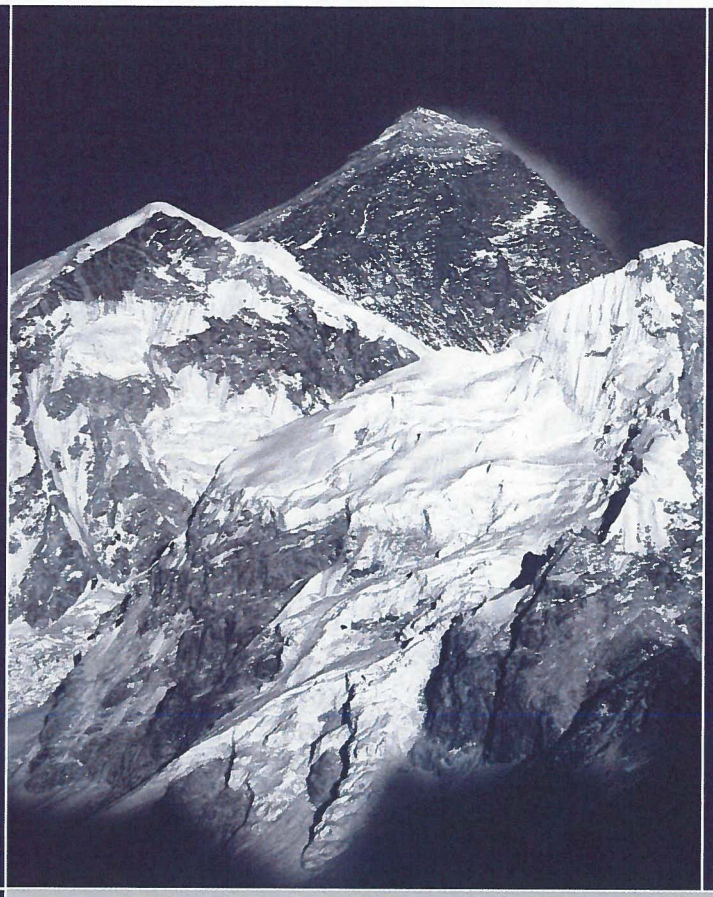


EVEREST®
MINIMALLY INVASIVE

Surgical Technique

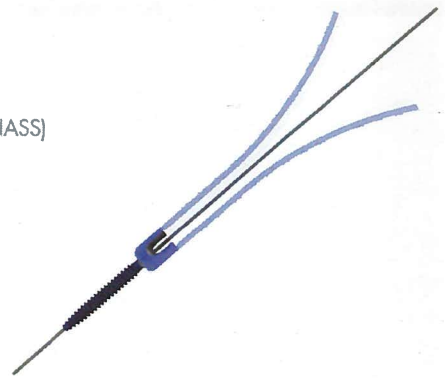
# EVEREST

## Minimally Invasive Spinal System

## Featuring the SERENGETI® Minimally Invasive Retractor 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)

K2M
COMPLEX SPINE INNOVATIONS™

# Surgical Technique Steps

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Dear Colleagues,

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

We have paired this system with the SERENGETI® Minimally Invasive Retractor System technology. The SERENGETI Retractor is designed for percutaneous delivery with the pedicle screw, thereby establishing a secure position to the anatomy and allowing for opening proximally. This novel method of retraction provides improved visualization and access to the screw heads for simplified rod insertion in posterior spinal fixation procedures. SERENGETI is state-of-the-art with several important features facilitating efficient intraoperative use of the system. The Retractor's flexible design simplifies rod insertion in multi-level constructs and its minimal instrumentation and compatibility with the EVEREST Minimally Invasive Spinal System may potentially help reduce the surgeon learning curve and operating room set up time. Additionally, the Retractor's polymer design allows for neuromonitoring during screw placement.

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 Spinal System paired with the SERENGETI Minimally Invasive Retractor System is, in my opinion, an advancement in minimally invasive surgery and 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 act as a guide to help explain the many important aspects of the EVEREST Minimally Invasive Spinal System.

Thank you again for your interest and support.

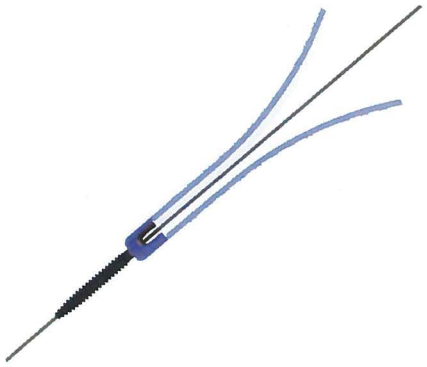
Sincerely,

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 33 for support data. Mechanical testing may not represent clinical results.*

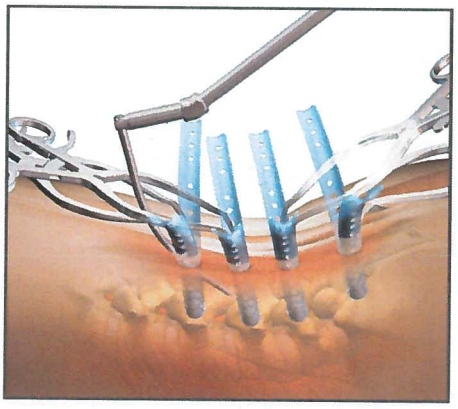
## FEATURES & BENEFITS

### EVEREST® Minimally Invasive Spinal System



- 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

### Featuring SERENGETI® Minimally Invasive Retractor System



*See page 33 for support data. Mechanical testing may not represent clinical results.

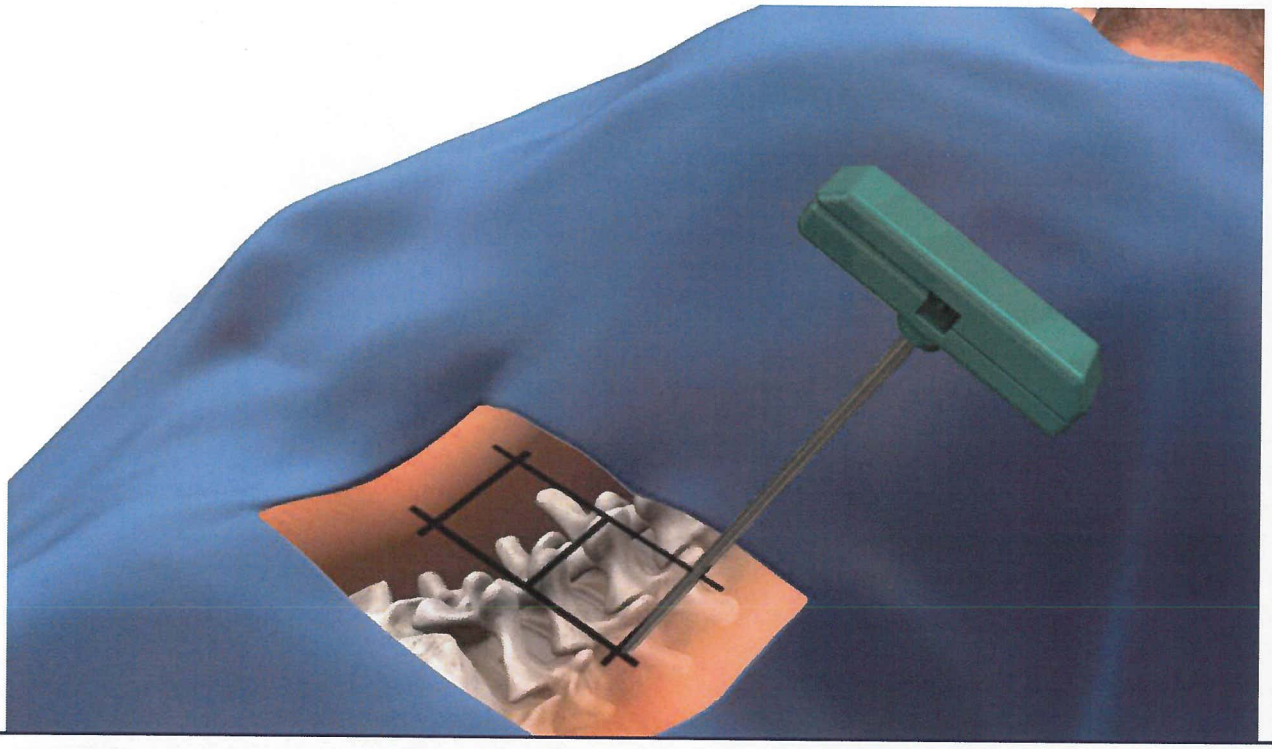
# EVEREST® MINIMALLY INVASIVE SURGICAL TECHNIQUE

3

# STEP 1 Surgical Technique Steps

## 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 the clear fluoroscopic imaging in the anteroposterior and lateral views.





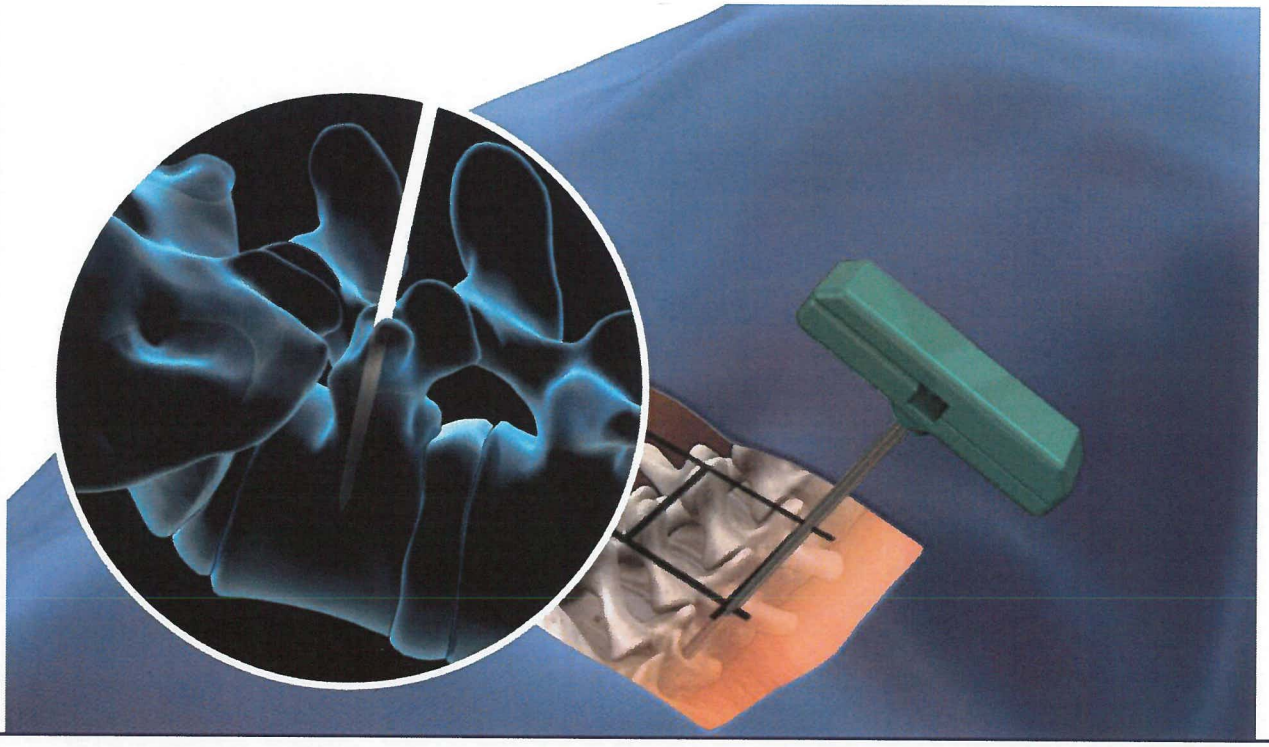
## PREOPERATIVE PLANNING

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.

# STEP 3 Surgical Technique Steps

PEDICLE ACCESS NEEDLE

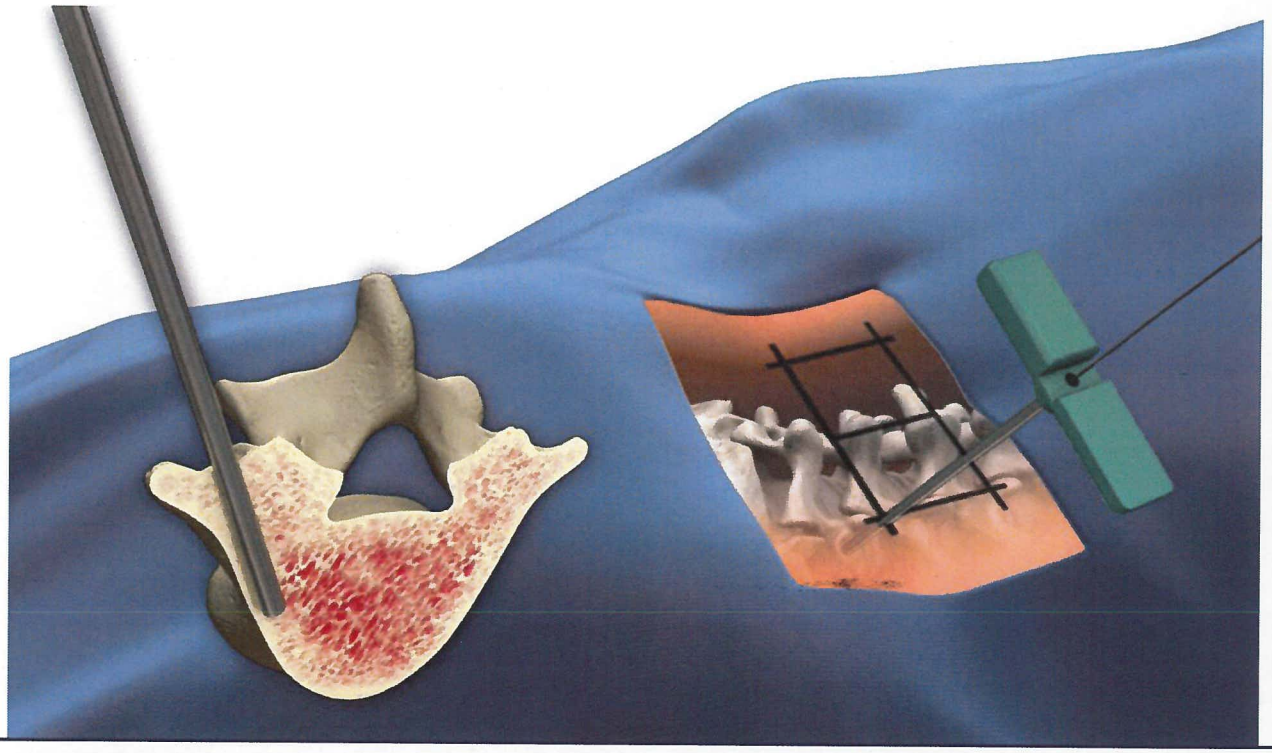


## ACCESSING THE PEDICLE

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 depth 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 anterior, posterior and lateral images.





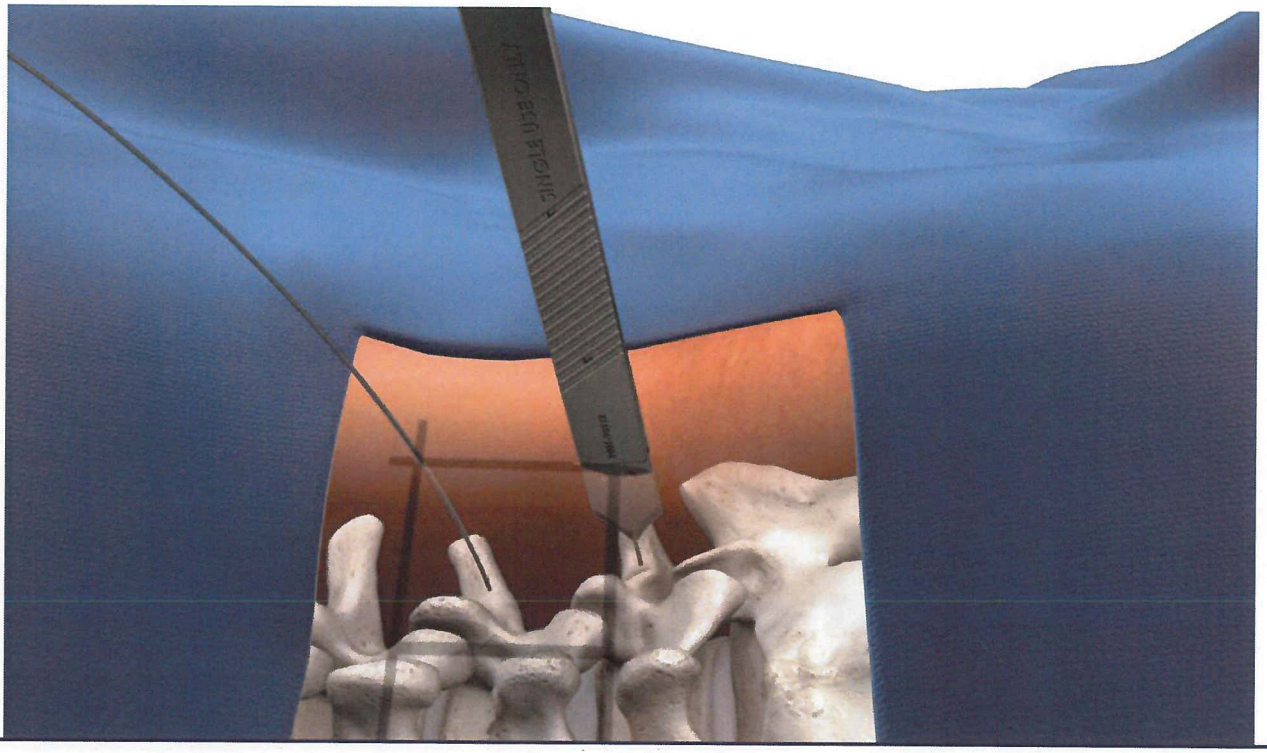
## GUIDEWIRE PLACEMENT

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 3 and 4 for all Guidewires for the procedure.

**Tip**: Place all Guidewires before proceeding.

# STEP 5 Surgical Technique Steps

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 SERENGETI Retractor. Use the safety cap to carefully position the cannula of the Perfect Scalpel over and down the Guidewire. Remove the safety cap to initiate the incision in the sagittal plane. After every use, clean out the cannula to avoid clogging.

INNER DILATOR

OUTER DILATOR



CANNULATED-TAP

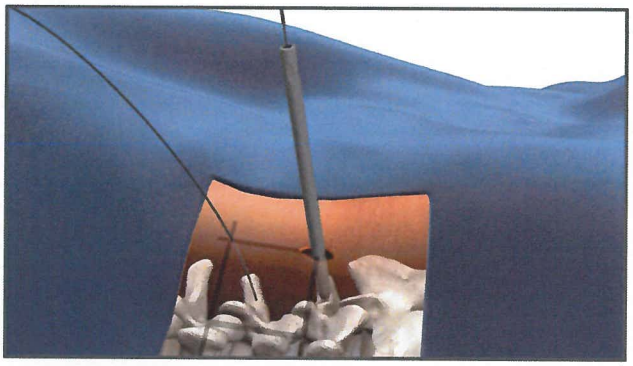


Figure 1

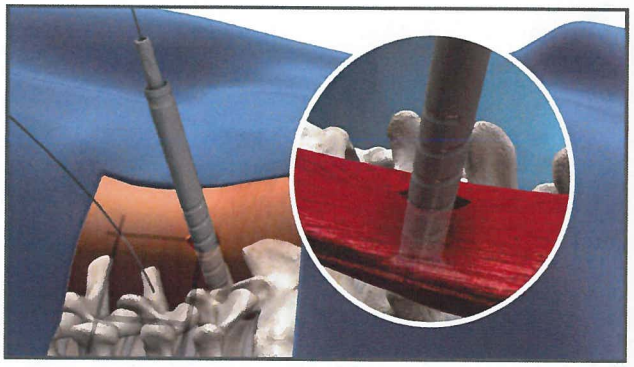


Figure 2

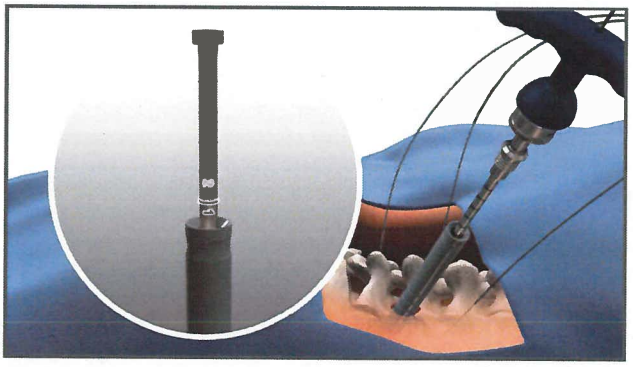


Figure 3



## PEDICLE PREPARATION

In preparation for tapping the pedicle, place the Inner Dilator over the Guidewire and advance to the pedicle (Figure 1). 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 (Figure 2).

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 (Figure 3). Use fluoroscopy to verify positioning of the Guidewire and Cannulated-Tap during the entire pedicle preparation step.

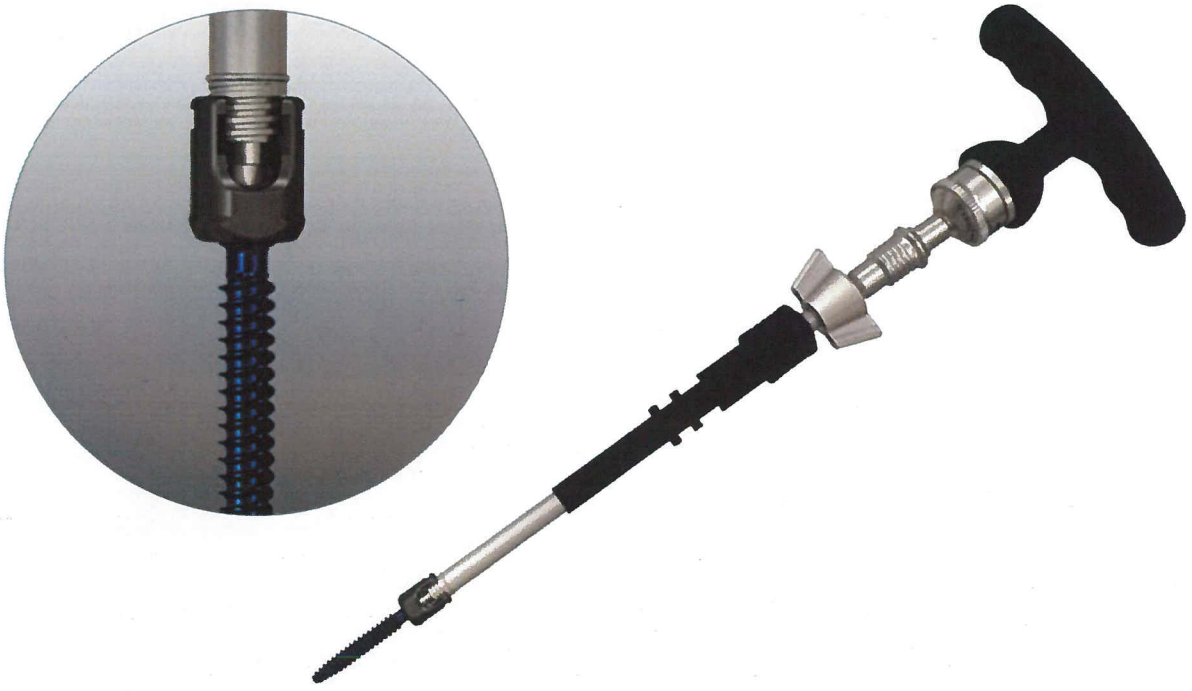
**NOTE**: Cannulated Taps are sized line-to-line.

# STEP 7 Surgical Technique Steps

POLYAXIAL SCREW INSERTER

RATCHETING T-HANDLE

RATCHETING PALM HANDLE



## SCREW INSERTION

When using an EVEREST MI 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 winged knob in a clockwise direction until the implant is securely attached to the Inserter. To disengage the Screw Inserter, gently turn the winged 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.



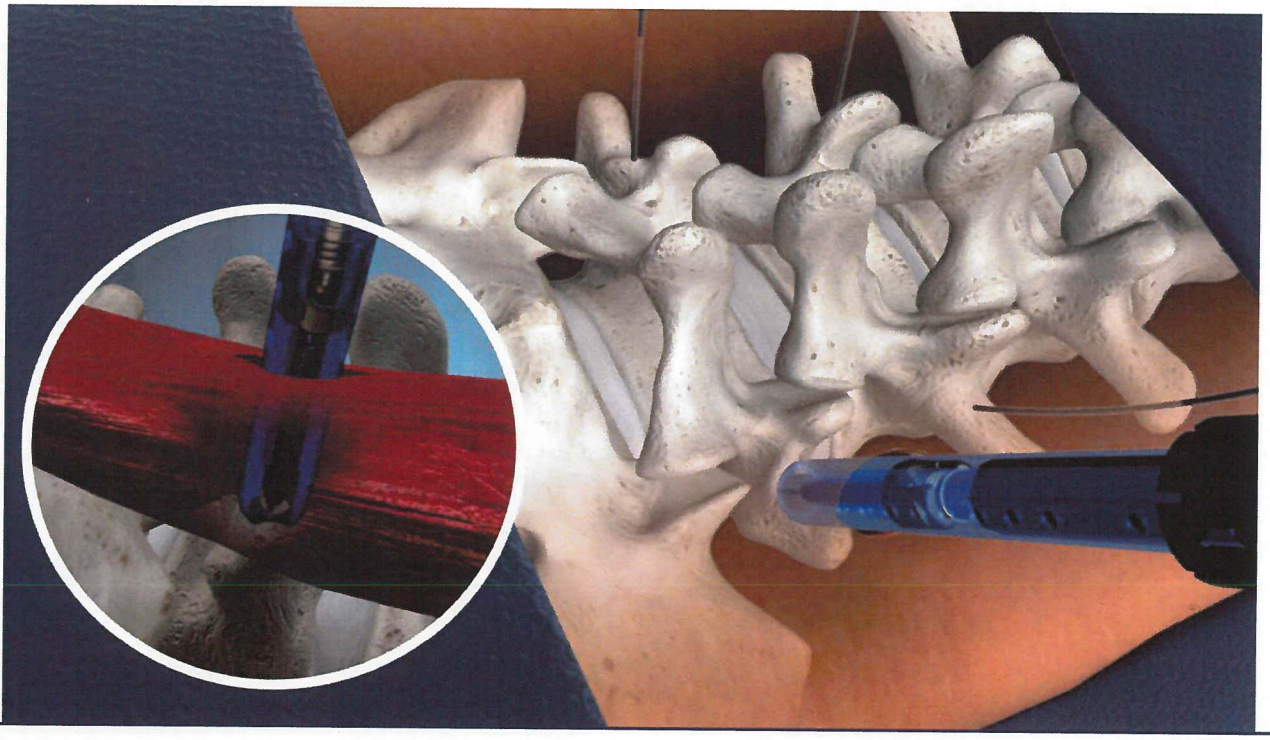
## LOADING THE SERENGETI® RETRACTOR

Assemble the SERENGETI Retractor over the screw. Attach the top two holes to the pegs on the black Anti-Rotation Sleeve of the Polyaxial Screw Inserter and slide the locking ring down to secure the Retractor.

STEP

# 9

# Surgical Technique Steps

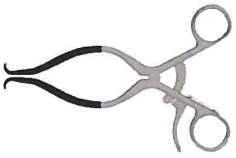


## INSERTING THE SCREW & THE SERENGETI® RETRACTOR

Advance the EVEREST MI 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 SERENGETI Retractor down to the pedicle to protect the soft tissue during screw insertion and insert the screw into the vertebral body. Use the external reference of the black Anti-Rotation Sleeve to ensure the screw is not advanced too far into the bone.

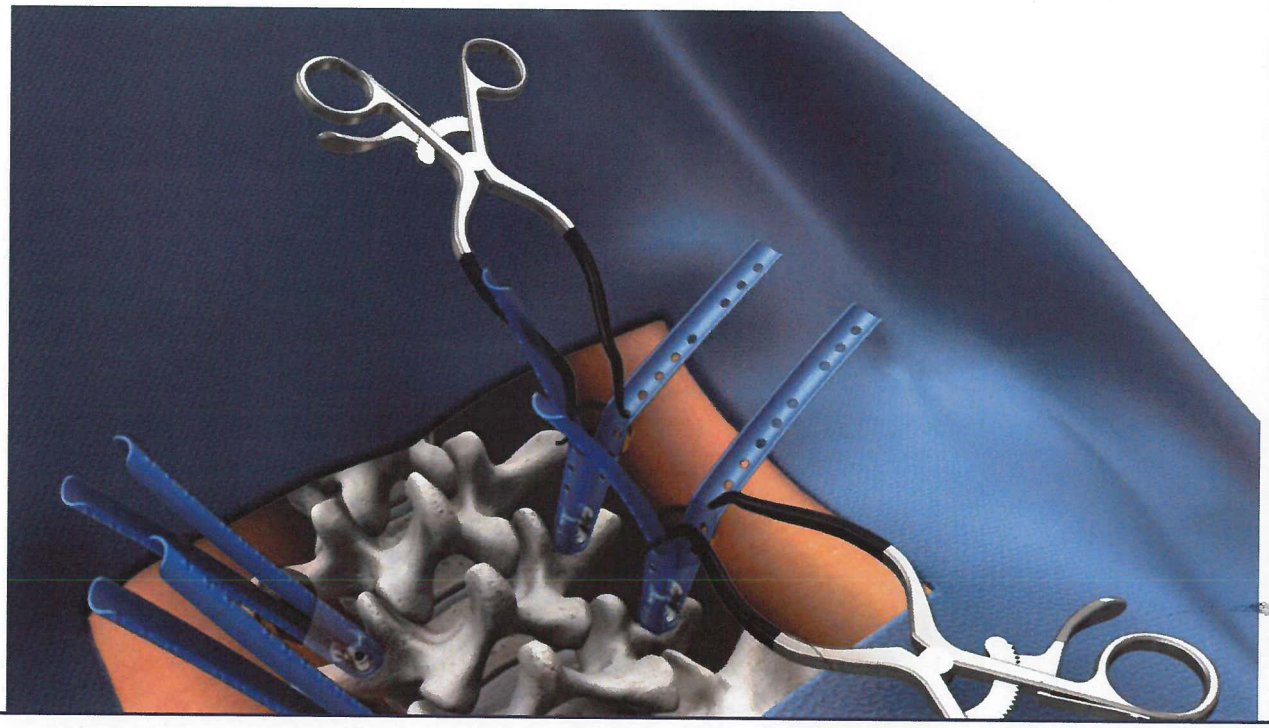
When the screw has reached the vertebral body, the black sleeve will meet the winged knob and the Guidewire may be removed. Once the screw is satisfactorily positioned, pull up on the black locking ring and spin the winged knob counter-clockwise to disengage the EVEREST MI Polyaxial Screw Inserter.

**NOTE:** The polymer design of the SERENGETI Retractor allows for neuromonitoring during screw placement.



GELPI RETRACTOR

SCREW HEAD ADJUSTER





## OPENING THE SERENGETI® RETRACTOR

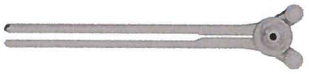
Gelpi Retractors are used to open the SERENGETI Retractors to allow direct visibility and access to the screw heads for rod insertion. The Screw Head Adjuster can be used to align the screw heads.

**NOTE:** For maximum visibility, place Gelpi Retractors one-to-two holes above skin level and open to an approximate 45° angle.

Repeat steps 5 – 10 for each pedicle requiring instrumentation.

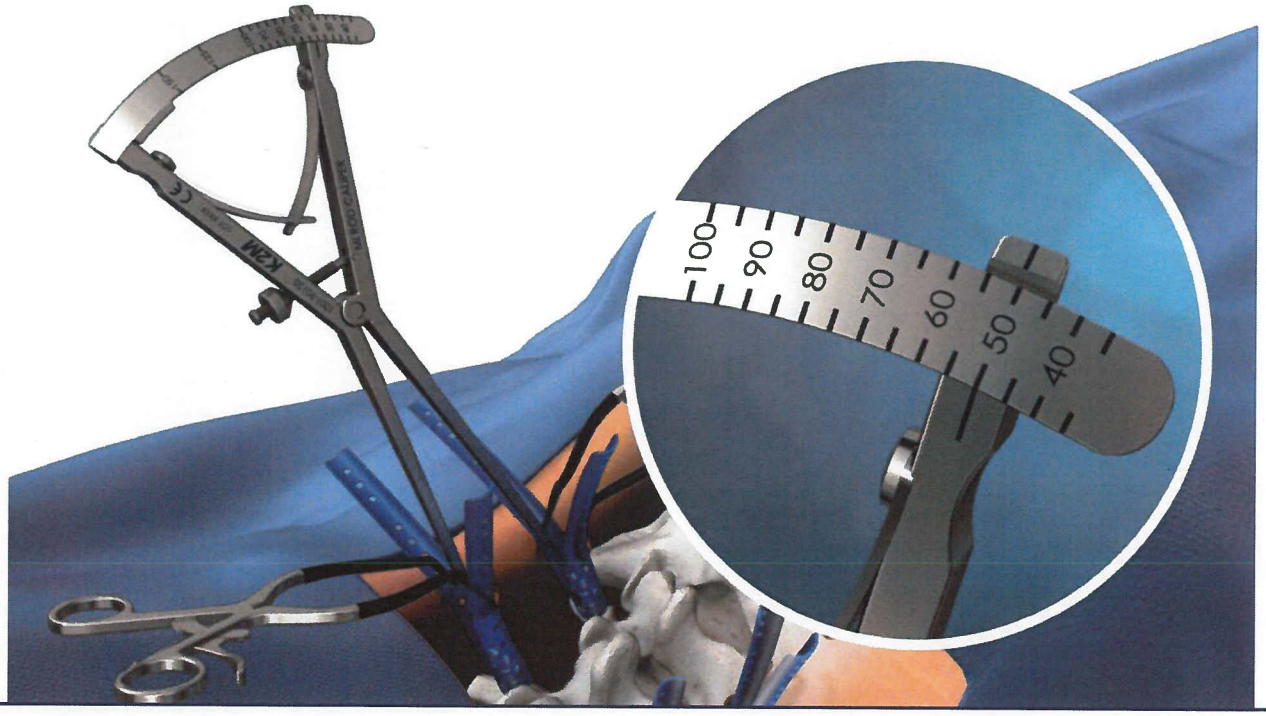
# STEP 11 Surgical Technique Steps

MI ROD CALIPER



FRENCH ROD BENDER

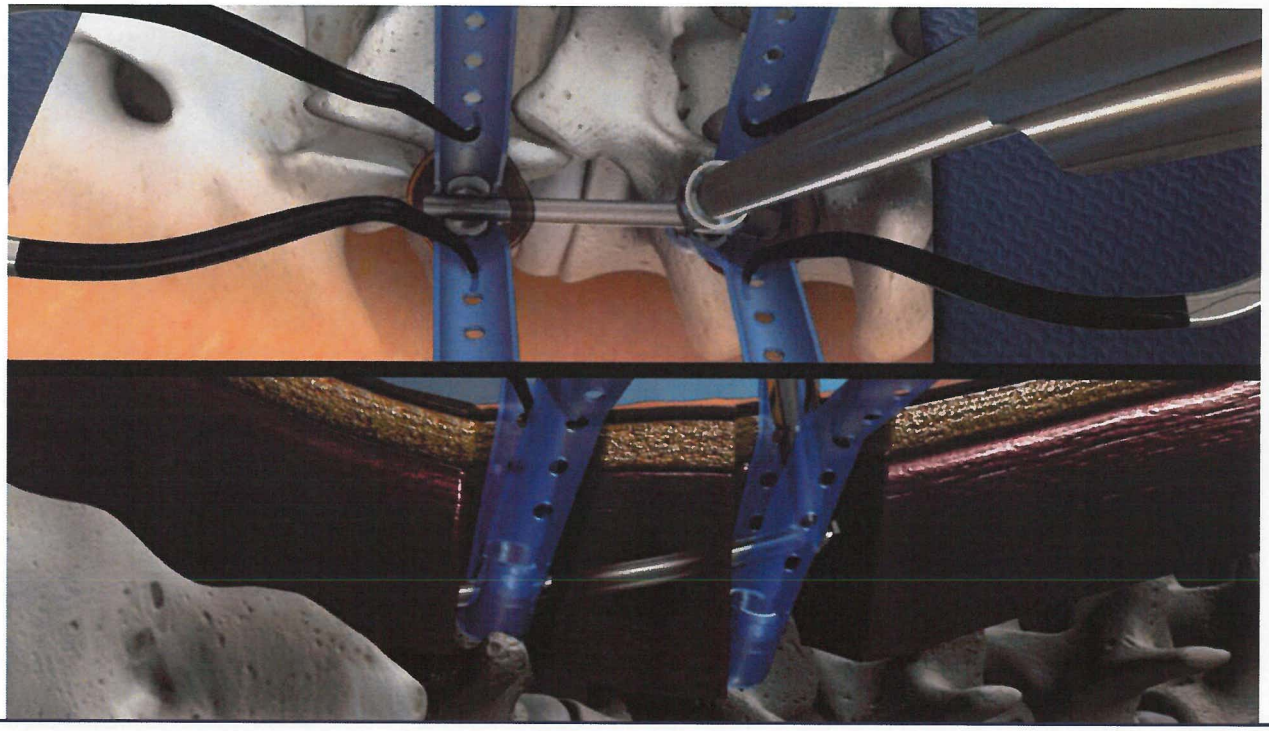
RODS




## ROD MEASUREMENT

The appropriate rod length can be determined by placing the ball tips of the 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 screw can accommodate both a Ø5.5 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).

MI ROD INSERTER

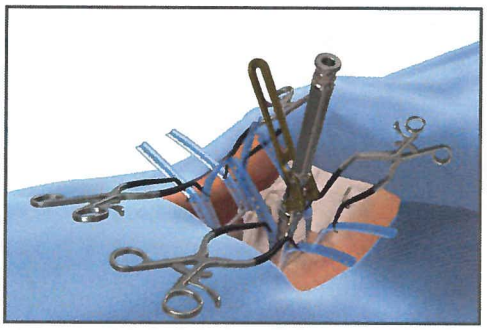




## ROD INSERTION

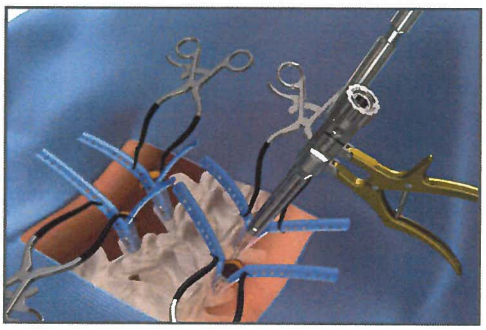
After properly measuring and selecting the rod, load it onto the MI Rod Inserter by rotating the dial at the proximal end to open, then secure the rod to the Inserter by tightening the dial. Initiating insertion of the rod near the saddle of the screw positions the rod for passage to the next screw location.

# Surgical Technique Steps



REDUCTION OPTION 1: MI Cicada™

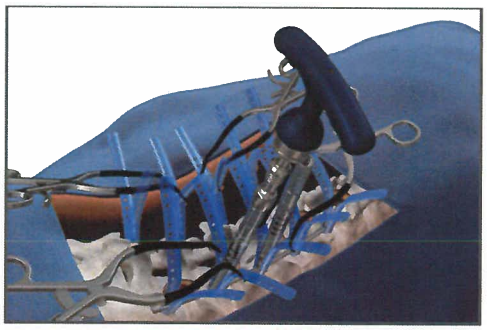
- 15 mm reduction
- Close handle to reduce rod



REDUCTION OPTION 2: Yellow Jacket™

- 20 mm reduction
- Fast action reduction: push locking bar forward & squeeze handles together
- Controlled reduction: turn proximal knob

**Tip:** To assist with engaging the Yellow Jacket™ onto the screw head, push the locking bar into the elbow of the front handle to prevent the instrument from prematurely reducing.



REDUCTION OPTION 3: MI Reduction Tunnel

**Tip:** Use any Quick Connect Handle with the Adapter Chuck to reduce the rod.



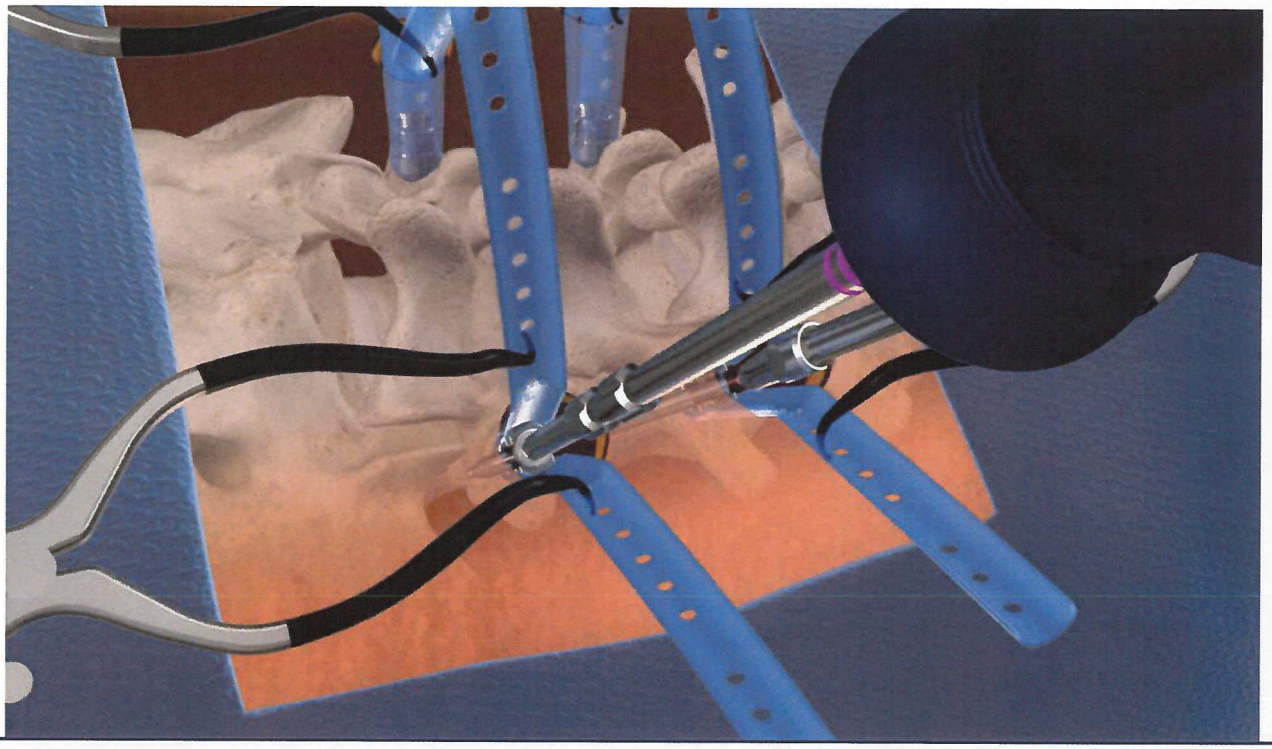
## ROD REDUCTION

Reducing the rod into the screw saddles can be accomplished by using a variety of instruments, including the Single Action Rod Reducer (MI Cicada™), MI Offset Reducer (Yellow Jacket™), or MI Reduction Tunnel. Position the reduction instrument into the SERENGETI Retractor and apply a downward force to engage the instrument to the screw head. Pull axially to confirm attachment.

PROVISIONAL SCREW DRIVER

TORQUE LIMITING WRENCH

TORQUE INDICATING WRENCH





## SET SCREW INSERTION & 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. If no reduction is necessary, the EVEREST set screw may be inserted into the EVEREST MI implant housing using a Set Screw Retaining Driver. 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 facilitates easy introduction and reduces the potential for cross-threading.

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

STEP

# 15

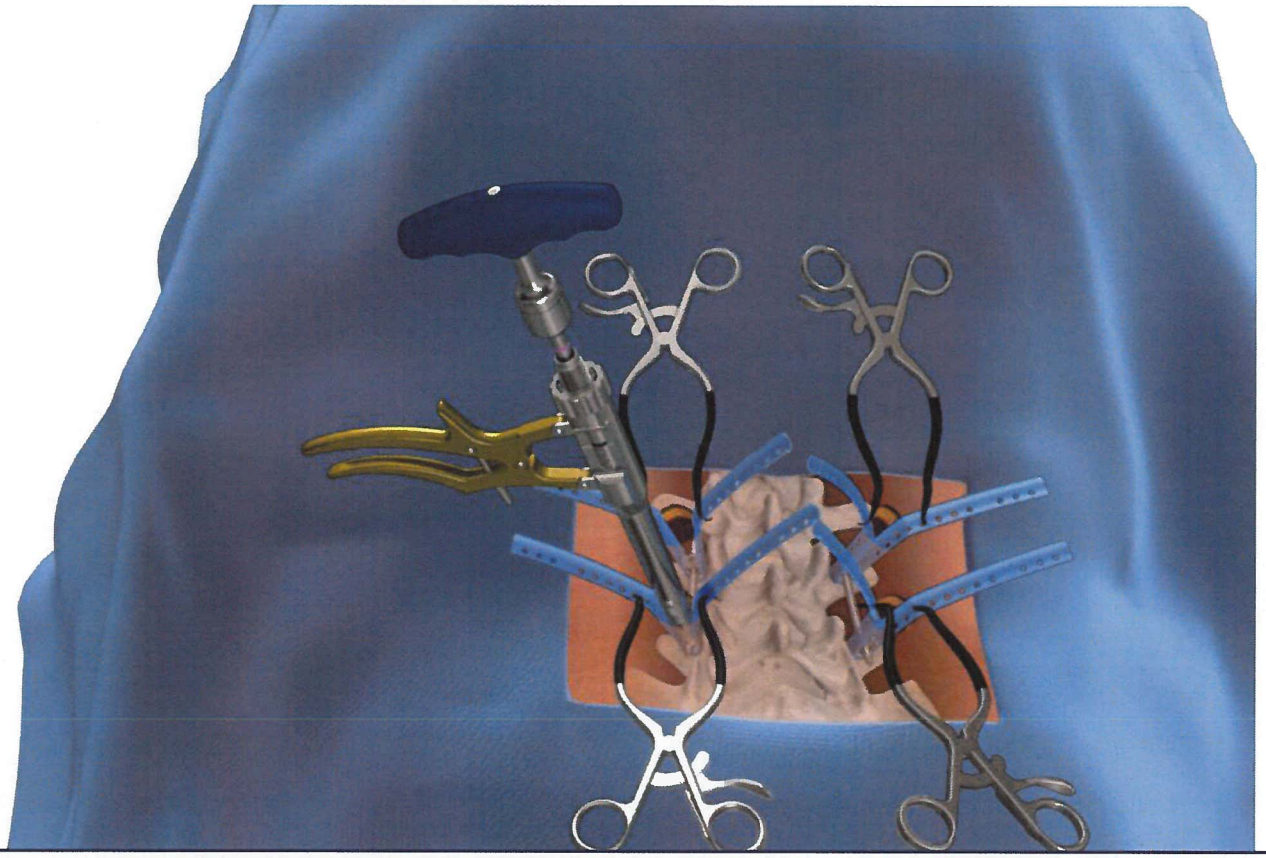
# Surgical Technique Steps

ANTI-TORQUE ALIGNMENT TUBE

ANTI-TORQUE HANDLE

TORQUE INDICATING WRENCH

MI CICADA™



## FINAL TIGHTENING

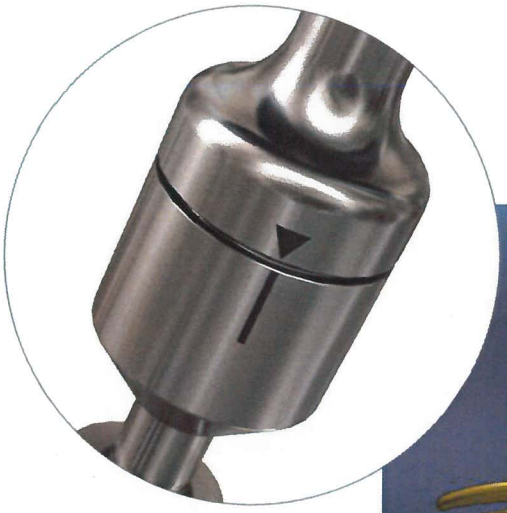
Final tightening of the EVEREST implants is achieved using either the Anti-Torque Alignment Tube, Cicada attached to the Anti-Torque Handle, or Yellow Jacket. Ensure the sliding mechanism of the Anti-Torque Handle is facing up to lock onto the instrument, slide the handle over the small diameter of the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

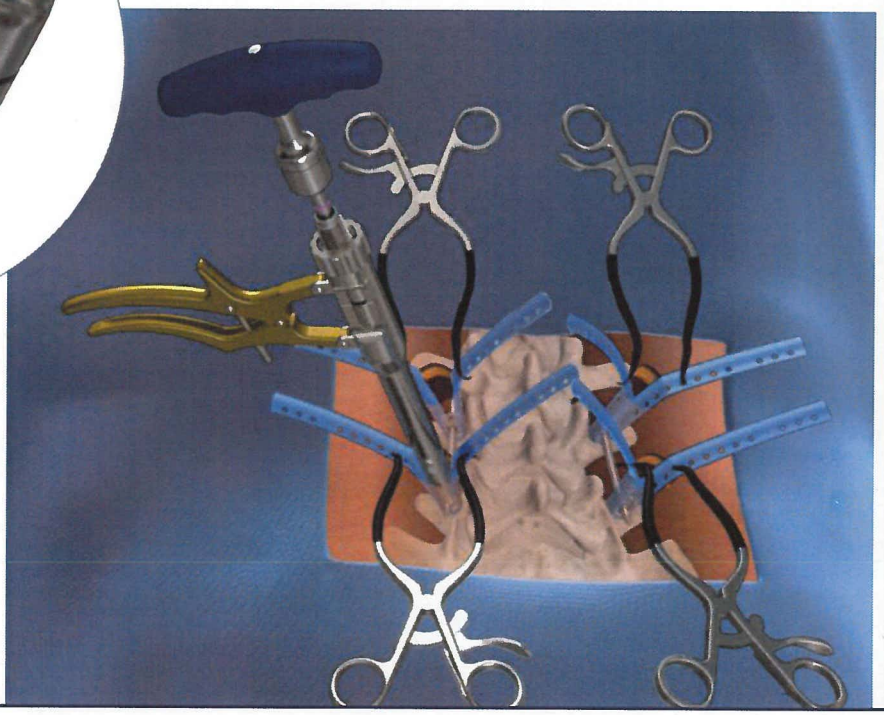
To disengage the Handle, pull back on the sliding mechanism and lift up. Insert the Torque Wrench into the top opening of the assembled Single Action Anti-Torque Rod Reducer or Anti-Torque Alignment Tube and Anti-Torque Handle before positioning the screw.

TORQUE LIMITING SHAFT

TORQUE INDICATING WRENCH

TORQUE LIMITING HANDLE





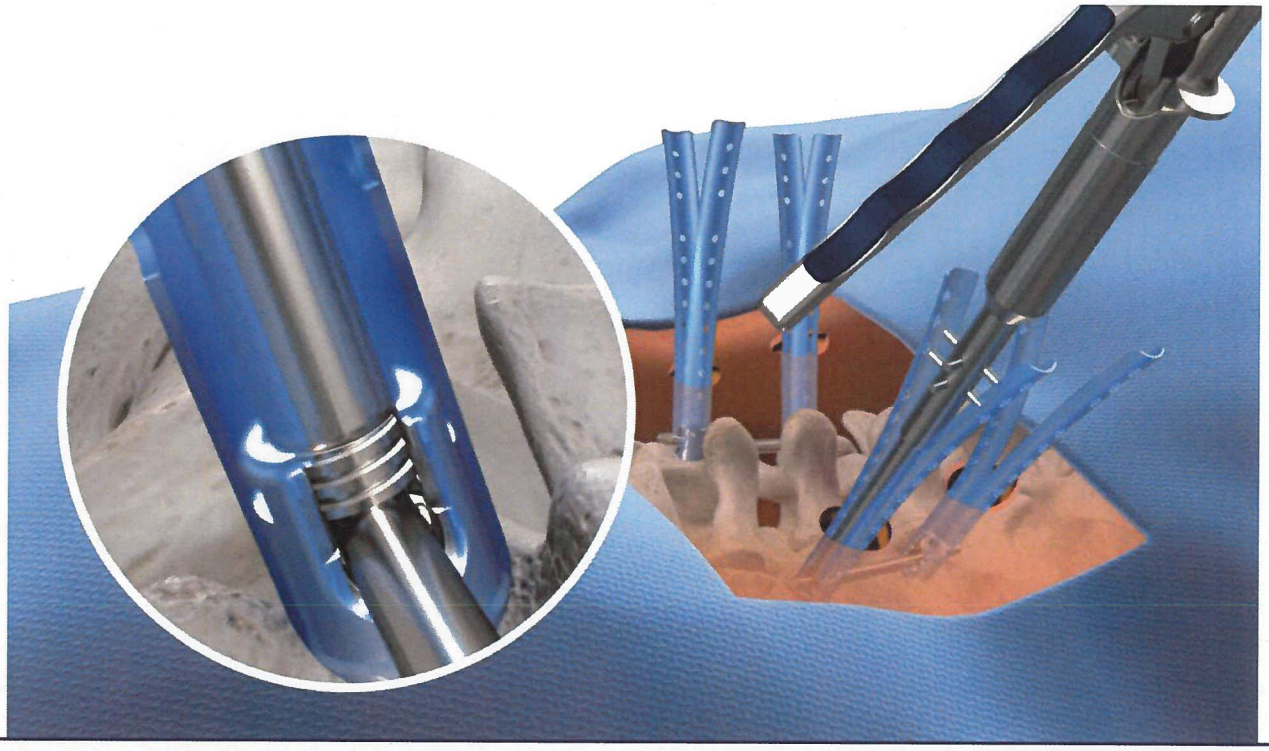


The Torque Indicating Wrench or assembled Torque Limiting Wrench and Torque Limiting Shaft both achieve 90 in-lbs of torque for final tightening.

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.

RETRACTOR EXTRACTOR



## RETRACTOR EXTRACTOR

The SERENGETI Retractor is designed with breakaway features for easy removal after locking the construct.

Position the Retractor Extractor onto the SERENGETI Retractor, ensuring the locking pin is securely placed into the set screw. Engage the second and third holes from the top of the SERENGETI Retractor to either of the pins on the shaft of the Retractor, depending on preference of handle orientation.

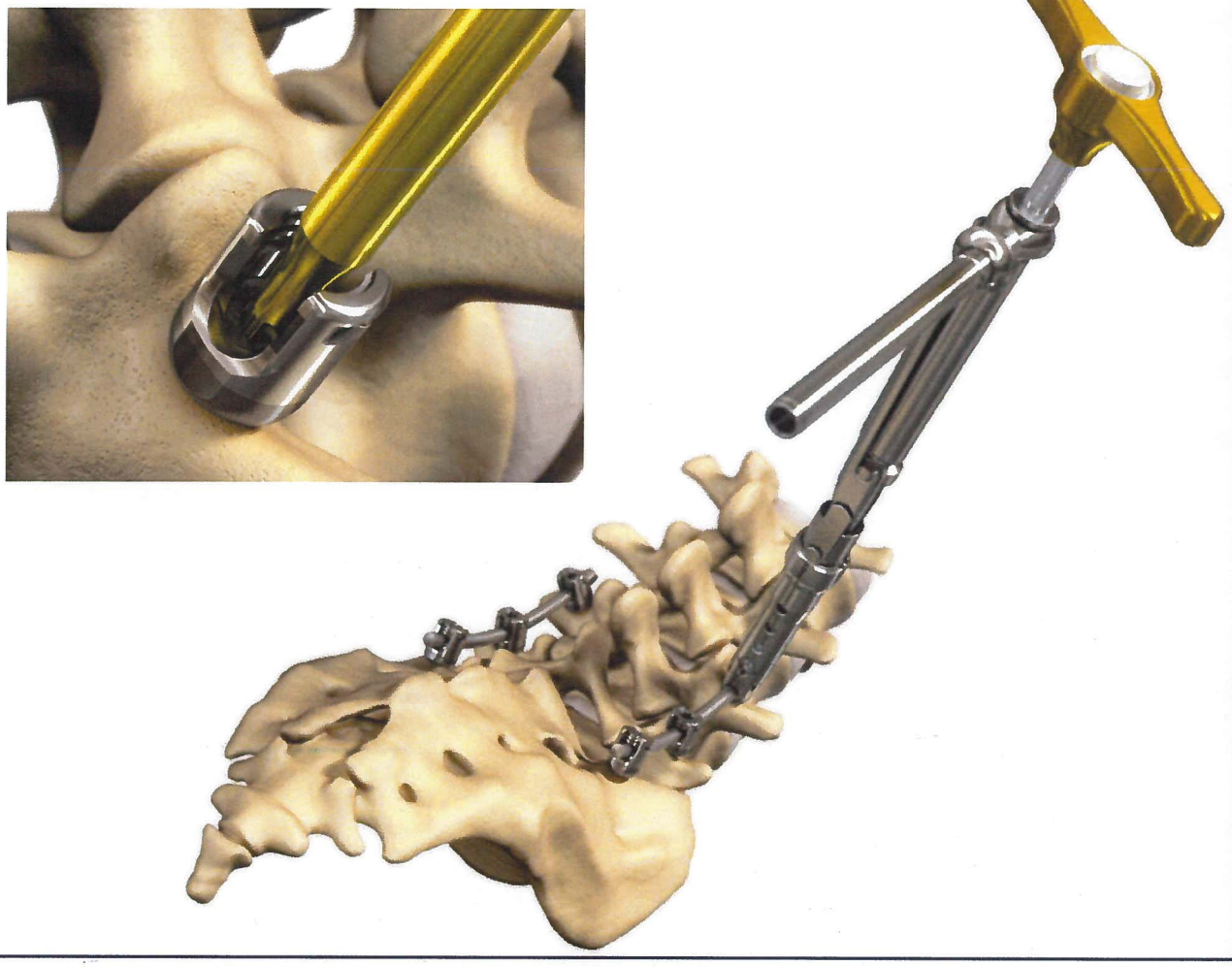
A rapid closing of the handle will separate the SERENGETI Retractor at the breakaway features.

SET SCREW
REMOVAL WRENCH

T-HANDLE



DRIVER, HEIGHT ADJUSTMENT



## 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 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.

# Notes

# EVEREST® MINIMALLY INVASIVE PRODUCT CATALOG

# Product Catalog

## IMPLANTS

**Ø5.5 – 8.5 mm SCREWS***
LENGTHS* (mm): 35, 40, 45, 50, 55

**EVEREST SET SCREW**


**Ø5.5 mm CONTOURED ROD**


**Ø6.0 mm CONTOURED ROD**



## IMPLANTS

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| EVEREST MI Screws | **See special note |
| EVEREST Set Screw | 2901-10001 |
| Ø5.5 mm Contoured Rod | 1001-E55xx |
| Ø6.0 mm Contoured Rod | 5101-E60xx |

*Additional sizes available by request.

**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 Spinal System implants.

## INSTRUMENTS

4.0 mm CANNULATED TAP

4.5 mm CANNULATED TAP

5.5 mm CANNULATED TAP

6.5 mm CANNULATED TAP

7.5 mm CANNULATED TAP

8.5 mm CANNULATED TAP

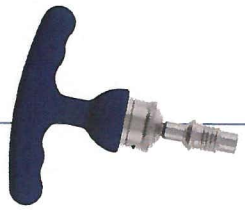


## INSTRUMENTS

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

# Product Catalog

## INSTRUMENTS



RATCHETING T-HANDLE

RATCHETING PALM HANDLE

CANNULATED LUMBAR PROBE

BALL TIP FEELER

POLYAXIAL SCREW INSERTER

INNER DILATOR

OUTER DILATOR

CANNULATED POWER DRIVER ATTACHMENT

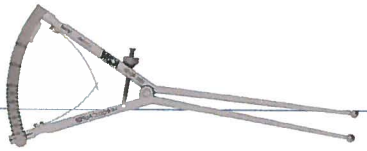
## INSTRUMENTS

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| Ratcheting T-Handle | 2901-90051 |
| Ratcheting Palm Handle | 2901-90050 |
| Cannulated Lumbar Probe | 5101-90014 |
| Ball Tip Feeler | 2801-90000 |

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| Polyaxial Screw Inserter | 5101-90000 |
| Inner Dilator | 5101-90008 |
| Outer Dilator | 5101-90009 |
| Cannulated Power Driver Attachment | 5101-90023 |

## INSTRUMENTS

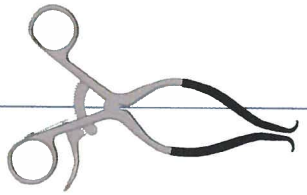
CANNULATED DRILL



ROD CALIPER

ROD INTRODUCING FORCEPS

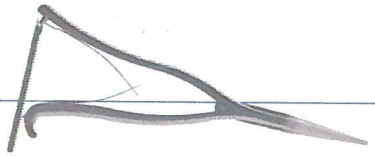
HEAD ADJUSTER



GELPIS

MI ANGLED COMPRESSOR

MI TUBE COMPRESSOR



MI ANGLED DISTRACTOR

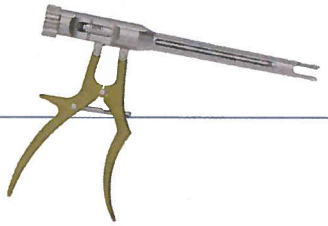


## INSTRUMENTS

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| Cannulated Drill | 1001-90053 |
| Rod Caliper | 1001-90135 |
| Rod Introducing Forceps | 101-90039 |
| Head Adjuster | 2901-90007 |

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| Gelpis | 1001-90079 |
| MI Angled Compressor | 1501-90011 |
| MI Tube Compressor | 5101-90026 |
| MI Angled Distractor | 5101-90014 |

## INSTRUMENTS



YELLOW JACKET

SINGLE ACTION ROD REDUCER

MI REDUCTION TUNNEL

ANTI TORQUE FOR MI REDUCTION TUNNEL

PROVISIONAL SCREWDRIVER SIZE 30, LONG

QUICK CONNECT ADAPTOR FOR MI REDUCTION TUNNEL

MI ROD INSERTER



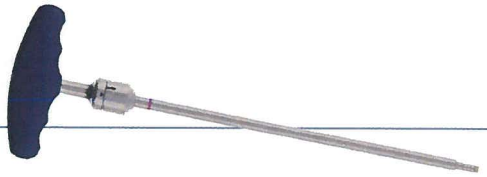
## INSTRUMENTS

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| Yellow Jacket | 5101-90012 |
| Single Action Rod Reducer | 5101-90016 |
| MI Reduction Tunnel | 5101-90013 |
| Anti Torque for MI Reduction Tunnel | 1001-90173 |
| Provisional Screw Driver Size 30, Long | 2901-90017 |
| Quick Connect Adaptor for MI Reduction Tunnel | 1001-90174 |
| MI Rod Inserter | 5101-90015 |

## INSTRUMENTS

**TORQUE LIMITING HANDLE 90 IN-LBS**

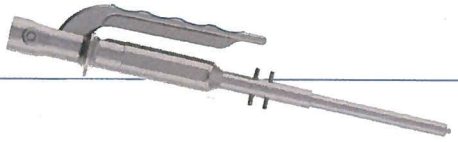
**DRIVER, HEIGHT ADJUSTMENT SIZE 25**



**TORQUE INDICATING WRENCH**

**ALIGNMENT TUBE**

**ANTI-TORQUE HANDLE**



**RETRACTOR EXTRACTOR**



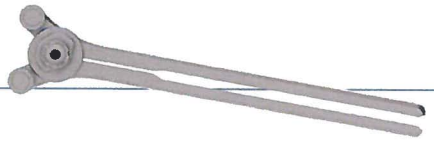
## INSTRUMENTS

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| Torque Limiting Handle 90 in-lbs | 2901-90133 |
| Driver, Height Adjustment, Size 25 | 5101-90107 |
| Torque Indicating Wrench | 2901-90018 |
| Alignment Tube | 2901-90015 |
| Anti-Torque Handle | 101-90051 |
| Retractor Extractor | 5101-90019 |

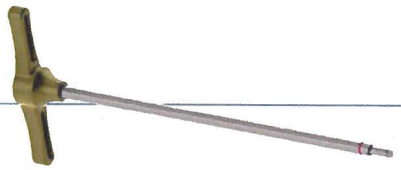
## INSTRUMENTS

**PROVISIONAL SCREWDRIVER SIZE 30, SHORT**

**TORQUE LIMITING SHAFT**



**Ø5.5/6.0 mm FRENCH ROD BENDER**



**EVEREST REMOVAL WRENCH**

**Ø5.5/6.0 mm RATCHETING ROD CUTTER**



## INSTRUMENTS

| DESCRIPTION | CATALOG NUMBER |
|---|---|
| Provisional Screwdriver Size 30, Short | 2901-90016 |
| Torque Limiting Shaft | 2901-90019 |
| Ø5.5/6.0 mm French Rod Bender | 2901-90025 |
| EVEREST Removal Wrench | 2901-90056 |
| Ø5.5/6.0 mm Ratcheting Rod Cutter | 5101-90042 |

## 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)**

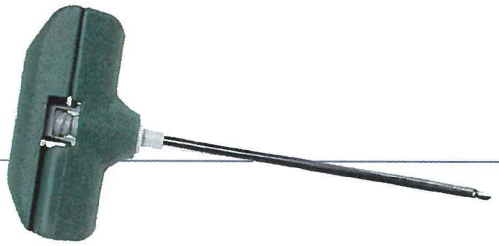
**PERFECT SCALPEL**



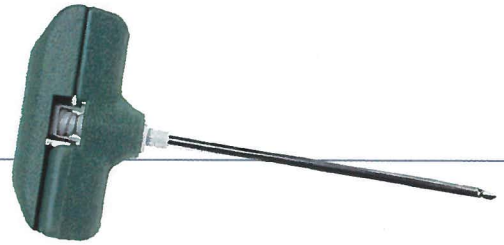
## STERILE PRODUCTS

| 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 |

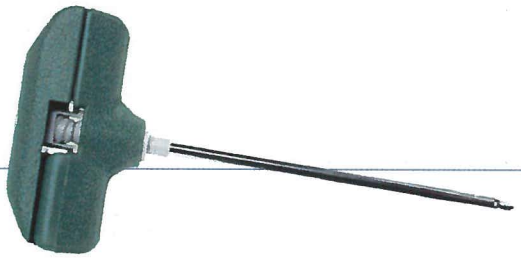
## STERILE PRODUCTS



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 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/ft$^3$ 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/ft$^3$) and porous material (10 lb/ft$^3$), 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)** | |
|---|---|---|
| *Substrate Density >>* | 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)

# 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 arthrodese 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
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# Notes

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K2-51-7000-02 Rev. 1
Actual device color may vary.
Consult product catalog for details.

CE
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