CERVICAL SPINE TRUSS SYSTEM (CSTS) 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 Cervical Spine Truss System (CSTS) Interbody Fusion Device is designed to provide mechanical support to the cervical 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 CSTS Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) of the cervical spine at one level or two contiguous disc levels. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. CSTS Interbody Fusion Devices are used as an adjunct to fusion in the cervical spine and are placed via an anterior approach at the C2 to T1 disc levels using autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. Patients should have received 6 weeks of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation.

CONTRAINDICATIONS:
The CSTS 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:
- Smoking
- Gross obesity
- Three or more levels to be fused
- Symptomatic cardiac disease
- Pregnancy
- Previous fusion attempts at the involved level(s)
- Spondylolisthesis or retrolisthesis
- Significant loss of bone stock as seen with osteoporosis or osteomalacia
- Conditions requiring chronic corticosteroid use
- Active drug abuse

The CSTS Interbody Fusion Device is for single use only.

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

All implants, sizers and instrumentation are provided non-sterile and must be steam sterilized prior to use. The 4WEB Spine Truss System Implants are intended to be used together with the 4WEB Spine Truss System instrumentation during spinal fusion interventions.

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

All implants, sizers 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 cervical spine 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 CSTS Interbody Fusion Device, method of application, instruments and surgical technique. The CSTS Interbody Fusion Device should be implanted singly. Correct positioning of the CSTS Interbody Fusion Device relative to the vertebrae should be checked intraoperatively with x-ray. The size (and more particularly the height) of the CSTS Interbody Fusion Device must be chosen on the basis of the patient's anatomy and desired correction.

Each CSTS 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.

Implantation of the CSTS Interbody Fusion Device must be used with supplemental fixation.

Following implantation, the product number and manufacturing serial 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.
- Adverse events related specifically to spine surgery: dural tear and CSF leak; nerve damage leading to radiculopathy, myelopathy, paraparesis, paresthesia or paralysis; meningitis; vertebral body damage or fracture; ligament damage; fractured sacrum; or retrograde ejaculation.
- Adverse events related to the device: implant crack or fracture, failure to achieve fusion, implant migration, dislodgement, or metal sensitivity to a foreign body, including possible tumor formation. Additional surgery may be necessary for implant removal, repositioning or replacement. Additional stabilization at the implanted level or surgery at another disc level may be necessary if non-union or anatomic change at an adjacent level develops.

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.
- The patient must be advised not to smoke or consume alcohol during period of the bone fusion process.
- The patient must be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- It is critical that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices 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:
Non-clinical testing has demonstrated the CSTS 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 CSTS 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 CSTS Interbody Fusion Device when imaged with a gradient echo pulse sequence and a 3 T MR system.

PACKAGING:
CSTS Interbody Fusion Devices and ancillary instrumentation are 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 should 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 CSTS 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 CSTS 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 ISO 15883-1 and ISO 15883-2 compliant 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 responsibility of the reprocessor 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
- No instruments provided with the CSTS Interbody Fusion Device require disassembly prior to cleaning.
- 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 disinfector 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 ANSI/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 an SAL of 10^{-6}.

Cycle	Temperature	Duration	Dry Time
Gravity	121° C (250° F)	30 min	45 min
Prevacuum	132° C (270° F)	4 min	45 min
*Prevacuum	134° C (273° F)	3 min	45 min

* 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 CSTS products should notify 4WEB, or, where applicable, their distributor, and the competent authority of the Member State in which the user and/or patient is established.

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

USA:
4WEB Medical
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Frisco, TX USA 75034
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CE 0344

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.
SN	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
REF	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.
NON STERILE	5.2.7	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.
MD	5.7.7	Medical Device	Indicates the item is a medical device.
UDI	5.7.10	Unique Device Identifier	Indicates a carrier that contains unique device identifier information.

MR	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.
Rx Only	21 CFR 801.109	Prescription only	Requires prescription in the United States.