

OPERATIVE TECHNIQUE

Cetra™

Anterior Cervical Plate

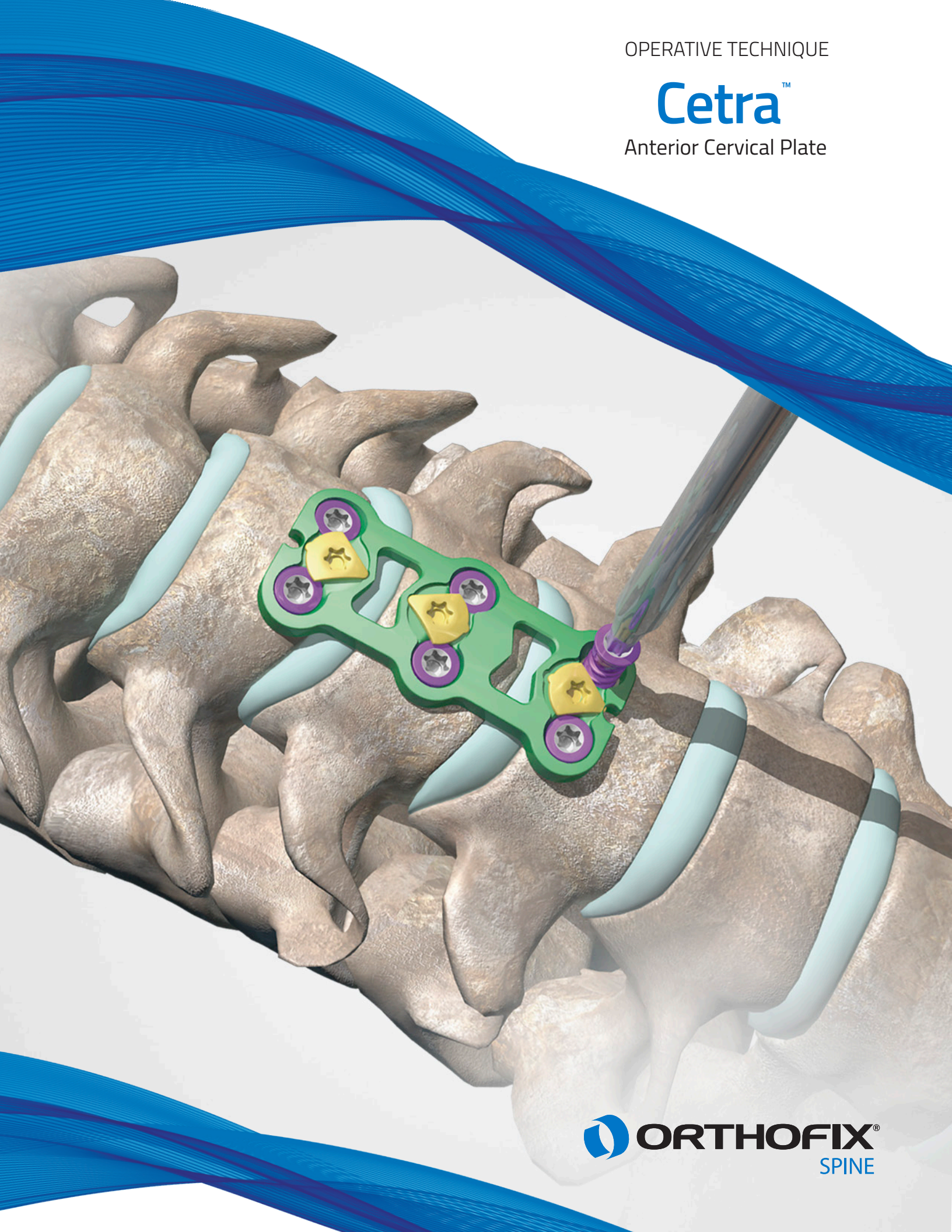
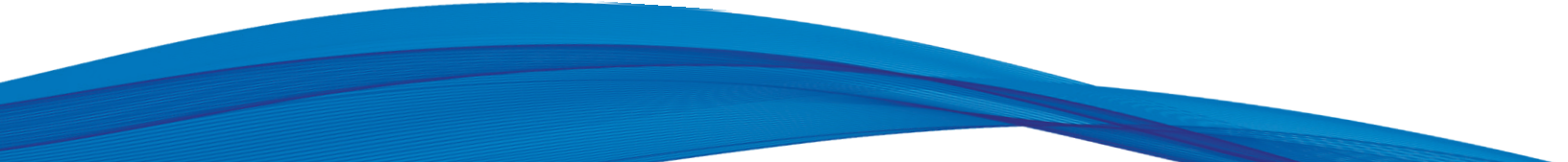


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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the Instructions For Use for the complete list of indications, warnings, precautions, and other important medical information.



INTRODUCTION

The CETRA™ Anterior Cervical Plate System offers a low profile plate with an intuitive locking mechanism, large graft windows, a high degree of screw angulation and simplified instrumentation.

The screw locking mechanism is designed to rotate and securely lock over the screw heads. The locking mechanism allows for visual and tactile feedback that the screws are locked.

The system features constrained and semi-constrained screws for procedural versatility.

Instrument options further enhance surgical technique versatility by matching surgeon preference regarding approach and screw pathway preparation.

The CETRA Anterior Cervical Plate is made of titanium alloy (Ti-6Al-4V), is 2.2mm thick inclusive of the locking mechanism, 17mm wide and pre-machined with lordosis. The large graft-viewing windows allow for visualization of the endplates to aid in graft positioning.

Screw Types

The CETRA Anterior Cervical Plate System offers constrained and semi-constrained bone screws. The semi-constrained bone screws feature a spherical head allowing increased angulation against the plate. The constrained bone screws can be used when a rigid construct is desired.

CETRA screws are self tapping, which feature a cutting flute and a less aggressive screw tip, and self-drilling, which have been designed with a sharp tip for insertion without prior drilling.

Screw Sizes

CETRA Anterior Cervical screws are available in 4.0mm and 4.5mm diameters and are color coded for easy identification.

Semi-Constrained Screw Angulation

Semi-Constrained screws have a wide range of variability in the degree of cephalad/caudal orientation.

Cephalad/Caudal Angulation

Cephalad/Caudal Holes: -5° to $+20^{\circ}$

Middle Holes: $\pm 10^{\circ}$

All holes 10° Medial Convergence

Constrained Screw Angulation

Constrained screws are positioned at a fixed trajectory at the following angles

Cephalad/Caudal Angulation

Cephalad/Caudal Holes: $+10^{\circ}$

Middle Holes: 0°

All holes: 10° Medial Convergence

1. PATIENT POSITIONING AND EXPOSURE

The patient is placed in a supine position with all bony prominences padded and the head in slight extension.

(Fig. 1) The cervical spine is supported to maintain cervical lordosis. For one or two level procedures, a transverse incision parallel to the skin creases of the neck is recommended. For longer level procedures, one may choose to do a transverse or oblique incision placed along the anterior border of the sternocleidomastoid. After blunt dissection through the various tissue layers, the anterior cervical spine is gently exposed.

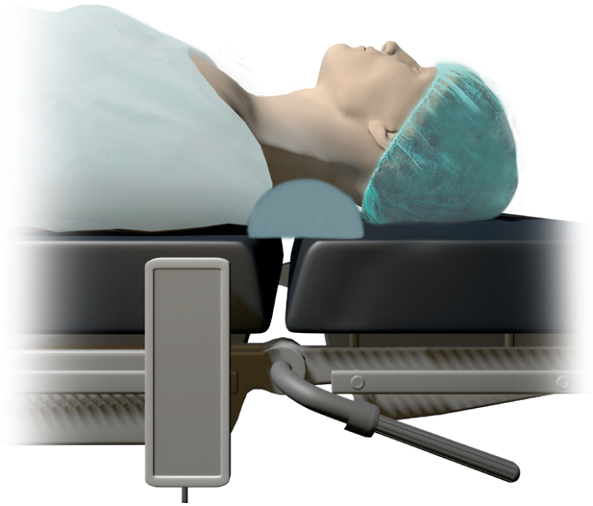


Fig. 1

Adequate visualization of the vertebrae and disc space is critical. Ventral soft tissue should be removed from the vertebral body to create a smooth surface for optimal surface exposure and plate placement. **(Fig. 2)**

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.

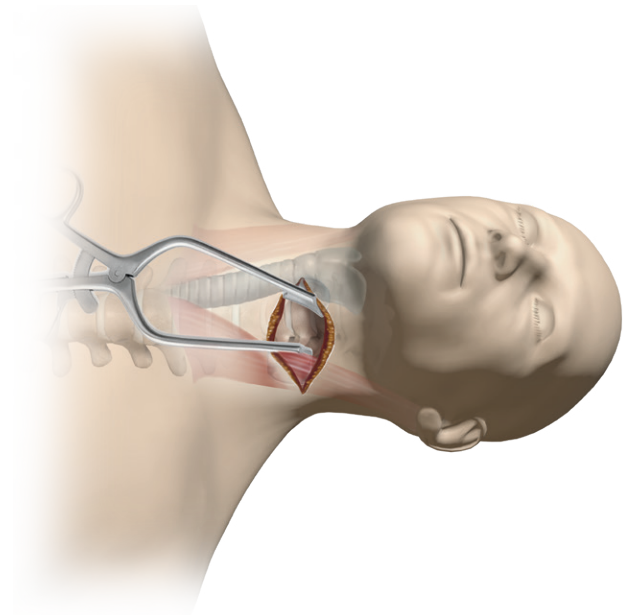


Fig. 2

2. PLATE LENGTH SELECTION

The sizing of the plates is measured from end to end of the plate. Select the appropriate size plate to fit patient anatomy. (Fig. 3)

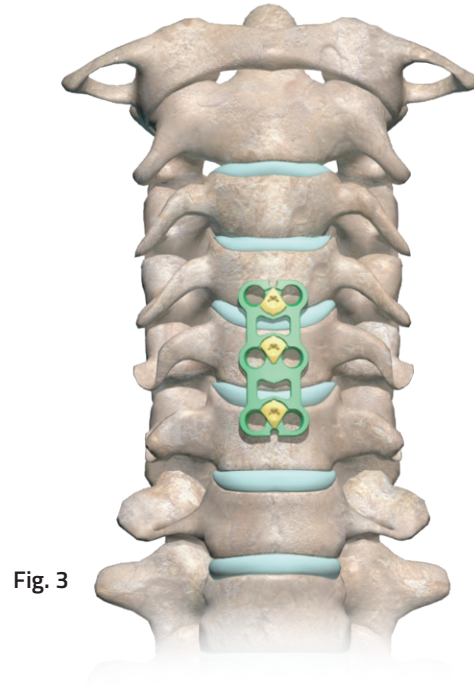


Fig. 3

3. CONTOURING THE PLATE

The CETRA plate is designed with a sagittal and axial bend to accommodate patient anatomy. If additional plate contouring is necessary, the **Plate Bender (19-9037)** may be used.

Insert the plate from the side into the plate bender.

The plate is positioned with the top portion of the plate in contact with the two barrels of the plate bender. There is one track in the plate bender for the locking mechanism.

Apply moderate pressure to the handles to bend the plate to the desired bend. (Fig. 4)

Note: Plate should be bent to contour to the ends of the vertebrae.

Note: Do not bend the plate over the locking mechanism as this could result in the locking mechanism failing.

WARNING: The correct handling of the implant is extremely important. Implants should not be excessively or repeatedly bent, notched or scratched. These operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.

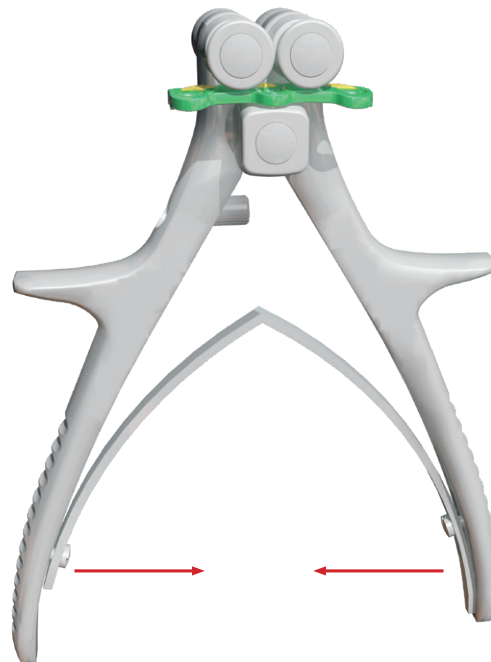


Fig. 4

4. HOLDING THE PLATE

Grasp the plate by the flats with the **Plate Holder (19-9003)**. The plate can be placed in situ and manipulated to its proper position. (**Fig. 5**)

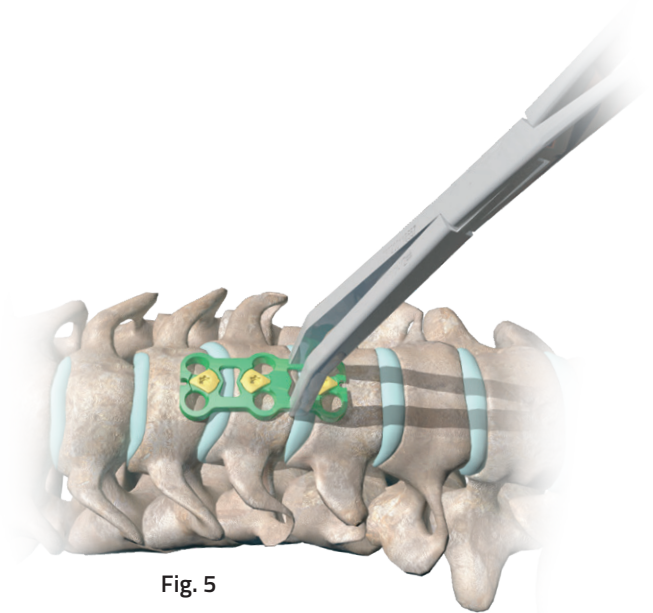


Fig. 5

5. SECURING THE PLATE

Tacks (86-9031 Threaded or 86-9032 Smooth) are available to temporarily hold the plate during screw hole preparation. Load the tack onto the tack holder by inserting a tack into the tip of the instrument while retracting the outer sleeve. (**Fig. 6a**)

Position a tack in the tack holes on the superior and inferior ends of the plate using the tack holder. Apply slight downward pressure while threading the tack into the bone until the tack is fully seated against the plate. When fully inserted, the tack can penetrate the bone up to 8mm.

The tack will secure the plate to the cervical column to prevent plate slippage during the initial screw placement. (**Fig. 6b**)

Remove the tacks after the plate is sufficiently stabilized with screws.

Note: Tacks are single use only devices.



Fig. 6a

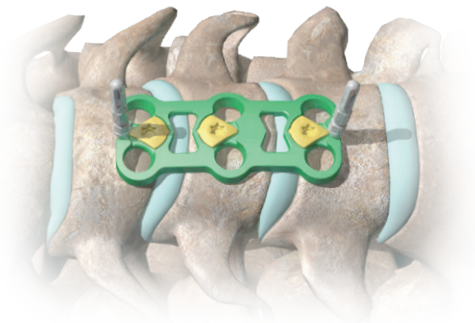


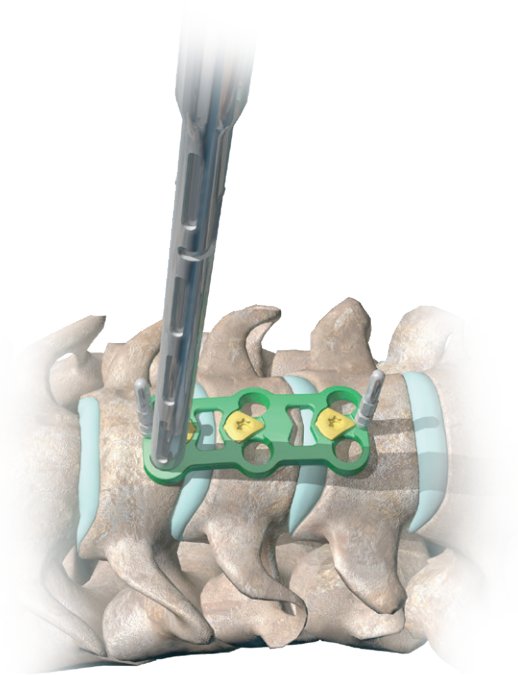
Fig. 6b

6. PENETRATION OF THE CORTEX

The CETRA Anterior Cervical Plate System provides the surgeon the option of using a **Bone Awl (86-9002)**. When fully deployed, the bone awl can penetrate up to 10mm of bone.

Firmly seat and angle the bone awl into the screw hole by applying pressure to penetrate the underlying cortex. (**Fig. 7**)

Fig. 7



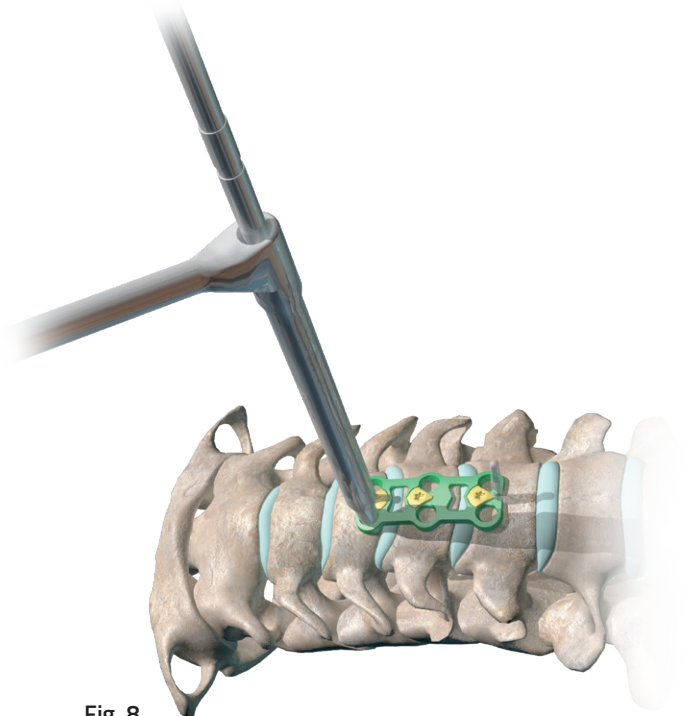
7. DRILL (OPTIONAL)

The drill guides are used to guide the **Drill (86-9012, 86-9014, 86-9016)** to prepare the screw pathway and must be engaged securely to the plate prior to screw hole preparation. The guides are designed to direct the drill trajectory within the effective working range of the system. (**Fig. 8**)

If drilling is desired, utilize one of the two guides provided. Do not drill the holes without use of one of the guides.

Drill bits are used in conjunction with the **Modular Handle (69-1030) (Fig. 9)**. The single-use, disposable drill bits are color coded for easy identification with their corresponding bone screw length. Screw and drill lengths are determined by the depth of the bone screw purchase required.

Fig. 8



Fixed



The **Fixed Angle Drill Guide (86-9004)** is attached to the plate at 10° of sagittal angulation in the end holes.

Variable



The **Variable Angle Drill Guide (86-9005)** features a spherical shape which allows it to angulate on the plate within the allowed range of the semi-constrained screw. Position the variable angle drill guide at an angle within the recommended range:

- Cephalad/Caudal Holes: -5° to +20°
- Middle Holes: +/- 10°
- All holes: 10° Medial Convergence

The guide must be removed prior to tapping or screw insertion.

Note: If using the Variable Angle Drill Guide, screw angles may be out of the recommended range. After final tightening, confirm all locking mechanisms are in the locked position.

8. TAP (OPTIONAL)

All screws are self-tapping. A tap may be used to cut threads in the bone screw holes.

The **12mm Tap (86-9022)** is used in conjunction with the modular handle. (**Fig. 10**)

Fig. 9



Fig. 10



9. BONE SCREW INSERTION

Six types of bone screws are provided in the system to allow for construct configuration to meet the patient's anatomy (**Fig. 12**):

1. Constrained self-tapping
2. Constrained self-drilling
3. Semi-Constrained self-tapping
4. Semi-Constrained self-drilling
5. Rescue Constrained self-tapping
6. Rescue Constrained self-drilling
7. Top view of 19-X5XX screws

Depress the Hexalobular tip of the **T10 Driver (19-9071)** into the desired screw head. The T10 Driver (19-9071) is designed with a slight taper to retain the screws. (**Fig. 11**)

Note: The T10 Driver (19-9071) can only be used with the 19-X5XX screw series.

Fig. 11

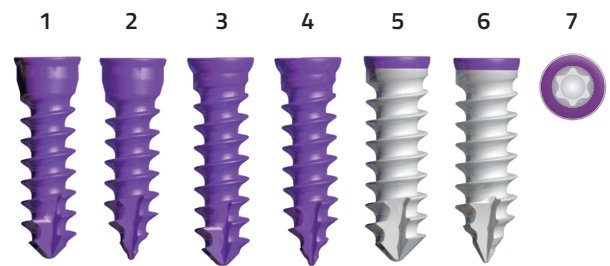
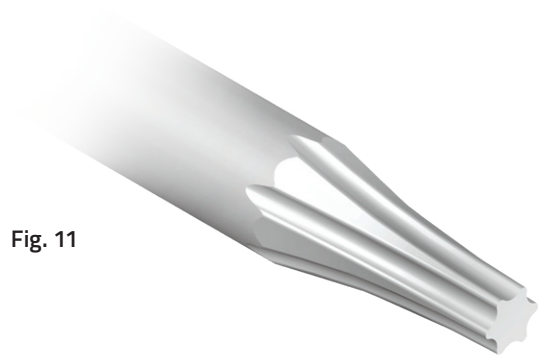


Fig. 12

9b. BONE SCREW INSERTION

Inserting the screws sequentially at opposite corners of the plate, working toward the center of the plate helps keep the plate flat against the bone. (**Fig. 13**)

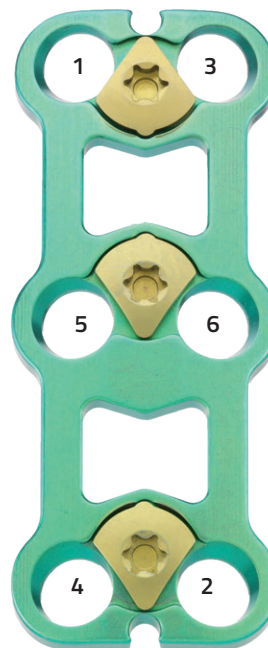


Fig. 13

10. SCREW LOCKING MECHANISM

Fully seat the **driver** and turn the locking mechanism clockwise 180° to lock the system securely. (**Fig. 14a**)

The 16mm and 17mm plates employ a different locking mechanism. Place the **Cover Plate Assembly (19-3000)** onto the plate with the **TLP Retainer (60-0061)**. (**Fig. 14b**) Tighten the locking plate screw with the **Top Locking Plate Torque Driver (60-0060)** until you hear a click (4.5 in-lbs).

Note: Confirm that all screws have been fully seated in the plate before locking.

Note: The locking mechanism is designed to be locked a maximum of two times. Locking more than two times may reduce the effectiveness of the locking mechanism.

Locked

Unlocked



Fig. 14a

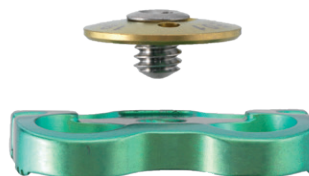


Fig. 14b

11. IMPLANT REMOVAL

Utilizing the driver, unlock the locking mechanism by rotating 180°. The 16mm and 17mm plates employ a different locking mechanism. Engage the **Cover Plate Assembly (19-3000)** with the **TLP Retainer (60-0061)**. Loosen the locking plate screw with the **Top Locking Plate Torque Driver (60-0060)** and remove the assembly.

Once the locking mechanisms are unlocked, place the **driver** securely into the bone screw and turn counter clockwise to remove the bone screws. (Fig. 15)

Plate Specifications

Locking Mechanism	Hexalobe
Profile Height	2.2mm
Profile Width	17mm

Revision Instruments

T10 Driver	19-9071
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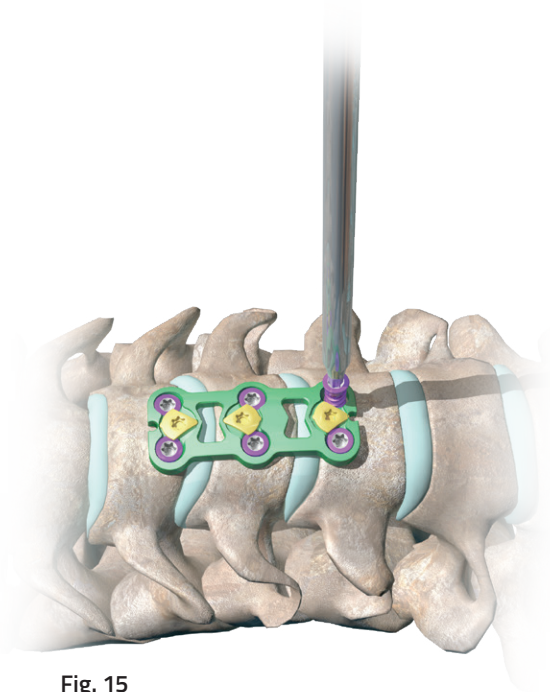


Fig. 15

Screw Specifications

Description	Pitch (mm)	Major Diameter (mm)	Minor Diameter (mm)	Thread Delta (mm)	Bone Screw Drive Feature (mm)
Primary Constrained Self-Tapping Screw					
4.0mm X 10mm- 19mm (1mm Increments)	0.059	4.0	2.5	1.5	Hexalobe
Primary Semi-Constrained Self-Tapping Screw					
4.0mm X 10mm- 19mm (1mm Increments)	0.059	4.0	2.5	1.5	Hexalobe
Primary Constrained Self-Drilling Screw					
4.0mm X 10mm- 19mm (1mm Increments)	0.059	4.0	2.5	1.5	Hexalobe
Primary Semi-Constrained Self-Drilling Screw					
4.0mm X 10mm- 19mm (1mm Increments)	0.059	4.0	2.5	1.5	Hexalobe
Rescue Self-Tapping Screw					
4.5mm X 10mm- 19mm (1mm Increments)	0.059	4.5	3.0	1.5	Hexalobe
Rescue Self-Drilling Screw					
4.5mm X 10mm- 19mm (1mm Increments)	0.059	4.5	3.0	1.5	Hexalobe

STANDARD Screws with T10 Driver 19-9071

Part #	Description
Primary Constrained Self-Tapping Screws	
19-3512	4.0mm X 12mm
19-3514	4.0mm X 14mm
19-3516	4.0mm X 16mm
Primary Semi-Constrained Self-Tapping Screws	
19-4512	4.0mm X 12mm
19-4514	4.0mm X 14mm
19-4516	4.0mm X 16mm
Primary Constrained Self-Drilling Screws	
19-5512	4.0mm X 12mm
19-5514	4.0mm X 14mm
19-5516	4.0mm X 16mm
Primary Semi-Constrained Self-Drilling Screws	
19-6512	4.0mm X 12mm
19-6514	4.0mm X 14mm
19-6516	4.0mm X 16mm
Rescue Constrained Self-Tapping Screws	
19-7512	4.5mm X 12mm
19-7514	4.5mm X 14mm
19-7516	4.5mm X 16mm
Rescue Constrained Self-Drilling Screws	
19-8512	4.5mm X 12mm
19-8514	4.5mm X 14mm
19-8516	4.5mm X 16mm



19-X5XX Screws

T10 Driver (19-9071)

Note: The T10 Driver (19-9071) can only be used with the 19-X5XX screw series.

OPTIONAL Screws with T10 Driver 19-9071

Part #	Description
Primary Constrained Self-Tapping Screws	
19-3510	4.0mm X 10mm
19-3511	4.0mm X 11mm
19-3513	4.0mm X 13mm
19-3515	4.0mm X 15mm
19-3517	4.0mm X 17mm
19-3518	4.0mm X 18mm
19-3519	4.0mm X 19mm
Primary Semi-Constrained Self-Tapping Screws	
19-4510	4.0mm X 10mm
19-4511	4.0mm X 11mm
19-4513	4.0mm X 13mm
19-4515	4.0mm X 15mm
19-4517	4.0mm X 17mm
19-4518	4.0mm X 18mm
19-4519	4.0mm X 19mm
Primary Constrained Self-Drilling Screws	
19-5510	4.0mm X 10mm
19-5511	4.0mm X 11mm
19-5513	4.0mm X 13mm
19-5515	4.0mm X 15mm
19-5517	4.0mm X 17mm
19-5518	4.0mm X 18mm
19-5519	4.0mm X 19mm
Primary Semi-Constrained Self-Drilling Screws	
19-6510	4.0mm X 10mm
19-6511	4.0mm X 11mm
19-6513	4.0mm X 13mm
19-6515	4.0mm X 15mm
19-6517	4.0mm X 17mm
19-6518	4.0mm X 18mm
19-6519	4.0mm X 19mm
Rescue Constrained Self-Tapping Screws	
19-7510	4.5mm X 10mm
19-7511	4.5mm X 11mm
19-7513	4.5mm X 13mm
19-7515	4.5mm X 15mm
19-7517	4.5mm X 17mm
19-7518	4.5mm X 18mm
19-7519	4.5mm X 19mm
Rescue Constrained Self-Drilling Screws	
19-8510	4.5mm X 10mm
19-8511	4.5mm X 11mm
19-8513	4.5mm X 13mm
19-8515	4.5mm X 15mm
19-8517	4.5mm X 17mm
19-8518	4.5mm X 18mm
19-8519	4.5mm X 19mm

STANDARD Plates

Part #	Description
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One Level Plates

19-0118	1-Level Plate Assembly, 18mm
19-0120	1-Level Plate Assembly, 20mm
19-0122	1-Level Plate Assembly, 22mm
19-0124	1-Level Plate Assembly, 24mm
19-0126	1-Level Plate Assembly, 26mm
19-0128	1-Level Plate Assembly, 28mm
19-0130	1-Level Plate Assembly, 30mm
19-0132	1-Level Plate Assembly, 32mm
19-0134	1-Level Plate Assembly, 34mm
19-0136	1-Level Plate Assembly, 36mm

Two Level Plates

19-0232	2-Level Plate Assembly, 32mm
19-0234	2-Level Plate Assembly, 34mm
19-0236	2-Level Plate Assembly, 36mm
19-0238	2-Level Plate Assembly, 38mm
19-0240	2-Level Plate Assembly, 40mm
19-0242	2-Level Plate Assembly, 42mm
19-0244	2-Level Plate Assembly, 44mm
19-0246	2-Level Plate Assembly, 46mm
19-0248	2-Level Plate Assembly, 48mm
19-0250	2-Level Plate Assembly, 50mm

Three Level Plates

19-0350	3-Level Plate Assembly, 50mm
19-0352	3-Level Plate Assembly, 52mm
19-0354	3-Level Plate Assembly, 54mm
19-0356	3-Level Plate Assembly, 56mm
19-0358	3-Level Plate Assembly, 58mm
19-0360	3-Level Plate Assembly, 60mm
19-0362	3-Level Plate Assembly, 62mm
19-0364	3-Level Plate Assembly, 64mm
19-0366	3-Level Plate Assembly, 66mm
19-0368	3-Level Plate Assembly, 68mm

Four Level Plates

19-0466	4-Level Plate Assembly, 66mm
19-0470	4-Level Plate Assembly, 70mm
19-0474	4-Level Plate Assembly, 74mm
19-0478	4-Level Plate Assembly, 78mm
19-0482	4-Level Plate Assembly, 82mm

OPTIONAL Plates

Part #	Description
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One Level Plates

19-3000	Cover Plate Assembly*
19-0116	1-Level Plate, Threaded, 16mm*
19-0117	1-Level Plate, Threaded, 17mm*
19-0119	1-Level Plate Assembly, 19mm

Two Level Plates

19-0252	2-Level Plate Assembly, 52mm
19-0254	2-Level Plate Assembly, 54mm

Three Level Plates

19-0348	3-Level Plate Assembly, 48mm
19-0370	3-Level Plate Assembly, 70mm
19-0372	3-Level Plate Assembly, 72mm
19-0374	3-Level Plate Assembly, 74mm

Four Level Plates

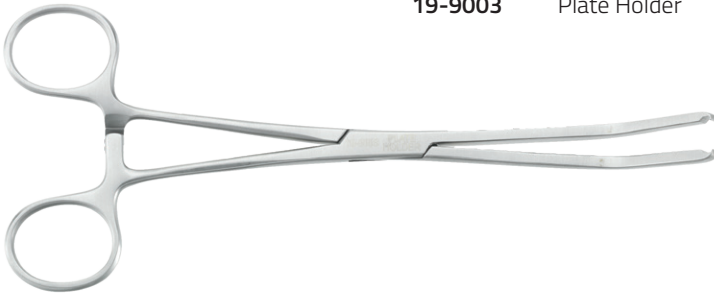
19-0462	4-Level Plate Assembly, 62mm
19-0486	4-Level Plate Assembly, 86mm
19-0490	4-Level Plate Assembly, 90mm
19-0494	4-Level Plate Assembly, 94mm

Note: The one level 16mm and 17mm plates require the cover plate assembly and additional instrumentation on page 15.

Instruments

Part #	Description
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19-9003	Plate Holder
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19-9030	Tack Holder
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19-9037	Plate Bender
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Instruments

Part #	Description
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19-9071	T10 Driver
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69-1030	Modular Handle With A/O Quick Connect
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86-9002	Bone Awl
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Instruments

	Part #	Description
	86-9004	Fixed Angle Drill Guide
	86-9005	Variable Angle Drill Guide
	86-9012	4.0mm Drill - 12mm
	86-9014	4.0mm Drill - 14mm
	86-9016	4.0mm Drill - 16mm
	86-9022	4.0mm Tap - 12mm

Instruments

	Part #	Description
	86-9031	Threaded Tack
	86-9032	Smooth Tack
	60-0060	Top Locking Plate Torque Driver*
	60-0061	TLP Retainer*



Notes

Notes

[illegible]

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