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Aversion Pedicle Screw System

Spinal Fixation for Open and
Minimally Invasive Surgical Procedures

Surgical Technique Guide
and
Instructions for Use

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The Aversion Pedicle Screw System

This technique guide provides instructions, directed towards the operating surgeon, to safely install the Aversion Pedicle Screw System. The surgeon must be experienced in the placement of pedicle screws, and understand all of the steps explained in this guide prior to attempting installation.

The complete instructions for use, including sterilization, are included at the end of this guide.

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Clinical Background

Pedicle screw systems have become standard practice within the field of spine surgery. Although many of the problems associated with the early use of pedicle screws have been addressed, such as facet joint irritation and screw breakage, the problem of nerve root injury continues to be a concern for the implanting surgeon.

Inappropriate contact between the threaded shaft of a pedicle screw and the associated nerve root can provide a spectrum of complaints including pain, numbness, weakness and functional impairment. Even with the addition of fluoroscopy, CT guidance, and neuro-monitoring, this problem has persisted. Successful placement of a pedicle screw can be hindered by the size of the patient, the size and shape of the pedicle, the hardness of the bone, as well as the quality of available imaging. On occasion, even the most experienced spine surgeon has faced this issue.

Persistent symptoms from a misdirected pedicle screw may require an additional operative procedure. The overall incidence of misplaced pedicle screws has been debated extensively in the medical literature, however, the Aversion Pedicle Screw System is the first pedicle screw to address this issue directly.

The Aversion Pedicle Screw System has been specifically modified to reduce the risk of contact between the threading of the screw and the nerve root. The screw contains a non-threaded section which can be strategically placed to face towards the nerve root. The surgeon is able to control both the depth and rotation of the non-threaded portion of the screw. Visual and fluoroscopic validation during insertion increases the confidence of the surgeon.

The Aversion Pedicle Screw System may be implanted through an open or minimally invasive technique.

K7 LLC is pleased to introduce the Aversion Pedicle Screw System. We believe strongly that this product provides the patient and surgeon advantages not available with other systems. We hope that surgeons will embrace the technology, and we welcome any feedback regarding the design, instrumentation, and usefulness of the system.

Surgical Implants

The Aversion Pedicle Screw System can be installed via a traditional open or minimally invasive technique. The implants include long arm, cannulated pedicle screws, connecting rods and set screws.

The long arm pedicle screws have break away tabs and a cannulation of 1.5 mm. Both fully threaded and modified versions are available in diameters of 5.5-8.5mm, and lengths ranging from 37.5-55mm. The large selection of implants allows for proper sizing for virtually all patients.

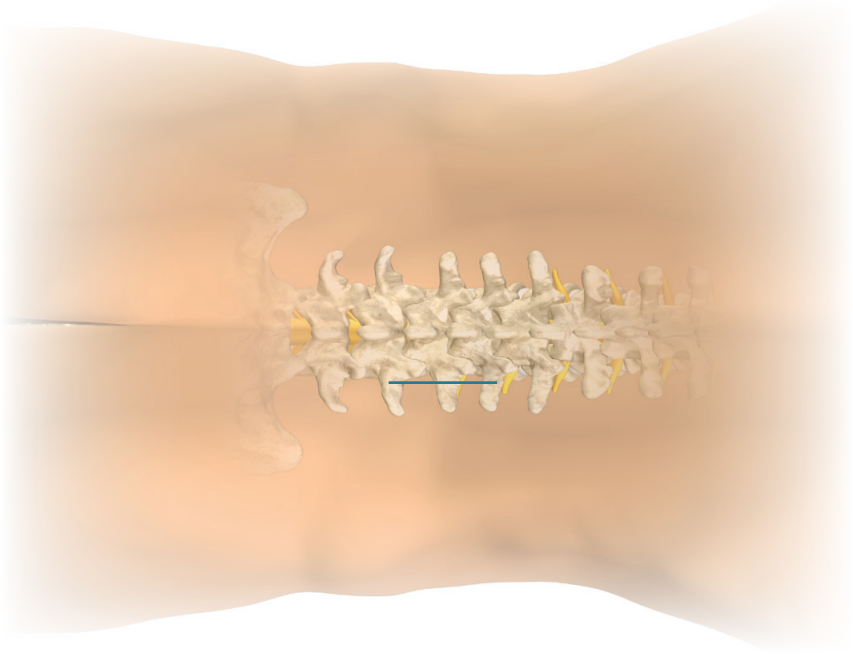
The connecting rods are 5.5mm in diameter and come in sizes 30-250mm.

Set Screws are precision machined to prevent stripping.

Surgical Technique

Placing the Pedicle Screws

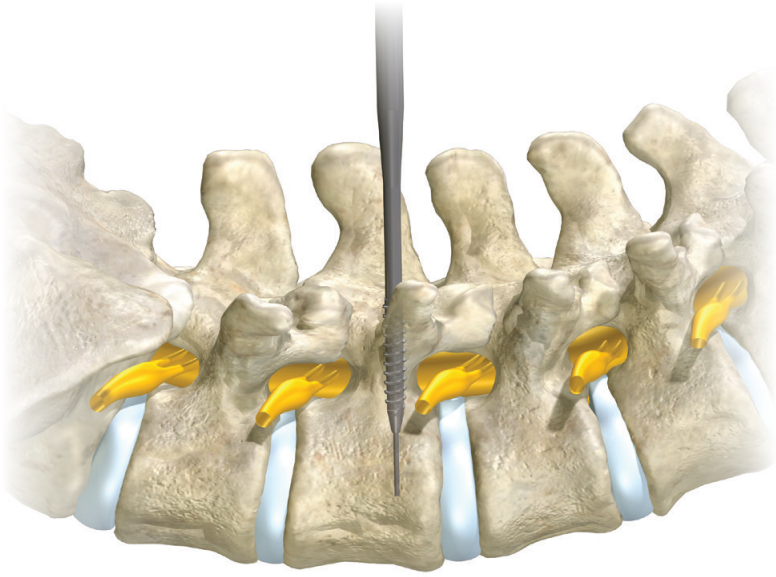
1. Identify the location of the most cephalad and caudal pedicles on an AP fluoroscopic view. Make a connecting incision 1-2cm lateral to the pedicles through the skin and fascia.



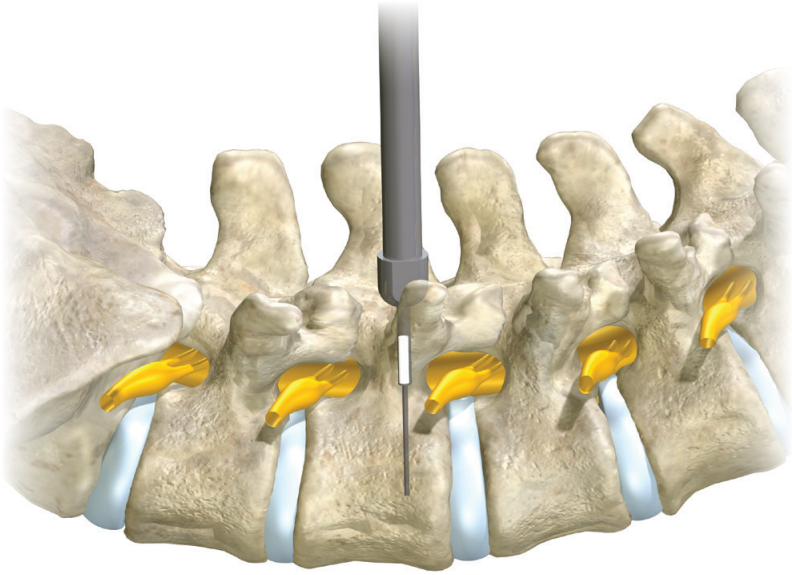
2. Insert a Vertebroplasty Needle (not supplied) at the desired starting point for the pedicle screw. The starting point is usually located at the junction of the transverse process and facet joint. Care should be taken not to damage any facet joint not to be included in the fusion. Using fluoroscopic guidance, advance the needle through the pedicle and into the vertebral body.

3. Replace the needle with a Guide Wire. Advance the Guide Wire into the vertebral body. Unintentional advancement of the VP Needle, or Guide Wire, can potentially be dangerous. With the Guide Wire secured, the VP needle is removed. Repeat these steps to place guide wires into each pedicle to be instrumented.

4. Advance the appropriate Tap over the Guide Wire, through the pedicle, and into the vertebral body. Tapping past the end of the Guide Wire may cause bone to become wedged in the end of the tap causing the Guide Wire to lose its purchase. Remove the Tap, without disturbing the Guide Wire.



5. Slide the Depth Gauge down over the Guide Wire until a bony stopping point is encountered. The end of the Depth Gauge mimics the shape of the tulip head of the pedicle screw.



Surgical Technique

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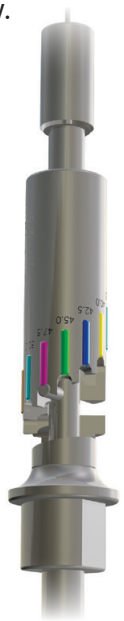
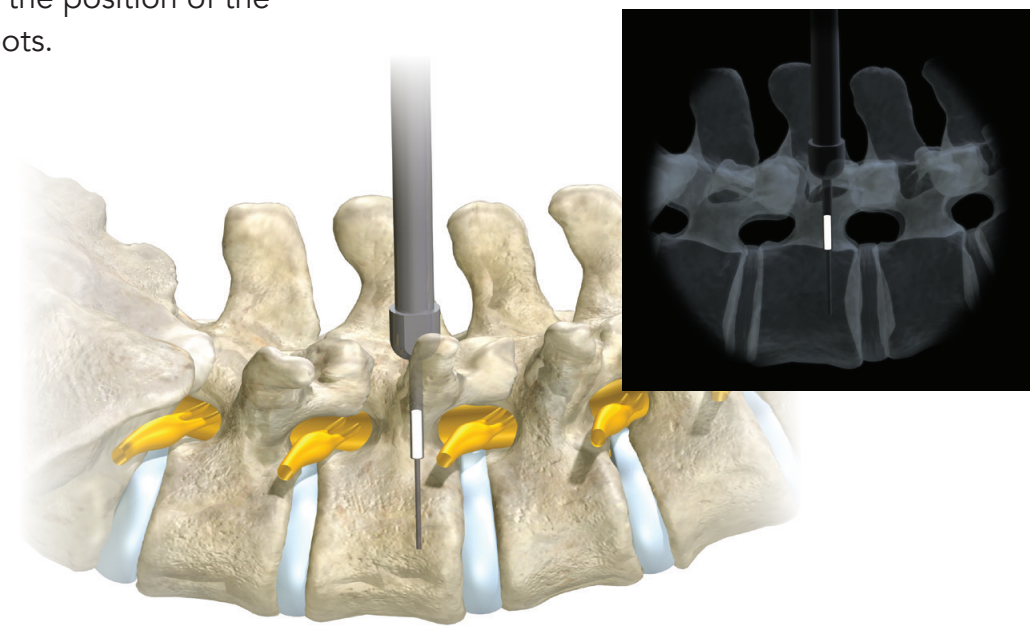


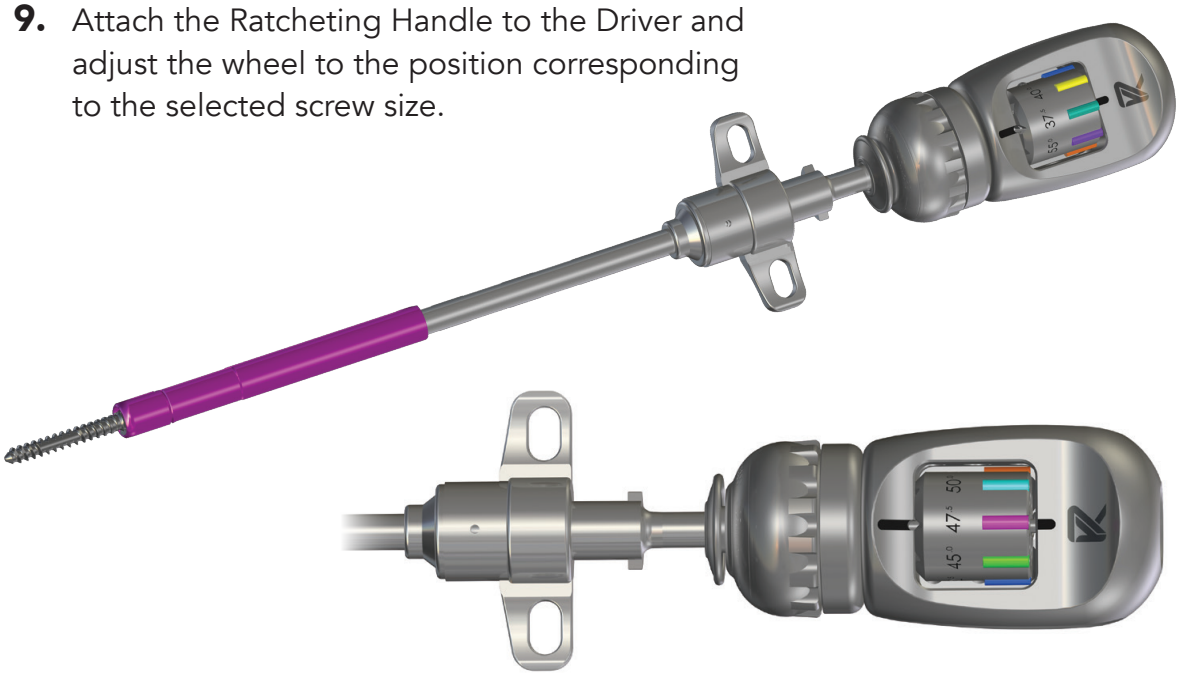
6. Adjust the depth gauge until the radiographic marker spans the presumed location of the associated nerve root. The most anterior part of the nerve root on a lateral fluoroscopic view is usually found at the junction of the posterior wall of the vertebral body and the pedicle. Ideally, the marker should be adjusted to a few millimeters beyond the posterior wall of the vertebral body on the lateral view. Preoperative scans should be consulted to verify the position of the nerve roots.



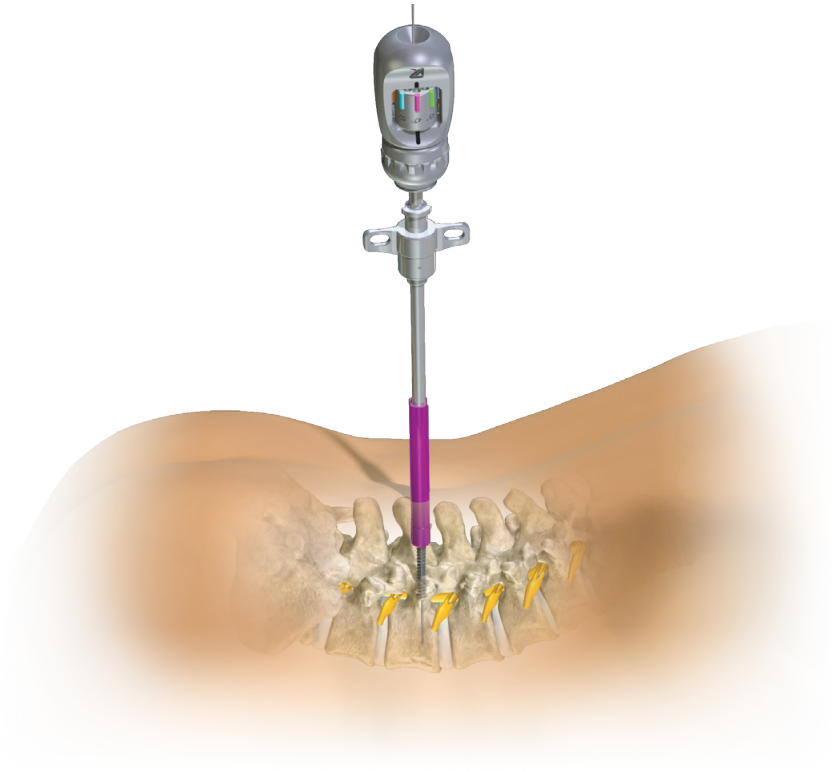
7. Select the proper length screw by reading the depth gauge.

8. Attach the screw to the driver. The head of each modified pedicle screw has a directional cutout that will only accept the Driver in one orientation. The Driver has an indicator just above the wings which corresponds to the non-threaded portion of the screw shaft. After the screw has been securely connected to the Driver, confirm the relationship between the rotational indicator on the Driver and the non-threaded portion of the screw.

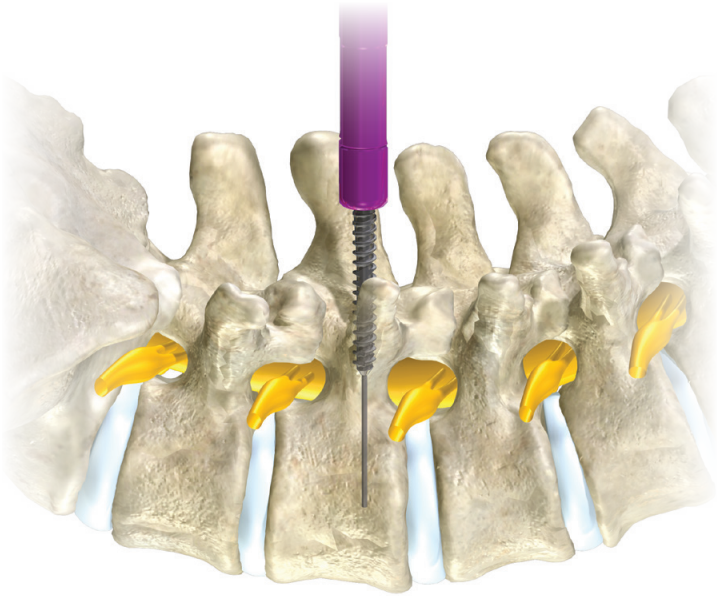
9. Attach the Ratcheting Handle to the Driver and adjust the wheel to the position corresponding to the selected screw size.



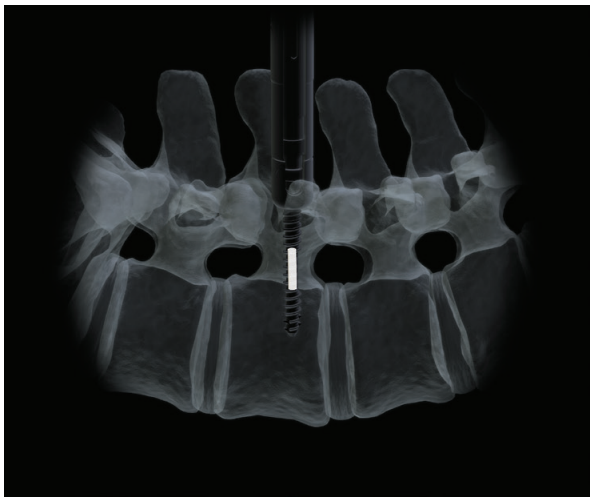
10. Advance the pedicle screw over the Guide Wire.



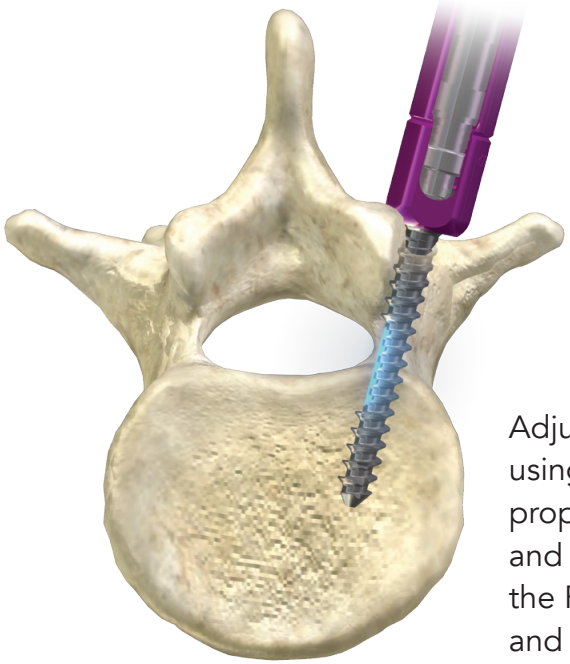
11. Once the screw has passed through the pedicle, replace the Guide Wire with the Radio-Opaque Marker. The marker is passed down through the Ratcheting Handle, through the Driver, and into the screw. Make certain the marker is properly seated in the ratcheting handle.



12. Continue to advance the pedicle screw under fluoroscopy until the Radio-Opaque Marker spans the presumed location of the nerve root.



13. With the screw inserted to the desired depth, rotate the screw to direct the non-threaded portion of the screw towards the nerve root. Visually confirm this using the rotational indicator on the Driver. The non-threaded portion covers approximately 150 degrees of the screw shaft, or approximately 5 hours on a clock.



Adjustments to the depth must be made using complete revolutions to maintain proper rotational alignment. After the depth and rotation have been optimized, remove the Radio-Opaque Marker from the driver, and disconnect the Driver from the screw.

Surgical Technique

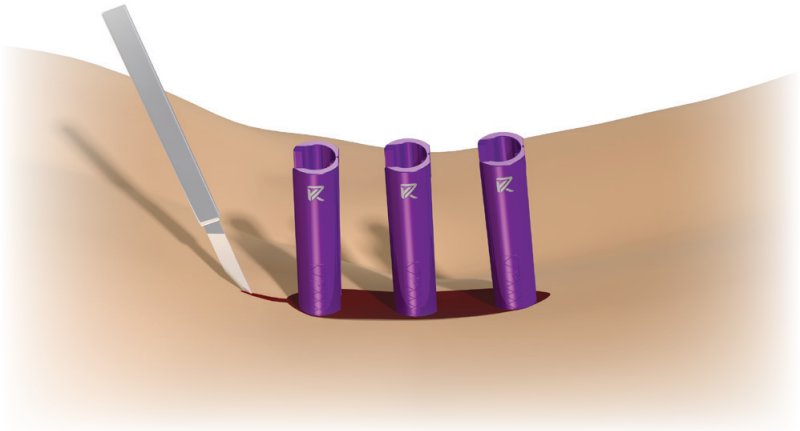
Passing and Securing the Connecting Rod

After the pedicle screws have been properly placed with regard to depth and rotation, the connecting rod can then be passed.

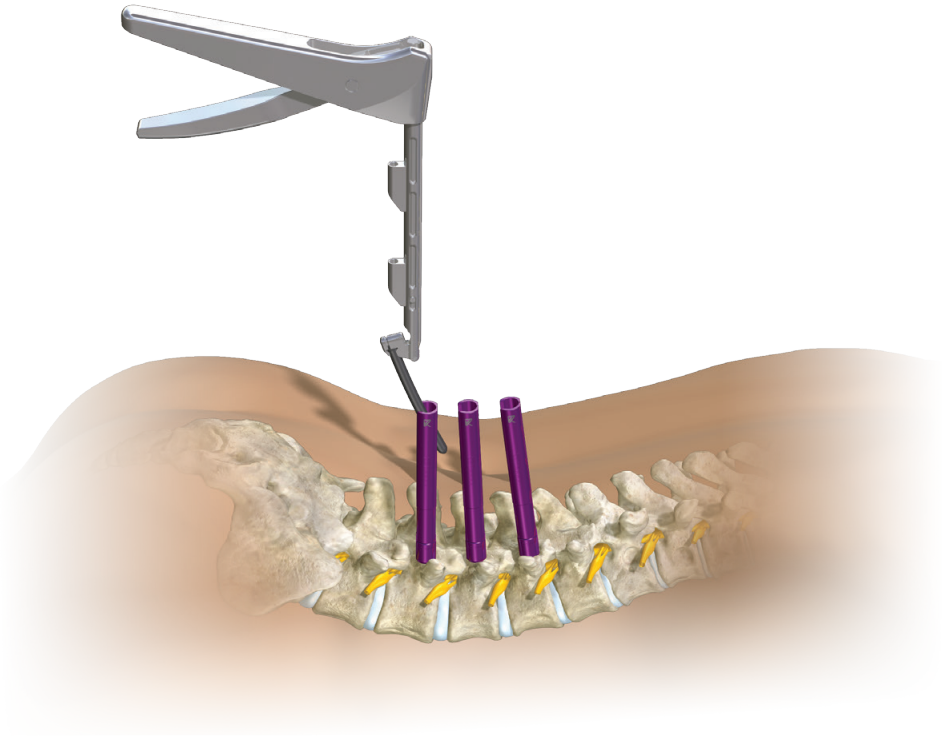
1. Select an appropriate length rod. The rod should be long enough to connect the screws with several millimeters of margin at each end.

2. Attach the heel of the rod to the Rod Delivery Tool using the clamping mechanism. Adjust the rotation of the rod as desired and tighten the clamping mechanism with the Driver. Remove the Driver.

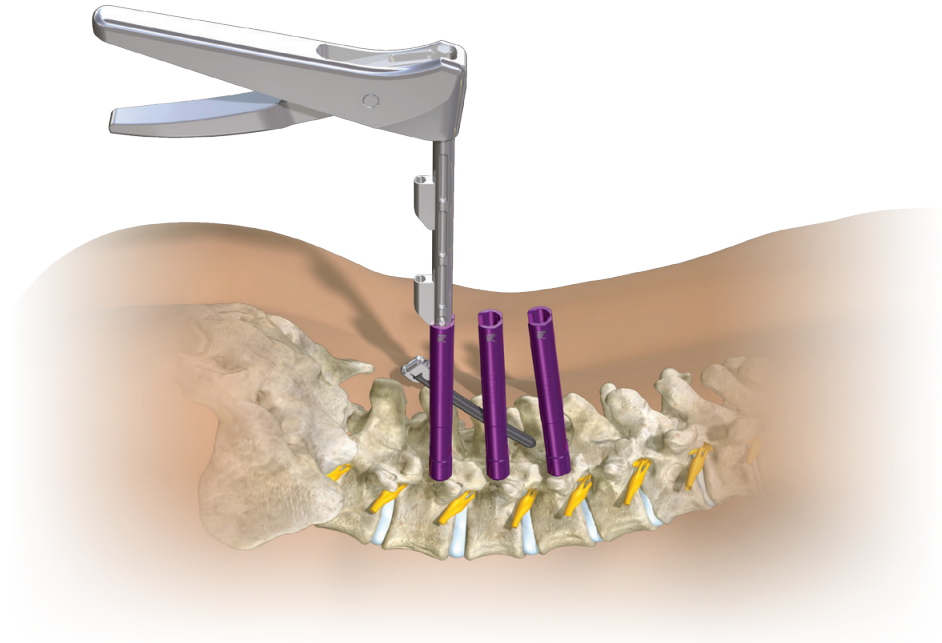
3. Before placing the rod, extend the incision to provide a pathway for the rod to be delivered.



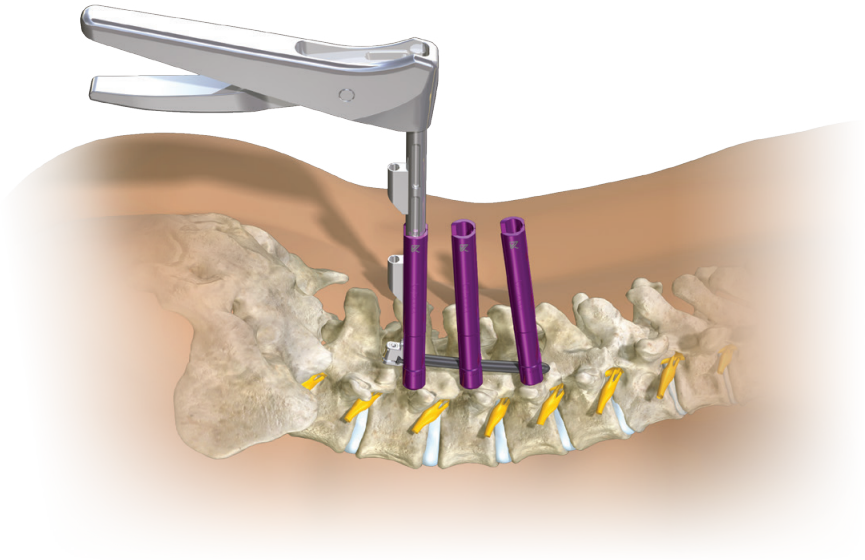
4. Position the tip of the rod completely through the walls of the first tower.



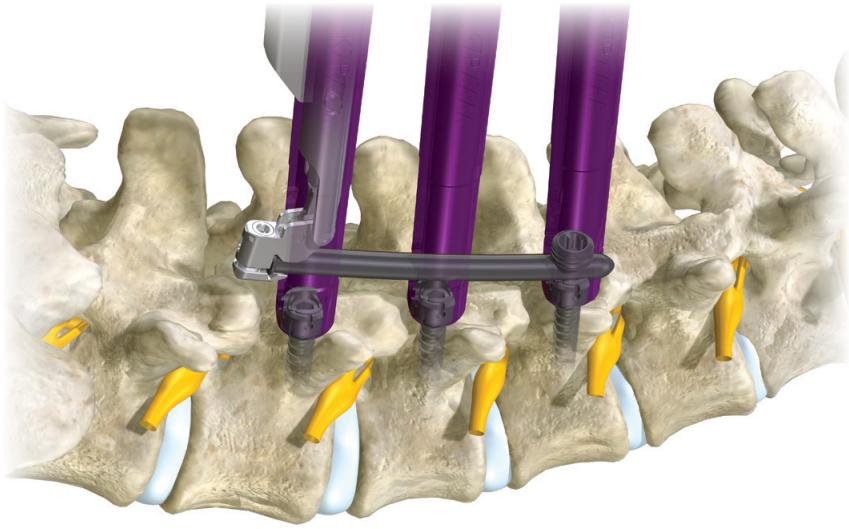
5. Advance the rod to the level of the tulip heads, then rotate the rod using the trigger mechanism to pass the rod through the second screw.



6. Continue to advance and rotate the rod until the rod has passed through each screw in the construct.

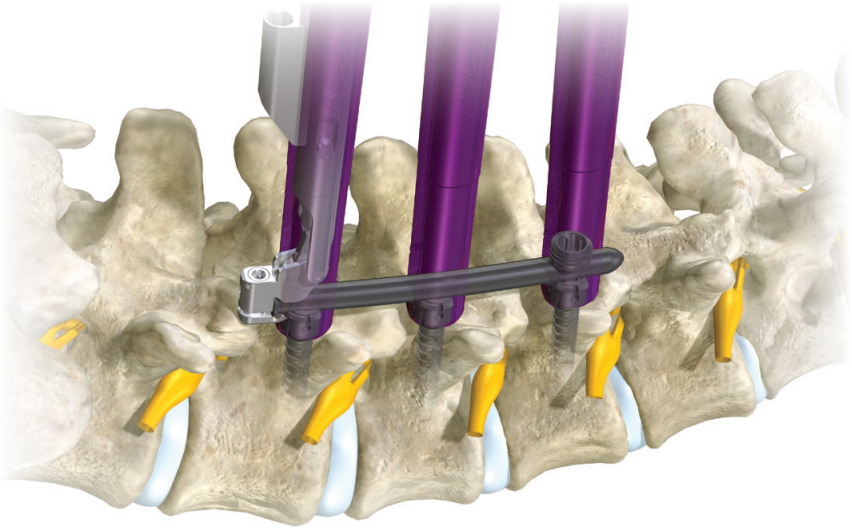


7. Before attempting to seat the heal of the rod into the tulip of the first screw, secure the opposite end of the rod with a locking nut.



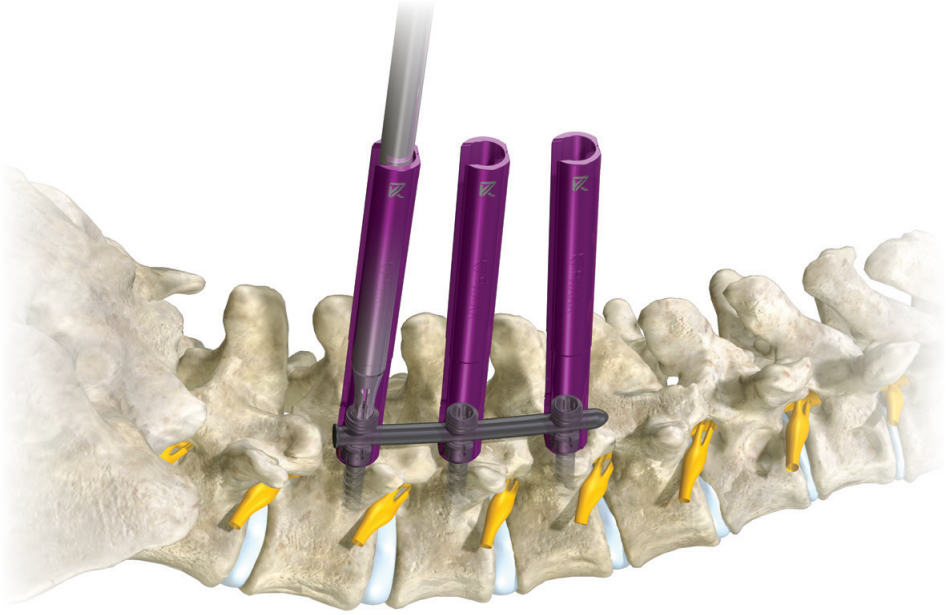
WARNING - If the rod is not seated as described, the construct should be modified by contouring the rod and repeating the rod delivery process. Failure to do this can alter the alignment of the spine during final tightening, or cause the screws to pull out of the bone.

8. After the locking nut has been placed, rotate the rod down into each of the sequential tulip heads, finishing with the first. In its final resting position, the rod should be firmly seated into all of the tulip heads.



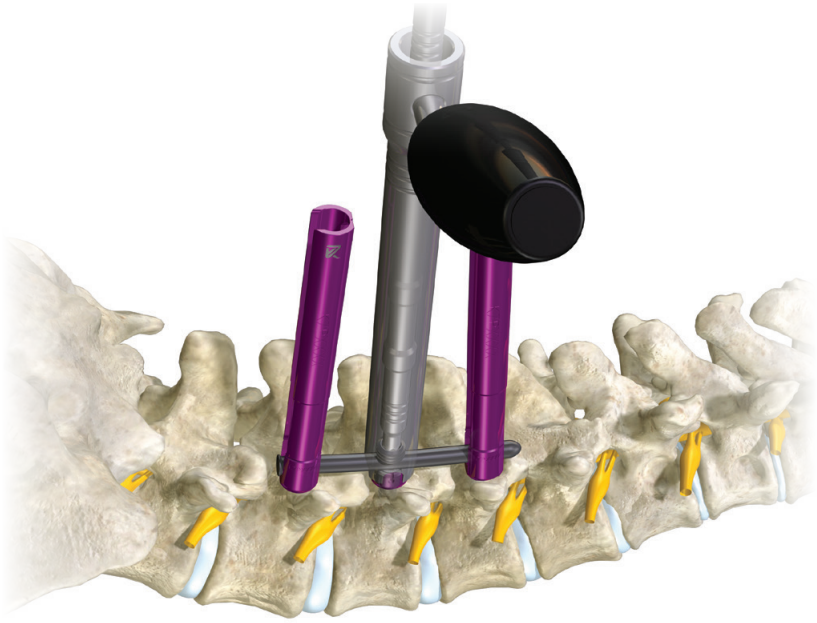
9. Additional locking nuts are placed to secure the rod.

10. Loosen and remove the rod delivery tool. Place the final locking nut.

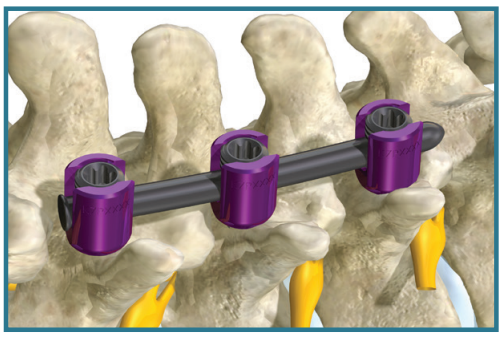


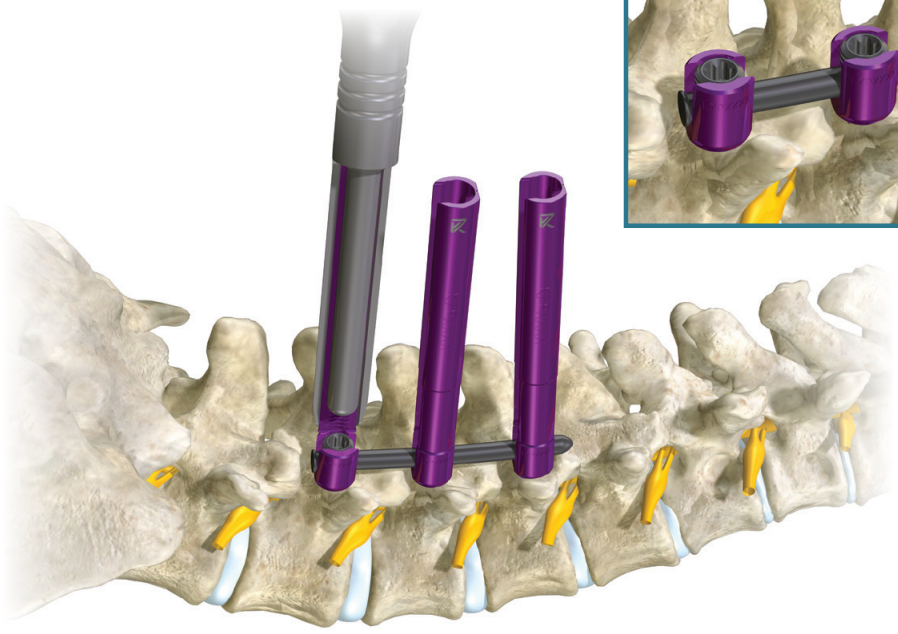
Surgical Technique

11. Using the Torque Wrench, tighten each nut to a final torque of 10Nm. The Anti-Torque Device must be used in combination with the Torque Wrench to prevent screw breakout.



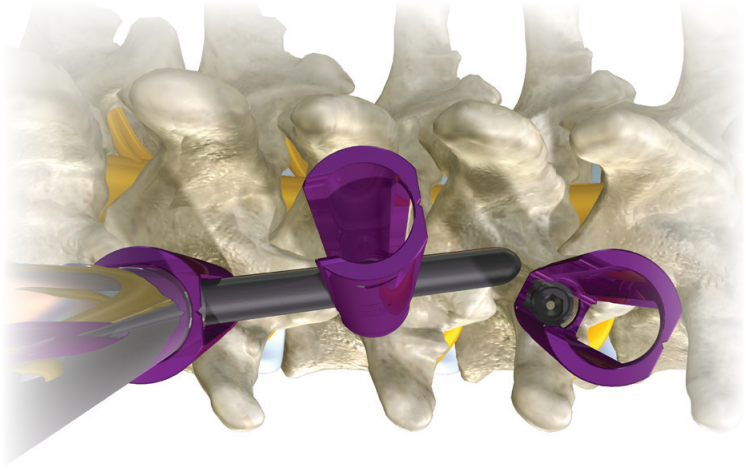
12. After cutting the small connecting bridge between the long arms of the screws, remove them with the Tab Breakaway Tool.



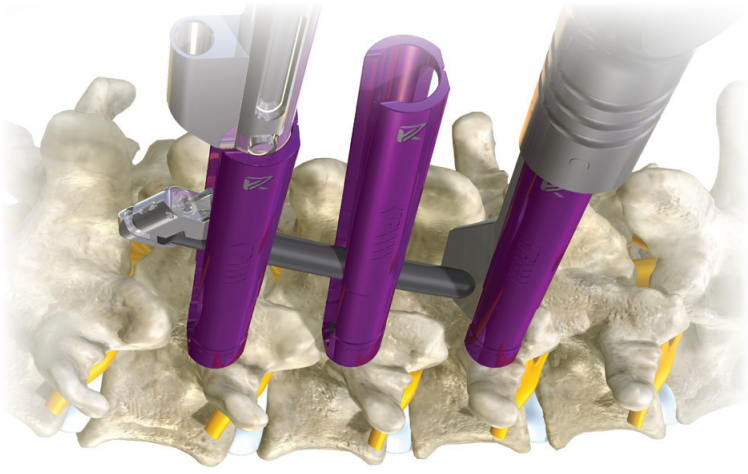


Rod Reduction Tool

1. Passing the rod between two adjacent screws is generally straightforward; however, the addition of a third or fourth screw can make the process more challenging – particularly if the screws do not form a straight line. If the surgeon encounters difficulty passing the rod, the Rod Reduction Tool should be employed.

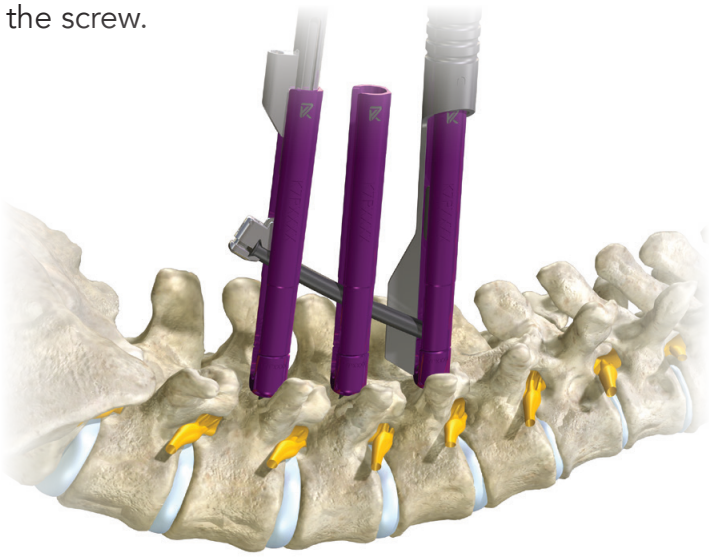


2. Advance the rod until it is adjacent to the screw. After removing the Sounding Shaft, slide the right or left sided Reduction Tool over the screw. It may be necessary to rotate the top of the screw 180 degrees to properly accept the Reduction Tool. This should be done by fingertip to avoid rotating the screw itself.



Surgical Technique

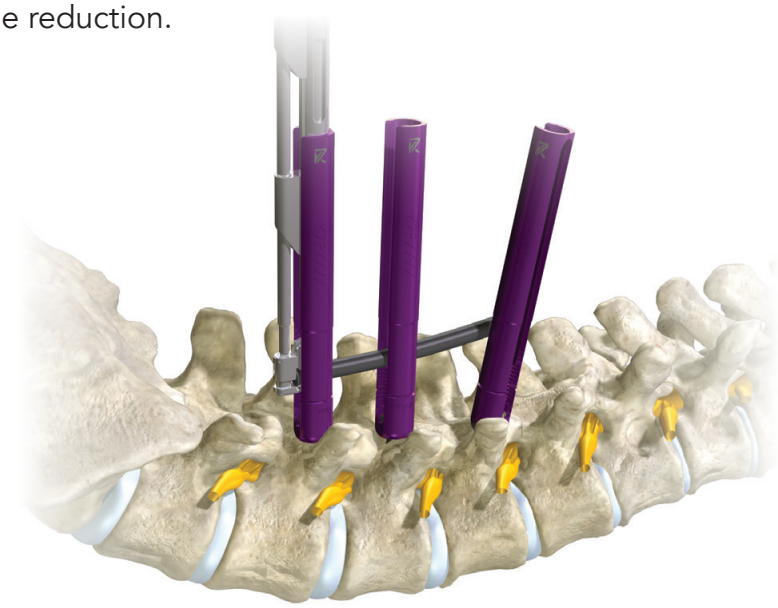
3. Rotate the Reduction Tool to intercept the rod and redirect it though the arms of the screw.



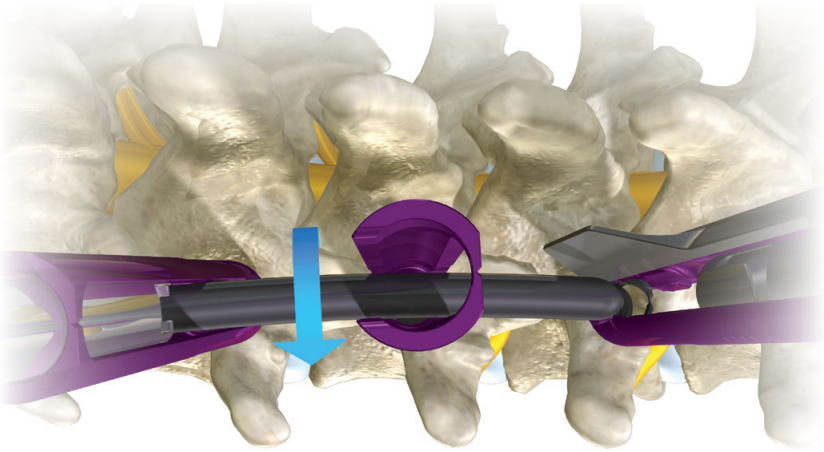
4. Successful passage of the rod is confirmed by passing the Sounding Shaft down the Reduction Tool. If the shaft bottoms out, the process was unsuccessful and should be repeated.

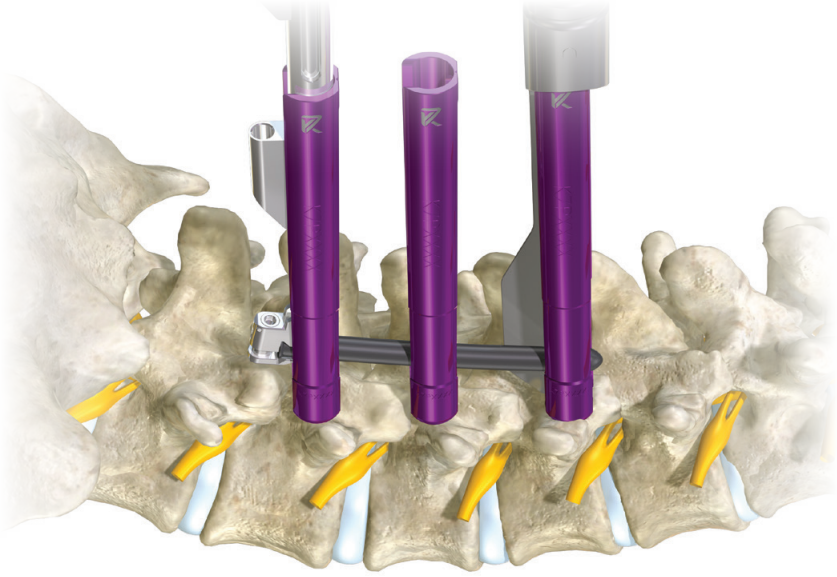
Loosen the Clamping Mechanism to assist in Rod Reduction

5. If the use of the Rod Reduction Tool is insufficient to persuade the rod, the clamping mechanism on the Rod Delivery Tool can be loosened to assist with the reduction.



6. With the clamping mechanism on the Rod Delivery Tool relaxed, the rod can be rotated with the Rod Delivery Tool - without being released. This maneuver is only effective if the rod is curved.





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Instruments

K7A-1001 Guide Wire

K7A-1002 Guide Wire Marker

K7A-1003 6.5mm Dilator

K7A-1004 2mm Dilator

K7A-1005 Pedicle Starter

K7A-1007-5.5 5.5mm Pedicle Tap

K7A-1007-6.5 6.5mm Pedicle Tap

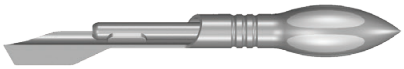
K7A-1007-7.5 7.5mm Pedicle Tap

K7A-1009 Tulip Break

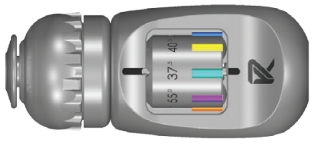
K7A-1008L Rod Persuader - Left

K7A-1008 Rod Persuader Checker

K7A-1008R Rod Persuader - Right



K7A-1011 K7 Depth Marker Adapter with Ratchet



K7A-1041 K7 Depth Gauge

K7A-1026 Rod Checker

K7A-1019 AR Driver - Removal Tool

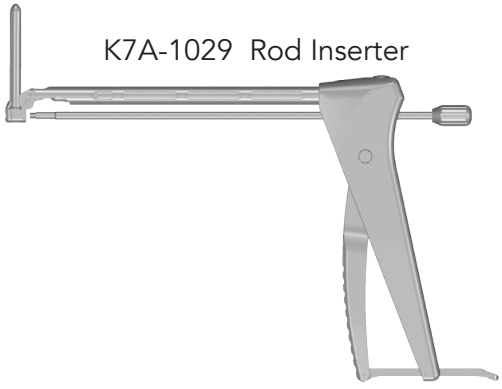
K7A-1019 AV Driver

K7A-1022 Nut Starter

K7A-1023 Nut Driver

K7A-1021 Anti Torque Driver

K7A-1029 Rod Inserter



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Part Numbers

PEDICLE SCREWS:

Pedicle screw part numbers are determined as follows:

Fully Threaded . . . . . AVRX.X-xxx
Modified Shaft. . . . . AVX.X-xxx
X.X indicates major diameter . . . . . 5.5-8.5 mm
xxx indicates screw length 37.5-55mm

Example:
1.AV6.5-42.5 indicates a modified screw 42.5 mm long: outer diameter of 6.5mm
2.AVR7.5-50 indicates a fully threaded screw 50mm long: outer diameter 7.5mm.

CONNECTING RODS

All connecting rods are 5.5mm outer diameter with a curved radius. Rods greater than 120mm are straight. All rods are designated by the prefix K7R followed by the rod length.

Example:
K7R-40 indicates a connecting rod 40 mm in length.
Note –actual length is 15mm greater than the lasermark.

LOCKING NUTS

All locking nuts are part number SS-00

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The Aversion Pedicle Screw System

INSTRUCTIONS FOR USE

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

GENERAL DESCRIPTION The Aversion Pedicle Screw System consists of straight and curved rods, various polyaxial screws, crosslinks and fastening set screws. These are available in a variety of sizes and lengths to accomodate differing patient anatomy. All components are manufactured from Ti6Al4V ELI.

IMPORTANT NOTE TO OPERATING SURGEON The Aversion Pedicle Screw System is designed to provide biomechanical stabilization as an adjunct to fusion in skeletally mature patients. Spinal fixation should only be undertaken after the surgeon has had hands on training in this method and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available for instructions on the important aspects of this surgical procedure. The surgical technique can be requested by contacting K7 LLC at the address or phone and fax numbers above.

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant, and potential adverse effects of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Postoperative evaluation of the fusion and implant status is necessary. The surgeon may remove the implant once a solid fusion is obtained. The patient must be informed of the potential of this secondary surgical procedure and the associated risks

INDICATIONS FOR USE The Aversion Pedicle Screw System is intended for posterior, non-cervical (T1-S1) pedicle fixation to provide immobilization and stabilization in skeletally mature patients as an adjunct to fusion for the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudarthrosis and failed previous fusion.

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CONTRAINDICATIONS

Use of the Aversion Pedicle Screw System and spinal fusion surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Prior fusion at the level(s) to be treated is a contraindication. Any condition not described in the Indications for Use is a contraindication.

Condition(s) that preclude the possibility of fusion are relative contraindications. These include but are not limited to: cancer, fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy and foreign body sensitivity.

WARNINGS AND PRECAUTIONS

1. **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 neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudo-arthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
2. **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.
3. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
4. These devices are provided as single use only implants and are not to be reused or reimplanted regardless of an apparent undamaged condition. Any retrieved devices must never be reused under any circumstances.
5. The Aversion Pedicle Screw System is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used.

6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Store the devices in a clean, dry area away from radiation and extreme temperatures and corrosive environments such as moisture, air, etc.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other system or manufacturer.
9. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct
10. The Aversion Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Aversion Pedicle Screw System has not been tested for heating or migration in the MR environment.
11. Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.
12. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.

POTENTIAL ADVERSE EFFECTS

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems and include, but are not limited to: Bending, fracture or loosening of implant component(s), nonunion or delayed union, fracture of the vertebra, neurological, vascular or visceral injury, metal sensitivity or allergic reaction to a foreign body, infection, decrease in bone density due to stress shielding, pain, discomfort or abnormal sensations due to the presence of the device, nerve damage due to surgical trauma, bursitis, dural Leak, paralysis and death.

CLEANING AND DECONTAMINATION

All instruments must first be thoroughly cleaned before sterilization and introduction into a sterile surgical field. The general instructions below provide a sequence of steps required to prepare K7 LLC surgical instruments for re-use or to prepare new instruments for use. As a precaution staff should always wear suitable protective clothing and equipment, no matter which method is used.

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Point of Use	• Keep devices moist to prevent soil from drying and remove gross soil from the surfaces, crevices, mating surfaces, cannulas, joints, and all other challenging or hard-to-clean design features. • Begin instrument cleaning as soon as possible after use of the device but absolutely within 2 hours. • Following these practices will improve the effectiveness of subsequent cleaning efforts. Transport to processing area
Transport to processing area	• Avoid damaging the devices during transport by separating heavy and delicate ones. • Do not overload instrument trays.
Pre-cleaning	• Presoak the surgical devices with an enzymatic solution, such as Enzol® by Advanced Sterilization Products, or equivalent, for a minimum of five minutes. Use the concentration, temperature and time not less than recommended by the enzymatic solution manufacturer. • Remove visible soil and debris from instrument surfaces using a soft-bristled nylon brush. Actuate movable features to expose all areas to solution. • Removes oil and debris from instrument challenging design features (such as cannulations, blind holes and the joints between movable parts) using a soft-bristled bottle brush, pipe cleaner and/or guide wire. Flush challenging design features using a syringe or waterjet. • Rinse each instrument thoroughly with flowing, warm deionized or purified water for a minimum of one minute. • Inspect instruments for visible soil and repeat the process until no visible debris remains.
Mechanical cleaning	• Prepare a cleaning solution using low foaming, pH neutral detergent, such as Renu-Klenz™ by STERIS Corporation, or equivalent. Use the concentration, temperature and water quality (i.e., hardness, pH) as recommended by the detergent manufacturer. • Sonicate the devices for a minimum of fifteen (15) minutes. • Rinse each instrument thoroughly with flowing, warm deionized or purified water for a minimum of two minutes. Flush cannulations using a syringe or water jet of deionized or purified water. Make sure to irrigate any challenging design features. • Inspect instruments for visibles oil. Repeat the cleaning steps until no visible soil remains.
Drying	• Thoroughly dry each device inside and out using a clean, soft, lint-free cloth. • Pays special attention to challenging design features (e.g., threads, ratchets and hinges) • Actuate movable features so that all areas are reached. • Use an airjet (clean compressed air) to reach challenging design features such as cannulas,

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AUTOMATED CLEANING

Automated cleaning may be used as an alternative to manual cleaning. The individual articles should be removed from the cases, and thoroughly rinsed under cool running water to remove any visible soil. All actuators should be manipulated to assist in soil removal. A shower gun may be used to flush visible soil from small crevices, and other hard to clean areas. The sets are then ready to be placed in the washer for additional processing. The following parameters should be programmed: set to high.

Phase	Time – minutes	Temperature	Detergent
Pre-Wash 1	2:00	Cold tap water	N/A
Enzyme Wash	2:00	Hot Tap Water	Metrizyme enzymatic cleaner ½ oz/gal
Wash 1	2:00	66.0 Deg C (set point)	Metriwash neutral Ph cleaner ¼ oz/gal
Rinse 1	0:15	Hot Tap Water	N/A

After removal from the washer, excess moisture should be removed with a clean, soft cloth.

AUTOMATED CLEANING

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. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

Cycle: Pre-vacuum – 4 pulses

Temperature: 132C (270F)

Exposure Time: 4 minutes

Drying Time: 45 minutes

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PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to K7 LLC immediately. K7 LLC should be notified immediately of any product malfunction by telephone, fax or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

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