Eisertech, LLC PLIF/T-PLIF Cage

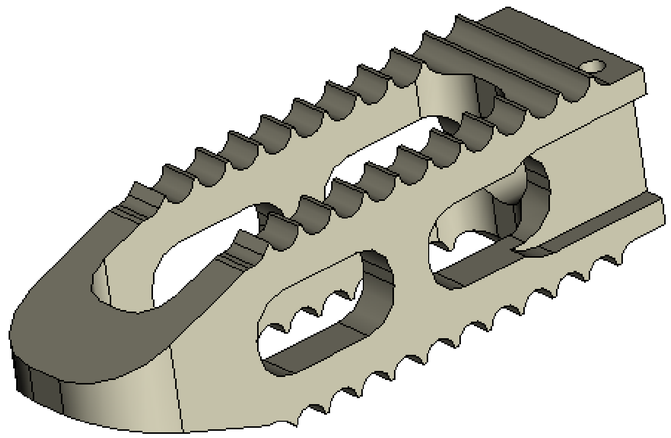
Surgical Technique

Notes

- This technique manual assumes that the surgeon is familiar with the techniques for performing a posterior lumbar interbody fusion (PLIF), or transforaminal interbody lumbar fusion (TLIF).
- This manual is not intended to teach a surgeon how to perform a PLIF or TLIF procedure.
- This manual provides instruction in how to appropriately use the equipment provided by Eisertech, LLC.

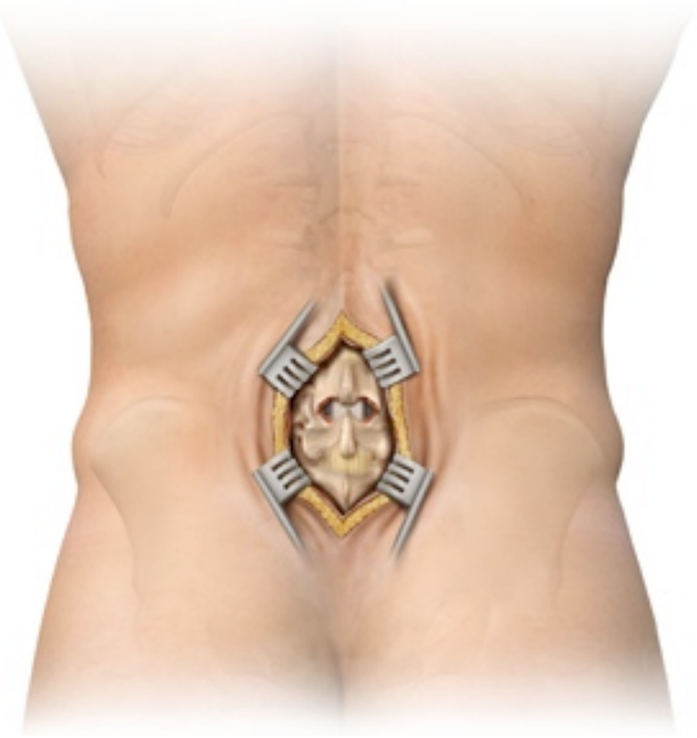
Cage Design

- Radiolucent PEEK allows the growth of bone through the center of the cage to be visualized.
- X-ray markers to visualize the cage
- Teeth ensure primary stability to prevent migration.



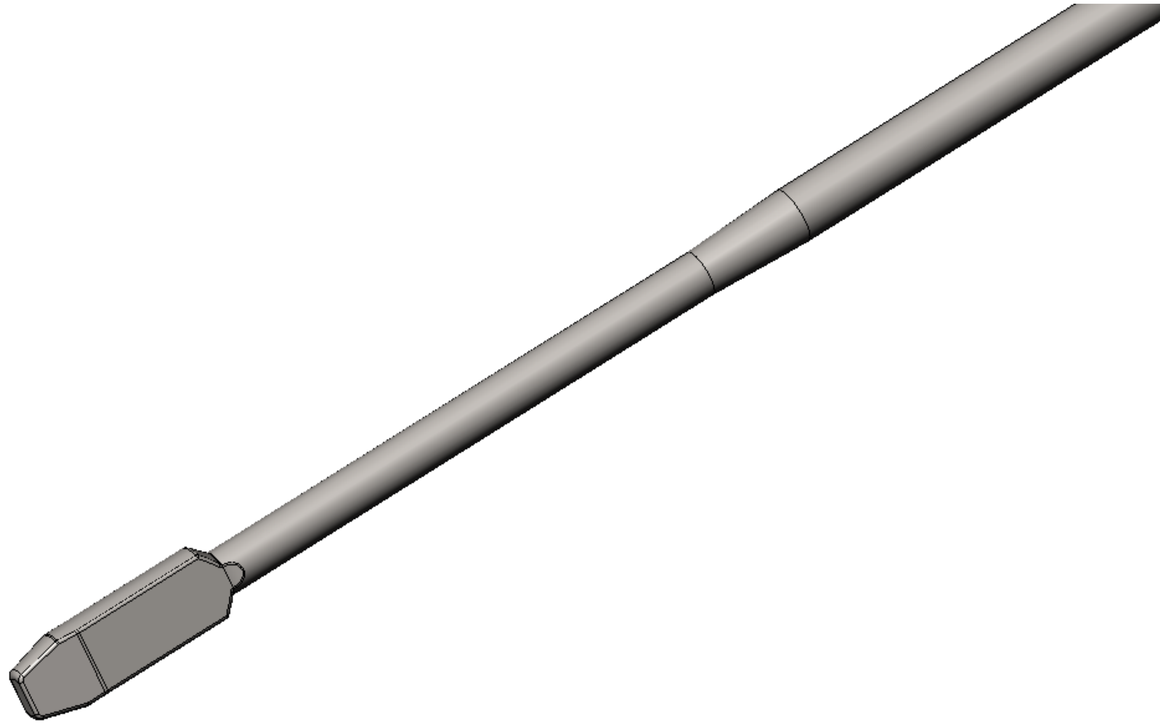
1. Expose the disc

- Expose the affected level through a conventional muscle-splitting posterior approach to the spine.
- Either a unilateral or bilateral approach may be utilized.



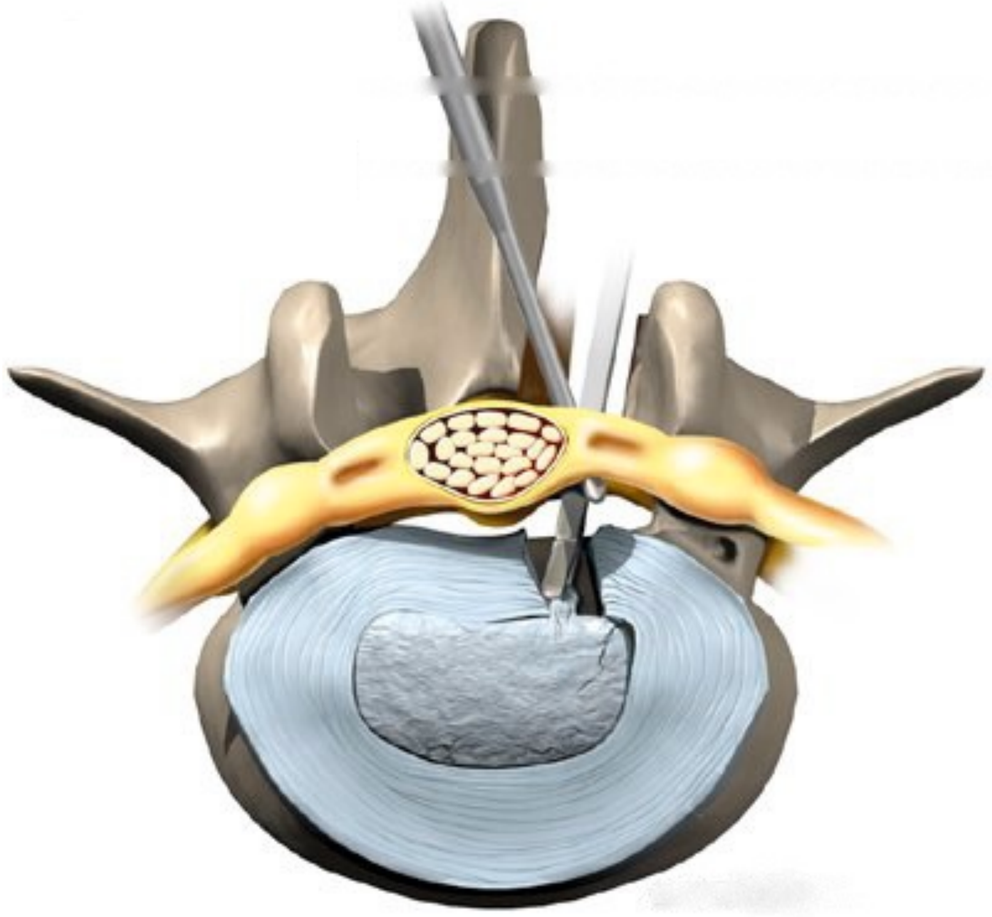
2. Distract the segment

- The smallest trial sizer may be used to apply initial distraction to the segment.
- A variety of conventional intradiscal or interlaminar distractors may also be utilized.



3. Perform the discetomy

- Perform the required discectomy, ensuring sufficient tissue removal that the PLIF/T-PLIF Cage and any planned surrounding graft material may be placed.

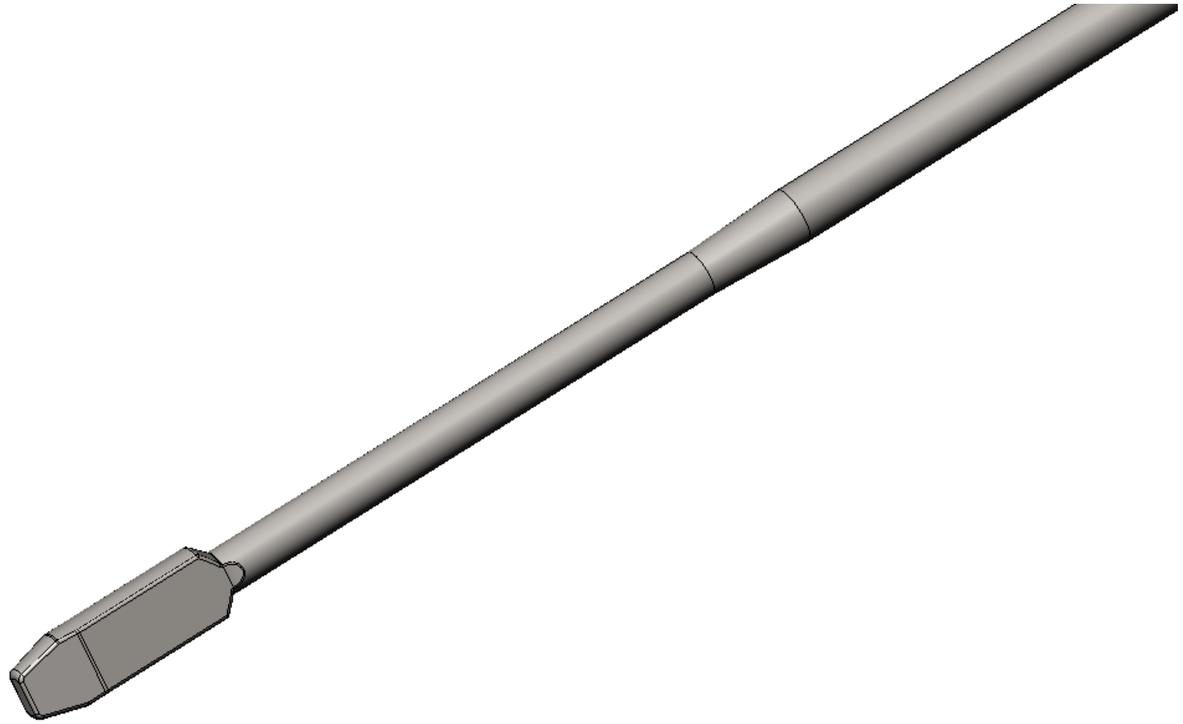


4. Prepare the endplates

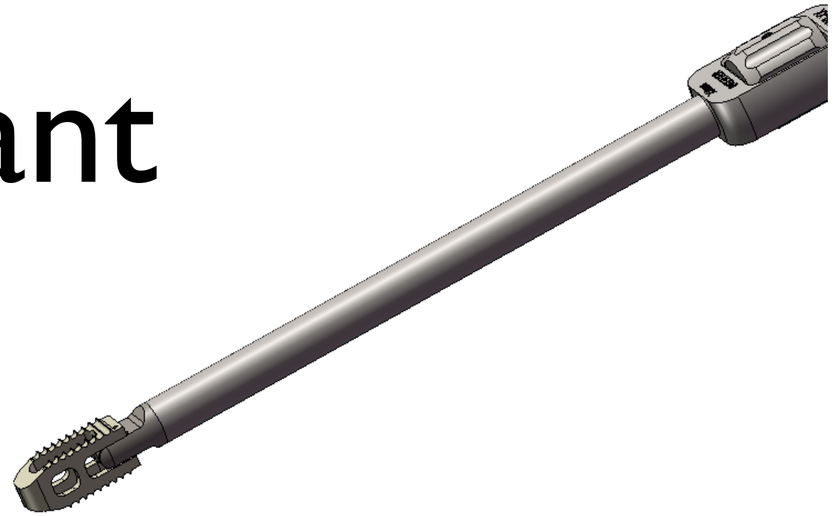
- Remove cartilaginous layers from the endplates to expose bleeding bone.
- This may be achieved by any combination of curettes, shavers, and rasps.

5. Trial the disc space

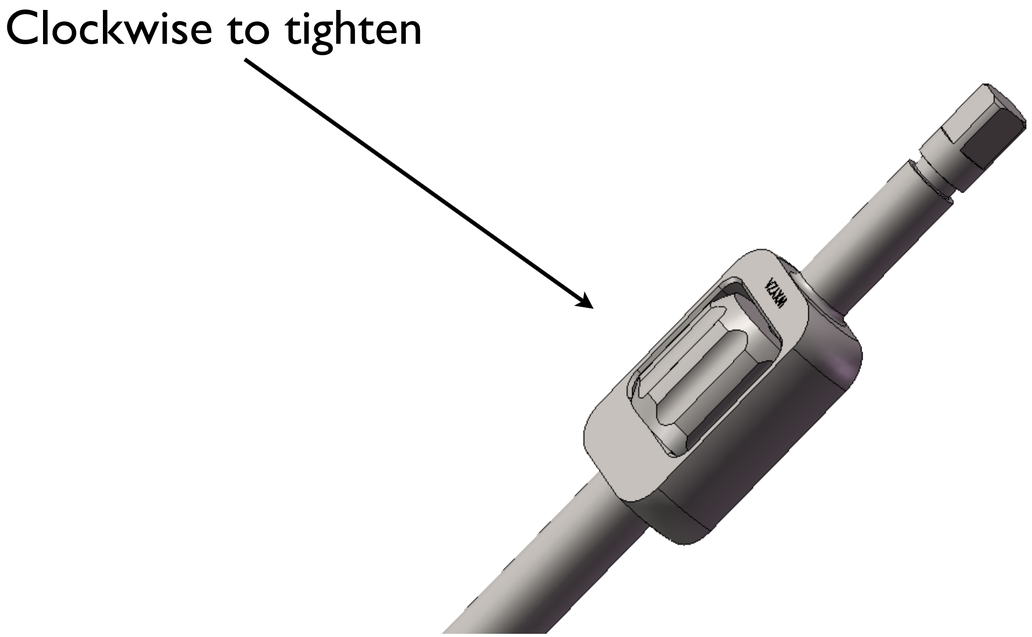
- Insert the smallest trial into the disc space.
- Progressively use larger trials until the the best fit is found.



6. Prepare the implant

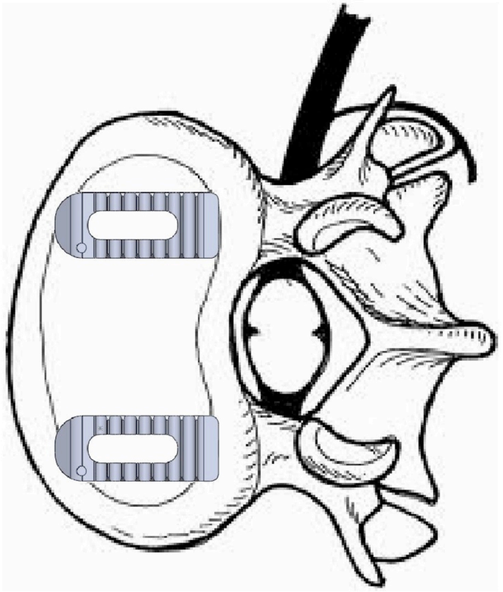


- Select the implant that matches the size found by trialing.
- Pack the implant with bone graft.
- Attach to the inserter by turning the tightening knob clockwise.



7. Insert the implant

- Insert the implant until it is fully in the disc space.
- Fluoroscopy may be used if desired to verify the implant position.
- If a single implant is used, it may be positioned towards the anterior portion of the disc space. Bilateral implants may be positioned along their insertion path, or slightly angled.



8. Add supplemental fixation

- Apply additional supplemental fixation as required for the stability of the fusion.

9. Close the incision

- Close the incision in the usual manner.

Revision

- Should it become necessary to remove the PLIF/T-PLIF Cage, the implant may be retrieved from the disc space by re-attaching the insertion tool and retrieving the device.

- It may be necessary to disrupt any fusion mass that extends into the PLIF/T-PLIF Cage's central aperture with a thin osteotome or elevator inserted between the implant and the vertebral endplate.

- Fusion mass external to the PLIF/T-PLIF Cage may be removed with rongeurs.

- An explanted PLIF /T-PLIF Cage must never be re-used or re-implanted. Even though the device appears undamaged, it may have defects and internal stresses that may lead to early breakage.

INDICATIONS

The PLIF/T-PLIF Cage is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These devices are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS

The PLIF/T-PLIF Cage should not be implanted in patients with active systemic infection or infection localized to the site of implantation. The PLIF/T-PLIF Cage is not indicated for prior fusion at the level to be treated.

WARNINGS

• Use as indicated. The safety and effectiveness when implanted in the spine for any other indications has not been established.

PRECAUTIONS

• Use of the PLIF/T-PLIF Cage should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with anterior lumbar fusion procedures and anterior lumbar fixation; and has had hands-on training in the use of
this device.

• One or two PLIF/T-PLIF Cages should be implanted at each surgical level.
• The PLIF/T-PLIF Cage should not be implanted in patients with severe osteoporosis or osteopenia.
• The surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
• The PLIF/T-PLIF Cage is supplied non-sterile. It must be sterilized before use.
• Implant components can break when subjected to the increased loading associated with delayed union or nonunion.
• Patients with previous spinal surgery at the level to be treated may have different outcomes compared to those without previous surgery.

The following potential adverse events (singly or in combination) could also result from the implantation of the PLIF/T-PLIF Cage:

1. Bursitis.
2. Decrease in bone density due to stress shielding.
3. Degenerative changes or instability of segments adjacent to fused vertebral levels
4. Fracture of bony structures.
5. Implant material sensitivity, or allergic reaction to a foreign body.
6. Infection, early or late.
7. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paraesthesia.
8. Nonunion, delayed union.
9. Discomfort, or abnormal sensations due to the presence of the device.
10. Paralysis.
11. Spinal cord impingement or damage.
12. Vascular damage could result in catastrophic or fatal bleeding
13. Death.