NEURO® STRUCTURES

Transom™

CERVICAL PLATE SYSTEM

SURGICAL TECHNIQUE GUIDE

Made in the USA

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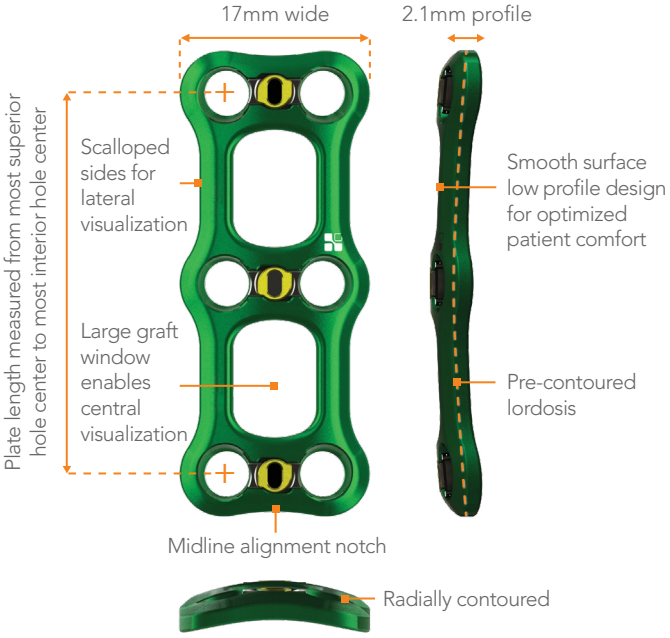
Transom™

This is intended as a guide only. There are multiple techniques for the delivery of an anterior cervical plate as with any surgical procedure. A surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use (IFU) insert for complete system description, indications and warnings.

Preoperative planning is essential to reduce the risk of intraoperative complications due to unrecognized anatomic aberrations. Measuring the vertebral body dimension in both A/P and lateral planes is recommended to determine the appropriate interbody device, cervical plate and bone screw sizes.

Plates



Screws

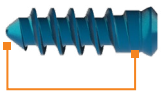
Variable – *gold*
4.0mm self-drilling

Variable – *light green*
4.0mm self-tapping

Variable – *green*
4.3mm self-tapping

Fixed – *magenta*
4.0mm self-drilling

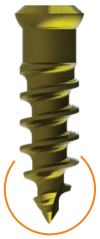
Fixed – *light blue*
4.0mm self-tapping



Fixed – *blue*
4.3mm self-tapping

SCREW LENGTH: Amount of purchase below plate

Enhanced screw and driver interface



Self-drilling

Self-tapping

Plate Size

Plates		Length (mm)										
Level	1	10	12	14	16	18	20	22	24	26		
	2	24	26	28	30	32	34	37	40	43	46	
	3	39	42	45	48	51	54	57	60	63	66	69
	4	60	64	68	72	76	80	84				
	5	85	90	95	100							

Standard Sizes Non-Standard Sizes

Fixed & Variable Screw Size

	Ø (mm)	Length (mm)				
Self-Tapping	4.0	10	12	14	16	18
	4.3	10	12	14	16	18
Self-Drilling	4.0	10	12	14	16	18

1 Preparation & Sizing

Select the appropriately sized plate.

Note: Plate length is measured from most superior hole center to most inferior hole center.

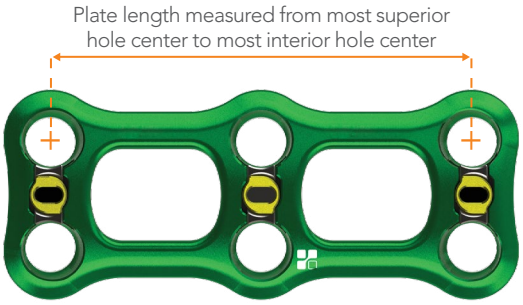


Figure 1

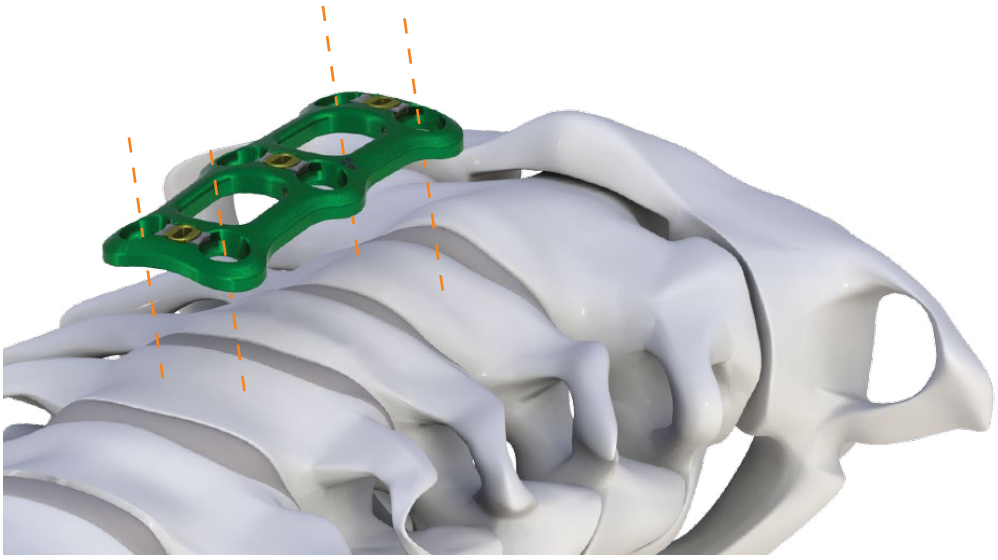
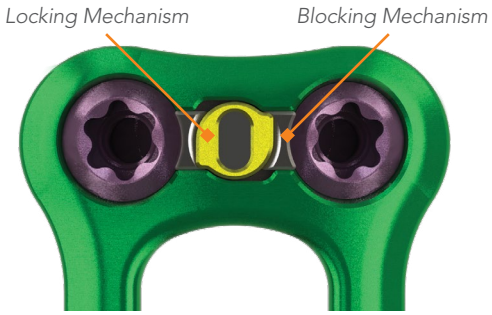


Figure 2



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

Fluoroscopy can be used to confirm plate position.

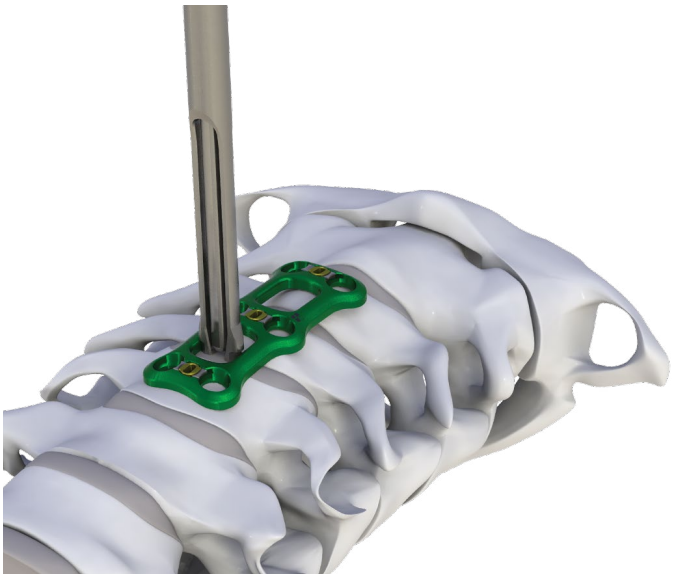


Figure 3

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

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.

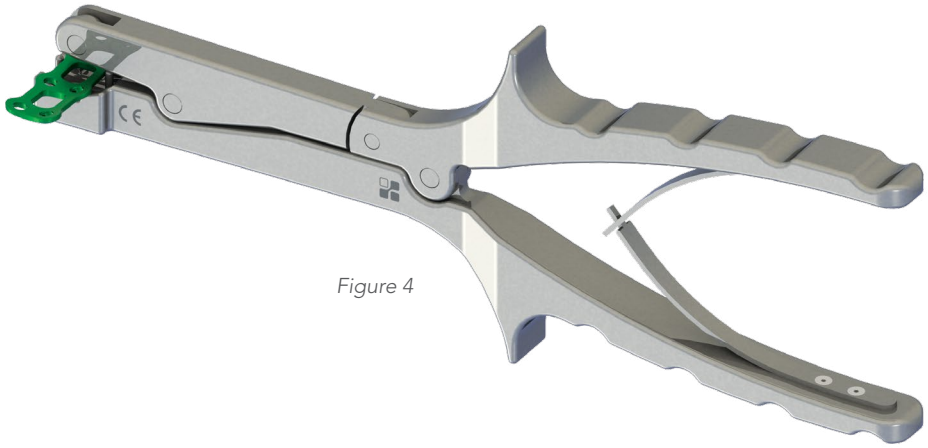


Figure 4

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

Caution: 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 *(Figure 5 & 6)*.

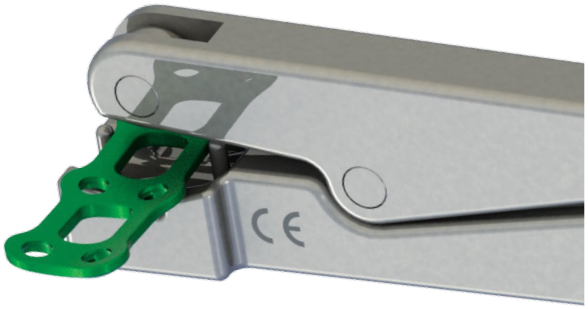


Figure 5

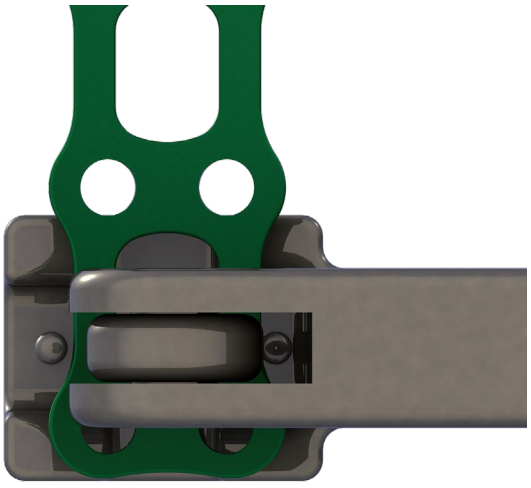


Figure 6

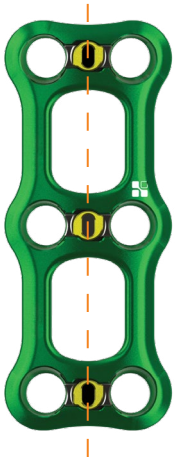
Note: When contouring the plate, care should be taken not to scratch, notch or dent the surface of the plate or the blocking mechanism, as the implant strength may be compromised. Plates 26mm or shorter should not be contoured.

2 Implant Delivery

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 *(Figure 7)*.

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)*.



Locking mechanism in the unlocked position

Cautionary Check: 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 8

Figure 7

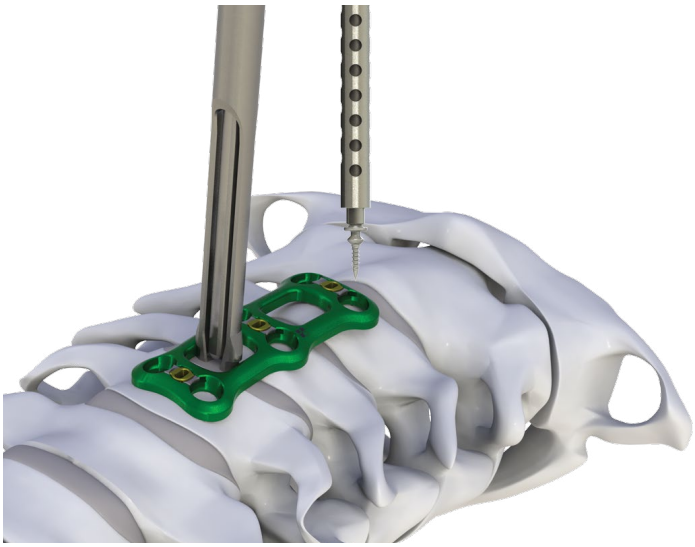


Figure 9

Figure 10

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

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

Option 1 | Shielded Spring Loaded Awl

There are 3 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)*.

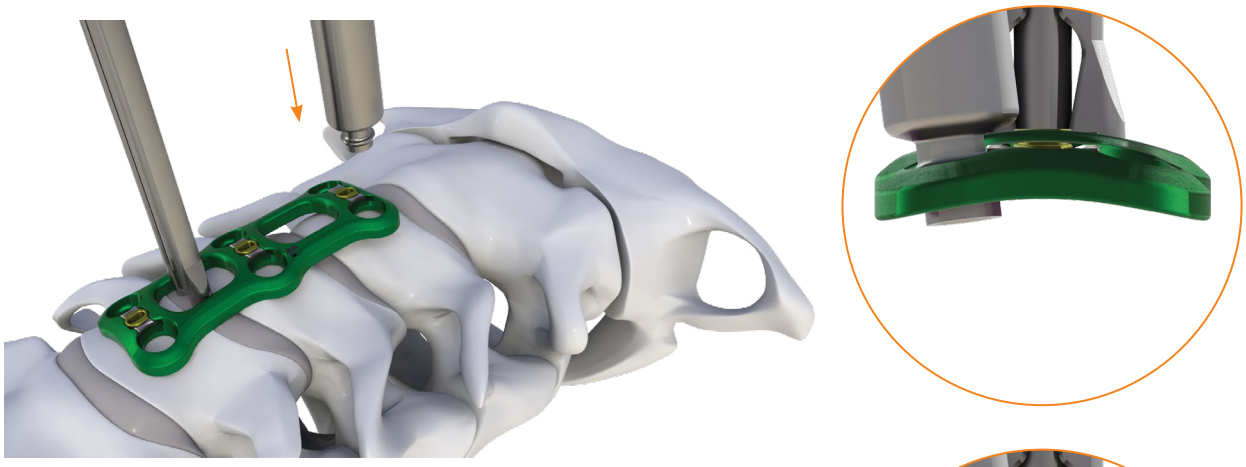


Figure 11

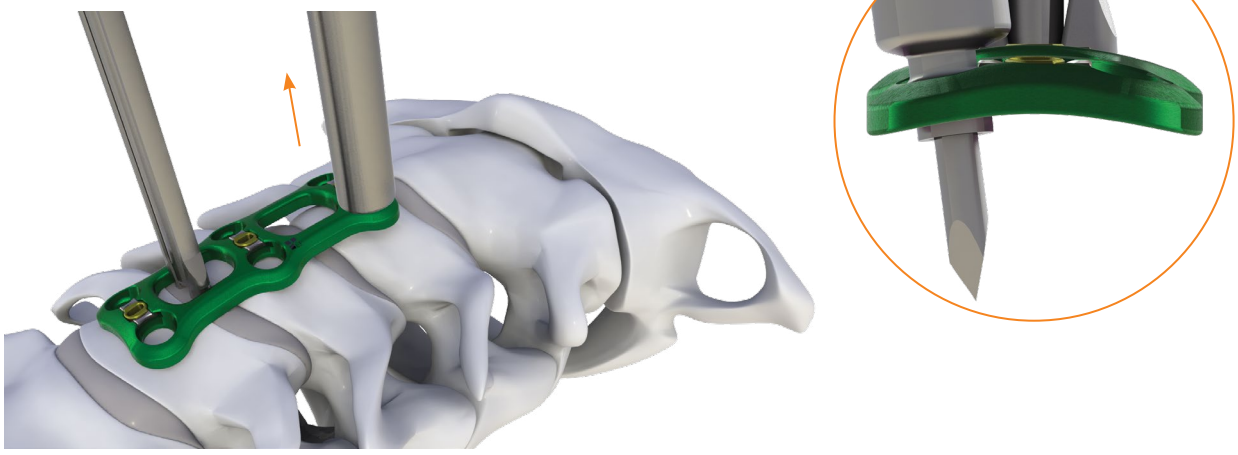


Figure 12

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.

Option 1 | Shielded Spring Loaded Awl cont.

Load the appropriate length screw onto the Screw Driver *(Figure 13)*. Advance the screw until the head of the screw is fully seated into the plate and below the blocking mechanism.

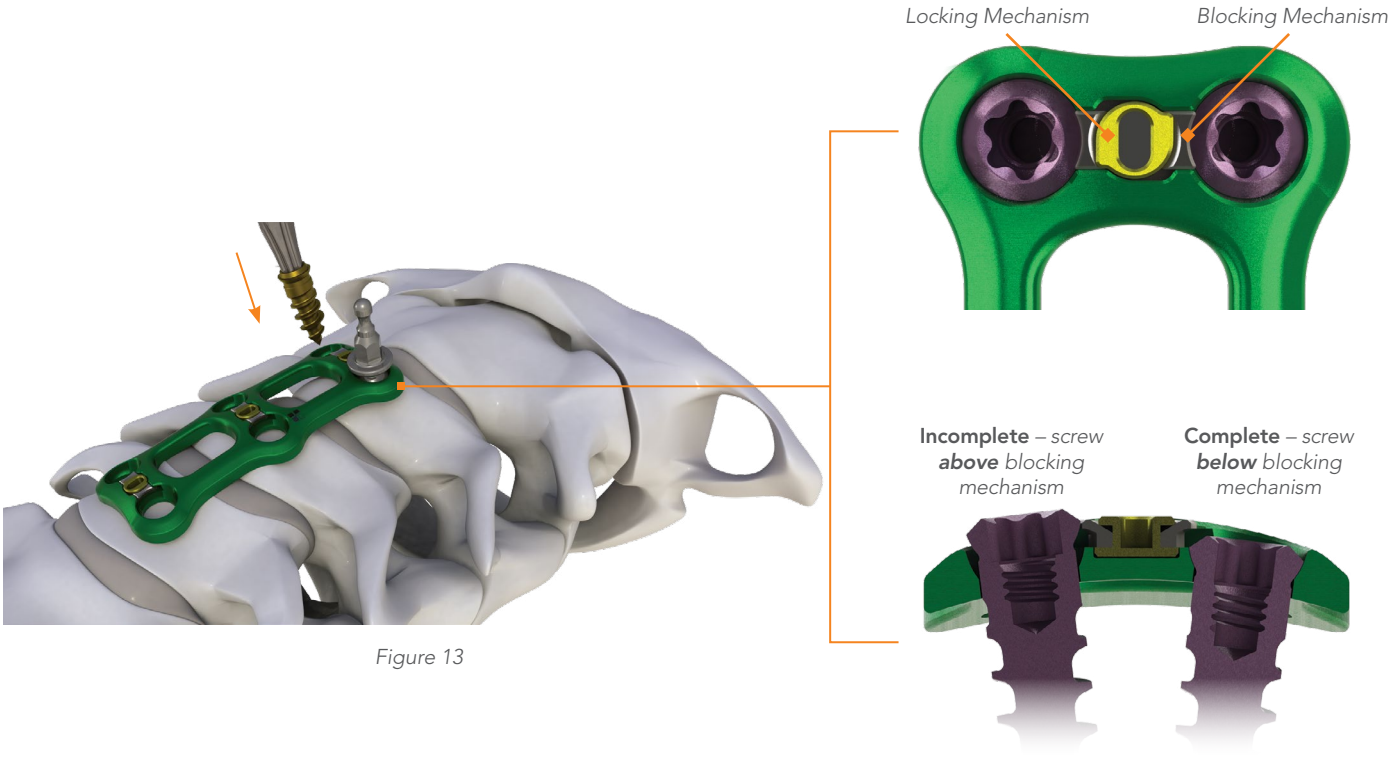


Figure 13

Note: The screw head seats below the blocking mechanism when the screw is fully advanced and inserted within the range of angulation.

Option 2 | Drill Guide

Select the corresponding color coded Drill Guide based on the type of screw selected, fixed or variable angle *(Figure 14 & 15)*.

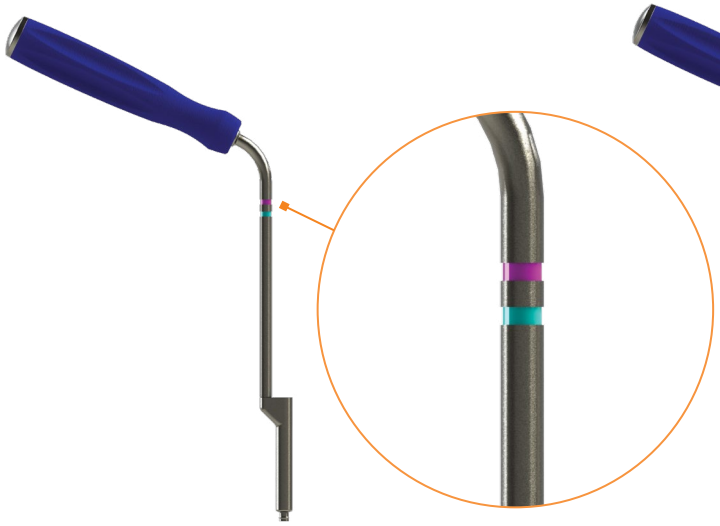


Figure 14

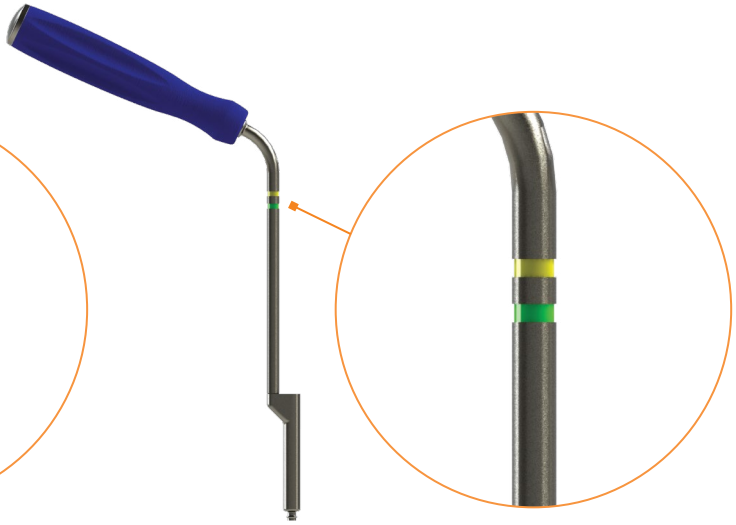


Figure 15

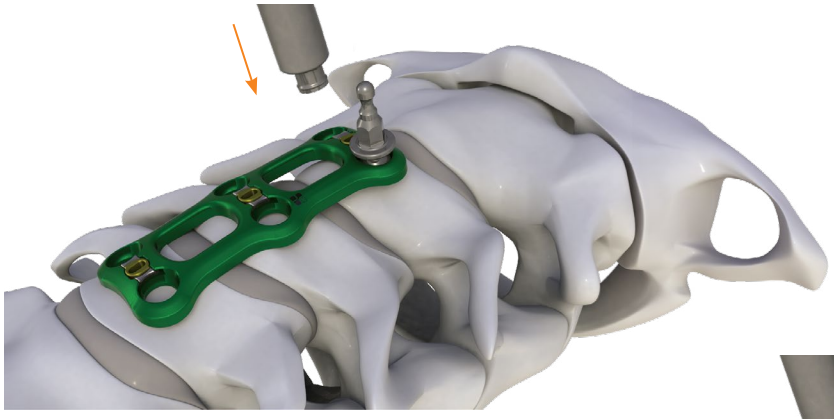


Figure 16

Insert the Drill Guide by pushing it into the desired screw hole of the plate *(Figure 16 & 17)*.

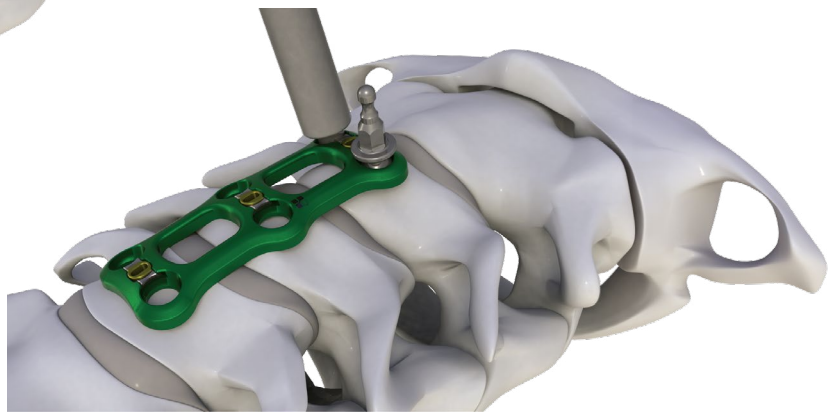


Figure 17

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.

Option 2 | Drill Guide cont.

Select the appropriate length Drill Bit with stop 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.

Remove Drill Guide

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

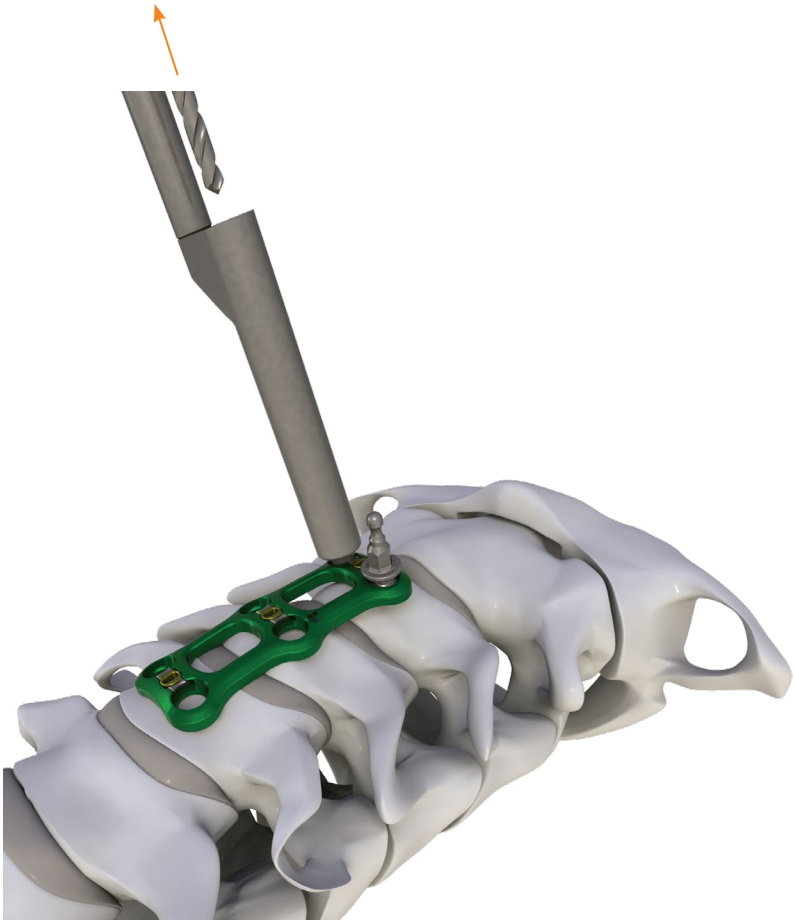


Figure 18

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

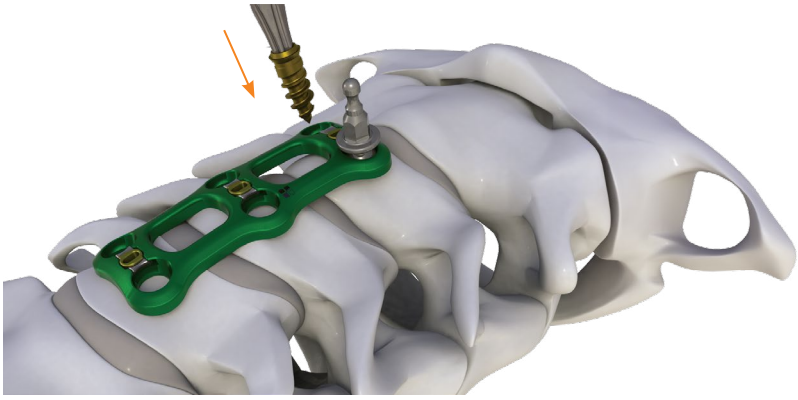


Figure 19

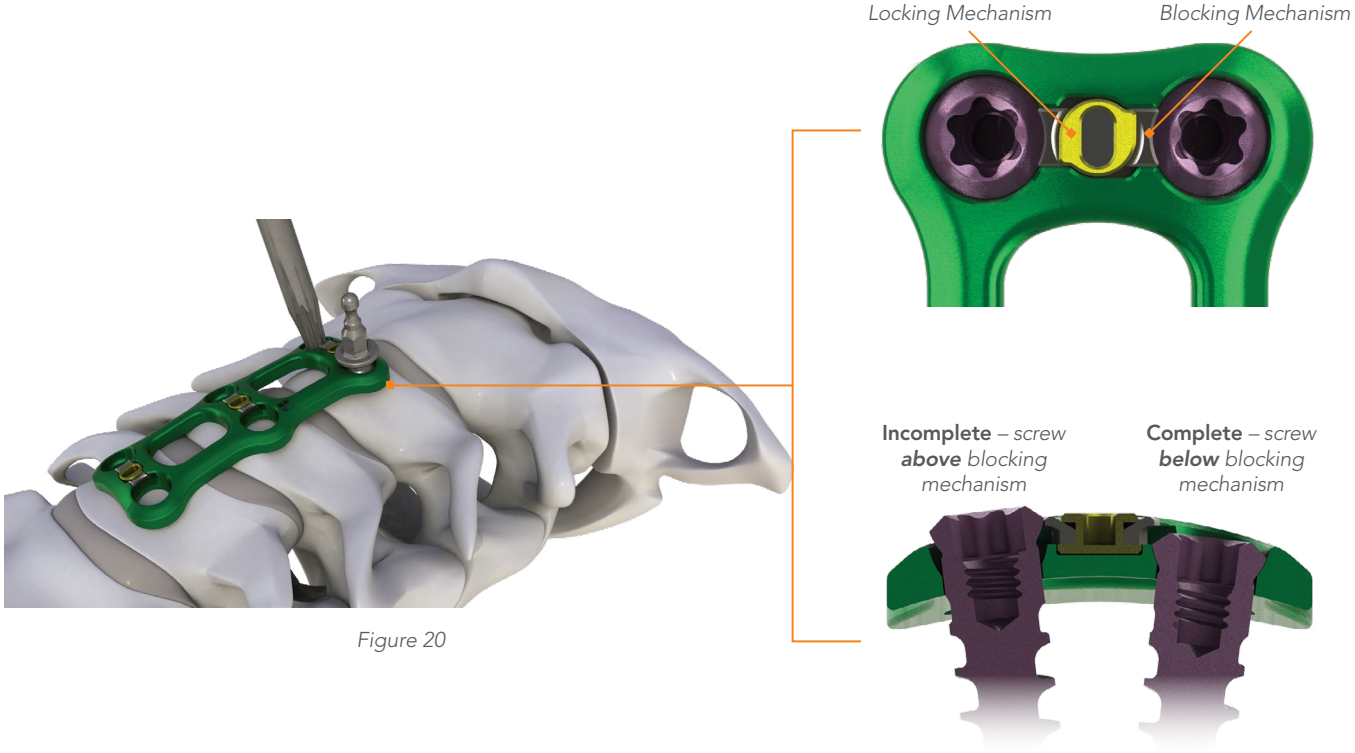


Figure 20

Note: The screw head seats below the blocking mechanism when the screw is fully advanced and inserted within the range of angulation.

Option 3 | All-in-One

All-in-One Single Barrel Guide

Figure 21

— OR —

All-in-One Double Barrel Guide

Figure 22

Figure 23

Note: The All-in-One Single and Double Barrel Guide do NOT come standard with the Transom Instrument Kit. To order this tool, please contact your NeuroStructures representative.

Drill

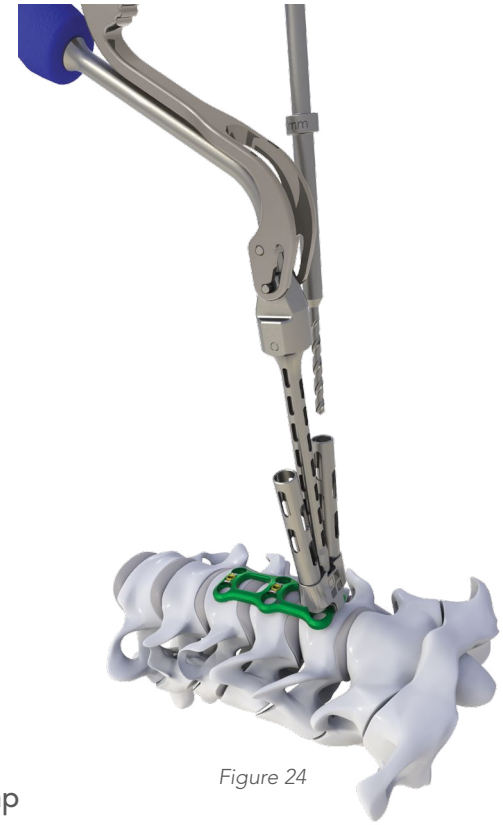


Figure 24

Tap

Figure 25

Screw

Figure 26

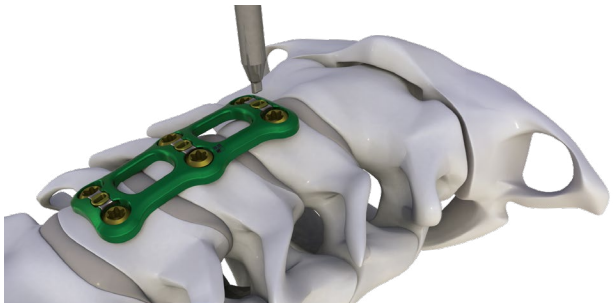


Figure 27

Ensure that the screws are fully seated and underneath the blocking mechanism. Rotate the locking mechanism to the locked position using the Plate Locking Driver. Verify that the line on the locking mechanism is in the horizontal position *(Figure 29)*.

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 locking mechanism and screw.

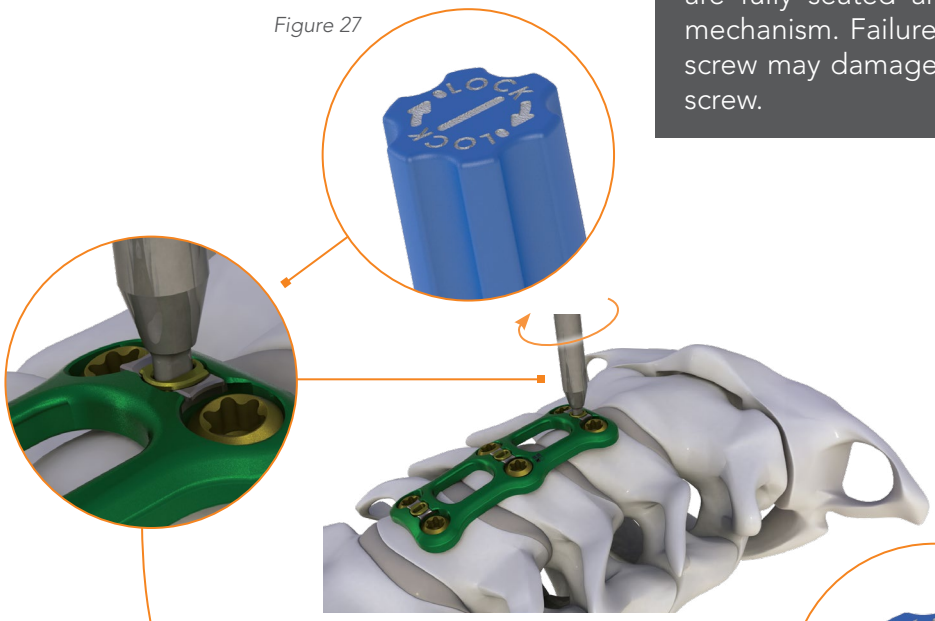


Figure 28

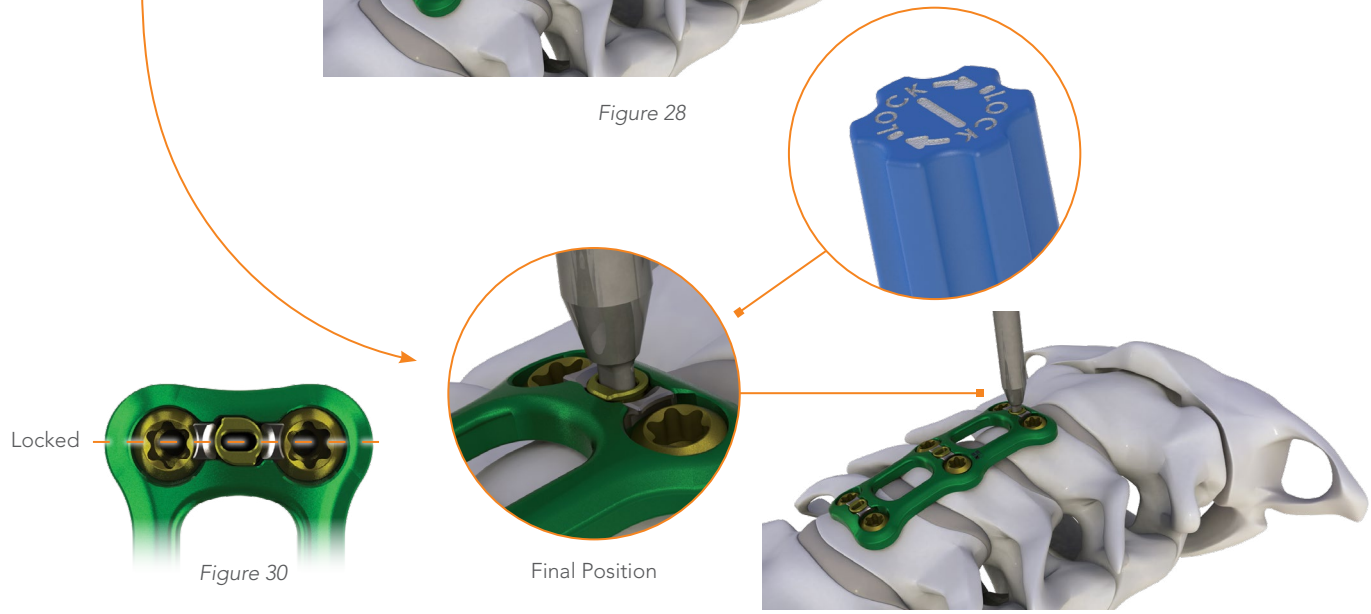


Figure 29

Figure 30

Inspect Plate Position

Check the final position of the plate and screws both visually and radiographically.

Ensure the locking mechanism is in the horizontal position *(Figure 30)*.

Note: Rotating the locking mechanism requires minimal effort. Damage to the plate or screw may occur if excessive force is used or over-tightened.

4 Final Position

Check the final position of the plate and screws.

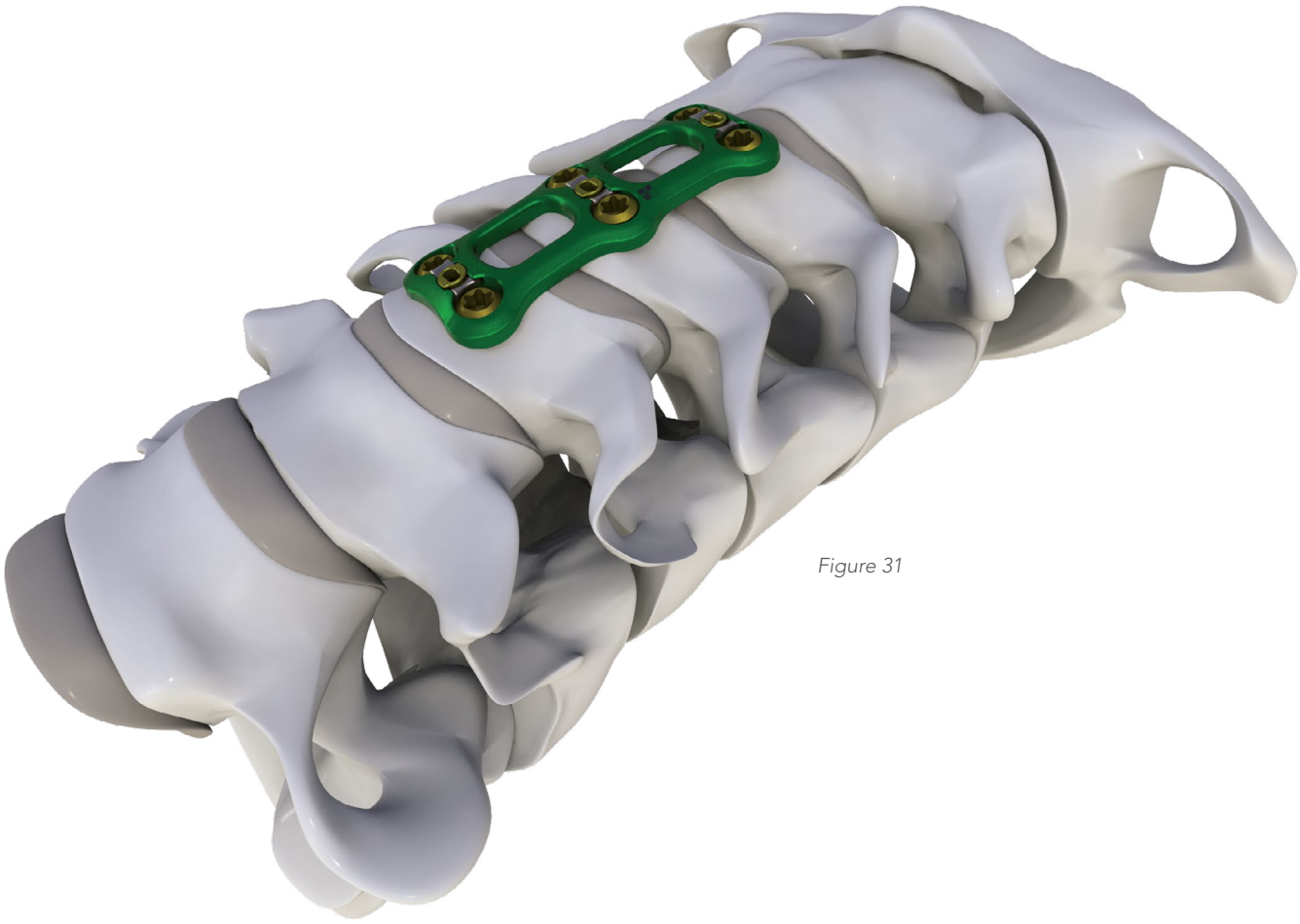


Figure 31

Note: Ensure that all screws are flush or recessed (never above) relative to the anterior surface of the plate covered by the blocking mechanism.

5 Implant Removal

Ensure that the lock is turned to the unlock position prior to screw removal (vertical position).

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

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)*.

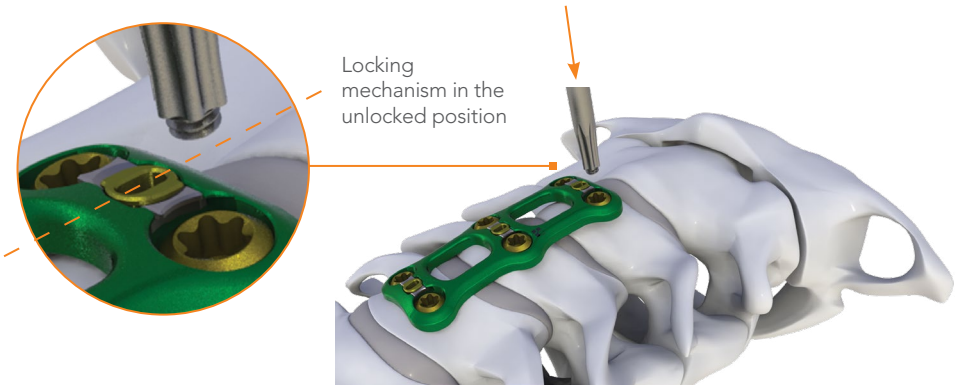


Figure 31

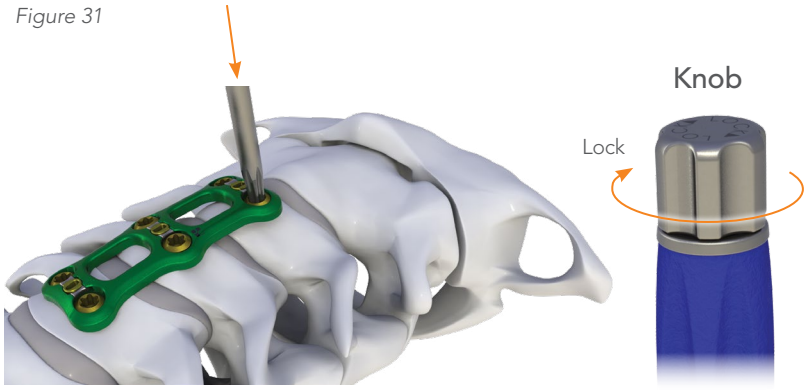


Figure 32

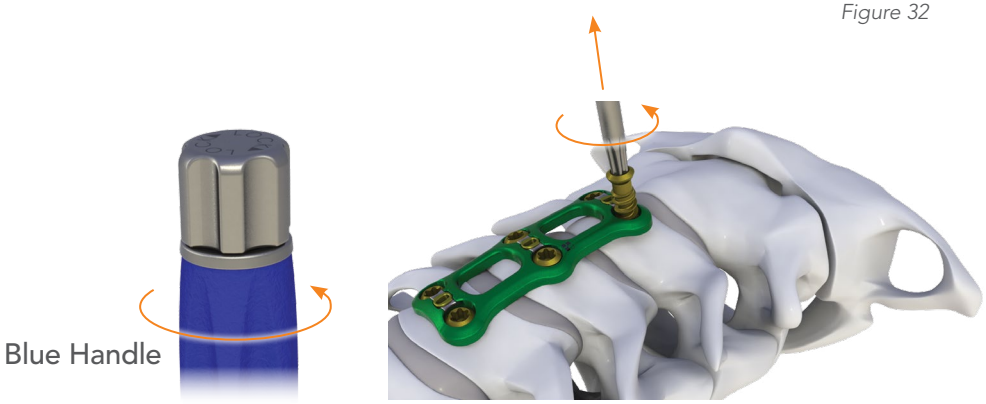


Figure 33

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

To remove the plate, repeat step 5 for all screws. Once the screws have been removed, the plate will no longer be attached to bone and can be removed.

11-90-001
Screw Driver

11-90-002
Plate Locking Driver

11-90-003
Temporary Fixation Pin

11-90-004
Temporary Fixation Pin Inserter

11-90-005
Plate Bender

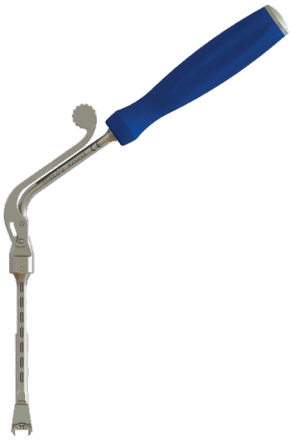
11-90-007
Plate Holder – Internal

11-90-008
Fixed Angle Drill Guide

11-90-009
All-in-One (DTS) Variable Guide – Double Barrel
(Not a Standard Instrument)

11-90-010
Variable Angle Drill Guide

11-90-011
Tap
Use with Drill Guide
(Not a Standard Instrument)



11-90-012
All-in-One (DTS) Variable Guide – Single Barrel
(Not a Standard Instrument)

11-90-013
Non-Ratcheting Axial Handle
(Not a Standard Instrument)

11-90-014
Shielded Spring Loaded Awl

11-90-015-XXX
Drill Bits

11-90-016
Stand Alone Tap
(Not a Standard Instrument)

11-90-018
Ratcheting Axial Handle

11-90-019
Revision Driver

Purpose:

The Transom Cervical Plate 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 Transom Cervical Plate System is via an anterior surgical approach.

Description:

The Transom Cervical Plate 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 Transom Plates include locking pins that cover the heads of the bone screws to reduce the potential for screw back-out. The locking pins come preassembled to the plate. Associated instruments are available to facilitate the implantation of the device.

The Transom Cervical Plate 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 Transom Cervical Plate System components with the components from any other system or manufacturer. NeuroStructures, Inc. expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Indications, Contraindications and Possible Adverse Effects

Indications:

The Transom Cervical Plate 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.

Warning:

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

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 for Use (IFU).
- Any patient unwilling to cooperate with the post operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

Potential Adverse Events:

All of the possible adverse events 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, microfracture, 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, retropulsed 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 and 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 Transom Cervical Plate 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 Transom Cervical Plate 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 Transom Cervical Plate 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 Transom Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The Transom Cervical Plate 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:

FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN. FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND 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 Transom Cervical Plate 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:

- Any available instruction manuals should be carefully followed.
- 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(s). 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 of the screws should be seated onto the plate. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Lock the anti-migration caps over the heads of the bone screws. Failure to do so may result in screw loosening. Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

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 Transom Cervical Plate 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, and
  (7) Bone loss due to stress shielding.

  While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should 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.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Transom Cervical Plate System components should ever 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, and should be returned to NeuroStructures, Inc.

Decontamination and Cleaning:

Unless just removed from an unopened package, 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) return of the product to NeuroStructures, Inc. 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.

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 Transom Cervical Plate System components are provided non-sterile. These products need to be steam sterilized by the hospital using one of the following methods:

Steam Sterilization Cycle Type	Exposure time at 132 °C (270 °F)	Drying Times
Dynamic Air Removal: Pre-Vacuum	4 min	20 – 30 min

Remove all packaging materials prior to sterilization. Only FDA-cleared wraps should be used. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and resterilize before handling or (if applicable) return to NeuroStructures, Inc.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the manufacturer, NeuroStructures, Inc. Further, if any of the implanted Transom Cervical Plate System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the manufacturer should be notified immediately. If any NeuroStructures Inc. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately

by telephone or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the manufacturer is requested.

Further Information:

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

NeuroStructures, Inc., 199 Technology, Suite 110, Irvine, CA 92618, 800-352-6103.

www.neurostructures.com

199 Technology Drive, Suite 110
Irvine, CA 92618
Ph/Fax: 800.352.6103

neurostructures.com

06/18 Rev. 007 NS-100-119