stryker®

Xia Precision System

Cannulated System of the Xia Family

Surgical Technique

LITe
Less Invasive Technologies

Xia Precision System
Surgical Protocol

Table of Contents

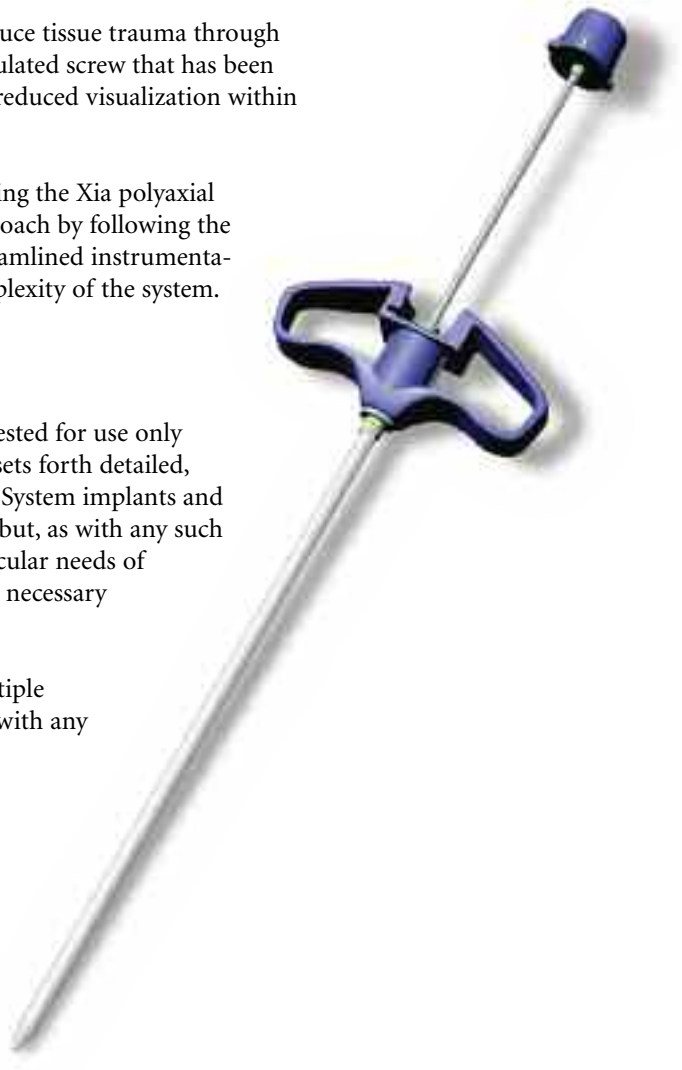
Acknowledgments

Stryker® Spine wishes to thank the global Xia Precision System Surgeon Panel for their dedication to the development of the Xia Precision System.

Introduction

Minimally invasive systems have been designed to reduce tissue trauma through smaller incisions. The Xia Precision System is a cannulated screw that has been developed to facilitate screw implantation due to the reduced visualization within these narrower working channels.

The Xia Precision System facilitates surgeons implanting the Xia polyaxial titanium screws through a less invasive posterior approach by following the path of the guidewire. This is accomplished with streamlined instrumentation to improve visualization while reducing the complexity of the system.



Important

The Xia implants and instruments are designed and tested for use only with the Xia Spinal System. This Surgical Technique sets forth detailed, recommended procedures for using the Xia 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.

Xia Precision System
Surgical Protocol

Key Design Features - Implants

Xia Precision Screw

Biomechanical Strength

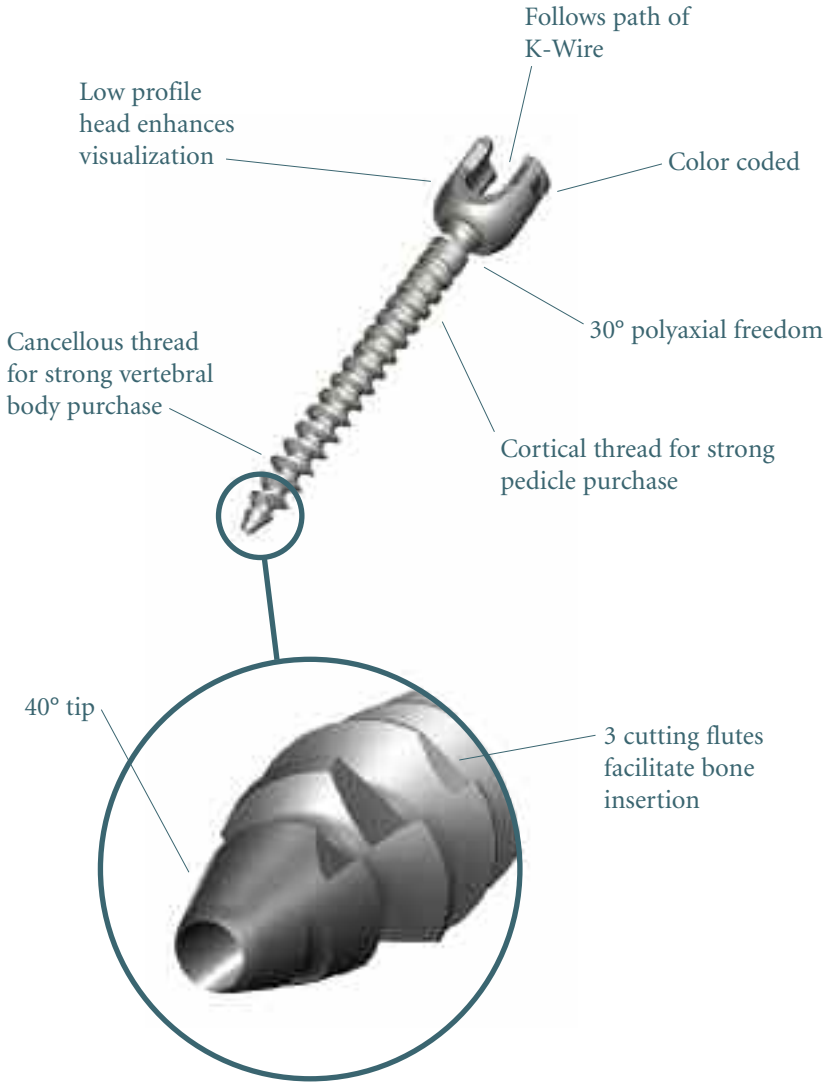
- Equivalent strength to non-cannulated screw under static corpectomy conditions*
- Titanium Alloy (Ti6Al4V)

Ease of Use

Cortical Cancellous Bone Thread

Aggressive Self-Tapping Screw

Screw Sizes:
5.5 x 35-50mm (5mm increments)
6.5 x 30-55mm (5mm increments)
7.5 x 30-55mm (5mm increments)



Xia Blocker

Patented Buttress Thread Closure Mechanism

- Potential for cross threading reduced when working through minimally invasive approach
- One step locking mechanism reduces lateral spreading forces during final tightening

6.0mm Pre-cut / Pre-bent Rods

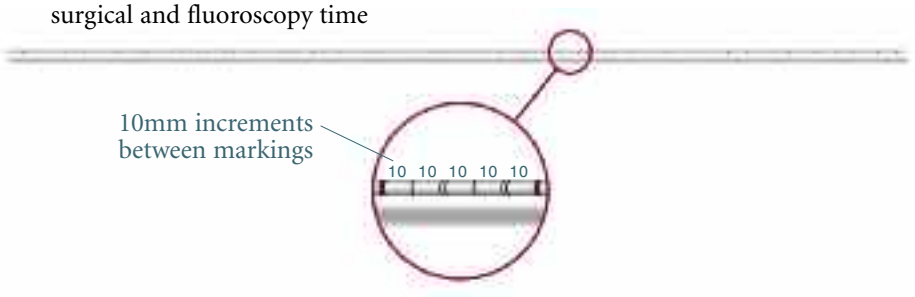
- Short lengths with tight bend for single level fusions
- Medium lengths with gradual bend for 1 & 2 level fusions
- Longer lengths to accommodate 2 & 3 level fusions

* Data on file at Stryker Spine

Key Design Features - Instruments

Safety

- Depth markings on guidewire provide real time feedback to reduce surgical and fluoroscopy time

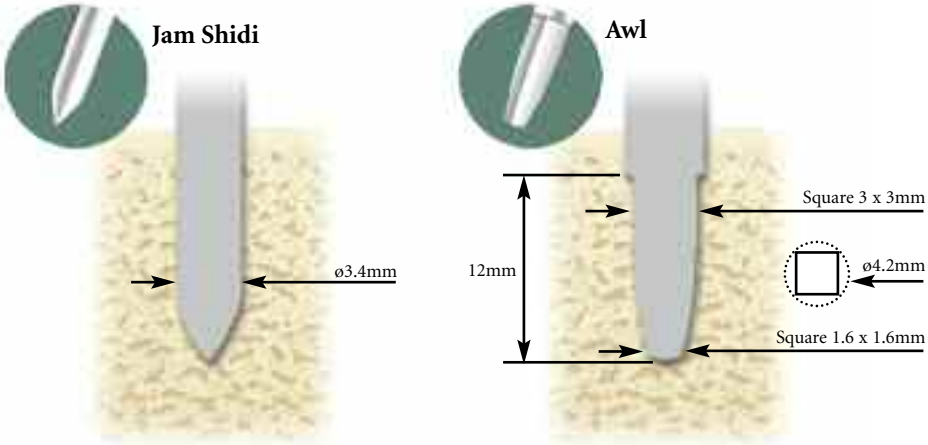


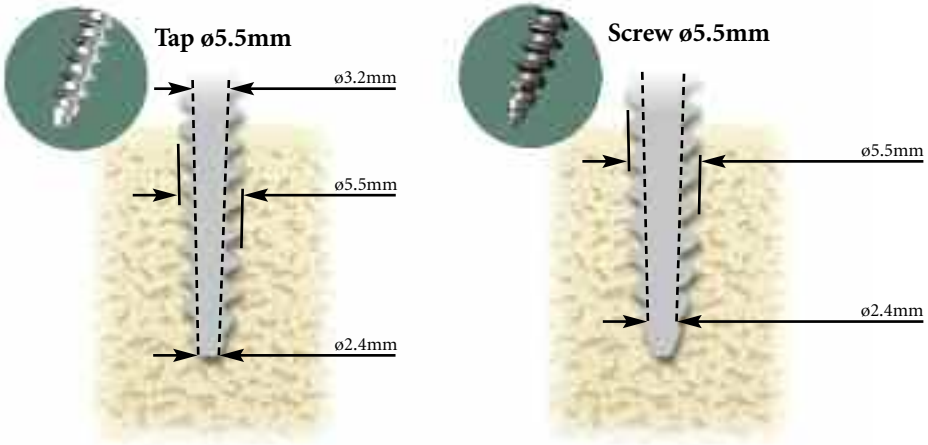
Streamlined Instruments

- Reduced instrument profiles increase visualization for minimally invasive procedures

Precision Guided

- Instrument & implant tips incrementally smaller to fit in previous channel





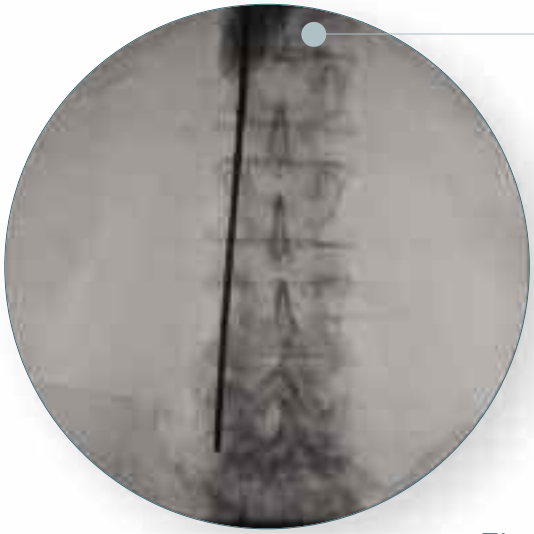


Figure 1

Pedicle Preparation

- A spinal needle, **Jam Shidi 48237 (105), (110), (115), (135)** is positioned on the skin directly over the pedicle using an A/P image.

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

Figure 2

- 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.

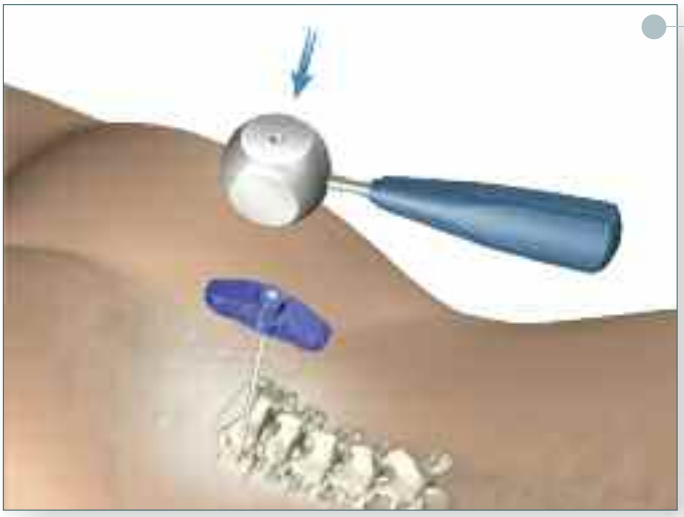
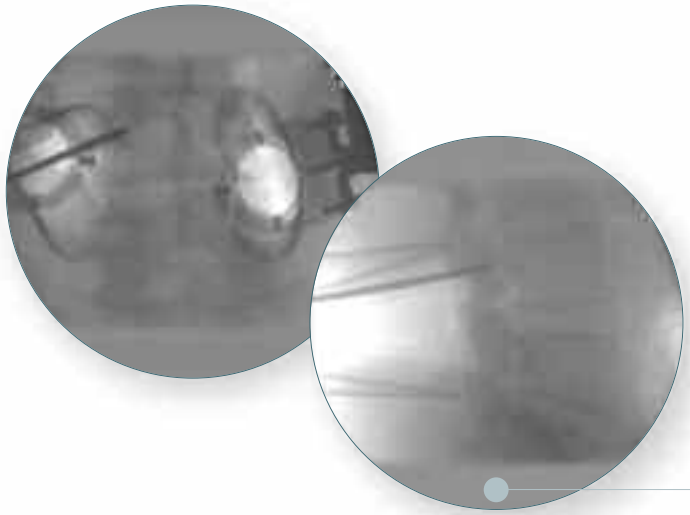


Figure 3

- 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 (48237120)**.

10 Gauge, 229 mm 48237110
10 Gauge, 127 mm 48237105
11 Gauge, 127 mm 48237115
13 Gauge, 127 mm 48237135
Jam Shidi

48237120
Slap Hammer



Figures 4A & 4B

▶ 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.

Figures 5A & 5B

▶ 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.

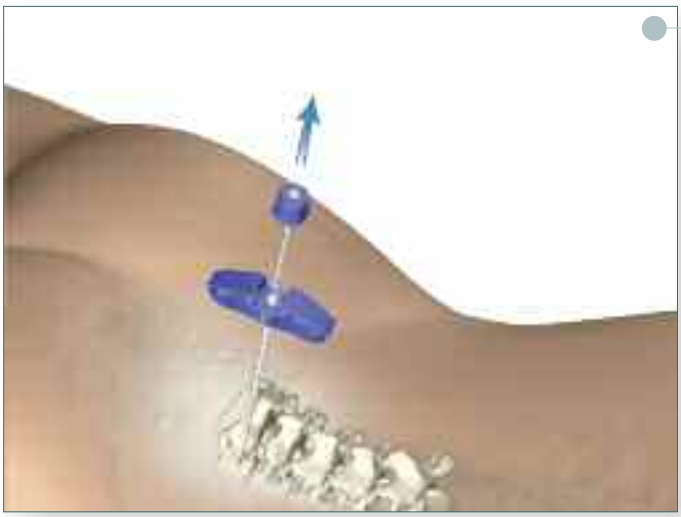


Figure 6

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

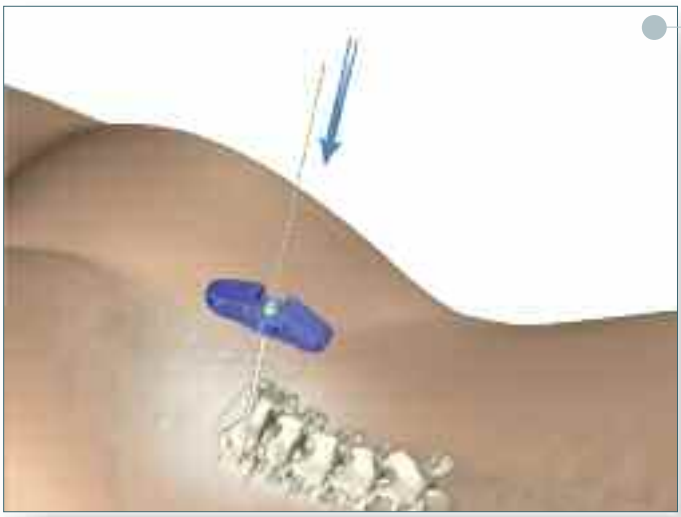


Figure 7

- The removal of the **Jam Shidi** inner trocar allows the **K-Wire** (**Sharp - 48230230, Blunt - 48230231**) to be inserted into the pedicle.
- Caution should be practiced with regard to the position of the **K-Wire** in order to avoid the advancement of the **K-Wire**.

Note: The **K-Wire** is 1.3 mm in diameter.

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

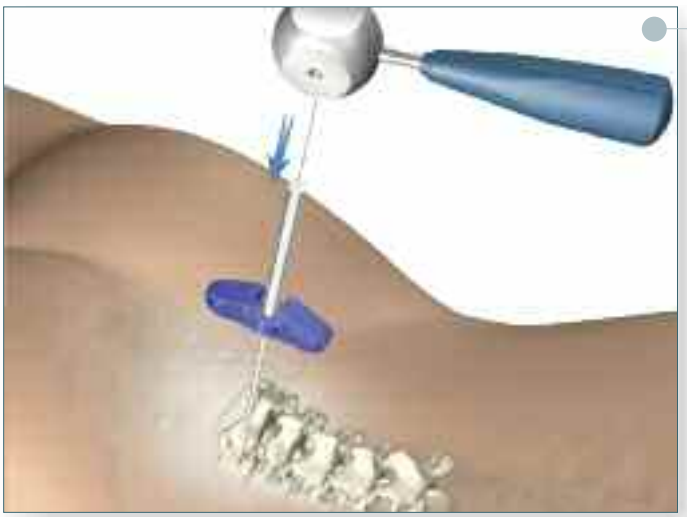


Figure 8

- The **K-Wire Guide Tube** (**48230235**) 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 on the **Jam Shidi**.
- The **Slap Hammer** can then be used to impact the **K-Wire**.

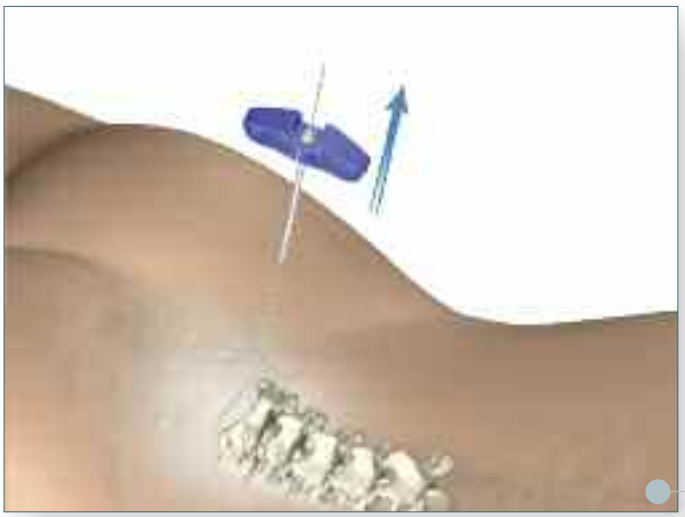


Figure 9

- 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**.

Figure 10

- The pedicle is prepared by placing the **Xia Precision Square Awl** (**48237001**) over the **K-Wire** and twisting into the pedicle.
- Hold the **K-Wire** in position when removing the **Awl**.
- Use the cannulation of the **Slap Hammer** to impact the **Awl**.

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

Instrument Bar

10 Gauge, 229 mm 48237110
10 Gauge, 127 mm 48237105
11 Gauge, 127 mm 48237115
13 Gauge, 127 mm 48237135
Jam Shidi

Sharp 48230230
Blunt 48230231
K-Wire

48230235
K-Wire Guide Tube

48237120
Slap Hammer

48237001
Xia Precision Square Awl

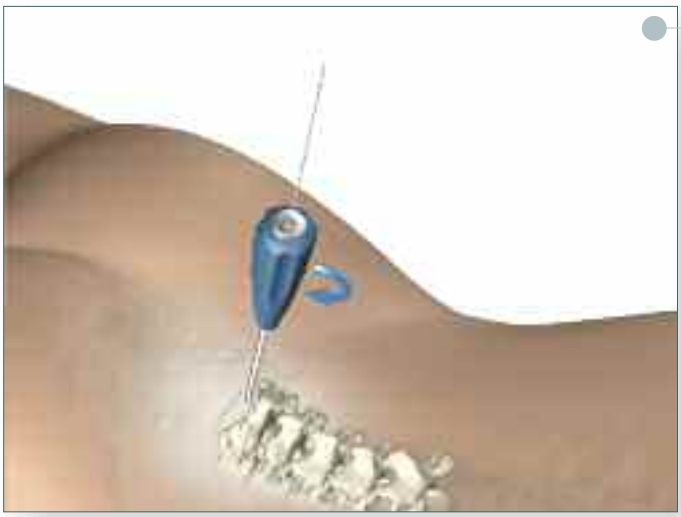


Figure 11

- If the bone is too hard, the appropriate **Tap** may be used to prepare the pedicle screw canal.
- The **Xia Precision Taps (5.5mm – 48230165, 6.5mm – 48230166, 7.5mm – 48230167)** are calibrated and laser etched with 10.0mm intervals to help indicate the depth at which the **Tap** has been inserted as well as to help determine proper screw length.

Note: The length of the **Taps'** thread is 25mm.

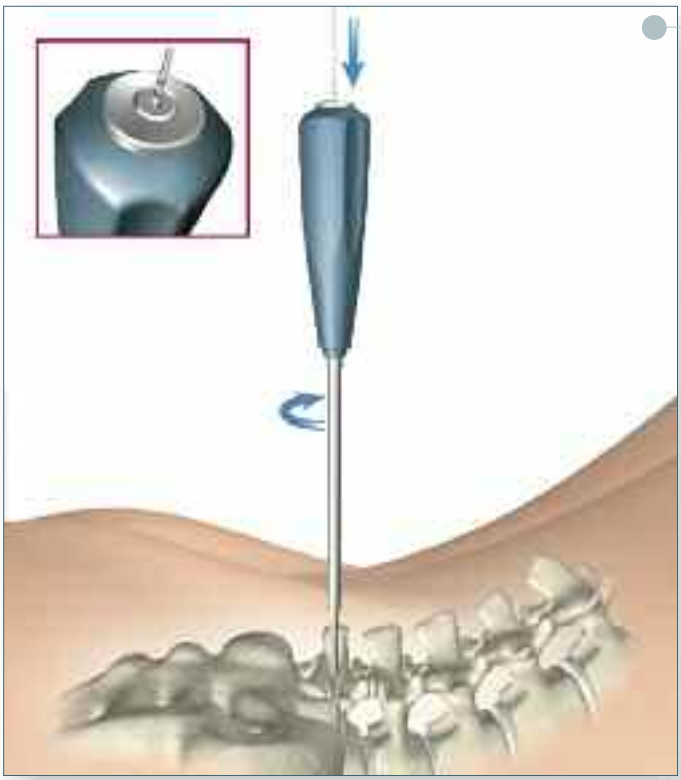


Figure 12

Note: 1.0cm 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 **Precision Square Awl** or **Precision Tap**.

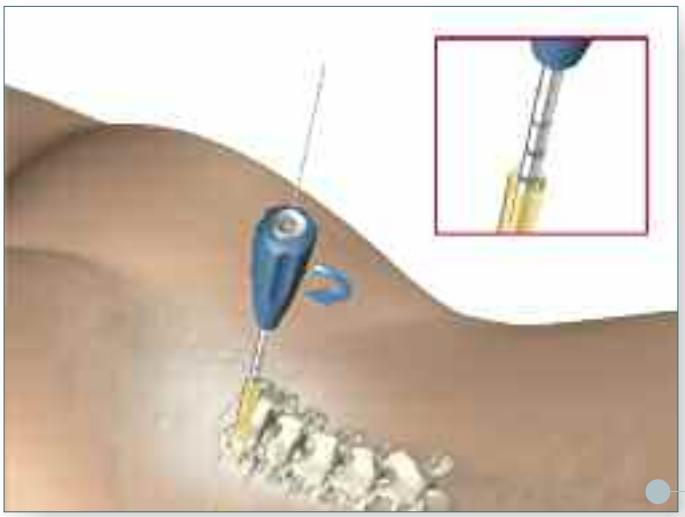


Figure 13

- The **Tap Sleeve (48231315)** can be used to prevent soft tissue from contacting the **Taps'** thread.

- Check pedicle depth with either fluoroscopy or read the depth from the **Tap Sleeve** as it moves along the proximal shaft of the **Taps**. 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**.

Sharp 48230230
Blunt 48230231
K-Wire

5.5mm 48230165
6.5mm 48230166
7.5mm 48230167
Xia Precision Taps

48231315
Tap Sleeve

Screw Insertion

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

The **Xia Precision Polyaxial Screwdriver** (**48231310**) provides 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.

- The **Screwdriver Protection Sleeve** (**48237009**) is pre-loaded onto the **Xia Precision Screwdriver**.

- A **Xia Precision Screw** is then placed on the distal end of the screwdriver and locked into place.

Figure 14

Note: With the **Xia Precision Screw** engaged with the **Precision Screwdriver**, the **Screwdriver Protection Sleeve** is slid over the proximal end of the screwhead to prevent the screwhead from contacting instruments during implantation.

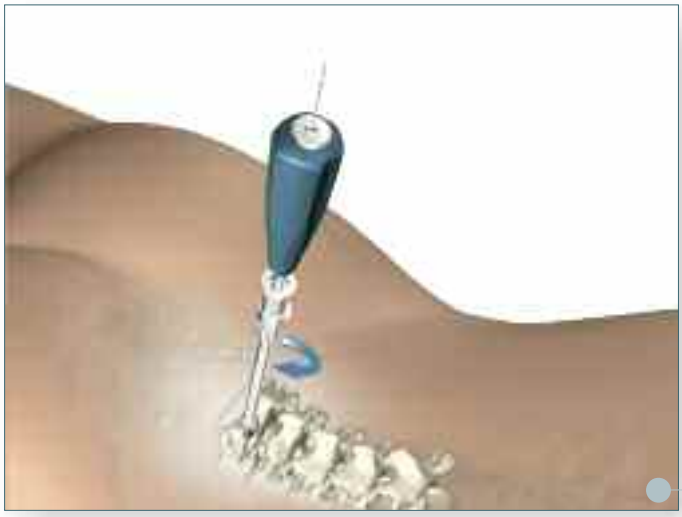


Figure 15

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

Instrument Bar

48231310
Xia Precision Polyaxial Screwdriver

48231200
Xia Precision T-Handle Ratchet

48231205
Xia Precision T-Handle Non-Ratchet

48231300
Xia Precision Round Handle Ratchet

48231305
Xia Precision Round Handle Non-Ratchet

48237009
Screwdriver Protection Sleeve

Sharp 48230230
Blunt 48230231
K-Wire

5.5mm 482315(35)-(50)
6.5mm 482316(30)-(55)
7.5mm 482317(30)-(55)
Xia Precision Screw

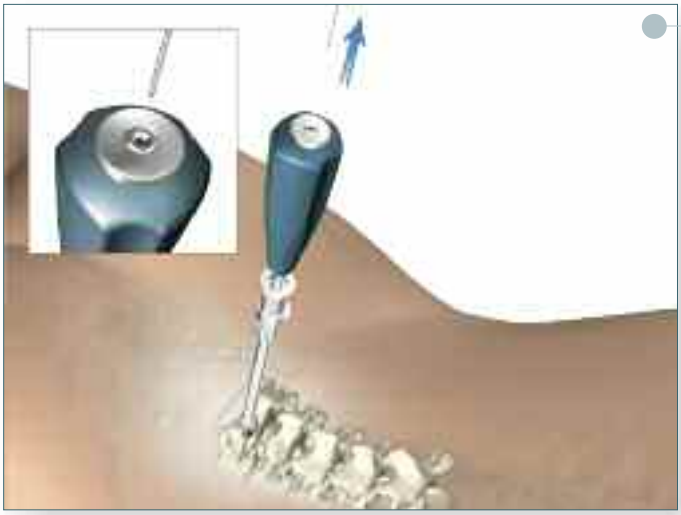


Figure 16

- After driving the screw assembly into the pedicle, remove the **K-Wire** to prevent it from advancing.
- Be certain that the screw assembly is not inserted too far. If the multi-axial head of the **Xia 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.

Figure 17

- The process is repeated for additional screws.
- After inserting both screws, the head of the screws should be the same height.

Note: The polyaxial screws may lock upon insertion. Use the **Xia Inserter** (**48047009**) to unlock the heads before introducing the rod.

Figure 18

Rod Insertion

- Once the rod is bent to the desired contour, it is placed into the grooves of the implant.

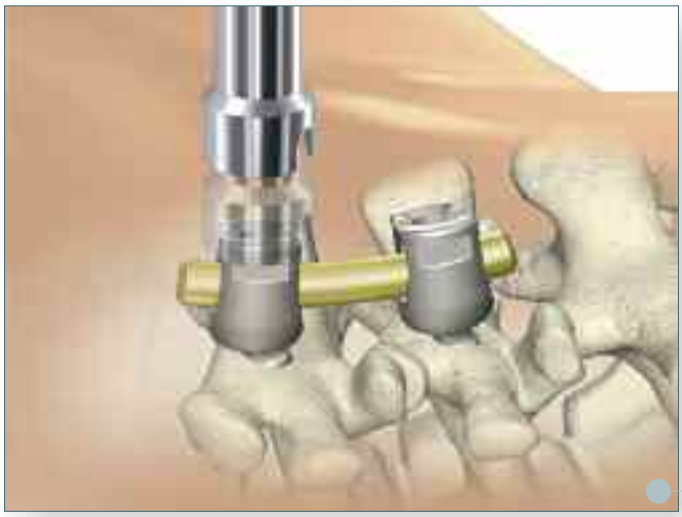


Figure 19

Tightening

- After verifying with A/P, lateral and oblique views that the rod is seated in the heads of both screws, the **Xia Blocker (03756230)** can be inserted into the screw head using the **Xia Universal Tightener 5mm (03807008)** and tightened.
- It is recommended to begin the closure at the easiest place. This may help facilitate the seating of the rod in adjacent implants.

Instrument Bar

5.5mm 482315(35)-(50)
6.5mm 482316(30)-(55)
7.5mm 482317(30)-(55)
Xia Precision Screw

Sharp 48230230
Blunt 48230231
K-Wire

48231310
Xia Precision Polyaxial Screwdriver

03756230
Xia Blocker

03807008
Xia Universal Tightener 5mm

48047009
Xia Inserter

6.0mm 482180(30)-(50)
6.0mm 482180(60)-(90)
Xia Rad Rod

6.0mm 482190(50)-(80)
Xia Max Rad Rod

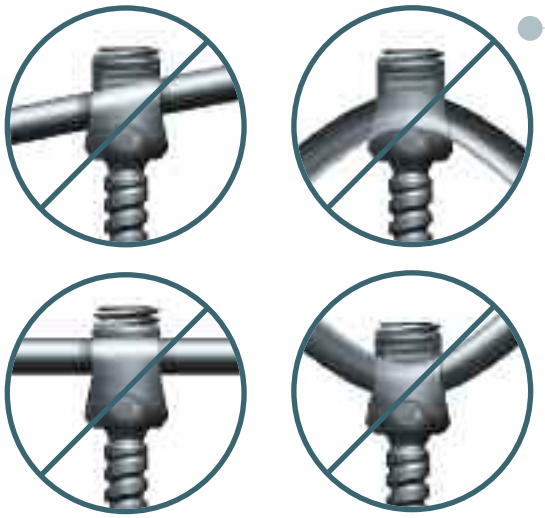


Figure 20

- In the event the rod is forced down while tightening the **Xia Blocker**, ensure that the **Blocker** is fully engaged into the screw head. This will help resist the high reactive forces generated by the final-tightening maneuver.

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.

Figure 21

- Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the **Blocker** is done by utilizing the **Anti-Torque Key (48027000)** and the **Torque Wrench (03807028)**.
- Line up the two arrows on the **Torque Wrench** to achieve the optimum torque of 12Nm for final tightening of the implants.

Note: The **Anti-Torque Key** must be used for final tightening. The **Anti-Torque** performs two important functions:
1. It allows the **Torque Wrench** to align with the axis of the tightening axis.
2. It allows one to maximize the torque needed to lock the implant assembly.

Note: If the **Anti-Torque Key** cannot be easily removed from the implant head, the rod may not be fully seated.

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

Note: For additional information, please refer to the Xia Surgical Technique.

Catalog #	Description

Instruments

48237000	Xia Precision Implant & Instrument Tray
48237005	K-Wire Container

48237110	Jam Shidi: 10 Gauge, 229 mm
48237105	Jam Shidi: 10 Gauge, 127 mm
48237115	Jam Shidi: 11 Gauge, 127 mm
48237135	Jam Shidi: 13 Gauge, 127 mm

48230230	K-Wire Sharp
48230231	K-Wire Blunt

48230235	K-Wire Guide Tube

48237001	Xia Precision Square Awl

48231200	Xia Precision T-Handle Ratchet
48231205	Xia Precision T-Handle Non-Ratchet

48231300	Xia Precision Round Handle Ratchet
48231305	Xia Precision Round Handle Non-Ratchet

Continued

	Catalog #	Description
Instruments (Continued)		
	**48230165**	Xia Precision Tap 5.5mm
	48230166	Xia Precision Tap 6.5mm
	48230167	Xia Precision Tap 7.5mm
	**48231310**	Xia Precision Screwdriver
	**48237120**	Slap Hammer
	**48231315**	Tap Sleeve
	**48237009**	Screwdriver Protection Sleeve

Catalog #	Description	
Implants		
03756230	Xia Blocker	
Polyaxial Screw		
482315(35)-(50)	Xia Precision Screw 5.5 x 35-50mm (5mm increments)	
482316(30)-(55)	Xia Precision Screw 6.5 x 30-55mm (5mm increments)	
482317(30)-(55)	Xia Precision Screw 7.5 x 30-55mm (5mm increments)	
Prebent Rod		
482180(30)-(50)	Xia Rad Rod 6.0 x 30-50mm (5mm increments)	
482180(60)-(90)	Xia Rad Rod 6.0 x 60-90mm (10mm increments)	
482190(50)-(80)	Xia Max Rad Rod 6.0 x 50-80mm (10mm increments)	

Indications

The Xia Spinal System is intended for use in the non-cervical spine. When used as a pedicle screw fixation system, the Xia Spinal System is intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw fixation system, the Xia Spinal System is also intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

When used as an anterior screw fixation system or a posterior hook and sacral/iliac screw fixation system, the Xia Spinal System is indicated for patients with degenerative disc disease which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis or revision of failed fusion attempts.

The 6mm diameter rods from DIAPASON Spinal System and OPUS Spinal System are intended to be used with the other components of Xia Titanium Spinal System. The Titanium Multi-Axis Cross Connectors are intended to be used with the other components of the Xia Titanium Spinal System.

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 weight bearing, reduction of high activity levels, the role excess weight has on the lifetime of the implant and fusion, 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) or engages in high impact recreational activities, she must be told 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 must 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. Patients must also be counseled that individual results vary and depend on specific clinical factors.

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

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 conditions 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 his decision. The above list is not exhaustive.

Precautions

Preoperative

Anyone using Stryker® Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from Stryker directly. Those using brochures published more than two years before the surgical intervention are advised to get an updated version.

Stryker Spine devices can only be used by doctors who are fully familiar with the surgical technique required and who have been trained to this end. The doctor operating must take care not to use the instruments to exert inappropriate stress on the spine or the implants and must scrupulously comply with any operating procedure described in the surgical technique provided by Stryker.
For example, the forces exerted when repositioning an instrument in-situ must not be excessive as this is likely to cause injury to the patient.

To reduce the risks of breakage, care must be taken not to distort the implants or nick, hit or score them with the instruments unless otherwise specified by the applicable Stryker Spine Surgical Technique.

Extreme care must be taken when the instruments are used near vital organs, nerves or vessels. Particular precautions must be taken when using the instruments in pediatrics.

Unless otherwise specified on the label, the instruments can be reused after decontamination, cleaning and sterilization.

Cautions

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.

Based on the fatigue testing results, 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 the system.

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 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 currently unknown.

Interconnection and Spinal Attachment Instructions

The Xia System consists of titanium rods attached to the spinal column through the use of hooks. Screws may be used to attach rods to the spinal column in certain select patients and certain select levels (See Indications, Warnings and Precautions sections). Cross bars may be used to connect rods to rods to provide a more rigid construct, as well as screws to rods, and hooks to rods. Screws and hooks are provided in several sizes to accommodate varying patient morphology. Screw offsets and offset clips are used to reduce excessive bending of a spinal rod in situations in which the point of attachment presents angular difficulty. Rod-to-rod connectors are used in situations in which a fusion needs to be extended to an adjacent motion segment.

Removal or Revision Procedures

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices usually 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
- Bone growth restraint due to the presence of the implants (in pediatric use)
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker can be used to remove the implants. Any decision by a physician to remove the internal fixation device should 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 should be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

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