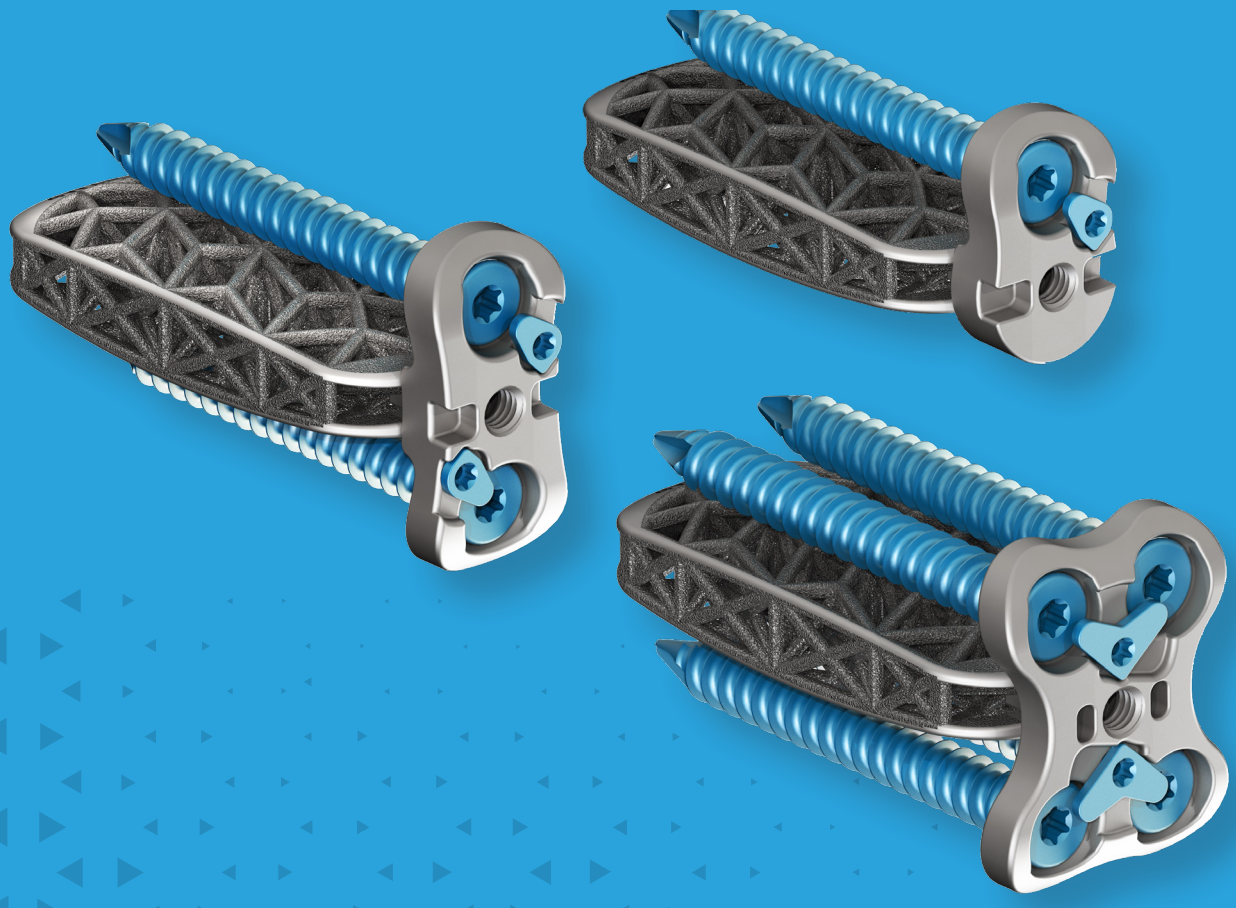
SURGICAL TECHNIQUE GUIDE

LUMBAR SPINE PLATING SOLUTION



4WEB®

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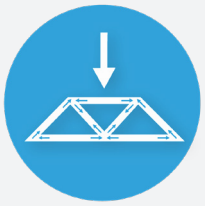
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the 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® at +1(800) 285-7090.

TRUSS IMPLANT TECHNOLOGY™

Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate which minimizes point loading and reduces the risk of subsidence.[1]

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 when compared to other interbody surfaces and materials.[2, 3]

Open architecture design allows for greater graft volume and bone growth throughout the entire construct.[1]



Distribution of load through the implant struts delivers strain to adjacent cellular material which stimulates a mechanobiologic response.[2]

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

[1] Data on file
[2] Lee et al., ORS, 2023 Annual Meeting, Dallas, TX
[3] Rowe et al., SMISS, Annual Forum '19, p.52

LSTS-PS OVERVIEW

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.

INDICATIONS

The 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

See package insert for warnings, precautions, adverse effects, and other essential product information. Before using the LSTS-PS Instrumentation, verify:

- Instruments have maintained design integrity; and,
- Proper size configurations are available.

For Instructions for Cleaning, Sterilization, Inspection and Maintenance, refer to IFU-LSTS-PS-05.

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.

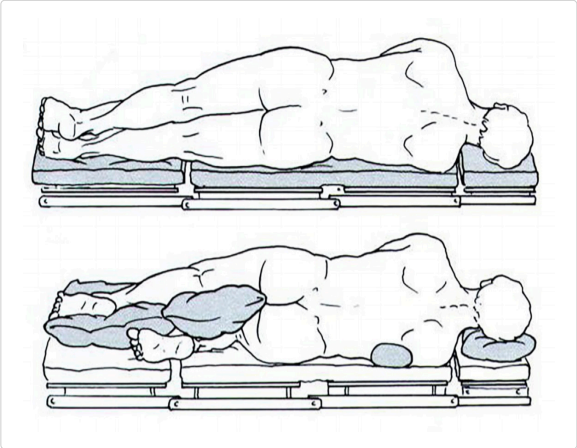


Figure 1

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

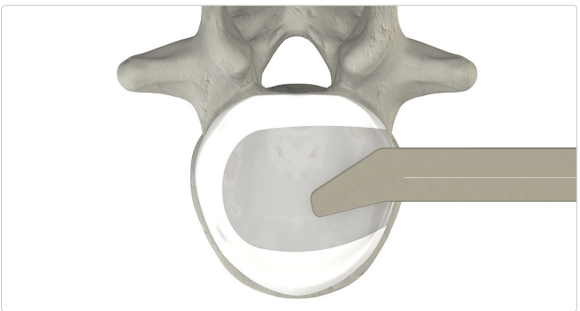


Figure 3

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.

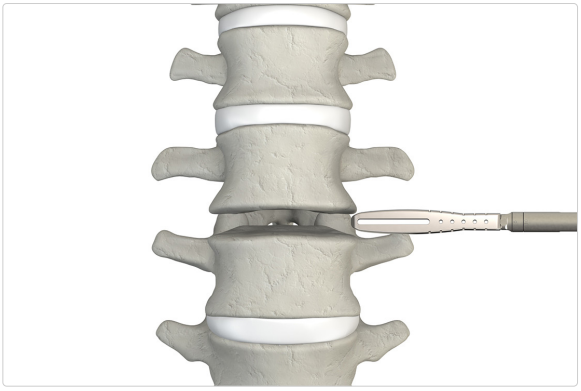


Figure 4

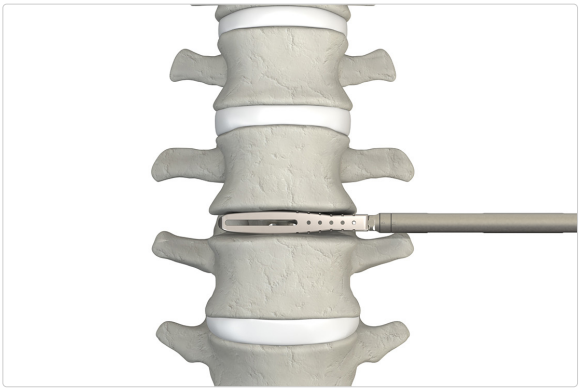


Figure 5

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).

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).

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 charts on page 15-16.

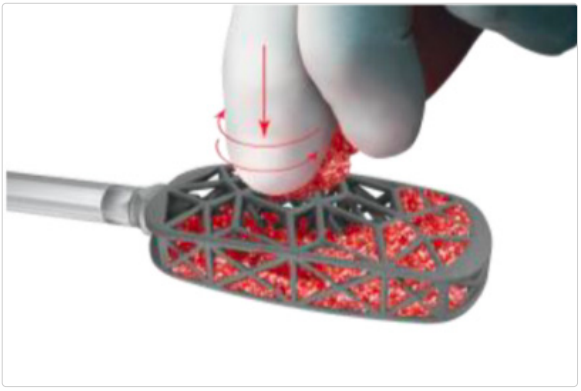


Figure 6

Figure 7

Figure 8

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

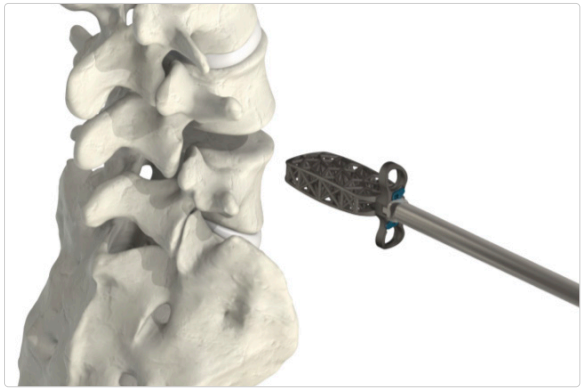


Figure 10

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.

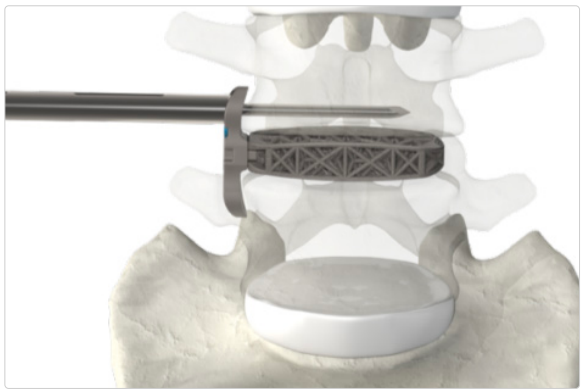


Figure 11

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).

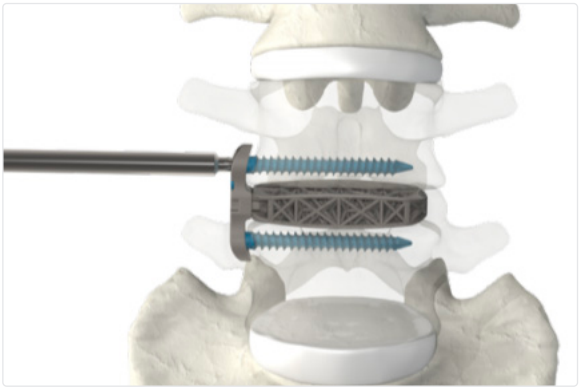


Figure 12

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.

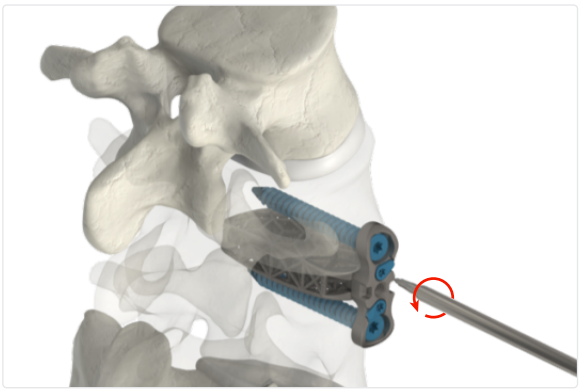


Figure 13

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

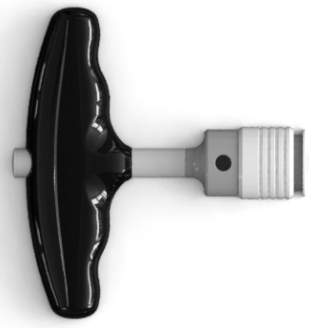
PART NUMBER	DESCRIPTION
LSTS-100034	AWL, VARIABLE DEPTH

LSTS-100035	DRILL, VARIABLE DEPTH

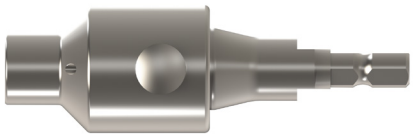
LSTS-100036	STRAIGHT AWL

LSTS-000014	RATCHETING STRAIGHT HANDLE

LSTS-000015	RATCHETING T-HANDLE



PART NUMBER	DESCRIPTION
LSTS-100044	ADAPTER, LSTS QUICK CONNECT TO JACOBS-HALL



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

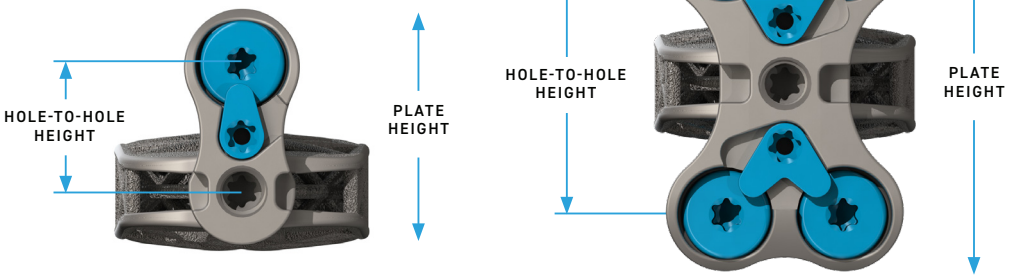
LSTS-100038	PLATE HOLDER

LSTS-100039	IN-SITU INSERTER

PART NUMBER	DESCRIPTION
LSTS-100040	OFFSET INSERTER

LSTS-100043	OSTEOPHYTE BITER

IMPLANT CATALOG

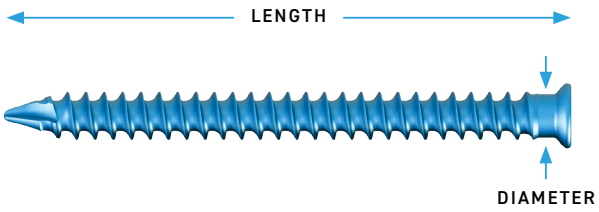


INTEGRATED PLATES

CATALOG NUMBER	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT
1-HOLE PLATES		
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 PLATES		
LSTS-PLT204-SP	30mm	18mm
LSTS-PLT208-SP	34mm	22mm
LSTS-PLT212-SP	38mm	26mm
LSTS-PLT216-SP	42mm	30mm
4-HOLE PLATES		
LSTS-PLT404-SP	30mm	18mm
LSTS-PLT408-SP	34mm	22mm
LSTS-PLT412-SP	38mm	26mm
LSTS-PLT416-SP	42mm	30mm

NON-INTEGRATED PLATES

CATALOG NUMBER	PLATE HEIGHT	HOLE-TO-HOLE HEIGHT
2-HOLE PLATES		
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 PLATES		
LSTS-PLT504-NS	30mm	18mm
LSTS-PLT508-NS	34mm	22mm
LSTS-PLT512-NS	38mm	26mm
LSTS-PLT516-NS	42mm	30mm



SCREWS

DIAMETER	LENGTH	
ø5.5mm	25-65mm *(5mm increments)*	Primary Screw
ø6.5mm	25-65mm *(5mm increments)*	Rescue Screw

2801 NETWORK BLVD. SUITE 620
FRISCO, TX 75034
4WEBMEDICAL.COM
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800.285.7090
ST-LSTS-PS-01 | REV D 06-2025