CoreLink
The Source for Spine™

TIGER® OCCIPITAL-CERVICAL-THORACIC SPINAL FIXATION SYSTEM

Surgical Technique Guide

TIGER OCT SPINAL FIXATION SYSTEM ADVANTAGE

The **Tiger Occipital-Cervical-Thoracic (OCT) Spinal Fixation System** features a wide assortment of instruments and implants to provide surgeons with the ability to customize sets based on preferred surgical technique and individual comfort.

DESIGN PHILOSOPHY

The Tiger OCT Spinal Fixation System was designed with the following goals in mind:

- Comprehensive system to accommodate individual anatomy
- Quality instrumentation for ease of use and efficiency

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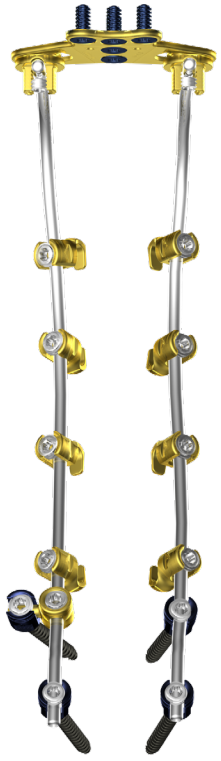
SYSTEM OVERVIEW

INTRODUCTION

The Tiger OCT System provides a full complement of instrument and implant options that seamlessly integrate from occiput to thoracic spine and tie into the Tiger Spine System. The system consists of occipital plates, occipital bone screws, cervical hooks, cervical and upper thoracic bone screws, titanium and cobalt chrome rods, transverse connectors, and other assorted connectors.

FEATURES

- Biased angle screws in both the cephalad/caudal and medial/lateral direction offer additional angulation for ease of use
- Occipital plates in a range of sizes to best suit individual patient anatomy
- Occipital plates with a rotating/translating rod connection, allow ideal rod alignment
- Transverse connector options designed to keep instruments away from the spinal canal while providing torsional stability

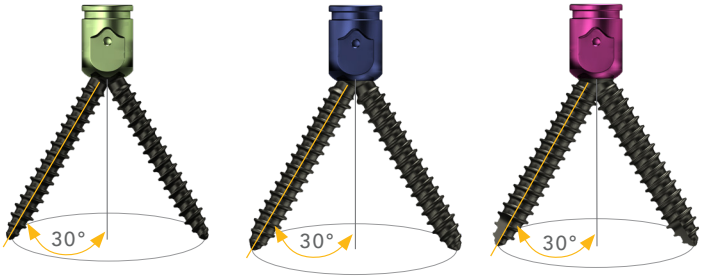


SYSTEM OVERVIEW (CONTINUED)

CERVICAL AND UPPER THORACIC SCREWS

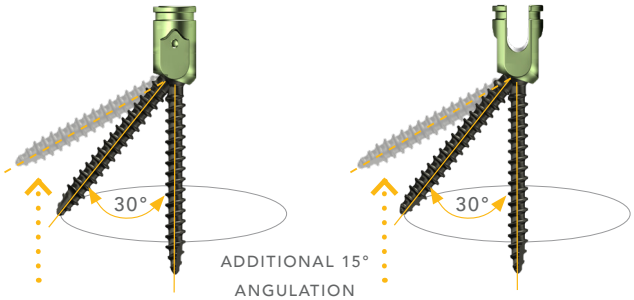
- Large cone of angulation
- Diameters of 3.5mm, 4.0mm, and 4.5mm ranging from 10mm to 26mm in length
- Biased angle screws allow for an additional 15 degrees of angulation in either cephalad/caudal or medial/lateral directions

SCREW ANGULATION



3.5MM DIAMETER | 4.0MM DIAMETER | 4.5MM DIAMETER

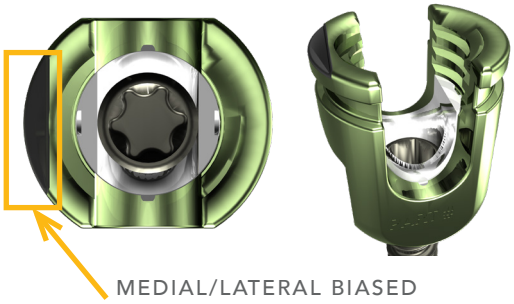
BIASED ANGLE SCREWS



CEPHALAD/CAUDAL | MEDIAL/LATERAL

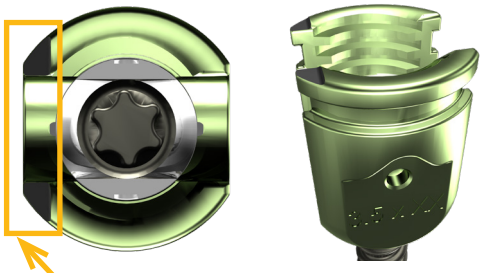
TULIP HEAD DIRECTION OF BIAS

TULIP HEAD CUT INDICATES BIAS DIRECTION



MEDIAL/LATERAL BIASED INDICATION CUTS

TULIP HEAD CUT INDICATES BIAS DIRECTION



CEPHALAD/CAUDAL BIASED INDICATION CUTS

TULIP HEAD COLORS

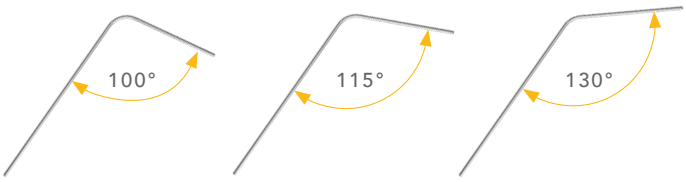
3.5MM SEAFOAM | 4.0MM DARK BLUE | 4.5MM MAGENTA

*Additional sizes may be available upon request

RODS

- Diameter of 3.5mm available in a range of lengths
- Titanium and cobalt chrome options
- Pre-bent angled options for occipital fixation

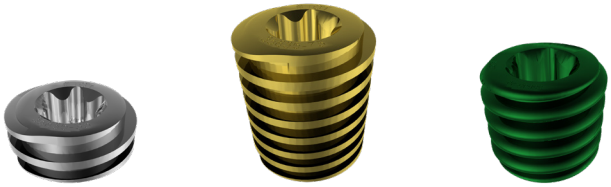
OCCIPITAL RODS



SET SCREWS

- One set screw is used through the majority of the system (occipital plate, cervical hooks, cervical and upper thoracic screws, and lateral offset connectors)
- The long set screw (in gold) is used for the Head-to-head Transverse Connector
- The green set screw is used for the Rod-to-rod Connectors

SET SCREWS



SET SCREW

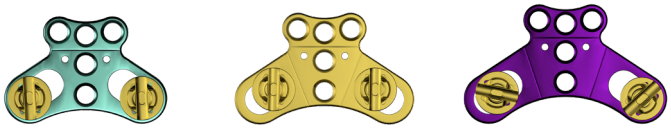
LONG SET SCREW

ROD-TO-ROD CONNECTOR SET SCREW

OCCIPITAL PLATES

- Three size options accommodate a wide range of patients
- Rotating and translating rod connection provide ease of use
- Five points of bone fixation

OCCIPITAL PLATES



SMALL PLATE

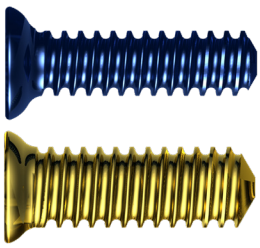
MEDIUM PLATE

LARGE PLATE

OCCIPITAL BONE SCREWS

- Diameters: 4.0mm and 5.0mm
- Lengths: 6mm – 16mm
- Screws with a uniform cortical thread to maximize purchase in the occipital bone

OCCIPITAL BONE SCREWS



4.0MM

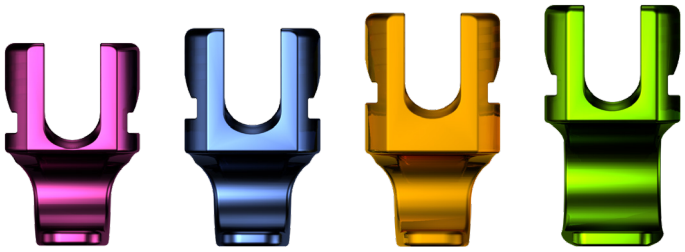
5.0MM

SYSTEM OVERVIEW (CONTINUED)

CERVICAL HOOKS

- Four cervical hook options available to best fit patient anatomy

CERVICAL HOOKS



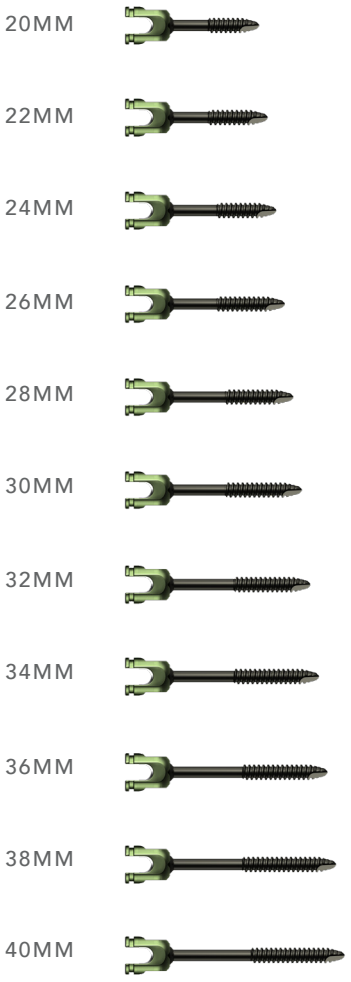
5MM SMALL | 5MM MEDIUM | 5MM LARGE | 7MM X-LARGE

LONG SHANK SCREWS

- Diameters: 3.5mm, 4.0mm, and 4.5mm
- Lengths: 20mm – 40mm
- Length of smooth shank varies in proportion with the overall length

LONG SHANK SCREWS		
OVERALL SCREW LENGTH (MM)	SMOOTH SHANK LENGTH (MM)	THREADED LENGTH (MM)
20	8	12
22	8	14
24	10	14
26	10	16
28	12	16
30	12	18
32	14	18
34	14	20
36	16	20
38	16	22
40	18	22

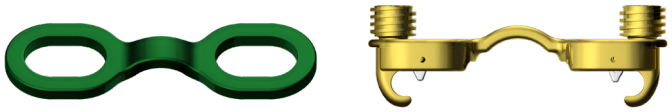
3.5MM LONG SHANK SCREWS



TRANSVERSE CONNECTORS

- Two options available in multiple sizes
- Designed to keep instruments away from the spinal canal during insertion
- Head-to-head Transverse Connector: 20mm – 56mm
- Rod-to-rod Transverse Connector: 17mm – 55mm

TRANSVERSE CONNECTORS

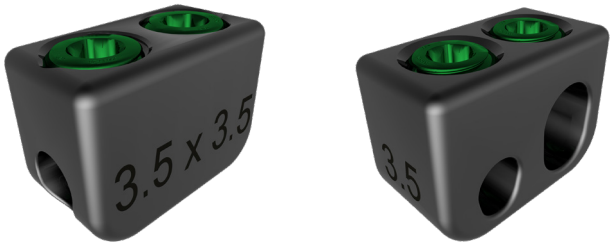


HEAD-TO-HEAD ROD-TO-ROD

ROD-TO-ROD CONNECTORS

- End-to-end and side-by-side options
- Allows for connecting a 3.5mm rod to either a 3.5mm or a 5.5mm rod

ROD-TO-ROD CONNECTORS

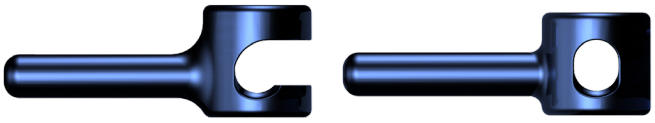


3.5MM 5.5MM

LATERAL CONNECTORS

- Top loading, open, and closed options available
- Lengths: 8.5mm, 16mm, and 30mm

LATERAL CONNECTORS



OPEN VS. CLOSED SIDE LOADING

TOP LOADING VS. SIDE LOADING

PATIENT POSITIONING AND APPROACH

After the induction of general anesthesia, the patient is positioned prone and the operative site is prepared and draped in the usual fashion. Radiographic guidance, such as C-arm fluoroscopy, should be considered throughout the procedure to ensure correct placement of implants.

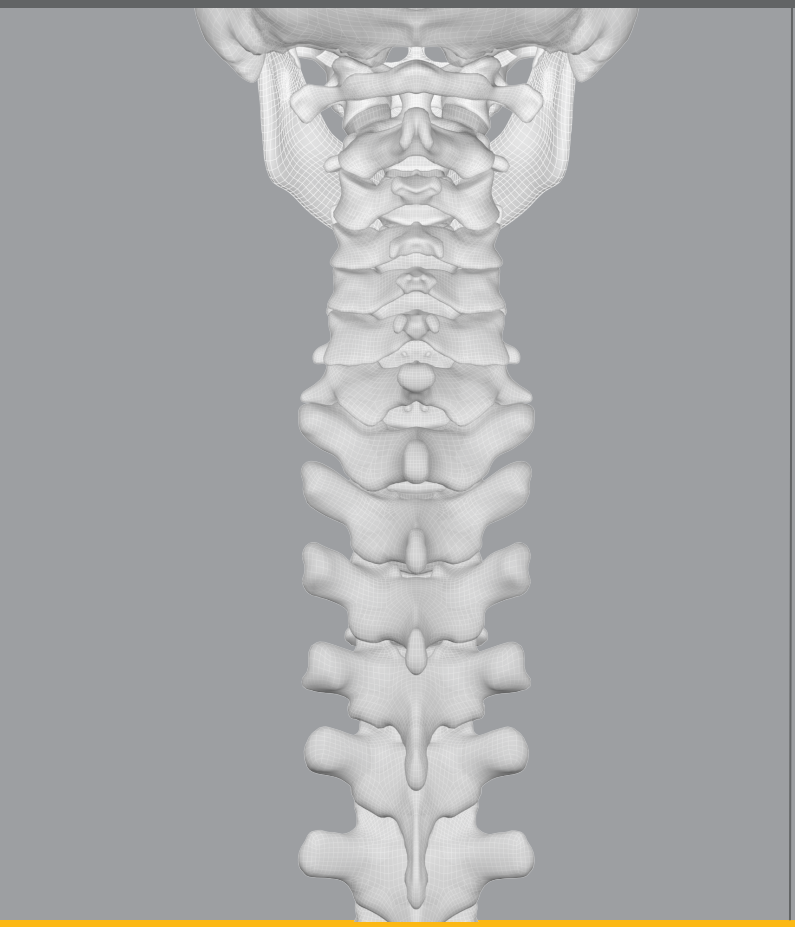
Use caution to avoid injury to the spinal cord, vertebral arteries, and nerve roots.

PEDICLE PREPARATION

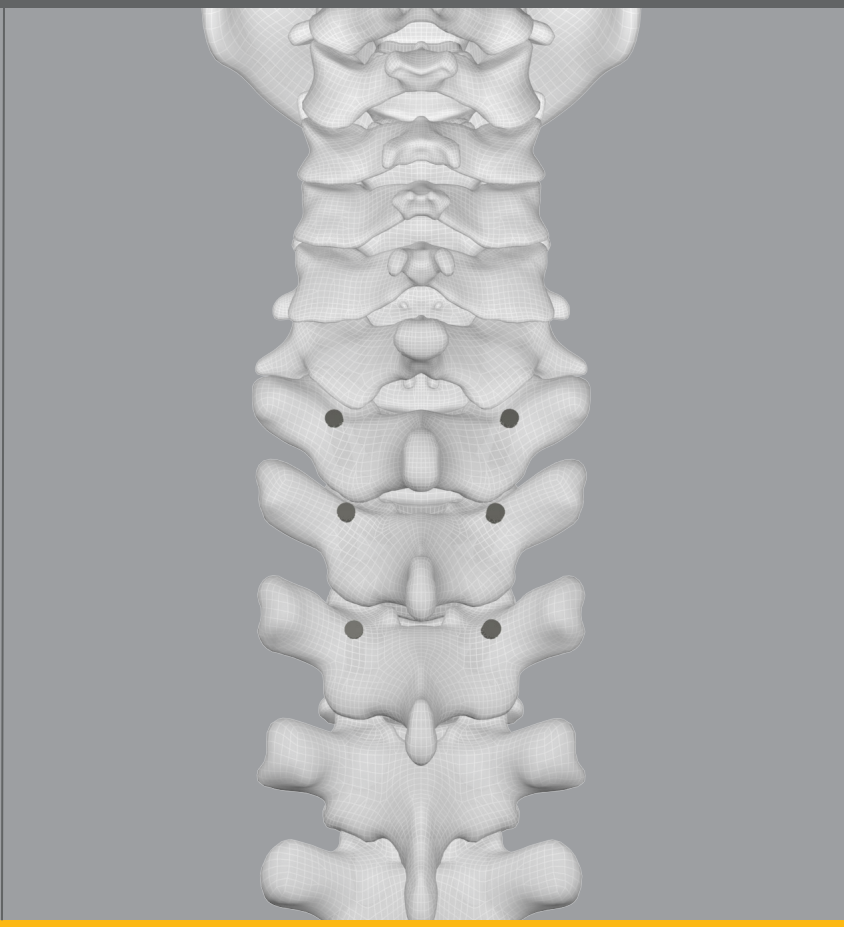
Determine the starting point and trajectory for each screw in the cervical or upper thoracic spine. Use the Awl to create a pilot hole by perforating the cortex of the pedicle. The Awl may be used with the spring-loaded protective sleeve. When used in this manner, the tip of the Awl extends approximately 6mm.

Two pedicle finder options are also available, one straight and one curved. This instrument may be used to create a track for the screw. Depth markings indicate length of the track.

EXPOSED POSTERIOR CERVICAL-THORACIC SPINE



PEDICLE T1, T2 AND T3 WITH CORRECT STARTING POINTS



The Adjustable Drill Guide may also be used allowing for depths to be drilled from 10mm to 40mm in 2mm increments. Pull back and rotate the knob 90 degrees releasing the Inner Shaft. Set Inner Shaft to desired length. Release knob to lock Inner Shaft into a fixed position.

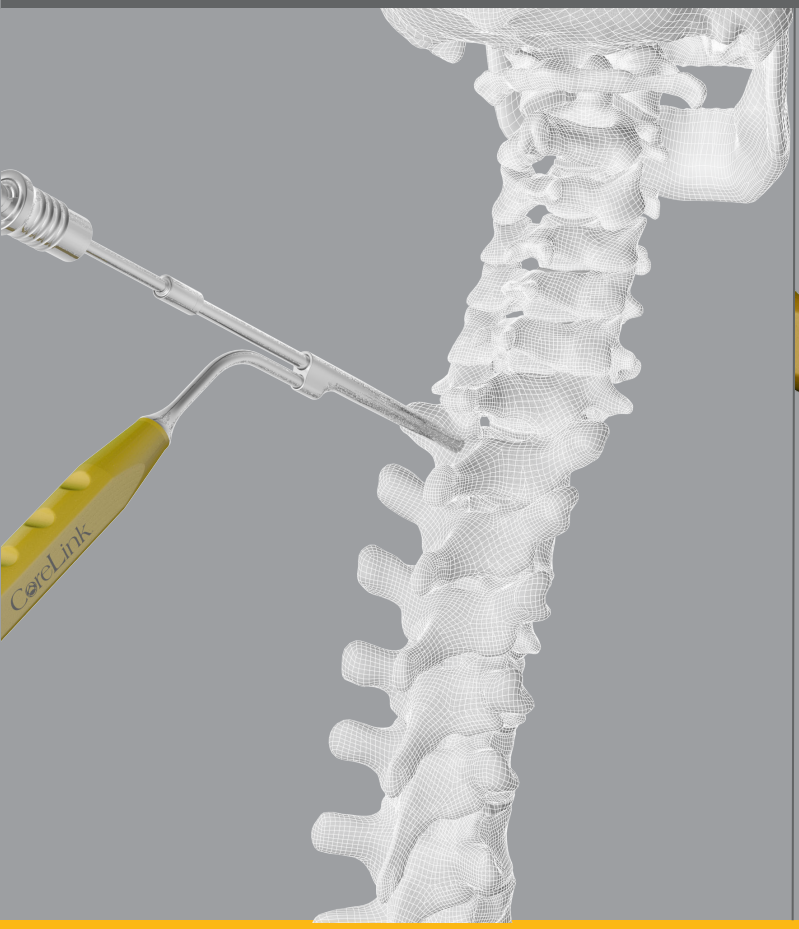
Insert the Adjustable Drill Bit onto an AO Connection Handle and through the Drill Guide.

A Fixed Length Drill Guide may also be used. Preset stops on the drill bits measure 12mm, 14mm, and 16mm.

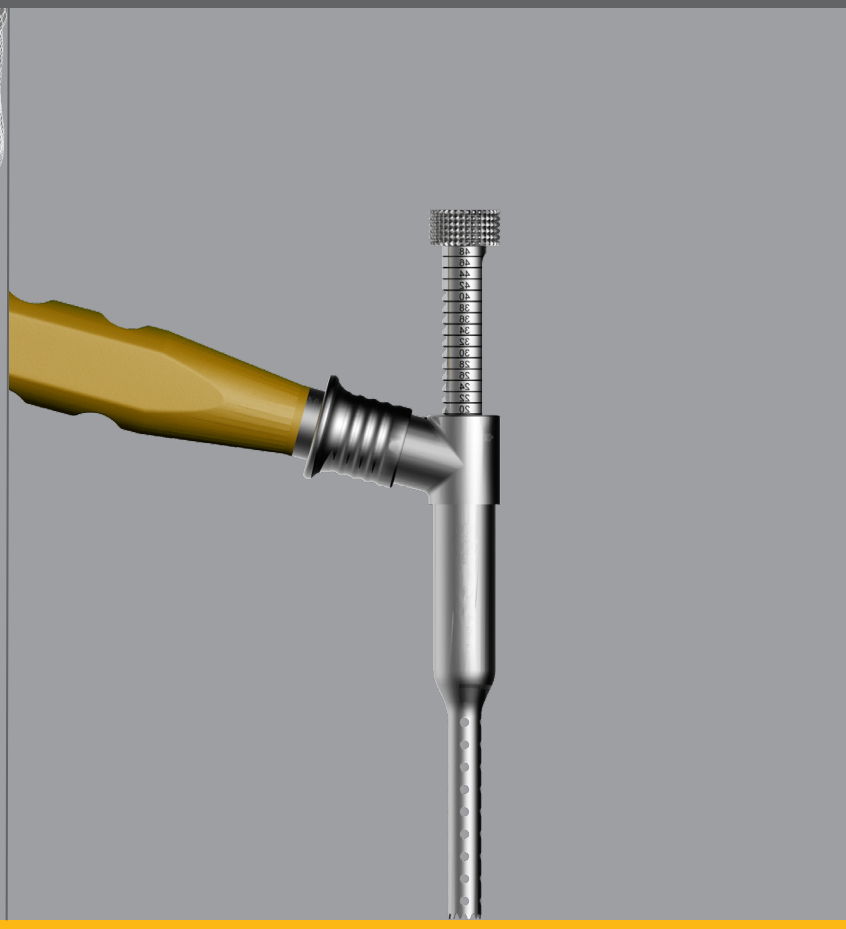
The polyaxial and bias angled screws are self-tapping. If surgeon preference and/or patient anatomy require tapping, a 3.5mm, 4.0mm, and 4.5mm Tap are available in the set.

The Ball-tip Probe may be used to explore the screw track.

FIXED LENGTH DRILL GUIDE



ADJUSTABLE DRILL GUIDE OPTION



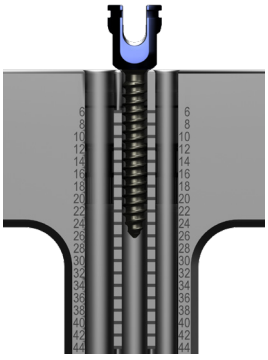
SCREW INSERTION

The appropriate diameter and length of screw should be determined using preoperative imaging and the Depth Gauge Instrument.

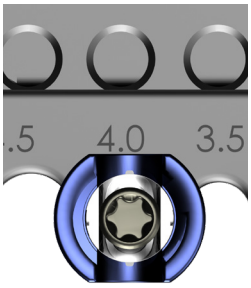
Two screw driver options are available in the standard set. One has a self-retaining feature to allow for ease of insertion. The hexalobe of the screw should be aligned with the hexalobe tip of the driver and force applied to retain the screw on the driver. Additionally a Polyaxial Screw Driver is available in the set. All screw drivers connect to the AO handles.

Verify the diameter and length of the screw before implantation. A gauge for diameter and length can be found on each screw caddy.

SCREW CADDY GAUGE MEASURING 4.0MM X 26MM SCREW



SIDE VIEW



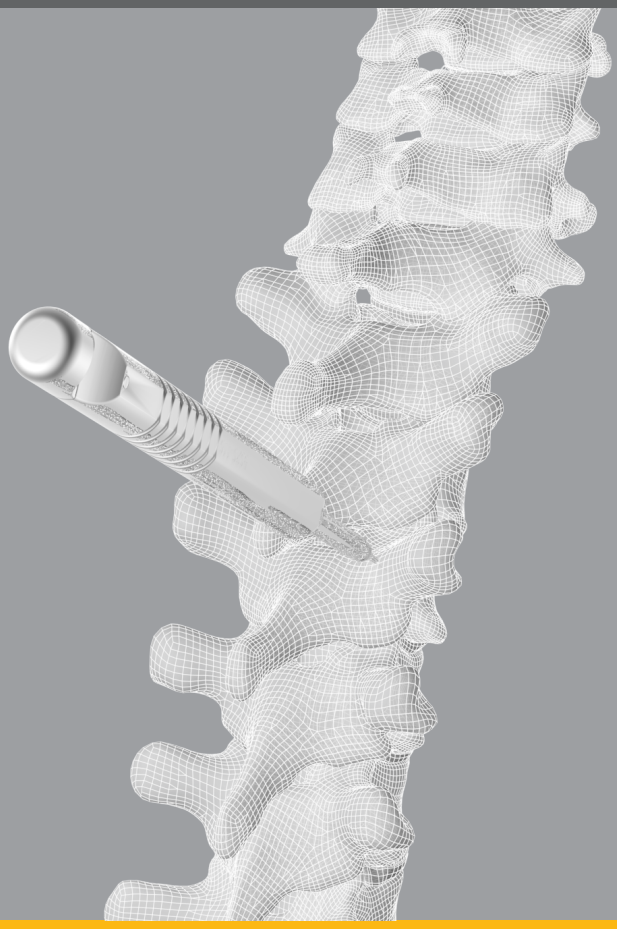
TOP VIEW

SCREW DRIVER OPTIONS

SELF-RETAINING

POLYAXIAL

DEPTH GAUGE

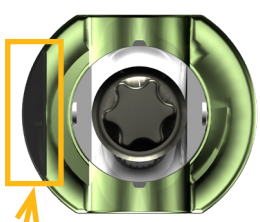


Insert the screws in the desired trajectory. To disengage the Self-retaining Screw Driver from the screw, pull up on the driver to release the hexalobe. Alternatively, to disengage the Polyaxial Screw Driver, turn the black knob counterclockwise to release the threads.

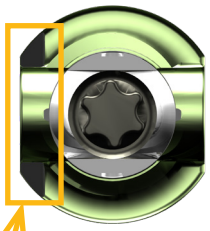
Polyaxial screws achieve at least 30 degrees of angulation in each direction. Bias angle screws add an additional 15 degrees in one direction. Bias angle screws are available in both cephalad/caudal and medial/lateral directions.

Indication grooves are cut on the top of the tulip head to indicate the direction of the bias.

After screws are inserted, use the Head Adjuster Instrument to align the tulip head prior to rod measurement and placement.



MEDIAL/LATERAL
BIASED INDICATION CUTS



CEPHALAD/CAUDAL
BIASED INDICATION CUTS

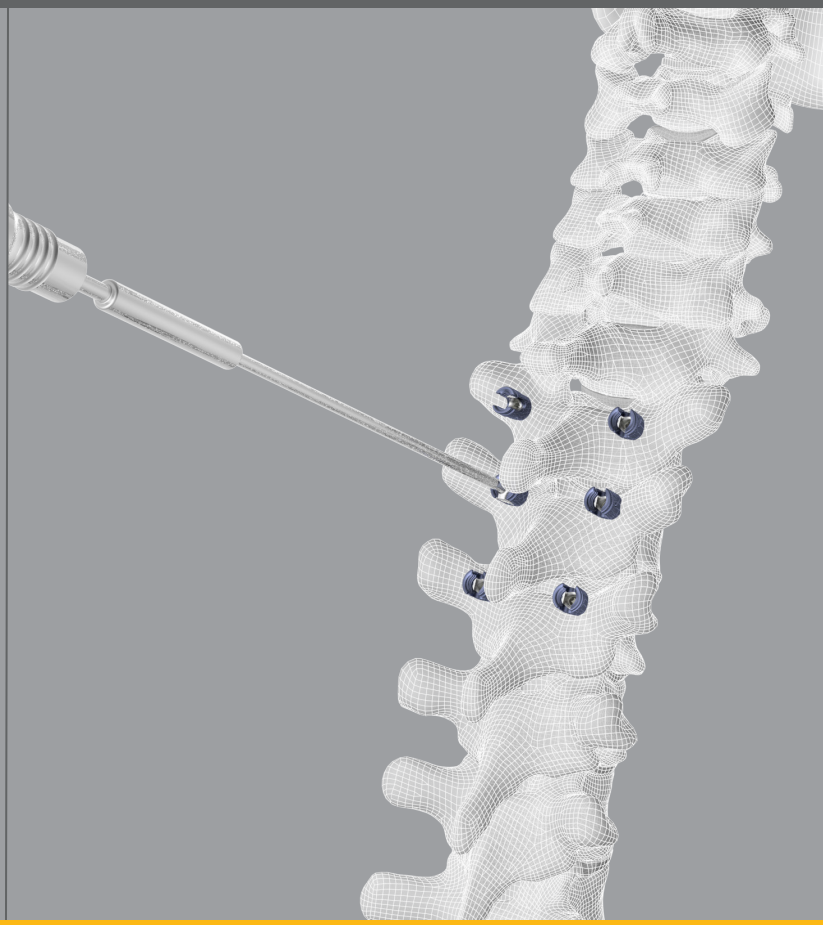
TULIP HEAD SCREWS COLORED CODED BY SCREW DIAMETER

3.5MM
SEAFOAM

4.0MM
DARK BLUE

4.5MM
MAGENTA

HEAD ADJUSTER INSTRUMENT



HOOK PLACEMENT

Hooks can be used for stabilization of the cervical spine. Use the Hook Holder Instrument to insert the Laminar Hooks. The Hook Pusher may also be used to place the hook in the desired position.

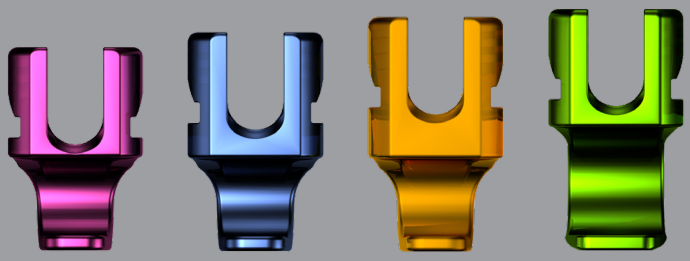
Choose the appropriate hook based on height and laminar size.

ROD MEASUREMENT

A rod template may be used to determine the curvature and length of the rod needed to fit the hook and screw construct.

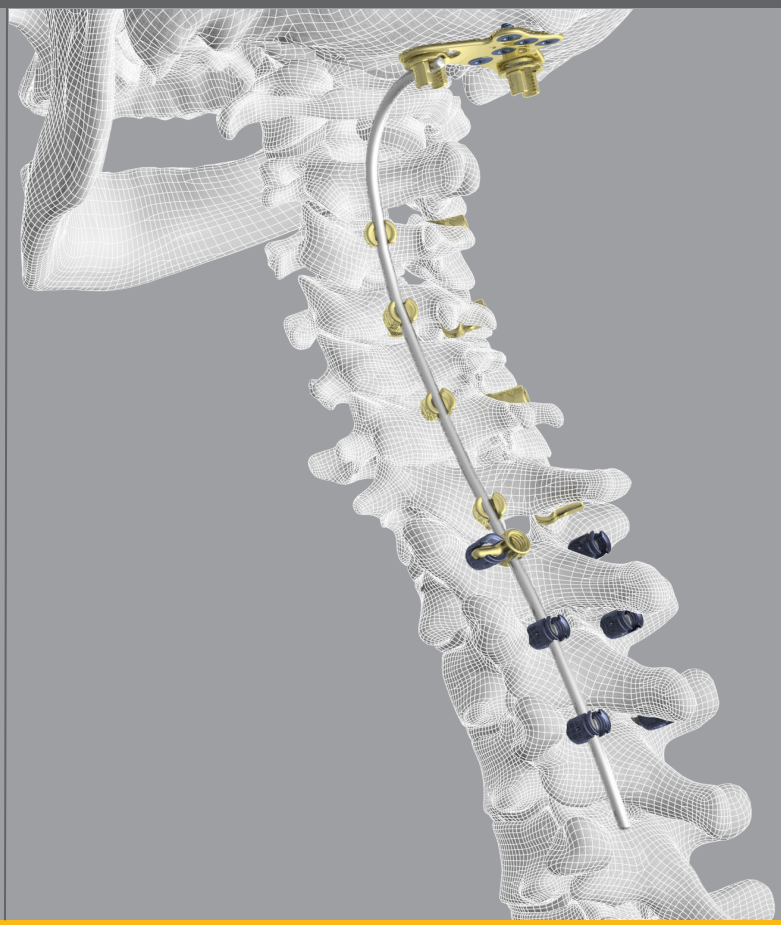
Length markings on the rod template indicate length of appropriate rod.

HOOK OPTIONS



5MM SMALL | 5MM MEDIUM | 5MM LARGE | 7MM X-LARGE

ROD MEASUREMENT



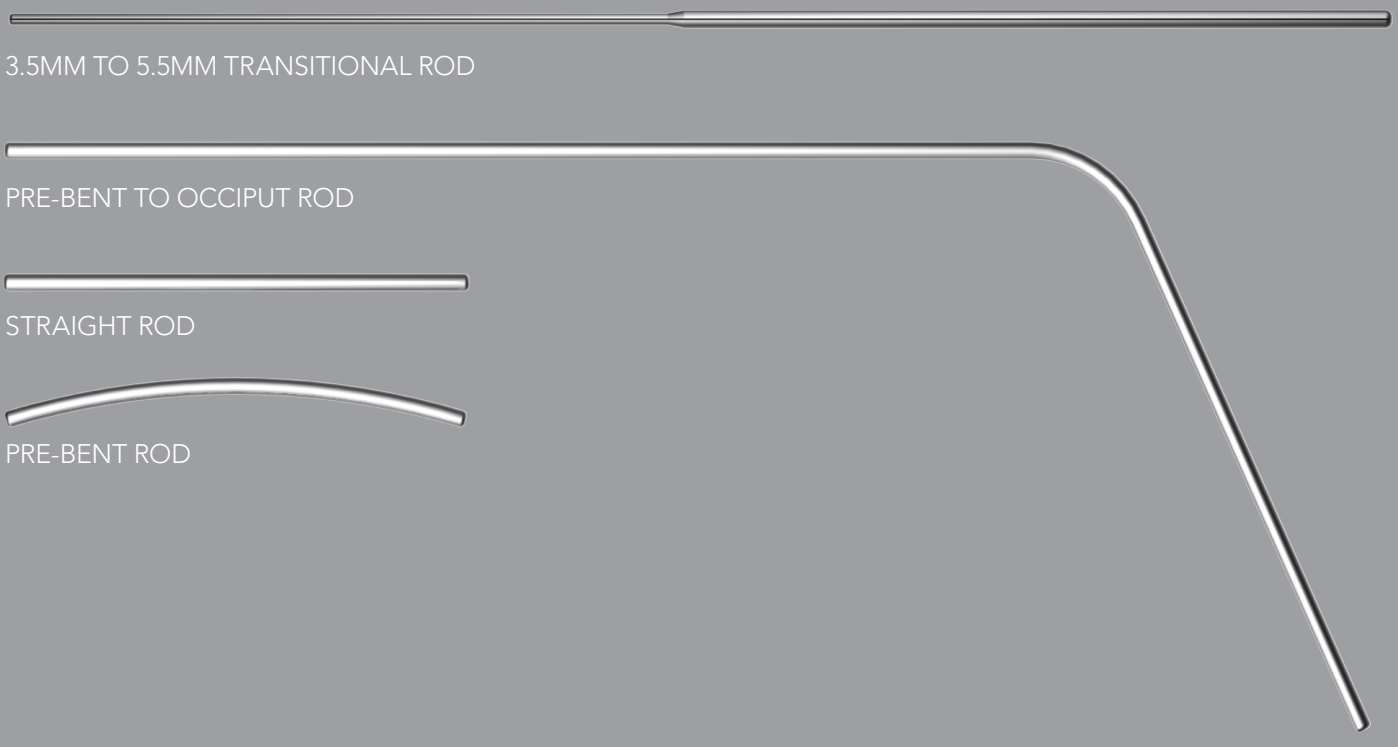
ROD SELECTION

Select the rod length that best suits the construct. Contouring and/or cutting may be necessary to accommodate patient anatomy.

Transitional Rods from a 3.5mm diameter to a 5.5mm diameter are also available to connect a cervical/upper thoracic constructs to a thoracolumbar construct. The lengths available are 420mm and 600mm.

These rods are compatible with both the Tiger Occipital-Cervical-Thoracic Spinal Fixation System and the Tiger Spine System.

ROD OPTIONS



3.5MM TO 5.5MM TRANSITIONAL ROD

PRE-BENT TO OCCIPUT ROD

STRAIGHT ROD

PRE-BENT ROD

ROD CUTTING

The 3.5mm diameter rods may be cut to accurately fit the spinal construct. An optional rod template can be used to determine the cut location. Cut at the desired point.

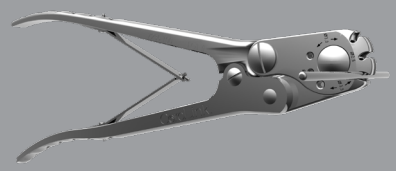
ROD BENDING

A Rod Bender may be used to contour the rod to fit the construct. Use caution when bending the rod as repetitive rod bending may weaken the material.

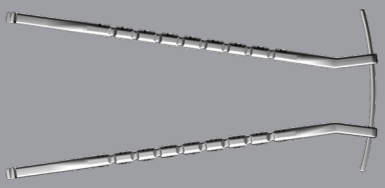
Once the rod is properly sized and contoured, use the Rod Holding Forceps to insert the rod into the construct.

If additional rod bending is needed in situ, the In Situ Benders (#7035-103, 7035-104) may be used to contour the rods in the sagittal plane and the Coronal Benders (#7035-101, 7035-102) in the axial (medial/lateral) plane. The Coronal Benders are available through customer service.

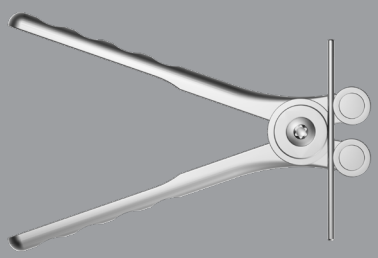
ROD CUTTING AND ROD BENDING



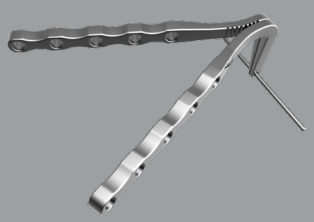
ROD CUTTER



IN SITU BENDERS

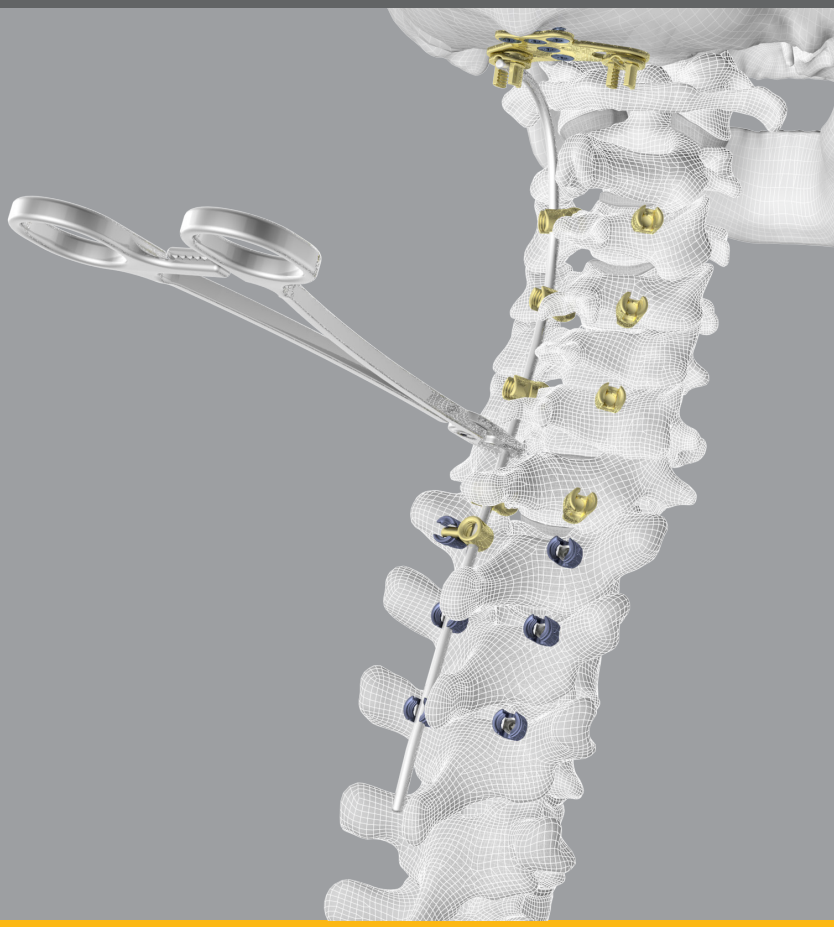


FRENCH BENDER



CORONAL BENDERS

ROD HOLDING FORCEPS



POSTERIOR CERVICAL SCREW PLACEMENT

Various surgical techniques exist for placing screws in the cervical spine. Most common techniques include lateral mass and pedicle screw placement. The level at which screws are being placed often dictates which technique is used, however individual patient anatomy must be considered. The common techniques based on level are described below.

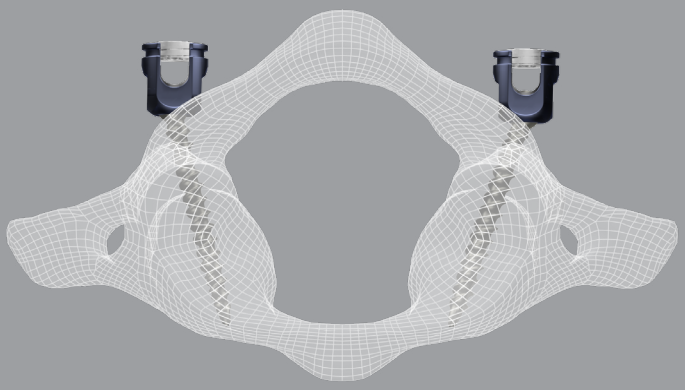
C1 Lateral Mass Screws

The starting point of C1 lateral mass screw placement is at the junction of the posterior arch and lateral mass, inferior to the arch. Smooth shank screws are available which may reduce the possibility of C2 nerve root irritation.

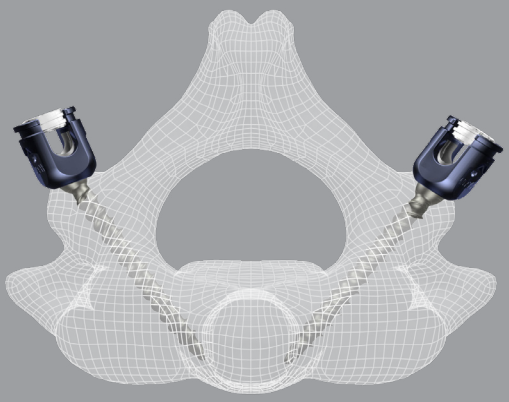
C2 Pedicle Screw Placement

The starting point of C2 pedicle screw placement is in the superior and medial portion of the C2 lateral mass. The medial angulation directs the screw away from the vertebral artery.

C1 LATERAL MASS SCREWS



C2 PEDICLE SCREW PLACEMENT



POSTERIOR CERVICAL SCREW PLACEMENT (CONTINUED)

Placement of Lateral Mass Screws (C3-C7)

The starting point for lateral mass screw placement should be near the center of the lateral mass. The tip of the screw should be directed cephalad and lateral, away from the nerve root, spinal cord, and vertebral artery.

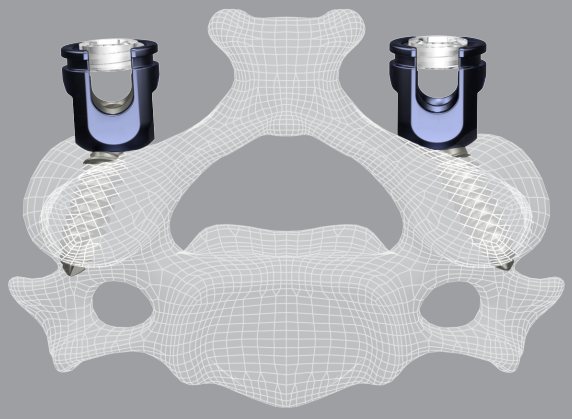
Note: It is possible to place screws in the pedicles of C3-C6, but it can be technically challenging due to the anatomical structure in this location. Careful consideration and preoperative planning should be conducted with imaging studies to verify screws can be safely placed in the pedicle. Intraoperative imaging should also be utilized during pilot hole preparation and screw insertion.

Placement of Pedicle Screws at C7

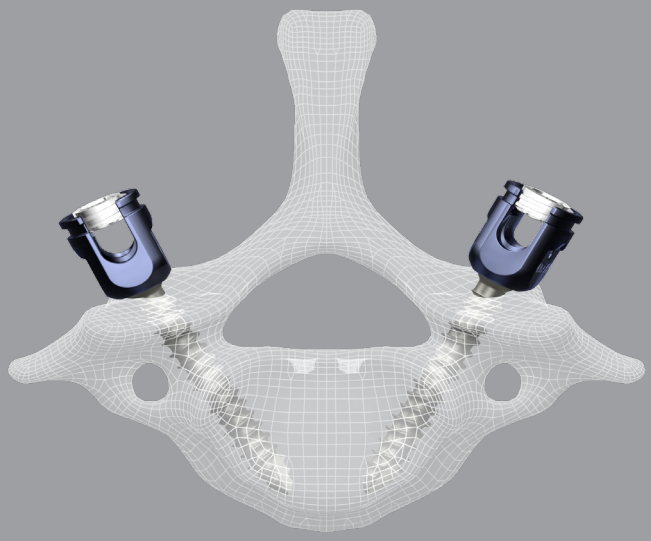
The C7 pedicle is slightly larger than the C3-C6 pedicles, therefore in a majority of cases, C7 favors pedicle screw placement over lateral mass screw placement. The entry point for the screw should start lateral and superior to the center of the lateral mass.

Note: In some instances, lateral mass and pedicle screw placement may not be appropriate due to inherent anatomic variability of the pedicles or other anatomical considerations such as proximity to vessels or nerve roots. Careful consideration should be given to patient anatomy prior to selecting the screw placement technique. Other available techniques include pars screws, translaminar screws, and transarticular screw placement.

LATERAL MASS SCREWS (C3-C7)



PEDICLE SCREWS AT C7

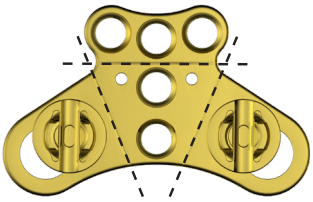


OCCIPITAL FIXATION

Occipital plates are available in small, medium, and large sizes with five holes for occipital bone screws.

The occipital plate should be centered between the midline of the external occipital protuberance (EOP) and the foramen magnum. The central bone screw holes should align with the internal occipital protuberance (IOP) or midline occipital keel. This will allow for bone screw placement in the thickest portion of the occiput.

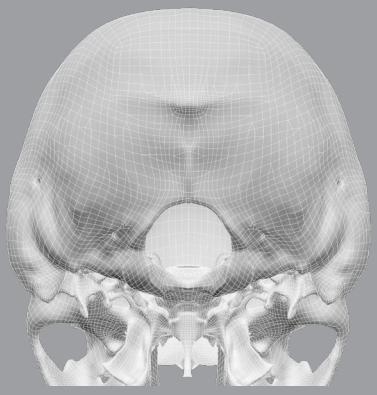
Each occipital plate has designated bend zones. These bend zones allow for contouring of the plate to best fit patient anatomy. The right wing bender fits over the right wing of the plate while the left wing bender fits over the left wing of the plate.



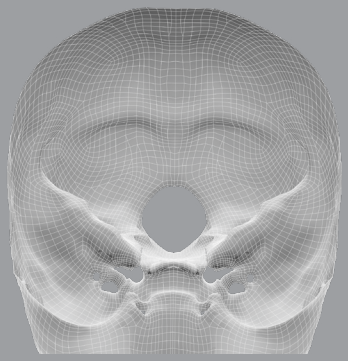
MEDIUM PLATE
BEND ZONES

Use the occipital plate holders to position the plate. The plate holder and counter torque engages the counter torque pinholes to steady the plate while screws are being inserted and tightened into place.

BONE SCREW PLACEMENT



EXTERNAL OCCIPITAL
PROTUBERANCE (EOP)

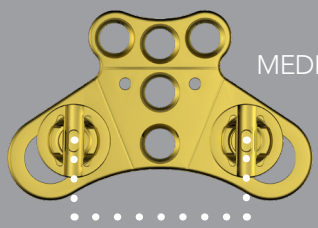


INTERNAL OCCIPITAL
PROTUBERANCE (IOP)

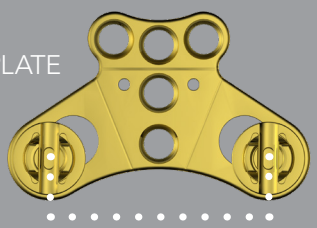
PLATE POSITIONING

DISTANCES BETWEEN RODS

PLATE	MINIMUM DISTANCE	MAXIMUM DISTANCE
SMALL	22MM	33MM
MEDIUM	30.5MM	38.5MM
LARGE	35MM	46MM



MEDIUM PLATE
MINIMUM DISTANCE
BETWEEN RODS



MAXIMUM DISTANCE
BETWEEN RODS

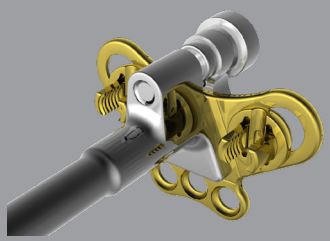


PLATE HOLDER,
CENTER INSTRUMENT

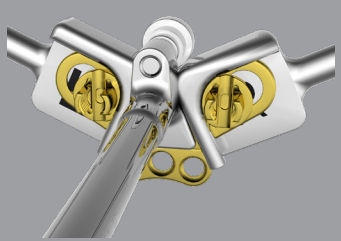


PLATE WINGS BENT
ON BEND ZONES

OCCIPITAL FIXATION (CONTINUED)

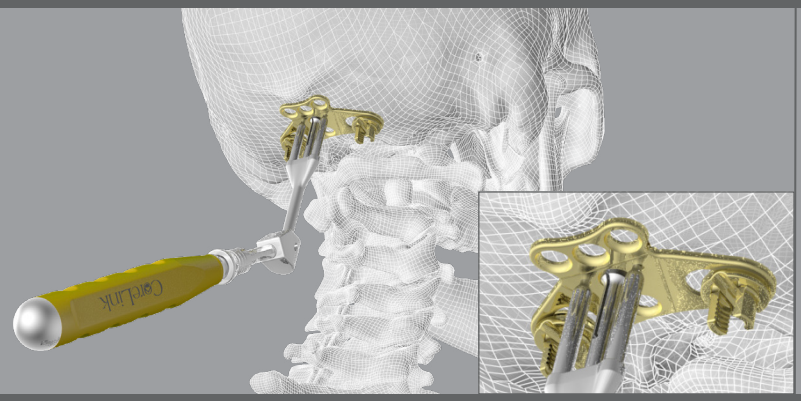
Use the Awl to create a pilot hole by perforating the cortex of the occipital bone. The Awl may be used with the Spring-loaded Protective Sleeve allowing for approximately 6mm of penetration.

It is recommended to both drill and tap the occipital bone screw holes due to the density of the bone. For ease of use, the drills and taps are available in straight, U-jointed, and flexible options. For added stabilization, a handle has been added to the U-jointed instruments.

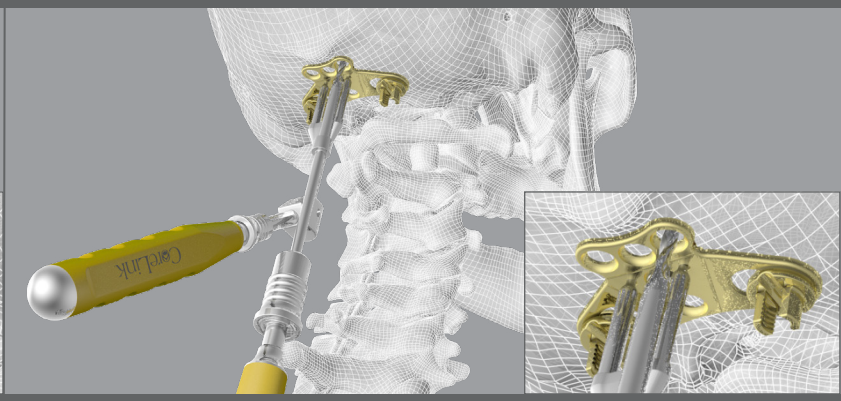
The Adjustable Drill Guide should be used to verify the depth of the drill. To use, pull back and rotate the knob 90 degrees, releasing the inner shaft. Set inner shaft to desired length. Release knob to lock inner shaft into a fixed position. Verify the desired length has been chosen using the indication lines on the slider. The Adjustable Drill Guide may be used for drilling and tapping.

Occipital bone screws are available in 4.0mm and 5.0mm diameters and lengths from 6mm to 16mm, in 2mm increments. To insert the screws, use one of the Self-retaining Screw Driver options.

PLATE HOLDER POSITIONING PLATE ON OCCIPUT

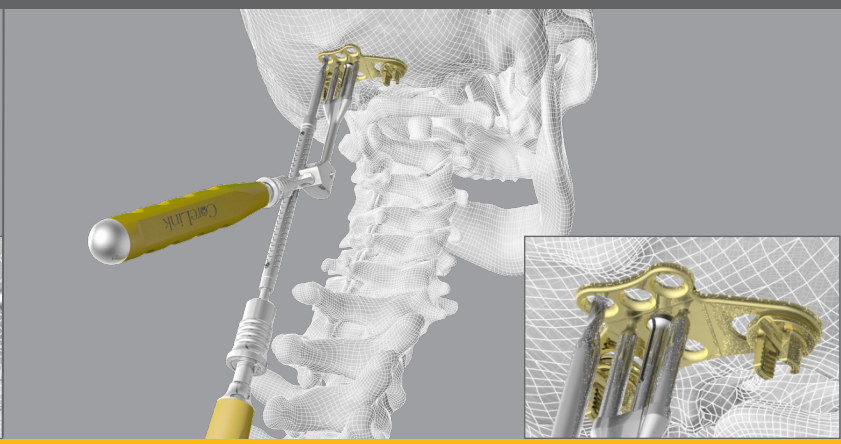


STRAIGHT DRILL



U-JOINTED DRILL

FLEXIBLE DRILL



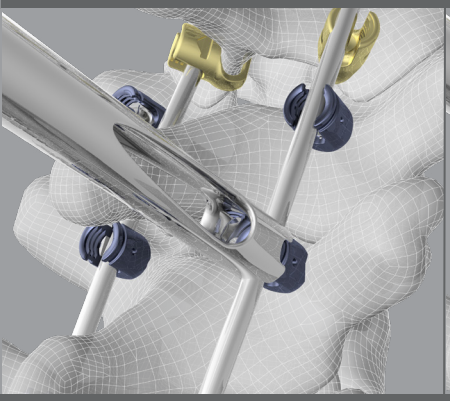
ROD REDUCTION

The Tiger Occipital-Cervical-Thoracic Spinal Fixation System has several options for rod reduction. If minimal reduction is needed, the In-line Counter Torque or L-shaped Counter Torque may be used to apply downward force on the rod and reduce the rod into the tulip head of the screw. The set screw may then be inserted through the Counter Torque.

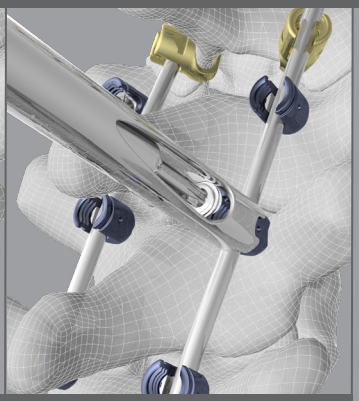
The Rod Rocker may also be used for rod reduction. The pins on the rocker will slide into the triangular groove on the sides of the tulip head. Use this instrument to lever the rod into the fully reduced position. The set screw may then be inserted using the set screw driver.

An Adjustable Rod Rocker (#3035-104) is an optional item which can be ordered through customer service.

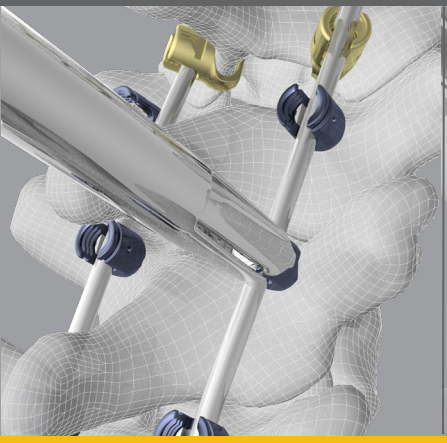
IN-LINE COUNTER TORQUE PUSHING ROD INTO PLACE



SET SCREW INSERTION VIA IN-LINE COUNTER TORQUE

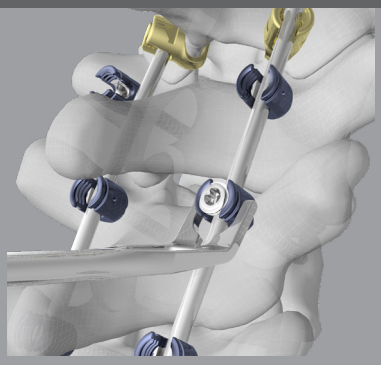


ROD REDUCER

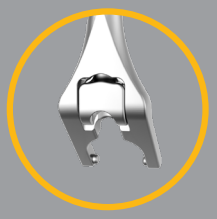


DIAL DOWN ROD REDUCER

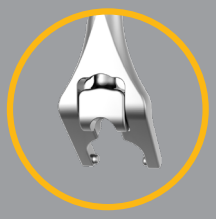
ROD ROCKER ROD REDUCTION



ROD ROCKER



RECESS IN RAISED POSITION



RECESS IN LOWERED POSITION

ADJUSTABLE ROD ROCKER

SET SCREW INSERTION

The set screws can be inserted with or without reduction instruments. If the rod is fully seated in the hook or pedicle screw, use the Self-retaining Set Screw Driver to insert the set screw.

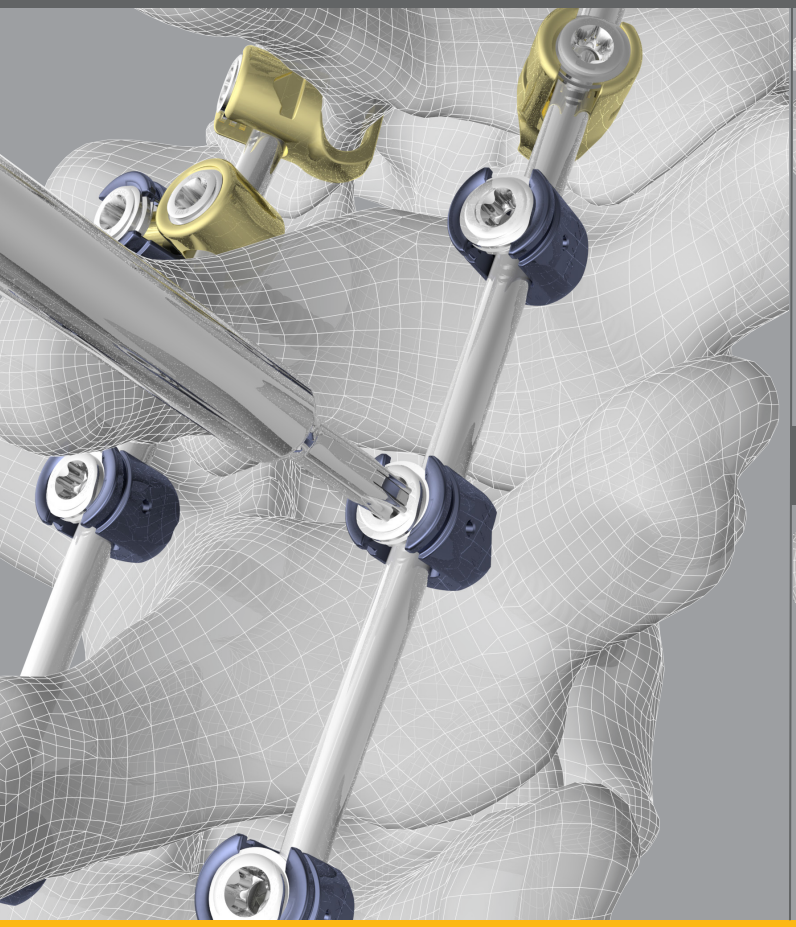
If reduction is needed, use any of the aforementioned reduction instruments in conjunction with the Set Screw Driver.

The Self-retaining Screw Driver will only provisionally tighten the set screw. Final tightening with the proper Torque Limiting Handle is required as a final step.

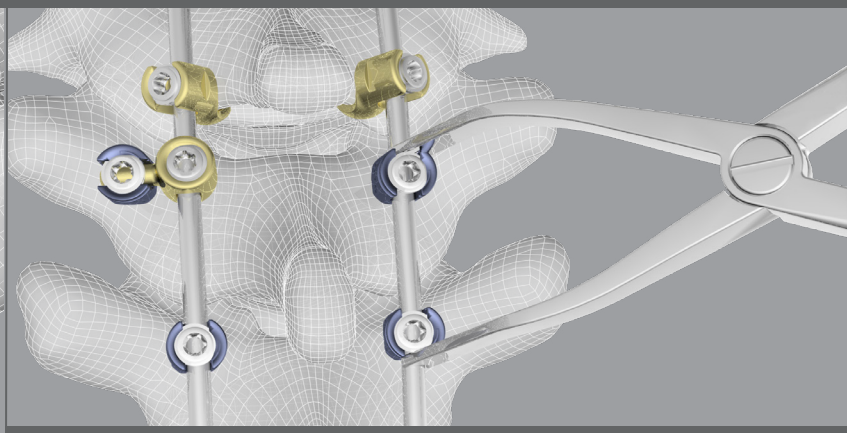
COMPRESSION AND DISTRACTION

The pedicle screws may be compressed or distracted along the rod once the set screws are in place using the Posterior OCT Compressor and Posterior OCT Distractor.

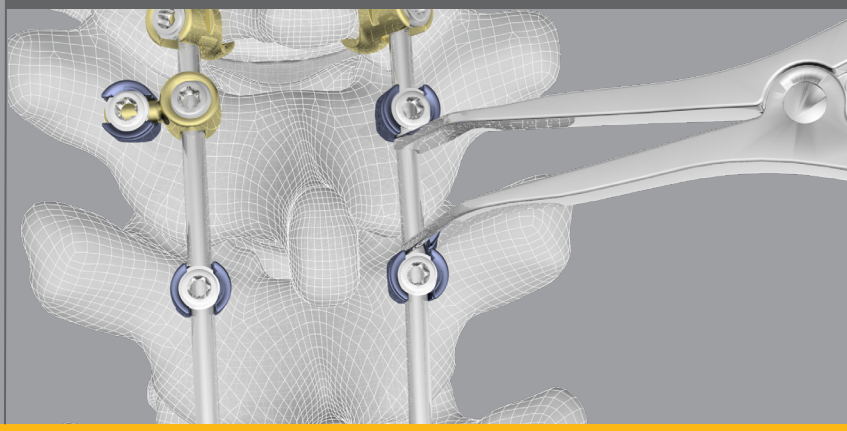
SET SCREW INSERTION



COMPRESSION



DISTRACTION



FINAL TIGHTENING

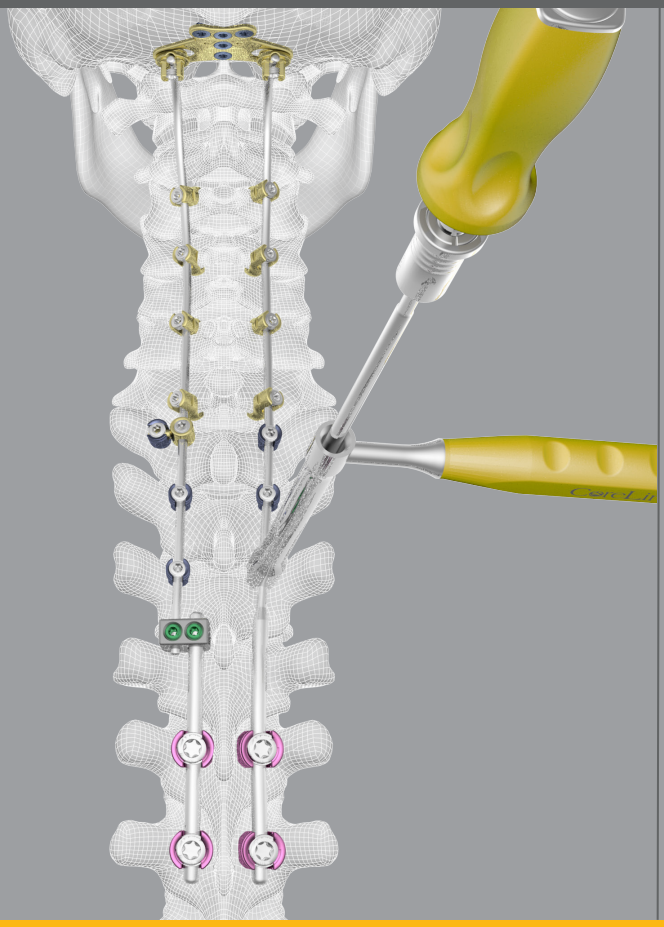
Final tightening of the set screws is required to secure the construct. The final tightening shaft should be used on the Torque Limiting Handle in conjunction with one of the counter torque options. The torque limiting value is 2Nm.

The locking of the set screws on the occipital plate should be done with the Final Tightening Shaft and the 2.5Nm Torque Limiting Handle.

IMPLANT REMOVAL

For revision or removal of this system, reverse all the insertion steps to remove the implants.

FINAL TIGHTENING



FINAL CONSTRUCT

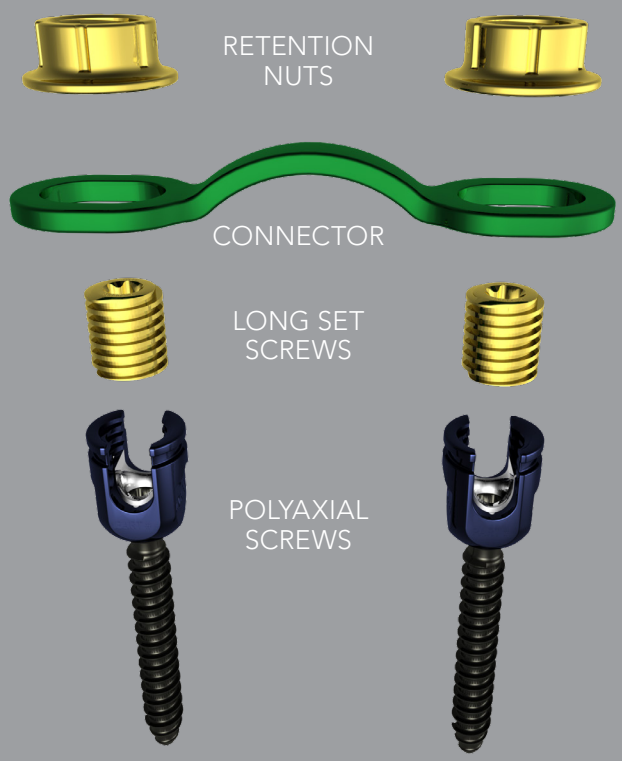
TRANSVERSE CONNECTORS

Transverse Connectors may increase construct stability. Two Transverse Connector options are available with this system: Head-to-head Connectors and Cross Connectors. The Head-to-head Connectors should never be used with cervical hooks; they are only for use with pedicle screws. The Cross Connectors hook between the rods. Both options are available in a range of sizes and allow for translation to fit individual patient anatomy.

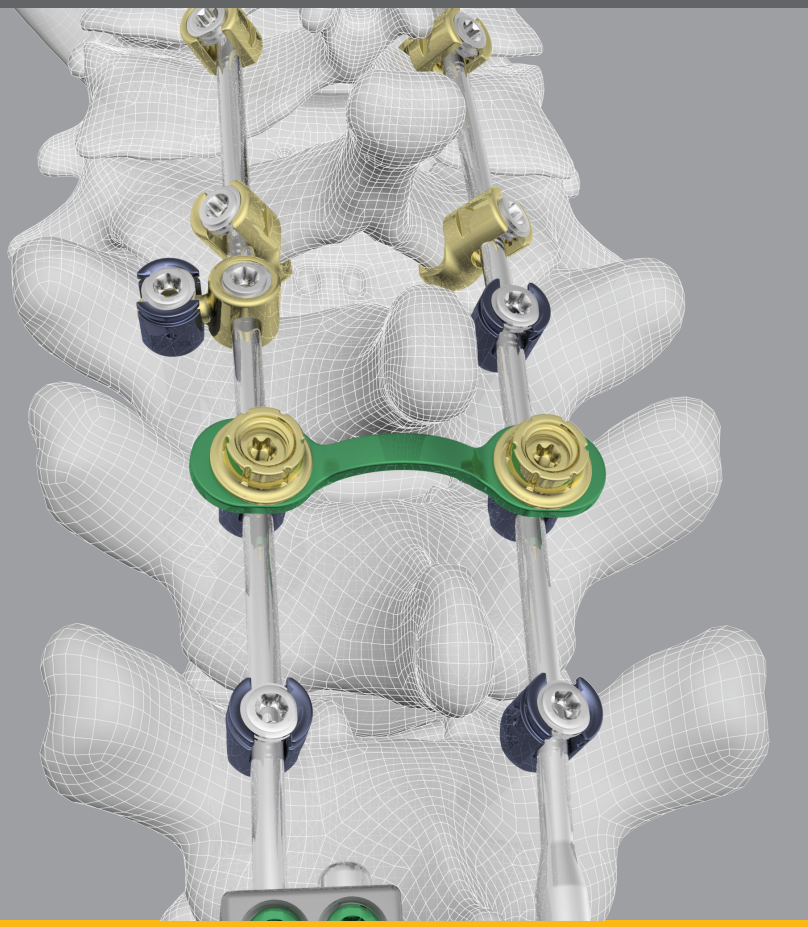
When using the Head-to-head Transverse Connector, insert the long set screw on both sides of the construct. Slide the connector over the long set screws and secure with the retention nut. The Retention Nut Final Tightener should be used to lock the nut into place. The torque limiting value is 2Nm.

The Cross Connector may be placed at any level of the construct. The retention nut will lock the translation and clip into place on the rod. The Retention Nut Final Tightener should be used to lock the nut into place. The torque limiting value is 2Nm.

HEAD-TO-HEAD CONNECTOR ASSEMBLY ORDER



CROSS CONNECTOR



LATERAL OFFSET CONNECTORS

Lateral Offset Connectors may be used to avoid excess contouring of a rod. Top Loading, Side Loading Open, and Side Loading Closed Connectors are available in lengths of 8.5mm, 16mm, and 30mm.

The Rod Holder may be used to help insert the Lateral Connector.

If necessary, the rod portion of the connector can be cut using the Rod Cutter.

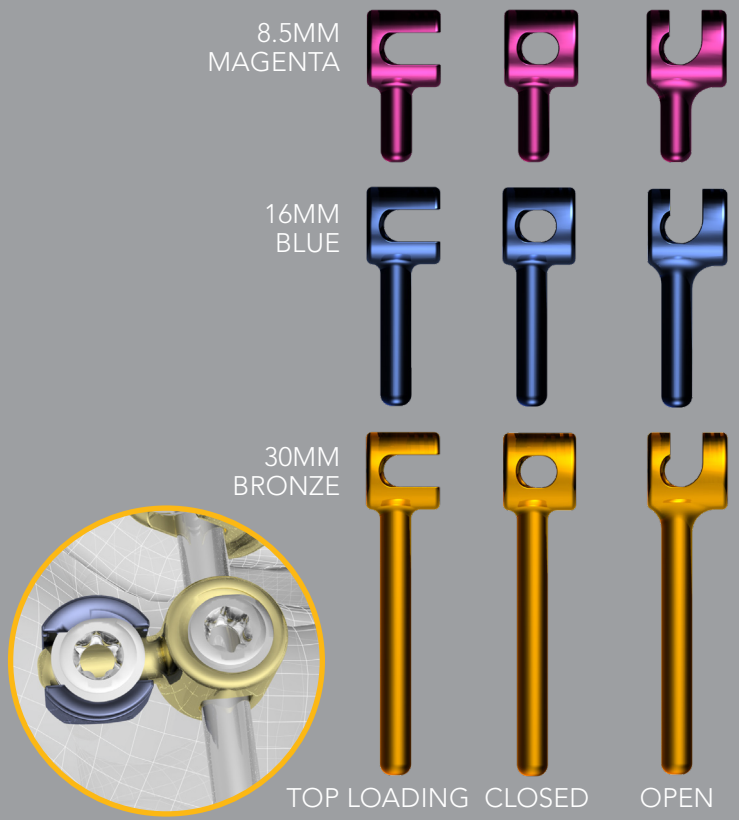
ROD-TO-ROD CONNECTORS

When transitioning from a titanium cervical/upper thoracic construct to a titanium thoracolumbar construct, Rod-to-rod Connectors may be used. These connectors join a 3.5mm rod to a 5.5mm rod via a side-by-side configuration or an end-to-end configuration. These connectors are available in open and closed versions.

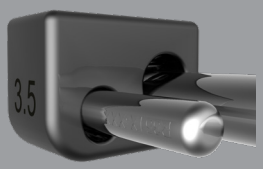
A 3.5mm Rod to 3.5mm Rod Connector is available to minimize the rod contouring necessary. Similarly, side-by-side and end-to-end configurations are available.

The green set screws in the Rod-to-rod Connectors must be final tightened with the Hexalobe Driver and the 2Nm Torque Limiting Handle.

LATERAL OFFSET CONNECTORS

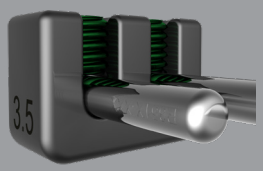


ROD-TO-ROD CONNECTORS



3.5MM TO 5.5MM
SIDE-BY-SIDE
CLOSED

3.5MM TO 5.5MM
SIDE-BY-SIDE
CLOSED



3.5MM TO 3.5MM
SIDE-BY-SIDE
OPEN

3.5MM TO 3.5MM
SIDE-BY-SIDE
CLOSED

INSTRUCTIONS FOR USE

TIGER® OCCIPITAL CERVICAL THORACIC SPINE SYSTEM

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

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

DESCRIPTION

The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is an implant system used to provide temporary immobilization and stabilization of the cervical spine and occipito-cervico-thoracic junction while fusion occurs. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System consists of screws, rods, hooks, plates, and connectors in various configurations which can be assembled to create a construct that meets the need of the patient. It can be used for single or multiple level fixation. Spinal rods and hooks may be contoured intraoperatively to meet specific anatomical requirements.

Implants in the Tiger Occipital-Cervical-Thoracic Spinal Fixation System are manufactured from the following materials:

• Medical grade titanium alloy (Ti6Al4V as per ASTM F136)

• Medical grade cobalt-chromium-molybdenum alloy per (CoCr as per ASTM F-1537)

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

Do not use any of the Tiger Occipital-Cervical-Thoracic Spinal Fixation System components with components from any other manufacturer or system unless specifically allowed to do so in this or other CoreLink document. Implants in this system must never be reused under any circumstance. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is provided with surgical instruments specifically for the implantation of the associated implants.

Implants designed to interface with a specific rod diameter are NOT compatible with other rod diameters unless otherwise specified (e.g. rod-to-rod connectors). Implants designed to interface with varying specific rod diameters are compatible with rods from other systems having the same diameter and same material as indicated on the implants and in the system Surgical Technique Guide.

INDICATIONS

The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Tiger Occipital-Cervical-Thoracic Spinal Fixation System may be connected to the components in the Tiger Spine System using the side by side and end to end rod to rod connectors.

CONTRAINDICATIONS

Do not use the Tiger Occipital-Cervical-Thoracic Spinal Fixation System in the presence of:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented metal allergy or intolerance.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling to follow postoperative instructions.
- Any case not described in the indications.

Other relative contraindications include severe bone resorption, including severe osteoporosis, and osteomalacia.

COMPLICATIONS AND POSSIBLE ADVERSE EFFECTS

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

- Loosening of any or all components.
- Disassembly, bending and/or breakage of any or all components.
- 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, damage or penetration of any spinal bone.
- Post-operative change in normal spinal curvature, loss of correction, height.
- Pain, skin penetration, irritation, fibrosis caused by skin pressure by implant components.
- Bursitis.
- 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 spinal fixation systems has been established only for spinal conditions with acute and chronic instabilities or deformities of the cervical and thoracic spine (C1 – T3): 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, stenosis, fracture, dislocation, atlanto/axial fracture

with instability, occipito-cervical dislocation, 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 implant components will fail in any of several modes. These modes may include bone-metal 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.

Contouring or bending of an implant may reduce its strength from fatigue and cause its fracture or deformation. If spinal implants (including rods) are excessively bent, bent forward and then backward or otherwise damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods must be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted and are to be discarded. Refer to the Tiger Occipital-Cervical-Thoracic Spinal Fixation System surgical technique manual for descriptions of appropriate bending instruments to be used with rods.

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, the patient must be informed about general surgical risks prior to surgery.

PRECAUTIONS: The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal 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 components. 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 from erroneous indication, wrong choice of implant size, incorrect operating procedure, and incorrect implant component combination. Internal fixation devices such as the Tiger Occipital-Cervical-Thoracic Spinal Fixation 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 Tiger Occipital-Cervical-Thoracic Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System has not been tested for heating migration, or image artifact in the MR environment. The safety of the Tiger Occipital-Cervical-Thoracic Spinal Fixation 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 Tiger Occipital-Cervical-Thoracic Spinal Fixation 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 Tiger Occipital-Cervical-Thoracic Spinal Fixation 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 an instrument is suspected to be 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 instrument in a lukewarm neutral pH enzyme solution and allow it to soak for a minimum of 10 minutes. Use a soft-bristled brush to gently clean the instrument (particular attention must be given to crevices, cannulations, hinges, mated surfaces and other hard-to clean areas) until all visible soil has been removed. Brushing steps should be performed while submerged to prevent aerosols. A lumen brush must be used to clean cannulations. The enzyme solution should be changed on a regular basis in order to ensure its effectiveness.
2. Remove the instrument from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled). Thoroughly flush cannulations, holes, and other difficult to reach areas with a syringe or equivalent tool.
3. Prepare a neutral pH cleaning solution according to the manufacturer's instructions and place in an ultrasonic cleaning unit at 45-50 kHz to aid in thorough cleaning of devices
4. Completely submerge device in cleaning solution and sonicate for minimum of 14 minutes.
5. Rinse instrument in running purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least one minute. There must be no sign of detergent, blood, or soil in the rinse stream.
6. Dry the instrument with a clean, disposable, absorbent, lint-free wipe. Instruments that require reassembly should be done so after drying.
7. Visually inspect instruments to ensure they are clean and in working order. If the device is found to not be visually clean, the previous cleaning steps must be repeated.

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

Automated Cleaning Instructions:

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

INSTRUCTIONS FOR USE (CONTINUED)

Typical Automated Washer Cycle for Surgical Instruments

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

Notes:

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

Sterilization Instructions

Implants and instruments of the Tiger Occipital-Cervical-Thoracic Spinal Fixation 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 Tiger Occipital-Cervical-Thoracic Spinal Fixation 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 Tiger Occipital-Cervical-Thoracic Spinal Fixation System is not recommended.

MAINTENANCE OF TORQUE WRENCH

Calibration: Regular calibration ensures the torque wrench performs according to its specifications. To ensure that the torque wrench operates properly and safely at all times, CoreLink recommends that the torque wrench be calibrated every six (6) months, after 200 autoclaves cycles, or approximately 3000 actuations (clicks), whichever comes first. Heavy use applications may require more frequent calibration. If at any time a device seems to be malfunctioning, remove it from service and return to CoreLink immediately for replacement or calibration.

IMPORTANT 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 implanted metals and alloys is typically low due to the presence of passive surface films on the implanted metals and alloys. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System implants are available in titanium alloy and cobalt chrome alloy. It is imperative that the Tiger Occipital-Cervical-Thoracic Spinal Fixation System implants do not come into contact in-vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment. Corrosion may accelerate failure of implants. Corrosion also causes metal compounds to be released into the body.
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 alignment 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.** Appropriate implant selection, placement, and fixation are critical factors that affect implant life. Strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to maximize implant longevity. 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. Care must be taken to protect the components from being marred, nicked, or notched. Alterations will product defects which may become the point for eventual implant breakage. Inspection and trial assembly are recommended to determine proper working order of the system. If any components are damaged in any way, do not use them and return them to CoreLink.
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.
   - **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, 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. 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. Inform the patient that improper activities may cause the implants to become displaced or damaged and 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: (1) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (2) 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 be removed after sufficient bone fusion develops. 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. If the device is not removed after sufficient bone fusion develops the following may occur: (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 must 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.

PRE-OPERATIVE PLANNING

Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

INTRAOPERATIVE INSTRUCTIONS

1. Extreme caution must be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components will cause injury to the patient or operative personnel.
3. The implant rods must not be repeatedly or excessively bent. The rods must not be reverse bent in the same location. Use great care to ensure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, drill a pilot hole corresponding to selected screw size and prepare screw site with a tap.

   Caution: Do not over-tap or use a screw that is either too long or too large. Over-tapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert.
6. Before closing the soft tissues, all set screws must be tightened firmly using the supplied torque wrench. Recheck the tightness of all screws or set screws after finishing to make sure that none loosened during the tightening of the other screws or set screws. Failure to do so will cause loosening of the other components.

POSTOPERATIVE MANAGEMENT

Postoperative management by the surgeon, including instruction and warning and compliance by the patient, of the following is essential:

1. The patient must have a complete understanding of and compliance with the purpose and limitations of the implant devices. The surgeon must instruct the patient on how to compensate for any loss in range of spinal motion due to bone fusion.
2. The surgeon must instruct the patient regarding amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts or other movements preventing proper healing and/or fusion development.
3. In the case of delayed, mal-, or non-union of bone, the patient must continue to be immobilized in order to prevent bending, dislocation, or breakage of the implant devices. Immobilization must continue until a complete bone fusion mass has developed and been confirmed.
4. Postoperative patients must be instructed not to smoke, consume alcohol, or consume non-steroidals or aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result must also follow implant surgery.
5. Implant devices must be revised or removed immediately if appropriate, upon a case of a non-union, pseudoarthrosis or if the devices have been bent, dislocated or broken.
6. The Tiger Occipital-Cervical-Thoracic Spinal Fixation System implants are designed and intended as temporary fixation devices. The device should be removed after complete healing has occurred. Devices, which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain desired result should also follow implant removal surgery.

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

LIMITED WARRANTY AND DISCLAIMER

CORELINK PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

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

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

INSTRUCTIONS FOR USE (CONTINUED)

For further information contact:

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

SYMBOLS GLOSSARY

Symbol	Description	ISO 15223 Reference
	Prescription Required	N/A
	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
	Caution – Indications 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
	Consult instructions for use - Indicates the need for the user to consult the instructions for use.	5.4.3
	Manufacturer - Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	5.1.1

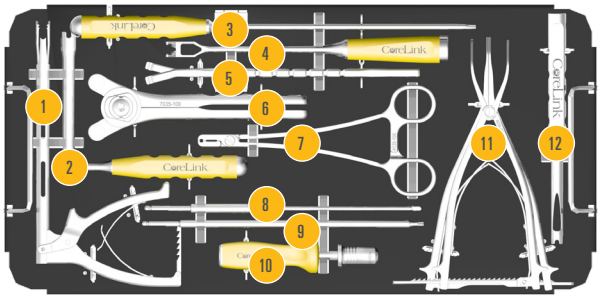
TIGER OCT INSTRUMENT TRAY

KIT ORDER #K50000081

INSTRUMENTS		
QTY	CATALOG NUMBER	DESCRIPTION
1	1035-035	TAP – 3.5MM
1	1035-040	TAP – 4.0MM
1	1035-135	DRILL – 3.5MM, 12MM STOP
1	1035-140	DRILL – 4.0MM, 12MM STOP
1	1035-235	DRILL – 3.5MM, 14MM STOP
1	1035-240	DRILL – 4.0MM, 14MM STOP
1	1035-435	DRILL – 3.5MM, ADJUSTABLE
1	1035-440	DRILL – 4.0MM, ADJUSTABLE
1	1135-114	DRILL GUIDE – FIXED LENGTH
1	1135-201	DRILL GUIDE – ADJUSTABLE LENGTH, LONG
2	2020-101	SELF-RETAINING SCREW DRIVER – #10 HEXALOBE
1	2035-110	COUNTER TORQUE
1	2035-111	COUNTER TORQUE – IN LINE
2	2035-115	SCREW DRIVER – POLYAXIAL
2	2035-200	FINAL TIGHTENER – SET SCREW
2	2035-202	SET SCREW DRIVER – SELF RETAINING
1	3035-110	ROD REDUCER – NO STOP
1	3035-101	ROD ROCKER
1	3035-102	HEAD ADJUSTER
1	4035-100	DISTRACTOR
1	4035-101	COMPRESSOR
1	4135-100	HOLDER – ROD
1	5020-100	CERVICAL AWL
1	5020-101	ANTERIOR CERVICAL AWL SLEEVE
1	5020-110	DEPTH GAUGE
1	5035-100	BALL TIP PROBE
1	5035-200	PEDICLE PROBE – STRAIGHT
1	5035-201	PEDICLE PROBE – CURVED
1	5035-302	ROD TEMPLATE – 200MM
1	7035-100	ROD BENDER
1	7035-103	IN SITU BENDER – RIGHT
1	7035-104	IN SITU BENDER – LEFT
3	8020-100	CERVICAL HANDLE – AO ADAPTER
1	9025-101	TORQUE LIMITING HANDLE, 2.0NM

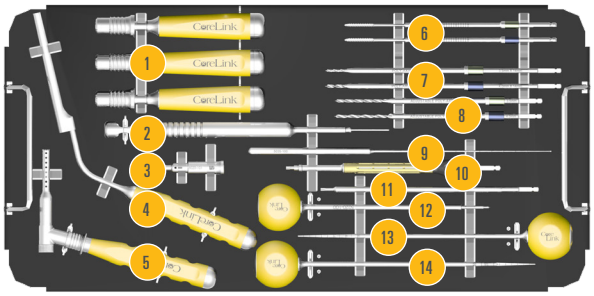
TOP TRAY

1. Rod Reducer
2. Counter Torque
3. Set Screw Driver
4. Rod Rocker
5. In Situ Benders
6. Rod Bender
7. Rod Holder
8. Head Adjuster
9. Final Tightener
10. Torque Limiting Handle, 2.0NM
11. Compressor/Distractor
12. Counter Torque - In Line



MIDDLE TRAY

1. Cervical Handle
2. Depth Gauge
3. Anterior Cervical Awl Sleeve
4. Drill Guide - Fixed Length
5. Drill Guide - Variable Length
6. Taps
7. Drills
8. Drills - Adjustable
9. Ball Tip Probe
10. Screw Driver - Polyaxial
11. Screw Driver - Self Retaining
12. Cervical Awl
13. Pedicle Probe - Straight
14. Pedicle Probe - Curved



*Contact CoreLink Customer Service for additional sizes and options

TIGER OCCIPITAL PLATE AND SCREW PRODUCT LISTING

KIT ORDER #K50000082

OCCIPITAL PLATES

QTY	CATALOG NUMBER	DESCRIPTION
2	35000-30	SMALL
2	35000-40	MEDIUM
2	35000-50	LARGE

OCCIPITAL PLATE SCREWS

QTY	CATALOG NUMBER	DESCRIPTION
6	35140-06	4MM X 6MM
6	35140-08	4MM X 8MM
6	35140-10	4MM X 10MM
6	35140-12	4MM X 12MM
6	35140-14	4MM X 14MM
6	35140-16	4MM X 16MM
6	35150-06	5MM X 6MM
6	35150-08	5MM X 8MM
6	35150-10	5MM X 10MM
6	35150-12	5MM X 12MM
6	35150-14	5MM X 14MM
6	35150-16	5MM X 16MM

OCCIPITAL RODS

QTY	CATALOG NUMBER	DESCRIPTION
2	R3530-100	3.5MM, 100°
2	R3530-115	3.5MM, 115°
2	R3530-130	3.5MM, 130°

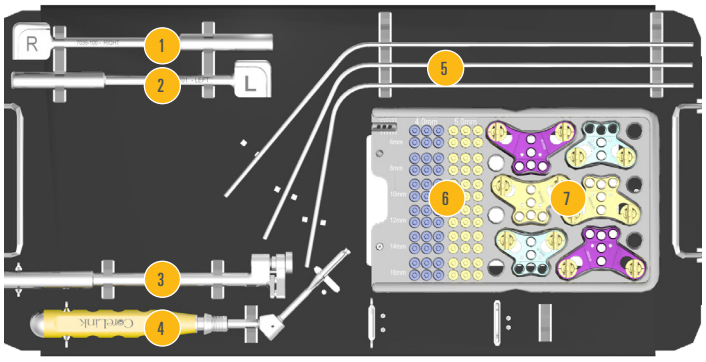
INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
1	1036-040	TAP – 4.0MM STRAIGHT
1	1036-041	TAP – 4.0MM U-JOINTED
1	1036-042	TAP – 4.0MM FLEXIBLE
1	1036-050	TAP – 5.0MM STRAIGHT
1	1036-051	TAP – 5.0MM U-JOINTED
1	1036-052	TAP – 5.0MM FLEXIBLE
1	1036-100	DRILL – STRAIGHT
1	1036-101	DRILL – U-JOINTED
1	1036-102	DRILL – FLEXIBLE
1	1136-200	OCCIPITAL DRILL GUIDE – ADJUSTABLE LENGTH
1	2036-100	SCREW DRIVER – STRAIGHT #15 HEXALOBE
1	2036-101	SCREW DRIVER – U-JOINTED
1	2036-102	SCREW DRIVER – SMALL
1	2036-110	COUNTER TORQUE – ROD ASSEMBLY
1	4136-102	HOLDER – OC PLATE, COUNTER TORQUE
1	7036-100	BENDER – OC PLATE, RIGHT WING
1	7036-101	BENDER – OC PLATE, LEFT WING
1	7036-102	BENDER – OC PLATE, CENTER
1	9035-100	TORQUE LIMITING HANDLE – 2.5NM

*Contact CoreLink Customer Service for additional sizes and options

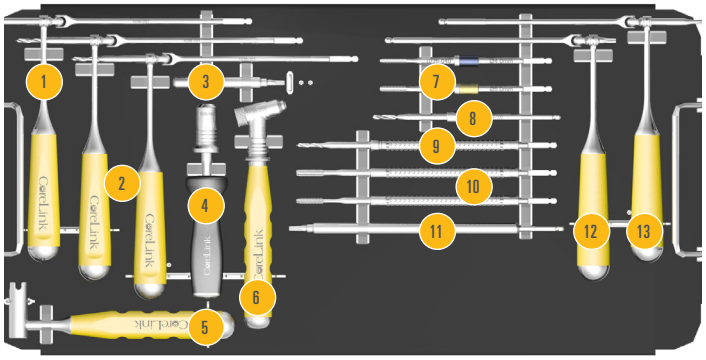
TOP TRAY

1. Bender - OC Plate, Right Wing
2. Bender - OC Plate, Left Wing
3. Bender - OC Plate, Center
4. OC Plate Holder Counter Torque
5. Rods
6. OC Plate Screws
7. OC Plates



BOTTOM TRAY

1. Tap - U-Jointed
2. Drills - U-Jointed
3. Screw Driver - Small
4. Handle - Torque Limiting
5. Counter Torque
6. Occipital Drill Guide
7. Taps - Straight
8. Drill - Straight
9. Drill - Flexible
10. Taps - Flexible
11. Screw Driver
12. Screw Driver - U-Jointed
13. Tap - U-Jointed



TIGER OCT SPECIALTY TRAY PRODUCT LISTING

KIT ORDER #K50000083

POSTERIOR CERVICAL HOOKS

QTY	CATALOG NUMBER	DESCRIPTION
2	35003-12	5MM, SMALL
2	35003-13	5MM, MEDIUM
2	35003-14	5MM, LARGE
2	35007-01	7MM, X-LARGE

ROD-TO-ROD CONNECTORS

QTY	CATALOG NUMBER	DESCRIPTION
2	35235-10	3.5MM X 3.5MM, END-TO-END CLOSED
2	35235-20	3.5MM X 3.5MM, SIDE-BY-SIDE CLOSED
2	35235-30	3.5MM X 3.5MM, END-TO-END OPEN
2	35235-40	3.5MM X 3.5MM, SIDE-BY-SIDE OPEN
2	35255-10	3.5MM X 5.5MM, END-TO-END
2	35255-20	3.5MM X 5.5MM, SIDE-BY-SIDE CLOSED

LATERAL CONNECTORS

QTY	CATALOG NUMBER	DESCRIPTION
2	35301-16	CLOSED, 16MM
2	35301-30	CLOSED, 30MM
2	35301-85	CLOSED, 8.5MM
2	35302-16	TOP LOADING, 16MM
2	35302-30	TOP LOADING, 30MM
2	35302-85	TOP LOADING, 8.5MM

SET SCREWS AND RETENTION NUTS

QTY	CATALOG NUMBER	DESCRIPTION
6	35635-20	SET SCREW – ROD-TO-ROD CONNECTOR

LONG SHANK SCREWS

QTY	CATALOG NUMBER	DESCRIPTION
2	35935-24	3.5MM X 24MM
2	35935-26	3.5MM X 26MM
2	35935-28	3.5MM X 28MM
2	35935-30	3.5MM X 30MM
2	35935-32	3.5MM X 32MM
2	35935-34	3.5MM X 34MM
2	35935-36	3.5MM X 36MM
2	35935-38	3.5MM X 38MM
2	35935-40	3.5MM X 40MM
2	35940-24	4.0MM X 24MM
2	35940-26	4.0MM X 26MM
2	35940-28	4.0MM X 28MM
2	35940-30	4.0MM X 30MM
2	35940-32	4.0MM X 32MM
2	35940-34	4.0MM X 34MM
2	35940-36	4.0MM X 36MM
2	35940-38	4.0MM X 38MM
2	35940-40	4.0MM X 40MM

TRANSITIONAL RODS

QTY	CATALOG NUMBER	DESCRIPTION
2	R3555-420	420MM, WITH LINE

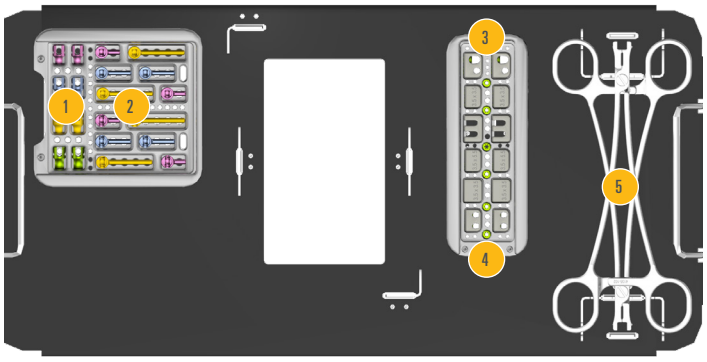
INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
1	1035-036	TAP – 3.5MM LONG SHANK SCREW
1	4135-102	HOLDER – HOOK

*Contact CoreLink Customer Service for additional sizes and options

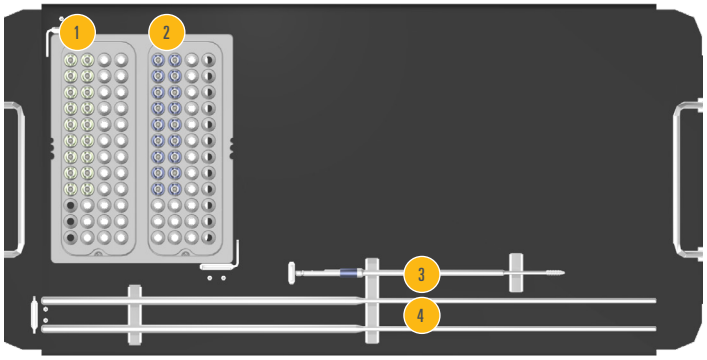
TOP TRAY

1. Cervical Hooks
2. Lateral Connectors
3. Rod-to-Rod Connectors
4. Set Screws
5. Holder - Hook



BOTTOM TRAY

1. Screws - 3.5mm Long Shank
2. Screws - 4.0mm Long Shank
3. Tap - 3.5mm Long Shank Screw
4. Transitional Rods



TIGER OCT STANDARD IMPLANT PRODUCT LISTING

KIT ORDER #K5000080

BIASED ANGLE SCREWS

QTY	CATALOG NUMBER	DESCRIPTION
CEPHALAD/CAUDAL		
8	35735-10	3.5MM X 10MM
14	35735-12	3.5MM X 12MM
14	35735-14	3.5MM X 14MM
12	35735-16	3.5MM X 16MM
4	35735-18	3.5MM X 18MM
4	35735-20	3.5MM X 20MM
4	35735-22	3.5MM X 22MM
4	35735-24	3.5MM X 24MM
4	35735-26	3.5MM X 26MM
8	35740-10	4.0MM X 10MM
14	35740-12	4.0MM X 12MM
14	35740-14	4.0MM X 14MM
12	35740-16	4.0MM X 16MM
4	35740-18	4.0MM X 18MM
4	35740-20	4.0MM X 20MM
4	35740-22	4.0MM X 22MM
4	35740-24	4.0MM X 24MM
4	35740-26	4.0MM X 26MM
MEDIAL/LATERAL		
4	35835-14	3.5MM X 14MM
4	35835-16	3.5MM X 16MM
4	35835-18	3.5MM X 18MM
8	35835-20	3.5MM X 20MM
8	35835-22	3.5MM X 22MM
8	35835-24	3.5MM X 24MM
8	35835-26	3.5MM X 26MM
4	35840-14	4.0MM X 14MM
4	35840-16	4.0MM X 16MM
4	35840-18	4.0MM X 18MM
8	35840-20	4.0MM X 20MM
8	35840-22	4.0MM X 22MM
8	35840-24	4.0MM X 24MM
8	35840-26	4.0MM X 26MM

CROSS CONNECTORS

QTY	CATALOG NUMBER	DESCRIPTION
1	TC3517-28	17MM – 28MM
1	TC3526-37	26MM – 37MM
1	TC3535-46	35MM – 46MM
1	TC3544-55	44MM – 55MM

TRANSVERSE CONNECTORS – HEAD-TO-HEAD

QTY	CATALOG NUMBER	DESCRIPTION
1	TC3620-26	20MM – 26MM
1	TC3625-31	25MM – 31MM
1	TC3630-36	30MM – 36MM
1	TC3635-41	35MM – 41MM
1	TC3640-46	40MM – 46MM
1	TC3645-51	45MM – 51MM
1	TC3650-56	50MM – 56MM

SET SCREWS AND INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
20	35635-35	SET SCREW
6	35635-75	SET SCREW, LONG
8	RN3501	RETENTION NUT – CROSS CONNECTOR
1	2035-201	FINAL TIGHTENER – CROSSLINKS

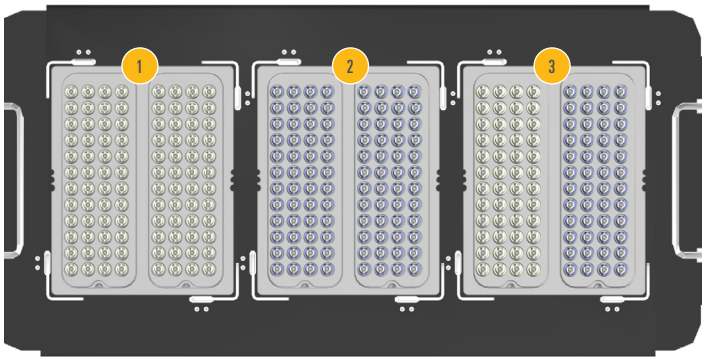
STRAIGHT RODS AND INSTRUMENTS

QTY	CATALOG NUMBER	DESCRIPTION
4	R3512-040	3.5MM X 40MM
4	R3512-080	3.5MM X 80MM
4	R3512-120	3.5MM X 120MM
4	R3512-240	3.5MM X 240MM
1	7235-101	ROD CUTTER – 3.5MM

*Contact CoreLink Customer Service for additional sizes and options

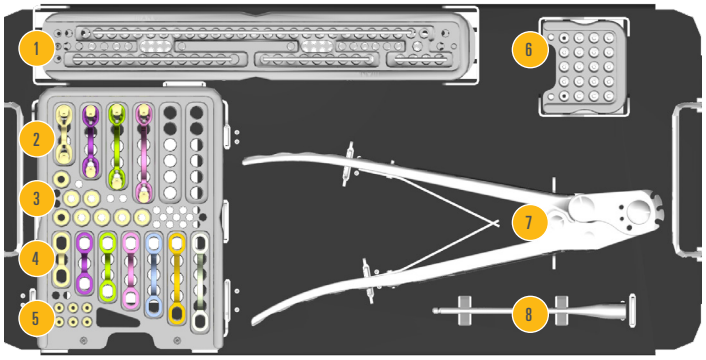
TOP TRAY

1. Screws - 3.5mm Cephalad/Caudal
2. Screws - 4.0mm Cephalad/Caudal
3. Screws - 3.5mm & 4.0mm Medial/Lateral



BOTTOM TRAY

1. Rods
2. Crosslinks - Cross Connector
3. Retention Nuts
4. Crosslinks - Transverse Connectors, Head to Head
5. Set Screws - Long
6. Set Screws
7. Rod Cutter
8. Final Tightener - Crosslinks



TIGER OCT ADDITIONAL IMPLANT PRODUCT LISTING

KIT ORDER #K50000193

POLYAXIAL SCREWS (3.5MM)		
QTY	CATALOG NUMBER	DESCRIPTION
8	35035-10	3.5MM X 10MM
14	35035-12	3.5MM X 12MM
14	35035-14	3.5MM X 14MM
12	35035-16	3.5MM X 16MM
4	35035-18	3.5MM X 18MM
4	35035-20	3.5MM X 20MM
4	35035-22	3.5MM X 22MM
4	35035-24	3.5MM X 24MM
4	35035-26	3.5MM X 26MM

KIT ORDER #K50000194

POLYAXIAL SCREWS (4.0MM)		
QTY	CATALOG NUMBER	DESCRIPTION
8	35040-10	4.0MM X 10MM
14	35040-12	4.0MM X 12MM
14	35040-14	4.0MM X 14MM
12	35040-16	4.0MM X 16MM
4	35040-18	4.0MM X 18MM
4	35040-20	4.0MM X 20MM
4	35040-22	4.0MM X 22MM
4	35040-24	4.0MM X 24MM
4	35040-26	4.0MM X 26MM

KIT ORDER #K50000225

BIASED ANGLE SCREWS - CEPHALAD/CAUDAL		
QTY	CATALOG NUMBER	DESCRIPTION
4	35745-14	4.5MM X 14MM
4	35745-16	4.5MM X 16MM
4	35745-18	4.5MM X 18MM
4	35745-20	4.5MM X 20MM
4	35745-22	4.5MM X 22MM
4	35745-24	4.5MM X 24MM
4	35745-26	4.5MM X 26MM

KIT ORDER #K50000161

POLYAXIAL SCREWS (4.5MM)		
QTY	CATALOG NUMBER	DESCRIPTION
4	35045-18	4.5MM X 18MM
4	35045-20	4.5MM X 20MM
4	35045-22	4.5MM X 22MM
4	35045-24	4.5MM X 24MM
4	35045-26	4.5MM X 26MM
4	35045-28	4.5MM X 28MM
4	35045-30	4.5MM X 30MM
4	35045-32	4.5MM X 32MM
4	35045-34	4.5MM X 34MM
4	35045-36	4.5MM X 36MM
4	35045-38	4.5MM X 38MM
4	35045-40	4.5MM X 40MM
8	35045-42	4.5MM X 42MM
8	35045-44	4.5MM X 44MM
8	35045-46	4.5MM X 46MM
8	35045-48	4.5MM X 48MM
8	35045-50	4.5MM X 50MM

KIT ORDER #K50000230

BIASED ANGLE SCREWS - MEDIAL/LATERAL		
QTY	CATALOG NUMBER	DESCRIPTION
4	35845-14	4.5MM X 14MM
4	35845-16	4.5MM X 16MM
4	35845-18	4.5MM X 18MM
4	35845-20	4.5MM X 20MM
4	35845-22	4.5MM X 22MM
4	35845-24	4.5MM X 24MM
4	35845-26	4.5MM X 26MM
4	35845-28	4.5MM X 28MM
4	35845-30	4.5MM X 30MM
4	35845-32	4.5MM X 32MM
4	35845-34	4.5MM X 34MM

*Contact CoreLink Customer Service for additional sizes and options

NOTES

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NOTES

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