

VIPER PRIME™ System

Let **one tool** inspire a new technique.





Introducing

MIS operational efficiency in its prime.

This is the VIPER PRIME™ System, a novel technique for percutaneous pedicle screw placement that eliminates the need for guidewires, Jamshidi needles and pedicle preparation instruments. Featuring a new screw tip design and a stylet that is fully controlled by the screwdriver, only the VIPER PRIME System enables surgeons to target pedicles and insert screws in one single instrument pass. How can less deliver more?

Improved OR Efficiency

- Reduction in pedicle prep and screw insertion job steps
- More organized back table with fewer instruments required

Improved Procedure Flow

- Eliminates guidewires and Jamshidi needles
- Fewer instrument passes between the surgeon and the back table

Streamlined Instrument Set

- Instrument Set footprint reduced from 6 trays to 2 trays*
- Reduce waste and processing costs associated with steam-autoclaved sets*

One-Tool Screw Insertion

Stylet

- Fully controlled, 1.65 mm Stylet
- Trocar-style distal tip facilitates docking on and advancing into bone.
- 3 mm starting point beyond the screw tip to penetrate the cortex and allow for sufficient docking on the posterior bone.

Red Stylet Control Handle

- Rotate clockwise to deploy the Stylet. Each audible click represents approximately 1 mm of Stylet advancement.
- Hold the red handle during screw advancement to control the Stylet and prevent further forward advancement.

Stylet Depth Gauge

 Track the Stylet position relative to the tip of the screw.



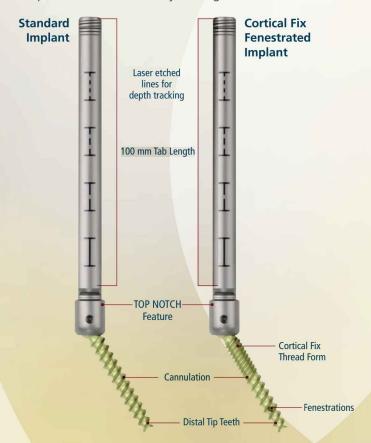
Implant Features and Benefits

X-Tab Head

- 100 mm tab length with 10 mm of reduction threads
- Laser etched lines at 10 mm increments track implant depth relative to the skin.
- Proximal threads enable driver engagement.
- TOP NOTCH® Feature
- Tab strength optimized to enable manipulation without ancillary sleeve.

Self-Starting Screw Shank

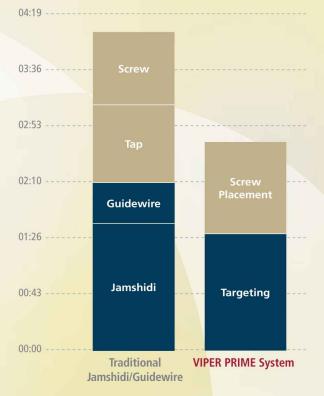
- Distal tip teeth enable insertion without pedicle prep (tap or awl).
- X25 drive feature
- Cannulation 1.75 mm diameter
- Optional Cortical Thread Form provides enhanced pedicle fixation.**
- Optional 1.6 1.75 mm fenestration diameters allow for the option of cement delivery for augmented screw fixation.***



- ** ADAPTIV DHF-100465-MEMO28. Bench test results may not be indicative of clinical performance.
- *** When used in conjunction with CONFIDENCE High Viscosity Spinal Cement, the VIPER and EXPEDIUM Fenestrated Screw Systems are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The VIPER and EXPEDIUM Fenestrated Screw Systems augmented with CONFIDENCE High Viscosity Spinal Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

Reduction in Pedicle Screw Insertion Time

Cumulative Time for Each Step in the Jamshidi/Guidewire Technique Compared to the VIPER PRIME System Technique (All Surgeons Combined)



NOTE: The "Jamshidi + Guidewire" steps are analogous to the "Targeting" step. The "Tap + Screw" steps are analogous to the "Screw Placement" step.

Eight surgeons each placed seven pedicle screws via the traditional Jamshidi/guidewire technique and seven pedicle screws via the VIPER PRIME System technique. The duration of time for screw placement with the VIPER PRIME System technique was approximately 33% shorter than the traditional Jamshidi/guidewire technique when analyzing the cumulative screw placement times for all surgeons and for all screws

The results of this cadaveric study demonstrate that the cumulative time for the "targeting" step using the VIPER PRIME System technique was 30% shorter than the cumulative time for the analogous "Jamshidi + Guidewire" steps.

Similarly, the cumulative time for "screw placement" using the VIPER PRIME System technique was 39% shorter than the cumulative time for the analogous "tap + screw placement" steps for the Jamshidi/Guidewire technique.

Reduction in Steps

New Steps:

- 1 Make Incision
- 2 Target Pedicles

Previous Steps:

- 3 Insert Jamshidi Needle
 - 4 Insert Guidewire
- Remove Jamshidi Needle
- 6 Insert Tap
- 7 Remove Tap
- 8 Start Screw
- 9 Remove Guidewire
- 3 Insert Screw
- 4 Remove Driver
- 5 Insert Rods
- 6 Insert Set Screws



Reduce instrument passes
Simplify back table
Eliminate the need for guidewires
Streamline Instrument and Implant Sets

Learn more at www.viperprimesystem.com

For complete labeling, please refer to the instructions for use available electronically at www.e-ifu.com.

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Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

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

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

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.



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Note: For recognized legal manufacturer, refer to the product label.



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