CoreLink
The Source for Spine™

TIGER® SPINE SYSTEM

Surgical Technique Guide

THE TIGER SPINE SYSTEM ADVANTAGE

DESIGN PHILOSOPHY

The Tiger Spine System was designed with two goals in mind:

- Safety and efficacy for the patient
- Ease of use for the surgeon

The CoreLink Tiger Spine System is supplied with high quality implants and instrumentation that feature:

- Multiple screw types including:
  - Poly-Axial
  - Mono-Axial
  - Uni-Planer
  - Reduction
  - Fracture
  - Cannulated
- Multiple hook and rod connection options designed to accommodate variances in patient anatomy
- Range of screw diameters from 4.5mm to 10.5mm
- Range of screw lengths from 25mm to 120mm
- Titanium and cobalt chrome rod options
- A robust offering of instrumentation including a reduction tower that allows up to 35mm of reduction

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TIGER SPINE SYSTEM PRODUCT OVERVIEW

The Tiger Spine System is a comprehensive spinal fixation system that includes pedicle screws, rods, set screws, hooks and various types of rod connectors. The system may be used in degenerative and deformity spinal surgeries.

The Tiger Spine System instrumentation can be used to reduce spondylolisthesis and help correct spinal deformities such as scoliosis or kyphosis.

PEDICLE SCREWS

POLY-AXIAL

The poly-axial pedicle screws allow for 360° of motion at up to ~30° angle each direction for the smaller diameter screws and ~21° each direction for the larger diameter screws.

The size range is:

- 5.5MM Diameter: 25MM – 55MM
- 6.5MM Diameter: 25MM – 55MM
- 7.5MM Diameter: 35MM – 120MM
- 8.5MM Diameter: 35MM – 120MM
- 9.5MM Diameter: 35MM – 120MM
- 10.5MM Diameter: 35MM – 120MM

POLY-AXIAL PEDICLE SCREW

POLY-AXIAL REDUCTION

The poly-axial reduction pedicle screws have extended tabs on the tulip head aiding in the reduction of the rod.

The size range is:

- 5.5MM Diameter: 25MM – 55MM
- 6.5MM Diameter: 35MM – 55MM
- 7.5MM Diameter: 35MM – 55MM

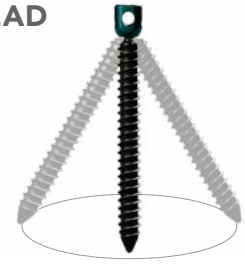
POLY-AXIAL REDUCTION PEDICLE SCREW

POLY-AXIAL CLOSED TULIP HEAD

The closed tulip head poly-axial pedicle screws allow for additional strength by adding material to the top of the tulip head of screws used for iliac fixation.

The size range is:

- 7.5MM Diameter: 60MM – 120MM
- 8.5MM Diameter: 60MM – 120MM
- 9.5MM Diameter: 60MM – 120MM
- 10.5MM Diameter: 60MM – 120MM



POLY-AXIAL CLOSED TULIP HEAD PEDICLE SCREW

MONO-AXIAL

The mono-axial pedicle screws are fixed screws allowing for no motion.

The size range is:

- 5.5MM Diameter: 25MM – 55MM
- 6.5MM Diameter: 35MM – 55MM
- 7.5MM Diameter: 35MM – 55MM

MONO-AXIAL PEDICLE SCREW

Note: Additional sizes available upon request. Please contact CoreLink customer service for details.

PRODUCT OVERVIEW (CONTINUED)

PEDICLE SCREWS (CONTINUED)

UNI-PLANAR

The uni-planar pedicle screws allow motion in the cephalad to caudal direction while restricting motion in the medial to lateral direction.

The size range is:

- 4.5MM Diameter: 25MM – 45MM
- 5.5MM Diameter: 25MM – 45MM
- 6.5MM Diameter: 25MM – 45MM
- 7.5MM Diameter: 25MM – 50MM

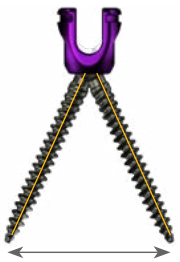
UNI-PLANAR PEDICLE SCREW

FRACTURE

The fracture pedicle screws allow motion in the medial to lateral direction while restricting motion in the cephalad to caudal direction.

The size range is:

- 4.5MM Diameter: 25MM – 55MM
- 5.5MM Diameter: 25MM – 55MM
- 6.5MM Diameter: 35MM – 55MM



FRACTURE PEDICLE SCREW

UNI-REDUCTION

The uni-reduction pedicle screws have the same functionality as the uni-planar screws with the addition of reduction tabs.

The size range is:

- 4.5MM Diameter: 25MM – 45MM
- 5.5MM Diameter: 25MM – 45MM
- 6.5MM Diameter: 25MM – 45MM
- 7.5MM Diameter: 25MM – 50MM

UNI-REDUCTION SCREW

CANNULATED OPEN

The cannulated open screws are poly-axial and allow for 360° of motion up to ~ 30° angle each direction for the smaller diameter screws and ~21° each direction for larger diameter screws.

The size range is:

- 5.5MM Diameter: 25MM – 55MM
- 6.5MM Diameter: 35MM – 55MM
- 7.5MM Diameter: 35MM – 55MM

TOP VIEW

CANNULATED OPEN SCREW

DUAL/QUAD

The Dual/Quad lead pedicle screws maintain a cortical style screw proximally that transition into a more cancellous type screw distally in order to obtain more purchase and increase pullout strength.

The size range is:

- 5.5MM Diameter: 30MM – 55MM
- 6.5MM Diameter: 35MM – 55MM
- 7.5MM Diameter: 35MM – 55MM

DUAL/QUAD SCREW

Note: Additional sizes available upon request. Please contact CoreLink customer service for details.

RODS

Rods are available in two materials: titanium and cobalt chrome. Both rod materials are available in straight and pre-bent versions. The bend is pre-lordosed to match the natural curvature of the lumbar spine. Both material and bend options are available with laser etched lines and/or hex ends. The laser etchings allow for better alignment and additional contouring. The hex ends help with derotation during deformity surgeries. Additionally, cobalt chrome rods are available in roughened versions to assist with rod gripping and annealed conditions to facilitate intraoperative bendability. All rods are available in a 5.5mm diameter.

STRAIGHT AND PRE-BENT RODS

TRANSVERSE CONNECTORS

Transverse connectors are available for additional axial stability. The connectors are available in many lengths to best fit patient anatomy.

14MM

16MM

18MM

20MM

22MM

25MM–30MM

30MM–37MM

37MM–50MM

50MM–80MM

PRODUCT OVERVIEW (CONTINUED)

HOOKS

Many hook options are available in the Tiger Deformity set. These hooks are designed to work with specific posterior anatomy such as the pedicle, lamina, or transverse process. The surgeon should choose the appropriate hook based on the patient's anatomy, the type of deformity, and method(s) of correction used.

PEDICLE HOOK

BIFID PEDICLE HOOK

WIDE BLADE HOOK

NARROW BLADE HOOK

LAMINAR HOOK

TRANSVERSE PROCESS, RIGHT

TRANSVERSE PROCESS, LEFT

WIDE BLADE, TALL

NARROW BLADE, TALL

LAMINAR, TALL

OFFSET, RIGHT

OFFSET, LEFT

OTHER CONNECTOR OPTIONS

Rod to rod connectors are available in several varieties adjoining 5.5mm diameter rods to other rod diameters. These are to connect the rods in a side by side or end to end fashion.

5.5MM X 5.5MM SIDE BY SIDE CLOSED

5.5MM X 6.35MM SIDE BY SIDE CLOSED

5.5MM X 3.5MM SIDE BY SIDE CLOSED

5.5MM X 5.5MM END TO END CLOSED

5.5MM X 6.35MM END TO END CLOSED

5.5MM X 3.5MM END TO END CLOSED

5.5MM IN-LINE

Lateral offset connectors are available in 0° (neutral), 75°, and 105° degrees in varying rod lengths. All three angulations and rod lengths are available in open and closed tulip head versions.

5500 SERIES LATERAL CONNECTOR, OPEN VS. CLOSED

5500 SERIES LATERAL CONNECTOR, NEUTRAL VS. 75^{0} VS. 105^{0}

APPROACH AND PREPARATION

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.

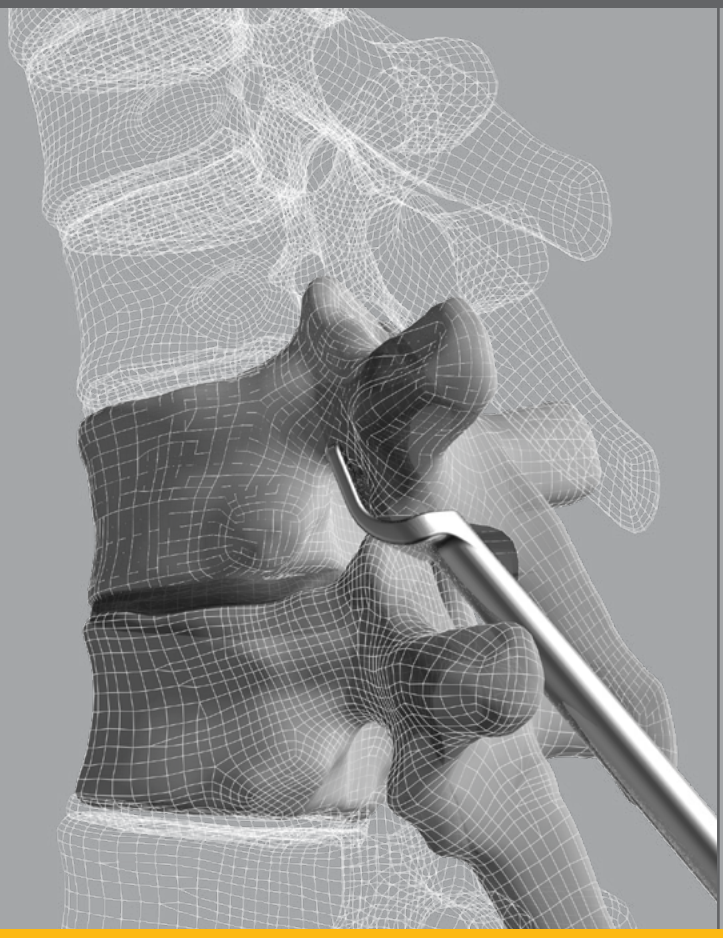
Proper dissection techniques are used to expose the levels of fusion. Exposure should be carried out to the tips of the transverse processes.

HOOK SITE PREPARATION

Preparation for hooks varies depending on surgeon preference as well as individual patient anatomy.

Up-going lamina hooks (infralaminar hooks) should ideally be used leaving the lamina bone intact. The lamina finder and elevator can be used to dissect the ligamentum flavum off the inferior lamina and allow subsequent up-going hook insertion. This is done utilizing hook holding forceps and a hook pusher and then impacting the hook into position taking care to keep the blade of the hook parallel to the lamina so as to not compromise the space available for the neural elements.

PEDICLE FINDER USED TO DISSECT PEDICLE



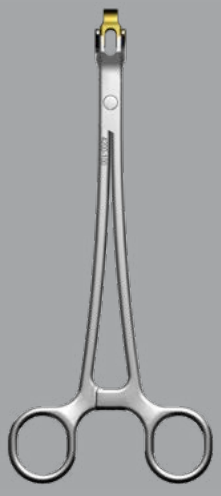
Pedicle hooks are typically utilized in the mid to upper thoracic spine using a specific up-going pedicle hook that has a special notch in the hook blade that is used to straddle the inferior portion of the pedicle. Prior to placement of a pedicle hook the facet capsule is removed and often a small portion of the inferior facet is removed with an osteotome or bur. The pedicle hook elevator is used to dissect and find the pedicle. Once this is done, the hook is inserted utilizing a hook holder and pusher, impacting it into position against the inferior portion of the pedicle.

Down-going (supralaminar) hooks are typically placed after a small laminotomy is made at the superior portion of the lamina. A small curette can be utilized to dissect the ligamentum off of the lamina. A hook holder and pusher should be utilized to place the hook being careful not to compromise the space available for the neural elements.

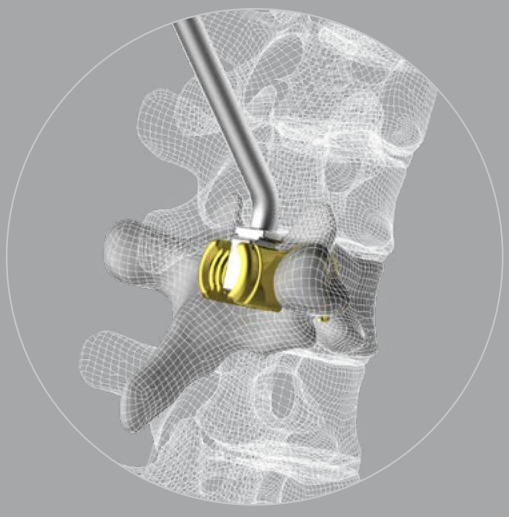
Transverse process hooks utilize a wider blade and are often placed in a claw construct (one transverse process with an up-going hook and the adjacent level with a down-going transverse process hook). Prior to placement, the ligamentous attachments are released from the lateral and undersurface of the transverse process. The hook finders and elevators are utilized to develop the plane between the transverse process and the rib. The hooks are inserted with the hook holding forceps and the hook pusher.

HOOK INSERTION

The hooks may be inserted with the hook holding forceps and hook pusher. The forceps clip securely around the tulip of the hook. Both instruments can be used to insert the hooks in the determined position. A combination of the instruments may be necessary to properly insert the hooks.



HOOK HOLDER FORCEPS



HOOK PUSHER BEING USED TO INSERT PEDICLE HOOK

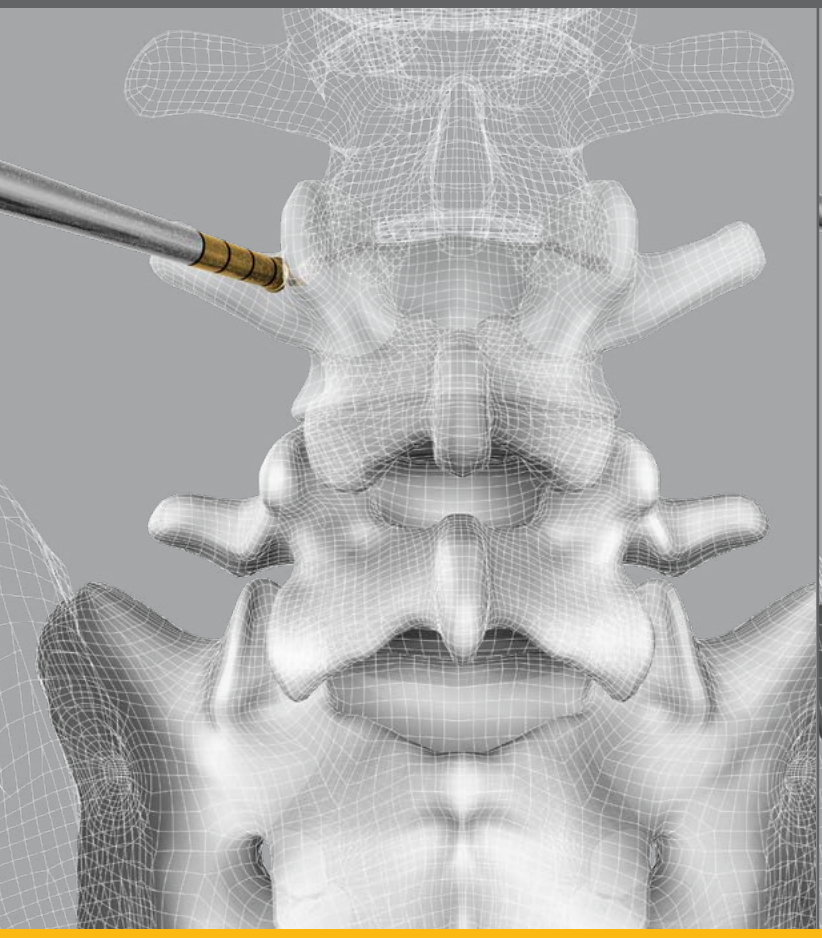
PEDICLE PREPARATION

Pedicle cannulation and preparation is performed utilizing a selection of awls, pedicle probes, ball tip feelers, and bone taps. These instruments have depth markings to indicate the length of penetration.

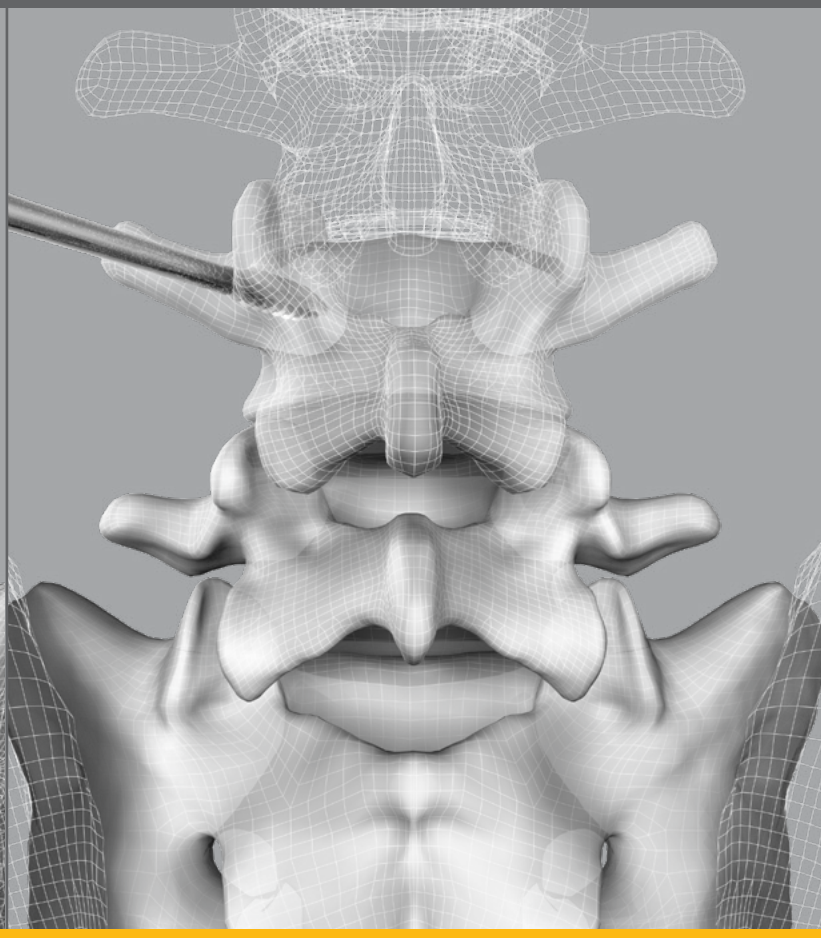
The CoreLink Tiger pedicle screws have a fully threaded, tapered tip to minimize the need for tapping. If necessary per surgeon preference or patient anatomy, bone taps are available in on-size and undersized options for each diameter screw. The undersized tap is designed with a major diameter of 0.5mm under the major diameter of the screw.

It is recommended that only the taps designed specifically for each diameter of screw, whether on-size or undersized, be used to prepare the pedicle. Example, use only the on-sized or undersized 6.5mm taps to prepare the pedicle in which a 6.5mm diameter screw is to be inserted.

PEDICLE AWL



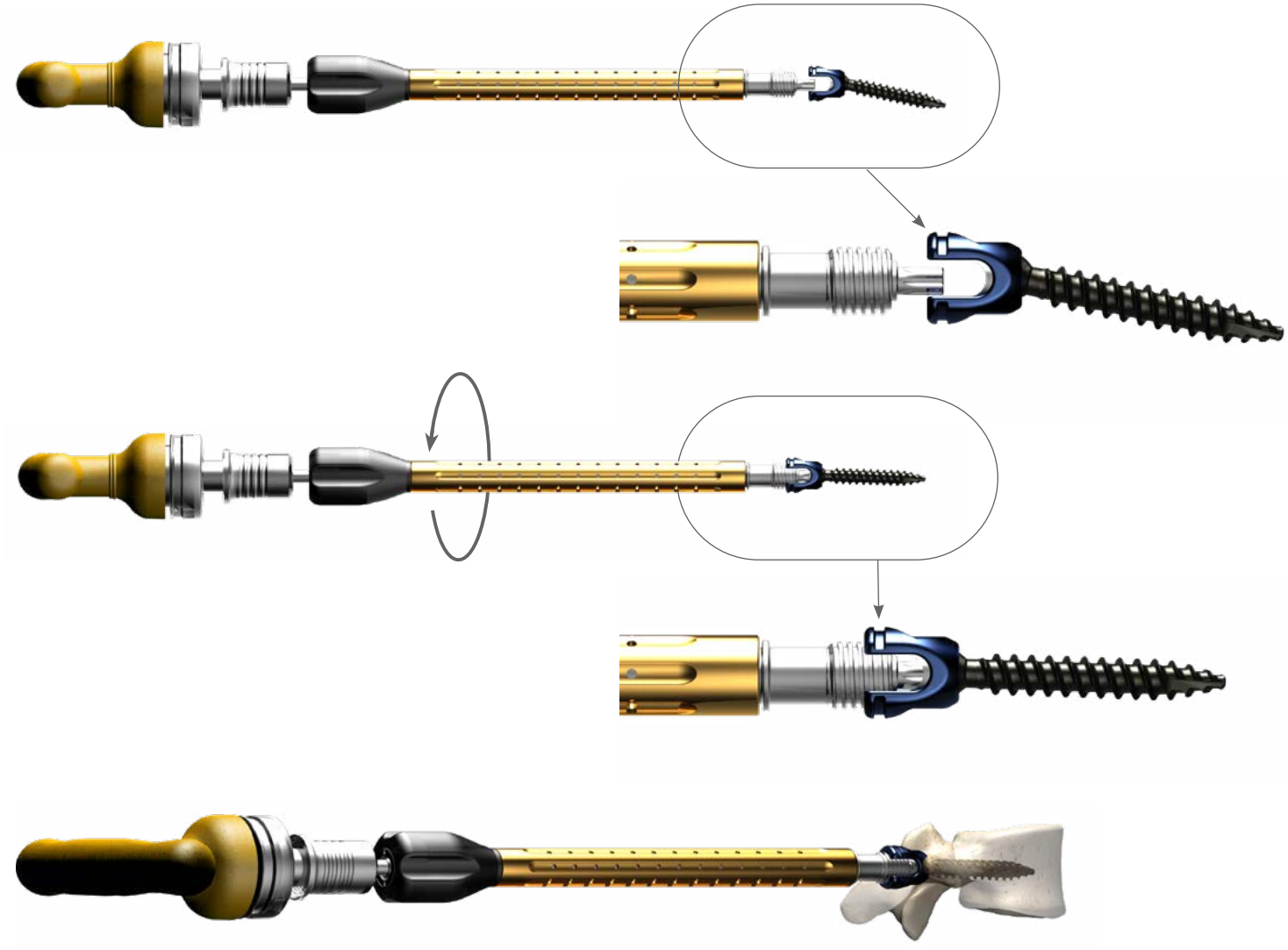
BONE TAP



PEDICLE SCREW INSERTION

The Tiger Spine System offers several screw driver options for the insertion of pedicle screws. Threaded and self-retaining options are available fitting a #25 hexalobe.

To use the threaded driver, align the poly-axial screw with the poly-axial screw driver. Place the tip of the poly-axial screw driver into the head of the screw. Apply downward pressure onto the screw and rotate the knob of the poly-axial screw driver clockwise into the tulip head of the screw until tight. To drive the screw into the prepared pedicle, attach a ¼" square handle, and rotate clockwise. To remove or back out, turn the handle counterclockwise. Disengage the poly-axial screw driver by unthreading the tip by turning the knob counterclockwise.



POLY-AXIAL HEAD ADJUSTMENT

The tulip head of the poly-axial screw can be rotated and positioned using the head turner instrument. This instrument may be attached to any ¼" square connection handle.

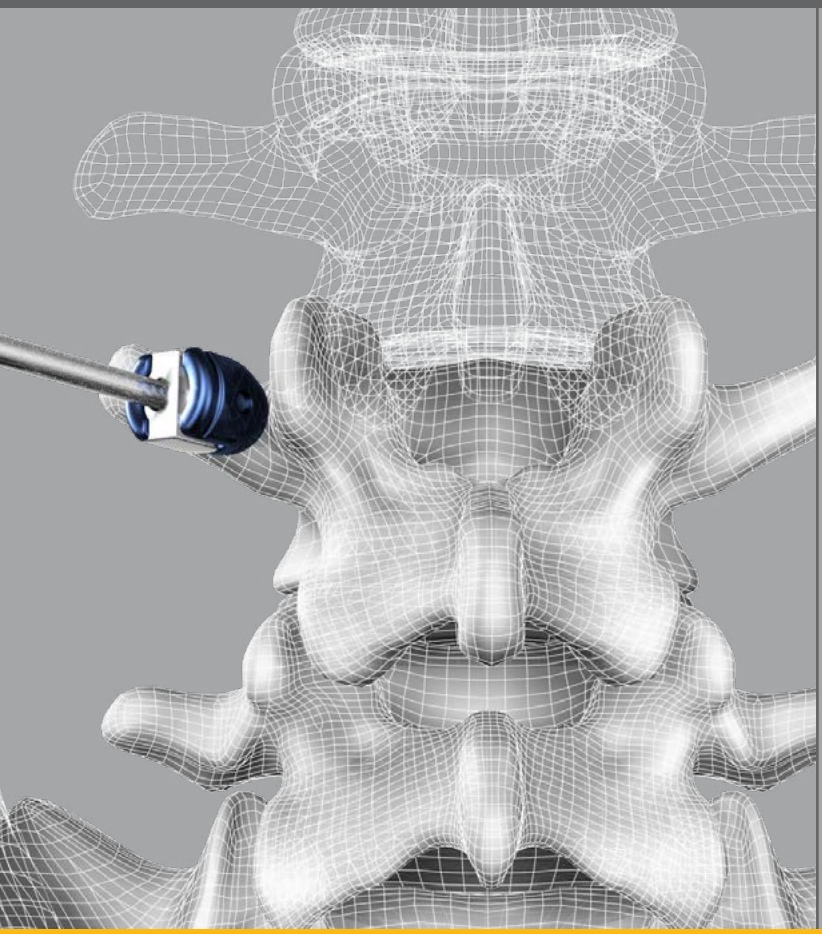
ROD MEASUREMENT AND CONTOURING

A rod template, or other measuring device, may be used to determine the proper length rod for the spinal construct. CoreLink rod templates may also be contoured by bending as needed. The rod templates are available upon request.

The French rod bender may be used to introduce lordosis or kyphosis into the rod. In situ bending may be performed using the in situ rod benders and/or coronal rod benders. Use caution when contouring the rod. Repeated bending is not recommended.

Rods may be cut as needed to appropriately fit the construct. A rod cutter is available upon request that may be used with or without a table top stand.

HEAD ADJUSTMENT INSTRUMENT

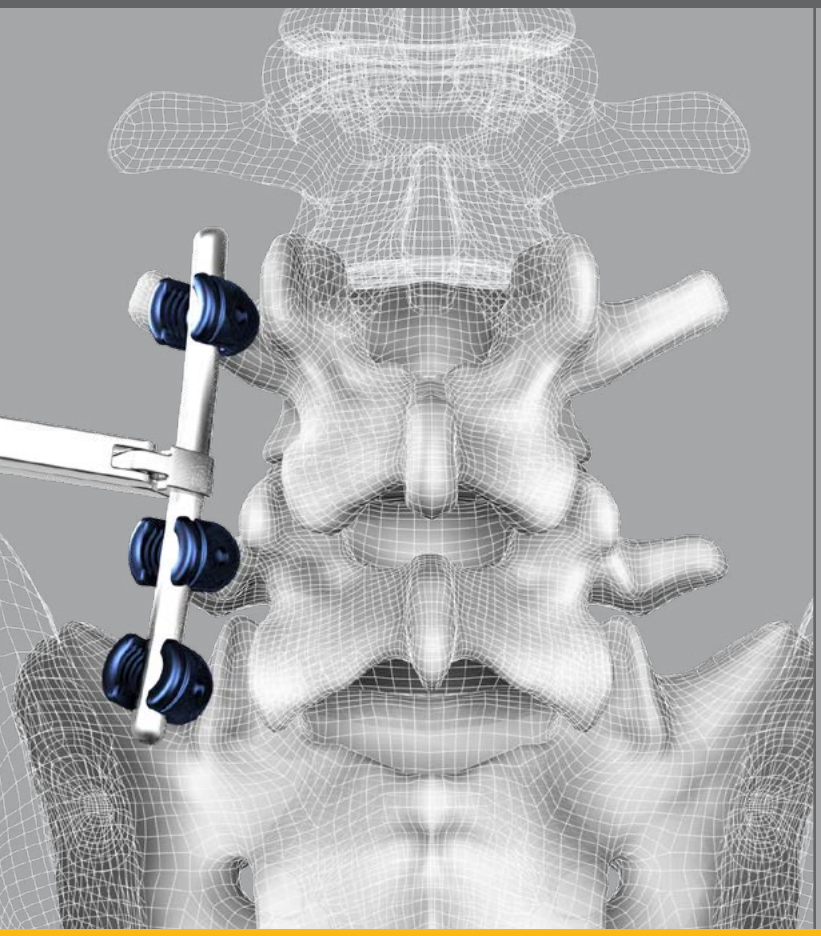


FRENCH ROD BENDER

ROD INSERTION

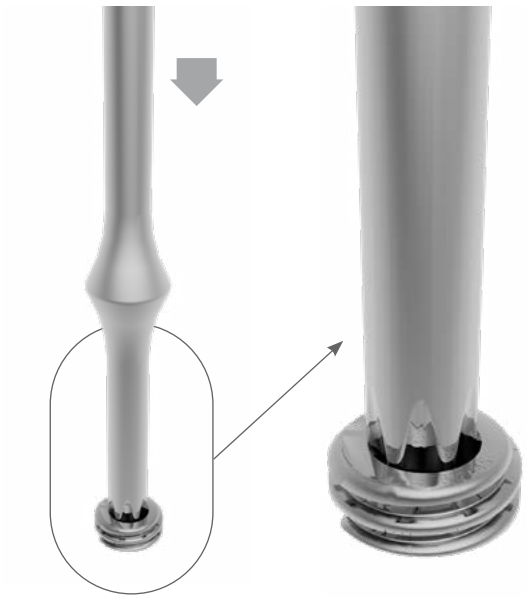
The appropriate length and contoured rod may be inserted into the construct. Multiple rod holder options are available to aid in the placement of the rods.

ROD INSERTION



SET SCREW INSERTION

The set screws may be loaded directly from the set screw caddy. The set screw driver is self-retaining. The set screw is aligned with the tulip head and threaded clockwise. This can be done free hand or through a set screw starter tube. The hexalobe size of the set screw is 30.



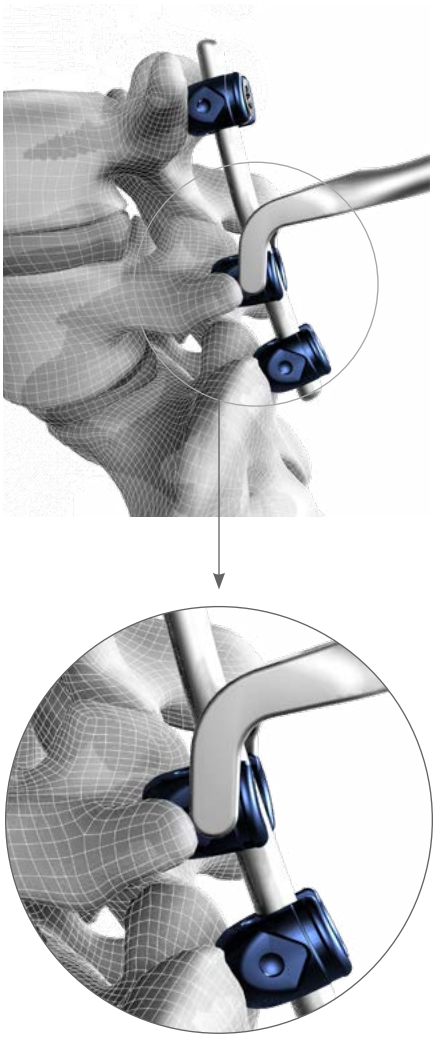
SELF-RETAINING SET SCREW DRIVER

SET SCREW BEING INSERTED THROUGH THE STARTER TUBE

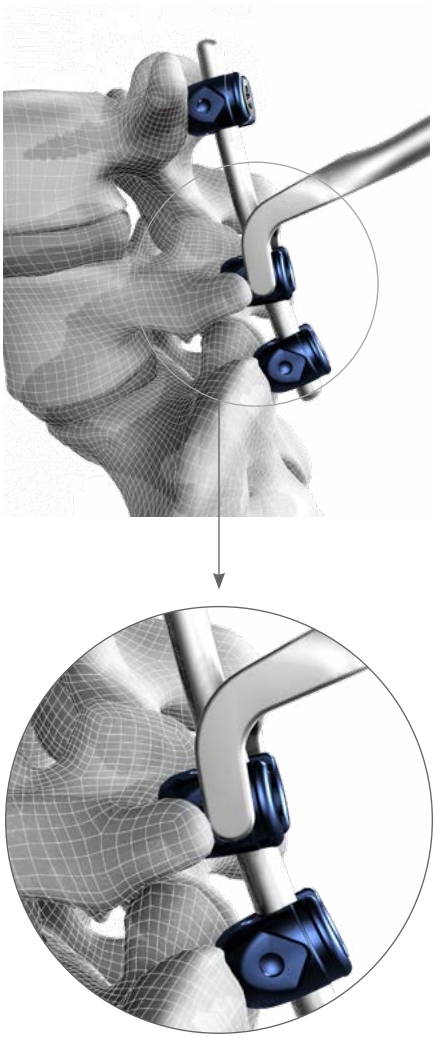
ROD REDUCTION

If minimal reduction is needed, the starter tube 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 instruments.

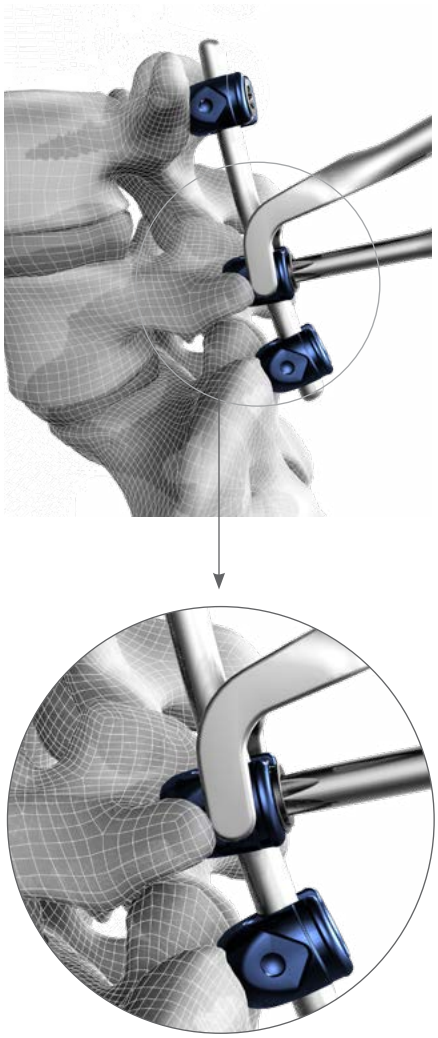
The rod rocker may also be used for rod reduction. The pins on the rocker arms will slide into the triangular groove on the sides of the tulip head. Use this instrument to lever the rod into the fully reduced position. The set screw may then be inserted using the set screw driver.



ROD ROCKER ARMS SLIDE INTO TRIANGULAR GROOVE ON SIDES OF TULIP HEAD



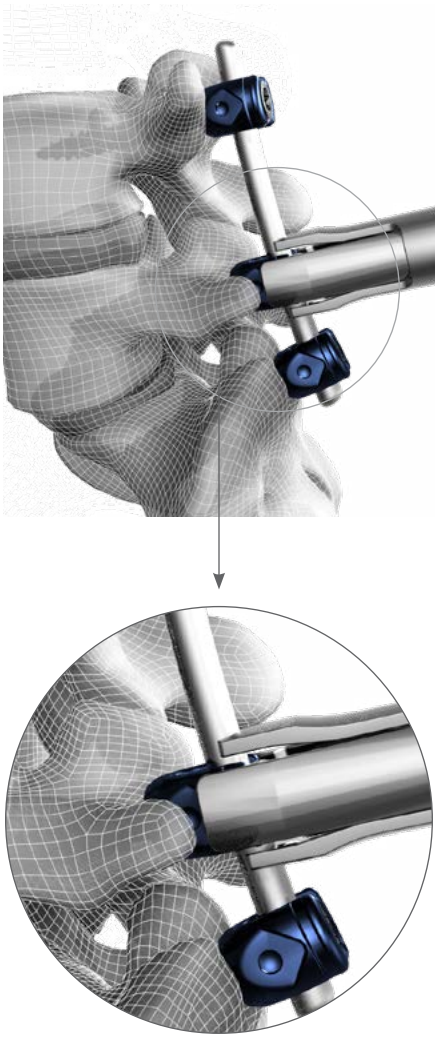
LEVER ROD INTO FULLY REDUCED POSITION



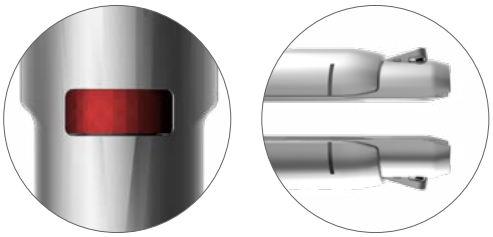
INSERT SET SCREW

ROD REDUCTION (CONTINUED)

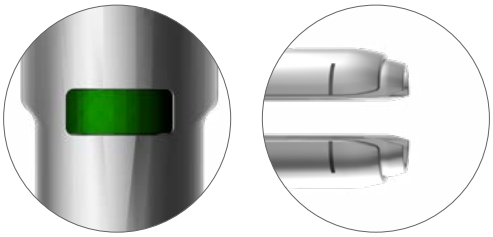
For maximum reduction, the rod reducer or two-piece dial down reducer may be used. To use the rod reducer, insert the tip over the screw head. Once in correct alignment, squeeze the handles to clamp down on the tulip head and reduce the rod. The set screw may be inserted through the rod reducer once the rod is fully seated in the tulip head. The two piece dial down reducer consists of a tower connection and reduction tower. The tower connection is placed over the tulip head in correct alignment. Rotate the knob clockwise to lock the connection tower onto the tulip head. The reduction tower may then be inserted into the tower connection.



ROD REDUCER

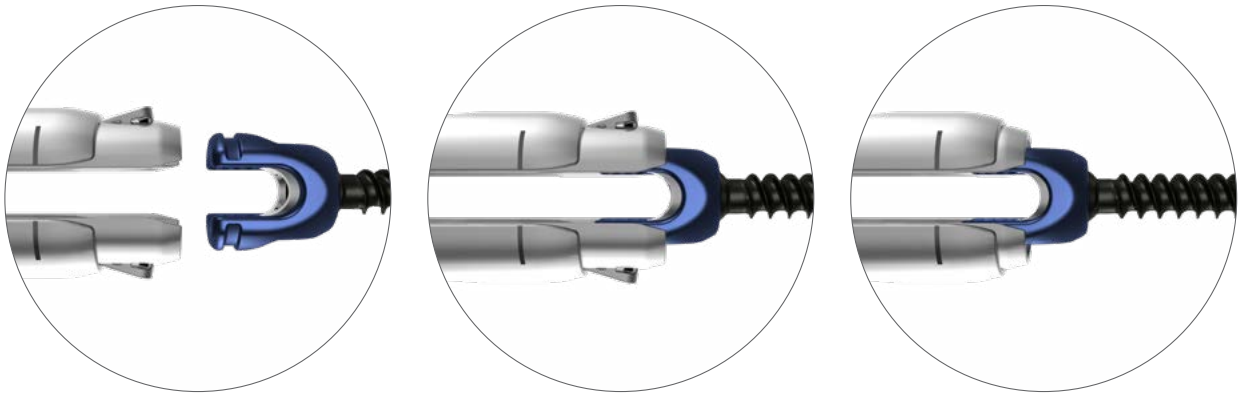


TOWER CONNECTION UNLOCKED

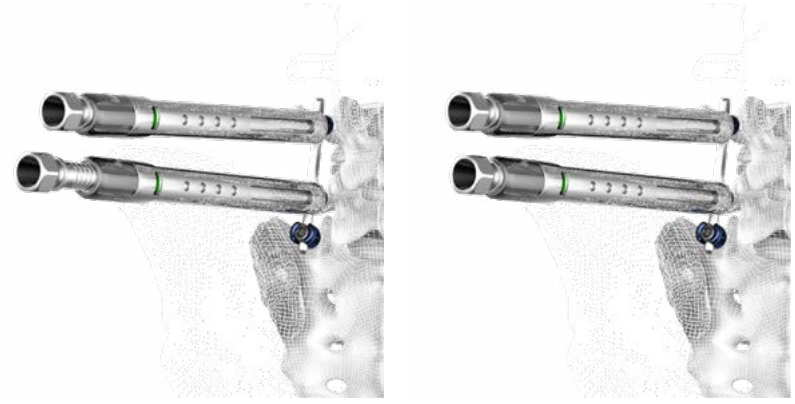


TOWER CONNECTION LOCKED

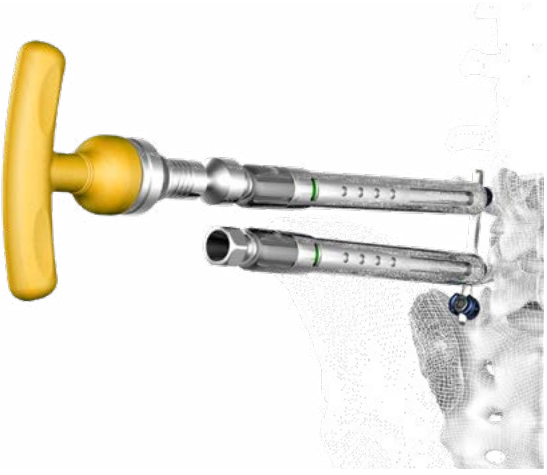
Threading the reduction tower clockwise will reduce the rod into the tulip head. Once fully reduced, the set screw may then be inserted using the set screw driver. The reduction tower adapter socket may be used with any ¼" square connection handles to aid in the reduction of the tower.



SCREW BEING INSERTED AND LOCKED INTO TOWER CONNECTION



TOWER REDUCERS BEING THREADED INTO TOWER CONNECTION

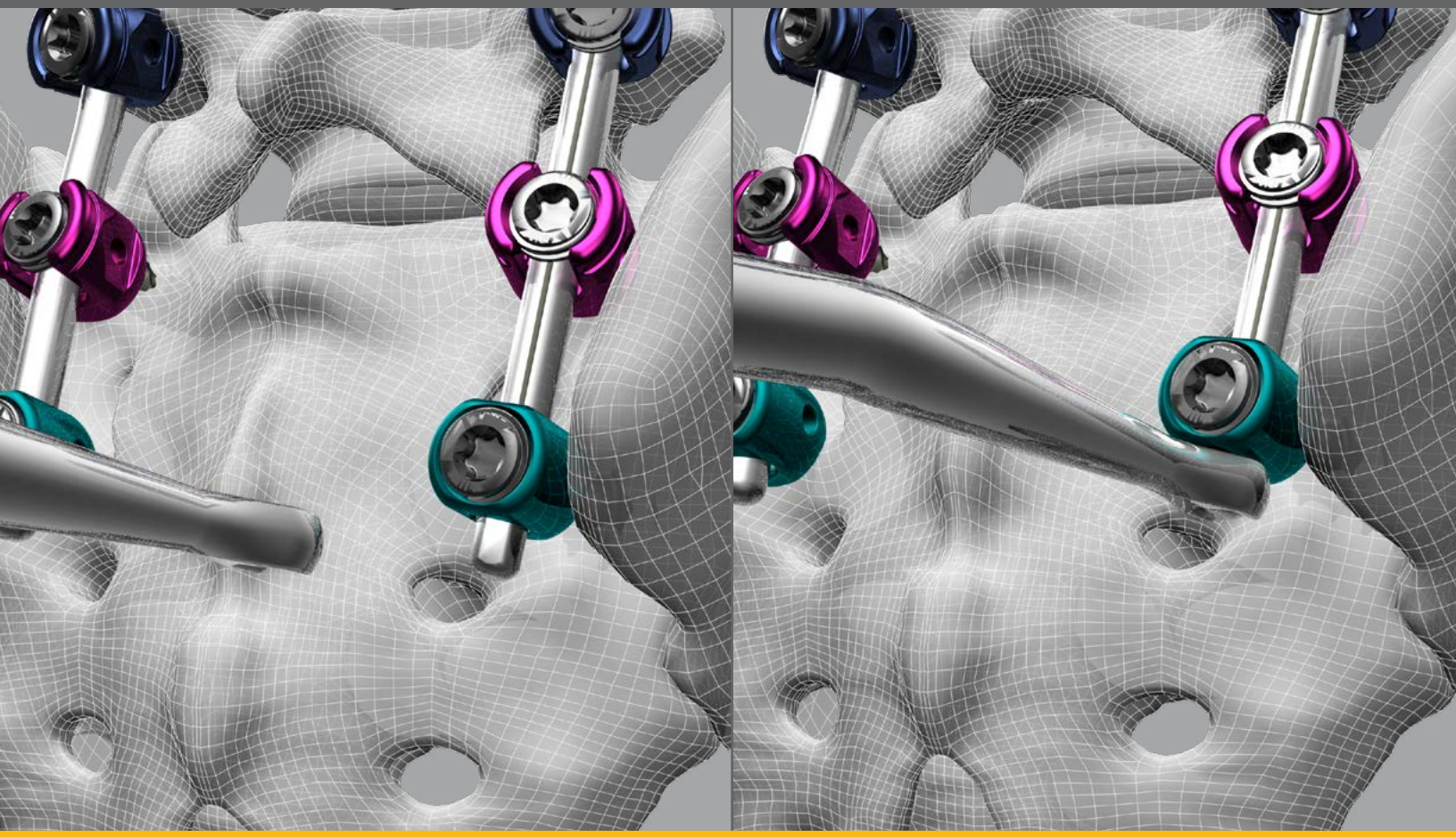


REDUCTION TOWER ADAPTER SOCKET ON RATCHETING T-HANDLE

DEROTATION

Axial derotation procedures may be performed with the Tiger Spine System. Rods in titanium and cobalt chrome are available with hex ends. The hex wrench may be used to derotate and align the spine. Alternatively, CoreLink offers several rod holder options that may be used to manually grip the rod and rotate as needed.

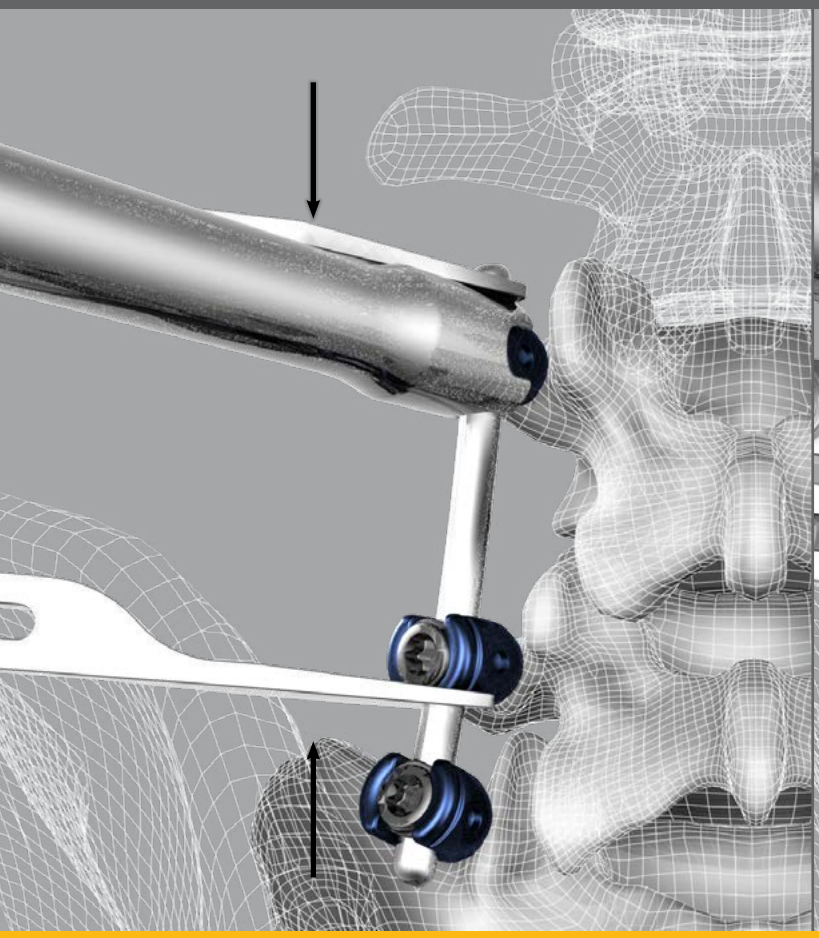
HEX WRENCH BEING USED IN CONJUNCTION WITH THE HEX ENDED ROD FOR DEROTATION OF SPINE IN THE AXIAL PLANE



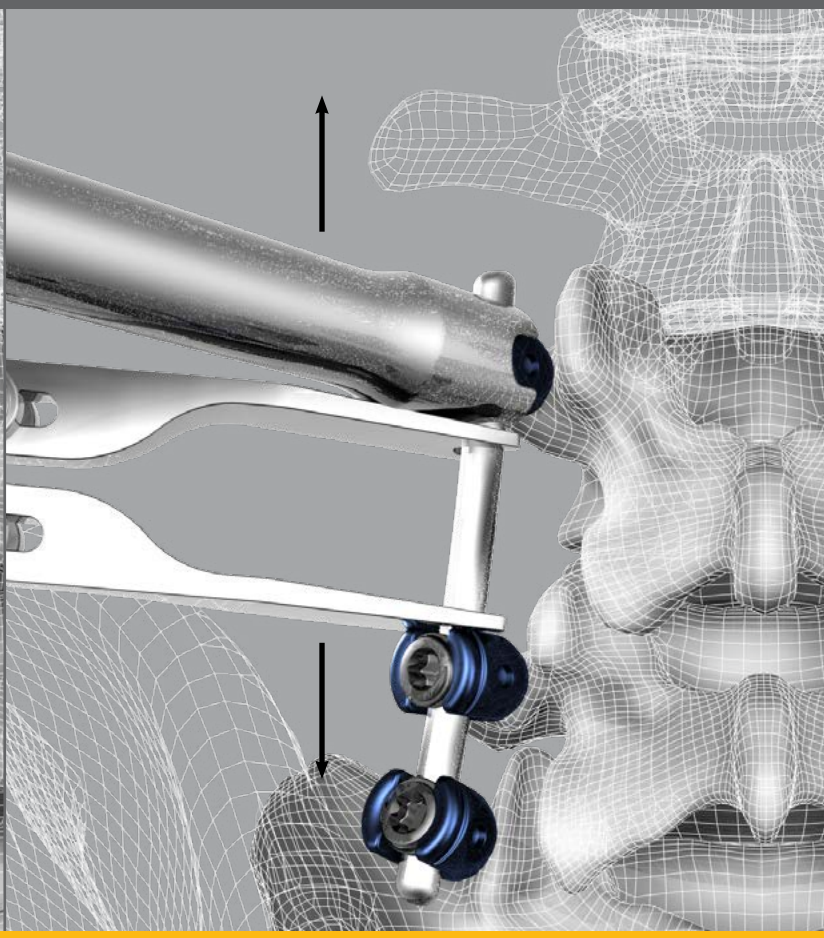
COMPRESSION AND DISTRACTION

Once all set screws have been placed, compression and distraction maneuvers may be performed. The set screws may be loosened and retightened to hold the construct in alignment.

COMPRESSION



DISTRACTION

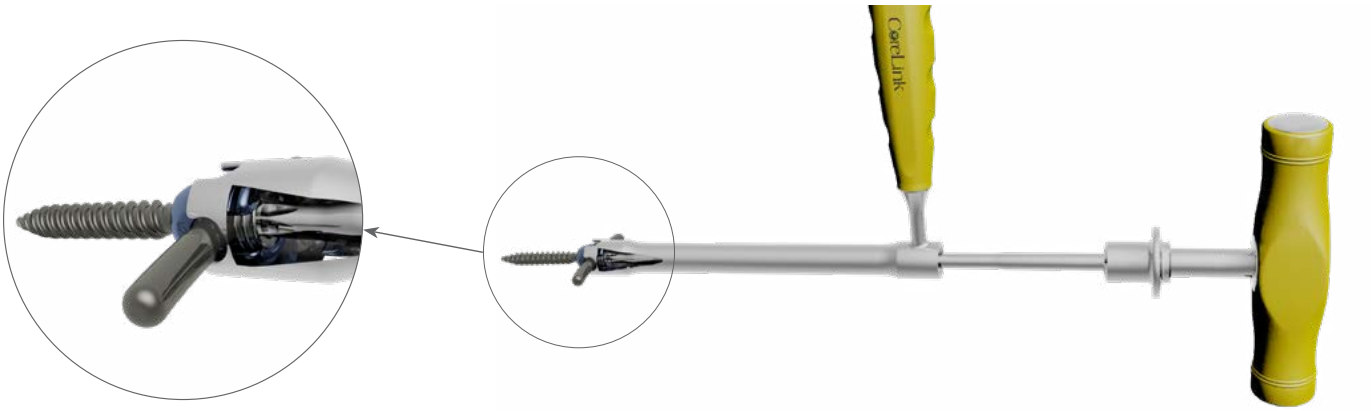


FINAL TIGHTENING

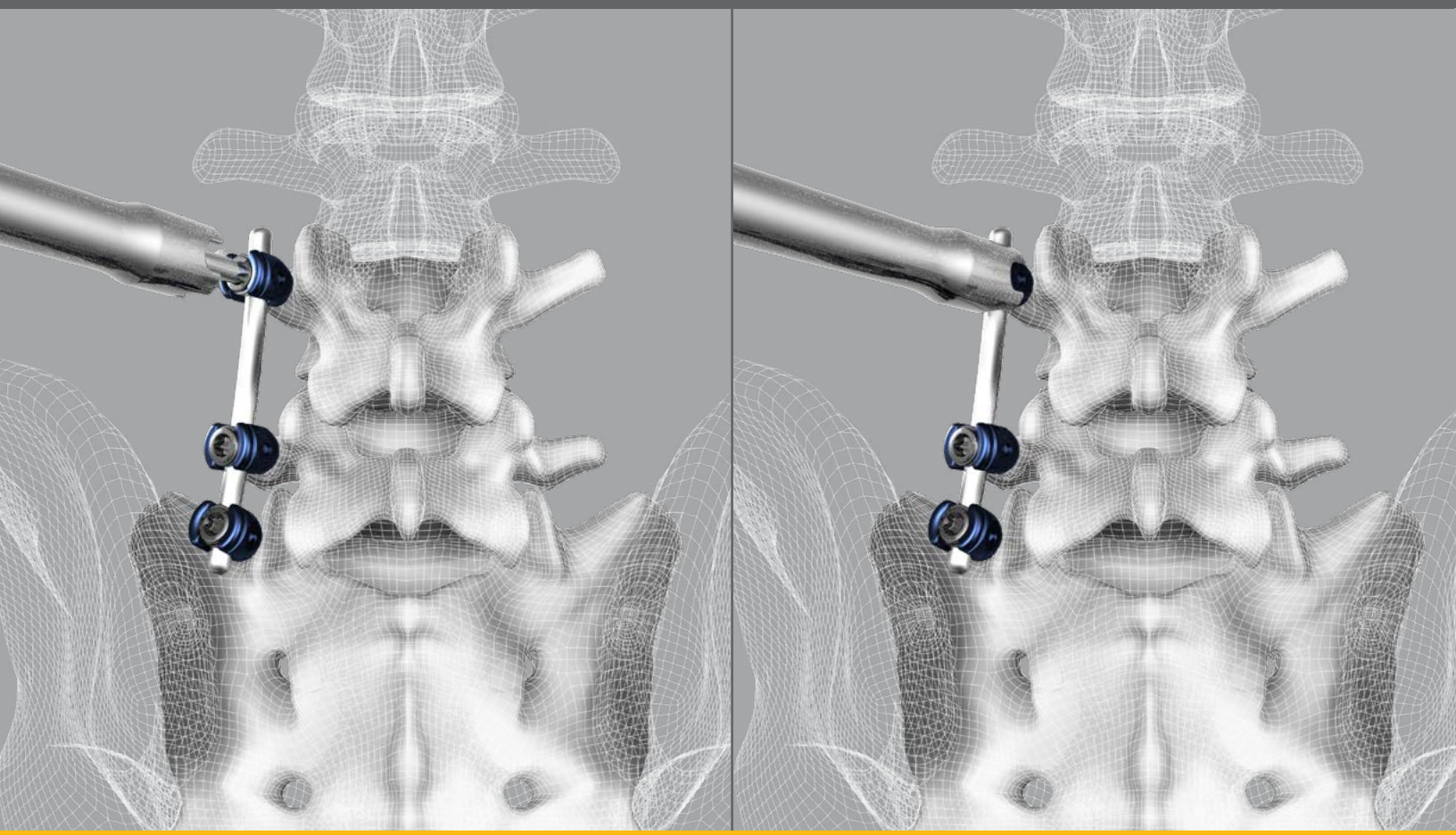
Final tightening of the set screws is required to secure the construct. The final tightening shaft should be used on the torque limiting handle in conjunction with the counter torque. The torque limiting value is 80 in-lbs.

HARDWARE REMOVAL

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



FINAL TIGHTENING WITH CONTOUR TORQUE



INSTRUCTIONS FOR USE

CORELINK TIGER SPINE SYSTEM

OPERATING SURGEON – IMPORTANT INFORMATION

TIGER® SPINE SYSTEM

This IFU applies to the following product families:

Tiger

Tiger MIS

Tiger Deformity

Tiger Posted

IMPORTANT NOTE: 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 Spine System is an implant system used to provide temporary immobilization and stabilization of the thoracolumbar spine while fusion occurs. The Tiger System consists of screws, rods, hooks, 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 Spine 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 pedicle screws 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 Spine 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 Spine System is provided with surgical instruments specifically for the implantation of the associated implants.

The Tiger Spine System includes a variety of manual surgical instruments manufactured from surgical grade stainless steel as per ASTM F899. The Tiger Spine System Navigation Instruments are nonsterile manual surgical instruments that are intended to be used with the Medtronic® StealthStation™ Surgical Navigation System to assist surgeons in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures for preparation and placement of pedicle screw system implants. This surgical imaging technology provides surgeons visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures. Use of these navigation systems provides the surgeon access to real-time, multi-plane 3D images (and 2D images) providing confirmation of hardware placement.

The Tiger Spine System Navigation Instruments are comprised of Taps and Screw Drivers. The Tiger Spine System Navigation Instruments were tested for compatibility utilizing the Medtronic® StealthStation™ S7 with software version 2.1.0 and StealthStation S8 Surgical Navigation System with software version1.2.0 (1.2.0-20), Violet, Orange, Green, and Gray Navlock Trackers (Part Numbers 9734682, 9734683, 9734734, and 9734590), Medtronic Navigation Instrument Drivers (Part Numbers 9735023, and NAV2019K) and the Navlock Small Passive Reference Frame (Part Number (9731478).

Use of the Tiger Spine System Navigation Instruments are limited to certain instrument and implant sizes based on the CoreLink implant system used. The Tiger Open and Tiger Deformity Navigation Instruments are limited to Taps ranging in sizes of 4.5mm to 10.5mm and bone screws ranging from 4.5mm to 10.5mm with lengths ranging from 25mm to 110mm. The Tiger MIS Navigation Instruments are limited to Taps ranging in sizes of 5.5mm to 10.5mm and bone screws ranging from 5.5mm to 10.5mm with lengths ranging from 25mm to 110mm. For a complete listing of compatible implants and navigation instruments, please refer to the navigation instrument and implant compatibility table in the surgical technique guide.

INDICATIONS

The Tiger Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

CoreLink Navigation Instruments are intended to be used during the preparation and placement of Tiger screw implants during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System S8 (V1.2.0), which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

CONTRAINDICATIONS

Do not use the Tiger Spine System in the presence of an active systemic infection or infections localized to the site of the proposed implantation. Other relative contraindications include:

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

Use of the Tiger Spine System Navigation Instruments and associated implants are contraindicated in any scenario that is contraindicated in the Medtronic StealthStation Instructions for Use. Use of the Tiger Spine System Navigation Instruments with implant systems other than those indicated in this document must not be performed.

COMPLICATIONS AND 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

INSTRUCTIONS FOR USE (CONTINUED)

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 pedicle screw spinal systems have been established only for spinal conditions with acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1 – S1/Ilium): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion pseudarthrosis. The safety and effectiveness of these devices for any other conditions are unknown.

Patients must be informed that implants cannot be made to last indefinitely, and the purpose of the implant is to provide temporary internal support while the fusion mass about the implant is developing. Without solid biological support provided by sufficient fusion mass, the 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 Spine 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 pedicle screw spinal systems is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure must be performed only by experienced spinal surgeons with specific training in the use of this 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 Spine 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 Spine System has not been evaluated for safety and compatibility in the MR environment. The Tiger Spine System has not been tested for heating migration, or image artifact in the MR environment. The safety of the Tiger Spine System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

USE OF NAVIGATION INSTRUMENTS

CAUTION: CoreLink is not a navigation provider. The navigation system must be set up per the manufacturer's instructions. The Tiger Spine System Navigation Instruments have been validated for use with the third-party Medtronic StealthStation S7 with software version 2.1.0 and StealthStation S8 Surgical Navigation System with software version 1.2.0 (1.2.0-20). Instructions for use and handling of third-party navigation systems are the responsibility of the hospital and navigation company. Refer to the navigation company's software and user guides for calibration and navigation guidance. Compatible third-party navigation clamps, reference frames, and arrays are listed in the Surgical Technique Guide. Ensure the hospital has the appropriate third-party navigation equipment prior to the surgical case. It is recommended to setup the operating room and instrument arrays such that camera view of all arrays remain uninterrupted at all times. A field assessment should be performed by positioning the navigation instrument tip on an identifiable anatomical landmark and comparing the actual tip location to that displayed by the system. If the inputs result in the correct and anticipated outputs, functional verification is confirmed.

WARNING: Navigation instruments are highly accurate and sensitive medical devices that must be handled with extreme care. If you drop or otherwise damage it, do not use it in a surgical case. Any instrument that is suspected of being damaged, inaccurate, or cannot be registered or verified must not be used in a surgical case and must be returned to CoreLink immediately. Failure to do so may lead to serious injury to the patient. Additionally, all navigation instruments and StealthStation tracking instruments must be continuously verified for correct registration with the Stealth Station software. Positional accuracy must be continuously monitored intraoperatively. Immediately discontinue use of the navigation instruments if an inaccuracy is detected. Inaccuracy may also occur if bending or other alteration of the instruments occurs.

Only surgeons and medical personnel trained in the use of StealthStation navigation are to use the Tiger Spine System Navigated Instruments when used with the StealthStation System.

Only the identified tool card is to be selected for each instrument to prevent patient injury from inaccurate navigation.

Only use the Tiger Spine System Navigated Instruments with the software version of StealthStation System for which the instrument accuracy was validated to prevent patient injury from inaccurate navigation.

Note: For information on use of disposable reflective marker spheres, refer to navigation manufacturers' user guide.

PREPARATION AT THE POINT OF USE

The implants and instruments of the Tiger Spine System and the Tiger Spine System Navigation Instruments are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. Instruments must be cleaned using the following 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 Spine 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, corrosion, and proper function. Drills and Taps must be inspected for wear and cutting flute damage. Drivers and inserters must be inspected to ensure correct and full engagement of implants. Dilators must allow for free passage of any instrument or implant. All navigation instruments must allow for free connection and rotation of any Navlock tracker. If you suspect an instrument is damaged, please contact CoreLink for a replacement. Do not use potentially defective instruments.

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.

Typical Automated Washer Cycle for Surgical Instruments

Step	Description
1	1-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	1-minute hot tap water rinse
5	2-minute thermal rinse (80-93°C/176-200°F)
6	10-second purified water rinse (64-66°C/146-150°F)
7	7 to 30-minute heated air dry (116°C/240°F)

Notes:

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

Sterilization Instructions

Implants and instruments of the Tiger Spine 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 to a 10-6 sterility assurance level (SAL) 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 Spine 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)
Exposure 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 Spine 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

INSTRUCTIONS FOR USE (CONTINUED)

alloys. The Tiger Spine System implants are available in titanium alloy and cobalt chrome alloy. It is imperative that the Tiger Spine 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 must be considered when evaluating whether a patient is a candidate for such a procedure.
   - **Weight.** An overweight or obese patient can produce loads on the device that may lead to failure of the implant component.
   - **Lifestyle or Activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even after the bone is fully healed, the patient may not be able to resume these activities.
   - **Alcoholism, Drug Abuse or Mental Conditions.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions leading to implant failure or other complications.
   - **Degenerative Diseases.** In some cases, the progression of a degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the implant component. In these cases, the use of the implant may only postpone potential outcomes and/or be of a temporary nature.
   - **Implant Sensitivity.** No preoperative test can completely exclude the possibility of sensitivity or allergic reaction. A patient may develop sensitivity or allergy after implants have been in the body for a period of time.
   - **Smoking.** Smoking has been linked to a higher rate of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Smoking can also lead to progressive degeneration of adjacent segments and late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

ADDITIONAL PRECAUTIONS

- Patient Instructions. Instructions for the patient's postoperative care, and the patient's ability and willingness to follow such instructions are extremely important for successful bone healing. In addition to the instructions described previously, 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: (i) the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage or migration of implants; or (ii) pulsatile erosion of the vessels occurs due to the placement of the implants adjacent to the vessels.
- Implant Removal. Spinal implants of this type may 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.

POSTOPERATIVE IMMOBILIZATION

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

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

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

LIMITED WARRANTY AND DISCLAIMER

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

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

The Aesculap SterilContainer System is FDA 510(k) cleared under K792558, K053389, K040865, K093493, K093649, K041623, and K073168. All third-party trademarks used herein are the trademarks of their respective owners. Aesculap and SterilContainer are trademarks of Aesculap, Inc., a B. Braun Company. StealthStation is a registered trademark of Medtronic Navigation, Inc.

For further information contact:

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St. Louis, MO 63026
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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 - Indicates the need for the user to consult the instructions for use for 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 PRODUCT LISTING

INSTRUMENT TRAY 1

CATALOG NUMBER	DESCRIPTION
1027-552	DUAL LEAD TAP UNDERSIZED 5.5MM
1027-652	DUAL LEAD TAP UNDERSIZED 6.5MM
1027-752	DUAL LEAD TAP UNDERSIZED 7.5MM
5000-110	BALL TIP PROBE – MALLEABLE
5000-105	PEDICLE PROBE – STRAIGHT
5000-106	PEDICLE PROBE – CURVED
5000-152	PEDICLE PROBE – STRAIGHT POINTED
5000-108	THORACIC PEDICLE PROBE
5000-112	PEDICLE AWL WITH IMPACT
8125-200	1/4" DRIVE MOLDED T-HANDLE
8225-201	1/4" DRIVE MOLDED STRAIGHT
8325-201	1/4" DRIVE MOLDED BALL HANDLE
2025-213	POLY-AXIAL SCREW DRIVER WITH LOCK
2025-232	TIGER OPEN POLY-AXIAL SCREWDRIVER, SLIM
2025-103	SCREW DRIVER – STRAIGHT
2025-107	SET SCREW STARTER-LONG
2025-109	SET SCREW STARTER TUBE

INSTRUMENT TRAY 2

CATALOG NUMBER	DESCRIPTION
2025-108	SET SCREW DRIVER – LONG
2025-110	COUNTER TORQUE – LONG
3000-100	ROD REDUCER
3000-101	ROD ROCKER
3000-102	HEAD ADJUSTER
3300-100	ROD PUSHER, STRAIGHT
3500-104	REDUCTION TOWER ADAPTER SOCKET
3500-105	5500 SERIES TOWER CONNECTION
3500-107	REDUCTION TOWER
4000-100	DISTRACTOR
4000-101	COMPRESSOR
4000-102	PROVISIONAL ROD DISTRACTOR
4100-100	ROD HOLDER – STRAIGHT
7000-100	FRENCH BENDER
7100-100	IN SITU BENDER – LH
7100-101	IN SITU BENDER – RH
9025-100	1/4" DRIVE TORQUE WRENCH

TIGER DEFORMITY

CATALOG NUMBER	DESCRIPTION
2025-130	POSTED SCREW FINAL TIGHTENER – SET SCREW
4200-100	HOOK HOLDER – FORCEPS
4200-101	HOOK PUSHER
4200-102	PEDICLE FINDER
4200-103	LAMINAR FINDER
4200-104	THORACIC FACET FINDER
4200-105	WIDE BLADE LAMINAR ELEVATOR
4200-106	NARROW BLADE LAMINAR ELEVATOR
4200-107	PEDICLE ELEVATOR
4200-108	TRANSVERSE PROCESS ELEVATOR
3200-100	HEX WRENCH
3500-104	REDUCTION TOWER ADAPTER SOCKET
3500-105	5500 SERIES TOWER CONNECTION
3500-107	REDUCTION TOWER
2025-113	SCREW DRIVER – PEDICLE, CROSS CONNECTOR
9025-101	CROSS CONNECTOR TORQUE LIMITING HANDLE

IMPLANTS

CATALOG NUMBER	DESCRIPTION	TRAY
SET SCREW		
55635-45	SET SCREW	TIGER IMPLANT
HOOKS		
55001-2	BIFID PEDICLE	TIGER DEFORMITY
55001-3	WIDE BLADE	TIGER DEFORMITY
55001-4	NARROW BLADE	TIGER DEFORMITY
55001-6	TRANSVERSE PROCESS, RIGHT	TIGER DEFORMITY
55001-7	TRANSVERSE PROCESS, LEFT	TIGER DEFORMITY
55001-8	WIDE BLADE, TALL	TIGER DEFORMITY
55001-9	NARROW BLADE, TALL	TIGER DEFORMITY
SPECIALTY HOOKS*		
55001-1	PEDICLE	TIGER DEFORMITY
55001-5	LAMINAR	TIGER DEFORMITY
55001-10	LAMINAR, TALL	TIGER DEFORMITY
55001-11	OFFSET, RIGHT	TIGER DEFORMITY
55001-12	OFFSET, LEFT	TIGER DEFORMITY

*AVAILABLE UPON REQUEST

TIGER PRODUCT LISTING (CONTINUED)

PEDICLE SCREWS		
CATALOG NUMBER	DESCRIPTION	TRAY
POLY-AXIAL PEDICLE SCREWS		
55055-25	5.5MM X 25MM	TIGER IMPLANT
55055-30	5.5MM X 30MM	TIGER IMPLANT
55055-35	5.5MM X 35MM	TIGER IMPLANT
55055-40	5.5MM X 40MM	TIGER IMPLANT
55055-45	5.5MM X 45MM	TIGER IMPLANT
55055-50	5.5MM X 50MM	TIGER IMPLANT
55055-55	5.5MM X 55MM	TIGER IMPLANT
55065-35	6.5MM X 35MM	TIGER IMPLANT
55065-40	6.5MM X 40MM	TIGER IMPLANT
55065-45	6.5MM X 45MM	TIGER IMPLANT
55065-50	6.5MM X 50MM	TIGER IMPLANT
55065-55	6.5MM X 55MM	TIGER IMPLANT
55075-35	7.5MM X 35MM	TIGER IMPLANT
55075-40	7.5MM X 40MM	TIGER IMPLANT
55075-45	7.5MM X 45MM	TIGER IMPLANT
55075-50	7.5MM X 50MM	TIGER IMPLANT
55075-55	7.5MM X 55MM	TIGER IMPLANT
55075-60	7.5MM X 60MM	TIGER SACROILIAC
55075-70	7.5MM X 70MM	TIGER SACROILIAC
55075-80	7.5MM X 80MM	TIGER SACROILIAC
55075-90	7.5MM X 90MM	TIGER SACROILIAC
55075-100	7.5MM X 100MM	TIGER SACROILIAC
55075-110	7.5MM X 110MM	TIGER SACROILIAC
55075-120	7.5MM X 120MM	TIGER SACROILIAC
55085-35	8.5MM X 35MM	TIGER IMPLANT – LARGE
55085-40	8.5MM X 40MM	TIGER IMPLANT – LARGE
55085-45	8.5MM X 45MM	TIGER IMPLANT – LARGE
55085-50	8.5MM X 50MM	TIGER IMPLANT – LARGE
55085-55	8.5MM X 55MM	TIGER IMPLANT – LARGE
55085-60	8.5MM X 60MM	TIGER SACROILIAC
55085-70	8.5MM X 70MM	TIGER SACROILIAC
55085-80	8.5MM X 80MM	TIGER SACROILIAC
55085-90	8.5MM X 90MM	TIGER SACROILIAC
55085-100	8.5MM X 100MM	TIGER SACROILIAC
55085-110	8.5MM X 110MM	TIGER SACROILIAC
55085-120	8.5MM X 120MM	TIGER SACROILIAC

PEDICLE SCREWS		
CATALOG NUMBER	DESCRIPTION	TRAY
POLY-AXIAL PEDICLE SCREWS		
55095-35	9.5MM X 35MM	TIGER IMPLANT – LARGE
55095-40	9.5MM X 40MM	TIGER IMPLANT – LARGE
55095-45	9.5MM X 45MM	TIGER IMPLANT – LARGE
55095-50	9.5MM X 50MM	TIGER IMPLANT – LARGE
55095-55	9.5MM X 55MM	TIGER IMPLANT – LARGE
55095-60	9.5MM X 60MM	TIGER SACROILIAC
55095-70	9.5MM X 70MM	TIGER SACROILIAC
55095-80	9.5MM X 80MM	TIGER SACROILIAC
55095-90	9.5MM X 90MM	TIGER SACROILIAC
55095-100	9.5MM X 100MM	TIGER SACROILIAC
55095-110	9.5MM X 110MM	TIGER SACROILIAC
55095-120	9.5MM X 120MM	TIGER SACROILIAC
55005-35	10.5MM X 35MM	TIGER IMPLANT – LARGE
55005-40	10.5MM X 40MM	TIGER IMPLANT – LARGE
55005-45	10.5MM X 45MM	TIGER IMPLANT – LARGE
55005-50	10.5MM X 50MM	TIGER IMPLANT – LARGE
55005-55	10.5MM X 55MM	TIGER IMPLANT – LARGE
55005-60	10.5MM X 60MM	TIGER SACROILIAC
55005-70	10.5MM X 70MM	TIGER SACROILIAC
55005-80	10.5MM X 80MM	TIGER SACROILIAC
55005-90	10.5MM X 90MM	TIGER SACROILIAC
55005-100	10.5MM X 100MM	TIGER SACROILIAC
55005-110	10.5MM X 110MM	TIGER SACROILIAC
55005-120	10.5MM X 120MM	TIGER SACROILIAC

PEDICLE SCREWS

CATALOG NUMBER	DESCRIPTION	TRAY
SPECIALTY POLY-AXIAL PEDICLE SCREWS*		
55045-25	4.5MM X 25MM	TIGER IMPLANT
55045-30	4.5MM X 30MM	TIGER IMPLANT
55045-35	4.5MM X 35MM	TIGER IMPLANT
55045-40	4.5MM X 40MM	TIGER IMPLANT
55045-45	4.5MM X 45MM	TIGER IMPLANT
55045-50	4.5MM X 50MM	TIGER IMPLANT
55045-55	4.5MM X 55MM	TIGER IMPLANT
55045-60	4.5MM X 60MM	TIGER IMPLANT
55055-60	5.5MM X 60MM	TIGER IMPLANT
55065-25	6.5MM X 25MM	TIGER IMPLANT
55065-30	6.5MM X 30MM	TIGER IMPLANT
55065-60	6.5MM X 60MM	TIGER IMPLANT
55075-25	7.5MM X 25MM	TIGER IMPLANT
55075-30	7.5MM X 30MM	TIGER IMPLANT

*AVAILABLE ON REQUEST

** AVAILABLE UPON REQUEST

ADDITIONAL PEDICLE SCREW OFFERING

CATALOG NUMBER	DIAMETERS AVAILABLE	DIAMETER CODE	LENGTHS (INCREMENTS)
REDUCTION POLY-AXIAL			
552__-__*	4.5MM	45	25MM – 60MM (5MM)
552__-__*	5.5MM	55	25MM – 60MM (5MM)
552__-__*	6.5MM	65	25MM – 60MM (5MM)
552__-__*	7.5MM	75	25MM – 60MM (5MM)
552__-__*	8.5MM	85	35MM – 55MM (5MM)
CANNULATED REDUCTION POLY-AXIAL			
572__-__*	5.5MM	55	35MM – 55MM (5MM)
572__-__*	6.5MM	65	35MM – 55MM (5MM)
572__-__*	7.5MM	75	35MM – 55MM (5MM)
572__-__*	8.5MM	85	35MM – 55MM (5MM)
UNI-PLANAR			
553__-__*	4.5MM	45	25MM – 60MM (5MM)
553__-__*	5.5MM	55	25MM – 60MM (5MM)
553__-__*	6.5MM	65	25MM – 60MM (5MM)
553__-__*	7.5MM	75	25MM – 60MM (5MM)
MONO AXIAL			
554__-__*	4.5MM	45	25MM – 60MM (5MM)
554__-__*	5.5MM	55	25MM – 60MM (5MM)
554__-__*	6.5MM	65	25MM – 60MM (5MM)
554__-__*	7.5MM	75	25MM – 60MM (5MM)
554__-___*	7.5MM	75	70MM – 120MM (10MM)
554__-__*	8.5MM	85	35MM – 60MM (5MM)
554__-___*	8.5MM	85	70MM – 120MM (10MM)
554__-__*	9.5MM	95	35MM – 60MM (5MM)
554__-___*	9.5MM	95	70MM – 120MM (10MM)
554__-__*	10.5MM	05	35MM – 60MM (5MM)
554__-___*	10.5MM	05	70MM – 120MM (10MM)
UNI-REDUCTION			
553__-__**	4.5MM	45	25MM – 60MM (5MM)
553__-__**	5.5MM	55	25MM – 60MM (5MM)
553__-__**	6.5MM	65	25MM – 60MM (5MM)
553__-__**	7.5MM	75	25MM – 60MM (5MM)

* CREATE CORELINK CATALOG NUMBERS USING THE ITEM CODE, SCREW DIAMETER, AND LENGTH.

EXAMPLE CATALOG NUMBER

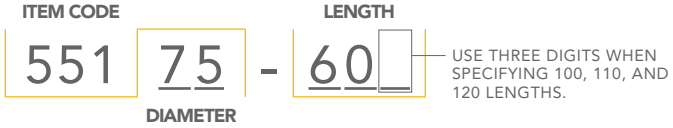
TIGER PRODUCT LISTING (CONTINUED)

ADDITIONAL PEDICLE SCREW OFFERING (CON'T.)

CATALOG NUMBER	DIAMETERS AVAILABLE	DIAMETER CODE	LENGTHS (INCREMENTS)
CANNULATED MONO AXIAL			
556__-__*	5.5MM	55	25MM – 60MM (5MM)
556__-__*	6.5MM	65	25MM – 60MM (5MM)
556__-__*	7.5MM	75	35MM – 60MM (5MM)
556__-___*	7.5MM	75	70MM – 120MM (10MM)
FRACTURE			
558__-__*	4.5MM	45	25MM – 60MM (5MM)
558__-__*	5.5MM	55	25MM – 60MM (5MM)
558__-__*	6.5MM	65	25MM – 60MM (5MM)
558__-__*	7.5MM	75	25MM – 60MM (5MM)
558__-___*	7.5MM	75	70MM – 120MM (10MM)
CANNULATED POLY-AXIAL			
555__-__*	5.5MM	55	25MM – 60MM (5MM)
555__-__*	6.5MM	65	25MM – 60MM (5MM)
555__-__*	7.5MM	75	25MM – 60MM (5MM)
555__-___*	7.5MM	75	70MM – 120MM (10MM)
555__-__*	8.5MM	85	35MM – 60MM (5MM)
555__-___*	8.5MM	85	70MM – 120MM (10MM)
555__-__*	9.5MM	95	35MM – 60MM (5MM)
555__-___*	9.5MM	95	70MM – 120MM (10MM)
555__-__*	10.5MM	05	35MM – 60MM (5MM)
555__-___*	10.5MM	05	70MM – 120MM (10MM)
DUAL/QUAD THREAD			
580__-__*	4.5MM	45	30MM – 60MM (5MM)
580__-__*	5.5MM	55	30MM – 60MM (5MM)
580__-__*	6.5MM	65	30MM – 60MM (5MM)
580__-__*	7.5MM	75	30MM – 60MM (5MM)
580__-__*	8.5MM	85	35MM – 60MM (5MM)
CLOSED HEAD POLY-AXIAL			
551__-___*	7.5MM	75	60MM – 120MM (10MM)
551__-___*	8.5MM	85	60MM – 120MM (10MM)
551__-___*	9.5MM	95	60MM – 120MM (10MM)
551__-___*	10.5MM	05	60MM – 120MM (10MM)

* CREATE CORELINK CATALOG NUMBERS USING THE ITEM CODE, SCREW DIAMETER, AND LENGTH.

EXAMPLE CATALOG NUMBER



RODS AND CONNECTORS

CATALOG NUMBER	DESCRIPTION	TRAY
PRE-BENT – WITH LINE		
R5510-035	5.5MM X 35MM	TIGER IMPLANT
R5510-040	5.5MM X 40MM	TIGER IMPLANT
R5510-045	5.5MM X 45MM	TIGER IMPLANT
R5510-055	5.5MM X 55MM	TIGER IMPLANT
R5510-065	5.5MM X 65MM	TIGER IMPLANT
R5510-075	5.5MM X 75MM	TIGER IMPLANT
R5510-085	5.5MM X 85MM	TIGER IMPLANT
R5510-095	5.5MM X 95MM	TIGER IMPLANT
STRAIGHT – WITH LINE		
R5511-150	5.5MM X 150MM	TIGER IMPLANT
R5511-200	5.5MM X 200MM	TIGER IMPLANT
STRAIGHT – WITH HEX AND LINE		
R5516-100	5.5MM X 100MM	TIGER DEFORMITY
R5516-200	5.5MM X 200MM	TIGER DEFORMITY
R5516-300	5.5MM X 300MM	TIGER DEFORMITY
R5516-400	5.5MM X 400MM	TIGER DEFORMITY
R5516-500	5.5MM X 500MM	TIGER DEFORMITY
ROD TO ROD CONNECTORS		
55000-10	5.5MM X 5.5MM, SIDE BY SIDE CLOSED	TIGER DEFORMITY
55000-13	5.5MM X 3.5MM, SIDE BY SIDE CLOSED	TIGER DEFORMITY
55000-20	5.5MM X 5.5MM, END TO END CLOSED	TIGER DEFORMITY
55000-22	5.5MM X 3.5MM, END TO END CLOSED	TIGER DEFORMITY
55000-50	5.5MM IN-LINE	TIGER DEFORMITY
SPECIALTY ROD TO ROD CONNECTORS		
55000-11	5.5MM X 6.35MM, SIDE BY SIDE, CLOSED	TIGER DEFORMITY
55000-21	5.5MM X 6.35MM, END TO END CLOSED	TIGER DEFORMITY
55000-51	6.35MM IN-LINE	TIGER DEFORMITY

RODS AND CONNECTORS

CATALOG NUMBER	DESCRIPTION	TRAY
LATERAL OFFSET CONNECTORS		
55300-15	NEUTRAL OFFSET, 15MM, OPEN	TIGER SACROILIAC
55300-30	NEUTRAL OFFSET, 30MM, OPEN	TIGER SACROILIAC
55300-60	NEUTRAL OFFSET, 60MM, OPEN	TIGER SACROILIAC
55300-80	NEUTRAL OFFSET, 80MM, OPEN	TIGER SACROILIAC
55310-15	75° OFFSET, 15MM, OPEN	TIGER SACROILIAC
55310-30	75° OFFSET, 30MM, OPEN	TIGER SACROILIAC
55310-60	75° OFFSET, 60MM, OPEN	TIGER SACROILIAC
55320-15	105° OFFSET, 15MM, OPEN	TIGER SACROILIAC
55320-30	105° OFFSET, 30MM, OPEN	TIGER SACROILIAC
55320-60	105° OFFSET, 60MM, OPEN	TIGER SACROILIAC
55301-15	NEUTRAL OFFSET, 15MM, CLOSED	TIGER SACROILIAC
55301-30	NEUTRAL OFFSET, 30MM, CLOSED	TIGER SACROILIAC
55301-60	NEUTRAL OFFSET, 60MM, CLOSED	TIGER SACROILIAC
55301-80	NEUTRAL OFFSET, 80MM, CLOSED	TIGER SACROILIAC
55311-15	75° OFFSET, 15MM, CLOSED	TIGER SACROILIAC
55311-30	75° OFFSET, 30MM, CLOSED	TIGER SACROILIAC
55311-60	75° OFFSET, 60MM, CLOSED	TIGER SACROILIAC
55321-15	105° OFFSET, 15MM, CLOSED	TIGER SACROILIAC
55321-30	105° OFFSET, 30MM, CLOSED	TIGER SACROILIAC
55321-60	105° OFFSET, 60MM, CLOSED	TIGER SACROILIAC
TRANSVERSE CONNECTORS		
TC5525-30	CROSS CONNECTOR, 25-30MM	TIGER TRANSVERSE CONNECTOR
TC5530-37	CROSS CONNECTOR, 30-37MM	TIGER TRANSVERSE CONNECTOR
TC5537-50	CROSS CONNECTOR, 37-50MM	TIGER TRANSVERSE CONNECTOR
TC5500-14	CROSS CONNECTOR, 14MM	TIGER TRANSVERSE CONNECTOR
TC5500-16	CROSS CONNECTOR, 16MM	TIGER TRANSVERSE CONNECTOR
TC5500-18	CROSS CONNECTOR, 18MM	TIGER TRANSVERSE CONNECTOR
TC5500-20	CROSS CONNECTOR, 20MM	TIGER TRANSVERSE CONNECTOR
TC5500-22	CROSS CONNECTOR, 22MM	TIGER TRANSVERSE CONNECTOR
TC5500-80	CROSS CONNECTOR, 50MM – 80MM	TIGER TRANSVERSE CONNECTOR

ADDITIONAL ROD OFFERING

ADDITIONAL ROD OFFERING		
CATALOG NUMBER	DIAMETERS AVAILABLE	LENGTHS (INCREMENTS)
PRE-BENT WITH HEX		
R5502-___*	5.5MM	35MM – 65MM (5MM)
PRE-BENT WITH LINE		
R5510-___*	5.5MM	35MM – 100MM (5MM)
R5510-___*	5.5MM	100MM – 150MM (10MM)
STRAIGHT WITH LINE		
R5511-___*	5.5MM	35MM – 100MM (5MM)
R5511-___*	5.5MM	100MM – 150MM (10MM)
R5511-___*	5.5MM	150MM, 200MM, 300MM, 450MM
STRAIGHT WITH HEX AND LINE		
R5516-___*	5.5MM	100MM – 600MM (100MM)

* CREATE CORELINK CATALOG NUMBERS USING THE ITEM CODE AND ROD LENGTH.

EXAMPLE CATALOG NUMBER

ITEM CODE: R5511 - 035 (LENGTH)

USE THREE DIGITS WHEN SPECIFYING LENGTH, INCLUDING LENGTHS UNDER 100MM.

ADDITIONAL ROD OFFERING		
CATALOG NUMBER	DIAMETERS AVAILABLE	LENGTHS (INCREMENTS)
COBALT CHROME - PRE-BENT WITH LINE		
R5505-___*	5.5MM	65MM – 90MM (5MM)
COBALT CHROME - STRAIGHT WITH HEX AND LINE		
R5513-___*	5.5MM	100MM – 600MM (100MM)
COBALT CHROME - STRAIGHT WITH HEX AND LINE, ROUGHENED		
R5526-___*	5.5MM	100MM – 600MM (100MM)
ANNEALED COBALT CHROME - STRAIGHT WITH HEX AND LINE, ROUGHENED		
R5526-301	5.5MM	300MM
R5526-401	5.5MM	400MM
R5526-501	5.5MM	500MM
R5526-601	5.5MM	600MM
COBALT CHROME - S-ROD WITH HEX AND LINE		
R5527-302	5.5MM	300MM, SMOOTH
R5527-303	5.5MM	300MM, ROUGH
R5527-402	5.5MM	400MM, SMOOTH
R5527-403	5.5MM	400MM, ROUGH
R5527-502	5.5MM	500MM, SMOOTH
R5527-503	5.5MM	500MM, ROUGH
R5527-602	5.5MM	600MM, SMOOTH
R5527-603	5.5MM	600MM, ROUGH
ANNEALED COBALT CHROME - S-ROD WITH HEX AND LINE		
R5527-300	5.5MM	300MM, SMOOTH
R5527-301	5.5MM	300MM, ROUGH
R5527-400	5.5MM	400MM, SMOOTH
R5527-401	5.5MM	400MM, ROUGH
R5527-500	5.5MM	500MM, SMOOTH
R5527-501	5.5MM	500MM, ROUGH
R5527-600	5.5MM	600MM, SMOOTH
R5527-601	5.5MM	600MM, ROUGH
TITANIUM - S-ROD WITH HEX AND LINE		
R5528-___*	5.5MM	300MM – 600MM (100MM)

NOTES

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