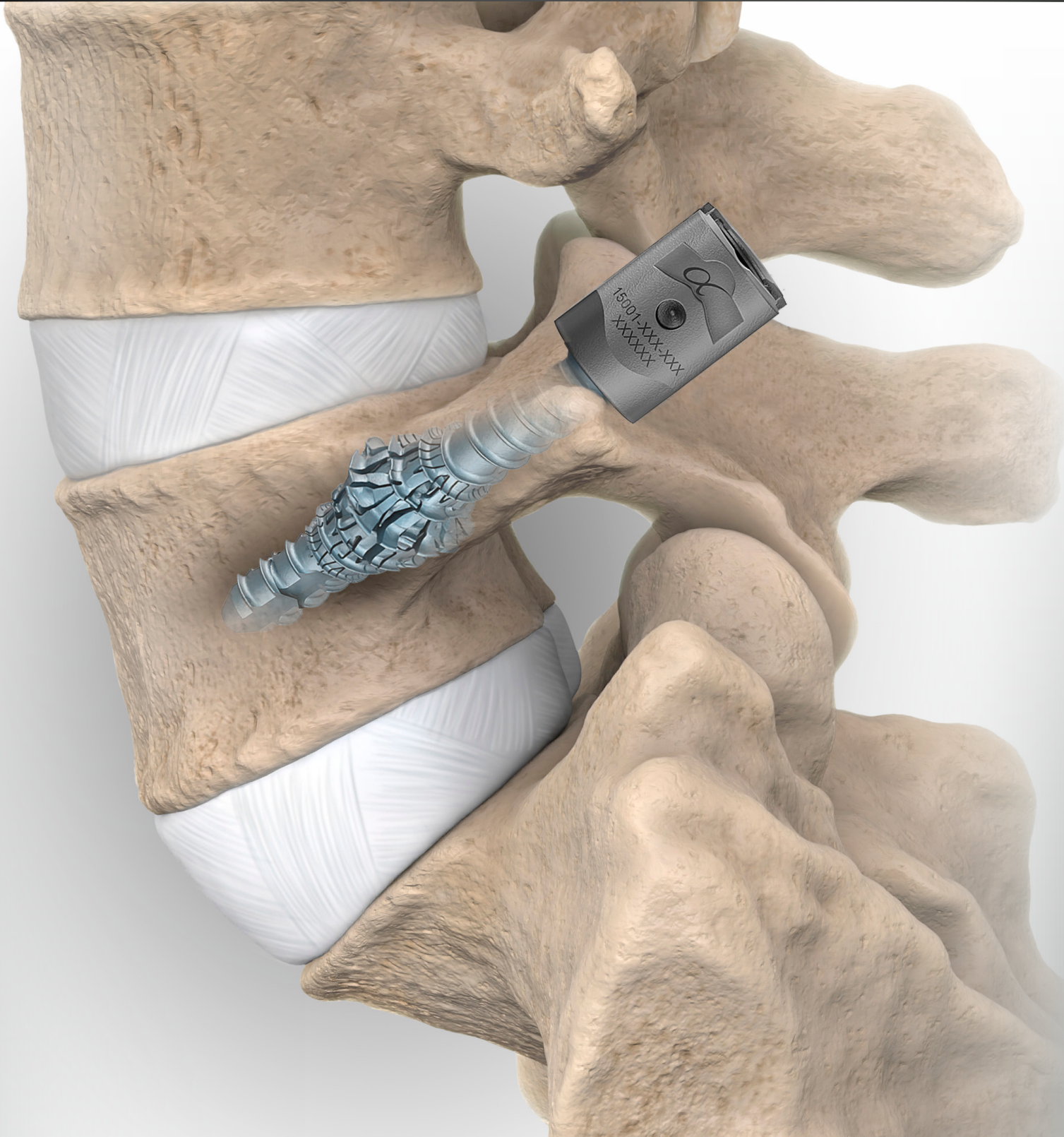


INVICTUS
OsseoScrew[®]
EXPANDABLE SPINAL FIXATION

αtec[™]



INVICTUS[®] OsseoScrew[®]

EXPANDABLE SPINAL FIXATION

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- Invictus OsseoScrew Instrument Set
- Invictus OsseoScrew Implant set
 - *Rods not included in set*

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

- Invictus MIS Core Instrument Set
- Invictus MIS Reduction Instrument SingleStep™ Set
- Invictus MIS Extended Tab Polyaxial Reduction Implant Set

Refer to the standard **Invictus Surgical Technique Guide (LIT-17001)** for all additional optional implant and instrument sets.

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

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INVICTUS®

SPINAL FIXATION SYSTEM

OPEN APPROACH

PATIENT POSITIONING

Place the patient on the operating table in prone position. Prepare and drape in a conventional manner. Uniplanar or biplanar fluoroscopy may be used. Place the necessary neuromonitoring electrodes on the patient and execute a twitch test to determine if neuromuscular blockades are clear.

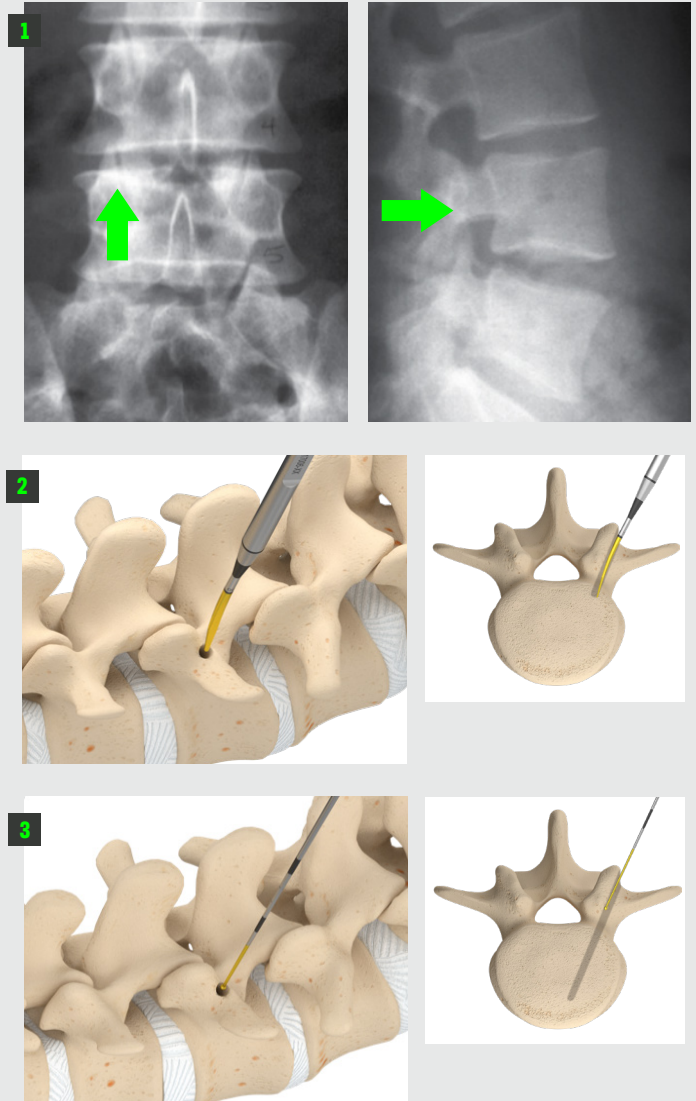
INTRA-OP IMAGING

Prior to preparing the pedicles for screw insertion, determine the sagittal and coronal orientation of the pedicles for the vertebrae to be instrumented. Utilize a true A/P and lateral radiograph or C-Arm image.

PEDICLE PREPARATION

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

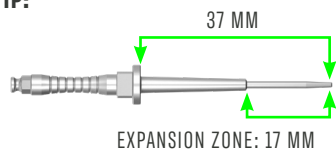
TIP: THORACIC PROBES AND BALL TIP PROBES HAVE A 30 MM GOLD TIP AND A BLACK BAND FROM 40 MM – 50 MM.



TRIAL MARKERS (OPTIONAL)

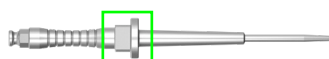
- 1** Trial Markers can be used after a Gearshift, prior to tapping to provide a radiographic confirmation of expansion location. Expansion location is denoted by the slim radiographic depth marker.

TIP:

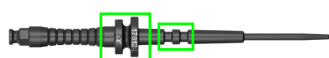


TIP:

RIGHT: GREY WITH SQUARE IDENTIFIER



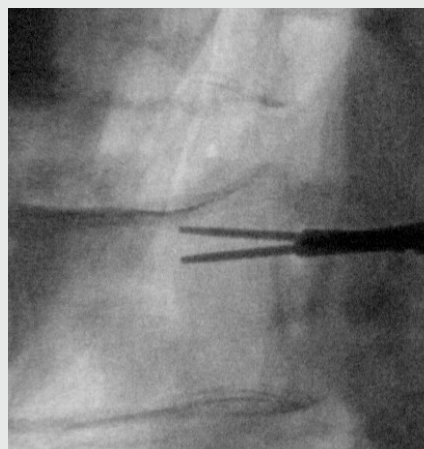
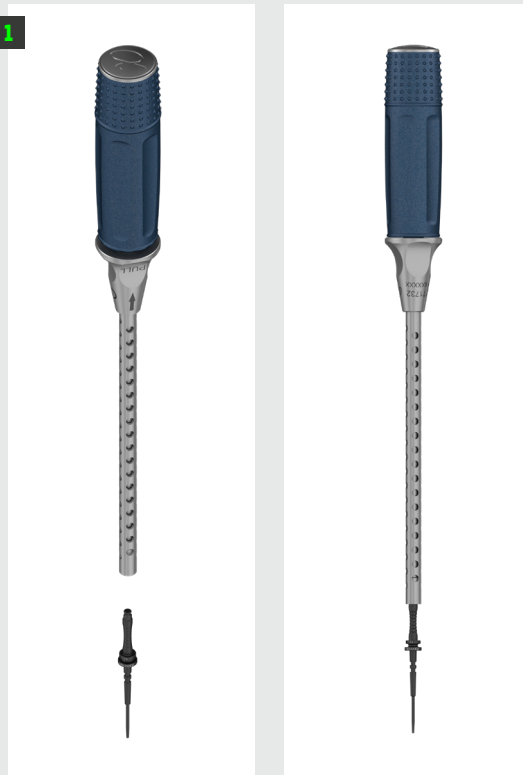
LEFT: BLACK WITH CIRCLE IDENTIFIER



Remove the Trial Marker from the caddy and attach it to the Trial Marker Inserter until fully seated. Insert the Trial Markers into the pedicle and confirm radiographically that the expansion zone is past the pedicle. Remove the Trial Markers prior to tapping the pedicle.

TIP: TRIAL MARKERS ARE OPTIMIZED TO WORK WITH A MINIMUM GEARSHIFT PROBE DEPTH OF 40 MM.

1



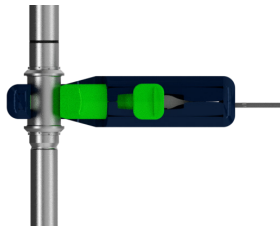
- 1 Attach the desired Ratcheting Handle to the appropriate diameter OsseoScrew Tap. Verify that the Ratcheting Handle covers the black laser-marked line on the proximal end of the OsseoScrew Tap. It is mandatory to Tap prior to inserting an OsseoScrew.

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



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

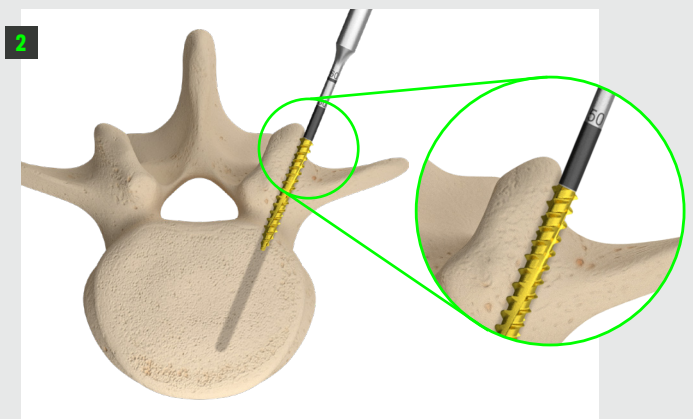
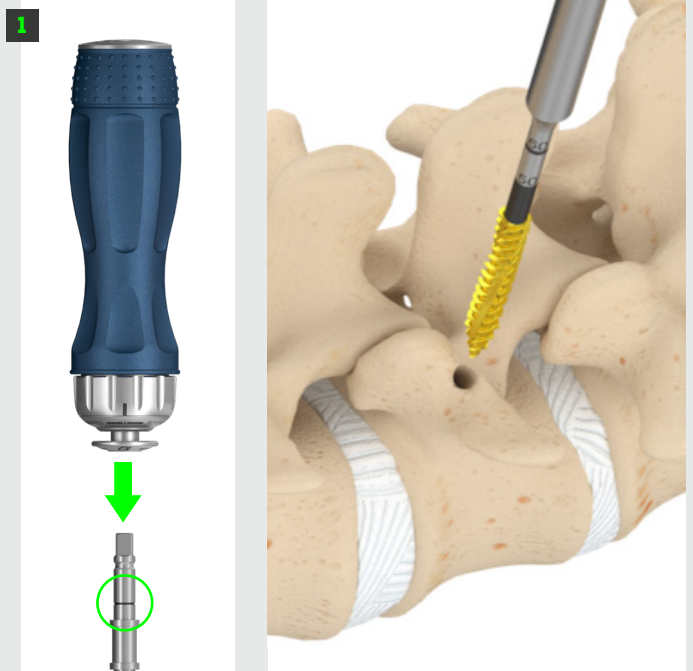
OPTIONAL:
Attach the Alpha Informatix™ Stimulation Clip to the proximal end of the Tap shaft to stimulate during Tap insertion.



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



TIP: OSSEOSCREW SHOULD BE TAPPED LINE TO LINE.



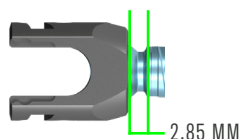
- 1 Once the preferred OsseoScrew has been determined, select the appropriate Invictus MIS Screwdriver. Cannulation of the Screwdriver is denoted by the gold-colored proximal end. Attach the green OsseoScrew Ratcheting Egg Handle to the Invictus MIS Screwdriver. Verify that the Ratcheting Handle covers the black line on the gold proximal end of the Screwdriver.

TIP: SCREWDRIVERS ARE DENOTED BY COLOR. INVICTUS MIS REDUCTION SCREWDRIVERS ARE BLACK, AND INVICTUS MIS POLYAXIAL SCREWDRIVERS ARE GRAY.

With the Screwdriver in the unlocked position, insert the Screwdriver into the desired screw in the caddy and rotate the silver thumbwheel clockwise.

- 2 Once fully tightened, slide the thumbwheel forward until the black line is visible, indicating that the Screwdriver is securely locked to the screw.

TIP: OSSEOSCREWS ARE MEASURED FROM THE TIP OF THE SCREW TO THE PROXIMAL THREAD. THEREFORE, THERE IS AN ADDITIONAL 2.85 MM OF SCREW BODY TO THE MOST PROXIMAL THREAD.



Verify that the gold band on the proximal end of the green OsseoScrew Ratcheting Handle is not visible. If the gold band is visible, insert the Expansion T-Handle into the proximal end of the Ratcheting Handle and turn the T-Handle counterclockwise until the gold band is no longer exposed. Remove the T-Handle from the green Ratcheting Handle.

1



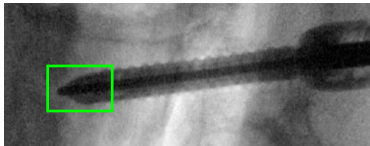
2



- 1** Select the Expansion Shaft that corresponds to the desired screw length. Verify that the Screwdriver is in the neutral position and slide the Expansion Shaft into the proximal end of the green Ratcheting Handle until the Expansion Shaft is seated within the OsseoScrew.
- 2** Rotate the Expansion Shaft clockwise to thread the Shaft into the distal tip of the screw.
- 3** Continue to rotate the Expansion Shaft until it bottoms out, then push the Shaft into the gold retention ring of the Handle to lock.

TIP: THE EXPANSION SHAFT WILL NOT SEAT INTO THE PROXIMAL END OF THE HANDLE UNTIL FULLY THREADED INTO THE SCREW TIP, SERVING AS A VISUAL AND TACTILE INDICATOR OF PROPER THREADING.

TIP: VERIFY THAT THE EXPANSION SHAFT IS PROTRUDING FROM THE DISTAL TIP OF THE SCREW TO ALLOW FOR PROPER ENGAGEMENT OF THE EXPANSION MECHANISM.

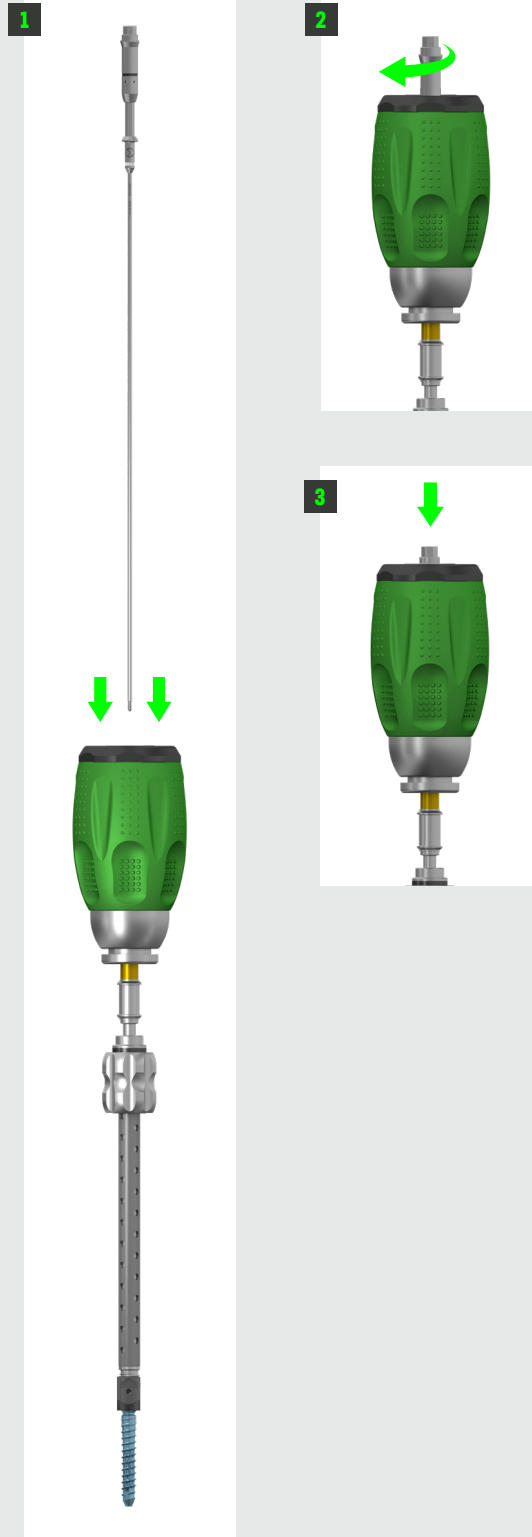
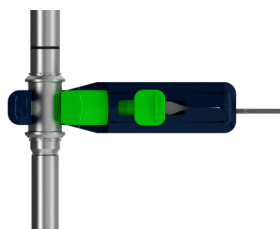


TIP: EXPANSION SHAFTS ARE COLOR-CODED TO DENOTE LENGTH IN ADDITION TO LASER MARKINGS ON THE PROXIMAL END.



- 40 MM SHAFT IS WHITE
- 45 MM SHAFT IS ORANGE
- 50 MM SHAFT IS NAVY BLUE
- 55 MM SHAFT IS RED

OPTIONAL:
Attach the Alpha Informatix™ Stimulation Clip to the proximal end of the Screwdriver to stimulate during Screw insertion.



SCREW INSERTION

- 1 Place the green Ratcheting Handle into the forward position. Insert the OsseoScrew into the prepared pedicle and rotate the Handle clockwise to advance the screw until it reaches the desired depth in the vertebral body.

TIP: PRIOR TO SCREW EXPANSION, VERIFY THAT THE EXPANSION SHAFT IS PROTRUDING FROM THE SCREW USING FLUOROSCOPY OR PRESS THE PROXIMAL END OF THE EXPANSION SHAFT TO VERIFY SPRINGINESS TO ALLOW FOR PROPER ENGAGEMENT OF THE EXPANSION MECHANISM.

SCREW EXPANSION

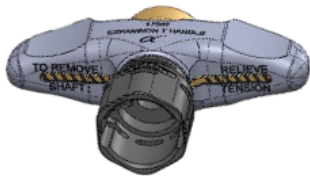
- 2 Once the OsseoScrew is properly implanted, seat the gray Expansion T-Handle into the proximal end of the green Ratcheting Handle. Once the T-Handle is properly seated in the Ratcheting Handle, rotate the T-Handle clockwise until the gold retention ring is fully visible and the T-Handle bottoms out, indicating screw expansion.

- 3 Confirm radiographically that the expansion zone is past the pedicle and the OsseoScrew is fully expanded.

CAUTION: AFTER THE INVICTUS OSSEOSCREW HAS BEEN EXPANDED, TENSION MUST BE RELIEVED BY ROTATING THE T-HANDLE ONE FULL TURN COUNTERCLOCKWISE PRIOR TO REMOVING THE EXPANSION SHAFT.

- 4 After expansion, rotate the T-Handle counterclockwise one full rotation to relieve the tension of the expansion mechanism.

TIP: SEE BOTTOM OF T-HANDLE FOR CAUTION.

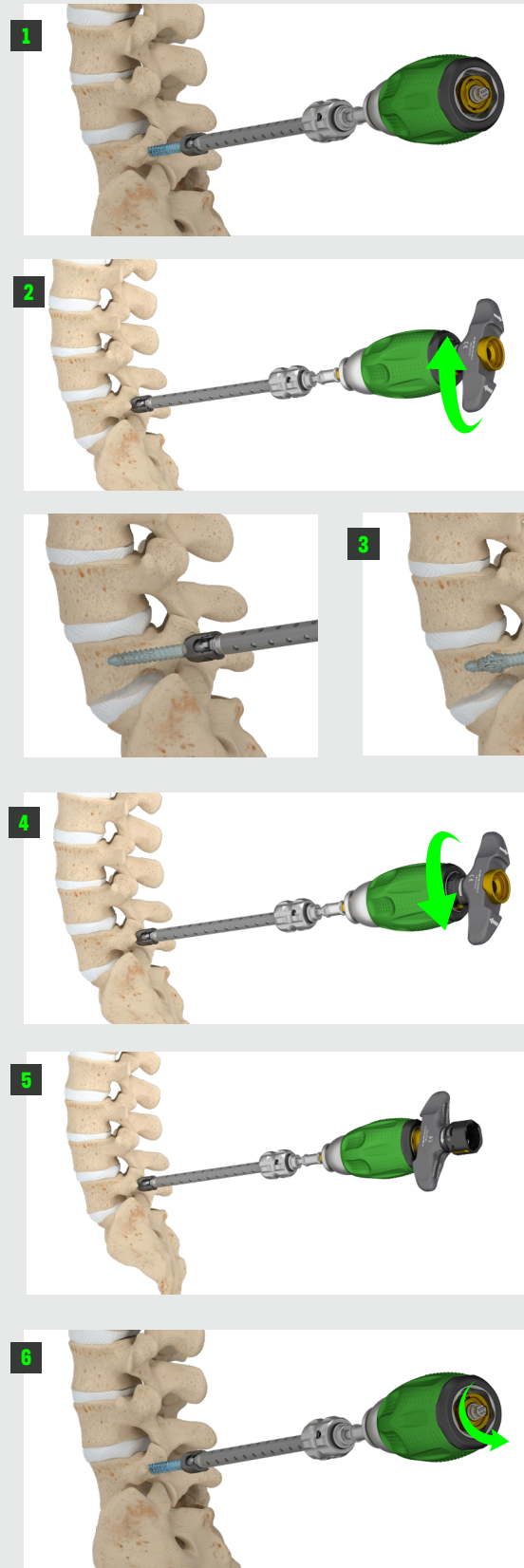


- 5 Remove the Gray Expansion T-Handle from the green Ratcheting Handle and flip upside down. Using the gold release feature on the proximal end of the Expansion T-Handle, press the gold retention ring to release the Expansion Shaft.

- 6 After the Shaft is released, rotate the Shaft counterclockwise to unthread it from the OsseoScrew. Unlock the Screwdriver by pulling up on the thumbwheel proximally and rotating the silver thumbwheel counterclockwise to disengage from the screw.

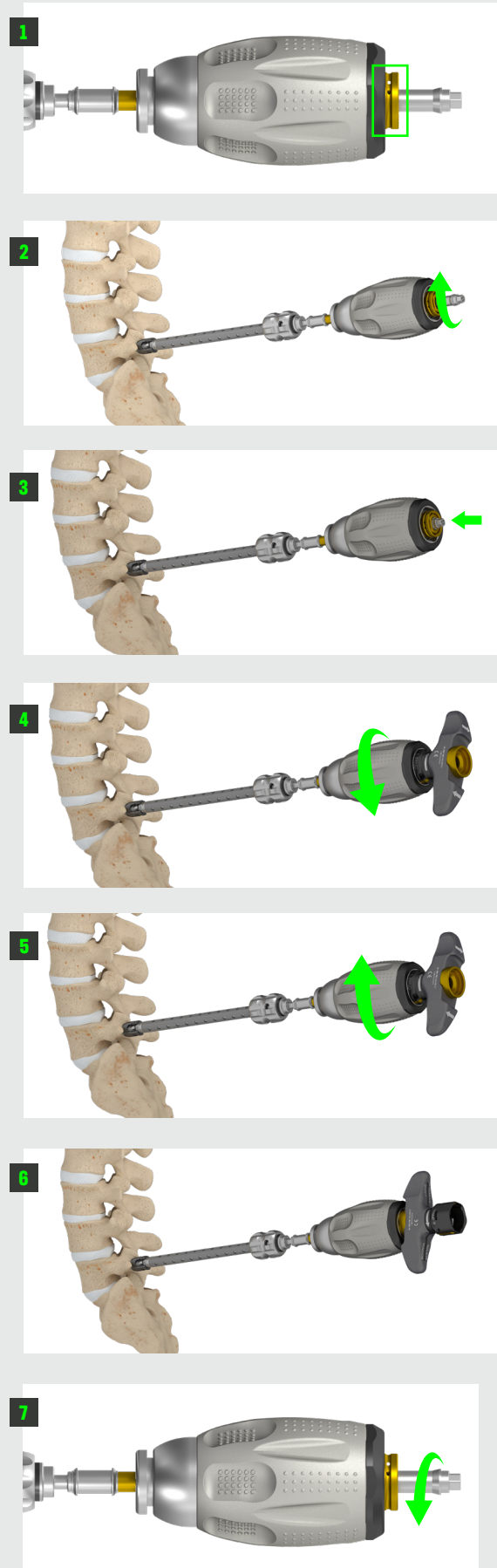
CAUTION: ONCE THE INVICTUS OSSEOSCREW IMPLANT HAS BEEN EXPANDED, IT MAY BE DIFFICULT TO COLLAPSE, RE-POSITION, OR REMOVE; THEREFORE, IT IS IMPORTANT TO CONFIRM PROPER PLACEMENT OF THE INVICTUS OSSEOSCREW PRIOR TO DEPLOYING THE EXPANSION FEATURE BY USE OF FLUOROSCOPY OR OTHER SUITABLE IMAGING TECHNIQUE.

TIP: THE GOLD BAND CAN BE SEEN IN THE T-HANDLE PERFORATIONS WHEN MAXIMUM TRAVEL HAS BEEN ACHIEVED.



- 1 Confirm that the gold retention ring on the gray Collapse Handle is fully visible.
- 2 Slide the Expansion Shaft into the proximal end of the gray Collapse Handle until the Expansion Shaft is seated within the OsseoScrew. Rotate the Expansion Shaft clockwise to thread the Shaft into the distal tip of the screw.
- 3 Continue to rotate the Expansion Shaft until it bottoms out, then push the Shaft into the gold retention ring of the Handle to lock.
- 4 Insert the gray Expansion T-Handle into the proximal end of the gray Collapse Handle and turn the gray Expansion T-Handle counterclockwise until the gold retention ring sits flush with the gray collapse Handle and the gray T-Handle bottoms out indicating screw collapse. Confirm screw collapse radiographically.
- 5 After collapse, rotate the T-Handle clockwise one full rotation to relieve the tension of the expansion mechanism.
- 6 Using the gold release feature on the proximal end of the gray Expansion T-Handle, press down of the gold retention ring to release the Expansion Shaft.
- 7 Rotate the Shaft counterclockwise to unthread the Shaft from the OsseoScrew. The implant is now collapsed and can be removed. If removal is not desired, pull up on the locking collar to place in the unlocked position and turn the thumbwheel counterclockwise to remove the driver from the screw.

CAUTION: AFTER THE INVICTUS OSSEOSCREW HAS BEEN COLLAPSED, TENSION MUST BE RELIEVED BY ROTATING THE T-HANDLE ONE FULL TURN CLOCKWISE PRIOR TO REMOVING THE EXPANSION SHAFT.



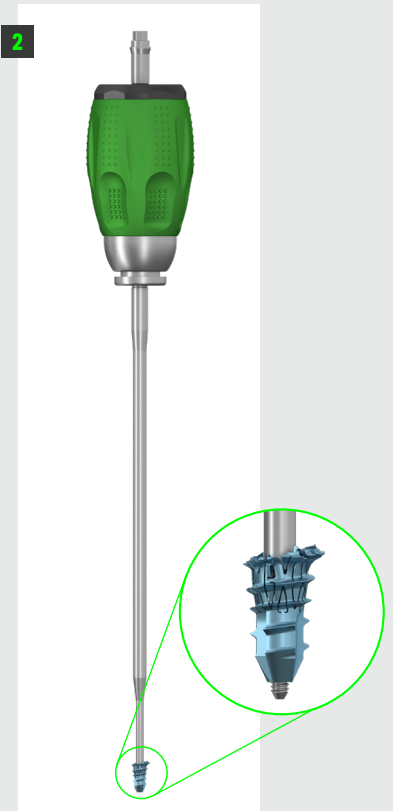
If a section of the distal tip of a removed screw remains in the vertebral body, the Invictus OsseoScrew Removal Tool can be used to engage and remove it.

- 1** Insert a Guidewire into the distal tip of the screw that remains in the vertebral body. Attach the green Ratcheting Egg Handle to the Invictus OsseoScrew Removal tool and verify that the gold band on the proximal end of the handle is not visible. Slide the Invictus OsseoScrew Removal Tool with the green Ratcheting Egg Handle over the Guidewire until it engages with the internal hex of the distal tip.
- 2** Remove the Guidewire and insert the 40 mm Expansion Shaft into the Invictus OsseoScrew Removal Tool. Thread the Expansion Shaft into the distal tip of the screw until it bottoms out.
- 3** Push the Shaft into the gold retention ring of the Handle to lock.
- 4** Seat the gray Expansion T-Handle into the proximal end of the green Ratcheting Egg Handle and rotate the T-Handle clockwise until tension is felt. Remove the T-Handle. Remove the fractured distal tip of the screw by rotating the green Ratcheting Egg Handle counterclockwise.

1



2



3



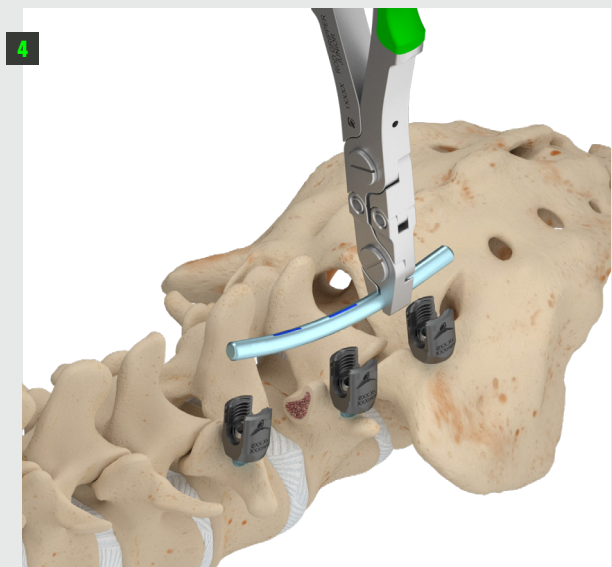
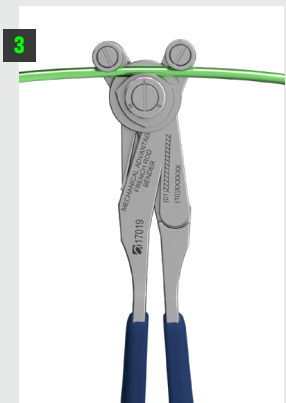
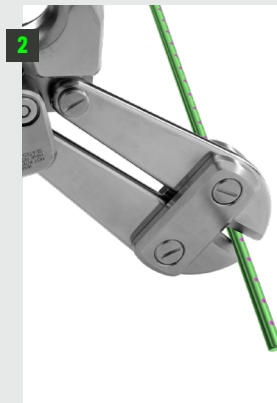
4



1 A rod template may be used to represent the desired rod contour, length, and diameter. Once the proper rod is selected, contour the rod using the Mechanical Advantage French Rod Bender. Insert the rod into the rod slot using the Rod Gripper and advance until the rod is seated within the tulip. Verify proper superior and inferior rod overhang.

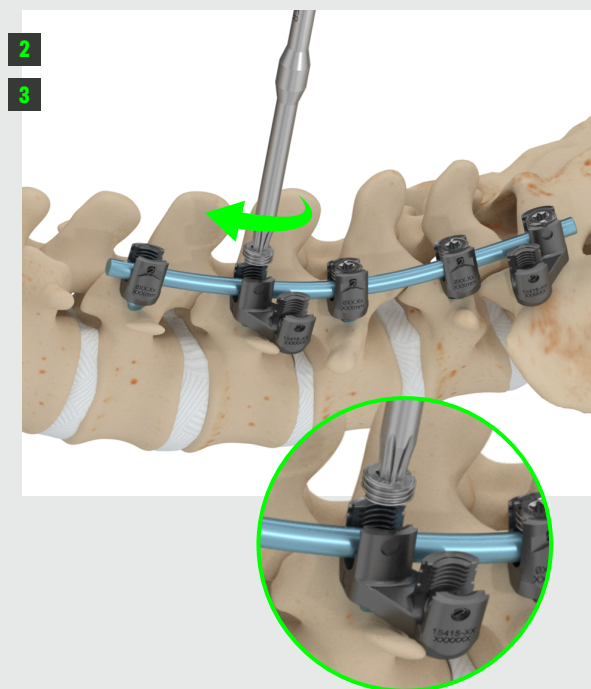
CAUTION: VERIFY SUPERIOR AND INFERIOR ROD OVERHANG. INADEQUATE OVERHANG MAY CAUSE IMPROPER SET SCREW PLACEMENT RESULTING IN AN UNSTABLE CONSTRUCT.

TIP: THE INVICTUS OSSEOSCREW TULIP ACCEPTS BOTH 5.5 MM AND 6.0 MM ROD DIAMETERS. 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 CIRCLE.



- 1 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. Thread the set screw into the tulip until the threads end and the set screw is properly seated.

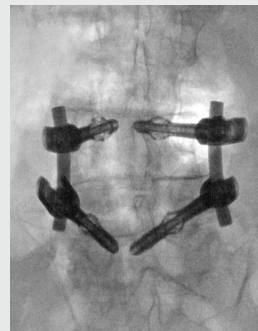
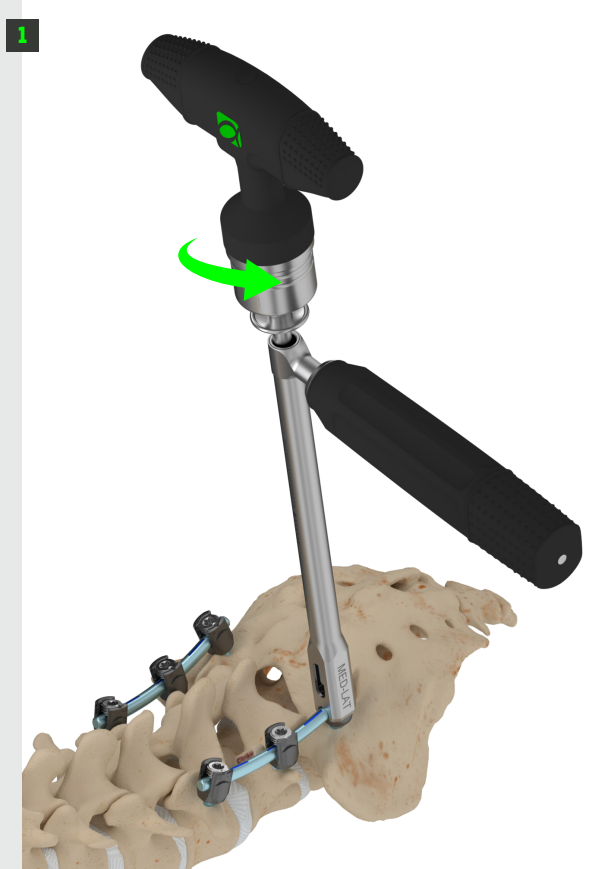
CAUTION: FAILURE TO TIGHTEN SET SCREWS USING THE RECOMMENDED INSTRUMENT(S) COULD COMPROMISE THE MECHANICAL STABILITY OF THE CONSTRUCT.



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

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.

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



INVICTUS[®] MIS

SPINAL FIXATION SYSTEM

APPROACH

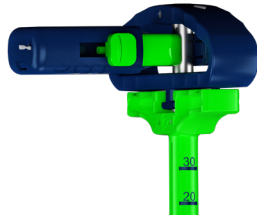
PATIENT POSITIONING

Place the patient on the operating table in prone position. Prepare and drape in a conventional manner. Uniplanar or biplanar fluoroscopy may be used. Place the necessary neuromonitoring electrodes on the patient and execute a twitch test to determine if neuromuscular blockades are clear.

PEDICLE PREPARATION

- 1 Use a Guidewire to target the affected level(s) and identify anatomic landmarks. Under A/P fluoroscopy place the Guidewire longitudinally along the lateral border of the pedicle and mark the skin. Place the Guidewire perpendicular to the longitudinal line at the level of the pedicles and mark the skin. The grid created identifies the appropriate entry point for the incision.

OPTIONAL: If EMG stimulation is desired during pedicle preparation, attach the Alpha Informatix™ Stimulation Clip to the Arcus™ Stimulating Targeting Needle.

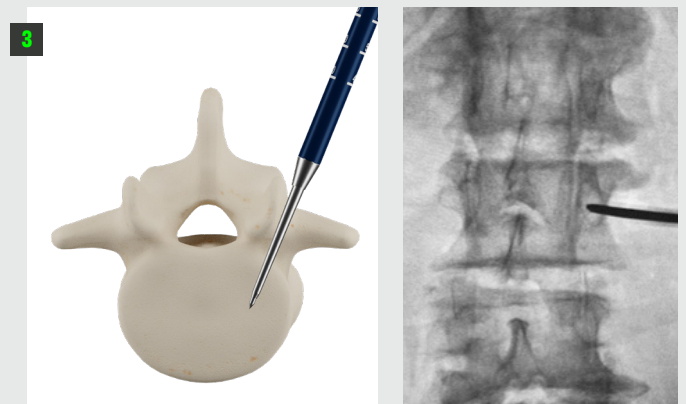
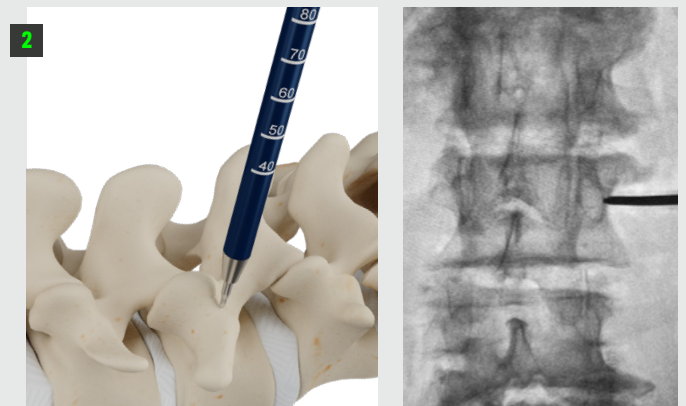
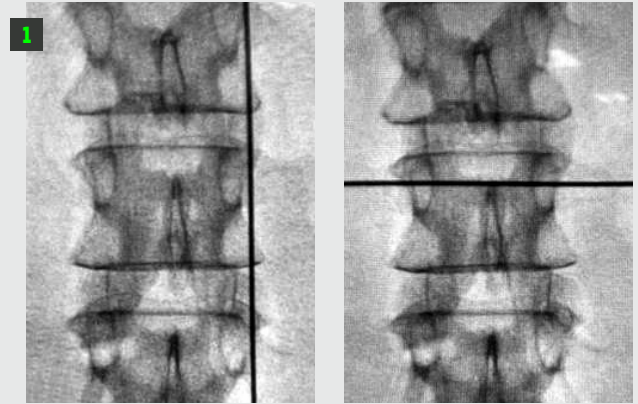


- 2 Advance the Arcus Needle through the skin until it meets the transition of the transverse process and facet joint. Using fluoroscopy, verify that the tip of the Arcus Needle is properly positioned at the center of the lateral border of the pedicle.
- 3 Perforate the cortex and create the entry pilot hole by advancing the Arcus Needle until the cannulation of the pedicle is complete. Using fluoroscopy, verify that the Arcus Needle has met the posterior edge of the vertebral body.

TIP: TO MEASURE DEPTH WITHIN BONE, REFERENCE THE DEPTH GAUGE ON THE ARCUS NEEDLE.



TIP: SEE INS-112 FOR INSTRUCTIONS FOR USE FOR THE ARCUS STIMULATING TARGETING NEEDLE.

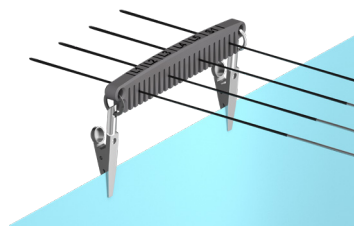


GUIDEWIRE PLACEMENT

- 1** Remove the inner Stylet of the Arcus Needle, being careful not to drift from the pilot hole.
- 2** Insert a Guidewire through the Arcus Needle until the desired depth within the vertebral body is achieved.
- 3** Remove the Arcus Needle, leaving the Guidewire in place.

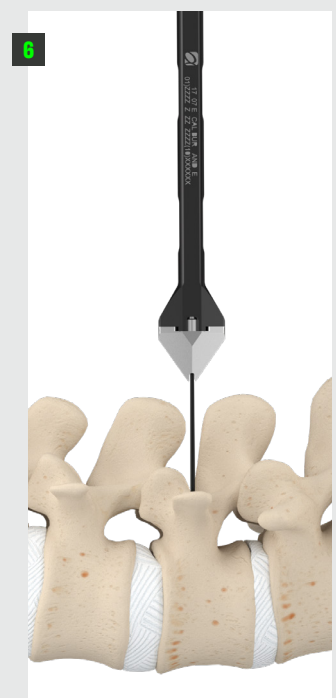
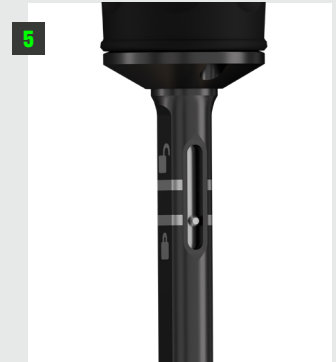
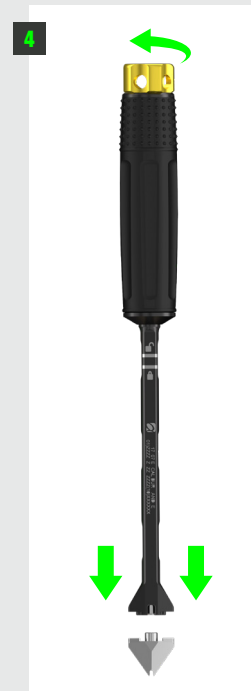
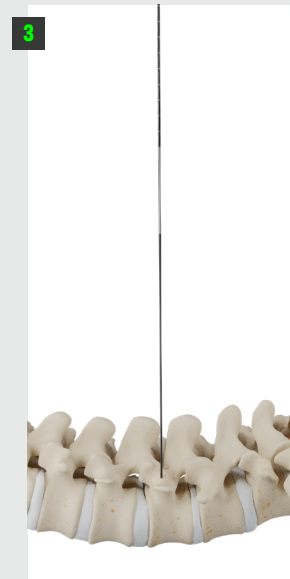
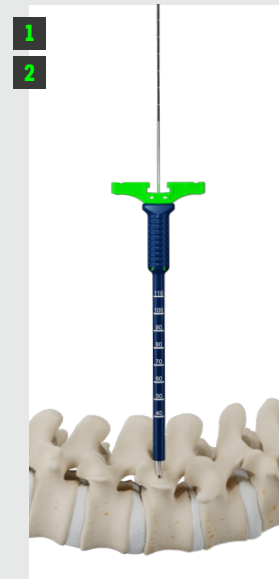
CAUTION: GUIDEWIRES SHOULD BE MONITORED USING FLUOROSCOPIC IMAGING TO AVOID ADVANCEMENT THROUGH THE VERTEBRAL BODY IN ORDER TO PREVENT DAMAGE TO UNDERLYING AND ASSOCIATED STRUCTURES.

TIP: TO MANAGE THE GUIDEWIRES, CLIP THE GUIDEWIRE COMB TO THE STERILE DRAPE AND INSERT THE PROXIMAL END OF THE GUIDEWIRE INTO THE COMB.



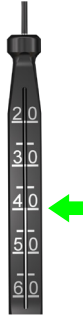
FASCIAL SPLITTER

- 4** On the back table, insert the Fascial Splitter (Excalibur) Handle into the Fascial Splitter Blade directly out of the Blade Caddy. Secure the Blade to the Handle by rotating the gold thumbwheel clockwise until it bottoms out.
- 5** Verify that the silver pin aligns with the lock symbol on the shaft of the Fascial Splitter Handle, indicating that the blade is secured to the Handle.
- 6** Slide the Fascial Splitter over the Guidewire, cutting through the fascia until the blade meets bony anatomy.
- 7** Upon removal of the Fascial Splitter, dispose of the sharp Fascial Splitter Blade properly.



- 1 Slide the Initial Dilator over the Guidewire and advance the Dilator to bony anatomy. Sequentially dilate with the Tap Dilator and Final Dilator.

TIP: TO MEASURE THE GUIDEWIRE DEPTH WITHIN BONE, REFERENCE THE WINDOW ON THE INITIAL DILATOR. THE NUMERICAL MARKING CLOSEST TO THE TOP OF THE SILVER BAND INDICATES GUIDEWIRE DEPTH. SCREW LENGTH CAN BE DETERMINED USING THIS TECHNIQUE.



TIP: VERIFY THAT THE FINAL DILATOR IS PROPERLY ADVANCED TO BONY ANATOMY BY CONFIRMING THAT THE BLACK LASER-MARKED LINE ON THE TAP DILATOR IS VISIBLE ABOVE THE FINAL DILATOR.

TIP: REFERENCE TABLE FOR DILATOR SPECIFICATIONS

DILATOR	INNER DIAMETER	OUTER DIAMETER	MATERIAL
Initial Dilator	2 mm	8 mm	Stainless Steel
Tap Dilator	8 mm	16 mm	Yellow Plastic
Final Dilator	16 mm	19 mm	Green Plastic

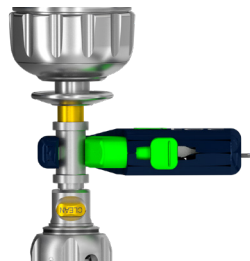


- 1** Remove the Initial Dilator. Attach the desired Ratcheting Handle to the appropriate diameter OsseoScrew Tap. Verify that the Ratcheting Handle covers the black line on the proximal end of the OsseoScrew Tap. It is mandatory to Tap prior to inserting an OsseoScrew.
- 2** Insert the Tap over the Guidewire and through the Tap Dilator. Rotate the Ratcheting Handle clockwise to tap into the pedicle. Reference the numerical laser marking on the Tap shaft to determine how far the Tap is advanced.

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



OPTIONAL: Attach the Alpha Informatix™ Stimulation Clip to the Stimulation Collar on the proximal end of the Tap shaft to stimulate during Tap insertion. To minimize shunting, verify that the Tap Dilator is flush on bone prior to stimulating the device.



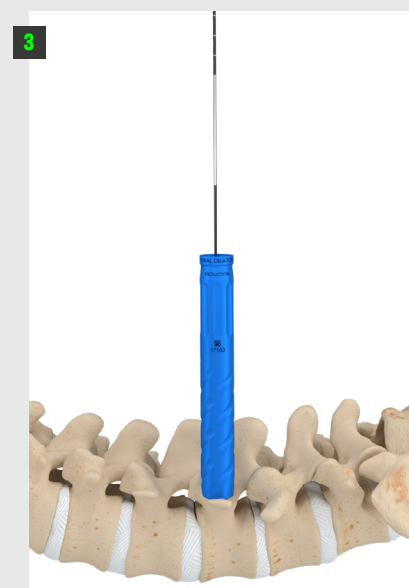
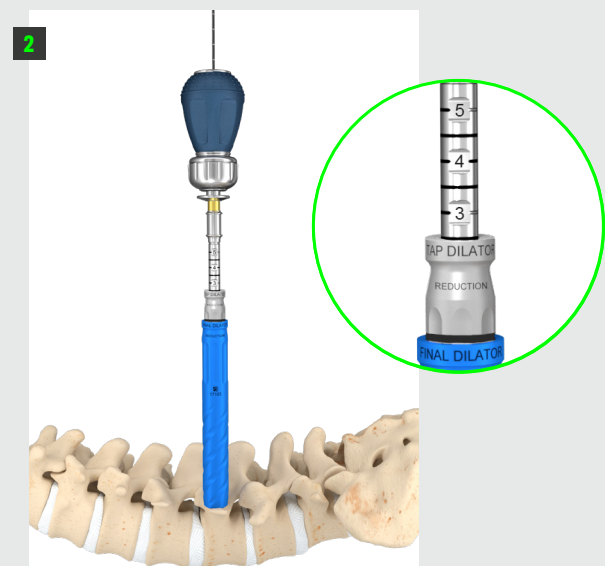
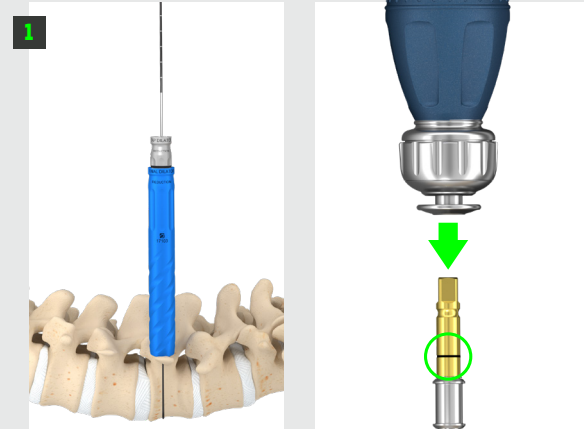
TIP: TAPS HAVE 40 MM OF GOLD LINE-TO-LINE THREADS AND A BLACK BAND FROM 40 MM – 50 MM.



CAUTION: GUIDEWIRES SHOULD BE MONITORED USING FLUOROSCOPIC IMAGING TO AVOID ADVANCEMENT THROUGH THE VERTEBRAL BODY IN ORDER TO PREVENT DAMAGE TO UNDERLYING AND ASSOCIATED STRUCTURES.

- 3** Remove the Tap Dilator, leaving the Guidewire and Final Dilator in place.

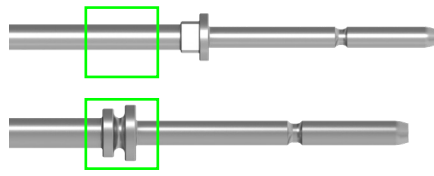
TIP: OSSEOSCREW SHOULD BE TAPPED LINE TO LINE.



TRIAL PROBES (OPTIONAL)

- 1 The Trial Probe can be used after tapping to provide a radiographic confirmation of expansion location. Expansion location is denoted by the two radiographic depth markers. The first indent indicates the start of expansion, and the end of the Probe indicates the end of the expansion zone.

TIP: RIGHT AND LEFT TRIAL PROBES ARE COLOR-CODED AND HAVE DIFFERENT RADIOGRAPHIC IDENTIFIERS ON THE SHAFT. RIGHT PROBES ARE GRAY AND HAVE A SQUARE IDENTIFIER AND LEFT PROBES ARE BLACK AND HAVE A CIRCLE IDENTIFIER.



With the Tap Dilator in situ, slide the Trial Probe over the Guidewire, and advance the Probe into bony anatomy. Confirm radiographically that the expansion zone is past the pedicle, then remove the Trial Probe while being mindful of the Guidewire.

CAUTION: TRIAL PROBES MUST BE REMOVED PRIOR TO SCREW PLACEMENT.



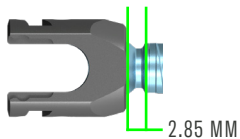
- 1 Once the preferred OsseoScrew has been determined, select the appropriate Invictus MIS Screwdriver. Cannulation of the Screwdriver is denoted by the gold-colored proximal end. Attach the green OsseoScrew Ratcheting Egg Handle to the Invictus MIS Screwdriver. Verify that the Ratcheting Handle covers the black line on the gold proximal end of the Screwdriver.

If using the Invictus MIS Tower System, select the Split Top Tower if an inline, sweeping rod insertion technique is preferred. Select the Closed Top Tower if a traditional MIS or Wiltse rod insertion technique is preferred. With the desired Polyaxial Screw in the caddy, load the tower by firmly pressing the distal end of the tower onto the tulip until an audible click is heard and proper engagement is achieved. Verify that the tower is locked to the tulip by pulling up and confirming that the tower covers the tulip dimple.

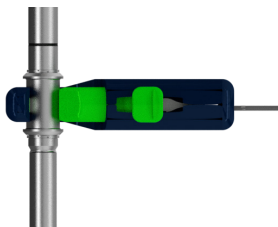
TIP: SCREWDRIVERS ARE DENOTED BY COLOR. INVICTUS MIS REDUCTION SCREWDRIVERS ARE BLACK, AND INVICTUS MIS POLYAXIAL SCREWDRIVERS ARE GRAY.

With the Screwdriver in the unlocked position, insert the Screwdriver into the desired screw in the caddy and rotate the silver thumbwheel clockwise. Once fully tightened, slide the thumbwheel forward until the black line is visible, indicating that the Screwdriver is securely locked to the screw.

TIP: OSSEOSCREWS ARE MEASURED FROM THE TIP OF THE SCREW TO THE PROXIMAL THREAD. THEREFORE, THERE IS AN ADDITIONAL 2.85 MM OF SCREW BODY TO THE MOST PROXIMAL THREAD.



OPTIONAL:
Attach the Alpha Informatix™ Stimulation Clip on the proximal end of the Screwdriver to stimulate during Screw insertion.



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- 1 Insert the Screwdriver over the Guidewire and rotate the Ratcheting Handle clockwise to advance the screw into the pedicle. Remove the Guidewire once the screw is safely through the pedicle and continue advancing the screw into the vertebral body.

The Guidewire Extractor may be used to advance or remove the Guidewire. Holding the Extractor vertically, slide the Guidewire into the Extractor. Grasp the Extractor tightly and pull up to remove the Guidewire. Holding the Extractor perpendicular to the Guidewire, slide the Guidewire into the Extractor until seated. Grasp the Extractor tightly and mallet the Extractor to advance the Guidewire.

- 2 Once the desired screw depth is achieved, confirm that the gold band on the proximal end of the Handle is not visible and thread the appropriate length Expansion Shaft into the distal tip of the screw.

- 3 Continue to rotate the Expansion Shaft until it bottoms out, then push the Shaft into the gold retention ring of the Handle to lock.

TIP: THE EXPANSION SHAFT WILL NOT SEAT INTO THE PROXIMAL END OF THE HANDLE UNTIL FULLY THREADED INTO THE SCREW TIP, SERVING AS A VISUAL AND TACTILE INDICATOR OF PROPER THREADING.

TIP: PRIOR TO SCREW EXPANSION, VERIFY THAT THE EXPANSION SHAFT IS PROTRUDING FROM THE SCREW USING FLUOROSCOPY OR PRESS THE PROXIMAL END OF THE EXPANSION SHAFT TO VERIFY SPRINGINESS TO ALLOW FOR PROPER ENGAGEMENT OF THE EXPANSION MECHANISM.

TIP: EXPANSION SHAFTS ARE COLOR-CODED TO DENOTE LENGTH IN ADDITION TO LASER MARKINGS ON THE PROXIMAL END.



- ☐ 40 MM SHAFT IS WHITE
- ☐ 45 MM SHAFT IS ORANGE
- ☐ 50 MM SHAFT IS NAVY BLUE
- ☐ 55 MM SHAFT IS RED

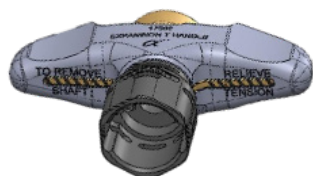


- 1 Once the OsseoScrew is properly implanted, seat the gray Expansion T-Handle into the proximal end of the green Ratcheting Handle. Once the T-Handle is properly seated in the Ratcheting Handle, rotate the T-Handle clockwise until the gold retention ring is fully visible and the T-Handle bottoms out, indicating screw expansion. Confirm radiographically that the expansion zone is past the pedicle and the OsseoScrew is fully expanded.

CAUTION: AFTER THE INVICTUS OSSEOSCREW HAS BEEN EXPANDED, TENSION MUST BE RELIEVED BY ROTATING THE T-HANDLE ONE FULL TURN COUNTERCLOCKWISE PRIOR TO REMOVING THE EXPANSION SHAFT.

- 2 After expansion, rotate the T-Handle counterclockwise one full rotation to relieve the tension of the expansion mechanism.

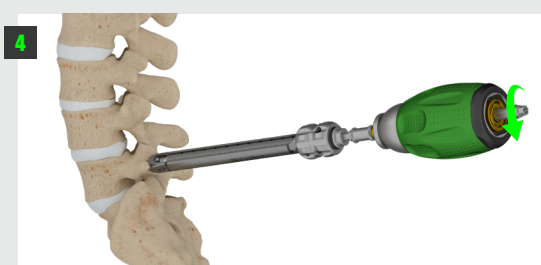
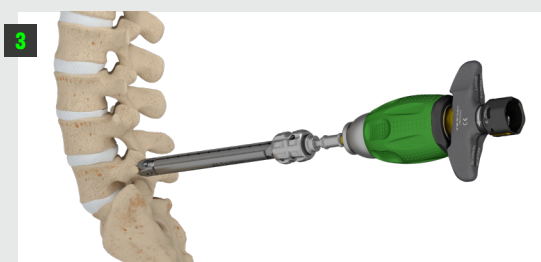
TIP: SEE BOTTOM OF T-HANDLE FOR CAUTION.



- 3 Remove the Gray Expansion T-Handle from the green Ratcheting Handle and flip upside down. Using the gold release feature on the proximal end of the Expansion T-Handle, press the gold retention ring to release the Expansion Shaft.
- 4 After the Shaft is released, rotate the Shaft counterclockwise to unthread it from the OsseoScrew.
- 5 Unlock the Screwdriver by pulling up on the thumbwheel proximally and rotating the silver thumbwheel counterclockwise to disengage from the screw.

CAUTION: ONCE THE INVICTUS OSSEOSCREW IMPLANT HAS BEEN EXPANDED, IT MAY BE DIFFICULT TO COLLAPSE, RE-POSITION, OR REMOVE; THEREFORE, IT IS IMPORTANT TO CONFIRM PROPER PLACEMENT OF THE INVICTUS OSSEOSCREW PRIOR TO DEPLOYING THE EXPANSION FEATURE BY USE OF FLUOROSCOPY OR OTHER SUITABLE IMAGING TECHNIQUES.

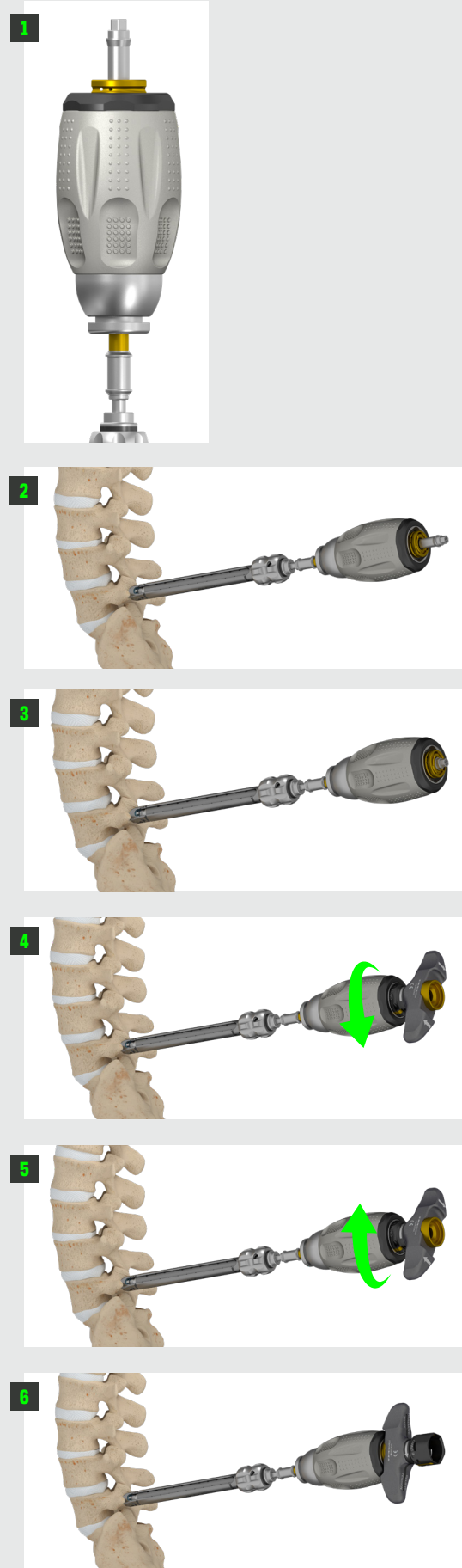
TIP: THE GOLD BAND CAN BE SEEN IN THE T-HANDLE PERFORATIONS WHEN MAXIMUM TRAVEL HAS BEEN ACHIEVED.



- 1 Confirm that the gold retention ring on the gray Collapse Handle is fully visible.
- 2 Slide the Expansion Shaft into the proximal end of the gray Collapse Handle until the Expansion Shaft is seated within the OsseoScrew. Rotate the Expansion Shaft clockwise to thread the Shaft into the distal tip of the screw.
- 3 Continue to rotate the Expansion Shaft until it bottoms out, then push the Shaft into the gold retention ring of the Handle to lock.
- 4 Insert the gray Expansion T-Handle into the proximal end of the gray Collapse Handle and turn the gray Expansion T-Handle counterclockwise until the gold retention ring sits flush with the gray collapse Handle and the gray T-Handle bottoms out indicating screw collapse. Confirm screw collapse radiographically.
- 5 After collapse, rotate the T-Handle clockwise one full rotation to relieve the tension of the expansion mechanism
- 6 Using the gold release feature on the proximal end of the gray Expansion T-Handle, press down of the gold retention ring to release the Expansion Shaft. Rotate the Shaft counterclockwise to unthread the Shaft from the OsseoScrew.

The implant is now collapsed and can be removed. If removal is not desired, pull up on the locking collar to place in the unlocked position and turn the thumbwheel counterclockwise to remove the driver from the screw.

CAUTION: AFTER THE INVICTUS OSSEOSCREW HAS BEEN COLLAPSED, TENSION MUST BE RELIEVED BY ROTATING THE T-HANDLE ONE FULL TURN CLOCKWISE PRIOR TO REMOVING THE EXPANSION SHAFT.



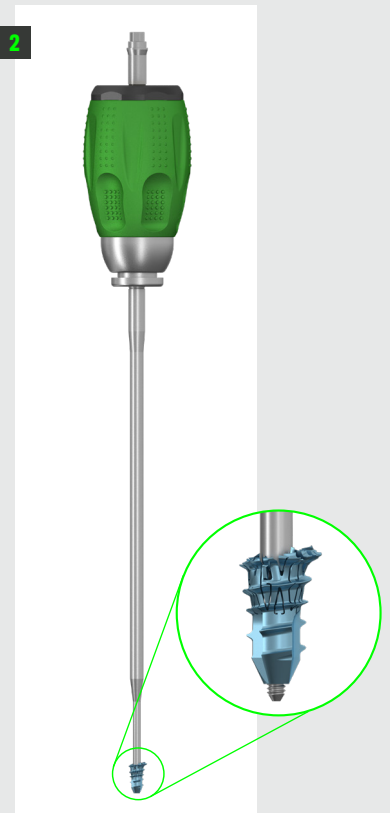
If a section of the distal tip of a removed screw remains in the vertebral body, the Invictus OsseoScrew Removal Tool can be used to engage and remove it.

- 1** Insert a Guidewire into the distal tip of the screw that remains in the vertebral body. Attach the green Ratcheting Egg Handle to the Invictus OsseoScrew Removal tool and verify that the gold band on the proximal end of the handle is not visible. Slide the Invictus OsseoScrew Removal Tool with the green Ratcheting Egg Handle over the Guidewire until it engages with the internal hex of the distal tip.
- 2** Remove the Guidewire and insert the 40 mm Expansion Shaft into the Invictus OsseoScrew Removal Tool. Thread the Expansion Shaft into the distal tip of the screw until it bottoms out.
- 3** Push the Shaft into the gold retention ring of the Handle to lock.
- 4** Seat the gray Expansion T-Handle into the proximal end of the green Ratcheting Egg Handle and rotate the T-Handle clockwise until tension is felt. Remove the T-Handle. Remove the fractured distal tip of the screw by rotating the green Ratcheting Egg Handle counterclockwise.

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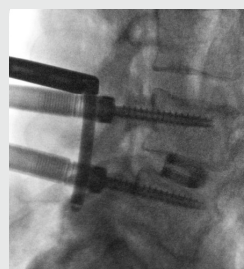
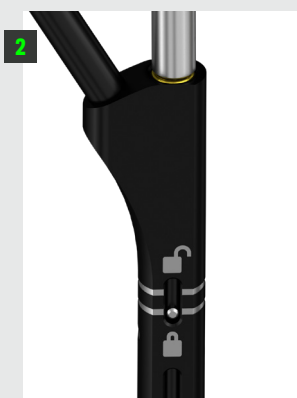
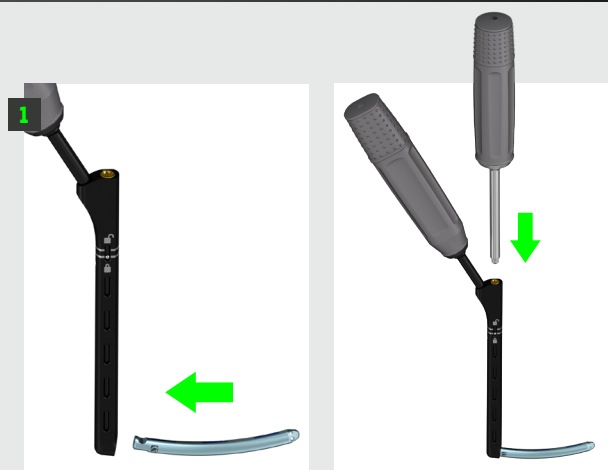
- 1 Insert the Rod Caliper arms into the superior and inferior Reduction Screws. Verify that the laser-marked lines on the Caliper arms are flush with the top of the tabs, indicating that the arms are properly seated within the tulips. Select the rod length based on the measurement that appears in the center of the gold box on the Rod Caliper.

On the back table, insert the engagement feature end of the desired rod into the MIS Rod Inserter. Seat the Rod Inserter Locking Driver into the gold hex on the MIS Rod Inserter and rotate the Driver clockwise to lock the rod to the Rod Inserter. Verify that the silver pin aligns with the lock symbol on the shaft of the MIS Rod Inserter, indicating that the rod is secured to the Inserter.

Insert the rod into the rod slot of the inferior tab and advance the MIS Rod Inserter until the rod is seated within the tulip. Verify that the top of the MIS Rod Inserter shaft is flush with the top of the adjacent tab indicating that the rod is fully seated within the tulip. Confirm rod placement using fluoroscopy.

TIP: THE INVICTUS OSSEOSCREW TULIP ACCEPTS BOTH 5.5 MM AND 6.0 MM ROD DIAMETERS. 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 CIRCLE.

CAUTION: VERIFY SUPERIOR AND INFERIOR ROD OVERHANG. INADEQUATE OVERHANG MAY CAUSE IMPROPER SET SCREW PLACEMENT RESULTING IN AN UNSTABLE CONSTRUCT.



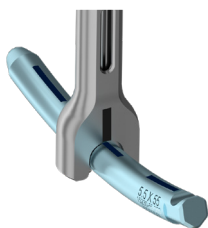
- 1 On the back table, attach the Wiltse Rod Inserter to the center of the desired rod. Seat the Rod Inserter Locking Driver into the gold hex on the Wiltse Rod Inserter and rotate the Driver clockwise to lock the rod to the Wiltse Rod Inserter.

Verify that the black laser-marked line aligns with the lock symbol on the shaft of the Wiltse Rod Inserter, indicating that the rod is secured to the Inserter.

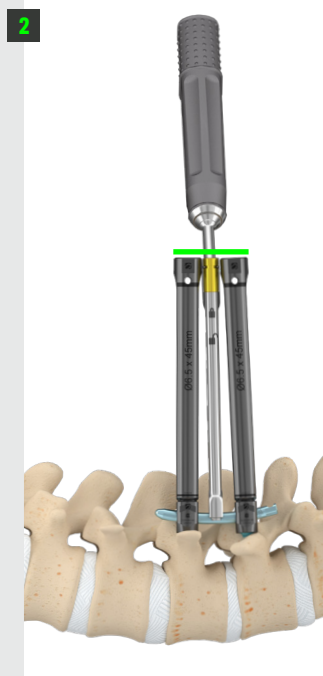
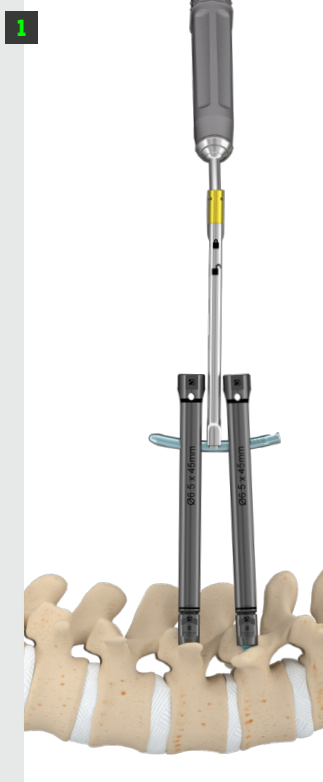
Insert the rod into the rod slots between the inferior and superior tabs and advance the Wiltse Rod Inserter until the rod is seated within the tulips. Verify that the top of the Wiltse Rod Inserter shaft is flush with the top of the adjacent tabs indicating that the rod is fully seated within the tulips.

Confirm rod placement using fluoroscopy.

TIP: THE WILTSE ROD INSERTER LOCKS TO THE CENTER OF THE ROD. WHEN LOCKED, A LASER-MARKED LINE WILL ALIGN WITH THE DASHES ON THE ROD.



CAUTION: VERIFY SUPERIOR AND INFERIOR ROD OVERHANG. INADEQUATE OVERHANG MAY CAUSE IMPROPER SET SCREW PLACEMENT RESULTING IN AN UNSTABLE CONSTRUCT.



- 1 Press the locking Set Screw Inserter into the set screw and rotate the gold thumbwheel clockwise until it bottoms out. Verify that the silver pin aligns with the lock symbol on the shaft of the Set Screw Inserter, indicating that the set screw is locked to the Inserter.

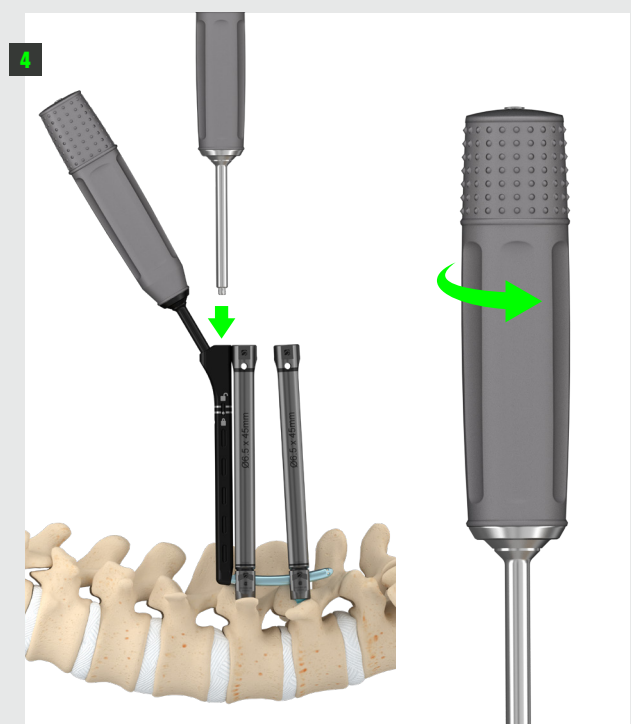
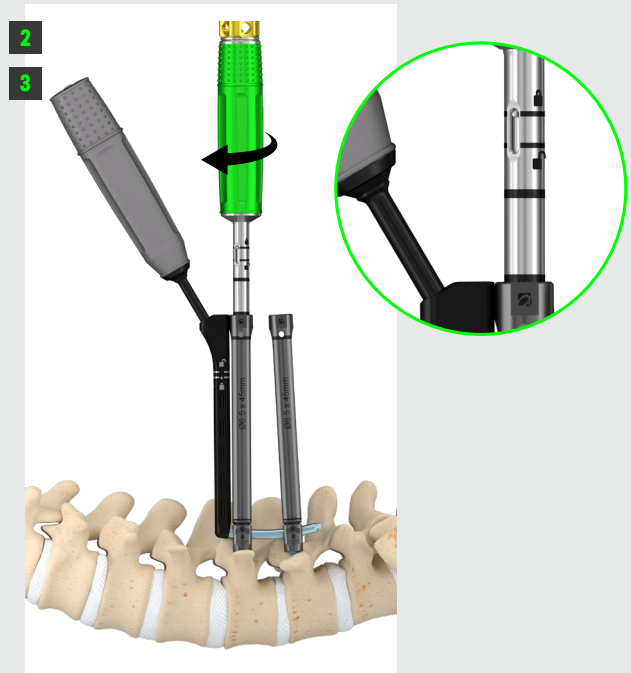
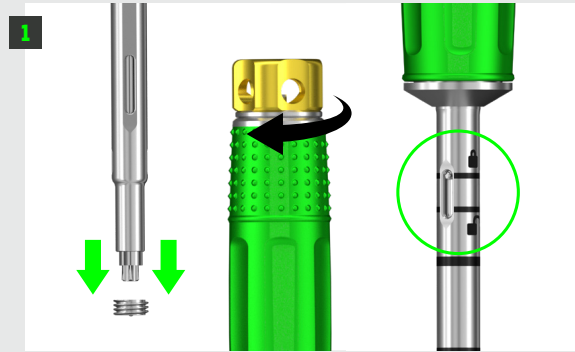
Insert the Set Screw Inserter into the inferior tab. Verify that the first black laser-marked line on the Set Screw Inserter shaft sits flush with the top of the tab, indicating that the set screw has met the top of the reduction threads.

Rotate the handle clockwise to advance the set screw to the bottom of the threads. Verify that the second black laser-marked line on the Set Screw Inserter shaft sits flush with the proximal end of the tab, indicating that the set screw is seated inside the tulip.

Rotate the gold thumbwheel counterclockwise to unlock the set screw and remove the Set Screw Inserter. Once set screws are provisionally tightened, insert the Locking Driver into the gold hex of the Rod Inserter and rotate counterclockwise to unlock and remove the Rod Inserter.

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

TIP: TO FACILITATE ROD REDUCTION, THE REDUCTION SCREWS INCLUDE 15 MM OF THREADS ABOVE THE TULIP.



- 1 Insert the Final Driver into the Torque Limiting Handle. Verify that the laser-marked line on the Final Driver is covered by the Handle. Attach the top loading end of the MIS Countertorque to the tops of the towers or tabs, in the medial/lateral or superior/inferior orientations.

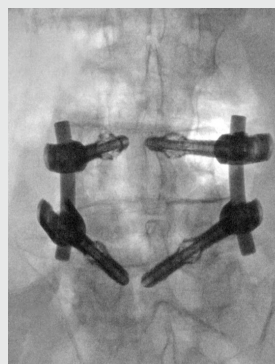
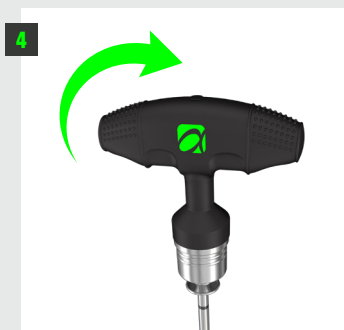
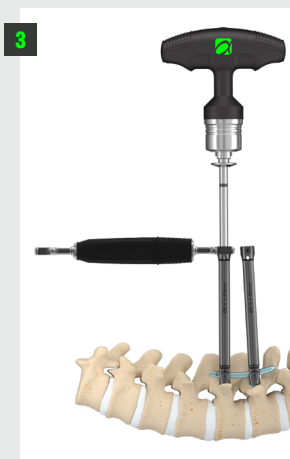
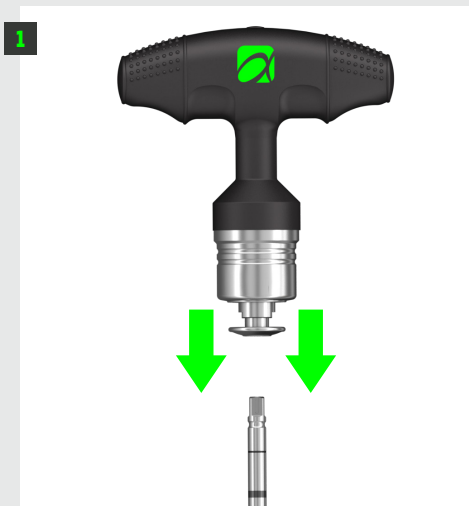
Insert the Final Driver into the extended tab or tower until seated in the set screw. Verify that the black laser-marked line on the Final Driver shaft aligns with the tips of the tabs, indicating that the Drivers are properly seated in the set screws. While holding the Countertorque steady, rotate the Torque Handle clockwise until the handle breaks away. Remove the Torque Driver assembly and Countertorque.

If using the MIS Tower System, insert the Tower Removal Tool down the tower, with the paddle handle parallel to the rod, until it bottoms out on the proximal end of the tower. Use fluoroscopy to confirm that the distal pin of the tool is sitting within the locked set screw. Gently rotate the Removal Tool 90° counterclockwise until the black laser-marked lines on the tower and Removal Tool align. Pull straight up to remove the tower.

If using Extended Tab Screws, insert the green Pop Top Tab Breaker into the proximal end of the tabs and squeeze the Pop Top Tab Breaker until the bridge at the top of the tab breaks. Slide the Tab Breaker down the lateral tab until the breaker sits flush against the locked set screw. Rock the Tab Breaker laterally to break the distal tab connection. Repeat for medial tab. Confirm that the distal tabs have been properly broken from the tulips using fluoroscopic imaging.

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

OPTIONAL: To final tighten through the Drop Tower, attach the Torque Limiting Handle to the Drop Tower Set Screw Bell. Using the side-loading end, secure the Countertorque medially or laterally around the Tab. While holding the Countertorque steady, rotate the Torque handle until the Handle breaks away.



PART NUMBER	DESCRIPTION
Invictus® OsseoScrew® Implants - VOSIMP	
17270	Invictus OsseoScrew Polyaxial Screw Caddy
15905-065-040	Invictus Osseoscrew, Polyaxial, Ø6.5 x 40 mm
15905-065-045	Invictus Osseoscrew, Polyaxial, Ø6.5 x 45 mm
15905-065-050	Invictus Osseoscrew, Polyaxial, Ø6.5 x 50 mm
15905-065-055	Invictus Osseoscrew, Polyaxial, Ø6.5 x 55 mm
15905-075-040	Invictus Osseoscrew, Polyaxial, Ø7.5 x 40 mm
15905-075-045	Invictus Osseoscrew, Polyaxial, Ø7.5 x 45 mm
15905-075-050	Invictus Osseoscrew, Polyaxial, Ø7.5 x 50 mm
15905-075-055	Invictus Osseoscrew, Polyaxial, Ø7.5 x 55 mm
17271	Invictus OsseoScrew Reduction Screw Caddy
15915-065-040	Invictus Osseoscrew, Reduction, Ø6.5 x 40 mm
15915-065-045	Invictus Osseoscrew, Reduction, Ø6.5 x 45 mm
15915-065-050	Invictus Osseoscrew, Reduction, Ø6.5 x 50 mm
15915-065-055	Invictus Osseoscrew, Reduction, Ø6.5 x 55 mm
15915-075-040	Invictus Osseoscrew, Reduction, Ø7.5 x 40 mm
15915-075-045	Invictus Osseoscrew, Reduction, Ø7.5 x 45 mm
15915-075-050	Invictus Osseoscrew, Reduction, Ø7.5 x 50 mm
15915-075-055	Invictus Osseoscrew, Reduction, Ø7.5 x 55 mm
15925-065-040	Invictus Osseoscrew, Extended Tab, Ø6.5 x 40 mm
15925-065-045	Invictus Osseoscrew, Extended Tab, Ø6.5 x 45 mm
15925-065-050	Invictus Osseoscrew, Extended Tab, Ø6.5 x 50 mm
15925-065-055	Invictus Osseoscrew, Extended Tab, Ø6.5 x 55 mm
15925-075-040	Invictus Osseoscrew, Extended Tab, Ø7.5 x 40 mm
15925-075-045	Invictus Osseoscrew, Extended Tab, Ø7.5 x 45 mm
15925-075-050	Invictus Osseoscrew, Extended Tab, Ø7.5 x 50 mm
15925-075-055	Invictus Osseoscrew, Extended Tab, Ø7.5 x 55 mm
17201	Invictus Set Screw Caddy
15100	Set Screw

PART NUMBER	DESCRIPTION
Invictus OsseoScrew Instruments - VOSINS	
17110	MIS Polyaxial Screwdriver, Locking
17111	MIS Reduction Polyaxial Screwdriver, Locking
17901	Invictus OsseoScrew Ratcheting Egg Handle, Cannulated
17902	OsseoScrew Expansion T-Handle
17814-040	Invictus OsseoScrew, Expansion Shaft 40 mm
17814-045	Invictus OsseoScrew, Expansion Shaft 45 mm
17814-050	Invictus OsseoScrew, Expansion Shaft 50 mm
17814-055	Invictus OsseoScrew, Expansion Shaft 55 mm
17903-L	OsseoScrew Trial Probe, Left, Cannulated
17903-R	OsseoScrew Trial Probe, Right, Cannulated
71732	Temporary Fixation Pin Insertor
17905-055	Invictus OsseoScrew Tap, Cannulated 5.5 mm
17905-065	Invictus OsseoScrew Tap, Cannulated 6.5 mm
17905-075	Invictus OsseoScrew Tap, Cannulated 7.5 mm
17906	Invictus OsseoScrew Removal Tool
17070	Dual Reduction Tab Breaker
17268	Invictus OsseoScrew Trial Marker Caddy
17812-L	OsseoScrew Trial Marker, Left
17812-R	OsseoScrew Trial Marker, Right
17904	OsseoScrew, Collapse Handle

INVICTUS® OSSEOSCREW® SYSTEM

INSTRUCTIONS FOR USE

GENERAL INFORMATION:

The Invictus OsseoScrew is a pedicle screw system that consists of pedicle screws and associated general instruments. Implant components are available in a variety of sizes to suit the individual pathology and anatomical conditions of the patient. The Invictus OsseoScrew is an implantable pedicle screw with a core manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and expandable screw shank that is manufactured from commercially pure titanium (CP Ti Grade 4) conforming to ASTM F67. The instruments in this system are intended for use in surgical procedures.

The Invictus OsseoScrew is designed to be compatible with the Invictus Spinal Fixation System screws, hooks, rods, connectors, and cross-connectors rods for the thoracolumbar spine and Invictus OCT Spinal Fixation System for the cervical (C1 to C7) to thoracic (T1-T3) spine.

INDICATIONS FOR USE:

The Invictus OsseoScrew System (for use with the Invictus Spinal Fixation System and the transition rods from the Invictus OCT Spinal Fixation System) is 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.

CONTRAINDICATIONS:

Contraindications include but are not limited to the following:

1. Use in the cervical spine
2. Use with bone cement
3. Patients with allergy to titanium or cobalt chrome
4. Patients with joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance
5. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities
6. Commingling of titanium and stainless-steel components within the same construct
7. Reuse or multiple uses
8. Use in bicortical purchase

WARNINGS/CAUTIONS/PRECAUTIONS:

1. The Invictus OsseoScrew System must be used in conjunction with Alphatec Spine's Invictus Spinal Fixation System in order to complete a full spinal construct.
2. The implants and instruments of the Invictus OsseoScrew System are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections in this Instruction for use.
3. The Invictus OsseoScrew 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.
4. The Invictus OsseoScrew Deployment Shafts are single-use devices. Do not reuse. Reuse of the single-use shafts may result in failure due to shearing of the threads or damage to the tip.
5. Once the Invictus OsseoScrew implant has been expanded, it may be difficult to collapse, re-position, or remove; therefore, it is important to confirm proper placement of the Invictus OsseoScrew prior to deploying the expansion feature by use of fluoroscopy or other suitable imaging technique.
6. The Invictus OsseoScrew should not be placed bicortically.
7. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity. 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 vertebra, 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.
8. 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 affect 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.
9. The implants and instruments of Alphatec Spine product lines should not be used with any other company's spinal systems.
10. 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.
11. The decision of when to use the Invictus OsseoScrew instead of an Invictus screw can only be determined by the surgeon after assessment of the patient's needs, anatomy, and careful analysis of variables such as length and diameter of the pedicle screw required.
12. The un-expanded Invictus OsseoScrew implant may be removed after placement, similar to a typical pedicle screw. However, the implant cannot be reused. Dispose of the used Invictus OsseoScrew per hospital protocol.
13. In the event that the Invictus OsseoScrew implant fails to deploy, the implant may remain in place. Alternatively, the Invictus OsseoScrew may be replaced with a larger diameter screw from the Invictus System.
14. Invictus OsseoScrew trial probes and trial markers should be removed before screw placement.
15. After the Invictus OsseoScrew has been expanded, tension must be relieved by rotating the T-handle one full turn counterclockwise prior to removing the expansion shaft. After the Invictus OsseoScrew has been collapsed, tension must be relieved by rotating the T-handle one full turn clockwise prior to removing the expansion shaft.
16. 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.

MRI SAFETY INFORMATION:

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

POSSIBLE ADVERSE EFFECTS

Possible adverse effects include:

1. Initial or delayed loosening, disassembly, bending, dislocation and/or breakage of device components
2. Physiological reaction to implant devices due to foreign body intolerance including inflammation, and local tissue reaction
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. Neurological injury, disorder, pain and/or abnormal sensations
8. Revision surgery
9. Death

PREOPERATIVE MANAGEMENT:

1. Only those patients meeting the criteria listed in the indication 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. Final Set Screw Tightening: All Set Screws must be tightened using the appropriate instrument (e.g., Torque Handle) as indicated in the Surgical Technique Guide.
3. Once the Invictus OsseoScrew implant has been expanded, it cannot be un-expanded, re-expanded, or removed. Therefore, it is critical to confirm proper placement of the Invictus OsseoScrew prior to deploying the expansion feature by use of fluoroscopy or other suitable imaging technique.

POSTOPERATIVE MANAGEMENT:

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

1. The 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. 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.
4. 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.
5. Retrieved implants should be properly disposed of and are not to be reused under any circumstance.

Excerpt from INS-124



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

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



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INVICTUS® OSSEOSCREW® SYSTEM INSTRUCTIONS FOR USE (AUSTRALIA)

GENERAL INFORMATION:

The Invictus OsseoScrew is a pedicle screw system that consists of pedicle screws and associated general instruments. Implant components are available in a variety of sizes to suit the individual pathology and anatomical conditions of the patient. The Invictus OsseoScrew is an implantable pedicle screw with a core manufactured from titanium alloy (Ti-6Al-4V ELI) conforming to ASTM F136 and expandable screw shank that is manufactured from commercially pure titanium (CP Ti Grade 4) conforming to ASTM F67. The instruments in this system are intended for use in surgical procedures.

The Invictus OsseoScrew is designed to be compatible with the Invictus Spinal Fixation System screws, hooks, rods, connectors, and cross-connectors rods for the thoracolumbar spine and Invictus OCT® Spinal Fixation System for the cervical (C1 to C7) to thoracic (T1-T3) spine.

INDICATIONS FOR USE:

The Invictus OsseoScrew System (for use with the Invictus Spinal Fixation System and the transition rods from the Invictus OCT Spinal Fixation System) is 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.

CONTRAINDICATIONS:

Contraindications include but are not limited to the following:

1. Use in the cervical spine
2. Use with bone cement
3. Patients with allergy to titanium or cobalt chrome
4. Patients with joint disease, deficient soft tissue at the wound site or probable metal and/or coating intolerance
5. Patients resistant to following postoperative restrictions on movement especially in athletic and occupational activities
6. Commingling of titanium and stainless-steel components within the same construct
7. Reuse or multiple uses
8. Use in bicortical purchase

WARNINGS/CAUTIONS/PRECAUTIONS:

1. The Invictus OsseoScrew System must be used in conjunction with Alphatec Spine's Invictus Spinal Fixation System in order to complete a full spinal construct.
2. The implants and instruments of the Invictus OsseoScrew System are provided non-sterile and must be cleaned and sterilized prior to use. Refer to the CLEANING and STERILIZATION sections in this Instruction for use.
3. The Invictus OsseoScrew 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.
4. The Invictus OsseoScrew Deployment Shafts are single-use devices. Do not reuse. Reuse of the single-use shafts may result in failure due to shearing of the threads or damage to the tip.
5. Once the Invictus OsseoScrew implant has been expanded, it may be difficult to collapse, re-position, or remove; therefore, it is important to confirm proper placement of the Invictus OsseoScrew prior to deploying the expansion feature by use of fluoroscopy or other suitable imaging technique.
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Excerpt from INS-124-01



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