



SI JOINT TRUSS SYSTEM (SJTS)

INSTRUCTIONS FOR USE

PLEASE READ CAREFULLY

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALES BY OR ON THE ORDER OF A PHYSICIAN.

INTENDED USE:

The SI Joint Truss System (SJTS) device is intended to provide stability and facilitate fixation/fusion of the sacrum with the ilium through the Sacroiliac (SI) joint space in an open, percutaneous or minimally invasive approach.

DEVICE DESCRIPTION:

The 4WEB SJTS is a comprehensive surgical solution for sacroiliac joint fusion procedures. The system consists of an instrument set and a wide range of threaded implants. The implants come in two distinct sterile implant offerings: a fully threaded implant with compression threads on the proximal head and a partially threaded lap implant with an accompanying washer. All implants in the 4WEB SJTS are cannulated, fenestrated, and made of medical grade Ti6Al4V alloy. The implant offering includes a choice of three different diameters with a variety of lengths to accommodate the patient's anatomy.

The SJTS is intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.

INDICATIONS FOR USE:

The SJTS is indicated for sacroiliac joint fusion for:
• Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
• Augmenting, immobilization, and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropetiv fixation as part of a lumbar or thoracolumbar fusion.

The SJTS is also indicated for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures.

CONTRAINDICATIONS:

The SJTS devices should not be implanted in patients with:
• An active infection at the operative site or other active systemic infection
• Deformities or anatomic variations that impede or interfere with implant placement
• Tumor of sacral or iliac bone
• Unstable fracture involving sacroiliac joint
• Known sensitivity to the material
• Compromised vascularity that would inhibit adequate blood supply to the operative site.
• Patients having inadequate soft tissue coverage in the operative site or inadequate bone stock or bone quality that cannot provide adequate support and/or fixation of the devices.
• Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS AND PRECAUTIONS:

Safety and effectiveness have not been established in the following conditions:
• Gross obesity
• Previous fusion attempts at the fusion site
• Significant loss of bone stock as seen with osteoporosis or osteomalacia
• Conditions requiring chronic corticosteroid use
• Active drug abuse
• 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.
• Individuals with comorbidities may have inferior clinical outcomes.

The SI Joint Truss System is single use only. No implant should be reused if it has come in contact with blood or other bodily fluids.

Bending or fracture of the implants or instruments can occur if not handled properly.

All instrumentation is provided non-sterile and must be steam sterilized prior to use.

Correct selection of the implant is important to minimize risks of symptomatic malposition, inadequate fracture fixation, inadequate stabilization of SI joint, or over-advancement of the implant.

All implants and instrumentation should be inspected prior to use for possible damage or defects. Any damaged or defective component should not be used and should be returned to 4WEB.

The SJTS device is intended to provide stability and facilitate fixation/fusion of the sacrum with the ilium. In the event of pseudarthrosis or delayed fusion, the risk of implant migration, loosening or breakage increases. The physician/surgeon should consider patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

Patients requiring abnormal or excessive forces on the implanted area may not be good candidates for this type of surgery.

Do not attach supplemental fixation hardware to or through the SJTS device.

In patients with a high level of activity, the benefits must be weighed against possible risks.

The correct implant size must be selected to provide adequate bone support.

In hard bone, adequately prepare the bone channel for implant delivery by drilling and tapping.

Avoid placement close to other spinopelvic hardware which may make placement and/or removal difficult.

When removing an implant, make sure to adequately separate the implant from surrounding bone prior to use of driver.

Only surgeons trained in SI joint fusion procedures should implant this device.

For disposal of a product that has come in contact with body fluids, follow standard hospital procedures for disposing of biologically hazardous material. For disposal of a product that has not been in contact with body fluids, follow procedures for removal of hospital waste in force within the institution.

OPERATIVE PRECAUTIONS:

The surgeon is to be thoroughly familiar with the SJTS devices, methods of application, instruments and surgical technique. Correct positioning and location of the SJTS device should be checked intraoperatively with x-ray. The size (and more particularly the length) of the SJTS device must be chosen on the basis of the patient's anatomy and desired correction.

POTENTIAL ADVERSE EVENTS:

Potential adverse events may be related to surgery in general, Sacroiliac (SI) specifically or to the device. These may include, but are not limited to the following:
• Adverse events related to any surgery: reactions to anesthesia, the anesthetic; or other medications, bruising, swelling, infection, ileus, atelectasis, pneumonia, urologic problems, anemia, symptomatic cardiac disease, heart attack, stroke or death.
• Adverse events related specifically to SI surgery: bleeding, infection, blood vessel damage, nerve or soft tissue damage, hematoma, seroma, wound dehiscence or incisional hernia, embolism, thrombophlebitis, or need for further surgery.
• Adverse events related to the device: implant crack or fracture, failure to achieve fusion, implant migration, dislodgement, altered biomechanics, or metal sensitivity to a foreign body, including possible tumor formation. Additional surgery may be necessary for implant removal, repositioning or replacement.

POSTOPERATIVE CARE:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
• Detailed instructions on the use and limitations of the device must be given to the patient. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur early or as result of excessive weight-bearing, muscular activity or sudden jolts or shock to the SI joint.
• The patient must be advised not to smoke or consume alcohol during the period of the bone fusion process.
• The patient must be advised of the inability to bend at the point of fusion and taught to compensate for physical restriction in body motion.
• It is critical that fusion of joint is established and confirmed by roentgenographic examination, if a non-union develops or if the device loosens, migrates, and/or breaks, the device must be revised and/or removed immediately before serious injury occurs.
• Any retrieved devices are not to be used in another surgical procedure.

MRI SAFETY INFORMATION:

MRI Safety Information	A patient with the 4WEB SI Joint Truss System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.
Name/Identification of Device	4WEB SI Joint Truss System
Nominal Value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Body Coils: See scan region limitation below. Local Coils: Head transmit-receive coil, no restrictions on local transmit-receive coils that the device is not within.
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR	See details below.
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
SAR and Scan Duration Limits Based on Anatomical Isocenter Landmarks	2 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks).
MR Image Artifact	The presence of this implant may produce an image artifact of 78mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

PACKAGING:

All SJTS devices are provided sterile and are clearly labeled as such in an unopened sterile package provided by 4WEB. The contents are considered sterile unless the package is damaged, opened, or the expiration date on the device label has passed. The integrity of the packaging should be checked to ensure that the sterility of the contents is not compromised.

Implants supplied sterilized from 4WEB must not be re-sterilized.

SJTS ancillary instrumentation is provided non-sterile and is supplied in a tray that is used for steam sterilization prior to use in the operating room. In the case of instrument restock, individual items will be sent in a plastic bag labeled for that device.

Storage conditions must maintain the integrity of the implants and their respective packaging. The condition of all implants and instruments must be checked before use. Damaged products must not be used and should be returned to 4WEB.

INFORMATION FOR CLEANING AND STERILIZATION OF SURGICAL INSTRUMENTS AND IMPLANTS:

CAUTION: THESE INSTRUCTIONS DO NOT APPLY TO SINGLE-USE DEVICES.

The instruments used to implant the SI Joint Truss System devices do not have an indefinite functional life. All reusable instruments are subjected to repeated stresses related to bone contact, impaction, routing, cleaning, and sterilization processes. Instruments should be carefully inspected before use to ensure that they are fully functional.

• Decontamination: Each hospital must use its own validated decontamination procedures.
• Cleaning: Wash instruments in a LANCER type (or equivalent) washing machine with the appropriate cleaning products, rinse, and dry. Any product which may alter the material is prohibited, i.e. bleach, formalin, hypochlorite solutions, saline solution, etc.

The reprocessing instructions provided have been validated as being capable of preparing reusable 4WEB instruments for reuse. It is the responsibility of the reprocessor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. Any deviation by the reprocessor from these instructions should be evaluated for effectiveness and potential adverse consequences.

WARNINGS:

• Follow the instructions and warnings issued by the suppliers of any cleaning and disinfection agents and equipment used.
• Do not exceed 140° C (284° F) during reprocessing steps.

• Avoid exposure to hypochlorite solutions, as these will promote corrosion.
• Scratches or dents can result in breakage.
• For instruments produced by another manufacturer, reference the manufacturer's instructions for use.
• Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument.

LIMITATIONS ON REPROCESSING:

• End of useful life is generally determined by wear or damage in surgical use.
• Carefully inspect instruments between uses to verify proper functioning and configuration.
• Damaged instruments must be replaced to prevent potential patient injury such as loss of metal fragments into the surgical site.

DECONTAMINATION CONSIDERATIONS – CREUTZFELDT-JAKOB DISEASE (CJD):

• For patients with, or suspected with, Creutzfeldt-Jakob disease (CJD), variant CJD or other transmissible spongiform encephalopathy (TSE) and related infections, it is recommended to treat the patient using single-use instruments.

REPROCESSING INSTRUCTIONS – CARE AT THE POINT OF USE:

• Use purified water obtained via ultra-filtration, RO, DI and/or distilled.
• Thoroughly clean instruments as soon as possible after use. If cleaning must be delayed, immerse instruments in a compatible pH neutral detergent solution and critical water to prevent drying and encrustation of surgical soil.
• Avoid prolonged exposure to saline to minimize the chance of corrosion.
• Remove excessive soil with a low lint disposable wipe.

DECONTAMINATION:

ALL INSTRUMENTS AND TRAYS
• No instruments provided with the SJTS device require disassembly prior to decontamination.
• Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions (1oz Enzol, or equivalent, per gallon of critical water). **Note:** the enzyme solution must be changed on a regular basis.
• Soak soiled instruments for 5 minutes in the enzymatic solution.
• Use a soft bristle brush to remove all traces of blood and debris; pay close attention to any hard-to-reach areas, textured surfaces, or crevices.
• Rinse the instrument thoroughly with critical water.
• Dry the instrument immediately after final rinse.

CLEANING

• Clean the instruments using the "INSTRUMENTS" cycle in a validated washer disinfectant and a pH neutral cleaning agent intended for use in automated cleaning. The cleaning cycle should incorporate enzymatic pre-wash, wash, rinse, thermal rinse, and drying steps.
• Place heavier instruments on the bottom of containers. Do not place heavy instruments on top of delicate instruments.
• For instruments with concave surfaces, such as cassettes, place instrument with the concave surface facing downward to facilitate draining.
• Clean the instruments using a validated washer disinfectant and the following parameters:

Process	Time	Reagent	Water Temperature
Pre-wash	2 min	Not applicable	Cold water
Enzyme wash	2 min	Enzol (2oz/gal) or equivalent	Hot water
Wash 1	2 min	Valsure Neutral (1oz/gal) or equivalent	65.5°C
Rinse 1	2 min	Not applicable	Hot water
Thermal rinse	1 min	Not applicable	90°C
Drying*	6 min	Not applicable	98.8°C

*Use lint-free cloths to dry residual water and filtered pressurized air at < 20 psi

CLEANING INSPECTION:

• Inspect all instruments and trays to verify that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process.

MAINTENANCE INSPECTION AND FUNCTIONAL TESTING:

• Visually inspect all instruments to ensure no damage and wear.
• Ensure there are no cracked handles and shafts are secure in handles.
• Ensure long instruments are free of any bending and distortion.
• Ensure instrument tips are free of defects or burrs.
• Ensure complex instruments with moving parts function appropriately.

WRAPPING:

WRAPPING TECHNIQUE
• Use instrument trays to contain instruments.
• Biological or Chemical Indicators (Bis or CIs) used for monitoring the performance of sterilization processes should be placed in the middle racks within wrapped trays. They should be tested according to the BI or CI manufacturer's directions.
• Do not wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANSI/AAMI S779.
• Use only FDA-cleared wraps.
• Label the contents of the wrapped tray using an indelible marker or other sterilization compatible label system.
• Allow 1 inch of free space between the instrument tray and the inside of the container lid for effective processing.

STERILIZATION:

• Use a validated, properly maintained and calibrated steam sterilizer.
• Effective steam sterilization can be achieved using the following cycle to achieve an SAL of 10⁻⁶.

Cycle	Temperature	Duration	Dry Time	Preconditioning pulses
Prevacuum	132°C (270°F)	4 min	60 min	4
*Prevacuum	134°C (273°F)	3 min	60 min	4

* The Prevacuum 134° C Sterilization Cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

NOTE: STERILIZATION DOES NOT REPLACE DECONTAMINATION OR CLEANING. ONLY A CLEAN PRODUCT CAN BE CORRECTLY STERILIZED. ONLY STERILE IMPLANTS AND INSTRUMENTS MAY BE USED FOR SURGERY.

PRODUCT COMPLAINTS:

Any healthcare professional (e.g. a surgeon using the product) who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of any SI Joint Truss System products should notify 4WEB, or, where applicable, their distributor.

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

SURGICAL TECHNIQUE MANUAL:

To receive additional copies of the Surgical Technique Manual (SI-SJTS-01 Lateral Approach or SI-SJTS-02 Posterior Approach), contact your local sales representative or the company at the address below.

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Standard: ISO 15223-1, Medical Devices - Symbols to be used with medical device labels, labelling and information to be supplied.

Symbol	Ref. Number	Title	Description of Symbol
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.1.5	Lot number	Indicates the manufacturer's lot number so that a specific medical device can be identified.
	5.1.6	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42 EEC, and 98/79 EC.
	5.1.3	Date of manufacture	Indicates the date when the medical device was manufactured.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	5.2.4	Sterile	Sterilized using irradiation. Indicates a medical device that has been sterilized using irradiation.
	5.2.6	Do not re-sterilize	Indicates a medical device that is not to be re-sterilized.
	5.2.8	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.2.12	Double Sterile Barrier System	Indicates two sterile barrier systems.
	5.7.7	Medical Device	Indicates the item is a medical device.
	5.7.10	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.

	ASTM F2503-13	MR Conditional	Medical device that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.
	21 CFR 801.109	Prescription only	Requires prescription in the United States.