



LATERAL SPINE TRUSS SYSTEM (LSTS) INTERBODY FUSION DEVICE

INSTRUCTIONS FOR USE (ENGLISH)

PLEASE READ CAREFULLY

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

INTENDED USE:

The Lateral Spine Truss System (LSTS) Interbody Fusion Device is designed to provide mechanical support to the Lumbar spine while biologic fusion takes place.

DEVICE DESCRIPTION: The device 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 Lateral Spine Truss System (LSTS) Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-L5. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the device. The device must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

CONTRAINDICATIONS:

The Lateral Spine Truss System (LSTS) 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
- Use of soft bristle brushes to remove all traces of blood and debris, pay close attention to any hard-to-reach areas, textured surfaces, or crevices.
- Soak soaked instruments for 5 minutes in the enzymatic solution.
- Use of a brush to 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/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 curettes, place instrument with the concave surface facing downward to facilitate drainage.

CLEANING INSTRUCTIONS:

• In order to ensure proper cleaning, that all visible debris is removed during cleaning and prior to sterilization. If debris is still visible after cleaning, repeat the cleaning process.

MAINTENANCE INSTRUCTIONS 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.

• 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 be not used and should be returned to 4WEB.

Interbody fusion devices are intended to provide mechanical support while biologic fusion occurs. In the event of pseudarthrosis 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.

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 PROCEDURES:

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

Each LSTS Interbody Fusion Device is to be filled with autologous 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.

• The Precavac 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 vials, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle and approved level of decontamination.

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 are 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; infection; ileus; blood clots; tissue damage; atelectasis; pneumonia; hematoma, seroma, wound healing or incisional hernia; urinary problems; anemia; colitis; thrombophlebitis; heart attack; stroke; or death.

• Adverse events related to spine surgery: dorsal tear and CSF leak; nerve damage leading to radiculopathy, myelopathy, paraparesis, anesthesia 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, implant migration, metal sensitivity to a foreign body, including possible tumor/foreign body. 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 in adjacent level develops.

POSTOPERATIVE CARE: The physician’s postoperative directions and warnings to the patient and the corresponding patient comments are extremely important.

• Detailed instructions on the use and limitations of the device must be given to the patient. The patient should be advised that loosening 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 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 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 the patient medically treated 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 LSTS 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 strength: 1.5 T

• Maximum spatial field gradient of 1900 Gauss/cm (19 T/m)

• Maximum RM system reported, whole body/average specific absorption rate (SAR) of ≤ 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, non-clinical testing results indicate the LSTS 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 LSTS Interbody Fusion Device when imaged with a gradient echo pulse sequence and a 3 T MR system.

PACKAGING: LSTS 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.

LSTS 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 LSTS 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 LSTS 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. Through 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 110 or equivalent ISO 15882-1 and ISO 15882-2 compliant washing machine with the appropriate cleaning products, rinse, and dry. Any product which may affect 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 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 complete enzymatic solution in a container of purified water to prevent drying and encrustation of surgical soil.

• Avoid prolonged exposure to saline to minimize the chance of corrosion.

• Remove excessive soil ure a disposable.

CLEANING:

ALL INSTRUMENTS

• Instructions for instruments requiring disassembly for cleaning may be found in the Surgical Technique Manual (ST-15TS-01).

• Prepare an enzymatic cleaning solution in accordance with the manufacturer’s instructions (1oz Enzyl, or equivalent, per gallon of purified water). **Note:** the enzyme solution must be changed on a regular basis.

• Soak soaked instruments for 5 minutes in the enzymatic solution.

• Rinse the instrument thoroughly with purified water.

• Clean 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.

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WRAPPING:

WRAPPING TECHNIQUE

• Use instrument trays to contain instruments that are provided in sets.

• Biological or Chemical Indicators (Bi, Ch) are 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 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	Temp	Exposure Time	Duration	Dry Time
Gravity	121° C (250° F)	30 min	45 min	
Precavac	132° C (270° F)	4 min	45 min	
•Precavac	134° C (273° F)	3 min	45 min	

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4WEB MEDICAL (GERMAN)

LATERALES SPINE TRUSS SYSTEM (LSTS) ZUR WIRBELKÖRPERFUSION

GEBRAUCHSANWEISUNG

BITTE AUFMERKSAM LESEN

ACHTUNG: NACH US-AMERIKANISCHEM BUNDEGESETZ DARF DIESES PRODUKT NUR VON EINEM ARZT BZW. AUF ANWEISUNG EINES ARZTES VERKAUFT WERDEN.

VERWENDUNGSZWECK:

Das Laterale Spine Truss System (LSTS) zur Wirbelkörperfusion ist dafür konzipiert, die Lendenwirbelsäule während der biologischen Fusion mechanisch zu stützen.

BESCHREIBUNG DES IMPLANTATS:
Das Lateral Implant hat sich eine offene Struktur, die aus einem mathematisch konstruierten Fachwerk besteht, sodass das Implantat als strukturelle Stütze fungiert und gleichzeitig offene Räume für Knochenwachstum und -fusion bietet. Das generative Fertigungsverfahren von 4WEB sorgt für eine hierarchische Oberflächenstruktur. Das Implantat ist aus Ti6Al4V-IV gefertigt.

Das Implantat ist in einer Vielzahl von Größen und Lordosewinkeln zur Anpassung an die Anatomie des Patienten erhältlich.

INDIKATIONEN:

Das Laterale Spine Truss System (LSTS) zur Wirbelkörperfusion ist zur Anwendung bei Patienten mit ausgereiftem Skelett vorgesehen, bei denen eine degenerative Bandscheibenerkrankung in einem oder zwei benachbarten Segmenten zwischen L2 und L5 vorliegt. Die degenerative Bandscheibenerkrankung (DDD) ist definiert als Rückenschmerz diskogenen Ursprungs in Verbindung mit einer anatomisch und radiologisch bestätigten Degeneration der Bandscheibe. Vor einer Versorgung mit dem Implantat müssen die Patienten mindestens sechs Monate eine nicht-operative Behandlung vornehmen, da diese die Korrosion begünstigen.

Das Implantat muss mit zusätzlicher Fixation und einem autologen Knochenstransplant angewendet werden. Bei Patienten mit DDD kann auch eine Spondylolythese ersten Grades oder eine Retrolisthese in den betroffenen Segmenten vorliegen.

KONTRAINDIKATIONEN:
Das LSTS-Implantat zur Wirbelkörperfusion darf nicht bei Patienten angewendet werden, bei denen Folgendes vorliegt:

• Aktive Infektion am Operationsortis oder andere aktive systemische Infektionen

• Tumorale Beteiligung am Operationsortis

• Einsatz von Instrumenten auf dem Operationsortis

• Bekannte Empfindlichkeit gegenüber dem Implantatmaterial

Die Sicherheit und Wirksamkeit unter folgenden Bedingungen ist nicht belegt:

• Adipositas per magna

• Mikrobiotaxis

• Mehr als zwei in jeder Ebene von Blut und sonstigen Rückständen entfernen. Dabei besonders auf schwer zugängliche Bereiche, Oberflächen von Struktur und Spalten achten.

• Das Instrument gründlich mit gereinigtem Wasser abwaschen.

• Das Instrument sofort nach dem abschließenden Abspülen trocknen.

• Spondylolythese oder Retrolisthese im Bereich der von Food and Drug Administration für die Verwendung in einem validierten Reinigungs- und Desinfektionszyklus mit dem Zyklus "INSTRUMENT" reinigen. Der Reinigungszyklus muss enzymatische Vorreinigung, Reinigung, Spülen, thermisches Spülen und Trocknung umfassen.

• Schwere Instrumente unter im Behälter platzieren. Keine schweren Instrumente auf empfindliche Instrumente legen.

• Instrumente mit konkaven Flächen, beispielsweise Küretten, mit der konkaven Seite nach unten hinlegen, um das Abtropfen zu erleichtern.

Alle Messvorrichtungen und Instrumente werden unsteril gelieft und müssen vor Gebrauch dampfsterilisiert werden. 4WEB Spine Truss System están diseñados para utilizarse junto con los instrumentos de 4WEB Spine Truss System durante las intervenciones de artrodesis vertebral.

Implantate, die mit Blut oder anderen Körperflüssigkeiten in Berührung gekommen sind, dürfen nicht wiederverwendet werden.

Alle Implantate, Messvorrichtungen und Instrumente sind vor Gebrauch auf Schäden oder Defekte zu kontrollieren. Beschädigte oder defekte Komponenten dürfen nicht verwendet werden und müssen an 4WEB zurückgegeben werden.

Implantate zur Wirbelkörperfusion dienen während der biologischen Knochenfusion als mechanische Stütze. Bei Pseudoarthrose oder verzögerter Fusion erhöht sich das Risiko einer Migration, Lockerung bzw. eines Bruchs des Implantats. Der Arzt/Chirurg sollte die Implantationsengnisse, das Gewicht des Patienten, sein Aktivitätsniveau sowie andere Patientenbedingungen erwägen, die sich auf die Leistung des Systems auswirken können.

Die Implantation dieses Produkts darf ausschließlich von Chirurgen durchgeführt werden, die entsprechend in Verfahren zur Lendenwirbelkörperfusion geschult sind.

Bei der Entorgung eines Produkts, das mit Körperflüssigkeiten in Kontakt gekommen ist, sind die Standardverfahren des Krankenhauses für die Entsorgung zu befolgen. Die korrekte Positionierung des LSTS-Implantats zur Wirbelkörperfusion in Bezug auf die Wirbelkörper muss intraoperativ durch Röntgenkontrolle überprüft werden. Die Größe (und insbesondere die Höhe) des LSTS-Implantats zur Wirbelkörperfusion muss entsprechend der Anatomie des Patienten gewählt werden.

Jedes LSTS-Implantat zur Wirbelkörperfusion wird mit autologem Knochenstransplant ausgefüllt, um die Knochenfusion zu fördern und zu unterstützen. Migration oder Lockerung des Implantats oder Operationstechnik. Die Implantate dürfen nur einmal implantiert werden. Explantierte Implantate dürfen unter keinen Umständen reimplantiert werden. Bei der unangemessenen Implantation können Spannungen und Brüche auftreten sein, auch wenn diese bei einer Sichtprüfung nicht erkennbar sind.

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