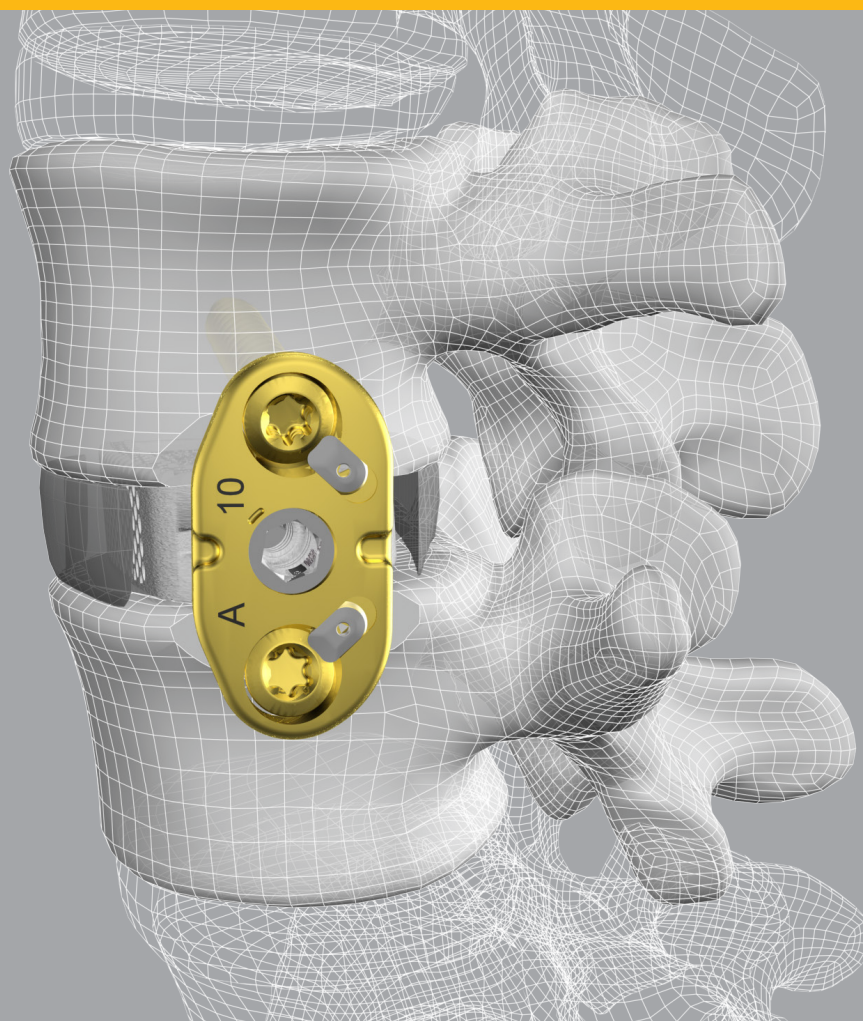




CoreLink.
The Source for Spine™

CORELINK ORO™ LATERAL PLATE SYSTEM

Surgical Technique Guide



THE CORELINK ORO™ LATERAL PLATE SYSTEM ADVANTAGE

Designed with surgeon's individual needs in mind, the CoreLink Oro Lateral Plate System is a flexible, all-encompassing lateral plate system allowing for the ability to treat a wide range of pathologies.

The CoreLink Oro Lateral Plate System is supplied with quality instruments and implants that feature:

- Two and four-hole* options in a variety of lengths ensure the surgeon achieves perfect fit every case
- Standard and rescue screw diameters to meet the most demanding of applications
- Automatic locking mechanisms to prevent screw back-out
- Low-profile design minimizes tissue disruption

*Four-hole Plates are Special Order

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ORO LATERAL PLATE PRODUCT OVERVIEW

PLATE FEATURES

- Zero-step Screw Locks
- Thickness: 4mm
- Two-hole Width: 15.5mm
- Four-hole Width: 19mm (at widest point)

SCREW FEATURES

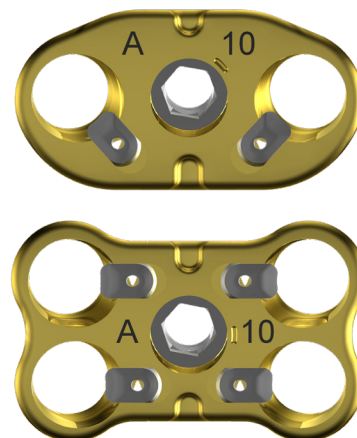
- Diameters: 5.5mm & 6mm
 - Lengths: 25mm - 65mm*, 5mm Increments
 - Variable Angle: 18 degrees Cephalad/Caudal
- *65mm length is non-standard and available upon request.

PLATE SIZES AND ORIENTATION

The Lateral Plate is marked to be read upright from the posterior side of the patient. The "A" identifies Anterior and the Plate Reference Number identifies size. See the table below for the complete Lateral Plate offering.

PLATE SIZES				
2-HOLE	4-HOLE*	PLATE REFERENCE NUMBER	SCREW TO SCREW LENGTH	PLATE LENGTH
•		6	16MM	26MM
•		8	18MM	28MM
•	•	10	20MM	30MM
•	•	12	22MM	32MM
•	•	14	24MM	34MM
	•	16	26MM	36MM
	•	18	28MM	38MM

*Special Order



IMPORTANT INFORMATION REGARDING THE CORELINK ORO LATERAL PLATE SYSTEM INDICATIONS:

The CoreLink Oro Lateral Plate System may be used with or without an interbody cage. The CoreLink Oro LPS has the ability to connect to CoreLink Lateral interbody devices to aid in delivery of the plate to the surgical site and to facilitate early removal of the inserter, clearing the retractor path for screw preparation instrumentation. The set screw in the CoreLink Oro LPS may be threaded into the CoreLink Lateral interbody. Once the screws have been placed and their positioning has been verified through fluoroscopic imaging, the set screw connecting the CoreLink Oro LPS to the CoreLink Lateral interbody may either be disconnected or remain connected.

If the CoreLink Oro LPS remains connected to CoreLink Lateral interbody, the following additional indication restrictions apply:

Alternatively, the CoreLink Oro LPS may remain attached to CoreLink lateral lumbar interbody devices after implantation. In this configuration the CoreLink Oro LPS must only be used to treat patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

The surgeon performing this procedure should be aware of this additional use limitation. For instructions on use of the Oro Lateral Plate System with the CoreLink Lateral interbody, please refer to CL-FORM-293.

SETUP AND PATIENT POSITIONING

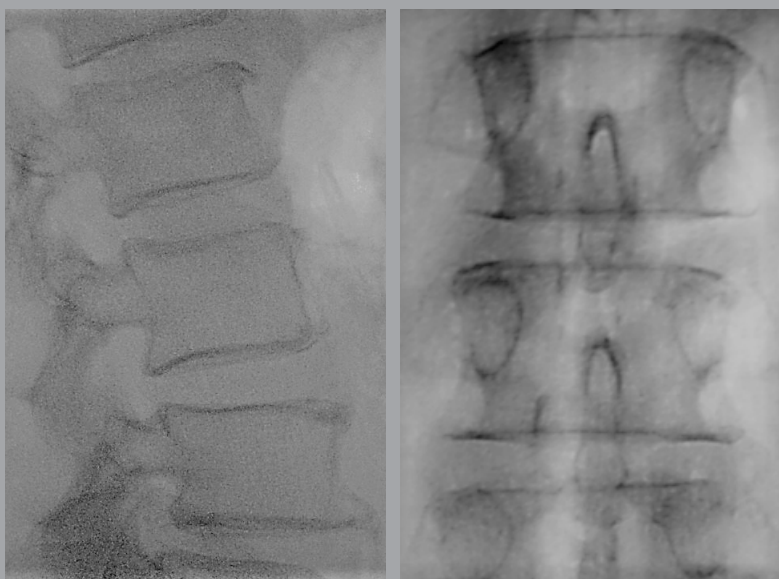
Proper operating room setup and patient positioning are key to successful completion of this procedure. The patient should be placed in the lateral decubitus position then secured to the table. Identify the appropriate disc space and further refine patient positioning using table adjustments and fluoroscopy until true (straight) A/P and lateral images are achieved with the C-arm at zero degrees and 90 degrees, respectively. Clean the operative site.

Further detail relating to setup, positioning, disc space preparation, and insertion of the CoreLink Lateral interbody fusion devices can be found in the Lateral Access System Surgical Technique Guide.

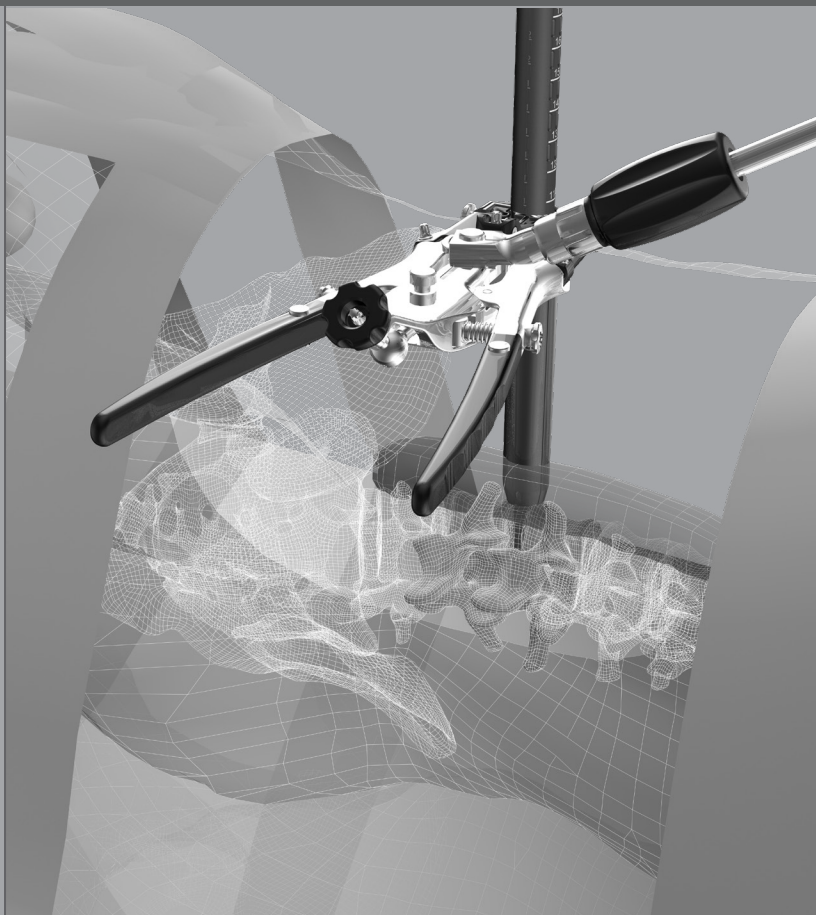
RETRACTOR INSERTION

Again using fluoroscopy, identify the middle of the disc space with the optional Targeting Tool or a K-wire. Mark the skin to indicate the intended incision location. Approach the desired disc space level and place the Retractor. Use of intraoperative neuromonitoring is recommended to ensure patient safety. It is especially critical during approach and Retractor placement.

LATERAL & AP FLUOROSCOPIC IMAGES



RETRACTOR PLACEMENT



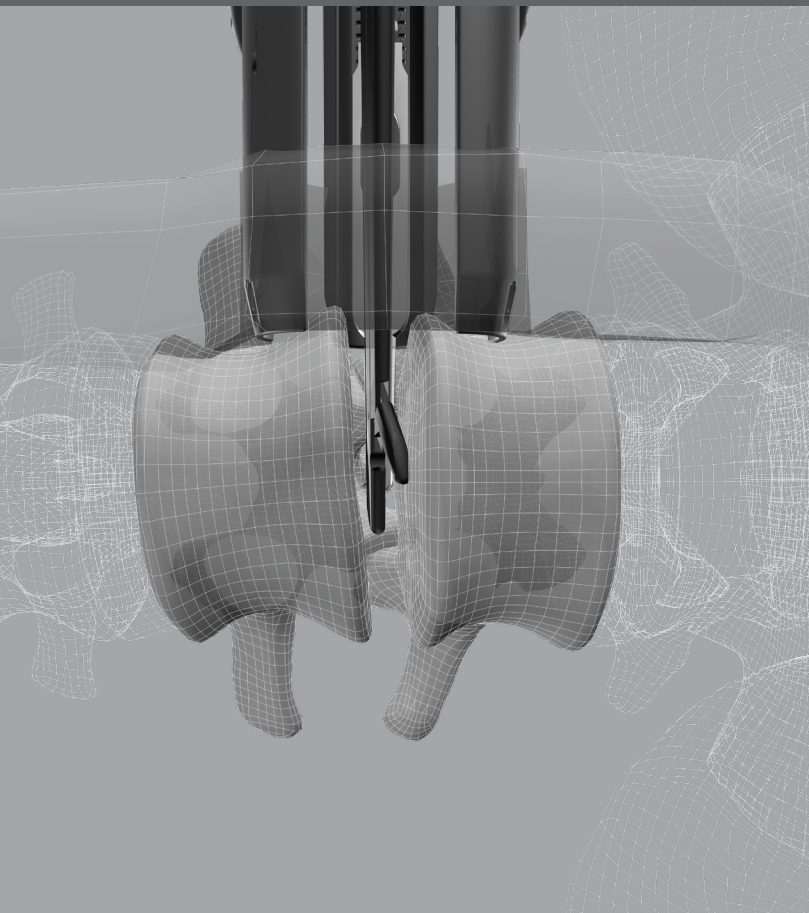
DISC SPACE PREPARATION

To facilitate bony fusion, adequate preparation of the intervertebral space must be performed. CoreLink offers a comprehensive suite of disc removal and endplate preparation instruments as seen in the Lateral Access System Surgical Technique Guide.

OSTEOPHYTE REMOVAL

Remove any anterior or lateral osteophytes or other bony structures that may prohibit the Lateral Plate from sitting flush on the vertebral body.

DISC PREPARATION



OSTEOPHYTE REMOVAL

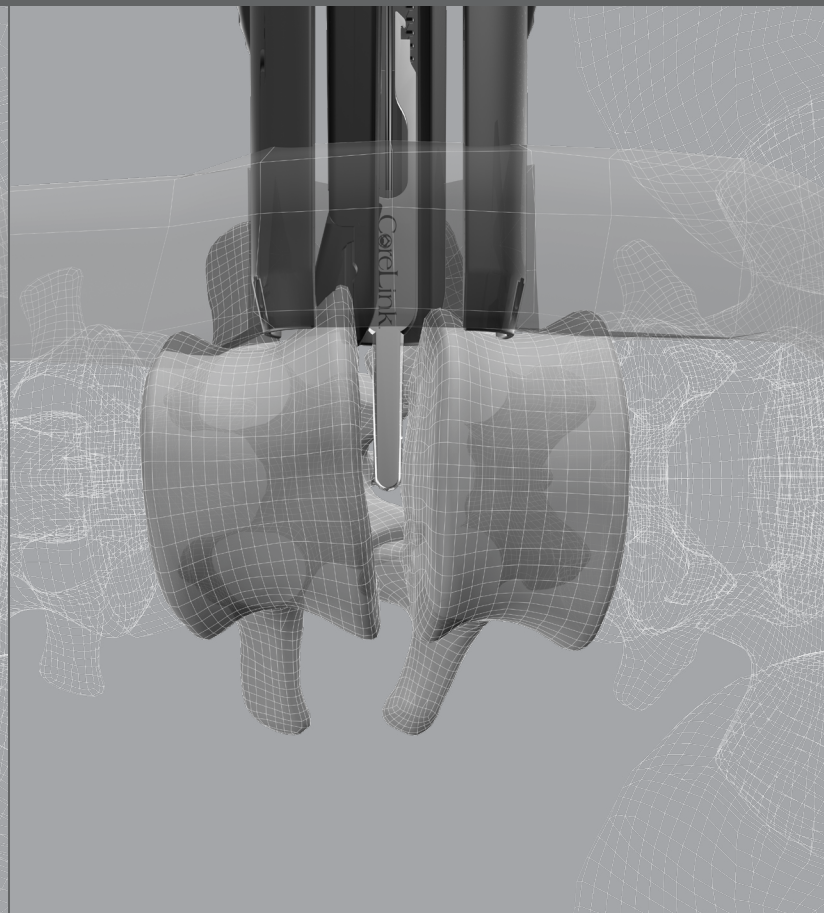


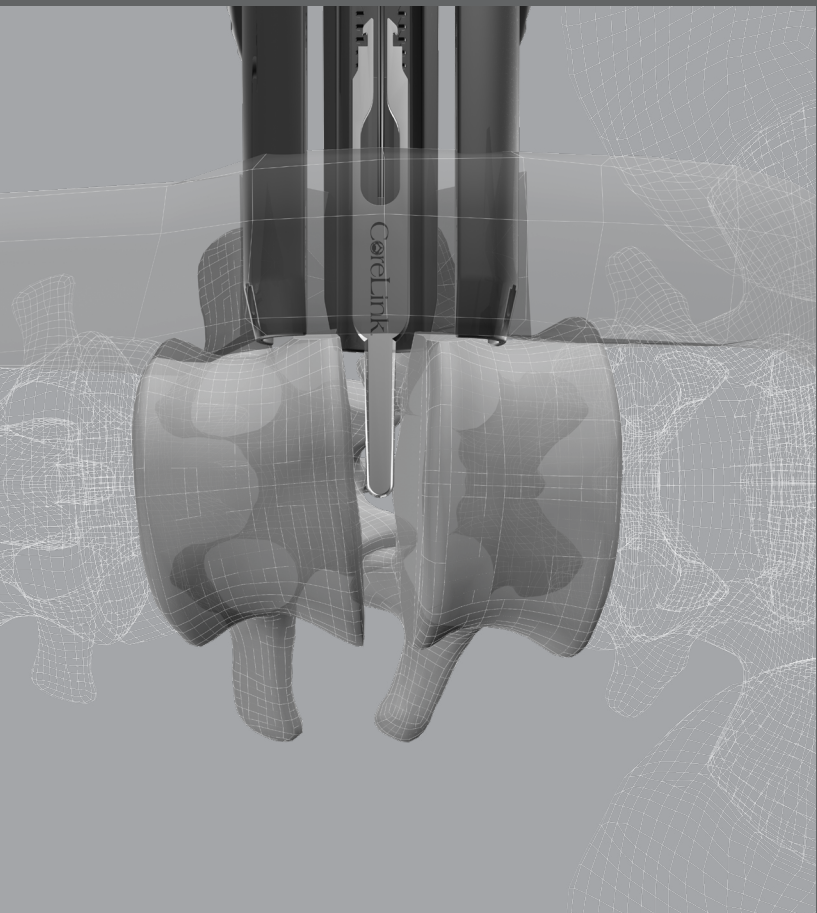
PLATE SELECTION

The CoreLink Oro Lateral Plate System is available in a variety of lengths as well as two-hole and four-hole configurations to best meet the patient requirements. The Lateral Plates are marked with an A indicating Anterior as well as a Plate Reference Number. Corresponding key dimensions are shown in the Plate Size Tables on Page 1.

The Lateral Plates are designed to provide minimal extension past the endplates of the adjacent level vertebral bodies.

Caution: When the Lateral Plate is used with an alternative interbody fusion device, the Lateral Plate size must be verified with the interbody fusion device to ensure that proper placement is achieved. Incorrect implant placement or sizing will result in surgical complications and/or device failure.

FULLY PREPARED SITE



CORELINK ORO LATERAL PLATES



PLATE INSERTION

A lateral interbody may be implanted prior to inserting the Lateral Plate. To avoid unwanted interference between the Lateral Plate and lateral interbody, recess the lateral interbody a minimum of 2mm into the disc space. Once the lateral interbody is correctly positioned, the Lateral Plate can be loaded directly out of the caddy onto the Plate Inserter. The Plate Inserter features spring-loaded stab-and-grab functionality that secures the Plate Inserter to the Lateral Plate.

Ensuring proper orientation, introduce the Lateral Plate into the surgical site and seat against the prepared vertebral bodies. The Plate Inserter can be removed in two different ways: 1) Place the Spring-loaded Awl through a screw hole acting as a temporary fixation pin to allow for the removal of the Plate Inserter or 2) Press the back knob of the Plate Inserter forward to eject the Lateral Plate from the Plate Inserter.

RECESSED INTERBODY PLACEMENT

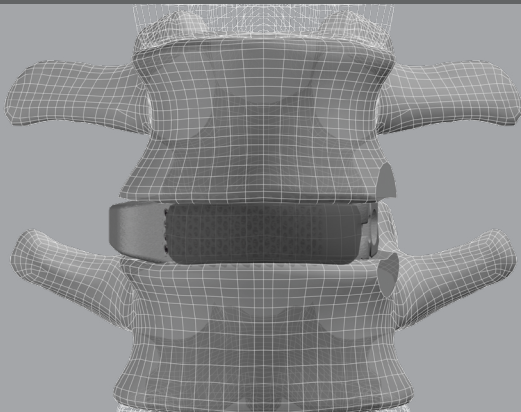


PLATE AND PLATE INSERTER

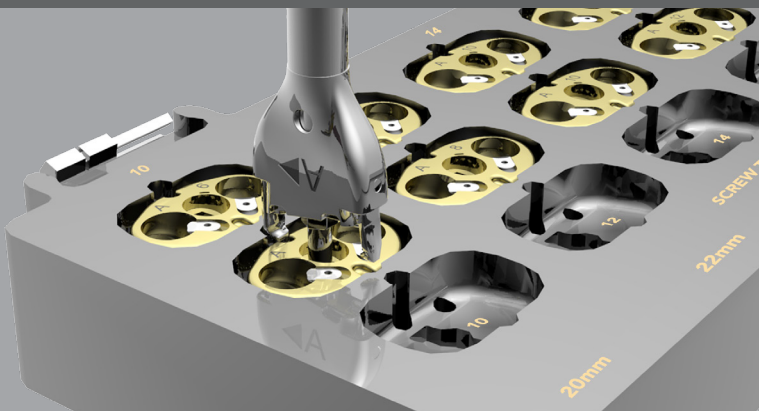
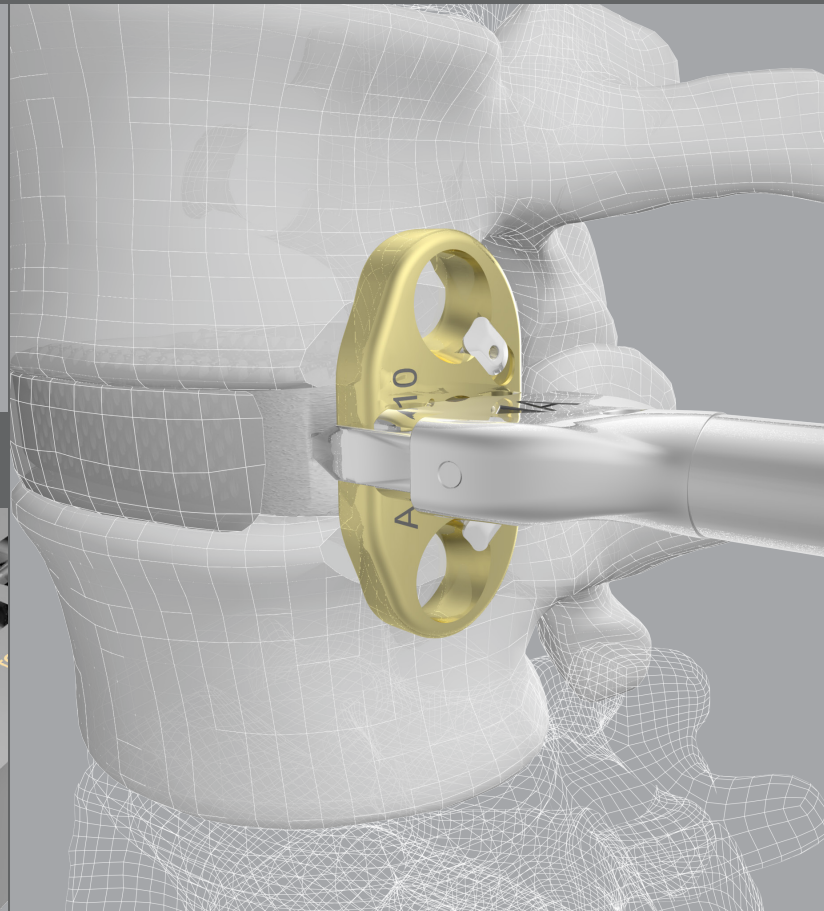


PLATE INSERTER



PILOT HOLE PREPARATION

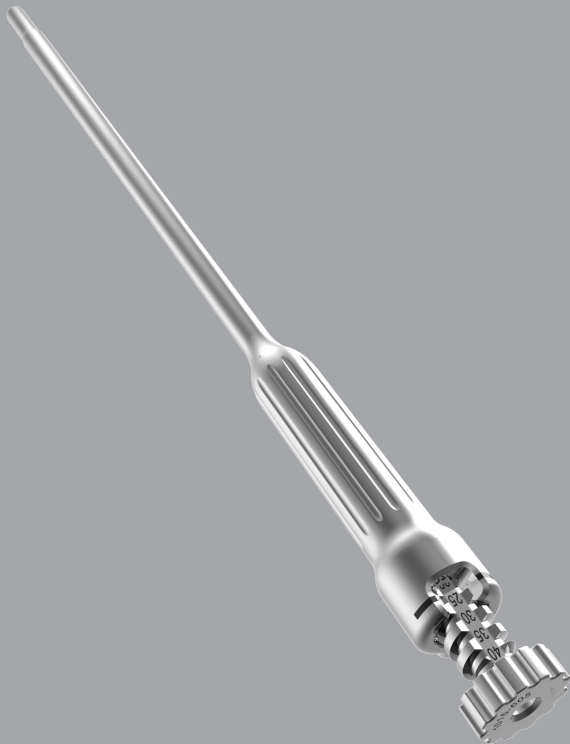
Thread the Depth Stop into the Guide Sleeve to create the Depth Guide Assembly. Use of the Guide Sleeve without the Depth Stop is not recommended and will result in patient injury. The Fixed Awl, Drill, and Tap utilize the Depth Guide Assembly to control hole depth and vary the hole trajectory.

Begin screw hole preparation through the use of either the Fixed Awl and the Depth Guide Assembly or the Spring-Loaded Awl. Ensure the instruments are securely seated in the Lateral Plate before use to prevent damage to the Lateral Plate and instruments. Depth is adjustable from 25mm - 40mm on both the Spring-loaded Awl and the Depth Guide Assembly. Failure to set the desired depth correctly will result in patient injury.

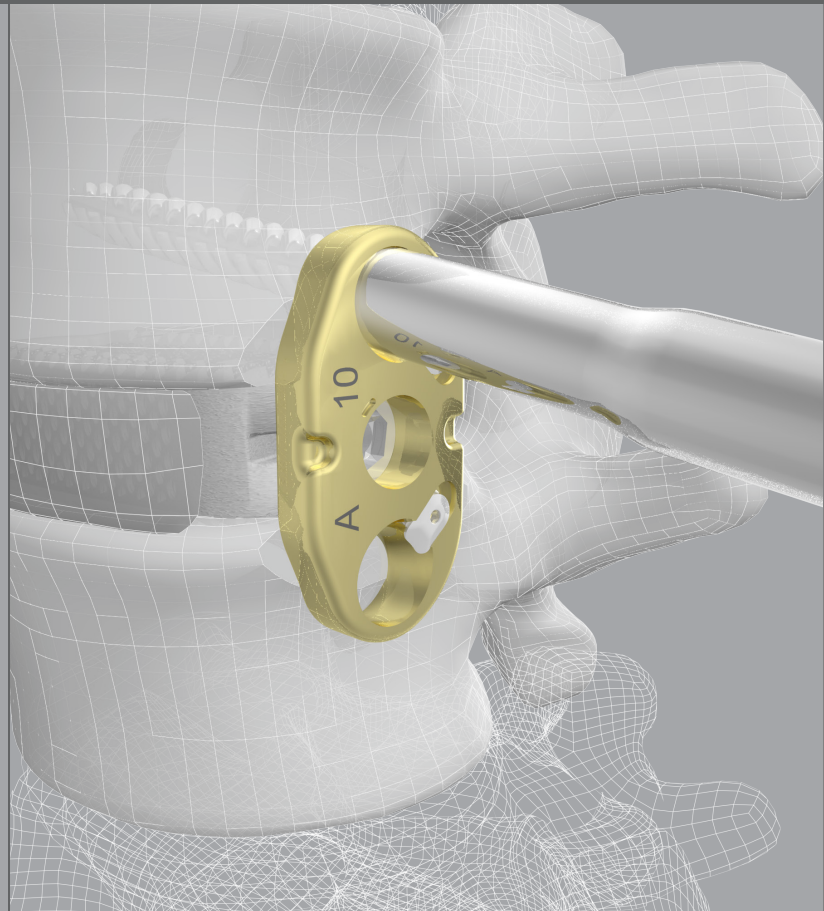
Connect either of the Ratcheting Handles to the Drill and insert through the Depth Guide Assembly. Connect the desired Ratcheting Handle to the Tap and insert through the Depth Guide Assembly. Tapping is required to prevent screw failure during insertion.

Application of excessive force to the Awls, Drill, or Tap will result in instrument failure. Use of powered instruments with the supplied screw preparation instruments is not recommended.

DEPTH GUIDE ASSEMBLY



TAP



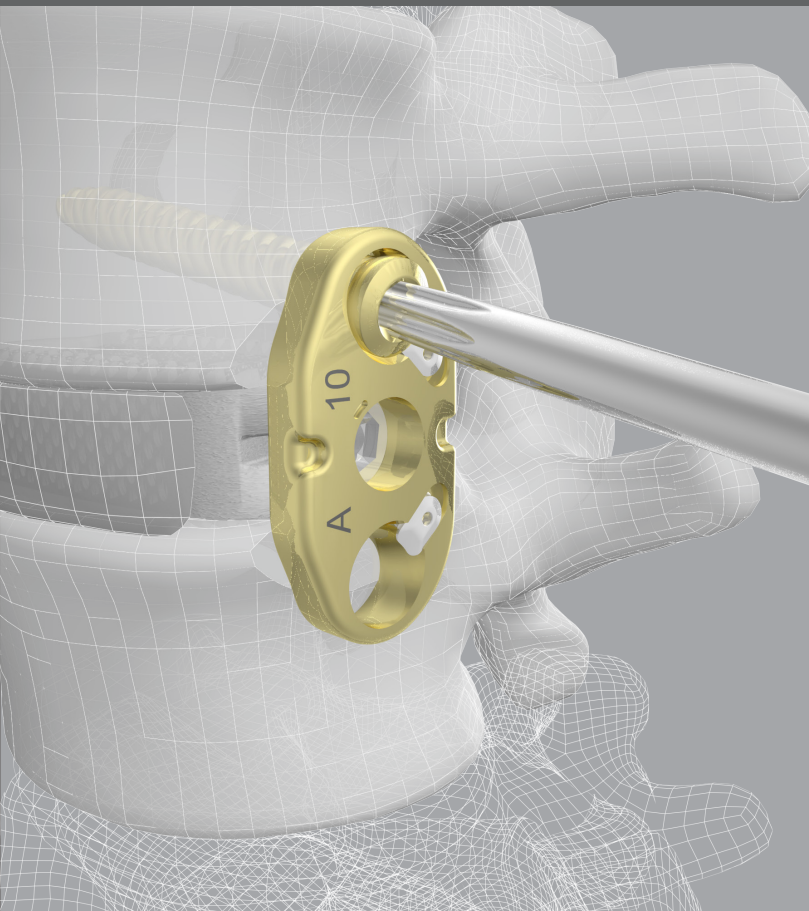
SCREW INSERTION

Attach the desired Ratcheting Handle to the Driver. Determine proper Screw length and load the Screw to the Driver. The Driver features a self-retaining tip.

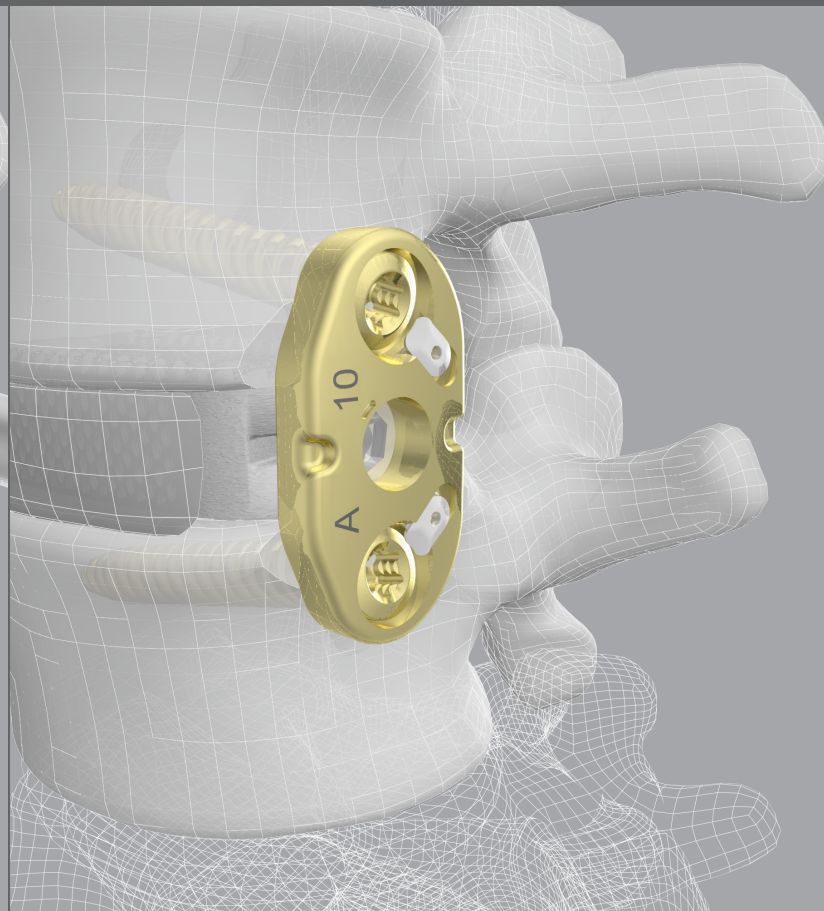
Drive the Screw through the Lateral Plate until fully seated. The Screw Lock will automatically move to allow Screw passage, returning to the locked position once the Screw is fully seated. Verify that Screw Locks are in locked position visually.

Verify Screw placement and trajectory using fluoroscopy. If alternate placement is desired, the Screw can be removed as described in Screw Removal. Repeat steps for all remaining Screws. For four-hole Lateral Plates, a crisscross sequence is recommended for even Lateral Plate seating.

SCREW AND DRIVER



SCREWS IN FINAL POSITION AND LOCKED

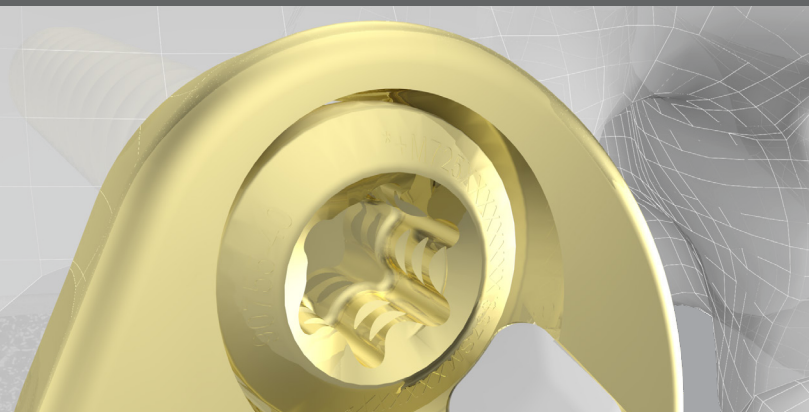


SCREW REMOVAL

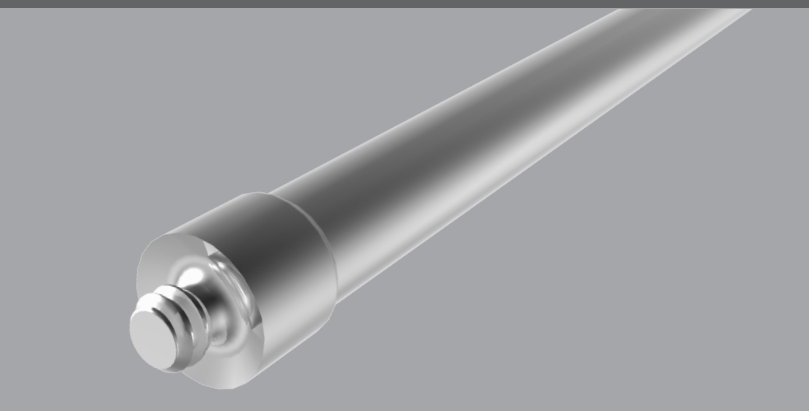
There are two methods for removing the Screws. To maintain Screw integrity for situations such as changing Screw trajectory, see below. For a destructive method for situations such as revision surgery, see the next page.

The first method of Screw removal utilizes the Bone Screw Remover and a Ratcheting Handle. The Bone Screw Remover features a reversed threaded tip which mates with reverse threads inside of the hexalobe of the Screw. Thread the Bone Screw Remover into the Screw in the counterclockwise direction. The Bone Screw Remover will automatically retract the Screw Lock, allowing Screw removal.

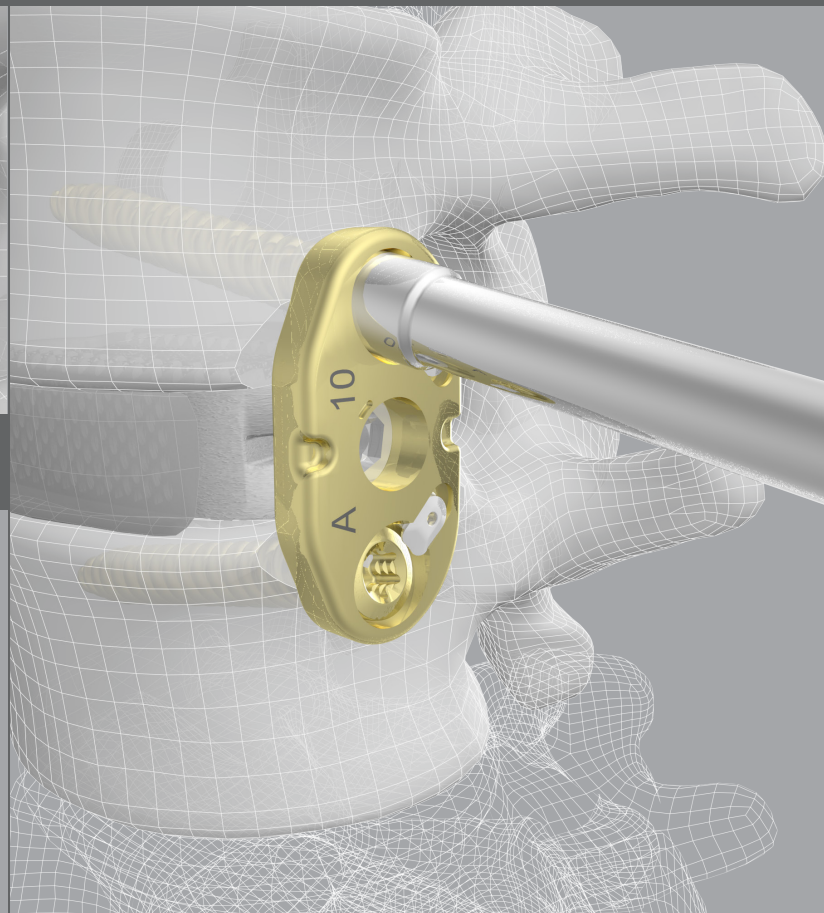
SCREW THREADS



BONE SCREW REMOVER



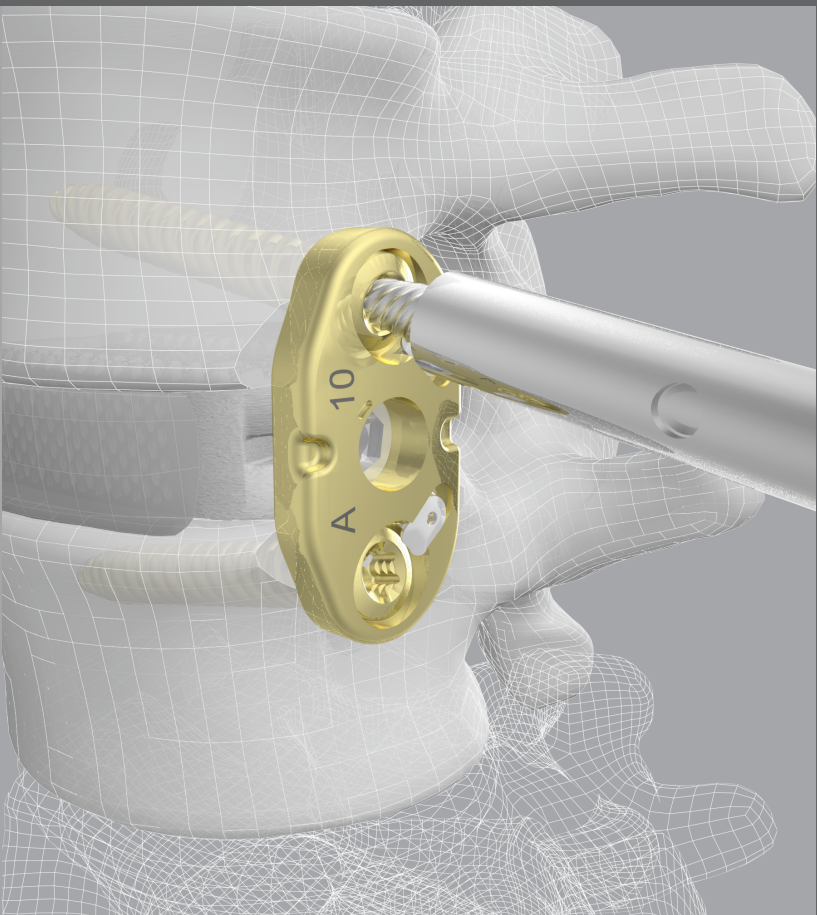
SCREW REMOVAL



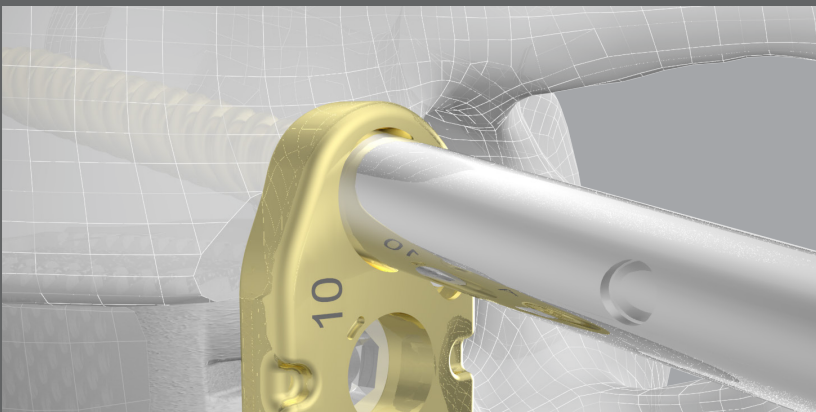
Alternatively, the Screws can be destructively removed using the Rescue Extractor, Lock Actuator, and a Ratcheting Handle. Fully thread the Lock Actuator onto the Rescue Extractor and attached a Ratcheting Handle. Thread the Rescue Extractor into the hexalobe in a counterclockwise motion until the Screw begins to back out then stop. Thread the Lock Actuator forward until it fully seats against the Screw and has retracted the Screw Lock. Continue the counterclockwise movement of the Rescue Extractor to fully remove the Screw.

Screws that are removed or extracted must be discarded and must not be reused.

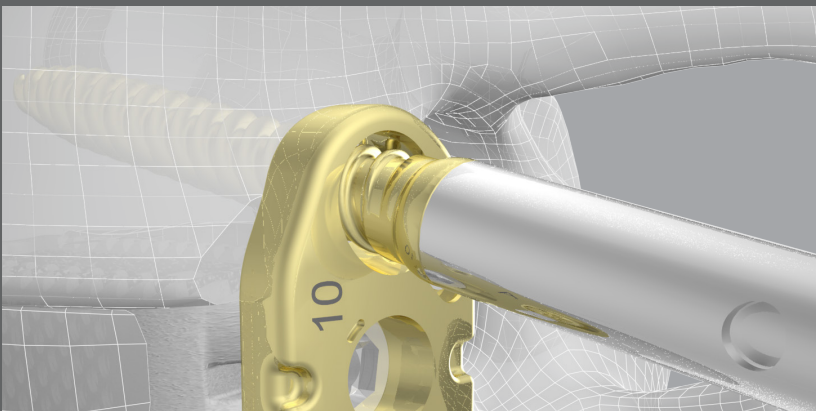
SCREW EXTRACTOR POSITIONED



LOCK ACTUATOR POSITIONED



SCREW REMOVAL



IMPLANT REMOVAL

Once the Screws have been removed, introduce the Plate Inserter to the surgical site and secure it to the Lateral Plate before removing from the surgical site.

PLATE WITH PLATE INSERTER

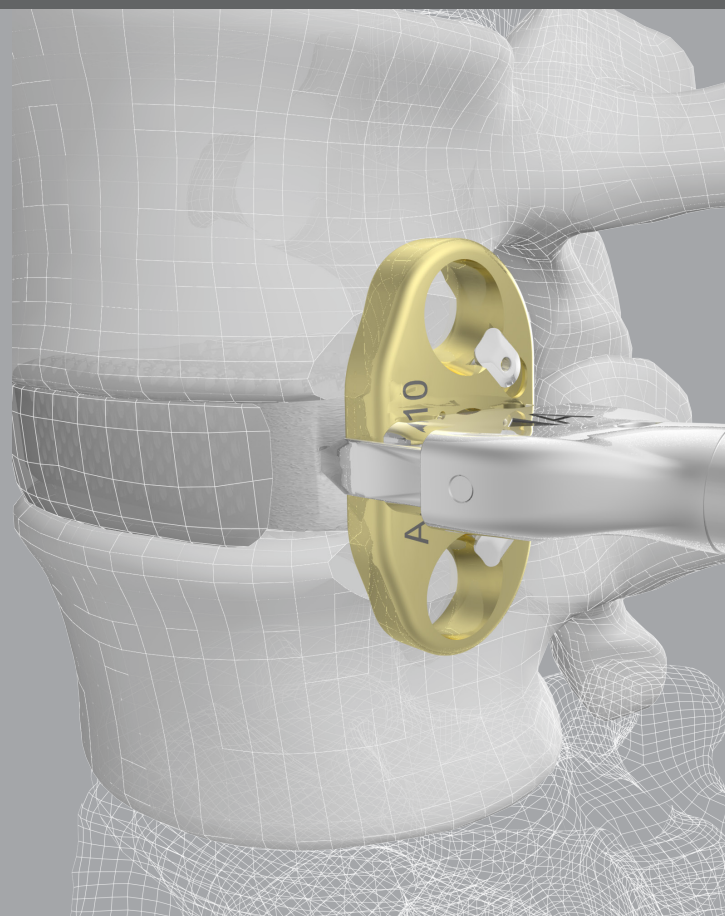
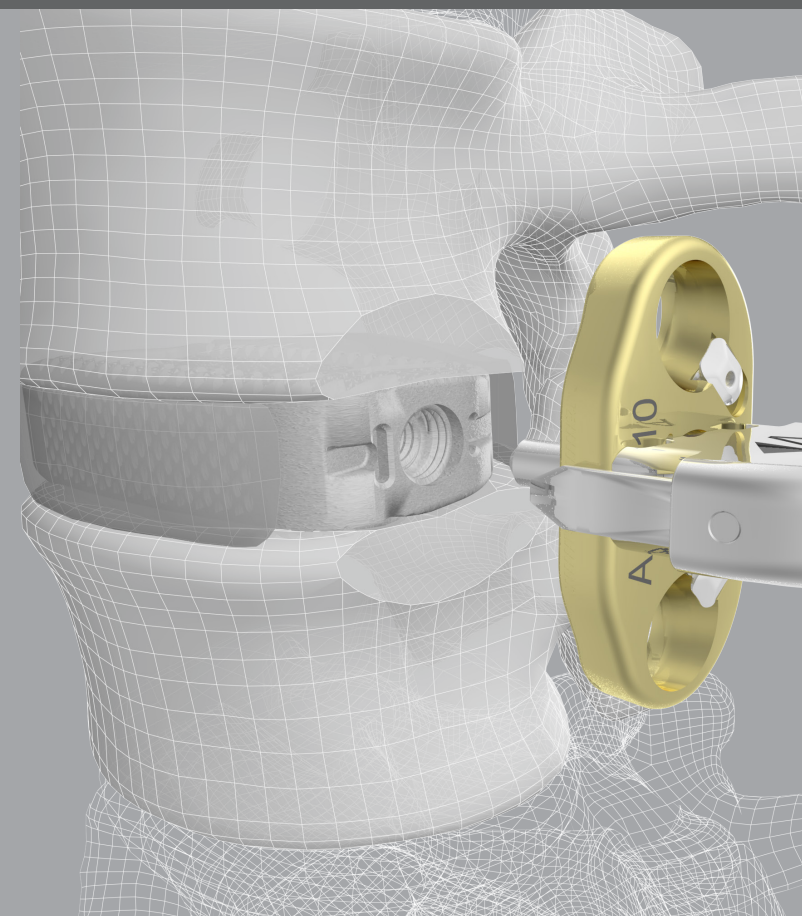


PLATE REMOVAL



INSTRUCTIONS FOR USE

CORELINK ORO LATERAL PLATE SYSTEM



OPERATING SURGEON – IMPORTANT INFORMATION

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 code on the product labeling.

DESCRIPTION

The CoreLink Oro Lateral Plate System consists of implants (plates and screws) intended for use as a laterally 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 Oro Lateral Plate System are manufactured from the following materials:

- Medical grade Titanium Alloy (Ti6Al4V per ASTM F136)
- Medical grade Nitinol (Nickel-Titanium Alloy per ASTM F-2063)

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 Oro Lateral 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 Oro Lateral Plate System implants or implant components should be reused under any circumstances. The instruments provided with the Oro Lateral Plate System are provided specifically for the implantation of the Oro Lateral 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 Oro Lateral Plate System Surgical Technique Manual for additional important information about specific CoreLink implants, in addition to the information described herein.

INDICATIONS

The CoreLink Oro Lateral Plate System (LPS) is intended for use as a laterally placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessel or via the anterior surgical approach, below the bifurcation of the great vessels. The CoreLink Oro Lateral Plate System is designed to provide temporary stability until fusion is achieved. It is intended for lateral or anterolateral 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, pseudarthrosis, and failed previous fusion.

Alternatively, the CoreLink Oro Lateral Plate System may remain attached to CoreLink Lateral lumbar interbody devices after implantation. In this configuration the CoreLink Oro LPS must only be used to treat patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels.

CONTRAINDICATIONS

Do not use the CoreLink Oro Lateral 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 may be required to correct these potential 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 (L2-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 Oro Lateral 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 Oro Lateral 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 Oro Lateral 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 Oro Lateral Plate System has not been evaluated for safety and compatibility in the MR environment. The CoreLink Oro Lateral Plate System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the CoreLink Oro Lateral 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 Oro Lateral 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 Oro Lateral 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.

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 implant surface or configuration.
- Pay particular attention to recesses as chemicals and rinse water may be entrapped in the recess after rinsing.
- Visually inspect all devices after cleaning to ensure cleanliness and function.

STERILIZATION INSTRUCTIONS

Implants and instruments of the CoreLink Oro Lateral 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 Oro Lateral 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 JK440, JK442, JK444, JK446 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 Oro Lateral 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 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:



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corelinksurgical.com | (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 manufacturer's batch code so that the batch or lot can be identified.	5.1.5
	Reference Number – Indicates manufacturer'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

STANDARD ORO LATERAL PLATE 1 KIT

KIT ORDER #K5000371

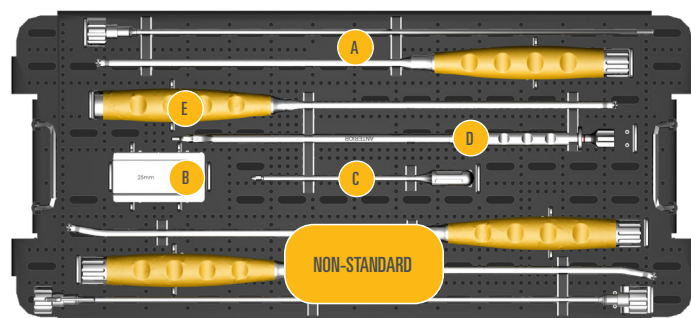
INSTRUMENTS		
QTY	CATALOG NUMBER	DESCRIPTION
1	2801-105	CONSTRUCT INSERTER
1	6310-010	CONSTRUCT ASSEMBLY BLOCK
1	2801-115	ALIGNMENT DRIVER
1	2801-118	PLATE INSERTER
1	1015-700	TAMP
1	2801-120	EXTENDED SET SCREW DRIVER
0*	2801-106	CONSTRUCT INSERTER ANGLED LEFT
0*	2801-107	CONSTRUCT INSERTER ANGLED RIGHT

TWO-HOLE PLATES		
QTY	CATALOG NUMBER	DESCRIPTION
2	900215-16	15MM X 16MM
2	900215-18	15MM X 18MM
2	900215-20	15MM X 20MM
2	900215-22	15MM X 22MM
2	900215-24	15MM X 24MM

FOUR-HOLE PLATES - SPECIAL ORDER		
QTY	CATALOG NUMBER	DESCRIPTION
0*	900415-20	15MM X 20MM
0*	900415-22	15MM X 22MM
0*	900415-24	15MM X 24MM
0*	900415-26	15MM X 26MM
0*	900415-28	15MM X 28MM

TOP TRAY

- A Construct Inserter
- B Assembly Block
- C Alignment Driver
- D Plate Inserter
- E Tamp



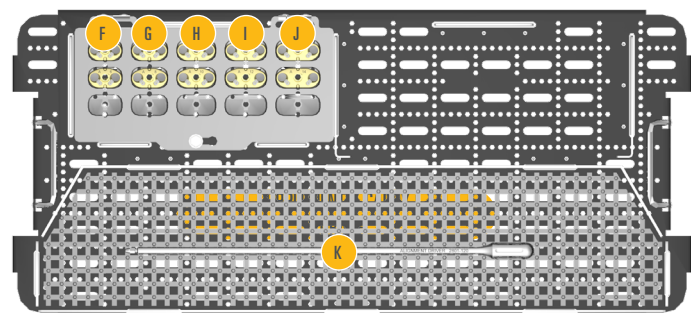
BOTTOM TRAY

TWO-HOLE PLATE

- F 15mm x 16mm
- G 15mm x 18mm
- H 15mm x 20mm
- I 15mm x 22mm
- J 15mm x 24mm

INSTRUMENTS

- K Extended Set Screw Driver



* Noted items are non-standard and available upon request.

STANDARD ORO LATERAL PLATE 2 KIT

KIT ORDER #K5000382

INSTRUMENTS

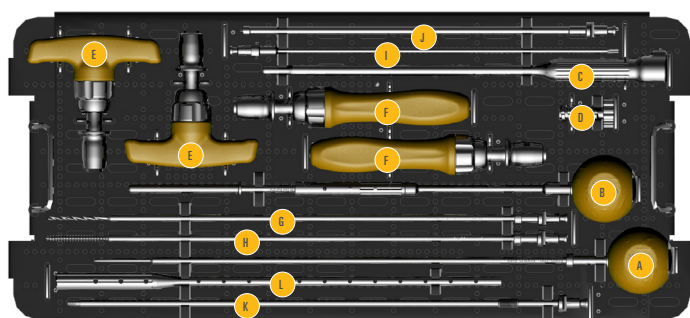
QTY	CATALOG NUMBER	DESCRIPTION
1	5060-103	FIXED AWL
1	5025-341	SPRING-LOADED AWL
1	1015-603	GUIDE SLEEVE - VARIABLE
1	1015-605	DEPTH STOP
2	8135-100	T-HANDLE
2	8235-100	STRAIGHT HANDLE
1	1015-341	DRILL
1	1015-500	TAP
1	2015-100	BONE SCREW DRIVER
1	2015-101	BONE SCREW REMOVER
2	2015-102	RESCUE BONE SCREW EXTRACTOR
1	2015-103	LOCK ACTUATOR
0*	2015-104	BONE SCREW DRIVER, STIFFENED

SCREWS

QTY	CATALOG NUMBER	DESCRIPTION
4	90755-25	5.5MM X 25MM
4	90755-30	5.5MM X 30MM
8	90755-35	5.5MM X 35MM
8	90755-40	5.5MM X 40MM
8	90755-45	5.5MM X 45MM
8	90755-50	5.5MM X 50MM
8	90755-55	5.5MM X 55MM
4	90755-60	5.5MM X 60MM
0*	90755-65	5.5MM X 65MM
4	90760-25	6MM X 25MM
4	90760-30	6MM X 30MM
8	90760-35	6MM X 35MM
8	90760-40	6MM X 40MM
8	90760-45	6MM X 45MM
8	90760-50	6MM X 50MM
8	90760-55	6MM X 55MM
4	90760-60	6MM X 60MM
0*	90760-65	6MM X 65MM

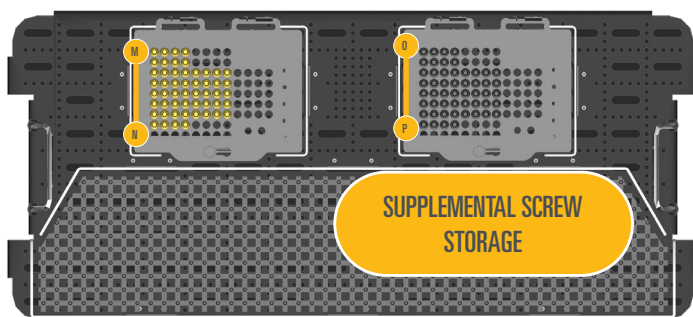
TOP TRAY

- A** Fixed awl
- B** Spring-loaded Awl
- C** Guide Sleeve - Variable
- D** Depth Stop
- E** T-handle
- F** Straight Handle
- G** Drill
- H** Tap
- I** Bone Screw Driver
- J** Bone Screw Remover
- K** Rescue Bone Screw
- L** Lock Actuator



BOTTOM TRAY

- M** 5.5mm screws from small
- N** to large
- O** 6.5mm screws from small
- P** to large



* Noted items are non-standard and available upon request.

NOTES

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.



INSIGHT | PERFORMANCE | VALUE

CoreLinkSurgical.com

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Designed and manufactured in St. Louis, MO 63026

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CL-FORM-307 Rev. 3