VELOX
Anterior Cervical Plate

VELOX Anterior Cervical Plate Surgical Technique

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VELOX ANTERIOR CERVICAL PLATE

SURGICAL TECHNIQUE

Techniques described by:

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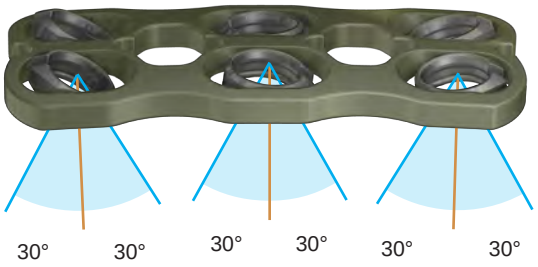
01. Design Rationale

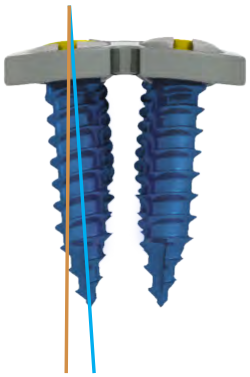
VELOX is a system of Anterior Cervical Plates and instruments designed for anterior cervical interbody fusion (ACIF). The following design requirements guided the development of the VELOX system:

- To maintain anterior cervical alignment when multi-level discectomies or corpectomies are performed
- To provide decreased reliance on prolonged external bracing
- To improve the stability of interbody fusion devices when used (like ORIO-C Cervical Cages)

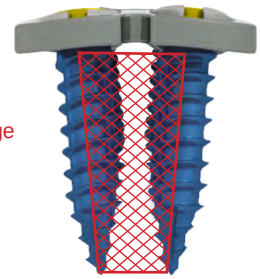
Screw Trajectory Ranges for Variable and Fixed Angle Screws



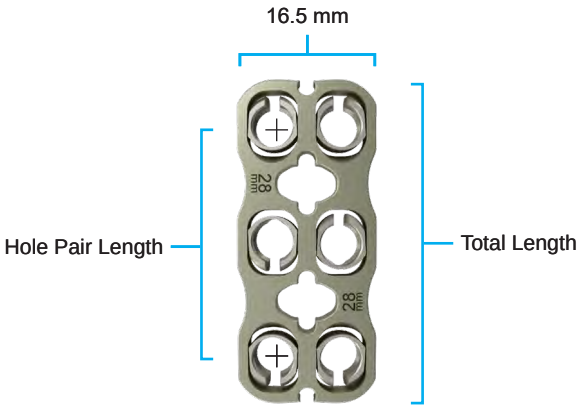
5° Medial
Inclination Angle



Entraped wedge
of bone



02. Plate Ordering Information



One-Level Plates	Cephalad to Caudal Hole Pair Length	Total Length
VPH2-110	10 mm	20.6 mm
VPH2-112	12 mm	22.6 mm
VPH2-114	14 mm	24.6 mm
VPH2-116	16 mm	26.6 mm
VPH2-118	18 mm	28.6 mm
VPH2-120	20 mm	30.6 mm
VPH2-122	22 mm	32.6 mm
VPH2-124	24 mm	34.6 mm
VPH2-126	26 mm	36.6 mm
Two-Level Plates	**Cephalad to Caudal Hole Pair Length**	**Total Length**
VPH2-222	22 mm	32.6 mm
VPH2-224	24 mm	34.6 mm
VPH2-226	26 mm	36.6 mm
VPH2-228	28 mm	38.6 mm
VPH2-230	30 mm	40.6 mm
VPH2-232	32 mm	42.6 mm
VPH2-234	34 mm	44.6 mm
VPH2-236	36 mm	46.6 mm
VPH2-238	38 mm	48.6 mm
VPH2-240	40 mm	50.6 mm
VPH2-242	42 mm	52.6 mm
VPH2-244	44 mm	54.6 mm
VPH2-246	46 mm	56.6 mm
Three-Level Plates	**Cephalad to Caudal Hole Pair Length**	**Total Length**
VPH2-339	39 mm	49.6 mm
VPH2-342	42 mm	52.6 mm
VPH2-345	45 mm	55.6 mm
VPH2-348	48 mm	58.6 mm
VPH2-351	51 mm	61.6 mm
VPH2-354	54 mm	64.6 mm
VPH2-357	57 mm	67.6 mm
VPH2-360	60 mm	70.6 mm
VPH2-363	63 mm	73.6 mm
VPH2-366	66 mm	76.6 mm
VPH2-369	69 mm	79.6 mm
Four-Level Plates	**Cephalad to Caudal Hole Pair Length**	**Total Length**
VPH2-460	60 mm	70.6 mm
VPH2-464	64 mm	74.6 mm
VPH2-468	68 mm	78.6 mm
VPH2-472	72 mm	82.6 mm
VPH2-476	76 mm	86.6 mm
VPH2-480	80 mm	90.6 mm
VPH2-484	84 mm	94.6 mm
VPH2-488	88 mm	98.6 mm
VPH2-492	92 mm	102.6 mm
VPH2-496	96 mm	106.6 mm

03. Screw Ordering Information

Fixed Angle Cervical Screws

Variable Angle Cervical Screws

Fixed Angle Cervical Screws	Length	Catalog No.
Fixed Angle Cervical Screw Ø4mm	12 mm	VFS2-4012
Fixed Angle Cervical Screw Ø4mm	14 mm	VFS2-4014
Fixed Angle Cervical Screw Ø4mm	16 mm	VFS2-4016
Fixed Angle Cervical Screw Ø4mm	18 mm	VFS2-4018
		VFS2-4512
Fixed Angle Cervical Screw Ø4.5mm	12 mm	
Fixed Angle Cervical Screw Ø4.5mm	14 mm	VFS2-4514
Fixed Angle Cervical Screw Ø4.5mm	16 mm	VFS2-4516
Fixed Angle Cervical Screw Ø4.5mm	18 mm	VFS2-4518

Variable Angle Cervical Screws	Length	Catalog No.
Variable Angle Cervical Screw Ø4mm	12 mm	VVS2-4012
Variable Angle Cervical Screw Ø4mm	14 mm	VVS2-4014
Variable Angle Cervical Screw Ø4mm	16 mm	VVS2-4016
Variable Angle Cervical Screw Ø4mm	18 mm	VVS2-4018
Variable Angle Cervical Screw Ø4.5mm	12 mm	VVS2-4512
Variable Angle Cervical Screw Ø4.5mm	14 mm	VVS2-4514
Variable Angle Cervical Screw Ø4.5mm	16 mm	VVS2-4516
Variable Angle Cervical Screw Ø4.5mm	18 mm	VVS2-4518

04. Instrument Ordering Information

Awl
4000-04

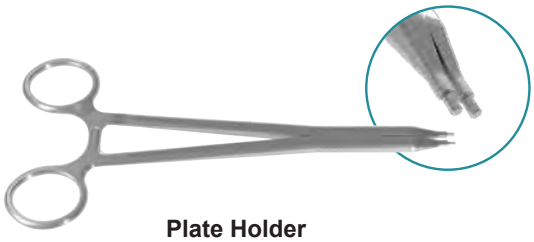
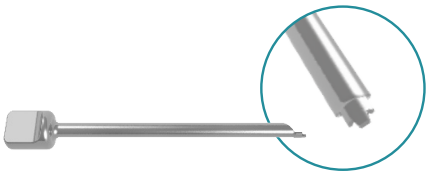


Plate Holder
4000-07

Endplate Drill Guide
4010-03



Screw Remover
4020-02B

Screw Extractor
4020-03

Variable Angle Drill Guide
4020-04

Screwdriver
4020-05-SP

Stripped Bone Screw Remover
4020-07

Temporary Pin Inserter
4000-03

Temporary Pin
4000-02

Quick Connect Handle
4000-06

Drill Bits

12mm	4000-05-12
14mm	4000-05-14
16mm	4000-05-16
18mm	4000-05-18

Inserter Drill Guide Sleeve

4mm & 5mm Cages	4010-07-45
6mm Cages	4010-07-60
7mm & 8mm Cages	4010-07-78

with

Inserter Drill Guide Shaft
4010-08

Caliper
4000-09

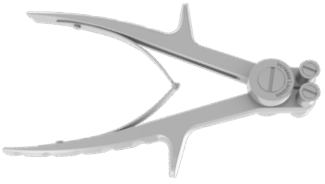


Plate Bender
4020-06

05. Surgical Technique

Site Preparation

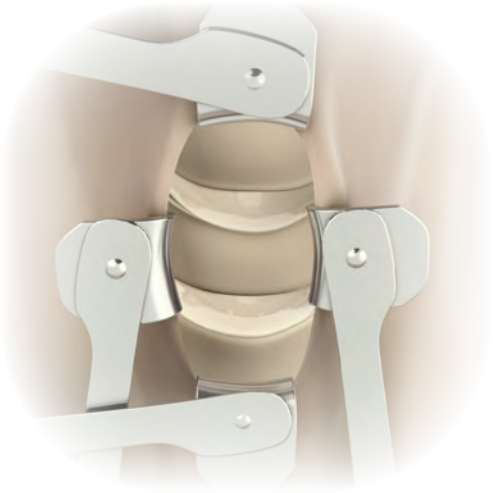
1

The standard positioning of a patient for an anterior cervical approach should be used.

Perform disc excision and spinal decompression using standard surgical technique. Insert appropriate allograft.

Care should be taken to perform appropriate soft tissue dissection and neural elements decompression.

Carefully remove anterior osteophytes to optimize bone-plate interface. When satisfied with the graft position, remove all bone distraction instruments.



Drilling with Endplate Drill Guide (optional)

2

Either of the most cranial screw holes may be drilled at this point with the Endplate Drill Guide, or later with the Variable Angle Drill Guide once the plate is temporarily affixed.

Drill only one of the most cranial holes, the other hole may be drilled once the plate is in position.

The Endplate Drill Guide creates a 30° angle.

To use the Endplate Drill Guide, insert into the disc space with the plate stopper flush against the cranial endplate.

The Awl may be used at this point to breach the cortex.

Choose a Drill Bit that corresponds with the planned screw length and attach to either a power drill or to the provided Quick Connect Handle.

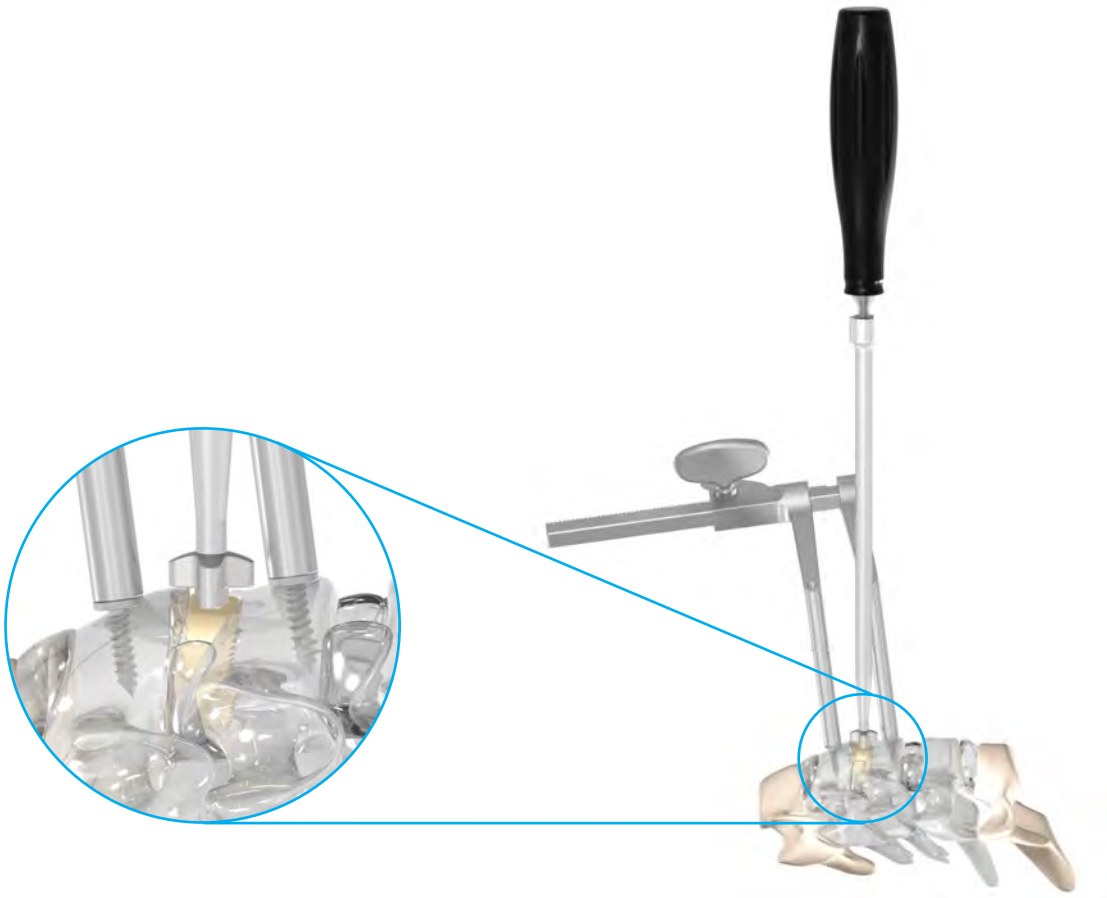
Advance the Drill Bit into the guide and drill until the stopper on the guide stops the bit.

Cage Implantation

3

Implant the ORIO-C Cervical Cages as described in the ORIO-C Surgical Technique.

Care should be taken to not over-compress the disc levels as this may result in delayed subsidence of the implants into the vertebral bodies.



Cage Implantation with Drilling (Optional)

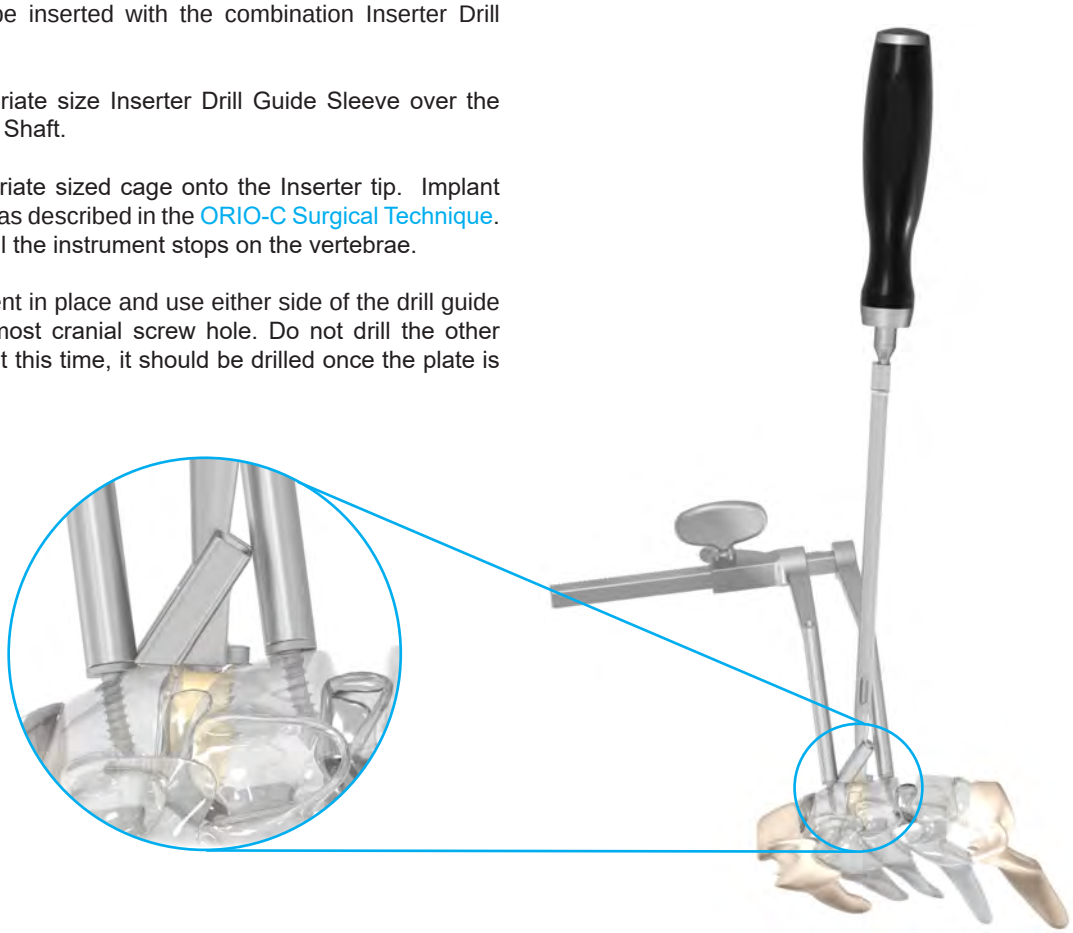
4

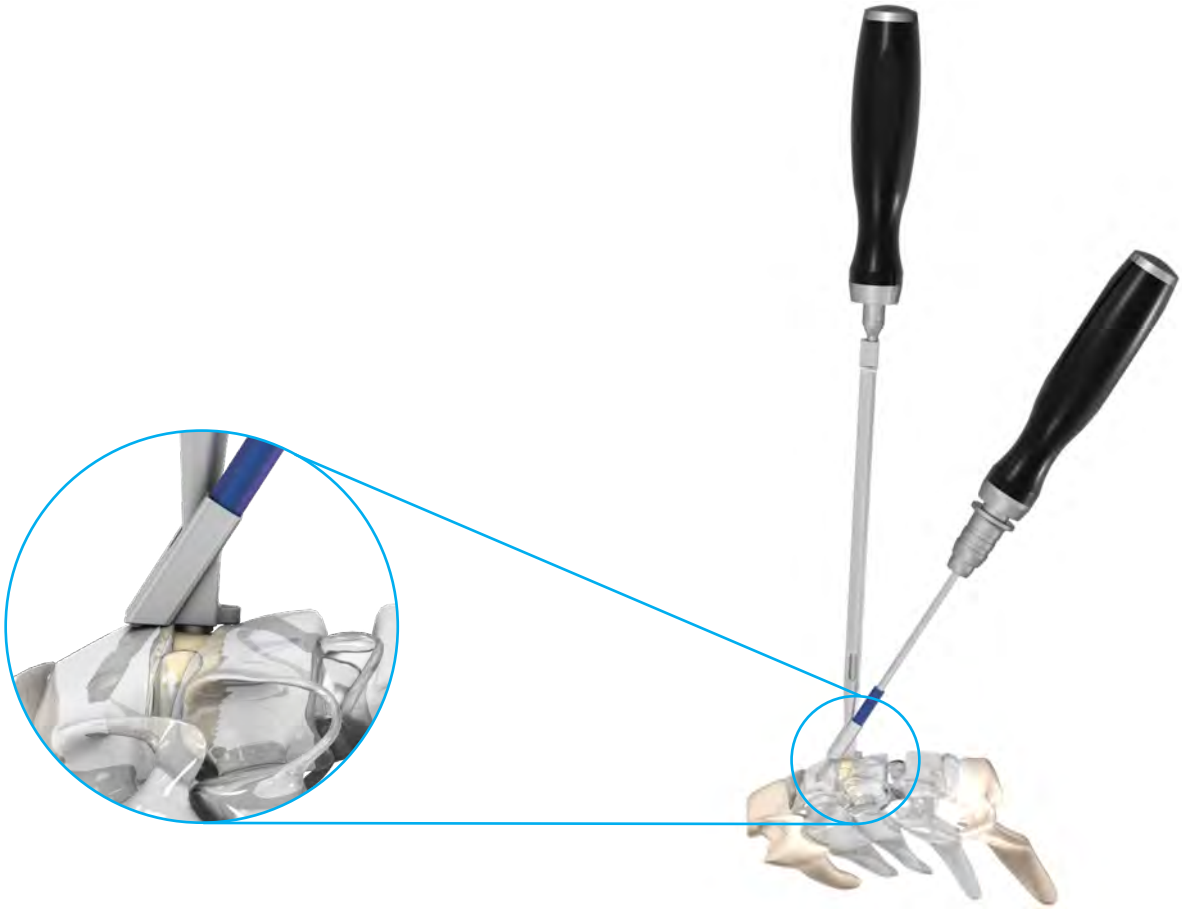
Cages may also be inserted with the combination Inserter Drill Guide.

Thread the appropriate size Inserter Drill Guide Sleeve over the Inserter Drill Guide Shaft.

Thread the appropriate sized cage onto the Inserter tip. Implant into the disc space as described in the ORIO-C Surgical Technique. Insert the cage until the instrument stops on the vertebrae.

Leave the instrument in place and use either side of the drill guide to make the first most cranial screw hole. Do not drill the other most cranial hole at this time, it should be drilled once the plate is in place.





Determining Plate Size

5

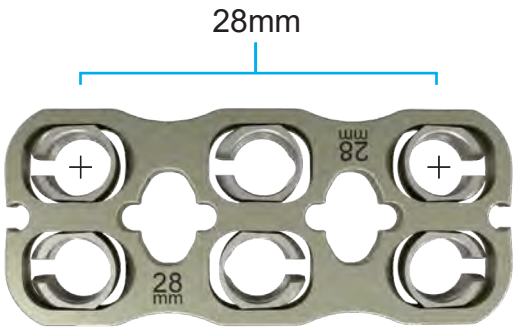
When choosing a suitable plate size, it must be considered that the intervertebral discs in the cervical spine are slightly inclined from anterocaudal to posterocranial.

Ensure that the screws will remain totally in the vertebral body and will not penetrate the intervertebral discs.

Make sure there will be enough space between the intact adjacent intervertebral discs and the screws.

Use the Caliper to determine plate hole length. The plates are labeled with the length between the centers of the cranial and caudal holes.

The cranial and caudal edges of the plate should be positioned close to the endplates of the levels the plate is spanning.



Placement of Cephalad to Caudal Hole Pair Length etchings

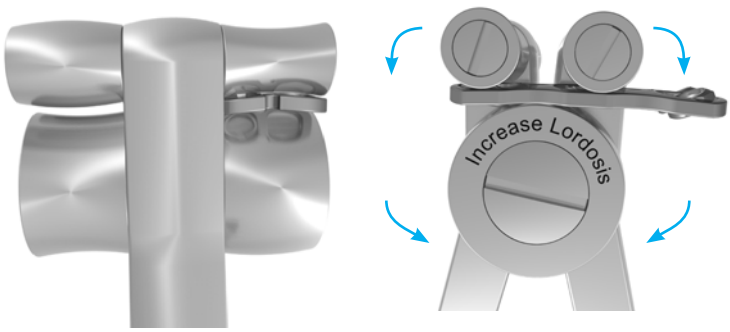
Plate Bending (optional)

6

VELOX Anterior Cervical Plates are prelordosed, but the lordosis of the plate can be increased or decreased using the plate bender.

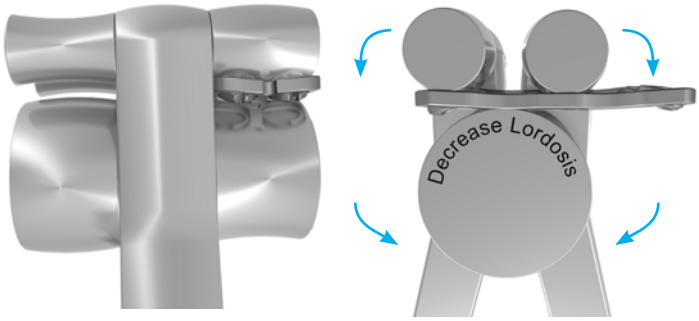
To increase lordosis: Place the plate in the Plate Bender with the convex side of the plate facing superiorly in between the pictured set of rollers. Squeeze the Bender arms together gently to bend the plate.

To decrease lordosis: Place the plate in the Plate Bender with the concave side of the plate facing superiorly in between the pictured set of rollers. Squeeze the Bender arms together gently to bend the plate.

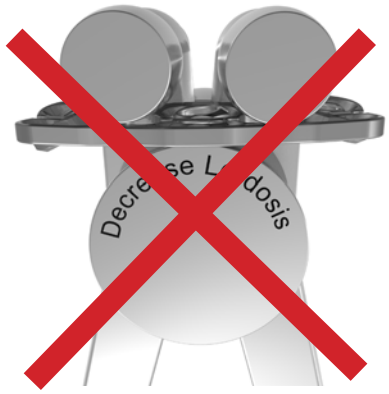


Increase Lordosis

Note: The plate should be bent in the areas between screw holes. Excessive bending of the plate or bending it back in the opposite direction will lead to weakened mechanical integrity and ***should be avoided****.*



Decrease Lordosis



Do not bend a plate at the level of the screw holes

Temporary Plate Fixation

7

Use the Plate Holder to position the plate on the midline (A).

The plate can be held in place with the Temporary Pins. The Plate Holder can be used to stabilize the plate while using the Temporary Pin Inserter to insert Pins (B).

Retract the Temporary Pin Inserter sleeve to attach or release a Temporary Pin.

Pins should be placed in the superior and inferior notches along the midline of the plate (C).

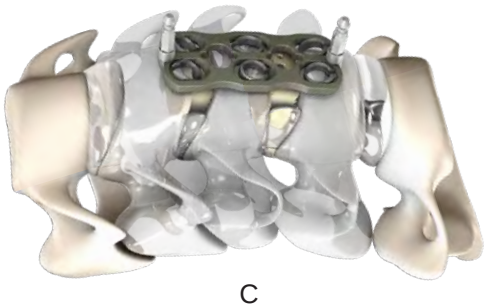
After temporary placement, check the plate position with fluoroscopy and determine screw trajectory (D).

*Note: Using any other instrument besides the Plate Holder to grasp, implant or manipulate the plate can cause **damage** to the locking rings. **Extra care** should be taken to avoid introducing any instruments not specifically intended to interface with the locking rings.*

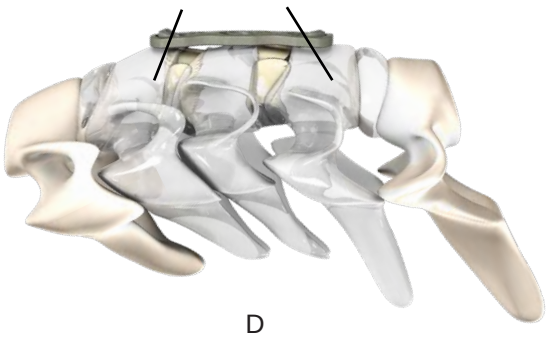
*Note: Temporary pins should **NEVER** be placed within the rings.*

A

B



C



D

Screw Selection

8

VELOX screws are color coded for diameter and length and are available as fixed angle (light blue anodized cam) and variable angle (gold anodized cam). Length should always be checked with a screw gauge.

VELOX screws are self-tapping and self-drilling.

VELOX plates can be used with all fixed angle screws, all variable angle screws, or a hybrid of the two.

Ø4.0mm screws are usually used in most cases. Ø4.5mm screws may be used as an emergency screw in cases where the Ø4.0mm screw has stripped the bone and a larger screw thread is required, or in revision cases.

*Note: **For long spans or poor bone quality:** Careful consideration should be given to the nature of such cases. The treatment may require the use of longer screws (16 mm), and/or posterior fixation for these kind of inherently unstable cases.*

SCREW TRAJECTORY

It is important to avoid trajectories that may injure nervous or vascular tissues. VELOX screws allow for variation in trajectory to accommodate for patient anatomical differences.

Fluoroscopy should be used to confirm drill bit trajectory and then later screw depth and angular orientation.

VARIABLE ANGLE SCREWS

These screws have gold anodized heads and are color coded for length.

Once locked, the screw can pivot along the sagittal plane to allow for subsidence.

FIXED ANGLE SCREWS

These screws have light blue anodized heads and are color coded for length.

Once locked, the screw cannot move, maintaining the intended angle.

*WARNING: The length of **all** Fixed and Variable Angle Screws **must** be verified before insertion. This is done using the Screw Length Indicator, which is located on the top center of all Screw Caddies. See image to the right.*

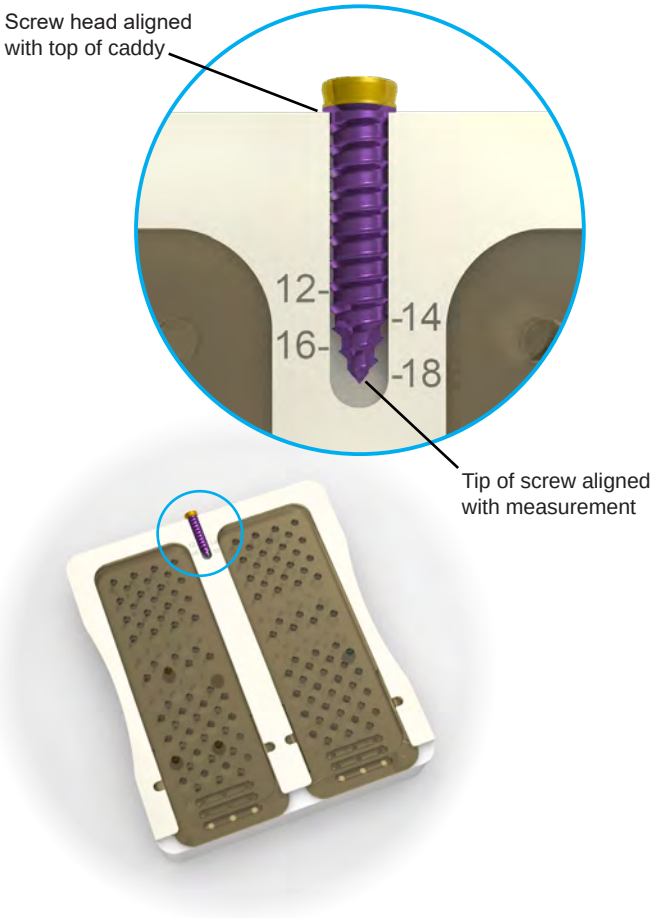
Cervical Screw Length and Diameter Colors

	12mm	14mm	16mm	18mm
Ø4.0mm				
Ø4.5mm				

Variable Angle Screw

Fixed Angle Screw

Screw Length Indicator



Placing the Variable Angle Drill Guide

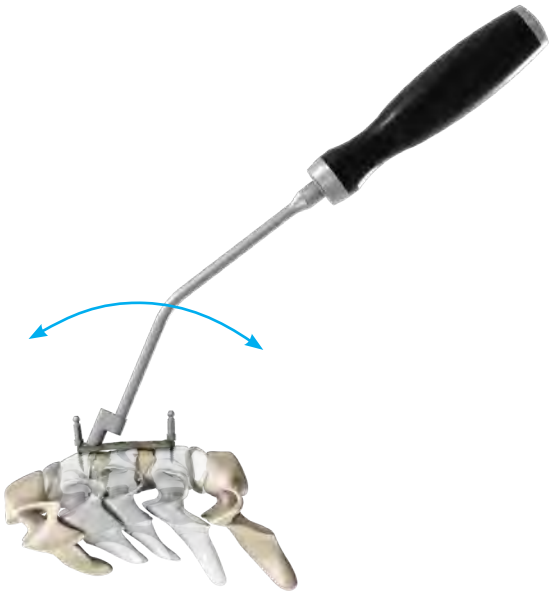
9

Place the Variable Angle Drill Guide in a cranial screw hole. Insert the tip of the Drill Guide into the ring until the shoulder seats against the top surface of the ring.

The Drill Guide can be rotated along the sagittal plane to allow for variation in drilling angle. The design allows for 60° of rotation in this plane only.

Refer to page 4 for an illustration of the angle limits.

Warning : The VELOX Plate already incorporates 5° medial screw angulation as shown on page 4; it is important not to attempt to angle the Variable Angle Drill Guide and the resulting screw trajectory further medially.



Screw Hole Drilling

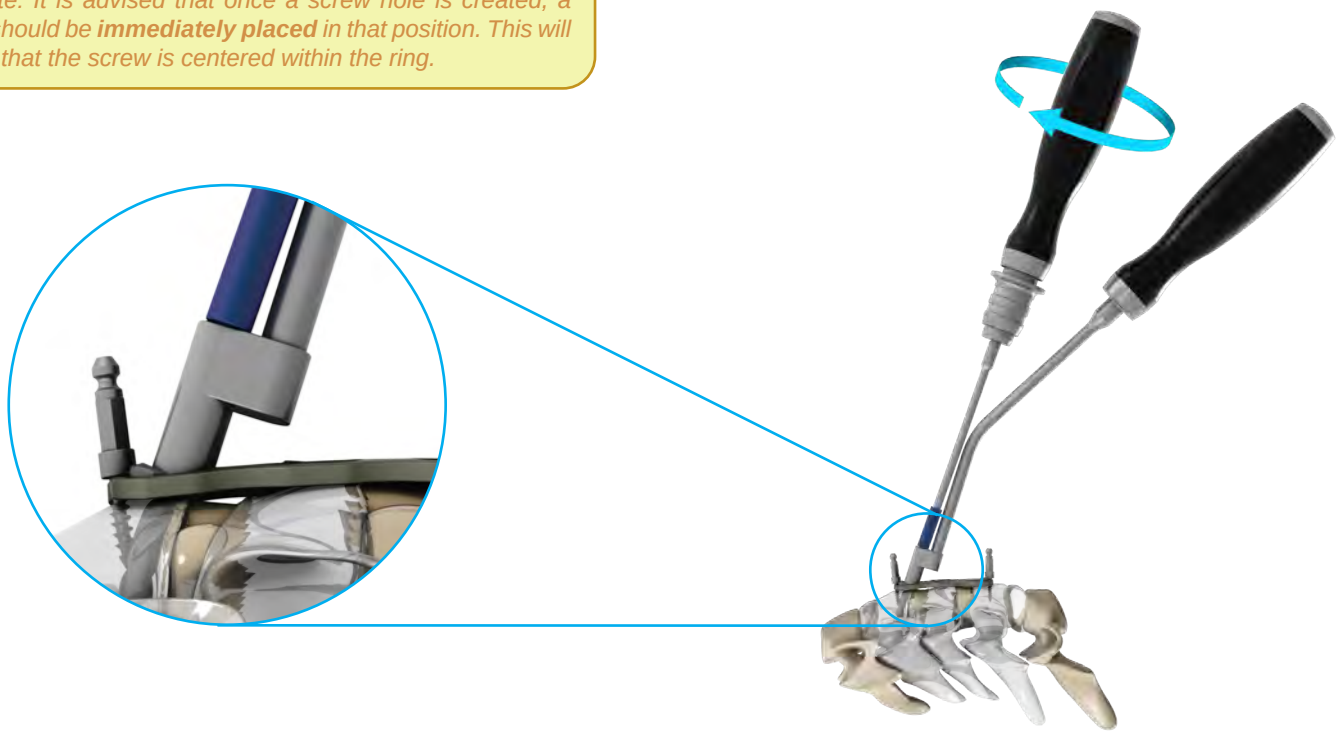
10

Select a Drill Bit with a depth that corresponds to the chosen screw length. Match the Ø4.0mm screw color to the anodized shoulder on the Drill Bit.

The Drill Bit can either be attached to a power drill or to the provided Quick Connect Handle.

Insert the drill in the Guide at the desired angle. The shoulder will stop the bit against the Guide at the set depth (12, 14, 16, or 18mm).

*Note: It is advised that once a screw hole is created, a screw should be **immediately placed** in that position. This will ensure that the screw is centered within the ring.*



Screw Implantation

11

Check screw length with the caddy screw gauge.

Firmly insert the Screwdriver tip in a screw to engage the self-retaining feature (A).

Implant the screw into the drilled hole. You will feel the screw head snapping into place in the plate ring once it reaches a certain depth. This prevents screw backout. After this, the Screw Remover is required (B).

The order of screw implantation is important. The first screw should be one of the most cephalad, the second screw should be placed diagonally from the first. The rest should be implanted in the order illustrated or symmetrically.

You may choose to partially tighten the 1st screw for ease of positioning the plate on the midline.

If the first screw was only partially tightened, make sure to fully tighten once all the other screws have been implanted. A fully locked screw may not be completely flush with the ring.

Note: Final screw tightening should be done slowly and care should be taken not to over- tighten screws. There is no stop feature within the ring and screw will continue to turn if forced. Use visual cues and tactile feedback to determine when the screw is fully seated.

Figure A.

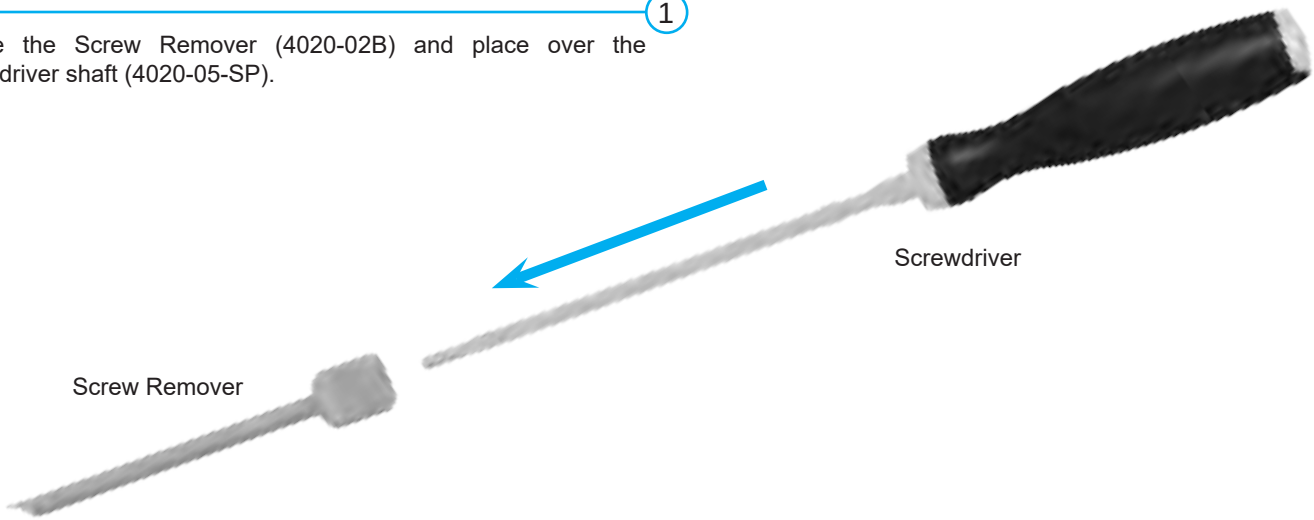
Figure B.

06a. Standard Bone Screw Removal

Assemble Instruments

1

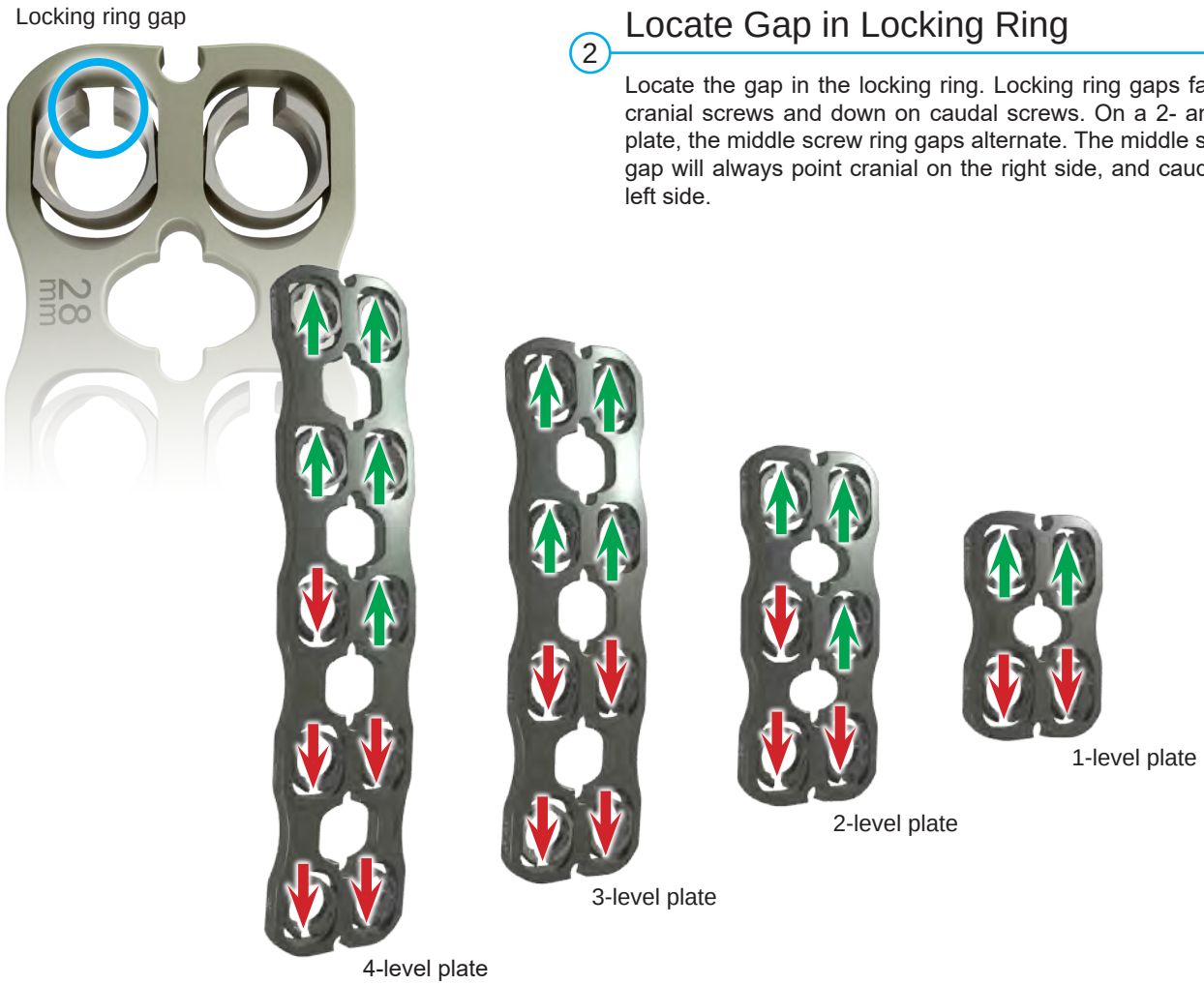
Locate the Screw Remover (4020-02B) and place over the Screwdriver shaft (4020-05-SP).



Locate Gap in Locking Ring

2

Locate the gap in the locking ring. Locking ring gaps face up on cranial screws and down on caudal screws. On a 2- and 4-level plate, the middle screw ring gaps alternate. The middle screw ring gap will always point cranial on the right side, and caudal on the left side.

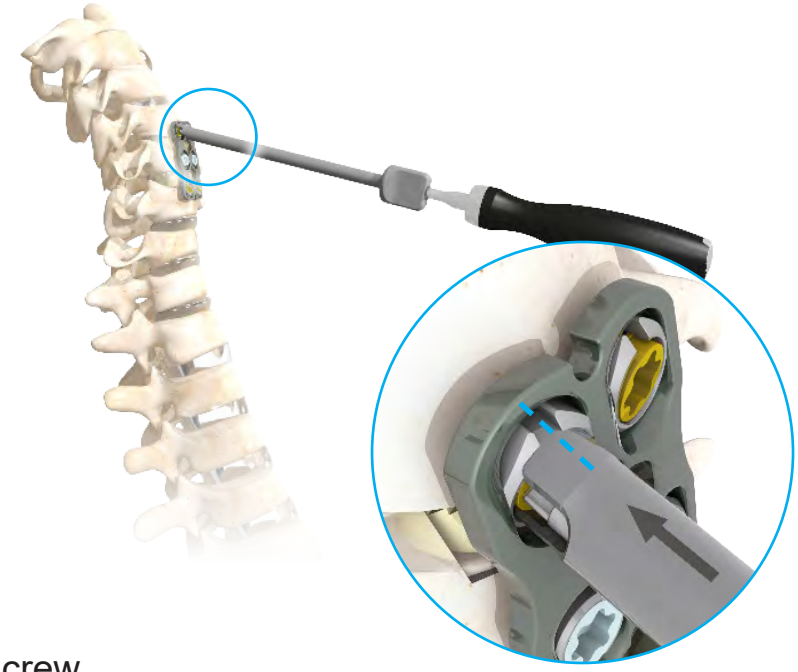


Ring Expansion Tip Indicator

Take note of the laser-etched arrow in the shaft of the Screw Remover. This arrow indicates the location of the ring expansion tip.

3 Engage Driver

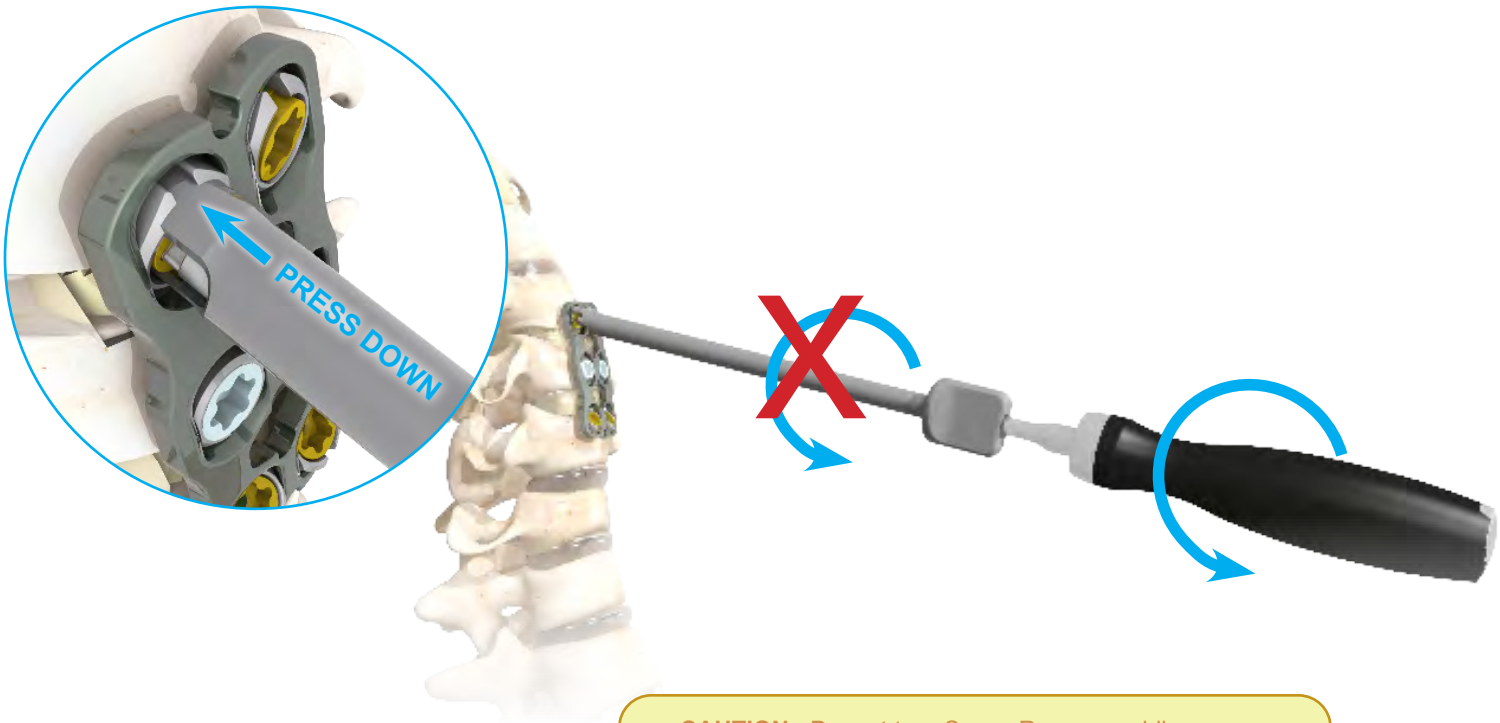
Engage the Screwdriver in the screw. Position Screw Remover so the ring expansion tip is aligned with the ring gap.



Unlock Ring, Begin Removing Screw

4

Push Screw Remover down so that ring expansion tip expands locking ring (inset). Maintain downward pressure on expansion instrument and simultaneously turn screwdriver counterclockwise. Continue turning the screwdriver counterclockwise until the screw head moves past locking ring.



CAUTION: **Do not** turn Screw Remover while turning Screwdriver.

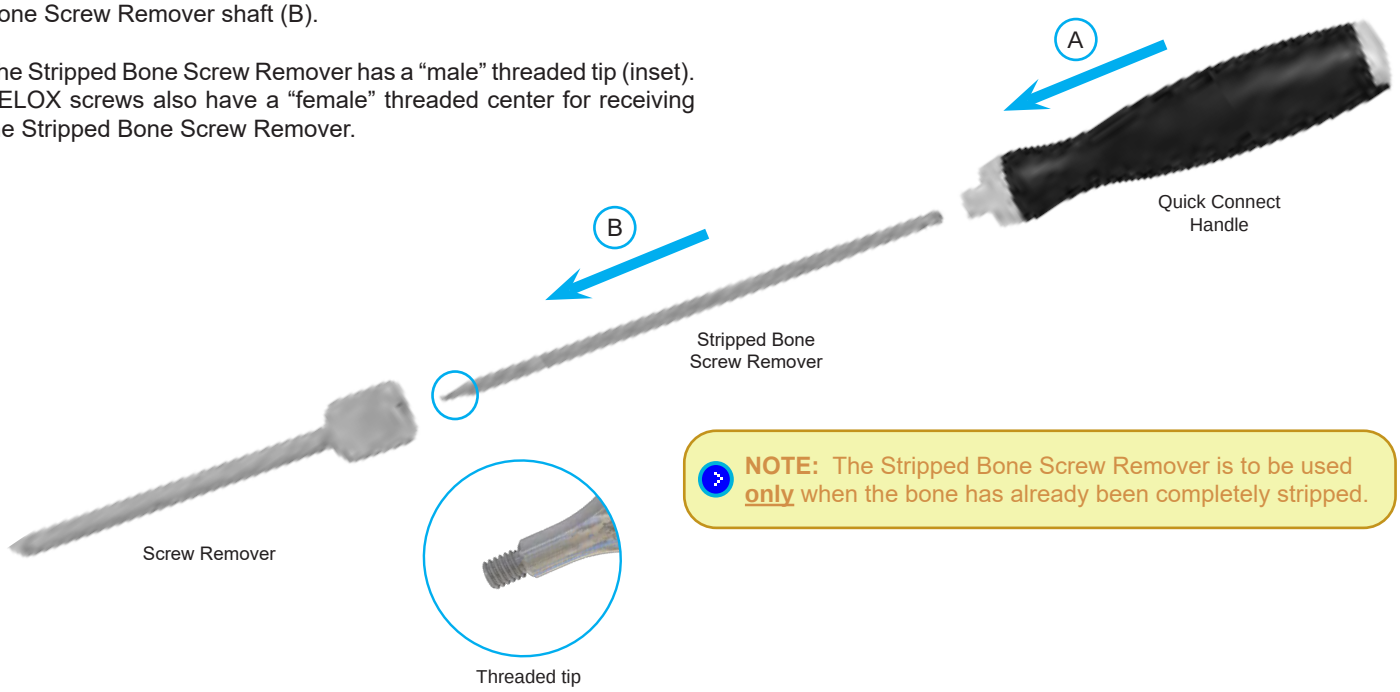
06b . Stripped Screw Removal

Assemble Instruments

1

Locate Stripped Bone Screw Remover and attach the Quick Connect Handle (A). Locate the Screw Remover and place over the Stripped Bone Screw Remover shaft (B).

The Stripped Bone Screw Remover has a “male” threaded tip (inset). VELOX screws also have a “female” threaded center for receiving the Stripped Bone Screw Remover.

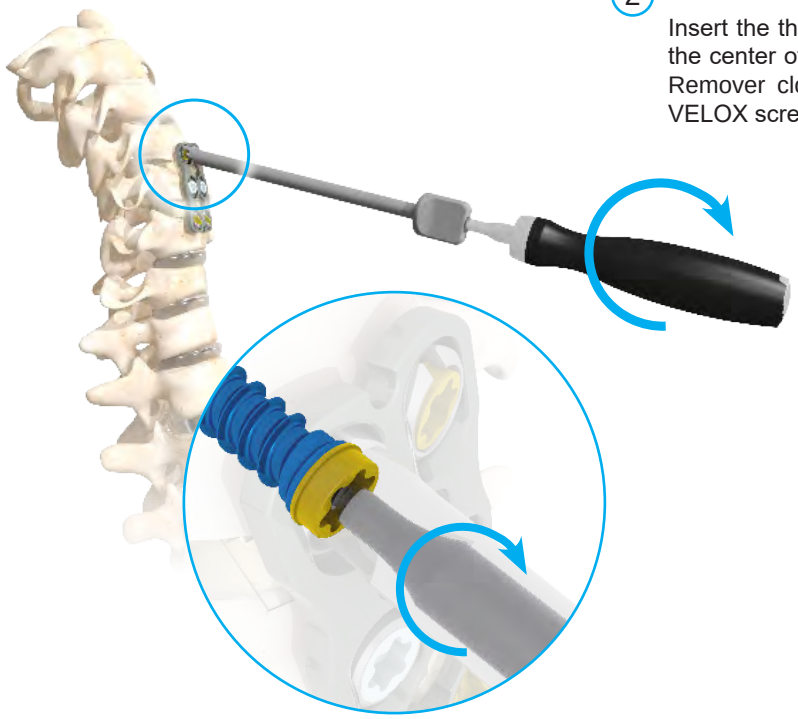


NOTE: The Stripped Bone Screw Remover is to be used **only** when the bone has already been completely stripped.

Engage Stripped Bone Screw Remover

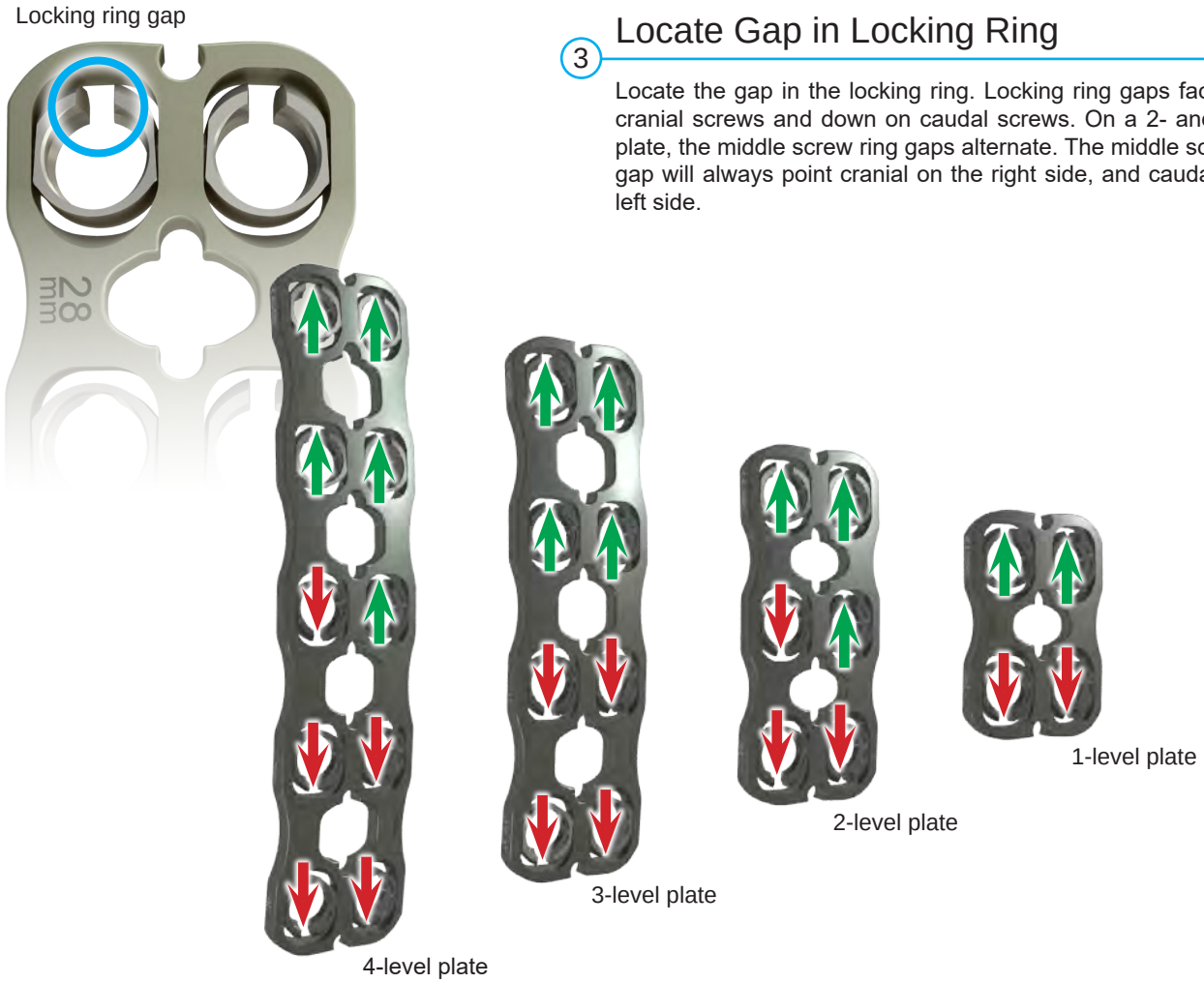
2

Insert the threaded tip of the Stripped Bone Screw Remover into the center of the VELOX screw and turn the Striped Bone Screw Remover clockwise until the threaded tip is fully seated in the VELOX screw.



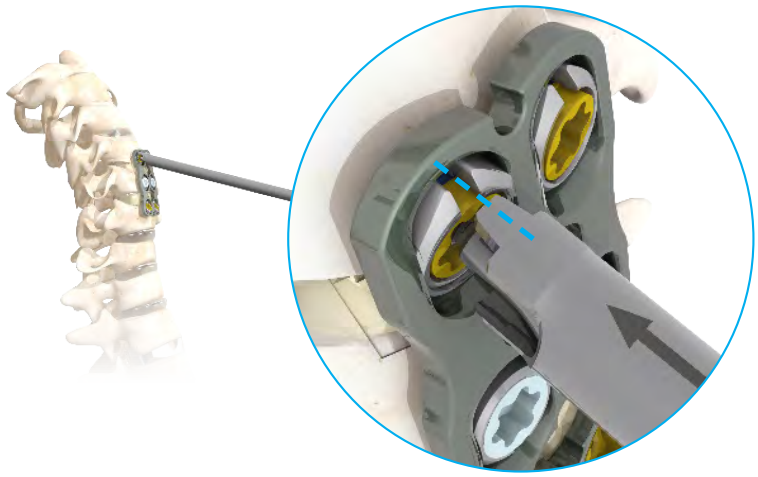
3 Locate Gap in Locking Ring

Locate the gap in the locking ring. Locking ring gaps face up on cranial screws and down on caudal screws. On a 2- and 4-level plate, the middle screw ring gaps alternate. The middle screw ring gap will always point cranial on the right side, and caudal on the left side.



4 Align Screw Remover

Position the Stripped Bone Screw Remover so that the ring expansion tip is aligned with the ring gap.



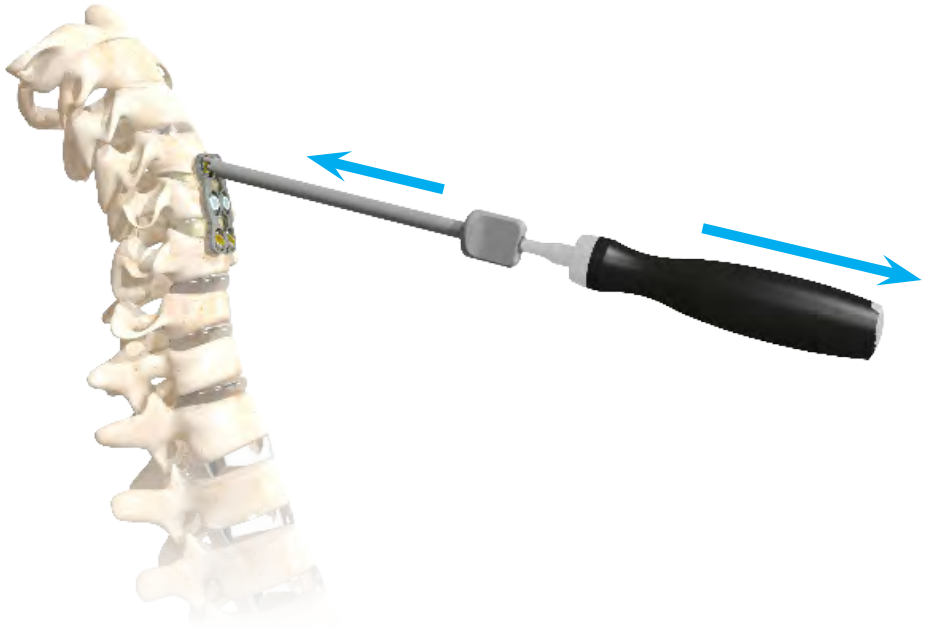
Ring Expansion Tip Indicator

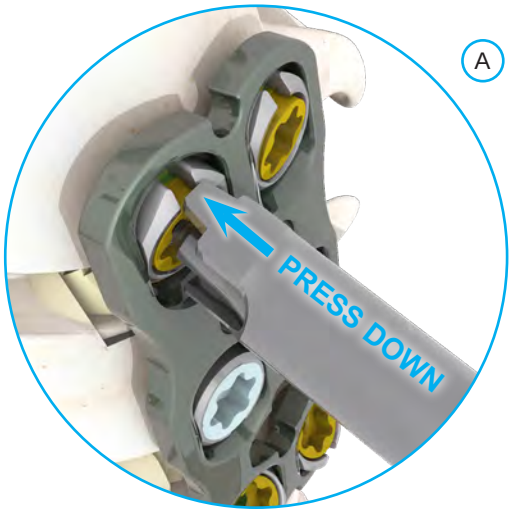
Take note of the laser-etched arrow in the shaft of the Screw Remover. This arrow indicates the location of the ring expansion tip.

Unlock Ring, Pull Out Screw

5

Push the Screw Remover down so that the ring expansion tip expands the locking ring (A). Maintain downward pressure on expansion instrument and simultaneously pull the stripped screw past the locking ring (A & B).





07. Instructions for Use

VELOX™ ANTERIOR CERVICAL PLATE SYSTEM IMPLANTS

CAUTION: USA law restricts this device to sale by or on the order of physician.

IMPORTANT NOTE TO OPERATING SURGEON

VELOX spinal implants, like any other temporary internal fixation devices, have a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking of the implant components. It is essential to instruct patients about restrictions to their activities in the postoperative period and to examine patients postoperatively to evaluate the development of the fusion mass and the status of the implant components. Even if solid bone fusion occurs, implant components may nevertheless bend, break, or loosen. Therefore, the patient must be made aware that implant components may bend, break, or loosen even though restrictions in activity are followed.

Because of the limitations imposed by anatomic considerations and modern surgical materials, metallic implants cannot be made to last indefinitely. Their purpose is to provide temporary internal support while the fusion mass is consolidating. These types of implants are more likely to fail if no bone graft is used, if a pseudo-arthrosis develops, or if patients have severe or multiple preoperative curves.

The surgeon may remove these implants after bone fusion occurs. The possibility of a second surgical procedure must be discussed with the patient, and the risks associated with a second surgical procedure must also be discussed. If the implants do break, the decision to remove them must be made by the physician who must consider the condition of the patient and the risks associated with the presence of the broken implant.

DESCRIPTION

The VELOX Anterior Cervical Plate System consists of a variety of bone plates and screws. Fixation is provided by the insertion of bone screws through the openings at each end of the plate into the vertebral bodies of the cervical spine. Associated instruments are also available to facilitate the implantation of the device.

The VELOX Anterior Cervical Plate System implant components (plate and screws) are made from titanium alloy conforming to ASTM F136 specifications. The screw retaining rings are made of CoCr28Mo6 per ASTM F1537. Do not use any of the VELOX Anterior Cervical Plate System components with the components from any other system or manufacturer.

INDICATIONS

The VELOX Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity, pseudarthrosis, failed previous fusion, spinal stenosis.

WARNING: The VELOX Anterior Cervical Plate System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

The VELOX Anterior Cervical Plate System has not been evaluated for safety and compatibility in the MR environment. The VELOX Anterior Cervical Plate System has not been tested for heating or migration in the MR environment.

STERILIZATION

Implants and instruments of the VELOX Anterior Cervical Plate System are supplied clean and not sterile. All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of VELOX instruments can be found in SpineCraft publication # RG-0032-1 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	**Pre-Vacuum**	270° F (132° C)	4 Minutes	30 Minutes

Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Or

Rigid Sterilization Container: The following Aesculap sterilization rigid container components are validated for use:

- Aesculap Extra-Long Container, Perforated Bottom, 5½ -inch (P/N JN443)
- Aesculap Extra-Long Container, Perforated Bottom, 8-inch (P/N JN445)
- Aesculap Extra-Long Container, Lid with Retention Plates (P/N JK490)
- Aesculap Single use 7 ½" diameter filter with indicator dot (P/N US751)
- Aesculap Single use 7 ½" diameter filter (P/N US994)

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Any medical or surgical condition, which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion or where fracture healing is not required.
11. Any case requiring the mixing of metals from different components.
12. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
13. Any case not described in the Indications.
14. Any patient unwilling to cooperate with the post-operative instructions.
15. Any time implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any condition not described in the Indications for Use.

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 minimize 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, accelerates 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 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 labor, 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.

B. 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.

C. 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.

D. 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.

E. Smoking. Patients who smoke have been observed to experience higher rates of pseudo-arthrosis 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 reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

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 localized 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 hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage 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.

6. IMPLANTS FATIGUE. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

7. PREVIOUS SPINAL SURGERY. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

POSSIBLE ADVERSE EFFECTS

1. Bending or fracture of implant.
2. Loosening of the implant.
3. Metal sensitivity, or allergic reaction to a foreign body.
4. Infection, early or late.
5. Nonunion, delayed union.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paraesthesia.
9. Bursitis.
10. Paralysis.
11. Dural tears experienced during surgery could result in the need for further surgery for dural repair, a chronic CSF leak or fistula, and possible meningitis.
12. Death.
13. Vascular damage due to surgical trauma or presence of the device. Vascular damage could result in catastrophic or fatal bleeding. Malpositioned implants adjacent to large arteries or veins could erode these vessels and cause catastrophic bleeding in the late postoperative period.
14. Screw back out, possibly leading to implant loosening, and/or reoperation for device removal.
15. Damage to lymphatic vessels and/or lymphatic fluid exudation.
16. Spinal cord impingement or damage.
17. Fracture of bony structures.
18. Degenerative changes or instability in segments adjacent to fused vertebral levels.

LIMITED WARRANTY AND DISCLAIMER: THE VELOX ANTERIOR CERVICAL PLATE SYSTEM PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at: +1 630-920-7300.

SURGICAL TECHNIQUE MANUAL CAN BE OBTAINED BY CONTACTING SPINECRAFT CUSTOMER SERVICE at +1 630-920-7300. ALSO, IT COULD BE DOWNLOADED DIRECTLY FROM THE COMPANY WEBSITE USING THE SURGEON LOG-IN.

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