SImmetry® Sacroiliac Joint Fusion System

CAUTION
Federal (USA) Law restricts this device to sale by or on the order of a physician.

PACKAGE CONTENTS
The package contains one or more of the various components of the SImmetry Sacroiliac Joint Fusion System:
- SImmetry SIJ Fusion Implant 8.5mm
- SImmetry SIJ Fusion Implant 10.5mm
- SImmetry SIJ Fusion Implant 12.5mm
- SImmetry SIJ Fusion Implant 14.5mm
- SImmetry SIJ Fusion Washer 8.5mm
- SImmetry SIJ Fusion Washer 10.5mm
- SImmetry SIJ Fusion Washer 12.5mm
- SImmetry SIJ Fusion Washer 14.5mm

The content of each package is evident from the respective product label.

DESCRIPTION
The SImmetry Sacroiliac Joint Fusion System consists of sterile packaged partially threaded or fully threaded, self-tapping cannulated titanium implants designed to transfix the sacrum and ilium, providing stability for bony fusion. The surgical implants are available in various sizes to accommodate patient anatomy. Implants have major diameters ranging from 8.5mm-14.5mm, in 2mm increments. Lengths in 5mm increments range from 30mm-110mm for fully threaded implants and 50mm to 110mm for partially threaded implants. All partially threaded implants have a pre-assembled washer. Individually sterile packaged washers are available for fully threaded implants having diameters ranging from 8.5mm-14.5mm.

MATERIAL
All SImmetry SIJ Fusion Screws and Washers are made from titanium 6-aluminum 4-vanadium alloy (ISO 5832-3).
The used material contains no nickel.
Not made with natural rubber latex.

INTENDED USE / INDICATION FOR USE
The SImmetry Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. The SImmetry Sacroiliac Joint Fusion System shall only be used by surgeons who are trained and familiar with the implant components, instruments, and surgical technique.

CONTRAINDICATIONS
Customary general contraindications associated with elective surgery should be observed. These include, but are not limited to: pregnancy; sensitivity or allergy to titanium; metabolic bone disease; clotting disorders; current treatment with therapeutic agents that may have an effect on the surgical site, surrounding tissue, or normal healing responses (e.g., chemotherapy, radiation therapy, chronic steroid treatment, anticoagulant therapy, kidney dialysis); or other metabolic or physical disorders that interfere with bone growth, bone maintenance, or wound healing.

Certain degenerative diseases or underlying physiological conditions may alter the healing process or prevent fusion, such as uncontrolled diabetes, active systemic infection, infection localized to the site of the proposed implantation, rheumatoid arthritis, or osteoporosis.

ADVERSE REACTIONS
Adverse reactions may include:
- Nonunion or delayed union
- Bending or fracture of implant
- Screw back out, bone stripping, possibly leading to implant loosening, migration, and/or reoperation
- Fracture of bony structures
- Decrease in peri-implant bone density, necrosis of bone, or bone loss
- Metal sensitivity, or allergic reaction to a foreign body
- Infection, early or late
- Pain, discomfort, or abnormal sensations due to the presence of the implant
- Iatrogenic vessel and/or nerve damage

SAFETY PRECAUTIONS
Correct selection of the implant size is important: The potential for satisfactory fixation, which is dependent on patient anatomy and bone density, is increased by the selection of the proper diameter, length and design of the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant but also in the mechanical and metallurgical aspects. Immobilization of the site should be maintained until firm bony union is established as confirmed by clinical and radiographic examination. It is important to note that these implants may break if they are subjected to an increased load and fatigue associated with delayed union or nonunion.

Correct handling of the implant is important: Avoid any notching, scratching, or bending of the implant. Surface damage may become the focal point for eventual breakage of the implant. Bending of screws will weaken them and may lead to failure.

Provide adequate instructions to 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 must be made aware of the limitations of the implant, and instructed to limit physical activities until bony healing can be verified by the surgeon. Noncompliance with postoperative care, especially prior to complete bone healing, can lead to loosening, back out or even breakage of the implant resulting in the need for a second surgery. It is also important to conduct postoperative examinations to evaluate the development of the patient's fusion mass and the status of implanted device(s).

Surgeons and patients should be aware that in some cases surgical implants may loosen, bend, or break even if solid bony fusion occurs.

MRI COMPATIBILITY
The SImmetry Sacroiliac Joint Fusion System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SImmetry Sacroiliac Joint Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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LBL 1799 Rev. C 2024-001

SIVANTAGE

STORAGE, INSPECTION & STERILIZATION

STORAGE

Store the device at room temperature in a dry and dust-free place. Always store the implant in the original protective packaging. Do not remove the implant from the packaging until immediately before use.

DISINFECTION / CLEANING

The SImmetry screw and washer implants are not designed to be disinfected or cleaned by the user.

RESTERILIZATION

The SImmetry implants and washers are not designed to be re-sterilized by the user.

DISPOSAL

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.
Contact SiVantage or your medical product representative if further information is needed.

TECHNIQUE

The SImmetry Sacroiliac Joint Fusion implants must be implanted only with the applicable SImmetry Sacroiliac Joint Fusion instruments. The instruments are available from the manufacturer at any time.

PREOPERATIVE

The operating surgeon draws up an operation plan specifying and documenting the following:
• Implant component(s) and their dimensions.
• Proper positioning of the implant components.
• Determination of intra-operative orientation points. The following conditions must be fulfilled prior to application:
• All required implant component(s) are readily available.
• Highly aseptic operating conditions are present.
• All requisite implantation instruments must be available and in working order.

Never use or process damaged or defective instruments. Contact your local representative or dealer for repair or replacement.

The use of an instrument for tasks other than those for which they are intended may result in damaged / broken instruments or patient injury.

• The operating surgeon must be especially trained in sacroiliac fusion surgery, biomechanical principles of the SI joint and the relevant operating techniques.
• The operating surgeon and operating room team must be thoroughly familiar with the operating technique, as well as the range of implants and instruments to be applied. Complete information on these subjects must be readily available at the workplace.
The operating procedure must be explained to the patient, and the patient's understanding of the following information must be documented:
• The patient is aware of the risks associated with neurosurgery, general surgery, orthopedic surgery and with general anesthesia.
• The patient has been informed about the advantages and disadvantages of the implant procedure and about possible alternative treatments.
• The implant can fail due to excessive load, wear and tear, or infection
• The service life of the implant is determined by body weight and physical activity. The implant must not be subjected to overload through extreme strain, or through work-related or athletic activities.
• Corrective surgery may be necessary if the implant fails. The patient must have their physician carry out follow-up examinations of the implant at regular intervals.

INTRA-OPERATIVE

Prior to use, please read and become familiar with the SImmetry Sacroiliac Joint Fusion System surgical technique, the corresponding implants and the instruments.

• Prior to use, verify the integrity of the sterile packaging. Never use implants if the packaging is damaged. If damage is found, call your SiVantage representative
• Prior to use, check the product expiration date. Never use implants that are past their expiration date.

The implants are labeled for single use only. Do not re-implant, reprocess, or re-sterilize the implant because this may create a risk of damage or contamination leading to injury, illness, or death of the patient.

IMPORTANT CONSIDERATIONS ON IMPLANT USAGE

Metallic surgical implants provide a means of bone fixation and are often used to aid in the management of fracture and reconstructive surgery; however, metallic implants cannot be made to last indefinitely. These implants are intended to provide internal support while the fusion mass is consolidating, but are not intended to replace normal body structures. Threaded implants, but especially partially threaded implants, require sufficient bony purchase. Bone threads may be inadvertently stripped or the implant heads may be driven into the bone if bone quality is low or if excessive torque is applied.

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

WARNINGS

<u>These devices can break when subjected to loading associated with delayed union or nonunion.</u> All metallic surgical implants are subject to repeated stresses in use, even in the absence of direct weight-bearing, which can result in metal fatigue and implant failure. Factors such as the patient's weight, activity level, and adherence to weight-bearing or load-bearing instructions have an effect on the stresses to which the implant is subjected, and therefore on the life of the implant. Delayed union or nonunion of bone in the presence of weight-bearing or load bearing could eventually cause an implant to break due to metal fatigue.

Vital structures are located adjacent to sacrum. The surgeon must understand the anatomy surrounding the sacrum to avoid perforation of vital structures. Proper implant size selection considering the angle of insertion, and visualization techniques should be used to avoid impingement of surrounding neurovascular structures or screw perforation of vital structures adjacent to the sacrum such as the L5 nerve root, the superior gluteal artery/vein and the superior gluteal and cluneal nerves.

MRI Safety. The SImmetry Sacroiliac Joint Fusion System has not been evaluated for safety and compatibility in the MR environment. The SImmetry Sacroiliac Joint Fusion System has not been tested for heating, migration or image artifacts at or near the implant site.

HOW SUPPLIED

GENERAL INFORMATION REGARDING TECHNIQUE
- Do not use implants that are damaged with scratches, notches or unintentional bending.
- Only use the instruments intended for the respective step.

NOTE
Detailed information regarding the use of the SImmetry Sacroiliac Joint Fusion System can be found in the SImmetry surgical technique guide. Further information regarding the procedure is available in workshops, product training or individual consultation with SiVantage.

POSTOPERATIVE
- Reiterate preoperative instructions to the patient.
- Ensure that the patient is aware of physical activity restrictions and possible adverse reactions.

REVISION SURGERY / IMPLANT REMOVAL
The SImmetry Sacroiliac Joint Fusion System is intended for permanent implantation and is typically not removed. However, removal of the implant can be necessary in the following situations:
- Implant breakage
- Pain due to the implant
- Infection
- Pseudarthrosis
- Allergic reactions

Implants which appear to be intact may have invisible damage.

WARRANTY
All warranty rights are lost if repairs or modifications are carried out by an unauthorized service center. The manufacturer does not take responsibility for any effects on safety, reliability or performance of the product if the product is not used in conformity with these instructions for use. Subject to technical modifications.

FOR FURTHER INFORMATION
Please contact SiVantage, or your medical product representative if further information is needed.

IMPORTANT NOTE
These instructions for use are complete at the time of publishing. The SImmetry Sacroiliac Joint Fusion System may be supplemented with new products in the future. If a new implant is used which is not mentioned in this document, please read the respective instructions for use.

SYMBOLS

	Manufacturer
	Date of manufacture
	Use-by date
LOT	Batch code
REF	Catalog number
QTY	Content of usable units(s)
STERILE R	Sterilized using irradiation
	Do not resterilize
	Do not use if package is damaged
	Keep dry
	Do not reuse
	Consult instructions for use.
	Caution
℞ ONLY	Federal (USA) Law restricts this device to sale by or on the order of a physician

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