



# Trinica<sup>®</sup> Select Anterior Cervical Plate System

Surgical Technique



A New Twist to Anterior Cervical Plates



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**Surgical Technique**  
**Trinica Select**  
**Anterior Cervical Plate**  
**System**

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## PATIENT INDICATIONS AND PREPARATION

### Indications

The *Trinica Select* Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine at levels C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.

**Warning: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.**

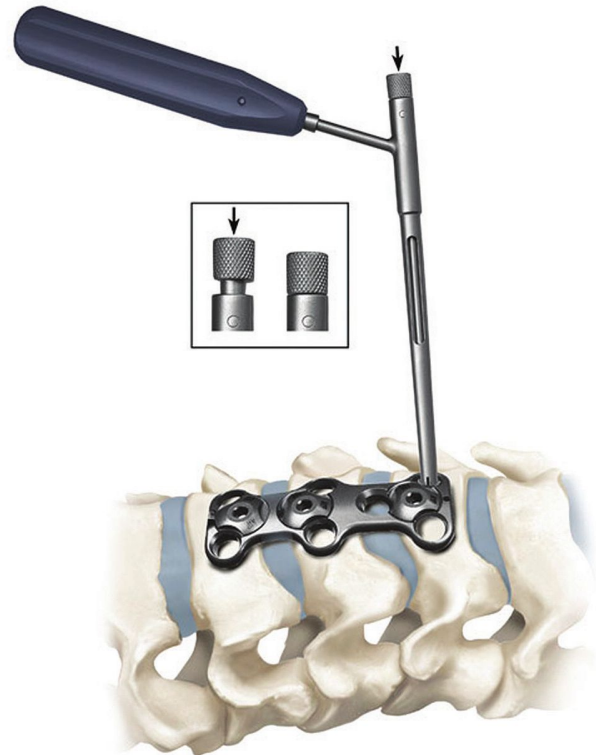
### Patient Positioning and Preparation

Prepare the patient for an anterior cervical fusion using standard surgical technique.

## Plate Selection

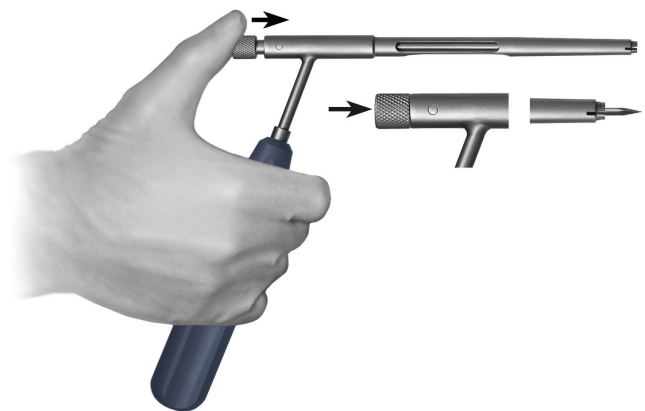
**Overview:** Select the appropriately-sized plate for fixation to the vertebral bodies. A properly-sized plate will bridge the affected segment(s) without overhanging into the adjacent disc space.

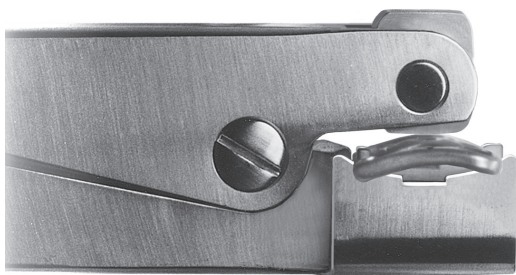
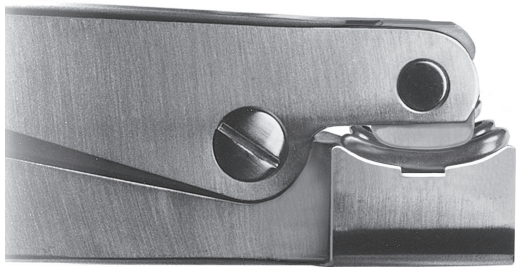
**Plate Holder:** A Plate Holder is included in the *Trinica Select* instrument set to facilitate plate selection and initial placement. It may be used to stabilize the plate during the insertion of the Temporary Fixation Pins or initial Bone Screws.



To use the Plate Holder, snap the tip into any of the bone screw holes. Rotate the plate as necessary to achieve proper orientation. Place the plate into position over the affected disc space and press down on the top cap of the Plate Holder to extend the bone pick.

To release the Plate Holder, retract the bone pick by pulling back on the top cap and tilt the Plate Holder toward the midline or center of the plate to free the tip from the plate.





### Plate Bending (Optional)

**Overview:** All plates in the *Trinica Select* Anterior Cervical Plate System are prelordosed to match the curvature of the cervical spine. A Plate Bender is also provided in the *Trinica Select* instrument set if additional plate contouring is desired.

**Increase Lordosis:** To increase the bend of the plate, insert the plate in the Plate Bender such that the concave surface of the plate is resting against the anvil and the hammer is positioned such that the convex portion is facing the plate. Once positioned, squeeze the pliers-style handle to obtain the desired plate curvature.

**Decrease Lordosis:** To decrease the bend of the plate, insert the plate in the Plate Bender such that the convex bottom surface of the plate is resting against the anvil and the hammer is positioned such that the concave portion is facing the plate. Once positioned, squeeze the pliers-style handle to obtain the desired plate curvature.

*Note: Plate Bending can significantly weaken the plate. Avoid plate bending when possible.*



### Temporary Fixation Pins (Optional)

**Overview:** The *Trinica Select* Anterior Cervical Plate System is equipped with Temporary Fixation Pins to provide short-term stability during plate placement and initial fixation. The Temporary Fixation Pins may be placed through the bone screw holes, the center of the locking cap or through the fixation hole on the *Trinica Select* plate.

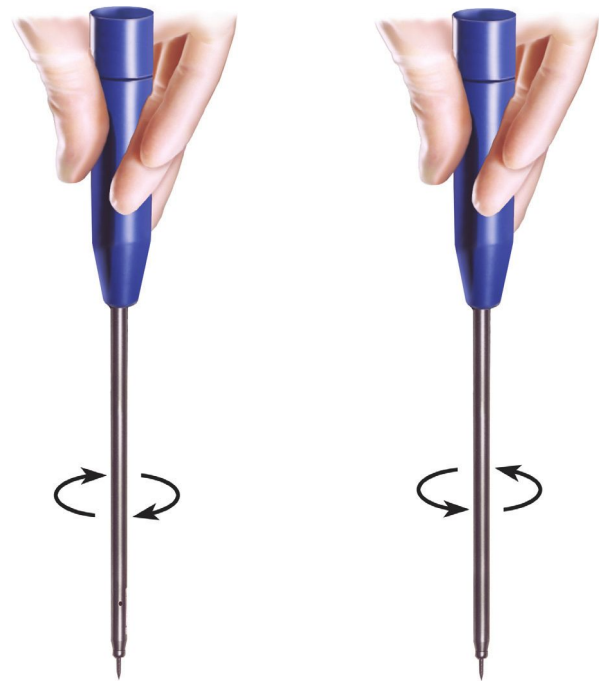
## Temporary Fixation Pins

**Pin Insertion:** To use the Temporary Fixation Pins, insert a pin into the Pin Inserter and place it in the desired plate hole. Rotate the Pin Inserter clockwise to advance the pin into the vertebra.

**Pin Removal:** To remove the Temporary Fixation Pins, use the Pin Inserter/Remover to engage the top portion of the pin and rotate counterclockwise to remove the pin.

*Note: The Temporary Fixation Pins are intended for single use only and should be disposed of after one use.*

*Note: Temporary Fixation Pins must be removed from the surgical site prior to closure.*



Pin Insertion

Pin Removal

## Screw Selection: Self-Tapping vs. Self-Drilling

The *Trinica Select* self-drilling screws seek to provide the surgeon the option to reduce the amount of instruments used in a *Trinica Select* Anterior Cervical Plate surgery. Reducing the amount of instruments has the potential to reduce the amount of retraction and time to implant a cervical plate.

The difference between the self-drilling and self-tapping screws is in the tip of the screw. The cutting flute design on the self-drilling screws eliminates the need for a drill or awl to penetrate the cortex of the vertebral body.

Fixed self-drilling screws can be identified by a gold anodized head and variable self-drilling screws can be identified by a green anodized head. The self-tapping screws are completely anodized.

*Note: The trajectory of the screws must be considered when using the free hand approach to placing self-drilling screws. It is recommended that the appropriate All-Through-One Guide Tube (variable or fixed angle) be used when placing self-drilling screws. If the angle of the screw trajectory is too great, it may not be possible to fully seat the screw within the plate and will cause difficulty when closing the Trinica Select locking mechanism.*



Self-Drilling  
Cutting Flute



Self-Tapping  
Blunt Tip



### Screw Selection – Alternative Screws

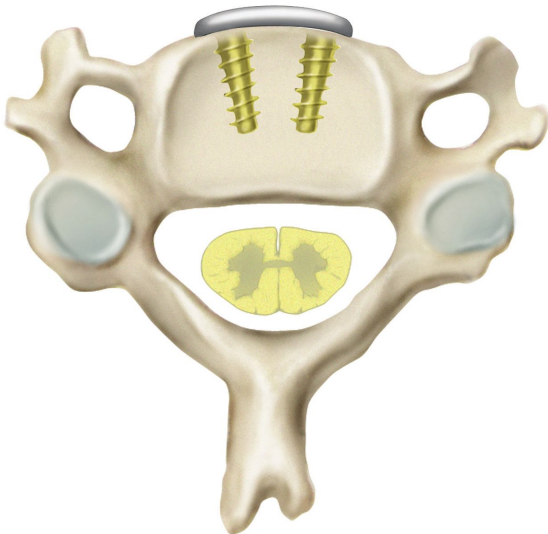
The *Trinica Select* System also provides alternative screw options for situations in which a 4.2mm Fixed or Variable Screw is not optimal.

#### Self-Tapping 4.6mm Fixed Screw (Blue)

A 4.6mm Fixed Bone Screw is available for situations where bony purchase has been lost with a 4.2mm Fixed Bone Screw. Use the screw in a manner similar to the 4.2mm Fixed Bone Screw, but without using a tap.

#### Self-Tapping 4.6mm Variable Screw (Magenta)

A 4.6mm Variable Bone Screw is available for situations where bony purchase has been lost with a 4.2mm Variable Bone Screw. Use the screw in a manner similar to the 4.2mm Variable Bone Screw, but without using a tap.



### Fixed Screw Placement (Drill Guide)

**Overview:** Fixed angle hole preparation can be achieved using the Fixed Angle Drill Guide (blue handle). The Fixed Angle Drill Guide is designed to place the bone screws perpendicular to the face of vertebral bodies. Medial-laterally, the bone screw preparation holes are placed with a convergent angle of  $6^\circ$  per side ( $12^\circ$  total angle) for the *Trinica Select* system.



## Fixed Screw Placement (Drill Guide) Continued

**Placement/Hole Preparation:** To prepare a bone screw insertion hole using the Fixed Angle Drill Guide, insert the tip of the Drill Guide into the desired screw pocket in the plate. Once positioned, insert the standard Drill into the Drill Guide and advance the Drill using a clockwise rotational motion until the positive stop on the Drill comes into contact with the Fixed Angle Drill Guide. When complete, remove the Drill from the Drill Guide.

*Note: The Drill is intended for single patient use only and should be disposed of after use.*



**Tapping (Optional):** A Tap is provided in the *Trinica Select* instrument set to create threads in bone. To use the Tap, position the Drill Guide over the previously drilled hole. Insert the Tap into the Drill Guide and advance using a clockwise rotational motion until the positive stop comes into contact with the Fixed Angle Drill Guide. Once contact is obtained, rotate the Tap counterclockwise until it is free of the bone and remove from the Drill Guide.

**Caution: Do not continue to rotate the Tap once the positive stop contacts the top of the Drill Guide. Continued rotation of the Tap may strip the bone threads.**

After the bone screw hole has been prepared, remove the Fixed Angle Drill Guide and place the bone screw as outlined. Repeat the bone screw preparation placement procedure for all remaining screw sites.



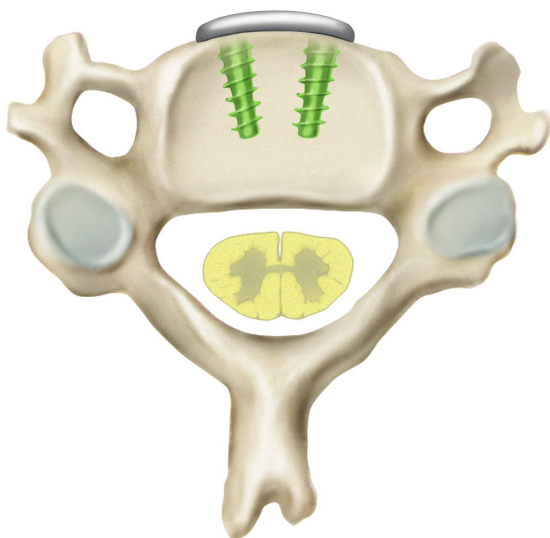


### Alternative: Fixed Screw Placement with Awl

**Overview:** As an alternative to the use of the Fixed Angle Drill Guide, Drill and Tap, a Fixed Angle Awl is included in the *Trinica Select* instrument set.

**Placement/Hole Preparation:** To use the Awl, place the tip into the desired screw pocket in the plate. Once inserted, twist the handle back and forth while applying downward pressure to the handle. Continue advancing the tip of the Awl until reaching the positive stop.

Remove the Fixed Angle Awl from the bone screw pocket and place the bone screw as outlined on page 12. Repeat the bone screw preparation and placement procedure outlined above for all remaining bone screw preparation sites.



### Alternative: Variable Screw Placement with Drill Guide

**Overview:** A Variable Angle Guide (green handle) is included in the *Trinica Select* instrument set. The Variable Angle Guide is designed to allow varied placement of the bone screws. This guide allows for screw placement at a conical angle of  $\pm 12^\circ$  (superior/inferior) from the fixed reference point.

### Alternative: Variable Screw Placement with Drill Guide Continued

**Placement/Hole Preparation:** To use the Variable Angle Drill Guide, insert the tip of the Drill Guide into the screw pocket and position the guide at the desired angle. Once positioned, insert the standard Drill into the Drill Guide. Advance the Drill using a clockwise rotational motion until the positive stop on the Drill comes into contact with the Variable Angle Drill Guide. When complete, remove the Drill from the Drill Guide.

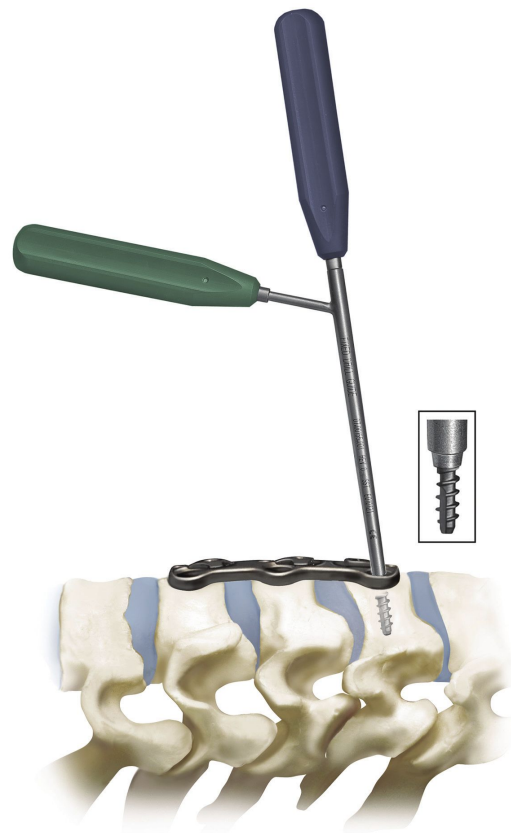
*Note: The Drill is intended for single patient use only and should be disposed of after use.*



**Tapping (Optional):** A Tap is provided in the *Trinica Select* instrument set to create threads in bone. To use the Tap, position the Drill Guide over the previously drilled hole. Insert the Tap into the Drill Guide and advance using a clockwise rotational motion until the positive stop comes into contact with the Variable Angle Drill Guide. Once contact is obtained, rotate the Tap counterclockwise until it is free of the bone and remove from the Drill Guide.

**Caution: Do not continue to rotate the Tap once the positive stop contacts the top of the Drill Guide. Continued rotation of the Tap may strip the bone threads.**

After the bone screw hole has been prepared, remove the Variable Angle Drill Guide and place the bone screw as outlined on page 12. Repeat the bone screw preparation and placement procedure outlined above for all remaining bone screw preparation sites.





## Screw Insertion

**Insertion:** Select the desired screw type and length. Insert the tip of the Hex Driver into the socket of the bone screw using downward pressure on the driver to secure the screw to the driver tip. Insert the screw in the desired bone site and rotate the Hex Driver clockwise to advance the screw until it is firmly seated.

**Caution:** Do not continue to advance the bone screw once the screw is firmly seated in the plate. Continued screw tightening may strip the bone threads.

## Securing the Locking Caps

**Overview:** The *Secure-Twist*® anti-migration caps are pre-installed and positioned on the plate to allow insertion of the bone screws. Each cap will retain the bone screws within the plate when the cap is rotated to a secure position.

**Placement/Positioning:** Once all bone screws have been placed, use the Hex Driver to rotate the *Secure-Twist* cap clockwise approximately 60° to secure it properly. The cap will tighten and you will be able to confirm visually the cap covering the screws.

**Optional:** The Ball-End Hex Driver (green handle) may be used in situations where the Standard Hex Driver cannot be inserted directly into the locking cap. This situation may exist at the plate extremes due to interference with anatomical structures or retraction limitations. The Ball-End Driver allows the tip to be inserted into the locking cap at angles up to 25° off the central axis.



## Trinica Select Single Barrel All-Through-One (ATO) Guide Tube



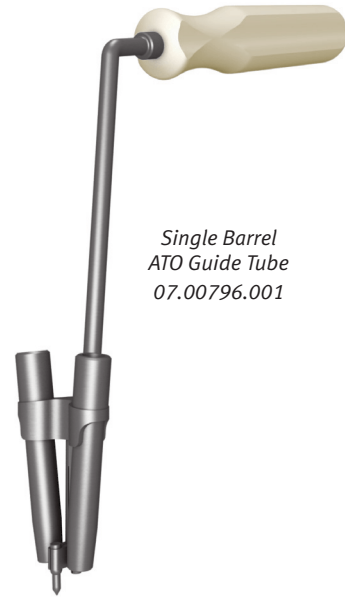
2.3mm Drill Bit – 07.00787.002



Tap – 07.00787.001



Hex Driver – 07.00788.001



Single Barrel  
ATO Guide Tube  
07.00796.001



### Plate Selection

Select the appropriate sized *Trinica Select* plate for fixation to the vertebral bodies. A properly sized plate will bridge the affected segment(s) without overhanging into the adjacent disc space(s). Ensure plate is positioned on midline of vertebral bodies.

A Plate Holder is included in the *Trinica Select* instrument set to facilitate plate selection and initial placement. It may be used to stabilize the plate during the insertion of the Temporary Fixation Pins or initial Bone Screws.

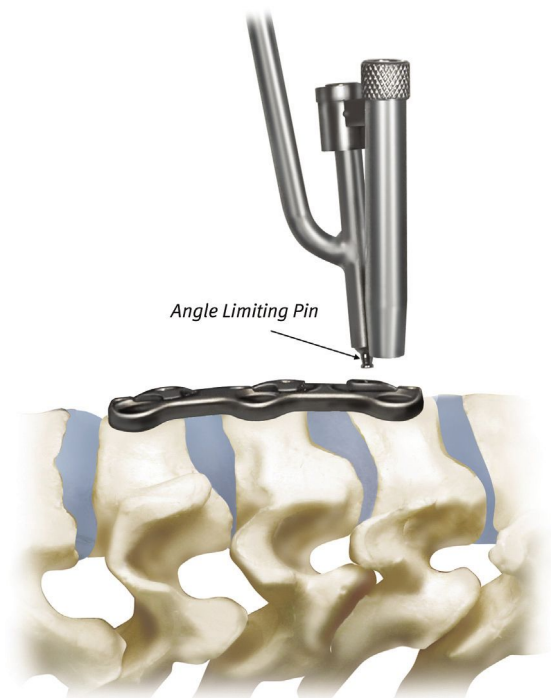
## Positioning the Plate

Place the *Trinica Select* plate in position over the affected disc space(s).



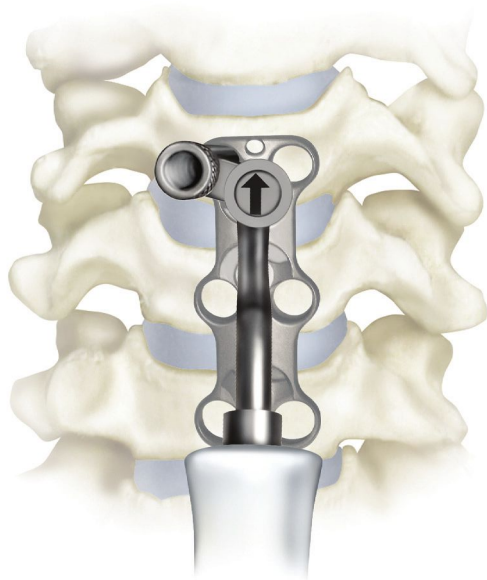
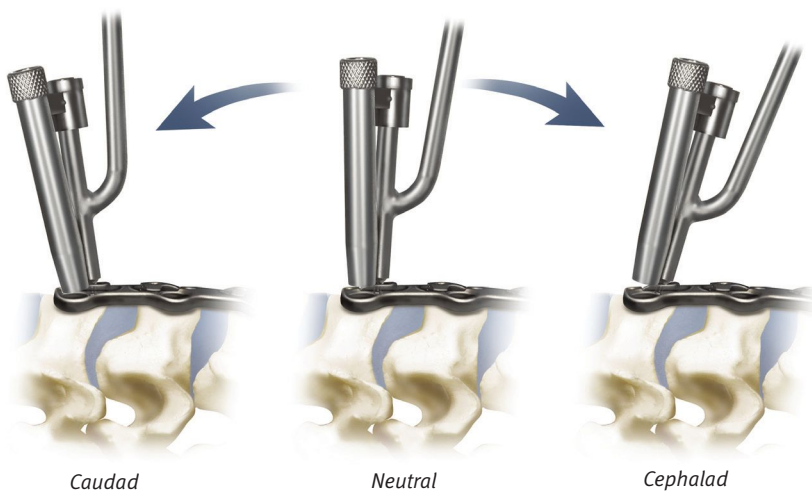
## Positioning the Guide Tube

Place the Angle-Limiting Pin of the Single Barrel ATO Guide Tube into the hex socket of the locking cap.



Tilt the Guide Tube caudad/cephalad until the desired drill angle is achieved. the Angle-Limiting Pin limits the angle to +/- 12°.

*Note: Once the Angle-Limiting Pin has been engaged into the hex socket of the Locking Cap and cephalad/caudad motion has stopped, refrain from placing undue force on the angle-limiting feature of the Single Barrel Guide.*

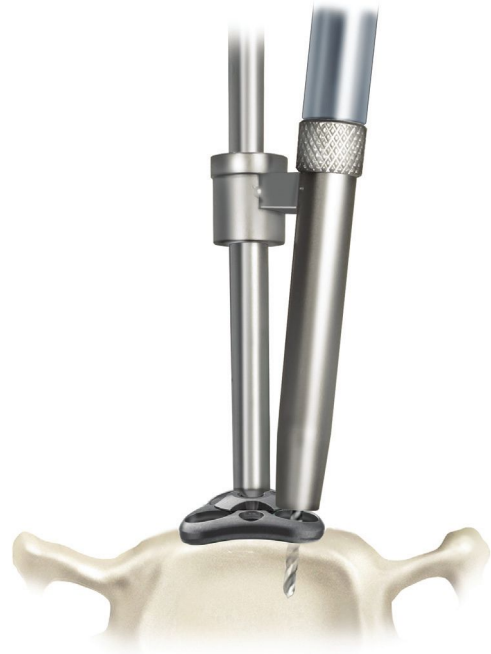


During use , the handle shaft of the Single Barrel ATO Guide Tube should be aligned over the midline of the plate, as shown, to avoid drilling or placing screws too far medially or laterally.



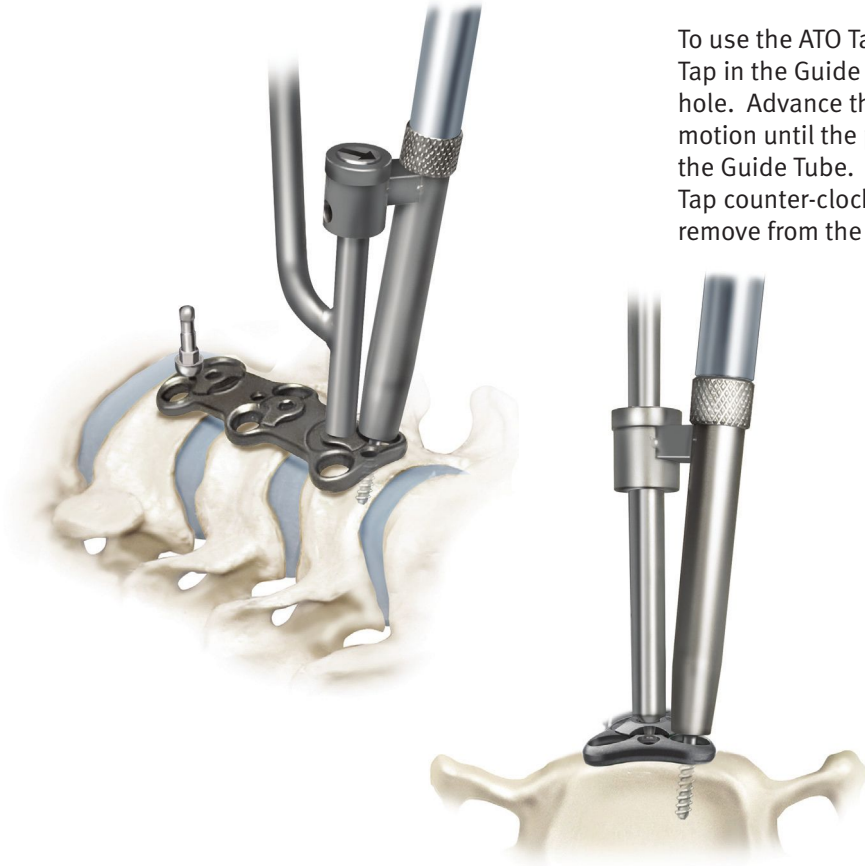
## Hole Placement/Preparation

Attach ONLY the ATO Drill Bit (Part# 07.00787.002) to either the manual drill handle (supplied in the *Trinica Select* Instrument Set) or a compatible device with an AO connector. Only use the ATO Drill Bit with the Single Barrel ATO Guide Tube. Insert ATO Drill Bit into the ATO Guide Tube and with minor downward pressure, advance the ATO Drill Bit in a clockwise rotational motion until the positive stop on the ATO Drill Bit comes into contact with the ATO Guide Tube. Continue to rotate the ATO Drill Bit in a clockwise rotation as you remove the ATO Drill Bit from the ATO Guide Tube.



### Tapping (Optional)

To use the ATO Tap (Part #07.00787.001), position the Tap in the Guide Tube and into the previously drilled hole. Advance the ATO Tap using a clockwise rotational motion until the positive stop comes into contact with the Guide Tube. Once contact is obtained, rotate the Tap counter-clockwise until it is free of the bone and remove from the Guide Tube.



### Screw Placement

Identify the appropriate style screw, Self-Drilling or Self-Tapping (see pages 7–8). Once a screw style has been determined, identify the correct screw type, Fixed or Variable, and length. Insert the tip of the ATO Hex Driver into the socket of the screw using downward pressure on the driver to secure the screw to the driver tip.

With the screw attached to the ATO Hex Driver, position the ATO Hex Driver in the Guide Tube. Insert the screw tip in the previously drilled and/or tapped hole. Rotate the ATO Hex Driver clockwise to advance the screw until it is firmly seated. Repeat process for second screw. Final adjustments may be needed once the Guide Tube has been removed.

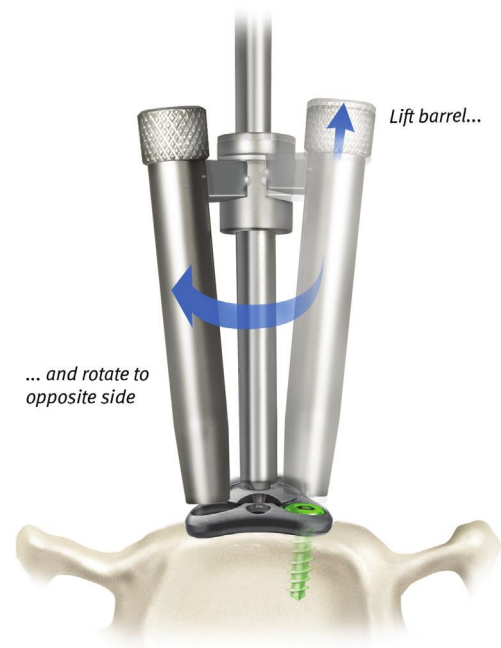
*Note: The ATO Hex Driver has a Visual Indicator incorporated on the shaft. When the Visual Indicator reaches the top of the Guide Tube, it is an indication that the screw is nearly seated.*



## Opposite Hole

Lift Guide Tube and rotate to align with opposite hole. Make sure to rotate until a positive stop is reached. Repeat steps. Final screw tightening may be needed after the Guide Tube has been removed.

*Note: Temporary Fixation Pin must be removed to allow Guide Tube to rotate while the Guide Tube is seated in the hex pocket of the locking cap.*



## Re-position Guide Tube

Upon the completion of one level, re-position the Single Barrel ATO Guide Tube in the remaining hex pocket(s). Repeat steps.

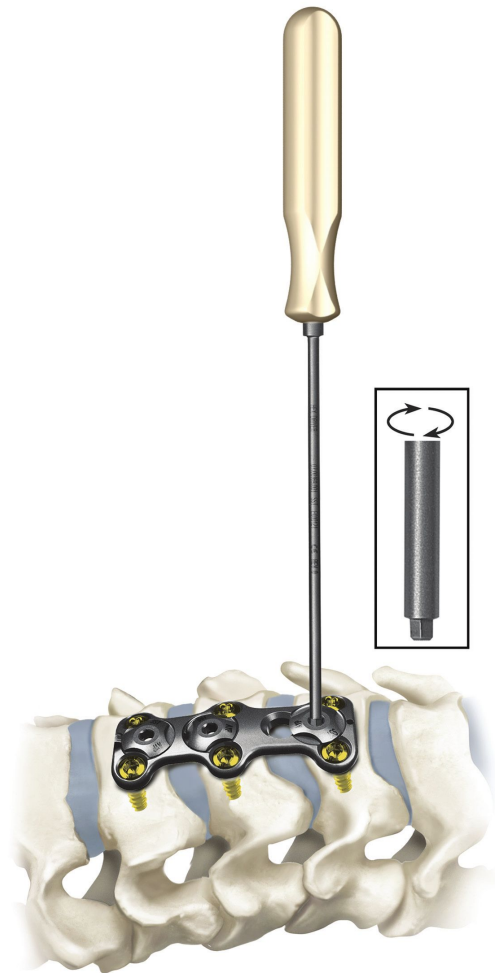


## Securing the Locking Caps

**Overview:** The *Secure-Twist* anti-migration caps are pre-installed and positioned on the plate to allow insertion of the bone screws. Each cap will retain the bone screws within the plate when the cap is rotated to a secure position.

**Placement/Positioning:** Once all bone screws have been placed, use the Hex Driver to rotate the *Secure-Twist* cap clockwise approximately  $60^\circ$  to secure it properly. The cap will tighten and you will be able to confirm visually the cap covering the screws.

**Optional:** The Ball-End Hex Driver (green handle) may be used in situations where the Standard Hex Driver cannot be inserted directly into the locking cap. This situation may exist at the plate extremes due to interference with anatomical structures or retraction limitations. The Ball-End Driver allows the tip to be inserted into the locking cap at angles up to  $25^\circ$  off the central axis.



### Trinica Select Double Barrel All-Through-One (ATO) Guide Tube



2.3mm Drill Bit – 07.00787.002



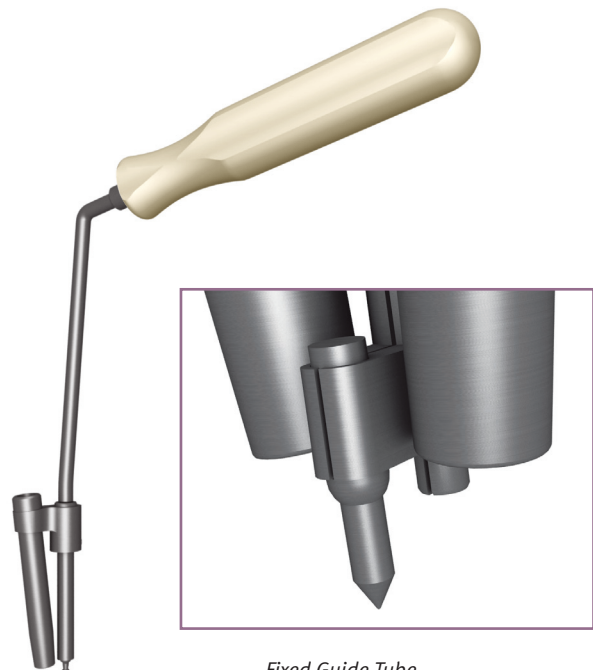
Tap – 07.00787.001



Hex Driver – 07.00788.001



Variable Guide Tube  
07.00782.001

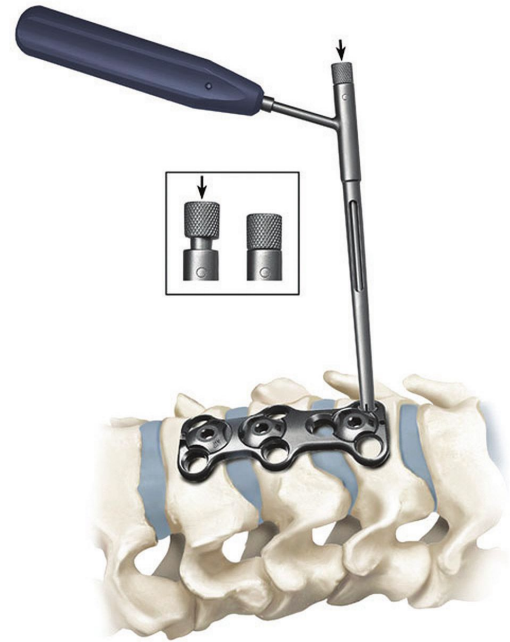


Fixed Guide Tube  
07.00784.001

## Plate Selection

Select the appropriately sized *Trinica Select* plate for fixation to the vertebral bodies. A properly sized plate will bridge the affected segment(s) without overhanging into the adjacent disc space(s). Ensure plate is positioned on midline of vertebral bodies.

A Plate Holder is included in the *Trinica Select* instrument set to facilitate plate selection and initial placement. It may be used to stabilize the plate during the insertion of the Temporary Fixation Pins or initial Bone Screws.



## Guide Tube/Screw Selection

Determine if Variable or Fixed screws are best for plate placement. Select the Variable or the Fixed ATO Double Barrel Guide Tube.



## Fixed Guide Tube

### Positioning Fixed ATO Double Barrel Guide Tube

Insert the slotted stem, of the Fixed ATO Double Barrel Guide Tube, into the hex pocket of the Locking Cap on the *Trinica Select* plate. At the same time, insert the bone pin through the corresponding fixation pin hole in the plate.

**Caution:** Avoid placing finger under fixation pin hole, of plate, while pressing bone pin through plate to avoid glove puncture.





Place the *Trinica Select* plate in position over the affected disc space(s). Tapping on the Guide Tube, to set the Bone Pin in the bone may be required.



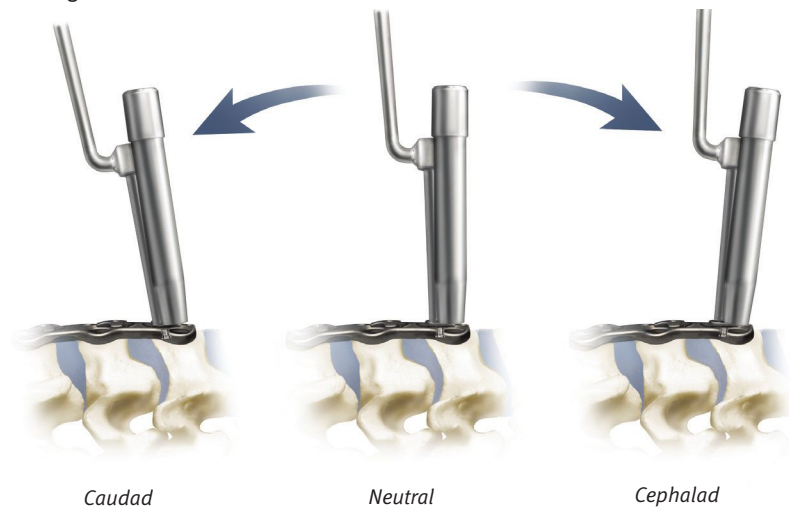
### Variable Guide Tube

#### Positioning Variable ATO Double Barrel Guide Tube

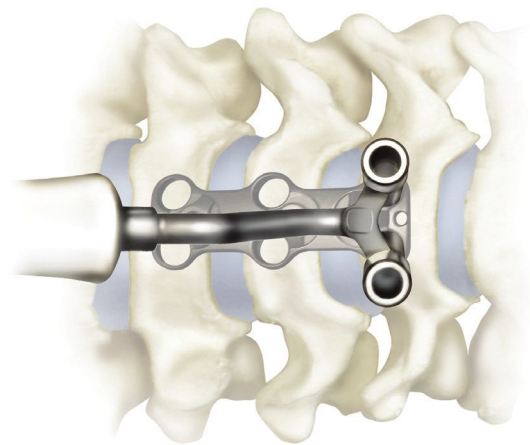
Place the Angle-Limiting Pin of the Variable ATO Guide Tube into hex pocket of the locking cap.

Position the Guide Tube until desired screw placement angle is achieved.

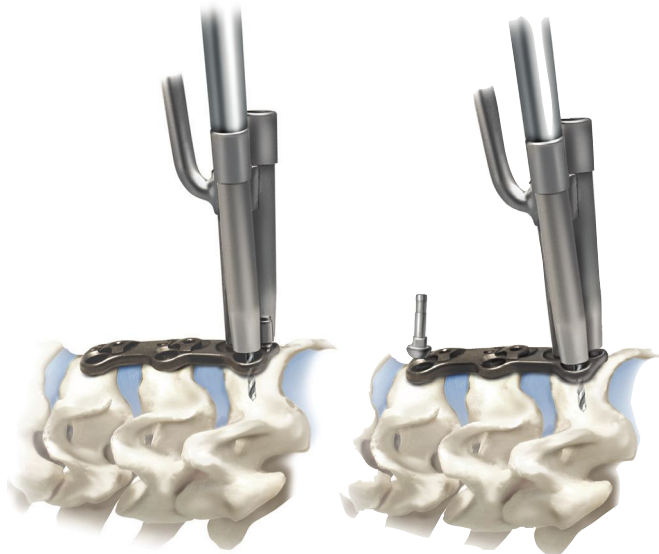
*Note: Once the Angle-Limiting Pin has engaged and travel has stopped refrain from placing undue force on the Angle-Limiting Pin of the Variable Guide Tube.*



*Note: The handle shaft of the Guide Tube should be aligned over midline of plate, as shown right, to avoid drilling or placing screws too far medial or lateral.*







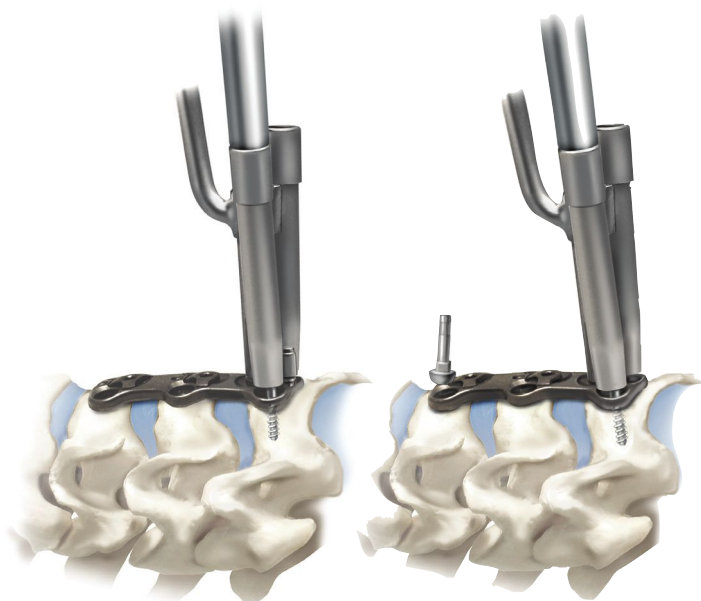
Fixed ATO  
Double Barrel Guide  
Tube

Variable ATO  
Double Barrel Guide  
Tube

## Hole Placement/Preparation

Attach **ONLY** the ATO Drill Bit (Part# 07.00787.002) to either the Manual Drill Handle (supplied in the *Trinica Select* Instrument Set) or a compatible device with an AO connector. Only use the ATO Drill Bit with the Variable ATO Double Barrel Guide Tube (Part #07.00782.001) or the Fixed ATO Double Barrel Guide Tube (Part #07.00784.001).

Insert ATO Drill Bit into the ATO Guide Tube and with minor downward pressure, advance the ATO Drill Bit in a clockwise rotational motion until the positive stop on the ATO Drill Bit comes into contact with the ATO Guide Tube. Continue to rotate ATO Drill Bit in a clockwise rotation as you remove the ATO Drill Bit from the ATO Guide Tube.



Fixed ATO  
Double Barrel Guide  
Tube

Variable ATO  
Double Barrel Guide  
Tube

## Tapping (Optional)

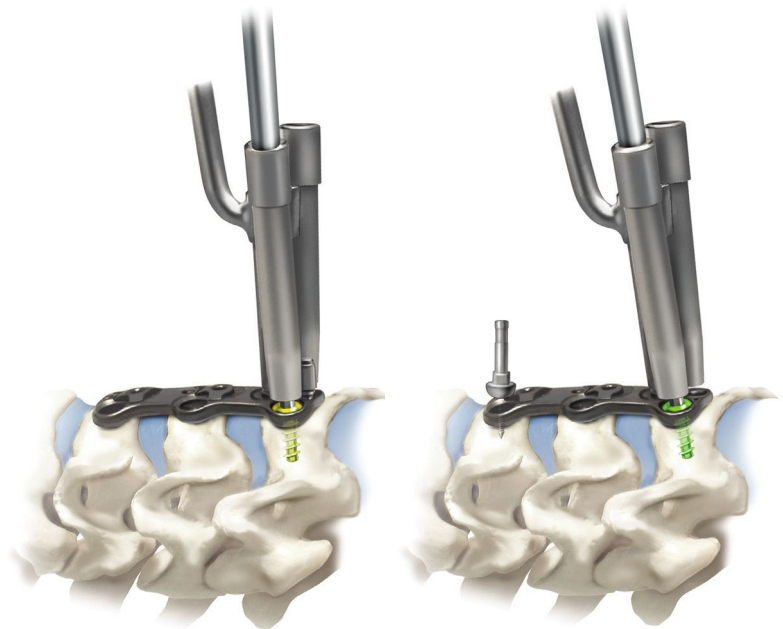
To use the ATO Tap (Part #07.00787.001), position the tap into the Guide Tube and into the previously drilled hole and advance the ATO Tap using a clockwise rotational motion until the positive stop comes into contact with Guide Tube. Once contact is obtained, rotate the ATO Tap counter-clockwise until it is free of the bone and remove from the Guide Tube.

## Screw Placement

Identify the appropriate style screw, Self-Drilling or Self-Tapping (see pages 7–8). Once a screw style has been determined, identify the correct screw type, Fixed or Variable, and length. Insert the tip of the ATO Hex Driver into the socket of the screw using downward pressure on the driver to secure the screw to the driver tip.

With the screw attached to the ATO Hex Driver, position the ATO Hex Driver in the Guide Tube. Insert the screw tip in the previously drilled and/or tapped hole. Rotate the ATO Hex Driver clockwise to advance the screw until it is firmly seated. Repeat process for second screw. Final adjustments may be needed once the Guide Tube has been removed.

*Note: The ATO Hex Driver has a Visual Indicator incorporated on the shaft. When the Visual Indicator reaches the top of the Guide Tube it is an indication that the screw is nearly seated.*

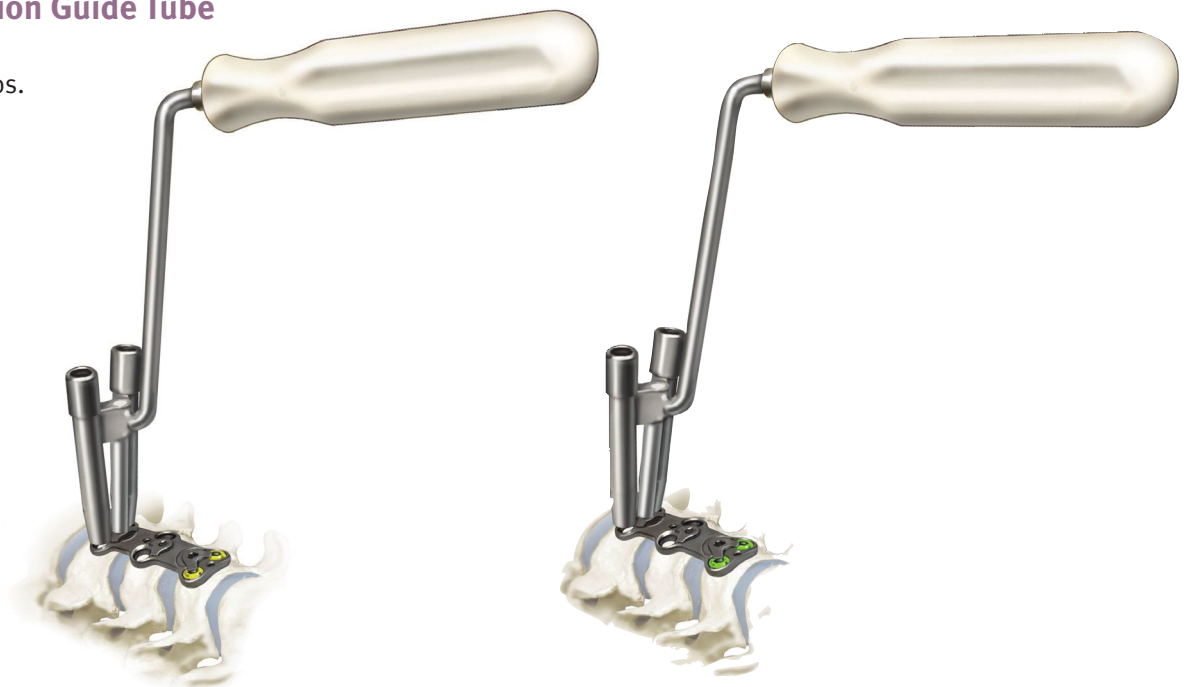


Fixed ATO  
Double Barrel Guide  
Tube

Variable ATO  
Double Barrel Guide  
Tube

## Re-Position Guide Tube

Repeat steps.

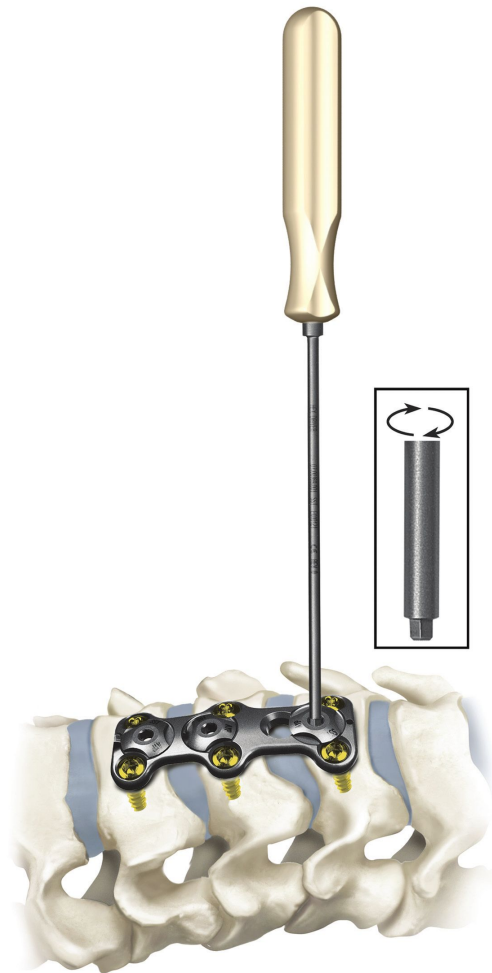


## Securing the Locking Caps

**Overview:** The *Secure-Twist* anti-migration caps are pre-installed and positioned on the plate to allow insertion of the bone screws. Each cap will retain the bone screws within the plate when the cap is rotated to a secure position.

**Placement/Positioning:** Once all bone screws have been placed, use the Hex Driver to rotate the *Secure-Twist* cap clockwise approximately  $60^\circ$  to secure it properly. The cap will tighten and you will be able to confirm visually the cap covering the screws.

**Optional:** The Ball-End Hex Driver (green handle) may be used in situations where the Standard Hex Driver cannot be inserted directly into the locking cap. This situation may exist at the plate extremes due to interference with anatomical structures or retraction limitations. The Ball-End Driver allows the tip to be inserted into the locking cap at angles up to  $25^\circ$  off the central axis.



#### DEVICE DESCRIPTION

The *Trinica Select* Anterior Cervical Plate System consist of cervical plates, locking caps, bone screws, and the instruments necessary to implant this specific system. All implant components are made from a titanium alloy (Ti-6Al-4V). The *Trinica Select* Anterior Cervical Plate System is intended to provide stabilization of the cervical vertebra for various indications (see below). The fixation construct consists of a cervical plate that is attached to the vertebral body of the cervical spine with self-tapping and self-drilling bone screws using an anterior approach. Bone screws are available for fixed angle or variable angle implantation. The *Trinica Select* Anterior Cervical Plate System is intended to be removed after solid fusion has occurred.

#### INDICATIONS

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

#### CONTRAINDICATIONS

Contraindications for use of the *Trinica Select* Anterior Cervical Plate System include:

- Overt infection or distant foci of infections
- Local inflammation, with or without fever or leukocytosis
- Pregnancy
- Diseases or conditions other than those specifically described in the Indications section
- Use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae
- Where attempted correction exceeds the limits of physiological conditions
- Uncooperative patient or patient with neurologic disorders rendering the patient incapable of following instructions
- Metabolic disorders that may impair bone formation
- Inadequate bone stock to support the device
- Inability to restrict high activity level
- Obesity
- Poor prognosis for good wound healing (e.g. decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
- Failure to explant the device after bony fusion

#### WARNINGS

Some metals, polymers, chemicals, and other materials utilized with orthopedic implants have been known to cause cancer and other adverse body reactions, or reports in the literature have suggested such causation. Any factor that causes chronic damage to tissues may be oncogenic. Cancer can metastasize from soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget's disease has been reported to progress to cancer; surgical candidates suffering from this disease should be warned accordingly.

Implantation of foreign material in tissues can elicit an inflammatory reaction. Current literature suggests that wear debris (including metal, polyethylene, ceramic, and cement particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening.

Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.

#### PRECAUTIONS

The *Trinica Select* Anterior Cervical Plate System instrumentation should only be used after the surgeon has had adequate training in this method of fixation and has become thoroughly knowledgeable about the spinal anatomy and biomechanics. A surgical technique for the *Trinica Select* Anterior Cervical Plate System is available upon request. This technique is not a substitute for training and is for general informational purposes only.

Components from other anterior cervical plating systems must not be intermixed with the *Trinica Select* Anterior Cervical Plate System components since compatibility of the components is not known.

Do not use implants made from dissimilar metals (such as cobalt chromium-molybdenum alloy or stainless steel) in contact with components of the *Trinica Select* Anterior Cervical Plate System; otherwise, galvanic corrosion may occur.

If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant(s) surface. The plates must not be repeatedly or excessively bent. Do not reverse bend the plate.

Contact your Zimmer Spine representative or visit us at  
[www.zimmerspine.eu](http://www.zimmerspine.eu)



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Lit.No.06.01353.012-Ed.11/2009



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