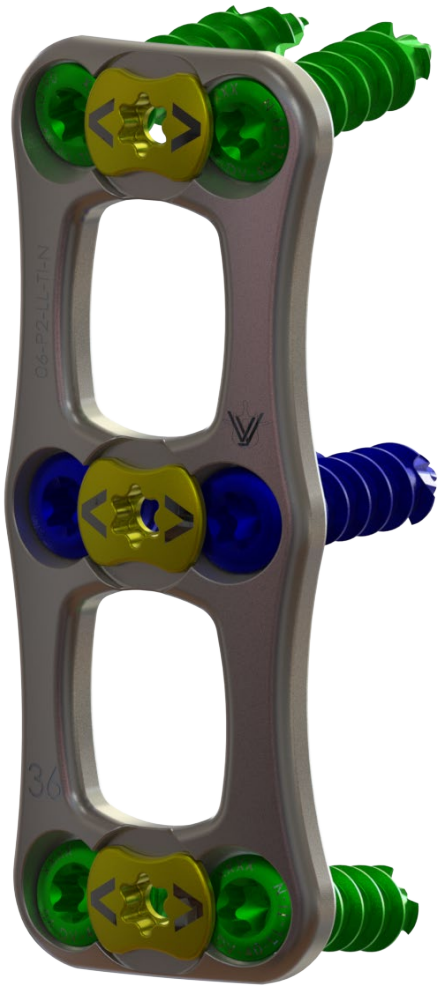
VySpine™

VyPlate™
Anterior Cervical Plate System

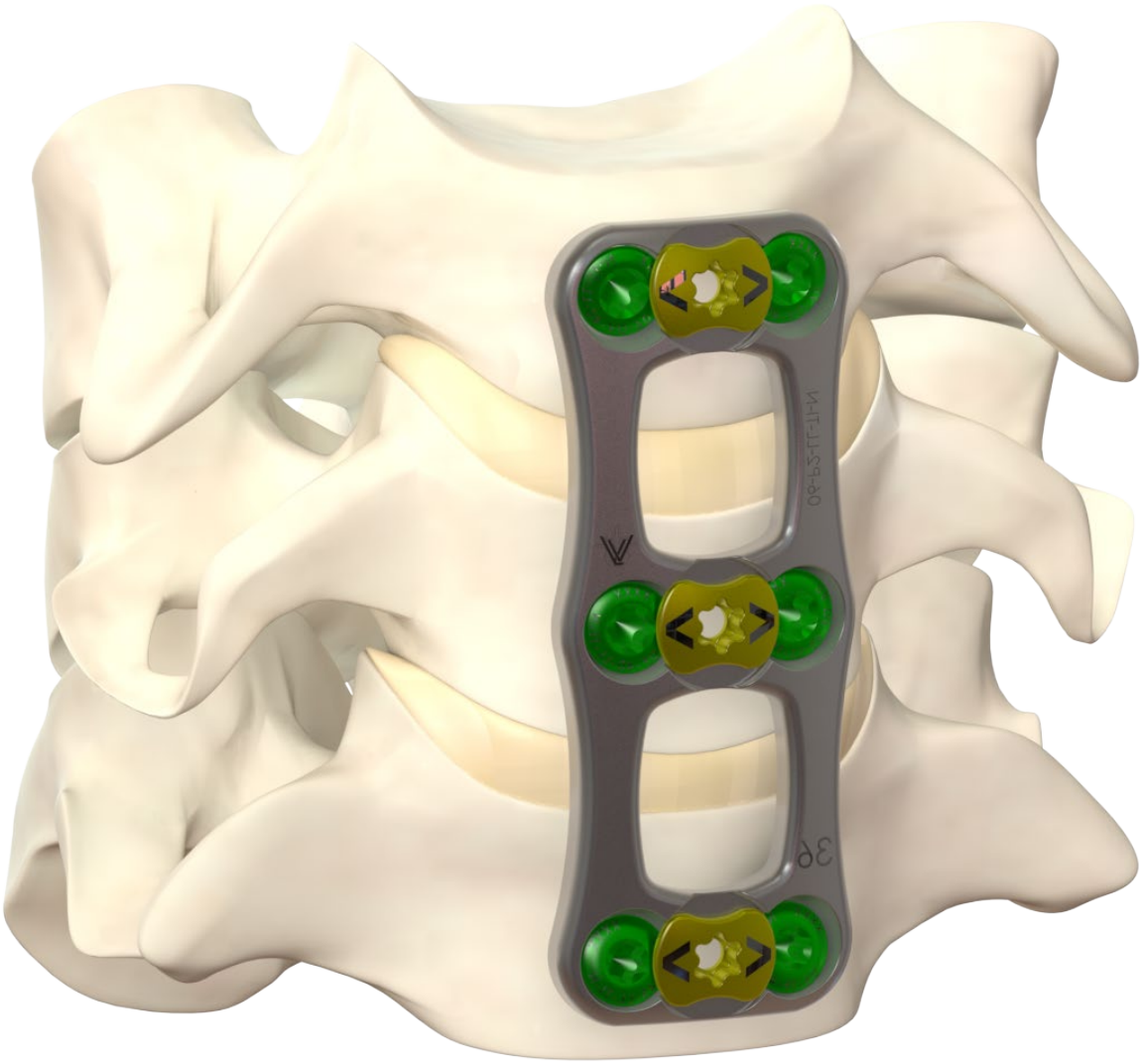
Surgical Technique



System Overview

Description:

The VyPlate™ Anterior Cervical Plate System device is intended to be used as an anterior cervical plate device. The VyPlate™ Anterior Cervical Plate System is comprised of implant and instrument components. The VyPlate™ Anterior Cervical Plate implant device is manufactured from Titanium alloy as specified by ASTM F-136. The VyPlate™ Cervical Plate System is a combination of the plate, cover plate, and bone screw components. The cover plate is integrated into the plate.



The VyPlate™ ACP System is offered in numerous sizes, ranging from single level to five level plates. Available plate sizes measure from 9mm all the way to 120mm, from the screw hole to screw hole. The VyPlate™ ACP System bone screws can either be variable (with a high degree of angulation), or in a fixed angle to the plate. Additionally, the VyPlate bone screws are available in self-drilling or self-tapping configurations. The screws come in a range of lengths and diameters to provide optimal fit with patient anatomy. The VyPlate™ ACP System has a unique and robust locking system, incorporating a integrated cover plate.

VyPlate™ Surgical Technique

Step 1. VyPlate™ Selection

Select the appropriate VyPlate™ Cervical ACP device to fit the anatomy. Use calipers to measure the anatomy.

NOTE:

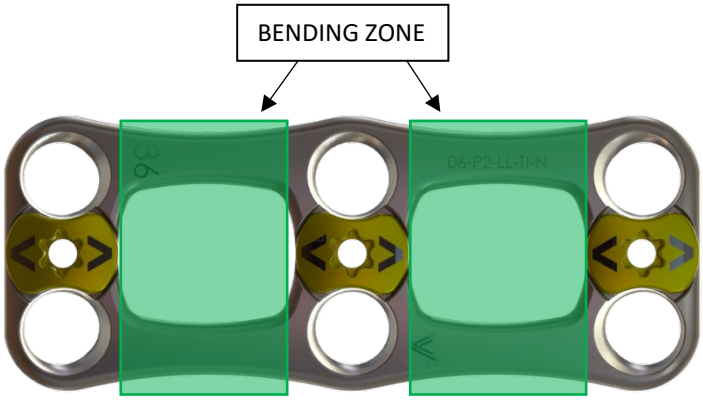
VyPlate™ Cervical Plates are measured from center of screw hole to center of screw hole. Add 7mm for edge to edge.

Step 2. VyPlate™ Bending

After the plate length has been determined, ensure the pre-lordosed plate fits the anatomy. The plate can be adjusted using the Plate Bender. Only bend within bending zones.

CAUTION:

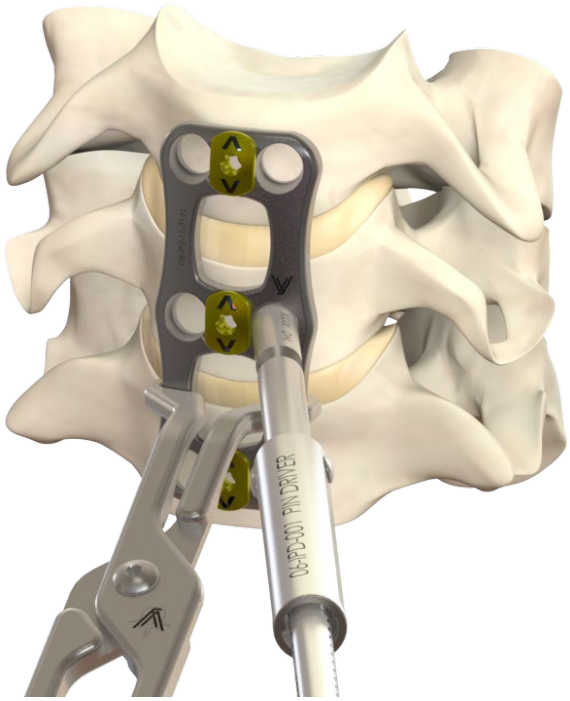
Repeated bending may weaken the plate. Do not bend the plate over the holes.



Step 3. VyPlate™ Placement

After selecting the appropriate VyPlate™, use the Plate Holder to grasp the plate and place it on the anatomy in the desired location.

VyPlate™ Surgical Technique

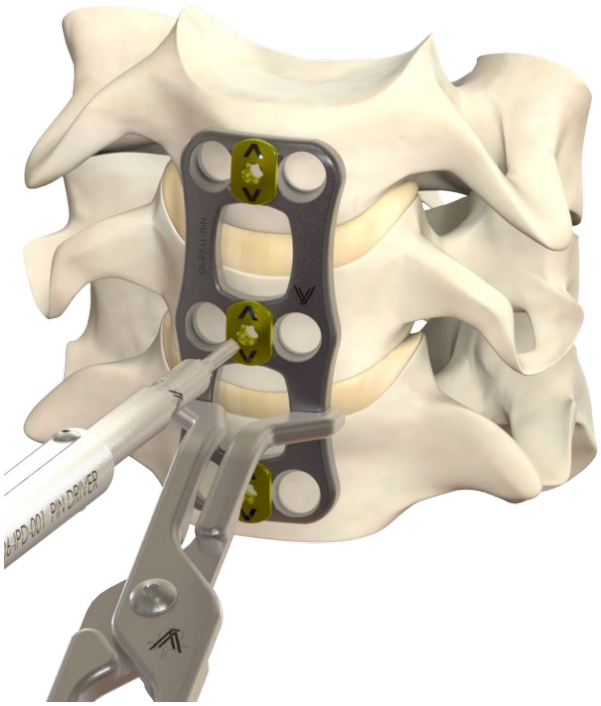


Step 4a. Temporary VyPlate™ Fixation

Slide the Pin Driver sleeve onto the ScrewDriver. Thread the Pin Driver sleeve onto the Temporary Fixation Pin. Note there is a threaded and a non-threaded Temporary Fixation Pin.

Step 4b. Temporary VyPlate™ Fixation

Ensure the VyPlate™ plate is properly aligned with respect to the endplates. Advance the Temporary Fixation Pin until fully seated in the bone screw hole of the plate.



Step 4c. Temporary VyPlate™ Fixation

Optional
Slide the Pin Driver sleeve onto the ScrewDriver. Thread the Pin Driver sleeve onto the Temporary Drive Fixation Pin.
Ensure the VyPlate™ plate is properly aligned with respect to the endplates. Advance the Temporary Drive Fixation Pin until fully seated in the cover plate through the VyPlate™.

Step 5a. Drill Guide

Attach the desired Drill Guide to the Quick Connect Handle. Place the Drill Guide into the desired bone screw hole of the VyPlate™.

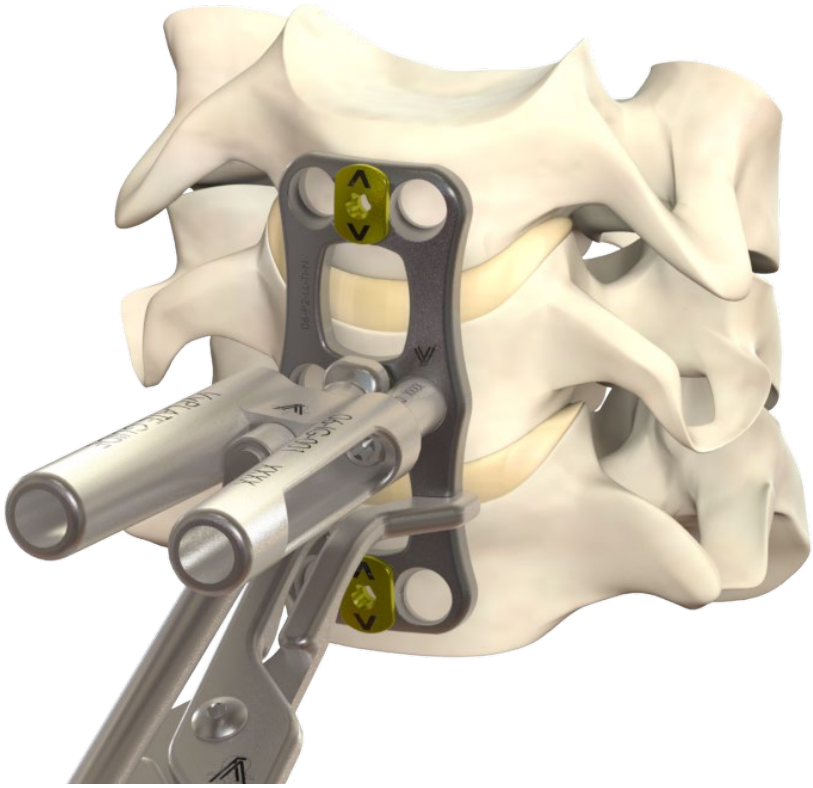
NOTE: There is a Fixed Angle Drill Guide and a Variable Angle Drill Guide, choose the appropriate guide for the desired corresponding screw type.

Step 5b. Double Barrel Drill Guide

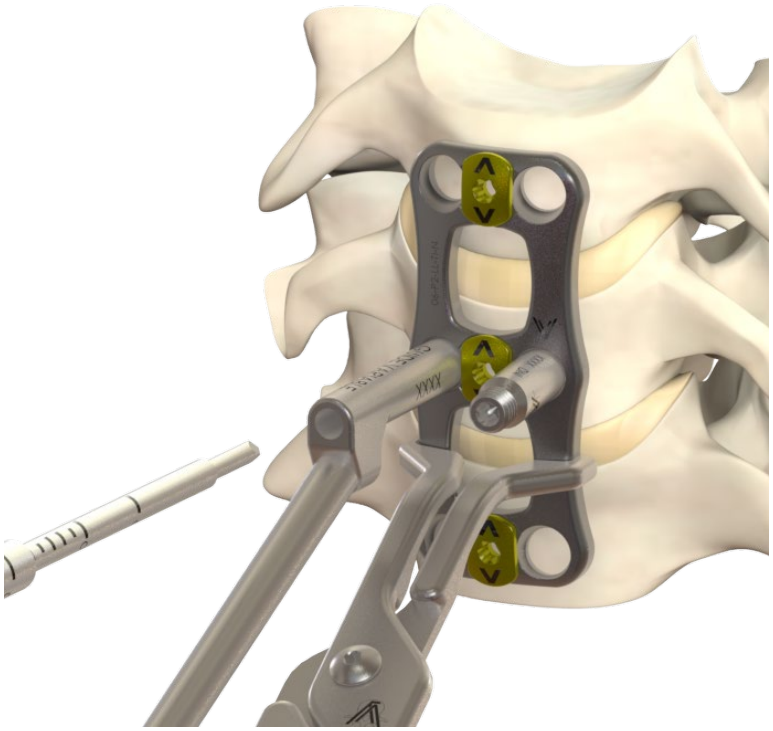
Optional

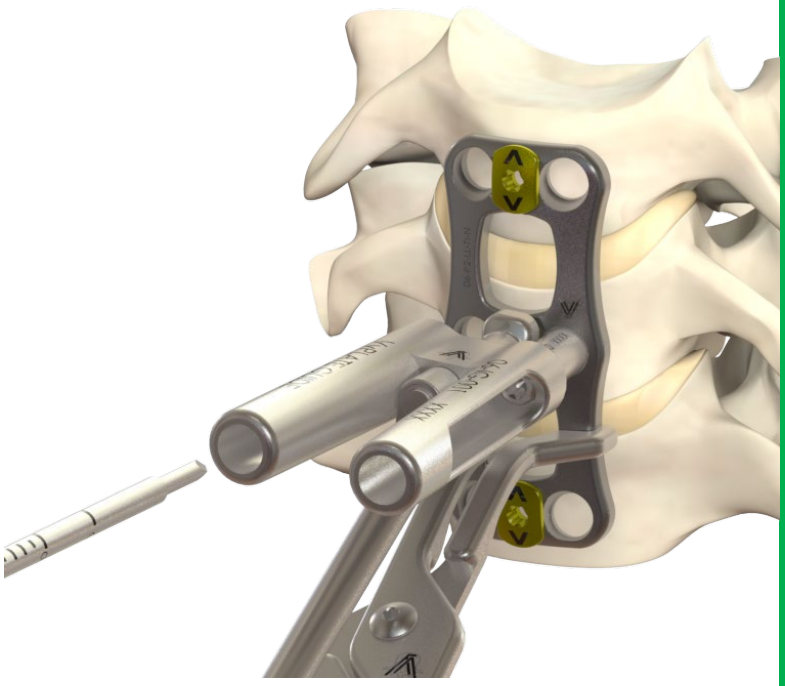
Attach the desired Double Barrel Drill Guide to the Quick Connect Handle. Place the Double Barrel Drill Guide onto the cover plate of the VyPlate™

NOTE: The Temporary Drive Fixation Pin cannot be used with the Double Barrel Drill Guide. If using the Double Barrel Drill Guide with the Temporary Fixation Pin at the same level, ensure the Double Barrel Drill Guide seats over the Temporary Fixation Pin.



VyPlate™ Surgical Technique





Step 6. Awl

Attach the Quick Connect Handle to the Awl. Place the Awl through the Drill Guide and lightly tap through the cortical surface of the vertebral body to create a pilot hole. Depth markings may be used to note depth of pilot hole.

NOTE:

The surgeon must take great care to properly position bone screw holes when using the Variable Angle Drill Guide. Excessively converging hole patterns may prohibit proper seating of the bone screws. Hole patterns angled beyond 10° may prohibit proper seating of the bone screws.

Step 7. Drilling Pilot Hole

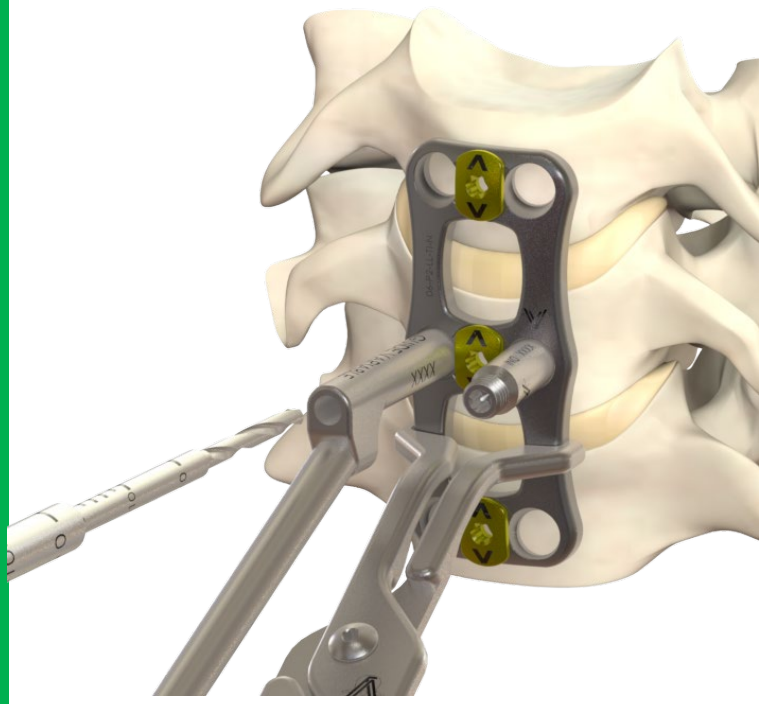
Attach the Quick Connect Handle to the Drill. Place the Drill through the Drill Guide and rotate the handle in a clockwise direction to create the pilot hole for the screw. Depth markings may be used to note depth of pilot hole.

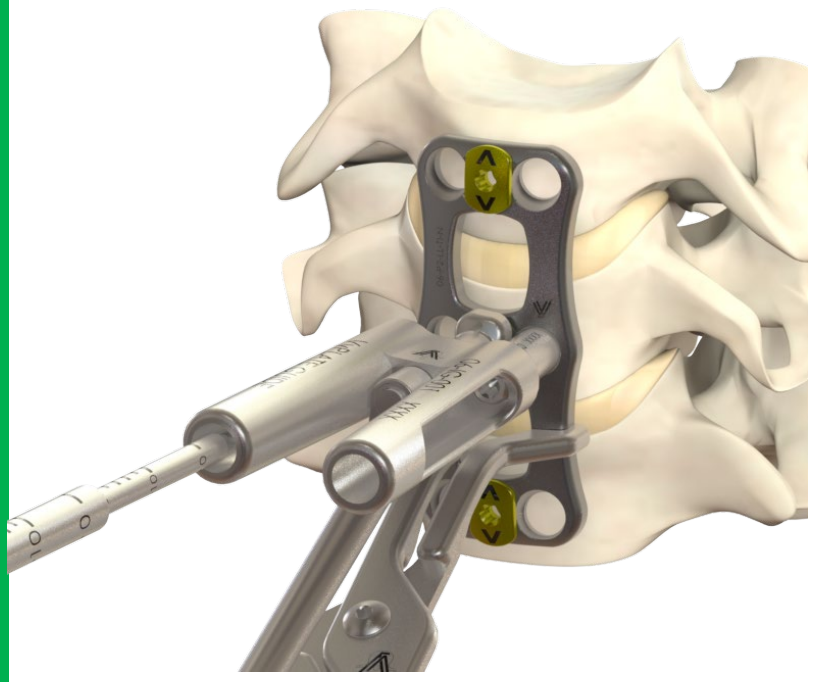
NOTE:

The surgeon must take great care to properly position bone screw holes when using the Variable Angle Drill Guide. Excessively converging hole patterns may prohibit proper seating of the bone screws. Hole patterns angled beyond 10° may prohibit proper seating of the bone screws.

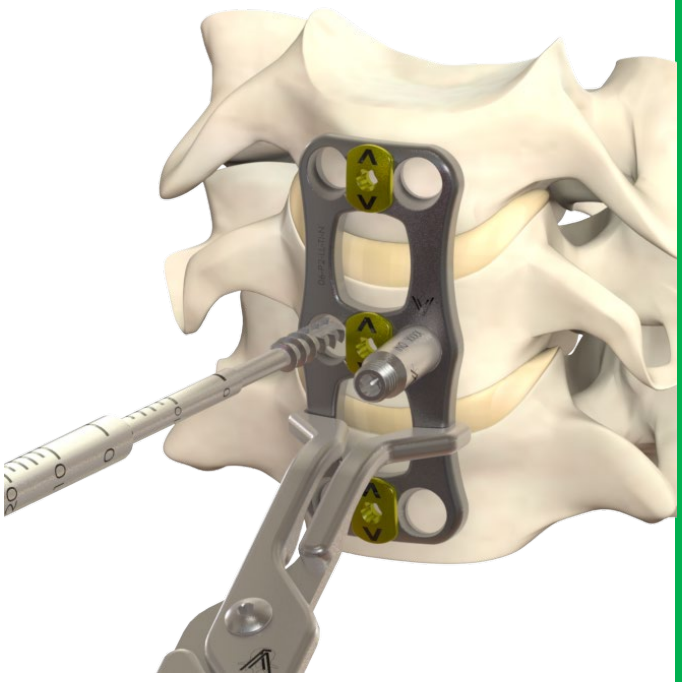
CAUTION:

For optimal performance, it is recommended that the drills and taps be treated as single use instruments.





VyPlate™ Surgical Technique



Step 8a. Tapping Pilot Hole

Optional

Although VyPlate™ screws are all self-tapping, additional pre-tapping maybe be desired.

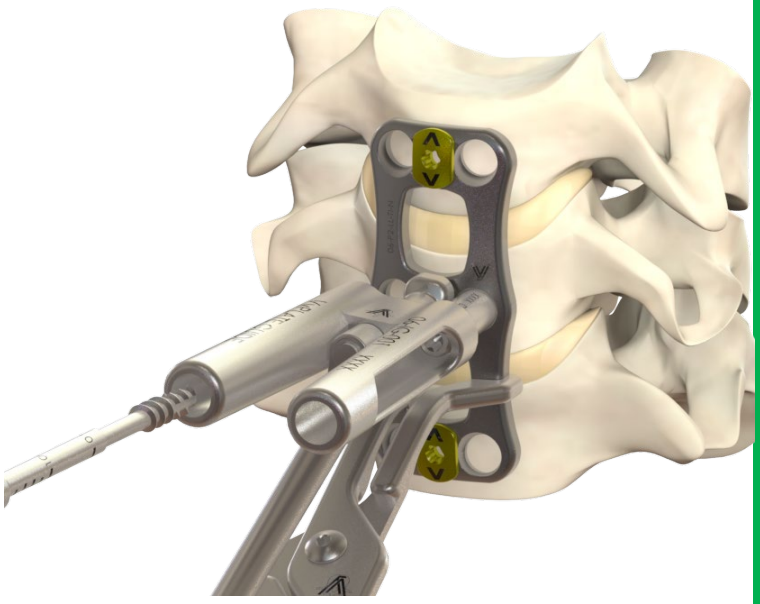
Attach the Quick Connect Handle to the Tap. Remove the Drill Guide. Place the Tap into the pilot hole, and advance, rotating clockwise, until the desired depth on the depth markings is reached.

NOTE:

The surgeon must take great care to properly position bone screw holes when using the Variable Angle Drill Guide. Excessively converging hole patterns may prohibit proper seating of the bone screws. Hole patterns angled beyond 7° may prohibit proper seating of the bone screws.

CAUTION:

For optimal performance, it is recommended that the drills and taps be treated as single use instruments.



Step 8b. Tapping Pilot Hole

Optional

Attach the Quick Connect Handle to the Tap. Place the Tap into the Double Barrel Drill Guide, and advance, rotating clockwise, until the desired depth on the depth markings is reached.

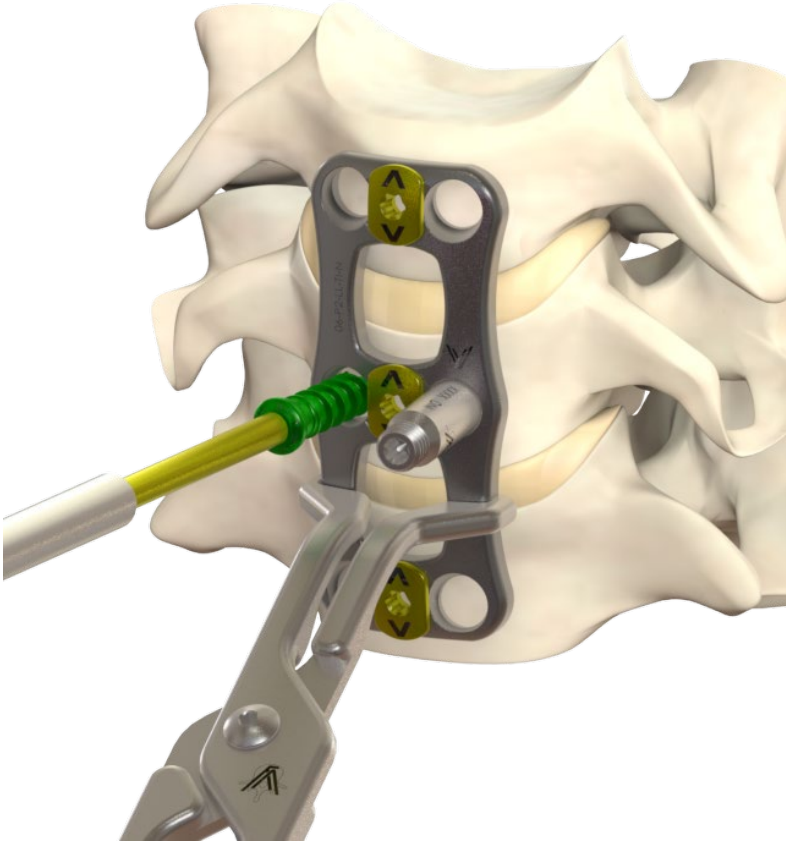
CAUTION:

For optimal performance, it is recommended that the drills and taps be treated as single use instruments.

VyPlate™ Surgical Technique

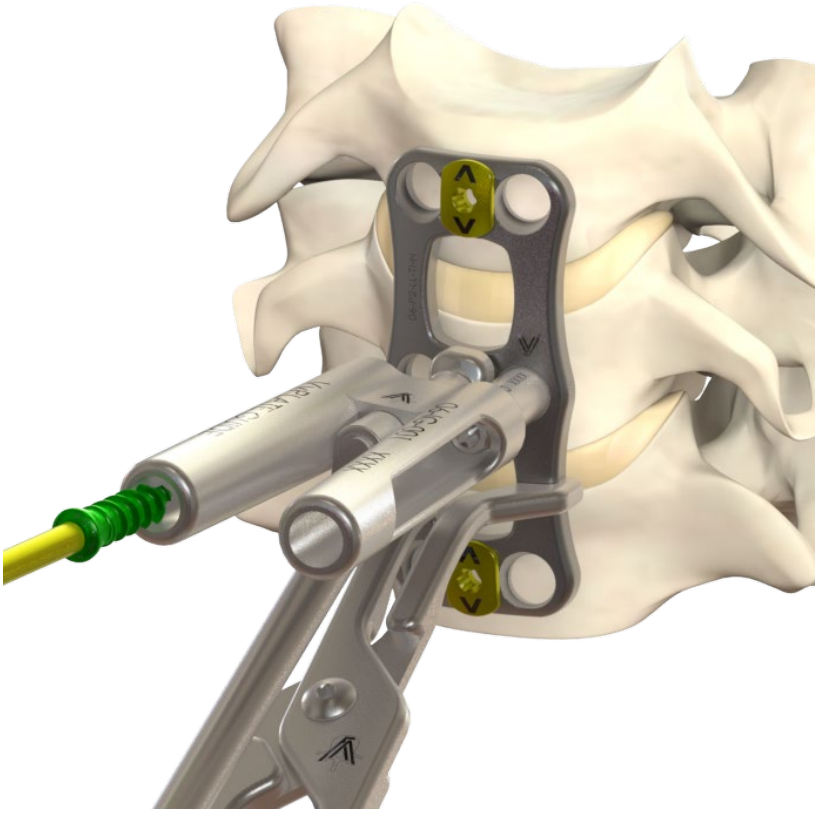
Step 9. Screw Insertion

Attach the Quick Connect Handle to the Screw Driver. Place the desired VyPlate™ screw onto the Screw Driver. Insert the screw into the pilot hole, and advance, rotating clockwise, until fully seated in the VyPlate™.

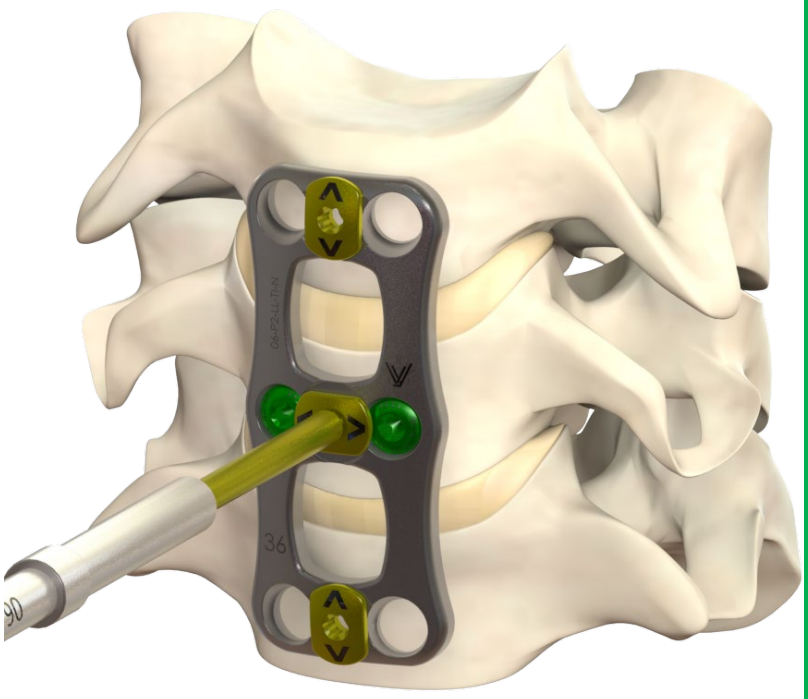


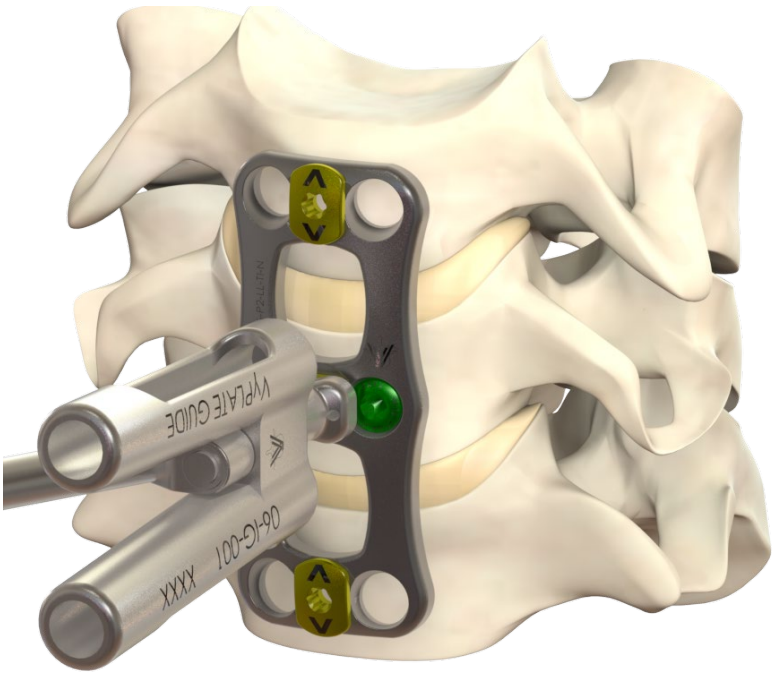
Step 10. Remaining Screw Insertion

(Not Pictured)
Remove Temporary Fixation Pins using Screw Driver and Pin Driver sleeve.
Repeat Steps 4-8 for remaining VyPlate™



VyPlate™ Surgical Technique





Step 11. Align Cover Plate

Place Cover Plate Adjuster onto the VyPlate™ cover plate, and rotate the cover plate so that it is aligned over the adjacent screw heads.
The Double Barrel Drill Guide can also be used to rotate the VyPlate™ cover plate.

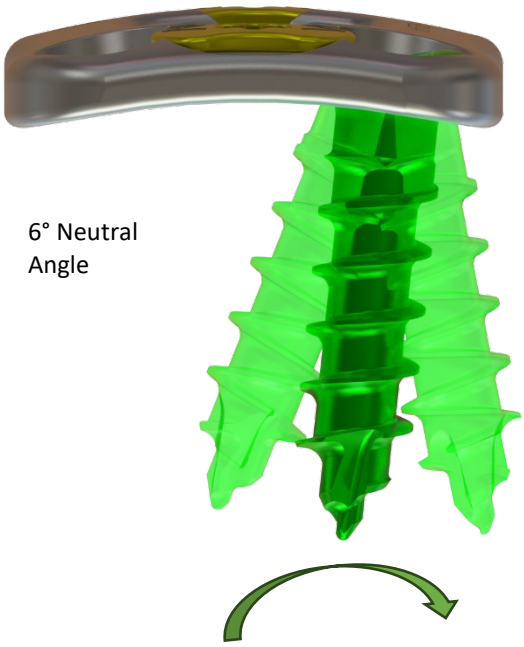
Step 12. Remaining Screws and Cover Plates

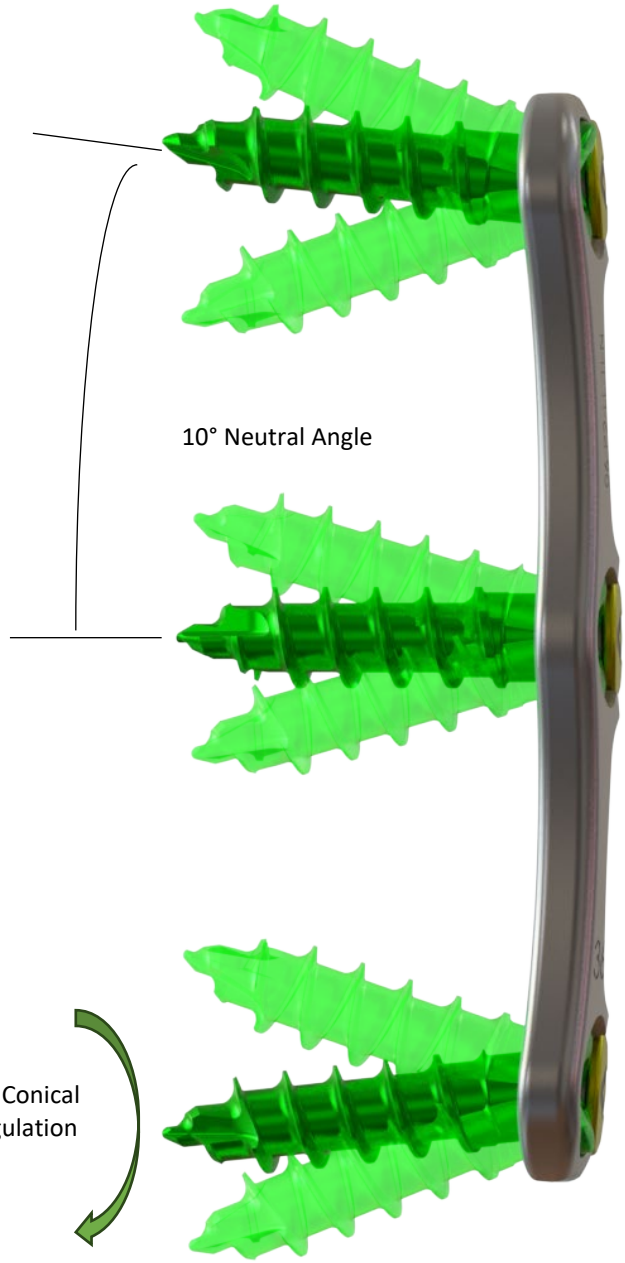
Remove all instrumentation, and the repeat Steps 5-11 for all remaining VyPlate™ screws and cover plates.

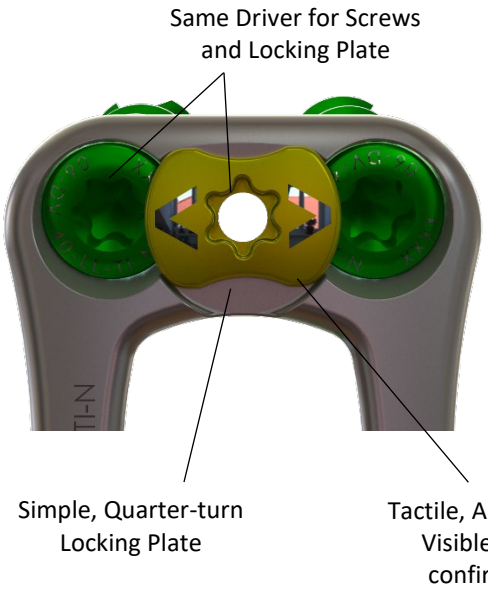
Optional. Removal of Device

To remove the VyPlate™ Cervical ACP device, loosen the set screw and rotate the cover plate so that the VyPlate screws are exposed. Remove the VyPlate screws, and then subsequently remove the VyPlate. Reasons for removal can be found in the "Possible Adverse Effects" section of the Package Insert.

VyPlate™ Features







VyPlate™ ACP Ordering Information

Single Level Plates

Part Number	Product Size
06-P1-12-TI-N	12mm
06-P1-14-TI-N	14mm
06-P1-16-TI-N	16mm
06-P1-18-TI-N	18mm
06-P1-20-TI-N	20mm
06-P1-22-TI-N	22mm
06-P1-24-TI-N	24mm
06-P1-26-TI-N	26mm

Two Level Plates

Part Number	Product Size
06-P2-24-TI-N	24mm
06-P2-28-TI-N	28mm
06-P2-32-TI-N	32mm
06-P2-36-TI-N	36mm
06-P2-40-TI-N	40mm
06-P2-44-TI-N	44mm
06-P2-48-TI-N	48mm
06-P2-52-TI-N	52mm

Three Level Plates

Part Number	Product Size
06-P3-36-TI-N	36mm
06-P3-42-TI-N	42mm
06-P3-48-TI-N	48mm
06-P3-54-TI-N	54mm
06-P3-60-TI-N	60mm
06-P3-66-TI-N	66mm
06-P3-72-TI-N	72mm
06-P3-78-TI-N	78mm

Other sizes available upon request

VyPlate™ ACP Ordering Information

Four and Five Level Plates

Part Number	Product Size
06-P4-48-TI-N	48mm
06-P4-56-TI-N	56mm
06-P4-64-TI-N	64mm
06-P4-72-TI-N	72mm
06-P4-80-TI-N	80mm
06-P4-88-TI-N	88mm
06-P4-96-TI-N	96mm

Part Number	Product Size
06-P5-60-TI-N	60mm
06-P5-70-TI-N	70mm
06-P5-80-TI-N	80mm
06-P5-90-TI-N	90mm
06-P5-100-TI-N	100mm
06-P5-110-TI-N	110mm
06-P5-120-TI-N	120mm

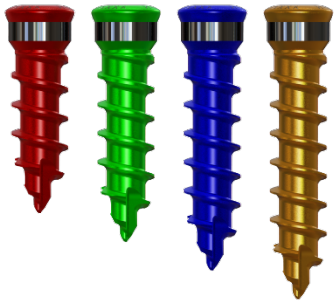
Other sizes available upon request

VyPlate™ ACP Ordering Information

Screw Options

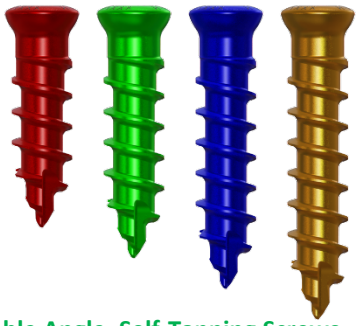
Fixed Angle, Self-Drilling Screws

Part Number	Product Size
06-DF-40-12-TI-N	Ø4.0mm, 12mm
06-DF-40-14-TI-N	Ø4.0mm, 14mm
06-DF-40-16-TI-N	Ø4.0mm, 16mm
06-DF-40-18-TI-N	Ø4.0mm, 18mm



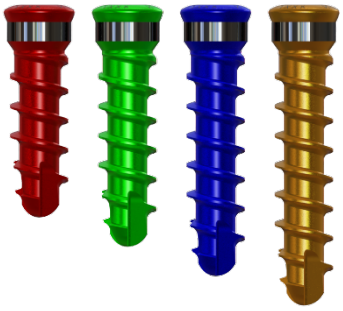
Variable Angle, Self-Drilling Screws

Part Number	Product Size
06-DV-40-12-TI-N	Ø4.0mm, 12mm
06-DV-40-14-TI-N	Ø4.0mm, 14mm
06-DV-40-16-TI-N	Ø4.0mm, 16mm
06-DV-40-18-TI-N	Ø4.0mm, 18mm



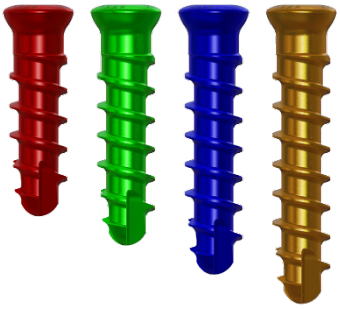
Fixed Angle, Self-Tapping Screws

Part Number	Product Size
06-TF-40-12-TI-N	Ø4.0mm, 12mm
06-TF-40-14-TI-N	Ø4.0mm, 14mm
06-TF-40-16-TI-N	Ø4.0mm, 16mm
06-TF-40-18-TI-N	Ø4.0mm, 18mm



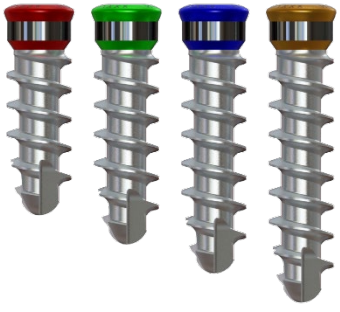
Variable Angle, Self-Tapping Screws

Part Number	Product Size
06-TV-40-12-TI-N	Ø4.0mm, 12mm
06-TV-40-14-TI-N	Ø4.0mm, 14mm
06-TV-40-16-TI-N	Ø4.0mm, 16mm
06-TV-40-18-TI-N	Ø4.0mm, 18mm



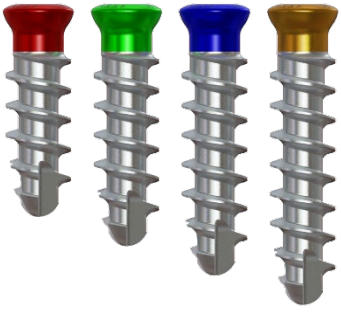
Fixed Angle, Self-Tapping Rescue Screws

Part Number	Product Size
06-TF-45-12-TI-N	Ø4.5mm, 12mm
06-TF-45-14-TI-N	Ø4.5mm, 14mm
06-TF-45-16-TI-N	Ø4.5mm, 16mm
06-TF-45-18-TI-N	Ø4.5mm, 18mm



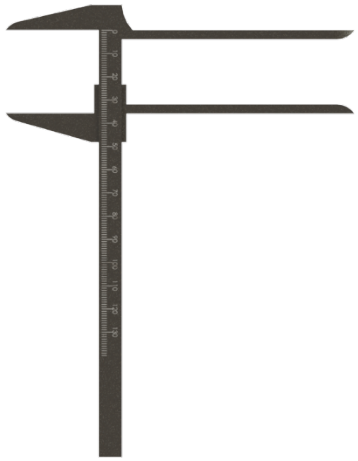
Variable Angle, Self-Tapping Rescue Screws

Part Number	Product Size
06-TV-45-12-TI-N	Ø4.5mm, 12mm
06-TV-45-14-TI-N	Ø4.5mm, 14mm
06-TV-45-16-TI-N	Ø4.5mm, 16mm
06-TV-45-18-TI-N	Ø4.5mm, 18mm



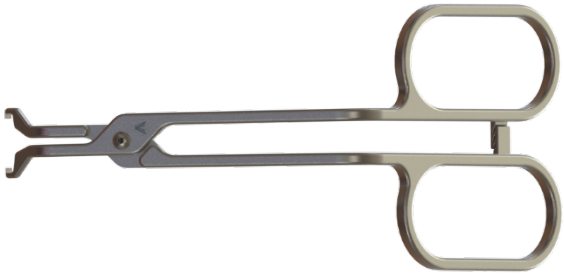
VyPlate™ ACP Ordering Information

Instrumentation Options

Part Number	Description	
	Caliper	
	Plate Bender	
	Ratchet Handle	
	Phenolic Handle	
06-IG-001	Double Barrel Drill Guide	

VyPlate™ ACP Ordering Information

Instrumentation Options

Part Number	Description	
06-IGF-001	Fixed Angle Drill Guide	
06-IGV-001	Variable Angle Drill Guide	
06-IPH-001	Plate Holder	

VyPlate™ ACP Ordering Information

Instrumentation Options

Part Number	Description	
06-IA-001	Awl	
06-ID-020	2.0mm Drill Bit	
06-IPD-001	Pin Driver	
06-ISD-001	Screw Driver	
06-IT-035	3.5mm Tap	
06-IFP-001	Temporary Fixation Pin	
06-ITP-001	Threaded Fixation Pin	
06-IDP-001	Drive Fixation Pin	

VyPlate™ ACP Ordering Information

Additional Sizes

The VyPlate™ Cervical ACP is available in additional sizes upon request. This is true for all types of plates and screws. Additionally, Self-Drilling Rescue Screws are also available upon request.

NOTES

Indications:

The VyPlate™ Anterior Cervical Plate System is indicated for stabilization of the anterior cervical spine from C2 to C7 employing unicortical screw fixation at the anterior face of the vertebral bodies. Specific clinical indications for anterior plating include:

- instability caused by trauma or fracture;
- instability associated with correction of cervical lordosis and kyphosis deformity;
- instability associated with pseudoarthosis as a result of previously failed cervical spine surgery;
- instability associated with major reconstructive surgery for primary tumors or metastatic malignant tumors of the cervical spine;
- instability associated with single or multiple level corpectomy in advanced degenerative disk disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), spinal canal stenosis and cervical myelopathy.

This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

FOR ADDITIONAL INFORMATION INCLUDING PRECAUTIONS, WARNINGS, CONTRAINDICATIONS, CLEANING AND STERILIZATION, PLEASE REFER TO THE PACKAGE INSERT

VySpine™, LLC
PO Box 1693
Bountiful, UT 84011
866-4-VY-SPINE
www.VySpine.com

06-SURG Rev D
May 2025