

# INVICTUS<sup>®</sup> OCT

SPINAL FIXATION SYSTEM

atec<sup>™</sup>  
INFORMED BY EOS



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SPINAL FIXATION SYSTEM

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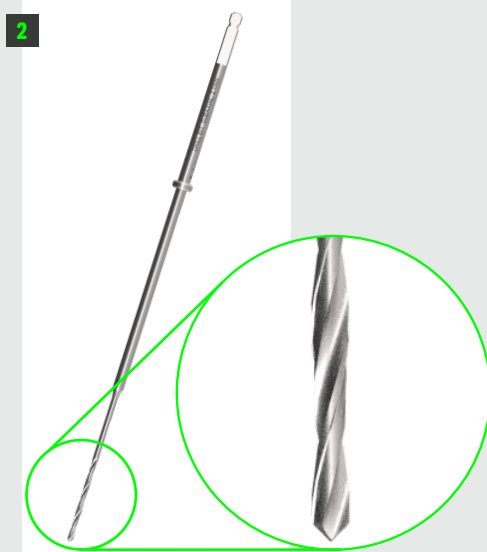
**ENTRY POINT**

- 1** Determine the appropriate entry point and create a pilot hole using an Awl or high-speed burr to penetrate the cortex of the bone.

**FIXED DRILL GUIDE AND ADJUSTABLE DRILL GUIDE**

- 2** A 2.1 mm Drill Bit may be used with a Fixed or Adjustable Drill Guide to drill to the desired depth. When used with the Fixed Drill Guide, a depth of 14 mm into bone may be achieved.
- 3** The Adjustable Drill Guide allows for a range of 10-30 mm of depth in 2 mm increments. Markings are etched on the distal barrel of the guide and on the proximal Drill Guide shaft to provide visual confirmation of Drill Bit depth. To select the desired Drill Bit depth, pull back on the proximal gold knob and turn the pin toward center. Then turn the Drill Guide shaft to the left or right so that the locking pin slides over and down, into the L-shaped notch, to lock into the desired depth.
- 4** Dock the distal tip of the Drill Guide to the prepared pilot hole and drill a hole. A Power Drill Bit Adapter is provided if power is preferred.

PART NUMBER	DESCRIPTION
19804-14	Fixed Drill Guide, 14 mm
19803	Adjustable Drill Guide
19805	Drill Bit, Sub-Axial, 2.1 mm



**TAPPING**

**5** Taps are true to size and available in sizes ranging from 3.0 mm to 5.5 mm to help create threads within the bone for screw insertion.

PART NUMBER	DESCRIPTION
19807-30	Tap, Cervical, 3.0 mm
19807-35	Tap, Cervical, 3.5 mm
19807-40	Tap, Cervical, 4.0 mm
19808-45	Tap, Thoracic, 4.5 mm
19808-50	Tap, Thoracic, 5.0 mm
19808-55	Tap, Thoracic, 5.5 mm

**6** Slide the proximal end of the selected Tap into the AO Quick Connect Handle.

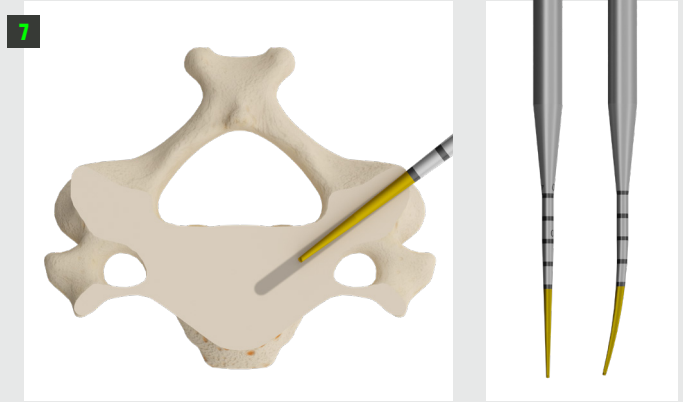
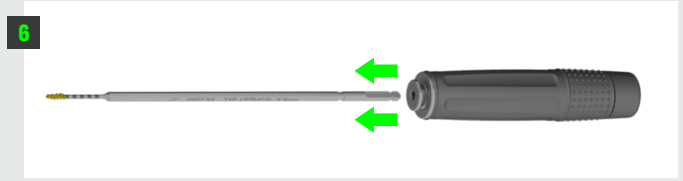
**TIP:**

**CERVICAL TAPS (Ø3.0, Ø3.5, AND Ø4.0 MM)**

- THE FIRST 10 MM OF THE TAP THREADS ARE COLORED GOLD TO HELP DETERMINE DEPTH.
- DEPTH MARKINGS 10-20 MM IN 2 MM INCREMENTS AND 20-30 MM IN 5 MM INCREMENTS.

**THORACIC TAPS (4.5, 5.0, 5.5 MM)**

- THE FIRST 20 MM OF THE TAP THREAD ARE COLORED GOLD TO HELP DETERMINE DEPTH.
- DEPTH MARKINGS 20-40 MM IN 5 MM INCREMENTS.



**GEARSHIFT PROBE (OPTIONAL)**

**7** A Straight or Curved Gearshift Probe may also be used to penetrate the cortex to create a pilot hole. The Gearshift Probes are sized (2.5 mm) to create pilot holes for 4.0 mm and larger diameter screws.

**BALL TIP PROBE**

**8** Use the Ball Tip Probe to confirm pilot hole depth and that the bone has not been breached.

**TIP:** THE FIRST 10 MM OF THE BALL TIP PROBE IS GOLD. DEPTH MARKINGS ON THE TIP ARE ETCHED WITH SOLID DARK BANDS FROM 10-14 MM IN 2 MM INCREMENTS.

PART NUMBER	DESCRIPTION
19801-01	Gearshift Probe, Straight, Ball Handle
19802-01	Gearshift Probe, Curved, Ball Handle
19868	Ball Tip Probe



### POLYAXIAL SCREW

- 1 Polyaxial Screws allow for up to an 80° cone of angulation or 40° in every direction for 3.5 and 4.0 mm screws and up to a 70° cone of angulation or 35° in every direction for 4.5, 5.0, and 5.5 mm screws.
- 2 Polyaxial Screws are available in 3.5, 4.0, 4.5, 5.0 and 5.5 mm diameters.
- 3 Polyaxial Screws accept both 3.5 and 4.0 mm rod diameters.

### FAVORED ANGLE SCREW

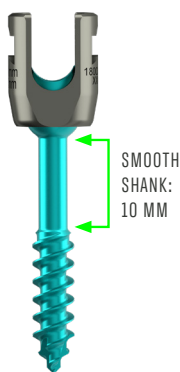
- 4 Two types of Favored Angle (FA) Screws are available if additional angulation is required within a specific plane:
  - 3.5 and 4.0 mm Medial/Lateral (ML) FA Screws (blue) allow for 55°/25° angulation.
  - 3.5 and 4.0 mm Cranial/Caudal (C/C) FA Screws (green) allow for 55°/25° angulation.
  - 4.5, 5.0, and 5.5 mm Medial/Lateral (ML) FA Screws (blue) allow for 50°/22.5° angulation.
  - 4.5, 5.0, and 5.5 mm Cranial/Caudal (C/C) FA Screws (green) allow for 50°/22.5° angulation.

**TIP:** FAVORED ANGLED SCREWS ARE BI-COLORED WITH THE COLORED PORTION OF THE SCREW INDICATING THE DIRECTION OF THE BIASED ANGLE.

### PARTIALLY THREADED SCREW

- 5 Partially Threaded Polyaxial Screws allow for an 80° cone of angulation or 40° in every direction.
- 6 Partially Threaded Screws are available in 3.5 and 4.0 mm diameters.

**NOTE:** THE PROXIMAL 10 MM OF THE SCREW SHANK IS SMOOTH TO AVOID POTENTIAL NERVE ROOT IRRITATION WHERE SCREW TRAJECTORIES ARE LIKELY TO PASS OUTSIDE OF BONE.

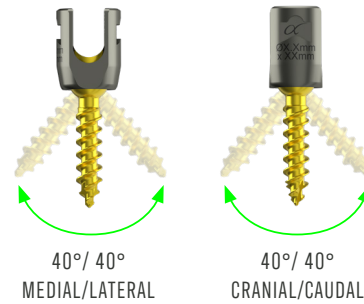


### POLYAXIAL REDUCTION SCREW

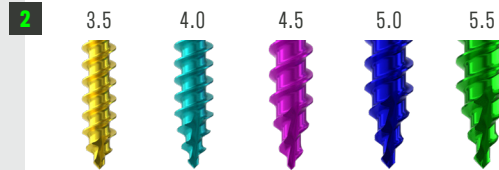
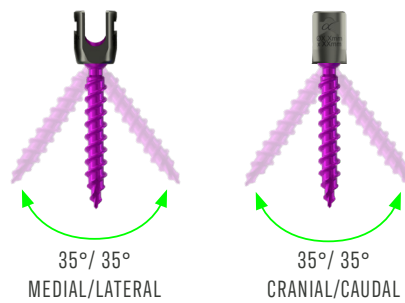
- 7 Polyaxial Reduction Screws are available for screw diameters in 4.0, 4.5, 5.0, and 5.5 mm. They allow for an additional 8 mm of reduction.

**NOTE:** UTILIZE THE REDUCTION FINAL DRIVER TO FULLY TIGHTEN THE SET SCREWS PRIOR TO BREAKING THE REDUCTION TABS

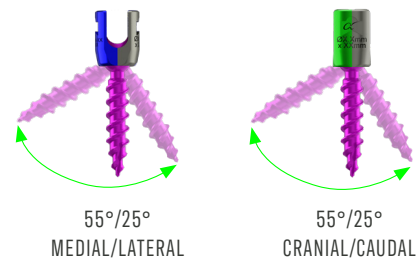
#### 1 3.5 AND 4.0 MM SCREW ANGULATION



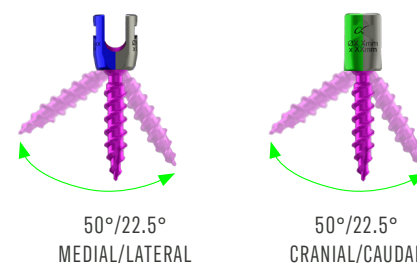
#### 4.5, 5.0, AND 5.5 MM SCREW ANGULATION



#### 4 3.5 AND 4.0 MM SCREW ANGULATION



#### 4.5, 5.0, AND 5.5 MM SCREW ANGULATION



**LOCKING POLYAXIAL SCREWDRIVER**

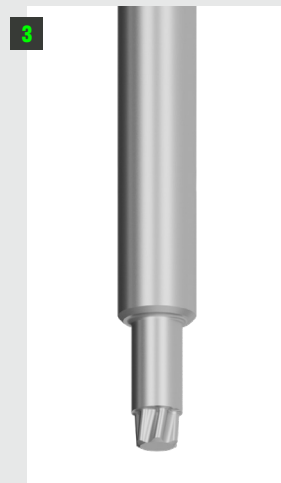
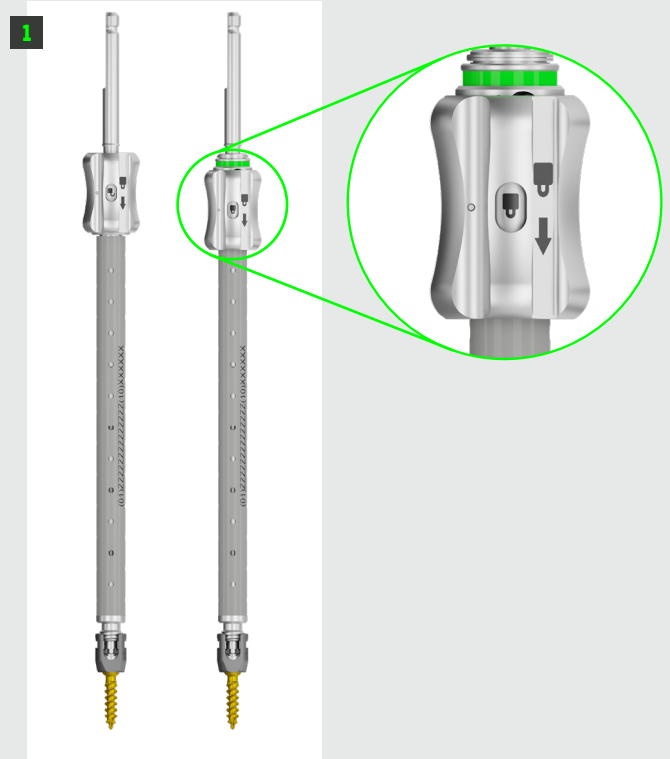
**1** Thread the distal tip of the Locking Screwdriver into the head of the tulip. Once tight with the screw, slide the thumbwheel at the proximal end of the Screwdriver down toward the screw to lock the Screwdriver into place for secure engagement during screw insertion. A green band will become visible when the Screwdriver has been securely locked.

**2** Drive the screw to the desired depth being sure to maintain the conical movement of the polyaxial screw head. To disengage the Locking Screwdriver, slide the thumbwheel up to the unlocked position, and unthread the Screwdriver.

**TWISTED HEXALOBE SCREWDRIVER**

**3** The Twisted Hexalobe Driver is a self-retaining T15 driver that has a twisted distal tip for passive screw retention. Place the distal tip of the Twisted Hexalobe Driver into the tulip and apply downward pressure (“stab and grab” technique) to engage the screw.

PART NUMBER	DESCRIPTION
19810	Polyaxial Screwdriver, Locking
18810	Screwdriver, Twisted Hexalobe



### SCREW ADJUSTER

- 1 The Screw Adjuster may be used to adjust polyaxial screw height anteriorly or posteriorly. Fully seat the Screw Adjuster into the shank of the polyaxial screw and turn until desired screw height is achieved.

### POLYAXIAL HEAD ADJUSTER

- 2 Slide the Polyaxial Head Adjuster into the head of the tulip to properly align the screw heads. Verify that the Polyaxial Head Adjuster fits securely inside the head of the tulip.

PART NUMBER	DESCRIPTION
19813	Screw Adjuster, T-Handle
19812	Polyaxial Head Adjuster



**1** Rods are available in 3.5 and 4.0 mm diameters and in titanium (Ti) and cobalt chromium (CoCr).

- 2** Rods are color-coded by material and diameter.
- 3.5 mm Ti rods are blue with dashed lines; 3.5 mm CoCr rods are silver with dashed lines.
  - 4.0 mm Ti rods are green with dotted lines; 4.0 mm CoCr rods are silver with dotted lines.
  - Markings on rod are in 5 mm increments to help with construct measurement and alignment.

**3 STRAIGHT RODS**

- 90, 120, 240 mm lengths
- 3.5 and 4.0 mm diameters

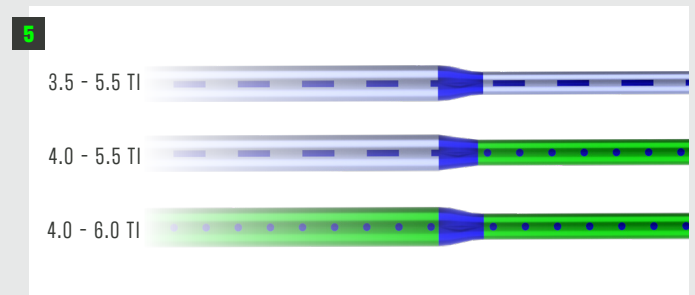
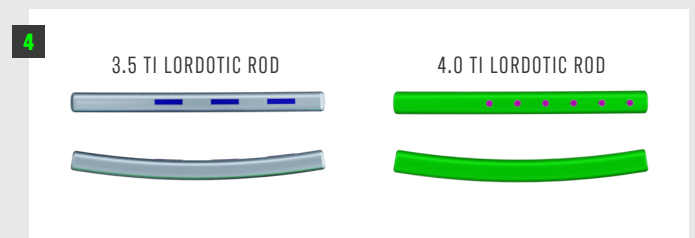
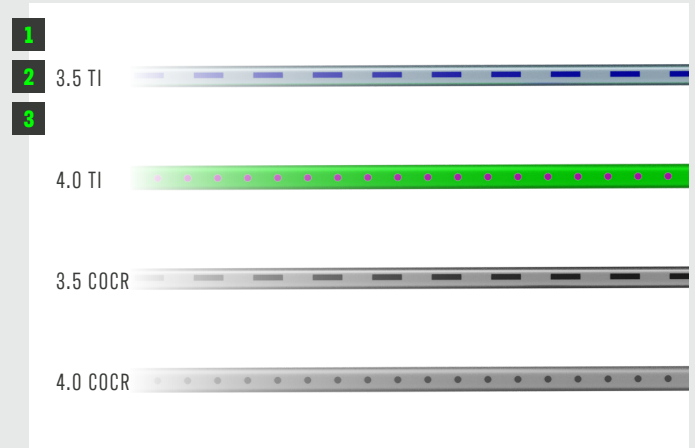
**4 LORDOTIC RODS PRE-CUT**

- 20 - 80 mm lengths in 5 mm increments
- 80 - 100 mm lengths in 10 mm increments
- 3.5 and 4.0 mm diameters

**5 TRANSITION RODS**

Transition Rods are available when crossing the junction.

- 3.5 - 5.5 mm diameter
- 4.0 - 5.5 mm diameter
- 4.0 - 6.0 mm diameter



**ROD TEMPLATE**

**6** A Rod Template is available in a 240 mm length. The Rod Template may be used to help determine the appropriate length and contour of rod.

**ROD CUTTER**

**7** The Rod Cutter may be used to cut 3.5 and 4.0 mm rods to the desired length. Place the selected rod through the center cut hole. Use the cut line on the Rod Cutter to confirm the location of the cut. If preferred, the scissor end of the cutter may be used to cut the rod.

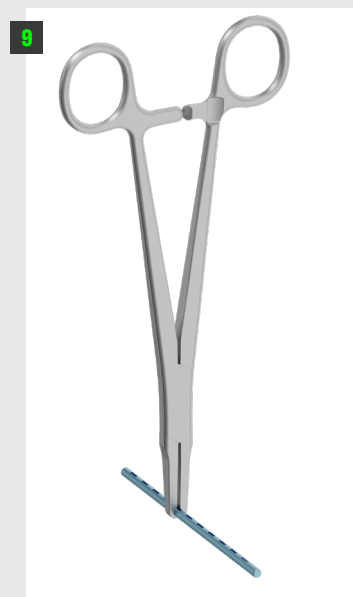
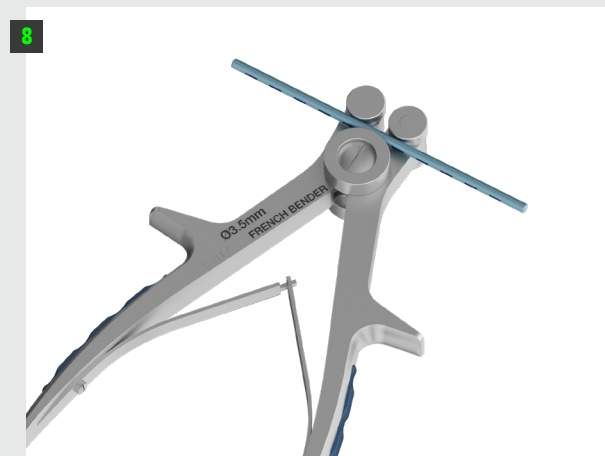
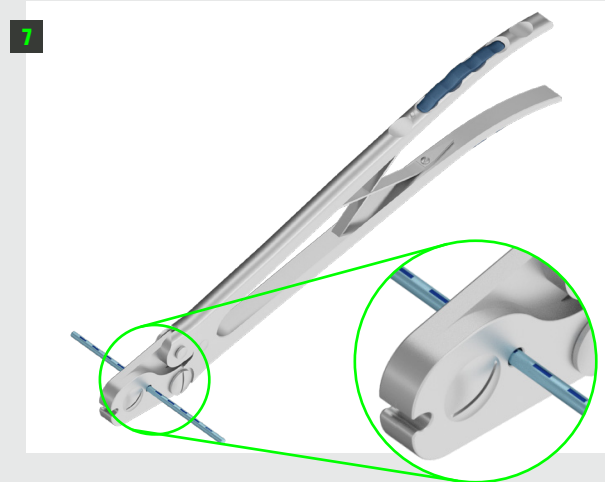
**ROD BENDER**

**8** The French Bender may be used to contour 3.5 and 4.0 mm diameter rods. The French Bender has two working sides labeled by diameter. Place the rod segment over the fulcrum and apply pressure until the desired bend is achieved.

**ROD HOLDER**

**9** Use the Rod Holder to grip and place the rod within the tulip of the Polyaxial Screw. Place the selected rod within the detents at the distal tip of the Rod Holder and close it to secure the Rod. Confirm that the Rod Holder is locked into place. Squeeze the proximal end of the handle to disengage the locking feature.

PART NUMBER	DESCRIPTION
18815-240	Rod Template, 240 mm
19819	Rod Pusher
18817	French Bender
19818	Rod Holder

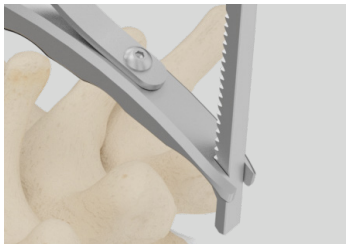




**PISTOL REDUCER**

**1** The Pistol Reducer may be used to fully reduce the rod into the tulip of the Polyaxial Screw prior to final tightening. To engage the Pistol Reducer to the tulip, verify that the ratcheting mechanism on the handle is fully released. Place the distal tip of the Pistol Reducer over the head of the tulip until it positively engages the chevron on the lateral walls of the tulip. Tactile feedback confirms that the Reducer is properly connected and secured to the tulip. Slowly squeeze the hand grip for reduction. To release, disengage the ratcheting mechanism and allow the handle to return to the starting position, then simultaneously press the gold tabs on the Pistol Reducer.

**TIP:** CONFIRM THAT THE RATCHETING MECHANISM IS COMPLETELY RELEASED AND THAT THE HANDLE RETURNS TO ITS INITIAL STATE TO ENGAGE AND RELEASE THE REDUCER FROM THE TULIP HEAD.

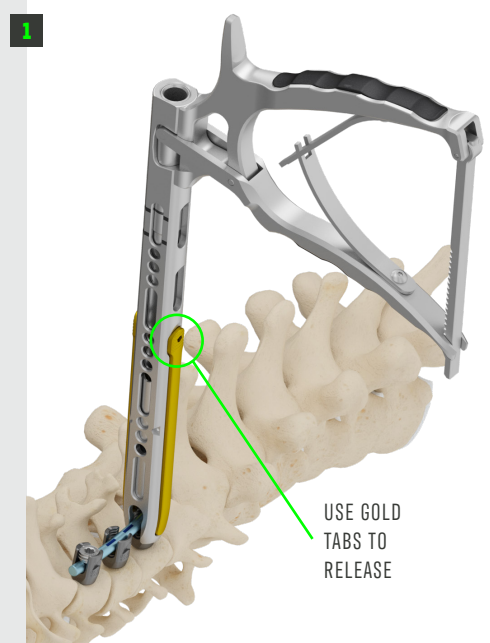


**AXIAL REDUCER**

**2** The Axial Reducer may be used to reduce the rod into the tulip of the polyaxial screw prior to final tightening. Place the distal tip of the Axial Reducer over the head of the tulip until it positively engages the chevron on the lateral walls of the tulip. Tactile feedback confirms that the reducer is properly connected and secured to the tulip. To reduce the rod, rotate the gold knurled knob clockwise until the desired amount of reduction is achieved. To release, simultaneously press the gold tabs on the Axial Reducer.

**TIP:** THE PISTOL REDUCER AND AXIAL REDUCER ALLOW FOR UP TO 10 MM OF ROD REDUCTION.

PART NUMBER	DESCRIPTION
19822	Pistol Reducer
19821	Axial Reducer



### ROD ROCKER

- 3** The Rod Rocker may be used to reduce a rod that is sitting proud when seating the set screw into the tulip of the polyaxial screw. Slide the Rod Rocker (inferior to superior) into the chevron cut on the lateral side of tulip. Tactile feedback confirms proper engagement with the tulip. Rotate the Rod Rocker cranially/caudally to reduce the rod further into the tulip head. To disengage, slide the Rod Rocker (superior to inferior) from the tulip.

**TIP:** THE ROD ROCKER ALLOWS FOR UP TO 5 MM OF ROD REDUCTION.

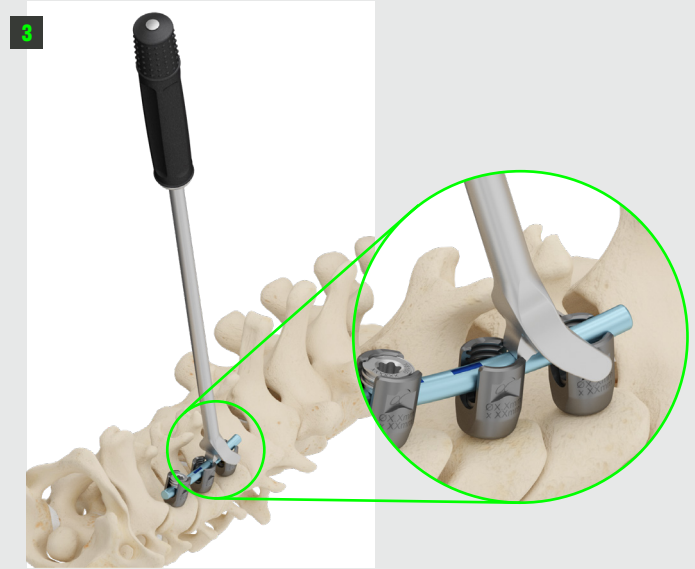
### ROD PUSHER

- 4** The Rod Pusher may be used to reduce a rod that is sitting slightly proud when seating a set screw into the tulip of the polyaxial screw.

### SET SCREW INSERTION

- 5** The Set Screw Inserter may be used to place the set screw through the Screw Countertorque, Axial Reducer, or Pistol Reducer. The Set Screw Inserter, Short may be used to seat the set screw through the Axial Reducer or Pistol Reducer. The Set Screw Inserter's spring-loaded distal tip allows for engagement and disengagement of the set screw. Load the set screw directly from the caddy. Place the distal tip of Set Screw Inserter into the hexalobe of the set screw and apply downward pressure to engage the set screw. Provisionally thread the set screw into the tulip.

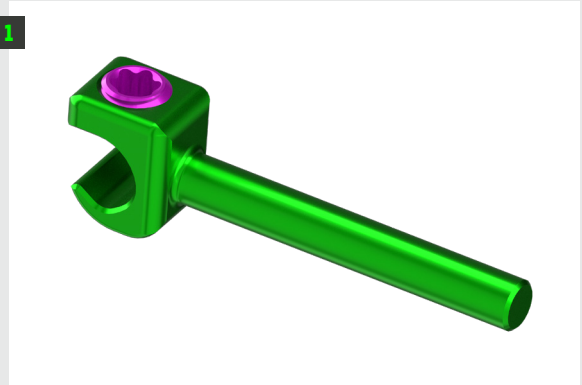
PART NUMBER	DESCRIPTION
19820	Rod Rocker
19819	Rod Pusher
18100	Set Screw
19814	Set Screw Inserter
19814-S	Set Screw Inserter, Short



**1** Lateral Offset Connectors are available in Open and Side loading configurations for intraoperative flexibility. Place the opening of the selected Offset Connector onto the seated rod. Provisionally tighten the Offset Connector to the rod and place the bar of the Offset Connector into the Polyaxial Screw.

**TIP:** OPEN AND SIDE LOADING CONNECTORS ARE AVAILABLE IN 10 MM AND 25 MM LENGTHS.

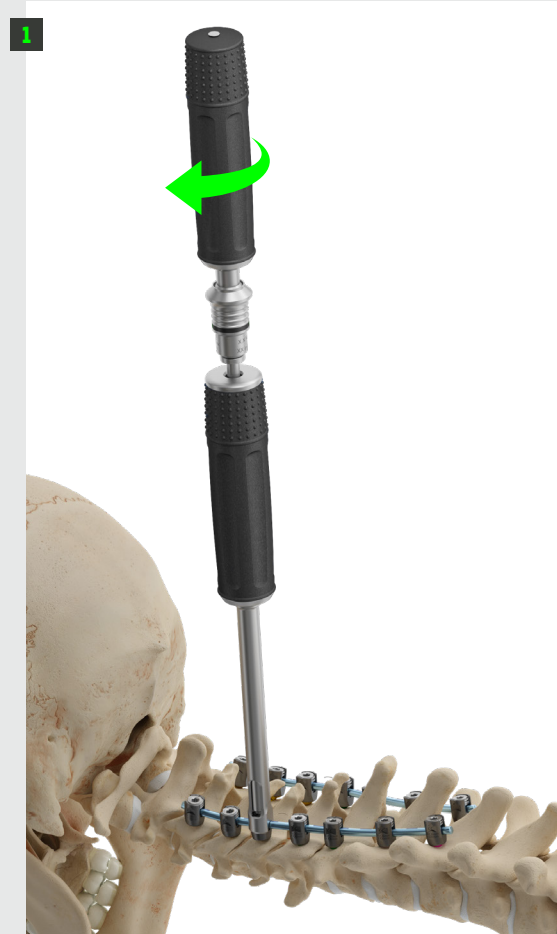
**1**



- 1 Once the screws are in place and rods have been fully seated, perform final tightening of the set screws. Use the Final Tightening Driver with the Torque Limiting Handle for final tightening of the Polyaxial Screws, Rod Connectors, and Lateral Offset Connectors at 25 in-lb.
- 2 Pull back on the collar of the Torque Limiting Handle and slide the proximal end of the AO Quick Connect into the handle until secured.
- 3 Place the Screw Countertorque over the tulip head until fully seated. Turn the Final Tightening Handle clockwise until there is an audible and tactile click and 25 in-lb torque break-off is achieved.

PART NUMBER	DESCRIPTION
19832	Final Tightening Driver
86002-0500-025-008	AO Torque Limiting Axial Handle, 25 in-lb, Black
19830	Screw Countertorque

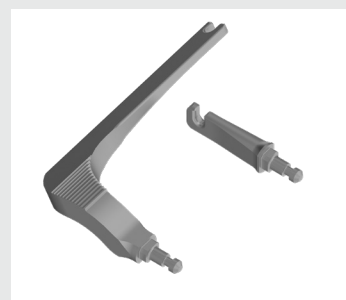
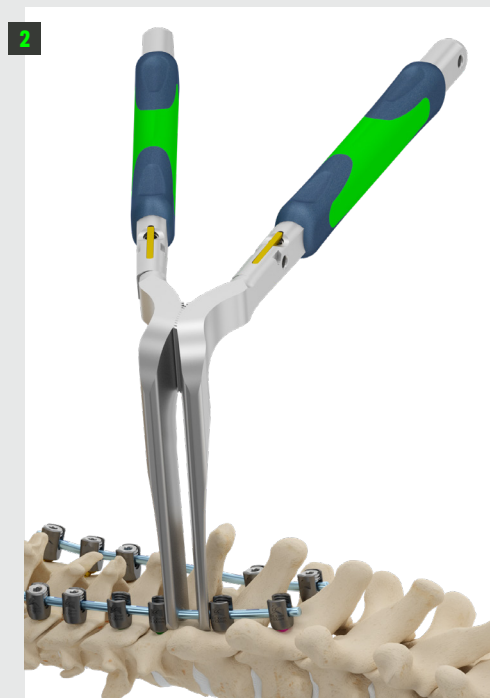
**CAUTION:** FAILURE TO TIGHTEN THE SET SCREWS USING THE RECOMMENDED INSTRUMENT(S) COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.



**1** If desired, in-situ rod contouring may be performed to improve alignment in both the sagittal and coronal planes. Straight Bender Tips are used to adjust kyphosis and lordosis in the sagittal plane. Angled Bender Tips may be used if greater manipulation is desired. Coronal Bender Tips may be used to adjust alignment of the rod in the coronal plane.

**2** Select the appropriate tip based on the amount of desired manipulation. Slide the proximal end of the Bender Tip into the Bender Handle until securely locked into the handle.

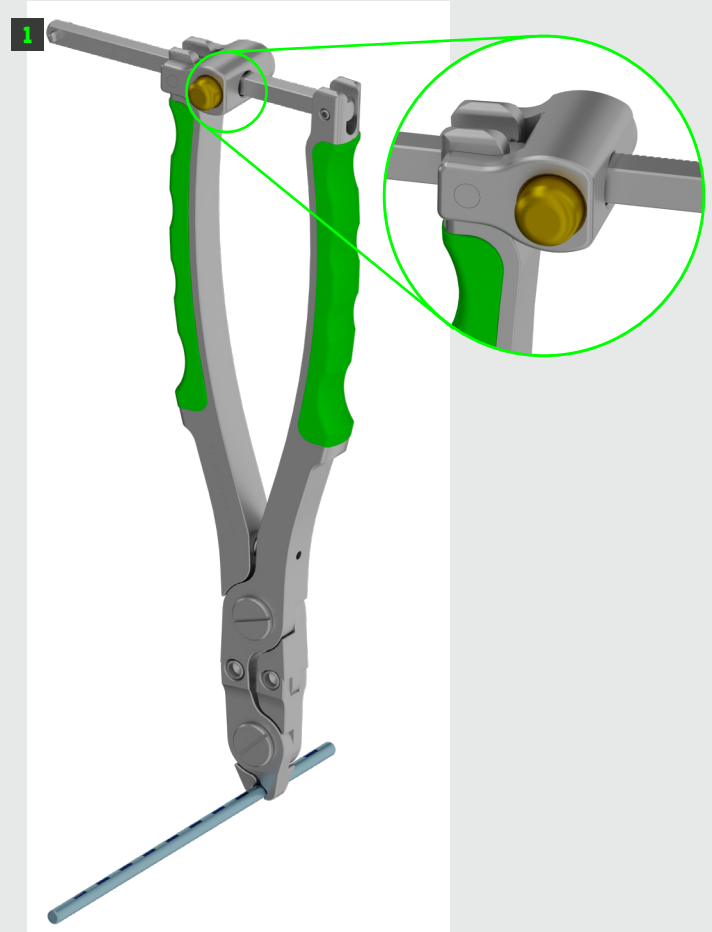
PART NUMBER	DESCRIPTION
18824	Bender Handle
19825-35	In-Situ Sagittal Bender Tip, Straight, 3.5 mm
19825-40	In-Situ Sagittal Bender Tip, Straight, 4.0 mm
19837-35	In-Situ Sagittal Bender Tip, Left, 3.5 mm
19838-35	In-Situ Sagittal Bender Tip, Right, 3.5 mm
19837-40	In-Situ Sagittal Bender Tip, Left, 4.0 mm
19838-40	In-Situ Sagittal Bender Tip, Right, 4.0 mm
19826-35	In-Situ Coronal Bender Tip, Left, 3.5 mm
19827-35	In-Situ Coronal Bender Tip, Right, 3.5 mm
19826-40	In-Situ Coronal Bender Tip, Left, 4.0 mm
19827-40	In-Situ Coronal Bender Tip, Right, 4.0 mm





**1** A Rod Gripper may be used if additional rod manipulation is desired. To engage, place the rod at the distal tip of the gripper, and squeeze the handle until the rod is secure. To release, press and hold the gold button until the rod is fully released.

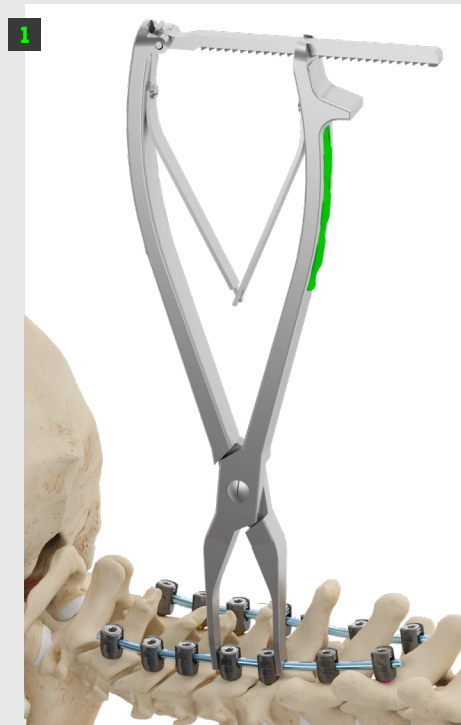
PART NUMBER	DESCRIPTION
19823	Rod Gripper



**1** If segmental compression or distraction is desired, loosen the set screw on one side of the motion segment while final tightening the set screw on the other side. This will allow for translation along the rod. To achieve compression, place the Compressor on the inferior/superior outermost walls of the Polyaxial Screw heads and slowly squeeze the proximal handle of the instrument until the desired amount of compression is achieved.

**2** To achieve distraction, place the Distractor on the inferior/superior innermost walls of the Polyaxial Screw heads and slowly squeeze the proximal handle of the instrument until the desired amount of distraction is achieved.

PART NUMBER	DESCRIPTION
18830	Compressor
18831	Distractor



**1** Rod-to-Rod Connectors are available in multiple forms to provide versatility and intraoperative flexibility. The rod-to-rod connectors allow for parallel connection of rods that are of the same or differing diameters.

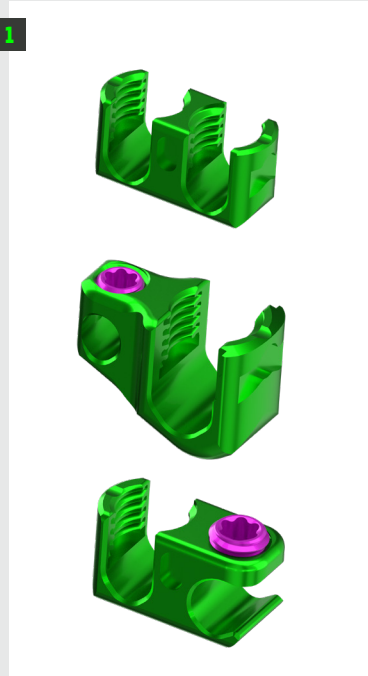
- Open-Open
- Open-Closed
- Open-Side

**2** The Rod Connector Inserter may be used to place the selected Rod Connector onto an existing rod construct. Place the Rod Connector onto the rod and tighten the set screw on one side, then connect the remaining rod. Final tighten both connections using the Final Tightening Driver and Torque Limiting Handle. If desired, final tightening may be performed through the Cross Connector Countertorque. Turn the handle clockwise until there is an audible click and 25 in-lb torque break-off is achieved.

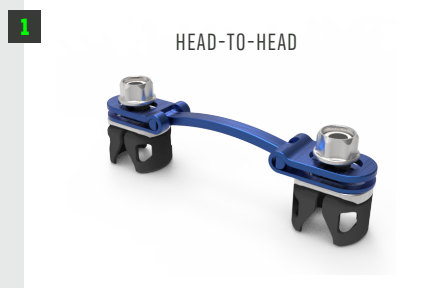
PART NUMBER	DESCRIPTION
18400-35-35	Open-Open Connector, 3.5 - 3.5 mm
18400-35-55	Open-Open Connector, 3.5 - 5.5 mm
19401-35-35	Open-Closed Connector, 3.5 - 3.5 mm
19401-35-55	Open-Closed Connector, 3.5 - 5.5 mm
19402-35-35	Open-Side Loading Connector, 3.5 - 3.5 mm
18402-35-55	Open-Side Loading Connector, 3.5 - 5.5 mm
19840	Rod Connector Inserter
18416	Axial Revision Connector, 3.5 - 5.5 mm

**CAUTION:** FAILURE TO TIGHTEN THE SET SCREWS USING THE RECOMMENDED INSTRUMENT(S) COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.

**1**



- 1 Following final tightening, Rod-to-Rod or Head-to-Head Cross Connectors may be used for increased torsional construct support.
- 2 Rod-to-Rod Cross Connectors are available specific to the diameter of rod. The Rod-to-Rod Cross Connectors are color-coded to match the rod diameter. Cross Connectors allow for secure “press and snap” fit onto the rod or tulip, providing tactile feedback when securely connected.
- 3 If desired, a Cross Connector Caliper is available by request. The Cross-Connector Caliper may be used to determine the appropriate size Cross Connector. Place the distal tips of the Caliper securely on the outside of the rods and read the measurement on the proximal end of the Caliper.

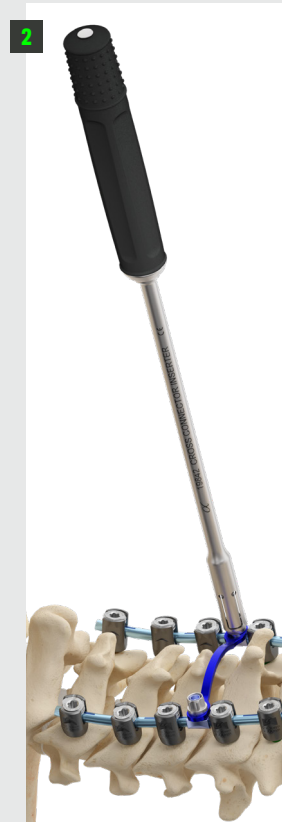


- 1 The Cross-Connector Inserter may be used to deliver the Cross Connector to the intended site. Place the Inserter over the locking nut of the Cross Connector and press down to engage.
- 2 To place the Rod-to-Rod Cross Connector, "press and snap" onto the rod with the Inserter while holding the opposite end of the connector. Remove the Cross Connector Inserter and repeat the connection of the Cross Connector on the contralateral side.
- 3 To place the Head-to-Head Cross Connector, align the tabs of the Cross Connector over the head of the tulip and "press and snap" onto the tulip to positively engage the chevron on the lateral walls of the tulip while holding the opposite end of the connector. Remove the Cross Connector Inserter and repeat the connection of the Cross Connector on the contralateral side. Place the Head-to-Head Cross Connector after final tightening of the Polyaxial Screw Set Screw.

**TIP:** IF DESIRED, HEAD-TO-HEAD AND ROD-TO-ROD CROSS CONNECTORS MAY BE CONTOURED FOR DESIRED FIT USING THE BENDER HANDLE AND CROSS CONNECTOR BENDER TIPS.

**TIP:** FOR INSERTION AND REMOVAL, CONFIRM THAT THE LOCKING NUT IS FULLY UNTHREADED. THE CROSS CONNECTOR INSERTER CANNOT BE ATTACHED TO THE CROSS CONNECTOR IF THE LOCKING NUT IS NOT FULLY UNTHREADED.

PART NUMBER	DESCRIPTION
19866	Cross Connector Inserter
19833	Cross Connector Bender Tip
18824	Bender Handle





**1** Perform final tightening using the Variable Cross Connector Driver and Torque Limiting Handle through the Cross Connector Countertorque. Place the distal tip of Countertorque securely over the locking nut and fully seat onto the Cross Connector. Secure final tightening cannot be achieved without use of the Cross Connector Countertorque.

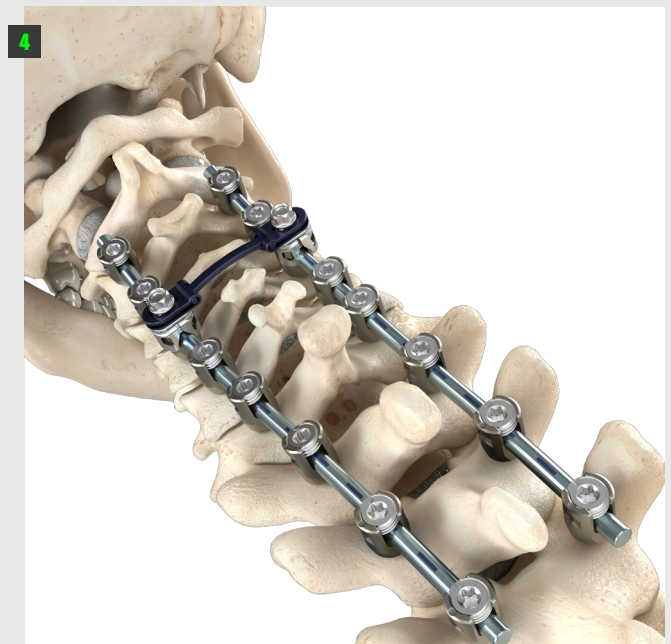
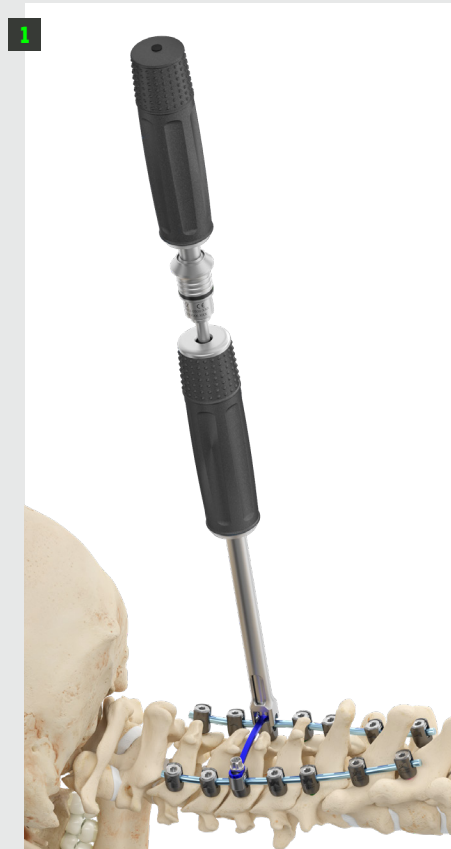
**2** Attach the Variable Cross Connector Driver shaft to the Torque Limiting Handle (25 in-lb) and engage the locking nut through the Cross Connector Countertorque. Turn the handle clockwise until there is an audible and tactile click and 25 in-lb torque break-off is achieved.

**TIP:** SECURE FINAL TIGHTENING CANNOT BE ACHIEVED WITHOUT USE OF THE CROSS CONNECTOR COUNTERTORQUE.

**3** For removal, use the Variable Cross Connector Driver to unthread the locking nut. Once fully unthreaded, place the Cross Connector Inserter over the locking nut, and rock cranial/caudal to remove the Cross Connector.

**4 FINAL CONSTRUCT**

PART NUMBER	DESCRIPTION
19836	Variable Cross Connector Driver
86002-0500-025-008	AO Torque Limiting Axial Handle, 25 in-lb, Black
19867	Cross Connector Countertorque



- 1** Remove Cross Connectors if necessary. Variable Cross Connectors are removed by loosening the locking nuts with the Cross Connector Driver and removing the Cross Connector using the Inserter.
- 2** Extra Connectors are removed by first loosening the Polyaxial Set Screw using the Final Tightening Driver, followed by the Polyaxial Screw Set Screws.
- 3** Polyaxial Screw Set Screws should be backed all the way out of the tulips.
- 4** Remove rods using the Holding Forceps.
- 5** Use the Twisted Hexalobe Driver or Polyaxial Screwdriver to remove Polyaxial Screws.

# Occipital Cervical

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## FIXATION

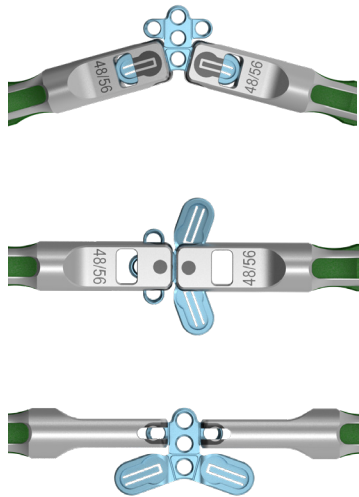
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**1** The Invictus OCT System offers 3 different Occipital Plate sizes to accommodate patient anatomy. Select the appropriately sized Occipital Plate based on patient anatomy.

**2** If necessary, the Occipital Plate can be contoured to match patient anatomy using the Plate Benders. The Plate Benders are dual-sided with one side of the bender optimized for use on 48/56 mm plates, and the other side for the 66 mm plate.

The plate contains bend zones to aid in contouring the plate. Place both Plate Benders over the bend zones and bend plate to match the contour of the patient's occiput.

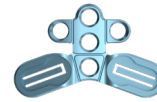
**TIP:** LASER MARKINGS ON PLATE BENDER ARE INTENDED TO REPLICATE THE DESIGN OF THE OCCIPITAL PLATE TO HELP IDENTIFY THE APPROPRIATE ORIENTATION.



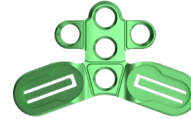
**3** Use the Plate Holder to secure the Plate at its midline. The proximal handle can be locked into place, securing the plate for placement to the desired position on the base of the skull.

**1**

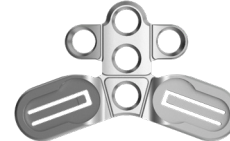
48 MM



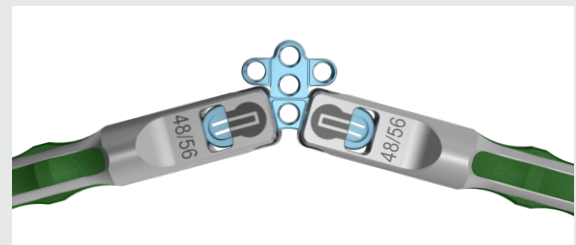
56 MM



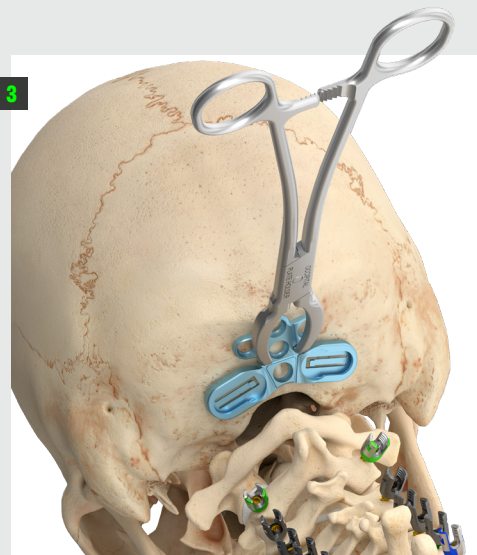
66 MM



**2**



**3**



**1** Use the Adjustable Drill/Tap Guide to prepare bone screw holes. To select the desired Drill Bit depth, pull back on the proximal gold knob and turn the pin toward center. Then turn the Drill Guide shaft to the left or right so that the locking pin slides over and down, into the L-shaped notch, to lock into the desired depth.

Attach the Drill Bit to power or the Quick Connect Ratcheting Egg Handle, and drill bone screw holes to the selected depth. Following drilling, attach the Tap to the Ratcheting Egg Handle and use with the Adjustable Drill/Tap Guide to tap previously drilled holes. A Straight or Angled Tap can be used to accommodate patient anatomy.

**TIP:** THE ADJUSTABLE DRILL/TAP GUIDE ALLOWS FOR A RANGE OF 6 - 16 MM OF DEPTH IN 2 MM INCREMENTS. MARKINGS ARE ETCHED ON THE DISTAL BARREL OF THE GUIDE AND ON THE PROXIMAL DRILL GUIDE SHAFT TO PROVIDE VISUAL CONFIRMATION OF DRILL BIT DEPTH.

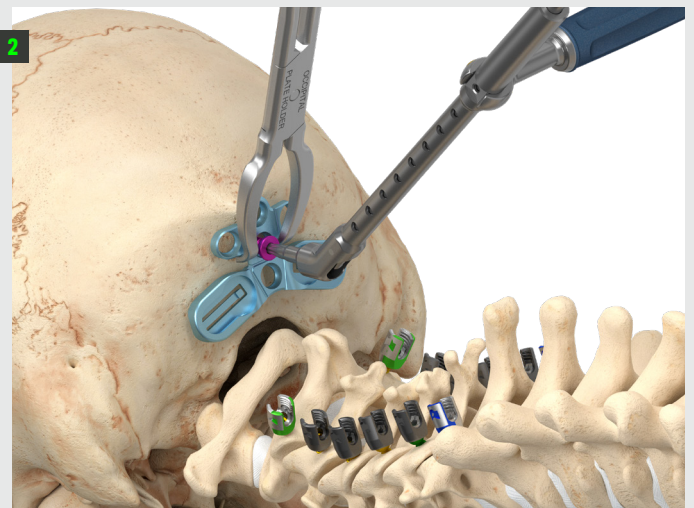
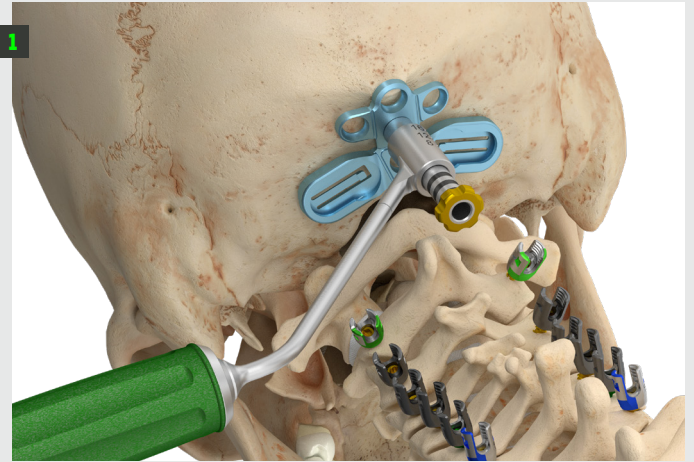
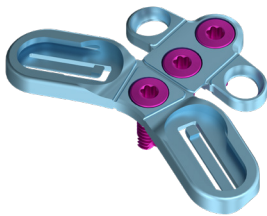


**TIP:** THE FIRST 6 MM OF THE TAP ARE COLORED GOLD TO HELP DETERMINE DEPTH. DEPTH MARKING ARE 8 - 16 MM IN 2 MM INCREMENTS. THE PILOT HOLE SHOULD BE FULLY TAPPED PRIOR TO SCREW INSERTION.



**2** Occipital screws are available in 4.5 mm and 5.0 mm diameters in 6 - 16 mm lengths. Select the proper screw length. A Straight or Angled Driver can be used based on patient anatomy. If desired, a Modular Countertorque Handle can be used with the Angled Driver for improved control during screw insertion. Attach the Modular Countertorque to the square flats on the proximal end of the Angled Driver. Use the Self-Retaining Driver to place selected screws into prepared bone screw holes.

**CAUTION:** AT MINIMUM, THREE SCREWS MUST BE PLACED THROUGH THE MIDLINE SCREW HOLES OF THE OCCIPITAL PLATE. FAILURE TO USE THREE SCREWS AT MIDLINE COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.

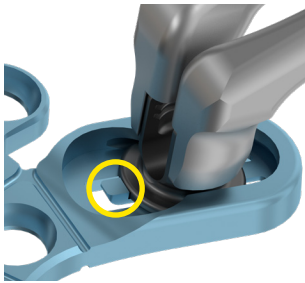




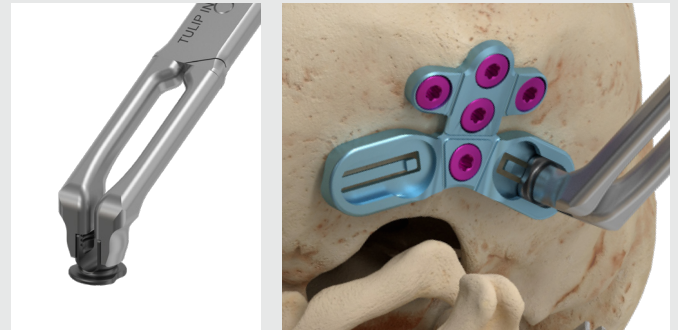
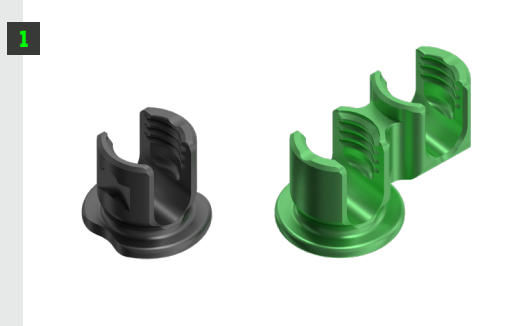
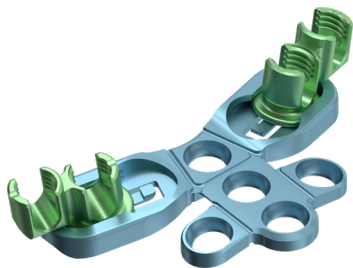
**1** The Invictus OCT System allows increased occipital cervical fixation of up to 4 rods (bi-lateral, parallel rod construct). Select a Single or Dual Tulip based on patient pathology and desired final construct.

Use the Tulip Inserter to slide the selected tulip into the track of the previously placed Occipital Plate until it is fully past the stop. The plate allows for translation of the tulip.

**CAUTION:** FAILURE TO FULLY SEAT A TULIP BEYOND THE STOP WITHIN THE TRACK OF THE OCCIPITAL PLATE COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.



**TIP:** DUAL TULIP CAN BE PLACED EITHER MEDIAL OR LATERAL.



**1** Select from **Prebent**, **Hinged**, and **Straight** rods to cross the occipital cervical junction. Cut and contour the rod to the desired shape using the Rod Cutter and French Bender.

ROD TYPE	DIAMETER	OCCIPITAL ROD ANGULATION	LENGTH OF ROD
Prebent	3.5 and 4.0 mm	45°	Occipital: 90 mm Subaxial: 210 mm
Hinged	3.5 and 4.0 mm	40° - 100°	Occipital: 90 mm Subaxial: 210 mm
Straight	3.5 and 4.0 mm	N/A	300 mm

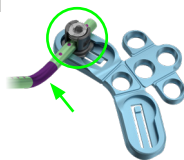
**TIP:** THE FRENCH BENDER MAY BE USED TO CONTOUR A 3.5 AND 4.0 MM DIAMETER ROD. THE FRENCH BENDER HAS TWO WORKING SIDES LABELED BY DIAMETER. IF DESIRED, THE PROXIMAL ENDS OF THE BENDER HANDLES CAN BE USED TO ACHIEVE A MORE ACUTE BEND OF THE ROD.



**2** Use the Rod Holder to place the rod into the Occipital Tulip. Confirm that the rods are normalized and extend slightly past the plate. The rod should contact both sides of the Occipital Plate. Use the Set Screw Inserter to seat the Set Screw and provisionally tighten into the Occipital Tulip.

**CAUTION:** THE INVICTUS OCT DUAL TULIP MUST BE USED WITH TWO RODS. FAILURE TO USE TWO RODS COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.

**CAUTION:** FAILURE TO CONFIRM THAT PREBENT RODS ARE NORMALIZED TO THE PLATE AND ROD-TO-PLATE CONTACT IS ACHIEVED OUTSIDE THE ANODIZED BEND ZONE MAY RESULT IN AN UNSTABLE CONSTRUCT.

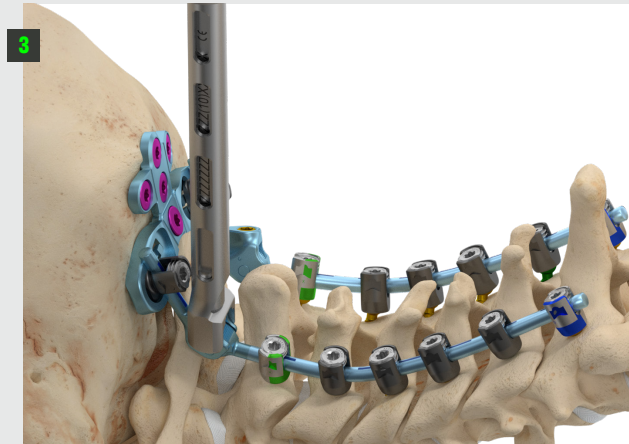
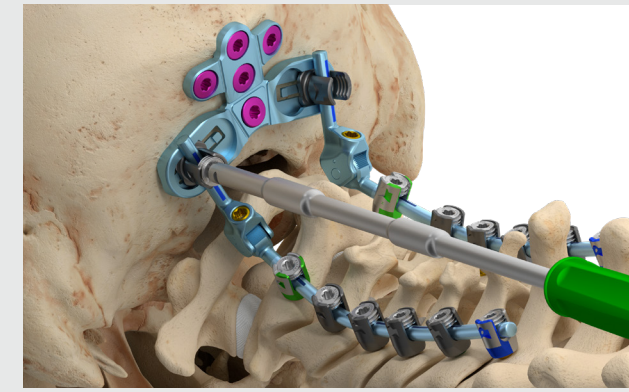
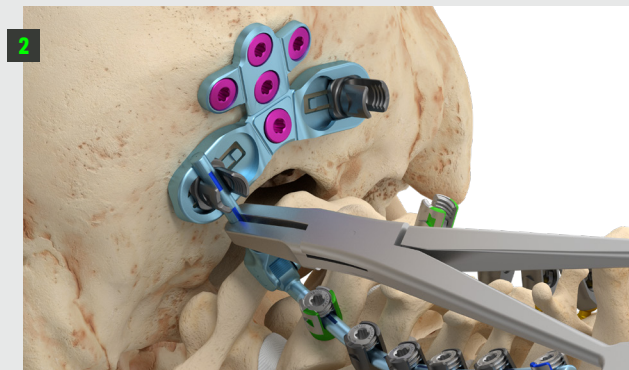
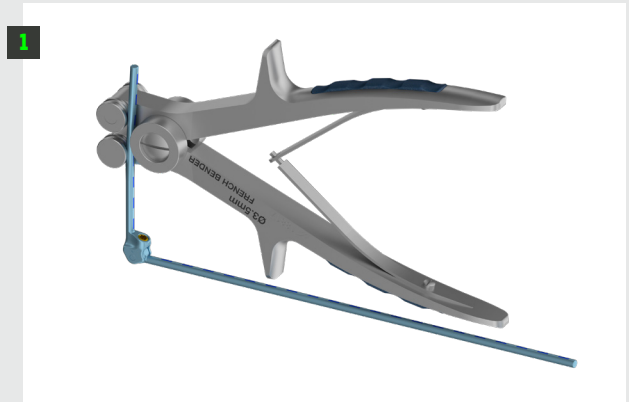


**TIP:** THE INVICTUS OCT AXIAL AND PISTOL ROD REDUCER CAN BE USED ON THE OCCIPITAL TULIP IF ROD REDUCTION IS NEEDED.

**TIP:** AS THE SET SCREW IS SEATED, THE OCCIPITAL TULIP IS COMPRESSED AGAINST THE TRACK OF THE OCCIPITAL PLATE CREATING A CLAMPING FORCE THAT LOCKS THE ROD INTO PLACE

**3** After the appropriate angle is selected, and the rod is seated into the Occipital Tulip, Hinged Rods may be locked into place. Connect the Final Tightening Driver to the 25-in-lb Torque Limiting Handle and final tighten through the Hinged Rod Countertorque.

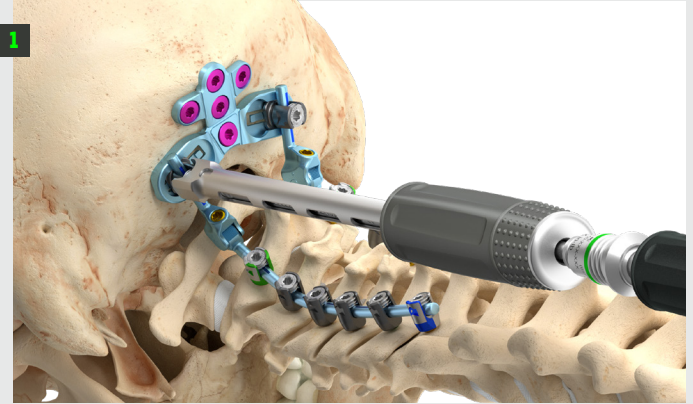
PART NUMBER	DESCRIPTION
19832	Final Tightening Driver
86002-0500-025-008	AO Torque Limiting Axial Handle, 25 in-lb, Black
19860	Countertorque, Hinged Rod



- 1 Final tighten Set Screws over seated rods using the Final Tightening Driver with Torque Handle through the Occipital Countertorque.

**CAUTION:** FAILURE TO TIGHTEN THE SET SCREWS USING THE RECOMMENDED INSTRUMENT(S) COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.

PART NUMBER	DESCRIPTION
19832	Final Tightening Driver
86002-0500-025-008	AO Torque Limiting Axial Handle, 25 in-lb, Black
19859	Countertorque, Occipital



- 1** Using the Inserter, remove the Cross Connectors and Rod Connectors if necessary. Variable Cross Connectors are removed by loosening the locking nuts with the Cross-Connector Driver and removing the Cross Connector using the Inserter.
- 2** Fully unthread the Set Screws from the Polyaxial Screws, Rod Connectors, and Occipital Tulips using the Final Tightening Driver.
- 3** Remove rods using the Rod Holder.
- 4** Use the Screwdriver to remove Screws.

## Invictus® OCT Spinal Fixation System INSTRUCTIONS FOR USE

### GENERAL INFORMATION:

The Invictus OCT Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the craniocervical junction, cervical spine (C1 to C7), and thoracic spine (T1 to T3). The Invictus OCT system is compatible with Arsenal® Spinal Fixation System or the Invictus Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods.

The Invictus OCT implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136 and cobalt chromium (Co-28Cr-6Mo) alloy per ASTM F1537. The Invictus OCT System consists of a variety of shapes and sizes of screws, rods, cross connectors, rod connectors, plates and general surgical instruments that provide internal fixation and stabilization during bone graft healing and/or fusion mass development.

The Invictus OCT implants are provided non-sterile to be steam sterilized by the end user. The instruments are made of stainless steel and other materials and are provided either sterile or non-sterile to be cleaned and sterilized by the end user. The instruments in this system are intended for use in surgical procedures.

### INDICATIONS FOR USE:

The Invictus OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical 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 Invictus OCT Spinal Fixation 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 advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Invictus OCT Spinal Fixation System may be connected to the components in the Arsenal Spinal Fixation System or the Invictus Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods.

### CONTRAINDICATIONS:

The system is contraindicated for:

1. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance (e.g., allergy to titanium or cobalt chrome).
2. Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and other medical conditions, which would prohibit beneficial surgical outcome.
3. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
4. Use with bone cement.
5. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
6. Reuse, or multiple use.

### WARNINGS/CAUTIONS/PRECAUTIONS:

1. The implants of the system are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. All instruments except the single-use sterile drills are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU. Sterile drills are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.
3. The following statements apply to single use sterile drills:
  - a. Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
  - b. Do not re-sterilize instruments.
  - c. Do not use scratched or damaged devices.
4. The system implants are to be used with the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices.
5. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
6. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
7. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
8. The product implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
9. The final operative procedure with the system must include tightening of the set screws in order to maintain construct integrity. Each locking mechanism must be rechecked for tightness before closing the soft tissues as noted in the Intraoperative Management section.
10. Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient conditions, which may impact the performance of the system when using this device. Use of these systems is significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection, and placement of implants. No spinal implant can withstand body loads for an indefinite period of time without the support of bone. In the event that successful fusion is not

achieved, bending, breakage, loosening, or disassembly of the device will occur.

11. Risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation/stabilization, non-union, vertebral fracture, neurological injury, vascular or visceral injury.
12. Risk factors that may affect successful surgical outcomes include: Alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
13. It is critical that Set Screws are final tightened as recommended in the Surgical Technique Guide, using the appropriate instrument(s), e.g., Torque Handle. Failure to tighten the Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct.
14. Do not comingle titanium and stainless steel components within the same construct.
15. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
16. The Invictus OCT occipital plate should only be connected to components of Invictus OCT Fixation System.
17. The Invictus OCT dual tulip must be used with two rods. Failure to use two rods could compromise the mechanical stability of the construct.
18. At minimum, three screws must be placed through the midline screw holes of the occipital plate. Failure to use three screws at midline could compromise the mechanical stability of the construct.
19. Failure to fully seat a tulip beyond the stop within the track of the occipital plate could compromise the mechanical stability of the construct.
20. Failure to confirm that prebent rods are normalized to the plate and rod-to-plate contact is achieved outside the anodized bend zone may result in an unstable construct.
21. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
22. Device components should be received and accepted only in packages that have not been damaged. Damaged implants and damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
23. Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.
24. Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

### MRI SAFETY INFORMATION:

The Invictus OCT Spinal Fixation System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Invictus OCT Spinal Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

### POSSIBLE ADVERSE EFFECTS:

Possible adverse effects include:

1. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
3. In the case of insufficient soft tissue at and around the wound site to cover devices, skin impingement and possible protrusion through the skin may occur.
4. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height
5. Infection and/or hemorrhaging
6. Bone graft, vertebral body fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level
7. Non-union and/or pseudarthrosis
8. Neurological disorder, pain and/or abnormal sensations
9. Revision surgery
10. Death

### PREOPERATIVE MANAGEMENT:

1. Only patients meeting the criteria listed in the indications for use section should be selected.
2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include construct strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.

### INTRAOPERATIVE MANAGEMENT:

1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times, especially upon insertion of spinal hooks.
2. Rods should be contoured in only one direction, one time. Avoid notching, scratching or reverse bending of the devices because these alterations will produce defects in the surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
3. If it is mandatory to cut the rods to a more specific length, rod cutting should be done at a distance from the operative range, and such that a non-sharp edge remains on the rod.
4. Bone taps should be inspected each time prior to use to ensure a sharp cutting edge and the absence of clogging bone debris. Use of the improper length or diameter of bone tap or bone screw may allow loosening of implants, nerve damage, and undesirable fusion.
5. System must include tightening of all set screws to the torque values indicated by the surgical technique with the instruments provided. Each locking mechanism must be rechecked for

- tightness before closing the soft tissues.
- Final Set Screw Tightening: All Set Screws must be tightened using the appropriate instrument (e.g., Torque Handle) as indicated in the Surgical Technique Guide.
  - Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
  - At minimum, three screws must be placed through the midline screw hole on the occiput in surgery.

**POSTOPERATIVE MANAGEMENT:**

Postoperative management by the surgeon is essential. This includes instructing, warning, and monitoring the compliance of the patient.

- Patient should be informed and compliant with the purpose and limitations of the implant devices.
- The surgeon should instruct the patient regarding amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are possible consequences of any type of early or excessive weight bearing, vibratory motion, fall, jolts, or other movements preventing proper healing and/or fusion development.
- In the case of delayed, mal-, or non-union of bone, the patient must continue to be immobilized in order to prevent bending, dislocation, or breakage of the implant devices. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
- Postoperative patients should be instructed to not use tobacco or nicotine products, consume alcohol, and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or aspirin. Complete postoperative management as determined by the surgeon following implant surgery to maintain the desired result.

Excerpt from INS-129



**Caution: Federal law (USA) restricts these instruments to sale by or on the order of a physician.**

**SYMBOLS:**

For a listing of Symbols and Explanations, see [atecspine.com/eifu](http://atecspine.com/eifu)



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**Invictus® OCT Spinal Fixation System  
INSTRUCTIONS FOR USE (AUSTRALIA)**

**GENERAL INFORMATION:**

The Invictus OCT Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the craniocervical junction, cervical spine (C1 to C7), and thoracic spine (T1 to T3). The Invictus OCT system is compatible with Arsenal® Spinal Fixation System or the Invictus Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods.

The Invictus OCT implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and cobalt chromium (Co-28Cr-6Mo) alloy per ASTM F1537. The Invictus OCT System consists of a variety of shapes and sizes of screws, rods, cross connectors, rod connectors, plates and general surgical instruments that provide internal fixation and stabilization during bone graft healing and/or fusion mass development.

The Invictus OCT implants are provided non-sterile to be steam sterilized by the end user. The instruments are made of stainless steel and other materials and are provided either sterile or non-sterile to be cleaned and sterilized by the end user. The instruments in this system are intended for use in surgical procedures.

**INDICATIONS FOR USE:**

The Invictus OCT Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments as an adjunct into fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability of deformity; failed previous fusions (e.g., pseudoarthrosis); tumors involving the cervical 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 Invictus OCT Spinal Fixation 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 advance stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Invictus OCT Spinal Fixation System may be connected to the components in the Arsenal Spinal Fixation System or the Invictus Spinal Fixation System offered by Alphatec Spine using various rod-to-rod connectors and/or transitional rods.

**CONTRAINDICATIONS:**

The system is contraindicated for:

- Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance (e.g., allergy to titanium or cobalt chrome).
- Patients with infection, inflammation, fever, tumors, elevated white blood count, obesity, pregnancy, mental illness, and other medical conditions, which would prohibit beneficial surgical outcome.
- Spinal surgery cases that do not require bone grafting and/or spinal fusion.
- Use with bone cement.
- Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities.
- Reuse, or multiple use.

**WARNINGS/CAUTIONS/PRECAUTIONS:**

- The implants of the system are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
- All instruments except the single-use sterile drills are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU. Sterile drills are disposable devices, designed for single use and should not be reused or reprocessed. Reprocessing of single use instruments may lead to instrument damage and possible improper function.
- The following statements apply to single use sterile drills:
  - Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
  - Do not re-sterilize instruments.
  - Do not use scratched or damaged devices.
- The system implants are to be used with the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices.
- Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
- The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
- The product implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
- The final operative procedure with the system must include tightening of the set screws in order to maintain construct integrity. Each locking mechanism must be rechecked for tightness before closing the soft tissues as noted in the Intraoperative Management section.
- Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient conditions, which may impact the performance of the system when using this device. Use of these systems is significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection, and placement of implants. No spinal implant



can withstand body loads for an indefinite period of time without the support of bone. In the event that successful fusion is not achieved, bending, breakage, loosening, or disassembly of the device will occur.

11. Risks identified with the use of these devices, which may require additional surgery, include device component failure, loss of fixation/stabilization, non-union, vertebral fracture, neurological injury, vascular or visceral injury.
12. Risk factors that may affect successful surgical outcomes include Alcohol abuse, obesity, patients with poor bone, muscle and/or nerve quality. Patients who use tobacco or nicotine products should be advised of the consequences that an increased incidence of non-union has been reported with patients who use tobacco or nicotine products.
13. It is critical that Set Screws are final tightened as recommended in the Surgical Technique Guide, using the appropriate instrument(s), e.g., Torque Handle. Failure to tighten the Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct.
14. Do not commingle titanium and stainless steel components within the same construct.
15. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
16. The Invictus OCT occipital plate should only be connected to components of Invictus OCT Fixation System.
17. The Invictus OCT dual tulip must be used with two rods. Failure to use two rods could compromise the mechanical stability of the construct.
18. At minimum, three screws must be placed through the midline screw holes of the occipital plate. Failure to use three screws at midline could compromise the mechanical stability of the construct.
19. Failure to fully seat a tulip beyond the stop within the track of the occipital plate could compromise the mechanical stability of the construct.
20. Failure to confirm that prebent rods are normalized to the plate and rod-to-plate contact is achieved outside the anodized bend zone may result in an unstable construct.
21. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
22. Device components should be received and accepted only in packages that have not been damaged. Damaged implants and damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
23. Preoperative planning prior to implantation of posterior cervical screw systems should include review of cross-sectional imaging studies (e.g., CT and/or MRI) to evaluate the patient's cervical anatomy including the transverse foramen, neurologic structures, and the course of the vertebral arteries. If any findings would compromise the placement of these screws, other surgical methods should be considered. In addition, use of intraoperative imaging should be considered to guide and/or verify device placement, as necessary.
24. Use of posterior cervical pedicle screw fixation at the C3 through C6 spinal levels requires careful consideration and planning beyond that required for lateral mass screws placed at these spinal levels, given the proximity of the vertebral arteries and neurologic structures in relation to the cervical pedicles at these levels.

#### MRI SAFETY INFORMATION:

The Invictus OCT Spinal Fixation System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Invictus OCT Spinal Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

#### POSSIBLE ADVERSE EFFECTS:

Possible adverse effects include:

1. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, local tissue reaction, and possible tumor formation.
3. In the case of insufficient soft tissue at and around the wound site to cover devices, skin impingement and possible protrusion through the skin may occur.
4. Loss of desired spinal curvature, spinal correction and/or a gain or loss in height
5. Infection and/or hemorrhaging
6. Bone graft, vertebral body fracture, and/or discontinued growth of fused bone at, above and/or below the surgery level
7. Non-union and/or pseudarthrosis
8. Neurological disorder, pain and/or abnormal sensations
9. Revision surgery
10. Death

#### PREOPERATIVE MANAGEMENT:

1. Only patients meeting the criteria listed in the indications for use section should be selected.
2. Surgeons should have a complete understanding of the surgical technique, system indications, contraindications, warnings and precautions, safety information, as well as functions and limitations of the implants and instruments.
3. Careful preoperative planning should include construct strategy, pre-assembly of component parts (if required), and verification of required inventory for the case.

#### INTRAOPERATIVE MANAGEMENT:

1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times, especially upon insertion of spinal hooks.
2. Rods should be contoured in only one direction, one time. Avoid notching, scratching or reverse bending of the devices because these alterations will produce defects in the surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
3. If it is mandatory to cut the rods to a more specific length, rod cutting should be done at a distance from the operative range, and such that a non-sharp edge remains on the rod.
4. Bone taps should be inspected each time prior to use to ensure a sharp cutting edge and the absence of clogging bone debris. Use of the improper length or diameter of bone tap or bone

- screw may allow loosening of implants, nerve damage, and undesirable fusion.
5. System must include tightening of all set screws to the torque values indicated by the surgical technique with the instruments provided. Each locking mechanism must be rechecked for tightness before closing the soft tissues.
6. Final Set Screw Tightening: All Set Screws must be tightened using the appropriate instrument (e.g., Torque Handle) as indicated in the Surgical Technique Guide.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. At minimum, three screws must be placed through the midline screw hole on the occiput in surgery.

#### POSTOPERATIVE MANAGEMENT:

Postoperative management by the surgeon is essential. This includes instructing, warning, and monitoring the compliance of the patient.

1. Patient should be informed and compliant with the purpose and limitations of the implant devices.
2. The surgeon should instruct the patient regarding amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are possible consequences of any type of early or excessive weight bearing, vibratory motion, fall, jolts, or other movements preventing proper healing and/or fusion development.
3. In the case of delayed, mal-, or non-union of bone, the patient must continue to be immobilized in order to prevent bending, dislocation, or breakage of the implant devices. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
4. Postoperative patients should be instructed to not use tobacco or nicotine products, consume alcohol, and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or aspirin. Complete postoperative management as determined by the surgeon following implant surgery to maintain the desired result.

Excerpt from INS-129-01

For a listing of Symbols and Explanations, see [atecspine.com/eifu](http://atecspine.com/eifu)



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