

INVICTUS

SPINAL FIXATION SYSTEM

SURGICAL TECHNIQUE GUIDE



INVICTUS SURGICAL TECHNIQUE

Table of Contents

OPEN Surgical Technique

Pedicle Preparation	2
Screwdriver Assembly	2
Screw Insertion	3
Hook Insertion	4
Rod Preparation	5
Rod Reduction	5
Set Screw Insertion	7
Rod Contouring	8
Compression and Distraction	9
Final Tightening	9
Cross Connector Insertion	10
Rod to Rod Connector Insertion	11
Implant Removal	13
Instructions For Use	14

STEP ONE: PEDICLE PREPARATION

Create a pilot hole in the pedicle at the junction of the transverse process and the superior articular process. Use a pedicle probe to complete the cannulation of the pedicle. A ball tip probe can be used to palpate the pedicle wall (**Figure 1**).



Figure 1

Select the appropriate diameter tap, and insert it into the pedicle until the desired depth is achieved. A ball tip probe can be used to palpate the pedicle wall.

STEP TWO: SCREWDRIVER ASSEMBLY

Connect a ratcheting axial or T handle to the proximal end of the Screwdriver, until the handle covers the black laser marked line. Insert the Screwdriver into the screw and rotate the thumbwheel clockwise, until it bottoms out (**Figure 2**). Once fully tightened, slide the thumbwheel collar distally until a black laser-marked line appears, indicating that the Screwdriver is locked to the screw.

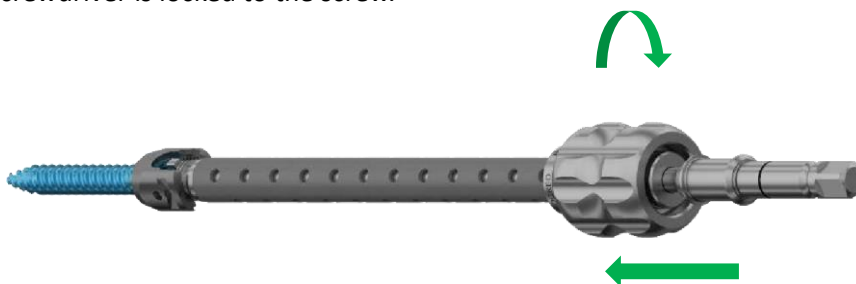


Figure 2

TIP: Screwdrivers are denoted by color. Gray Screwdrivers are designed to be used with the polyaxial, closed, and uniplanar screws. Black Reduction Screwdrivers are designed to be used with the polyaxial reduction and uniplanar reduction screws.

STEP THREE: SCREW INSERTION

With the screw assembled to the Screwdriver, insert the screw into the pedicle by rotating the ratcheting handle clockwise. Once the desired screw depth is achieved, unlock the Screwdriver by pulling the collar proximally and rotating the thumbwheel counterclockwise. Confirm screw placement using fluoroscopic imaging.

Screw Diameter	Screw Lengths (mm)											
4.0 mm	20	25	30	35	40	45						
4.5 mm	20	25	30	35	40	45						
5.0 mm		25	30	35	40	45						
5.5 mm		30	35	40	45	50						
6.5 mm			35	40	45	50	55					
7.5 mm			35	40	45	50	55	60	70	80		
8.5 mm			35	40	45	50	55	60	70	80	90	100
9.5 mm			35	40	45	50	55	60	70	80	90	100
10.5 mm			35	40	45	50	55	60	70	80	90	100



TIP: If iliac screws are required, large diameter Taps and a Rigid Ball Tip Probe, Iliac Connectors, and iliac polyaxial and closed screws are available in the Implant tray.

TIP: Use the Head Adjuster to adjust the tulip head to support rod passage.

STEP FOUR: HOOK INSERTION (OPTIONAL)

Select the desired Hook type and size based on anatomy, degree of deformity, and intended method of correction. Prepare the Hook site using the appropriate Hook elevator. Load the selected Hook to the preferred Hook Inserter by applying downward pressure on the proximal portion of the Hook. Insert the Hook in either the up-going or down-going orientation, depending on the Hook's anatomical location (**Figure 3**).



Figure 3

Once the Hook is in position, insert the preferred rod into the rod slot. Thread an Invictus Set Screw into the Invictus Hook until the threads come to an end (**Figure 4**).

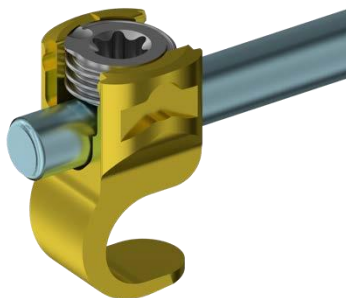


Figure 4

TIP: All Invictus Hooks accept both 5.5 mm and 6.0 mm diameter rods. The Hook diameters are color-coded to match the shank diameter colors.

STEP FIVE: ROD PREPARATION

A rod template may be used to represent the desired contour, length, and diameter. Once the proper rod is selected, contour the rod using the Mechanical Advantage French Rod Bender (**Figure 5**). Alternatively, the use of an Invictus Patient-Specific Rod that is pre-bent to the surgeon's plan, based on the patient's anatomy, may be used.



Figure 5

TIP: Titanium 5.5 mm diameter rods are light blue with dark blue dashed lines. Cobalt chrome 5.5 mm diameter rods are silver with dashed lines. Titanium 6.0 mm diameter rods are lime green with magenta circles. Cobalt chrome 6.0 mm diameter rods are silver with silver circles.

CAUTION: 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.

CAUTION: 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.

CAUTION: The Invictus Patient-Specific Rod is designed for a specific patient. Any modifications of the patient anatomy can alter the fit with patient vertebrae. The patient should be surveyed for potential anatomical changes prior to performing surgery.

CAUTION: The rod must be inserted in the correct orientation and position as requested by the user.

STEP SIX: ROD REDUCTION

If rod reduction is required, a variety of implants and instruments may be used to properly reduce the rod.

If using the AR 30, confirm that the Reducer is in the open position. Attach the Reducer to the tulip *in situ*, by applying downward pressure until the Reducer clips into place. Fasten a gray Mushroom or T- Reducer Handle to the proximal end of the Reducer. Rotate the handle clockwise to reduce the rod. Verify reduction utilizing the silver laser markings along the Reducer face (**Figure 6**).

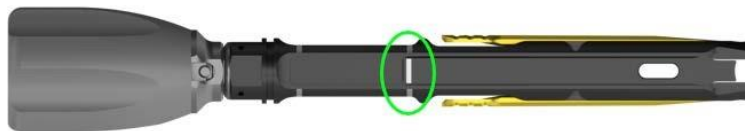
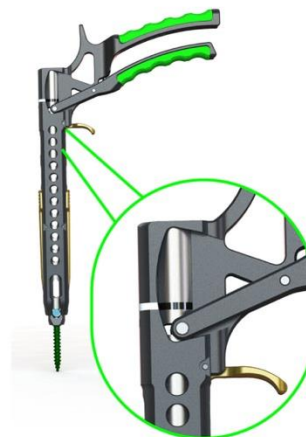


Figure 6

If using the Pistol Reducer, confirm that the Reducer is in the fully open state (Figure 7). Attach the Reducer to the tulip *in-situ* by applying downward pressure until the Reducer clicks onto the tulip. To reduce, squeeze the handles together until the rod is fully reduced and verify reduction using the laser markings on the body of the Reducer (Figure 8). Use the Set Screw Inserter to seat the set screw through the cannula of the Reducer. To remove the Reducer, release the trigger and press the gold buttons to remove from the tulip.



Fully unreduced state
(Figure 7)



Fully reduced state
(Figure 8)

TIP: The Rocker offers 10 mm of rod reduction. The reduction Polyaxial tulip offers 15 mm of reduction threads. The Axial Reducer and Shotgun Reducer offer 30 mm of rod reduction. The Pistol Reducer offers 25 mm of rod reduction.

If using the Shotgun Reducer (**Figure 9**), confirm that the Reducer is in the open and unlocked position (**Figure 10**). To secure the Reducer to the Tulip *in-situ*, press the gold buttons on the proximal end and apply downward pressure to the Tulip. Once the Reducer mates with the Tulip release the gold buttons. Fasten a gray Mushroom or T- Reducer Handle to the silver hex end of the Reducer and rotate the handle clockwise to begin locking the Reducer while simultaneously reducing the rod. Verify reduction utilizing the black laser markings along the Reducer face (**Figure 10 – Unlocked, Figure 11 – Fully Reduced**). Once the desired reduction is achieved, unlock the Reducer by rotating the Reducer Handle counterclockwise until bottomed out (**Figure 10**), then press the gold buttons and remove from the Tulip.



Figure 9



Figure 10



Figure 11

STEP SEVEN: SET SCREW INSERTION

Attach the T27 set screw to the Set Screw Inserter. Align the alignment notch on the face of the set screw with the notch on the tulip (**Figure 12**). Thread the set screw into the tulip until the threads end and the set screw is properly seated.



Figure 12

TIP: Invictus Set Screw PN 15100 mates with both 5.5 mm and 6.0 mm rod diameters.

STEP EIGHT: ROD CONTOURING

If *in-situ* bending is required, sagittal and coronal benders may be used. Both benders utilize Modular Bender handles. Select a 5.5 or 6.0 mm bender tip based on the preferred rod diameter, and attach it to the Sagittal Modular Bender handle (**Figure 13**) or the Coronal Modular Bender handle (**Figure 14**). The bender tips will lock into place.



Figure 13



Figure 14

An adjustable Coronal Link can be attached to the coronal handles to create a fulcrum while bending the rod *in-situ*.

TIP: The bender tips vary in diameter. The silver 5.5 mm tips are designed to be use with a 5.5 mm diameter rod. The black 6.0 mm tips are designed to be used with 6.0 mm diameter rods.

STEP NINE: COMPRESSION AND DISTRACTION

Compression can be performed at any level to help restore alignment. Confirm that the set screw is provisionally tightened at the motion segment. Place the Invictus Hinged Compressor outside of the screw heads and squeeze until desired compression is achieved. Use the Set Screw Inserter to tighten the set screw and maintain compression.

Distraction can be performed at any level to help restore alignment. Confirm that the set screw is provisionally tightened at the motion segment. Place the Invictus Hinged Distractor inside of the screw heads and squeeze until desired distraction is achieved. Use the Set Screw Inserter to tighten the set screw and maintain distraction.

STEP TEN: FINAL TIGHTENING

Connect the 90 inch-pound Torque Limiting Handle to the final tightening driver (**Figure 15**). Slide the Counter Torque around the screw until fully seated. The Counter Torque will accept both 5.5 mm and 6.0 mm diameter rods. A Closed Counter Torque must be used with the Closed Polyaxial Screws.



Figure 15

Insert the Torque Driver assembly through the Counter Torque until it engages with the set screw. Turn the Torque Handle clockwise until the handle breaks away. The construct is complete (**Figure 16**).

TIP: Use the Reduction Tab Breaker to remove Reduction Screw Tabs after Final Tightening.



Figure 16

CAUTION: Failure to tighten the set screws using the recommended instrument(s) could compromise the mechanical stability of the construct.

STEP ELEVEN: UNIVERSAL CROSS CONNECTOR INSERTION (OPTIONAL)

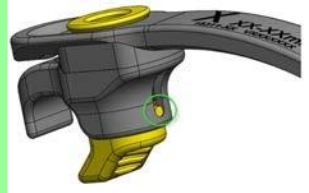
If desired, Universal Variable, Locking, Universal Variable, Universal Counter Variable, or Universal Fixed Cross Connectors (**Figure 17**) may be added to the construct. Use the Universal Cross Connector Caliper to measure the distance between each rod and determine the proper Cross Connector Length. Match the corresponding number displayed on the Caliper to the number associated with the Cross Connector sizes within the implant caddy.



Figure 17

Secure the yellow handled Cross Connector Inserters to the Cross Connectors by firmly pressing the Inserters into either gold Set Screw. Once attached to the Inserters, clamp one side of the connector onto one rod then span the construct to clamp onto the other rod. Confirm both sides of the Connector are seated and provisionally tighten both Set Screws with the Inserters.

TIP: Visually confirm that the Universal Cross Connector is unlocked and ready to accept either a 5.5 mm or 6.0 mm diameter rod by confirming that the gold pin on the medial side of the clamp is fully flush with the bottom of the slot.



Connect the 40-inch pound Torque Limiting T-Handle to the Universal Cross Connector Final Driver. Seat the Universal Cross Connector Counter Torque over the Cross Connector in-situ and insert the Final Driver assembly through the Counter Torque until it engages with the Set Screw. Rotate the Torque Handle clockwise until the handle breaks away.

TIP: The 40 inch-pound Torque Limiting T-handle is light grey and denoted by a bright yellow ATEC logo on the handle.

NOTE: If more or less arc is desired, the Universal Cross Connector Benders may be used (**Figure 18**). Insert each clamp of the Connector into the Right and Left Bender and close the gold thumb slide to secure the implant. Press the handles towards one another to increase arc or pull the handles apart to flatten.



Figure 18

STEP TWELVE: ROD TO ROD CONNECTOR INSERTION (OPTIONAL)

The Invictus Spinal Fixation System offers a variety of static and Pivoting Connectors to facilitate rod-to-rod connection if a revision or extension surgery is required (**Figure 19**).

TIP: Pivoting Connectors come fully assembled in the set and provide 3 mm of lateral translation and 35 degrees of cranial/caudal angulation. All Revision Connectors accept 5.5 mm, 6.0 mm, and 6.35 mm diameter rods.



Figure 19

Load the selected Connector implant to the preferred Connector Inserter (**Revision Connector Inserter, Figure 20, or Open Connector Holder, Figure 21**) and insert one side of the Connector onto the working rod. If using a Pivoting Connector, place the Open Connector Holder over the pivoting rod slot, identifiable by purple coloring.

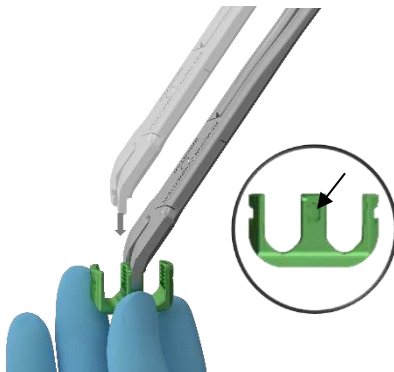


Figure 20

Use the distal prongs of the Revision Connector Inserter to attach to cranial and caudal indentions on static connectors

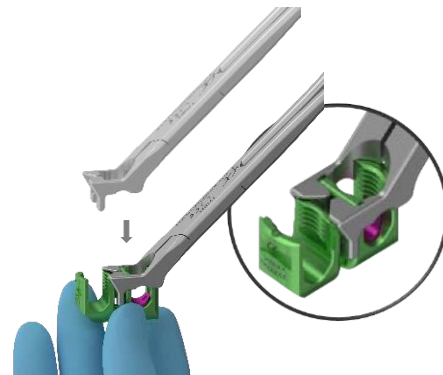


Figure 21

Load the Pivoting Connector to the Open Connector Holder by dropping the distal legs between the rod slots so that the top of the inserter is flush with the connector

Insert the Connector around the working rod. If using a Pivoting Connector, insert the static rod slot, identifiable by the fully green color, on the working rod. Secure the Connector to the rod by threading a Set Screw until provisionally tightened (**Figure 22**).

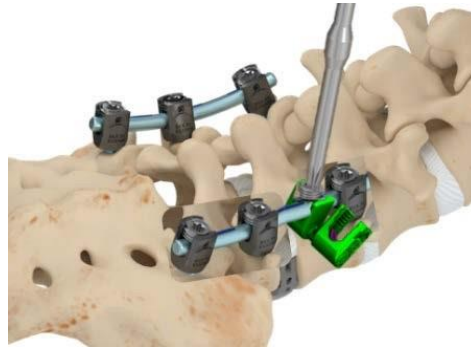


Figure 22

Once the adjacent rod is cut and contoured, use a Rod Gripper to insert the rod into the other, empty side of the Connector. Secure the adjacent rod to the Connector by threading a Set Screw until provisionally tightened.

NOTE: If using a Pivoting Connector, the Connector will be locked into a static position and secured to the rod upon threading a Set Screw into the pivoting side, denoted by the magenta bushing on the tulip saddle.

Final tighten each Connector using the standard 90-inch pound Torque Limiting Handle and Final Driver assembly with the appropriate Rod to Rod Counter Torque.

CAUTION: When using Pivoting Connectors to extend a construct, failure to use either two Pivoting Connectors or one Pivoting Connector and one static Connector per side may result in an unstable construct.

STEP THIRTEEN: IMPLANT REMOVAL

The Set Screws may be unlocked using a Final Torque Driver and removed using a Set Screw Insertor. The rods may be removed using forceps and/or a rod gripper. The screws may be removed using a Screwdriver and/or Screw Adjuster.

In the event of a revision surgery, rod-to-rod connectors may also be used to stabilize the construct. If a fusion mass exists, utilize the appropriate Dome Chisel and/or Bear Claw to create space around the rod. Once enough bone has been removed, a rod-to-rod connector may be attached.

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/Sl.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 Sl.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 Sl.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, SingleStepTM 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 Inserter to seat a Modular Tulip onto a Modular Shank.
31. Failure to reset the Tulip Inserter 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/SI.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. 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.

50. Failure to tap line-to-line when using cortical thread screws may result in pedicle fracture.
51. 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.
52. 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 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 devices to sale by or on the order of a physician.



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INVICTUS SPINAL FIXATION SYSTEM

INSTRUCTIONS FOR USE (International)

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.

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.

INDICATIONS FOR USE:

The Invictus Spinal Fixation System is intended for posterior, non-cervical 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.

CONTRAINDICATIONS:

The system is contraindicated for:

1. Use in the cervical spine.
2. Use with bone cement.
3. Patients with allergy to titanium or cobalt chrome.
4. Patients with osteopenia, bone absorption, bone and/or joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance.
5. 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.
6. Patients resistant to following postoperative restrictions on movement especially in athletic and

occupational activities.

7. Spinal surgery cases that do not require bone grafting and/or spinal fusion.
8. 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 Invictus Core/Sl.Core Screw 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 Sl.Core Screws are not intended for use with saline or radiopaque dye.
7. 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.
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 instruments in the Invictus Spinal Fixation System are reusable surgical devices except for the Fascial Blades, SingleStepTM Stylets, Sterile Drills, 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.
10. Do not combine titanium and stainless steel components within the same construct.
11. 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.

12. 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.
13. 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.
14. 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.
15. 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.
16. 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.
17. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
18. To prevent Guidewire breakage, do not use a kinked or bent Guidewire.
19. Guidewires should be monitored using fluoroscopic imaging to avoid advancement through the vertebral body in order to prevent damage to underlying structures.
20. The SingleStep stylet should be monitored using fluoroscopic imaging to prevent advancement through the vertebral body in order to prevent damage to underlying structures.
21. Verify superior and inferior rod overhang. Inadequate overhang may cause improper set screw placement resulting in an unstable construct.
22. Do not final tighten under compression or distraction as the rod may not be normalized to the tulips, resulting in rod slippage.
23. 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.
24. 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.
25. 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.
26. 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.
27. Failure to verify that the Modular Tulip is secured to the Modular Shank could compromise the mechanical stability of the construct.
28. Failure to tighten set screws using the recommended instrument(s) could compromise the mechanical stability of the construct.
29. To prevent implant damage, do not mallet on the Tulip Inserter to seat a Modular Tulip onto a Modular Shank.

30. Failure to reset the Tulip Inserter prior to Tulip attachment will result in a prematurely deployed Tulip and therefore an unstable construct.
31. An Iliac Connector must be final tightened before an Iliac Screw to allow for proper seating of the rod.
32. Care must be taken when handling the Hook Blade as the distal blade has a sharp tip and inner cutting surface.
33. 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.
34. 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.
35. 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.
36. Set Screws must not be final tightened during any derotation, compression/distraction, or in-situ bending maneuvers.
37. 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/SI.CORE screws.
38. 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.
39. Failure to tap line-to-line when using cortical thread screws may result in pedicle fracture.

MRI SAFETY INFORMATION:

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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.

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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.

POSTOPERATIVE MANAGEMENT:

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

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Excerpt from INS-111-01

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