



Ceres Anterior Cervical Plates System

SURGICAL TECHNIQUE

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Features and Benefits

- EASE-OF-USE
- SAFETY AND RELIABILITY
- OPRIMIZED BY SIZE
- IMPROVED INSTRUMENTS



The Ceres Anterior Cervical Plate is a semi-constrained (semi-rigid) system designed to offer the surgeon the possibility to choose intra-operatively the screw trajectory that best fits the individual patient anatomy presented. The 'load sharing' design concept accommodates the safe transfer of axial load to the bone graft without putting strain on either the screws or the plate as can occur in more constrained (rigid) systems.

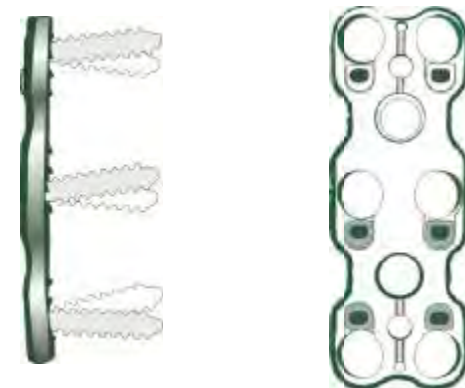


Plate thickness is an important consideration in protecting the patient against risk of dysphagia. With a profile of 2.3mm, Ceres is one of the lowest profile anterior cervical plates currently available today.



1. Variable angle semi-rigid fixation system

Design elements, such as the Ceres Cam-lock mechanism, ensure that all implants screws hold the plate securely in place and are prevented from backing out. The cams do not interfere with screw placement and do not add to the profile of the plate.



2. Numerous screw and plate surgeon convenience

The Ceres system totally includes 25 sizes—one level, two level and three level plates. Self-drilling and Self-tapping screws both are included in multiple lengths. Every implant option is at the surgeon's fingertips during the procedure.



4. Optimized by size

The Ceres plates have 2.3mm profile and 16mm width. The plates have contoured shape edges. The pre-curved design makes the cervical reconstruction as the normal curve.



5. Anti Skid Cleats

Resists plate movement during the holes preparation and screws insertion. The Character adds zero profile to overall construct—cleats “dig in”



3. Compact and user-friendly instrumentation

In optimized designed instrumentation of Ceres, every element is not only designed with ergonomics ideology, but also designed to work in concert with the whole system. For example, color coating of the drill match the screws color. All the instruments make the procedures more simple and convenient.



Surgical Technique



- Instability caused by trauma;
- Instability associated with correction of cervical lordosis and kyphosis deformity;
- Instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery;
- Instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;
- Instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

INTRODUCTION

The Ceres Plate is a semi-rigid system intended for anterior cervical intervertebral body fixation. Ceres is based on a comprehensive, clinically proven design, modified to incorporate current market technology.

The Ceres System offers maximum implant versatility & integrated instrumentation. The Ceres Anterior Cervical Plate system is indicated for stabilization of the cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior cervical plate include:

Note:

- The described technique presents only one of many approaches to the stabilization of the anterior cervical spine. The surgeon is encouraged to utilize the Ceres Anterior Cervical Plating system with those techniques most familiar to the operation surgeon.



Step 1 Patient Positioning and Approach

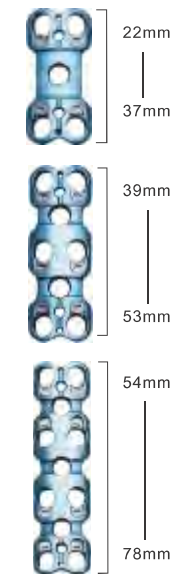


The patient is placed in the supine position with the head in slight extension. The posterior cervical spine is supported to establish and maintain normal cervical lordosis. The surgeon must then choose a right- or left-sided approach to the cervical column. After exposing the cervical spine, the self retaining retractor is placed to provide optimal visualization. A vertebral body distractor (899702) may be used. The distraction shafts (899712) are positioned midline in the vertebral bodies adjacent to the level to be treated. The distractor is placed over the shafts and the appropriate amount of distraction is applied. Discectomy are completed. Median corpectomy will be completed if required. Pituitary forceps, curettes, and Kerrison may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament.

Bone graft/substitute (Diamesh, e.g.) is then positioned between both vertebrae.

Step 2 Choosing Plate Size

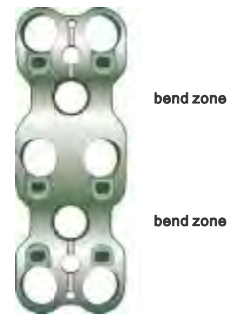
Ceres Anterior Cervical Plates are available in 1-3 level configuration with a length ranging from 22-78mm. When handling plate use the caution to avoid scratching or notching the plate surface. Following anterior bone graft placement, use the forceps (899703) to select the appropriate plate size and place it on the vertebrate column. Confirm that the length is appropriate. The plate should span the entire fusion segment, preferably using the shortest plate possible, therefore avoiding the adjacent disc space. Fluoroscopy may be utilized to optimize plate selection and screw placement.





Step 3 Adjusting Plate Curvature

The Ceres Plate has a precontoured lordotic curvature (13" Radius) anatomically appropriate in the majority of procedures. If desired, the Plate Bender (899705) may be utilized to optimally contour the sagittal plane to ensure maximum bone/plate interface. It is critical to bend the plate in the specified BEND ZONE(S), which has a smooth undersurface and reduced cross sectional thickness.



For additional lordosis, the desired plate BEND ZONE is placed between the lobes (cleats facing downward) of the Plate Bender. The BEND ZONE must be centrally located on the lower lobe of the PLATE BENDER. Plate bending should be evenly distributed at the BEND ZONES along the length of the plate. For straightening of kyphotic bending, the opposite side of the Plate Bender is used. The BEND ZONE is placed between the lobes of the bender (cleats facing upward). Contouring titanium plates can weaken and compromise the mechanical integrity of the device. The fatigue life of the contoured implant in vivo cannot be precisely predicted. Do not bend the plates repeatedly, excessively, or any more than absolutely necessary. Once the sagittal contour has been altered by the Plate Bender, do not bend on the reverse direction.



Increase the lordosis
Step3: Adjusting Plate Curvature

Reduce the lordosis
Step3: Adjusting Plate Placing Temporary Fixation Pins

Step 4 Placing Temporary Fixation Pins

After selecting the appropriate plate use the temporary Fixation Pins (899713) (TFPs) to hold the plate in place while drilling and placing the screws.

Using one of the plate holders mentioned in step 4 hold and lay the plate evenly on the anterior cervical spine. Place the Temporary Fixation Pin through the pinhole on the plate using the Temporary Fixation Pin Holder (899711).

Note:
• Pre-drilling is not required for Temporary Fixation Pin insertion.

After placing the two TFPs, fluoroscopy can be used to confirm optimal screw placement and trajectory. Any necessary adjustments may be done at this time and reconfirmed with fluoroscopy. Removing soft tissue and large osteophytes may improve bone-plate interface.





Step 5 Preparing Screw Hole

Before drilling you may need to prepare your screw hole with an awl. To use the Ceres Awl, place the tip of the awl(899701)shaft against the screw hole on the plate and press it in the direction of the screw angle desired (Figure 5a).The awl will protrude into the desired hole.The awl also has a striking plate on the handle should you need to strike it.



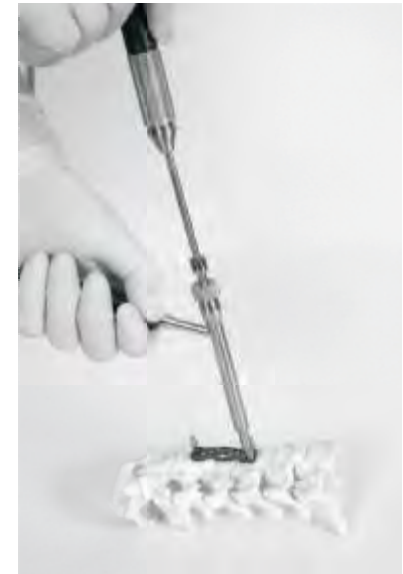
Step 6 Drilling Holes

Screw angle may be selected and the plate stabilized during the drilling procedure. The plate Holder/Drill Guide (899704) may be attached to the plate by placing the expandable end into a lateral screw hole and turning the knurled knob clockwise.



Step 7 Selecting and Using Drill Bits

The Ceres Anterior Cervical Plate System offers the ability to select various angles of screw placement to confirm to individual patient anatomy.Certain angles may direct the screws at vulnerable vascular and neural tissues. Use fluoroscopy to confirm drill bit penetration depth and angular orientation to assure that those structures are not at risk. Depth of screw insertion and angular orientation of the screw must also be confirmed by fluoroscopy. Typical screw placement is 5-10 degrees rostral &caudal to correspond with the superior and inferior disc space respectively. Avoid severe angulation of the superior screw (greater than 16 degrees) which may prevent optimal locking of the screw with the cam.The drill length should correspond to the depth of the bone purchase required,taking into consideration the size of the vertebra, the quality of the bone, diagnosis etc. The Ceres System is available with 12mm (blue) 14mm (gold) and 16mm (magenta) fixed length drill bits. These colors correspond to their respective screw size colors.





Step 8 Using The Tap

The Ceres System is provided with self-tapping screws. Hence, tapping is not always necessary. However, if tapping is not always necessary. However, if tapping is required to prepare the passage of the screw, the Variable Depth Tap (899710) can be adjusted in 1mm increments to correspond to the drill depth setting. The length of the Tap that will extend beyond the soft tissue protection sleeve is set by turning the cylinder gauge mounted near the handle of the Tap in either direction. Please ensure that the release button is locked in place at the desired measure before using the Variable Depth Tap.



Note:

- The setting for the Variable Depth Tap can be approximated by preoperative radiographic measurements (CT or MRI) or by intraoperative measurement of the exposed vertebral endplates following decompression. The use of intraoperative fluoroscopy while drilling and tapping, will further improve the accuracy of screw length selection.

Step 9 Inserting Screws

The Ceres screws are available as self-drilling (4.5mm major diameter) in lengths ranging from 12-16mm or self-tapping (4.5mm major diameter). Large-diameter screws (4.8mm major diameter) are available in 12, 14, and 16mm lengths. For identification purposes the screws are colored according to screw types.

- 12mm screws are blue colored.
- 14mm screws are gold colored.
- 16mm screws are rose colored.



Select the appropriate screw length corresponding to the hole drilled. Using the Hex Driver (899714), pick up the screw from the tray and insert it through the plate. Drill the first hole, tap if desired, and place screw without tightening completely.



After confirming proper plate positioning, drill, tap if desired and place screws in all remaining screw holes. Begin with the lateral hole that is opposite and diagonal to the first prepared hole. Remove Temporary Fixation Pins and perform final tightening of all screws in the same sequences as mentioned above.



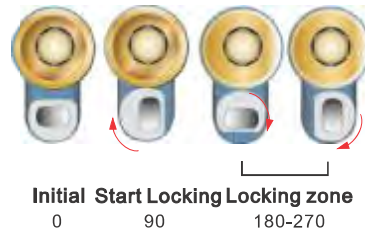


Step 10 Locking the CAMs

Locking all screws within the plates is the last step in the plating procedure. All screws should be secured to the vertebral bodies as previously described before beginning the cam locking procedure. To lock the screw, engage the CAM-LOC mechanism (899716) by fully seating the Cam Tightener straight into the slot of the cam. It is important to maintain a relatively perpendicular orientation of the Cam Tightener to the cam slot during the entire locking procedure. Additional exposure may be temporarily required to properly align the Cam Tightener with the cam.



Rotate the Cam Tightener clockwise, resistance will be felt as the cam contacts the head of the screw. Ensure you do not rotate cam beyond 270 degrees (vertical slot). Failure to maintain proper alignment of the Cam Tightener may result in a stripped cam.



For rostral and caudal screw trajectories more than 16 degrees, the cam may not interfere with the screw head and therefore the torque limiter will not release. In this case, the cam should be positioned within the locking zone to provide screw within the locking zone to provide screw backout resistance.

Note:

- Exact position of a locked cam is dependent on a number of factors and may vary within the typical locking zone. Do not turn cam past 270°.

Product Catalog

Implants

Ceres Anterior Cervical Plates



| Product No. | Length | Remark |
|-------------|--------|--------|
| TA | | |
| 31331022 | 22mm | |
| 31331025 | 25mm | |
| 31331027 | 27mm | |
| 31331029 | 29mm | |
| 31331031 | 31mm | |
| 31331033 | 33mm | |
| 31331035 | 35mm | |
| 31331037 | 37mm | |
| 31332039 | 39mm | |
| 31332041 | 41mm | |
| 31332043 | 43mm | |
| 31332045 | 45mm | |
| 31332047 | 47mm | |
| 31332049 | 49mm | |
| 31332051 | 51mm | |
| 31332053 | 53mm | |
| 31333054 | 54mm | |
| 31333057 | 57mm | |
| 31333060 | 60mm | |
| 31333063 | 63mm | |
| 31333066 | 66mm | |
| 31333069 | 69mm | |
| 31333072 | 72mm | |
| 31333075 | 75mm | |
| 31333078 | 78mm | |



Ceres Screws, self-tapping



| Product No. TA | Size | Color |
|-------------------|-----------|-------|
| 31335012 | Φ4.5×12mm | Blue |
| 31335014 | Φ4.5×14mm | Gold |
| 31335016 | Φ4.5×16mm | Rose |

Ceres Screws, large diameter



| Product No. TA | Size | Color |
|-------------------|-----------|-------|
| 31336012 | Φ4.8×12mm | Blue |
| 31336014 | Φ4.8×14mm | Gold |
| 31336016 | Φ4.8×16mm | Rose |

Ceres Screws, self-drilling



| Product No. TA | Size | Color |
|-------------------|-----------|-------|
| 31337012 | Φ4.5×12mm | Blue |
| 31337014 | Φ4.5×14mm | Gold |
| 31337016 | Φ4.5×16mm | Rose |

Instruments

Ceres Anterior Cervical Plates System Instruments Set

| Instrument No. | Product Description | Quantity |
|----------------|---|----------|
| 899700 | Ceres Anterior Cervical Plates InstrumentsSet | |
| | Ceres Anterior Cervical Plates InstrumentsSet (empty) | 1 |
| 899701 | Awl-Assembly | 1 |
| 899702 | Distractor | 1 |
| 899703 | Forceps Plate Holder | 1 |
| 899704 | Plate Holder/Drill Guide | 1 |
| 899705 | Plate Bender | 1 |
| 899706 | Fixed Depth Drill Assembly, 12mm | 1 |
| 899707 | Fixed Depth Drill Assembly, 14mm | 1 |
| 899708 | Fixed Depth Drill Assembly, 16mm | 1 |
| 899709 | Handle with Quick Coupling | 2 |
| 899710 | Variable Depth Tap | 1 |
| 899711 | Multifunctional Holder | 1 |
| 899712 | Position Rod | 2 |
| 899713 | Temporary Fixation Pin | 2 |
| 899714 | Hex Screwdriver | 2 |
| 899715 | Screw Holding Sleeve | 1 |
| 899716 | Cam Tightener Shaft | 2 |



899701 Awl-Assembly



899702 Distractor



899703 Forceps Plate Holder



899704 Plate Holder/Drill Guide



899705 Plate Bender



899706 Fixed Depth Drill Assembly, 12mm



899707 Fixed Depth Drill Assembly, 14mm



899708 Fixed Depth Drill Assembly, 16mm



899709 Handle with Quick Coupling



899710 Variable Depth Tap



899711 Multifunctional Holder



899712 Position Rod



899713 Temporary Fixation Pin



899714 Hex Screwdriver



899715 Screw Holding Sleeve



899716 Cam Tightener Shaft

INDICATIONS

The Ceres Anterior Cervical Plate system is indicated for stabilization of the cervical bodies, spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral. Specific clinical indications for anterior cervical plate include:

- Instability caused by trauma;
- Instability associated with correction of cervical lordosis and kyphosis deformity;
- Instability associated with pseudoarthrosis as a result of previously failed cervical spine surgery;
- Instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;
- Instability associated with single or multiple level corpectomy in advanced degenerative disc disease, spinal canal stenosis and cervical myelopathy.

WARNING:

- The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.