SImmetry® Sacroiliac Joint Fusion System

Instructions for Use

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.

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.

INDICATIONS 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

The implant is contraindicated and should not be used on patients with the following:

- 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

WARNINGS/CAUTIONS/PRECAUTIONS

These devices can break when subjected to loading associated with delayed union or nonunion. 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.

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.

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.

POTENTIAL ADVERSE EFFECTS

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

MAGNETIC RESONANCE IMAGING (MRI) SAFETY

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.

GENERAL INSTRUCTIONS FOR USE

This package insert is designed to assist in using surgical instruments only and is not intended to provide information on surgical 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. Contact Surgalign customer service for the specific product Surgical Technique Manual.

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

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 Surgalign Spine Technologies or Paradigm Spine.

STORAGE, INSPECTION & STERILIZATION

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. Please contact Surgalign Spine Technologies, Paradigm Spine, or your medical

product representative if further information is needed.

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.
- 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 Surgalign Spine Technologies 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.

Use the device prior to the “Use By” date on the product label.

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.

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 non-visible damage.

CLEANING & REPROCESSING

Non-Sterile Instruments:

- Instruments must be cleaned and sterilized per the below instructions prior to introduction into a sterile surgical field or (if applicable) return of the product to the manufacturer.
- Neutral pH enzymatic and cleaning agents are recommended and preferred for cleaning instruments. Alkaline or acidic agents may corrode or discolor some stainless steel and aluminum instruments.
- To minimize corrosion and prolong the usable life of instruments used during surgery, remove gross traces of blood and residues then thoroughly clean and dry immediately after use. Do not allow soils to dry.
- Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- Prior to and during use, including reprocessing, inspect instruments for:
    - Damage such as but not limited to, wear, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
    - Proper function including but not limited to, sharpness, movement of hinges and couplings, joint stability, and legible markings.
- Instruments that show signs of damage or an inability to function should not be used and should be returned to the manufacturer.

Note: Decorticators are shipped with their cutting element fully extended and must be cleaned and sterilized in that extended configuration to preclude potential extension and retraction difficulty.

CLEANING

AUTOMATED (MECHANICAL) CLEANING:
Equipment required: Automated washer/disinfector and neutral pH enzymatic detergent

1. Remove the lid and inner tray of the instrument tray. Wash the lid, inner tray and the base of the tray in the separated state. Instruments should be secured in brackets. Do not stack instrument trays.

   DO NOT OPERATE, DISASSEMBLE OR FLUSH the Decorticators as reassembly requires special tools. The internal components of the Decorticators are cleaned prior to shipment to a user facility and therefore disassembly or flushing for pre-surgical cleaning is not required and could render the Decorticators inoperable prior to surgical use. **The flush port on the Decorticator is to be used for POST-SURGICAL cleaning only.**

2. Process the instruments through a standard washer/disinfector cycle. The following parameters are essential for thorough cleaning and disinfection.

Step	Description
1	Pre-wash for 2:00-15:00 min with cold tap water
2	Pulsed-Enzyme Wash for 5:00-15:00 min with hot water using a neutral pH enzymatic cleaner
3	Rinse for 15 sec-15:00 min with hot tap water
4	Wash for 3:00-15:00 min with hot water using a neutral pH enzymatic cleaner
5	Rinse for 15 sec-15:00 min with heated tap water (43.3-82.2°C)
6	Thermal Rinse for 1:00-10:00 min with purified water at 82.2-95.0°C
7	Dry for 6:00-30:00 min at 82.2°C

   Note: Follow the enzymatic cleaner manufacturer's recommendations for water quality, temperature, exposure times and concentration of the enzymatic cleaner. Use only cleaning agents recommended for the specific type of automated washer/disinfector being used.
   Note: The washer/disinfector manufacturer's instructions should be strictly adhered to and a washer/disinfector with approved efficacy (e.g. CE Mark, FDA approval and validation according to ISO 15883) should be used.

3. Inspect each instrument to ensure there is no visible debris.
4. If visible debris remains, repeat cleaning procedures 1 through 3 for the contaminated instruments.

MANUAL CLEANING

Equipment required: Ultrasonic cleaner, soft-bristled nylon brush and pipe cleaners in several diameters and lengths, soft low-linting cloths and compressed air

1. Preparation of Cleaning Agents
    a. Do not prepare cleaning solutions until they are needed.
    b. Select neutral pH enzymatic cleaning agents with low foaming surfactants.
    c. Prepare solution according to manufacturer's instructions, ensuring dry powders are completely dissolved.
2. Remove instruments from the instrument tray.

    DO NOT OPERATE, DISASSEMBLE OR FLUSH the Decorticators as reassembly requires special tools. The internal components of the Decorticators are cleaned prior to shipment to a user facility and therefore disassembly or flushing for pre-surgical cleaning is not required and could render the Decorticators inoperable prior to surgical use. **The flush port on the Decorticator is to be used for POST-SURGICAL cleaning only.**
3. Submerge the instruments in a prepared pH-neutral enzymatic solution and soak for a minimum of 20 minutes.
4. After soaking, gently remove all visible debris on the outside of each instrument by performing the following steps while holding each instrument under the solution level:
    a. Use a soft nylon brush to remove debris.
    b. Use a long narrow nylon brush or pipe cleaner to reach cannulations and other hard-to-clean areas.
    c. Flush all cannulations and other hard-to-clean areas for 20 seconds minimum with the enzymatic solution.
5. Remove all instruments from the enzymatic solution.
6. Rinse all instruments with tap water for a minimum of 3 minutes.
7. Flush all cannulations and other hard-to-clean areas with tap water for a minimum of 20 seconds each.
8. Place the instruments in a sonication unit containing freshly prepared enzymatic solution.
9. Sonicate instruments for a minimum of 15 minutes at the frequency recommended by the manufacturer of the unit.
10. After sonication, remove and rinse all instruments in purified water for a minimum of 3 minutes, ensuring all cannulations, joints, holes and crevices are rinsed and flushed vigorously.
11. Repeat sonication and rinsing procedures 9 and 10 above.
12. Dry the instruments thoroughly with a soft cloth or compressed air.
13. Inspect each instrument to ensure there is no visible debris.
14. If visible debris remains, repeat cleaning steps 1 through 13 for the contaminated instruments.
15. Return instruments to instrument tray.

STERILIZATION

Non-Sterile Instruments:
The autoclave manufacturer's operating instructions and recommended guidelines for maximum sterilization load and load configuration should be followed. The autoclave must be properly installed, maintained and calibrated.

1. Gravity Displacement Cycle

   Sterilize the wrapped instrument tray and any separately wrapped instruments using a steam autoclave at 121°C (250°F) for 30 minutes with a 30-minute drying cycle.

2. Dynamic Air Removal Steam Sterilization Cycle

   Sterilize the wrapped instrument tray and any separately wrapped instruments using a qualified pre-vacuum steam autoclave cycle at 132°C (270°F) for 4 minutes with a 30-minute drying cycle. This same cycle may be used for items that need to be re-sterilized during a surgery.

Table 1: Validated Steam Sterilization Cycles				
Cycle Type	**Cycle Temperature**	**Cycle Exposure Time (wrapped)**	**Recommended Dry Time**	**Special Instructions**
Gravity Displacement	121°C (250°F)	30 minutes	30 minutes	Items shipped outside of the instrument tray must be sterilized outside of the instrument tray.
Dynamic Air Removal	132°C (270°F)	4 minutes	30 minutes	

- Use of an FDA cleared wrap is recommended to ensure product sterility.
- Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted.
- The values specified here (duration/temperature) can achieve a sterility assurance level (SAL) of at least 10^{-6}.

Storage
Reusable devices that will be stored between cleaning and sterilization should be dried with a low-linting, non-abrasive soft cloth to prevent microbial contamination that could result from wet instruments. Non-sterile instrument trays can be stacked for storage.

Sterilized packaged instruments should be stored in a designated, limited-access area that is well ventilated and provides protection from dust, moisture, direct sunlight, pests and extremes of temperature and humidity. Stacking of sterilized instrument trays is not recommended.

Note: Sterile instrument packages should be carefully examined prior to use to ensure that package integrity has not been compromised.

MANUAL CLEANING PROCESS: POST-SURGICAL

Note: This process must be used for instruments that are not to be returned to the distributor.

Note: See the applicable Surgical Technique Manual and addendum for specific instructions regarding cleaning and disassembly.

Note: Clean the Decorticator (ZYG-10121, ZYG-10122, or ZYG-10123) with the cutting element extended. Extend the cutting element by rotating the orange knob clockwise until it stops. Flush the Decorticator with the cutting element pointed down and away.

1. Rinse and/or flush instruments in cool water to remove gross debris. Water temperature should not exceed 45°C (113°F).
2. Follow manual cleaning process steps in applicable Surgical Technique Manual

Note: Decorticator (142-000001, 142-000002, 142-000003) must be disassembled prior to cleaning per Surgical Technique Guide and addendum.

PRODUCT COMPLAINTS

Complaints or dissatisfaction with the device quality, safety, reliability, durability, effectiveness and/or performance, brought forth by a health care professional, whether via a customer or user of the product, should be immediately conveyed to Surgalign customer service via telephone at (844) 894-7752 or email at customerservice@surgalign.com. It is important to note that when filing a complaint, the following information must be included to properly respond to the complaint:

Name and address; nature of the complaint; the component(s) trade name and catalog number; applicable lot number(s); and notification of whether a written report is being solicited.

Surgalign Spine Technologies, Inc.
520 Lake Cook Road, Suite 315
Deerfield, IL 60015 USA
Tel: (844) 894-7752
www.surgalign.com

For product information including surgical technique manuals, brochures, or questions pertaining to sales and service, please contact Surgalign customer service via telephone at (844) 894-7752 or email at customerservice@surgalign.com.

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