

INVICTUSTM MODULAR

SPINAL FIXATION SYSTEM



SURGICAL TECHNIQUE GUIDE

INVICTUSTM MODULAR

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INVICTUS MOD CORE SETS

- Invictus MOD Implant Set
- Invictus MOD Instrument Set

INVICTUS CORE SETS

- Invictus Core A Instrument Set
- Invictus Core B Instrument Set
- Invictus Core Polyaxial Implant Set

OPTIONAL SYSTEM OFFERINGS

Refer to the standard Invictus Surgical Technique Guide (LIT-16001) for all additional optional implant and instrument sets.

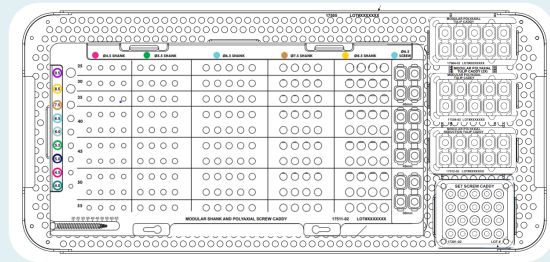
Additionally, refer to other ATEC system guides for complete procedural offerings including:

- SafeOp™
- Interbody Implant Systems
 - IdentiTi™ PC
 - IdentiTi™ PO
- Biologics

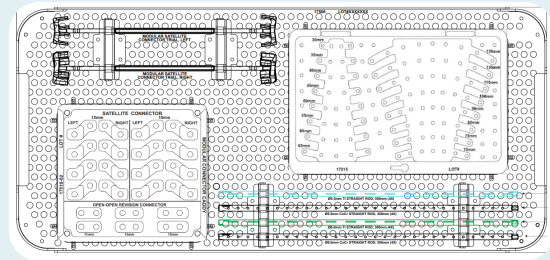
PATIENT POSITIONING

Place the patient on the operating table in prone position. Prepare and drape in a conventional manner. Uniplanar or biplanar fluoroscopy may be used.

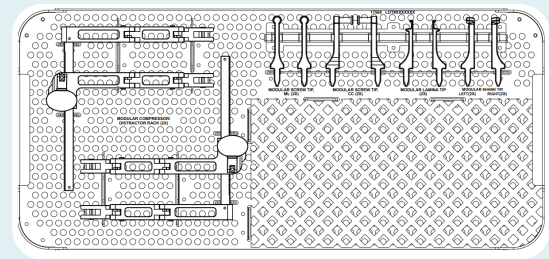
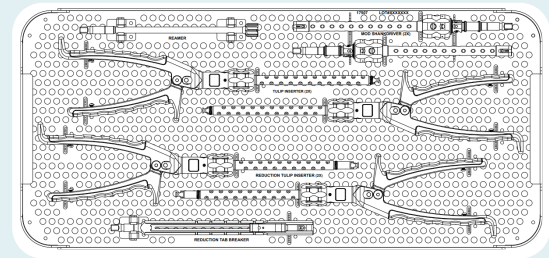
Place the necessary neuromonitoring electrodes on the patient according to the SafeOp™ monitoring guide and execute a train of four test to determine neuromuscular blockades are clear.



MOD Implant Set

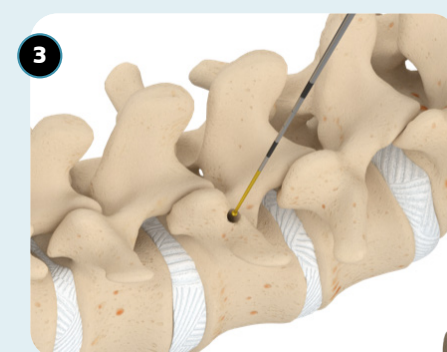
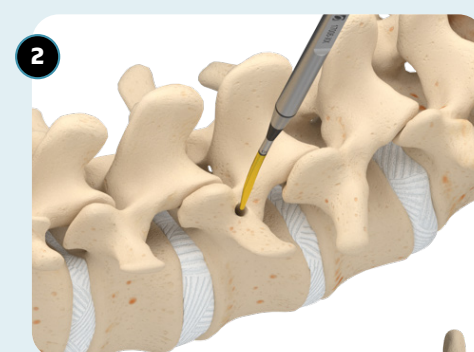
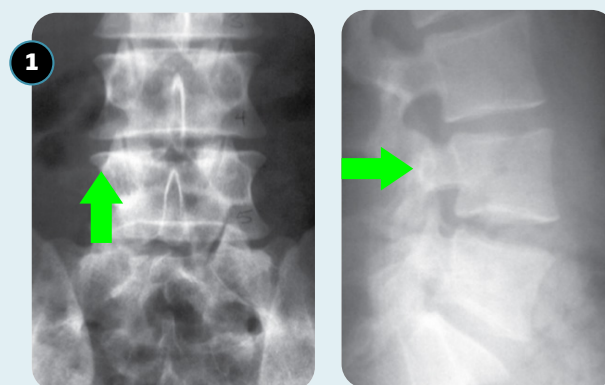


MOD Instrument Set



- 1 Determine the preferred entry point into the pedicle and perforate the cortex with a high-speed burr.
- 2 Create a pilot hole in the pedicle with the Thoracic Probe at the junction of the transverse process and the superior articular process.
- 3 The Ball Tip Probe can be used to palpate the pedicle wall to assess pilot hole integrity.

TIP: THORACIC PROBES AND BALL TIP PROBES HAVE A 30 MM GOLD TIP AND A BLACK BAND FROM 40 MM – 50 MM.



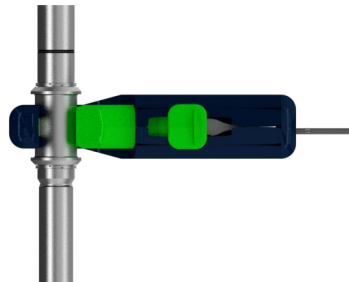
- 1 If tapping is preferred, attach the desired Ratcheting Handle to the appropriate diameter Tap. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Tap.

TIP: ALL TAPS HAVE A COLOR BAND TO INDICATE TAP DIAMETER THAT MATCHES SHANK AND SCREW DIAMETER COLOR.

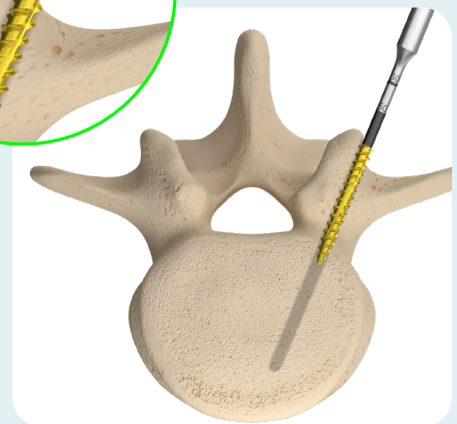
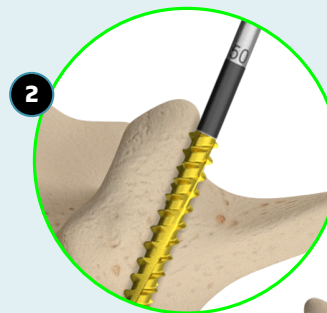
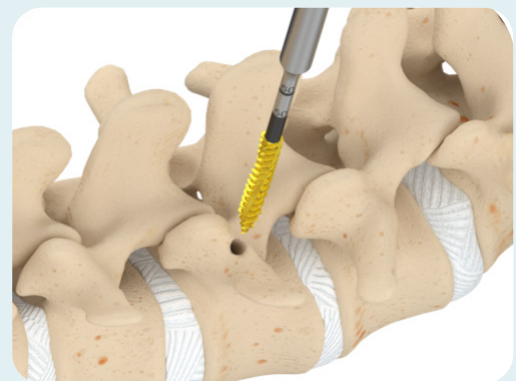


- 2 Set the Ratcheting Handle to the “Forward” position and rotate clockwise to advance into the pedicle. Reference the numerical markings on the distal end of the Tap shaft to determine depth in bone.

OPTIONAL:
Attach the Alpha Informatix™ Stimulation Clip to the Stimulation Collar on the proximal end of the Tap shaft to stimulate during Tap insertion.



TIP: TAPS HAVE 40 MM OF GOLD LINE-TO-LINE THREADS AND A BLACK BAND FROM 40 MM – 50 MM.



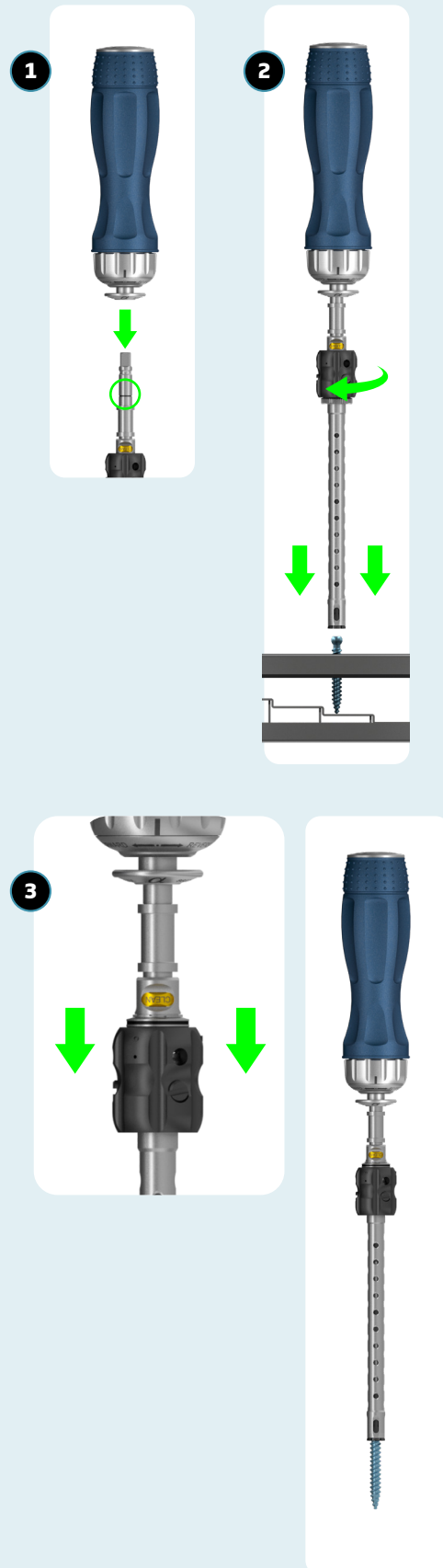
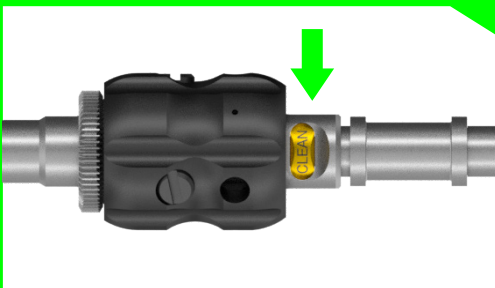
- 1 Attach the desired Ratcheting Handle to the MOD Shankdriver. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Shankdriver.

TIP: CONFIRM THAT THE RATCHETING HANDLE IS IN THE "NEUTRAL" POSITION WHEN LOADING THE SHANK.



- 2 With the desired Shank in the caddy, press the Shankdriver onto the Shank head until fully encapsulated. Rotate the black thumbwheel clockwise until it bottoms out.
- 3 Slide the black thumbwheel distally until the black laser-marked line is visible, indicating that the secondary lock is engaged.

TIP: PRESS THE GOLD "CLEAN" BUTTON ABOVE THE THUMBWHEEL TO REMOVE THE INNER SHAFT AND DISASSEMBLE THE SHANKDRIVER FOR CLEANING.



- 1 Insert the Shank into the pedicle and rotate the Ratcheting Handle clockwise. Continue advancing the Shank into the vertebral body until the distal tip of the Shankdriver contacts bone.

TIP: WHEN BOTTOMED OUT, THE SHANKDRIVER LEAVES APPROPRIATE SHANK NECK EXPOSED FOR TULIP ATTACHMENT.

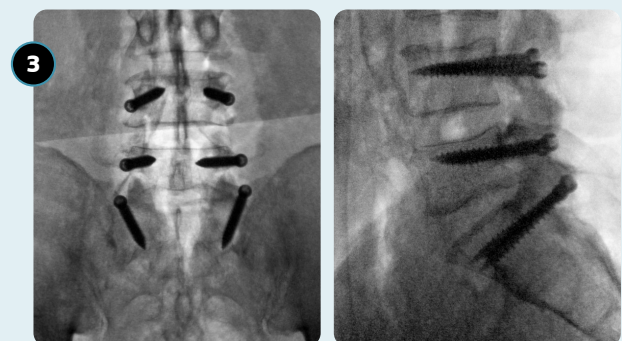
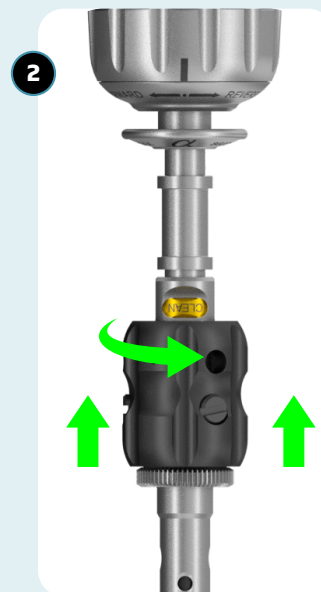
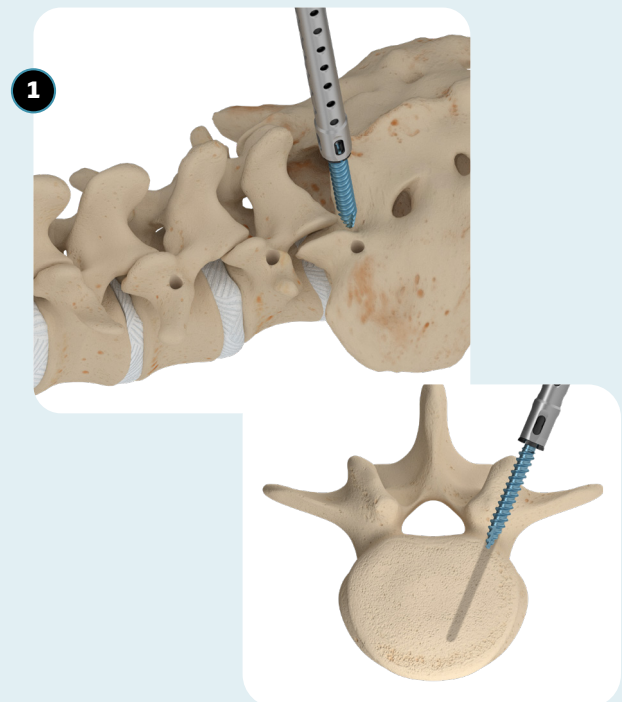
- 2 Unlock the Shankdriver by pulling up on the thumbwheel and rotate counterclockwise to disengage from the Shank.

- 3 Confirm Shank placement using fluoroscopic imaging.

OPTIONAL: Attach the Alpha Informatix™ Stimulation Clip to the Stimulation Collar on the proximal end of the MOD Shankdriver shaft to stimulate during Shank insertion. OR use the Alpha Informatix™ Stimulating Ball-Tip Probe to test screw placement after insertion.



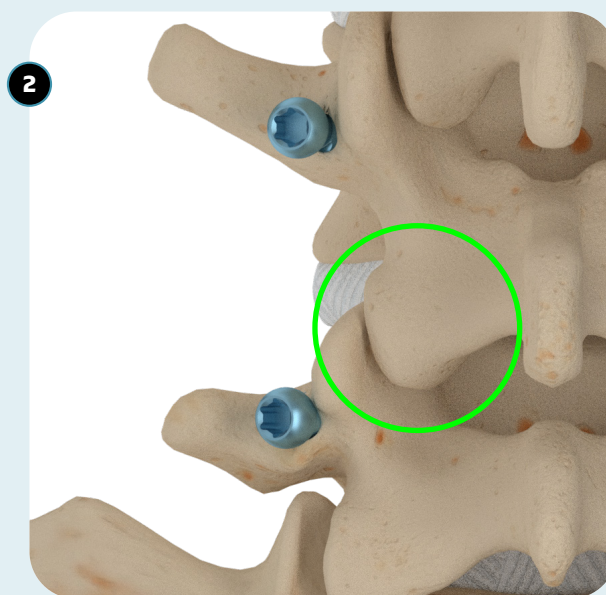
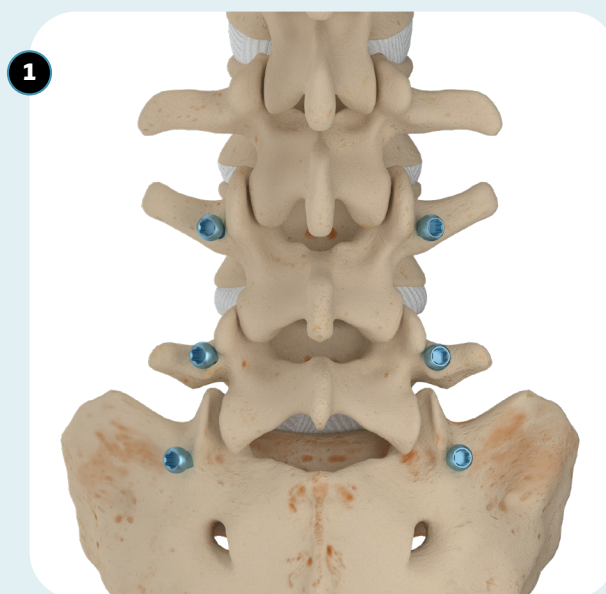
TIP: IF SHANK ADJUSTMENT IS DESIRED, USE THE INVICTUS SCREW ADJUSTER TO FURTHER ADVANCE OR BACK OUT THE SHANK.



1 Identify key anatomy, such as the facet joint, pars interarticularis, transverse process, and inferior edge of the lamina based upon their locations relative to the pedicles.

2 Resect the inferior articular process of the cephalad vertebra with an Osteotome or high-speed burr. Excise the superior articular process of the caudal vertebra to the pedicle optimizing entry to the disc space. Care should be taken to avoid the pedicle cortex if using a high-speed burr. If preferred, the spinous processes may be removed as well.

TIP: THE LOCAL BONE MAY BE SAVED, DECORTICATED, AND USED AS BONE GRAFT MATERIAL.



To distract the disc space for interbody implant insertion, use the Modular Compressor/Distractor Rack with the Modular Compressor/Distractor Rack Tips of choice.

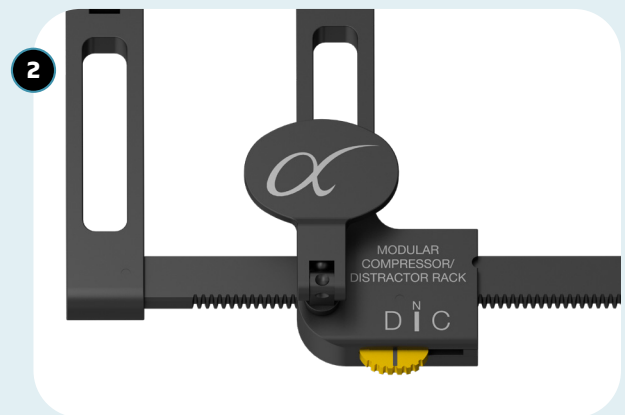
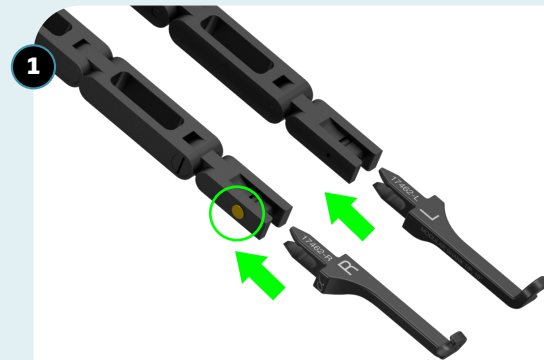
- 1 To attach the preferred Rack Tip, press the gold button on the distal end of the Rack arm and slide the Tip into place.
- 2 Position the gold slide on the rack body to distract (D) and rotate the thumb paddle counterclockwise to apply distraction.

METHOD 1: SHANK TIPS

- 3 If distraction off the modular Shank is desired, select the Modular Shank Tips. Once the Tips are attached to the Rack body, seat the circular Shank Tips around the neck of the Shank.



TIP: THE MODULAR RACK MAY BE ATTACHED FROM THE IPSILATERAL OR CONTRALATERAL SIDE DEPENDING ON PREFERRED TECHNIQUE.



SHANK TIPS



METHOD 2: LAMINA TIPS

- 4 If distraction off the lamina is desired, select the Modular Lamina Tips. Once the Tips are attached to the Rack body, seat the Lamina Tips on the base of the spinous process or lamina.



METHOD 3: SCREW TIPS

- 5 If distraction off the Tulip is desired, select the Modular Screw Tips and verify that all necessary Tulips are secured. Once the Tips are attached to the Rack body, seat the heel of the Tip into the Tulip and secure with a Set Screw.

TIP: CRANIAL/CAUDAL TULIP TIPS ARE GOLD AND SEAT IN THE TULIP PARALLELING THE SPINOUS PROCESS. MEDIAL/LATERAL TULIP TIPS ARE BLACK AND SEAT IN THE TULIP PERPENDICULAR TO THE SPINOUS PROCESS.



LAMINA TIPS



SCREW TIPS - CRANIAL/CAUDAL



SCREW TIPS - MEDIAL/LATERAL

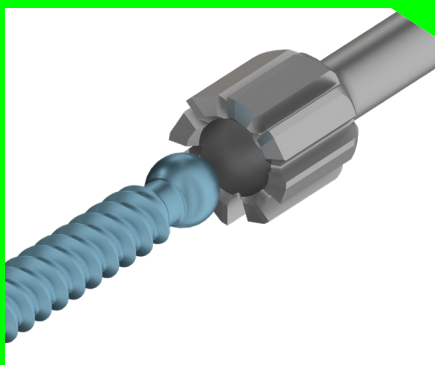


- 1 Perform an annulotomy to access the disc space. Remove as much disc as possible using Pituitary Rongeurs, Disc Shavers, and Curettes. Thoroughly prepare endplates with Rasps or Endplate Scrapers to remove cartilage and create bleeding of the subchondral plate.
- 2 Refer to the relevant interbody implant system's surgical technique guide.



- 1 If reaming is preferred, attach the desired Ratcheting Handle to the Reamer. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Reamer.
- 2 Insert the Reamer over the desired Shank head *in situ* and rotate the handle back and forth until the Reamer bottoms out on the Shank head.

TIP: THE SHAPE AND SIZE OF THE REAMER'S DISTAL TIP MATCHES THE SHAPE AND SIZE OF THE MODULAR TULIP TO CONFIRM APPROPRIATE SPACE FOR TULIP ATTACHMENT.



Utilizing Fenestrated Modular Shanks

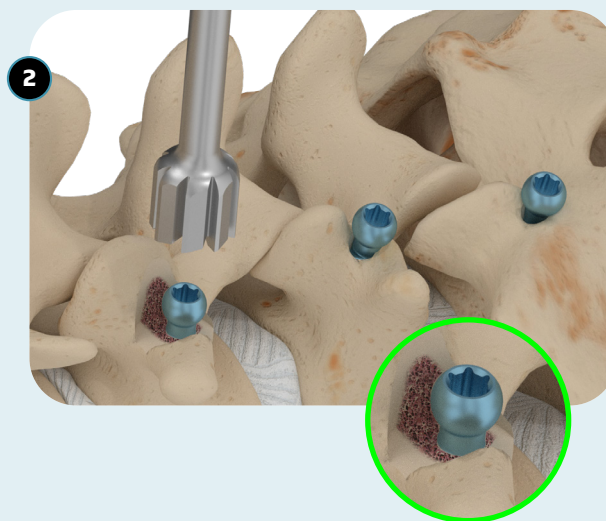
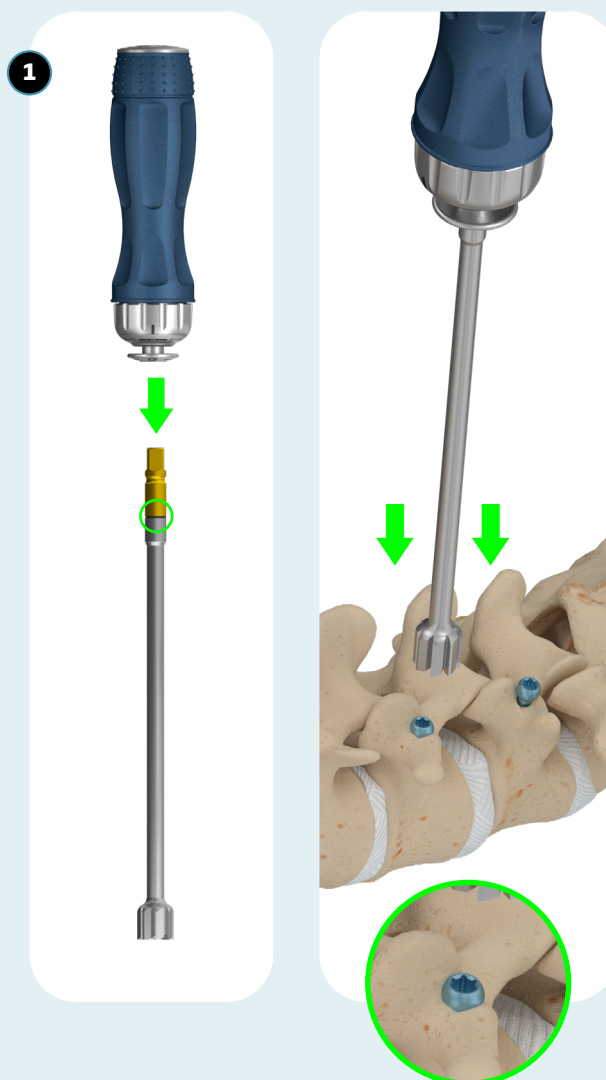
TIP: FOR USE WITH THE INVICTUS FENESTRATED SYSTEM, ADDITIONAL SYSTEM DETAILS CAN BE FOUND IN THE FOLLOWING SURGICAL TECHNIQUE GUIDES:

LIT-17106 | INVICTUS OPEN FENESTRATED

LIT-17107 | INVICTUS MIS FENESTRATED

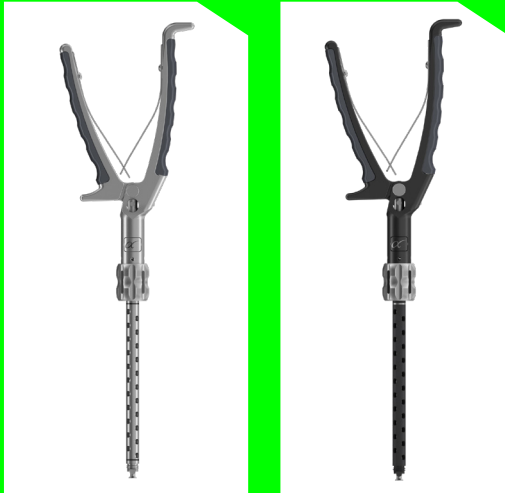
When the Fenestrated Modular Shank has been assembled to the Tulip, continue onto either Open or MIS Fenestrated instrument workflows referencing the surgical techniques above.

CAUTION: CEMENT MUST ONLY BE INJECTED INTO A FULLY ASSEMBLED FENESTRATED SCREW. INJECTING CEMENT DIRECTLY INTO A FENESTRATED SHANK WITHOUT A TULIP MAY RESULT IN CEMENT LEAKAGE AND UNSATISFACTORY RESULTS.



- 1 Choose the appropriate Tulip Inserter based on the desired Tulip.

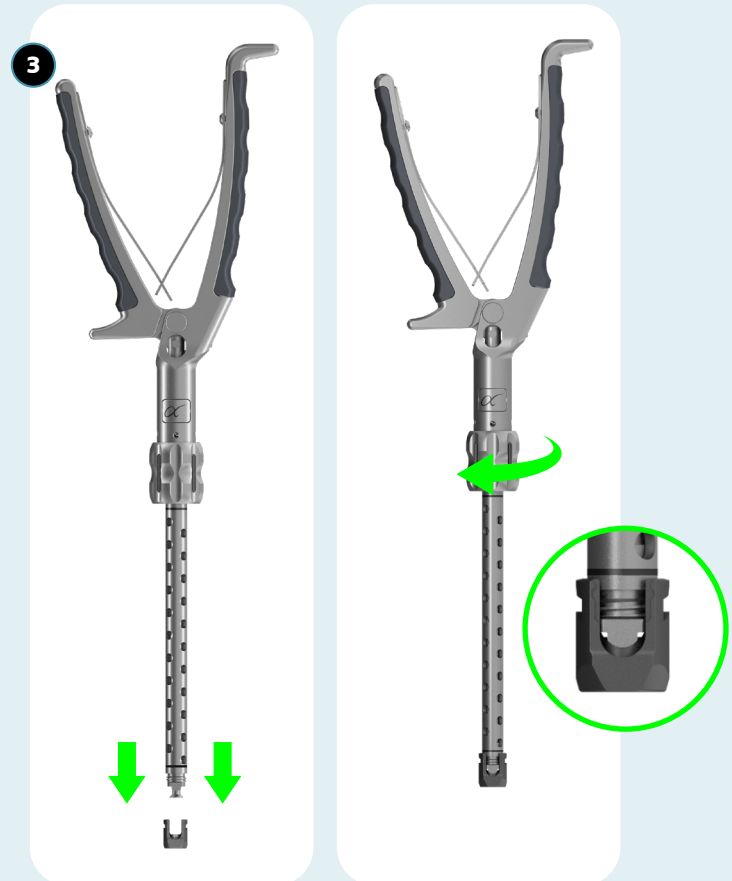
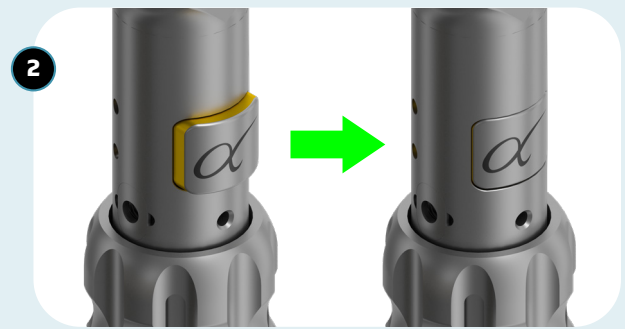
TIP: THE STANDARD POLYAXIAL TULIP INSERTER IS SILVER WITH GRAY HANDLES. THE REDUCTION POLYAXIAL TULIP INSERTER IS BLACK WITH BLACK HANDLES. IF USING A MODULAR SATELLITE CONNECTOR, USE THE STANDARD POLYAXIAL TULIP INSERTER.



- 2 Prior to loading a Tulip, press the “α” button on the Tulip Inserter in until flush with the housing.

CAUTION: FAILURE TO RESET THE TULIP INSERTER PRIOR TO TULIP ATTACHMENT WILL RESULT IN A PREMATURELY DEPLOYED TULIP AND THEREFORE AN UNSTABLE CONSTRUCT.

- 3 With the desired Tulip in the caddy, insert the distal tip of the Tulip Inserter into the Tulip. While applying downward pressure, rotate the thumbwheel clockwise until it bottoms out. Verify that the laser-marked line on the Inserter shaft is flush with the top of the Tulip, indicating that the Tulip is properly threaded.



- 1 Apply downward pressure to seat the Tulip onto the Shank head *in situ*. If resistance is encountered, select a new Tulip and repeat.

CAUTION: TO PREVENT IMPLANT DAMAGE, DO NOT Mallet on the Tulip Inserter to seat a modular Tulip onto a modular Shank.

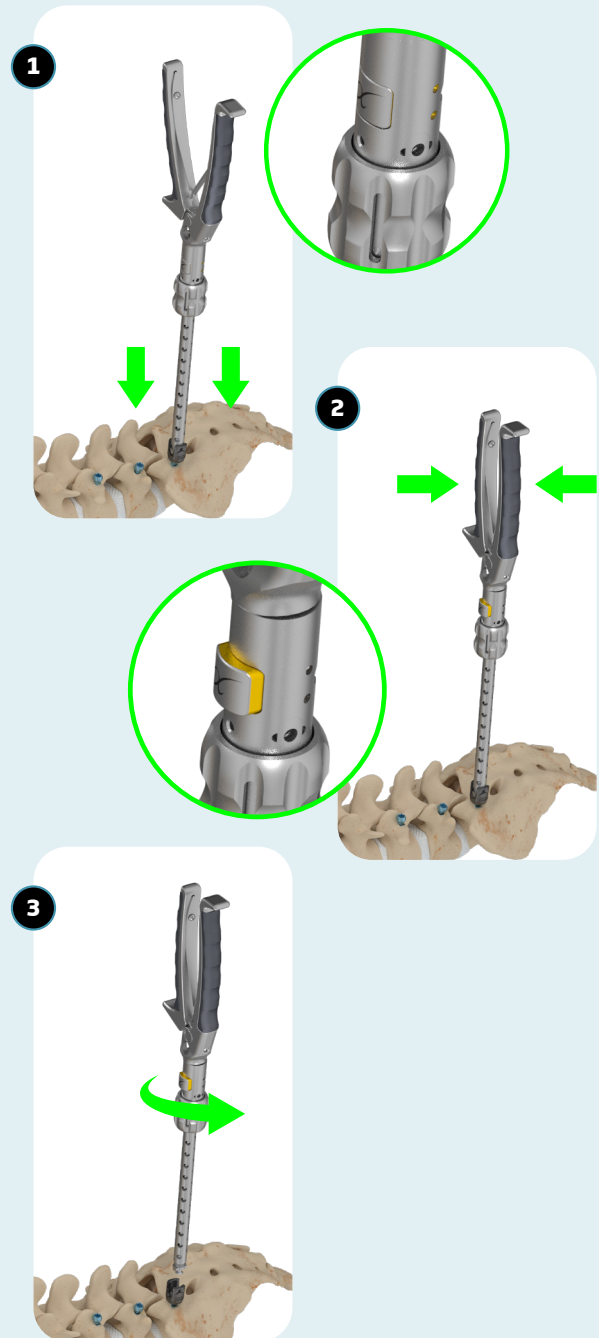
- 2 Squeeze the Tulip Inserter handles to secure the Tulip onto the Shank. Verify that the gold “α” button on the Inserter is popped out, indicating that the Tulip is properly secured. Once the Tulip is secured to the Shank, it cannot be removed.

TIP: INABILITY TO SQUEEZE THE TULIP INSERTER HANDLES TOGETHER *IN SITU* INDICATES THAT THE TULIP IS NOT PROPERLY SEATED ON THE SHANK HEAD. REMOVE THE TULIP BY PULLING UP WITH THE INSERTER AND REPOSITION OR USE THE REAMER TO CLEAR SOFT TISSUE AROUND THE SHANK HEAD.

CAUTION: FAILURE TO VERIFY THAT THE MODULAR TULIP IS SECURED TO THE MODULAR SHANK COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.

- 3 Remove the Tulip Inserter by rotating the thumbwheel counterclockwise and pulling up.

TIP: USE THE HEAD TURNER TO VERIFY FULL POLYAXIAL MOTION OF THE TULIP.



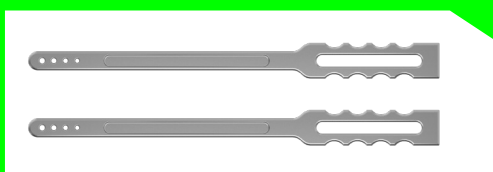
- 1 Once all Tulips are attached, a rod template can be used to measure the length and desired contour of the construct.

TIP: THE LONGITUDINAL MARKINGS ON THE RODS ARE SPACED 10 MM APART AND DESIGNED TO AID IN PROPER SAGITTAL ROD PLACEMENT.

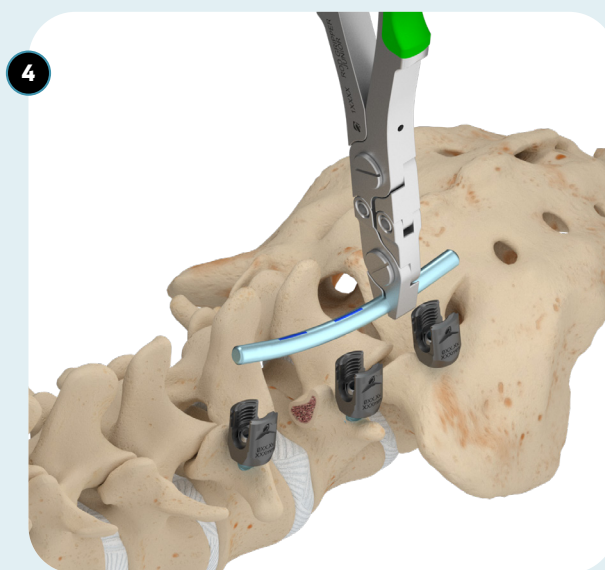
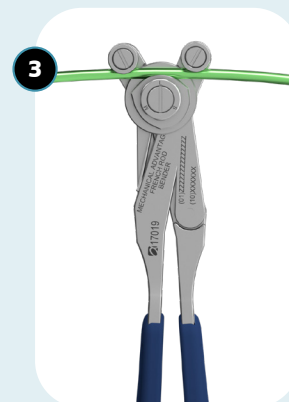
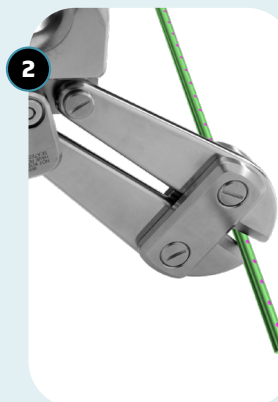


- 2 If needed, a rod cutter may be used to achieve the preferred rod length.
- 3 If contouring is required, use the Mechanical Advantage French Rod Bender. Rotate the central dial to small, medium, or large to select the desired bend radii.

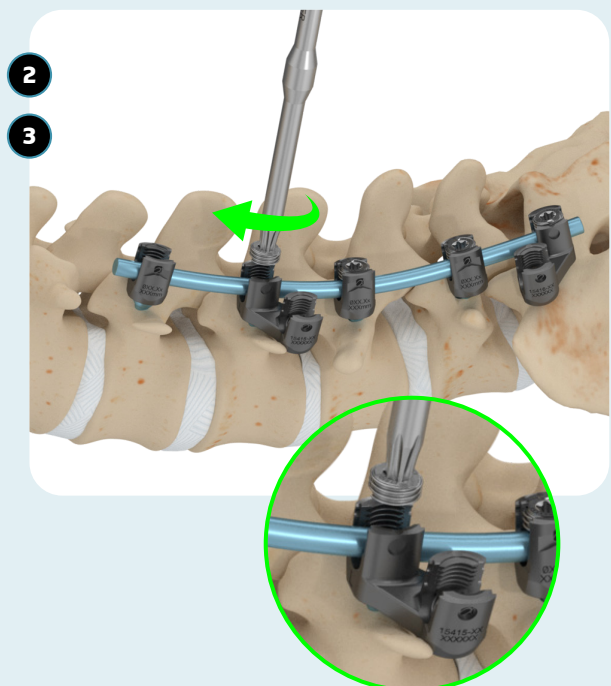
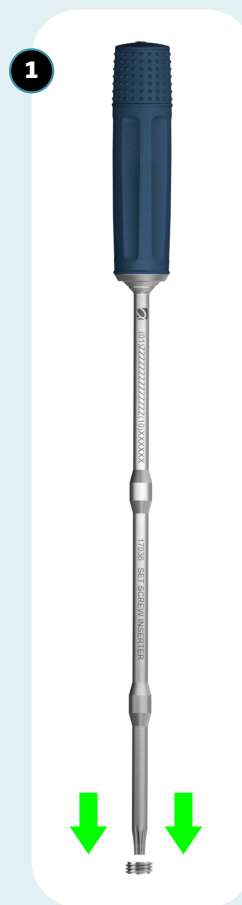
TIP: PLATE BENDERS MAY BE USED TO CREATE TIGHTER OR LARGER RADIUS BENDS AND ACCEPT BOTH 5.5 MM AND 6.0 MM DIAMETER RODS.



- 4 Grasp the rod with the Rod Gripper Junior by squeezing the handles until the rod is secured. Insert the rod into the Tulips. Follow steps on page 14 to insert Set Screws. To release, press the gold button on the proximal ratchet.



- 1** Load the T27 Set Screw directly out of the caddy by applying downward pressure with the Set Screw Inserter.
- 2** Align the alignment notch on the face of the Set Screw with the alignment notch on the Tulip.
- 3** Rotate the Set Screw Inserter clockwise to thread the Set Screw into the Tulip until bottoming out on the rod.



A variety of instruments and implants may be used to properly reduce the rod.

METHOD 1: REDUCTION TULIPS

- 1 Reduction Tulips provide 15 mm of instrument-free reduction. Follow instructions for Tulip Attachment and Tulip Insertion on page 11-12.

TIP: THE REDUCTION SCREW TAB RING CAN BE USED TO REINFORCE THE REDUCTION TULIP TABS.



- 2 Once final tightened, remove the reduction tabs using the Reduction Tab Breaker. Seat the Tab Breaker onto the tab with the numerical laser markings facing away from the Tulip. Rock the Tab Breaker away from the Tulip. Repeat on the other tab.
- 3 Slide the gold button distally to eject the broken tabs from the Reduction Tab Breaker.

TIP: THE REDUCTION TAB BREAKER CAN HOLD UP TO 8 TABS AT A TIME.

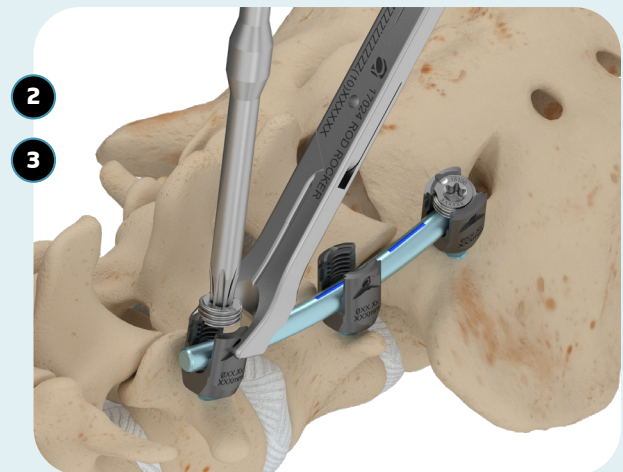


METHOD 2: ROD ROCKER

The Rod Rocker may be used to achieve up to 10 mm of reduction.

- 1 With the Rocker forceps handle in the open position, align the Rocker pins with the chevron mating feature on the medial and lateral surface of the Tulip. Squeeze the handles to lock the Rocker onto the Tulip.
- 2 Rock the handle towards the rod until the heel of the rocker contacts the rod. Continue pressing down until the rod is fully seated in the tulip.
- 3 Insert the T27 Set Screw using the Set Screw Inserter to secure the rod within the Tulip and remove the instrument by releasing the forceps.

TIP: THE HEEL OF THE ROD ROCKER WILL FIT WITHIN AN ADJACENT TULIP DURING REDUCTION.

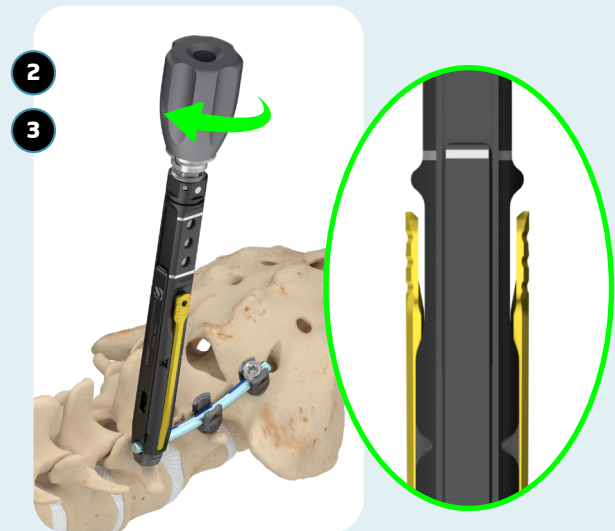


METHOD 3: AR 30

The AR 30 may be used to achieve up to 30 mm of reduction.

- 1 Attach the desired Mushroom or T Reducer Handle to the proximal end of the AR 30. Rotate the handle counterclockwise until the silver line on the reduction sleeve aligns with the proximal silver line on the housing, indicating that the Reducer is in the fully unreduced position.
- 2 Capture the rod within the mouth of the Reducer *in situ* and apply downward pressure to attach the AR 30 to the Tulip.
- 3 Rotate the Reducer Handle clockwise until the silver line on the reduction sleeve aligns with the distal silver line on the housing, indicating full reduction.
- 4 Insert the Set Screw through the AR 30's cannulation using the Set Screw Inserter and provisionally tighten. To release the Reducer, press the gold wings and pull up.

TIP: THE REDUCER ADAPTER AND RATCHETING HANDLE CAN BE USED TO APPLY MORE TORQUE AND MINIMIZE INTERFERENCE WITH ADJACENT REDUCERS.



Compression or distraction can be performed at any level to help restore proper alignment.

- 1 Confirm that the Set Screw at the motion segment is provisionally tightened and the adjacent Set Screw is loose to allow movement.

COMPRESSION

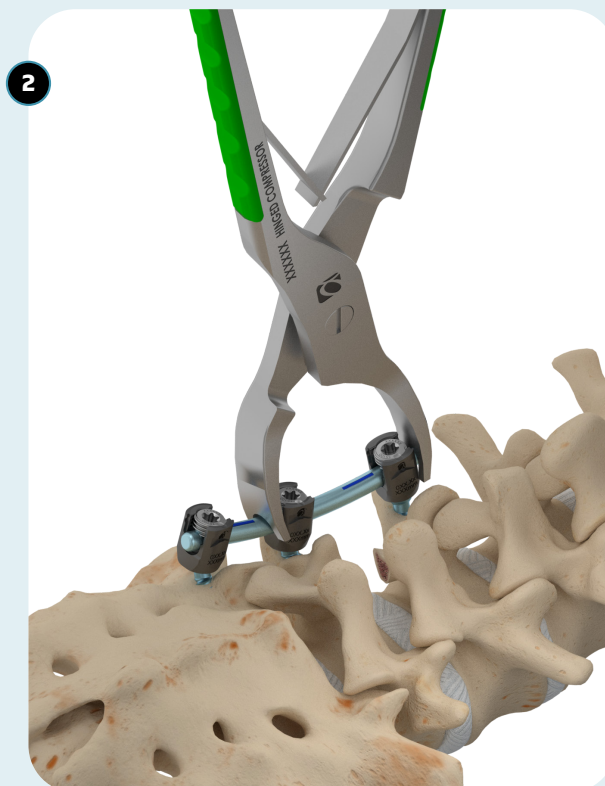
- 2 Place the Parallel or Hinged Compressor onto the rod around the desired motion segment Tulips and squeeze until desired compression is achieved.
- 3 Use the Set Screw Inserter to provisionally tighten the loose Set Screw prior to final tightening. Pull up on the ratchet bar to release the instrument.

DISTRACTION

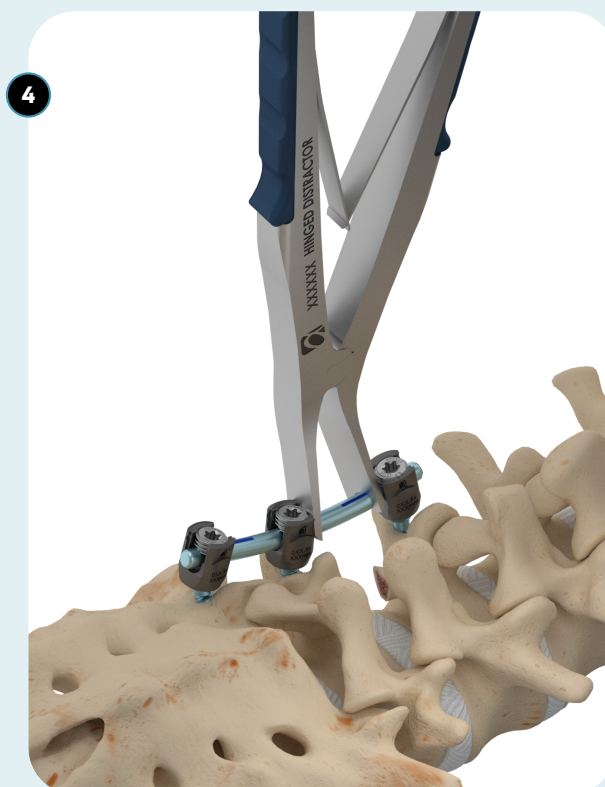
- 4 Place the Hinged Distractor onto the rod inside of the desired motion segment Tulips and squeeze until desired distraction is achieved.
- 5 Use the Set Screw Inserter to provisionally tighten the loose Set Screw prior to final tightening. Pull up on the ratchet bar to release the instrument.

CAUTION: DO NOT FINAL TIGHTEN UNDER COMPRESSION OR DISTRACTION AS THE ROD MAY NOT BE NORMALIZED TO THE TULIPS, RESULTING IN ROD SLIPPAGE.

COMPRESSION



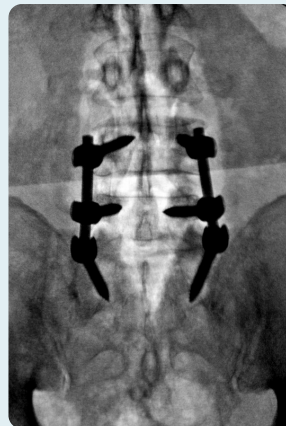
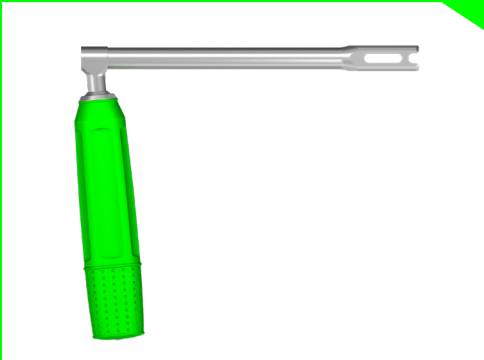
DISTRACTION



- 1 Connect the 90 inch-pound Torque-Limiting T-Handle to the Final Driver.
- 2 Seat the Counter Torque around the Tulip until secure on the rod.
- 3 Insert the Torque Driver assembly through the counter torque until it engages with the Set Screw and rotate the Torque Handle clockwise until it breaks away.

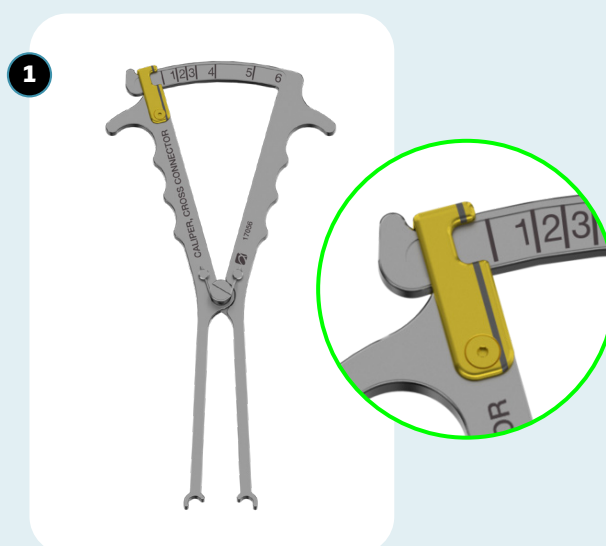
TIP: 90 IN-LB TORQUE-LIMITING HANDLE AND STANDARD COUNTER TORQUE HAVE BLACK HANDLES.

TIP: IF USING REDUCTION TULIPS, USE THE COUNTER TORQUE, CLOSED WITH A GREEN HANDLE.

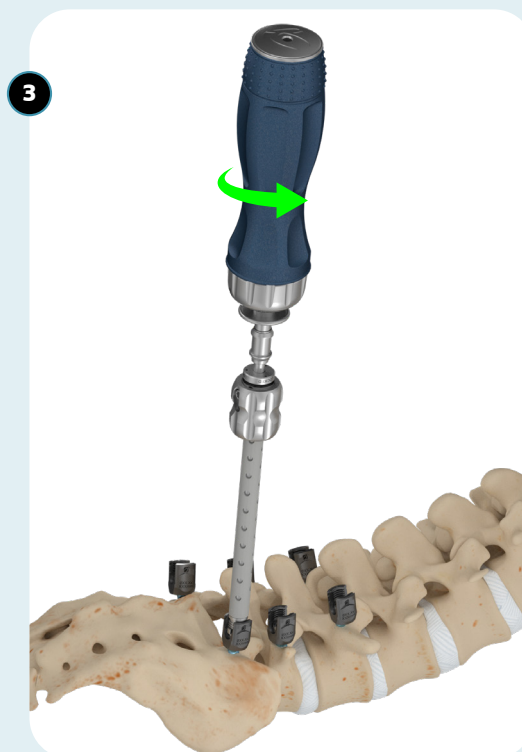
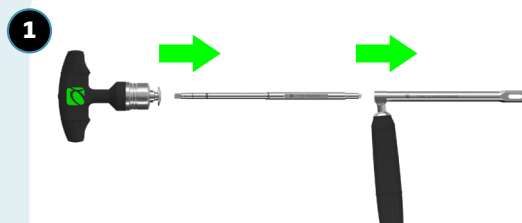


- 1 To determine the appropriate Cross Connector size, expand then seat the Cross Connector Caliper on bilateral rods. Select the Connector size based on the number that appears in the gold bracket of the Caliper.
- 2 With the Connector in the caddy, firmly press the Cross Connector Inserter into either lateral integrated gold Set Screw.
- 3 Seat the free side of the Connector onto one rod and use the Inserter to span to the opposite rod. Rotate the Inserter Handle clockwise to provisionally tighten all integrated gold Set Screws.
- 4 To final tighten, connect the 40 inch-pound Torque-Limiting T-Handle to the Cross Connector Final Driver.
- 5 Seat the Cross Connector Counter Torque over each Set Screw making sure that the Set Screw is fully encapsulated.
- 6 Insert the Torque Driver assembly through the Counter Torque until it engages with the Set Screw and rotate the Torque Handle clockwise until it breaks away. Final tighten both lateral Set Screws before final tightening the medial Set Screw.

TIP: GOLD SET SCREWS INDICATE A 40 IN-LB TORQUE VALUE AND ALL 40 IN-LB TORQUE LIMITING INSTRUMENTS HAVE LIGHT GREY HANDLES.



- 1 To remove hardware, connect the 90 inch-pound Torque-Limiting T-Handle to the T27 Final Driver. Seat the Final Driver into the Set Screw and rotate counterclockwise until the Set Screw is fully unthreaded. Remove each Set Screw.
- 2 With all Set Screws removed, remove the rods.
- 3 Seat a Polyaxial Screwdriver into the T25 Shank hex. Rotate the Screwdriver thumbwheel clockwise until it bottoms out. Once fully tightened, slide the thumbwheel distally until the black laser-marked line is visible, indicating that the secondary lock is engaged. Rotate the Screwdriver counterclockwise until the Screw is removed.



INVICTUSTM

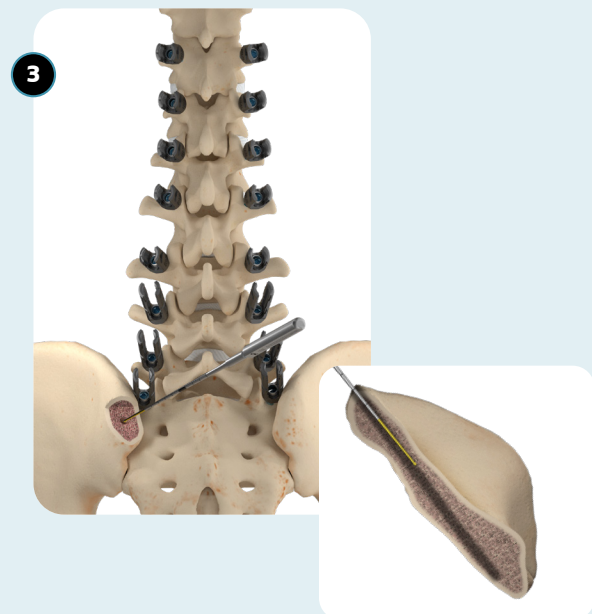
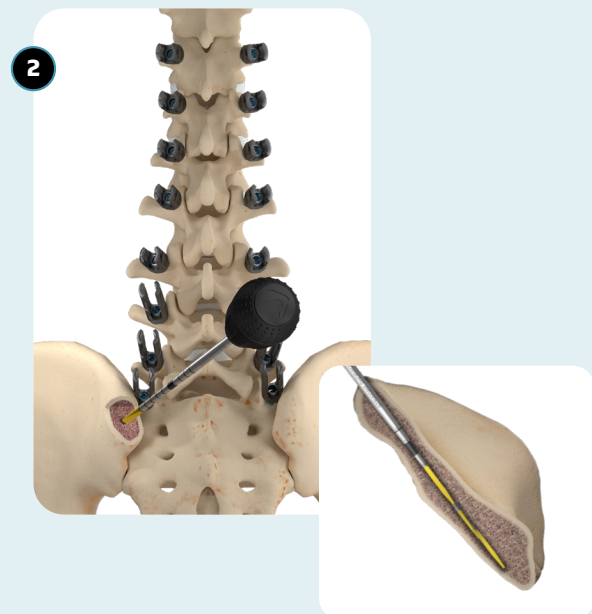
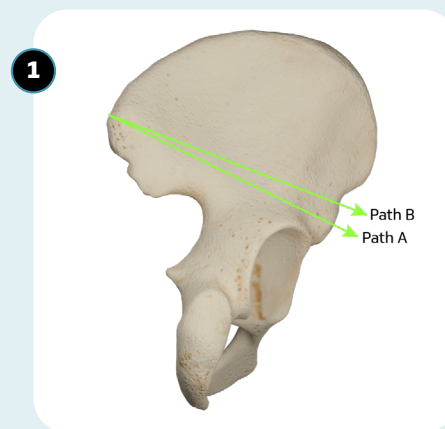
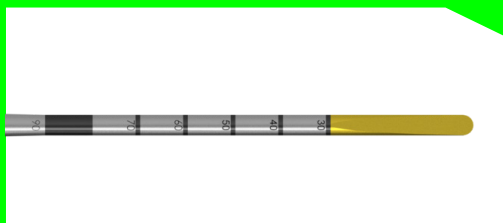
SPINAL FIXATION SYSTEM



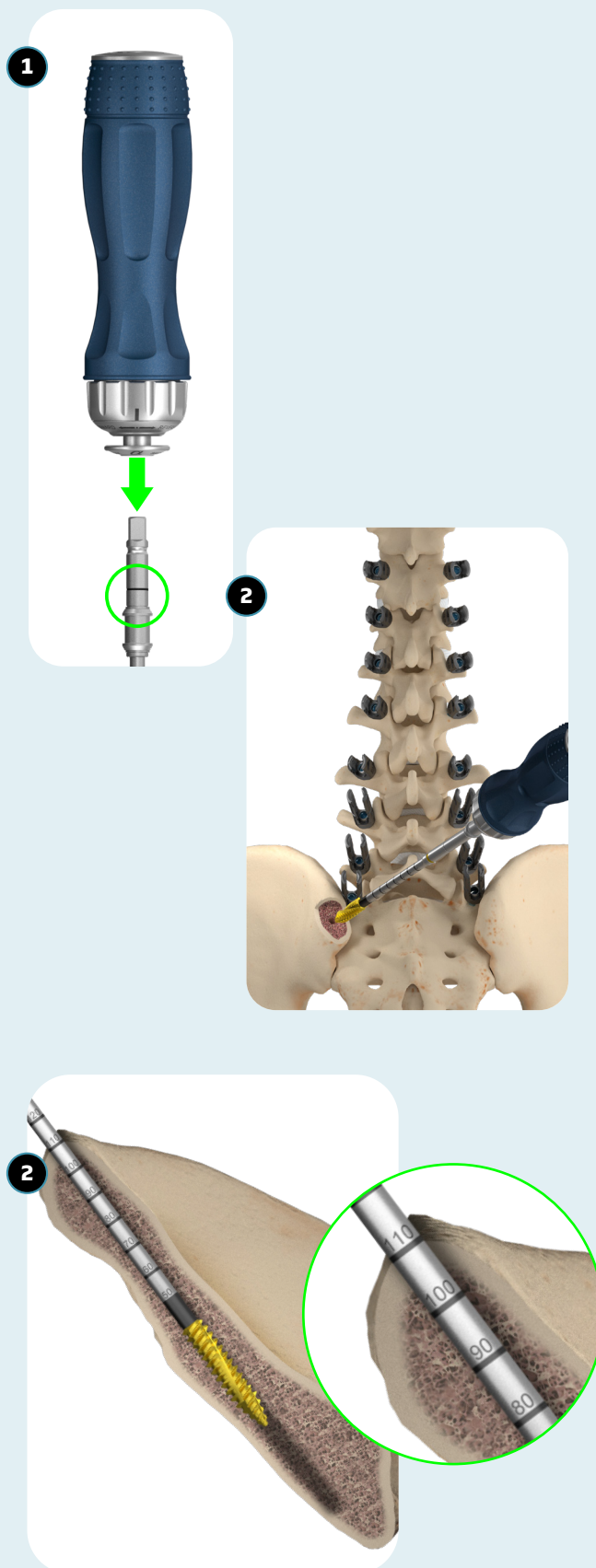
ADVANCED APPLICATIONS

- 1 If Iliac fixation is desired, resect bone from the posterior superior iliac spine (PSIS). Use a high-speed burr or rongeur to create a starting point in the crest.
- 2 Use the Iliac Probe to create a pilot hole aiming 25° lateral and 30° caudal towards the anterior inferior iliac spine (AIIS) to the desired depth (Path B). Path A shows a trajectory from the PSIS to the superior rim of the acetabulum.
- 3 The Rigid Ball Tip Probe can be used to palpate pilot hole integrity.

TIP: ILIAC PROBES AND RIGID BALL TIP PROBES HAVE A 30 MM GOLD TIP AND A BLACK BAND FROM 80 MM – 90 MM.

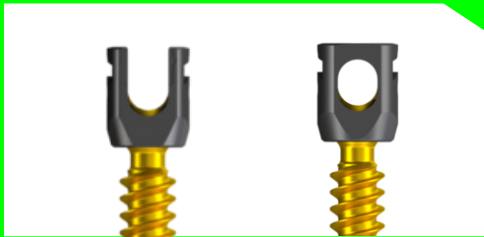


- 1** If tapping is preferred, attach the desired Ratcheting Handle to the appropriate diameter Tap. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Tap.
- 2** Set the Ratcheting Handle to the “Forward” position and rotate clockwise to advance into the ilium. Reference the numerical markings on the distal end of the Tap shaft to determine depth in bone.

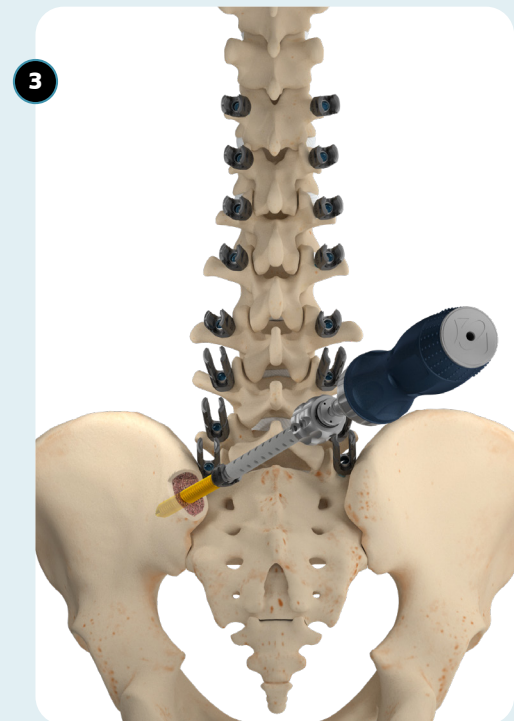
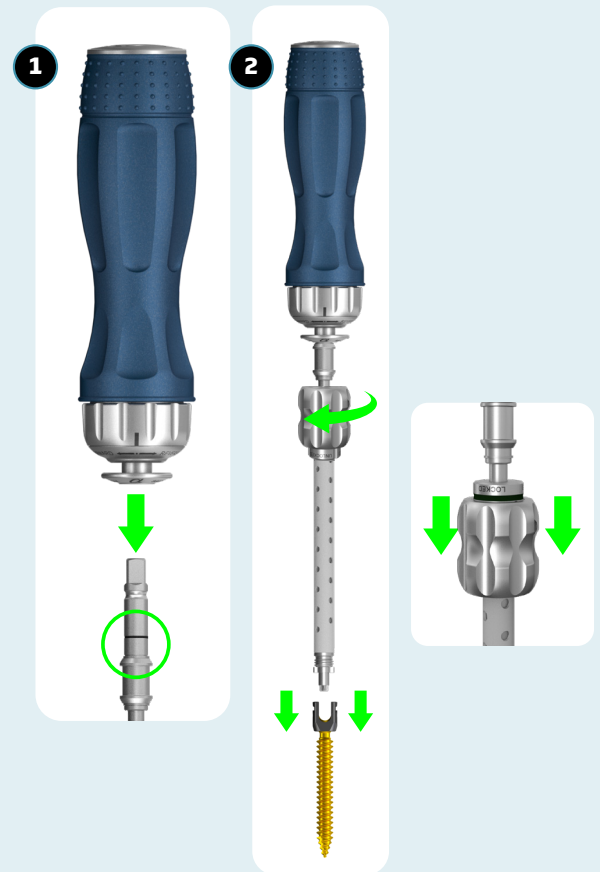


- 1 Attach the desired ratcheting Handle to the Polyaxial Screwdriver, Locking. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Driver.
- 2 Insert the distal tip of the Driver into the desired size Polyaxial Iliac Screw and rotate the thumbwheel clockwise until it bottoms out. Slide the thumbwheel distally until the black "LOCKED" laser-marked line is visible, indicating that the secondary lock is engaged.

TIP: THE POLYAXIAL SCREWDRIVER, LOCKING IS COMPATIBLE WITH BOTH STANDARD POLYAXIAL ILIAC SCREWS AND CLOSED POLYAXIAL ILIAC SCREWS.



- 3 Insert the Screw into the Ilium and rotate the Ratcheting Handle clockwise to advance.
- 4 Once the desired Screw depth is achieved, unlock the Driver by pulling up on the thumbwheel and rotating the thumbwheel counterclockwise.

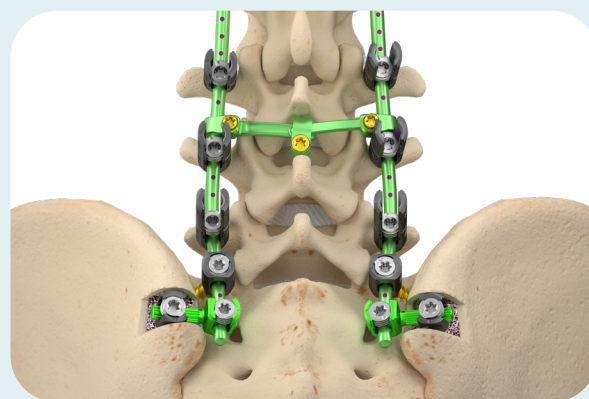


- 5 Confirm Screw placement using fluoroscopic imaging.
- 6 Open or Closed Iliac Connectors accept 5.5, 6.0, and 6.35 mm rods and may be used to connect Iliac Screws to the rod.

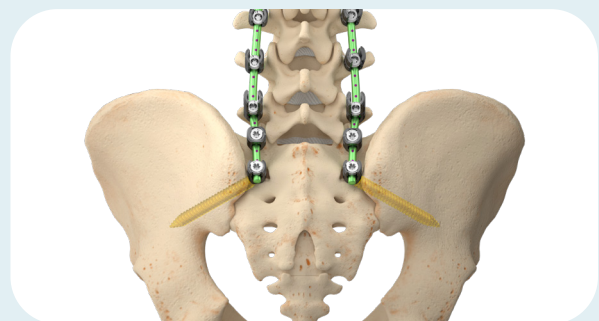
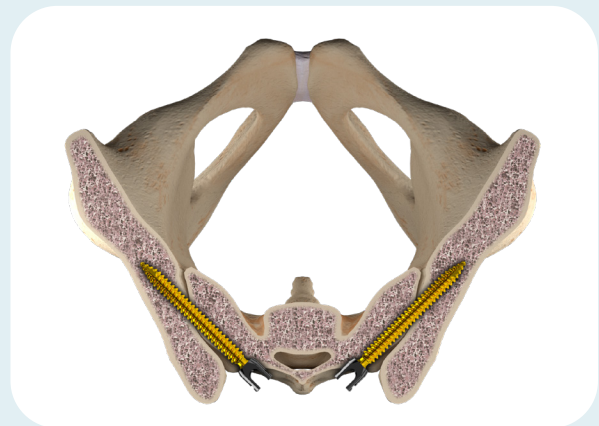
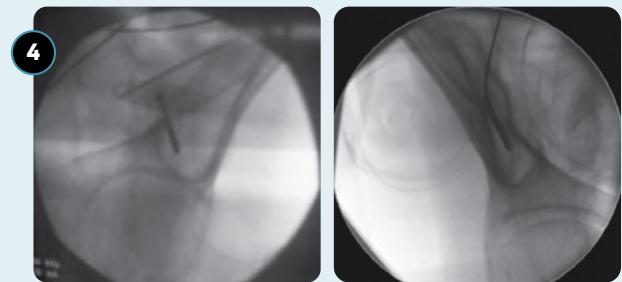
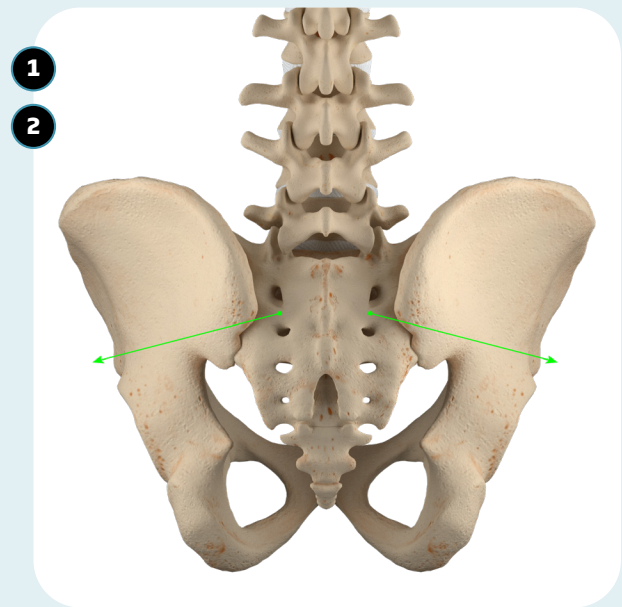
TIP: OPEN ILIAC CONNECTORS USE STANDARD INVICTUS T27 SET SCREWS. CLOSED ILIAC CONNECTORS HAVE AN INTEGRATED CLOSED SET SCREW. BOTH ARE FINAL TIGHTENED WITH THE STANDARD FINAL DRIVER AND 90 INCH-POUND TORQUE LIMITING T-HANDLE.

CAUTION: AN ILIAC CONNECTOR MUST BE FINAL TIGHTENED BEFORE AN ILIAC SCREW TO ALLOW FOR PROPER SEATING OF THE ROD.

6

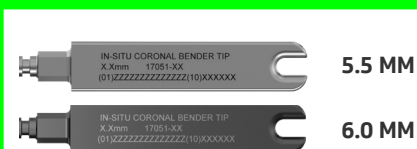


- 1 If S2-iliac fixation is desired, resect bone from the PSIS to expose S1 and S2 foramina, as the starting point will be inline with the S1 screw.
- 2 Locate the intersection between the S1 and S2 dorsal foramina and the lateral border of the foramen. Using a high-speed burr or Iliac Probe, create a pilot hole aiming for the AILS, which can be found by palpating the top of the greater trochanter. Adjust the probe as needed to maintain a 20-30° caudal trajectory and 40-50° horizontal trajectory.
- 3 The Rigid Ball Tip Probe can be used to palpate pilot hole integrity.
- 4 Verify under fluoroscopy that the trajectory passes above the sciatic notch and towards the iliac teardrop.
- 5 If tapping is preferred, follow steps on page 24.
- 6 For Screw placement, follow steps on page 25-26.
- 7 Confirm Screw placement using fluoroscopic imaging.



If *in situ* rod bending is required, Sagittal and Coronal Benders may be used. Both Benders use modular handles and tips.

TIP: TIPS ACCEPTING 5.5 MM DIAMETER RODS ARE SILVER. TIPS ACCEPTING 6.0 MM DIAMETER RODS ARE BLACK.

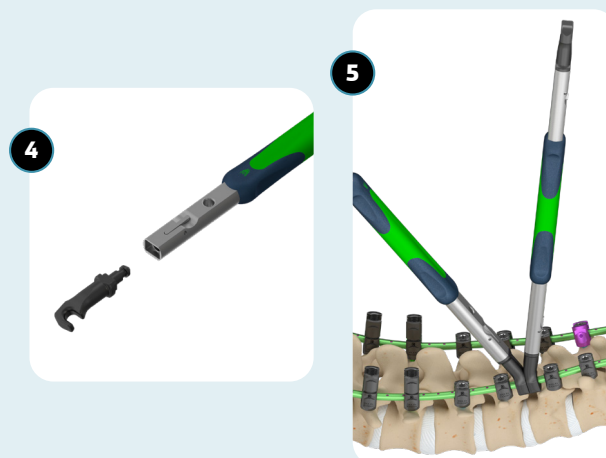
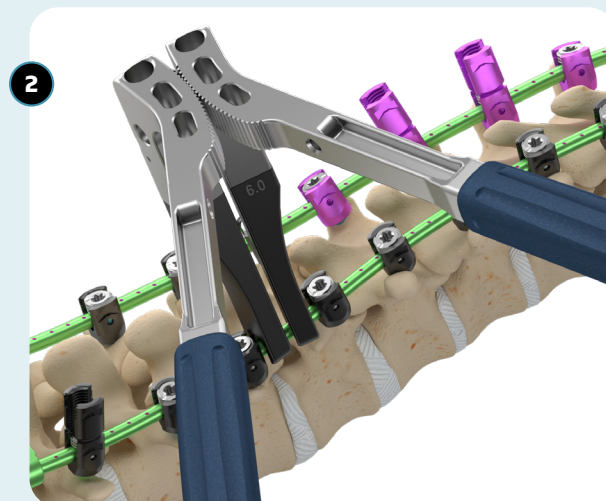


METHOD 1: CORONAL BENDING

- 1 Insert the appropriate Coronal Bender Tips into the Coronal Bender Handles with the “α” logo facing outward.
- 2 Seat the Benders onto the rod and compress the handles together or rotate the handles apart to achieve the desired coronal bend.
- 3 If bending over multiple levels, use the Coronal Bender Link to create a fulcrum. To adjust the length of the Link, press the “α” button on the side with variability and slide to desired length.
- 4 Press the “α” button on the top of each side of the Link and insert the pins into the hole on each Bender.

METHOD 2: SAGITTAL BENDING

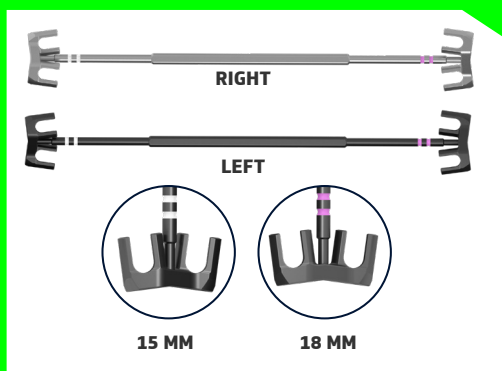
- 5 Insert the appropriate Sagittal Bender Tips into the Sagittal Bender Body by clicking into place.
- 6 Seat either the angled or straight end of the Bender onto the rod. Compress the Bender Bodies together to achieve lordosis or pull the Bender Bodies away from one another to achieve kyphosis.



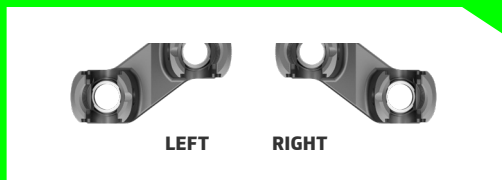
If a tertiary or quad rod construct is desired to increase the stability of a long construct, a Modular Satellite Connector may be used in lieu of a Modular Polyaxial Tulip.

- 1 With all Shanks in place, determine the preferred levels for the Satellite Connectors.
- 2 To determine adequate rod-to-rod distance and satellite Tulip orientation, select the Modular Satellite Connector Trial. Firmly press one end of the Trial onto the Shank head *in situ*.
- 3 Repeat Step 2 at all levels where a Satellite Connector is desired.

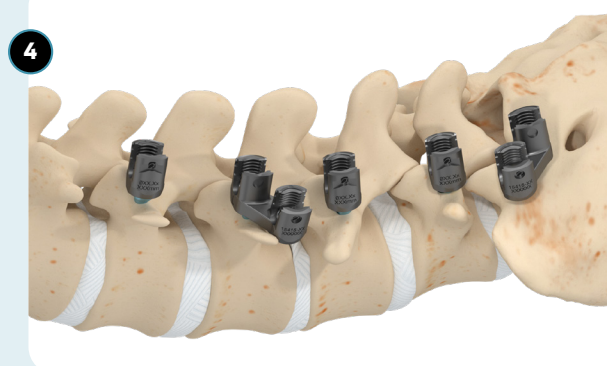
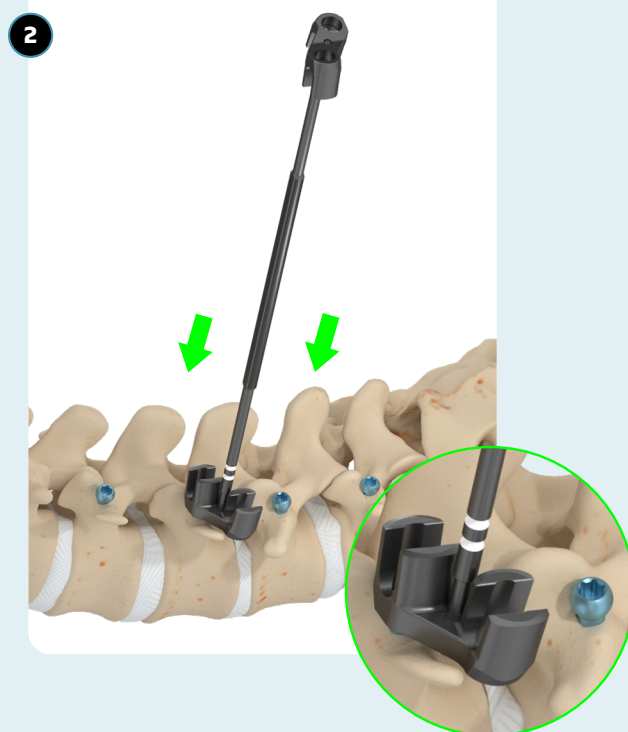
TIP: MODULAR SATELLITE CONNECTOR TRIALS ARE COLORED TO DENOTE LEFT AND RIGHT ORIENTATION AND ROD-TO-ROD DISTANCE. THE RIGHT TRIAL IS SILVER AND THE LEFT TRIAL IS BLACK. THE 15 MM END IS IDENTIFIABLE BY WHITE COLOR BANDS AND THE 18 MM END IS IDENTIFIABLE BY PINK COLOR BANDS.



TIP: MODULAR SATELLITE CONNECTORS ARE NOT SIDE SPECIFIC. "RIGHT" AND "LEFT" INDICATE A DOWNWARD ORIENTATION OF THE LATERAL TULIP BUT CAN BE USED ON EITHER SIDE OF THE CONSTRUCT.

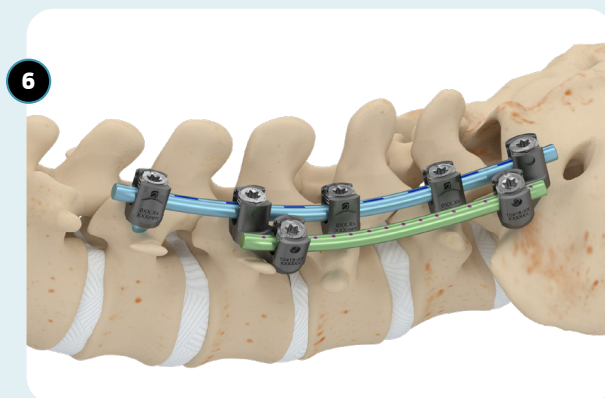
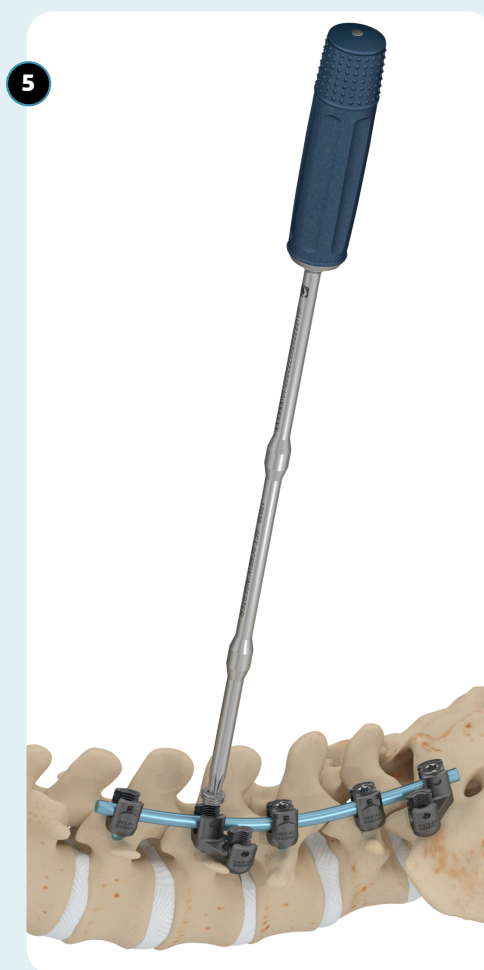


- 4 Once the desired Satellite Connector is determined, follow instructions for Tulip Attachment and Tulip Insertion on page 11-12.



- 5 Seat the desired rod into the Connector's medial Tulips in-line with the rest of the construct. Using the Set Screw Inserter, seat all Set Screws until provisionally tightened.
- 6 Seat the tertiary or quad rod into the Connector's lateral Tulips. Using the Set Screw Inserter, seat the Set Screw until provisionally tightened.

TIP: THE AR 30 REDUCER AND COUNTER TORQUE ARE COMPATIBLE WITH BOTH SATELLITE CONNECTOR TULIPS.



INVICTUS MODULAR IMPLANTS - VOMODIM	
Part Number	Product Description
15704-045-025	Modular Screw Shank, 4.5 mm X 25 mm
15704-045-030	Modular Screw Shank, 4.5 mm X 30 mm
15704-045-035	Modular Screw Shank, 4.5 mm X 35 mm
15704-045-040	Modular Screw Shank, 4.5 mm X 40 mm
15704-045-045	Modular Screw Shank, 4.5 mm X 45 mm
15704-055-030	Modular Screw Shank, 5.5 mm X 30 mm
15704-055-035	Modular Screw Shank, 5.5 mm X 35 mm
15704-055-040	Modular Screw Shank, 5.5 mm X 40 mm
15704-055-045	Modular Screw Shank, 5.5 mm X 45 mm
15704-055-050	Modular Screw Shank, 5.5 mm X 50 mm
15704-055-055	Modular Screw Shank, 5.5 mm X 55 mm
15704-065-030	Modular Screw Shank, 6.5 mm X 30 mm
15704-065-035	Modular Screw Shank, 6.5 mm X 35 mm
15704-065-040	Modular Screw Shank, 6.5 mm X 40 mm
15704-065-045	Modular Screw Shank, 6.5 mm X 45 mm
15704-065-050	Modular Screw Shank, 6.5 mm X 50 mm
15704-065-055	Modular Screw Shank, 6.5 mm X 55 mm
15704-075-035	Modular Screw Shank, 7.5 mm X 35 mm
15704-075-040	Modular Screw Shank, 7.5 mm X 40 mm
15704-075-045	Modular Screw Shank, 7.5 mm X 45 mm
15704-075-050	Modular Screw Shank, 7.5 mm X 50 mm
15704-075-055	Modular Screw Shank, 7.5 mm X 55 mm
15704-085-035	Modular Screw Shank, 8.5 mm X 35 mm
15704-085-040	Modular Screw Shank, 8.5 mm X 40 mm
15704-085-045	Modular Screw Shank, 8.5 mm X 45 mm
15704-085-050	Modular Screw Shank, 8.5 mm X 50 mm
15704-085-055	Modular Screw Shank, 8.5 mm X 55 mm
15004-065-040	Polyaxial Screw, 6.5 mm X 40 mm
15004-065-045	Polyaxial Screw, 6.5 mm X 45 mm
15004-065-050	Polyaxial Screw, 6.5 mm X 50 mm
17511	Modular Shank and Polyaxial Screw Caddy
15600	Modular Polyaxial Tulip
17504	Modular Polyaxial Tulip Caddy
15610	Modular Polyaxial Reduction Tulip
17512	Modular Polyaxial Reduction Tulip Caddy
15100	Set Screw
17201	Set Screw Caddy

INVICTUS MODULAR IMPLANTS - VOMODIM	
Part Number	Product Description
15415-15	Modular Satellite Rod Connector, Left, 15 mm
15416-15	Modular Satellite Rod Connector, Right, 15 mm
15415-18	Modular Satellite Rod Connector, Left, 18 mm
15416-18	Modular Satellite Rod Connector, Right, 18 mm
15400-11	Open-Open Revision Connector, 11 mm
15400-5	Open-Open Revision Connector, 15 mm
15400-18	Open-Open Revision Connector, 18 mm
17510	Modular Connector Caddy
17442	Modular Satellite Rod Connector Trial, Left
17441	Modular Satellite Rod Connector Trial, Right
15210-55-30	Ti Lordotic Rod, 5.5 mm X 30 mm
15210-55-35	Ti Lordotic Rod, 5.5 mm X 35 mm
15210-55-40	Ti Lordotic Rod, 5.5 mm X 40 mm
15210-55-45	Ti Lordotic Rod, 5.5 mm X 45 mm
15210-55-50	Ti Lordotic Rod, 5.5 mm X 50 mm
15210-55-55	Ti Lordotic Rod, 5.5 mm X 55 mm
15210-55-60	Ti Lordotic Rod, 5.5 mm X 60 mm
15210-55-65	Ti Lordotic Rod, 5.5 mm X 65mm
15210-55-70	Ti Lordotic Rod, 5.5 mm X 70 mm
15210-55-80	Ti Lordotic Rod, 5.5 mm X 80 mm
15210-55-90	Ti Lordotic Rod, 5.5 mm X 90 mm
15210-55-100	Ti Lordotic Rod, 5.5 mm X 100 mm
15210-55-110	Ti Lordotic Rod, 5.5 mm X 110 mm
15210-55-120	Ti Lordotic Rod, 5.5 mm X 120 mm
15210-55-130	Ti Lordotic Rod, 5.5 mm X 130 mm
17215	Invictus Ti Lordotic Rod Caddy, 5.5 mm
15200-55-300	Ti Straight Rod, 5.5 mm X 300 mm
15202-55-300	CoCr Straight Rod, 5.5 mm X 300 mm
15200-60-300	Ti Straight Rod, 6.0 mm X 300 mm
15202-60-300	CoCr Straight Rod, 6.0 mm X 300 mm

INVICTUS MODULAR INSTRUMENTS - VOMODIN	
Part Number	Product Description
17410	MOD Shankdriver
17402	Tulip Inserter
17412	Reduction Tulip Inserter
16403	Reamer
17038	Reduction Tab Breaker
17404	Modular Compressor/Distractor Rack
17406-ML	Modular Screw Tip, Medial-Lateral
17406-CC	Modular Screw Tip, Cranial-Caudal
17407	Modular Lamina Tip
17462-R	Modular Shank Tip 15°, Right
17462-L	Modular Shank Tip 15°, Left

Invictus® Spinal Fixation System INSTRUCTIONS FOR USE

GENERAL INFORMATION:

The Invictus Spinal Fixation System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The Invictus Spinal Fixation System consists of a variety of shapes and sizes of rods, screws, hooks, connectors, and cross connectors that provide internal fixation and stabilization during bone graft healing and/or fusion mass development. The screws, hooks, connectors, and cross connectors are manufactured from surgical grade titanium alloy (Ti-6Al-4V ELI). The rods are available in commercially pure titanium (CP Ti Grade 4), titanium alloy (Ti-6Al-4V ELI), and cobalt chrome (Co-28Cr-6Mo). The instruments in this system are intended for use in surgical procedures.

The Invictus Patient-Specific Rods are designed and manufactured to the surgeon's plan based on the patient's anatomy. The Invictus Patient Specific Rods shall not be used on any other patient.

If additional levels of fixation are required, the Invictus Spinal Fixation System rods may be used in conjunction with Invictus® OCT Spinal Fixation System, and with Solanas® Posterior System. The Invictus Cross Connectors accept various rod diameters and are appropriate for use with Alphatec Spine's 5.5 mm diameter rod-based systems, including the Arsenal® Spinal Fixation System and the Zodiac® Spinal Fixation System.

Invictus Bone Cement for use with Invictus fenestrated screws is a self-hardening and ready to use polymethylmethacrylate (PMMA) bone cement with a high amount of radiopaque agent. The cement is made of two sterile components: the polymer in powder and the liquid monomer. The liquid component is mainly composed of methyl methacrylate. The major powder components are polymethylmethacrylate, methyl methacrylate, and zirconium dioxide. Benzoyl peroxide, which initiates polymerization, is included in the polymer powder. The powder and liquid monomer are in a double sterile packaging. Each unit contains a sterile ampoule of liquid within a blister pack and a powder within a double peelable pouch, the whole being packaged in a box.

Refer to the Invictus Bone Cement Instructions for Use for information related to the cement, and the Invictus Operating Procedure for information related to cement mixing and injection.

INDICATIONS FOR USE:

The Invictus Spinal Fixation System is intended for non-cervical posterior and anterolateral fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Invictus Spinal Fixation System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Invictus Spinal Fixation System is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis / spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. Pediatric pedicle screw fixation is limited to a posterior approach.

The Invictus Spinal Fixation System is intended to be used with autograft and/or allograft.

Invictus Si.CORE Screws are intended to be used with Invictus rods for sacroiliac joint fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Invictus Core and Invictus Si.CORE Screws are not intended for use with cement; all other fenestrated screws may be used with Invictus Bone Cement. When used in conjunction with Invictus Bone Cement, the Invictus Fenestrated Screws are 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Invictus Fenestrated Screws augmented with Invictus Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

CONTRAINDICATIONS:

The system is contraindicated for:

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

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 instruments marked as sterile, are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU.
3. The following statements apply to single use sterile instruments:
 - 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. 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.
5. 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.

6. The safety and effectiveness of the Invictus Core/Si.CORE Screws has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). Invictus Core and Invictus Si.CORE Screws are not intended for use with cement, saline, or radiopaque dye; all other fenestrated screws may be used with cement, saline, or radiopaque dye.
7. When use of Si.CORE screws is intended for fusion, women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following Si joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
8. 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.
9. 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.
10. The instruments in the Invictus Spinal Fixation System are reusable surgical devices except for the Fascial Blades, SingleStep™ Stylets, Targeting Needle Stylets, Sterile Drills, Cement Delivery Cannula, and Guidewires used with the Invictus Spinal Fixation System, which are single use only. Single-use instruments are disposable devices, designed for single use and should not be re-used or re-processed. Reprocessing of single-use instruments may lead to instrument damage and possible improper function.
11. Do not comingle titanium and stainless steel components within the same construct.
12. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 segment, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
13. Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and other 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.
14. 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.
15. 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.
16. 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.
17. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines. 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.
18. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
19. To prevent Guidewire breakage, do not use a kinked or bent Guidewire.
20. Guidewires should be monitored using fluoroscopic imaging to avoid advancement through the vertebral body in order to prevent damage to underlying structures.
21. The SingleStep stylet should be monitored using fluoroscopic imaging to prevent advancement through the vertebral body in order to prevent damage to underlying structures.
22. Verify superior and inferior rod overhang. Inadequate overhang may cause improper set screw placement resulting in an unstable construct.
23. Do not final tighten under compression or distraction as the rod may not be normalized to the tulips, resulting in rod slippage.
24. Care should be taken when disengaging the SingleStep assembly after screw insertion. Avoid the sharp end of the stylet protruding from the screwdriver tip. Properly dispose of sharps after use.
25. Inability to identify the entirety of each VI Rod through-hole with fluoroscopy may cause improper Set Screw placement or inadequate rod overhang, resulting in an unstable construct.
26. Inability to identify Lipped Rod lip positioning against the Tulip may cause improper set screw placement or inadequate rod overhang, resulting in an unstable construct.
27. If using standard Invictus MIS Lordotic Rods (15230-XX-XXX) or VI2 Rods (15295-XX-XXX), do not uncross the Towers during Set Screw insertion prior to final tightening, as this may result in improper rod normalization and may lead to rod slippage.
28. Failure to verify that the Modular Tulip is secured to the Modular Shank could compromise the mechanical stability of the construct.
29. Failure to tighten set screws using the recommended instrument(s) could compromise the mechanical stability of the construct.
30. To prevent implant damage, do not mallet on the Tulip Insertter to seat a Modular Tulip onto a Modular Shank.
31. Failure to reset the Tulip Insertter prior to Tulip attachment will result in a prematurely deployed Tulip and therefore an unstable construct.
32. An Iliac Connector must be final tightened before an Iliac Screw to allow for proper seating of the rod.
33. Care must be taken when handling the Hook Blade as the distal blade has a sharp tip and inner cutting surface.
34. When using pivoting connectors to extend a construct, failure to use either two pivoting connectors or one pivoting and one static connector per side may result in an unstable construct.
35. Pedicle screws and rod-to-rod connectors cannot be used on the tapered section of transition rods. If using pedicle screws and rod-to-rod connectors with transition rods, only attach them on constant diameter rod sections.
36. Due to the mechanical advantage of the C/D Rack, care must be taken during instrument use. Use slow and controlled compression or distraction when using the C/D Rack.
37. Set Screws must not be final tightened during any derotation, compression/distraction, or in-situ bending maneuvers.
38. The Favored Angle and Favored Angle CORE/Si.CORE screws are compatible with the T27 Screwdriver (PN: 17950-225). Do not use the T25 Screwdriver (PN: 17110) with the Favored Angle

and Favored Angle CORE/Sl.CORE screws.

39. Controlled cement delivery is essential to proper screw augmentation. Overly aggressive cement injection may result in cement leakage and unsatisfactory results. Immediately stop cement injection if extravasation is detected.
40. Prior to injection of the Invictus Bone Cement into the Invictus Fenestrated Screws, it is important to radiographically confirm the proper positioning of each screw using AP and lateral fluoroscopy. Invictus Bone Cement injection should only be performed under fluoroscopic control. Once Invictus Bone Cement has been injected, the position of the Invictus Fenestrated Screws cannot be modified. Verify that the fenestrated tips of all Fenestrated Screws are within the vertebral body and not beyond the anterior cortex or in the pedicle.
41. If cement leakage is detected during injection, stop the injection. Back off pressure of delivery system to stop flow of Invictus Bone Cement prior to removal of delivery cannula from screw.
42. Manipulation of the cement-augmented Invictus Fenestrated Screws, such as rod reduction, compression, distraction, and final tightening, must not be performed until after the setting time of the Invictus Bone Cement.
43. Do not attempt to force the injection of cement if excessive resistance is felt. Determine the cause of the resistance and use a new cement package, if necessary.
44. Failure to confirm the Auto Alignment Guide properly covers the proximal laser marked line of the Quick Connect Tower will result in misalignment with the fenestrated screw shank, the inability for the cement Delivery Cannula to pass through the Guide, and unsuccessful delivery of the cement. Confirm the red epoxy band is not present on the Guide prior to cement delivery through the cement Delivery Cannula.
45. Failure to confirm the manual Alignment Guide is properly threaded into the screw tulip will result in misalignment with the fenestrated screw shank, the inability for the Cement Delivery Cannula to pass through the Guide, and unsuccessful delivery of cement. Confirm the green epoxy band is present on the Guide prior to cement delivery through the cement Delivery Cannula.
46. When using cement to augment multiple screws or levels, attention must be paid not to exceed the working time of the cement prior to completion of cement delivery through the screw. When the cement working time is close to completion, a new cement package should be opened to mix and deliver cement through the next screw/level(s).
47. After cement introduction is complete, immediately remove the Delivery Cannula to avoid cement setting and difficulty in removal.
48. Monitor injection gun cement volume during use. Discontinue use once volume reaches less than 1 cc. If additional cement is required, open and prepare a new Invictus Spinal Cement System kit.
49. Cement must only be injected into a fully assembled fenestrated screw. Injecting cement directly into a fenestrated shank without tulip may result in cement leakage and unsatisfactory results.
50. Care must be taken during use of the Over Tulip Reamer. Use a non-powered handle to manually rotate the Over Tulip Reamer for controlled removal of bony anatomy surrounding the tulip.
51. Failure to tap line-to-line when using cortical thread screws may result in pedicle fracture.
52. Each Invictus Patient-Specific Rod is intended for a specific patient and must not be used for another patient. If the Invictus Patient-Specific Rod does not perform as intended, alter the rod as necessary or use a standard Invictus rod to complete the surgery.
53. The Invictus Patient-Specific Rod is designed for a specific patient. Any modifications of the patient anatomy can reduce the fit with patient vertebrae. The patient should be surveyed for potential anatomical changes prior to performing surgery.

MRI SAFETY INFORMATION:

The Invictus 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 Spinal Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POSSIBLE ADVERSE EFFECTS:

The following complications and adverse reactions have been shown to occur with the use of similar spinal instrumentation. These effects and any other known by the surgeon must be discussed with the patient preoperatively.

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, seroma, 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
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 and/or sacral 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

POSSIBLE ADVERSE EFFECTS RELATED TO FENESTRATED SCREWS WITH CEMENT:

1. Cement leakage
2. Cement embolism
3. Cement-related cardiopulmonary complications
4. Tissue necrosis from cement heat
5. Difficulty with screw or cement removal

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.
4. The Invictus Patient-Specific Rod is designed from patient imaging data (X-ray, CT, MRI). The patient anatomy may change over time. We recommend using imaging data that are less than 6 months old. For tumoral cases, imaging data must be less than one month old. The surgeon is responsible for determining if the device is adequately pre-contoured for the patient anatomy. 5. If using Invictus Patient-Specific Rods, prior to implantation, confirm the Patient ATEC ID on the rod matches the Patient ATEC ID on the label.

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.

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 graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
5. Final tightening of Set Screws: All Set Screws must be tightened using the appropriate instruments (e.g., Torque Handle, Final Driver, and Counter Torque) as indicated in the Surgical Technique Guide.
6. During Guidewire placement, it is recommended to frequently use alternate imaging planes. Ideally, an A-P, lateral, and oblique view should be taken at all critical steps during the procedure to confirm proper positioning and alignment, and to prevent kinking or breakage of the devices.
7. It is recommended that a maximum of 1cc of Invictus Bone Cement be injected in the vertebral body for each screw in the thoracic spine (except T11 and T12) and that a maximum of 2 cc of Invictus Bone Cement be used in T11, T12, and the lumbar spine. However, the injected volume of cement and Invictus Fenestrated screw size should be selected based on individual patient anatomy, as different screws may be applicable for different vertebral levels.
8. If SI joint fusion is desired, two SI.CORE screws should be placed across the SI joint in sacral alar iliac trajectories.

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 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. Implant devices should be revised or removed if bent, dislocated, or broken.
4. Immobilization should be considered in order to prevent bending, dislocation, or breakage of the implant device in the case of delayed, mal-union, or non-union of bone. Immobilization should continue until a complete bone fusion mass has developed and been confirmed.
5. Postoperative patients should be instructed not to use tobacco or nicotine products, consume alcohol, or use non-steroidal anti-inflammatory drugs and aspirin, as determined by the surgeon. Complete postoperative management to maintain the desired result should also follow implant surgery.

Excerpt from INS-111



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



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