Xia® 4.5 Spinal System

Deformity techniques

Surgical technique
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Surgical technique

**Patient positioning - posterior approach**

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.
Hook design

Implant selection
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, 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.
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 can be used with great care to help size and seat the implant. Once a large enough window is prepared to accommodate the implant, the blade is turned down 90° and seated on the lamina. This technique will assist in stabilization of the hook, which can help facilitate rod introduction.

Once the site is prepared, the selected lamina hook is loaded on either the Hook Holder, the Straight Hook Holder, or the Lateral Hook Holder. 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.
Infracranial hooks
Infracranial 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 may be used with the Hook Holder to facilitate hook seating against the inferior lamina.
Pedicle hooks
Pedicle hooks are always directed cephalad and are implanted from T1 to T10. 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 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 allows for 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. 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.
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.
Preparing the pedicle

**Thoracic pedicle entry**
Landmarks usually lie at the intersection of a vertical line through the middle of the convex part of each articular process and a horizontal line drawn across the middle to upper third of the base of the transverse process. This intersection is usually 2mm below the edge of the articular cartilage and just level with the small horizontal crest of bone. The use of CT scans may be used to verify any anatomic variations.

A pedicle, and the drilling direction, is usually globally perpendicular to the posterior plane of the vertebra (plane of the transverse process).

This is an important point to consider, especially when instrumenting the apical vertebrae, which are usually the most rotated ones.

**Lumbar pedicle entry**
Landmarks are at the intersection of a vertical line through the facet joint space and a horizontal line through the middle of the base of the transverse process.

These two lines intersect at a small sharp crest of cortical bone which can be a reliable landmark since it is extra-articular and not affected by osteoarthritic deformities.
Once anatomical landmarks are identified, remove the cortical crest with a rongeur or power burr to expose the underlying cancellous bone.

Prepare the entry point with the **Awl**. The awl is designed with a stop at 13mm to prevent overplunging.

**Awl diameter = 2.9mm**

When placing sacral screws, the **Sacral Awl** can be used. Set the depth indicator on the sacral awl to the desired length; the sacral awl depth indicator can be set from 30mm to 60mm. The stop on the sacral awl is designed to prevent overplunging while breaching the anterior cortex.

**Sacral awl diameter = 4.1mm**

**Note:** The sacral awl must only be used for 6.5mm diameter screws and larger.

Using the **Curved Blunt Probe**, the **Thoracic Pedicle Probe** or the **Adjustable Curette Probe**, create a pathway into the pedicle. The correct rotational insertion of the instrument allows the probe to follow a path of least resistance without violating the pedicle walls. In the case that resistance is met, the entry point and trajectory should be reevaluated.
There are three probe options available with Xia 3. The primary differentiating feature between the curved blunt probe, the thoracic pedicle probe and the adjustable curette probe is the tip. The curved blunt probe has a flat tip, while the thoracic pedicle probe has a sharp tip designed to optimize its use in the thoracic region of the spine. The adjustable curette probe has a curette tip as another blunt tip option.

The curved blunt probe and the thoracic pedicle probe are laser marked in 5mm intervals to help indicate the depth to which the probe has been inserted. The adjustable curette probe has an adjustable depth stop which allows the probe to be inserted to the indicated depth; the depth indicator can be set from 35mm to 50mm. These depth indicators on the probes are also helpful in determining the appropriate screw length.

**Note:** The curved blunt probe and the adjustable curette probe must not be used to prepare holes for 4.0mm diameter screws. The thoracic pedicle probe is recommended for 4.0mm diameter screws.

Follow the prepared pathway with the Pedicle Feeler to confirm the walls of the pedicle have not been violated. Pedicle feelers are available in Malleable, Medium and Stiff. Pedicle feelers are laser marked in 10mm intervals. A Double Ended Pedicle Feeler is also available to feel the pedicle walls for any breaches.
For increased bone purchase, use the Modular Taps to prepare the pedicle canal. After attaching a Xia 3 handle, insert the modular tap into the pedicle and into the vertebral body. The modular taps are laser marked with lines in 5mm increments and numbers in 10mm increments.

Taps are available in the following sizes:
- Ø3.0mm Modular Tap
- Ø3.5mm Modular Tap
- Ø4.0mm Modular Tap
- Ø4.5mm Modular Tap
- Ø5.0mm Modular Tap
- Ø5.5mm Modular Tap
- Ø6.0mm Modular Tap
- Ø6.5mm Modular Tap
- Ø7.0mm Modular Tap
- Ø7.5mm Modular Tap
- Ø8.5mm Modular Tap
- Ø9.5mm Modular Tap
- Ø10.5mm Modular Tap

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<td>48230105</td>
<td>Ø10.5mm Modular Tap</td>
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Note: The nomenclature describing the taps represents the actual tap line to line diameter. This is different from previous versions of the Xia System.
The modular taps can be attached to any one of the following Xia 3 handles:

- **T-Handle**
- **T-Handle, Ratchet**
- **Round Handle**
- **Round Handle, Ratchet**
- **Small Round Handle**
- **Small Round Handle, Ratchet**

**Note:** The Jacobs Chuck Handle is another handle option for the Xia 3 system. This handle can be hand tightened or the chuck key can be used to secure the handle. Ensure proper engagement between the handle teeth and the instrument shaft surface.
Screw Types
The Xia 4.5 Evolution Spinal System offers an extremely low profile implant that is available in a wide range of diameters and lengths and four different screw types:

The Xia 4.5 thread pattern was designed for optimal purchase in both cortical and cancellous bone.

The Xia 4.5 thread pattern was designed to compress bone and create high performance pull out strength.
Xia 4.5 Spinal System

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For easy identification in the OR, Xia 4.5 Evolution implant tulips are anodized a specific color. Each tulip head color corresponds to a screw diameter.

**Xia 4.5 Evolution screw diameters**

<table>
<thead>
<tr>
<th>Diameter</th>
<th>4.0mm</th>
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<th>5.0mm</th>
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<th>7.0mm</th>
<th>7.5mm</th>
<th>8.5mm</th>
<th>9.5mm</th>
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**Screw insertion**

With the pedicle pathway prepared, and the proper screw diameter and length determined, the screw can be inserted into the pedicle using the appropriate screwdriver.

The Xia 4.5 Evolution screw can be inserted either manually or using Stryker’s powered screw insertion technique.

**Manual screw insertion**

The **Polyaxial Screwdriver** and **Monoaxial Screwdriver** provide a rigid connection between the screw and the screwdriver.

The polyaxial screwdriver is compatible with both polyaxial and polyaxial reduction screws. The monoaxial screwdriver is compatible with both monoaxial and monoaxial reduction screws.
To assemble the polyaxial and monoaxial screwdrivers:

**Step 1:**
Insert the inner shaft up through the distal end of the outer sleeve.

**Step 2:**
Slide the locking nut over the inner shaft with the serrated teeth facing downward.

**Step 3:**
Fully insert the inner shaft into the quick connect mechanism of the handle.

To load a screw onto the screwdriver:

**Step 1:**
Hold the screw by the threaded portion and engage the inner shaft into the saddle of the screw head.

**Step 2:**
For a polyaxial screw, align the four prongs of the distal tip of the inner shaft with the four prongs on the head of the bone screw. For a monoaxial screw, align the “U”-shaped distal tip with the monoaxial tulip head.

**Step 3:**
Fully seat the inner shaft into the screw head. Turn the outer sleeve clockwise until the threads of the shaft are fully engaged with the threads of the screw head.

**Step 4:**
Depress the button on the locking nut and slide the locking nut forward into the outer sleeve to lock the screw to the screwdriver.
To disengage the screwdriver from the screw:

**Step 1:**
Depress the button on the locking nut and slide the locking nut back up out of the outer sleeve along the inner shaft.

**Step 2:**
Turn the outer sleeve counterclockwise to disengage the threads of the shaft from the threads of the screw head.

**Step 3:**
Pull upward on the screwdriver.

To disassemble the screwdriver:

**Step 1:**
Release the quick connect handle from the inner shaft.

**Step 2:**
Remove the locking nut from the inner shaft.

**Step 3:**
Remove the inner shaft from the outer sleeve.

**Note:** After insertion, the screw positions may be adjusted as needed by attaching the appropriate inner shaft directly to a handle.
**Powered screw insertion**

Stryker’s powered screw insertion technique can also be used to insert Xia 4.5 Evolution implants.

Stryker’s powered screw insertion was developed with the goal of reducing the repetitive stress and fatigue spine surgeons encounter when inserting pedicle screws manually.

Depending on surgeon preference, the **Cordless Driver 3** or **RemB Universal Driver** can both be used to insert screws under power when combined with the **Hudson Modified Trinkle Reamer** attachment and **Power Adaptor**. Both handpieces are lightweight and modular, with the cordless driver 3 representing a battery-powered option while the remB universal driver is powered by the CORE console.

The same screwdriver and steps for screw insertion as described above are followed, with the **Xia 4.5 Evolution Screwdriver** interfacing with the power adaptor instead of a quick connect handle.

Please refer to the “**Powered Screw Insertion Guide – Cordless Driver 3**” (Literature Number: TLPOWBR1205) or the “Introducing Powered Screw Insertion” document (Literature Number: TLPOWSS110801) for more details.

**Navigation use:** The Xia 4.5 Spinal System can be used with Stryker’s navigated Xia 4.5 polyaxial screwdriver to facilitate bone screw insertion. The navigated Xia 4.5 polyaxial screwdriver is a navigated manual surgical instrument intended to be used as an accessory to Stryker’s Spine Navigation System, when used with SpineMap 3D navigation software.

Please refer to Stryker’s navigated Xia 4.5 polyaxial screwdriver package insert, NOLISPINAVIN, and the rotational navigation adaptor instructions for use, provided with the rotational navigation adaptor, for the indications for use. For further details and instructions on using the navigated Xia 4.5 instruments with the Xia 4.5 Spinal System refer also to Stryker’s Navigated Spine Instruments Quick Guide provided with the rotational navigation adaptor.
**Rod contouring/insertion**

Once all anchors are placed, the Rod Template 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. For a stiffer construct, the surgeon may opt for a 4.5mm diameter vitallium rod.

**Note:** The rod should be cut to the appropriate length with approximately 4mm of rod overhanging the screw.

**Note:** As the vitallium rod requires greater force to cut, the Xia Table-Top Rod Cutter is recommended.

To fit the desired spinal contours, rod bending is performed. Bending can be performed with the French Benders or the Tube Benders. To contour the rod, a series of small incremental adjustments will bend the rod gradually and help ensure even stress distribution on the rod.

**Note:** Do not repeatedly contour the rod. Care should be taken to not make extreme bends, so as to avoid stress concentration and notching of the rod. Do not contour a bent rod in the opposite direction; i.e. avoid bending and unbending the rod.

**Note:** The numbers on the nose of the french benders indicate the ideal diameter rod for that position. For example, the ideal setting for a Ø4.5mm rod is “4.” For a more gradual bend of a Ø4.5mm rod, a higher setting can be selected.
The **In-Situ Rod Benders** and the **Coronal Rod Benders** can be used to achieve final incremental correction maneuvers. Care should be taken to not make extreme bends in order to avoid stress concentration and notching of the rod.

**Rod insertion**

Once the rod is bent to the desired contour, the **Rod Gripper** 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** can be used to help manipulate the rod to the screw head.
Reduction techniques

Scoliosis, spondylolisthesis and spondylolysis
The Xia 4.5 System offers four options for reducing the rod to the spine.

**Option 1: Inserter tube**
The Inserter Tube can help align the 4mm Blocker Inserter, Long with the implant.

**Note:** 4mm blocker inserter, long is not to be used for final tightening.

**Option 2: Rod fork**
The Rod Fork 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 when the rod is fully seated into the head of the implant.

**Note:** 4mm blocker inserter, short is not to be used for final tightening.

**Option 3: Persuader**
The Persuader 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.
Turn the head of the persuader until the indication line moves to 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.
**Option 4: Reduction screws**

Xia 4.5 reduction screws can be used to help seat the rod.

The **Xia 4.5 Reduction Monoaxial and Polyaxial Screwdrivers** are used to insert the Xia 4.5 reduction screws into the pedicles.

Final tightening will take place once the blocker is inserted and the arms are broken off.

**Reduction Monoaxial Screwdriver**

481301310

**Polyaxial Screwdriver**

481301320

**Reduction Polyaxial Screwdriver**

481301320

**Monoaxial Screwdriver**

48138020

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**Note:** The Polyaxial Screwdriver is compatible with both polyaxial and polyaxial reduction screws. The Monoaxial Screwdriver is compatible with both monoaxial and monoaxial reduction screws.

When the Xia 4.5 reduction screws are used, the arms are broken off when the reduction is complete. A snap line allows a clean and easy break. The first arm is broken away using the rod rotation forceps to grip the arm and bend it in a back and forth motion.

The second arm is broken off in the same manner as the first.
Growing rod technique

Early onset scoliosis

Xia Growth Rod Conversion Set

The Xia Growth Rod Conversion Set can be used with the Xia 4.5 System to create a growing rod system.

The Ø4.5 Xia growth rod connectors are designed to be used with either Xia 4.5 hooks or pedicle screws and 4.5mm rods. While multiple techniques exist, the following describes the “dual growing rod technique,” the primary goal of which is to promote spinal growth while maintaining deformity correction and minimizing complications1. This technique details the following: 1) fusing proximal and distal “foundation” segments, 2) tunneling rod-connector assemblies subcutaneously from the distal end of the construct and 3) surgically lengthening the construct at appropriate time intervals.

Exposure

In order to create a growing rod construct, the surgeon must first perform subperiosteal dissection at two surgical sites – one for the proximal foundation and one for the distal foundation.

Foundation anchor placement - hooks and/or pedicle screws

Step-by-step instructions for hook placement and pedicle screw insertion described earlier in this technique can be followed in order to create the proximal and distal “foundations” or fusion constructs. Taking the patient’s bone quality, the severity and flexibility of the curve and the risk for curve progression into account, the surgeon may opt for a one, two or three level foundation both proximally and distally.

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**Rod-to-growth rod connector assembly preparation**

1. Measure, cut and contour the first rod to the appropriate length and sagittal curvature for the whole construct. Since the thoracolumbar junction is often chosen as the growth segment due to its neutral sagittal curvature, this portion of the rod should be kept relatively straight.

2. In order to determine where the rod will be cut, slide the **Growth Rod Connector** to the desired location on the rod (typically the growth segment). It is recommended to then mark the rod using a marking pen at the distal end of the growth rod connector window. Remove the growth rod connector and cut the rod using either the Xia 4.5 rod cutter or the Xia 3 table top rod cutter.

3. Insert the proximal portion of the rod back into the growth rod connector, and fasten the two together by tightening a Xia 4.5 blocker into the proximal end of the connector with the 4mm blocker driver.

4. Insert the other piece of rod into the distal end of the connector. A second blocker may be inserted into the distal portion of the connector to help maintain the alignment of the two rods (optional).
Rod-connector assembly insertion
The whole assembly is now ready to be inserted. Due to the typical rod curvature in these cases, it is recommended to insert the rod-connector assembly distally and then tunnel it subcutaneously to the proximal foundation anchors (hooks or screws). Once the assembly is fully inserted, take care to ensure that enough material extends past the tulip heads of both the proximal and distal fusion anchors. Using the 4mm blocker inserter, seat the rod into the hooks or pedicle screws with Xia 4.5 blockers at both the proximal and distal foundations.

Cross connector placement (optional)
In patients with compromised bone quality, it is recommended to utilize a transverse connector at the proximal and distal foundations in order to enhance torsional rigidity. Transverse connectors are also indicated if hook anchors are utilized, as studies have shown that transverse connectors add significant stability to the construct if pedicle screws are not used2. The Xia 4.5 monobloc cross connectors or polyaxial cross connectors may be used at this step. Please refer to page 36 for detailed instructions on inserting both types of connectors.

Final tightening
Once both rod-connector assemblies are securely in place, final tightening should be performed on the proximal and distal foundation anchors (hooks and/or pedicle screws. Please refer to page 35 for detailed instructions on final tightening.

2. Bagheri R, Oka R, Mahar A, Hostial P, Akbarnia BA. Biomechanical comparison of different anchors (foundations) used in the growing dual rod technique. Read at the annual International Meeting on Advanced Surgical Techniques (IMAST); 2004 Jul 2; Southampton, Bermuda.
**Lengthening**
As one of the primary goals of a dual growing rod construct is maintaining spinal growth, it is necessary to access the growth segment of these constructs at an appropriate time interval (surgeon discretion - six months is typical).

**Step 1:**
Expose the necessary levels at the growth segment.

**Step 2:**
Once access to the growth rod connectors(s) is achieved, loosen the proximal blockers using the 4mm blocker inserter.

**Step 3:**
Lengthening can be achieved by inserting the tips of the Xia 4.5 distractor into the groove of the connector and applying a distraction force between the two rods. Take care at this step to disturb as little surrounding tissue as possible. Iatrogenic fusion caused by excessive exposure and subsequent periosteal stimulation at the growth segment can hinder spinal growth, and should be avoided.
Deformity techniques surgical technique

Correction techniques

Adolescent idiopathic scoliosis, neuromuscular scoliosis, congenital scoliosis

Deformity correction

Deformity correction may be obtained using one of four different techniques.

1. Rod rotation
2. Translation
3. Compression/distraction
4. In-situ bending

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

Option 1: Rod rotation

This technique begins by contouring the rod to the desired sagittal curvature. The rod can be inserted in the implants up to 90° out of phase in order to minimize the amount of implant approximation necessary. Ensure that all blockers are inserted but not fully tightened using the 4mm blocker inserter. The rod is then rotated, not to derotate the spine, but to place the implants and the rod in the proper alignment. Final correction is then achieved using distraction and compression techniques.
**Option 2: Translation**
This technique begins by contouring the rod to the desired sagittal curvature. The rod is then inserted into the implants in phase, i.e. in the sagittal plane. Translation can be achieved by utilizing various persuading tools. Initially persuaders are typically placed at the distal and proximal ends of the apex of the curve. As the rod is carefully translated to the spine at these points, the blockers are inserted and the implants are secured. The persuaders may then be moved sequentially toward the apex of the curve until the translation is complete, or other persuader tools may be utilized, including the rod fork, the rod pusher, the inserter tube or the reduction screws.

**Note:** The standard Xia 4.5 set definition contains only one persuader. In order to perform the translation technique as described here, an additional persuader is required.

**Option 3: 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 inserter. Create distraction on the concavity of the deformity with the **Distractor**. Create compression on the convexity of the deformity with the **Compressor**. Once the construct is in the right position, lock the blockers with the 4mm blocker driver to maintain the correction.
Option 4: In situ bending
Great care must be taken during in situ bending not to overload the bone implant interface. Also care must be used not to acutely notch the rod, which may weaken the implant.

Ensure that the closure screws are not completely tightened during rotation maneuvers or the compression/distraction process.

Pelvic fixation
Neuromuscular scoliosis, tumor trauma, pseudoarthrosis

Surgical access to the pelvis Posterior Superior Iliac Spine (PSIS)
The lumbar spine exposure, surgical procedure (decompression, etc.) and instrumentation can be done before or after placement of iliac/pelvic screws. The Posterior Superior Iliac Spine (PSIS) can be exposed using a separate longitudinal skin incision, though it is often more convenient to extend the same midline dorsal lumbar skin incision used for spine exposure. The subcutaneous tissues are then raised laterally to expose the PSIS. The dissection proceeds above the dorsal lumbar fascia to expose the periosteum of the PSIS. The inner table is exposed to a depth of approximately 1.5cm to facilitate notching the crest and tunneling of the connector. This tunneling approach is straightforward and leaves the muscle attached, providing better coverage and a simpler closure.
Pelvic screw path preparation
The pathway is opened up with the blunt probe. When the trajectory and depth are proven, measure the depth of the canal using the laser markings on the probe.

The starting point, which traditionally is about one centimeter cephalad to the PSIS, is prepared using either an osteotome or a rongeur. In some cases, a more distal starting point closer to the PSIS may be preferable since it still allows iliac crest autograft to be harvested from the more cephalad portion of the hemipelvis. In addition, this may allow placement of an additional iliac screw from the more cephalad portion of the PSIS, and in some cases may make it easier to mate with an L5 or S1 screw. When the iliac screw is placed at the inferior pole of the PSIS, it generally allows more room between the iliac screw and the S1 screw and avoids the “hardware crowding” associated with transverse connector placement and the S1 screw. It is sometimes helpful to have the lumbar and sacral anchors in place to allow determination of the optimal precise starting point of the pelvic fixation.

Two iliac screws in each hemipelvis may be required in revision surgery, treatment of sacral fractures or treatment of sacropelvic instability.

The iliac screw path is prepared with a blunt probe standing from the opposite side of the hemipelvis.

The ideal trajectory of the iliac screw is slightly above the sciatic notch and terminates in the quadrilateral plate of the pelvis. The trajectory offers superior osseous purchase.
Adequate placement of the screw requires appropriate identification of the greater sciatic notch. The outer table of the hemipelvis can be exposed with subperiosteal dissection of the gluteal muscles. The sciatic notch may then be palpated digitally. The greater sciatic notch may also be visualized fluoroscopically and the tract prepared under fluoroscopic guidance with the fluoroscope in the 30° oblique position.

With more experience and understanding of the pelvic anatomy, the greater sciatic notch can be identified and/or palpated digitally without soft-tissue dissection of the outer table. The tract is then prepared using an anatomic probing technique. The integrity of the osseous tract is verified using the tapered ball probe to palpate the floor and all four bony walls.

**Pelvic screw placement**

With the pelvic pathway prepared and proper screw length and diameter determined, the screw is prepared for insertion.

Verification of the appropriate osseous tract either by anatomic probing or tapping of the cancellous channel may or may not be necessary.

The screw is then inserted into the hemipelvis in standard fashion. The top portion of the screw head should be at least flush or countersunk below the PSIS to avoid hardware prominence, which is considered the most common reason for pain.

Both the Xia 4.5 monoaxial screwdriver and the polyaxial screwdriver provide a rigid connection between the screw and screwdriver.
Iliac connectors
Choose the appropriate Iliac Connector 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 inserter. 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 inserter. The rods can be translated for adjustment before final tightening. Tighten the blockers using the 4mm blocker driver.

Offset connectors
The Offset Connector 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 blocker driver.

Note: Do not final tighten with the 4mm blocker inserter. Final tightening must be done with the anti-torque key and the torque wrench.
**Revision techniques**

**Extending an existing construct**

### Rod to rod connectors

#### Axial connectors

Through the use of an axial connector, 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 **Rod to Rod Connector**. Tighten the set screws using the **3mm Screwdriver**.

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>48135000</td>
<td>Ø4.5mm-Ø4.5mm Axial Rod to Rod Connector</td>
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<tr>
<td>48135001</td>
<td>Ø4.5mm Ø6.0mm Axial Rod to Rod Connector</td>
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<td>48135004</td>
<td>Ø4.5mm-Ø5.5/Ø6.0mm Axial Rod to Rod Connector</td>
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<td>48135006</td>
<td>Ø4.5mm-Ø4.5mm Parallel Rod to Rod Connector</td>
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#### Parallel connectors

Through the use of a parallel connector, it is possible to connect to another rod in a parallel construct. Ensure that the pre-assembled set screws are adequately backed out to allow for rod introduction. Slide the tips of the rod to be linked deep into the **Parallel Connector**. Tighten the set screws using the **3mm Screwdriver**.

Another option is to slide the parallel connector 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 **4mm Blocker Driver**.

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<tr>
<td>48135105</td>
<td>Parallel Connector</td>
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<tr>
<td>48137058</td>
<td>4mm Blocker Driver</td>
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<td>48138008</td>
<td>4mm Blocker Inserter</td>
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</table>
Final tightening

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 and the Torque Wrench. 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:** During final tightening, 8 Nm must not be exceeded.

**Note:** The anti-torque key must be used for final tightening. The anti-torque key performs two important functions:
1) Allows the torque wrench to align with the tightening axis.
2) Maximizes 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.

Anti-Torque Key 48137026

Torque Wrench 48137028
Cross connectors

Cross connector assembly
Once the final tightening of the construct is completed, choose the appropriate cross connector size by using the Caliper. Depending on the size you may use a Monobloc or Polyaxial Cross Connector.

Monoaxial 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. 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 screwdriver.

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 screwdriver. Finally, tighten the center bolt with the 8mm Screwdriver.
**Removal of implants**

Remove the blocker with the 4mm Blocker Driver from the appropriate anchorage point. Next, remove the rod with the Rod Gripper. Lastly, remove the implants by using the Polyadjustment Driver for polyaxial screws, the Monodriver for monoaxial screws, or the Straight Hook Holder for hooks.

**Note:** The same removal technique can be applied as necessary for revisions.
## Xia 4.5 implants

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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

48135000 | Ø4.5mm-Ø4.5mm Axial Rod to Rod Connector
48135001 | Ø4.5mm-Ø6.0mm Axial Rod to Rod Connector
48135004 | Ø4.5mm-Ø5.5/Ø6.0mm Axial Rod to Rod Connector
48135008 | Ø4.5mm-Ø5.5/Ø6.0mm Parallel Rod to Rod Connector (Large)
48135003 | Ø4.5mm-Ø5.5/Ø6.0mm Parallel Rod to Rod Connector (Small)
48135005 | Ø4.5mm-Ø4.5mm Parallel Rod to Rod Connector (Small)
48135006 | Ø4.5mm-Ø4.5mm Parallel Rod to Rod Connector (Large)
48145010 | Ø4.5mm-Ø5.5/6.0mm Side Loading Top Loading Connector
48145011 | Ø4.5mm-Ø5.5/6.0mm Angled Side Loading Side Loading Connector
48140134 | Ø4.5mm-Ø5.5/6.0mm 0° Rod to Rod Connector (Small)
48140135 | Ø4.5mm-Ø5.5/6.0mm 30° Rod to Rod Connector (Small)
48140136 | Ø4.5mm-Ø5.5/6.0mm 0° Rod to Rod Connector (Large)
48140137 | Ø4.5mm-Ø5.5/6.0mm 10° Rod to Rod Connector (Large)
### Xia 4.5 Spinal System

**Deformity techniques surgical technique**

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<td>48135106</td>
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<td>Iliac Connector 45°</td>
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<td>48133012-3024</td>
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<td>48133224</td>
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### Xia growth rod conversion set implants

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## Xia 4.5 Evolution

### Instruments

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<td>48237061</td>
<td>Double-Ended Ball Tip Probe</td>
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<td>48237024</td>
<td>Curved Blunt Probe</td>
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## Deformity techniques surgical technique

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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
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
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Xia 3, Xia 4.5, and Xia Growth Rod Conversion Set

Stryker Spine Spinal Fixation Systems

Non-sterile and sterile product

The STRYKER Spine Spinal Fixation Systems are made of devices for fixation of the non-cervical spine. They include smooth rods, screws, hooks, closure screws, connectors, and staples. The components are manufactured from either titanium material (Titanium alloy and CP Titanium), Stainless Steel or Cobalt-Chromium-Molybdenum Alloy.

Materials

Xia 3 Spinal System
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, closure screws, connectors and rods.

Pure Titanium: CP Ti grade 4 according to ISO 5832-2 and ASTM F-67: Rods

Cobalt-Chromium-Molybdenum Alloy #1 according to ISO 5832-12 and ASTM F-1537: Rods.

Xia 4.5 Spinal System
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Screws, hooks, closure screws, connectors, rods, and staples.

Cobalt-Chromium-Molybdenum Alloy #1 according to ISO 5832-12 and ASTM F-1537: Rods.

Xia Growth Rod Conversion Set
Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136: Growth Rod Connectors

Titanium and Stainless steel implants should not be mixed in a patient; otherwise corrosion may occur resulting in decreased mechanical resistance.

Cobalt-Chromium-Molybdenum Alloy and Stainless steel implants should not be mixed in a patient; otherwise corrosion may occur resulting in decreased mechanical resistance.

Materials identification


Indications

Xia 3 Spinal System
The Xia 3 Spinal System is intended for use in the non-cervical spine. When used as an anterior/anteralateral and posterior, non-cervical pedicle and non-pedicle fixation system, the Xia 3 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:

- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

The 5.5 mm rods from the Stryker Spine Radius Spinal System and 6.0 mm Vitallium rods from the Xia Spinal System are intended to be used with the other components of the Xia 3 Spinal System.

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Xia 3 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia 3 Spinal System is intended for use with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Xia 4.5 Spinal System
The Xia 4.5 Spinal System is intended for anterior/anteralateral and posterior, non-cervical pedicle and non-pedicle fixation for the following indications:

- Degenerative Disc Disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e. fracture of dislocation)
- Spinal stenosis
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudarthrosis
- Failed previous fusion

The Stryker Spine DIAPASON Spinal System, Opus Spinal System, and Xia 4.5 Spinal System can be linked to the Xia 4.5 Spinal System via the rod-to-rod connector when used for the aforementioned indications in skeletally mature patients as an adjunct to fusion.

Except for the staples, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the Xia 4.5 Spinal System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Xia 4.5 Spinal System is intended to treat pediatric patients diagnosed with: spondylolisthesis/ spondylolyisis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Xia Growth Rod Conversion Set
The Xia Growth Rod Conversion Set is indicated in patients with potential for additional spinal growth under 10 years of age who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early-onset spinal deformities associated with thoracic insufficiency, including early-onset scoliosis. The Xia Growth Rod Conversion Set may be used with any cleared Xia 4.5 Spinal System rod construct. The Xia Growth Rod Conversion Set is not intended for use in conjunction with staples.

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.
- 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.

Additional contraindications for pediatric patients

- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
• Patients having inadequate tissue coverage of the operative site or inadequate bone stock or quality.

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

General conditions of use

The implantation of pedicle screw spinal systems must 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 these devices. 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 home 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 these devices 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, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and make aware of possible adverse effects. The surgeon must warn the patient that the devices cannot and do not replace the flexibility, strength, reliability or durability of normal healthy bone, that the implants can break or become damaged as a result of strenuous activity or trauma, and that the devices may need to be replaced at one time or another. If the patient is involved in an occupation or activity which the surgeon must warn the patient that the devices cannot and do not replicate the flexibility, strength, reliability of normal healthy bone, that the implants can break or become damaged as a result of stresses and strains.

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 is advisable to use antibiotic prophylaxis before and after such procedures.

Instruments

Instruments are provided by STRYKER Spine and must be used to assure accurate implantation of the devices. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative procedure and number of procedures, disposal attention. Instruments must be examined for wear or damage prior to surgery. Surgeons must verify that the instruments are in good condition and operating order prior to each use during surgery.

Reuse

Re-sterilization of implants provided sterile is strictly forbidden, regardless of the method that might be employed.

Never reuse or re-implant 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.

Handling

Correct handling of the implant is extremely important. The operating surgeon should avoid notching or scratching the device.

Allergy and hypersensitivity to foreign bodies

When hypersensitivity is suspected or proven, it is recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

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.

Patients who are 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 is recommended only 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 low-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

Metal components

some of the alloys utilized to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomena.

System compatibility

while some degree of corrosion occurs on all implanted metal and alloys, contact of dissimilar metals may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system may also increase. Internal fixation devices, such as rods, hooks, screws, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, components of the system should not be used in conjunction with components from any other manufacturer’s spinal system. Any such use will negate the responsibility of STRYKER Spine for the performance of the resulting mixed component implant.

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 may be employed. Surgeons must instruct patients 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. Surgeons must instruct patients 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.

**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 component 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.
- Loss of proprioception, 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 cannot 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 wear, corrosion, 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.

**Additional adverse effects for pediatric patients**

- Inability to use pedicle screw fixation due to limitations (pedicle dimensions and/or distorted anatomy).
- Pedicle screw malpositioning, with or without neurological or vascular injury.
- Proximal or distal junctional kyphosis.
- Patients may exhibit persistent pain.
- Unintended fusion in Growth Rod patients
- Increased risk of post-operative infection and wound-healing issues in Growth Rod patients
- Increased risk of implant breakage in Growth Rod patients
- Implant prominence (symptomatic or asymptomatic).
- Pressure on the skin from component parts patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.
- Post-operative change in spinal curvature, loss of correction, height, or reduction.
- Development of respiratory problems (e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.)

**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 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.

**Packaging, storage and recommendations for sterile implants**

- The implants are single use devices that are provided sterile. Implants sold sterile are always presented in individual packaging and are clearly labeled as “sterile” on the package label. Implants that are not labeled as such are not sterile. Packaged sterile product must be stored in a clean, dry and temperate place. Sterile products may be stored at room temperature.
- The sterilization method applied is indicated on the product label. The implants have been exposed to a minimum of 25 kGy of gamma radiation.
- The packaging of sterile product must be intact at the time of receipt. The packaging is exposed to normal transportation conditions. However, the integrity of the original packaging must be verified before use. Sterility is ensured only if there is no trace of damage to the packaging. If damage to packaging is detected, the product must not be used.
- Do not use if the packaging is opened or damaged or after the “Use by” date on the label has expired. STRYKER shall not be responsible for the use of products presenting package deterioration or expiration of shelf-life.
- Care must be taken to prevent contamination of implant after opening of the packaging prior to use.

**Packaging and storage for non-sterile medical devices**

- The implants are delivered in packages; these must be intact at the time of receipt.
- The systems are sometimes supplied as a complete set: implants and instruments are arranged on trays and placed in specially designed storage boxes.
- They must be stored in a clean, dry and temperate place.

**Caution**

Stryker Spine has not validated and does not recommend Flash Sterilization. For Product being used in the US, a sterilization wrap that is FDA cleared for the cycle parameters noted is required.

**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.

Caution

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

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, spondylolisthesis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

The Xia 3 Spinal System, Xia 4.5 Spinal System, and Xia Growth Rod Conversion Set have not been tested for heating or migration in the MR environment.

Additional warnings for pediatric patients

The safety and effectiveness of the Xia 3 Spinal System has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Growth rod systems should only be used by surgeons who are experienced with pediatric posterior spine surgery procedures and have undergone hands-on training in both device and adjustment. Only surgeons who are familiar with the implant components, instruments, procedure, clinical applications, biomechanics, adverse events, and risks associated with growth rod systems should use this device. A lack of adequate experience and/or training may lead to a higher incidence of adverse events, including neurologic complications.

Growth rod constructs typically require repeated planned-lengthening procedures until a determination is made that the patient is ready for a final fusion procedure. Growth rod patients are more susceptible to post-operative infections and wound-healing issues, as well as the potential for implant breakage requiring unplanned surgical procedures. The physician should discuss these and all other potential complications with the patient and the patient’s guardian.

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature or skeletal immaturity. Pediatric patients may have smaller spinal structures (pedicle diameter and length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletal immaturity that undergo spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.

Other adverse effects related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device related injury because of their small stature.

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.

While the final decision on implant removal is up to the surgeon and the patient, in most patients removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) corrosion, with localized tissue reaction or pain; (2) migration of implant position possibly resulting in injury; (3) risk of additional injury from postoperative trauma; (4) bending, loosening, and breaking which could make removal impractical or difficult; (5) pain, discomfort, or abnormal sensations due to the presence of the device; (6) possible increased risk of infection; (7) bone loss due to stress shielding; and (8) potential unknown or unexpected long term effects such as carcinogenesis.

Additional precautions for pediatric patients

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

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

Complaints

Any health professional having a complaint or grounds for dissatisfaction relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a device should notify STRYKER Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, STRYKER Spine or its representative must be advised immediately.

If a STRYKER Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or STRYKER Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and a complete description of the event to help STRYKER Spine understand the causes of the complaint.

For further information or complaints, please contact:

STRYKER SPINE
2 Pearl Court,
Allendale, NJ  07401-1677 USA
Tel. 201-760-8000
http://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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