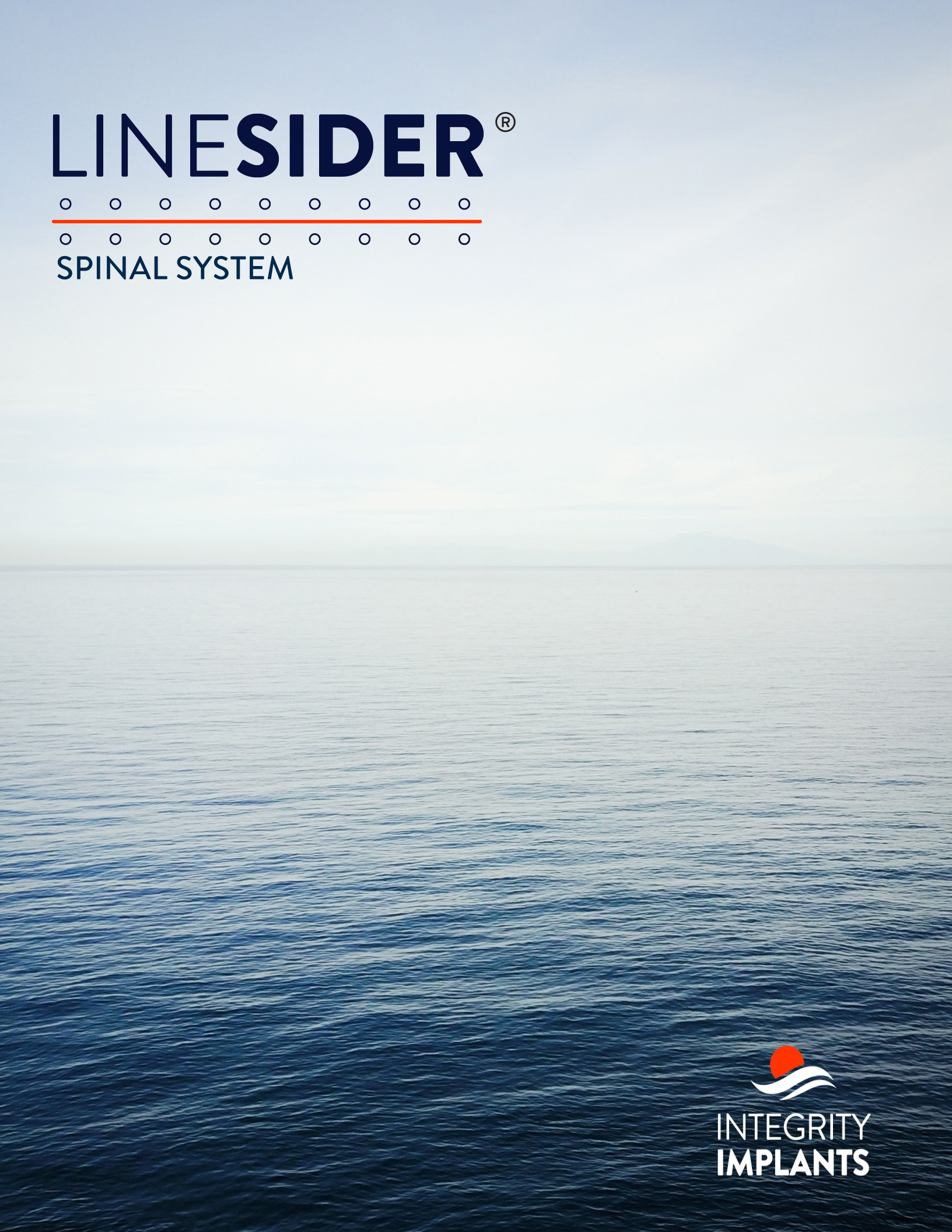
LINESIDER®

SPINAL SYSTEM



INTEGRITY IMPLANTS

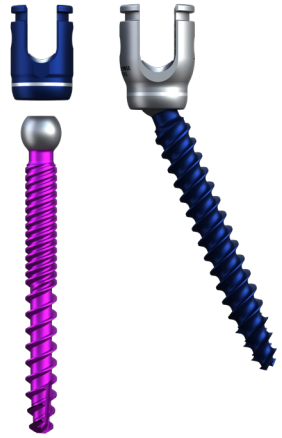
TABLE OF **CONTENTS**

OVERVIEW **& INTENDED USE**

MODULAR IMPLANTS

LineSider® Spinal System offers modularity and industry-leading versatility.

The surgeon can create an ultra-small skin incision by utilizing the slim tulip paired with a 5.0mm CoCr Rod, or they can tackle complex pathology with a robust, low-profile tulip and a 5.5mm or 6.0mm Rod system.



Screw Shanks are designed for strong purchase and ease of insertion. They start with a chiseled tip, designed to cut its way into bone with minimal downward pressure. The tip flows into either a dual lead or dual-to-quad lead thread pattern designed to maximize bone purchase.

ELEGANT INSTRUMENTATION

Function meets form in the LineSider Spinal System. Surgical efficiency is maximized with the system's practical, versatile, and ergonomic instrumentation.

- Drivers and adjustment tools were created to be robust and simple but also function smoothly and flawlessly. The same Screwdriver can be used for both Standard and Reduction Screws.
- Reducers and Benders were made to maximize leverage and minimize unneeded motion and steps.

STREAMLINED SETS

LineSider sets are designed for a clean, uncluttered, and functional operating room back table. The goal is to allow the surgical team to deliver the system efficiently and effectively to the surgeon.

- Tray layouts are set up with surgical steps and back table flow in mind.
- No Tray is more than two levels.

INDICATIONS **FOR USE**

LineSider™ Spinal System, with or without MIS instrumentation, is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

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

Refer to the LineSider Spinal System Instructions for Use (IFU) for a complete listing of indications, contraindications, warnings, and precautions.

IMPLANT **FEATURES**

TULIP HEADS

LineSider is a modular pedicle screw system offering two head sizes that can accommodate four different rod sizes. The heads were designed with low-profile attachment points to facilitate streamlined instrumentation.

- The slim version will accept a 4.5mm or 5.0mm rod that is offered in cobalt-chrome (CoCr) and 5.0mm in Ti Alloy (Ti6Al4V).
- The standard version will accept a 5.5mm or 6.0mm rod that is offered in both Ti Alloy (Ti6Al4V) and cobalt-chrome (CoCr).

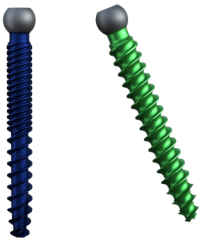
Both Tulip sizes have been designed to accept a universal Shank.

UNIVERSAL SHANK

The Shanks are offered in a wide range of lengths and diameters. The thread patterns include dual lead and dual-to-quad lead. All Shanks are designed to accommodate any of the Tulip Heads in the LineSider portfolio. Shank colors correspond to Screw diameter.

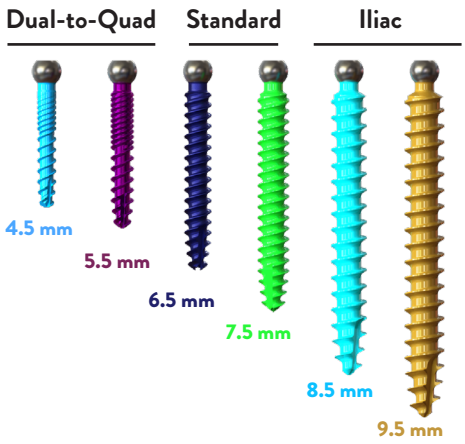
STANDARD (DUAL LEAD THREADS)

4.5 x 30 mm	5.5 x 30 mm				
4.5 x 35 mm	5.5 x 35 mm	6.5 x 35 mm	7.5 x 35 mm	8.5 x 35 mm	9.5 x 35 mm
4.5 x 40 mm	5.5 x 40 mm	6.5 x 40 mm	7.5 x 40 mm	8.5 x 40 mm	9.5 x 40 mm
4.5 x 45 mm	5.5 x 45 mm	6.5 x 45 mm	7.5 x 45 mm	8.5 x 45 mm	9.5 x 45 mm
4.5 x 50 mm	5.5 x 50 mm	6.5 x 50 mm	7.5 x 50 mm	8.5 x 50 mm	9.5 x 50 mm
4.5 x 55 mm	5.5 x 55 mm	6.5 x 55 mm	7.5 x 55 mm	8.5 x 55 mm	9.5 x 55 mm
		6.5 x 60 mm	7.5 x 60 mm	8.5 x 60 mm	9.5 x 60 mm



CORTICAL/CANCELLOUS (DUAL-TO-QUAD LEAD THREADS)

4.5 X 25 mm	5.5 x 25 mm		
4.5 x 30 mm	5.5 x 30 mm	6.5 x 30 mm	7.5 x 30 mm
4.5 x 35 mm	5.5 x 35 mm	6.5 x 35 mm	7.5 x 35 mm
4.5 x 40 mm	5.5 x 40 mm	6.5 x 40 mm	7.5 x 40 mm
4.5 x 45 mm	5.5 x 45 mm	6.5 x 45 mm	7.5 x 45 mm
	5.5 x 50 mm	6.5 x 50 mm	7.5 x 50 mm
		6.5 x 55 mm	7.5 x 55 mm

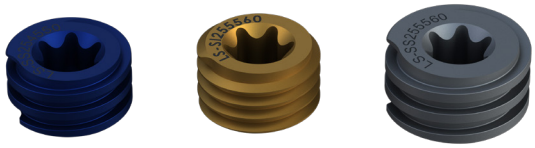


ILIAC SHANKS

7.5 x 70 mm	8.5 x 70 mm	9.5 x 70mm
7.5 x 80 mm	8.5 x 80 mm	9.5 x 80 mm
7.5 x 90 mm	8.5 x 90 mm	9.5 x 90 mm
7.5 x 100 mm	8.5 x 100 mm	9.5 x 100 mm

SET SCREWS

LineSider offers three different Set Screws. They are differentiated by color. The color of the Set Screw matches the color of the Tulip or Connector that is associated with the Set Screw.



4.5 & 5.0 Set Screw	5.5 & 6.0 Closed Set Screw	5.5 & 6.0 Set Screw
4.5 & 5.0 Standard Tulip	5.5 & 6.0 Closed Standard Tulip	5.5 & 6.0 Standard Tulip
4.5 & 5.0 Reduction Tulip	5.5 & 6.0 Offset Connector	5.5 & 6.0 Reduction Tulip

CROSSLINKS

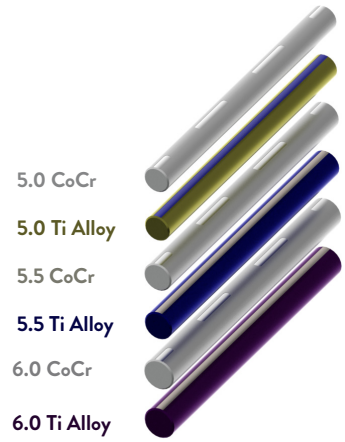
Crosslinks are offered in slim and low-profile designs with 20 degrees of angulation, allowing for easy rod-to-rod alignment. There are two sizes of Crosslinks to accommodate the different Rod sizes and they are distinguished by color. Both of those sizes are offered in a range of adjustable lengths. Blue Crosslinks fit 4.5 & 5.0 Rods and silver Crosslinks fit 5.5 & 6.0 Rods.

4.5 & 5.0 Rods

5.5 & 6.0 Rods

RODS

LineSider offers titanium alloy and cobalt-chrome Rods in multiple diameters. The Rods are available in both curved and straight options.



TRAY ORDERING OPTIONS

5.5 & 6.0 OPEN CASE	CORTICAL CASE	4.5 & 5.0 MIS CASE	5.5 & 6.0 MIS CASE
General Instrument Tray	General Instrument Tray	General Instrument Tray	General Instrument Tray
Open Instrument Tray	Open Instrument Tray	Percutaneous Instrument Tray	Percutaneous Instrument Tray
5.5 & 6.0 Open Implant Tray	Cortical Inst. Tray	4.5 & 5.0 Percutaneous Implant Tray	5.5 & 6.0 Percutaneous Implant Tray
5.5 & 6.0 Open Instrument Tray	Cortical Implant Tray		

Additional trays available on request:

- Iliac Tray
- Extra Screw Tray
- Long Construct Implant Tray
- 5.5 - 6.0 QC Reducer Tray

LINESIDER®

OPEN SURGICAL TECHNIQUE

Place the patient in a prone position on the desired surgical table. (Figure 1) Prepare and drape in a conventional manner. The fluoroscope should have easy access to the surgical field for both A/P and lateral views. Uniplanar or biplanar fluoroscopy may be used.

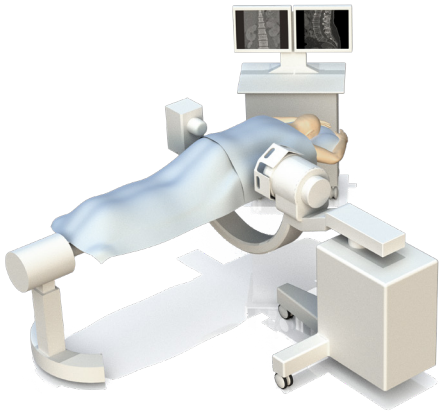


Figure 1. Prone Positioning

PEDICLE PREPARATION

1. Locate the desired entry point into the pedicle and perforate the cortex with a high-speed burr. Create a pilot hole by passing a Gear Shift Probe through the pedicle and into the vertebral body. (Figure 2)

   Note: Gear Shifts, Taps, and Probes are marked with a solid black band between 40mm and 50mm to assist in visualizing the instrument depth in bone.

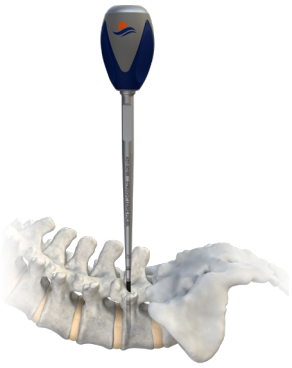


Figure 2. Gear Shift Probe

2. Inspect the pilot hole for perforations and desired length with the Ball Tip Pedicle Probe by palpating the pedicle wall on all sides. (Figure 3)

3. If tapping is desired, select the preferred Ratcheting Handle and attach the appropriate size Tap. (Figure 4)

   Note: LineSider Screws are self-tapping and can be inserted once it has been established that there is not a breach in the pedicle.

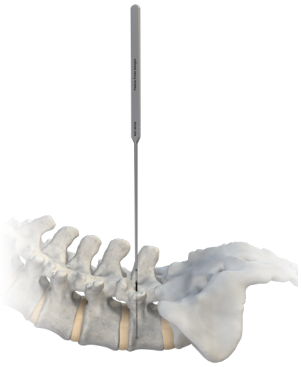


Figure 3. Ball Tip Probe

   Note: All Taps are line-to-line as marked and all threads are 30mm in length.

   Note: When engaging a Handle from the LineSider System with any instrument (Tap, Screwdriver, etc.), the engraved black line on the instrument must sit in-line or flush with the Handle.

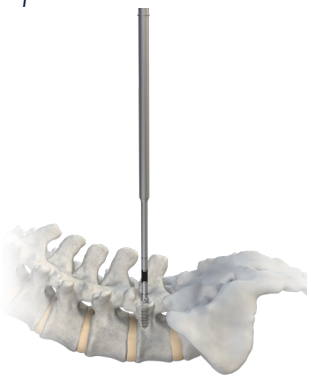


Figure 4. Tap

4. If a Tap was used, it is recommended that another inspection be done of the pedicle with the Ball Tip Probe to ensure its structural integrity.

SCREW INSERTION (Tulip Preassembled)

1. Select the desired Pedicle Screw Shank and remove it from the Shank Caddy. Insert it into the Loading Block (located in the implant tray) with the ball end facing up. (Figure 5)

   Note: Prior to inserting the Screw into the Loading Block, it is recommended to utilize the measuring cutout on the Caddy to confirm length.

   Note: The Loading Block is located on the side of the Screw Shank Caddy.

2. Select the desired size and style of Tulip and load it on the Tulip Inserter. Make sure that the silver indicator button on the tulip inserter is depressed and flush with the top of the handle. (Figure 6)

3. Place the Tulip over the Shank and apply firm downward pressure. When the Tulip is fully seated, the silver button on the Tulip Inserter handle will sit proud of the handle. (Figure 7)

4. Before the Tulip is removed from the Tulip Inserter it is recommended that a polyaxial motion be made with the Tulip Inserter as well as a gentle tug be given to the Shank to ensure the two have been assembled correctly. (Figure 8)

Note: Because of the mechanism in the Tulip Inserter that causes the silver button on the proximal end of the instrument to sit proud after the Tulip has properly loaded on the Shank it is important not to have the surgeon either mallet or place his hand over the back of the instrument. Doing so could cause a false "no-load" of the Tulip.

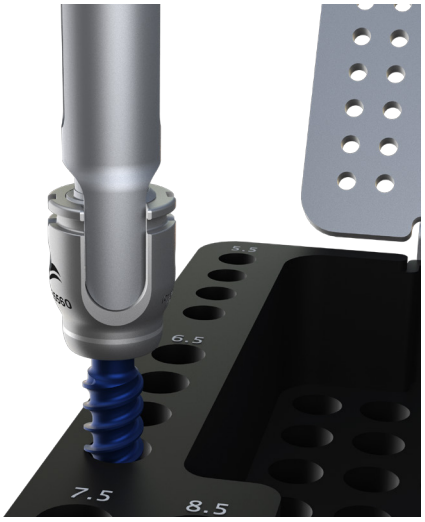


Figure 5. Loading Block

Figure 6. Flush

Figure 7. Proud

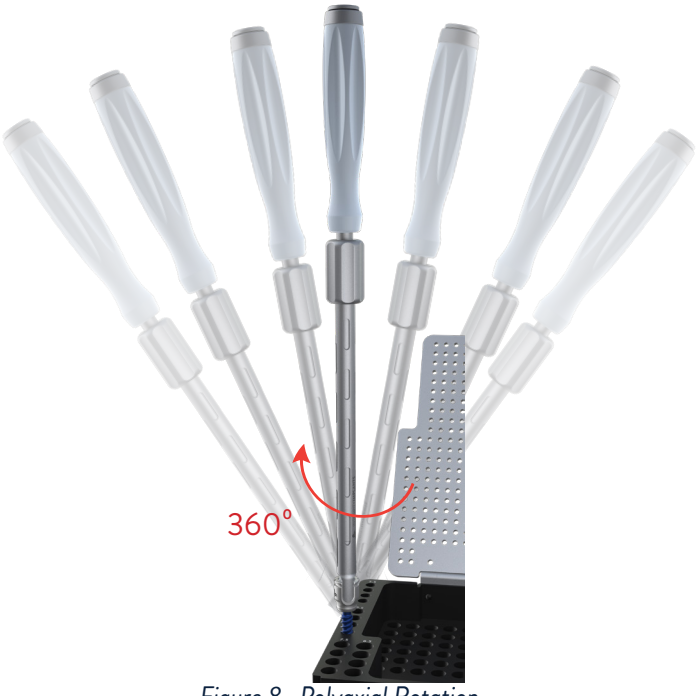


Figure 8. Polyaxial Rotation

5. Once the Tulip and Shank are assembled, select the Polyaxial Screwdriver. Attach the Ratcheting Handle of choice to the Screwdriver.

6. The Polyaxial Screwdriver can be adjusted for compatibility with Polyaxial Screws (Figure 9) or Polyaxial Reduction Screws (Figure 10) by depressing the button on the knob and translating the inner shaft.

   Note: Ensure the Sleeve is assembled on the Driver. This is accomplished by pushing the Sleeve on the Driver until a click is heard. The Sleeve is held on with a friction fit. Once the click is heard, it is fully assembled.

7. To load the Screwdriver, insert the distal drive feature into the Shank of the Screw and secure the Tulip by turning the knob clockwise and engaging the threads. Verify that the Screw and Screwdriver interface is rigid and the Shank is aligned straight.

8. Introduce the Screw into the pilot hole and advance until the desired depth is reached. The Screwdriver's Sleeve is designed to rotate freely, allowing the instrument to be firmly grasped throughout insertion without unthreading the Driver from the Screw.

9. To release the Screwdriver, hold the blue-gray Handle and turn the knob counterclockwise until the Screwdriver is fully unthreaded from the Tulip, and then remove from the Screw.

10. If adjustment to Screw depth is required, the Stand-and-Grab Driver or the Set Screw Final Driver may be used. The Tulip Adjuster may be used to adjust the cephalad/caudal or medial/lateral orientation of the Tulip prior to Rod insertion. (Figure 11)

Figure 9. Standard Screw Assembly

Figure 10. Reduction Screw Assembly

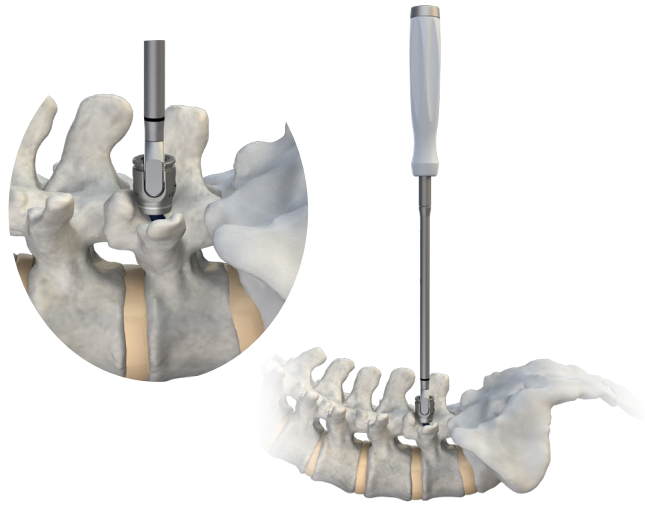


Figure 11. Tulip Adjuster

SCREW INSERTION
(Without Tulip Preassembled)

1. Select the Shank Driver (located in the general instrument tray) and attach the desired Handle. (Figure 12)

2. To load the Screwdriver, turn the silver knob counterclockwise until the collet is fully open and insert the distal drive feature over the Shank's ball. (Figure 13) Secure the Shank by turning the knob clockwise. Verify that the Screw and Screwdriver interface is rigid and the Shank is aligned straight.

   Note: The Screw is properly engaged when the collet that holds the ball of the Shank is fully recessed inside the metal sleeve. (Figure 14)

3. Introduce the Screw into the pilot hole and advance until the desired depth is reached. The Screwdriver's black Sleeve is designed to rotate freely, allowing the instrument to be firmly grasped throughout insertion without unthreading the Driver from the Screw. (Figure 15)

4. To release the Screwdriver, hold the blue-gray Handle and turn the knob counterclockwise until the distal shank capture feature is completely open and then remove from the Screw.

5. If adjustment to Screw depth is required, the Final Set Screwdriver may be used.

Figure 12. Shank Driver

Figure 13. Collet Fully Open

Figure 14. Collet Fully Recessed

Figure 15. Advance Screw

TULIP INSERTION IN-SITU

1. After the Shank has been inserted, the Tulip can then be inserted and assembled onto the Shank. If there is a need for further preparation of the bone surrounding the Screw Shank the Shank Decorticator is available and can be found in the general instrument tray. (Figure 16)

   Caution: The Shank Decorticator should never be used with power. It should only be used with one of the Ratcheting Handles provided in the LineSider set.

2. Load the Tulip onto the Tulip Inserter by grasping the knurled collar and rotating the handle clockwise. This will thread the Tulip Inserter into the Tulip. Make sure that the silver indicator button on the Tulip Inserter is depressed and flush with the top of the handle. (Figure 17)

3. Place the Tulip over the Shank and apply firm downward pressure. When the Tulip is fully seated the silver button on the top of the Tulip Inserter handle will sit proud of the handle. (Figure 18)

   Note: Because of the mechanism in the Tulip Inserter that causes the silver button on the proximal end of the instrument to sit proud after the Tulip has properly loaded on the Shank it is important not to have the surgeon either mallet or place his hand over the back of the instrument. Doing so could cause a false "no-load" of the Tulip.

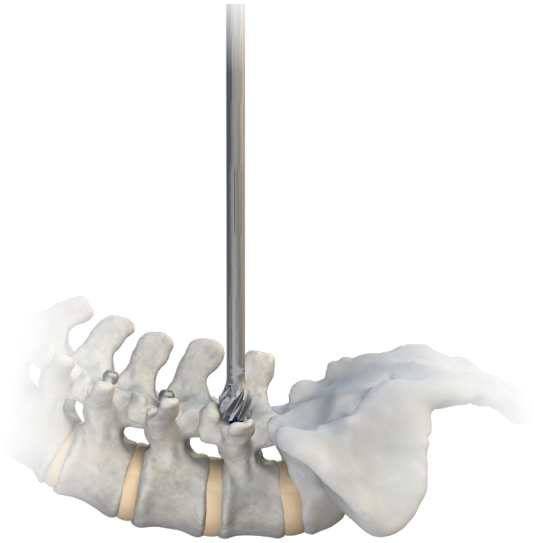


Figure 16. Shank Decorticator

Figure 17. Flush

Figure 18. Proud

4. Before the Tulip is removed from the Tulip Inserter it is recommended that a 360 degree polyaxial motion be made to the Tulip Inserter while maintaining a downward force. A final gentle tug on the Tulip Inserter will confirm the assembly. (Figure 19)

5. The Tulip Adjuster may be used to adjust the cephalad/caudal or medial/lateral orientation of the Tulip prior to Rod insertion.

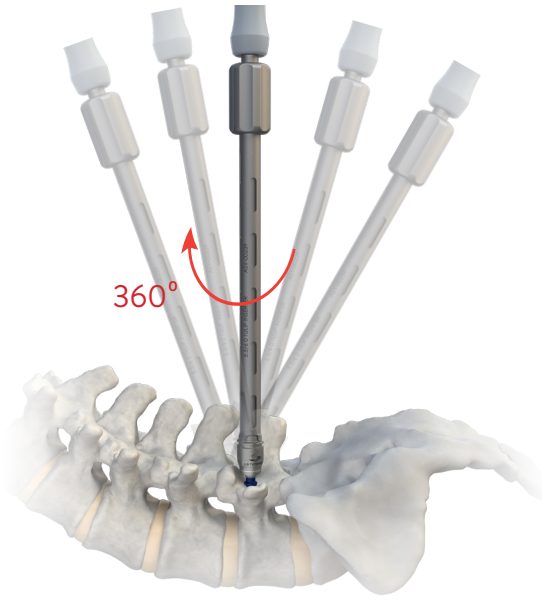


Figure 19. Polyaxial Motion

ROD CONTOURING

Once all Screws are in position, measure the Rod length needed with either the Rod Template or another preferred technique and bend the appropriately sized Rod.

1. Precut Rods are available in the set or one of the longer Rods can be cut to fit the length of a longer construct using a table top rod cutter or large pin cutter style rod cutter.

2. The French Bender can be utilized to contour the Rods at multiple points. (Figure 20) Use the dial to select the bend radii: small, medium, or large. (Figure 21)

3. For minor bend adjustments, or Rod bending when the Rod is partially in the Screw construct, a set of In-situ (Figure 22) or Coronal Benders can be used.

   Notes: In-situ Benders are available for 5.5mm and 6.0 mm Rods. To avoid any notching in the Rod, be sure to use the In-situ Benders that are designed for the Rod diameter being used.

   Coronal Benders can be ordered by special request from Customer Service.

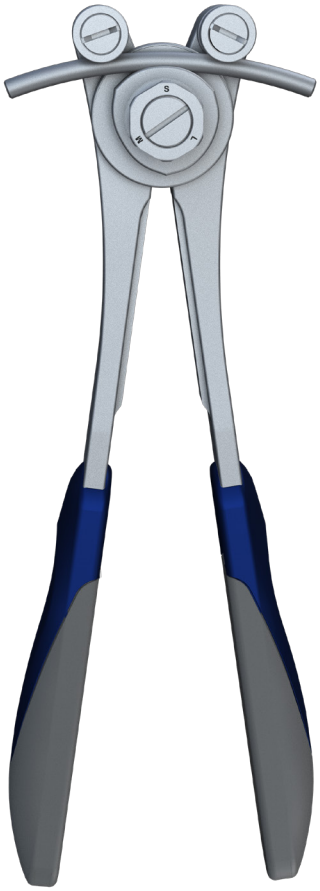


Figure 20. Rod Contouring French Bender

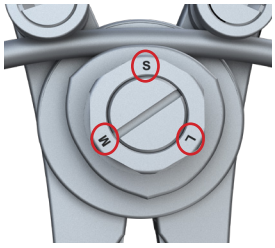


Figure 21. Dial For Bend Radii

Figure 22. Rod Contouring In-situ

ROD AND SET SCREW INSERTION

After choosing the appropriate size Rod or cutting the Rod to fit, place the Rod into the implants and provisionally tighten the Set Screws to secure the Rod. (Figure 23)

The system offers two types of Rod Holders. The first is an articulating Forceps Holder (Figure 24) that can be used to deliver the Rod into the Tulips. The second is a Rod Gripper (Figure 25) that can be used to clamp down on the Rod and manipulate it into place. The Rod Gripper can also be used if a Rod rotation maneuver is required.

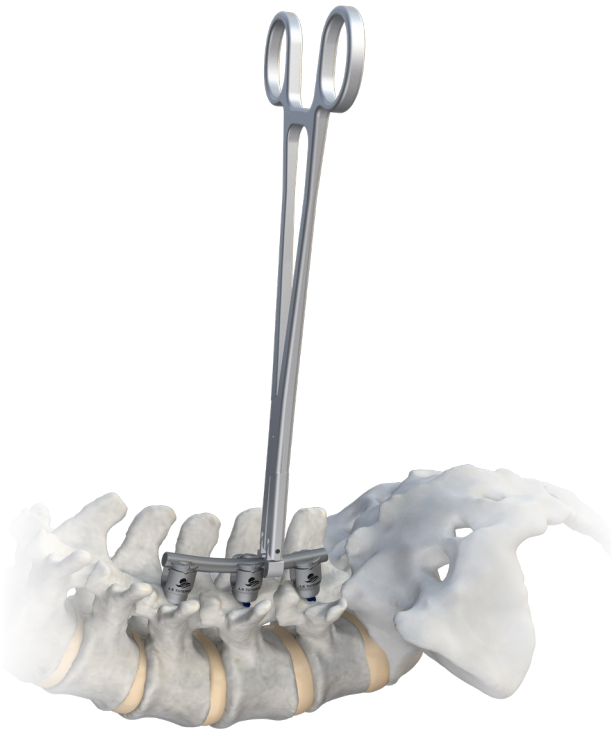


Figure 23. Place and Secure Rod

Figure 24. Forceps Holder

Figure 25. Rod Gripper

There are two styles of Set Screw Starters that can be used to deliver and provisionally tighten the Set Screws:

1. A self-retaining, Double-ended "stick-style" Set Screw Starter. (Figure 25)
2. A Locking Set Screw Starter with a solid retention feature to hold the Set Screw. (Figure 26)

When utilizing the Locking Set Screw Starter, insert the instrument into the Set Screw and rotate the proximal silver knob clockwise one-half turn. This will ensure the Set Screw is firmly engaged with the instrument and it can then be handed to the surgeon.

Note: Do not use either Set Screw Starter for final tightening as this may damage the instruments.

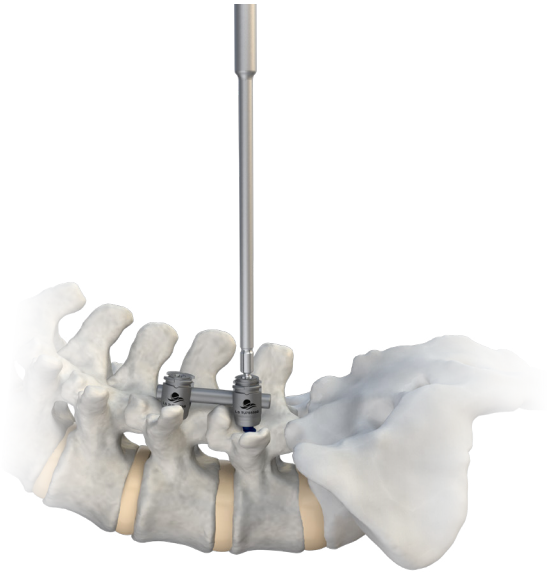


Figure 26. Double-ended Set Screw Starter

Figure 27. Locking Set Screw Starter

ROD REDUCTION

Multiple options are available depending on the amount of reduction that is needed.

Tower Reducer

The Tower Reducer should be used when the greatest amounts of reduction are required (up to 35mm).

1. Ensure the threaded reduction sleeve is retracted by turning it counterclockwise until sufficient space is available within the rod slot.

   Caution: The reduction sleeve must be retracted to the laser-marked "10mm" line to engage or disengage the Tulip. (Figure 28)

2. Capture the Rod within the rod slot of the Reducer and align the distal tip of the Reducer with the Tulip. Push down on the Reducer to engage the Tulip. The spring-loaded capture mechanism in the Reducer will allow the attachment feature to grab the Tulip with only a stab-and-grab movement from the surgeon. Verify proper engagement by pulling up on the Reducer.

3. Drive the Reducer down until the Rod bottoms out in the Tulip. (Figure 29)

   Note: There is a laser-marked line that reads "Down" when the Rod is fully reduced. (Figure 30)

Figure 28. 10mm Marker Line

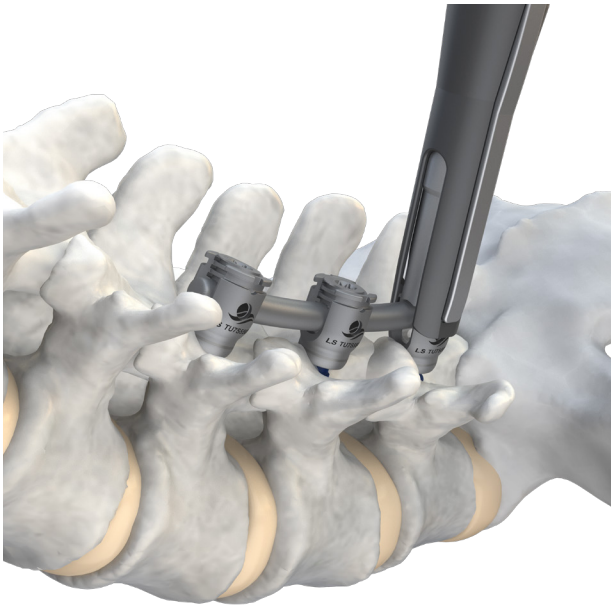


Figure 29. Reducer Seated On Tulip

Figure 30. Down Marker Line

Note: There are two options that can be utilized to drive down the Reducer.

4. The Reducer T-Handle (Figure 31) is recommended on short constructs where the turning of T-Handle will not come into contact with other instruments, such as additional Reduction Towers. The T-Handle is designed to have a Set Screw inserted through it without removing it from the Reducer. This will only work with the Double-ended Set Screw Starter.

5. If the construct requires reduction over multiple levels the Reducer Driver Adapter (Figure 32) is recommended and can be placed on a Ratcheting In-line Handle. (Figure 33) Using this method will minimize interference with adjacent Reducers.

6. Once reduction is achieved, insert the Set Screw using the preferred Set Screw Starter. Then remove the Reducer by first unthreading the reduction sleeve to the laser-marked "10mm" line and then depressing the medial/lateral tabs (Figure 34) located midway up the reducer body and pulling upward.

Note: If there is difficulty disengaging the Reducer it is recommended to loosen the tension an additional 10mm and then try a gentle, back-and-forth rotation movement while applying upward pressure.

Figure 31. Reducer T-Handle

Figure 32. Reducer Driver Adapter

Figure 33. Ratcheting In-line Handle & Adapter

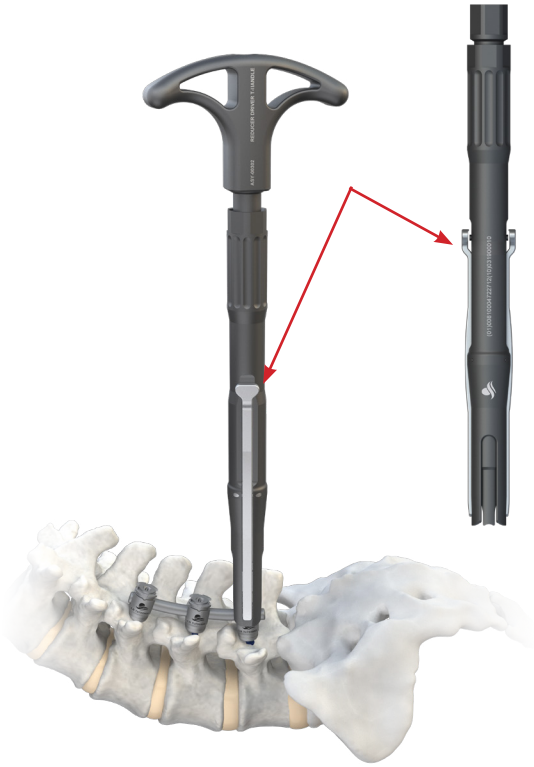


Figure 34. Depress Tabs

Pistol Grip Reducer

The Pistol Grip Reducer should be used when a moderate amount of reduction is required (less than 15mm).

1. Ensure that the handles are all the way open to allow the distal tangs of the Reducer to be in a position to capture the Tulip. (Figure 35)

2. Push down on the Reducer until the tangs of the instrument slide over the Tulip (Figure 36) then squeeze the handles until three audible clicks are heard. At this point the Reducer is fully engaged with the Tulip. Engagement can be confirmed by gently pulling up on the instrument.

3. Slowly squeeze on the handles until the Rod seats into the Tulip. (Figure 37) When the Rod is fully reduced, a Set Screw can then be delivered through the Reducer with either the Double-ended Set Screw Starter or the Locking Set Screw Starter.

4. The Reducer can be disengaged by fully releasing the ratchet and pulling up on the instrument.

Figure 35. Pistol Grip Reducer In Open Position

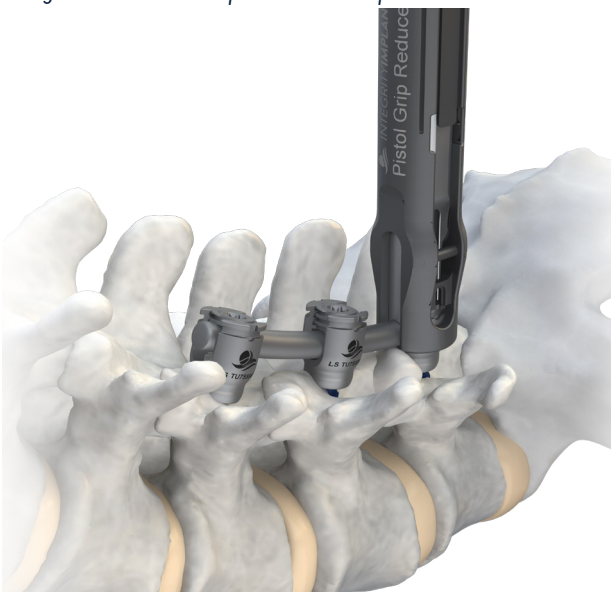


Figure 36. Reducer Fully Engaged

Figure 37. Squeeze and Seat the Rod

Rocker

The Rocker should be used when only a small amount of reduction is required (less than 9mm).

5. With the Rocker in an upright position, align the Rocker pins to the circular divot (red circle) features on the medial and lateral sides of the Tulip. (Figure 38)

6. Squeeze the handles until the Rocker securely grasps the Tulip. The ratchet arm on the Rocker can be used to hold compression of the handles so engagement of the Tulip can be maintained while reducing the Rod.

7. Rotate the Rocker downward to seat the keel onto the rod. Continue to rotate the Rocker until the Rod is fully seated in the Tulip.

8. Insert a Set Screw using the Set Screw Starter and then remove the Rocker by releasing the ratchet. (Figure 39)

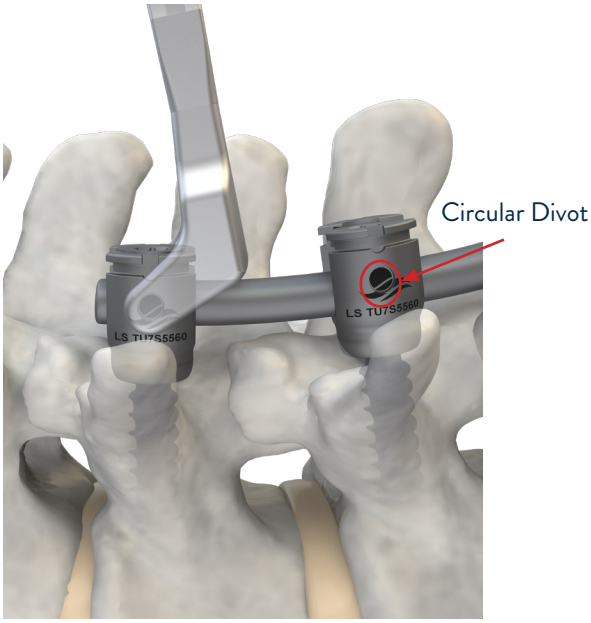


Figure 38. Rocker Aligned To Divot

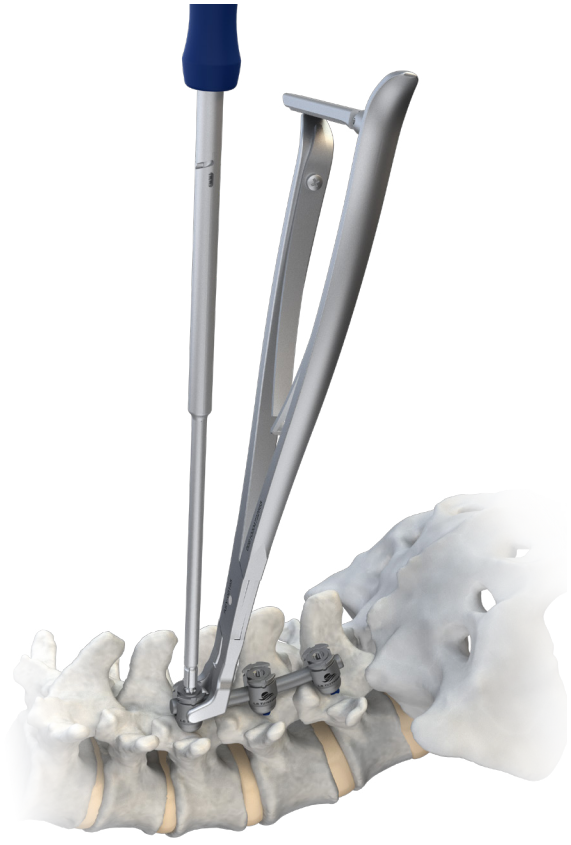


Figure 39. Set Screw Insertion

COMPRESSION & DISTRACTION

If compression or distraction is desired, provisionally tighten a Set Screw on one side of the motion segment, leaving the adjacent Set Screw loose to allow movement along the rod.

1. Choose the Compressor (Figure 40) or Distractor (Figure 41) and place over the Rod, against the Tulip Heads of the targeted Screws.

2. With the instrument properly engaged, deliver the desired level of compression or distraction. Provisionally tighten the loose Set Screw to hold the construct in position prior to final tightening.

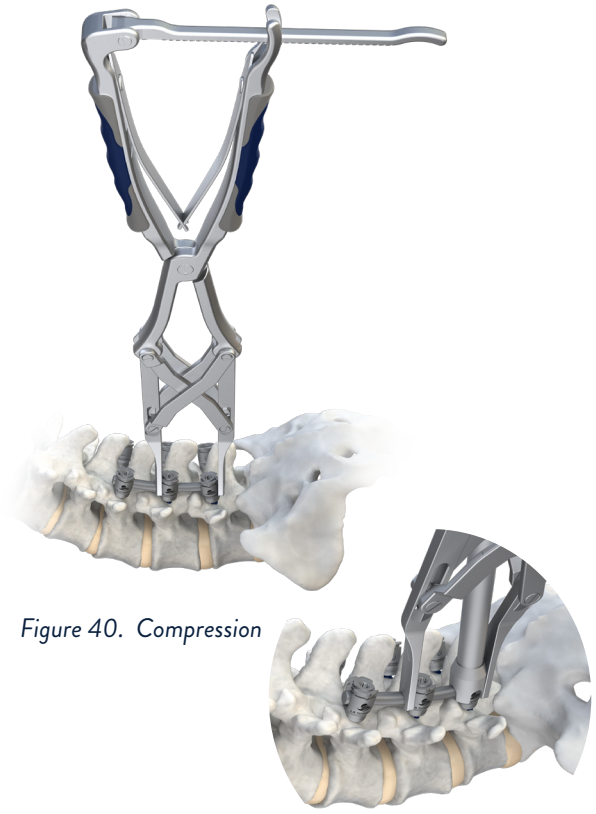


Figure 40. Compression

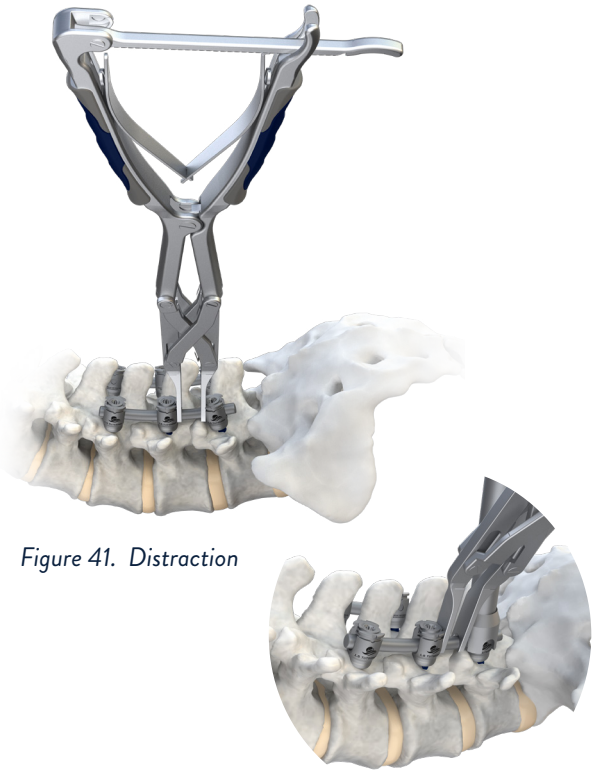


Figure 41. Distraction

FINAL TIGHTENING

All Set Screws must be tightened to a torque of 90 in-lbs. to ensure a secure construct.

Attach the Torque T-Handle to the Final Set Screw Driver. Slide the Counter-torque over the Tulip until the instrument bottoms out. Insert the Final Set Screw Driver through the Counter-torque and seat securely into the Set Screw. Turn the Torque T-Handle clockwise until the target torque is reached. This is indicated by one or more clicks of the Breakaway Torque T-Handle. Repeat on each Screw. (Figure 42)

Figure 42. Final Tightening

CROSSLINKS

A low-profile Crosslink is available.

1. To select the correct Crosslink, determine the distance between the Rods using the Crosslink Measuring Device. (Figure 43)

2. Using a finger insertion technique, place the Crosslink down on the Rods at the desired level until it is firmly seated and captures the Rods.

3. Using the Palm Crosslink Torque Limiting Handle and Crosslink Driver, tighten the Set Screws that lock the Crosslink to the Rod until the breakaway torque is reached. Then tighten the middle Set Screw that allows for translation of the Crosslink. (Figure 44)

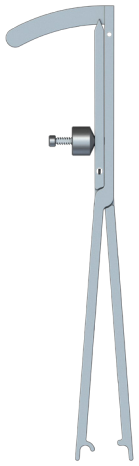


Figure 43. Crosslink Measuring Device

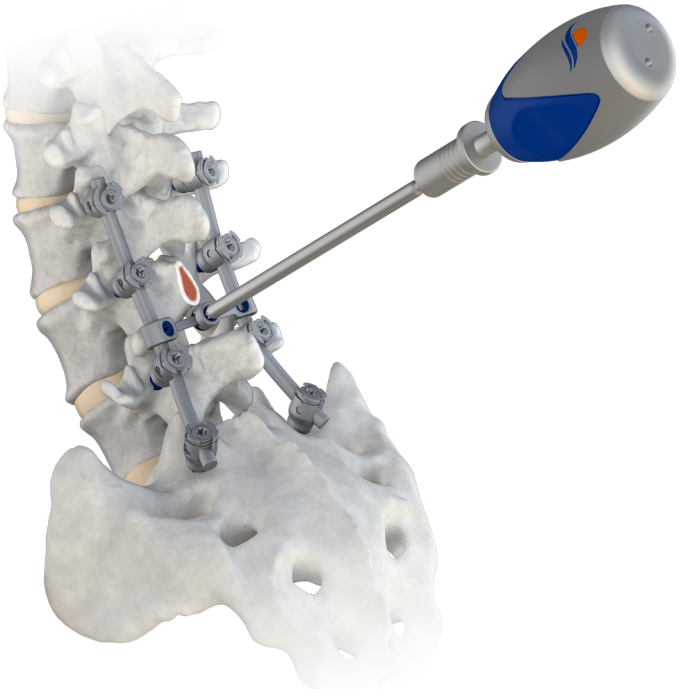


Figure 44. Tighten Crosslink Set Screws

REDUCTION SCREWS

1. Follow the pedicle preparation and insertion steps previously mentioned in this surgical technique guide.

2. With the Reduction Screws and Rod in place, slide the Counter-torque for the appropriate Tulip size over the Tulip until it seats flush on the Rod.

   Note: The Counter-torque is used to help drive the Rod downward while also preventing any splaying of the Reduction Tulip.

3. Using the Set Screw Starter, reduce the Rod by threading a Set Screw down the Reduction Tulip. Be sure to maintain downward force on the Counter-torque so the slot remains fully seated on the Rod during reduction. The Rod is fully reduced when the top of the Set Screw sits below the groove on the outside diameter of the Reduction Tulip.

4. When the Rod is fully reduced, remove the Counter-torque.

5. Place the Reduction Tulip Tab Breaker over one of the Tulip Tabs. Rock the Tab Breaker in a medial/lateral direction until it breaks free from the Tulip. Repeat this process with the opposite Tab. (Figure 45)

   Note: If the Tabs are broken off and the Set Screw is still partially proud of the Tulip, the Rocker can be utilized to apply downward pressure on the Rod so the Set Screw can be fully seated without resistance.

6. After all Reduction Tabs have been removed, final tighten each Screw utilizing the final tightening directions previously mentioned in this surgical technique on page 21.

   Caution: The Tower Reducer and Pistol Grip Reducer **cannot** be used with Reduction Screws. Only the Rocker is compatible with Reduction Screws.

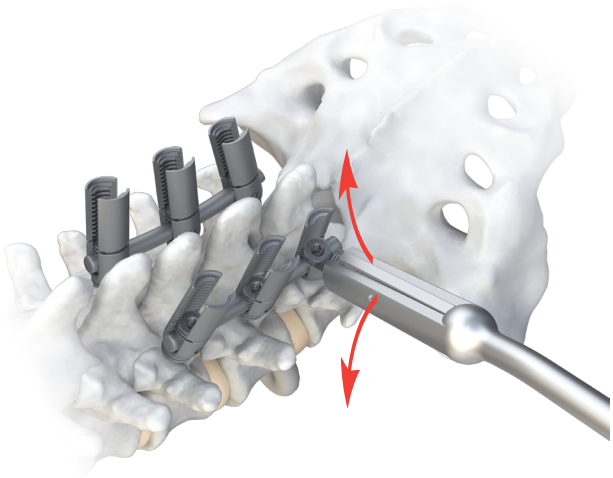


Figure 45. Medial/Lateral Rocking the Tab Breaker

4.5 & 5.0 Reduction Tulip

5.5 & 6.0 Reduction Tulip

ILIAC SCREWS

1. If iliac screw fixation is desired, expose the posterior superior iliac spine and decorticate the entry point using a burr or rongeur.

2. Use the Gear Shift to create a pilot hole, aiming for the thick bone just above the greater sciatic notch. Inspect the pilot hole for cortical wall violations using the Ball Tip Pedicle Probe.

3. Tap the pilot hole using the Iliac Taps located in the Iliac Instrument tray. The markings on the Tap shaft combined with fluoroscopy can be utilized to monitor depth. Re-inspect the pilot hole for perforations.

4. With the ilium prepared, select the Iliac Screw in the appropriate size.

5. Insert the Iliac Screw into the pilot hole and advance until the desired depth is reached. If Screw adjustment is needed, use the Stab-and-Grab Driver or the Set Screw Final Driver to adjust. (Figure 46)

   Note: A Straight or Curved Duck Bill Gear Shift located in the General Open Instrument Tray is the suggested gear shift for creating a pilot hole for Iliac Screws.

   Note: The Iliac Taps have a different thread pattern than the standard Taps. The single lead pattern aligns them with the Iliac Screws and therefore should only be utilized when tapping the ilium.

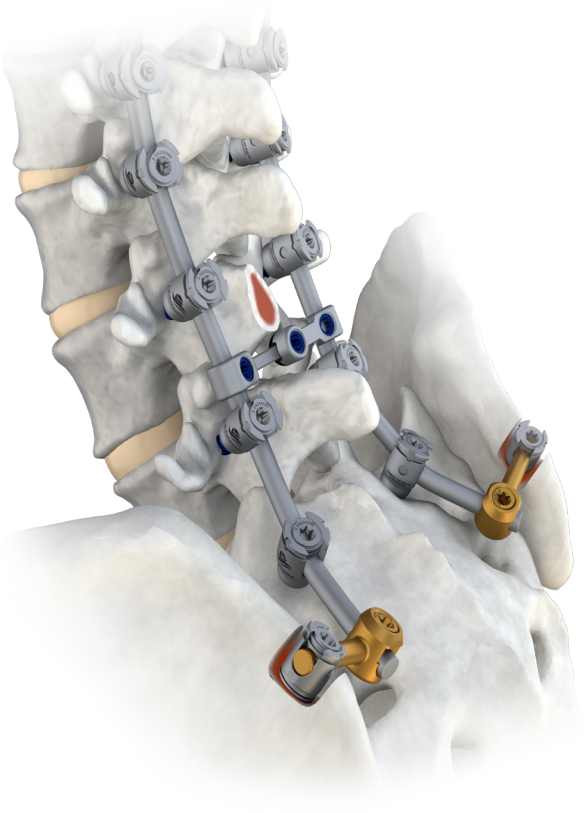


Figure 46. Final Construct With Iliac Screws and Offset Connectors

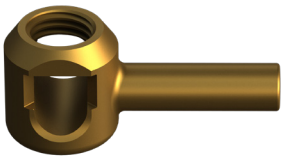
Offset Iliac Connectors

An Offset Connector may be used to connect the Iliac Screw to the Rod.

1. Determine the offset length required and use the Rod Holder to insert the shaft of the preferred Connector into the rod slot of the Iliac Screw.

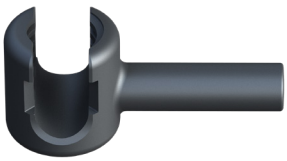
2. To hold the Offset Connector in position, insert the appropriate Set Screw into the Tulip of the Iliac Screw using the Set Screw Starter and provisionally tighten the Set Screw.

3. Attach the Torque T-Handle to the Final Set Screw Driver. Slide the Counter-torque over the Tulip or Offset Connector until the instrument bottoms out. Insert the Final Set Screw Driver through the Counter-torque and seat securely into the Set Screw. Turn the Torque T-Handle clockwise until the target torque is reached. Repeat on each Screw or Offset Connector.



5.5 & 6.0 Closed Offset Connector

5.5 & 6.0 Closed Set Screw



5.5 & 6.0 Offset Connector

5.5 & 6.0 Set Screw

LINESIDER®

MIS SURGICAL TECHNIQUE

Place the patient in a prone position on the desired surgical table. (Figure 47) Prepare and drape in a conventional manner. The fluoroscope should have easy access to the surgical field for both A/P and lateral views. Uniplanar or biplanar fluoroscopy may be used.

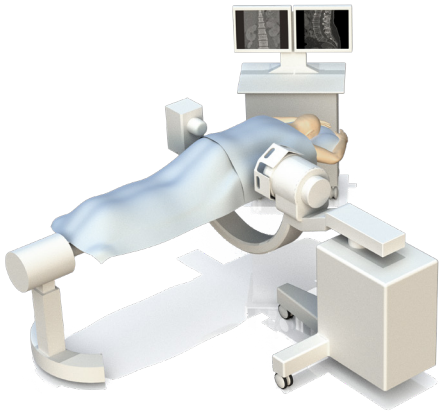


Figure 47. Prone Positioning

TARGETING & ACCESSING PEDICLES

Targeting

1. Using A/P fluoroscopy, place a K-wire longitudinally along the lateral margins of the targeted pedicle.

2. Move the K-wire laterally 1-3cm, depending on the size of the patient, and mark the skin along the K-wire.

3. Place the K-wire perpendicular to the longitudinal line over the center of the pedicle and mark the skin. The intersection of the two lines represents the skin incision location and entry point for a Jamshidi needle. (Figure 48.)

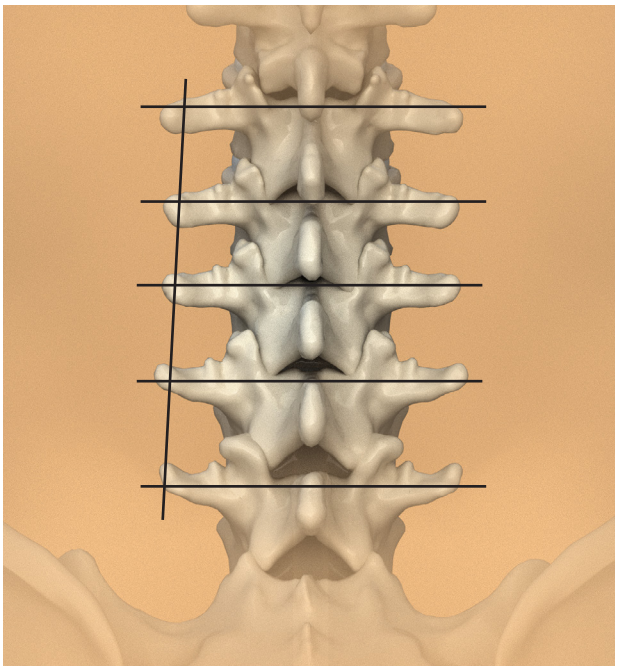


Figure 48. MIS Targeting and Marking

Accessing Pedicles

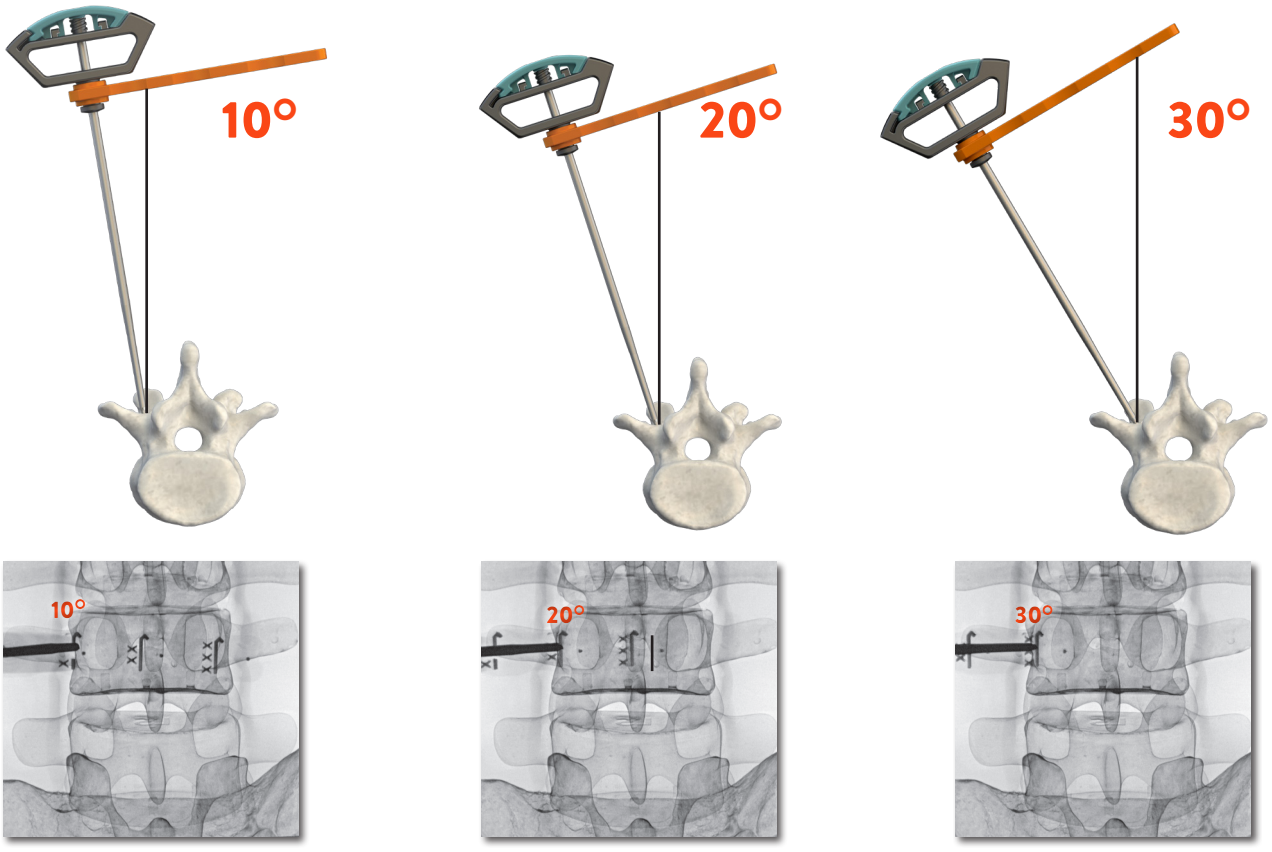
1. Make a 2cm skin incision at the intersection of the two previously drawn lines.

2. Attach the SightLine™ Radiographic Template to the Access Needle. (Figure 49.)

3. Advance the Access Needle down to the transition of the transverse process and facet joint.

   Note: Utilizing the Jamshidi supplied by Integrity Implants with SightLine attached assists the surgeon with their trajectory to the desired angle.

Figure 49. SightLine Orientation



4. Using A/P fluoroscopy, verify the Needle is positioned slightly superior and lateral to the center of the pedicle.

5. Insert the tip of the Needle a few millimeters into the bone to secure its position. Prior to advancing into the pedicle, use lateral fluoroscopy to verify that the trajectory will follow the desired path through the pedicle.

6. With an oblique trajectory, advance the Needle into the pedicle. Continue to pass the Needle into the vertebral body, using fluoroscopy for guidance.

7. Remove the Access Needle Stylette and introduce a K-wire through the cannulation, leaving approximately 1cm of the K-wire extending into the vertebral body.

8. Remove the Needle's outer sheath, leaving the K-wire in position.

9. If advancement or removal of the K-wire is desired the K-wire Driver can be utilized. Begin by opening the inner cannulation of the K-wire Driver by depressing the lever on the body of the Driver and introducing the Driver over the K-wire. (Figure 50.)

10. Once the desired position on the K-wire is reached, release the lever to secure the Driver in position.

11. Use the integrated slap hammer to either advance, retract, or remove the K-wire, using lateral fluoroscopy to monitor depth.

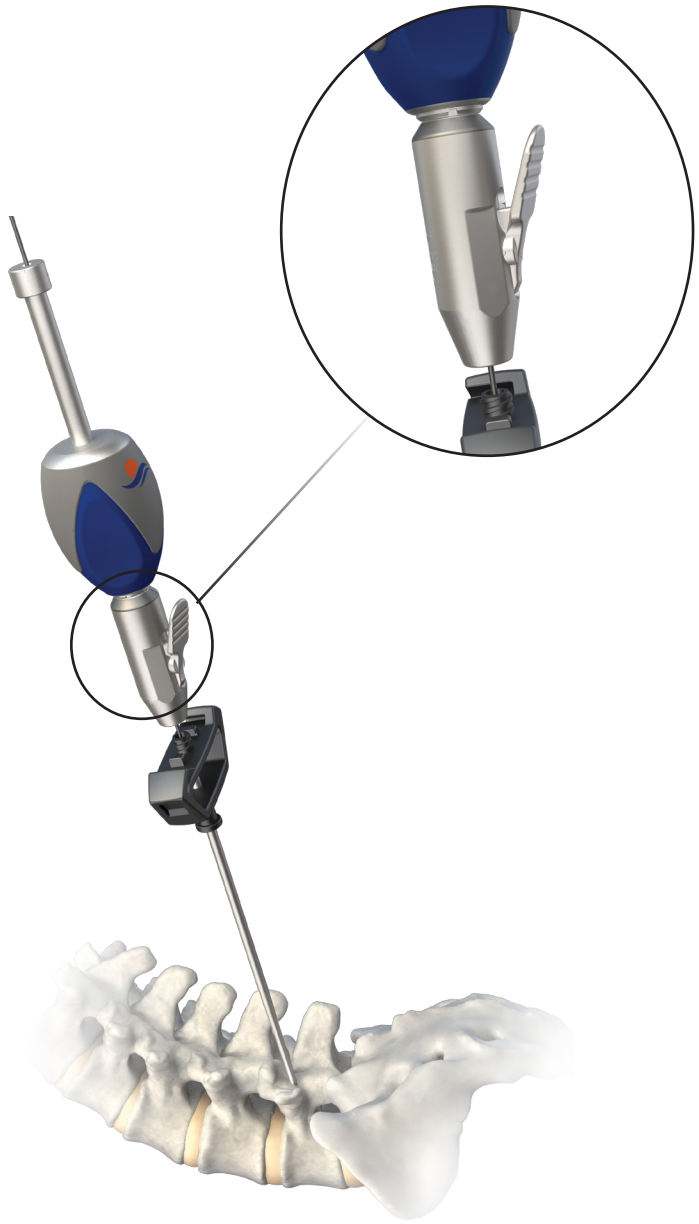


Figure 50. K-wire Driver

SCREW ASSEMBLY

1. Select the desired Pedicle Screw Shank and remove it from the Shank Caddy. Insert it into the Loading Block (located in the Implant Tray) with the ball end facing up.

2. Load the MIS Tulip on the MIS Tulip Inserter by sliding the instrument into the Tulip until the proximal end of the Tulip is recessed into the Inserter. Next, turn the handle clockwise while holding the Tulip and housing until the instrument is fully seated. (Figure 51.)

3. Place the Tulip over the Shank and apply firm downward pressure. When the Tulip is fully seated, the gold button on the Inserter Shaft will be at the height of the laser marked ring on the Inserter. (Figure 52) &(Figure 53)

4. Before the Tulip is removed from the Tulip Inserter it is recommended that a 360° polyaxial motion be made to the Tulip Inserter while maintaining a downward force. (Figure 54) A final gentle tug on the Tulip Inserter will confirm the assembly.

5. Once the Tulip and Shank are assembled, select the Polyaxial Screwdriver. Attach the ratcheting handle of choice to the Screwdriver.

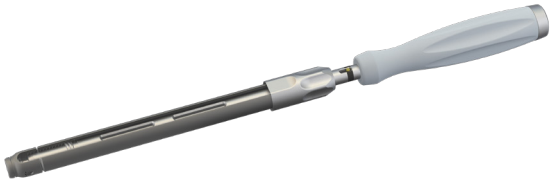


Figure 51. Inserter Threaded Into Tulip

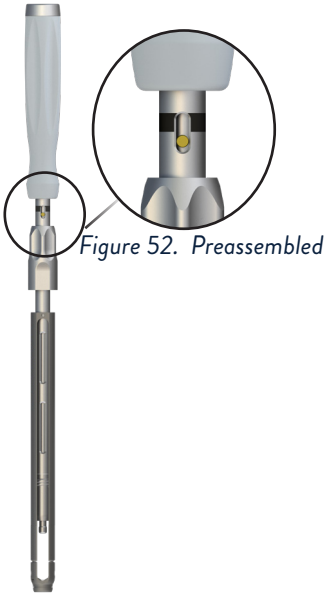


Figure 52. Preassembled

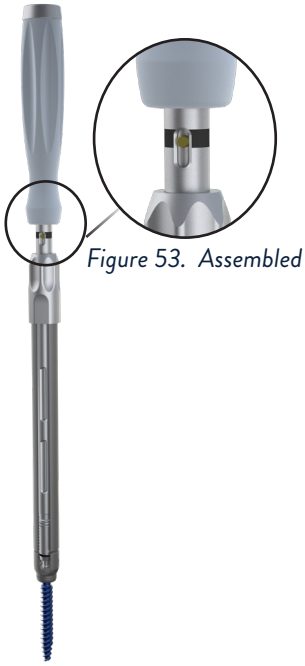


Figure 53. Assembled

Figure 54. Polyaxial Motion

SCREW INSERTION

1. Introduce the First Dilator over the K-wire and advance to the pedicle. (Figure 55)

   Note: When the Dilator is fully advanced the window on the Dilator can be used in conjunction with the mark on the K-wire to know how far the K-wire has been advanced and thus give the surgeon an indicator for Screw length.

2. Sequentially dilate with the Second Dilator and Third Dilator, ensuring all Dilators are fully seated onto bone. (Figure 56)

   Note: The Second and Third Dilators act as sheaths and prevent shunting if the surgeon chooses to stimulate the Tap or the Screw.

   Note: The Second and Third dilators are rifled to ease insertion. It is recommended that the surgeon turn with a slight clockwise twisting motion when inserting them into the incision.

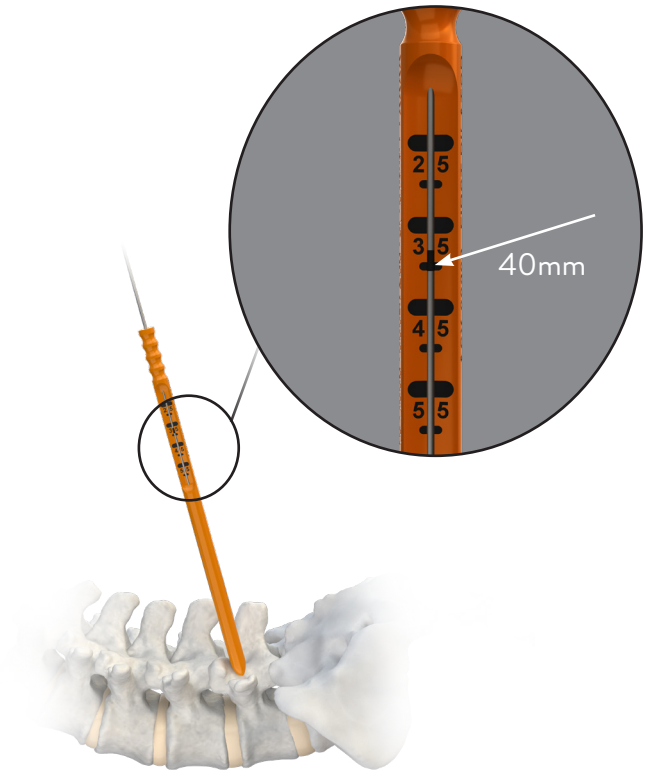


Figure 55. First Dilator

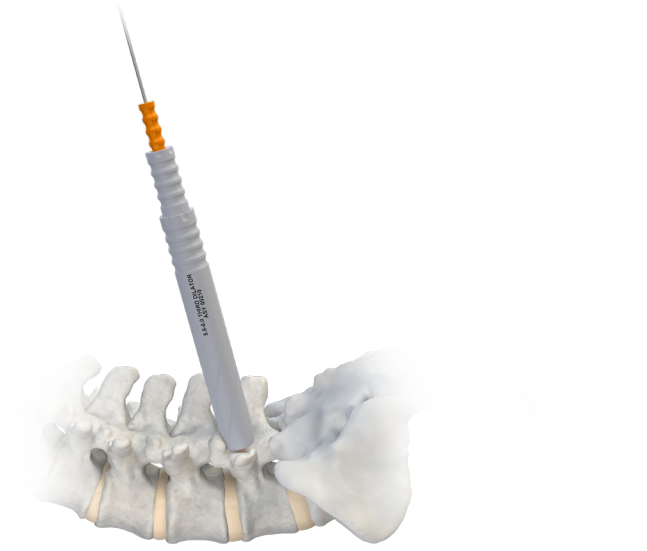


Figure 56. Second and Third Dilators

3. Remove the First Dilator, leaving the K-wire, Second Dilator, and Third Dilator in position. At this point the appropriately sized cannulated Tap can be attached to the desired Ratcheting Handle and inserted over the K-wire to create a pathway for the Screw. (Figure 57)

4. Using the LineSider Polyaxial Screwdriver, the desired Screw Shank with an MIS Tulip can be loaded onto the Driver.

   Note: Prior to loading the Screw on to the Screwdriver, the Screwdriver must be placed in reduction mode. This is accomplished by pressing the button on the knurled knob and translating the shaft back towards the handle.

5. Slide the Screwdriver down the slot of the MIS Tulip and engage the hexalobe feature of the Screw. Once engagement is confirmed, thread the Screwdriver into the Tulip using the knob at the proximal end of the Screwdriver.

   Note: LineSider Screws are self-tapping and do not require a Tap. However, if tapping is desired, use the top of the Second Dilator as a reference point to monitor the depth of the desired cannulated Tap. To ensure correct reading, the Second Dilator must be fully seated on the bone. (Figure 58)

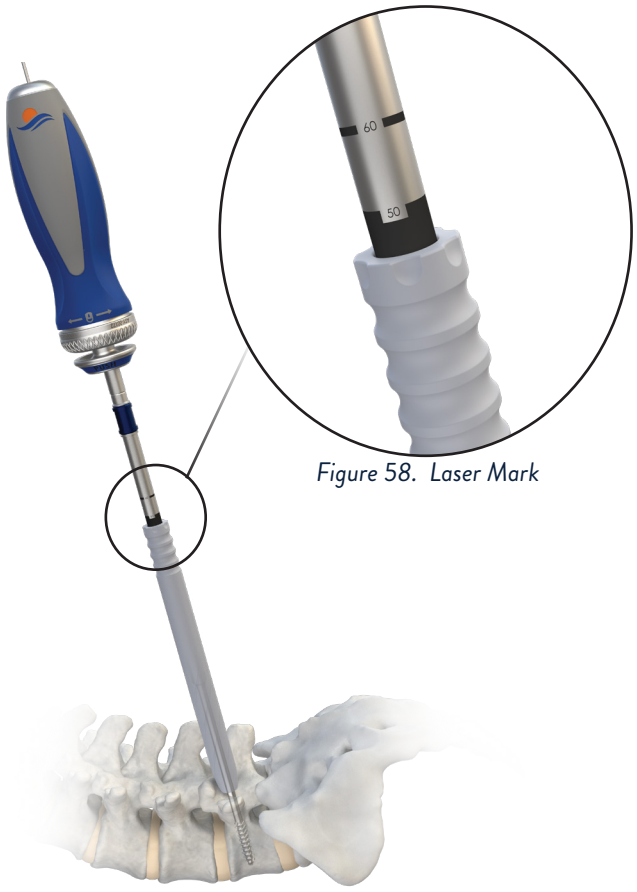


Figure 58. Laser Mark

Figure 57. Tap Within Dilator

6. After tapping, or before Screw insertion without tapping, remove the Second Dilator leaving only the outermost Third Dilator in place.

7. The assembled Screw can now be inserted in the prepared pedicle. (Figure 59)

8. Advance the Screw until the distal tip of the Screw reaches the posterior wall of the vertebral body.

9. Remove the K-wire and then continue to advance the Screw to the desired depth.

10. Remove the Screwdriver from the Screw and move the Tulip in an orbital motion to ensure the Screw is not driven too far down.

Note: If micro-adjustments need to be made the Set Screw Final Driver can be utilized.

Figure 59. MIS Screwdriver

ROD MEASUREMENT

1. Insert the arms of the MIS Rod Length Indicator into the proximal ends of the inferior and superior Tulips and advance the arms down into the Tulip. (Figure 60)

2. Full seating of the MIS Rod Length Indicator occurs when the laser-marked lines at the top of the arms align with the top of both Tulips. (Figure 61)

Note: It may be necessary to angle the MIS Rod Length Indicator cephalad or caudal to fully seat the distal end of the measurement tool into the Screws.

Note: The displayed measurement indicates the distance between the Screw Shanks (Figure 62) ; therefore, it is necessary for the surgeon to add length to the Rod size to facilitate the necessary Rod overhang. Use 5–10mm on one & two level constructs and 10–20mm on constructs of three levels and above. If the measurement taken on the MIS Rod Length Indicator is in between sizes always round up and then add the necessary length.

Caution: The bulleted portion of the nose of the Rod must extend fully outside the Tulip capturing that end of the Rod. The same applies to the section of the Rod with the Rod Inserter capture feature. It must extend outside the Tulip that it's nearest to and not be factored into the overhang because it does not provide the necessary fixation surface. (Figure 63)

Note: If the construct spans multiple levels (usually four or higher), it may be necessary to calculate Rod length with two measurements. For example: If the construct spans from L2–S1 then measure between L2–L4 & L4–S1 and add the measurements to get the total Rod length.

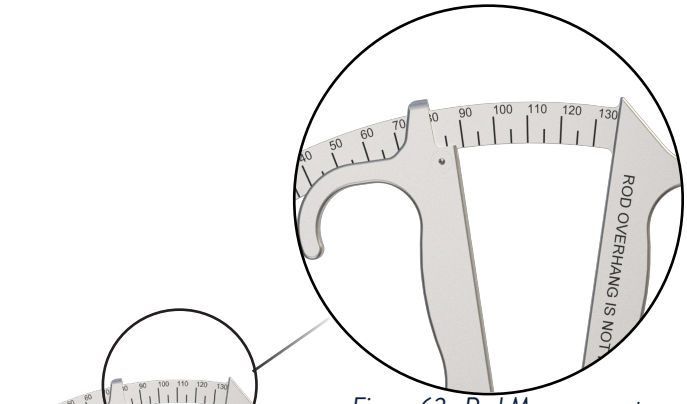


Figure 62. Rod Measurement

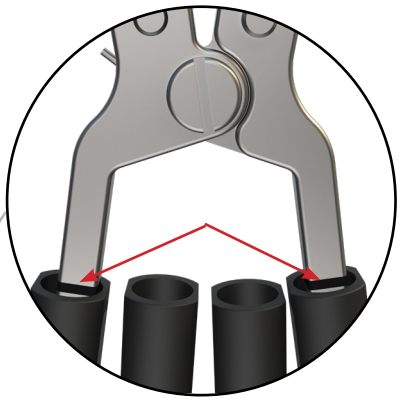


Figure 61. Laser Mark

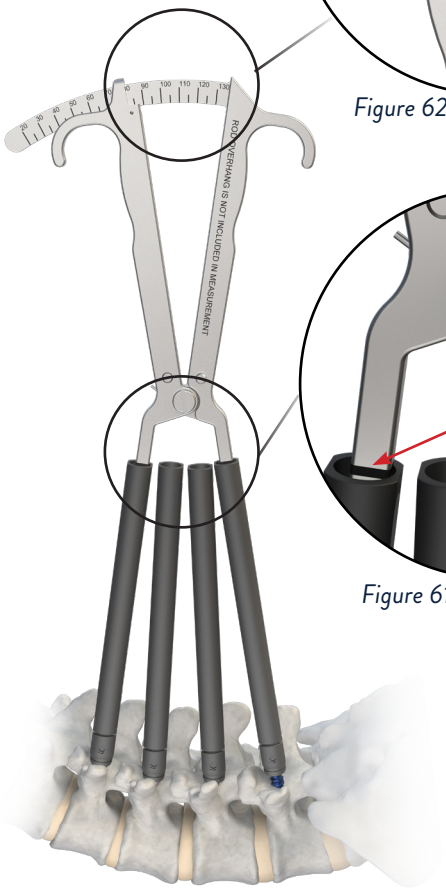


Figure 60. MIS Rod Length Indicator

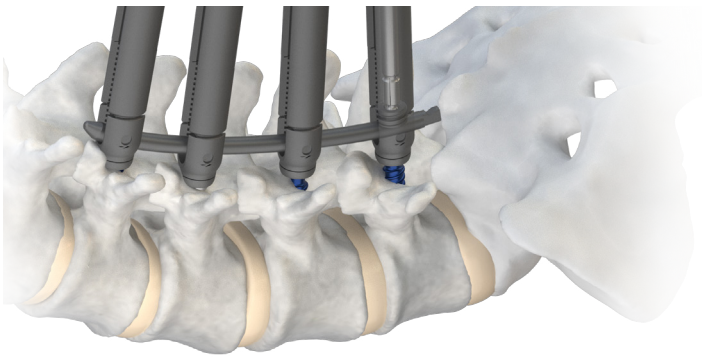


Figure 63. Rod Overhang

ROD INSERTION

Align the rod slot of the MIS Tulips along the Rod pathway by utilizing the Tulip Adjuster. If desired, clear a pathway through the muscle and fascia between the Tulips by using the Fascia Splitter.

1. Place the squared end of the rod into the distal tip of the Fixed Rod Inserter. (Figure 64)

   Note: When loading the Rod in the Fixed Rod Inserter, it is important to load it with the V-groove on the Rod Inserter Capture Feature facing up towards the inserter.

2. Engage the MIS Rod Inserter Locking Driver onto the hexalobe on the proximal end of the MIS Rod Inserter.

3. Turn the Rod Inserter Locking Driver clockwise to engage and lock the Rod to the Fixed Rod Inserter. (Figure 65)

4. Insert the Rod into the incision from either the cephalad or caudal end of the construct and seat the Rod into the Screws by applying an even amount of downward force throughout the Rod.

   Note: On multilevel constructs, before Set Screw insertion, it is recommended to confirm that the Rod has passed through each Tulip by gently trying to rotate each Tulip with the MIS Tulip Adjuster. (Figure 66) If a Tulip was missed, the Tulip retains its polyaxial motion and can spin.

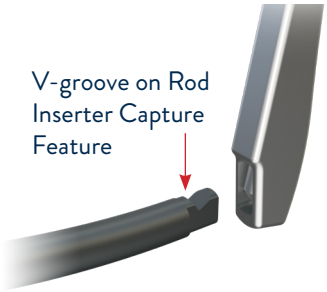


Figure 64. Square Rod Tip

Figure 65. Rod Inserter Engaged

Figure 66. MIS Tulip Adjuster

5. To disengage the rod from the inserter, engage the Rod Inserter Set Screw Driver onto the hexalobe on the proximal end of the Rod Inserter and turn counterclockwise.

   Note: It may be necessary to make fine adjustments to the angle and rotation of the MIS Tulips and Fixed Rod Inserter during Rod passage to accommodate variances in medial/lateral Screw alignment. This adjustment can be made gently by hand or with the Tulip Adjuster.

   Note: The Top Breaker can be utilized to break the top of the Tulip so a Rod can be delivered down or manipulated down the length of the Tulip if there is challenging pathology. (Figure 67)

Figure 67. MIS Top Breaker

SET SCREW INSERTION

1. Before engaging the Set Screw, ensure the knob on the Locking Set Screw Starter is in the unlocked position.

2. With the Set Screw in the caddy, engage the Locking Set Screw Starter into the Set Screw. Rotate the proximal knob clockwise to expand the hexalobe tip and retain the Set Screw. (Figure 68)

3. Deliver the Set Screws through the Tulips until they engage with the thread and then provisionally tighten until the Rod is fully seated in the saddle of the Screw. (Figure 69)

4. To release the Set Screw, turn the knob counterclockwise and remove the Locking Screw Starter from the Set Screw by pulling up.

   Note: The Set Screw is fully seated when the black line on the Locking Set Screw Starter is in line with the top of the MIS Tulip.

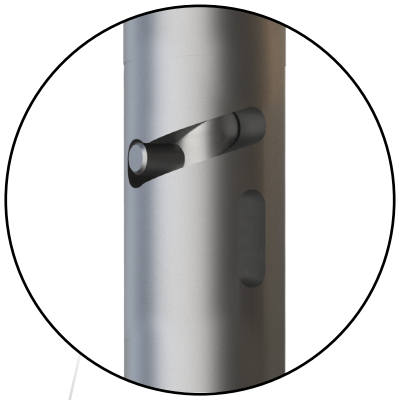


Figure 68. Locked Position

Figure 69. Locking Set Screw Starter

COMPRESSION / DISTRACTION

1. Before compressing or distracting, make sure that one of the Set Screws on the segment that is being manipulated is locked down. The other Set Screw in the segment should be free to allow the Rod to move inside the Tulip.

   Note: Place the "tower holder" on the Tulip that is on the side of the segment that has been locked down. (Figure 70)

2. Before compression or distraction can be applied to a segment it is necessary to engage the MIS Tulip Sleeves (Figure 71) over the MIS Tulips. The Sleeves will help protect the Tulips and assist in preventing them from deforming or prematurely breaking off.

   Note: The MIS Tulip Sleeves have a slot cut out at the distal end to accommodate for the rods. In order for the Sleeves to protect the Tulip it is important that the Sleeves be fully seated on the Tulip.

3. Prior to engaging the Compressor and Distractor it will be necessary to select the MIS Compressor / Distractor Pivot Block that is best suited for the segment being manipulated. (Figure 72) Based on the distance between the Tulips, the Blocks are available in 20mm, 30mm, and 45mm lengths. The Pivot Block will be assembled onto the MIS Compressor / Distractor and act as the fulcrum between the two MIS Tulips that are being distracted or compressed. The greater the distance between the two MIS Tulips the larger the MIS Compressor / Distractor Pivot Block that will be necessary. (Figure 73)

   Note: If the Distance between the Tulips is less than 20mm the Compressor / Distractor can be used with no additional Pivot Block.

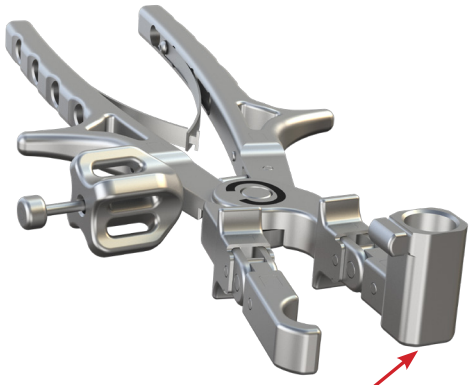


Figure 70. Tower Holder (red arrow)

Figure 71. MIS Tulip Sleeve

Figure 72. Pivot Blocks

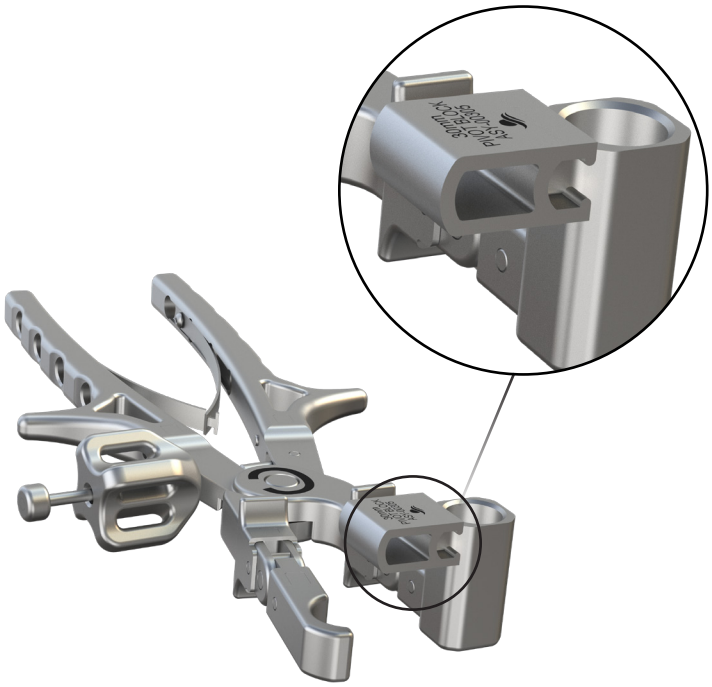


Figure 73. Compressor and Attached Pivot Block

4. Engage the Compressor / Distractor with the Tulips and push the instrument down until the lowest portion of the instrument is touching the skin.

   Note: The Compressor / Distractor is marked with a "C" and a "D". Whichever letter is facing up, or towards the surgeon, represents what the instrument will do when the handles are squeezed together.

5. Squeeze the handles until the desired compression or distraction is delivered. (Figure 74) & (Figure 75)

   Note: The speed nut on the side of the instrument can be utilized to hold distraction or compression until a Set Screw can be delivered into the Tulip that was left open.

6. Utilizing the Locking Set Screw Starter, engage a Set Screw on the side that was left open and deliver it until it is provisionally tightened, holding the compression or distraction in place.

   Note: If final tightening is desired at this point the Counter Torque can be placed on the MIS Tulip Sleeve and the Set Screw can be tightened to the targeted torque using the Torque Limiting T-Handle and the Set Screw Final Driver.

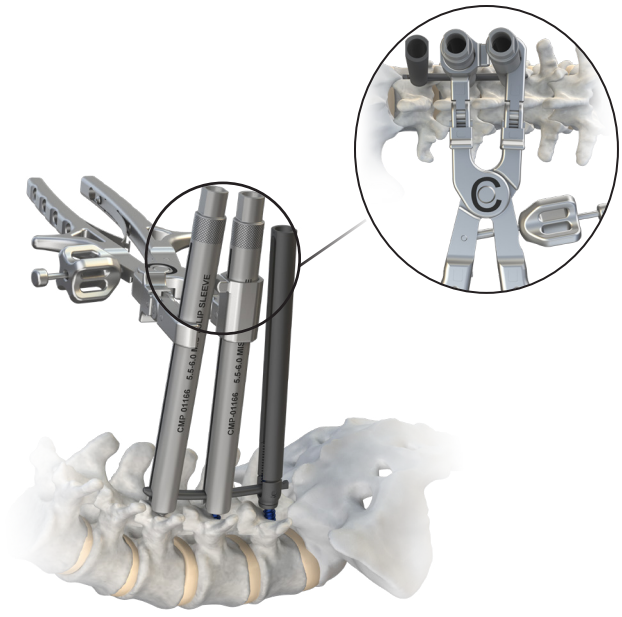


Figure 74. Squeezing of Compressor

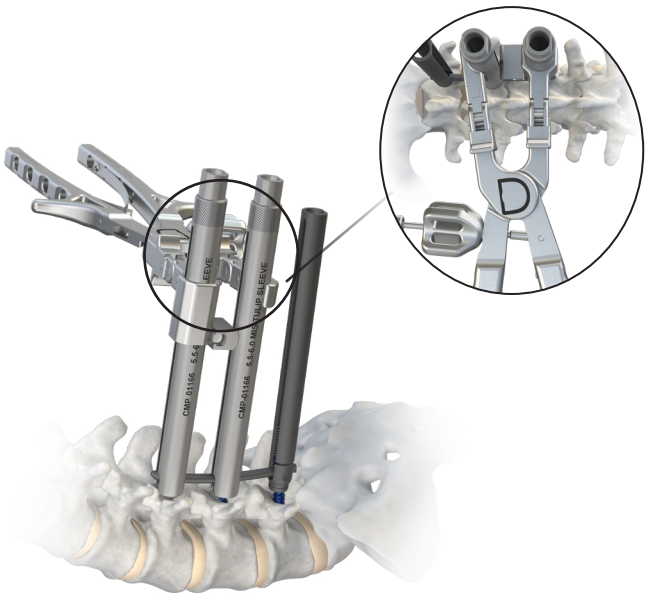


Figure 75. Squeezing of Distractor

FINAL TIGHTENING

1. Engage the Torque Limiting T-handle with the Set Screw Final Driver and slide the assembled driver through the MIS Counter Torque.

2. Engage the MIS Counter Torque on to the top of the Tulip. The Counter Torque keeps the Tulip rigid for final tightening. (Figure 76)

3. Turn the Torque T-Handle clockwise until the targeted torque is reached. This is indicated by one or more clicks of the Breakaway Torque T-Handle.

4. Repeat this step with each Screw.

Figure 76. MIS Final Driver and Counter Torque

BREAK AWAY EXTENDED TABS

Note: Make sure the Set Screw is fully seated and the full reduction of the Rod has been completed before breaking away the tabs on the Tulip.

1. Slide the MIS Tab Breaker down into the Tulip until it bottoms out and sits on the Set Screw, then rotate in a clockwise direction until each tab has broken away. (Figure 77)

2. Alternatively, the Top Breaker can be used to break the top of the tabs on the Tulip. The tabs can then be toggled in a medial/lateral direction and broken at the slotted breakpoint.

3. Remove both tabs and discard.

4. Repeat this step for each Screw.

Caution: Be careful when palpating the construct after breaking the Tulip tabs. The top of the Tulips may be sharp.

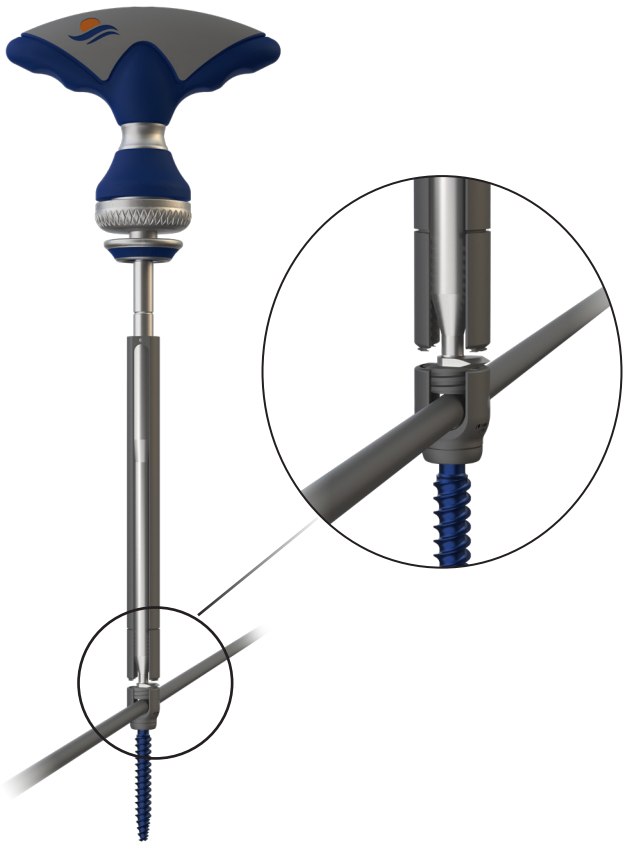


Figure 77. MIS Tab Breaker

LINESIDER®

TRAY CONFIGURATIONS & PART NUMBERS

GENERAL **INSTRUMENT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00347	LineSider General Instrument Tray	1
ASY-00190	Rod Pusher	1
ASY-00180	French Bender	1
ASY-00171	T-Handle - Ratcheting (Cannulated)	2
ASY-00172	Straight Handle - Ratcheting (Cannulated)	2
ASY-00037	Shank Driver for Modular Screws T25	2
ASY-00238	Decorticator for Screw Shank	1
ASY-00199	Locking Set Screw Starter	2
ASY-00174	T-Handle Torque Limiting	1

OPEN **INSTRUMENT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00260	LineSider Open Instrument Tray	1
ASY-00162	Pedicle Probe Straight	1
ASY-00163	Pedicle Probe Curved	1
ASY-00166	Pedicle Probe Double Ended	1
ASY-00167	Gear Shift Lenke Curved	1
ASY-00168	Gear Shift Lenke Straight	1
ASY-00169	Gear Shift Duck Bill Curved	1
ASY-00170	Gear Shift Duck Bill Straight	1
ASY-00177	Awl	1
ASY-00228	4.5mm Dual Lead Tap	1
ASY-00229	5.5mm Dual Lead Tap	1
ASY-00230	6.5mm Dual Lead Tap	1
ASY-00231	7.5mm Dual Lead Tap	1
ASY-00232	8.5mm Dual Lead Tap	1
CMP-00159	Set Screw Starters - Double-ended T25	2
ASY-00218	Breakaway Tool for Reduction Tulip Tabs	1
ASY-00178	Compressor (Assembled Screw)	1
ASY-00179	Distractor (Assembled Screw)	1
ASY-00173	Palm Handle Torque Limiting for Crosslink	1
ASY-00198	Crosslink Driver Shaft (AO Connection)	1
ASY-00266	Crosslink Measuring Device	1
ASY-00164	Rod Gripper (Dual Action) 5.0 -- 6.0mm Rod	1
CMP-00267	Reducer Driver Adapter	1
ASY-00302	Reducer T-Handle	1
ASY-00136	Rod Holder 5.0 - 6.0mm Rod	1
ASY-00197	Tulip Adjuster	1

5.5 - 6.0MM **INSTRUMENT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00259	LineSider 5.5 - 6.0 Instrument Tray	1
ASY-00202	Poly Screwdriver 5.5/6.0mm Tulip	2
ASY-00203	5.5/6.0 Polyaxial Screwdriver Sleeve	2
ASY-00304	Stab-and-Grab Driver 5.5 - 6.0 Tulip	2
ASY-00267	In-Situ Benders 5.5 mm Rod - Left	1
ASY-00268	In-Situ Benders 5.5 mm Rod - Right	1
ASY-00194	Counter-torque 5.5 mm Rod	1
ASY-00375	Open Set Screw Final Driver	2
ASY-00205	Pistol Grip Reducer 5.5 - 6.0 Tulip	1
ASY-00206	Tower Reducer 5.5 - 6.0 Tulip	2
ASY-00195	Rod Fork/Rocker 5.5 - 6.0 mm Tulip	1
ASY-00239	Tulip Inserter 5.5 - 6.0	2
ASY-00379	Tapered Set Screw Starter	1

5.5 - 6.0MM **IMPLANT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00258	LineSider 5.5 - 6.0 Implant Tray	1
LS-SC7G5535	Cannulated Screw, Dual Lead, 5.5mm x 35mm	4
LS-SC7G5540	Cannulated Screw, Dual Lead, 5.5mm x 40mm	4
LS-SC7G5545	Cannulated Screw, Dual Lead, 5.5mm x 45mm	6
LS-SC7G5550	Cannulated Screw, Dual Lead, 5.5mm x 50mm	4
LS-SC7G5555	Cannulated Screw, Dual Lead, 5.5mm x 55mm	2
LS-SC7G6535	Cannulated Screw, Dual Lead, 6.5mm x 35mm	4
LS-SC7G6540	Cannulated Screw, Dual Lead, 6.5mm x 40mm	8
LS-SC7G6545	Cannulated Screw, Dual Lead, 6.5mm x 45mm	8
LS-SC7G6550	Cannulated Screw, Dual Lead, 6.5mm x 50mm	8
LS-SC7G6555	Cannulated Screw, Dual Lead, 6.5mm x 55mm	8
LS-SC7G6560	Cannulated Screw, Dual Lead, 6.5mm x 60mm	2
LS-SC7G7535	Cannulated Screw, Dual Lead, 7.5mm x 35mm	4
LS-SC7G7540	Cannulated Screw, Dual Lead, 7.5mm x 40mm	6
LS-SC7G7545	Cannulated Screw, Dual Lead, 7.5mm x 45mm	6
LS-SC7G7550	Cannulated Screw, Dual Lead, 7.5mm x 50mm	6
LS-SC7G7555	Cannulated Screw, Dual Lead, 7.5mm x 55mm	4
LS-SC7G7560	Cannulated Screw, Dual Lead, 7.5mm x 60mm	2
LS-SC7G8535	Cannulated Screw, Dual Lead, 8.5mm x 35mm	2
LS-SC7G8540	Cannulated Screw, Dual Lead, 8.5mm x 40mm	4
LS-SC7G8545	Cannulated Screw, Dual Lead, 8.5mm x 45mm	4
LS-SC7G8550	Cannulated Screw, Dual Lead, 8.5mm x 50mm	4
LS-SC7G8555	Cannulated Screw, Dual Lead, 8.5mm x 55mm	4
LS-SC7G8560	Cannulated Screw, Dual Lead, 8.5mm x 60mm	2

5.5 - 6.0MM **IMPLANT TRAY (CONT.)**

Part Numbers	Description	Quantity Per Tray
LS-SS255560	Set Screw 5.5/6.0	20
LS-TU7S5560	Standard Tulip 5.5/6.0	16
LS-TU7R5560	Reduction Tulip 5.5/6.0	6
LS-RD55B030	Ti Curved Rod, 5.5x30mm	3
LS-RD55B035	Ti Curved Rod, 5.5x35mm	3
LS-RD55B040	Ti Curved Rod, 5.5x40mm	3
LS-RD55B045	Ti Curved Rod, 5.5x45mm	3
LS-RD55B050	Ti Curved Rod, 5.5x50mm	3
LS-RD55B055	Ti Curved Rod, 5.5x55mm	3
LS-RD55B060	Ti Curved Rod, 5.5x60mm	3
LS-RD55B065	Ti Curved Rod, 5.5x65mm	3
LS-RD55B070	Ti Curved Rod, 5.5x70mm	3
LS-RD55B075	Ti Curved Rod, 5.5x75mm	3
LS-RD55B080	Ti Curved Rod, 5.5x80mm	3
LS-RD55B090	Ti Curved Rod, 5.5x90mm	3
LS-RD55B100	Ti Curved Rod, 5.5x100mm	3
LS-RD55B110	Ti Curved Rod, 5.5x110mm	3
LS-RD55B120	Ti Curved Rod, 5.5x120mm	3
LS-RD55B130	Ti Curved Rod, 5.5x130mm	3
LS-RD55D030	Ti Straight Rod, 5.5x30mm	3
LS-RD55D035	Ti Straight Rod, 5.5x35mm	3
LS-RD55D040	Ti Straight Rod, 5.5x40mm	3
LS-RD55D045	Ti Straight Rod, 5.5x45mm	3
LS-RD55D050	Ti Straight Rod, 5.5x50mm	3
LS-RD55D055	Ti Straight Rod, 5.5x55mm	3
LS-RD55D060	Ti Straight Rod, 5.5x60mm	3
LS-RD55D065	Ti Straight Rod, 5.5x65mm	3
LS-RD55D070	Ti Straight Rod, 5.5x70mm	3
LS-RD55D075	Ti Straight Rod, 5.5x75mm	3
LS-RD55D080	Ti Straight Rod, 5.5x80mm	3
LS-RD55D090	Ti Straight Rod, 5.5x90mm	3
LS-RD55D100	Ti Straight Rod, 5.5x100mm	3
LS-RD55D110	Ti Straight Rod, 5.5x110mm	3
LS-RD55D120	Ti Straight Rod, 5.5x120mm	3
LS-RD55D130	Ti Straight Rod, 5.5x130mm	3
LS-RD55D300	Ti Straight Rod, 5.5x300mm	3
LS-RD55C300	CoCr Straight Rod, 5.5x300mm	3
LS-CL6-3338	5.5/6.0mm Rod Crosslink 33-38mm	2
LS-CL6-3847	5.5/6.0mm Rod Crosslink 38-47mm	2
LS-CL6-4457	5.5/6.0mm Rod Crosslink 44-57mm	1
LS-CL6-5070	5.5/6.0mm Rod Crosslink 50-70mm	1

CORTICAL **INSTRUMENT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00339	LineSider Cortical Instrument Tray	1
ASY-00233	Adjustable Drill Guide 20-50mm	1
ASY-00221	4.0mm Quad Lead Tap	1
ASY-00222	4.5mm Quad Lead Tap	1
ASY-00223	5.5mm Quad Lead Tap	1
ASY-00224	6.5mm Quad Lead Tap	1
ASY-00234	3.5mm Drill Bit	1
ASY-00235	4.0mm Drill Bit	1
ASY-00236	4.5mm Drill Bit	1
ASY-00239	Tulip Inserter 5.5 - 6.0	2
ASY-00175	Palm Handle Ratcheting (Cannulated)	1
ASY-00315	Adapter 1/4 Square - AO	1
ASY-00202	Poly Screwdriver 5.5/6.0mm Tulip	2
ASY-00203	Radel Sleeve for Large Poly Screwdriver	2
ASY-00304	Stab-and-Grab Driver 5.5 - 6.0 Tulip	1
ASY-00194	Counter-torque 5.5 mm Rod	1
ASY-00205	Pistol Grip Reducer 5.5 - 6.0 Tulip	1
ASY-00195	Rod Fork/Rocker 5.5 - 6.0 mm Tulip	1

CORTICAL **IMPLANT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00340	LineSider Cortical Implant Tray	1
LS-SC7E4525	Dual to Quad Lead, 4.5mm x 25mm	4
LS-SC7E4530	Dual to Quad Lead, 4.5mm x 30mm	6
LS-SC7E4535	Dual to Quad Lead, 4.5mm x 35mm	6
LS-SC7E4540	Dual to Quad Lead, 4.5mm x 40mm	6
LS-SC7E4545	Dual to Quad Lead, 4.5mm x 45mm	4
LS-SC7E5525	Dual to Quad Lead, 5.5mm x 25mm	4
LS-SC7E5530	Dual to Quad Lead, 5.5mm x 30mm	6
LS-SC7E5535	Dual to Quad Lead, 5.5mm x 35mm	6
LS-SC7E5540	Dual to Quad Lead, 5.5mm x 40mm	6
LS-SC7E5545	Dual to Quad Lead, 5.5mm x 45mm	6
LS-SC7E5550	Dual to Quad Lead, 5.5mm x 50mm	6
LS-SC7E6530	Dual to Quad Lead, 6.5mm x 30mm	4
LS-SC7E6535	Dual to Quad Lead, 6.5mm x 35mm	4
LS-SC7E6540	Dual to Quad Lead, 6.5mm x 40mm	6
LS-SC7E6545	Dual to Quad Lead, 6.5mm x 45mm	6
LS-SC7E6550	Dual to Quad Lead, 6.5mm x 50mm	4
LS-SC7E6555	Dual to Quad Lead, 6.5mm x 55mm	4

CORTICAL **IMPLANT TRAY (CONT.)**

Part Numbers	Description	Quantity Per Tray
LS-RD55B030	Ti Curved Rod, 5.5x30mm	3
LS-RD55B035	Ti Curved Rod, 5.5x35mm	3
LS-RD55B040	Ti Curved Rod, 5.5x40mm	3
LS-RD55B045	Ti Curved Rod, 5.5x45mm	3
LS-RD55B050	Ti Curved Rod, 5.5x50mm	3
LS-RD55B055	Ti Curved Rod, 5.5x55mm	3
LS-RD55B060	Ti Curved Rod, 5.5x60mm	3
LS-RD55B065	Ti Curved Rod, 5.5x65mm	3
LS-RD55B070	Ti Curved Rod, 5.5x70mm	3
LS-RD55B075	Ti Curved Rod, 5.5x75mm	3
LS-RD55B080	Ti Curved Rod, 5.5x80mm	3
LS-RD55B090	Ti Curved Rod, 5.5x90mm	3
LS-RD55B100	Ti Curved Rod, 5.5x100mm	0
LS-RD55B110	Ti Curved Rod, 5.5x110mm	0
LS-RD55B120	Ti Curved Rod, 5.5x120mm	0
LS-RD55B130	Ti Curved Rod, 5.5x130mm	0
LS-RD55D030	Ti Straight Rod, 5.5x30mm	3
LS-RD55D035	Ti Straight Rod, 5.5x35mm	3
LS-RD55D040	Ti Straight Rod, 5.5x40mm	3
LS-RD55D045	Ti Straight Rod, 5.5x45mm	3
LS-RD55D050	Ti Straight Rod, 5.5x50mm	3
LS-RD55D055	Ti Straight Rod, 5.5x55mm	3
LS-RD55D060	Ti Straight Rod, 5.5x60mm	3
LS-RD55D065	Ti Straight Rod, 5.5x65mm	3
LS-RD55D070	Ti Straight Rod, 5.5x70mm	3
LS-RD55D075	Ti Straight Rod, 5.5x75mm	3
LS-RD55D080	Ti Straight Rod, 5.5x80mm	3
LS-RD55D090	Ti Straight Rod, 5.5x90mm	3
LS-RD55D100	Ti Straight Rod, 5.5x100mm	0
LS-RD55D110	Ti Straight Rod, 5.5x110mm	0
LS-RD55D120	Ti Straight Rod, 5.5x120mm	0
LS-RD55D130	Ti Straight Rod, 5.5x130mm	0
LS-SS255560	Set Screw 5.5/ 6.0	14
LS-TU7S5560	Standard Tulip 5.5/ 6.0	12
LS-TU7R5560	Reduction Tulip 5.5/ 6.0	4
ASY-00379	Tapered Set Screw Starter	2

LONG CONSTRUCT IMPLANT TRAY

Part Numbers	Description	Quantity Per Tray
ASY-00343	LineSider Long Construct Implant Tray	
LS-SC7G4530	Cannulated Screw, Dual Lead, 4.5mm x 30mm	2
LS-SC7G4535	Cannulated Screw, Dual Lead, 4.5mm x 35mm	6
LS-SC7G4540	Cannulated Screw, Dual Lead, 4.5mm x 40mm	6
LS-SC7G4545	Cannulated Screw, Dual Lead, 4.5mm x 45mm	6
LS-SC7G4550	Cannulated Screw, Dual Lead, 4.5mm x 50mm	4
LS-SC7G4555	Cannulated Screw, Dual Lead, 4.5mm x 55mm	2
LS-SC7G5530	Cannulated Screw, Dual Lead, 5.5mm x 30mm	2
LS-SC7G5535	Cannulated Screw, Dual Lead, 5.5mm x 35mm	4
LS-SC7G5540	Cannulated Screw, Dual Lead, 5.5mm x 40mm	4
LS-SC7G5545	Cannulated Screw, Dual Lead, 5.5mm x 45mm	4
LS-SC7G5550	Cannulated Screw, Dual Lead, 5.5mm x 50mm	2
LS-SC7G5555	Cannulated Screw, Dual Lead, 5.5mm x 55mm	2
LS-SC7G6535	Cannulated Screw, Dual Lead, 6.5mm x 35mm	4
LS-SC7G6540	Cannulated Screw, Dual Lead, 6.5mm x 40mm	6
LS-SC7G6545	Cannulated Screw, Dual Lead, 6.5mm x 45mm	6
LS-SC7G6550	Cannulated Screw, Dual Lead, 6.5mm x 50mm	6
LS-SC7G6555	Cannulated Screw, Dual Lead, 6.5mm x 55mm	4
LS-SC7G6560	Cannulated Screw, Dual Lead, 6.5mm x 60mm	2
LS-SC7G7535	Cannulated Screw, Dual Lead, 7.5mm x 35mm	2
LS-SC7G7540	Cannulated Screw, Dual Lead, 7.5mm x 40mm	4
LS-SC7G7545	Cannulated Screw, Dual Lead, 7.5mm x 45mm	4
LS-SC7G7550	Cannulated Screw, Dual Lead, 7.5mm x 50mm	4
LS-SC7G7555	Cannulated Screw, Dual Lead, 7.5mm x 55mm	4
LS-SC7G7560	Cannulated Screw, Dual Lead, 7.5mm x 60mm	2
LS-SC7G8540	Cannulated Screw, Dual Lead, 8.5mm x 40mm	4
LS-SC7G8545	Cannulated Screw, Dual Lead, 8.5mm x 45mm	4
LS-SC7G8550	Cannulated Screw, Dual Lead, 8.5mm x 50mm	4
LS-SC7G8555	Cannulated Screw, Dual Lead, 8.5mm x 55mm	4
LS-SC7G8560	Cannulated Screw, Dual Lead, 8.5mm x 60mm	2
LS-SC7G9535	Cannulated Screw, Dual Lead, 9.5mm x 35mm	2
LS-SC7G9540	Cannulated Screw, Dual Lead, 9.5mm x 40mm	4
LS-SC7G9545	Cannulated Screw, Dual Lead, 9.5mm x 45mm	4
LS-SC7G9550	Cannulated Screw, Dual Lead, 9.5mm x 50mm	4
LS-SC7G9555	Cannulated Screw, Dual Lead, 9.5mm x 55mm	4
LS-SC7G9560	Cannulated Screw, Dual Lead, 9.5mm x 60mm	2

LONG CONSTRUCT IMPLANT TRAY (CONT.)

Part Numbers	Description	Quantity Per Tray
LS-SS255560	Set Screw 5.5/ 6.0	20
LS-TU7S5560	Standard Tulip 5.5/ 6.0	10
LS-TU7R5560	Reduction Tulip 5.5/ 6.0	6
LS-RD60C300	CoCr Straight Rod - 6.0 x 300mm	3
LS-RD60D300	Ti Straight Rod - 6.0 x 300mm	3
LS-RD60C500	CoCr Straight Rod - 6.0 x 500mm	3
LS-RD60D500	Ti Straight Rod - 6.0 x 500mm	3
ASY-00269	In-Situ Benders 6.0 mm Rod - Left	1
ASY-00270	In-Situ Benders 6.0 mm Rod - Right	1

EXTRA SCREW **TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00342	LineSider Extra Screw Tray	1
LS-SC7G5530	Cannulated Screw, Dual Lead, 5.5mm x 30mm	4
LS-SC7G5535	Cannulated Screw, Dual Lead, 5.5mm x 35mm	4
LS-SC7G5540	Cannulated Screw, Dual Lead, 5.5mm x 40mm	4
LS-SC7G5545	Cannulated Screw, Dual Lead, 5.5mm x 45mm	4
LS-SC7G5550	Cannulated Screw, Dual Lead, 5.5mm x 50mm	4
LS-SC7G6530	Cannulated Screw, Dual Lead, 6.5mm x 30mm	4
LS-SC7G6535	Cannulated Screw, Dual Lead, 6.5mm x 35mm	4
LS-SC7G6540	Cannulated Screw, Dual Lead, 6.5mm x 40mm	4
LS-SC7G6545	Cannulated Screw, Dual Lead, 6.5mm x 45mm	4
LS-SC7G6550	Cannulated Screw, Dual Lead, 6.5mm x 50mm	4
LS-SC7G7535	Cannulated Screw, Dual Lead, 7.5mm x 35mm	2
LS-SC7G7540	Cannulated Screw, Dual Lead, 7.5mm x 40mm	4
LS-SC7G7545	Cannulated Screw, Dual Lead, 7.5mm x 45mm	4
LS-SC7G7550	Cannulated Screw, Dual Lead, 7.5mm x 50mm	4

ADDITIONAL REDUCTION **INSTRUMENT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00344	LineSider Additional Reduction Instrument Tray	1
ASY-00206	Tower Reducer 5.5/6.0 Tulip	4
CMP-00267	Reducer Driver Adapter	1

ILIAC TRAY

Part Numbers	Description	Quantity Per Tray
ASY-00341	LineSider Iliac Tray	1
ASY-00242	7.5 Single Lead Tap	1
ASY-00243	8.5 Single Lead Tap	1
ASY-00244	9.5 Single Lead Tap	1
LS-SC7R7570	Single Lead Screw, Solid, 7.5mm x 70mm	3
LS-SC7R7580	Single Lead Screw, Solid, 7.5mm x 80mm	3
LS-SC7R7590	Single Lead Screw, Solid, 7.5mm x 90mm	3
LS-SC7R7500	Single Lead Screw, Solid, 7.5mm x 100mm	3
LS-SC7R8570	Single Lead Screw, Solid, 8.5mm x 70mm	3
LS-SC7R8580	Single Lead Screw, Solid, 8.5mm x 80mm	3
LS-SC7R8590	Single Lead Screw, Solid, 8.5mm x 90mm	3
LS-SC7R8500	Single Lead Screw, Solid, 8.5mm x 100mm	3
LS-SC7R9570	Single Lead Screw, Solid, 9.5mm x 70mm	3
LS-SC7R9580	Single Lead Screw, Solid, 9.5mm x 80mm	3
LS-SC7R9590	Single Lead Screw, Solid, 9.5mm x 90mm	3
LS-SC7R9500	Single Lead Screw, Solid, 9.5mm x 100mm	3
LS-IC55T15	Offset Iliac Connector 15mm	3
LS-IC55T20	Offset Iliac Connector 20mm	3
LS-IC55T30	Offset Iliac Connector 30mm	3
LS-IC55T75	Offset Iliac Connector 75mm	3
LS-IC55C15	Offset Iliac Connector Closed 15mm	3
LS-IC55C20	Offset Iliac Connector Closed 20mm	3
LS-IC55C30	Offset Iliac Connector Closed 30mm	3
LS-IC55C75	Offset Iliac Connector Closed 75mm	3
LS-TU7C5560	Closed Tulip 5.5/6.0mm	6
LS-SI255560	Closed Set Screw 5.5/6.0	6

PERCUTANEOUS **INSTRUMENT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00261	LineSider Percutaneous Instruments	1
ASY-00249	4.5mm Tap Cannulated	1
ASY-00250	5.5mm Tap Cannulated	1
ASY-00251	6.5mm Tap Cannulated	1
ASY-00252	7.5mm Tap Cannulated	1
ASY-00208	First Dilator	1
ASY-00209	5.5-6.0 Second Dilator	1
ASY-00350	4.5-5.0 Second Dilator	1
ASY-00210	5.5-6.0 Third Dilator	1
ASY-00351	4.5-5.0 Third Dilator	1
ASY-00335	MIS Tulip Adjuster	1
ASY-00212	K-wires Standard	12
ASY-00038	MIS Rod Inserter	1
ASY-00157	Rod Inserter Locking Driver	1
ASY-00213	MIS Rod Length Indicator	1
ASY-00214	Fascia Splitter	1
ASY-00219	MIS Compressor / Distractor	1
ASY-00305	MIS Compressor / Distractor Pivot Block 30	1
ASY-00220	MIS Compressor / Distractor Pivot Block 45	1
ASY-00189	K-wire Driver	1
ASY-00216	MIS Top Breaker	1
CMP-01166	5.5-6.0 MIS Tulip Sleeve	3

5.5 - 6.0MM **PERCUTANEOUS IMPLANT TRAY**

Part Numbers	Description	Quantity Per Tray
ASY-00348	LineSider 5.5 - 6.0 Percutaneous Implant Tray	1
ASY-00202	5.5-6.0mm Polyaxial Screw Driver	2
ASY-00334	5.5-6.0 MIS Counter Torque	1
ASY-00201	Set Screw Final Driver - 5.5/6.0	1
ASY-00217	5.5-6.0 MIS Tab Breaker	1
ASY-00352	5.5-6.0 MIS Tulip Inserter	2
ASY-00304	Stab and Grab Driver 5.5 - 6.0 Tulip	1
LS-TU7M5560	5.5 / 6.0 MIS Tulips	12
LS-SS255560	Set Screw 5.5 / 6.0	12
LS-SC7G5535	Cannulated Screw, Dual Lead, 5.5mm x 35mm	4
LS-SC7G5540	Cannulated Screw, Dual Lead, 5.5mm x 40mm	4
LS-SC7G5545	Cannulated Screw, Dual Lead, 5.5mm x 45mm	6
LS-SC7G5550	Cannulated Screw, Dual Lead, 5.5mm x 50mm	4
LS-SC7G6535	Cannulated Screw, Dual Lead, 6.5mm x 35mm	4

5.5 - 6.0MM **PERCUTANEOUS IMPLANT TRAY (CONT.)**

Part Numbers	Description	Quantity Per Tray
LS-SC7G6535	Cannulated Screw, Dual Lead, 6.5mm x 35mm	4
LS-SC7G6540	Cannulated Screw, Dual Lead, 6.5mm x 40mm	8
LS-SC7G6545	Cannulated Screw, Dual Lead, 6.5mm x 45mm	8
LS-SC7G6550	Cannulated Screw, Dual Lead, 6.5mm x 50mm	8
LS-SC7G6555	Cannulated Screw, Dual Lead, 6.5mm x 55mm	8
LS-SC7G7535	Cannulated Screw, Dual Lead, 7.5mm x 35mm	4
LS-SC7G7540	Cannulated Screw, Dual Lead, 7.5mm x 40mm	6
LS-SC7G7545	Cannulated Screw, Dual Lead, 7.5mm x 45mm	6
LS-SC7G7550	Cannulated Screw, Dual Lead, 7.5mm x 50mm	6
LS-SC7G7555	Cannulated Screw, Dual Lead, 7.5mm x 55mm	4
LS-SC7G8535	Cannulated Screw, Dual Lead, 8.5mm x 35mm	2
LS-SC7G8540	Cannulated Screw, Dual Lead, 8.5mm x 40mm	4
LS-SC7G8545	Cannulated Screw, Dual Lead, 8.5mm x 45mm	4
LS-SC7G8550	Cannulated Screw, Dual Lead, 8.5mm x 50mm	4
LS-RD55F030	MIS Ti Curved Rod, 5.5x30mm	3
LS-RD55F035	MIS Ti Curved Rod, 5.5x35mm	3
LS-RD55F040	MIS Ti Curved Rod, 5.5x40mm	3
LS-RD55F045	MIS Ti Curved Rod, 5.5x45mm	3
LS-RD55F050	MIS Ti Curved Rod, 5.5x50mm	3
LS-RD55F055	MIS Ti Curved Rod, 5.5x55mm	3
LS-RD55F060	MIS Ti Curved Rod, 5.5x60mm	3
LS-RD55F065	MIS Ti Curved Rod, 5.5x65mm	3
LS-RD55F070	MIS Ti Curved Rod, 5.5x70mm	3
LS-RD55F075	MIS Ti Curved Rod, 5.5x75mm	3
LS-RD55F080	MIS Ti Curved Rod, 5.5x80mm	3
LS-RD55F090	MIS Ti Curved Rod, 5.5x90mm	3
LS-RD55F100	MIS Ti Curved Rod, 5.5x100mm	3
LS-RD55F110	MIS Ti Curved Rod, 5.5x110mm	3
LS-RD55F120	MIS Ti Curved Rod, 5.5x120mm	3
LS-RD55F130	MIS Ti Curved Rod, 5.5x130mm	3
LS-RD55H200	MIS Ti Straight Rod, 5.5x200mm	3
LS-RD55H300	MIS Ti Straight Rod, 5.5x300mm	3

Device Description
The Integrity Implants LineSider Spinal System consists of variety of screws, hooks, rods, lock screws, transverse connectors, rod-to-rod connectors and iliac connectors manufactured from Ti-6A1-4V ELI per ASTM F136, Grade 4 CP Ti per ASTM F67, or cobalt chromium per ASTM F1537.

Indications
LineSider™ Spinal System, with or without MIS instrumentation, is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

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

Contraindications
Contraindications include but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Reusable or multiple uses.

Compatibility:
Do not use LineSider Spinal System with components of other systems than LineSider.

Method of Use:
Please refer to the Surgical Technique Manual (STM-00005) for this device.

Warnings/Precautions
The subject device is intended for use only as indicated.

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

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.

Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic and internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Care should be taken to ensure that all components are ideally fixated prior to closure.

All implants should be used only with the appropriately designated instrument (Reference Surgical Technique Manual).

The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

Iliac screws have a single lead thread on the shaft and must be used with single lead taps to ensure proper purchase in bone.

Be careful when palpating the break point as the Tulip may be sharp.

Reducers are not compatible with polyaxial reduction tulips and may damage the implant if used. Only the Rocker may be used with these reduction tulips.

K-wire should be removed when screw has reached the posterior wall of the pedicle to avoid kink in tip.

Ensure the K-wire is not advancing as the path is created over the K-wire. Use lateral

fluoroscopy to properly manage the K-wire during pedicle preparation to confirm proper placement and avoid anterior advancement of the K-wire.

All set screws should be final-tightened with the Counter-torque and Torque T-handle. Do not final-tighten through compression instruments in the set, as the rod may not be able to normalize to the tulip. Be cautious not to over compress or distract as you can loosen the screws in the spine and potentially pull out the screw.

The bulleted portion of the nose of the rod and the faceted portion of the rod (where the inserter locks down on the rod) must extend fully outside of the most inferior or most superior tulip on the construct. The set screw cannot be locked down on this unusable portion of the rod, as this may compromise the stability of the construct.

Possible Adverse Effects

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

Pre-Operative Warnings:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Devices should be inspected for damage prior to implantation.
6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

Patient Education:

Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware

that implant components may bend, break or loosen even though restrictions in activity are followed.

Post-Operative Warnings:
During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments. Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration, as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices must be checked periodically postoperatively, using appropriate radiographic techniques.

Single Use:
Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.

Magnetic Resonance (MR) Safety:
The LineSider Spinal System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the LineSider Spinal System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Packaging
Packages for each of the components should be intact upon receipt. Devices should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used and should be returned to Integrity Implants. The instruments and implants of the system are provided non-sterile. All implants are single use and should be sterilized per instructions provided below. Instruments provided non-sterile can be single-use or reusable. Reusable instruments should be reprocessed using instructions provided below. Discard single-use instruments after use.

Cleaning and Decontamination
All instruments must first be thoroughly cleaned using the validated methods prescribed below before sterilization and introduction into a sterile surgical field.

- For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
- After surgical procedure remove debris from each instrument using a water moistened pad, exchanging pad if it becomes soiled
- Neutral pH enzymatic and cleaning agents with low foaming surfactants are recommended.
- Alkaline agents with pH ≤ 12 may be used in countries where required by law or local ordinance. Alkaline agents should be followed with a neutralizer and/or thorough rinsing.
- Only agents with proven efficacy (FDA cleared, VAH listed, or CE mark) should be used.
- All cleaning agents should be prepared at the use-dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare cleaning agents. Use of recommended temperatures is important for optimal performance of cleaning agents.

- Dry powdered cleaning agents should be

completely dissolved prior to use to avoid staining or corrosion of instruments and to ensure correct concentration.
- Fresh cleaning solutions should be prepared when existing solutions become grossly contaminated (bloody and/or turbid).

Manual Cleaning/Disinfection Instructions

1. Completely submerge instruments in an enzyme or alkaline (pH ≤12) solution and allow to soak for 20 minutes. Use a soft-bristled, nylon brush to gently scrub the instruments until all visible soil has been removed. Actuate the instruments through a full range of motion while brushing and ensure to brush all hard to reach areas. Attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a sterile syringe and a long, narrow, soft-bristled brush (i.e. pipe cleaner brush) to clean, flush each end of the instruments with 60 mL.
2. Remove the devices from the cleaning solution and rinse in tap water 3 minutes. Thoroughly flush lumens, holes, slots and other difficult-to-reach areas. For lumens, flush using a sterile syringe at each end of the instrument with 60 mL. Repeat until all visible residues have been removed and water runs clear. If instruments are not visibly clean repeat cleaning process.
3. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
4. Perform visual inspection on the instrument and verify that they are clean, dry and in proper working order prior to sterilization.

Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible, contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used and should be returned to Integrity Implants. Contact your local representative or Integrity Implants directly for any additional information related to cleaning of Integrity Implants surgical instruments.

Sterilization

All non-sterile instruments and implants are sterilizable by steam autoclave using standard hospital practices, in addition to Integrity Implant's validated parameters. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in Table 1 for recommended minimum sterilization parameters that have been validated by Integrity Implants to provide a 10-6 sterility assurance level (SAL).

- The hospital is responsible for in-house procedures for the inspection and packaging of the devices after they are thoroughly cleaned in a manner that will ensure steam sterilant penetration and adequate drying. Provisions for protection of any sharp or potentially dangerous areas of the instruments should also be recommended by the hospital.
- Moist heat/steam sterilization is the preferred and recommended method for Integrity Implants device sets.
- Sterilizer manufacturer recommendations should always be followed. When sterilizing multiple sets in one sterilization cycle, ensure that the manufacturer's maximum load is not exceeded.
- Devices should be properly prepared and packaged in trays, caddies and/or cases that will allow steam to penetrate and make direct contract with all surfaces.

- Double-wrap the devices for sterilization and handling with an FDA-cleared wrap using the envelope technique per ANSI/AAMI ST79.
- Ethylene oxide or gas plasma sterilization methods should not be used unless package inserts for the applicable product specifically provide instructions for sterilization using these methods.
- Gravity displacement sterilization cycles are not recommended because cycle times are too long to be practical.

Table 1: Recommended Pre-Vacuum Steam Sterilization Parameters[1]

Temperature	Exposure Time	Minimum Dry Time[2]
132°C/270°F	4 minutes	20 minutes

[1]This cycle is not to be used for the inactivation of prions.
[2]Drying times vary according to load size and should be increased for larger loads.

Note: The Sterilizer Manufacturer's instructions for operation and load configuration should be followed explicitly.

Information
To obtain a Surgical Technique Manual or should any information regarding the products or their uses be required, please contact your local representative or Integrity Implants directly at +1-561-529-3861 or 800-201-9300. You may also email: customerservice@IntegrityImplants.com.

INTEGRITYIMPLANTS
Integrity Implants Inc.
354 Hiatt Drive
Palm Beach Gardens, FL 33418 USA
Phone: 800 201 9300 or 561 529 3861
Email: customerservice@integrityimplants.com

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

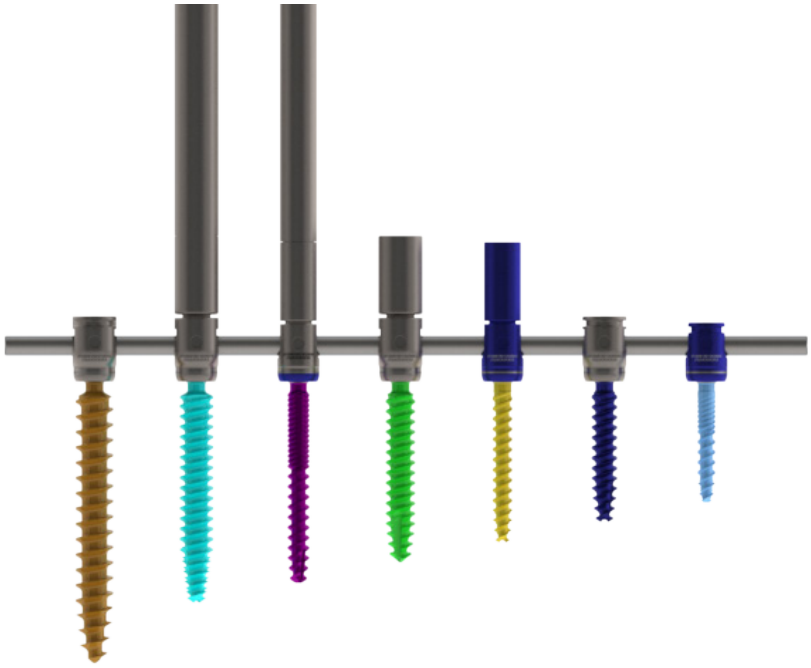
Note: A surgical technique manual is available by contacting Integrity Implants.

Symbol	Definition
REF	Reference number (Catalogue number)
LOT	Batch code (Lot number)
	Consult instructions for use
	Do not re-use / Single Use Only (Single Patient, Single-Use)
	Manufacturer
NON STERILE	Non-sterile - Implants and/or Instruments

Symbol	Definition
℞ Only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.
IP	Intellectual Property: The labeled item or components within are protected under intellectual property according to US, state and federal law as well as foreign law. Detailed intellectual property information can be found at the website address.

LINESIDER®

SPINAL SYSTEM



Integrity Implants Inc.
354 Hiatt Drive, Palm Beach Gardens, FL 33418 USA
Phone: 800 201 9300 or 561 529 3861
Email: customerservice@integrityimplants.com

INTEGRITY
IMPLANTS
integrityimplants.com
STM-00005 RevC