



INVICTUS™ SPINAL FIXATION SYSTEM

SURGICAL TECHNIQUE

LIT-16001A

INVICTUS™

SPINAL FIXATION SYSTEM

SURGICAL TECHNIQUE GUIDE



ALPHATEC SPINE, INC. 5818 EL CAMINO REAL | CARLSBAD, CA | 92008

INVICTUS SURGICAL TECHNIQUE

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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 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. Reference page 26 for additional implant options.

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**).

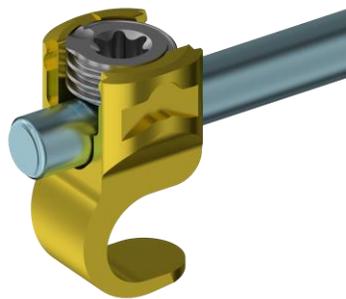


Figure 4

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**).

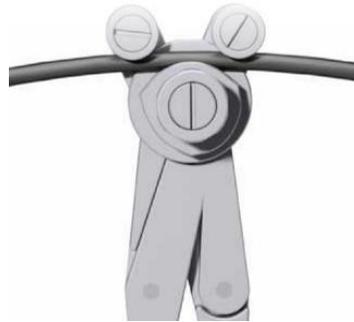


Figure 5

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.

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**).

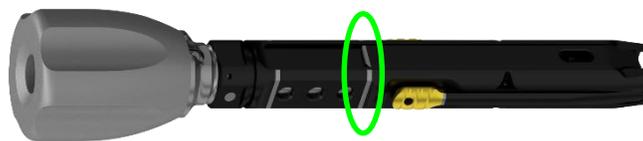


Figure 6

TIP The Rocker offers 10 mm of rod reduction. The reduction Polyaxial tulip offers 15 mm of reduction threads. The Axial Reducer offers 30 mm of rod reduction.

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 7**). Thread the set screw into the tulip until the threads end and the set screw is properly seated.

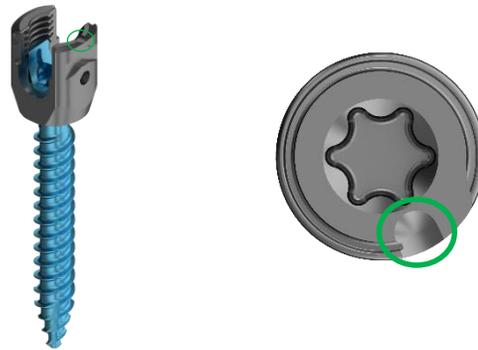


Figure 7

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 8**) or the Coronal Modular Bender handle (**Figure 9**). The bender tips will lock into place.

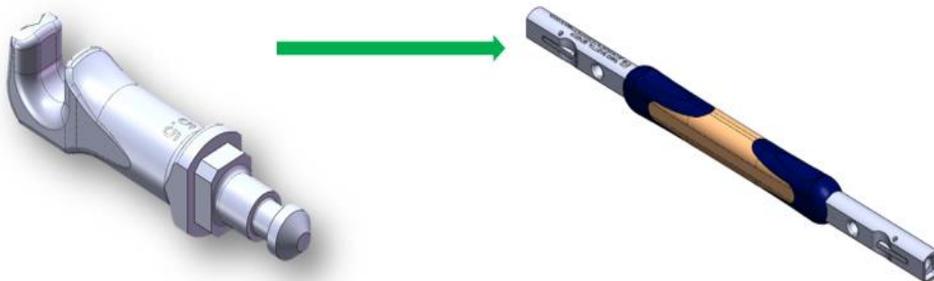


Figure 8

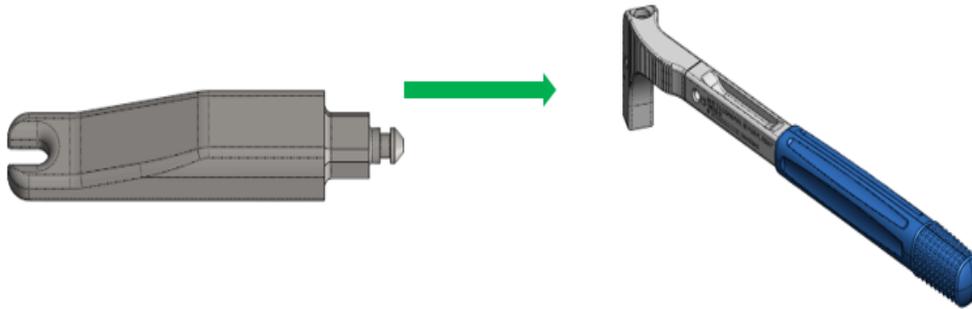


Figure 9

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 10**). 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 10

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 11**).

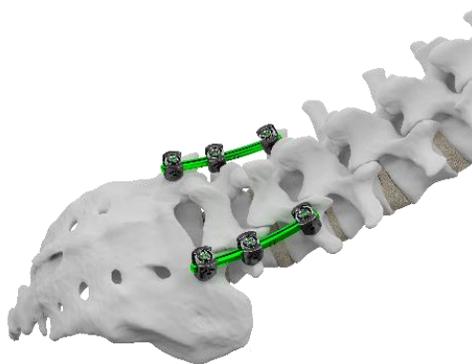


Figure 11

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

STEP ELEVEN: CROSS CONNECTOR INSERTION (OPTIONAL)

Cross Connectors (*Figure 11*) may be added at each end of the construct to potentially increase construct rigidity. Use the 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.

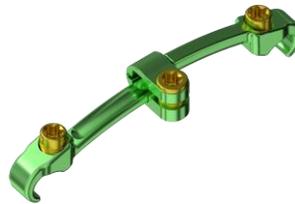


Figure 11

Engage the Cross Connector using the Cross Connector Inserter. Once attached to the Inserter, hook the Cross Connector around each rod and provisionally tighten the set screws within the Cross Connector using the Inserter.

TIP Cross connectors only accept one rod size. If the construct uses a 5.5 mm diameter rod, a blue Cross Connectors must be used. If the construct uses a 6.0 mm diameter rod, lime green Cross Connectors must be used.

To final tighten, connect the 40 inch-pound Torque Limiting T-Handle to the Final Tightener. Slide the Counter Torque around the medial portion of the Cross Connector until fully seated. Inserter 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.

STEP TWELVE: IMPLANT REMOVAL

The Set Screws may be unlocked using a Final Torque Driver and removed using a Set Screw Inserter. 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 revision surgery, rod-to-rod connectors may also be used to stabilize the construct. If a fusion mass exists, utilize the Dome and/or Bear Claw Chisels to create space around the rod. Once enough bone has been removed, a rod-to-rod connector may be attached.

INVICTUS MIS SURGICAL TECHNIQUE

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TRADITIONAL MIS TECHNIQUE

STEP ONE: PEDICLE TARGETING

Localize the affected level utilizing fluoroscopic imaging and create a skin incision. Use a Targeting Needle (**Figure 1**) to create a pilot hole at the junction of the transverse process and the superior articular process. Advance the targeting needle through the pedicle to the posterior edge of the vertebral body, and then remove the inner Stylet of the Targeting Needle.



Figure 1

STEP TWO: GUIDEWIRE PLACEMENT

Insert the Guidewire through the Targeting Needle cannula and remove the Targeting Needle sheath. To prevent Guidewire breakage, do not use a kinked or bent Guidewire.

TIP To maintain positioning of the Guidewire insert the proximal end of the Guidewire into the Guidewire Comb, and clip the Comb to the sterile drape.

***Caution:** *Guidewire advancement should be monitored using fluoroscopic imaging. Failure to do so may cause the Guidewire or part of it to advance through the bone and into a location that may cause damage to underlying structures.*

TIP The cannulated Excalibur Fascial Blade may be inserted over the Guidewire to create a pathway to bony anatomy.

STEP THREE: DILATOR INSERTION

Place the Initial Dilator over the Guidewire and advance to bony anatomy. Measure the depth of Guidewire into the pedicle through the window on the Initial Dilator. Sequentially dilate using the Tap and Final Dilators.

TIP: Reference table for Dilator specifications

#	Dilator	Inner Diameter	Outer Diameter	Material
1	Initial Dilator	2 mm	8 mm	Stainless Steel
2	Tap Dilator	8 mm	13.5 mm	Plastic
3	Final Dilator	14 mm	17 mm	Plastic

STEP FOUR: PEDICLE PREPARATION – TAP (OPTIONAL)

Select the appropriate diameter Tap (**Figure 2**) and insert it over the Guidewire and into the pedicle until the desired depth is achieved.



Figure 2

TIP The gold Tap threads are 40 mm in length. Laser markings on the proximal end of the Tap shaft indicate depth of insertion against the Tap Dilator.

STEP FIVE: SCREW INSERTION

SCREWDRIVER ASSEMBLY

Connect a ratcheting Handle to the gold proximal end of the Locking Reduction Polyaxial Screwdriver until fully engaged. Verify that the black laser line on the proximal end of the Screwdriver is covered. Insert the Screwdriver into the Cannulated Extended Tab Reduction Screw and rotate the thumbwheel clockwise until the thumbwheel bottoms out. Once fully tightened, slide the thumbwheel collar distally until it stops and a black laser mark appears (**Figure 3**).



Figure 3

Advance the screw over the Guidewire into the pedicle by rotating the ratcheting Handle clockwise. Remove the Guidewire and unlock the Screwdriver by pulling the thumbwheel proximally and rotating the thumbwheel counterclockwise. Remove the Screwdriver and Final Dilator together.

Confirm screw placement using fluoroscopic imaging.

Cannulated Poly Reduction Screws									
Diameter	Lengths (mm)								
4.5 mm	30	35	40						
5.5 mm		35	40	45	50	55			
6.5 mm		35	40	45	50	55			
7.5 mm		35	40	45	50	55			
8.5 mm		35	40	45	50			70	80

Light blue	Standard
Dark blue	Optional

TIP If needed, use the Guidewire Extractor to remove a Guidewire. Slide the Extractor over the Guidewire, squeeze, and pull or mallet the Extractor up.

STEP SIX: ROD MEASUREMENT

Insert the Rod Caliper down the Cannulated Extended Tab Reduction Screws until fully seated. Verify that the laser-marked lines on the Caliper arms are covered by the proximal end of the extended tabs. Select the rod length based on the measurement that appears in the center of the gold indicator box on the Caliper (**Figure 5**).

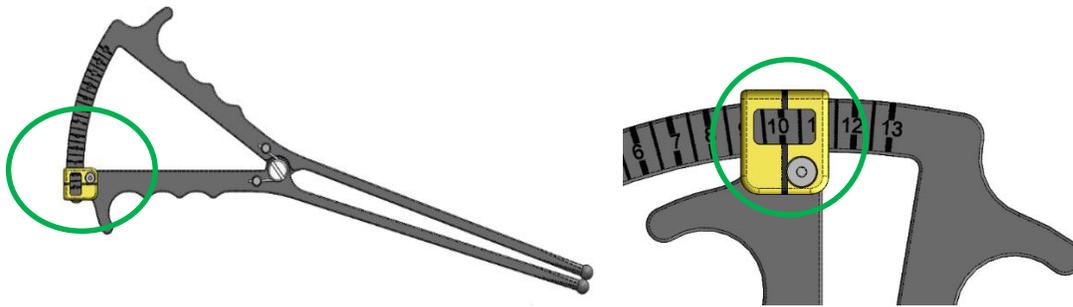


Figure 5

STEP SEVEN: ROD INSERTION

Align the extended tab rod slots using the Extended Tab Adjuster. Insert the gold Rod Inserter Locking Driver into the gold hex on the Rod Inserter. Rotate the Locking Driver clockwise to lock the MIS rod to the MIS Rod Inserter. When locked, a laser-marked line will align with the lock symbol on the shaft of the Rod Inserter (**Figure 6**).

Advance the Inserter down the extended tab rod slot until the rod is seated within the tulip. Confirm rod placement using fluoroscopic imaging.

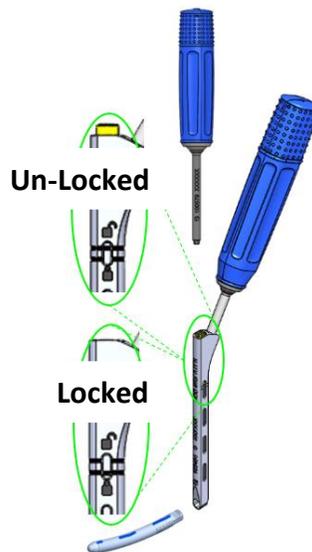


Figure 6

TIP A Wiltse rod inserter may also be used. The Wiltse Inserter locks to the center of the rod, as opposed to the distal end.

STEP EIGHT: SET SCREW INSERTION

Press the Locking Set Screw Inserter into the Set Screw and rotate the gold thumbwheel clockwise to lock the set screw to the Inserter (**Figure 7**). Thread the set screw down the extended tab screw until the 15 mm of reduction threads come to an end. Rotate the thumbwheel counterclockwise to disengage the Driver from the set screw.

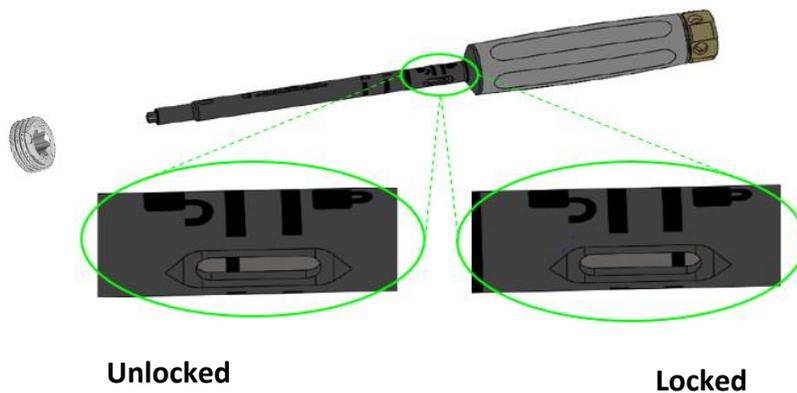


Figure 7

Once set screws are provisionally tightened, rotate the MIS Rod Inserter Driver counterclockwise to disengage the MIS Rod Inserter.

STEP NINE: ROD REDUCTION (OPTIONAL)

Press the Drop Tower Reducer into the set screw. Insert the Drop Tower Reducer down the Cannulated Extended Tab Reduction Screw until the gold wings on the Drop Tower Reducer lock to the proximal end of the Reduction Screw. Attach the large silver end of Drop Tower Handle to the silver hex on the Drop Tower Reducer (**Figure 8**). Rotate the handle clockwise until reduction is achieved.



Figure 8

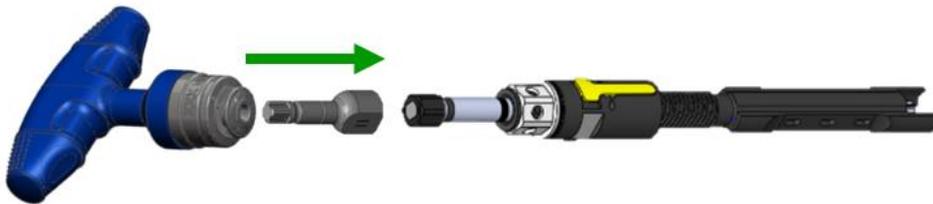
If additional torque during reduction is needed, utilize the Drop Tower Reduction Bell.

Once the rod has been reduced, flip the Reduction Handle and attach the small black end to the black hex on the Drop Tower Reducer. Rotate the Handle clockwise to thread the set screw into the tulip until the threads come to an end (**Figure 10**).



Figure 10

If desired, the Drop Tower can be used for final tightening. Attach the Torque Limiting handle to the Set Screw Bell, and engage the black hex on the Drop Tower Reducer (**Figure 11**). Rotate the Torque Handle until it breaks away. Use the Dual Counter Torque to resist motion during Final Tightening.



Disengage the Drop Tower Reducer from the extended tabs by pushing the gold wings and pulling up.

STEP TEN: COMPRESSION AND DISTRACTION

Verify that the set screws are provisionally tightened at the motion segment.

If compression is desired, place the Fulcrum tool (**Figure 12**) between the proximal end of the extended tabs and compress the tabs below the Fulcrum.

If distraction is desired, place the Fulcrum tool between the distal end of the extended tabs and compress the tabs above the Fulcrum. Tighten the set screws to maintain compression/distraction.

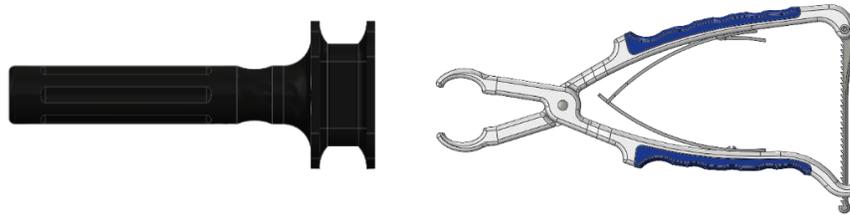


Figure 12

STEP ELEVEN: SPONDYLOLISTHESIS REDUCTION (OPTIONAL)

Attach the Spondy Reducer to the proximal end of the extended tabs until the gold wings lock into place. Verify that the sliding housing located closest to the handle (**Figure 13**) is attached to the extended tab of the misaligned vertebra. Repeat steps to attach an additional Reducer on the contralateral side.

Slowly pull up on the Reducer handles until the desired amount of reduction is achieved. Confirm reduction of the segment using fluoroscopic imaging. Provisionally tighten the set screws with the Locking Set Screw Inserter through the Spondy Reducer to maintain this reduction, or if desired, final tighten through the Spondy Reducer with the Final Driver. Disengage the Reducer by pressing on the gold wings on each housing.

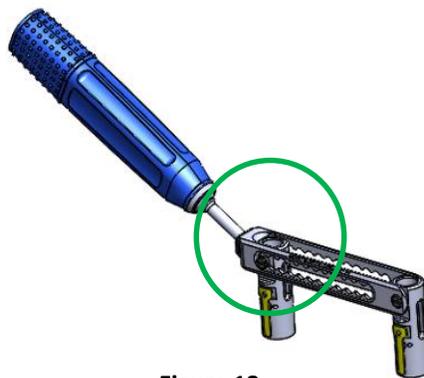


Figure 13

STEP TWELVE: FINAL TIGHTENING

Connect the Torque Limiting Handle (90 inch-pounds) to the MIS Final Driver (*Figure 14*) and verify that the laser-marked line on the MIS Final Driver is covered by the Handle.

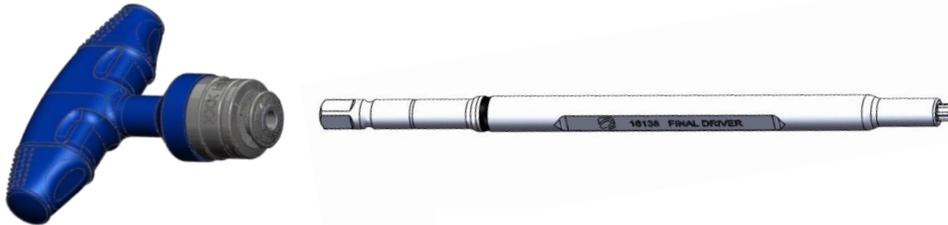


Figure 14

TIP The 90 inch-pound Torque Handle is denoted by a bright blue color band on the handle. Verify that the blue band on the handle matches the blue band on the Final Driver shaft.

Attach the Dual Counter Torque to the extended tab. Insert the Torque Driver through the extended tab until it engages the set screw. Rotate the Torque Handle clockwise while holding the Counter Torque steady until the handle breaks away. Remove the Torque Driver assembly and Counter Torque.



TIP The side-loading end fits around the extended tab and the top-loading end fits over the proximal end of the extended tab.

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

EXTENDED TAB REMOVAL

Insert the MIS Reduction Tab Breaker into the proximal end of the extended tabs (**Figure 15**) and squeeze. Break away the distal ends of the extended tabs by pulling the tabs medial/lateral. Using fluoroscopy as needed, visually verify that the distal tabs have been properly broken from the tulips (**Figure 16**). The construct is complete (**Figure 17**).



Figure 15



Figure 16

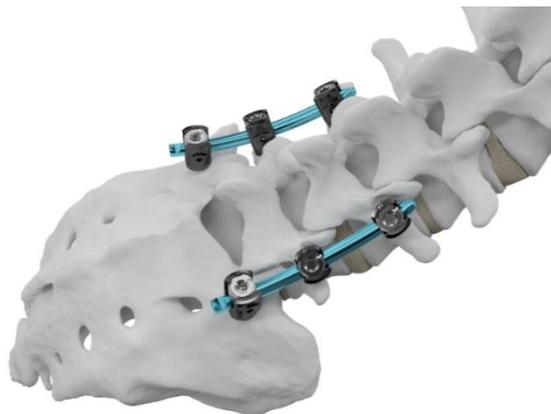


Figure 17

SINGLESTEP™ TECHNIQUE

STEP ONE: SINGLESTEP DRIVER ASSEMBLY

The SingleStep Driver Assembly is made up of the SingleStep Stylet, SingleStep Adapter, Locking Reduction Polyaxial Screwdriver, SingleStep Connector Key, and the Modular Egg Handle.

Select a SingleStep Stylet length based upon the pre-determined screw length. Insert the SingleStep Stylet into the proximal end of the SingleStep Adapter by pressing the gold button on the Adapter (**Figure 18**).

TIP The SingleStep Stylet is top-loading. Verify the Stylet is locked into place within the SingleStep Adapter by confirming the Stylet sits flush with the proximal end of the adapter.



Figure 18

TIP SingleStep Stylets are color-coded to denote length.



Insert the Reduction Polyaxial Screwdriver into the Extended Tab Screw and rotate the thumbwheel clockwise until the thumbwheel bottoms out. Once fully tightened, slide the thumbwheel collar distally until a black laser-marked line appears (**Figure 19**).



Figure 19

Slide the SingleStep Adapter and Stylet Assembly into the Screwdriver assembly and verify that the laser-marked line on the proximal end of the Screwdriver is covered by the SingleStep Adapter (**Figure 20**).



Figure 20

A laser-marked line and number 0 should appear on the proximal end of the Adapter black handle, indicating that the Stylet will protrude 0 mm from the tip of the extended tab screw.

Attach the SingleStep Connector Key to the ratcheting Egg Handle (**Figure 21**).



Figure 21

STEP TWO: PEDICLE TARGETING

Localize the affected level utilizing fluoroscopic imaging and create a skin incision. Extend the SingleStep Stylet 10 mm by rotating the black knurled handle clockwise (*Figure 22*).

Create a pilot hole at the junction of the transverse process and the superior articular process by malleting on the proximal end of the SingleStep Adapter. Continue to advance the Stylet into the pedicle by rotating the black handle until the entire Stylet has been deployed 25 mm and the depth gauge bottoms out (*Figure 23*). Continuously verify proper positioning using lateral fluoroscopy.



Figure 22

***Caution: During SingleStep Stylet usage, Stylet advancement should be monitored using fluoroscopic imaging.**



Figure 23

TIP If redirection is desired, retract the Stylet by rotating the black knurled handle counterclockwise, and then re-advance the Stylet by rotating the black knurled handle clockwise.

STEP THREE: SCREW INSERTION

Attach the preassembled ratcheting Egg Handle and SingleStep Connector Key to the proximal end of the SingleStep Assembly (**Figure 24**). Advance the screw into the prepared pedicle by rotating the Egg Handle clockwise. Maintain grip on the black handle during screw insertion to allow the screw to advance over the Stylet.



Figure 24

Unlock the Screwdriver by pulling the thumbwheel proximally then unthread the Screwdriver from the tulip by rotating thumbwheel counterclockwise. Pull straight up to remove the SingleStep assembly. Follow Steps 6-12 from the Traditional MIS Technique to complete the MIS construct (**Figure 25**).

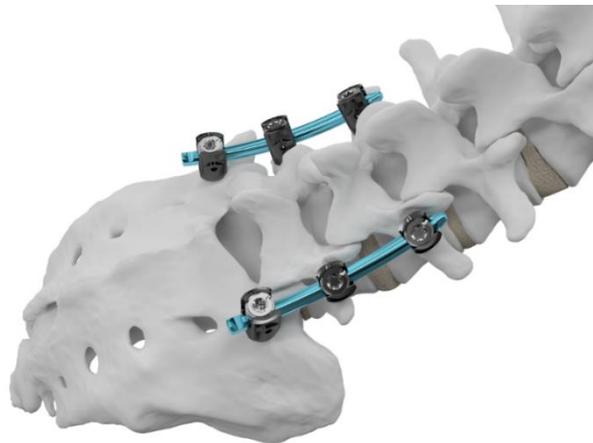


Figure 25

INVICTUS™ SPINAL FIXATION SYSTEM

GENERAL INFORMATION:

The Invictus Spinal Fixation System is intended for posterior, non-cervical, spinal fixation as an adjunct to fusion for the treatment of degenerative disease, deformity, and trauma indications.

The Invictus Spinal Fixation System consists of a variety of shapes and sizes of rods, screws, hooks, connectors, and cross connectors that provide temporary 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, titanium alloy, and cobalt chrome (CP Ti Grade 4, Ti-6Al-4V ELI, and Co-28Cr-6Mo).

If additional levels of fixation are required, the Invictus Spinal Fixation System rods may be used in conjunction with Alphatec Spine's Solanas® Posterior System, which may connect to the Avalon® Occipital Plate 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:

1. The implants and instruments of the system are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. 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.
3. The system implants are used only to provide temporary internal fixation during the bone fusion process 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.
4. The implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.
5. 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.
6. The instruments in the Invictus Spinal Fixation System are reusable surgical devices except for the Fascial Blades, SingleStep Stylets, 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.
7. Do not comingle titanium and stainless steel components within the same construct.
8. 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.
9. Based on the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and patient conditions, which may impact the

performance of the system when using this device. Use of these systems is significantly affected by the surgeon's proper patient selection, preoperative planning, proper surgical technique, proper selection and placement of implants.

10. 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.
11. 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.
12. 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.
13. The final operative procedure with the system must include tightening of the set screws in order to maintain construct integrity using the appropriate instrument(s), e.g., Torque Handle. Failure to tighten the Set Screws using the recommended instrument(s) could compromise the mechanical stability of the construct. Each locking mechanism must be rechecked for tightness before closing the soft tissues as noted in the Intraoperative Management section.
14. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
15. To prevent Guidewire breakage, do not use a kinked or bent Guidewire.
16. Guidewire advancement should be monitored using fluoroscopic imaging. Failure to do so may cause the Guidewire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
17. During SingleStep Stylet usage, Stylet advancement should be monitored using fluoroscopic imaging.

PRECAUTIONS:

1. 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.
2. 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.
3. The physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may have an impact on the performance of the system.

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

PREOPERATIVE MANAGEMENT:

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

INTRAOPERATIVE MANAGEMENT:

1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
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.

POSTOPERATIVE MANAGEMENT:

Postoperative management by the surgeon, including instruction and warning and compliance by the patient, of the following is essential:

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.
6. The implants are designed and intended as temporary fixation devices. The devices should be removed after complete healing has occurred. Devices which are not removed after serving their intended purpose may bend, dislocate, or break and/or cause corrosion, localized tissue reaction, pain, infection, and/or bone loss due to stress shielding. Complete postoperative management to maintain the desired result should also follow implant removal surgery.

REPROCESSING OF REUSABLE INSTRUMENTS

General Information for all Instruments:

- **Point-of-Use Processing:** To facilitate cleaning, instruments should be cleaned initially directly after use in order to facilitate more effective subsequent cleaning steps. Place instruments in a tray and cover with a wet towel to prevent drying.
- The cleaning process is the first step in effectively reprocessing reusable instruments. Adequate sterilization depends on thoroughness of cleaning.
- The cleaning and sterilization processes in this IFU have been validated and demonstrate that soil and contaminants have been removed leaving the devices effectively free of viable microorganisms.
- It is recommended that all new relevant clinical practice guidelines be followed as per the CDC guidance, "Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008."

- It is recommended to rinse the device components with water that meets specifications for AAMI TIR34 “Water for the reprocessing of medical devices, 2014” for example, DI/RO water.

Instrument Preparation:

- Cleaning, inspection, lubrication, and sterilization must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Instruments must be cleaned prior to lubrication and sterilization.
- All instrument hinged, rotating, and articulating parts must be lubricated prior to sterilization with a water soluble and sterilizable lubricant intended for surgical instruments (Hinge-Free® for example).

Cleaning Instructions for all Instruments:

- Instruments must be cleaned prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures involving contaminant removal.
- Disconnect all handles/knobs prior to cleaning.
- Complex instruments, such as those with, cannulas, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe where debris could become trapped.
- Ensure all moving parts of instruments are cleaned at both extents of travel.
- Handle all products with care. Mishandling may lead to damage and possible improper functioning.
- Clean the instruments, trays and inserts using only recommended cleaning solutions. Use of caustic solutions (caustic soda) will damage the instruments.
- Visually inspect each instrument for deterioration such as corrosion and worn components; ensure that the laser markings are legible and verify that all actuating parts move freely. Visual inspection must be performed at each cleaning to determine if an instrument is acceptable for use. If an instrument is not acceptable for use, return to the manufacturer.

Cleaning of Instruments, Containers, and Trays:

- All solutions for cleaning must be prepared per the manufacturer’s instructions.
- Instruments provided in a set must be removed from the set for cleaning. Instrument trays, containers, and lids must be thoroughly cleaned separately until visually clean.
- Ensure instruments are in the fully extended, open position throughout cleaning. Disconnect Quick Connect handles from the shafted instruments prior to cleaning.
- Pay special attention during cleaning to complex instruments, such as those with cannulas, hinges, retractable features, mated surfaces, and textured surface finishes.
- Use of water with high mineral content should be avoided.

Visually inspect the instrument after each cleaning step to ensure the instrument is clean. If not clean, repeat the step until clean.

Manual Cleaning Steps for Instruments

<u>Step</u> 1	<u>Rinse devices in ambient temperature tap water to remove visible soil.</u>
<u>Step</u> 2	<u>Prepare enzymatic solution, such as <i>Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner</i> or equivalent, per manufacturer’s recommendations and submerge device in enzyme solution. Actuate the device while it is submerged and soak for a minimum of 10 minutes.</u>
<u>Step</u> 3	<u>Actuate and scrub the device using an appropriately sized soft bristled brush, such as a <i>Spectrum Surgical code #M-16</i> or 45-542 (or equivalent), to brush the lumen for a minimum of 2 minutes. If needed, actuate at several locations to access all surfaces. Use of a syringe (minimum of 50 ml) or water jet is recommended for the hard to reach areas and repeat 3 times.</u>
<u>Step</u> 4	<u>Rinse devices in DI/RO water for a minimum of 1 minute.</u>
<u>Step</u> 5	<u>Prepare cleaning solution, such as <i>Prolystica® 2X Concentrate Alkaline Detergent</i>, per manufacturer’s recommendations and submerge and actuate devices in cleaning solution and sonicate for a minimum of 10 minutes.</u>
<u>Step</u> 6	<u>Thoroughly rinse devices with DI/RO water to remove all detergent residues.</u>
<u>Step</u> 7	<u>Dry devices with a clean, lint free cloth or filtered compressed air.</u>

Automatic Washer Cleaning Steps for Instruments

Step 1	Complex instruments, such as those with cannulations, lumens, hinges, retractable features, mated surfaces, and textured surface finishes, require special attention during cleaning. Brush tight tolerance areas with an appropriately sized brush and flush using a water jet or syringe with ambient temperature tap water where debris could become trapped. Place them into the Washer/Disinfector and process through a standard surgical instrument cycle.
Step 2	Prewash with cold tap water for 2 minutes.
Step 3	Enzyme wash using cleaner such as <i>Prolystica® 2X Concentrate Enzymatic Presoak & Cleaner</i> or equivalent, per manufacturer’s recommendations, hot tap water, 1 minute.
Step 4	Detergent wash using detergent such as <i>Prolystica® 2X Concentrate Alkaline Detergent</i> , per manufacturer’s recommendations, hot tap water (66°C/150°F), 2 minutes.
Step 5	Rinse 2 times, hot tap water, 15 seconds.

Step 6	Purified water rinse (66°C/150°F), 10 seconds.
Step 7	Hot air dry (115°C/239°F) for at least 10 minutes.

INSPECTION:

- Inspect each instrument, container, and tray to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning/disinfection process.
- Check the action of moving parts (e.g., hinges, box-locks, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
- Check instruments with long slender features (particularly rotating instruments) for distortion.
- Drill bits, reamers, rasps and other cutting instruments should be inspected after processing with alkaline detergents.
- Inspect instruments for any other damage, wear, and/or corrosion.

STERILIZATION and RESTERILIZATION (for all Instruments and Implants):

- All implants and instruments are provided non-sterile and must be steam sterilized prior to use in the trays provided, using the validated cycle parameters in **Tables 1 and 2**.
- Alphatec products have been validated to achieve sterility using FDA cleared sterilization accessories (sterilization wraps, container and filters).
- Instrument sets have been validated in standard configurations. **No additional items should be added to the set for sterilization.**

Sterilization Parameters

System	Cycle Type	Temperature	Minimum Exposure Time	Minimum Drying Time	Cool Down Time
Invictus Spinal Fixation System Sets	Pre-vacuum	270°F (132°C)	4 minutes	45 minutes	15 minutes

Sterilization Notes:

- The cycle conditions in the tables above were validated to achieve a SAL of 10⁻⁶.
- These parameters are consistent with the appropriate version of *ANSI/AAMI ST79 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities."*

COMPLAINT HANDLING/REPORTING:

All product complaints relating to safety, efficacy or performance of the product should be reported immediately to Alphatec Spine by telephone, fax, e-mail, or letter, per contact information below. All complaints should be accompanied by name, part number, and lot numbers. The person formulating the complaint should provide their name, address, and as many details as possible. You may contact Customer Service directly at: customerservice@atecspine.com.

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

For a listing of Symbols and Explanations, see atecspine.com/eifu

 **Alphatec Spine, Inc.**

5818 El Camino Real
Carlsbad, CA 92008 USA
Ph: (760) 431-9286
Ph: (800) 922-1356
Fax: (800) 431-9722
atecspine.com