



Simmerty[®]
si joint fusion system

INSTRUCTIONS FOR USE

Rx Only

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

The Simmetry+ SI Joint Fusion System consists of sterile packaged 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 9.5mm-14.5mm, in 1mm increments. Lengths in 5mm increments range from 30mm-110mm.

INDICATION FOR USE

The Simmetry+ SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including:

- Sacroiliac joint disruptions and degenerative sacroiliitis.

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.

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 require sufficient bony purchase. Bone threads may be inadvertently stripped 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

These devices can break when subjected to loading associated with delayed union or nonunion. All metallic surgical implants are subject to repeated stress 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 influence 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+ SI Joint Fusion System has not been evaluated for safety and compatibility in the MR environment. The Simmetry+ SI Joint Fusion System has not been evaluated for heating, migration, or image artifacts at or near the implant site.

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 the surgeon can verify bony healing. 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.

POTENTIAL ADVERSE EFFECTS

- Nonunion or delayed union
- Bending or fracture of implant
- Screw back out, bone stripping, 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

HOW SUPPLIED

Implants of the Simmetry+® SI Joint Fusion System are supplied STERILE using a gamma radiation process. Do not use if the sterile barrier is damaged. If damage is found, call your Tenon Medical representative.

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 expiration date on the product label.

STORAGE

Store the device at room temperature.

DISPOSAL

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Cleaning and Sterilization of Simmetry®+ Surgical Instruments

Warnings and Precautions

- Prior to sterilization and promptly following each surgical procedure, thoroughly and carefully clean all instruments according to the applicable procedures below. The sterilization cycles listed in Table 1 are only valid for devices that are adequately cleaned.
- Decorticators must be cleaned and sterilized in the configuration provided by Tenon Medical to ensure effective reprocessing and proper device function.
- It is recommended that contaminated instruments not be allowed to dry prior to reprocessing. Effective cleaning, decontamination, and sterilization procedures require the removal of blood, body fluid, bone and tissue debris, saline, and disinfectants from instruments.
- Simmetry+ instruments are critical devices and must be terminally sterilized by steam sterilization prior to surgical use.
- Saline and cleaning/disinfection agents containing aldehyde, mercury, active chlorine, chloride, bromine, bromide, iodine, or iodide are corrosive and should not be used. Do not soak instruments in Ringers Solution.
- Soaking in disinfectants should be avoided. Disinfectants may corrode or discolor instruments.
- Soiled instruments should not be rinsed with hot water (>45°C/113°F), concentrated alcohol, certain liquid chemical sterilants or high-level disinfectants (e.g., glutaraldehyde, ortho-phthalaldehyde). This may denature protein-based contaminants, making them hard and difficult to remove.
- Silicone- or oil-based lubricants should not be used because sterilants might not penetrate these lubricants, which can protect microorganisms and thus inhibit sterilization.
- Safety Precautions:
 - o Personal Protective Equipment (PPE) should be worn when handling or working with contaminated or potentially contaminated materials, devices, and equipment. PPE includes gown, mask, goggles or face shield, gloves, and shoe covers. This also applies to handling and packaging of instruments to be returned to Tenon Medical.
 - o Universal precautions should be observed by all personnel that work with contaminated or potentially contaminated devices. Caution should be exercised when handling devices with sharp points.
 - o Manual scrubbing with brushes should always be performed with the instrument below the surface of the cleaning solution to prevent liberation of contaminants into the air.

Cleaning Agents:

- o Select enzymatic solutions intended for breakdown of blood, body fluids, fat, and tissues. Enzymatic solutions designed specifically for breakdown of fecal matter or other organic contaminants are not suitable choices for orthopedic instruments.
- o Cleaning agents with low foaming surfactants should be used during manual cleaning procedures to ensure that instruments are visible in the cleaning solution.
- o Cleaning agents selected must be easily and completely rinsed from device surfaces to prevent accumulation of detergent residue.
- o 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.
- o Select cleaning agents that are appropriate for the cleaning equipment with which they are used.
- o Follow the cleaning agent manufacturer's recommendations for water quality, temperature, exposure times, and concentration of cleaning agents.
- o These cleaning procedures were validated using ENZOL® enzymatic solution (Johnson & Johnson®) and Prolystica Ultra Concentrate Enzymatic Cleaner (Steris®). These cleaning agents are not required for proper cleaning of Simmetry+ instruments, provided the cleaning agents used meet the above criteria.

Water:

- o Use of hard water should be avoided. Softened tap water may be used for initial rinsing. Purified water should be used for final rinsing to eliminate mineral deposits on instrument surfaces. Purified water is obtained by one of the following processes: ultra filtration (UF), reverse-osmosis (RO), deionization (DI), or equivalent.

Manual Cleaning Tools:

- o Metal brushes or scouring pads must not be used during manual cleaning procedures. These materials may damage the surface and finish of instruments.
- o User facility tools necessary for manual cleaning include soft-bristled nylon brush and pipe cleaners in several diameters and lengths, soft low-linting cloths and tools for flushing cannulations (e.g., luer lock syringes, water jet gun.)
- o Select brushes of the appropriate length and diameter to easily pass down cannulations but still provide full contact of bristles to all internal surfaces for the full length of the cannulations.

Limitations on Reprocessing

When processed in accordance with these instructions it is expected that these surgical instruments will have a long service life; however, mishandling, inadequate cleaning or inadequate protection can diminish instrument lifetime. If an instrument no longer performs properly due to long use, mishandling, or improper care, do not continue to use the instrument.

If pitting, corrosion, fatigue, bending or any other evidence of instrument degradation are noted, contact your Tenon Medical representative to address any questions or for information related to return or disposal of an instrument or instrument tray.

Pre-Surgical Cleaning and Sterilization Processes

Prior to surgical use, thoroughly and carefully clean and sterilize all instruments according to the procedures below. Two methods of cleaning and two sterilization cycles are provided. Either cleaning methods and sterilization methods are acceptable to use based on equipment availability and capabilities.

Washer/Disinfector Cleaning Process: Pre-Surgical

Equipment required: Automated washer/disinfector and neutral pH enzymatic detergent.

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

NOTE: Decorticators must be cleaned and sterilized in the configuration provided by Tenon Medical to ensure effective reprocessing and proper device function.

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. A washer/disinfector with approved efficacy (e.g., CE Mark, FDA approval, and validation according to ISO 15883) should be used.

Inspect each instrument to ensure there is no visible debris.

If visible debris remains, repeat cleaning procedures 1 through 3 for the contaminated instruments.

Manual Cleaning Process: Pre-Surgical

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.

NOTE: Decorticators shall be cleaned and sterilized in the configuration provided by Tenon Medical to ensure effective reprocessing and proper device function.

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 steps 1 through 3 for the contaminated instruments.
15. Return instruments to instrument tray.

Inspection, Maintenance and Testing

NOTE: If damage or wear is noted that may compromise the function of the instrument, contact your Tenon Medical representative to address any questions or for information related to return or disposal of an instrument or instrument tray.

1. Visually inspect for completeness, damage, and/or excessive wear.
2. Check instruments with long slender features (particularly rotating instruments) for distortion.
3. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

Packaging Prior to Sterilization

Prior to sterilization, the SImmetry+ instruments should be secured in the dedicated SImmetry+ instrument tray(s) provided. The SImmetry+ instrument tray(s) should be double wrapped according to AAMI/CSR technique.

Only legally marketed, FDA-cleared wraps should be used for packaging terminally sterilized devices.

WARNING: Tenon Medical has validated the following sterilization cycles for only the instruments provided in the dedicated SImmetry+ instrument tray. Any instrument(s) provided outside of the instrument tray must be wrapped separate from the instrument tray and sterilized outside of the instrument tray.

WARNING: Tenon Medical does not recommend the use of rigid containers for steam sterilization. This configuration could limit steam penetration and prevent effective sterilization of the instruments.

Steam Sterilization: Pre-Surgical

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 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 the instrument tray
Dynamic Air Removal	132C (270°F)	4 Minutes	30 Minutes	

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.

Post-Surgical Cleaning and Sterilization Process

After surgical use, thoroughly and carefully clean and sterilize all instruments according to the procedure below.

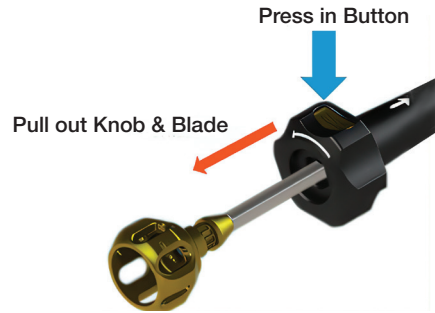
Point of Use Preparation for Cleaning

- Do not return soiled instruments to the instrument tray.
- For optimal results, instruments should be cleaned within 30 minutes of use to minimize the potential for drying prior to cleaning.
- Remove excess body fluids and tissue from instruments including cannulas, mating surfaces, joints, and all other hard-to-clean design features by flushing and/or using a disposable, non-shedding wipe.
- Place instruments in a basin of water or in a tray covered with towels moistened with water. Do not allow saline, blood, body fluids, tissue, bone fragments, or other organic debris to dry on instruments prior to cleaning. Dried soil is difficult to remove.
- Contaminated instruments must be transported to the area for cleaning in a way that avoids contamination of personnel and user facility.

Manual Cleaning Process: Post-Surgical

NOTE: The flush port on the Decorticator provides the fluid pathways necessary to clean the interior of the instrument.

NOTE: Disassemble the Decorticator Blade from Decorticator Body by pushing the “Button” and removing the cutting blade.



Equipment required: Ultrasonic cleaner equipped with flushing ports (if available), soft-bristled nylon brush and pipe cleaners in several diameters and lengths, soft-bristled nylon brush and pipe cleaners in several diameters and lengths, tool for flushing cannulations (e.g. syringe, water jet gun), 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 and cleaning agents with low foaming surfactants.
 - c. Prepare solution according to manufacturer’s instructions, ensuring dry powders are completely dissolved.
2. Rinse and/or flush instruments in cool water to remove gross debris. Water temperature should not exceed 45°C (113°F).
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. Pay particular attention to cutting ends, moving joints and long cannulations. Rotate the orange knob of the Decorticator to extend the cutting element for exposure to brushing.
 - c. Flush all cannulations and other hard-to-clean areas with the enzymatic solution for a minimum of 20 seconds or until the fluid runs clear. The Decorticator has a female luer lock flush port to aid in flushing.
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. If possible, flush cannulations during sonication.
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 steps 1 through 13 for the contaminated instruments.
15. Return instruments to instrument tray.

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 sterilization during the procedure.

Table 2: 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	

Steam Sterilization: Post-Surgical

Refer to Table 2 for a summary of steam sterilization parameters and follow the instructions.










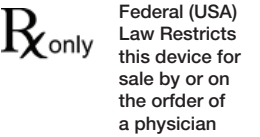



1. **Gravity Displacement Cycle**

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.

REFERENCE DOCUMENTS

Tenon Medical has based the validations for cleaning and sterilization on guidance from the following standards.

Reference Document	Title
ANSI/AAMI TIR12	Designing, testing, and labeling reusable medical devices for reprocessing in healthcare facilities.
AAMI TIR30	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ISO/ANSI/AAMI 17665-1	Sterilization of health care products-Moist heat-Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices
ISO/ANSI/AAMI 17665-2	Sterilization of health care products-Moist heat-Part 2: Guidance on the application of ISO 17665-1
ANSI/AAMI ST79	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ISO 17664 1st ed.	Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices

 Do Not Reuse	 Use By	 Titanium	 Batch Code	 Keep Dry
 Do Not Resterilize	 Caution	 Catalog Number	 Sterilized using Irradiation	
 Do Not Use If Package is Damaged	 Manufacturer	 Batch Code		