

**The information contained in this document  
is intended for healthcare professionals only.**

# Xia® 4.5 Spinal System

## Operative Technique

Xia 4.5 Operative Technique



# Xia 4.5 Operative Technique

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### Acknowledgements - Introduction

Stryker® Spine is proud to introduce the Xia® 4.5 Spinal System. Stryker® Spine's new Xia® 4.5 Spinal System was developed and built upon the Xia® Spinal System foundation. We have retained the ease of use, superior closure mechanism of the Xia® buttress thread and the Xia® cortical/cancellous thread pattern\*. This comprehensive, anterior and posterior, offering of implants and instruments has been designed for use with a 4.5mm diameter rod to address complex spinal pathologies.

Stryker Spine would like to extend our thanks to the following surgeons for their participation in the continued development of the Xia® 4.5 Spinal System:

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David Gray, M.D., Fort Worth, TX  
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\*Data on file at Stryker Spine



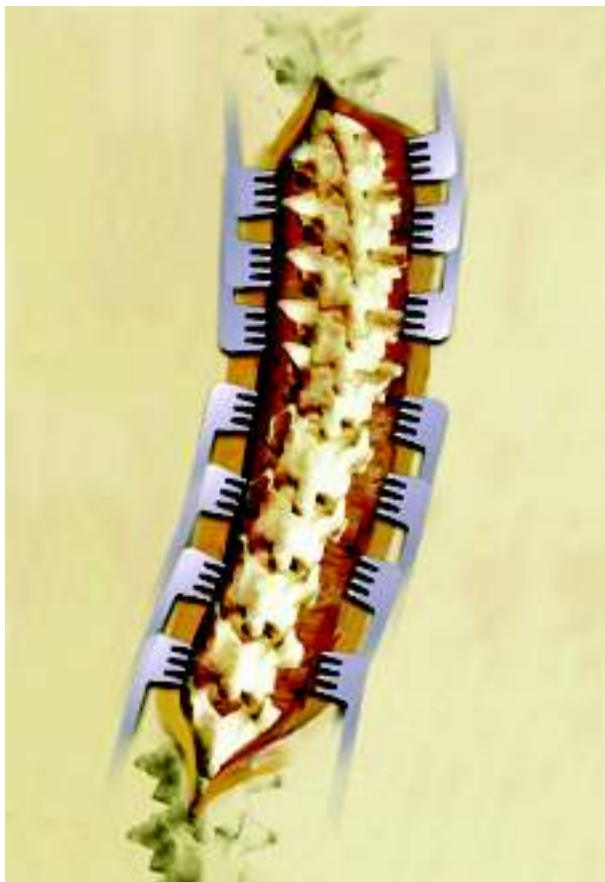
# A. Patient Positioning - Posterior Approach

## Patient Positioning



The diagnosis of spinal deformity and goals of surgical treatment are based upon patient history, physical findings and preoperative radiographic assessment. The Xia 4.5 Spinal System can be used for fusion applications in the non-cervical spine.

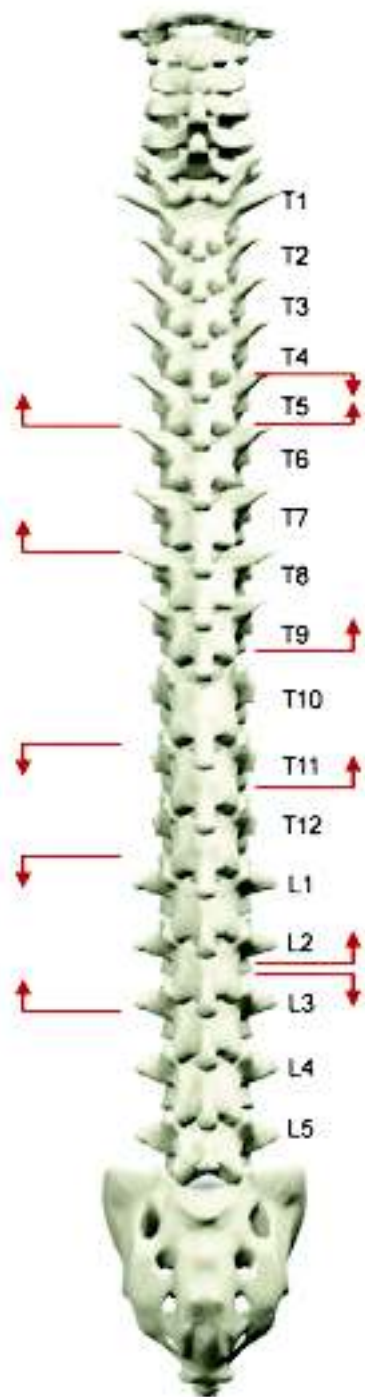
The patient is usually positioned prone on an appropriate spinal table. Chest and table bolsters are sometimes too large for small stature patients, and rolls of padding are often more effective at stabilizing the patient and keeping the abdomen free to facilitate venous drainage. Care is taken to pad all bony prominences.



Surgical levels may be verified clinically or radiographically. To ensure adequate exposure, the incision is made to extend just beyond the length of the intended surgical levels. Special care should be taken not to disturb the ligamentous integrity above or below the intended levels of surgery so as to avoid an iatrogenic junctional deformity. In some cases, special care must be made to avoid disturbing facets, decorticating or placing bone graft in areas where fusion is not intended given the inclination that some patients may have towards fusion.

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## B. Hook Design



### Implants

The Xia 4.5 Spinal System includes a variety of titanium implants which serve as anchors for the rods. Presurgical planning defines the most appropriate implants as well as the optimal location of the implants to be inserted. Options include pedicle screws and various hooks, downsized to meet the needs of a small stature patient.

### Hook Insertion

The appropriate implant is chosen according to a number of factors that include patient anatomy, hook location, bone quality, correction technique to be used and the forces to be applied.



Hooks may be inserted in the thoracic or lumbar segments of the spine. The Xia 4.5 hooks vary in blade width, throat height, body extension and shape. Offset connectors can be helpful in lining up hook connections for rod insertion, especially when used in conjunction with pedicle screws at adjacent segments.

# C. Hook Insertion



## Supralaminar Hooks

Supralaminar hooks are directed caudally. The blade of the hook sits within the epidural space. The ligamentum flavum is dissected from the lamina and a small laminotomy is made.

Once the site is developed, the **Lamina Preparer (48137021)** can be used with great care to help size and seat the implant. Once the window is prepared large enough to accommodate the implant, the blade is turned down 90 degrees and seated on the lamina. This technique will assist in stabilization of the hook, which can help facilitate rod introduction.



Once the site is confirmed to be well prepared, the selected lamina hook is loaded on either the **Hook Holder (48137027)** or **Lateral Hook Holder (48131040)**. The hook is inserted in a downward rotational movement so that the tip of the blade hugs the anterior surface of the lamina at all times. A gentle burring of the posterior lamina is sometimes necessary to allow hook rotation to access the canal.



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## C. Hook Insertion

### Infralaminar Hooks



Infralaminar hooks are directed cephalad. The **Lamina Preparer** is used to dissect the ligamentum flavum from the inferior lamina and prepare a path for the hook. The blade is seated between the anterior surface of the lamina and the ligamentum flavum, and is not located directly in the canal.



A wide blade hook may be selected if the patient's anatomy permits. The hook is loaded onto a **Hook Holder** and inserted into the path created by the **Lamina Preparer**.



The **Hook Impactor (48137029)** may be used with the **Hook Holder** to facilitate hook seating against the inferior lamina.

## C. Hook Insertion



### Pedicle Hooks

Pedicle hooks are always directed cephalad and are implanted from T10 to T1. A limited facetectomy at the base of the facet opens the facet joint, squares the lamina and exposes the underlying articular cartilage of the superior facet of the caudal vertebra. The **Pedicle Preparer (48137025)** is inserted into the facet joint aiming lateral of the midline with the aim to span the pedicle. Once the **Pedicle Preparer** seats, a gentle laterally based force should engage the pedicle and confirm localization. The **Pedicle Preparer**, properly engaged on the pedicle, can be used to confirm a reliable fit on the vertebra by mobilizing the vertebra laterally.

The hook is firmly gripped by the **Hook Holder**. The **Hook Impactor** is inserted into the hook. The hook is slid into the desired position, and then gently tamped against the pedicle.

This combination provides an optimal level of force and guidance to safely insert the hook.

Alternate method: The hook is temporarily secured to the **Hook Impactor** by tightening a **Blocker (48130000)**. The blocker may be removed once the hook has been placed

**Note:**  
To facilitate the introduction of the pedicle hook it may be necessary in some situations to remove a small amount of the prominence of the caudal lamina below the pedicle hook insertion site.



## Xia 4.5 Operative Technique

### C. Hook Insertion



#### Transverse Process Hook

A transverse process hook or a standard lamina hook may be used over a transverse process. The **Lamina Preparer** can be used to dissect around the superior and anterior surface of the transverse process to create room between the anterior aspect of the transverse process and the rib head.

Care should be taken to completely elevate the ligament off of the anterior surface of the transverse process prior to directing the lamina preparer caudally, so as not to enter within the transverse process and create a fracture.

Caudally directed transverse process hooks are often the top portion of the transverse pedicle claw configuration. The transverse process hook is designed to line up with the inferior pedicle hook to allow easy introduction of the rod and blocker.



## D. Screw Insertion



### Pedicle Entry

The small cortical crest is removed with a rongeur or power burr to expose the underlying cancellous bone.

The entry point may be prepared with a high speed burr or with the **Awl (675021)**, which should be driven in no more than 13mm.

A pathway is then opened up with the **Blunt Probe (03807024)** or the **Thoracic Pedicle Probe (48137055)**. The probe should be directed laterally at the outset and then turned medially after approximately one centimeter.

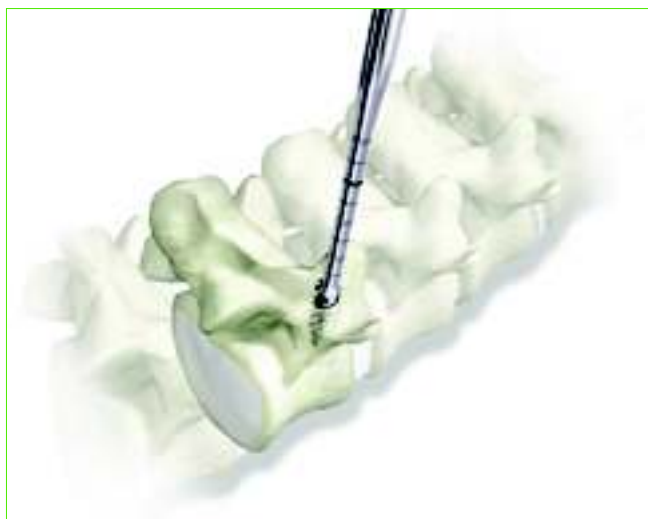
The correct rotational insertion of the instrument will allow the probe to follow a path of least resistance without violating the pedicle walls. In the event that resistance is felt, the entry point and trajectory should be re-evaluated.

The prepared pathway is checked with the **Tapered Ball Probe (48137059)** to verify that all walls (superior, inferior, medial and lateral) of the pedicle have not been violated and that cancellous bone is felt at the distal end of the path.

# Xia 4.5 Operative Technique

## D. Screw Insertion

### Screw Preparation and Insertion



**Modular Taps** may be used to prepare the pedicle screw canal. The **Tap** sizes are **4.0mm (480401540)**, **4.5mm (48040154)**, **5.0mm (48040150)**, **5.5mm (48040155)** and **6.5mm (48040156)**. If a **Tap** is used, the pedicle should be probed again to verify that the pedicle has not been breached.



Both **Polyaxial (48131310)** and **Monoaxial Screwdrivers (48131320)** provide a rigid connection between the screw and screwdriver.



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

## E. Rod Contouring



Once all anchors are placed, the **Rod Template (48130620)** may be used to determine the appropriate rod length.



The surgeon chooses the appropriate rod and cuts it to the correct length with the **Rod Cutter (48137800)**. To achieve a stiffer construct, the surgeon may opt for a 4.5mm diameter **Vitallium Rod (48132601)** 600mm in length.

**Note:**  
As the **Vitallium Rod** requires greater force to cut, the **Xia Table Top Rod Cutter (03808400)** is recommended.

Rod bending is performed to fit the desired spinal contours. The **Rod Template** may be used to reproduce the spinal contour. Rod contouring is performed with the **French Benders (48137010)**. To contour the rod, a series of small incremental adjustments will bend the rod gradually and ensure even stress distribution on the rod.



The **Bending Irons (48137011R/L)** may be used for in-situ bending to achieve final incremental correction maneuvers. **Coronal Plane Benders (48130910R/L)** may also be used in order to accomplish the desired rod contouring. Care should be taken to not make extreme bends, so as to avoid stress concentration and notching of the rod.

# Xia 4.5 Operative Technique

## E. Rod Contouring

### Rod Insertion

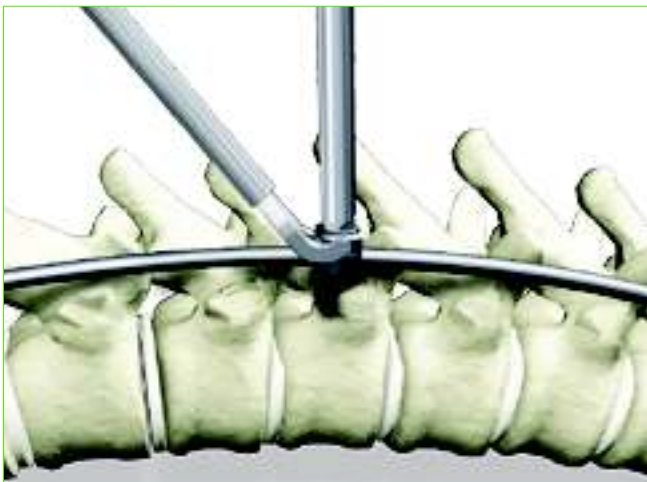
Once the rod is bent to the desired contour, the **Rod Gripper (48130140)** may be used to facilitate placement of the rod into either the hooks or screws. This can be done in any sequence at the discretion of the surgeon.



The **Rod Pusher (48137019)** can be used to help manipulate the rod to the screw head.



## F. Rod Linkage



The Xia 4.5 System offers three options for linking the rod to the spine

### Inserter Tube

The **Inserter Tube** (48137009) can help align the **4mm Blocker Inserter, Long** (48137008L) with the implant.



### Rod Fork

The **Rod Fork** (48137018) is used when the rod is slightly proud with respect to the seat of the implant.

The **Rod Fork** easily slides into the lateral grooves on the implant head and is rotated backwards. This levers the rod into the head of the implant. The blocker is inserted with the **4mm Blocker Inserter, Short** (48137008S) when the rod is fully seated into the head of the implant.



### Persuader

The **Persuader** (48137016) is used when additional force is needed to bring the rod to the implant.

In the position "0", connect the **Persuader** to the head of the implant.



## Xia 4.5 Operative Technique

### F. Rod Linkage

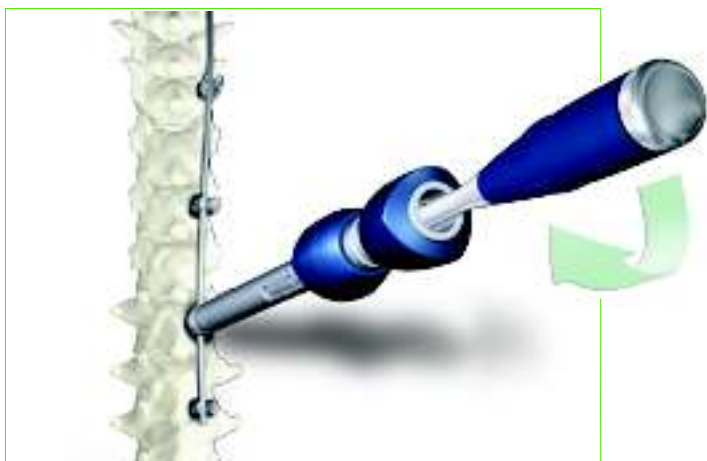


Turn the head of the **Persuader** until the indication line moves to the position "1". The **Persuader** is now locked to the implant. From this position the rod can be pushed into the screw.



Turn the head of the **Persuader** until the indication line moves into position "2". The rod is now fully seated allowing insertion of the blocker. Introduce the blocker through the persuader using the **4mm Blocker Inserter, Long**.

To remove the **Persuader**, turn the head of the instrument back to the position "0" and rotate the complete instrument.



## F. Rod Linkage



### Rod to Rod Connectors

#### Axial Connector

Through the use of the **4.5-4.5 Axial Connector (48135000)**, or the **4.5-6.0 Axial Connector (48135001)**, it is possible to axially connect the construct to another rod. Ensure that the pre-assembled set screws are adequately backed out to allow for rod introduction. Slide the tips of the rods to be linked deep into the **Axial Connector**. Tighten the set screws using the **3mm Hexdriver (48137057)**.



#### Parallel Connector

Slide the **Parallel Connector (48135105)** under the primary rod of the construct. Insert a blocker into the tulip using the **4mm Blocker Inserter**. Prepare the second rod to be linked to the construct into the tulip of the **Parallel Connector** and insert a second blocker into the tulip using the **4mm Blocker Inserter**. The rods may be translated for adjustment before final tightening. Tighten the blockers using the **T-Handle Blocker Driver (48137058)**.



#### Offset Connector

The **Offset Connector (48135101-5102)** can be bent prior to insertion or in situ using **Bending Irons** in order to connect the construct to an offset screw or hook.

The **Offset Connector** can also be cut with a **Rod Cutter** to the appropriate length before insertion. Slide the tulip of the **Offset Connector** under the rod of main construct. Insert a blocker in the tulip of the connector using the **4mm Blocker Inserter**. Seat the stem of the **Offset Connector** in the screwhead and insert a blocker in the tulip of the screw using the **4mm Blocker Inserter**. Tighten the blocker of the **Offset Connector** using the **4mm Blocker Driver**. Tighten the blocker of the screw using the **T-Handle Blocker Driver**.

#### Note:

**It is important that to refrain from final tightening with the 4mm Blocker Inserters. Final tightening should be done with the T-Handle Blocker Driver.**

## Xia 4.5 Operative Technique

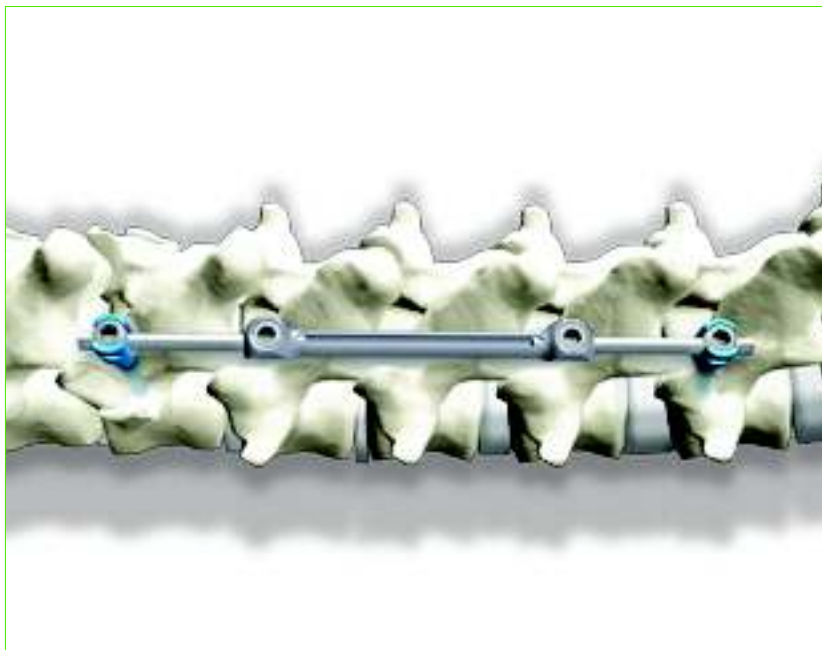
### F. Rod Linkage



#### Connectors Assembly

##### Iliac Connectors

Choose the appropriate **Iliac Connector (48135106-5109)** depending on the angle between the main construct and the iliac screw. Slide the Iliac Connector under the primary rod of the construct, and insert a blocker into the tulip using a **4mm Blocker Insert**. Prepare a second rod to bridge the span from the primary construct to the ilium, and insert the rod to be linked to the construct into the tulip of the **Iliac Connector**. Insert a second blocker into the tulip using the **4mm Blocker Insert**. The rods can be translated for adjustment before final tightening. Tighten the blockers using the **4mm Blocker Driver**.



##### Extended Connector

Slide the tips of the rods to be linked into the **Extended Connector (48135103-5104)**. The **Extended Connector** can be maneuvered using the **Threaded Tube** (part of Round Handle Monoaxial/Polyaxial Screwdriver 481312320/48131310) screwed in the threaded holes. Insert two blockers at both ends of the **Extended Connector** using the **4mm Blocker Insert**. Tighten the blockers using the **4mm Blocker Driver**.

In order to extend the construct, loosen the blockers and spread using the **Distractor (48136000)** by inserting the tips in the groove and applying a distraction force.

##### Note:

**When using an Extended Connector, the uncut ends of the rod should be inserted into the connector. Also, it is important to keep the rods straight along the length of the Extended Connector for proper insertion.**



# G. Reduction Procedures



## Deformity Correction

Deformity correction may be obtained using one of four different reduction procedures:

1. Rod Derotation
2. Translation
3. Distraction/Compression
4. In Situ Bending

These maneuvers may be utilized independently or in any combination to facilitate optimal spinal deformity correction.

## Rod Derotation

### Option 1: Traditional Rod Derotation:

Ensure that all blockers are inserted but not tightened using the **4mm Blocker Inserter**.

Typically, the rod is then rotated to an arch of 90 degrees converting a scoliotic deformity in the thoracic spine into a sagittal kyphosis and translating a lumbar scoliotic deformity into lumbar lordosis. Once the rod has been fully rotated, the blockers are provisionally tightened.

The rod is rotated using the **Rod Rotation Forceps (48130100)**. The surgeon may opt to combine one of the **Rod Rotation Forceps** with a **Rod Rotation Key (48137056)** connected at the hexagonal tips of the rod. Once the rod is fully rotated, the blockers can be provisionally tightened with the **4mm Blocker Driver**.



## G. Reduction Procedures



### Option 2: Rod Rotation for Implant Approximation:

The rotation technique for approximation is to contour the rod in the sagittal plane to the desired shape. The rod can then be inserted in the implants up to 90 degrees out of phase to minimize the implant approximation necessary. The rod is then rotated, not to derotate the spine, but to place the implants in the proper alignment. Final correction is then performed using distraction and compression techniques.

### Translation

Translation can be achieved by utilizing the **Persuader**. Two **Persuaders** are typically placed at the distal and proximal ends of the curve apex. As the spine is carefully translated at these points, the blockers are inserted and the implants secured.

The **Persuaders** are then moved toward the apex of the curve until translation is complete.

**Note:**  
The standard Xia 4.5 set definition contains only one **Persuader**. In order to perform this translation technique, an additional **Persuader** is required.



### Distraction/Compression

Spinal deformities can be further affected by creating a distraction in the concavity of the deformity and compression on the convexity of the deformity.

**Note:**  
Posterior distraction creates a **kyphosis** in the sagittal plane, compression creates a **lordosis** in the sagittal plane.

Ensure all blockers are inserted but not tightened using the **4mm Blocker Insertor**. Create distraction on the concavity of the deformity with the **Distraction**. Create compression on the convexity of the deformity with the **Compressor (48136100)**. Once the construct is in the right position, lock the blockers with the **4mm Blocker Driver** to maintain the correction.

## H. Final Tightening



### In Situ Bending

Bend the rod in situ in the sagittal plane by utilizing the **Bending Irons**. If bending is required in the frontal plane, use the **Coronal Plane Benders**. Care must be taken not to overload the bone implant interface or notch the rod.

### Using the Torque Wrench

Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the blockers is done by utilizing the **Anti-Torque Key (48137026)** and the **Torque Wrench (48137028)**. The **Torque Wrench** indicates the appropriate torque that has to be applied to the implant for final tightening. Line up the arrow to the line in order to achieve this final tightening torque of 8 Nm.

#### Note:

It is not recommended to exceed 8 Nm during final tightening.

#### Note:

The **Anti-Torque Key** must be used for final tightening. The **Anti-Torque Key** performs two important functions:

- 1) It allows the **Torque Wrench** to align with the tightening axis.
- 2) To maximize the torque needed to lock the implant assembly.

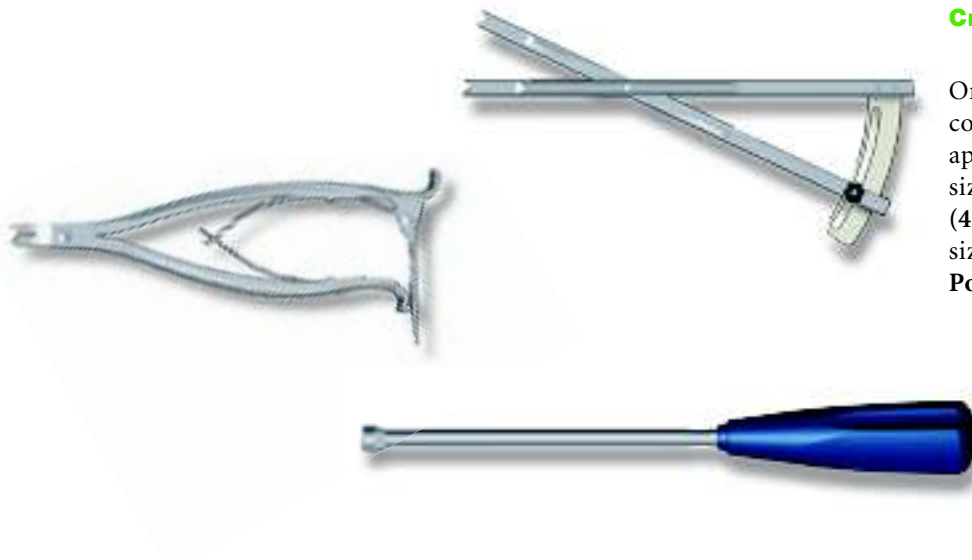
#### Note:

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



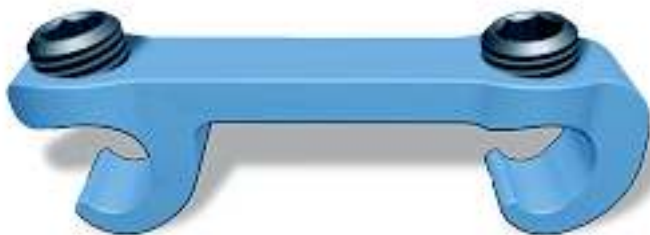
## Xia 4.5 Operative Technique

# I. Cross Connector



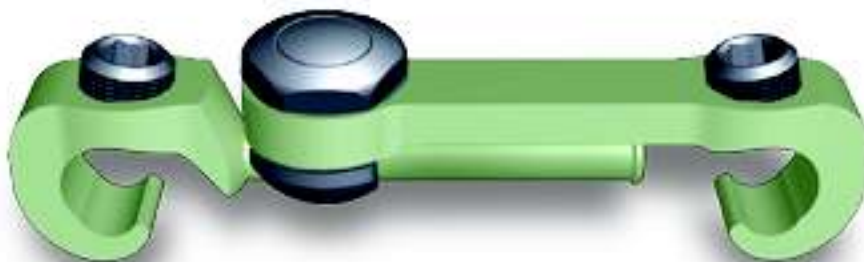
### Cross Connector Assembly

Once the final tightening of the construct is completed, choose the appropriate **Cross Connector** size by using the **Calliper (48130130)**. Depending on the size you may use **Monobloc** or **Polyaxial Cross Connector**.



### Mono Axial Cross Connector (Monobloc)

Place one or two appropriate **Cross Connectors** at the top and the bottom of the construct by using the **Cross Connector Holder (48130120)**. The rods must be parallel in order to properly assemble the **Monobloc Cross Connector**. While holding the **Connector** with the **Cross Connector Holder**, tighten the set screws onto the rods with the **3mm Hexdriver**.



### Polyaxial Cross Connector

To make the assembly of the **Polyaxial Cross Connector** easier, ensure that the center bolt is loose to achieve full range of motion and that the set screws on the claws are adequately backed out. With the **Cross Connector Holder**, place the **Cross Connector** on the rod. Tighten the set screws with the **3mm Hexdriver**. Finally, tighten the center bolt with the **8mm Screwdriver (675023)**.

## J. Anterolateral Approach



**Note:**  
The largest Dual Hole Staple that fits the vertebral body should be used to ensure the greatest surface-to-surface contact.



### Patient Positioning

The patient is usually approached via a transcostal approach in the thoracic spine or retoperitoneal approach in the lumbar area. A combined incision can be used to access both.

The patient is usually positioned in lateral decubitus position with the convex side up. The highest intended instrumented vertebra is selected and typically defines the rib to be excised (e.g. 6th rib to access 6th thoracic vertebra). The rib can be morcellized for bone graft.

Exposure of the vertebral bodies is completed allowing discectomies and release of the anterior longitudinal ligament and concave soft tissue.

### Dual Hole Staple Placement

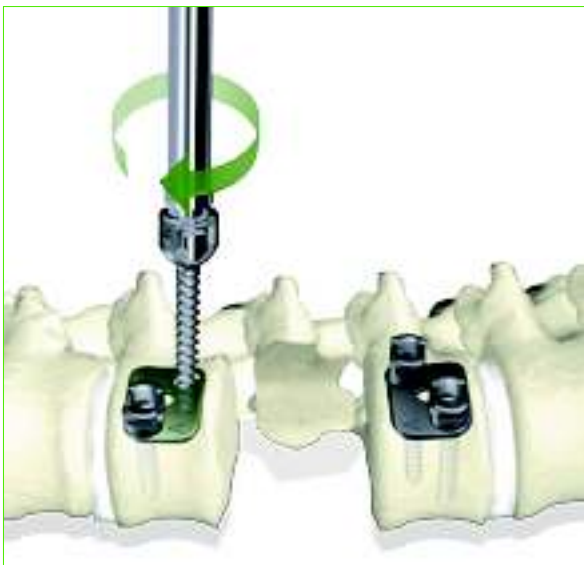
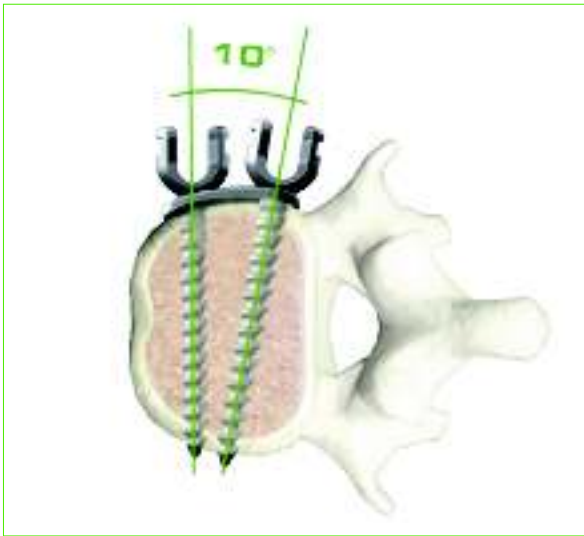
Implantation begins with the placement of the **Dual Hole Staple**. The **Dual Hole Staples** are to be implanted between T4 and L4. **Rostral Staples** are green and **Caudal Staples** are gray. Thread the **Dual Staple Impactor (48139241)** to the staple. Ensure that the tetra spikes of the staple are facing the vertebral body and affix the staple using a mallet.

The **Dual Hole Staples** are marked anterior and posterior for left-sided approaches so be careful with right-sided approaches as these markings will be reversed. This system is designed so that when the construct is complete, the anterior rod is longer. In some cases, it may be convenient for the longer rod to be placed posterior. In either case, avoid a parallelogram configuration with the same sized rods as this may be weaker than trapezoidal constructs.

Once the entry point and screw direction are defined (directed away from the spinal canal) the cortex can be perforated using the Awl.



## J. Anterolateral Approach



### Dual Hole Staple Placement

For the posterior screw tracts use the **AwI** to create a pathway angled 10 degrees anteriorly to avoid the spinal canal. For the anterior screw tracts use the **AwI** to create a pathway perpendicular to the vertebral body.

#### Note:

**There is a tendency for surgeons to place the staple too far anteriorly on the vertebral body. To avoid this, surgeons should generously resect the rib head and adequately retract the solis muscle. The surgeon should then be able to pass a probe along the posterior cortex and use this as a guide for staple placement.**

### Screw Insertion

The length of the screws is selected according to Computed Tomographic (CT) scans or the use of a standard depth gauge. Monoaxial screws are connected rigidly to the **Monoaxial Screwdriver** to be driven in the vertebral body. Screw selection for the anterior approach is limited to 4.0, 4.5, 5.0, 5.5 and 6.5mm diameter monoaxial screws.

For patients with larger vertebral bodies or significant osteoporosis, surgeons should consider using larger diameter screws available.

Avoid placing 6.5mm diameter screws in at angles greater than 10 degrees to prevent the screw from ginding in the **Dual Hole Staple**. Screw purchase should be bicortical for optimal fixation.

For information regarding rod contouring and insertion, deformity correction and final tightening, refer to the corresponding section of this operative technique. Crosslinking via an anterolateral approach is restricted to **Monobloc Cross Connectors**.



# Indications & Contraindications

## Indications for Use

The Xia® 4.5 Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The Stryker Spine Diapason Spinal System, Opus Spinal System and Xia Spinal System can be linked to the Xia 4.5 Spinal System via the 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: 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.

- 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 his decision. The above list is not exhaustive.

# Xia 4.5 Operative Technique

## General Conditions of Use

### General Conditions of Use

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.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

### 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 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.

### Infection

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

# General Conditions of Use

## Implant Selection and Use

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice which depends on each patient.

Patient's overweight may be responsible for additional stresses and strains on the device which can speed up metal fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants should be taken into consideration by the surgeon at the time of the choice of the implant, during implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause metal fatigue or fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

Improper selection, placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Contouring or bending of rods or plates only is recommended if necessary according to the surgical technique of each system. Rods or plates should only be contoured with the proper contouring instruments. Incorrectly contoured rods/plates, or rods/plates which have been repeatedly or excessively contoured must not be implanted. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery. Refer to the STRYKER Spine surgical protocols for additional procedural information. Periodic follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

## Postoperative Care

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting be employed. The patient should be instructed regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. The patient should also be instructed to report any unusual changes of the operative site to his/her physician. The physician should closely monitor the patient if a change at the site has been detected.

# Xia 4.5 Operative Technique

## General Conditions of Use

### Adverse Effects

- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws and rods, has occurred.
- Pain, discomfort, or abnormal sensations due to the presence of the device.
- Pressure on skin from components where inadequate tissue coverage exists over the implant, with the potential extrusion through the skin.
- Dural leak requiring surgical repair.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) should be revised or removed immediately before serious injury occurs.
- Loosening of spinal fixation implants can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, migration and/or pain.
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Serious complications may be associated with any spinal surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Neurological, vascular, or soft tissue damage due directly to the unstable nature of the fracture, or to surgical trauma.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Decrease in bone density due to stress shielding.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft, the intervertebral body, pedicle, and/or sacrum above and/or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock. Adverse effects may necessitate reoperation or revision. The surgeon must warn the patient of these adverse effects as deemed necessary.

# General Conditions of Use

## 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
- bone growth restraint due to the presence of the implants (in paediatric use)
- 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 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.

## Pre-Operative Precautions

Anyone using STRYKER Spine products can obtain a Surgical Technique brochure by requesting one from a distributor or from STRYKER Spine 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 Spine. 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.

## Caution

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

## 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 unknown.

## Precautions















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.



# Xia universal application

## Xia<sup>®</sup> Implants

















	REF	Description		
	48130000	Xia 4.5 Rod Blocker		
	48134020-4040	Monoaxial Screw	Ø4.0mm	20mm-40mm
	48134525-4545	Monoaxial Screw	Ø 4.5mm	25mm-45mm
	48135025-5050	Monoaxial Screw	Ø 5.0mm	25mm-50mm
	48135525-5555	Monoaxial Screw	Ø 5.5mm	25mm-55mm
	48136530 - 6560	Monoaxial Screw	Ø 6.5mm	30mm-60mm
	48144020-4040	Polyaxial Screw	Ø4.0mm	20mm-40mm
	48144525-4570	Polyaxial Screw	Ø4.5mm	25mm-70mm
	48145025-5070	Polyaxial Screw	Ø 5.0mm	25mm-70mm
	48145525-5570	Polyaxial Screw	Ø 5.5mm	25mm-70mm
	48146530-6570	Polyaxial Screw	Ø6.5mm	30mm-70mm
	48133200	Titanium Long Rod	Ø4.5mm	200mm
	48133480	Titanium Long Rod	Ø4.5mm	480mm
	48132601	Vitallium™ Rod	Ø4.5mm	600mm















# Xia<sup>®</sup> Implants

REF	Description
48130220	Pedicle Hook Small
48130221	Pedicle Hook Large
48130201	Laminar Hook Small
48130202	Laminar Hook Medium
48130203	Laminar Hook Large
48130208	Laminar Hook Angled
48130210	Thoracic Laminar Hook
48130204	Extended Laminar Hook
48130230	Transverse Process Hook, Right
48130231	Transverse Process Hook, Left
48130212	Thoracic Laminar Hook, Right
48130213	Thoracic Laminar Hook, Left
48130214	Supralaminar Thoracic Hook, Right
48130215	Supralaminar Thoracic Hook, Left
48130110	Dual Hole Staple Small, Caudal
48130111	Dual Hole Staple Small, Rostral
48130112	Dual Hole Staple Large, Caudal
48130113	Dual Hole Staple Large, Rostral

# Xia universal application













## Xia<sup>®</sup> Implants

	REF Titanium	Description	
	48135000	Ø4.5mm- Ø4.5mm Rod to Rod Connector	
	48135001	Ø4.5mm- Ø6.0mm Rod to Rod Connector	
	48135101	30mm Offset Connector	
	48135102	70mm Offset Connector	
	48135103	Extended Connector Small	
	48135104	Extended Connector Large	
	48135105	Parallel Connector	
	48135106	Iliac Connector 15 degree	
	48135107	Iliac Connector 25 degree	
	48135108	Iliac Connector 35 degree	
	48135109	Iliac Connector 45 degree	
	48133012-3024	Monobloc Cross Connector	12mm-24mm
	48133224	Polyaxial Cross Connector Small	24mm-30mm
	48133230	Polyaxial Cross Connector Medium	30mm-36mm
	48133236	Polyaxial Cross Connector Large	36mm-45mm
	48133245	Polyaxial Cross Connector Extra Large	45mm-60mm

	REF	Description
	675021	Awl
	03807024	Blunt Probe
	48137055	Thoracic Pedicle Probe
	48137059	Tapered Ball Probe
	480401540	Ø4.0mm Modular Tap
	48040154	Ø4.5mm Modular Tap
	48040150	Ø5.0mm Modular Tap
	48040155	Ø5.5mm Modular Tap
	48040156	Ø6.5mm Modular Tap
	48131320	Round Handle Monoaxial Screwdriver
	48131321	Shaft for Monoaxial Screwdriver
	48131310	Round Handle Polyaxial Screwdriver
	48131311	Shaft for Polyaxial Screwdriver
	48137025	Pedicle Preparer
	48137021	Lamina Preparer
	48137027	Hook Holder
	48131040	Lateral Hook Holder

# Xia universal application

## Xia® Instruments

	REF	Description
	48137029	Hook Impactor
	48130620	Ø4.0mm Rod Template
	48137800	Ø4.5mm Rod Cutter
	48130140	Rod Gripper
	48137010	French Bender
	48137018	Rod Fork
	48137009	Inserter Tube
	48137016	Persuader Small
	48137019	Rod Pusher
	48130100	Rod Rotation Forceps
	48137056	Rod Rotation Key
	48137058	4mm Blocker Driver
	48137008L	4mm Blocker Inserter Long
	48137008S	4mm Blocker Inserter Short
	48137011R	Bending Iron, Right
	48137011L	Bending Iron, Left



# Xia® Instruments



REF	Description
48130190R	Coronal Plane Benders, Right
48130190L	Coronal Plane Benders, Left
48136000	Distracter
48136100	Compressor
48137026	Anti-Torque Key
48137028	Torque Wrench
48130130	Calliper
48130120	Cross Connector Holder
48137057	3mm Screwdriver
675023	8mm Screwdriver
48130241	Dual Staple Impactor
48130001	Implant Box - Screws and Cross Connectors
48130002	Implant Box - Hooks and Components
48130003	Instrument Box 1
48130004	Instrument Box 2

# Xia universal application

## Notes

# Notes

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**Joint Replacements**

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**Trauma, Extremities & Deformities**

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**Craniomaxillofacial**

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**Spine**

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**Biologics**

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**Surgical Products**

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**Neuro & ENT**

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**Interventional Pain**

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**Navigation**

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**Endoscopy**

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**Communications**

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**Imaging**

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**Patient Handling Equipment**

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**EMS Equipment**

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