occurs. After fusion occurs, the devices are made to survive the life of the patient.

Can I Have an MRI After The Devices are Implanted?

SI-LOK® SI joint fixation has not been evaluated for safety and compatibility in the MR environment, and these devices have not been tested for heating or migration in the MR environment.

Contraindications and Adverse Effects

You may be contraindicated (not suitable) for this device if you have an infection, fever or high white blood cell count, congenital abnormality, tumors, certain allergies, rheumatoid arthritis, osteoarthritis, osteopenia, osteoporosis, or cancer, or are obese, pregnant, or diabetic. In addition, patients whose mental or physical impairment places undue stresses on the implant during healing may be at a higher risk of implant failure.

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

Other adverse effects that may be associated with any spinal procedure include non-union or delayed union, pseudarthrosis, pain, secondary surgery, bleeding, infection, staining, tumor formation and/or autoimmune disease, loss of spinal mobility, spinal cord and/or nerve damage, incisional complication, scar formation, blood vessel damage, organ damage, tissue damage, cardiovascular system compromise, respiratory problems, complications due to bone grafting, reactions to anesthesia, inability to perform activities of daily living, impotence, sexual dysfunction, paralysis, and death.

If you experience any of the above adverse effects, please contact a health professional. This list does not include all possible contraindications and adverse effects. Please consult your surgeon for additional information on this topic and how it applies to your particular medical condition.

If you experience a serious adverse event in relation to the implanted device, please report the incident to your local health authority and to Globus Medical. Some health authorities are listed below for your convenience.

Region	Authority	Website
All	Globus Medical	https://www.globusmedical.com/international/about/contact/
Australia	Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/
New Zealand	Medicines and Medical Device Safety Authority (MEDSAFE)	https://www.medsafe.govt.nz/
United Kingdom	Medicines and Healthcare Products Regulatory Agency (MHRA)	https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
Other	Report to your local health authority per local guidelines	

About Globus Medical: Globus Medical, Inc. is a leading musculoskeletal implant company based in Audubon, PA. The company was founded in 2003 by an experienced team of professionals with a shared vision to create products that enable surgeons to promote healing in patients with musculoskeletal disorders.

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