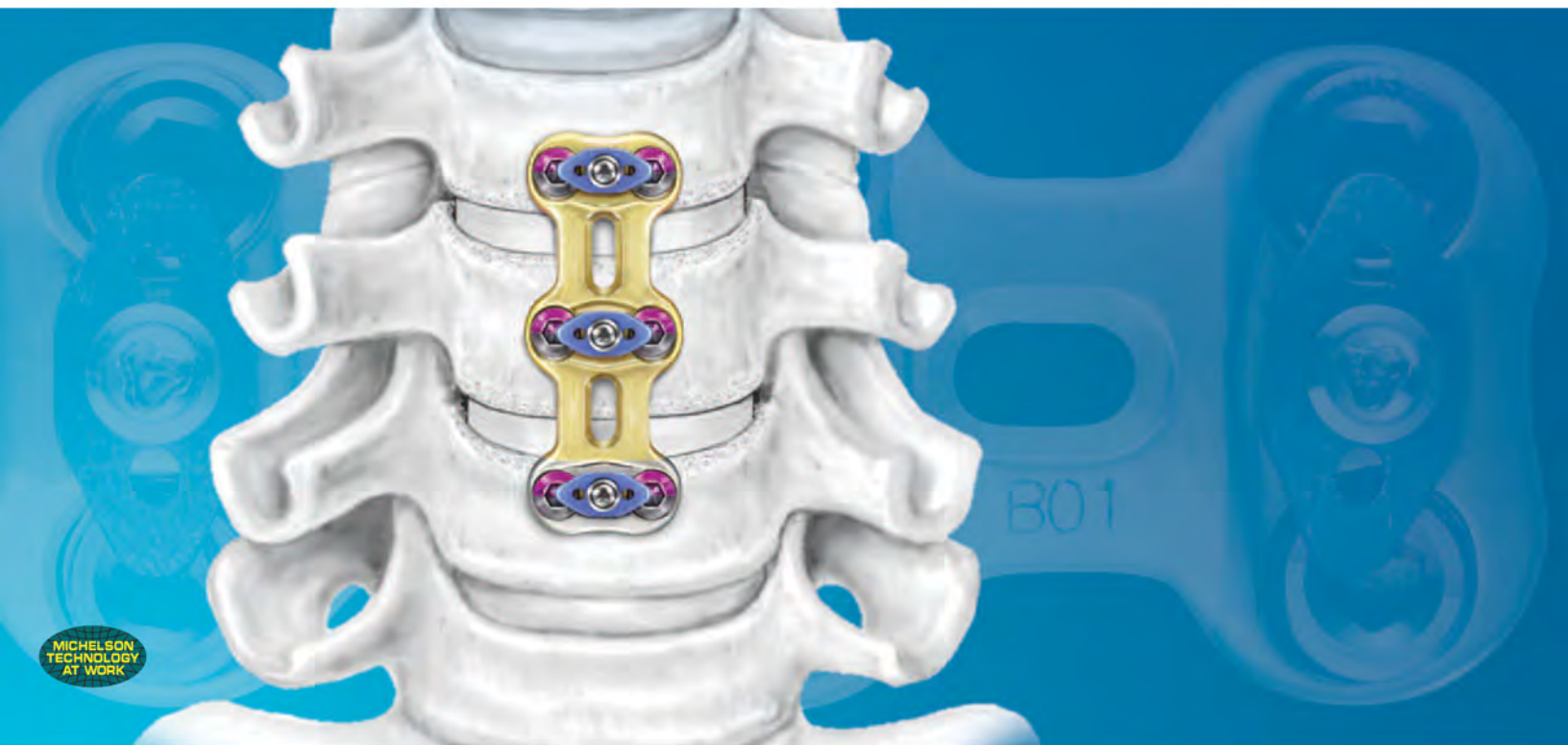




Reliant™

Anterior Cervical Plating (ACP) System



Reliant Operative Technique



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INTRODUCTION

The Gold Standard in Semi-Constrained Fixation

The consummate solution for semi-constrained anterior spinal fusion, the Reliant Anterior Cervical Plate (ACP) System simplifies the procedure with an improved system that offers controlled subsidence and fast, reproducible results

Demonstrating engineering excellence, the Reliant ACP System features a sleek ultra-thin plate for easy insertion and large slate slots for enhanced visual confirmation of the allograft.

Key Benefits:

- Ultra-thin plate profile for greatest comfort in the anatomy
- Large visual access areas for maximum allograft viewing through and around plate
- Elongated screw holes offer controlled subsidence
- One screw type for semi-constrained fixation

Giving Surgeons Complete Control

With up to four level cervical plates and varying color-coded system components, surgeons can find the right solution for every patient. The plate itself offers obvious benefits, particularly the large plate slots allowing surgeons optimal viewing of the fusion bed. Smart and intuitive instrumentation allows surgeons to drill and tap without changing instruments.

- Easy-to-use variable and fixed angle freehand drill guides allow for variable angle bone screw placement
- Top-locking screw driver uses a plate rotator that automatically locates the holes in the top locking plate for easy engagement
- Retention mechanism ensures complete control during insertion

The Reliant ACP System offers a full complement of colored cervical plates and color-coded bone screws that can be adapted to suit surgeon preferences as they repair a wide spectrum of anterior spinal disorders where semi-constrained fusion is indicated.



Fig. 1

1. PATIENT POSITIONING

As with any spine surgery, preoperative planning is essential to reduce the chances of intraoperative complications due to unrecognized anatomic aberrations. Measuring the vertebral body dimension in both A/P and lateral planes is recommended to determine the appropriate interbody device, cervical plate and bone screw sizes.

The patient is placed in a supine position with all bony prominences padded and the head in slight extension. The cervical spine is supported to maintain cervical lordosis.



Fig. 2

2. EXPOSURE

Adequate visualization of the vertebrae and disc space are critical. Ventral soft tissue should be removed from the vertebral body to create a smooth surface for optimal surface exposure and plate placement.

Following decompression and anterior bone graft placement, osteophytes or irregularities should be removed from the anterior surface of the spine so the selected plate fits flush across the graft space.

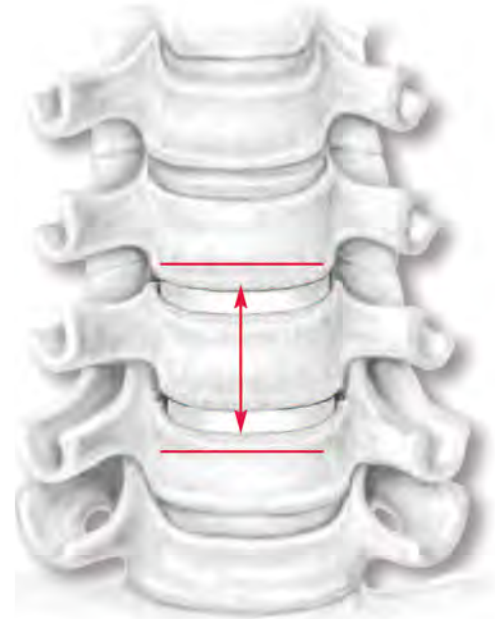


Fig. 3

3. PLATE LENGTH SELECTION

Measure the distance between the inferior endplate of the superior vertebral body to the superior endplate of the inferior vertebral body. This distance should be equal to or slightly smaller than the distance between the top locking screws on the plate.

The length of the plate should be selected so that the bone screws enter the respective superior and inferior vertebral body as close to the edge of the disc space as possible. The bone screw holes and plate should not abut the proximal or distal unfused disc spaces immediately adjacent to the plate.

PLATE PREPARATION

Place the top locking plates and top locking screws in the open position. Top locking plates should rotate freely to allow for bone screw placement.



Fig. 4

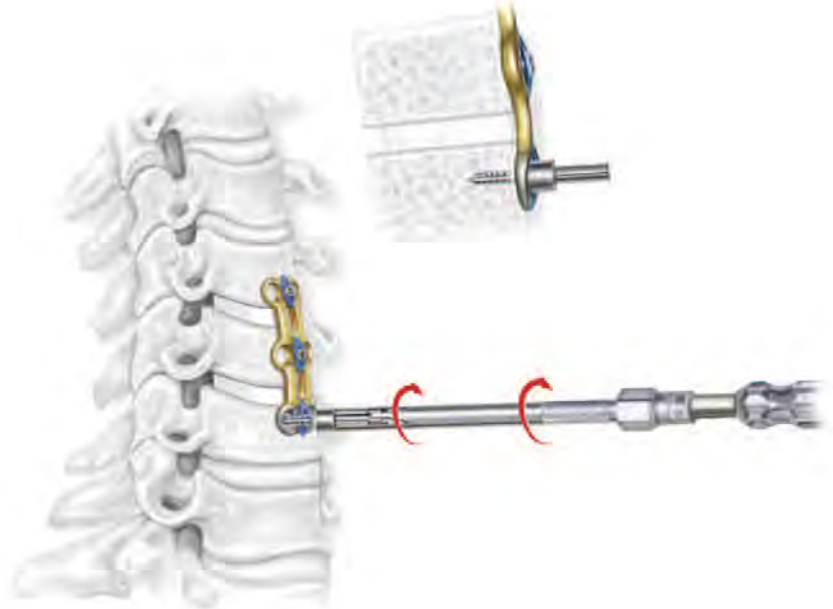


Fig. 5

4. CONTOURING THE PLATE

The Reliant Anterior Cervical Plate is machined with an 8° lordosis. The plate can be contoured for additional lordosis by using the plate bender.

To contour the plate:

- The top locking plates should be secure and in the open position.
- Lift the plate bender cover and place the plate with the top locking plates facing the cover. The posts on the cover of the plate bender should fit the slots of the plate.
- Apply moderate pressure to the handles. The plate should be bent only between the bone screw holes.
- It is recommended that the plate bender is used only to increase plate lordosis.

Caution: Due to titanium's notch sensitivity, Orthofix does not recommend decreasing the contour if the plate has been over bent.

5. SECURING THE PLATE

After the plate is properly positioned, a temporary fixation tack may be inserted into the bone screw hole using the tack holder. The temporary tack will secure the plate to the vertebrae to prevent plate slippage during the initial screw placement.

The tack should be inserted perpendicular to the plate.



Fig. 6

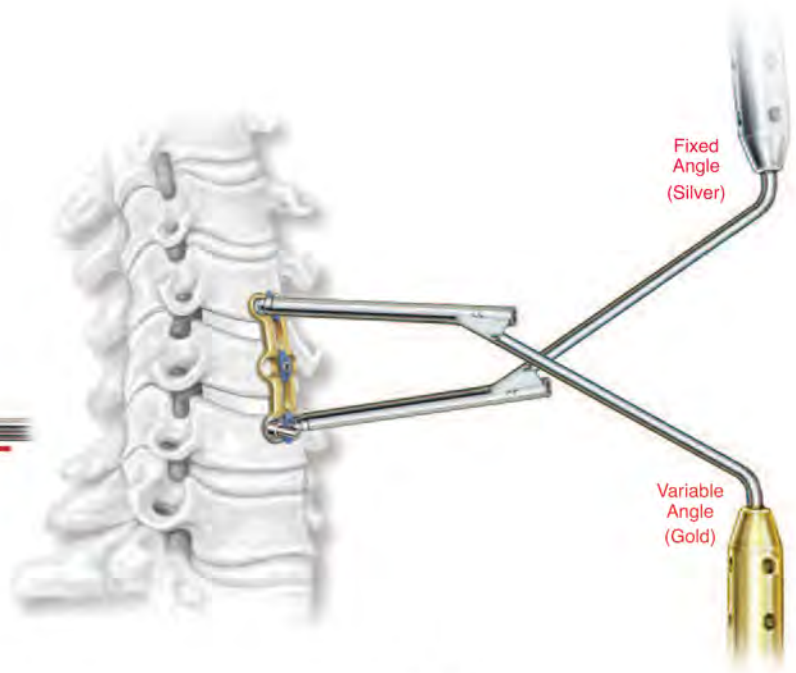


Fig. 7

6. PENETRATION OF THE CORTEX

The Reliant ACP System provides the surgeon the option of using a bone awl.

Bone awls (standard and sleeved) are used in conjunction with the modular handle.

STANDARD BONE AWL

Insert the standard bone awl securely into the modular handle. Position the freehand drill guide and standard bone awl in the desired bone screw hole. Angle the drill guide and bone awl as desired and apply gentle pressure to penetrate the underlying cortex.

SLEEVED BONE AWL

The sleeved bone awl provides quick one step penetration of the cortex.

Insert the sleeved bone awl securely into the modular handle. Firmly seat and angle the sleeved bone awl in the preferred bone screw hole. Apply pressure to the bone awl to penetrate the underlying cortex.

7. DRILL GUIDE

The variable angle freehand drill guide and fixed angle freehand drill guide are used to protect the adjacent soft tissues and ensure proper drilling depth and screw alignment. Both freehand drill guides provide the ability to drill and tap through the respective guide.

It is important to seat the drill guide securely within the plate hole prior to drilling.

Position the drill guide to the appropriate angle.

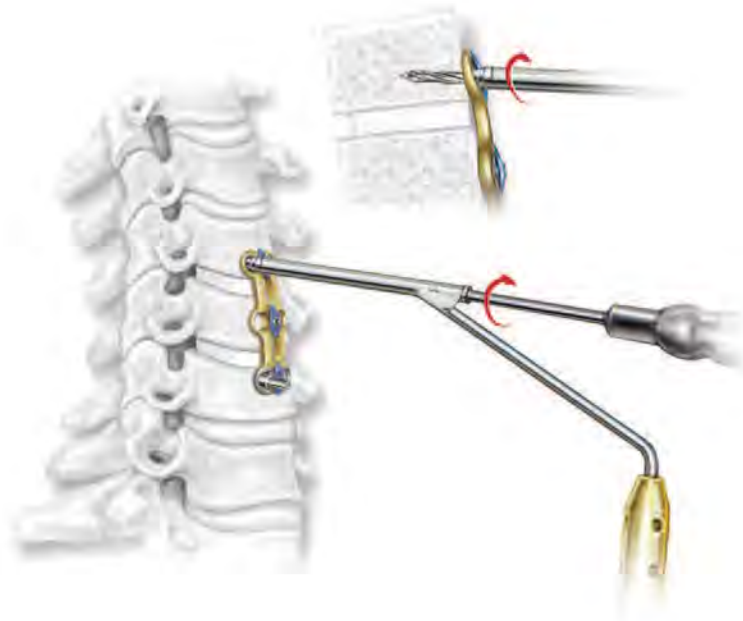


Fig. 8

8. DRILL

Drills bits are used in conjunction with the modular handle.

Insert the drill bit securely into the modular handle. The single-use, disposable drill bits are color coded for easy identification with their corresponding bone screw length. Screw and drill length is determined by the depth of bone screw purchase required.

Position the freehand drill guide securely in the desired bone screw hole. Insert the drill into the drill guide, angle the drill guide and drill. Drill to the appropriate depth. When used in conjunction with the freehand drill guide, there is a positive stop on the drill bits to prevent over-drilling.

9. TAP (OPTIONAL)

The 12mm tap is used in conjunction with the modular handle. Place the tap securely into the modular handle.

Position the freehand drill guide securely in the desired bone screw hole. Insert the tap into the drill guide, angle the drill guide and tap. Tap only to the desired length.



Fig. 10

10. SELF DRILLING/SELF TAPPING PRIMARY BONE SCREWS

Primary – 4.4mm diameter

Variable angle bone screw holes (gold portion of the plate) offer up to 1mm of controlled subsidence. Bone screws placed in the fixed angle bone screw holes (silver portion of the plate) are fixed at the angle placed.

SELF TAPPING RESCUE BONE SCREWS

Rescue – 4.75mm diameter

Rescue bone screws are used for revisions or when greater purchase is required.

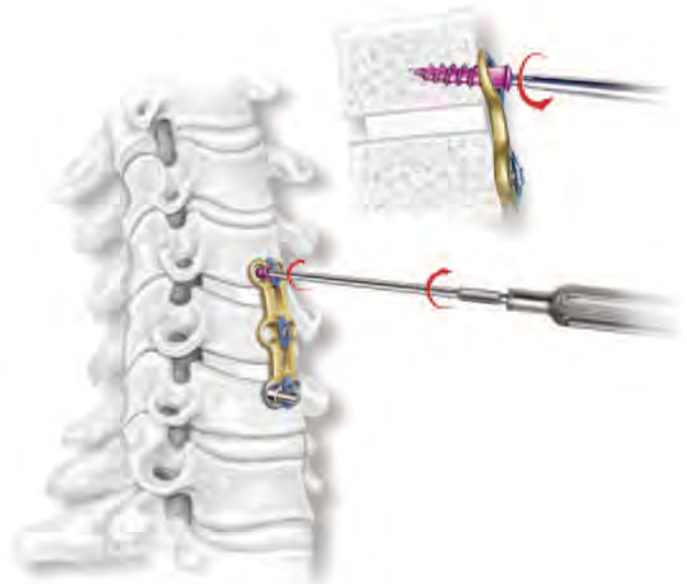


Fig. 11

11. BONE SCREW PLACEMENT

Place the bone screw driver securely into the modular handle.

The bone screw driver has an integral screw retention spring that ensures secure screw attachment to the screw driver.

Insert the appropriate length bone screw. The hex-tip on the screw driver must be completely seated into the hex-head of the bone screw during insertion to ensure proper placement.

Proper bone screw selection is dependent on bony structure and composition, surgeon preference, and intraoperative circumstances. Orthofix recommends the choice reflects optimal patient safety and minimal risk.



Fig.12

12. PREFERRED METHOD OF BONE SCREW PLACEMENT

Drill, tap, and place one bone screw.

Drill, tap, and place second bone screw opposite and diagonal from the first screw position.

Remove temporary tack, if appropriate.

Drill, tap, and place bone screws in the remaining bone screw holes.

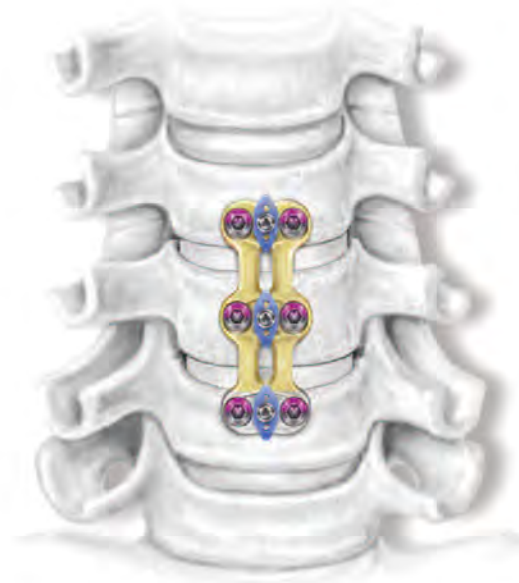


Fig.13

13. FINAL TIGHTENING OF BONE SCREWS

Final tightening of the bone screws is completed sequentially (in order of bone screw placement). Ensure that all bone screws are seated flush and within the bone screw holes.

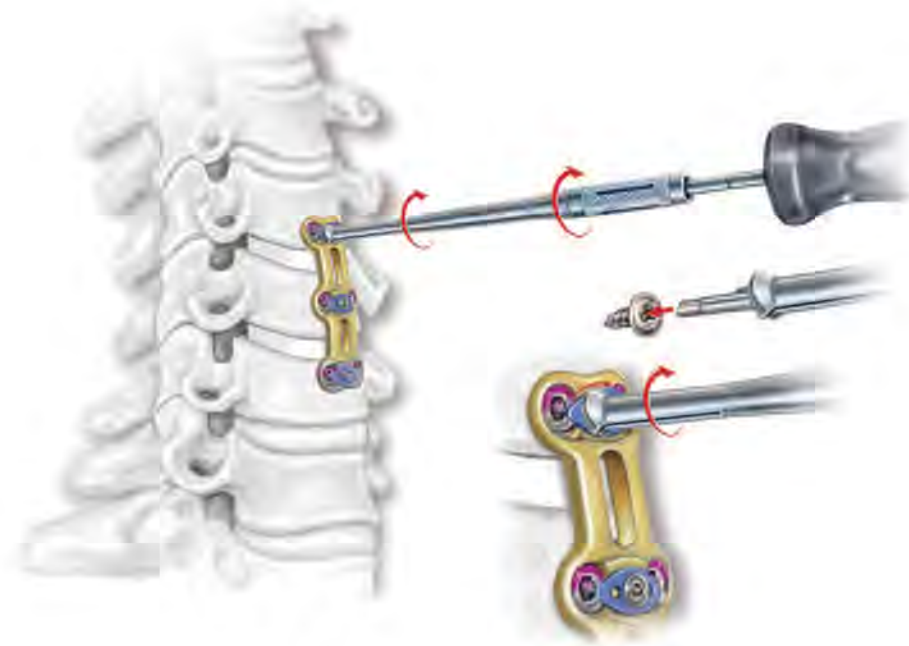


Fig.14

14. TIGHTENING OF TOP LOCKING MECHANISM

The locking mechanism rotates easily over the bone screws to prevent screw back-out.

The top locking plate rotator aligns easily with the holes in the top locking plate for complete control during insertion. Securely engage the prongs of the top locking plate rotator into the holes of the top locking plate. Insert the top locking screw driver into the top locking plate rotator and seat into the tri-lobe of the top locking screw.

Rotate the top locking plate over the bone screws. Proper alignment of the top locking plate is critical for a secure construct. In the locked position, top locking plates should be perpendicular to the long axis of the cervical plate.

While firmly grasping the top locking plate with the top locking plate rotator, rotate the top locking screw driver clockwise to tighten the top locking screw and secure the top locking plate. The top locking plate rotator and top locking screw driver should be perpendicular to the cervical plate when tightening the top locking screw.

Continue tightening the top locking screw until an audible click is heard. The click ensures that the top locking screw has been tightened to the required torque of 4.5 in-lbs.

Proper alignment of the top locking plate is critical for a secure construct. In the locked position, top locking plates should be perpendicular to the long axis of the cervical plate.

If any pair of bone screw holes is not used, completely remove the top locking mechanism and top locking screw for proper plate performance.

Warning: When performing a corpectomy procedure using a Reliant Anterior Cervical Plate, ensure that the top locking mechanisms are only used on the superior and inferior portions of the cervical plate prior to final tightening of the top locking plates to avoid potential plate performance deterioration.

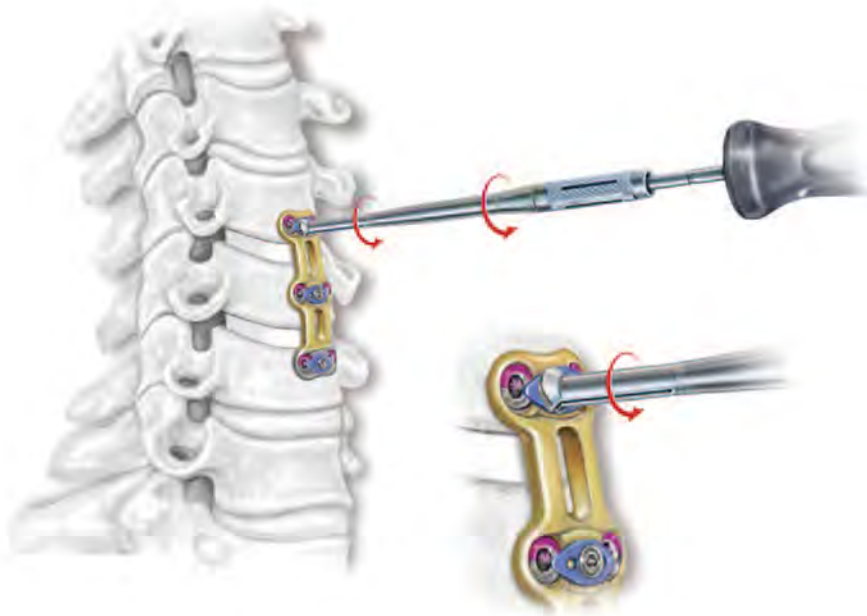


Fig.15

15. TOP LOCKING SCREW REMOVAL

To remove the top locking screw:

- Insert the top locking plate rotator onto the top locking screw driver.
- Securely engage the top locking plate with the top locking plate rotator and seat completely the top locking screw driver in the top locking screw.
- While firmly grasping the top locking plate with the top locking plate rotator, turn the top locking screw driver counter clockwise until the top locking screw and top locking plate can be removed.

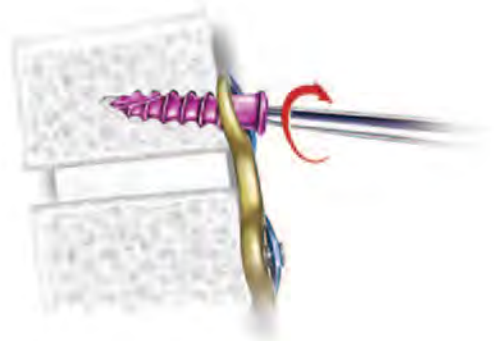


Fig.16

16. BONE SCREW REMOVAL

To remove the bone screws:

- Place the bone screw driver securely into the modular handle.
- Seat completely the hex-tip on the bone screw driver into the hex-head of the bone screw.
- Turn the bone screw driver counter clockwise to remove the bone screws.

INSTRUMENTATION

64-0010 Fixed Angle Drill Guide	60-0025 Modular Handle	60-0045 12mm Tap	64-0090 System Case
64-0012 Variable Angle Drill Guide	64-0030 Sleeved Bone Awl	60-0050 Bone Screw Driver	64-0091 Four Level Plate Caddy
60-0020 Tack Holder	64-0035 12mm Modular Drill	60-0060 Top Locking Screw Driver	
60-0021 Cervical Tack, Threaded Tip	64-0036 14mm Modular Drill	64-0061 Top Locking Plate Rotator	
60-0022 Cervical Tack, Trocar Tip	64-0037 16mm Modular Drill	64-0070 Plate Bender	

1 LEVEL CERVICAL PLATES

64-6200 20mm 1 Level Plate	64-6300 30mm 1 Level Plate
64-6220 22mm 1 Level Plate	64-6320 32mm 1 Level Plate
64-6240 24mm 1 Level Plate	64-6340 34mm 1 Level Plate
64-6260 26mm 1 Level Plate	64-6360 36mm 1 Level Plate
64-6280 28mm 1 Level Plate	64-6380 38mm 2 Level Plate

2 LEVEL CERVICAL PLATES

64-6400 40mm 2 Level Plate	64-6500 50mm 2 Level Plate
64-6420 42mm 2 Level Plate	64-6520 52mm 2 Level Plate
64-6440 44mm 2 Level Plate	64-6540 54mm 2 Level Plate
64-6460 46mm 2 Level Plate	
64-6480 48mm 2 Level Plate	

3 LEVEL CERVICAL PLATES

64-6560 56mm 3 Level Plate	64-6700 70mm 3 Level Plate
64-6580 58mm 3 Level Plate	64-6740 74mm 3 Level Plate
64-6600 60mm 3 Level Plate	64-6780 78mm 3 Level Plate
64-6620 62mm 3 Level Plate	64-6820 82mm 3 Level Plate
64-6640 64mm 3 Level Plate	64-6860 86mm 3 Level Plate
64-6660 66mm 3 Level Plate	64-6900 90mm 3 Level Plate
64-6680 68mm 3 Level Plate	64-6764 76mm 4 Level Plate

4 LEVEL CERVICAL PLATES

64-6804 80mm 4 Level Plate	64-6108 108mm 4 Level Plate
64-6844 84mm 4 Level Plate	64-6112 112mm 4 Level Plate
64-6884 88mm 4 Level Plate	64-6116 116mm 4 Level Plate
64-6924 92mm 4 Level Plate	64-6120 120mm 4 Level Plate
64-6964 96mm 4 Level Plate	
64-6100 100mm 4 Level Plate	
64-6104 104mm 4 Level Plate	

BONE SCREWS

Primary Screws

60-3100 Self-Drilling / Self-Tapping Primary Bone Screw 4.4 x 10mm
60-3120 Self-Drilling / Self-Tapping Primary Bone Screw 4.4 x 12mm
60-3140 Self-Drilling / Self-Tapping Primary Bone Screw 4.4 x 14mm
60-3160 Self-Drilling / Self-Tapping Primary Bone Screw 4.4 x 16mm
60-3180 Self-Drilling / Self-Tapping Primary Bone Screw 4.4 x 18mm

Rescue Screws

60-2100 Self-Tapping Rescue Bone Screw 4.75mm x 10mm
60-2120 Self-Tapping Rescue Bone Screw 4.75mm x 12mm
60-2140 Self-Tapping Rescue Bone Screw 4.75mm x 14mm
60-2160 Self-Tapping Rescue Bone Screw 4.75mm x 16mm
60-2180 Self-Tapping Rescue Bone Screw 4.75mm x 18mm

TOP LOCKING PLATE / TOP LOCKING SCREW

64-5000 Top Locking Plate / Top Locking Screw Assembly

Please visit Orthofix.com/IFU for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.



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