

VIPER®

3D MIS Correction Set

# Surgical Technique Guide



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## CONTENTS

INSTRUMENT AND IMPLANT OPTIONS FOR SURGICAL PROCEDURE	01
Screw Options	03
Rod Options	04
SURGICAL PROCEDURE	05
Pedicule Cannulation	07
Reduction	10
Spondylolisthesis Correction	16
Compression / Distraction	23
Pelvic Fixation	28

NOTE: For a comprehensive surgical technique, refer to the VIPER 2 System Guide. The information herein describes proper usage instructions for VIPER 3D components only.

## *Instrument and Implant Options for Surgical Procedure*

- *Screw Options*
- *Rod Options*



## Instrument and Implant Options for Surgical Procedure

During preoperative planning, it is critical to be aware of all instrument and implant options to help facilitate a balanced three-dimensional correction of the spine. Understanding the subtle differences in implant options and, more importantly, where to place them throughout the construct will enable a more simplified manipulation of individual spinal elements.

The instrument and implant options listed herein are components of the VIPER® MIS Spine System. This list is not intended to be comprehensive; rather, it is shown here as a method of describing options available for the treatment of complex spinal pathologies. By providing a choice of instruments and implants, the VIPER Platform allows surgeons to treat patients minimally invasively by using techniques they are accustomed to using in an open procedure.

### Screw Options

#### CANNULATED POLYAXIAL

- Dual lead thread form
- 4.35–9 mm
- Self tapping

#### CANNULATED MONOAXIAL

- Single lead thread form
- No head toggle – acts as long solid post when attached to screw extension

NOTE: Can be used for fracture reduction or listhesis reduction.  
Rod passage may be difficult if screw placement is poor.

#### CANNULATED POLYAXIAL LONG SHANK SCREW

- Longer shank to accommodate anatomy
- Same VIPER head size

NOTE: Used to link up to pelvis or in larger anatomy.



FIGURE 1: VIPER Cannulated Screw

#### CANNULATED UNIPLANAR

- Single lead thread form
- Head resists motion in the medial/lateral direction

NOTE: Helpful when used towards the apex of the curve on the convexity for derotation and medial/lateral translation.

#### CANNULATED POLYAXIAL EXTENDED TAB

(10 mm and 25 mm options)

- 10 mm or 25 mm of built in reduction threads
- Smaller diameter prevents crowding

NOTE: Not intended for medial/lateral manipulation due to tab break-off

FIGURE 2: VIPER Cannulated Extended Tab Screw



## Rod Options

### COBALT CHROMIUM ALLOY (CoCr)

- Provides for a stiffer construct than Ti
- If rod is improperly contoured, reduction may be difficult and cause high forces on bone/screw interface and/or screw/screw extension interface
- Better imaging properties compared with stainless steel
- Can be used with Ti screws

### TITANIUM ALLOY (Ti)

- Easy to contour vs. CoCr
- Straight, pre-lordosed or pre-kyphosed
- 30–600 mm

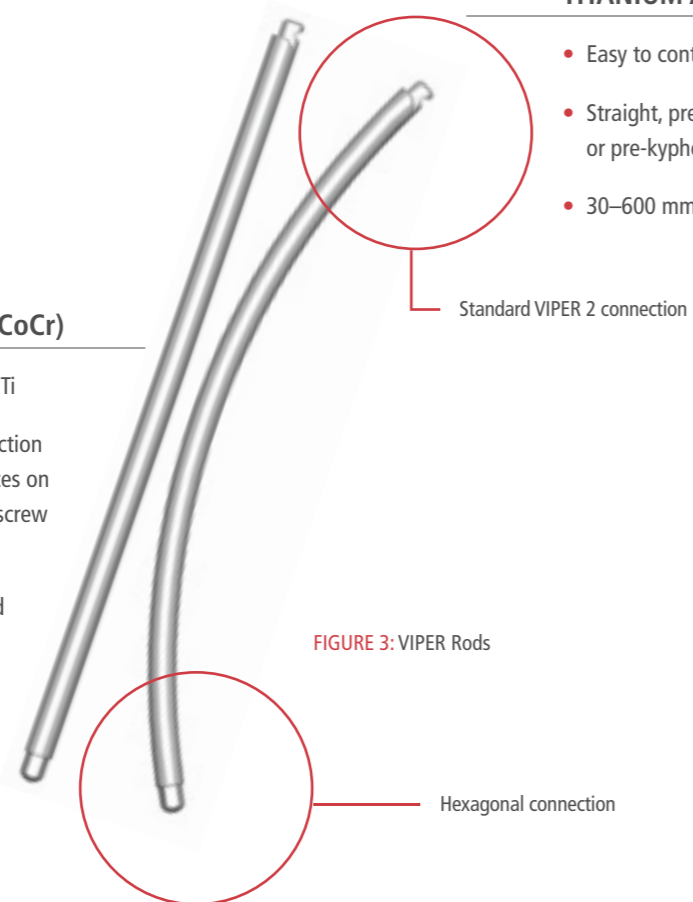


FIGURE 3: VIPER Rods

## Surgical Procedure

- *Pedicle Cannulation*
- *Reduction*
- *Spondylolisthesis Correction*
- *Compression / Distraction*
- *Pelvic Fixation*



## *Surgical Procedure*

Contraindications will vary with surgeon experience and may change with the advent of new technologies and techniques. At the moment, it is generally accepted that these contraindications may include a grade 3 or higher spondylolisthesis, rigid curves with severe sagittal or coronal imbalance, tissue depth or body mass index (BMI) that would prevent use of MIS instruments from accessing or viewing critical anatomy, and/or osteopenia preventing adequate imaging of critical anatomy.

There are many methods used for MIS approaches to address complex spinal pathologies. With increased experience, surgeons learn various techniques and develop their preferred method for patient treatment based on the individual anatomy. It is also important to consider the types of pathologies amenable to an MIS approach, as discussed earlier in this monograph.

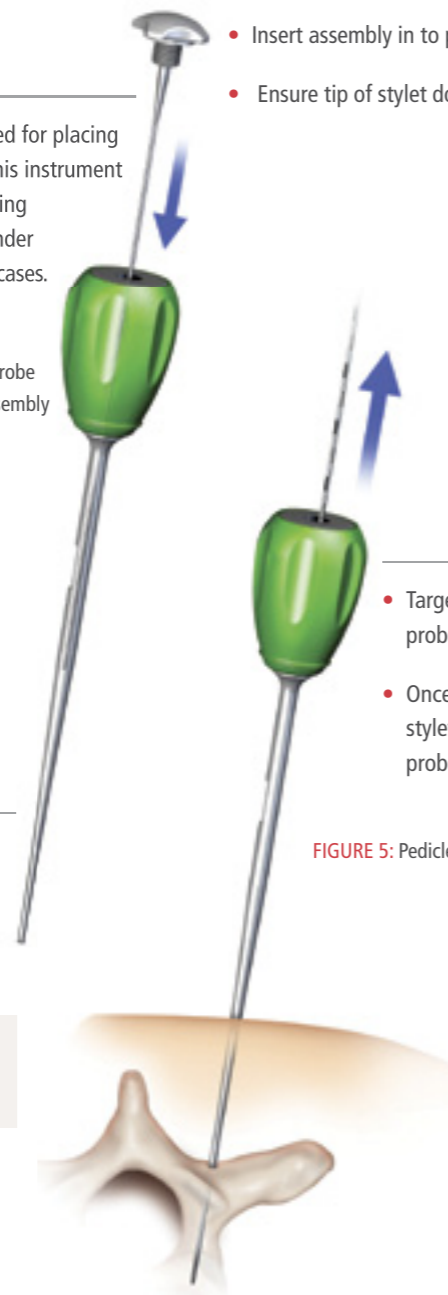
## *Pedicle Cannulation*



## Pedicle Cannulation

- The cannulated pedicle probe can also be used for placing guidewires into the vertebral bodies. While this instrument provides familiar tactile feedback for navigating the pedicle, the probe should be advanced under fluoroscopic guidance in minimally invasively cases.

FIGURE 4: Pedicle probe stylet assembly



### CANNULATED PROBE

- Remove back knob from probe
- Thread inner stylet into metal knob
- Insert assembly in to probe and thread all the way down
- Ensure tip of stylet does not stick out past tip of the probe

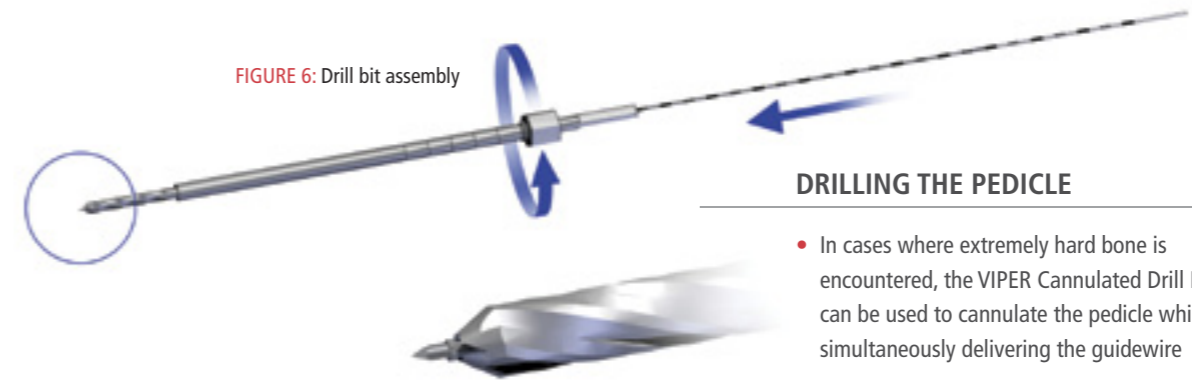
- Place a guidewire down through the cannulation of the cannulated pedicle probe
- Hold the guidewire in place while removing the cannulated pedicle probe

NOTE: A Kocher should be used to remove the stylet from the pedicle probe knob for disassembly and cleaning.

- Target and advance the cannulated pedicle probe through the appropriate pedicle
- Once through the pedicle, remove the inner stylet by turning the cannulated pedicle probe knob counterclockwise

FIGURE 5: Pedicle probe

FIGURE 6: Drill bit assembly



### DRILLING THE PEDICLE

- In cases where extremely hard bone is encountered, the VIPER Cannulated Drill Bit can be used to cannulate the pedicle while simultaneously delivering the guidewire
- Insert a **sharp tip** guidewire into the cannulated drill bit and lock sharp guidewire within the drill bit by turning the collar clockwise. The guidewire should protrude out approximately 1–2 mm from the distal end of the drill bit.

- Attach the drill bit and guidewire assembly to a cannulated power drill (not included with the VIPER 3D Instruments)
- Using the cannulated high-speed drill, advance the drill bit and guidewire assembly through the pedicle under fluoroscopic guidance

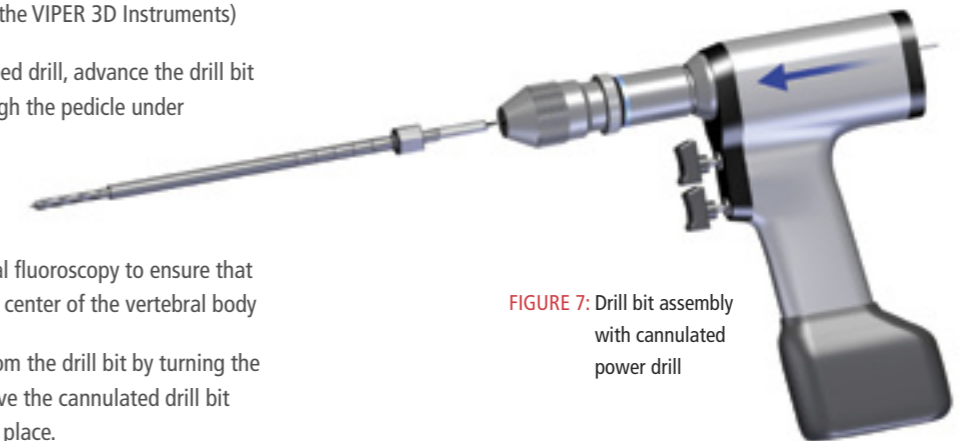


FIGURE 7: Drill bit assembly with cannulated power drill

- Confirm wire depth with lateral fluoroscopy to ensure that the guidewire has reached the center of the vertebral body
- Unlock the sharp guidewire from the drill bit by turning the collar counterclockwise. Remove the cannulated drill bit while leaving the guidewire in place.

NOTE: The guidewire depth should be drilled at least beyond the pedicle/vertebral body junction.

## Reduction



### Rod Reduction

If reduction is required across multiple levels, it is important to reduce incrementally across all levels to ensure proper load sharing and to avoid overloading any one screw.

At levels which require reduction, attach the reduction caps to the screw extensions.

Prior to loading, ensure the locking ring is fully retracted toward the proximal end, past the black alignment etching. Line up the black vertically etched line of the reduction cap with the vertically etched line on the screw extension.

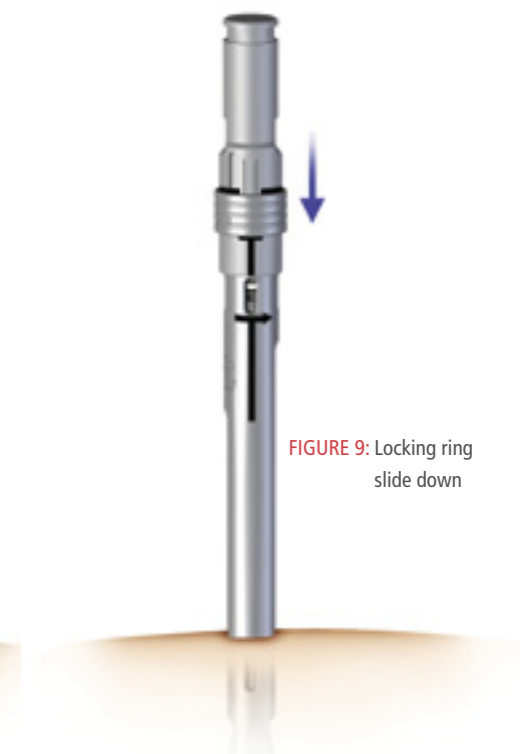
**NOTE:** Prior to performing any rod reduction manoeuvres, care should be taken to ensure that rods are optimally contoured, screw heights are properly aligned, and that the rod has been placed below the fascia. Any of these issues have the potential to cause *in situ* bending, high forces on the screw/screw extension, or even screwpull out when reducing the rod.

- Push reduction cap straight down on screw extension until it clicks and locks onto the notches of the screw extension
- Slide the locking ring on the reduction cap down past the distal black alignment etching

FIGURE 8: Attach reduction cap



FIGURE 9: Locking ring slide down



#### ROD REDUCTION DEVICE USES

- Threaded reduction for increased power – rod approximation – spondy reduction
- Internal to existing screw extensions
- Enhances tactile feedback
- Maintains low profile
- 1 torque-limiting handle to be added soon



## Rod Reduction



FIGURE 10: Assembly

- Place the hexagonal end of the reduction driver into the threaded post at the threaded end. You should feel a slight click when the driver is properly seated.
- The threaded portion of the threaded post should be flush against the plastic washer of the reduction driver or rod pusher
- Load a set screw onto the distal end of the reduction driver. ensure that the set screw is fully seated on the driver. There should be 1 mm of driver tip sitting past the set screw.



FIGURE 11: Final assembly

- Insert this assembly into the top of the reduction cap and 'finger tighten' the threaded post by turning it clockwise until the reduction driver contacts the rod
- Etchings on the threaded post allow for visual feedback on the amount of approximation remaining before the set screw will be engaged
- Repeat this process at all levels requiring reduction

## Multi-Piece Reduction Handle



- Assemble the multi-piece reduction handle by depressing the button of the lower handle and inserting the metal shaft of the upper handle

FIGURE 12: Two-piece reduction handle assembly

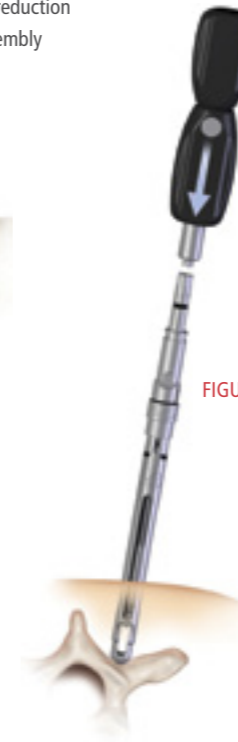


FIGURE 13: Handle inserted into threaded post

### REDUCTION SHAFT AND THREADED POST

- Attach post onto top of shaft
- Load set screw on shaft
- Insert post/shaft assembly into reduction cap

- Using the multi-piece reduction handle, place the handle onto the threaded post. Ensure the handle assembly is engaged into both drive features on the threaded post and reduction driver.

NOTE: This handle will not lock onto the threaded post. care should be taken during placement or removal to prevent dropping the handle.

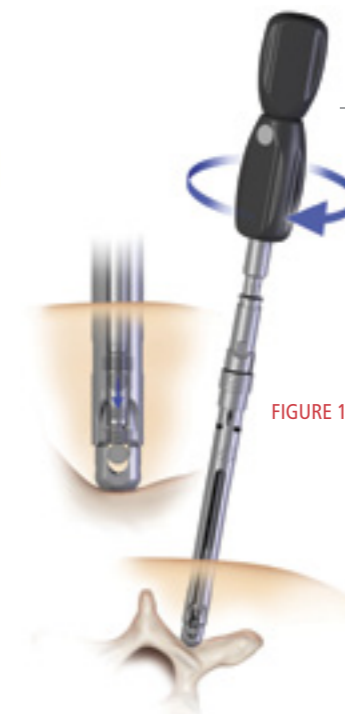


FIGURE 14: Initial reduction

- Rotate the bottom handle clockwise to reduce the rod. The rod should be reduced incrementally across all levels requiring reduction.

## Multi-Piece Reduction Handle

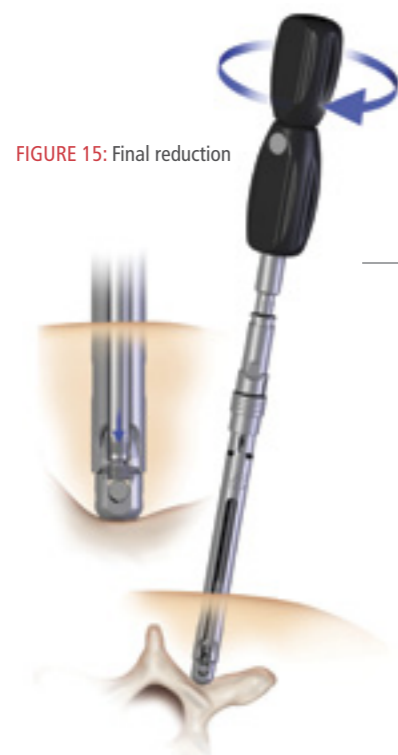


FIGURE 15: Final reduction

### INNER AND OUTER REDUCTION HANDLE

- Attach handle to reduction cap assembly
  - Turn bottom handle to reduce rod (etching indicates amount of reduction)
  - Turn top handle to turn set screw
- 
- Continue to advance the reduction until the bottom of the solid black line on the threaded post is flush with the top reduction cap. This indicates that the set screw is at the top of the screw. Rotate the top handle clockwise to advance the set screw.
  - For the first few turns, continue to turn the upper handle while slowly turning the lower handle. This will continue reducing the rod and will help seat the set screw. Top and bottom handles should not be rotated at the same rate, as minimal force is required on the bottom handle.

NOTE: Fully turning the lower handle to reduce the rod without turning the top handle to capture the set screw will result in damaging the threads of the set screw, overloading the screw extension/screw interface, or the screw/bone interface.

- To remove the reduction assembly, the reduction force must first be released. Turn the lower handle counter-clockwise (backwards) 1/4 turn. Remove the two piece reduction handle. Slide the locking ring straight up to remove the entire assembly.
- If a large amount of reduction is required across multiple levels, or if CoCr rods are being used, an alternating series of rod pushers and set screw Inserters should be used to incrementally reduce the rod across all levels. The rod pusher can be used to push the rod down while delivering a set screw at the adjacent level with the reduction driver. This will avoid overloading and possibly damaging a set screw. Once a series of set screws are in place and have fully captured the rod, remove the rod pushers and place set screws.

NOTE: If reduction is not needed, set screws can be placed using the intermediate driver.

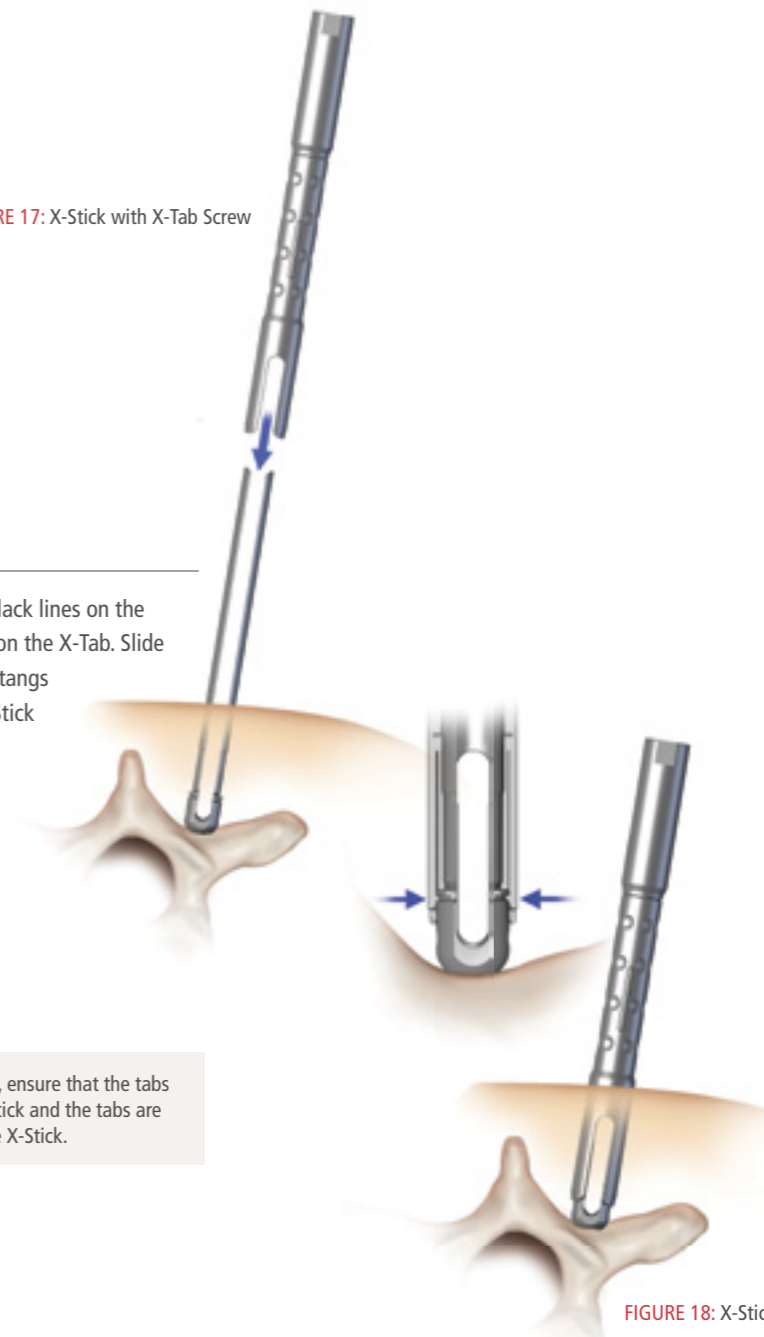


FIGURE 16: Rod pusher

## Extended Tab Screws – Medial/Lateral Manipulation

VIPER Derotation Sleeves (X-Sticks) can be used with Extended Tab (X-Tab) Screws where significant medial/lateral manipulation is required. The X-Sticks attach to the top notch feature of the X-Tab Screws and therefore reduce the potential of inadvertent tab breakage while forceful manoeuvres are being performed.

FIGURE 17: X-Stick with X-Tab Screw

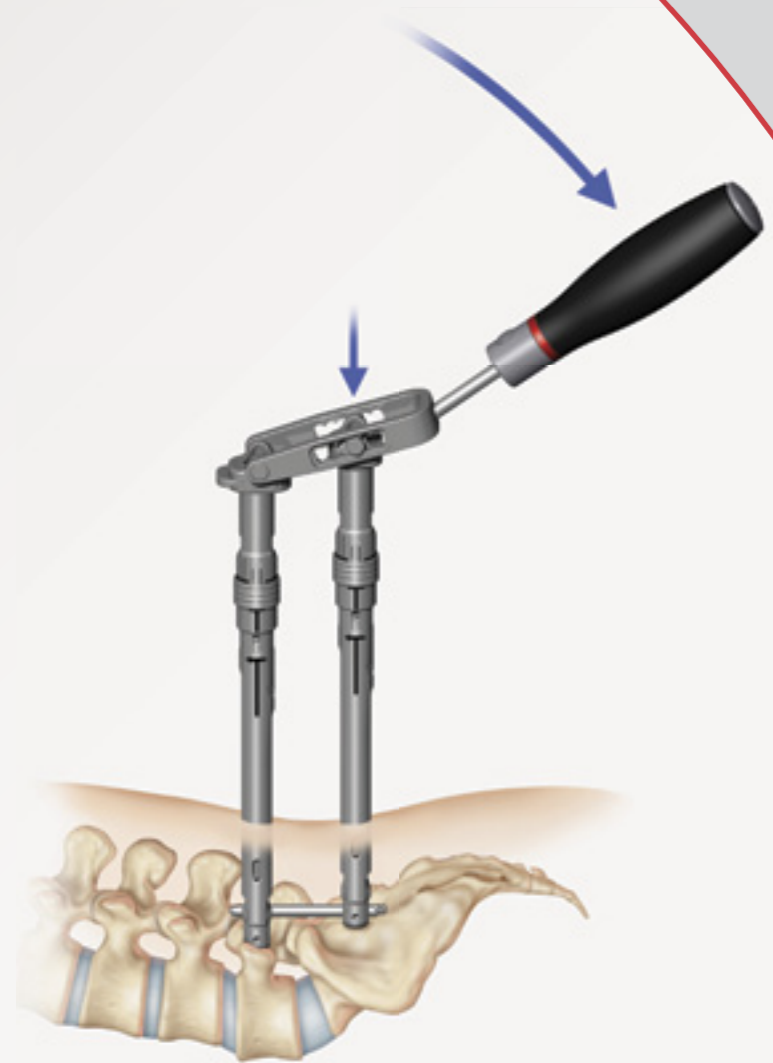


- To attach the VIPER X-Sticks, line up the black lines on the distal portion of the X-Stick and the lines on the X-Tab. Slide the X-Sticks down over the tabs, until the tangs reach the tulip of the X-Tab Screw. The X-Stick should slide easily.
- To engage the tangs onto the top notch, push straight down with a little extra force until an audible 'click' is heard
- To remove the X-Sticks, pull straight up until the tangs have pulled past the top notch feature

NOTE: If significant resistance is encountered, ensure that the tabs are captured in grooves inside the X-Stick and the tabs are not being 'pinched' together inside the X-Stick.

FIGURE 18: X-Stick in place

## Spondylolisthesis Correction



### Spondylolisthesis Correction

#### SPONDY REDUCTION DEVICE USES

- One level spondy reduction
- No need for 3-screw construct
- Simple quick attachment
- Top loading/locking feature
- Adjusts variety of distances
- Powerful in reducing spondy or de-rotating bilaterally
- Allows for simultaneous reduction

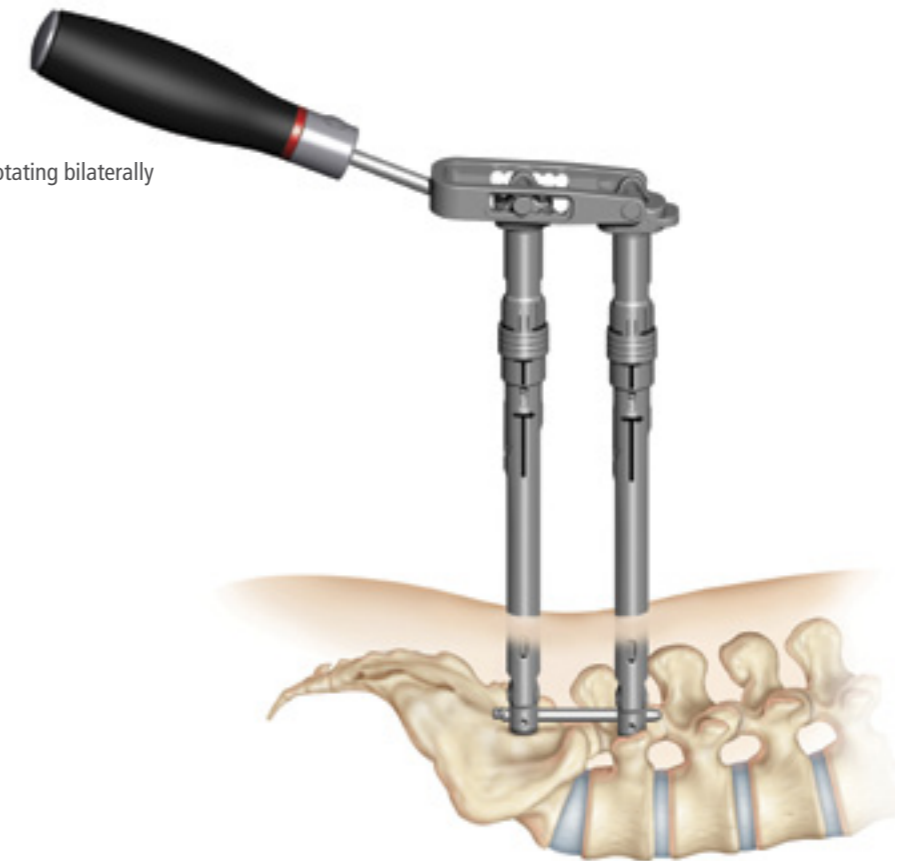


FIGURE 19: Spondy reduction lever assembly

## Spondylolisthesis Reduction

If the reduction of a spondylolisthesis (spondy) is required, vertebral bodies can be manipulated with either an 'implant only' approach or through the use of VIPER 3D instrumentation.

To aid in the reduction manoeuvres, X-Tab screws (10 mm of built in reduction threads) and deformity X-Tab screws (25 mm of built in reduction threads) may be placed at the levels of the spondylolisthesis.

After final tightening the neutral levels, the reduction threads of the X-Tab screws are used to persuade the misaligned vertebral bodies up into proper alignment by turning down the set screw.

### TOP LOADING SPONDY REDUCER (HANDLE NOT INCLUDED)

- Place rod
- Lock set screw at neutral level
- Ensure cap is unlocked
- Approach from top down
- Lock on to reduction cap

## Using the Spondy Reduction Lever

After placing the rod and final tightening the neutral level, attach reduction caps to the screw extensions. The rod will be proud at the level of the spondy slip, as shown.

- Ensure the sliding lock on the spondy reduction lever is in the unlocked position (indicated when red line is visible) and attach the locking end to the vertebral body which requires reduction
- Lower the locking end straight down until it is fully seated on the reduction cap
- Slide the lock to the locked position, ensuring that it fully captures the groove on the reduction cap

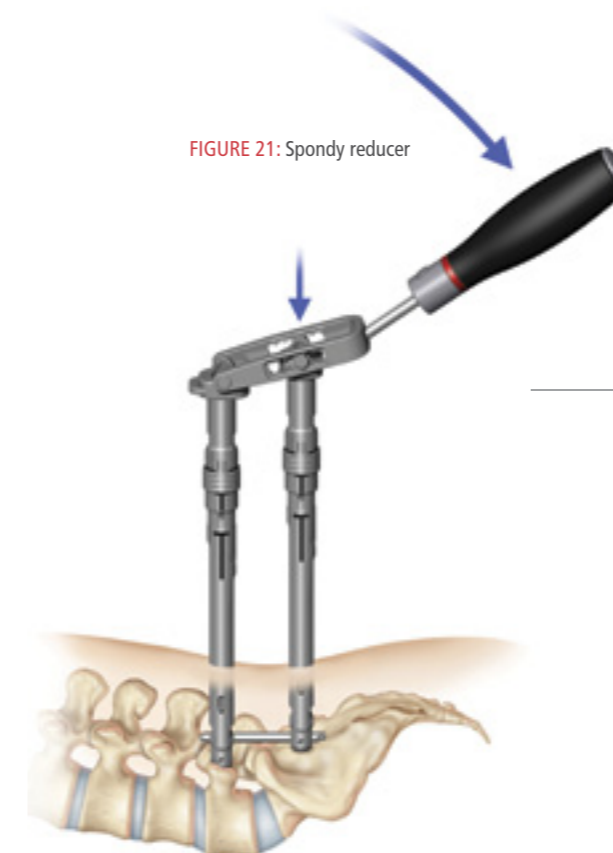


FIGURE 21: Spondy reducer

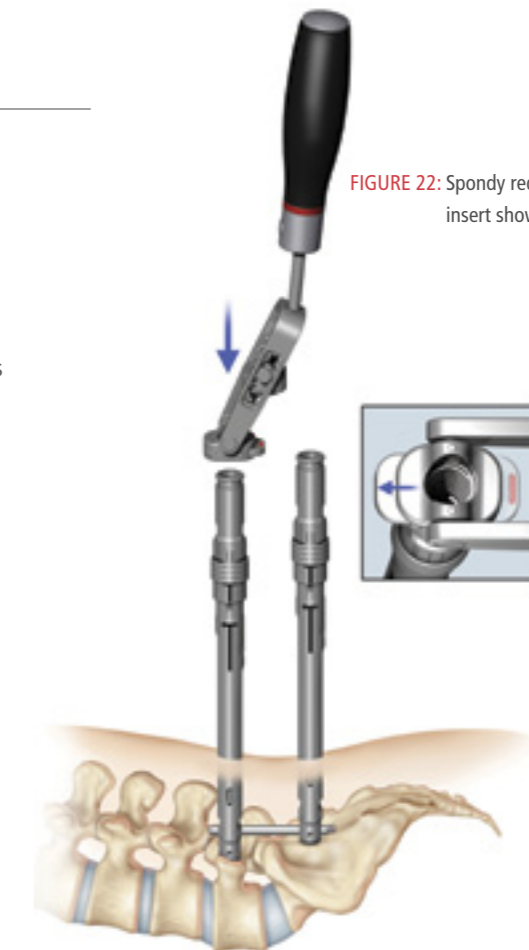


FIGURE 22: Spondy reducer with insert showing locking

- Lower the free end of the spondy reduction lever onto the adjacent reduction cap and use as a pivot point for applying reduction force.

NOTE: Separate set screw inserter is currently in production to negate reduction handle.

- Lever down to reduce spondy
- Reduce spondy by leveraging off adjacent level
- Simple quick attachment
- Lock body into place with reduction handle

### Using the Spondy Reduction Lever

- Carefully pull up on the desired vertebral body by pushing down on the spondy reduction lever handle
- For maximum mechanical advantage, position the extensions as parallel as possible

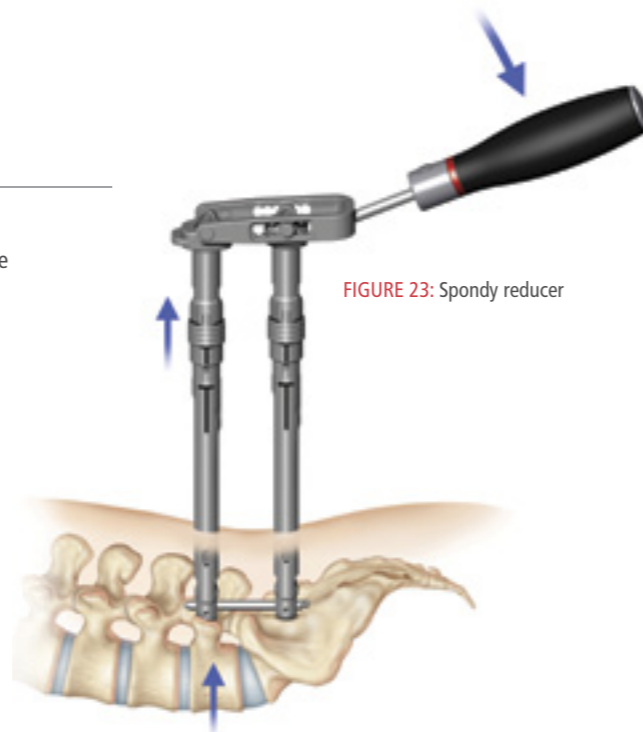


FIGURE 23: Spondy reducer

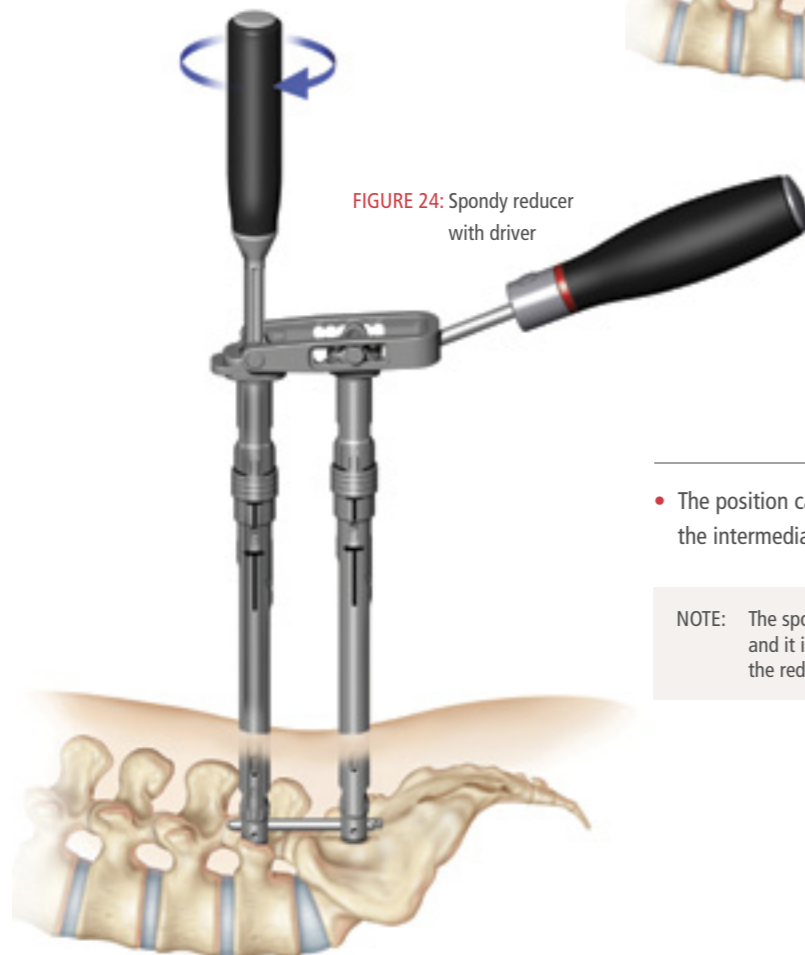


FIGURE 24: Spondy reducer with driver

- The position can be locked by placing set screws using the intermediate driver

NOTE: The spondy reduction lever should be used bilaterally and it is recommended to monitor the progression of the reduction via lateral fluoroscopy.

### Spondylolisthesis Correction

Single-level, high-grade spondylolistheses can be reduced either using an implant-only approach (based off the interbody cage and reduction screws) or by using supplemental instrumentation to lever off from a locked neutral level. With the latter technique, leaving the rod proud above the level of the listhesis and levering down onto the neutral level should result in pulling the slipped vertebral body into proper alignment to allow for set screws to capture and hold the correction. Adequate anterior release may be necessary to allow for proper reduction.

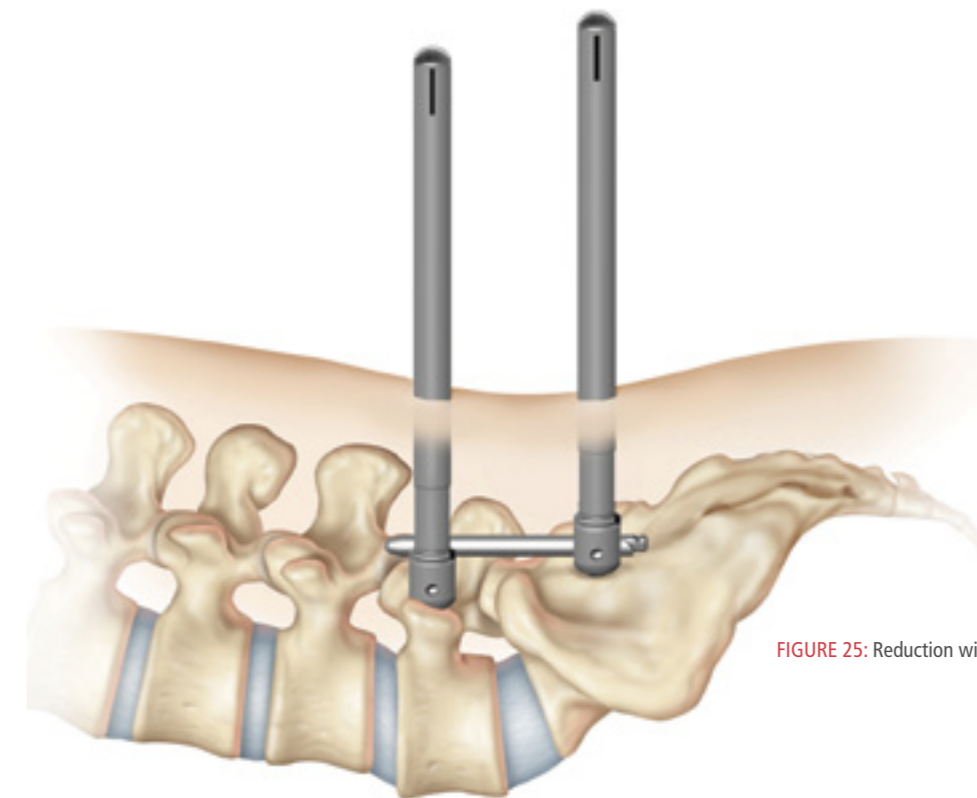


FIGURE 25: Reduction with extended tab screws

NOTE: Care should be taken in the presence of osteopenia to avoid screw pullout and pedicle fracture. Sleeves should be used when reducing with extended tab screws.

- After final tightening of the neutral levels, the reduction threads of the extended tab screws are used to persuade the misaligned vertebral bodies up into proper alignment by turning down the set screw

*Compression / Distraction*

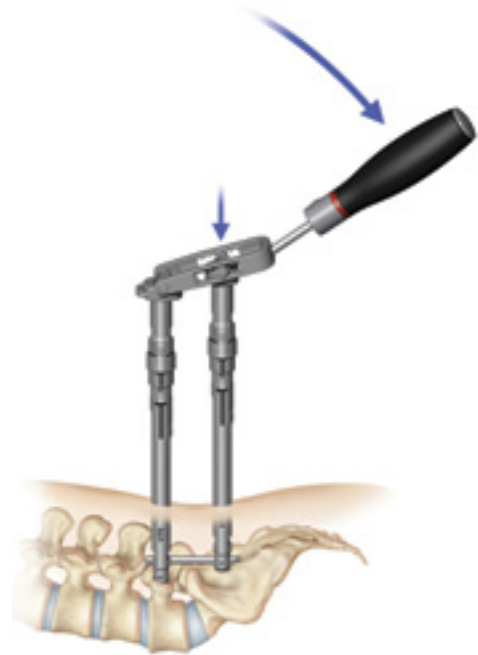


FIGURE 26: Spondy lever used to bring L5 body back to proper alignment

- When using the spondy reduction lever, the rod should be in place (proud above the level of the spondy) and the set screw of the neutral level should be finally tightened. Levering down on the neutral level should result in a posterior movement of the anteriorly slipped vertebral body.

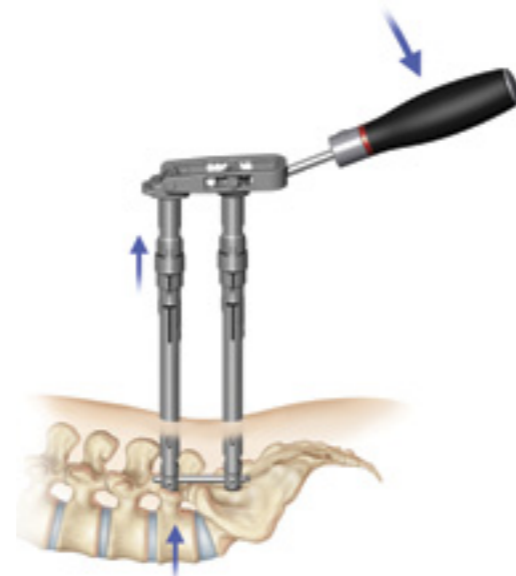


FIGURE 27: Spondy lever pulling L5 vertebral body up by leveraging down on S1

NOTE: The spondy reduction lever should be used bilaterally and it is recommended to monitor the progression of the reduction via lateral fluoroscopy.

- This technique can also be used to restore lumbar lordosis in deformity cases

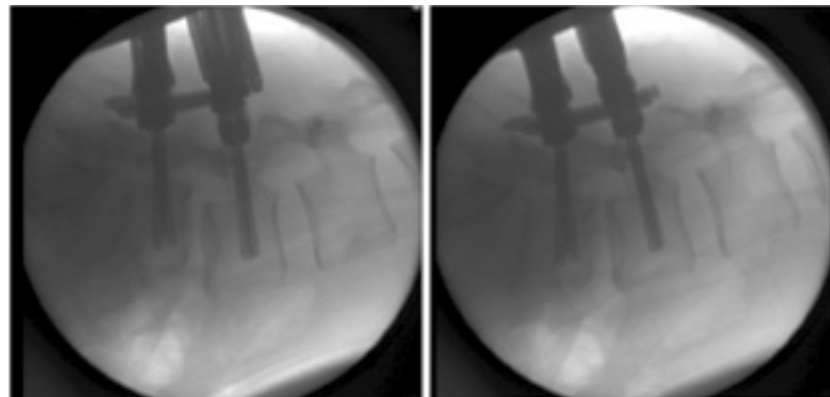
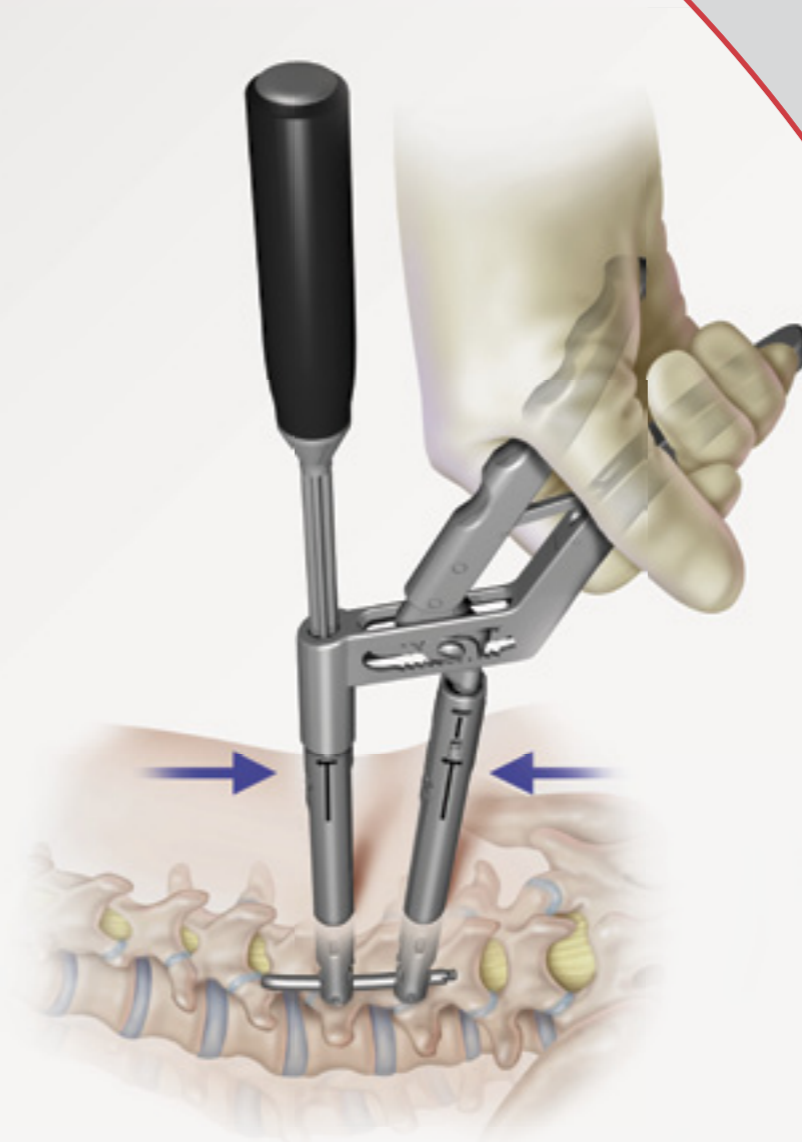


FIGURE 32: Before (left) and after (right) lateral fluoro images of spondylolisthes correction using VIPER Spondy Reduction Lever



## Compression and Distraction

Compression and distraction can be performed across fractures using either monoaxial screws or polyaxial screws. Monoaxial screws are fixed angle screws and thus attaching VIPER Screw Extensions creates a long lever arm to facilitate manipulation of the spine during fracture reduction.

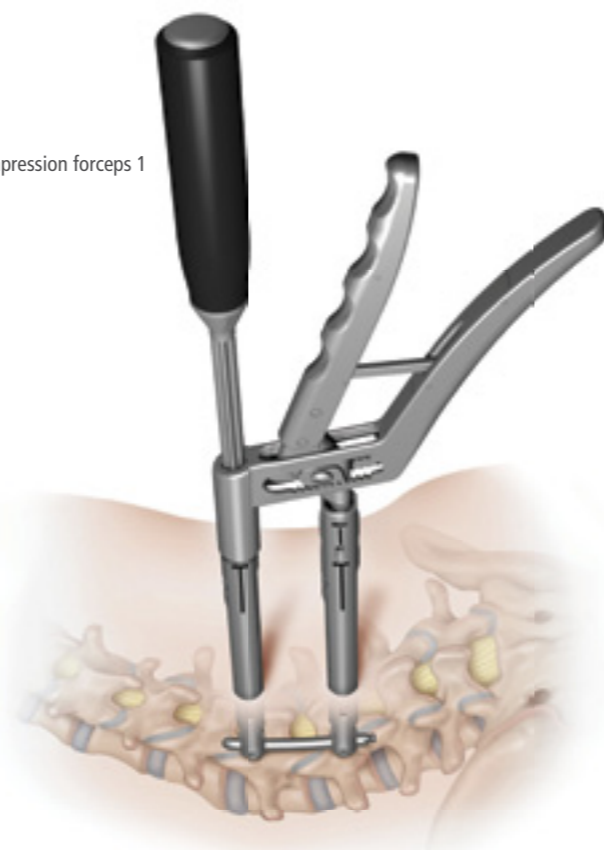
In the setting of a burst fracture, distracting across the fracture will aid in reduction of that fracture.

There are two instrument options for multi-level compression and distraction in VIPER 3D. Either option can be used to correct across the apex of a deformity, distract across a spinal fracture or to maintain the position of an interbody spacer.

### USER NEEDS

- Compress across multiple levels
- Direct forces as close as possible to screw head
- Minimal or no increase to incision

FIGURE 28: Compression forceps 1



### USING THE COMPRESSION FORCEPS

- Final tighten one set screw at the level to remain neutral or the level closest to the VIPER 2 Rod Connection end. Ensure the other set screw is captured but loose to allow for travel.
- Adjust the forceps until both ends line-up as parallel as possible with the screw extensions. Insert the post-end of the forceps into the screw extension containing the final tightened set screw. Continue to lower the forceps until the cap end of the forceps is fully seated onto the extension containing the loosened set screw. Insert the intermediate driver through the cap and engaged into the hex of the set screw.

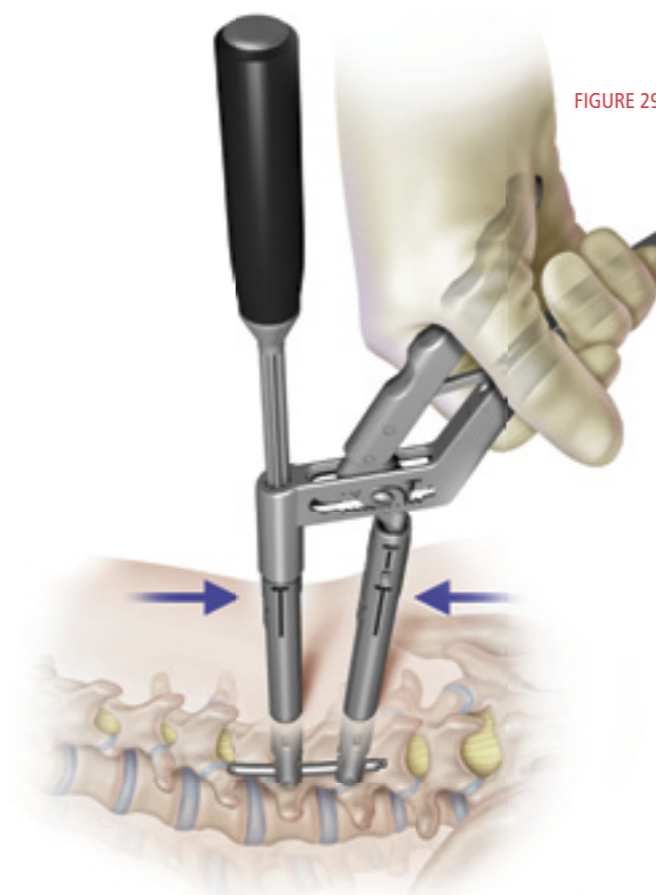


FIGURE 29: Compression forceps 2

- Compress the construct by squeezing the forceps handles together. Ensure the adjustable fulcrum has locked and the ends are as parallel as possible. Use the intermediate driver to lock the position by tightening the set screw.

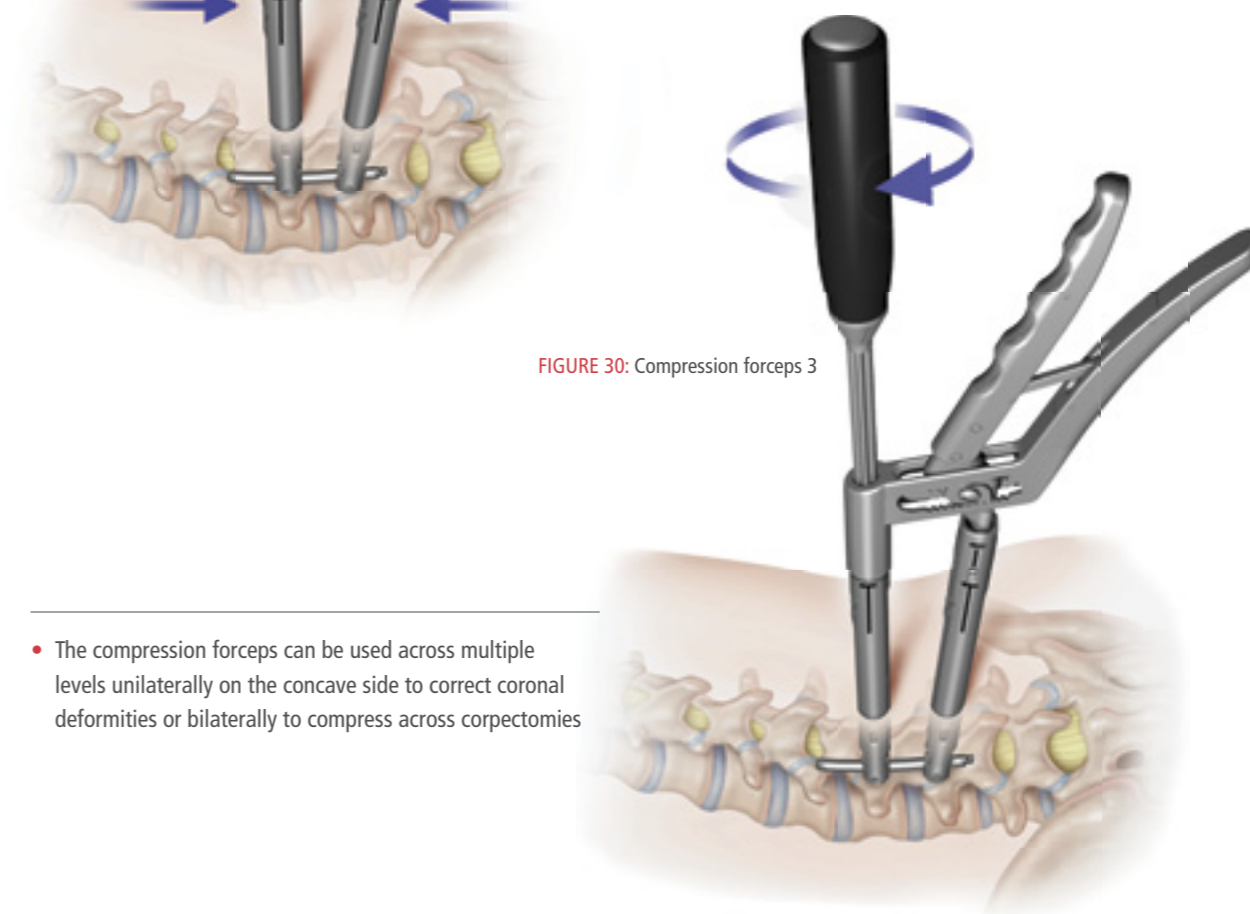


FIGURE 30: Compression forceps 3

- The compression forceps can be used across multiple levels unilaterally on the concave side to correct coronal deformities or bilaterally to compress across corpectomies

## Compression and Distraction

### USING THE COMPRESSION/DISTRACTION RACK

- Final tighten one set screw at the level to remain neutral or the level closest to the VIPER 2 Rod Connection end. Ensure the other set screw is captured but loose to allow for travel.
- Ensure the compression sleeves are unlocked. Line-up the compression sleeves with the distal most extensions to be compressed or distracted. Slide the direction button to 'N' for neutral or depress the release button to enable the locking end of the rack to slide freely for easier loading. Slide the compression/distraction rack over screw extensions.
- Using the compression/distraction driver, lock the screw extension positions as parallel as possible by tightening the locking nut on the side of the compression/distraction rack

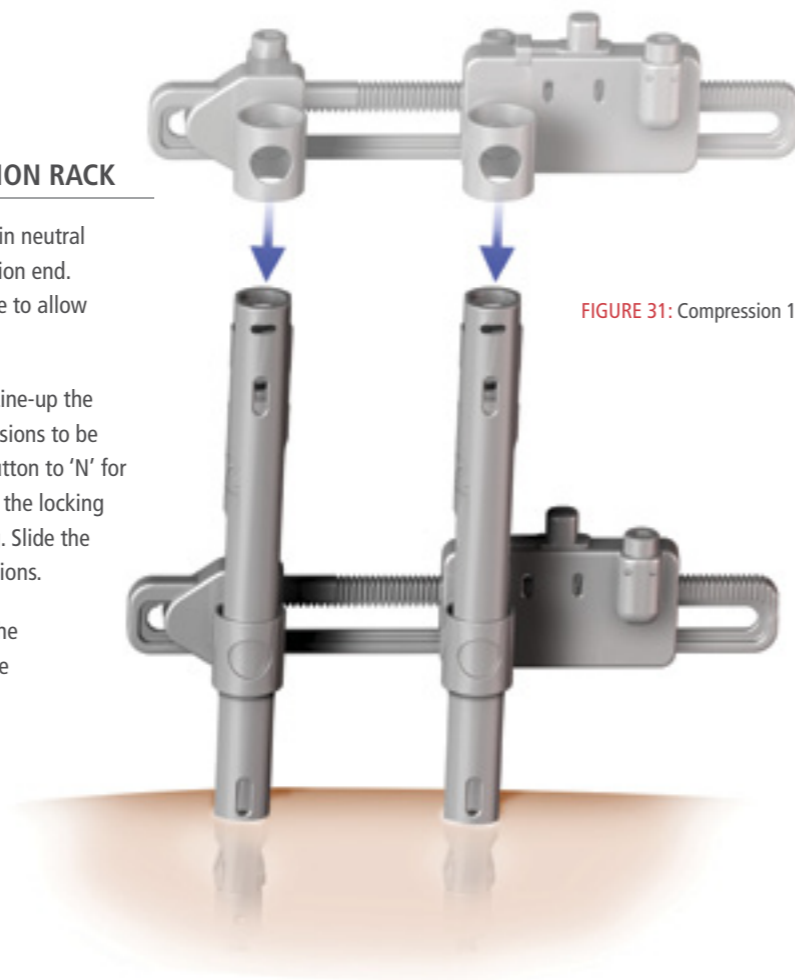
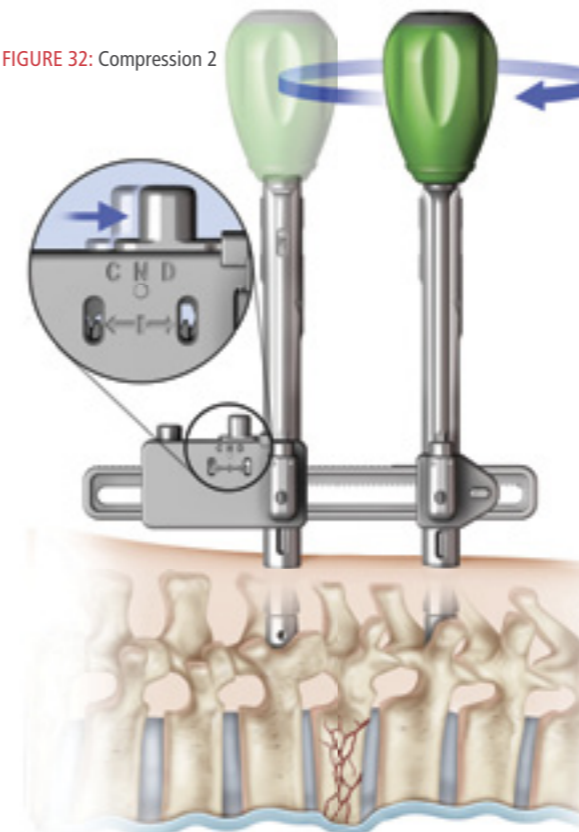


FIGURE 31: Compression 1

FIGURE 32: Compression 2



- Slide button to either 'C' or 'D' for compression or distraction respectively
- Insert the driver into the drive nut of the compression/distraction rack and slowly compress or distract by turning the driver
- Insert intermediate driver into the extension with the loose set screw, engage and tighten the set screw

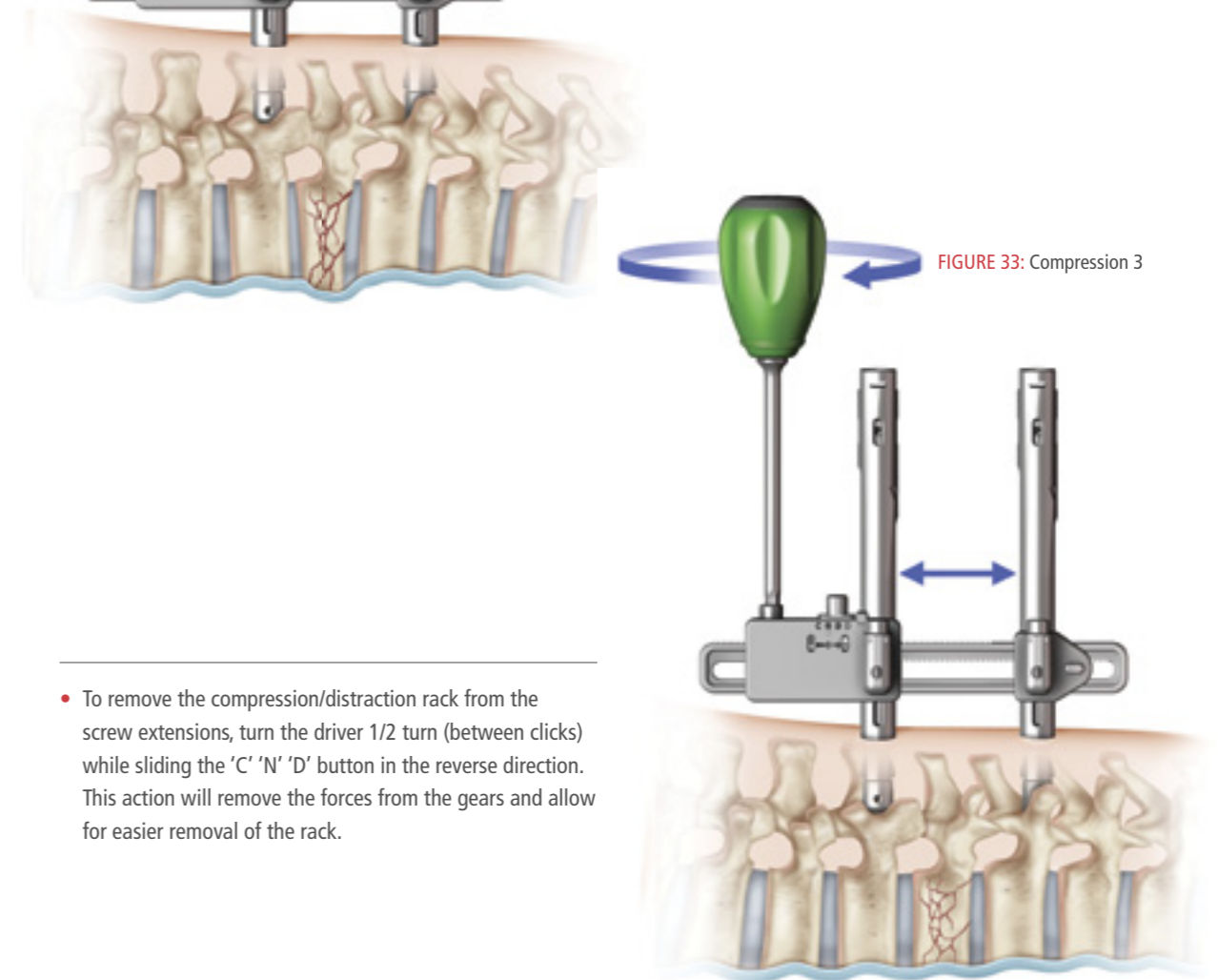
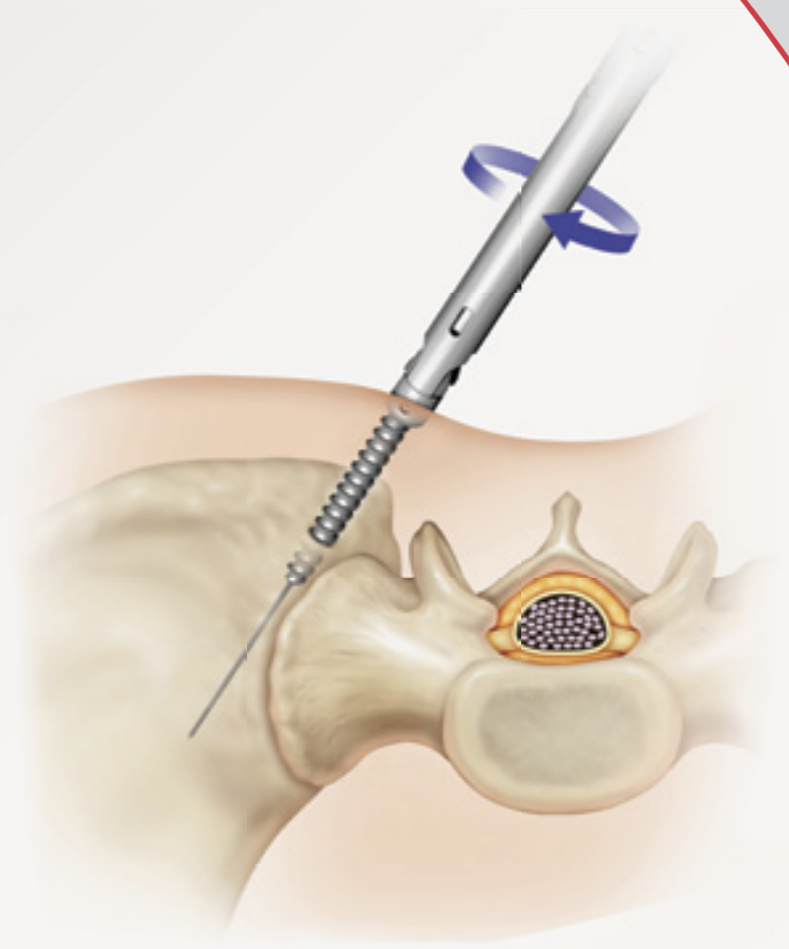


FIGURE 33: Compression 3

- To remove the compression/distraction rack from the screw extensions, turn the driver 1/2 turn (between clicks) while sliding the 'C' 'N' 'D' button in the reverse direction. This action will remove the forces from the gears and allow for easier removal of the rack.



## Pelvic Fixation



### Pelvic Fixation

Pelvic fixation is an important tool in spinal stabilisation and provides anchor points in long constructs to treat coronal and sagittal plane deformities. Although the placement of iliac screws has become widely accepted since first described by Allen and Ferguson,<sup>1</sup> the technique requires significant lateral muscle dissection. This has led many surgeons to try alternate techniques for solid stabilisation points near the sacro-iliac junction. One such technique, described by Wang,<sup>2</sup> uses the principles of MIS to safely target, cannulate and place screws into the ilium.

- Three methods for linking a spinal construct to the pelvis via a minimally invasive technique are:
  1. Using standard Gelpi retractors, a mini-open technique can be employed whereby a lateral bend is created in the rod (in the coronal plane) and the rod is simply laid into place after being passed subfascially through the in-line screw construct.

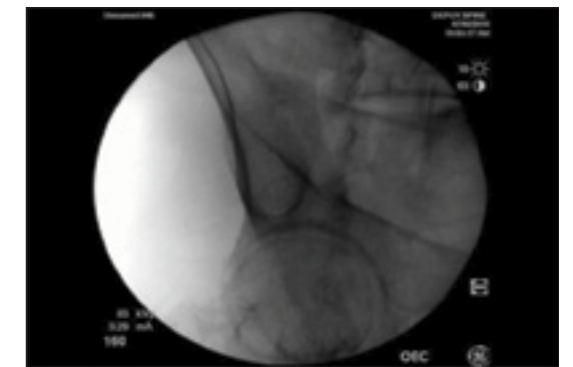


FIGURE 33: Fluoroscopic 'tear drop' view showing both inner and outer tables of the ilium



FIGURE 34: Screw being placed percutaneously into ilium

2. A lateral connector can be employed in a minimally invasive fashion to connect the laterally offset iliac screw to the inline pedicle screw construct
  - a. Place an appropriately sized screw onto a screw extension, insert over the guidewire and thread into the ilium
  - b. Place a lateral connector onto a screw extension and insert a monoaxial screw driver down through the screw extension to lock the angle of the rod on the connector. The extension can now be used as a rod holder to pass the connector.
  - c. Pass the lateral connector from medial to lateral by placing it subfascially into the adjacent screw/screw extension while attached to the screw extension and monoaxial driver
  - d. Lock into place with a set screw. The lateral connector/screw extension assembly should now be in-line with the lumbar pedicle screws and allow for linking up to the pelvis. The monoaxial driver can be removed from the lateral connector/screw extension assembly.

## Pelvic Fixation

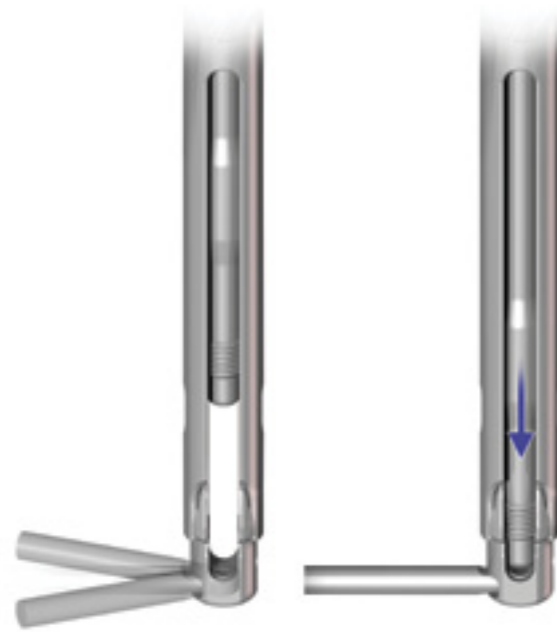


FIGURE 35: Polyaxial lateral connector being locked using a monoaxial screw driver

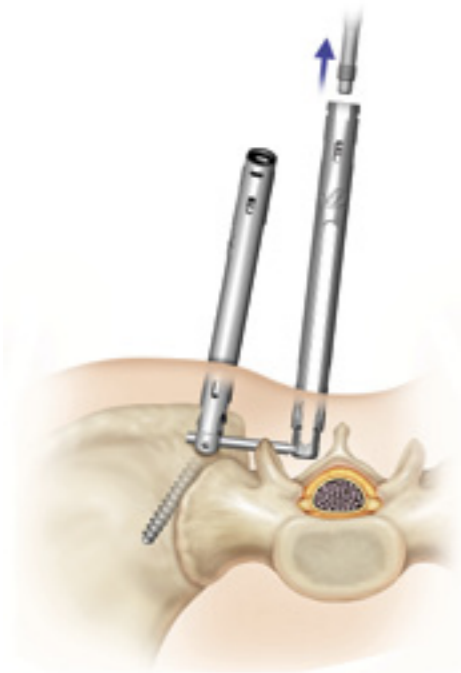


FIGURE 37: Monoaxial screwdriver being removed from screw extension, positioning offset screw inline for rod passage

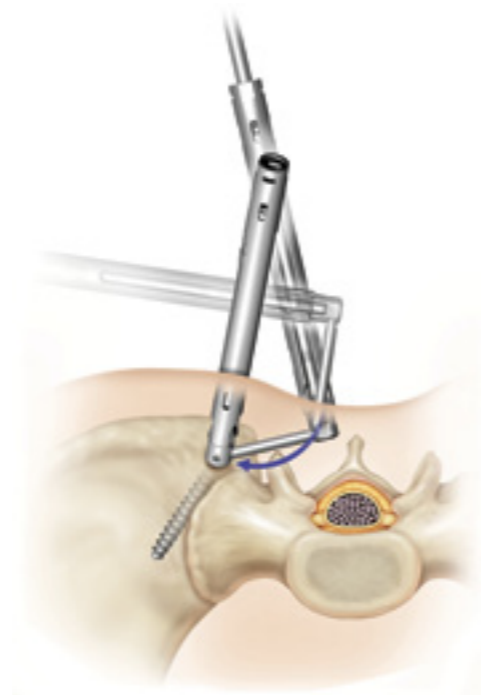


FIGURE 36: Lateral connector being placed subfascially into the offset screw

3. As another option, an inline technique allows for cannulation of the column of iliac bone from the inner table of the posterior superior iliac spine towards the anterior superior iliac spine which facilitates connection to the thoracolumbar pedicle screws.

## References

1. Allen BL and Ferguson RL. The Galveston technique for L rod instrumentation of the scoliotic spine. *Spine* 1982;**7**(3):276-284.
2. Wang MY, et al. Percutaneous iliac screw placement: description of a new minimally invasive technique. *Neurosurg Focus* 2008;**25**(2):E17.





## INDICATIONS

The VIPER Systems are indicated for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (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); tumour; pseudarthrosis; and failed previous fusion in skeletally mature patients. When used in a percutaneous, posterior approach with MIS instrumentation, the VIPER Systems' screw components are intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (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); and failed previous fusion in skeletally mature patients. The PEEK rods of the VIPER Spine System are contraindicated for degenerative disc disease except when used with the VIPER Spine System Semi-Constrained Screw combined with anterior column support.

## CONTRAINDICATIONS

The PEEK rods of EXPEDIUM Spine System and VIPER Systems are contraindicated for degenerative disc disease. Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localised to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis, or osteopenia) is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation, activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure. See also the WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES.

## WARNINGS, PRECAUTIONS AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

### WARNINGS

#### 1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.

The potential for satisfactory fixation is increased by the selection of the proper size, shape and design of the implant. While proper selection can help minimise risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

#### 2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.

Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

**3. MIXING METALS CAN CAUSE CORROSION.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

**4. PATIENT SELECTION.** In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

- A. The patient's weight.** An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
- B. The patient's occupation or activity.** If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labour, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
- C. A condition of senility, mental illness, alcoholism or drug abuse.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- D. Certain degenerative diseases.** In some cases, 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. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.
- E. Foreign body sensitivity.** The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
- F. Smoking.** Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

## PRECAUTIONS

- 1. SURGICAL IMPLANTS MUST NEVER BE REUSED.** An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.
- 2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.** Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.
- 3. CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING.** If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localised tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant, thus eliminating the risks involved with a second surgery.
- 4. ADEQUATELY INSTRUCT THE PATIENT.** Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
- 5. CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT.** Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal haemorrhage and risks of neurologic damage with the use of this product. Serious or fatal haemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.

DePuy Spine EMEA is a trading division of DePuy International Limited.

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EMEA: 908586000 08/11

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