EMINENT
SPINE

3D PLIF and TLIF System

Surgical Technique

Eminent Spine

PRODUCT FEATURES

- 3D printed Titanium
- Aggressive teeth to resist migration
- Large central opening for maximum bone graft material
- Tapered nose, lordosis and rounded edges allows for ease of insertion

PLIF

TLIF

IMPLANT PROFILES

	HEIGHT (1mm)	LENGTH X WIDTH	LORDOSIS
PLIF	8-12 mm	24 mm x 9 mm	6°
	7-16 mm	28 mm x 9 mm	6°
	7-16 mm	31 mm x 9 mm	6°

	HEIGHT (1mm)	LENGTH X WIDTH	LORDOSIS
TLIF	7-16 mm	32 mm x 11 mm	6°

EMINENT SPINE

Step 1 : Patient Positioning

Place the patient in the prone position. Perform posterior approach to the lumbar spine at the affected disc level.

Step 2 : Perform Laminectomy/Discectomy

Perform a laminectomy and discectomy. Start by incising the disc and making a rectangular window. Protect the Dura with a nerve root retractor (Figure 1). Use peapods & pituitary rongeurs to remove further disc material (Figure 2, 3).

Figure 1

Figure 2

Figure 3

Surgical Pearl: Identify the superior exiting nerve root to avoid injury (Figure 4).

Figure 4

If needed, remove the medial aspect of the facet joint (Figure 5, 6). Remove the superior and inferior osteophytes with a straight pituitary or kerrison in order to open up the orifice of the disc space. This allows the bullet nose of the implant to be easily inserted into the disc space (Figure 7).

Figure 5

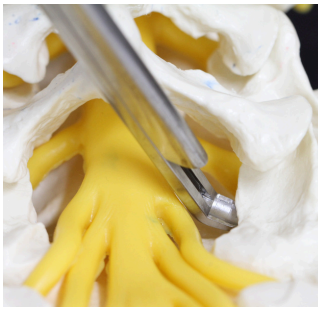
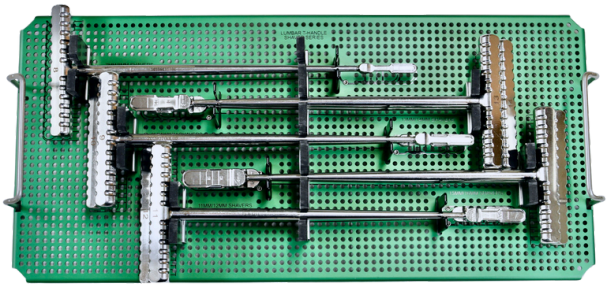


Figure 6

Figure 7

Step 3 : Shavers

Use the disc shavers for thorough removal of disc material and cartilaginous tissue from the disc space. Multiple fluted sizes are available (Figures 8 and 9). The shavers are in one piece and do not allow for "play" between the T-handle and the shaft.



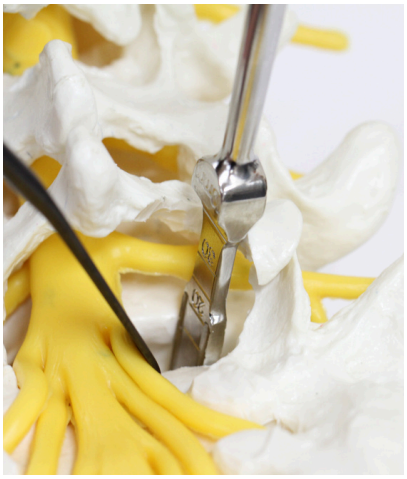
Shavers (Figure 8)

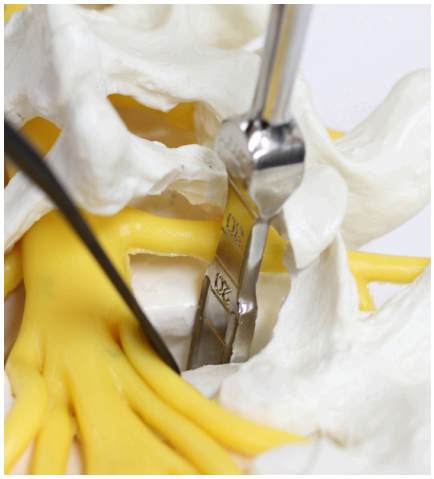
Shavers (Figure 9)

*Parallel to the endplate

*Marked shavers show depth of disc space

*Rounded edges of the shavers lessen neural injury



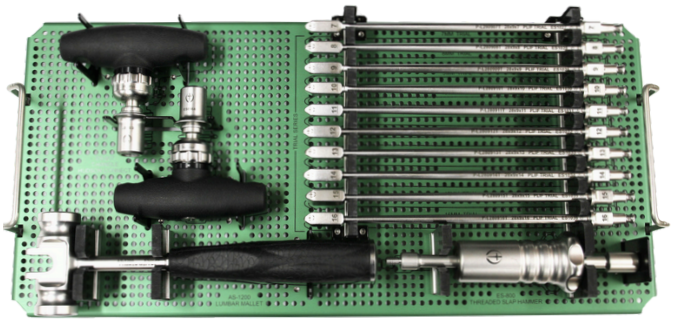


*Rotate the shaver

*Perpendicular to the endplate and will distract the disc space

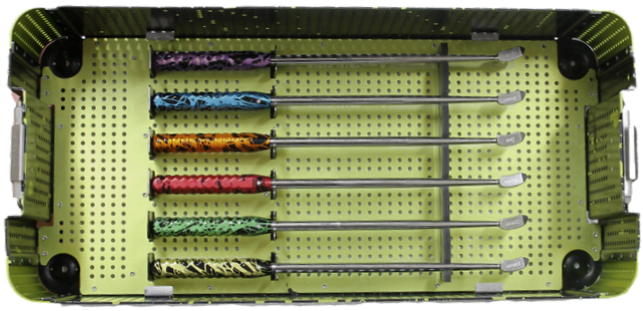
Step 4 : Trial Spacers

Trial spacers 8mm-13mm are available (Figure 10 and 11).



PLIF trials 8-13mm

Figure 10



TLIF trials 8-13mm

Figure 11

PLIF trial

Insert the trial into the disc space (Figure 12, 13, 14).

Figure 12

Figure 13

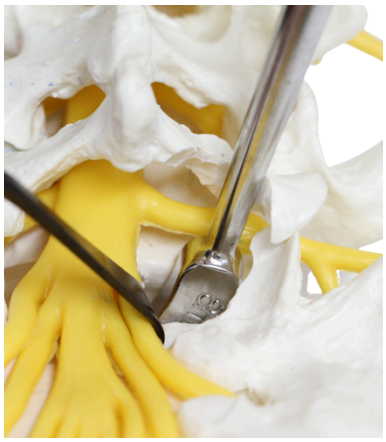


Figure 14

Step 5 : Inserter

Select the appropriate Implant determined by the trial. Then assemble the implant onto the inserter. While holding the interbody on the inserter, rotate the inserter knob clockwise to securely attach the interbody (Figure 15).

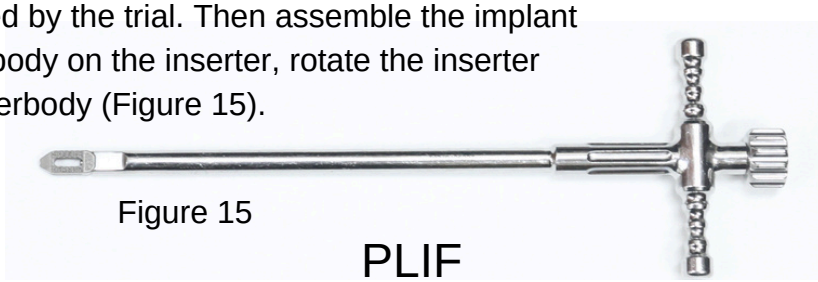
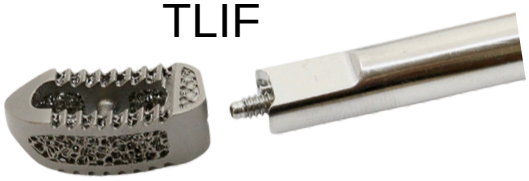


Figure 15

TLIF



PLIF

The tabs of the inserter resist it from stripping out of the implant, and provides rotational stability while inserting the implant (Figure 16).

Figure 16

Note: The inserter is designed so that the surgeon can visualize the implant upon insertion. This eliminates blind insertion of the implant (Figure 17).

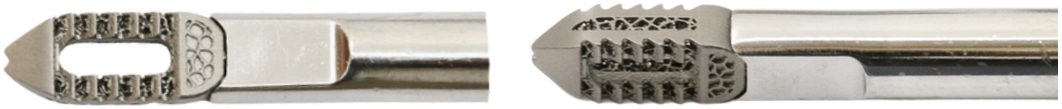


Figure 17

Step 6 : Packing Final Implant

Place the implant into the footprint on the Graft Packing Block (Figure 18,19). Fill the chamber of the implant with bone and impact the bone with the Bone Tamp. Impacting the bone graft ensures proper dense bone packing in the implant.

TLIF

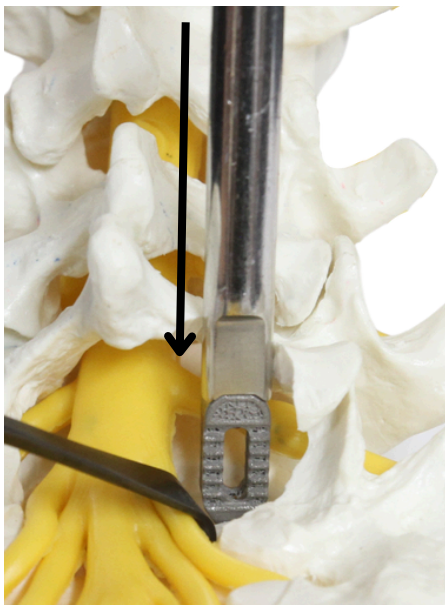
Figure 18

PLIF

Figure 19

Step 7 : Implant Positioning

Protect the Dura with a nerve root retractor and be aware of the superior nerve root. Do not apply excessive retraction. Obtain AP & Lateral Fluoroscopy images. Make sure the implant is not too far posterior and does not impinge on any neural structure. Use the implant impactor for final implant positioning (Figure 20).



*Straight in

*Parallel to endplate

PLIF Fusion

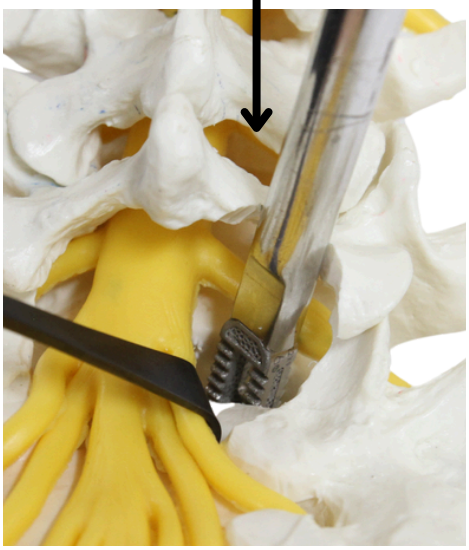


Figure 20

*PLIF implant has rounded edge to allow for rotational insertion

Step 7 : Implant Positioning

Note: Inserter allows surgeon to visualize the implant (Figure 21).

Figure 21

Final Implant Positioning:

Obtain AP & Lateral Fluoroscopy images to verify correct placement of the implant. Visually inspect the implant and it should be well positioned in the disc space. The implant should not impinge on any neural structure (Figure 22).

Figure 22

Step 7 : Implant Positioning

Use the implant impactor for final implant positioning. The design of the implant will rotate into the disc space (Figure 23).

Option: Surgeon can insert pedicle screws, then apply a temporary rod to distract the pedicle screws, then insert the cage, then remove the temporary rod.

Figure 23

TLIF Fusion

Obtain AP & Lateral Fluoroscopy images to verify correct placement of the implant. Visually inspect the implant and it should be well positioned in the disc space. The implant should not impinge on any neural structure (Figure 24).

Figure 24

Step 8: Implant Removal & Revisions

All implants can be removed by performing the insertion steps in reverse. Attach the implant Inserter to the implant and carefully remove the implant (Figure 25).

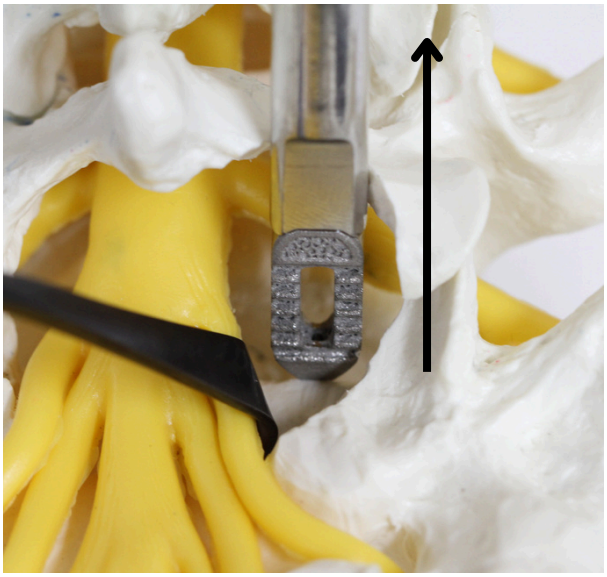
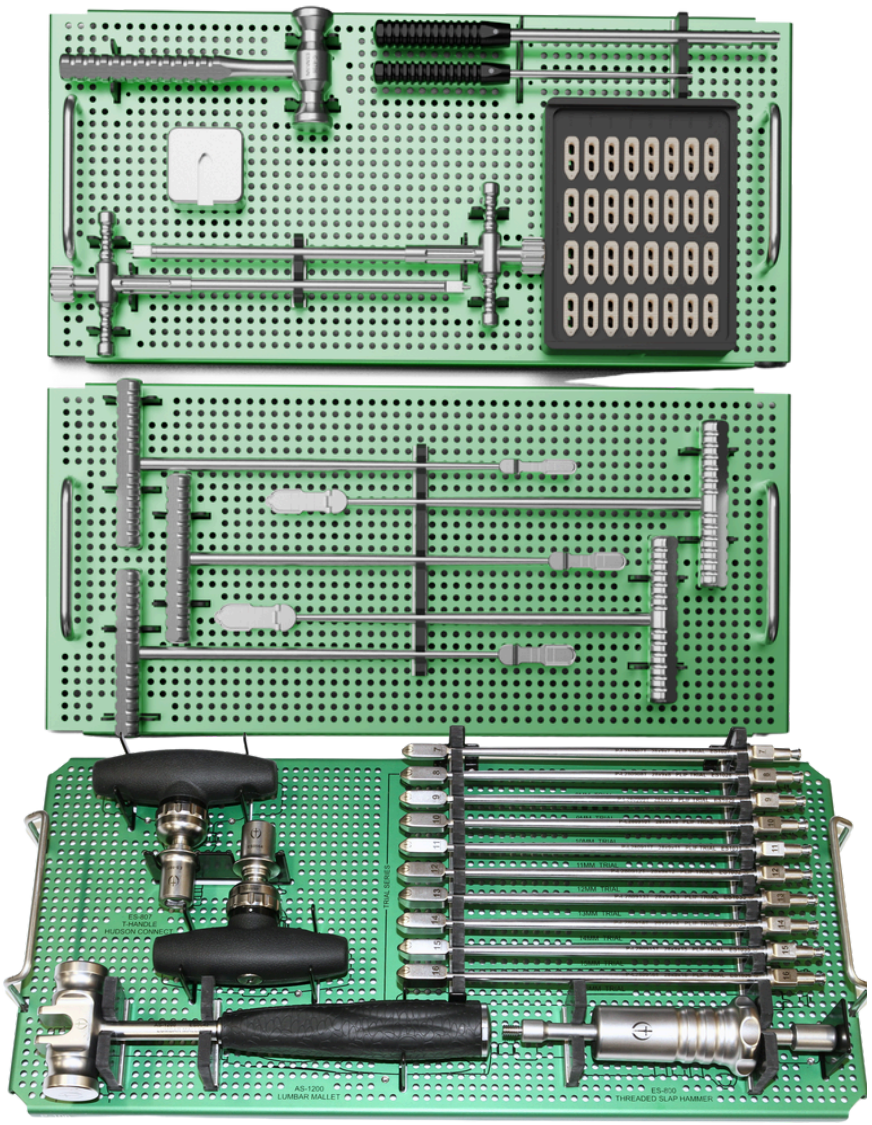


Figure 25

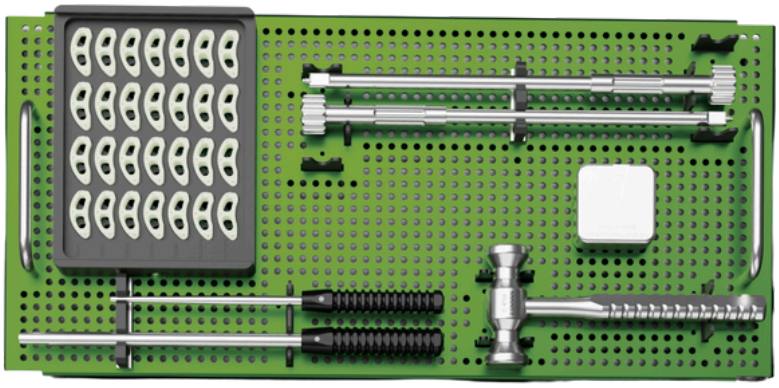
PLIF Tray Layout

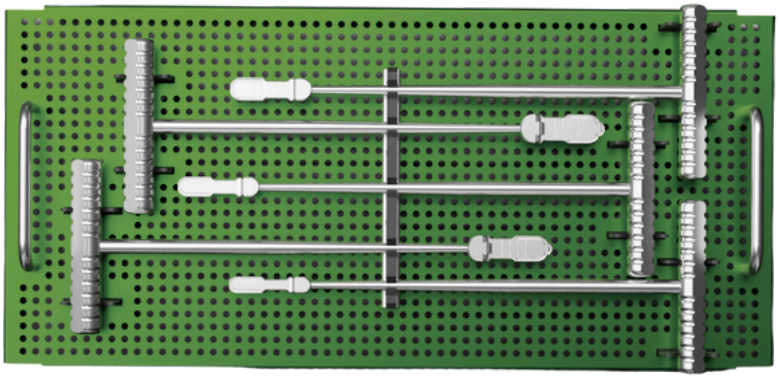


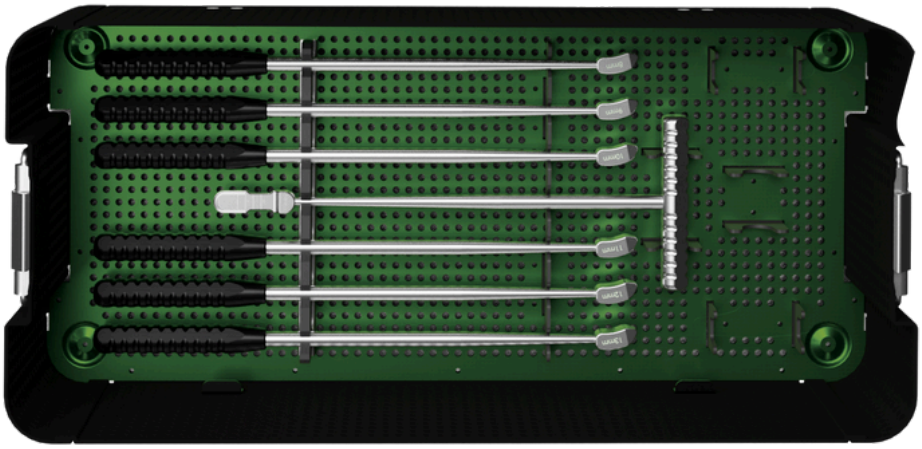
LAYOUT:

1. Mallet
2. Graft Packing Block
3. Packing Block Tamp
4. Implant Tamp
5. Implant Caddy
6. T-Handle Inserter
7. Shavers
8. Trials

TLIF Tray Layout



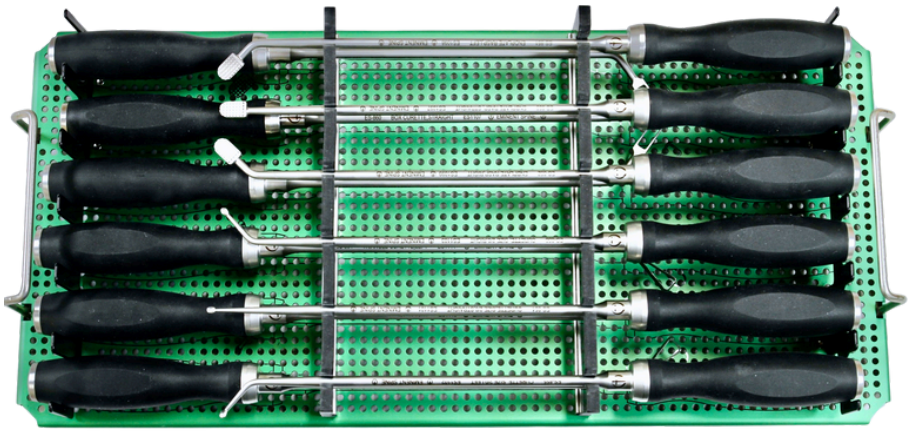


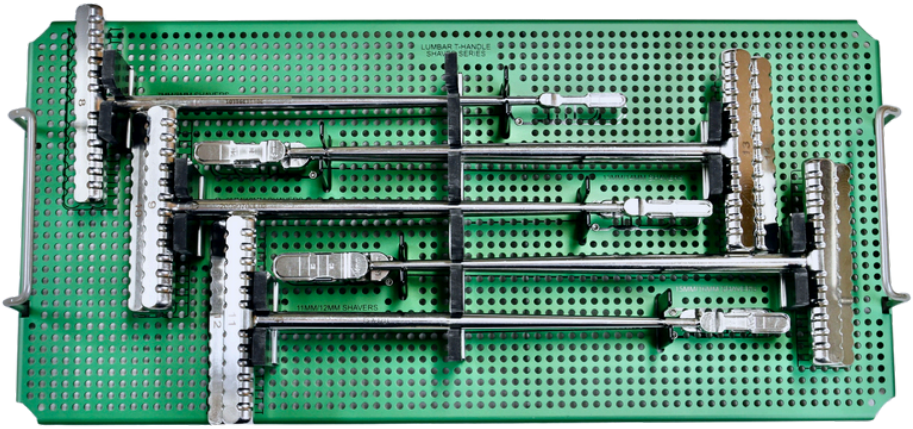


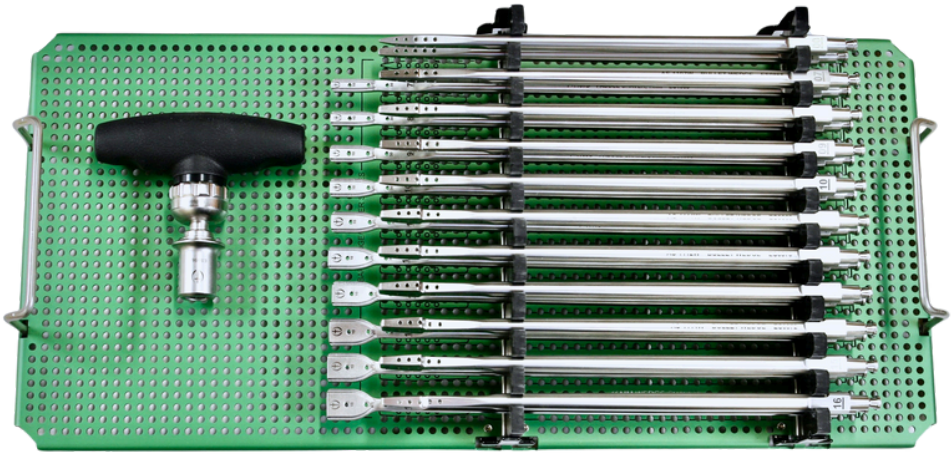
LAYOUT:

1. Implant Caddy
2. Implant Inserter
3. Packing Block Tamp
4. Implant Tamp
5. Graft Packing Block
6. Mallet
7. Shavers
8. Trials

TLIF/PLIF Prep Set Layout







LAYOUT:

1. Shavers
2. Hudson
3. T-Handle Shavers
4. Currettes
5. End Plate Rasps

PLIF System
Product Codes/ Options

PLIF IBFD - PEEK

Code	Profile	Heights	Material	Lordosis
P10XX	22mm x 9mm	8mm-16mm	PEEK	0°
P20XX	24mm x 9mm	8mm-16mm	PEEK	0°
P30XX	28mm x 9mm	7mm-16mm	PEEK	0°
PL30XX	28mm x 9mm	7mm-16mm	PEEK	6°
PL40XX	25mm x 10mm	7mm-16mm	PEEK	6°
PL50XX	32mm x 9mm	7mm-16mm	PEEK	6°
PL2512XX	25mm x 12mm	8mm-15mm	PEEK	6°

PLIF IBFD - Machined Ti

Code	Profile	Heights	Material	Lordosis
P22XX	24mm x 9mm	7mm-16mm	Machined Ti	0°
PL32XX	28mm x 9mm	8mm-16mm	Machined Ti	6°

PLIF IBFD - 3D Printed Ti

Code	Profile	Heights	Material	Lordosis
P3L2409XX	24mm x 9mm	*8mm-12mm*	3D Printed Ti	6°
P3L2809XX	28mm x 9mm	7mm-16mm	3D Printed Ti	6°
P3L3109XX	31mm x 9mm	7mm-16mm	3D Printed Ti	6°

* = Limited

Code “XX” = Height

Ex: PLIF IBFD - 3D Printed Ti

Profile: 28mm x 9mm, **Height: 10mm**, Lordosis: 6°

Product Code = P3L280910

TLIF System
Product Codes/ Options

TLIF IBFD - PEEK

Code	Profile	Heights	Material	Lordosis
T30XX	28mm x 11mm	7mm-16mm	PEEK	0°
T40XX	30mm x 11mm	7mm-16mm	PEEK	0°

TLIF IBFD - Machined Ti

Code	Profile	Heights	Material	Lordosis
T32XX	32mm x 11mm	7mm-13mm	Machined Ti	0°
TL32XX	32mm x 11mm	7mm-16mm	Machined Ti	6°

TLIF IBFD - 3D Printed Ti

Code	Profile	Heights	Material	Lordosis
T3L3221XX	32mm x 11mm	7mm-16mm	3D Printed Ti	6°

* = Limited

Code "XX" = Height

Ex: TLIF IBFD - 3D Printed Ti

Profile: 32mm x 11mm, **Height: 10mm**, Lordosis: 6°

Product Code = T3L3221**10**

Eminent Spine LLC Lumbar Interbody Fusion Systems:
ALIF, LLIF, OLIF, PLIF, TLIF and TPLIF

Eminent Spine LLC
2004 Ventura Drive #100
Plano, TX 75093
Phone : 972-499-3593

System Contents:

Non-Sterile Implants – Single Use Only
Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION and INTENDED USE:
The Eminent Spine LLC Lumbar Interbody Fusion Systems (ALIF, LLIF, OLIF, PLIF, TLIF and TPLIF) are comprised of various sizes and configurations to accommodate individual patient anatomy. The configurations are designed to provide the surgeon with different surgical approach options. The ALIF implants are cylinder shaped blocks, which are available in a parallel or lordotic configuration of various heights. The hollow cylinders allow for placement of bone graft and facilitate fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. ALIF is intended to be implanted singularly via an anterior approach.

The LLIF implants are rectangular shaped blocks with bowed sides in a parallel configuration of various heights. Large bone graft windows are located through the body of the device to allow for placement of bone graft and facilitate fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. LLIF implants are designed to be implanted singularly via a lateral approach.

The OLIF implants are rectangular shaped blocks with parallel sides, tapered bullet tip cannulated nose for insertion and offered only in a parallel configuration of various lengths and heights. Large bone graft windows are located through the body of the device to allow for placement of bone graft and facilitate fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. OLIF implants are designed to be implanted singularly via a transforaminal approach.

The PLIF implant consists of conical shaped blocks in a parallel configuration of various heights. Large bone graft windows are located through the body of the device to allow for placement of bone graft and facilitate fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. PLIF may be implanted singularly or in pairs via a posterior approach.

The TLIF implant consists of banana shaped blocks in a parallel configuration of various heights. Large bone graft windows are located through the body of the device to allow for placement of bone graft and facilitate fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants. TLIF may be implanted singularly via a transforaminal approach.

The TPLIF implants are rectangular shaped blocks with parallel sides, tapered bullet tip nose for insertion and offered in a parallel and lordotic configuration of various lengths and heights. Large bone graft windows are located through the body of the device to allow for placement of bone graft and facilitate fusion. The superior and inferior surfaces of the devices have a diagonal pattern of teeth to provide increased stability and inhibit movement of the implants. TPLIF implants are designed to be implanted singularly via an oblique approach.

INDICATIONS:
When used as an intervertebral body fusion device, the implants (ALIF, LLIF, OLIF, PLIF, TLIF and TPLIF) are indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and autograft to facilitate fusion.

When used as a vertebral body replacement device, the implants (ALIF, LLIF, OLIF, PLIF, TLIF and TPLIF) are indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The implant is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental internal fixation and autograft or allograft bone. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

CONTRAINDICATIONS:
1. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to PEEK or Titanium alloy 6Al-4V material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be noncompliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:
Eminent Spine LLC implants are manufactured from either PEEK (Optima LT1 or VESTAKEEP i4R) with Tantalum pins or entirely of Titanium alloy 6Al-4V with no pins. Surgical instruments provided with the implants are manufactured from stainless steel.

CLEANING of INSTRUMENTS and IMPLANTS:
1. Clean all instruments and implants prior to use, and as soon as possible after use. Do not allow blood or debris to dry on the instruments that were used in surgery. If cleaning must be delayed, place instruments that were used in surgery in a covered container with neutral pH detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts. Remove implants (in caddies) from set cases.
3. Immerse the instruments and implants in a neutral pH detergent or enzymatic solution prepared in accordance with the manufacturer's instructions and soak for 15 minutes.
4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard-to-clean areas) until all visible soil has been removed.
5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hard to clean areas.
6. After manual cleaning has been completed, load the parts into a suitable automated cleaner and follow the manufacturer's recommended practices. Use only neutral pH enzymatic cleaners and detergents. Avoid excessively acidic or alkaline solutions.

INSPECTION:
1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Eminent Spine LLC representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Eminent Spine LLC representative for a replacement.

STERILIZATION:
All implants and instruments are supplied visually clean and nonsterile and must be sterilized prior to use. The following sterilization cycle has been validated:

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270ºF (132ºC)
Exposure Time: 4 minutes
Number of pulses: 4
Dry time: 30 minutes

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged. Instruments composed of more than one part or with sliding pieces or removable parts should be disassembled. Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: A42013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79:A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging.

POSTOPERATIVE MOBILIZATION:
The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:
Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.
1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc, facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record, including radiographic studies and applicable diagnostic tests, should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.

b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant or subsidence.
d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS:
1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. The surgeon should use trials to determine the appropriate implant to use. The implant should be tall enough to provide segmental distraction and stability. The implant should be wide enough to maintain contact with the cortical rim of the vertebral body else the risk of subsidence may increase.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is non-compliant with post-operative guidance is particularly at risk during the early postoperative period.
6. MAGNETIC RESONANCE ENVIRONMENT. The Eminent Spine LLC Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The Eminent Spine LLC Interbody Fusion System has not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS:
1. Non-union, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
10. Paralysis.
11. Death.
12. Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/or death.

LIMITED WARRANTY:
Eminent Spine LLC products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed. If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Eminent Spine LLC for current information.

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For product information or questions pertaining to sales and service, please contact your local sales representative or Eminent Spine LLC customer service.

EMINENT SPINE

Eminent Spine is dedicated to manufacture biomechanically sound spinal implants and focus on surface technology.

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