

Surgical Technique

EVEREST

Minimally Invasive XT 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)



Surgical Technique

TABLE OF CONTENTS

Preface	1
Features & Benefits	2
<hr/>	
PEDICLE SCREW SURGICAL TECHNIQUE STEPS	
<hr/>	
STEP 1: Patient Positioning	4
STEP 2: Preoperative Planning	5
STEP 3: Accessing the Pedicle	6
STEP 4: Guidewire Placement	7
STEP 5: Creating the Incision	8
STEP 6: Pedicle Preparation	9
STEP 7: Screw Insertion	10
STEP 8: Inserting the Screw	11
STEP 9: Rod Measurement	12
STEP 10: Rod Insertion	13
STEP 11: Set Screw Insertion, Rod Reduction, & Provisional Tightening	14
STEP 12: Final Tightening	16
STEP 13: Breaking the Tab	18
<hr/>	
OPTIONAL STEPS	
<hr/>	
Unlocking & Removal	20
Tower Rescue	21
Injector Alignment Guide & Needle Assembly	24
<hr/>	
Product Catalog	
<hr/>	
Implants	26
Instruments	27
Sterile Products	32
<hr/>	
Product Insert	34

Dear Colleagues,

Welcome to K2M and the EVEREST® Minimally Invasive (MI) XT 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.

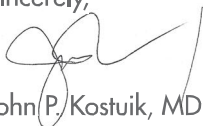
The implant technology is state-of-the-art, with several enhancing features to facilitate more efficient intraoperative use of the system. The EVEREST MI XT cannulated polyaxial screw provides 70° range of motion and features a mixed-metal (Ti/CoCr) head to minimize head splay when tested against an all-titanium alloy screw, 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. The system features rigid closed-top break-off extension tabs designed for MI rod passage. Inner threads provide 25 mm of reduction while streamlined instrumentation provides a simple two-step extension tab removal technique.

Great efforts have been made in the instrument design 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 Minimally Invasive XT Spinal System is, in my opinion, an advancement in minimally invasive surgery and a step forward in the design of pedicle screw systems. The following manual clearly outlines the procedural details and options, and will act as a guide to help explain the many important aspects of the EVEREST Minimally Invasive XT 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)

*Support data available upon request. Mechanical testing may not represent clinical results.

FEATURES & BENEFITS

EVEREST® Minimally Invasive XT Spinal System



Implant Design

- One-step, True Percutaneous Delivery of Screw & Built-in Extension
 - ♦ Built-in Extension Tab Does Not Require Intraoperative Assembly
- Closed-top Design Provides Rigid Connection for in-situ Rotation of the Screw Heads
- Internal Threads for up to 25 mm of Reduction
- Post-tab Removal Screw Head Compatible With All EVEREST System Instrumentation

Instrument Design

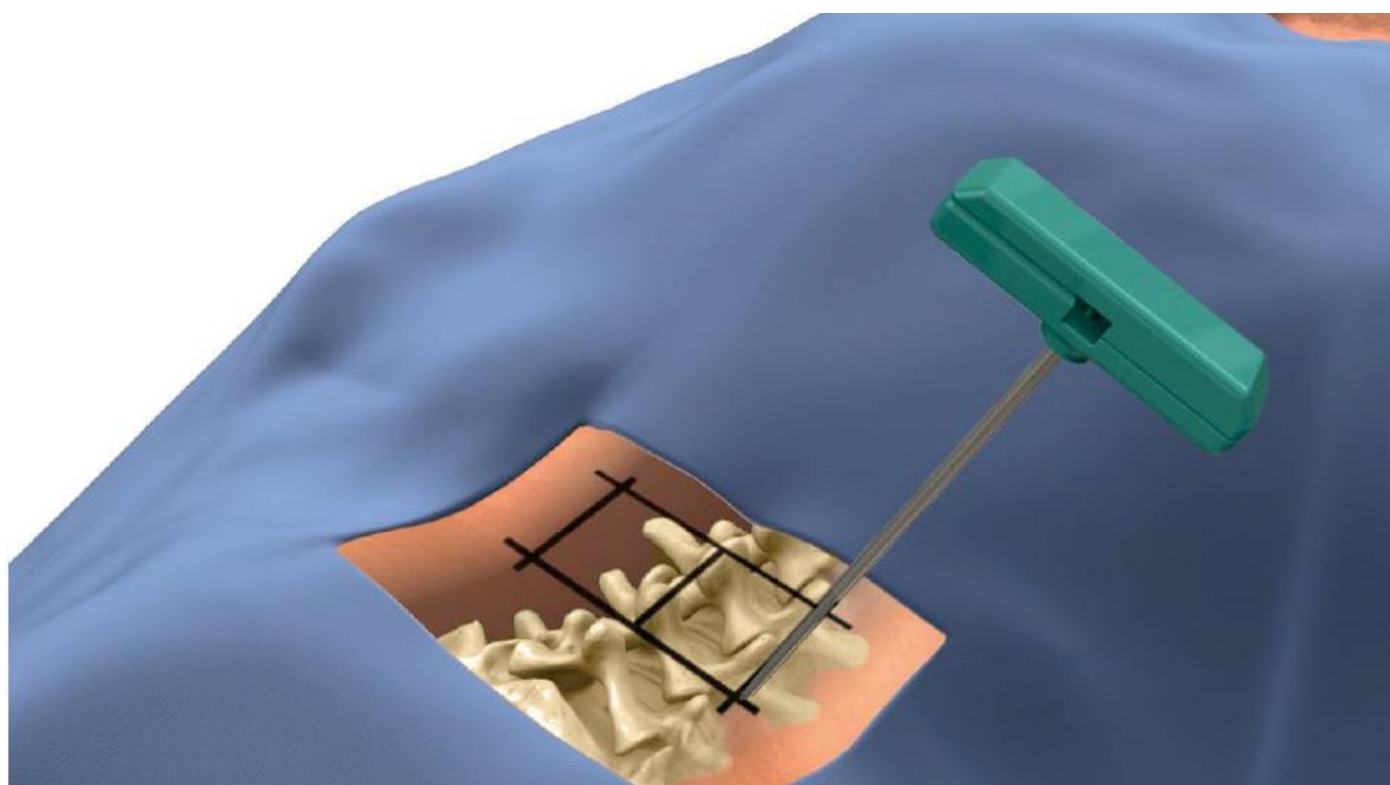
- Modular Compressor Features Closed/Open & Closed/Closed Design With Adjustable Fulcrum
- Split Tip Provisional Driver Uses Splayed T30 Connection
- Cap Breaker Allows for Open Extension Tab Use
- Tab Breaker Fully Encloses Extension Tabs to Ensure Complete Removal

EVEREST®
MINIMALLY INVASIVE XT
SURGICAL TECHNIQUE



PATIENT POSITIONING

Place the patient in a prone position appropriate for a standard percutaneous posterior approach, taking care to preserve or improve sagittal alignment of the spine. Proper patient positioning will assist in accurately assessing pedicle location. The use of a Jackson table, or similar radiolucent table, will allow for clear fluoroscopic imaging in the anteroposterior and lateral views.



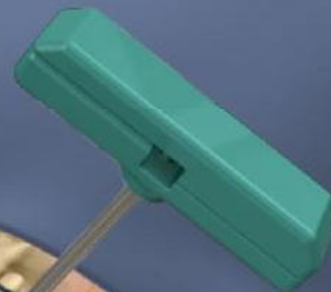
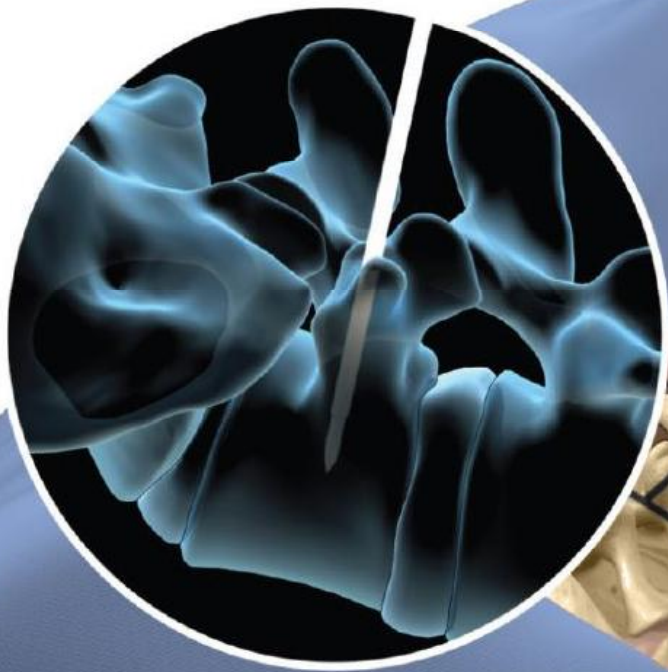
PREOPERATIVE PLANNING

Identify anatomic landmarks using standard techniques with fluoroscopic imaging in the A/P and lateral views. Use preferred intraoperative techniques to locate the pedicles under fluoroscopy and identify appropriate starting points and trajectory.

TIP: Creating a grid on the skin with a marking pen can assist with identifying anatomic landmarks and appropriate starting points.



PEDICLE ACCESS NEEDLE



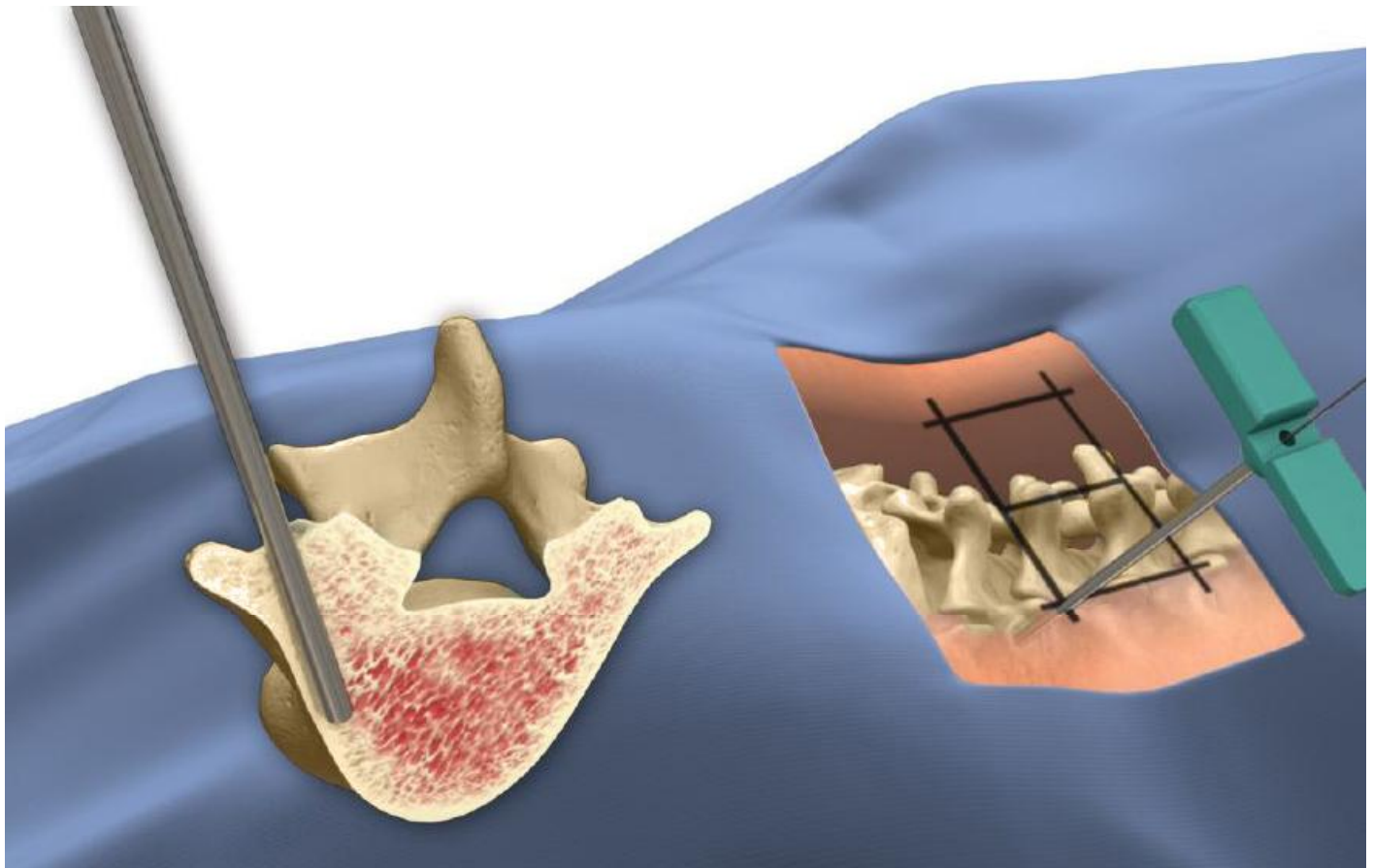
ACCESSING THE PEDICLE

A Pedicle Access Needle is used to locate the pedicle for correct positioning of the Guidewire. Using standard intraoperative techniques with fluoroscopy, advance the Pedicle Access Needle to the desired path within the vertebral body, being cautious to ensure the pedicle is not breached during placement. After confirming the desired depth with

fluoroscopy, remove the inner stylet.

TIP: The use of two C-arms can allow for obtaining easier sequential A/P and lateral images.

GUIDEWIRE

**GUIDEWIRE
PLACEMENT**

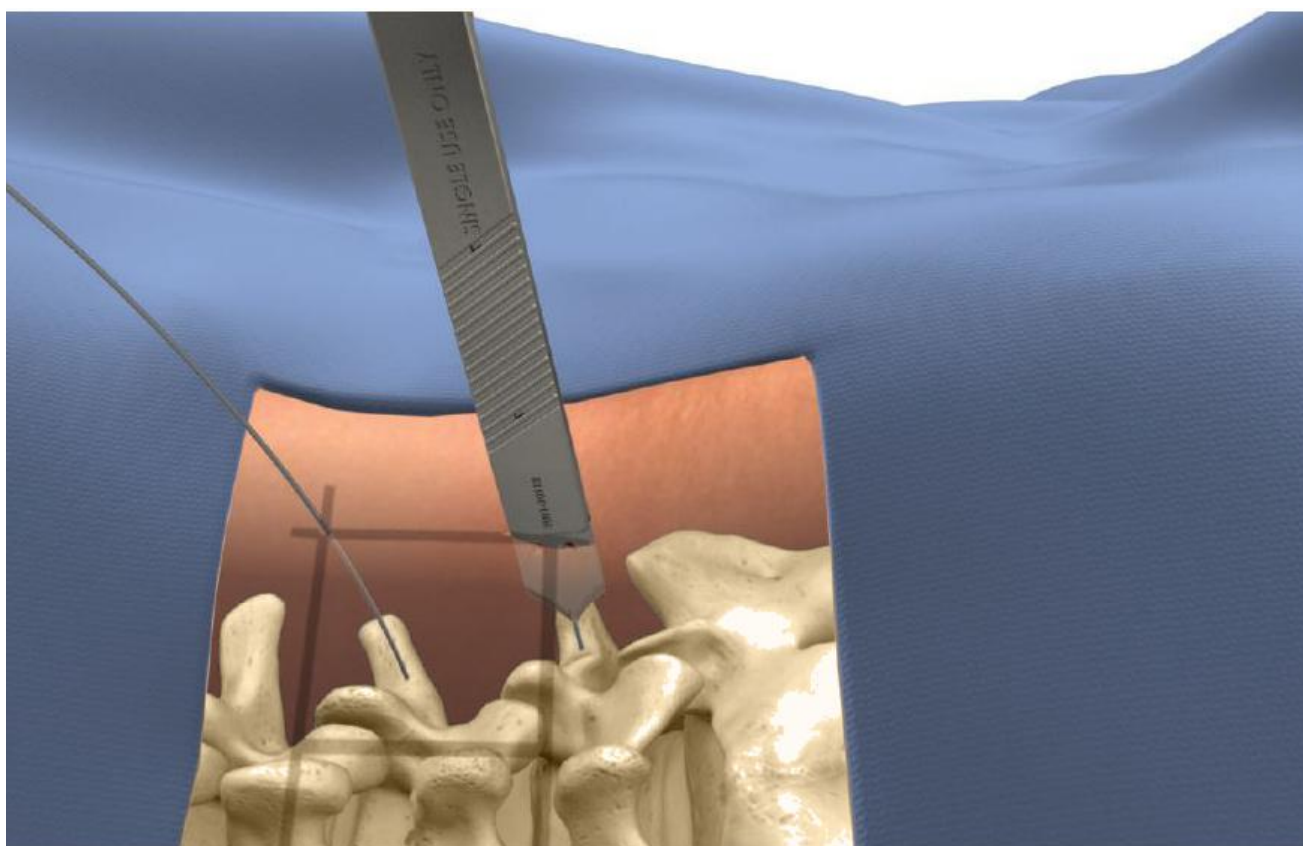
The Guidewire is inserted into the Pedicle Access Needle cannula after removal of the inner stylet. Advance the Guidewire past the distal end of the cannula and approximately two-thirds into the vertebral body, using fluoroscopy for positioning verification. Carefully remove the Pedicle Access Needle from the vertebral body while securing the Guidewire. Throughout the

remainder of the procedure, carefully monitor the position and depth of the Guidewire to prevent further advancement or accidental pullout. Repeat steps three and four for all Guidewires for the procedure.

TIP: Place all Guidewires before proceeding.



PERFECT SCALPEL



CREATING THE INCISION

The Perfect Scalpel™ is a cannulated instrument used to create an incision through the skin and fascia to assist with placement of the EVEREST Minimally Invasive (MI) XT screw. Use the safety cap to carefully position the cannula of the Perfect Scalpel over and down the Guidewire.



INNER DILATOR



OUTER DILATOR



CANNULATED TAP

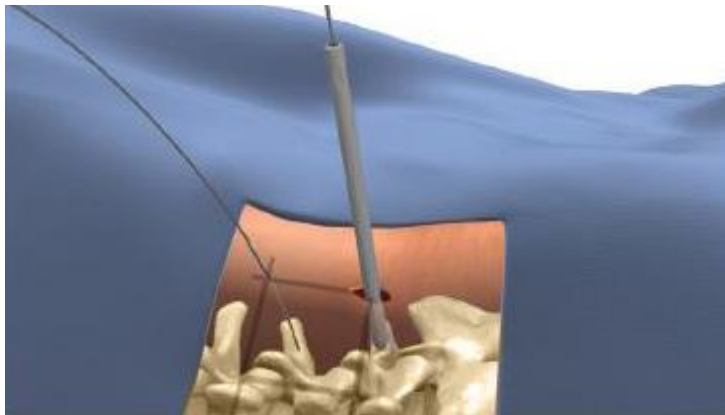


FIGURE 1

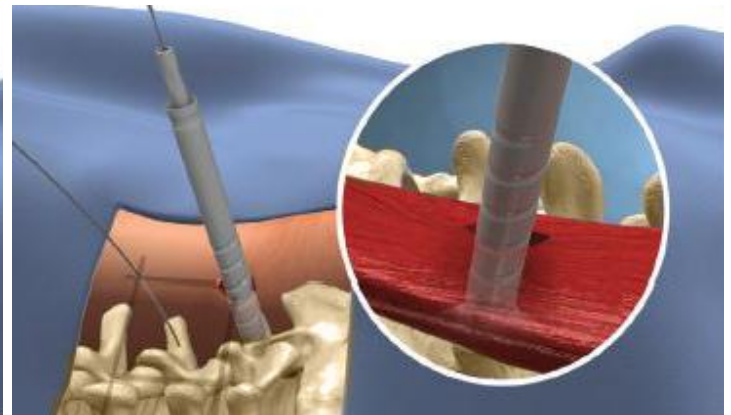


FIGURE 2



FIGURE 3

PEDICLE PREPARATION

In preparation for tapping the pedicle, place the Inner Dilator over the Guidewire and advance to the pedicle. This is followed by the Outer Dilator. Remove the Inner Dilator while maintaining downward pressure on the Outer Dilator, ensuring a flush position to the bone. The Outer Dilator will protect the soft tissue while the pedicle is being prepared.

Prepare the pedicle by positioning the Cannulated Tap over the Guidewire to penetrate the cortex of the vertebral body and create a thread pattern into the bone. Use fluoroscopy to verify positioning of the Guidewire and Cannulated Tap during the entire pedicle preparation step.

NOTE: Cannulated Taps are sized line-to-line.



EVEREST MI XT POLYAXIAL
SCREW INSERTER



RATCHETING T-HANDLE



RATCHETING PALM HANDLE

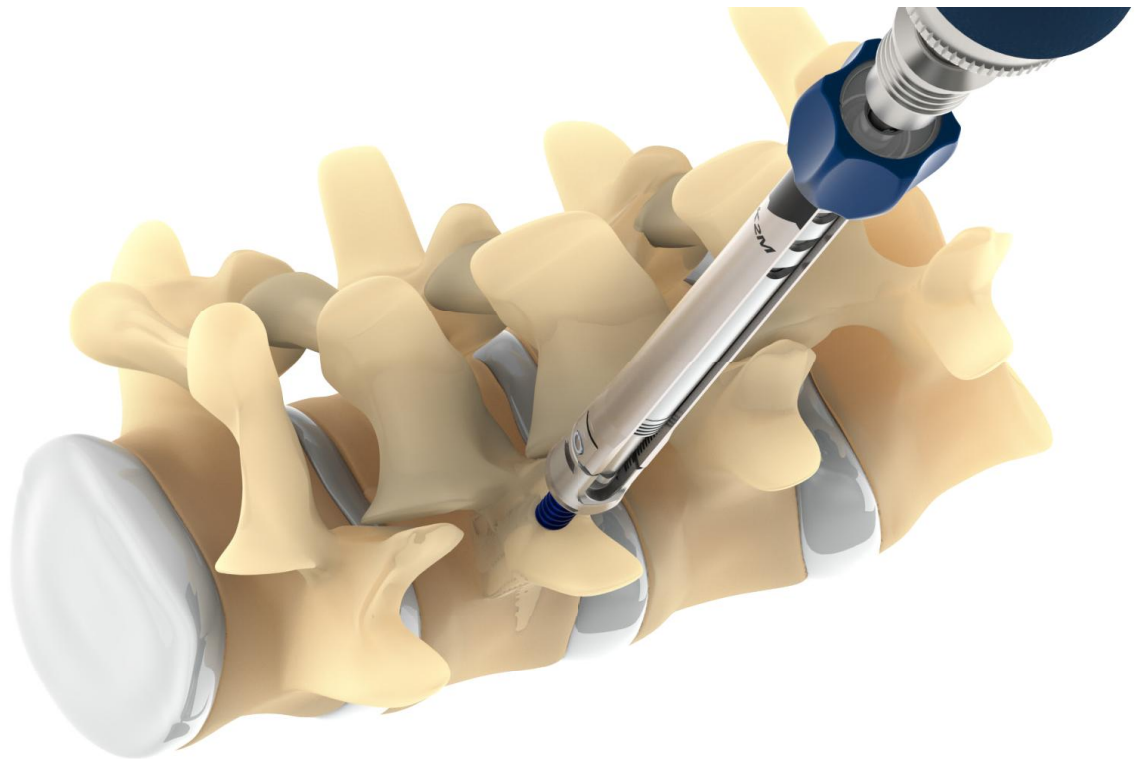


SCREW INSERTION

When using an EVEREST MI XT 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 thumb knob in a clockwise direction until the implant is securely attached to the inserter.

To disengage the Screw Inserter, gently turn the thumb knob in a counter-clockwise direction and remove it from the surgical field. Ratcheting Handles are available in both Palm and T-Handle styles. Tighten or loosen positions are selected by adjusting the pull down knob into forward, neutral, or reverse.

GUIDEWIRE



INSERTING THE SCREW

Advance the EVEREST MI XT Polyaxial Screw Inserter over the Guidewire. Once the screw reaches the pedicle, take a lateral X-ray to ensure the screw is collinear with the Guidewire. Push the EVEREST MI XT Screw Inserter down to the pedicle and insert the screw into the vertebral body. Once the screw is satisfactorily positioned,

spin the thumb knob counter-clockwise to disengage the EVEREST MI XT Polyaxial Screw Inserter.



LONG MI ROD CALIPER



ROD MEASUREMENT

The appropriate rod length can be determined by placing the ball tips of the Long MI Rod Caliper into the outside edges of the most cranial and caudal screw housings. Use the inside edges of the ball tips to identify the appropriate rod length. Unless compression or distraction is required, there is no need to adjust the measurement provided,

as it already takes into account the hex end and bullet nose of the rod. The EVEREST MI XT screw can accommodate both a $\varnothing 5.5$ 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 INSERTER



RODS

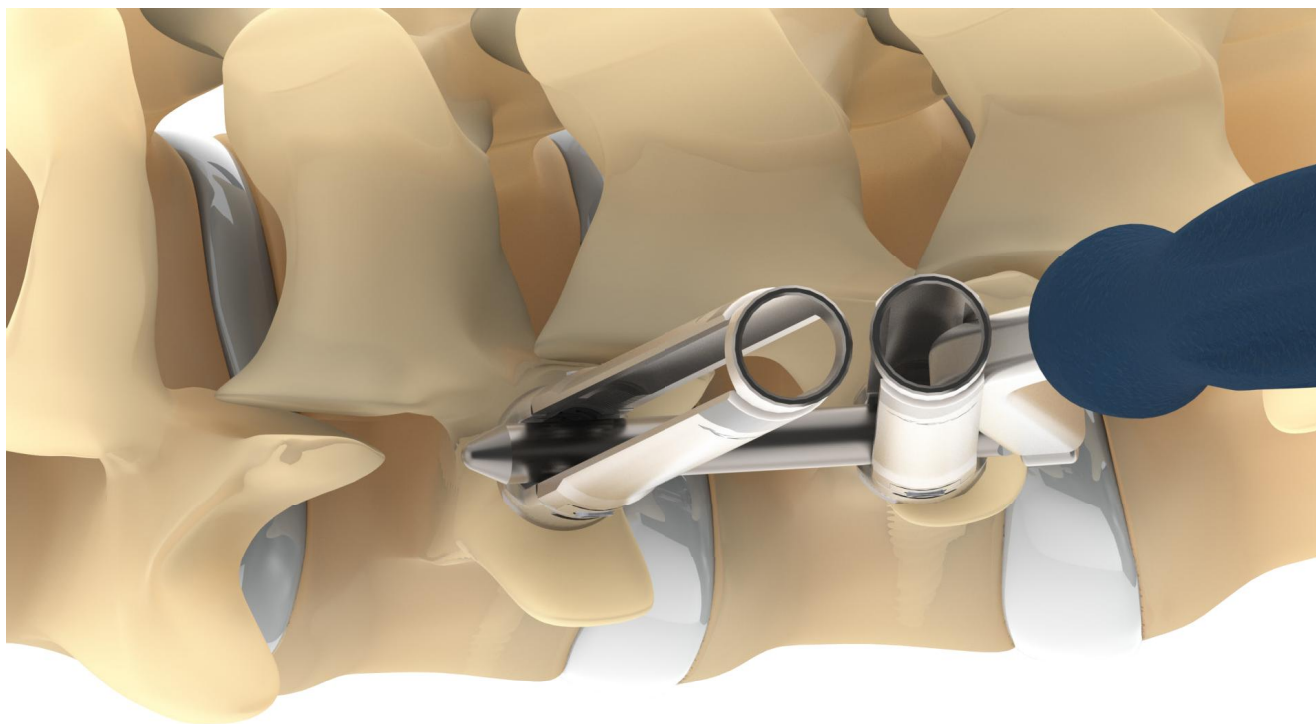


ROD INSERTION

After properly measuring and selecting the rod, load the rod onto the MI XT Rod Inserter by rotating the dial at the proximal end to open. Then, secure the rod to the Inserter by tightening the dial. Initiating insertion of the rod near the saddle of the screw positions the rod for passage to the next screw location.



SPLIT TIP PROVISIONAL DRIVER



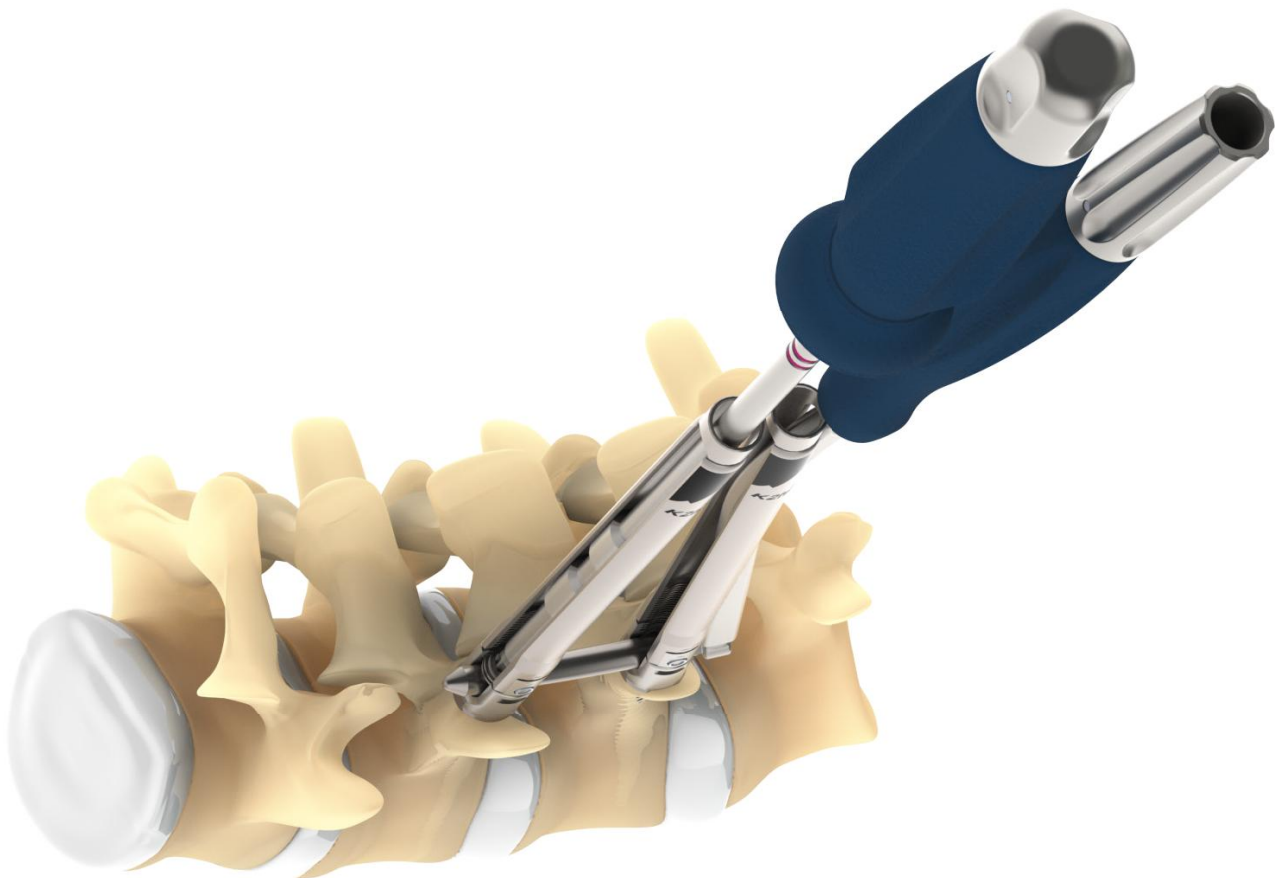
SET SCREW INSERTION, ROD REDUCTION, & PROVISIONAL TIGHTENING

Prior to set screw insertion, use caution to ensure the bullet nose and hex-end features of the rod are positioned outside of the screw saddle. The EVEREST set screw may be inserted into the EVEREST MI XT implant housing using the Split Tip Provisional Driver. Ensure the instrument is perpendicular to the caddy when engaging the split tip

with the set screw. Rotate proximal knob clockwise to secure the EVEREST set screw to the Split Tip Provisional Driver. Due to its design, the EVEREST set screw facilitates easy introduction and reduces the potential for cross threading.



STABILIZATION TUBE



If the rod is seated above the screw thread, apply downward force on the Split Tip Provisional Driver within the EVEREST MI XT screw housing. Continue downward pressure until the set screw threads into the extended tab and continues into the screw housing until the rod is properly seated below the set screw.

To disengage the Split Tip Provisional Driver from the set screw, rotate the proximal knob counter-clockwise. Once the rod has been reduced and the set screw provisionally tightened, remove the EVEREST MI XT Rod Inserter by rotating the dial at the proximal end counter-clockwise until the rod disengages.

NOTE: The Stabilization Tube may be used during set screw insertion if additional rod reduction is needed.



STABILIZATION TUBE



ANTI-TORQUE HANDLE



FINAL TIGHTENING

Final tightening of the EVEREST MI XT screws is achieved using the Anti-Torque Stabilization Tube and the Anti-Torque Handle. The Anti-Torque Stabilization Tube will fit over the EVEREST MI XT screw and lock on the exterior of the screw head. Ensure the sliding mechanism of the Anti-Torque Handle is facing up to lock onto the Anti-Torque Stabilization Tube. Slide the handle over the small diameter of the

Tube and 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 Anti-Torque Stabilization Tube before positioning the screw.

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

EVEREST® Minimally Invasive XT Spinal System



TORQUE LIMITING SHAFT



TORQUE LIMITING HANDLE



TORQUE INDICATING WRENCH



The Torque Indicating Wrench, or the assembled Torque Limiting Handle and Torque Limiting Shaft achieve 90 in-lbs of torque for final tightening. The proper torque level is achieved with the Torque Indicating Wrench when the line and the arrow meet on the shaft. The assembled Torque Limiting Handle and Torque Limiting Shaft will emit an audible “pop” once the necessary torque is achieved.

NOTE: Repeat final tightening steps for each screw to ensure the construct is final tightened properly.

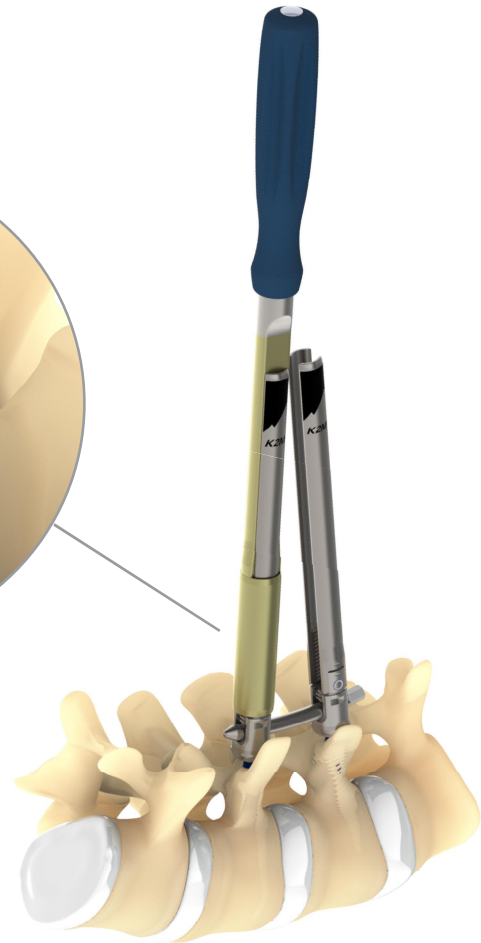
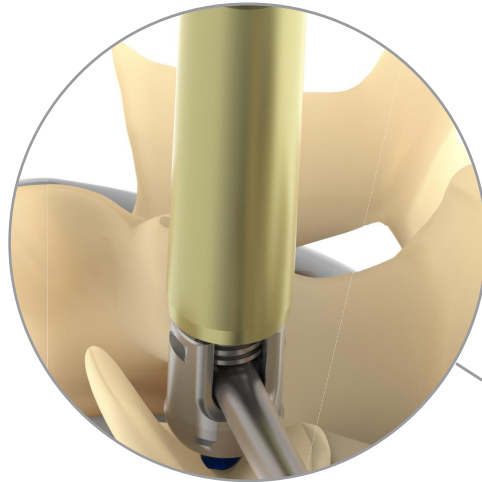
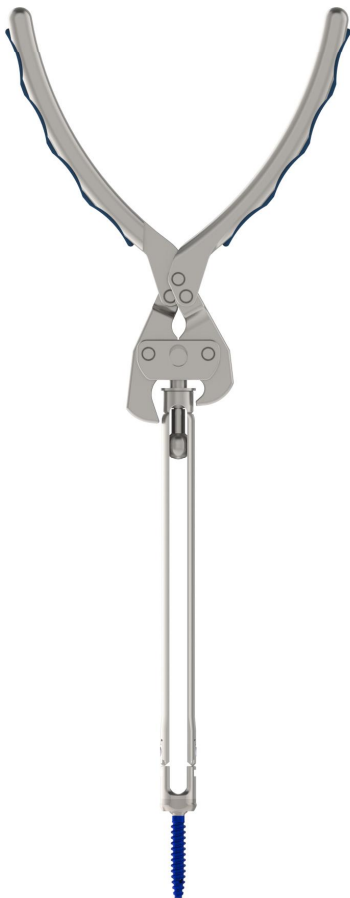
13



TAB CAP REMOVAL TOOL



TAB REMOVAL TOOL

**BREAKING
THE TAB**

The EVEREST MI XT screw is designed with breakaway features for easy removal after locking the construct. Position the Tab Cap Removal Tool on the cap of the EVEREST MI XT screw. Ensure the central knob of the Tab Cap Removal Tool is firmly seated in the cap of the extended tab. Compress the handles of the Tab Cap Removal Tool to break one side of the extension tabs

from the cap. Then rotate the instrument 180° to break the remaining side of the tab connecting to the cap. Once the cap has been removed, insert the Tab Removal Tool over the remaining tabs. Once positioned over the tabs, the instrument can be pushed medially or laterally to remove the extended tab from the EVEREST MI XT screw. Remove the Tab Removal Tool and tab.

Surgical Technique Steps



SET SCREW
REMOVAL WRENCH



STABILIZATION TUBE



ANTI-TORQUE HANDLE



T-HANDLE



EVEREST SCREW
REMOVAL SHAFT



UNLOCKING & REMOVAL

Once the EVEREST set screw 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 Set Screw 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.



RECOVER ALIGNMENT TOOL



RESCUE TOWER



TOWER RESCUE

In the event that the extended tab is damaged or removed before final tightening of the set screw, the EVEREST MI XT Screw Rescue Tower can be used to complete the procedure.

Ensure the extended tab is completely removed prior to attaching the Rescue Tower. Ensure the Recover Alignment

Tool is properly seated within the XT screw housing to prepare for Rescue Tower Attachment. Slide the Rescue Tower over the Recovery Head Adjuster until it snaps into the outer grooves on the screw head housing. Use the Recovery Head Adjuster to orient the tower openings in line with the construct.

Surgical Technique Steps



RESCUE TOWER
REDUCTION DRIVER



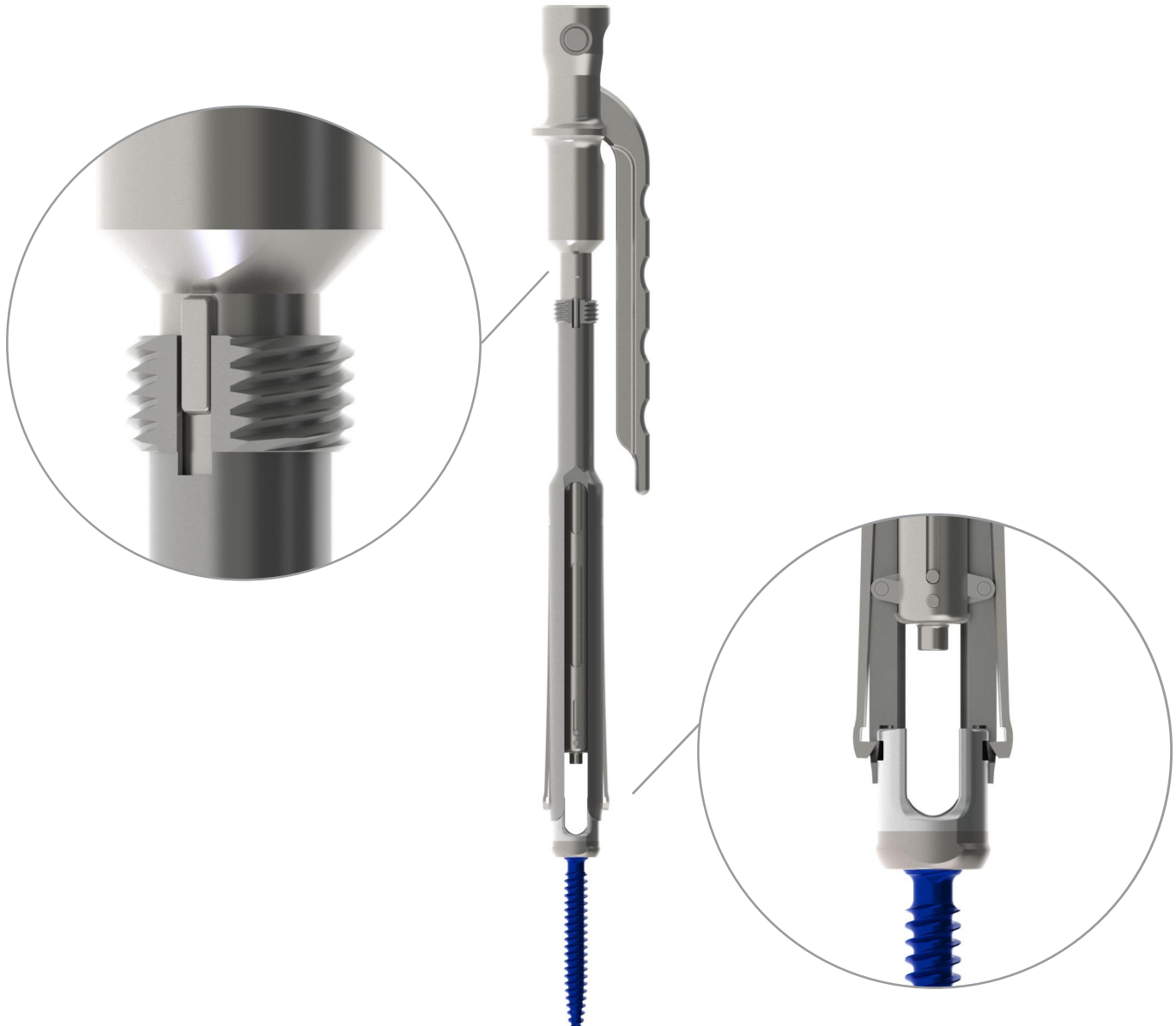
TOWER RESCUE (CONT.)

The EVEREST set screw may be inserted into the Rescue Tower using the Rescue Tower Reduction Driver. Ensure the instrument is perpendicular to the caddy when engaging the Rescue Tower Reduction Driver. Due to its design, the EVEREST set screw facilitates easy introduction and reduces the potential for cross threading. If the rod is seated above the screw thread, apply downward force on the Rescue Tower Reduction

Driver within the Rescue Tower housing. Continue downward pressure until the set screw threads into the screw housing and the rod is properly seated below the set screw. Final tightening can occur with the Rescue Tower using the Tower Anti-Torque Handle, which will attach to the Rescue Tower, along with the Torque Limiting Handle and Torque Limiting Shaft.



TOWER EXTRACTOR



To remove the Rescue Tower, insert the Tower Extractor into the Rescue Tower until the top of the tower is flush with the instrument and keys to the slots on the top of the Tower. Ensure the Tower and instrument are properly aligned. Close the handle of the Tower Extractor to remove the Rescue Tower from the EVEREST MI XT screw.



INJECTOR ALIGNMENT GUIDE & NEEDLE ASSEMBLY

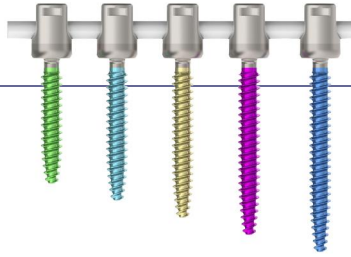
Thread the Injector Alignment Guide through the extension tabs of the EVEREST XT Screw and into the screw head.

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 closewise 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.

EVEREST®
MINIMALLY INVASIVE XT
PRODUCT CATALOG

IMPLANTS



Ø5.5 SCREWS

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



EVEREST SET SCREW



Ø5.5 mm BULLETED CONTOURED HEX END ROD

5 mm increments, 100–150 mm

IMPLANTS

DESCRIPTION

CATALOG NUMBER

EVEREST MI XT Screws

*See special note

EVEREST Set Screw

2901-10001

Bulleted Contoured Hex Rod

1001-E55xx

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

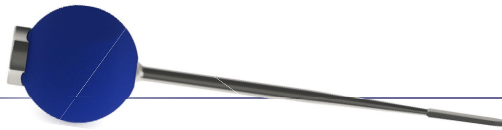
INSTRUMENTS



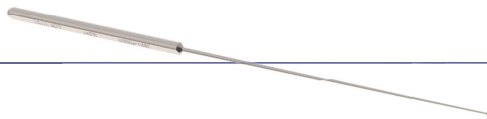
RATCHETING T-HANDLE



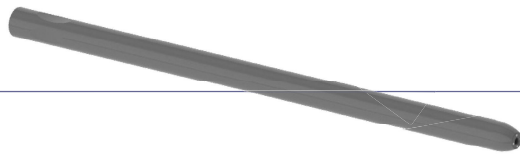
RATCHETING PALM HANDLE



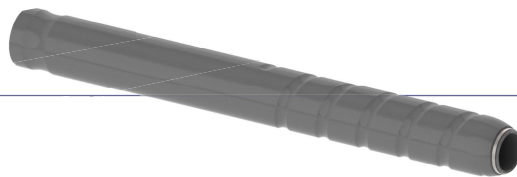
**CANNULATED LUMBAR
PROBE WITH INNER STYLET**



BALL TIP FEELER



INNER DILATOR



OUTER DILATOR

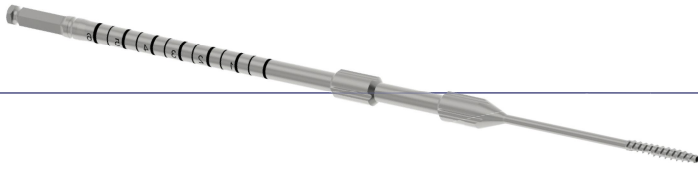


CANNULATED DRILL

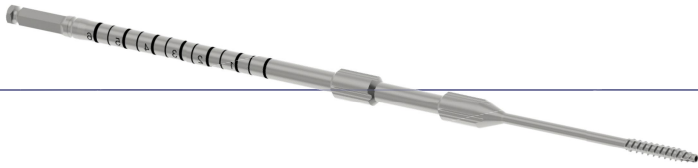
INSTRUMENTS

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Ratcheting T-Handle	2901-90051	Inner Dilator	5101-90008
Ratcheting Palm Handle	2901-90050	Outer Dilator	5101-90009
Cannulated Lumbar Probe with Inner Stylet	5101-90131	Cannulated Drill	1001-90053
Ball Tip Feeler	2801-90000		

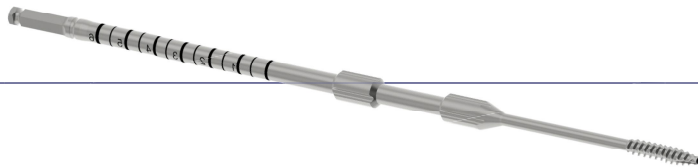
INSTRUMENTS



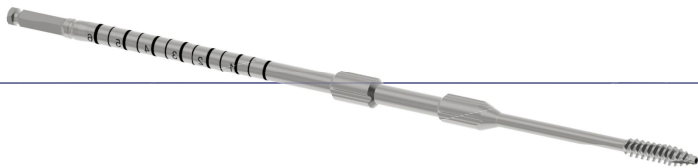
4.0 mm TAP



4.5 mm TAP



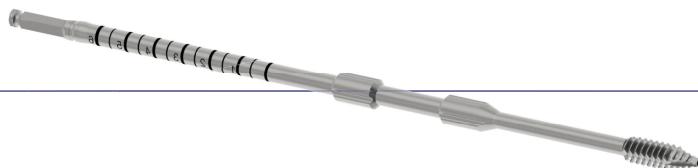
5.5 mm TAP



6.5 mm TAP



7.5 mm TAP



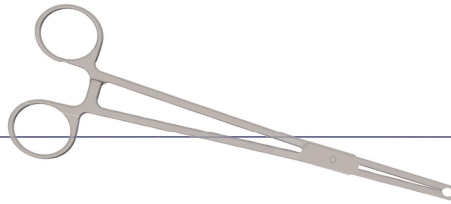
8.5 mm TAP

INSTRUMENTS

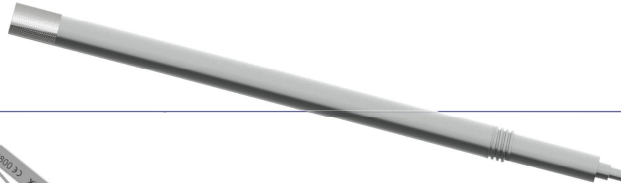
DESCRIPTION	CATALOG NUMBER
4.0 mm Tap	5101-90002
4.5 mm Tap	5101-90003
5.5 mm Tap	5101-90004
6.5 mm Tap	5101-90005
7.5 mm Tap	5101-90006
8.5 mm Tap	5101-90007

EVEREST® Minimally Invasive XT Spinal System

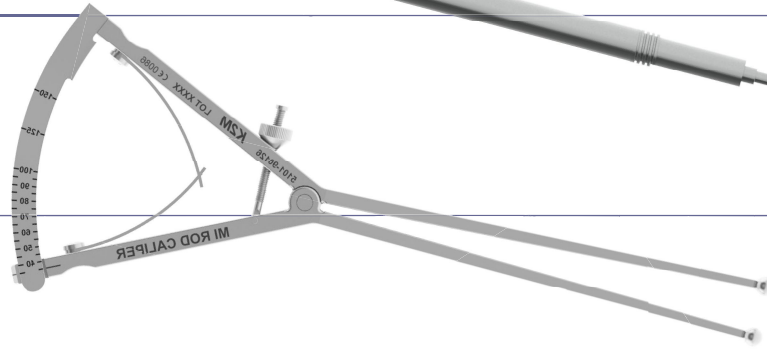
INSTRUMENTS



ROD INTRODUCING FORCEPS



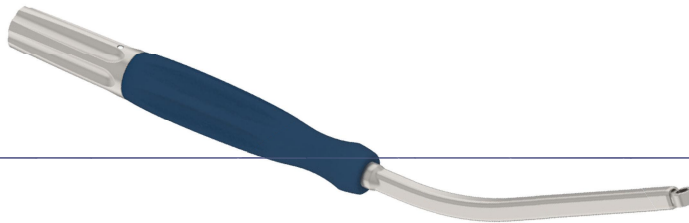
TAB FENESTRATED ALIGNMENT GUIDE



MI LONG ROD CALIPER



POLYAXIAL SCREW INSERTER



ROD INSERTER



PROVISIONAL SET SCREW DRIVER

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Rod Introducing Forceps	101-90039
Tab Fenestrated Alignment Guide	5001-90019
MI Long Rod Caliper	5101-90126
Polyaxial Screw Inserter	5101-90104
Rod Inserter	5101-90091
Provisional Set Screw Driver	5101-90129

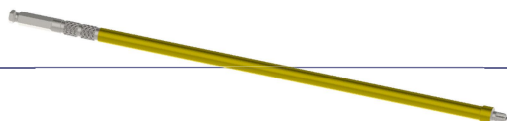
INSTRUMENTS



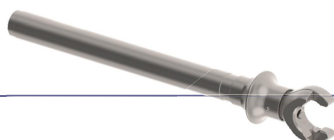
TORQUE LIMITING SHAFT



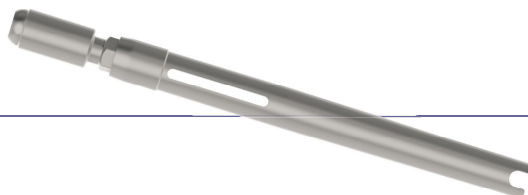
TORQUE LIMITING HANDLE 90-IN LBS



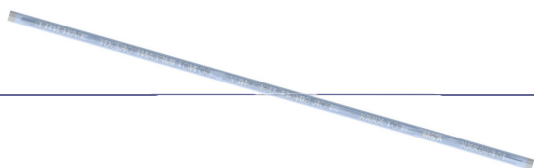
T25 GOLD DRIVER / RECOVERY TOOL



ANTI-TORQUE HANDLE



STABILIZATION TUBE




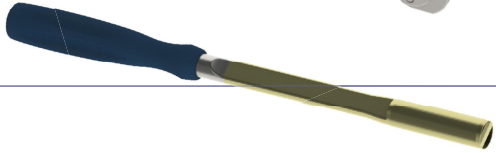

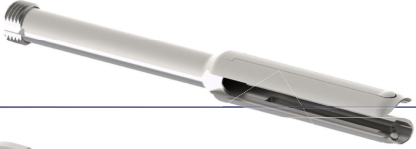
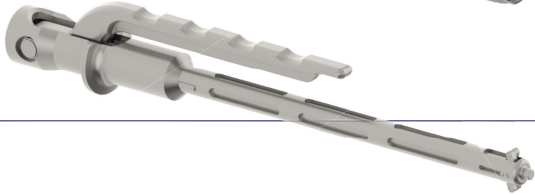
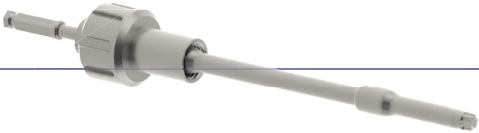



ROD TEMPLATE, 400 mm

INSTRUMENTS

DESCRIPTION	CATALOG NUMBER
Torque Limiting Shaft	5101-90106
Torque Limiting Handle 90-in lbs	5101-90133
T25 Gold Driver / Recovery Tool	5101-90107
Anti-Torque Handle	101-90051
Stabilization Tube	5101-90127
Rod Template, 400 mm	101-90143

EVEREST® Minimally Invasive XT Spinal System

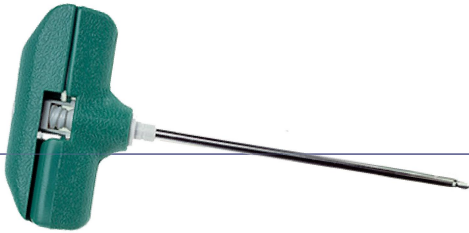
INSTRUMENTS

	TAB CAP REMOVAL TOOL
	TAB REMOVAL TOOL
	DANDIE CAP
	BASIC TOWER
	TOWER REMOVAL TOOL
	REDUCTION DRIVER
	RECOVERY HEAD ADJUSTER
	TOWER ANTI-TORQUE HANDLE
	T-HANDLE TIGHTENER

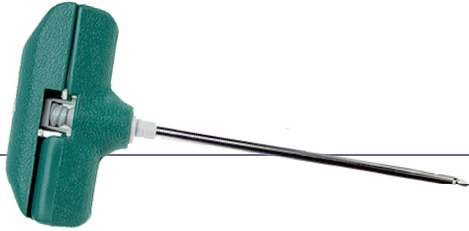
INSTRUMENTS

DESCRIPTION	CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER
Tab Cap Removal Tool	5101-90130	Recovery Head Adjuster	5101-90128
Tab Removal Tool	5101-90141	Tower Anti-Torque Handle	5101-90132
Dandie Cap	5101-90104	T-Handle Tightener	5303-90109
Basic Tower	5101-90122		
Tower Removal Tool	5101-90125		
Reduction Driver	5101-90124		

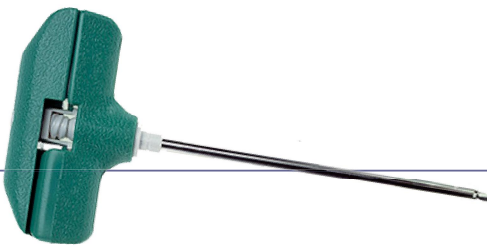
STERILE PRODUCTS



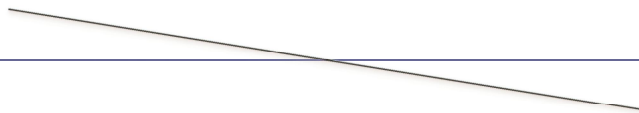
**BEVELED PEDICLE ACCESS NEEDLE
(11 GAUGE)**



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



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



**1.4 mm GUIDEWIRE
STAINLESS STEEL (~0.055 in)**



PERFECT SCALPEL

INSTRUMENTS

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
1.4 mm Guidewire Stainless Steel (~0.055 in)	5101-90057
Perfect Scalpel	5101-90021-SG

Product Insert



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

PI026-0A11-00 Rev. 0
K2M Inc. 751 Miller Dr. SE
Leesburg, VA 20175
1.571.919.2000



K2M, Inc.

751 Miller Drive SE
Leesburg, Virginia 20175
USA

PH 1.866.526.4171 • 1.571.919.2000

FX 1.866.862.4144



Emergo Europe

Molenstraat 15
2513 BH, The Hague
The Netherlands

PH +31.70.345.8570

FX +31.70.346.7299



www.K2M.com

©2016 K2M, Inc. All rights reserved.
K2-51-7036-02 Rev. 0
Actual Device Color may Vary.
Consult Product Catalog for Details.



0086

