

SURGICAL TECHNIQUE GUIDE

LUMBAR SPINE PLATING SOLUTION

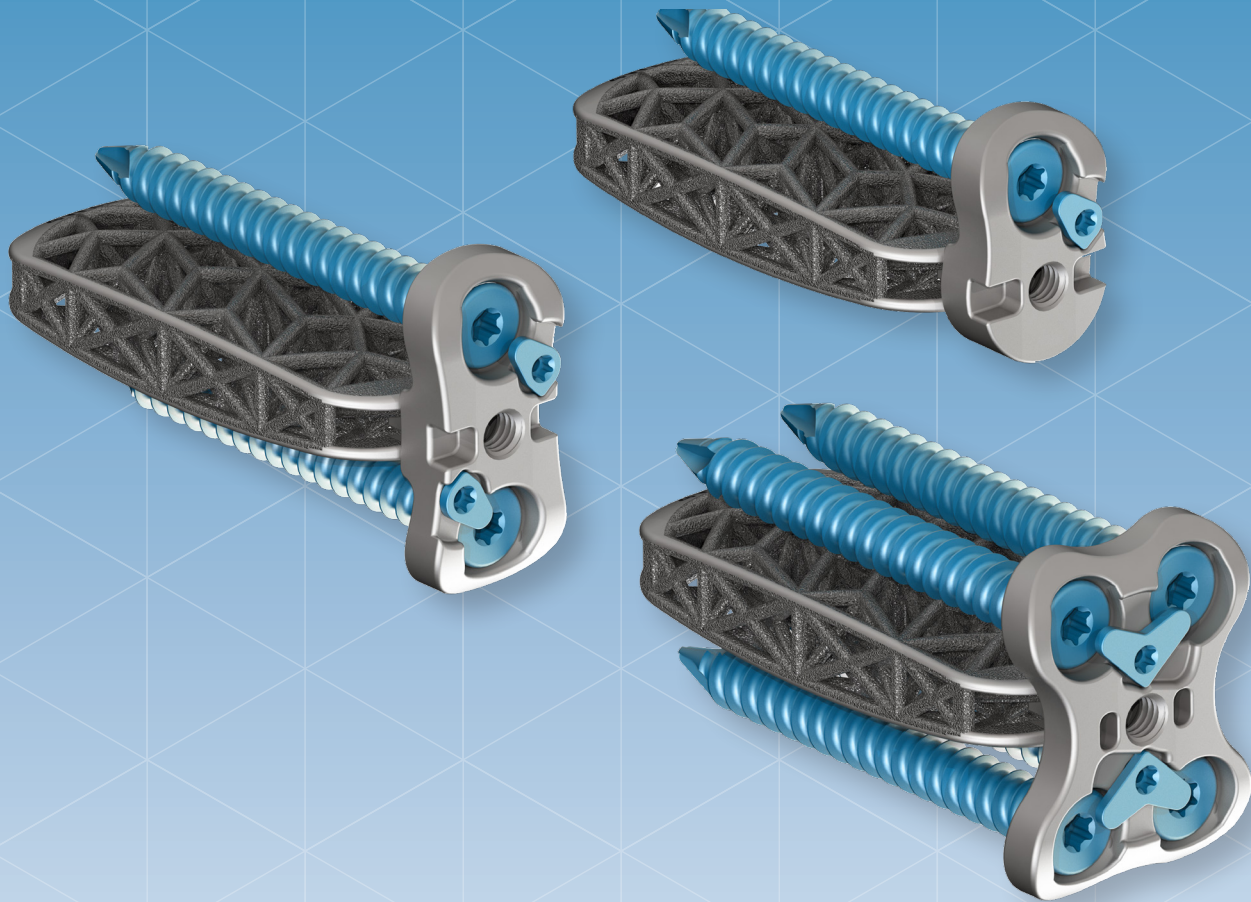


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Federal law (USA) restricts these devices to sales by or on the order of a physician.

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™



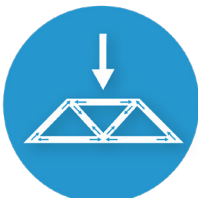
Novel Truss Implant Technology™ provides a Snow Shoe Interface that distributes load across the endplate minimizing point loading which reduces the risk of subsidence.*



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.

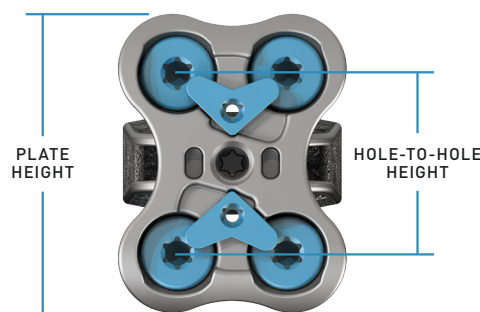
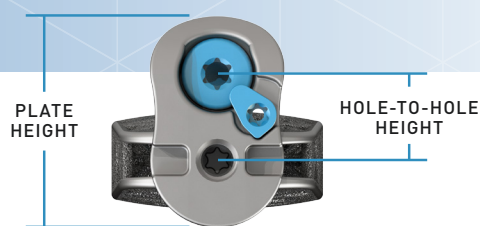
LSTS-PS IMPLANT SPECIFICATIONS

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 |

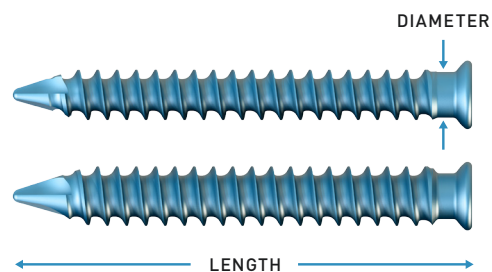
SCREWS

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



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 |



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.

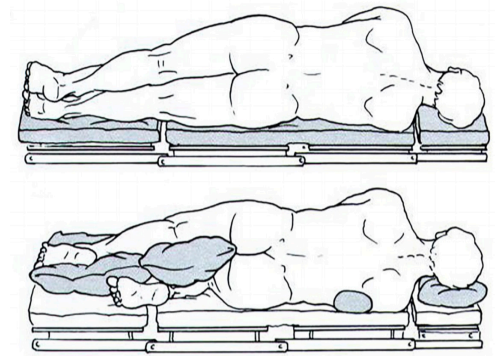


Figure 1

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.

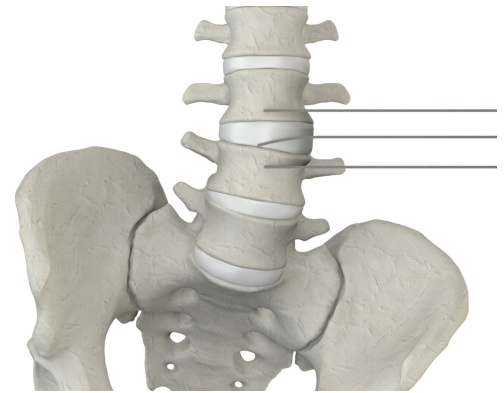


Figure 2

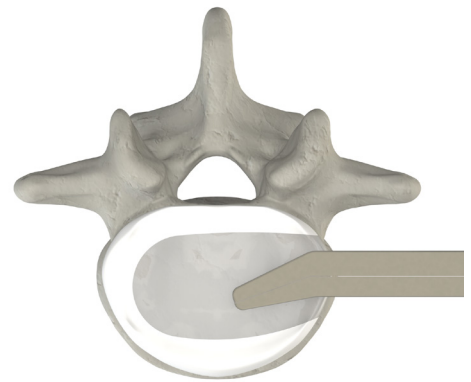


Figure 3

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.

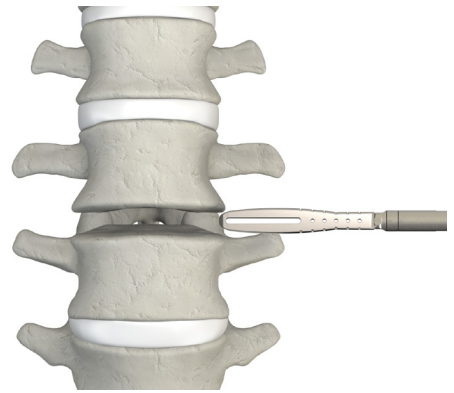


Figure 4

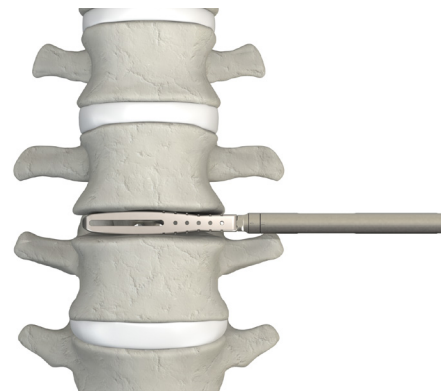


Figure 5

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).

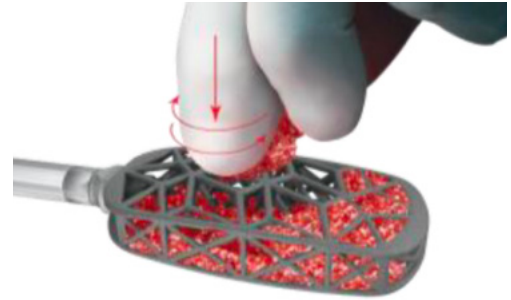


Figure 6



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.

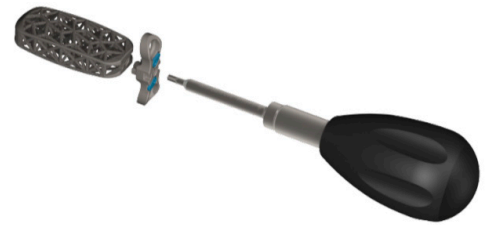


Figure 9

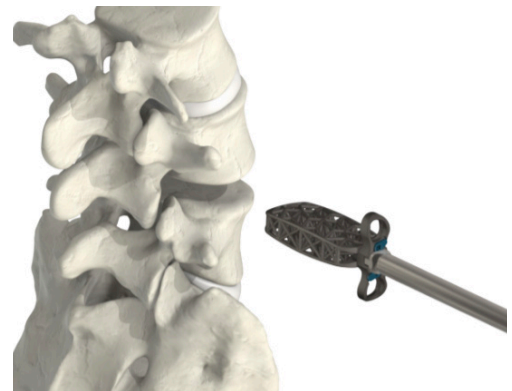


Figure 10

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.

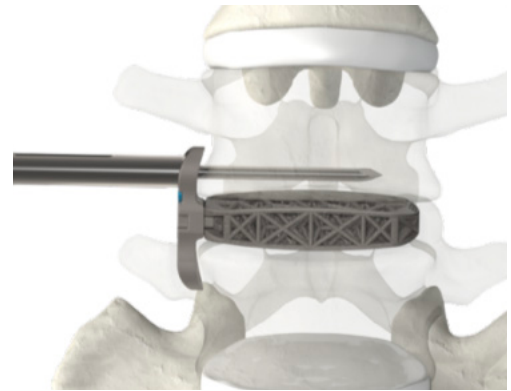


Figure 11

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).

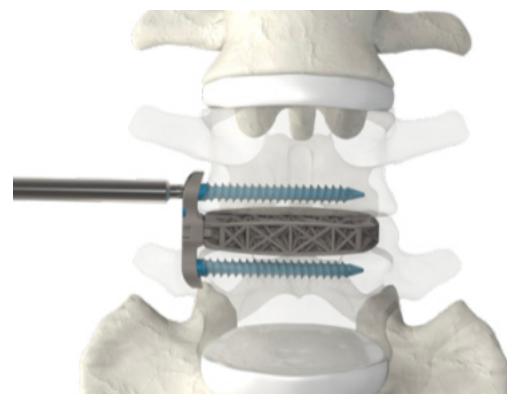


Figure 12

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.

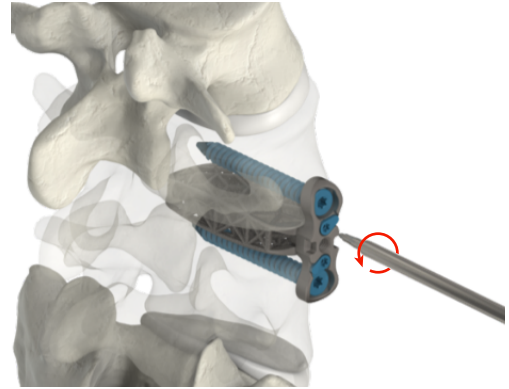


Figure 13







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 | DRIVER, PRESS FIT, T25 |
|  | |
| ASTS-SA-100020 | ANTI-BACKOUT PLATE DRIVER |
|  | |
| LSTS-100032 | ASSEMBLY TOOL, T10 |
|  | |
| LSTS-100033 | ASSEMBLY TOOL, IN SITU, T10 |
|  | |
| LSTS-100034 | AWL, VARIABLE DEPTH |
|  | |

| PART NUMBER | DESCRIPTION |
|-------------|-----------------------|
| LSTS-100035 | DRILL, VARIABLE DEPTH |



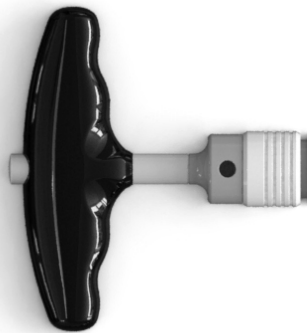
| | |
|-------------|---------------|
| LSTS-100036 | AWL, STRAIGHT |
|-------------|---------------|



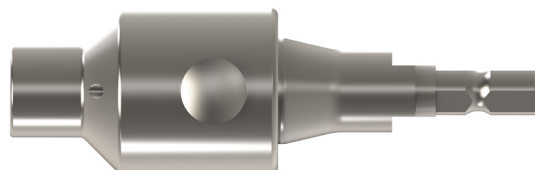
| | |
|-------------|----------------------------|
| LSTS-000014 | RATCHETING STRAIGHT HANDLE |
|-------------|----------------------------|



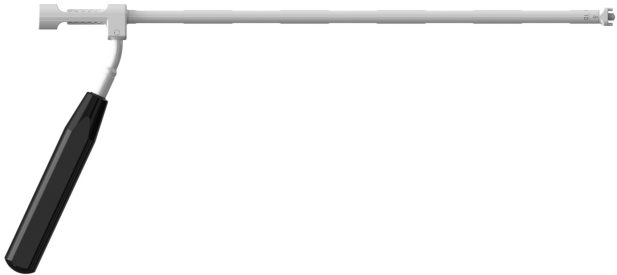
| | |
|-------------|---------------------|
| LSTS-000015 | RATCHETING T-HANDLE |
|-------------|---------------------|



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



| PART NUMBER | DESCRIPTION |
|-------------|--------------------------------------|
| LSTS-100038 | PLATE HOLDER, MIDLINE, OFFSET HANDLE |



| | |
|-------------|-------------------------|
| LSTS-100039 | PLATE HOLDER, SPLIT TIP |
|-------------|-------------------------|



| | |
|-------------|--|
| LSTS-100040 | PLATE HOLDER, SPLIT TIP, IMPACTION FEATURE |
|-------------|--|



| | |
|-------------|------------------|
| LSTS-100043 | OSTEOPHYTE BITER |
|-------------|------------------|





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