ORION® Anterior Cervical Plate System
Surgical Technique

as described by:
Gary L. Lowery, M.D., Ph.D.
Preliminary Steps

- Position the head in a stable supine position (head rest or traction) with slight extension of the neck. Confirm positioning and vertebral levels to be visualized via fluoroscopy. Traction on the arms is often helpful.

- A standard transverse incision can be made for one or two level corpectomies. It is important to dissect the fascial planes fully for longer constructs. Occasionally a carotid incision is necessary for difficult exposures and long reconstructions.

- Perform corpectomy or prepare interbody fusion receptor sites.

- Obtain cervical lordosis and/or distraction, if necessary.

- Prepare trapezoidal strut construct or trapezoidal interbody fusion wedge(s).

- Carefully position and impact strut or interbody fusion construct(s).

- Release distraction (promoting compression) and check stability of construct.

- Again, ensure levels to be instrumented can be easily identified on fluoroscopy.

- Ensure all anterior osteophytes are removed for proper plate positioning.
Surgical Technique

**STEP 1**

**Determine appropriate plate length:** Position the plate screw holes close to the graft receptor site at both cranial and caudal ends (figure 1A). This allows for the 15° cephalad and caudal screw angulation (figure 1B) and helps ensure that the plate does not extend over the adjacent disc spaces (ORION Anterior Cervical Plate x-ray templates are available for referencing plate length and positioning).
1A Bone Graft and Plate Position

1B Cephalad/Caudal Screw Angulation

Convergent Plate
Adjust lordotic curvature of plate if necessary: The amount of lordosis designed into the ORION Anterior Cervical Plate is acceptable in a majority of cases. If required, changes can be made to the standard machined lordotic curve by using the ORION Plate Bender (figure 2A). A gentle bend should be made over the entire length of the plate and sharp angulations must be avoided. It is important to note that plate contouring will alter the standard cranial and caudal angulation of the end screws (figure 2B).
2A Changing the Plate Contour

THE ORION PLATE BENDER

BENDING POINT

FRONT VIEW WITH ORION PLATE BENDER

2B The Standard Cranial and Caudal Angulation of Screws

15°
Surgical Technique

**STEP 3**

Secure the ORION Anterior Cervical Plate to the Plate Holder: The Plate Holder (figure 3A) will lock within any of the central slots on the various plates. The smallest plates do not have diagonal central slots. A kocher, bayonet, sucker tip, etc. will suffice for holding these smaller size plates.

To attach the Plate Holder to the plate, slide the sleeve toward the handle and engage the feet into the plate’s diagonal slot. Slide the sleeve down toward the plate to lock the holder to the plate (figure 3B).
**3A** The Plate Holder

- **SLEEVE** (open position)

- **Feet engage into diagonal slots in plate**

**3B** Plate Holder

Locked Into Plate
Surgical Technique

STEP 4

Position the ORION Plate on the anterior surface of the spine:
Review landmarks to ensure the plate is centered medially/laterally on the spine (figure 4A). The uncinate processes serve as excellent reference points.
Positioning the Plate Medially/Laterally

Plate Holder (sleeve in locked position)


Surgical Technique

**STEP 5**

**Insert the Drill Guide:** Seat the Drill Guide into the plate at the correct cranial/caudal and convergent angle (figure 5A). For Convergent Plate constructs, the Drill Guide angles $6^\circ$ toward the midline of the plate.

Once the Drill Guide is correctly seated into the plate, the Drill Guide can then be securely locked into the plate by applying light downward pressure on the Drill Guide handle, making sure to align the handle along the longitudinal axis of the plate (figure 5B).
5 A  Angulation of Drill Guide in Cranial/Caudal Direction

Light downward pressure, “locks” Drill Guide into plate

5 B  Locking The Drill Guide Into Plate

Light Pressure applied at Drill Guide handle applies force to “lock” Drill Guide into position

Drill Guide
Plate

SIDEVIEW:
END OF PLATE
Surgical Technique

**STEP 6**

**Drill holes for taps/screws:** Insert the appropriate Drill Bit into the Drill Guide. Drill the screw holes using either the 13 mm Drill Bit (figure 6A) or the Adjustable Drill Bit and Adjustable Drill Stop (figure 6B). Screw length is determined by the depth of bone purchase required (figure 6C).

For standard unicortical screw purchase, the 13 mm Drill Bit is used. For screws other than 13 mm in length, the Adjustable Drill Bit (10-26 mm depth) and Adjustable Drill Stop are used (figure 6B). If required, controlled penetration of the posterior cortex may be achieved by setting the Adjustable Drill Stop at the appropriate depth. The Adjustable Drill Stop provides for 1 mm increments and an additional safety factor during the drilling procedure, in addition to fluoroscopic visualization.
6A Drill Guide and 13mm Drill Bit

6B Drill Guide with Adjustable Drill Bit and Adjustable Drill Stop

Adjustable Drill Bit adjusts from 10mm to 26mm depth in one millimeter increments

6C Determining Bone Screw Length

13mm screw size results in 13mm of bone purchase
Surgical Technique

STEP 7

**Tap the vertebral bodies:** Remove the Drill Guide, insert the appropriate Tap into the predrilled hole at the same angulation, and tap the vertebral bodies using the Tap which corresponds to the Drill Bit length determined in Step 6. Taps are available in the same configuration as the Drill Bits, i.e. 13 mm Screw Tap (figure 7A) and Adjustable Screw Tap and Adjustable Tap Stop for 10-26 mm (figure 7B).
13mm Screw Tap

Adjustable Screw Tap and Adjustable Tap Stop

Adjustable Screw Tap adjusts from 10mm to 26mm depth in one millimeter increments
Surgical Technique

STEP 8

Implant screws: If required, a Depth Gauge may be used to confirm depth of hole for proper screw length. The Depth Gauge works either through the plate (figure 8A) or against the bone (figure 8B) and is accurate for both unicortical and bicortical techniques.

The appropriate length screw can be verified using the Screw/Plate Gauge (figure 8C).

Insert the appropriate length screw through the plate, using the Screwdriver with tapered, self-holding tip and tighten screw securely (not final tightening) (figure 8D).

Note: The preferred method of screw insertion is as follows:

1. Drill, tap and place one screw securely through the plate (if concerns requiring mediolateral tilt or positioning arise, obtain an AP radiograph prior to drilling the screw hole).

2. Then, drill, tap and place one screw securely at the opposite end of the plate, diagonally from the first screw position.

3. The remaining two screw implant sites are then drilled and tapped with the screws securely inserted.
8A Depth Gauge Through Plate

8B Depth Gauge On Bone

8C Verifying Screw Length

8D Screw Insertion
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STEP 9

**Final tightening of bone screws:** Normally, the Plate Holder is not required after the first one or two screws have been implanted. If required, though, it can be used throughout the entire procedure and can also be easily repositioned during implantation.

Tighten the screws to ensure they are seated below the surface of the plate (figure 9A). Obtain radiographs to ensure that screw length and screw position are appropriate. Although plate malposition may be determined from a lateral radiograph (i.e. screws not aligned in the same plane,) an AP radiograph provides additional information regarding verification of implant position.

Screws can now be placed in the diagonal slot (figure 9B) if deemed necessary (i.e. multi-level interbody fusions or long strut graft reconstructions).

It is recommended that the gold colored 4.35 mm diameter screws are used (11, 13 or 15 mm lengths) in the diagonal slots. The Drill Guide is positioned in the center slot of the plate and the hole is drilled to either an 11, 13 or 15 mm depth. These holes should be drilled in a straight manner into the bone as shown (figure 9B). The gold colored 4.35 mm Tap and Adjustable Tap Stop are then used to tap the hole to the appropriate depth. The 4.35 mm screws are then inserted using the screwdriver and firmly tightened.
9A Final Tightening of Bone Screws

Bone screws fully seated into plate

9B Placing Screw in Diagonal Slot
**Surgical Technique**

**STEP 10**

**Insert the locking screws:** Attach the Lock Screw Holder to the Lock Screw by gently squeezing the prongs, then engage the Holder into the Lock Screw (figure 10A). Slide the sleeve down toward the end of the holder. After the Lock Screw is initially threaded into the plate (figure 10B), detach the Lock Screw Holder by pulling the sleeve up and tilting the holder to release from the Lock Screw. *(Note: Do not attempt to tighten the Lock Screw with the Lock Screw Holder. Doing so will cause damage to the instrument.)* Final tightening of the Lock Screw is accomplished through the use of the Lock Screw Driver (figure 10C). One the Lock Screw Driver is firmly placed into the slot, turn the Lock Screw clockwise until the Screw Driver slips out of the slot (this is a self-limiting device). The Lock Screw is now firmly secured.

Irrigate wound and close wound over a drain.
The completed ORION Anterior Cervical Plate Construct
Postoperative Protocol

Postoperative protocol varies with the surgeon’s personal preference and training. The ORION ANTERIOR CERVICAL PLATE SYSTEM provides secure selective vertebral immobilization obviating, in certain cases, the need for external brace support while allowing freedom of movement of the unaffected levels. External support (i.e. hard collar) while in a moving vehicle may be beneficial for a time. Radiographic evaluation should be performed at 2, 6, and 12 weeks and then on each of the extended follow-up visits (6 month, 12 month, etc.) Physical therapy usually consists of home exercises for range of motion and isometric strengthening.
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## Instruments

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*All instruments sold separately.*
Purpose: The ORION Anterior Cervical Plate System components are temporary implants that are intended for anterior intervertebral screw fixation of the cervical spine for the purpose of spinal fusion.

Description: The ORION Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates (screws and washers are pre-assembled to the plates), screws and associated instruments. Fixation is provided by bone screws inserted into the vertebroplasty system components, which are inserted into the vertebrae so that the screw heads are located on the lateral aspect of the vertebrae. The ORION Anterior Cervical Plate System implant components are made from titanium alloy such as described by ASTM F136 or other FDA approved material. Where indicated, the plate is contoured to fit the curvature of the cervical spine. Titanium implant components should not be used together in a construct. Sofamor Danek expressly warrants that these devices are fabricated from the foregoing material specifications. The implants, associated instruments, or plates may be impacted, implanted, or sterilized. Implanted material should be structurally sound and satisfactory for the purpose or use as specifically indicated here.

Indications, Contraindications, and Possible Adverse Effects

Indications: This system is intended for anterior intervertebral screw fixation of the cervical spine. The indications and contraindications of spinal instrumentation systems should be well-understood by the surgeon. The system is indicated for use in the surgical stabilization of vertebrae (including fusion) in the cervical spine (whether anterior, posterior, or lateral) for patients with: 1) degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), 2) kyphosis, lordosis, or scoliosis, 3) trauma (including fractures), 4) tumors, 5) deformity, and 6) Failed previous fusion.

Contraindications: The ORION Anterior Cervical Plate System components are temporary implants that are intended for anterior intervertebral screw fixation of the cervical spine. Contraindications include, but are not limited to:

1. Any case not needing a bone graft and fusion or where fracture healing is not required.
2. Any case requiring the mixing of metals from different components.
3. Any attempt to pretreat the surfaces of the bone, bone cement, or other implant components.
4. Any attempt to use the bone cement as a bone substitute. Bone cement should not be used since this material is used for temporary fixation of the implants.
5. Any implant time interval interface with unusual anatomical structures or expected physiological performance.

Potential Adverse Events: All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a few additional events may occur, but is limited to:

2. Infection.
3. Wound dehiscence.
5. Spinal cord injury.
6. Vertebral body fracture.
7. Dural tears.
8. Infection.
9. Suspected or documented metal allergy or intolerance.

Note: This device is intended for anterior intervertebral screw fixation of the cervical spine. It is contraindicated for use as weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position. Failure to perform the surgical result or the device should be removed to mechanical advantage, or if the device has functioned properly, or if the device is no longer functional.

Other preoperative, intraoperative, and postoperative warnings are as follows:

Postoperative:
1. Any patient with contraindications in the conditions described in the indications should be avoided.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Surgery should not begin until the bone has become rigid.
4. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
5. Healing is more rapid if the bone is in a weight supporting position and can withstand body loads without the support of bone.
6. Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the cement solidification can cause damage to tissues and surrounding bone.
7. Fixation is provided by bone screws inserted into the vertebrae so that the screw heads are located on the lateral aspect of the vertebrae. The ORION Anterior Cervical Plate System components are temporary implants that are intended for anterior intervertebral screw fixation of the cervical spine. Contraindications include, but are not limited to:
8. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
9. All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. All, as in the same assortment and order, must be in the same containers.
10. Cases in which the components must be deconstructed and cleaned using established hospital methods before sterilization and reintroduction into a sterile field are not to be used.
11. Further information should be obtained before the onset of implant size failures.
12. Certain cleaning solutions such as those containing bleach or formaldehyde may damage some devices and they must not be used.
13. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.
14. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be warned of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine surgery.

Contraindications include, but are not limited to:

1. Infection, toxic to the plate system.
2. Fever or leukocytosis.
3. Moribund condition.
5. Previous radiation therapy to the area.
6. Bone loss or decrease in bone density, possibly caused by stress shielding.
7. Loss of bone and/or cancellous bone, requiring bone graft.
8. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rates unrelated to other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Bone infection.
10. Infection.
11. Any case requiring the mixing of metals from different components.
12. Any case not requiring a bone graft.
13. Any case not needing a bone graft and fusion or where fracture healing is not required.
14. Any case requiring the mixing of metals from different components.
15. Any case not requiring a bone graft.
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25. Any case not requiring a bone graft.

Adverse Changes:

1. Any case not needing a bone graft and fusion or where fracture healing is not required.
2. Any case requiring the mixing of metals from different components.
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Other preoperative, intraoperative, and postoperative warnings are as follows:

Preoperative:

1. Any instruction manuals should be carefully followed.
2. All information from the instrument manufacturer should be reviewed.
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Postoperative:

1. Any postoperative directions and warnings to the patient and the corresponding patient compliance, are extremely important.
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For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek products, contact your MEDTRONIC SOFAMOR DANEK USA, INC. Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA, INC. Customer Service toll free: 800-933-2635.

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U.S. Patent No. 5,364,399 and other patents pending.
WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.