

PETRA TLIF Cage

Calvary Spine, LLC

Instructions for Use

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training or experience).

DEVICE DESCRIPTION

The Petra TLIF Cage is a single component device. It is augmented with a posterior pedicle screw fixation system. The Petra TLIF Cage component is manufactured of PEEK-OPTIMA[®] with tantalum radiographic markers and is supplied as non-sterile. The Petra TLIF Cage is radiolucent. Petra TLIF Cage is a banana shaped cage with pyramidal teeth to resist implant pullout. Intra-operative 65° and 80° insertion options allow for variable angled TLIF approaches. The design is a wedged configuration. One device is implanted at each level. Cage must be used with a posterior pedicle screw fixation system and may be manufactured from various grades of stainless steel or titanium and include the following:

- Pedicle screws
- Plates or Rods available in a variety of lengths
- Washers
- Transverse connectors

INDICATIONS

The Petra TLIF Cage System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Petra TLIF Cage implants are to be used with autogenous bone graft and implanted via an open transforaminal approach. The Petra TLIF Cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

The Petra TLIF Cage System should not be implanted in patients with active systemic infection or infection localized to the site of implantation. The Petra TLIF Cage System is not indicated for prior fusion at the level(s) to be treated.

WARNINGS

- These devices are to be used as indicated and the safety and effectiveness when implanted in the spine for any other indications has not been established.
- When more than two involved spinal levels are treated, longer operative times and higher blood loss are likely to occur.

- As the number of previous surgeries at the involved spinal level(s) increases, the potential for intra-operative dural tears increases.

PRECAUTIONS

- Use of the Petra TLIF Cage System should only be undertaken after the surgeon has become thoroughly knowledgeable about spinal anatomy and biomechanics; has had experience with TLIF procedures and pedicle screw spinal system fixation; and has had hands-on training in the use of this device.
- One Petra TLIF Cages should be implanted at each surgical level.
- The Petra TLIF Cage should not be implanted in patients with severe osteoporosis or osteopenia.
- Based on the fatigue testing results, the physician/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 Petra TLIF Cage component is supplied non-sterile. It must be sterilized before use according to the complete sterilization instructions included in the "How Supplied" section.
- Implant components can break when subjected to the increased loading associated with delayed union or nonunion.
- Patients with previous spinal surgery at the level(s) to be treated may have different outcomes compared to those with previous surgery. The following potential adverse events (singly or in combination) could also result from the implantation of the Petra TLIF 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

INFORMATION FOR PRESCRIBERS

- Correct selection of the appropriate implant size is extremely important.
- Excessive loads, such as excessive torque applied to long handle insertion tools attached to threaded insertion holes or direct application of loads to the threads or a small area of the Petra TLIF Cage component, can split or fracture the cage implants. Split or fractured cages should be removed

and replaced.

- Post-operative care should include external immobilization, which is recommended for the first month. Patients should be asked to avoid bending, lifting, stooping, or twisting for at least 3 months, and to avoid heavy activity for 6 months.
- Surgical implants must never be reused or reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- Once the fusion has healed, the surgeon and patient should carefully weigh the risks and benefits if considering to remove the posterior pedicle screw fixation system components.
- The surgical technique manual will be made available upon request.

DEVICE RETRIEVAL EFFORTS

Should it be necessary to remove a Petra TLIF Cage, please call Calvary Spine, LLC at the number below to receive instructions regarding data collection, including histopathological, mechanical and adverse event information. Please note that the cages should be retrieved as carefully as possible in order to keep the implant and surrounding tissue intact. Also, please provide descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal methods, e.g., intact or in pieces.

HOW SUPPLIED

1. STERILIZATION

Petra TLIF Cage component:

Petra TLIF Cage components are supplied non-sterile. ISO 8828 or ACORN recommended practices for in-hospital sterilization should be followed for all components. Laboratory testing was conducted to develop the following RECOMMENDATIONS FOR STEAM

STERILIZATION:

Cycle: Pre-Vacuum

Temperature: 270° F (132° C)

Exposure time: 6 min.

LIMITED WARRANTY AND DISCLAIMER: Calvary 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.

MANUFACTURED BY:

Calvary Spine, LLC

308 North Wind Rd.

Towson, MD 21204USA

(410) 294-1101