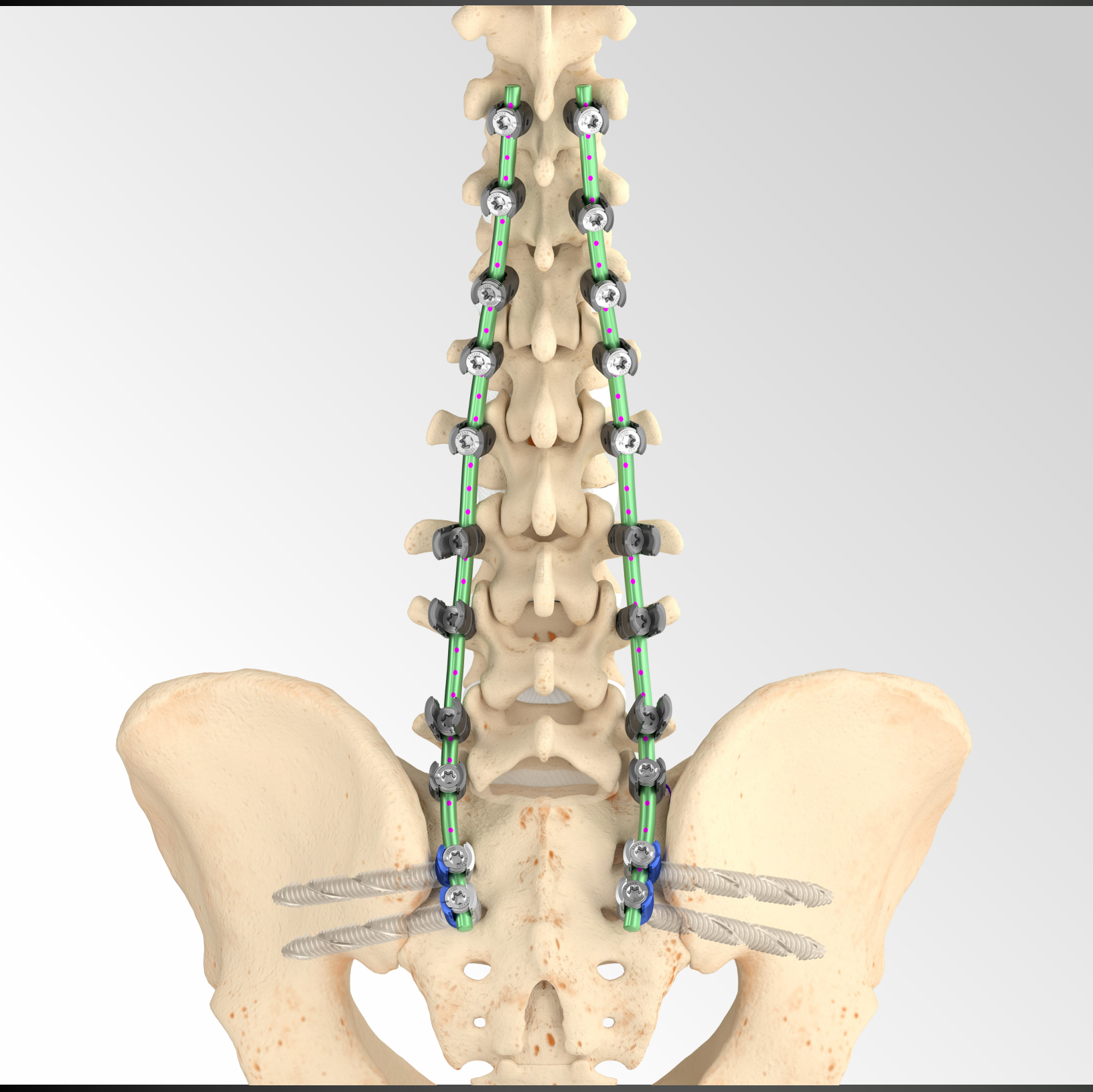
INVICTUS® SI.CORE

A SELF-HARVESTING SCREW

atec™ INFORMED BY EOS



POSTERIOR FIXATION | Surgical Technique Guide

INVICTUS® SI.CORE

A SELF-HARVESTING SCREW

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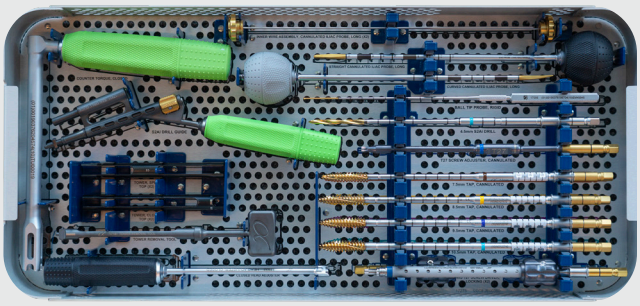
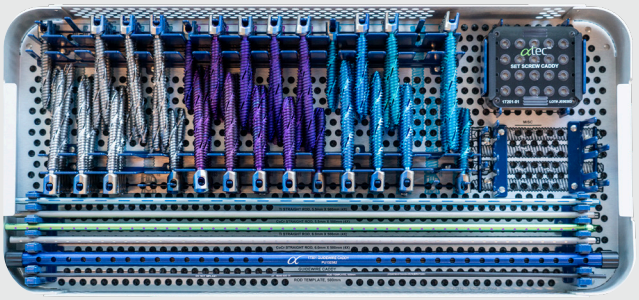
INVICTUS SI.CORE AND FAVORED ANGLE INSTRUMENT SET



INVICTUS SI.CORE IMPLANT SET



PATIENT POSITIONING

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

Place the necessary neuromonitoring electrodes on the patient and execute a twitch test to determine if neuromuscular blockades are clear.

1

S2AI C-ARM POSITIONING

1 When determining the correct angle of the C-arm to localize the appropriate starting point for S2AI screws, begin with a true A/P fluoro view to locate the S1 and S2 dorsal foramina. The C-arm should be positioned opposite to the surgeon.

2 The teardrop view is utilized to position S2AI screws and is formed by the overlap of the anterior inferior iliac spine (AIIS) and the posterior superior iliac spine (PSIS). To find the teardrop, angle the C-arm at 20-30° of cranial-caudal tilt and 40-50° off-midline. If experiencing difficulty finding the teardrop, tilting the table or live fluoroscopy may be helpful. When looking at the teardrop, the curved side is medial, whereas the straight side is lateral.

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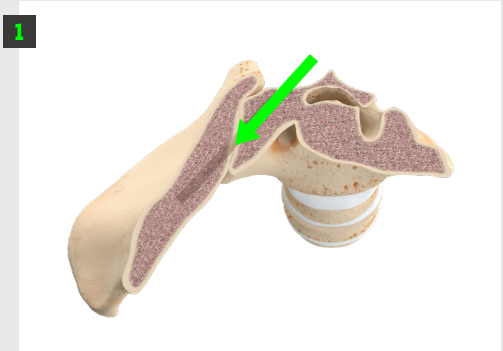

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S2AI TRAJECTORY

1 In an open approach, the S2AI entry point is the midpoint between the S1 and S2 dorsal foramina, 3 mm medial to the lateral sacral crest. This will position the S2AI screw in line with the S1 screw. When determining the angle, palpate the greater trochanter and aim the Straight or Cannulated Iliac Probe towards the AIIS. Penetrate the cortex at the midpoint between the S1 and S2 dorsal foramina with a high-speed burr or Cannulated Straight or Curved Iliac Probe. Verify the trajectory with fluoroscopy.

2 Utilize the crosshair feature on the Straight or Curved Cannulated Iliac Probe to determine if the distal tip of the Probe is within the teardrop. The distal tip of the Iliac Probe will be superimposed beneath the center of the crosshair Cap when it is appropriately positioned.

TIP: THE SACRO-ILIAC JOINT (SIJ) WILL BE REACHED AT ABOUT 40-50 MM OF PROBE DEPTH, DEPENDING ON PATIENT ANATOMY.

WHEN USING THE CURVED CANNULATED ILIAC PROBE, AIM THE CURVE CRANIALLY TO AVOID ANTERIOR ANATOMICAL ELEMENTS.

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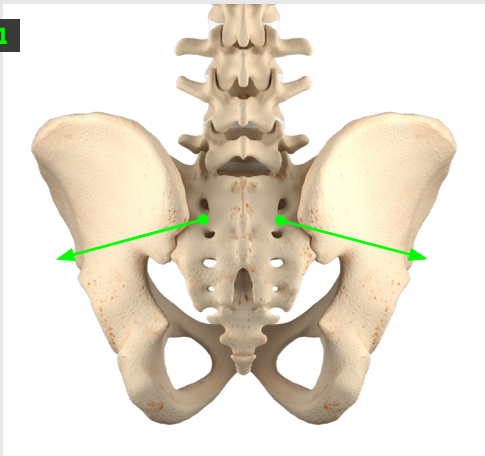

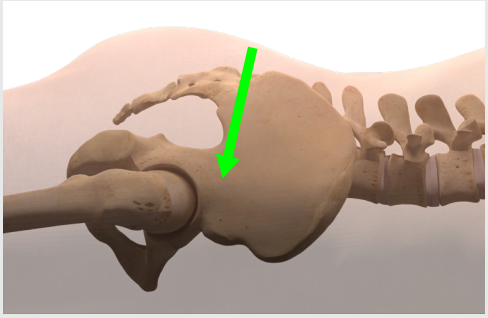

3 Under fluoroscopy, verify that the distal tip of the Probe is superimposed by the proximal end of the Gearshift. When superimposed, the Cannulated Iliac Probe is directly in line with the C-arm and teardrop trajectory. If the distal end is not superimposed, the C-arm angle may need to be adjusted. If experiencing difficulty, the Cannulated Iliac Probe may need to be repositioned within the teardrop.

4 Verify the integrity of the pilot hole with the Rigid Ball Tip Probe.

5 After the Cannulated Iliac Probe has been appropriately placed, spin the Luer lock feature counterclockwise to remove the inner stylet.

6 Insert a Guidewire through the Cannulated Iliac Probe. Verify under fluoroscopy that the trajectory passes above the sciatic notch and towards the iliac teardrop.

TIP: 18" NITINOL TROCAR TIP GUIDEWIRES ARE PROVIDED IN THE SET. LONGER LENGTHS ARE AVAILABLE BY REQUEST. (PN 17100-20-1)

UTILIZE THE CROSSHAIRS ON THE LUER LOCK CAP TO DETERMINE IF THE DISTAL END OF THE CANNULATED PROBE IS SUPERIMPOSED IN THE PREFERRED TRAJECTORY.

THE CURVED DISTAL END OF THE PROBE IS INDICATED BY THE INDENT ON THE PROXIMAL END OF THE PROBE SHAFT. THERE IS 30 MM OF GOLD COATING AT THE DISTAL END WITH BLACK BANDS AT 30-40 MM AND 80-90 MM AND LASER-MARKED LINES EVERY 10 MM, UP TO 120 MM.

THE INNER STYLET IS DISPOSABLE.

CAUTION: GUIDEWIRES SHOULD BE MONITORED USING FLUOROSCOPIC IMAGING TO MITIGATE DAMAGE TO UNDERLYING AND ASSOCIATED STRUCTURES.

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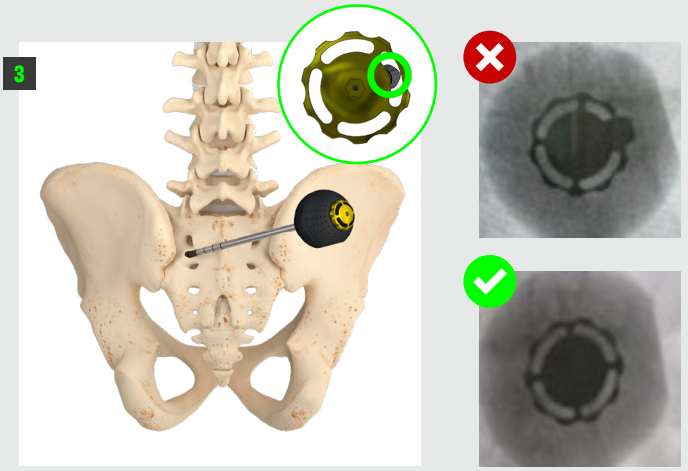

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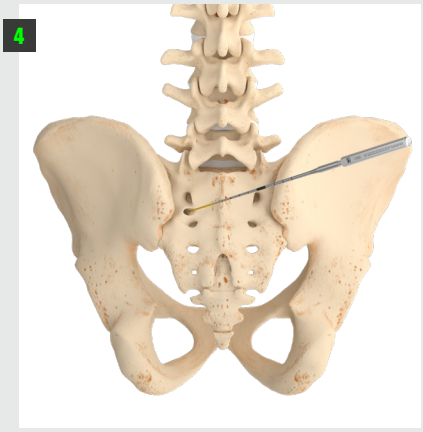

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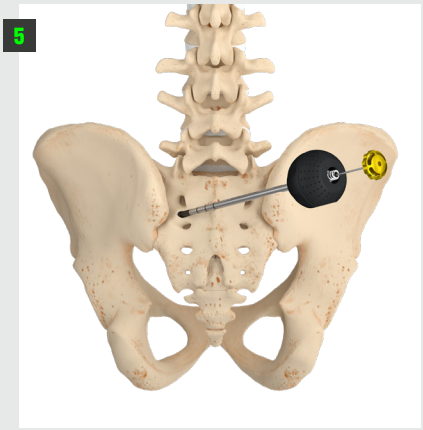

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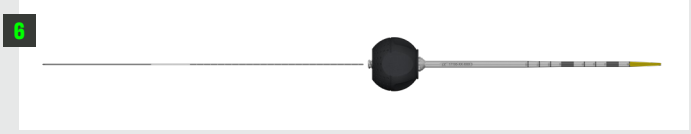

TAPPING

1. Maintain the trajectory with a Guidewire and cautiously remove the Cannulated Straight or Curved Iliac Probe. Verify the trajectory with fluoroscopy. Attach the cannulated Tap 1 mm smaller in diameter than the SI.CORE or Favored Angle Screw diameter to the desired Ratcheting Handle.

2. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Tap. Set the Ratcheting Handle to the “Forward” position and feed the Tap over the Guidewire.

3. Rotate the Handle clockwise to advance the Tap into the appropriate S2AI trajectory. Reference the markings on the distal end of the Tap shaft to determine its depth in bone.

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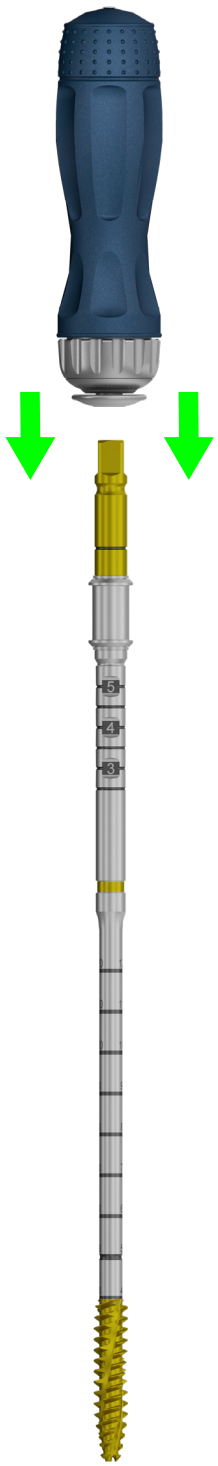

SCREWDRIVER ASSEMBLY

1 Place the desired Cannulated Ratcheting Axial or T-handle onto the T27 Screwdriver. The T27 Screwdriver is denoted by the black thumbwheel and distal blue ring. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Driver.

2 To load the desired closed or open tulip SI.CORE or Favored Angle screw onto the T27 Screwdriver, mate the screw hex with the Driver and spin the black thumbwheel clockwise. Once bottomed out, slide the thumbwheel distally until the black "LOCKED" laser-marked line is visible, indicating that the secondary lock is engaged.

3 Set the Ratcheting Handle to the "Forward" position and feed the Cannulated T27 Driver over the Guidewire to verify the appropriate trajectory for the S2AI screw.

SI.CORE SET OFFERINGS					
Diameters	Lengths				
9.0 mm	60 mm	70 mm	80 mm	90 mm	100 mm
9.5 mm	60 mm	70 mm	80 mm	90 mm	100 mm
10.5 mm	60 mm	70 mm	80 mm	90 mm	100 mm

FAVORED ANGLE SET OFFERINGS					
Diameters	Lengths				
7.5 mm	60 mm	70 mm	80 mm	90 mm	100 mm
8.5 mm	60 mm	70 mm	80 mm	90 mm	100 mm
9.5 mm	60 mm	70 mm	80 mm	90 mm	100 mm
10.5 mm	60 mm	70 mm	80 mm	90 mm	100 mm

TIP: ADDITIONAL SI.CORE AND FAVORED ANGLE SCREW IMPLANT SIZES ARE AVAILABLE BY REQUEST.

CAUTION: THE FAVORED ANGLE AND FAVORED ANGLE CORE/SI.CORE SCREWS ARE COMPATIBLE WITH THE PROVIDED T27 SCREWDRIVER. DO NOT USE A T25 SCREWDRIVER WITH THE FAVORED ANGLE AND FAVORED ANGLE CORE/ SI.CORE SCREWS.

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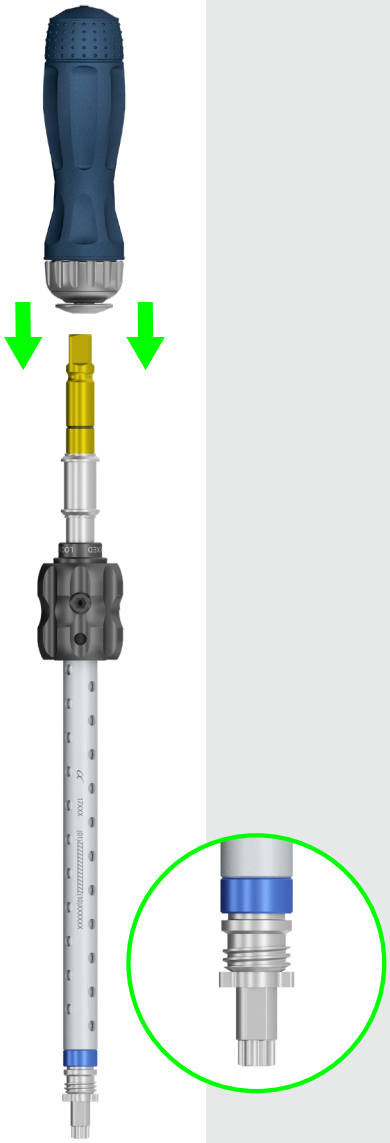

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SCREW INSERTION

1 After inserting the SI.CORE or Favored Angle Screw, check the placement with fluoroscopy. In a true A/P view, the screw should be crossing the SIJ and above the sciatic notch.

2 In a teardrop view, the SI.CORE or Favored Angle screw should be centered, with the distal end of the screw superimposed. If desired, utilize the T27 Screw Adjuster to adjust screw height. The Closed Head Turner can be used at this time to orient the blue Favored Angle tulip laterally.

TIP: THE CLOSED HEAD ADJUSTER IS COMPATIBLE WITH ALL SCREW TYPES.

CAUTION: THE SAFETY AND EFFECTIVENESS OF THE FENESTRATED SCREWS AND INVICTUS CORE/SI.CORE SCREW HAVE NOT BEEN ESTABLISHED WHEN USED IN CONJUNCTION WITH BONE CEMENT OR FOR USE IN PATIENTS WITH POOR BONE QUALITY (E.G., OSTEOPOROSIS, OSTEOPENIA). INVICTUS CORE AND INVICTUS SI.CORE SCREWS ARE NOT INTENDED FOR USE WITH SALINE OR RADIOPAQUE DYE; ALL OTHER FENESTRATED SCREWS ARE INTENDED FOR USE WITH SALINE OR RADIOPAQUE DYE.

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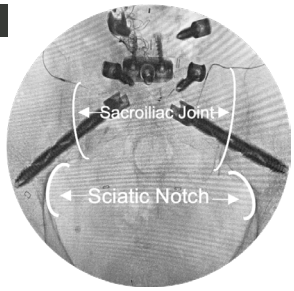

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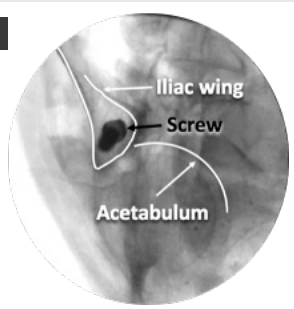

DUAL S2AI SCREW PLACEMENT

1 If additional fixation is preferred, place bilateral, dual S2AI screws. In an open approach, the primary S2AI screw starting point will be slightly inferior, or superior to the midpoint of the S1 and S2 dorsal foramina, to accommodate space for the secondary S2AI screw. This will position the S2AI screw in line with the S1 screw.

2 Follow the prior steps for placement of the primary S2AI screw.

3 Insert the fixed post of the S2AI Drill Guide into the primary screw hex. Engage the post to the hex and spin the gold thumbwheel clockwise until it bottoms out. The plunger proximal to the thumbwheel will rise when the Drill Guide post is properly aligned into the primary screw hex. Verify that the laser-marked line on the distal end of the plunger is flush with the top of the thumbwheel. This indicates that the post is properly seated within the hex.

4 The S2AI Drill Guide will rigidly fix into the desired position and assist in verifying the trajectory of the secondary S2AI screw. The S2AI Drill Guide will accommodate 17.5 mm of distance from screws, center-to-center. The screws will be aligned parallel, with 4 mm of distance distally, after insertion.

TIP: 18" NITINOL TROCAR TIP GUIDEWIRES ARE PROVIDED IN THE SET. LONGER LENGTHS ARE AVAILABLE BY REQUEST. (PN 17100-20-1)

THE DRILL GUIDE WILL PLACE SCREWS 17.5 MM APART, CENTER-TO-CENTER WITH 4 MM OF DISTAL CONVERGENCE.

CAUTION: GUIDEWIRES SHOULD BE MONITORED USING FLUOROSCOPIC IMAGING TO MITIGATE DAMAGE TO UNDERLYING AND ASSOCIATED STRUCTURES.

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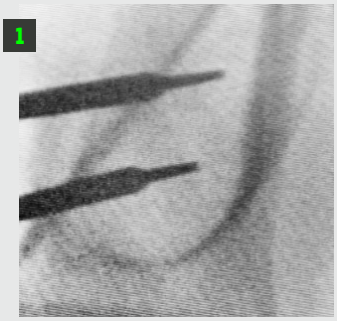

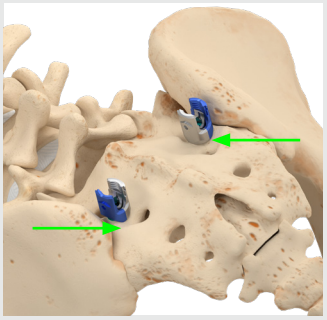

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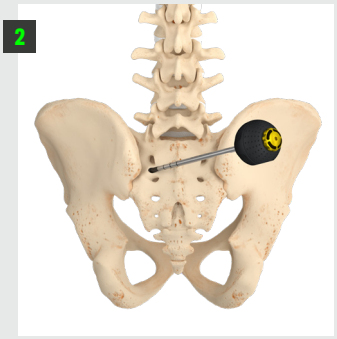

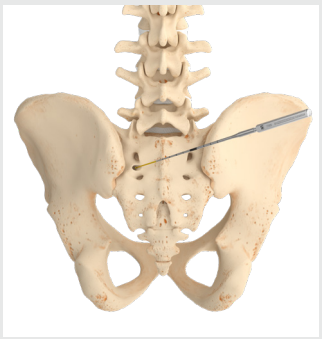

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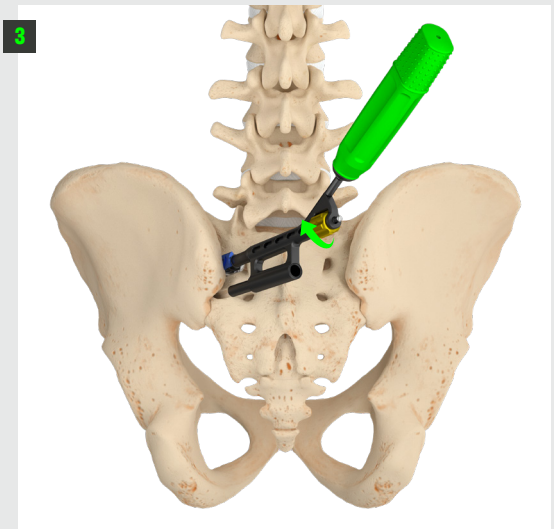

DUAL S2AI SCREW PLACEMENT CONT'D

5 Attach the desired Ratcheting Handle or power drill to the 4.5 mm S2AI Drill. When the appropriate position has been reached and verified with fluoroscopy, utilize the 4.5 mm S2AI Drill to penetrate the cortex of the sacrum for the secondary S2AI screw. Rotate the 4.5 mm S2AI Drill clockwise to advance the Drill. When drilling, verify the trajectory every 20 mm with fluoroscopy.

6 Reference the laser-marked depth markers on the shaft of the Drill, when aligned with the Drill Guide.

7 The joint will be reached at about 40 mm of Drill depth, depending on patient anatomy. A blue band indicates 60 mm of Drill depth.

8 If desired, drill to the length of the desired SI.CORE screw. After utilizing the Drill, remove the S2AI Drill Guide from the primary screw hex and verify the integrity of the pilot hole with the Rigid Ball Tip Probe. If preferred, a Guidewire may be placed through the S2AI Drill Guide to maintain the trajectory when removing the S2AI Drill Guide.

9 After the starting point has been determined and the pilot hole is prepared, follow the previous steps for screw placement.

> **CAUTION:** THE SAFETY AND EFFECTIVENESS OF THE FENESTRATED SCREWS AND INVICTUS CORE/SI.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 SI.CORE SCREWS ARE NOT INTENDED FOR USE WITH SALINE OR RADIOPAQUE DYE; ALL OTHER FENESTRATED SCREWS ARE INTENDED FOR USE WITH SALINE OR RADIOPAQUE DYE.

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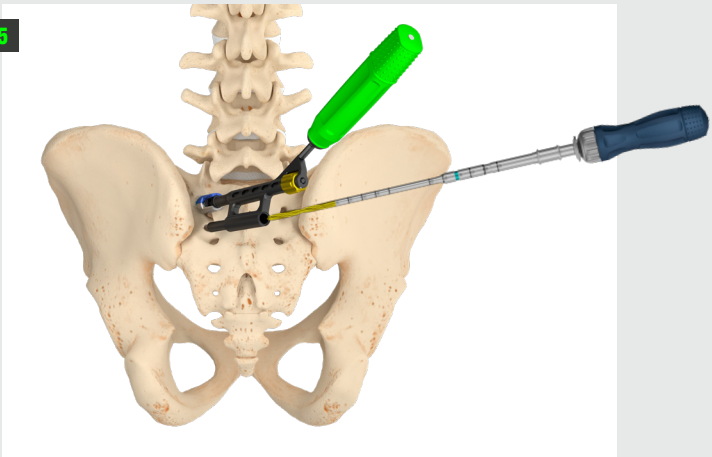

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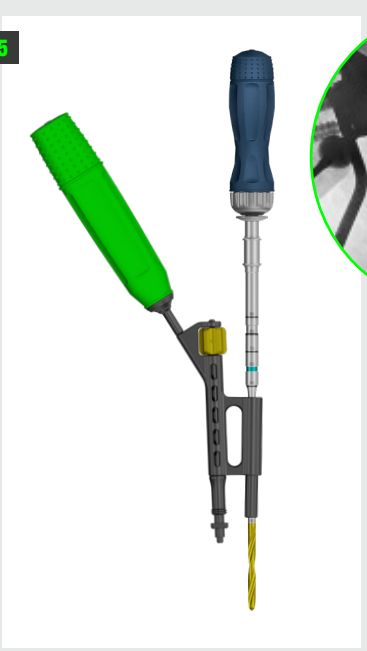

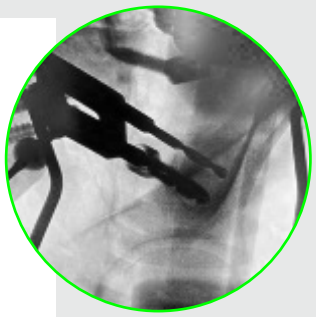

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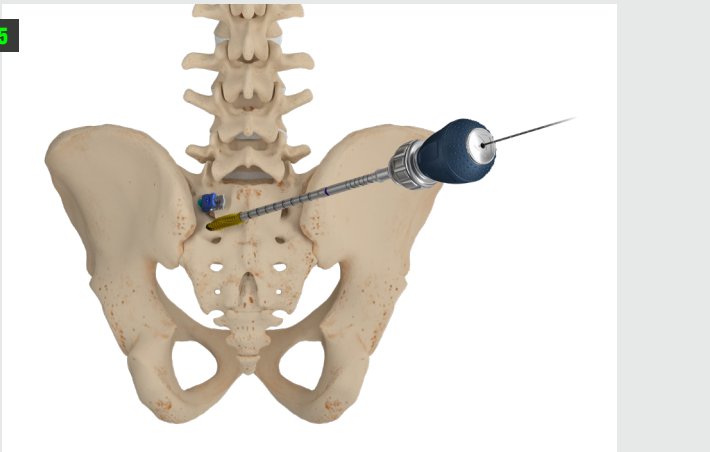

ROD CONTOURING

1 For rod measurement, contouring, and seating, reference LIT-16001, “Invictus Open Surgical Technique Guide.”

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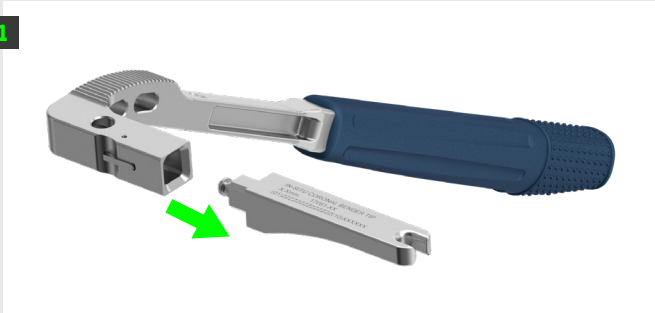

FINAL TIGHTENING

1. Connect the 90 inch-pound Torque Limiting Handle to the Final Tightening Driver. Slide the Closed Countertorque around the screw until fully seated. The Closed Countertorque will accept both 5.5 mm and 6.0 mm diameter rods.

2. Insert the Torque Driver assembly through the Countertorque until it engages with the set screw. Turn the Torque Handle clockwise until the handle breaks away. The construct is complete.

TIP: UTILIZE THE CLOSED COUNTERTORQUE FOR CLOSED SI.CORE AND FAVORED ANGLE SCREWS, IN ADDITION TO STANDARD POLYAXIAL AND POLYAXIAL REDUCTION SCREWS.

110 INCH-POUND TORQUE LIMITING HANDLES ARE AVAILABLE BY REQUEST. (PN: 17093-110)

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

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

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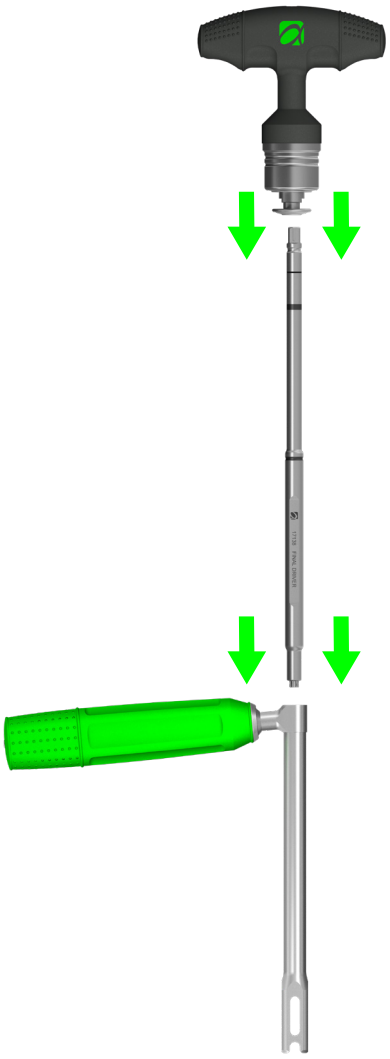

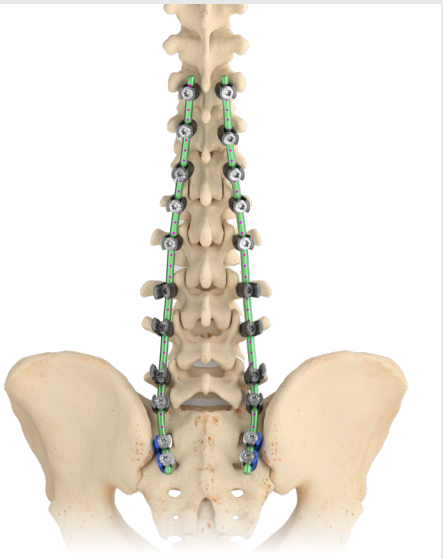

FINAL S2AI CONSTRUCT

INVICTUS® SI.CORE

A SELF-HARVESTING SCREW

ILIAC FIXATION WITH SI.CORE AND FAVORED ANGLE SCREWS

ILIAC FIXATION

1. If iliac fixation is desired, resect bone from the posterior superior iliac spine (PSIS). Utilize a high-speed burr or rongeur to create a starting point in the crest.
2. Use either the Straight or Curved Cannulated Iliac Probe to create a pilot hole aiming 25° lateral and 30 ° caudal, towards the anterior inferior iliac spine (AIIS).
3. Utilize the crosshair feature on the Straight or Curved Cannulated Iliac Probe to determine if the distal tip of the Probe is within the teardrop. The distal tip of the Iliac Probe will be superimposed beneath the center of the crosshair cap when it is appropriately positioned. The Rigid Ball Tip Probe may be used to verify pilot hole integrity.
4. Remove the inner stylet of the Cannulated Probe by twisting the gold shaft cap counter-clockwise and place a Guidewire. Remove the Cannulated Iliac Probe, leaving the Guidewire in place.

TIP: THERE ARE LASER MARKINGS FROM 30 MM – 120 MM, EVERY 10 MM. THE TIP OF THE STRAIGHT OR CURVED ILIAC PROBE IS 2.0 MM WITH A 1.5 MM STYLET DIAMETER.

THE INNER STYLET IS REMOVABLE AND SECURED BY A LUER LOCK FEATURE. IF PREFERRED, BONE MARROW ASPIRATE (BMA) MAY BE EXTRACTED THROUGH THE LUER LOCK FEATURE. THE INNER STYLET IS DISPOSABLE.

CAUTION: GUIDEWIRES SHOULD BE MONITORED USING FLUOROSCOPIC IMAGING TO MITIGATE DAMAGE TO UNDERLYING AND ASSOCIATED STRUCTURES.

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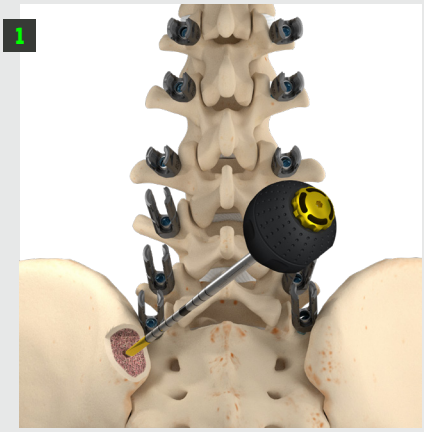

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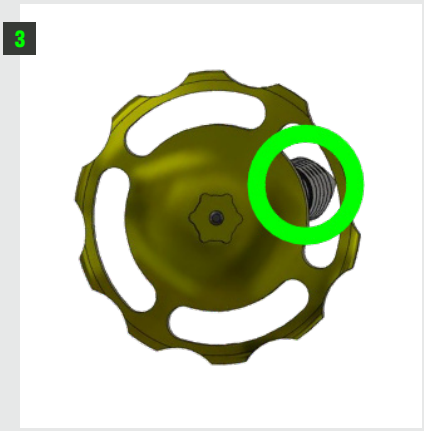

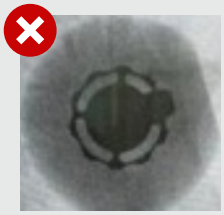

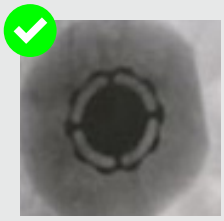

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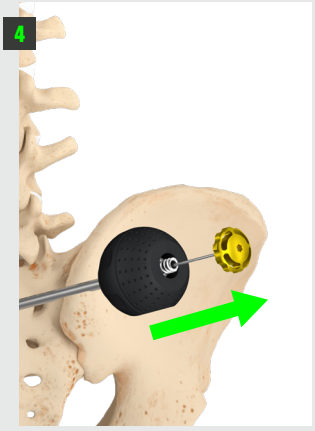


TAPPING

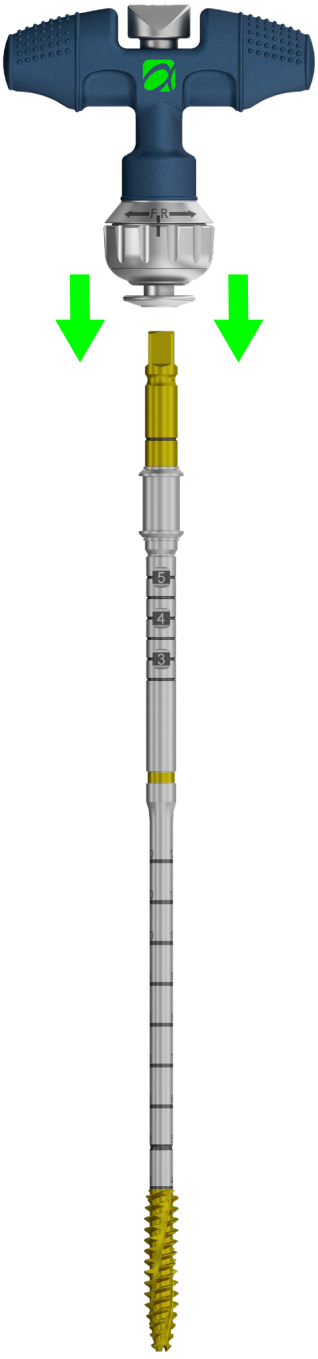
1 If tapping is preferred, attach the desired Ratcheting Handle to the appropriate diameter cannulated iliac Tap.

2 Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the Tap. Set the Ratcheting Handle to the “Forward” position and feed the Tap over the Guidewire.

3 Rotate the Handle clockwise to advance the Tap into the proper trajectory. Reference the markings on the distal end of the Tap shaft to determine its depth in bone.

> **TIP:** T27 SCREWDRIVERS ARE DENOTED BY COLOR. GRAY SCREWDRIVERS WITH A DISTAL BLUE BAND INDICATE T27 HEXALOBE INTERFACES, DESIGNED TO BE USED WITH THE FAVORED ANGLE AND SI.CORE SCREWS.

1



SCREWDRIVER ASSEMBLY

1. Connect a Ratcheting Axial or T-handle to the proximal end of the cannulated T27 Screwdriver, until the handle covers the black laser-marked line.

2. Insert the Screwdriver into the desired SI.CORE or Favored Angle screw and rotate clockwise until it bottoms out. Once fully tightened, slide the thumbwheel collar distally until a black laser-marked line appears, indicating that the Screwdriver is locked to the screw.

3. With the screw assembled to the Screwdriver, insert the screw over the Guidewire and into the ilium by rotating the Ratcheting Handle clockwise. Remove the Guidewire once the ideal screw trajectory has been identified using fluoroscopic imaging. Once the desired depth is achieved, unlock the Screwdriver by pulling the collar proximally and rotating the thumbwheel counterclockwise. Confirm screw placement with fluoroscopy.

4. Utilize the T27 Head Adjusters or T27 Screw Adjuster if preferred. Open or closed Iliac Connectors accept 5.5, 6.0, and 6.35 mm rods and may be used to connect iliac screws to the rod.

CAUTION: THE SAFETY AND EFFECTIVENESS OF THE FENESTRATED SCREWS AND INVICTUS CORE/SI.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 SI.CORE SCREWS ARE NOT INTENDED FOR USE WITH SALINE OR RADIOPAQUE DYE; ALL OTHER FENESTRATED SCREWS ARE INTENDED FOR USE WITH SALINE OR RADIOPAQUE DYE.

CAUTION: GUIDEWIRES SHOULD BE MONITORED USING FLUOROSCOPIC IMAGING TO MITIGATE DAMAGE TO UNDERLYING AND ASSOCIATED STRUCTURES.

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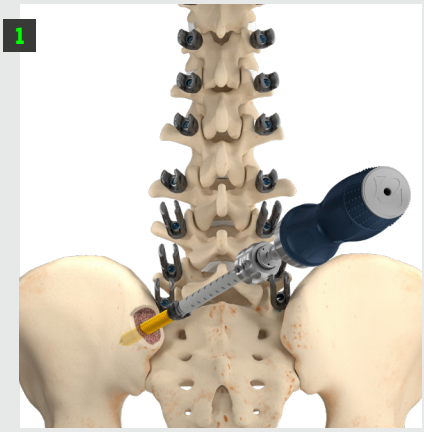

ROD CONTOURING

1 For rod measurement, contouring, and seating, reference LIT-16001, “Invictus Open Surgical Technique Guide.”

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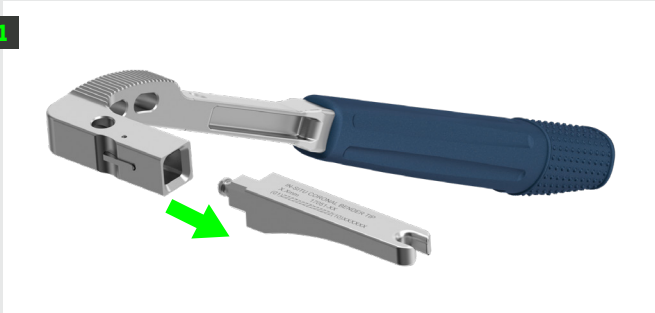

FINAL TIGHTENING

1. Connect the 90 inch-pound Torque Limiting Handle to the Final Tightening Driver. Slide the Closed Countertorque around the screw until fully seated. The Closed Countertorque will accept both 5.5 mm and 6.0 mm diameter rods.

2. Insert the Torque Driver assembly through the Countertorque until it engages with the set screw. Turn the Countertorque Handle clockwise until the Handle breaks away. The construct is complete.

TIP: UTILIZE THE CLOSED COUNTERTORQUE FOR CLOSED SI.CORE AND FAVORED ANGLE SCREWS, IN ADDITION TO STANDARD POLYAXIAL AND POLYAXIAL REDUCTION SCREWS.

110 INCH-POUND TORQUE LIMITING HANDLES ARE AVAILABLE BY REQUEST. (PN: 17093-110)

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

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

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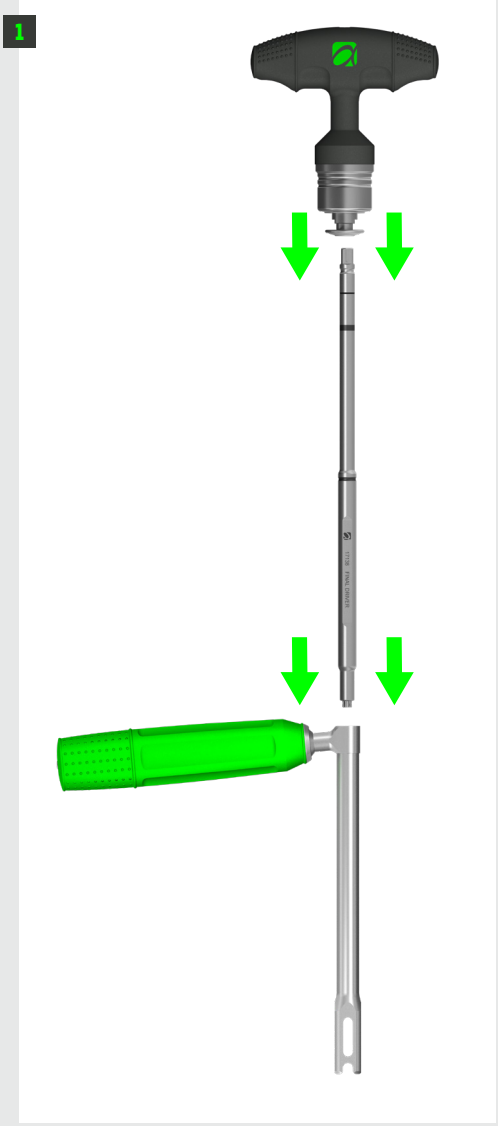

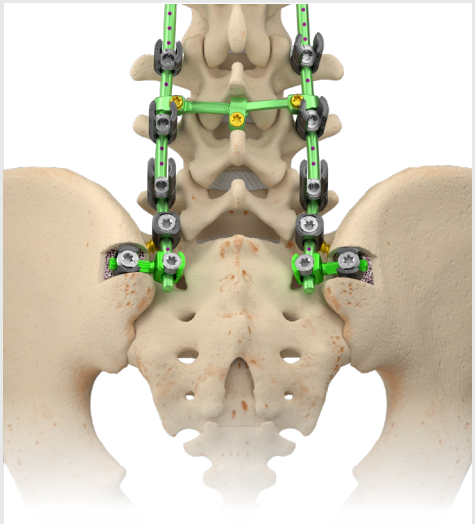

FULL CONSTRUCT
WITH ILIAC FIXATION

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.

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

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

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

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

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

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

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

Invictus Core and Invictus SI.Core Screws are not intended for use with cement; all other fenestrated screws may be used with Invictus Bone Cement. When used in conjunction with Invictus Bone Cement, the Invictus Fenestrated Screws are intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Invictus Fenestrated Screws augmented with Invictus Bone Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised.

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

WARNINGS/CAUTIONS/PRECAUTIONS:
1. The implants of the system are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections.
2. All instruments, except instruments marked as sterile, are provided non-sterile and must be cleaned and sterilized prior to surgery. See CLEANING and STERILIZATION sections in this IFU.
3. The following statements apply to single use sterile instruments:
    a. Visually inspect the packaging for signs of damage and breaches of packaging integrity prior to use. Do not use devices if package is opened, damaged, or past the expiry date.
    b. Do not re-sterilize instruments.
    c. Do not use scratched or damaged devices.
4. Device components should be received and accepted only in packages that have not been damaged. Damaged implants and damaged or worn instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.
5. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
6. The safety and effectiveness of the Invictus Core/SI.Core Screws has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). Invictus Core and Invictus SI.Core Screws are not intended for use with cement, saline, or radiopaque dye; all other fenestrated screws may be used with cement, saline, or radiopaque dye.
7. When use of SI.CORE screws is intended for fusion, women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
8. The system implants are to be used with the assistance of a bone graft. A successful result may not be achieved in every instance of use with these devices. Without solid bone fusion, these devices cannot be expected to support the spine indefinitely and may fail due to bone-metal interface, rod failure or bone failure.
9. The product implants are single use devices. Do not reuse. While an implant may appear undamaged, it may have small defects or internal stress patterns that could lead to fatigue failure. In addition, the removed implant has not been designed or validated for the decontamination of microorganisms. Reuse of this product could lead to cross-infection and/or material degradation as a result of the decontamination process.
10. The instruments in the Invictus Spinal Fixation System are reusable surgical devices except for the Fascial Blades, 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 tighted 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.

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.

INTRAOPERATIVE MANAGEMENT:

1. To prevent possible nerve damage and associated disorders, extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
2. Rods should be contoured in only one direction, one time. Avoid notching, scratching or reverse bending of the devices because these alterations will produce defects in the surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
3. If it is mandatory to cut the rods to a more specific length, rod cutting should be done at a distance from the operative range, and such that a non-sharp edge remains on the rod.
4. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
5. Final tightening of Set Screws: All Set Screws must be tightened using the appropriate instruments (e.g., Torque Handle, Final Driver, and Counter Torque) as indicated in the Surgical Technique Guide.
6. During Guidewire placement, it is recommended to frequently use alternate imaging planes. Ideally, an A-P, lateral, and oblique view should be taken at all critical steps during the procedure to confirm proper positioning and alignment, and to prevent kinking or breakage of the devices.
7. It is recommended that a maximum of 1cc of Invictus Bone Cement be injected in the vertebral body for each screw in the thoracic spine (except T11 and T12) and that a maximum of 2 cc of Invictus Bone Cement be used in T11, T12, and the lumbar spine. However, the injected volume of cement and Invictus Fenestrated screw size should be selected based on individual patient anatomy, as different screws may be applicable for different vertebral levels.
8. If SI joint fusion is desired, two SI.CORE screws should be placed across the SI joint in sacral alar iliac trajectories.

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

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

Excerpt from INS-111

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

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

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