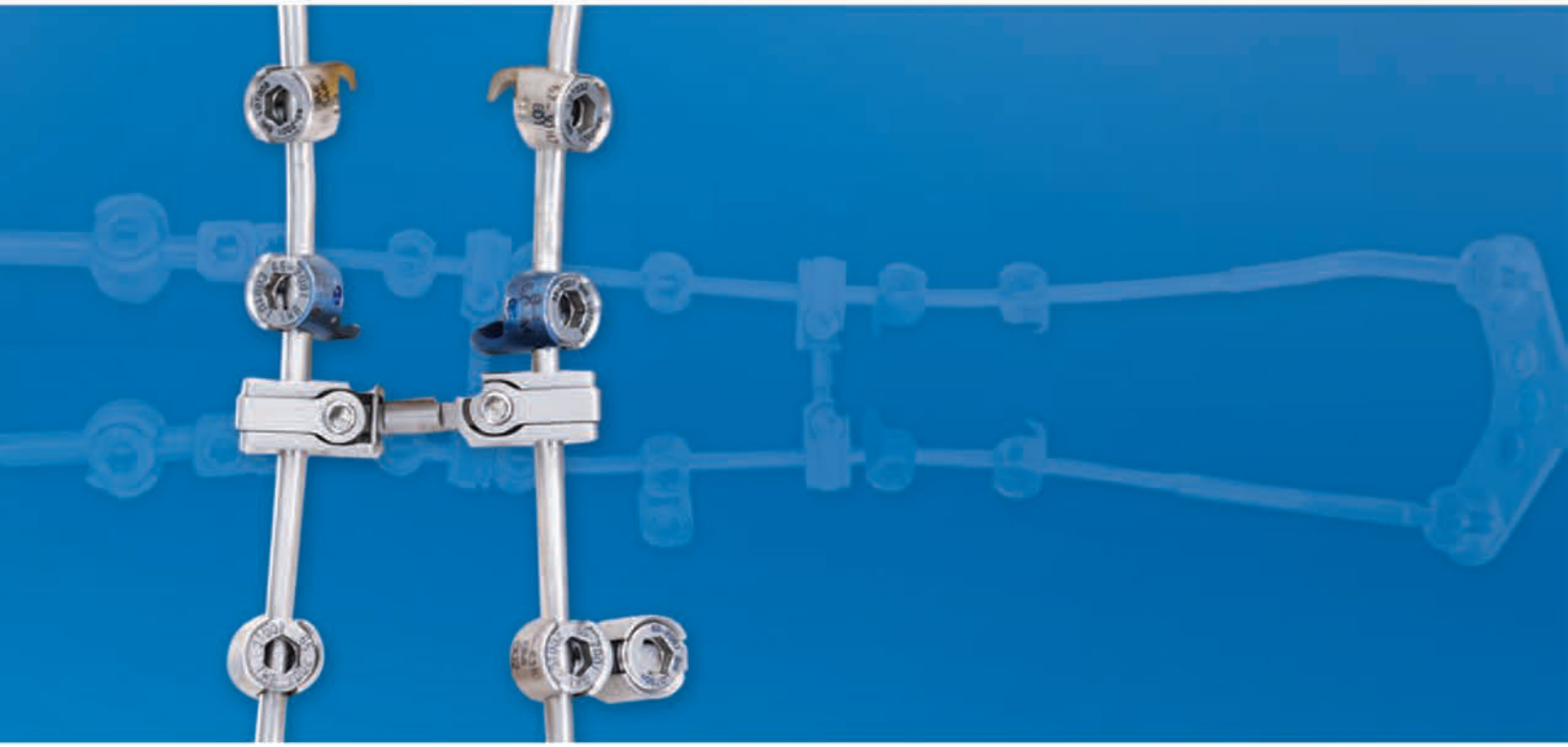
OPERATIVE TECHNIQUE

Ascent™ LE

Posterior Occipital Cervico-Thoracic (POCT) System



Ascent LE Operative Technique

ORTHOFIX®
Spinal Implants

INTRODUCTION

The Ascent LE POCT system allows surgeons to address complicated fusion cases from the base of the skull down to the thoracic region. The multi-axial screws feature 66° of angulation which minimizes rod contouring, while the biased angle screws accommodate a range of patient anatomies. The multi-plane adjustable cross connectors are pre-assembled and utilize a drop-in design for easy insertion. Ascent LE also offers optional occipital fixation plates and is compatible with songer cable systems. The ASCENT LE builds upon the proven success of the original ASCENT design philosophy, incorporating several technological advances required by the complex demands of Posterior Occipito Cervico Thoracic surgical procedures.

Ascent™ LE

Posterior Occipital Cervico-Thoracic (POCT) System

Fig. 1

1. PREOPERATIVE PLANNING AND PATIENT POSITIONING

Preoperative planning is critical in the preparation for spinal surgery.

A complete radiographic evaluation (A/P and lateral films) of the patient should be completed for proper diagnosis prior to surgery.

Carefully place the patient in the prone position following induction of anesthesia.

Fig. 2

2. EXPOSURE

Incise the skin and subcutaneous tissue longer than the planned fusion. Once bleeding is controlled, deepen the exposure through the fascia level and dissect laterally to the transverse processes.

THORACIC Pedicle Identification

In general, the entrance of the pedicle is located at the intersection of a horizontal line parallel to the upper 1/3 of the transverse process and a vertical line through the middle of the superior facet.

Fig. 3a

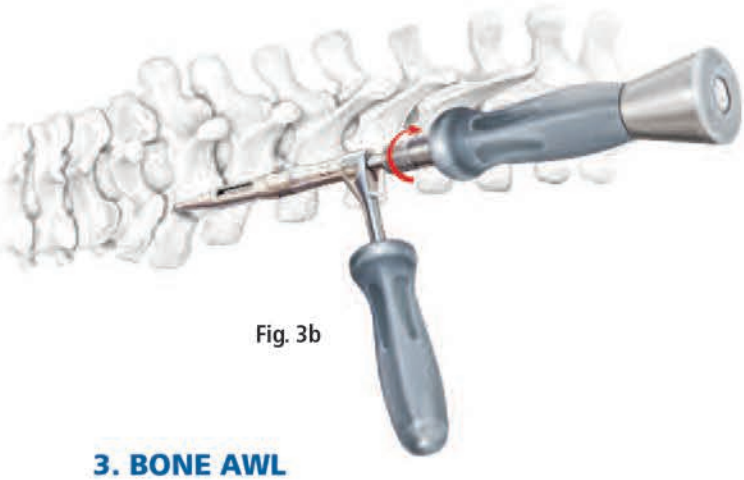


Fig. 3b

3. BONE AWL

Pedicle Preparation and Screw Length Selection

Penetrate the cortex of the bone with the bone awl. **(Fig. 3a)**

Place the appropriate drill size securely into the modular handle. Set the drill stop to the appropriate drilling depth (between 6-34mm in 1mm increments)

Insert the drill into the drill guide at the appropriate depth **(Fig. 3b)**. A positive stop on the drill guide will prevent over drilling.

X-rays may be helpful in the intraoperative assessment of appropriate pedicle depth and screw length.

Fig. 4

Fig. 5a

4. BONE PROBE

Use the bone probe to elongate the hole to the desired depth in the pedicle canal.

WARNING: If resistance is felt while advancing the probe, the position in the pedicle canal should be evaluated via radiograph. When advancing the probe, a change in resistance is a warning that the wall of the pedicle is in danger of being perforated.

A laminectomy can be performed to visualize and feel the medial, cephalad and caudad aspect of the pedicle.

5. EVALUATION

5a. Sounders

Use the straight sounder or the curved sounder to evaluate the condition of the cortical wall of the pedicle. Apply the appropriate probe and externally or internally palpate the wall or canal of the pedicle to ensure the wall is not perforated.

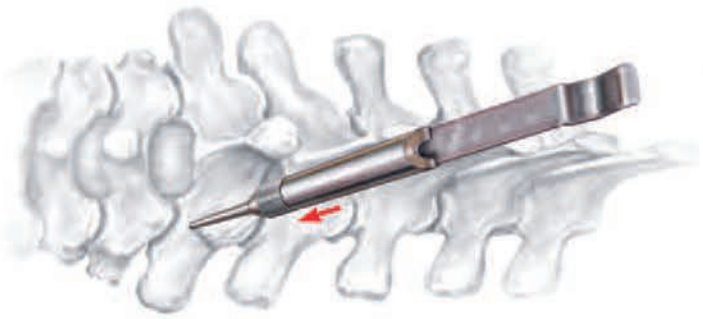


Fig.5b

Fig. 5c

5b. Depth Gauge

Check the final screw position by placing a series of K-wires or X-ray markers* in the pedicle canals and taking a lateral and A/P X-ray. Use the depth gauge to confirm the depth of the pilot hole.

*X-ray markers not supplied.

5c. Tap

Place the tap securely into the modular handle. Tap to the appropriate depth.

The rotating sleeve on the tap rises as it is advanced into the pedicle. Gradations on tap indicate depth of penetration.

Fig. 6a

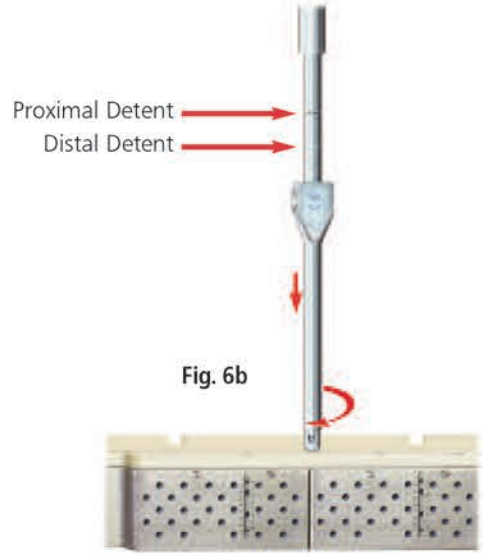


Fig. 6b

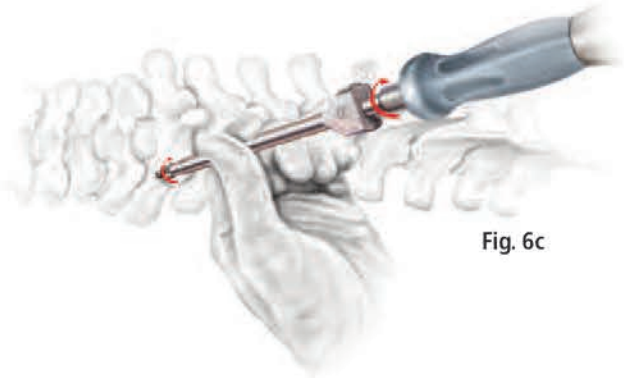


Fig. 6c

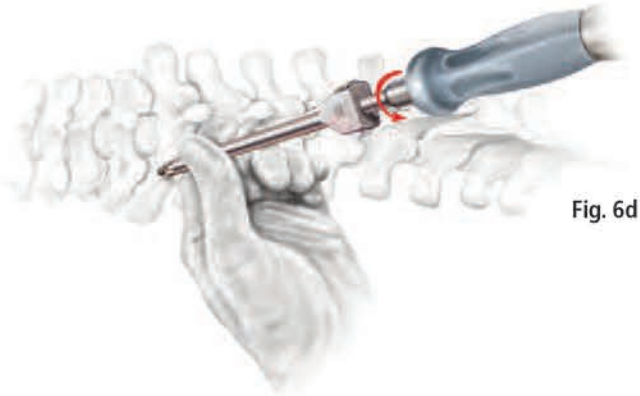


Fig. 6d

6. SCREW INSERTION

Place the multi-axial screw driver securely into the modular handle. Next, slide the screw driver sleeve onto the multi-axial screw driver until it reaches the proximal detent (**Fig. 6a**)

Align hex of multi-axial screw driver with implant allowing for proper connection. Advance tabs of screw driver sleeve into saddle of screw implant. While holding the screw driver sleeve stationary, rotate the modular handle in order to thread the implant onto the screw driver. Pull the screw driver sleeve back to the proximal detect for screw insertion. This allows the sleeve to act as a soft tissue protector. (**Fig. 6b)**

Insert the multi-axial screw into the prepared pedicle until it is positioned to the correct level. The screw should extend approximately 50% to 80% into the vertebral body and should not create soft tissue impingement at closure (**Fig. 6c)**

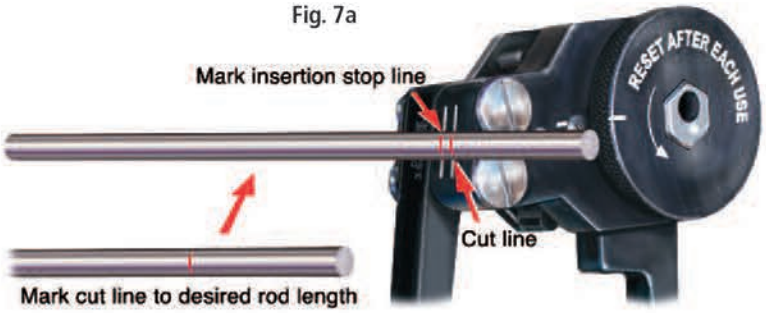
When removing driver from implant return the tabs to the saddle of the implant while holding sleeve stationary. Next turn handle counter-clockwise (**Fig. 6d)**

Screw Adjusters
Use the screw adjuster (65-1062) to adjust the sagital height of the multi-axial screw and the screw head adjuster (65-1045) to align the saddles of the multi-axial screw.

At the cephalad aspect of the construct, the screws should not impinge upon the facet joint.

NOTE: The distal detent will prevent the driver sleeve from falling into the operative site.

Fig. 7a



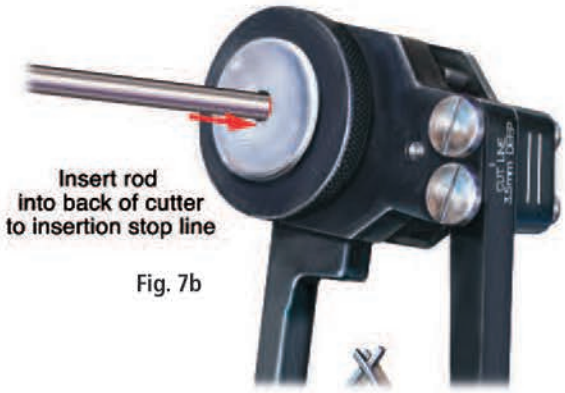


Fig. 7b

Fig. 7c

7. ROD CUTTER

The first step to fit cut the 3mm rod is determining the proper cut length.

1. Lay the rod in the saddle of the screws in order to determine the length required. Using a sterile marker, place a cut line on the rod to indicate where the rod will be cut. Next, mark the insertion stop line on the rod 3.5mm to the outside of the cut line. The template on the topside of the rod cutter is used as an aid in marking. **(Fig. 7a)**

2. Insert the rod into the rod cutter until the insertion stop line is flush with the left side face of the cutter. The original cut line will not be visible. **(Fig. 7b)**

3. Make sure the rod cutter is reset prior to cutting. While holding the rod stationary to the cutter, actuate the handle of the rod cutter repeatedly until the rod is cut. Be sure to reset the rod cutter after each use. **(Fig. 7c)**

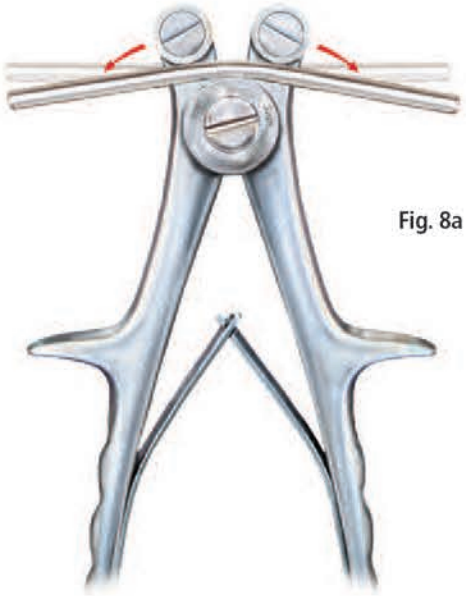


Fig. 8a

8. ROD BENDER

Utilizing the 3mm side of the rod bender, create the correct contour, referencing the rod template as a guide. **(Fig. 8a)**

NOTE: Use the 4.65 mm side of the rod bender to increase the bend of the occipital rod.

Fig. 9

9. ASSEMBLY

Orient the screws so that the screw saddles are in the longitudinal plane. Once positioning is achieved, place the rod in the screw saddles.

Fig. 10a

Fig. 10b

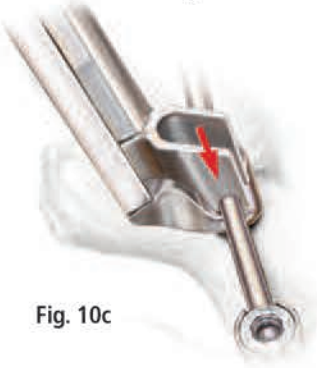


Fig. 10c

Fig. 11

10. SET SCREW PLACEMENT

Use the set screw holder to position and tighten the set screw on the multi-axial screw. Seat the rod fully in the screw saddle with the aid of the rod pusher.

Rod Reduction

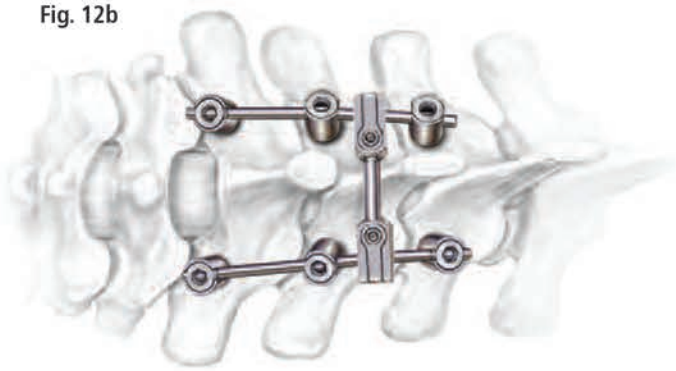
The rod reducer is used to seat the rod into the screw saddle for subsequent set screw placement. Notches on the screw body can be engaged either medially or laterally with the reducer.

11. FINAL TIGHTENING

Position the counter torque wrench over the multi-axial screw. Place the torque limiting driver securely into the hex of the set screw. Turn the torque limiting driver clockwise to tighten the set screw to 22 in – lbs.

Fig. 12a

Fig. 12b



12. CROSS CONNECTORS

Cross connectors provide additional torsional rigidity to the construct by bridging the parallel rods. Position the cross connector template directly over the rods and measure the distance across the rods. **(Fig. 12a)**

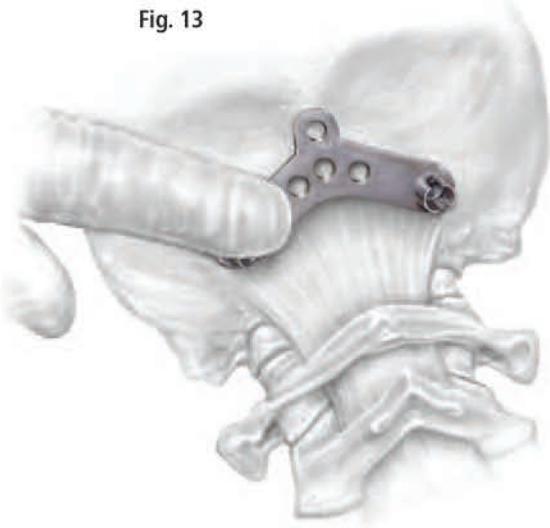
Select the appropriate cross connector and position on the rods. Lock the cross connectors into position using the cross connector torque limiting driver.

An audible click will indicate when the final torque of 10 in–lb is achieved. **(Fig. 12b)**

Axial Rod Connector

The Ascent LE POCT System can be linked to any Orthofix Spinal Implants thoracolumbar system using the axial rod connector.

Fig. 13



13. OCCIPITAL ANCHOR PLATE POSITIONING

The exterior occipital protuberance (EOP) and the nuchal line may be used as a guide for plate position and placement. Position the occipital plate below the EOP and the superior nuchal lines.

Fig. 14

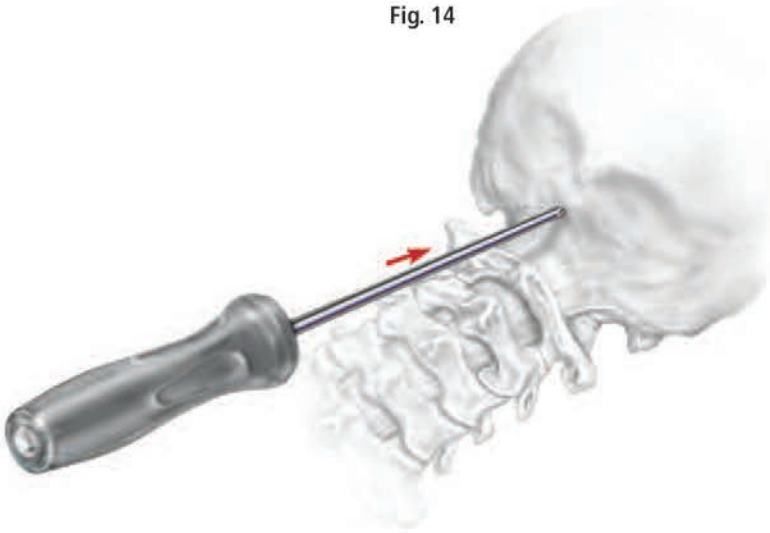
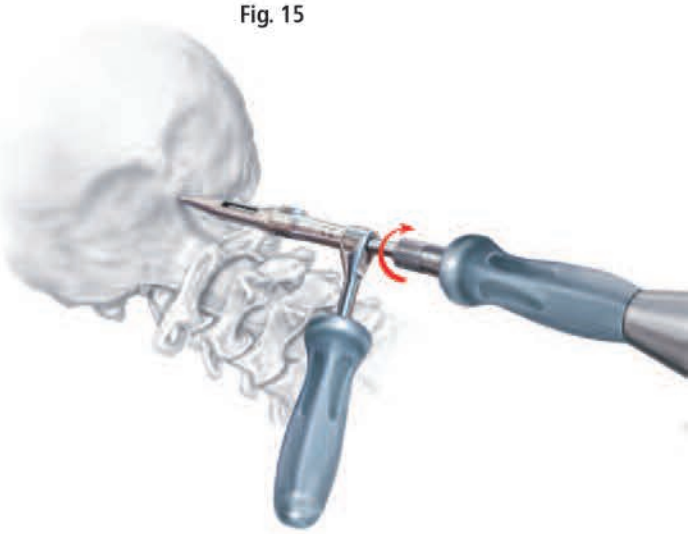


Fig. 15



14. OCCIPUT PREPARATION

Bone Awl

Penetrate the cortex of the occiput using the bone awl.

15. DRILL

Slide the adjustable drill stop over the drill. Place the appropriate drill securely into the modular handle. Set the drill stop to the appropriate drilling depth (between 6-14mm in 1mm increments).

Occipital screws should be placed biocortically to obtain adequate fixation.

Fig. 16

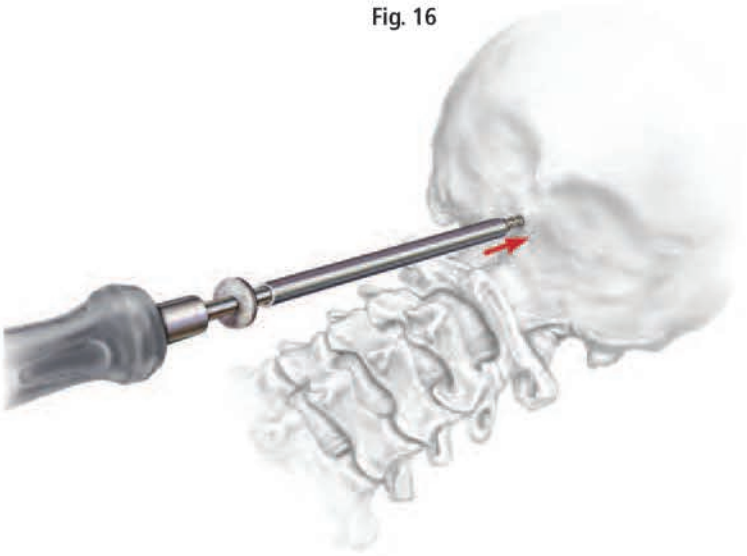
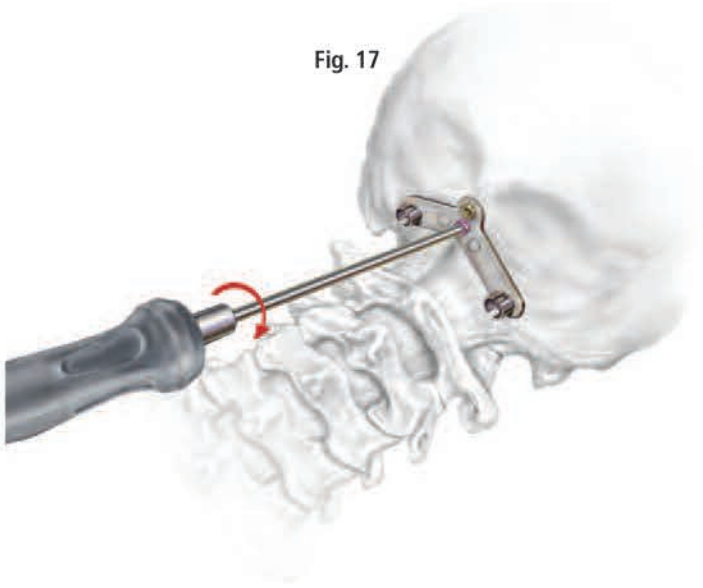


Fig. 17



16. TAP

Place the tap securely into the modular handle. Tap to the appropriate depth.

17. OCCIPITAL BONE SCREW INSERTION

Place the occipital anchor plate into its previously determined position. Attach the appropriate length occipital bone screw to the occipital bone screw driver. Insert the occipital bone screw into the prepared hole locking the occipital anchor plate into position.

Place remaining screws using the same technique.

NOTE: Rescue screws can be used, which can be indentified by their silver heads

Fig. 18

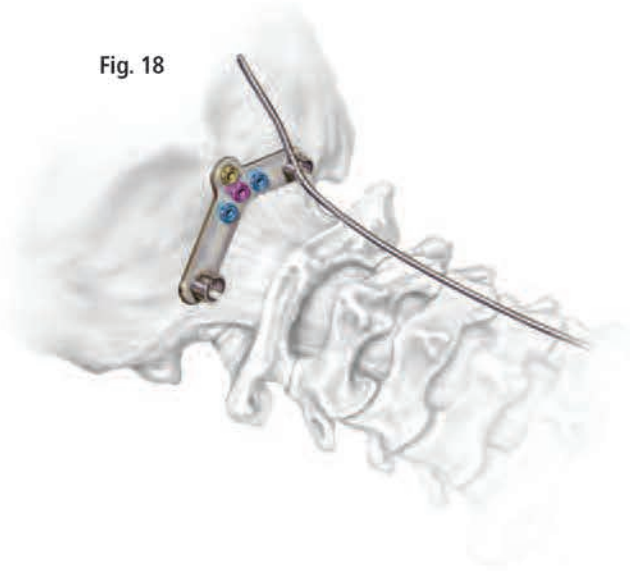
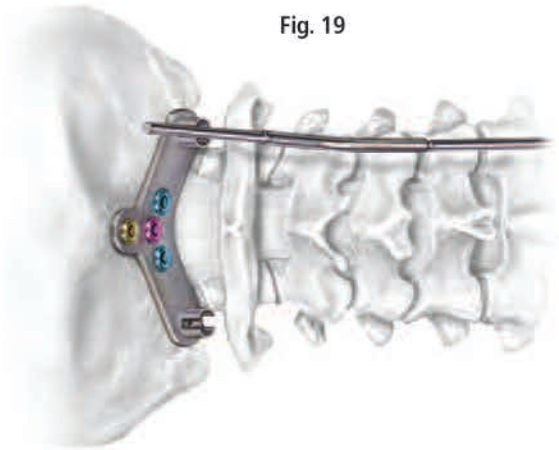


Fig. 19



18. OCCIPITO-CERVICAL ROD

Determine the appropriate occipito-cervical lordotic length with the rod template.

Rod Cutter

Once the correct length is established, use the rod cutter to cut the rod to the desired requirements.

NOTE: For contouring occipital bend use 4.65mm side of rod bender

19. CONSTRUCT ASSEMBLY

Once positioning is achieved, place the rod in the saddle of the occipital anchor plate.

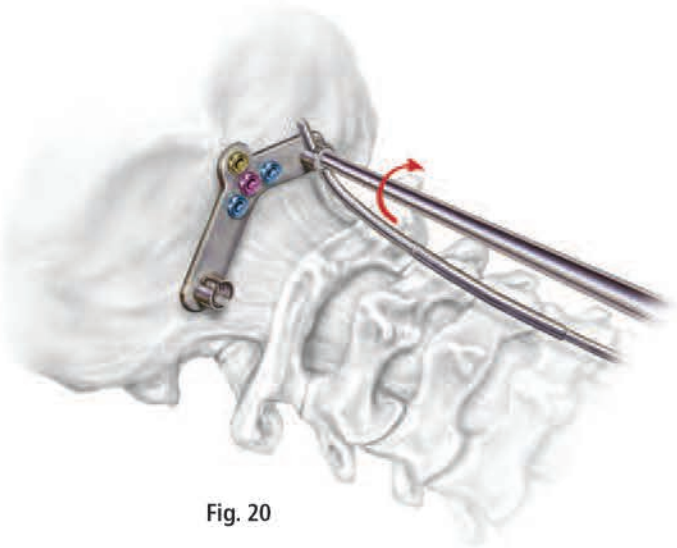


Fig. 20

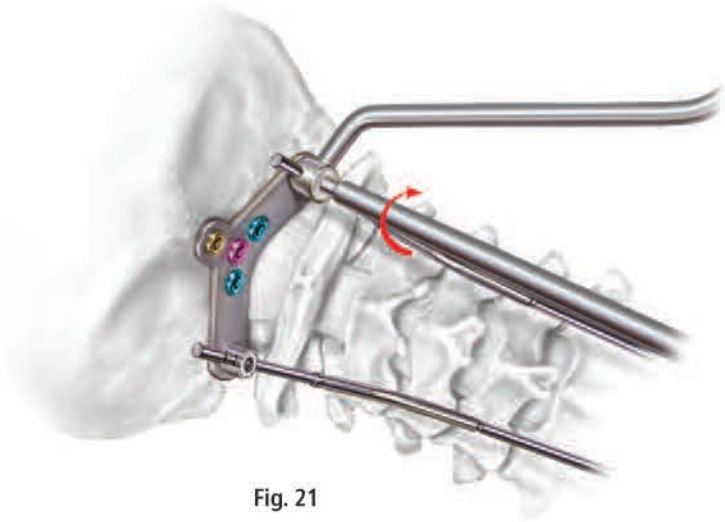


Fig. 21

20. FINAL TIGHTENING

Use the set screw holder to position the set screw on the occipital anchor plate.

21. SONGER SPINAL CABLE SYSTEM

Position the occipital counter torque wrench over the set screw and rod. Place the torque limiting driver securely into the hex of the set screw. Turn the torque limiting driver clockwise to tighten the set screw to 22 in – lb.

The Songer Spinal Cable System, to be used with the Ascent LE POCT System, allows for wire/cable attachment to the posterior spine.

22. IMPLANT REMOVAL

To remove set screws from multi-axial screws or the saddles on the occipital plate, use **Set Screw Driver 65-1064** attached to **Handle (36-1011 or 52-1011)**.

To remove set screws from cross connectors, use the **Driver (HD2060787)** attached to **Extension (EX201076)** and **Handle (MA101000-A or TA101000)** from the Evolution-C kit.

To remove set screws from hooks, use the **Driver (57-0027)** attached to **Handle (36-1011 or 52-1011)**.

PRIMARY IMPLANT CASE

MULTI-AXIAL SCREWS

66-3310	3.5mm x 10mm	**66-3328**	3.5mm x 28mm	**66-3414**	4.0mm x 14mm	**66-3432**	4.0mm x 32mm
66-3312	3.5mm x 12mm	**66-3330**	3.5mm x30mm	**66-3416**	4.0mm x 16mm	**66-3434**	4.0mm x 34mm
66-3314	3.5mm x 14mm	**66-3332**	3.5mm x 32mm	**66-3418**	4.0mm x 18mm	**66-3434**	4.0mm x 36mm
66-3316	3.5mm x 16mm	**66-3334**	3.5mm x 34mm	**66-3420**	4.0mm x20mm	**66-3438**	4.0mm x 38mm
66-3318	3.5mm x 18mm	**66-3336**	3.5mm x 36mm	**66-3422**	4.0mm x 22mm	**66-3440**	4.0mm x40mm
66-3320	3.5mm x20mm	**66-3338**	3.5mm x 38mm	**66-3424**	4.0mm x 24mm	**66-3442**	4.0mm x 42mm
66-3322	3.5mm x 22mm	**66-3340**	3.5mm x40mm	**66-3426**	4.0mm x26mm		
66-3324	3.5mm x 24mm	**66-3410**	4.0mm x 10mm	**66-3428**	4.0mm x28mm		
66-3326	3.5mm x 26mm	**66-3412**	4.0mm x 12mm	**66-3430**	4.0mm x30mm		

CERVICAL HOOKS

67-3010	4.5mm Cervical Hook
67-3011	6.0mm Cervical Hook

RODS

65-2070	70mm Rod
65-2120	120mm Rod
65-2000	200mm Rod
66-2020	Transition Rod, 200 mm, 3.5mm to 5.5mm

CROSS CONNECTOR ASSEMBLIES

65-5320	20mm Cross Connector
65-5325	25mm Cross Connector
65-5330	30mm Cross Connector
65-5335	35mm Cross Connector
65-5340	40mm Cross Connector
65-5345	45mm Cross Connector
65-5350	50mm Cross Connector

OTHER

65-2002	Setscrew
65-6310	Lateral Offset Adapter
65-6425	5.5mm, 3.0mm Axial Connector
65-6405	5.5mm, 3.0mm Single Offset Connector

BIAS ANGLE SCREWS - MEDIAL/LATERAL

66-3510	3.5mm x 10mm	**66-3522**	3.5mm x 22mm	**66-3612**	4.0mm x 12mm	**66-3620**	4.0mm x 20mm
66-3512	3.5mm x 12mm	**66-3524**	3.5mm x 24mm	**66-3610**	4.0mm x 10mm	**66-3622**	4.0mm x 22mm
66-3514	3.5mm x 14mm	**66-3526**	3.5mm x 26mm	**66-3612**	4.0mm x 12mm	**66-3624**	4.0mm x 24mm
66-3516	3.5mm x 16mm	**66-3528**	3.5mm x 28mm	**66-3614**	4.0mm x 14mm	**66-3626**	4.0mm x 26mm
66-3518	3.5mm x 18mm	**66-3530**	3.5mm x 30mm	**66-3616**	4.0mm x 16mm	**66-3628**	4.0mm x 28mm
66-3520	3.5mm x 20mm	**66-3610**	4.0mm x 10mm	**66-3618**	4.0mm x 18mm	**66-3630**	4.0mm x 30mm

Optional Bias Angle Screws - Medial/Lateral (Available Upon Request)

66-3532	3.5mm x 32mm	**66-3538**	3.5mm x 38mm	**66-3634**	4.0mm x 34mm	**66-3640**	4.0mm x 40mm
66-3534	3.5mm x 34mm	**66-3540**	3.5mm x 40mm	**66-3636**	4.0mm x 36mm	**66-3642**	4.0mm x 42mm
66-3536	3.5mm x 36mm	**66-3632**	4.0mm x 32mm	**66-3638**	4.0mm x 38mm		

PRIMARY IMPLANT CASE (CONTINUED)

BIAS ANGLE SCREWS - CEPHALAD/CAUDAL

66-3710	3.5mm x 10mm	**66-3722**	3.5mm x 22mm	**66-3812**	4.0mm x 12mm	**66-3824**	4.0mm x 24mm
66-3712	3.5mm x 12mm	**66-3724**	3.5mm x 24mm	**66-3814**	4.0mm x 14mm	**66-3826**	4.0mm x 26mm
66-3714	3.5mm x 14mm	**66-3726**	3.5mm x 26mm	**66-3816**	4.0mm x 16mm	**66-3828**	4.0mm x 28mm
66-3716	3.5mm x 16mm	**66-3728**	3.5mm x 28mm	**66-3818**	4.0mm x 18mm	**66-3830**	4.0mm x 30mm
66-3718	3.5mm x 18mm	**66-3730**	3.5mm x 30mm	**66-3820**	4.0mm x 20mm		
66-3720	3.5mm x 20mm	**66-3810**	4.0mm x 10mm	**66-3822**	4.0mm x 22mm		

Optional Bias Angle Screws - Cephalad/Caudal (Available Upon Request)

66-3732	3.5mm x 32mm	**66-3738**	3.5mm x 38mm	**66-3834**	4.0mm x 34mm	**66-3840**	4.0mm x 40mm
66-3734	3.5mm x 34mm	**66-3740**	3.5mm x 40mm	**66-3838**	4.0mm x 36mm	**66-3842**	4.0mm x 42mm
66-3736	3.5mm x 36mm	**66-3832**	4.0mm x 32mm	**66-3838**	4.0mm x 38mm		

SMOOTH SHANK (OPTIONAL)

66-3126	3.5mm x 26mm	**66-3132**	3.5mm x 32mm	**66-3228**	4.0mm x 28mm	**66-3232**	4.0mm x 32mm
66-3128	3.5mm x 28mm	**66-3226**	4.0mm x 26mm	**66-3230**	4.0mm x30mm	**66-3232**	4.0mm x 34mm
66-3130	3.5mm x30mm						

Optional Smooth Shank Screws (Available Upon Request)

66-3118	3.5mm x 18mm	**66-3134**	3.5mm x 34mm	**66-3218**	4.0mm x 18mm	**66-3232**	4.0mm x 36mm
66-3120	3.5mm x20mm	**66-3136**	3.5mm x 36mm	**66-3220**	4.0mm x20mm	**66-3238**	4.0mm x 38mm
66-3122	3.5mm x 22mm	**66-3138**	3.5mm x 38mm	**66-3222**	4.0mm x22mm	**66-3240**	4.0mm x40mm
66-3124	3.5mm x 24mm	**66-3140**	3.5mm x40mm	**66-3224**	4.0mm x 24mm	**66-3242**	4.0mm x 42mm

AUXILIARY CASE

OCCIPITAL ANCHOR PLATES

66-2040	31mm Occipital Anchor
66-2041	37mm Occipital Anchor
66-2042	45mmOccipitai Anchor
66-2043	50mm Occipital Anchor

OTHER

66-2040	Occipital Rod
66-1050	Universal Joint Inserter
65-1063	Occipital Screw Inserter
66-1052	Counter Torque Wrench
65-2002	Setscrew
65-1030	Modular Handle

OCCIPITAL BONE SCREWS

65-2006	6mm Occipital Screw
65-2008	8mm Occipital Screw
65-2010	10mm Occipital Screw
65-2012	12mm Occipital Screw
65-2014	14mm Occipital Screw
66-2006	6mm Occipital Rescue Screw
66-2008	8mm Occipital Rescue Screw
66-2010	10mm Occipital Rescue Screw
66-2012	12mm Occipital Rescue Screw
66-2014	14mm Occipital Rescue Screw

INSTRUMENTS CASES

INSTRUMENT CASE 1

66-1038	Multi-Axial Screw Driver Sleeve
66-1042	Rod Cutter
66-1042	Rod Bender
65-1043	Rod Holder
65-1045	Screw Head Adjuster
65-1049	Canulated Rod Pusher
66-1060	Set Screw Holder
65-1062	Screw Adjuster
65-1064	Domed Set Screw Driver
65-1065	Torque Limiting Driver
66-1065	Straight Handle Torque Limiting Driver
65-1066	Counter Torque Wrench
66-1071	Rod Reducer

INSTRUMENT CASE 2

55-1072	Cross Connector Bender Left
55-1073	Cross Connector Bender Right
57-0027	Set Screw Driver (Spine Drive)
57-0047	Set Screw Torque Handle
65-1048	Compressor
65-1070	Distractor
65-1082	Cross Connector Set Screw Driver
65-1083	Cross Connector Torque Limiting Driver
65-1086	Cross Connector Template, 20mm
65-1087	Cross Connector Template, 25-30mm
65-1088	Cross Connector Template, 35-40mm
65-1089	Cross Connector Template, 45-50mm
67-0001	Hook Holder, Straight
67-0003	Hook Holder, Angled
67-0040	Laminar Elevator

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.

Orthofix
3451 Plano Parkway
Lewisville, Texas 75056-9453 USA
1.214.937.3199
1.888.298.5700
www.orthofix.com

EC REP Medical Device Safety Services (MDSS):
Schiffgraben 41
30175, Hannover
Germany
+49 511 6262 8630
www.mdss.com

Australian Sponsor
Emergo Australia
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Sydney, NSW 2000
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