MET ONE TECHNOLOGIES

Surgical Technique

Kodiak Lumbar Spacer System

STG-06 Rev A
11-15-2023

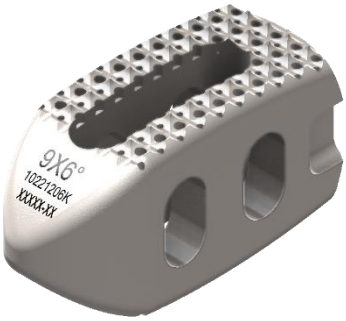
TABLE OF CONTENTS

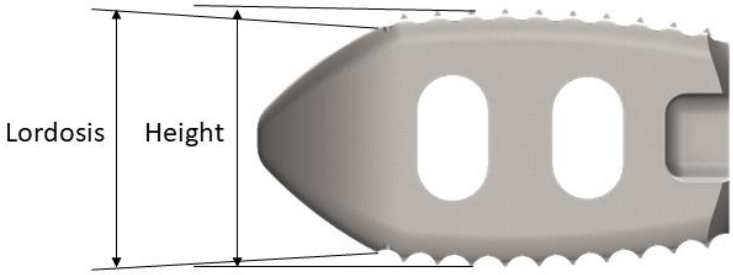
PRODUCT OVERVIEW

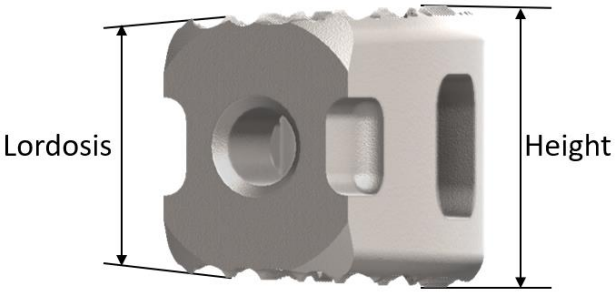
The Kodiak Lumbar Spacer System consists of implants, trials, and instruments. The Kodiak Lumbar Spacer System may be implanted bilaterally using a posterior (PLIF) approach, or as a single device employing a transforaminal (TLIF) approach.

MATERIALS

The Kodiak Lumbar Spacer System is comprised of a family of implants that have bodies manufactured from Grade 23 Ti-6Al-4V ELI (Titanium) in compliance with ASTM F3001.







FEATURES

- Bullet-shaped nose for effortless implant insertion
- Large graft windows create maximum contact between the graft and endplate
- Superior instrumentation for the most efficient application of implants
- Quick-release inserter prevents cage cross-threading and allows for easier implant insertion
- Sizes available for all surgical needs
- Strong, solid design for a more reliable implant
- Textured superior/inferior surfaces prevent expulsion in any direction

KODIAK PL IMPLANT OVERVIEW

All implants available in parallel (0°) and 6°

Height \ Length / Width	20 mm	25 mm	9 mm	9.25 mm
8 mm	•	•	•	
9 mm	•	•	•	
10 mm	•	•	•	
11 mm	•	•	•	
12 mm	•	•	•	
13 mm	•	•	•	
14 mm	•	•	•	
15 mm	•	•		•
16 mm	•	•		•

KODIAK TL IMPLANT OVERVIEW

All implants available in parallel (0°) and 6°

Height \ Length / Width	27 mm	32 mm	9 mm
8 mm	•	•	•
9 mm	•	•	•
10 mm	•	•	•
11 mm	•	•	•
12 mm	•	•	•
13 mm	•	•	•
14 mm	•	•	•
15 mm	•	•	•
16 mm	•	•	•

INSTRUMENT OVERVIEW

30290138 Inserter

30290103 Straight Tamp

30290104 Hemispherical Tamp

30290145 Left Curette

30290143 Right Curette

30290144 Straight Curette

TBD 7mm – 16mm Shaver

30290154 T-Handle

04-07G Graft Block

30290129 Slap Hammer

04-2207P0 – 04-2216P0 22mm PLIF Trial, 0°, Sizes 7mm - 16mm

04-2607P0 – 04-2616P0 26mm PLIF Trial, 0°, Sizes 7mm - 16mm

04-2207P6 – 04-2216P6 22mm PLIF Trial, 6°, Sizes 7mm - 16mm

04-2607P6 – 04-2616P6 26mm PLIF Trial, 6°, Sizes 7mm - 16mm

04-2707T0 – 04-2716T0 27mm TLIF Trial, 0°, Sizes 7mm - 16mm

04-3207T0 – 04-3216T0 32mm TLIF Trial, 0°, Sizes 7mm - 16mm

04-2707T6 – 04-2716T6 27mm TLIF Trial, 6°, Sizes 7mm - 16mm

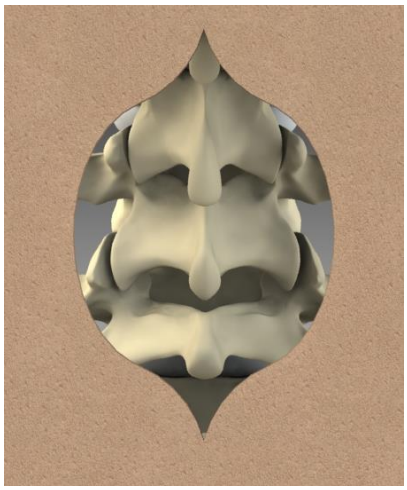
04-3207T6 – 04-3216T6 32mm TLIF Trial, 6°, Sizes 7mm - 16mm

► POSITION PATIENT

Place the patient in the prone position on a lumbar support. Radiographic equipment can be used to confirm optimal positioning of relevant spine segment.

► EXPOSURE

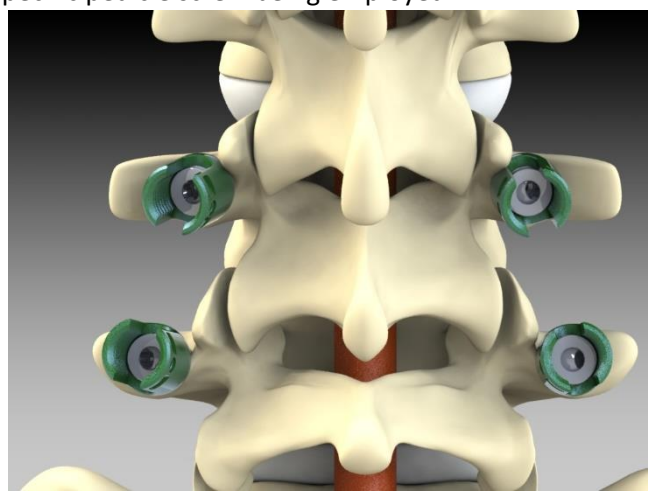
Incise and dissect laterally from the midline and locate the spinous processes, transverse processes, facets, lamina, dura and nerve roots.



Exposure

► PLACE PEDICLE SCREWS

Place approved pedicle screws using standard techniques. Refer to the surgical technique associated with the specific pedicle screw being employed.

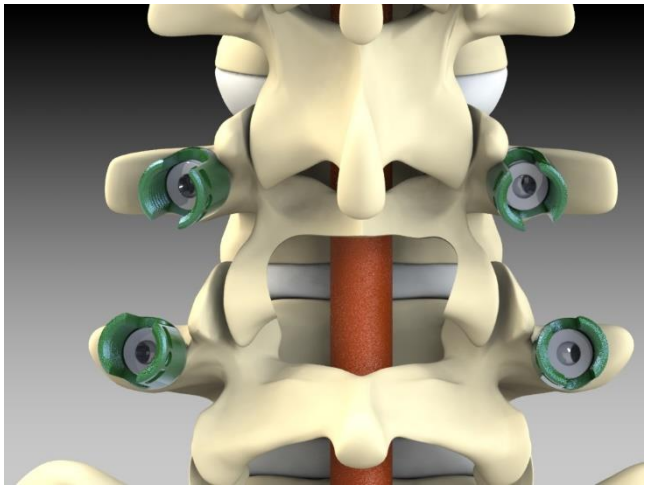


Pedicle screw placement

► SITE PREPARATION

1. Perform laminectomy – for traditional PLIF approach

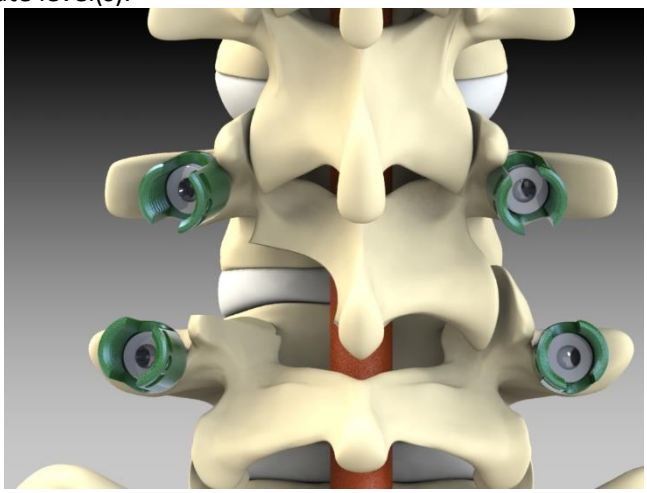
   Perform a laminectomy sufficiently large to accommodate the PLIF procedure. Protect the dura by employing a nerve root retractor. Reserve any bone removed for use as bone graft later in the procedure.



PLIF Laminectomy

2. Create transforaminal window – for traditional TLIF approach

   Employing appropriate instruments, create the transforaminal window by removing the inferior facet of the cephalad vertebra and the superior facet of the caudal vertebra at the appropriate level(s).

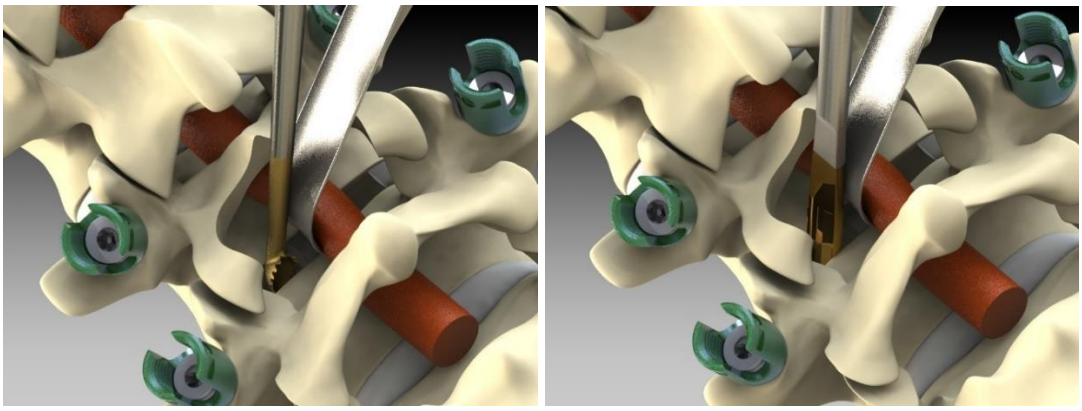


TLIF Transforaminal window

► PERFORM DISCECTOMY

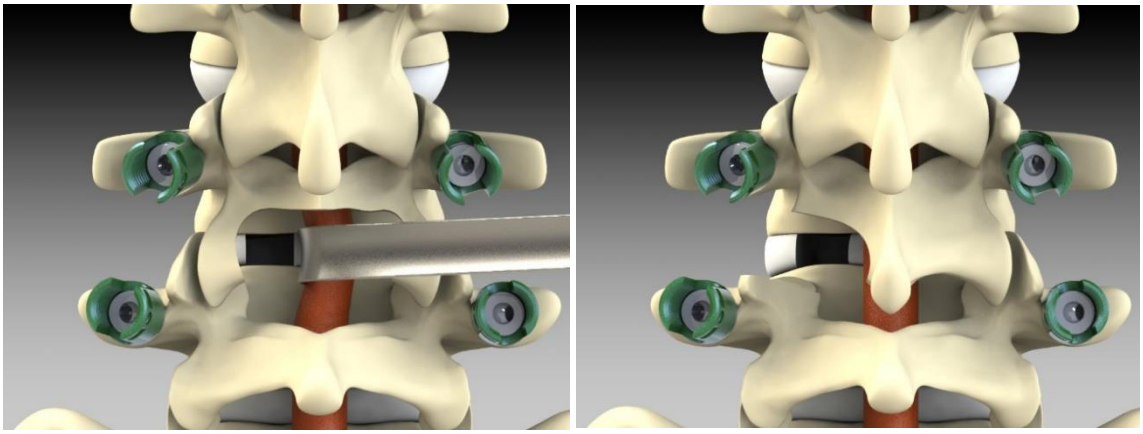
Protecting the dura and nerve roots with a nerve root retractor, start the discectomy by incising the disc and making a rectangular window. Remove the nucleus pulposus and any necessary disc annulus of the endplate employing curettes, shavers and pituitary rongeurs.

Use appropriate instruments to ensure complete removal of disc material while preserving the lateral and anterior walls of the annulus. Additionally, remove cartilaginous tissue from the disc space down to bleeding bone, while maintaining the integrity of the bony endplates. Care must be taken during to prevent excessive removal of the subchondral bone which may result in weakening of the endplate, and reduced stability of the vertebral body.



Discectomy: typical curette (left), typical shaver (right)
Left side PLIF approach shown.

In the case of a traditional PLIF approach, repeat this process of the contralateral side of the dura.

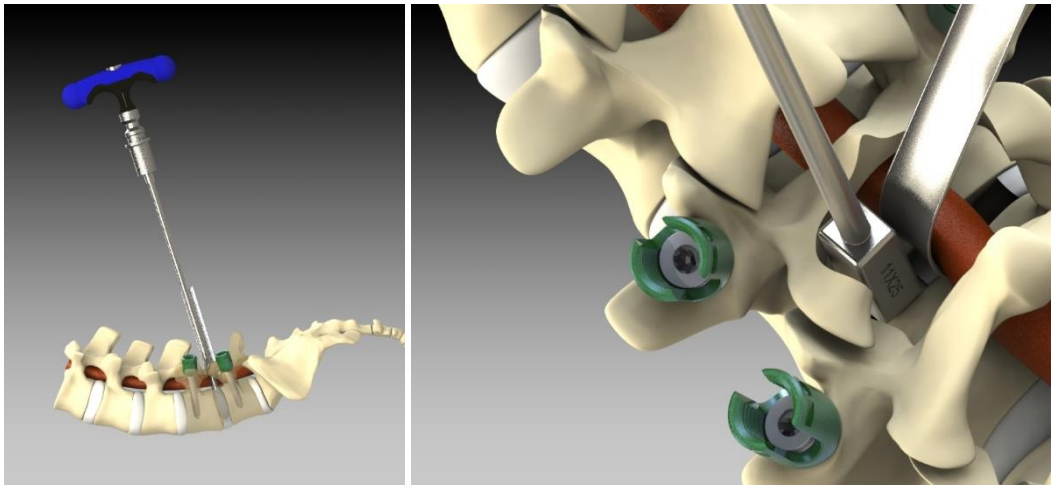


Discectomy: PLIF (left) and TLIF (right)
Left side PLIF and TLIF shown.

ESTABLISH IMPLANT SIZE

Determine appropriate implant height employing the implant trials provided. Slight impaction may be used to introduce the trial into the intervertebral space. Use a smaller trial if the fit is too tight, or a larger trial if the fit is too loose.

The trials should also be used to determine the appropriate length with the use of fluoroscopy. In the case of a traditional PLIF approach, implant trials are supplied at lengths of 22mm and 26mm. Initial trialing should be done employing 22mm length trials and should be checked fluoroscopically. If fluoroscopy confirms there is room, then a 26mm trial may be employed.

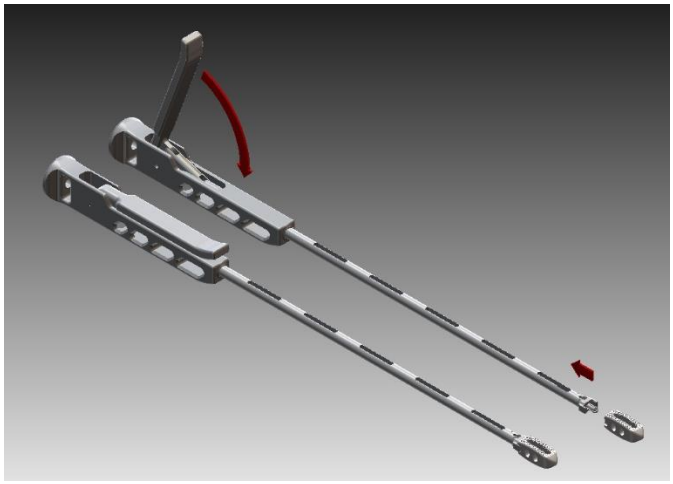


Trialing implant size

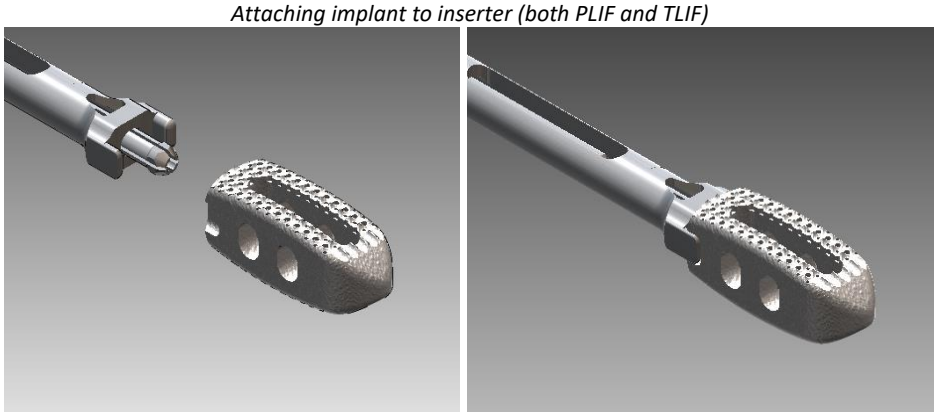
In the case of a traditional TLIF approach, implant trials are supplied at lengths of 27mm and 32mm. Initial trialing should be done employing 27mm length trials and should be checked fluoroscopically. If fluoroscopy confirms there is room, then a 32mm trial may be employed.

► IMPLANT SELECTION AND PREPARATION

Select the implant that matches the appropriate implant trial. Attach the selected implant to the inserter and place it in the graft loading block.

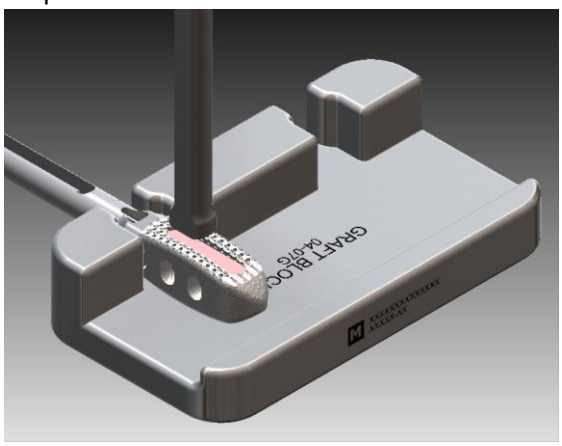


Attaching implant to inserter (both PLIF and TLIF)



Attaching implant to inserter (both PLIF and TLIF)

Employing the graft block provided, fill the implant with bone graft and pack it down with the flat impactor tool. Do not use a hammer to pack down the bone graft as this may damage the structural integrity of the implant.



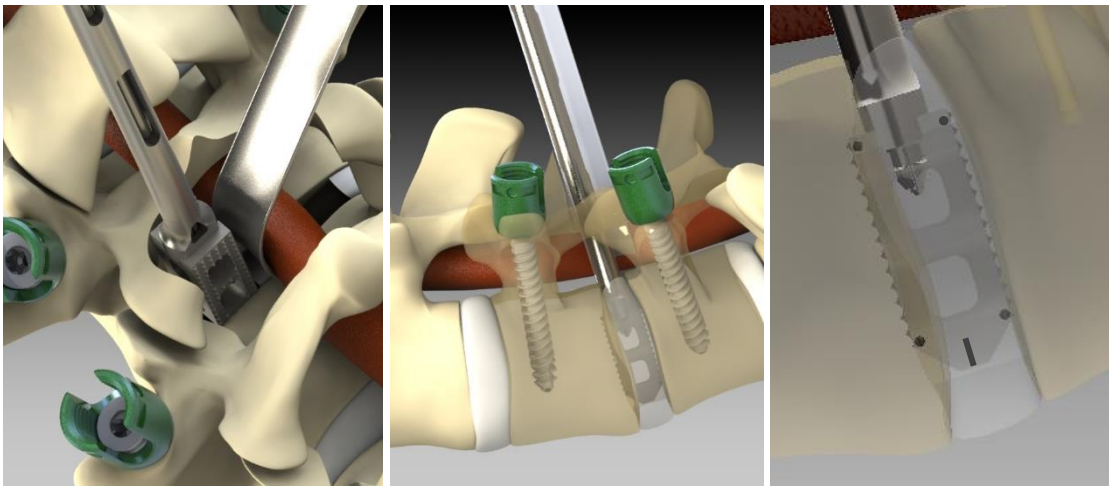
Graft block (PLIF shown)

► IMPLANT INSERTION

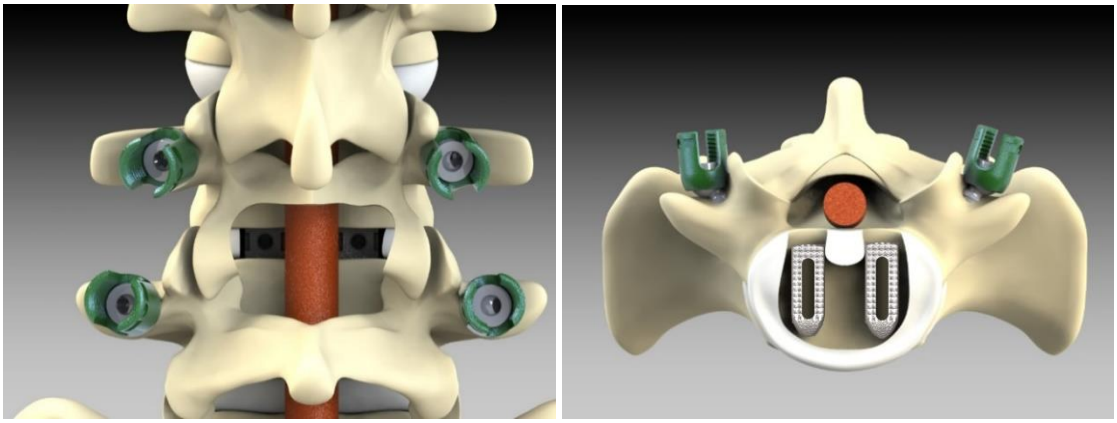
1. PLIF Insertion

   Protecting the dura using a nerve root retractor, place autogenous cancellous bone or bone graft substitute anterior and lateral to the space where the implant will be placed. Pack employing the flat impactor.

   Protecting the dura with a nerve root retractor, place the implant in the prepared intervertebral space making sure to orient the implant such that the serrated sides are in contact with the vertebral endplates. Confirm that implant is in desired location via fluoroscopy. Remove implant from inserter.



Insertion of PLIF implant (Note radiographic markers)



Typical final position of PLIF implants

In the case of a traditional PLIF approach, repeat this process on the contralateral side of the dura.

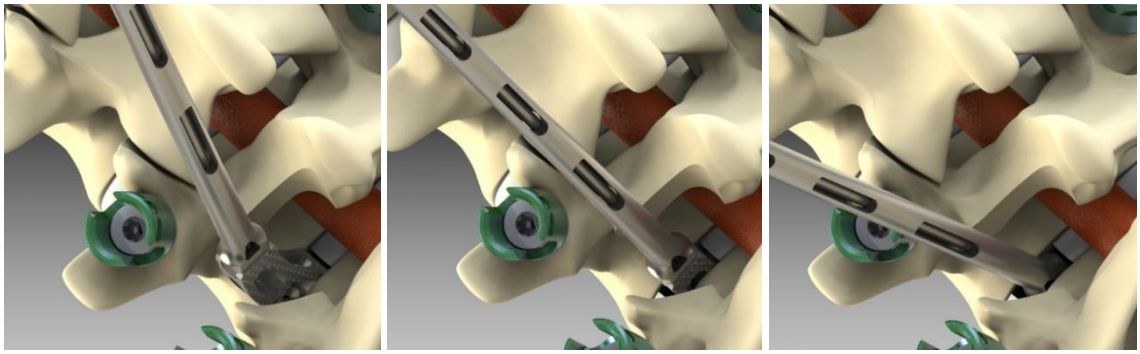
Use the impactor to reposition implants as deemed necessary.

Protecting the dura with a nerve root retractor, place autogenous cancellous bone or an appropriate bone graft substitute in the medial space between the implants as well as the space posterior to the implants.

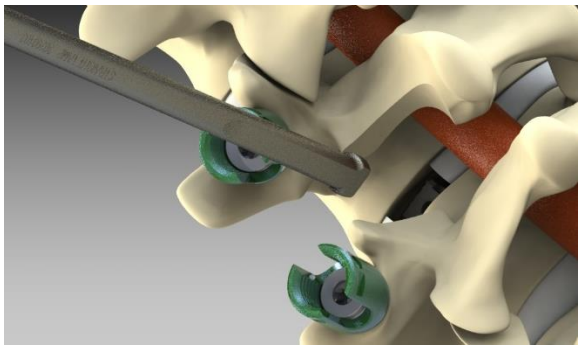
2. TLIF Insertion

Protecting the dura using a nerve root retractor, place autogenous cancellous bone or bone graft substitute anterior and lateral to the space where the implant will be placed. Pack employing the flat impactor.

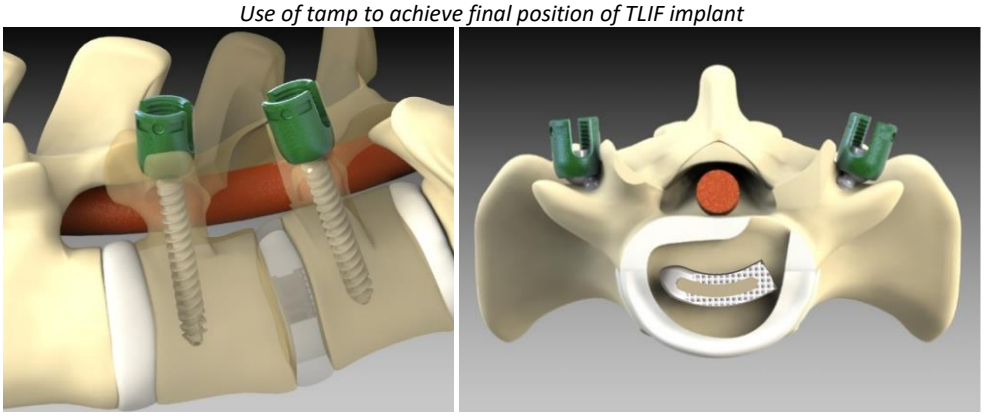
Protecting the dura with a nerve root retractor, place the implant in the prepared intervertebral space making sure to orient the implant such that the serrated sides are in contact with the vertebral endplates. Rotate the orientation of the implant as the insertion gets deeper. When the inserter head reaches the periphery of the intervertebral space, remove implant from inserter. Use the flat tamp provided to orient the implant into the desired location.



Insertion of TLIF implant showing rotation of implant/inserter



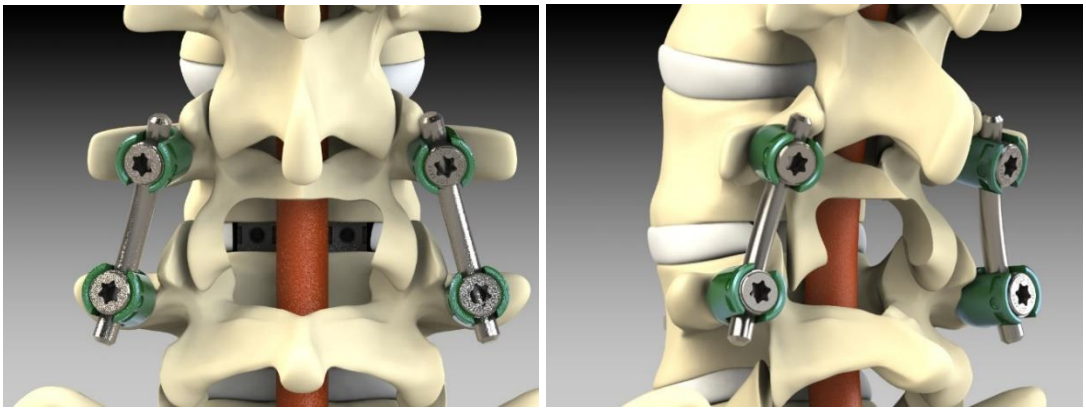
Use of tamp to achieve final position of TLIF implant



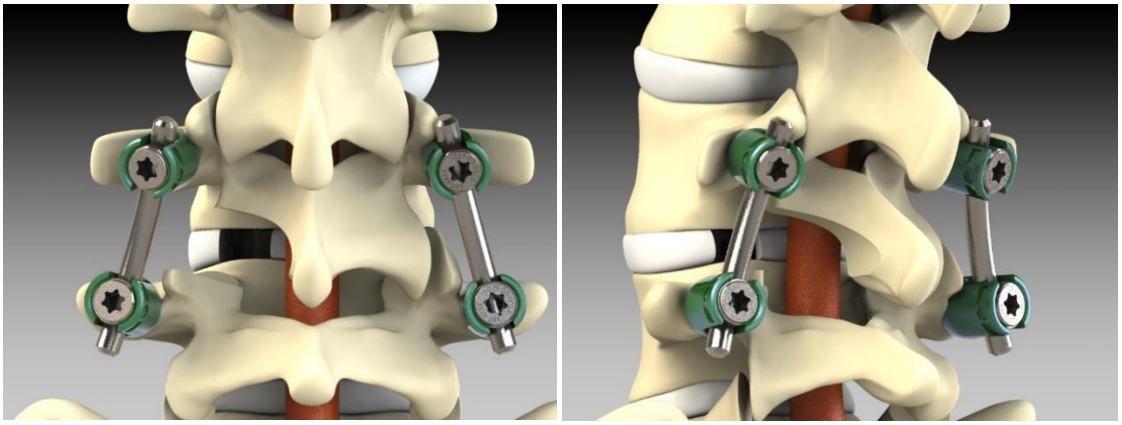
Final position of TLIF implant

► SEGMENTAL COMPRESSION

Adding rods and blocker screws to the previously placed pedicle screws, compress the fused joint(s) to allow loading of the anterior column and to restore sagittal alignment.



PLIF implant with posterior instrumentation complete

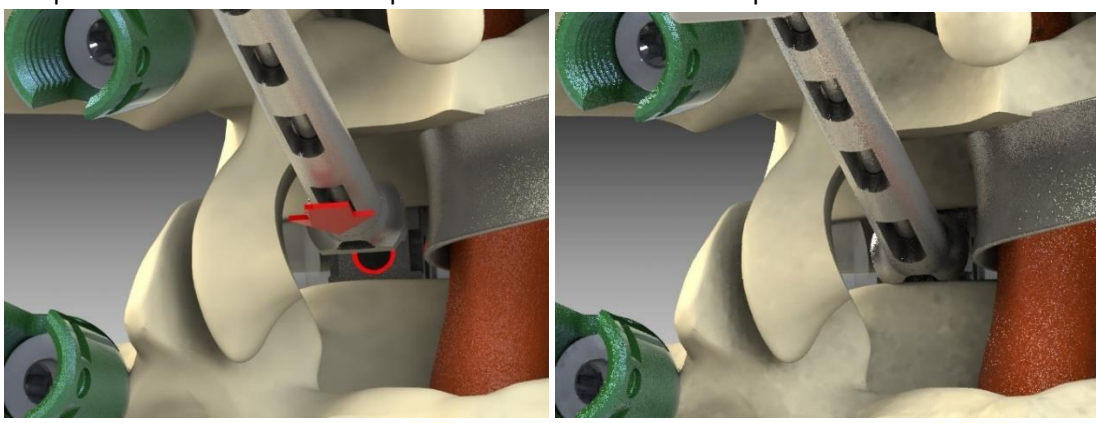


TLIF implant with posterior instrumentation complete

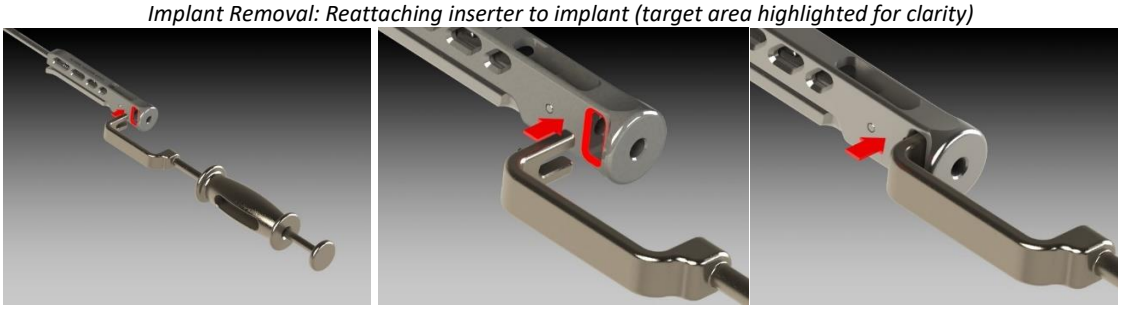
IMPLANT REMOVAL

If the implant(s) require removal from the intervertebral space, use the inserter to reengage the implant. With the inserter in the open position, align the expanding collet into the receiving hole in the implant and ensure that the side tabs have also engaged the implant. Move the inserter level to the closed position to lock the implant to the inserter.

If needed, attach the slap hammer instrument to the proximal end of the inserter and gently tap the slap hammer to remove the implant from the intervertebral space.



Implant Removal: Reattaching inserter to implant (target area highlighted for clarity)



Implant Removal: Attachment of slap hammer (target area highlighted for clarity)

In the event that the surgeon is not able to successfully reattach the inserter to an implant that requires removal, employ the emergency removal tool provided in the instrument set. Carefully align the tip of the instrument with the receiving hole in the implant and attach the removal tool to the implant.

Attach the slap hammer instrument to the proximal end of the removal tool (below the t-handle) and gently tap the slap hammer to remove the implant from the intervertebral space. NOTE: Emergency removal tool should be used only in the event that the inserter cannot be successfully attached to the implant.

IMPORTANT NOTE: Any implant removed from an intervertebral space using either of these methods may incur damage that may impact the structural integrity of the implant. Therefore, any implant removed must be discarded and must neither be reimplanted nor returned to the implant caddies.

► PLIF CAGES

DESCRIPTION	CATALOG #	IMPLANT SIZE
KODIAK PLIF IMPLANT 07X22mm, 0°	10220700K	07 x 22 mm, 0°
KODIAK PLIF IMPLANT 08X22mm, 0°	10220800K	08 x 22 mm, 0°
KODIAK PLIF IMPLANT 09X22mm, 0°	10220900K	09 x 22 mm, 0°
KODIAK PLIF IMPLANT 10X22mm, 0°	10221000K	10 x 22 mm, 0°
KODIAK PLIF IMPLANT 11X22mm, 0°	10221100K	11 x 22 mm, 0°
KODIAK PLIF IMPLANT 12X22mm, 0°	10221200K	12 x 22 mm, 0°
KODIAK PLIF IMPLANT 13X22mm, 0°	10221300K	13 x 22 mm, 0°
KODIAK PLIF IMPLANT 14X22mm, 0°	10221400K	14 x 22 mm, 0°
KODIAK PLIF IMPLANT 15X22mm, 0°	10221500K	15 x 22 mm, 0°
KODIAK PLIF IMPLANT 16X22mm, 0°	10221600K	16 x 22 mm, 0°
KODIAK PLIF IMPLANT 07X26mm, 0°	10260700K	07 x 26 mm, 0°
KODIAK PLIF IMPLANT 08X26mm, 0°	10260800K	08 x 26 mm, 0°
KODIAK PLIF IMPLANT 09X26mm, 0°	10260900K	09 x 26 mm, 0°
KODIAK PLIF IMPLANT 10X26mm, 0°	10261000K	10 x 26 mm, 0°
KODIAK PLIF IMPLANT 11X26mm, 0°	10261100K	11 x 26 mm, 0°
KODIAK PLIF IMPLANT 12X26mm, 0°	10261200K	12 x 26 mm, 0°
KODIAK PLIF IMPLANT 13X26mm, 0°	10261300K	13 x 26 mm, 0°
KODIAK PLIF IMPLANT 14X26mm, 0°	10261400K	14 x 26 mm, 0°
KODIAK PLIF IMPLANT 15X26mm, 0°	10261500K	15 x 26 mm, 0°
KODIAK PLIF IMPLANT 16X26mm, 0°	10261600K	16 x 26 mm, 0°
KODIAK PLIF IMPLANT 07x22mm, 6~	10220706K	07 x 22 mm, 6°
KODIAK PLIF IMPLANT 08x22mm, 6~	10220806K	08 x 22 mm, 6°
KODIAK PLIF IMPLANT 09x22mm, 6~	10220906K	09 x 22 mm, 6°
KODIAK PLIF IMPLANT 10x22mm, 6~	10221006K	10 x 22 mm, 6°
KODIAK PLIF IMPLANT 11x22mm, 6~	10221106K	11 x 22 mm, 6°
KODIAK PLIF IMPLANT 12x22mm, 6~	10221206K	12 x 22 mm, 6°
KODIAK PLIF IMPLANT 13x22mm, 6~	10221306K	13 x 22 mm, 6°
KODIAK PLIF IMPLANT 14x22mm, 6~	10221406K	14 x 22 mm, 6°
KODIAK PLIF IMPLANT 15x22mm, 6~	10221506K	15 x 22 mm, 6°
KODIAK PLIF IMPLANT 16x22mm, 6~	10221606K	16 x 22 mm, 6°
KODIAK PLIF IMPLANT 07x26mm, 6~	10260706K	07 x 26 mm, 6°
KODIAK PLIF IMPLANT 08x26mm, 6~	10260806K	08 x 26 mm, 6°
KODIAK PLIF IMPLANT 09x26mm, 6~	10260906K	09 x 26 mm, 6°
KODIAK PLIF IMPLANT 10x26mm, 6~	10261006K	10 x 26 mm, 6°
KODIAK PLIF IMPLANT 11x26mm, 6~	10261106K	11 x 26 mm, 6°
KODIAK PLIF IMPLANT 12x26mm, 6~	10261206K	12 x 26 mm, 6°
KODIAK PLIF IMPLANT 13x26mm, 6~	10261306K	13 x 26 mm, 6°
KODIAK PLIF IMPLANT 14x26mm, 6~	10261406K	14 x 26 mm, 6°
KODIAK PLIF IMPLANT 15x26mm, 6~	10261506K	15 x 26 mm, 6°
KODIAK PLIF IMPLANT 16x26mm, 6~	10261606K	16 x 26 mm, 6°

Kodiak PLIF Cage

► TLIF CAGES

DESCRIPTION	CATALOG #	IMPLANT SIZE
KODIAK TLIF IMPLANT 07X27mm, 0°	20270700K	07 x 27 mm, 0°
KODIAK TLIF IMPLANT 08X27mm, 0°	20270800K	08 x 27 mm, 0°
KODIAK TLIF IMPLANT 09X27mm, 0°	20270900K	09 x 27 mm, 0°
KODIAK TLIF IMPLANT 10X27mm, 0°	20271000K	10 x 27 mm, 0°
KODIAK TLIF IMPLANT 11X27mm, 0°	20271100K	11 x 27 mm, 0°
KODIAK TLIF IMPLANT 12X27mm, 0°	20271200K	12 x 27 mm, 0°
KODIAK TLIF IMPLANT 13X27mm, 0°	20271300K	13 x 27 mm, 0°
KODIAK TLIF IMPLANT 14X27mm, 0°	20271400K	14 x 27 mm, 0°
KODIAK TLIF IMPLANT 15X27mm, 0°	20271500K	15 x 27 mm, 0°
KODIAK TLIF IMPLANT 16X27mm, 0°	20271600K	16 x 27 mm, 0°
KODIAK TLIF IMPLANT 07X32mm, 0°	20320700K	07 x 32 mm, 0°
KODIAK TLIF IMPLANT 08X32mm, 0°	20320800K	08 x 32 mm, 0°
KODIAK TLIF IMPLANT 09X32mm, 0°	20320900K	09 x 32 mm, 0°
KODIAK TLIF IMPLANT 10X32mm, 0°	20321000K	10 x 32 mm, 0°
KODIAK TLIF IMPLANT 11X32mm, 0°	20321100K	11 x 32 mm, 0°
KODIAK TLIF IMPLANT 12X32mm, 0°	20321200K	12 x 32 mm, 0°
KODIAK TLIF IMPLANT 13X32mm, 0°	20321300K	13 x 32 mm, 0°
KODIAK TLIF IMPLANT 14X32mm, 0°	20321400K	14 x 32 mm, 0°
KODIAK TLIF IMPLANT 15X32mm, 0°	20321500K	15 x 32 mm, 0°
KODIAK TLIF IMPLANT 16X32mm, 0°	20321600K	16 x 32 mm, 0°
KODIAK TLIF IMPLANT 07X27mm, 6°	20270706K	07 x 27 mm, 6°
KODIAK TLIF IMPLANT 08X27mm, 6°	20270806K	08 x 27 mm, 6°
KODIAK TLIF IMPLANT 09X27mm, 6°	20270906K	09 x 27 mm, 6°
KODIAK TLIF IMPLANT 10X27mm, 6°	20271006K	10 x 27 mm, 6°
KODIAK TLIF IMPLANT 11X27mm, 6°	20271106K	11 x 27 mm, 6°
KODIAK TLIF IMPLANT 12X27mm, 6°	20271206K	12 x 27 mm, 6°
KODIAK TLIF IMPLANT 13X27mm, 6°	20271306K	13 x 27 mm, 6°
KODIAK TLIF IMPLANT 14X27mm, 6°	20271406K	14 x 27 mm, 6°
KODIAK TLIF IMPLANT 15X27mm, 6°	20271506K	15 x 27 mm, 6°
KODIAK TLIF IMPLANT 16X27mm, 6°	20271606K	16 x 27 mm, 6°
KODIAK TLIF IMPLANT 07X32mm, 6°	20320706K	07 x 32 mm, 6°
KODIAK TLIF IMPLANT 08X32mm, 6°	20320806K	08 x 32 mm, 6°
KODIAK TLIF IMPLANT 09X32mm, 6°	20320906K	09 x 32 mm, 6°
KODIAK TLIF IMPLANT 10X32mm, 6°	20321006K	10 x 32 mm, 6°
KODIAK TLIF IMPLANT 11X32mm, 6°	20321106K	11 x 32 mm, 6°
KODIAK TLIF IMPLANT 12X32mm, 6°	20321206K	12 x 32 mm, 6°
KODIAK TLIF IMPLANT 13X32mm, 6°	20321306K	13 x 32 mm, 6°
KODIAK TLIF IMPLANT 14X32mm, 6°	20321406K	14 x 32 mm, 6°
KODIAK TLIF IMPLANT 15X32mm, 6°	20321506K	15 x 32 mm, 6°
KODIAK TLIF IMPLANT 16X32mm, 6°	20321606K	16 x 32 mm, 6°

Kodiak TL Implant

The physicians we work with are Renaissance thinkers. Their mastery, scientific insight and innovative minds inspire our product development. Met One puts advanced technology to work for physicians who artfully transform patients' lives.

INDICATIONS FOR USE

The Kodiak Lumbar Spacer System is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at the involved level may be treated with the Kodiak Lumbar Spacer System. Patients must have undergone a regimen of at least six (6) months of nonoperative treatment prior to being treated with the Kodiak Lumbar Spacer System.

The Kodiak Lumbar Spacer System is designed for use with autogenous bone graft. The system is also intended to be used with supplemental fixation systems that are cleared by the FDA for use in the lumbar spine.

For additional product information including warnings, precautions and adverse effects concerning spinal fixation implants refer to the product insert.

CONTRAINDICATIONS

The Kodiak Lumbar Spacer System is contraindicated for use in patients with the following:

- Active infectious process or significant risk of infection (immunocompromised)
- Signs of local inflammation
- Fever or leukocytosis
- Osteoporosis or similar loss of bone density
- Morbid obesity
- Pregnancy
- Gross distorted anatomy caused by congenital abnormalities
- Suspected or documented metal allergy or intolerance
- Prior fusion at the level being treated
- Any case not described in the indications

WARNINGS

Potential risks identified with the use of this intervertebral body-fusion device, which may require additional surgery, include device component fracture, loss of fixation, pseudoarthrosis (i.e., non-union), fracture of the vertebra, neurological injury, and vascular or visceral Injury.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.

Never reuse an internal fixation device under any circumstances.

Only surgeons trained in and experienced with spinal-fusion and bone-grafting techniques should use the Kodiak Lumbar Spacer System. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants, are essential considerations in the utilization of this device.

Do not reuse implants. Discard used, damaged or otherwise suspect implants. AN IMPLANT SHOULD NEVER BE REUSED. Any implant, once used, should be discarded.

PRECAUTIONS

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the intervertebral body-fusion device.

The implantation of the intervertebral body-fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device, as this is a technically demanding procedure presenting a risk of serious injury to the patient.

Magnetic Resonance (MR) Safety: The Kodiak Lumbar Spacer System has not been evaluated for safety and compatibility in the MR environment. The Kodiak Lumbar Spacer System has not been tested for heating or migration in the MR environment.

Accepted medical practices, in addition to any local and national requirements, should be employed in the handling and disposal of all contaminated implants.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician.

CLEANING

Implants are provided clean but not sterile. ISO 8828 or ACORN-recommended practices for in-hospital sterilization should be followed for all components.

Once an implant comes in contact with any human tissue or bodily fluid, it should not be resterilized before use. Please discard all contaminated implants.

1. Prepare an enzymatic cleaning solution in accordance with the manufacturer's instructions.
2. Immediately after the procedure, soak and manually agitate the soiled instruments in the solution for the minimum recommended time specified by the solution manufacturer or 10 minutes, whichever is longer.
3. Using a soft bristle brush, scrub instruments to remove all traces of blood and debris from the instrument surfaces. Employ a soft bristle brush or pipe cleaner to reach the entire length of all instrument lumens.
4. Rinse instruments with warm 85°-104°F (30°C-40°C) tap water for a minimum of one minute and until visual evidence of debris, soil and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
5. Ultrasonically clean the instruments for 10 minutes in a neutral pH detergent, prepare in accordance with the manufacturer's instructions.
6. Rinse instruments again with warm 85°-F104°F (3°C-40°C) tap water for a minimum of one minute and until visual evidence of debris, soil and cleaning solution are gone. Pay particular attention to flushing all instrument lumens.
7. Dry the instruments immediately after final rinse with a clean towel or clean, dry compressed air until visibly dry.

INSPECTION

1. Carefully inspect all instruments before sterilization to ensure all visible blood and soil have been removed from surfaces, lumens, holes and moveable parts.
2. If damage or biological residue is observed on an implant, the implant must be discarded.

► STERILIZATION

All implants should be placed in the provided implant caddies. All instruments should be placed in their appropriate locations within the instrument case(s).

Instrument case(s) to be double wrapped with FDA approved 1-ply polypropylene wrap (Kimguard KC600 or equivalent) with a surgical towel placed between the tray and the wrap.

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132°C)	4 minutes	30 minutes

Recommended sterilization parameters

► MRI SAFETY INFORMATION

The Kodiak Lumbar Spacer System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Kodiak Lumbar Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

LIMITED WARRANTY

Met One Technologies products are sold with a limited warranty to the original purchaser against defects in the workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.
If more than two years have elapsed between the date of issue/revision of this insert and the date of consultation, contact Met One Technologies for current information.

MANUFACTURED BY

Met One Technologies
4519 Osborne Dr, Suite C
El Paso, TX 79922