



Surgical Technique

EVEREST

Fenestrated Spinal System

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)

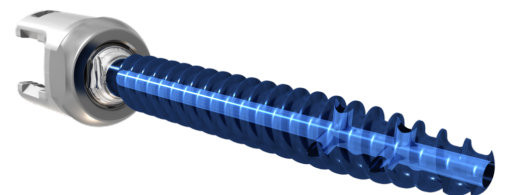


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Dear Colleagues,

Welcome to K2M and the EVEREST® Fenestrated Spinal System. With this product, K2M strives to attain the highest level of excellence in the medical device industry. 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 a pedicle screw system focused on both the implant and instrument design.

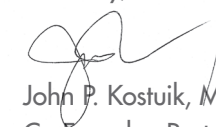
The implant technology is state-of-the-art with several enhancing features to facilitate more efficient intraoperative use of the system. The EVEREST polyaxial screw provides 70° range of motion and features a CoCr head designed to minimize head splay, dual-lead thread pattern designed to increase fixation in bone, a modified square thread design facilitating 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 Fenestrated 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 unique aspects of the EVEREST Fenestrated Spinal System for use in treating our patients.

Thank you again for your interest and support.

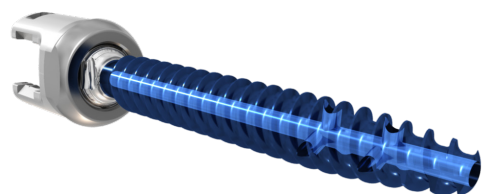
Sincerely,



John P. Kostuik, MD
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 Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery
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FEATURES & BENEFITS

EVEREST® Fenestrated Spinal System



Implants

- Six Distal Fenestrations
- Accepts Both Titanium & Cobalt Chrome Rods of 5.5 & 6.0 mm Diameters to Address Clinical Pathologies
- Mixed-metal (Ti/Cr) Tulip Minimized Head Splay & Demonstrated Improved Biomechanical Performance When Tested Against an All-Titanium Alloy Screw*
- Modified Square Thread Design of the Set Screw Facilitates Set Screw Introduction
- Dual-lead Thread Pattern for Faster Insertion & Increased Pullout Strength*
- Distinct Color-coded Screws Allow for Surgical Staff to Quickly Identify the Correct Implant
- Self-tapping Screws Provide 70° Polyaxial Range of Motion to Allow for Greater Flexibility in Screw Placement

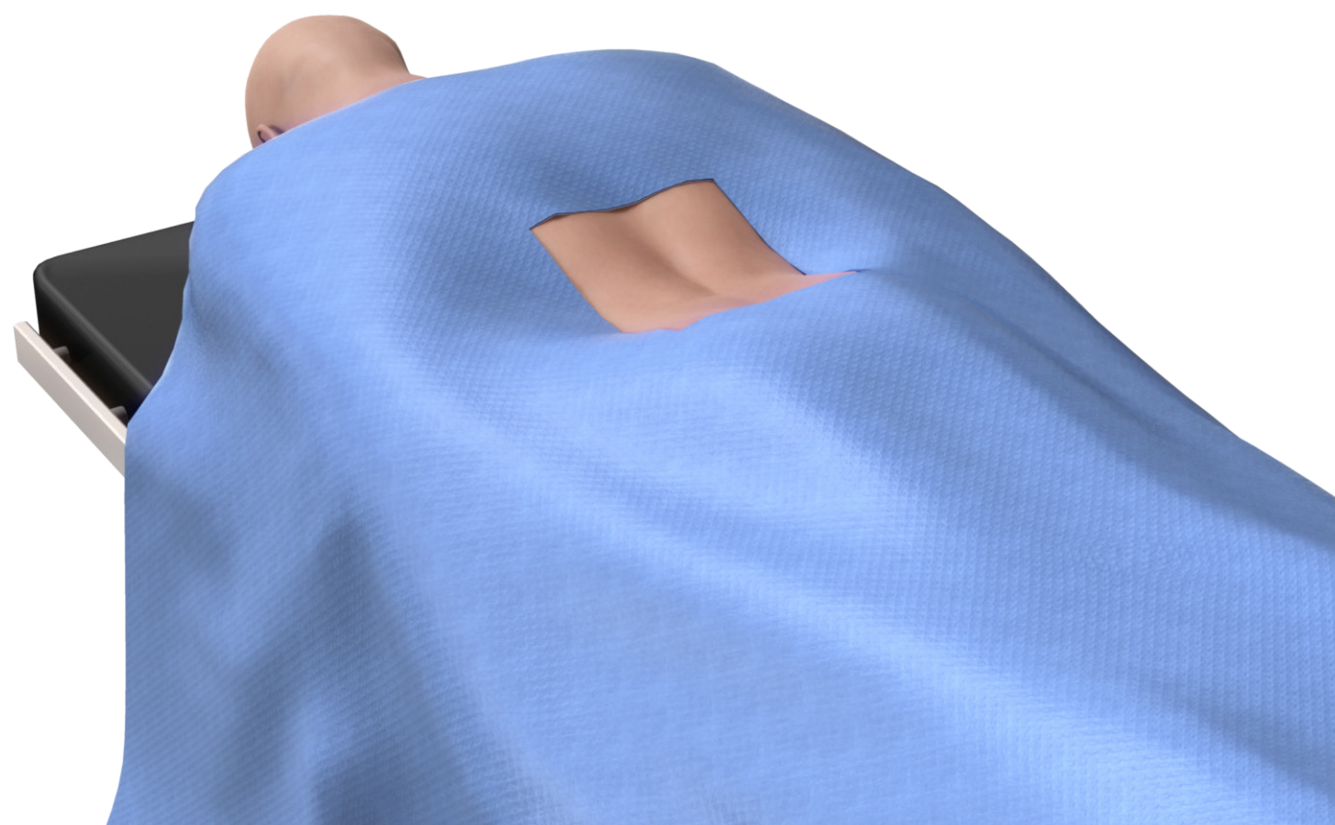
Instruments

- Injector Alignment Guide Features Universal Luer Lock Connection
- 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
- Modular Instrument Sets Allow for Customization

EVEREST® FENESTRATED
SURGICAL TECHNIQUE

*See page 31 for Support Data

1

**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.

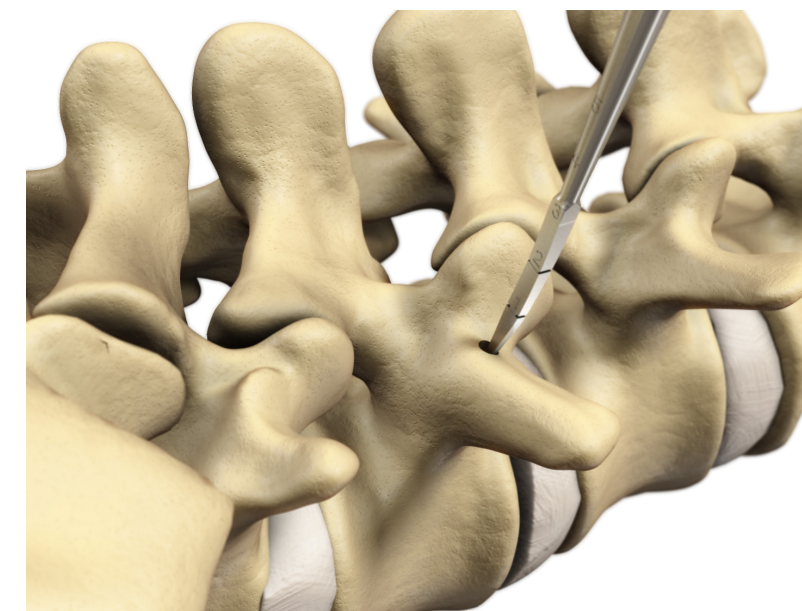
Pre-surgical planning defines the type of construct and the most appropriate implants, as well as the optimal location of where the implants should be inserted.

2



TAP

PROBE

**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 the 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.

5

3



POLYAXIAL SCREW INSERTER

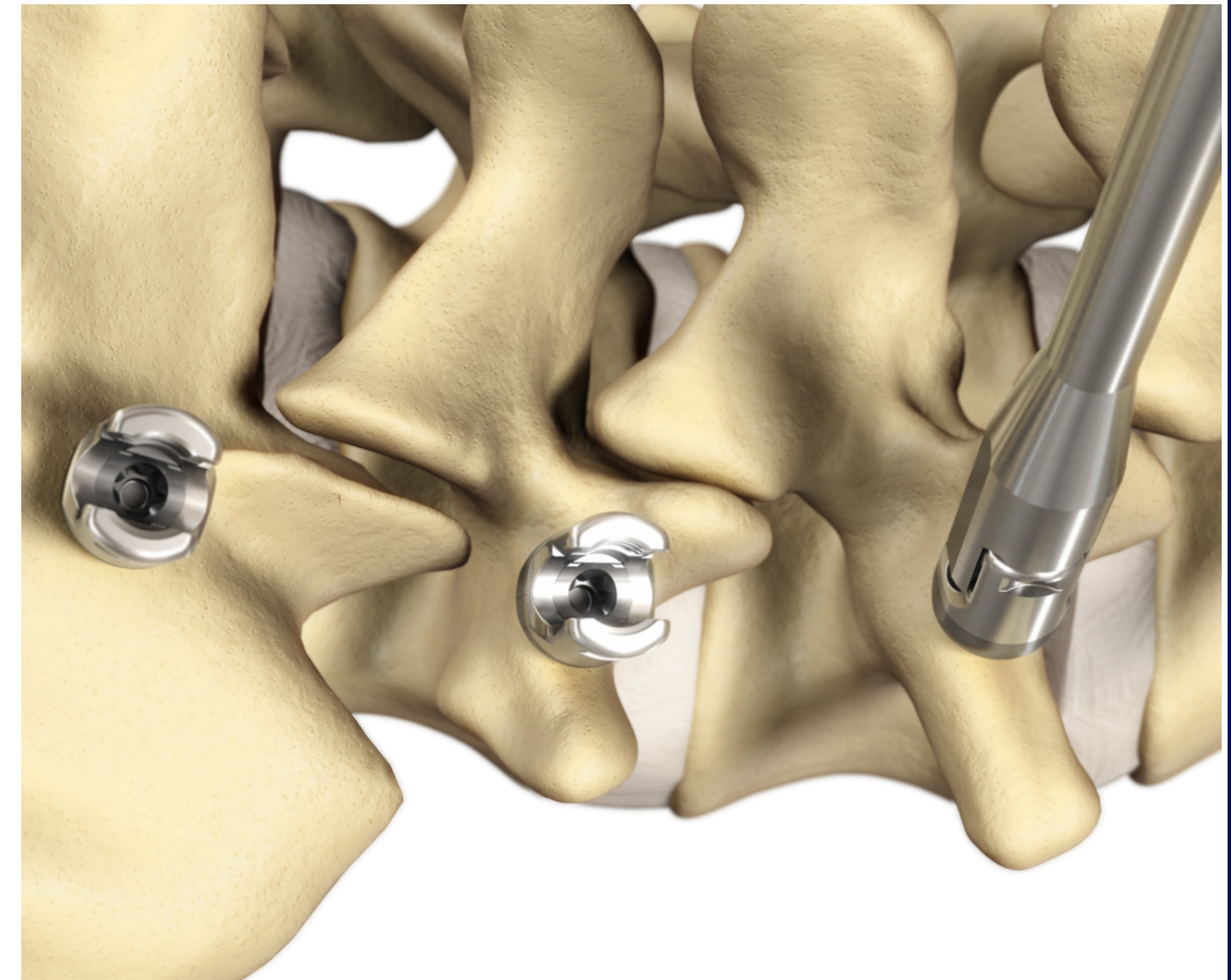


T-HANDLE



SCREW HEAD ADJUSTER

4

**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.

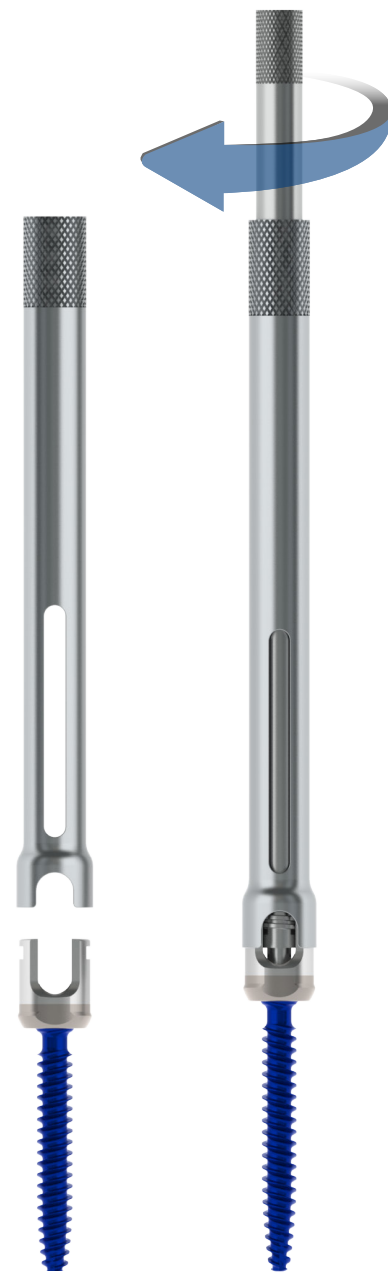
Thread the knurled wheel in a clockwise direction until the implant is securely attached to the Inserter. To disengage the Screw Inserter, gently turn the knurled wheel in a counter-clockwise direction and remove from the surgical field.

SCREW HEAD 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. Alternatively, the Anti-Torque Alignment Tube can be used to manipulate the screw housing.

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

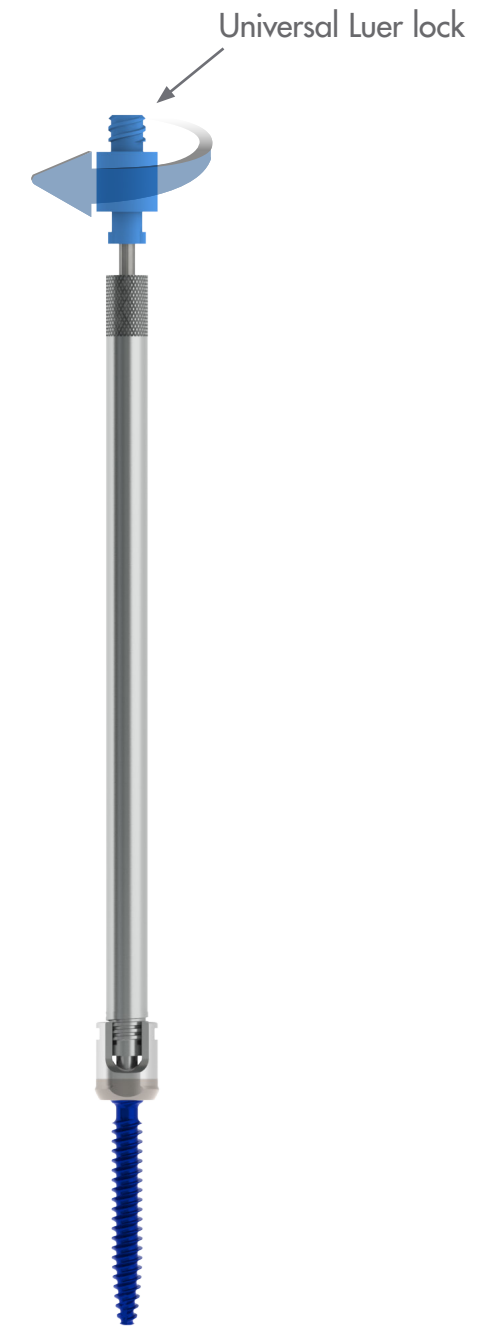
5



INJECTOR ALIGNMENT GUIDE ASSEMBLY

Place the short Alignment Tube over the EVEREST screw head. Thread the Injector Alignment Guide through the Alignment Tube and into the EVEREST screw head.

6

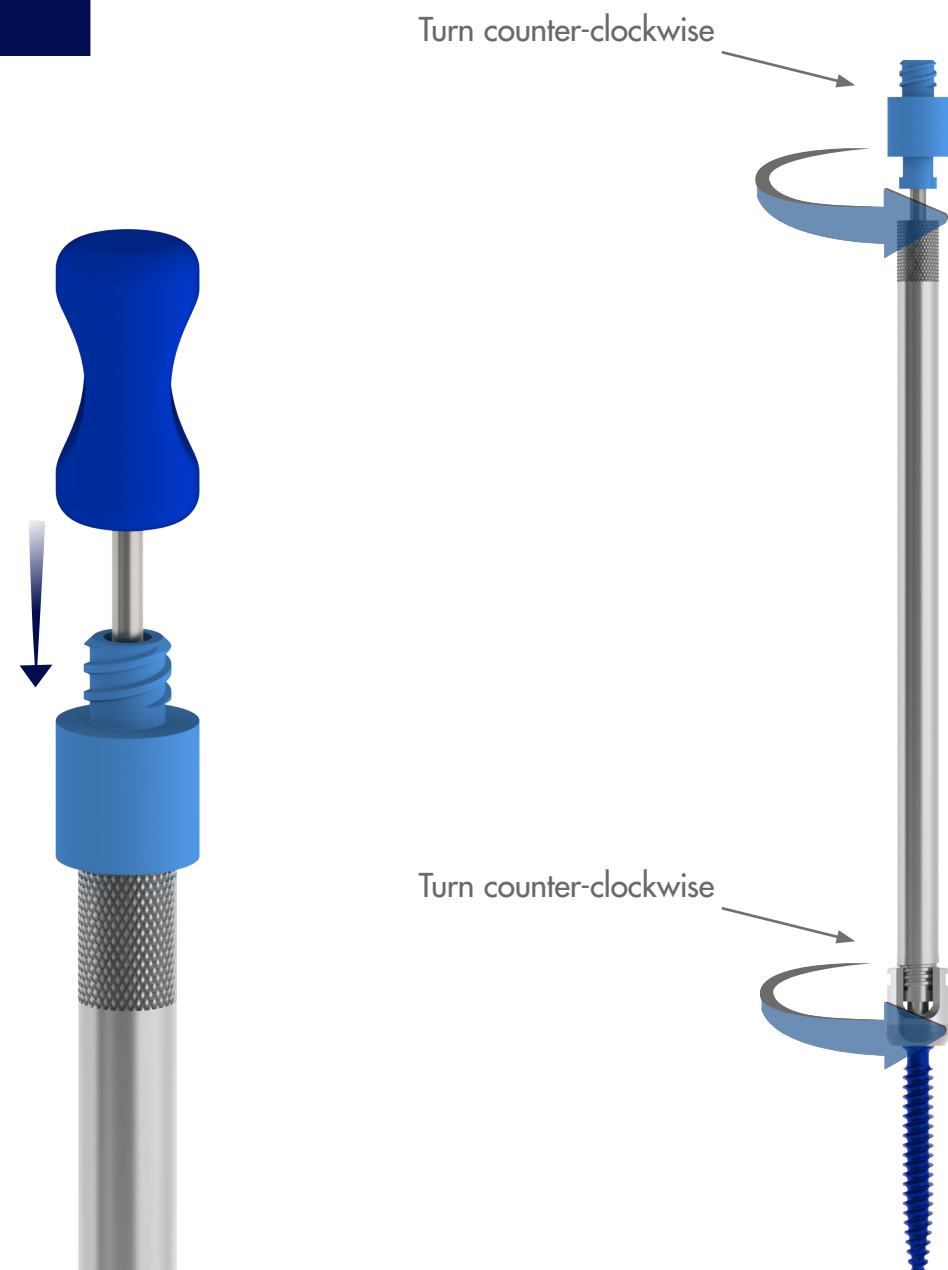


INJECTOR NEEDLE ASSEMBLY

Insert the Injector Needle down the shaft of the Alignment Guide. The tapered tip of the Injector Needle will be positioned inside of the screw cannula in its final position. Twist the injector needle clockwise to snap into the Alignment Guide. It is important these two instruments are securely connected. A fluid delivery system can be connected to the Luer lock.

7

8



Turn counter-clockwise

Turn counter-clockwise



FRENCH ROD BENDER



REMOVAL OF ALIGNMENT GUIDE & NEEDLE

If desired, the Plunger may be inserted down the Injector Needle.

Disengage the Injector Needle from the Injector Alignment Guide by turning it counter-clockwise, then turn the Injector Alignment Guide counter-clockwise to disengage from the screw head.

Repeat steps 5-8 for each screw, as desired.

ROD PREPARATION

Pre-contoured rods are available in the set in several lengths. The EVEREST screw can accommodate both a 5.5 and 6.0 mm diameter 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).

9



ROD INTRODUCING FORCEPS



12

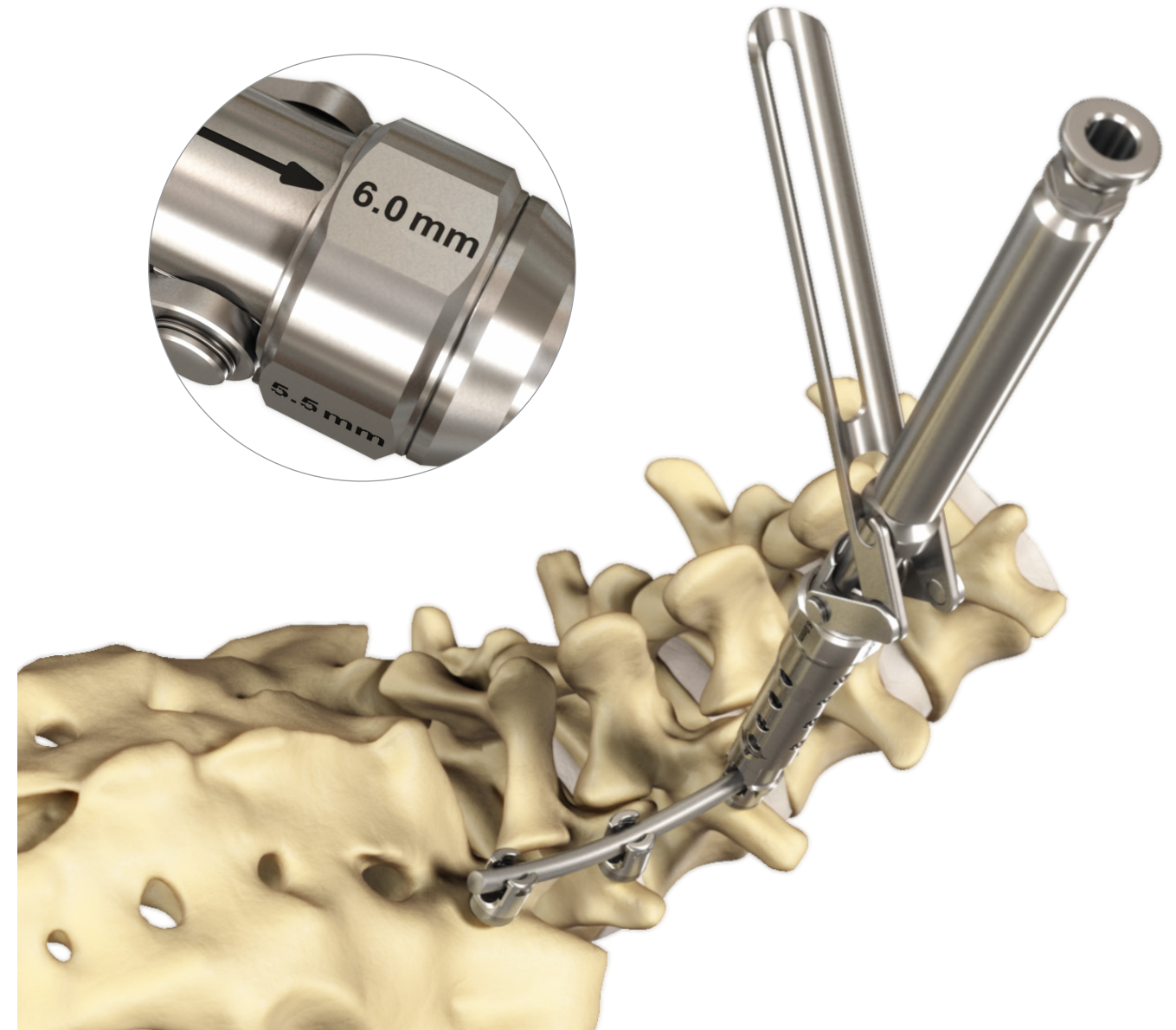
ROD INSERTION

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.

10



CICADA™



13

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 (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.

10



QUICK CONNECT ADAPTER



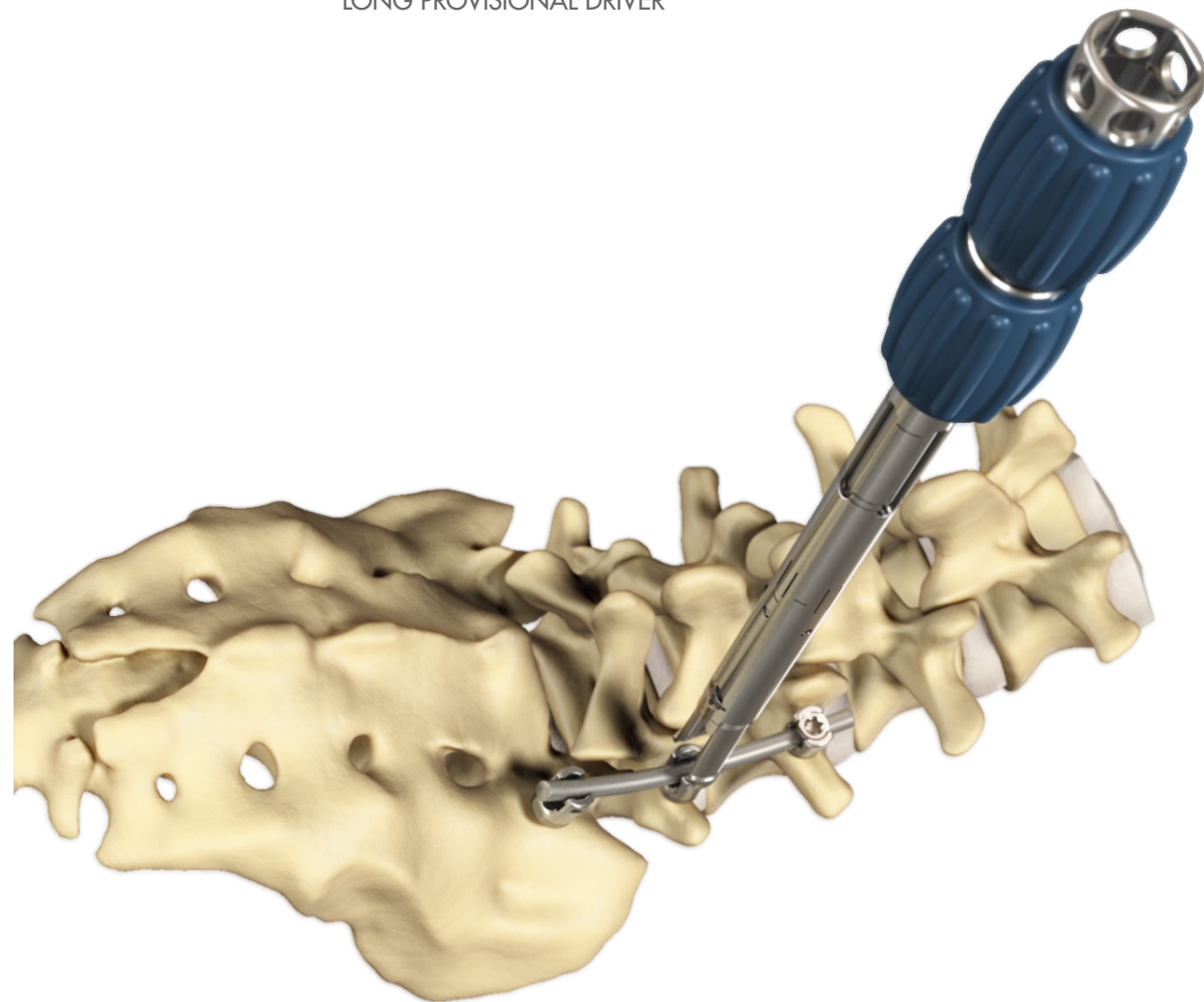
T-HANDLE



THREADED ROD REDUCER



LONG PROVISIONAL DRIVER



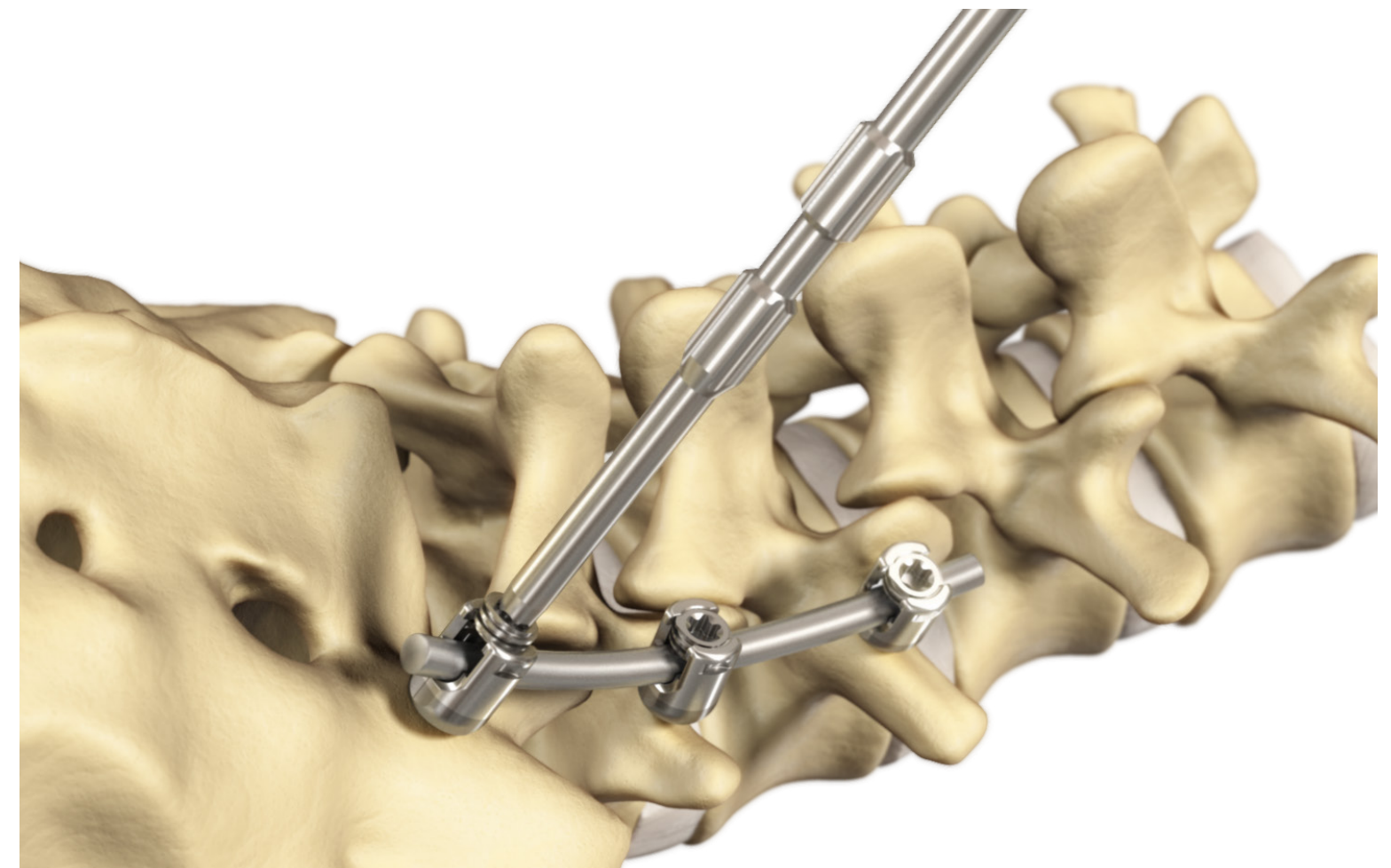
ROD PERSUASION & REDUCTION (CONT.)

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

For greater reductions up to 30 mm, the EVEREST Threaded Rod Reducer may be utilized. 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.

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PROVISIONAL SCREW DRIVER,
SIZE 30, LONGPROVISIONAL 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 design, the EVEREST set screw helps facilitate easy introduction and may reduce the potential for cross-threading.

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

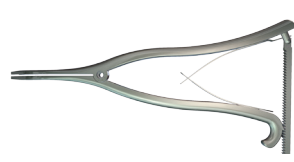
12



ROD PUSHER



COMPRESSOR



DISTRACTOR



CICADA™

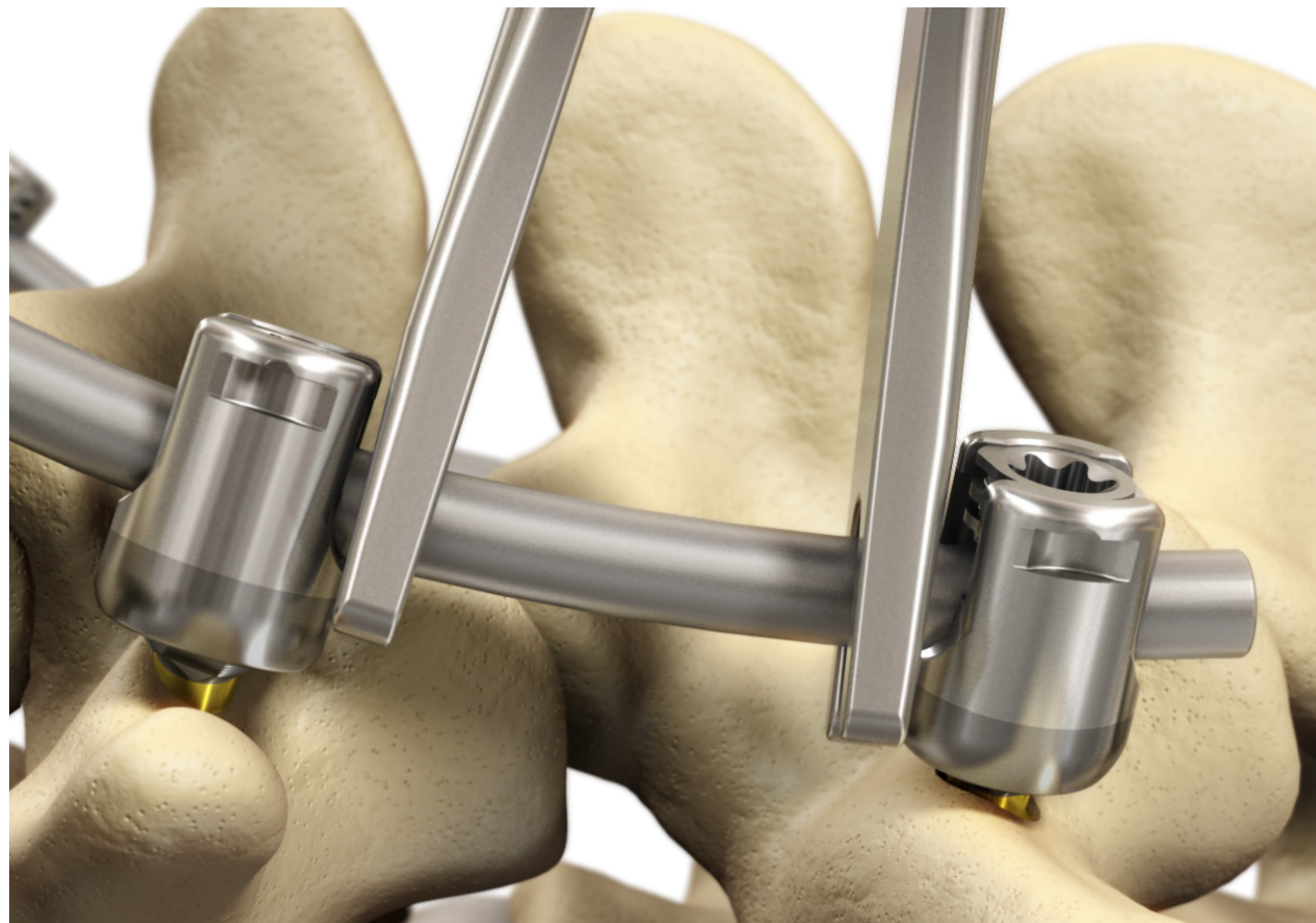


ANTI-TORQUE HANDLE



ANTI-TORQUE ALIGNMENT TUBE

13



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.

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.



TORQUE INDICATING WRENCH



TORQUE LIMITING HANDLE



TORQUE LIMITING SHAFT



EVEREST® FENESTRATED IMPLANT REMOVAL

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 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.



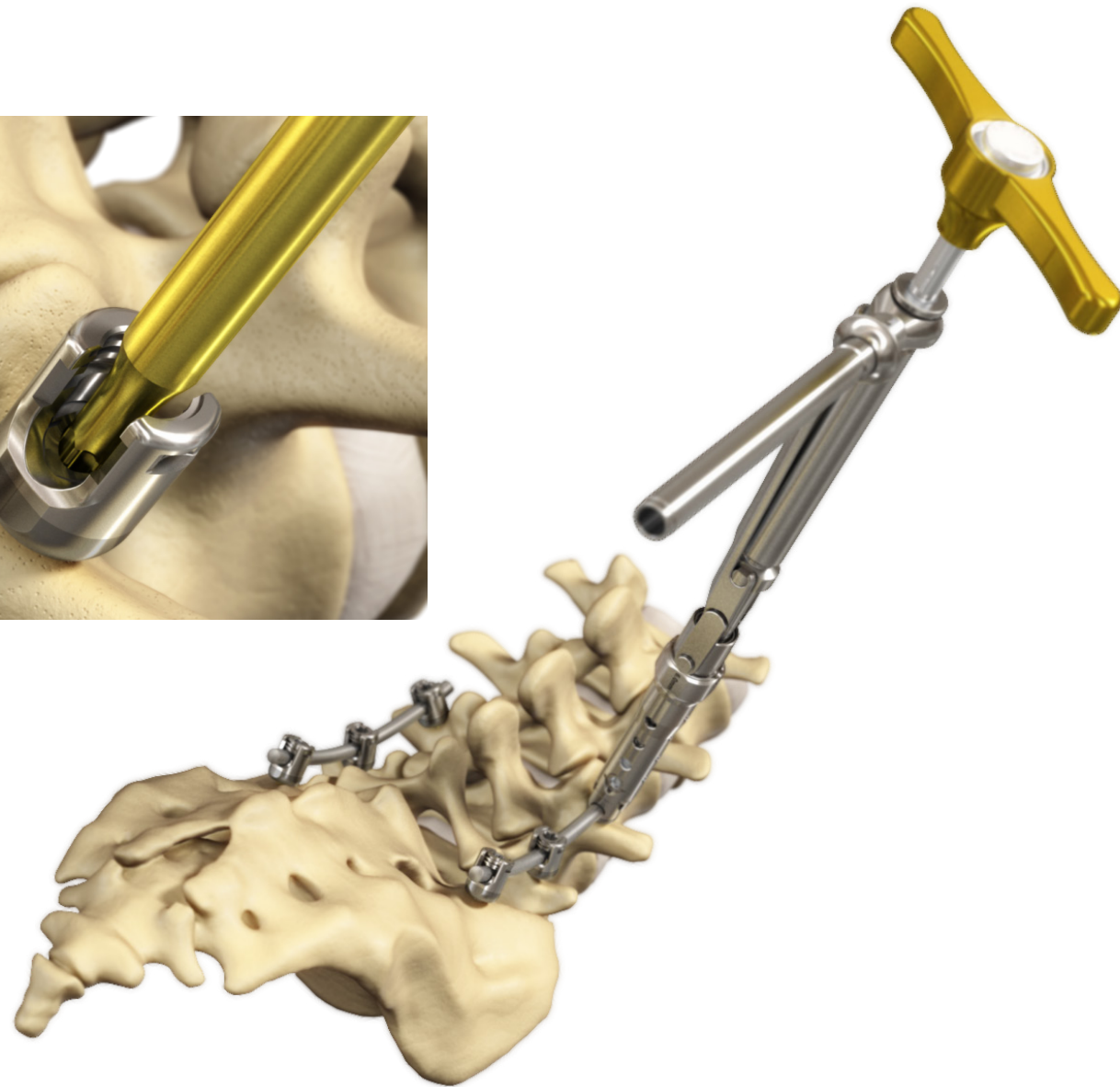
SET SCREW REMOVAL WRENCH



T-HANDLE



SCREW REMOVAL SHAFT

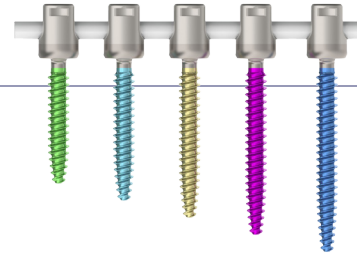
**UNLOCKING &
REMOVAL**

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 the 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 EVEREST Screw Removal Shaft 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.

IMPLANTS



Ø5.5 – Ø8.5 mm SCREWS*
LENGTHS* (mm): 35, 40, 45, 50, 55



EVEREST SET SCREW

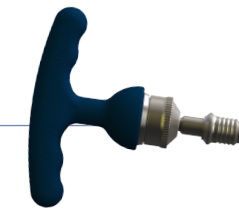


5.5 mm CONTOURED ROD



6.0 mm CONTOURED ROD

INSTRUMENTS



RATCHETING T-HANDLE



RATCHETING PALM HANDLE



PYRAMID AWL, LONG



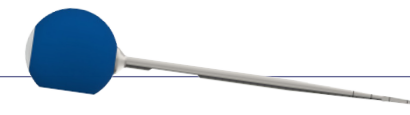
CURVED LUMBAR PROBE



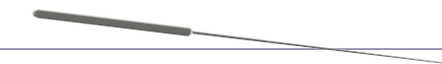
STRAIGHT LUMBAR PROBE



CURVED THORACIC PROBE



STRAIGHT THORACIC PROBE



BALL TIP FEELER

IMPLANTS

DESCRIPTION	CATALOG NUMBER
EVEREST Fenestrated 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.

**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 Fenestrated Spinal System implants.

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



3.5 mm TAP



4.5 mm TAP



5.5 mm TAP



6.5 mm TAP

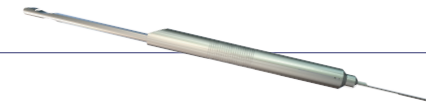


7.5 mm TAP



8.5 mm TAP

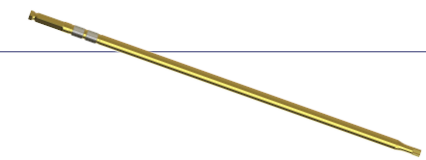
INSTRUMENTS



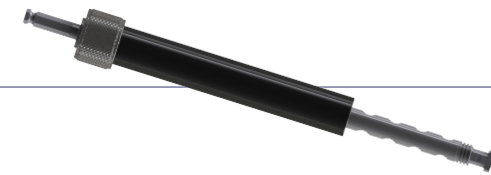
DEPTH GAUGE



TORQUE LIMITING HANDLE, 90 IN-LBS



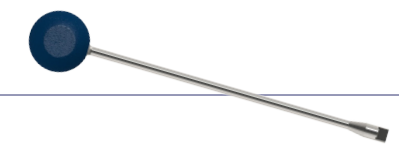
SCREW REMOVAL TOOL, SIZE 25



POLYAXIAL SCREW INSERTER



TORQUE LIMITING SHAFT



HEAD ADJUSTER

INSTRUMENTS

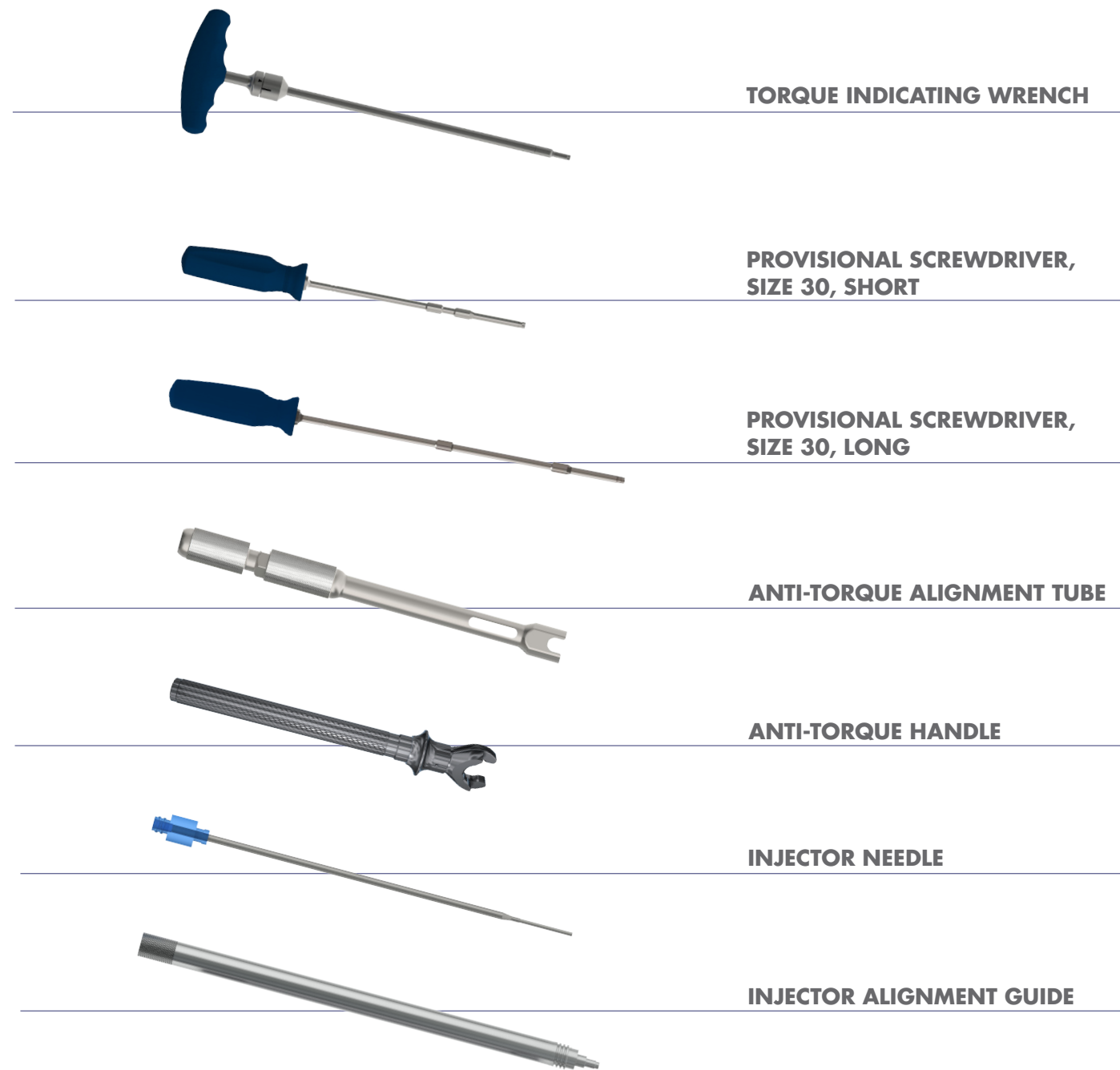
DESCRIPTION	CATALOG NUMBER
3.5 mm Tap	2901-90041
4.5 mm Tap	2901-90042
5.5 mm Tap	2901-90043
6.5 mm Tap	2901-90044
7.5 mm Tap	2901-90045
8.5 mm Tap	2901-90046

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Depth Gauge	101-90011
Torque Limiting Handle, 90 in-lbs	101-90219
Screw Removal Tool, Size 25	801-90001
Polyaxial Screw Inserter	2901-90006
Torque Limiting Shaft	2901-90019
Head Adjuster	2901-90007

INSTRUMENTS

INSTRUMENTS



TORQUE INDICATING WRENCH

PROVISIONAL SCREWDRIVER, SIZE 30, SHORT

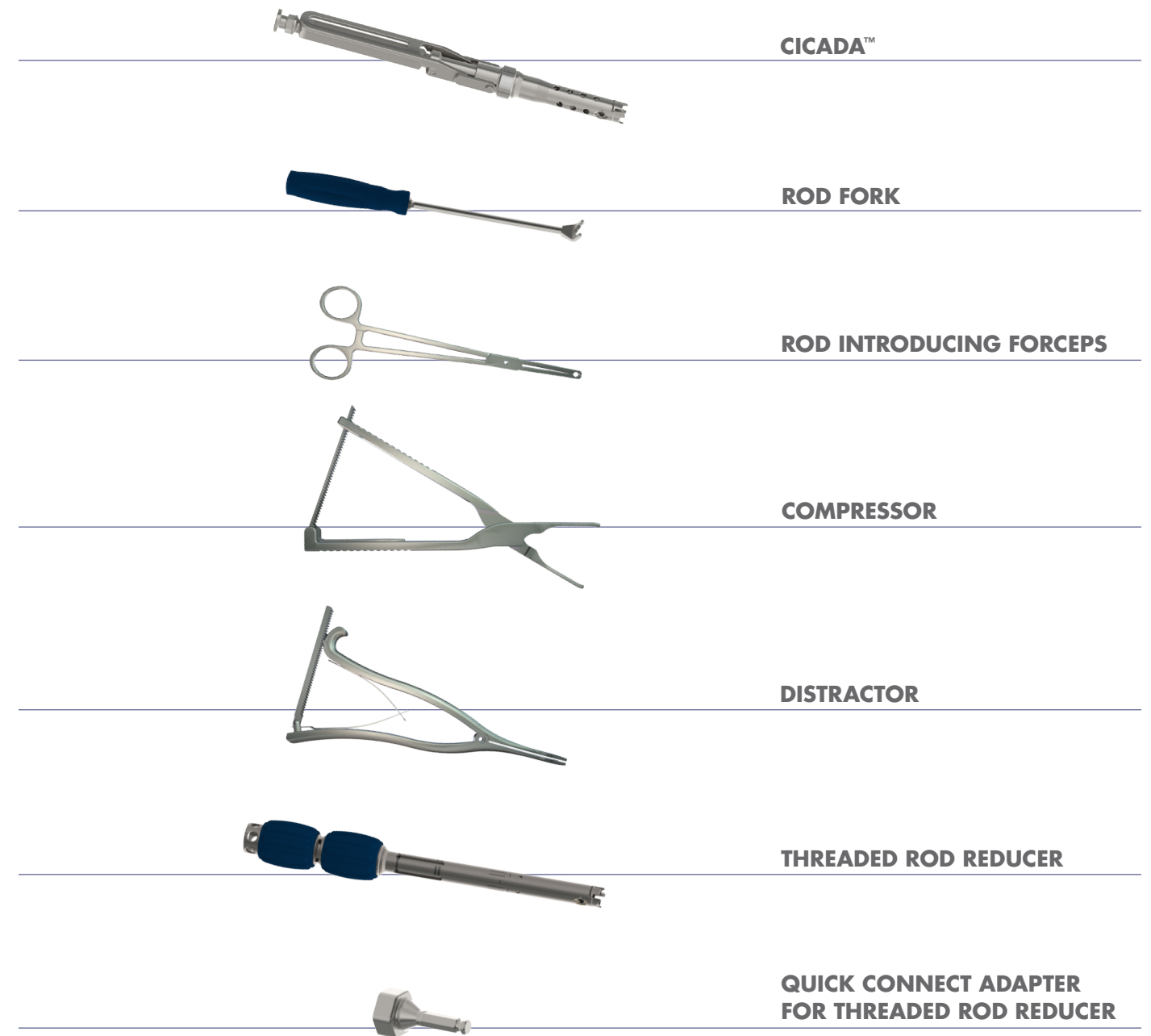
PROVISIONAL SCREWDRIVER, SIZE 30, LONG

ANTI-TORQUE ALIGNMENT TUBE

ANTI-TORQUE HANDLE

INJECTOR NEEDLE

INJECTOR ALIGNMENT GUIDE



CICADA™

ROD FORK

ROD INTRODUCING FORCEPS

COMPRESSOR

DISTRACTOR

THREADED ROD REDUCER

QUICK CONNECT ADAPTER FOR THREADED ROD REDUCER

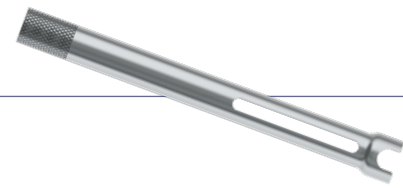
INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Torque Indicating Wrench	2901-90018
Provisional Screwdriver, Size 30, Short	2901-90016
Provisional Screwdriver, Size 30, Long	2901-90017
Anti-Torque Alignment Tube	2901-90015
Anti-Torque Handle	101-90051
Injector Needle	5001-90009
Injector Alignment Guide	5001-90018

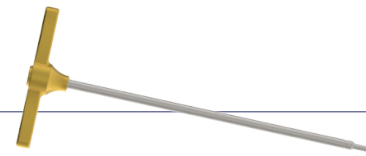
INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Cicada™	2901-90010
Rod Fork	2901-90047
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

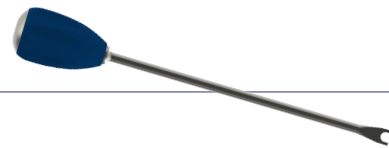
INSTRUMENTS



ALIGNMENT TUBE



EVEREST REMOVAL WRENCH

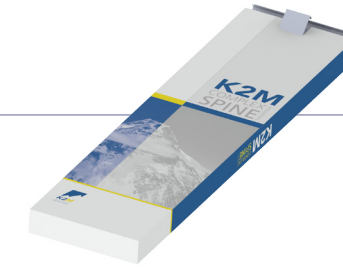


ROD PUSHER

STERILE PRODUCTS



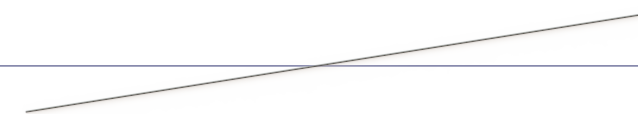
SERENGETI MINIMALLY INVASIVE RETRACTORS



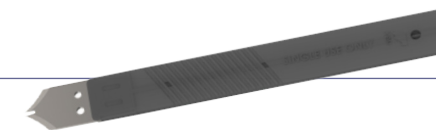
EVEREST MI ONE LEVEL KIT



EVEREST MI ADD-ON KITS



1.4 mm GUIDEWIRES
STAINLESS STEEL (~0.055 in)



PERFECT SCALPEL™

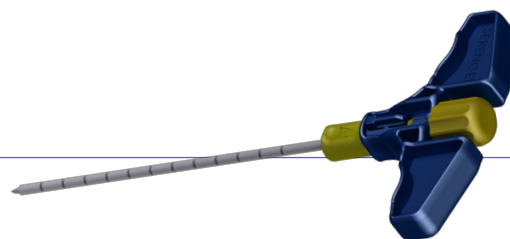
INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Alignment Tube	5001-90021
EVEREST Removal Wrench	2901-90056
Rod Pusher	2901-90013

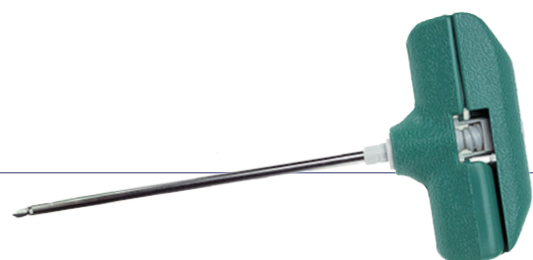
STERILE PRODUCTS

DESCRIPTION	CATALOG NUMBER
SERENGETI Minimally Invasive Retractors (Qty 2)	1001-90160
EVEREST MI One Level Kit (Qty 4 Guidewires & Qty 4 SERENGETI Retractors)	5101-90077
EVEREST MI Add-On Kits (Qty 2 Guidewires & Qty 2 SERENGETI Retractors)	5101-90067
Guidewire Pack (Qty 2 Guidewires, 20.5 inch)	5101-90057
Perfect Scalpel™	5101-90021-SG

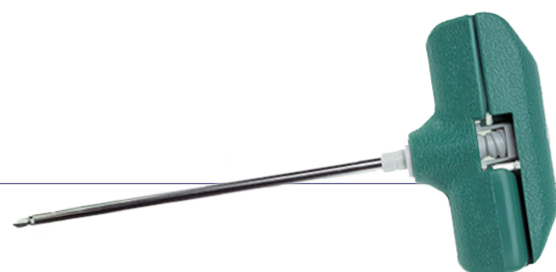
STERILE PRODUCTS



**BEVELED PEDICLE ACCESS NEEDLE
(11 GAUGE)**



**DOUBLE DIAMOND TIP PEDICLE
ACCESS NEEDLE (8 GAUGE)**



**BEVELED TIP PEDICLE ACCESS
NEEDLE (8 GAUGE)**

STERILE PRODUCTS

DESCRIPTION	CATALOG NUMBER
Beveled Pedicle Access Needle (11 Gauge)	1001-90157
Double Diamond Tip Pedicle Access Needle (8 Gauge)	1001-90162
Beveled Tip Pedicle Access Needle (8 Gauge)	1001-90183

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 System screws have a head that is 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 that had 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 System 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)

(K2M Test Report TR-486)

 **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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Actual Device Color may Vary.
Consult Product Catalog for Details.
This Product is Not Available for Sale
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