

Surgical Technique



VIPER[™]



D E S I G N I N G S U R G E O N S

D. Greg Anderson, MD
Thomas Jefferson University Hospital
Philadelphia, PA

Robert Heary, MD
University of Medicine and Dentistry of New Jersey
Newark, NJ

Carl Laurysen, MD
Institute for Advanced Spinal Research in California
Los Angeles, CA

Tony Tannoury, MD
Williamson Memorial Hospital
Williamson, WV

Cornelius Wimmer, MD
University of Innsbruck
Innsbruck, Austria

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I N T R O D U C T I O N

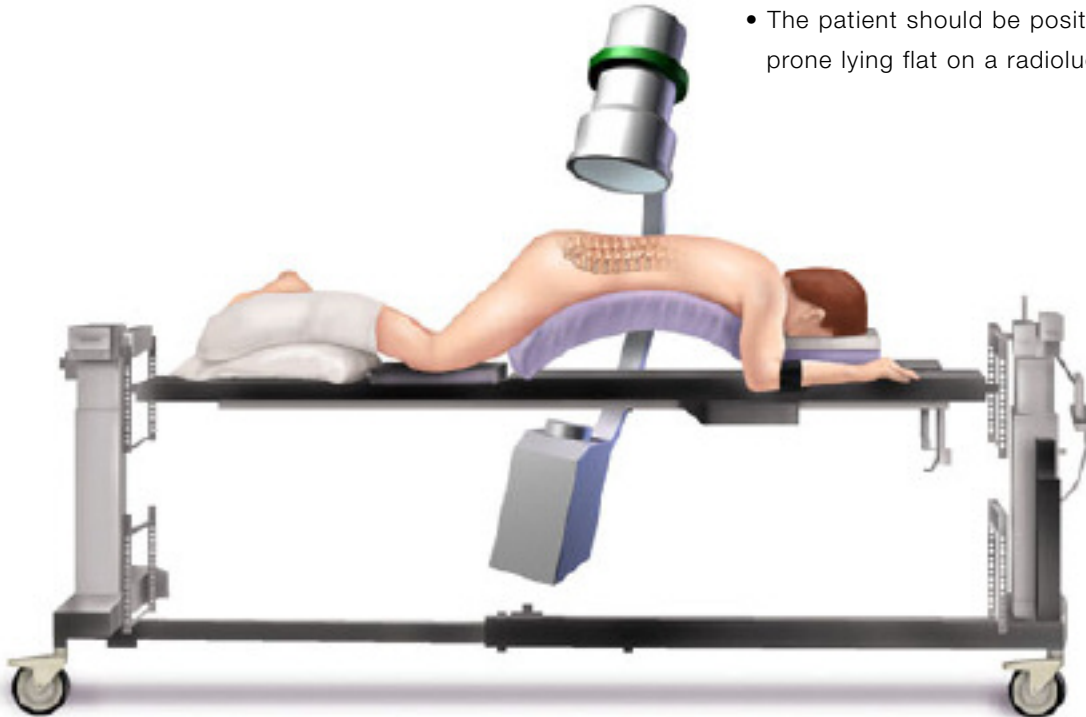
Born from the EXPEDIUM™ Spine System, the VIPER™ System continues the tradition of speed, security and simplicity in a next-generation minimally invasive fixation system. The VIPER System incorporates technique driven designs, including a cutting-edge Closure Mechanism, Cannulated Polyaxial Screws and a customized Pre-Lordosed Rod created in conjunction with unique instrumentation designed specifically for a percutaneous procedure. Enabling effortless rod placement through two small incisions while reducing the muscle trauma associated with open techniques, the VIPER System helps take the guesswork out of percutaneous spine surgery.

VIPER

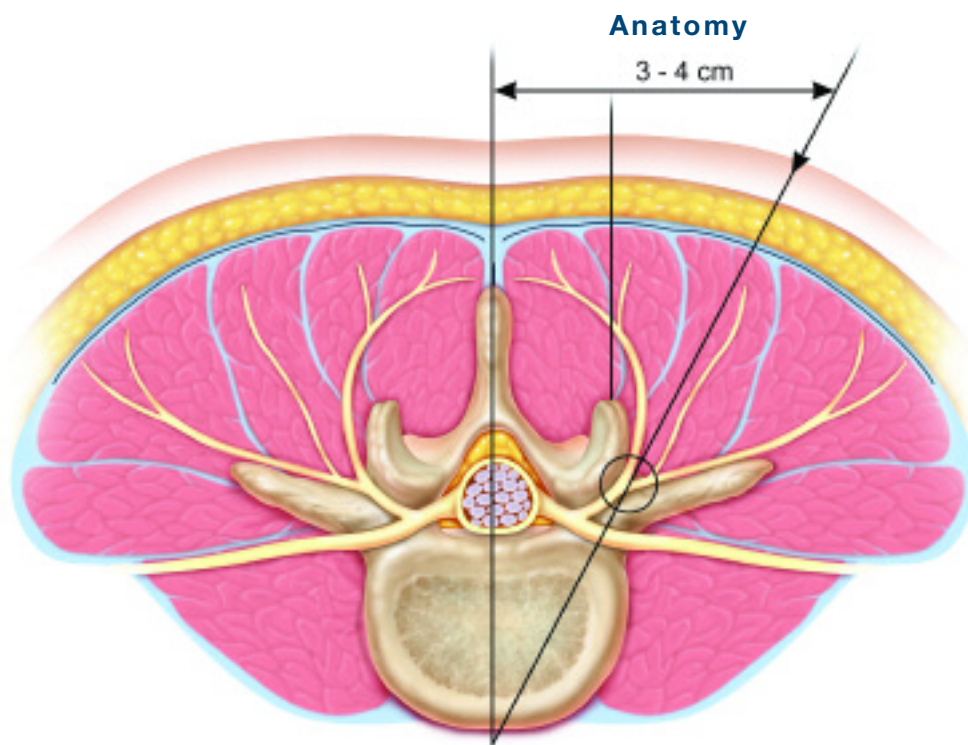
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OR Set-Up

- The patient should be positioned prone lying flat on a radiolucent table.



- It is recommended to use a Jackson Table, to assist in achieving the proper position, and provide an unrestricted view for imaging. Confirming the C-Arm will allow for easy rotation in the lateral, oblique and A/P positions around the table. Tables that prohibit clear A/P and lateral images should be avoided.



Fluoroscopic Planning

- Use A/P and lateral fluoroscopy to identify and target the appropriate levels. Plan the pedicle entry point to allow room for the screw lateral to the facet.
- Use a C-Arm to identify the lateral wall of the pedicle. The starting skin incision should be at least 1cm lateral to this point but will vary based on patient size.

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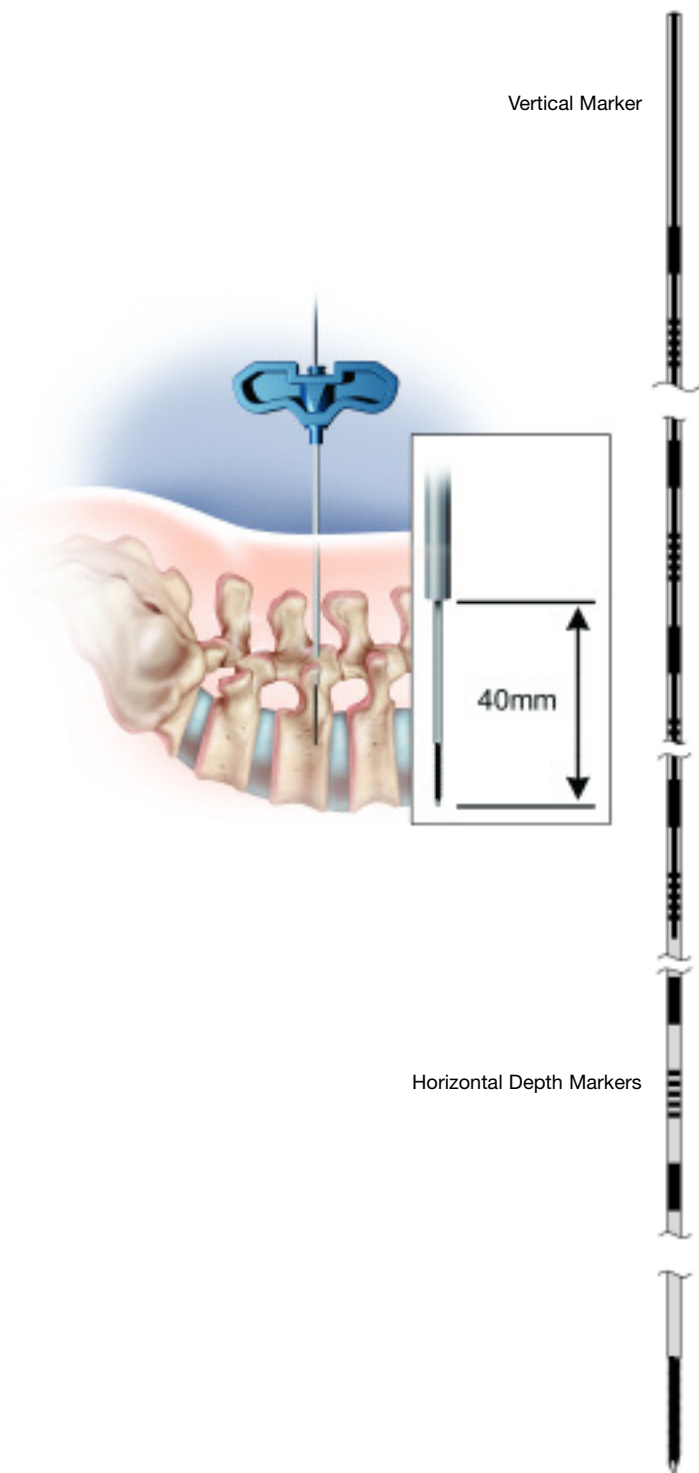
Jamshidi Needle Placement

- 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 seen later in the procedure). Insert the Jamshidi Needle. Using A/P and lateral fluoroscopy, advance the Jamshidi Needle to the pedicle entry point at the intersection of the facet and transverse process. Confirm that the tip of the Jamshidi Needle is at the lateral border of the pedicle on an AP image. Gently tap the Jamshidi Needle down the center of the pedicle. Confirm placement with A/P and lateral fluoroscopy to ensure that the Jamshidi Needle does not breach the wall of the pedicle. Remove the inner stylet of the Jamshidi Needle.

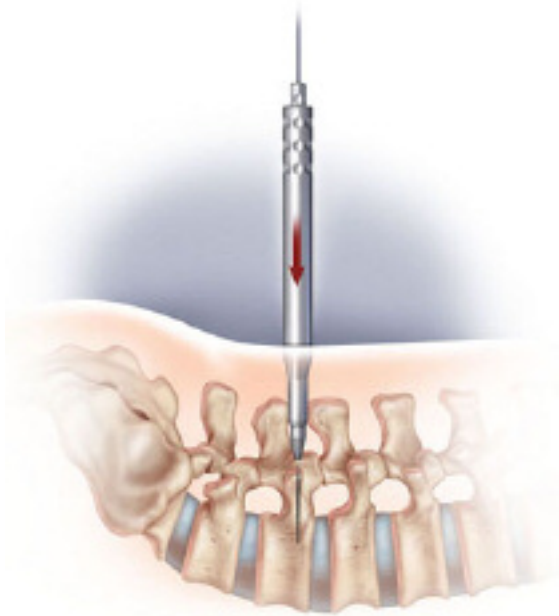


Guidewire Placement

- Select the threaded Guidewire with a blunt or sharp tip, based on surgeon preference. Insert the Guidewire into the Jamshidi Needle. Advance the Guidewire past the tip of the Jamshidi Needle to obtain a bony purchase, typically 35mm-40mm. The Guidewire should be placed deeper than both the Jamshidi Needle and the upcoming Tap to be used in the next step of the procedure.
- **Use caution when placing the Guidewire.** Horizontal markers in 5mm increments will help to identify the depth. These depth markers will be used later in the procedure to monitor unintentional advancement of the Guidewire. A vertical marker can also be used to monitor unintentional rotation. After the Guidewire is placed to the desired depth, carefully remove the Jamshidi Needle while securing the Guidewire.
- Repeat the steps above and place multiple Guidewires at each level, based on surgeon preference. This may improve the flow of the procedure and reduce the amount of fluoroscopy required.

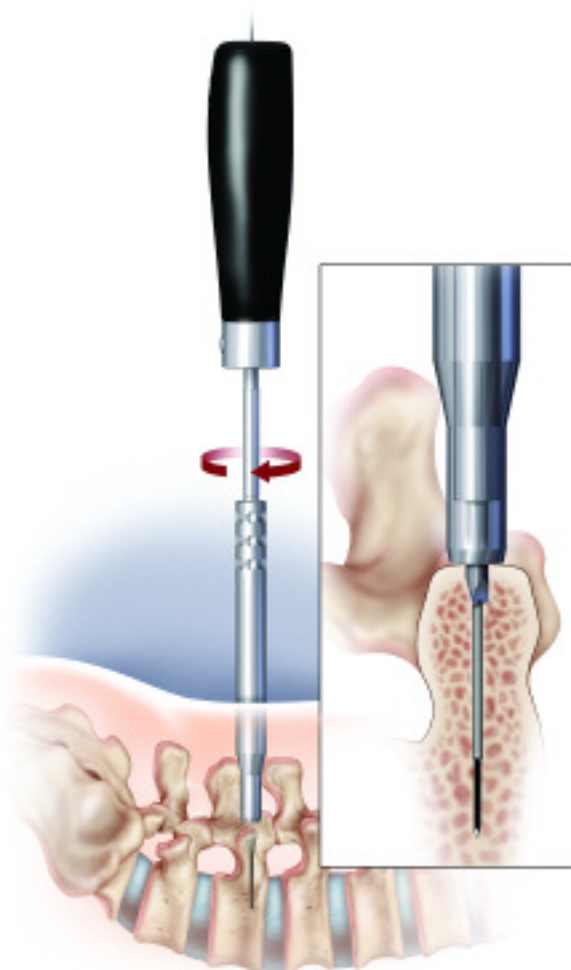


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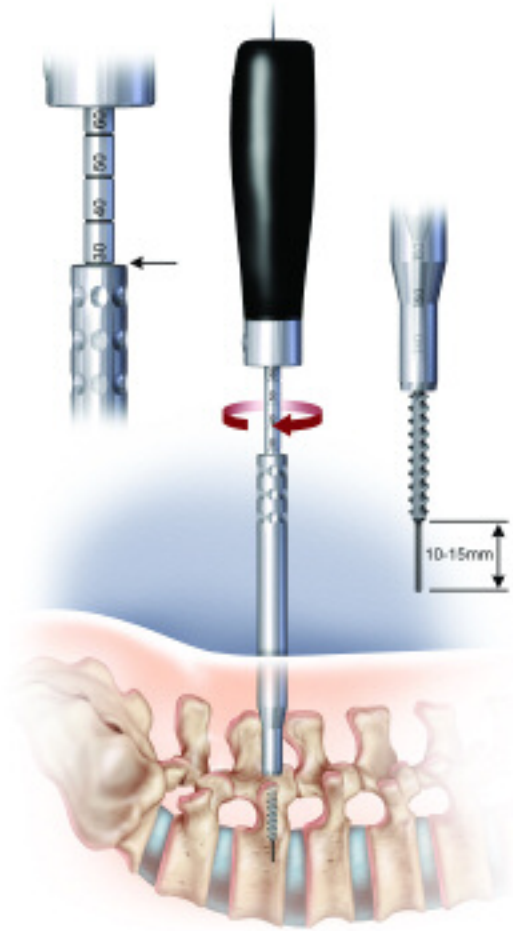


Pedicle Preparation

- In preparation for tapping the pedicle, advance the 7mm Dilator over the Guidewire down to the bone. Confirm with fluoroscopy. Place the Pedicle Preparation Cannula over the Dilator and fully seat it at the pedicle entry point. The Cannula will protect the soft tissue while the pedicle is being prepared. Remove the Dilator while securing the Guidewire and the Cannula.
- Optionally, irrigation can be used when placing the Pedicle Preparation Cannula.



- Advance the Cannulated Drill over the Guidewire to create a hole in the cortex at the pedicle entry point.



- Advance the appropriate size Cannulated Self-Drilling Tap over the Guidewire into the pedicle. While tapping, watch the depth markers and vertical marker on the Guidewire to avoid unintentional advancement and rotation.
- **Do not advance the Tap beyond the tip of the Guidewire as bone may get wedged in the distal hole of the Tap and the Guidewire may lose purchase.** The Guidewire may be unintentionally removed with the Tap. **Use caution not to bend or kink the Guidewire with the Tap.**
- Depth markers on the Tap, referenced to the Pedicle Preparation Cannula, can be used to determine the appropriate screw length. **It is recommended that fluoroscopy be used while tapping to monitor the depth of the Tap and ensure the Guidewire is not unintentionally advanced.**
- Manually stabilize the Guidewire as the Tap is removed. If necessary to maintain contact with the Guidewire, detach the modular handle from the Tap. Turn the Tap counterclockwise to remove.
- Verify the integrity of the pedicle with a Ball-Tip Feeler placed along side the Guidewire.

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Closed Screw
Extension



Open Screw
Extension – Small



Open Screw
Extension – Large

Screw and Screw Extension Assembly

- For a one-level percutaneous procedure, one Open Screw Extension and one Closed Screw Extension are recommended.
- The Open Screw Extension may be planned cephalad or caudal based on surgeon preference. The selected Screw should be matched to the appropriate Screw Extension.
- **To accommodate all patient sizes, the Open Screw Extensions are available in two sizes – small and large.**
- Depth Markers on the Pedicle Preparation Cannula can be used to determine the appropriate Open Screw Extension.
- The Small Open Screw Extension is recommended for patients with skin to pedicle depths of 30mm - 60mm. The Large Open Screw Extension is recommended for patients with skin to pedicle depths of 60mm - 100mm.



Screw Extension Loading Template

Attaching the Screw Extensions to the Screws

- To ensure proper attachment, the Screws should be loaded using the Screw Extension Loading Template and Alignment Guide. Insert the proper Screw into the Screw Extension Loading Template.

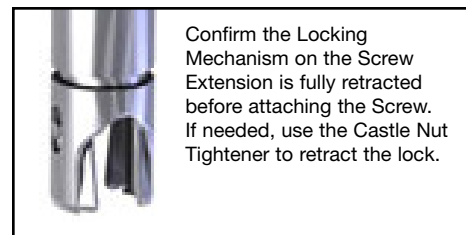


Screw Extension Alignment Guide

- Attach the Alignment Guide to the top of the Loading Template.



The Screw head has a TOP NOTCH™ Feature that interlocks with the Screw Extensions.



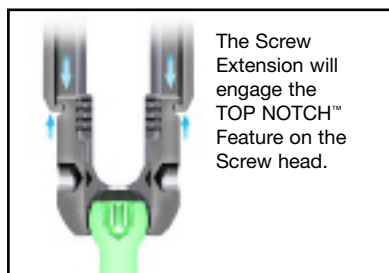
Confirm the Locking Mechanism on the Screw Extension is fully retracted before attaching the Screw. If needed, use the Castle Nut Tightener to retract the lock.

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Screw and Screw Extension Assembly (continued)

- Match up the indentation on the Alignment Guide with the etched line on the Open Screw Extension.
- While maintaining the orientation of the Open Screw Extension, advance it down the Alignment Guide until it reaches the Screw head. Twist the Screw Extension 90° to engage the Screw. Listen for the Alignment Guide to click indicating the Screw has been engaged.



- Use the Castle Nut Tightener to secure the Screw to the Screw Extension. The Screw must be properly attached to the Screw Extension before inserting the Screwdriver. **Use caution to avoid over tightening.** It may prevent the rod from fully seating inside the Screw heads.



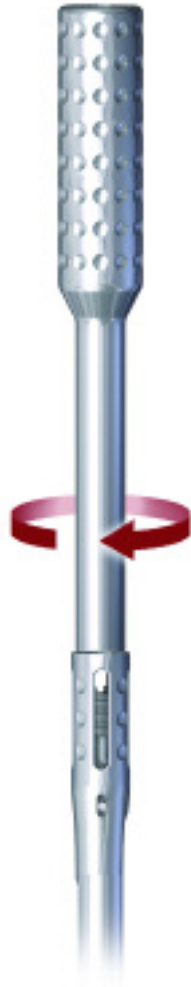
- To verify proper attachment, remove the Screw and Screw Extension assembly and either visually inspect the connection or insert a VIPER Pre-Lordosed Rod into the Screw Extension Slot and Screw head. If secure, advance the Screw Extension Sleeve over the Open Screw Extension to confirm clearance.
- Optionally, to avoid removing the assembly from the Screw Extension Loading Block, pull up on the Screw Extension to confirm the Screw has been captured.



- Insert the Screwdriver inside the Open Screw Extension and rotate clockwise until the Screw is properly attached.

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Screw and Screw Extension Assembly (continued)

- Repeat the same steps for the Closed Screw Extension except the Castle Nut Tightener will be inserted inside the Closed Screw Extension.



Pedicle Screw Insertion

- Guide the first Screw Assembly over the Guidewire down to the pedicle and insert the Polyaxial Screw. The Guidewire may be removed once the Screw engages the pedicle. While inserting the Screw into the pedicle, monitor the horizontal depth markers and vertical marker on the Guidewire to avoid unintentional advancement and rotation.
- It is recommended that fluoroscopy be used while inserting the Screw to ensure proper placement.



- To remove the Screwdriver, turn the handle counterclockwise while firmly holding the Closed Screw Extension or the Screw Extension Sleeve on the Open Screw Extension. **Use caution not to bend or kink the Guidewire, if still in place.**
- To maintain full polyaxial capability, the Screw head should not be fully seated against bone.

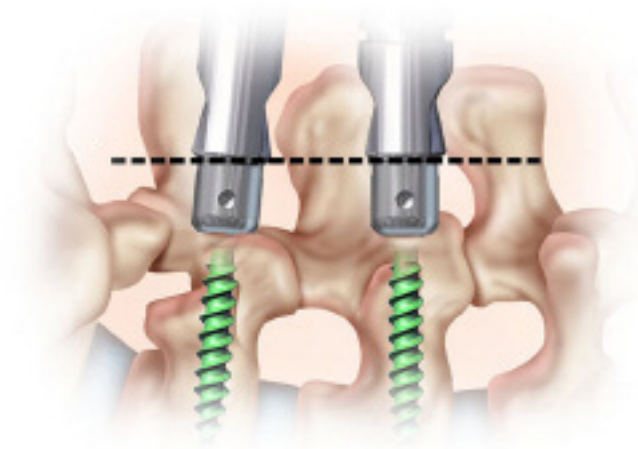
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Pedicle Screw Insertion (continued)

- Repeat Screw Placements at all levels.
- Verify the polyaxial capability of the Screw by manipulating the Screw Extensions.
- Remove the Screw Extension Sleeve on the Open Screw Extension.

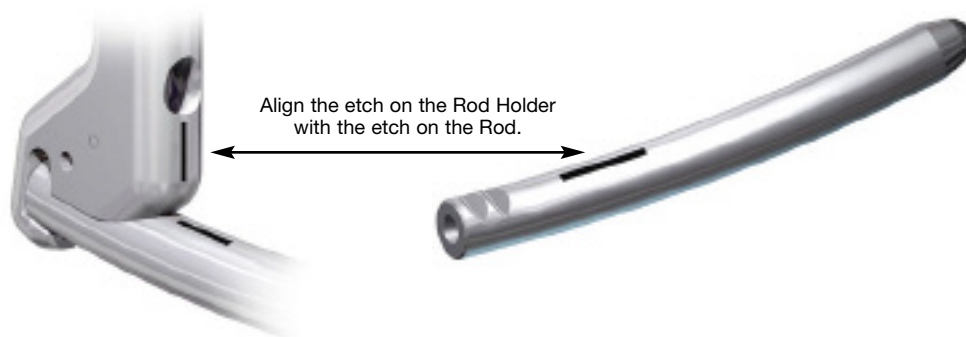


- To plan for the upcoming Rod insertion, confirm the Screw heights are of approximately equal heights, and bone will not impede the Rod pathway.



Attaching the Rod Holder to the Rod

- Using the Rod Gauge, determine the appropriately sized VIPER Pre-Lordosed Rod.
- To ensure proper attachment, the Rod should be carefully aligned with the Rod Holder by matching up the line on the Rod Holder with the line on the Rod.
- Insert the X15 Rod Tightener down the shaft of the Rod Holder until the tip is engaged. Tighten the X15 Rod Tightener until the Rod is secure. **Use caution to avoid over tightening.**
- Remove and confirm the Rod is properly attached.



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Rod Insertion

One-Level Percutaneous Procedure

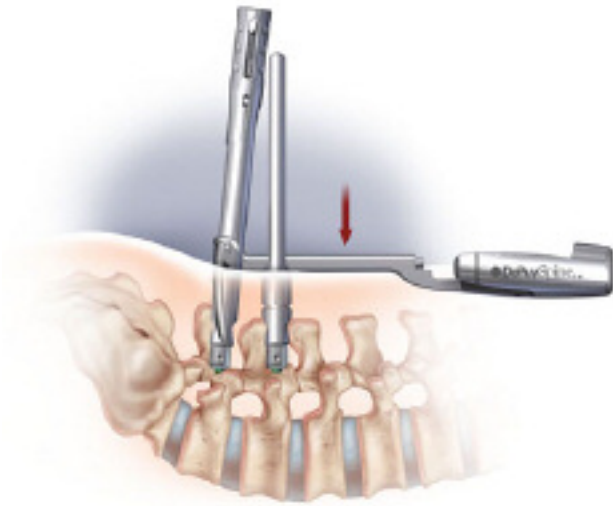
STEP 1



- **Align the openings of the Screw Extensions and rotate the Closed Screw Extension so the arrow faces the Open Screw Extension.** Position the Rod Holder Handle to be parallel to the skin surface, with the Rod perpendicular. Insert the Rod Holder Assembly through the Open Screw Extension, 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.
- For deeper patients, manipulate the Rod Holder as appropriate to fit inside both Screw Extensions.
- 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.



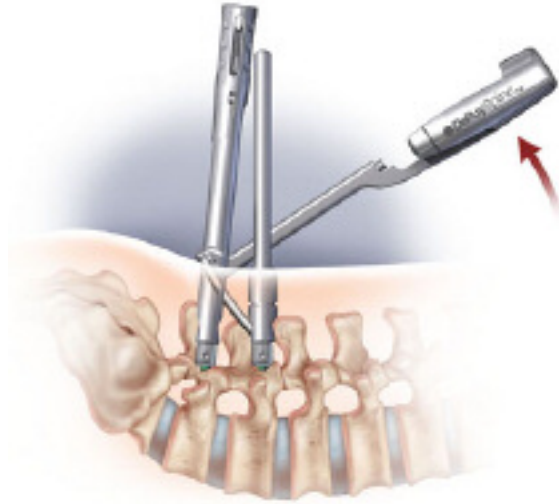


STEP 2

- **Lower the Rod down the Closed Screw Extension until it touches the top of the Screw head or it is as deep as the tissue will allow.** At a minimum, the tip of the Rod should be sub-fascial. Move the Open Screw Extension toward the Closed Screw Extension and hold them together.

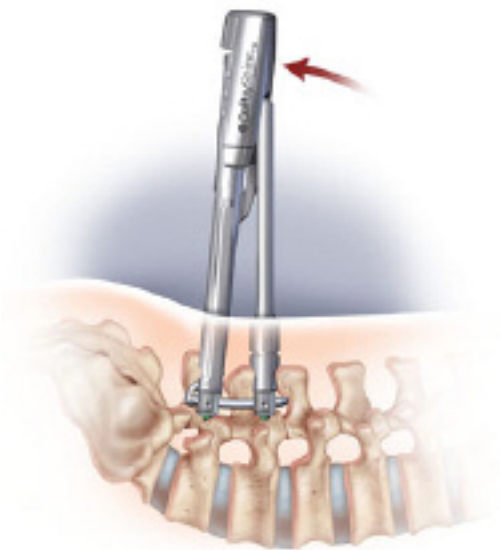
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STEP 3

- **Rotate the Rod Holder 90°.** This action will guide the Rod into the bottom slot of the Open Screw Extension.
- For deeper patients, ensure the Rod is guided into the bottom slot of the Open Screw Extension.



STEP 4

- **Engage the Rod Holder Handle with the proximal end of the Closed Screw Extension.**
- To confirm the Rod is seated inside the Closed Screw Extension, align the marker on the Rod Holder with the line on the Closed Screw Extension.
- To verify the Rod is within the bottom slot of the Open Screw Extension, rotate the Rod in the coronal plane and observe the Open Screw Extension. The Open Screw Extension should move in both directions corresponding with the Rod rotation. Fluoroscopy can also be used to confirm Rod placement.

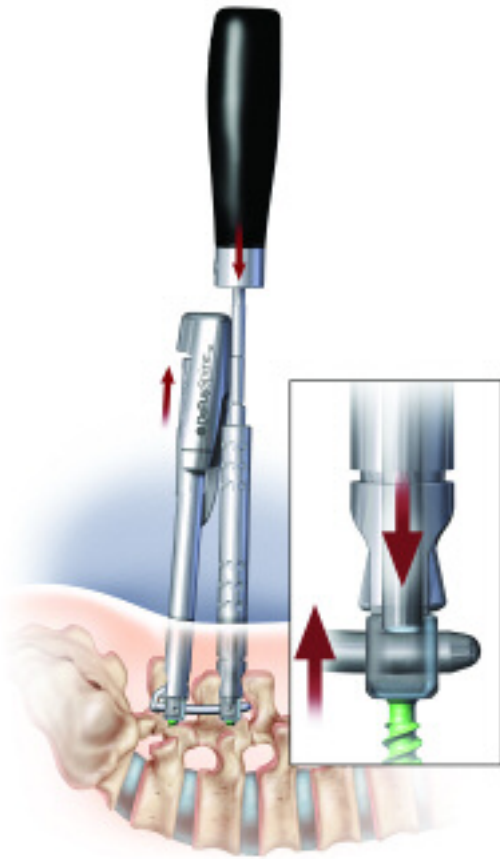
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Rod Insertion (continued)

- Insert the Screw Extension Sleeve over the Open Screw Extension.
Drive the Rod Pusher down the Open Screw Extension. If the depth marker on the Rod Pusher labeled "O" for Open Extension is aligned with the top of the Open Screw Extension, then the Rod is fully seated within the proximal Screw head. If the Rod Pusher indicates the Rod is not fully seated, manipulate Screw Extensions to drop the Rod into place. Angling the Screw Extensions laterally may avoid bony anatomy which could prevent the Rod from fully seating.
- Confirm Rod placement with fluoroscopy.



- To reconfirm the Rod is seated, pull-up on the Rod Holder while the Rod Pusher is inside of the Open Screw Extension. If the Rod Pusher advances up, that will indicate the Rod is pushing up on the Rod Pusher and the Rod is inside the Screw head.

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Rod Insertion (continued)

Tips for Rod Insertion

- If the proximal end of the Rod will not seat within the head of the Screw, the Rod may be caught on the fascia outside the Closed Screw Extension. If manipulation of the Rod Holder does not relieve this, remove the Rod Holder Assembly. Insert the Fascia Separator inside the Closed Screw Extension. Guide the instrument outside the proximal slot of the extension to create a path through the fascia.





Set Screw Insertion

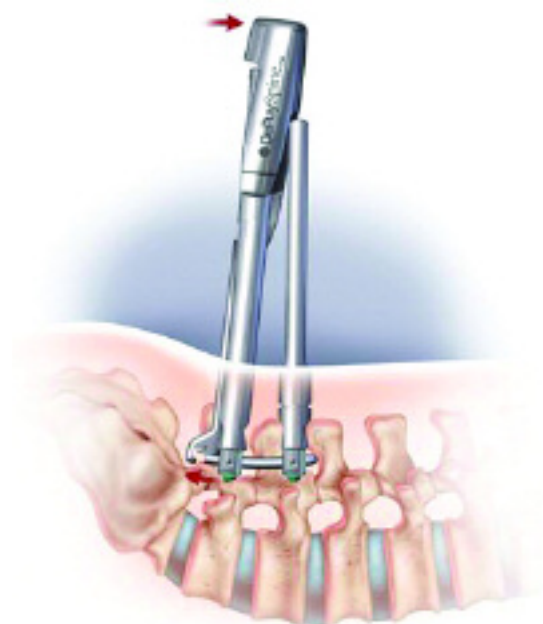
- Load a Set Screw from the caddy onto the X25 Inserter. Twist the proximal knob on the handle until the Set Screw is secured. Guide the X25 Inserter into the Open Screw Extension and loosely tighten the Set Screw to capture the Rod. The Screw head should remain mobile to enable repositioning of the Open Screw Extension, which may assist during the next steps.
- If the proximal depth marker on the X25 Inserter is aligned with the top of the Open Screw Extension, then the Set Screw is seated within the Screw head. Remove the X25 Inserter.
- After threading the Set Screw into the Screw head, pull-up slightly on the X25 Inserter to ensure the Set Screw is captured in the Screw head before disengaging.
- If the Set Screw becomes disengaged, retrieve it using forceps.

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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 Screw head.** Insert the X15 Rod Tightener inside the Rod Holder to engage the inner nut. Turn the X15 Rod Tightener counter-clockwise to disengage the Rod from the Rod Holder.



- Remove the X15 and the Screw Extension Sleeve. Move the Rod Holder toward the Open Screw Extension and remove.
- Repeat steps to secure the Set Screw within the Closed Screw Extension.

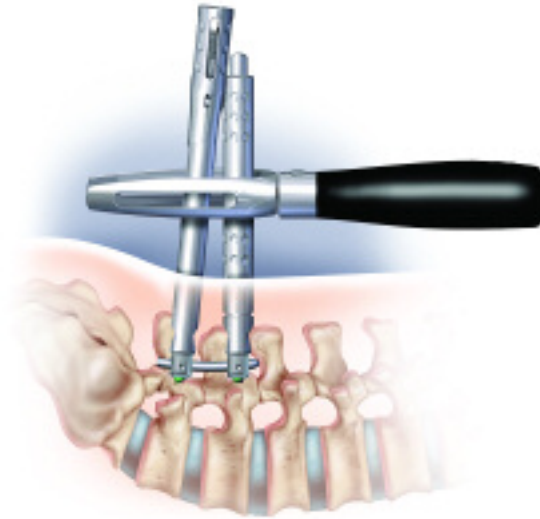


Compression

- With both closure mechanisms loosely captured, provisionally tighten the Set Screw inside the Closed Screw Extension to allow for compression maneuvers. Due to the Notch Rod, it is important the Open Screw Extension is mobile.
- Slide the Compressor over both Screw Extensions down to the level of the skin surface. Insert the VIPER T-Bar above the Compressor between both Screw Extensions. Advance the X25 Intermediate Tightener down the Closed Screw Extension to engage the Set Screw. Apply compression forces and tighten the Set Screw. Distraction may also be applied by inserting the VIPER T-bar below the Compressor.

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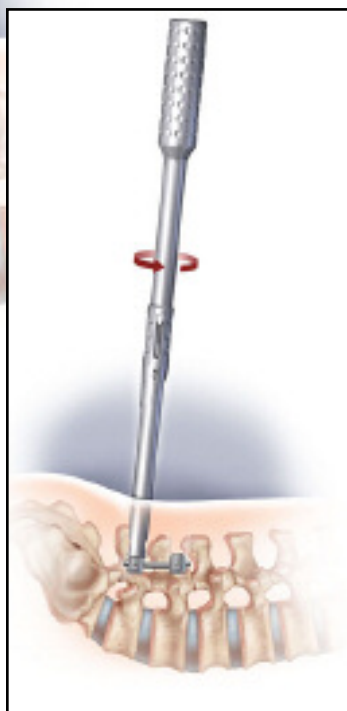
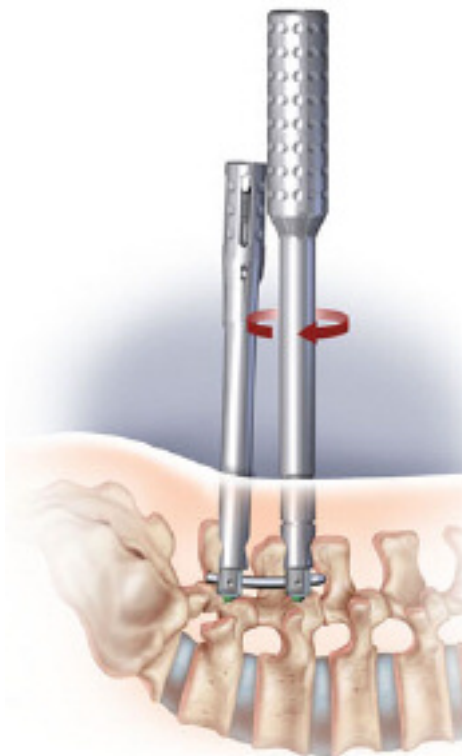


Final Tightening

- Once the construct is confirmed with fluoroscopy, the Rod should have approximately 5mm overhang outside each screw. (The notches on the rod will be outside the Screw head).
- To perform final tightening, place the Anti Torque/Rod Stabilizer around both Extensions. Insert the X25 Final Tightener with the Torque Wrench Handle through the Screw Extension to engage the Set Screw. Rotate the Torque Wrench Handle clockwise until it clicks and resistance is no longer evident. Repeat for additional Set Screws.

Screw Extension Removal

- Remove the Screw Extension Sleeve on the Open Screw Extension. Use the Castle Nut Tightener to detach the Open Screw Extension.
- Rotate the Screw Extension 90° to remove.
- Repeat the same steps for the Closed Screw Extension.



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Surgical Technique



Two-level Procedure

Follow the previous steps used in this Surgical Technique with the following differences:

Fluoroscopic Planning and Jamshidi Needle Placement

(Two-level Procedure)

Plan each pedicle entry point in a straight line.

Screw and Screw Extension Assembly

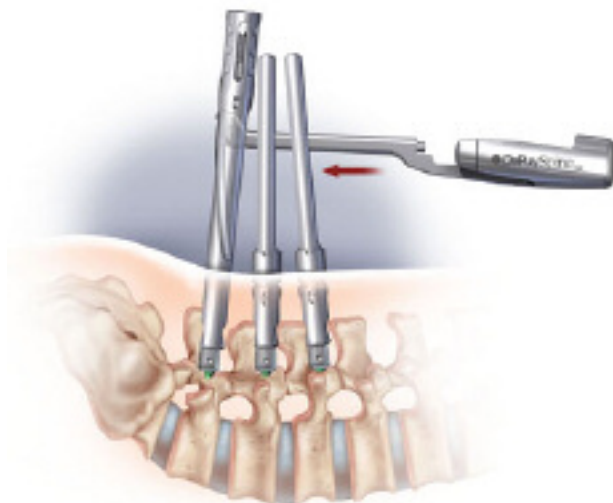
(Two-level Procedure)

It is suggested to use two Large Open Screw Extensions and one Closed Screw Extension.

Pedicle Screw Insertion

(Two-level Procedure)

The Closed Screw Extension should be placed either cephalad or caudal based on surgeon preference.



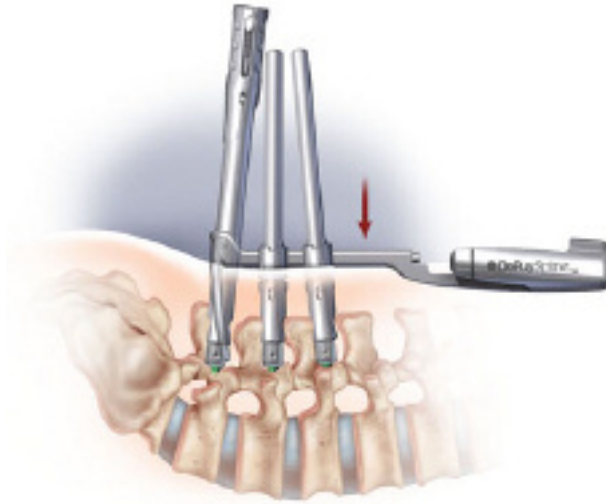
Rod Insertion (Two-level Procedure)

STEP 1

- **Align the openings of the three Screw Extensions and rotate the Closed Screw Extension so the arrow faces the Open Screw Extensions.** Position the Rod Holder Handle parallel to the skin surface, with the Rod perpendicular. Insert the Rod Holder Assembly through the proximal opening of the Open Screw Extensions, and advance the Rod Holder into the slot of the Closed Screw Extension. The entire Rod should be contained within the Closed Screw Extension.

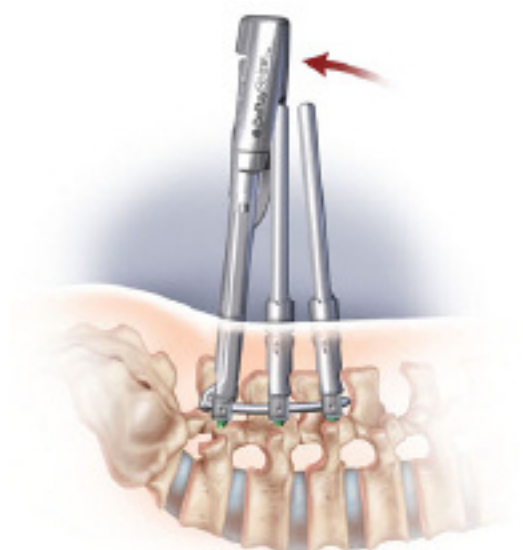
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STEP 2

- **Lower the Rod down the Closed Screw Extension until it touches the top of the Screw head or it is as deep as the tissue will allow.** At a minimum, it should be sub-fascial.
- Move the Open Screw Extensions toward the Closed Screw Extension and hold them together.

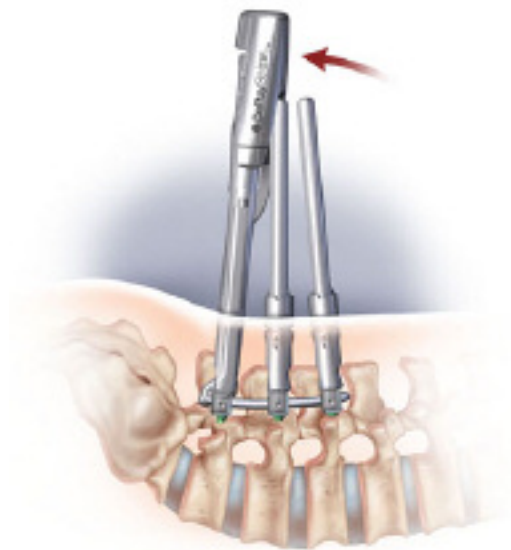


STEP 3

- **Rotate the Rod Holder 90°** when the Rod touches the proximal Screw head or with the Rod Holder fully depressing the tissue. This action will guide the Rod into the bottom slot of the first Open Screw Extension. Rotate the Rod in the coronal plane and observe the Open Screw Extension. The Open Screw Extension should move in both directions corresponding with the rod rotation.
- Continue to guide the Rod into the second Open Screw Extension.

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STEP 4

- Engage the Rod Holder into the proximal end of the Closed Screw Extension.
- Drive the Rod Pusher down the distal Open Screw Extension to fully seat the rod. Next, drive the Rod Pusher down the middle Open Screw Extension. If the depth marker on the Rod Holder is aligned with the line on the Open Screw Extension, then the Rod is fully seated within the second Screw head. Confirm Rod placement with fluoroscopy.
- Insert the Screw Extension Sleeves over both Open Screw Extensions.
- For deeper patients, ensure the Rod is guided below the locking mechanisms on both slots of the Open Screw Extensions.

Ordering Information

PRODUCT CODE

DESCRIPTION

One-Time Use Instruments

8002	VIPER Jamshidi Needle, Bevel and Disposable
2867-05-200	VIPER 1.37mm Threaded Guidewire, Blunt and Disposable
2867-05-210	VIPER 1.37mm Threaded Guidewire, Sharp and Disposable

Instruments

2867-10-100	VIPER 7mm Dilator
2867-10-110	VIPER Pedicle Preparation Cannula
2867-10-200	VIPER Ball Tip Feeler
2867-10-210	VIPER Drill, Cannulated
2867-10-400	VIPER Modular T Handle, Cannulated
2867-10-410	VIPER Modular Straight Handle, Cannulated
2867-10-490	VIPER Ratcheting Adapter, Cannulated
2867-10-500	VIPER 5mm Self-Drilling Tap, Cannulated and Dual Lead
2867-10-600	VIPER 6mm Self-Drilling Tap, Cannulated and Dual Lead
2867-10-700	VIPER 7mm Self-Drilling Tap, Cannulated and Dual Lead
2867-20-000	VIPER Polyaxial Screw Driver Shaft, Cannulated
2867-20-015	VIPER X15 Hexlobe Rod Tightener
2867-20-020	VIPER T20 Hexlobe Driver Shaft
2867-20-200	VIPER Screw Extension, Closed
2867-20-300	VIPER Screw Extension, Open - Small
2867-20-350	VIPER Screw Extension, Open - Large
2867-20-400	VIPER Castle Nut Tightener
2867-20-500	VIPER Screw Extension Sleeve
2867-30-050	VIPER Rod Gauge
2867-30-060	VIPER Rod Gauge Measuring Block
2867-30-100	VIPER Rod Holder, Angled
2867-30-110	VIPER Rod Holder, Bolt
2770-30-110	VIPER Rod Holder, Kerrison
2867-30-150	VIPER Rod Pusher Guide
2867-30-400	VIPER X25 Set Screw Inserter, Self Retaining
2731-22-201	VIPER T-bar

Ordering Information

PRODUCT CODE	DESCRIPTION
Instruments (Continued)	
2867-40-000	VIPER Compressor
2867-40-100	VIPER Rod Stabilizer/Anti-Torque
2797-12-550	VIPER Intermediate Tightener X25
2867-40-210	VIPER X25 Final Tightener Driver Shaft
2770-40-510	VIPER Torque Wrench Handle
2867-00-000	VIPER Instrument Case and Tray
2867-00-050	VIPER Implant Case and Tray
2867-00-100	VIPER Set Screw and Rod Caddy
2867-00-300	VIPER Screw Extension Loading Template
2867-00-350	VIPER Screw Extension Alignment Guide
2867-00-600	VIPER 6mm Cannulated Screw Caddy
2867-00-700	VIPER 7mm Cannulated Screw Caddy
Implants	
1867-15-635	VIPER Cannulated Polyaxial Screw, 6x35mm, Ti
1867-15-640	VIPER Cannulated Polyaxial Screw, 6x40mm, Ti
1867-15-645	VIPER Cannulated Polyaxial Screw, 6x45mm, Ti
1867-15-650	VIPER Cannulated Polyaxial Screw, 6x50mm, Ti
1867-15-655	VIPER Cannulated Polyaxial Screw, 6x55mm, Ti
1867-15-735	VIPER Cannulated Polyaxial Screw, 7x35mm, Ti
1867-15-740	VIPER Cannulated Polyaxial Screw, 7x40mm, Ti
1867-15-745	VIPER Cannulated Polyaxial Screw, 7x45mm, Ti
1867-15-750	VIPER Cannulated Polyaxial Screw, 7x50mm, Ti
1867-15-755	VIPER Cannulated Polyaxial Screw, 7x55mm, Ti
1867-15-000	VIPER Single-Innie Set Screw
1867-62-635	VIPER Pre-Lordosed Rod, 35mm, Ti
1867-62-640	VIPER Pre-Lordosed Rod, 40mm, Ti
1867-62-645	VIPER Pre-Lordosed Rod, 45mm, Ti
1867-62-650	VIPER Pre-Lordosed Rod, 50mm, Ti
1867-62-655	VIPER Pre-Lordosed Rod, 55mm, Ti
1867-62-660	VIPER Pre-Lordosed Rod, 60mm, Ti
1867-62-665	VIPER Pre-Lordosed Rod, 65mm, Ti
1867-62-670	VIPER Pre-Lordosed Rod, 70mm, Ti



MIS for Spine.

Product Family Portfolio

VIPER™



Minimally Invasive
Percutaneous Posterior
Fixation



PIPELINE™

Access System



Minimally Invasive
Access Systems



CONCORDE™

Minimally Invasive
Interbody Instruments



INDICATIONS

The VIPER™ System was cleared under the EXPEDIUM™ Family for the following indications:

The VIPER System is intended for noncervical pedicle fixation for the following indications: degenerative disc disease (defined by 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 in skeletally mature patients.

When used in a percutaneous, posterior approach with MIS instrumentation, the EXPEDIUM MIS Screw (VIPER) components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined by 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 in skeletally mature patients.

LIMITED WARRANTY AND DISCLAIMER:

DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767
USA
Tel: +1 (800) 227-6633