SI Solutions – OptumSI Implant System Instruction for Use

℞ only

Manufactured for:
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DEVICE DESCRIPTION:

The OptumSI Implant System is a collection of additively manufactured sacroiliac joint (SI) implants and associated instrumentation. The SI implants are diamond-shaped, cannulated devices and are offered in an assortment of sizes to accommodate the individual anatomic and clinical circumstances of each patient. The system utilizes a transverse approach with a lateral or lateral-to-medial trajectory from the ilium to the sacrum. Each implant device comprises of a solid core, surrounded by a dual micro-lattice structure. The intervening lattice structures are characterized by >40% porosity. The system implants are manufactured from Ti-6Al-4V ELI per ASTM F3001.

The OptumSI instruments are reusable; implants are provided as single-use and sterile. Manual surgical instruments are provided **non-sterile** in an instrument set as a part of the OptumSI to facilitate placement, implantation and removal of the system implants.

INDICATIONS FOR USE:

The OptumSI Implant System is intended for sacroiliac fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute and non-traumatic fractures involving the sacroiliac joint.

CONTRAINDICATIONS:

1. Deformities or anatomic variations that prevent or interfere with OptumSI placement
2. Tumor of sacral or iliac bones
3. Active infection at treatment site
4. Unstable fracture of sacrum and/or ilium involving the sacroiliac joint
5. Allergy to metal components

WARNINGS:

1. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
2. Single-use devices (e.g. implant.) must not be reused as they are not designed to perform as intended after their initial use.
3. Caution should be exercised when handling instruments and implants, as they are sharp and can puncture or tear gloves, or cause injury.
4. Follow the instructions and warnings issued by the suppliers of any cleaning solutions and equipment used.
5. Avoid exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion.
6. Cleaning agents with pH of 7-9 are recommended.
7. Highly alkaline conditions (pH > 11) can damage aluminum components.
8. Manual pre-cleaning must be performed prior to Automated Cleaning for all instruments.
9. Soiled or used devices should not be loaded into instrument trays for cleaning in a mechanical washer. Soiled instruments must be processed separate from trays and cases. The instrument trays are designed to be an organization tool for the steam sterilization process, a storage tool for all medical devices and an organizational tool for surgery.
10. The parameters listed are only valid for properly installed, maintained, calibrated and compliant reprocessing equipment in accordance with ISO 15883 and ISO 17665.

PRECAUTIONS:

1. Carefully read and follow all instructions prior to use.
2. Patient Adherence to post-operative physical activity instructions is important to support long-term service life of the implant.
3. Pay careful attention to selection of implant size. Pre-operative X-rays and/or CT scan may be helpful in selecting optimal implant size.
4. Appropriate patient selection is necessary as patient factors such as size and weight may be helpful in selecting optimal implant size.
5. Inspect implants and instruments for damage prior to use. Do not use if damaged or worn. Do not attempt to repair.
6. Do not use any component from an opened or damaged package.
7. Do not use implants after the expiration date.
8. If placing the implants in conjunction with an open procedure, the surgeon should take care not to destabilize the joint prior to placing the implants.

MRI SAFETY INFORMATION:

The OptumSI Implant 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 the OptumSI Implant 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.

RISKS:

As with other surgical procedures used to treat SI Joint conditions, including acute, non-acute, and non-traumatic fractures involving the SI Joint, the risks associated with the OptumSI Implant System surgical procedure include, but are not limited to the following:

1. Adverse reactions to anesthesia
2. Hemorrhage
3. Muscle damage
4. Hematoma or seroma
5. Neurological deficit, nerve root or peripheral nerve injury, irritation or damage
6. Vascular injury or damage that may result in catastrophic or fatal bleeding
7. Neurovascular injury
8. Injury to inter-pelvic structures
9. Infection of the wound, deep infection, peritonitis
10. Wound dehiscence
11. Thrombosis, thrombophlebitis
12. Death
13. Bruising
14. Local swelling
15. Radiation exposure
16. Loss of fracture fixation

Potential risks specifically associated with the OptumSI Implant System include, but are not limited to the following:

1. Infection
2. Pain, discomfort, or abnormal sensations to the presence of the implant
3. Instrument failure resulting in a complication
4. Migration, loosening, or fracture of the implant
5. Pain in muscle(s) due to altered biomechanics
6. Nerve root or peripheral nerve irritation due to local swelling or altered biomechanics
7. Loss of fixation/stabilization
8. Metal sensitivity or allergic reaction
9. Failure to improve symptoms and/or fracture
10. Increased pain at treated or adjacent levels
11. Implant rejection
12. Decrease in bone density due to stress shielding
13. Failure to achieve SI joint fusion
14. Potential difficulty in delivering fetus vaginally due to device-related restriction of SI joint motion
15. Fracture of the sacrum and/or ilium

HOW SUPPLIED:

Implants are provided sterile; do not re-sterilize. The instrumentation is provided separately, non-sterile, and must be sterilized prior to using the **CLEANING** and **STERILIZATION** instructions. See DHF-SI-018 OptumSI Cleaning and Sterilization Instruction for more information.

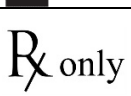
STORAGE/HANDLING:

1. Store packaged implants at room temperature.
2. Handle the OptumSI Implant with care to prevent damage to the device.

DIRECTIONS FOR USE:

1. A minimum of two (2) implants per sacroiliac joint are recommended for treatment. Treatment typically involves at least three (3) OptumSI Implants per SI joint.
2. For detailed information, refer to the relevant Surgical Technique Manual(s) prior to use of the OptumSI Implant System.

GRAPHIC SYMBOL GLOSSARY:

	**Model Number**
	**Lot Number**
	**Serial Number**
	**Quantity**
	**Sterilization by Irradiation**
	**Use by Date**
	**Caution: Federal law restricts this device to sale by or on the order of a physician**
	**Consult Instructions for Use**
	**Do Not Reuse (Single Use)**
	**Manufacturer**
	**Date of Manufacturer**