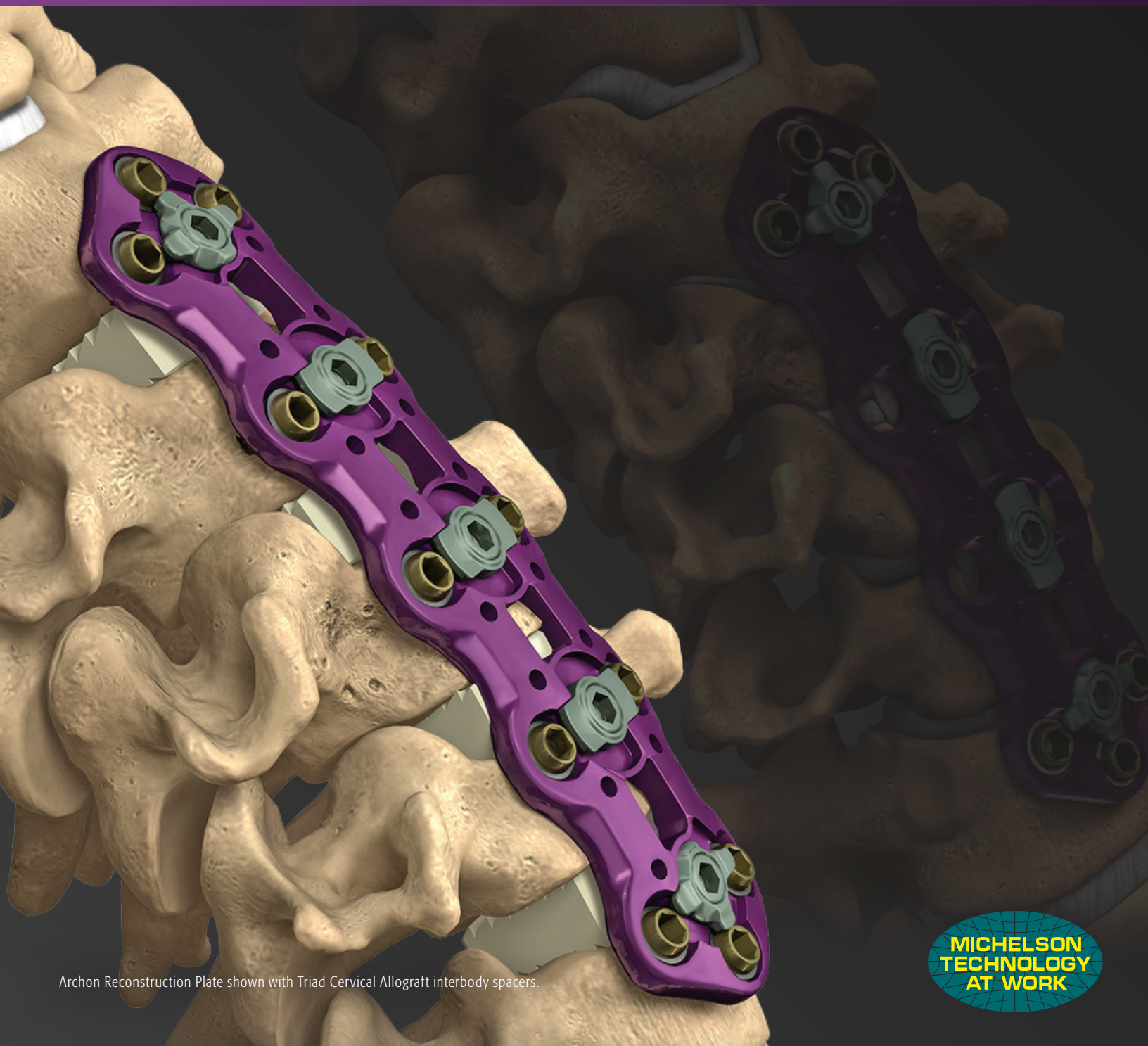
NuVasive

ARCHON
RECONSTRUCTION SYSTEM

Technique Guide



Archon Reconstruction Plate shown with Triad Cervical Allograft interbody spacers.

MICHELSON TECHNOLOGY AT WORK

CONTENTS

PREFACE

Fellow Colleagues:

Over the past two decades of cervical plate development, the advancements in plating technologies and options have, in many cases, focused on form over functional utility. Ultimately, a cervical plating system should be able to address simple and complex pathologies, where revision and failure rates are particularly high. The NuVasive Archon Anterior Reconstruction system was designed to address these complex multi-level pathologies with innovative implant and instrument offerings.

The incorporation of a third screw at the terminal ends of the construct, and the increased width between screws, work to provide additional construct rigidity that may contribute to reduced complications and resulting revisions.

This design, paired with the ability to engage the lock mechanism with the same drivers as the screws, and a complementary driver for angulated lock engagement, accommodates placement of the plate, even with challenging patient anatomies. The Archon system was designed with a wide array of plate size offerings and design elements meant to complement precise placement within differing anatomies. Large graft windows and high screw angulation combine to allow for placement away from and minimize disruption to adjacent-level pathology.

The Archon Reconstruction system is offered in conjunction with the Archon Degenerative system in order to address various challenging anatomical requirements. Both systems were designed by surgeons with an emphasis on tactile interfaces and confident feedback. Aggressive screws with newly redesigned thread and tactile feedback surfaces were designed for aggressive purchase and improved pullout resistance. Additionally, the screw plate interface allows the plate to be lagged to the vertebral body for a secure plate/screw/bone interface.

We are pleased to announce the release of the Archon Reconstruction system.

Best regards,





Nevan G. Baldwin, M.D.
Neurosurgical Associates
Lubbock, TX
USA

Paul K. Kim, M.D.
Carolina Neurosurgery &
Spine Associates
Charlotte, NC
USA

Paul D. Sawin, M.D.
American Board of
Neurological Surgery
Winter Park, FL
USA

David Schwartz, M.D.
OrthoIndy
Indianapolis, IN
USA

Christopher I. Shaffrey, M.D.
University of Virginia
Charlottesville, VA
USA

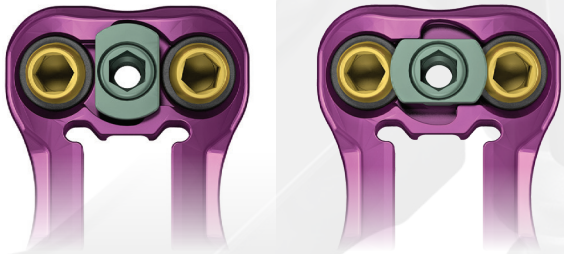
THE ARCHON SYSTEM

The NuVasive Archon Anterior Degenerative and Reconstruction systems were designed to address standard degenerative to advanced reconstruction pathologies, including corpectomies. The plating technology was designed with a simple-to-use locking mechanism, robust screw design, and simplified instrumentation. In addition, the reconstruction plating offering was designed to provide additional fixation and additional biomechanical stability over traditional anterior cervical plating systems. These benefits, along with a procedurally integrated offering, allows for a surgeon to address simple to complex pathologies.

LOCKING TECHNOLOGY

Attached, simple and secure

- Designed to lock securely and with confidence, utilizing the same driver as the bone screws.
- Verification is simple and also features a hard stop when the lock is fully engaged.
- A Ball-Hex Driver option accommodates for angulated lock engagement of up to 25°.

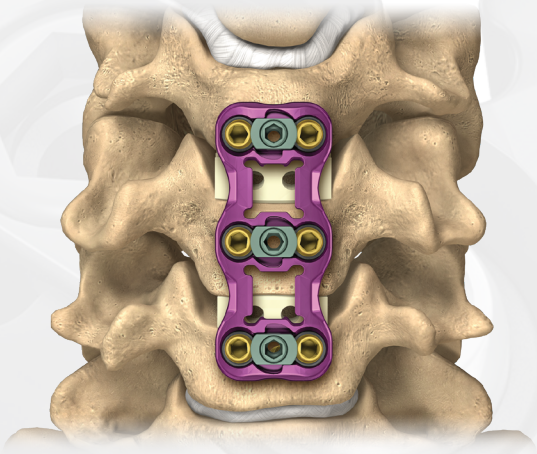


UNLOCKED LOCKED

PLATING TECHNOLOGY

Designed for ease of placement

- The Archon plating technology features a low-profile and slim width, along with large graft windows and low plate overhang.
- Combined with an aggressive amount of screw angulation, the design is intended to allow the surgeon to place the plate away from adjacent levels.
- Crossover plate sizing in one-level to five-level (degenerative plates) and two-level to five-level (reconstruction plates) configurations allows for sizing to match a wide variety of patient anatomies.

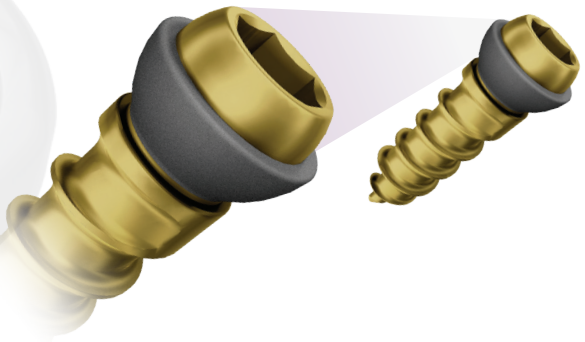


ENHANCED SCREW TECHNOLOGY

Designed to:

- Offer variable, fixed, self-tapping, and self-drilling configurations
- Provide a more robust screw design for aggressive purchase in differing bone types
- Feature a tactile feedback surface that binds to the plate when the screw and plate are flush against the bone
- Increase strength of screw by 1.9 times over current designs[†]

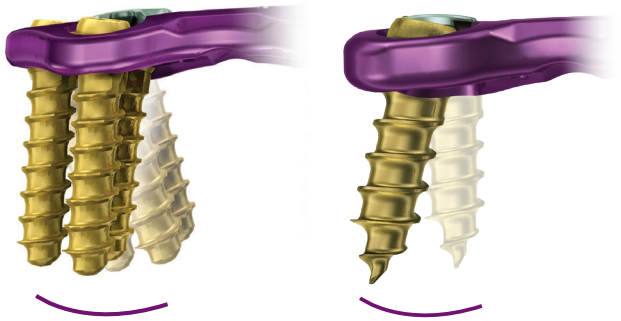
[†]Theoretically determined using the bending stress equation with the worst case circular minor diameter cross-section.



AGGRESSIVE SCREW ANGULATION

Maximized for flexibility and precision of placement

- A 29° favoured cone of angulation allows for precise placement and maximization of screw length and purchase.
- This high degree of angulation allows for flexibility in screw placement to deal with varying patient anatomies.
- Paired with the ability to actuate the locking mechanisms with the angled driver, the angulation allows the surgeon to address more challenging anatomical situations.



29° CONE FROM -2° TO 27°

29° CONE FROM -2° TO 27°

CROSSOVER PLATE SIZE OFFERINGS

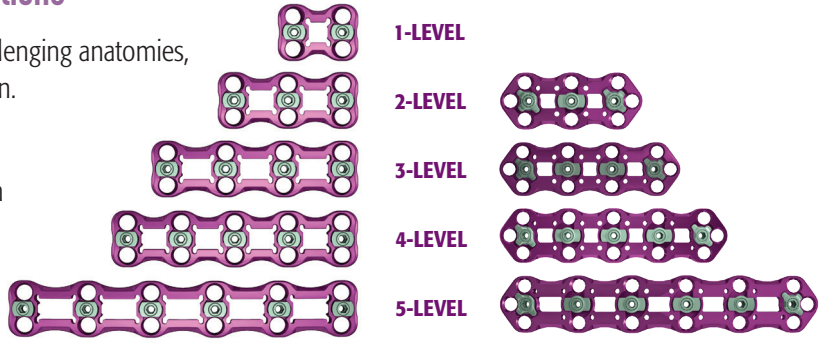
Available in one-level to five-level configurations

Crossover sizes are also included for small patients or challenging anatomies, designed to reduce the chance of adjacent-level ossification.

Degenerative plates*
- 1 to 5 levels, 20-110mm

Reconstruction plates
- 2 to 5 levels, 32-105mm

**1-level, 18mm plates are available by special order. Plate sizes are measured from end-to-end.*



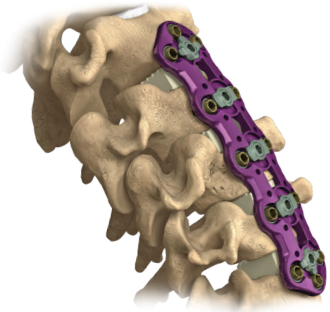
ARCHON RECONSTRUCTION OVERVIEW

ARCHON ANTERIOR CERVICAL RECONSTRUCTION

ADDITIONAL FIXATION

Designed to:

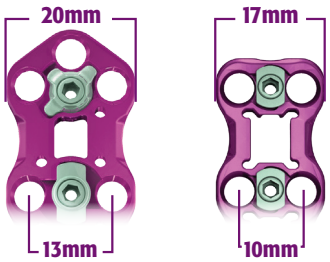
- Provide a 3rd screw fixation point at cranial/caudal ends of construct
- Decrease chance of screw pullout
- Reduce opportunity for screw breakage
- Increase rigidity of overall construct
- Decrease the risk of screw subsidence

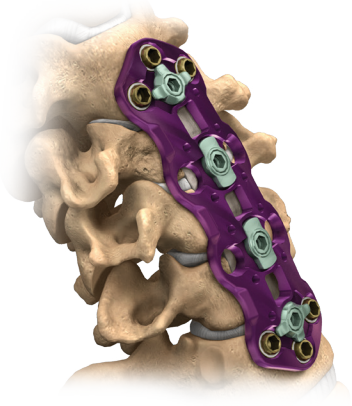


OPTIMIZED PLATE WIDTH AND GEOMETRY

Designed to:

- Increase distance between fixation points (an additional 3mm)
- Provide for larger bone wedge to reduce pullout
- Increase rigidity of overall construct
- Remain no wider than currently marketed plates





CORPECTOMIES

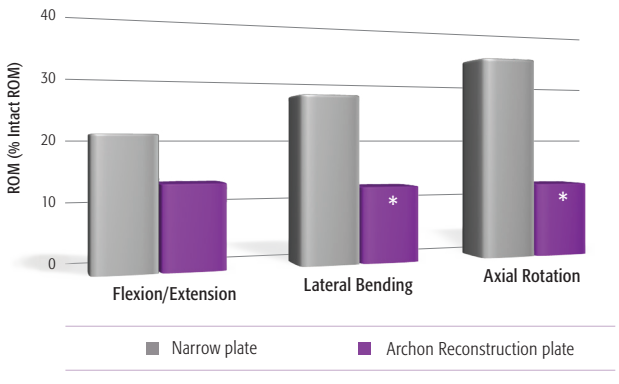
Multi-level cervical reconstruction corpectomy procedures can have up to a 71% incidence of failure and often require additional posterior fixation.[1] The particular design of the Archon Reconstruction system† is unique to this system and differentiated from all other anterior cervical reconstruction systems currently on the market.

With the addition of the Archon Reconstruction plate, additional posterior fixation may not be required in certain cases, as determined by the surgeon, to address more challenging anatomical situations. The Archon Reconstruction plate is indicated for use only in patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures.

†*Please reference the complete indications for use in the Archon Instructions for Use.*

Biomechanical Testing Results

In a multi-level ACDF construct, the Archon Reconstruction plate construct improved rigidity with respect to the narrow plate, with a reduction in motion of 40% in flexion/extension, 57% in lateral bending, and 65% in axial rotation, reaching statistical significance in lateral bending and axial rotation.[2]



*p-value < 0.05 vs. Narrow plate

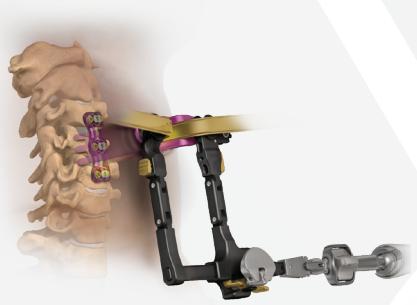
[1]*Sasso RC, Ruggiero RA Jr, Reilly TM, et al. Early reconstruction failures after multilevel cervical corpectomy. Spine 2003;28(2):140-142.*

[2]*Sawin PD, Schwartz D, Baldwin NG, et al. Biomechanical investigation of anterior-only reconstruction of the cervical spine. ISASS 14th Annual Conference; April 30 - May 2, 2014; Miami, FL.*

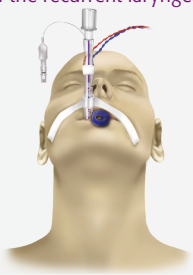
NUVASIVE PROCEDURAL INTEGRATION

NuVasive provides a suite of procedural offerings (including monitoring, access, hardware, implants, and biologics) with a goal of supplying surgeons with a single procedural source. Our intent with this combination of products is to increase surgical convenience, procedural fluidity, and surgeon confidence, and ultimately to provide a single source to satisfy a surgeon's needs.

MaXcess-C
Targeted retraction, maximized visualization.



NuVasive ET Tube
Monitoring of the recurrent laryngeal nerve (RLN).

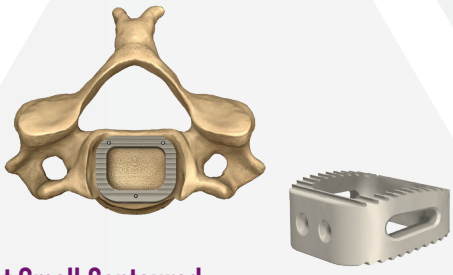


NVM5
Comprehensive nerve root monitoring, RLN, positioning, and spinal cord monitoring.

Archon Reconstruction
Designed to address complex anterior cervical pathologies

Triad CR Cortical Ring Allograft
Saline-packaged cervical ring allograft

Osteocel Pro
Designed to mimic the physiological profile of autograft, with osteogenic, osteoinductive, and osteoconductive properties. To be used with structural allograft.



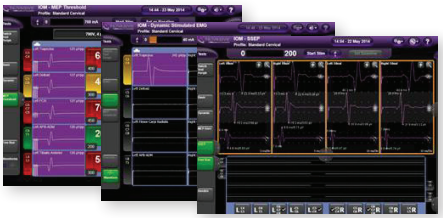
CoRoent Small Contoured
Cervical interbody designed to fit the natural shape of the disc space.

ARCHON 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

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. Optionally, apply a standard vertebral body distractor to the adjacent vertebrae in the usual manner. Perform a complete discectomy and decompression. After thorough removal of the disc material, prepare the endplates for interbody placement *(Fig. 1)*.



NVM5 – comprehensive diagnostic technology for ACDF:

- *Recurrent laryngeal nerve monitoring (EMG Endotracheal Tube)*
- *Nerve root monitoring (EMG)*
- *Anterior and posterior spinal cord monitoring (MEP, SSEP)*
- *Monitoring for potential positional deficits (SSEP)*

STEP 2:
INTERBODY PLACEMENT

Place interbody graft into the evacuated disc space *(Fig. 2)*.

Triad CR with Osteocel Pro (optional)

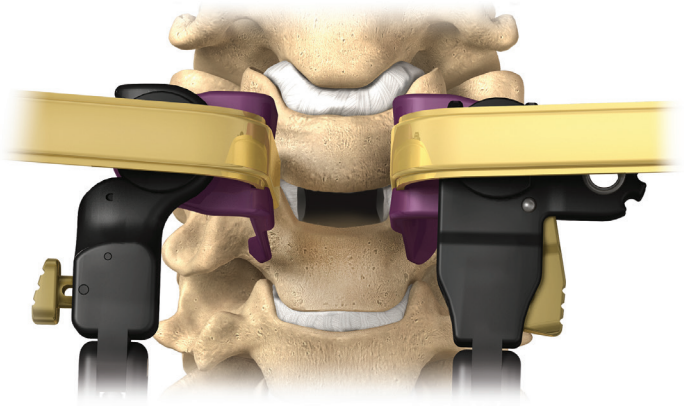
Triad CR is a saline-packed cortical allograft *(Fig. 3)*. For best results, use with Osteocel Pro, designed to mimic physiological profile of autograft with osteogenic, osteoinductive, and osteoconductive properties *(Fig. 4)*.

CoRoent Small Cervical Contoured Implants *(Fig. 5)*

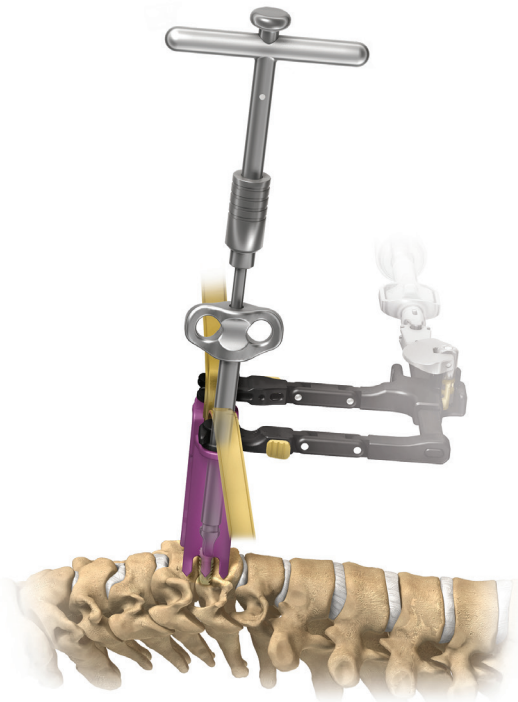
Offered in:

- 15 x 12mm Lordotic
- 17 x 14mm Lordotic
- 19 x 16mm Lordotic

Intended for use at one level from levels C2-C3 to C7-T1.



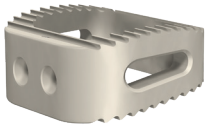
(Fig. 1)



(Fig. 2)

(Fig. 3)

(Fig. 4)



(Fig. 5)

STEP 3:
ARCHON RECONSTRUCTION: CORPECTOMY GRAFT PLACEMENT (OPTIONAL)

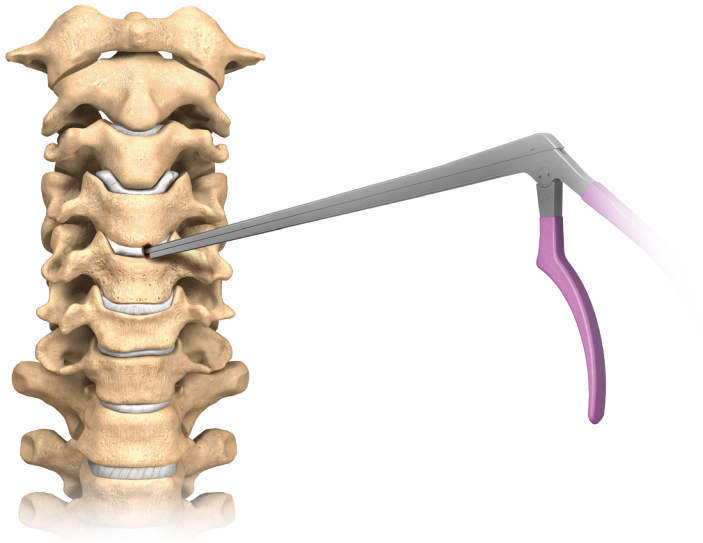
In the event a corpectomy is required:

After achieving access to the target anatomy, perform an anterior corpectomy at the appropriate spinal level(s) following a standard technique *(Figs. 6, 7)*.

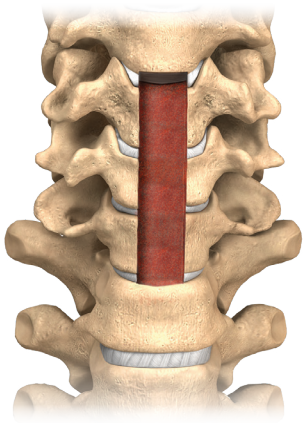
Place appropriately sized strut graft into the created corpectomy defect *(Fig. 8)*.

After graft placement, instrumentation steps are identical to those outlined in the remainder of the surgical technique for both plates outside of those differences outlined on pages 8-9.

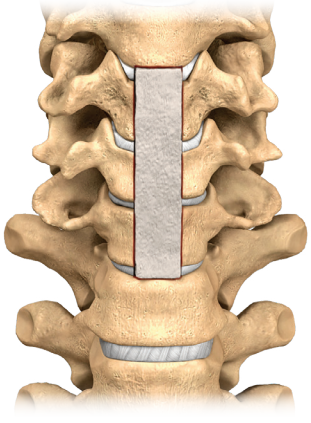
Note
The Archon Reconstruction implant system is indicated for use only in patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures.



(Fig. 6)



(Fig. 7)



(Fig. 8)

ARCHON TECHNIQUE GUIDE

STEP 4:
ARCHON RECONSTRUCTION: PREOPERATIVE AND INTRAOPERATIVE CASE PLANNING

Surgical Technique Explanation

All instrumentation is universal between the Degenerative and Reconstruction systems. Outside of the pre-op and intraoperative considerations below, instrumentation usage and technique are identical between the two systems.

Ordering Requirements

A Degenerative Implants and Instruments tray is REQUIRED when utilizing the Reconstruction set. There are no instruments specific, or in addition, to the Reconstruction set required to complete a case.

The Archon Reconstruction system is indicated for use only in patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures. Please reference the complete Instructions for Use (IFU) included in this Technique Guide.

Surgeon Discretion and Proper Preoperative Planning Steps

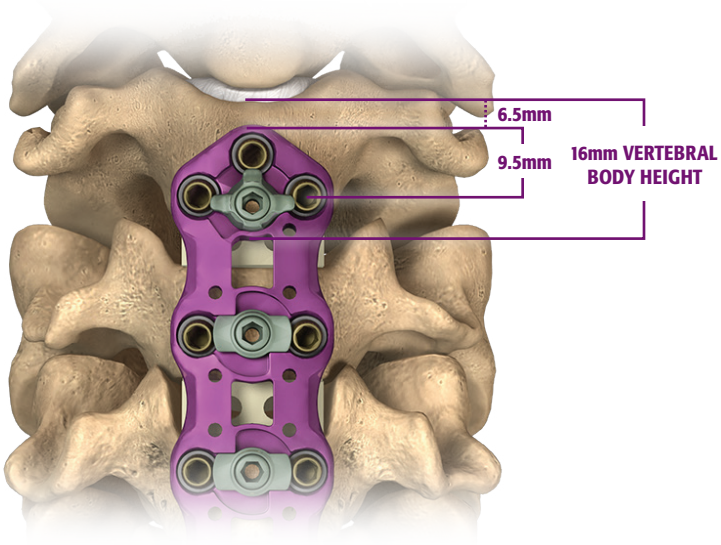
Preoperative measurements of the vertebral bodies should be taken such that the screw holes are positioned as close as possible to the inferior third of the superior vertebral body, as well as the superior third of the inferior vertebral body *(Fig. 9)*.

Vertebral body heights at the terminal ends of the construct should measure at least 16mm *(Fig. 9)*.

The length of the plate should allow the ends of the plate to be located at least 6.5mm away from the adjacent-level disc spaces to decrease the likelihood of adjacent-level ossification.

Based on endplate removal and vertebral body surfacing (gardening) techniques, additional preoperative vertebral body height may be required at the surgeon's discretion.

Please compare preoperative measurements of the vertebral bodies to the 20mm width of the Archon Reconstruction plate when considering usage of the system *(Fig. 10)*.



(Fig. 9)

(Fig. 10)

STEP 4:
ARCHON RECONSTRUCTION: PREOPERATIVE AND INTRAOPERATIVE CASE PLANNING (CONT.)

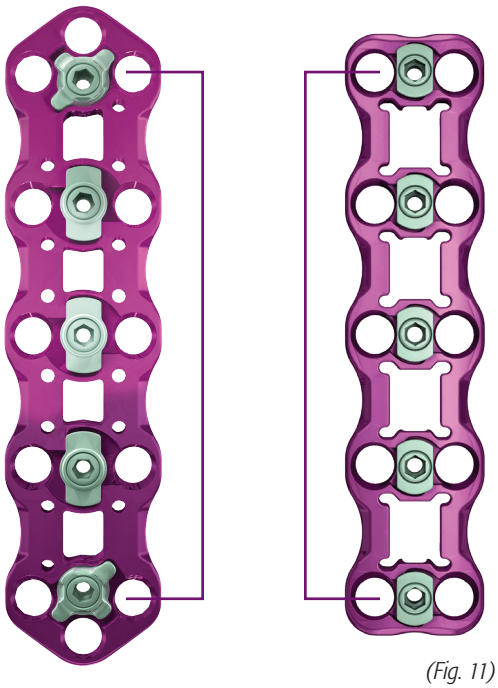
Plate Sizing

If the Reconstruction plate is not conducive to the patient's anatomy, the sizing convention used to measure the Degenerative and Reconstruction plate allows for the same size plate to be used with identical screw alignment (i.e., a 54mm Degenerative plate will match up screw hole distance with a 54mm Reconstruction plate with a 3mm decrease in plate width) (*Fig. 11*).

Screw Placement Considerations

Additional care should be taken when positioning the most inferior or superior screws of the Reconstruction plate construct. Fluoroscopy is advised, along with surgeon discretion, to position the screw's angle and length appropriately away from the adjacent-level disc space.

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



(Fig. 11)

STEP 5:
PLATE PLACEMENT

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 *(Fig. 12)*.

Proper Plate Sizing

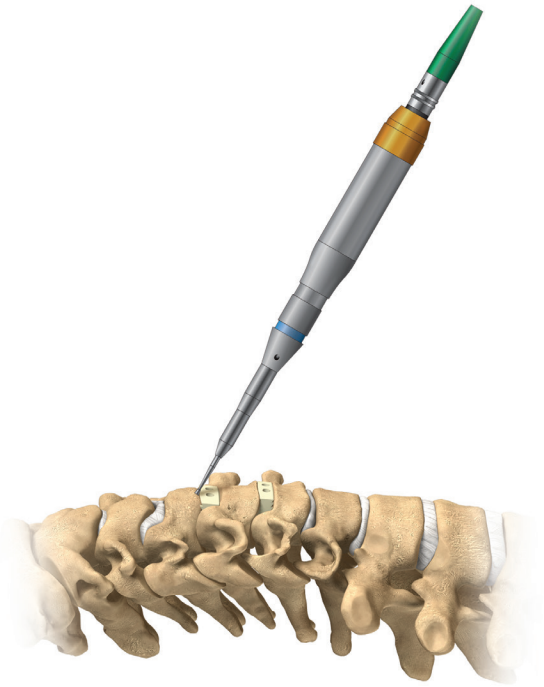
Select the proper length Archon plate such that the screw holes are positioned over the inferior-most portion of the cranial vertebral body and the superior-most portion of the caudal vertebral body *(Fig. 13)*.

Plate Holder

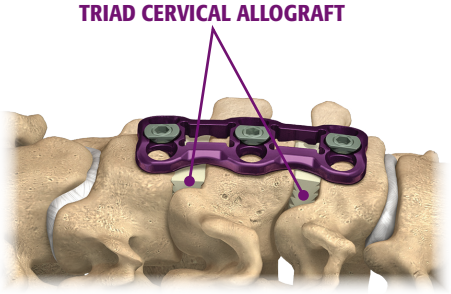
The Plate Holder is designed to engage and grip the plate within any of the available screw holes. The Plate Holder can be engaged by pulling up on the trigger, placing the distal tip of the Plate Holder into the screw hole, and releasing the trigger *(Fig. 14)*. Please note that the Plate Holder features a small anti-migration spike at its distal tip that can be engaged against bone to resist plate migration when downward force is applied.

To disengage the Plate Holder, pull up on the trigger until it disengages from the plate.

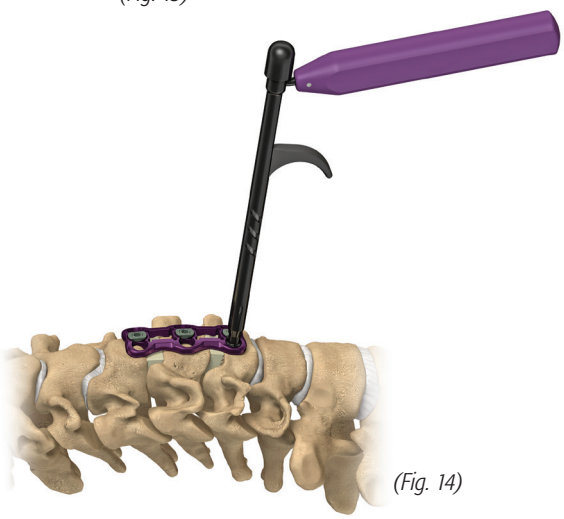
> ***Note***
> *Archon is designed to be inserted in any cranial/caudal orientation. Placement is solely based on surgeon preference. Increased angulation, graft windows, and additional plate size offerings allow the surgeon to position the plate near the endplates. Utilize guides or Self-Centering Awls to limit screw insertion angulation. If angulation is exceeded, increase plate length to accommodate.*



(Fig. 12)



(Fig. 13)



(Fig. 14)

STEP 6:
DRIVER USAGE

Engagement

To engage the selected driver to the Universal Handle, pull back on the connection mechanism, as indicated by arrows in illustration *(Fig. 15)*.

Driver Shaft Options:

The primary driver to be used with the Archon Screws is the Archon Tapered Driver Shaft (black) connected to the Archon Small Universal Handle. This driver will engage, pick up, and hold a screw using the tapered hex tip *(Fig. 16)*. Retention force of this driver is proportional to the axial force applied to the shaft when engaging the screw. This driver can also be used to turn the locking mechanism.

The Archon Straight Hex Driver Shaft (silver) should be used as a bailout option if the Archon Tapered Driver Shaft is not desired *(Fig. 17)*. Please note that the Archon Straight Hex Driver Shaft does not retain screws and should be used only for final tightening or to turn the locking mechanism.

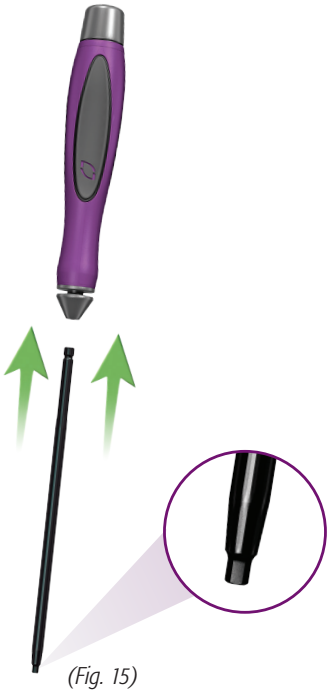
The Archon Ball-Hex Driver Shaft can be used to turn the locking mechanism when angulation is needed. Archon Ball-Hex Driver Shaft will not retain screws and is recommended only to turn the locking mechanism *(Fig. 18)*.

OPTIONAL

The Archon Large Universal Handle may be utilized for extremely dense bone applications where additional driving force is needed to implant screws. The Archon Large Universal Handle is not recommended for final tightening, for standard screw placement, or to articulate the locking mechanism as tactile feedback and screw purchase are significantly reduced.

Note

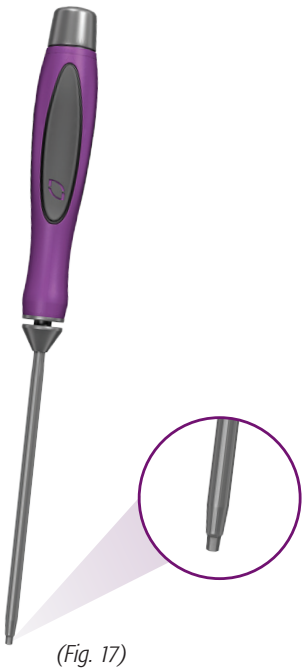
Retention force of this driver is proportional to the axial force applied to the shaft when engaging the screw. A firm downward pressure should be applied when engaging screws with the screw driver to ensure a secure fit. To disengage the drivers, use a rocking motion to detach the driver from the screws.



(Fig. 15)

(Fig. 16)

TAPERED DRIVER



(Fig. 17)

STRAIGHT HEX DRIVER

(Fig. 18)

BALL-HEX DRIVER

STEP 7:
TEMPORARY TACK PLACEMENT (OPTIONAL)

There are several options available for temporary fixation of the plate in the Archon system.

Option 1: Standard Temporary Tack

The Standard Temporary Tack should be used with the Primary Driver and should be inserted into the through hole of the locking mechanism *(Fig. 19)*.

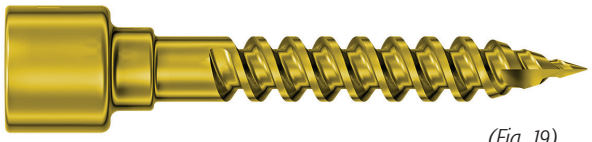
CAUTION
Caution should be taken not to over-tighten the Standard Temporary Tack once it has tightened against the plate. Please note that the Standard Temporary Tack extends 10mm into bone.

Option 2: Screw Hole Temporary Tack

The Screw Hole Temporary Tack can be inserted into either the screw hole or through hole of the locking mechanism *(Fig. 20)*. The Screw Hole Temporary Tack can be utilized with either the Primary Driver or the Archon Positive Engagement Tack Driver. Please note that the depth that the Screw Hole Temporary Tack extends into bone is 13mm when placed through the screw hole, but 10mm when placed into the through hole of the locking mechanism.

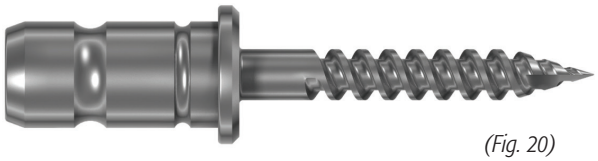
To engage the Archon Positive Engagement Tack Driver to the Screw Hole Temporary Tack, pull back on the connection mechanism, as indicated by arrows in illustration *(Fig. 21)*.

Note
Posterior surface texturing was added to the Archon plates to aid in positioning by limiting the amount of migration when a downward force is applied to the plate.



(Fig. 19)

STANDARD TEMPORARY TACK



(Fig. 20)

SCREW HOLE TEMPORARY TACK

(Fig. 21)

STEP 8:
SCREW PLACEMENT

Archon Fixed- or Variable-Angle Awl

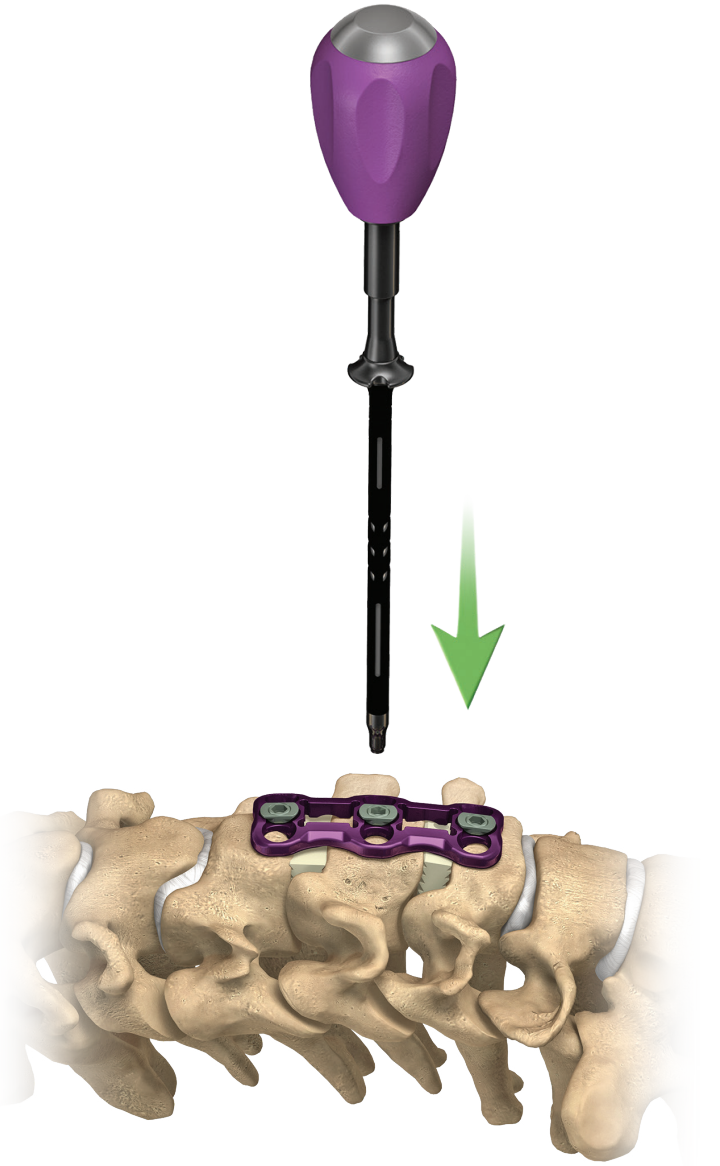
Screws are offered in either self-drilling or self-tapping configurations. It is advised that surgeons use the Archon Self-Centering Awl (either fixed or variable) prior to screw placement to ensure proper screw trajectory and final locking *(Fig. 22)*.

If Self-Centering Awls are not utilized, it is recommended that a guide be used to ensure appropriate trajectory and locking of the screws.

Note
Before utilizing any instrumentation or placing screws, verify that the locking mechanism is in the unlocked position and not covering the screw hole. If adjustment is required, utilize the standard screw driver to rotate the lock to the unlocked position.

Note
The maximum depth of the Self-Centering Awls is 10mm. If a mallet is used in combination with the Self-Centering Awls, a twisting motion can be used to disengage awl from the bone.

CAUTION
To ensure proper utility of the locking mechanism during screw placement, use the Self-Centering Awl to create a centered screw hole into the vertebral bodies.



(Fig. 22)

STEP 8:
SCREW PLACEMENT (CONT.)

Fixed- or Variable-Angle Drill Guide

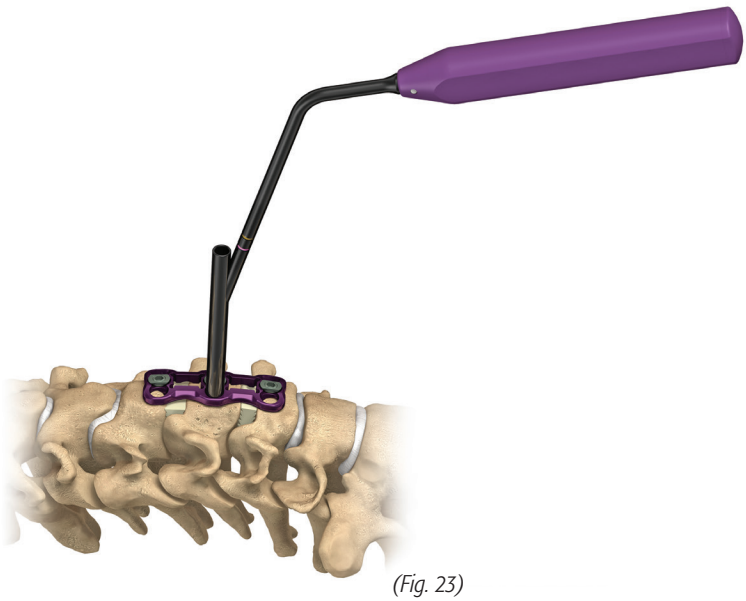
Pre-drilling of the host bone may be performed with either a Fixed-Angle or Variable-Angle Drill Guide *(Fig. 23)*. The Fixed-Angle Drill Guide prepares the bone for a 10° insertion trajectory at the cranial and caudal ends of the plate and 0° at all intermediate levels. The Variable-Angle Drill Guide prepares angle trajectories of -2° to 27° cranial or caudal, for a 29° cone.

Two drills are offered in 10 and 13mm depths. Drills can be used with the Universal Handles if hand-drilling is preferred. If power is preferred, the Drill Bits may be used with a power drill. The Drill Bits feature a stop that limits the distal tip of the drill from extending more than the stated depth of 10 or 13mm. The Drill Bits also feature an AO engagement.

Static Awl

If an awl is preferred for use with the Drill Guides, select Archon Self-Centering Awls. To use Archon Self-Centering Awl in the Drill Guides, remove the cleaning sleeve revealing the fixed shaft *(Fig. 24)*. The static awl can then be placed down the guide and will extend to a depth of 10mm.

CAUTION
Do not use static awls without a Drill Guide. For freehand screw insertion where an awl is desired, use of the static awl with a Drill Guide is required at all times to avoid incomplete or improper locking.



(Fig. 23)

(Fig. 24)

STEP 8:
SCREW PLACEMENT (CONT.)

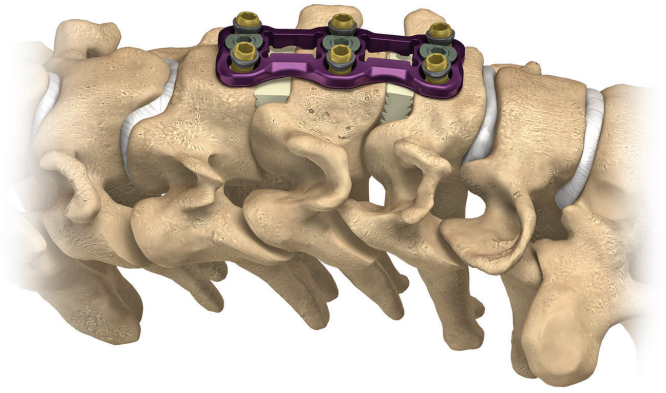
Screw Selection

Self-Drilling Screws have a self-tapping flute and feature a sharp tip for maximum efficiency in hard bone. Self-Tapping Screws feature a blunt tip to allow bi-cortical purchase, if desired for additional fixation. Caution should be used when placing bi-cortical screws to avoid perforation of the posterior cortex. All screw options offer an aggressive thread pattern and tactile feedback surface to maximize purchase and tactile feel, and are available in 11, 13, and 15mm (Self-Drilling) and 11, 13, 15, 17, and 19mm (Self-Tapping) lengths. Screw length is measured from the posterior surface of the plate (amount of screw in bone; e.g., an 11mm screw reaches a depth of 11mm in bone).

All screws are shared and cross-compatible with Archon Degenerative and Reconstruction plates.

STEP 9:
FINAL SCREW TIGHTENING

If you are inserting screws in a 2-level construct, it is recommended that screws be placed at the intermediate levels first before remaining screws are sequentially placed. It is advised that all screws be left slightly proud before final tightening for proper visualization and even plate seating against the anterior vertebral surfaces *(Fig. 25)*. The Archon plate and screws allow for lagging of the plate to the vertebral bodies. It is advised to verify that all screws are firmly seated before engaging locking mechanism.



(Fig. 25)

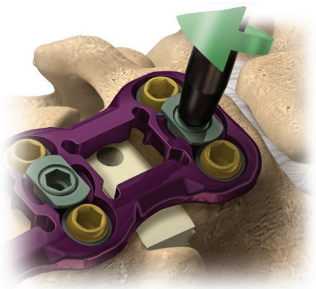
STEP 10:
FINAL TIGHTENING AND LOCKING MECHANISM

Once screws are firmly seated in place, use the driver to engage the locking mechanism. The locking mechanism is engaged by rotating the lock 90° from a 12 o'clock to a 3 o'clock position (relative to the top of the plate) *(Fig. 26)*.

Verification of locking can be made visually if the lock has reached the 3 o'clock position, or once the lock has come to a stop against the plate *(Fig. 27)*.

> ***Note***
> *If the lock does not reach the 3 o'clock position because of contact with screws, verify the screw is fully seated, and remove and reposition (if necessary) at a more shallow angle.*

UNLOCKED *(Fig. 26)*



LOCKED *(Fig. 27)*

IMPLANT REMOVAL

Screw Extraction (Optional)

In the unlikely event that an implant requires removal, the user should dissect to the anterior portion of the cervical spine where the Archon is placed. Using the driver, turn the locking covers counterclockwise 90° and remove the screws from the plate, taking care to minimize the amount of tissue or scar disruption. Any explanation resulting from failure of hardware should be reported to NuVasive immediately.

If there is difficulty in removing the screw for reasons such as stripping of screws in soft bone, utilize the Archon Screw Removal Driver to positively engage the screw and remove.

To engage the Screw Removal Driver:

Insert the driver into the screw. Rotate the knurled knob in a clockwise direction until screw has been engaged *(Fig. 28)*.

The screw can then be rotated out counterclockwise while pulling up on the Screw Removal Driver *(Fig. 28)*.

> ***Note***
> *The Screw Removal Driver cannot be used to drive screws. It is intended only for screw removal.*

Plate Removal (Optional)

Once screws have been removed the plate can be removed from the incision with forceps or the Plate Holder.

(Fig. 28)

ARCHON UNIVERSAL INSTRUMENTS

SMALL UNIVERSAL HANDLE

LARGE UNIVERSAL HANDLE

ARCHON TAPERED DRIVER SHAFT (PRIMARY)

ARCHON STRAIGHT HEX DRIVER SHAFT (RESCUE)

ARCHON BALL-HEX DRIVER SHAFT

ARCHON SCREW HOLE PLATE HOLDER

ARCHON SELF-CENTERING AWL, FIXED

ARCHON SELF-CENTERING AWL, VARIABLE

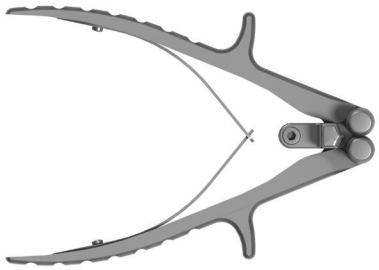
ARCHON DRILL GUIDE, FIXED

ARCHON SYSTEM

ARCHON UNIVERSAL INSTRUMENTS (CONT.)

ARCHON DRILL GUIDE, VARIABLE

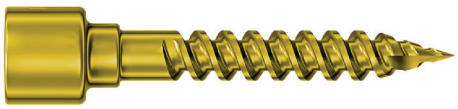
ARCHON PLATE BENDER



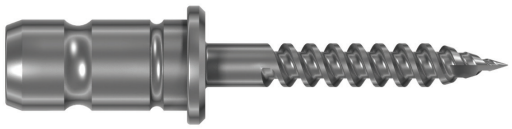
ARCHON POSITIVE ENGAGEMENT TACK DRIVER

SCREW REMOVAL DRIVER

ARCHON STANDARD TEMPORARY TACK



ARCHON SCREW HOLE TEMPORARY TACK

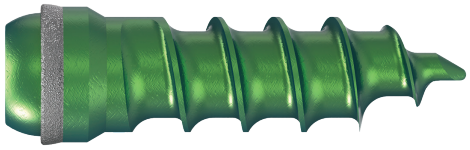


10mm DRILL BIT

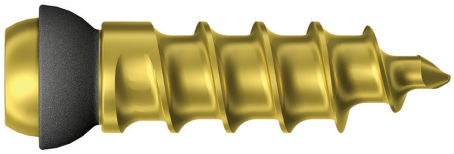
13mm DRILL BIT

ARCHON UNIVERSAL SCREWS

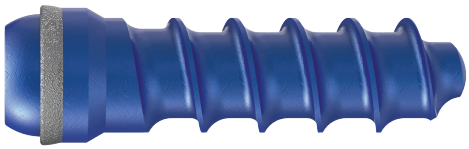
4.0mm SELF-DRILLING FIXED SCREW



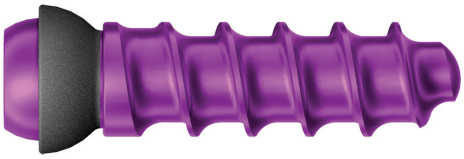
4.0mm SELF-DRILLING VARIABLE SCREW



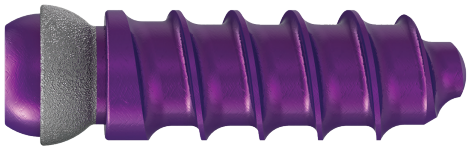
4.0mm SELF-TAPPING FIXED SCREW



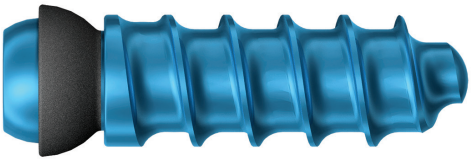
4.0mm SELF-TAPPING VARIABLE SCREW



4.5mm SELF-TAPPING RESCUE FIXED SCREW

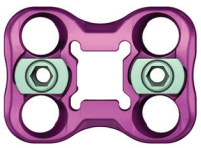


4.5mm SELF-TAPPING RESCUE VARIABLE SCREW



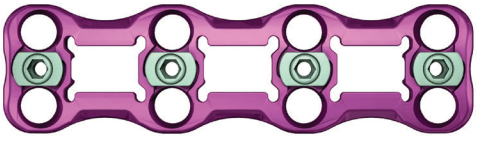
ARCHON DEGENERATIVE IMPLANTS

1-LEVEL PLATE

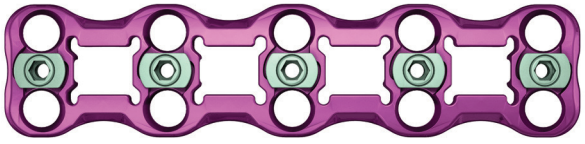


2-LEVEL PLATE

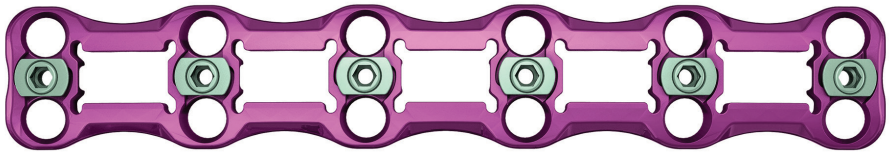
3-LEVEL PLATE



4-LEVEL PLATE



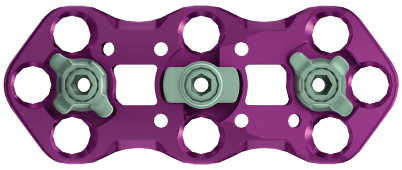
5-LEVEL PLATE



ARCHON SYSTEM

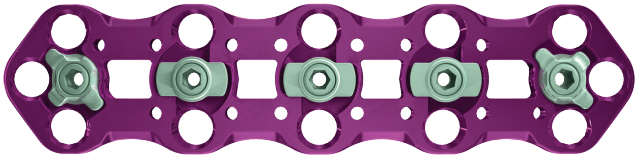
ARCHON RECONSTRUCTION IMPLANTS

2-LEVEL PLATE



3-LEVEL PLATE

4-LEVEL PLATE



5-LEVEL PLATE

ARCHON DEGENERATIVE PLATES

DESCRIPTION	CATALOG #
1-Level Archon Degenerative Plates	
1-Level Archon Plate, 20mm	8787120
1-Level Archon Plate, 22mm	8787122
1-Level Archon Plate, 24mm	8787124
1-Level Archon Plate, 26mm	8787126
1-Level Archon Plate, 28mm	8787128
1-Level Archon Plate, 30mm	8787130
1-Level Archon Plate, 32mm	8787132
1-Level Archon Plate, 34mm	8787134
*1-Level Archon Plate,18mm (Special Order)	8787118
2-Level Archon Degenerative Plates	
2-Level Archon Plate, 32mm	8787232
2-Level Archon Plate, 34mm	8787234
2-Level Archon Plate, 36mm	8787236
2-Level Archon Plate, 38mm	8787238
2-Level Archon Plate, 40mm	8787240
2-Level Archon Plate, 42mm	8787242
2-Level Archon Plate, 44mm	8787244
2-Level Archon Plate, 46mm	8787246
2-Level Archon Plate, 48mm	8787248
2-Level Archon Plate, 50mm	8787250
2-Level Archon Plate, 52mm	8787252
2-Level Archon Plate, 54mm	8787254
3-Level Archon Degenerative Plates	
3-Level Archon Plate, 50mm	8787350
3-Level Archon Plate, 52mm	8787352
3-Level Archon Plate, 54mm	8787354
3-Level Archon Plate, 56mm	8787356
3-Level Archon Plate, 58mm	8787358
3-Level Archon Plate, 60mm	8787360
3-Level Archon Plate, 62mm	8787362
3-Level Archon Plate, 64mm	8787364
3-Level Archon Plate, 66mm	8787366
3-Level Archon Plate, 68mm	8787368
4-Level Archon Degenerative Plates	
4-Level Archon Plate, 66mm	8787466
4-Level Archon Plate, 68mm	8787468
4-Level Archon Plate, 70mm	8787470
4-Level Archon Plate, 74mm	8787474
4-Level Archon Plate, 78mm	8787478
4-Level Archon Plate, 82mm	8787482
4-Level Archon Plate, 86mm	8787486
4-Level Archon Plate, 90mm	8787490

ARCHON DEGENERATIVE PLATES (CONT.)

DESCRIPTION	CATALOG #
5-Level Archon Degenerative Plates	
5-Level Archon Plate, 95mm	8787595
5-Level Archon Plate, 100mm	8787500
5-Level Archon Plate, 105mm	8787505
5-Level Archon Plate, 110mm	8787510
Archon IFU	9401672

ARCHON RECONSTRUCTION PLATES

DESCRIPTION	CATALOG #
2-Level Archon Reconstruction Plates	
2-Level Archon Plate, 32mm Reconstruction	8687232
2-Level Archon Plate, 34mm Reconstruction	8687234
2-Level Archon Plate, 36mm Reconstruction	8687236
2-Level Archon Plate, 38mm Reconstruction	8687238
2-Level Archon Plate, 40mm Reconstruction	8687240
2-Level Archon Plate, 42mm Reconstruction	8687242
2-Level Archon Plate, 44mm Reconstruction	8687244
2-Level Archon Plate, 46mm Reconstruction	8687246
2-Level Archon Plate, 48mm Reconstruction	8687248
2-Level Archon Plate, 50mm Reconstruction	8687250
2-Level Archon Plate, 52mm Reconstruction	8687252
2-Level Archon Plate, 54mm Reconstruction	8687254
3-Level Archon Reconstruction Plates	
3-Level Archon Plate, 50mm Reconstruction	8687350
3-Level Archon Plate, 52mm Reconstruction	8687352
3-Level Archon Plate, 54mm Reconstruction	8687354
3-Level Archon Plate, 56mm Reconstruction	8687356
3-Level Archon Plate, 58mm Reconstruction	8687358
3-Level Archon Plate, 60mm Reconstruction	8687360
3-Level Archon Plate, 62mm Reconstruction	8687362
3-Level Archon Plate, 64mm Reconstruction	8687364
3-Level Archon Plate, 66mm Reconstruction	8687366
3-Level Archon Plate, 68mm Reconstruction	8687368
4-Level Archon Reconstruction Plates	
4-Level Archon Plate, 66mm Reconstruction	8687466
4-Level Archon Plate, 68mm Reconstruction	8687468
4-Level Archon Plate, 70mm Reconstruction	8687470
4-Level Archon Plate, 72mm Reconstruction	8687472
4-Level Archon Plate, 74mm Reconstruction	8687474
4-Level Archon Plate, 76mm Reconstruction	8687476
4-Level Archon Plate, 78mm Reconstruction	8687478
4-Level Archon Plate, 80mm Reconstruction	8687480

CATALOG

ARCHON RECONSTRUCTION PLATES (CONT.)

DESCRIPTION	CATALOG #
4-Level Archon Reconstruction Plates (cont.)	
4-Level Archon Plate, 82mm Reconstruction	8687482
4-Level Archon Plate, 84mm Reconstruction	8687484
4-Level Archon Plate, 86mm Reconstruction	8687486
4-Level Archon Plate, 88mm Reconstruction	8687488
4-Level Archon Plate, 90mm Reconstruction	8687490
5-Level Archon Reconstruction Plates	
5-Level Archon Plate, 87mm Reconstruction	8687587
5-Level Archon Plate, 90mm Reconstruction	8687590
5-Level Archon Plate, 93mm Reconstruction	8687593
5-Level Archon Plate, 96mm Reconstruction	8687596
5-Level Archon Plate, 99mm Reconstruction	8687599
5-Level Archon Plate, 102mm Reconstruction	8687502
5-Level Archon Plate, 105mm Reconstruction	8687505

ARCHON UNIVERSAL SCREWS

DESCRIPTION	CATALOG #
Self-Drilling Screws (Variable, 4mm)	
4 x 11mm Self-Drilling Variable Screw	8780211
4 x 13mm Self-Drilling Variable Screw	8780213
4 x 15mm Self-Drilling Variable Screw	8780215
Self-Drilling Screws (Fixed, 4mm)	
4 x 11mm Self-Drilling Fixed Screw	8780711
4 x 13mm Self-Drilling Fixed Screw	8780713
4 x 15mm Self-Drilling Fixed Screw	8780715
Self-Tapping Screws (Variable, 4mm)	
4 x 11mm Self-Tapping Variable Screw	8780411
4 x 13mm Self-Tapping Variable Screw	8780413
4 x 15mm Self-Tapping Variable Screw	8780415
4 x 17mm Self-Tapping Variable Screw	8780417
4 x 19mm Self-Tapping Variable Screw	8780419
Self-Tapping Screws (Fixed, 4mm)	
4 x 11mm Self-Tapping Fixed Screw	8780811
4 x 13mm Self-Tapping Fixed Screw	8780813
4 x 15mm Self-Tapping Fixed Screw	8780815
4 x 17mm Self-Tapping Fixed Screw	8780817
4 x 19mm Self-Tapping Fixed Screw	8780819

ARCHON UNIVERSAL SCREWS (CONT.)

DESCRIPTION	CATALOG #
Self-Tapping Screws (Variable, 4.5mm)	
4.5 x 11mm Self-Tapping Rescue Variable Screw	8780911
4.5 x 13mm Self-Tapping Rescue Variable Screw	8780913
4.5 x 15mm Self-Tapping Rescue Variable Screw	8780915
4.5 x 17mm Self-Tapping Rescue Variable Screw	8780917
4.5 x 19mm Self-Tapping Rescue Variable Screw	8780919
Self-Tapping Screws (Fixed, 4.5mm)	
4.5 x 11mm Self-Tapping Rescue Fixed Screw	8780511
4.5 x 13mm Self-Tapping Rescue Fixed Screw	8780513
4.5 x 15mm Self-Tapping Rescue Fixed Screw	8780515
4.5 x 17mm Self-Tapping Rescue Fixed Screw	8780517
4.5 x 19mm Self-Tapping Rescue Fixed Screw	8780519

ARCHON UNIVERSAL INSTRUMENTS

DESCRIPTION	CATALOG #
Small Universal Handle	8789700
Large Universal Handle	8789710
Archon Straight Hex Driver Shaft (Rescue)	8789702
Archon Tapered Driver Shaft (Primary)	8789701
Archon Ball-Hex Driver Shaft	8789705
Archon Screw Hole Plate Holder	D8789732
Archon Self-Centering Awl, Fixed	D8789703
Archon Self-Centering Awl, Variable	D8789704
Archon Drill Guide, Fixed	8789724
Archon Drill Guide, Variable	8789725
Archon Plate Bender	8789744
Archon Positive Engagement Tack Driver	8789730
Screw Removal Driver	8789790

ARCHON UNIVERSAL TEMPORARY FIXATION PINS

DESCRIPTION	CATALOG #
Archon Standard Temporary Tack	8789731
Archon Screw Hole Temporary Tack	8789733

ARCHON UNIVERSAL DRILL BITS

DESCRIPTION	CATALOG #
10mm Drill Bit	7812025
13mm Drill Bit	1015625

INSTRUCTIONS FOR USE

DESCRIPTION

The *NuVasive Archon Anterior Cervical Plate 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-6A1-4V ELI) conforming to ASTM F136 or ISO 5832-3.

INDICATIONS FOR USE

The *NuVasive Archon Anterior Cervical Plate 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 the 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. Additionally, the three-hole version of the implant system may be appropriate only for patients with large vertebral bodies, and is particularly suited for use following corpectomies for the treatment of tumors and burst fractures.

WARNING: The *NuVasive Archon Anterior Cervical Plate 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 Archon Anterior Cervical Plate 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. 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: 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 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.

CAUTION: 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.

Implant Selection: The *NuVasive Archon Anterior Cervical Plate 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.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of patient anatomy may present limitations on the size of the chosen implants.

Delayed Union or Nonunion: The *NuVasive Archon Anterior Cervical Plate 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.

Mixed Metals: The *NuVasive Archon Anterior Cervical Plate System* is available in titanium alloy. It is imperative that this metal does not come into contact in vivo with other dissimilar metals. Accelerated corrosion may occur when two dissimilar metals are in contact within the body environment.

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.

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 Archon Anterior Cervical Plate 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: Bending of the *NuVasive Archon Anterior Cervical Plate 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 slots and 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 slots or 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.

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

Compatibility: Do not use the *Archon Anterior Cervical Plate 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.

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.

NOTES

NOTES

To order, please contact your NuVasive Sales Consultant or Customer Service Representative today at:
NuVasive, Inc. 7475 Lusk Blvd., San Diego, CA 92121 USA • phone: 800-475-9131 fax: 800-475-9134
EC REP **NuVasive Netherlands B.V.** Jachthavenweg 109A, 1081 KM Amsterdam, The Netherlands • phone: +31 20 72 33 000

nuvasive.com

CE 2797