The VIPER PRIME™ System is the next generation of our flagship VIPER® System family.
VIPER PRIMETM System Surgical Technique Overview - DSEM/SPN/0617/0699 (2/63)
The VIPER PRIME™ System includes a modified X-Tab design with a more aggressive, self-starting screw tip.

The VIPER PRIME™ System uses a streamlined LIS technique that is centered around a multi-functional inserter that allows you to go from pedicle targeting to screw insertion with one tool.

The streamlined instrument set includes two trays that fit into one case.
Current Technique

1. Mark Patient
2. Target pedicles with Jamshidi
3. Insert Jamshidi & remove stylet
4. Insert Guidewires
5. Dilate over wire & tap each pedicle
6. Remove tap
7. Start screw
8. Remove Guidewire
9. Insert screw fully
10. Remove poly driver inserter & sleeve
11. Insert rods
12. Insert distal set screw
13. Remove rod inserter
14. Insert proximal set screw
15. Final tighten all set screws
VIPER PRIME™ Technique

The current percutaneous screw workflow includes 8 steps for pedicle preparation and screw insertion.

1. Mark Patient
2. Target pedicles with Jamshidi
3. Insert Jamshidi & remove stylet
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Target Pedicle and Insert Screw

The VIPER PRIME™ System workflow replaces these 8 steps with a single incision-to-insertion step.
VIPER PRIME™ Implant

- Proximal Threads
- Depth Markings @ 10mm
- Top Notch Feature
- 100mm Tab Length
- Cortical Fix Threads
- Fenestrations
- Distal Tip Teeth
VIPER PRIME™ Tray Layout

Top Tray 1
VIPER PRIME™ Tray Layout

Bottom Tray 2
VIPER PRIME™ Surgical Technique Highlights

OR Setup

The patient should be positioned prone lying face down on a radiolucent table.

Precautions:
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 not be used for this procedure.
Fluoroscopic Planning

Use A/P and lateral fluoroscopy to identify and target the appropriate level(s).
VIPER PRIME™ Surgical Technique Highlights

Determine the Skin Incision Location

Using A-P fluoroscopy, place guidewires on the patient that are perpendicular and parallel to the axis of the spine at the targeted level.

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 the size of the patient.
VIPER PRIME™ Surgical Technique Highlights

Plan Screw Length(s)

With traditional percutaneous pedicle screw techniques, surgeons may or may not plan out the length and diameter of the screw pre-operatively.

However, with this system, it’s required that surgeons plan the screw length based on pre-operative images.

The reason is that the screw/ inserter assembly is used for targeting and screw insertion. There is no tapping step to estimate screw length or diameter.
VIPER PRIME™ Surgical Technique Highlights

Identify the parts of the Inserter

Carrier  Drive Tube  Red Stylet Control Handle  Shaft

Pre-operative Planning  Inserter Assembly  Pedicle Targeting  Screw Insertion  Rod Insertion  Optional Compression  Final Steps
Insert the Carrier into the Drive Tube.

Lead with the 'red ring' portion of the Carrier as you slide it into the open slotted side of the Drive Tube so this red ring is visible through the depth gauge scale.
Assemble the Red Stylet Control Handle

Then thread the Red Stylet Control Handle over the Carrier.

This is a reverse thread and should be rotated *counterclockwise*.
First, ensure that the two Set Screws on the sides of the shaft are fully backed out.

Then insert the tabs of the Drive Tube into the Shaft and snap into place.
Using the Set Screw Driver, tighten both Set Screws on the Inserter Shaft.

VIPER PRIME™ Surgical Technique Highlights

Hand-Tighten the Set Screws

Using the Set Screw Driver, tighten both Set Screws on the Inserter Shaft.
Attach the Modular Handle

Attach a VIPER PRIME Modular Handle (T-Handle or Palm) to the proximal end of the Inserter.

The Modular Handle may be removed at any time for visualization.
VIPER PRIME™ Surgical Technique Highlights

Select the screw length, diameter and load the Screw

Load the Pedicle Screw onto the Inserter.

Ensure that the Inserter is fully seated in the Screw X-tab drive feature. The proximal etch mark on the screw tab will line up with the etch mark on the Driver Shaft to form a complete circle.

Tighten the green knob to secure the implant.

VIPER PRIME™ System Surgical Technique Overview - DSEM/SPN/0617/0699 (19/63)
VIPER PRIME™ Surgical Technique Highlights

Load the Stylet

Next, introduce the Stylet.

- On the Stylet Depth Adjustor, identify the slot that corresponds to the chosen Screw length.
- Ensure that the slot on the retaining sleeve is rotated into the “open” position.
VIPER PRIME™ Surgical Technique Highlights

**Load the Stylet**

- Insert the Stylet into the Depth Adjustor, and place it in the slot for the chosen screw length.
- Then rotate the retaining sleeve 180 degrees to capture the Stylet and make sure it is properly retained.
Insert Depth Adjustor into the Handle

Insert the entire Depth Adjustor (and Stylet) into the top of the VIPER PRIME Inserter.
Then insert the X25 Set Screw Driver and rotate it clockwise until a stop is reached (there is no overtightening needed for this component. user should tighten until stop is reached and this confirms they have properly assembled depth adjustor).
Turn the Red Stylet Control Handle counterclockwise until it stops to fully retract the stylet.

The tip of the Stylet should extend approximately 3 mm beyond the distal tip of the screw.

**Precaution:** If the Stylet is not visible beyond the screw tip or you cannot retract it to 3 mm, disassemble the Depth Adjustor and confirm that the stylet flange is seated in the appropriate screw length slot.
Assemble the Dilator to the Dilator Sleeve. The instruments will snap together.
OPTIONAL: Dilator Insertion

Advance the assembled instrument until the distal tip contacts the pedicle. Confirm placement with fluoroscopy.

The metal tip will be visible under fluoroscopy.

Push down on the Dilator Sleeve while pulling back on the Dilator until it separates from the Dilator and contacts the bone. Remove the Dilator while holding the Dilator Sleeve in place.
Insert the VIPER PRIME Inserter assembly through the incision and dock the Stylet tip on the bony anatomy of the desired level.
At initial insertion, the Stylet should extend past the tip of the screw to dock onto the pedicle.

The Stylet can be extended further if needed to adequately dock to the posterior anatomy.

Confirm the position using fluoroscopy.
VIPER PRIME™ Surgical Technique Highlights

Extend Stylet if Needed

To extend the Stylet, turn the red Stylet Control Handle clockwise while applying gentle downward pressure.

Each ‘click’ represents approximately 1 mm of Stylet extension.

Precaution: It is not recommended to mallet on the Stylet when it is extended more than 5 mm beyond the tip of the screw outside of the bone.

Warning: If the Stylet trajectory is not monitored by fluoroscopy, there is a potential for pedicle or anterior wall breach, potentially resulting in neurological damage or damage to the great vessels.
VIPER PRIME™ Surgical Technique Highlights

Extend Stylet if Needed

Use fluoroscopy to confirm the Stylet is positioned properly.

Targeting forceps can be used to keep surgeon’s hand out of the fluoroscopy field. Attach the forceps just above the green knob on the inserter.

Do not extend the Stylet more than 5 mm at a time before impacting on the black handle.
Turn the Red Stylet Control Handle clockwise to continue to advance the stylet up to 5 mm at a time until it is fully advanced through the pedicle, up to a distance of 25 mm.

Using a mallet, gently tap the Modular Handle to advance the Stylet into the pedicle.

Use the Stylet Depth Gauge to track the position of the Stylet.
VIPER PRIME™ Surgical Technique Highlights

Advance Stylet into Pedicle

PRECAUTIONS:

- It is not recommended to mallet on the Stylet when it is extended more than 5mm beyond the tip of the screw outside of the bone.
VIPER PRIME™ Surgical Technique Highlights

Begin Advancing Screw over Stylet

To advance the screw over the Stylet, **hold the red Stylet control handle** while rotating the proximal handle of the Inserter clockwise.

Hold the Red Control Stylet Handle

Screw advances over the Stylet
WARNING:

It is critical to hold the Red Stylet Control Handle at all times while advancing the screw. Holding the Red Stylet Control Handle will retract the Stylet as the screw is advancing into the pedicle.

As a result, the tip of the Stylet will not advance further into the vertebral body as the screw is inserted.

If the Red Stylet Control Handle is not held, the Stylet will remain extended and advance in front of the screw, potentially leading to an anterior wall breach, neurological damage or damage to the great vessels.
Confirm the Stylet is Fully Retracted

Once the Stylet is fully retracted, the Red Stylet Control Handle will no longer rotate independent of the inserter assembly.

The tip of the Stylet is now approximately 3 mm beyond the tip of the screw and can be confirmed by the red line position on the Stylet Depth Gauge on the proximal end of the inserter.
Finish Seating the Screw

Release the Red Stylet Control Handle and insert the screw the remaining distance using the proximal handle until the screw is fully seated.

**Warning:** It is recommended that fluoroscopy be used while inserting the screw to monitor the depth of the screw and ensure that the Stylet is not unintentionally advanced, which might lead to a breach of the anterior wall of the vertebral body, neurological damage or damage to the great vessels.
VIPER PRIME™ Surgical Technique Highlights

Finish Seating the Screw

Disengage the screw from the inserter by loosening the green knob.

Pull up on the Red Stylet Control Handle to remove the Inserter and Stylet.

Be careful and remain aware of the Stylet location when pulling out of the screw cannula and through the X-tab screw tab.
Insert Additional Screws

Follow the previous steps for the remaining screws.

- If the length of the subsequent screw is the same, the Stylet and Stylet Depth Adjustor do not need to be changed.

- If the length of the subsequent screw is different, remove the Stylet Depth Adjustor using the Set Screw Driver.

- Open the retaining sleeve and move the Stylet flange to the appropriate slot for the new screw length.
OPTIONAL: Cement Augmentation Procedure

Alignment of the screw

Insert the VIPER PRIME Fenestrated Alignment Device into the VIPER PRIME X-Tab screw and thread it into the screw head while holding the X-tabs to provide counter torque.
Confirm that the Alignment Device is fully seated by checking that the alignment device handle and the top of the X-Tab screw are in close proximity.

The head will be locked to the shank when it is properly aligned.
VIPER PRIME™ Surgical Technique Highlights

OPTIONAL: Cement Augmentation Procedure

Attachment of additional Alignment Devices

Repeat until Alignment Devices are attached to all levels intended for cement augmentation

**Precaution:** The alignment guide MUST be used for each screw intended for cement augmentation. Without the alignment guide, there is a potential risk of cannula breakage. Use of the alignment guide will prevent undue stress from being applied to the cannula.

Once the screws are in place and the Alignment Devices are attached to the levels selected to be augmented, refer to the VIPER Cortical FIX Fenestrated Screw System Guide for instructions on Cement Preparation and Delivery

**Precaution:** Only the open cannulas are compatible with the VIPER PRIME X-Tabs.
Measure the Rods

Insert one arm of the Rod Gauge into each of the outermost X-Tabs until each leg is fully seated in the screw heads.

Placement can be verified by ensuring that the circumferential lines on the shafts of the Rod Gauge align with the top of each X-tab.

Measure straight rods using the circumferential lines on the Rod Gauge leg.
Assemble the Rod Holder

The Rod Holder is made of three components:

- Push Rod
- Rod Holder Stem
- Threaded Shaft

1. Insert the Push Rod into the Rod Holder Stem.
2. Thread the shaft into the top of the Rod Holder Stem.
Assemble the Rod Holder

Insert the connection end of the rod into the pocket of the Rod Holder.
Assemble the Rod Holder

Then tighten the knob on the proximal end of the Rod Holder to capture and lock the rod.
VIPER PRIME™ Surgical Technique Highlights

Rod Insertion

Align the slots of the X-Tabs so they are in line with each other.

Position the Rod Holder parallel to the skin’s surface, tip facing downward.

Then insert the Rod Holder assembly through the cranial X-Tab and advance it into the slot of the caudal X-Tab(s).
Rod Insertion

Advance the distal end of the rod towards the screw, down the caudal X-Tab until it touches the top of the screw head or it is as deep as the tissue will allow.

Twist the X-Tabs to verify that the rod has passed through the screw.

If the tab rotates, then the rod is not contained within the tab. Re-attempt rod placement.

Use fluoroscopy to verify adequate rod overhang at each end of the construct.
VIPER PRIME™ Surgical Technique Highlights

Attach Set Screw to Set Screw Driver

Ensure that the Set Screw driver handle is in unlocked position.

Fully seat driver into the Set Screw; raise and drop the slap handle to secure the Set Screw to the Set Screw Driver.

Return the handle to the proximal end of the driver and lock in place.
VIPER PRIME™ Surgical Technique Highlights

Insert Set Screws

Use the driver to advance the Set screw through the X-Tabs and into the screw head.

Once the proximal laser etch band on the shaft of the Set Screw Driver is in line with the top of the screw, then the Set screw and rod are fully seated within the screw head.

**Precaution:** If substantial reduction forces are expected during set screw insertion, the VIPER PRIME Counter-Torque should be used. This will allow the Set Screw Driver to fully reduce the rod into the head of the polyaxial screw and reduce the chance of tab splay and subsequent set screw cross threading.
VIPER PRIME™ Surgical Technique Highlights

Identify the components of the Compressor

Driver Leg

Solid Compressor Leg

X25 Compressor Driver

Pre-operative Planning
Inserter Assembly
Pedicle Targeting
Screw Insertion
Rod Insertion
Optional Compression
Final Steps
Final tighten one Set screw and provisionally (temporarily) tighten the remaining Set screws.

Place the driver leg (1) through the X-Tab at the provisionally tightened Set screw.
Then secure the Driver Leg to the implant by threading the green knob onto the external threads at the proximal end of the X-Tab.
Attach the Solid Compressor Leg

Place the Solid Compressor Leg (2) through the X-Tab with the final tightened set screw.

Orient the foot of the Solid Compressor Leg so that it seats on the edge of the Set screw and faces towards the disc space intended for compression.
VIPER PRIME™ Surgical Technique Highlights

Connect the Compressor Legs

Connect the Compressor Legs by sliding them together axially or by depressing the spring tab and sliding them together laterally.
Next, insert the X25 Compressor Driver (3) through the driver leg (1).

**Precaution:** The X25 Compressor Driver is only designed to be a provisional set screw tighten and not a final tighten. The Set Screw Driver and Final Tightening Torque Handle provided in the VIPER PRIME Instrument Set should be used for final tightening.
Slightly loosen the provisionally tightened Set screw until the rod is free to slide in the screw head.

Squeeze the two handles together to compress while provisionally tightening the Set screw.
**VIPER PRIME™ Surgical Technique Highlights**

**Remove Compressor Instruments**

Release the compressor by unthreading the knob on the driver leg.

Then remove both legs from the implants.
Final-Tighten Set Screws

To perform final tightening, place the Counter-Torque over one of the X-Tabs.

Ensure that the notches of the Counter-Torque straddle the rod.
VIPER PRIME™ Surgical Technique Highlights

Final-Tighten Set Screws

Attach the Set Screw Driver to the Final Tightening Torque handle with the handle in the lower locked position, pass through the X-Tab, and engage the Set screw.
VIPER PRIME™ Surgical Technique Highlights

Final-Tighten Set Screws

Rotate the Torque Wrench Handle clockwise, while applying counter-torque, until the torque handle clicks. Repeat for all additional set screws.

The final torque applied will be 80 in-lbs.
VIPER PRIME™ Surgical Technique Highlights

X-Tab Removal

Place the Tab Breaker over one tab and advance it until it reaches the set screw and can no longer be advanced.
Then rock the Tab Breaker outward until the tab breaks away from the screw head.

The tab will be retained inside the tab breaker. Remove the tab by depressing the button at the top of the Tab Breaker Handle.
Indications and Contraindications

INDICATIONS
The VIPER Sytem is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VIPER Sytems is 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); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER System is 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); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

CONTRAINDICATIONS
• 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 localized 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 or 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.

INDICATIONS
The VIPER PRIME fenestrated screws are intended for use with CONFIDENCE High Viscosity Spinal Cement to provide immobilization and stabilization of spinal segments in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine in patients with diminished bone quality (e.g., osteoporosis, osteopenia, metastatic disease). The screws are intended to provide temporary internal support and fixation while the fusion mass is consolidating or fracture is healing, or for palliative reconstruction in tumor patients.

CONTRAINDICATIONS
The use of the fenestrated screws in conjunction with CONFIDENCE High Viscosity Spinal Cement is contraindicated in patients presenting with any of the following conditions:
• Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices
• Acute compromise of the vertebral body or walls of the pedicles and disruption of the posterior cortex
• Anatomical damage of the vertebral body or walls of the pedicles or disruption of the posterior cortex
• Active or incompletely treated infection
• Coagulation disorders, or severe cardiopulmonary disease.
• Haemorrhagic diathesis.
• Spinal stenosis > 20% caused by retropulsed fragments.
• Vertebral body collapse to less than 1/3 (33%) original height
• Coagulopathy or inability to reverse anti-coagulant therapy (both during and approximately 24 hours post-procedure).
• Allergic reaction to any of the components of the cement or metal used

Relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient’s occupation or 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.