ZIMMER BIOMET

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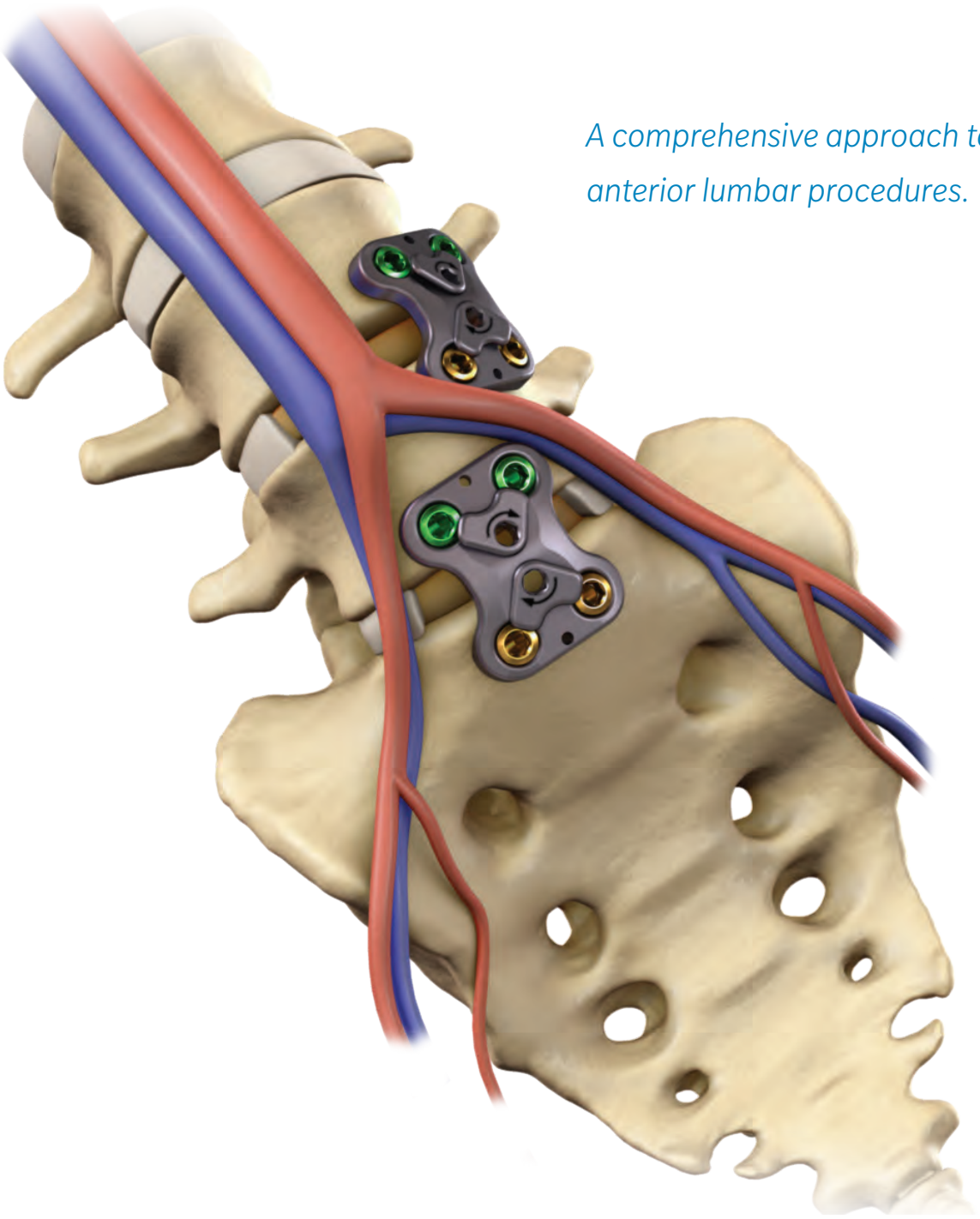
Thoracolumbar Solutions

Trinica® ALP

Anterior Lumbar Plate System

Surgical Technique Guide

MICHELSON TECHNOLOGY AT WORK



A comprehensive approach to anterior lumbar procedures.

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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.

PREPARATION AND ACCESS

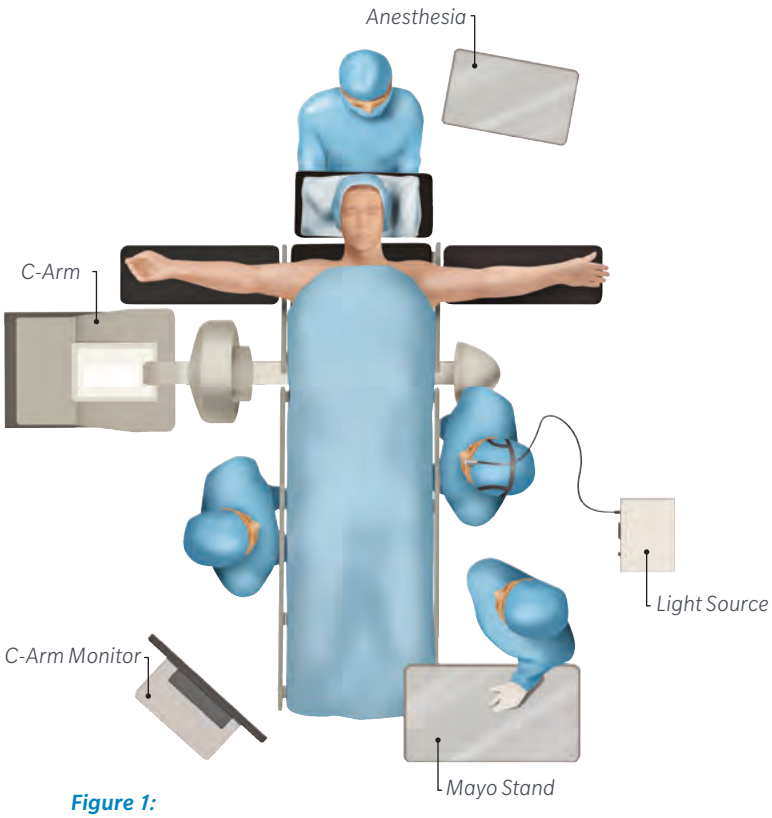


Figure 1:
Surgical exposure and site preparation

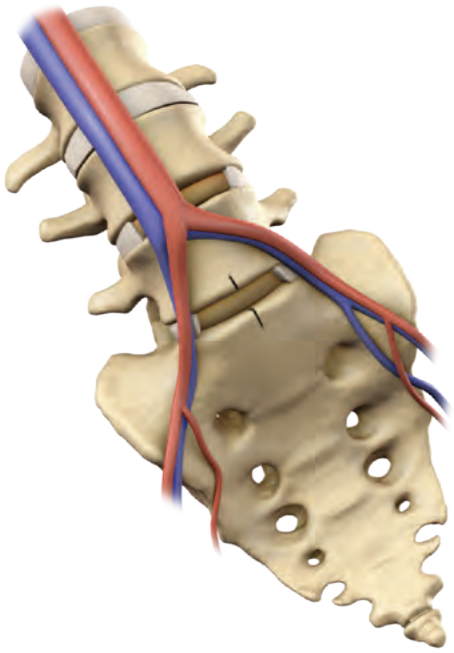


Figure 2:
Vertebral body preparation

STEP 1

- Position and drape the patient in the usual fashion (Figure 1).
- Prepare the patient for an anterior lumbar fusion using the standard surgical technique.
- Confirm the location of the great vessels using MRI or CT scans. Once the location of the great vessels has been determined, confirm the position of the Trinica Anterior Lumbar Plate.
- It is highly recommended that this procedure be done under fluoroscopic monitoring.
- Following the placement of the preferred interbody device, prepare the vertebral bodies by removing any prominent osteophytes to allow improved placement of the Trinica Anterior Lumbar Plate. Identifying and marking the midline of the vertebral body will help you orient the plate in the center of the vertebral body, where applicable. Marking the midline is recommended (Figure 2).

PLATE SIZE SELECTION

Figure 3:
Plate size selection

STEP 2

- The plate sizers and/or x-ray templates may be used to determine the appropriate length Trinica lumbar/sacral plate (Figure 3). An appropriately sized plate will position the screws as close to the vertebral endplates as possible without interfering with the interbody device. If fusing two levels, make sure adequate space is available for the adjacent level plate.

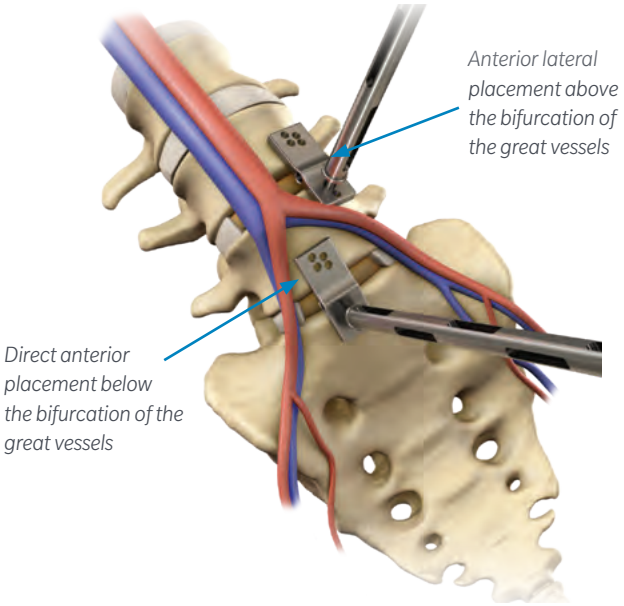


Figure 4:
Plate size selection - Visual

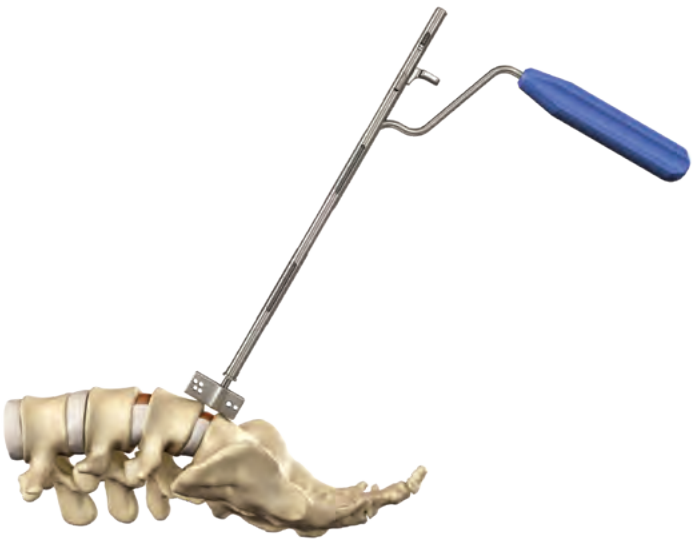


Figure 5:
Plate size selection - Fluoroscopy

STEP 3: *Option 1*

- When placed flat against the spine, the plate sizer assists in visually selecting the appropriate length trinica plate. Attach the appropriate plate sizer to the plate holder using the hole in the middle of the plate sizer. Position the plate sizer so the bottom hole is positioned on the inferior vertebral body. Visually confirm which hole on the opposite end of the plate sizer would be the best location for the superior screws (Figure 4).
- The number adjacent to each screw hole on the superior end of the plate sizer indicates the plate length. If the standard plate sizer doesn't span the interbody disc space, attach the macro plate sizer to the plate holder and repeat sizing steps.

  Note: *Lumbar plates are designed to be used from L1 to L5 only. Sacral plates are designed to be used at L5-S1 only.*

STEP 3: *Option 2*

- Attach the standard plate sizer to the plate holder using the single hole on the side of the plate (Figure 5).
- Position the plate sizer so the bottom hole on the sizer's face is positioned on the inferior vertebral body. A lateral fluoroscopy image should then be taken. Determine which one of the multiple holes on the plate sizer would be the best location for the superior screws.
- The number adjacent to each screw hole on the superior end of the plate sizer indicates the plate length. If the standard plate sizer doesn't span the interbody disc space, attach the macro plate sizer to the plate holder and repeat sizing steps.

  Note: *Lumbar plates are designed to be used from L1 to L5 only. Sacral plates are designed to be used at L5-S1 only.*

PLATE ANGLE SELECTION

The Trinica Anterior Lumbar Plate System offers multiple angle plates in both the lumbar and sacral configurations. Multiple angles eliminate the need for plate bending. Various configurations facilitate an optimal fit between the plate and anatomical variations in the vertebral body.

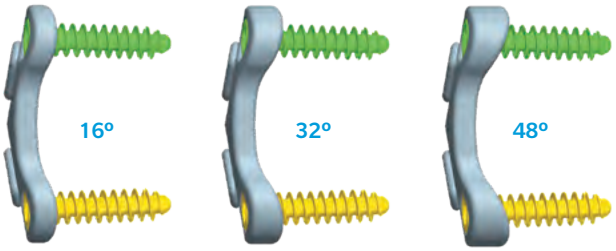


Figure 6:
Lumbar plate angles

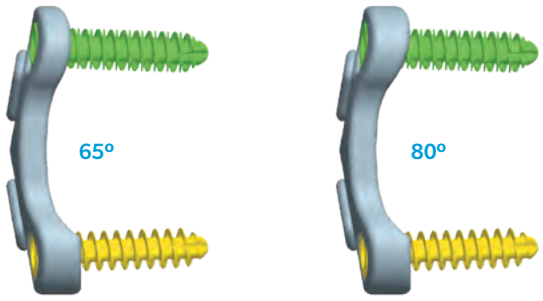


Figure 7:
Sacral plate angles

STEP 4

- The lumbar plate is offered in 16°, 32°, or 48° configurations (Figure 6).
- X-ray templates should be utilized to determine the appropriate "Bone Deficit Filling" plate.
- The sacral plate is available in 65° or 80° configurations (Figure 7).
- X-ray templates should be utilized to determine the appropriate "Bone Deficit Filling" plate.

PLATE POSITIONING

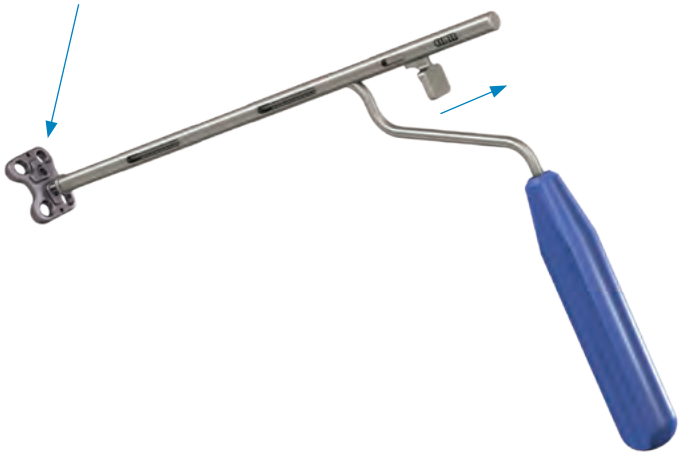


Figure 8:
Standard plate holder

Figure 9:
Fixed plate holder

STEP 5: *Option 1*

- Attach the appropriately sized lumbar or sacral plate to the standard plate holder. The tip of the standard plate holder interfaces with the plate in the center hex hole of the locking cap. Pull the standard plate holder's trigger and press its tip completely into the center hex hole on the plate's locking cap. Release the trigger to lock the tip of the standard plate holder to the plate (Figure 8).
- The radius of the standard plate holder's tip allows its handle to be turned and positioned where necessary while interfacing with the hex hole in the locking cap.

  Note: *It is recommended that rotational adjustments to the standard plate holder be done in a counterclockwise motion to avoid prematurely rotating the locking cap over the screw holes.*

  Note: *Ensure that the locking cap is in the open position to prevent interference with the guide tubes and screws during insertion.*

STEP 5: *Option 2*

- Attach the appropriately sized lumbar or sacral plate to the fixed plate holder. Pull the fixed plate holder's trigger and press its tip completely into the center hex hole on the plate's locking cap. Release the trigger to lock the tip of the fixed plate holder to the plate.
- Insert the fixed plate holder into the locking cap on the end of the plate where the first set of screw holes will be prepared, orienting the handle over the opposite set of screw holes (Figure 9).

  Note: *If the fixed plate holder does not fully engage the plate, use the self-retaining screwdriver to rotate the locking cap until it no longer interferes with the fixed plate holder.*

  Note: *The fixed plate holder is not designed to interface with the plate sizers. If using the sizers, select the standard plate holder instead.*

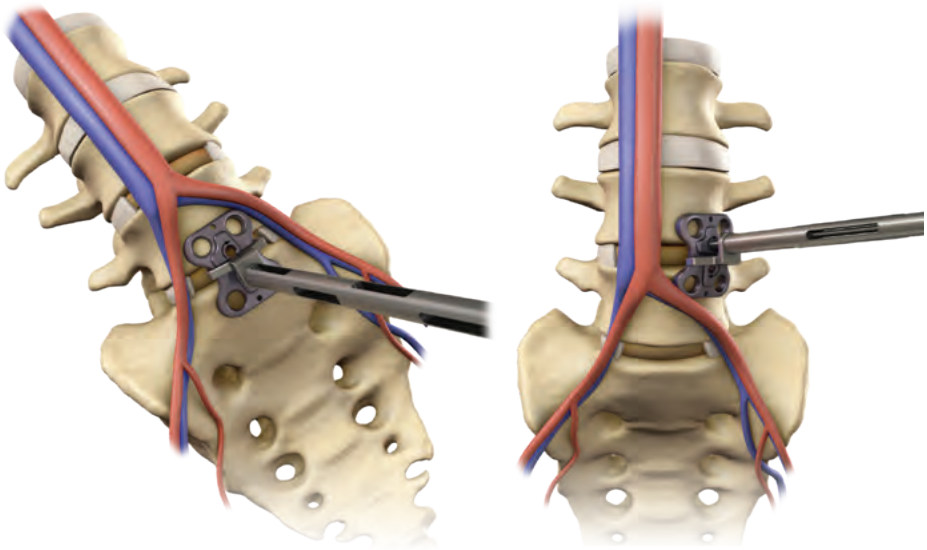


Figure 10:
Plate positioning

STEP 6

- Once the appropriate plate has been selected and attached to the plate holder, position the plate so the screw holes are as close to the vertebral body endplates as possible without interfering with the interbody device (Figure 10).

Note: *If placing the Trinica lumbar plate from purely an anterior approach, the plate must be placed below the bifurcation of the great vessels.*

Note: *The sacral plate is labeled "SACRUM" on the end that should be positioned over the sacrum.*

TEMPORARY FIXATION PINS *(Optional)*

The Trinica ALP System offers two styles of temporary fixation pins to provide short-term stability during plate placement and initial fixation. The Trinica ALP standard temporary fixation pin (07.01090.001) may be placed through either the fixation pin hole or the screw hole on the Trinica lumbar or sacral plate.

The Trinica ALP large temporary fixation pin (07.01311.001) will only pass through the screw holes of the lumbar and sacral plates due to its increased diameter.

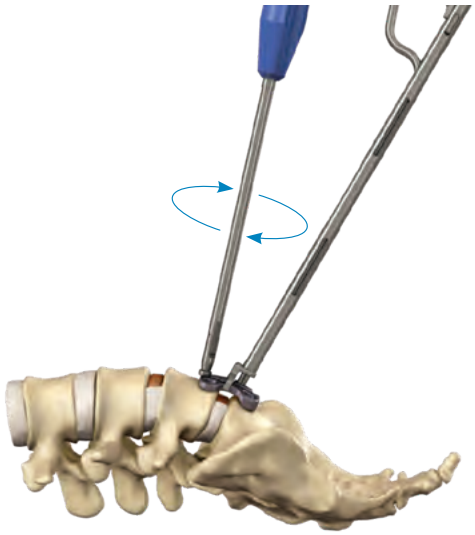


Figure 11:
Standard temporary fixation pin

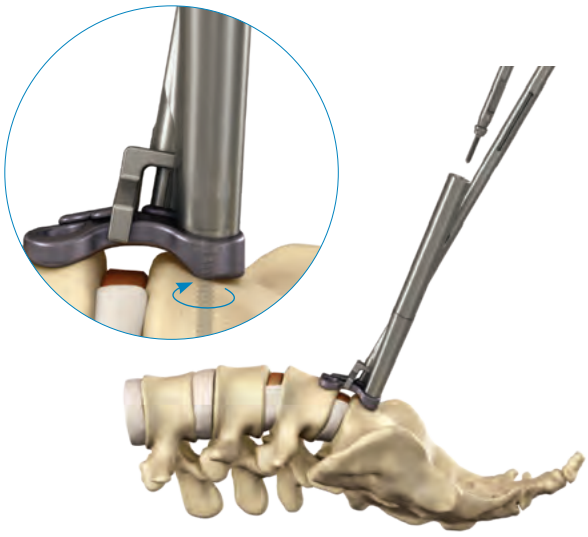


Figure 12:
Large temporary fixation pin

STEP 7: *Option 1*

- Insert a standard temporary fixation pin into the pin inserter and place it in either the superior or inferior temporary fixation pin hole or the appropriate screw hole on the plate (opposite the end that initial bone screws will be inserted into).

  Note: *If the standard temporary fixation pin is used at the sacrum, the pin must be inserted through one of the sacral screw holes to ensure adequate pin thread engagement.*

- Rotate the pin inserter clockwise to advance the pin into the vertebra (Figure 11).

  Note: *The cervical trinica temporary fixation pin (07.00656.002) should not be used with the Trinica ALP System.*

STEP 7: *Option 2*

- Insert a large temporary fixation pin into the pin inserter. To ensure that placement of the large temporary fixation pin does not compromise final screw placement, utilization of the appropriate angle ato guide tube is recommended. (See Step 8 for instructions on placing the guide tube.)

- Rotate the pin inserter clockwise to advance the pin into the vertebra (Figure 12).

  Note: *The cervical trinica temporary fixation pin (07.00656.002) should not be used with the Trinica ALP System.*

ATO GUIDE TUBE SELECTION

The Trinica Anterior Lumbar Plate System offers three double-barrel ATO Guide Tube options. All Guide Tubes are designed to place the screws at a convergent angle of 7.5° per side (15° included angle).

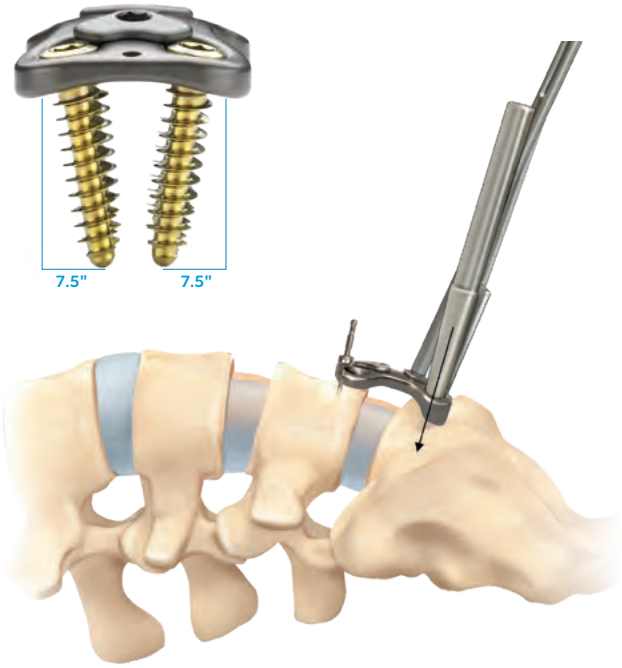


Figure 13:
Fixed angle guide tube, 0°

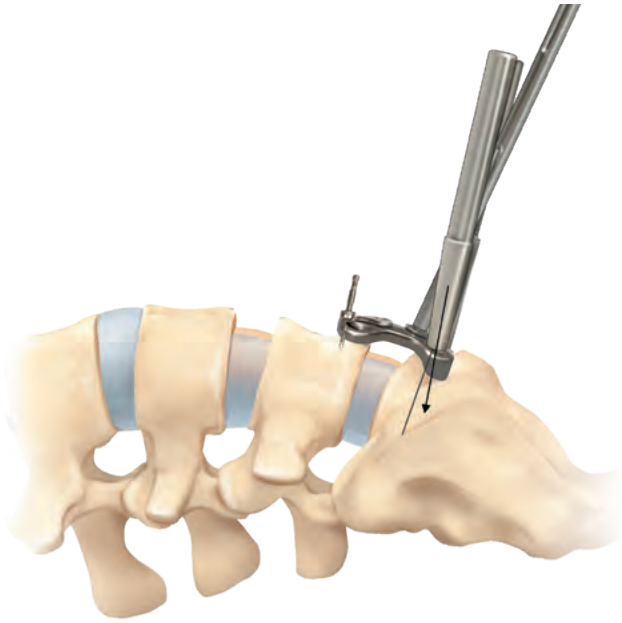


Figure 14:
Variable angle guide tube, 3°

STEP 8: *Option 1*

- A trajectory of 0° places the screws perpendicular in relation to the plate or parallel to the vertebral endplates (Figure 13).

  Note: *You must use the fixed angle guide tube when placing fixed angle screws. The fixed angle screws may not interface with the plate appropriately if the 3° or 6° ATO guide tubes are used to prepare the screw holes. Any of the three guide tube options can be utilized when placing variable angle screws.*

STEP 8: *Option 2*

- The angle of this tube places screws in a 3° trajectory away from the vertebral endplates (Figure 14).

  Note: *you must use the fixed angle guide tube when placing fixed angle screws. The fixed angle screws may not interface with the plate appropriately if the 3° or 6° ATO guide tubes are used to prepare the screw holes. Any of the three guide tube options can be utilized when placing variable angle screws.*

ATO GUIDE TUBE SELECTION *(continued)*

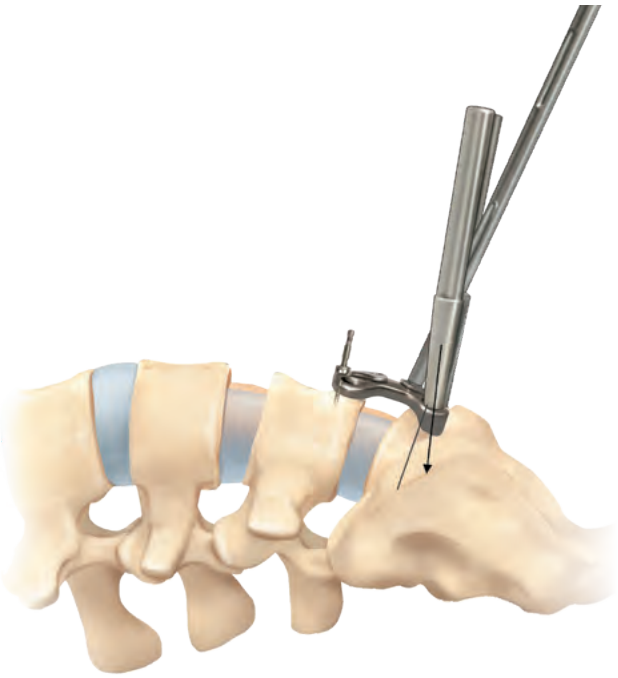


Figure 15:
Variable angle guide tube, 6°

Figure 16:
Attach the ATO guide tube to the plate holder

STEP 8: *Option 3*

- The angle of this tube places screws in a 6° trajectory away from the vertebral endplates (Figure 15).

  Note: *You must use the fixed angle guide tube when placing fixed angle screws. The fixed angle screws may not interface with the plate appropriately if the 3° or 6° ATO guide tubes are used to prepare the screw holes. Any of the three guide tube options can be utilized when placing variable angle screws.*

STEP 9

- Position the predetermined ATO guide tube over the top of the plate holder shaft; slide the guide tube down the shaft until it contacts the plate (Figure 16).
- If using the standard plate holder, rotate the guide tube either left or right until the pin on the guide tube is within the plate's temporary fixation pin hole.

  Note: *The temporary fixation pin should be removed from the end of the plate on which you are working.*

SCREW HOLE PREPARATION

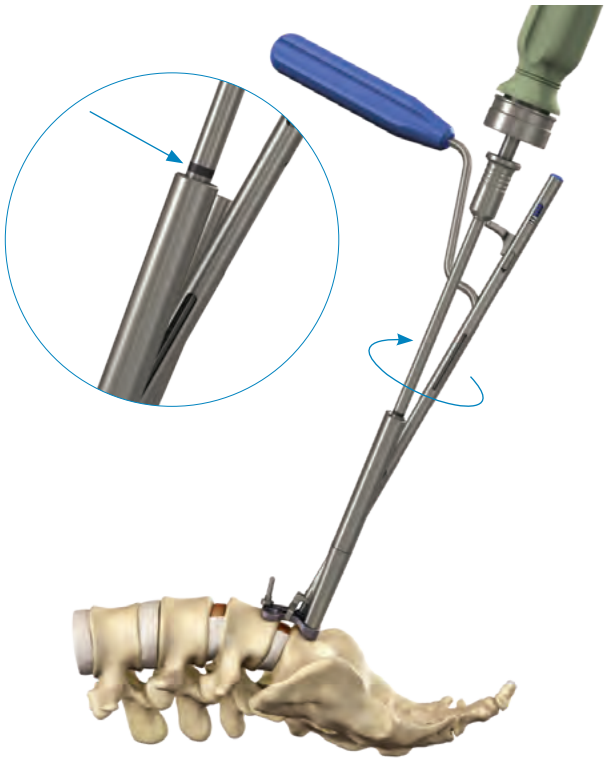


Figure 17:
Drilling

Figure 18:
Bone awl

STEP 10: *Option 1*

- The angle of this tube places screws in a 6° trajectory away from the vertebral endplates (Figure 17).

  Note: *You must use the fixed angle guide tube when placing fixed angle screws. The fixed angle screws may not interface with the plate appropriately if the 3° or 6° ATO guide tubes are used to prepare the screw holes. Any of the three guide tube options can be utilized when placing variable angle screws.*

STEP 10: *Option 2*

- An awl is included in the Trinica ALP set an an alternative to the drill and tap. Place the awl into the guide tube of the hole to be prepared. Once inserted, twist the handle back and forth while applying downward pressure on the handle (Figure 18). Continue advancing the tip of the awl until you reach the positive stop. A mallet may also be used to impact the awl.
- Remove the awl from the guide tube by twisting the handle back and forth while pulling the handle out of the guide tube. Apply slight downward pressure to the guide tube when removing the awl to ensure that the guide tube remains appropriately oriented to the plate. Repeat for all remaining bone screw preparations.

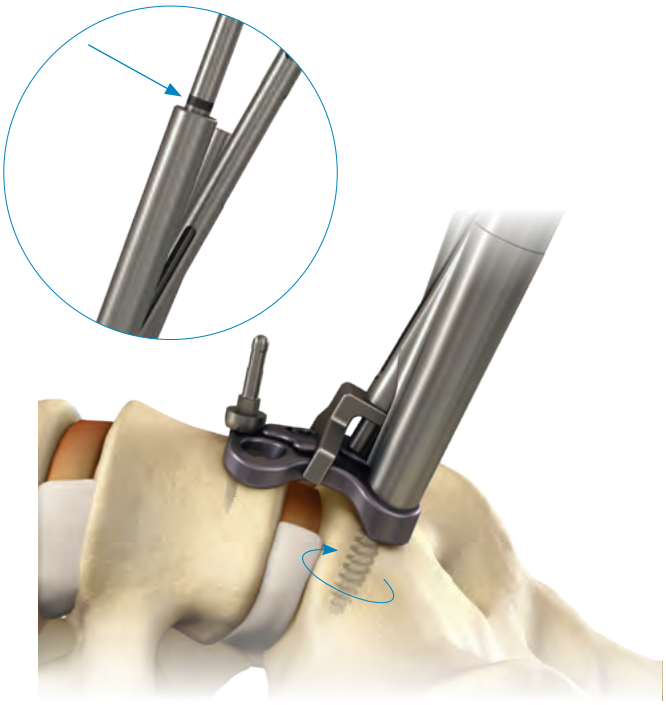


Figure 19:
Tapping

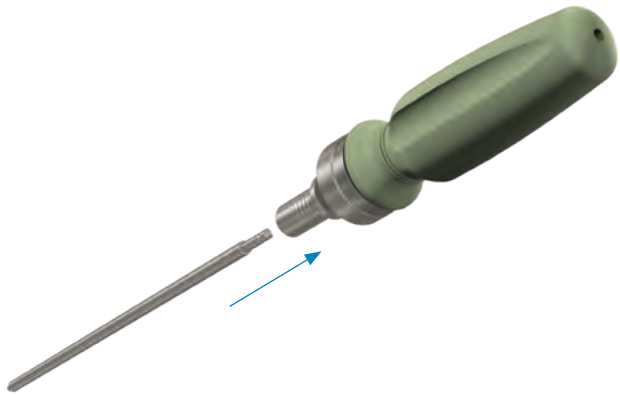


Figure 20:
Self-retaining screw driver assembly

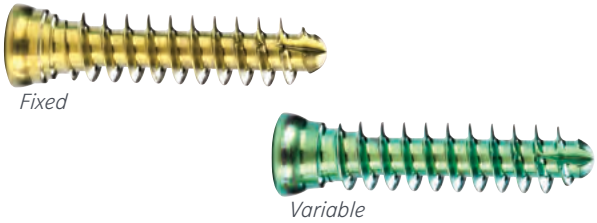


Figure 21:
Screw selection

STEP 11: Tapping *(Optional)*

- Attach the ratcheting driver handle to the tap. Insert the tap into the guide tube; rotate the tap clockwise, advancing it until the laser-marked line on the shaft of the tap lines up with the top of the guide tube. This represents a fully advanced tap position; do not advance past the laser-marked line.
- To remove, rotate the tap counterclockwise until it is free. Remove it from the guide tube. Apply slight downward pressure to the guide tube when removing the tap to ensure that the guide tube remains in appropriate orientation with the plate (Figure 18).

  Caution: *Do not continue to rotate the tap once the lasermarked line meets the top of the guide tube. Continued rotation of the tap may strip the bone threads.*

STEP 12

- Assemble the self-retaining screwdriver shaft to the ratcheting driver handle (Figure 20).
- Select the appropriate screw type (fixed or variable angle) and length (22 to 34 mm) (Figure 21).
- X-ray templates can be used to confirm the appropriate length fixed or variable angle screw

  Surgical Recommendation: *Ensure that the bone screw extends two-thirds of the way into the vertebral body.*

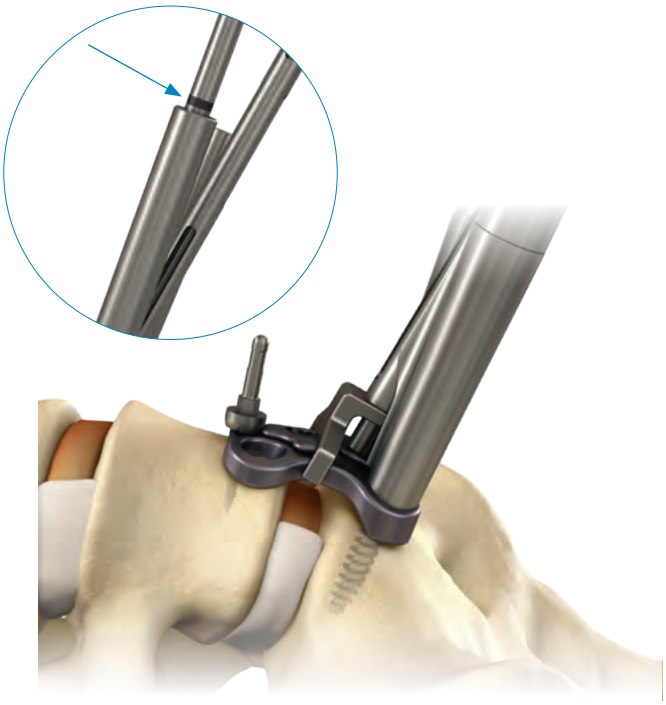


Figure 22:
Screw insertion

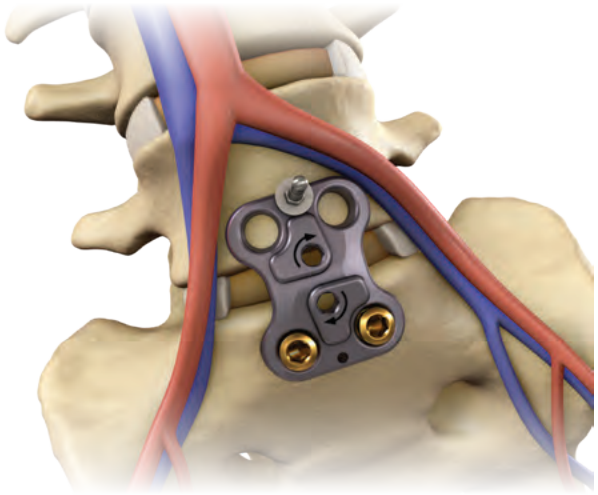


Figure 23:
Instrument removal

STEP 13

- Insert the tip of the self-retaining screwdriver into the hex of the bone screw using downward pressure on the driver to secure the screw to the driver tip.
- Insert the bone screw through the guide tube into the desired prepared screw hole and rotate clockwise to advance the bone screw until the laser-marked line on the self-retaining screwdriver meets the top of the guide tube. This will position the screw about two turns from a fully seated position (Figure 22).
- Apply slight downward pressure to the guide tube when removing the self-retaining screwdriver to ensure that the guide tube remains in appropriate orientation with the plate. Repeat steps 10-13 for the opposite screw hole.

  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.*

STEP 14

- Once both the screws have been provisionally placed, remove the plate holder/guide tube assembly (Figure 23).

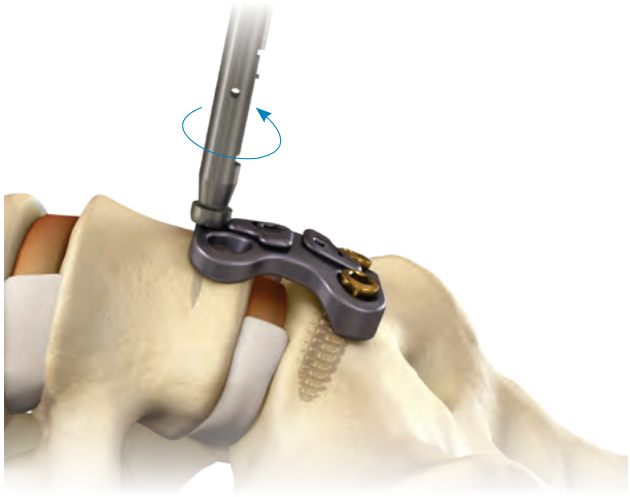


Figure 24:
Temporary fixation pin removal

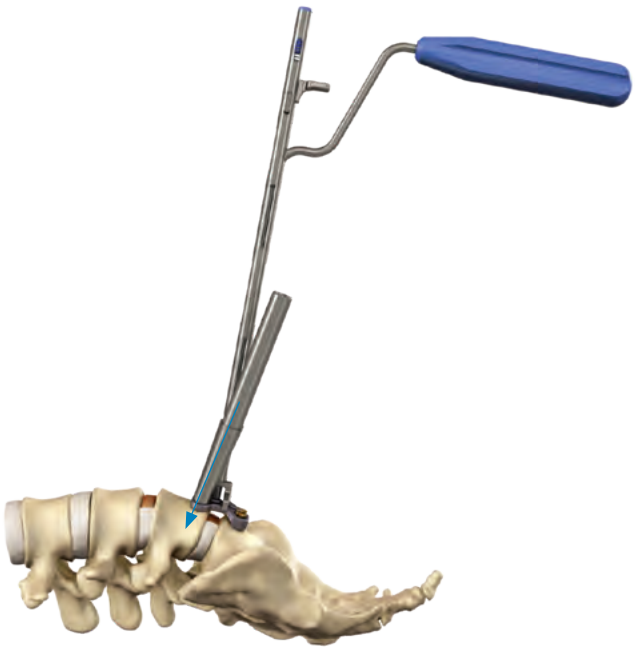


Figure 25:
Remaining screw hole preparation

STEP 15

- Remove the temporary fixation pins before repositioning the ATO guide tube. Use the pin inserter to engage the top portion of the pin; rotate counterclockwise to remove the temporary fixation pin (Figure 24).

  Note: *The temporary fixation pins are intended for single use only. Discard after use. Temporary fixation pins must be removed from the surgical site prior to closure.*

STEP 16

- Reposition the Plate Holder and appropriate Guide Tube over the next set of screw holes and repeat steps 10-14 (Figure 25).

FINAL TIGHTENING

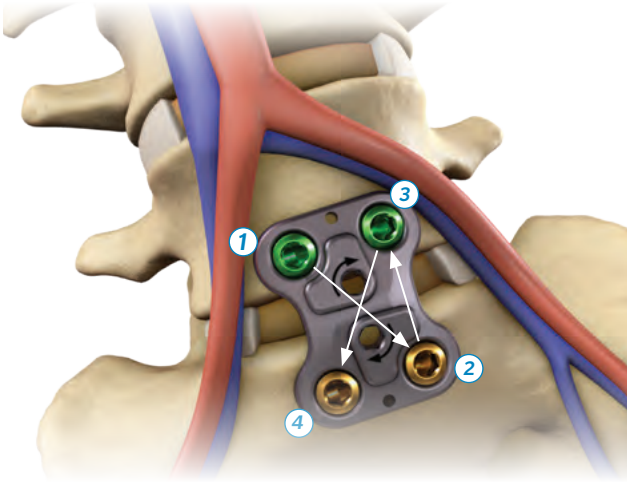


Figure 26:
Final tightening

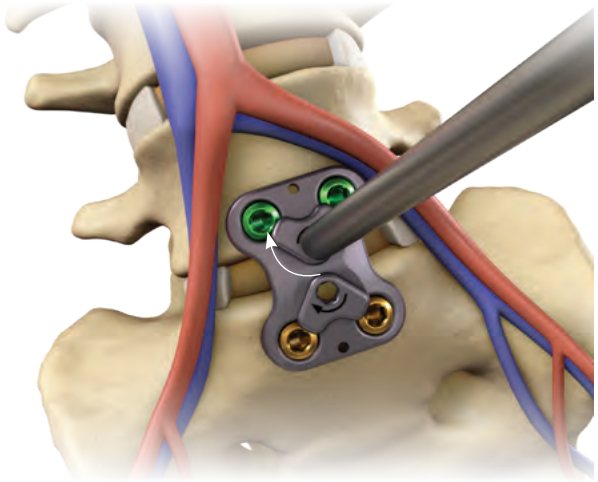


Figure 27:
Secure locking caps

STEP 17

- Once all four screws have been provisionally inserted, the screws should be fully tightened under direct visualization. It is recommended that screws be fully tightened in a star pattern to ensure the lumbar or sacral plate seats evenly against the vertebral bodies (Figure 26).

STEP 18

- *Secure-Twist* anti-migration locking caps are pre-installed and positioned on the plate to allow insertion of the bone screws. Each cap will secure the bone screws within the plate when the cap is rotated to a secure closed position.
- Once all bone screws are placed, use the self- retaining screwdriver to rotate the secure-twist cap clockwise to secure it. The cap will tighten and you will be able to visually confirm that the locking cap covers the screws (Figure 27).

IMPLANT REMOVAL / REVISION

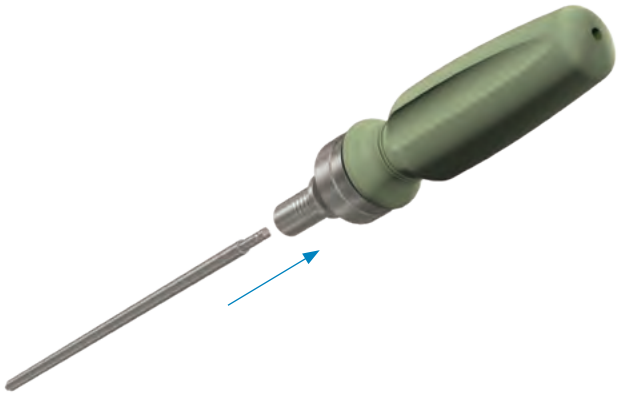


Figure 28

- Attach the self-retaining screwdriver to the ratcheting driver handle (Figure 28).

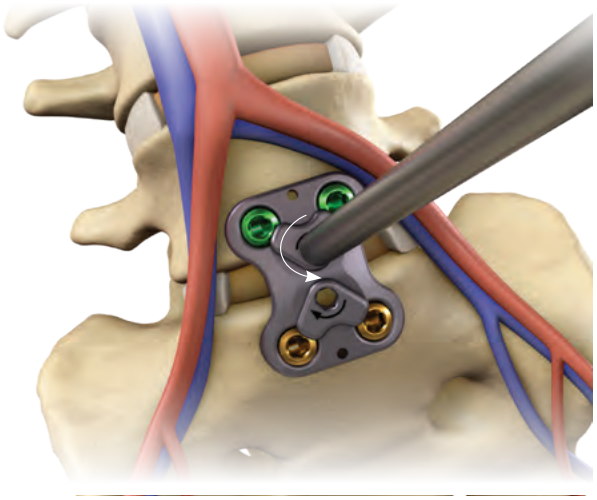


Figure 29

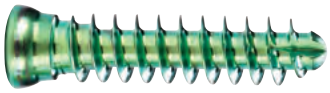
- Insert the tip of the self-retaining screwdriver into the hex cap on the secure-twist locking cap. Rotate the cap counterclockwise until it is clear of all screw heads (Figure 29).
- Insert the tip of the self-retaining screwdriver into the hex of the screw. Rotate it counterclockwise to remove the screw. Repeat for all remaining screws.
- After all screws have been removed, remove the plate.

TRINICA ALP IMPLANTS

Lumbar Plate	PART NUMBER
16º (35-51 mm)	07.01008.002 – 07.01008.010
32º (35-43 mm)*	07.01009.002 – 07.01009.006
48º (35-43 mm)*	07.01010.002 – 07.01010.006

Sacral Plate	PART NUMBER
65º (35-47 mm)	07.01011.002 – 07.01011.008
80º (35-41 mm)*	07.01012.002 – 07.01012.005

Fixed Screw	PART NUMBER
22-34 mm	07.01013.001 – 07.01013.007



Variable Screw	PART NUMBER
22-34 mm	07.01014.001 – 07.01014.007

**Longer sizes available by special request*

TRINICA ALP INSTRUMENTS

Standard Plate Holder	PART NUMBER
	07.01042.001

Fixed Plate Holder	PART NUMBER
	07.01259.001

Plate Sizer	PART NUMBER
Standard	07.01050.001
Macro	07.01051.001

Temporary Fixation Pin Inserter	PART NUMBER
	07.00352.001

Temporary Fixation Pin	PART NUMBER
Standard	07.01090.001
Large	07.01311.001

TRINICA ALP INSTRUMENTS

ATO Guide Tube	PART NUMBER
3°	07.01043.001
6°	07.01045.001
Fixed Angle	07.01044.001

Straight Ratcheting Driver Handle	PART NUMBER
	07.00438.001

Ratcheting T-Handle	PART NUMBER
	07.00563.001

Drill, 3mm	PART NUMBER
	07.01047.001

Awl	PART NUMBER
	07.01046.001

Tap	PART NUMBER
	07.01048.001

Self-Retaining Screw Driver, 3.5 mm	PART NUMBER
	07.01053.001

TRINICA ALP KIT CONTENTS

Implant Kit 07.01008.402

DESCRIPTION	QTY	PART NUMBER
35 mm Lumbar Plate, 16°	1	07.01008.002
37 mm Lumbar Plate, 16°	1	07.01008.003
39 mm Lumbar Plate, 16°	1	07.01008.004
41 mm Lumbar Plate, 16°	1	07.01008.005
43 mm Lumbar Plate, 16°	1	07.01008.006
45 mm Lumbar Plate, 16°	1	07.01008.007
47 mm Lumbar Plate, 16°	1	07.01008.008
49 mm Lumbar Plate, 16°	1	07.01008.009
51 mm Lumbar Plate, 16°	1	07.01008.010
35 mm Lumbar Plate, 32°	1	07.01009.002
37 mm Lumbar Plate, 32°	1	07.01009.003
39 mm Lumbar Plate, 32°	1	07.01009.004
41 mm Lumbar Plate, 32°	1	07.01009.005
43 mm Lumbar Plate, 32°	1	07.01009.006
35 mm Lumbar Plate, 48°	1	07.01010.002
37 mm Lumbar Plate, 48°	1	07.01010.003
39 mm Lumbar Plate, 48°	1	07.01010.004
41 mm Lumbar Plate, 48°	1	07.01010.005
43 mm Lumbar Plate, 48°	1	07.01010.006
35 mm Sacral Plate, 65°	1	07.01011.002
37 mm Sacral Plate, 65°	1	07.01011.003
39 mm Sacral Plate, 65°	1	07.01011.004
41 mm Sacral Plate, 65°	1	07.01011.005
43 mm Sacral Plate, 65°	1	07.01011.006
45 mm Sacral Plate, 65°	1	07.01011.007
47 mm Sacral Plate, 65°	1	07.01011.008
35 mm Sacral Plate, 80°	1	07.01012.002
37 mm Sacral Plate, 80°	1	07.01012.003
39 mm Sacral Plate, 80°	1	07.01012.004
41 mm Sacral Plate, 80°	1	07.01012.005

DESCRIPTION	QTY	PART NUMBER
ø5.5 mm x 22 mm Fixed Screw	5	07.01013.001
ø5.5 mm x 24 mm Fixed Screw	5	07.01013.002
ø5.5 mm x 26 mm Fixed Screw	5	07.01013.003
ø5.5 mm x 28 mm Fixed Screw	5	07.01013.004
ø5.5 mm x 30 mm Fixed Screw	5	07.01013.005
ø5.5 mm x 32 mm Fixed Screw	5	07.01013.006
ø5.5 mm x 34 mm Fixed Screw	5	07.01013.007
ø5.5 mm x 22 mm Variable Screw	5	07.01014.001
ø5.5 mm x 24 mm Variable Screw	5	07.01014.002
ø5.5 mm x 26 mm Variable Screw	5	07.01014.003
ø5.5 mm x 28 mm Variable Screw	5	07.01014.004
ø5.5 mm x 30 mm Variable Screw	5	07.01014.005
ø5.5 mm x 32 mm Variable Screw	5	07.01014.006
ø5.5 mm x 34 mm Variable Screw	5	07.01014.007

TRINICA ALP KIT CONTENTS *(continued)*

Instrument Kit 07.01008.401

DESCRIPTION	QTY	PART NUMBER
Temporary Fixation Pin Inserter	1	07.00352.001
Straight Ratcheting Handle	1	07.00438.001
Plate Holder	1	07.01042.001
ATO Guide Tube, 3-Degree	1	07.01043.001
ATO Guide Tube, Fixed	1	07.01044.001
ATO Guide Tube, 6-Degree	1	07.01045.001
Awl	1	07.01046.001
Drill, 3mm	1	07.01047.001
Tap, 5.5mm	1	07.01048.001
Plate Sizer, Standard	1	07.01050.001
Plate Sizer, Macro	1	07.01051.001
Tapered Hex Driver	1	07.01053.001

Special-Order Implants

The implants listed in this section are not included in the Trinica ALP Implant Kit. They may be ordered individually by part number.

DESCRIPTION	QTY	PART NUMBER
45 mm Lumbar Plate, 32°	1	07.01009.007
47 mm Lumbar Plate, 32°	1	07.01009.008
49 mm Lumbar Plate, 32°	1	07.01009.009
51 mm Lumbar Plate, 32°	1	07.01009.010
45 mm Lumbar Plate, 48°	1	07.01010.007
47 mm Lumbar Plate, 48°	1	07.01010.008
49 mm Lumbar Plate, 48°	1	07.01010.009
51 mm Lumbar Plate, 48°	1	07.01010.010
43 mm Sacral Plate, 80°	1	07.01012.006
45 mm Sacral Plate, 80°	1	07.01012.007
47 mm Sacral Plate, 80°	1	07.01012.008
49 mm Sacral Plate, 80°	1	07.01012.009
51 mm Sacral Plate, 80°	1	07.01012.010

Additional Instruments

The instruments listed in this section are not included in the Trinica ALP Instrument Set. They may be ordered individually by part number.

DESCRIPTION	PART NUMBER
Trinica ALP Threaded Fixation Pin, Standard	07.01090.001
Trinica ALP Threaded Fixation Pin, Large	07.01311.001
Trinica ALP Fixed Plate Holder	07.01259.001

X-Ray Templates

Templates may be ordered individually by part number.

DESCRIPTION	PART NUMBER
Trinica Lumbar Lateral Cross Section Surgical Template	L1349
Trinica Lumbar Anterior/Posterior Surgical Template	L1350
Trinica Sacral Lateral Cross Section Surgical Template	L1351
Trinica Sacral Anterior/Posterior Surgical Template	L1352
Trinica ALP Surgical Templates – Outlying Sizes	L1370

IMPORTANT INFORMATION ON THE TRINICA ALP SYSTEM

Device Description

The Trinica Anterior Lumbar Plate System is a temporary supplemental fixation device consisting of a variety of shapes and sizes of plates and screws. The Trinica Anterior Lumbar Plate System is used as an implant for the correction and stabilization of the spine. This system provides temporary stabilization and augments the development of a solid spinal fusion. Additionally, this system provides the surgeon with the ability to supplement an interbody device with anterior plate fixation. The Trinica Anterior Lumbar Plate System components can be locked into a variety of configurations and each construct may be customized to individual cases. The plates are low profile and anatomically designed to provide optimal fit from either anterior or anterior-lateral approach. This system also features anti-migration locking caps to help secure the fixation screws. All implants supplied with this package insert are intended for single use only. Instruments supplied with this package insert may be reused. Refer to product label to determine if the instrument is intended for single use only.

Materials:

Implants: The Trinica Anterior Lumbar Plate System implants (plates and bone screws) are manufactured from Titanium alloy (Ti-6AI-4V ELI) per ASTM F-136.

Instruments: The Trinica Anterior Lumbar Plate System instrumentation is made from medical/surgical grade: stainless steel, plastic, aluminum, and silicone.

Do not use any of the Trinica Anterior Lumbar Plate System components with the componentsfrom any other system or company unless otherwise stated in this document.

Indications For Use

The Trinica Anterior Lumbar Plate System is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels. This system is indicated in the treatment of lumbar or lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), pseudoarthrosis, spondylolisthesis, scoliosis, lordotic deformities of the spine, spinal stenosis, or a failed previous fusion.n.

Contraindications

Contraindications for the Trinica Anterior Lumbar Plate System include:

- Use in the cervical spine
- Active systemic or local infection
- Local inflammation with or without fever or leukocytosis
- Pregnancy
- Obesity
- Alcohol or drug abuse
- Use in the posterior elements (pedicles) of the cervical, thoracic, or lumbar vertebrae
- Where attempted correction exceeds the limits of physiological conditions
- Uncooperative patients or patients with neurological disorders or mental illness rendering the patient incapable of or unwilling to follow instructions
- Inability to restrict high activity level
- Suspected or documented metal allergy or intolerance
- Any case needing to mix metals from different components
- Poor prognosis for good wound healing (e.g. decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition)
- Any medical or surgical condition that would preclude the potential benefit of spinal implant surgery or prevent secure component fixation that has the potential to decrease the useful life of the device, such as the presence of tumors or congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Osteoporosis is a relative contraindication because the condition may limit the degree of obtainable correction and/or the amount of mechanical fixation
- Any case not needing a bone graft and fusion or requiring fracture healing
- Any patient with inadequate tissue coverage over the operative site, or inadequate bone stock or bone quality such as in the sacrum
- Any time implant utilization would interfere with anatomical structures or expected physiological performance
- Diseases or conditions other than those specifically described here or in the Indications section

Contraindications of this device are consistent with those of other anterior spinal instrumentation systems. This spinal implant system is not designed, intended, or sold for uses other than those indicated.

Warnings and Precautions

Following are specific WARNINGS and PRECAUTIONS, that should be understood by the surgeon and explained to the patients. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic surgical implants. General surgical risk should be explained to the patients prior to surgery.

A. Implant Selection

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in implant selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete. This may in turn result in further injury or the need to remove the device prematurely.

Implantation of foreign material in tissues can elicit an inflammatory reaction. Current literature suggests that wear debris (including metal, polyethylene, 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 are a result of the presence of nickel, cobalt, and chromium found in medical grade stainless steel and cobalt-chrome alloys.

The Trinica Anterior Lumbar Plate System instrumentation should only be used after the surgeon has had adequate training in this method of fixation and is thoroughly knowledgeable about the spinal anatomy and biomechanics. A surgical technique for the Trinica Anterior Lumbar 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 lumbar plating systems must not be intermixed with the Trinica Anterior Lumbar Plate System components since compatibility of these components is not known.

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

Physician Note:

Although the physician is the educated intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

B. Preoperative

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindication should be avoided.
- Care should be taken in the handling and storage of the implant components. The implants should not be scratched or damaged. Implants and instruments should especially be protected from corrosive environments during storage.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. Do not combine Trinica components with the components from another manufacturer. Different metal types should not be used together.
- All non-sterile instruments should be cleaned and sterilized prior to use. All non-sterile implants are provided clean and must be sterilized prior to use Additional sterile components should be available in case of an unexpected need.

C. Intraoperative

- Follow all instruction manuals carefully.
- Use extreme caution around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- When the configuration of the bone cannot be fitted with an available temporary internal fixation device and contouring is absolutely necessary, it is recommended that such contouring be gradual and that great care be taken to avoid notching or scratching the surface of the device(s). Scratching or notching of the implant surface may reduce the functional strength of the construct.
- Do not bend implants.
- To assure proper fusion below and around the locations of the instrumentation, a bone graft should be used.
- Do not use bone cement because this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.

- Before closing, all of the screws should be seated onto the plate. Caution: Do not over tighten; over tightening screws may strip the threads. Additional sterile components should be available in case of an unexpected need.

D. Postoperative

The physician's postoperative instructions and warnings to the patient and the corresponding patient compliance are extremely important.

- Provide the patient with detailed instructions on the use and limitations of the device. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the device are complications which can occur as a result of excessive weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may increase if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be advised to avoid falls or sudden jolts in spinal position.
- To allow the best chance for a successful surgical result the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. Warn the patient of this possibility and instruct him or her to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. Advise the patient not to smoke during the bone graft healing process.
- Advise the patient of their inability to bend at the point of spinal fusion and teach them to compensate for this permanent physical restriction in body motion.
- If a non-union occurs or if the components loosen, bend, and/or break, revise and/or remove the devices immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the fracture or surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination.
- Trinica Anterior Lumbar Plate System implants 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 may be removed at surgeon's discretion. In most cases, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain, (2) Migration of implant position resulting in injury, (3) Risk of additional injury from postoperative trauma, (4) Bending, loosening and/or breakage, which could make removal impractical or difficult, (5) Pain, discomfort, or abnormal sensations due to the presence of the device, (6) Possible increased risk of infection, and (7) Bone loss due to stress shielding. Implant removal, should be followed by adequate postoperative management to avoid fracture or refracture.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. None of the Trinica Anterior Lumbar Plate System implant components should be reused under any circumstances.

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. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.*

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