CoreLink
The Source for Spine™

ZOU® ANTERIOR LUMBAR PLATE SYSTEM

Surgical Technique Guide

ZOU ANTERIOR LUMBAR PLATE SYSTEM

The **Zou Anterior Lumbar Plate System** is a comprehensive solution with a low profile, anterior, intradiscal plate designed to reduce the risk of vascular vessel disruption.

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SYSTEM OVERVIEW

INTRODUCTION

The Zou Anterior Lumbar Plate System is comprised of a lumbar plate and screws. The lumbar plate has a rotatable anti-back-out "lock" for each screw position to prevent back-out of the screw. When used in conjunction with the Torque-limiting Handle, the patented anti-back-out mechanism provides visual, tactile, and audible confirmation.

FEATURES

- Low profile, intradiscal plate reduces impingement on adjacent tissues
- Simple and effective anti-back-out locking mechanism
- Optimal screw trajectory is 18 degrees in the sagittal plane and 10 degrees lateral in the axial plane
- Can be used anteriorly as well as obliquely

OPTIONS

LENGTHS: 15MM - 25MM
(2MM INCREMENTS)

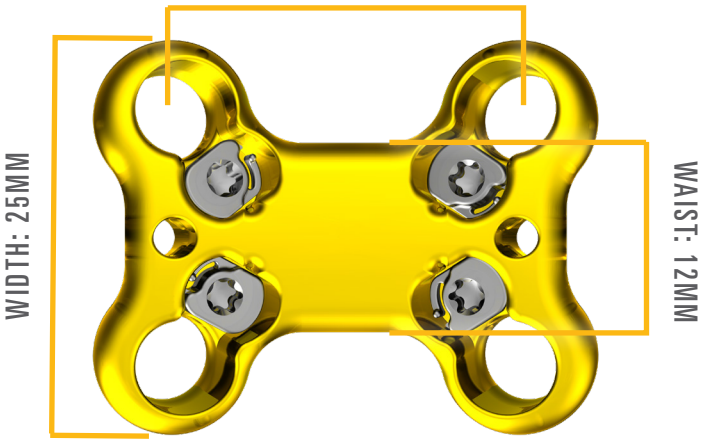


PLATE PROFILE
(4.5MM TO 5.8MM THICK)

MATERIAL: TI-6AL-4V ELI CONFORMING TO ASTM F136

NOTE: FOR ADDITIONAL SIZE OFFERINGS CONTACT CORELINK CUSTOMER SERVICE

SYSTEM OVERVIEW (CONTINUED)

SCREW DIAMETERS

The screws are available in a variety of lengths (21mm, 24mm, 28mm, 32mm, and 36mm) and are color coded by length for easy identification.

The screws have a major diameter of 5.5mm.

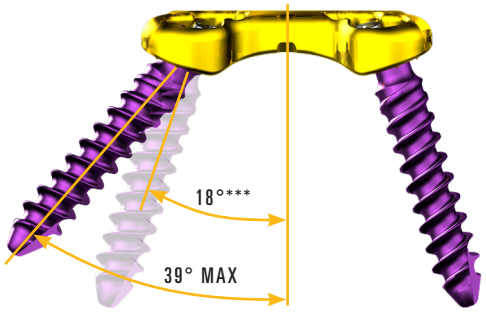
Standard screws are self-tapping*.

21MM** GOLD | 24MM PURPLE | 28MM GREEN | 32MM MAGENTA | 36MM** BLUE

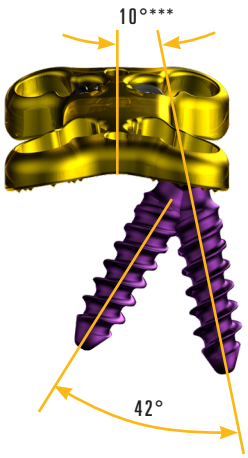
SCREW ANGULATION

Variable angle screws allow for screw hole placement up to 39 degrees sagittal and 42 degrees medial. The preferred screw trajectories are 18 degrees sagittal and 10 degrees lateral.

SAGITTAL VIEW



AXIAL VIEW



*Self-drilling/self-tapping screws are available upon request
**Screw lengths are available upon request
***18° and 10° are preferred angles, respectively

PATIENT POSITIONING AND APPROACH

After the induction of general anesthesia, the patient is positioned supine and the operative site is prepared and draped in the usual fashion. Standard dissection techniques are used to expose the appropriate level for fusion.

The disc space is prepared, and a bone graft or an interbody fusion device is inserted into the disc space. The vertebral bodies are then prepared for the plate by removing any anterior osteophytes and hypertrophic soft tissue. In some cases it may be advantageous to shave away some of the anterior cortical rim bone to facilitate better contact between the bone and the angled portions of the bottom of the plate.

PLATE SELECTION

Use the Plate Trials to determine the appropriate implant size. For optimal purchase, the screw holes should be positioned directly over the bone of the cortical rim. A plate that is too long will have screw holes that extend past the respective cortical rims. If the screw holes are visually not at least half filled by the cortical rim bone of each vertebral body, the plate is too small.

The plate is offered in lengths from 15mm to 25mm in 2mm increments. The plate length description denotes the distance from the center of the cephalad holes to the center of the caudal holes.

ANTERIOR LUMBAR SPINE

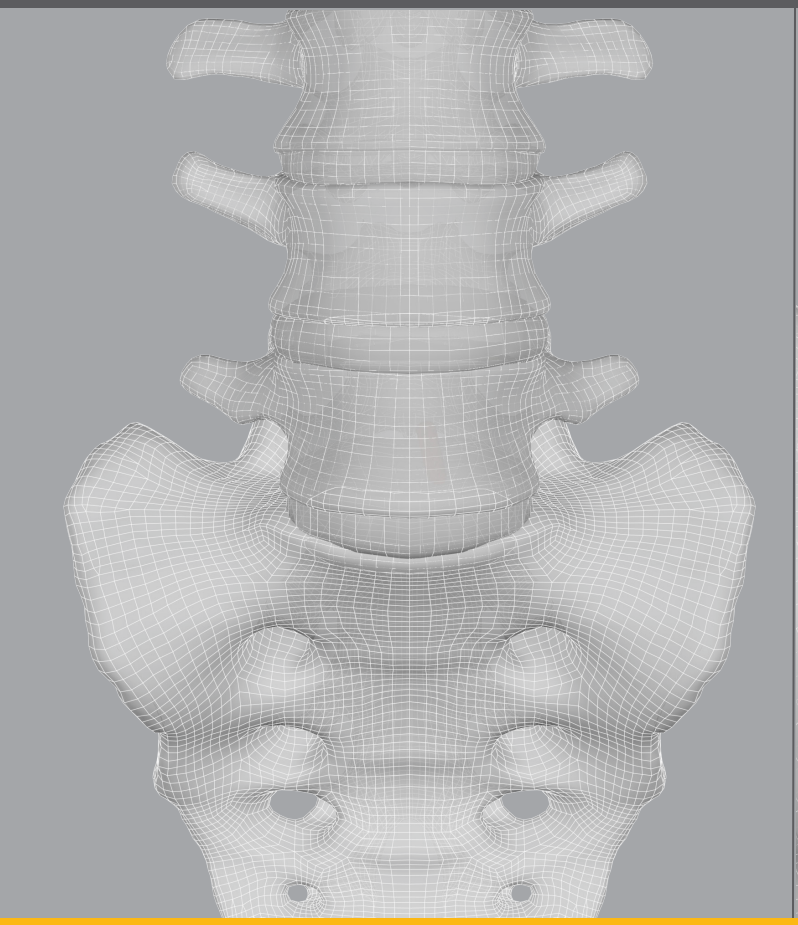


PLATE TRIALING

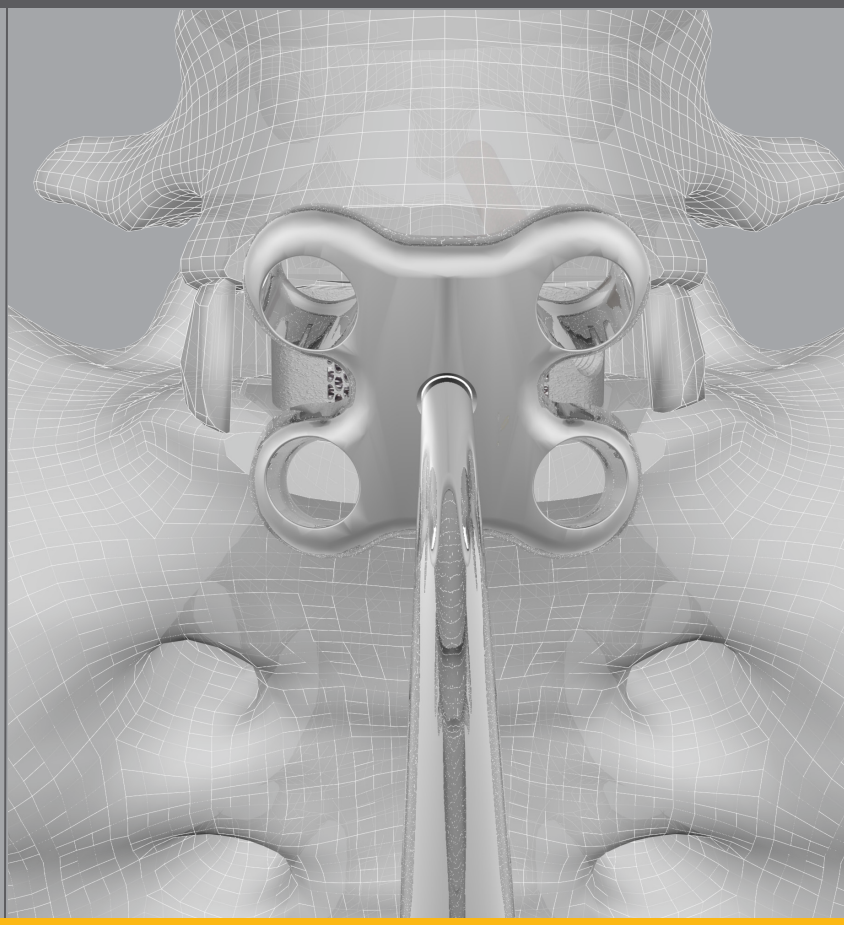
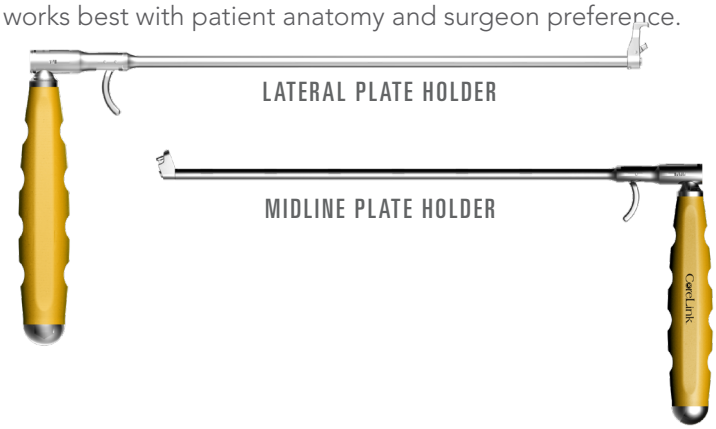


PLATE APPLICATION

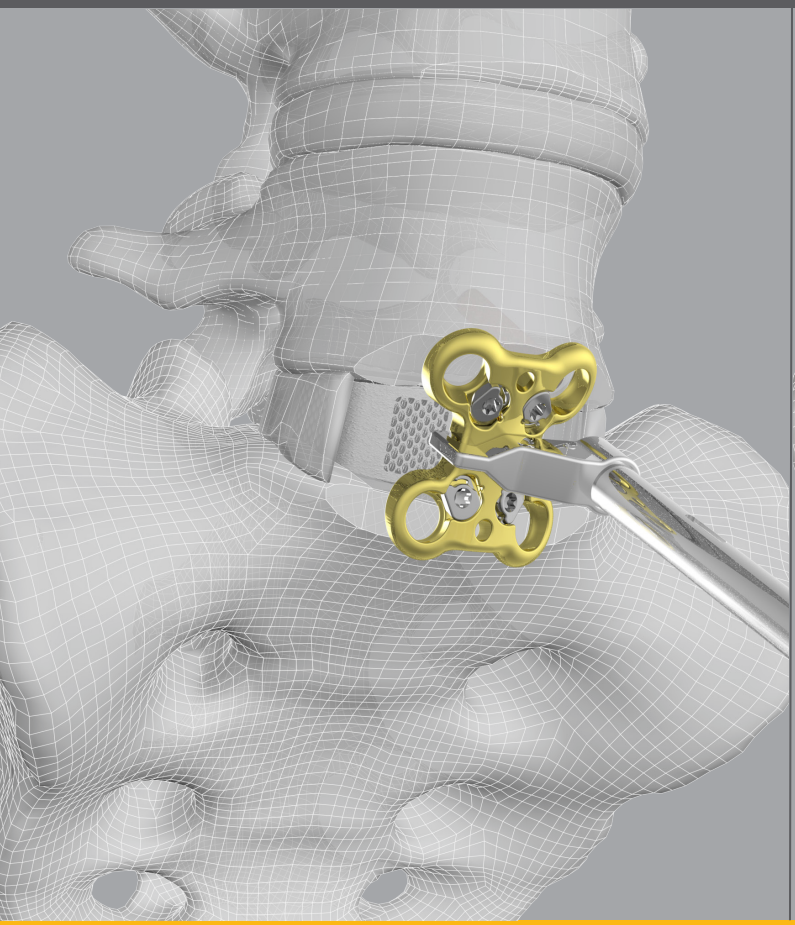
After the appropriately sized plate is chosen, use a Plate Holder to position the plate on the vertebral bodies. Two plate holder options are provided in the set: a Lateral hHlder and a Midline Holder. Select the plate holder that works best with patient anatomy and surgeon preference.



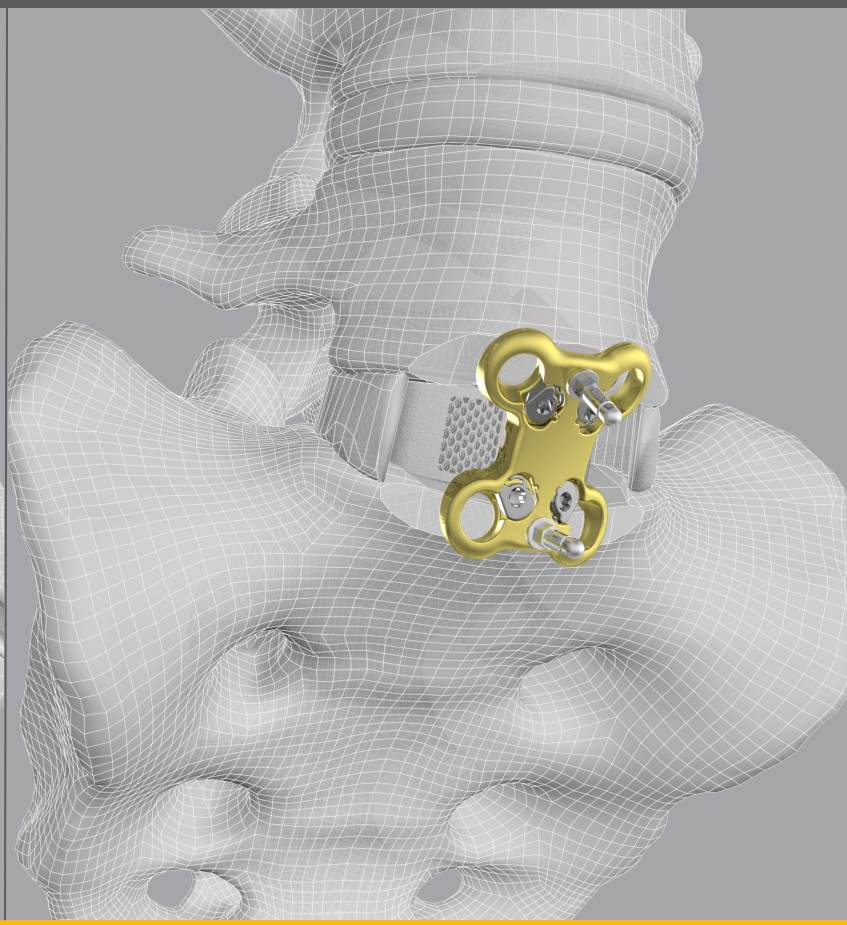
Once the plate is inserted, the Temporary Pin Inserter may be used to insert either Threaded or Non-threaded Temporary Pins (both are provided) to hold the plate in the required position. When using the Pin Inserter, the sagittal plane trajectory of the Temporary Fixation Pins is fixed and matches the ideal screw trajectory of 18 degrees in the sagittal plane and 10 degrees in the axial plane. Use this angle to help guide all screw hole preparation instruments.

Use caution when inserting and removing Temporary Fixation Pins.

LATERAL PLATE HOLDER



TEMPORARY FIXATION PINS



SCREW HOLE PREPARATION

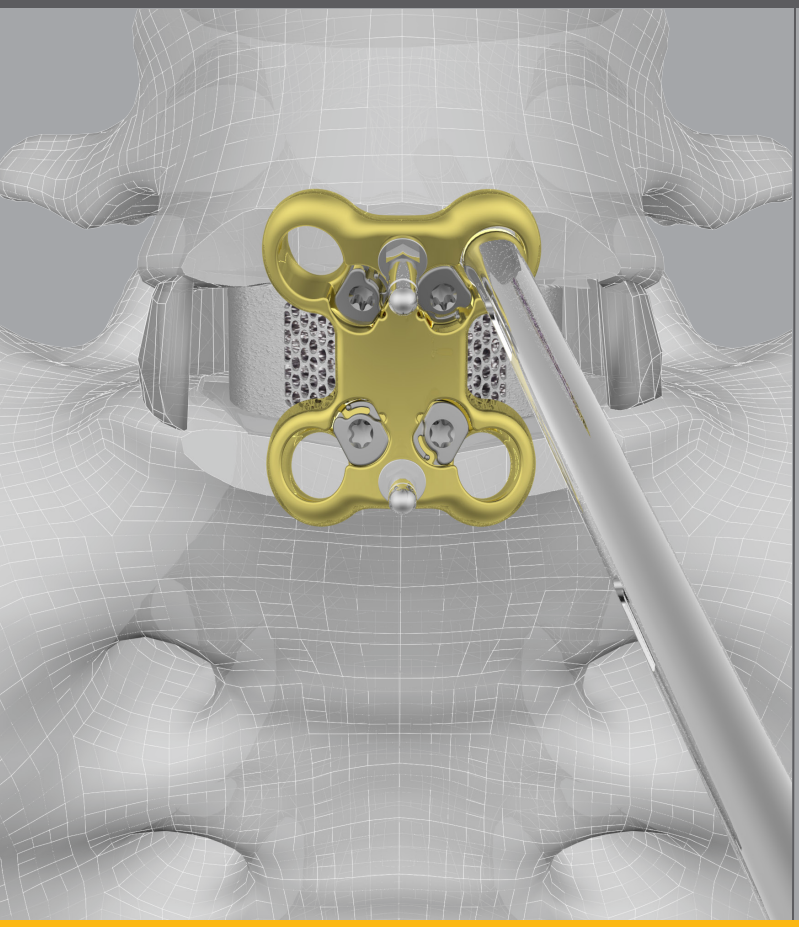
The Awl is recommended as the first instrument for screw hole preparation. The Awl has a 20 degree cone of angulation and is 20mm in length. The Awl should be used to puncture the bone rim for easier screw insertion.

Drilling and tapping are usually not necessary, as the screws have been designed to be self-tapping. However, in the event that it is necessary to drill a track for the screw, both Variable Angle and Fixed Angle Drill Guides are available to accommodate patient anatomy and surgeon preference.

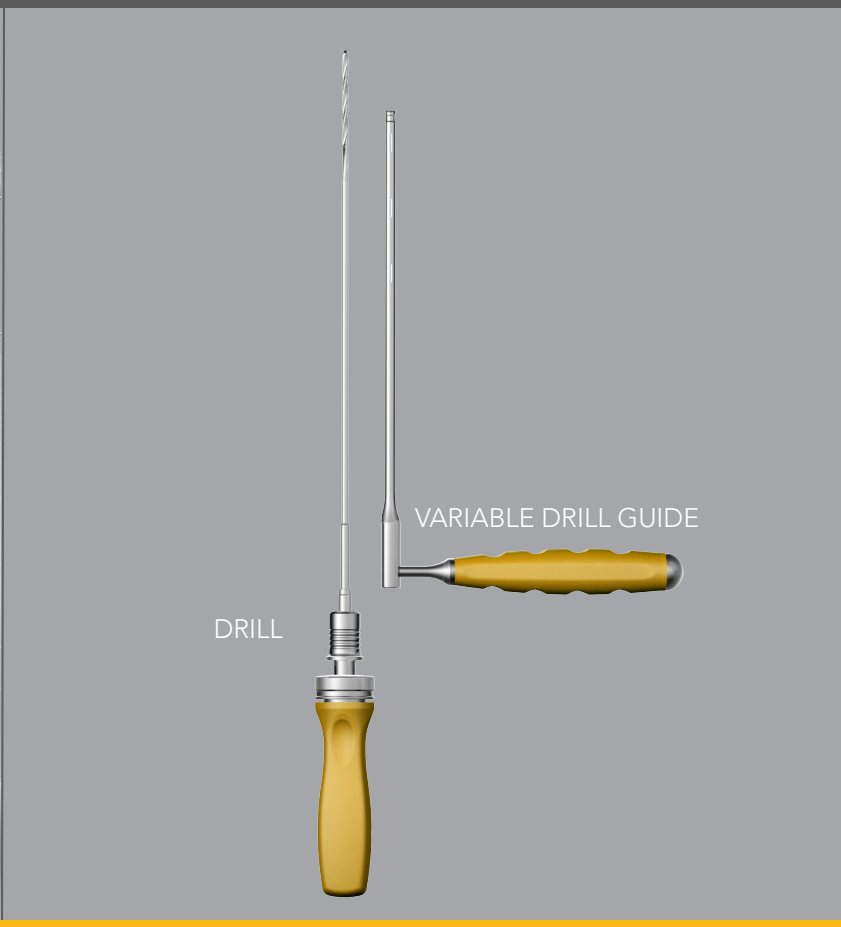
Caution: Self-tapping and Self-drilling / Self-tapping Screws are sharp. Handle with care.

The Fixed Angle Drill Guide fits securely in the plate with a trajectory of 18 degrees in the sagittal plane and 10 degrees lateral in the axial plane. The Drills have pre-set stops at 24mm, 32mm, and 36mm respectively.

AWL PREPPING SCREW HOLE



DRILL BIT AND DRILL GUIDE



SCREW INSERTION

A Depth Gauge and fluoroscopy are used to determine appropriate screw length.

To insert each screw, use the Screw Driver in conjunction with the Driver Sleeve, which has a self-retention feature to hold the screw.

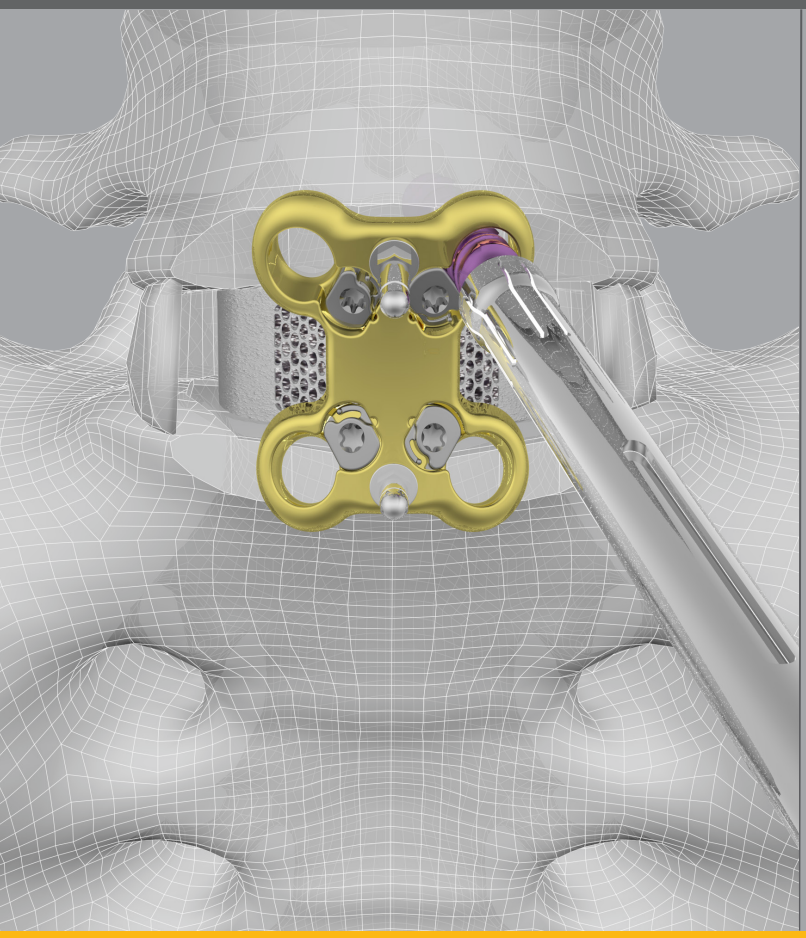
It is recommended that all screws be inserted before final tightening any individual screws.

Note that long screws may converge when inserted. Please use caution when choosing the screw length.

Screw lengths range from 21mm-36mm, as illustrated below. All screws are self-tapping, have a variable insertion angle, and are 5.5mm in diameter. All standard screws are self-tapping. Self-drilling/self-taping screws are special order. 21mm and 36mm screws are special order.

21MM GOLD | 24MM PURPLE | 28MM GREEN | 32MM MAGENTA | 36MM BLUE

REMOVAL TOOL ON SCREW

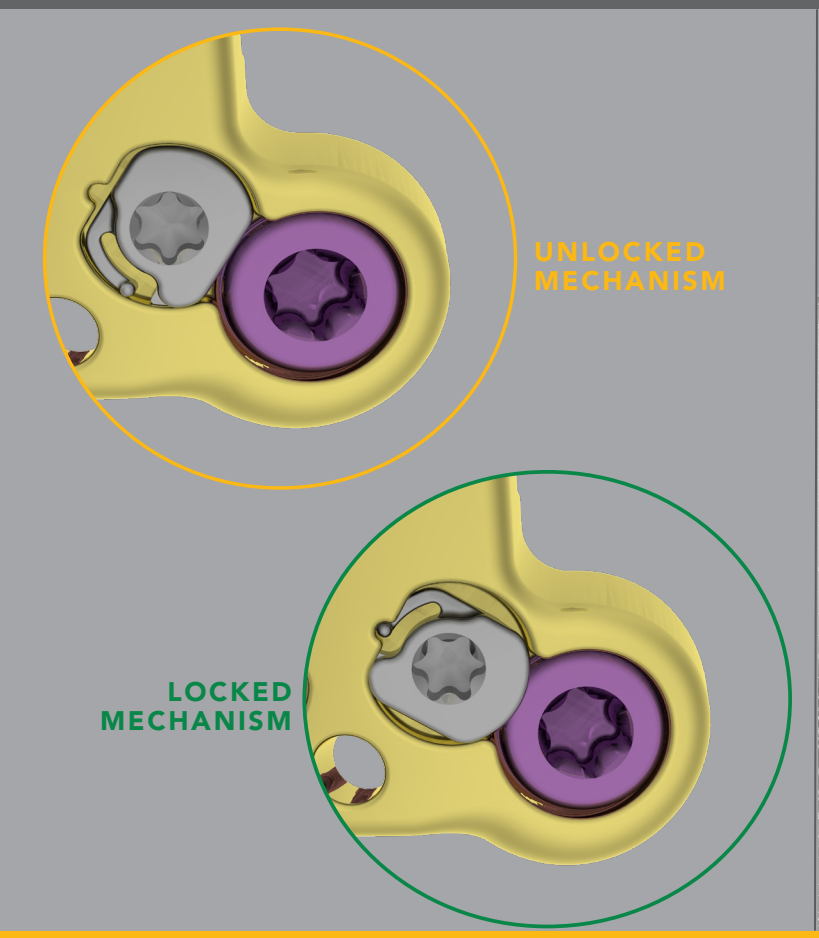


SCREW DRIVER AND SLEEVE

ANTI-BACK-OUT LOCKING MECHANISM

Once the bone screws are securely in place, remove all Temporary Fixation Pins. Using the Lock Driver on the black Torque-limiting Handle, rotate each locking mechanism on the plate clockwise approximately one quarter of a turn (90 degrees). This patented locking mechanism will act as an interference point prohibiting the screws from backing out. You will receive confirmation that the locking mechanism is properly engaged via an audible click, a tactile stop, and direct visualization of the locking mechanism position.

LOCKING MECHANISM



LOCKING DRIVER ENGAGED CLOCKWISE

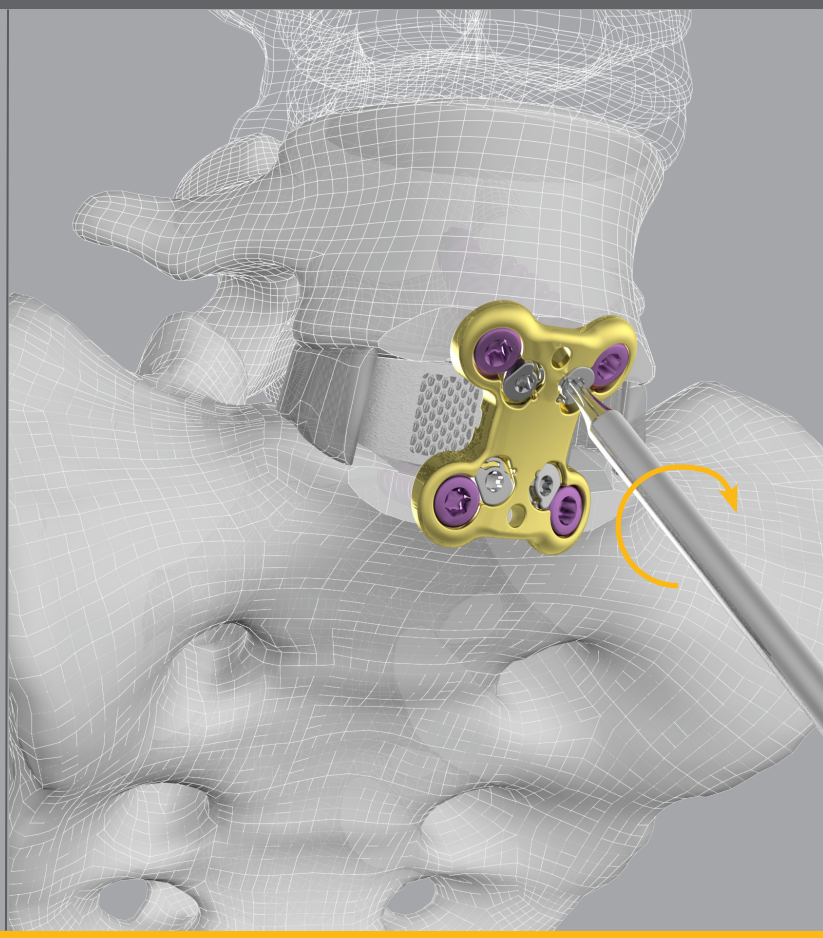
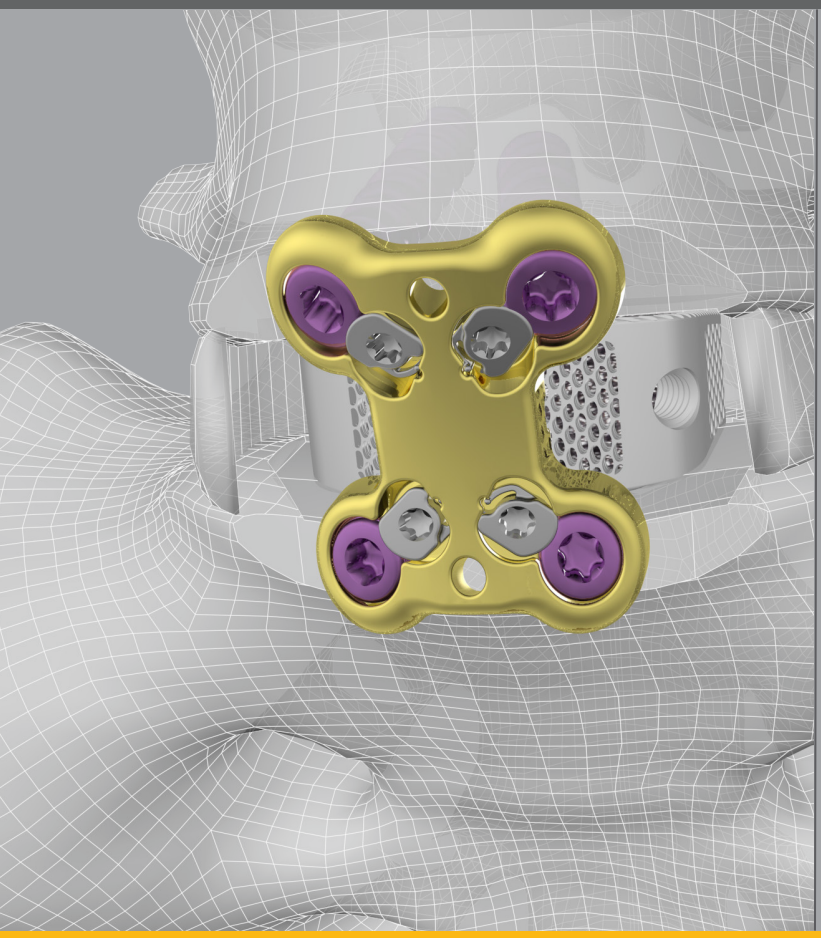


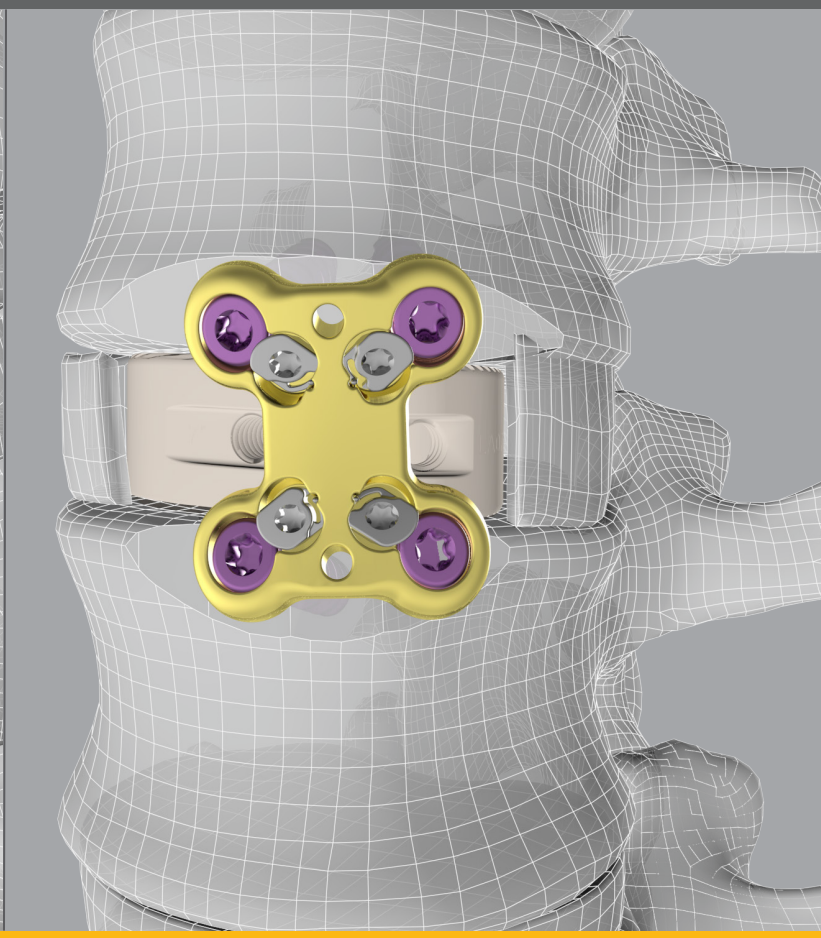
PLATE REMOVAL

Using either the provided Lock Driver or other standard hexalobe #8 driver, rotate the locking mechanism counterclockwise approximately 90 degrees to disengage the anti-back-out mechanism. Use the Screw Driver provided in the set (standard hexalobe #15) to remove each of the four bone screws via counterclockwise rotation. Either of the plate holders may be used to lift the plate from the anterior anatomy once all four bone screws are removed.

FINAL CONSTRUCT



OBLIQUE VIEW OF PLATE AT L1-L2



NOTES

INSTRUCTIONS FOR USE

CORELINK ZOU® ANTERIOR LUMBAR PLATE SYSTEM

IMPORTANT NOTE: The user of this system must read and acknowledge the conditions of this insert prior to use.

Consult the product electronic instructions for use for all current languages and latest document revision at corelinksurgical.com/ifu or by scanning the barcode on the product labeling.

DESCRIPTION

The CoreLink Zou Anterior Lumbar Plate System consists of implants (plates and screws) intended for use as an anteriorly placed supplemental fixation device via the lateral or anterior lateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach below the bifurcation of the great vessels.

Implants in the Zou Anterior Lumbar Plate System are manufactured from the following materials:

- Medical grade Titanium Alloy (Ti6Al4V per ASTM F136)

The screws are anodized to facilitate size selection. Changes or variations in color during use or preparation do not affect implant quality.

Do not use any of the Zou Anterior Lumbar Plate System components with components from any other manufacturer or system unless specifically allowed to do so in this or any other CoreLink document. None of the Zou Anterior Lumbar Plate System implants or implant components should be reused under any circumstances. The instruments provided with the Zou Anterior Lumbar Plate System are provided specifically for the implantation of the Zou Anterior Lumbar Plate System implants and associated CoreLink interbody fusion devices referenced in this document.

CoreLink provides Surgical Technique Manuals demonstrating the use of CoreLink implants and instruments. Please contact your CoreLink sales representative to obtain copies of these Surgical Technique Manuals. Reference the Zou Anterior Lumbar Plate System Surgical Technique Manual for additional important information about specific CoreLink implants, in addition to the information described herein.

INDICATIONS

The CoreLink Zou Anterior Lumbar Plate System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterior lateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels.

The CoreLink Zou Anterior Lumbar Plate System is designed to provide temporary stability until fixation is achieved. It is intended for anterior lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

CONTRAINDICATIONS

Do not use the CoreLink Zou Anterior Lumbar Plate System in the presence of an active systemic infection or infections localized to the site of the proposed implantation. Use of implants in this setting may lead to future infection and implant failure. Other relative contraindications include:

- Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices.
- Severe osteoporosis as it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.
- Any entity or condition that totally precludes the possibility of fusion (e.g., cancer, kidney dialysis, osteopenia).
- Obesity.
- Certain degenerative diseases.
- Foreign body sensitivity.
- A patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure and non-union.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

Use and/or misuse of this system may result in the following list of complications and potential adverse effects:

- Bending and/or breakage of any or all devices.
- Inadequate fixation.
- Non-union, delayed union or mal-union.
- Allergic reaction to implant material, debris, corrosion products including metallosis, staining, tumor formation, and/or autoimmune disease.
- Infection.
- Wound healing disorders or hematomas.
- Fracture, microfracture, resorption, damage or penetration of any spinal bone at, above, and/or below the level of surgery.
- Herniated nucleus pulposus, disc disruption or disc degeneration at, above or below the level of surgery.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of sensory and/or motor function including paralysis (complete/incomplete), dysesthesia, hyperesthesia, paresthesia, radiculopathy, pain, numbness, spasms, sensory loss, tingling sensation and/or visual deficit.
- Neuropathy, paraplegia, paraparesis, reflex deficit, irritation, neurological deficit (transient or permanent) and/or muscle loss.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Damage to the urological, gastrointestinal, and/or reproductive systems resulting in compromises including urinary retention, loss of bladder control, gastritis, bowel obstruction, loss of bowel control, sterility, consumption, sexual dysfunction etc.
- Decrease in bone density potentially caused by stress shielding.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Limited ability to perform daily activities.
- Continuation of symptoms that were to be treated for by the implantation.
- Change in mental status.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Death.

Additional surgery might become necessary to correct adverse effects and/or outcomes.

USE OF IMPLANT COMPONENTS

WARNING: The safety and effectiveness of lumbar plating systems have been established only for spinal conditions with acute and chronic instabilities or deformities of lumbar and sacral/iliac spine (L1-S1): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion pseudarthrosis. The safety and effectiveness of these devices for any other conditions are unknown.

Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while the fusion mass about the implant is developing. Without solid biological support provided by sufficient fusion mass, the implants will fail in any of several modes. These modes may include bone-implant interface failure, implant fracture, or bone failure. Spinal implants of this type are more likely to fail if no bone graft is used, if a pseudarthrosis develops, or if patients have severe or multiple preoperative curves.

Spinal implants, like other implants or temporary internal fixation devices, have a limited life. The life of the implant is directly impacted by the level of activity of the patient. Inform the patient that any activity increases the risk that the implant components may become loose, bend, or break. Instruct patients about restrictions to their activity levels in the postoperative period. Examine patients postoperatively to evaluate the condition of implant components and the development of the fusion mass about the implant components. Instruct the patient that implant components may bend, break, or loosen even though restrictions in activity are followed and even if fusion mass about the implant component sufficiently develops.

This device is not intended or expected to be the only mechanism of support of the spine. Regardless of the spinal pathology for which implantation of this device was chosen, solid biological support is anticipated but is not always obtained. Without solid biological support provided by bony fusion, the device cannot be expected to support the spine indefinitely and will lose effectiveness in any of several modes. These modes include, but are not limited to, bone-metal interface failure, rod fracture or deformation, and/or bone failure.

Spinal implants of this type may be removed after sufficient bone fusion develops. However, please inform the patient that a second surgical procedure may be necessary and that there are risks associated with a second surgical procedure. The decision to remove a broken implant must be made by the physician who must consider the risks associated with the presence of the broken implant and the condition of the patient.

Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudarthrosis, disc height loss, adjacent level disc degeneration, allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion. Risks and potential benefits must be provided to patients for whom this treatment modality is suggested.

This device must not be reused. Reuse may result in patient injury or other complications including but not limited to component fracture and/or deformation, breakage, difficulty with implantation, incompatibility with mating components and infection. It is the physician's responsibility to discard all damaged or mishandled implants.

Altering an implant may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants are damaged during insertion or adjustment, they may not remain implanted and must be replaced. Refer to the CoreLink Zou Anterior Lumbar Plate System surgical technique manual for descriptions of appropriate implant handling and insertion techniques.

Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant fracture or deformation may result.

In addition to the warnings and precautions discussed above, patients must be informed about general surgical risks prior to surgery.

PRECAUTIONS: The implantation of the CoreLink Zou Anterior Lumbar Plate System is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this intervertebral body fusion device system. The surgeon must be thoroughly knowledgeable in the medical and surgical aspects of the implant procedure, and the surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the implant. It is the surgeon's responsibility to ensure that the operating procedure is performed correctly. The Surgical Technique can be requested from CoreLink by calling the phone number at the end of this document. No manufacturer can be responsible for complications resulting erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the CoreLink Zou Anterior Lumbar Plate System rely upon individual patient physiological response, and proper use of the device does not guarantee any result.

Use of the system off-label is forbidden by CoreLink.

The CoreLink Zou Anterior Lumbar Plate System has not been evaluated for safety and compatibility in the MR environment. The CoreLink Zou Anterior Lumbar Plate System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the CoreLink Zou Anterior Lumbar Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PREPARATION AT POINT OF USE

The implants and instruments of the CoreLink Zou Anterior Lumbar Plate System are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization. Remove all packaging that individual devices may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. Some instruments in the CoreLink Zou Anterior Lumbar Plate System must be disassembled to facilitate cleaning. All instruments should be reassembled following cleaning, prior to sterilization.

Prior to use, instruments must be inspected for signs of wear, damage and proper function. If you suspect an instrument is damaged, please contact CoreLink for a replacement.

Follow the Cleaning and Sterilization procedures below.

CLEANING AND STERILIZATION

Instruments exposed to tissue must be thoroughly cleaned after use. Dried residues from surgery will make the cleaning process more difficult and/or ineffective. Maximum recommended time between use and cleaning is 4 hours. Instruments should not be exposed to elevated air temperatures (>100 °F). Certain cleaning solutions such as those containing fixatives, alcohols, aldehydes, chlorides, and/or excessive amounts of basic detergents can cause degradation of stainless-steel surfaces and laser marking. Use a cleaning and disinfecting agent that is compatible with aluminum, stainless steel, plastics, and silicone according to the manufacturer's instructions.

All instruments must be fully disassembled prior to cleaning (e.g. handles must be detached from shafts, driver shafts removed from drivers, and implants disconnected from mating instruments).

Manual Cleaning Instructions:

1. Completely submerge the instruments in a lukewarm neutral pH enzyme solution and allow soaking for a minimum of 10 minutes. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
3. Prepare a neutral pH cleaning solution according to the manufacturer's instructions and place in an ultrasonic cleaning unit at 45-50 kHz to aid in thorough cleaning of devices.
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

NOTE: Instrument cases, trays, and caddies must be thoroughly cleaned according to the above instructions. Inspect the containment devices and if found to not be visually clean, repeat the previous cleaning steps.

Automated Cleaning Instructions:

1. Rinse devices under running tap to remove gross soils. Particular attention must be given to crevices, lumens, mated surfaces and other hard-to-clean areas. Use a syringe or jetted water to flush difficult to reach areas.
2. Place instruments in a suitable washer basket and process through a standard instrument washer. The table below represents the minimum parameters required for proper cleaning and disinfection.

INSTRUCTIONS FOR USE (CONTINUED)

Typical Automated Washer Cycle for Surgical Instruments

Step	Description
1	2-minute prewash with cold tap water
2	1-minute enzyme spray with hot tap water
3	2-minute detergent wash with hot tap water (64-66°C/146-150°F)
4	15-second hot tap water rinse
5	2-minute thermal rinse (80-93°C/176-200°F)
6	10-second purified water rinse (64-66°C/146-150°F)
7	7 to 30-minute heated air dry (116°C/240°F)

Notes:

- The washer manufacturer's instructions should be strictly adhered to.
- Avoid impact, scratching, bending or surface contact with any material that might affect the instrument surface or configuration.
- Pay particular attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect and reassemble all devices after cleaning to ensure cleanliness and function.

Sterilization Instructions

Implants and instruments of the CoreLink Zou Anterior Lumbar Plate System are provided non-sterile. The non-sterile condition is conspicuously set forth on the product label. Implants supplied non-sterile are clean. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all components.

Sterilization: In a properly functioning calibrated steam sterilizer, testing has shown that effective sterilization may be achieved as follows:

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

Instruments and implants should be sterilized in the steam sterilization cases provided by CoreLink. Instrument and implant sets must be wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600 – 510(k) K082554 or similar wrap) using sequential envelope techniques. Only wraps validated to maintain sterility after processing are to be used. Saturated steam with a quality of 97-100% must be used.

REUSABLE RIGID STERILIZATION CONTAINERS

The Zou Anterior Lumbar Plate System provided in a perforated steam sterilization case may be placed directly into Aesculap™ SterilContainers™. Testing has demonstrated the system, when processed in Aesculap SterilContainer systems JN440, JN442, JN444, JN446 rigid containers (with corresponding JK series lid and re-usable JK series filter assembly), can be sterilized to a 10-6 sterility assurance level (SAL) in a Dynamic Air Removal (pre-vacuum) steam sterilization cycle when processed using the required sterilization cycle.

Required Sterilization Cycle

Sterilizer type:	Pre-vacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C (270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	30 Minutes (allow for cool-down)

CoreLink does not recommend the use of gravity displacement steam cycles for sterilization in Aesculap rigid container systems. Ensure that the supplied reusable rigid sterilization container is in proper working order prior to sterilization. Aesculap SterilContainer System has been validated ONLY with Aesculap reusable filters. For more information on the use of the Rigid Sterilization Containers please consult the Instructions for Use of the Manufacturer (https://www.aesculapusa.com/products/instructions-for-use).

THE STERILIZATION PARAMETERS PROVIDED IN THIS INSTRUCTIONS FOR USE SUPERCEDE THOSE LISTED IN THE AESCULAP INSTRUCTIONS FOR USE. ALL OTHER USAGE, CARE AND MAINTENANCE INSTRUCTIONS SPECIFIED IN AESCULAP DOCUMENTATION REMAIN APPLICABLE.

It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the US FDA for the selected sterilization cycle.

Flash sterilization of the Zou Anterior Lumbar Plate System is not recommended.

IMPORTANT SYSTEM CONSIDERATIONS AND WARNINGS

1. **Corrosion from Mixed Metals.** Damage from corrosion may occur following surgical implantation of metals. All implanted metals and alloys display general or uniform corrosion, and the rate of corrosion of implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. However, the presence of dissimilar metals in contact accelerates corrosion. For instance, where titanium and stainless steel are in contact, the stainless steel is subject to corrosive attack. Corrosion may accelerate failure of implants through fatigue fracture. Corrosion also causes metal compounds to be released into the body. To minimize effects from corrosion, implant components that encounter other metal objects, must be made from like or compatible metals.
2. **Failure of Implants Due to Excessive Demands in Connection with Delayed Union or Nonunion.** Implants of this type are temporary devices that are used to obtain disc height restoration until normal healing occurs and bone fusion mass is developed. If healing is delayed, or does not occur, the implant may fail over time due to metal fatigue. The useful life of the implant will be in part affected by the degree or success of implant to bone union, loads produced by weight bearing, and activity levels. The useful life of the implant will be also in part affected by notches, scratches or bending of the implant which may occur during the surgical procedure. Please inform patients of the risks of implant failure.
3. **Implant Selection.** The selection of the proper size, shape, and design of the implant greatly contribute to the potential of satisfactory fixation. However, the size and shape, and condition of the patient's bones present limitations on the size, shape and strength of implants. Implants cannot withstand activity levels equal to those placed on normal healthy bone. As mentioned above, implants of this type are temporary and should not be expected to withstand indefinitely the unsupported stress of full weight bearing.
4. **Patient Considerations.** The following should be considered when evaluating whether a patient is a candidate for such a procedure:
   - **Weight.** An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
   - **Lifestyle or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even after the bone is fully healed, the patient may not be able to resume these activities.
   - **Alcoholism, drug abuse, or mental conditions.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions leading to implant failure or other complications.
   - **Degenerative diseases.** In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant component. In these cases, the use of the implant may only postpone potential outcomes and/or be of a temporary nature.
   - **Implant sensitivity.** No preoperative test can completely exclude the possibility of sensitivity or allergic reaction. A patient may develop sensitivity or allergy after implants have been in the body for a period of time.
   - **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

- **Patient Instructions.** Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, please instruct the patient on the limitations of the implant, and to limit and restrict physical activities, especially lifting and twisting motions and sports-related activities. Please inform the patient that an implant is not as strong as normal healthy bone, and that the implant could loosen, bend, and/or break if excessive demands are placed on the implant, especially in the absence of complete bone mass fusion. Please inform the patient that improper activities may cause the implants to become displaced or damaged and may cause the implant to migrate

and damage nerves or blood vessels. As mentioned above, a patient having certain conditions, such as alcoholism, drug abuse, or other mental conditions may not properly use weight-supporting devices and may be particularly at risk during postoperative rehabilitation.

- **Implant Location.** Because vascular and neurological structures are located near to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurological damage during and after implantation procedure. Serious or fatal hemorrhage may occur if: (i) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (ii) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
- **Implant Removal.** Spinal implants of this type may require removal if the desired clinical and surgical outcomes are not obtained. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. When the implant is removed, the surgeon should provide postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery. Although uncommon, permanent implantation of this device may result in the following:: (1) Corrosion, with localized tissue reaction or pain; (2) Possible increased risk of infection; (3) Bone loss due to stress shielding (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Migration of implant position resulting in injury; and (7) Risk of additional injury from postoperative trauma.
- **Do Not Reuse Implants.** An implant previously implanted should never be reused. An implant previously implanted may have small defects that are not readily visible that may lead to early breakage, and compromise device performance and patient safety. Reuse may also lead to cross contamination and patient infection.

POSTOPERATIVE IMMOBILIZATION

Until X-rays confirm the development of a fusion mass, external immobilization (such as bracing or casting) is recommended.

Please inform the patient to reduce stress on the implants in order to reduce the risk of complications from fixation failure.

CAUTION: Under federal law, this device may only be sold by or on the order of a physician.

LIMITED WARRANTY AND DISCLAIMER

CORELINK 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 TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/ REVISION OF THIS INSERT AND THE DATE OF CONSULTATION, CONTACT CORELINK CUSTOMER SERVICE FOR CURRENT INFORMATION AT 888-349-7808.

The Aesculap SterilContainer System is FDA 510(k) cleared under K792558, K053389, K040865, K093493, K093649, K041623, and K073168. Aesculap and SterilContainer are trademarks of Aesculap, Inc., a B. Braun Company.

For further information contact:

CoreLink, LLC
2072 Fenton Logistics Park
St. Louis, MO 63026
(888) 349-7808

SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
	Prescription Required – Federal Law restricts this device to sale by or on the order of a licensed practitioner.	N/A
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.	5.1.1
	Lot Number – Indicates the manufacture's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacture's catalogue number so that the medical device can be identified	5.1.6
	Non-Sterile – Indicates a medical device that has not been subject to a sterilization process.	5.2.7
	Do not re-use - Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	5.4.2
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Caution – Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	5.4.4

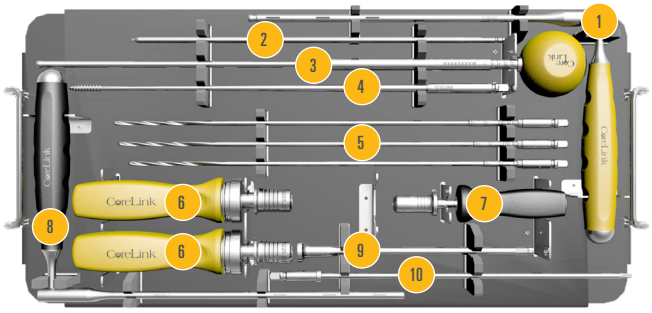
INSTRUMENT STANDARD PRODUCT LISTING

KIT ORDER #K5000055

ZOU ANTERIOR LUMBAR INSTRUMENTS		
QTY	CATALOG NUMBER	DESCRIPTION
1	1010-055	TAP - 5.5MM
2	1010-124	DRILL - 24MM
2	1010-132	DRILL - 32MM
2	1010-136	DRILL - 36MM
1	1110-100	DRILL GUIDE- FIXED
1	1110-101	DRILL GUIDE - VARIABLE
2	2010-100	DRIVER SLEEVE - SELF RETAINING SCREW
2	2010-101	SCREW DRIVER SHAFT
2	2010-102	LOCK DRIVER
1	2010-103	SCREW REMOVAL TOOL
1	4010-100	PLATE HOLDER - MIDLINE
1	4010-101	PLATE HOLDER - LATERAL
1	5010-016	TRIAL - 15MM, 17MM
1	5010-020	TRIAL - 19MM, 21MM
1	5010-024	TRIAL - 23MM, 25MM
1	5010-102	AWL - 20MM
1	5010-110	DEPTH GAUGE
1	5010-120	PROBE
1	5010-200	FIXATION PIN INSERTER
2	8225-201	STRAIGHT AXIAL HANDLE - 1/4" SQUARE
1	9010-100	TORQUE LIMITING HANDLE
1	14A00100	TRAY BASE
1	14A00101	INNER TRAY 1
1	14A00102	INNER TRAY 2
1	14G00500	CORELINK LID

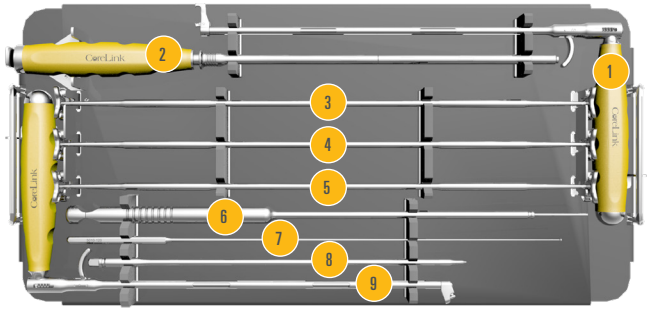
TOP TRAY

1. Variable Drill Guide
2. Lock Driver
3. Awl
4. Tap
5. Drills
6. Straight Handles (qty. 2)
7. Torque Limiting Handle
8. Fixed Drill Guide
9. Screw Driver Sleeve
10. Screw Driver Shaft



BOTTOM TRAY

1. Plate Holder - Lateral
2. Fixation Pin Inserter
3. Trial - 15mm, 17mm
4. Trial - 19mm, 21mm
5. Trial - 23mm, 25mm
6. Depth Gauge
7. Lumbar Probe
8. Screw Removal Tool
9. Plate Holder - Midline



Contact CoreLink Customer Service for additional sizes and options

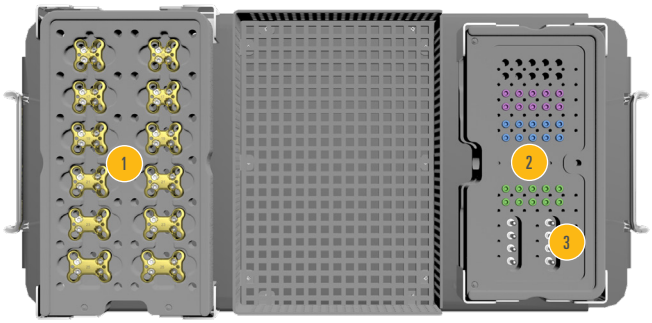
IMPLANT STANDARD PRODUCT LISTING

KIT ORDER #K5000044

ZOU ANTERIOR LUMBAR IMPLANTS		
QTY	CATALOG NUMBER	DESCRIPTION
PLATES		
2	10000-015	ZOU PLATE - 15MM
2	10000-017	ZOU PLATE - 17MM
2	10000-019	ZOU PLATE - 19MM
2	10000-021	ZOU PLATE - 21MM
2	10000-023	ZOU PLATE - 23MM
2	10000-025	ZOU PLATE - 25MM
SCREWS		
10	10155-24	5.5MM X 24MM VARIABLE SCREW
10	10155-28	5.5MM X 28MM VARIABLE SCREW
10	10155-32	5.5MM X 32MM VARIABLE SCREW
INSTRUMENTS		
4	6010-100	FIXATION PIN - NON-THREADED
4	6010-101	FIXATION PIN - THREADED
CADDIES		
1	14A00084	PLATE CADDY
1	14A00085	SCREW CADDY
CONTAINERS		
1	14A00141	TRAY BASE
1	14A00142	INNER TRAY 1
1	14G00500	CORELINK LID

TRAY

1. Plate Caddy
2. Screw Caddy
2. Fixation Pins



*Special order. Contact CoreLink Customer Service for additional sizes and options

SPECIAL ORDER PRODUCT LISTING

ORDER INDIVIDUALLY

ZOU SELF-TAPPING/SELF-DRILLING SCREWS		
QTY	CATALOG NUMBER	DESCRIPTION
1*	11155-21	VARIABLE, 5.5MM X 21MM SCREW
1*	11155-24	VARIABLE, 5.5MM X 24MM SCREW
1*	11155-28	VARIABLE, 5.5MM X 28MM SCREW
1*	11155-32	VARIABLE, 5.5MM X 32MM SCREW
1*	11155-36	VARIABLE, 5.5MM X 36MM SCREW
1*	11355-21	FIXED, 5.5MM X 21MM SCREW
1*	11355-24	FIXED, 5.5MM X 24MM SCREW
1*	11355-28	FIXED, 5.5MM X 28MM SCREW
1*	11355-32	FIXED, 5.5MM X 32MM SCREW
1*	11355-36	FIXED, 5.5MM X 36MM SCREW

*Contact CoreLink Customer Service for additional sizes and options

NOTES

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Designed and manufactured in St. Louis, MO 63026

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