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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,

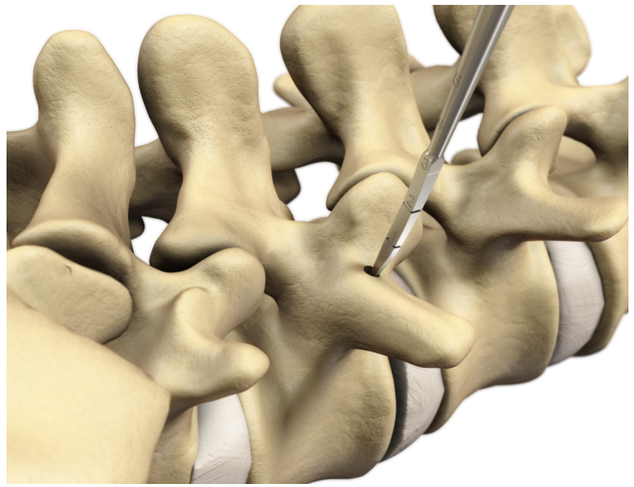
John P. Kostuik, MD
Co-Founder, Past Chairman & Chief Medical Officer – K2M, Inc.
Professor Emeritus – Johns Hopkins University, Orthopaedics & Neurosurgery
Past President – Scoliosis Research Society (SRS) & North American Spine Society (NASS)

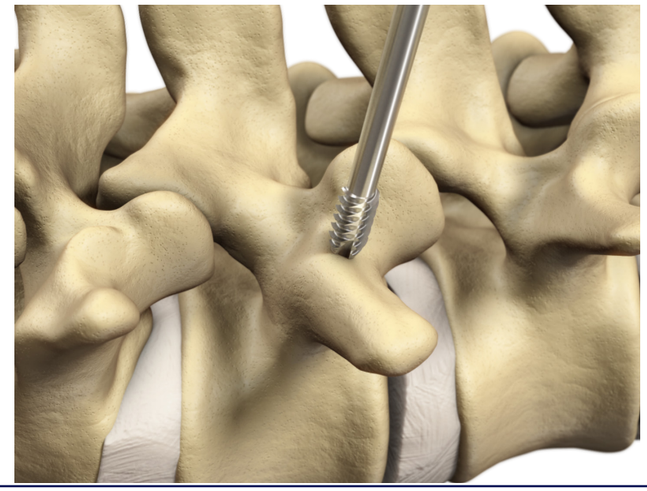
EVEREST® FENESTRATED SURGICAL TECHNIQUE

*See page 31 for Support Data

TAP

PROBE



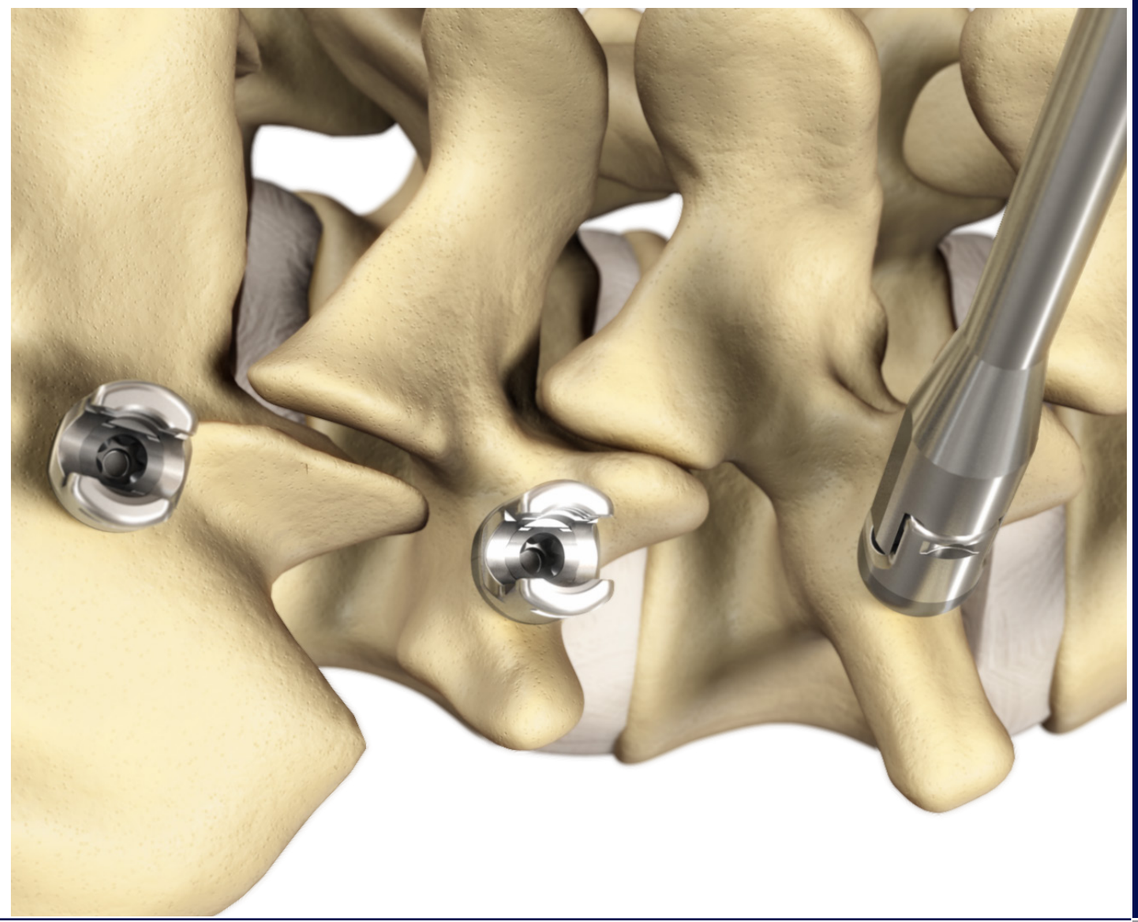


SCREW SITE PREPARATION

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.

SCREW HEAD ADJUSTER



SCREW HEAD ADJUSTMENT

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

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.

FRENCH ROD BENDER

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).

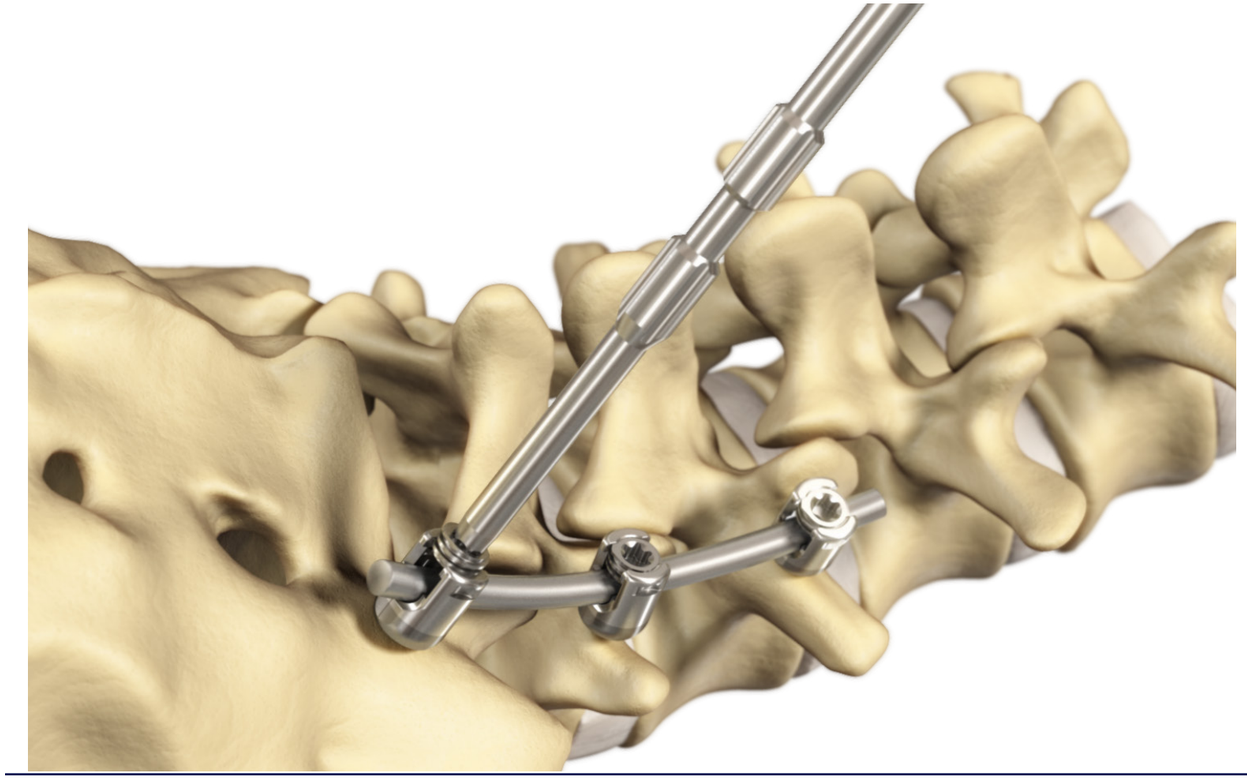
CICADA™

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.

PROVISIONAL SCREW DRIVER,
SIZE 30, LONG

PROVISIONAL SCREW DRIVER,
SIZE 30, SHORT



SET SCREW INSERTION & PROVISIONAL TIGHTENING

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

Due to its 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.

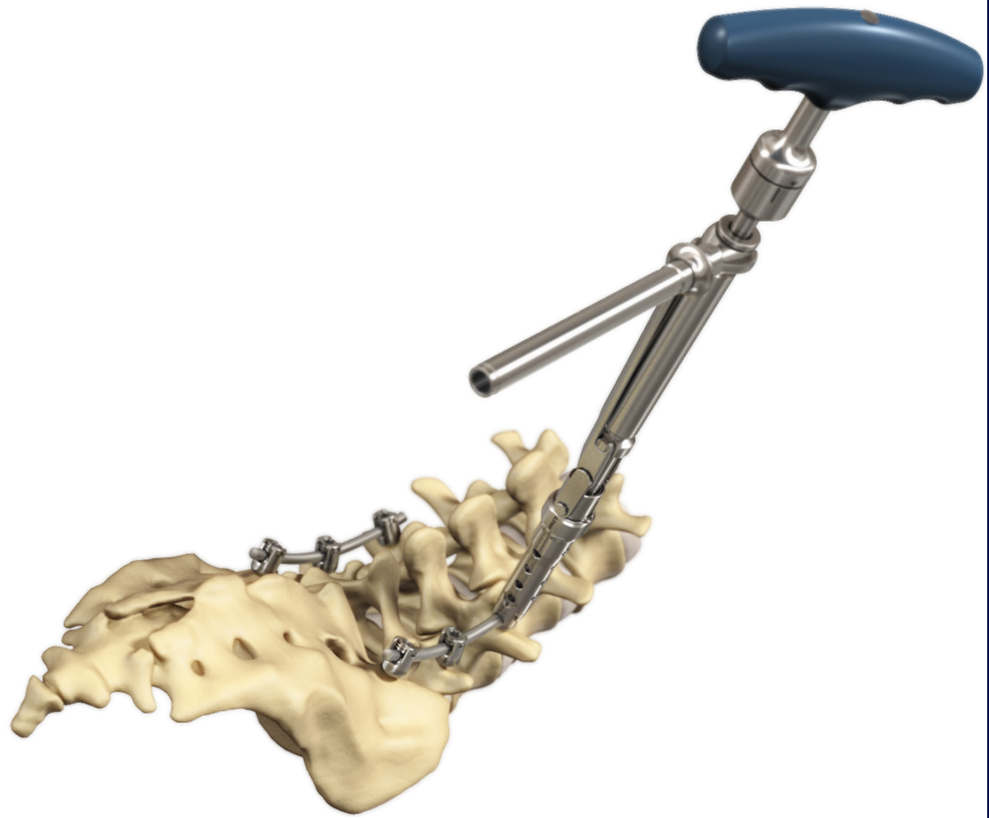
Threaded Rod Reducer for additional leverage.

proper position, turn the proximal handle in a clockwise direction until desired reduction

CICADA™

ANTI-TORQUE HANDLE

ANTI-TORQUE ALIGNMENT TUBE



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.

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EVEREST® FENESTRATED IMPLANT REMOVAL

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device and turn the handle of the instrument

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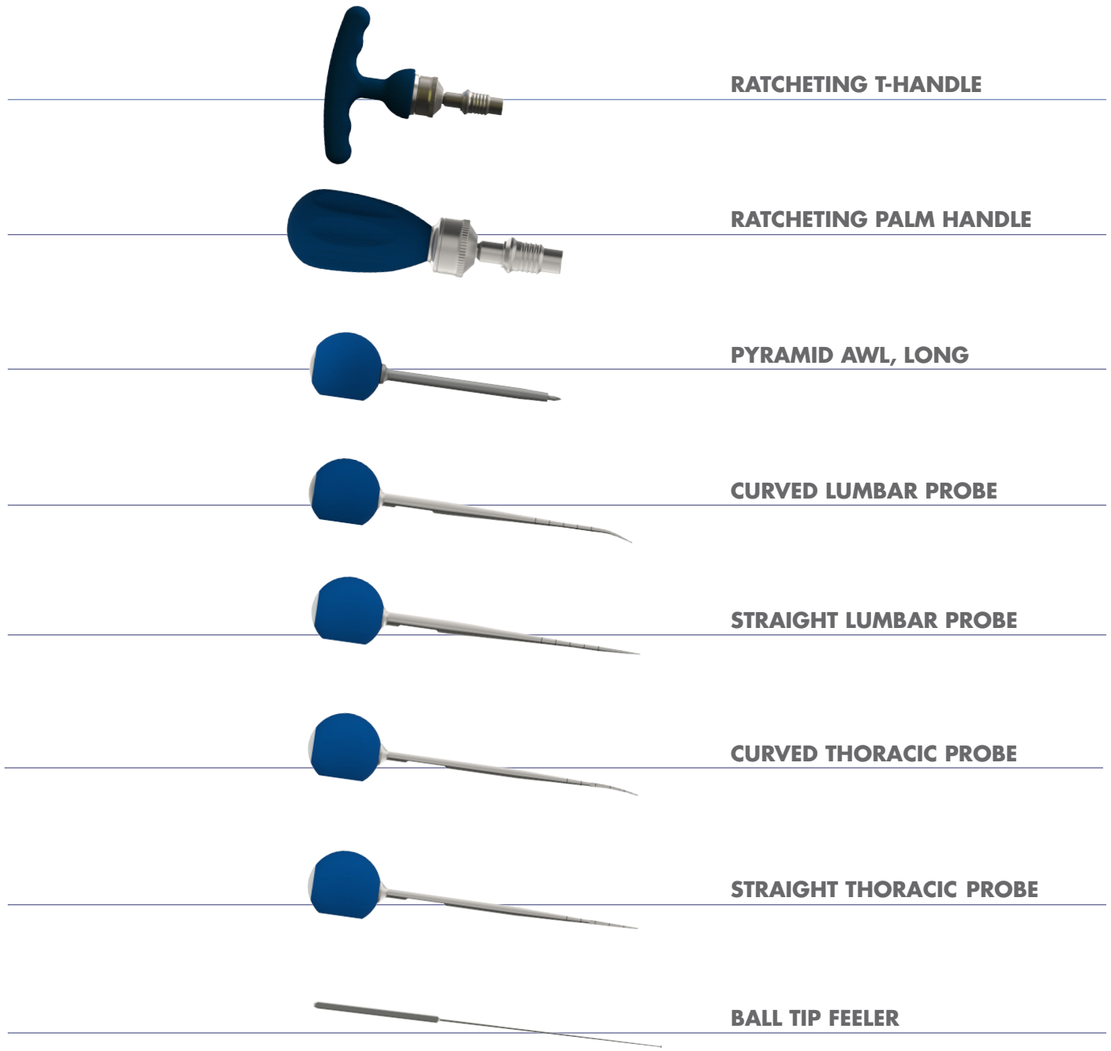
implants.

INSTRUMENTS



INSTRUMENTS

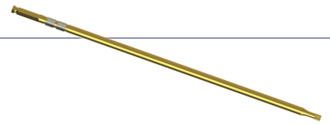
DESCRIPTION	CATALOG NUMBER
Ratcheting T-Handle	2901-90051
Ratcheting Palm Handle	2901-90050
Pyramid Awl, Long	2801-90008
Curved Lumbar Probe	2901-90031

DESCRIPTION	CATALOG NUMBER
Straight Lumbar Probe	2901-90032
Curved Thoracic Probe	2901-90033
Straight Thoracic Probe	2901-90034
Ball Tip Feeler	2801-90000

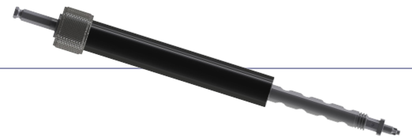
INSTRUMENTS

DEPTH GAUGE

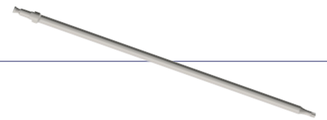
TORQUE LIMITING HANDLE, 90 IN-LBS



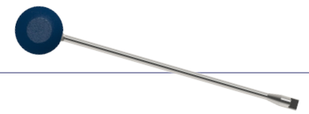
SCREW REMOVAL TOOL, SIZE 25



POLYAXIAL SCREW INSERTER



TORQUE LIMITING SHAFT



HEAD ADJUSTER

INSTRUMENTS

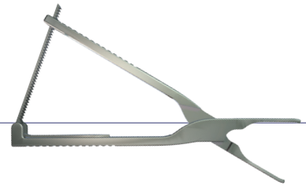
DESCRIPTION	CATALOG NUMBER
Depth Gauge	101-90011
Torque Limiting Handle, 90 in-lbs	101-90219
Screw Removal Tool, Size 25	801-90001
Polyaxial Screw Inserter	2901-90006
Torque Limiting Shaft	2901-90019
Head Adjuster	2901-90007

INSTRUMENTS

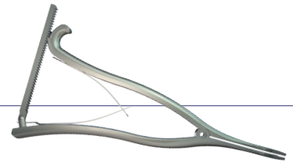
CICADA™

ROD FORK

ROD INTRODUCING FORCEPS



COMPRESSOR



DISTRACTOR

THREADED ROD REDUCER

QUICK CONNECT ADAPTER
FOR THREADED ROD REDUCER

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

Injector Alignment Guide	5001-90018

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

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/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)

procedures for assuring sterility.

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

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K2M Inc. 751 Miller Dr. SE
Leesburg, VA 20175
1.571.919.2000

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