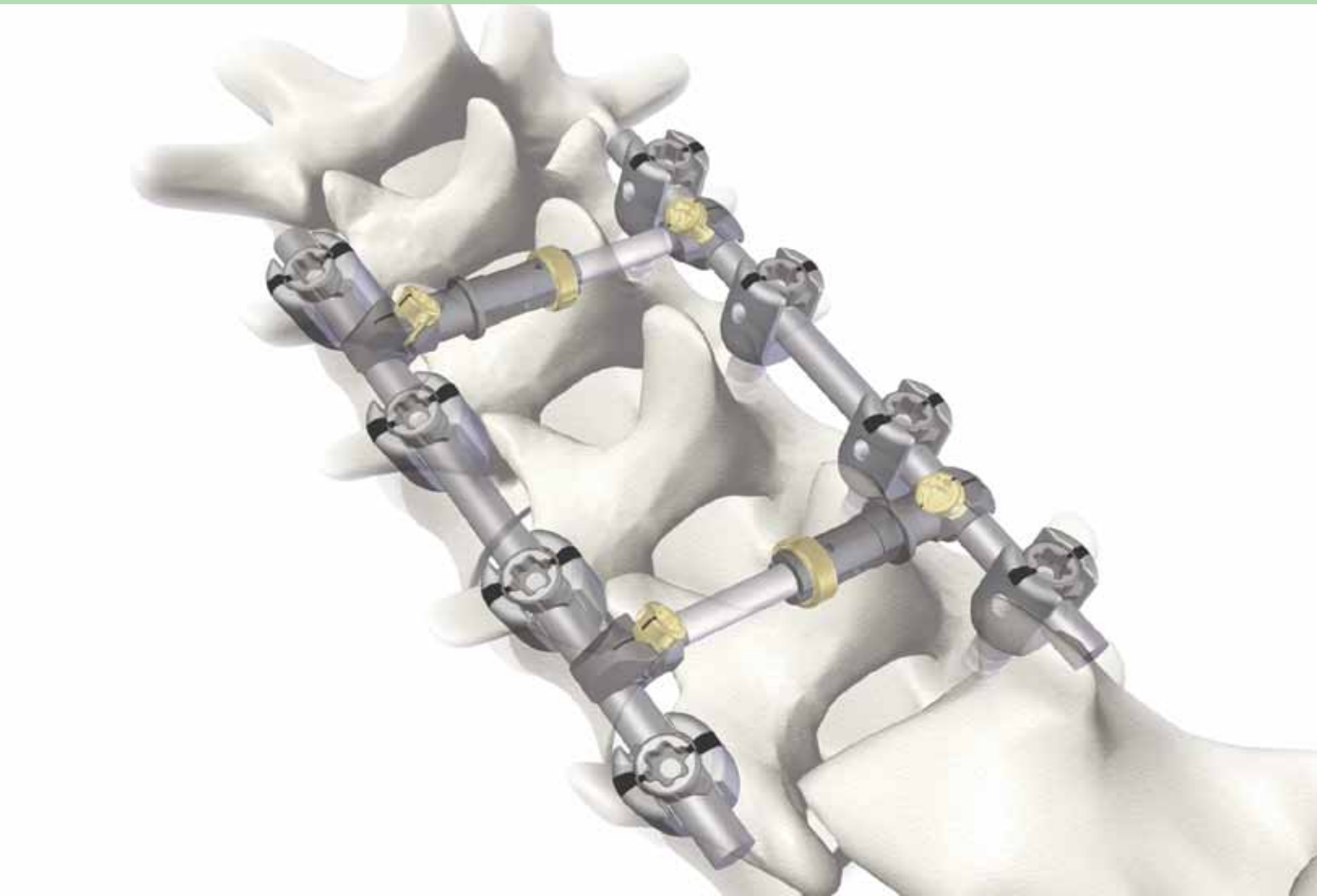
stryker

Spine

Radius® Spinal System
Surgical Technique

Complex Cases



Introduction

The Radius spinal system incorporates a number of engineering features that makes the system unique. These features include a **one-step (two-stage) locking mechanism**, a floating saddle designed to provide circumferential locking of the rod and a **defined locking position** of the rod into the implant seat.

Most spinal systems use conventional threaded set screws that must be tightened to a predetermined torque limit and are known to occasionally cross-thread. The Radius system has a **non-threaded locking mechanism** that requires **no torque measuring device. The locking mechanism is designed to reduce the potential for false locking and cross-threading**. This award winning non-threaded technology is designed to help increase **the speed, ease, and reliability** of connecting rods to screws.[+]

This surgical technique sets forth detailed, recommended procedures for using the Radius spinal system in complex cases, included but not limited to corrections of spinal deformities, such as scoliosis, kyphosis, and lordosis, using reduction procedures.

Acknowledgements

Stryker Spine would like to extend their thanks to the following surgeons for their participation in the development of the Radius system:

- Bruce V. Darden, MD
- Eric B. Laxer, MD
- R. Alden Milam, MD
- Daniel B. Murrey, MD
- Alfred L. Rhyne, MD

Important: The Radius implants and instruments are designed and tested for use only with the Radius Spinal System. This Surgical Technique sets forth detailed, recommended procedures for using the Radius Spinal System implants and instruments. It offers guidance that you should heed but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when necessary and as required. Always refer to the package insert, product label and/or instructions before using any Stryker implant or instrument.

Note: **This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon must be trained before proceeding.**

[+]Edmund Scientific Award for Excellence in Design. Featured in the Design News article on "Fastening innovations speed spine surgery", 2/26/01.

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Surgical Technique for Complex Cases

Key Design Features

Ease of Use
An easy, low torque twist locks the construct – it's that simple!

Low Profile
The unique dovetail feature of the helical Wedgelock mechanism allows for a low volume, multi-angle screw and is designed to keep the screw head from spreading during locking.

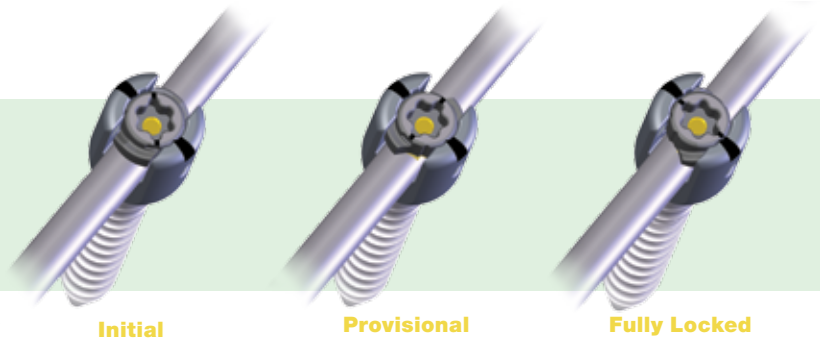
- Low screw head height is patient-friendly
- Small screw head diameter may allow for less facet joint impingement and more room for bone graft
- Short rod run-out is well-suited for L5 – S1 fusions and fitting cross connectors
- Less overall profile enables better visualization of the anatomy

Defined Locking Position
At the fully locked position, the locking cap is designed to consistently and securely seat the rod to the implant in the optimal position. When in the fully locked position, the laser marked lines on the locking cap are within the laser marked zone on the screw head, giving a visual indicator that the system is fully locked.

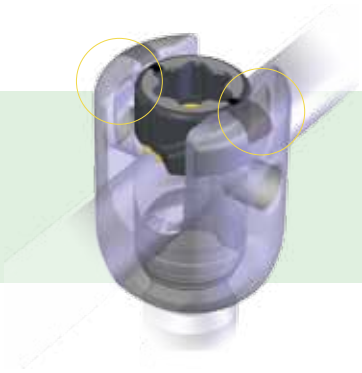
Comprehensive top loading spinal rod system consisting of titanium and Vitallium implants and instruments designed for stabilization of the spine.

Large surface area of locking cap saddle designed to **evenly distribute load onto the rod** to help increase sliding strength and reduce risk of notching.

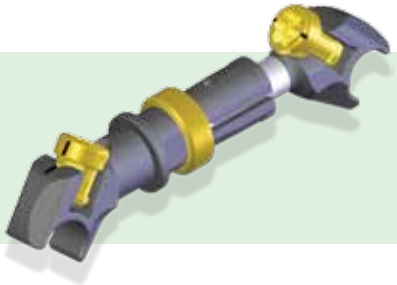
Two-stage (provisionally and fully locked) **locking cap** designed to allow for easy compression and distraction adjustments.



Locking cap helical wedge ramp facilitates **optimized seating of the rod without** the need for a **torque wrench**.



Telescoping cross connector with angled locking plugs is oriented to allow cross-wound tightening. A multi-angle cross connector is available with a polyaxial head on one side designed to eliminate the need to bend the cross connector to accomodate divergent rods.



The dual lead cortical thread of the Radius Rapid Screws is designed to help increase the speed of screw insertion.

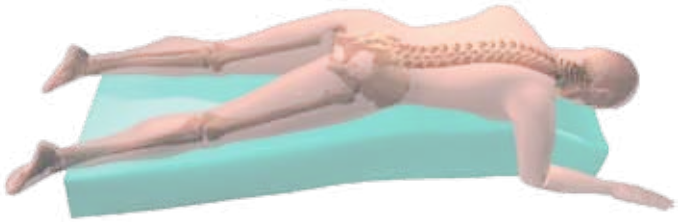
Indications for Use

The Radius Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

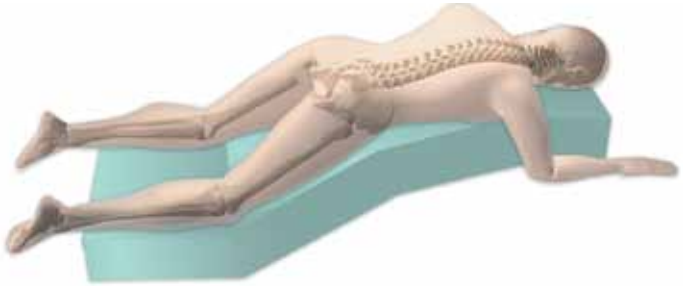
- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
- Tumor;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

The Radius Spinal System can also be linked to the Xia Titanium Spinal System via the Ø5.5mm to Ø6.0mm Radius rod-to-rod connector.

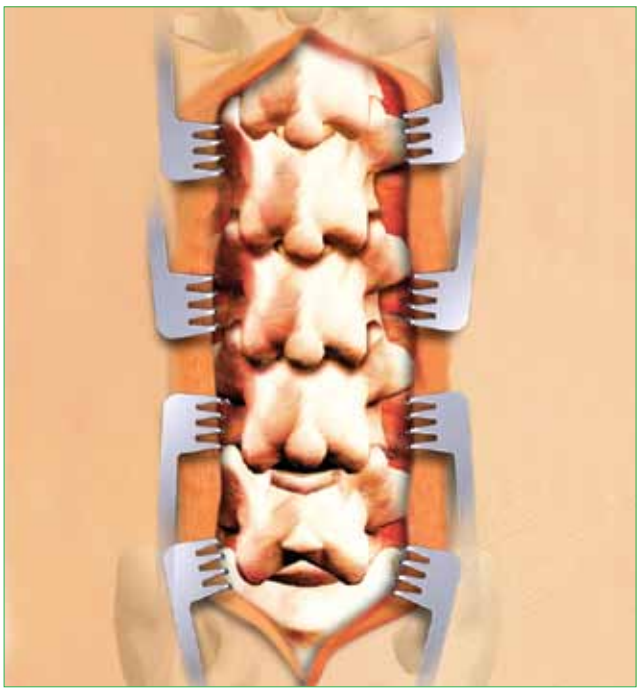
I. Patient Positioning



Diagnosis is based upon patient history, physical findings, and preoperative radiographic assessment.



The patient can be positioned on the spine table in the prone position. Care should be taken to pad all bony prominences. To facilitate venous drainage, do not compress the abdomen.



Surgical levels may be verified clinically or radiographically. To ensure adequate exposure, the incision is made to extend just beyond the length of the intended fusion.

Use presurgical planning to define the most appropriate implants as well as the optimal location of where the implants should be inserted.

II. Pedicle Preparation

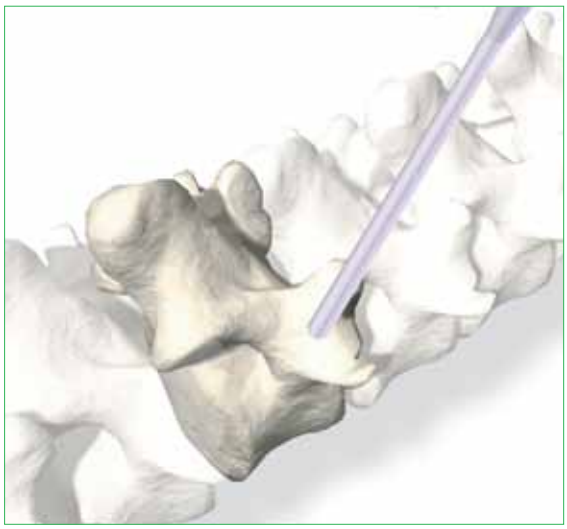
Pedicle Preparation

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

The entry point may be prepared with a Pedicle Awl.

Note: It is recommended that you use the OASYS Awl (48560010) and Probe (48561115) when preparing a pathway for the Radius 4.0mm diameter screws. DO NOT use the the Radius Awl and Probe for this screw diameter.

Pedicle Awls



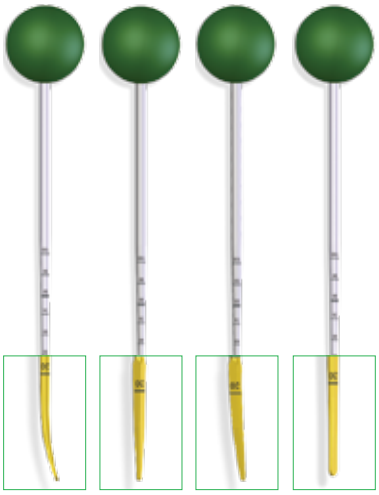
A pathway is then opened with a Probe. The Probe should contact the bone at all times. The correct rotational insertion of the instrument will allow the Probe to follow a path of least resistance without violating the pedicle walls.

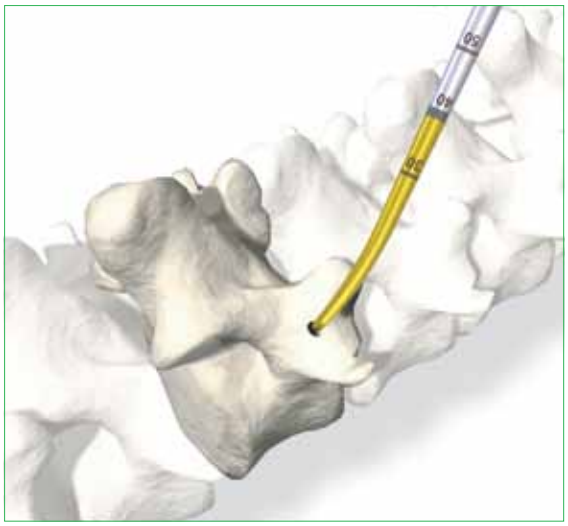
In the event that resistance is felt, the entry point and trajectory should be reevaluated.

The Probe is laser etched with 10mm intervals to indicate the depth in which the Probe has been inserted as well as to help determine the proper screw length.

The Probes have been colored gold up to 40mm to allow easy visualization of 40mm depth, which represents the most common screw length.

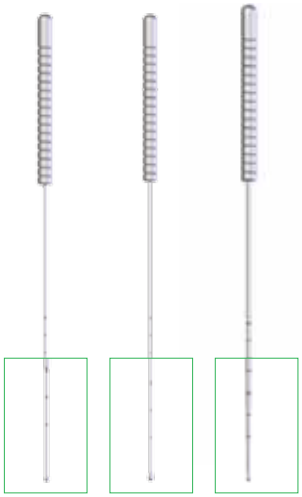
Probes

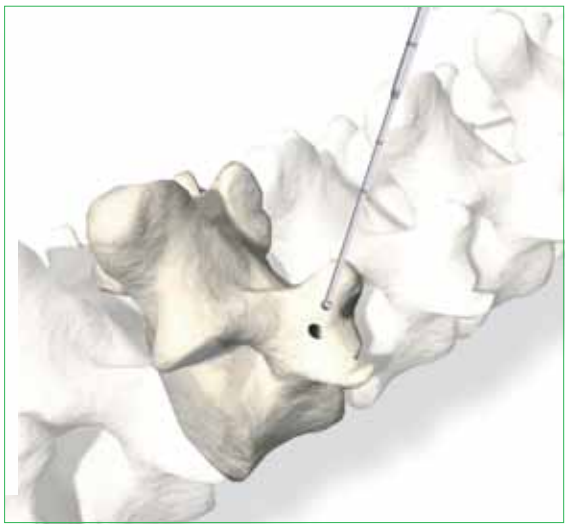




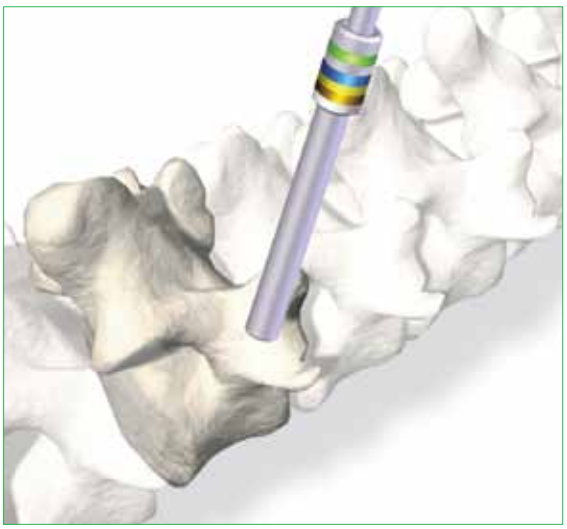
Check the prepared pathway with a Pedicle Tester to verify that all walls of the pedicle have not been violated and that cancellous bone is felt at the distal end of the path.

Pedicle Testers





II. Pedicle Preparation



The appropriate Tap may be used to prepare the pedicle canal when the surgeon is having difficulty starting the screw. The Tap sizes are Ø3.5mm, Ø4.25mm, Ø5.25mm, Ø6.25mm, Ø7.25mm, Ø8.25mm, and Ø9.25mm.

Note: Use the Taps when preparing the pedicle canal for Standard and Multi-Angle Screws. Use the Rapid Taps when using Radius Rapid Multi-Angle Screws. The Rapid Taps come in diameters of 5.25mm, 6.25mm, 7.25mm, 8.25mm, and 9.25mm.

The Taps are laser etched with 10mm intervals to indicate the depth to which they have been inserted as well as to help determine proper screw length. The Taps are 0.5mm smaller than the corresponding screw and feature a spiral cutting flute to minimize toggle during tapping.

The Taps have been colored gold to 40mm to allow easy visualization of 40mm depth, which represents the most common screw length.

The Drill Sleeve serves as both a soft tissue protector and a depth indicator and is intended to be used with the Taps.

Note: The Drill Sleeve color rings denote which Tap sizes fit through the Sleeve.

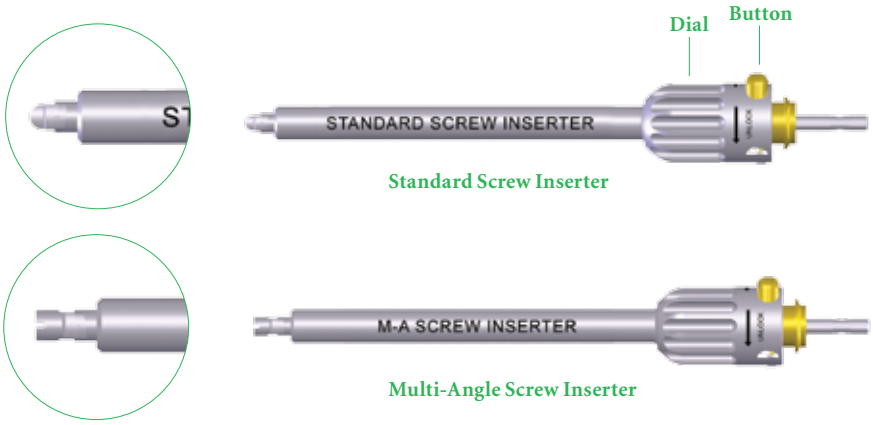
Tip: If soft tissue unintentionally redirects the Tap laterally toward the pedicle, the Drill Sleeve can be used to lever against the soft tissue without bending the Tap.

Tip: It is recommended that you use the Drill Sleeve for the Ø3.5mm Tap.

III. Screw Insertion

Both the Standard Screw Inserter and the Multi-Angle Screw Inserter are designed to provide a very rigid connection with the Standard Screws and Multi-Angle Screws.

With the pedicle pathways prepared and proper screw length and diameter determined, the screw is ready for insertion.



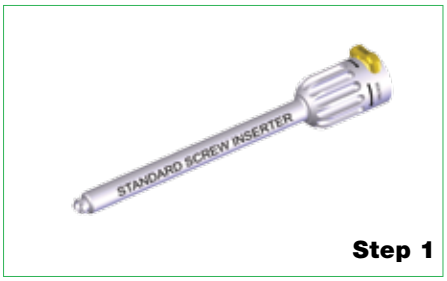
Standard Screw Inserter

Multi-Angle Screw Inserter

Standard Screws

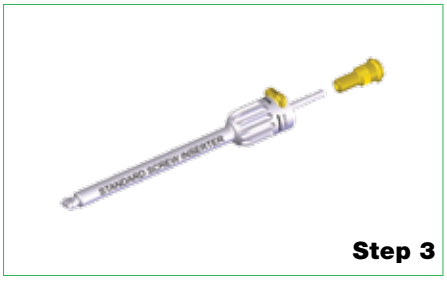
To assemble the Standard Screw Inserter:

1. Insert the inner shaft through the body of the Standard Screw Inserter.
2. Insert the ratchet down the shaft of the Standard Screw Inserter. Verify that the ratchet is bottomed out.
3. Connect to the desired handle.
4. Ensure that the Standard Screw Inserter is fully unlocked.
5. Align the Standard Screw Inserter shaft with the internal geometry of the standard screw head while holding the bone screw.
6. Rotate the dial on the Standard Screw Inserter clockwise to firmly seat the screw onto the Standard Screw Inserter.

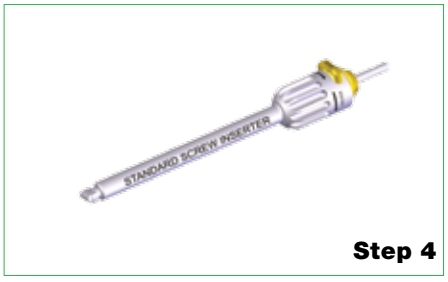


Step 1

Step 2



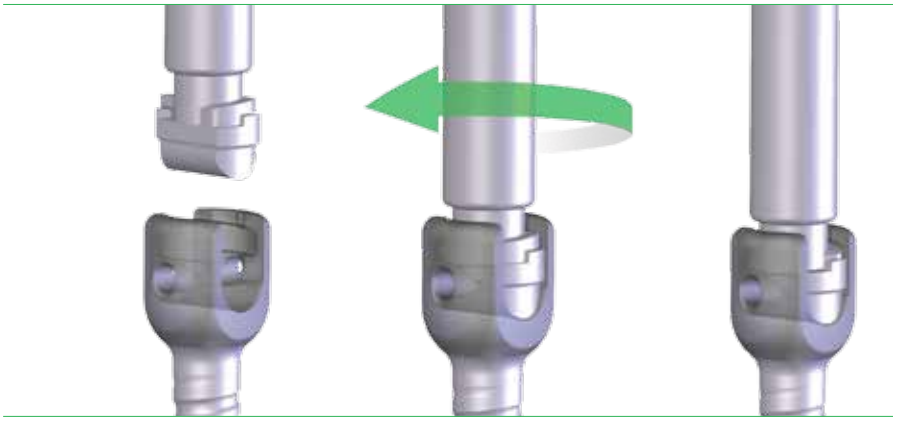
Step 3



Step 4

To remove the Standard Screw Inserter:

1. Once the screw is inserted into the pedicle, push the gold button and rotate the dial on the Standard Screw Inserter counter-clockwise until the Standard Screw Inserter is loose from the screw.
2. Remove the Standard Screw Inserter from the screw.

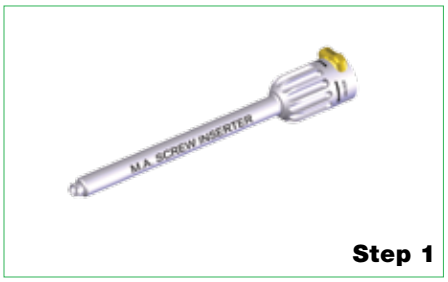


Standard Screw Inserter

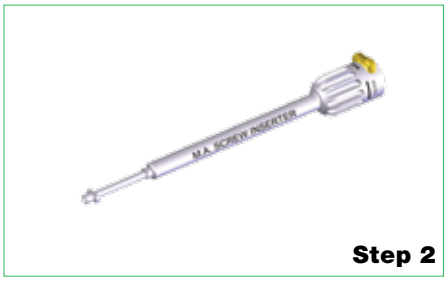
Tip: The Standard Screw Inserter can also be used to hold hooks for insertion.

Note: Use the Rocker for removal of the Standard Screws.

III. Screw Insertion



Step 1



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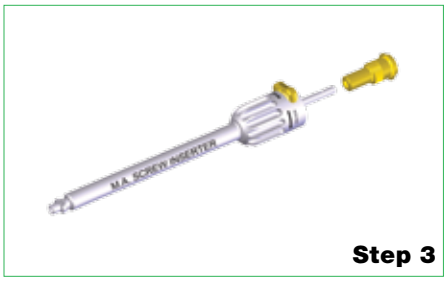
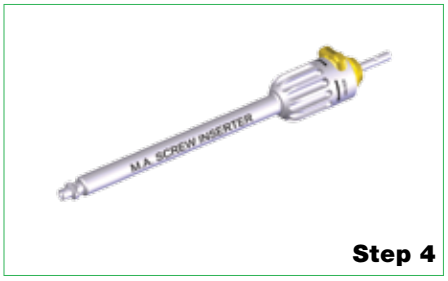
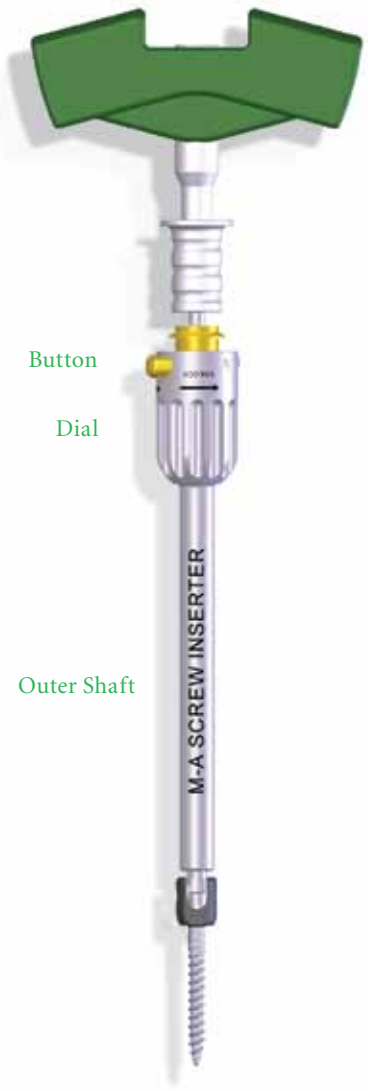
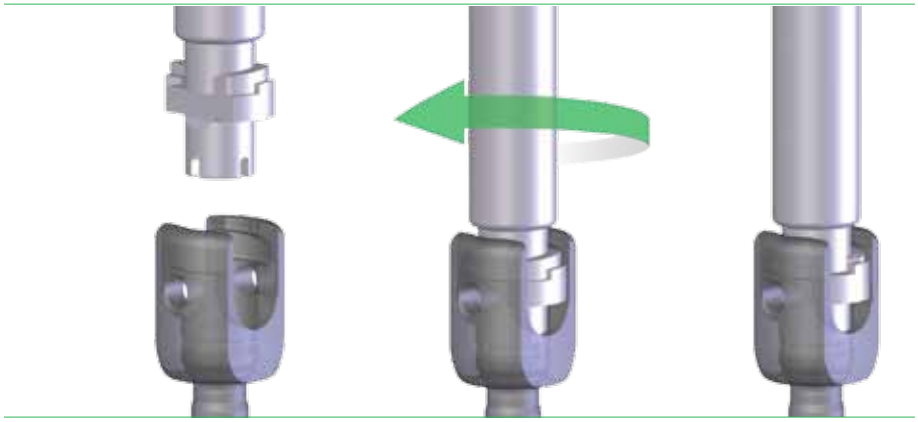


Step 3



Step 4





Multi-Angle Screw Inserter

Multi-Angle Screws

To assemble the Multi-Angle Screw Inserter:

1. Insert the inner shaft through the body of the Multi-Angle Screw Inserter.
2. Insert the ratchet down the shaft of the Multi-Angle Screw Inserter. Verify that the ratchet is bottomed out.
3. Connect to the desired handle.
4. Ensure that the Multi-Angle Screw Inserter is fully unlocked.
5. Align the tabs on the Multi-Angle Screw Inserter shaft with the external quad on the screw head while holding the bone screw.
6. Rotate the dial on the Multi-Angle Screw Inserter clockwise to firmly seat the screw onto the Multi-Angle Screw Inserter.

To remove the Multi-Angle Screw Inserter:

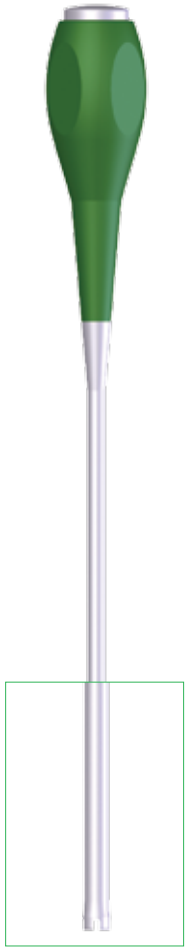
1. Once the screw is completely inserted into the pedicle, press and hold the gold button while turning the silver dial counter-clockwise until the Multi-Angle Screw Inserter is loose from the screw.
2. Remove the Multi-Angle Screw Inserter from the head of the screw.

Note: The Multi-Angle Screw Inserter is used for both the Multi-Angle Screws and the Rapid Multi-Angle Screws.

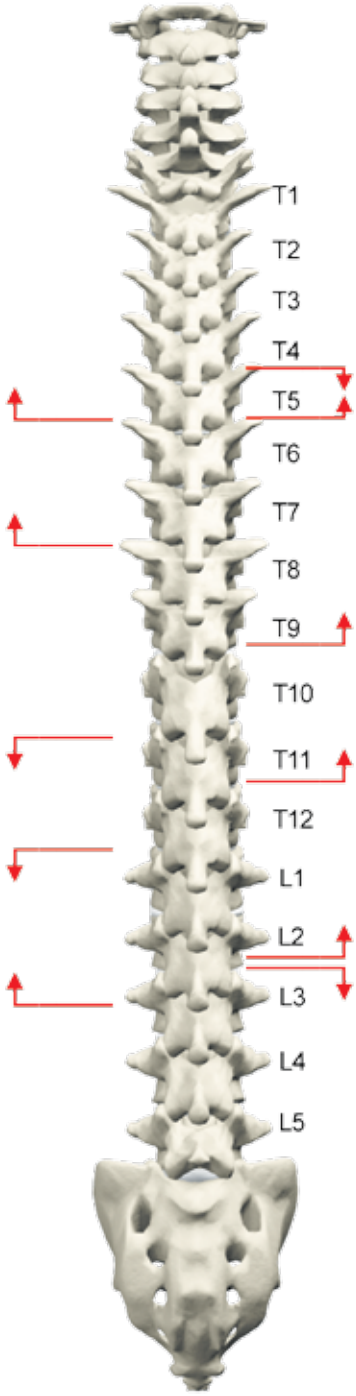
Tip: When using either the Standard Screw Inserter or the Multi-Angle Screw Inserter there are 4 choices of handles which can be used: Cannulated T-Handle, Cannulated Racheting T-Handle, Cannulated Standard Handle or Cannulated Standard Ratcheting Handle.

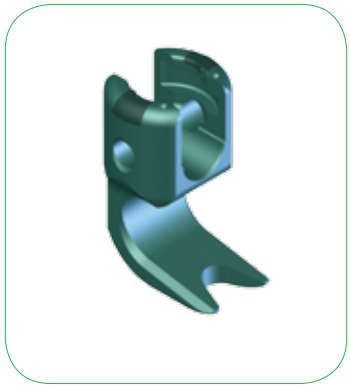
Height Adjustment

The Multi-Angle Screw can more easily be adjusted once you remove the Screw Inserter, using the Multi-Angle Adjustment Tool. Simply attach the Adjustment Tool to the inner cruciform and turn counter-clockwise to raise the screw. The Adjustment Tool is able to engage the Multi-Angle Screw at +/-30° in any direction.



IV. Hook Design





Pedicle Hook

Hook Preparation and Insertion

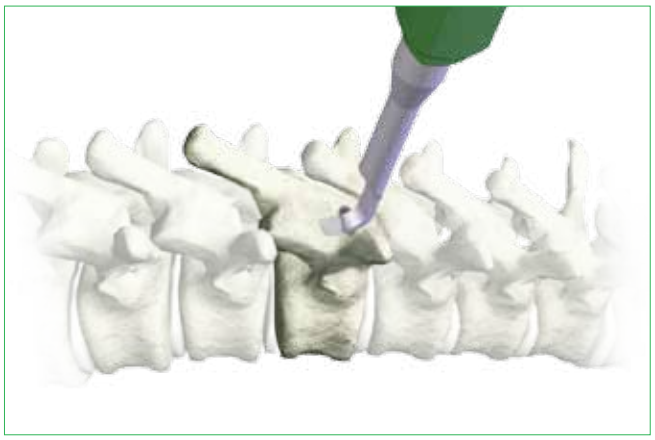
Once appropriate dissection has been achieved and anatomic levels are confirmed by x-ray and anatomic landmarks, the hook sites are identified and prepared. The appropriate hook is chosen according to a number of factors: patient anatomy, bone quality, correction technique, and the forces applied. The surgeon has several options in choosing a hook pertaining to the blade width, throat length, body extension, and hook shape. Hooks consist of three blade types. They are standard blade, narrow blade, and bifid pedicle blade. The surgeon should choose the hooks that will allow the most successful outcome of the procedure.

Offset hooks are available in both wide and narrow blade widths. They may be inserted in thoracic or lumbar segments. Offset connectors can be helpful in lining up hook connections.

V. Hook Insertion

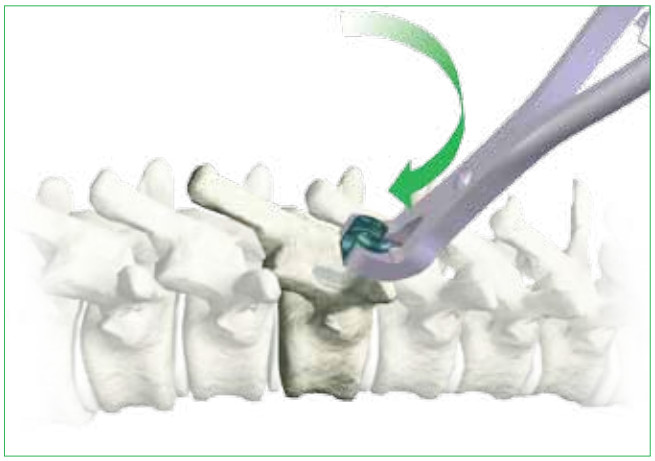
Supralaminar Hooks

Supralaminar hooks are directed caudally. The blade of the hook sits within the epidural space. A narrow blade hook with a throat size that does not allow pistoning on the lamina is recommended. The ligamentum flavum is dissected from the lamina and a small laminatomy is made. The Lamina and Transverse Process Finder may be used to estimate the appropriate hook size. Care must be utilized in introducing hooks and instruments into the open spinal canal. The Lamina and Transverse Process Finder is available in two blade widths designed to better match the patient's anatomy.

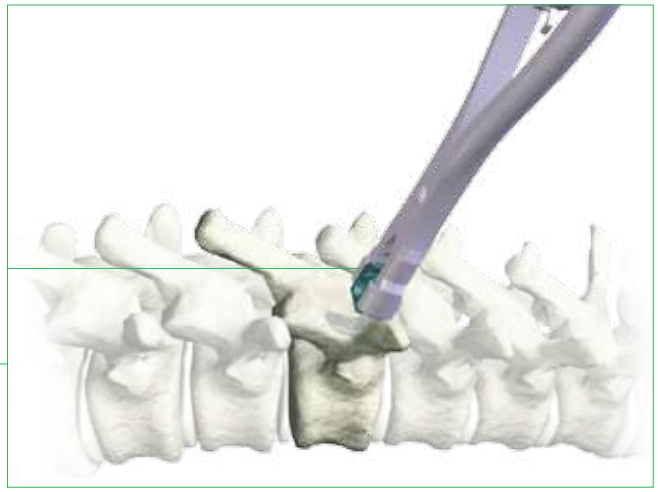


The appropriate hook is determined by the patient's anatomy. Once the site is confirmed to be well prepared, the selected lamina hook is loaded onto a Hook Holder.

Two options are possible for preparing the site and to insert the hook.

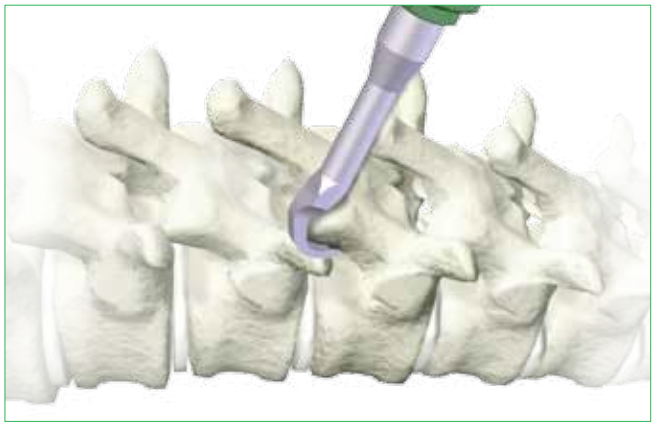


Option 1: A horizontal window is created by excising the ligamentum flavum combined with a limited osteotomy of the edge of the lamina. The window is prepared large enough to accommodate the blade of the hook to be inserted. The blade is then turned down 90° and seated on the lamina. This technique will assist in the stabilization of the hook, which can help facilitate rod introduction.



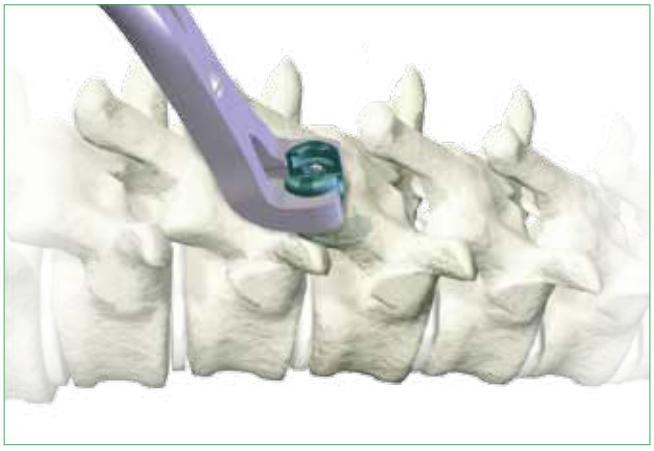
Option 2: A more squared window is managed by opening the ligamentum flavum in conjunction with a limited laminotomy. A Lamina and Transverse Process Finder may be used with great care to dissect the ligamentum flavum. Once the site is confirmed to be well prepared, the selected lamina hook is loaded straight on the Hook Holder. The hook is inserted in a downward rotational movement so that the tip of the blade hugs the anterior surface of the lamina at all times. A gentle burring of the lamina is sometimes necessary to ease the access to the canal.

V. Hook Insertion

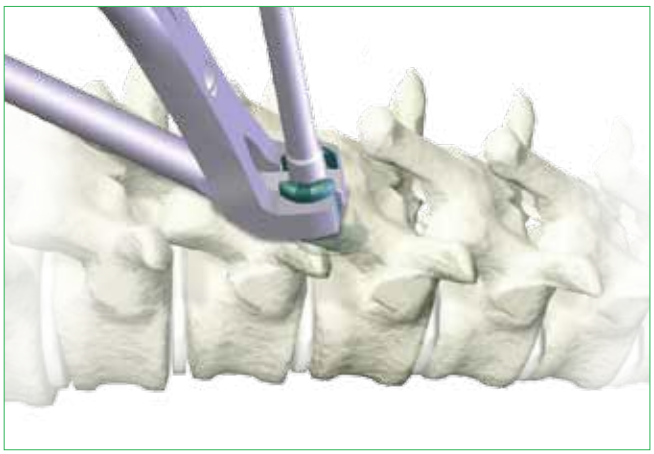


Infralaminar Hooks

Infralaminar hooks are directed cephalad. The Lamina and Transverse Process Finder is used to dissect the ligamentum flavum from the inferior lamina and prepare a path for the hook. The blade will seat between the anterior surface of the lamina and the ligamentum flavum and not interdural.



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

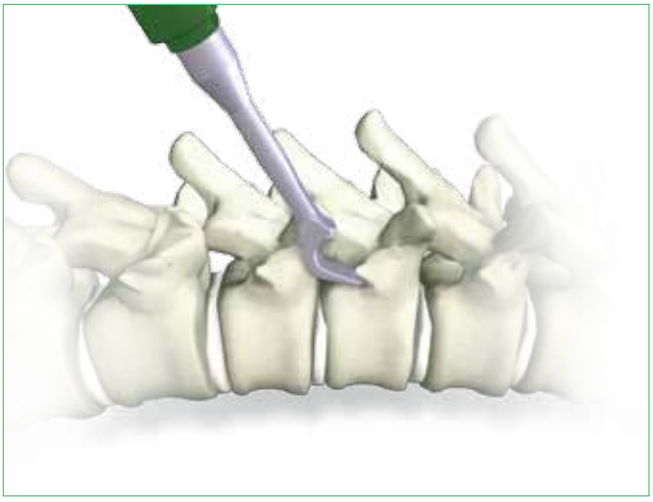


The Hook Impactor and Hook Impactor Blocker may be used in conjunction with the Hook Holder to help facilitate hook seating against the inferior lamina.

V. Hook Insertion

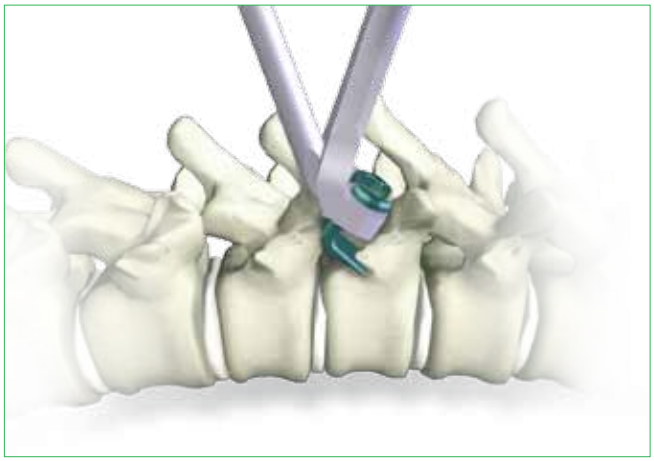
Pedicle Hooks

The pedicle hook is always directed cephalad and is often used at T10 and above. A limited osteotomy (facetectomy) at the base of the facet opens the facet joint and exposes the underlying articular cartilage of the superior facet of the caudal vertebra. The Pedicle Finder is inserted into the facet joint with great care, aiming slightly lateral of the midline to identify the pedicle. Once the pedicle is localized, the bifid on the Pedicle Finder can be utilized to help ensure that the fork is well applied onto the pedicle. The preparer, properly engaged on the pedicle, can be used to confirm a reliable fit on the vertebra by mobilizing the vertebra laterally. A prominent element indicates the appropriate location of the final osteotomy so that the hook will evenly seat onto the pedicle and the facet.



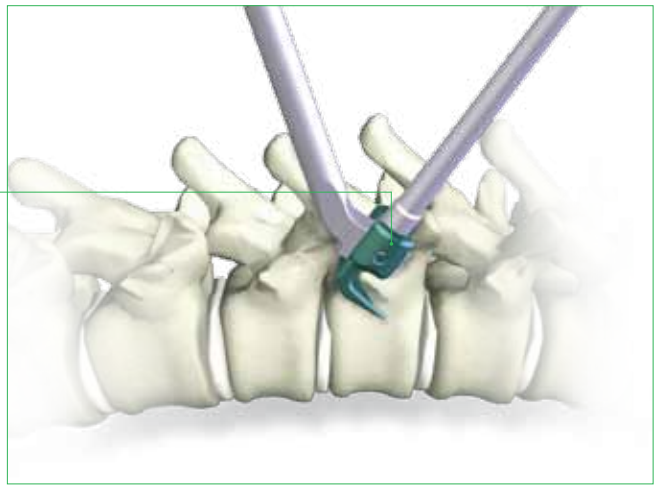
Once the site of the pedicle hook is clearly identified, the pedicle hook is inserted.

The hook is firmly gripped by the Hook Holder. The Hook Impactor is inserted into the hook. The hook is slid into the desired position, and then gently tamped against the pedicle. The hook is then moved side to side to help ensure the hook is around the pedicle.



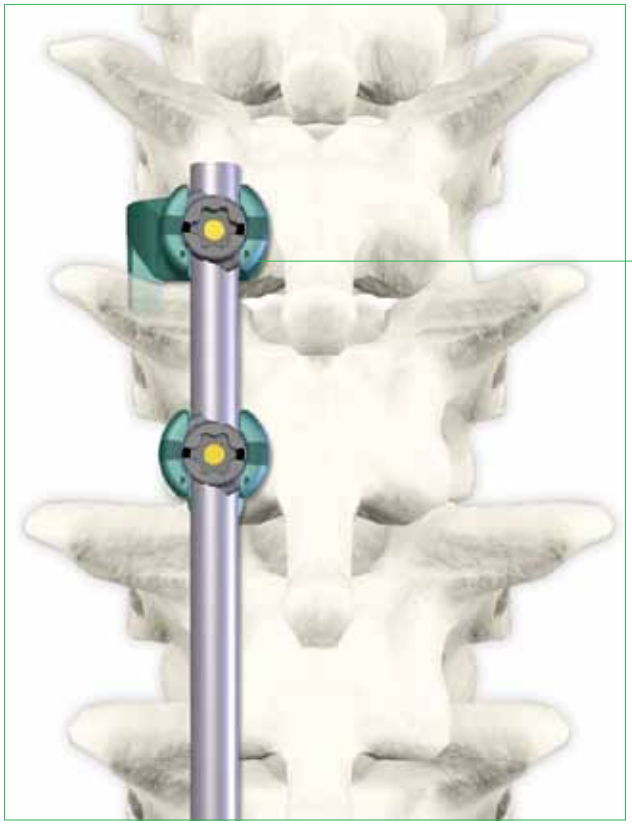
This combination is designed to provide an appropriate level of force and guidance to safely insert the hook.

Alternate method: The hook is temporarily secured to the Hook Impactor by tightening the Hook Impactor Blocker. The screw may be removed once the hook has been placed.



Note: To help facilitate the introduction of the pedicle hook it may be necessary to remove the prominence of the caudal lamina below the hook.

V. Hook Insertion



Based on the patient's anatomy, a transverse process hook or a standard lamina hook may be selected. The hook is loaded onto a Hook Holder. The hook is then inserted into the space created with the Lamina and Transverse Process Finder.

The transverse process hook may be directed cephalad or caudal.

Caudally directed transverse process hooks are often the top portion of the transverse pedicle claw configuration. The Transverse Process Hook can be used to facilitate easier rod insertion with a more medial placed hook or screw.

Again, the Lamina and Transverse Process Finder can be used to dissect around the superior and anterior surface of the transverse process to help create room between the anterior aspect of the transverse process and the rib head.

VI. Rod Contouring

Once all screws and/or hooks are inserted, use the appropriate precut and/or prebent rods.

Rod bending may be needed to fit the desired spinal contours.

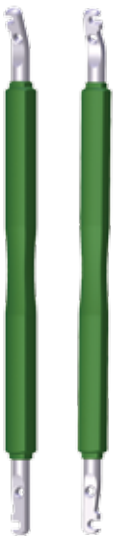
Note: Care should be taken to not make extreme bends as that can cause stress, concentration, and notching of the rod.

Bending can be performed with the Rod Bender. To contour the rod, a series of small incremental adjustments will bend the rod gradually and provide even stress distribution along the rod.

Rod Bender

Rod bending can also be performed using the bending iron feature on the In-Situ Benders. Insert the rod into the holes on each bender and gently pull upwards on one bender to contour the rod.

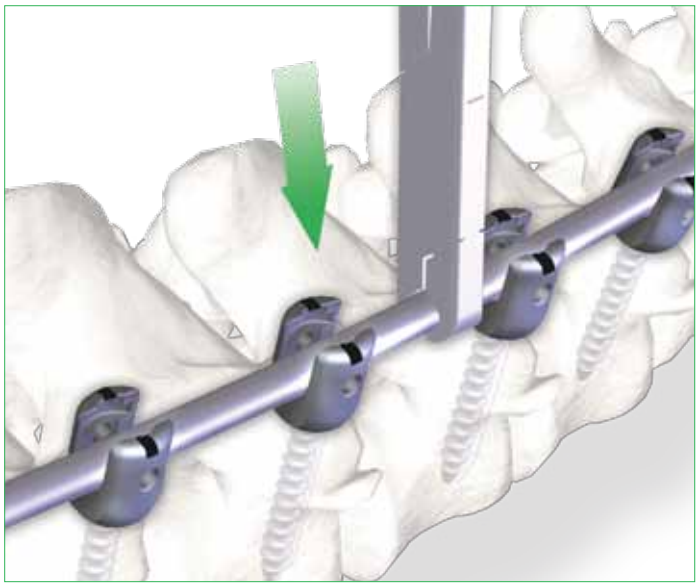
Tip: The Rod Template (03710620) can be used to measure the necessary curvature of the rod prior to contouring.



In-Situ Bender Right

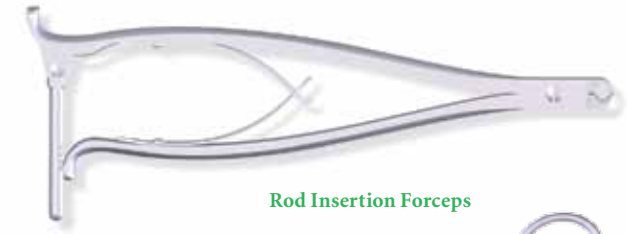
In-Situ Bender Left

VII. Rod and Cap Insertion

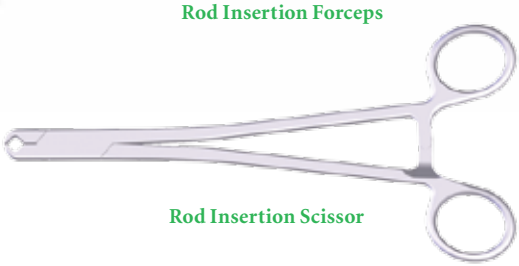


Rod Insertion

Once the rod is bent to the desired contour, a rod holder can be used to place the rod into the grooves of the implant.



Rod Insertion Forceps



Rod Insertion Scissor

Cap Insertion

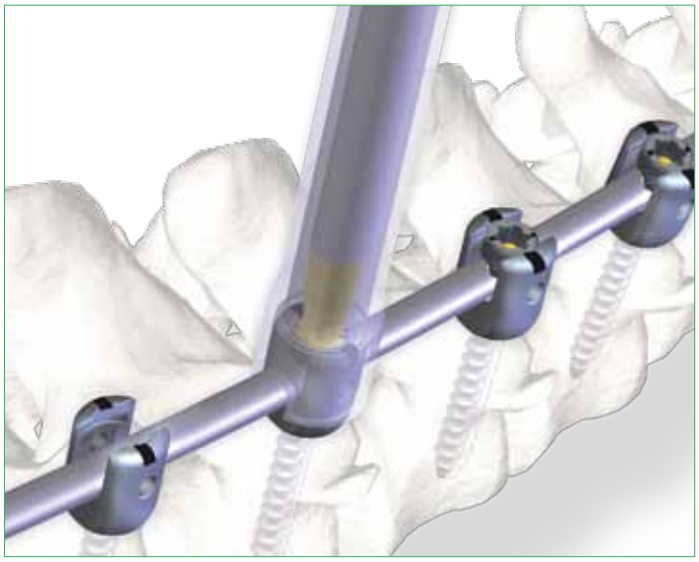
Assemble the Locking Cap onto the Initial Inserter by using thumb pressure or pushing firmly onto a Locking Cap in the Locking Cap Caddy (recommended).

Place the Locking Cap into the screw head, apply downward pressure to ensure the Locking Cap is firmly seated against the rod, then rotate clockwise until the cap snaps into the provisional locked position. This position is indicated when the laser markings on the cap and the Initial Inserter are parallel with the rod. The Locking Cap is now provisionally seated, the rod is blocked and the Initial Inserter can be removed.

Tip: When using the Initial Inserter, make sure the laser lines on the Initial Inserter line up with the laser lines on the Locking Cap.

Tip: Do not turn the Locking Cap past the provisional position with the Initial Inserter. This must be done with the Final Driver (see the Final Tightening section).

Note: The Initial Inserter Tube can be used to guide the Locking Cap into the screw head.



VIII. Rod Linkage

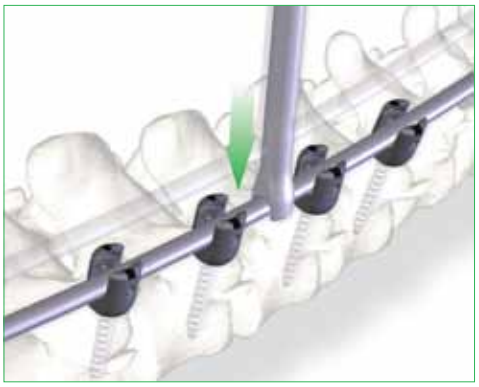
The Radius System offers three options for linking the rod to the spine:

Option 1:
Rod Pusher and Initial Inserter
The Rod Pusher is designed to push the rod down in-situ and is helpful for small adjustments.

While utilizing the Rod Pusher, perform the Cap Insertion Technique.

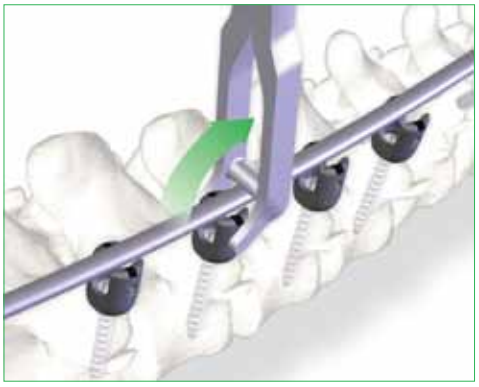
Note: Do not perform final tightening of the Locking Cap with the Initial Inserter.

Rod Pusher

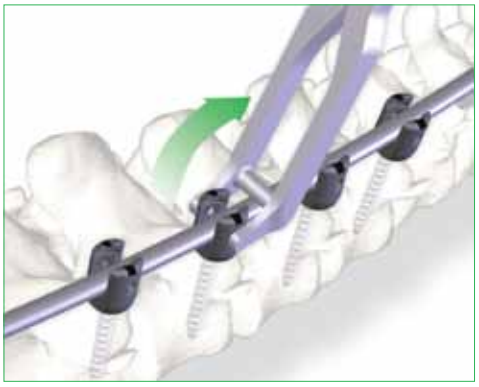


Option 2:
Rocker and Initial Inserter
The Rocker is used when the rod is slightly proud with respect to the seat of the implant.

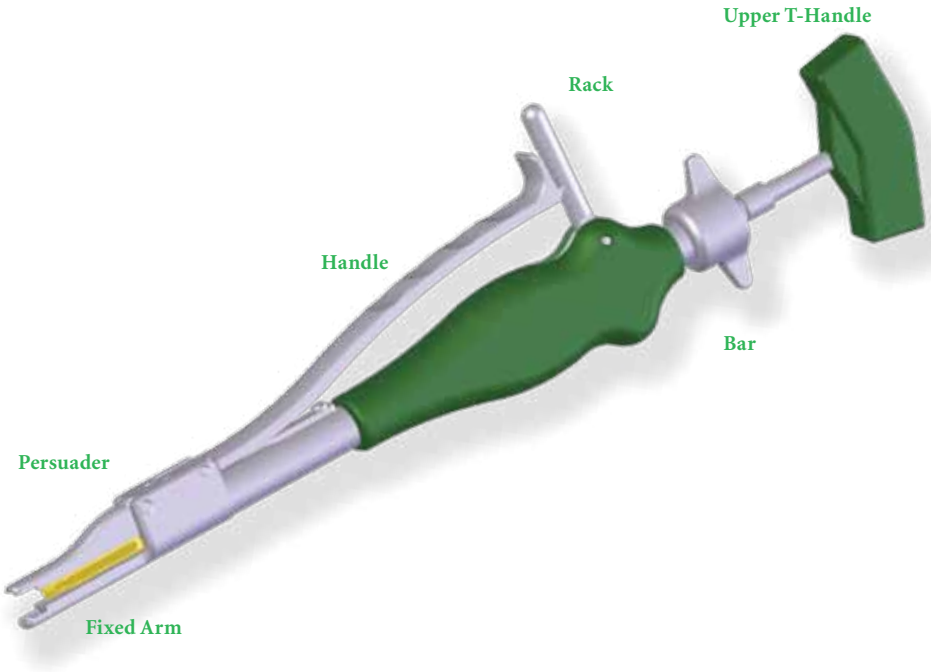
The Rocker is designed to easily slide into the lateral holes on the implant head. Lever the Rocker back. This forces the rod into the head of the implant. Insert the Locking Cap with the Initial Inserter when the rod is fully seated in the head of the implant.



Rocker



VIII. Rod Linkage

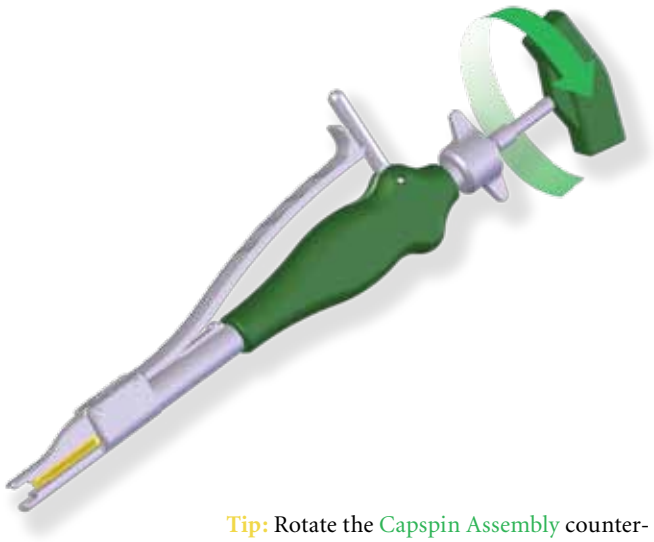


Option 3:
Persuader and Capspin

Use the Rod Persuader when additional force is needed to bring the rod to the implant. The Rod Persuader uses the Locking Cap to persuade the rod directly into the screw head and automatically loads the Locking Cap into the provisional locked position.

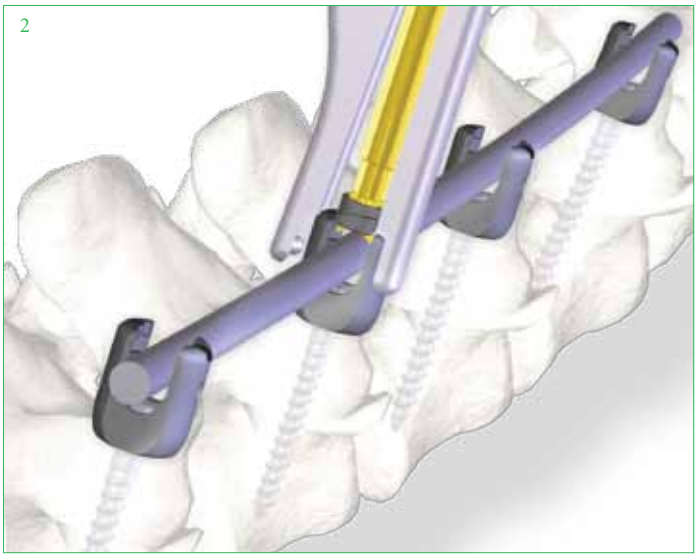
1. Ensure that the lower Bar is in the neutral position. Load the Locking Cap onto the Capspin Assembly of the Rod Persuader by pushing firmly on the Locking Cap in the Locking Cap Magazine.

1



Tip: Rotate the Capspin Assembly counter-clockwise, using the Upper T-Handle to avoid allowing the Locking Cap to contact the rod early which would prevent the Rod Persuader from attaching to the screw head.

2



2. With the Locking Cap assembled, place the Rod Persuader onto the screw head by clamping the forceps into the lateral holes on the implant head.

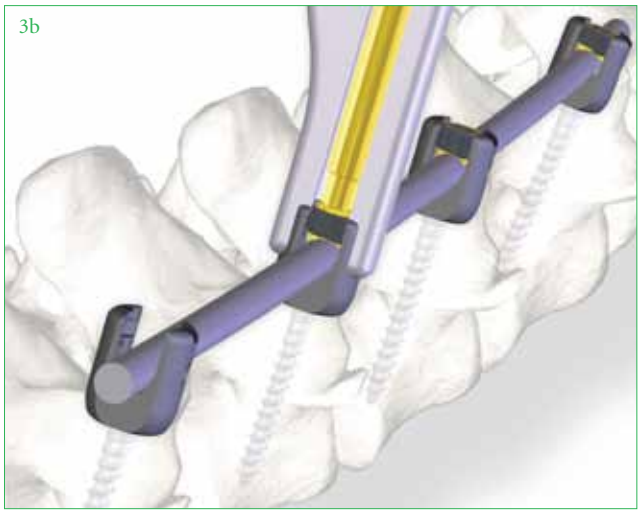
VIII. Rod Linkage

3. Turn the Upper T-Handle clockwise until the rod is fully seated. The bottom Bar will rotate and click into the provisionally locked position indicating that the rod is completely captured and provisionally locked.

Tip: If the Bar does not turn, hand tighten or loosen and try again.

3a

3b



4. Once the Bar turns to provisional lock, turn the Upper T-Handle 3 or 4 rotations counter-clockwise while holding firm the Bar in the provisionally locked position. Then lift the Rack and remove the Rod Persuader.

Tip: Make sure the Bar does not rotate backwards.

Tip: The rod cannot be linked to the screws or the hooks if the rod has a sharp, acute bend at the point of linkage.

Note: The Rod Persuader is not designed to bend the rod.

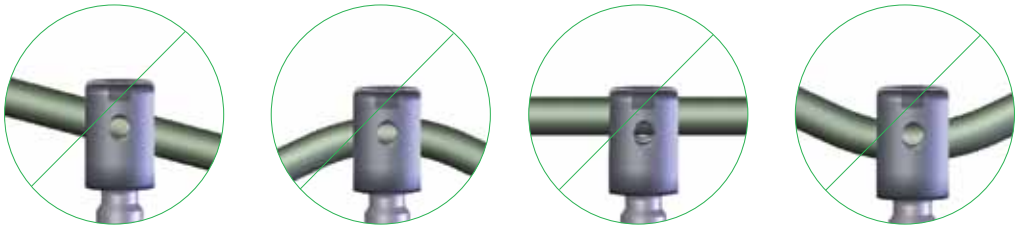
4

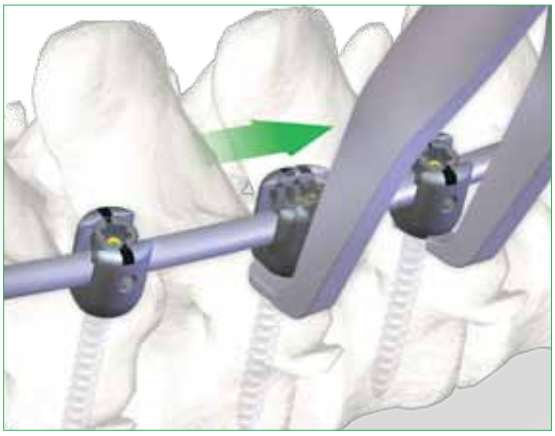
VIII. Rod Linkage

Note: In the event that the rod is forced down while tightening the Locking Cap be sure that the Locking Cap is fully engaged in the screw head.

Extra caution is advised when:

1. The rod is not horizontally placed into the screw head.
2. The rod is high in the screw head.
3. An acute convex or concave bend is contoured into the rod.



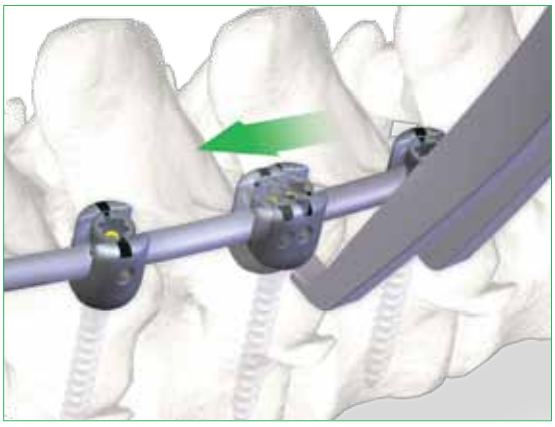


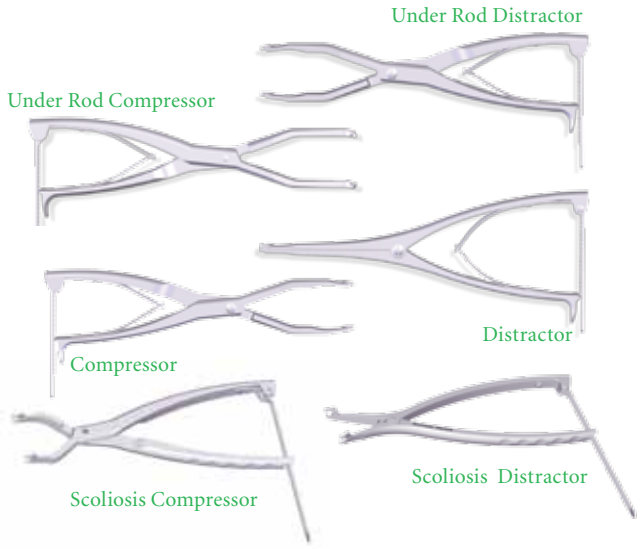
Compression and Distraction

To compress or distract:

1. Final tighten one of the screws.
2. Place the Counter Torque Tube instrument over the provisionally locked adjacent screw.
3. Compress or distract using the Compressor or Distractor.

Tip: Compression and distraction using the under rod instruments depends on how proud the screw is since the instruments may not fit under the head of the screw.





4. After compression or distraction has occurred, place the Final Driver through the Counter Torque Tube to tighten.

IX. Reduction Procedures

Deformity Correction

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

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

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

Rod Derotation: Option 1: Traditional Rod Derotation

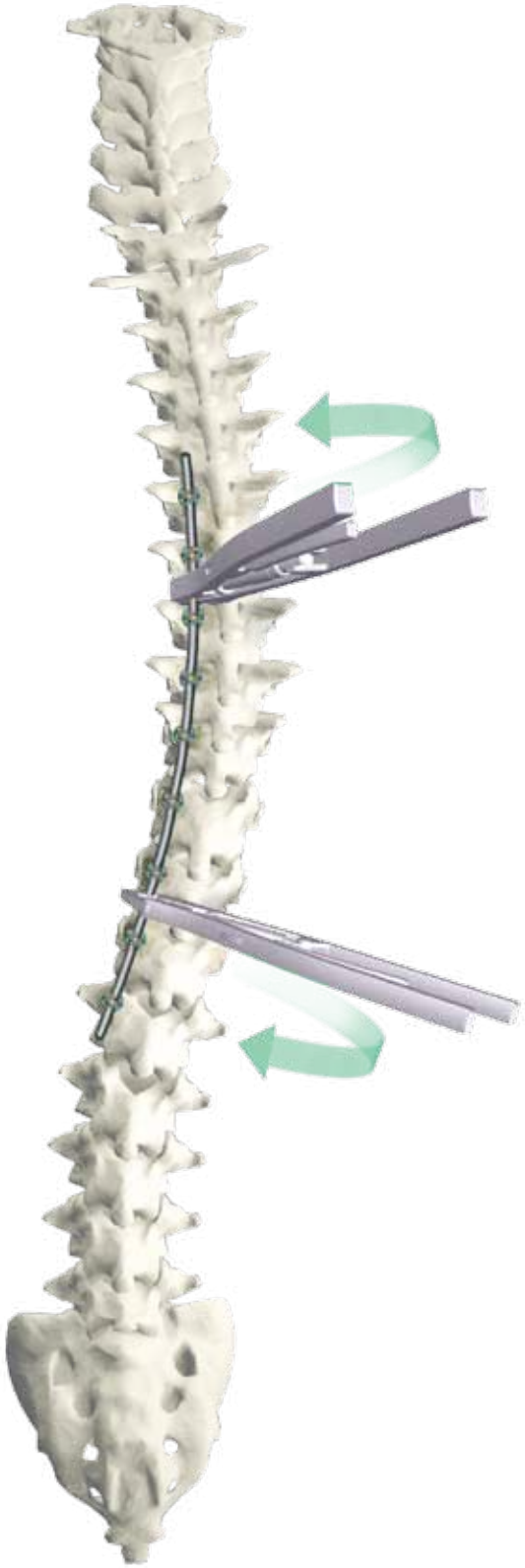
With the rod inserted into all of the implants and the Locking Caps inserted and provisionally tightened, the rotational correction maneuver can be applied.

The rod may be rotated using the Rod Gripper. Ensure that the Locking Caps are only provisionally tightened to allow free movement of the rod.

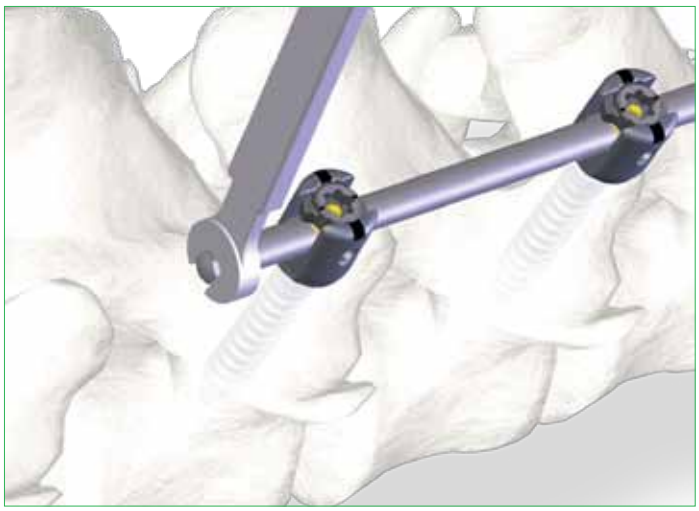
Typically, the rod is then rotated to an arch of 90° converting a scoliotic deformity in the thoracic spine into a sagittal kyphosis and translating a lumbar scoliotic deformity into lumbar lordosis. Once the rod has been fully rotated, the Locking Caps are final tightened.

Additional deformity correction may be obtained by further distraction/ compression maneuvers.

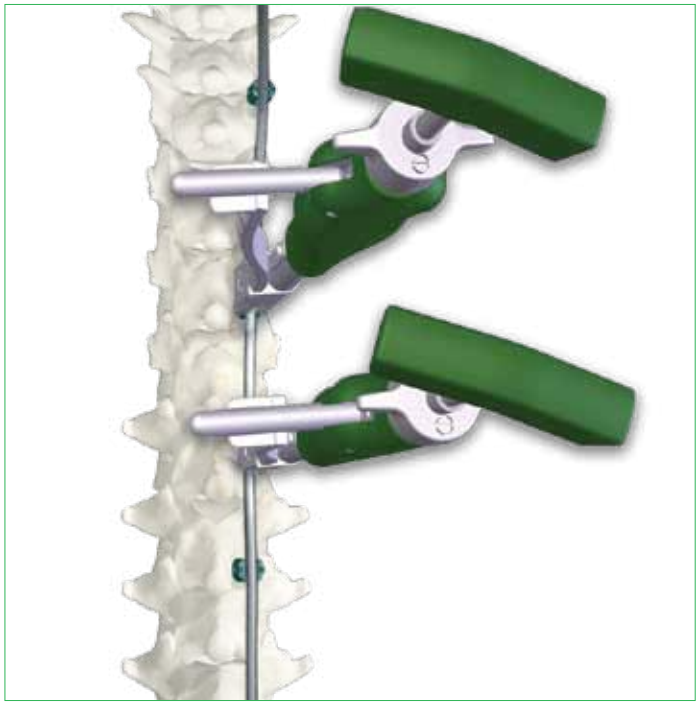
Rod Gripper

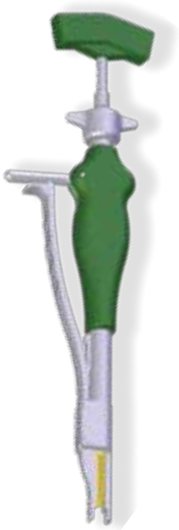


IX. Reduction Procedures



An alternative method to perform rod derotation is by use of the Rod with Hex. The rod is implanted and the Locking Caps are provisionally tightened. By attaching the 4.5mm Combination Wrench to the hex end of the rod, the rod can be rotated by advancing the combination wrench.





Option 2: Translation

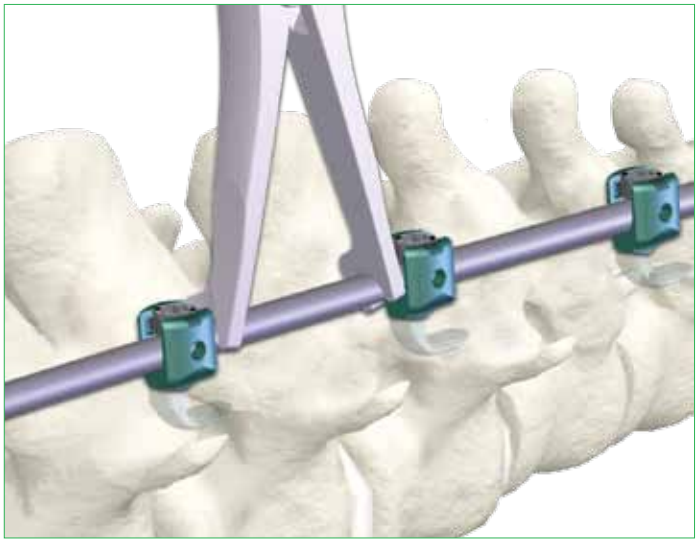
Translation can be achieved by utilizing the Persuader instruments. If using the Persuader instruments to perform translation, utilize the two Persuaders contained in the set. These Persuaders are typically placed at the distal and proximal ends of the curve apex. As the spine is carefully translated at these points the Locking Caps are provisionally locked. The Persuaders are then moved toward the apex of the curve until translation is complete.

IX. Reduction Procedures

Option 3:
Distraction/Compression

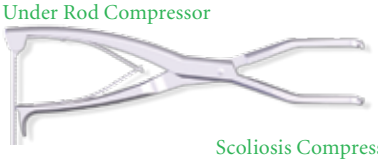
Spinal deformities can be further effected by creating a distraction in the concavity of the deformity and compression on the convexity of the deformity.

Note: Posterior distraction creates a kyphosis in the sagittal plane, compression creates a lordosis in the sagittal plane. Compression is achieved with the **Compressor** and distraction can be achieved with the **Distractor**. Once the construct is in the desired position, lock the **Locking Cap** with the **Final Driver** and **Counter Torque Tube**.



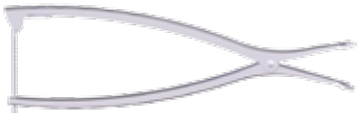
Under Rod Distractor

Under Rod Compressor

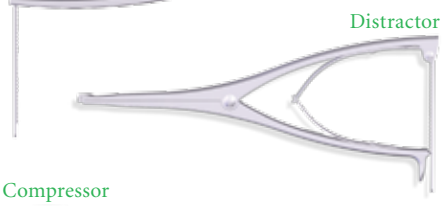


Scoliosis Compressor

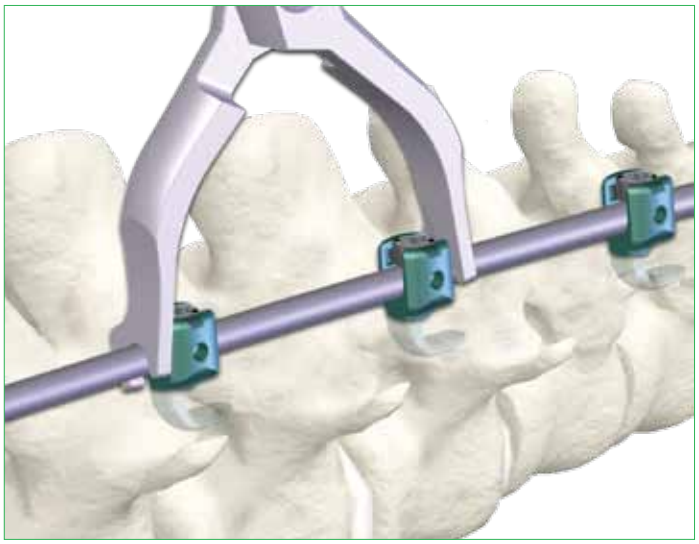
Scoliosis Distractor



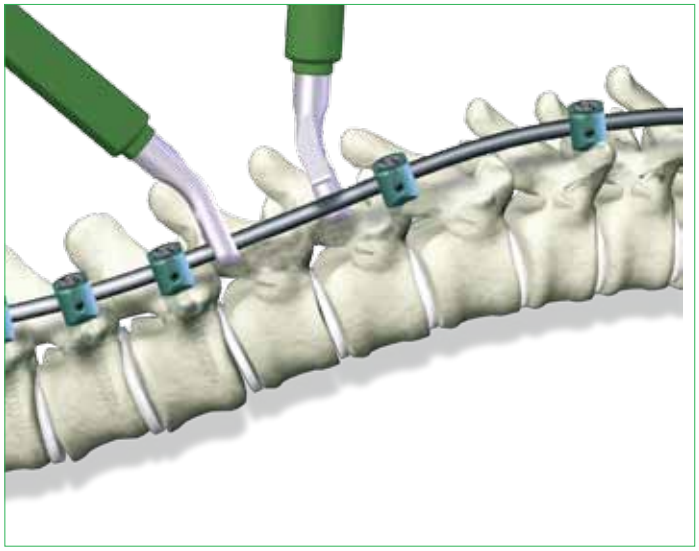
Distractor



Compressor



IX. Reduction Procedures



Option 4: In-Situ Bending

Great care must be taken during in-situ bending not to overload the bone implant interface. Also care must be used not to acutely notch the rod, which may weaken the implant.

Note: Ensure that the Locking Caps are not completely tightened during rotation maneuvers or the compression/distraction process.

In-Situ Bender Right

In-Situ Bender Left

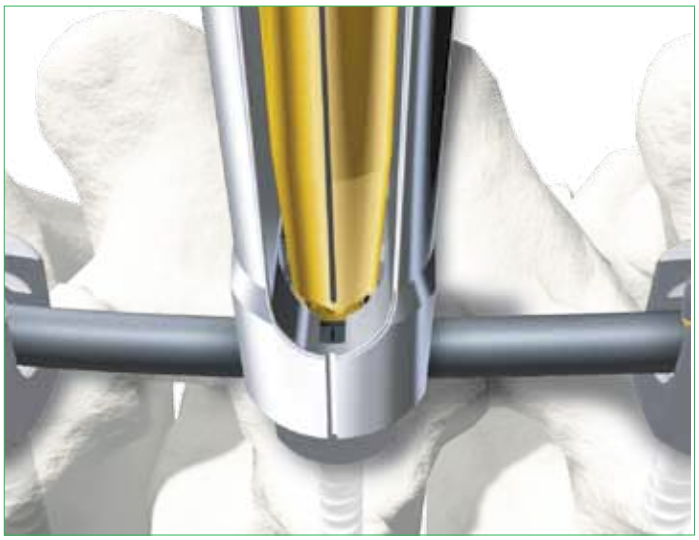
X. Final Tightening

1. Place the Counter Torque Tube around the screw head and over the rod.

2. Place the Final Driver into the star on the Locking Cap by first aligning the lines on the Final Driver shaft with the lines on the Locking Cap.

3. Twist the Final Driver until the handle of the Final Driver is perpendicular to the handle of the Counter Torque Tube or until the Final Driver no longer twists. The laser marked lines on the Locking Cap should be within the laser marked zone on the screw head.

Tip: It is important to position the Counter Torque Tube before the Final Driver is inserted to minimize the risk of instrument slippage.



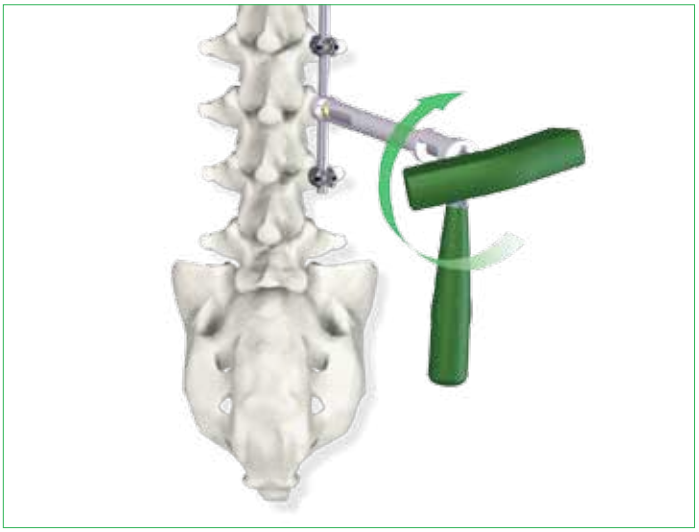
Tip: For final locking, the line on the Final Driver should be centered in the distal window.

Note: The Counter Torque Tube must be used for final tightening. The Counter Torque Tube is designed to perform three important functions:

1. To align the Final Driver with the tightening axis.

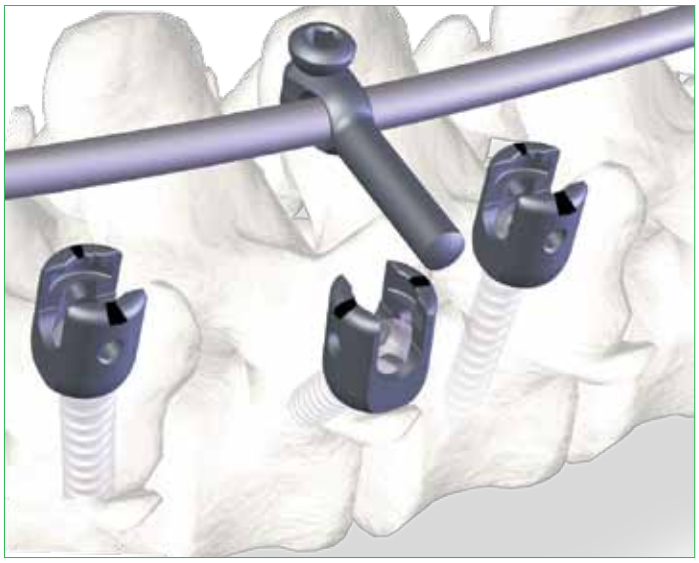
2. To maximize the torque needed to lock the implant assembly.

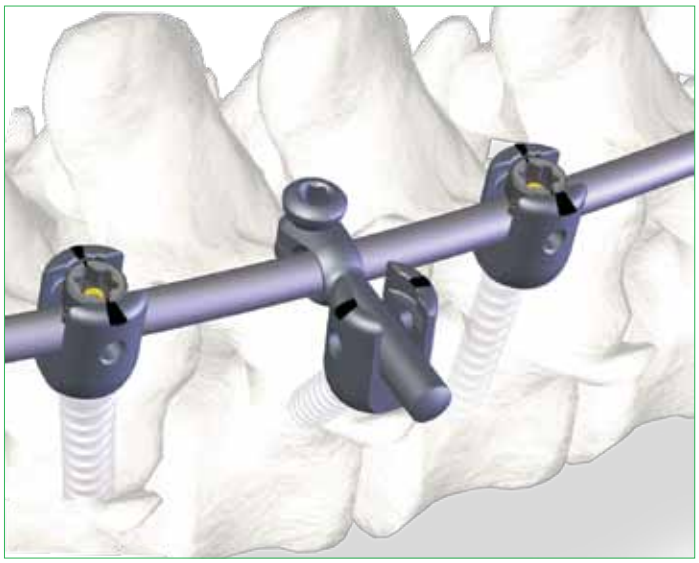
3. To hold the construct in place during final tightening.

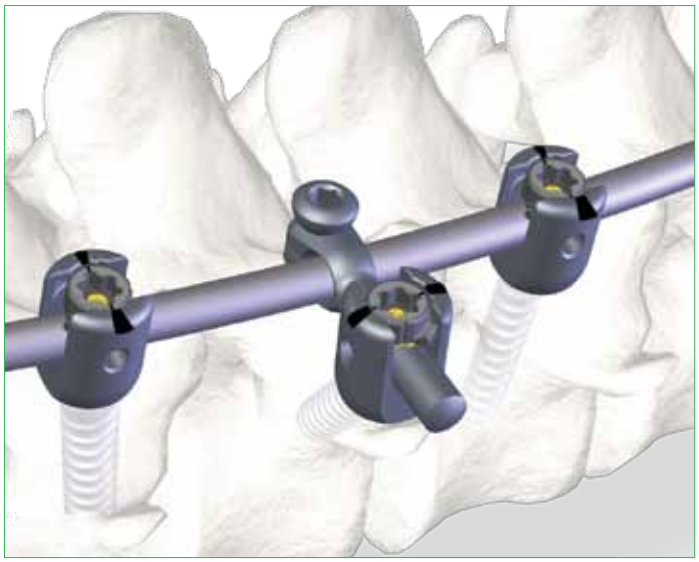


Note: For removal reverse the final tightening sequence.

XI. Lateral Offset Connector







Screw Offsets
The Offset Connector allows medial-lateral variability in connecting screws to the rod. This is useful when the rod does not line up with the implant. The head of the screw is rotated 90° clockwise to accommodate the Offset Connector.

The Offset Connector is preloaded onto the rod in the appropriate orientation.

The Offset Connector is inserted into the head of the screw. Care must be taken to ensure that at least 1.0mm of the Offset Connector is protruding out of the screw head.

The Locking Cap is then applied using the Initial Inserter. The final tightening sequence for the Offset Connector is identical to that for the pedicle screws.

Tip: Lateral Offsets are particularly useful for pelvic fixation. For additional Lateral Offset Connectors please see the Iliac Fixation section.

Note: Ensure that the Screw Offset is perpendicular to the screw head.

Offset Connector

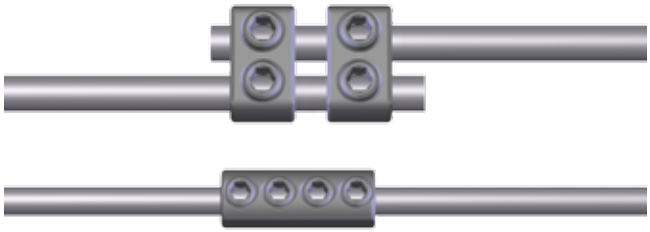
XII. Rod-to-Rod Connectors

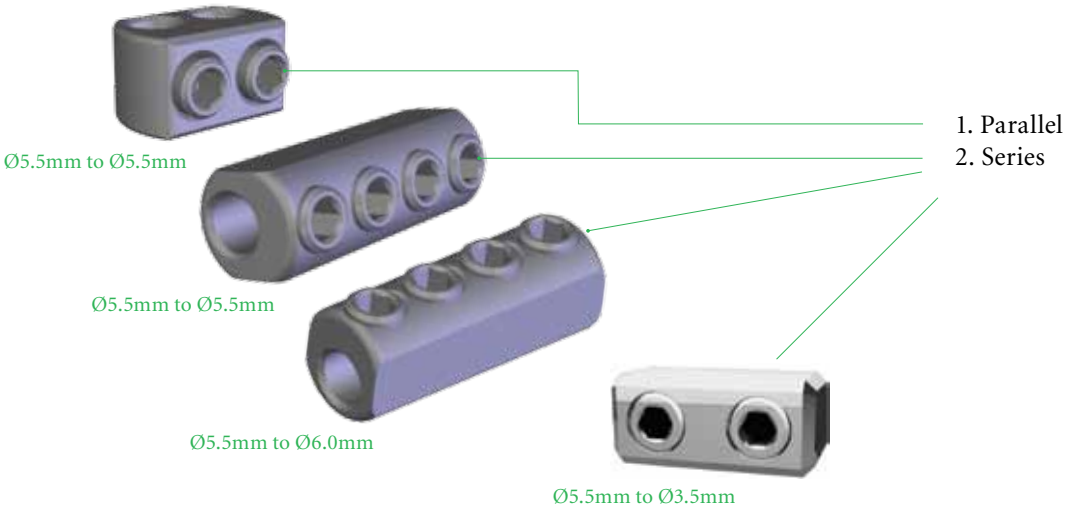
Rod-to-Rod Connection

Rod-to-Rod connection is occasionally necessary. There are two options available:

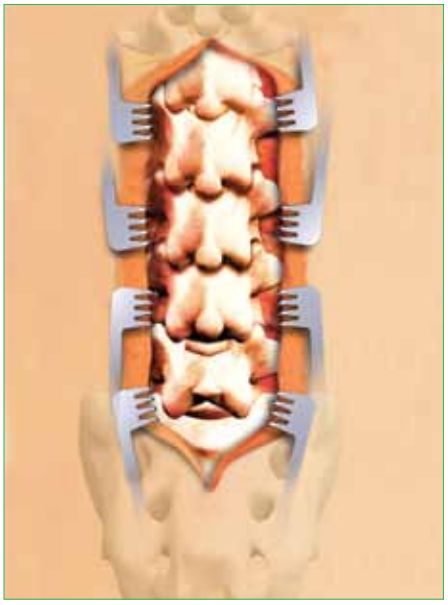
1. Rod-to-Rod Connector Series
2. Rod-to-Rod Connector Parallel

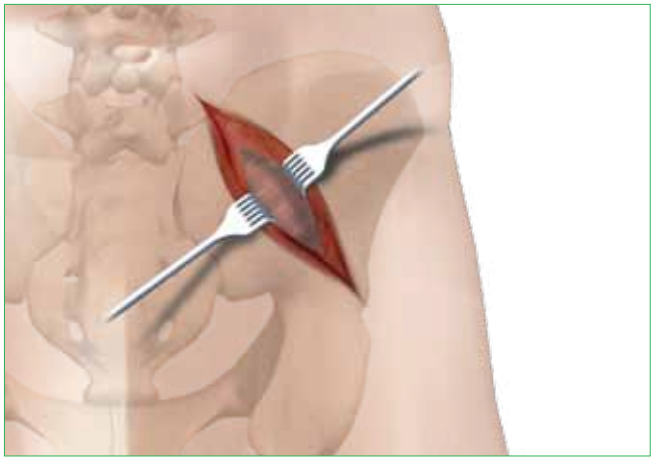
For tightening the Parallel Connector and the Series Connector use the 3.5mm **Hexagonal Driver**.





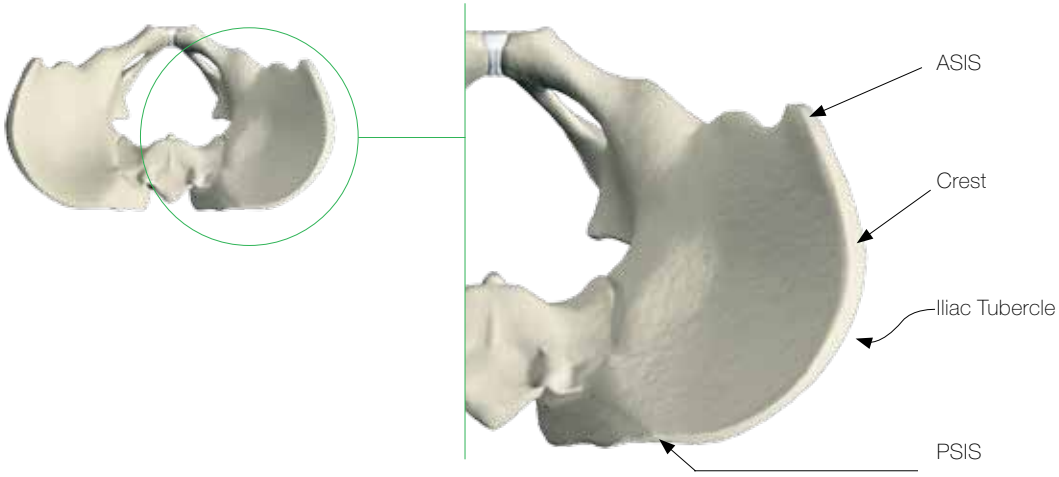
XIII. Iliac Fixation





Surgical Access

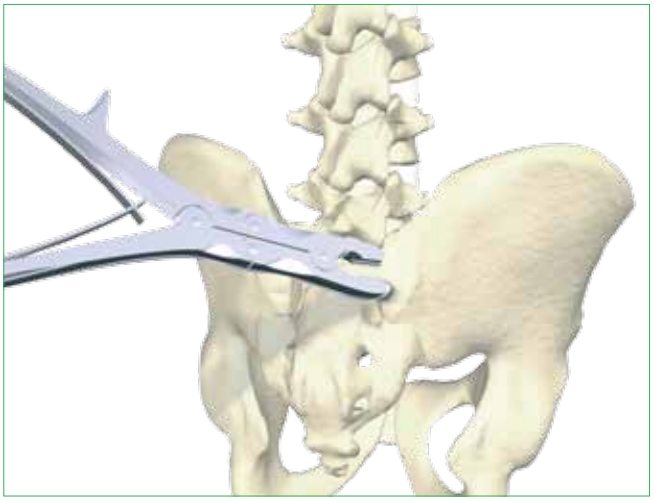
The lumbar spine is exposed first. To begin the pelvic anchorage procedure, a separate fascial incision over the posterior iliac crest is made to allow placement of intra iliac screws. The lumbar spine exposure, surgical procedure (decompression, etc) and instrumentation are completed prior to placement of iliac/pelvic screws. Following the initial incision, a subperiosteal dissection of the outer table of the pelvis provides access to the pelvic anchorage site. The inner table is exposed to a depth of approximately 1.5cm to facilitate notching the crest and tunneling of the connector. This tunneling approach is straight forward and leaves the muscle attached, providing better coverage and a simpler closure.

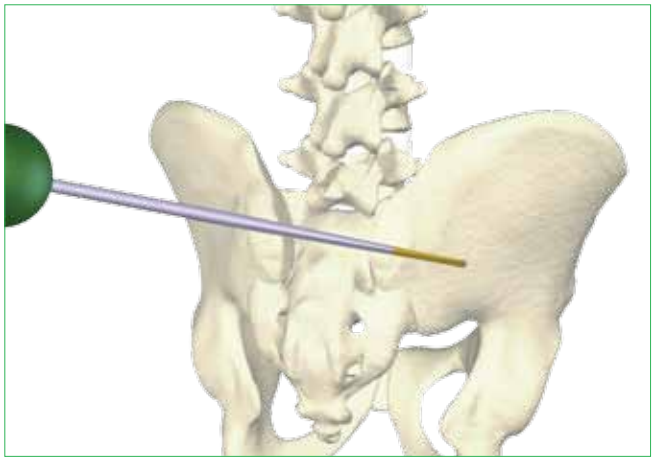


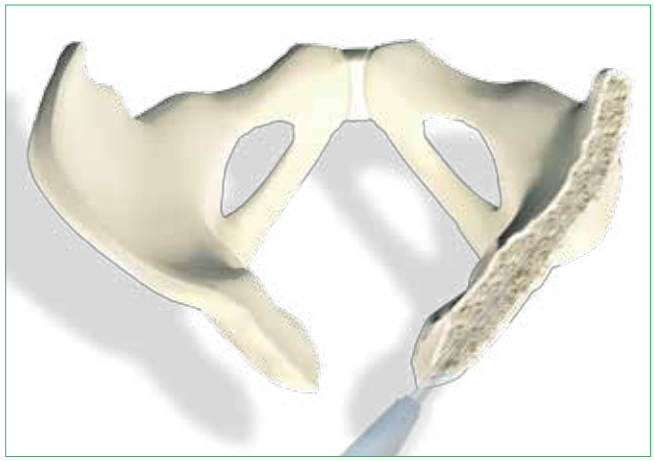
XIII. Iliac Fixation

Pelvic Screw Path Preparation

With the posterior crest and outer table exposed the surgeon is ready to place the pelvic screw. Approximately 1.0 to 2.0cm up from the tip of the spine is an ideal starting point. At this point, the crest widens and provides a wide channel for the implant. Use a rongeur to make a notch in the crest of sufficient depth and width to accept the head of the implant. The top of the implant (after insertion) should not be proud beyond the contour of the crest. Prominent implants can be a problem in this area. Use a curette to start the path between the tables of the pelvis. This curette is used for the first 1.0 to 2.0cm. After the curette, use a Straight Probe to sound the path between the tables over the notch. Stop every few centimeters to check with a Ball Tip Feeler to verify integrity of the canal. When the trajectory and depth are proven, measure the depth of the canal using the laser markings on the Probe.





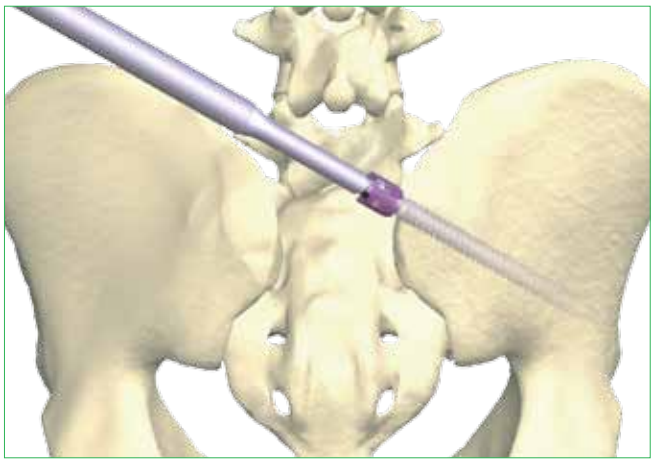


XIII. Iliac Fixation

Pelvic Screw Placement

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

Generally a 6.75mm – 8.75mm diameter screw by 80mm long is used in most patients.

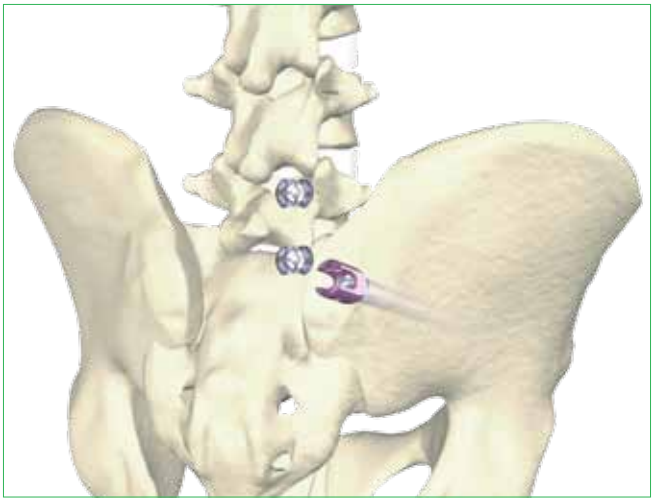


Both the **Multi-Angle Screw Inserter** and the **Standard Screw Inserter** are designed to provide a rigid connection between the screw and screwdriver.

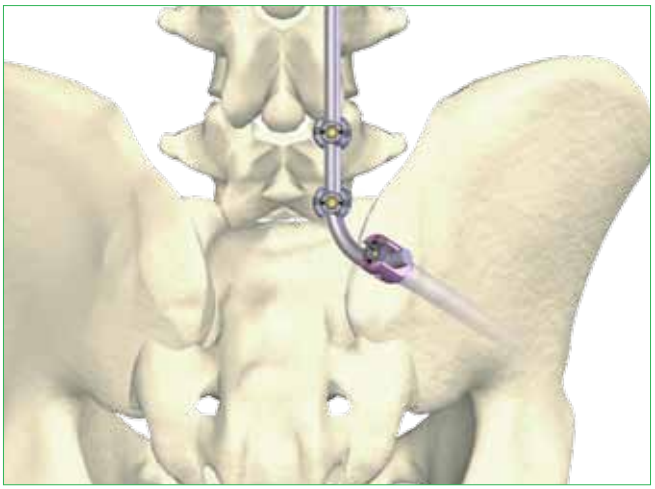
XIII. Iliac Fixation

Axial Connection

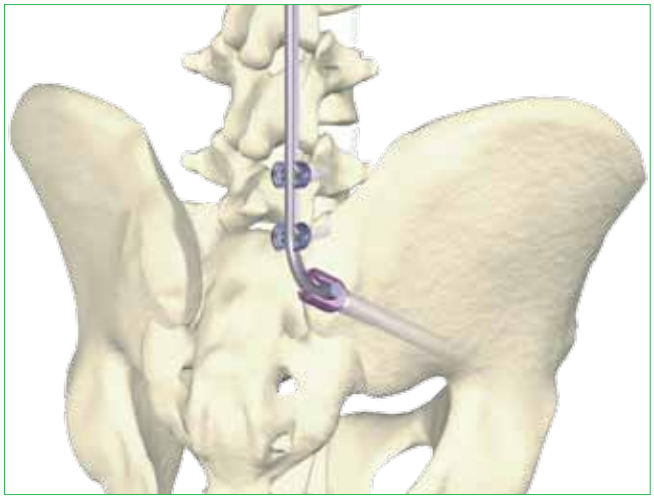
The connection of the pelvic screw to the axial construct can either be direct (main construct rod captured by the iliac screw) or with a connecting implant.



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

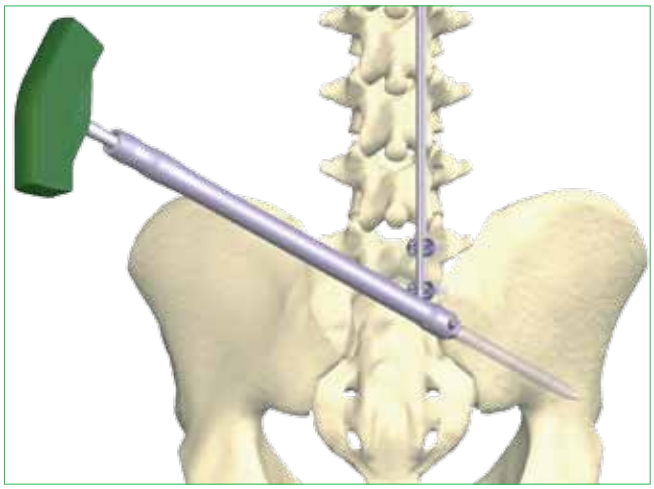


XIII. Iliac Fixation

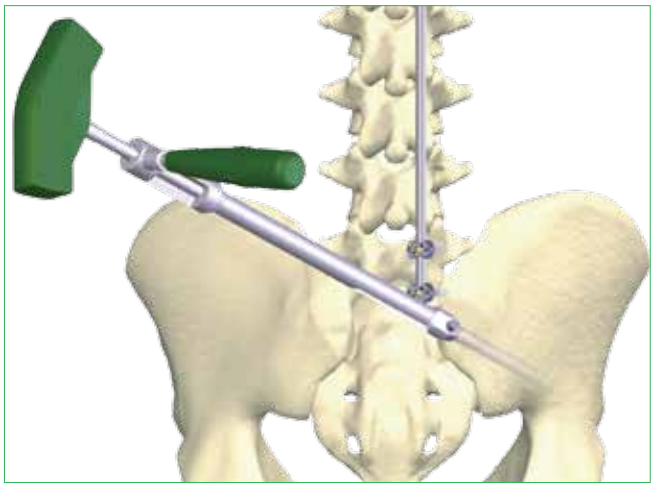


Axial Connection

Use a Shindt Clamp in order to tunnel to the lumbar wound. After tunneling through the wound, pass the axial rod or connector through.



The Initial Insertion Tube can help align the Locking Cap with the implant.



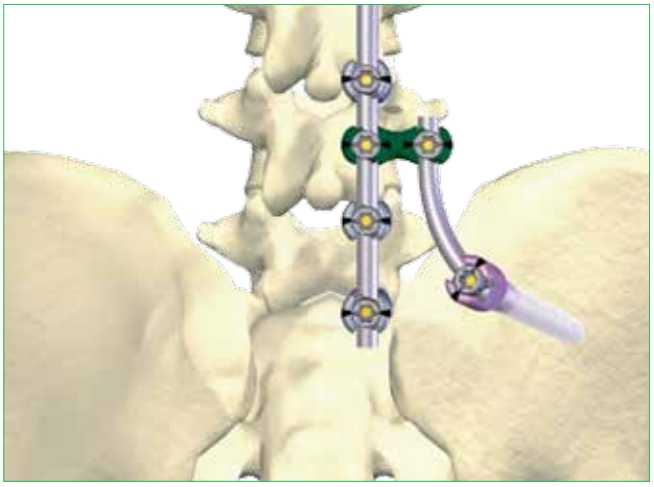
The final tightening of the Locking Cap is done by utilizing the Counter Torque Tube and Final Driver. Verify that the laser marked lines on the Locking Cap are aligned with the laser marked zone on the screw to confirm that the construct is fully locked.

XIII. Iliac Fixation

Parallel Connection

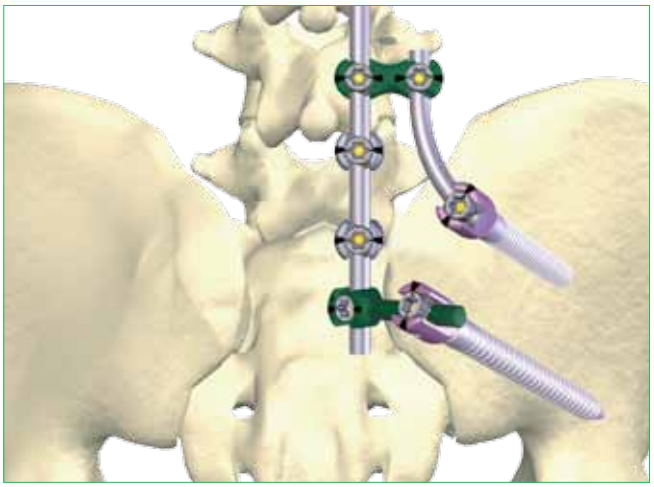
The Radius Spinal System also offers a parallel connection from the main construct to the ilium. The Rod-to-Rod Connectors help enable a surgeon to connect from the lumbar region to the ilium using one of four options:

1. Small Rod-to-Rod Connector (Neutral)
2. Small Rod-to-Rod Connector (30°)
3. Large Rod-to-Rod Connector (Neutral)
4. Large Rod-to-Rod Connector (10°)



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

1. Offset Connector (75° bend)
2. Offset Connector (Neutral)
3. Offset Connector (105° bend)
4. Long Offset Connector (Neutral)



Offset Connector
75° bend

Offset Connector
Neutral

Offset Connector
105° bend

Long Offset Connector
Neutral

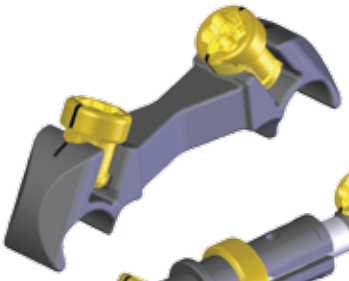
Small Rod-to-Rod Connector
Neutral

Small Rod-to-Rod Connector
30°

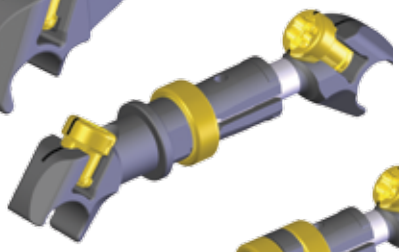
Large Rod-to-Rod Connector
Neutral

Large Rod-to-Rod Connector
10°

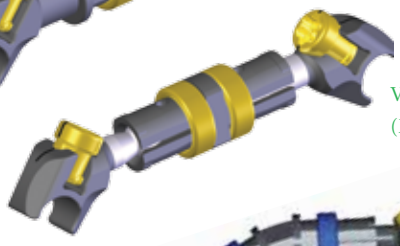
XIV. Cross Connectors



Fixed Cross Connector
(22mm - 36mm)

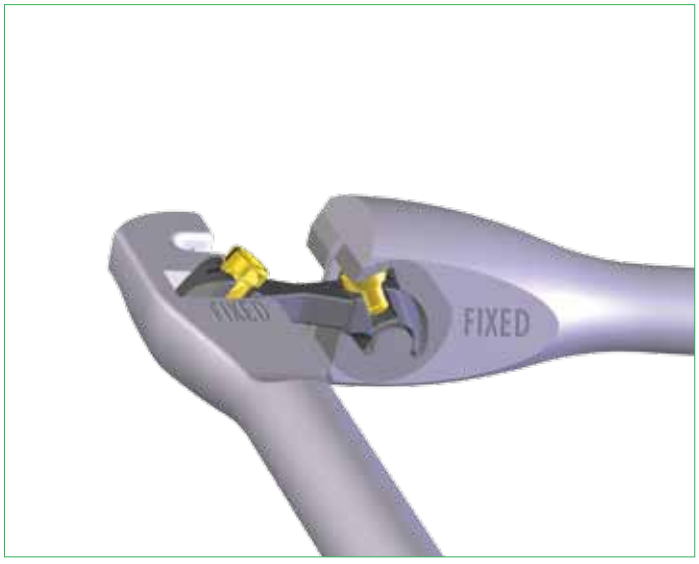


Variable Cross Connector
(Short, Med, Long; 35mm-86mm)



Variable Multi-Angle Cross Connector
(Med, Long; 46mm-75mm)

Variable Multi-Angle Curved Cross Connector
(XS, S, Med, Long, XL, XXL; 35mm-104mm)



Cross Connectors

Cross Connectors are recommended for increased rotational stability of the construct.

Use the Cross Connector Caliper to determine the appropriate size cross connector.

Choose the appropriate Variable or Fixed Cross Connector length and place it onto the rod.

Note: The Variable Multi-Angle Curved Cross Connector is designed to be used when only a portion of the spinous process is removed.

Accommodating Divergent Rods

Two options are available to accommodate divergent rods. The Multi-Angle Cross Connector features a variable head on one side which allows the connector to be placed on divergent rods without bending.

If using the Variable Cross Connector or the Fixed Cross Connector, bending may be performed to accommodate divergent rods.

The set of Cross Connector Benders has been etched to help indicate which slots will accommodate Fixed or Variable Cross Connectors.

Bending Fixed Cross Connectors

1. To bend a Fixed Cross Connector, place either Fixed Cross Connector Clamp into the Fixed Cross Connector Slot of the Cross Connector Bender.

2. Place the other Clamp of the Fixed Cross Connector into the Fixed Nest Slot built into the top of the Cross Connector J-Tip Bender.

Tip: The Fixed Cross Connector may be bent up to 22°. Overbending will result in immediate implant fatigue and possible breakage.

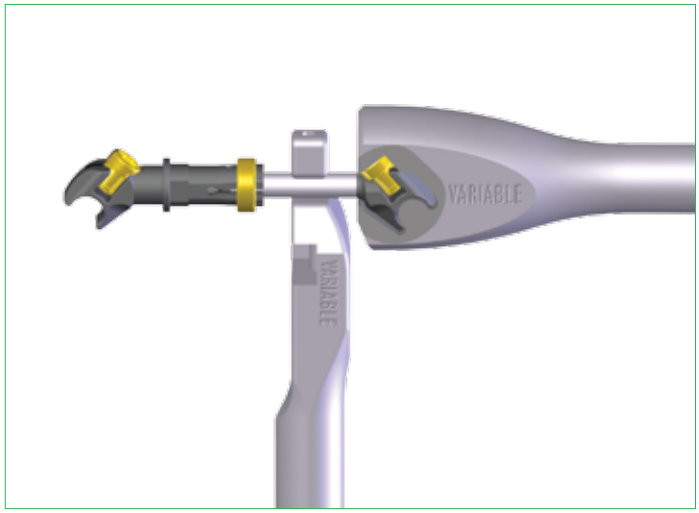
XIV. Cross Connectors

Bending Variable Cross Connectors

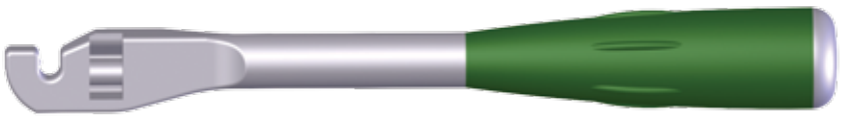
1. To bend Variable Cross Connector, place the Variable Cross Connector Clamp into the "Variable" Slot of the Cross Connector Bender.

Tip: To alleviate confusion, the Slot on the Cross Connector Bender will only accommodate the Clamp on the rod side of the Variable Cross Connector.

2. Grasp the internal bar of the Variable Cross Connector with the "Variable" Nest Slot built into the top of the Cross Connector Bender. Bend the internal bar.



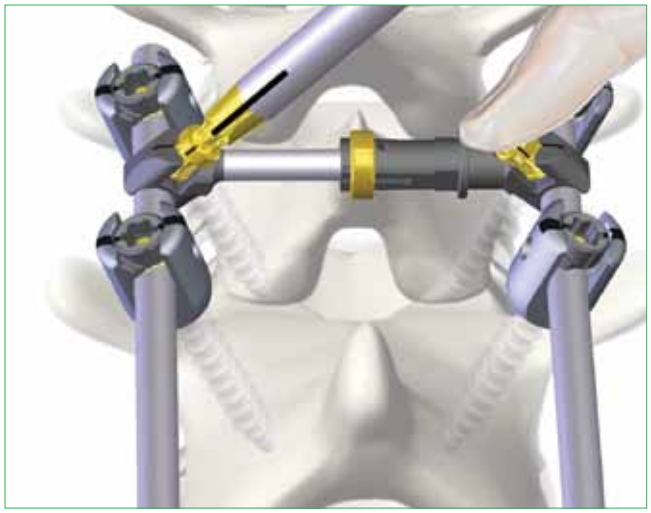
Tip: It is recommended that the bend be introduced into the rod as close to the Clamp as possible so as not to interfere with the locking procedure.



Cross Connector Bender Left

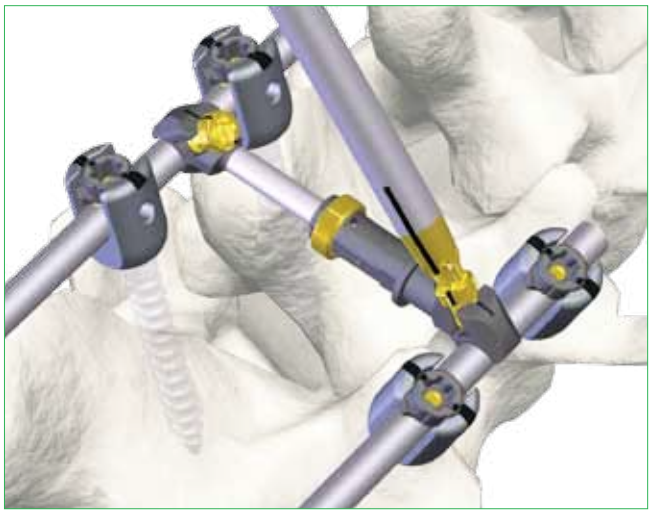
Cross Connector Bender Right

XIV. Cross Connectors

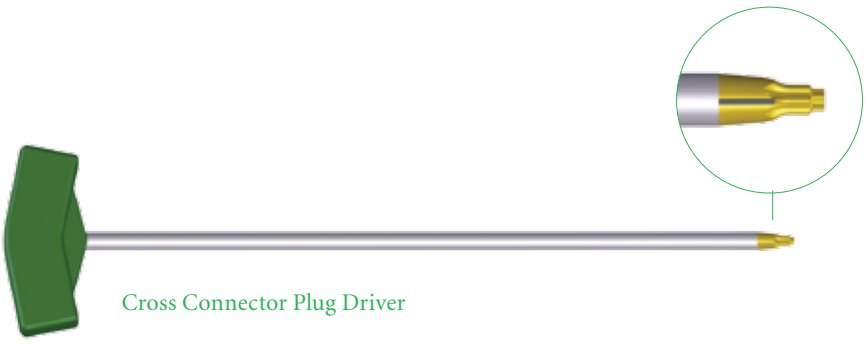


Cross Connector Tightening

1. Use the Cross Connector Plug Driver to twist the Locking Plug in either direction until the line on the Locking Plug is aligned with the laser marked line on the Clamp. Using the cross connector holder, place the connector on the rods and press downward until the clamp engages the rod.



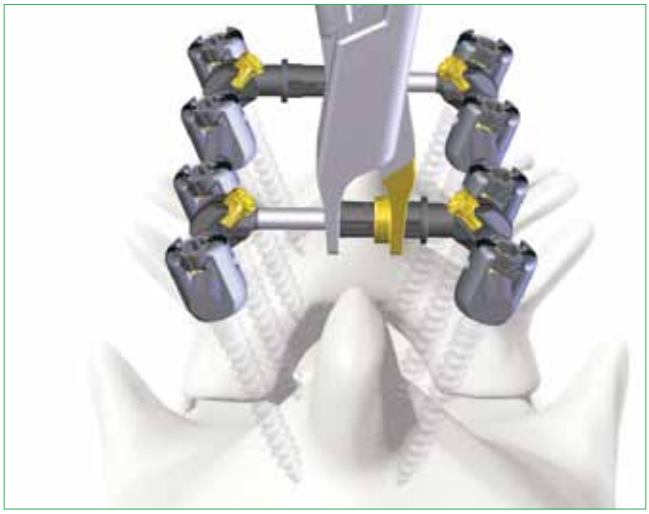
2. Stabilize the Cross Connector using a finger in the middle of Cross Connector and tighten the Locking Plug on the opposite side.



Cross Connector Plug Driver

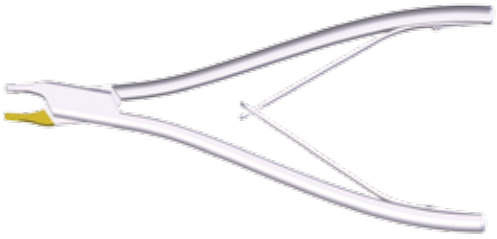
XIV. Cross Connectors

3. If using a Variable Cross Connector, use the Cross Connector Closer to squeeze the Locking Collet to completely lock the Variable Cross Connector.



Tip: The gold jaw of the Cross Connector Closer is placed against the gold collet of the Cross Connector during tightening.

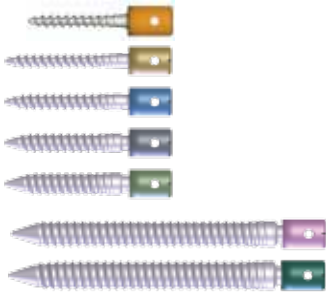
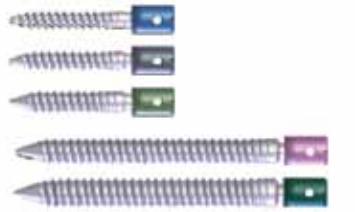
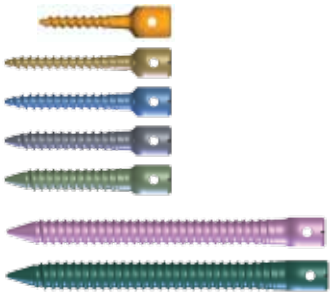
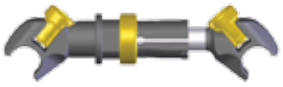
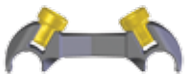
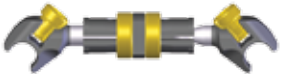
Tip: It is easier to lock the fixed-head of the Variable Cross Connector first.



Cross Connector Closer

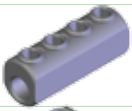
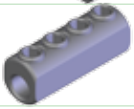
Apply bone graft to the fusion site and close in the usual manner.

Implants

	Reference Number	Description
	486610000	Locking Cap
	4866113 (15) to (55) Ø4.00 4866114 (25) to (55) Ø4.75 4866115 (25) to (65) Ø5.75 4866116 (25) to (00) Ø6.75 4866117 (25) to (00) Ø7.75 4866118 (70) to (00) Ø8.75 4866119 (30) to (00) Ø9.75	Multi-Angle Screws
	4866185 (25) to (65) Ø5.75 4866186 (25) to (00) Ø6.75 4866187 (25) to (00) Ø7.75 4866188 (30) to (00) Ø8.75 4866189 (30) to (00) Ø9.75	Multi-Angle, Rapid Screws
	4866103 (15) to (55) Ø4.00 4866104 (25) to (55) Ø4.75 4866105 (25) to (65) Ø5.75 4866106 (25) to (00) Ø6.75 4866107 (25) to (00) Ø7.75 4866108 (70) to (00) Ø8.75 4866109 (30) to (00) Ø9.75	Screws, Standard
	486614100 - Short 486614110 - Medium 486614120 - Long	Variable Cross Connectors (35mm-86mm)
	4866140(22) to (36)	Cross Connectors (22mm-36mm)
	486614170 - Medium 486614180 - Long	Variable Multi-Angle Cross Connectors (46mm-75mm)
	486614128 - Extra Small 486614129 - Small 486614130 - Medium 486614140 - Long 486614150 - Extra Long 486614160 - Extra Extra Long	Variable Multi-Angle Curved Cross Connectors (35mm-104mm)
	486614565	Offset Connector
	486614375	Offset Connector 75 ° Bend
	486614310	Offset Connector Neutral

Reference Number	Description	
486614305	Offset Connector 105° Bend	
486614320	Long Offset Connector Neutral	
486614300	0° Small Rod-to-Rod Connector	
486614330	30° Small Rod-to-Rod Connector	
486614400	0° Large Rod-to-Rod Connector	
486614430	10° Large Rod-to-Rod Connector	
486616000	Laminar Hook Small, Standard Blade	
486616002	Laminar Hook Large, Standard Blade	
486616001	Laminar Hook Small, Narrow Blade	
486616003	Laminar Hook Large, Narrow Blade	
486616005	Laminar Hook Offset, Right	
486616006	Laminar Hook Offset, Left	
486616004	Laminar Hook Extended Body	
486616007	Laminar Hook Angled Blade	
486616008	Thoracic Laminar Hook, Standard Blade	
486616009	Thoracic Laminar Hook, Narrow Blade	
486616010	Thoracic Laminar Hook, Small Offset, Right	

Implants

	Reference Number	Description
	486616011	Thoracic Laminar Hook, Small Offset, Left
	486616012	Thoracic Laminar Hook, Large Offset, Right
	486616013	Thoracic Laminar Hook, Large Offset, Left
	486616014	Pedicle Hook Small
	486616015	Pedicle Hook Large
	486616016	Traverse Process Hook Right
	486616017	Traverse Process Hook Left
	486616018	RHB Laminar Hook, Narrow Blade
	486616019	RHB Laminar Hook, Standard Blade
	486616020	RHB Laminar Hook, Angled Blade
	486616021	RHB Thoracic Laminar Hook, Narrow Blade
	486616022	RHB Pedicle Hook
	48551086	Rod-to-Rod Connector Series (Ø3.5mm to Ø5.5mm)
	486614550	Axial Rod-to-Rod Connector (Ø5.5mm to Ø5.5mm)
	486614555	Parallel Rod-to-Rod Connector (Ø5.5mm to Ø5.5mm)
	486614560	Axial Rod-to-Rod Connector (Ø5.5mm to Ø6.0mm)

Reference Number	Description	
4866150 (30) to (20)	Ø5.5mm Titanium Rad Rod (30mm-120mm)	
4866155 (50) to (20)	Ø5.5mm Titanium Max Rad Rod (30mm-120mm)	
4866130 (03) to (20)	Ø5.5mm Titanium Spinal Rod, without Hex (30mm-120mm)	
486613 (50) to (600)	Ø5.5mm Titanium Spinal Rod, with Hex (50mm-600mm)	
486613602 486613601 486613242 486613241	Ø5.5mm x 600mm Vitallium Spinal Rod, with Hex Ø5.5mm x 600mm Vitallium Spinal Rod, without Hex Ø5.5mm x 240mm Vitallium Spinal Rod, with Hex Ø5.5mm x 240mm Vitallium Spinal Rod, without Hex	
4866151 (60) to (20)	Ø5.5mm Vitallium Rad Rod, with Hex (60mm-120mm)	
4866152 (60) to (20)	Ø5.5mm Titanium Rad Rod, with Hex (60mm-120mm)	

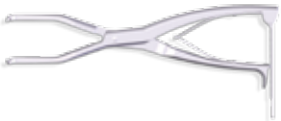
Instruments

	Reference Number	Description
	486619400	Screw Insertion Tray
	486619000	Pedicle Awl
	486619001	Pedicle Awl Conical
	486619002	Pedicle Awl Conical with Stop
	486619030	Sharp Probe Straight
	486619035	Sharp Probe Curved
	486619005	Blunt Probe Straight
	486619010	Blunt Probe Curved
	486619020	Blunt Probe Shaft
	486619025	Blunt Probe Shaft Grooved
	486619085	Probe Shaft T-Handle
	486619041	Pedicle Tester Malleable
	486619043	Pedicle Tester Flexible
	486619040	Pedicle Tester

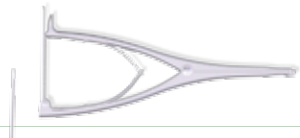
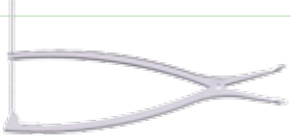
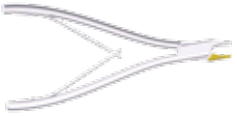
Instruments

Reference Number	Description		
486619050	Drill Sleeve	Ø4.00mm Ø4.75mm Ø5.75mm Ø6.75mm Ø7.75mm	
486619051	Drill Sleeve	Ø8.75mm Ø9.75mm	
486619052 486619055 486619056 486619057 486619058 486619315 486619320	Ø3.50mm Tap Ø4.25mm Tap Ø5.25mm Tap Ø6.25mm Tap Ø7.25mm Tap Ø8.25mm Tap Ø9.25mm Tap		
486619060 486619061 486619062 486619063 486619064	Ø5.25mm Rapid Tap Ø6.25mm Rapid Tap Ø7.25mm Rapid Tap Ø8.25mm Rapid Tap Ø9.25mm Rapid Tap		
486619095	Multi-Angle Screw Inserter		
486619110	Standard Screw Inserter		
486619100	Multi-Angle Adjustment Tool		
486619080	Cannulated T-Handle		
486619070	Cannulated Ratcheting T-Handle		
486619075	Cannulated Standard Handle		
486619065	Cannulated Standard Ratcheting Handle		
486619120	3.5mm Hex Shaft		
486619410	Fixation Tray		
486619480	Rapid Fixation Tray		

Instruments

	Reference Number	Description
	486619170	Rod Bender
	486619145	Rod Insertion Scissor
	486619146	Rod Insertion Forceps
	486619175	Rod Gripper
	486619180	Rod Pusher
	486619185	Rocker
	486619187	Locking Cap Magazine
	486619190	Rod Persuader
	486619210	Capspin
	486619215	Initial Inserter
	486619220	Initial Inserter Tube
	486619380	Under Rod Distractor
	486619390	Under Rod Compressor

Instruments

Reference Number	Description	
48026000	Compressor	
48026100	Distractor	
486619395	Scoliosis Compressor	
486619385	Scoliosis Distractor	
486619235	Counter Torque Tube	
486619240	Final Driver	
486619431	Cross Connector Tray	
486619280	Cross Connector Caliper	
48040247	Cross Connector Holder	
486619255	Cross Connector Bender Left	
486619260	Cross Connector Bender Right	
486619250	Cross Connector Plug Driver	
486619245	Cross Connector Closer	

Instruments

	Reference Number	Description
	486619421	Thoracic Tray
	486619125	Pedicle Finder
	486619130	Lamina and Traverse Process Finder
	486619165	Hook Holder
	486619166	Hook Holder Straight
	486619135	Hook Impactor
	486619138	Hook Impactor Blocker
	03710621	Rod Template
	486619155	In-Situ Bender Right
	486619150	In-Situ Bender Left
	486619160	4.5mm Combination Wrench
	486619451	Iliac Tray

Indications

The Radius Spinal System is intended for use in the noncervical spine. When used as an anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation system, the Radius Spinal System is intended to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities:

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

The Radius Spinal System can also be linked to the Xia Titanium Spinal System via the Ø5.5mm to Ø6.0mm Radius rod-to-rod connector.

Contraindications

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

- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Insufficient quality or quantity of bone which would inhibit rigid device fixation.
- Previous history of infection.
- Excessive local inflammation.
- Open wounds.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Patients having inadequate tissue coverage of the operative site.
- Pregnancy.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure, or other complications.
- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
- Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.

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

Cautions and Warnings

CAUTIONS (U.S.A.)

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

WARNING (U.S.A.)

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to spondylolisthesis (grades 3 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
Radius implant components have not been tested for heating or migration in MR environment.

Removal of Implants

These implants are temporary internal fixation devices designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and can be removed. Removal may also be recommended in other cases, such as:

- Corrosion with a painful reaction
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains
- Failure or mobilization of the implant

Standard ancillaries provided by Stryker Spine can be used to remove the implants. Any decision by a physician to remove the internal fixation device must take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal. Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically. Implant removal must be followed by adequate postoperative management to avoid fracture or re-fracture. Removal of the implant after fracture healing is highly recommended. Metallic implants can loosen, bend, fracture, corrode, migrate, cause pain or stress shield bone.

Information for Patients

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weightbearing, activity levels, and the necessity for periodic medical follow-up.
The patient must be warned of the surgical risks and made aware of possible adverse effects. The patient must be warned that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) he/she should be warned that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For diseased patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.

REUSE

Never reuse or reimplant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.
It is recommended to verify that the instruments are in good condition and operating order prior to use during surgery.

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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