

Surgical Technique

EVEREST

Degenerative

As Described By:

John P. Kostuik, MD
Co-Founder, Past Chairman & Chief Medical Officer – K2M, Inc.
Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery
Past President – Scoliosis Research Society (SRS) & North American Spine Society (NASS)



Surgical Technique Steps

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Dear Colleagues,

Welcome to K2M and the EVEREST® Degenerative Spinal System. The EVEREST Degenerative Spinal System, named after the tallest mountain on Earth, truly raises the standard of excellence to new heights. With the help of experts in both the orthopedic and neurosurgical community, our Product Development team and I are extremely proud to provide surgeons with an excellent pedicle screw system focused on both the implant and instrument design.

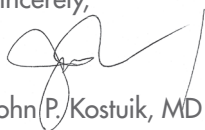
The implant technology is state-of-the-art, with several enhancing features to facilitate more efficient intraoperative use of the system. The EVEREST polyaxial screw provides 70° range of motion and features a mixed-metal (Ti/CoCr) head to minimize head splay, a dual-lead thread pattern for faster insertion and increased pullout strength, a set screw featuring a modified square thread design which facilitates set screw introduction, and the ability to accept both Ø5.5 and 6.0 mm rods.*

Great efforts have been made in the instrument design in an effort to provide the surgeon with multiple options in one system during surgery. These designs include several new and modular ideas for simplifying surgical application of the implants.

The EVEREST Degenerative Spinal System is, in my opinion, a significant step forward in the design of pedicle screw systems for the treatment of our patients. The following manual clearly outlines the procedural details and options, and will offer a guide to help understand the many important aspects of the EVEREST Degenerative Spinal System.

Thank you again for your interest and support.

Sincerely,



John P. Kostuik, MD

Co-Founder, Past Chairman & Chief Medical Officer – K2M, Inc.

Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery

Past President – Scoliosis Research Society (SRS) & North American Spine Society (NASS)

**See page 35 for support data. Mechanical testing may not represent clinical results.*

FEATURES & BENEFITS

EVEREST® Degenerative Spinal System



Implants

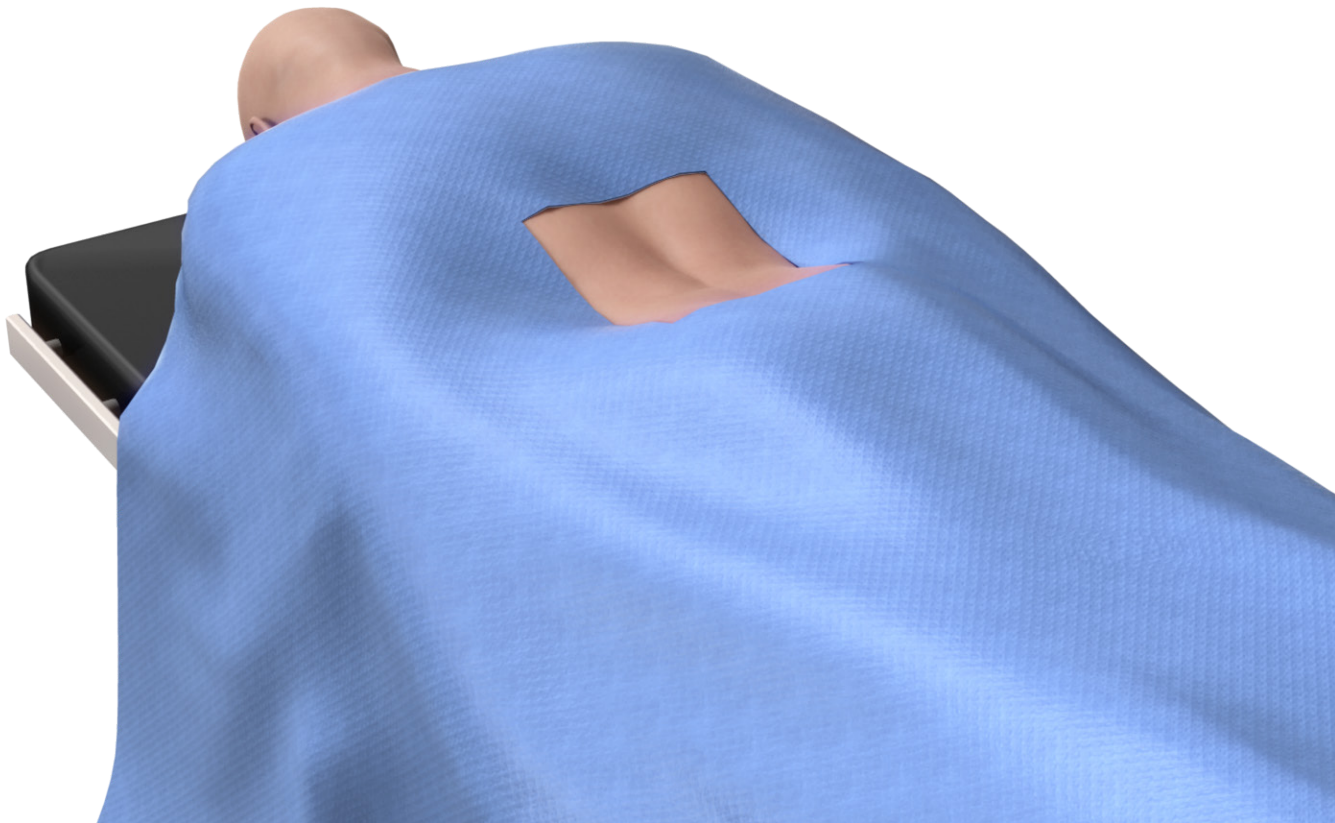
- Ability to Accept Ø5.5 & 6.0 mm Rods
- EVEREST Set Screw Features a Modified Square Thread Design, Facilitating Set Screw Introduction
- Dual-lead Thread Pattern for Faster Insertion & Increased Pullout Strength*
- Mixed-metal (Ti/CoCr) Tulip Minimized Head Splay & Demonstrated Improved Biomechanical Performance When Tested Against an All-titanium Alloy Screw*
- Polyaxial Range of Motion for Ease of Use Intraoperatively

Instruments

- Single Action Anti-Torque Rod Reducer (Cicada™): Allows for up to 15 mm of Rapid & Simultaneous Rod Reduction & Decreases Potential for Set Screw Cross-threading, While Allowing for Provisional & Final Tightening
- Threaded Rod Reducer: Allows for up to 30 mm of Controlled Rod Reduction
- EVEREST Basecamp™ Reducer Provides 60 mm of Quick or Controlled Reduction
- Modular Instrument Sets: Allow for Customization

*See page 35 for support data. Mechanical testing may not represent clinical results.

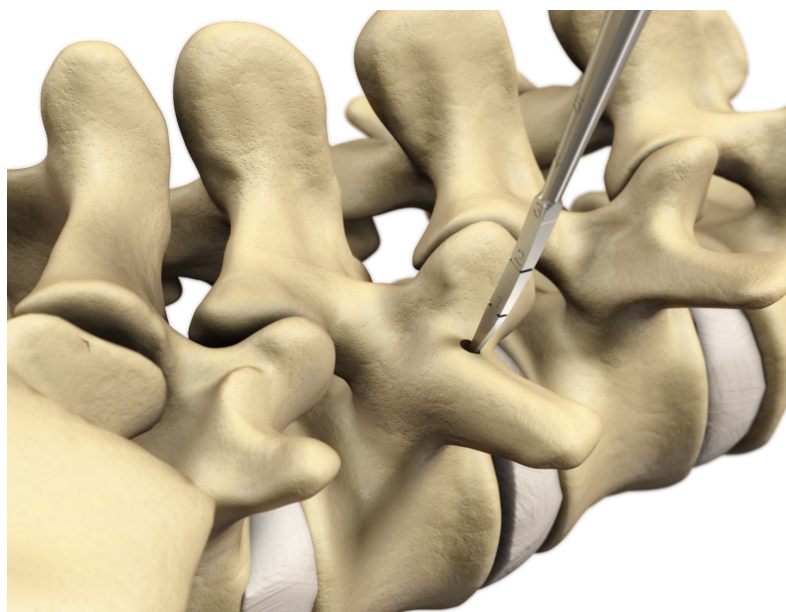
PEDICLE SCREW SURGICAL TECHNIQUE



PATIENT POSITIONING

The patient should be positioned as appropriate for a posterior approach, taking care to preserve or improve sagittal alignment of the spine. Care should be taken to pad all bony prominences. The abdomen should not be compressed to facilitate venous drainage.

Pre-surgical planning defines the type of construct and the most appropriate implants, as well as the location of where the implants should be inserted.



SCREW SITE PREPARATION

The small cortical crest of the pedicle is perforated with an Awl or removed with an available Rongeur or Burr to expose the underlying cancellous bone. The entry point is cannulated with the Curved or Straight Lumbar Probe in the lumbar spine and the Curved or Straight Thoracic Probe in the thoracic spine. The Probe is advanced to the appropriate depth, as determined by the surgeon.

Both the Probes and Taps are laser-etched at 10 mm increments, from 10 to 50 mm, indicating the depth to which this instrument has been inserted. These markings also help the surgeon assess proper screw length. The appropriate size Tap may be used to prepare the pedicle screw canal. Each Tap is sized to the screw diameter.



POLYAXIAL SCREW INSERTER



T-HANDLE



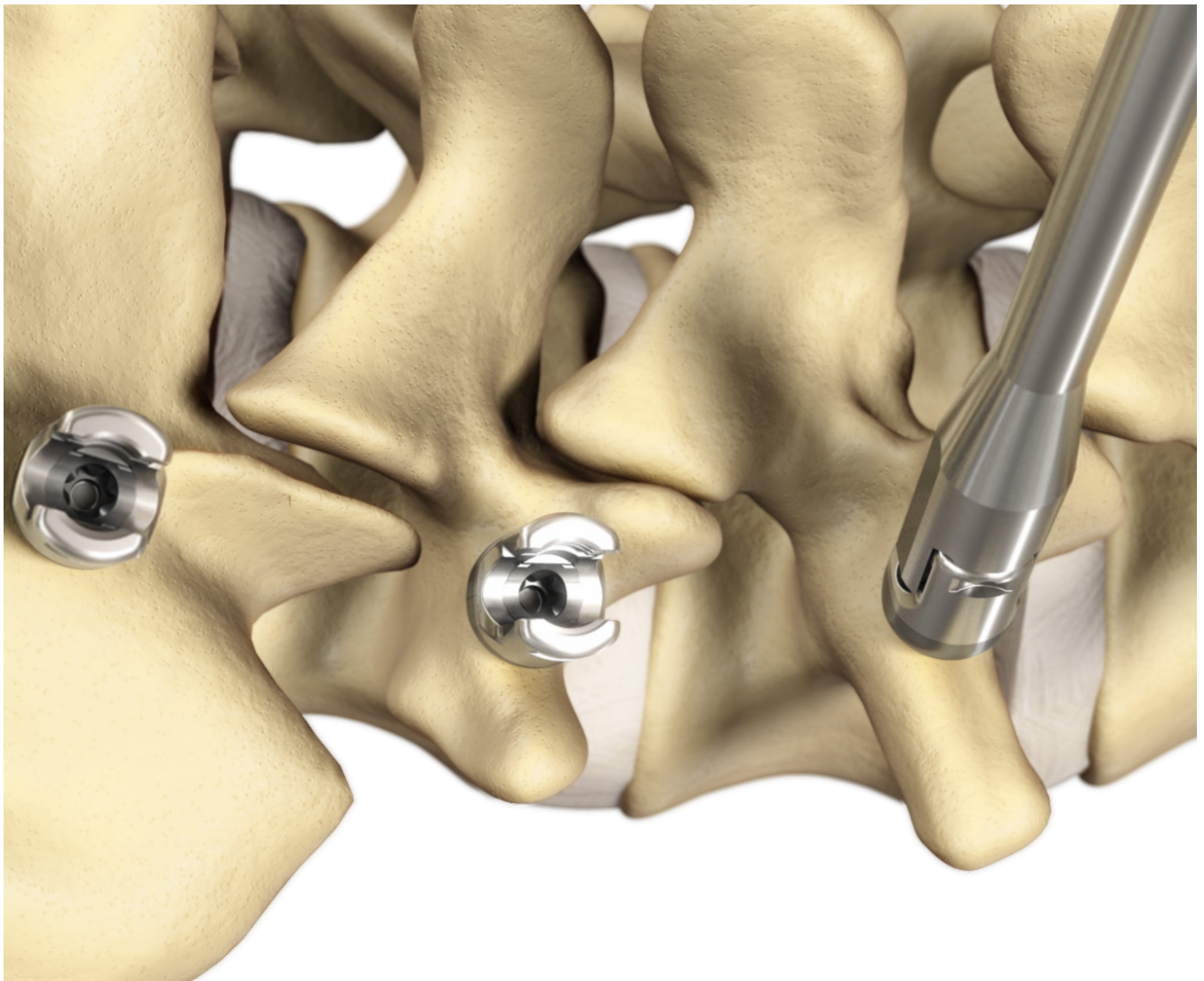
SCREW INSERTION

When using an EVEREST Polyaxial Screw Inserter, grasp the implant by the shaft of the screw and apply a downward force to engage the screw into the hexalobe fitting of the screwdriver shaft.

Thread the knurled wheel in a clockwise direction until the implant is securely attached to the inserter. To disengage the Screw Inserter, gently turn the knurled wheel in a counter-clockwise direction, and remove from the surgical field.



SCREW HEAD ADJUSTER



SCREW HEAD ADJUSTMENT

Once the appropriate screw height has been achieved, it may be necessary to realign the implant heads prior to rod insertion. The polyaxial housing of the screw can be manipulated with the Screw Head Adjuster.

NOTE: The EVEREST screw has a poseable friction head so it will hold position when adjusted with the Screw Head Adjuster.



FRENCH ROD BENDER



ROD PREPARATION

Pre-contoured rods are available in the set in several lengths. The EVEREST screw can accommodate both a $\text{\O}5.5$ and 6.0 mm rod. If an increased bend is needed, a French Rod Bender may be used to contour the rods to the desired amount of lordosis or kyphosis.

By pulling out and rotating the dial, the rod may be bent to the desired curvature (small, medium, or large).



ROD INTRODUCING FORCEPS



ROD INSERTION

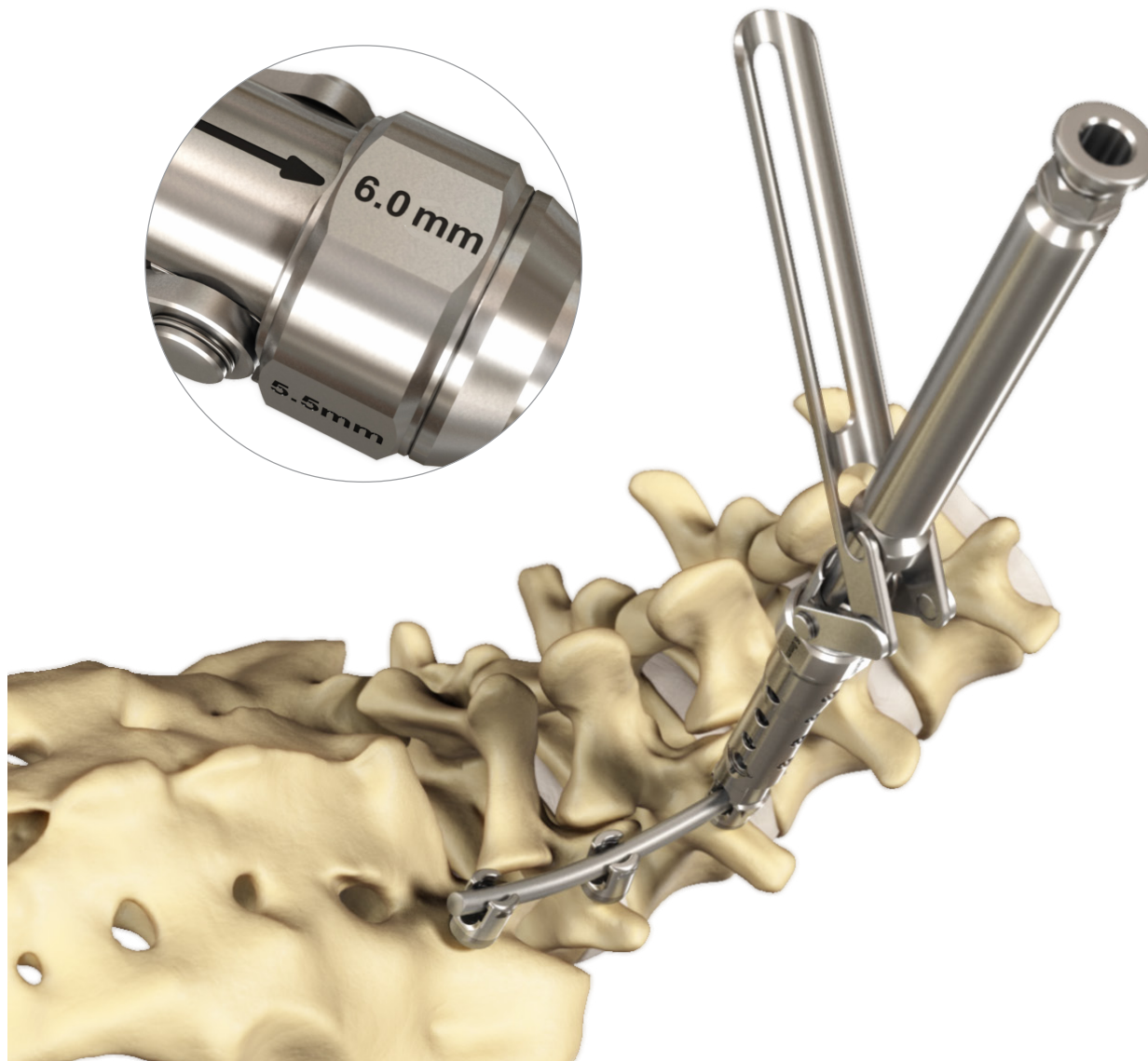
Once the desired length and contour of the rod is achieved, the Rod Introducing Forceps can be used to fit the rod into the screws.



CICADA™



LONG PROVISIONAL DRIVER



ROD PERSUASION & REDUCTION

The Cicada™ may be used for common reductions up to 15 mm into EVEREST implants. Adjust the knurled wheel on the instrument to accommodate the proper rod diameter, either 5.5 or 6.0 mm. When docking the Single Action Anti-Torque Rod Reducer (Cicada), hold the center shaft of the instrument to receive better tactile feedback. Once the instrument is engaged by grasping the feet around the

screw head, squeeze the silver lever to reduce the rod into the implant housing. The EVEREST set screw may be passed through the center of the Cicada and threaded into the implant housing using the Long Provisional Driver. Open the silver lever fully to disengage the feet from the head of the implant and pull upward.



QUICK CONNECT ADAPTER



T-HANDLE



THREADED ROD REDUCER



For reductions up to 30 mm, the EVEREST Threaded Rod Reducer may be used. For initial application, ensure the proximal rotation handle is turned counter-clockwise to its stopped position. This will ensure the feet are fully splayed open and prepared to engage the implant. Grasp both handles and introduce the feet around the head of the screw.

Once the instrument is in proper position, turn the proximal handle in a clockwise direction until desired reduction is achieved and the rod is fully seated. The EVEREST set screw may be passed through the center of the EVEREST Threaded Rod Reducer and threaded into the implant housing using the Long Provisional Driver to provisionally tighten the construct.

To disengage the instrument, turn the proximal handle counter-clockwise until it stops, splaying the feet open, and pull upward to disengage from the implant housing.

NOTE: The T-Handle and Quick Connect Adapter can be attached to the Threaded Rod Reducer for additional leverage.



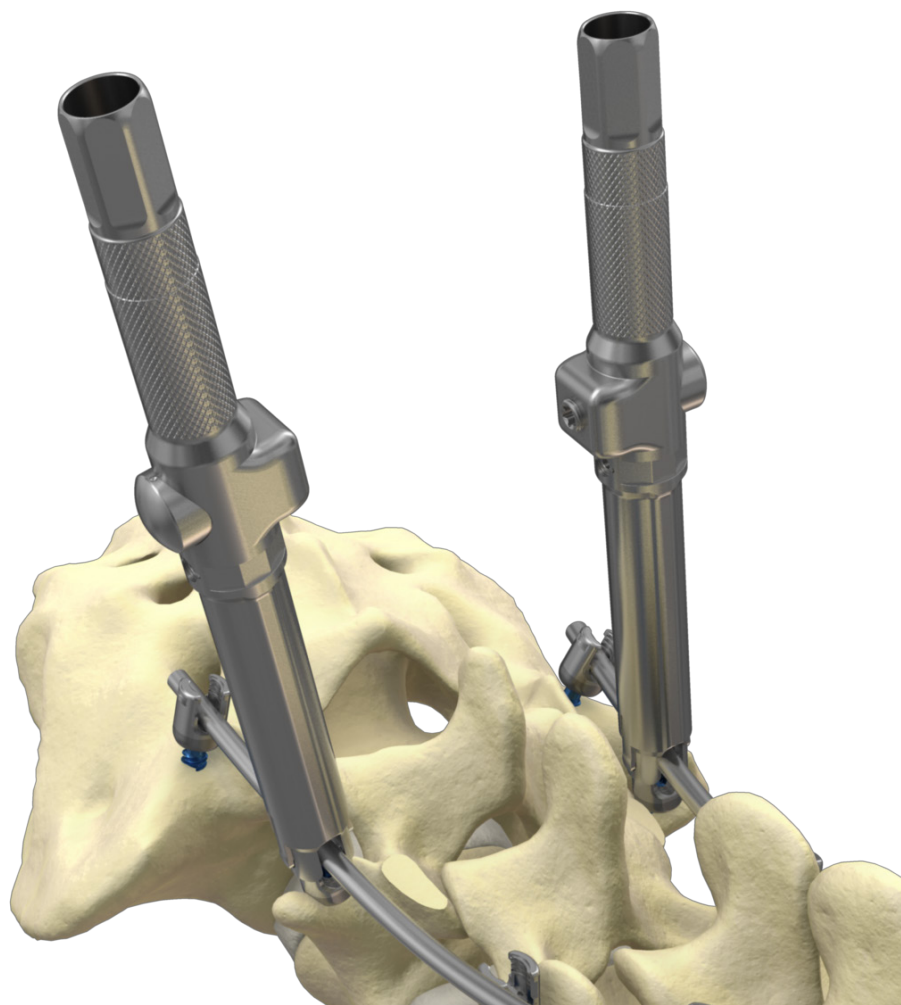
EVEREST BASECAMP™ REDUCER



QUICK CONNECT HEX WRENCH



PROVISIONAL DRIVER



ROD PERSUASION & REDUCTION (CONT.)

For reductions up to 60 mm into EVEREST screws, the EVEREST Basecamp™ Reducers may be used. The Reducers grasp onto the screw head by applying an axial downward force. Multiple Basecamp Reducers may be used on adjacent segments to facilitate correction. For quick reduction, press the release button

on the Basecamp Reducer and slide the tube down to meet the rod. If gradual or more powerful reduction is desired, rotate the proximal end of the Reducer in a clockwise direction. If additional torque or a ratchet mechanism is needed to persuade the rod, a T-Handle can be connected to the proximal end of the Reducer for additional leverage using a Quick Connect Hex Wrench. Once the instrument is in its proper position, turn the

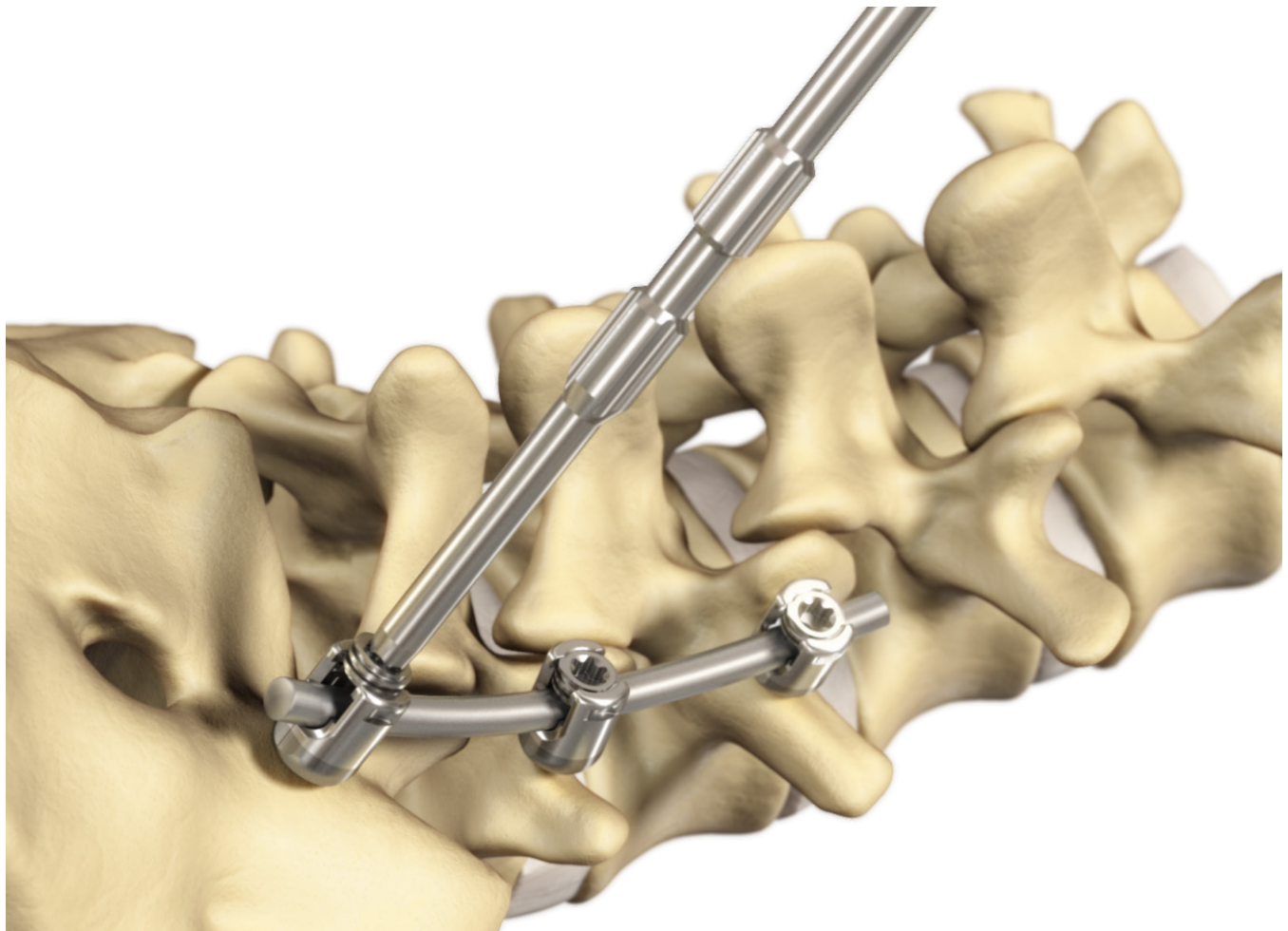
proximal Handle in a clockwise direction until desired reduction is achieved and the rod is fully seated. The EVEREST set screw may be passed through the center of the Basecamp Reducer and threaded into the implant housing using the Provisional Driver to provisionally tighten the construct. To disengage the Basecamp Reducer, press the release button and pull the Reducer upward while twisting to disengage from the implant housing.



PROVISIONAL SCREW DRIVER,
SIZE 30, LONG



PROVISIONAL SCREW DRIVER,
SIZE 30, SHORT



SET SCREW INSERTION & PROVISIONAL TIGHTENING

If no reduction is necessary, the EVEREST set screw may be inserted into the EVEREST implant housing using either the Long or Short Provisional Screwdriver. Ensure the instrument is perpendicular to the caddy when engaging the hexalobe tip with the EVEREST set screw.

Due to its modified square thread design, the EVEREST set screw helps facilitate introduction and may reduce the potential for cross-threading.

NOTE: Final tightening must be accomplished with a Torque Limiting Wrench or Torque Indicating Wrench.



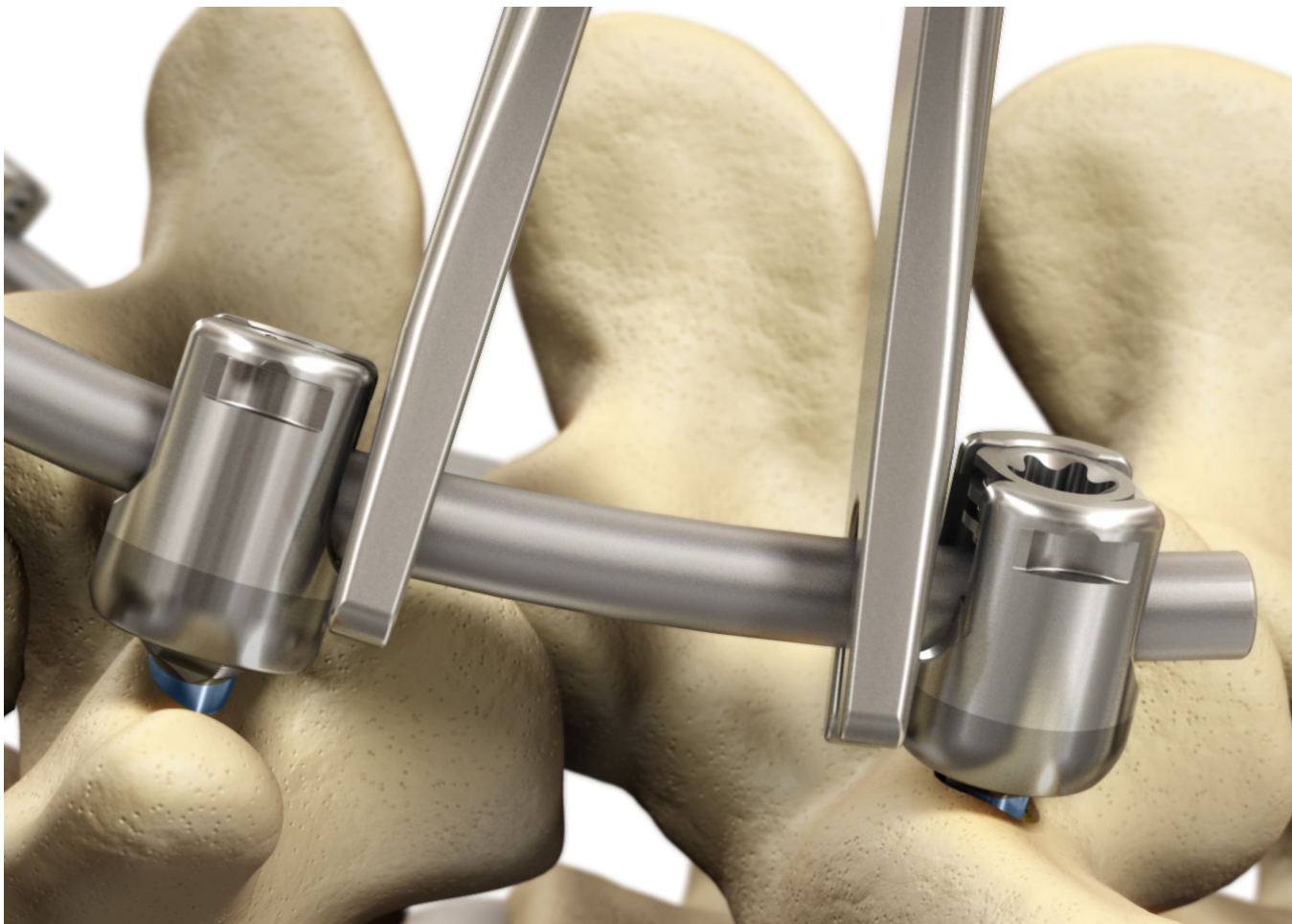
ROD PUSHER



COMPRESSOR



DISTRACTOR



COMPRESSION & DISTRACTION

In cases of deformity or severely degenerated discs, there may be instances where the implant heads touch each other. If a distractionary force is required between the heads, the Rod Pusher may be used.

Compression and distraction may be performed with the EVEREST implants

while the set screws are provisionally tightened. Once the desired amount of compression and distraction has been achieved, it is necessary to provisionally tighten the EVEREST set screw to hold the implant in position.



CICADA™



ANTI-TORQUE HANDLE



ANTI-TORQUE
ALIGNMENT TUBE



TORQUE INDICATING WRENCH



FINAL TIGHTENING

Final tightening of the EVEREST implants is achieved utilizing either the Anti-Torque Alignment Tube or the Cicada attached to the Anti-Torque Handle. Ensure the sliding mechanism of the Anti-Torque Handle is facing up to lock onto the instrument. Slide the handle over the small diameter of the tube and then push down onto the hex portion of the instrument.

To disengage the Handle, pull back on the sliding mechanism and lift up. Insert the Torque Wrench into the top opening of the assembled Single Action Anti-Torque Rod Reducer or Anti-Torque Alignment Tube and Anti-Torque Handle before positioning the screw.

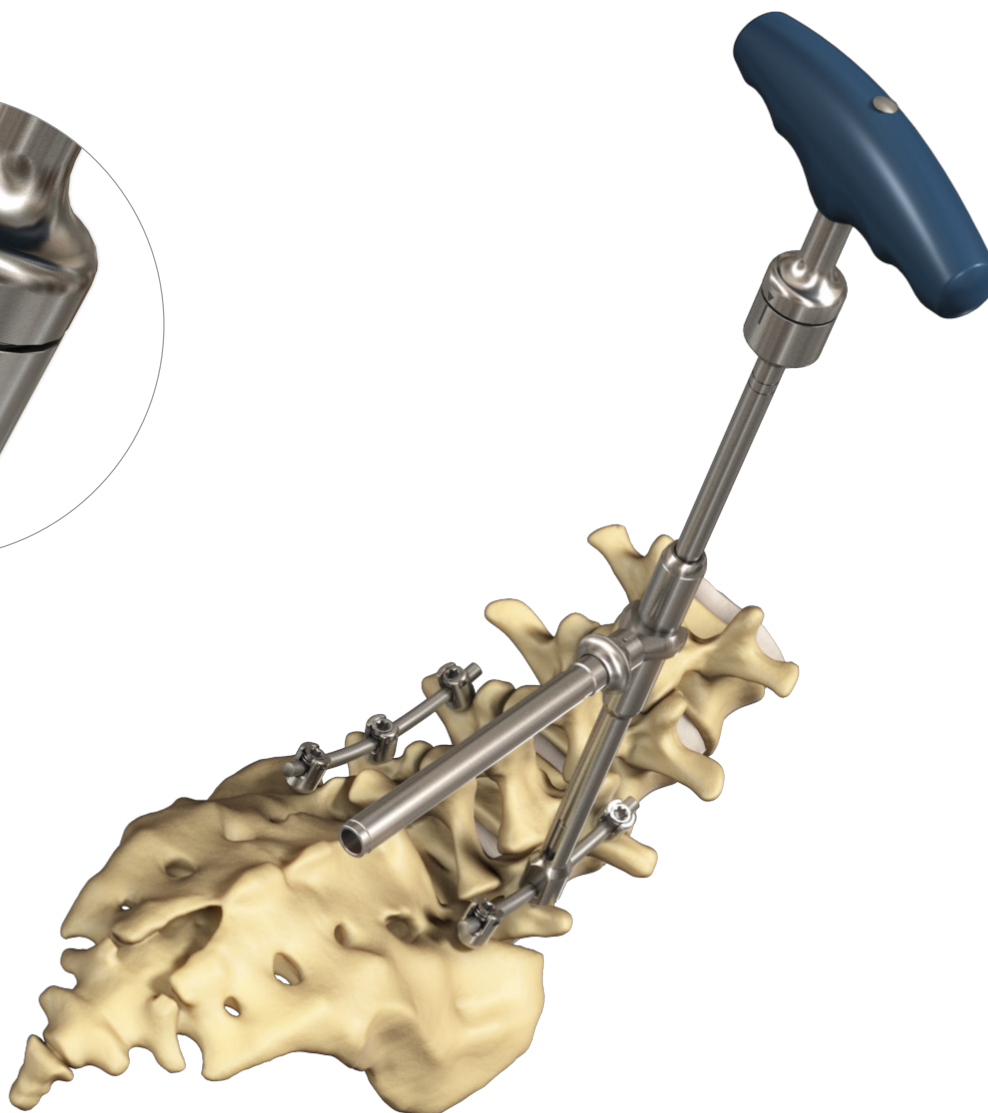
10



TORQUE INDICATING WRENCH



TORQUE LIMITING WRENCH

FINAL TIGHTENING
(CONT.)

Introduce the Torque Wrench tip into the EVEREST set screw, and then slide the assembled handle down and engage the screw. Final torque tightening may now be performed. The Torque Indicating Wrench or assembled Torque Limiting Handle and Torque Limiting Shaft both achieve 90 in-lbs of torque for final tightening.

The Torque Limiting Wrench will “pop” once the necessary torque is achieved. The proper torque level is achieved with the Torque Indicating Wrench when the line and the arrow meet.

NOTE: Do not exceed recommended torque or DAMAGE TO THE INSTRUMENT OR IMPLANT MAY RESULT.

HOOK SURGICAL TECHNIQUE

Surgical Technique Steps



HOOK PUSHER



HOOK SEATER



OFFSET HOOK HOLDER



LATERAL HOOK HOLDER



HOOK INSERTION

Pedicle hooks are always placed upgoing in the infralaminar position. A limited facetectomy is typically performed using an available straight quarter inch osteotome before hook insertion. It is imperative the pedicle hook be placed into the joint cavity, taking precaution not to split the inferior articular process. Lumbar laminar hooks may be used downgoing (caudal) or upgoing (cranial). Elevators are used to separate the ligamentum flavum from the inferior surface of

the lamina. Attach the hook to the appropriate Hook Holder. The implant may be inserted with the Lateral Hook Holder or the Offset Hook Holder. Place the hook into the desired position. The Hook Pusher and the Hook Seater may be used to facilitate hook placement, if necessary.

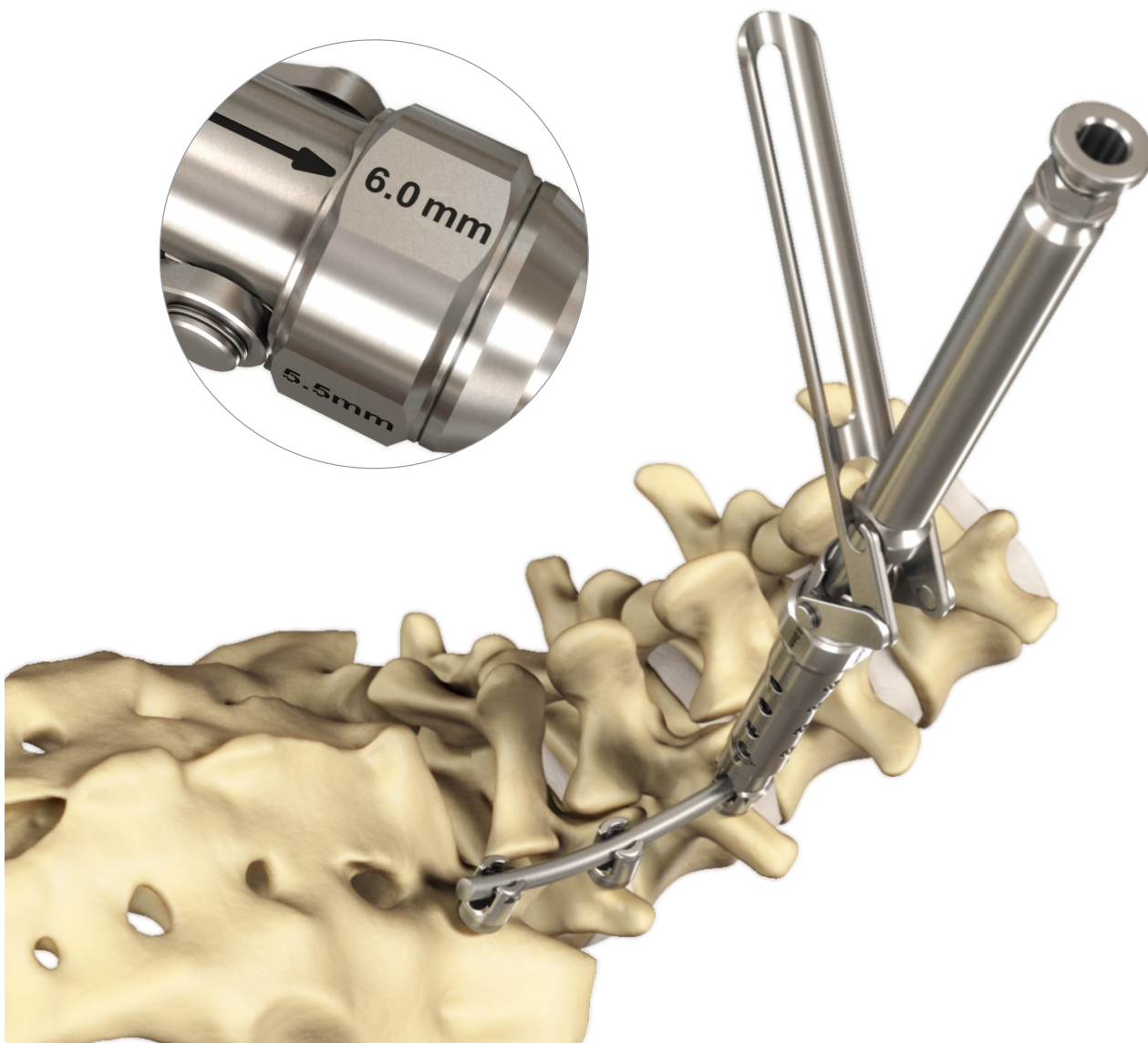
NOTE: Additional hook styles are also available including: anatomical, angled, closed, extended body, offset, and transverse process.



CICADA™



LONG PROVISIONAL DRIVER



ROD PERSUASION & REDUCTION

The Cicada may be utilized for common reductions up to 15 mm into EVEREST implants. Adjust the knurled wheel on the instrument to accommodate the proper rod diameter, either 5.5 or 6.0 mm. When docking the Single Action Anti-Torque Rod Reducer, hold the center shaft of the instrument to receive better tactile feedback. Once the instrument is engaged by grasping the feet around the

hook/implant head, squeeze the silver lever to reduce the rod into the implant housing. The EVEREST set screw may be passed through the center of the Cicada and threaded into the implant housing using the long provisional driver. Open the silver lever fully to disengage the feet from the head of the implant and pull upward.

Surgical Technique Steps



ANTI-TORQUE HANDLE



ANTI-TORQUE ALIGNMENT TUBE



TORQUE INDICATING WRENCH



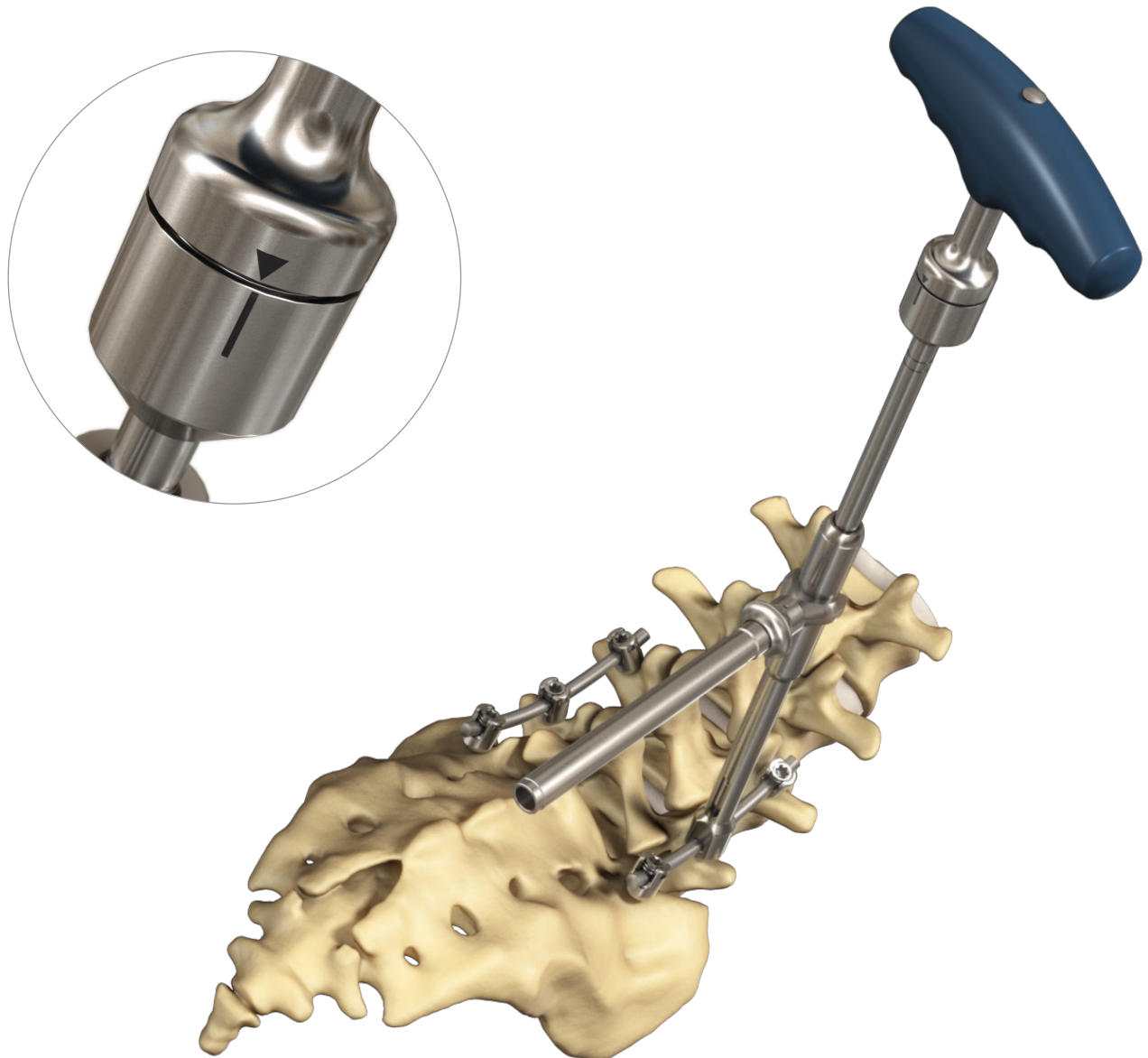
TORQUE LIMITING WRENCH



HOOK REDUCTION & FINAL TIGHTENING

Final tightening of EVEREST implants is achieved utilizing either the Anti-Torque Alignment Tube or Cicada attached to the Anti-Torque Handle. Ensure the sliding mechanism of the Anti-Torque Handle is facing up to lock onto the instrument. Slide the Handle over the small diameter of the tube and then push down onto the hex portion of the instrument. To

disengage the Handle, pull back on the sliding mechanism and lift up. Insert the Torque Wrench into the top opening of the assembled Cicada and Anti-Torque Handle before positioning it on the screw.



Introduce the Torque Wrench tip into the EVEREST set screw, then slide the assembled handle down and engage the hook/implant. Final torque tightening may now be performed. The Torque Indicating Wrench or assembled Torque Limiting Wrench and Torque Limiting Shaft both achieve 90 in-lbs of torque for final tightening.

The Torque Limiting Wrench will “pop” once the necessary torque is achieved. The proper torque level is achieved with the Torque Indicating Wrench when the line and the arrow meet.

NOTE: Do not exceed recommended torque or DAMAGE TO THE INSTRUMENT OR IMPLANT MAY RESULT.

EVEREST® DEGENERATIVE
IMPLANT REMOVAL

Surgical Technique Steps



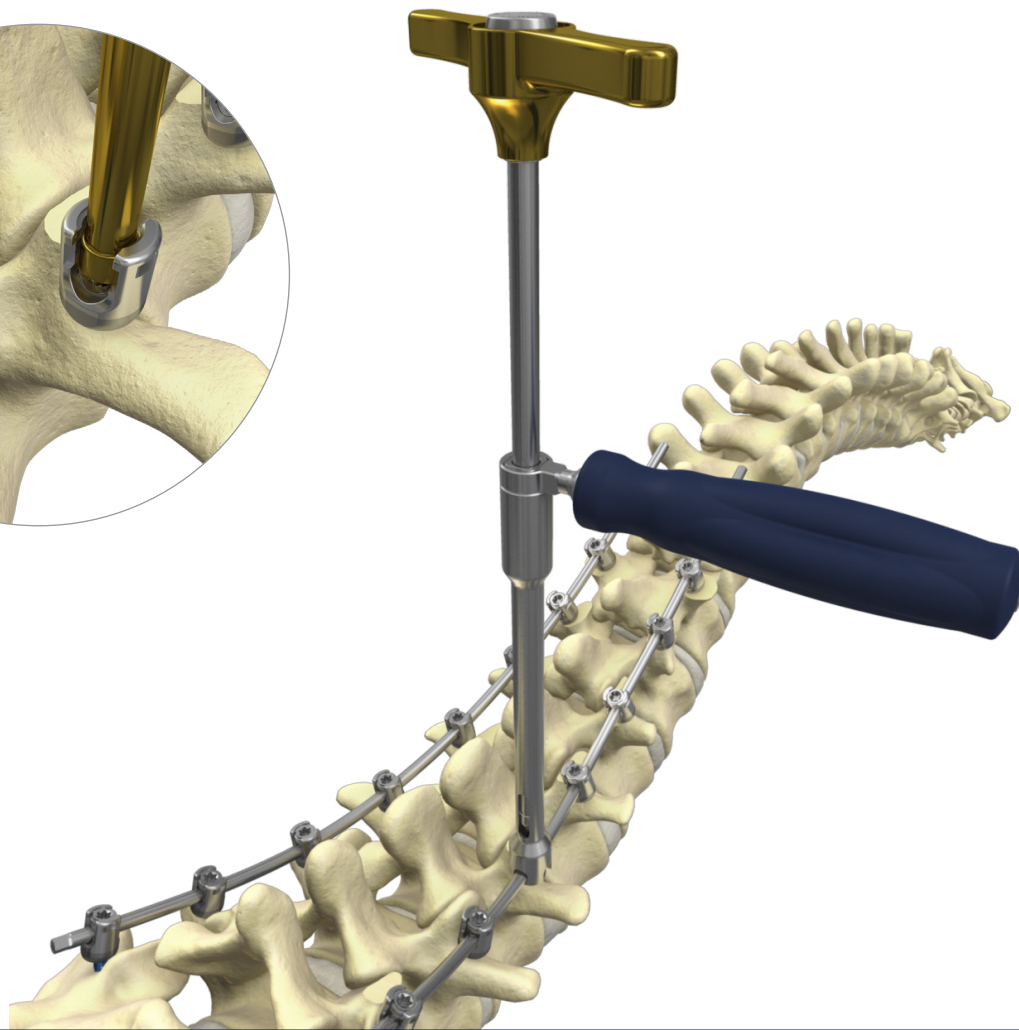
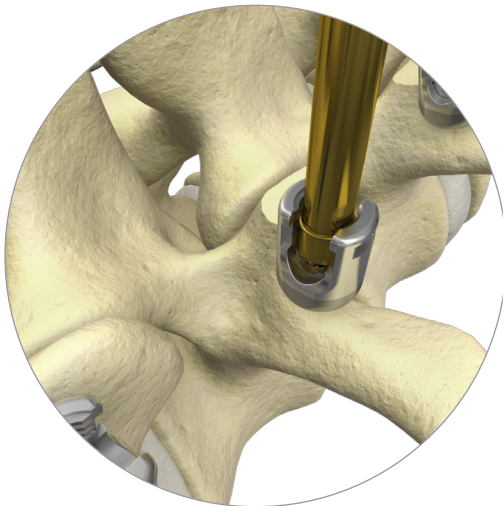
SET SCREW REMOVAL WRENCH



T-HANDLE



DRIVER, HEIGHT ADJUSTMENT,
SIZE 25



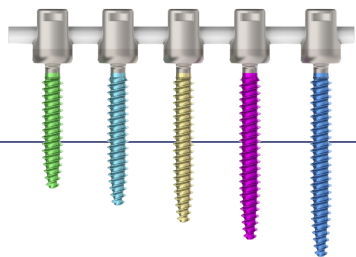
UNLOCKING & REMOVAL

Once the set screw in either the EVEREST screw or EVEREST hook has been final tightened, it may be loosened using the Set Screw Removal Wrench. This instrument ratchets when it is turned in a clockwise direction, so it does not function as a final tightener. Insert the Removal Wrench through the Anti-Torque

Device and turn the handle of the instrument counter-clockwise to loosen the EVEREST set screw. The screw may be removed with the Driver and T-Handle. Engage the Driver tip with the inner hexalobe of the implant and turn in a counter-clockwise direction to remove the screw.

EVEREST® DEGENERATIVE
PRODUCT CATALOG

IMPLANTS



Ø5.5 – 8.5 SCREWS*

LENGTHS* (mm): 35, 40, 45, 50, 55



EVEREST SET SCREW



5.5 mm CONTOURED ROD**



6.0 mm CONTOURED ROD**

IMPLANTS

DESCRIPTION

CATALOG NUMBER

EVEREST Polyaxial Screws

***See special note

EVEREST Set Screw

2901-10001

5.5 mm Contoured Rod

101-655xx

6.0 mm Contoured Rod

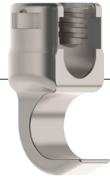
2901-660xx

*Additional sizes available by request.

**Straight rods available upon request.

***Unique catalog numbers exist for screw length in each diameter. Please contact your local sales consultant with any questions you may have about ordering the EVEREST Degenerative Spinal System implants.

HOOKS



**LUMBAR LAMINAR HOOK LARGE,
STANDARD BLADE**



PEDICLE HOOK, LARGE

HOOKS

DESCRIPTION

Lumbar Laminar Hook Large, Standard Blade

Pedicle Hook, Large

CATALOG NUMBER

2901-80004

2901-80008

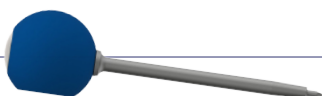
INSTRUMENTS



RATCHETING T-HANDLE



RATCHETING PALM HANDLE



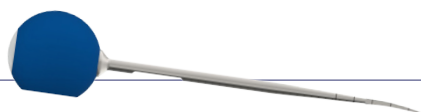
PYRAMID AWL, LONG



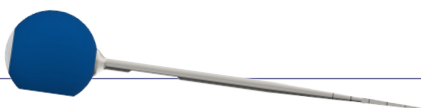
CURVED LUMBAR PROBE



STRAIGHT LUMBAR PROBE



CURVED THORACIC PROBE



STRAIGHT THORACIC PROBE

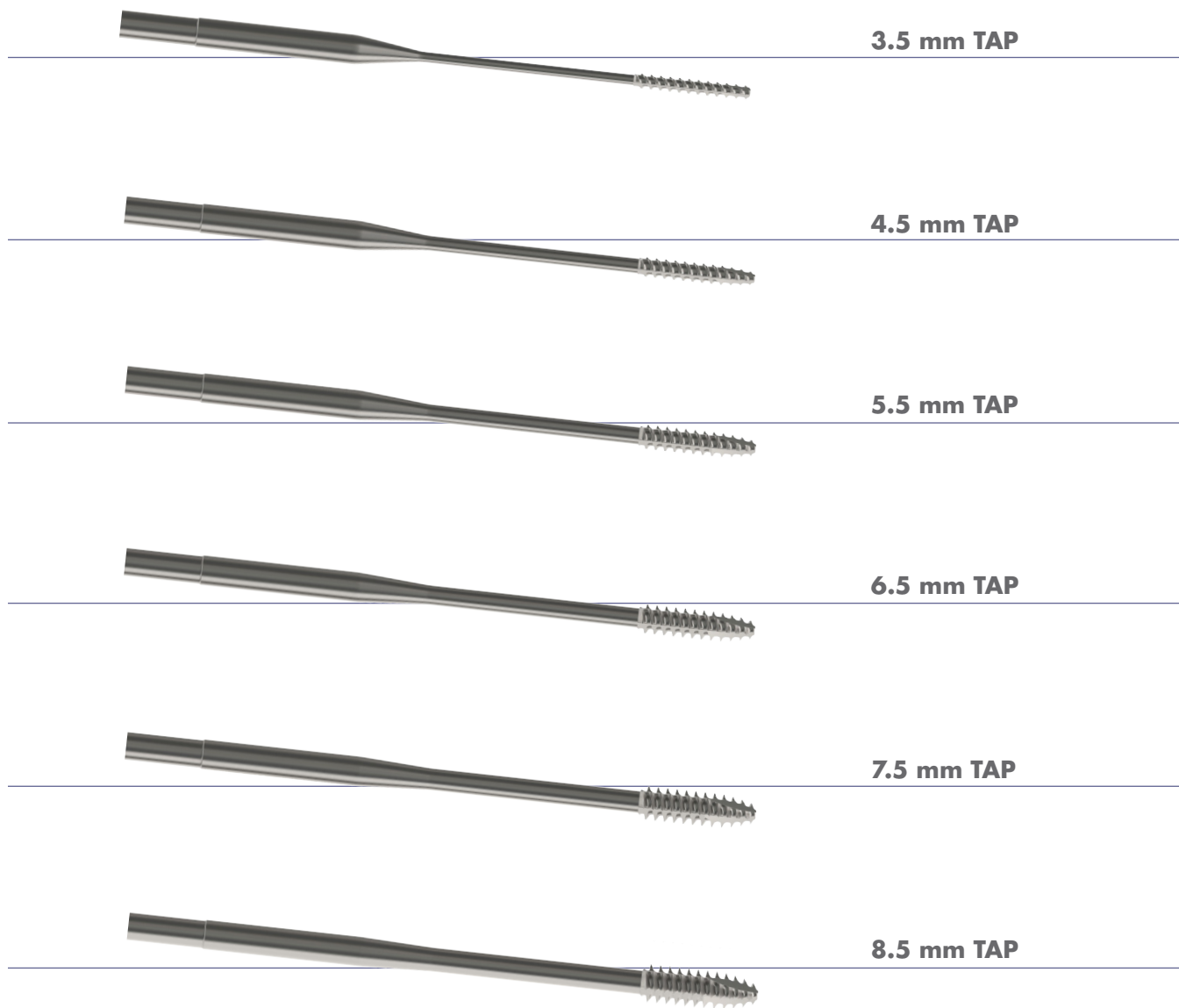


BALL TIP FEELER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Ratcheting T-Handle	2901-90051	Straight Lumbar Probe	2901-90032
Ratcheting Palm Handle	2901-90050	Curved Thoracic Probe	2901-90033
Pyramid Awl, Long	2801-90008	Straight Thoracic Probe	2901-90034
Curved Lumbar Probe	2901-90031	Ball Tip Feeler	2801-90000

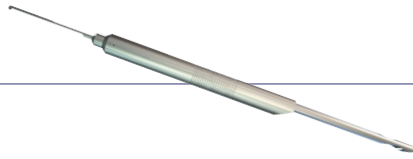
INSTRUMENTS



INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
3.5 mm Tap	2901-90041
4.5 mm Tap	2901-90042
5.5 mm Tap	2901-90043
6.5 mm Tap	2901-90044
7.5 mm Tap	2901-90045
8.5 mm Tap	2901-90046

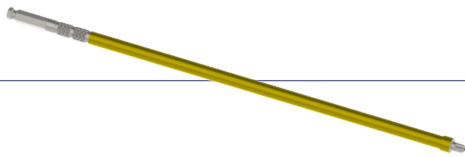
INSTRUMENTS



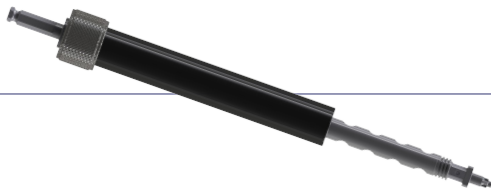
DEPTH GAUGE



TORQUE LIMITING HANDLE,



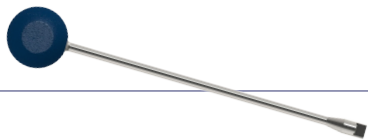
DRIVER, HEIGHT ADJUSTMENT,
SIZE 25



POLYAXIAL SCREW INSERTER



TORQUE LIMITING SHAFT

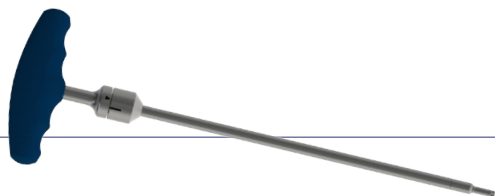


HEAD ADJUSTER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Depth Gauge	101-90011
Torque Limiting Handle	2901-90133
Driver, Height Adjustment, Size 25	5101-90107
Polyaxial Screw Inserter	2901-90006
Torque Limiting Shaft	2901-90019
Head Adjuster	2901-90007

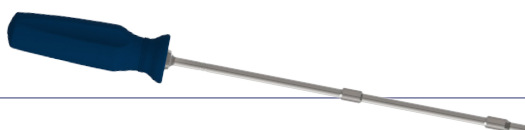
INSTRUMENTS



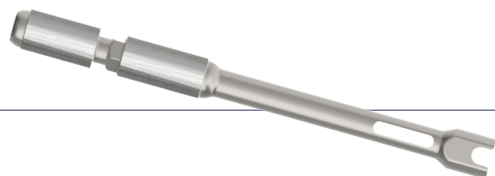
TORQUE INDICATING WRENCH



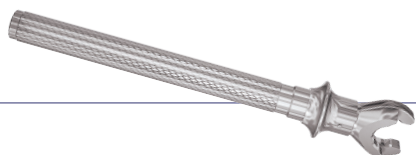
**PROVISIONAL SCREWDRIVER,
SIZE 30, SHORT**



**PROVISIONAL SCREWDRIVER,
SIZE 30, LONG**



ALIGNMENT TUBE

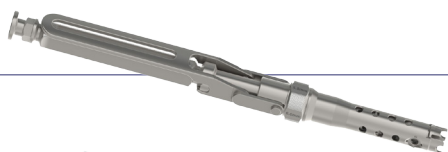


ANTI-TORQUE HANDLE

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Torque Indicating Wrench	2901-90018
Provisional Screwdriver, Size 30, Short	2901-90016
Provisional Screwdriver, Size 30, Long	2901-90017
Alignment Tube	2901-90015
Anti-Torque Handle	101-90051

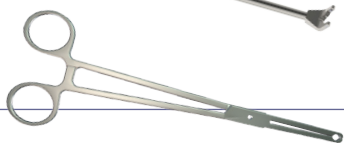
INSTRUMENTS



CICADA



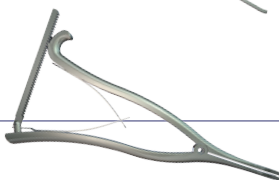
ROD FORK



ROD INTRODUCING FORCEPS



COMPRESSOR



DISTRACTOR



THREADED ROD REDUCER



**QUICK CONNECT ADAPTER
FOR THREADED ROD REDUCER**



EVEREST BASECAMP REDUCER


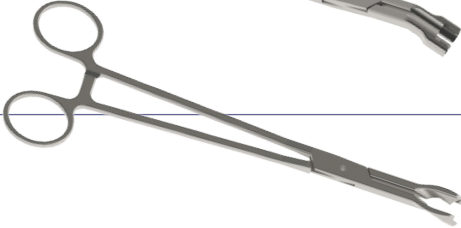




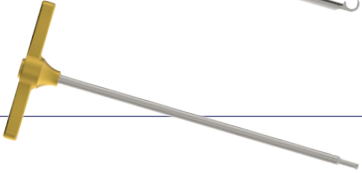
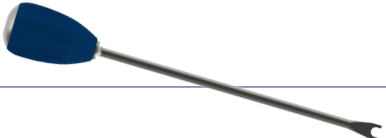


QUICK CONNECT HEX WRENCH

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Cicada	2901-90010	EVEREST Basecamp Reducer	2901-90110
Rod Fork	2901-90047	Quick Connect Hex Wrench	1001-90174
Rod Introducing Forceps	101-90039		
Compressor	801-90027		
Distractor	801-90028		
Threaded Rod Reducer	2901-90011		
Quick Connect Adapter for Threaded Rod Reducer	2901-90012		

INSTRUMENTS

	LATERAL HOOK HOLDER
	OFFSET HOOK HOLDER
	HOOK PUSHER
	HOOK SEATER
	STRAIGHT LUMBAR HOOK ELEVATOR
	ANGLED LUMBAR HOOK ELEVATOR
	EVEREST REMOVAL WRENCH
	ROD PUSHER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Lateral Hook Holder	2901-90021
Offset Hook Holder	2901-90020
Hook Pusher	2901-90027
Hook Seater	2901-90028
Straight Lumbar Hook Elevator	2901-90029
Angled Lumbar Hook Elevator	2901-90030
EVEREST Removal Wrench	2901-90056
Rod Pusher	2901-90013

Head Splay Comparison

Head splay is a common issue with pedicle screws that employ a set screw-based locking mechanism. The reaction forces resulting from the tightening of the set screw have a tendency to force the head of the screw outward. In extreme cases, the housing may deflect enough to allow ejection of the set screw.

EVEREST screw heads are comprised of cobalt chromium and titanium alloys. The cobalt chromium alloy is intended to provide structural support to the head of the screw, to resist head splay. To evaluate this, EVEREST screws were compared side-by-side with an experimental prototype with the cobalt chromium alloy component replaced by a titanium alloy component. Screw assemblies were assembled with 90 in-lbf of torque and the change in the outward splay of the head was measured. As expected, the rigidity of the cobalt chromium alloy component in the EVEREST screw resulted in less head splay compared to the all-titanium alloy construction.

	Mean Head Splay (inches) @ 90 in-lbf assembly torque
EVEREST® Screw with CoCr-Titanium Alloy Construction	.009 (.001 std dev)
Experimental Prototype with All-Titanium Alloy Construction	.013 (.001 std dev)

Pullout Testing

The pullout strength of EVEREST screws was compared with screws from competitive systems. The testing was conducted in accordance with ASTM F543 (Standard Specification and Test Methods for Metallic Medical Bone Screws). Screws were inserted into 20 lb/ft³ polyurethane foam blocks that simulated human cancellous bone and conformed to ASTM F1839 (Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments). Screws were placed to a depth of 20 mm and extracted at a controlled rate. The screws were tested in both dense (20 lb/ft³) and porous material (10 lb/ft³), to assess whether the screws would perform differently in normal or osteoporotic bone. The EVEREST screw had a higher pullout load than the competitive samples, regardless of substrate density.

	PULLOUT FORCE (N)	
	20 lb/ft ³	10 lb/ft ³
EVEREST®	1167 (30)	599 (56)
Stryker Xia	999 (43)	578 (91)
Medtronic CD Horizon	891 (49)	487 (44)
DePuy Expedium	1008 (30)	518 (31)



BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION

IMPORTANT

This booklet is designed to assist in using the EVEREST Spinal System. It is not a reference for surgical techniques.

CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of, a physician.

INDICATIONS

The EVEREST Spinal System may be used in conjunction with the RANGE® (MESA® and DENALI®) Spinal Systems, all of which are cleared for the following indications:

Non-cervical, pedicle screw fixation device for posterior stabilization as an adjunct to fusion for the following indications: Trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/ or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/ or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

MATERIALS

All implant components are manufactured from Titanium alloy, CP Titanium and Cobalt Chrome, per ASTM and ISO standards.

CLEANING/ REPROCESSING OF K2M SURGICAL INSTRUMENTS

K2M surgical instruments are supplied non-sterile. While it is recommended that the following steps are included in a decontamination/ reprocessing protocol the end-user bears the ultimate responsibility for the cleanliness of the device. These instructions are not intended for K2M implants or disposable surgical instruments.

Presoak the instruments with an enzymatic solution for a minimum of 5 minutes. Following the presoak the instruments should be wiped or scrubbed using a brush, cloth or sponge that does not mar the surface of the instrument. Remove soil from cannulated parts with a nylon bristle brush or appropriately sized guide wire. Rinse parts under water for one minute. Repeat the process until no visible debris remains. Clean K2M surgical instruments with an appropriate brush, cloth or sponge and low foaming, pH neutral detergent solution. The use of abrasive compounds or excessively acidic or alkaline solutions may cause damage to the instruments and should be avoided. Rinse parts under warm or hot flowing water for a minimum of 1 minute including direct contact with all surfaces for at least 10 seconds. Repeat rinsing step using distilled, reverse osmosis or deionized water. Automatic cleaning may be used in addition to manual cleaning. Do not ultrasonically clean torque limiting handles. For instruments that can be disassembled, please refer to the appropriate instructions provided by your local K2M sales representative.

STERILIZATION

Packaged components are packaged individually in sealed poly bags. **Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use.** Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. The following steam autoclave cycles were validated to an SAL of 10^{-6} using the biological indicator (BI) overkill method however sterilization should be in accordance with the sterilizer manufacturer's instructions and the Institution's procedures for assuring sterility.

	Autoclave Cycle	Temperature	Time	Drying Time
USA	Prevacuum	270°F (132°C)	4 minutes	30 minutes
Outside USA	Prevacuum	273°F (134°C)	3 minutes	30 minutes

Usage of an FDA cleared wrap to ensure that the device is actually sterile prior to implantation is recommended.

Use caution during sterilization and storage. Do not allow contact with metal or other hard objects that could damage the finish or prevent proper use. (See Preoperative Warnings and Precautions.)

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital's prion decontamination protocol. K2M recommends contacting the Centers for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

INSTRUCTIONS FOR USE

(For complete instructions refer to the appropriate surgical technique provided by your local K2M sales representative.)

CONTRAINDICATIONS

1. K2M spinal systems are contraindicated in the presence of infection, pregnancy, metabolic disorders of calcified tissues, grossly distorted anatomy, inadequate tissue coverage, drug/ alcohol abuse, mental illness, general neurological conditions, immunosuppressive disorders, patients with known sensitivity to materials in the device, obesity, patients who are unwilling to restrict activities or follow medical advice, and any condition where the implants interfere with anatomical structures or precludes the benefit of spinal surgery.
2. Biological factors such as smoking, use of nonsteroidal anti-inflammatory agents, the use of anticoagulants, etc. all have a negative effect on bony union. Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation.
3. This device is not intended for use except as indicated.

POTENTIAL ADVERSE EVENTS

1. Potential adverse events include, but are not limited to pseudoarthrosis; loosening, bending, cracking or fracture of components, or loss of fixation in the bone with possible neurologic damage, usually attributable to pseudoarthrosis, insufficient bone stock, excessive activity or lifting, or one or more of the factors listed in Contraindications, or Warnings and Precautions; infections possibly requiring removal of devices; palpable components, painful bursa, and/or pressure necrosis; and allergies, and other reactions to device materials which, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
2. Potential risks also include those associated with any spinal surgery resulting in neurological, cardiovascular, respiratory, gastrointestinal or reproductive compromise, or death.

WARNINGS AND PRECAUTIONS

Pedicle Screw Spinal Systems

WARNING: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any

other conditions are unknown.

The implants are for single use only and are not designed to be combined with devices from other manufacturers. ⊗

PRECAUTION: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. The surgeon should refer to the product labeling for details on use of this spinal system and the associated instrumentation to facilitate correct selection and placement of the implants. The size and shape of bones and soft tissue place limitations on the size and strength of the implants and proper selection will reduce the risk of neurological injury during implantation as well as metal fatigue leading to bending or breakage of the device.

Temporary Metallic Internal Fixation Devices

1. Patient selection and compliance is extremely important. Based on fatigue testing results, the K2M EVEREST Spinal System has been determined to be substantially equivalent to predicate devices however, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system. Spinal implant surgery on patients with conditions listed under Contraindications may not be candidates for this procedure. The patient must be made aware of the limitations of the implant and that physical activity and load bearing have been implicated in premature loosening, bending or fracture of internal fixation devices. The patient should understand that a metallic implant is not as strong as a normal, healthy bone and will fracture under normal load bearing in the absence of complete bone healing. An active, debilitated or uncooperative patient who cannot properly restrict activities may be at particular risk during postoperative rehabilitation.
2. Potential risks identified with the use of this device system which may require additional surgery include device component failure, loss of fixation, non-union, fracture of the vertebra, and neurological, vascular or visceral injury.
3. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided where possible. These, in turn may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Especially avoid sharp or reverse bends and notches.
4. Special protection of implants and instruments during storage is recommended when exposed to corrosive environments such as moisture, salt, air, etc.
5. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids and alkalis which can cause corrosion. Putting dissimilar metals (e.g. titanium and stainless steel) in contact with each other can accelerate the corrosion process which in turn may enhance fatigue fractures of implants. Thus every effort should be made to use compatible metals and alloys. Fretting or wear at the interface between components of a device may also accelerate the corrosion process and may lead to the generation of wear debris which has been associated with localized inflammatory response.
6. The K2M spinal implants are intended to provide temporary stabilization. If an implant remains implanted after complete healing it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus the benefits when deciding whether to remove the implant.
7. This device has not been evaluated for safety and compatibility in the MR environment. This device has not been tested for heating or migration in the MR environment.

PREOPERATIVE

1. Patient conditions and/or predispositions such as those previously addressed in Contraindications and Warnings and Precautions should be avoided.
2. Preoperative testing (simple bend and where necessary, stretch testing) should identify degree of correction possible without neurological damage and levels to be spanned using techniques similar to other spinal fusion procedures.
3. Use care in handling and storage of the implants. Prior to surgery components should be inspected for any evidence of damage or corrosion.
4. An adequate inventory of implant sizes should be available at the time of the surgery.
5. All components should be cleaned and sterilized before use.
6. Before the initial experience we recommend that the surgeon critically review all available information and consult with other surgeons having experience with the device.




OPERATIVE

1. The primary goal of this surgery is to arthrodesis selected vertebrae. Adequate exposure, bony preparation and grafting are essential to achieving this result.
2. Rods may be prebent to the degree of correction determined by preoperative testing however reverse bends should be avoided.
3. The use of two rods and crosslinking the rods will provide a more rigid construct.
4. The placement of screws should be checked radiographically prior to assembly of the rod construct.
5. Care should be taken when positioning the implants to avoid neurological damage.

POSTOPERATIVE

1. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful healing.
2. Internal fixation devices are load sharing devices which maintain alignment until healing occurs. If healing is delayed or does not occur the implant could eventually break, bend or loosen. Loads produced by load bearing and activity levels will impact the longevity of the implant.
3. Metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a bone has healed. If an implant remains implanted after complete healing, it can actually increase the risk of refracture in an active individual. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture.
4. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of reduced activity and/or early revision considered.
5. Surgical implants must never be reused. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small imperfections and internal stress patterns which may lead to early breakage.

SYMBOL KEY

-  Caution: Consult Accompanying Documentation
-  Consult Instructions For Use
-  Do Not Reuse



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K2-29-7001-02 Rev. 1
Actual device color may vary.
Consult product catalog for details.



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