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VueLock[®] Anterior Cervical Plate System

Surgical Technique



VueLock[®]



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Introduction

The VueLock® Anterior Cervical Plate System offers spine surgeons simplicity, efficiency, and versatility. Overall, the **VueLock** Anterior Cervical Plate System's low profile and various component options provide a competitive edge within the cervical spine market.



Design Features

VueLock Cervical System

The system includes Self-Tapping and Self-Drilling Bone Screws, which are positioned and locked in a one-step procedure that facilitates surgeon ease of use. This unique locking mechanism eliminates the need for additional locking components. Additionally, the bone screws may be positioned at a fixed or variable angle.

The unique open design provides excellent intra-operative visualization of the bone graft and endplates, allowing for greater postoperative visualization on the AP x-ray.



Self-Tapping Bone Screw design provides exceptional purchase.



Self-Drilling Bone Screw design offers optimized cutting flutes that provide quicker bone screw purchase. No pre-drilling required.



Excellent intra-operative and post-operative visualization of the intervertebral space.

One-step locking mechanism



System Components - Implants

VueLock Cervical System

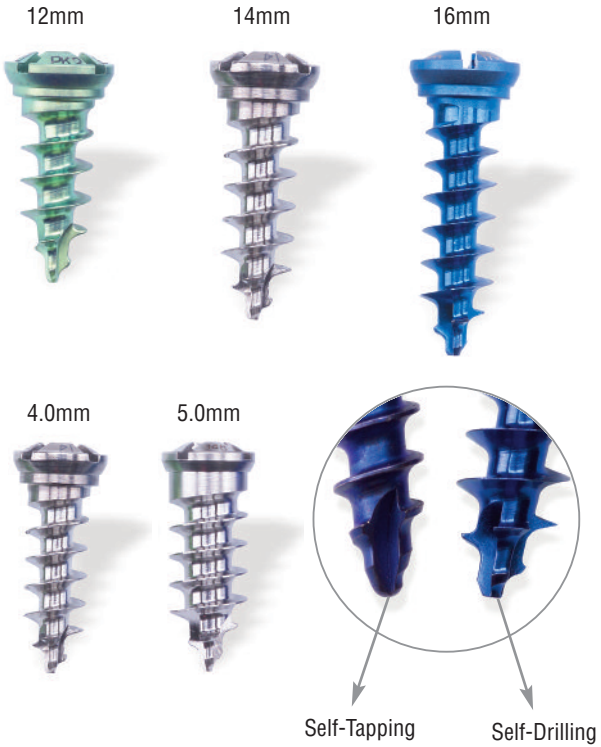
The **VueLock** Anterior Cervical Plate System is an anterior cervical spinal fixation device made from titanium alloy (Ti-6Al-4V). Precontoured plates that conform to the natural lordotic curvature of the spine are available in one, two, three and four level configurations ranging from 12mm - 92mm in length. The system also includes Self-Tapping and Self-Drilling Bone Screws available in two diameters and several lengths.



Plates

- One, two, three and four level configurations
- Sizes ranging from 12mm - 92mm in length

Bone Screws



- Color Coded Bone Screw Lengths
 - 12mm - green
 - 14mm - silver
 - 16mm - blue
- 4.0mm and 5.0mm diameters
- Self-Tapping / Self-Drilling

System Components - Instruments



Caliper



Plate Bender



Mid-Plate Bender



Plate Holder



Tack Inserter



Temporary Fixation Tack



General Handle



Drill Bits



Fixed Drill Guide



Screw Retaining Sleeve



Variable Drill Guide



Screw Inserter



Self Centering Awl



Final Tightener



Standard Awl



Screw Remover

Surgical Technique

Surgical Approach and Preparation

The patient is positioned supine on the operative table with a folded towel beneath the intrascapular region to maintain the head in slight extension. The use of a head halter attached to an outrigger for traction may be helpful. If fluoroscopy is used, it can be utilized at this point to confirm positioning and check that the desired vertebral levels can be adequately visualized. (See Figure 1)

The standard anterior approach to the mid and lower cervical spine is utilized. This can be through one of several incisions with the exposure typically medial to the carotid sheath and lateral to the trachea and esophagus. Adequate fascial plane release is important for optimal exposure. After identification of the disc space through intraoperative confirmation of levels with x-ray, preparation for anterior interbody fusion is begun. (See Figure 2)

The discectomy and resection of osteophytes is performed. Further preparation of the interbody fusion bed or for corpectomy is performed as indicated. (See Figure 3)

Interbody grafts or a strut graft is then positioned and impacted into place. Any distraction previously applied can be released at this point to assess graft stability. It is critical to remove anterior osteophytes for proper plate placement. Repeat the procedure at each disc space as necessary. (See Figure 4)

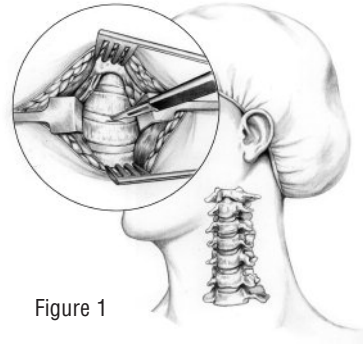


Figure 1

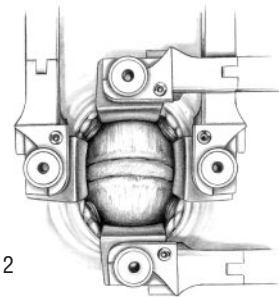


Figure 2

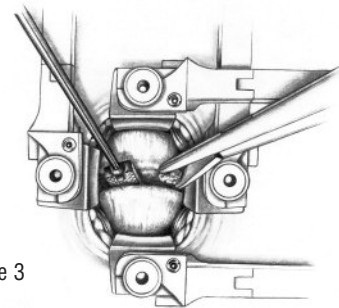


Figure 3

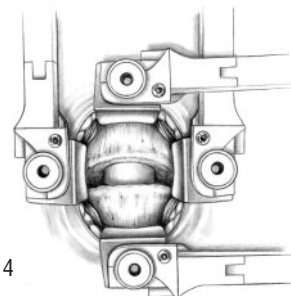


Figure 4

Plate Selection and Positioning

The Plate Holder may be utilized to insert and hold the plate during the selection process.

The Plate Holder will lock onto any portion of the central post(s). To attach the Plate Holder to the plate, engage the distal tips around the central post and depress the handles together to lock in place.

The **VueLock** plates are available in one, two, three and four level styles and range in length from 12mm to 92mm. Select the desired style and estimated plate length.

The appropriate plate length is determined by utilizing the Caliper. Position the legs of the Caliper until the desired screw position is achieved at the superior and inferior ends. This allows for cephalad and caudal screw angulation and helps ensure that the plate does not extend over the adjacent unfused disc spaces.

Insert and position the plate on the anterior surface of the spine with the Plate Holder. Review landmarks to ensure that the plate is centered appropriately medially/laterally on the spine. Confirm that the superior and inferior screw holes are in correct position on the vertebral bodies.



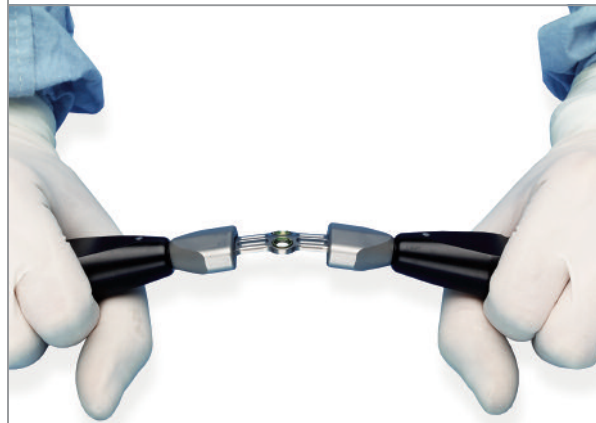
Surgical Technique (Continued)

Adjust Lordotic Curvature Of Plate (Optional)

The amount of lordosis designed into the **VueLock** Anterior Cervical Plate is acceptable in the majority of cases. If required, changes can be made to the standard lordotic curvature by using the Plate Bender or Mid-Plate Bender.

If a consistent bend is required, attach a Plate Bender to each end of the plate and gradually bend to the desired contour. Avoid abrupt changes in the curvature.

If an intermediate bend is required, attach a Plate Bender to one end and the Mid-Plate Bender to the other. Ensure that the rings are fully seated and gradually apply pressure on the plate until desired contour is achieved.



Temporary Fixation Tack Insertion (Optional)

After the plate has been positioned, a Temporary Fixation Tack may be inserted into any of the screw holes to provide fixation while drilling holes and inserting bone screws. The Temporary Fixation Tack is positioned utilizing the Temporary Fixation Tack Inserter. The fixation tacks are loaded into the tack inserter by pulling back on the locking sleeve and sliding the tack into place.

The Temporary Fixation Tack is inserted by turning the tack inserter in a clockwise direction. Once the tack shoulder is fully seated into the screw hole, the tack inserter is removed by pulling back on the locking sleeve and releasing. Additional fixation tacks may be inserted, if desired.



Surgical Technique (Continued)

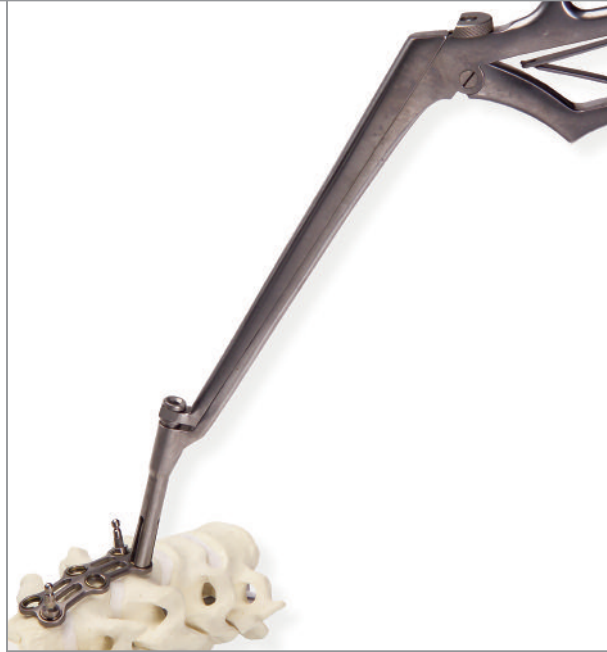
Drill Guide Positioning

Drill Guide options are as follows:

- The Fixed Drill Guide presets the convergent angle at 10° toward the midline of the plate. The cranial/caudal angle is neutral.
- The Variable Angle Drill Guide allows for a 20° cone of angulation.

For each guide, the drill guide tip should be fully seated into the screw hole of the plate. Once the drill guide is inserted into the bone screw hole, the Variable Angle Drill Guide is securely locked into the plate by applying light downward pressure on the drill guide handle. The drill guide is considered to be fully locked when the distal tip is flush with the plate. The drill guide tip will engage within the snap ring in the screw hole.

If the Fixed Drill Guide is used, the guide is locked by compressing the Rongeur handle and rotating the wheel 180° clockwise.



Awl Positioning (Optional)

As an alternative to drilling, an awl may be used to pierce the anterior cortex to the minor diameter of a 4.0mm bone screw within the vertebral body. Awl options are as follows:

- The Standard Awl penetrates to a 9mm depth with a Fixed or Variable Drill Angle Guide.
- The Self Centering Awl pierces the cortex within the desired depth range of 8-16mm.

Note: To adjust the depth of the Self Centering Awl, depress the button on the handle and turn the sleeve clockwise to desired depth marking.



Surgical Technique (Continued)

Drill Holes For Bone Screws

The appropriate size Drill Bit is selected based on the corresponding bone screw size. Bone screw length is measured by the overall length. After the bone screw is inserted through the plate, the bone screw purchase is 1mm less (i.e. 14mm length bone screw results in 13mm of bone purchase). Screws are available in the following dimensions:

Drill Bits (Color Coded)

- 12mm (Green)
- 14mm (Silver)
- 16mm (Blue)
- 4.0/5.0mm diameters

Bone Screw Diameters:

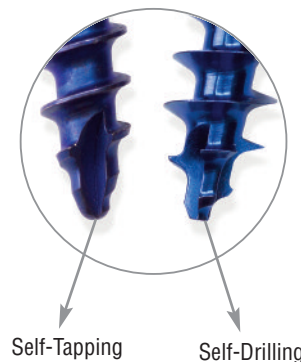
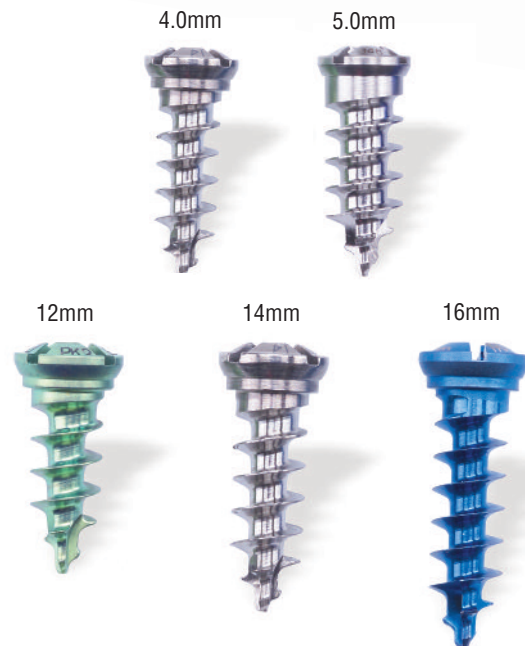
- 4.0mm (Primary)
- 5.0mm (Salvage/Rescue)

Bone Screw Lengths:

- 12 mm (Green)
- 14mm (Silver)
- 16mm (Blue)

Bone Screw Styles:

- Self-Drilling
- Self-Tapping



The depth of drilling is controlled by the preset drill stop at the length of the bone screw. The Drill Bit is designed to pierce the anterior cortex of the vertebral body and create the appropriate size and trajectory for the bone screw. Select the appropriate Drill Bit. The Drill Bits are color-coded and correspond with the bone screw length colors.

The Drill Bit may be inserted with power or by hand utilizing the General Handle. If utilizing by hand, attach the desired Drill Bit to the General Handle by pulling the locking sleeve back and inserting the Drill Bit into the opening.

Insert the Drill Bit into the drill guide barrel and advance the drill into the anterior vertebral body to the maximal depth allowed by the drill stop. For standard applications, bicortical screw purchase is not necessary. The Self-Tapping Bone Screw design does not require a separate tap.

Note: Remove the Variable Drill Guide by tilting the guide medially to release. If utilizing the Fixed Drill Guide, rotate the wheel until the straight edge releases the guide.



Surgical Technique (Continued)

Verify Bone Screws

Attach the appropriate size bone screw to the Screw Inserter by inserting the distal tip into the screw head and turning the red knob in a clockwise direction until “secured”.

The appropriate length and diameter can be verified using the Screw Gauge located on the screw holding racks.

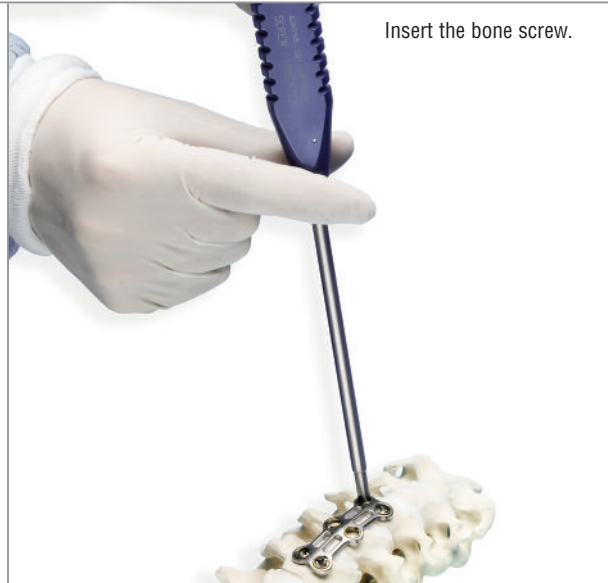


Insert And Lock Bone Screws

Insert the appropriate length bone screw through the plate until the screw head fully seats below the gold locking ring within the screw hole. Once the screw head snaps inside the locking ring, the bone screw is securely locked in place. Remove the Screw Inserter from the bone screw by turning the red knob in a counterclockwise direction until the bone screw disengages.

Screw locking may be confirmed by visually inspecting that the screw head is below the ring or by turning the locking ring. If the locking ring spins freely, the bone screw is locked in place and firmly secured.

If desired, the Final Tightener and Screw-Retaining Sleeve may be alternative tools to aid in bone screw insertion.

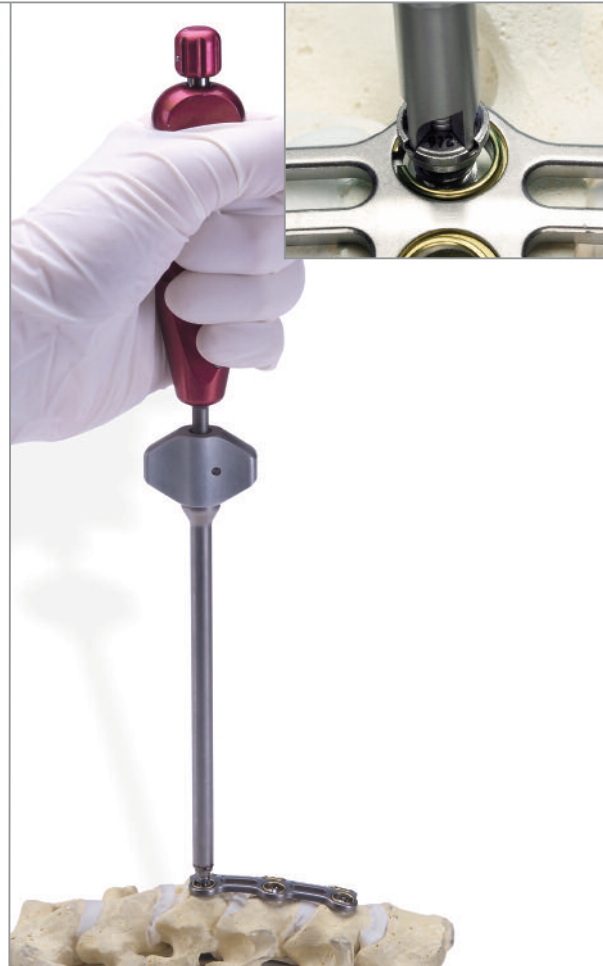


Surgical Technique (Continued)

Screw Removal

If a bone screw needs to be repositioned, the Screw Remover is utilized. Position the distal tip of the Screw Remover until the cross seats into the bone screw. Turn the small red knob clockwise until the threads on the inner shaft engage with the threads in the bone screw. Turn the silver handle until the cylindrical shaft expands the locking ring.

Turn the red handle counterclockwise until the bone screw releases. To ease bone screw removal, a Plate Holder may be used to apply light downward pressure onto the plate. The screw may now be repositioned utilizing the Screw Inserter.



Additional Surgical Options

For cleaning purposes, the Screw Inserter components may be disassembled by hand. Unthread the inner shaft counterclockwise until the inner shaft has exited the large blue outer housing.

For cleaning purposes, the Screw Remover components may be disassembled by hand. Unthread the inner shaft counterclockwise until the inner shaft has exited the red housing. In addition, unthread the silver outer handle clockwise until the shaft has been completely removed. The components may be sterilized according to sterilization recommendations.

Closure and Post-Operative Care

Closure

After implantation of the **VueLock** Anterior Cervical Plate System is complete, closure is performed in layers according to standard protocol.

Post-Operative Care

A soft collar may be used postoperatively for patient comfort. Postoperative radiographs should be taken.

Implant Removal

Removal of the **VueLock** Anterior Cervical Plate System is performed by reversing the order of the implant procedure. The Screw Remover is used first to remove the screws from the locking rings.



Indications For Use

The **VueLock** Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthroses, and/or failed previous fusions.

Contraindications

The **VueLock** Anterior Cervical Plate System is contraindicated in patients with spinal infection or inflammation; morbid obesity; mental illness, alcoholism or drug abuse; pregnancy; metal sensitivity/foreign body sensitivity; inadequate tissue coverage over the operative site; or open wounds local to the operative area.

Warnings

This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. Benefit of spinal fusions utilizing any screw fixation system has not been adequately established in patients with stable spines. Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury. See the Warnings, Precautions, and Possible Adverse Effects sections of the package insert for a complete list of potential risks.

Sterilization Recommendations

The **VueLock** Anterior Cervical Plate System is provided nonsterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

Cycle:	High Vacuum
Temperature:	270° F/ 132° C
Time:	4 minutes
Note:	Allow For Cooling

See Package Insert

Ordering Information

VueLock Cervical System Implants

1-Level Plates

Catalog#	Description	Qty
83112	12mm Plate	2
83114	14mm Plate	2
83116	16mm Plate	2
83118	18mm Plate	2
83120	20mm Plate	2
83122	22mm Plate	2
83124	24mm Plate	2

2-Level Plates

Catalog#	Description	Qty.
83226	26mm Plate	2
83228	28mm Plate	2
83230	30mm Plate	2
83232	32mm Plate	2
83234	34mm Plate	2
83236	36mm Plate	2
83238	38mm Plate	2
83240	40mm Plate	2
83242	42mm Plate	2

3-Level Plates

Catalog#	Description	Qty.
83344	44mm Plate	2
83346	46mm Plate	2
83348	48mm Plate	2
83350	50mm Plate	2
83352	52mm Plate	2
83354	54mm Plate	2
83356	56mm Plate	2
83358	58mm Plate	2
83360	60mm Plate	2
83362	62mm Plate	2
83364	64mm Plate	2
83366	66mm Plate	2

4-Level Plates

Catalog#	Description	Qty.
83460	60mm Plate	2
83464	64mm Plate	2
83468	68mm Plate	2
83472	72mm Plate	2
83476	76mm Plate	2
83480	80mm Plate	2
83484	84mm Plate	2
83488	88mm Plate	2
83492	92mm Plate	2

VueLock Cervical System Bone Screws

Self-Tapping Bone Screws

Catalog#	Description	Qty.
63025	4.0mm x 12mm	8
63027	4.0mm x 14mm	16
63029	4.0mm x 16mm	8
63050	5.0mm x 12mm	6
63052	5.0mm x 14mm	6
63054	5.0mm x 16mm	6

Self-Drilling Bone Screws

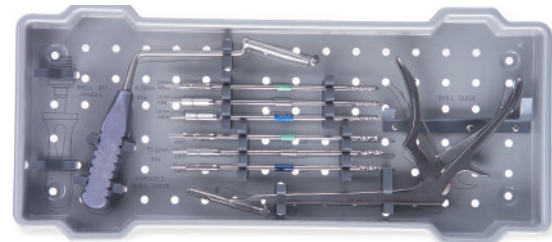
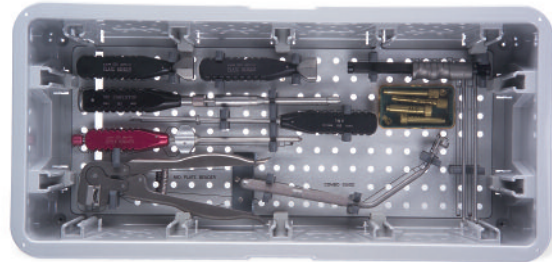
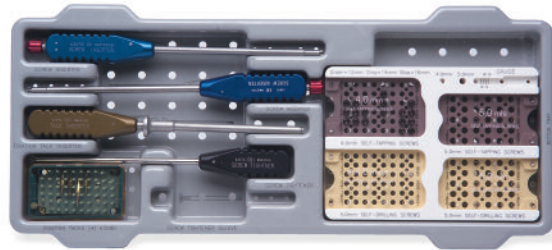
Catalog#	Description	Qty.
63024	4.0mm x 12mm	1
63028	4.0mm x 14mm	1
63030	4.0mm x 16mm	1
63051	5.0mm x 12mm	2
63053	5.0mm x 14mm	2
63055	5.0mm x 16mm	2

Ordering Information (Continued)

VueLock Cervical System Instruments

Instruments

Catalog#	Description	Qty.
63068	4.0mm Screw Drill Bit with Stop, 12mm	1
63069	4.0mm Screw Drill Bit with Stop, 14mm	1
63070	4.0mm Screw Drill Bit with Stop, 16mm	1
63071	5.0mm Screw Drill Bit with Stop, 12mm	1
63072	5.0mm Screw Drill Bit with Stop, 14mm	1
63073	5.0mm Screw Drill Bit with Stop, 16mm	1
63075	Final Tightener	1
63074	Standard Awl	1
63077	Plate Holder	1
63079	General Handle	1
63080	Temporary Fixation Tack	1
63081	Self Centering Awl	1
63085	Fixed Drill Guide	1
63092	Screw Retaining Sleeve	1
63093	Caliper	1
63094	Screw Remover	1
63095	Screw Inserter	4
63096	Temporary Fixation Tack Inserter	4
63098	Variable Drill Guide	1
63099	Plate Bender	1
63599	Mid-Plate Bender	1





Further Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This brochure describes the surgical technique used by Dr. Paul Glazer, M.D. Biomet Spine, as the manufacturer of this device, does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

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Notes: _____

