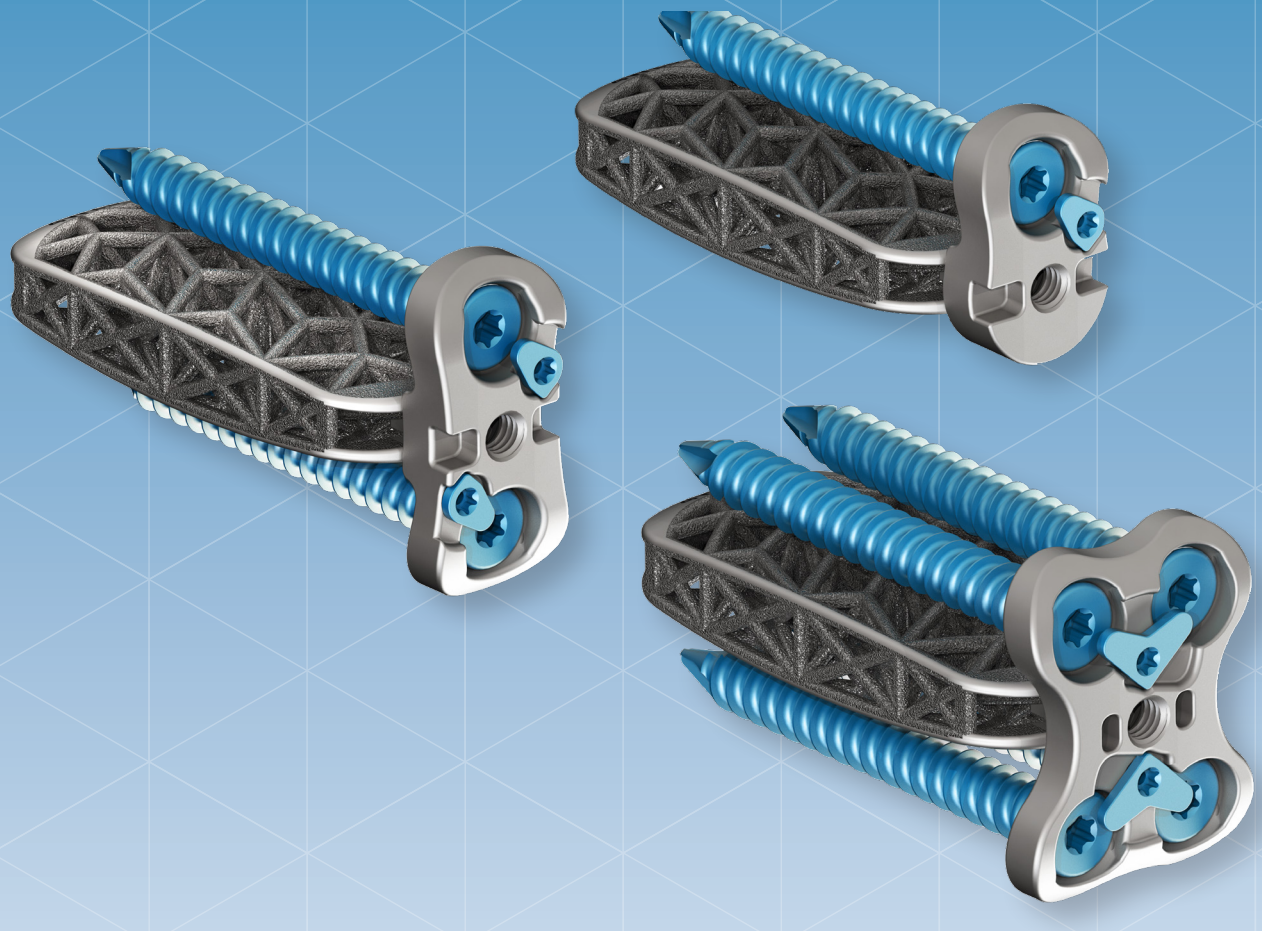
SURGICAL TECHNIQUE GUIDE

LUMBAR SPINE PLATING SOLUTION



4WEB® MEDICAL

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Federal law (USA) restricts these devices to sales by or on the order of a physician.

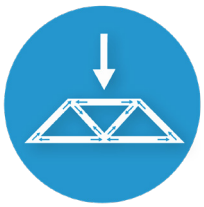
Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedure based on his or her medical training and experience. Prior to use of the system, the surgeon should refer to the product's Instructions For Use (IFU) for complete warnings, precautions, indications, contraindications and adverse effects. IFUs are available by contacting 4WEB MEDICAL, +1 (800) 285-7090.

TRUSS IMPLANT TECHNOLOGY™

Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate minimizing point loading which reduces the risk of subsidence.*

Hierarchical surface roughness spans from the macro to nano scale. These surface features have been shown to stimulate increased gene expression of certain osteogenic markers.[1]

Open architecture design allows for greater graft volume and bone growth throughout the entire construct.*



Distribution of load through the implant struts delivers strain to adjacent cellular material which stimulates a mechanobiologic response.

Truss Implant design provides maximum strength with a minimal amount of material, which limits imaging artifacts.

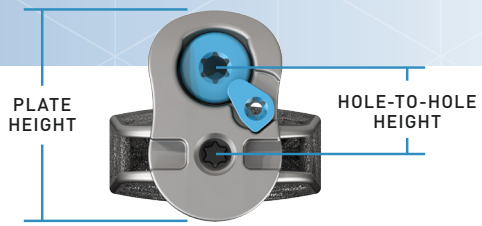
[1] Rowe et al, SMISS, AnnualForum'19, p.52 * Data on file

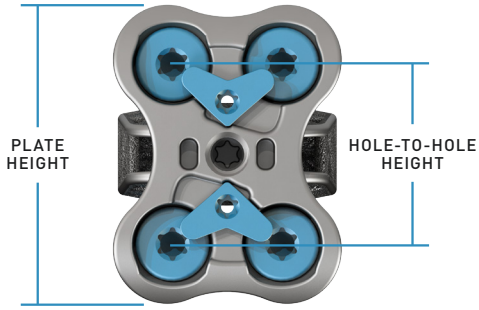
LSTS-PS OVERVIEW

4WEB Medical's Truss Implant Technology™ leverages multidisciplinary engineering principles such as truss design, load transfer and adjacent material reaction to produce orthopedic implants that provide structural support with open space throughout the implant for bone growth and fusion.

The 4WEB Lumbar Plating Solution (LSTS-PS) consists of a wide variety of modular plating configurations to address multiple lumbar spine pathologies and approaches. The device provides an integrated and non-integrated offering with a one, two and four screw option. The plate design also features a single-step locking mechanism to prevent screw backout.

LSTS-PS IMPLANT SPECIFICATIONS





INTEGRATED PLATES

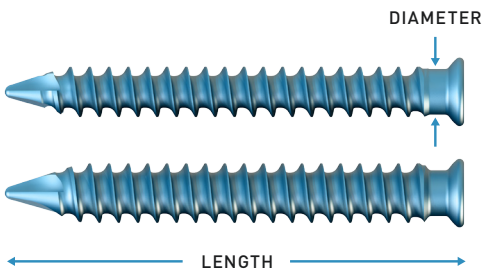
PART NUMBER	PLATE HEIGHT	HOLE TO HOLE
1-HOLE		
LSTS-PLT104-SP	22mm	9mm
LSTS-PLT108-SP	22.5mm	11mm
LSTS-PLT112-SP	24.5mm	13mm
LSTS-PLT116-SP	26.5mm	15mm
2-HOLE		
LSTS-PLT204-SP	30mm	18mm
LSTS-PLT208-SP	34mm	22mm
LSTS-PLT212-SP	38mm	26mm
LSTS-PLT216-SP	42mm	30mm
4-HOLE		
LSTS-PLT404-SP	30mm	18mm
LSTS-PLT408-SP	34mm	22mm
LSTS-PLT412-SP	38mm	26mm
LSTS-PLT416-SP	42mm	30mm

NON-INTEGRATED PLATES

PART NUMBER	PLATE HEIGHT	HOLE TO HOLE
2-HOLE		
LSTS-PLT304-NS	30mm	18mm
LSTS-PLT306-NS	34mm	22mm
LSTS-PLT308-NS	37mm	22mm
LSTS-PLT312-NS	41mm	26mm
LSTS-PLT316-NS	45mm	30mm
4-HOLE		
LSTS-PLT504-NS	30mm	18mm
LSTS-PLT508-NS	34mm	22mm
LSTS-PLT512-NS	38mm	26mm
LSTS-PLT516-NS	42mm	30mm

SCREWS

DIAMETER	LENGTH
PRIMARY SCREW Ø5.5mm	25-65mm (5mm increments)
RESCUE SCREW Ø6.5mm	25-65mm (5mm increments)



SURGICAL PROCEDURE

APPROACH

- Position the patient in the lateral decubitus position (Fig. 1).
- Per surgeon preference, perform a standard lateral or anterolateral approach to the spine.
- Locate the correct operative level under fluoroscopic guidance. A lateral or anterolateral incision can be used to access the appropriate operative level(s).
- A lateral retractor system as well as neuromonitoring may be necessary to properly retract tissue as well as avoid any damage to nerves of the lumbar plexus.

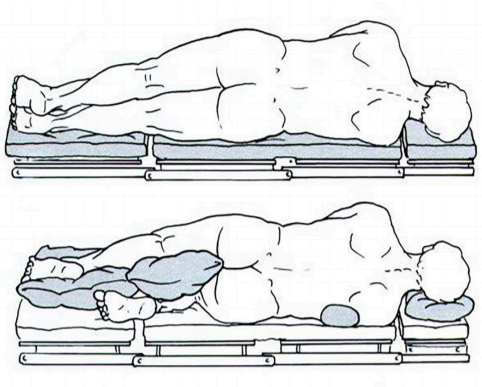


Figure 1

DISCECTOMY & ENDPLATE PREPARATION

- Perform an annulotomy and subsequent lumbar channel discectomy to prepare for implant insertion (Fig. 2). It is important to also release the contralateral annulus to ensure proper indirect decompression with the LSTS interbody.

- A 4WEB Lateral Discectomy Preparation set can be used to expose and remove disc material. (Fig. 3). To promote the fusion process, prepare the vertebral endplate by carefully removing the superficial cartilaginous layers. Take care to maintain the integrity of the cortical endplates.

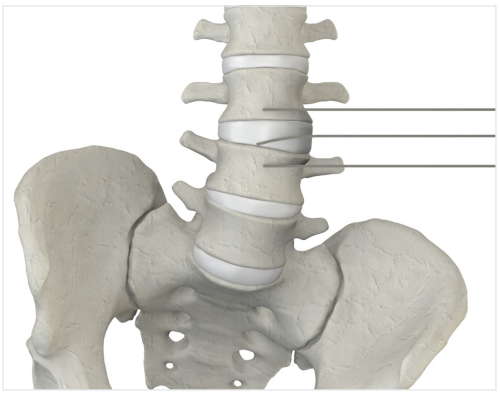


Figure 2

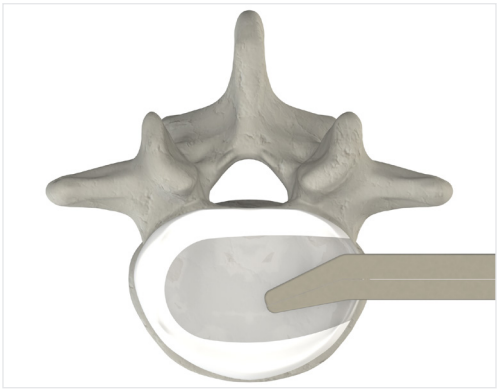


Figure 3

SIZING

- Select the appropriate Sizer and attach it to either a Straight Handle or T-Handle. Height, footprint, and angle measurements are clearly marked on the sizers.
- Carefully impact the sizer into the disc space. Check the correct fit of the Sizer with the aid of fluoroscopy and palpation (Fig. 4 & 5).
- In order to maintain disc height and ensure segment stabilization, select a Sizer height that provides a secure fit. Start with the smallest height, progressing to taller heights until the desired fit is achieved.

Note: The LSTS Sizers are sized at a 1:1/measurement ratio with the implants.

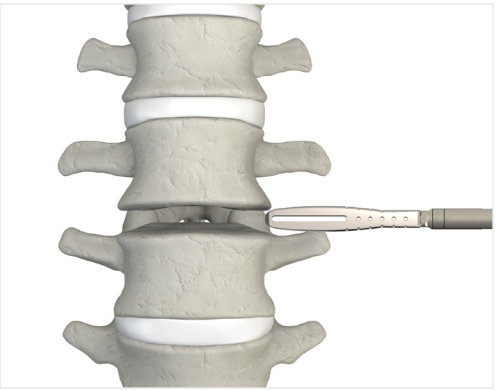


Figure 4

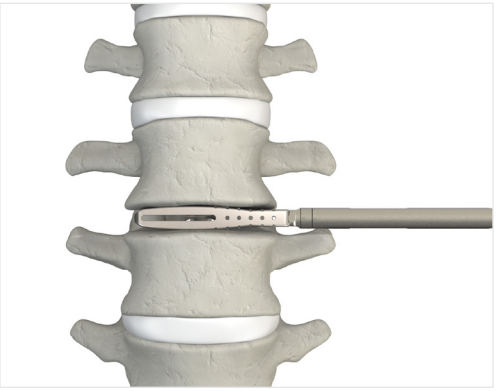


Figure 5

IMPLANT INSERTION & PACKING IMPLANT

- Pack the LSTS implant with autologous and/or allogenic bone graft. For best results, cut or morselize the bone graft into 1-2mm sized particles. Place the morselized bone into the top or bottom web structure (top and bottom are interchangeable). In a downward, circular motion, massage the graft material into the implant (Fig. 6).

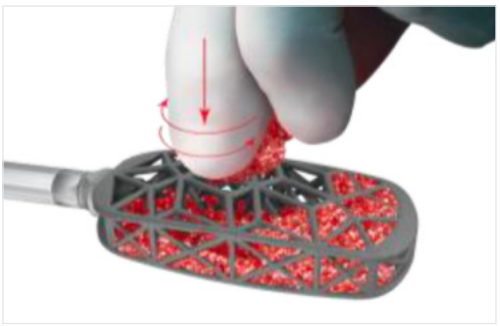


Figure 6

- If a non-integrated plate configuration is desired, the LSTS Interbody should be inserted into the disc space first (Fig. 7). Once the LSTS Interbody is in place, the appropriate LSTS Plate may be inserted using LSTS Plate Holder spanning the operative level (Fig. 8).

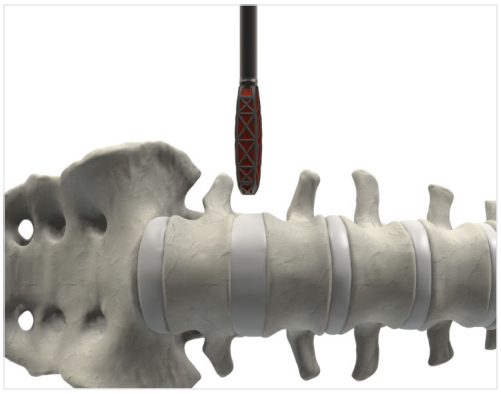


Figure 7

Figure 8

- For both integrated and non-integrated LSTS Plates, select the proper plate size and configuration to accommodate the patient's anatomy as well as the LSTS Interbody. For proper plate height in relation to LSTS Interbody, refer to the chart on page 5.

- If an integrated plate is desired, the appropriate LSTS Plate may be attached to the LSTS Interbody on the back table using the LSTS Plate Driver (Fig. 9). After the LSTS Plate is attached to the LSTS Interbody, thread the LSTS Inserter into the LSTS Plate to insert the LSTS Plate and LSTS Interbody as one construct (Fig. 10).

- Once assembled, the LSTS Interbody/Plate construct should be inserted into the disc space.

- The LSTS Plate may also be assembled in situ using the In Situ Assembly Tool. This can be accomplished by first attaching the LSTS Plate to the LSTS Split Tip Plate Holder and then using the In Situ Assembly Tool to thread the set screw into the implanted LSTS cage.

Figure 9

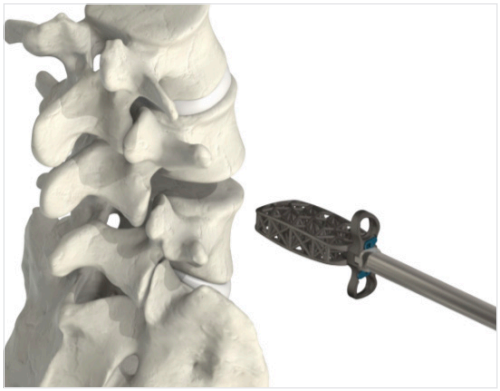


Figure 10

SCREW HOLE PREPARATION

- The LSTS Plate Solution offers multiple Awl and Drill options for screw hole preparation (Fig. 11).
- To use, insert the distal end of the Awl through the screw hole in the plate. Puncture the bone by applying axial force to the end of the Awl Handle. Should a Drill be desired, use the ratcheting handle in the set to prepare the screw hole in a similar fashion.

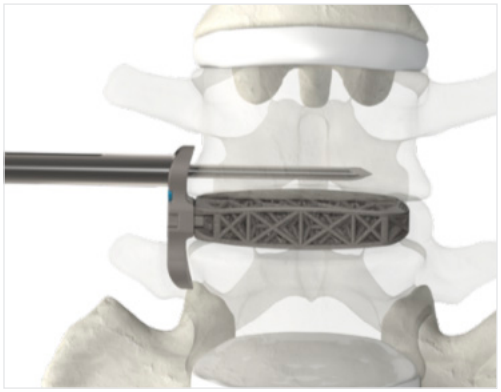


Figure 11

SCREW INSERTION

- The LSTS Plate Solution offers locking and press-fit Drivers for screw insertion. Select the desired driver and attach the handle to the proximal end of the instrument. Select the desired length screw and fix it to the distal end of the Driver. Insert the screw through the hole in the plate. Drive the screw until it is fully seated in the plate (Fig. 12).

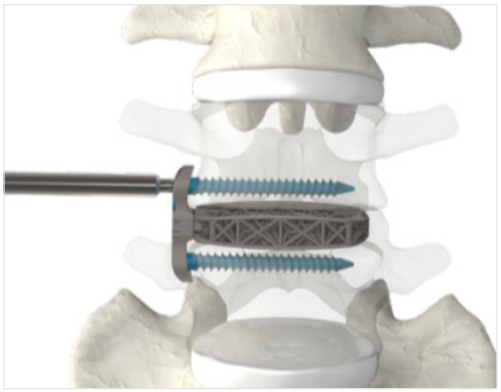


Figure 12

LOCKING THE ANTI-BACKOUT PLATES

- After placement of the Screws, rotate the one or two Locking Plates with the Anti-Backout Plate Driver counterclockwise to lock the Screws into the Implant. The wings of the Locking Plate will stop against the recess on the anterior face of the LSTS Plate (Fig. 13).

Note: Do not attempt to rotate the Anti-Backout Plate beyond the locked position. Damage to the Anti-Backout Plate Driver may occur if excess torque is applied.

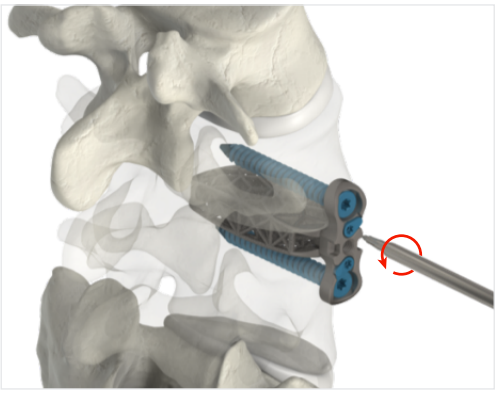


Figure 13

FINAL IMPLANT POSITION

- Inspect implant for correct position and assembly and confirm with fluoroscopy.

IMPLANT REMOVAL/REVISION

- If implant removal is necessary, rotate the Locking Plates clockwise until the screws are no longer retained. Remove the screws using the screwdriver.
- If implant removal is required, the intervertebral space should be distracted in the same manner as for implant insertion.
- Once distracted, the implant may be removed by using either of the LSTS Inserters. If necessary, the Slap Hammer can be attached to the Inserter for additional removal force.

INSTRUMENT CATALOG

PART NUMBER	DESCRIPTION
LSTS-100049	DRIVER, LOCKING, T25

LSTS-100045	SCREW DRIVER

ASTS-SA-100029	ANTI-BACKOUT PLATE DRIVER

LSTS-100032	PLATE LOCKING DRIVER, SHORT

LSTS-100033	IN-SITU DRIVER

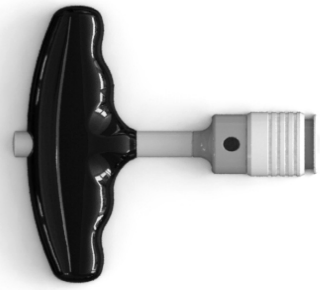
LSTS-100034	AWL, VARIABLE DEPTH

PART NUMBER	DESCRIPTION
LSTS-100035	DRILL, VARIABLE DEPTH

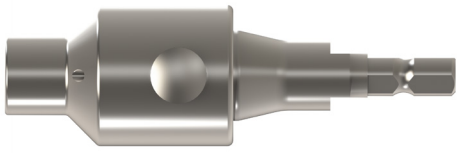
LSTS-100036	STRAIGHT AWL

LSTS-000014	RATCHETING STRAIGHT HANDLE

LSTS-000015	RATCHETING T-HANDLE

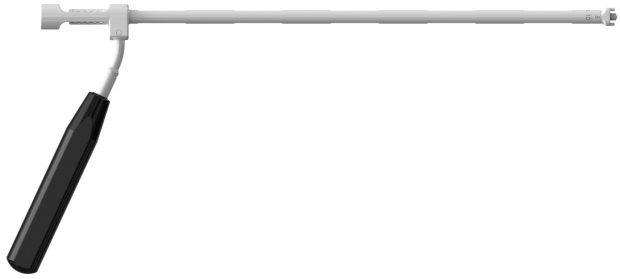


LSTS-100044	ADAPTER, LSTS QUICK CONNECT TO JACOBS-HALL



ASTS-SA-100030	TORQUE LIMITING HANDLE, BI-DIRECTIONAL

PART NUMBER	DESCRIPTION
LSTS-100038	PLATE HOLDER



LSTS-100039	IN-SITU INSERTER

LSTS-100040	OFFSET INSERTER

LSTS-100043	OSTEOPHYTE BITER

LUMBAR SPINE TRUSS SYSTEM PLATING SOLUTION (LSTS-PS)

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 Lumbar Spine Truss System Plating Solution (LSTS-PS) is intended to provide supplemental fixation as either a stand-alone plate or as an integrated fixation plate for the Lateral Spine Truss System (LSTS) Interbody Fusion Device in the lumbar spine while biologic fusion takes place.

DEVICE DESCRIPTION:
The Lumbar Spine Truss System Plating Solution (LSTS-PS) is comprised of lumbar plates and screws. The lumbar plates have a rotating locking tab for each screw position to prevent back-out of the screw. The plates are available in 1-hole, 2-hole, and 4-hole integrated configurations and 2-hole and 4-hole non-integrated configurations. Each plate is available in multiple lengths for single level fusion. The screws are available in two diameters and various lengths to accommodate the patient's anatomy. All LSTS-PS plates and screws are made from Ti6Al4V alloy.

INDICATIONS FOR USE:
The Lumbar Spine Truss System Plating Solution (LSTS-PS) without integrated fixation is intended for use as a laterally placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The LSTS-PS is designed to provide temporary stability until fusion is achieved. It is intended for lateral or anterolateral lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

The LSTS-PS with integrated fixation is intended to be attached and remain attached to the Lateral Spine Truss System (LSTS) Interbody Fusion Device after implantation. In this configuration the LSTS-PS must only be used to treat patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. The 1-hole 4WEB LSTS-PS with integrated fixation is intended to be used with supplemental fixation (e.g. posterior fixation).

CONTRAINDICATIONS:
The LSTS-PS 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 for integrated configurations
- Known sensitivity to the material

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

The LSTS-PS is for single use only.

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

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

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

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.

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.

WARNING: THIS DEVICE IS NOT INTENDED FOR SCREW ATTACHMENT OR FIXATION TO THE POSTERIOR ELEMENTS (PEDICLES) OF THE CERVICAL, THORACIC, OR LUMBAR SPINE.

OPERATIVE PRECAUTIONS:
The surgeon is to be thoroughly familiar with the LSTS-PS, methods of application, instruments and surgical technique. The LSTS-PS should be implanted singly. Correct positioning of the LSTS-PS relative to the vertebrae should be checked intraoperatively with x-ray. The height of the LSTS-PS must be chosen on the basis of the patient's anatomy and desired correction provided by the interbody fusion device. Implantation of the LSTS-PS is intended to be used with one, two, or four titanium alloy screws which accompany the device.

The LSTS-PS is 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.
- Adverse events related specifically to spine surgery: dural tear and CSF leak; nerve damage leading to radiculopathy, myelopathy, parapa-resis, 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 that the LSTS-PS and LSTS Interbody Fusion Device are MR Conditional. A patient with these devices 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 LSTS-PS produces a maximum temperature rise of no more than 6.0°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-PS when imaged with a gradient echo pulse sequence and a 3 T MR system.

PACKAGING:
LSTS-PS may be 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-PS ancillary instrumentation and implants provided non-sterile and are supplied in a tray or caddy that is used for steam sterilization prior to use in the operating room. In the case of instrument and implant 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 AND IMPLANTS:

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

The instruments used to implant the LSTS-PS 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-PS and certain implants 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 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 low lint disposable wipe.

CLEANING:
ALL INSTRUMENTS
- No instruments provided with the LSTS-PS 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 LSTS-PS products should notify 4WEB, or, where applicable, their distributor.

SURGICAL TECHNIQUE MANUAL:
To receive additional copies of the Surgical Technique Manual, 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.
LOT	5.1.5	Lot number	Indicates the manufacturer's lot 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.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
STERILE R	5.2.4	Sterile	Sterilized using irradiation. Indicates a medical device that has been sterilized using irradiation.
	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
	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.

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.

NOTES

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