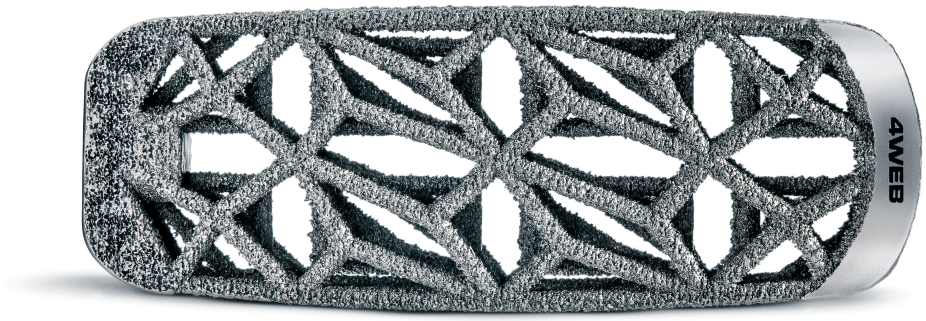


LATERAL SPINE TRUSS SYSTEM

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 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 Lateral Spine Truss System (LSTS) 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 stand alone device and must be used with supplemental fixation. The LSTS implants are provided sterile. Sizers and instruments are provided non-sterile and require sterilization prior to use.

4WEB® MEDICAL

1: 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.

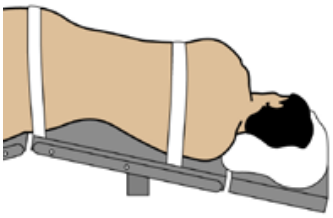
Determine the surgical approach based on the surgeon's preference. Implants and sizers are equipped with straight and off set instrument orientations.

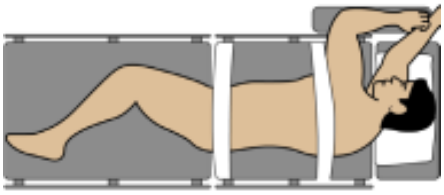
2: PATIENT POSITIONING

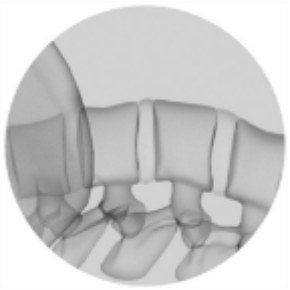
Place the patient in a lateral decubitus position on the operating table with the lumbar spine in neutral to slight extension.

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.





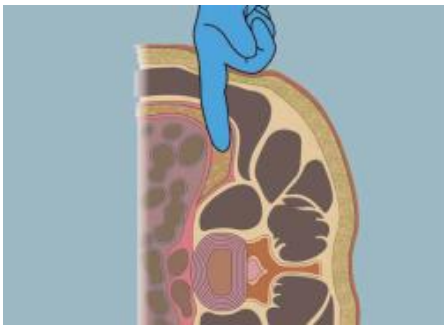


NOTE: *At times you may want to break the table in order to gain better access to the operative level(s). Although infrequent, a few patients may have a deep-seated L4 – L5 disc space that could be difficult to reach via a direct lateral approach, even if table-breaking options are employed. If anatomical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

3. 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.*

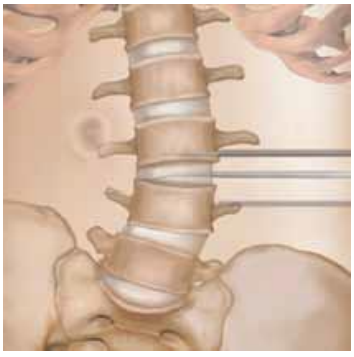
4. TISSUE DIALATION AND RETRACTION

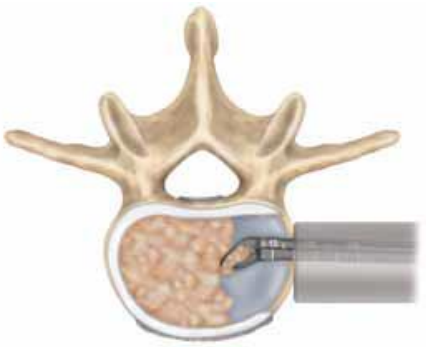
Use the surgeons preferred dilator and retraction system to gain access to the disc space. Perform tissue dilation and retraction according to instrument manufactures instructions for use.

5. 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 autologous bone 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.*

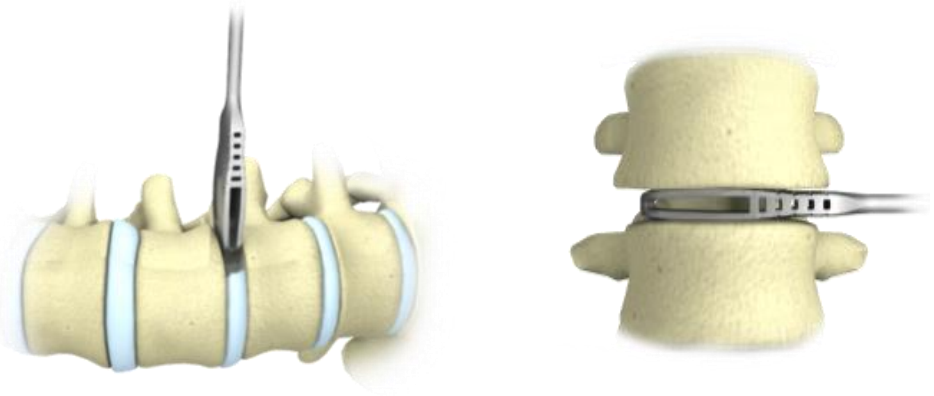
6. DISTRACTING AND SIZING

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.



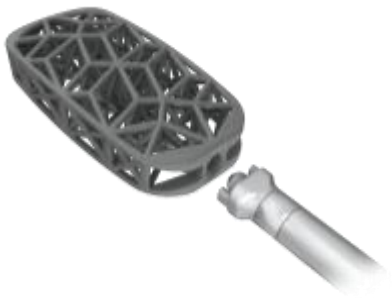
NOTE: *Although over distraction of the disc space is to be avoided, the largest implant that can be safely implanted in the disc space is generally the optimal implant size. Maximizing the implant surface with the vertebral endplates and providing an appropriate amount of preload through disc space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

7. IMPLANT PREPARATION

Attaching Implant Inserter:
LSTS implants are provided in a sterile package. Select the implant that corresponds to the appropriate sizer. Open the implant package using proper sterile technique.

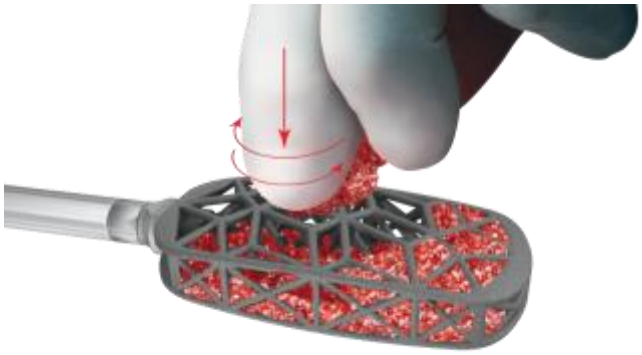
Attach the implant to the inserter. Ensure the prongs are fully seated and no threads are visible.

Be careful not to over-tighten.



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.

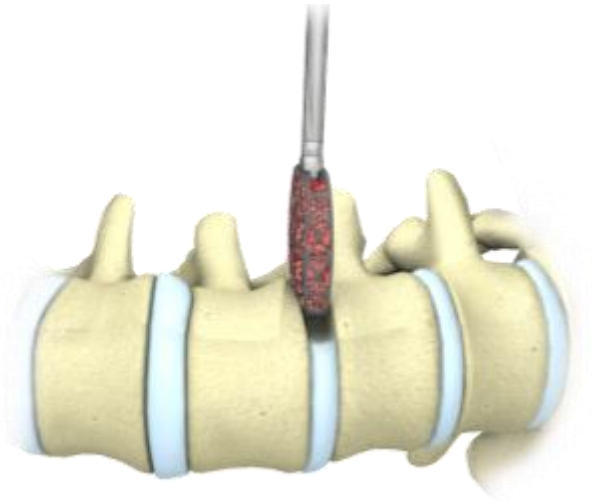
Once packing has been completed through the top web structure, turn the implant over and repeat the placement of bone into the bottom web structure. Pack autologous and/or allogenic bone into the implant as appropriate.

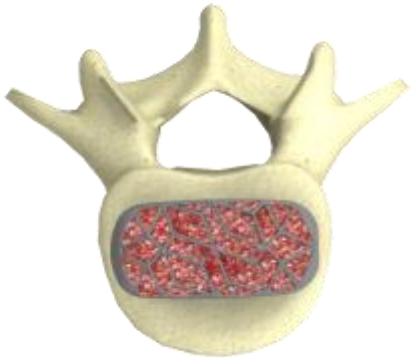


8. IMPLANT INSERTION

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.





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.

9. 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.

PRODUCT SPECIFICATIONS

ITEM	CATALOG NUMBER	FOOTPRINT	LORDOSIS
0 DEGREE LORDOTIC			
1	LSTS-SM0008-45-SP	18W x 45L x 8H	0°
2	LSTS-SM0010-45-SP	18W x 45L x 10H	0°
3	LSTS-SM0012-45-SP	18W x 45L x 12H	0°
4	LSTS-SM0014-45-SP	18W x 45L x 14H	0°
5	LSTS-SM0008-50-SP	18W x 50L x 8H	0°
6	LSTS-SM0010-50-SP	18W x 50L x 10H	0°
7	LSTS-SM0012-50-SP	18W x 50L x 12H	0°
8	LSTS-SM0014-50-SP	18W x 50L x 14H	0°
9	LSTS-SM0008-55-SP	18W x 55L x 8H	0°
10	LSTS-SM0010-55-SP	18W x 55L x 10H	0°
11	LSTS-SM0012-55-SP	18W x 55L x 12H	0°
12	LSTS-SM0014-55-SP	18W x 55L x 14H	0°
13	LSTS-MD0008-45-SP	22W x 45L x 8H	0°
14	LSTS-MD0010-45-SP	22W x 45L x 10H	0°
15	LSTS-MD0012-45-SP	22W x 45L x 12H	0°
16	LSTS-MD0014-45-SP	22W x 45L x 14H	0°
17	LSTS-MD0008-50-SP	22W x 50L x 8H	0°
18	LSTS-MD0010-50-SP	22W x 50L x 10H	0°
19	LSTS-MD0012-50-SP	22W x 50L x 12H	0°
20	LSTS-MD0014-50-SP	22W x 50L x 14H	0°
21	LSTS-MD0008-55-SP	22W x 55L x 8H	0°
22	LSTS-MD0010-55-SP	22W x 55L x 10H	0°
23	LSTS-MD0012-55-SP	22W x 55L x 12H	0°
24	LSTS-MD0014-55-SP	22W x 55L x 14H	0°
6 DEGREE LORDOTIC			
25	LSTS-SM0608-45-SP	18W x 45L x 8H	6°
26	LSTS-SM0610-45-SP	18W x 45L x 10H	6°
27	LSTS-SM0612-45-SP	18W x 45L x 12H	6°
28	LSTS-SM0614-45-SP	18W x 45L x 14H	6°
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35	LSTS-SM0612-55-SP	18W x 55L x 12H	6°
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54	LSTS-MD0610-60-SP	22W x 60L x 10H	6°
55	LSTS-MD0612-60-SP	22W x 60L x 12H	6°
56	LSTS-MD0614-60-SP	22W x 60L x 14H	6°
12 DEGREE LORDOTIC			
57	LSTS-SM1208-45-SP	18W x 45L x 8H	12°
58	LSTS-SM1210-45-SP	18W x 45L x 10H	12°
59	LSTS-SM1212-45-SP	18W x 45L x 12H	12°
60	LSTS-SM1214-45-SP	18W x 45L x 14H	12°
61	LSTS-SM1208-50-SP	18W x 50L x 8H	12°
62	LSTS-SM1210-50-SP	18W x 50L x 10H	12°
63	LSTS-SM1212-50-SP	18W x 50L x 12H	12°
64	LSTS-SM1214-50-SP	18W x 50L x 14H	12°
65	LSTS-SM1208-55-SP	18W x 55L x 8H	12°
66	LSTS-SM1210-55-SP	18W x 55L x 10H	12°
67	LSTS-SM1212-55-SP	18W x 55L x 12H	12°
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71	LSTS-SM1212-60-SP	18W x 60L x 12H	12°
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78	LSTS-MD1210-50-SP	22W x 50L x 10H	12°
79	LSTS-MD1212-50-SP	22W x 50L x 12H	12°
80	LSTS-MD1214-50-SP	22W x 50L x 14H	12°
81	LSTS-MD1208-55-SP	22W x 55L x 8H	12°
82	LSTS-MD1210-55-SP	22W x 55L x 10H	12°
83	LSTS-MD1212-55-SP	22W x 55L x 12H	12°
84	LSTS-MD1214-55-SP	22W x 55L x 14H	12°
85	LSTS-MD1208-60-SP	22W x 60L x 8H	12°
86	LSTS-MD1210-60-SP	22W x 60L x 10H	12°
87	LSTS-MD1212-60-SP	22W x 60L x 12H	12°
88	LSTS-MD1214-60-SP	22W x 60L x 14H	12°

Products not available for sale outside of the United States.

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 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:

Safety and effectiveness have not been established in the following conditions:

- Gross obesity
- Three or more levels to be fused
- Symptomatic cardiac disease
- Pregnancy
- Previous fusion attempts at the involved level(s)
- Spondylolisthesis or retrolisthesis greater than Grade I
- Significant loss of bone stock as seen with osteoporosis or osteomalacia
- Conditions requiring chronic corticosteroid use
- Active drug abuse

The LSTS Interbody Fusion Device is for single use only.

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

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

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

All implants, sizers 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.

OPERATIVE PRECAUTIONS:

The surgeon is to be thoroughly familiar with the LSTS Interbody Fusion Device, methods of application, instruments 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 and/or allogenic bone to promote bone fusion. 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.

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, paraparesis, 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 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 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 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:

Please see Instructions For Use (OUS-IFU-LSTS-01)

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CE 0344

ST-LSTS-01 Rev D 02/19