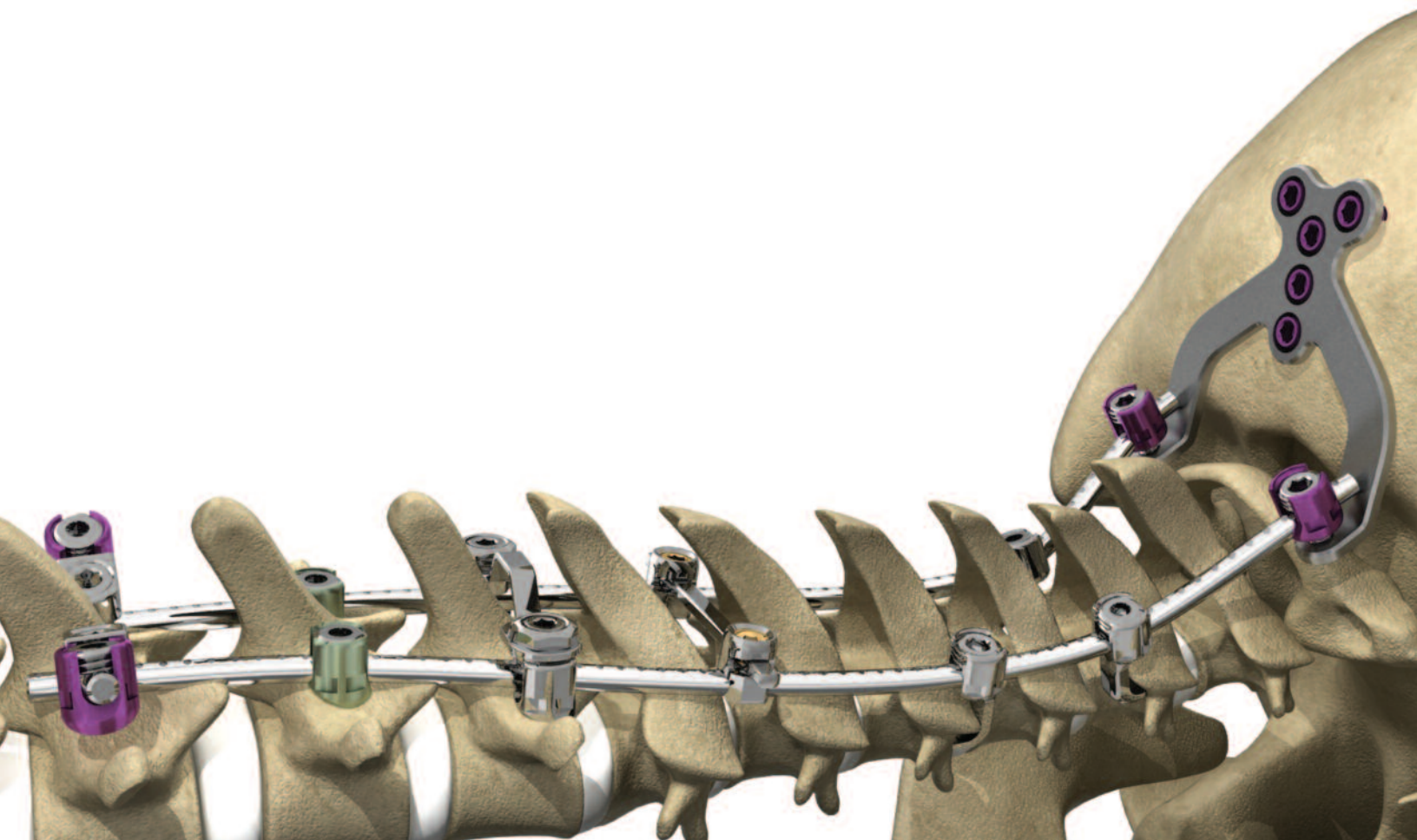
stryker®

Spine

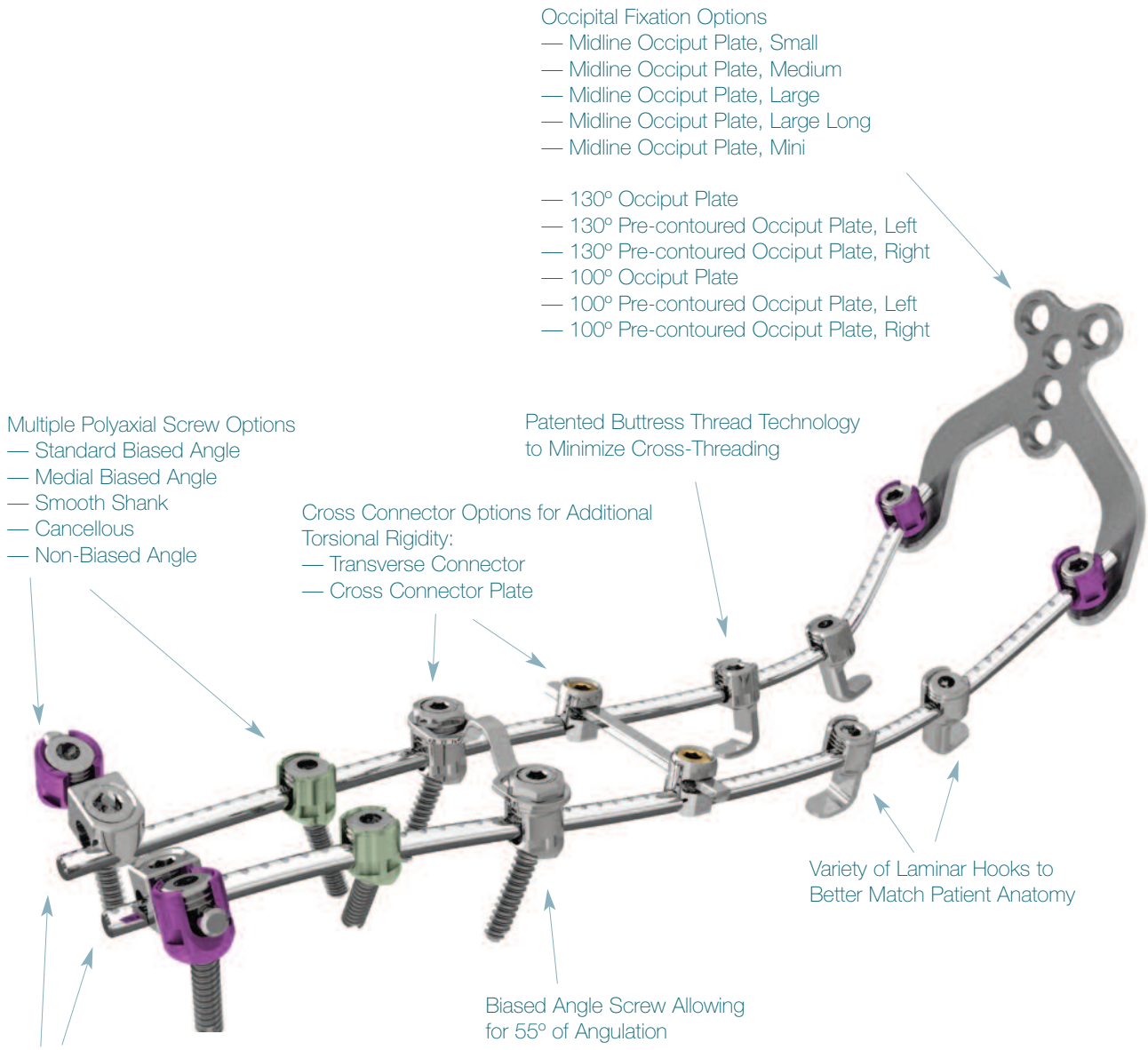
OASYS®
Surgical Technique

Occipito-Cervico-Thoracic System



System Overview

The OASYS Occipito-Cervico-Thoracic System was developed to provide the surgeon with versatility for the treatment of pathologies of the occipitocervical junction, and the posterior cervical and upper thoracic spine. The modular system consists of hooks, polyaxial screws and rods as well as plates and bone screws. A variety of occiput plates and connectors complement the product line.



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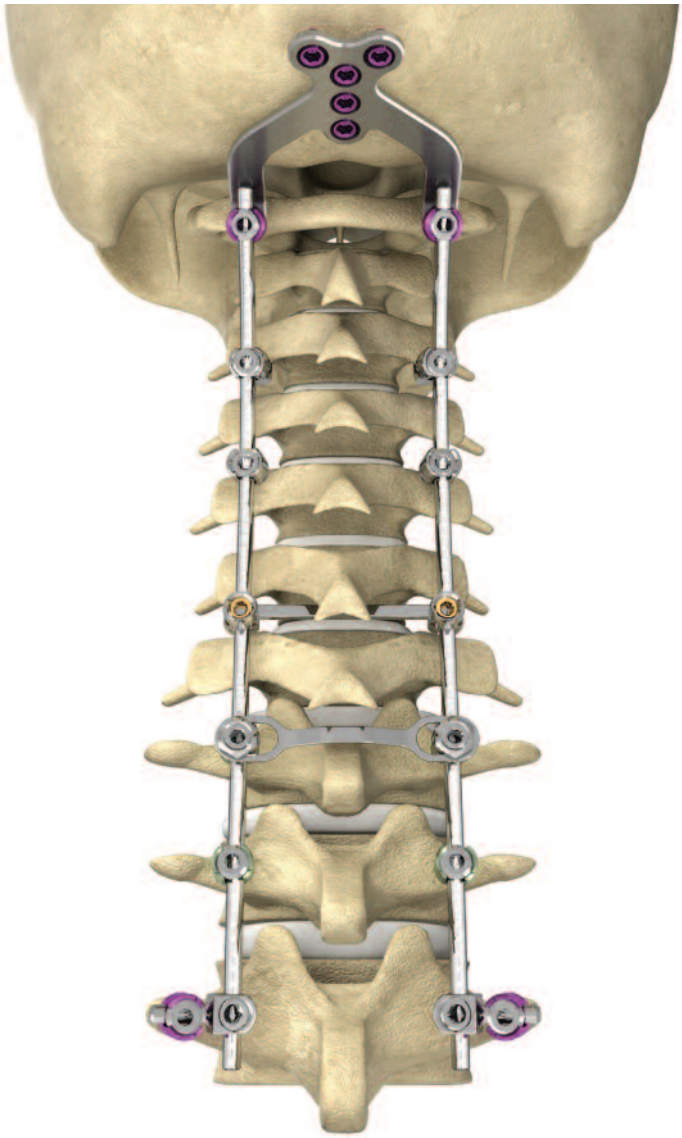
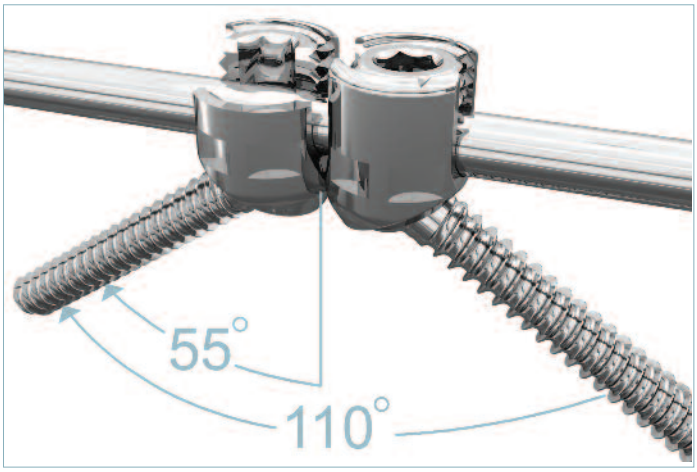


Stryker Spine would like to thank
John J. Carbone, MD
Baltimore, Maryland
for his contribution.

Implant Overview

Polyaxial Screws

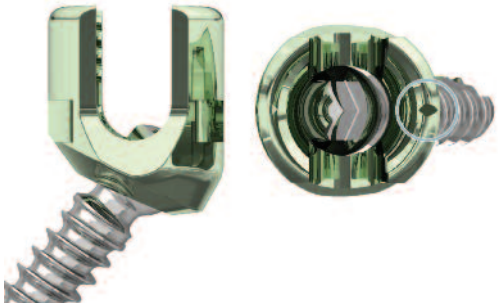
One of the key features of the Biased Angle Polyaxial Screw is the offset angle of the screw head, which allows for combined **divergent screw angulation of 110° (or 55° in one direction).**



The high degree of angulation promotes screw placement at an optimal anatomic position, helping to simplify the surgical procedure by minimizing the need for rod contouring due to linear placement of the screw heads.

There are five types of polyaxial screws available in the OASYS System. (See complete screw listing on page 35-37).

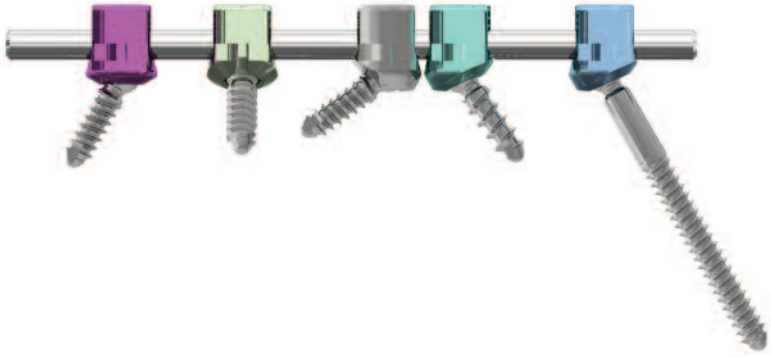
The standard **Biased Angle Screws** are available in diameters of 3.5mm (10 to 54mm lengths in 2mm increments) and 4.0mm (10 to 42mm in 2mm increments, 46 and 50mm lengths). The 4.0mm Biased Angle Screws are anodized blue for easy identification.



Medial Biased Angle Screw

The **Medial Biased Angle Screws** are available in diameters of 3.5mm (20, 22, and 24 to 40mm lengths in 4mm increments) and 4.0mm diameters (20 to 52mm lengths in 4mm increments). The tulip heads of the Medial Biased Angle Screws are anodized green for easy identification.

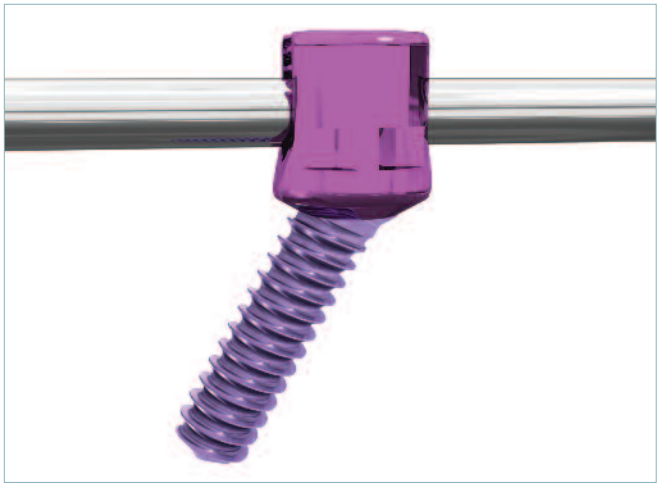
The **Smooth Shank Biased Angle Screws** are available in a 3.5mm diameter (22 to 40mm lengths in 2mm increments). These screws have a 10mm non-threaded shank to potentially avoid nerve root or tissue irritation. The tulip heads of the Smooth Shank Biased Angle Screws are anodized blue for easy identification.



The **Cancellous Biased Angle Screws** are available in diameters of 3.5mm and 4.0mm (10 to 24mm lengths in 2mm increments). These screws have a thread geometry designed for purchase in cancellous bone. The tulip heads of the Cancellous Biased Angle Screws are anodized blue-green for easy identification.

The **Non-Biased Angle Polyaxial Screws** are available in diameters of 3.5mm, 4.0mm and 4.5mm. The 3.5mm and 4.0mm screws are 10 to 20mm in length in 2mm increments while the 4.5mm screws are 20 to 52mm in length in 4mm increments. The Non-Biased Angle Polyaxial Screws offer up to 30° of angulation in each direction or 60° conical. These screws can be used in instances where the surgeon does not need the angulation offered with the Biased Angle Screws. A combined color approach has been used to identify the screw type and diameter.

The tulip heads of the Non-Biased Angle Polyaxial Screws are anodized fuchsia while the 4.5mm bone screws are anodized purple.

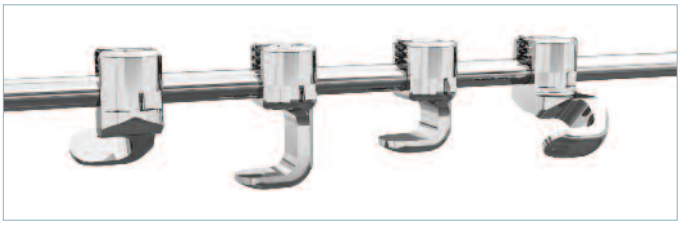


Non-Biased Angle Polyaxial Screw

Screw Type	Diameter	Lengths	Tulip Head Color	
Biased Angle Screws	**3.5mm**	**10 - 54mm (in 2mm increments)**	**Silver**	
	4.0mm	**10 - 42mm, 46 and 50mm (in 2mm increments)**	**Silver**	
Medial Biased Angle Screws	**3.5mm**	**20, 22 and 24 - 40mm (in 4mm increments)**	**Green**	
	4.0mm	**20 - 52mm (in 4mm increments)**	**Green**	
Smooth Shank Biased Angle Screws	**3.5mm**	**22 - 40mm (in 2mm increments)**	**Blue**	
Cancellous Biased Angle Screws	**3.5mm**	**10 - 24mm (in 2mm increments)**	**Blue-Green**	
	4.0mm	**10 - 24mm (in 2mm increments)**	**Blue-Green**	
Non-Biased Angle Polyaxial Screws	**3.5mm**	**10 - 20mm (in 2mm increments)**	**Fuchsia**	
	4.0mm	**10 - 20mm (in 2mm increments)**	**Fuchsia**	
	4.5mm	**20 - 52mm (in 4mm increments)**	**Fuchsia**	

Hooks

A variety of laminar **Hooks** are available to better match the individual patient's anatomy. Standard hooks are available in four throat heights: 3.5, 5.0, 6.5 and 8.0mm. Right and left offset hooks are also available for both right and left application.



Part #	Description
48551049	Hook, Standard, 3.5mm
48551050	Hook, Standard Short, 5.0mm
48551053	Hook, Standard, 6.5mm
48551055	Hook, Standard Tall, 8.0mm
48551060	Hook, Offset Right
48551065	Hook, Offset Left

Hook, Standard, 3.5mm

Hook, Standard Short, 5.0mm

Hook, Standard, 6.5mm

Hook, Standard Tall, 8.0mm

Hook, Offset Right

Hook, Offset Left

Rods

A variety of **Rod** offerings are available to provide intraoperative solutions. For added stiffness, Vitallium is available. Titanium and Vitallium pre-cut offerings are available with the OASYS System, as well as Titanium Commercially Pure in 240mm.

Part #	Description
48553080	3.5mm x 80mm Vitallium Rod
48553120	3.5mm x 120mm Vitallium Rod
48553240	3.5mm x 240mm Vitallium Rod
48553350	3.5mm x 350mm Vitallium Rod
48552025	3.5mm x 25mm Titanium Alloy Rod
48552030	3.5mm x 30mm Titanium Alloy Rod
48552040	3.5mm x 40mm Titanium Alloy Rod
48552050	3.5mm x 50mm Titanium Alloy Rod
48552060	3.5mm x 60mm Titanium Alloy Rod
48552070	3.5mm x 70mm Titanium Alloy Rod
48552080	3.5mm x 80mm Titanium Alloy Rod
48552120	3.5mm x 120mm Titanium Alloy Rod
48552240	3.5mm x 240mm Titanium Alloy Rod
48551240	3.5mm x 240mm Titanium, Commercially Pure Rod
48551350	3.5mm x 350mm Titanium Alloy Rod

Rod

Occipital Fixation

The OASYS System offers a midline occiput plate option as well as bilateral occiput plates to better match individual patient anatomy.

Part #	Description
48551040	130º Occiput Plate
48551041L	130º Pre-contoured Occiput Plate, Left
48551041R	130º Pre-contoured Occiput Plate, Right
48551042	100º Occiput Plate
48551043L	100º Pre-contoured Occiput Plate, Left
48551043R	100º Pre-contoured Occiput Plate, Right
48551044	Midline Occiput Plate, Small
48551045	Midline Occiput Plate, Medium
48551046	Midline Occiput Plate, Large
48551047	Midline Occiput Plate, Large Long
48551048	Midline Occiput Plate, Mini

Midline Plate | Straight Plates | Pre-contoured Plates

Bone Screws

The following bone screws are available for use with the OASYS plates:

Diameter	Lengths (in 2mm increments)	Color	
3.5mm	6 – 16mm	Silver	
4.0mm	6 – 16mm	Blue	
4.5mm	6 – 16mm	Purple	

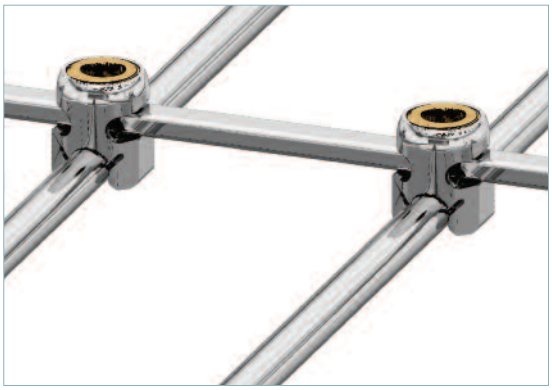
Connectors

Several types of **Connectors** are available in the OASYS System.

Transverse Connector

The **Transverse Connector** is designed for added torsional rigidity of a bilateral rod construct. The clip-on design features a very low profile and does not add significantly to the height of the construct. The transverse bar is available in 40, 60, and 80mm lengths. The bar of the transverse connector can be cut so that the length can be adjusted to better match individual patient anatomy.

Part #	Description
48551070	Transverse Connector, 80mm
48551071	Transverse Connector, 60mm
48551072	Transverse Connector, 40mm

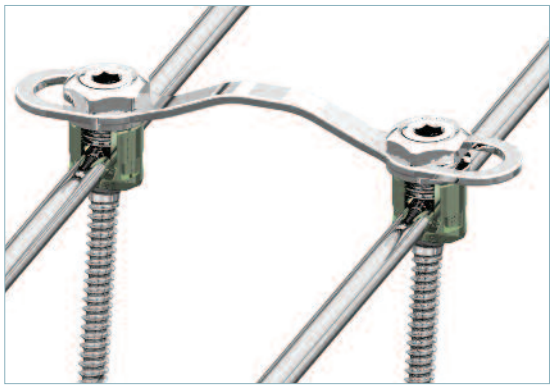


Transverse Connector

Cross Connector Plate

In cases where screws are closer together, this arched implant allows connection to the tulip heads. The arch is designed for additional clearance above the dura and spinal cord. The **Cross Connector Plate** is available in 24, 32, and 40mm lengths with 10mm of additional variability for each plate. The plates can be bent to adapt to variable patient anatomy.

Part #	Description
48551073	Cross Connector Plate, 24mm
48551074	Cross Connector Plate, 32mm
48551075	Cross Connector Plate, 40mm

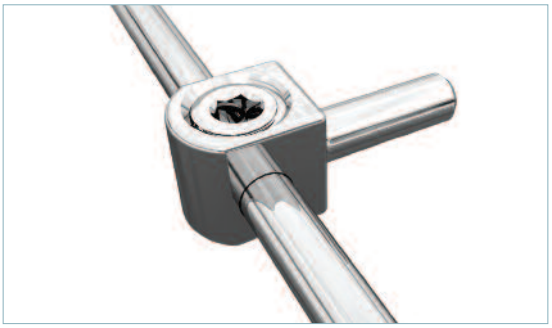


Cross Connector Plate

Offset Connector

As an alternative to offset rod contouring in cases of non-linear screw or hook placement, **Offset Connectors** can be used to provide additional medial-lateral offset. The bar is available in 12 and 20mm lengths.

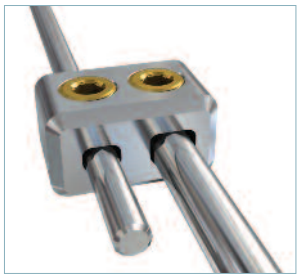
Part #	Description
48551080	Offset Connector, 20mm
48551081	Offset Connector, 12 mm

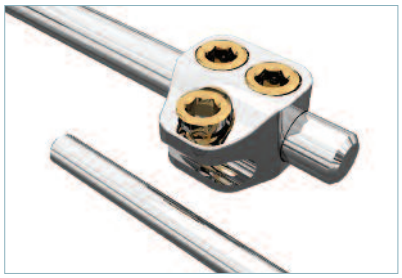


Offset Connector

Rod-to-Rod Connector

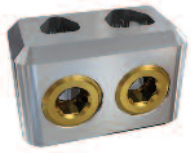
The **Rod-to-Rod Connector** facilitates connection of the 3.5mm diameter rod to a spine construct using: 3.5, 4.5, 5.5, or 6.0mm diameter rods.





Parallel Rod-to-Rod Connectors

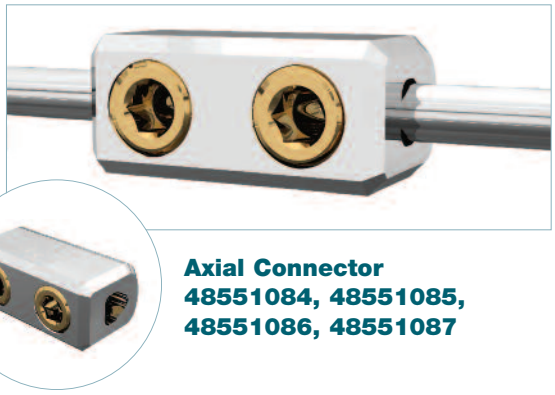
Part #	Description
48551088	3.5mm to 3.5mm Parallel Rod-to-Rod Connector
48551091	3.5mm to 4.5mm Parallel Rod-to-Rod Connector
48551089	3.5mm to 5.5mm Parallel Rod-to-Rod Connector
48551090	3.5mm to 6.0mm Parallel Rod-to-Rod Connector



Parallel Connector
48551088, 48551091

Parallel Connector
48551089, 48551090

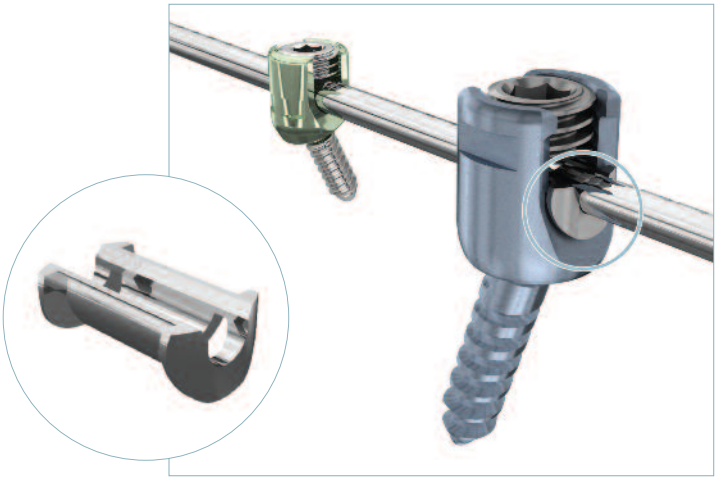
Part #	Description
48551085	3.5mm to 3.5mm Axial Connector
48551084	3.5mm to 4.5mm Axial Connector
48551086	3.5mm to 5.5mm Axial Connector
48551087	3.5mm to 6.0mm Axial Connector



Axial Connector
48551084, 48551085,
48551086, 48551087

Saddle Connector

The **Saddle Connector** is an additional connector option which helps to allow connection of the 3.5mm rod to a spine construct using Xia II and/or Xia 3* Polyaxial Screws. The Saddle Connector is to allow the use of a larger size bone screw in the thoracic area of T1 to T3 per the current OASYS indications.



Saddle Connector
48551094

*Refer to the Xia Surgical Technique Guide for information on screw insertion and blocker final tightening.

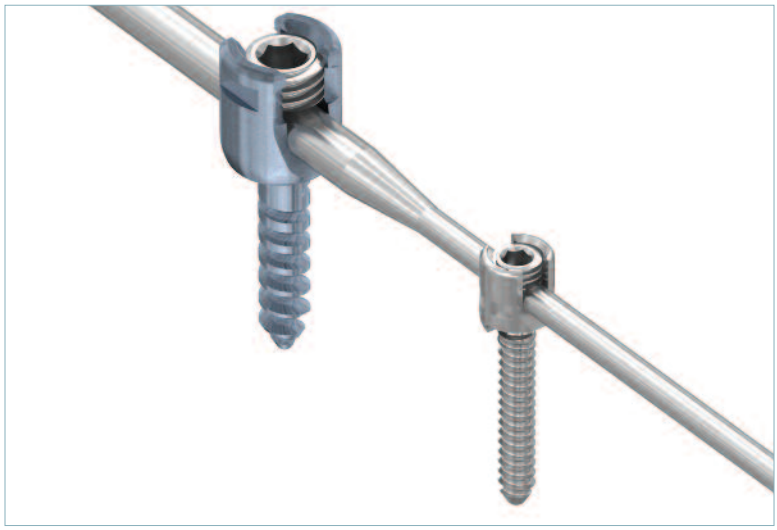
Transition Rod

The OASYS **Transition Rod** provides an additional option for spanning the cervico-thoracic junction.

Transition Rods are available to connect the following systems:
- OASYS and Xia
- OASYS and Xia 4.5
- OASYS and SR90D

Transition Rods are offered in two different rod composition options, Titanium Alloy and Vitallium for added stiffness. Each rod is 600mm long.

Refer to the Surgical Technique for Xia, Xia 4.5, and/or SR90D for instructions on usage of the larger diameter of the Transition Rod.



Transition Rod

Part #	Description
48553600	Titanium Alloy 3.5mm-4.5mm Transition Rod
48553602	Vitallium 3.5mm-4.5mm Transition Rod
48553604	Titanium Alloy 3.5mm-5.5mm Transition Rod
48553606	Vitallium 3.5mm-5.5mm Transition Rod
48553608	Titanium Alloy 3.5mm-6.0mm Transition Rod
48553610	Vitallium 3.5mm-6.0mm Transition Rod

Transition Rod Construct *in situ*

Surgical Procedure

Preoperative Planning

Use the appropriate imaging techniques to outline the patient's osseous anatomy and to determine the proper size and type of instrumentation to be used. Identify the components to be used for the assembly. Keep in mind that changes to the final configuration may become necessary based on intraoperative findings.

Patient Positioning and Exposure

The patient is placed in the prone position with head and neck held securely in optimum alignment. A standard midline incision is performed at the appropriate levels. The exposure may be extended for one or two levels below the inferior end of the planned fusion to allow for easy placement of the instrumentation.

Polyaxial Screw Placement

Following exposure, penetrate the cortex with an **Awl**, burr, or a drill to mark the entry point of all the screws using anatomic, fluoroscopic, or image-guided technique. To minimize the need for rod contouring and for easy rod insertion, it is advisable to align the screw holes as much as possible.

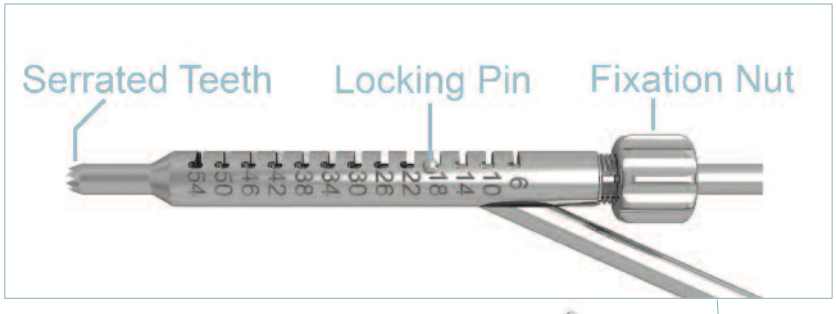
In applicable anatomic areas, a **Pedicle Probe** – followed by a **Tap** – can be used to prepare the screw pathway. In all other cases, the preparation of the screw hole should follow the steps below, using the appropriate Drill Bit and Tap.

The **Adjustable Drill Guide** allows for a single **Drill Bit** to be used for preparation of variable depths. To set the depth which corresponds to the final screw length, grasp knob, then rotate the locking pin into the slot corresponding to the desired depth. Push the pin forward and lock the fixation nut at the end of the sleeve by rotating clockwise.

Awl
48562010

Pedicle Probe
48562118

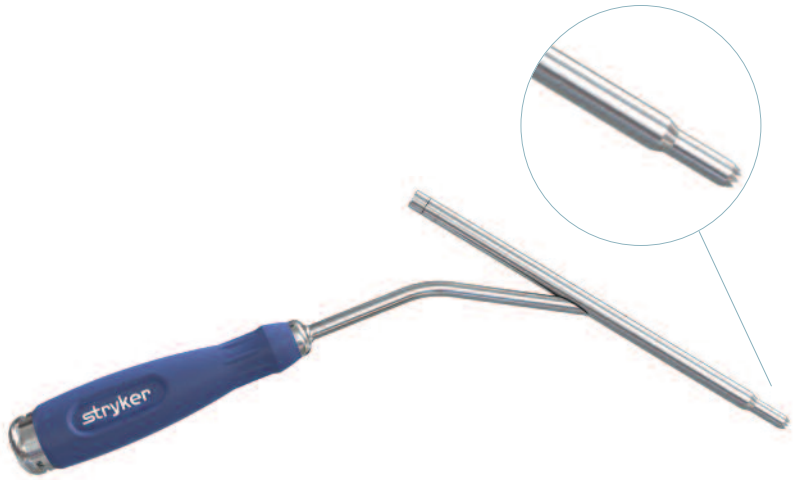
4.5 Pedicle Probe
48562115



Adjustable Drill Guide
48562011

If the sleeve is not moving freely, loosen the fixation nut before manipulating the pin. Drill depth can be adjusted while the Drill Bit is inserted in the Adjustable Drill Guide, however, it is not recommended while drilling. The fixation nut and the inner sleeve may be disassembled for cleaning purposes.

For common screw lengths, **Fixed Drill Guides** are also available. These Fixed Drill Guides are available for 12 and 14mm screws. The 14mm guide has a gold band around it for easy identification.



Fixed Drill Guide

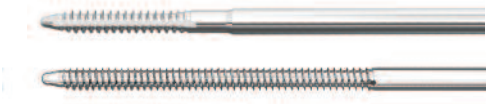
Part #	Description
48562034	Fixed Drill Guide, 12mm
48562035	Fixed Drill Guide, 14mm

Select the **Drill Bit** that is appropriate for the size of the screw to be used (3.5mm, 4.0mm, or 4.5mm). The Drill Bits are undersized by 1mm (i.e., the 3.5mm drill has a diameter of 2.5mm), corresponding to the inner diameter of the screws. The Drill Bits can be attached to the **Quick-Release Handle** or used with standard power equipment (AO attachment).

Part #	Description
48560323	2.5mm Drill for 3.5mm Polyaxial Screw
48560423	3.0mm Drill for 4.0 & 4.5mm Polyaxial Screws

Tap Sleeve
48561914
48561915

It is recommended that a Tap be used to finalize the preparation of the screw pathway. Taps are available in two lengths, 18mm and 54mm, and three diameters, 3.5mm, 4.0mm, and 4.5mm. There are two types of taps - cancellous and cortical - to match the thread pitch of the screws being used. The optional **Tap Sleeve** may be used to accurately measure the tapping depth or to protect soft tissue.



Cortical Taps

Part #	Description
48561314	3.5mm Tap, 18mm
48561414	4.0mm Tap, 18mm
48560314	3.5mm Tap
48560414	4.0mm Tap
48560514	4.5mm Tap

When preparing a screw hole for a screw up to 18mm, a shorter Tap option is available. The 18mm Tap can be used to help prevent contact between the cutting edges of the Tap and soft tissue when the Tap Sleeve is not used.

Cancellous Tap

Part #	Description
48561916	3.5mm Cancellous Tap
48561917	4.0mm Cancellous Tap

Note: Using incorrect Tap or Drill combination can result in reduced bone purchase or possibility of instrument breakage.

The **Ball Tip Probe** can be used to feel the integrity of the pedicle wall after drilling or tapping. The probe has a 1.8mm ball tip for smaller pedicles. The **Depth Gauge** can be used to confirm the screw length.

Note: The 4.0mm Drill followed by the 4.5mm Tap should be used to prepare the pathway for the 4.5mm Non-Biased Angle Screws. Also, when preparing the pathway for the Cancellous Screws, make sure to use the Cancellous Tap. The Cancellous Tap has a different thread geometry to match the geometry of the Cancellous Screws. The standard Tap Sleeve can be used with both the 3.5mm and 4.0mm Standard and Cancellous Taps. For the 4.5mm Tap, use the 4.5mm Tap Sleeve.

A polyaxial screw is attached to the **Polyaxial Screwdriver** by placing the hex head socket over the bone screw and threading the end of the outer sleeve into the polyaxial screw head for stable fixation. Prior to screw implantation, use the gauges incorporated into the implant tray to verify the screw dimensions. Aligning the Polyaxial Screwdriver in the same axis as the screw hole facilitates screw insertion. Once the screw has been inserted, the Polyaxial Screwdriver can be removed by unthreading the end of the sleeve from the screw. There is an optional outer sleeve that may be used on the Polyaxial Screwdriver. This sleeve allows you to hold the shaft of the Polyaxial Screwdriver for better stabilization without having the polyaxial screw disengage from the Polyaxial Screwdriver. The sleeve can be placed on the Polyaxial Screwdriver by holding in the button while sliding the sleeve over the shaft.

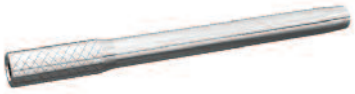
The **Locking Screwdriver** provides another option for screw insertion. The Driver attaches to the screw in the same manner as the standard Polyaxial Screwdriver. However, the Locking Screwdriver can be locked by depressing the tab. Once locked, the Locking Driver assembly becomes monolithic. The screw can only be loosened by rotating the Driver counterclockwise. This instrument helps reduce any risk of accidental disengagement of the Driver from the screw during screw insertion.

Tip: If the tip of a biased angle screw hits the bone before the screw is fully inserted, and the screw is unable to be driven in further, unthread the screwdriver sleeve from the tulip head while leaving the hex socket engaged with the screw to allow the screw head to spin freely and the bone screw to be driven in further.

Note: Ensure the screwdriver sleeve is tightly assembled to the Polyaxial Screwdriver shaft before attempting to attach a screw.

Note: To clean the Polyaxial Screwdriver, remove the sleeve by pressing the button. The holes in the shaft of the Polyaxial Screwdriver are designed to allow flushing of the instrument.

Quick Release Handle
48562012



Tap Sleeve
48561914
48561915

Polyaxial Screwdriver
48562018

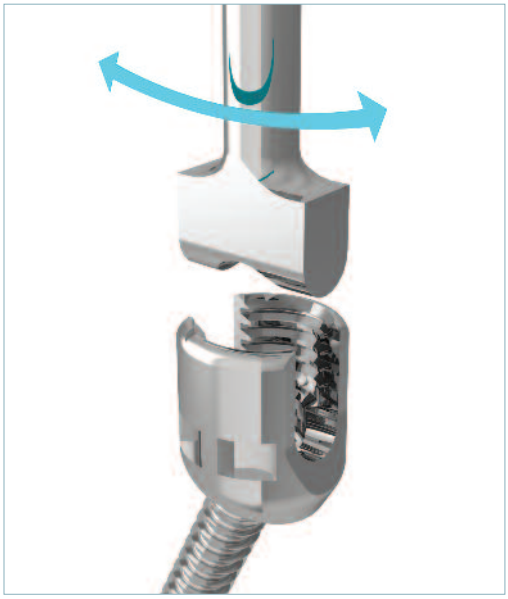
Polyaxial Screwdriver
with optional outer sleeve detached

Locking Screwdriver
48563016

To minimize the potential for rigid locking and limiting the range of angulation, do not seat the screw head too tightly to the bone. Should the screw head become locked to the bone screw, use the **Screw Head Adjuster** to break the lock. If needed, the screw may be backed out about half a turn to allow for the head to move freely.

If it becomes necessary to remove a screw, begin by unthreading the bone screw with the hex portion of the Polyaxial Screwdriver, and then reattach the outer sleeve to complete the removal.

For additional height adjustments to the screw, the **Poly Adjustment Driver** can be used in place of the Polyaxial Screwdriver. This instrument has the same internal hex as the Polyaxial Screwdriver, but has no sleeve to impede vision.



Screw Head Adjuster
48560021

Rod Placement

Once all the bone screws and hooks have been inserted and aligned, a **Rod Template** is available to estimate the required rod length and contour. If the screw heads need to be aligned in a more linear fashion, the Screw Head Adjuster can be used for this purpose. Because of the angle of the biased cut and the corresponding range of angulation of the screw, it is recommended that the notched lines on the screw head face in the direction in which the maximum bone screw angulation is desired (corresponds to the smallest angle between the screw and the rod). All screws should be aligned prior to rod and blocker insertion as further adjustments will become difficult once the construct has been assembled.

Rod Template
48560017

To prepare the **Rod/Plate Cutter** for rod insertion, move the handles into the "open" position as indicated with the laser-marked arrows. Insert the rod into the head of the Rod/Plate Cutter from the side with the laser-marked arrows, and compress the handles as indicated. Since the rod will be cut slightly below the surface of the cutting head, there will be approximately 3mm added to the rod length from the point of insertion. It is

recommended that the rod be cut to the desired length prior to contouring as it may become difficult to cut a rod that has already been bent.

Note: Lubrication of the Rod/Plate Cutter is required to maintain ease of use of the instrument.

Note: If using the Rod/Plate Cutter on a Transition Rod this instrument should only be used on the 3.5mm diameter portion of the rod and not on the larger diameter or transition zone. Please reference the Surgical Technique documents for Xia, Xia 4.5, and SR90D for instructions on how to cut the larger diameter portion of the Transition Rod using the appropriate instrumentation.

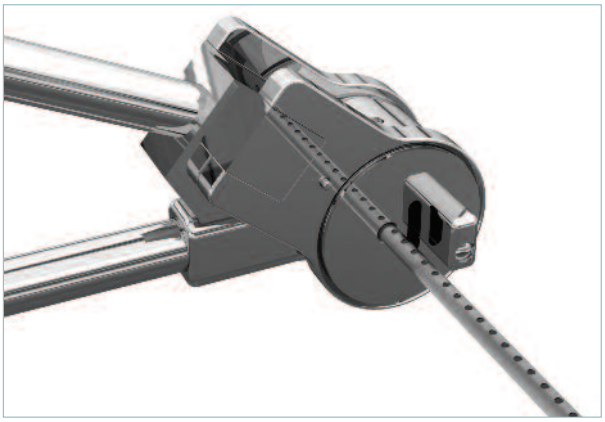
A simple, "pin cutter" style **Small Rod Cutter** is also available to cut the rods. This cutter is for 3.5mm diameter rods only.

Using the **Rod/Plate Bender** (the side with the round bending iron), the rod can be contoured to match the sagittal alignment of the spine as well as the coronal orientation of the screws. Avoid sharp, excessive, or repeated bending of the rod to maintain material integrity. Prior to implantation, inspect the rod for any damage (e.g., notching) it may have sustained during preparation.

If damaged, use new rod. ***In-situ* Benders** are also available for additional contour adjustments.

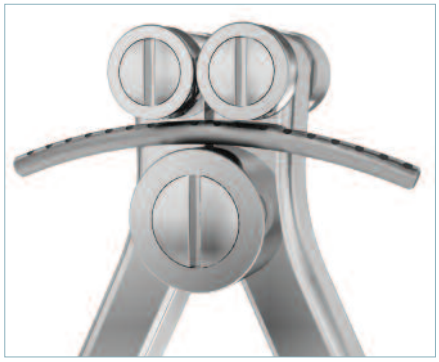
Once the rod has been shaped to its final configuration, introduce the rod into the screw heads using the **Rod Forceps**.

The **Rod Rotation Forceps** allow for minor rod rotation maneuvers. The tips have serrated teeth for better grip on the rod.

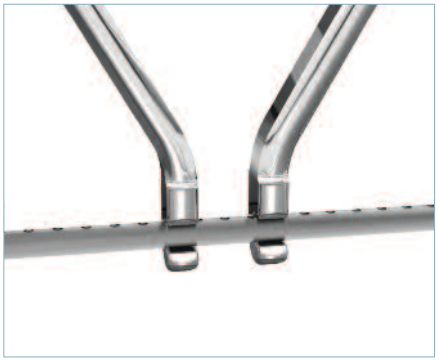


Rod/Plate Cutter
48560018

Small Rod Cutter
48561038



Rod Plate Bender
48560019



***In-situ* Benders**
48560022 - Right
48560023 - Left

Rod Rotation Forceps
48561039

Blocker Insertion

There are six options for insertion and alignment of the Blockers:

1. Corkscrew Persuader and Hexdriver
2. Locking Persuader and Hexdriver
3. Persuader and Hexdriver
4. Insertion Tube and Hexdriver
5. Rod/Blocker Inserter and Hexdriver
6. Hexdriver by itself

To facilitate rod insertion, any of the three types of persuaders may be applied to fully seat the rod into a tulip head. While keeping the persuader aligned with the course of the rod, slide the tip of the instrument over a tulip head to persuade the rod into the tulip head. The shaft of the Persuader is cannulated to allow for the passage of the **Hexdriver** and engagement of the blocker while the Persuader is in place.

Persuader
48560024

Locking Persuader
48561024

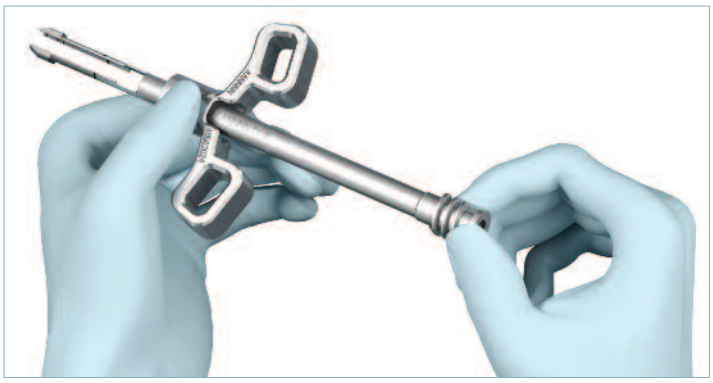
Note: The Persuader, Locking Persuader, and Corkscrew Persuader are not used for spinal correction.

Note: Any Persuader must be properly seated before any application of force.

The **Corkscrew Persuader** has an inner shaft that engages the tulip head of an implant and an outer shaft that reduces a rod upon turning the T-handle. The window at the most distal end of the outer shaft is intended to help allow for visualization of the blocker and Hexdriver while being inserted through the persuader.

Corkscrew Persuader
48562024

To assemble the Corkscrew Persuader, slide the T-handle onto the distal end of the inner shaft until the T-handle meets the threads. Turn the T-handle counterclockwise until it is fully threaded, then slide the Inner Shaft/T-handle assembly into the Outer Shaft while aligning the laser mark lines on the inner and outer shafts until the inner shaft is exposed. The distal tip of the inner shaft will mate with the distal tip of the outer shaft when properly assembled.



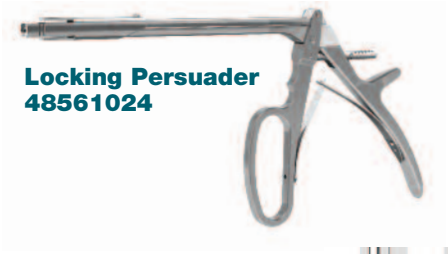
To connect the Corkscrew Persuader to a tulip head, ensure the distal end of the inner shaft is fully exposed by pulling upward on the blue, Stryker-branded handle so that it is meets the T-handle. Keep the blue handle connected to the T-handle while attaching the instrument to the implant tulip head. Once the instrument is fully seated on the tulip head, turn the T-handle clockwise to drive the outer shaft onto the rod until the rod is seated. A laser mark line on the inner shaft will appear within the window

labeled “ROD SEATED” on the outer shaft to confirm that the rod is seated enough to allow for blocker insertion.

Note: The T-handle will freely rotate once the instrument’s maximum amount of persuasion is achieved.

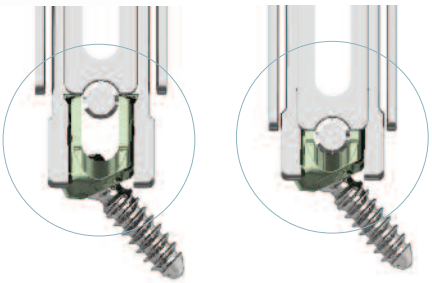
After provisionally tightening the blocker to the tulip head, remove the instrument from the construct by slightly lifting up on the blue handle while turning the T-handle counterclockwise. Continue to turn the T-handle counterclockwise until it stops. Avoid turning the T-handle further once it bottoms out. Keeping the T-handle and blue handle together, simultaneously lift and twist the persuader to disengage the instrument from the construct.

Disassemble the corkscrew persuader by pinching the distal tip of the inner shaft while pulling the inner shaft out of the outer shaft. Unscrew the T-handle from the inner shaft to complete disassembly.



Locking Persuader
48561024

The **Locking Persuader** has two bars that push down on both sides of the rod. It also has a ratcheted trigger design that locks the Locking Persuader arms and allows you to maintain the rod reduction without requiring a tight grip on the trigger. When attaching to the screw head, align the side windows parallel to the rod. To disengage, press the thumb release button, rotate the Locking Persuader slightly to either side, and gently pull it off the screw head.



Persuader seating rod into the tulip head of the screw

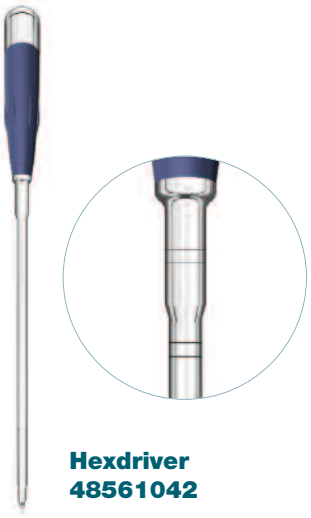
When using the non-locking Persuader, pressure must be maintained on the trigger while the blocker is inserted. To disengage, release the trigger, rotate the Persuader slightly to either side, and gently pull it off the screw head.

Persuader
48560024

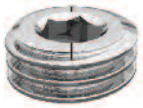
As an alternative to using the Persuader, the cannulated **Insertion Tube/Anti-Torque Key** can be used to push the rod down into the screw head and align the Polyaxial Screwdriver during blocker insertion. A specially designed ring on the inside of the **Insertion Tube** provides an interference fit with a fully inserted Hexdriver to potentially reduce the risk for an accidental disassembly. It is recommended to hold both instruments during their removal from the rod construct.

Insertion Tube/Anti-Torque Key
48562027

Load the blocker firmly onto the tip of the **Hexdriver** and place it into the screw head, using the cannulated instruments as guides or in a free-hand manner. For proper loading onto the Hexdriver, the blockers should be stored in the tray with the laser-marked line facing up. The buttress thread design of the blocker and proper alignment of the Hexdriver minimize the potential for cross-threading.* Turning the blocker counter-clockwise about a quarter turn when first introduced facilitates the insertion into the screw head or hook. When used with the Persuader or with the Insertion Tube, laser markings on the Hexdriver aid in visually assessing the depth of blocker insertion. The lower of the two lines indicates the level at which the blocker engages the screw head; the Hexdriver should be removed when the upper laser marking has been reached.



Hexdriver
48561042



Blocker
48551000

The **Rod/Blocker Inserter** is another option that can insert the rod directly in the tulip head and is cannulated to allow blocker insertion. Place the Inserter over the rod and press down to snap into place. Then grab the desired tulip head with the Inserter. Position the tulip head as desired using the Inserter instrument. Insert the blocker with the Hexdriver through the cannula of the Inserter.

Rod/Blocker Inserter
48562100

Note: The laser markings on the Hexdriver do not correspond with the Rod/Blocker Inserter.

Note: The Hexdriver should be used for blocker insertion and provisional tightening only. Do not perform final tightening with the Hexdriver as it will result in damage to the instrument over time and incorrect final implant torque.

Once all of the blockers have been inserted, the Insertion Tube or the Persuader, in combination with the **Torque Wrench** or **Audible Torque Wrench**, should be used for final tightening. The blocker is completely tightened when the two arrows on the shaft of the Torque Wrench are aligned, which corresponds to 3Nm. The blocker is completely tightened to 3Nm when the Audible Torque Wrench clicks once.

Torque Wrench
48562028

Audible Torque Wrench
48561028

Note: The Audible Torque Wrench must be disposed of after use in surgery. It cannot be sterilized.

Note: It is important to tighten the blocker to the recommended torque to ensure future integrity of the construct. Tightening under or over the torque limit is inadvisable and should be avoided. Appropriate counter-torque must be applied with the Insertion Tube or Persuader.

Compressor
48561026

Distractor
48561041

Should compression of the adjacent instrumented levels be desired prior to final blocker tightening, it can be achieved by placing the **Compressor** over the neighboring screw heads or hooks and using the ratchet mechanism to adjust the amount of compression needed. Similarly, the **Distractor** may be used to achieve distraction of adjacent levels.

*Data on file at Stryker Spine

Transverse Connection

Two options are available for transverse connection to offer additional torsional rigidity for bilateral constructs:

1. Transverse Connectors
2. Cross Connector Plates

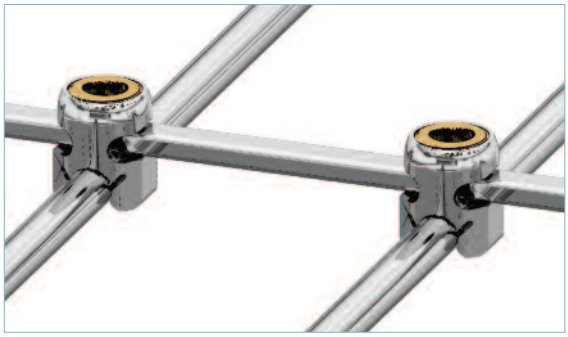
The **Transverse Connector** attaches directly to the rod resulting in a low profile construct. To insert, measure the distance between the rods, cut the connector bar with the Rod/Plate Cutter to the appropriate length (distance between the rods plus 10mm for adequate fit within the connector clip), and pre-load both connector clips onto the connector bar. If the bar is contoured with the Rod/Plate Bender, use the appropriate precautions as described previously.

Note: Usage of the Connector Clip Inserter is strongly recommended to neutralize the forces needed for assembly and prevent damage to implant.

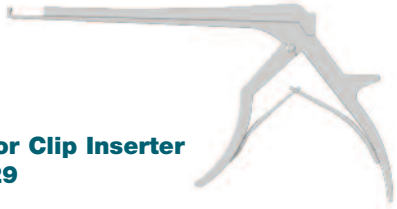
Note: Transverse Connectors and Cross Connector Plates should only be used on the 3.5mm diameter portion of a Transition Rod and not on the larger diameter or transition zone.

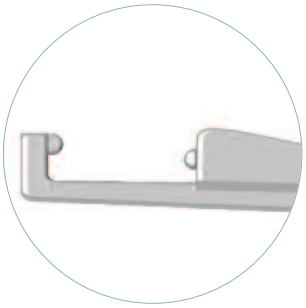
Place the hooked part of the Connector Clip Inserter under the rod, position the connector on the pin protruding from the sliding upper shaft, and snap the clip onto the rod by squeezing the Connector Clip Inserter handle. Repeat the insertion steps for the contra-lateral clip. Check that the connector bar protrudes outside both clips for proper locking. To secure both clips in their final position, the Insertion Tube in combination with the Torque Wrench should be used for final tightening. The recommended torque value is the same as for the blockers: 3Nm.

If the Transverse Connector needs to be removed from the rod construct, remove the set screws from both clips using the Hexdriver and pull out the transverse bar. By advancing the **Connector Clip Remover** into the head of the clip, the clip will be released from the rod.

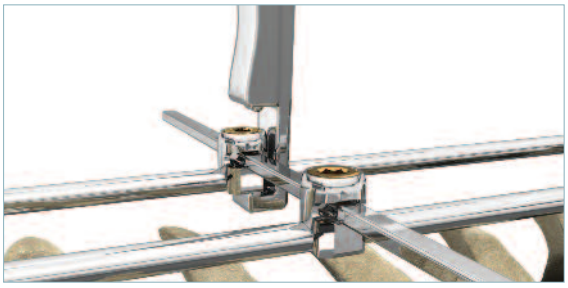


Transverse Connector

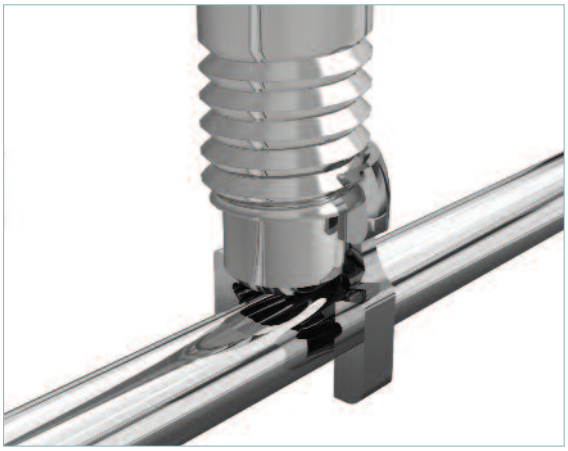




Connector Clip Inserter
48560029



Connector Clip Inserter on bone



Connector Clip Remover
48560129

The **Cross Connector Plate** attaches to the tulip heads to accommodate narrow spaces between the screws. When using this type of connector, you must use a connector plate blocker instead of the standard blocker to tighten the rod to the two screws where you wish to make the transverse connection. A locking nut is then used to tighten the plate onto the identified tulip heads.

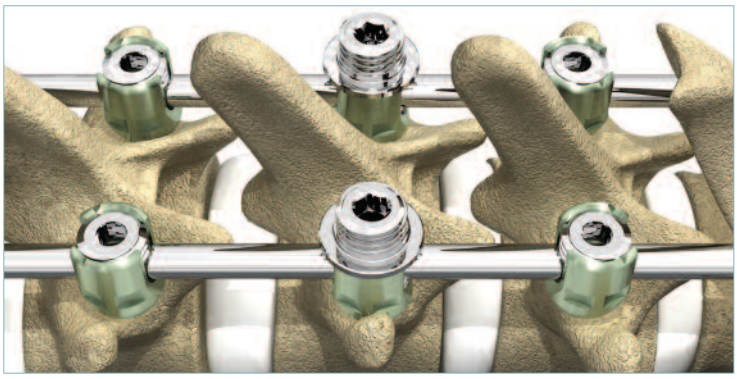
In preparation to place the cross connector, you may choose to remove the preassembled cross connector nuts manually or by using the **Cross Connector Nut Inserter**. The Cross Connector Nut Inserter holds two nuts, one on each end. After the nuts have been removed from the Cross Connector Plate and are being held by the Cross Connector Nut Inserter, place the standard blockers on all screws except where the cross connector will be used. Insert the connector plate blockers onto those tulip heads using the Hexdriver.

Note: The Persuaders do not fit over the connector plate blockers. Thus, if persuasion is needed, the Persuader or Insertion Tube must be attached to the tulip heads of the levels adjacent to the cross connector placement.

Once the rod placement is verified, perform final tightening on all blockers. For final tightening of the connector plate blockers, place the Torque Wrench on the blocker and place the **Anti-Torque Key** on an adjacent level.

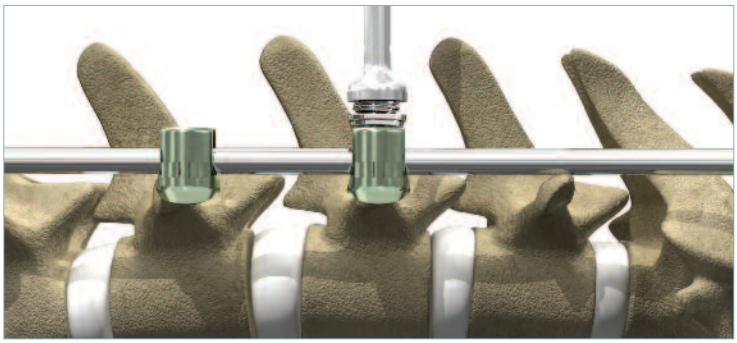
Next, choose the appropriate size Connector Plate (24, 32, or 40mm) by measuring the distance between the rods. The Connector Plate's screw hole is slotted to accommodate up to an additional 10mm of distance between the rods. You can further contour the Connector Plate using the Connector Plate Bender. To bend the Connector Plate, slide one side of the plate fully into the first bender (benders are exactly the same—there is no left or right). Then slide the other side of the plate into the second bender. To straighten the arch, insert the plate with the arch facing down. To increase the bend, insert the plate with the arch facing up. You can also apply a slight twist as needed.

Note: To maximize strength of the construct, it is important that the Connector Plate lay flatly on the blockers. If the Connector Plate does not fit properly, contour the plate using the Connector Plate Benders.

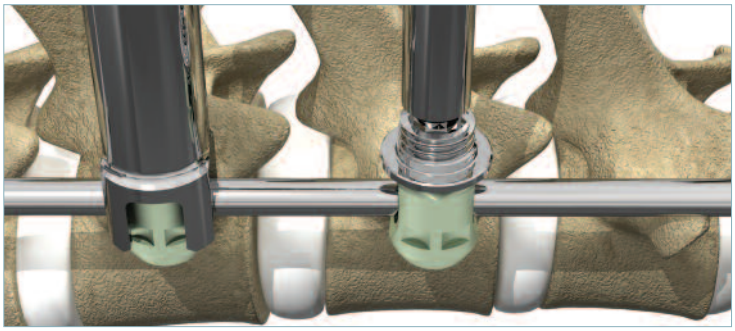


Extended blocker placed onto medial-biased tulip head.

Cross Connector Nut Inserter



Use Cross Connector Nut Inserter to remove preassembled cross connector nuts.



Anti-Torque Key is placed at adjacent level. Final tighten to 3Nm with Torque Wrench.

Bend Cross Connector Plate, if necessary.

Next, lay the Connector Plate on the connector plate blockers; then put the nuts on the plate.

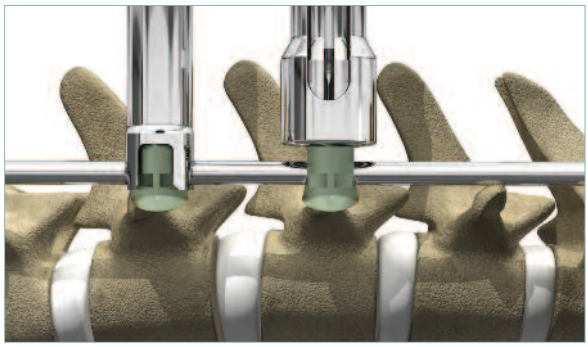
There are two options for inserting the nuts:

1. **Locking Nut Socket** and Torque Wrench

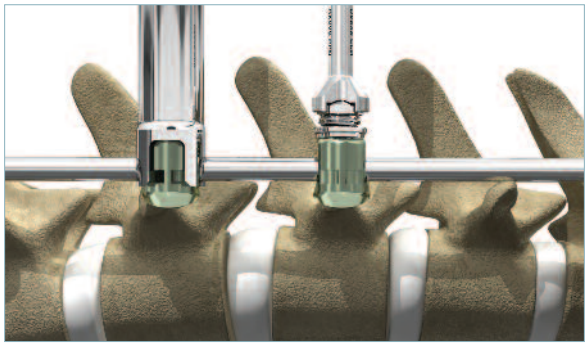
Attach the Locking Nut Socket to the Torque Wrench, and use the assembled instrument to place the locking nut over the Connector Plate. After verifying the correct fit of the Connector Plate, tighten the locking nuts by attaching the Anti-Torque Key to the adjacent tulip head and aligning the Torque Wrench arrows to achieve the 3Nm torque.

2. Cross Connector Nut Inserter, **Cross Connector Nut Tightener** and Torque Wrench

Using the Cross Connector Nut Inserter, seat the nuts on the Cross Connector Plate. Next, attach the Cross Connector Nut Tightener to the Torque Wrench, and use the assembled instrument to final tighten the nuts to 3Nm by attaching the Anti-Torque Key to the adjacent tulip head.



Attach Locking Nut Socket to Torque Wrench.



Attach Cross Connector Nut Tightener to Torque Wrench.

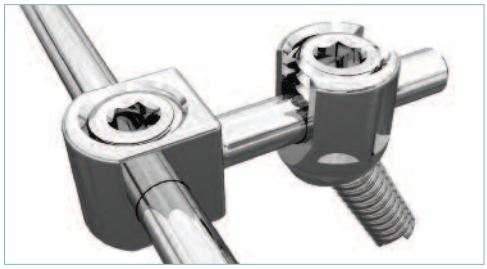
Offset and Rod-to-Rod Connectors

In cases in which the patient's anatomy requires significantly different lateral or medial screw positions, Offset Connectors may be used to facilitate rod attachment.

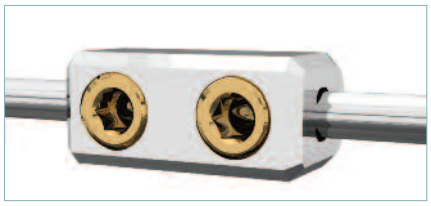
The bar of the **Offset Connector** is available in two sizes: 12mm and 20mm. The 12mm length allows for up to 4mm of offset from the axial alignment, while the 20mm connector will allow for up to 12mm. If desired, the bar can be shortened by using the Rod/Plate Cutter as described previously.

The **Rod-to-Rod Connectors** are available to connect the system to a construct with a 6.0, 5.5, 4.5, or 3.5mm diameter rod. All four sizes are available in a side-to-side and axial version. It is recommended that the Rod-to-Rod Connector be preloaded on the larger rod: Xia or SR90D. Slide the 3.5mm rod into the connector, and then use the Hexdriver to provisionally tighten the connector set screws to secure the assembly in place.

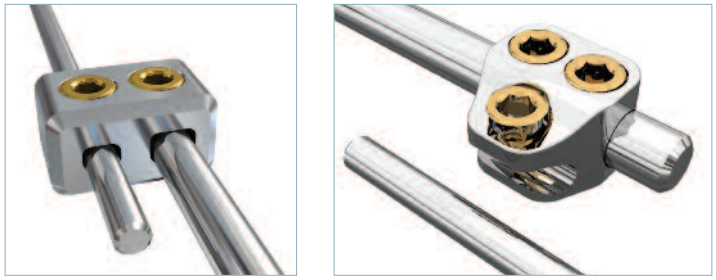
The Torque Wrench must be used for final tightening of all connector set screws. The recommended torque value is the same as for the blockers: 3Nm.



Offset Connector



Axial Connector



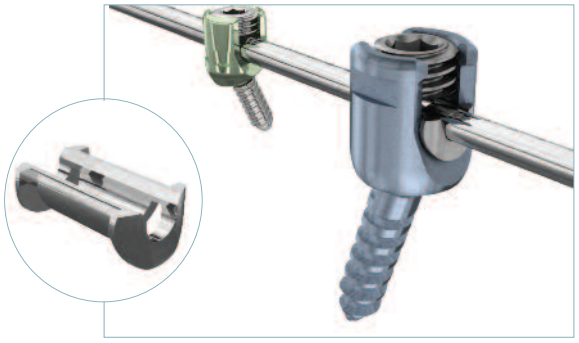
Parallel Rod-to-Rod Connectors

Note: The connector set screws used in the Transverse, Offset, and Rod-to-Rod Connectors are smaller than the blockers used with the Polyaxial Screws, Hooks, and Occiput Plates. Connector set screws and blockers are not interchangeable.

Saddle Connector

The **Saddle Connector** is available to connect the OASYS Occipital-Cervico-Thoracic System to a construct with Xia II or Xia 3 Polyaxial screws.* The Saddle Connector is designed to allow the use of a larger size bone screw in the thoracic area of T1 to T3 per the current OASYS indications.

To use the Saddle Connector, first follow the surgical technique for screw insertion for the Xia II or Xia 3 polyaxial screws and the OASYS surgical technique for placement of OASYS polyaxial screws. Place the OASYS Saddle Connector in the tulip-head of the Xia screw. The Saddle Connector should be facing upwards in a U-shape. Introduce the OASYS rod into the Saddle Connector of the Xia screw and into the adjacent OASYS tulip heads. Fix the rod to the screw using standard Xia blockers in the Xia screw tulip heads and standard OASYS blockers in the OASYS screw tulip heads.



Saddle Connector in Polyaxial Screw

Hook Placement

Lamina preparation and hook size templating is facilitated by using the **Hook Preparer**. The two blades of the Hook Preparer – one on each end – correspond to the short and tall standard hook blades.

Hook Preparer
48560032

Select the appropriate Hook and use the **Hook Forceps** to place it into position.

Hook Forceps
48560033

For rod sizing, contouring, and insertion as well as final construct fixation (i.e., blocker insertion), follow the steps described in the section on Polyaxial Screws above.

*Refer to the Xia Surgical Technique Guide for information on screw insertion and blocker final tightening.

Transition Rod

The OASYS Transition Rod is another option for creating constructs that span the cervico-thoracic junction. Transition Rods allow constructs to be created using the OASYS Occipital-Cervico-Thoracic System and Xia, Xia 4.5, or SR90D systems.

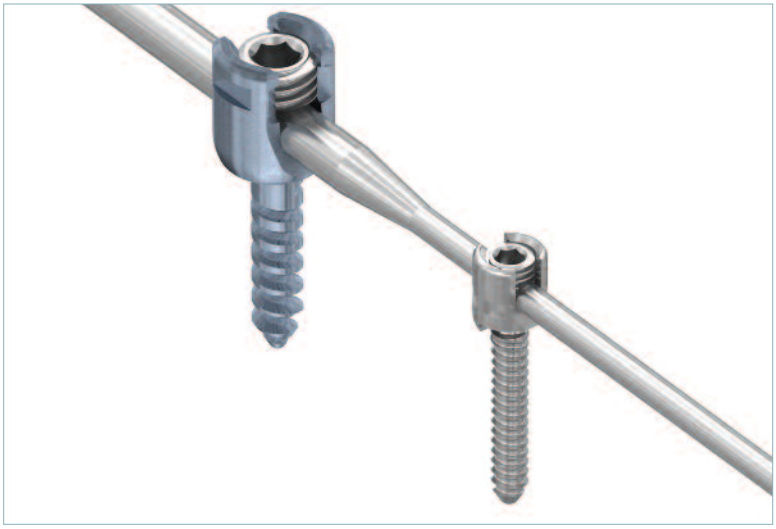
To use the Transition Rod, first follow the Xia, Xia 4.5, or SR90D surgical technique for pedicle screw insertion. Next follow the OASYS surgical technique for hook placement in the cervical spine and/or polyaxial screw placement in the upper thoracic spine. After the cervico-thoracic fixation points have been placed, select the appropriate diameter and material Transition Rod and cut and contour the rod to accommodate the patient's anatomy. To cut the 3.5mm portion of the Transition Rod, use the OASYS Rod/Plate Cutter or Small Rod Cutter. To cut the larger diameter portion of the Transition Rod, use the appropriate rod cutters from the Xia, Xia 4.5 or SR90D systems. To contour the 3.5mm portion of the rod, use the OASYS Rod/Plate Bender. To contour the larger diameter portion of the rod, use the appropriate rod benders from the Xia, Xia 4.5, or SR90D systems.

Align the Transition Rod so that the 3.5mm diameter portion sits in the OASYS tulip heads and the larger diameter (4.5, 5.5, or 6.0mm) portion sits in the Xia, Xia 4.5 or SR90D tulip heads. Follow the OASYS surgical technique for fixation of the 3.5mm portion of the rod using the OASYS blockers and the respective Xia, Xia 4.5, or SR90D surgical techniques for fixation of the larger portion of the rod.

Note: Do not place hooks or screws in the rod's transition zone as this can lead to incomplete fastening of the hooks/screws to the rod.

Note: All OASYS instruments, connectors, hooks, and blockers should be utilized on the 3.5mm portion of the Transition Rod and not on the transition zone or the rod's larger diameter.

Note: The 3.5mm portion of the OASYS Transition Rod is not intended to be used beyond T3.



Transition Rod

Transition Rod Construct *in situ*

Occipital Fixation

Implant Overview

OASYS implants are intended for use as an aid in spine fusion. Use with bone graft is recommended.

Bone Screws

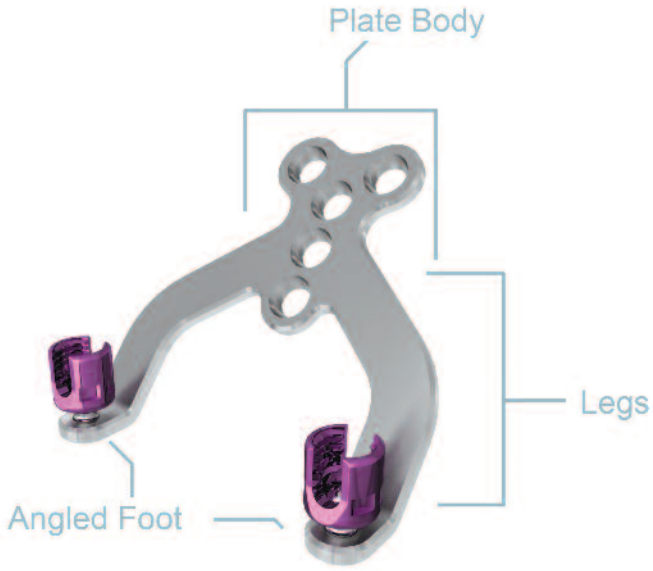
The following bone screws are available for use with the OASYS plates:

Diameter	Lengths (in 2mm increments)	Color	
3.5mm	6 – 16mm	Silver	
4.0mm	6 – 16mm	Blue	
4.5mm	6 – 16mm	Purple	

Midline Occiput Plates

The OASYS system features a Midline Occiput Plate. This single plate allows for positioning directly on the midline keel of the occiput.

The Midline Occiput Plate is uniquely designed to contour to the patient's anatomy to reduce the need or amount of rod-contouring. The plate is available in four standard sizes*: Small, Medium, Large and Large Long. The implant has a plate **body** that attaches to the occiput, two **legs** that extend the plate to the cervical spine and two **feet** that hold the rod-to-plate connection. The four sizes vary in length and width of the plate legs. The body and feet of the plate remain constant.



Midline Occiput Plate

Part #	Description
48551044	Midline Occiput Plate, Small
48551045	Midline Occiput Plate, Medium
48551046	Midline Occiput Plate, Large
48551047	Midline Occiput Plate, Large Long
48551048	Midline Occiput Plate, Mini

Midline Plate

Midline Plate, Mini

* Mini can be specially ordered

Implant Design Features

Plate Body

- Allows five points of fixation to the occiput, three points on the midline*, and two additional points at the superior lateral end
- Can be contoured in the sagittal and coronal planes to adapt to varying occipital anatomy
- Curved shape at the top of the plate is designed to be positioned just beneath the inion, and is constant for all sizes
- Hole configuration is the same for all sizes, allowing for interchangeability if needed.

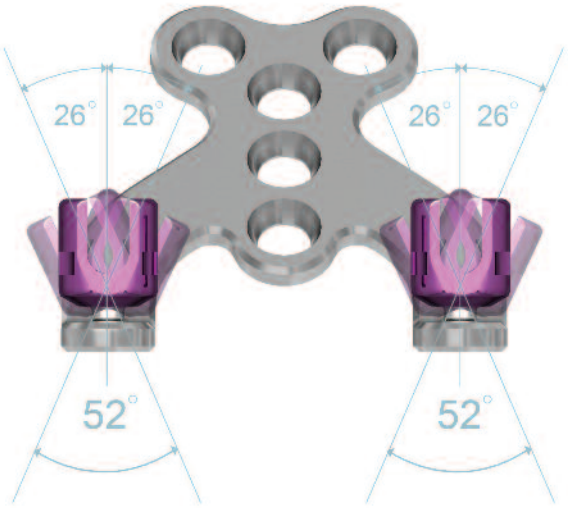


Plate Legs

- Extend the plate to the cervical spine to help reduce rod contouring
- Length and width vary (See Table 1)
- Width of the legs should match the width of the cervical fixation points as best as possible to minimize rod contouring
- Can be contoured in the sagittal and coronal planes to adapt to varying occipital anatomy

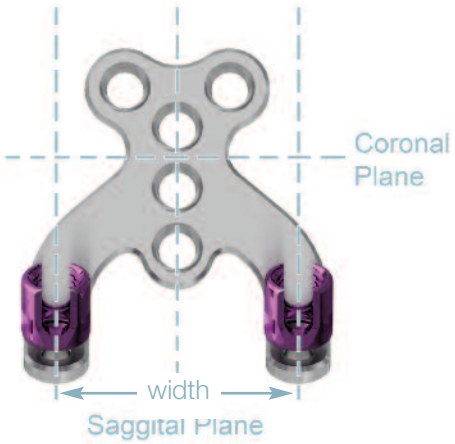
Plate Feet

- Designed to sit above the ring of C1, in line with the cervical fixation points
- Pre-angled at 130° (cannot be contoured further)
- Polyaxial tulip head connects the rod to the plate, and offers 26° of variability in each direction

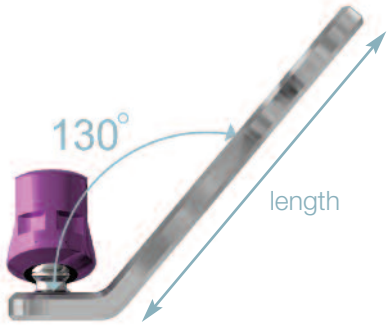
Table 1

Part #	Description	Length	Width	# Holes
48551044	Midline Occiput Plate, Small	37	30	5
48551045	Midline Occiput Plate, Medium	40	38	5
48551046	Midline Occiput Plate, Large	45	43	5
48551047	Midline Occiput Plate, Large Long	49	43	5
48551048	Midline Occiput Plate, Mini*	33	27	4

*Special Order



Width is measured from the center of one polyaxial tulip to the center of the second polyaxial tulip.

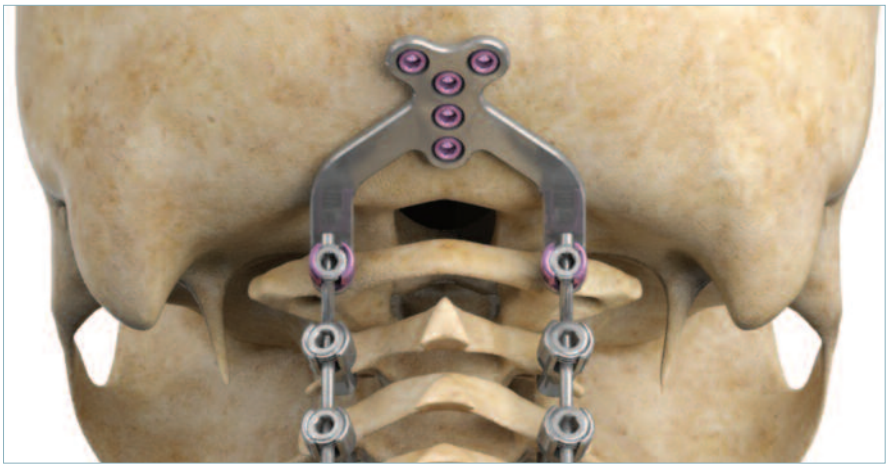


Length is measured from the top of the plate to the base of the foot in the plate.

*The Mini plate offers two points of midline fixation

Midline Occiput Plate Placement

The midline occipital plate is uniquely designed to contour to the patient's anatomy. The base of the plates is pre-bent to 130° and has polyaxial heads designed to optimize the connection to the cervical fixation points. To reduce long moment arms and minimize the stress on the construct, it is recommended to minimize the length between the fixation points on the rod and maximize the number of cervical fixation points. More fixation points allow for better load sharing. Distributing the loads reduces the stress on the individual parts.



1. Select Plate Size

The proper Occiput Plates should be selected allowing application immediately below the level of the inion. Size selection should attempt to minimize the distance between the polyaxial heads of the plate and the cervical fixation point. The pre-angled feet of the plate are designed to sit above the ring of C1.

Note: A short distance between fixation points reduces bending moments thus reducing stress on the fixation points.

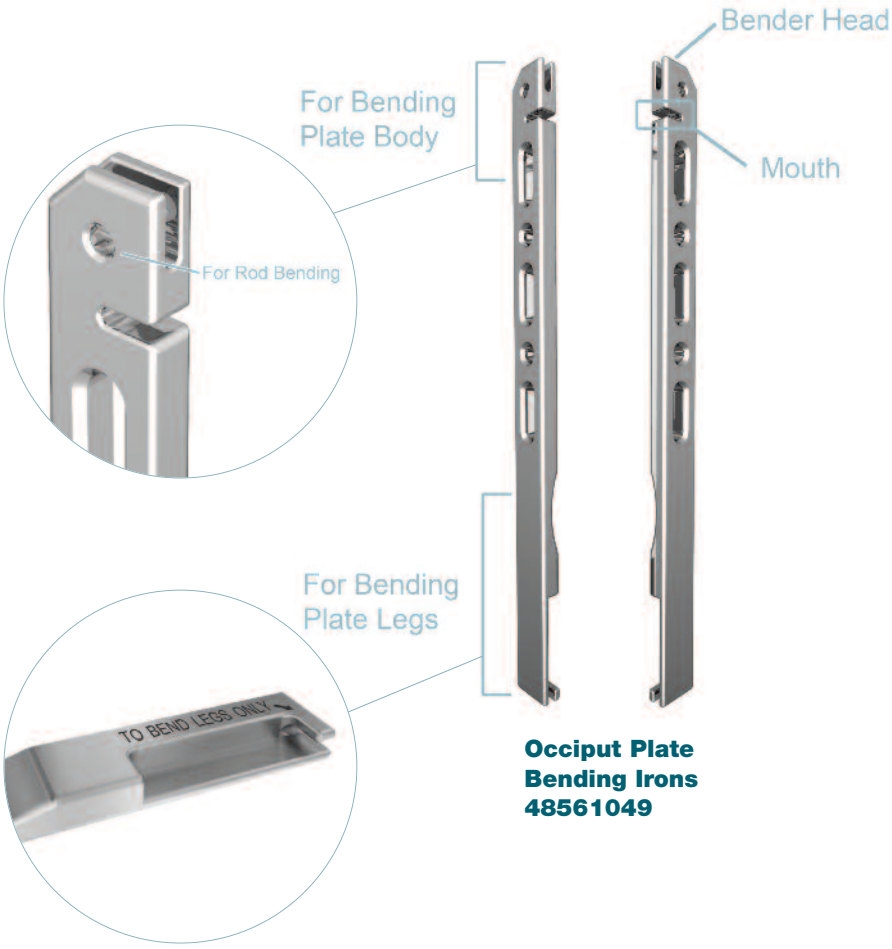
Midline Plate

Midline Plate, Mini

2. Plate Contouring

To contour the Midline Occipital Plate use the **Occiput Plate Bending Irons**. The **Occiput Plate Bending Irons** can be used in a variety of positions. Plates should be contoured to better accommodate the patient's occipital anatomy.

Warning: It is important to avoid excessive plate bending, especially over the midline screw holes.



Occiput Plate Bending Irons 48561049

The midline plate can be bent in both the coronal and sagittal planes.

To contour plate to the patient's occipital anatomy, first bend the **legs** of the plate (Image 1 and 2) in the sagittal plane.

Image 1

Image 2

To bend plate legs, place the **mouth of one bender** over the **superior portion of the plate leg** and the **legs of the bender** over the adjacent leg of the plate. Benders are marked **"TO BEND LEGS ONLY"** (Image 3).

Warning: Do not bend the angled foot of the plate as excessive bends can effect the integrity of the construct and/or damage the polyaxial tulip head.

Image 3

Continue to produce a symmetrical bend on the adjacent side, if necessary (Image 2).

Image 2

To create a **sagittal bend** of the plate body, place the **head of the bender** on the **head of the plate**. Place the **mouth** of the other bender on the **inferior portion of the plate body** (Image 4).

Image 4

To create a **coronal bend**, hold both benders with the **mouth** facing upwards. Benders should align (Image 5) to contour the plate down the midline. Bend of the plate body should align with final contour of the plate legs.

Image 5

Tip: Holding the far ends of the bending iron helps to contour the plate appropriately.

It is important to avoid point bending (Image 6) as excessive bending can damage the plate resulting in plate breakage.

Warning: Do not repeatedly bend the plate. Care should be taken to not make extreme bends so as to avoid stress concentrations on the plate.

Image 6

Plate Placement

Use the **Plate Holder** to hold plate in position below the level of the inion with the polyaxial heads of the plate above the ring of C1 in line with the cervical fixation points. With the Plate Holder in place, implant the bone screws.

Plate Holder
48510300

Plate Holder on bone

Screw Placement

a) Use the **Awl** to penetrate the cortex and mark the bone screw entry point.

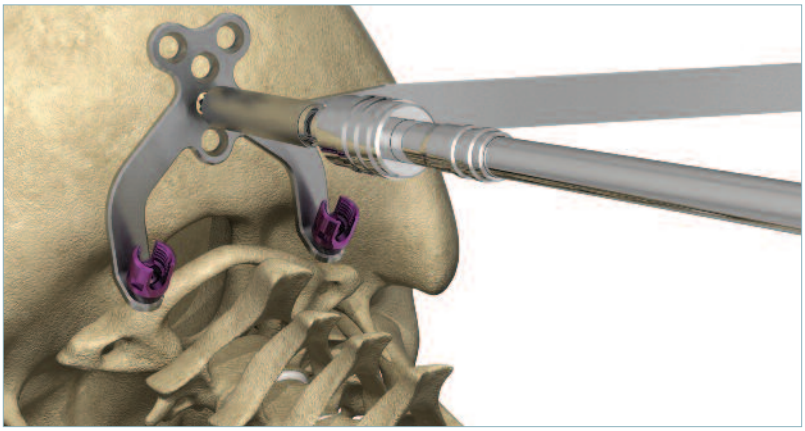
b) **Drill** depth should be determined based on approximating the thickness of the occiput from preoperative imaging and based on the anatomy. Drilling should be performed through the Occiput Plate using the appropriate Drill Guide. Two-sided Occiput Fixed Drill Guides are available in depths of 6 & 8mm, 10 & 12mm, 14 & 16mm and can be used with all diameter screws.

Awl
48562010

Occiput Fixed Drill Guide

Part #	Description
48561044	Occiput Fixed Drill Guide, 6 & 8mm
48561045	Occiput Fixed Drill Guide, 10 & 12mm
48561046	Occiput Fixed Drill Guide, 14 & 16mm

Note: It is recommended to Drill as close to full thickness into the occiput as can be safely performed. Drill depth should be determined based on approximating the thickness of the occiput from preoperative imaging and based on patient anatomy. Drilling should be performed through the Occiput Plate with the Drill Guide set.



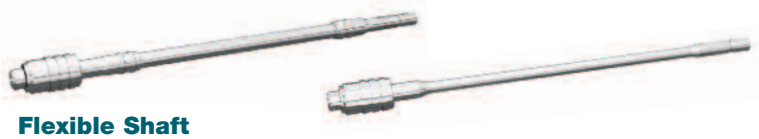
The Occiput Drill Bits are available in three diameters and are color-coded to match the corresponding screw diameters:

- 2.5mm Drill for 3.5mm Screw
- 3.0mm Drill for 4.0mm Screw
- 3.5mm Drill for 4.5mm Screw

Screw Diameter	Corresponding Drill	Corresponding Tap
3.5mm **485543(06-16)*** 	**2.5mm Drill** **48565323** 	**Occiput Set Tap, 3.5mm** **48561053** 
4.0mm **485544(06-16)*** 	**3.0mm Drill** **48565423** 	**Occiput Set Tap, 4.0mm** **48561054** 
4.5mm **485545(06-16)*** 	**3.5mm Drill** **48565523** 	**Occiput Set Tap, 4.5mm** **48561055** 

***2mm increments**

Drill Bits can be attached to the **Short Quick Release Handle** for manual drilling. Alternatively, you can attach the Drill Bits to a power drill using either the **Flexible Shaft** or the **Straight Shaft.**



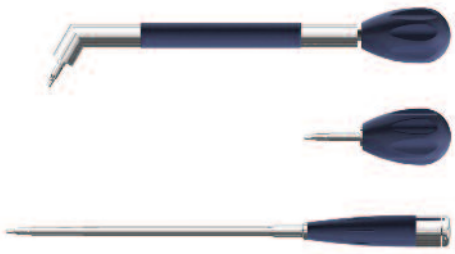
Flexible Shaft
48561051

Straight Shaft
48561056

Warning: Be sure to use the corresponding Drill and Tap. Using a smaller diameter Drill can result in Tap breakage. Tapping in a hole too small can result in a sheared tap.

c) Attach the appropriate sized **Occiput Set Tap** (color-coded to match the screw diameter) to the Short Quick Release Handle, and be sure to tap the entire length of the hole. Measure the length tapped to ensure appropriate screw length.

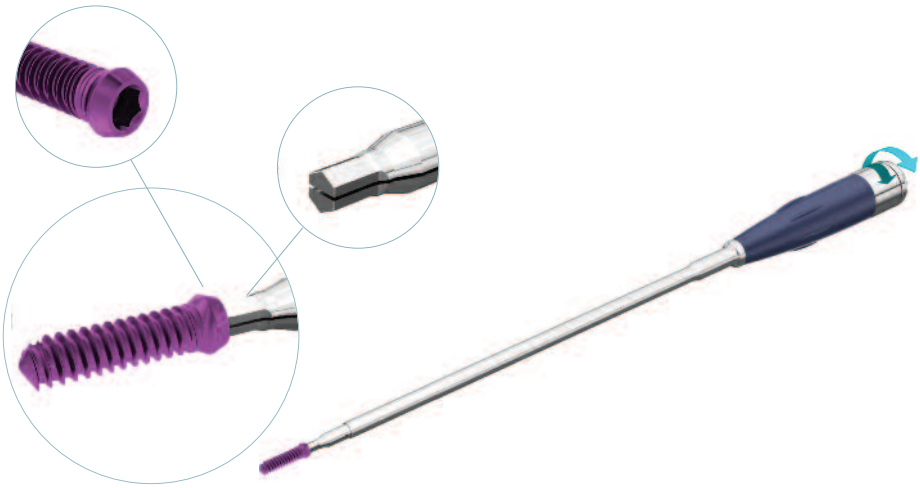
d) Insert the bone screw using the **Short Driver**, **Angled Driver** or the **Hexdriver**. No matter which driver is used to initially insert the bone screw, it is recommended that the Short Driver be used for final tightening. Three or more of screws should be used.



Angled Driver
48561043

Short Driver
48561050

Hexdriver
48561042

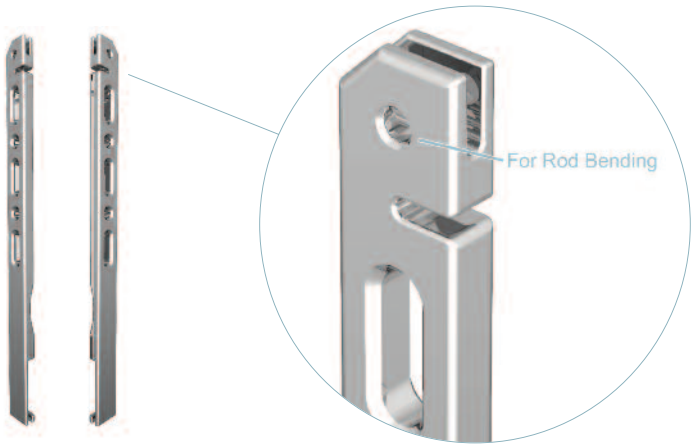


3. Contour Rod

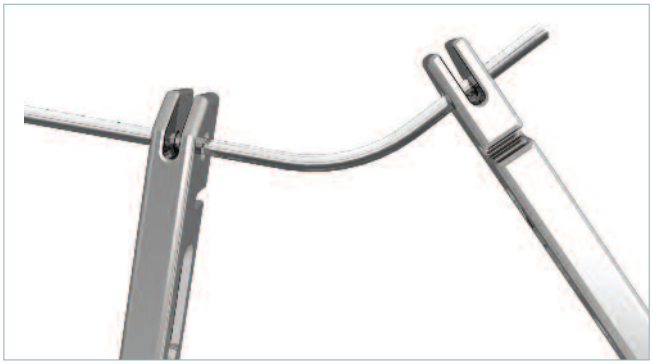
Contour the rod as required, using the Rod/Plate Bender. For a more acute angle, you may also bend the rods using the small holes of the Occiput Plate Bending Irons.

Note: If bending the larger diameter portion of a Transition Rod please refer to Surgical Technique documentation for Xia, Xia 4.5, and/or SR90D for appropriate instrument usage instructions.

Note: It is important to contour the rod to the curvature of the spine. Failure to do so could result in excessive loading of the construct.



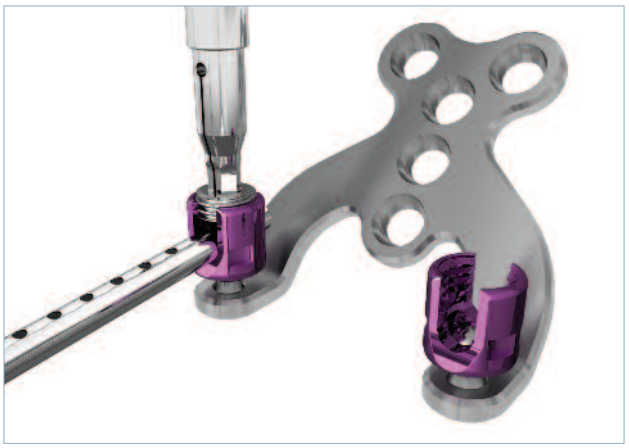
Occiput Plate Bending Irons
48561049



Lay the rod into the tulip heads of the Occiput Plate and the cervical fixation points. The rod is fixed to the Occiput Plate with the standard blocker. Insert the blockers with the Hexdriver, utilizing the Persuader and/or Insertion Tube as necessary. Final tighten all blockers on the cervical fixation points to 3Nm. The Rod must extend through the polyaxial head but should not touch the plate legs for proper fixation.

Use the Anti-Torque Key and Torque Wrench or Audible Torque Wrench on the polyaxial heads. The standard blocker, which should be tightened by the Torque Wrench to 3Nm, is used to secure the plate-to-rod assembly.

Note: Crosslinks are recommended to be placed close to the plate/rod fixation points to increase construct stability and stiffness.



Hexdriver inserts blocker into polyaxial tulip.

Final tighten blocker to 3Nm.

Bilateral Occiput Plate Placement

The OASYS system also features bilateral plates that can be contoured as required to the patient's anatomy. Both straight and pre-contoured Occiput Plates are available in 100° and 130° foot angles.

The Occiput Plates feature four round anchor holes and one slot, as well as a foot, which connects the plates into a rod construct in the cervical spine. The angle minimizes the amount of rod contouring necessary in the sagittal plane to fit the implants.

Bilateral Occiput Plates

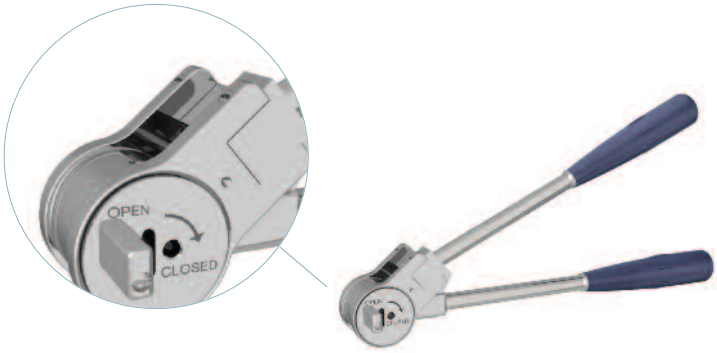
Part #	Description
48551040	130º Occiput Plate
48551041L	130º Pre-contoured Occiput Plate, Left
48551041R	130º Pre-contoured Occiput Plate, Right
48551042	100º Occiput Plate
48551043L	100º Pre-contoured Occiput Plate, Left
48551043R	100º Pre-contoured Occiput Plate, Right

Both the 100° and 130° plates are offered in a "left" and "right" pre-contoured version. The plates have approximately a 30° radius, and cannot be contoured further in the frontal plane using the Rod/Plate Bender.

Note: The pre-contoured Bilateral Occiput Plates cannot be cut.

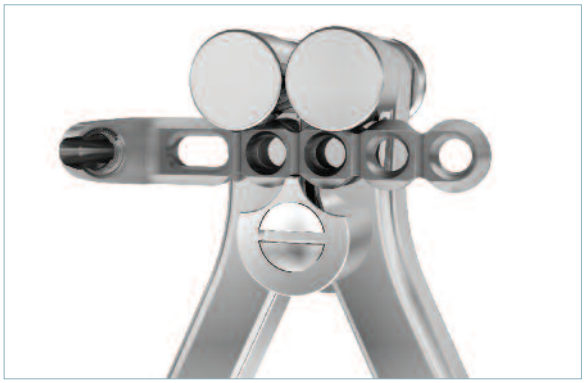
To prepare the Rod/Plate Cutter for Straight Occiput Plate insertion, move the handles into the "open" position as indicated with the laser-marked arrows. Insert the plate into the slot in the head of the Rod/Plate Cutter from the side that contains the laser marking (arrow), and position it so that the bending groove between holes lines up with the end of the small gauge block situated above the insertion slot. This position allows the plate to be cut through the area between holes. Compress the handles as indicated by the arrow to shorten the plate.

Note: If plate is overcontoured in lateral direction, replace with new implant.



Rod/Plate Cutter 48560018

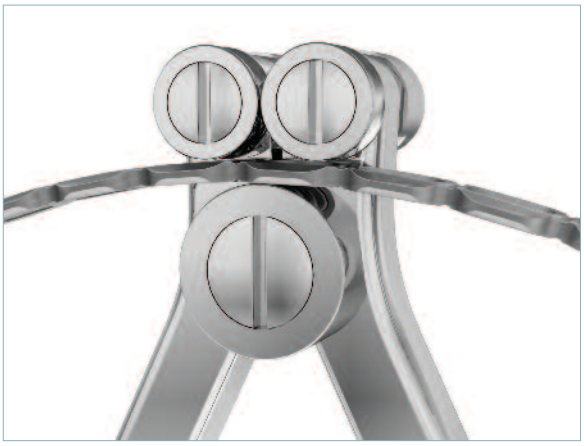
Using the **Bilateral Occiput Plate Bend Template**, determine the desired position and contour of the implant. The side of the Rod/Plate Bender without the round bending iron is used to bend the plate in the frontal plane. Slide the plate in the undercut portion of the top bending arms and position the bending tip between the plate holes. Once bent in the frontal plane, the plate should never be reverted to its original shape as it would compromise its strength.



Rod/Plate Bender
48560019

The opposite side of the Rod/Plate Bender with the round bending iron is used to bend the plate in the sagittal plane. It is recommended that the plate be bent gradually from both sides and to avoid excessive contouring, which may compromise the plate material integrity. Bending the plate in the area between the screw holes minimizes deformation of the screw holes and allows proper screw fit.

Note: The plate should always be bent in the frontal plane first. The plate should not be contoured more than 8° per segment. If plate is damaged or overbent, replace implant.



Sagittal bending with Rod/Plate Bender

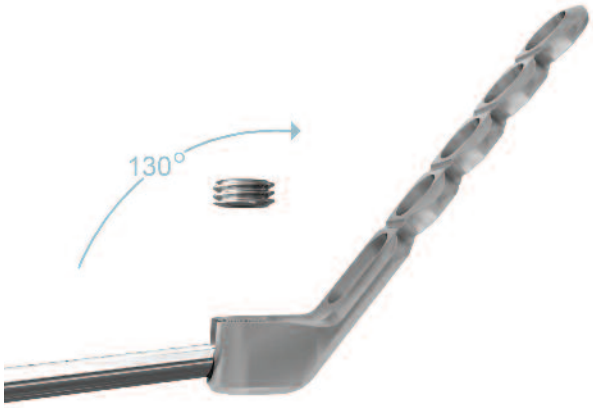
When the plate has been contoured to its desired shape and placed in position with the Plate Holder, use it as a guide to mark the entry points for the pilot holes with the Awl. As an alternative, the blue plate template can also be used for this purpose. Proceed with drilling the holes, using the Drill Guide and the appropriate size Drill (3.5, 4.0 or 4.5mm, depending on the diameter of the screw to be used). Drill depth should be determined based on approximating the thickness of the occiput from preoperative imaging and based on the anatomy. Drilling should be performed through the Occiput Plate with the Drill Guide set to the appropriate length. The hole should then be tapped.

Plate Holder and Awl

To connect the Occiput Plate to a cervical construct, it is recommended that the plate be pre-assembled onto the rod prior to implanting the plate. The standard blocker, which should be tightened by the Torque Wrench to 3Nm, is used to secure the plate-to-rod assembly. Connect the plate to the rod prior to putting in the bone screws.

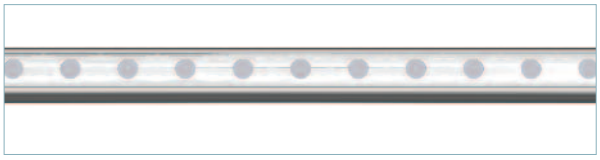
Position the final plate implant, and insert and final tighten the occiput bone screws with the Angled Driver, Hexdriver or Short Driver.

Insert blocker into plate with Hexdriver



For increased stiffness and strength, an added Vitallium rod option is available.

Part #	Description
48553080	3.5mm x 80mm Vitallium Rod
48553120	3.5mm x 120mm Vitallium Rod
48553240	3.5mm x 240mm Vitallium Rod
48553350	3.5mm x 350mm Vitallium Rod



Vitallium Rod

Note: For increased construct strength, at least two bone screws should be placed in any of the four anchor holes. A bone screw should also be inserted into the slot at the base of the plate for a total of at least three screws in each plate. Crosslinks are recommended to increase construct stability and stiffness.

Implants

Part #	Description
Biased Angle Screws	
48552310	3.5mm x 10mm Biased Angle Screw
48552312	3.5mm x 12mm Biased Angle Screw
48552314	3.5mm x 14mm Biased Angle Screw
48552316	3.5mm x 16mm Biased Angle Screw
48552318	3.5mm x 18mm Biased Angle Screw
48552320	3.5mm x 20mm Biased Angle Screw
48552322	3.5mm x 22mm Biased Angle Screw
48552324	3.5mm x 24mm Biased Angle Screw
48552326	3.5mm x 26mm Biased Angle Screw
48552328	3.5mm x 28mm Biased Angle Screw
48552330	3.5mm x 30mm Biased Angle Screw
48552332	3.5mm x 32mm Biased Angle Screw
48552334	3.5mm x 34mm Biased Angle Screw
48552336	3.5mm x 36mm Biased Angle Screw
48552338	3.5mm x 38mm Biased Angle Screw
48552340	3.5mm x 40mm Biased Angle Screw
48552342	3.5mm x 42mm Biased Angle Screw
48552344	3.5mm x 44mm Biased Angle Screw
48552348	3.5mm x 48mm Biased Angle Screw
48552350	3.5mm x 50mm Biased Angle Screw
48552352	3.5mm x 52mm Biased Angle Screw
48552354	3.5mm x 54mm Biased Angle Screw

48552410	4.0mm x 10mm Biased Angle Screw
48552412	4.0mm x 12mm Biased Angle Screw
48552414	4.0mm x 14mm Biased Angle Screw
48552416	4.0mm x 16mm Biased Angle Screw
48552418	4.0mm x 18mm Biased Angle Screw
48552420	4.0mm x 20mm Biased Angle Screw
48552422	4.0mm x 22mm Biased Angle Screw
48552424	4.0mm x 24mm Biased Angle Screw
48552426	4.0mm x 26mm Biased Angle Screw
48552428	4.0mm x 28mm Biased Angle Screw
48552430	4.0mm x 30mm Biased Angle Screw
48552432	4.0mm x 32mm Biased Angle Screw
48552434	4.0mm x 34mm Biased Angle Screw
48552436	4.0mm x 36mm Biased Angle Screw
48552438	4.0mm x 38mm Biased Angle Screw
48552440	4.0mm x 40mm Biased Angle Screw
48552442	4.0mm x 42mm Biased Angle Screw
48552446	4.0mm x 46mm Biased Angle Screw
48552448	4.0mm x 48mm Biased Angle Screw
48552450	4.0mm x 50mm Biased Angle Screw

Part #	Description
Medial Biased Angle Screws	
48555320	3.5mm x 20mm Medial Biased Angle Screw
48555322	3.5mm x 22mm Medial Biased Angle Screw
48555324	3.5mm x 24mm Medial Biased Angle Screw
48555328	3.5mm x 28mm Medial Biased Angle Screw
48555332	3.5mm x 32mm Medial Biased Angle Screw
48555336	3.5mm x 36mm Medial Biased Angle Screw
48555340	3.5mm x 40mm Medial Biased Angle Screw

48555420	4.0mm x 20mm Medial Biased Angle Screw
48555422	4.0mm x 22mm Medial Biased Angle Screw
48555424	4.0mm x 24mm Medial Biased Angle Screw
48555428	4.0mm x 28mm Medial Biased Angle Screw
48555432	4.0mm x 32mm Medial Biased Angle Screw
48555436	4.0mm x 36mm Medial Biased Angle Screw
48555440	4.0mm x 40mm Medial Biased Angle Screw
48555444	4.0mm x 44mm Medial Biased Angle Screw
48555448	4.0mm x 48mm Medial Biased Angle Screw
48555452	4.0mm x 52mm Medial Biased Angle Screw

Smooth Shank Biased Angle Screws	
48556322	3.5mm x 22mm Smooth Shank Biased Angle Screw
48556324	3.5mm x 24mm Smooth Shank Biased Angle Screw
48556326	3.5mm x 26mm Smooth Shank Biased Angle Screw
48556328	3.5mm x 28mm Smooth Shank Biased Angle Screw
48556330	3.5mm x 30mm Smooth Shank Biased Angle Screw
48556332	3.5mm x 32mm Smooth Shank Biased Angle Screw
48556334	3.5mm x 34mm Smooth Shank Biased Angle Screw
48556336	3.5mm x 36mm Smooth Shank Biased Angle Screw
48556338	3.5mm x 38mm Smooth Shank Biased Angle Screw
48556340	3.5mm x 40mm Smooth Shank Biased Angle Screw

Cancellous Biased Angle Screws	
48557310	3.5mm x 10mm Cancellous Biased Angle Screw
48557312	3.5mm x 12mm Cancellous Biased Angle Screw
48557314	3.5mm x 14mm Cancellous Biased Angle Screw
48557316	3.5mm x 16mm Cancellous Biased Angle Screw
48557318	3.5mm x 18mm Cancellous Biased Angle Screw
48557320	3.5mm x 20mm Cancellous Biased Angle Screw
48557322	3.5mm x 22mm Cancellous Biased Angle Screw
48557324	3.5mm x 24mm Cancellous Biased Angle Screw

48557410	4.0mm x 10mm Cancellous Biased Angle Screw
48557412	4.0mm x 12mm Cancellous Biased Angle Screw
48557414	4.0mm x 14mm Cancellous Biased Angle Screw
48557416	4.0mm x 16mm Cancellous Biased Angle Screw
48557418	4.0mm x 18mm Cancellous Biased Angle Screw
48557420	4.0mm x 20mm Cancellous Biased Angle Screw
48557422	4.0mm x 22mm Cancellous Biased Angle Screw
48557424	4.0mm x 24mm Cancellous Biased Angle Screw

Part #	Description
Non-Biased Angle Polyaxial Screws	
 48558310	3.5mm x 10mm Non-Biased Angle Screw
48558312	3.5mm x 12mm Non-Biased Angle Screw
48558314	3.5mm x 14mm Non-Biased Angle Screw
48558316	3.5mm x 16mm Non-Biased Angle Screw
48558318	3.5mm x 18mm Non-Biased Angle Screw
48558320	3.5mm x 20mm Non-Biased Angle Screw
 48558410	4.0mm x 10mm Non-Biased Angle Screw
48558412	4.0mm x 12mm Non-Biased Angle Screw
48558414	4.0mm x 14mm Non-Biased Angle Screw
48558416	4.0mm x 16mm Non-Biased Angle Screw
48558418	4.0mm x 18mm Non-Biased Angle Screw
48558420	4.0mm x 20mm Non-Biased Angle Screw
 48558520	4.5mm x 20mm Non-Biased Angle Screw
48558524	4.5mm x 24mm Non-Biased Angle Screw
48558528	4.5mm x 28mm Non-Biased Angle Screw
48558532	4.5mm x 32mm Non-Biased Angle Screw
48558536	4.5mm x 36mm Non-Biased Angle Screw
48558540	4.5mm x 40mm Non-Biased Angle Screw
48558544	4.5mm x 44mm Non-Biased Angle Screw
48558548	4.5mm x 48mm Non-Biased Angle Screw
48558552	4.5mm x 52mm Non-Biased Angle Screw

Rods

 48553080	3.5mm x 80mm Vitallium Rod
48553120	3.5mm x 120mm Vitallium Rod
48553240	3.5mm x 240mm Vitallium Rod
48553350	3.5mm x 350mm Vitallium Rod
48552025	3.5mm x 25mm Titanium Alloy Rod
48552030	3.5mm x 30mm Titanium Alloy Rod
48552040	3.5mm x 40mm Titanium Alloy Rod
48552050	3.5mm x 50mm Titanium Alloy Rod
48552060	3.5mm x 60mm Titanium Alloy Rod
48552070	3.5mm x 70mm Titanium Alloy Rod
48552080	3.5mm x 80mm Titanium Alloy Rod
48552120	3.5mm x 120mm Titanium Alloy Rod
48552240	3.5mm x 240mm Titanium Alloy Rod
48551240	3.5mm x 240mm Titanium Rod, CP
48551350	3.5mm x 350mm Titanium Alloy Rod

Part #	Description
Connectors	
 48551070	Transverse Connector, 80mm
48551071	Transverse Connector, 60mm
48551072	Transverse Connector, 40mm
 48551073	Cross Connector Plate, 24mm
48551074	Cross Connector Plate, 32mm
48551075	Cross Connector Plate, 40mm
 48551080	Offset Connector, 20mm
48551081	Offset Connector, 12mm
 48551085	3.5mm to 3.5mm Axial Connector
48551084	3.5mm to 4.5mm Axial Connector
48551086	3.5mm to 5.5mm Axial Connector
48551087	3.5mm to 6.0mm Axial Connector
 48551088	3.5mm to 3.5mm Parallel Rod-to-Rod Connector
48551091	3.5mm to 4.5mm Parallel Rod-to-Rod Connector
 48551089	3.5mm to 5.5mm Parallel Rod-to-Rod Connector
48551090	3.5mm to 6.0mm Parallel Rod-to-Rod Connector
 48551094	Saddle Connector
 48551000	Blocker
 48551006	Set Screw

Transition Rods

 48553600	3.5mm-4.5mm Titanium Alloy Transition Rod
48553602	3.5mm-4.5mm Vitallium Transition Rod
48553604	3.5mm-5.5mm Titanium Alloy Transition Rod
48553606	3.5mm-5.5mm Vitallium Transition Rod
48553608	3.5mm-6.0mm Titanium Alloy Transition Rod
48553610	3.5mm-6.0mm Vitallium Transition Rod

**Special Order Only*

 48553800	3.5mm-4.5mm Titanium Transition Rod 800mm
48553804	3.5mm-5.5mm Titanium Transition Rod 800mm
48553808	3.5mm-6.0mm Titanium Transition Rod 800mm
48553802	3.5mm-4.5mm Vitallium Transition Rod 800mm
48553806	3.5mm-5.5mm Vitallium Transition Rod 800mm
48553810	3.5mm-6.0mm Vitallium Transition Rod 800mm
 48553820	3.5mm-4.5mm Titanium Transition Rod 860mm
48553824	3.5mm-5.5mm Titanium Transition Rod 860mm
48553828	3.5mm-6.0mm Titanium Transition Rod 860mm
48553822	3.5mm-4.5mm Vitallium Transition Rod 860mm
48553826	3.5mm-5.5mm Vitallium Transition Rod 860mm
48553830	3.5mm-6.0mm Vitallium Transition Rod 860mm

Bone Screws

Part #	Description
48554306	3.5mm x 6mm Bone Screw
48554308	3.5mm x 8mm Bone Screw
48554310	3.5mm x 10mm Bone Screw
48554312	3.5mm x 12mm Bone Screw
48554314	3.5mm x 14mm Bone Screw
48554316	3.5mm x 16mm Bone Screw
48554406	4.0mm x 6mm Bone Screw
48554408	4.0mm x 8mm Bone Screw
48554410	4.0mm x 10mm Bone Screw
48554412	4.0mm x 12mm Bone Screw
48554414	4.0mm x 14mm Bone Screw
48554416	4.0mm x 16mm Bone Screw
48554506	4.5 x 6mm Bone Screw
48554508	4.5 x 8mm Bone Screw
48554510	4.5 x 10mm Bone Screw
48554512	4.5 x 12mm Bone Screw
48554514	4.5 x 14mm Bone Screw
48554516	4.5 x 16mm Bone Screw

Hooks

Part #	Description
48551049	Hook, Standard, 3.5mm
48551050	Hook, Standard Short, 5.0mm
48551053	Hook, Standard, 6.5mm
48551055	Hook, Standard Tall, 8.0mm
48551060	Hook, Offset Right
48551065	Hook, Offset Left

Occiput Fixation

48551044	Midline Occiput Plate, Small
48551045	Midline Occiput Plate, Medium
48551046	Midline Occiput Plate, Large
48551047	Midline Occiput Plate, Large Long
48551048	Midline Occiput Plate, Mini
48551040	130º Occiput Plate
48551041L	130º Pre-contoured Occiput Plate, Left
48551041R	130º Pre-contoured Occiput Plate, Right
48551042	100º Occiput Plate
48551043L	100º Pre-contoured Occiput Plate, Left
48551043R	100º Pre-contoured Occiput Plate, Right

Instruments

	Part #	Description
	Trays	
	48562000	Standard Implant Container
	48562001	Standard Instrument Container
	48562002	Auxiliary Instrument Container
	48562000H	Modular Screw Caddy
	48560002	Rod Cutter Tray
	48561004	Container 4, Occiput Fixation Tray
	Instruments	
	48560010	Awl
	48562010	Awl
	48561011	Adjustable Drill Guide
	48562011	Adjustable Drill Guide
	48561034	Fixed Drill Guide, 12mm
	48562034	Fixed Drill Guide, 12mm
	48561035	Fixed Drill Guide, 14mm
	48562035	Fixed Drill Guide, 14mm
	48560012	Quick Release Handle
	48562012	Quick Release Handle

	Part #	Description
	48561052	Short Quick Release Handle
	48561051	Flexible Shaft
	48561056	Straight Shaft
	48560323	2.5mm Drill for 3.5mm Screw
	48560423	3.0mm Drill for 4.0 & 4.5mm Screws
	48565323	2.5mm Drill for 3.5mm Bone Screw
	48565423	3.0mm Drill for 4.0mm Bone Screw
	48565523	3.5mm Drill for 4.5mm Bone Screw
	48561044	Occiput Fixed Drill Guide, 6 & 8mm
	48561045	Occiput Fixed Drill Guide, 10 & 12mm
	48561046	Occiput Fixed Drill Guide, 14 & 16mm
	48561314	3.5mm Tap, 18mm
	48561414	4.0mm Tap, 18mm
	48560314	3.5mm Tap
	48560414	4.0mm Tap
	48560514	4.5mm Tap
	48561916	3.5mm Cancellous Tap
	48561917	4.0mm Cancellous Tap

	Part #	Description
	48561914	Tap Sleeve, 3.5 & 4.0mm
	48561915	Tap Sleeve, 4.5mm
	48561053	Occiput Set Tap, 3.5mm
	48561054	Occiput Set Tap, 4.0mm
	48561055	Occiput Set Tap, 4.5mm
	48560015	Depth Gauge
	48561036	Ball Tip Probe
	48561115	Pedicle Probe, 3.5mm
	48562115	Pedicle Probe, 4.5mm
	48562118	Pedicle Probe
	48562016	Polyaxial Screwdriver
	48562018	Polyaxial Screwdriver
	48563016	Polyaxial Screwdriver, Locking
	48562037	Poly Adjustment Driver
	48561043	Angled Driver
	48561050	Short Driver
	48560017	Rod Template
	48560030	Bilateral Occiput Plate Bend Template
	48560018	Rod/Plate Cutter

	Part #	Description
	48561038	Small Rod Cutter
	48560019	Rod/Plate Bender
	48562100	Rod/Blocker Inserter
	48560020	Rod Forceps
	48561039	Rod Rotation Forceps
	48560021	Screw Head Adjuster
	48560022	*In-situ* Bender, Right
	48560023	*In-situ* Bender, Left
	48561049	Occiput Plate Bending Irons (2)
	48562024	Corkscrew Persuader
	48561024	Locking Persuader
	48560024	Persuader
	48561042	Hexdriver
	48561026	Compressor
	48561041	Distractor
	48560027	Insertion Tube/Anti-torque Key
	48562027	Insertion Tube/Anti-torque Key
	48560028	Torque Wrench
	48562028	Torque Wrench

	Part #	Description
	48561028	Audible Torque Wrench
	48560029	Connector Clip Inserter
	48560129	Connector Clip Remover
	48561071	Connector Plate Bender
	48561073	Locking Nut Socket, Connector Plate
	48561074	Cross Connector Nut Inserter
	48561075	Cross Connector Nut Tightener
	48510300	Plate Holder
	48560032	Hook Preparer
	48560033	Hook Forceps

STRYKER SPINE OASYS SYSTEM

NON STERILE PRODUCT

DESCRIPTION

The STRYKER Spine OASYS System is intended for use as an aid in spine fusion. It consists of screws, hooks, plates, rods and connectors. These components are available in a variety of lengths in order to accommodate individual patient physiology and pathology and to facilitate posterior stabilization of the spine.

INDICATIONS

The Stryker Spine OASYS System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The Stryker Spine OASYS System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Stryker Spine OASYS System can be linked to the XIA System, SR90D System and XIA 4.5 Spinal System via the rod-to-rod connectors and transition rods.

The Stryker Spine OASYS System can also be linked to the polyaxial screws of the XIA II and XIA 3 Systems via the saddle connector.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- Any abnormality present, which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, 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, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

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

INFORMATION FOR THE PATIENT

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion must be directed to the issues of premature weightbearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and make the patient aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. 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 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.

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. The following list is representative, though not all inclusive, of the potentially adverse effects that the surgeon must consider whenever implanting a spinal fixation system or device:

- Bending, disassembly or fracture of any or all implant components.
- Fatigue fracture of spinal fixation devices, including screws, rods, and hooks 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. This risk is related to the surgical procedure. The intended use of the device does not require it to be close to the dura.
- Cessation of growth of the fused portion of the spine.
- Loss of proper spinal curvature, correction, height and/or reduction.
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight

bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must 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.
- Cervical spine procedures may be associated with vascular and neural complications such as arterial injury or mechanical compromise, cord contusion and damage, peripheral nerve compromise and damage, including but not limited to peripheral paralysis, sensory disorders, vascular disorders, loss or disturbance of bladder and bowel functions.
- Serious complications may be associated with any 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 lateral mass 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.

REMOVAL OF IMPLANTS

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:
- Corrosion with a painful reaction.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions.
- Pain or abnormal sensations due to the presence of the implants.
- Infection or inflammatory reactions.
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.
- Bone growth restraint due to the presence of the implants.
- Failure or mobilization of the implant.

Instruments are provided by STRYKER Spine to 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 must 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.

PREOPERATIVE PRECAUTIONS

Surgical Technique brochures may be by requested from a distributor or from STRYKER Spine directly. Those using brochures published more than two years before the surgical intervention are advised to obtain 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.

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

WARNINGS

Federal law restricts this device to sale by or on the order of a licensed physician.

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability requiring fusion with instrumentation. These conditions are significant mechanical instability of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

PRECAUTIONS

The implantation of pedicle screw spinal systems must 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 must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the system.

The STRYKER Spine OASYS System has not been evaluated for safety and compatibility in the MR environment. STRYKER Spine OASYS System has not been tested for heating or migration in the MR environment.

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