

Xia® 3 SUK®

Surgical Technique

Direct Vertebral Rotation (DVR) System



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Introduction

Stryker Spine is committed to helping spine surgeons meet their patients' needs. Building on the successful foundation of Xia and collaborating with leading spine specialists, Stryker Spine has developed this Surgical Technique for our Xia 3 SUK Direct Vertebral Rotation (DVR) System.

Our Xia 3 Spinal System is a comprehensive system designed to treat modern spinal deformity and deliver "Simplicity with Options." The Xia 3 implants and instruments have been developed to meet and address the challenges spine surgeons face in treating complex deformities. The Xia 3 SUK Direct Vertebral Rotation (DVR) System utilizes the power of pedicle screw fixation and provides surgeons a three dimensional approach to correcting deformity. This Surgical Technique outlines the use of the Xia 3 SUK DVR System to perform *Segmental* as well as *En Bloc* vertebral body derotation maneuvers.

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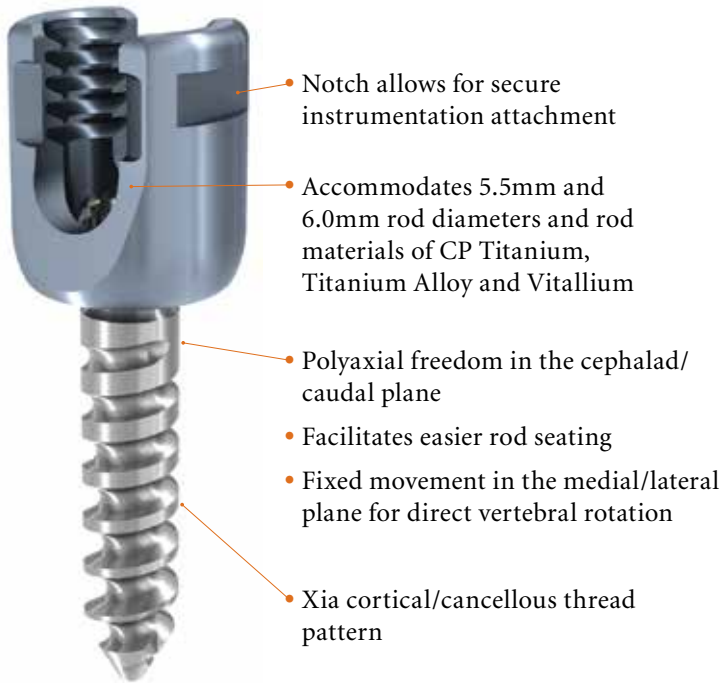
Michael Schmitz, MD
Atlanta, Georgia

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Unique Design

Xia 3 Uniplanar Screws and Uniplanar Reduction Screws

Xia 3 Uniplanar Reduction Screws



- Xia buttress thread blocker helps eliminate cross threading, prevents screw head splaying and helps ensure secure closure



Xia 3 SUK Direct Vertebral Rotation (DVR) System

Xia 3 SUK Direct Vertebral Rotation (DVR) System

- Quick
- Simple
- Modular



SUK DVR system

SUK Derotator Clamp



SUK Derotator Clamp
48237067

• Release lever for quick disassembly

SUK Tube - One Piece



SUK Tube - One Piece
48237087

SUK Tube - Two Piece



SUK Tube - Two Piece
48237077

T - Handle, SUK Tube

- Used with two piece tubes
- Aids in tightening outer sleeve to the notch on the tulip head
- Provides access to tightening mechanism when tubes are close together



T - Handle, SUK Tube
48237097

Surgical Technique

Direct Vertebral Rotation

Correction of spinal deformities in the sagittal and coronal planes is obtained through rod rotation and *in-situ* rod contouring. With derotation maneuvers, surgeons can correct spinal deformities in the axial plane, thereby encompassing all three dimensions in the correction (Fig. 1) and (Fig. 2).

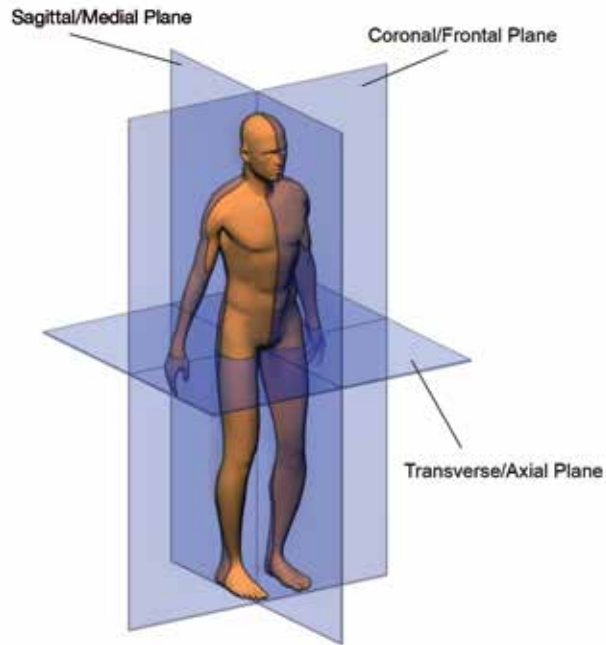


Figure 1 - Anatomical Planes

Screw Placement

Pedicle screw selection and placement is key in successful derotation of the spine. Derotation maneuvers are typically performed at the apical and end vertebrae, and fixed head pedicle screws offer the most stability during the correction. Polyaxial screws can be used but may limit the amount of correction maintained (Fig. 3).

On the **concave side** of the curve, Monoaxial, Uiplanar, or Polyaxial screws should be placed at every level. In severe curves, the use of Reduction Uiplanar screws at the apex of the concavity should be considered (Fig. 3).

On the **convex side** of the curve, Monoaxial, Uiplanar, or Polyaxial screws should be placed at the apex of the curve as well as at the proximal and distal ends (Fig. 3).

Note: Pedicle preparation and pedicle screw insertion should follow the same procedures thoroughly detailed in our Xia 3 Spinal System Surgical Technique. Placement and length of screws should be confirmed using fluoroscopy or plain X-rays prior to rod insertion.



Figure 2 - Scoliosis Deformity



Monoaxial



Uiplanar



Polyaxial

Figure 3 - Screw Offerings

Xia 3 SUK Direct Vertebral Rotation (DVR) System

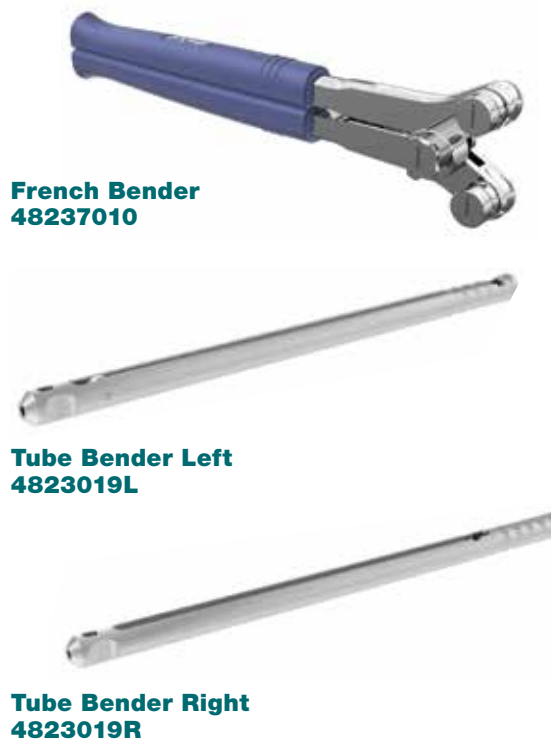
Rod Contouring

Contour the rod to be placed on the **concave side** of the curve with extra kyphosis. This kyphotic contour will pull the apical vertebrae dorsally and correct apical lordosis.

Contour the rod to be placed on the **convex side** of the curve with less kyphosis. The derotation maneuver will cause the rod to push downward on the convex side of the vertebral bodies displacing them anteriorly and decrease rib prominence.

Note: Rod material will affect the amount of kyphotic rod contouring required. The less stiff the rod material, the more kyphosis should be contoured into the rod as the contouring may be reduced during the correction maneuvers (Fig. 5).

Note: The rod can be contoured using the French Benders and/or the Tube Benders (Fig. 4).



French Bender
48237010

Tube Bender Left
4823019L

Tube Bender Right
4823019R

Figure 4

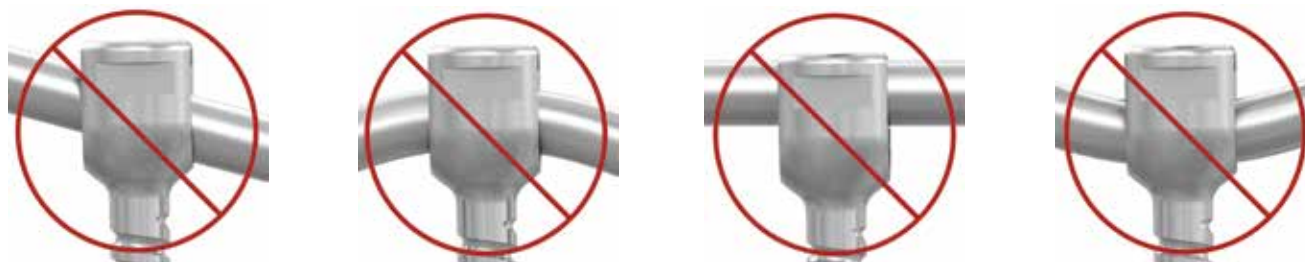


Figure 5

Ø5.5mm Rod Options

Radius Ø5.5 x 30-120mm Titanium Spinal Rod, without hex	4866130 (03) - (20)
Radius Ø5.5 x 110-600mm Titanium Spinal Rod, with hex	486613 (110) – (600)
Radius Ø5.5 x 600mm Vitallium Spinal Rod	486613601
Radius Ø5.5 x 600mm Vitallium Spinal Rod, with hex	486613602

Ø6.0mm Rod Options

Xia 3 Ø6.0 x 30-150mm, 480mm, 600mm CP Ti Rod	482320 (30) – (150), 480, 600
Xia 3 Ø6.0 x 30-150mm, 480mm, 600mm Ti Alloy Rod	482330 (30) – (150), 480, 600
Xia II Ø6.0 x 600mm Vitallium Rod	03822601
Xia 3 Ø6.0 x 600mm Vitallium Rod, with Hex	48232601

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Rod Placement

Insert the appropriately contoured rod into the pedicle screws on the concave side of the curve. Using the **Universal Tightener** insert the blockers leaving them loose inside the pedicle screw tulip (Fig. 6).

Note: The **Universal Tightener** is not to be used for final tightening.

Translation of the Rod:

Insert the rod into the proximal and distal pedicle screw. Using the **Universal Tightener**, insert and provisionally tighten the blockers. At this point, the rod is in the correct sagittal plane. The apical screws are translated to the rod segmentally using reduction instrumentation: **Rod Fork**, **Rod Pusher**, **Persuader**, or **One Handed Persuader**, and/or **Uniplanar Reduction screws** (Fig. 7). As the spine is carefully translated at these points the blockers are inserted and provisionally tightened.

Rotation of the Rod:

Place the rod into the pedicle screws. Using the **Universal Tightener**, insert the blockers leaving them loose inside the pedicle screw tulip. The rod may be rotated using the **Vise Grip**, the **Rod Gripper**, or the **Rod Rotation Key** until the rod is positioned in the correct sagittal plane (Fig. 8). Once the rod has been fully rotated, the blockers are provisionally tightened.



Figure 6 - Universal Tightener, 5mm 48237008



Rod Fork 48237018



Rod Pusher 48237019



Persuader 48237016



One Handed Persuader 48237015

Figure 7



Vise Grip 48230100

Rod Gripper 48231140

Rod Rotation Key 48237056

Figure 8

Segmental Direct Vertebral Rotation Technique

Note: Segmental DVR can be performed as the primary derotation maneuver or in addition to the *En Bloc* derotation maneuver.

Insert the contoured rods into the pedicle screws on the concave and convex sides of the curve. Use the Universal Tightener to insert the blockers (Fig. 9). Leave the blockers loose inside the pedicle screw tulips except for the blockers in the distal neutral vertebra, which should be provisionally tightened. If using only one rod for the technique, place the rod on the concave side of the curve.

Starting at the distal neutral vertebra, attach two SUK Tubes (Fig. 10). Attach the inner sleeve of the 2-piece tube to the notches on the tulip head of the screw. Tighten the outer sleeve until it reaches the bottom of the inner sleeve to ensure a secure connection. Then attach two SUK Tubes to the next proximal vertebra (Fig. 11). The SUK Derotator Clamps may be used to connect the tubes bilaterally at the two individual levels (Fig. 12). With the SUK Tubes on the distal vertebra held to provide a counter-rotation force, the proximal vertebral body is derotated to achieve a neutral position in reference to the neutral distal vertebra (Fig. 13).

After the derotation maneuver, provisionally tighten the blockers (Fig. 14). Leaving the two SUK Tubes on the distal neutral vertebra, remove the SUK Tubes on the derotated vertebra and move them to the next proximal vertebra (Fig. 15). Repeat the derotation maneuvers, moving toward the apex of the curve (Fig. 16).

Note: Leaving the Universal Tightener in the SUK Tubes while derotating the vertebral body will ensure ease of tightening the blockers.

The derotation maneuvers may need to be repeated at some levels due to the viscoelastic relation of the spine. Care must be taken not to loosen the bone-screw interface while performing the corrections.



Figure 9



Figure 10



Figure 11



Figure 12



Figure 13



Figure 14



Figure 15



Figure 16

En Bloc Direct Vertebral Rotation Technique

Attach SUK Tubes to the apical pedicle screw heads on both the concave and convex sides of the curve. The SUK Derotator Clamps can be used to unilaterally or bilaterally join the SUK Tubes together to aid in the derotation maneuvers. While a downward force is applied to the convex pedicle screws and ribs, the concave and convex screws are rotated in the direction that will reduce the rib prominence. The derotation maneuvers should be performed simultaneously to limit the forces induced on the bone-screw interface (Fig. 17).

Triangulation/Quadrangulation of the SUK Tubes will decrease “ploughing” during the rotation technique.

Use the Universal Tightener to provisionally tighten the blockers on the concave rod holding the corrected position. Then, provisionally tighten the blockers on the convex rod. If the convex rod is not already in place, remove the SUK Tubes and Derotator Clamps, insert the convex rod, and insert and provisionally tighten the blockers.

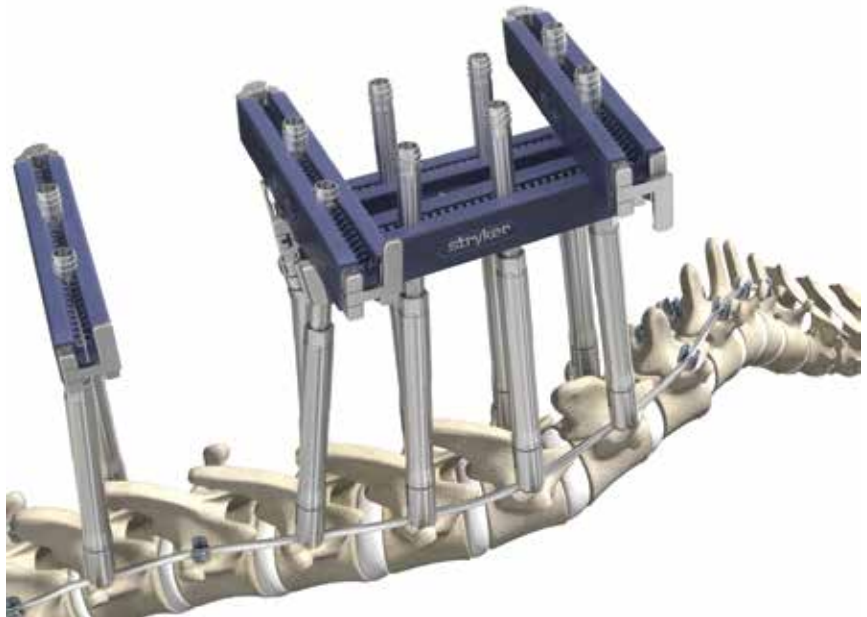


Figure 17 - Multiple tubes and clamps on vertebral bodies

Distraction/Compression

Spinal deformities can be further corrected by creating a distraction in the concavity of the curve and compression on the convexity. Posterior distraction creates a kyphosis in the sagittal plane, whereas compression creates a lordosis. Distraction can be achieved with the **Small Distractor** or **Large Distractor** and compression can be achieved with the **Small Compressor** or **Large Compressor** (Fig. 18).

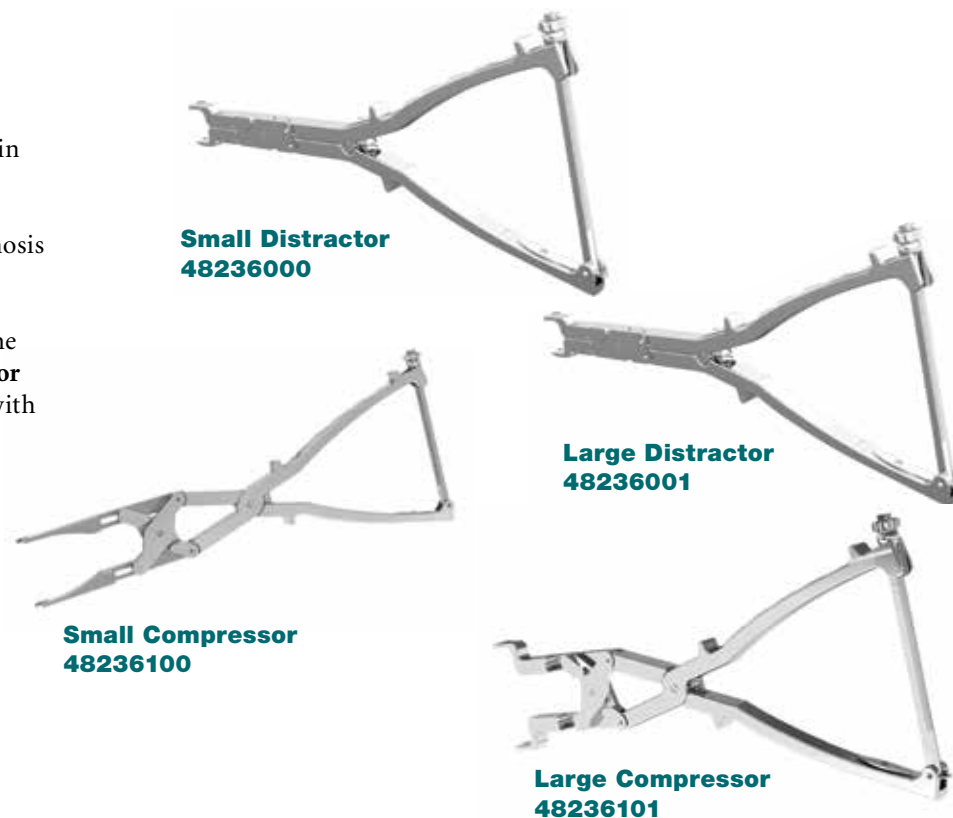


Figure 18

In-Situ Bending

Additional coronal correction can be achieved using the **Coronal Plane Benders** and **Ball Joint**, and additional sagittal correction can be achieved using the **In Situ Benders** (Fig. 19). Care must be taken to not overload the bone-screw interface or acutely notch the rod, which may weaken the implant.

Note: The Blockers should not be completely tightened during the rotation maneuvers, distraction/compression or *in-situ* bending.



Figure 19

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Final Tightening

Once the correction maneuvers have been carried out and the spine is fixed in a satisfactory position, the blockers can be final tightened. Use the **Anti-Torque Key** and the **Torque Wrench** (Fig.20).

Place the Anti-Torque Key around the screw tulip head. Place the Torque Wrench through the Anti-Torque Key until it is guided into the Blocker.

The markings on the Torque Wrench indicate the optimal torque force that must be applied to the implant for final tightening. Line up the two arrows to achieve the final tightening torque of 12 Nm.

Note: Do not exceed 12 Nm during final tightening.

Note: The ES2 Torque Wrench or the MANTIS Redux Torque Wrench may also be used as an alternative to the Xia 3 Torque Wrench to final tighten the Xia 3 blockers (Fig. 21).

Note: The ES2 Counter Torque Tube may also be used in conjunction with the Xia 3 Torque Wrench (Fig. 22).

Anti-Torque Key

- Must be used for final tightening.
- Allows the Torque Wrench to align with the tightening axis.



**Figure 20 - Anti-Torque Key
48237026**

Figure 21



**Figure 22 -
ES2 Counter Torque Tube
48280080**

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Xia 3 SUK Tubes Disassembly Instructions for Cleaning

Step 1: Unthread the outside tube (1) from the inside tube (2) (Fig. 23).

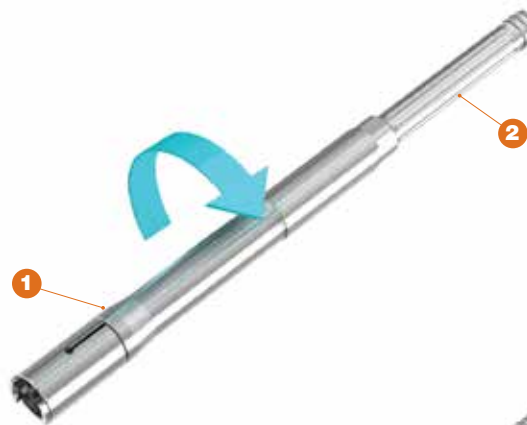


Figure 23 - Step 1

Step 2: Once the first level of threads is cleared, slide the outside sleeve (1) back until it reaches the stop threads (3) (Fig. 24).



Figure 24 - Step 2

Step 3: Unthread the outside sleeve (1) until the stop threads (3) are cleared and continue to pull the outside sleeve off of the inside tube (2) (Fig. 25).

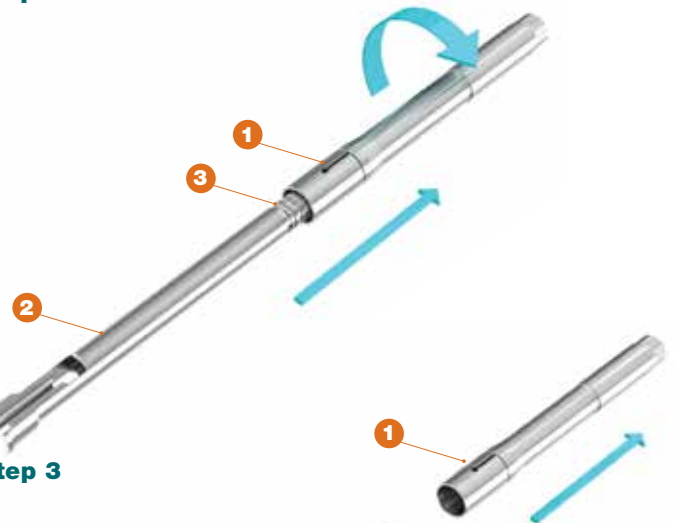


Figure 25 - Step 3







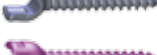

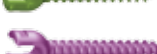













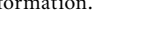
Step 4: Further separate the outside sleeve (1) from the inside tube (2) (Fig. 26).



Figure 26 - Step 4

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Implants

Reference #	Sterile* Reference #	Description	
48230000	48230000S	Xia 3 Blocker	
4823040 (20) - (45)	4823040 (20) - (45)S	Xia 3 Ø4.0 x 20-45mm Monoaxial Screw	
4823045 (20) - (45)	4823045 (20) - (45)S	Xia 3 Ø4.5 x 20-45mm Monoaxial Screw	
4823050 (20) - (50)	N/A	Xia 3 Ø5.0 x 20-50mm Monoaxial Screw	
4823055 (25) - (55)	4823055 (25) - (55)S	Xia 3 Ø5.5 x 25-55mm Monoaxial Screw	
4823060 (25) - (90)	N/A	Xia 3 Ø6.0 x 25-90mm Monoaxial Screw	
4823065 (25) - (90)	4823065 (25) - (90)S	Xia 3 Ø6.5 x 25-90mm Monoaxial Screw	
4823070 (25) - (90)	N/A	Xia 3 Ø7.0 x 25-90mm Monoaxial Screw	
4823075 (25) - (90)	4823075 (25) - (90)S	Xia 3 Ø7.5 x 25-90mm Monoaxial Screw	
4823085 (25) - (00)	4823085 (25) - (00)S	Xia 3 Ø8.5 x 25-100mm Monoaxial Screw	
4823095 (40) - (00)	4823095 (40) - (00)S	Xia 3 Ø9.5 x 40-100mm Monoaxial Screw	
4823015 (40) - (00)	4823015 (40) - (00)S	Xia 3 Ø10.5 x 40-100mm Monoaxial Screw	
4823140 (20) - (45)	4823140 (20) - (45)S	Xia 3 Ø4.0 x 20-45mm Polyaxial Screw	
4823145 (20) - (45)	4823145 (20) - (45)S	Xia 3 Ø4.5 x 20-45mm Polyaxial Screw	
4823150 (20) - (50)	N/A	Xia 3 Ø5.0 x 20-50mm Polyaxial Screw	
4823155 (25) - (55)	4823155 (25) - (55)S	Xia 3 Ø5.5 x 25-55mm Polyaxial Screw	
4823160 (25) - (90)	N/A	Xia 3 Ø6.0 x 25-90mm Polyaxial Screw	
4823165 (25) - (90)	4823165 (25) - (90)S	Xia 3 Ø6.5 x 25-90mm Polyaxial Screw	
4823170 (25) - (90)	N/A	Xia 3 Ø7.0 x 25-90mm Polyaxial Screw	
4823175 (25) - (90)	4823175 (25) - (90)S	Xia 3 Ø7.5 x 25-90mm Polyaxial Screw	
4823185 (25) - (00)	4823185 (25) - (00)S	Xia 3 Ø8.5 x 40-100mm Polyaxial Screw	
4823195 (40) - (00)	4823195 (40) - (00)S	Xia 3 Ø9.5 x 40-100mm Polyaxial Screw	
4823115 (40) - (00)	4823115 (40) - (00)S	Xia 3 Ø10.5 x 40-100mm Polyaxial Screw	

*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker Sales Representative for more information.

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Reference #	Sterile* Reference #	Description	
482334 (20) - (45)	482334 (20) - (45)S	Xia 3 Ø4.5 x 20-45mm Uniplanar Screw	
4823350 (20) - (45)	4823350 (20) - (45)S	Xia 3 Ø5.0 x 20-45mm Uniplanar Screw	
482335 (20) - (55)	482335 (20) - (55)S	Xia 3 Ø5.5 x 20-55mm Uniplanar Screw	
4823360 (25) - (60)	N/A	Xia 3 Ø6.0 x 25-60mm Uniplanar Screw	
482336 (25) - (60)	482336 (25) - (60)S	Xia 3 Ø6.5 x 25-60mm Uniplanar Screw	
4823370 (30) - (60)	N/A	Xia 3 Ø7.0 x 30-60mm Uniplanar Screw	
482337 (30) - (60)	482337 (30) - (60)S	Xia 3 Ø7.5 x 30-60mm Uniplanar Screw	
4823645 (20) - (45)	4823645 (20) - (45)S	Xia 3 Ø4.5 x 20-45mm Uniplanar Reduction Screw	
4823650 (20) - (45)	4823650 (20) - (45)S	Xia 3 Ø5.0 x 20-45mm Uniplanar Reduction Screw	
4823655 (20) - (55)	4823655 (20) - (55)S	Xia 3 Ø5.5 x 20-55mm Uniplanar Reduction Screw	
4823660 (25) - (60)	N/A	Xia 3 Ø6.0 x 25-60mm Uniplanar Reduction Screw	
4823665 (25) - (60)	4823665 (25) - (60)S	Xia 3 Ø6.5 x 25-60mm Uniplanar Reduction Screw	
4823670 (30) - (60)	N/A	Xia 3 Ø7.0 x 30-60mm Uniplanar Reduction Screw	
4823675 (30) - (60)	4823675 (30) - (60)S	Xia 3 Ø7.5 x 30-60mm Uniplanar Reduction Screw	
486613601	N/A	Radius Ø5.5 x 600mm Vitallium Spinal Rod	
486613602	N/A	Radius Ø5.5 x 600mm Vitallium Spinal Rod, with hex	
4866130 (03) - (20)	N/A	Radius Ø5.5 x 30-120mm Titanium Spinal Rod, without hex	
486613 (110) - (600)	N/A	Radius Ø5.5 x 110-600mm Titanium Spinal Rod, with hex	
482320 (30) - (150)	482320 (30) - (150)S	Xia 3 Ø6.0 x 30-150mm, CP Ti Rod	
48232480	48232480S	Xia 3 Ø6.0 x 480mm CP Ti Rod	
48232600	N/A	Xia 3 Ø6.0 x 600mm CP Ti Rod	
482330 (30) - (150)	482330 (30) - (150)S	Xia 3 Ø6.0 x 30-150mm Ti Alloy Rod	
48233480	N/A	Xia 3 Ø6.0 x 480mm, Ti Alloy Rod	
48233600	N/A	Xia 3 Ø6.0 x 600mm Ti Alloy Rod	
03822601	N/A	Xia II Ø6.0 x 600mm Vitallium Rod	
48232601	N/A	Xia 3 Ø6.0 x 600mm Vitallium Rod, with Hex	

*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker Sales Representative for more information.

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Instruments

Reference #	Description	
48237010	French Benders	
48230191L	Tube Bender Left	
48230191R	Tube Bender Right	
48237008	Universal Tightener	
48237018	Rod Fork	
48237019	Rod Pusher	
48237016	Persuader	
48237015	One Handed Persuader	
48230100	Vise Grip	
48231140	Rod Gripper	
48237056	Rod Rotation Key	
48236000	Small Distractor	
48236001	Large Distractor	
48236100	Small Compressor	
48236101	Large Compressor	
48230180	Coronal Plane Bender Left	
48230190	Coronal Plane Bender Right	
48230180S	Ball Joint	
48237011L	In Situ Bender Left	
48237011R	In Situ Bender Right	
48237026	Anti-Torque Key	

Xia 3 SUK Direct Vertebral Rotation (DVR) System

Instruments

Reference #	Description	
48237028	Xia 3 Torque Wrench	
48280081	ES2 Torque Wrench	
48287028	MANTIS Redux Torque Wrench	
48280080	ES2 Counter Torque Tube	
48237067	SUK Derotator Clamp	
48237068	Short SUK DVR Clamp	
48237069	Long SUK DVR Clamp	
48237097	T-Handle, SUK Tube	
48237087	SUK Tube - One Piece	
48237077	SUK Tube - Two Piece	
48237078	SUK DVR Reduction Tube	
48237079	Reduction Clip	

Trays

Reference #	Description
48230003	Complex Spine Implant Tray
48230004	Complex Spine Instrument Tray
48230005	Complex Spine Hooks and Instrument Tray
48230006	Rod and Cross Connector Tray
48230013	Uniplanar Tray
48230015	SUK Tray
48230020	Outlier Implant Tray
48230010	Outlier Instrument Tray

Xia 3 SUK Direct Vertebral Rotation (DVR) System

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

Titanium: symbol **T**

Stainless Steel: symbol **S**

Cobalt-Chromium-Molybdenum: symbol **C**

INDICATIONS

Xia 3 Spinal System

The Xia 3 Spinal System is intended for use in the non-cervical spine. When used as an anterior/anterolateral 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:

- 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 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 to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, 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 4.5 Spinal System

The Xia 4.5 Spinal System is intended for anterior/anterolateral 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/spondylolysis, 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

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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 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 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 replicate 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 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) the surgeon must advise the patient that resultant forces can cause failure of the devices. Patients who smoke have been shown to have an increased incidence of non-unions. Surgeons must advise patients of this fact and warn 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 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 precaution, 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 follow-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

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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 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.
- 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.

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.
- Pancreatitis.
- 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 in 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

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implant after fracture healing is recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

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, scoliosis, 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 implantation 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 skeletally immature. 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 skeletally mature 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.

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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.

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