Spinal Simplicity Patriot-SI Posterior Implant System

IMPORTANT INFORMATION ON THE PATRIOT-SI POSTERIOR IMPLANT SYSTEM

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Rx Only

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ENGLISH IMPORTANT INFORMATION ON THE PATRIOT-SI POSTERIOR IMPLANT SYSTEM

Purpose:
The Patriot-SI Posterior Implant System is a minimally invasive sacroiliac (SI) joint fusion implant. The Patriot-SI Posterior Implant System is intended for implantation on a trajectory in line with the joint space (i.e., the device is an "in-line" or "intra-articular" implant). The Patriot-SI Posterior Implant System device is required to be implanted with the Spinal Simplicity Liberty-SI Lateral System device implanted across the same sacroiliac joint to create a hybrid SI joint fusion construct for the purpose of stabilizing and fusing the sacroiliac joint. The Patriot-SI Posterior Implant is placed using a posterior minimally invasive procedure supported by dedicated instruments.

Description:
The Patriot-SI Posterior Implant consists of additively manufactured titanium alloy Ti-6Al-4V ELI per ASTM F3001 and features a hydroxyapatite (HA) coating per ASTM F1185 standards. It is available in one size and may be implanted using the designated surgical instruments through a posterior approach, fixating on both the sacrum and ilium. Bone graft materials may be used with the Patriot-SI Posterior Implant System. The Patriot-SI Posterior Implant System is provided sterile and individually packed.

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

Indications for Use:
The Patriot-SI Posterior Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the Patriot-SI Posterior Implant System (i.e., an "in-line" or "intra-articular" device) is implanted, it must be used with a Spinal Simplicity Liberty-SI Lateral System device (i.e., a "transfixing" device) implanted across the same sacroiliac joint to create a hybrid SI joint fusion construct.

Contraindications:
The Patriot-SI Posterior 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
- Unstable fracture of sacrum and/or ilium involving the sacroiliac joint as they may reduce the effectiveness of the implants to temporarily stabilize the affected region for assistance in bony fusion
- Tumor of sacral or iliac bone
- Morbid obesity
- Mental illness
- Any medical or surgical condition which would preclude the potential benefit of SI joint 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
- Any entity or condition that totally precludes the possibility of fusion (i.e., cancer, kidney dialysis, osteopenia)
- Inadequate ability to visualize with proper imaging equipment/bone landmarks

Possible Adverse Effects:
Device related:

- Implant dislodgement/migration
- Implant not positioned correctly
- Bone Fracture
- Additional surgery, including removal of the Patriot-SI Posterior Implant System
- 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 joint mobility or function
- Inability to perform activities of daily living

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 or 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
- Injury to pelvis and intra-pelvic structures
- Damage to the lymphatic vessels and/or lymphatic fluid exudation
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/ or visual deficit
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/ or muscle loss
- Scar formation possibly causing neurological compromise or pain.
- Numbness or tingling
- Damage to the urological and/or gastrointestinal systems resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, consumption, etc.
- Development of respiratory problems, e.g., Pulmonary embolism, bronchitis, pneumonia, etc.
- Difficulty in delivering fetus vaginally due to device-related restrictions of sacroiliac joint stretching
- Reproductive system compromise including sterility, sexual dysfunction
- Radiation exposure
- Death

Additional surgery may be required to correct these potential adverse events and/or outcomes.

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 SI joint procedures in general but are important considerations particular to orthopedic implants. General SI joint procedure risks should be explained to the patient prior to the implantation procedure.

Warnings:
The Patriot-SI Posterior Implant System are not to be connected to the components of devices from another manufacturer. 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 SI joint procedures, where many extenuating circumstances may compromise the results.

Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following sacroiliac joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.

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 Patriot-SI Posterior 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 placement planning.

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 SI joint 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 Patriot-SI Posterior Implant components. 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 Patriot-SI Posterior Implant. An adequate inventory of implant(s) should be available at the time of procedure.
- 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 spinal cord 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 Patriot-SI Posterior Implant, a guide wire may be used, followed by a sharp drill/decorticator or tap. 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 joint and into a location that may cause damage to underlying structures.

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. 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 occur as a result of this activity, or 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. Implant migration may damage nerves or blood vessels.
- 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. Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result. 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 graft healing 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.

Please inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure.

Sterility:

Gamma irradiation is indicated by the “Sterile-R” symbol on the Patriot-SI Posterior Implant labeling. These devices remain sterile as long as the package's integrity has not been violated.

Packaging:
Packages for each of the Patriot-SI Posterior 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. If a loaner or consignment instrument system is used, all sets should be carefully checked for completeness to ensure there is no damage prior to use. Damaged packages or products should never be used and should be returned to the manufacturer.

Handling and storage:
The Patriot-SI Posterior 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 Patriot-SI Posterior Implant Instruments 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 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 Patriot-SI Posterior Implant Instruments 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 at least 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