

Eisertech, LLC Cervical Plate

Surgical Technique

Notes

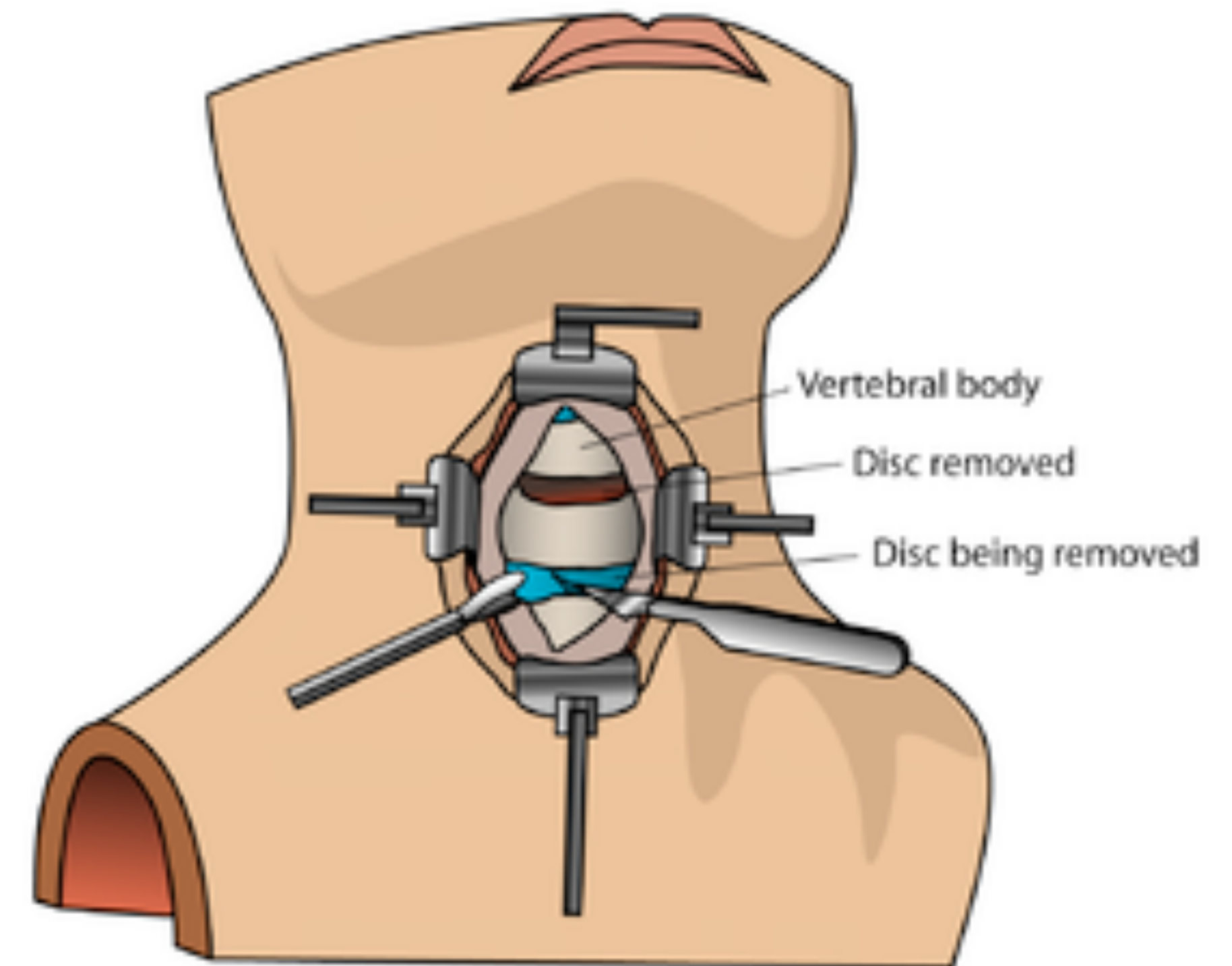
- This technique manual assumes that the surgeon is familiar with the techniques for performing an anterior cervical discectomy and fusion.
- This manual is not intended to teach a surgeon how to perform an anterior cervical discectomy or fusion.
- This manual provides instruction in how to appropriately use the equipment provided by Eisertech, LLC.

Plate Design

- Titanium alloy plates spanning from 1 to 4 levels of fusion are available.
- Variable angle and fixed angle screws are provided in lengths of 10, 12, and 14mm and diameters of 4.0 and 4.5mm.
- Screws may be secured to the plate by attaching a solid lock cover at each screw level.

I. Expose and prepare the disc

- Expose the affected disc and adjacent vertebral bodies through an anterior approach to the cervical spine.
- Perform the discectomy and interbody fusion procedure.



2. Apply the plate

- Using the plate holding forceps, lay the plate over the levels to be fused.
- The plate ends should not overhang the adjacent (non-operated) discs.
- If desired, one or more temporary fixation pins may be driven into the bone to secure the plate. These are driven with the screw driver.



3. Prepare a pilot hole

- A pilot hole for a bone screw may be created using either one of the awls or one of the drill guides, per the surgeon's preference.
- The fixed awls and drill guides will create a hole along a set trajectory, while the variable angle awls and drill guides allow a few degrees of angular variation.



4. Drive the first screw

- The self-retaining screw driver is used to drive the desired screw.
- The first screw should be driven into the bone until it is contacting the plate, but should not be fully tightened at this point.



5. Create additional pilot holes

- Utilizing either the awls or drill guides, create the remaining pilot holes for the bone screws.



6. Drive remaining screws

- Insert one screw into each pilot hole.
- As with the first screw, drive them until they contact the plate, but do not fully tighten any screws until all screws have been inserted.



7. Tighten Screws

- Tighten the screws, starting at first with opposite ends (e.g. caudal left, cephalad right, caudal right, cephalad left) in an “X” pattern.
- Tighten screws at any intermediate levels.

8. Apply lock cover

- Pick up a lock cover with the lock cover driver.
- Insert the lock cover tip into the threaded opening in the Cervical Plate.
- Tighten the lock cover until the head rests against the screw heads.



Revision

- Should it become necessary to remove the Cervical Plate, the implant may be retrieved utilizing the instruments used to insert it.
- The lock covers must be removed with the company's lock cover driver.
- An explanted Cervical Plate or its components 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 Plate is intended for anterior screw fixation to the cervical spine (C2-C7) *for immobilization and stabilization as an adjunct to fusion in skeletally mature patients* for the following indications:

- Degenerative disc disease (DDD, defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies).
- Spondylolisthesis
- Spinal stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudoarthrosis
- Deformity (i.e. kyphosis, lordosis, and/or scoliosis).

CONTRAINDICATIONS

- Severe osteoporosis
- Any indication where fusion is not required

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 Plate 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.
- 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 Plate 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 Plate:

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, headaches, dural tears, 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. Early or late loosening of any or all of the components.
14. Disassembly, bending, and/or breakage of any or all of the components.
15. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
16. Change in mental status.
17. Death.

Additional surgery may be necessary to correct some of these anticipated adverse events.