



POSTERIOR SPINE TRUSS SYSTEM (PSTS) INTERBODY FUSION DEVICE

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 Posterior Spine Truss System (PSTS) Interbody Fusion Device is designed to provide mechanical support to the lumbar spine while biologic fusion takes place.

DEVICE DESCRIPTION: The device is an open architecture truss design mathematically formulated to provide structural support with open space throughout the implant for bone growth and fusion. The 4WEB additive manufacturing process provides a hierarchical surface roughness. The implant is made from Ti6Al4V alloy.

The device is available in a variety of sizes and lordotic angles to accommodate the patient's anatomy.

INDICATIONS FOR USE: The Posterior Spine Truss System (PSTS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.

CONTRAINDICATIONS: The PSTS Interbody Fusion Device should not be implanted in patients with: An active infection at the operative site or other active systemic infections; Tumor involvement at the operative site; Prior fusion at the level(s) to be treated; Known sensitivity to the material.

WARNINGS AND PRECAUTIONS: Safety and effectiveness have not been established in the following conditions: Gross obesity; Three or more levels to be fused; Symptomatic cardiac disease; Pregnancy; Previous fusion attempts at the involved level(s); Spondylolisthesis or retrolisthesis greater than Grade I; Significant loss of bone stock as seen with osteoporosis or osteomalacia; Conditions requiring chronic corticosteroid use; Active drug abuse.

The PSTS Interbody Fusion Device is for single use only.

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

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

No implant should be reused if it has come in contact with blood or other bodily fluids.

All implants, sizes 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.

Interbody fusion devices are intended to provide mechanical support while biologic fusion occurs. In the event of pseudoarthrosis or delayed fusion, the risk of implant migration, loosening or breakage increases. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

Only surgeons trained in lumbar spine fusion procedures should implant this device.

OPERATIVE PRECAUTIONS: The surgeon is to be thoroughly familiar with the PSTS Interbody Fusion Device, methods of application, instruments and surgical technique. Correct positioning of the PSTS Interbody Fusion Device relative to the vertebrae should be checked intraoperatively with x-ray. The size (and more particularly the height) of the PSTS Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction.

Each PSTS Interbody Fusion Device is to be filled with autologous and/or allograft bone to promote bone fusion (See Surgical Technique Manual for complete details). The implants are for single-implant use only. An explanted implant must never be re-implanted. Stresses and fracture, even though not noticeable by visual inspection, may have been created during initial implantation.

Following implantation, the product number and manufacturing lot number of the device that has been implanted must be reported in the patient's surgical file.

POTENTIAL ADVERSE EVENTS: Potential adverse events may be related to surgery in general, spine surgery specifically or 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; bleeding; infection; ileus; blood vessel damage; nerve or soft tissue damage; atelectasis; pneumonia; hematoma; seroma; wound dehiscence or incisional hernia; urologic problems; embolism; anemia; colitis; thrombophlebitis; heart attack; stroke; or death.

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 as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.

MRI SAFETY INFORMATION:

Non-clinical testing has demonstrated the PSTS Interbody Fusion Device is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions: Static magnetic field of 3 T or 1.5 T; Maximum spatial field gradient of 1900 gauss/cm (19 T/m); Maximum MR system reported, whole body averaged specific absorption rate (SAR) of ≤ 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, non-clinical testing results indicate the PSTS Interbody Fusion Device produces a maximum temperature rise of no more than 5.0°C after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends approximately 28 mm from the PSTS Interbody Fusion Device when imaged with a gradient echo pulse sequence and a 3 T MR system.

PACKAGING: PSTS Interbody Fusion Device is provided sterile and is 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.

Posterior STS 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, associated ancillary instruments 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:

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

The instruments used to implant the PSTS Interbody Fusion Device 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.

All ancillary instruments of the PSTS Interbody Fusion Device are delivered non-sterile and therefore, must be decontaminated, cleaned and sterilized prior to surgical use. Decontamination reduces the population of microorganisms and facilitates the subsequent cleaning stage. Strict compliance with the instructions for use pertaining to decontamination and cleaning is mandatory, particularly the concentration and exposure time requirements. Thorough rinsing with water must be conducted following decontamination and cleaning.

- Decontamination: Each hospital must use their 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. It is the responsi-

bility of the processor to ensure that the reprocessing is actually performed using appropriate equipment, materials, and personnel to achieve the desired result. This normally requires validation and routine monitoring of the process. 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.
Highly alkaline conditions can damage products with aluminum parts.
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):

- Under certain classifications of risk, the World Health Organization (WHO) or local regulatory authorities recommend special CJD (Creutzfeldt-Jakob Disease) inactivation processing procedures. For use of this product outside the United States, consult WHO and local regulations for further information.

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 purified 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 disposable low lint wipe.

CLEANING:

- ALL INSTRUMENTS
Instructions for instruments requiring disassembly for cleaning may be found in the Surgical Technique Manual (ST-PSTS-01).
Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions (1oz Enzol, or equivalent, per gallon of purified 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 purified water.
Dry the instrument immediately after final rinse.
Clean using the "INSTRUMENTS" cycle in a validated washer disinfecter 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 curettes, place instrument with the concave surface facing downward to facilitate draining.

CLEANING INSPECTION:

- Inspect all instruments 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 that are provided in sets.
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.
Double wrap instruments in accordance with local procedures, using standard wrapping techniques such as those described in ANS/ AAMI ST79.
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 a SAL of 10⁻⁴.

Table with 4 columns: Cycle, Temperature, Duration, Dry Time. Rows include Gravity, Prevacuum, and a final cycle.

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 PSTS products should notify 4WEB, or, where applicable, their distributor.

SURGICAL TECHNIQUE MANUAL:

To receive additional copies of the Surgical Technique Manual (ST-PSTS-01), contact your local sales representative or the company at the address below.

USA: 4WEB Medical, 2801 Network Blvd, Suite 620, Frisco, TX USA 75034
OUTSIDE USA: 4WEB EU B.V., Industrieweg 13b, 1566JN Assendelft, The Netherlands

Table with 4 columns: Symbol, Ref. Number, Title, Description of Symbol. Contains ISO 15223-1 symbols for Caution, Do not re-use, Consult instructions for use, Lot number, Catalog number, Manufacturer, Date of manufacture, Use-by date, Sterile, Do not resterilize, and Do not use if package is damaged.

Table with 4 columns: Symbol, Ref. Number, Title, Description of Symbol. Contains MR and Rx Only symbols.