ACP

Surgical technique guide

NuVasive

This document is intended exclusively for physicians.

This document contains general information on the products and/or procedures discussed herein and should not be considered as medical advice or recommendations regarding a specific patient or their medical condition.

This surgical technique guide offers guidance but is not a substitute for the comprehensive training surgeons have received. As with any such technique guide, each surgeon should use his or her own independent medical judgment to consider the particular needs of the patient and make appropriate clinical decisions as required. A successful result is not always achieved in every surgical case.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and the implant, including the use of ACP. It may not be appropriate for all patients and all patients may not benefit.

It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning.

This surgical technique guide provides information supplemental to information provided in the individual system instructions for use (IFU) regarding the products referenced herein.

Contents

Preface

Fellow colleagues,

It is with great excitement that we introduce to you a better solution for anterior cervical surgery.

NuVasive engaged an accomplished team of surgeons and senior engineers with a blank slate to make a **deliberate assessment** of the current shortcomings when surgically managing differing cervical pathologies.

This team has been designing cervical products for over 30 years, including many popular cervical systems. The surgeons have recognized that there have been numerous iterative changes in anterior plating systems that have resulted in generally good clinical outcomes but still areas where further improvement can occur. The team strived to reimagine ACDF and what we could offer to better serve your patients.

This demanded **nuance.**

Our analysis of current limitations led us to focus on three main areas:

1. Plate thinness/Postoperative dysphagia

2. Construct versatility/Dynamic loading

3. Construct stiffness/Spinal alignment preservation

The NuVasive Anterior Cervical Plating (ACP) system has:

- The thinnest plate system on the market* with the **ACP 1.6**
- The thinnest plate* that offers both fixed and variable screws with the **ACP 1.9**
- The optimal long segment stiffness with the **ACP 2.1**

Anterior column chemistry is our defining principle. That is the interaction of one element with another, the interplay between the plate and interbody. With a robust interbody portfolio, surgeons have the choice to customize the construct for any given pathology and/or spinal alignment.

We are pleased to announce the release of our new anterior cervical plating system, **The NuVasive ACP.**

Best Regards,

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*Data on file. Based on review of publicly made available materials at the time of this release.

Overview

The NuVasive ACP system is intended for anterior screw fixation of the cervical spine C2–C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis and spinal stenosis.

As with all surgical procedures and permanent implants, there are risks and considerations associated with surgery and use of this device. It may not be appropriate for all patients and all patients may not benefit.

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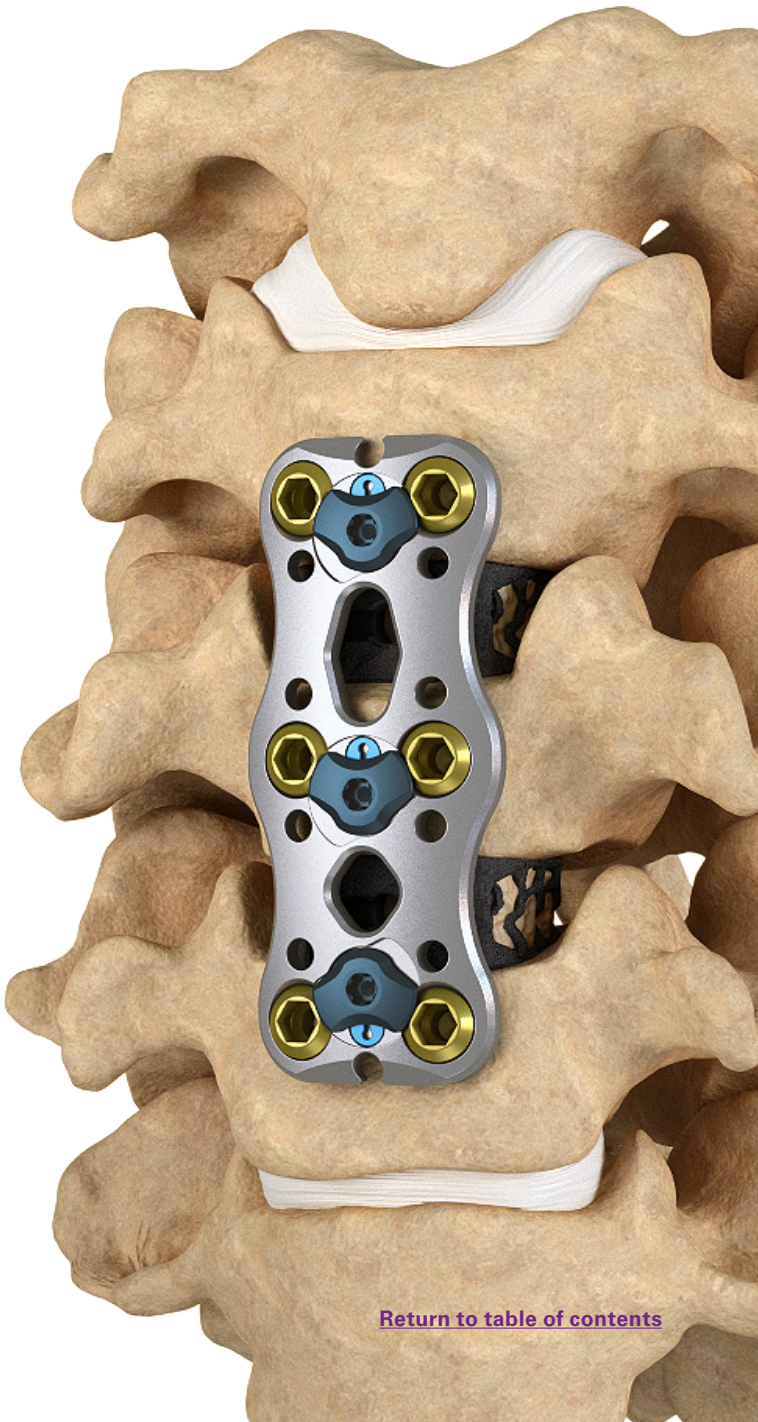


ACP surgical technique

Step 1

Position, incision and exposure

Place the patient in the supine position with the neck supported posteriorly to achieve desired segmental lordosis *(Fig. 1)*. Perform a standard incision to expose the cervical spine and elevate the longis colli muscles with medial/lateral retractor blades. Cranial/caudal retractor blades are optional and may be used. Complete the decompression by using standard surgical techniques to distract the intervertebral disc space.

Note: *If the intradiscal drill guide will be used, confirm that caspar pin placement is a minimum of 5 mm from the operative level in order to confirm desired distance is maintained between the distraction pins and drill guide.*

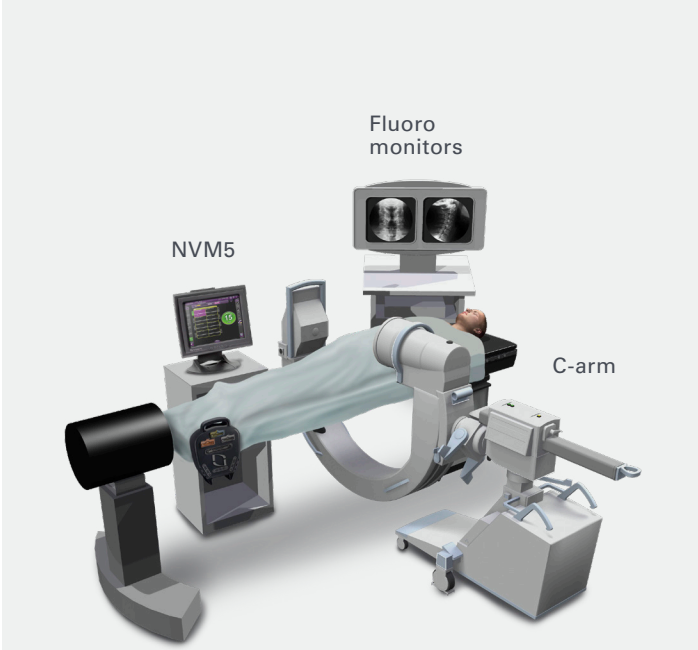


Fig. 1

Step 2

Discectomy and graft site preparation

Care should be taken when performing soft tissue dissection. Perform a discectomy at each surgical level using standard methods. Remove anterior osteophytes from the adjacent vertebral bodies to allow for an optimized bone to plate interface. Removal of soft tissue and osteophytes should allow the plate to sit flush on the anterior cortex *(Fig. 2)*.

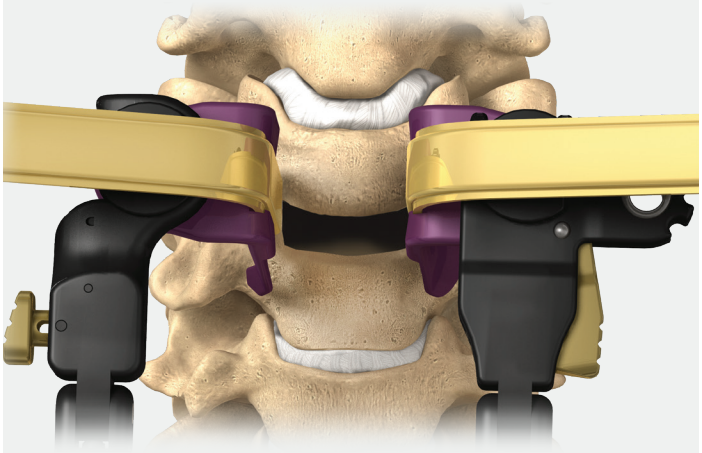


Fig. 2

Step 3 (optional)

Intradiscal drill guide

The intradiscal drill guides are designed to optimize the distance from the end of the plate to the adjacent level disc by drilling bone screw holes relative to the anterior endplate surface at a trajectory of 10° or 25° *(Fig. 3)*.

Once the discectomy and graft site preparation is complete, choose the intradiscal drill guide height and bone screw trajectory that is appropriate for the patient anatomy. Place the intradiscal portion of the instrument into the intervertebral disc space and drill cranial (or caudal) bone screw holes by placing the desired awl or drill through the guides *(Fig. 4)*.

Note: *The intradiscal drill guide is not designed to trial the interbody. Follow the surgical instructions provided by the interbody of choice.*

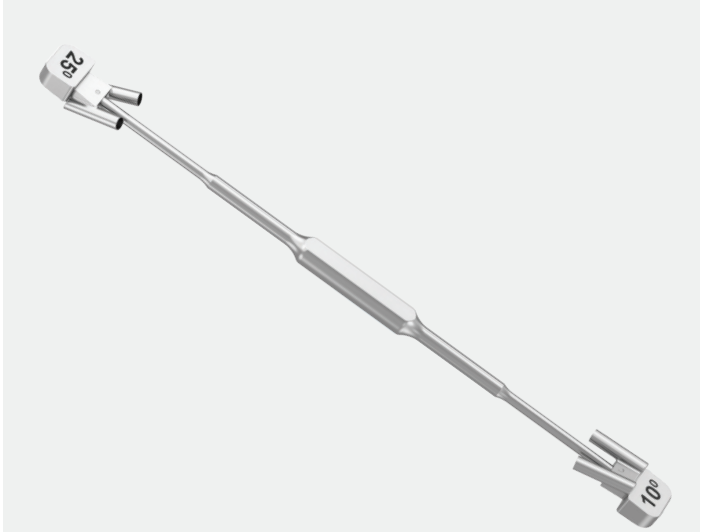


Fig. 3

Step 4

Interbody insertion

After the discectomy is complete, trial and insert the desired interbody spacer. If indicated, corpectomy may be performed using standard surgical techniques *(Fig. 5)*.

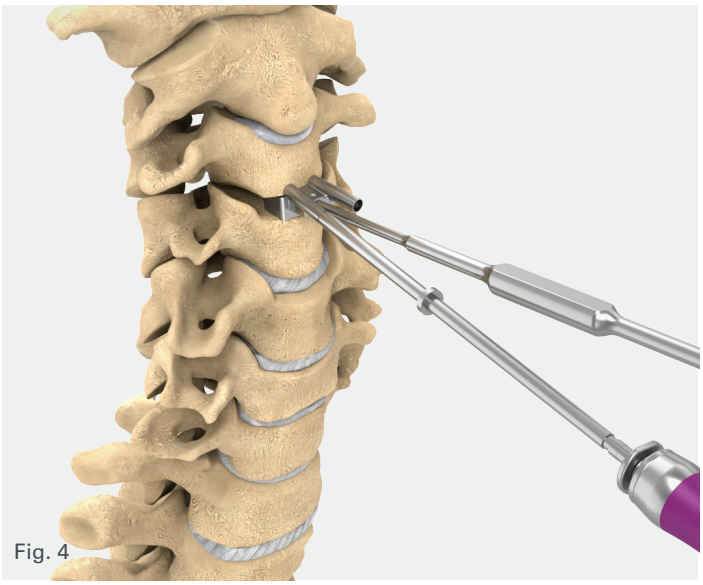


Fig. 4

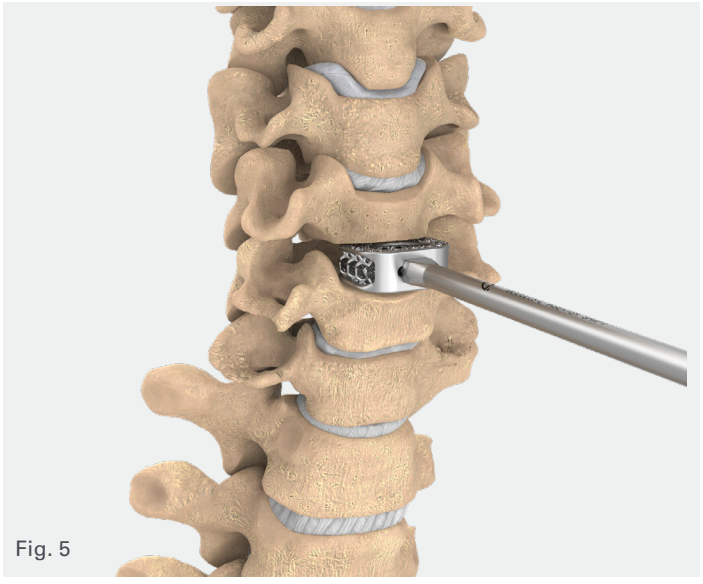


Fig. 5

Step 5

Plate selection

The ACP system offers a variety of plate lengths from one to five levels. Select the desired plate length that sits flush and will position all screw holes on the anterior cortex for optimal fixation. Plate length is measured from end to end. Fluoroscopy may be used to determine the desired plate length and anticipated screw trajectories. If necessary, the plate may be further contoured with the plate bender to match the lordotic curve on the anterior cervical spine *(Fig. 6)*.

Note: *All plate lengths are designed with a fixation pin feature on the superior/inferior aspects of the plate. When using single level plates, the fixation pin feature identifies the cephalad/caudal orientation of the plate.*

ACP system offerings

Levels	1.6 mm	1.9 mm	2.1 mm
One	•	•	
Two	•	•	
Three		•	
Four			•
Five			•

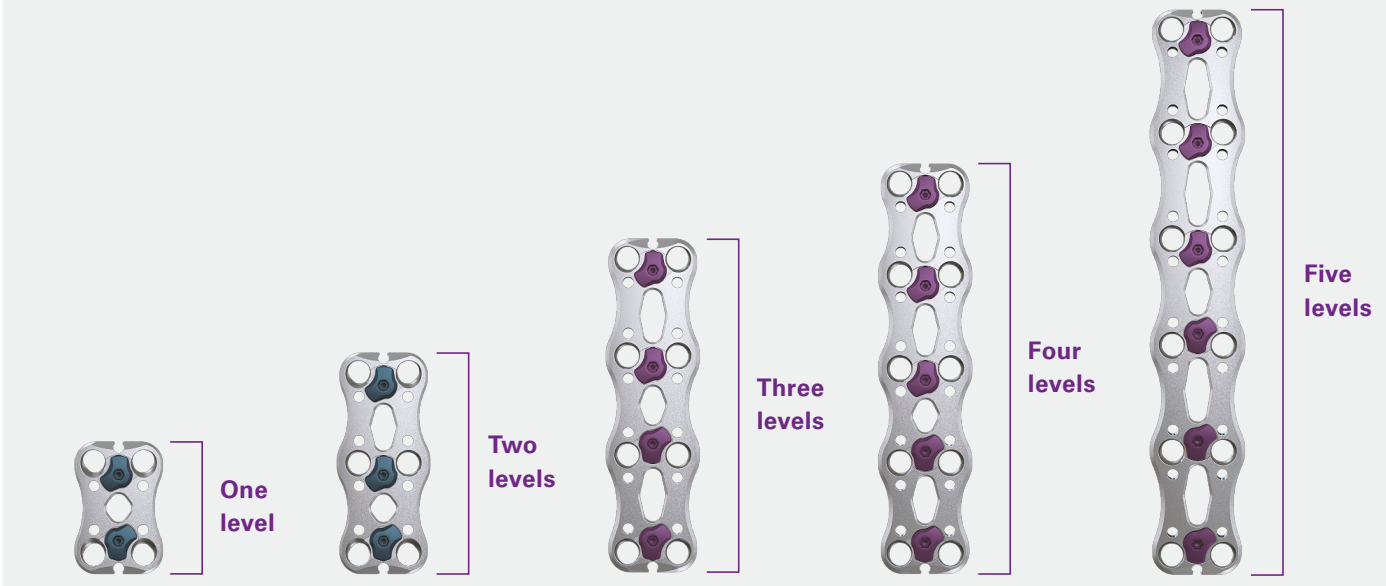


Fig. 6

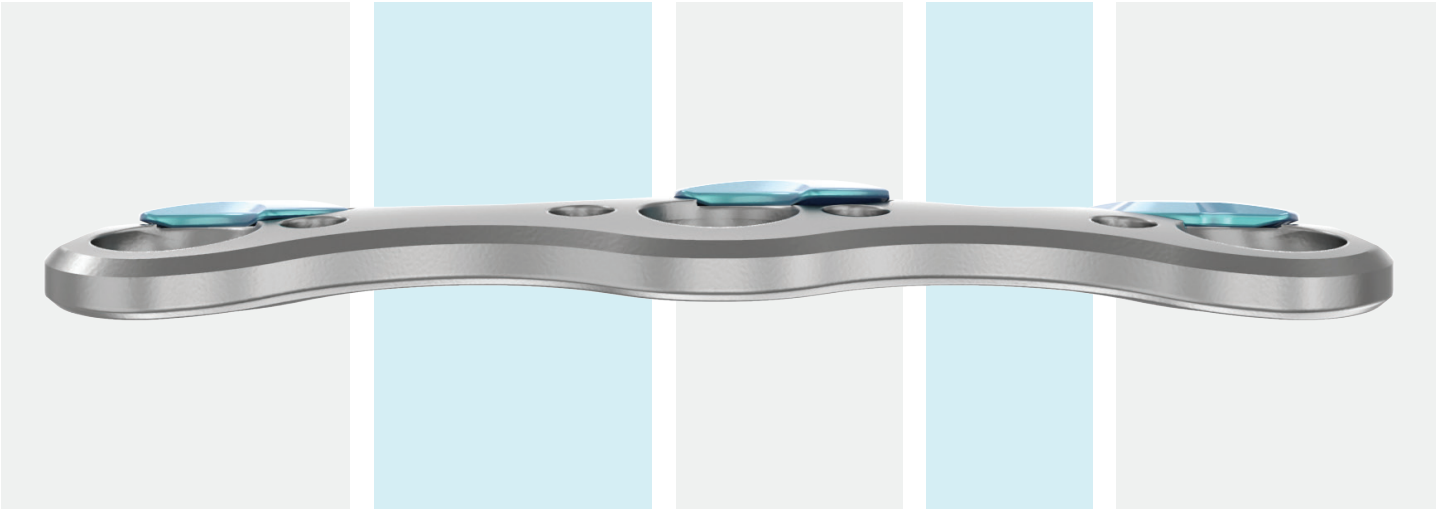
Step 6

Plate contouring

The plate is designed with a lordotic curve to match the patient's anatomy. If necessary, the plate may be contoured to increase the lordotic curvature or decrease lordotic curvature with the plate bender. To increase the lordotic curvature of the plate, turn the mandrel knob on the back of the instrument so that the front bending mandrel has the "+" symbol shown on top. To decrease the lordotic curvature of the plate, turn the mandrel knob 180° from the first position so that the front bending mandrel has the "-" symbol shown on top. Place plate within bender once desired lordotic curvature has been chosen and set on the bender. Apply a gradual bend and avoid abrupt changes in curvature of the plate. Bending the plate in the locking zone will compromise the proper actuation of the locking mechanism *(Figs. 7, 8)*. Care should be taken when contouring.

Precaution: *Bending of the 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 and retaining mechanisms. Inspect the plate for damage after bending.*

Fig. 7



Bending area (if required) Do not bend in this area

Fig. 8

Step 7

Plate holder, positioning and temporary fixation

The plate holder is designed to grasp any edge of the plate and screw holes. The instrument features notches on the distal tips to allow for variability to maneuver and position the plate in situ. Use the plate holder to insert and position the plate on the anterior surface of the cervical spine *(Fig. 9)*.

Review anatomical landmarks and confirm that the plate is centered laterally on the spine. After the plate has been properly positioned, temporary fixation pins may be used to temporarily secure the plate to the anterior vertebra. Temporary fixation pins may be placed into the bone screw holes or the indentations at the cephalad and caudal edges of the plate *(Fig. 10)*.

Caution: To prevent compromising the bone-screw interface, caution should be taken not to over-torque the temporary fixation pin once it has tightened against the plate.

Use the temporary fixation pin driver in conjunction with the temporary fixation pin. To engage the temporary fixation pin, pull the shaft towards the handle on the temporary fixation pin driver. Place over the distal tip of the temporary fixation pin and release the shaft to secure the temporary fixation pin to the driver *(Fig. 11)*. Once the temporary fixation pin is seated into the anterior vertebra, the temporary fixation pin driver can be disengaged from the temporary fixation pin. To remove the temporary fixation pin, use the primary driver or temporary fixation pin driver.

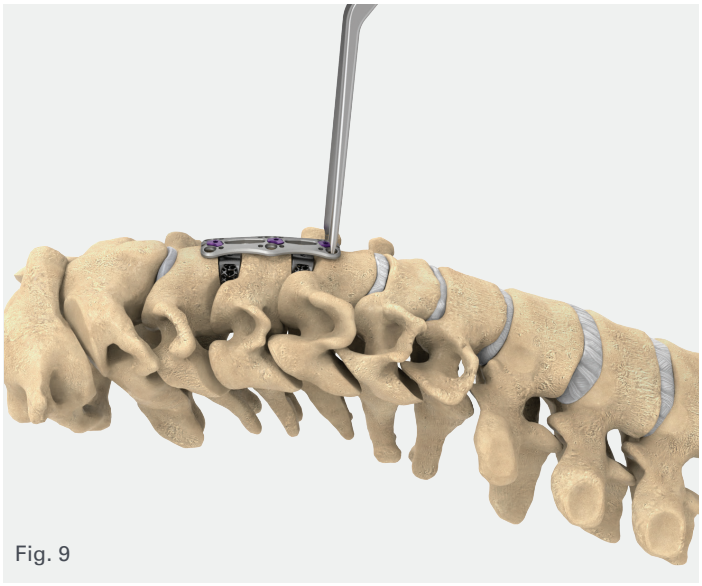


Fig. 9

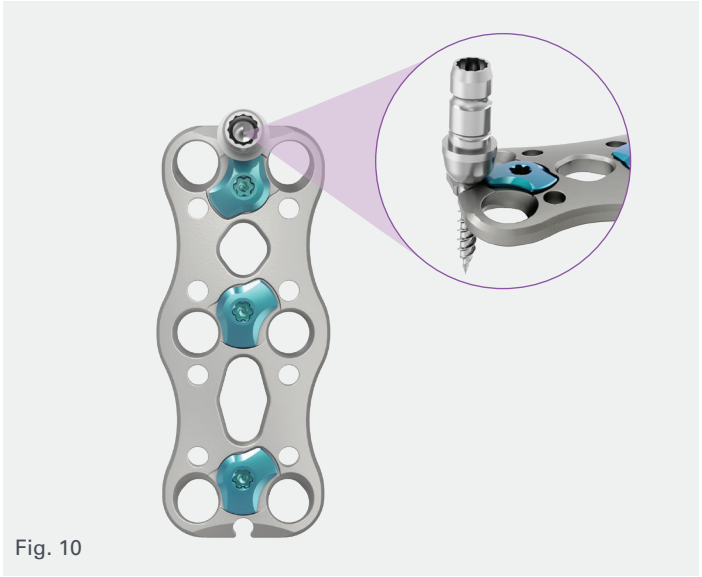


Fig. 10

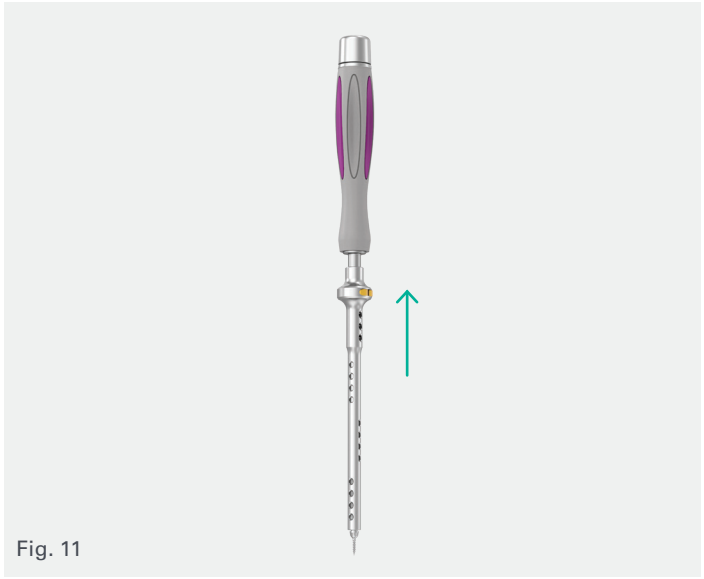


Fig. 11

Step 8

Screw and construct options

The ACP system offers versatility to place fixed and/or variable screws to create a constrained, semi-constrained or hybrid construct. Bone screws are offered in a variety of lengths and designs, including self-drilling and self-tapping. The plate offers versatility to place screws at varying trajectories into the vertebral bodies.

The images show options for fixed and variable screw placement *(Fig. 12)*.

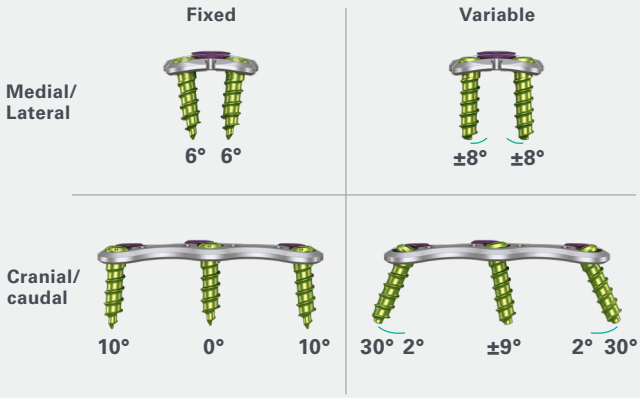


Fig. 12

Step 9

Bone screw positioning and preparation

The variable and fixed drill guides may be used to provide the desired positioning in conjunction with the awl or drill to protect the surrounding anatomy *(Figs. 13a, 13b)*. Place the distal end of the drill guide into the bone screw hole of the plate. Confirm the guide is securely placed into the bone screw hole and apply downward pressure on the guide handle *(Fig. 14)*. The variable drill guide allows for a trajectory of 30° to 2° cephalad or caudal and 14° to -2° medial to lateral. The fixed drill guide allows for a trajectory of 10° cephalad or caudal and 6° medial.

Variable drill guide

Fig. 13a

Fixed drill guide

Fig. 13b

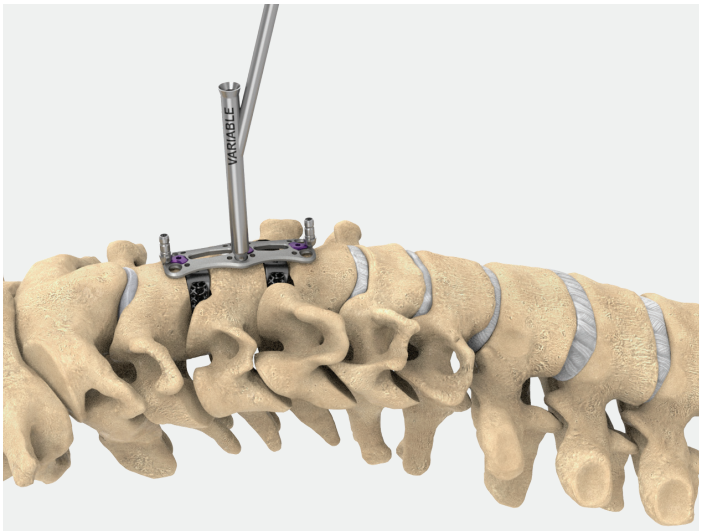


Fig. 14

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Bone screw positioning and preparation (cont.)

The awl may be used to perforate the anterior cortex of the vertebra and must be used through the fixed or variable drill guide. Use the universal handle to facilitate the awl through the fixed or variable drill guide handle. Insert the proximal end of the awl into the universal handle. Confirm the preferred drill guide is securely placed into the bone screw hole and advance the awl through the fixed or variable drill guide barrel. Apply downward pressure on the universal handle to perforate the cortex. The awl is designed with a stop collar to limit the depth of bone penetration to 10 mm.

Drills are offered in 2.25 mm diameter in 11 or 13 mm lengths. Use the universal handle to facilitate the drill through the drill guide barrel. Insert the proximal end of the drill into the universal handle.

Advance the drill through the guide barrel and rotate the universal handle clockwise to the depth permitted by the stop collar. The drill is designed with a stop collar to limit the depth of bone penetration to 11 or 13 mm *(Figs. 15a, 15b)*.

Precaution: *To allow for proper utility of the locking mechanism during screw placement, use a drill-guide with the awl and/or drill to create a centered screw hole into the vertebral bodies.*

Caution: Care should be taken when using screws longer than 15 mm at greater than 10° medial convergence as screw contact may occur.

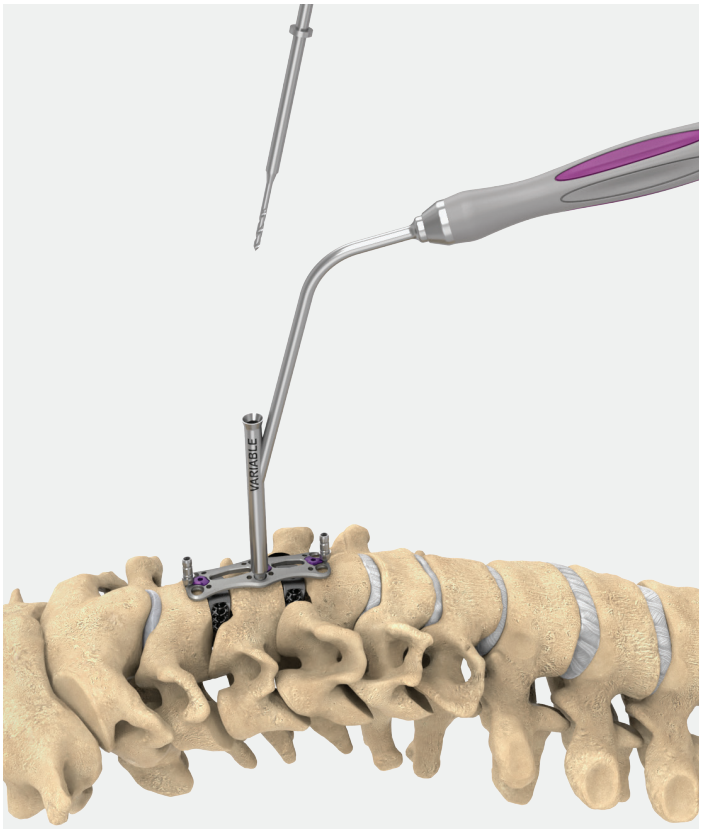


Fig. 15a

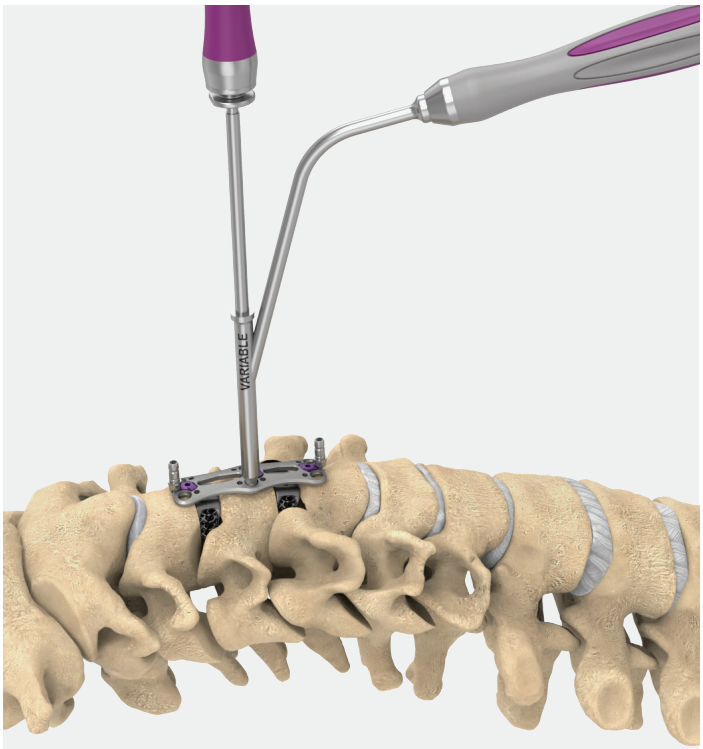


Fig. 15b

Step 10 (optional)

Bone screw positioning and preparation

The DTS guide may be used to provide desired positioning in conjunction with the awl, drill, or tap to protect the surrounding anatomy. The DTS guide may also be used as a plate holder, eliminating the need for temporary fixation and bone screw insertion.

To align and attach the DTS guide to the plate, insert the docking clip into the indentation on the superior or inferior edge of the plate *(Figs. 16a, 16b)*. Then apply downward pressure to position the docking pins into the docking ports at the superior or inferior end of the plate. Rotate the locking knob to secure the DTS guide to the plate *(Figs. 16c, 16d)*.

Turn the swivel knob clockwise or counter clockwise to alternate the barrel to the adjacent bone screw hole. Once the bones screws are final tightened, apply a slight forward motion towards the proximal end of the instrument to disengage the DTS guide from the plate *(Fig. 16d)*.

Note: *The DTS guide cannot be used with the punch awl, fixed screws and the 16 and 18 mm plates.*

Note: *Confirm the DTS guide is unlocked before aligning and attaching to the plate.*

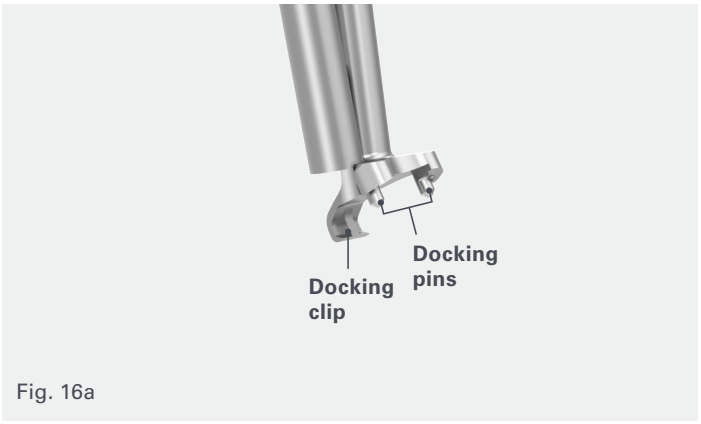


Fig. 16a

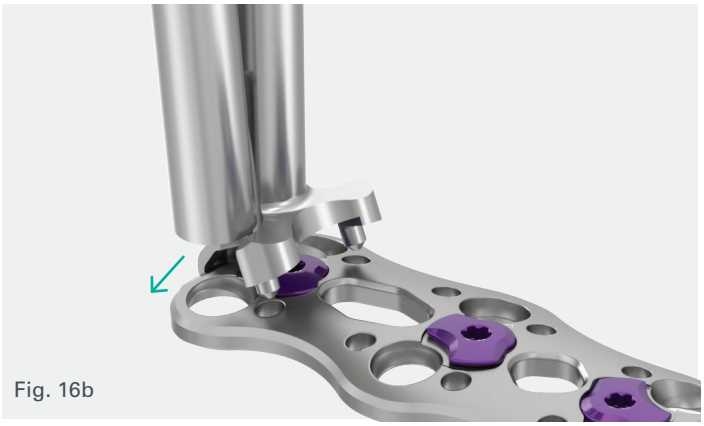


Fig. 16b


Fig. 16c

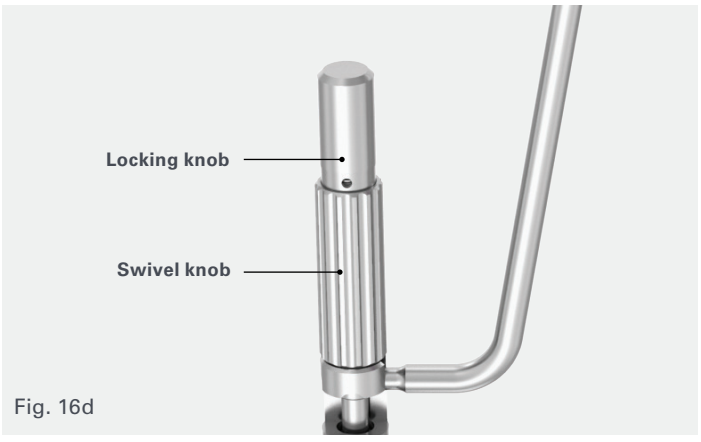


Fig. 16d

Step 11

Bone screw selection and insertion

The ACP system offers a variety of bone screws lengths and designs, including self-drilling and self-tapping.

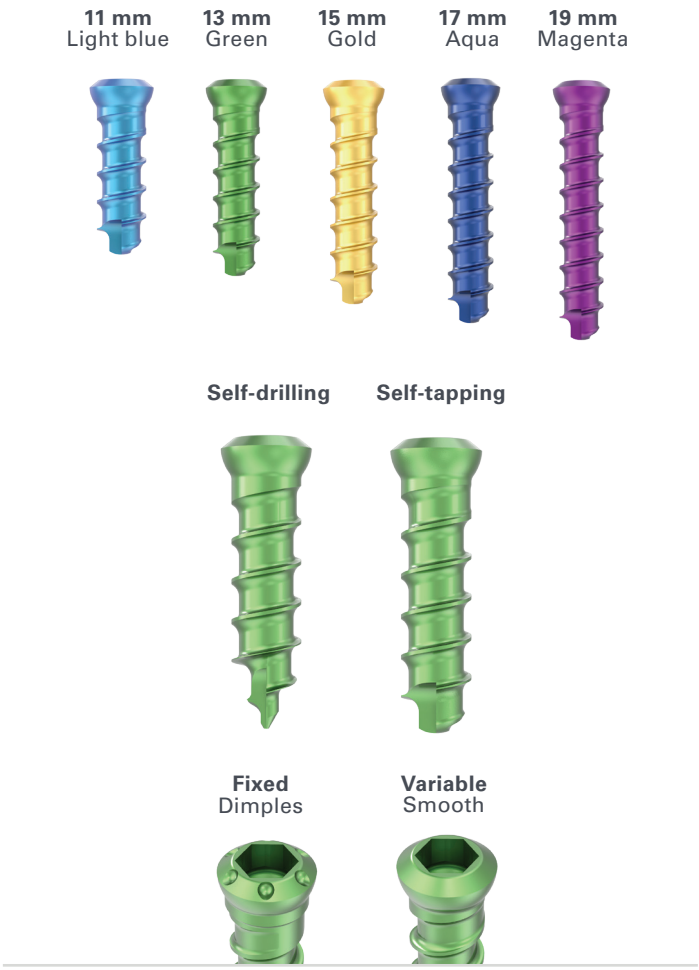
Use the screw and lock driver to facilitate bone screw insertion. Insert the proximal end of the screw and lock driver into the universal handle. The screw and lock driver incorporates a tapered hex design that provides a self-retaining fit between the bone screw and primary driver. Select the desired bone screw length and use the screw and lock driver to pick-up the bone screw. The bone screw is measured from the posterior surface of the plate to the distal tip. Insert the distal tip of the bone screw into the prepared bone screw hole. Apply downward pressure on the screw and lock driver and rotate the universal handle clockwise to advance and provisionally tighten the bone screw to the plate. Once all bone screws are inserted into the plate, final tighten each bone screw *(Fig. 17)*.

Caution: Caution should be used when placing bi-cortical screws to avoid perforation of the posterior cortex.

Note: *The ACP 1.6 mm plate can only be used with variable screws.*

Screw options and designs

- 3.5 and 4 mm bone screw diameters
- 3.5 mm diameter bone screws are color coded by length (4 mm diameter not colored)
- 2.5 mm hex driver feature on screw head
- 11–19 mm bone screw lengths in 2 mm increments
- Self-drilling and self-tapping designs
- Fixed and variable designs



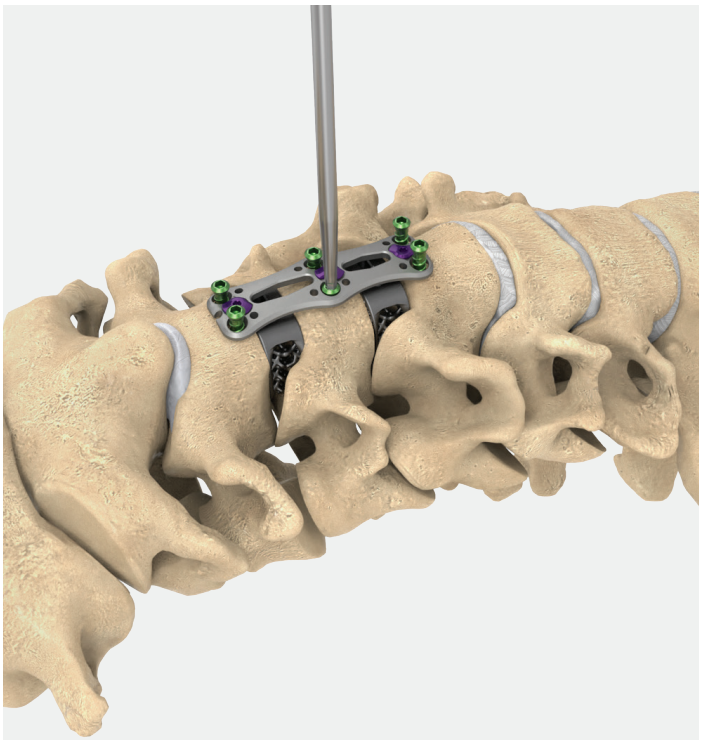


Fig. 17

Step 12

Bone screw locking

The ACP system is designed with a locking cover that is attached to the plate to restrict bone screw back out. The locking cover provides visual and tactile confirmation designed to indicate that the lock is rotated over the bone screw heads. The locking cover is not intended to tighten down on the bone screws.

Use the screw and lock driver (same driver used for bone screw insertion) to function the locking cover in conjunction with the universal handle. Insert the distal tip of the screw and lock driver into the locking cover and rotate clockwise until the locking mechanism covers both bone screw heads. **Do not** turn the locking cover beyond the locked and unlocked position *(Figs. 18, 19)*.

Note: *The ball hex driver can be used when trying to access the lock at an angle.*

Note: *The ACP lock rescue driver can be used to rotate the locking mechanism if the driver engagement is compromised.*

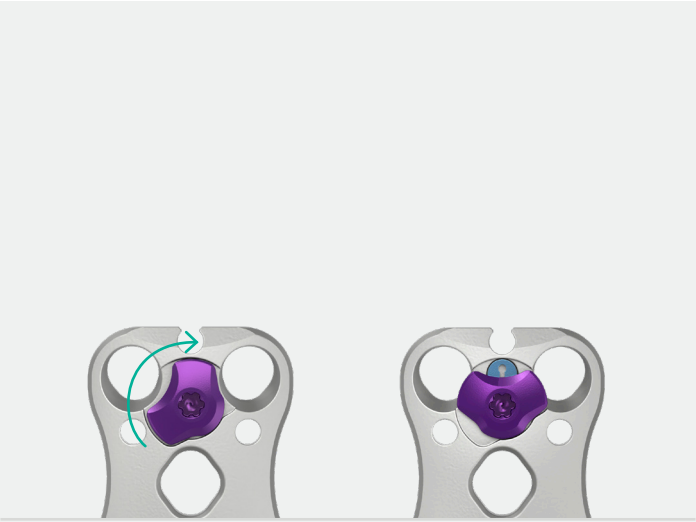


Fig. 19

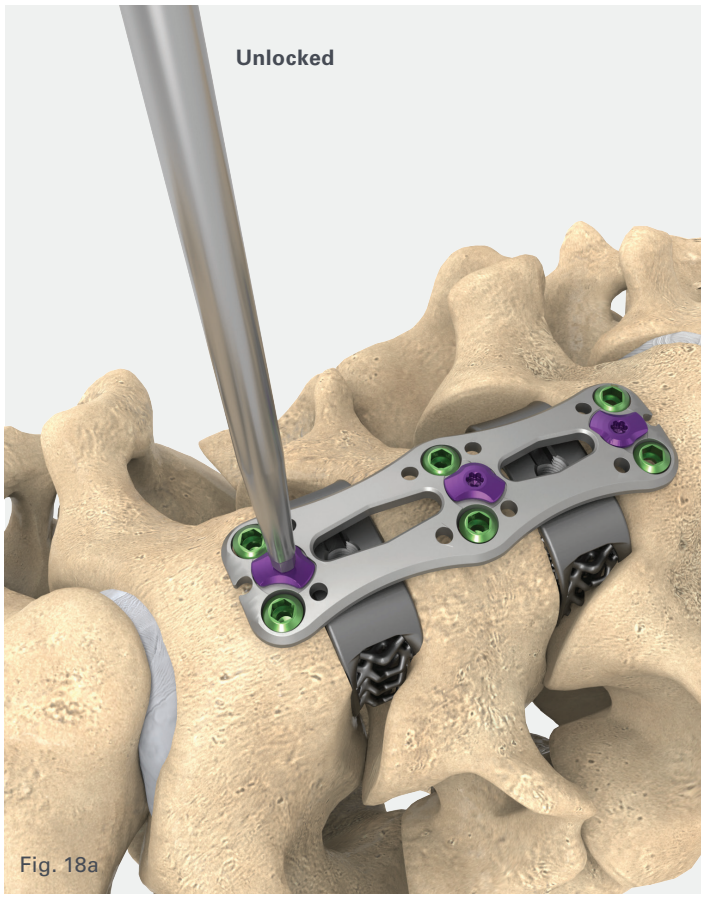


Fig. 18a

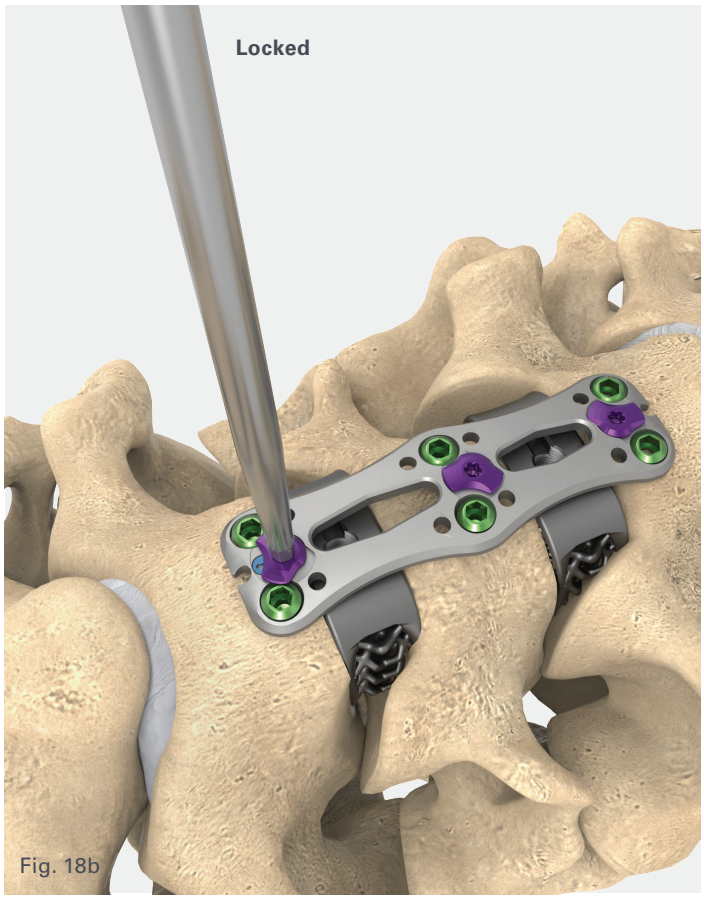


Fig. 18b

Step 13

Bone screw and plate removal

If a bone screws needs to be removed, use the screw and lock driver to rotate the locking cover counterclockwise to uncover the bone screw heads.

Use the screw and lock driver to remove all of the bone screws and then remove the plate. The screw rescue driver may be used to remove bone screw heads that are compromised *(Fig. 20)*.

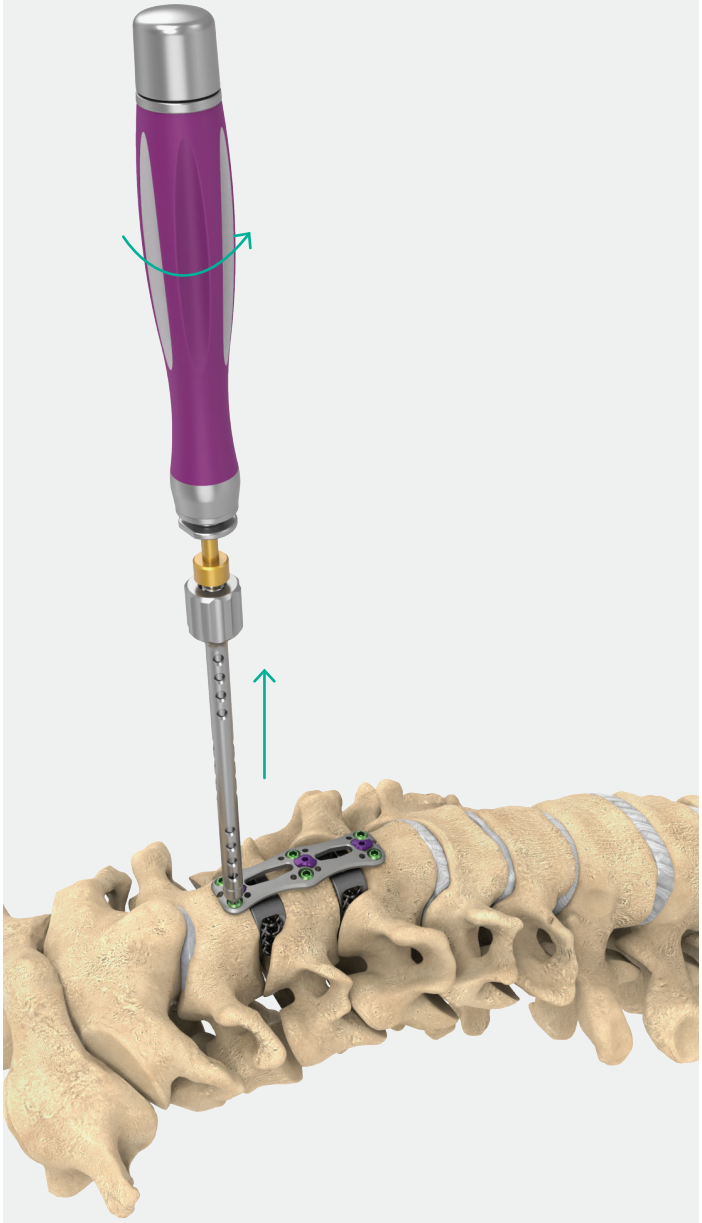


Fig. 20

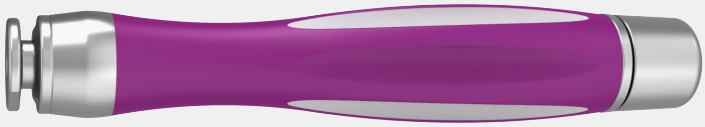
ACP instruments and implant system

ACP instruments

ACP variable angle drill guide

ACP fixed angle drill guide

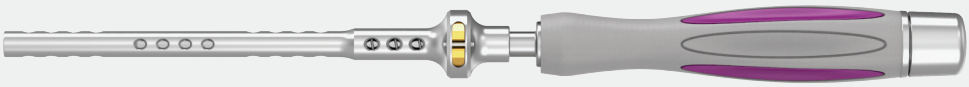
ACP universal handle



ACP plate holder

ACP plate bender

ACP temporary fixation pin driver



ACP drill, 11 mm

ACP drill, 13 mm

ACP awl, 10 mm

ACP tap, 3.5x10 mm

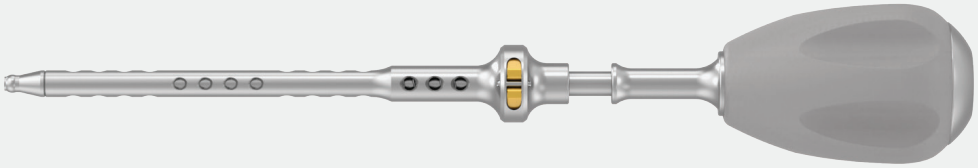
ACP screw and lock driver

ACP ball hex driver

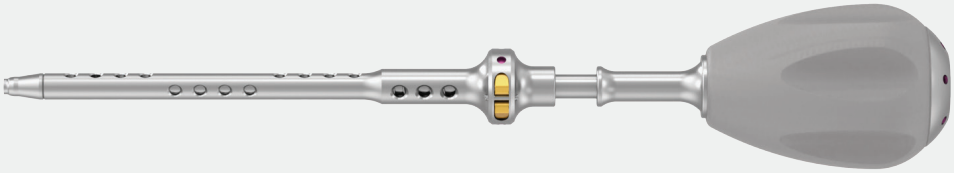
ACP screw rescue driver

ACP lock rescue driver

ACP punch awl, variable



ACP punch awl, fixed

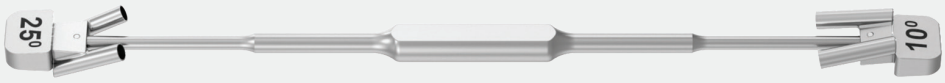


ACP DTS guide, end, 10° and 25°

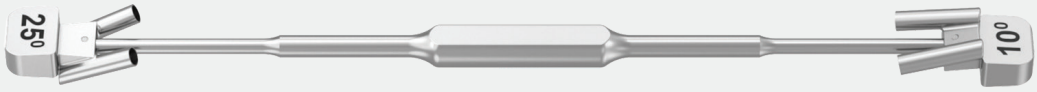
ACP guide, DTS mid 0°

ACP intradiscular drill guide, 6 mm

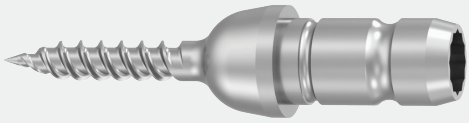
ACP intradiscular drill guide, 7 mm



ACP intradiscal drill guide, 8 mm

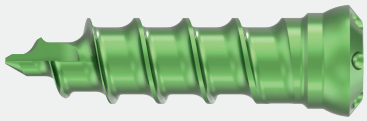


ACP temporary fixation pin

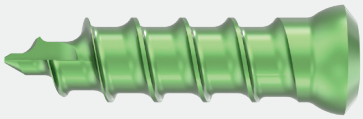


ACP implants

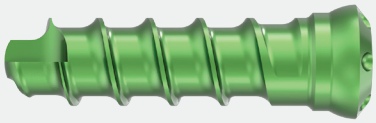
ACP screw, 3.5x13 mm self-drilling fixed



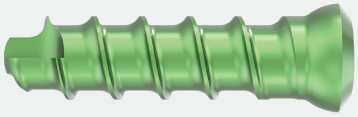
ACP screw, 3.5x13 mm self-drilling variable



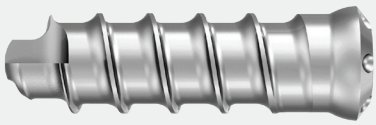
ACP screw, 3.5x13 mm self-tapping fixed



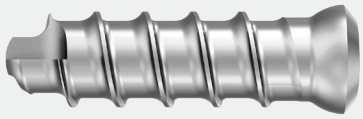
ACP screw, 3.5x13 mm self-tapping variable



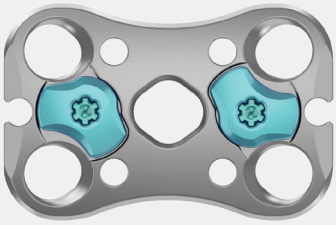
ACP screw, 4x13 mm self-tapping fixed



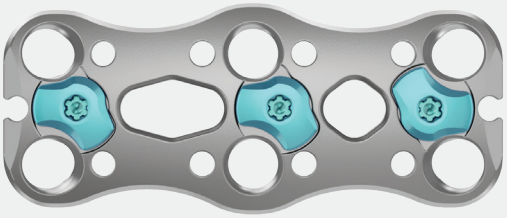
ACP screw, 4x13 mm self-tapping variable



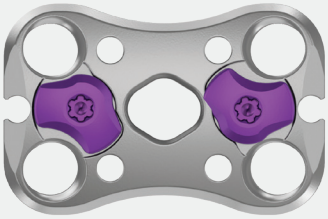
ACP 1.6 1-Level plate



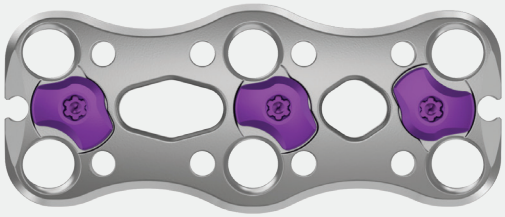
ACP 1.6 2-Level plate



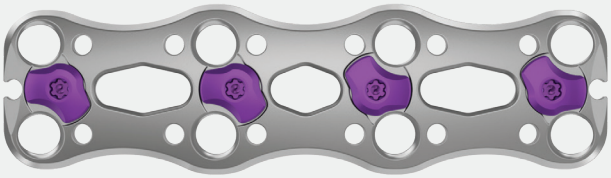
ACP 1.9 1-Level plate



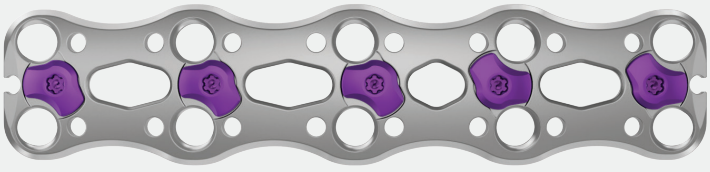
ACP 1.9 2-Level plate



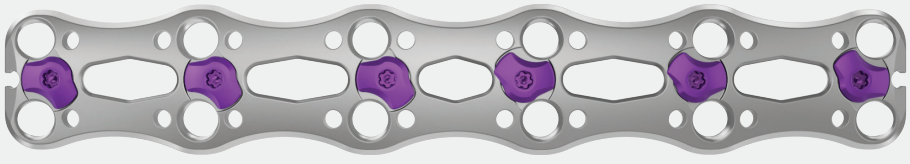
ACP 1.9 3-Level plate



ACP 2.1 4-Level plate



ACP 2.1 5-Level plate



Instructions for use

DESCRIPTION

The NuVasive ACP System is an anterior cervical plating system that consists of a variety of implant components including screws and plates, as well as associated manual general surgical instruments. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient. The subject device components are manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 or ISO 5832-3.

INDICATIONS FOR USE

The NuVasive ACP System is intended for anterior screw fixation of the cervical spine C2-C7. These implants have been designed to provide stabilization as an adjunct to cervical fusion. Indications for the use of implant system include degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

CONTRAINDICATIONS

Use of the NuVasive 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: fever, mental illness, alcoholism or drug abuse, osteoporosis or osteopenia, neurotrophic diseases, obesity, pregnancy and foreign body sensitivity.

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: heterotopic ossification at adjacent spinal levels (e.g., ALOD); loss of motion at adjacent spinal levels associated with adjacent-level ossification; 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)
- Loss of fixation
- 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 NuVasive ACP System is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

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.

Because there may be an association between adjacent-level ossification and the plate-to-disc distance following anterior cervical plate procedures, the adjacent vertebrae should be at least 14.5 mm in vertical height and the plate should be placed at least 5 mm away from the adjacent-level disc space to decrease the likelihood of adjacent-level ossification.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. These devices are not intended to be used as the sole support for the spine. While proper selection can minimize risks, the size and shape of patient anatomy may present limitations on the size of the chosen implants.

The NuVasive ACP System is designed to assist in providing an adequate biomechanical environment for fusion. 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.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

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.

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 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.

Bending of the NuVasive 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 and retaining mechanisms. Inspect the plate for damage after bending.

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.

Notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage.

To prevent compromising the bone-screw interface, caution should be taken not to over-torque the Temporary Fixation Pin once it has tightened against the plate.

To allow for proper utility of the locking mechanism during screw placement, use a Drill-Guide with the Awl and/or Drill to create a centered screw hole into the vertebral bodies.

Caution should be used when placing bi-cortical screws to avoid perforation of the posterior cortex.

Care should be taken when using screws longer than 15mm at greater than 10° medial convergence as screw contact may occur.

Follow proper instrument selection as specified in Surgical Technique. The NuVasive 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.

Care should be taken to insure that all components are ideally fixated prior to closure.

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/Do not re-use: 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.

MRI safety information: Refer to the NuVasive ACP Instructions for Use for MR safety information.

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

All implants should be used only with the appropriately designated instrument (Reference Surgical Technique). Instruments and implants are not interchangeable between systems.

PREOPERATIVE WARNING

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. Refer to the cleaning and sterilization instructions below for all non-sterile parts.
5. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POSTOPERATIVE WARNING

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

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.

Please refer to the NuVasive ACP System IFU found at **www.nuvasive.com/eifu** for additional important labeling information.

Notes

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