REV A

Cervical Plate System

Surgical Technique Manual

Step by Step Guide

Tray Description

Product Sizes

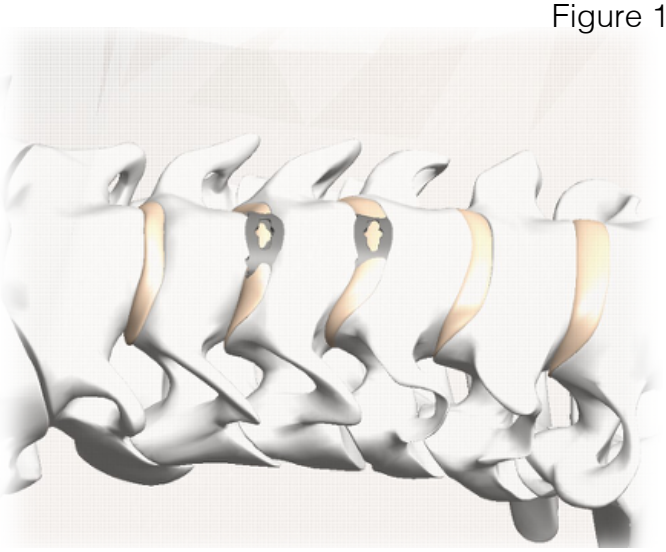
Step 1 : Plate Site Preparation

Expose the anterior cervical spine and perform a discectomy or corpectomy of the correct level.

Place the graft so that it is flush or below the anterior margin of the vertebral body (Figure 1). Anterior plating is applied only after adequate grafting.

Confirm the vertebral levels to be instrumented using fluoroscopy.

Figure 1



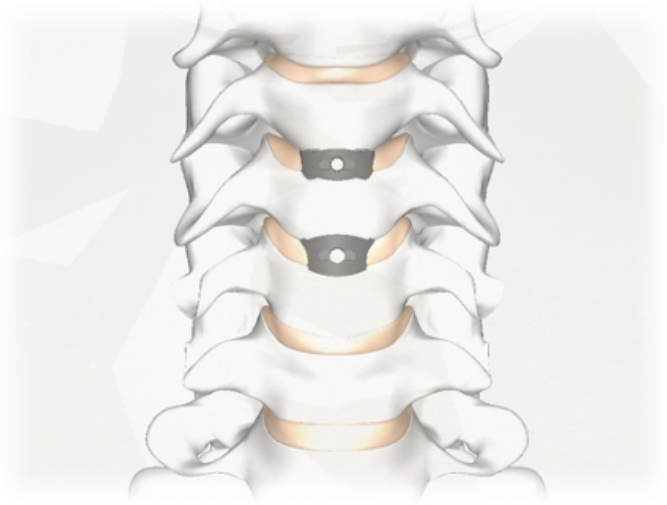
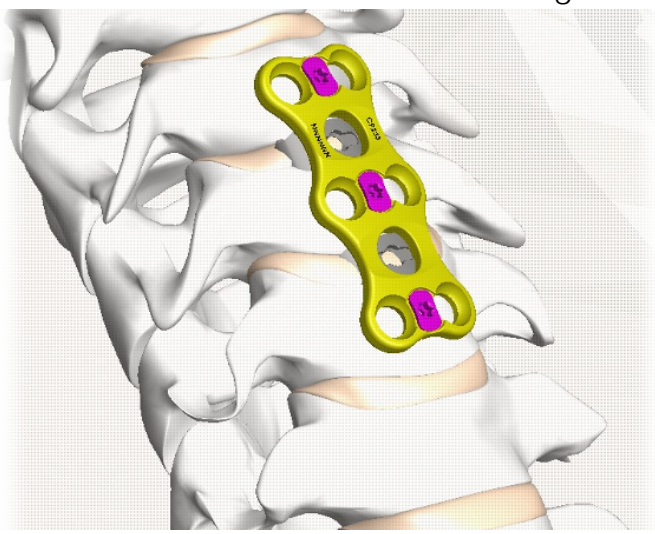


Figure 2

Surgical Pearl: “Remove the anterior osteophytesto allow the plate to lie flush on the “true” anterior cortex of the vertebral body.” (Figure 2)

Step 2 : Plate Selection and Placement

Figure 3



Select the appropriate length of the anterior cervical plate. Once the appropriately sized plate has been selected, use the plate holder to grip the plate and check to ensure that the plate fits the anatomy (Figure 3).

Bend the plate as needed to match the contour of the spine.

1, 2, 3 and 4 level plates are available. (Size table provided at end of technique.)

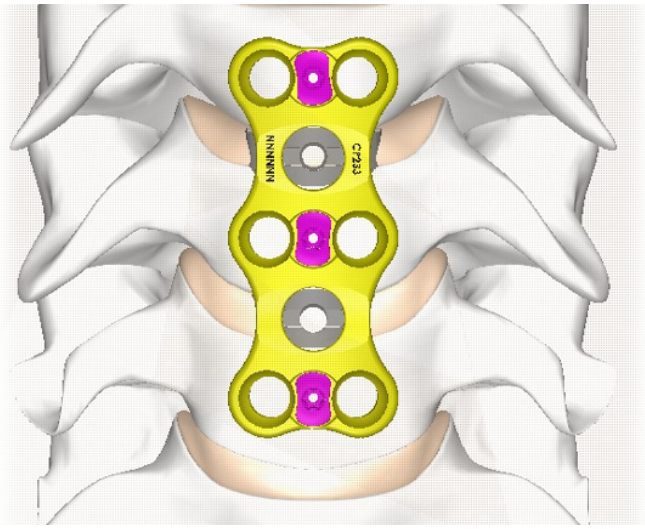


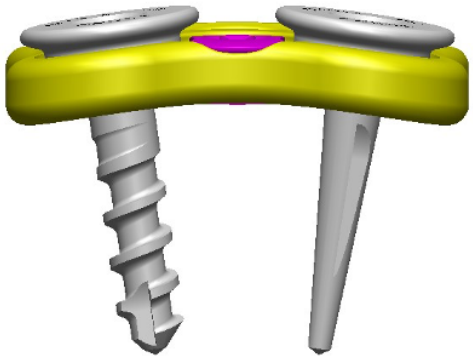
Figure 4

Surgical Pearl: “The plate should be centrally positioned on the midline and should not overlie adjacent non-fused disc segments.”

“The caudal and cephalad screw holes should be placed as close to the graft site without compromising the vertebral endplate.”
(Figure 4).

Step 2 : Plate Selection and Placement - Temporary Plate Pins

Figure 5



Temporary plate pins are available prior to screw insertion. Two options are available, threaded, and non-threaded (Figure 5).

Use the pin inserter to secure a pin located in the screw caddy. Select the appropriate hole and secure the pin over the plate, into the vertebral space.

Remove the temporary pins after permanent screw insertion.

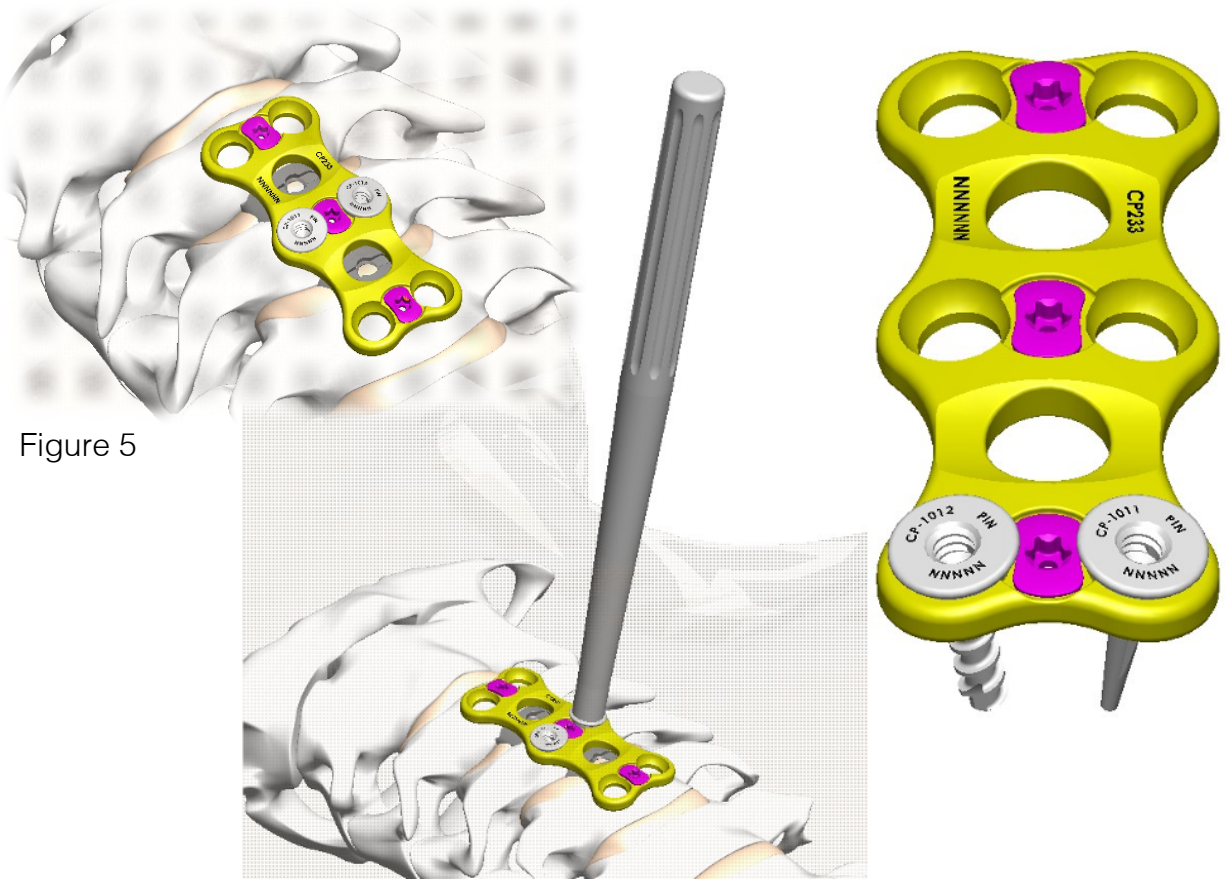
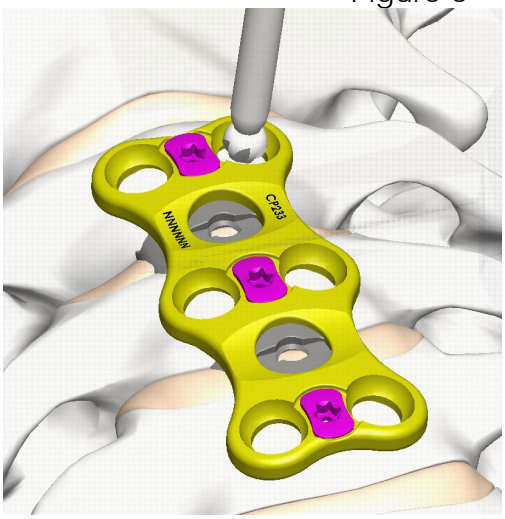


Figure 5

Step 3 : Screw Hole Preparation - Awl Option

If preferred, use a standard operating room burr to penetrate the anterior cortex of the vertebral body. (Figure 6)

Figure 6



Bone awl options are also provided. The bone awl is 1.70mm in diameter and 12mm in length. The awl can be guided using a spring-loaded linear guide, or a spring-loaded offset guide with a handle (Figure 7). Each option allows for you to conically angle the guide to the desired screw angle (Figures 8, 9)

Figure 7

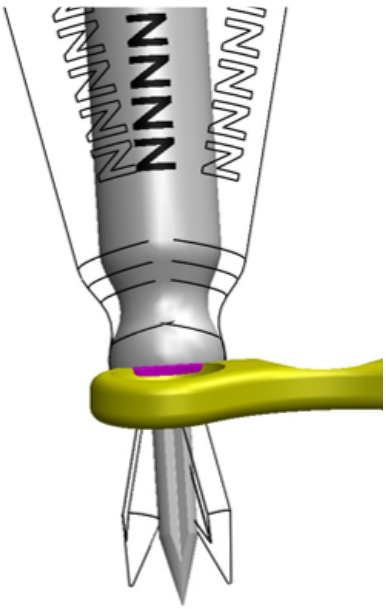


Figure 8

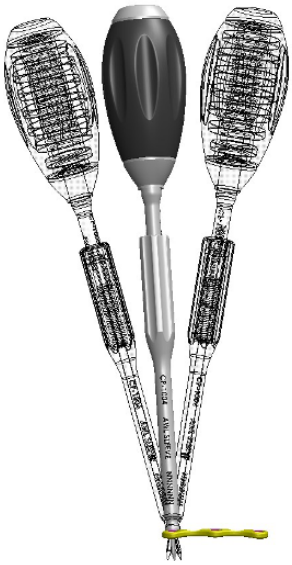


Figure 9

Step 3 : Screw Hole Preparation - Drill Option

Drill length options are also provided. The 3 drill options are 1.75mm in diameter and correspond to the screw length (Figure 10).

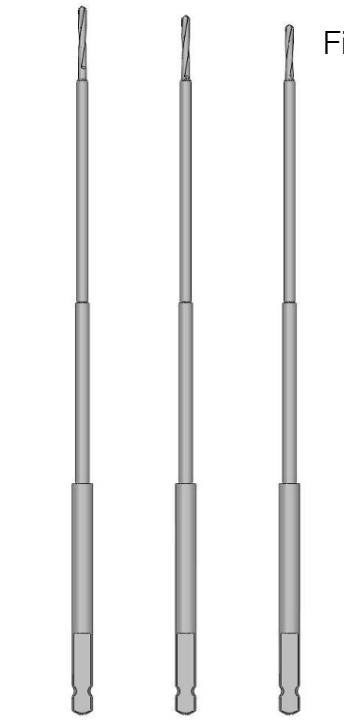


Figure 10

The drill bit shaft is attached to the AO drive ratchet handle.

Assemble the drill bit into the guide options. You can use the spring-loaded linear guide or the spring-loaded offset guide with a handle. (Figure 11)

Guides allow the drill to be inserted at the desired conical angle for screw angle preparation (Figure 12).

Figure 11

The tip of the drill guide should be seated into the cervical plate screw hole (Figure 12).

Apply light downward pressure on the drill guide and rotate the drill clockwise. Advance the drill into the bone until the stop of the drill contacts the back of the selected drill guide. Remove the drill from the bone by turning the drill counterclockwise while pulling back on the drill.

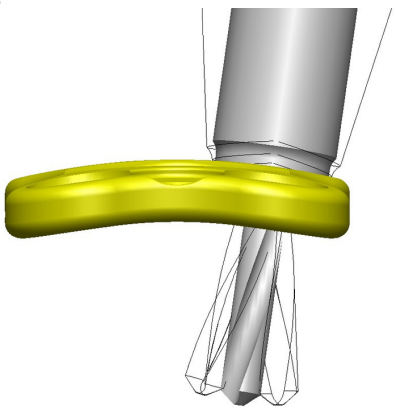


Figure 12

Step 4 : Screw Insertion

Once the screw hole has been prepared, select the appropriate screw length and diameter. Screws are available in 12mm, 14mm and 16mm lengths and 4.0mm and 4.25mm in diameter (Figure 13).

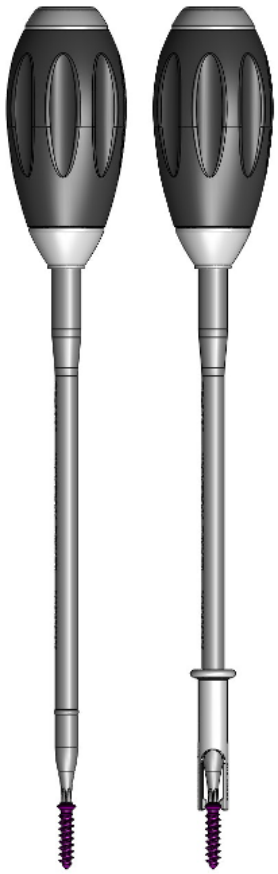


Figure 13

Screws can be secured to the driver with two options: Standard and Sleeved. The Standard options simply captures the screw with a tapered inserter tip on the universal driver (Figure 13).

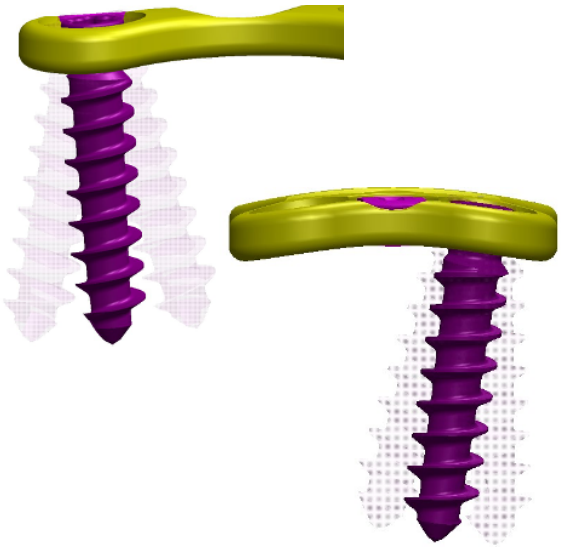
To use the sleeved option, slide the screw clip onto the universal driver. One assembled, attached the screw to the inserter tip, then snap the screw clip over the head of the screw (Figure 13).

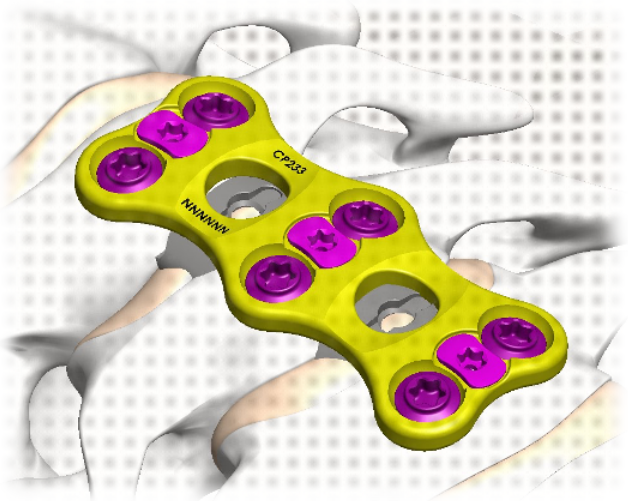
Step 4 : Screw Insertion (Continued)

Tighten the screws so that the plate is seated evenly and flush to the anterior cortex of the cervical spine. Since all screws are self-tapping, tapping is not required.

Intraoperative radiographs or fluoroscopy should be used to check plate position before screw insertion.

Remove temporary pins.





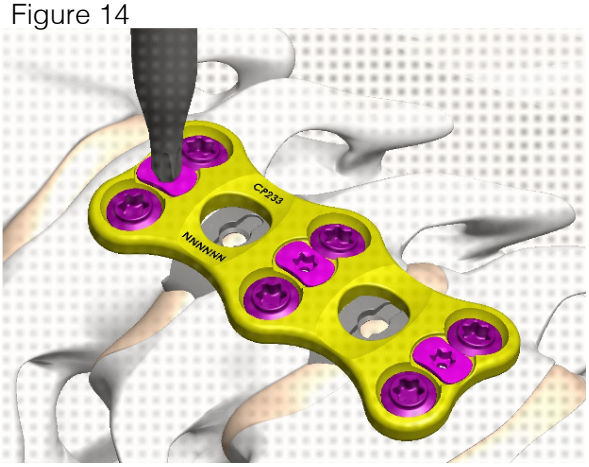
Surgical Pearl: “The screws should be contained in the vertebral body and not penetrate into the spinal canal or adjacent disc space.

Step 5 : Locking Tab

The locking tab driver (Figure 14) is placed on the locking tab.

Rotate the locking tab driver clockwise 90 degrees. The locking tab edges should cover the head of the cervical screw. (Figure 15)

Figure 14



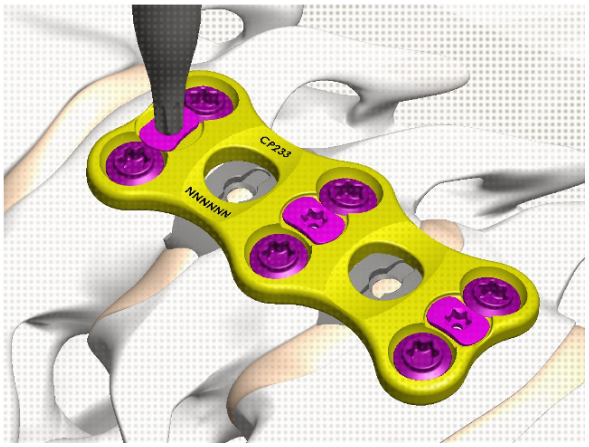


Figure 15

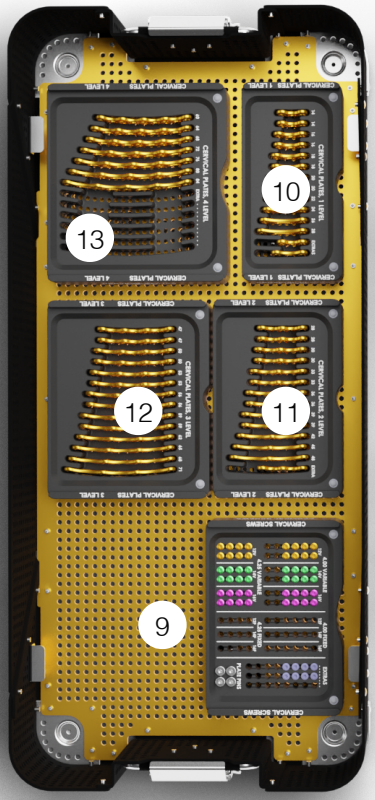
Obtain AP and lateral radiographs for final plate and screw position.

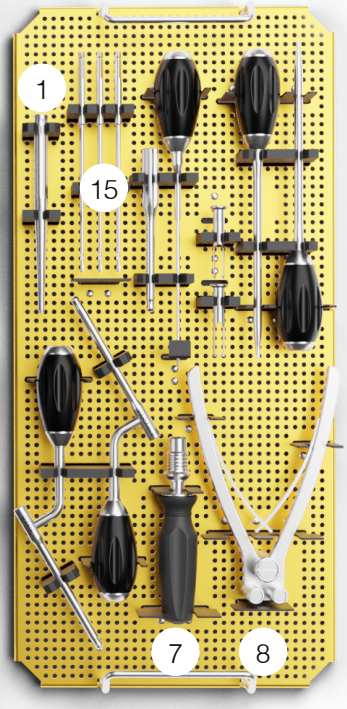
Step 6 : Screw and Plate Removal

Attach the locking cap driver on the locking cap and rotate it counter-clockwise 90 degrees. Attach the cervical screwdriver into the cervical screw and remove the screw. After all cervical screws have been removed, then remove the cervical plate.

Cervical Plate Instrument Tray

Lid, Sides, Ends - Color BLACK
Tray Bottom - Color GOLD
Electropolished TRI-corners - Color SILVER Chrome
Laser Marked Interior, Lid, Sides, and Ends - Color WHITE
Custom Lid Options Available





LAYOUT:

1. Universal Driver
2. Screw Clips
3. Bone Awl
4. Awl Sleeve
5. Variable Guide
6. Fixed Guide
7. Straight Ratchet
8. Plate Bender
9. Cervical Screw Caddy
10. Cervical Plates, 1 Level Caddy
11. Cervical Plates, 2 Level Caddy
12. Cervical Plates, 3 Level Caddy
13. Cervical Plates, 4 Level Caddy
14. Fixation Pin Inserter
15. 2.1mm x 12,14 &16mm Drills

Cervical Plate System
Product Sizes

Cervical Plates	Part #
14mm 1 Level Plate	CP114
16mm 1 Level Plate	CP116
18mm 1 Level Plate	CP118
20mm 1 Level Plate	CP120
22mm 1 Level Plate	CP122
24mm 1 Level Plate	CP124
26mm 1 Level Plate	CP126
28mm 1 Level Plate	CP128
28mm 2 Level Plate	CP228
30mm 2 Level Plate	CP230
33mm 2 Level Plate	CP233
36mm 2 Level Plate	CP236
39mm 2 Level Plate	CP239
42mm 2 Level Plate	CP242
45mm 2 Level Plate	CP245
48mm 2 Level Plate	CP248
47mm 3 Level Plate	CP347
50mm 3 Level Plate	CP350
53mm 3 Level Plate	CP353
56mm 3 Level Plate	CP356
59mm 3 Level Plate	CP359
62mm 3 Level Plate	CP362
65mm 3 Level Plate	CP365
68mm 3 Level Plate	CP368
71mm 3 Level Plate	CP371
60mm 4 Level Plate	CP460
64mm 4 Level Plate	CP464
68mm 4 Level Plate	CP468
72mm 4 Level Plate	CP472
76mm 4 Level Plate	CP476
80mm 4 Level Plate	CP480
84mm 4 Level Plate	CP484

Fixed Screws	Part #
4.00mm x 12mm	CSF4012
4.00mm x 13mm	CSF4013
4.00mm x 14mm	CSF4014
4.00mm x 15mm	CSF4015
4.00mm x 16mm	CSF4016
4.00mm x 17mm	CSF4017
4.00mm x 18mm	CSF4018
4.25mm x 12mm	CSF4212
4.25mm x 13mm	CSF4213
4.25mm x 14mm	CSF4214
4.25mm x 15mm	CSF4215
4.25mm x 16mm	CSF4216
4.25mm x 17mm	CSF4217
4.25mm x 18mm	CSF4218

Variable Screws	Part #
4.00mm x 10mm	CS4010
4.00mm x 11mm	CS4011
4.00mm x 12mm	CS4012
4.00mm x 13mm	CS4013
4.00mm x 14mm	CS4014
4.00mm x 15mm	CS4015
4.00mm x 16mm	CS4016
4.00mm x 17mm	CS4017
4.00mm x 18mm	CS4018
4.25mm x 12mm	CS4212
4.25mm x 13mm	CS4213
4.25mm x 14mm	CS4214
4.25mm x 15mm	CS4215
4.25mm x 16mm	CS4216
4.25mm x 17mm	CS4217
4.25mm x 18mm	CS4218

Eminent Spine LLC Cervical Plate System

Eminent Spine LLC
2004 Ventura Drive STE 100
Plano, TX 75093

System Contents:
2

Non-Sterile Implants – Single Use Only
Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION:
The Eminent Spine LLC Cervical Plate system consists of selftapping screws and plates. Screws are offered in 4.0mm and 4.25mm diameters with overall lengths ranging from 12 to 16mm. One to fourlevel plates are offered in lengths ranging from 14mm (shortest onelevel) to 84mm (longest four-level).

INDICATIONS:
The Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2-C7) as an adjunct to fusion. These implants have been designed to provide stabilization for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumor, pseudarthrosis or failed previous fusion.

CONTRAINDICATIONS:
1. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to Titanium alloy 6Al-4V material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be noncompliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:
The implants and screws are manufactured from Titanium alloy 6Al4V material. Surgical instruments provided with the Cervical Plate System are manufactured from stainless steel.

CLEANING of INSTRUMENTS and IMPLANTS:
1. Clean all instruments and implants prior to use, and as soon as possible after use. Do not allow blood or debris to dry on the instruments that were used in surgery. If cleaning must be delayed, place instruments that were used in surgery in a covered container with neutral pH detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts. Remove implants (in caddies) from set cases.
3. Immerse the instruments and implants in a neutral pH detergent or enzymatic solution prepared in accordance with the manufacturer's instructions and soak for 15 minutes.
4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard-to-clean areas) until all visible soil has been removed.
5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hardto-clean areas.
6. After manual cleaning has been completed, load the parts into a suitable automated cleaner and follow the manufacturer's recommended practices. Use only neutral pH enzymatic cleaners and detergents. Avoid excessively acidic or alkaline solutions.

INSPECTION:
1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Eminent Spine® representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Eminent Spine® representative for a replacement.

STERILIZATION:
All implants and instruments are supplied visually clean and nonsterile and must be sterilized prior to use. The following is the recommended sterilization cycle:

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Number of pulses: 4
Dry time: 35 minutes

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged.

Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: A42013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79:A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging.

POSTOPERATIVE MOBILIZATION:
The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be used as a guide in the lifting of these restrictions.

WARNINGS:
Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.
1. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
2. Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine
3. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc. facets or bony stenosis). These conditions may be present at the index level or adjacent levels. Careful review of the clinical record including radiographic studies and applicable diagnostic tests should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and this should be discussed with the patient.
b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant.
d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
e) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used.
f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

PRECAUTIONS:
1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SPINAL SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. Based upon the fatigue 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.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. MIXED METALS. The Eminent Spine LLC Cervical Plate System is available in titanium alloy. It is imperative that this metal does not come into contact in vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.
5. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant
6. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is noncompliant with post-operative guidance is particularly at risk during the early postoperative period.
7. MAGNETIC RESONANCE ENVIRONMENT. The Eminent Spine® Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The Cervical Plate System has not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS:
1. Non-union, delayed union.
2. Bending or fracture of implant
3. Anterior or posterior migration of the implant
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.
10. Paralysis.
11. Death.

LIMITED WARRANTY:
Eminent 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. If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Eminent Spine LLC for current information.

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For product information or questions pertaining to sales and service, please contact your local sales representative or Eminent Spine LLC customer service.