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 Calvary Cervical Cage is a single component device. It is augmented with an anterior cervical plate fixation system. The Calvary Cervical Cage component is manufactured of PEEK-OPTIMA® with tantalum radiographic markers and is supplied as nonsterile. The Calvary Cervical Cage is radiolucent. It is a rectangular shaped cage with grooved teeth to resist implant migration. The design is a wedged lordotic configuration. One device is implanted at each level. The Calvary Cervical Cage must be used with an anterior cervical plate system which may be manufactured from various grades of stainless steel or titanium and include the following:

- Plate
- Screws

INDICATIONS

The Calvary Cervical Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Calvary Cervical Cage implants are used to facilitate intervertebral body fusion in the cervical spine and are placed via an open anterior cervical approach at the C3-T1 disc levels using autogenous bone. The Calvary Cervical Implant is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

CONTRAINDICATIONS

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

WARNINGS

- These devices are to be used as indicated. 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.

PRECAUTIONS

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

- One Calvary Cervical Cage should be implanted at each surgical level.
- The Calvary Cervical Cage System 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 Calvary Cervical 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 Calvary Cervical Cage:

1. Dysphagia or dysphonia.
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, 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, airway compromise or stroke.

INFORMATION FOR PRESCRIBERS

- Correct selection of the appropriate implant size is extremely important. Use a Calvary Trial Spacer to confirm size and adequate preparation before inserting the Calvary Cervical Cage.
- Excessive loads or direct application of loads to a small area of the Calvary Cervical 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 forceful neck bending, twisting, or heavy upper extremity lifting for at least 3 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 anterior cervical plate system components.

DEVICE RETRIEVAL EFFORTS

Should it be necessary to remove a Calvary Cervical 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

Calvary Cervical Cage component:

Calvary Cervical 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:

Sterilization Type:	Prevacuum
Preconditioning Pulses:	4
Minimum Temperature:	270° F (132° C)
Full Cycle time:	4 min.
Minimum Dry Time:	30 min.
Test Article Configuration:	Wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554) using sequential envelope folding techniques with a surgical towel placed between the tray and the wrap.

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:
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Towson, MD 21204 USA
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• The surgical technique manual will be made available upon request.