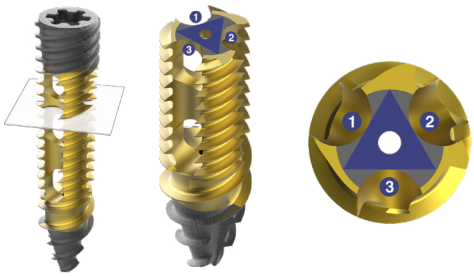
SACRIX



The Sacrix® titanium triangular implant (TTI) uses a 3 axial bone graft reservoir design with the following benefit targets:

- Promote stable fusion with 3 graft locations
- Graft reservoir edges support autograft harvest during insertion
- Bone growth in the triangular reservoirs support anti-rotation of the implant

Sacrix® Sacroiliac Joint Fusion System

Instructions for Use

CAUTION: U.S.A. Law restricts this device to sale by or on the order of a physician.

PURPOSE: The **Sacrix® Sacroiliac Joint Fusion System** is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

DESCRIPTION: The **Sacrix® Sacroiliac Joint Fusion System** is intended to be used from a lateral oblique approach. Implants are available in varying diameters and lengths, and are fabricated from medical grade titanium alloy (Ti-6Al-4V ELI). Implants are provided both sterile and non-sterile, and are intended for single use only.

Implants, instruments, and other components of the **Sacrix® Sacroiliac Joint Fusion System** are not designed to be used in conjunction with any other surgical systems.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:

The **Sacrix® Sacroiliac Joint Fusion System** is intended for fusion of the sacroiliac joint for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

CONTRAINDICATIONS:

Contraindications include but are not limited to:

- Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
- Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopedic implants. Patients with severe obesity, osteopenia, or degenerative diseases may place excessive stresses on bone and implants and may be at higher risk of implant failure.
- Conditions that reduce the likelihood of successful fusion, such as radio- or chemotherapy for cancer, kidney dialysis, or osteopenia are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician, taking into account the risks versus the benefits to the patient.
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, lifestyle may interfere with their ability to follow post operative restrictions and who may place undue stresses on the implant during bony healing and may be at higher risk of implant failure.

POTENTIAL ADVERSE EFFECTS:

This list may not include all complications caused by the surgical procedure itself. Potential adverse events include but are not limited to:

1. Nonunion or delayed union.
2. Bending or fracture of implant. Loosening of the implant.
3. Metal sensitivity or allergic reaction to a foreign body.
4. Infection, early or late.
5. Decrease in bone density due to stress shielding.
6. Pain, discomfort, or abnormal sensations due to the presence of the device.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia.
8. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could cause erosion of these vessels and catastrophic bleeding in the late post-operative period.
9. Bursitis.
10. Paralysis.
11. Reflex sympathetic dystrophy.
12. Solid and Fenestrated Implant back-out, possibly leading to implant loosening and/or re-operation for device removal.
13. Fracture of bony structures.
14. Death.

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

WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS:

The following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to internal fixation devices. General surgical risks should be explained to the patient before surgery.

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing. Due to limitations imposed by anatomic considerations and modern surgical materials, implants cannot be made to last indefinitely.

2. MIXING METALS CAN CAUSE CORROSION. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as screws, that come into contact with other metal objects, must be made from like or compatible materials.

3. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

a. Previous Surgery: Patients with previous surgery at the area(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

b. The patient's weight. An overweight or obese patient can produce loads on the device which can lead to failure of the appliance and the operation.

c. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing the patient may not be able to return to these activities successfully.

d. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the device, leading to implant failure or other complications.

e. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the device. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.

f. Foreign body sensitivity. Where material allergy or sensitivity is suspected, appropriate tests (such as skin sensitivity testing) should be made prior to implant selection or use. The surgeon is advised that no pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

g. Smoking. Smoking has been shown to cause diffuse degeneration and slowing of fusion. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

h. Poor Bone Quality. Conditions such as osteoporosis increase the risk of bone fracture during the surgical procedure and may prevent adequate fixation of the implant after implantation.

4. PREVENT NERVE DAMAGE. Caution should be taken when using instruments to avoid the sacral foramen, nerve roots, and other structures of the nervous system.

5. DELAYED FUSION. If bony fusion does not occur within an expected period of time, the system may become fatigued due to the high and sustained loading of these devices. This has been noted in patients with pseudarthrosis or non-union and can result in the need to revise the device(s).

6. MAGNETIC RESONANCE (MR). The **Sacrix® Sacroiliac Joint Fusion System** has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Sacrix® Sacroiliac Joint Fusion System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction

PRECAUTION:

1. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT**. The operating surgeon should avoid any notching, scratching or bending of the devices during implantation. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage of the implant. Do not use implant if damage is suspected. Excessive torque applied to the implants when seating into bone may cause failure of the bone resulting in stripped threads and/or compromised implant purchase.

2. **IMPLANT TRAJECTORY**. Excessive angling of the implants from the lateral or posterior approach may cause breaching of the Sacral Cortices or Sacral Foramen.

3. **A SUCCESSFUL RESULT IS NOT ALWAYS ACHIEVED IN EVERY SURGICAL CASE**. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results.

4. Preoperative and operating procedure, including knowledge of surgical techniques and proper selection and placement of the fixation implants, are important considerations in the successful utilization of the system by the surgeon.

5. The physician/surgeon should consider patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

PHYSICIAN NOTE:Sacroiliac Joint Fusion should only be undertaken after the surgeon has had hands-on training in these methods of spinal fixation, and has become thoroughly knowledgeable about spinal anatomy and biomechanics. Surgical technique manuals are available for detailed instructions on the correct use of the **Sacrix® Sacroiliac Joint Fusion System**. Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product. Even for surgeons already experienced in spinal instrumentation and procedures, new skills may be required that are best learned by working with an experienced surgeon or through a course of formal instruction with laboratory training. Lack of experience or expertise with these metal implants may result in complications.

Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

DEVICE FIXATION: Refer to the **Sacrix® Sacroiliac Joint Fusion System** Surgical Technique for instructions for implant and instrument use.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or pre-dispositions such as those addressed in the previous contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. Notches, scratches or bending of the implant during the course of surgery may contribute to non-union or mechanical failure.
5. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
6. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the device to verify that all parts and necessary instruments are present before surgery begins. The **Sacrix® Sacroiliac Joint Fusion System** components (described in the DESCRIPTION section) are not be combined with the components from another system or manufacturer. Dissimilar metals in contact, such as titanium and stainless steel, can accelerate the corrosion process of stainless steel.
7. Before use, instruments and implants should be visually inspected and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, DO NOT USE!
8. Before use, all instruments and implants are to be checked for debris, or other foreign contaminants. If any instruments or implants are observed to have any foreign debris or other contaminants, the entire convenience kit is to be returned to central processing for cleaning per the listed instructions. DO NOT USE!

INTRAOPERATIVE:

1. Extreme caution should be used around the sacral foramen, nerve roots, and insertion of instruments near the sacral cortices. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. Caution must be taken to avoid over-insertion of the implants to prevent impingement of the sacral foramen.

POSTOPERATIVE:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation. The risk of bending, loosening, or breaking of an internal fixation device during postoperative rehabilitation may be increased if the patient is active. The surgeon should instruct the patient on the amount of time after surgery before resuming any physical activity that they determine to be adequate. The patient should be warned to avoid falls, sudden jolts, or sudden blows directly to or near the operative area.
2. The surgeon should inform the patient of the seriousness of the procedure performed and the limitations of the device(s) implanted. The surgeon should instruct the patient to limit or restrict physical activities, especially lifting and twisting motions, and any other activities that they identify that may cause large forces to be placed on the Sacroiliac Joint (i.e. sport activities). The surgeon should also instruct the patient on how to properly recover during the healing process (i.e. range of motion, limiting physical activities, etc.) that they determine to be necessary.
3. Patients should be instructed not to smoke, consume alcohol, or consume non-steroidals and aspirin, as determined by the surgeon. Patients should follow all surgeon postoperative activities and follow ups.
4. Implant should be revised or removed if appropriate for the following conditions: non-union, pseudoarthrosis, fractured implant, or if the surgeon determines the implant needs to be revised or removed for other reasons.

PRECAUTION:

Surgical implants must never be reused. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the **Sacrix® Sacroiliac Joint Fusion System** components should never be reused under any circumstances.

PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to LESspine®.

CARE AND HANDLING:

- Refer to ASTM standard F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Care should be taken to protect implants from mechanical damage.
- All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the implant or instrumentation.
- Before use, instruments should be visually inspected and function should be tested to assure instruments are functioning properly. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, DO NOT USE!

CLEANING AND DECONTAMINATION:

Instruments are to be disassembled as needed according to CI-42-00001 "Sacrix System Assembly/Disassembly Instructions for Cleaning" and cleaned according to CI-99-00001 "LESspine Cleaning Instructions - Instruments" prior to sterilization and introduction into the sterile surgical field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be decontaminated and cleaned prior to sterilization and reintroduction into a sterile surgical field.

All devices should be positioned to allow sterilant to come in contact with all surfaces. on and reintroduction into a sterile surgical field. All devices should be positioned to allow sterilant to come in contact with all surfaces.

STERILIZATION:

Sacrix® Sacroiliac Joint Fusion System Solid and Fenestrated Implants are provided both sterile and non-sterile. Product provided sterile is clearly labeled, supplied for single use only, and are not to be re-sterilized. Do not use if damage has occurred to the device or if the sterilization barrier has been damaged or broken. Do not use after the "use by" (expiration) date printed on the label. Store in a cool, dry area.

Product not marked sterile by its label are provided non-sterile and should be stored in their original packaging until sterilized according to the recommended guidelines listed below. Implants are single-use devices, thus do not clean or re-sterilize an implant that has been in contact with or contaminated by blood or other infectious substances. The manufacturer and distributor assume no responsibility for cleaning and re-sterilization of sterilizable implants, components, or reusable instruments performed by the individual or hospital. The instrumentation of the **Sacrix® Sacroiliac Joint Fusion System** is supplied non-sterile.

ISO 8828 or AORN recommended practices for in-hospital sterilization to meet a SAL of 10-6 should be followed for all components.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications listed below.

STEAM STERILIZATION			
Sterilizer Type:	Minimum Temperature:	Exposure Time:	Minimum Dry Time:
Pre-Vacuum	270°F (132°C)	4 minutes	20 minutes

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Instruments cases are not to be externally stacked.

PRODUCTS COMPLAINTS:

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or LESspine®. Further, if any of the implanted **Sacrix® Sacroiliac Joint Fusion System** component(s) ever "malfunctions", (i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any LESspine® product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax or written correspondence. When filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

SYMBOL DEFINITION TABLE		
USE BY	DO NOT USE IF PACKAGE IS DAMAGED	MANUFACTURER
STERILE R STERILIZED USING IRRADIATION	REF CATALOGUE NUMBER	UDI UNIQUE DEVICE IDENTIFICATION
DO NOT REUSE	CAUTION (see note 1)*	Rx Only PRESCRIPTION ONLY

* Note 1: Caution. Consult Accompanying Documents. Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.

LIMITED WARRANTY AND DISCLAIMER:

LESspine® PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT LESspine®, FOR CURRENT INFORMATION AT LESspine®, Inc.

FURTHER INFORMATION:

In case of complaint, or for supplementary information, or further directions for use of this system, please see the address on this page.

Manufacturer Customer Service Department
LESspine Innovations
200 Summit Drive, Suite 505
Burlington, MA 01803
P: (978) 232-3990

IFU-42-00001 Rev. E

LESspine
Less Exposure Surgery Technologies