Radius™ Surgical Technique

- Zone of locking security
- No cross threading
- Simpler, no torque closure
- Low profile screw design
Stryker Promise

At Stryker, we believe results speak louder than words. Since the Company’s founding in 1941, that philosophy has made us a leader in the worldwide orthopaedic market and placed us at the forefront of medicine’s most promising solutions. Today, we are one of the preeminent medical products and services companies in the world.

Introduction

The Radius™ Anterior Spinal System incorporates a number of engineering features that make the system unique. These features include a one-step (two stage) locking mechanism, a floating saddle 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 and is designed to reduce the potential for false locking and cross threading. This award winning non-threaded technology helps increase the speed, ease of use, and reliability of connecting rods to screws.

This surgical technique sets forth detailed, recommended procedures for using the Radius™ Anterior Spinal System.

Stryker Spine would like to extend their sincere gratitude to the following surgeons for their participation in the development of the Radius™ Anterior Spinal System:

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

Important – The Radius™ Anterior 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™ Anterior 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.

Please 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 should be trained before proceeding.
I. Patient Positioning
II. Staple Placement
III. Screw Preparation and Insertion
IV. Vertebral Body Distraction
V. Rod Placement and Compression
VI. Final Tightening
VII. Cross Connectors

Implants
Instruments
Key Design Features

Ease of Use
An easier, no-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 standard screw and is designed to keep the screw head from spreading during locking.

- Low screw head height is designed to be patient friendly
- Small screw head diameter is designed to lead to less facet joint impingement and more room for bone graft*
- Short rod run-out is designed to be ideal for L5 – S1 fusions and cross connector placement
- Less overall profile helps to enable 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 lasermarked lines on the locking cap are within the lasermarked zone on the screwhead, giving a visual indicator that the system is fully locked.

* Data on file at Stryker Spine.
I. Patient Positioning

Anterior thoracolumbar instrumentation procedures are generally performed in the straight lateral position with the assistance of a general, thoracic, or vascular surgeon. Consult with the access surgeon to decide the optimal side of approach. An approach from the side of worst pathology is recommended in this Operative Technique. Though in general (below the thoracolumbar junction), the spine is often approached from the left to avoid the liver. Higher in the thoracic spine, a right-sided approach is recommended.

For approaches in the lumbar spine, flex the ipsilateral lower extremity to decrease lumbar-sacral plexus and psoas tension. Typically, vascular surgery will flex the contralateral lower extremity.

Maintain the position of the patient with bean bags and balsters. Larger patients will benefit from kidney rests or other devices that fix to the operating table. Carefully pad all bony prominences and maintain appropriate cervical spine alignment.

Improve surgical access by increasing the distance between the shoulder girdle and the pelvic rim. For flat spinal frames, center a gel roll at the intended surgical level. For flexible or standard operative tables, secure the table at the intended surgical level. Be careful about these maneuvers as iatrogenic scoliosis is possible in patients with burst fractures or other unstable lesions. Always unlatch the table or remove the gel roll prior to final implant tightening.

Next, confirm level localization. The involved level is often obvious with tumors and fractures, but a radiograph helps to orient the surgeon to regional anatomy. Combine a rib count with the radiograph to confirm the level of the thoracic spine.
II. Staple Placement

Staple Preparation and Insertion

Implantation begins with the placement of the **Dual Staple**. These staples come in extra-small, small, medium, and large sizes and help distribute cantilever loads across the entire vertebral body. The largest **Dual Staple** for the vertebral body should be used to ensure the greatest surface-to-surface contact. Rostral staples are green and Caudal staples are gray.

Clamp the staple with the **Dual Staple Holder/Impactor**, then tighten by turning the clamp until finger tight. Ensure that the spikes on the staple are facing towards the vertebral body when implanting. Fix the staple onto the vertebral body with a mallet.

**Note:** There is a tendency for surgeons to place the staple too far anteriorly on the vertebral body. To avoid this, surgeons should generously resect the rib head and adequately retract the psoas muscle. The surgeon should then be able to pass a probe along the posterior cortex and use this as a guide for staple placement.

The **Dual Staples** are marked anterior and posterior for left-sided approaches so be careful with right-sided approaches as these markings will be reversed. This system is designed so that when the construct is complete, the anterior rod is longer. In some cases, it may be convenient for the longer rod to be placed posterior. In either case, avoid a parallelogram configuration with the same sized rods as this may be weaker than trapezoidal constructs.

**Note:** A **Single Staple** is available and can be used in place of the **Dual Staples** if needed.

**Note:** A single **Washer** as well as a series of **Tall Washers**, in diameters 4.75mm – 8.75mm, are available and can be used under the tulip head to provide additional support to the screw if needed.
III. Screw Preparation and Insertion

Once the staples are placed, proceed with screw insertion. The entry point can be further prepared with the Anterior Awl.

The pathway is then completed with the Pedicle Probe. Advance the Pedicle Probe slowly and palpate the contralateral cortex before penetration. The surgeon should feel the Pedicle Probe piercing the opposite cortex. To ensure bicortical passage of the vertebral body, measure the depth of the vertebral body using the Pedicle Probe.

For the posterior screw tracts use the Anterior Awl to create a pathway angled 10 degrees anteriorly to avoid the spinal canal. For the anterior screw tracts use the Anterior Awl to create a pathway perpendicular to the vertebral body.
The Radius™ Anterior Spinal System is limited to use with 4.75, 5.75, 6.75, and 7.75mm Standard (monoxial) Screws.

Four Standard Screw diameters (4.75, 5.75, 6.75, and 7.75mm) are available in lengths ranging from 25 to 65mm except the 4.75mm diameter screws, which are available from 25 to 55mm. The 6.75mm screw is used in the majority of cases. For patients with large vertebral bodies or significant osteoporosis, surgeons should consider using 7.75mm diameter screws.

The Standard Screw Inserter provides a rigid connection between the standard screws and the inserter. After the vertebral body pathway is prepared, and proper screw length and diameter have been determined, the screw can be inserted.

The Standard Screw Inserter is designed to provide a very rigid connection with the Standard Screw. With the pedicle pathways prepared and proper screw length and diameter determined, the screw is ready for insertion.

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 tabs on the Standard Screw Inserter shaft with the external quad on the 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.

To insert Standard Screw:
1. Ensure that the Standard Screw Inserter is fully unlocked.
2. Drop the Standard Screw Inserter into the head of the screw.
3. Rotate the dial on the Standard Screw Inserter clockwise to firmly lock the screw onto the Standard Screw Inserter.
4. 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.
5. Remove the Standard Screw Inserter from the screw.

III. Screw Preparation and Insertion

Standard Screw
Once all screws are in place, distract the corpectomy defect using the Parallel Distractor. Place the feet of the Parallel Distractor into the heads of the most anterior screws to aid in graft placement. Distract the vertebral space by expanding the arms of the Parallel Distractor by rotating the key clockwise. Measure and place bone graft or an intervertebral body device into the corpectomy site. Release the distractor by depressing the key.

**Note:** It is recommended to use VLIFT® or VBOSS® as a vertebral body replacement system.
Once the graft or device is seated, use the appropriate pre-cut rods. Insert the rod into the screw heads and insert the Locking Caps.

**Note:** Bending of the rod is seldom necessary but if needed can be performed with the Rod Bender.

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

**Cap Insertion**

1. Assemble the Locking Cap onto the Initial Inserter by pushing firmly onto a Locking Cap in the Locking Cap Caddy.
2. Place the Locking Cap into the screw head and rotate clockwise until the lasermarkings on the Locking Cap and the Initial Inserter are parallel with the rod. The Locking Cap is now provisionally locked, the rod is blocked and the Initial Inserter can be removed.

V. Rod Placement and Compression
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.

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

Tip: Do not turn the Locking Cap past the provisional position with the Initial Inserter. Final tightening must be done with the Counter Touque Tube and Final Driver.
**V. Rod Placement and Compression**

**Rod Persuader and Capspin**

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

1. Ensure that the lower Bar on the Rod Persuader is in the neutral position, parallel to the rack.
2. Load the Locking Cap onto the Capspin of the Rod Persuader by pushing firmly on the Locking Cap in the Locking Cap Magazine.
3. With the Locking Cap assembled, place the Rod Persuader onto the screw head by clamping the forceps into the lateral grooves on the implant head.
4. Turn the upper T-Handle clockwise until the rod is fully seated. The 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.

5. Once the Bar turns to provisional lock, turn the Upper T-Handle 3 or 4 rotations counter-clockwise, then lift the Rack and remove the Rod Persuader.

Once the Locking Caps are provisionally locked, compress the corpectomy defect to lock the graft or intervertebral body device using the Parallel Compressor.
Once the correction procedures have been carried out and the spine is fixed in a satisfactory position, the final tightening of the Locking Cap is done by utilizing the Final Driver and the Counter Torque Tube.

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 aligning the lines on the Final Driver shaft with the lines on the Locking Cap.
3. Turn the Final Driver until the handle is perpendicular to the handle of the Counter Torque Tube or until the Final Driver no longer turns. The lasermarked lines on the Locking Cap should be within the laseretched zone on the screw head.

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

**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 allow one to maximize the torque needed to lock the implant assembly.
3) To hold the construct in place during final tightening.
VII. Cross Connectors

Cross connectors may help to improve the construct’s torsional rigidity. Use the Cross Connector Caliper to measure the appropriate size Cross Connector. Cross Connectors are available in sizes 15-20mm, increasing in 1mm increments.

Place the Cross Connector onto the rod using the Cross Connector Holder and press downward until the clamp engages the rod. Use the Cross Connector Plug Driver to turn the locking plug in either direction until the line on the locking plug is lined up with the line on the clamp. Stabilize the Cross Connector using a finger in the middle of the Cross Connector and tighten the locking plug on the opposite side.
<table>
<thead>
<tr>
<th>Part number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>486610000</td>
<td>Locking Cap</td>
</tr>
<tr>
<td>4866104 (25) to (55) Ø4.75</td>
<td>Standard Screws</td>
</tr>
<tr>
<td>4866105 (25) to (65) Ø5.75</td>
<td></td>
</tr>
<tr>
<td>4866106 (25) to (65) Ø6.75</td>
<td></td>
</tr>
<tr>
<td>4866107 (25) to (65) Ø7.75</td>
<td></td>
</tr>
<tr>
<td>486613 (050) - (110)</td>
<td>5.5mm Spinal Rod, with Hex</td>
</tr>
<tr>
<td>4866170 (06), (10), (20,), (30)</td>
<td>Ti Dual Staple, Caudal</td>
</tr>
<tr>
<td>4866170 (05), (15), (25), (35)</td>
<td>Ti Dual Staple, Rostral</td>
</tr>
<tr>
<td>486617040</td>
<td>Single Staple</td>
</tr>
<tr>
<td>4866142 (15) - (20)</td>
<td>Cross Connector</td>
</tr>
<tr>
<td>486617045</td>
<td>Washer</td>
</tr>
<tr>
<td>4866170 (50) - (54)</td>
<td>Tall Washer 4.75mm - 8.75mm Height</td>
</tr>
</tbody>
</table>
### Instruments

<table>
<thead>
<tr>
<th>Part number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>486619440</td>
<td>Anterior I Implants</td>
</tr>
<tr>
<td>486619445</td>
<td>Anterior II Instruments</td>
</tr>
<tr>
<td>486619265</td>
<td>Anterior Awl</td>
</tr>
<tr>
<td>486619270</td>
<td>Single Staple Impactor</td>
</tr>
<tr>
<td>48040241</td>
<td>Dual Staple Holder Impactor</td>
</tr>
<tr>
<td>486619010</td>
<td>Blunt Probe Curved</td>
</tr>
<tr>
<td>486619110</td>
<td>Standard Screw Inserter</td>
</tr>
<tr>
<td>486619170</td>
<td>Rod Bender</td>
</tr>
<tr>
<td>486619190</td>
<td>Rod Persuader</td>
</tr>
<tr>
<td>486619210</td>
<td>Capspin</td>
</tr>
<tr>
<td>48361500</td>
<td>Parallel Distractor</td>
</tr>
<tr>
<td>48040244</td>
<td>Parallel Compressor</td>
</tr>
<tr>
<td>Part number</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>---------------------------------------</td>
</tr>
<tr>
<td>486619215</td>
<td>Initial Inserter</td>
</tr>
<tr>
<td>486619220</td>
<td>Initial Inserter Tube</td>
</tr>
<tr>
<td>486619235</td>
<td>Counter Torque Tube</td>
</tr>
<tr>
<td>486619240</td>
<td>Final Driver</td>
</tr>
<tr>
<td>486619280</td>
<td>Cross Connector Caliper</td>
</tr>
<tr>
<td>48040247</td>
<td>Cross Connector Holder</td>
</tr>
<tr>
<td>486619250</td>
<td>Cross Connector Plug Driver</td>
</tr>
<tr>
<td>486619065</td>
<td>Cannulated Standard</td>
</tr>
<tr>
<td></td>
<td>Ratcheting Handle</td>
</tr>
<tr>
<td>486619070</td>
<td>Cannulated T- Ratcheting Handle</td>
</tr>
<tr>
<td>486619075</td>
<td>Cannulated Standard Handle</td>
</tr>
<tr>
<td>486619080</td>
<td>Cannulated T-Handle</td>
</tr>
</tbody>
</table>
Indications

INDICATIONS OUTSIDE USA FOR THE RADIUS™ SPINAL FIXATION SYSTEM
The Radius™ Spinal System is indicated for temporary or permanent correction or stabilization of the vertebral column from the thoracic to the sacrum with the aim of helping consolidation or bone fusion. Radius™ Spinal System is designed for posterior fixation procedures. It is indicated for degenerative disc disease of the thoracic and lumbar spine, which is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

INDICATIONS FOR USA
The Radius™ Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle, and non-pedicle fixation for the following indications: 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 Stryker Spine DIAPASON® Spinal System, OPUS® Spinal System, Oasys Spinal System, and XIA® Spinal System can be linked to the Radius™ Spinal System via the 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

**CAUTION (S)**
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.

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 (in pediatric use)
- 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 surgeon must warn patients 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) the surgeon must warn the patients 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.
The information presented in this brochure is intended to demonstrate a Stryker product. Always refer to the package insert, product label and/or user instructions before using any Stryker product. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

Products referenced with ™ designation are trademarks of Stryker.
Products referenced with ® designation are registered trademarks of Stryker.

Literature Number: TLRADST08031
LFM/GS 2.0m 03/08

Copyright © 2008 Stryker
Printed in USA