Eisertech, LLC Cervical Cage

Surgical Technique

Notes

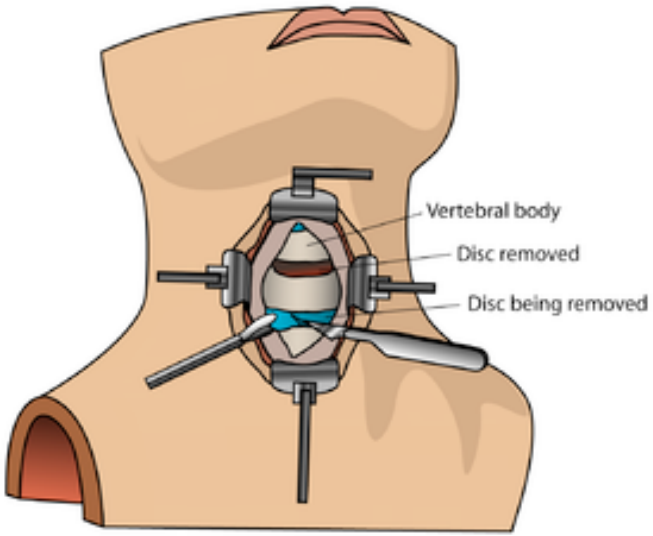
- This technique manual assumes that the surgeon is familiar with the techniques for performing an anterior cervical discectomy and fusion.
- This manual is not intended to teach a surgeon how to perform an anterior cervical discectomy or fusion.
- This manual provides instruction in how to appropriately 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 and prepare the disc

- Expose the affected disc and adjacent vertebral bodies through an anterior approach to the cervical spine.
- Cut a rectangular window in anterior longitudinal ligament over the affected disc, ranging from endplate to endplate, and matching at least the planned width of the Cervical Cage.
- Perform a discectomy at least as wide as the window in the anterior longitudinal ligament.

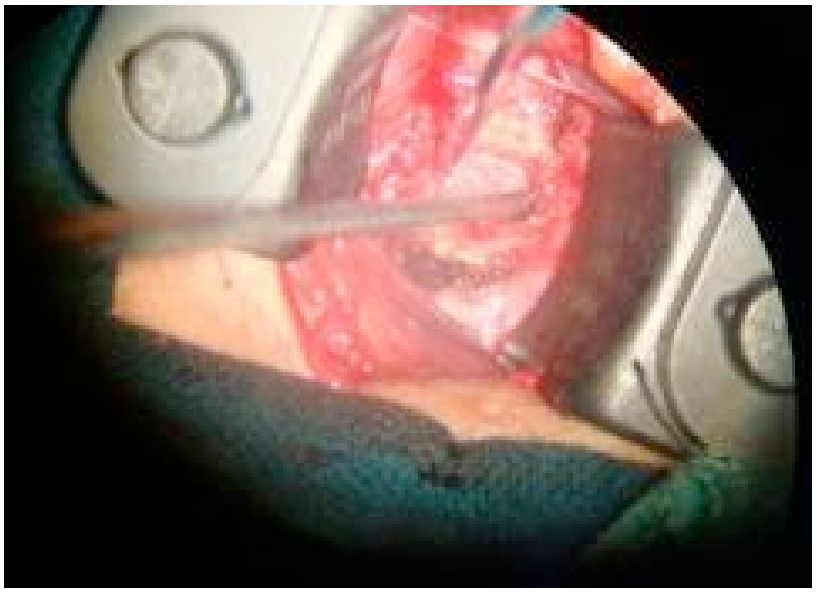


2. Distract the segment

- Distraction may be applied by skull traction, via positioning, or by the use of a standard bone distractor.

3. Prepare the endplates

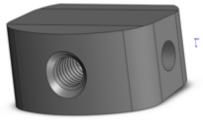
- Remove cartilaginous layers from the endplates to expose bleeding bone.
- This may be achieved by any combination of curettes, shavers, and rasps.



4. Trial the disc space

- Attach a trial sizer to the inserter by means of the threaded connection.
- Insert the trial into the disc space.
- Repeat until the fit that best matches the size of the disc space if found.

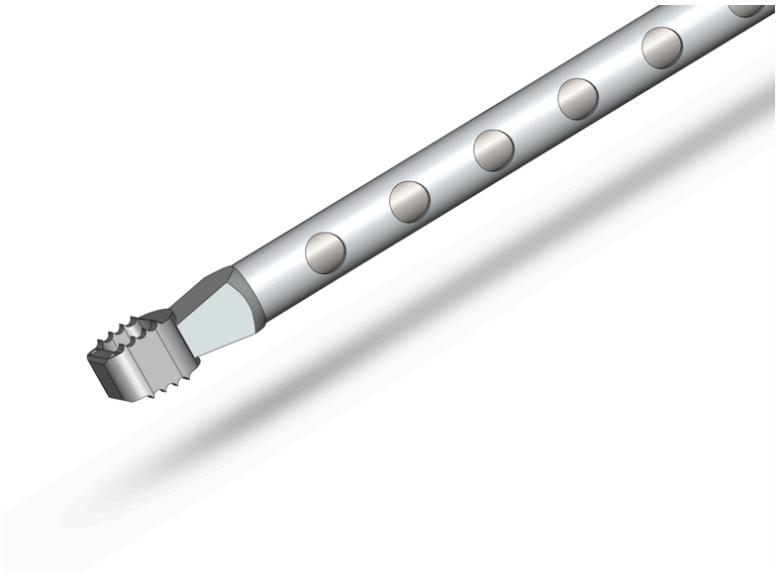
Inserter



Trial Sizer

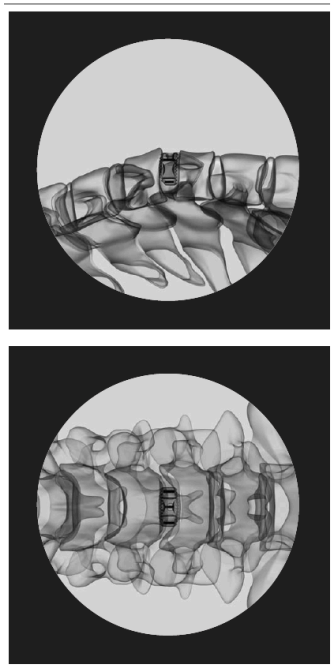
5. Prepare the implant

- Select the implant that matches the size found by trialing.
- Pack the implant with bone graft.
- Attach to the inserter with the threaded connection.



6. Insert the implant

- Insert the implant until it is just past the anterior margin of the disc space.
- Fluoroscopy may be used if desired to verify the implant position.
- The implant should be centered on the AP plane



7. Add supplemental fixation

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

8. Close the incision

- Close the incision in the usual manner.

Revision

- Should it become necessary to remove the Cervical 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 Cervical Cage's central aperture with a thin osteotome or elevator inserted between the implant and the vertebral endplate.
- Fusion mass external to the Cervical Cage may be removed with rongeurs.
- An explanted Cervical 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 Cervical Cage is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with autogenous bone graft. The Cervical Cage is intended to be used with a supplemental fixation system.

CONTRAINDICATIONS

The Cervical Cage should not be implanted in patients with active systemic infection or infection localized to the site of implantation. The Cervical 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 Cervical Cage 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 Cervical Cage should be implanted at each surgical level.
• The Cervical 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 Cervical 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 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.
13. Death.