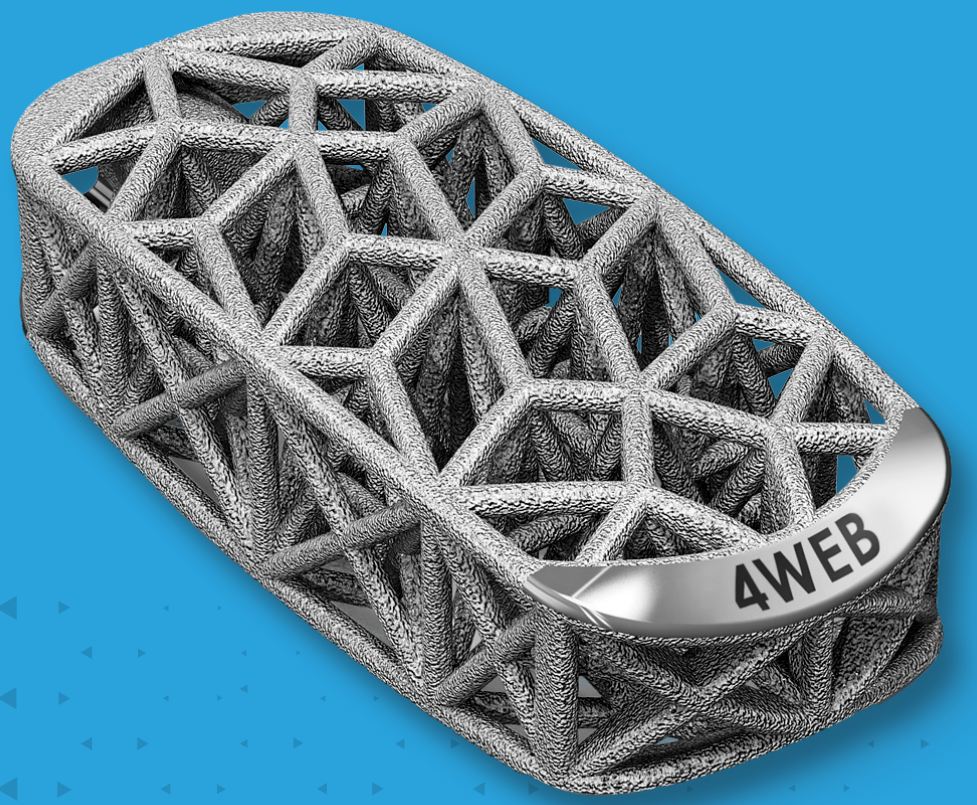
SURGICAL TECHNIQUE GUIDE

LATERAL SPINE TRUSS SYSTEM



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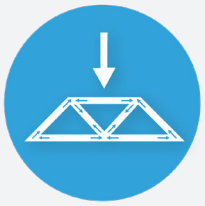
Federal law (USA) restricts these devices to sales by or on the order of a physician. Proper surgical procedure and technique are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the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

The Lateral Spine Truss System (LSTS) Interbody Fusion Device contains multiple footprints in a variety of heights and lordotic angles to accommodate the patient's anatomy. It is not intended to be used as a standalone device and must be used with supplemental fixation. The LSTS Interbody Fusion Device implants are provided sterile. Sizers and instruments are provided non-sterile and require sterilization prior to use.

INDICATIONS

The 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 devices. 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 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
- Prior fusion at the level(s) to be treated
- 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 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-05 or OUS-IFU-LSTS-03.

SURGICAL PROCEDURE

PRE-OPERATIVE PLANNING

Pre-operative planning with radiographs and other advanced imaging modalities can be helpful in estimating the appropriately sized implants with the goal of restoring disc height and fractional lordosis.

Determine the surgical approach based on the surgeon's preference. Implants and sizers are equipped with straight and offset instrument orientations.

PATIENT POSITIONING

Place the patient in a lateral decubitus position on the operating table with the lumbar spine in neutral to slight extension.

Fluoroscopy can be utilized to aid with patient positioning.

Using fluoroscopy, verify the location of the iliac crest and lower ribs in relation to the disc space of interest.

Note: At times you may want to break the table in order to gain better access to the operative level(s). Although infrequent, a few patients may have a deep-seated L4 – L5 disc space that could be difficult to reach via a direct lateral approach, even if table-breaking options are employed. If anatomical restrictions are present that prevent direct access to the disc space an alternative surgical approach should considered.

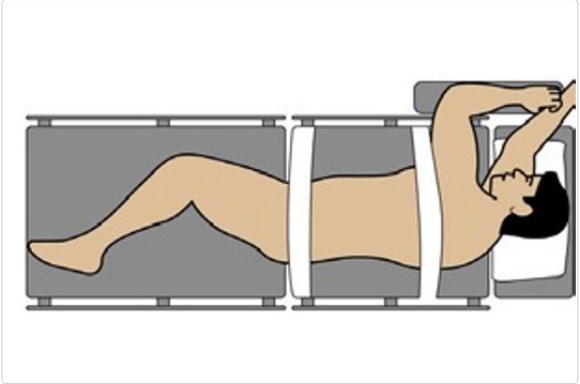


Figure 1

ACCESS AND EXPOSURE

Locate the correct operative level under fluoroscopic guidance. Confirm the target segment and mark the initial incision site. Make a skin incision targeting the anterior third of the disc space. Separate the abdominal oblique muscles with blunt dissection and enter the retroperitoneal space. Move the peritoneum anterior with forefinger and continue blunt dissection to palpate down to the psoas muscle.

Once the operative level(s) have been exposed, confirm the centerline of the affected level(s) with fluoroscopic imaging.

Note: Any bone removed during access and exposure may be used for autologous graft packing.

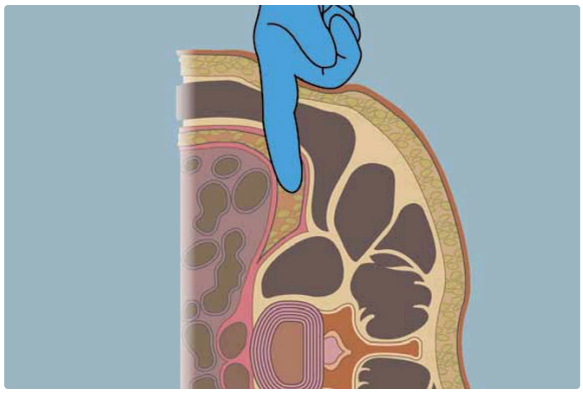


Figure 2

TISSUE DILATION AND RETRACTION

Use the surgeon's preferred dilator and retraction system to gain access to the disc space. Perform tissue dilation and retraction according to the instrument manufacturer's instructions for use.

DISCECTOMY AND ENDPLATE PREPARATION

Perform an annulotomy and subsequent lateral lumbar discectomy within the constraints of the operative window.

Remove the superficial layers of the cartilaginous endplates down to bleeding bone while trying to avoid compromising the integrity of the boney endplates.

Additional distraction may be applied as desired to increase visualization.

Note: Appropriate cleaning of the endplates is important to provide blood flow to the graft packed inside the implant. Excessive cleaning, on the other hand, can weaken the endplates. Take care to ensure that no damage is caused to the nerve roots.

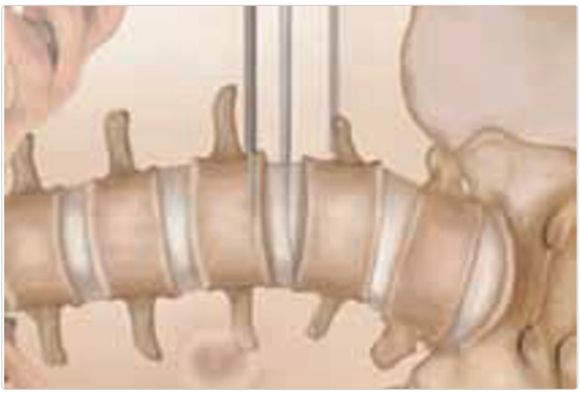


Figure 3

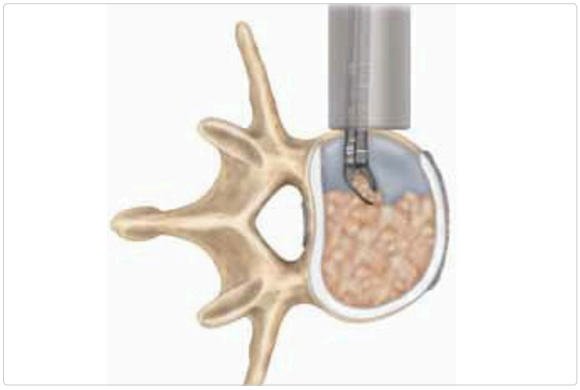


Figure 4

DISTRACTING AND SIZING

Select the appropriate sizer by footprint, height and lordotic angle, and attach it to the Straight or T Quick Connect Handle. Footprint, height, and lordotic angle measurements are clearly marked on the face of the sizers.

Carefully impact the sizer into the disc space. Check the correct fit of the sizer with the aid of fluoroscopy and palpation.

If the sizer is too loose or too tight, try the next larger/ smaller size until a secure fit is achieved.

Remove the sizer from the prepared disc space and select the corresponding implant.

Note: Although over distraction of the disc space is to be avoided, the largest implant that can be safely implanted in the disc space is generally the optimal implant size. Maximizing the implant surface with the vertebral endplates and providing an appropriate amount of preload through disc space distraction will help to create a stable environment conducive to new bone formation.

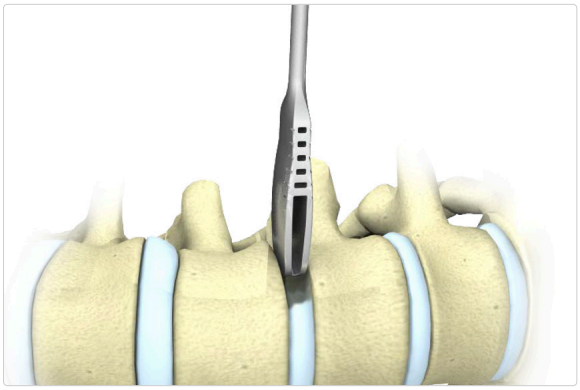


Figure 5

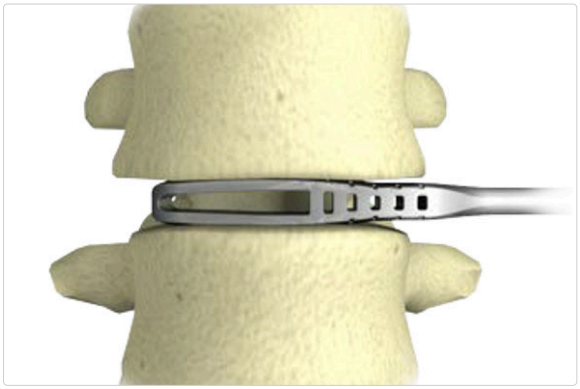


Figure 6

IMPLANT PREPARATION

Attaching Implant Inserter:

LSTS Interbody Fusion Device implants are provided in a sterile package. Select the implant that corresponds to the appropriate sizer. Open the implant package using proper sterile technique.

Attach the implant to the inserter. Ensure the prongs are fully seated and no threads are visible.

Be careful not to over-tighten.

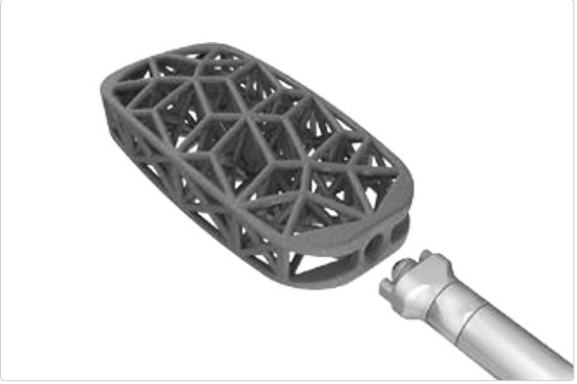


Figure 7

Attaching LSTS-PS Integrated Plate:

If an integrated plate is desired, the appropriate LSTS-PS Plate may be attached to the LSTS Interbody on the back table using the LSTS Plate Driver. 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.

Note: The LSTS Integrated Plates have an internal fixation screw for locking the Plate to the Interbody. The LSTS Integrated Plate must be used with interbodies with 18° of lordosis or greater. If using a 1-hole Integrated Plate, additional supplemental fixation is required (e.g. posterior fixation). Please refer to the LSTS-PS Surgical Technique Manual for additional information, ST-LSTS-PS-01.

Note: The LSTS plates are currently available in the US only.

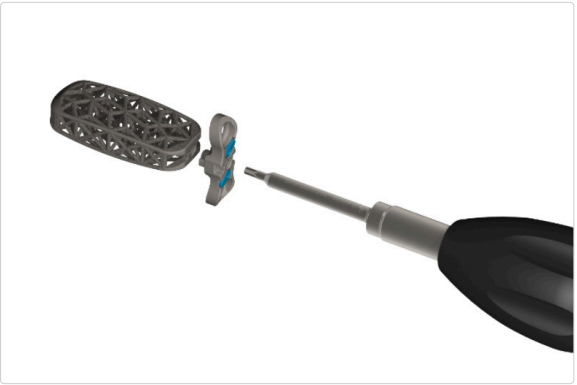


Figure 8

Figure 9

Packing Implant:

Pack the implant with autologous and/or allogenic bone graft. For best results, cut or morselize the autologous bone 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 bone particles into the implant.

Once packing has been completed through the top web structure, turn the implant over and repeat the placement of bone into the bottom web structure. Pack autologous and/or allogenic bone into the implant as appropriate.

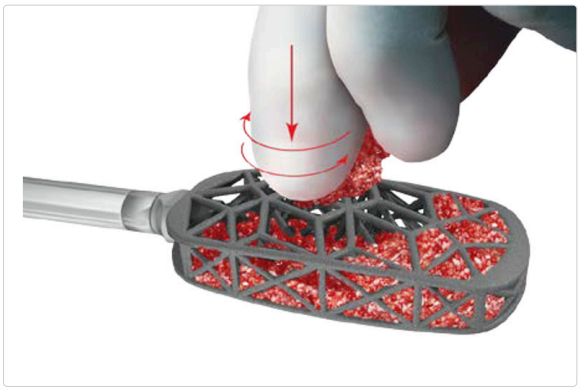


Figure 10

IMPLANT INSERTION

Insertion without Plate:

Introduce the implant into the prepared intervertebral space and tap it into place with a mallet. Confirm the proper placement of the implant using fluoroscopy.

Once the implant is in the proper position, disengage and remove the inserter.

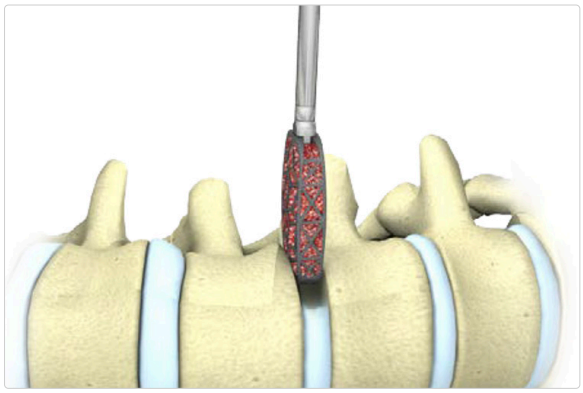


Figure 11

Insertion with Plate:

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 LSTS Plate Driver. Please refer to the LSTS-PS Surgical Technique Manual for information regarding screw hole preparation, ST-LSTS-PS-01.

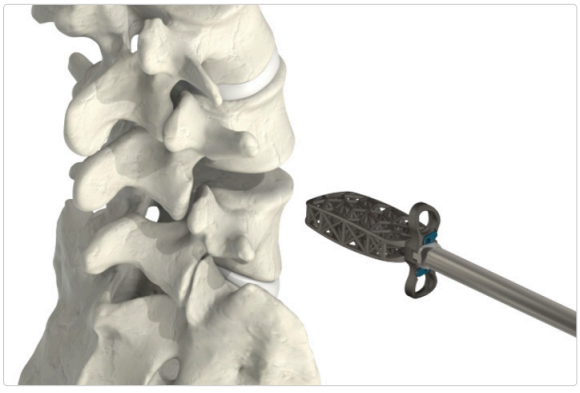


Figure 12

Distractor Shims:

Optional Distractor Shims are provided in the Implant Manipulation Tray. The Distractor Shims can be assembled on the Straight Inserter to aid in implant insertion. Confirm the proper placement of the implant using fluoroscopy.

Once the implant is in the proper position, disengage and remove the inserter.

Implant Positioning:

If the implant needs to be positioned further into the prepared space, gently tap the implant with the tamp provided in the instrument tray.

Verify final placement of the implant with fluoroscopic imaging.

IMPLANT REMOVAL

If implant removal is required, the intervertebral space should be distracted in the same manner as for implant placement. Once distracted, the implant may be removed by using the insertion tool.

The implant should be disengaged from the superior and inferior endplates with the surgeon's preferred technique. The surgeon should apply slight back-pressure in order to remove the implant.

If greater force is required, use the slap hammer provided in the Implant Manipulation Tray to remove the implant.

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