CENTINEL SPINE®

FORTOS-C™

Anterior Cervical Plating System

SURGICAL TECHNIQUE GUIDE

FORTOS-C™

Cervical Plating System

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CENTINEL SPINE®

A dedicated spine company with a singular focus

30+ YEARS OF CLINICAL SUCCESS SINCE 1988

About Centinel Spine

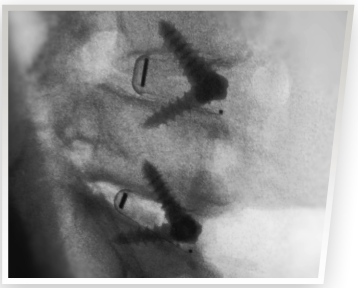
Centinel Spine was founded in 2008 through the merger-acquisition of two pioneering medical device companies (Raymedica, LLC and Surgicraft LTD.) and is the largest privately-held spine company focused on anterior column reconstruction. The company offers a continuum of motion-preserving and fusion solutions—providing the most robust Total Disc Replacement and Integrated Interbody™ portfolios in the world.

Pioneering Integrated Interbody Solutions

The Stand-Alone/No Profile® device category was founded in 1988 with the release of the Hartshill Horseshoe product, the foundation for the technology platform known today as **STALIF®**. Centinel Spine remains a leader in Stand-Alone solutions today, with over 30 years of clinical history and over 75,000[1] devices implanted. **STALIF** still remains the only Stand-Alone device demonstrating biomechanical equivalence to anterior plate & cage in independent peer-reviewed publications.[2,3]

STALIF technology incorporates a proven design rationale based on AO principles of fracture fixation and Wolff's Law of Bone Healing. The No Profile design utilizes unique integrated compressive lag fixation technology to enhance stability and compress endplates to the cage and graft material. The system utilizes simple, elegant instrumentation — perfected over years of clinical use and proven to reduce surgical time by 40%, compared to reported alternatives.[4,5] **STALIF** technology is currently available in PEEK, **Ti-ACTIVE**™ microporous texturized titanium surface, and **FLX**™ proprietary 3D-Printed titanium trabecular scaffold.

STALIF® For Fusion

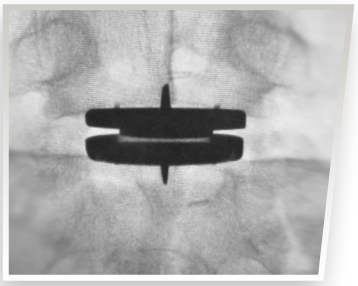


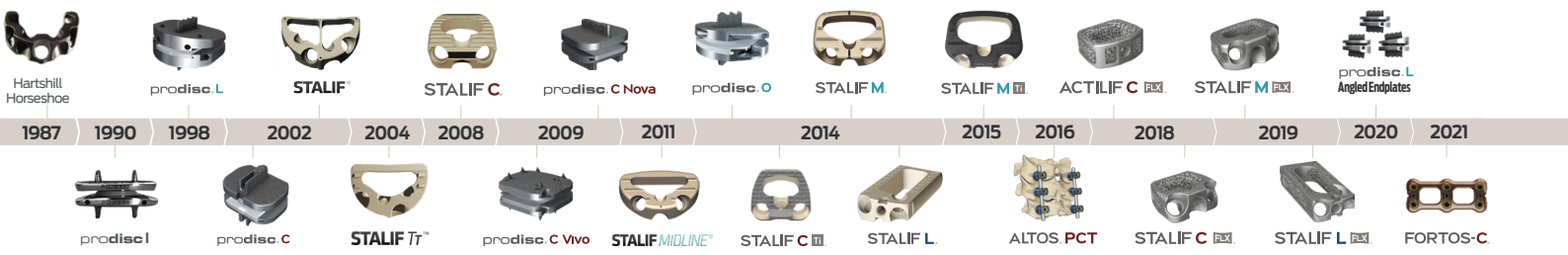
Clinically-Proven Motion Preservation

Centinel Spine couples its market-leading fusion portfolio with best-in-class prodisc Total Disc Replacement (TDR) technology. Centinel Spine offers an unmatched number of six cervical / lumbar TDR products, globally, and is the only company with both lumbar and cervical approval in the U.S. No other disc replacement system has been studied to this extent, with over 13,000 patients reported on in more than 540 articles over a global clinical usage period of almost 30 years.[6]

prodisc®, the most clinically-proven Total Disc Replacement system in the world, utilizes a mechanism of action to deliver predictable and controlled motion. The prodisc product line provides surgeons with a variety of options to suit a patient's activity levels and anatomy, as well as a variety of endplate configurations to suit different degenerative conditions. The prodisc design has been validated with over 225,000 device implantations and a reported reoperation rate of less than 1%.[7]

prodisc® For Motion





Device Description

The **FORTOS-C** Anterior Cervical Plating System implant components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The implantation of the **FORTOS-C** Anterior Cervical Plating System is via an anterior surgical approach.

The **FORTOS-C** Anterior Cervical Plating System consists of a variety of bone plates and screws. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The **FORTOS-C** Plates include a blocking mechanism that cover the heads of the bone screws to reduce the potential for screw back-out. The blocking mechanisms come preassembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The **FORTOS-C** Anterior Cervical Plating System implant components are made from titanium alloy such as described by ASTM F136. This material is not compatible with other metal alloys. Do not use any of the **FORTOS-C** Anterior Cervical Plating System components with the components from any other system or manufacturer.

Indications for Use

The **FORTOS-C** Anterior Cervical Plating System is intended for anterior cervical fixation (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Contraindications

Contraindications include, but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

Complications & Potential Adverse Effects

All of the possible adverse effects associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, micro fracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Non-union (or pseud-arthrosis). Delayed union. Mal union.
- Loss of spinal mobility or function. Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retro pulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

Warnings & Precautions

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The **FORTOS-C** Anterior Cervical Plating System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the **FORTOS-C** Anterior Cervical Plating System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone.

In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the **FORTOS-C** Anterior Cervical Plating System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

Magnetic Resonance Environments

The **FORTOS-C** Anterior Cervical Plating System has not been evaluated for safety and compatibility in the MR environment. The **FORTOS-C** Anterior Cervical Plating System has not been tested for heating or migration in the MR environment.

Physician Note

Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

Caution

FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

Other Prepoperative, Intraoperative, & Postoperative warnings are as follows.

Implant Selection

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The **FORTOS-C** Anterior Cervical Plating System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative

- Refer to the surgical technique guide for instruction on how to implant the **FORTOS-C** construct.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device. The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
- Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
- Before closing the soft tissues, all screws should be fully seated in the plate and below the blocking mechanism. Recheck the tightness of all screws.

  Caution: Excessive torque on the screw threads may cause the threads to strip in the bone, reducing fixation. Carefully rotate each blocking mechanism over the heads of the bone screws. Rotate each blocking mechanism to reach its stop position. Failure to cover the screw heads with the blocking mechanism may result in screw back out.

Postoperative

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- The **FORTOS-C** Anterior Cervical Plating System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. In most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur:
  1. Corrosion, with localized tissue reaction or pain.
  2. Migration of implant position possibly resulting in injury.
  3. Risk of additional injury from postoperative trauma.
  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. Possible increased risk of infection.
  7. Bone loss due to stress shielding.
- The surgeon makes the final decision on implant removal. If safe and practical, bone fixation devices can be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.
- The **FORTOS-C** Anterior Cervical Plating System implants should never be reused under any circumstances.

Packaging

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used.

Decontamination & Cleaning

All instruments and implants must be disassembled (if applicable), and thoroughly cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field, or (if applicable) returned to Centinel Spine. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Follow the enzymatic cleaner of detergent manufacturer's instruction for use for correct exposure time, temperature, water quality, and concentration.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. No visual contamination shall be present after cleaning, so the instruments shall be re-cleaned if they are not visually clean.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

Sterilization

Unless noted otherwise on the package labeling, the **FORTOS-C** Anterior Cervical Plating System components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Item	Exposure time at 132 °C (270 °F)	Drying Times
Wrapped Tray	4 min	20-30 min

Remove all packaging materials prior to sterilization. Use only FDA-cleared wraps. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and sterilize before handling or returning to Centinel Spine.

Product Complaints

Please contact Centinel Spine regarding any deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of **FORTOS-C** Anterior Cervical Plating System.

Centinel Spine should be notified immediately if malfunction or deterioration in the characteristics and / or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, user or other person, or to a serious deterioration in their state of health.

When reporting a complaint, please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint.

complaints@centinelspine.com

Instrument Overview

Self-Retaining Screw Driver
13-90-001

Plate Locking Driver
13-90-002

Temporary Fixation Pin
13-90-003

Temporary Fixation Pin Inserter
13-90-004M

Plate Holder - Internal
13-90-007

Tap, 10mm
13-90-011-10

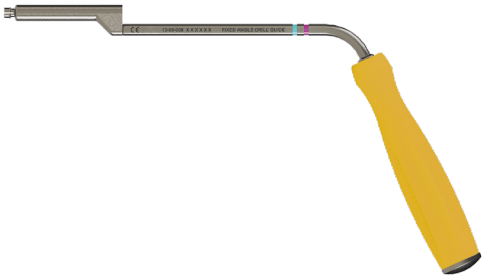
Non-Ratcheting Axial Handle
13-90-013M

Shielded Spring Loaded Awl
13-90-014M

Drill Bits
13-90-015-10
13-90-015-12
13-90-015-14
13-90-015-16
13-90-015-18

Revision Driver
13-90-017M

Plate Bender
13-90-005



Fixed Angle Drill Guide
13-90-008M

Variable Angle Drill Guide
13-90-010M

Implant Overview

PLATE FEATURES

Simple, One-Step Blocking Mechanism

- Included at Each Level with Visible Lock Verification

Open Plate Architecture

- Enables Central Visualization
- Enables Graft & Anatomical Landmark Identification

Scalloped Sides

- For Lateral Visualization

Smooth Surface, Low Profile Design

- Optimized For Patient Comfort

Pre-Contoured Lordosis

- Plates are Available in a Large Assortment of Lengths to Simplify the Surgical Procedure

Radially Contoured

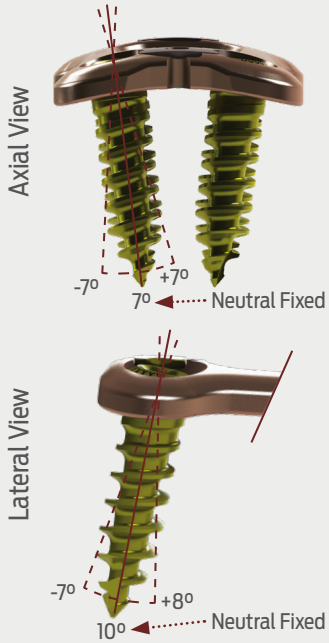
PLATE SIZES

Length (mm)	Level 1	Level 2	Level 3
	10	24	39
	12	26	42
	14	28	45
	16	30	48
	18	32	51
	20	34	54
	22	37	57
	24	40	60
	26	43	63
		46	66
			69

Plate Length: Distance Between Screw Holes

SCREW FEATURES

Variable Screw Angulation

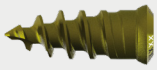


Self-Drilling, Self-Tapping, Fixed & Variable Angle Screws

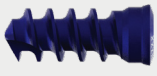
- For Hybrid Constructs


Fixed, 4.0mm Self-Drilling
Magenta


Fixed, 4.0mm Self-Tapping
Light Blue


Variable, 4.0mm Self-Drilling
Gold


Variable, 4.0mm Self-Tapping
Light Green


Fixed, 4.3mm Self-Tapping
Dark Blue

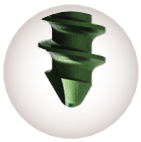

Variable, 4.3mm Self-Tapping
Dark Green


Enhanced Screw & Driver Interface

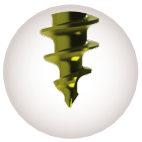
SCREW SIZES

Length (mm)	Diameter (mm) 4.0	4.3	4.0
	10	10	10
	12	12	12
	14	14	14
	16	16	16
	18	18	18

Self-Tapping



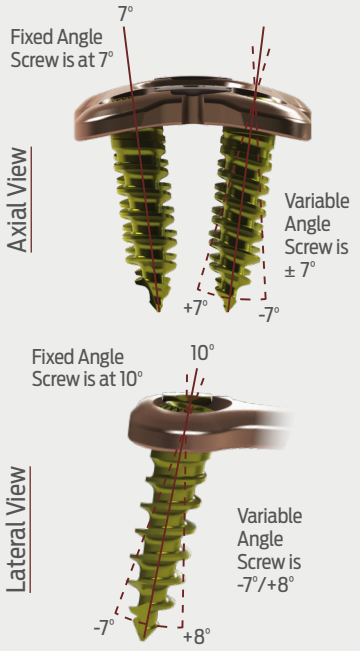
Self-Drilling



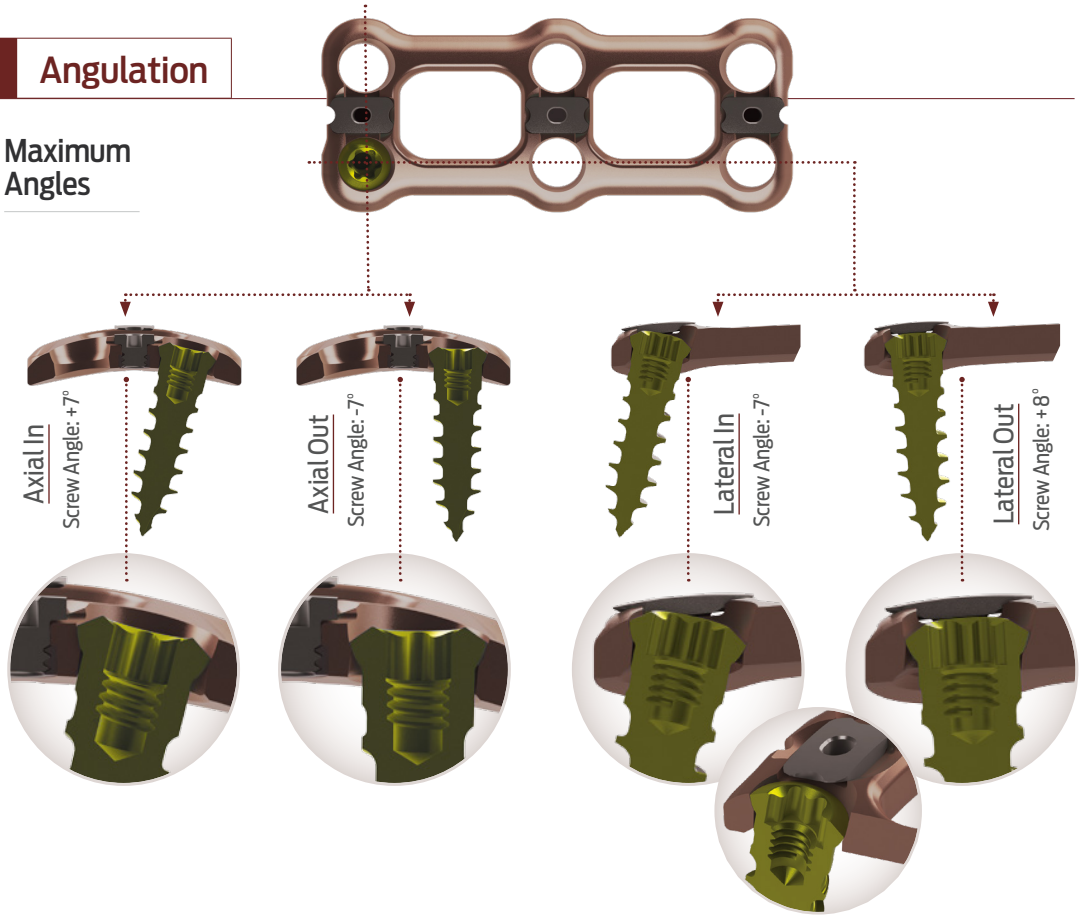
Screw Length: Amount of Purchase Below Plate

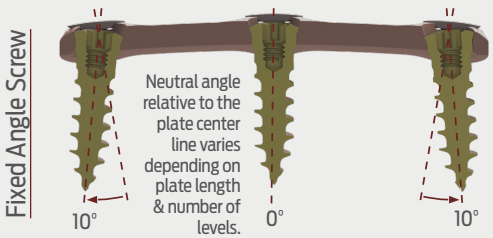
SCREW PLACEMENT Angulation

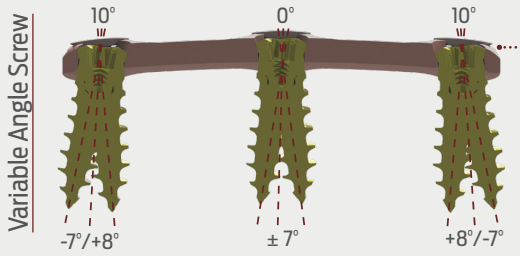
Screw Angulation Measurements



Maximum Angles







NOTE: Even at maximum convergence, the screw head is flush respective to the plate and below the blocking mechanism.

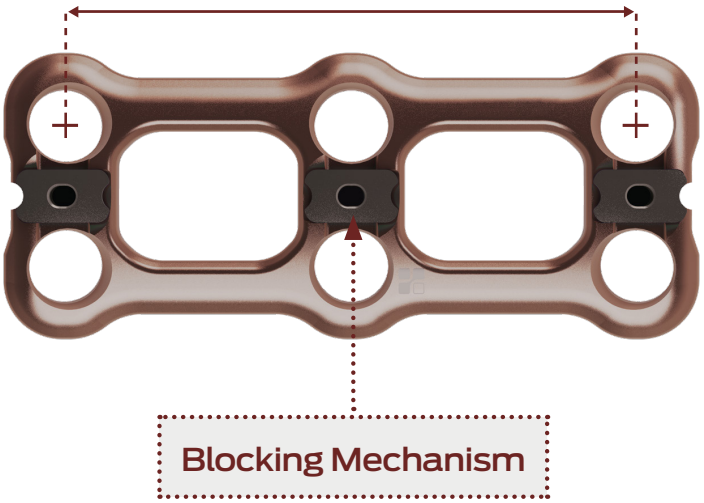
CRITICAL DIMENSIONS	Diameter (mm)	Purchase Below Plate (mm)
Temporary Fixation Pin	2.1	9.5
Awl	2.3	8.5

Surgical Technique

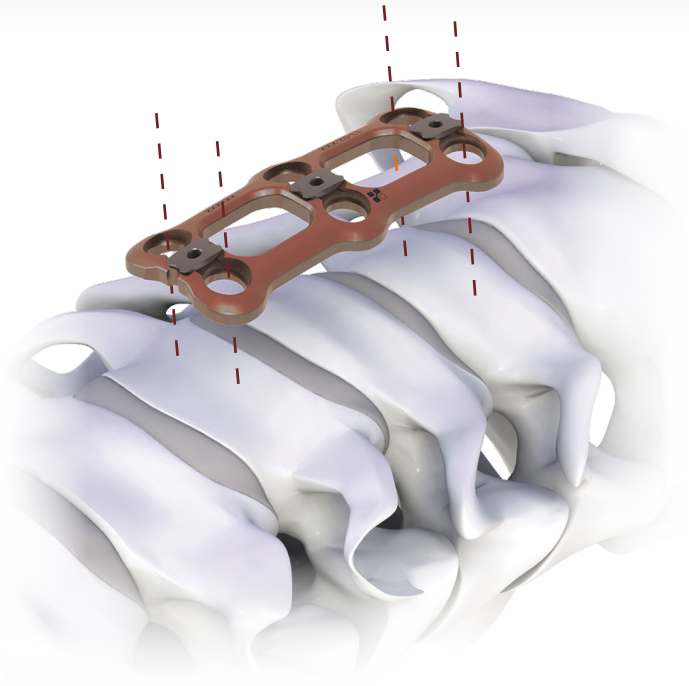
Preparation & Sizing

Select the appropriately sized plate. The plate length is measured from the most superior hole center to the most interior hole center **(Figure 1)**.

1. Plate Sizing



2. Aligning the Plate



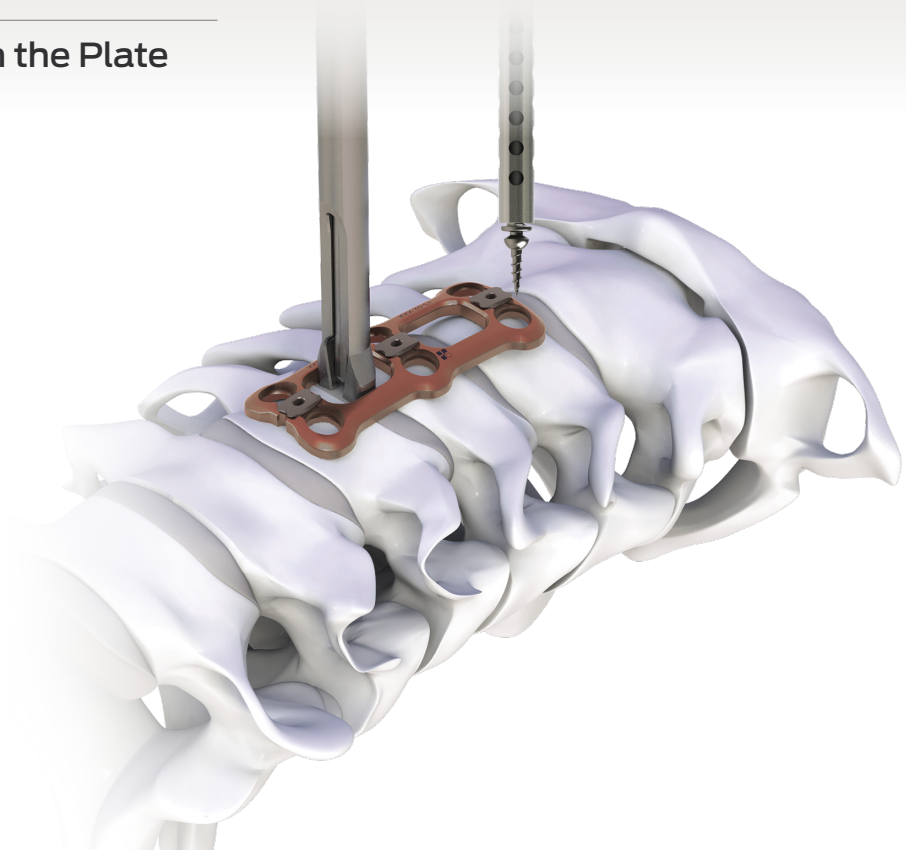
please NOTE *Plate length is measured from most superior hole center to most inferior hole center (Figure 1).*

Use the Plate Holder to position the plate into the operative site for placement and sizing verification **(Figure 3)**.

Fluoroscopy can be used to confirm plate position.

Plate Holder - Internal
13-90-007

3. Positioning the Plate with the Plate Holder



tech TIP

Verify that the size of plate selected allows the screws to be inserted within the range of angulation.

Surgical Technique (Cont'd)

Plate Contouring

The plate is precontoured with lordosis. Should additional contouring be required, the plate can be contoured to the desired degree of lordosis or kyphosis utilizing the Plate Bender. The Plate Bender does not remove lordosis.

Insert the plate into the Plate Bender as shown. Squeeze the handles of the Plate Bender together to contour the plate **(Figure 4)**.

Plate Bender
13-90-005

4. Contouring the Plate with the Plate Bender

***please* NOTE** *Do not place the Plate Bender over the blocking mechanism, as damage can occur and affect its function.*

Contouring along the graft window, starting from outer edge working inward, helps ensure an even contour of the plate **(Figures 5 & 6)**.

5. Contouring the Plate Along the Graft Window from the Outer Edge

6. Contouring the Plate Working Inwards

please NOTE *When contouring the plate, care should be taken not to scratch, notch or dent the surface of the plate or the blocking mechanism, as the implant strength may be compromised. Single level plates 26mm or shorter should not be contoured.*

Surgical Technique (Cont'd)

Implant Delivery

Before surgery the plate should be inspected to make sure that the blocking mechanisms are in the unlocked position (vertically aligned to the length of the plate) **(Figure 7)**.

Ensure the plate is properly aligned with respect to the end plates. Use the Temporary Fixation Pin to hold the plate stationary for screw placement.

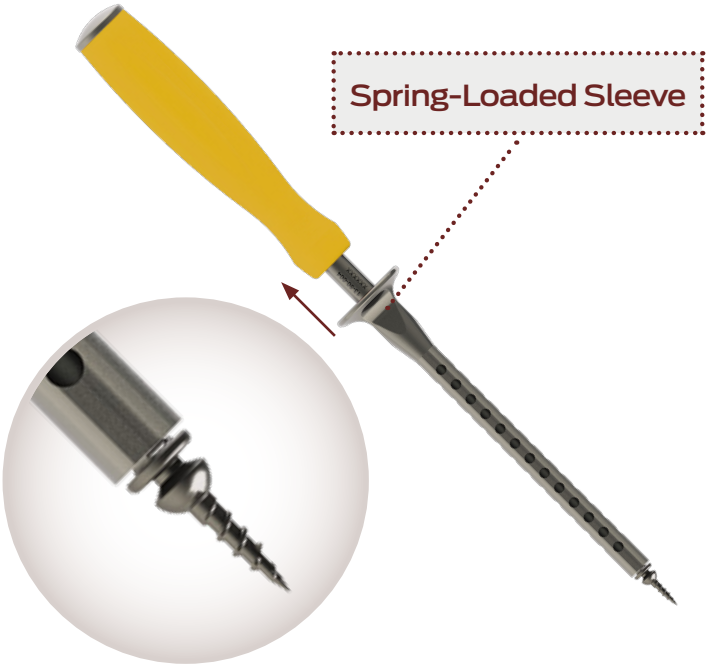
Load the Temporary Fixation Pin onto the Temporary Fixation Pin Inserter by pulling up on the spring loaded sleeve on the Temporary Fixation Pin Inserter **(Figure 8)**.

Temporary Fixation Pin
13-90-003

Temporary Fixation Pin Inserter
13-90-004M

7. Locking Mechanisms in the Unlocked Position

8. Attaching the Temporary Fixation Pin onto the Temporary Fixation Pin Inserter

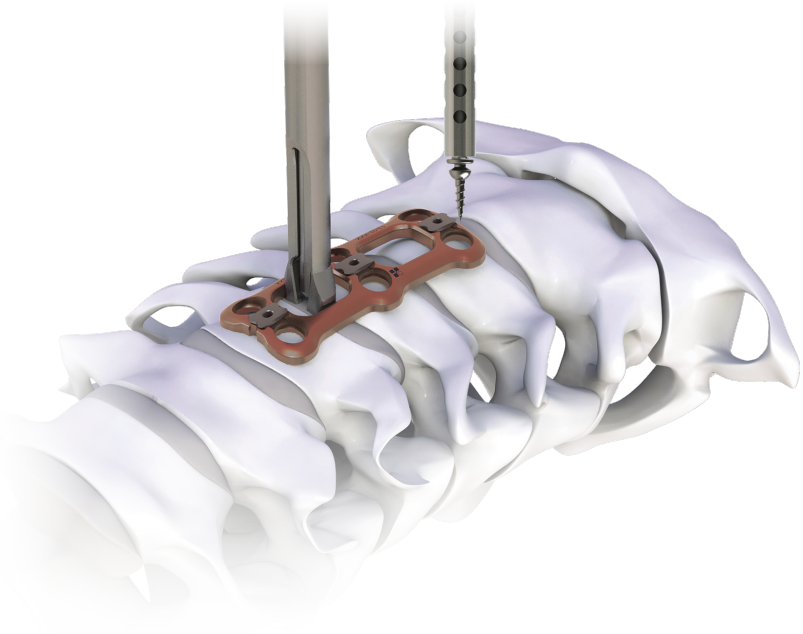


tech TIP

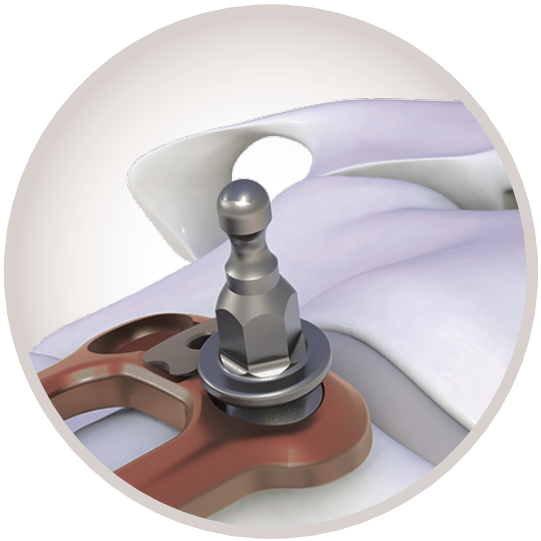
Before surgery the plate should be inspected to make sure that the blocking mechanisms are in the unlocked position (vertically aligned to the length of the plate).

Advance the Temporary Fixation Pin until it is fully seated in the plate **(Figures 9 & 10)**.

9. Inserting the Temporary Fixation Pin



10. Temporary Fixation Pin Fully Seated in the Plate



Surgical Technique (Cont'd)

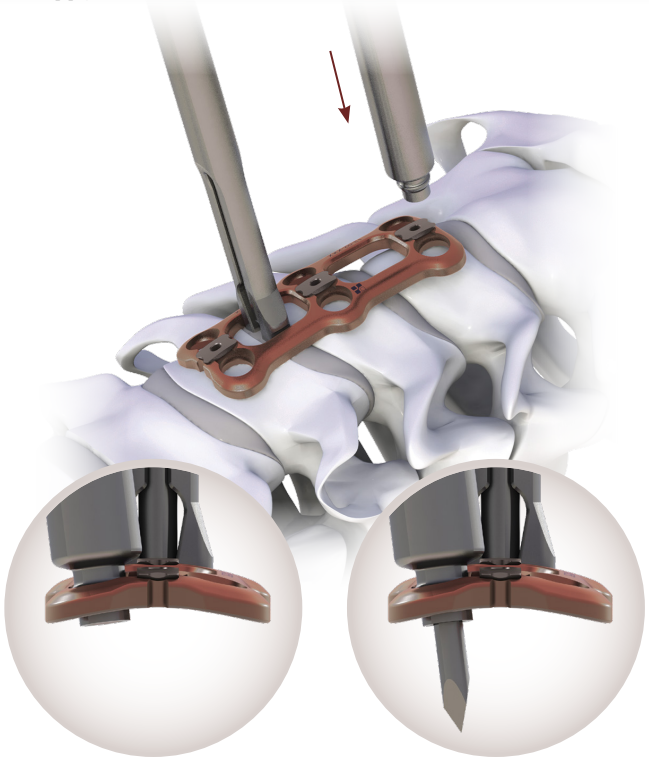
Delivery Option 1: Shielded Spring Loaded Awl

There are 2 options to create the pilot hole when using screws.

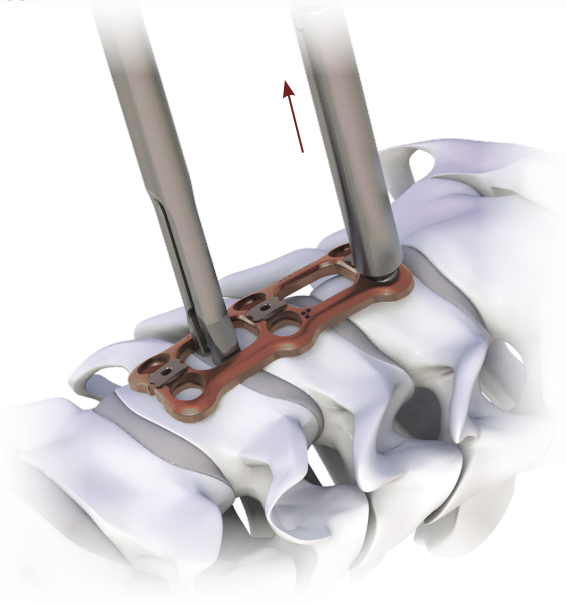
Insert the Shielded Spring Loaded Awl into the screw hole and lightly tap through the cortical surface to create a pilot hole **(Figure 11)**. Remove the Shielded Spring Loaded Awl by pulling straight up on the instrument **(Figure 12)**.

Shielded Spring Loaded Awl
13-90-014M

11. Inserting the Shielded Spring Loaded Awl



12. Removing the Shielded Spring Loaded Awl



please NOTE *Great care must be taken to properly position bone screw holes when using the Shielded Spring Loaded Awl. Excessively converging hole patterns prohibit proper seating of the bone screws.*

After removing the Shielded Spring Loaded Awl, an optional 10mm Tap may be used.

Load the appropriate length screw onto the Self-Retaining Screw Driver and insert the screw into the pilot hole **(Figure 13)**.

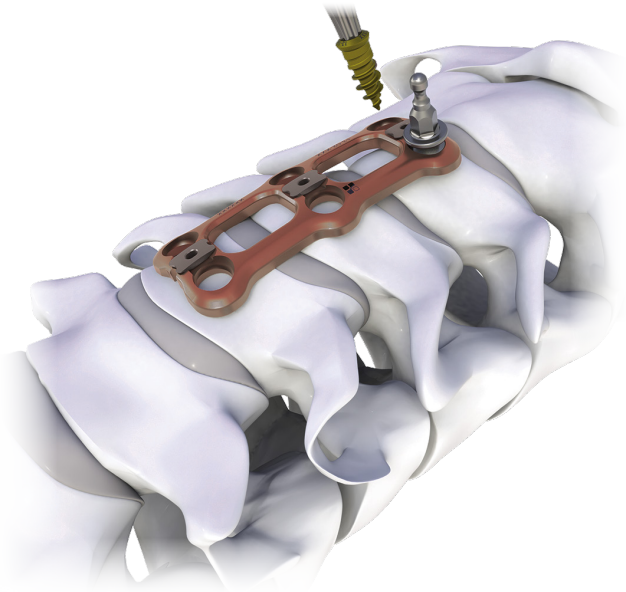
Advance the screw until the head of the screw is fully seated into the plate and below the blocking mechanism **(Figure 14)**.

Tap, 10mm
13-90-011-10

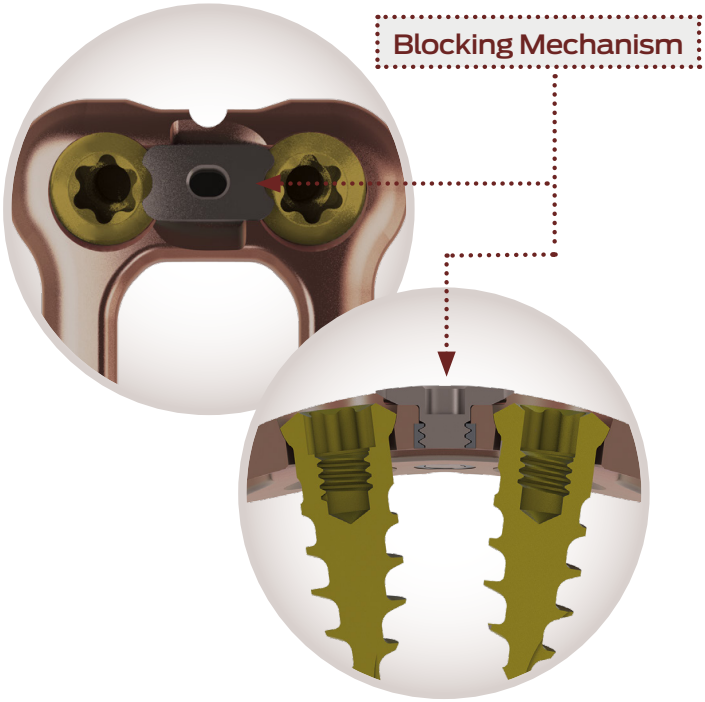
Self-Retaining Screw Driver
13-90-001

Non-Ratcheting Axial Handle
13-90-013M

13. Inserting the Screw into the Pilot Hole



14. Advancing the Screw Until the Head is Full Seated Below Blocking Mechanism



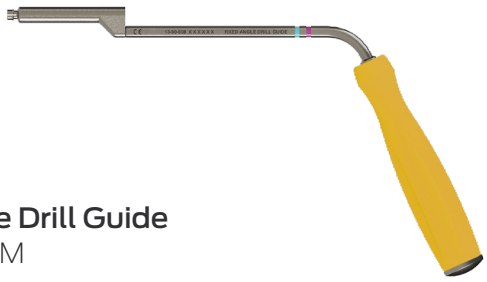
please NOTE *Use of an Awl or a Drill Guide is necessary to ensure the proper trajectory, depth, and angulation of the screw hole.*

please NOTE *The screw head seats below the blocking mechanism when the screw is fully advanced and inserted within the range of angulation.*

Surgical Technique (Cont'd)

Delivery Option 2: Drill Guide

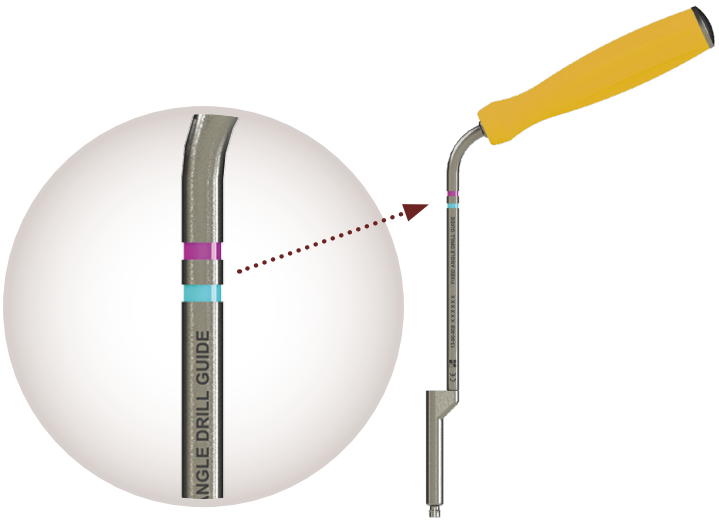
Select the corresponding color coded Drill Guide based on the type of screw selected, fixed or variable angle **(Figures 15 & 16)**.



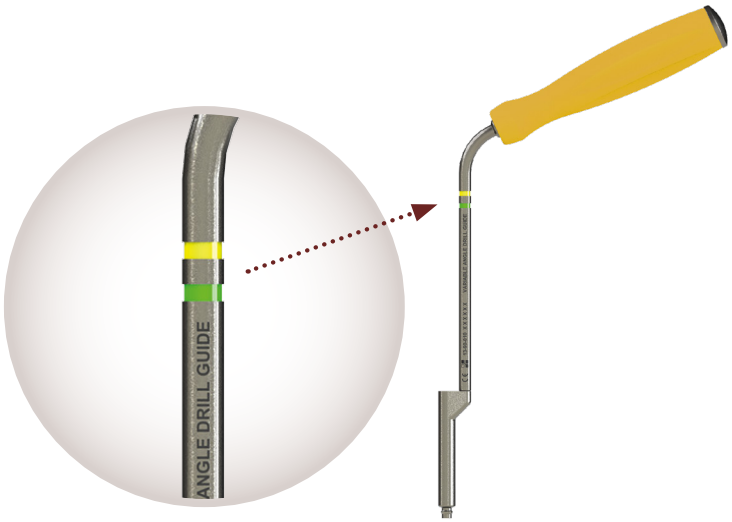
Fixed Angle Drill Guide
13-90-008M

Variable Angle Drill Guide
13-90-010M

15. Selecting the Fixed Angle Drill Guide

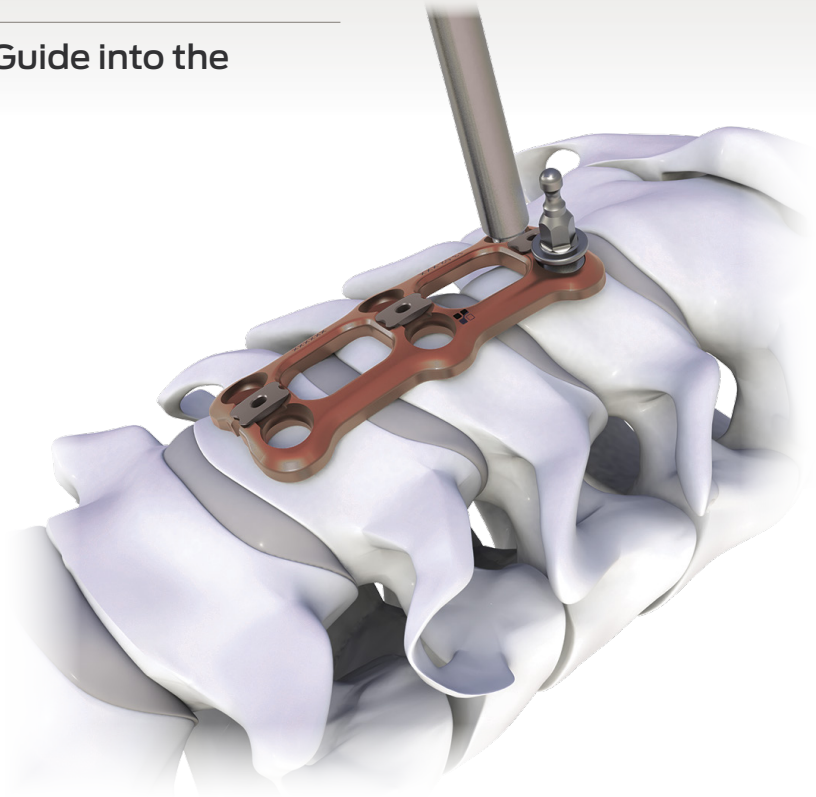


16. Selecting the Variable Angle Drill Guide



Insert the Drill Guide by pushing it into the desired screw hole of the plate **(Figure 17)**.

17. Inserting the Drill Guide into the Screw Hole



please NOTE *Great care must be taken to properly position bone screw holes when using the Drill Guide. Excessively converging hole patterns prohibit proper seating of the bone screws.*

Surgical Technique (Cont'd)

Delivery Option 2: Drill Guide (Cont'd)

Select the appropriate length Drill Bit and attach it to the quick connect handle. Insert the Drill Bit into the Drill Guide and rotate the handle in a clockwise direction to create the pilot hole for the screw. The depth stop will limit the drilling depth by contacting the Drill Guide.

Once the hole has been created, remove the Drill Guide by pulling up to disengage it from the plate **(Figure 18)**.

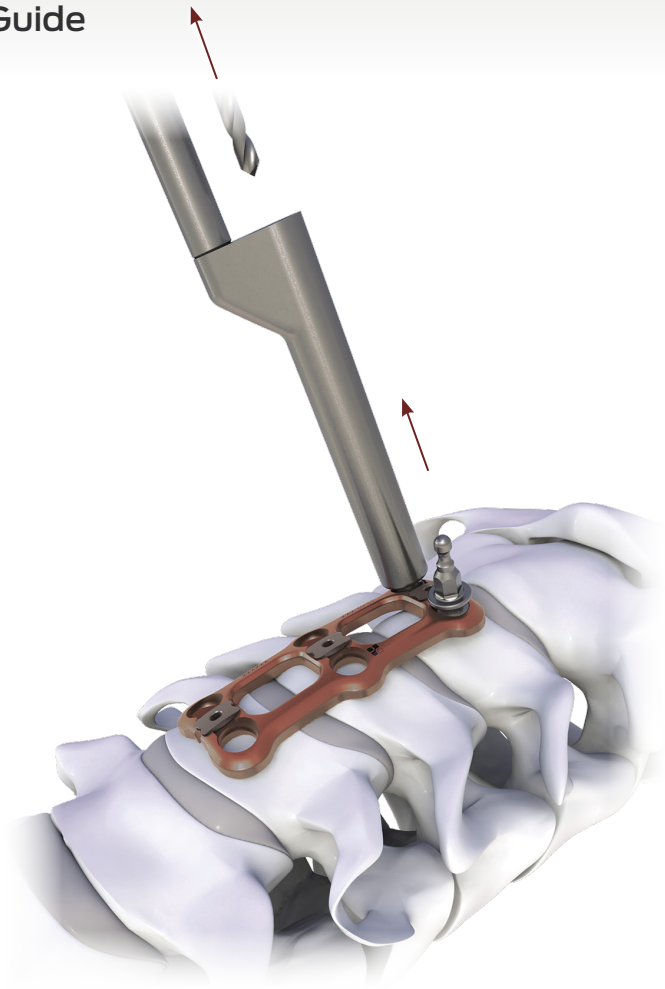
After removing the Drill Guide, an optional 10mm Tap may be used.

Drill Bits
13-90-015-10, 13-90-015-12, 13-90-015-14, 13-90-015-16, 13-90-015-18

Tap, 10mm
13-90-011-10

Non-Ratcheting Axial Handle
13-90-013M

18. Removing the Drill Bit and Drill Guide

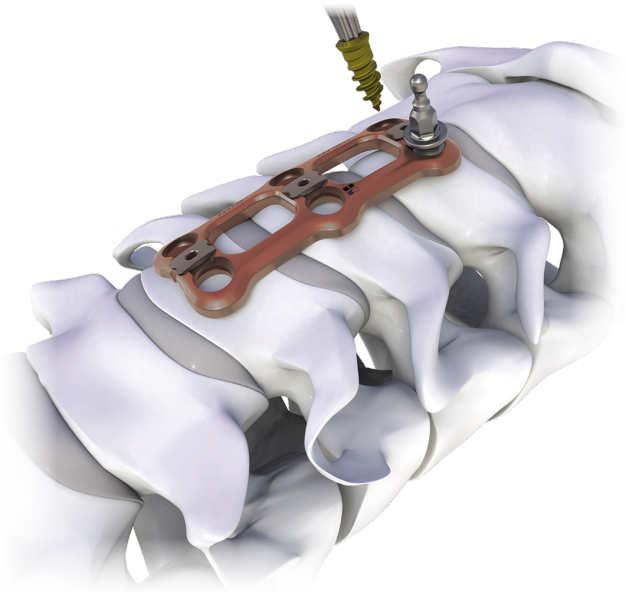


Load the appropriate length screw onto the Self-Retaining Screw Driver. Advance the screw until the head of the screw is fully seated into the plate and below the blocking mechanism **(Figures 19 & 20)**.

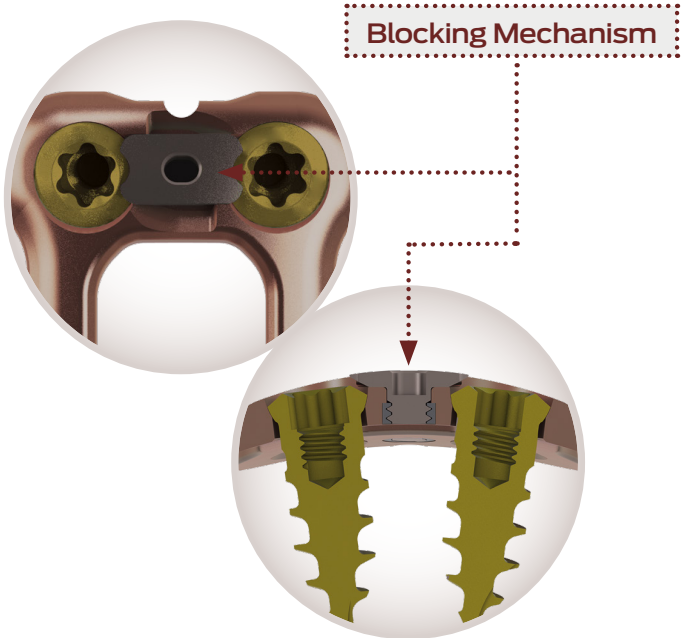
Self-Retaining Screw Driver
13-90-001

Non-Ratcheting Axial Handle
13-90-013M

19. Inserting the Screw into the Pilot Hole



20. Advancing the Screw Until the Head is Full Seated Below Blocking Mechanism



please NOTE *The screw head seats below the blocking mechanism when the screw is fully advanced and inserted within the range of angulation.*

Surgical Technique (Cont'd)

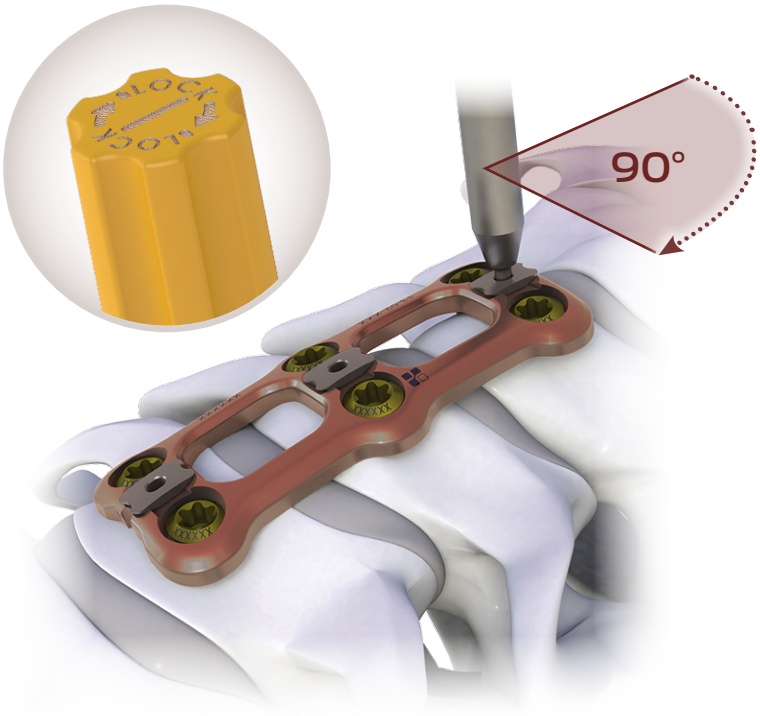
Implant Alignment & Locking

Ensure that the screws are fully seated and underneath the blocking mechanism. Rotate the blocking mechanism 90° to the locked position **(Figure 27)**.

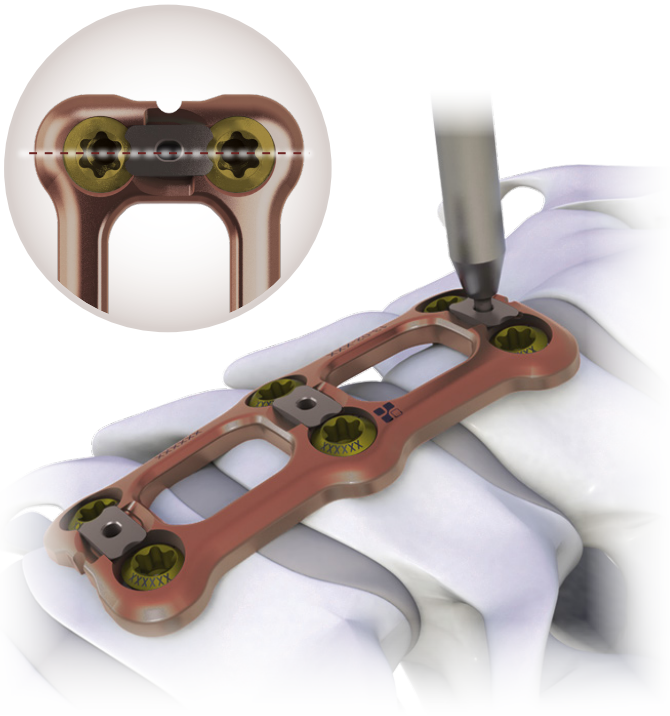
Verify that the blocking mechanism is in the horizontal position **(Figure 28)**.

Plate Locking Driver
13-90-002

21. Rotating the Blocking Mechanism with the Plate Locking Driver



22. Verifying the Blocking Mechanism is in the Locked (Horizontal) Position



please NOTE

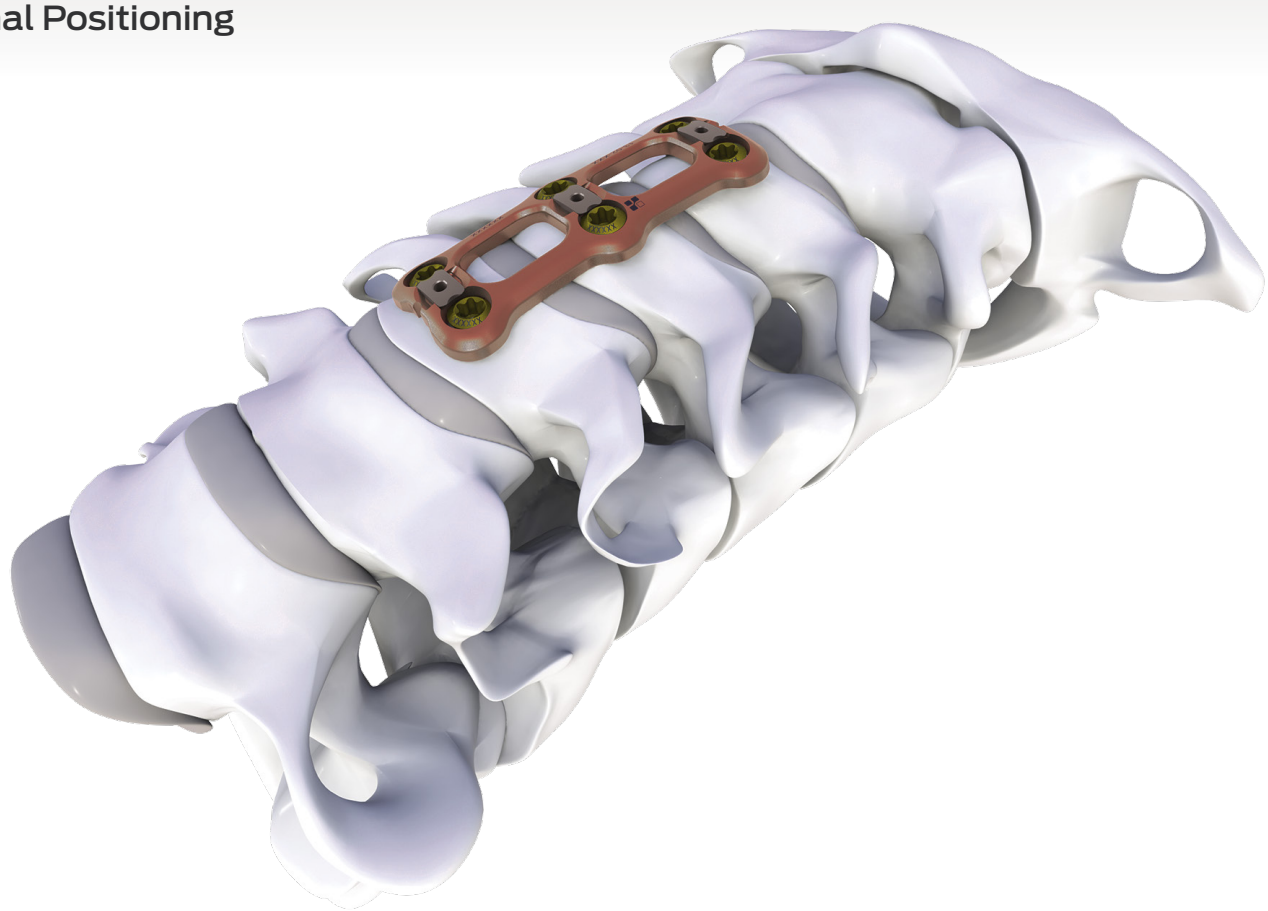
Prior to locking, verify that all the screws are fully seated and underneath the blocking mechanism. Failure to fully seat each and every screw may damage the blocking mechanism and screw.

Rotating the blocking mechanism requires minimal effort. Damage to the plate or screw may occur if excessive force is used or the mechanism is rotated beyond 90°.

Final Position

Check the final position of the plate, screws, and blocking mechanisms **(Figure 29)**.

23. Final Positioning



please NOTE

Ensure that all screws are flush or recessed (never above) relative to the anterior surface of the plate, and are covered by the blocking mechanisms.

Implant Removal

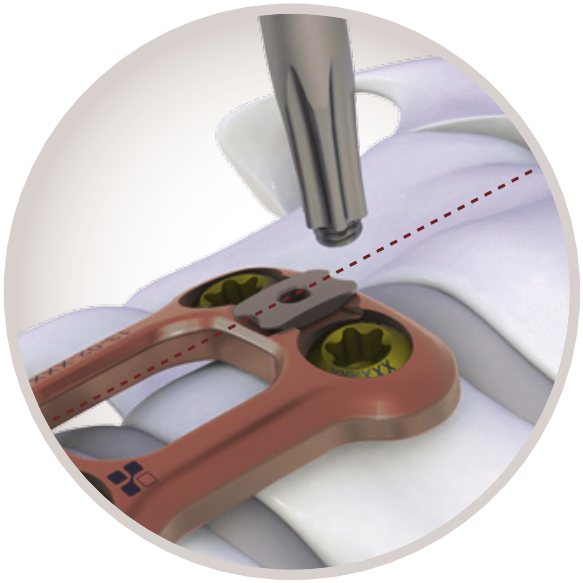
Ensure that the blocking mechanism is turned to the unlocked (vertical) position prior to screw removal **(Figure 30)**. To unlock a locked blocking mechanism, use the Plate Locking Driver to rotate the blocking mechanism 90° counter-clockwise.

Insert the tip of the Revision Driver into the head of the desired screw **(Figure 31)**.

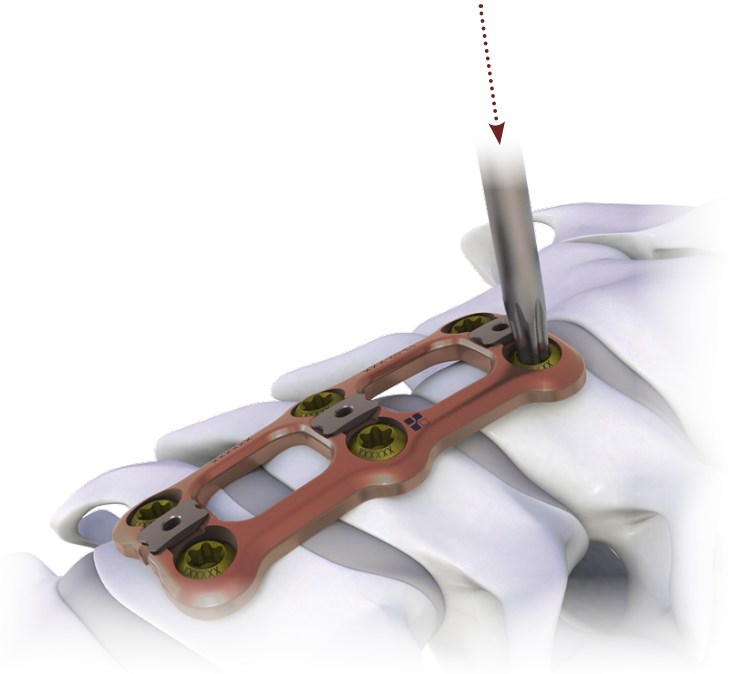
Plate Locking Driver
13-90-002

Revision Driver
13-90-017M

24. Verifying the Blocking Mechanism is in the Unlocked (Vertical) Position



25. Inserting the Revision Driver Tip into the Screw Head



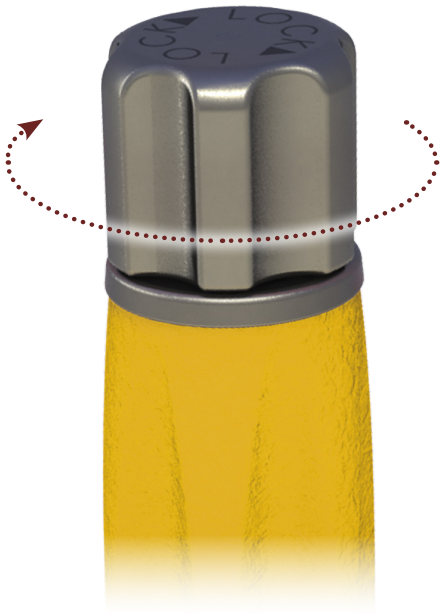
please NOTE *Prior to screw removal, verify that the blocking mechanism is in the unlocked position (vertically aligned to the length of the plate).*

Ensure the tip is fully seated within the screw head. Thread the inner shaft into the screw's internal threads, capturing the screw. Use the knob at the end of the handle to engage the screw by rotating the knob clockwise to the locked position **(Figure 32)**.

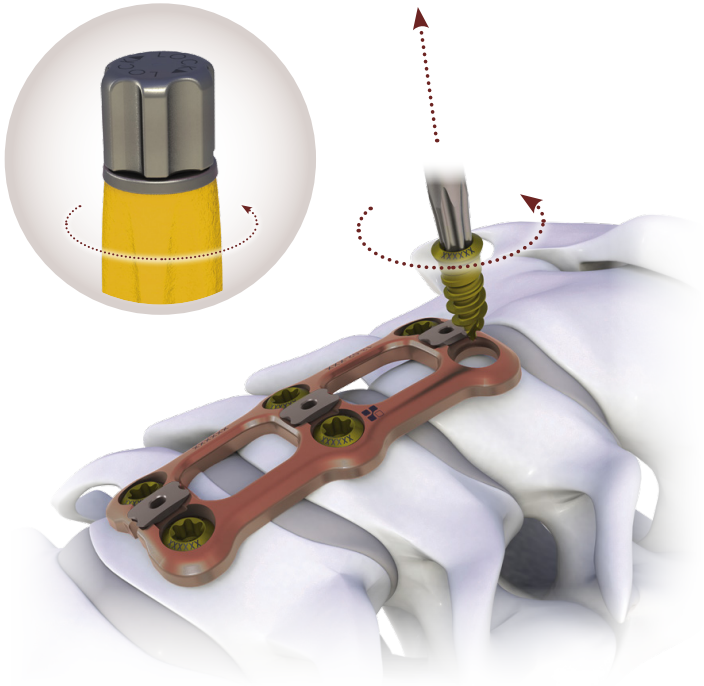
Rotate the Revision Driver counter-clockwise until the screw is removed from the plate **(Figure 33)**.

To remove the plate, repeat this process for all screws. Once the screws have been removed, the plate will no longer be attached to bone and can be removed.

26. Rotating the Knob Clockwise to the Locked Position



27. Rotating the Revision Driver Counter-Clockwise to Remove the Screw



References

[1] *Since 1991, Hartshill Horseshoe, STALIF, STALIF TT, STALIF C, STALIF MIDLINE, STALIF L, STALIF C-Ti, STALIF C FLX, STALIF M, STALIF M-Ti, STALIF M FLX, STALIF L FLX*

[2] *Stein MI, et al. The Spine Journal, 14(1): 128-136, 2014.*

[3] *A.N. Nayak, et al. The Spine Journal, 2014.*

[4] *Interim Report of Prospective STALIF C Study – Protocol SC-001.*

[5] *Represents single-level fusion data presented as part of IDE Clinical Study for Mobi-C cervical disc, including the Mobi-C experimental arm and the ACDF control arm. ACDF's were treated using an anterior cervical plate with screws [SLIM-LOC™ Anterior Cervical Plate System (DePuy Spine) and ATLANTIS™ or ATLANTIS™ VISION Anterior Cervical Plate Systems (Medtronic)] and corticocancellous allograft bone. Reference: Hisey, MS, et al. Multi-center, Prospective, Randomized, Controlled Investigational Device Exemption Clinical Trial Comparing Mobi-C Cervical Artificial Disc to Anterior Discectomy and Fusion in the Treatment of Symptomatic Degenerative Disc Disease in the Cervical Spine. International Journal of Spine Surgery. 8(7), doi: 10.14444/1007, 2014.*

[6] *Search performed on Pubmed, Embase, Ovid Medline® covering 1988 – 2017.*

[7] *Based upon US complaint handling units for prodisc since launch in 2006.*

Notes

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