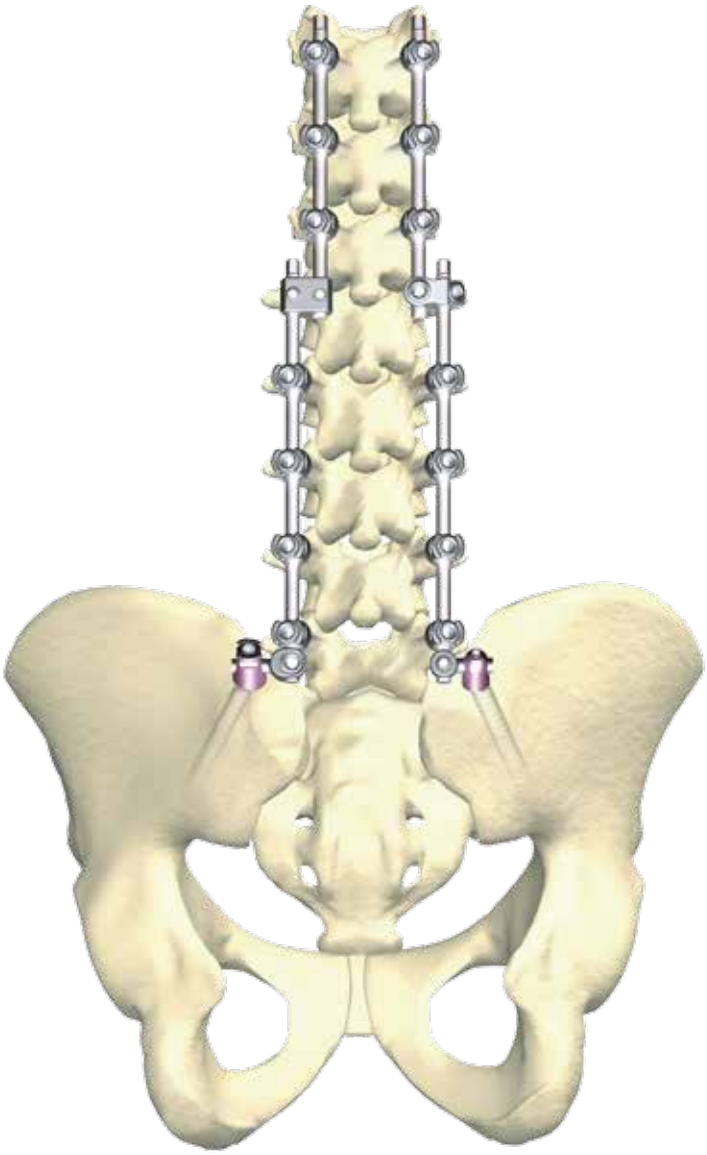
stryker

Xia® 3
Spinal System



Ilios and revision surgical technique

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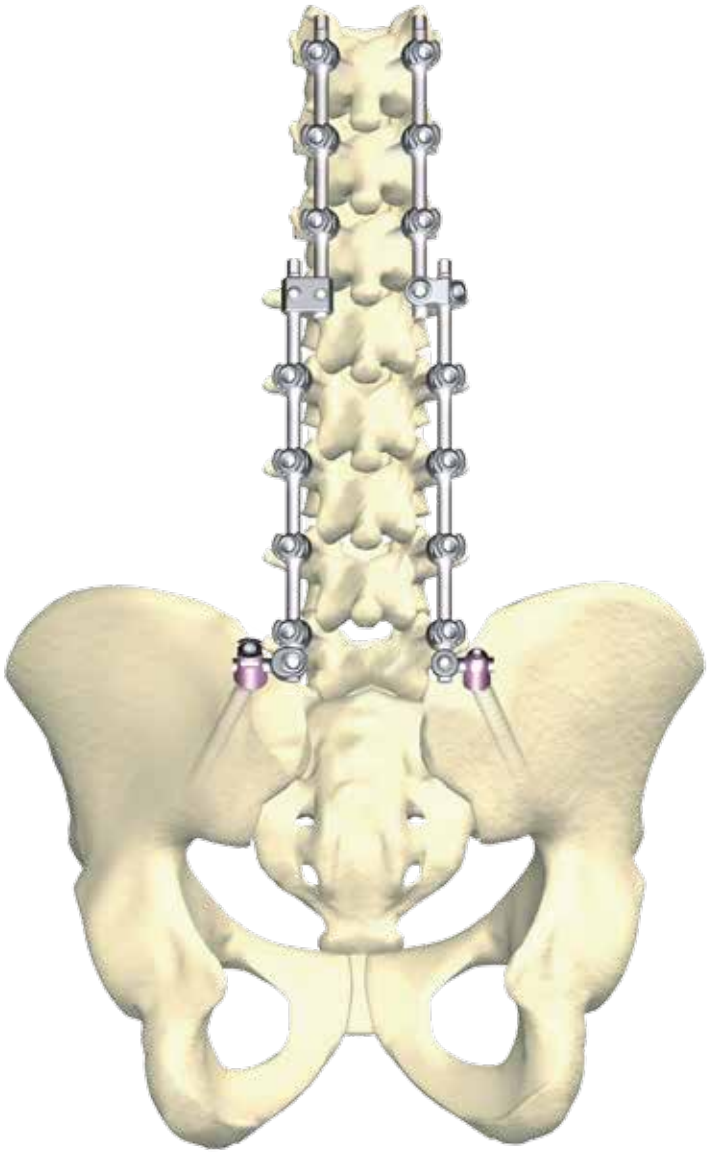
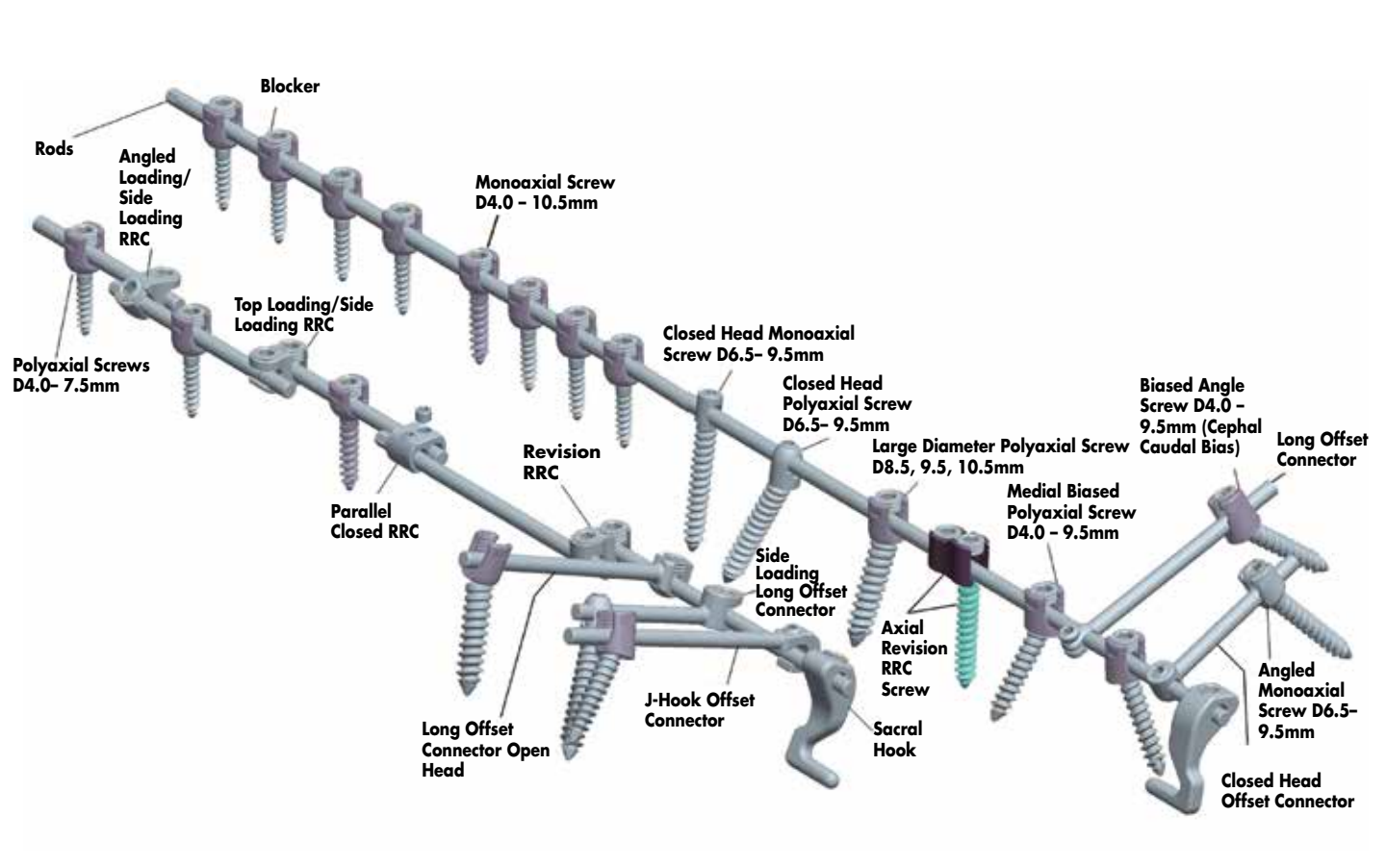
Introduction

The evolution of the Xia 3 ilios and revision application is further evidence of the Stryker commitment to continue to listen to the global surgeon community and to provide implants and instruments that strive to offer optimal surgical solutions.

The new ilios application was developed and built upon the success of the Xia Spinal System. The Ilios system provides a comprehensive offering of Xia long screws, closed head screws, biased-angle screws, offset connectors and rod-to-rod connectors as options for sacral-iliac fixation and revision applications.

These implants are used for the treatment in long fusions to the sacrum in sagittal and/or coronal plane spinal deformities (scolosis, high-grade spondylolisthesis, flatback syndrome, etc.). Also, the system may be used in revision surgery (L5-S1 pseudoarthrosis) and in the treatment of sacral fractures.




Blocker
Rods
Angled Loading/ Side Loading RRC
Monoaxial Screw D4.0 – 10.5mm
Top Loading/Side Loading RRC
Polyaxial Screws D4.0– 7.5mm
Closed Head Monoaxial Screw D6.5– 9.5mm
Closed Head Polyaxial Screw D6.5– 9.5mm
Biased Angle Screw D4.0 – 9.5mm (Cephal Caudal Bias)
Long Offset Connector
Large Diameter Polyaxial Screw D8.5, 9.5, 10.5mm
Revision RRC
Medial Biased Polyaxial Screw D4.0 – 9.5mm
Parallel Closed RRC
Side Loading Long Offset Connector
Axial Revision RRC Screw
Angled Monoaxial Screw D6.5– 9.5mm
J-Hook Offset Connector
Sacral Hook
Long Offset Connector Open Head
Closed Head Offset Connector

Patient positioning

The patient is usually positioned prone on an appropriate spinal table. Care is taken to pad all bony prominences. The abdomen should not be compressed to help lower venous pressure (Fig. 1 and Fig. 2).

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 fusion.

Pre-operative planning defines the most appropriate implants, as well as the optimal location of insertion.

Figure 1

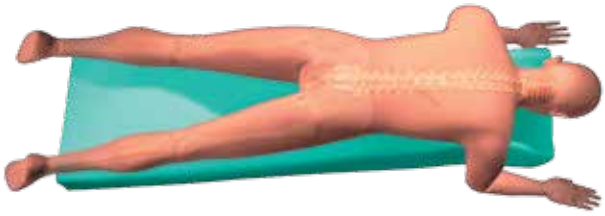


Figure 2

Surgical access to the posterior superior iliac spine (PSIS)

The lumbar spine is exposed first (Fig. 3). The lumbar spine exposure, surgical procedure (decompression, etc.) and instrumentation are completed prior to placement of iliac/pelvic screws. Iliac screw placement requires access to the hemipelvis, and specifically to the PSIS. The PSIS can be exposed using a separate longitudinal skin incision.

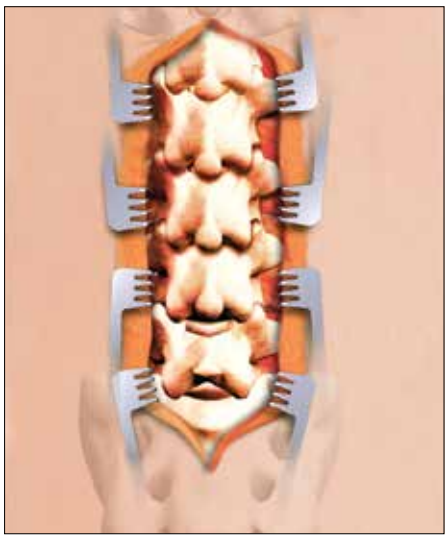


Figure 3

Alternatively, the PSIS may be exposed through the same midline dorsal lumbar skin incision. 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 straight forward and leaves the muscle attached, providing better coverage and a simpler closure (Fig. 4).

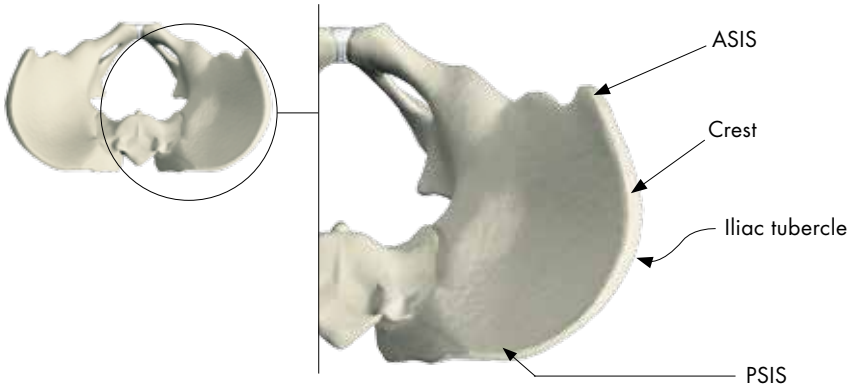


Figure 4

Pelvic screw path preparation

When the trajectory and depth are proven, measure the depth of the canal using the **Xia Depth Gauge (884025)**.

The starting point, which ideally is at the inferior pole of the PSIS, is prepared using either an osteotome or a rongeur (Fig. 5).

The inferior pole of the PSIS may be preferable in most situations since it still allows iliac crest autograft to be harvested from the more cephaled portion of the hemipelvis.

Furthermore, it still allows placement of an additional iliac screw from the more cephalad portion of the PSIS.

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 scew. 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 probe may be either **Flat (48237062)** or **Curved (48237024)** (Fig. 6).

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 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 a **Pedicle Feeler (48237059)** to palpate the floor and all four bony walls (Fig. 7).

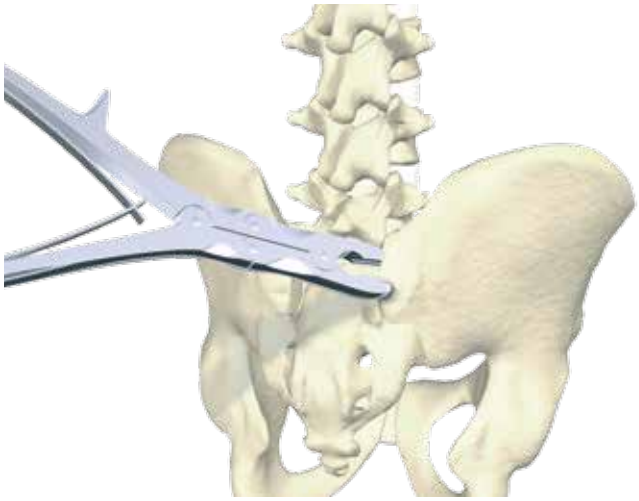


Figure 5

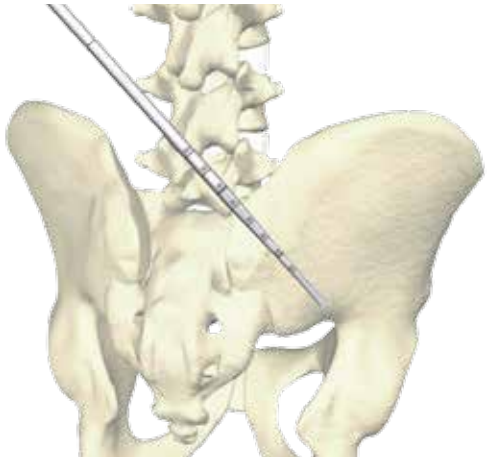


Figure 6

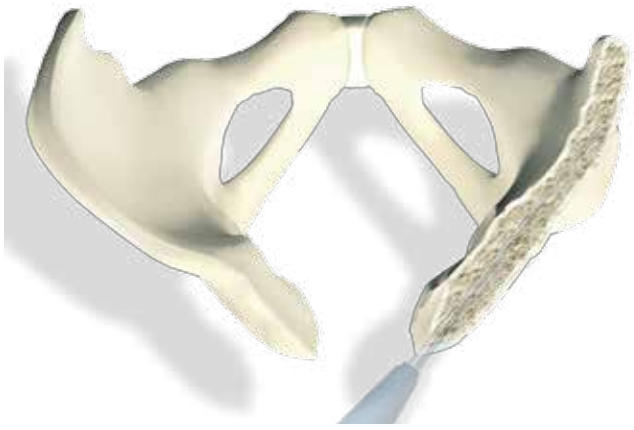


Figure 7

Pelvic screw placement

With the pelvic pathway prepared and proper screw length and diameter determined, the screw is prepared for insertion (Fig. 8).

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 (Fig. 9).

Generally speaking, a 6.5 - 8.5mm diameter screw by 80mm long is used in most adult patients.

Both the **Xia 3 Polyaxial Screwdriver (48231330)** and **Xia 3 Monoaxial Screwdriver (48231320)** provide a rigid connection between the screw and screwdriver (Fig. 10).

Xia 3 also offers a new improved **Iliac Screwdriver (48231326)** compatible with the following implants:

- Closed Head Monoaxial Screw 48232DDLL
- Closed Head Polyaxial Screw 48237DDLL

Note: Handles are compatible with the monoaxial, polyaxial and iliac screwdrivers.

Figure 8

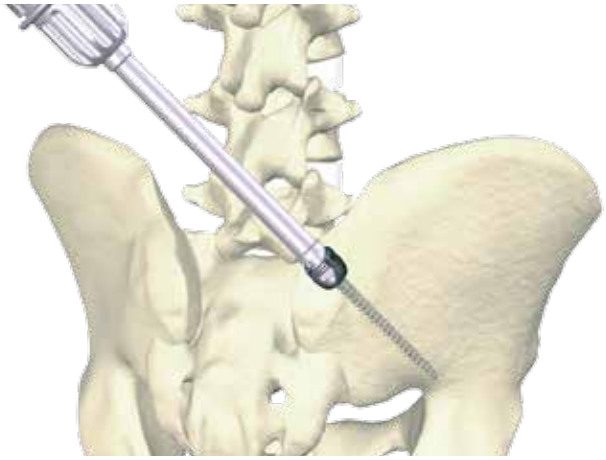


Figure 9

T-Handle
48231201

T-Handle Ratchet
48231202

Round Handle
48231301

Round Handle Ratchet
48231302

Xia 3 Iliac Screwdriver
48231326

Xia 3 Polyaxial Screwdriver
48231330

Xia 3 Monoaxial Screwdriver
48231320

Axial connection

The connection of the pelvic screw to the axial construct can either be direct (main construct rod captured by the iliac screw) or with a connecting implant (Fig. 10).

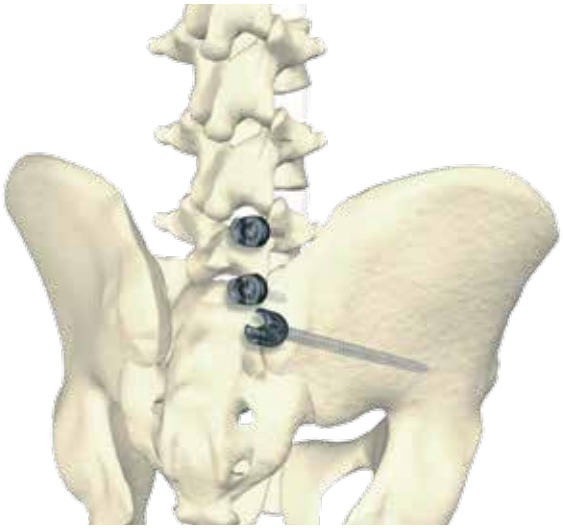


Figure 10

Frequently on the convex side of the fractional lumbosacral curve, the axial rod can be easily contoured to continue from the S1 screw to the pelvic screw without the need of an additional connector.

The preferable location of the offset connector is below the S1 screws as this provides stability at the distal foundation, augmenting the stability of the S1 SCR and immobilizing the lumbosacral junction (Fig. 11).

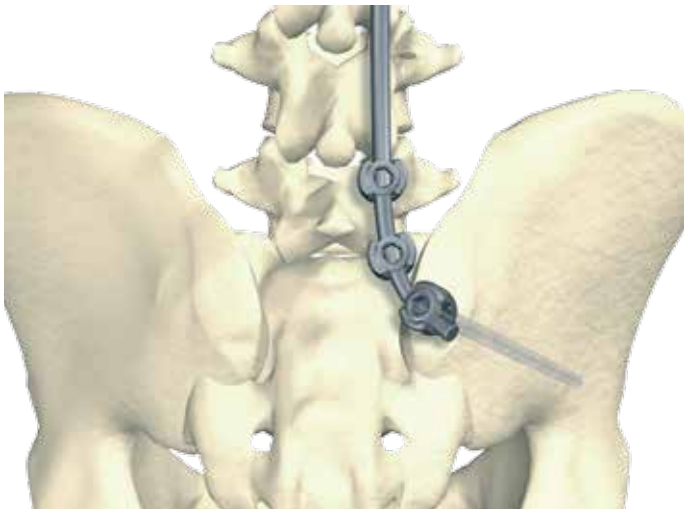


Figure 11

The connection of the iliac screw to the longitudinal rod can be obtained with use of the **Xia Offset Connectors (03820130, 03820131, 03820132, 03820133, 48230138, 48230139, 48230143, 48230144)** (Fig. 12).

Note: When using Xia Titanium implants, the surgeon may select a **Xia Vitallium Rod.** Vitallium Rod is recommended to be cut by the **Table Top Rod Cutter** or **Table Top Rod Cutter Stand.**

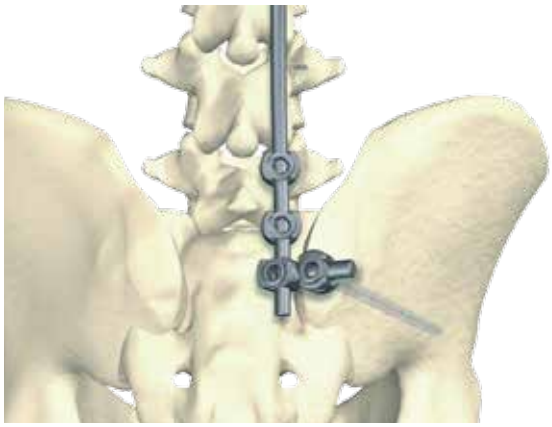


Figure 12

The **Xia 3 Inserter Tube** can help align the **Xia 3 Universal Tightener, 5mm** and the **Blocker** with the implant (Fig. 13).

Note: The Xia 3 Universal Tightener is not to be used for final tightening.

Note: The following connectors are compatible with a 6.0mm rod ONLY:

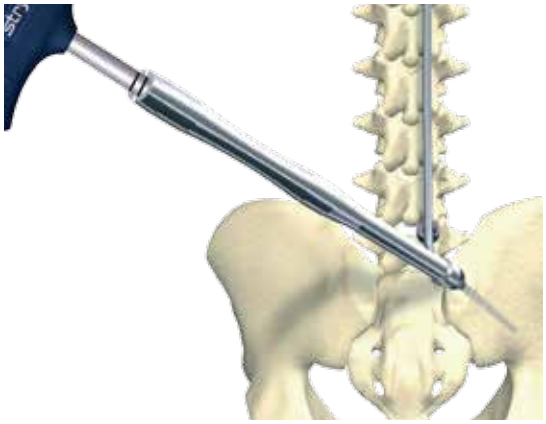


Figure 13

Xia Vitallium Rod
03822601

Table Top Rod Cutter
48238400

Table Top Rod Cutter Stand
48238400S

Xia 3 Inserter Tube
48237109

Xia 3 Universal Tightener, 5mm
48237008

Blocker 48230000

	Reference number	Description
	03820101	Xia II Low Profile Closed Offset Connector
	48230133	Xia 3 Low Profile Long Closed Offset Connector
	03805001	Xia Rod-to-Rod Clamp Parallel
	03805002	Xia Rod-to-Rod Clamp Axial

Parallel connection

The Xia Spinal System also offers a parallel connection from the main construct to the ilium. The **Xia 3 Rod-to-Rod Connectors** enable a surgeon to connect from the lumbar region to the ilium using a variety of options (Fig. 14):

- Xia II 0° Small Rod-to-Rod Connector 03820134
- Xia II 30° Small Rod-to-Rod Connector 03820135
- Xia II 0° Large Rod-to-Rod Connector 03820136
- Xia II 10° Large Rod-to-Rod Connector 03820137
- Xia 3 7mm Closed Parallel RRC 48230141
- Xia 3 11mm Closed Parallel RRC 48235009
- Xia 3 Angled Loading - Side Loading RRC 48235010
- Xia 3 Top Loading - Side Loading RRC 48235011
- Xia 3 12mm Parallel Revision Connector Open-Closed 48235007
- Xia 3 22mm Parallel Revision Connector Open-Closed 48235008

These connectors can be used for iliac fixation in a revision surgery, on a stand alone basis or can be used in conjunction with an offset rod connection to place two screws in the ilium for supplemental iliac fixation. This offers surgeons added strength and flexibility in treating complicated spinal disorders in the lumbar and sacral regions.

The picture to the right shows an L2-S1 Revision case with iliac fixation implanted for stability. Then, because of junctional disease, the construct was extended up to T9 using various Xia 3 Rod-to-Rod Revision Connectors.

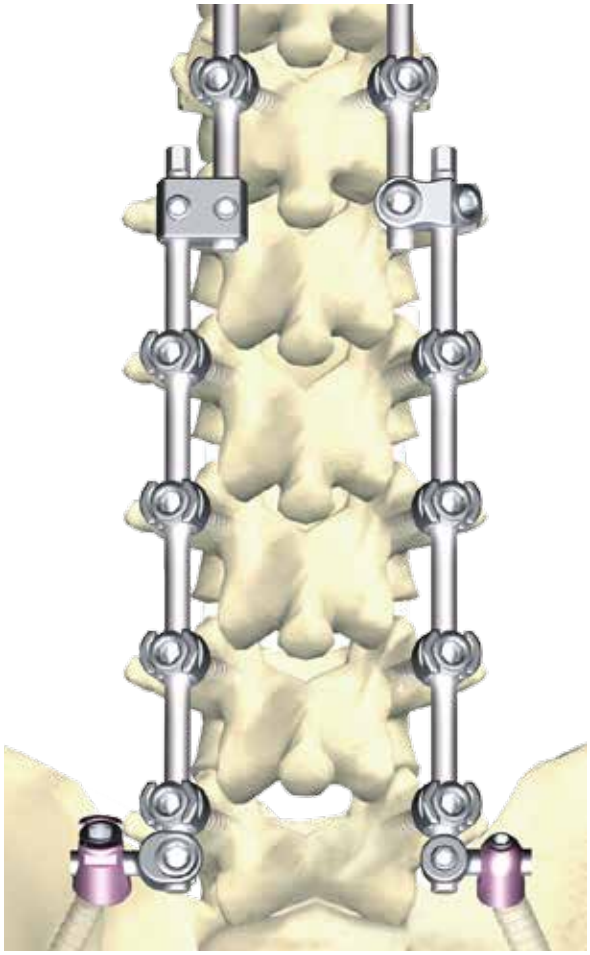


Figure 14

Note: The following connectors are compatible with a 6.0mm rod ONLY:

	Reference number	Description
	03820101	Xia II Low Profile Closed Offset Connector
	48230133	Xia 3 Low Profile Long Closed Offset Connector
	03805001	Xia Rod-to-Rod Clamp Parallel
	03805002	Xia Rod-to-Rod Clamp Axial

Final tightening

The final tightening of the Xia Blocker is done by utilizing the **Xia 3 Anti-Torque Key** and the **Torque Wrench** or **Audible Torque Wrench**. The Torque Wrench indicates the optimum force which has to be applied to the implant for final tightening. Line up the two arrows to achieve this optimum torque of 12Nm. If using the Audible Torque Wrench, the blocker is completely tightened to 12Nm when the Audible Torque Wrench clicks once.

Note: Do not overtighten.

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.

Note: The ES2 Counter Torque Tube may also be used in conjunction with the Xia 3 Torque Wrench or Audible Torque Wrench.

Anti-Torque Key
48237026

Torque Wrench
48237028

12Nm Audible Torque T-Handle (Standard)
G412161

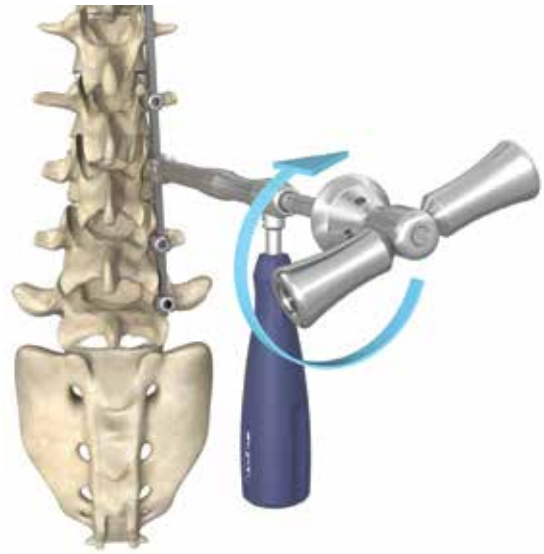
5mm Hex Shaft (12Nm)
GC100184

Audible Torque Wrench

Note: The Audible Torque Wrench consists of the 12Nm Audible Torque T-Handle (Standard) connected to the 5mm Hex Shaft (12Nm).

ES2 Torque Wrench
48280081

ES2 Counter Torque Tube
48280080



Rod-to-rod connectors

Nine rod-to-rod connectors are offered with this set. All designs are available in stainless steel and titanium. All of these connectors use the Xia Blocker for final rod fixation.

1) **Xia II 0° Small Rod-to-Rod Connector**
This open rod-to-rod connector accommodates parallel rods that are 12mm apart.

Xia II 0° Small Rod-to-Rod Connector 03820134

2) **Xia II 30° Small Rod-to-Rod Connector**
This open rod-to-rod connector accommodates rods that are 12mm apart at angles of 30°.

Xia II 30° Small Rod-to-Rod Connector 03820135

3) **Xia II 0° Large Rod-to-Rod Connector**
This open rod-to-rod connector accommodates parallel rods that are 16mm apart.

Xia II 0° Large Rod-to-Rod Connector 0382013

4) **Xia II 10° Large Rod-to-Rod Connector**
This open rod-to-rod connector accommodates rods that are 16mm apart at angles of 10°.

Xia II 10° Large Rod-to-Rod Connector 03820137

Note: The following connectors are compatible with a 6.0mm rod ONLY: 03820101, 48230133, 03805001, 03805002.

5) **Xia 3 Angled Loading-Side Loading RRC**
This angled open rod-to-rod connector accommodates rods that are 9.65mm apart and provides an easy connection for revision applications, with a 45˚ angle.

Xia 3 Angled Loading-Side Loading RRC 48235010

6) **Xia 3 Top Loading-Side Loading RRC**
This top-loading/side-loading open connector provides an easy connection for revision applications, and accomodates rods that are 11mm apart.

Xia 3 Top Loading-Side Loading RRC 48235011

7) **Xia 3 12mm Parallel Revision Connector Open-Closed**
This open/closed rod-to-rod connector accommodates rods that are 12mm (small) and 22mm (large) apart.

Xia 3 12mm Parallel Revision Connector Open-Closed 48235007

8) **Xia 3 7mm Closed Parallel RRC**
This closed parallel rod-to-rod connector accommodates rods that are 7mm apart.

Xia 3 7mm Closed Parallel RRC 48230141

9) **Xia 3 11mm Closed Parallel RRC**
This closed parallel rod-to-rod connector accommodates rods that are 11mm apart.

Xia 3 11mm Closed Parallel RRC 48235009

Note: The following connectors are compatible with a 6.0mm rod ONLY: 03820101, 48230133, 03805001, 03805002.

Offset connectors

Nine offset connector designs are offered in the ilios application. All designs are available in stainless steel and titanium. All of these connectors use a Xia Blocker for final rod fixation.

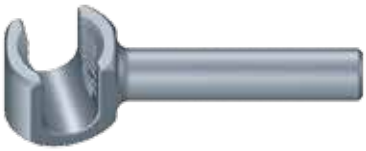
1) **Xia II Long Offset Connector Neutral**
This connector is 80mm long and will be perpendicular to the rod when attached. This connector can be cut and bent for additional inter-operative flexibility.

Xia II Long Offset Connector Neutral
03820133

2) **Xia II Offset Connector Neutral**
This connector is 35mm long and will be perpendicular to the rod when attached.

Xia II Offset Connector Neutral
03820131

3) **Xia 3 75° Offset Connector Bend**
This connector is 35mm long and has a 75° angle allowing better anatomical placement of the connector in the iliac region.



Xia 3 75° Offset Connector Bend
03820130

4) **Xia II 105° Offset Connector Bend**
This connector is 35mm long and has a 105° angle allowing better anatomical placement of the connector in the iliac region.

Xia II 105° Offset Connector Bend
03820132

5) **Xia 3 Long Offset Connector Open-Head**
This connector is 100mm long and will be perpendicular to the rod when attached. This connector can be cut and bent for additional inter-operative flexibility.

Xia 3 Long Offset Connector Open-Head
48230139

Note: The following connectors are compatible with a 6.0mm rod ONLY: 03820101, 48230133, 03805001, 03805002.

Offset Connectors

6) **Xia 3 Open-Side Loading Offset Connector**
This connector is 69mm long and will be perpendicular to the main rod construct. The open side allows or easy connection and flexibility.

Xia 3 Open-Side Loading Offset Connector 48230144

7) **Xia 3 Small Closed Head Offset Connector**
This connector is 65mm long and offers a low-profile closed-head connection to the rod.

Xia 3 Small Closed Head Offset Connector 48230138

8) **Xia 3 Low Profile Long Closed Offset Connector**
This connector is 100mm long and is similar to the Xia II closed offset connector, but in a longer length.

Note: Short Xia II Connector.

Xia 3 Low Profile Long Closed Offset Connector 48230133

Xia II Short Offset Connector 03820101

9) **Xia 3 J Hook Offset Connector**
This connector is 100mm long and connects to the rod like the M.A.C. connectors, allowing for a simple connection to the rod.

Xia 3 J Hook Offset Connector 48230143

Note: The following connectors are compatible with a 6.0mm rod ONLY: 03820101, 48230133, 03805001, 03805002.

Implants

	Reference number	Sterile reference number*	Description
	03820134	N/A	Xia II 0° Small Rod-to-Rod Connector
	03820135	N/A	Xia II 30° Small Rod-to-Rod Connector
	03820136	N/A	Xia II 0° Large Rod-to-Rod Connector
	03820137	N/A	Xia II 10° Large Rod-to-Rod Connector
	48235007	48235007S	Xia 3 12mm Parallel Revision Connector Open-Closed
	48235008	48235008S	Xia 3 22mm Parallel Revision Connector Open-Closed
	48235010	48235010S	Xia 3 Angled Loading - Side Loading RRC
	48235011	48235011S	Xia 3 Top Loading - Side Loading RRC
	48230141	48230141S	Xia 3 7mm Closed Parallel RRC
	48235009	48235009S	Xia 3 11mm Closed Parallel RRC

*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker sales representative for more information.
Note: The following connectors are compatible with a 6.0mm rod ONLY: 03820101, 48230133, 03805001, 03805002.

	Reference number	Sterile reference number*	Description
	03820130	N/A	Xia II 75° Offset Connector Bend
	03820131	N/A	Xia II Offset Connector Neutral
	03820132	N/A	Xia II 105° Offset Connector Bend
	03820133	N/A	Xia II Long Offset Connector Neutral
	48230133	48230133S	Xia 3 Low Profile Long Closed Offset Connector
	48230138	48230138S	Xia 3 Small Closed Head Offset Connector
	48233500**	N/A	Set Screw for Xia 3 Small Offset Connector Closed Head (M6 x 1)
	48230139	48230139S	Xia 3 Long Offset Connector Open-Head
	48230143	48230143S	Xia 3 J Hook Offset Connector
	48230144	48230144S	Xia 3 Open Side-Loading Offset Connector

Revision implants

	Reference number	Sterile reference number*	Description
	48235012	48235012S	Xia 3 Axial Revision RRC
	48230260	N/A	Xia 3 Sacral Hook

*Sterile implants are only available in certain markets outside the U.S. Please contact your Stryker sales representative for more information.
**These set screws come pre-packaged with these implants. This part need only be ordered as a replacement if lost or damaged.
Note: The following connectors are compatible with a 6.0mm rod ONLY: 03820101, 48230133, 03805001, 03805002.

	Reference number	Description
	4823840(20) – (45)	Xia 3 Ø4.0 x 20-45mm Biased Angle Polyaxial Screw
	4823845(20) – (45)	Xia 3 Ø4.5 x 20-45mm Biased Angle Polyaxial Screw
	4823850(20) – (45)	Xia 3 Ø5.0 x 20-45mm Biased Angle Polyaxial Screw
	4823855(25) – (55)	Xia 3 Ø5.5 x 25-55mm Biased Angle Polyaxial Screw
	4823865(25) – (90)	Xia 3 Ø6.5 x 25-90mm Biased Angle Polyaxial Screw
	4823875(25) – (90)	Xia 3 Ø7.5 x 25-90mm Biased Angle Polyaxial Screw
	4823885(60) – (100)	Xia 3 Ø8.5 x 60-100mm Biased Angle Polyaxial Screw
	4823895(60) – (100)	Xia 3 Ø9.5 x 60-100mm Biased Angle Polyaxial Screw
	48237140(20) – (45)	Xia 3 Ø4.0 x 20-45mm Medial Biased Angle Polyaxial Screw
	48237145(20) – (45)	Xia 3 Ø4.5 x 20-45mm Medial Biased Angle Polyaxial Screw
	48237150(20) – (45)	Xia 3 Ø5.0 x 20-45mm Medial Biased Angle Polyaxial Screw
	48237155(25) – (55)	Xia 3 Ø5.5 x 25-55mm Medial Biased Angle Polyaxial Screw
	48237165(25) – (90)	Xia 3 Ø6.5 x 25-90mm Medial Biased Angle Polyaxial Screw
	48237175(25) – (90)	Xia 3 Ø7.5 x 25-90mm Medial Biased Angle Polyaxial Screw
	48237185(60) – (90)	Xia 3 Ø8.5 x 60-90mm Medial Biased Angle Polyaxial Screw
	48237195(60) – (90)	Xia 3 Ø9.5 x 60-90mm Medial Biased Angle Polyaxial Screw
	4823765(30) – (00)	Xia 3 Ø6.5 x 30-100mm Closed Head Polyaxial Screw
	4823775(30) – (00)	Xia 3 Ø7.5 x 30-100mm Closed Head Polyaxial Screw
	4823785(30) – (00)	Xia 3 Ø8.5 x 30-100mm Closed Head Polyaxial Screw
	4823795(30) – (00)	Xia 3 Ø9.5 x 30-100mm Closed Head Polyaxial Screw
	48233500	Set Screw for Xia 3 Closed Head Screw (M6 x 1)

These set screws come pre-packaged with these implants. This part need only be ordered as a replacement if lost or damaged.

	Reference number	Sterile reference number*	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
	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 25-100mm 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.

Instruments

	Reference number	Description
	48237092	Double-Ended 3.5 Setscrew Inserter
	48237061	Double Ended Pedicle Feeler
	48237065	Dual-Ended Universal Tightener
	48231314	Iliac Screwdriver – One piece
	48231326	Iliac Screwdriver – Two piece
	48230085	8.5mm Modular Tap
	48230095	9.5mm Modular Tap
	48230105	10.5mm Modular Tap
	48237091	Modular Monodriver Shaft
	48237080	Pedicle Marker Inserter
	48237081	Pedicle Markers (Set of 6)
	48231140	Rod Gripper

	Reference number	Description
	48231350	Rod to Rod Connector Holder
	48231313	Self-Holding Polyaxial Screwdriver Shaft
	48237093	Soft Tissue Retractor
	48237062	Straight Blunt Probe
	48237067	SUK Derotator Clamp
	48237097	T-Handle, SUK Tube
	48237087	SUK Tube One-Piece
	48237077	SUK Tube Two-Piece
	48238400S	Table-Top Rod Cutter Stand
	48238400	Table-Top Rod Cutter
	48230191L	Tube Bender Left
	48230191R	Tube Bender Right

	Reference number	Description
	03710620	Rod Template
	482300 (30) - (00)	3.0 Modular Tap 3.5 Modular Tap 4.0 Modular Tap 4.5 Modular Tap 5.0 Modular Tap 5.5 Modular Tap 6.5 Modular Tap 7.5 Modular Tap 8.5 Modular Tap 9.5 Modular Tap 10.5 Modular Tap
	48230100	Vise Grip
	48230110	Narrow Lamina Hook Preparer
	48230120	Cross Connector Inserter
	48230121	3.5mm Hex Driver
	48230122	8.0mm Hex Driver
	48230123	Cross Connector Measuring Device
	48230140	Rod Insertion Forceps
	48230180	Coronal Plane Bender Left
	48230190	Coronal Plane Bender Right
	48230180S	Ball Joint

	Reference number	Description
	48231020	Standard Hook Holder
	48231040	Lateral Hook Holder
	48231170	Straight Hook Holder
	48231201	T-Handle
	48231202	T-Handle, Ratchet
	48231301	Round Handle
	48231302	Round Handle, Ratchet
	48231320	Monoaxial Screwdriver (without handle)
	48231321	Shaft for Monoaxial Screwdriver
	48231330	Polyaxial Screwdriver (without handle)
	48231311	Shaft for Polyaxial Screwdriver
	48236000	Small Distractor
	48236001	Large Distractor

	Reference number	Description
	48236100	Small Compressor
	48236101	Large Compressor
	48237003 48237059 48237060	Pedicle Feeler - Stiff Pedicle Feeler - Medium Pedicle Feeler - Malleable
	48237008	Universal Tightener
	48237109	Inserter Tube
	48237010	French Bender
	48237015	One Handed Persuader
	48237016	Persuader
	48237017	Hex Drive T-Handle
	48237018	Rod Fork
	48237019	Rod Pusher
	48237021	Lamina Hook Preparer
	48237024	Curved Blunt Probe

	Reference number	Description
	48237025	Pedicle Hook Preparer
	48237026	Anti-Torque Key
	48237028	Xia 3 Torque Wrench
	48280081	ES2 Torque Wrench
	48287028	MANTIS Redux Torque Wrench
	G412161	12Nm Audible Torque T-Handle (Standard)
	G415163	12Nm Audible Torque T-Handle (Offset)
	GC100184	5mm Hex Shaft (12Nm)
	48280080	ES2 Counter Torque Tube
	48237029	Hook Impactor
	48237032	Monodriver
	48237033	Poly Adjustment Driver (without handle)
	48237055	Thoracic Pedicle Probe
	48237056	Rod Rotation Key
	48237111	Awl

	Reference number	Description
	48231330S	PA Screwdriver Sleeve, Sleeve for Screwdriver
	48237011L	In Situ Bender Left
	48237011R	In Situ Bender Right
	48230008	Ilios Tray
	48230010	Outlier Instrument Tray
	48230015	SUK Tray
	48230020	Outlier Implant Tray

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 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 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 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.

Spine Division

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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Manufactured by:

Stryker Spine
2 Pearl Court
Allendale, NJ 07401 USA
t: 201 749 8000

www.stryker.com