



Technique Guide



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NUVASIVE HELIX ACP SYSTEM OVERVIEW

NuVasive Helix ACP

- NuVasive Helix ACP plate has a 2.4mm profile to reduce the chance of postoperative discomfort.
- 5-Level plates available via special order.
- Fixed and Variable Angle Bone Screws for the perfect construct type, depending on patient needs.
- Variable Angle Bone Screws feature a 20° cone-of-angulation to accommodate surgeon needs.



UNLOCKED

Ledge of bone screw is visible, and head of screw is proud to plate surface.



LOCKED

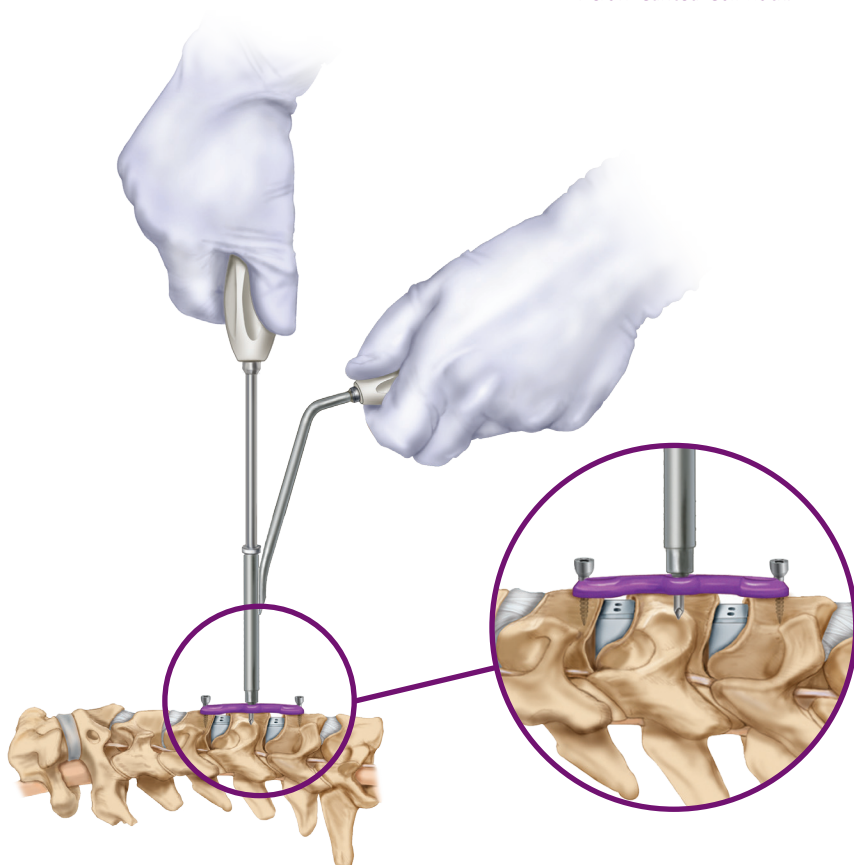
Ledge of bone screw is completely covered, and head of screw is seated below Canted Coil Lock.

Canted Coil Lock (CCL)

- Canted Coil Lock consistently and securely blocks bone screws into the plate while still allowing the plate to be securely lagged to bone for a tight fit.
- Bone screws can be removed and repositioned easily while maintaining CCL integrity.
- Aggressive bone screws in a full complement of lengths and diameters accommodate a variety of surgical scenarios.

Balanced and Intuitive Instrumentation

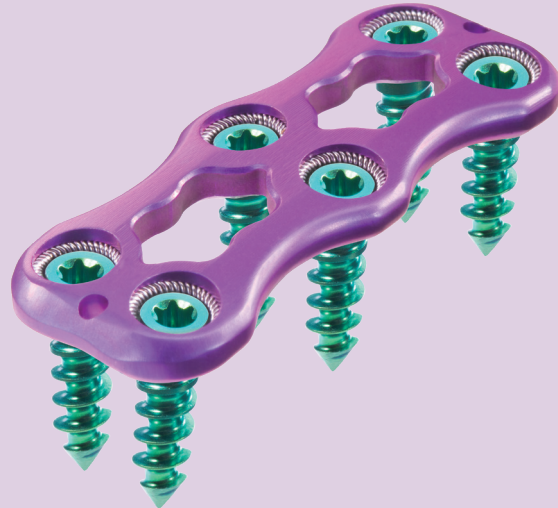
- DTS Guides allow pre-drilling, tapping, and bone screw placement without changing insertion angle.



NUVASIVE HELIX ACP SYSTEM OVERVIEW

Low-Profile Leading Edge

- Plate sits flush against anterior cervical spine.
- Decreased “step” on leading edge of plate to reduce esophageal discomfort postoperatively.
 - 1mm leading profile.



Narrow Plate Reduces Retraction During Placement

- Reduced retraction for easy placement.
- Less than 16mm at widest point.



Intraoperative Visualization

- Large portals allow for graft placement verification.



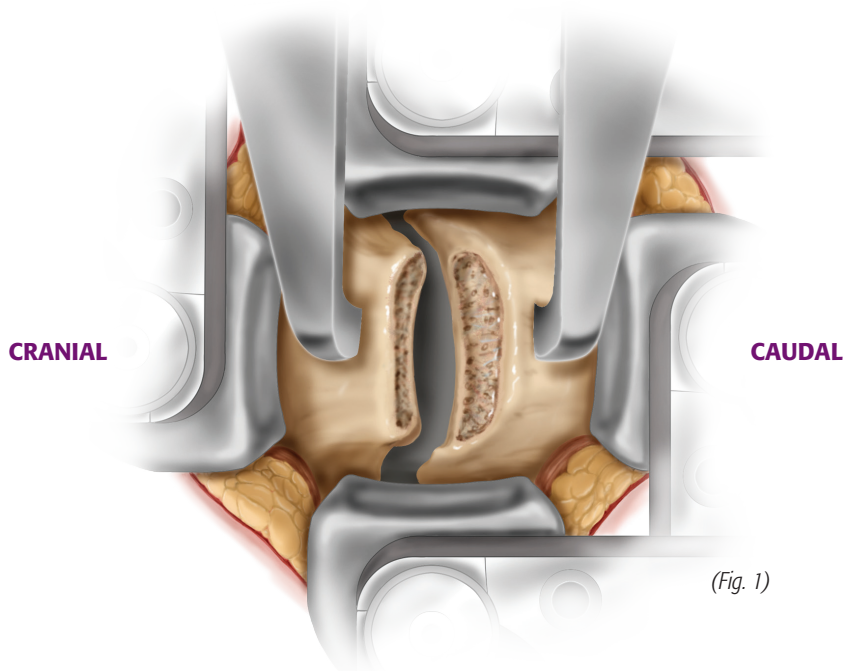
NUVASIVE HELIX ACP TECHNIQUE GUIDE

For a complete list of intended uses, indications, device description, contraindications, warnings, and precautions, please refer to the Instructions for Use (IFU) in the back of this technique guide.

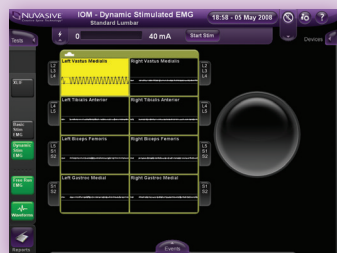
STEP 1:

DISCECTOMY AND DECOMPRESSION

A Place the patient's neck in a supine position, chin extended on the operating table. Carry out the anterior approach to the appropriate levels of the cervical spine in the usual manner. The technique must allow for direct anterior access to the disc and adjacent vertebral bodies. Apply a standard vertebral body distractor to the adjacent vertebrae in the usual manner (Fig. 1).

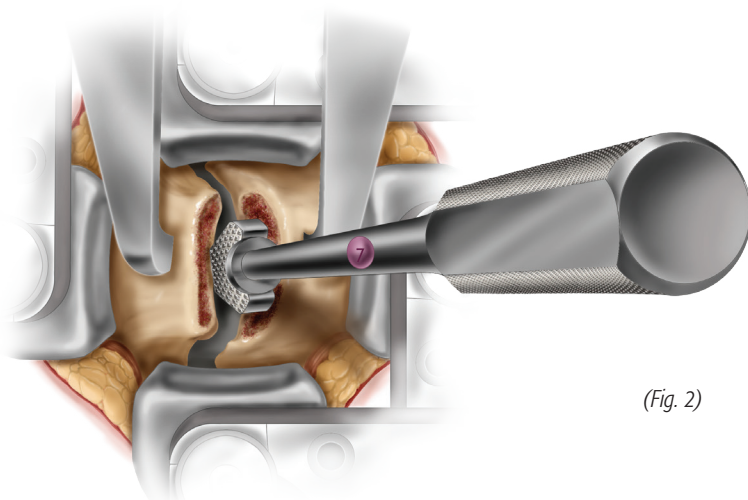


(Fig. 1)



The NVM5 system has proven useful when used in Free Run Mode to monitor for any spontaneous neurological activity during discectomy, decompression, interbody placement, and bone screw placement. Refer to the NVM5 Reference Guide for further information on the utility of this system in the cervical spine.

B Perform a complete discectomy and decompression. After thorough removal of the disc material, remove the cartilaginous endplates with standard curettes, drill, or rasps (Fig. 2).



(Fig. 2)

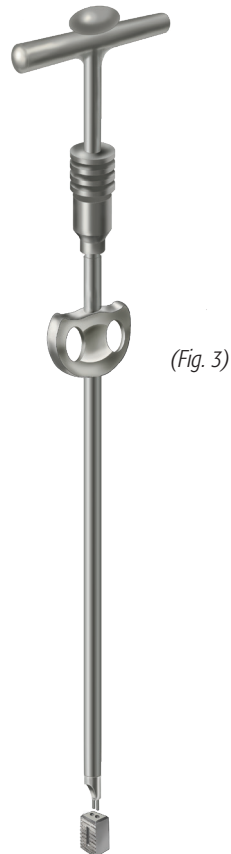
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STEP 2: INTERBODY PLACEMENT (2-LEVEL)

A Place interbody graft into the evacuated disc spaces
(Figs. 3, 4).



For best results, use
saline-packaged Triad
Cervical Allograft.



(Fig. 3)



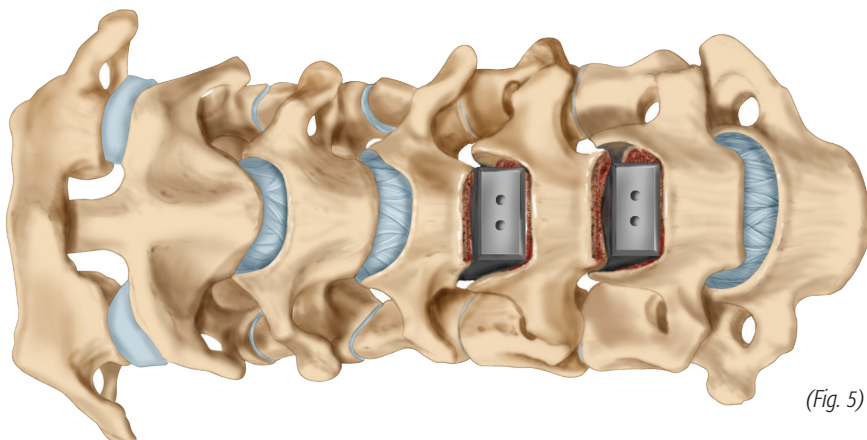
(Fig. 4)

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STEP 2: INTERBODY PLACEMENT (2-LEVEL) (CONT.)

Surface Preparation

The surface of the vertebral body may require some preparation (commonly called gardening) in order for the plate to fit flush to the spine (*Figs. 5, 6*).



(Fig. 5)



(Fig. 6)

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STEP 3: PLATE PLACEMENT

Proper Plate Sizing

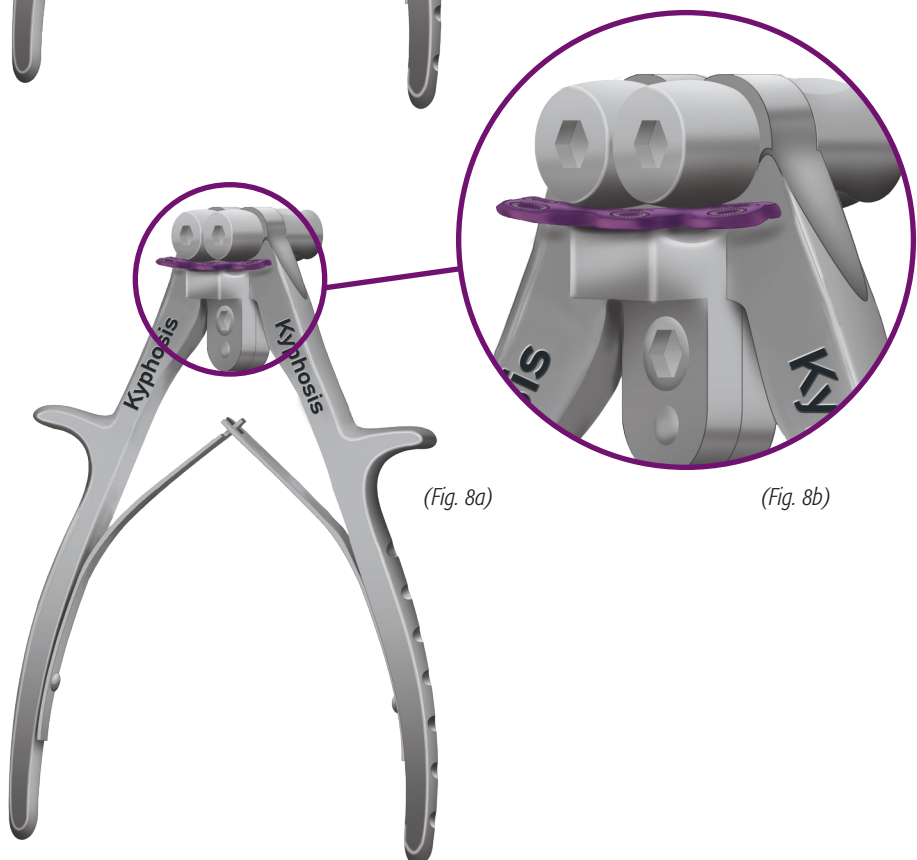
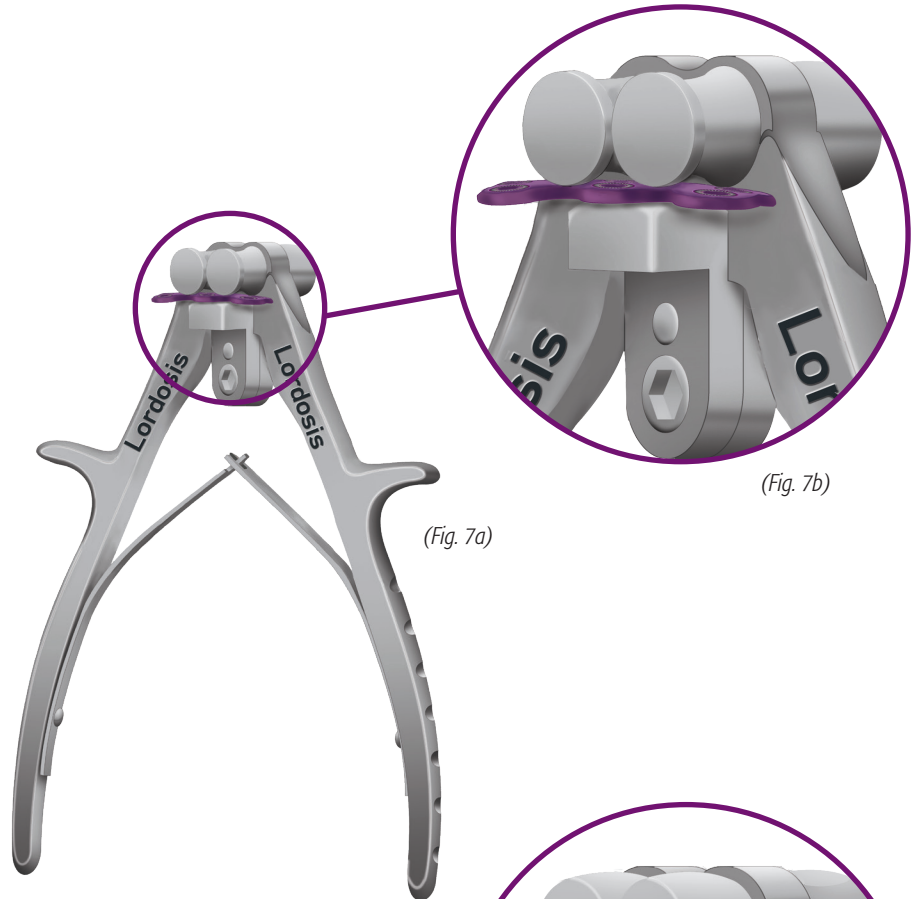
Select the proper length NuVasive Helix ACP such that the bone screw holes are positioned over the inferior-most portion of the cranial vertebral body and the superior-most portion of the caudal vertebral body.

Plate Bending (optional)

The plate may be bent into either further lordosis or into kyphosis in order to accommodate patient pathology.

Plate bending: To bend the plate into further lordosis, ensure that the plate bender is aligned properly with "LORDOSIS" laser mark facing the user. The plate should be bent in the bend zones between the bone screw holes (Fig. 7a, 7b).

To bend the plate into further kyphosis, reverse the plate bender so that the "KYPHOSIS" laser mark faces the user (Fig. 8a, 8b).

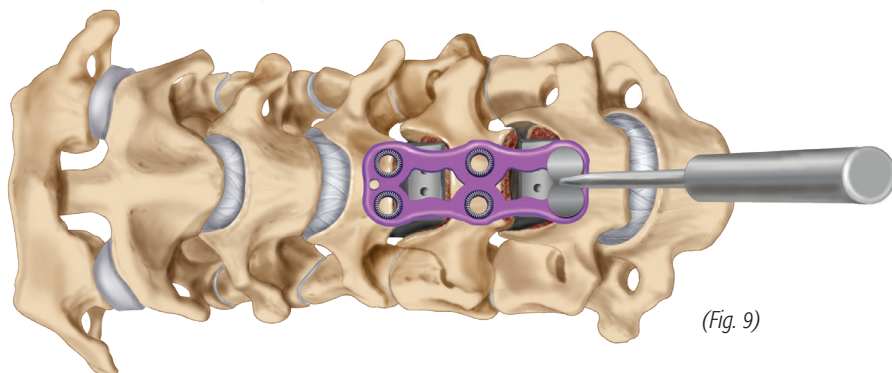


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**STEP 3:
PLATE PLACEMENT (CONT.)****Plate Holder**

The plate holder may be used to place the plate. The plate holder may be used to hold the plate in place during freehand bone screw placement, or prior to temporary tack placement (*Figs. 9, 10*).

To disengage the plate holder, rock the instrument to one side until it disengages from the plate.



(Fig. 9)

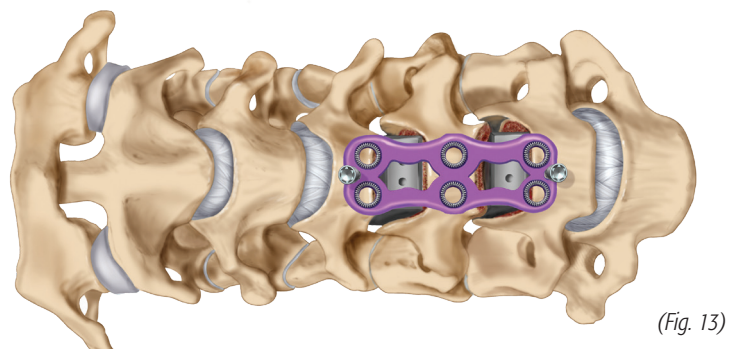
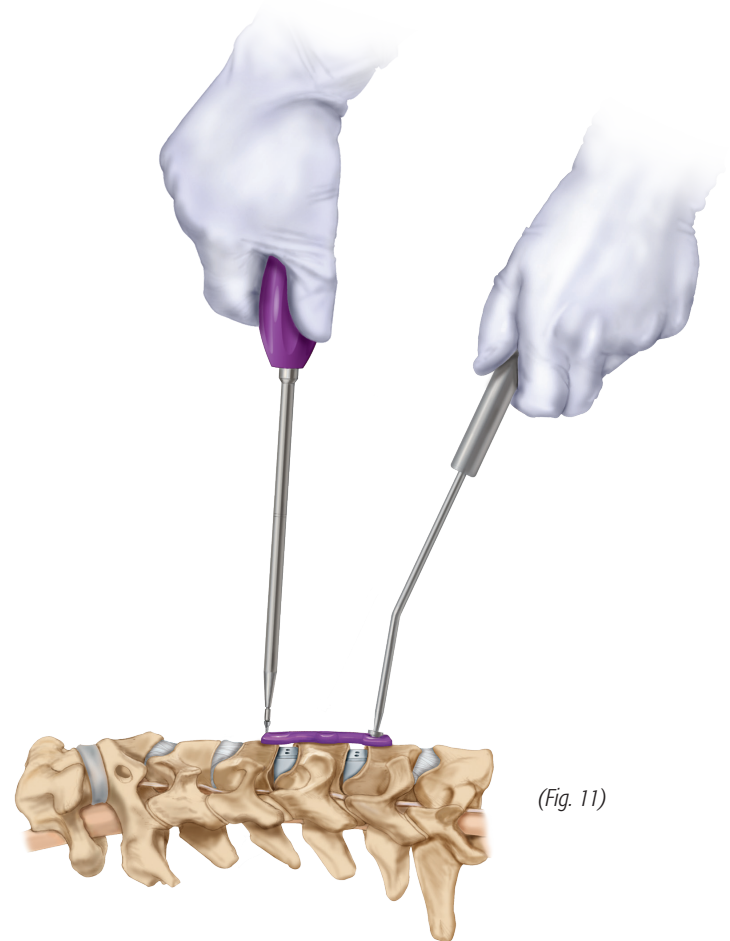


(Fig. 10)

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STEP 4: TEMPORARY TACK PLACEMENT (OPTIONAL)

Using the bone screw driver, the temporary tacks may be placed at the cranial and/or caudal end of the plate. Driving the tack into bone in the same manner that you would a bone screw will allow for secure purchase in host bone as well as allow for easy removal (*Figs. 11-13*).



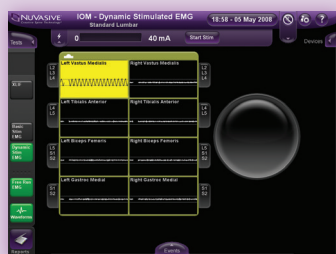
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**STEP 5:
BONE SCREW PLACEMENT****Fixed or Variable Angle Awl**

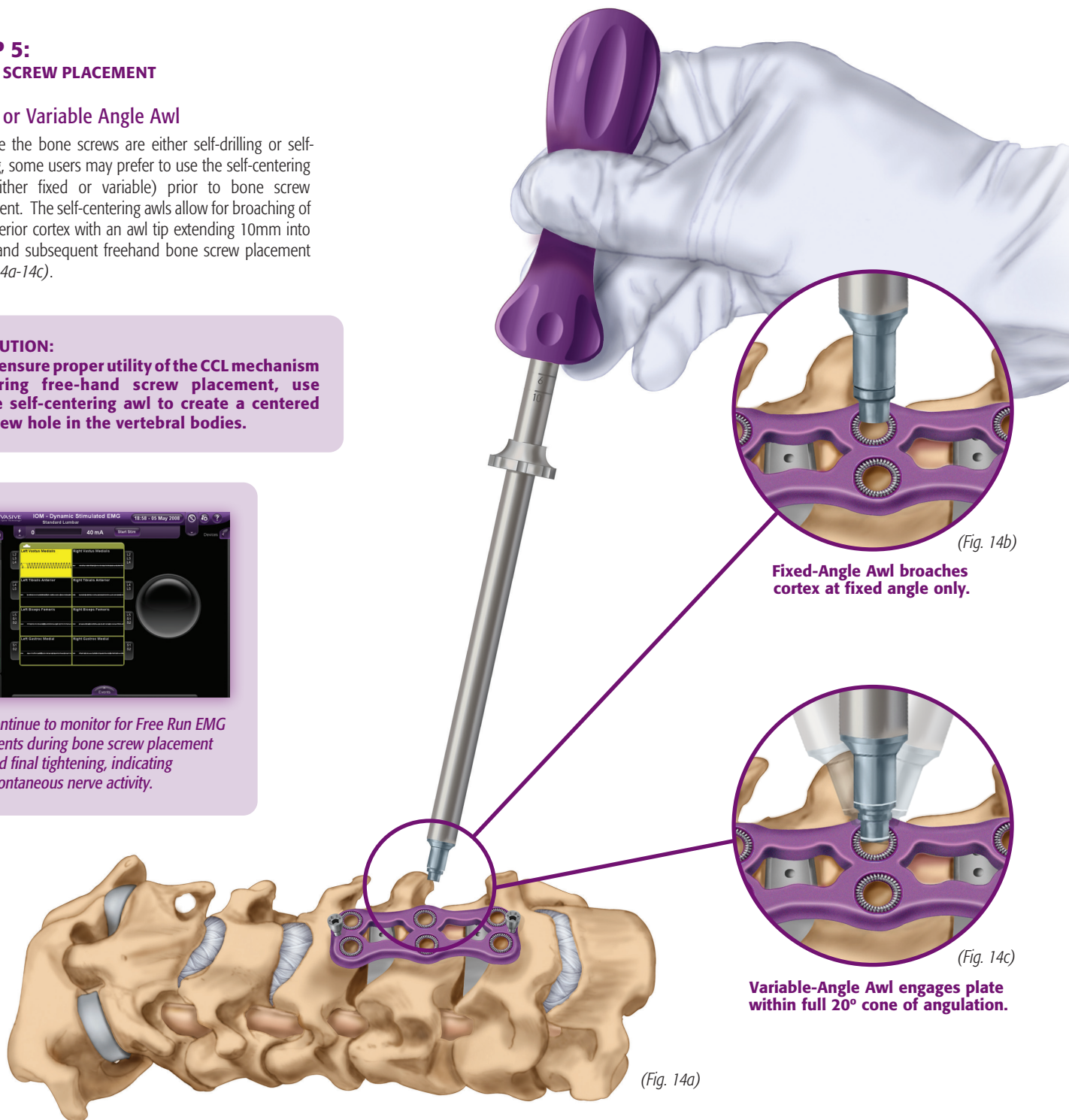
Because the bone screws are either self-drilling or self-tapping, some users may prefer to use the self-centering awl (either fixed or variable) prior to bone screw placement. The self-centering awls allow for broaching of the anterior cortex with an awl tip extending 10mm into bone, and subsequent freehand bone screw placement (Figs. 14a-14c).

CAUTION:

To ensure proper utility of the CCL mechanism during free-hand screw placement, use the self-centering awl to create a centered screw hole in the vertebral bodies.



Continue to monitor for Free Run EMG events during bone screw placement and final tightening, indicating spontaneous nerve activity.



(Fig. 14b)

Fixed-Angle Awl broaches cortex at fixed angle only.

(Fig. 14c)

Variable-Angle Awl engages plate within full 20° cone of angulation.

(Fig. 14a)

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STEP 5: BONE SCREW PLACEMENT (CONT.)

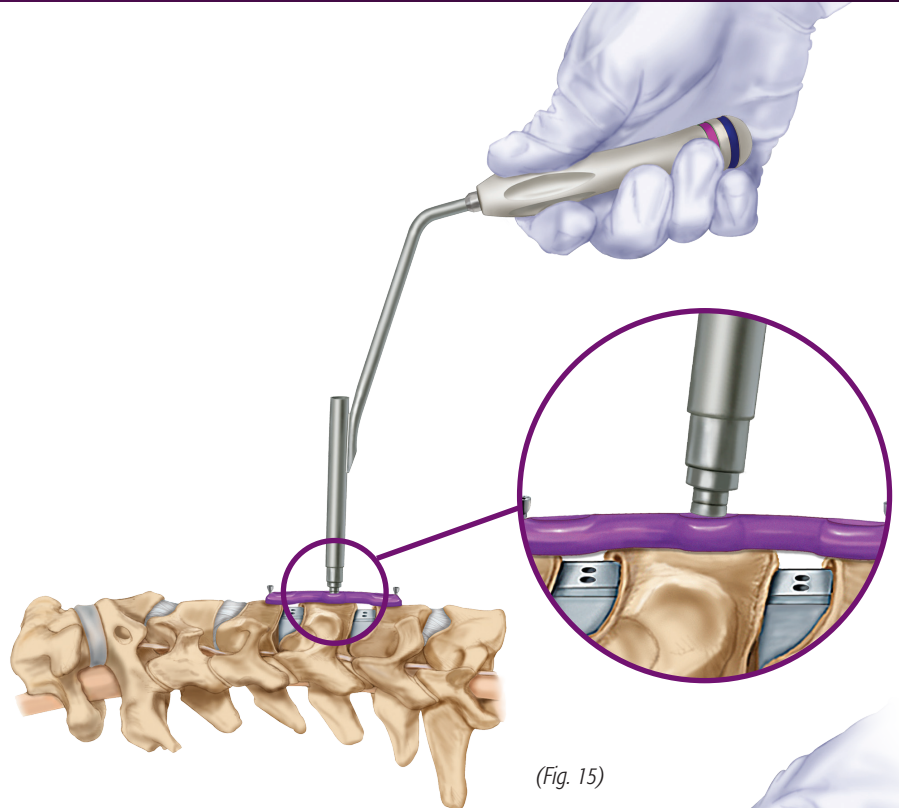
Fixed or Variable Angle Drill Guide

Pre-drilling of the host bone may be performed with either a fixed or variable angle drill guide. The fixed angle guide prepared the bone for 7° insertion trajectory at the cranial and caudal ends of the plate and 0° at all intermediate levels. The variable angle guide will prepare angle trajectories of -3° to +17° cranial or caudal, for a 20° cone of angulation (*Fig. 15*).

Fixed Angle

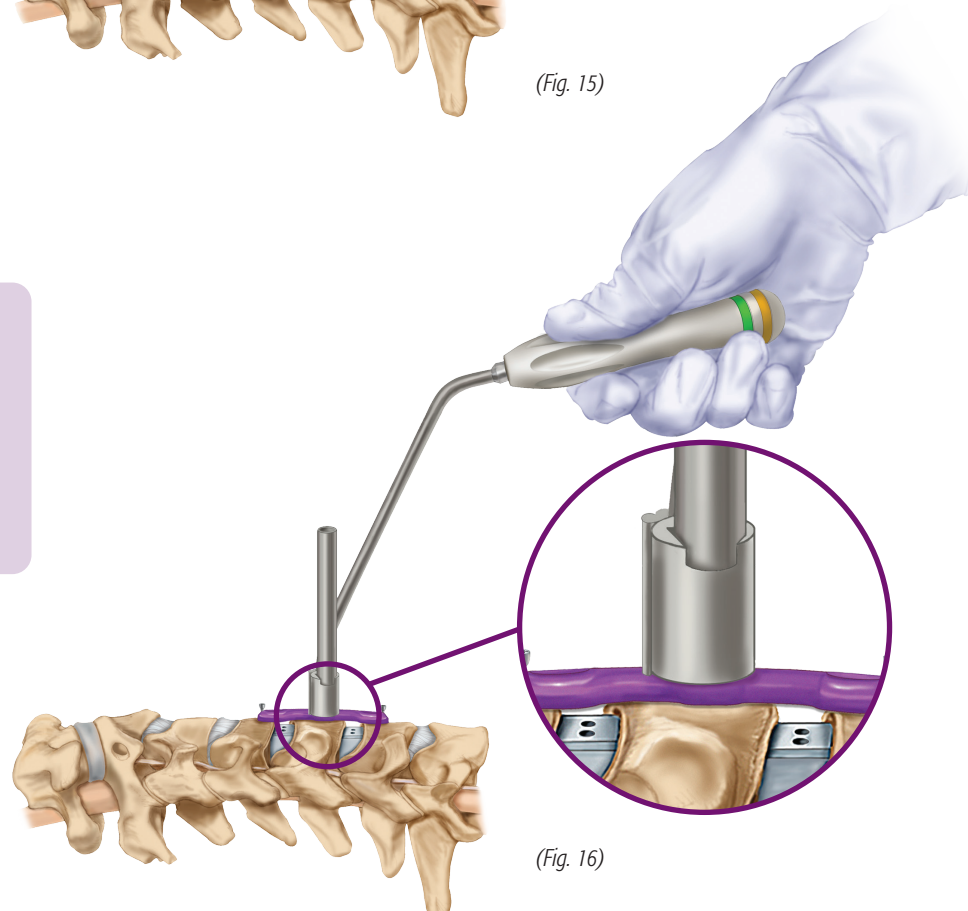


Variable Angle



DTS GUIDE USAGE:

In addition, the DTS guides may be used at both the cranial and caudal ends of the construct (7° DTS Guide), or at intermediate levels (0° DTS Guide). The DTS Guides engage securely onto the plate and allow centered awl placement, pre-drilling, pre-tapping, and finally, bone screw placement – all without removal of the guide instrument (*Fig. 16*).



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**STEP 5:
BONE SCREW PLACEMENT (CONT.)****Drill Guide Awl**

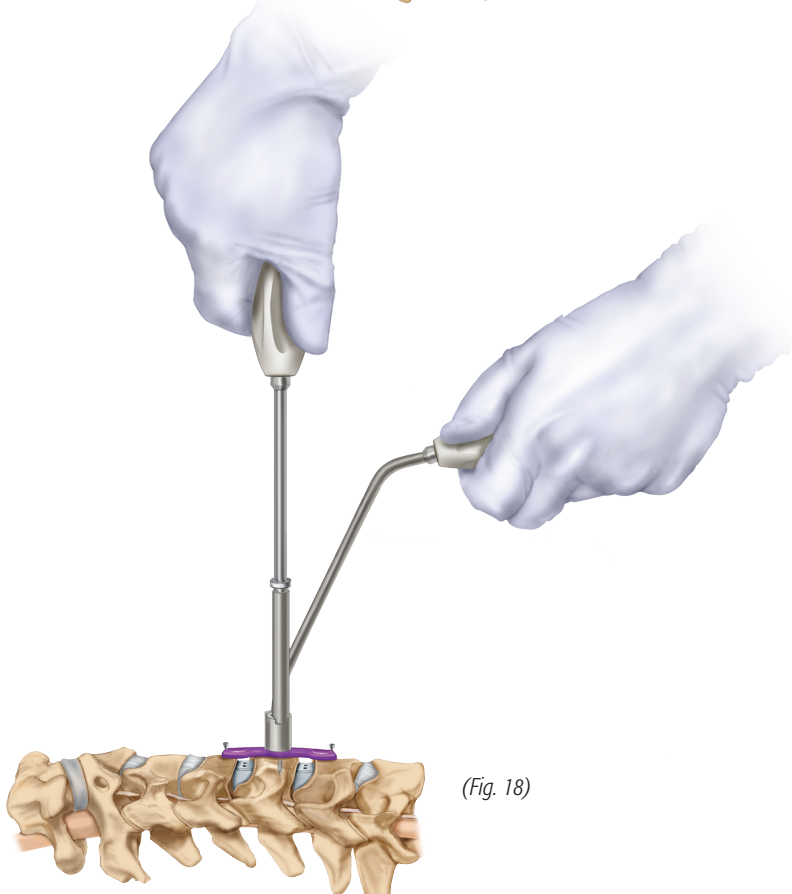
Once the guide is placed, use the awl to broach the cortex and allow easy bone screw placement in hard bone. The Drill Guide Awl must be used in conjunction with a Guide (Fixed, Variable, or DTS) (*Figs. 17, 18*).

CAUTION:

Do not use Drill Guide Awl without a drill guide or DTS Guide. For freehand bone screw insertion where an awl is desired, use of the Self-Centering Awl is required at all times.



(Fig. 17)



(Fig. 18)

NUVASIVE HELIX ACP TECHNIQUE GUIDE

STEP 5: BONE SCREW PLACEMENT (CONT.)

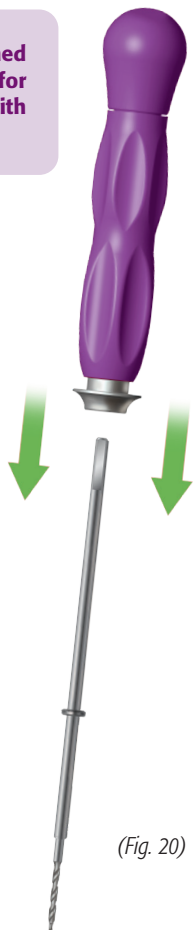
13mm Sterile Drill Bit (optional)

The 13mm drill bit can be used with the Universal Handle if hand drilling is preferred. If power is preferred, the drill bit may be used with the power drill for even more efficient pre-drilling. The drill bit measures 13mm in bone when fully seated through the Fixed, Variable, or DTS Guides. The drill bit comes sterile packaged and is single use only (*Figs. 19-21*).

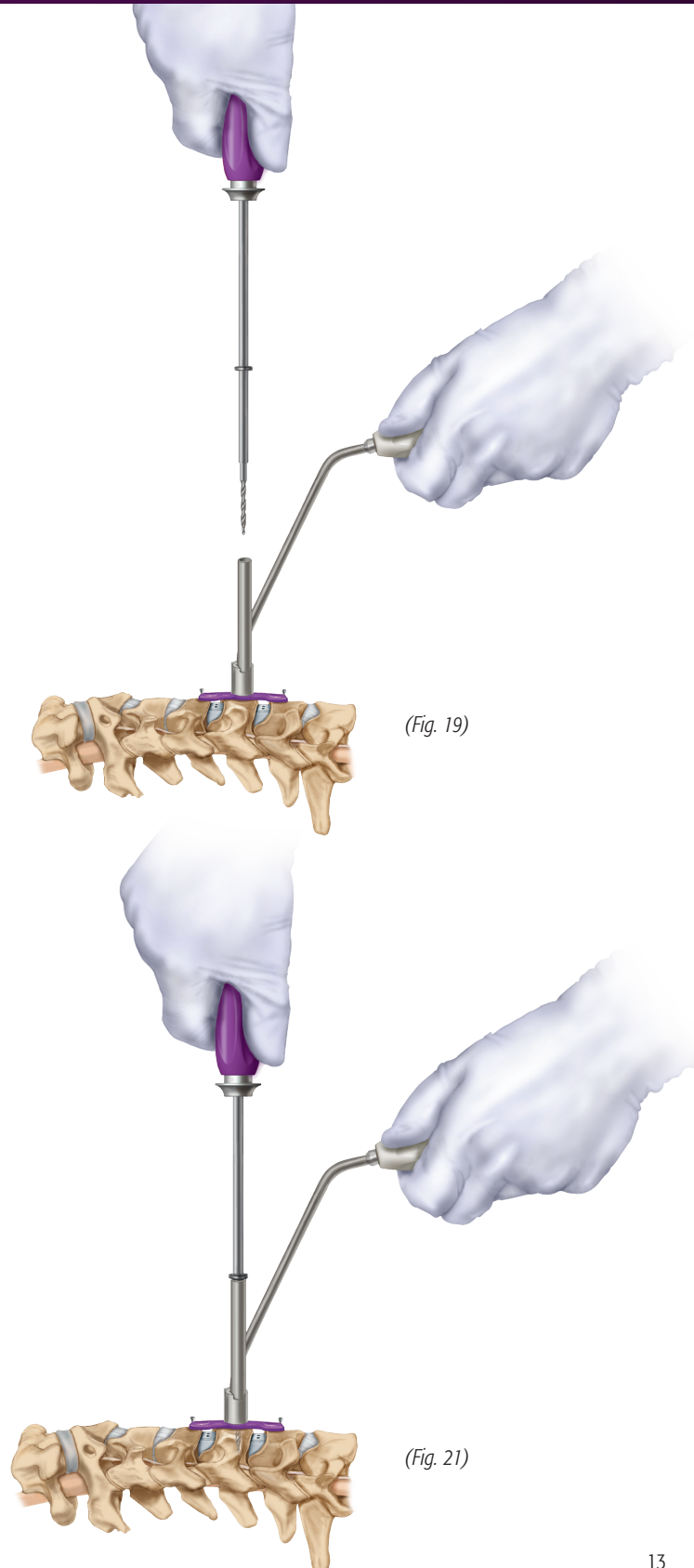
Tap Bit (optional)

(Not illustrated) In order to maximize purchase in hard cortical bone the tap may be used through the DTS Guides.

Drill Bit may be attached to the Universal Handle for hand drilling or used with a power drill.



(Fig. 20)



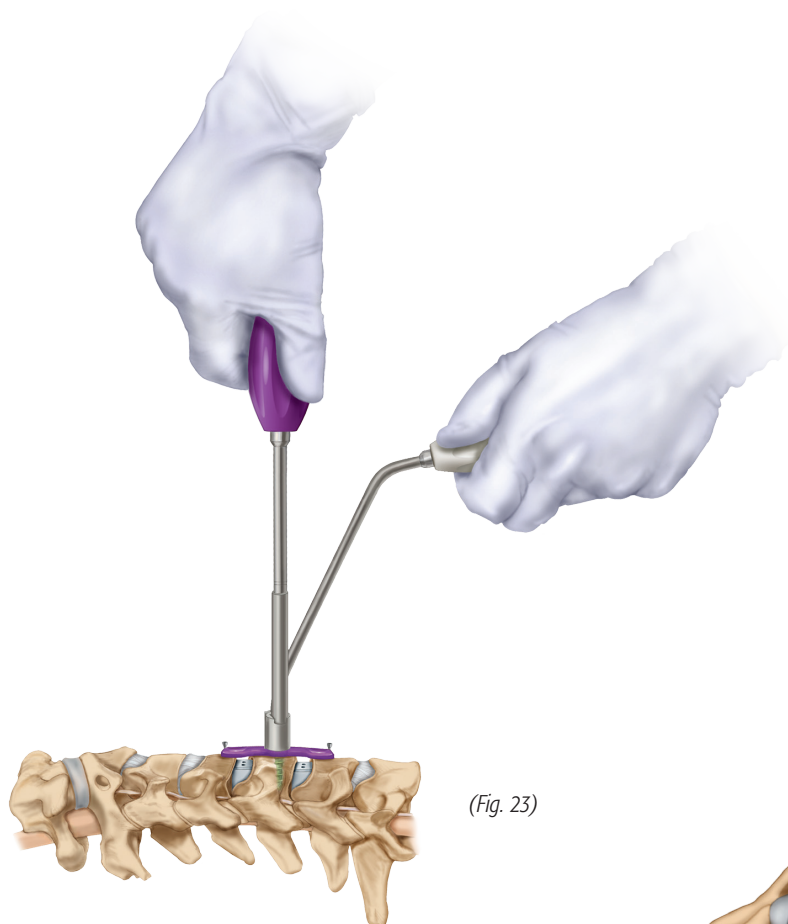
(Fig. 19)

(Fig. 21)

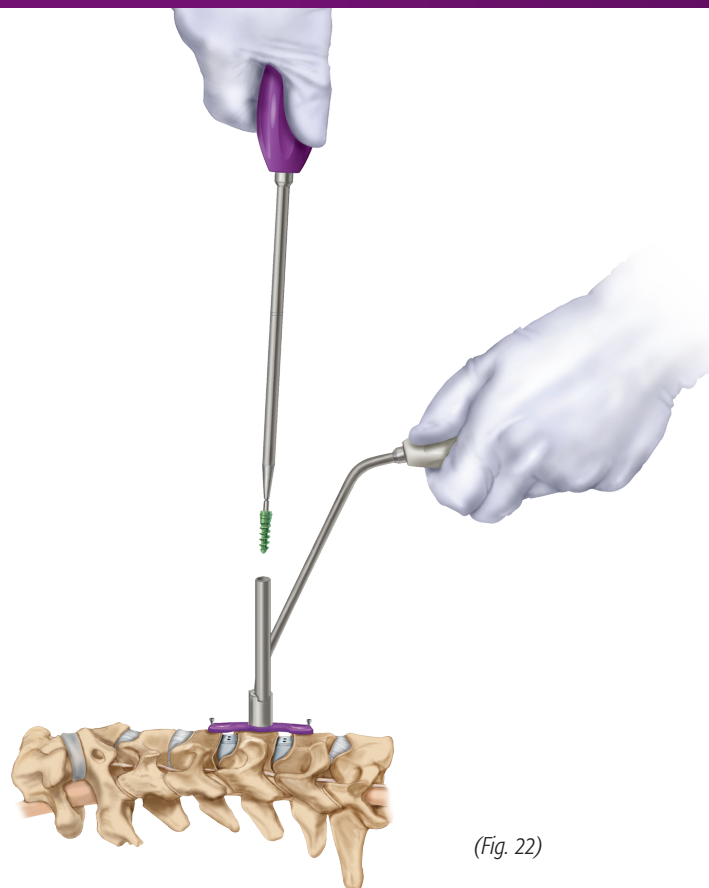
NUVASIVE HELIX ACP TECHNIQUE GUIDE

**STEP 6:
FINAL BONE SCREW TIGHTENING**

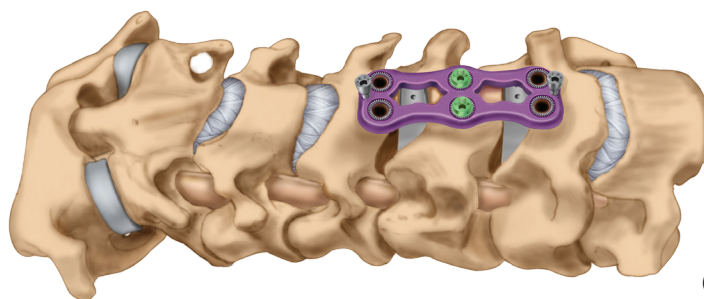
If inserting bone screws in a two-level construct, it is recommended that bone screws be placed at the intermediate levels first. Tighten bone screws to 75% and insert subsequent bone screws. Leave all bone screws slightly proud until final tightening (*Figs. 22-24*).



(Fig. 23)



(Fig. 22)

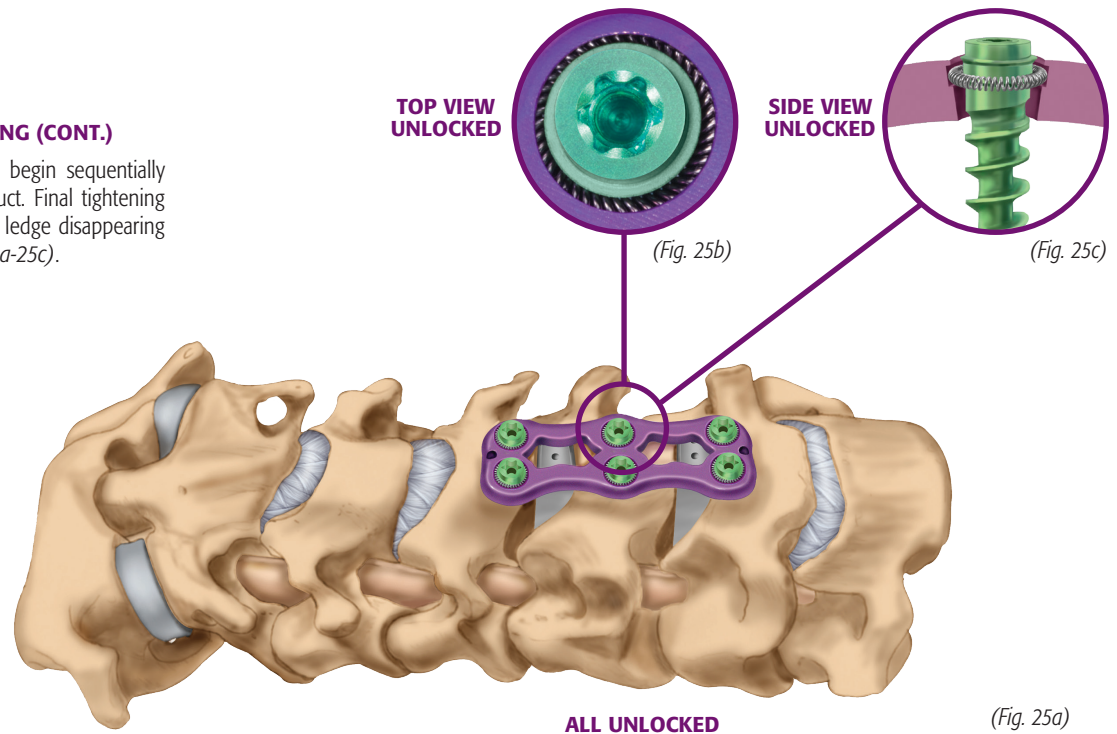


(Fig. 24)

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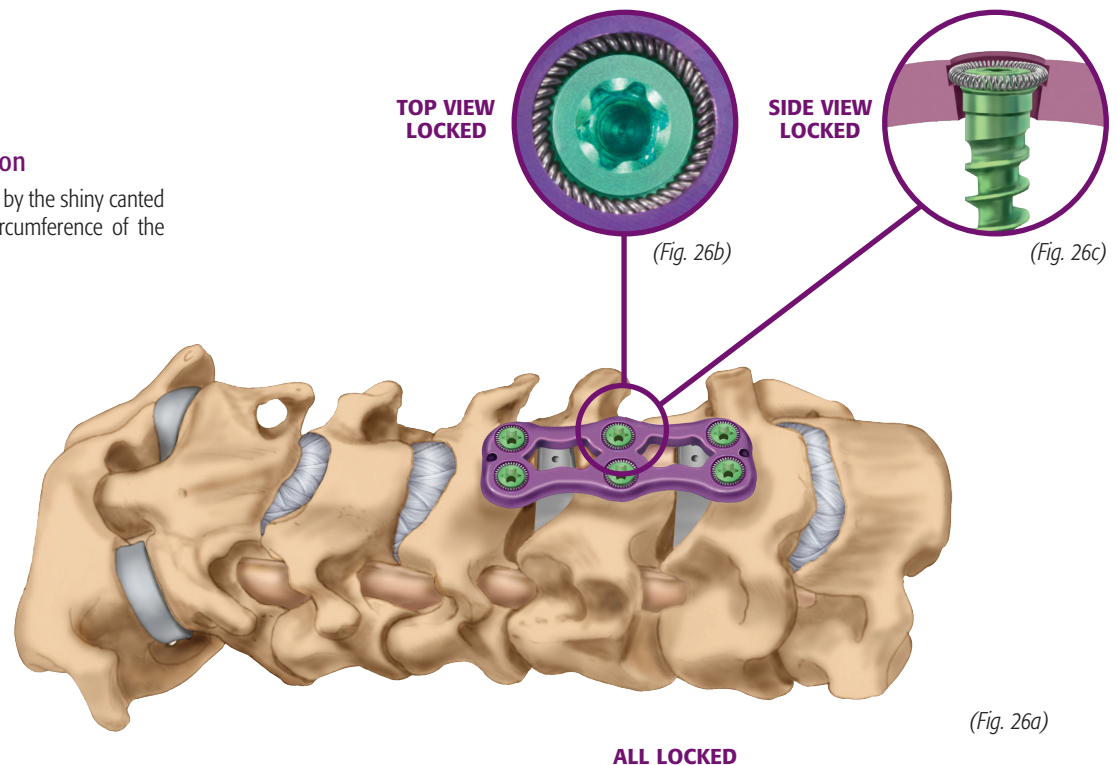
STEP 6: FINAL BONE SCREW TIGHTENING (CONT.)

Once all bone screws are inserted, begin sequentially tightening each screw in the construct. Final tightening will be indicated by the bone screw ledge disappearing below the Canted Coil Lock (Figs. 25a-25c).



Canted Coil Lock Confirmation

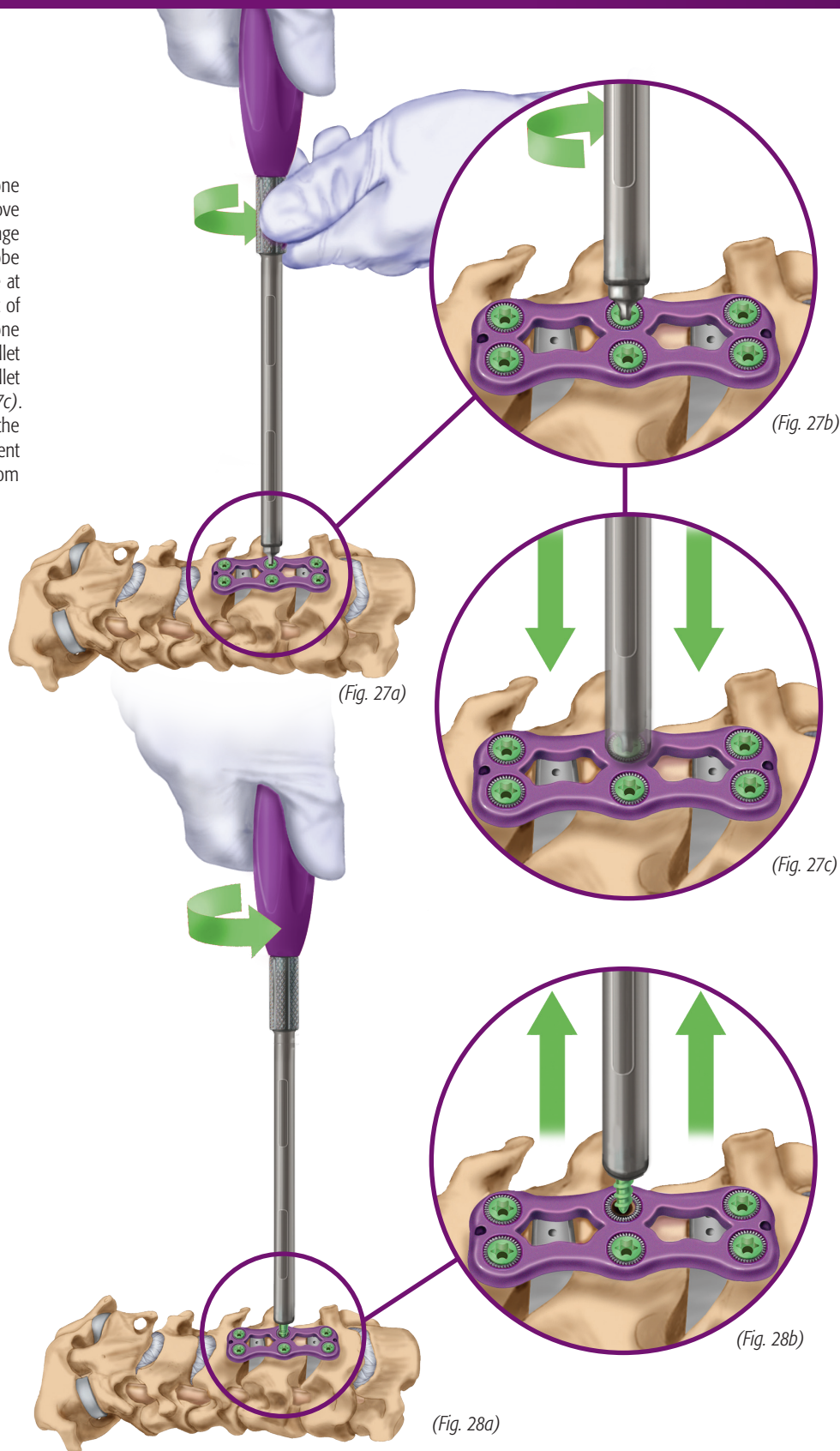
Confirmation of final lock is indicated by the shiny canted coil being visible around the full circumference of the screw ledge (Figs. 26a-26c).



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**STEP 7:
SCREW EXTRACTION (OPTIONAL)**

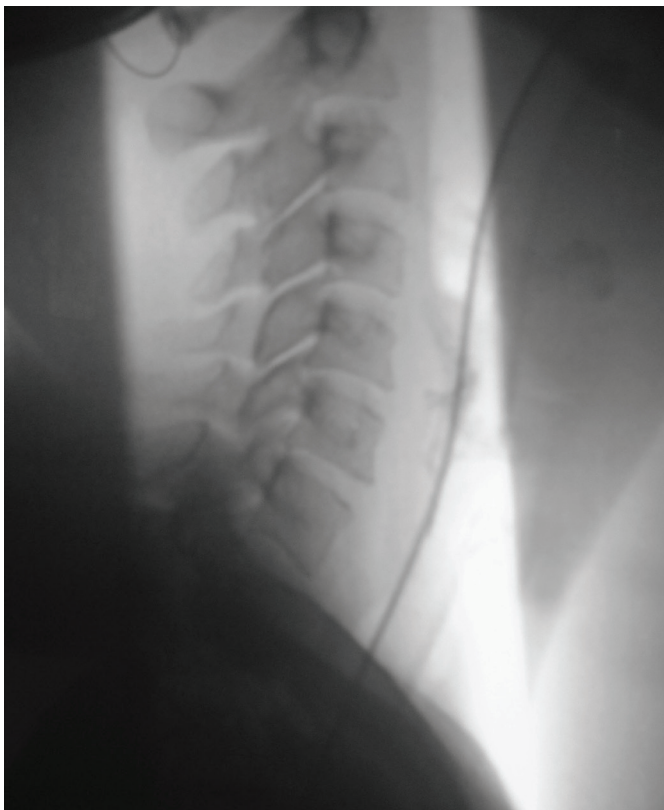
If repositioning of the bone screw is needed, the Bone Screw Extractor may be used to reengage and remove the bone screw. To use the Bone Screw Extractor, engage the male Hexalobe of the driver into the female Hexalobe of the Bone Screw. Using the knurled spindle handle at the proximal tip of the handle, tighten the inner shaft of the instrument into the female engagement in the Bone Screw. Once this has been tightened, rotate the collet sleeve of the instrument clockwise to bring the collet sleeve down to the plate's anterior surface (Figs. 27a-27c). With the collet sleeve held static and pushing against the plate, rotate the larger purple handle of the instrument counter-clockwise to remove the bone screw from the construct (Figs. 28a, 28b).



NUVASIVE HELIX ACP TECHNIQUE GUIDE

POST-OP VERIFICATION

Verify bone screw and plate placement via postoperative fluoroscopy.



PRE-OP



POST-OP

NUVASIVE HELIX ACP SYSTEM

NUVASIVE HELIX ACP INSTRUMENTS

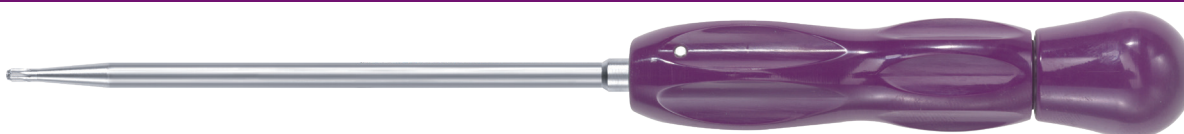
DRILL BIT



TAP



BONE SCREW DRIVER



DRILL GUIDE AWL



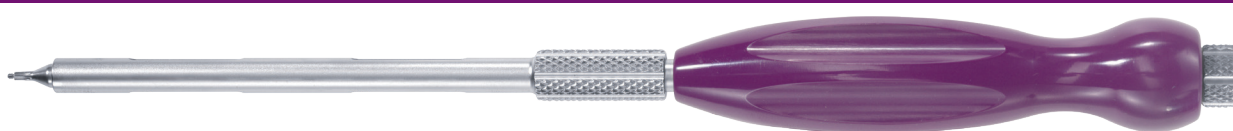
SELF-CENTERING AWL, VARIABLE



SELF-CENTERING AWL, FIXED



BONE SCREW EXTRACTION TOOL



NUVASIVE HELIX ACP SYSTEM

NUVASIVE HELIX ACP INSTRUMENTS

TEMPORARY TACK



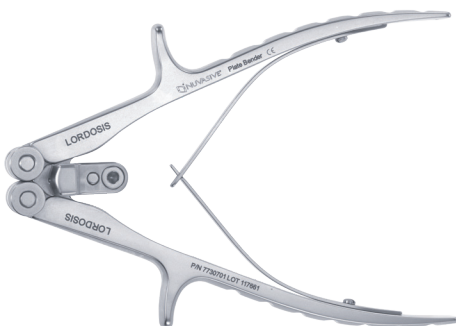
VARIABLE ANGLE DRILL GUIDE



FIXED ANGLE DRILL GUIDE



PLATE BENDER



UNIVERSAL HANDLE



NUVASIVE HELIX ACP SYSTEM

NUVASIVE HELIX ACP IMPLANTS

4.0mm SELF-DRILLING VARIABLE BONE SCREW



4.0mm SELF-DRILLING FIXED BONE SCREW



4.0mm SELF-TAPPING VARIABLE BONE SCREW



4.0mm SELF-TAPPING FIXED BONE SCREW



4.5mm SELF-TAPPING VARIABLE BONE SCREW



4.5mm SELF-TAPPING FIXED BONE SCREW



1-LEVEL PLATE



2-LEVEL PLATE



3-LEVEL PLATE



4-LEVEL PLATE



CATALOG

IMPLANTS	CATALOG #
Self-Drilling Bone Screws (Variable, 4.0)	
4.0 x 11mm Self-Drilling Variable Screw	7731111
4.0 x 13mm Self-Drilling Variable Screw	7731113
4.0 x 15mm Self-Drilling Variable Screw	7731115
Self-Tapping Bone Screws (Variable, 4.0)	
4.0 x 11mm Self-Tapping Variable Screw	7733111
4.0 x 13mm Self-Tapping Variable Screw	7733113
4.0 x 15mm Self-Tapping Variable Screw	7733115
4.0 x 17mm Self-Tapping Variable Screw	7733117
4.0 x 19mm Self-Tapping Variable Screw	7733119
Self-Tapping Bone Screws (Variable, 4.5)	
4.5 x 13mm Self-Tapping Variable Screw	7735113
4.5 x 15mm Self-Tapping Variable Screw	7735115
4.5 x 17mm Self-Tapping Variable Screw	7735117
4.5 x 19mm Self-Tapping Variable Screw	7735119
Self-Drilling Bone Screws (Fixed, 4.0)	
4.0 x 11mm Self-Drilling Fixed Screw	7732111
4.0 x 13mm Self-Drilling Fixed Screw	7732113
4.0 x 15mm Self-Drilling Fixed Screw	7732115
Self-Tapping Bone Screws (Fixed, 4.0)	
4.0 x 11mm Self-Tapping Fixed Screw	7734111
4.0 x 13mm Self-Tapping Fixed Screw	7734113
4.0 x 15mm Self-Tapping Fixed Screw	7734115
4.0 x 17mm Self-Tapping Fixed Screw	7734117
4.0 x 19mm Self-Tapping Fixed Screw	7734119
Self-Tapping Bone Screws (Fixed, 4.5)	
4.5 x 13mm Self-Tapping Fixed Screw	7736113
4.5 x 15mm Self-Tapping Fixed Screw	7736115
4.5 x 17mm Self-Tapping Fixed Screw	7736117

TEMPORARY FIXATION	CATALOG #
Temporary Fixation Pin (Temporary Tack)	7737110

IMPLANTS	CATALOG #
1-Level NuVasive Helix ACP, 20mm	7738120
1-Level NuVasive Helix ACP, 22mm	7738122
1-Level NuVasive Helix ACP, 24mm	7738124
1-Level NuVasive Helix ACP, 26mm	7738126
1-Level NuVasive Helix ACP, 28mm	7738128
1-Level NuVasive Helix ACP, 30mm	7738130
1-Level NuVasive Helix ACP, 32mm	7738132
1-Level NuVasive Helix ACP, 34mm	7738134
2-Level NuVasive Helix ACP, 36mm	7738236
2-Level NuVasive Helix ACP, 38mm	7738238
2-Level NuVasive Helix ACP, 40mm	7738240
2-Level NuVasive Helix ACP, 42mm	7738242
2-Level NuVasive Helix ACP, 44mm	7738244
2-Level NuVasive Helix ACP, 46mm	7738246
2-Level NuVasive Helix ACP, 48mm	7738248
2-Level NuVasive Helix ACP, 50mm	7738250
2-Level NuVasive Helix ACP, 52mm	7738252
2-Level NuVasive Helix ACP, 54mm	7738254
3-Level NuVasive Helix ACP, 56mm	7738356
3-Level NuVasive Helix ACP, 58mm	7738358
3-Level NuVasive Helix ACP, 60mm	7738360
3-Level NuVasive Helix ACP, 62mm	7738362
3-Level NuVasive Helix ACP, 64mm	7738364
3-Level NuVasive Helix ACP, 66mm	7738366
3-Level NuVasive Helix ACP, 68mm	7738368
4-Level NuVasive Helix ACP, 70mm	7738470
4-Level NuVasive Helix ACP, 74mm	7738474
4-Level NuVasive Helix ACP, 78mm	7738478
4-Level NuVasive Helix ACP, 82mm	7738482
4-Level NuVasive Helix ACP, 86mm	7738486
4-Level NuVasive Helix ACP, 90mm	7738490

5-Level NuVasive Helix ACP plates are not part of the standard configuration, but may be ordered separately by contacting NuVasive Customer Service.

INSTRUMENTS	CATALOG #
13mm Drill (Sterile)	7730016
13mm Tap Bit	7730026
Bone Screw Driver	7730041
Awl	7730062
Self-Centering Awl (Variable)	7730063
Self-Centering Awl (Fixed)	7730064
Bone Screw Extractor	7730071
Drill Guide, Fixed	7730081
Drill Guide, Variable	7730091
Plate Bender	7730701
NuVasive Helix ACP Sterilization Tray	7730002
DTS Guide - Fixed, 0°	7730086
DTS Guide - Fixed, 7°	7730088
Plate Holder	7730043
Universal Handle	7730600

INSTRUCTIONS FOR USE

DESCRIPTION

The NuVasive HELIX ACP System consists of a variety of types and sizes of plates and attachment screws made from titanium alloy (ASTM F136/1472). The plates also include components manufactured from Nickel-Cobalt-Chromium-Molybdenum alloy (MP35N per ASTM F562). Instruments required to implant the device are also available.

INDICATIONS FOR USE

The NuVasive HELIX ACP System is intended for anterior screw fixation of the cervical spine. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of this implant system include degenerative disc disease defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma, spinal stenosis, deformity, tumor, pseudarthrosis or failed previous fusion.

WARNING: The NuVasive HELIX ACP System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

CONTRAINDICATIONS

Use of the NuVasive HELIX ACP System and spinal fixation surgery are contraindicated when there was recent or local active infection near or at the site of the proposed implantation. Any conditions that preclude the possibility of fusion are relative contraindications. These include but are not limited to: cancer, fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy and foreign body sensitivity. See also the WARNINGS, CAUTIONS AND PRECAUTIONS, AND POTENTIAL ADVERSE EVENTS AND COMPLICATIONS sections of this insert.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur include: early or late infection which may result in the need for additional surgeries; damage to blood vessels; spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; impotence; permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s).
- Nonunion or delayed union.
- Fracture of the vertebra.
- Neurological, vascular or visceral injury.
- Metal sensitivity or allergic reaction to a foreign body.
- Infection.
- Decrease in bone density due to stress shielding.
- Pain, discomfort or abnormal sensations due to the presence of the device.
- Nerve damage due to surgical trauma.
- Bursitis.
- Dural Leak.
- Paralysis.
- Death.

WARNINGS, CAUTIONS AND PRECAUTIONS

- The subject device is intended for use only as indicated.
- The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- 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.
- Implant Selection: The NuVasive HELIX ACP System is available in a variety of sizes to insure proper sizing of implanted components. The potential for the success of the fusion is increased by selecting the correct size of the implant. These devices are not intended to be used as the sole support for the spine. Optional 1-Level, 18mm Plates are not compatible with End DTS Guides.

Single Barrel Drill Guides or Self-Centering Awl's must be used as substitutes.

- Delayed Union or Nonunion: The NuVasive HELIX ACP System is designed to assist in providing an adequate biomechanical environment for fusion. It is not intended to be and must not be used as the sole support for the spine. If a delayed union or nonunion occurs the implant may fail due to metal fatigue. Patients should be fully informed of the risk of implant failure.
- Patient Selection: Proper patient selection is critical to the success of the procedure. Only patients who satisfy the criteria set forth under the INDICATIONS section of this document AND who do not have any of the conditions set forth under the CONTRAINDICATIONS section of this document should be considered for spinal fixation surgery using the NuVasive HELIX ACP System. In addition, patients who smoke have been shown to have an increased incidence of pseudarthrosis. Based upon 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.

WARNING: This device contains nickel. Do not implant in patients with known or suspected nickel sensitivity.

CAUTION: must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

BENDING: Bending of the NuVasive HELIX ACP System is not recommended. Bending will compromise the mechanical performance of the plate and may adversely affect fit and function of the screw retaining mechanisms. If bending is unavoidable, be certain to bend the plate between the screw holes. Inspect the plate for damage after bending. Do not bend the plate against the curvatures manufactured into the plate. Do not bend the plate in the vicinity of the screw holes.

HANDLING: Implant components should be handled and stored appropriately to protect them from unintentional damage. The surgeon should avoid introducing notches or scratches into the plate surfaces as these may induce premature failure of the component.

PATIENT EDUCATION: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

SINGLE USE ONLY: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.

MAGNETIC RESONANCE (MR) SAFETY: The HELIX ACP System has not been evaluated for safety and compatibility in the MR environment. The HELIX ACP System has not been tested for heating or migration in the MR environment.

COMPATIBILITY: Do not use HELIX ACP with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

IMPORTANT: Prior to locking bone screws into the plate, ensure that ALL bone screws are inserted (driven) 75% into bone prior to final tightening. Failure to do so may reduce the chance of properly locking the bone screw into the plate construct.

IMPORTANT: If Fixed Bone Screws are being placed, Drill or Awl must be used in conjunction with the Fixed Guide.

- Do not bend plate over Bone Screw holes. Inspect plate after each bend for excessive wear.
- Temporary Tacks are a disposable item meant for single use only.
- Care should be taken to insure that all components are ideally fixated prior to closure.
- All implants should be used only with the appropriately designated instrument (Reference Surgical Technique).
- Instruments and implants are not interchangeable between systems.
- All components should be final tightened per the specifications in the Surgical Technique. Implants should not be tightened past the locking point, as damage to the implant may occur.
- Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.
- To maintain the mechanical integrity of the plate, once the plate is bent in one direction with either tool, further ending only in that same direction should be attempted. Unbending of the plate may cause mechanical compromise.

INSTRUCTIONS FOR USE

IMPORTANT NOTE TO OPERATING SURGEON

- The NuVasive HELIX ACP System is designed to provide biomechanical stabilization as an adjunct to cervical fusion and should be used with anterior column support. Without anterior column support, its use may not be successful. Spinal fixation should only be undertaken after the surgeon has had hands on training in this method of spinal fixation and has become thoroughly knowledgeable about spinal anatomy and biomechanics. A surgical technique is available for instructions on the important aspects of this surgical procedure.
- Postoperative evaluation of the fusion and implant status is necessary. The surgeon may remove the implant once a solid fusion is obtained. The patient must be informed of the potential of this secondary surgical procedure and the associated risks.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage, and from corrosive environments.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Devices should be inspected for damage prior to implantation.
6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS

1. During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.
2. Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

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To order, please contact your NuVasive Sales Consultant or Customer Service Representative today at:

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