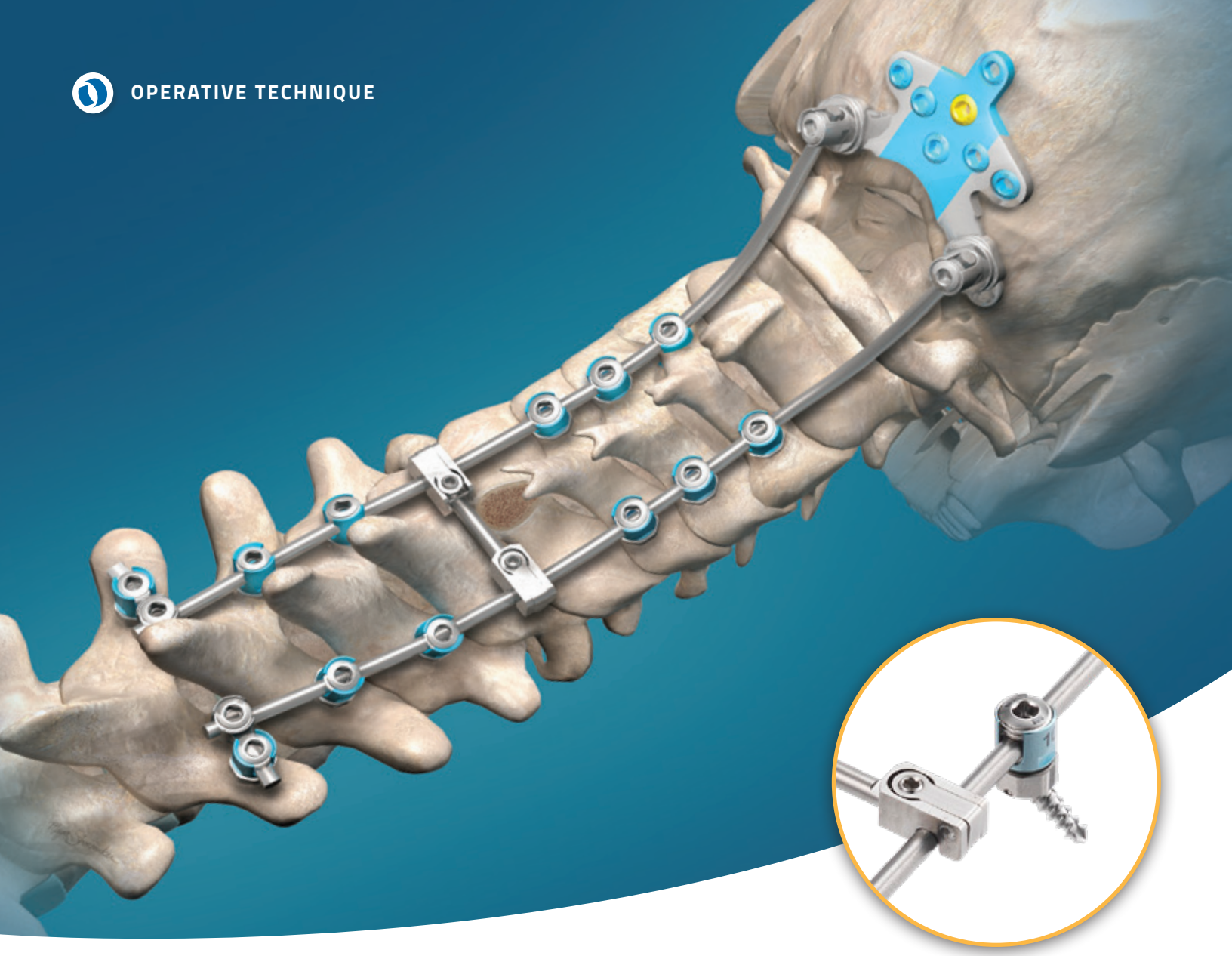
OPERATIVE TECHNIQUE



CENTURION®

POSTERIOR OCCIPITAL CERVICO-THORACIC (POCT) SYSTEM

ORTHOFIX®

TABLE OF CONTENTS

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 Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

INTRODUCTION

The Centurion® Posterior Occipital Cervico-Thoracic System offers versatile solutions for posterior stabilization through an assortment of multi-axial screws, hooks, rods, lateral offset adapters, rod connectors, and occipital plates. The system is designed to stabilize the occiput, cervical and thoracic spine during fusion.

Titanium multi-axial screws achieve up to 100° of maximum conical angulation. The drive body rotates independent of the rod saddle and features an inferior notch allowing for maximum angulation. 3.5mm, 4.0mm, 4.5mm and 5.0mm screw diameters provide adequate grip in larger vertebrae. The 3.5mm and 4.0mm multi-axial screws are available with either smooth shank or standard threads.

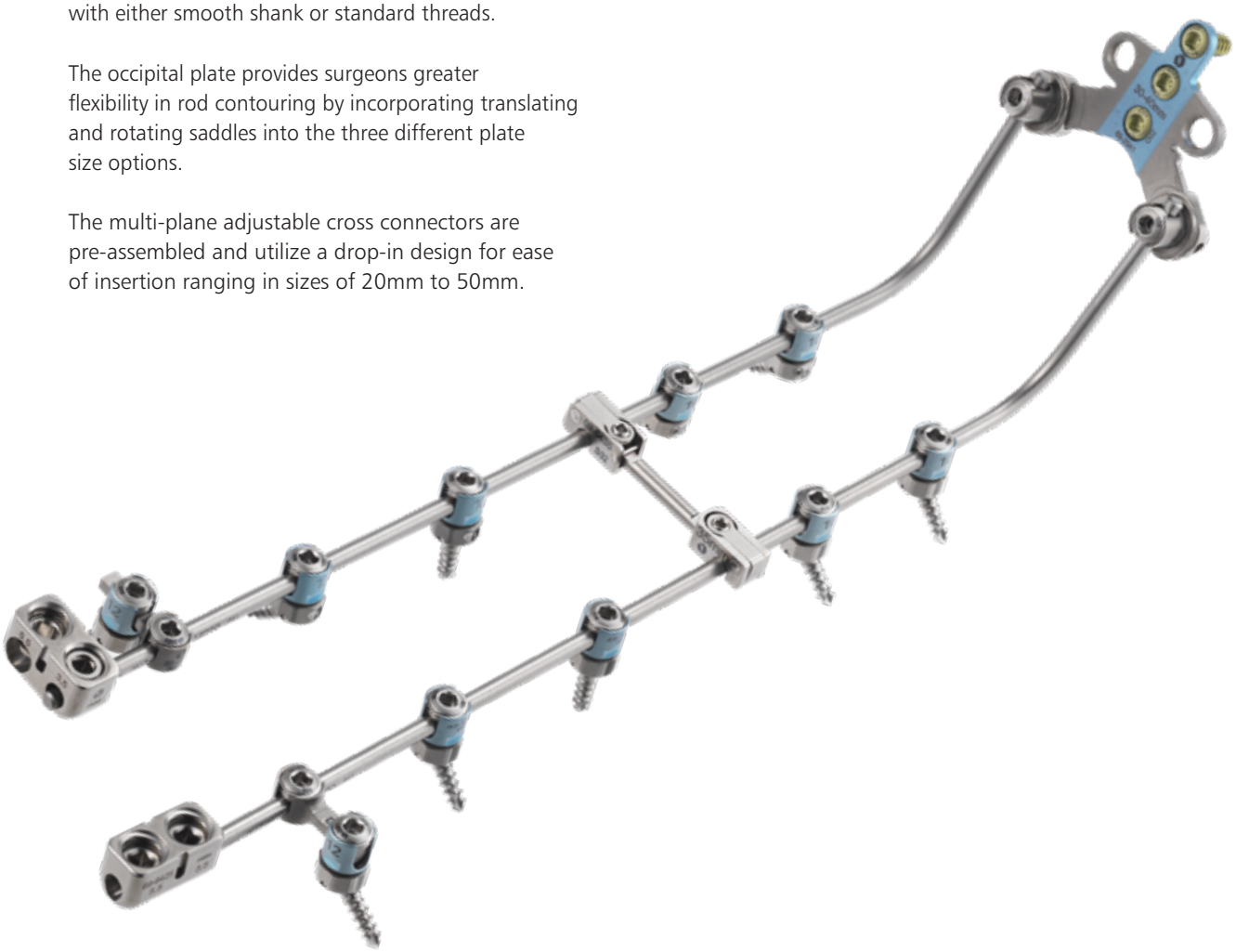
The occipital plate provides surgeons greater flexibility in rod contouring by incorporating translating and rotating saddles into the three different plate size options.

The multi-plane adjustable cross connectors are pre-assembled and utilize a drop-in design for ease of insertion ranging in sizes of 20mm to 50mm.

In order to reduce manipulation, multiple 3.5mm rod options are available. Titanium and cobalt chrome rods are provided in the standard set configuration.

Lateral offset adapters allow the construct to accommodate unique patient anatomy with minimal disruption and trauma to the vertebrae.

The ergonomic instrumentation facilitates precise implant placement and aids in easy insertion.



SYSTEM OVERVIEW

Occipital Plate:
- Small – 20mm-30mm Rod Spacing
- Medium – 30mm-40mm Rod Spacing
- Large – 40mm-50mm Rod Spacing

Multi-Axial Screws
- **3.5mm and 4.0mm** – 10mm-52mm (2mm increments)
- **4.5mm and 5.0mm** – 10mm-50mm (5mm increments)
- Maximum 50° angulation (from screw axis) when aligned with inferior notch as indicated by the laser line.; 33° in all other positions
- The Drive Body rotates for dorsal height adjustment and extra angulation when aligned with the inferior notch
- Rod Saddles are color coded to match the corresponding drills and taps

3.5mm and 4.0mm Smooth Shank Screw:
- 22mm-40mm (2mm increments)
- Constant 16mm threaded region

4.5mm and 5.0mm Occipital Bone Screw and Rescue Screw:
- Rescue Screws are identified by non-anodized heads
  6mm - 14mm (2 increments)

Set Screw:
- Universal set screw for all Multi-Axial Screws, Hooks, and Occipital Plate

3.5mm Titanium or Cobalt Chrome Rod:
- 70mm,120mm, 200mm lengths

Titanium or Cobalt Chrome Transition Rod:
- 3.5mm to 5.5mm
- 200/200mm, 200/300mm, 300/300mm lengths

Titanium or Cobalt Chrome Occipital Rod:
- 3.5mm
- 110°, 120°, 135° angles

Parallel Rod Connector and Axial Rod Connector:
- 3.5mm / 5.5mm Parallel Rod Connector
- 3.5mm / 5.5mm Axial Rod Connector

Lateral Offset Adapter
- 10mm offset
- Accommodates rod attachment of non-aligned screw placement

Cervical Hook
- 4.5mm and 6.0mm throat

Cross Connector
- 20mm to 50mm (5mm increments)

Cervical Operative Technique

The following section demonstrates the procedure for cervical operative technique.

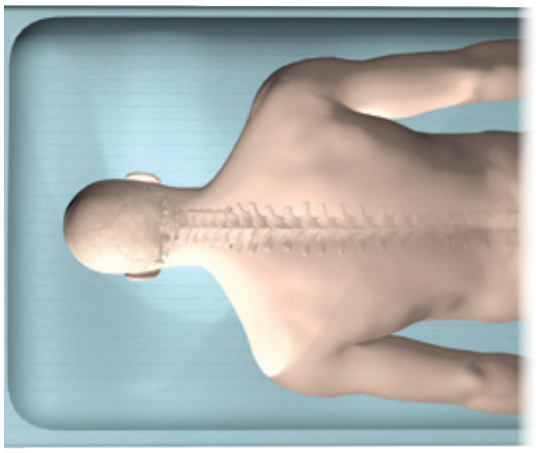


Fig. 1

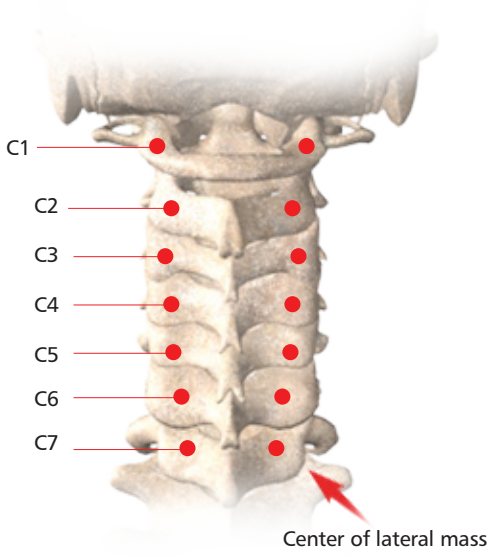


Fig. 2a

1. 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. Perform a standard midline incision. Once bleeding is controlled, deepen the exposure through the fascia level and dissect laterally to expose the facets and transverse processes. **(Fig. 1)**

Precaution: PRE-OP PLANNING – Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

2. LATERAL MASS AND/OR PEDICLE IDENTIFICATION AND PREPARATION IN THE CERVICAL SPINE

Posterior fixation in the cervical spine could be achieved by utilizing pedicle and lateral mass screws implanted from C1 to C7 levels. **(Fig. 2a)**

The technique described on the next page shows how to prepare the lateral mass in the cervical region. But, the same technique could be used to prepare the pedicle of the cervical region as well.

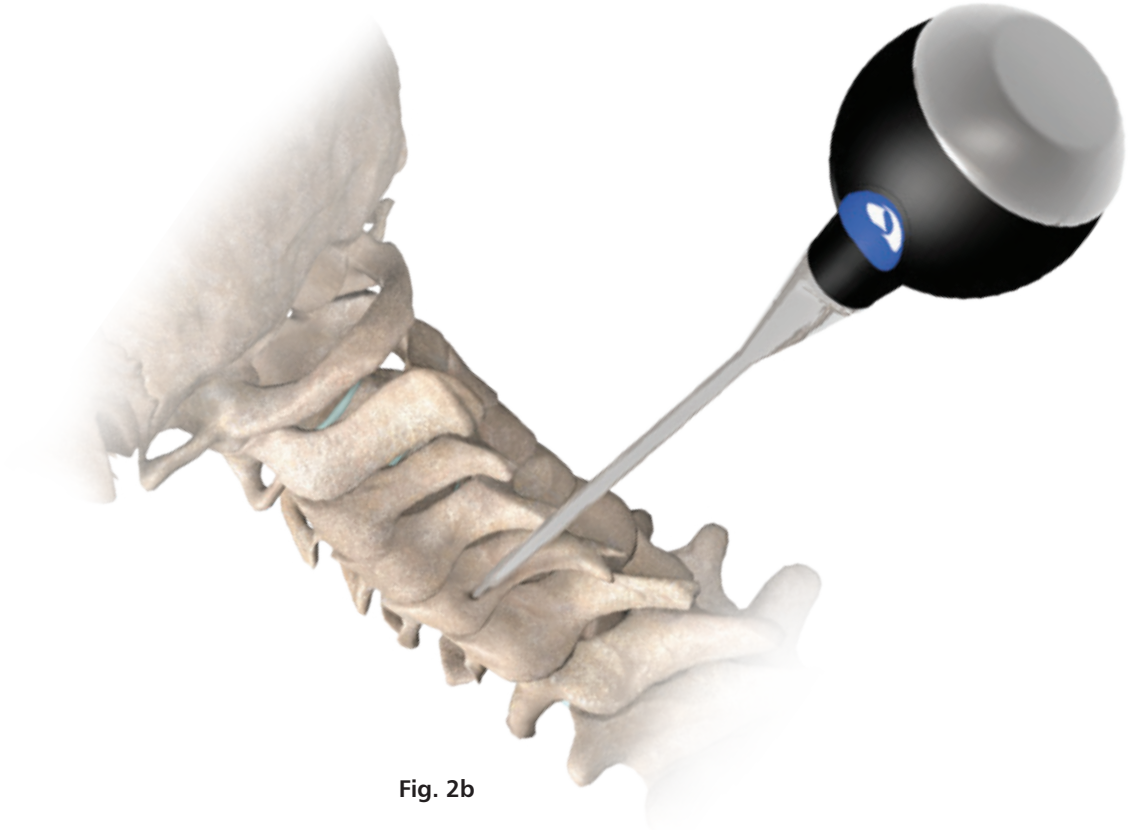


Fig. 2b

Identify anatomical landmarks to determine the entry point of the lateral mass **(Fig. 2a)**. Note any anatomical variations on preoperative CT scans and A/P radiographs. Additionally, utilize intraoperative imaging to facilitate lateral mass screw placement.

C1 Lateral Mass Screws:

- Starting point at the junction of posterior arch and lateral mass.

C2-C7 Lateral Mass Screw:

- Starting point near center of lateral mass.
- Direct screw tip cephalad and lateral.
- Away from nerve root, spinal cord, and vertebral artery.

Precaution: The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.

After determining the entry point to the lateral mass, penetrate the cortex with the bone Awl (69-1001) while ensuring the instrument does not slip off the intended position **(Fig. 2b).**

A bone Probe (69-1002) can be used to elongate the hole to the desired depth utilizing the depth markings.

Note: Excessive force should not be applied while utilizing the bone Awl (69-1001) or bone Probe (69-1002).

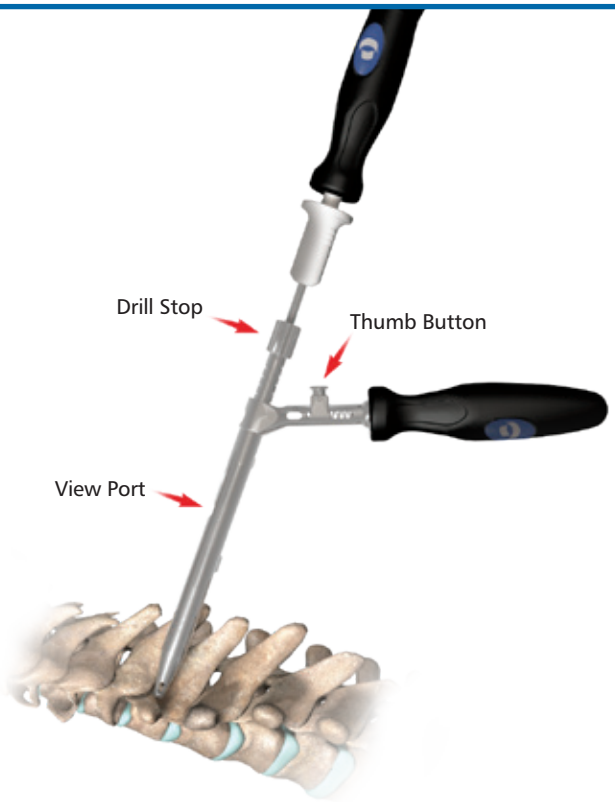


Fig. 3a

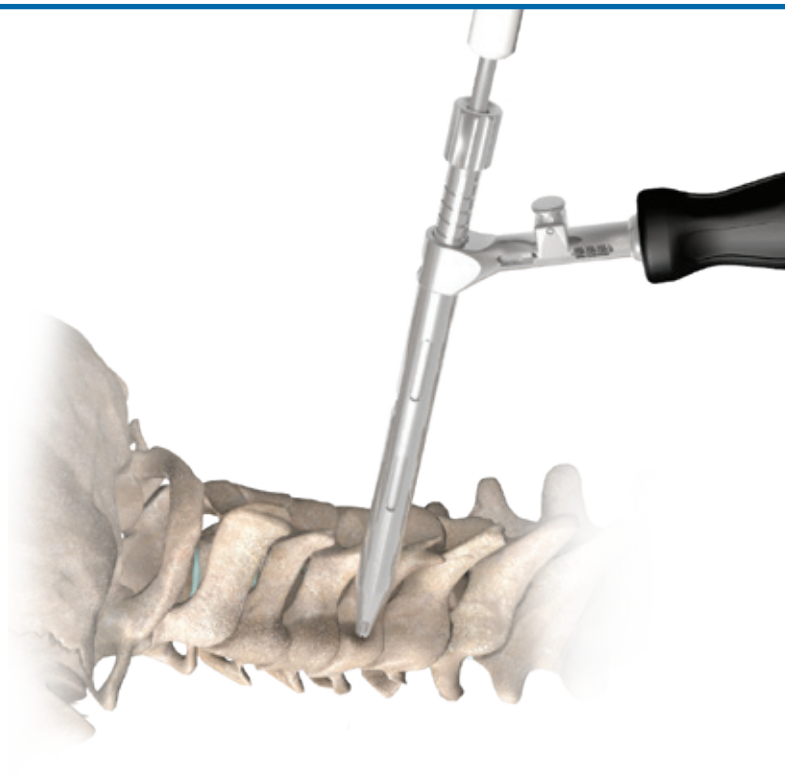


Fig. 3b

3. DRILLING AND SCREW SELECTION FOR THE CERVICAL SPINE

Prepare the Drill Guide (69-1010) by depressing the thumb button and rotating the drill stop until the number in the view port is set to the desired drilling depth (9mm - 52mm in 1mm increments). **(Fig. 3a)**

Note: Release the thumb button to lock the drill stop. Always ensure the drill stop is fully locked (does not rotate) and the thumb button is fully released prior to use.

Determine the diameter of the screw that will be used and insert the corresponding Drill (69-101X) securely into Modular In-Line Handle (69-1032) by sliding back the collar on the handle and ensuring full engagement.

Position the Drill Guide (69-1010) in desired position and drill the lateral mass until reaching the stop. **(Fig. 3b)**

Note: Always use the Drill Guide (69-1010) to prevent drilling deeper than intended.

Note: The Modular In-Line Handle (69-1032) utilizes an AO connection that is used with several modular instruments in the system. Always ensure the handle is securely attached to the instrument prior to use.

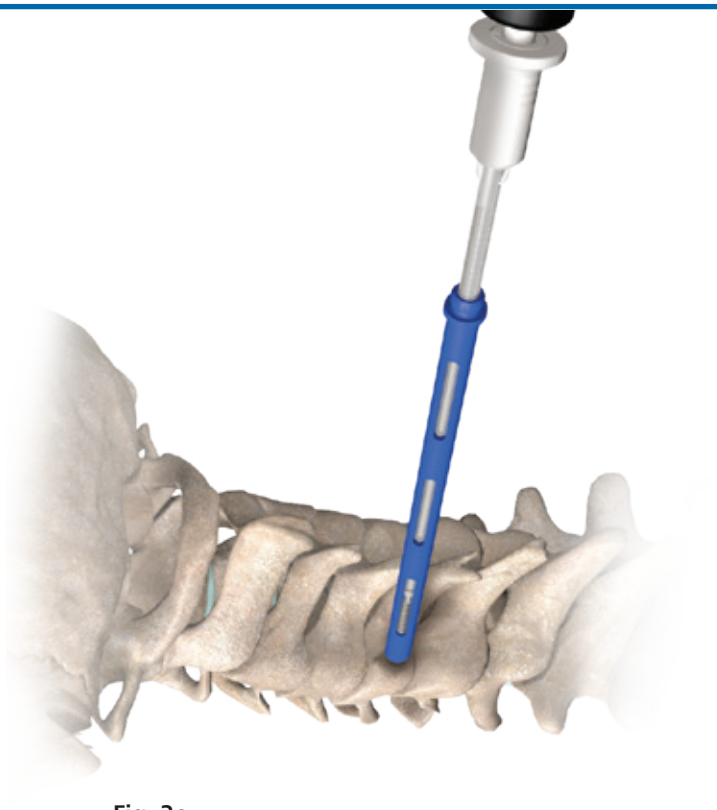


Fig. 3c

Fig. 3d

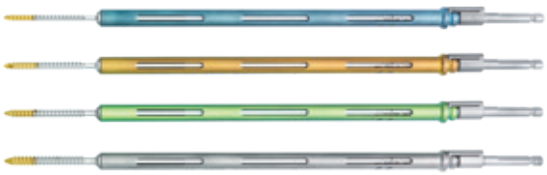


Fig. 3e

Select the appropriate diameter Tap (69-102X) and insert securely into Modular In-Line Handle (69-1032). **(Fig. 3c)**

Tap to the appropriate depth. The rotating sleeve on the tap rises as the tip is advanced into the lateral mass, indicating the depth of penetration in millimeters by the markings.

Note: All drills **(Fig. 3d)** and taps **(Fig. 3e)** are color-coded and differentiated by diameter.

Note: Do not apply excessive force while tapping to avoid bending shaft.

Note: All gold tipped instruments denotes 12mm depth.

Fig. 3e

Fig. 3g

3. DRILLING AND SCREW SELECTION FOR THE CERVICAL SPINE (cont.)

Palpate the wall or canal with the Dual Sounder (69-1005) for evaluating the condition of the cortical wall of the lateral mass. **(Fig. 3e)**

Use the Depth Gauge (69-1006) to determine the screw length. **(Fig. 3g)**

Thoracic Operative Technique

The following section demonstrates the procedure for thoracic operative technique.

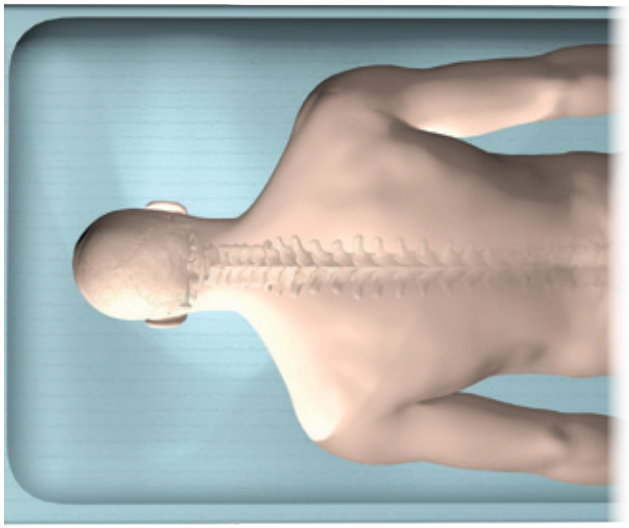


Fig. 1

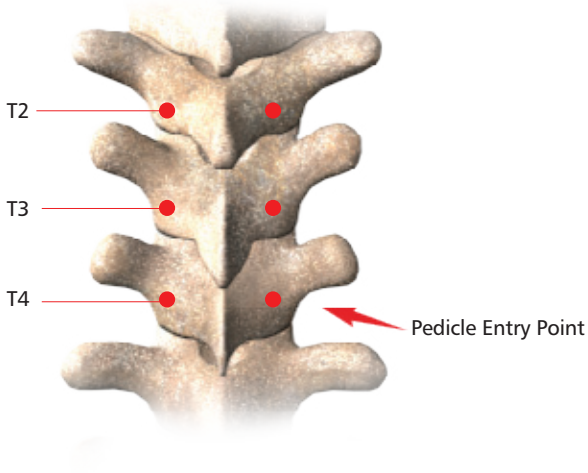


Fig. 2a

1. 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. Perform a standard midline incision. Once bleeding is controlled, deepen the exposure through the fascia level and dissect laterally to expose the facets and transverse processes. **(Fig. 1)**

2. PEDICLE IDENTIFICATION AND PREPARATION

Identify anatomical landmarks to determine the entry point to the pedicle. Note any anatomical variations on preoperative CT scans and A/P radiographs. Additionally, utilize intraoperative imaging to facilitate thoracic pedicle screw placement. A laminectomy can be performed to visualize and feel the medial, cephalad, and caudal aspect of the pedicle. **(Fig. 2a)**

Fig. 2b

Fig. 2c

After determining the entry point to the pedicle, penetrate the cortex with the bone Awl (69-1001) while ensuring the instrument does not slip off the intended position. **(Fig. 2b)**

A bone Probe (69-1002) can be used to elongate the hole to the desired depth utilizing the depth markings. **(Fig. 2c)**

Note: Excessive force should not be applied while utilizing the bone Awl (69-1001) or bone Probe (69-1002)

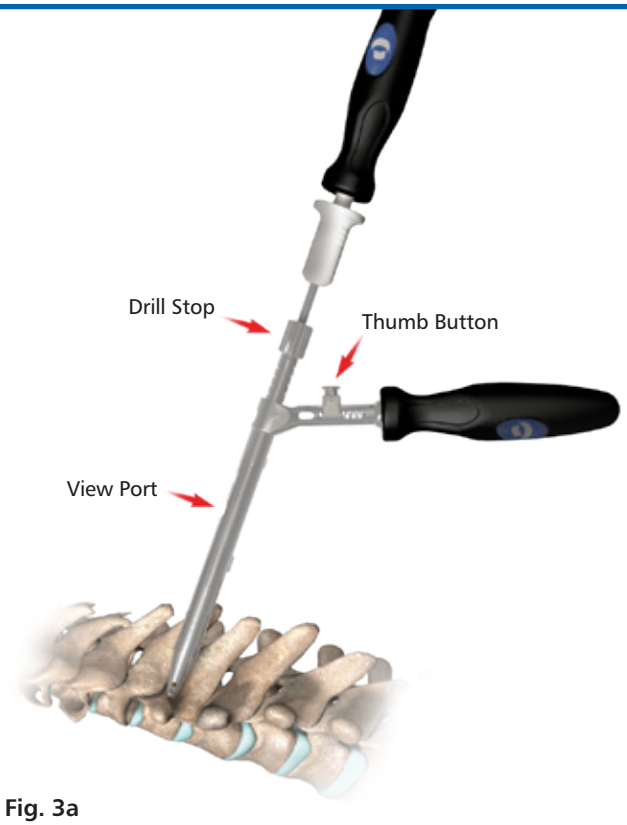


Fig. 3a

Fig. 3b

Fig. 3c

3. DRILLING AND SCREW SELECTION

Prepare the Drill Guide (69-1010) by depressing the thumb button and rotating the drill stop until the number in the view port is set to the desired drilling depth (9mm - 52mm in 1mm increments).

Note: Release the thumb button to lock the drill stop. Always ensure the drill stop is fully locked (does not rotate) and the thumb button is fully released prior to use.

Determine the diameter of the screw that will be used and insert the corresponding Drill (69-101X) securely into Modular In-Line Handle (69-1032) by sliding back the collar on the handle and ensuring full engagement.

Position the Drill Guide (69-1010) in desired position and drill the pedicle until reaching the stop. **(Fig. 3a)**

Note: Always use the Drill Guide (69-1010) to prevent drilling deeper than intended.

Note: The Modular In-Line Handle (69-1032) utilizes an AO connection that is used with several modular instruments in the system. Always ensure the handle is securely attached to the instrument prior to use.

Select the appropriate diameter Tap (69-102X) and insert securely into Modular In-Line Handle (69-1032). **(Fig. 3b)**

Tap to the appropriate depth. The rotating sleeve on the tap rises as the tip is advanced into the pedicle, indicating the depth of penetration in millimeters by the markings. **(Fig. 3c)**

Fig. 3d

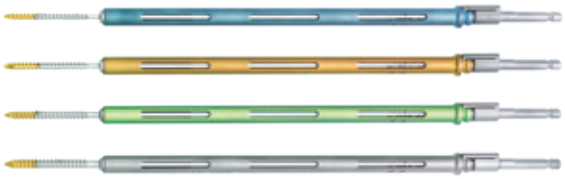


Fig. 3e

Fig. 3f

Note: All drills **(Fig. 3d)** and taps **(Fig. 3e)** are color-coded and differentiated by diameter.

Note: Do not apply excessive force while tapping to avoid bending shaft.

Note: All gold tipped instruments denotes 12mm depth

Palpate the wall or canal with the Dual Sounder (69-1005) for evaluating the condition of the cortical wall of the pedicle. **(Fig. 3f)**

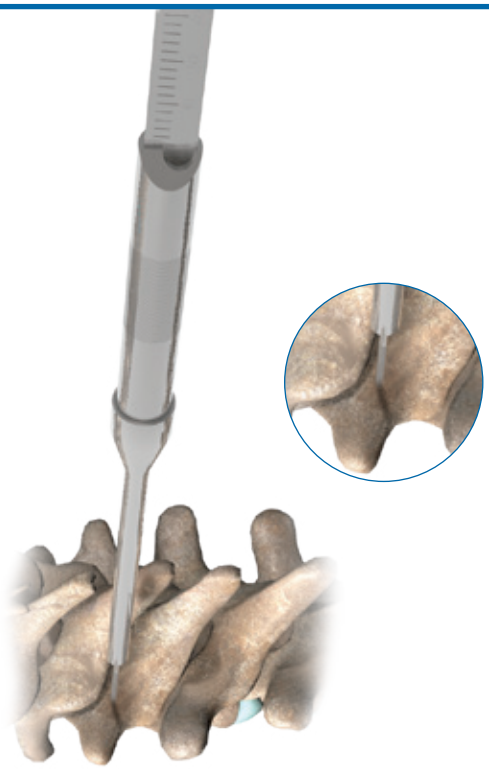


Fig. 3g

Use the Depth Gauge (69-1006) to determine the screw length. **(Fig. 3g)**

Laser Marked Line Edge

Fig. 4b

Fig. 4a

4. MULTI-AXIAL SCREW PLACEMENT

Connect the Multi-Axial Screw Driver (69-1036) to the Modular In-Line Handle (69-1032).

Attach the desired screw (both size and length) to the driver by aligning and inserting the driver tip into the screw. Rotate the rod saddle slot to align with the flanges of the driver. Turn the tri-lobe knob clockwise to thread into the rod saddle. **(Fig. 4a)**

The Multi-Axial Screw Driver (69-1036) disassembles for cleaning. It is important to follow instructions when assembling. Components are laser marked for order and orientation of assembly. Refer to Instructions for Use. **(Fig. 4b)**

Multi-Axial Screw is comprised of three key components: the saddle body, used to retain the rod; the drive body, used for dorsal height adjustment; and the bone screw. The drive body has an inferior notch indicated by a laser marked line used to provide additional angulation.

Fig. 4c

Fig. 4d

Insert the screw into the previously prepared pedicle. Confirm the screw position using intraoperative fluoroscopy.

Once the screw has been placed/implanted, turn the tri-lobe knob counter-clockwise to disengage the screw from the driver. **(Fig. 4c)**

NOTE: Do not apply excessive force when removing the instrument.

Place remaining screws using a similar technique.

Prior to rod placement, the rod saddle slots may be aligned using the spring loaded tip of the Off-Axis Driver (69-1045). **(Fig. 4d)**

Additional angulation of the screw body can also be obtained using the Off-Axis Driver (69-1045) by engaging the spring loaded tip in the rod saddle slot, aligning the window and laser marked line with the corresponding laser marked line on the drive body, and pressing downwards to engage to drive body. Rotate the drive body to align the inferior notch to the orientation required for additional angulation. The dorsal height adjustment is accomplished in the same manner.

Note: It is important to provide downward pressure on the Off-Axis Driver (69-1045) to ensure proper engagement of the implant drive body during rotation and alignment maneuvers.

Fig. 4e

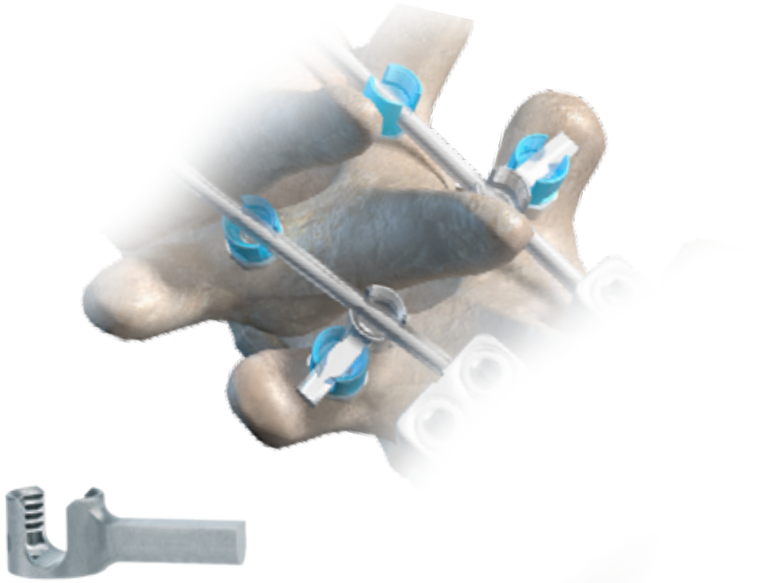


Fig. 4f

OPTIONAL HOOK AND LATERAL OFFESET PLACEMENT

4.5mm Cervical Hooks (69-3010), and 6.0mm Cervical Hooks (69-3011) are provided for use in the cervical region. Prepare the lamina for cervical hook placements using the Laminar Elevator (69-0040). **(Fig. 4e)**

Choose the appropriate hook based on the thickness of the lamina. Attach the hook to either the Straight Hook Inserter (67-0001) or Angled Hook Inserter (67-0003), and place in the appropriate position.

Note: Ensure the Hook Inserter (67-0001/67-0003) properly engages the cervical hook.

For additional medial/lateral offset to facilitate rod placement, 10mm Lateral Offset Adapters (69-6310) are provided for attachment to the multi-axial screw. **(Fig. 4f)** Provisionally tighten the set screws on the adapter and the multi-axial screw to allow adjustments for final rod placement prior to final tightening.

Note: Ensure the Lateral Offset Adapter is properly inserted into the aligned multi-axial screw. The Lateral Offset Adapter should be inserted into the multi-axial screw such that the set screw will always seat on the flat face of the extension of the Lateral Offset Adapter.

Note: Ensure proper reduction of the rod prior to final tightening of the set screw.

Note: The saddle body of the Lateral Offset Adapter should not be butted tightly against the Multi-Axial Screw. Improper seating of the set screw may occur.

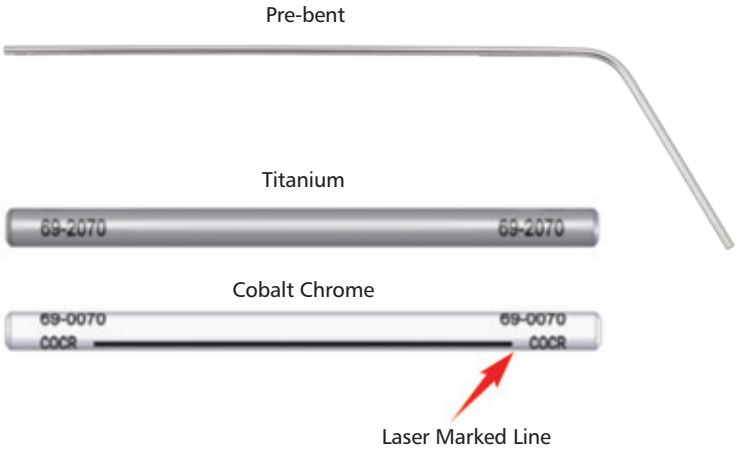


Fig. 5a

Fig. 5b

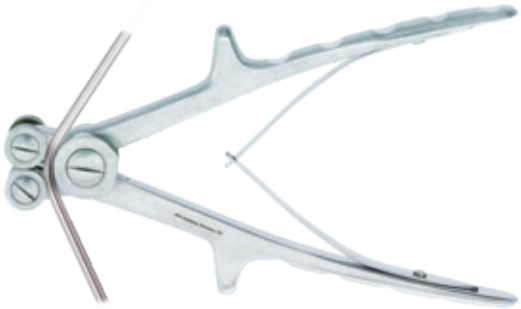


Fig. 5c

5. ROD PREPARATION

Once all screws and hooks are in place, determine the appropriate rod material. Straight and pre-bent 3.5mm rods of various lengths are provided in both titanium or cobalt chrome. **(Fig. 5a)**

Cobalt chrome rods are differentiated with a linear laser marked line.

Trial Rods (65-105X) are available to aid in determining the length and curvature requirements for final rod placement.

Note: A Rod Reducer (69-1072) is provided to aid in controlled rod to saddle reduction. Properly align the rod reducer with engagement features on the multi-axial screw.

Insert the rod into the Rod Cutter (69-1041). Clamp down on the handles to cut the rod. **(Fig. 5b)**

To add curvature to the rod, Place the rod between the large and small wheels on the Rod Bender (69-1042). Compress the handles to create the correct contour, referencing the trial rod as a guide. Rod ends will bend towards the handles. **(Fig. 5c)**

Note: 5.5mm segment of the transition rod CAN NOT be bent with the Rod Bender (69-1042).

Warning: Rods 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. 6a

Fig. 6b

6. ROD PLACEMENT

To facilitate rod placement into the rod saddles, a Rod Holder (69-1043) **(Fig. 6a)** is provided. Reduction of the rod into the rod saddles can be accomplished using either the Rod Rocker (69-1049), or the Rod Reducer (69-1072). The Set Screw Inserter (69-1063) or the Set Screw Inserter Dual Sided (69-1060) is used in conjunction with the rod reducer for insertion and provisional tightening of the set screw.

Note: Ensure the **Rod Holder (69-1043)** properly engages the rod and is properly locked in the closed position.

Note: Ensure the **Rod Rocker (69-1049)** fully engages the engagement features of the rod saddle and that there is no interference of tissue, implants, or instruments prior to usage.

Note: An **Adjustment Driver (69-1046)** is provided for dorsal height adjustments while the rod is in place. Ensure that there is no interference of tissue, implants, or instruments, and that there is proper engagement with the drive body of the Multi-Axial Screw.

Note: Ensure the Rod Reducer (69-1072) properly engages the engagement features of the rod saddle. The rod reducer tips should clip onto and sit squarely on the rod saddle engagement feature. **(Fig. 6b)** If the rod reducer lever cannot be fully actuated (or stops after partial actuation), release the lever and check the engagement.

Note: When using the Rod Reducer (69-1072) and either the Set Screw Inserter (69-1063) or the Set Screw Inserter Dual Sided (69-1060), ensure that there is no excessive side forces applied to prevent misalignment of the set screw inserter during insertion of the set screw and removal of the set screw inserter.

Fig. 6c

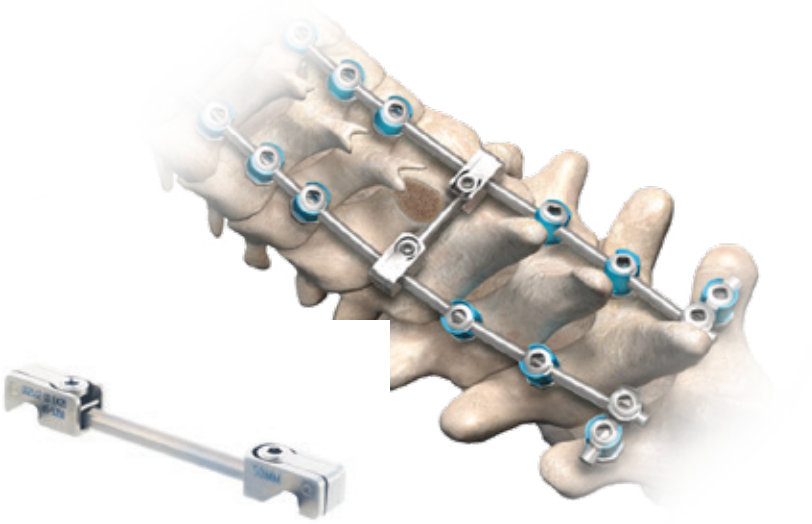


Fig. 6d

CROSS CONNECTOR

Cross connectors provide additional torsional rigidity to the construct by bridging the parallel rods. Position the Cross Connector Sizer (69-1101) directly over the rods and measure the distance across the rods. **(Fig. 6c)**

Select the appropriate Cross Connector (69-54xx) and position on the rods. Ensure rods are fully seated in the notches on the bodies of the Cross Connector. Lock the cross connector into position using the Cross Connector Set Screw Driver (65-1082) and Cross Connector Torque Limiting Driver Handle (65-1083).

An audible click will indicate when the final torque of 10 in-lb is achieved. **(Fig. 6d)**

Fig. 6e

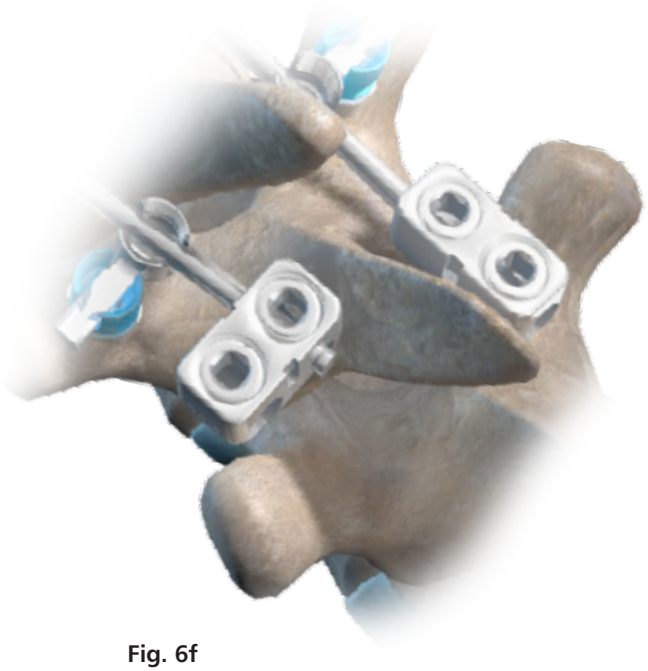


Fig. 6f

ROD CONNECTOR (optional)

3.5mm/5.5mm Parallel Rod Connectors (69-6405) and 3.5mm/5.5mm Axial Rod Connectors (69-6425) **(Fig. 6e)** are provided to enable the transition from 3.5mm rods to 5.5mm rods at a given location. The Rod Connector Inserter (52-1035) can be used to facilitate placement of the rod connectors.

The Rod Connector Driver (69-1038) and Rod Connector Torque Limiting Driver (69-1037) can be used for final tightening of the rod connectors after placement of the rod.

Note: Ensure the Rod Connector Inserter (52-1035) properly engages the rod connector and is properly locked in the closed position.

Note: Ensure the rod connector set screw is sufficiently backed out to enable insertion of the rod, and ensure the rod is fully inserted into the rod connector prior to final tightening.

Note: Counter Torque Wrench (69-1066) can be used offset from the Rod Connector implant to provide counter torque.

Note: The Rod Connector Driver (69-1038) and Rod Connector Torque Limiting Driver (69-1037) utilize a special tri-lobe connection that is not compatible with the Set Screw Driver (69-1061) and Torque Limiting Driver (69-1065). **(Fig. 6f)**

Note: Ensure the Rod Connector Driver (69-1038) is securely engaged with the Rod Connector Torque Limiting Driver (69-1037) as well as with the set screw prior to application of torque (80 in-lbs).

Fig. 7b

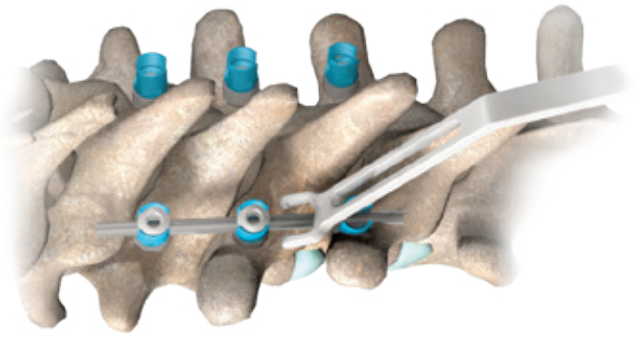


Fig. 7a

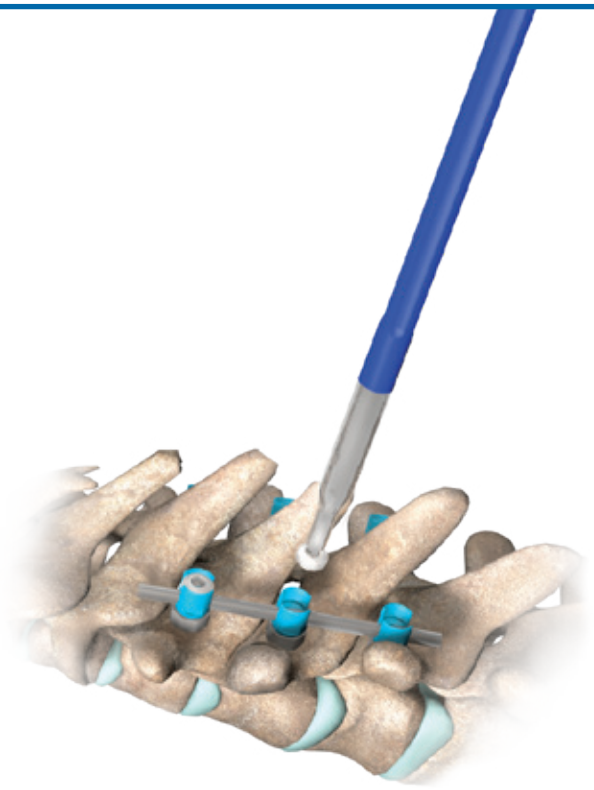


Fig. 7c

7. SET SCREW PLACEMENT

Seat the rod into the saddle for subsequent set screw placement with the aid of the either the Rod Reducer (69-1072), or the Rod Rocker (69-1049). **(Fig. 7a)**

Set screw inserters are provided to provisionally tighten set screws.

Both the Set Screw Inserter (69-1063) and the Set Screw Inserter Dual Sided (69-1060) instruments utilize a stab and grab approach with a foot for retention of the set screw. **(Fig. 7b)**

When introducing the set screw into the saddle a half turn in the counter clockwise direction before advancing in the clockwise orientation will help reduce cross threading. **(Fig. 7c)**

Fig. 8a

Fig. 8b

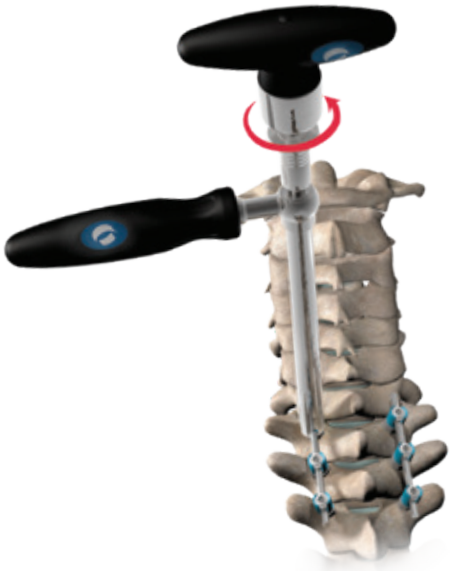


Fig. 9

8. FINAL TIGHTENING

Utilize the Compressor (69-1048) or Distractor (69-1070) to compress or distract vertebrae as required during final tightening.

If needed, the Adjustment Driver (69-1046) can be used to adjust the height of the Multi-Axial Screw prior to final tightening without removing the rod. (Fig. 8b)

Position the Counter Torque Wrench (69-1066) over the multi-axial screw and rod making sure to engage tips to align rod within screw body. Attach the Set Screw Driver (69-1061) to the Torque Limiting Driver (69-1065) handle, and insert the Set Screw Driver (69-1061) through the cannulation of the counter torque wrench and into the hex of the set screw. Turn the Torque Limiting Driver (69-1065) clockwise while stabilizing the rod with the Counter Torque Wrench (69-1066) stationary until the Torque Limiting Driver (69-1065) clicks and releases. **(Fig. 8a)**

Note: There are Compressor (69-1048) and Distractor (69-1070) instruments available to provide compression or distraction. It is important to properly align with implants to allow for application of force. **(Fig. 8b)**

9. REVISION

In order to remove the multi-axial screws, fully seat the Set Screw Driver (69-1061) securely into the set screw and turn counterclockwise to loosen the set screw. Use of the Counter Torque Wrench (69-1066) is recommended to avoid potential damage to the bony elements. **(Fig. 9)**

Carefully remove all set screws.

NOTE: For post operative revision utilize the Multi-Axial Screw Driver (69-1036).

CENTURION CASE

Part Number List

Part #	Description	Qty
Instrument Case Core System		
69-1094	**Instrument Case** (includes all trays, caddies, base & lid)	1
69-8121	**Top Tray, Instrument Case**	1
69-1001	Awl	1
69-1002	Probe	1
69-1005	Dual Sounder	1
69-1006	Depth Gauge	1
69-1015	3.5mm Drill	2
69-1016	4.0mm Drill	2
69-1017	4.5mm Dril	2
69-1018	5.0mm Drill	2
69-1025	3.5mm Bone Tap	2
69-1026	4.0mm Bone Tap	2
69-1027	4.5mm Bone Tap	2
69-1028	5.0mm Bone Tap	2
69-1032	Modular In-Line Handle	3
69-1036	Multi-Axial Screw Driver	2
69-8122	**Middle Tray, Instrument Case**	1
65-1055	70mm Trial Rod	2
65-1056	120mm Trial Rod	2
65-1057	200mm Trial Rod	2
69-1010	Drill Guide	1
69-1045	Off Axis Driver	1
69-1046	Adjustment Driver	1
69-1049	Rod Rocker	1
69-1060	Set Screw Inserter Dual Sided	2
69-1061	Set Screw Driver	2
69-1063	Set Screw Inserter Single Sided	2
69-1065	Torque Limiting Driver	1
69-1066	Counter Torque Wrench	1
69-1072	Rod Reducer	1
69-8124	**Bottom Tray, Instrument Case**	1
69-1042	Rod Bender	1
69-1048	Compressor	1
69-1070	Distractor	1
69-1101	Cross Connector Sizer	1
65-1082	Cross Connector Set Screw Driver	1
65-1083	Cross Connector Torque Limiting Driver Handle	1
Implant Case Core System		
69-1092	Implant Case (includes all trays, caddies, base, and lid)	1
69-8221	**Top Tray, Implant Case**	1
69-0070	3.5mm Rod, CoCr, 70mm	2
69-0120	3.5mm Rod, CoCr, 120mm	2
69-2070	3.5mm Rod, Ti, 70mm	6
69-2120	3.5mm Rod, Ti, 120mm	4
69-8201	**Set Screw Caddy**	1
69-2001	Set Screw	30

Part Number List (Cont.)

Part #	Description	Qty
69-8202	**3.5mm Multi-Axial Screw Caddy**	1
69-3310	3.5mm x 10mm Multi-Axial Screw	8
69-3312	3.5mm x 12mm Multi-Axial Screw	16
69-3314	3.5mm x 14mm Multi-Axial Screw	16
69-3316	3.5mm x 16mm Multi-Axial Screw	8
69-3318	3.5mm x 18mm Multi-Axial Screw	4
69-3320	3.5mm x 20mm Multi-Axial Screw	4
69-3322	3.5mm x 22mm Multi-Axial Screw	4
69-3324	3.5mm x 24mm Multi-Axial Screw	4
69-3326	3.5mm x 26mm Multi-Axial Screw	4
69-3328	3.5mm x 28mm Multi-Axial Screw	4
69-3330	3.5mm x 30mm Multi-Axial Screw	4
69-8203	**4.0mm Multi-Axial Screw Caddy**	1
69-3410	4.0mm x 10mm Multi-Axial Screw	4
69-3412	4.0mm x 12mm Multi-Axial Screw	8
69-3414	4.0mm x 14mm Multi-Axial Screw	8
69-3416	4.0mm x 16mm Multi-Axial Screw	4
69-3418	4.0mm x 18mm Multi-Axial Screw	2
69-3420	4.0mm x 20mm Multi-Axial Screw	2
69-3422	4.0mm x 22mm Multi-Axial Screw	2
69-3424	4.0mm x 24mm Multi-Axial Screw	2
69-3426	4.0mm x 26mm Multi-Axial Screw	2
69-3428	4.0mm x 28mm Multi-Axial Screw	2
69-3430	4.0mm x 30mm Multi-Axial Screw	2
69-8204	**4.5mm & 5.0mm Multi-Axial Screw Caddy**	1
69-3520	4.5mm x 20mm Multi-Axial Screw	4
69-3525	4.5mm x 25mm Multi-Axial Screw	4
69-3530	4.5mm x 30mm Multi-Axial Screw	4
69-3535	4.5mm x 35mm Multi-Axial Screw	4
69-3540	4.5mm x 40mm Multi-Axial Screw	4
69-3545	4.5mm x 45mm Multi-Axial Screw	4
69-3625	5.0mm x 25mm Multi-Axial Screw	4
69-3630	5.0mm x 30mm Multi-Axial Screw	4
69-3635	5.0mm x 35mm Multi-Axial Screw	4
69-3640	5.0mm x 40mm Multi-Axial Screw	4
69-3645	5.0mm x 45mm Multi-Axial Screw	4
69-8205	**Smooth Shank Screw Caddy**	1
69-3126	3.5mm x 26mm Multi-Axial Screw, Smooth Shank	4
69-3128	3.5mm x 28mm Multi-Axial Screw, Smooth Shank	4
69-3130	3.5mm x 30mm Multi-Axial Screw, Smooth Shank	4
69-3132	3.5mm x 32mm Multi-Axial Screw, Smooth Shank	4
69-3226	4.0mm x 26mm Multi-Axial Screw, Smooth Shank	2
69-3228	4.0mm x 28mm Multi-Axial Screw, Smooth Shank	2
69-3230	4.0mm x 30mm Multi-Axial Screw, Smooth Shank	2
69-3232	4.0mm x 32mm Multi-Axial Screw, Smooth Shank	2
69-3234	4.0mm x 34mm Multi-Axial Screw, Smooth Shank	2

Part Number List (Cont.)

Part #	Description	Qty
69-8207	**Hook and Connector Caddy**	1
69-3010	4.5mm Cervical Hook	6
69-3011	6.0mm Cervical Hook	6
69-6310	10mm Lateral Offset Adapter	6
69-6405	3.5mm/5.5mm Parallel Rod Connector	2
69-6425	3.5mm/5.5mm Axial Rod Connector	2
69-8208	**Cross Connector Caddy**	1
69-5420	20mm Cross Connector	2
69-5425	25mm Cross Connector	2
69-5430	30mm Cross Connector	2
69-5435	35mm Cross Connector	2
69-5440	40mm Cross Connector	2
69-5445	45mm Cross Connector	2
69-5450	50mm Cross Connector	2
69-8222	**Bottom Tray, Implant Case and Instruments**	1
52-1035	Rod Connector Inserter	1
67-0001	Hook Holder - Straight	1
67-0003	Hook Holder - Angled	1
69-0022	3.5mm/ 5.5mm Transition Rod, CoCr, 200mm/ 200mm	3
69-0040	Laminar Elevator	1
69-1038	Rod Connector Driver	1
69-1041	Rod Cutter	1
69-1043	Rod Holder	1
69-2020	3.5mm/ 5.5mm Transition Rod, Ti, 200mm/ 200mm	3
69-1037	Rod Connector Torque Driver	1
69-0200	3.5mm Rod, CoCr, 200mm	2
69-2200	3.5mm Rod, Ti, 200mm	2

Multi-Axial Screw Driver Disassembly and Assembly

Contains 4 Individual Components

1. Screw Extender Assembly

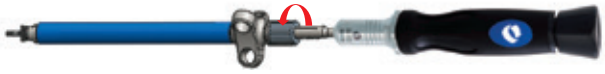
2. Sleeve

3. Driver Assembly

4. AO Adapter Assembly

Disassembly

Step 1 – With the Modular Handle attached to the AO Adaptor Assembly **(4)**, grip the modular handle with one hand and use the other hand to unscrew the knurled cylindrical knob on the AO Adaptor Assembly **(4)** above the tri-lobe handle using a counterclockwise rotation.



Step 2 – Remove the modular handle from the AO Adaptor Assembly **(4)**.

Step 3 – Once the knurled cylindrical knob is completely unscrewed, disengage the AO Adaptor Assembly **(4)** from the tri-lobe handle by pulling it away.

Step 4 – While maintaining a grip on the distal tip of the Driver Assembly **(3)** between thumb and forefinger with one hand, pull gently on the tri-lobe handle to separate the Driver Assembly **(3)** from the Screw Extender Assembly **(1)**.

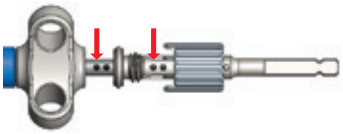
Step 5 – While maintaining a grip on the tri-lobe handle, pull gently on the blue Sleeve (2) to remove it from the tri-lobe handle shaft.

Assembly

Step 1 – Hold the Screw Extender Assembly **(1)** by the tri-lobe handle with one hand and slide the blue Sleeve **(2)** up the shaft of the Screw Extender Assembly (1) until it clicks.

Step 2 – Hold the Driver Assembly **(3)** between thumb and forefinger by the hexagonally shaped tip and slide it into the shaft of the Screw Extender Assembly **(1)** starting from the end opposite the tri-lobe handle.

Step 3 - While maintaining a grip on the distal tip of the instrument between thumb and forefinger with one hand, slide the AO Adaptor Assembly **(4)** over the shaft proximal to the tri-lobe handle and rotate it until the two dots on each surface align, then press together gently until it clicks.



Step 4 – Screw the knurled cylindrical knob of the AO Adaptor Assembly **(4)** clockwise until it is fully seated and the spring clips engage (Note: if gripping the distal tip is difficult, reinstall and grasp Modular Handle instead).

Occipital Plate Operative Technique

The following section demonstrates the procedure for occipital plate implant and revision technique.

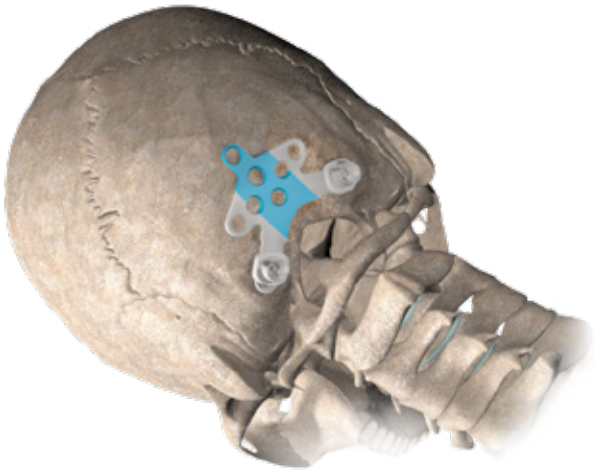


Fig. 1a

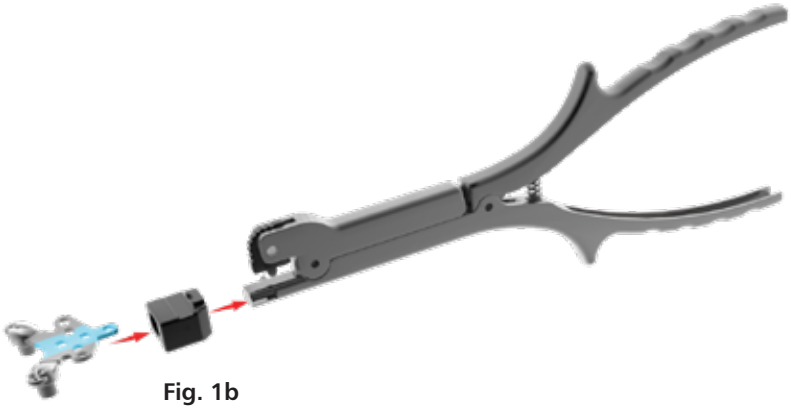


Fig. 1b

Fig. 1c

1. OCCIPITAL PLATE PREPARATION

The occipital plate should be positioned such that it is centered in the midline between the external occipital protuberance and the posterior border of the foramen magnum, in order to maximize bone purchase and achieve a low profile. **(Fig. 1a)**

If the superior tab needs to be contoured, slide the Anvil (69-0043) onto the distal shaft of the Occipital Plate Bender (69-0042) with the curved surface oriented away from the Occipital Plate Bender (69-0042) thumbwheel and the flat side oriented distally **(Fig. 1b).** When fully engaged the Anvil (69-0043) will click into position. Rotate the thumbwheel on the distal tip of the Occipital Plate Bender (69-0042) until the protrusion is pointed toward the Anvil (69-0043).

Insert the superior tab of the occipital plate onto the Anvil (60-0043) and ensure that the superior tab is registered against the curved seat on the Anvil (60-0043). Apply clamping pressure to obtain the desired curvature **(Fig. 1c).**

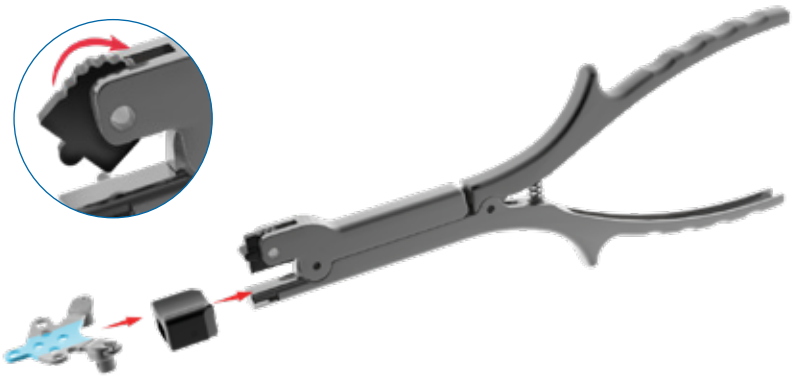


Fig. 1d

Fig. 1e

If the medial lateral curvature of the plate needs to be increased, rotate the thumbwheel on the distal tip of the Occipital Plate Bender (69-0042) until the protrusion is pointed distally. Slide the Anvil (69-0043) onto the distal shaft of the Occipital Plate Bender (69-0042) with the curved surface facing toward the Occipital Plate Bender (69-0042) thumbwheel and the flat side oriented distally. **(Fig. 1d)** When fully engaged the Anvil (69-0043) will click into position.

Insert the occipital plate with the superior tab oriented distally and the occipital plate saddles facing the Anvil (69-0043). While holding the occipital plate stationary with one hand, apply clamping pressure until the desired curvature is attained **(Fig. 1e).**

Note: Medial lateral curvature is not permitted on a small occipital plate (20mm – 30mm).

WARNING: The occipital plate 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.

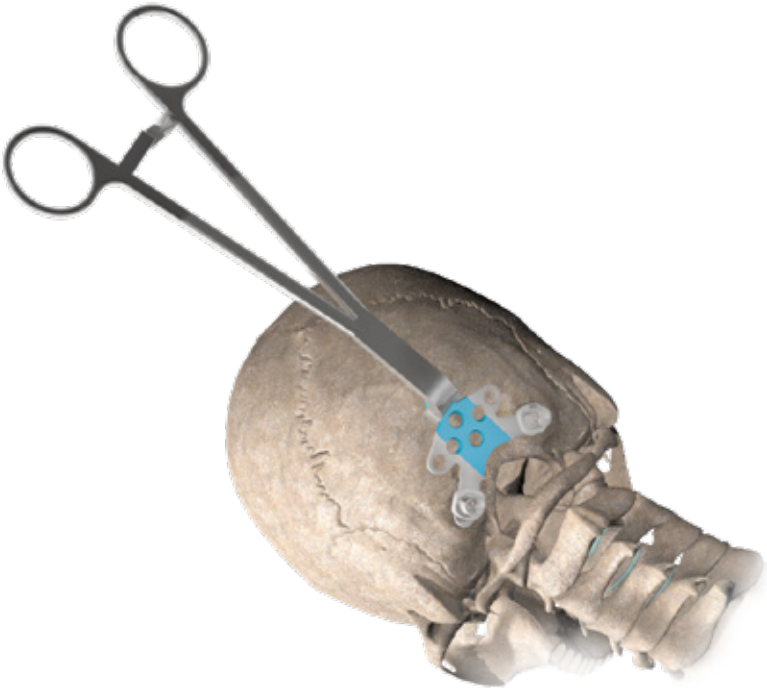


Fig. 2

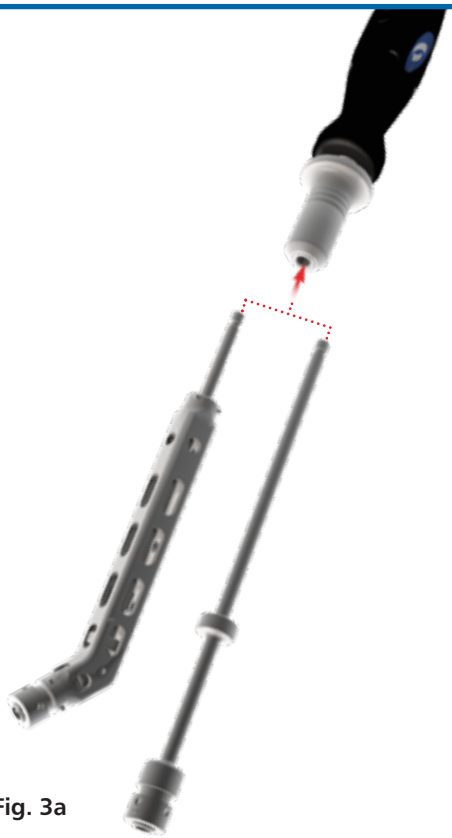


Fig. 3a

2. OCCIPITAL BONE SCREW HOLE POSITIONING

For occipital plate placement attach the Plate Holder (69-0005) to the superior tab of the occipital plate, and position the occipital plate on the required location on the occiput. **(Fig. 2).**

3. DRILLING

Attach a Modular In-Line Handle (69-1032) to the AO quick-connect shaft of the Occipital Driver, Straight (69-0068) or Occipital Driver, Angled (69-0069). Once attached, pull on the driver to ensure the handle is fully engaged **(Fig. 3a).**

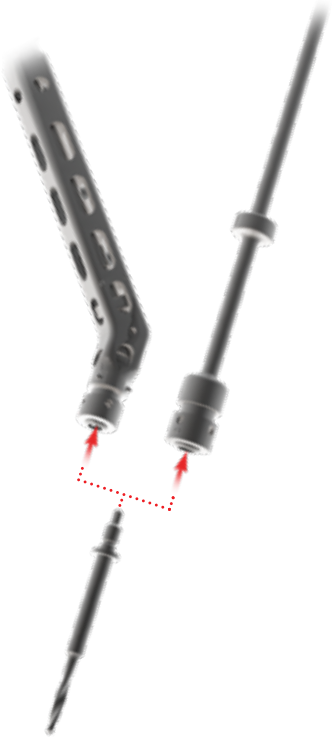


Fig. 3b

Fig. 3c

Pull back on the spring-loaded collar at the distal tip of the occipital driver and insert the square shaft of the Occipital Drill (69-0006). Rotate the drill slightly as needed to orient the square drive of the shaft with the driver's port. Once the drill is seated, release the spring-loaded collar and pull on the attached bit to ensure it is fully engaged **(Fig. 3b).**

The Occipital Driver, Angled (69-0069) has an optional Handle Adapter (69-0067) that may be used to attach a secondary Modular In-Line Handle (69-1032) for additional control. Attach to the body of the Occipital Driver, Angled (69-0069) prior to attachment of the Modular In-Line Handle (69-1032) onto the AO quick-connect shaft of the Occipital Driver, Angled (69-0069) **(Fig. 3c).**

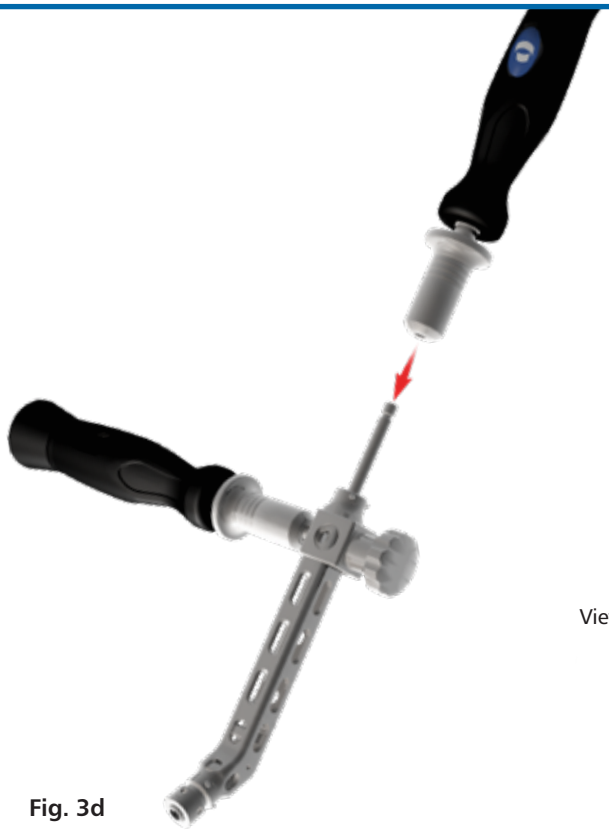


Fig. 3d

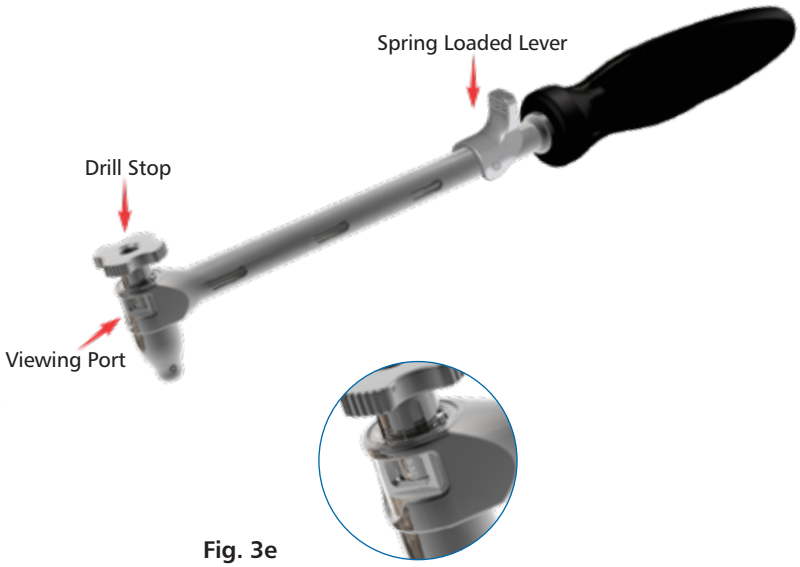


Fig. 3e

3. DRILLING (Cont.)

Attach a Modular In-Line Handle (69-1032) to the AO quick-connect shaft of the Handle Adapter (69-0067). Once attached, pull on the Handle Adapter (69-0067) to ensure the handle is fully engaged.

Turn the thumb knob of the Handle Adapter (69-0067) counterclockwise until it stops rotating. Slide the opening of the Handle Adapter (69-0067) over the body of the Occipital Driver, Angled (69-0069) until it contacts the stop. Turn the thumb knob of the Handle Adapter (69-0067) clockwise until fully tightened **(Fig. 3d).**

Note: The Handle Adapter (69-0067) may be attached as either left or right handed.

Note: When detaching the Handle Adapter (69-0067) from the Occipital Driver, Angled (69-0069), turn the knob on the Handle Adapter (69-0067) counterclockwise until it stops rotating then slide it off.

Prepare the Occipital Drill Guide (69-1112) by sliding the spring loaded lever back and rotating the drill stop until the number in the viewing port is set to the desired drilling depth (4mm -14mm in 1mm increments) **(Fig. 3e).**

Note: Release the spring loaded lever to lock the drill stop. Always ensure the drill stop is fully locked (does not rotate when the lever is fully released) prior to use.

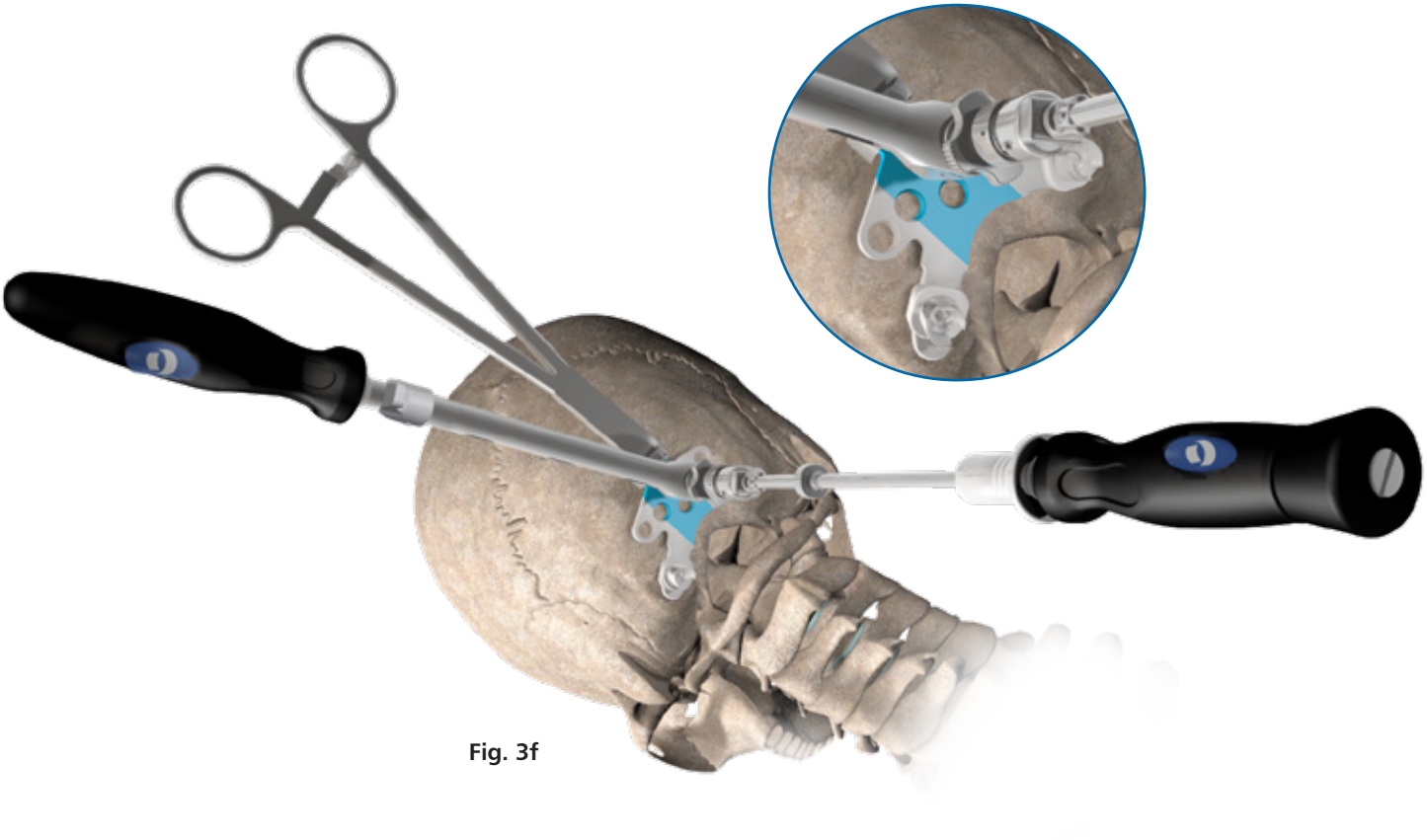


Fig. 3f

Insert the Occipital Drill (69-0006) assembly through the cannulation of the Occipital Drill Guide (69-1112). Seat the distal tip of the Occipital Drill Guide (69-1112) into the selected hole of the occipital plate. Rotate the drill clockwise with a constant trajectory until the Occipital Drill (69-0006) contacts the drill stop. **(Fig. 3f).**

Note: It is not recommended to use powered instruments when drilling, tapping or placing bone screws in the occiput.

Note: The distal tip of the Occipital Drill Guide (69-1112) features a spherical tip which matches the spherical pockets of the holes on the occipital plate, in order to provide accurate hole placement.

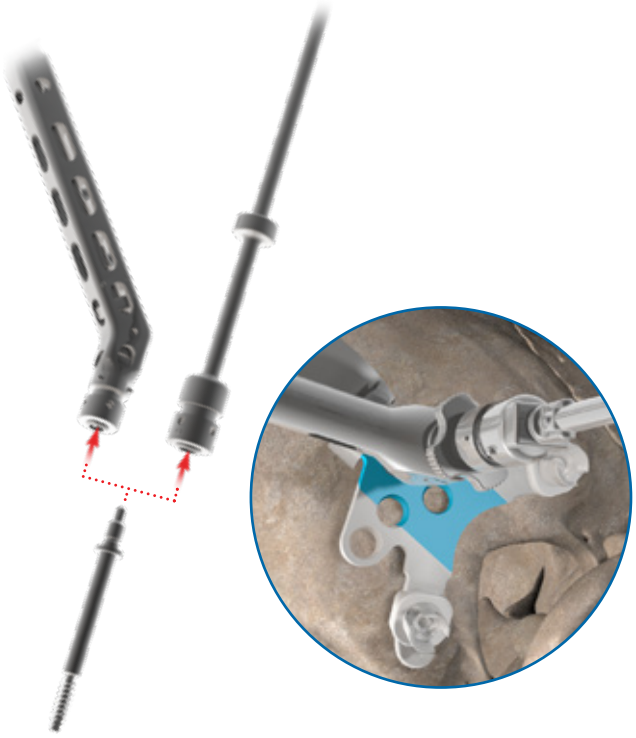


Fig. 4

Fig. 5a Fig. 5b Fig. 5c

4. TAPPING

To engage the Occipital Tap (69-0106) pull back on the spring-loaded collar at the distal tip of the occipital driver and insert the square shaft of the Occipital Tap (69-0106). Rotate the Occipital Tap (69-0106) slightly as needed to orient the square drive of the shaft with the driver's port. Once the Occipital Tap (69-0106) is seated, release the spring-loaded collar and pull to ensure it is fully engaged.

Insert Occipital Tap (69-0106) assembly through the cannulation of the Occipital Drill Guide (69-1112). Seat the distal tip of the Occipital Drill Guide (69-1112) onto the selected hole of the occipital plate. Insert the Occipital Tap (69-0106) into the desired pilot hole prepared by the occipital drill while ensuring the angulation is appropriate for the intended screw trajectory. Rotate the tap clockwise with a constant trajectory until the Occipital Tap (69-0106) contacts the drill stop **(Fig. 4).**

5. OCCIPITAL BONE SCREW PLACEMENT

Pull back on the spring-loaded collar at the distal tip of either the Occipital Driver, Straight (69-0068), or the Occipital Driver, Angled (69-0069) to detach the drill or tap and insert the square shaft of the Occipital Bone Screw Inserter (69-0060). Rotate the Occipital Bone Screw Inserter (69-0060) slightly as needed to orient the square drive of the shaft with the driver's port. Release the spring-loaded collar and pull on the attached inserter to ensure it is fully engaged. **(Fig. 5a).** Select the appropriate length of occipital bone screw based on the patient's anatomy **(Fig. 5c).**

Note: The occipital bone screws are color coded and laser marked on the head to identify the length.

Attach the bone screw to the Occipital Bone Screw Inserter (69-0060) by inserting the split tip of the Occipital Bone Screw Inserter (69-0060) into the head of the screw until fully seated. The occipital bone screw will be self-retained on the Occipital Bone Screw Inserter (69-0060) **(Fig. 5b).**

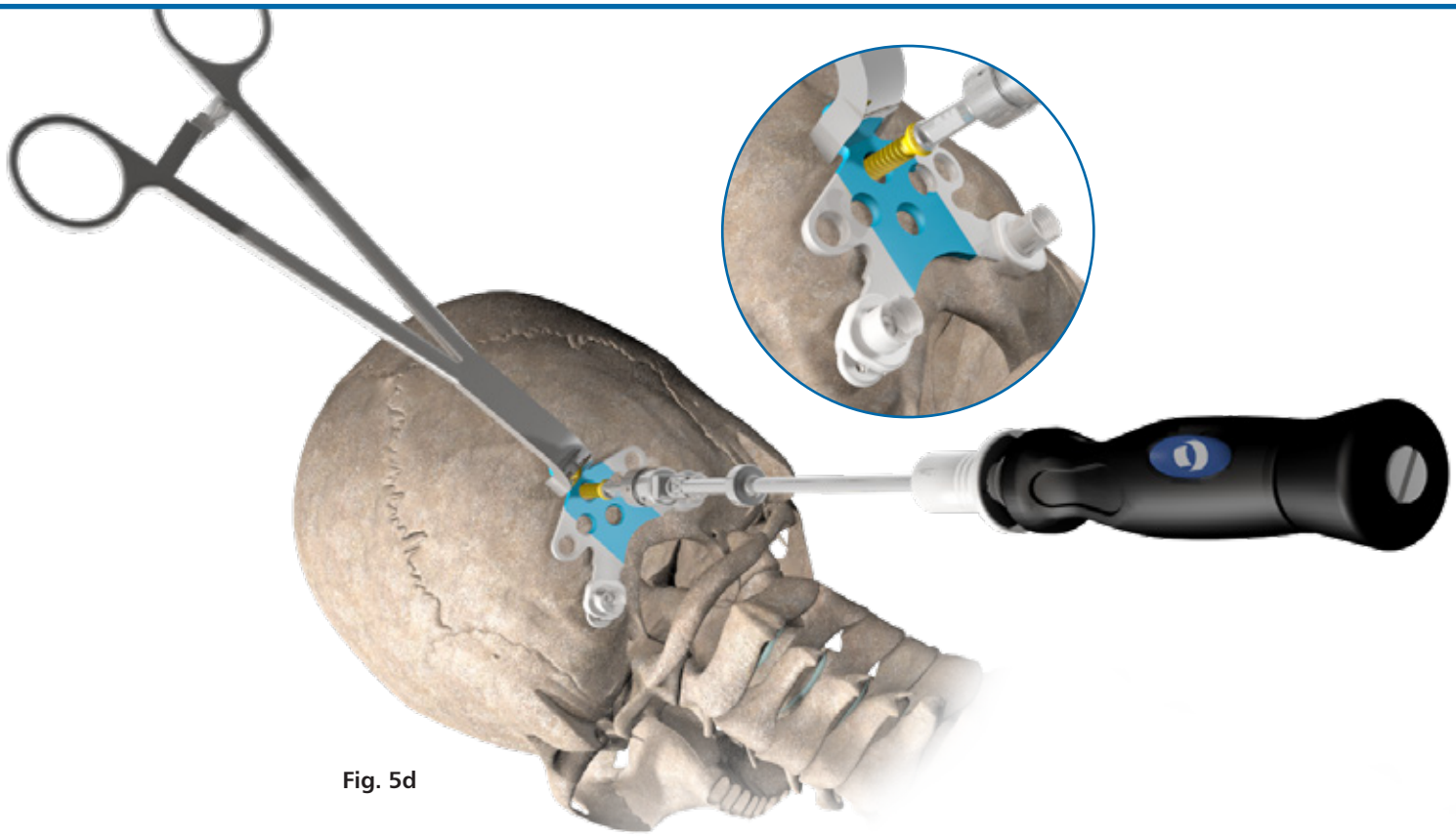


Fig. 5d

Holding the occipital plate in place insert the occipital bone screw through the occipital plate into the prepared hole and rotate clockwise to thread the screw into position **(Fig. 5d).**

Note: It is recommended to drill, tap, and place one occipital bone screw for initial occipital plate fixation prior to drilling, tapping, and placement of the remaining occipital bone screws.

Note: Avoid applying excessive torque during insertion to prevent stripping the threads in the bone.

Note: Do not fully tighten the occipital bone screws until rods have been seated to allow for translation and rotation of the occipital plate's saddles during rod positioning.

Note: Rescue screws are available and can be differentiated by the non-anodized heads.

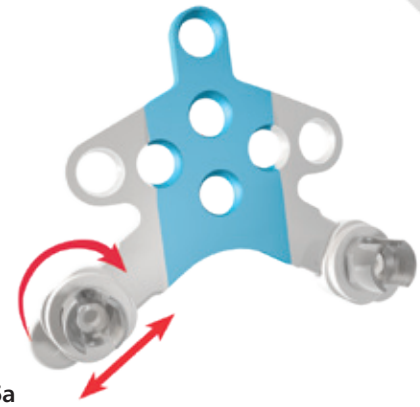


Fig. 6a

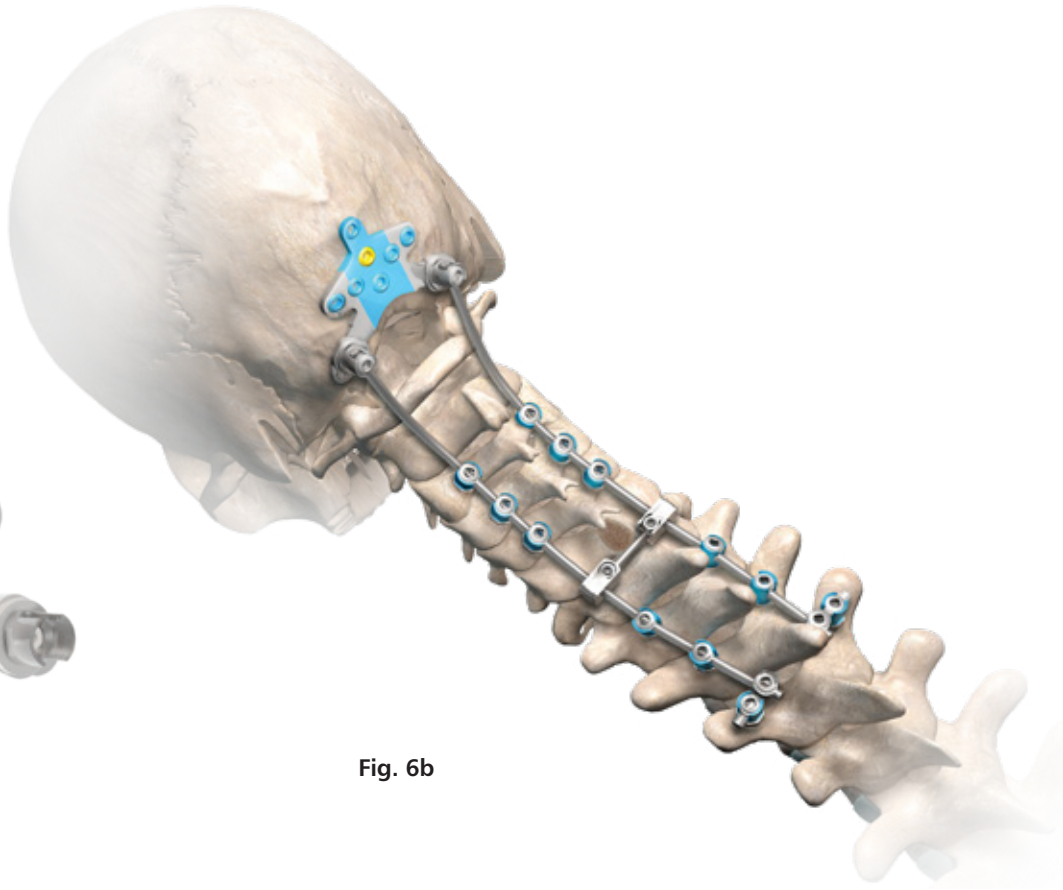


Fig. 6b

6. OCCIPITAL ROD PLACEMENT

The occipital plate has saddles which accommodate 3.5mm diameter titanium or cobalt chrome rods. In order to facilitate rod placement, the saddles have the ability to translate along the legs of the occipital plate, and rotate about its axis, prior to tightening of the set screws **(Fig. 6a)**.

Once all screws, hooks and the occipital plate are in place determine the appropriate rod. 3.5mm rods of various lengths are provided in either titanium or cobalt chrome **(Fig. 6b)**.

Cobalt chrome rods are differentiated with a linear laser marked line.

Note: The occipital rods are available in 110°, 120°, and 135° bends. Rod trialing, cutting, and bending are detailed in the core system operative technique. **(Refer to Page 11)**

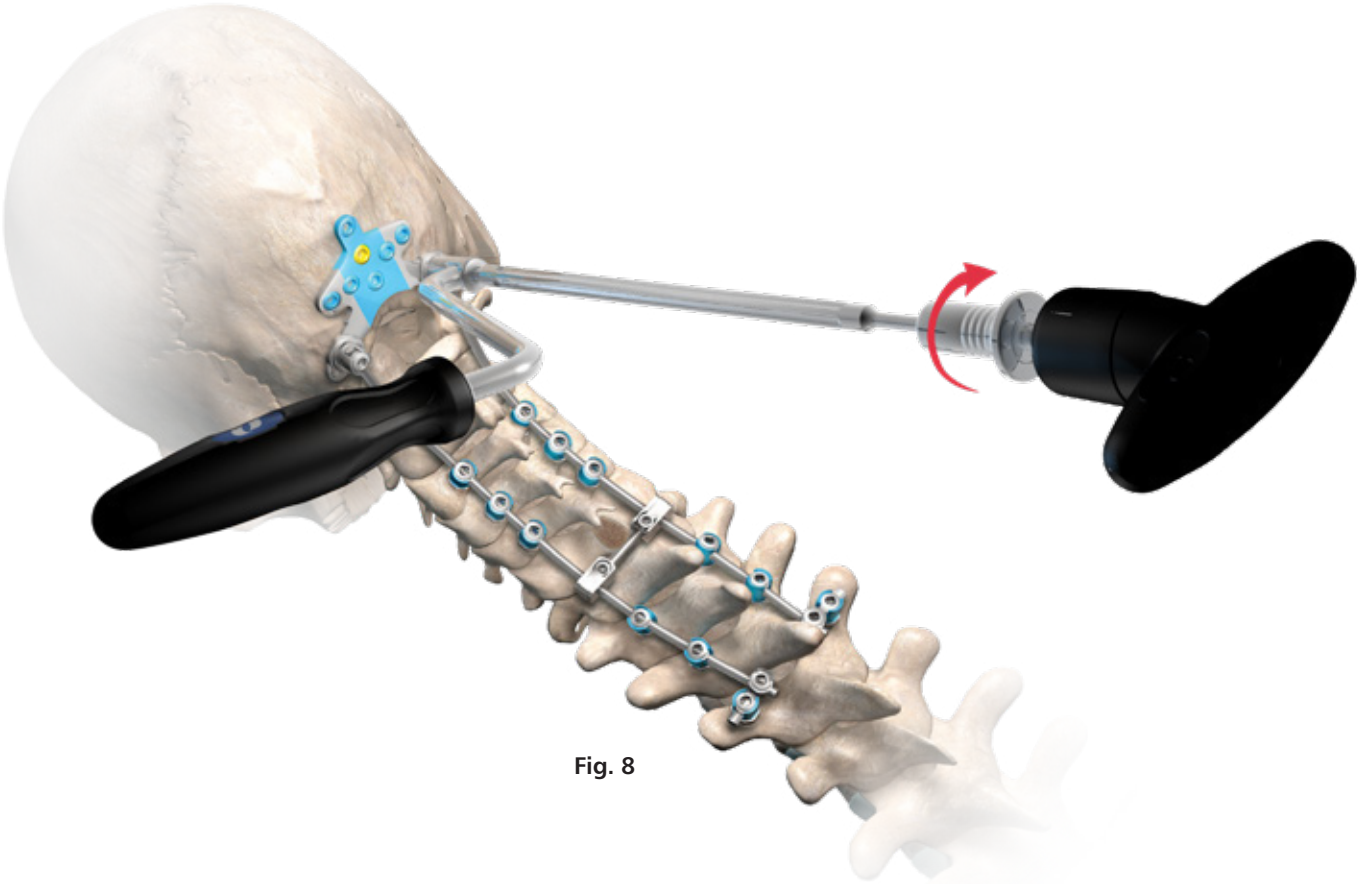


Fig. 8

7. OCCIPITAL SET SCREW PLACEMENT

Provisionally insert set screws into the occipital plate saddles using the Set Screw Inserter Single Sided (69-1063) or Set Screw Inserter Dual Sided (69-1060).

When introducing the set screw into the saddle a half turn in the counterclockwise direction before advancing in the clockwise orientation will help reduce cross threading.

8. OCCIPITAL FINAL TIGHTENING

Attach the Torque Limiting Driver (69-1065) to the AO quick-connect shaft of the Occipital Set Screw Driver (69-1062). Once attached, pull on the shaft to ensure the driver is fully engaged.

Position the Occipital Counter Torque Wrench (69-0109) over the occipital plate saddle and engage the rod. Place the distal tip of the Occipital Set Screw Driver (69-1062) through the cannulation of the Occipital Counter Torque Wrench (69-0109) and align properly to engage the set screw. Ensure that the Occipital Set Screw Driver (69-1062) is fully seated into the set screw for secure engagement during final tightening.

Turn the Torque Limiting Driver Handle (69-1065) clockwise while stabilizing the rod with the Occipital Counter Torque Wrench (69-0109) stationary until the Torque Limiting Driver (69-1065) clicks and releases (25 in-lbs).

Note: It is recommended to final tighten the occipital plate set screws at the occipital plate prior to tightening the set screws of the remaining construct.

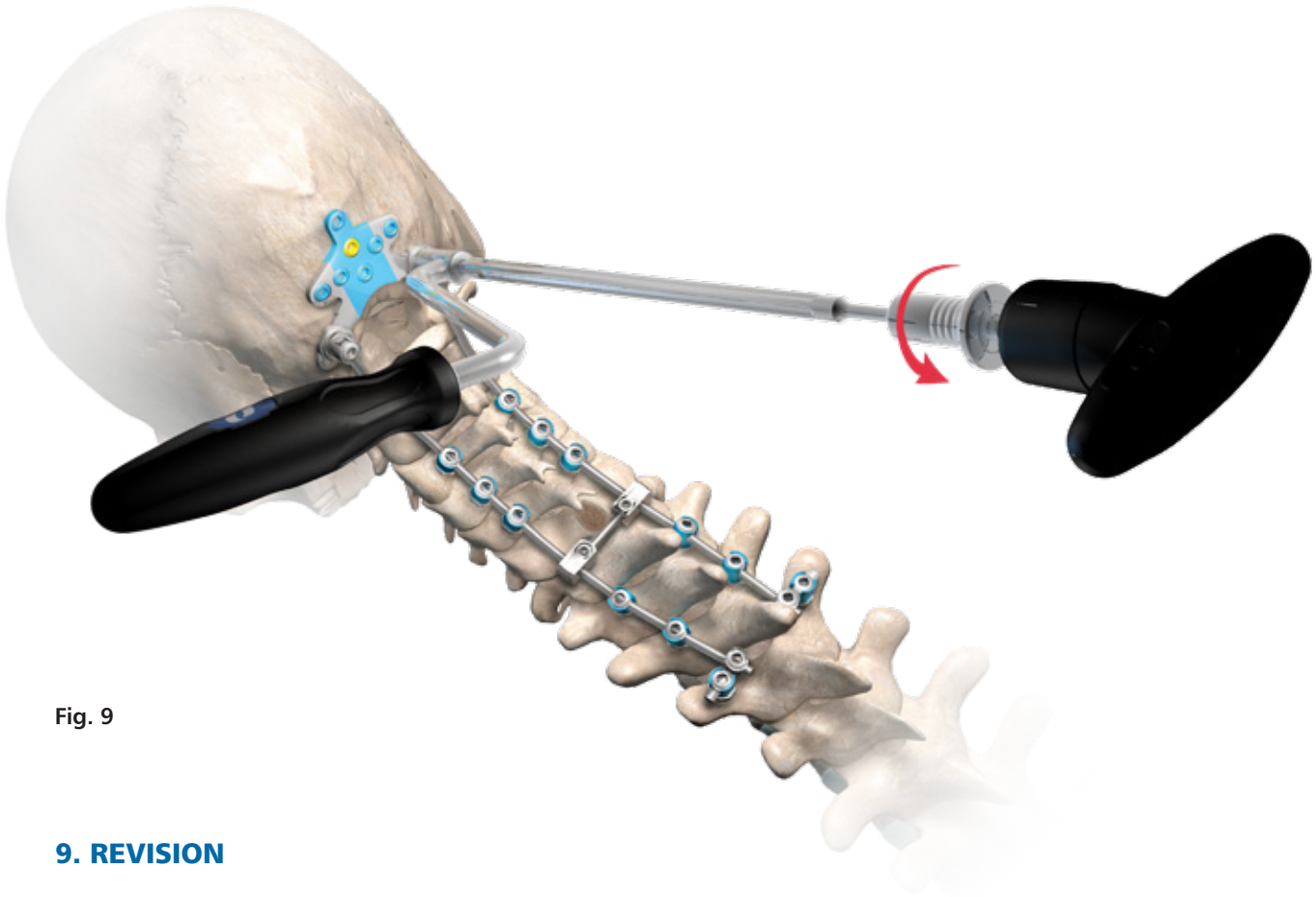


Fig. 9

9. REVISION

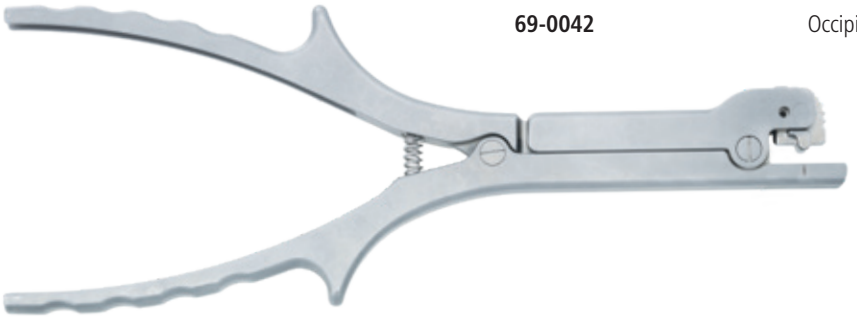
In order to remove the occipital plate, attach the Torque Limiting Driver (69-1065) to the AO quick-connect fitting on the Occipital Set Screw Driver (69-1062). Once attached, pull on the shaft to ensure the driver is fully engaged.

Fully seat the Occipital Counter Torque Wrench (69-0109) over the plate's saddle and engage the rod. Place the distal tip of the Set Screw Driver (69-1062) through the cannulation in the Occipital Counter Torque Wrench (69-0109).

Turn the Torque Limiting Driver (69-1065) counter clockwise while stabilizing the rod with the Occipital Torque Wrench (69-0109) stationary to loosen the set screw. Carefully remove all set screws.

OCCIPITAL CASE

Instruments

	Part #	Description	Qty
	**69-0005**	Plate Holder	1
	**69-0042**	Occipital Plate Bender	1
	**69-0043**	Anvil	1
	**69-0060**	Occipital Bone Screw Inserter	2
	**69-0067**	Handle Adapter	1
	**69-0068**	Straight Occipital Driver	2
	**69-0069**	Angled Occipital Driver	2

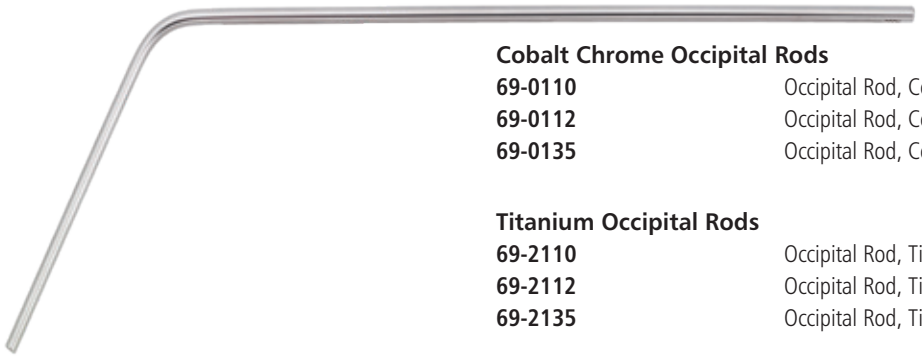
OCCIPITAL CASE

Instruments

	Part #	Description	Qty
	**69-0106**	Occipital Tap	2
	**69-1112**	Occipital Drill Guide	1
	**69-0109**	Occipital Counter Torque Wrench	1
	**69-1032**	Modular In-Line Handle	1
	**69-1062**	Occipital Set Screw Driver	1
	**69-0006**	Occipital Drill	2

OCCIPITAL CASE

Implants

	Part #	Description	Qty
		**Cobalt Chrome Occipital Rods**	
	69-0110	Occipital Rod, CoCr 110 Degree	2
	69-0112	Occipital Rod, CoCr 120 Degree	2
	69-0135	Occipital Rod, CoCr 135 Degree	2
		Titanium Occipital Rods	
	69-2110	Occipital Rod, Ti 110 Degree	2
	69-2112	Occipital Rod, Ti 120 Degree	2
	69-2135	Occipital Rod, Ti 135 Degree	2
		**Occipital Plates**	
	69-2140	Occipital Plate Assy, 20mm - 30mm	2
	69-2141	Occipital Plate Assy, 30mm - 40mm	2
	69-2142	Occipital Plate Assy, 40mm - 50mm	2
		**4.5mm Occipital Bone Screw**	
	69-2006	6mm Occipital Bone Screw, Primary	6
	69-2008	8mm Occipital Bone Screw, Primary	6
	69-2010	10mm Occipital Bone Screw, Primary	6
	69-2012	12mm Occipital Bone Screw, Primary	6
	69-2014	14mm Occipital Bone Screw, Primary	6
		**5.0mm Occipital Bone Screw**	
	69-2206	6mm Occipital Bone Screw, Rescue	2
	69-2208	8mm Occipital Bone Screw, Rescue	2
	69-2210	10mm Occipital Bone Screw, Rescue	2
	69-2212	12mm Occipital Bone Screw, Rescue	2
	69-2214	14mm Occipital Bone Screw, Rescue	2
	69-1093	Occipital Case, Implants and Instruments	
	69-8301	Occipital Bone & Set Screw Caddy	
	69-8321	Top Tray, Occipital Case	
	69-8322	Bottom Tray, Occipital Case	

OCCIPITAL CASE

Instruments

Part #	Description	Qty
Instrument Case Core System		
69-1093	**Occipital Case** (includes all trays, caddies, base & lid)	1
69-8321	**Top Tray, Occipital Case**	1
69-0110	Occipital Rod, CoCr 110°	4
69-0112	Occipital Rod, CoCr 120°	4
69-0135	Occipital Rod, CoCr 135°	4
69-2140	Occipital Plate Assy, 20mm - 30mm	2
69-2141	Occipital Plate Assy, 30mm - 40mm	2
69-2142	Occipital Plate Assy, 40mm - 50mm	2
69-2110	Occipital Rod, Ti 110°	4
69-2112	Occipital Rod, Ti 120°	4
69-2135	Occipital Rod, Ti 135°	4
69-8301	**Occipital Bone & Set Screw Caddy**	
69-2001	Set Screw	12
69-2006	6mm Occipital Bone Screw, Primary	6
69-2008	8mm Occipital Bone Screw, Primary	6
69-2010	10mm Occipital Bone Screw, Primary	6
69-2012	12mm Occipital Bone Screw, Primary	6
69-2014	14mm Occipital Bone Screw, Primary	6
69-2206	6mm Occipital Bone Screw, Rescue	2
69-2208	8mm Occipital Bone Screw, Rescue	2
69-2210	10mm Occipital Bone Screw, Rescue	2
69-2212	12mm Occipital Bone Screw, Rescue	2
69-2214	14mm Occipital Bone Screw, Rescue	2
69-8322	**Bottom Tray, Occipital Case**	
69-0005	Plate Holder	1
69-0006	Occipital Drill	2
69-0042	Occipital Plate Bender	1
69-0043	Anvil	1
69-0060	Occipital Bone Screw Inserter	2
69-0067	Handle Adapter	1
69-0068	Occipital Driver, Straight	2
69-0069	Occipital Driver, Angled	2
69-0106	Occipital Tap	2
69-0109	Occipital Counter Torque Wrench	1
69-1112	Occipital Drill Guide	1
69-1032	Modular In-Line Handle	1
69-1062	Occipital Set Screw Driver	1

Order by Request

69-1031	Modular Ball Handle
69-1033	Occipital Modular In-Line Handle

Description: The Centurion POCT System is a temporary, multiple component system comprised of a variety of non-sterile, single use components made of Titanium alloy or Cobalt Chrome alloy that allow the surgeon to build a spinal implant construct. The Centurion POCT System consists of an assortment of rods, set screws, axial connectors, lateral offset adapters, multi-axial screws, hooks, plates, bone screws, and cables (titanium).

Levels of Use: When used in the occipito-cervico-thoracic spine, the Centurion POCT System may be used from the Occiput to T3.

Indications for Use: The Centurion POCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 – T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Centurion POCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

The Centurion POCT System can also be linked to the Orthofix Spinal Fixation System using the Axial or Parallel Rod Connector.

Contraindications include, but are not limited to:

1. Morbid obesity
2. Mental Illness
3. Alcoholism or drug abuse
4. Pregnancy
5. Metal sensitivity/allergies
6. Severe osteopenia
7. Patients unwilling or unable to follow post-operative care instructions
8. Any circumstances not listed under the heading indications.

Potential Adverse Events:

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

1. Device component fracture
2. Loss of fixation
3. Non-union
4. Fracture of the vertebra
5. Neurological injury
6. Vascular or visceral injury
7. Early or late loosening of any or all of the components
8. Disassembly and/or bending of any or all components
9. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease
10. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain
11. Post-operative change in spinal curvature, loss of correction, height, and/or reduction
12. Infection
13. Pain, discomfort, or abnormal sensations due to the presence of the device
14. Hemorrhage
15. Cessation of any potential growth of the operated portion of the spine
16. Death

Note: Potential risks identified with the use of the device system may require additional surgery.

Warnings and Precautions:

1. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
2. Single use only.
3. Non-sterile; the screws, set screws, hooks, rods, offset adapters, cross connectors, plates, rod connectors, and instruments are sold non-sterile, and therefore must be sterilized before use.
4. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
5. Excessive torque applied to the screws may strip the threads in the bone.
6. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
7. The implantation of POCT systems should be performed only by experienced spinal surgeons with specific training in the use of this POCT system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
8. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
9. The Centurion POCT System has not been evaluated for safety and compatibility in the MR environment, nor has the Centurion POCT System been tested for heating or migration in the MR environment.
10. Mixing of dissimilar metals can accelerate the corrosion process. Do not use the components of this system with implants from other manufacturers unless specifically stated.
11. 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.
12. The implantation of spinal fixation systems should be performed only by experienced spinal surgeons with specific training in the use of these spinal systems because this is a technically demanding procedure presenting a risk of ser ious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant diameter and length.
13. PRE-OP PLANNING – Use of cross sectional imaging (i.e., CT and/or MRI) for posterior cervical screw placement is recommended due to the unique risks in the cervical spine. The use of planar radiographs alone may not provide the necessary imaging to mitigate the risk of improper screw placement. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.

Notes

Distributed by:

Manufactured by:
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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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