Spinal Simplicity Liberty SI Lateral Implant System

IMPORTANT INFORMATION ON THE LIBERTY SI LATERAL IMPLANT SYSTEM

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Rx only

STERILE R

ENGLISH IMPORTANT INFORMATION ON THE LIBERTY SI LATERAL IMPLANT SYSTEM

Purpose:
The Liberty SI Lateral Implant System is a minimally invasive sacroiliac (SI) joint fusion implant that is intended for implantation across the joint space (i.e., the implant transfixes the SI joint) for the purpose of stabilizing and fusing the SI joint. The Liberty SI Lateral Implant is placed using a lateral minimally invasive procedure supported by dedicated instruments.

Description:
The Liberty SI Lateral Implant is made of titanium alloy Ti-6Al-4V ELI per ASTM F136 and features a hydroxyapatite coating per ASTM F1185. The Liberty SI Lateral Implant is available in two (2) diameters, 10mm and 12mm, and various lengths to accommodate patient anatomy. Bone graft materials may be used with the Liberty SI Lateral Implant. The Liberty SI Lateral Implant is individually packaged in sterile condition.

MRI Safety Information:
The Liberty SI Lateral Implant 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 the Liberty SI Lateral Implant in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in patient injury or device malfunction.

Indications for Use:
The Liberty SI Lateral Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Contraindications:
The Liberty SI Lateral Implant System is contraindicated in patients with:

- An allergy to titanium or titanium alloy
- Active systemic infection or infection localized to the site of implantation
- Insufficient quality or quantity of bone, which would not accept the device
- Pregnancy
- Deformities or anatomic variations that would prevent implantation of the device, or cause the device to be unstable
- Tumor of sacral or ilium bone
- Morbid obesity
- Mental illness
- Any medical or surgical condition which would preclude the potential benefit of spinal implant procedures, such as the presence of tumors or congenital abnormalities
- Any case where metals must be mixed from different components
- Any case where the implant components selected for use would be too large or too small to achieve a successful result
- Any case in which implant utilization would interfere with anatomical structures or expected physiological performance
- Any patient unwilling to follow post-operative instructions

Possible Adverse Effects:
Device related:

- Implant dislodgement/migration
- Implant not positioned correctly
- Bone fracture
- Additional surgery, including removal of the Liberty SI Lateral Implant
- Foreign body reaction including irritation or sensitivity to the implants due to an allergic reaction to the metal implants
- Mechanical failure of the device
- Failure of the device/procedure to improve symptoms and/or function
- Pain, discomfort, and/or abnormal sensations due to the presence of the implant in the body
- Infection
- Instrument failure resulting in a complication
- Nerve root or peripheral nerve root irritation due to local swelling, placement of instrumentation, or altered biomechanics
- Increased pain at operative or adjacent levels
- Potential difficulty delivering a fetus vaginally due to restriction of the SI joint by the implanted device
- Decrease in bone density
- Loss of spinal mobility or function
- Inability to perform activities of daily living

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Procedure related:

- Myocardial infarction
- Development of respiratory problems, including pulmonary embolism, venous thrombosis, lung embolism and cardiac arrest
- Infection
- Blood vessel damage/bleeding (Hemorrhage)
- Deep vein thrombosis
- Hematoma or bleeding
- Pneumonia
- Neurological system compromise including neurological defect, nerve root or peripheral nerve irritation, damage, or injury
- Stroke
- Paralysis
- Thrombus formation and/or thrombophlebitis
- Dural Tear
- Wound dehiscence and delayed healing
- Pain/discomfort at the operative site
- Negative or adverse reactions to anesthesia
- Muscle/tissue damage
- Bruising and/or local swelling
- Vascular injury or damage that could result in catastrophic or fatal injury
- Damage to the lymphatic vessels and/or lymphatic fluid exudation
- Injury to pelvis and intra-pelvic structures
- Radiation exposure
- Scar formation causing neurologic compromise or pain
- Numbness or tingling
- Injury to organs including urinary retention, loss of bladder, or other types of urologic system compromise
- Gastrointestinal system compromise
- Reproductive system compromise including sterility, sexual dysfunction
- Death

Additional surgery may be necessary to correct some of these effects.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of fracture fixation of large bones and large bone fragments of the pelvis.

These warnings do not include all adverse effects which could occur with spinal procedures in general but are important considerations particular to orthopedic implants. General spinal procedure risks should be explained to the patient prior to the implantation procedure.

Warnings:
Titanium implants should not be mixed with stainless steel implants in the same construct. A successful result is not always achieved in every case. This fact is especially true in sacroiliac (SI) joint procedures, where many extenuating circumstances may compromise the results.

Women with the potential for childbearing should be cautioned that vaginal delivery of a fetus may not be advisable following fusion of the SI joint. If a pregnancy is possible or occurs, women should review delivery options with her physician.

Precautions:
Preoperative and operating procedures, including knowledge of implantation techniques and proper selection and placement of implants, are important considerations in the successful utilization of the Liberty SI Lateral Implant by the physician. Further, the proper selection and compliance of the patient will greatly affect the results. Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of the consequences. Obese, malnourished, and/or alcoholic patients are poor candidates for sacroiliac fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for sacroiliac fusion. Patients should be instructed to adhere to the post operative physical activity instructions from his or her physician to support long term service life of the implant.

The physician must be fully conversant with all aspects of the implantation technique and know the indicators and contra-indicators of this type of implant. Before beginning the procedure, the physician must be acquainted with the specific technique for insertion of the implant, which is available from the manufacturer. Pre-operative imaging including x-rays and/or CT scans may be helpful in implant size selection as careful attention to the appropriate implant size is needed.

Never re-use any implant even if it appears unmarked or undamaged. Any implant implanted and then removed must be discarded.

Use only new implants for each case. Implants are not to be re-sterilized.

General Conditions of Use:
The information contained in this package insert is necessary but not sufficient for the use of this device. This information is not intended as a substitute for the professional judgment, skill and experience of the physician in: careful patient selection; preoperative planning; device selection; knowledge of the anatomy and biomechanics of the SI Joint; understanding of the material and the mechanical characteristics of the implants used; training and skill in both spinal procedures and use of associated instruments for implantation; securing the patient's cooperation in following an appropriately defined postoperative management program, and conducting postoperative follow-up examinations.

Preoperative:

- As part of the preoperative examination, the physician must check that no factors, especially biological and biomechanical, will affect the correct performance of the implant during the operation and postoperative period.
- Only patients that meet the criteria described in the Indications For Use should be selected.
- Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindications should not be selected.
- Care should be used in the handling and storage of the Liberty SI Lateral Implant. Implants and instruments should be protected during storage, especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the procedure. Based on the fatigue testing results, the physician should consider location of implantation, patient weight, patient activity level, other patient conditions, etc. which may have an impact on the performance of the Liberty SI Lateral Implant. An adequate inventory of implant(s) should be available at the time of the procedure. An optional second implant may be placed for additional stabilization of the SI joint at the physician's discretion.
- Since mechanical parts are involved, the physician should be familiar with the various instruments before using the equipment and should personally assemble each device to be used to verify that all parts and necessary instruments are present before the procedure begins. Damaged or defective instruments should not be used. Contact the manufacturer for repair or replacement instructions.
- Additional sterile components should be available in case of an unexpected need.

Intraoperative:

- At all times, extreme caution should be used around the vascular structures and nerve roots. Damage to nerves may result in loss of neurological functions.
- Breakage, slippage or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The correct positioning of the implant is extremely important to allow maximum chances for a successful result.
- To insert the Liberty SI Lateral Implant, a guide wire may be used, followed by a sharp drill. Ensure that the guide wire, if used, is not inserted too deep, becomes bent, and/or breaks. Also ensure that the guide wire does not advance during drilling and/or implant insertion. Remove the guide wire and confirm that it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
- Full implant Wing deployment is necessary to allow for compression across the SI joint. Verify using fluoroscopy that implant Wings are fully deployed in the cancellous bone of the sacrum. If resistance is felt during wing deployment, it is likely that the Wings are not fully advanced into the cancellous bone of the sacrum. Advance the implant a small amount (a half to one full revolution) and again attempt to deploy the Wings. Continue in this manner until the Wings are fully deployed. If the Wings cannot be deployed, the device should not be implanted and should be removed from the patient.

Postoperative:

- The physician's postoperative directions and warnings to the corresponding patient are important to allow maximum chances for a successful result. Detailed instructions on the use and limitations of the device should be given to the patient. If excessive or early weight-bearing, or excessive muscular activity is discouraged during the early postoperative rehabilitation period, the patient must be warned that bending, loosening or breakage of the components are complications which can occur as a result of this activity. The risks of bending, loosening or breakage of the components are complications which can also occur if the patient is debilitated, demented, or using weight supporting devices. The patient should be warned to avoid falls or sudden jolts to lessen the possibility for bending, loosening or breakage of the device.
- To allow maximum chances for a successful result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility, and instructed to limit physical activities, especially lifting, twisting and any type of sport participation. The patient should be advised not to smoke, utilize nicotine products or consume alcohol or nonsteroidal anti-inflammatory drugs such as aspirin during the bone fusion process.
- If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s).
- The patient should be fully instructed in the appropriate postoperative care. The patient's ability and willingness to follow, as well as comprehension of the importance of following instructions are one of the most important aspects of successful postoperative healing.
- Explanted implants must never be reused.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics should be considered, especially for patients with increased risk for infection.

Sterility:
Gamma irradiation is indicated by the "Sterile-R" symbol on the Liberty SI Lateral Implant labeling. These devices remain sterile as long as the package's integrity has not been violated.

Packaging:
Packages for each of the Liberty SI Lateral Implant should be intact upon receipt. Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded.

Once opened, the component must be used, discarded, or returned to the manufacturer. Damaged packages or products should never be used and should be returned to the manufacturer.

Handling and storage:
The Liberty SI Lateral Implant and instruments must be stored with care. Before use, inspect all instrumentation for proper function, possible damage, wear or non-function. Damaged or defective instruments should not be used. Note: At some point in time, instruments wear out and should be replaced. Contact the manufacturer for repair or replacement instructions.

Recommendations for Care and Cleaning of the Liberty SI Lateral Implant Instrument System (Instruments, Cases, and Trays):

After completion of the procedure, it is recommended to immediately remove gross soil using either single-use, non-shedding wipes soaked in cleaning solution or transfer of the medical devices into a water bath to prevent drying of soil and contaminants in and on the instrumentation.

Both physical and chemical (detergent) processes are necessary to minimize the bioburden on all soiled items. Chemical (detergent) cleaners alone cannot remove all soil and debris; therefore, a careful manual cleaning of each item is essential for maximum decontamination. Spinal Simplicity recommends the use of a mild enzymatic detergent with a near-neutral pH prepared following the manufacturer's instructions for preparation and use. Saline solution should NOT be used, as saline has a corrosive effect on stainless steel. Remove heavy or large debris using single-use, non-shedding wipes soaked in cleaning solution. Immerse instruments in a prepared bath. Using a soft bristle brush (do not use steel brushes) brush all surfaces of the instruments while they are submerged in bath, ensuring that all visible soil is removed. Whenever applicable use a pipe cleaner and syringe to clean all cannulae, lumens, crevices, grooves and hard to reach areas. Repeatedly operate/bend/articulate all movable components while cleaning. Allow instruments to soak in detergent prepared bath for manufacturer's recommended soaking time.

Final cleaning and disinfecting should be performed via sonication or an automated washer/disinfector cycle. See below recommendations for each:

Sonication:
1. Remove the instruments from bath and rinse in utility water (per ANSI/AAMI ST108) for a minimum of 3 minutes. Thoroughly and aggressively flush lumen, holes, and difficult-to-reach areas.
2. Place prepared cleaning agents in a sonication unit. Completely submerge instruments in cleaning solution and sonicate for 10 minutes at 45-50 kHz.
3. Rinse instruments in critical water (per ANSI/AAMI ST108) for at least 3 minutes.
4. Visually inspect to determine if all visible soil has been removed from the surfaces, lumen, cannulae, crevices, serrations, threading, etc. If visible soil remains, repeat the cleaning/disinfecting procedure.
5. Dry the instruments with single-use, non-shedding absorbent wipes and/or medical compressed air (e.g., interiors and cannulae). Be sure to completely dry the instruments immediately after rinse to inhibit corrosion.

Automated Washer:
1. Remove instruments from bath and rinse in utility water for a minimum of 1 minute. Thoroughly and aggressively flush lumen, holes, and difficult-to-reach areas.
2. Place instruments in a suitable washer/disinfector basket and process through a standard washer/disinfector cleaning cycle. The following minimum parameters are essential for thorough cleaning and disinfecting.
   a. 2 minute prewash with cold utility water
   b. 20 second enzyme spray with hot utility water
   c. 1 minute enzyme soak
   d. 15 second cold utility water rinse
   e. 2 minute detergent wash with hot utility water (64-66°C/146-150°F)
   f. 15 second hot utility water rinse
   g. 2 minute thermal rinse (80-93°C/176-200°F)
   h. 10 second critical water rinse (64-66°C/146-150°F)
   i. 7 to 30 minute hot air dry (116°C/240°F)

   NOTE: The washer/disinfector manufacturer's instructions should be strictly adhered to.
3. Visually inspect to determine if all visible soil has been removed from the surfaces, lumen, cannulae, crevices, serrations, threading, etc. If visible soil remains, repeat the cleaning/disinfecting procedure.

Caution: certain cleaning solutions such as those containing formalin, glutaraldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, iodide, and/or alkaline cleaners may damage some instruments. Such cleaning solutions should not be used.

Inspection:
Check all instruments for corrosion, damage to surfaces, chipping, pitting, discoloration, and contaminants. Remove and adequately dispose of any instruments that show signs of damage.

Recommendations for Sterilization of the Liberty SI Lateral Implant Instrument System (Instruments, Cases, and Trays):
For typical steam autoclave cycles, the following are recommended times and temperatures:

1. Prevacuum Sterilizer:
Wrapped cases, trays and instruments, or cases, trays and instruments should be exposed to 135° C (275° F) for 3 minutes. Dry for 30 minutes. A legally marketed, FDA-cleared sterilization barrier (e.g., wrap, pouch, or container) should be used to maintain sterility after processing.

Caution: Do not stack trays during sterilization.

Product Complaints:
Communicate suspected deficiencies in product quality, identity, durability, reliability, safety, effectiveness and/or performance directly to Spinal Simplicity, LLC. When filing a complaint provide component name(s), part number(s), lot number(s), your name and address, the nature of the complaint and patient case number. Sterilize and return all component(s) to Spinal Simplicity, LLC. Notify Spinal Simplicity, LLC immediately of any complaints and any incidents resulting in patient death or serious injury.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Symbols Glossary

Symbol	Symbol Title	Explanatory Text	Standard Text	Standard Reference
	Manufacturer	Indicates the Medical Device Manufacturer	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.1
	Date of Manufacture	Indicates the date when the medical device was manufactured	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.3
	Use-By-Date	Indicates the date after which the medical device is not to be used	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.4
	Lot Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	Medical devices — Symbols to be used with information to be supplied by the manufacturer —Part 1: General requirements	ISO 15223-1 Reference #5.1.5
	Catalogue Number	Indicates the manufacturer's Catalogue number so that the medical device can be identified	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.1.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.2.4
	Do not re-use	Indicates a medical device that is intended for one single use only	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.4.2
	Do not use if packaged is damaged	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.2.8
	Consult instruction for use	Indicates the need for the user to consult the instructions for use	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	ISO 15223-1 Reference #5.4.3
	Prescription Only	Caution: Federal law restricts this device to sale by or on the order of a physician	US FDA Code of Federal Regulations	21 CFR 801.15(c)(1)(i)F and 21 CFR 801.109
	Quantity	Custom symbol denotes Quantity per box	NA	NA
	Diameter	Custom symbol indicates the Diameter	NA	NA
	Length	Custom symbol indicates the minimum/maximum Lengths	NA	NA
	Size	Custom symbol indicates Size	NA	NA