NEXXT Spine

Leading the Fusion Revolution

INERTIA® MIS

PEDICLE SCREW SYSTEM

SURGICAL TECHNIQUE

Table of Contents

INERTIA® MIS Pedicle Screw System

INDICATIONS FOR USE

The Inertia™ MIS Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1 to S2): severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; spinal stenosis; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

CLEANING / REPROCESSING OF SURGICAL INSTRUMENTS

All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Refer to the Nexxt Spine ***Reprocessing Instructions for Reusable Instruments*** document available at www.NexxtSpine.com/Nexxt_Spine_Products or by calling 317-436-7801 for a copy of the detailed cleaning instructions.

STERILIZATION

The Inertia® Pedicle Screw and Deformity Correxxion™ System implants can be supplied sterile or non-sterile. All sterile products are labeled “STERILE” and supplied in protective sterile barrier packaging. Do not use sterile products if the packaging has been damaged or previously opened. Do not re-sterilize or autoclave sterile implants. If not specifically labeled sterile, components are supplied clean but non-sterile and must be cleaned and sterilized prior to surgery.

Non-sterile components are supplied clean and not sterile. All implants and instruments should be cleaned and sterilized prior to surgery. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). AORN recommended practices for in hospital sterilization should be followed. The use of an FDA cleared sterilization wrap is recommended.

Sterilization testing of components has shown the following recommendations for sterilization are effective to an SAL of 10^{-6}:

Method:	Steam
Cycle:	Prevacuum
Temperature:	270°F (132°C)
Exposure Time:	4 minutes
Drying Time:	30 minutes

NOTE: Instruments that may have been exposed to Creutzfeldt-Jakob disease (CJD) should be treated according to the hospital’s prior decontamination protocol. Nexxt Spine recommends contacting the Center for Disease Control and the World Health Organization for the most recent information on CJD transmission and deactivation.

Preparation

1
Patient Positioning and Pedicle Identification

Position the patient on a radiolucent OR table in the prone position. To obtain optimal visualization of the spine, the OR table should have enough clearance available for a fluoroscopic C-arm to rotate freely for AP, oblique and lateral views (Figures 1, 2).

Accurate visualization of anatomic landmarks and fluoroscopic visualization of the pedicles is imperative for using the Inertia MIS Pedicle Screw System (Figure 3).

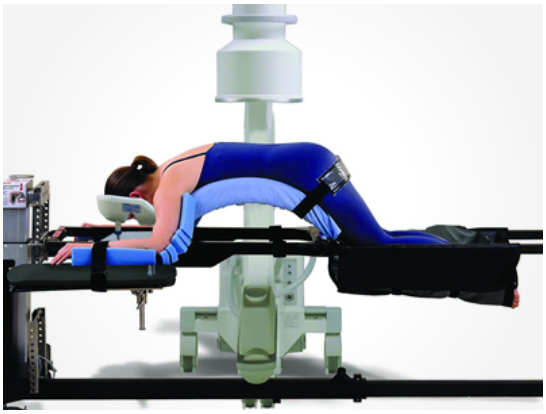

Figure 1

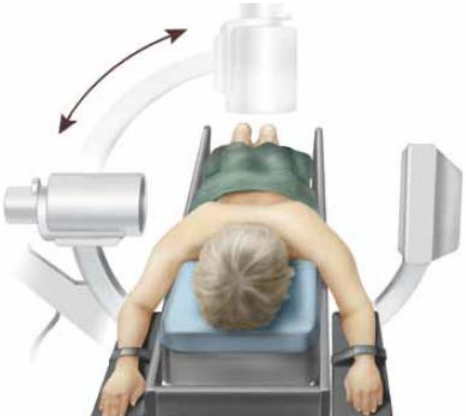

Figure 2

Figure 3

Note: On AP fluoroscopy, the spinous processes should lie midway between both pedicles.

Note: On AP and lateral fluoroscopy, the end plates should be linear and not rounded.

Note: AP and lateral fluoroscopy projections should be parallel to the end plates nearest the screw to be inserted.

Warning: Some tables have pedestals that make it difficult to get a true AP view of the pedicles. While adjustments in patient positioning can be made, tables that limit good AP fluoroscopy should generally be avoided.

2
Pedicle Identification

Instruments

Nitinol K-wire, Threaded Trocar Tip

Orient the C-arm to provide a true AP image that is parallel with the endplates nearest the screw to be inserted (Figure 4).

Place a K-wire on the patient perpendicular to the axis of the spine at the targeted level. Using AP fluoroscopy, position the K-wire such that its projection transects the center of both pedicles in the cephalad-caudal direction. Use a surgical marker to transfer that plane to the patient.

Place K-wire on the patient parallel to the axis of the spine. Using AP fluoroscopy, position the K-wire such that its projection aligns to the lateral pedicle wall of the targeted level and the adjacent levels. The lateral pedicle wall of adjacent levels may also be estimated at this time. Use a surgical marker to transfer this plane onto the patient (Figure 5).

The skin incision for each level should be at least 1cm lateral to the intersection of the two lines. This distance may vary depending on size of the patient (Figure 6).

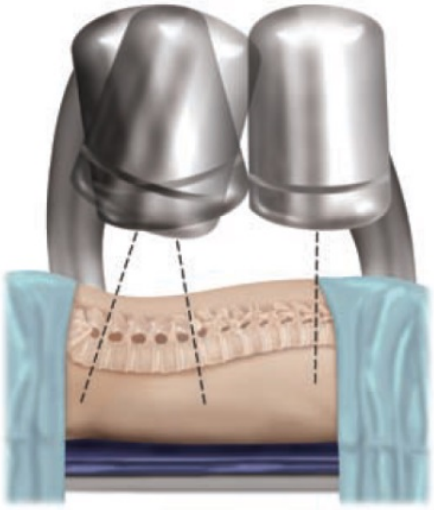

Figure 4

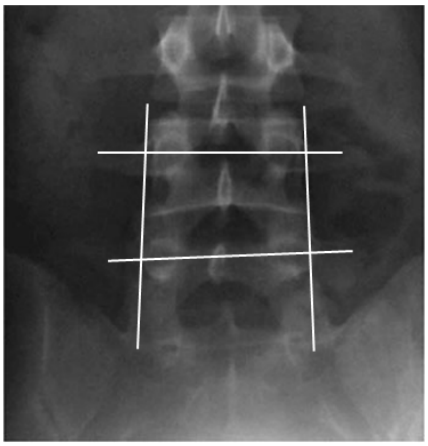

Figure 5

Figure 6

3

Surgical Access

Jamshidi Needle Placement

Instruments

Jamshidi Needle, Sterile, 11G x 150mm

Make a 2.5mm incision with #11 scalpel. Insert the Jamshidi Needle through incision and dock the tip on the pedicle entry point at the intersection of the facet and transverse process of the desired level (Figure 7).

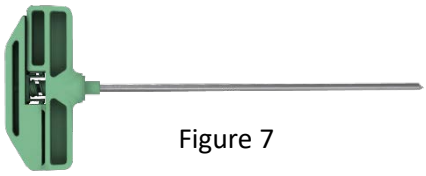

Figure 7

Confirm that the appropriate pedicle starting place has been determined using both AP and lateral fluoroscopy. Gently tap the Jamshidi Needle to engage the trocar tip into the pedicle (Figure 8).

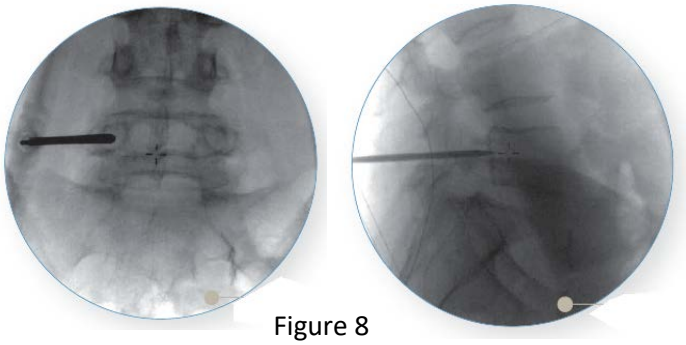

Figure 8

Advance the Jamshidi needle through pedicle using AP fluoroscopy to direct the tip towards the center of the pedicle. The needle should not advance more than three quarters of the way across pedicle, starting from the lateral edge of the pedicle. Continue advancement until the needle enters the vertebral body. Confirm placement with AP and lateral fluoroscopy to ensure that the Jamshidi Needle does not breach the wall of the pedicle.

Remove the inner stylet of the Jamshidi Needle (Figure 9).

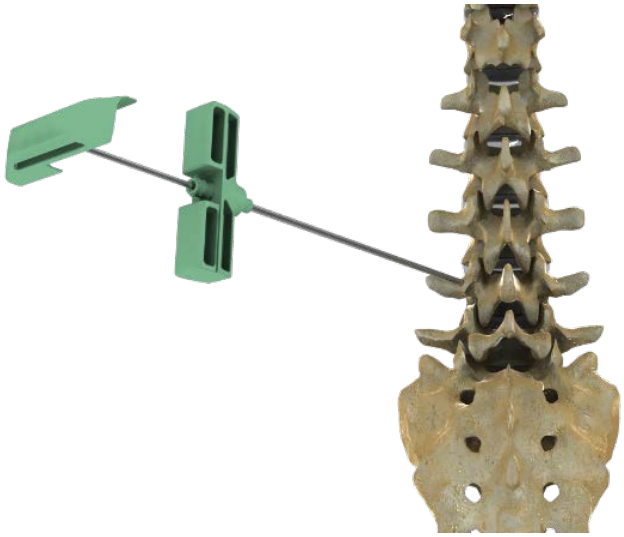

Figure 9

4
K-wire Insertion

Instruments

Nitinol K-wire, Threaded Trocar Tip
Optional: K-wire Installer

Insert the K-wire (Figure 10) by hand or with the assistance of the K-wire Installer (Figure 11) through the Jamshidi needle. Advance the K-wire beyond the tip of the needle (approximately 20mm) to ensure adequate fixation into the cancellous bone.

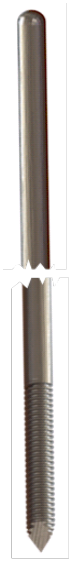

Figure 10

Figure 11

Confirm placement with AP and lateral fluoroscopy to ensure that the K-wire does not breach the wall of the pedicle or the vertebral body.

Once the K-wire is placed to desired depth, carefully remove the Jamshidi Needle while holding the K-wire to ensure that it remains in position. To ensure proper depth, drive the K-wire by clamping the K-wire Installer (forceps) onto the K-wire 20mm proximal to the Jamshidi handle and impacting the K-wire Installer until it contacts the Jamshidi.

Note: For multi-level constructs it is recommended to place ALL K-wires prior to inserting Pedicle Screws.

Note: The K-wire should be advanced approximately 50%–70% into the vertebral body to allow for proper screw placement.

Note: K-Wires and Jamshidi Needles are single use instruments.

Note: The diameter of the K-wire is 1.4mm.

5
Sequential Dilation

Instruments
MIS Dilator 1
MIS Dilator 2

With the K-wire placed, insert Dilation Tube #1 over the K-wire through the tissue twisting clockwise while directing it toward the pedicle.

Continue advancing Dilation Tube #1 through the thoracolumbar fascia until the tip of the tube is docked onto bony anatomy (Figure 12). Confirm positioning of Dilation Tube #1 with imaging.

Slide Dilation Tube #2 over K-wire and Dilation Tube #1 until the tip of the tube is docked onto bony anatomy. Carefully remove Dilation Tube #1 while keeping K-wire and Dilation Tube #2 in place (Figure 13).

Note: Tactile feel, fluoroscopy, anatomical knowledge, review of preoperative images and partial visualization may all contribute towards desired instrument placement accuracy.

Note: Care should be taken when removing Dilation Tube #1 to ensure the K-wire is not removed.

Warning: Dilation tube #2 must be fully seated against pedicle entry point for accurate depth measurement with the tap.

Figure 12

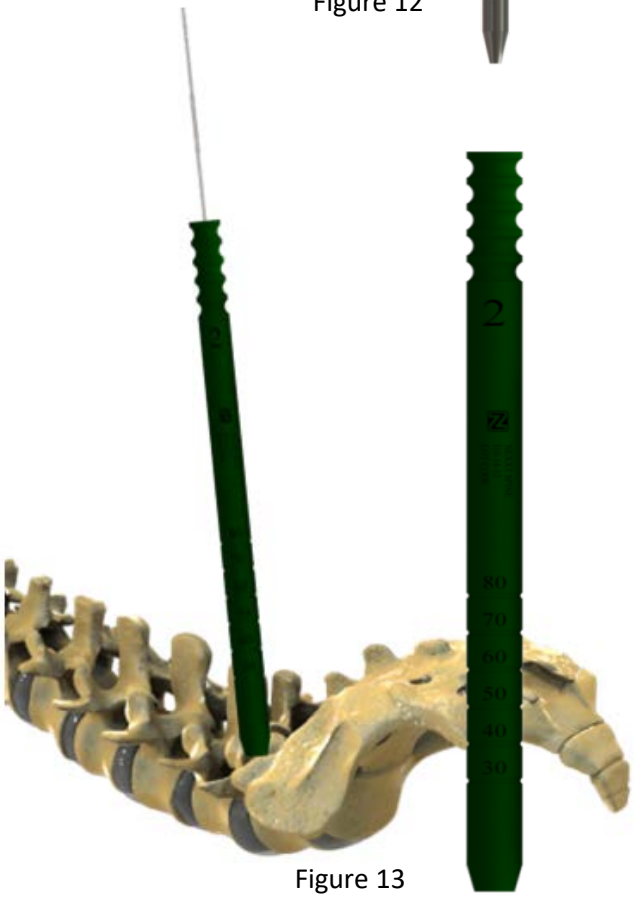

Figure 13

6
Pedicle Preparation

Instruments

9mm Awl
Straight Probe

With Dilator #2 in place, prepare the pedicle by placing the 9mm Awl (Figure 14) or Straight Probe (Figure 15) over the K-Wire and impact into the pedicle with a twisting motion.

The 9mm Awl has a protective depth stop at 9mm.

The shaft of the Straight Probe is laser marked in 5mm increments from 30mm to 50mm to indicate the depth at which the probe tip has been inserted. The laser mark lines also assist with the determination of proper screw length.

As an instrument advances into the pedicle, the proximal end of the instrument will move relative to the K-Wire. If this does not occur, the surgeon should stop and fluoroscopy should be used to verify the position of the K-Wire.

Hold the K-Wire in position when removing the 9mm Awl or Straight Probe.

Warning: To prevent inadvertent advancement of the K-wire, align the trajectory of the awl and/or probe with the K-wire and monitor the K-wire position using fluoroscopy.

Figure 14

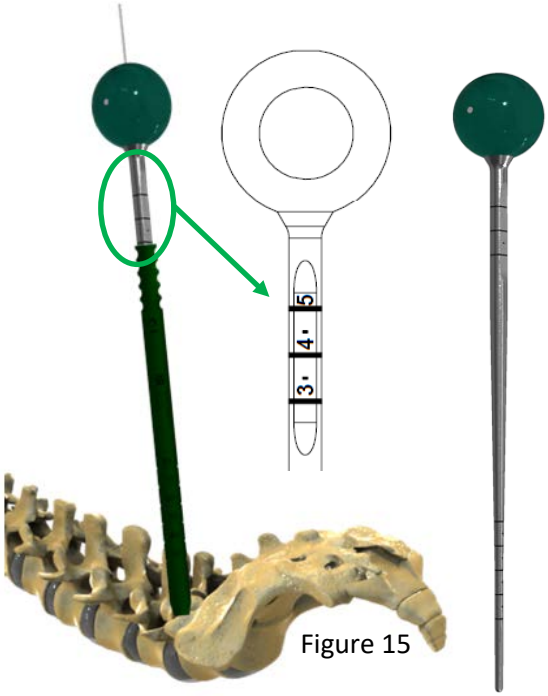

Figure 15

7
Tapping

Instruments

4.5mm MIS Tap (Use With 5.5mm Screw)
5.5mm MIS Tap Line To Line
6.5mm MIS Tap Line To Line
7.5mm MIS Tap Line To Line
T-Handle, ¼ SQ, Ratcheting

Taps are not undersized and are “as labeled” on shaft. Inertia MIS screws are self-tapping; however, the Tap may be used to prepare the pedicle if desired.

Securely attach the Ratcheting T-Handle to the Tap. Set the T-Handle clockwise to the forward setting. Advance the Tap over the K-wire and through Dilation Tube #2 to the pedicle entry point (Figure 16).

Taps are laser marked in 5mm increments from 20mm to 60mm. The proximal end of the Dilation Tube #2 is used as a reference point to ascertain the depth at which the Tap has been advanced. To ensure accuracy, the Dilation Tube must be docked on pedicle entry point.

Utilizing fluoroscopy to ensure the K-wire does not unintentionally migrate during Tap advancement; simultaneously advance Tap in a clockwise direction to the desired depth. Do not advance the Tap beyond the tip of the K-wire. Use caution to avoid bending or kinking the K-wire while advancing the Tap.

The appropriate screw length may be selected referencing the depth measurement on the Tap with the rim of Tube #2.

It is important to hold the K-wire in position when removing the tap.

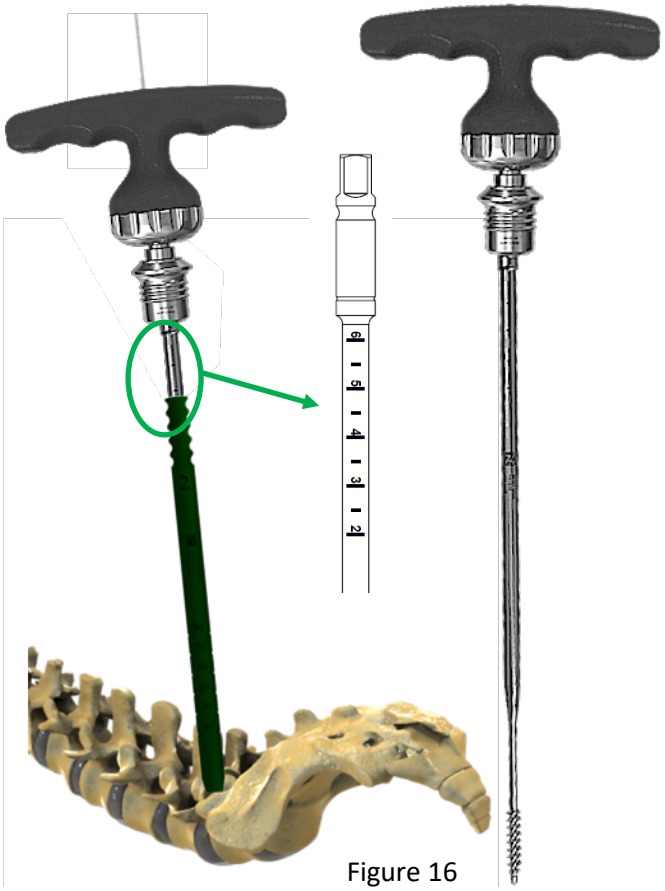

Figure 16

Warning: To prevent inadvertent advancement of the K-wire, align the trajectory of the Tap with the K-wire and monitor the K-wire position using fluoroscopy.

Note: If you tap beyond the tip of the K-wire, bone within the end of the MIS Tap may cause the K-wire to pull out as you remove it. To avoid this, do not advance the tip of the MIS Tap beyond end of K-wire.

Note: Total thread length of the Tap measures 25mm for visual reference on fluoroscopy.

Note: After the tip of the Tap enters the vertebral body one can redirect it if necessary by pulling the K-wire tip back into the tap and redirecting it. The K-wire is then pushed back through the Tap and into the vertebral body.

8
Percutaneous Tower Attachment

Instruments

MIS Dilator 3
Percutaneous Tower
Tower Attachment Tool
Screw Loading Guide

Slide Dilation Tube #3 over K-wire and Dilation Tube #2 until the tip of the tube is docked onto bony anatomy. Carefully remove Tube #2 while keeping K-wire and Tube #3 in place (Figure 18).

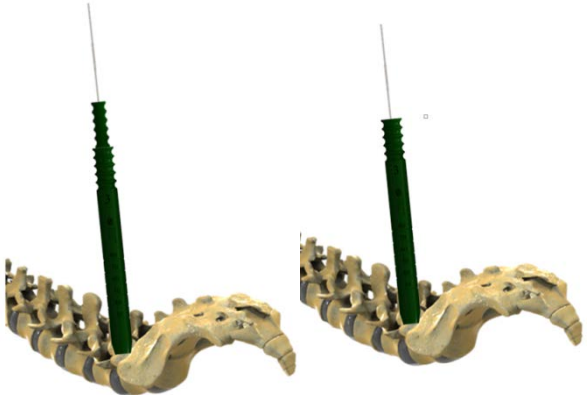

Figure 18

The Tower Attachment Tool and Screw Loading Guide are required for connection of Tower to the housing (tulip) of the Pedicle Screw.

Place Pedicle Screw in the Screw Loading Guide as shown with the arrow on the Screw housing matching the arrow on the Guide (Figure 19 and 20c).

Figure 19

Figure 20a

Figure 20b

Place the Tower Attachment Tool inside of the Tower by aligning the male feature inside of the alignment slot on the Tower (Figure 20a).

Turn Screw Attachment Tool ¼ turn clockwise to splay distal end of the Tower (Figure 20b).

Align splayed Tower over top of the Screw head retained in Screw Loading Guide with all 3 arrows aligned (Figure 20c).

Figure 20c

Turning Screw Attachment Tool ¼ turn counter-clockwise will allow Percutaneous Tower to securely capture Screw head (Figure 20d).

Figure 20d

Remove Screw from Guide, remove Tower Attachment Tool from inside Tower; Screw and Tower remain attached. (Figure 21).

Figure 21

Confirm Screw/Tower attachment by visual inspection and pulling on the Screw while holding the Tower.

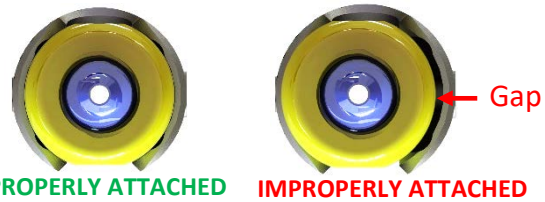

Figure 22 Bottom of Tower View

9
Screw Insertion

Instruments

MIS Screw Inserter
T-Handle, ¼ SQR, Ratcheting
Optional: In-situ Driver

Attach Ratcheting T-Handle to MIS Screw Inserter ¼ SQR adapter. Set the handle to the clockwise position for Screw insertion. Confirm secondary locking collar (Figure 23) is in the unlocked position.

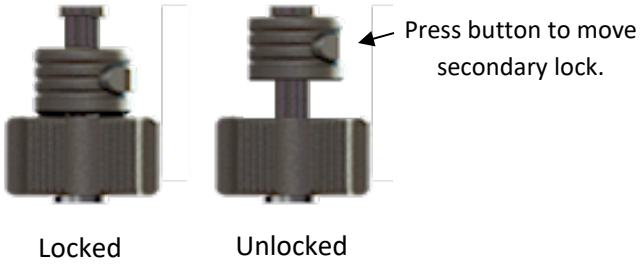

Figure 23

Slide the inserter into the Screw/Tower assembly and fully seat the tip into the female hexalobe feature within the screw (Figure 24a). Rotate the primary locking collar clockwise (distal/wider collar) advancing outer sleeve into the screw housing (tulip) to secure the implant. Once screw is securely attached, depress the button on the secondary locking collar sliding it downward in contact with the primary locking collar. Inserter is now in the locked position.

Advance the Tower/Screw assembly over the K-Wire and into the prepared pedicle through Tube #3. Remove K-wire as soon as the Screw is through the pedicle and enters the vertebral body (Figure 24b).

Figure 24a Figure 24b

Confirm Screw depth fluoroscopically. To maintain full polyaxial capability, the Screw head (tulip) should not be fully seated against the bone.

Once the Screw is inserted to the desired depth, unlock the Screw Inserter by pressing the lock button and raising the lock collar, then rotating lock wheel counterclockwise. Remove Inserter from tower by pulling upward. Verify polyaxial capability by rotating the tower in multiple directions.

Note: After gaining initial purchase into the pedicle with the Tower/Screw assembly, remove the K-wire to prevent it from being advanced too far.

9
Screw Insertion (cont.)

Once all Screw/Tower assemblies are in place, rotate the Towers as needed to ensure rod channels are oriented cephalad/caudal for rod insertion.

Rotate Tower that will be used to introduce the Rod to have arrow pointing in direction of Rod advancement (Figure 25). Subsequent Towers do not require arrow alignment, their direction is irrelevant.

For single level constructs, confirm the Screw heads are at equal heights. For multi-level constructs, verify that the Screw heads replicate the curvature of the Pre-lordosed Rod. Screw height can be verified with lateral fluoroscopy or by checking the alignment of the top of the Towers. Screw height adjustments can be made with the In-Situ Driver.

Repeat Screw placement procedures at each surgical level.

Arrow on 1st Tower to match direction of planned Rod insertion.

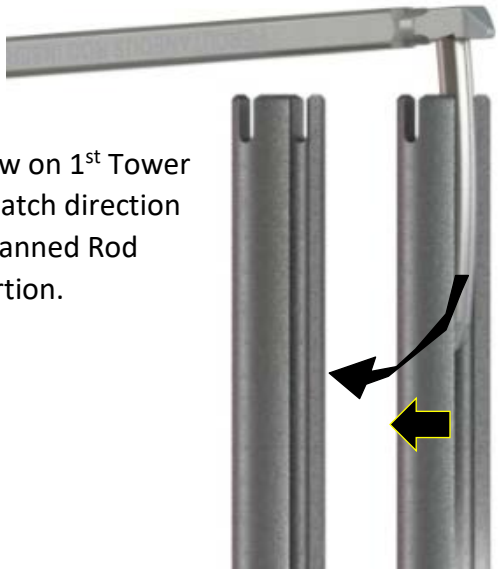

Figure 25

Warning: Do not advance the MIS Screw into the pedicle until the screw axis is aligned with the K-wire to prevent kinking or unintended advancement. Monitor the tip of the K-wire under fluoroscopy to ensure it does not penetrate the anterior wall of the vertebral body.

Note: A nerve hook may be used to pull fascial and skin edges around the Tower/Screw assembly once the Screw is secured.

Note: Under fluoroscopy, visualize screws to ensure medial/lateral alignment for rod as much as possible.

10
Rod Measuring

Instruments
Rod Measuring Caliper

Accurate rod length determination is dependent on proper positioning of Rod Measuring Caliper (Figure 26) within Screw housings (tulip).

Slide the Rod Measuring Caliper into the Towers on both ends of the construct until an audible “click” or tactile feel confirms the caliper is properly retained within the screw housing (tulip). Laser marking on both legs of the caliper should be flush with the top of the tower (Figure 27). Check retention of caliper tips within screw housings by pulling up lightly.

Figure 26

The reference arrow indicates rod length <u>including</u> overhang on each end of the construct to accommodate the hex and bulleted tip features. If the reading is between two numbers, the larger number should be used.

For long constructs (3+ levels), it may be necessary to determine rod length with two measurements. Add the two readings together and subtract 10mm from the total (rod overhang of 5mm at each end = 10mm)

Rod length formula: AB + BC – 10mm = Rod length.

Example:
AB = 95mm, BC = 60mm
95 + 60 – 10 = 145mm

Figure 27

11
Rod Insertion
Option 1: Percutaneous

Instruments

Perc. Rod Inserter
MIS Initial Set Screw Driver
Rod Bender
Blunt Tissue Dissector Straight or Curved

Select the appropriate length Rod and contour with Rod Bender to accommodate anatomy (if required).

Ensure the rod retention screw is fully loosened prior to attempting to insert the hex end of the rod to the Rod Inserter (Figure 28). Confirm orientation of the lordotic/kyphotic bend in Rod relative to Rod Inserter.

Manually tighten the rod retention screw (finger tighten) to provisionally secure Rod. While tightening, visually confirm Rod is being loaded onto the correct side of the Rod Inserter as shown.

Perform tightening of the Rod to Inserter with the Initial Set Screw Driver.

Rotate Towers so Rod channels are in alignment for Rod placement. Blunt Tissue Dissector (Figure 29) may be utilized to gently dissect tissue planes or cut interfering tissue for creation of a pathway between Towers for Rod placement.

Figure 28

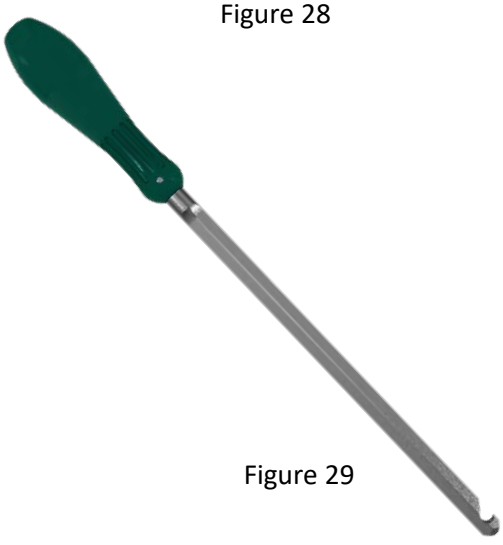

Figure 29

11
Rod Insertion
Option 1: Percutaneous (Cont.)

Begin insertion by introducing the Rod down the first Tower (Figure 30a), insuring direction matches arrow of 1st Tower (Figure 30b). Insert down the aligned Towers to desired depth, then rotate Rod into subsequent Towers (Figure 30c). Verify rod position frequently with fluoroscopy until fully seated.

The Rod Pusher (Figure 31a) may be utilized within any of the Towers to push the rod downward into Screw housings.

Final Rod position has been achieved when the following criteria have been met (Figure 31b):

A. Inserter shaft should be parallel to adjacent Tower.

B. "Heel" of Rod Inserter should be positioned against Screw housing (by tactile feel).

C. Bulleted tip of Rod must be outside of Screw housing on end of construct. Rod is contanined within all Screw housing at each level.

Note: Rod reduction is complete when laser mark line on Rod Pusher shaft aligns with top of Tower. Use imaging to confirm rod placement.

Figure 30a

Figure 30b

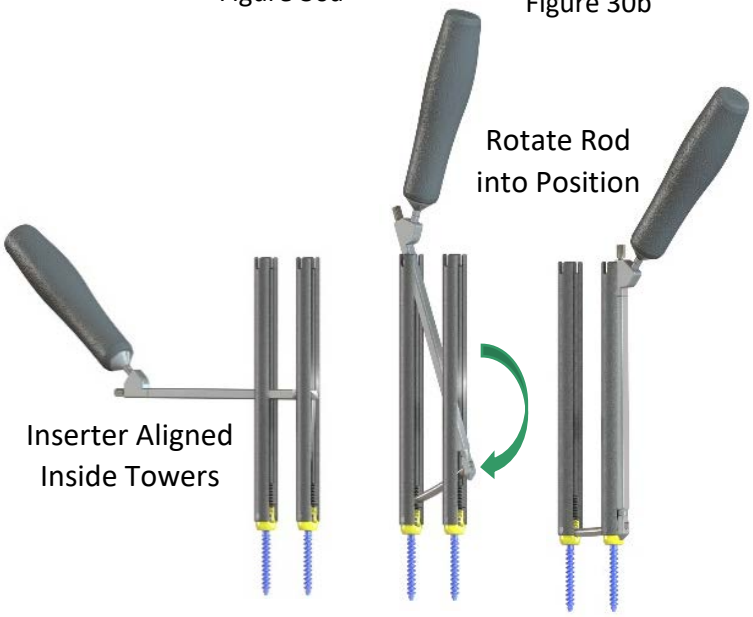

Figure 30c

Figure 31a

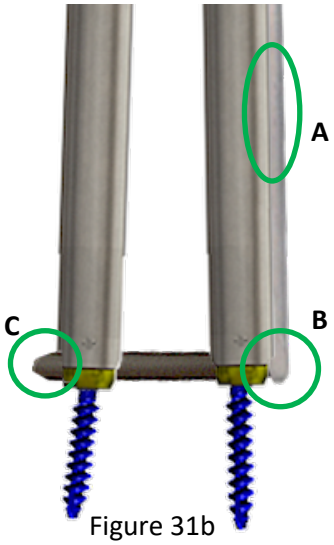

Figure 31b

12
Rod Insertion
Option 2: Wiltse Muscle Splitting

Instruments

Straight or Curved Blunt Tissue Dissector
Forcep Rod Inserter or Kerrison Rod Inserter
Rod Bender
Optional: Rod Pusher

Select appropriate length rod based on the Rod Measuring Caliper reading and contour with Rod Bender if required.

Rotate Towers so arrows point outward and rod channels are in alignment for rod placement (Figure 32).

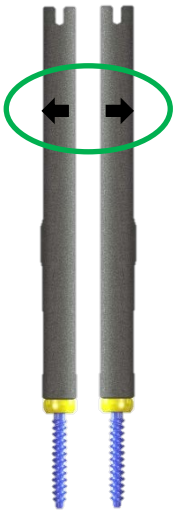

Figure 32

Figure 33

Figure 34

Blunt Tissue Dissector (Figure 33) may be utilized to gently dissect tissue planes or cut interfering tissue for creation of a pathway between Towers for Rod placement.

Grasp the Rod with the Kerrison Rod Inserter or Forcep (Figures 34, 35) and guide it through the previously aligned Towers. Press inserter down while manipulating/rocking the Rod through the tissue until it engages and seats firmly within the screw housings.

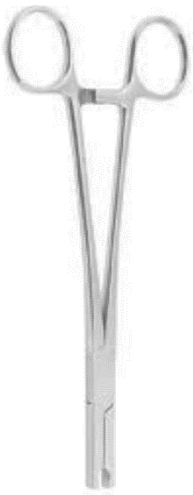

Figure 35

Figure 36

The Rod Pusher (Figure 36) may be utilized within any of the Towers to push the rod downward into Screw housings.

Final Rod position has been achieved when the following criteria have been met (Figure 37):

A. Inserter shaft should be parallel to adjacent Tower.
B. "Heel" of Rod Inserter should be positioned against Screw housing (by tactile feel).
C. Bulleted tip of Rod must be outside of Screw housing on end of construct. Rod is contanined within all Screw housing at each level.

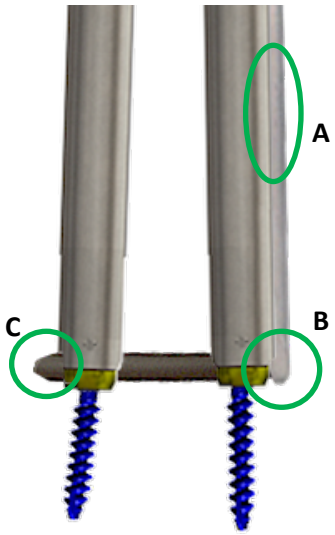

Figure 37

Note: Rod reduction is complete when laser mark line on Rod Pusher shaft aligns with top of tower. Use imaging to confirm rod placement.

13
Set Screw Insertion & Rod Reduction

Instruments

Initial Set Screw Driver
Optional: Set Screw Driver Handle
Optional: Rod Pusher & Blunt Tissue Dissector Straight

Load Set Screw from caddy by pressing downward on the tapered tip of the gold handled Initial Set Screw Driver to activate “stab and grab” retention feature (Figure 38).

Guide Set Screw down the Tower with the Initial Set Screw Driver (Figure 39a). Thread Set Screw down Tower to reduce the Rod (Figure 39b). Set Screw Driver Handle may be loaded on top of Inserter for ease of rotating the Inserter (Figure 39c). Tip of Inserter will release press-fit Set Screw once tightening Rod into final position.

Provisionally tighten (finger tight) Set Screw to capture the Rod. Repeat threading Set Screws down all Towers. Repeat on contra-lateral Rod.

Note: Do NOT tighten any Set Screws until Rod is reduced into all housings. Locking a Rod off-angle will hinder reduction.

The Blunt Tissue Dissector should be considered to remove soft tissue interference for delivery of Set Screw.

Rod Pusher may be utilized within any of the Towers to push the Rod into position within Screw housings.

Fluoroscopy may be used at any time to confirm rod positioning.

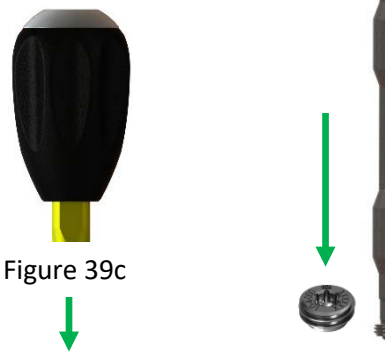

Figure 39c

Figure 38

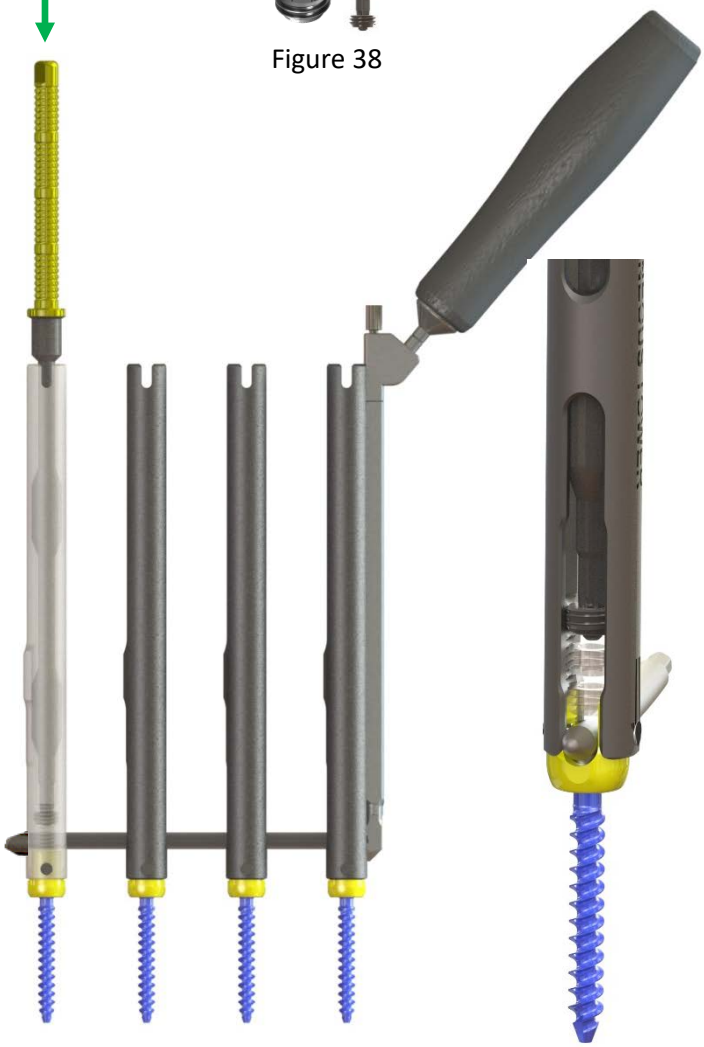

Figure 39a

Figure 39b

13
Rod Reduction (cont.)

Locking a Set Screw into a housing will lock the polyaxial screw with the Rod at that angle. If the Rod is not reduced into all housings, then reducing the Rod into subsequent housings will be very difficult. The Inertia Pedicle Screw System is designed to lock into a rigid construct, hence not allow the Rod to move (Figures 40 and 41).

If the Rod will not reduce, the Towers are designed to 'forgive' the Set Screw force and you will experience a skipping effect. There are two options if skipping occurs:

1) Ensure all Set Screws are not locked, ensure Rod Inserter is not inside the housing, and ensure soft tissue interference is minimized.
2) Anti-Splay Tube may be placed over the Tower to ensure Set Screw can be torqued down (Figure 42). Set Screw force on the Rod can exceed 750 pounds, so ensure construct is correct before torquing Set Screw.

Anti-Splay Tubes should be used over Towers to reduce spondylolisthesis (Figure 43). The Anti-Splay Tube will ensure the Towers do not splay, as well as, ensure the Set Screw does not skip.

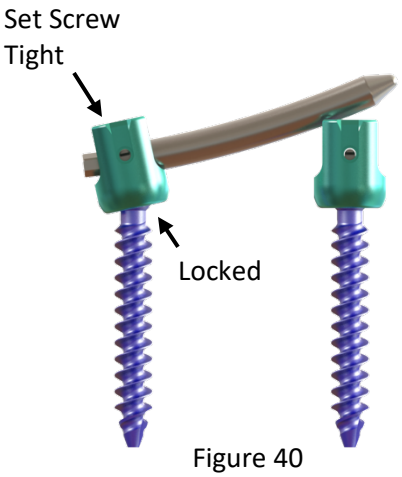

Figure 40

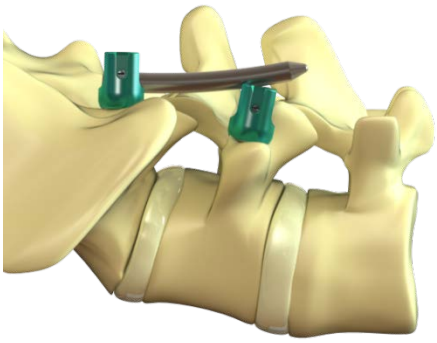
Figure 41

Figure 42

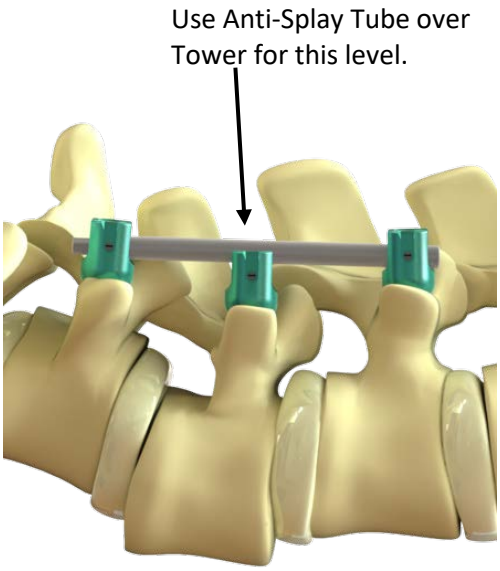

Figure 43

14
Compression / Distraction

Instruments

MIS Distractor/Compressor Body
1 Level Distractor Arm
1 Level Compressor Arm
2 Level Compressor Arm
Locking Collar
MIS Final Set Screw Driver
Torque Limiter 90 In. Lbs.

Assemble the Compressor/Distractor components according to the desired function of the instrument:

1. COMP/DIST Body (Figure 46)
2. 1 or 2 Level Compressor Arm (Figure 47)
3. Distraction Arm (Figure 48)
4. Locking Collar (Figure 49)

The MIS Distractor/Compressor Body is the foundation for all compression and distraction maneuvers. The reference surface is labeled “Comp” for Compressor arm and “Dist” for Distractor arm connection.

Final tighten the Set Screw on one end of the construct. It is imperative that there is adequate Rod overhang outside of the MIS Screw Head and Percutaneous Tower assembly to ensure appropriate Screw/Rod interface is established. Next, ensure the Set Screw at the adjacent location is loosely affixed (not tightened).

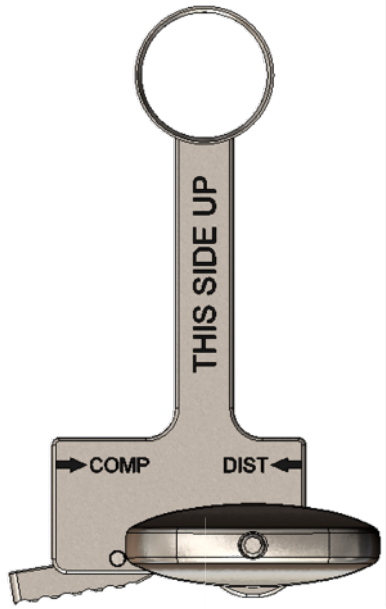

Figure 46

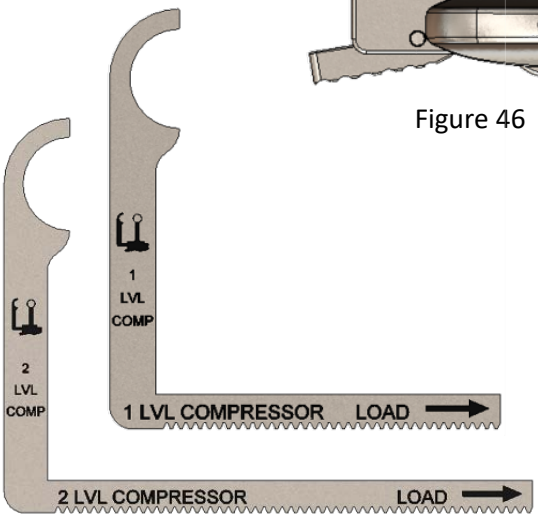

Figure 47

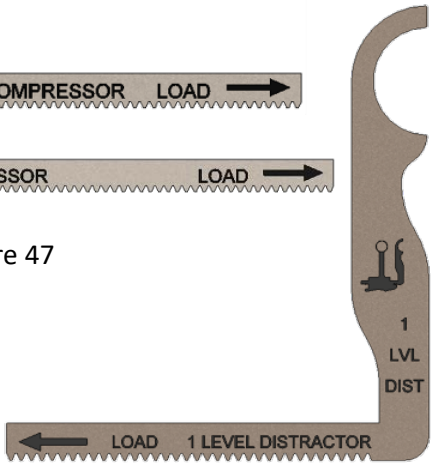

Figure 48

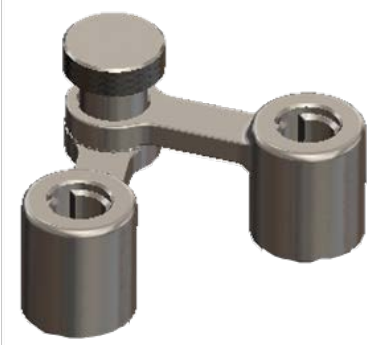

Figure 49

14
Compression / Distraction (cont.)

Compression

Slide the Compressor Arm into the designated side of the MIS Distractor/Compressor Body until resistance is felt and audible “clicks” from engagement of the gear are heard. Laser marked surfaces on both components should be facing upwards (Figure 50).

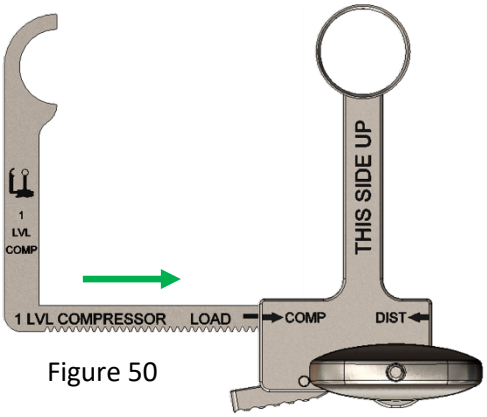

Figure 50

Distraction

Slide the Distraction Arm into the designated side of the MIS Distractor/Compressor Body until resistance is felt and audible “clicks” from engagement of the gear are heard. Continue to slide Distraction arm as far as possible along gear track. Laser marked surfaces on both components should be facing upwards (Figure 51).

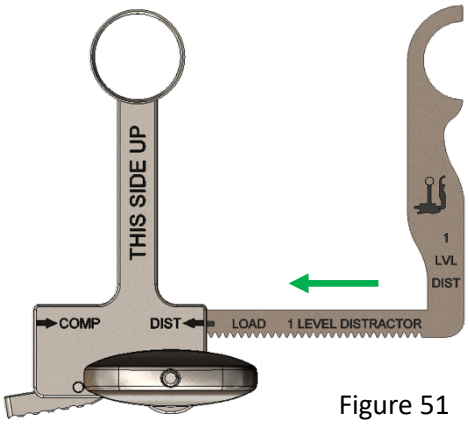

Figure 51

Attach assembled Compressor (Figure 52) or Distractor to the Tower by sliding the closed arm (attached to the Distractor/Compressor Body) down over top of the Tower. Allow instrument to rest on patient’s skin.

Slide the Compressor/Distractor Arm into position against the adjacent Tower. In some instances the Quick Release Lever may need to be depressed to facilitate movement of adjustable arms on gear track.

Attach Locking Collars on top of Towers to act as a fixed distance fulcrum. Loosen center locking knob prior to placement of Locking Collars on Tower tops. Placement on Towers may be tilted to accommodate Tower angles. Turn wheel to tighten Locking Collars once positioned on top of Towers (Figure 52).

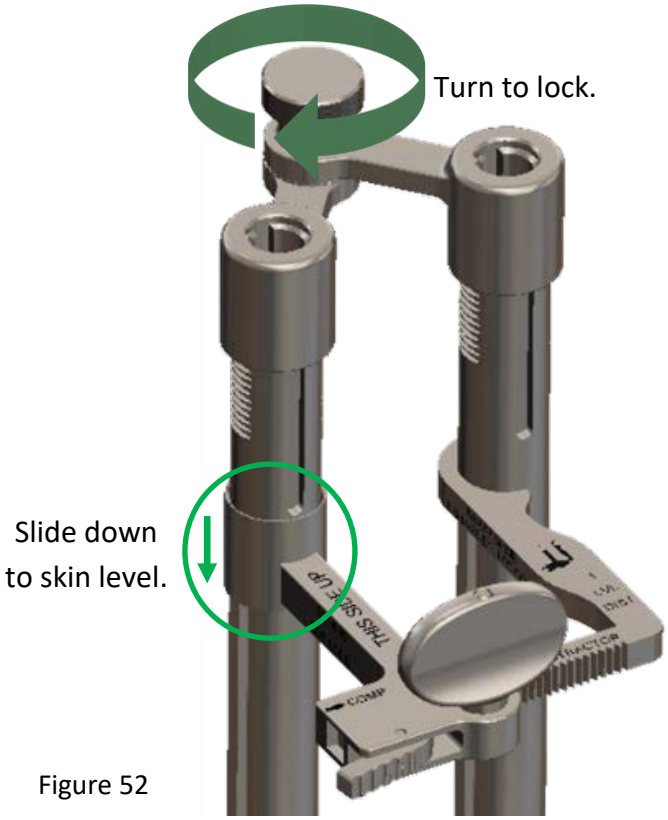

Figure 52

14
Compression / Distraction (cont.)

Place Initial Set Screw Driver inside of tower and re-engage the loosely affixed Set Screw. Perform Compression (Figure 53) or Distraction (Figure 54) by turning COMP/DIST Knob clockwise. Once compression or distraction is achieved, tighten the Set Screw with the Initial Set Screw Driver.

Unlock Locking Collar and remove from Towers. Depress Quick Release Lever to release Compressor/ Distractor.

Lift DIST/COMP Body up and off of Tower.

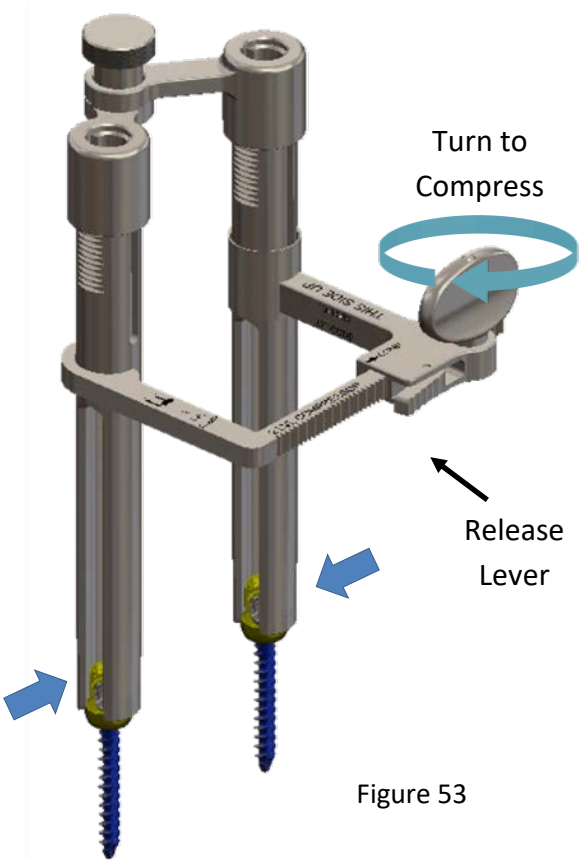

Figure 53

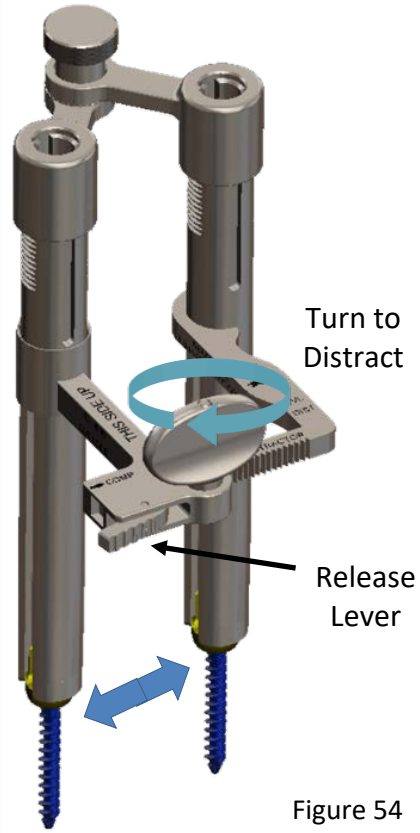

Figure 54

15
Final Tightening/Counter Torque

Instruments

Counter Torque
Final Set Screw Driver
Torque Limiter 90 In. Lbs.

Perform Final Tightening with Counter Torque Handle (Figure 55) and Final Set Screw Driver attached to the 90 IN-LB Torque Limiting Handle on Set Screw (Figure 56).

Using fluoroscopy, verify that the Rod overhangs the outermost screws on both ends of the construct by 5mm.

Slide Counter Torque Wrench over Tower, which can be used at any point above the skin. Attach 90 IN-LB Torque Handle to Final Driver, insure inserted to "Connect Line" on shaft.

Rotate the Final Set Screw Driver clockwise, while applying resistance in the opposite direction with the Counter Torque Handle. The Torque Handle will produce an audible “click” once the desired 90 IN-LB torque value has been achieved. Repeat procedure for all Set Screws.

Once final tightening is performed, the “Fully Seated Line” indicated by a laser band on the proximal end of the Final Set Screw Driver should be positioned slightly below the top of the tower.

Figure 55

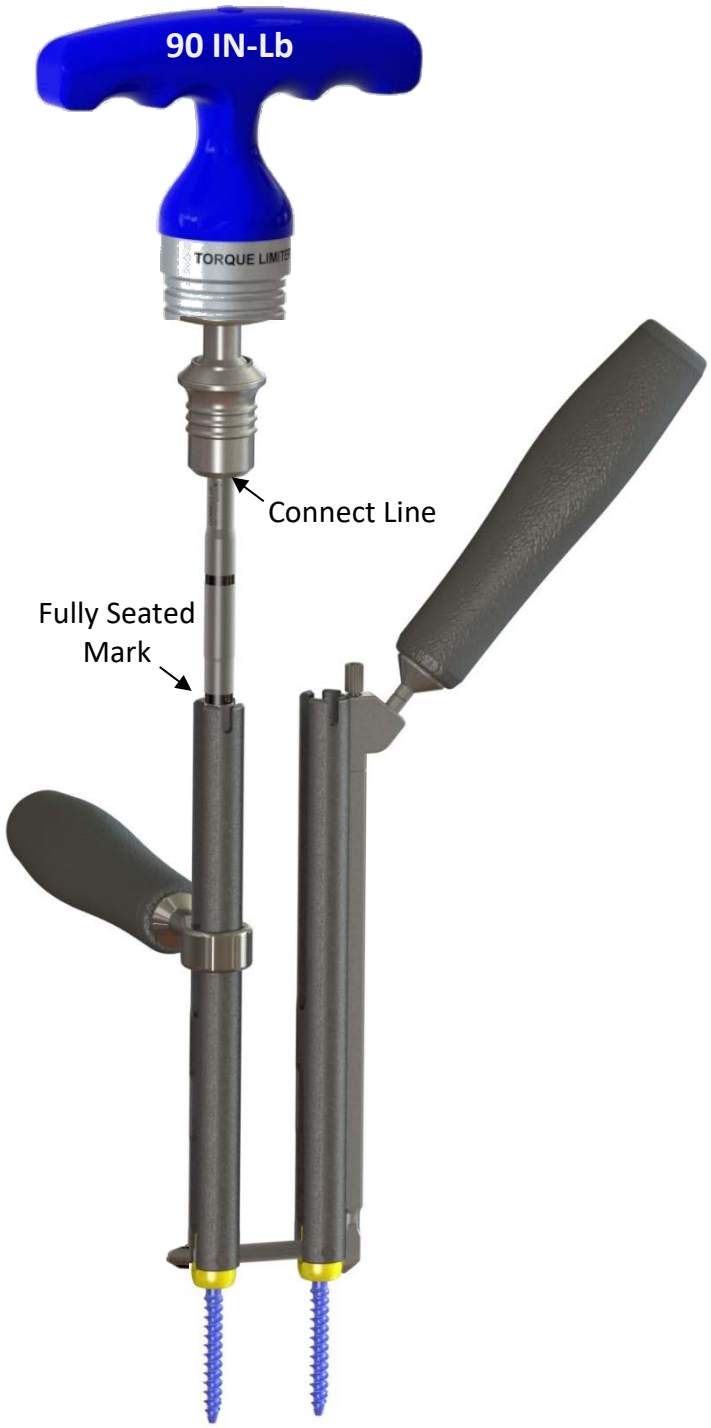

Figure 56

16
Percutaneous Tower Removal

Instruments
Tower Attachment Tool

Place the Tower Attachment Tool inside of the Tower by aligning the tool's male feature inside of the alignment slot on the Tower (Figure 57).

Turn Tower Attachment Tool ¼ turn clockwise to splay and release distal end of the Tower from the Screw housing. The Tower Attachment Tool is now retained within the Tower (Figure 58) and can be removed from the wound.

Repeat steps for remaining Screws.

Remove the Rod Inserter from the rod with the Final Set Screw Driver attached to any T-Handle in the set (Figures 59, 60).

Note: Confirm final tightening of all construct screws before removing the towers.

Figure 57

Figure 58

Figure 59

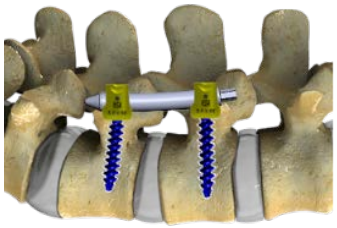

Figure 60

17

In-situ Percutaneous Tower Reattachment

Without Rod and Set Screw in Place

Instruments

Tower Attachment Tool
Tower Reattachment Guide
Optional: Reattachment Tube

If desired, slide Reattachment Dilation Tube back into surgical wound and dock to anatomy surrounding targeted Screw housing for Tower reattachment.

Insert the Reattachment Guide (Figure 61) down Dilation Tube and into the Screw housing (Figures 62a). Apply pressure downward to engage tip of Guide within Screw Housing (Figures 62b) until Guide snaps into Screw's retaining feature. Apply light upward pressure to confirm tip of instrument is seated properly within Screw housing.

Place the Tower Attachment Tool inside of the Tower aligning the male feature inside of the slot on the Tower. Turn Attachment Tool ¼ turn clockwise to splay distal end of the Tower apart (Figure 63).

Carefully guide Attachment Tool /Tower assembly over top of Reattachment Guide and down until the Tower engages with the Screw housing (Figure 64). Turn handle ¼ turn counter-clockwise to allow Tower to securely capture Screw housing. Remove Attachment Tool from inside Tower followed by removing Reattachment Guide. Confirm implant/tower attachment by pulling upward on the Tower.

A reference mark on proximal end of the Reattachment Guide will be in alignment with the top of the end of the Attachment Tool. This is confirmation that the Tower is properly attached to Screw Housing (Figure 65).

Note: Flat surfaces on the thin Guide handle should align with Rod direction to insure Screw housing is rotated correctly (Figure 65).

Figure 62a

Figure 62b

Figure 61

Figure 63

Figure 64

Figure 65

18
Revision / Removal

Instruments

T-Handle, SQR, Ratcheting
Final Set Screw Driver
Forcep Rod Inserter
In-Situ Driver

If required, the INERTIA® MIS Pedicle Screws, Set Screws and Rods may be removed from the patient. To attain exposure, use a dissection or preferably dilation technique to visualize the head of each Screw.

Following exposure of the Polyaxial Screw Heads, insert the hex portion of the Final Set Screw Driver into the Set Screw to be removed. Attach the Ratcheting T-Handle to the opposite end of the Final Set Screw Driver shaft and adjust the handle to permit counterclockwise rotation of the Set Screw. Fully extract the Set Screw by turning in a counterclockwise direction.

Using the Forcep Rod Inserter, remove the Rod. Fully extract each pedicle screw from the vertebral body with the T-15 In-Situ Driver by turning in a counterclockwise direction.

Take post-operative radiographs to assure that all hardware has been removed.

Explanted components should be properly discarded and not used for re-implantation.

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