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Cervical Solutions

Trinica[®] and Trinica[®] Select Anterior Cervical Plate System

Surgical Technique Guide





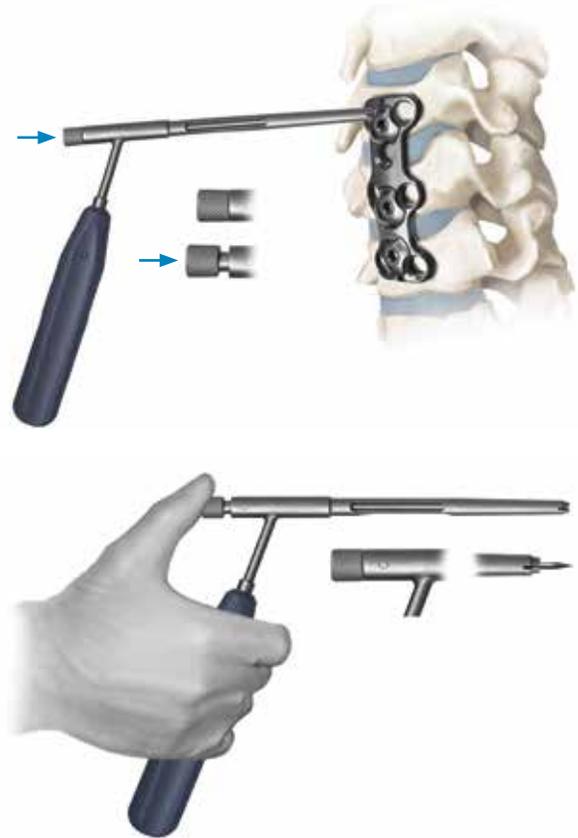
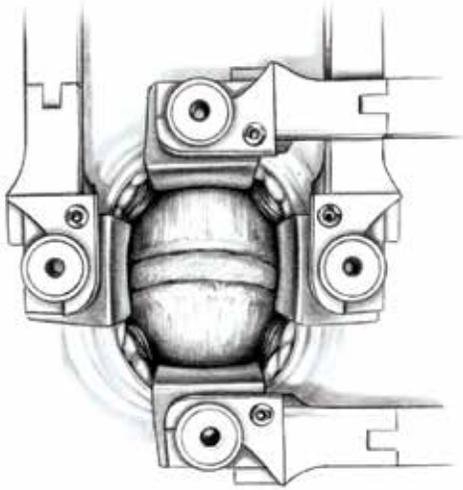
The Trinica Select System affords versatility through a full range of plate and screw sizes to ensure a better anatomical fit with little or no plate contouring.

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

PATIENT POSITIONING AND PREPARATION



STEP 1

- Prepare the patient for an anterior cervical fusion using the standard surgical technique.
- Select the appropriately-sized plate for fixation to the vertebral bodies. A properly-sized plate will bridge the affected segment(s) without overhanging into adjacent disc space.

Plate Holder

A plate holder is included in the Trinica instrument kit to facilitate plate selection and initial placement. It may be used to stabilize the plate during 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)



STEP 2

All plates in the Trinica and 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 instrument kit if additional plate contouring is desired.

Increased Lordosis

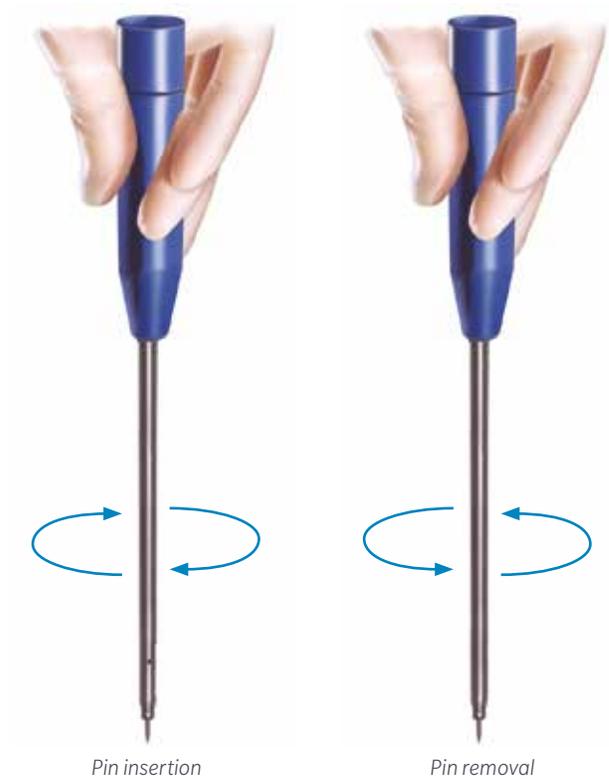
- To increase the bend of the plate, insert the plate in the plate bender with the anterior surface resting against the anvil. Turn the plate bender's hammer so the convex portion is facing the plate. Once positioned, squeeze the pliers-style handle to obtain the desired plate curvature.

Decrease Lordosis

- To decrease the bend of the plate, insert the plate in the plate bender with the posterior surface resting against the anvil. Turn the plate bender's hammer so 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)



STEP 1

The Trinica and 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, through the center of the locking cap or through the fixation hole on the trinica select plate.

Pin Insertion and Removal

- 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.

- 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 discarded after one use.

Note: Temporary fixation pins must be removed from the surgical site prior to closure.

SCREW SELECTION



Self-tapping
blunt tip



Self-drilling
cutting flute



Self-tapping
fixed screw



Self-tapping
variable screw

STEP 2

Self-tapping vs. Self-drilling

The Trinica and Trinica Select self-drilling screws seek to give the surgeon the option to reduce the number of instruments used in a Trinica 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 may be identified by a gold anodized head and variable self-drilling screws may 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 freehand 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 locking mechanism.

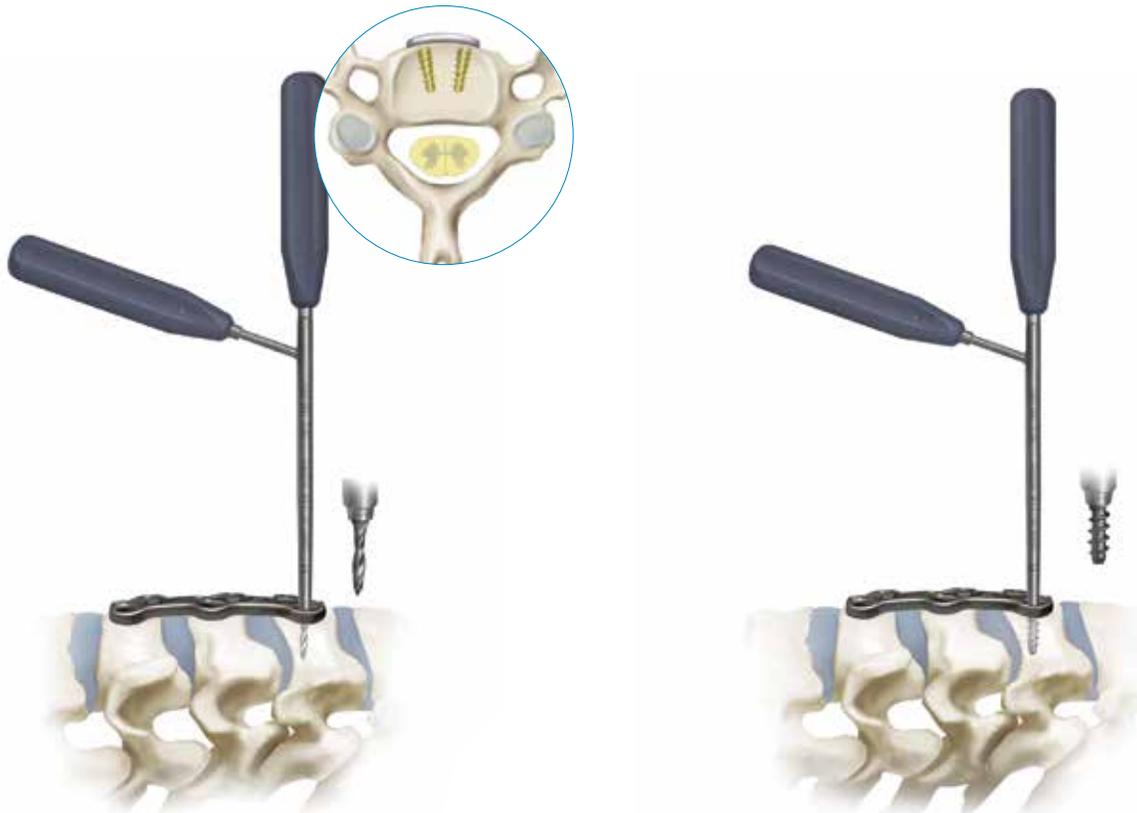
Alternative Screws

The Trinica and Trinica Select Systems also provide alternative screw options for situations in which a $\varnothing 4.2$ mm fixed or variable screw is not optimal.

A $\varnothing 4.6$ mm fixed bone screw (blue) is available for situations where bony purchase has been lost with a $\varnothing 4.2$ mm fixed bone screw. Use the screw in a manner similar to the $\varnothing 4.2$ mm fixed bone screw, but without using a tap.

A $\varnothing 4.6$ mm variable bone screw (magenta) is available for situations where bony purchase has been lost with a $\varnothing 4.2$ mm variable bone screw. Use the screw in a manner similar to the $\varnothing 4.2$ mm variable bone screw, but without using a tap.

FIXED SCREW PLACEMENT (DRILL GUIDE OR AWL)



STEP 3

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 9° per side (18° total angle) for the Trinica system and 6° per side (12° total angle) for the Trinica Select system.

Drill Guide 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 by rotating clockwise until the positive stop on the drill contacts 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 discarded after use.

Tapping (Optional)

- A tap is provided in the Trinica instrument kit 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 by rotating clockwise until the positive stop contacts the fixed-angle drill guide. Once contact is obtained, rotate the tap counterclockwise until it is free of the bone and remove it 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.

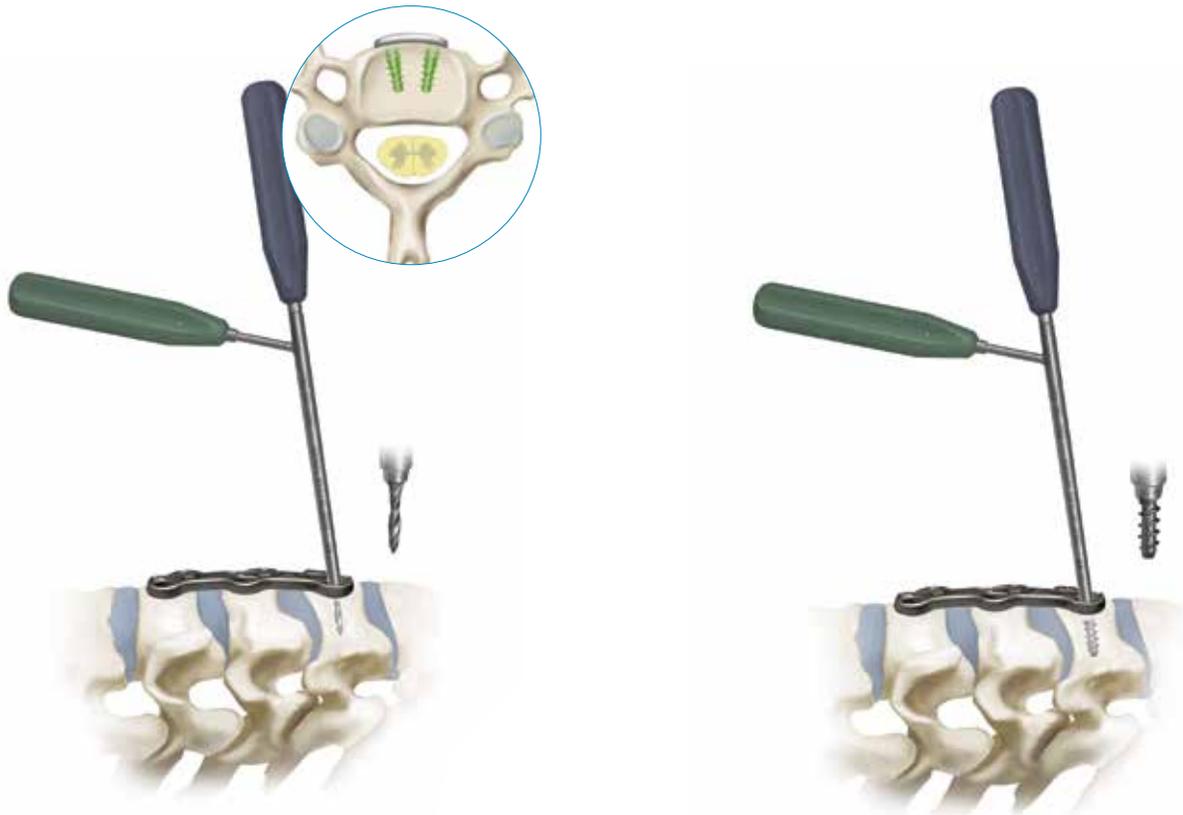


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- As an alternative to using the fixed-angle drill guide, drill and tap, a fixed-angle awl is included in the Trinica instrument kit.

Awl 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 directed. Repeat the bone screw preparation and placement procedure outlined above for all remaining bone screw preparation sites.

VARIABLE SCREW PLACEMENT (DRILL GUIDE)



STEP 4

A variable-angle guide (green handle) is included in the Trinica instrument kit. 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.

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 by rotating clockwise until the positive stop on the drill contacts 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 discarded after use.

Tapping (Optional)

A Tap is provided in the Trinica instrument kit 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 rotation 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 it 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 directed. Repeat the bone screw preparation and placement procedure outlined above for all remaining bone screw preparation sites.

SCREW INSERTION



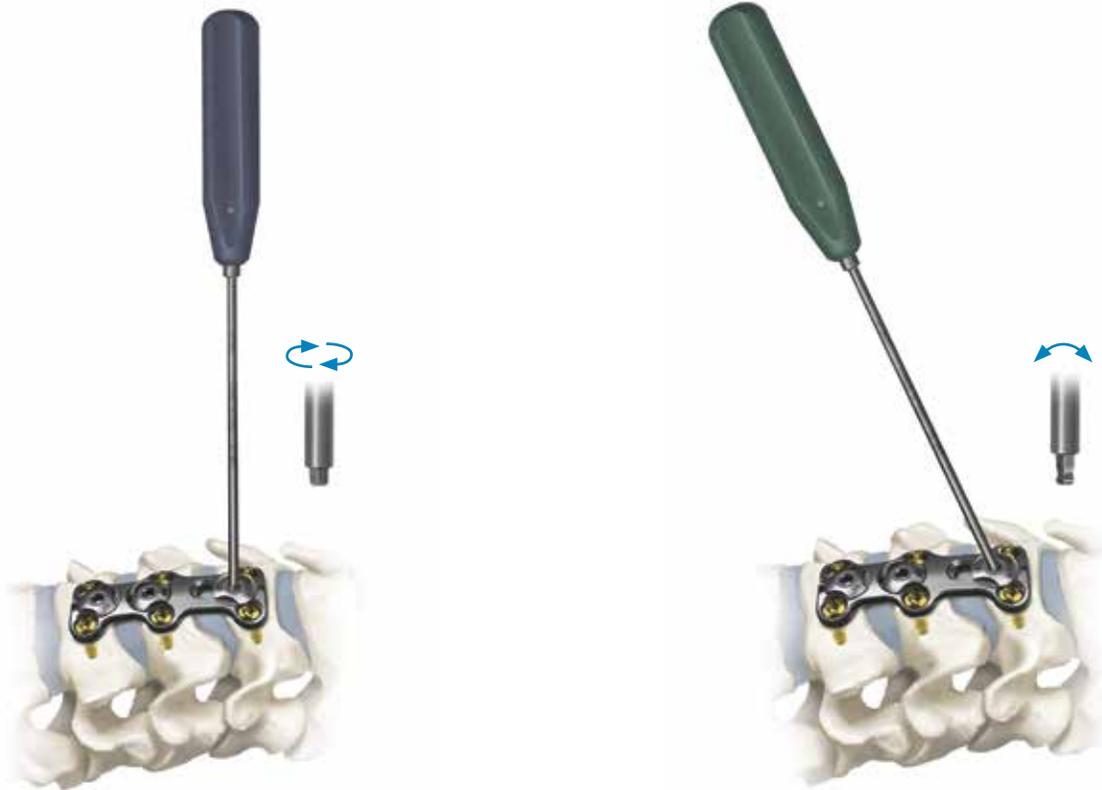
STEP 5

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.

SECURE THE LOCKING CAPS



STEP 6

The Secure-Twist™ anti-migration caps are preinstalled 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 visually confirm 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.

ALL-THROUGH-ONE GUIDE TUBE

Single-barrel Option



STEP 1

Plate Selection and Positioning

- 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 instrument kit 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.
- Place the Trinica Select plate in position over the affected disc space(s).

ALL-THROUGH-ONE GUIDE TUBE

Single-barrel Option (Continued)



STEP 2

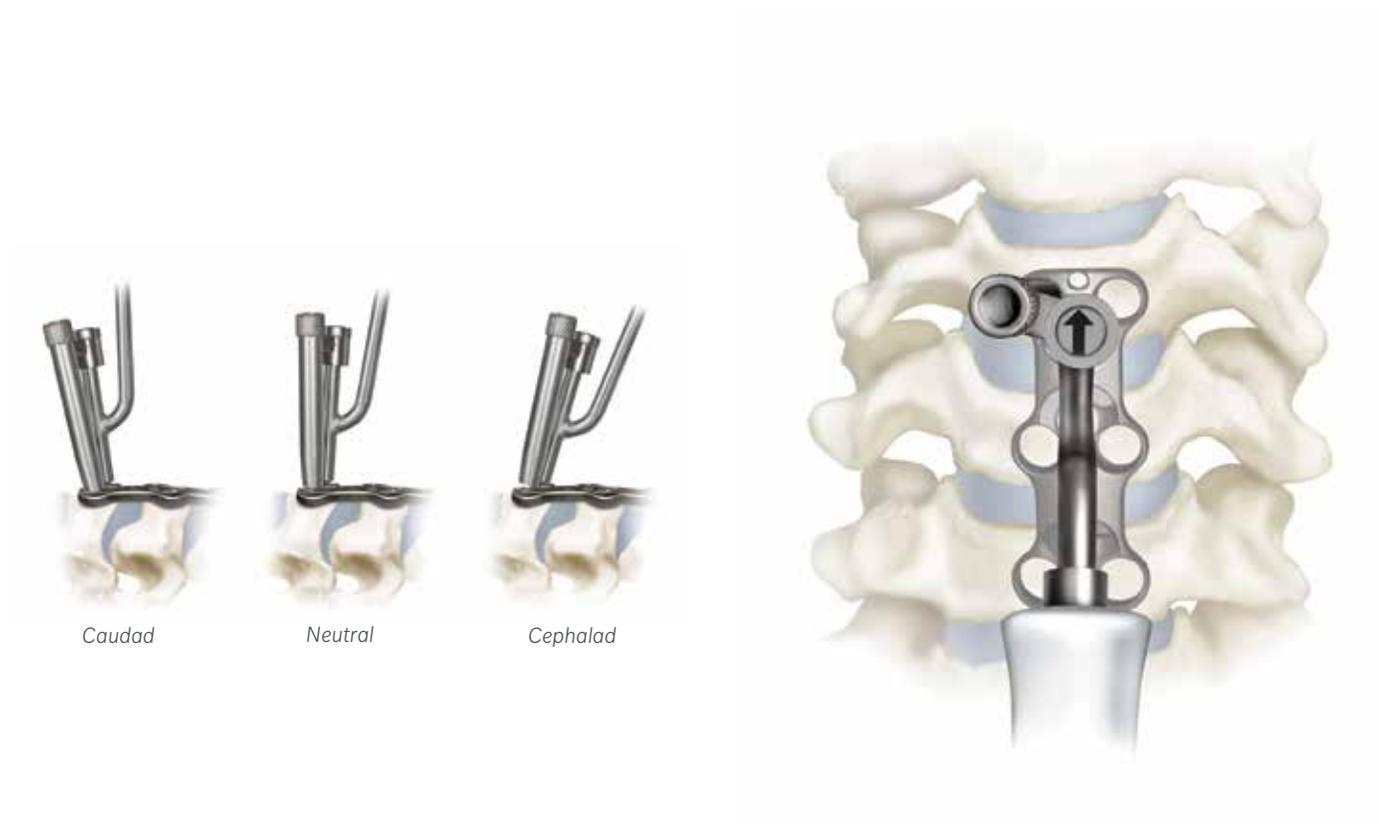
Temporary Fixation Pins (Optional)

The Trinica and 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, through the center of the locking cap or through the fixation hole on the Trinica Select plate.

STEP 3

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 $\pm 12^\circ$.

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.

ALL-THROUGH-ONE GUIDE TUBE

Single-barrel Option (Continued)



STEP 4

Hole Placement/Preparation

- Only attach the ATO drill bit (07.00660.003) to either the manual drill handle (supplied in the Trinica instrument kit) 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 by rotating clockwise until the positive stop on the ATO drill bit contacts the ATO guide tube. Continue to rotate the ATO drill bit clockwise as you remove the ATO drill bit from the ATO guide tube.



STEP 5

Tapping (Optional)

- To use the ATO tap (07.00787.001), position the tap in the guide tube and into the previously drilled hole. Advance the ATO tap rotating clockwise until the positive stop contacts the guide tube. Once contact is made, rotate the tap counterclockwise until it is free of the bone and remove it from the guide tube.

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.



STEP 6

Screw Placement and Reposition Guide Tube

- Identify the appropriate style screw, self-drilling or self-tapping. Once a screw style has been determined, identify the correct screw type, fixed or variable, and the 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 into the previously drilled and/or tapped hole. Rotate the ATO hex driver clockwise to advance the screw until it is firmly seated. Final adjustments may be needed once the guide tube has been removed.

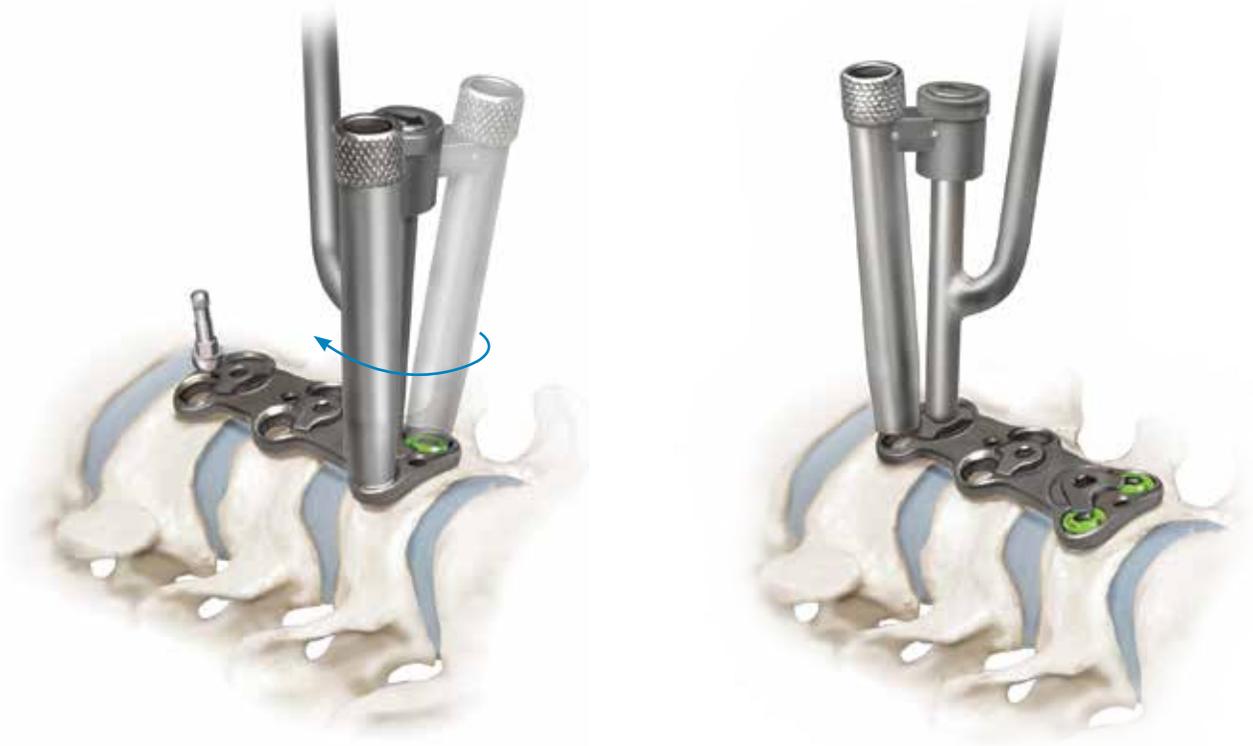
Note: The ATO hex driver has a visual indicator incorporated on the shaft. When the visual indicator reaches the top of the guide tube, the screw is nearly seated.

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.

- 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.

ALL-THROUGH-ONE GUIDE TUBE

Single-barrel Option (Continued)



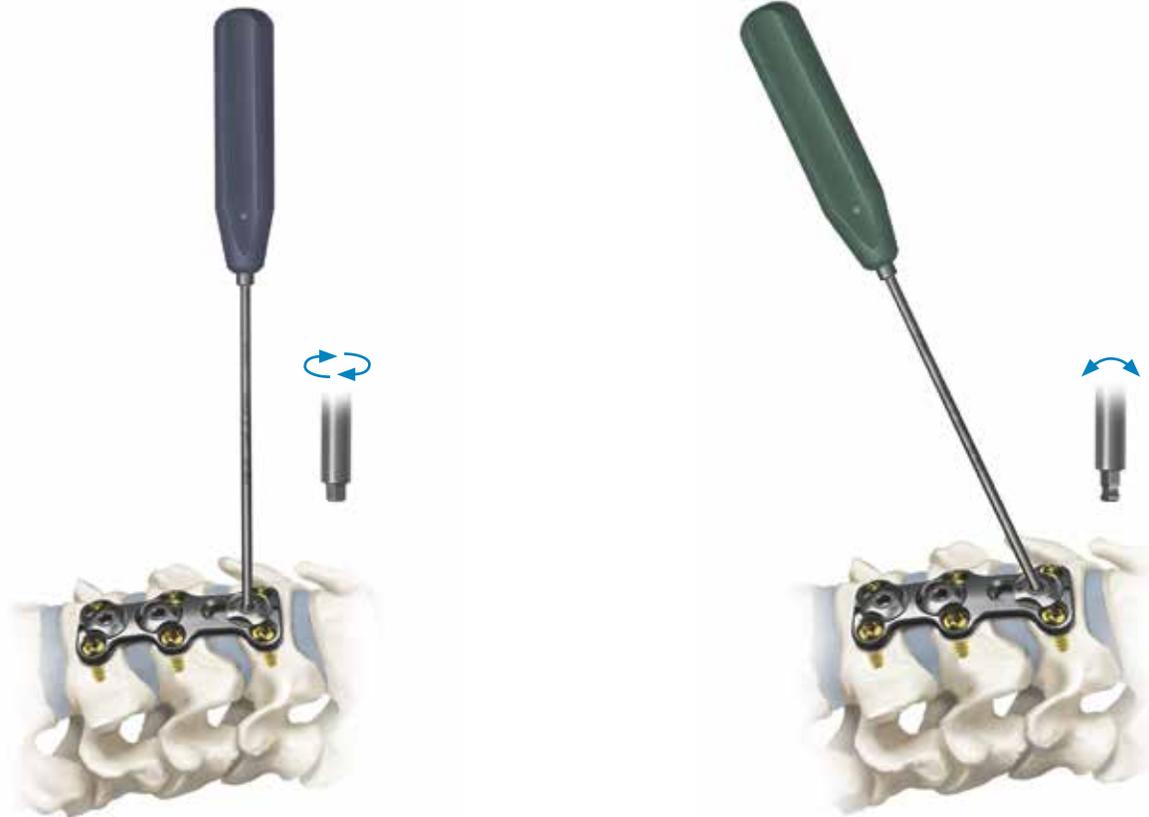
STEP 6 (Continued)

Note: The 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.

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.

- Upon the completion of one level, reposition the single-barrel ATO guide tube in the remaining hex pocket(s). Repeat steps.

SECURING THE LOCKING CAPS



STEP 7

The Secure-Twist anti-migration caps are preinstalled 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 that the cap is 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.

ALL-THROUGH-ONE GUIDE TUBE

Double-barrel Option



STEP 1

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 the midline of the vertebral bodies.
- A plate holder is included in the Trinica instrument kit 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.

STEP 2

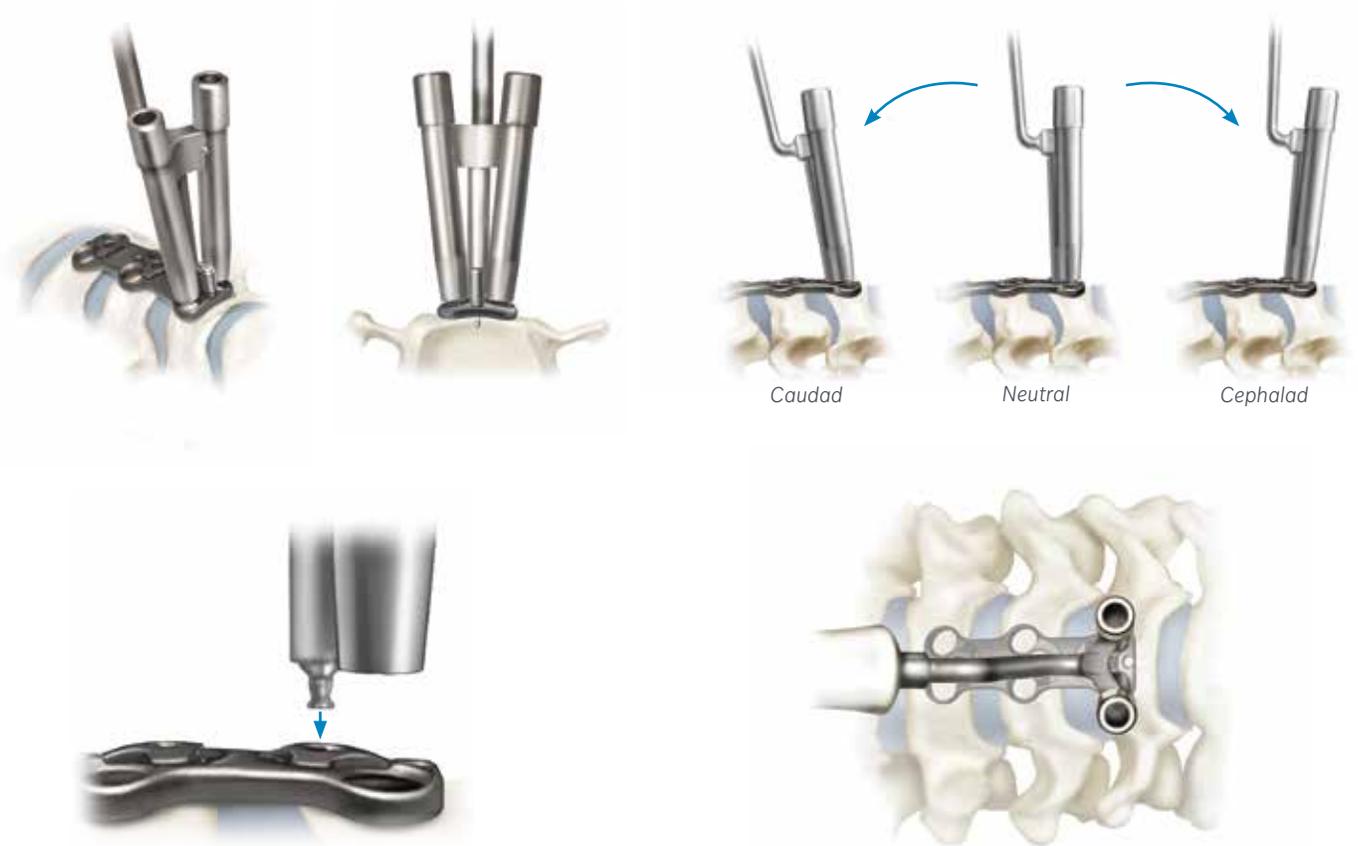
Guide Tube/Screw Selection

- Determine if variable or fixed screws are best for plate placement. Select the variable or the fixed ATO double-barrel guide tube.

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: To avoid glove puncture, do not place finger under the fixation hole of the plate while pressing the bone pin through the plate.



- Place the Trinica Select plate in position over the affected disc space(s). You may need to tap on the guide tube to set the bone pin in the bone.

Positioning Variable ATO Double-barrel Guide Tube

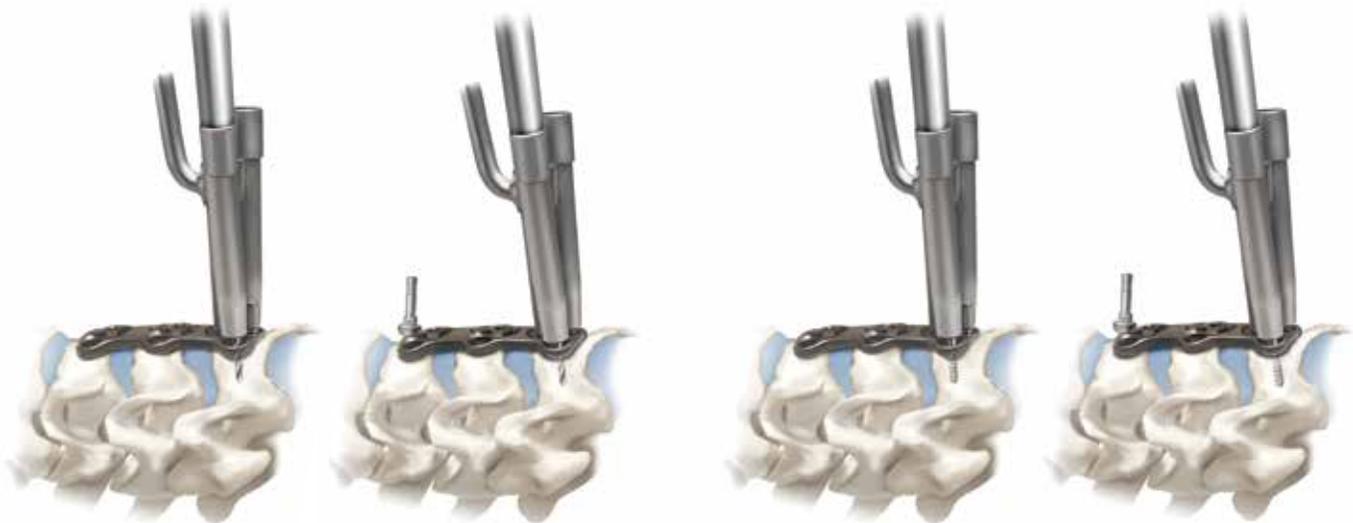
- Place the angle-limiting pin of the variable ATO guide tube into hex pocket of the locking cap.
- Reposition the guide tube until the desired screw placement angle is achieved.

Note: Once the angle-limiting pin is 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 the midline of the plate, as shown right, to avoid drilling or placing screws too far medially or laterally.

ALL-THROUGH-ONE GUIDE TUBE

Double-barrel Option (Continued)



Fixed ATO double-barrel guide tube

Variable ATO double-barrel guide tube

Fixed ATO double-barrel guide tube

Variable ATO double-barrel guide tube

STEP 3

Hole Placement/Preparation

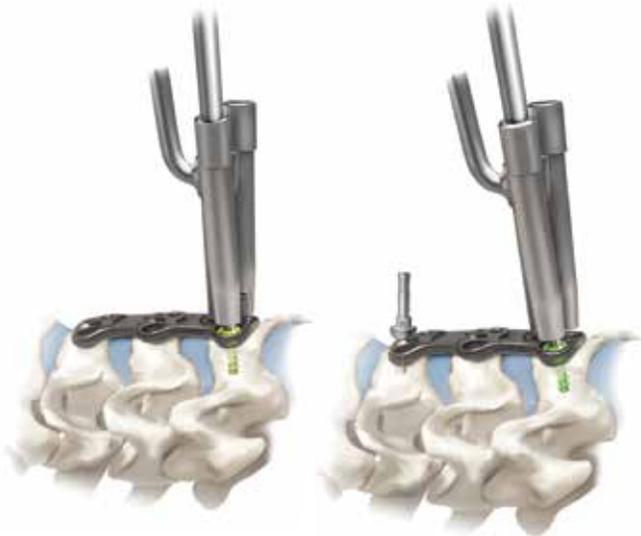
- Attach only the ATO drill bit (07.00660.003) to either the manual drill handle (supplied in the Trinica instrument kit) or a compatible device with an ATO connector. Only use the ATO drill bit with the variable ATO double-barrel guide tube (07.00782.001) or the fixed ATO double-barrel guide tube (07.00784.001).
- Insert ATO drill bit into the ATO guide tube and with minor downward pressure, advance the ATO drill bit by rotating clockwise until the positive stop on the ATO drill bit contacts the ATO guide tube. Continue to rotate ATO drill bit clockwise as you remove the ATO drill bit from the ATO guide tube.

STEP 4

Tapping (Optional)

- To use the ATO Tap (07.00787.001), position the tap into the guide tube and into the previously drilled hole and advance the ATO tap by rotating clockwise until the positive stop contacts the guide tube. Once contact is made, rotate the ATO tap counterclockwise until it is free of the bone and remove from the guide tube.

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.



Fixed ATO double-barrel guide tube

Variable ATO double-barrel guide tube



STEP 5

Screw Placement and Reposition Guide Tube

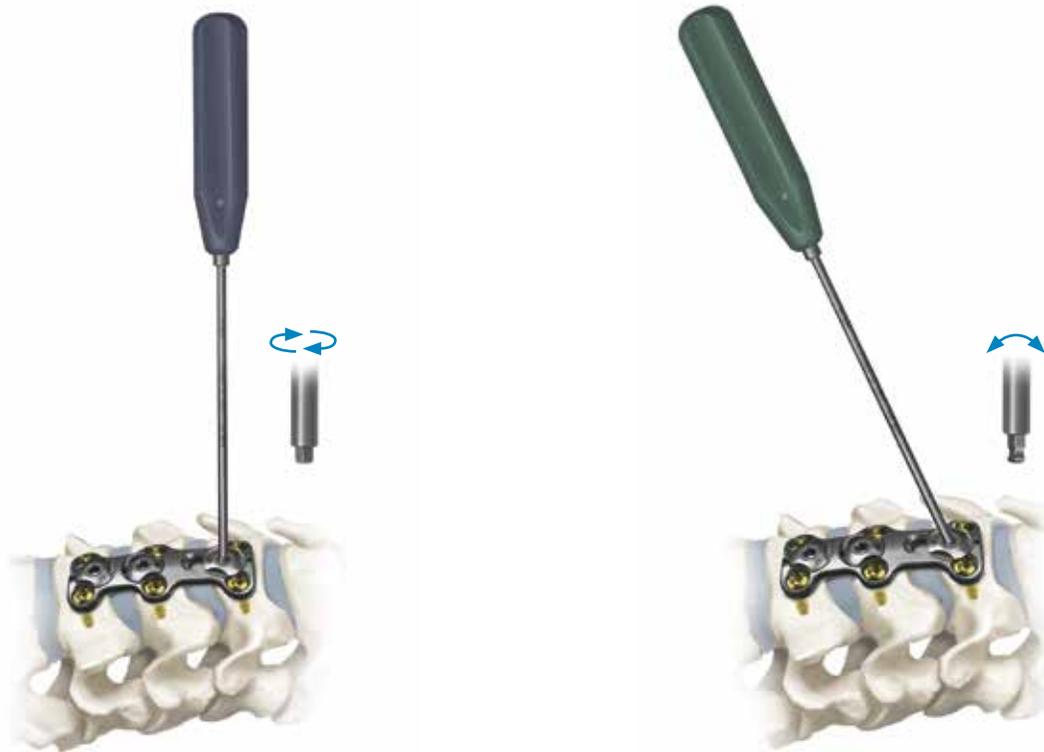
- Identify the appropriate style screw, self-drilling or self-tapping. Once a screw style has been determined, identify the correct screw type (fixed or variable) and length. Insert the tip of the ATO hex driver into the socket of the screw using downward pressure on the driver to secure the screw to 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 the 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, the screw is nearly 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.

- Repeat steps

SECURING THE LOCKING CAPS



STEP 6

The Secure-Twist anti-migration caps are preinstalled 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 visually confirm that the cap is 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 AND TRINICA SELECT IMPLANTS

Trinica Select 1-3 Level Plates

DESCRIPTION	PART NUMBER
20 mm 1 Level Plate	07.00340.009
22 mm 1 Level Plate	07.00340.001
24 mm 1 Level Plate	07.00340.002
26 mm 1 Level Plate	07.00340.003
28 mm 1 Level Plate	07.00340.004
30 mm 1 Level Plate	07.00340.005
32 mm 1 Level Plate	07.00340.006
34 mm 1 Level Plate	07.00340.007
36 mm 2 Level Plate	07.00341.009
38 mm 2 Level Plate	07.00341.001
40 mm 2 Level Plate	07.00341.002
42 mm 2 Level Plate	07.00341.003
44 mm 2 Level Plate	07.00341.004
46 mm 2 Level Plate	07.00341.005
48 mm 2 Level Plate	07.00341.006
50 mm 2 Level Plate	07.00341.007
52 mm 2 Level Plate	07.00341.008
51 mm 3 Level Plate	07.00342.001
54 mm 3 Level Plate	07.00342.002
57 mm 3 Level Plate	07.00342.003
60 mm 3 Level Plate	07.00342.004
63 mm 3 Level Plate	07.00342.005
66 mm 3 Level Plate	07.00342.006
69 mm 3 Level Plate	07.00342.007
72 mm 3 Level Plate	07.00342.008



Trinica Standard 1-4 Level Plates

DESCRIPTION	PART NUMBER
22 mm 1 Level Plate	07.00192.001
24 mm 1 Level Plate	07.00101.001
26 mm 1 Level Plate	07.00101.002
28 mm 1 Level Plate	07.00101.003
30 mm 1 Level Plate	07.00101.004
32 mm 1 Level Plate	07.00101.005
34 mm 1 Level Plate	07.00101.006
36 mm 1 Level Plate	07.00101.007
38 mm 2 Level Plate	07.00102.001
40 mm 2 Level Plate	07.00102.002
42 mm 2 Level Plate	07.00102.003
44 mm 2 Level Plate	07.00102.004
46 mm 2 Level Plate	07.00102.005
48 mm 2 Level Plate	07.00102.006
50 mm 2 Level Plate	07.00102.007
52 mm 2 Level Plate	07.00102.008
54 mm 2 Level Plate	07.00102.009
51 mm 3 Level Plate	07.00187.001
54 mm 3 Level Plate	07.00187.002
57 mm 3 Level Plate	07.00187.003
60 mm 3 Level Plate	07.00187.004
63 mm 3 Level Plate	07.00187.005
66 mm 3 Level Plate	07.00187.006
69 mm 3 Level Plate	07.00187.007
72 mm 3 Level Plate	07.00187.008
68 mm 4 Level Plate	07.00188.001
71 mm 4 Level Plate	07.00188.002
74 mm 4 Level Plate	07.00188.003
77 mm 4 Level Plate	07.00188.004
80 mm 4 Level Plate	07.00188.005
83 mm 4 Level Plate	07.00188.006
86 mm 4 Level Plate	07.00188.007
89 mm 4 Level Plate	07.00188.008
92 mm 4 Level Plate	07.00188.009

TRINICA AND TRINICA SELECT IMPLANTS (*continued*)



Self-drilling
Fixed Screw



Self-drilling
Variable Screw

Trinica Self-drilling Screws

DESCRIPTION	PART NUMBER
ø4.2 mm x 12 mm Self-drilling Fixed Screw, Gold/Silver	07.00811.003
ø4.2 mm x 14 mm Self-drilling Fixed Screw, Gold/Silver	07.00811.005
ø4.2 mm x 16 mm Self-drilling Fixed Screw, Gold/Silver	07.00811.007
ø4.2 mm x 12 mm Self-drilling Variable Screw, Green/Silver	07.00812.003
ø4.2 mm x 14 mm Self-drilling Variable Screw, Green/Silver	07.00812.005
ø4.2 mm x 16 mm Self-drilling Variable Screw, Green/Silver	07.00812.007



Self-tapping
Fixed Screw



Self-tapping
Variable Screw

Trinica Self-tapping Screws

DESCRIPTION	PART NUMBER
ø4.2 mm x 12 mm Self-tapping Variable Screw, Green	07.00117.001
ø4.2 mm x 14 mm Self-tapping Variable Screw, Green	07.00117.002
ø4.2 mm x 16 mm Self-tapping Variable Screw, Green	07.00117.003
ø4.6 mm x 12 mm Self-tapping Variable Screw, Magenta	07.00118.001
ø4.6 mm x 14 mm Self-tapping Variable Screw, Magenta	07.00118.002
ø4.6 mm x 16 mm Self-tapping Variable Screw, Magenta	07.00118.003
ø4.2 mm x 12 mm Self-tapping Fixed Screw, Gold	07.00119.001
ø4.2 mm x 14 mm Self-tapping Fixed Screw, Gold	07.00119.002
ø4.2 mm x 16 mm Self-tapping Fixed Screw, Gold	07.00119.003
ø4.6 mm x 12 mm Self-tapping Fixed Screw, Blue	07.00120.001
ø4.6 mm x 14 mm Self-tapping Fixed Screw, Blue	07.00120.002
ø4.6 mm x 16 mm Self-tapping Fixed Screw, Blue	07.00120.003

TRINICA AND TRINICA SELECT INSTRUMENTS



DESCRIPTION	PART NUMBER
2.3 mm Drill Bit	07.00660.003



DESCRIPTION	PART NUMBER
Tap	07.00787.001



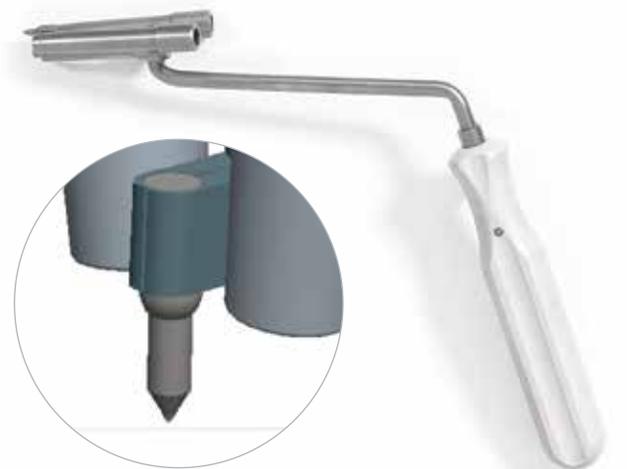
DESCRIPTION	PART NUMBER
Hex Driver	07.00788.001



DESCRIPTION	PART NUMBER
Single-barrel ATO Guide Tube	07.00796.001

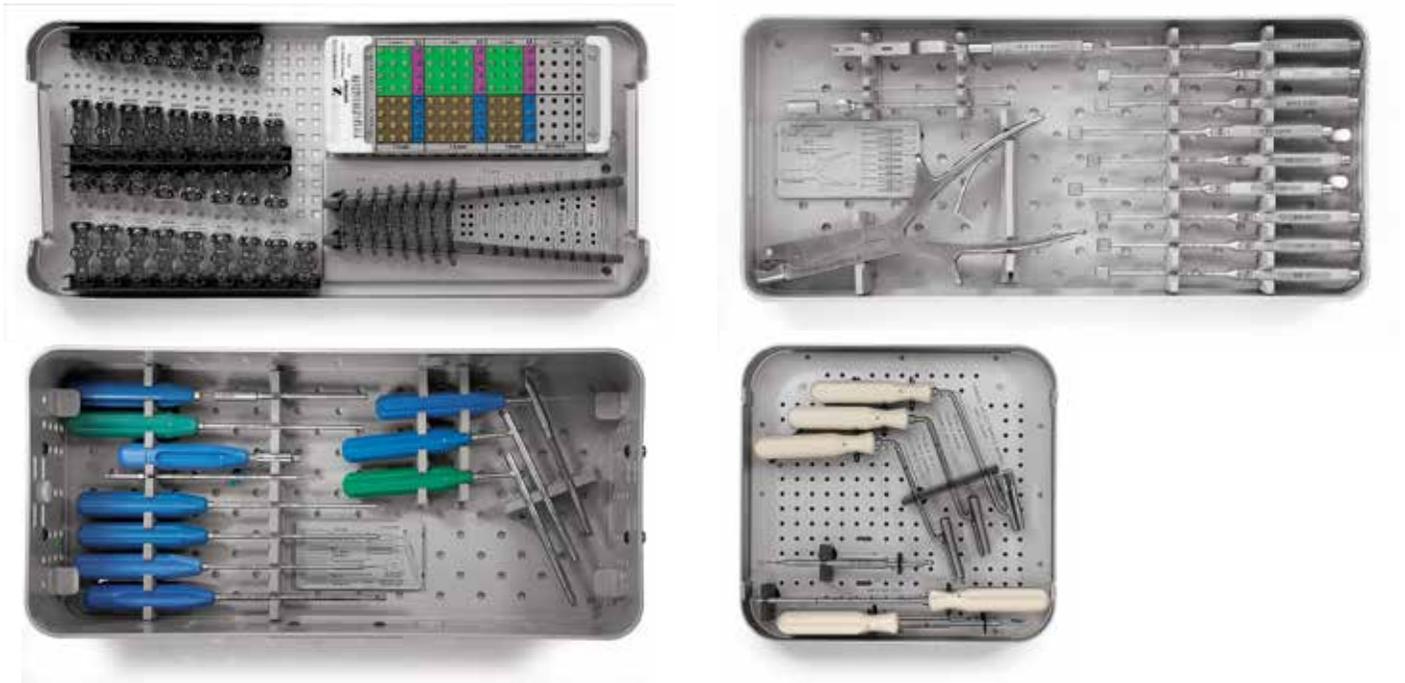


DESCRIPTION	PART NUMBER
Variable Guide Tube	07.00782.001



DESCRIPTION	PART NUMBER
Fixed Guide Tube	07.00784.001

TRINICA AND TRINICA SELECT KIT CONTENTS



Trinica Select 1-3 Level Plates and Instruments Kit Number: 07.00939.400

DESCRIPTION	Qty	PART NUMBER
22 mm 1 Level Plate	2	07.00340.001
24 mm 1 Level Plate	2	07.00340.002
26 mm 1 Level Plate	2	07.00340.003
28 mm 1 Level Plate	2	07.00340.004
30 mm 1 Level Plate	1	07.00340.005
32 mm 1 Level Plate	1	07.00340.006
34 mm 1 Level Plate	1	07.00340.007
20 mm 1 Level Plate	1	07.00340.009
38 mm 2 Level Plate	2	07.00341.001
40 mm 2 Level Plate	2	07.00341.002
42 mm 2 Level Plate	2	07.00341.003
44 mm 2 Level Plate	2	07.00341.004
46 mm 2 Level Plate	2	07.00341.005
48 mm 2 Level Plate	1	07.00341.006
50 mm 2 Level Plate	1	07.00341.007
52 mm 2 Level Plate	1	07.00341.008
36 mm 2 Level Plate	1	07.00341.009

DESCRIPTION	Qty	PART NUMBER
51 mm 3 Level Plate	1	07.00342.001
54 mm 3 Level Plate	1	07.00342.002
57 mm 3 Level Plate	1	07.00342.003
60 mm 3 Level Plate	1	07.00342.004
63 mm 3 Level Plate	1	07.00342.005
66 mm 3 Level Plate	1	07.00342.006
69 mm 3 Level Plate	1	07.00342.007
72 mm 3 Level Plate	1	07.00342.008
Drill Guide, Fixed	1	07.00155.001
Drill Guide, Variable	1	07.00158.001
Awl, Fixed	1	07.00160.001
Bone Tap	1	07.00168.001
Hex Driver	2	07.00169.001
Ball-end Hex Driver	1	07.00171.001
Plate Bender	1	07.00176.001
Plate Holder	1	07.00177.001
Threaded Pin Inserter	1	07.00352.001
AO Quick Connect Handle	1	07.00393.001
Depth Gauge BAK/C	1	6200-0029-00
Ruler SS 6in BAK/C Lite	1	6200-0033-00

Trinica 1-4 Level Plates and Instruments

Kit Number: 07.02300.400

DESCRIPTION	Qty	PART NUMBER
22 mm 1 Level Plate	2	07.00192.001
24 mm 1 Level Plate	2	07.00101.001
26 mm 1 Level Plate	2	07.00101.002
28 mm 1 Level Plate	2	07.00101.003
30 mm 1 Level Plate	1	07.00101.004
32 mm 1 Level Plate	1	07.00101.005
34 mm 1 Level Plate	1	07.00101.006
36 mm 1 Level Plate	1	07.00101.007
38 mm 2 Level Plate	2	07.00102.001
40 mm 2 Level Plate	2	07.00102.002
42 mm 2 Level Plate	2	07.00102.003
44 mm 2 Level Plate	2	07.00102.004
46 mm 2 Level Plate	2	07.00102.005
48 mm 2 Level Plate	1	07.00102.006
50 mm 2 Level Plate	1	07.00102.007
52 mm 2 Level Plate	1	07.00102.008
54 mm 2 Level Plate	1	07.00102.009
51 mm 3 Level Plate	1	07.00187.001
54 mm 3 Level Plate	1	07.00187.002
57 mm 3 Level Plate	1	07.00187.003
60 mm 3 Level Plate	1	07.00187.004
63 mm 3 Level Plate	1	07.00187.005
66 mm 3 Level Plate	1	07.00187.006
69 mm 3 Level Plate	1	07.00187.007
72 mm 3 Level Plate	1	07.00187.008
68 mm 4 Level Plate	1	07.00188.001
71 mm 4 Level Plate	1	07.00188.002
74 mm 4 Level Plate	1	07.00188.003
77 mm 4 Level Plate	1	07.00188.004
80 mm 4 Level Plate	1	07.00188.005
83 mm 4 Level Plate	1	07.00188.006
86 mm 4 Level Plate	1	07.00188.007
89 mm 4 Level Plate	1	07.00188.008
92 mm 4 Level Plate	1	07.00188.009

DESCRIPTION	Qty	PART NUMBER
Drill Guide, Fixed	1	07.00155.001
Drill Guide, Variable	1	07.00158.001
Awl, Fixed	1	07.00160.001
Bone Tap	1	07.00168.001
Hex Driver	2	07.00169.001
Ball-end Hex Driver	1	07.00171.001
Plate Bender	1	07.00176.001
Plate Holder	1	07.00177.001
Pin Inserter, Threaded	1	07.00352.001
AO Quick Connect Handle	1	07.00393.001
Depth Gauge BAK/C	1	6200-0029-00
Ruler SS 6in BAK/C Lite	1	6200-0033-00

TRINICA AND TRINICA SELECT KIT CONTENTS (*continued*)

Trinica Self-drilling Screws Kit Number: 07.02500.400

DESCRIPTION	Qty	PART NUMBER
ø4.6 mm x 12 mm Self-tapping Variable Screw, Magenta	4	07.00118.001
ø4.6 mm x 14 mm Self-tapping Variable Screw, Magenta	4	07.00118.002
ø4.6 mm x 16 mm Self-tapping Variable Screw, Magenta	4	07.00118.003
ø4.6 mm x 12 mm Self-tapping Fixed Screw, Blue	4	07.00120.001
ø4.6 mm x 14 mm Self-tapping Fixed Screw, Blue	4	07.00120.002
ø4.6 mm x 16 mm Self-tapping Fixed Screw, Blue	4	07.00120.003
ø4.2 mm x 12 mm Self-drilling Fixed Screw, Gold/Silver	10	07.00811.003
ø4.2 mm x 14 mm Self-drilling Fixed Screw, Gold/Silver	12	07.00811.005
ø4.2 mm x 16 mm Self-drilling Fixed Screw, Gold/Silver	8	07.00811.007
ø4.2 mm x 12 mm Self-drilling Variable Screw, Green/Silver	10	07.00812.003
ø4.2 mm x 14 mm Self-drilling Variable Screw, Green/Silver	12	07.00812.005
ø4.2 mm x 16 mm Self-drilling Variable Screw, Green/Silver	8	07.00812.007

Trinica Microscope Kit Number: 07.00762.002

DESCRIPTION	Qty	PART NUMBER
Hex Driver Swivel Hand	2	07.00359.001
Bone Tap, Short	1	07.00360.001
Drill Guide, Variable, Short	1	07.00363.001
Drill Guide, Fixed, Short	1	07.00363.002
2.3 mm Microscope Drill Bit	1	07.00660.002
AO Connector Assembly, Short Hand	1	07.00904.001

Trinica Select ATO Instruments Kit Number: 07.00860.001

DESCRIPTION	Qty	PART NUMBER
Variable ATO Guide	1	07.00782.001
Fixed ATO Guide	1	07.00784.001
ATO Tap	1	07.00787.001
ATO Hex Driver	1	07.00788.001
ATO Drill Guide	1	07.00796.001
AO Connector Assembly, Short Hand	1	07.00904.001

Trinica Self-tapping Screws Kit Number: 07.00940.400

DESCRIPTION	Qty	PART NUMBER
ø4.2 mm x 12 mm Self-tapping Variable Screw, Green	12	07.00117.001
ø4.2 mm x 14 mm S Self-tapping Variable Screw, Green	16	07.00117.002
ø4.2 mm x 16 mm Self-tapping Variable Screw, Green	12	07.00117.003
ø4.6 mm x 12 mm Self-tapping Variable Screw, Magenta	4	07.00118.001
ø4.6 mm x 14 mm Self-tapping Variable Screw, Magenta	4	07.00118.002
ø4.6 mm x 16 mm Self-tapping Variable Screw, Magenta	4	07.00118.003
ø4.2 mm x 12 mm Self-tapping Fixed Screw, Gold	12	07.00119.001
ø4.2 mm x 14 mm Self-tapping Fixed Screw, Gold	16	07.00119.002
ø4.2 mm x 16 mm Self-tapping Fixed Screw, Gold	12	07.00119.003
ø4.6 mm x 12 mm Self-tapping Fixed Screw, Blue	4	07.00120.001
ø4.6 mm x 14 mm Self-tapping Fixed Screw, Blue	4	07.00120.002
ø4.6 mm x 16 mm Self-tapping Fixed Screw, Blue	4	07.00120.003

Trinica Drill Fixation Pin Kit Number: 07.01432.401

DESCRIPTION	Qty	PART NUMBER
Fixation Pin, Large	2	07.00656.002
Self-Tapping Drill Bit	2	07.00660.001
2.3 mm Microscope Drill Bit	2	07.00660.002
ATO Drill Bit, Sterile	2	07.00660.003

IMPORTANT INFORMATION ON THE TRINICA AND TRINICA SELECT SYSTEM

Device Description

The Trinica® and Trinica® Select Anterior Cervical Plate Systems 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 and Trinica Select Anterior Cervical Plate Systems are 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 and Trinica Select Anterior Cervical Plate Systems are intended to be removed after solid fusion has occurred.

Indications

The Trinica and Trinica Select Anterior Cervical Plate Systems are intended for anterior interbody screw fixation of the cervical spine C2–T1. 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.

Warning: *These devices are not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.*

Contraindications

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

- Overt infection of 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)

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 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.

Trinica and Trinica Select Anterior Cervical Plate Systems are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and must be removed. Implant removal, should be followed by adequate postoperative management to avoid fracture or refracture.

Precautions

The Trinica and Trinica Select Anterior Cervical Plate Systems 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 and Trinica Select Anterior Cervical Plate Systems 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 and Trinica Select Anterior Cervical Plate Systems 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 and Trinica Select Anterior Cervical Plate Systems; 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.

All implants and some instruments are intended for single use only; refer to the product label to determine if the instrument is intended for single use only. Single use devices should not be re-used. Possible risks associated with re-use of single use devices include:

- Mechanical malfunction
- Transmission of infectious agents

Prior to use, instruments should be visually inspected for wear and tested to assure they are functioning properly. If instruments are discolored, show evidence of corrosion, have loose screws/pins, are out of alignment, are cracked or have other irregularities, Do Not Use. Instrumentation that appears damaged should be returned to the manufacturer.

Adverse Effects

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery.

Possible neurologic operative/postoperative adverse reactions that may require medical or surgical intervention (e.g., implant removal with or without re-instrumentation) include:

- Paralysis, complete or incomplete. Delayed onset has occurred even when evoked potential was unaffected during surgery
- Dural tear leading to cerebrospinal fluid fistula or pseudo meningocele
- Other spinal cord injuries not otherwise described due to positioning of the spinal attachment device
- Laminar erosion
- Epidural bleeding
- Abnormal sensations
- Radiculopathy

Possible device postoperative complications/adverse reactions that may require medical or surgical intervention (e.g., implant removal with or without re-instrumentation) include:

- Loosening, bending, breaking, disassembly, and/or migration of the components
- Collapse of a fracture and/or fusion site
- Device failure
- Corrosion at the screw/locking cap interface contributing to breakage, and/or pseudoarthrosis
- Discomfort or pain, soft tissue erosion, or protrusion due to prominent implanted hardware
- Attachment device pullout, especially with short constructs and osteoporotic bone
- Implant or graft extrusion through the skin
- Postural deformities, pain, skin breakdown, or residual neural compression due to kyphosis or lordosis occurring at the top of the segment being instrumented
- Bone loss or fracture due to stress shielding
- Foreign body reaction to the device including tumor formation, autoimmune disease, metallosis, and/or scarring
- Non-union or pseudoarthrosis
- Cessation of growth at the fusion site
- Discitis, arachnoiditis, and/or other types of inflammation

Possible general or local postoperative complications/adverse reactions that may require medical or surgical intervention (e.g., implant removal with or without re-instrumentation) include:

- Hemothorax
- Deep vein thrombosis, thrombophlebitis and/or pulmonary embolism that may be fatal; may be due to patient position and/or length of the surgical procedure
- Decubitus ulcer
- Wound infection, deep or superficial, which may require implant removal and/or other medical interventions
- Wound dehiscence, delayed wound healing, or hematoma
- Pain, possibly severe in nature
- Urinary tract infection
- Blood vessel damage and/or blood loss or hemorrhage
- Fracture(s) of the bone
- Gastrointestinal, urological and/or reproductive system compromise including sterility, impotency and/or loss of consortium
- Bone graft donor site pain
- Inability to resume activities of normal daily living

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.



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