



VIPER™ 2.



SYSTEM GUIDE

DEGENERATIVE



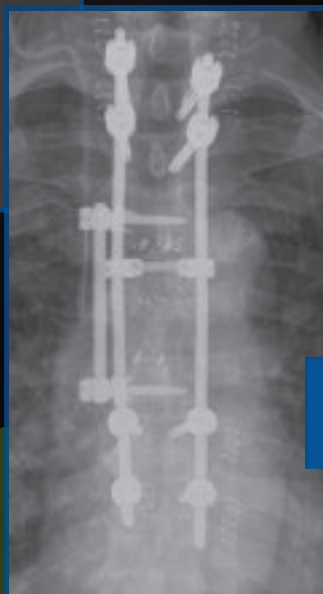
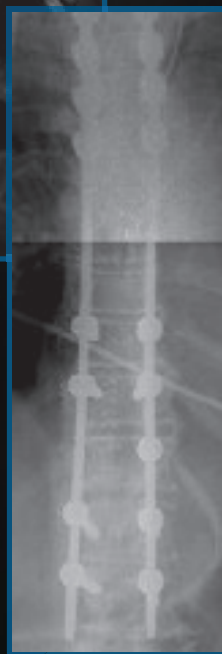
DEFORMITY

VIPER²

TAKING PERCUTANEOUS FIXATION TO THE NEXT LEVEL.



TRAUMA



TUMOR

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SYSTEM OVERVIEW

VIPER™ 2, the evolution of minimally invasive spine surgery. Building upon the groundbreaking design and intuitive techniques established by the original VIPER™ System, VIPER2 empowers Spine Surgeons to treat an unparalleled range of pathologies with a single platform solution.

By delivering a comprehensive range of instrumentation and implant options, VIPER2 provides Surgeons with the confidence and control required to address more advanced indications with a less invasive approach.

Born from EXPEDIUM™, evolved from VIPER, VIPER2 takes percutaneous fixation to the next level.

DEGENERATIVE



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TAKING PERCUTANEOUS FIXATION TO THE NEXT LEVEL.

PERCUTANEOUS TREATMENT OF A DEGENERATIVE SPONDYLOLISTHESIS USING THE VIPER2 SYSTEM

Carl Laurysen, MD and Pablo Pazmino, MD
Olympia Medical Center, Los Angeles, CA

History of Present Illness and Radiographs:

- 45 year female with intense lower back and leg pain who previously underwent, L4 - S1 laminectomy and discectomy five years ago
- Her symptoms gradually worsened over the past 5 years and currently reports a VAS of 10
- Imaging revealed a grade 1 spondylolisthesis at L5 - S1, and pars fracture at L4 - L5 with evidence of instability on flexion extension films (Figures 1, 2 & 3)



Figure 1: Flexion



Figure 2: Neutral



Figure 3: Extension

Treatment Method and Materials:

- Two level interbody fusions were performed from an anterior approach at L4/L5 and L5/S1
- The graft was secured using an AEGIS™ lumbar plate at L5/S1 and a buttress screw at L4/L5
- The patient was flipped and posterior MIS decompression was performed using the SPOTLIGHT™ tubular retractor system
- Six VIPER pedicle screws were placed percutaneously at the L4, L5 and S1 levels

- Two 70mm pre-lordosed rods were placed percutaneously and once in place, the VIPER2 reduction instrument was used to reduce the spondylolisthesis at L5
- Total anesthesia time was 4 hrs and the blood loss was 100cc's

Follow-up Results:

- Patient was discharged on post-op day three and at one week reported relief of pre-operative symptoms
- At three months follow up, radiographs demonstrated evidence of fusion and good alignment at operative levels (Figures 4 and 5)
- Presently, she reports good pain relief and has resumed nearly full job functions

The VIPER2 System provided a quick and easy-to-use option for reducing this patient's degenerative spondylolisthesis with minimal muscle trauma.



Figure 4: Lateral Post-op X-Ray



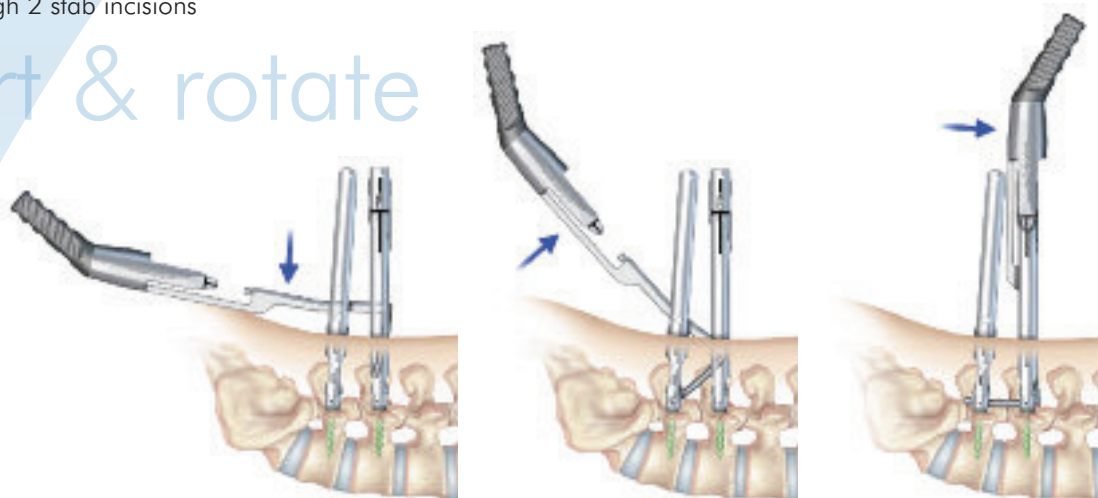
Figure 5: A-P Post-op X-Ray

A faster, simpler approach to percutaneous degenerative fixation.

STREAMLINED ROD PLACEMENT

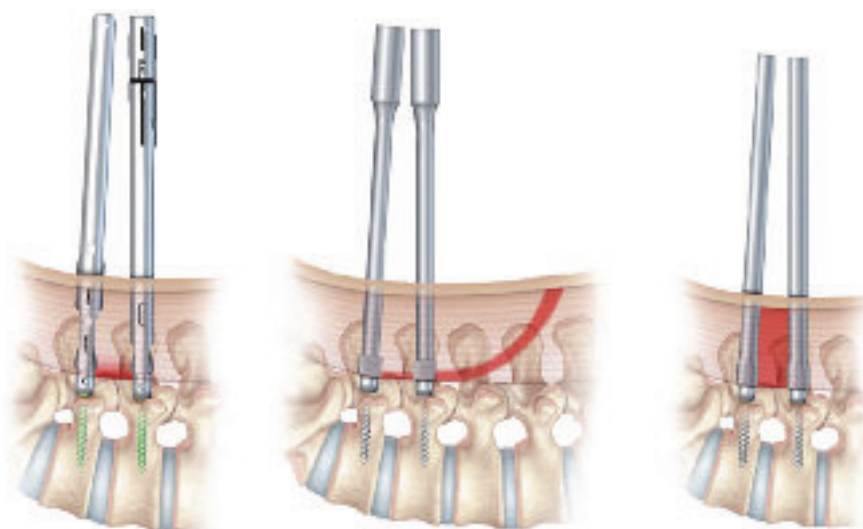
Simple and repeatable rod
placement through 2 stab incisions

insert & rotate



MINIMAL MUSCLE TRAUMA

A truly percutaneous technique
eliminates any unnecessary incisions
and tissue trauma



VIPER 2

Competitor 1

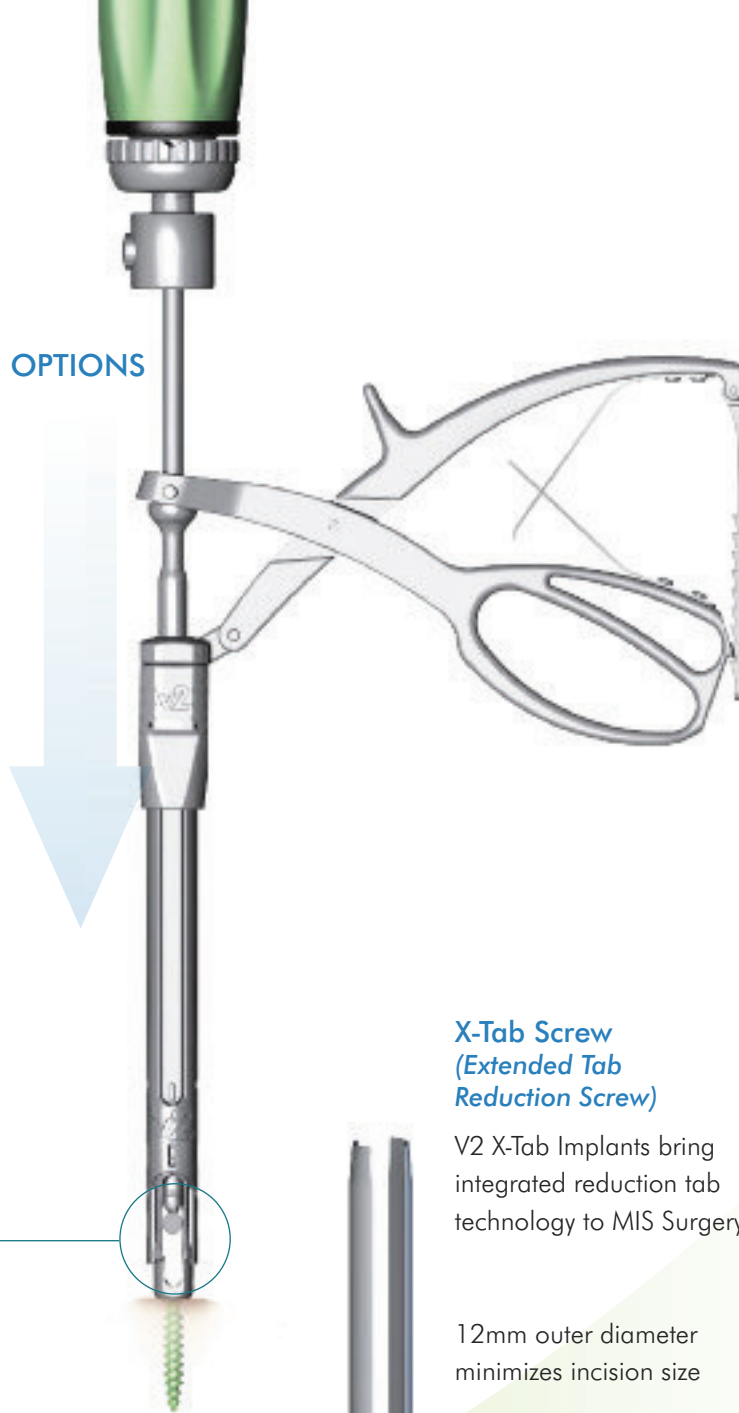
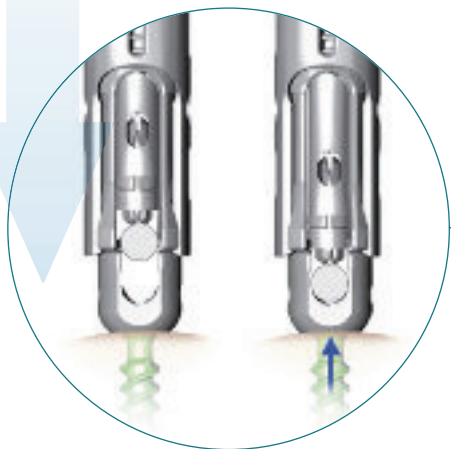
Competitor 2

SIMPLE PERCUTANEOUS REDUCTION OPTIONS

Comprehensive internal rod reduction options to simplify even the most difficult cases without compromising incision size

Pistol-Grip Reducer

Quickly connect to any V2 Extension for easy one-step internal reduction



X-Tab Screw (Extended Tab Reduction Screw)

V2 X-Tab Implants bring integrated reduction tab technology to MIS Surgery

12mm outer diameter minimizes incision size

Integrated break-off reduction tabs eliminate the need for extension assembly



Simple threaded reduction

DEFORMITY

VIPER².

TAKING PERCUTANEOUS FIXATION TO THE NEXT LEVEL.

PERCUTANEOUS SHORT SEGMENT ADULT DEFORMITY TREATMENT USING THE VIPER2 SYSTEM

D. Greg Anderson, MD

Thomas Jefferson University, Department of Orthopaedics

History of Present Illness and Radiographs:

- 57 year old male presented with a bilateral back, buttock and thigh pain and reports symptoms had progressively worsened for the last 5 years
- The patient had been treated with physical therapy, NSAIDS and epidural injections, but these treatments had become ineffective over last year
- Imaging revealed the presence of a 30° degenerative scoliotic curve in the lumbar spine (Figures 1 and 2)



Figures 1 and 2: AP and lateral views

Treatment Method and Materials:

- Interbody fusions and releases of the deformity were performed at the L2 - L5 disc spaces using a lateral approach
- The patient was then flipped and the SPOTLIGHT tubular retractor system was used to posteriorly decompress areas of lateral recess stenosis at the L2 - L5 levels. Bilateral decortication of the facet joints for fusion was also performed at L2 - L5 at this time
- Using the same skin incisions, seven percutaneous VIPER pedicle screws were placed under fluoroscopic guidance at the L2, L3 (unilateral), L4 and L5 levels
- Two 200mm straight VIPER2 rods were cut and contoured using the tops of the screw extensions as a guide
- The rods were placed percutaneously and once in place, VIPER2 reduction and compression instruments were used to help correct the sagittal and coronal alignment
- The total anesthesia time for both stages of the surgery was 4.5 hrs and the blood loss was 150cc's

Follow-up Results:

- Patient was mobilized to a chair the evening of surgery and discharged on postoperative day two
- By post-op week two, he reported good relief of his pre-operative symptoms and was able to resume normal work functions, including attending a conference in another state by week three
- At one year, radiographs demonstrated a solid fusion at all operative levels (Figures 3 and 4)
- Presently, he reports excellent pain relief and has resumed an active life style

The VIPER2 System allows for minimally invasive treatment of adult degenerative scoliosis, while still achieving satisfactory reconstruction and alignment. The decreased muscle trauma afforded by the system allowed this patient to quickly return to normal activities without compromising long term results.



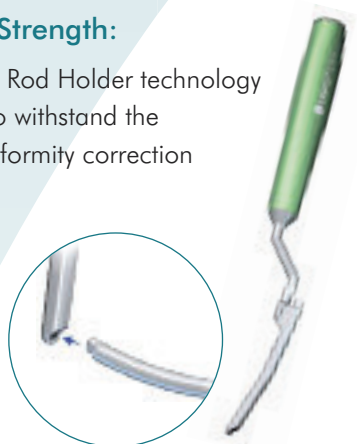
Figures 3 and 4: AP and lateral views of the spine at the 1-year postoperative visit

The confidence to treat deformity with an MIS approach

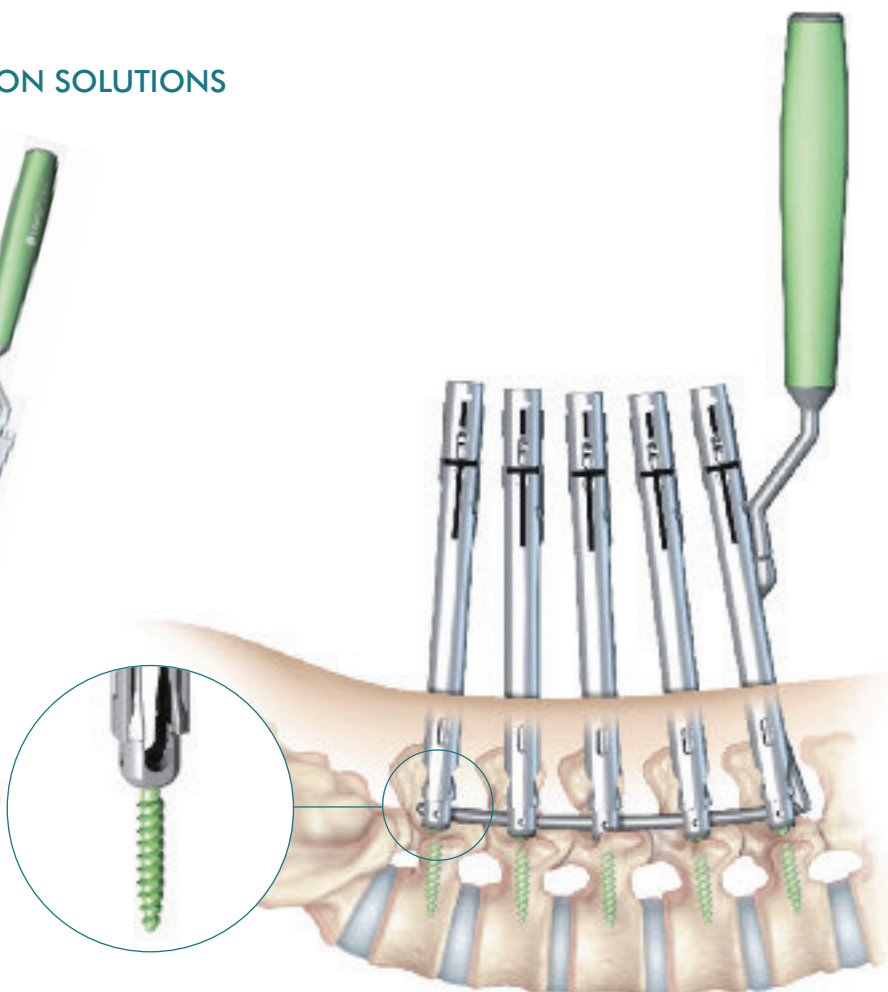
VERSATILE & SECURE CORRECTION SOLUTIONS

Connection Strength:

V2 Extension & Rod Holder technology are designed to withstand the demands of deformity correction



V2 extension connection strength allows for vertebral body manipulation before or after rod insertion



Hex-End Rod Design:

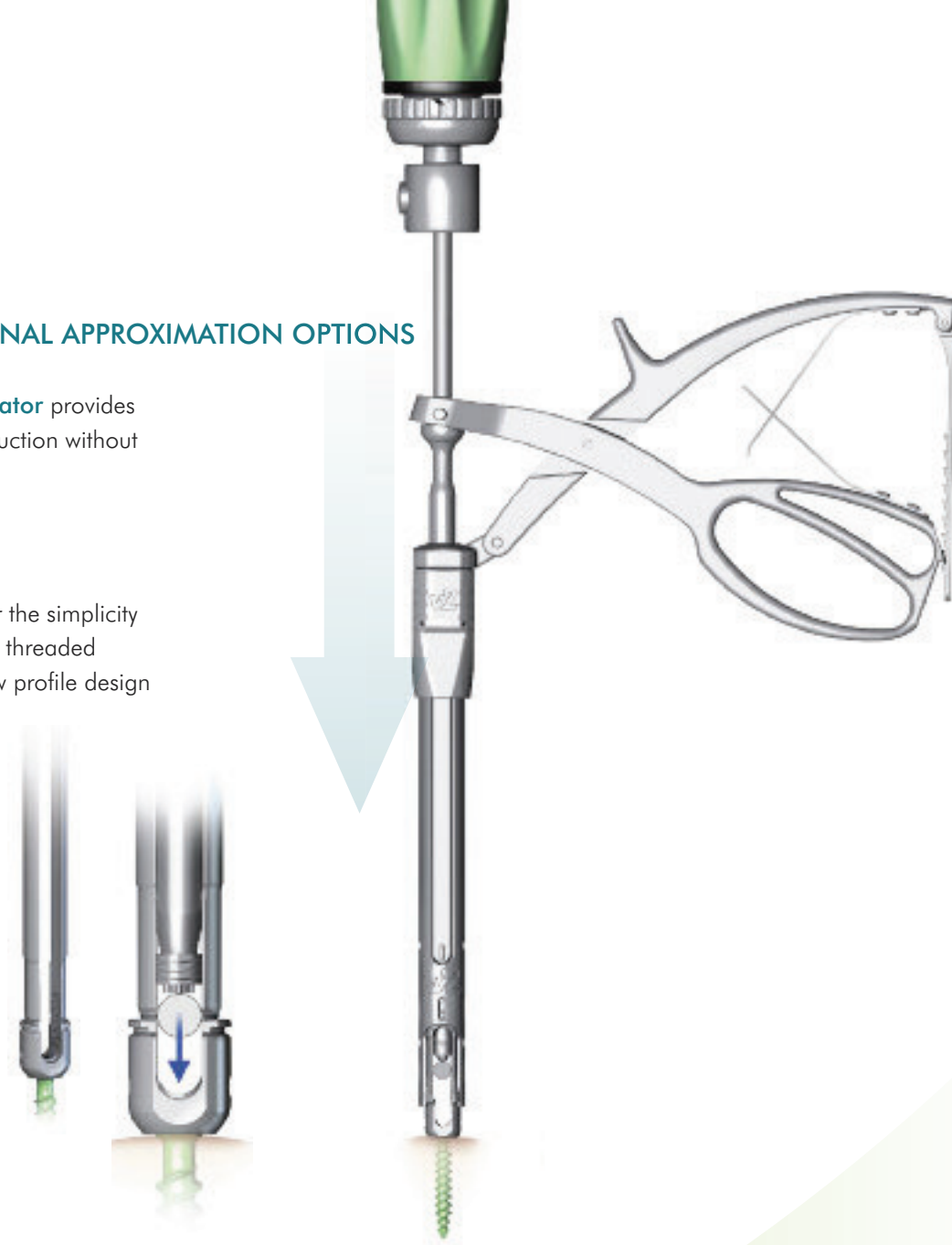
Bullethead V2 Hex-End Rod and novel connection feature provide 360° of percutaneous rod rotation control during and after rod placement



POWERFUL INTERNAL APPROXIMATION OPTIONS

Pistol Grip Approximator provides quick, intuitive rod reduction without bulky external sleeves

V2 X-Tab Screws offer the simplicity & control of integrated threaded reduction in a ultra-low profile design



LOW-PROFILE INSTRUMENT DESIGN

V2 Extensions & X-Tab Screws designs are optimized to reduce instrument crowding and incision size for complex surgery



TRAUMA



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PERCUTANEOUS SPINAL TRAUMA TREATMENT USING THE VIPER2 SYSTEM

Tony Tannoury, MD
Boston University, Department of Orthopaedics

History of Present Illness and Imaging

- A 48-year old male construction worker arrived at the ER after falling from a three story building
- The patient was neurologically intact but demonstrated signs of bilateral leg weakness
- Imaging revealed L1 and L2 burst fractures with a severely compromised canal at both levels (Figures 1, 2, & 3)



Figure 1: Lateral CT Scan

Treatment Method and Materials:

- An anterior corpectomy was performed at L1/ L2 and an 80mm mesh cage was inserted into the space left from T12 to L3
- A unilateral anterior EXPEDIUM rod and screw construct was inserted laterally from T12 to L3 to support the anterior column
- Nine percutaneous VIPER screws were placed bi-laterally at every level from T12 to L4 except in the left pedicle on L1
- Bilateral 120mm VIPER 2 rods were placed percutaneously starting from T12 (Figures 4 & 5) to L4
- OR time for the posterior portion of the case was approximately 75 minutes with 75cc of blood loss and no complications

Follow-up Results

- The patient was ambulating on post-operative day 3 and was discharged on day 4
- At the time of discharge, the patient reported almost no posterior muscle pain despite the 5-level instrumentation
- At 6 months post-op, the patient was back to normal function and had no signs of adjacent level degeneration or post-traumatic alignment issues
- The patient has no complaints of incisional or muscle pain and the skin incisions were observed to have healed completely at 6 months

The VIPER2 System's percutaneous posterior fixation allowed us to fully stabilize this patient's spine while contributing to little blood loss, minimal posterior muscle damage and a fast recovery.

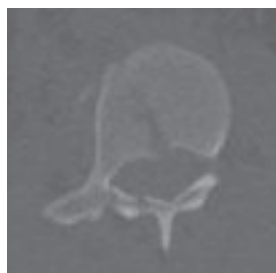


Figure 2: Axial CT of L1

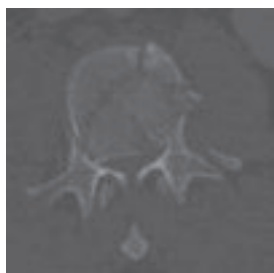


Figure 3: Axial CT of L2



Figure 4: Post-op Lateral Radiograph

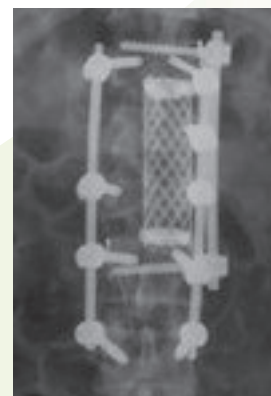


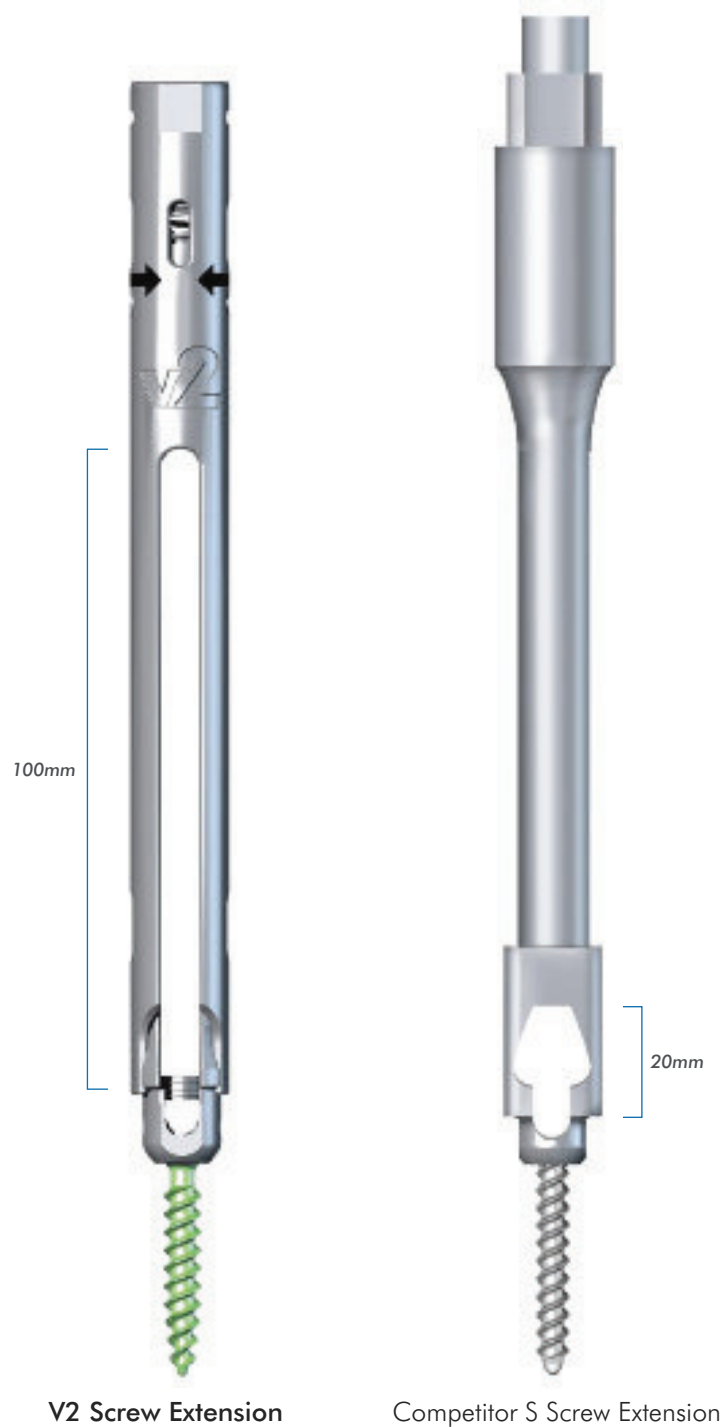
Figure 5: Post-op A-P Radiograph

Versatility for the demands of MIS trauma stabilization

THE IMPORTANCE OF SLOT HEIGHT FOR SPINAL TRAUMA

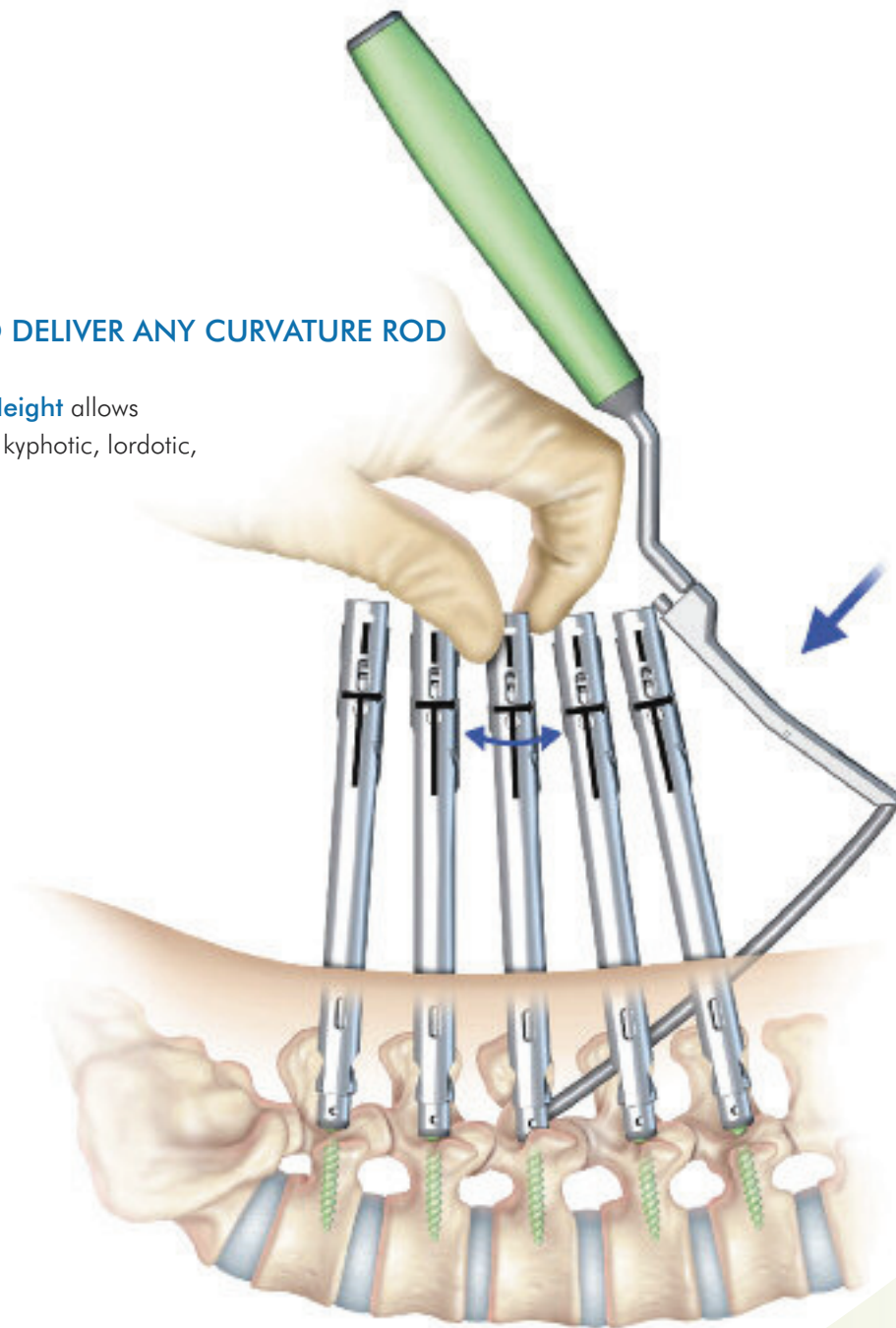
Speed & Security of Rod Delivery Through Proximal Extension:

- V2 Extension Slots allow controlled rod passage through the proximal extension, eliminating the uncertainty of rod insertion through a remote incision
- Immediate rod capture confirmation provides the surgeon the confidence to quickly advance the V2 Rod through multiple extensions



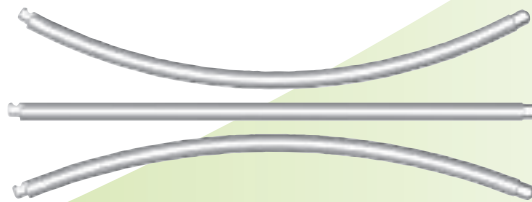
FLEXIBILITY TO DELIVER ANY CURVATURE ROD

Optimized Slot Height allows simple passage of kyphotic, lordotic, or dual curve rods



Rod Options

- V2 Rods come in straight, lordosed and kyphosed configurations from 30mm – 480mm



TUMOR



VIPER².

TAKING PERCUTANEOUS FIXATION TO THE NEXT LEVEL.

MINIMALLY INVASIVE TREATMENT OF SPINAL TUMORS USING THE VIPER2 SYSTEM

Ira Goldstein, MD & Robert F. Heary, MD

University of Dentistry and Medicine, New Jersey, Department of Neurosurgery

History of Present Illness and Imaging:

- A 56-year-old male with a squamous cell tumor in L2, collapse of the L2 vertebral body and accompanying severe stenosis at the spinal canal (Figure 1)
- Imaging revealed lesions at the L1, L2, L3, L4 and L5 vertebral bodies. (Figure 2)

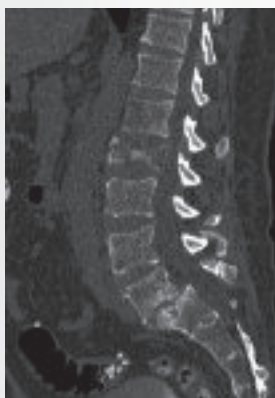


Figure 1: CT Scan

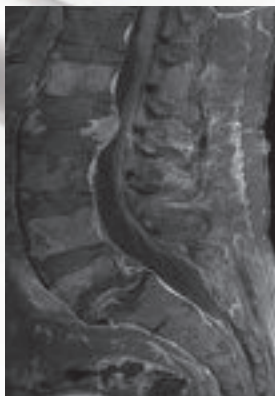


Figure 2: MRI Scan

Treatment Method and Materials:

- Bilateral transpedicular tumor resection and decompression was performed at L2 through the PIPELINE™ Expandable retractor placed through a 30mm mid-line incision
- Vertebroplasties were performed at L1, L3, L4 and L5 to support the weakened bone
- Ten Percutaneous VIPER Screws were placed bi-laterally at T11 - L3 and L4
- Two 200mm VIPER2 rods were percutaneously inserted starting from T11
- OR time was approximately 3.5 hours with 200cc of blood loss and no complications

Follow-up Results:

- Patient was ambulating on post-operative day 1 and was discharged on day 3
- Post-op imaging showed full height restoration at the L2 level (Figure 3) and good sagittal and coronal alignment (Figure 4)
- At three months, patient reports back pain is resolved and has resumed many normal activities

For this unfortunate tumor case, the VIPER2 System allowed us to fully treat this weakened patient with minimal blood loss. These minimally invasive stabilization techniques are extremely beneficial for ailing patients who may not be able to tolerate a traditional open procedure.

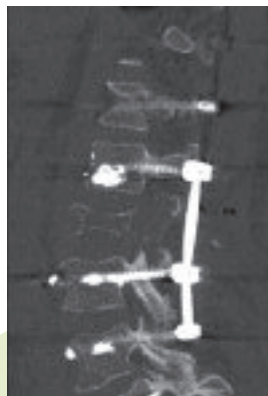


Figure 3: Lateral CT Scan

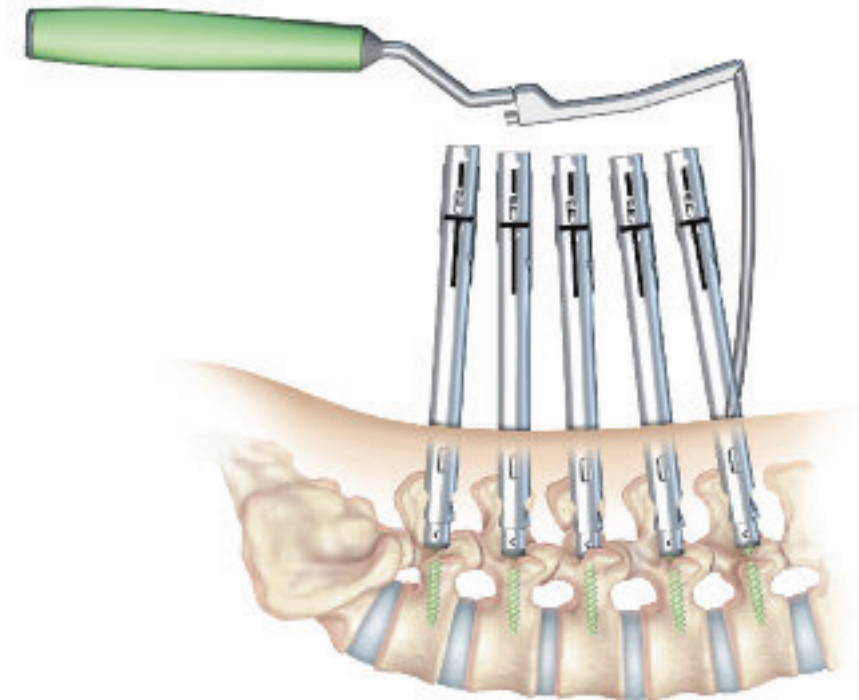


Figure 4: A-P Radiograph

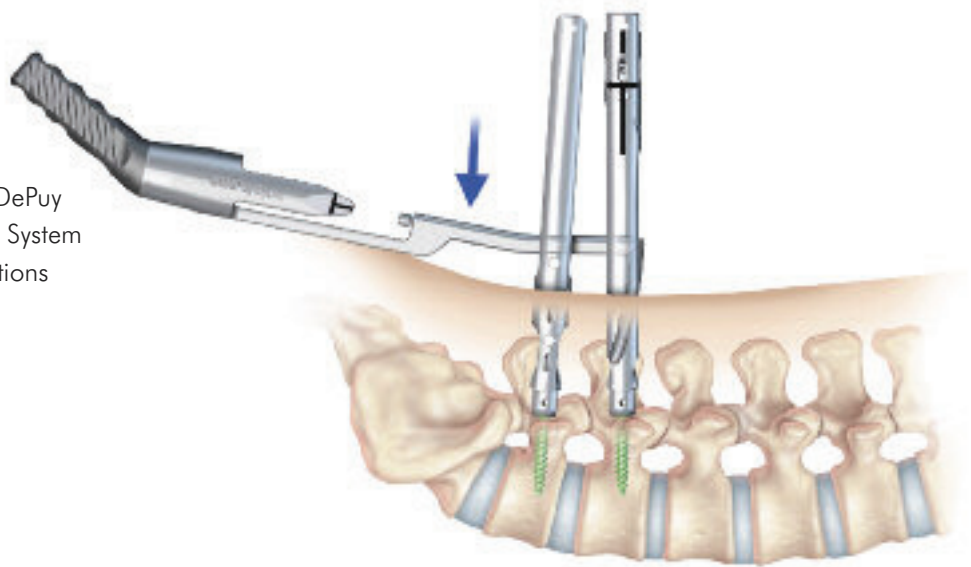
Streamlined MIS Posterior Fixation for Tumor Surgery

VERSATILITY TO INSTRUMENT THE ENTIRE THORACOLUMBAR SPINE:

- A wide range of rod options for kyphotic & lordotic curves
- Truly percutaneous rod introduction options optimized for short & long segments

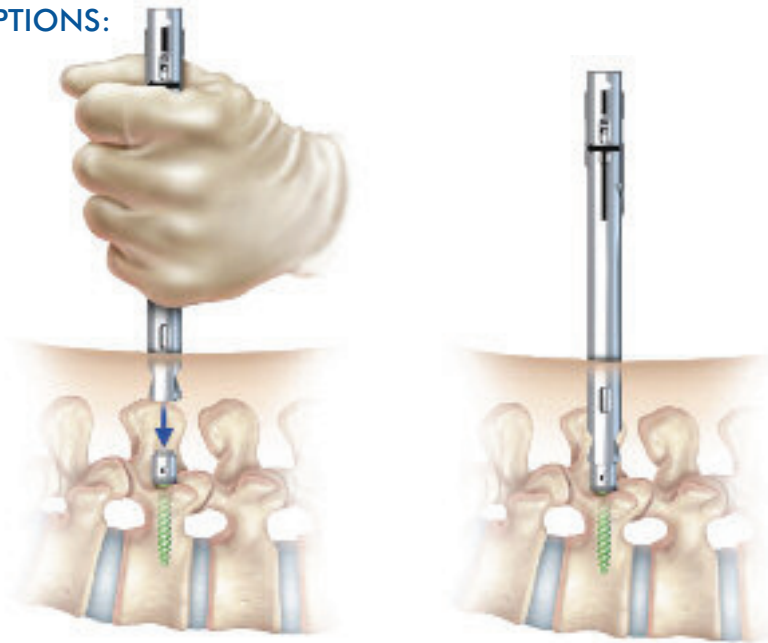


- Full compatibility with DePuy Spine's EXPEDIUM 5.5 System for hybrid construct options



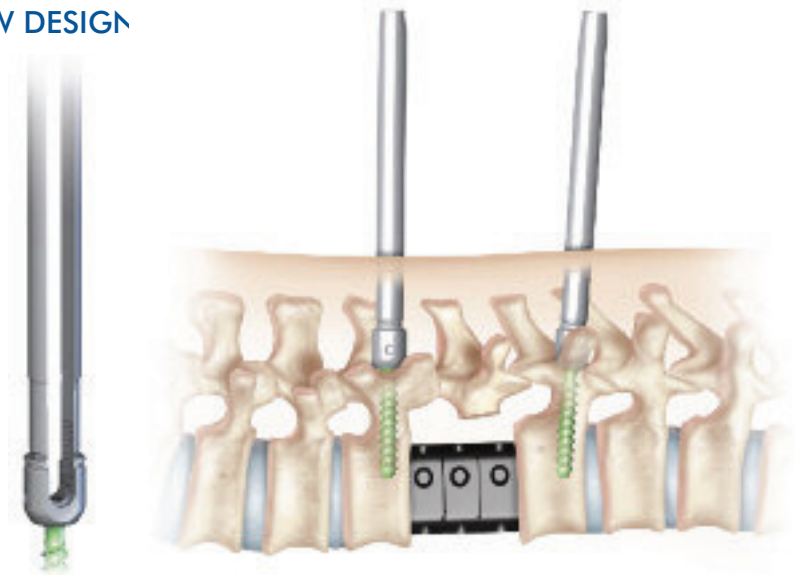
PERCUTANEOUS REVISION OPTIONS:

- V2 screw extensions can be quickly re-attached *in-situ* to revise & extend constructs



ELEGANCE OF THE X-TAB SCREW DESIGN

- 12mm outer diameter minimizes skin incision & muscle trauma
- Built-in threaded reduction for easy rod approximation
- Integrated break-off reduction tabs eliminate the need for extension assembly



SURGICAL TECHNIQUE

Pedicle Targeting

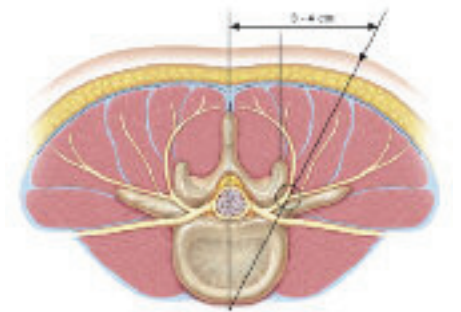
OR SET-UP

- The patient should be positioned prone lying face down on a radiolucent table.
- It is recommended to use a Jackson Table, to assist in achieving the proper patient positioning and an unrestricted fluoroscopic view. Confirm the C-Arm will allow for easy rotation in the lateral, oblique, and A/P positions around the table.
- Tables that prohibit unobstructed A/P and lateral images should be not be used for this procedure.



FLUOROSCOPIC PLANNING

- Use A/P and lateral fluoroscopy to identify and target the appropriate level(s).
- Ensure that the C-Arm is positioned correctly for each targeted level by adjusting the position of the C-Arm until both endplates are parallel and the spinous process is equidistant from the center of each pedicle when viewed on A-P fluoroscopy.
- The C-Arm may need to be repositioned for each appropriate level.



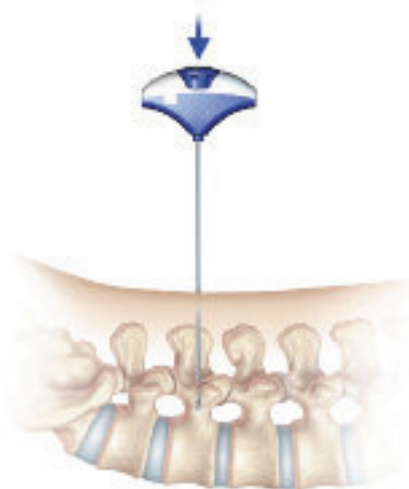
DETERMINE THE SKIN INCISION LOCATION

- Place a guidewire on the patient perpendicular to the axis of the spine at the targeted level. Using A-P fluoroscopy, position the guidewire such that its projection transects the center of both pedicles in the cephalad-caudal direction. Use a surgical marker to transfer that plane to the patient.
- Place guidewires on the patient parallel to the axis of the spine. Using A-P fluoroscopy, position the guidewire such that its projection aligns to the lateral pedicle wall of the targeted level and the adjacent levels. The lateral pedicle wall of adjacent levels may also be estimated at this time. Use a surgical marker to transfer this plane onto the patient.
- The skin incision for each level should be at least 1 cm lateral to the intersection of the two lines. This distance may vary depending on size of the patient.



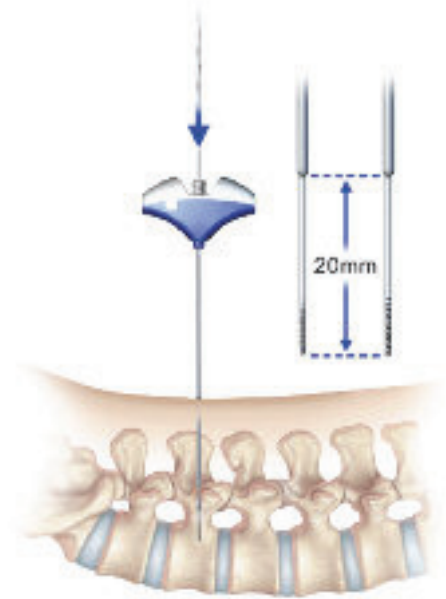
JAM SHIDI NEEDLE PLACEMENT

- A longitudinal incision about 1.5cm is made through the skin and fascia. (An incision of 1.5cm will match the diameter of the Screw Extensions used later in the procedure). Insert the Jam Shidi Needle through incision and dock the tip on the bony anatomy of the desired level. **Confirm position by using lateral fluoroscopy.**
- Using A-P fluoroscopy, advance the Jam Shidi Needle to the pedicle entry point at the intersection of the facet and transverse process. Confirm that the tip of the Jam Shidi Needle is at the center of the lateral border of the pedicle on an A-P image. Gently tap the Jam Shidi Needle to engage the trocar tip into the pedicle.
- **Tip: Using a surgical marker, draw a line on the Jam Shidi Needle approximately 20mm proximal to the patient's skin. When this mark is flush with the patient's skin, the distal end of the needle should be through the typical pedicle and into the vertebral body.**
- Advance the Jam Shidi needle through pedicle using A-P fluoroscopy to direct the tip towards the center of the pedicle. The needle should not advance more than three quarters of the way across pedicle, starting from the lateral edge of the pedicle. Continue advancement until the needle enters the vertebral body. **Confirm placement with A/P and lateral fluoroscopy to ensure that the Jam Shidi Needle does not breach the wall of the pedicle.**
- Remove the inner stylet of the Jam Shidi Needle.



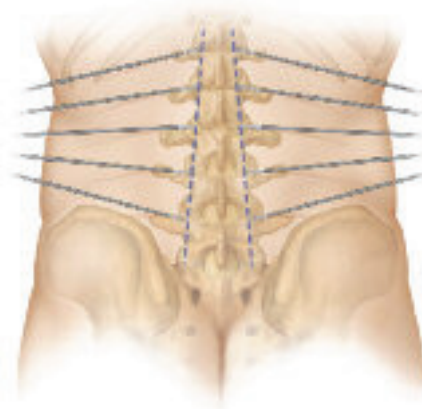
Guidewire Placement

- Select a guidewire with either a sharp or blunt tip, based on surgeon preference. Insert the guidewire into the Jam Shidi needle. Advance the guidewire beyond the tip of the Jam Shidi needle (approximately 20mm) to ensure adequate fixation into the cancellous bone. **Confirm placement with A/P and lateral fluoroscopy to ensure that the Guidewire does not breach the wall of the pedicle or the vertebral body.**
- *Tip: To ensure proper depth, drive the guidewire by clamping a needle Driver (forceps) onto the guidewire 20mm proximal to the Jam Shidi handle and impacting the forceps until the needle Driver contacts the Jam Shidi.*



- Use caution when placing the guidewire. Markings on the wire designate 5mm increments and can be used to determine penetration depth. Additionally, the depth markers can be used to monitor unintentional guidewire advancement or rotation.
- Once the guidewire is placed to desired depth, carefully remove the Jam Shidi Needle while holding the guidewire.

Note: For multi-level constructs it is recommended to place ALL guidewires prior to inserting Pedicle Screws.

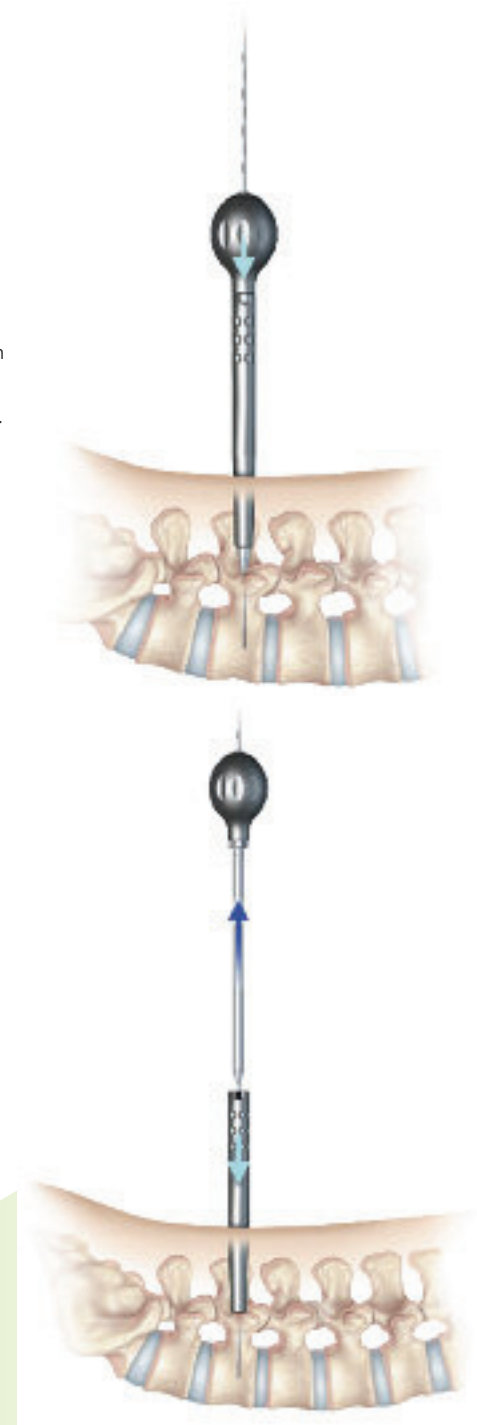


Pedicle Preparation

Two options are provided for dilating soft tissue in preparation for tapping.

OPTION 1: A COMBINED DILATOR/CANNULA

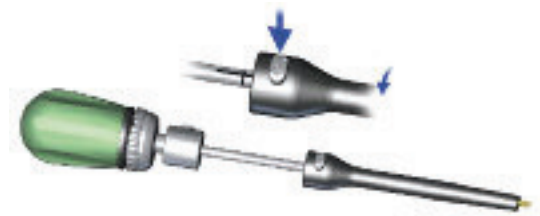
- Insert the 7mm Dilator with Handle into the Pedicle Preparation Cannula and rotate with downward pressure until the two pieces “snap” and lock together.
- Advance the combined instrument over the guidewire until the distal tip of the instrument contacts the pedicle. Confirm placement with fluoroscopy. Push down on the outer cannula until it separates from the 7mm dilator and contacts the bone. Remove the Dilator while holding the guidewire and the cannula in place.
- Advance the appropriate sized Cannulated Self-Drilling Tap over the guidewire and into the outer Cannula. Proceed to the Pedicle Tapping section of this surgical technique.



SURGICAL TECHNIQUE

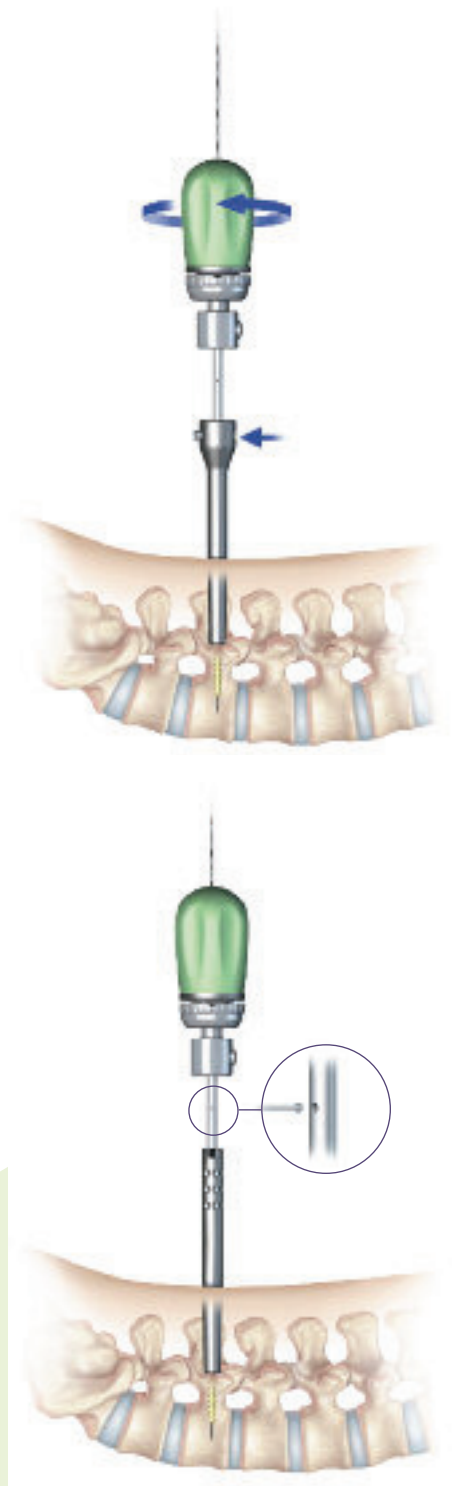
OPTION 2: TAP SHEATH

- Depress the Unlock button on the side of the Tap Sheath and insert the Cannulated Self-Drilling Tap into the top of the Sheath. Advance the tap until the horizontal marking on the tap shaft aligns with the top of the sheath then rotate until the vertical markings align with those on the Sheath. Depress the Lock button to secure the assembly together. The Cannulated Self-Drilling Tap and the Tap Sheath should now be coupled.
- **Verify that the tap does not move relative to the sheath while the lock button is engaged.**
- Advance Tap Sheath assembly over the guidewire until the distal end of the tap contacts the pedicle. Confirm position with fluoroscopy. Depress the unlock button and proceed to the Pedicle Tapping section of this surgical technique.



Tap Pedicle

- While controlling the tap sheath or the tap cannula, advance the appropriate size Cannulated Self-Drilling Tap over the guidewire into the pedicle by turning the tap in a clockwise manner. Depth markings on the proximal half of the tap can be used to determine the tap depth and appropriate Screw length.
- **While tapping, care should be taken to avoid unintentional guidewire advancement or rotation. Do not advance the tap beyond the tip of the guidewire as doing so may result in unintentional wire removal.** Use caution not to bend or kink the guidewire while advancing the tap.
- It is recommended that fluoroscopy be used while tapping to monitor the depth of the tap and ensure the guidewire is not unintentionally advanced.

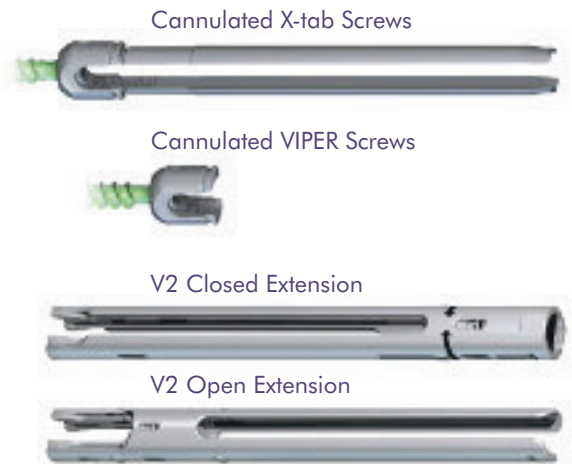


SURGICAL TECHNIQUE

Screw Loading

Choose the appropriate length, diameter, and type of Screw.
There are two Screw types:

Use the appropriate loading procedure described below for each type of Screw.



CANNULATED POLYAXIAL VIPER SCREWS WITH EXTENSIONS

- Prior to attempting to attach a Screw Extension to a Screw, **ensure the Castle Nut is fully loosened** by turning it counterclockwise with the Castle Nut Tightener.
- Open both hinged doors on the appropriate Screw caddy exposing the top of the Screw Heads. Ensure that all of the Screws are fully seated in the caddy. Guide the Alignment Block into the grooves located in the top of the caddy until it is fully seated.
- **Note:** The loading block **MUST** be fully seated in order to function properly.



- Insert the Screw Extension into through the Alignment Block Assembly Press down firmly to engage the Extension with the Screw Head. An audible “pop” will signal that the Extension is **provisionally** attached to the TOP NOTCH feature on the Screw Head.
- ***Note:** If excessive resistance is encountered, double check the fit of the Alignment Block, ensure that the Castle Nut is fully loosened and verify that the force applied is vertical.*



Alternatively, a small plastic mallet may be used to deliver a quick strike to the top of the extension for loading.

- Remove the Screw Extension and check the provisional attachment by lightly tugging on the Screw while holding the Extension and verifying that the Screw is aligned with the Extension. Once this has been verified, use the Castle Nut Tightener to fully secure the Screw to the Screw Extension. **Use caution to avoid over tightening.**



SURGICAL TECHNIQUE

CANNULATED POLYAXIAL EXTENDED TAB (X-TAB) REDUCTION VIPER SCREW LOADING:

- Guide an X-Tab Sleeve over the tabs of the Screw until it is fully seated against the Screw Head. This sleeve will help prevent unintentional separation of the tabs from Screw Heads. If resistance is encountered, ensure that the sleeve is properly aligned with the tabs.

Screw Insertion

- Insert the appropriate Polyaxial Driver into the assembly and thread the instrument into the Screw Head rotating clockwise until it stops. This step should align the Screw Shank with the extended tabs and lock the polyaxial motion of the Screw.

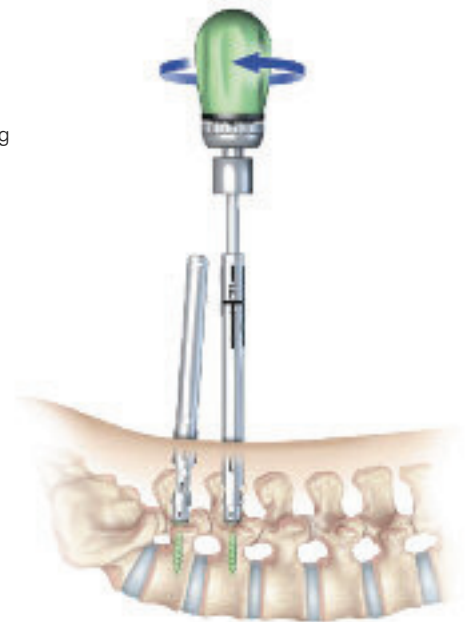
Note: An insertion sleeve **MUST** be placed over the tabs of the Screw prior to insertion. This will allow for greater manipulation of the Screw and prevent premature detachment of the tabs.

Note: If using an Open Screw Extension, the reinforcement post should be inserted to provide increased stability and to reduce tissue hang-ups.

- Guide the first Screw Extension assembly over a guidewire down to the pedicle and thread the polyaxial Screw into the pedicle. The guidewire should be removed as soon as the Screw is through the pedicle and enters the vertebral body. While inserting the Screw into the pedicle, monitor the markers on the guidewire to avoid unintentional advancement and rotation.



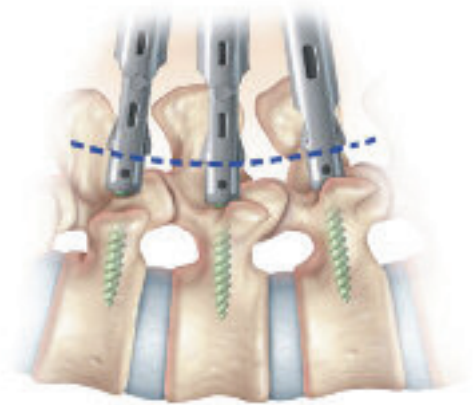
- To maintain full polyaxial capability, the Screw Head should not be fully seated against the bone.
- Once the Screw is inserted to the desired depth, remove the Polyaxial Driver or X-Tab Polyaxial Driver by turning the handle counterclockwise while firmly holding the Screw Extension or Extended Tab assembly. Verify polyaxial capability by manipulating the Screw Extension.



- The height of each Screw must be set appropriately to accommodate the curvature of the Rod. Screw height can be verified with lateral fluoro or by checking the alignment of the top of the extensions. For single level constructs, confirm that the Screw Heads are at equal heights. For multi-level constructs, verify that the Screw Heads replicate the curvature of the Rod.



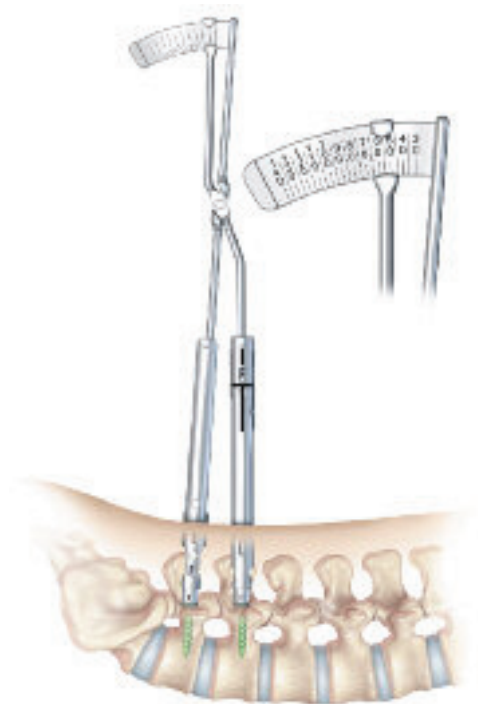
- Remove the Reinforcement Posts for the Open Extensions. Repeat Screw placement procedures at each surgical level.



SURGICAL TECHNIQUE

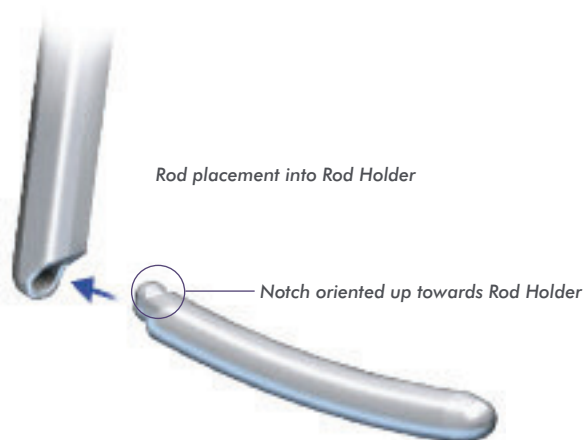
Rod Measuring

- Insert one arm of the Rod Measuring Caliper into each of the outermost extensions until each leg is fully seated in the Screw Head. Check placement via fluoroscopy. Additionally, placement can be verified by ensuring that the circumferential lines on the shafts of the Rod Measuring Caliper align with the top of each extension.
- Once correctly positioned, read the Rod length measurement indicated at the top of the caliper.
- **Note:** The Rod Measuring Caliper can be used to measure segments greater than 140mm by adding two or more measurements together.



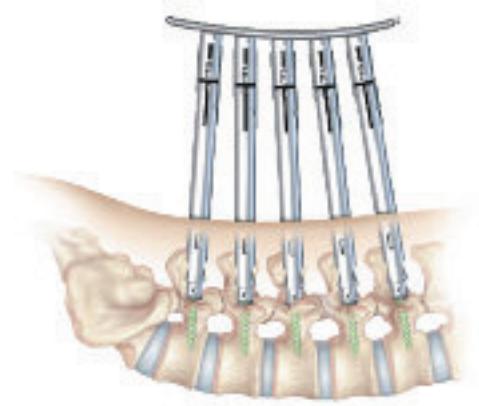
ATTACH ROD TO APPROPRIATE ROD HOLDER

- Select the appropriate Rod Holder based on the length of Rod that will be inserted.
 - Conventional Rod Holder for Rod lengths of 100mm or less
 - Advanced Rod Holder for Rod lengths greater than 100mm
- Depending on the curvature of the spine at the operated levels, select the pre-lordosed or pre-kypshosed Rod that best fits the measured Rod length. Alternatively, straight Rods can be contoured to the patient's anatomy.



Angled and Advanced Rod Holders

- *Note: The appropriate sagittal plane contour can be estimated by placing the Rod atop the Screw Extensions or directly on the patient's skin adjacent to the Screw Extensions.*

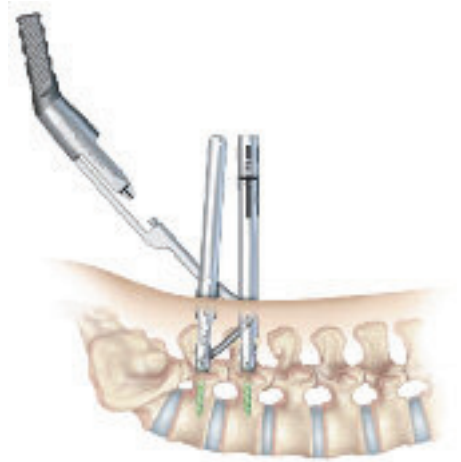
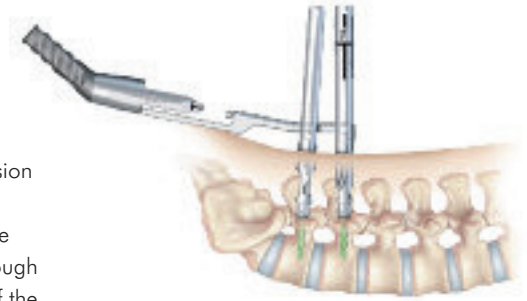


- After choosing the appropriate length Rod, contour and corresponding Rod Holder, insert the connection end of the Rod into the pocket of the Rod Holder ensuring that the notch on the connection end of the Rod is facing up towards the handle of the Rod Holder.
- Connect the Torque Limiting Handle to the X-15 Rod Tightening shaft. Use this instrument to tighten the Rod Locking Bolt of the Rod Holder until the Torque Limiting handle "clicks." Verify that the Rod is securely attached to the Rod Holder.

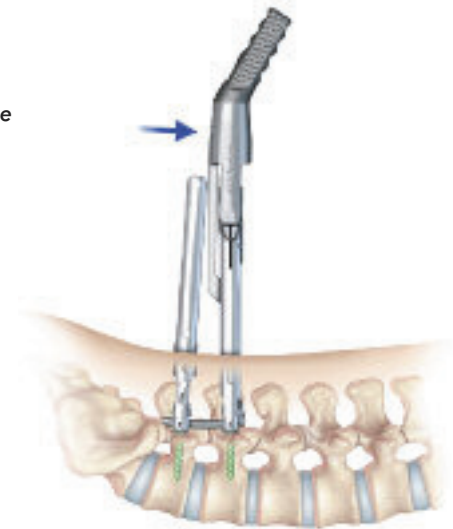


Conventional Rod Insertion

- **Use both Closed and Open Extensions in conjunction with the Conventional Rod Holder.**
- Align the slots of the Screw Extensions and rotate the Closed Screw Extension so that the arrow points towards the Open Screw Extension. Position the Conventional Rod Holder handle to be parallel to the skin surface with the lead tip of the Rod facing downward. Insert the Rod Holder Assembly through the Open Screw Extension(s), and advance the Rod Holder into the slot of the Closed Screw Extension. The entire Rod should be contained within the Closed Screw Extension.
- Use the Rod Holder to align the Screw Extensions until they are parallel with one another.
- If the Screw Extensions are crossed, the surgeon should attempt to uncross them. If it is not possible, use the Rod Holder to bypass the Open Screw Extension and guide the Rod into the slot of the Closed Screw Extension.
- Advance the distal end of the Rod towards the Screw, down the Closed Screw Extension until it touches the top of the Screw Head or it is as deep as the tissue will allow. It is necessary for the distal end of the Rod to be below the fascia before proceeding.
- **Rotate the Rod Holder Handle Upwards 90° until it nests with the proximal end of the Closed Extension.** This action will guide the Rod into the distal slot of the Open Screw Extension(s). To confirm the Rod is seated inside the Closed Screw Extension, align the vertical and horizontal markers on the Rod Holder with the arrow and vertical line on the Closed Screw Extension.



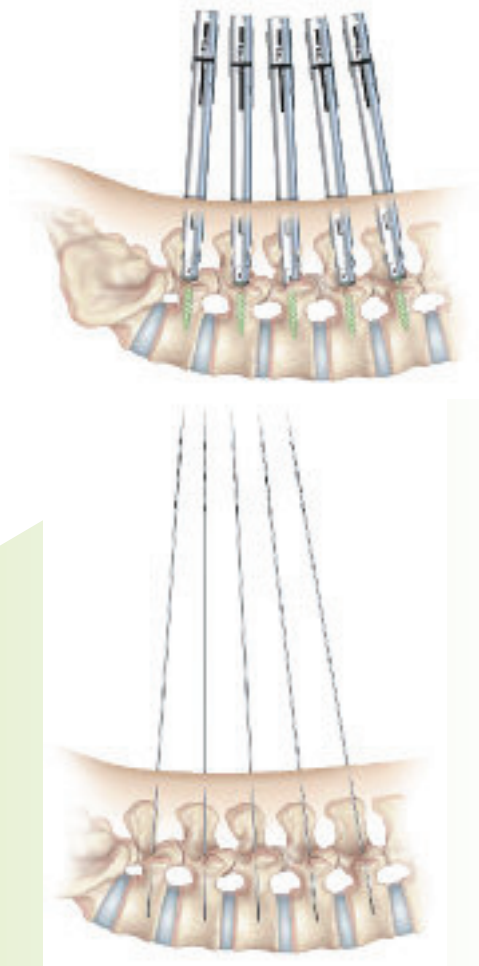
- *Note: To verify the Rod has passed through the Open Screw Extension(s), twist the Open Extension about its axis. If the Extension does not rotate, then the Rod has been properly passed. If the Extension is able to rotate, the Rod is not contained within the Extension and Rod placement should be re-attempted. FLUOROSCOPY SHOULD BE USED TO VERIFY ADEQUATE ROD OVERHANG AT EACH END OF THE CONSTRUCT.*



Advanced Rod Insertion

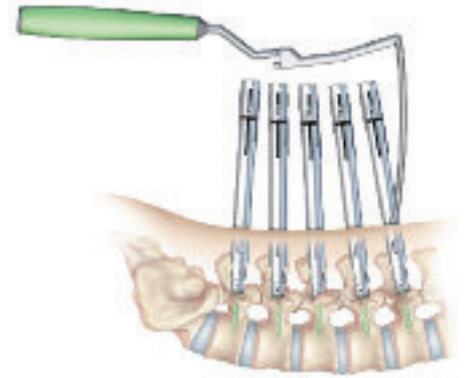
Use Closed Extensions and/or X-Tab Screws with the Advanced Rod Holder.

- Assemble and insert Closed Extensions or Screws over Guidewires. Align the openings of the Screw Extensions as much as possible. Rotate the cephalad-most Screw Extensions so the arrow points in the cephalad direction.



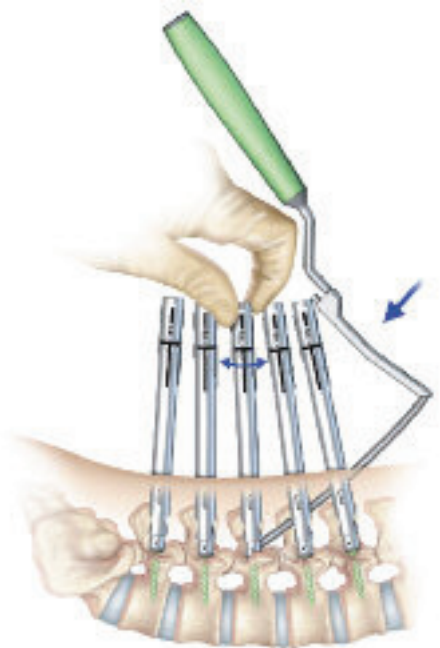
SURGICAL TECHNIQUE

- Position the Rod Holder Handle to be as parallel as possible to the skin surface, with the Rod parallel to the axis of the slots of the Extension (perpendicular to the skin). Insert the Rod into the cephalad slot of the Extension. The tip of the Rod should be contained within the Closed Screw Extension. Advance the distal end of the Rod straight down towards the Screw until it touches the top of the Screw Head or it is as deep as the tissue will allow. It is necessary for the distal end of the Rod to be below the fascia before proceeding.

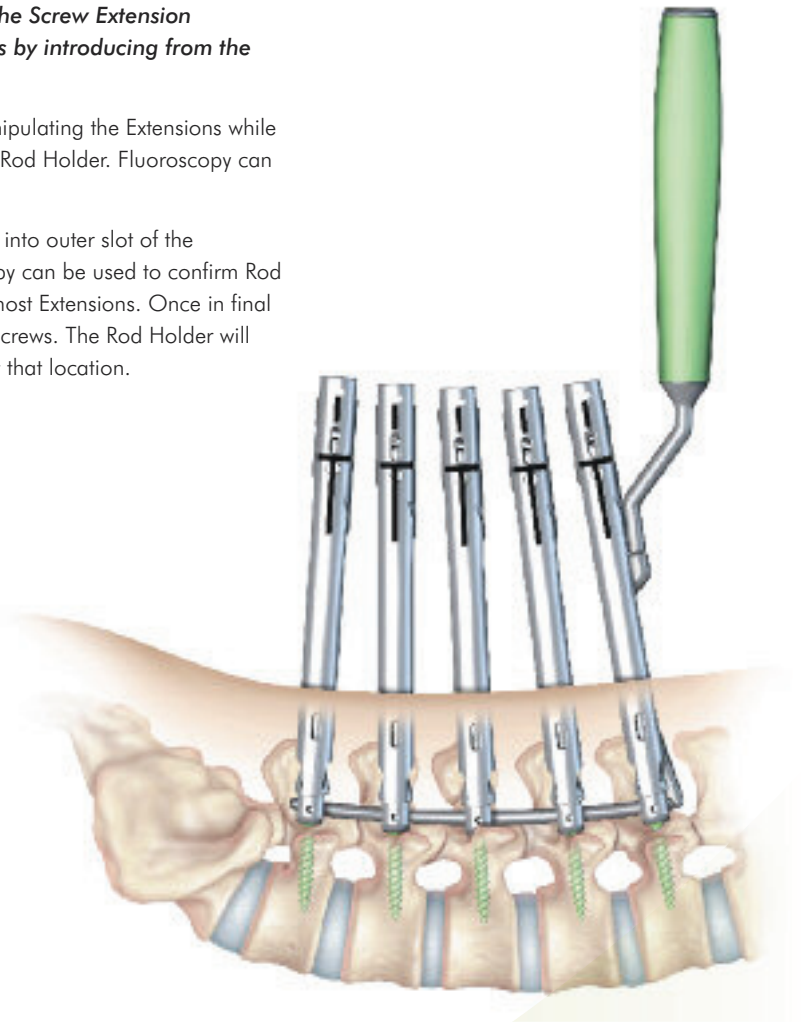


- Rotate the handle of the Rod Holder toward the cephalad direction approximately 45°. This action will guide the tip of the Rod towards each successive Extension.
- **Note:** Depending on the curvature of the spine, the Rod Holder may need to be rotated along an arc that parallels that curvature of the spine.

- Continue to advance the Rod subfascially into the adjacent Extensions by moving the Rod Holder towards each subsequent Extension in a linear fashion. Verify that the Rod has passed through an Extension by attempting to rotate the Extension about its axis. If you are unable to rotate the Extension, the Rod has properly passed within the Extension. This process should be conducted as the Rod is passed at each level. The Rod passage should end inside the most caudal Extension.



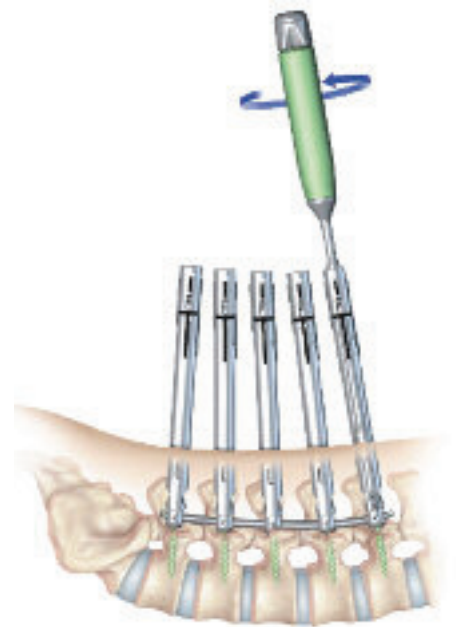
- **Note:** To help align multiple Extensions, guide the Screw Extension Alignment guide on the outside of all Extensions by introducing from the caudal direction.
- When necessary, the Rod can be “directed” by manipulating the Extensions while adjusting the Rod position and orientation with the Rod Holder. Fluoroscopy can provide additional guidance during Rod insertion.
- Engage the distal half of the Advanced Rod Holder into outer slot of the cephalad-most Closed Screw Extension. Fluoroscopy can be used to confirm Rod placement and appropriate overhang at the outermost Extensions. Once in final position, the Rod should be locked down with Set Screws. The Rod Holder will need to be removed prior to placing a Set Screw at that location.



SURGICAL TECHNIQUE

Set Screw Insertion

- Load a Set Screw from the caddy onto the X25 Inserter. Twist the proximal knob on the handle until the Set Screw is secured. Do not over tighten the locking feature. Doing so may damage the instrument. Guide the X25 Inserter into any Screw Extension not occupied by the Rod Holder and loosely tighten the Set Screw to capture the Rod. The Screw Head should remain mobile to enable repositioning of the Screw Extension, which may assist during subsequent steps.
- If the proximal depth marker on the shaft of the X25 Inserter is the top of the Screw Extension, then the Set Screw is seated within the Screw Head. To verify proper engagement, pull-up slightly on the X25 Inserter to ensure the Set Screw is captured in the Screw Head before disengaging. Remove the X25 Inserter by turning the proximal knob counter-clockwise and withdrawing the instrument.
- **Note:** *If difficulty is encountered introducing the Set Screw into the Screw Head, the Rod may lie above the Screw Head. Use Fluoroscopy to verify Rod placement. If Rod approximation is required, utilize the Rod Approximator to deliver the Set Screw using the procedure described in the Rod Approximator section.*



Rod Approximation using the VIPER2 Rod Approximator

- **Attach the cap of the Rod Approximator to the Screw Extension.** Align the vertical lines on the cap with the corresponding lines on the proximal end of the Extension. Push the cap of the Rod Approximator onto the Screw Extension until the Approximator snaps into place and the buttons engage the slots. To verify secure attachment, lightly pull on the cap to check attachment to Extension.
- **Note:** *When using the Rod Approximator with the Open Extension, insert the Open Screw Reinforcement Post before use.*

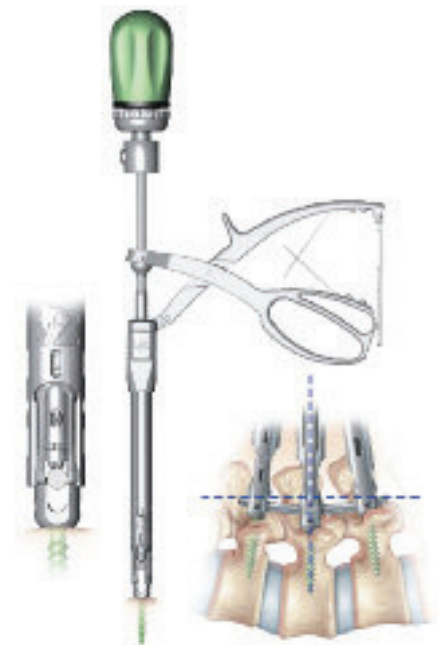


- Load a Set Screw on the Self-Retaining Approximating Set Screw Driver by pushing down on a Set Screw until it is fully seated on the flange of the Self-Retaining Set Screw Driver.
- **Note:** *Ensure that the tip of the Driver is protruding past the Set Screw by approximately 1mm.*

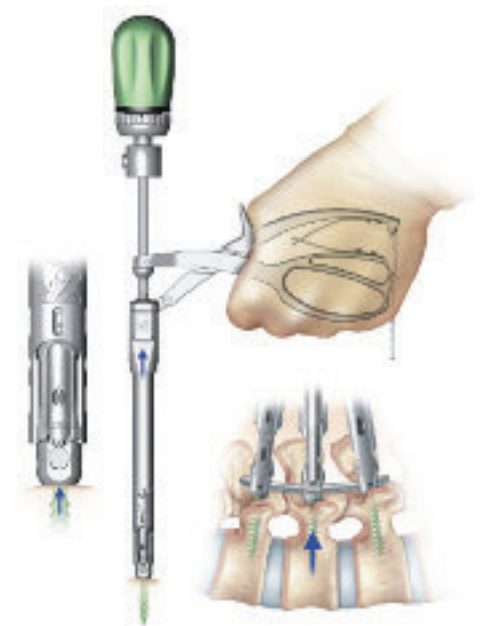


SURGICAL TECHNIQUE

- Insert the loaded Self-Retaining Set Screw Driver through the Rod Approximator cap and into the Extension. The Driver tip will contact the Rod.



- Rotate the Rod approximator handle up to engage flange on the Self-Retaining Approximating Set Screw Driver. Squeeze the Approximator handle to introduce the Rod into the Screw Head. Continue to squeeze the handle until the Rod is driven into the Screw Head and the instrument reaches the final locked position.
- **Note:** *Incremental reduction can be accomplished by utilizing any one of the multiple teeth on the locking rack.*



- The amount of approximation can be measured by using the marker bands on the proximal end of the Self-Retaining Set Screw Driver. The distance between each band is 5mm. Proper Rod placement can be verified by ensuring the final marker band is aligned with the top of the Cap of the Pistol Grip. **Only after reaching the final locked position should the Set Screw Driver handle be rotated to engage the Set Screw threads.**
- To remove the Rod Approximator, depress both buttons on the cap simultaneously and pull-up.



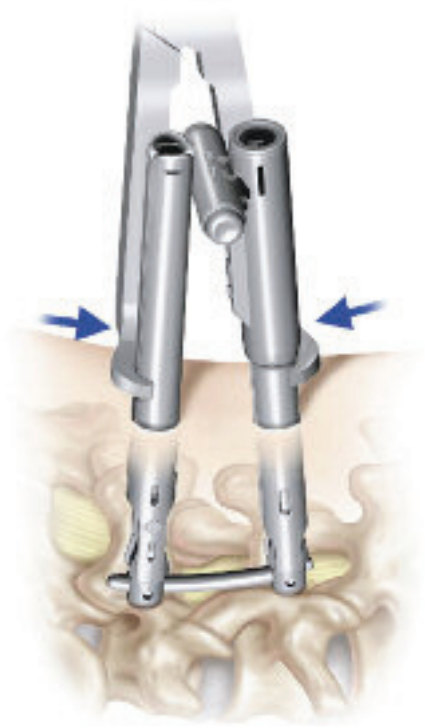
Rod Approximation with the X-Tab Reduction Screws

- Load a Set Screw from the caddy onto the X25 Inserter. Twist the proximal knob on the handle until the Set Screw is secured. Guide the first Set Screw into the center of the Extended Reduction tab. The Set Screw should engage the reduction thread approximately 7mm above the top of the Screw Head. Rotate the handle of the Driver clockwise to engage the reduction threads and drive the Rod into the Screw Head.
- **Note: The X-Tab Screws will provide approximately 7mm of Rod reduction. If greater correction is needed, Standard VIPER Screws connected to VIPER2 Screw Extensions should be used and Rod approximation should be accomplished with the Rod Approximator instrument.**
- Continue to rotate the Set Screw Driver until the Rod is fully seated in the Screw Head. The proximal depth marker on the X25 Inserter should be aligned with the top of the Reduction Tabs when the Set Screw is seated within the Screw Head. Remove the X25 Inserter by rotating the proximal knob counter-clockwise to loosen from the Set Screw.



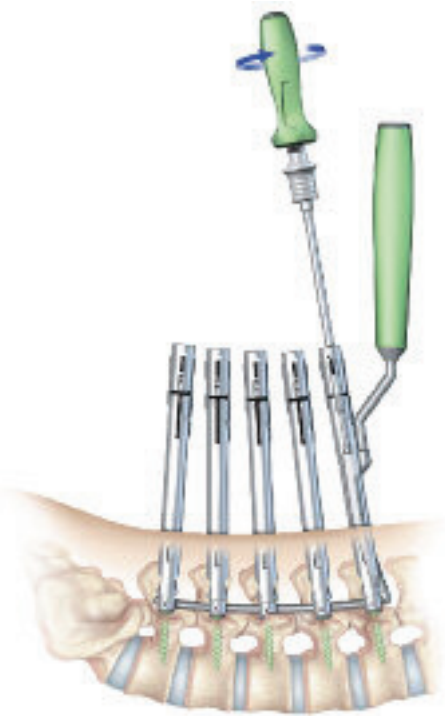
Compression/Distraction

- Assemble the Compression/Distraction Adjustable Fulcrum to the Sleeve by aligning the slots on the Adjustable Fulcrum with the opposite geometry on the track of the Sleeve. Simultaneously depress both buttons on the Adjustable Fulcrum and slide it into the track of the Compression/Distraction Sleeve.
- Final tighten the Set Screw at the end of the construct. **It is imperative that the connection features on the ends of the Rod are located outside of the Screw Head to ensure that the appropriate Screw/Rod interface is established.** Next, ensure that the Set Screw at the adjacent location is loosely affixed (not tightened).
- Slide the Compression/Distraction Sleeve over the Extension that has not yet been final tightened. The top of the Sleeve will interface with the flats on the Screw Extension or Reinforcement Post. Adjust the Fulcrum so that it is positioned at the top of the Compression/Distraction Sleeve. Advance the X25 Final Tightener down the Screw Extension that has not been final tightened to engage the Set Screw.
- **Note: If compressing or distracting with an Open Extension, insert the Open Screw Extension Reinforcement Post. If compressing or distracting with a X-Tab Reduction Screw, insert the X-Tab Sleeve over the tabs to provide an appropriate fit with the Compression/Distraction Sleeve and to prevent premature tab detachment.**
- Introduce the Compression Forceps as low as possible below the Fulcrum and compress. Once in the desired position, tighten the Set Screw.
- Distraction may also be applied by moving the Adjustable Fulcrum as low as possible (close as possible to the skin) and advancing the X25 Final Tightener down the Screw Extension to engage the Set Screw. Introduce the Compression Forceps as high as possible above the Fulcrum and compress. Once in the desired position, tighten the Set Screw.



Rod Holder Removal

- Before removal of the Rod Holder, it should be confirmed fluoroscopically that the proximal end of the Rod is fully seated inside the Screw Head with approximately 5mm overhang from each of the Screw Head.
- Insert the X15 Rod Tightener shaft inside the Rod Holder to engage the Rod Holder bolt.
- Turn the X15 Rod Tightener counter-clockwise to disengage the Rod from the Rod Holder.
- Remove the X15 Rod Tightener. Rotate the Rod Holder forward slightly while pulling the holder away from the patient to remove.



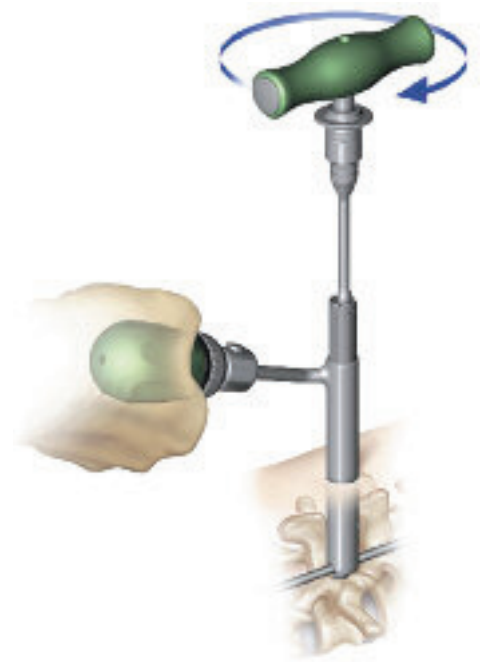
Final Tightening/Counter-Torque

- Using fluoroscopy, verify that the Rod overhangs the outermost Screws by approximately 5mm. (The Rod connection features should be fully outside the Screw Head).
- To perform final tightening, place the Counter-Torque/Rod Stabilizer around one of the Extensions. Ensure that the notches of the stabilizer straddle the Rod. Assemble the X25 Final Tightener to the Final Tightening Torque Handle, pass through the Screw Extension, and engage the Set Screw.
- **NOTE:** If Final tightening on a X-Tab Screw, ensure that the smaller X-Tab Counter-Torque stabilizer is used.



SURGICAL TECHNIQUE

- Rotate the Torque Wrench Handle clockwise, while applying Counter-Torque via the Counter-Torque/Rod Stabilizer, until the torque handle clicks. Repeat for additional Set Screws.



For patients with good bone quality, the Counter-Torque wrench can alternatively be used to provide Counter-Torque.

- Slide the Counter-Torque Wrench over the Extension and engage the flats. When used on an Open Extension, the Open Screw Extension reinforcement post should also be used. Follow the final tightening procedure described above.



Screw Extension Removal

- Assemble the Castle Nut Driver for removal by inserting the Inner Removal Sleeve into the top of the Castle Nut Driver until snaps and locks into place. Insert the Inner Removal Shaft into the Inner Removal Sleeve until the proximal head of the Shaft “snaps” into the first groove of the Inner Removal Sleeve. This is the “Unlocked” position and there should be a gap between the plastic handle and the metal proximal cap.

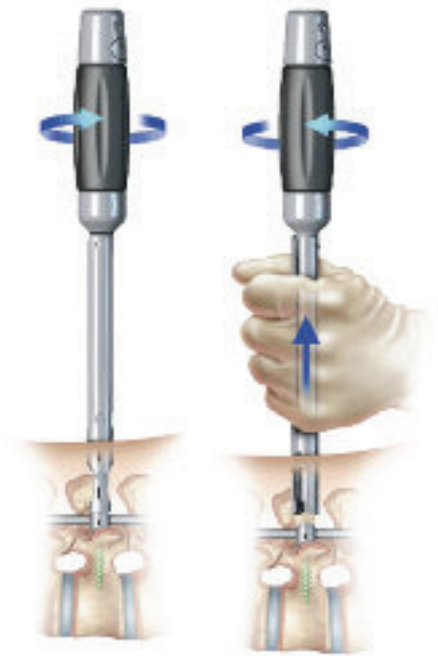


- Insert the Castle Nut Driver into the Screw Extension until the Driver engages the Castle Nut of the Extension. To verify engagement, the top of the Extension should be aligned with the circumferential marker band on the Castle Nut Driver Assembly.
- Note:** *The marker band is located on the distal end of the Castle Nut Driver when being used to remove a Closed Screw Extension. The marker band is located on the proximal end of the Castle Nut Driver, just distal to the handle, when being used to remove an Open Screw Extension.*
- Once the Castle Nut is engaged, push down on the head of the Inner Removal Shaft, until it engages the second groove on the Inner Removal Sleeve, this is the Locked position. The Castle Nut Driver and Screw Extension are now linked together.



SURGICAL TECHNIQUE

- Rotate the Castle Nut Driver four (4) full turns. This action will loosen the Extension from the Screw Head. If the Screw Extension does not automatically disconnect from the Screw, rotate the Screw Extension 90° and apply slight upward pressure.
- **Note:** The Extension will not require significant force to be removed. If there is difficulty removing the Extension, verify that the Castle Nut Driver is coupled to the Extension then continue to rotate the Driver while applying gentle upward force.



- To remove the Extension from the Castle Nut Driver. Push the “Lock/Unlock” button and separate the Extension from the Castle Nut Driver. The Castle Nut Driver should now be in the unlocked position.



X-Tab Removal

- Insert the Tab Removal tool into the center of the two tabs ensuring that the large cylinder portion is inside the Screw tabs (centered over the Screw Head) while the thin tang portion is fully capturing the outside of the tab. Advance the Tab Remover until it reaches the Screw Head and can no longer be advanced.
- Rock the Tab Remover outward (away from the center of the Screw) approximately 15° until the tab breaks away from the Screw Head.
- **Note:** *This motion may need to be repeated a few times to ensure proper breakage.*
- The tab should be retained inside the Tab Remover. Remove the tab by depressing the button at the top of the Tab Remover handle. Ensure that the tab is removed prior to repeating this technique on the next tab.

