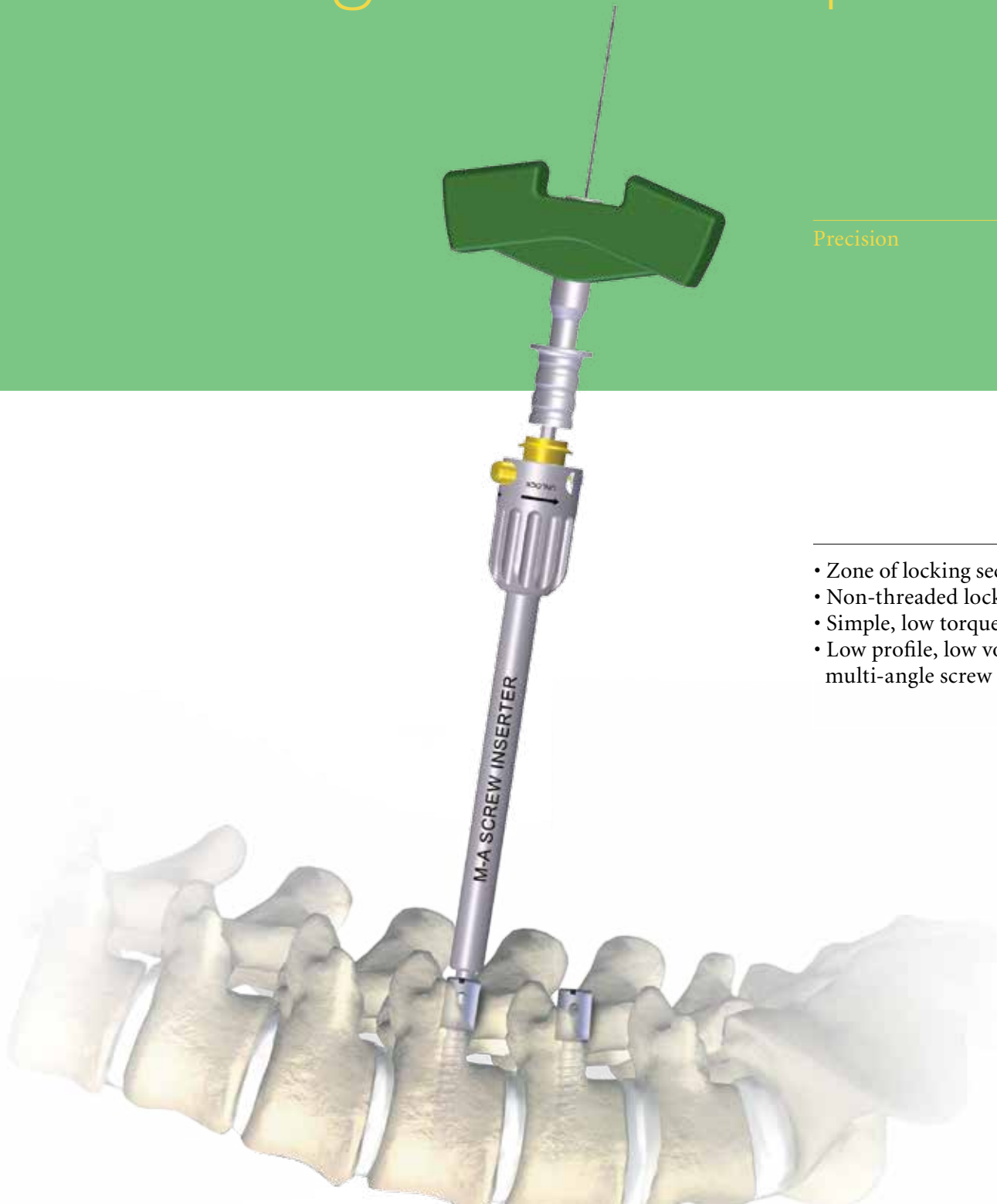


Radius®

Surgical Technique

Precision

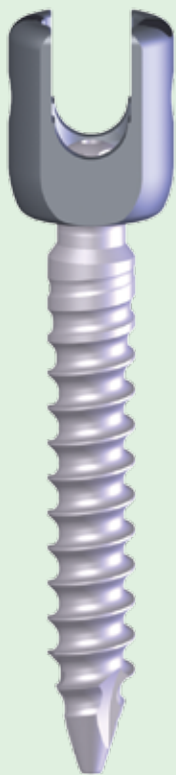


- Zone of locking security
- Non-threaded locking mechanism
- Simple, low torque closure
- Low profile, low volume multi-angle screw

Introduction

Minimally invasive systems have been designed to reduce tissue trauma through smaller incisions. The Radius Precision System for minimally invasive surgery contains cannulated screws that have been developed to facilitate screw implantation due to the reduced visualization within these narrower working channels.

The Radius Precision System helps surgeons implant the Radius cannulated polyaxial titanium screws through a less invasive posterior approach by following the path of a guide wire. This is accomplished with streamlined instrumentation designed to maximize visualization while minimizing the complexity of the system.



Important: The Radius implants and instruments are designed and tested for use only with the Radius Spinal System. This surgical technique sets forth detailed, recommended procedures for using the Radius Precision System implants and instruments. It offers guidance that you should heed but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required.

Note: This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding.



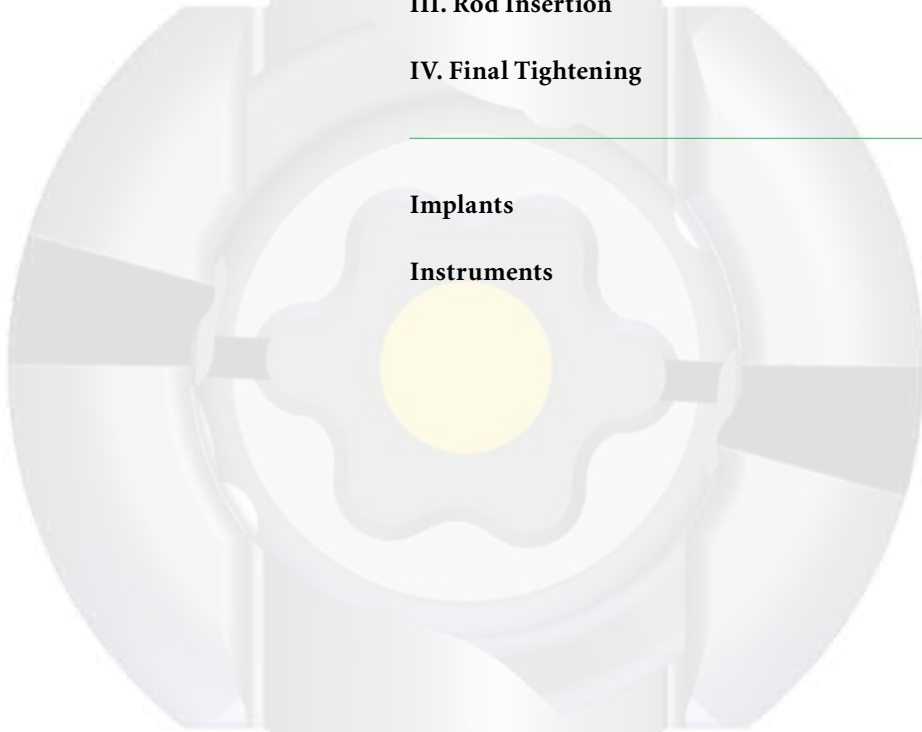
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Precision Surgical Technique

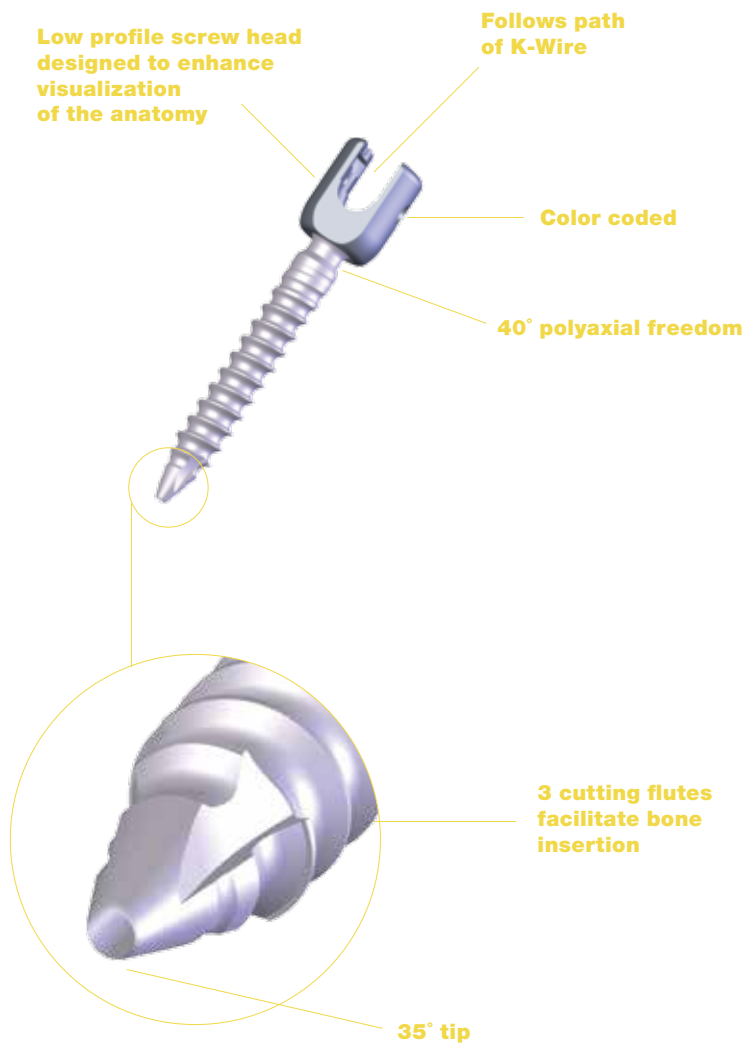
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Key Design Features - Implants



Radius Precision Screw Biomechanical Strength

- Equivalent strength to non-cannulated screw under static corpectomy conditions*
- Titanium Alloy (Ti6Al4V)

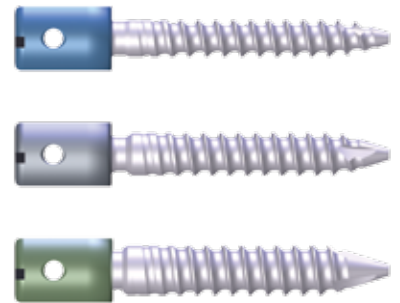
Self-Tapping Screw

Screw Sizes:

Ø5.75 x 35-50mm (5mm increments)

Ø6.75 x 30-55mm (5mm increments)

Ø7.75 x 30-55mm (5mm increments)



Radius Locking Cap



Ø5.5mm Pre-Cut / Pre-Bent Rods



- Short lengths with tight bend for single level fusions
- Medium lengths with gradual bend for 1 and 2 level fusions
- Longer lengths to accommodate 2 and 3 level fusions
- Titanium Alloy (Ti6Al4V)

* Data on file at Stryker Spine:
Engineering Analysis K060705

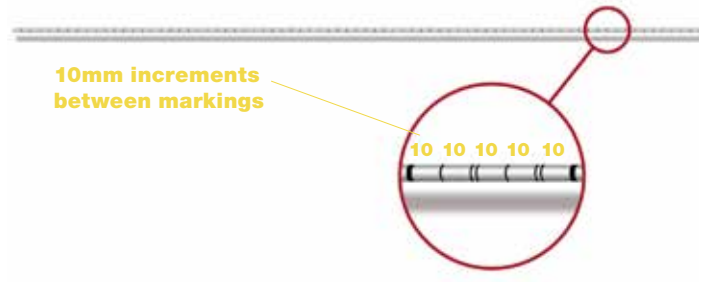
Key Design Features - Instruments

Safety

- Depth markings on guide wire are designed to provide real time feedback to minimize surgical and fluoroscopy time.

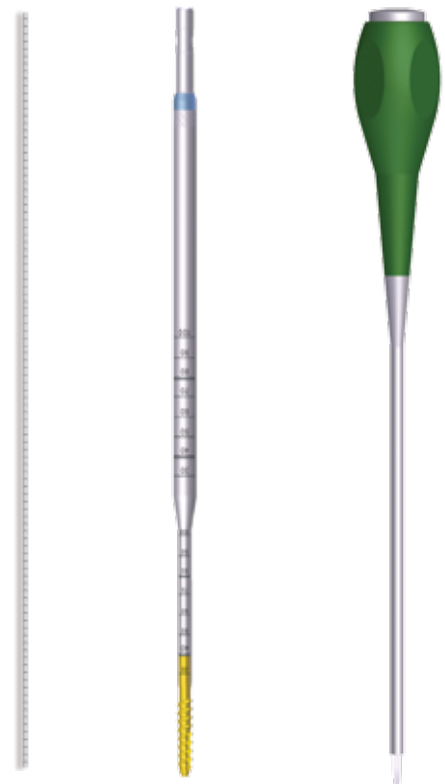
Note: The Radius K-Wire is 1.5mm in diameter and is specifically designed for use with the Radius Precision System.

Note: The Radius K-Wire differs from the Xia/MANTIS K-Wire. Radius K-Wire measures $\text{Ø}1.5\text{mm}$ while the Xia/MANTIS K-Wire is $\text{Ø}1.3\text{mm}$.

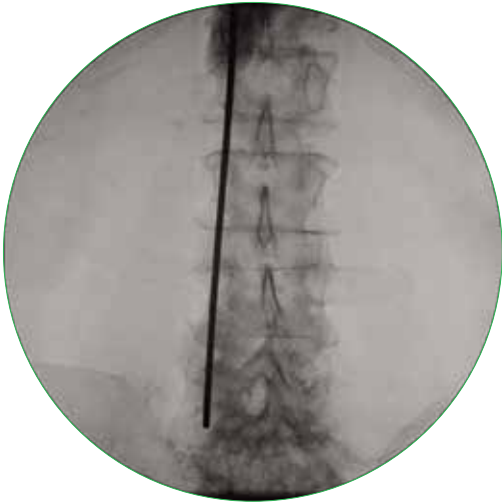


Streamlined Instruments

- Reduced instrument profiles are designed to maximize visualization for minimally-invasive procedures.
- All instruments are cannulated to allow easy placement over the guide wire.

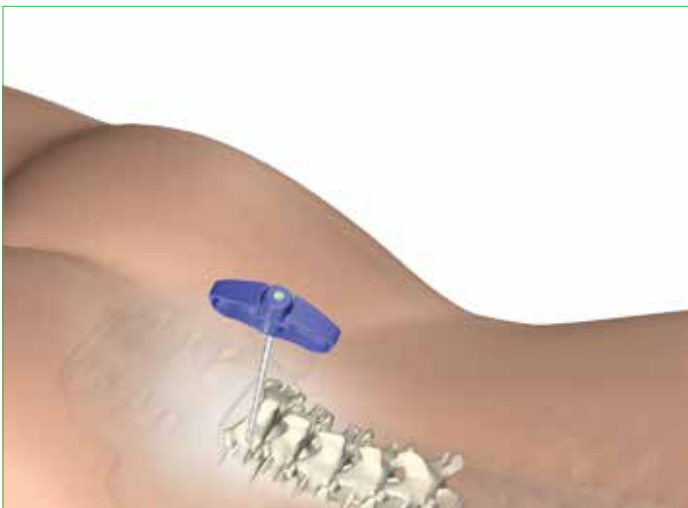


I. Pedicle Preparation



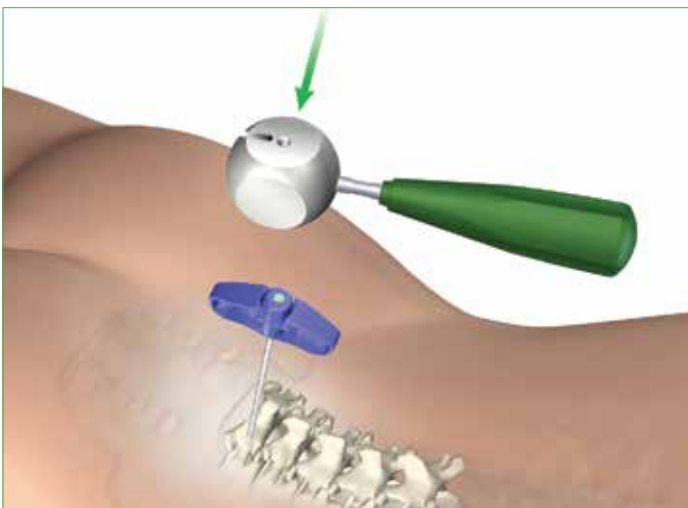
A spinal needle, **Jam Shidi**, is positioned on the skin directly over the pedicle using an A/P image.

Note: The **Jam Shidi** is a single use instrument, which is provided sterile.



The **Jam Shidi** is then moved 1 to 2cm lateral to the markings and inserted through the skin to the intersection of the facet and transverse process.

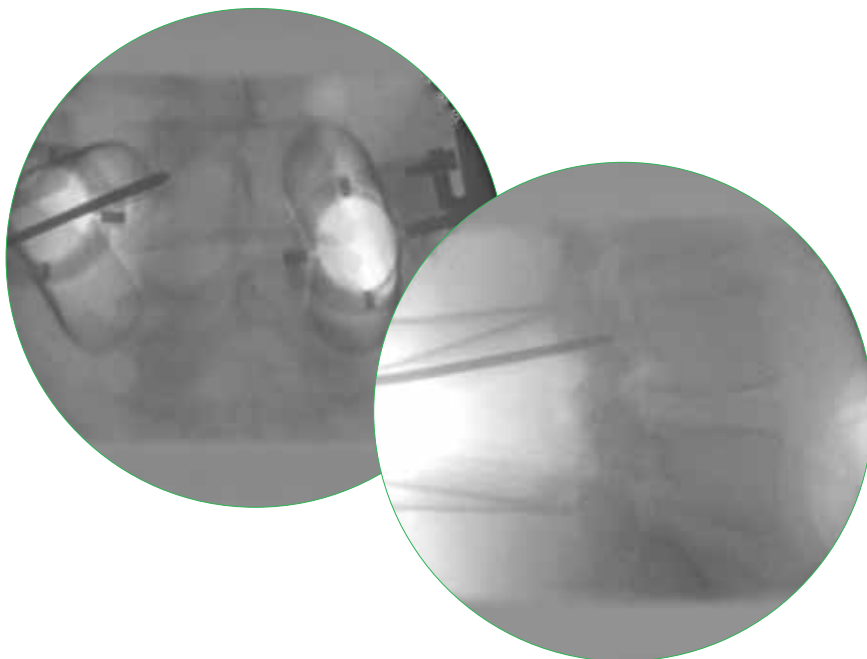
Both A/P and lateral images confirm that the appropriate starting place has been determined.



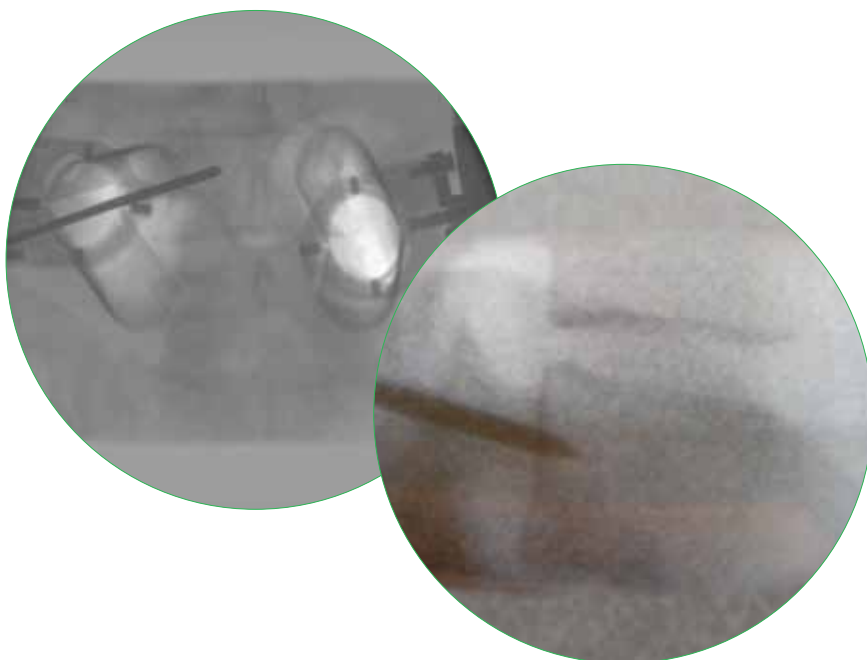
The **Jam Shidi** needle is used to gain access to the pedicle. After placing the **Jam Shidi** at the intersection of the facet and the transverse process, the needle may be advanced partially through the pedicle using the **Slap Hammer**.

I. Pedicle Preparation

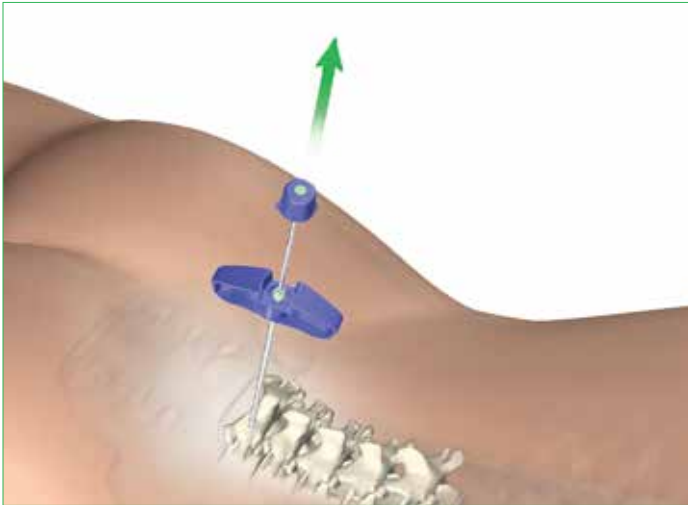
As the pedicle is navigated with the **Jam Shidi**, it should approach the medial wall of the pedicle on the A/P view and should approach the base of the pedicle on the lateral view.



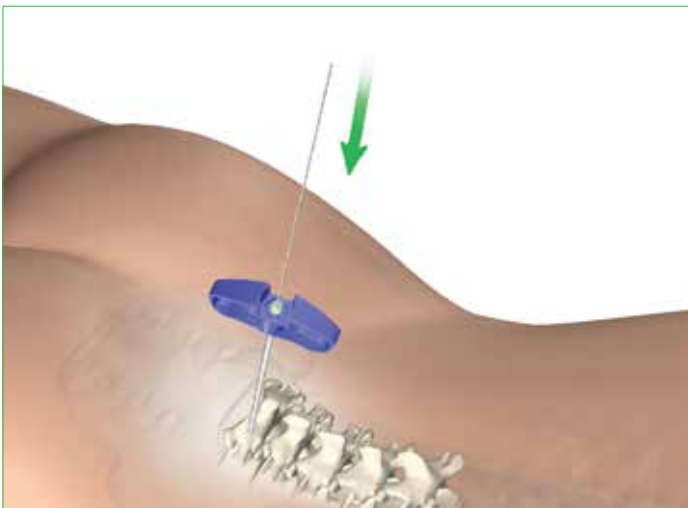
When the needle reaches the medial wall on the A/P view, verification should be performed in the lateral view to ensure the needle is past the base of the pedicle.



I. Pedicle Preparation



The inner trocar of the **Jam Shidi** is removed.

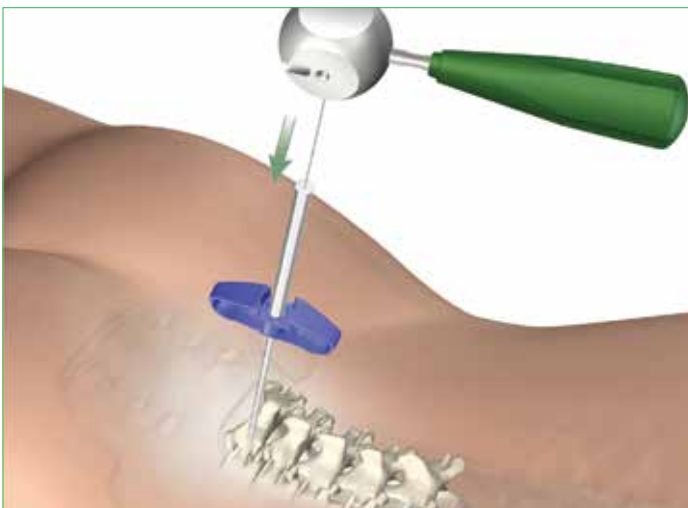


The removal of the **Jam Shidi** inner trocar allows the **K-Wire** (Sharp or Blunt) to be inserted into the pedicle.

Caution must be practiced with regard to the position of the **K-Wire** in order to avoid advancement of the **K-Wire**.

Note: The Radius **K-Wire** is 1.5mm in diameter. The MANTIS and Xia **K-Wire** is 1.3mm in diameter.

Note: The **K-Wire** is a single use instrument.



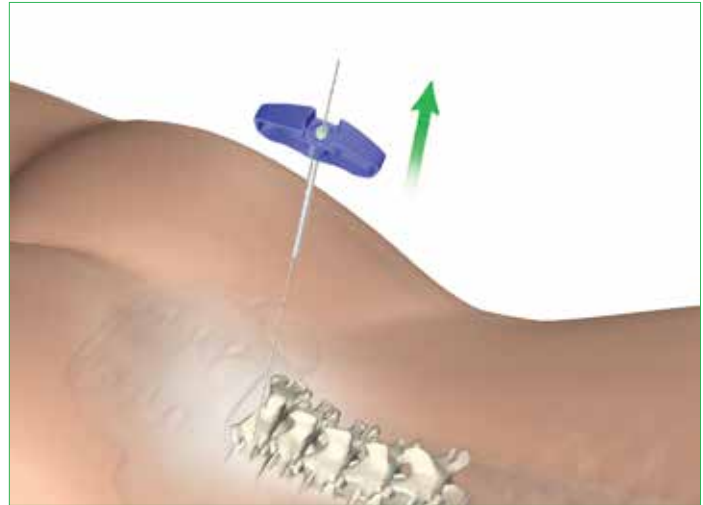
The **K-Wire Guide Tube** can be used to prevent the **K-Wire** from bending or moving during insertion. Place the **K-Wire Guide Tube** over the **K-Wire** and dock it on the **Jam Shidi**.

The **Slap Hammer** can then be used to impact the **K-Wire**.

I. Pedicle Preparation

Once the **K-Wire** is inserted, the outer shaft of the **Jam Shidi** may be removed.

Hold the **K-Wire** in position when removing the **Jam Shidi**.

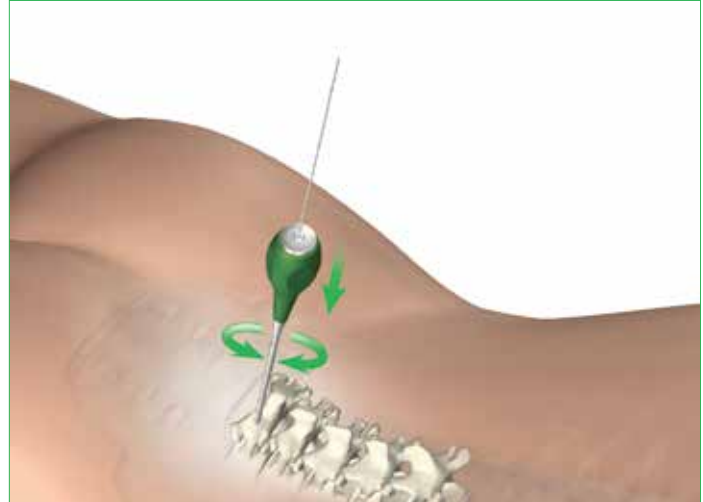


The pedicle is prepared by placing the **Cannulated Pedicle Awl** over the **K-Wire** and twisting it into the pedicle.

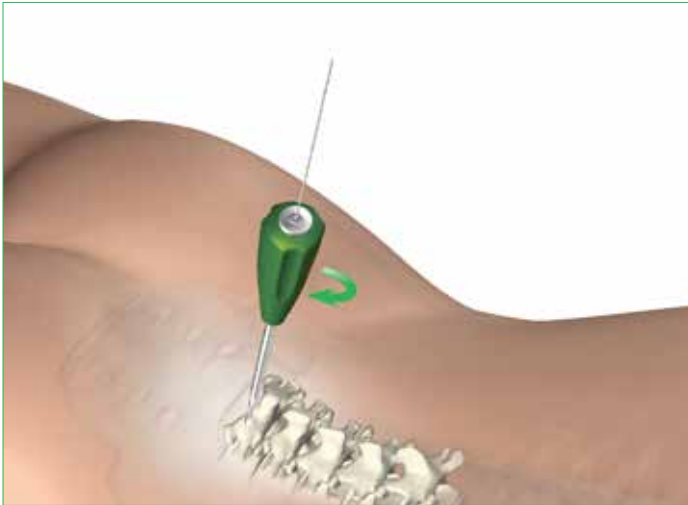
Hold the **K-Wire** in position when removing the **Awl**.

Use the cannulated **Slap Hammer** to impact the **Awl**.

Note: The **Cannulated Pedicle Awl** has a stop at 12.0mm.



I. Pedicle Preparation

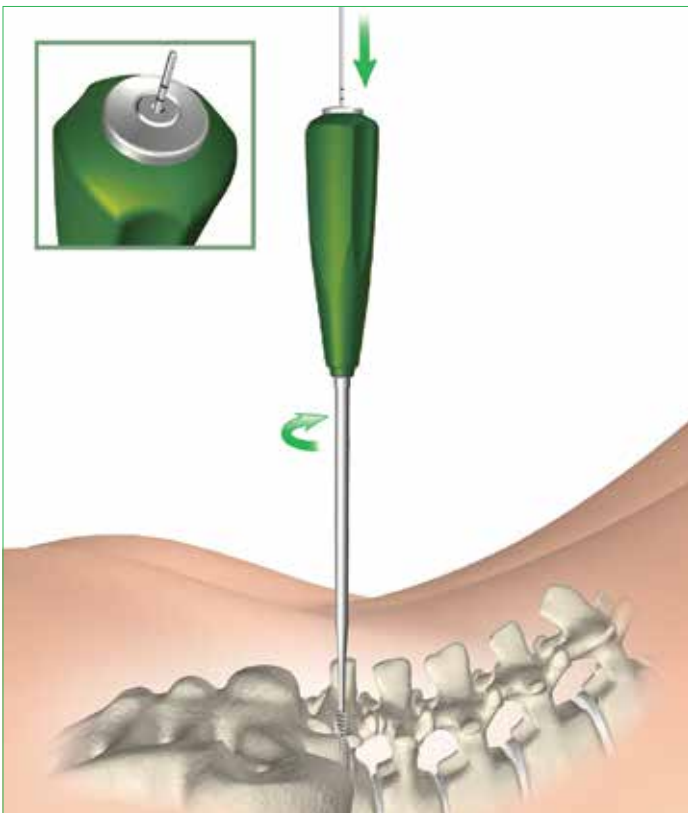


If the bone is too hard, the appropriate **Cannulated Tap** may be used to prepare the pedicle screw canal.

The Radius **Cannulated Taps** are laser etched with 10mm intervals to help indicate the depth at which the **Cannulated Tap** has been inserted as well as to help determine proper screw length.

The **Cannulated Taps** have been colored gold up to 40mm to allow for easy visualization of 40mm depth, which represents the most common screw length.

Note: The length of the **Cannulated Tap** thread is 25mm.



Note: The 1cm interval markings on the **K-Wire** provide the cannulated instrument's depth in the pedicle.

As an instrument advances into the pedicle, the proximal end of the instrument will move relative to the markings. If this does not occur during insertion the procedure should be stopped and fluoroscopy should be used to verify the position of the **K-Wire** in relation to the **Awl** or **Tap**.

I. Pedicle Preparation

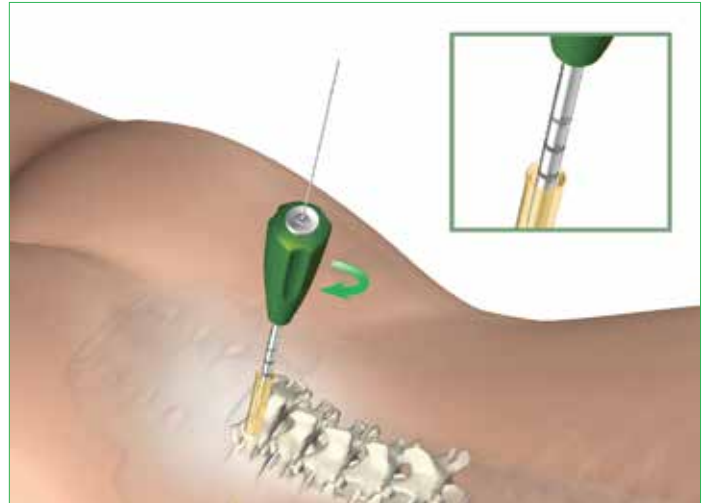
The **Tap Sleeve** can be used to prevent soft tissue from contacting the threads of the **Tap**.

Check pedicle depth with either fluoroscopy or read the depth from the **Tap Sleeve** as it moves along the proximal shaft of the **Tap**. There are markings at 30, 40, and 50mm.

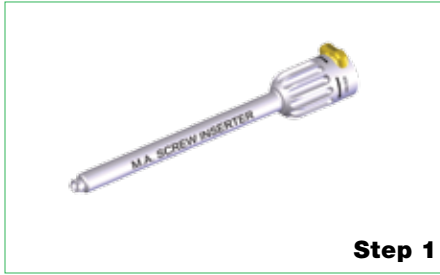
Note: The **Tap Sleeve** is made of radiolucent Ultem Poly Ether Imide.

Note: Slide the **Tap Sleeve** proximal to the tap shaft to engage the friction fit.

Hold the **K-Wire** in position when removing the **Precision Tap**.



II. Screw Insertion



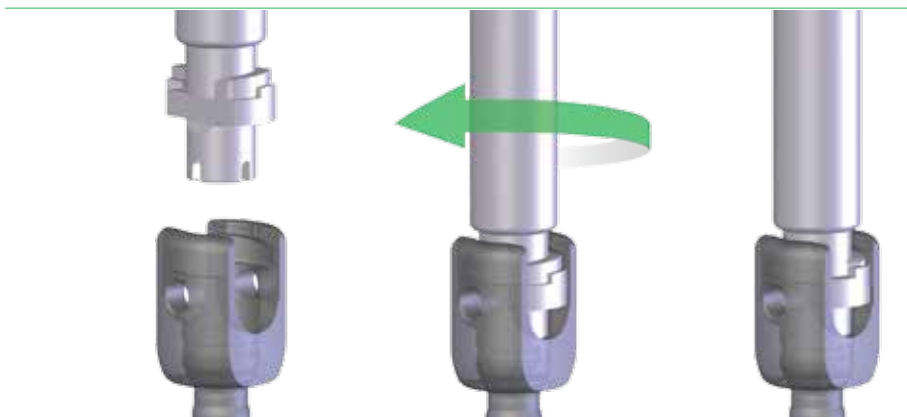
With the pedicle pathways prepared and proper screw length and diameter determined, the screw is ready for insertion.

The Radius **Cannulated Multi-Angle Screw Inserter** is designed to provide a rigid connection between the polyaxial screw and the screwdriver. The screwdriver can be attached to any of the cannulated modular handles using the quick release mechanism.

Cannulated Multi-Angle Screws

To assemble the **Cannulated Multi-Angle Screw Inserter**:

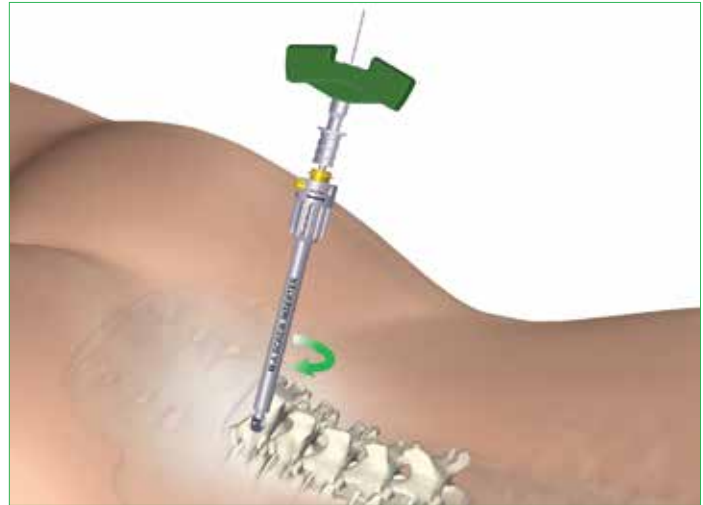
1. Insert the inner shaft through the body of the **Cannulated Multi-Angle Screw Inserter**.
2. Insert the ratchet down the shaft of the **Cannulated Multi-Angle Screw Inserter**. Verify that the ratchet is bottomed out.
3. Connect to the desired handle.
4. Ensure that the **Cannulated Multi-Angle Screw Inserter** is fully unlocked.
5. Align the tabs on the **Cannulated Multi-Angle Screw Inserter** shaft with the external quad on the screw head while holding the bone screw.
6. Rotate the dial on the **Cannulated Multi-Angle Screw Inserter** clockwise to firmly seat the screw onto the **Cannulated Multi-Angle Screw Inserter**.



Cannulated Multi-Angle Screw Inserter

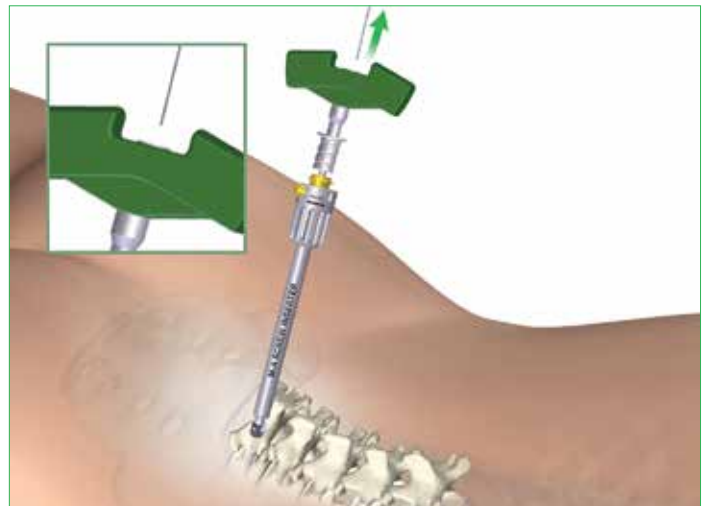
II. Screw Insertion

The Radius Precision Screw is then placed over the K-Wire and inserted into the pedicle.



After driving the screw into the pedicle, remove the K-Wire to prevent it from advancing.

Be certain that the screw is not inserted too far. If the multi-axial head of the Radius Precision Screw is driven too forcefully against bone, it will lose its multi-axial capabilities making it difficult to connect the assemblies during subsequent steps.



Once the screw is inserted into the pedicle, push the gold button and rotate the dial on the Multi-Angle Screw Inserter counter-clockwise until the Cannulated Multi-Angle Screw Inserter is loose from the screw.

Remove the Cannulated Multi-Angle Screw Inserter from the screw.

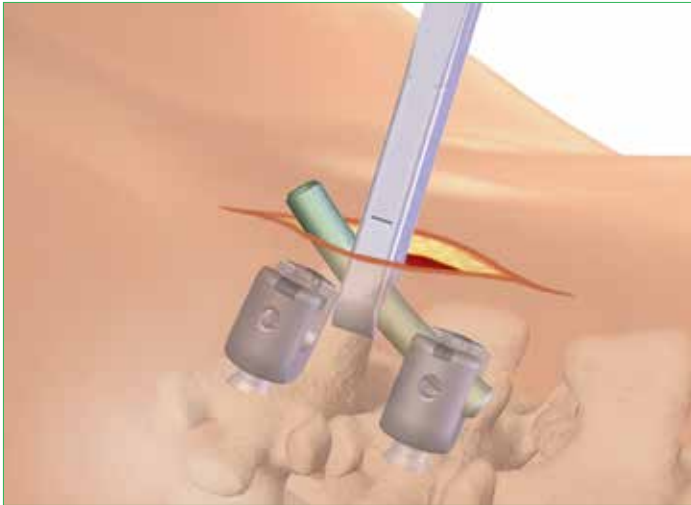
The process is repeated for additional screws.

After inserting both screws, the head of the screws should be the same height.

Note: The Cannulated Multi-Angle Screw Inserter can be used for the removal of Cannulated Screws.



III. Rod Insertion



Once the rod is bent to the desired contour, it is placed into the tulip heads of the screw using a rod inserter.

IV. Final Tightening



After verifying with A/P, lateral, and oblique views that the rod is seated in the heads of both screws, the **Locking Cap** must be inserted into the screw head using the **Initial Inserter**. Apply downward pressure to ensure the **Locking Cap** is firmly seated against the rod, then turn the **Locking Cap** to its provisionally locked position. The **Locking Cap** is provisionally locked when the laser etched lines on the **Locking Cap** are parallel to the rod.

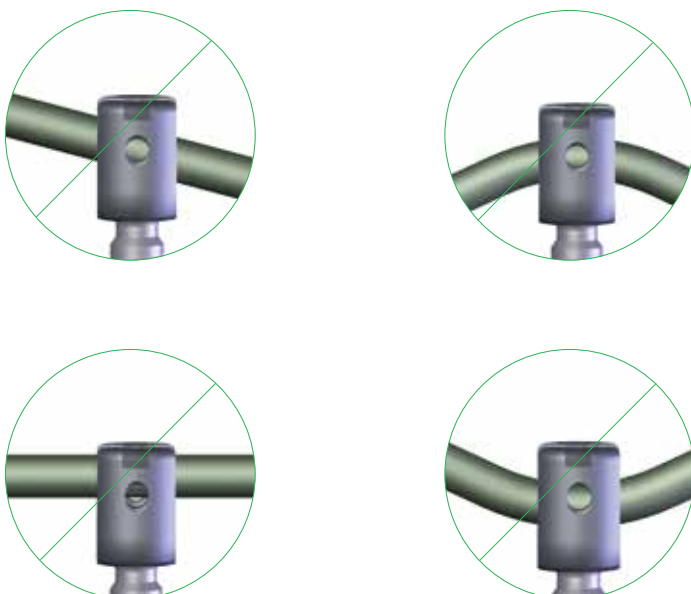
Note: The **Initial Inserter Tube** can be used to guide the **Locking Cap** into the screw head.

Tip: It is recommended to begin closure at the easiest point in the construct. This may help facilitate the seating of the rod in adjacent implants.

When a rod that is sitting slightly proud is forced down during tightening, ensure that the locking cap is fully engaged into the screw head. This will help resist the high reactive forces generated during final tightening.

Extra caution is advised when:

1. The rod is not horizontally placed into the screw head.
2. The rod is high in the screw head.
3. An acute convex or concave bend is contoured into the rod.



IV. Final Tightening

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the **Locking Caps** is done by utilizing the **Counter Torque Tube** and the **Final Driver**.

1. Place the **Counter Torque Tube** around the screw head and over the rod.
2. Place the **Final Driver** into the star on the **Locking Cap** by first aligning the lines on the **Final Driver** shaft with the lines on the **Locking Cap**.
3. Twist the **Final Driver** until the handle of the **Final Driver** is perpendicular to the handle of the **Counter Torque Tube** or until the **Final Driver** no longer twists. The laser marked lines on the **Locking Cap** should be within the laser marked zone on the screw head as shown in the figure below.

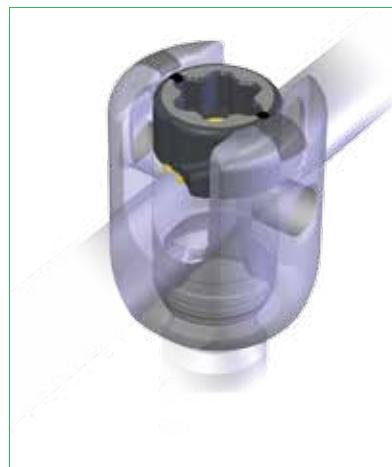
Tip: It is important to position the **Counter Torque Tube** before the **Final Driver** is inserted to minimize the risk of instrument slippage.

Note: The **Counter Torque Tube** must be used for final tightening. The **Counter Torque Tube** is designed to perform three important functions:

1. To align the **Final Driver** with the tightening axis.
2. To maximize the torque needed to lock the implant assembly.
3. To hold the construct in place during final tightening.

Apply bone graft to the fusion site and close in the usual manner.

Note: For removal reverse the final tightening sequence.



Implants

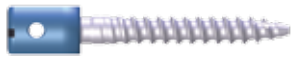
Part number

Description



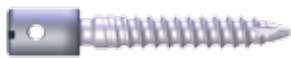
486610000

Locking Cap



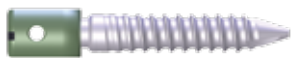
4866125 (35) - (50)

Screw, Multi-Angle,
Cannulated Ø5.75 x 35mm-50mm



4866126 (30) - (55)

Screw, Multi-Angle,
Cannulated Ø6.75 x 30mm-55mm



4866127 (30) - (55)

Screw, Multi-Angle,
Cannulated Ø7.75 x 30mm-55mm



4866150 (30) - (90)


















Ø5.5mm Titanium Rad Rod
30mm-90mm lengths



4866155 (50) - (80)

Ø5.5mm Titanium Max Rad Rod
50mm-80mm lengths

Instruments

Part number	Description	Instruments
486619461	Precision Tray	
48237110 48237105 48237115 48237135	Jam Shidi 10 Gauge 9 Inch (x6) Jam Shidi 10 Gauge 5 Inch (x6) Jam Shidi 11 Gauge 5 Inch (x6) Jam Shidi 13 Gauge 5 Inch (x6)	
486619046 486619045	K-Wire Blunt K-Wire Sharp	
486619055	K-Wire Guide Tube	
486619345	Cannulated Pedicle Awl	
486619350 486619355 486619360	Ø5.75mm Cannulated Tap Ø6.75mm Cannulated Tap Ø7.75mm Cannulated Tap	
486619370	Slap Hammer	
48231315	Tap Sleeve	
486619090	Multi-Angle Screw Inserter Cannulated	
486619080	Cannulated T-Handle	
486619070	Cannulated T-Ratcheting Handle	
486619075	Cannulated Standard Handle	
486619065	Cannulated Standard Ratcheting Handle	
486619215	Initial Inserter	
486619220	Initial Inserter Tube	
486619235	Counter Torque Tube	
486619240	Final Driver	

Indications

The Radius Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

- 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;
- Curvature (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

The Radius Spinal System can also be linked to the Xia Titanium Spinal System via the Ø5.5mm to Ø6.0mm Radius rod-to-rod connector.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure, or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

These contraindications can be relative or absolute and must be taken into account by the physician when making a decision. The above list is not exhaustive.

Cautions and Warnings

CAUTIONS (U.S.A.)

Federal law (U.S.A) restricts this device to sale by or on the order of a licensed physician.

The implantation of pedicle screw spinal systems must 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.

Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the system.

WARNING (U.S.A.)

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 spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, 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.

Radius implant components have not been tested for heating or migration in MR environment.

Removal of Implants

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal must be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is highly recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

Information for Patients

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weightbearing, activity levels, and the necessity for periodic medical follow-up.

The patient must be warned of the surgical risks and made aware of possible adverse effects. The patient must be warned that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) he/she should be warned that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

REUSE

Never reuse or reimplant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

It is recommended to verify that the instruments are in good condition and operating order prior to use during surgery.

Reconstructive

Hips
Knees
Trauma & Extremities
Foot & Ankle
Joint Preservation
Orthobiologics & Biosurgery

MedSurg

Power Tools & Surgical Accessories
Computer Assisted Surgery
Endoscopic Surgical Solutions
Integrated Communications
Beds, Stretchers & EMS
Reprocessing & Remanufacturing

Neurotechnology & Spine

Craniomaxillofacial
Interventional Spine
Neurosurgical, Spine & ENT
Neurovascular
Spinal Implants



Stryker Spine
2 Pearl Court
Allendale, NJ 07401-1677 USA
t: 201-760-8000
www.stryker.com

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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