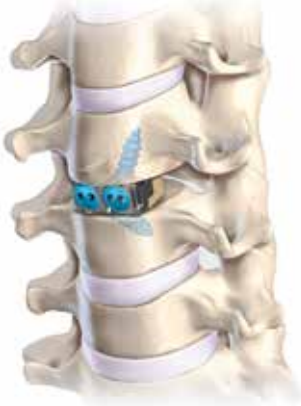
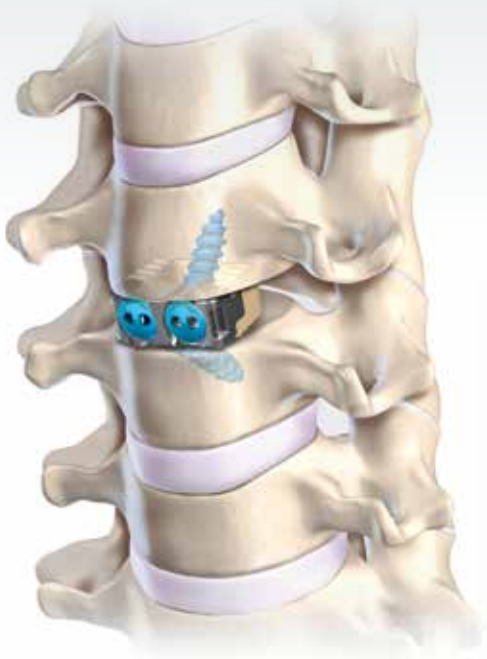
Alta™

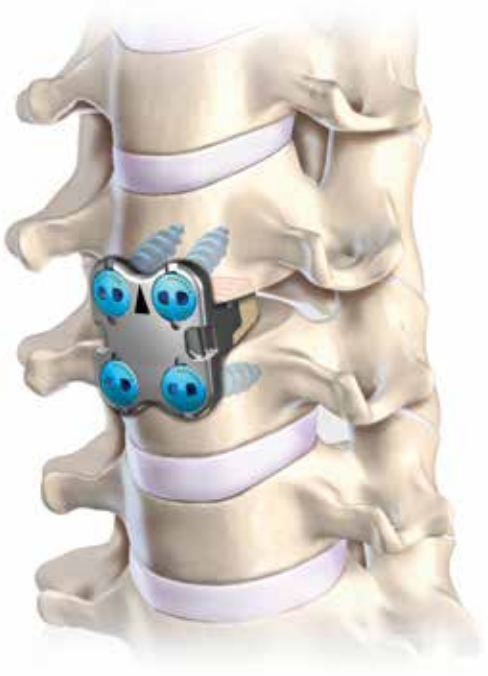
ACDF System

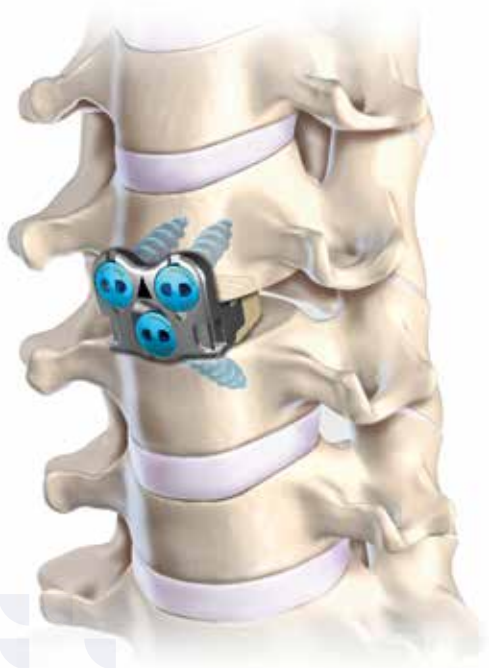
Surgical Technique Guide



ZimVie







A comprehensive system to address a continuum of fixation requirements and anatomic demands.

Table of Contents

ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

System Overview

Zero-Plate

The Zero-Plate construct sits entirely within the interbody space to minimize contact with the esophagus. The two screws that engage the vertebral endplates and the anti-rotation spikes provide adequate fixation while facilitating an efficient surgical procedure.

Half-Plate

The Half-Plate construct, with two low-angle screws and one central endplate screw, offers additional options to deal with challenging anatomy. For example, the implant can be positioned in the upper cervical region with the low-angle screws positioned inferiorly, which allows for straight instruments to be used while avoiding the chin. The central screw is conveniently placed in the midline of the implant to avoid potential obstructions.

Full-Plate

The Full-Plate construct offers four low-angle screws in the anterior cortex of the vertebral body. This option most closely approximates a standard anterior cervical plate system, while offering the convenience of a single construct for efficient implantation.

The Alta ACDF System is a cervical interbody implant intended to promote fusion in the cervical region of the spine (C3–T1). By combining the interbody and screws into one implant system, the Alta system performs the function of a PEEK–OPTIMA® LT1 cervical interbody spacer and an anterior cervical plate.

The Alta system is distinguished among cervical systems by offering a variety of plate options to give the surgeon flexibility to accommodate varying anatomic and surgical requirements.

Each screw is prevented from backing out by a locking cap that provides an audible, tactile and visual confirmation that it is locked, resulting in a secure locking mechanism.

Other features of the Alta system include two footprint options with a full range of heights for a precise anatomical fit, very large graft windows for maximum fusion area and multiple technique options with intuitive instrumentation to seamlessly address a variety of clinical requirements.

Preparation and Access

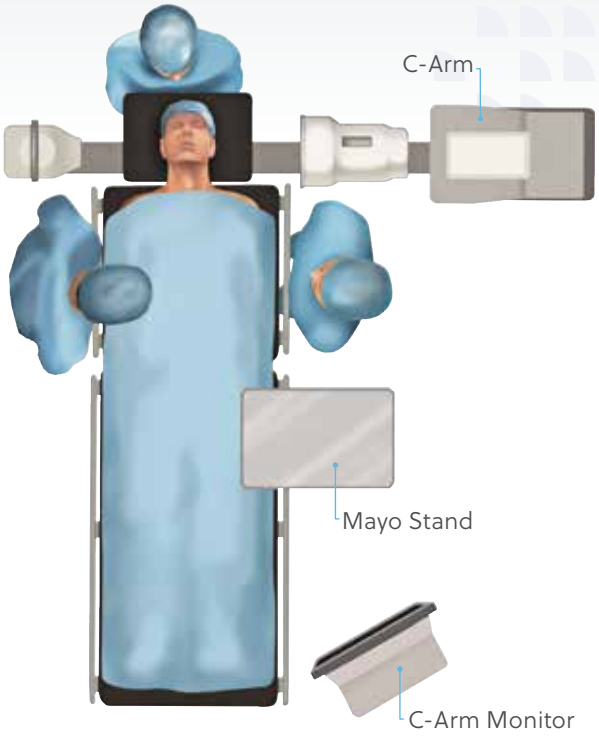


Figure *1*
Patient positioning

- Review and inspect all instrumentation and implants prior to sterilization.
- Replace or add any necessary components for the planned surgery.
- Surgeon must be fully experienced with the required spinal fusion techniques.

STEP 1

- Position and drape the patient in the usual fashion **(Figure 1)**.
- Expose the affected levels via a standard incision and tissue dissection.
- Place any retraction pins in locations that will allow for the planned implant and instrumentation.
- Perform any necessary bone and tissue removal.
- Prepare vertebral endplates via the use of a combination of curettes, rasps, osteotomes, disc shavers or rongeurs to remove disc material and cartilage.

Implant Selection and Assembly

Figure 2
Trialing

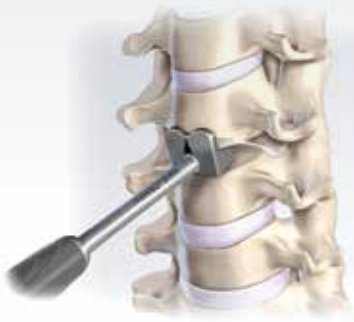


Figure 3a

Figure 3b

Figure 3c

Figure 3
Half-plate and full-plate trialing

STEP 2

- Insert the trials into the disc space to determine the size of the desired implant, starting with the smallest footprint and height of the trial, and progressing to larger and taller sizes as needed **(Figure 2)**.

- The Alta Half-Plate and Full-Plate implants are designed to precisely fit the anatomy of the cervical spine. The Half-Plate is available in a Cranial version and a Caudal version. The Half-Plate and Full-Plate implants are marked by an arrow head "▲" indicating the cranial direction, which is duplicated on the corresponding trials.
- Use the Half-Plate or Full-Plate trial to assess the fit of the plate against the anterior of the vertebral bodies and determine the degree of osteophyte removal necessary **(Figure 3a, 3b, 3c)**.

Note: *Half-Plate and Full-Plate trials are available in 15x13 mm footprints only. Implants are available in 15x13 mm and 17x14 mm footprints.*

Figure 4a
Implant assembly

Align plate to peek

Figure 4b

Figure 4c

Figure 4d

Final assembly

STEP 3

- Select the appropriate PEEK-OPTIMA® LT1 interbody spacer (footprint and height) and the plate type (Zero-Plate, Half-Plate Cranial, Half-Plate Caudal or Full-Plate) of the same height.
- Assemble the plate to the interbody spacer by first matching the tabs on the plate to the recesses on the spacer **(Figure 4a, 4b)**.
- Then insert the interbody spacer and plate into the assembly tool and compress the plate onto the spacer firmly until they are engaged **(Figure 4c, 4d)**. Ensure the plate and spacer are fully seated (no gap).

Precaution: *If the plate and interbody spacer are disassembled, they must be discarded and new components must be used to create a new assembly.*

Note: *It is recommended to pack the central graft cavity of the assembled implant with autogenous bone graft prior to implantation.*

Implant Insertion

For Zero-Plates, use Method A or Method B for inserting the implant and preparing and inserting the screws. For Half-Plates and Full-Plates, use only Method A.

Method A: Freehand Technique uses a tamp-style inserter to insert the implant and freehand instruments to prepare and insert the screws (pages 8–11).

Method B: Drill Guide Technique uses double-barreled fixed drill guides to insert the implant into the intervertebral disc space, and to prepare and insert the screws (pages 12–14).

Method A: Freehand Screw Insertion Technique

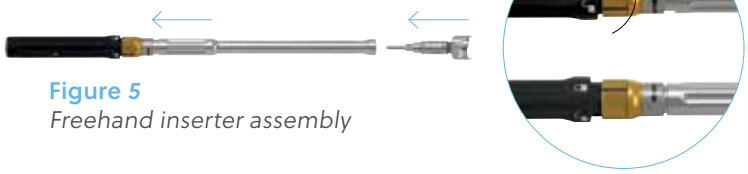


Figure 5
Freehand inserter assembly

Figure 6a
Loading implant

Figure 6b

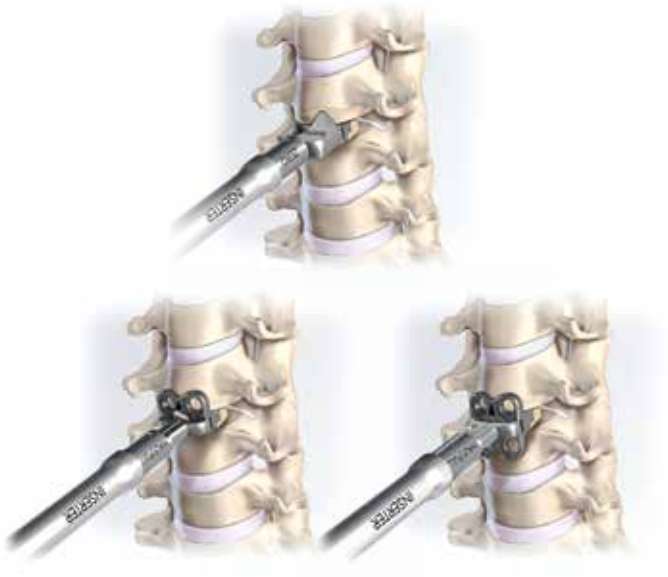


Figure 7
Freehand implant insertion

STEP 4A

- Select either the Zero-Plate freehand tip with stop, Zero-Plate freehand tip with no stop or Half-Plate and Full-Plate inserter tip, and assemble it to the inserter handle by pulling back on the sleeve, inserting the tip until fully seated, and releasing the outer sleeve.
- Turn the gold collar to the lock position to ensure the tip does not disengage from the inserter handle **(Figure 5)**.
- Load the implant onto the inserter and secure by turning the black handle in a clockwise direction until tight. **(Figure 6a, 6b)**.

STEP 5A

- Insert the assembled implant into the disc space **(Figure 7)**. Radiographically confirm the position and placement of the implant.

Note: *The edges of the radiographic markers are approximately 0.5 mm from the posterior edge of the implant.*

Note: *For the Zero-Plate, the inserter may be left in place during screw insertion to maintain anterior placement of the implant.*

Figure *8*
Freehand awl/drill selection

Figure 10
Angled driver assembly

STEP 6A

- Select the awl or drill, in straight or angled configuration, with a fixed or variable self-centering sleeve.
- Select the fixed angle sleeve (silver) to place the screw in the nominal trajectory or variable angle sleeve (gold) to aim the screw in an alternate trajectory **(Figure 8)**. Fixed angle screws must be prepared using a fixed angle sleeve. Variable angle screws may be prepared using either fixed angle or variable angle sleeves, which allow for an additional 6° of angulation in any direction.

Note: *The fixed or variable sleeve must be manually extended over the tip of the awl or drill prior to each insertion into the plate.*

- The optional freehand awl does not have a self-centering sleeve. If the freehand awl is selected, care must be taken to insert it in the center of the screw hole at an appropriate orientation.

The angled driver is used to drive the angled awl or drill tips, as well as the angled screw driver tips. To assemble the angled driver, attach the AO handle to the shaft, then loosen the threaded cap (gold) until it slides freely. Retract the shaft slightly and insert a drill/awl or driver tip through the hole on the elbow of the sleeve. Reposition the shaft and assemble the threaded cap until fully seated **(Figure 9a,9b,9c)**. Ensure the shaft and tip can rotate freely within the sleeve.

The optional side handle can be assembled to the angled driver by positioning it over the distal end of the sleeve, pulling back the trigger (gold) and sliding the side handle proximally until it stops. The orientation of the side handle can be adjusted by pulling back on the trigger and rotating the handle into position **(Figure 10a,10b)**.

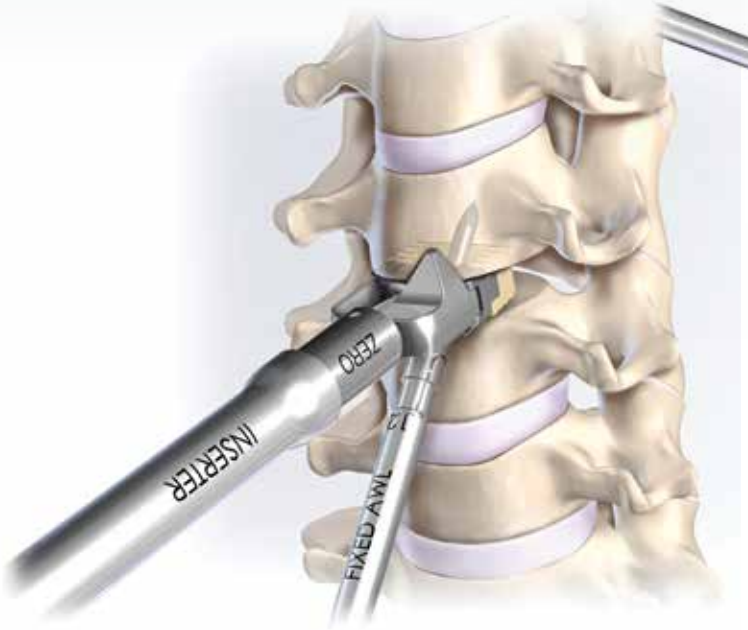


Figure *11*
Freehand awl/dril insertion

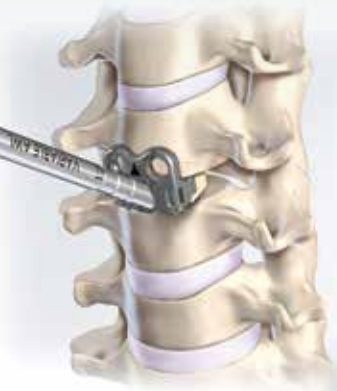


Figure *12a*
Half-plate screw preparation

Figure *12b*
Full-plate screw preparation

STEP 7A

- Insert the tip of the awl or drill into the screw pocket on the plate and then insert the awl or drill into the bone until the stop is reached **(Figure 11)**.
- The inserter handle must be removed prior to preparing the screws for the Half-Plate or Full-Plate **(Figure 12a,12b)**.
- For the Half-Plate, start by preparing and fully inserting the center screw of the Half-Plate in order to lag the implant against the anterior cortex prior to inserting the screws on the flange.

Figure *13*
Freehand screw insertion

STEP 8A

- Load the appropriate length and type of screw (see page 23) onto the straight screw driver or angled screw driver. A diagram of the screw lengths is provided on page 18.

Note: *Short driver tip should only be used if inserter has been removed prior to screw insertion.*

- Insert the screw into the prepared screw hole **(Figure 13)**.

Note: *Fixed angle screws can only be used when the bone is prepared using fixed angle self-centering sleeves.*

Figure 14
Freehand inserter removal

STEP 9A

- Remove the inserter by turning the black handle in a counterclockwise direction until the implant is fully released **(Figure 14)**.

Continue to Step 10 on page 15.

Method B: Drill Guide Screw Insertion Technique

Continued from page 7 after Step 3.

Figure *15a*

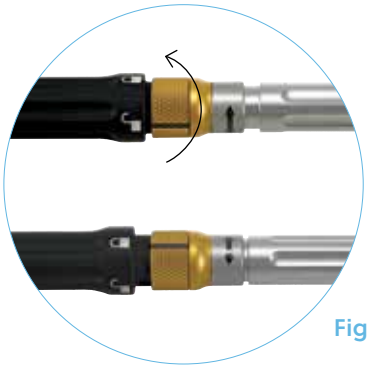


Figure *15b*

Figure *15*
Drill guide assembly

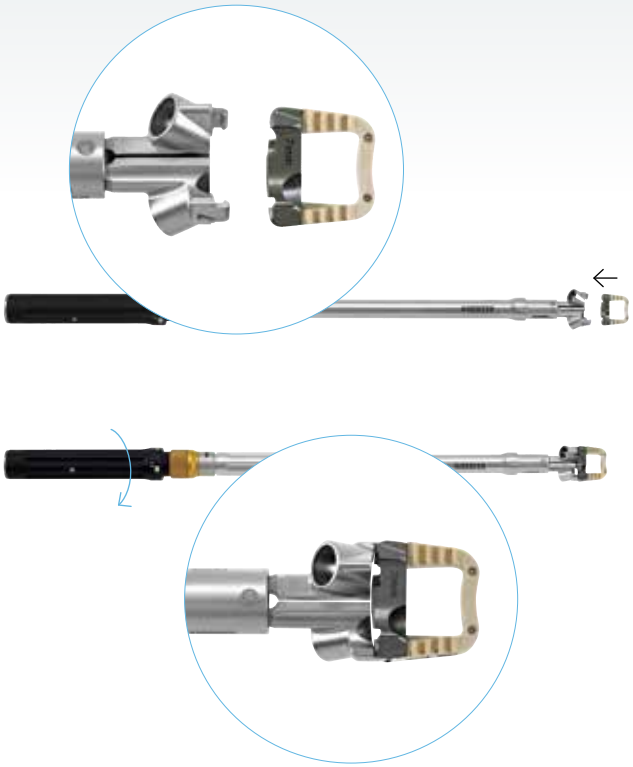


Figure *16*
Inserter attachment

STEP 4A

- Assemble the appropriate height drill guide tip to the inserter handle by pulling back on the sleeve, inserting the drill guide until fully seated and releasing the outer sleeve **(Figure 15a)**.
- Turn the gold collar to the lock position to ensure the tip does not disengage from the inserter handle **(Figure 15b)**.
- Load the implant onto the inserter and secure by turning the black handle in a clockwise direction until tight **(figure 16)**.

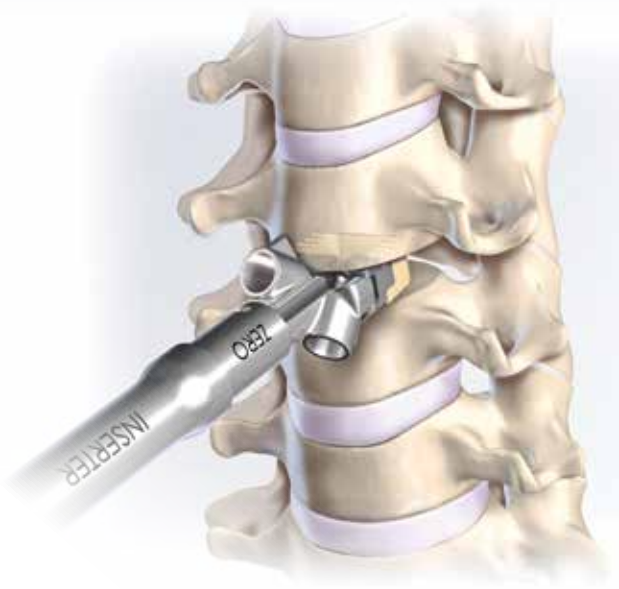


Figure *17*
Drill guide implant insertion

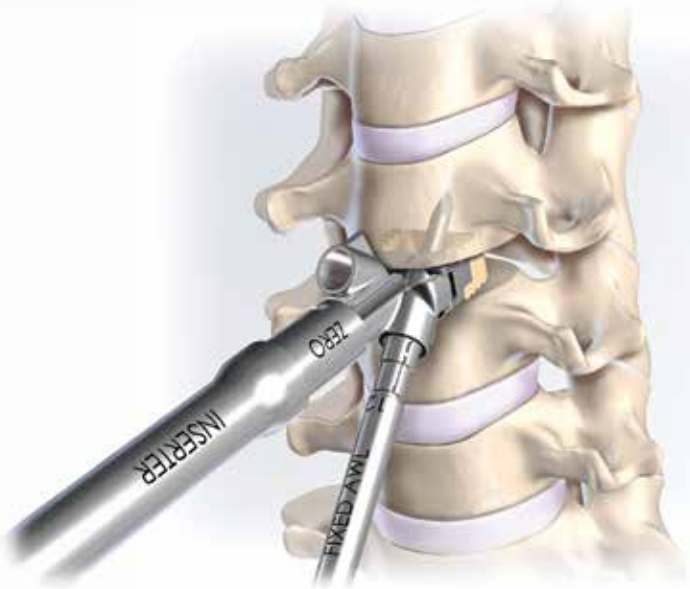


Figure *18*
Drill guide awl/drill insertion

STEP 5B

- Insert the assembled implant into the disc space **(Figure 17)**. Radiographically confirm the position and placement of the implant.

Note: *The edges of the radiographic markers are approximately 0.5mm from the posterior edge of the implant (see page 22).*

STEP 6B

- Select the awl or drill, in straight or angled configuration, with the fixed angle sleeve (see page 9 for angled driver assembly).

Note: *The fixed sleeve must be manually extended over the tip of the awl or drill prior to each insertion into the guide.*

- Sequentially insert the awl or drill into both barrels of the drill guide until the stop is reached **(Figure 18)**.

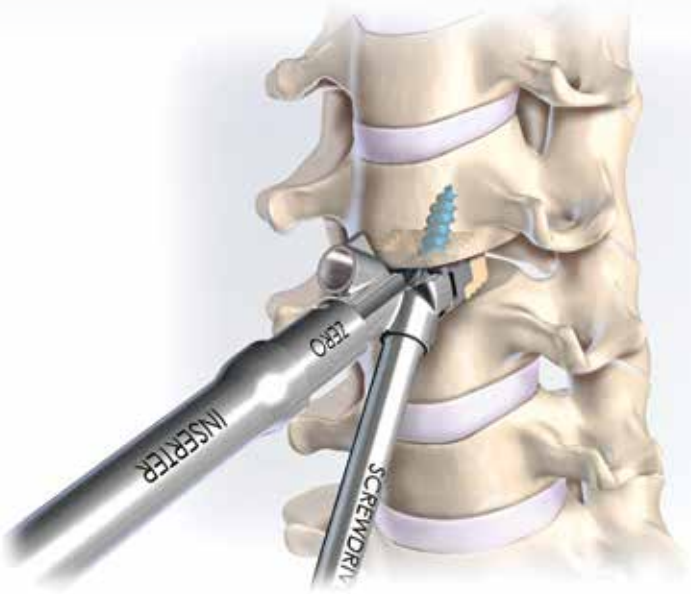


Figure *19*
Drill guide screw insertion

Figure *20*
Drill guide removal

STEP 7A

Drill Guide Screw Insertion

- Load the appropriate length and type of screw (see page 23) onto the straight screw driver or angled screw driver (see page 9 for angled driver assembly). A diagram of the screw lengths is provided on page 18.
- The longer driver tip should be used through the drill guide.
- Insert the screw through the drill guide tip into the prepared screw hole. A line on the screw driver indicates approximately when the screw has reached the full depth, but the final screw depth should be determined by the bony purchase **(Figure 19)**.

STEP 8A

- Remove the drill guide by turning the black handle in a counterclockwise direction until the implant is fully released **(Figure 20)**.

Securing the Locking Caps Into the Alta Plate

For all plate configurations, a locking cap is used over each screw head to prevent the screw from backing out.
Caution: *Locking caps are single-use and must not be reused after locking into the plate assembly.*

Figure 21
Locking cap inserter assembly

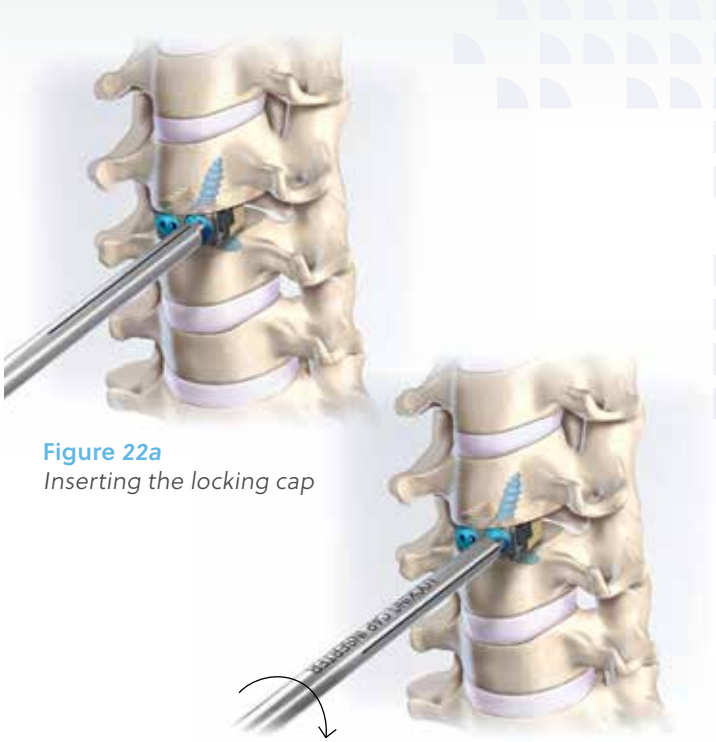


Figure 22a
Inserting the locking cap

Figure 22b

STEP 9

- Assemble the locking cap inserter by sliding the outer sleeve over the inner shaft.

  To load a locking cap, slide the sleeve of the locking cap inserter towards the handle to the unlock position, then insert the tips of the locking cap inserter through the holes of the locking cap, and finally slide the locking cap inserter sleeve downwards until resistance is felt. The tip of the sleeve will not touch the locking cap **(Figure 21)**.

Note: *High angle locking caps are available in the caddy if the standard locking cap does not fit over the screw head.*

STEP 10

- Insert the locking cap into the plate with the locking cap tabs and the line on the inserter oriented in the direction of the cut-outs on the plate **(Figure 22a)**.
- Rotate the locking cap clockwise until the line on the inserter is approximately 60° from cranial-caudal. A tactile "click" should be felt as the cap locks into position **(Figure 22b)**. Do not turn beyond this "click."

Removing the Locking Cap Inserter

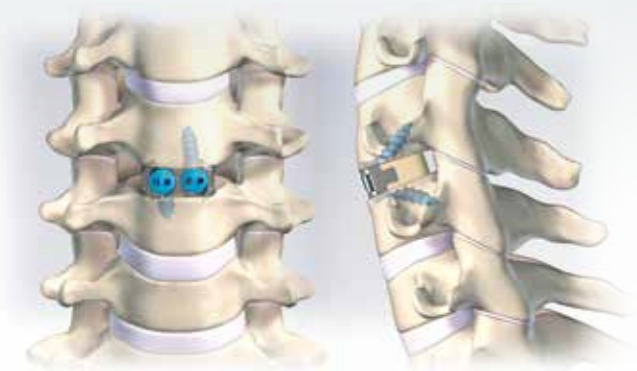
- Slide the sleeve of the locking cap inserter upward towards the handle to disengage the locking cap inserter from the locking cap.

Figure 23
Inspect the locking cap

STEP 11

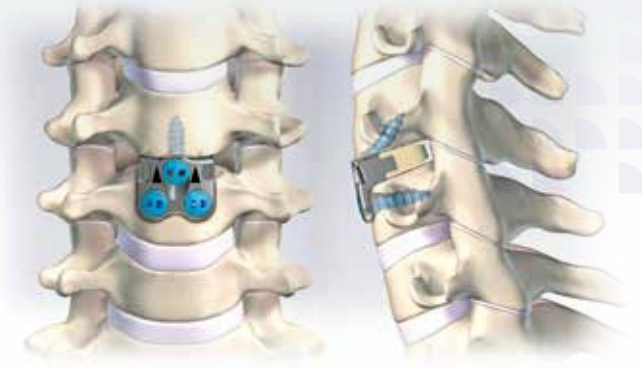
- Visually confirm that the locking caps are in their final secured position by verifying the two holes in the locking caps are horizontal to the body axis. Additionally, confirm that the locking cap tabs are NOT visible. The caps are free to wiggle slightly. **(Figure 23)**.

Final Implant Position



Zero-Plate

Figure 24



Half-Plate Caudal

Figure 25

Half-Plate Cranial

Figure 26

Full-Plate

Figure 27

STEP 12

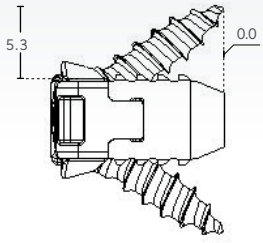
- Inspect final implant for correct position and assembly. **(Zero-Plate: Figure 24; Half-Plate Caudal: Figure 25; Half-Plate Cranial: Figure 26; Full-Plate: Figure 27)**.
- Close the fascia and skin incision in the usual manner.

Removing the Alta Implant (If Necessary)

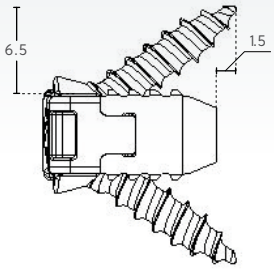
- Remove the locking caps with the locking cap inserter by inserting the tip into the caps, sliding the sleeve down and turning the caps 60° counterclockwise.
- Remove all screws using the straight screw driver or angled screw driver.
- Attach the inserter tip to the inserter handle, and tighten to the plate by turning the black handle in a clockwise direction **(Refer to page 8, Figures 6a and 6b)**.
- Pull the inserter until the implant is removed from the disc space.

Alta Screws Length Diagrams

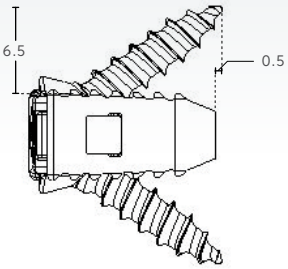
Zero-Plate



Small Spacer (15x13 mm)
12 mm Screw

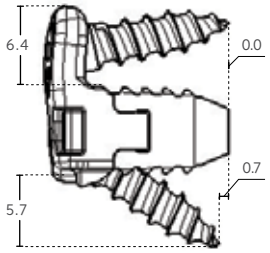


Small Spacer (15x13 mm)
14 mm Screw

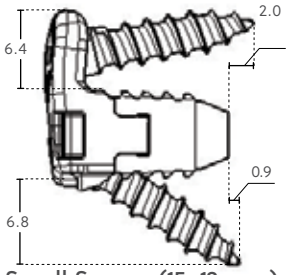


Large Spacer (17x14mm)
14 mm Screw

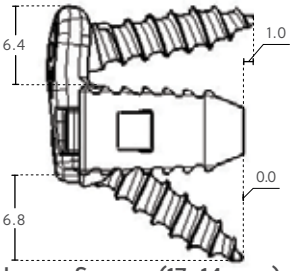
Half-Plate Cranial



Small Spacer (15x13 mm)
12 mm Screw

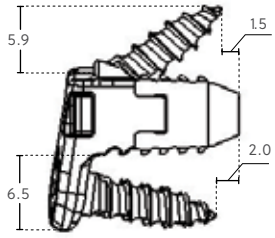


Small Spacer (15x13 mm)
14 mm Screw



Large Spacer (17x14 mm)
14 mm Screw

Half-Plate Caudal



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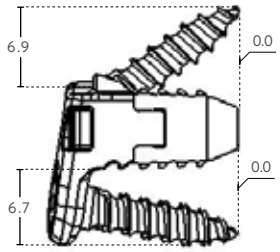
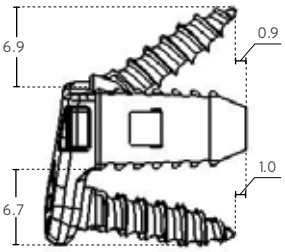


Small Spacer (15x13 mm)
14 mm Screw



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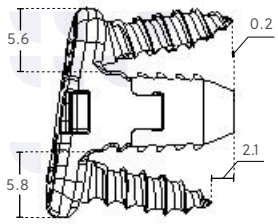
14 mm Screw

Full-Plate



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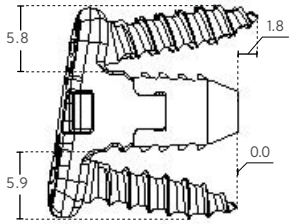
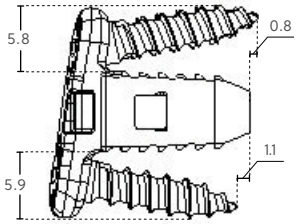


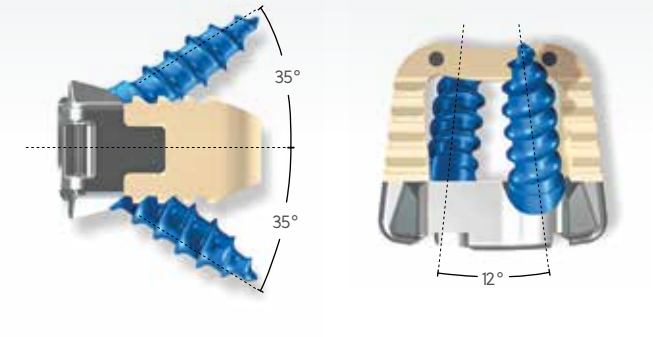
Small Spacer (15x13 mm)
14 mm Screw



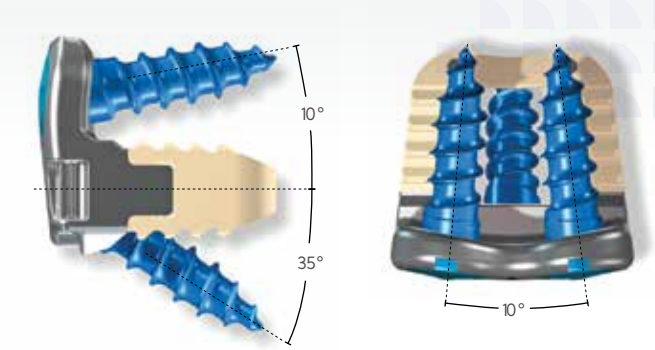
Large Spacer (17x14 mm)
14 mm Screw

Alta Screws Angle Diagrams

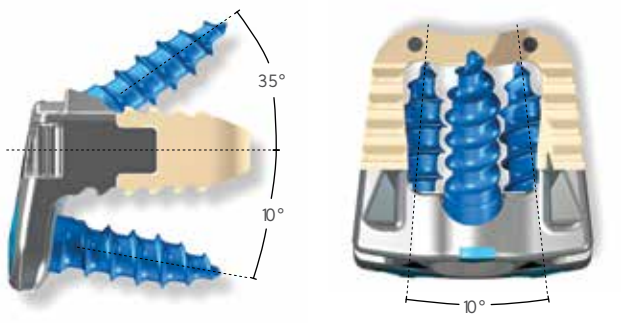
Zero-Plate



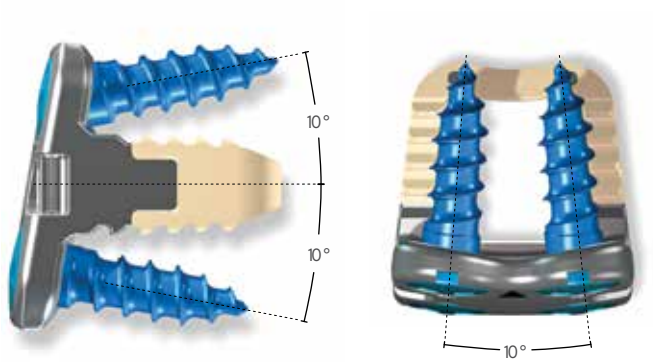
Half-Plate Cranial



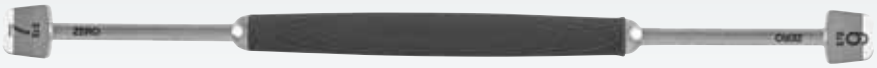
Half-Plate Caudal



Full-Plate



Alta Instruments and Implants



Zero-Plate 15x13	PART NUMBER
6 & 7 mm, 0°	8438-0006
6 & 7 mm, 5°	8438-0506
8 & 9 mm, 0°	8438-0008
8 & 9 mm, 5°	8438-0508
10 & 11 mm, 0°	8438-0010
10 & 11 mm, 5°	8438-0510

Zero-Plate 17x14	PART NUMBER
6 & 7 mm, 0°	8439-0006
6 & 7 mm, 5°	8439-0506
8 & 9 mm, 0°	8439-0008
8 & 9 mm, 5°	8439-0508
10 & 11 mm, 0°	8439-0010
10 & 11 mm, 5°	8439-0510

Half-Plate Cranial 15x13	PART NUMBER
6 & 7 mm, 0°	8438-1006
6 & 7 mm, 5°	8438-1506
8 & 9 mm, 0°	8438-1008
8 & 9 mm, 5°	8438-1508
10 & 11 mm, 0°	8438-1010
10 & 11 mm, 5°	8438-1510

Half-Plate Caudal 15x13	PART NUMBER
6 & 7 mm, 0°	8438-2006
6 & 7 mm, 5°	8438-2506
8 & 9 mm, 0°	8438-2008
8 & 9 mm, 5°	8438-2508
10 & 11 mm, 0°	8438-2010
10 & 11 mm, 5°	8438-2510

Full-Plate 15x13	PART NUMBER
6 & 7 mm, 0°	8438-3006
6 & 7 mm, 5°	8438-3506
8 & 9 mm, 0°	8438-3008
8 & 9 mm, 5°	8438-3508
10 & 11 mm, 0°	8438-3010
10 & 11 mm, 5°	8438-3510

Assembly Tool	PART NUMBER
	8434-1000

Inserter Handle	PART NUMBER
	8431-1400

Tamp	PART NUMBER
	8435-0002

Locking Cap Inserter	PART NUMBER
	8431-1100

Zero-Plate Guide Tip	PART NUMBER
6 mm	8434-1406
7 mm	8434-1407
8 mm	8434-1408
9 mm	8434-1409
10 mm	8434-1410
11 mm	8434-1411

Zero-Plate Freehand Tip with Stop	PART NUMBER
	8431-1403

Zero-Plate Freehand Tip No Stop	PART NUMBER
	8431-1401

Half-Plate and Full Plate Inserter Tip	PART NUMBER
	8431-1404

Alta Instruments and Implants (continued)

Straight Awl Variable Tip	PART NUMBER
12 mm	8430-1102

Straight Awl Fixed Tip	PART NUMBER
12 mm	8430-1202

Freehand Awl	PART NUMBER
12 mm	8430-1402

Straight Screw Driver	PART NUMBER
	8430-1101

Straight Drill - Variable	PART NUMBER
10 mm	8430-1110
12 mm	8430-1112
14 mm	8430-1114
16 mm	8430-1116
18 mm	8430-1118

Straight Drill - Fixed	PART NUMBER
10 mm	8430-1210
12 mm	8430-1212
14 mm	8430-1214
16 mm	8430-1216
18 mm	8430-1218

Angled Driver	PART NUMBER
	8430-1000

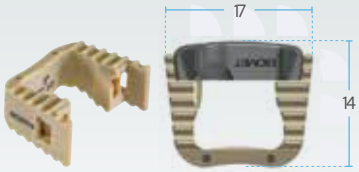
Angled Driver Side Handle	PART NUMBER
	8430-1006

Angled Awl Tips 12mm	PART NUMBER
Variable	8430-1002
Fixed	8430-1003

Angled Screw Driver Tips	PART NUMBER
Long	8430-1004
Short	8430-1005

Angled Drill Tips - Variable	PART NUMBER
10 mm	8430-0110
12 mm	8430-0112
14 mm	8430-0114
16 mm	8430-0116
18 mm	8430-0118

Angled Drill Tips- Fixed	PART NUMBER
10 mm	8430-0210
12 mm	8430-0212
14 mm	8430-0214
16 mm	8430-0216
18 mm	8430-0218



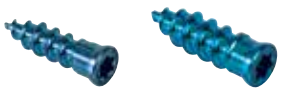
Straight Tap	PART NUMBER
12 mm	8435-1235

AO Handle	PART NUMBER
12 mm	9801-0173

Angled Tap Tip	PART NUMBER
12 mm	8434-1235

Locking Caps	PART NUMBER
Standard	8405-1000
High Angle	8405-1203

Self-Drilling Screws - Fixed	Standard (3.5 mm)	Rescue (4.0 mm)
12 mm	8425-3512	8424-4012
14 mm	8425-3514	8424-4014
16 mm	8425-3516	8424-4016
18 mm	8425-3518	8424-4018



Self-Drilling Screws - Variable	Standard (3.5 mm)	Rescue (4.0 mm)
12 mm	8425-3512	8424-4012
14 mm	8425-3514	8424-4014
16 mm	8425-3516	8424-4016
18 mm	8425-3518	8424-4018

Plates	Zero-Plate	Half-Plate Cranial	Half-Plate Caudal	Full-Plate
6 mm	8409-0006	8409-1106	8409-2106	8409-1206
7 mm	8409-0007	8409-1107	8409-2107	8409-1207
8 mm	8409-0008	8409-1108	8409-2108	8409-1208
9 mm	8409-0009	8409-1109	8409-2109	8409-1209
10 mm	8409-0010	8409-1110	8409-2110	8409-1210
11 mm	8409-0011	8409-1111	8409-2111	8409-1211

Self-Tapping Screws - Fixed	Standard (3.5 mm)	Rescue (4.0 mm)
12 mm	8424-3512	8424-4012
14 mm	8424-3514	8424-4014
16 mm	8424-3516	8424-4016
18 mm	8424-3518	8424-4018

Self-Tapping Screws - Variable	Standard (3.5 mm)	Rescue (4.0 mm)
12 mm	8426-3512	8426-4012
14 mm	8426-3514	8426-4014
16 mm	8426-3516	8426-4016
18 mm	8426-3518	8426-4018

Graft Volumes

Graft Volume - Small (15x13 mm), 5° Lordosis*

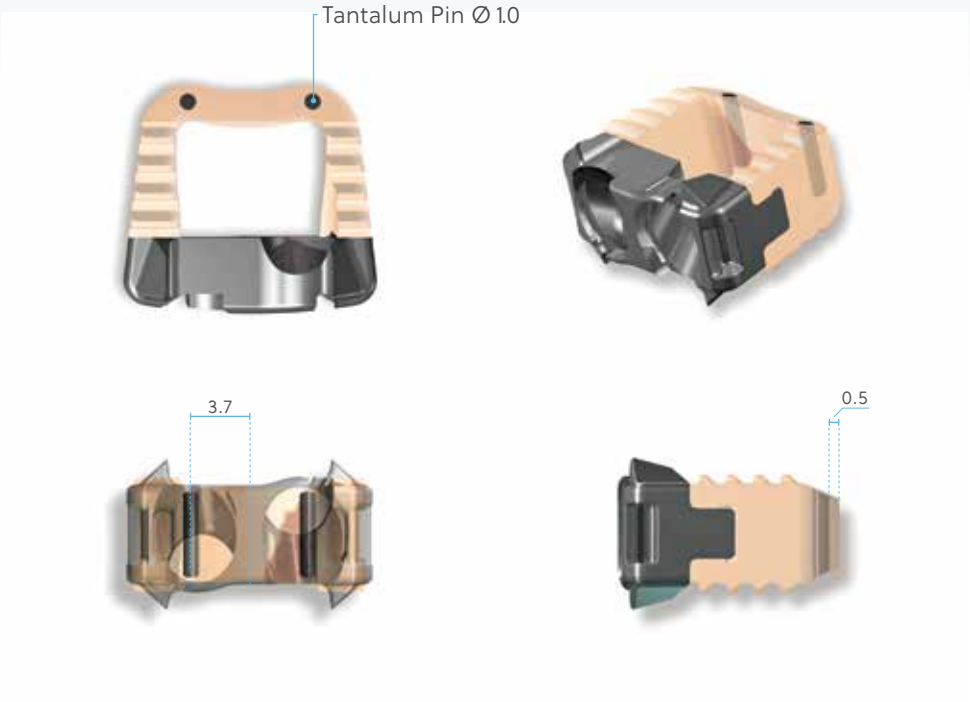
Plates	Zero-Plate	Half-Plate Cranial	Half-Plate Caudal	Full-Plate
6 mm	0.34cc	0.38cc	0.42cc	0.47cc
7 mm	0.40cc	0.45cc	0.49cc	0.55cc
8 mm	0.46cc	0.51cc	0.56cc	0.62cc
9 mm	0.52cc	0.58cc	0.63cc	0.70cc
10 mm	0.58cc	0.64cc	0.70cc	0.78cc
11 mm	0.64cc	0.71cc	0.77cc	0.86cc

Graft Volume - Large (17x14 mm), 5° Lordosis*

Plates	Zero-Plate	Half-Plate Cranial	Half-Plate Caudal	Full-Plate
6 mm	0.42cc	0.46cc	0.49cc	0.54cc
7 mm	0.49cc	0.54cc	0.58cc	0.63cc
8 mm	0.56cc	0.62cc	0.66cc	0.73cc
9 mm	0.64cc	0.70cc	0.74cc	0.82cc
10 mm	0.71cc	0.77cc	0.83cc	0.91cc
11 mm	0.64cc	0.85cc	0.91cc	1.01cc

* For 0° Parallel, add 0.02cc.

Alta Marker Placement



Important information on the Alta ACDF System

Device Description

The Alta System device is a cervical interbody fusion device consisting of a PEEK-OPTIMA LT1® intervertebral spacer, titanium plate and screws. The PEEK spacer has a generally rounded shape with various heights and footprints and has a central cavity to accommodate autogenous bone graft. The upper and lower surfaces have a series of transverse grooves formed to improve stability and fixation once the device is inserted. The titanium plate has holes for receiving bone screws and features to assemble locking caps to prevent screw back-out. The Alta system is available in a variety of sizes and configurations to approximate anatomical variation in different vertebral levels and/or patient anatomy. The Alta system is provided non-sterile.

Indications For Use

The Alta system is a stand-alone cervical fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3–T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The Alta device is to be filled with autogenous bone graft material, and is to be used with titanium alloy screws which accompany the implant.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

- Allergy to PEEK, titanium or cobalt chrome alloys, or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- Known or suspected infection/immune system incompetence. Acute or chronic infectious diseases of any etiology or localization.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site, or certain metabolic disorders affecting osteogenesis.
- Morbid Obesity. An overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or failure of the device itself.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Open Wounds.
- Pregnancy.
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood cell (WBC) count or a marked left shift in the WBC differential count.
- Any case requiring the mixing of components from two different systems.
- Any case requiring the mixture of stainless steel with titanium or stainless steel with cobalt chrome implant components.
- Fever or leukocytosis.
- Signs of local infection or inflammation.
- Previous history of infection.
- Prior fusion at the level to be treated.
- Alcoholism or heavy smoking.
- Senility, mental illness or substance abuse, of a severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Any patient unwilling to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.

Possible Complications

Possible complications specific to the device may include:

- Early or late implant bending, breakage, failure, loosening or movement/migration.
- Bone fracture.
- Allergic reaction to implant material.

Other general complications associated with any spinal surgical procedure may include: Non-union or delayed union, pseudarthrosis; pain; second surgery; bleeding; infection, early and late; tissue or nerve damage, including dural tears or other neurological problems; incisional complications; scar formation; damage to blood vessels and cardiovascular system compromise; changes in mental status; damage to internal organs and connective tissue; complications due to the use of bone grafting, including graft donor site complications; respiratory problems; reactions to anesthesia and/or death.

Warnings

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes than previous surgical outcomes. The risk of a device expulsion and migration is higher without the use of integrated fixation screws as indicated.

Precautions

- The Alta implants are for single use only. Never reuse any implant even if it appears unmarked or undamaged. Reuse of the implant components may result in reduced mechanical performance, malfunction or failure of the device. Any

implant implanted and then removed must be discarded. Use only new implants for each case.

- Only experienced spinal surgeons should perform the implantation of this system with specific training in the use of vertebral implants. The surgical procedure is technically demanding and presents a risk of serious injury to the patient.
- The Alta system is intended to be used only by surgeons specialized in spinal surgery and having thorough knowledge of vertebral anatomy, regional vertebral morphology, and the biomechanical principles of the spine. It is advised that the surgeon also be thoroughly familiar with the surgical techniques relative to the use of the device.
- Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
- Risks associated with neurosurgery, general surgery, orthopedic surgery and the use of general anesthesia should be explained to the patient prior to surgery. It is recommended that the advantages and disadvantages of using implants, as well as alternative treatment methods, are explained to the patient.
- Preoperatively: The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product, which is available from the manufacturer. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the postoperative period. An appropriate range of implant sizes must be available at the time of the operation.
- Intraoperatively: The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important.
- Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implants. The implant can be removed after bony healing.
- Correct selection and placement of the implants is extremely important. Implant selection must be based upon the bone defect to be treated as well as the patient's weight, height, occupation or degree of physical activity.
- Proper handling of the implant before and during the operation is crucial.
- Use of the locking caps to prevent back-out of the screws is mandatory.
- If a locking cap is disassembled from a plate, it must be discarded and not reused.
- If a plate is disassembled from a PEEK interbody implant, it must be discarded and not reused.
- The Alta device must not be used with vertebral components or instruments from other manufacturers.
- Before use, inspect all instrumentation for possible damage, wear, or non-function. Damaged or defective instruments should not be used or processed. Contact your local ZimVie Spine representative or dealer for repair or replacement.
- The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments.
- Do not apply excessive force or stress. Misuse can damage instruments or implants.
- Perform a careful preoperative review to be sure that all necessary implant components are available and that the instrument set is complete and in working order prior to initiating surgery.
- The Alta system has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The Alta system has not been tested for heating or migration in the MR environment.
- Mixing of dissimilar metals can accelerate or initiate the corrosion process. Titanium components must NOT be used together in building a construct that involves other implant materials. Titanium and cobalt chrome may be used together within the same construct.

For more information, visit ZimVie.com

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ZimVie.com

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