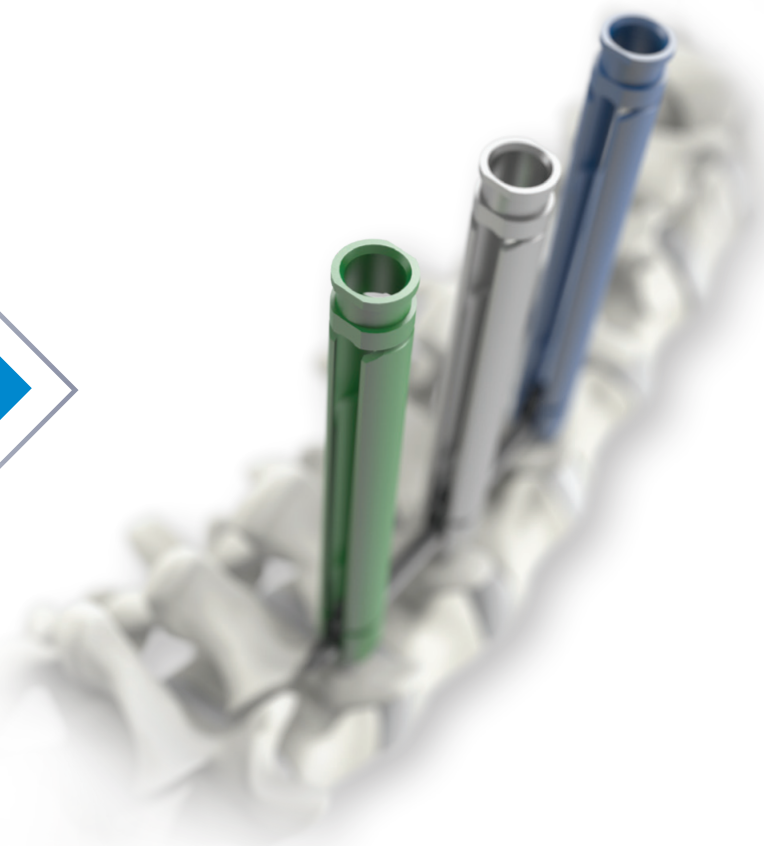


Streamline[®] MIS

Spinal Fixation System



SURGICAL TECHNIQUE

DESCRIPTION

Streamline MIS Spinal Fixation System is a temporary, multiple component cannulated pedicle screw system comprised of a variety of components that allow the surgeon to build a spinal implant construct through an open or percutaneous approach. The implant components include rods, extended tab cannulated polyaxial pedicle screws, crosslinks, and locking set screws that are fabricated from titanium alloy (ASTM F136) and provided nonsterile. The components are available in various sizes to accommodate differing patient anatomy. The system is attached to the pedicles by means of screws to the posterior, noncervical spine. The spinal construct is completed by connecting the screws with titanium alloy rods. Crosslinks can be used if additional stabilization is necessary.

INDICATIONS FOR USE

The Streamline MIS Spinal Fixation System is intended for posterior, noncervical pedicle fixation, T1-S2 or sacral/iliac screw fixation. Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion. The device is indicated for all the following indications: degenerative disc disease (DDD) (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; deformities or curvatures (i.e. scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. Streamline MIS Instrumentation, when used with the Streamline MIS Spinal Fixation System, is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

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Information contained in this document was gathered and compiled by experts in the field and company employees to the best of their knowledge. Care was taken to ensure the information contained herein is accurate and understandable. The company does not assume any liability, however, for the accuracy and/or completeness of the quality of the information, and is not liable for any losses whatsoever of any kind or any nature that may be caused by the use and/or reliance of said information.

INTRODUCTION

System Overview

The Streamline® MIS Spinal Fixation System allows a rigid construct to be created in the thoracolumbar spine via a percutaneous or mini-open approach using cannulated pedicle screws, set screws and rods. The system offers a broad range of implants and instruments providing the ability to tailor treatment to a specific patient for a more efficient and streamlined surgical experience.

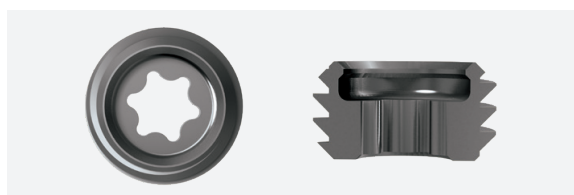
Cannulated Pedicle Screws

- Integrated, disposable and easily detached extension sleeves
- Double lead thread design for faster implantation
- 60° conical screw angulation provides intraoperative flexibility
- Extensive size offering of polyaxial screws
 - Standard diameters: 5.5, 6.5 and 7.5mm
 - Optional diameters: 4.5 and 8.5mm
 - Screw lengths: 20-55mm, depending on screw diameter
- Composed of Ti-6Al-4V



Set Screws

- Designed to reduce incidence of cross-threading
- Use a standard T25 drive mechanism
- Fit all screw sizes
- Composed of Ti-6Al-4V



MIS Rods

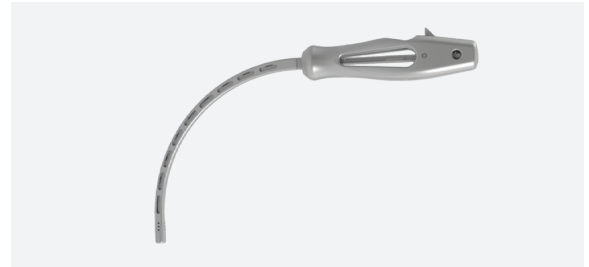
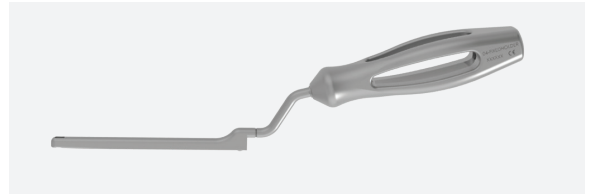
- Standard Ø5.5mm pre-bent rods from 35-150mm
- Optional straight rod set for thoracic procedures
- Optional long rod set for long constructs
- Composed of Ti-6Al-4V



INTRODUCTION

Rod Insertion Options

- Fixed rod holder for standard constructs
- Curved rod holder for long constructs



Reduction Options

- Standard reduction threads (15mm) integrated into extension sleeve
- Optional reduction (up to 30mm) available with the rod reducer or threaded rod reducer



Step 1: Patient Positioning

- Place the patient in the prone position lying flat on a radiolucent table. Ensure that unobstructed fluoroscopic images of the operative levels can be taken in both the A/P and lateral view. Clean and drape the operative site.

Step 2: Pedicle Targeting and Guidewire Placement

- Obtain an A/P image of the targeted vertebral body. Ensure that the endplates are parallel and that the spinous processes are centered on the image. Prepare for screw placement by aligning the first guidewire in a cephalad/caudal orientation along the lateral borders of the pedicles. Transfer the guidewire outline using a skin marker. Next, align a transverse guidewire along the center of both pedicles. Transfer the outline of the second guidewire using the skin marker. Intersect this line with the cephalad/caudal line. Repeat for each pedicle, progressing in a cephalad direction.

For placement of each percutaneous screw, make a longitudinal skin incision through the fascia approximately 2cm long, located 1 to 2cm lateral to the vertical line that marks the lateral border of the pedicle.

Note: Heavier patients require incisions with a greater lateral distance from the pedicle.

Insert the pedicle targeting needle (Figure 1) through the incision. Using A/P fluoroscopy, confirm the needle position at the lateral border of the pedicle. Using a mallet, advance the needle slightly to dock it into the bone and stabilize. Reference a lateral fluoroscopic image to confirm that the cephalad/caudal trajectory matches the pedicular anatomy.

Continue advancing the needle under A/P fluoroscopy. As the tip of the needle approaches the middle of the pedicle cylinder, it should be approximately one third into the vertebral body when viewed on a lateral image. Advance the needle to the desired depth, but no further than half the depth of the vertebral body.

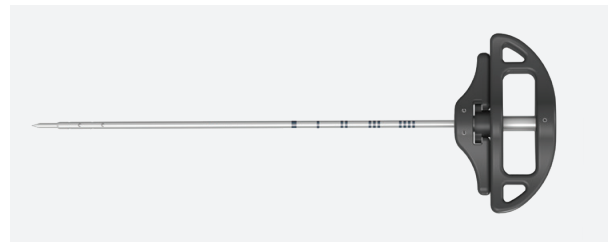


Figure 1

SURGICAL TECHNIQUE

A depth gauge (Figure 2) is available for measuring the depth of the pedicle targeting needle. Slide the pedicle targeting needle through the depth gauge (Figure 3) prior to insertion into the pedicle. Once the assembly is placed into the pedicle, slide the depth gauge down until it contacts the bone. Lines are etched on the pedicle targeting needle at 10mm (one line), 20mm (two lines), 30mm (three lines) and 40mm (four lines). Figure 4 shows the depth gauge and pedicle targeting needle indicating a depth of 30mm.

Remove the inner trocar of the pedicle targeting needle by turning the top handle 90° to the cannula handle (Figures 5 and 6). Carefully advance the guidewire past the tip of the targeting needle and firmly into cancellous bone. Ideal placement of the guidewire tip is approximately two-thirds of the depth of the vertebral body. Remove the pedicle targeting needle while maintaining the position of the guidewire.

Repeat these steps for all pedicles that are intended for screw placement.

Note: Do not advance or remove the guidewire while placing instruments over the guidewire during the procedure.

Note: Do not advance the pedicle targeting needle cannula without the trocar.

Note: Do not bend the guidewire. Bending the guidewire could cause it to kink and/or break.



Figure 2

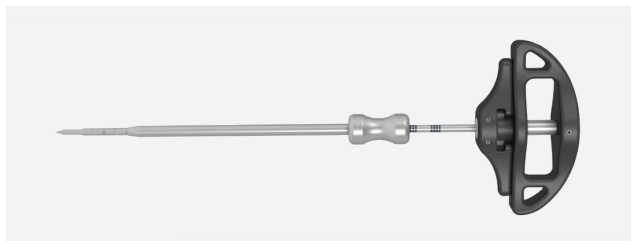


Figure 3*

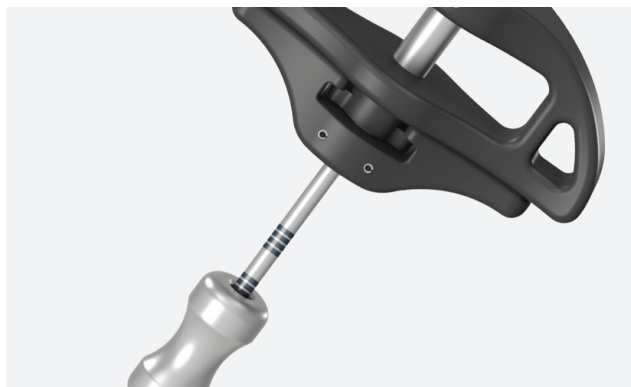


Figure 4*



Figure 5*



Figure 6*

*Optional reusable pedicle targeting needle shown

SURGICAL TECHNIQUE

Step 3: Tissue Dilation

- Assemble the initial dilator with the tap sleeve and screw sleeve (Figures 7 and 8). If desired, the initial dilator can be used with the tap sleeve only (Figure 9). Slide the assembled initial dilator over the guidewire. Twist the initial dilator back and forth while advancing it down the guidewire until it contacts the bone (Figure 10). Push the tap sleeve down against the bone. Remove the initial dilator, leaving the tap sleeve/screw sleeve assembly and guidewire in place (Figure 11).

Note: The screw sleeve has a thin wall. Do not grip during insertion. Handle carefully to avoid damage and/or breakage of screw sleeve.

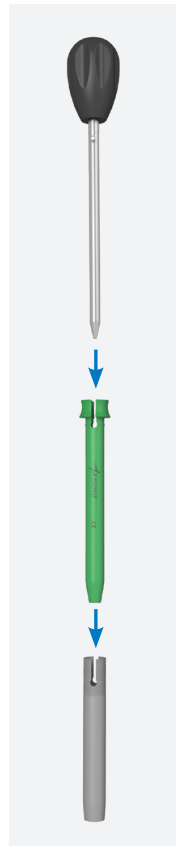


Figure 7

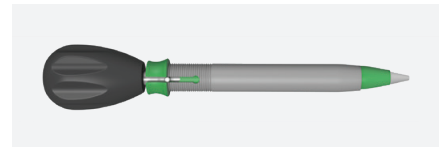


Figure 8



Figure 9



Figure 10

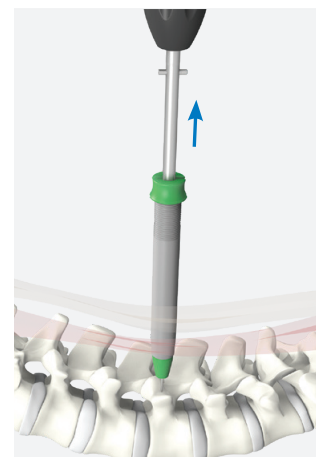


Figure 11

SURGICAL TECHNIQUE

Step 4: Pedicle Preparation

➤ If the patient has sclerotic bone, the cannulated drill or cannulated bone awl can be used to penetrate the cortex in order to gain access to the vertebral body.

Attach the desired tap to a handle and slide it over the guidewire, through the tap sleeve/screw sleeve assembly to the bone (Figure 12). Advance the tap by turning the handle clockwise while applying firm downward pressure, cutting threads into the pedicle.

Note: Select the proper sized tap. Excessive tapping can lead to construct instability and screw loosening.

Note: Taps are “true to size” (not undersized) and are available in standard sizes of 4.5, 5.5 and 6.5mm. Optional sizes of 4.0 and 7.5mm are available by special request.

Note: Do not advance the tap past the tip of the guidewire.

Confirm position using lateral fluoroscopy and stop at the appropriate depth.

Estimate the tap depth by referencing the proximal end of the tap sleeve to the etched depth marks on the tap. These depth marks range from 30 to 45mm and are etched in 5mm increments. Figure 13 shows the tap at a depth of 30mm. The tip of tap sleeve must be contacting bone to obtain an accurate measurement.

Three reference points on the tap, visible under fluoroscopy, can also estimate tap depth. The first is at the end of the tap threads, which occurs at 30mm. The second is a notched depth groove that occurs at 40mm. Finally, there is a shelf on the tap at 50mm (Figure 14).

Note: There is no 40mm notched depth groove on the 4.0 and 4.5mm taps.

Remove the tap while keeping the guidewire in place (Figure 15). Push the screw sleeve down towards the bone to separate the tap sleeve from the screw sleeve (Figure 16). Remove the tap sleeve, leaving the screw sleeve and guidewire in place (Figure 17).



Figure 12

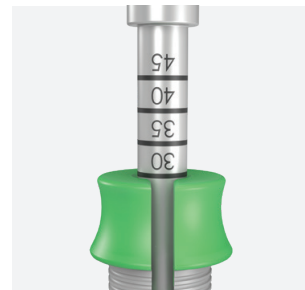


Figure 13

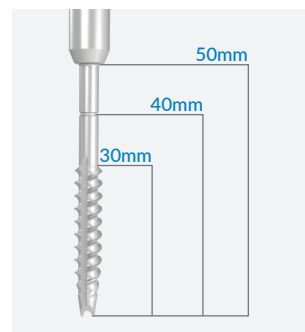


Figure 14



Figure 15

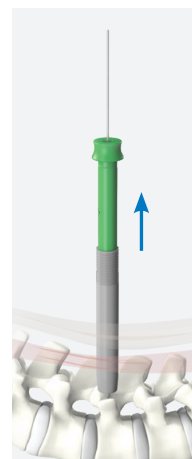


Figure 16



Figure 17

SURGICAL TECHNIQUE

Step 5: Pedicle Screw Placement

- Two styles of screw inserters are available for pedicle screw placement: the simple driver (Figure 18) and the threaded screw inserter (Figure 19).

Caution: To facilitate MIS pedicle screw implantation, instrumentation is often extended in length versus instrumentation used for open techniques. Additional length can subject implants to increased leverage forces. Excessive leverage forces may increase the risk for premature extension breakage, tulip head dissociation, screw fracture, pedicle fracture and/or screw pullout.

Note: Select proper screw size based on anatomy. Undersized screws can break, causing instability.

Simple Driver

Attach the simple driver to a handle and insert the assembly through the screw extension and down into the head of the pedicle screw. If needed, push and twist the simple driver until it fully seats into the screw head (Figure 20).

Note: The simple driver is fully seated into the pedicle screw when the screw extension is flush with the shelf on the simple driver (Figure 21).

After loading a screw onto the simple driver, place it over the guidewire and slide it down through the screw sleeve to the bone. Rotate the handle of the simple driver clockwise to implant the screw into the pedicle (Figure 22). Continue rotating the handle of the simple driver until the screw is at the appropriate depth. Keep the screw and simple driver in line with the guidewire during insertion. Use fluoroscopy to confirm the trajectory and depth of the screw.

Note: Remove the guidewire after advancing the screw past the posterior cortex of the vertebral body.

Caution: To maintain the polyaxial characteristics of the pedicle screw, avoid bottoming and/or impinging the tulip head against bony elements. Limited polyaxial motion may increase stresses to the screw and screw extension when leverage forces are applied.

To disengage the screw from the simple driver, pull up on the attached handle and slide the simple driver out of the screw.

Note: Do not deform extensions when handling screws.



Optional Only: Simple Driver

Figure 18



Optional Only: Simple Driver

Figure 19



Figure 20



Figure 21



Figure 22

Threaded Screw Inserter

Insert the threaded screw inserter shaft into the threaded screw inserter sleeve (Figure 23). Attach the shaft to a handle and insert the assembly through the screw extension and down into the head of the screw (Figure 24). Rotate the threaded screw inserter sleeve (Figure 25) into the tulip of the screw head until it is firmly in place and comes to a stop (Figure 26).

After loading a screw onto the threaded screw inserter, place it over the guidewire and slide it down through the screw sleeve to the bone. Rotate the handle of the threaded screw inserter clockwise to implant the screw into the pedicle (Figure 27). Continue rotating the handle of the threaded screw inserter until the screw is implanted to the appropriate depth. Keep the screw and threaded screw inserter in line with the guidewire during insertion. Use fluoroscopy to confirm the trajectory and depth of the screw.

Note: Do not hold the threaded screw inserter sleeve while inserting the screw. This will cause the threaded screw inserter assembly to detach from the screw.

Caution: To maintain the polyaxial characteristics of the pedicle screw, avoid bottoming and/or impinging the tulip head against bony elements. Limited polyaxial motion may increase stresses to the screw and screw extension when leverage forces are applied.

To disengage the threaded screw inserter from the screw, hold the screw extension while rotating the threaded screw inserter sleeve counterclockwise until it disengages from the screw. Pull up on the attached handle and slide the threaded screw inserter out of the screw.

Repeat Step 5 until all of the screws are implanted.

Note: After guidewire removal, additional screw adjustments may be made with either the simple driver or the final driver.

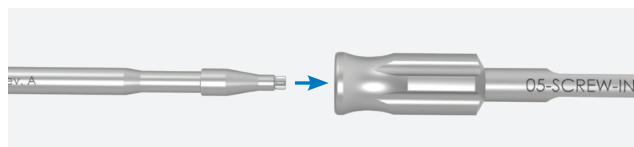


Figure 23



Figure 24

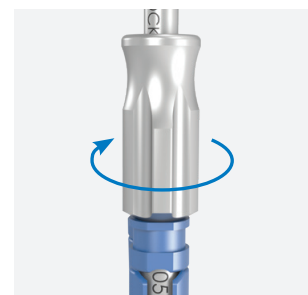


Figure 25



Figure 26



Figure 27

SURGICAL TECHNIQUE

Rod Overview

Proper rod orientation is important when bending the rod or inserting the rod into any rod holder. The rod is properly oriented for insertion into the rod holders when the circle and notch are both facing upward in relation to the oval slot. For proper orientation of the rod during rod bending, please refer to Figure 31 for lordotic bends and Figure 32 for kyphotic bends on page 10.



Step 6: Rod Measurement

- The Streamline® MIS Instrument Set includes a rod caliper to provide guidance prior to rod length selection. Insert the posts of the rod caliper into the most cephalad and caudal screw extensions. Slide the posts down the screw extensions until the shelves of the posts are flush with and resting on top of the extensions (Figure 28). Read the value on either side of the scale at the top of the rod caliper (Figure 29). The value shown on the rod caliper represents the functional pre-bent rod length as depicted in Figure 30. Any intended distraction or compression must also be considered as part of rod length selection. An appropriately sized rod extends slightly beyond the cephalad and caudal ends of the screw head so that set screw locking occurs on the functional length of the rod. Determination of appropriate rod length is ultimately verified following rod insertion (Step 8) using A/P and lateral fluoroscopy.

Note: The screw extension may need to be adjusted in the sagittal plane in order to fully seat the rod caliper.



Figure 28



Figure 29



Figure 30

Step 6: Rod Measurement (continued)

➤ **Note:** The Streamline® MIS straight rods are intended to be bent prior to insertion. To simplify the measuring process, the measurement etched on the rod indicates the approximate functional length after the rod is bent to an average 9.5 inch radius. The difference between the etched length and the actual straight functional length increases proportionally as the rod length increases and is most noticeable on straight rods measuring 160mm and longer. For the actual functional lengths see Table 1.

Part Number	Etched Length	Functional Length
04-55-RR-160	160mm	163mm
04-55-RR-170	170mm	173mm
04-55-RR-180	180mm	184mm
04-55-RR-190	190mm	195mm
04-55-RR-200	200mm	206mm
04-55-RR-210	210mm	217mm
04-55-RR-220	220mm	228mm
04-55-RR-230	230mm	239mm
04-55-RR-240	240mm	251mm
04-55-RR-250	250mm	263mm
04-55-RR-300	300mm	323mm
04-55-RR-350	350mm	391mm

Table 1: MIS Straight Rod Measurement

Step 7: Rod Contouring

➤ To make changes to the contour of the rod, select an appropriate bend radius on the rod bender and place the rod between the rollers of the rod bender. There are three bend radius settings on the center roller. Compress the rod bender until the desired contour is achieved.

Caution: Consider proper rod orientation before bending the rod. Proper rod orientation is important when placing the rod into any of the two rod holders mentioned in Step 8. When applying a lordotic bend to the rod, the rod should be positioned as shown in Figure 31. When applying a kyphotic bend to the rod, the rod should be positioned as shown in Figure 32.

Caution: Avoid creating a sharp bend or undoing a contour in the rod, as this may lead to premature material fatigue of the implant. Do not bend the rod in the reverse direction, as this may introduce micro fractures that compromise its strength. If reverse rod bending or excessive bending has occurred, the bent rod must be discarded. Please contact RTI Surgical at (888) 778-8771 with any questions in regard to contouring rod prior to surgery.

Caution: Ensure rod contouring places the rod segment within polyaxial screw yoke. Improper rod contouring may result in exceeding the $\pm 30^\circ$ or 60° conical range of motion of the polyaxial screw. Exceeding these limits may inhibit proper locking or cause permanent damage to the polyaxial screw, such as yoke disassociation from the screw head.

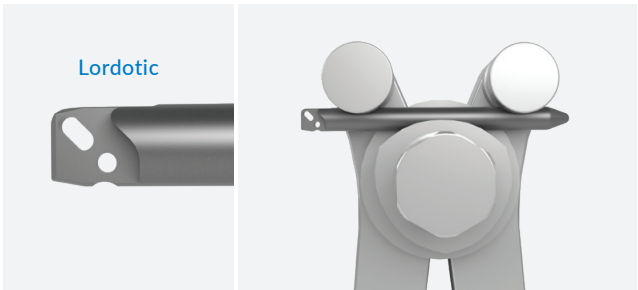


Figure 31

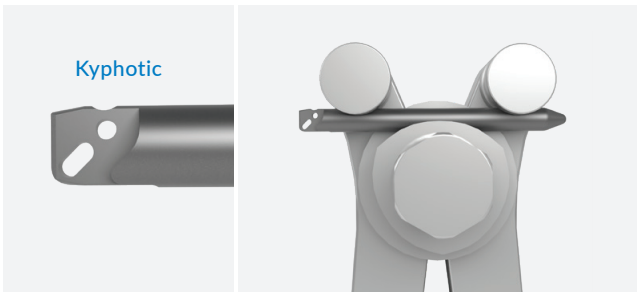


Figure 32

SURGICAL TECHNIQUE

Rod Overview

Proper rod orientation is important when bending the rod or inserting the rod into any rod holder. The rod is properly oriented for insertion into the rod holders when the circle and notch are both facing upward in relation to the oval slot. For proper orientation of the rod during rod bending, please refer to Figure 31 for lordotic bends and Figure 32 for kyphotic bends on page 10.



Step 8: Rod Insertion

- The Streamline® MIS system provides two instrument options for rod insertion: the fixed rod holder and the curved rod holder.

Note: If using a mini-open technique, the muscle splitting wedge can be used to create a plane for rod passage (Figure 33).

Option 1: The Fixed Rod Holder

To insert a rod with the fixed rod holder (Figure 34), place the gold fixed rod holder locking screw (Figure 35) into the fixed rod holder and advance slightly so that the locking screw is not visible in the rod slot of the fixed rod holder. With the rod properly oriented, place the connection end of the rod into the fixed rod holder. Tighten the locking screw with the set screw inserter to secure the rod to the fixed rod holder (Figures 36 and 37).

Note: Only the set screw inserter should be used to tighten the gold locking screw.



Figure 33

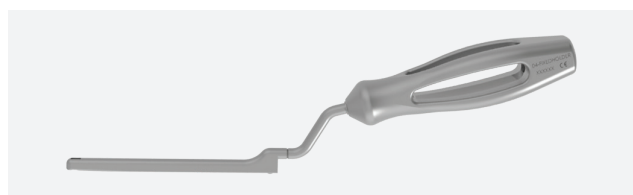


Figure 34

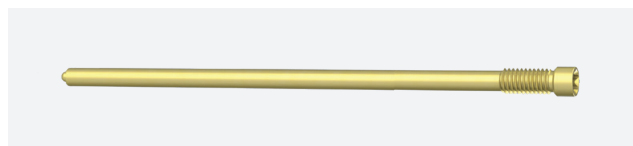


Figure 35



Figure 36

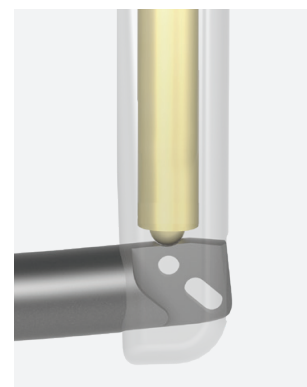


Figure 37

SURGICAL TECHNIQUE

Orient the handle of the rod holder parallel to the patient's skin surface with the tip of the rod facing downward. Insert the tip of the rod into the incision of the screw extension with the fixed rod holder on the outside of the screw extension (Figure 38). Advance the tip of the rod downward through the screw extension toward the screw until it touches the screw head or as far the tissue will allow (Figure 39). Ensure that the distal end of the rod is below the fascia. Begin to rotate the handle of the rod holder up while keeping the shaft of the rod holder as close to the screw extension as possible (Figure 40). Continue to rotate the handle up to a vertical position while guiding the distal tip of the rod into the adjacent screw extension slot until the top of the rod holder shaft is flush with the top of the screw extension (Figures 41 and 42). Verify that the rod is in position using A/P and lateral fluoroscopy. Ensure that the rod extends slightly beyond the cephalad and caudal ends of the screw head.

Note: Do not release the rod from the rod holder until at least one set screw has been provisionally tightened. Proceed to Step 9 for instruction on set screw placement.

After a set screw has been provisionally tightened, release the rod from the fixed rod holder by loosening the gold locking screw with the set screw inserter. Pull the fixed rod holder away from the rod to separate the connection. Lift the instrument up to remove it from the patient.

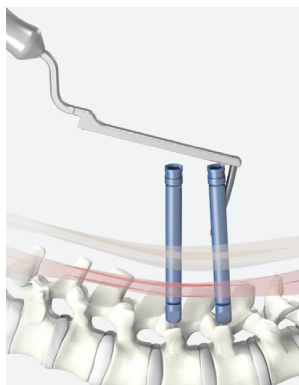


Figure 38

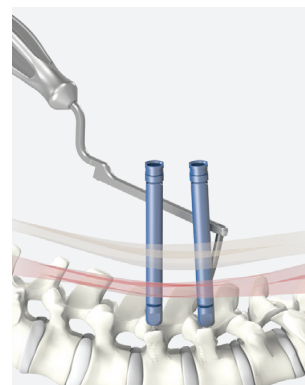


Figure 39

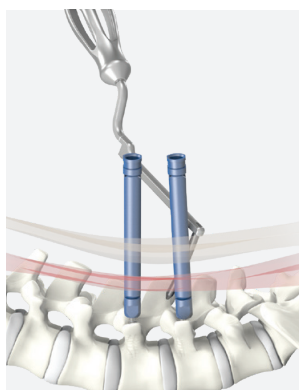


Figure 40

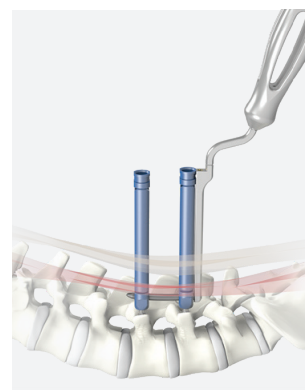


Figure 41



Figure 42

SURGICAL TECHNIQUE

Rod Overview

Proper rod orientation is important when bending the rod or inserting the rod into any rod holder. The rod should face upward, with the circle and notch aligned relative to the oval slot, for proper insertion. For proper orientation of the rod during rod bending, please refer to Figure 31 for lordotic bends and Figure 32 for kyphotic bends on page 10.



Option 2: The Curved Rod Holder

To insert a rod with the curved rod holder (Figure 43), open the thumb lever (Figure 44) located in the handle of the curved rod holder. With the rod properly oriented, place the connection end of the rod into the tip of the curved rod holder (Figures 46 and 47). Close the thumb lever to secure the rod to the curved rod holder (Figure 45).

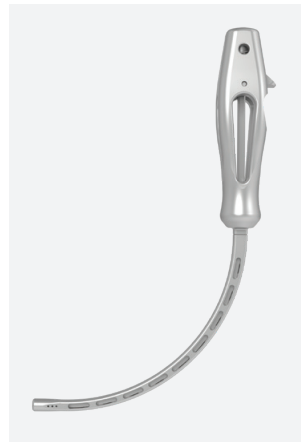


Figure 43



Figure 44



Figure 45

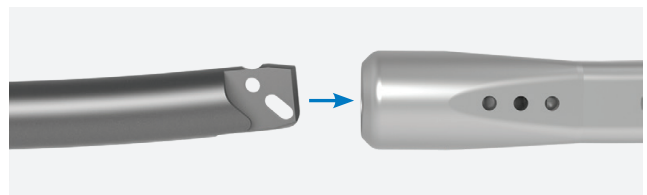


Figure 46

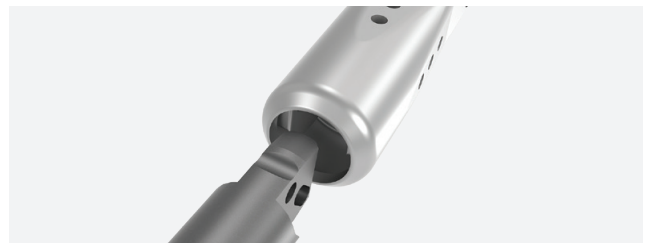


Figure 47

SURGICAL TECHNIQUE

When using the curved rod holder, the rod entry point will be cephalad to the most superior screw in the construct (Figure 48). This allows laminar shingling to serve as a safety measure when inserting the rod. Estimate the rod entry point depending on patient size and make a vertical incision approximately 1cm in length. Insert the rod through the incision and below the fascia (Figure 49). Using A/P and lateral fluoroscopy, guide the rod through all extensions. Verify that the rod is in position using A/P and lateral fluoroscopy (Figures 50 and 51). Ensure that the rod extends slightly beyond the cephalad and caudal ends of the screw head.

Note: Do not release the rod from the rod holder until at least one set screw has been provisionally tightened. Proceed to Step 9 for instruction on set screw placement.

After a set screw has been provisionally tightened, release the rod from the curved rod holder by opening the thumb lever. Pull and lift the instrument to remove it from the patient.

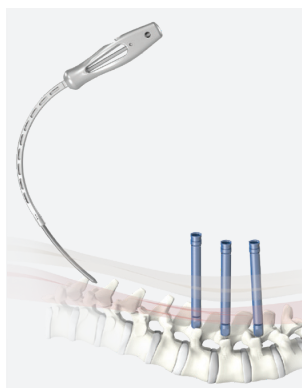


Figure 48

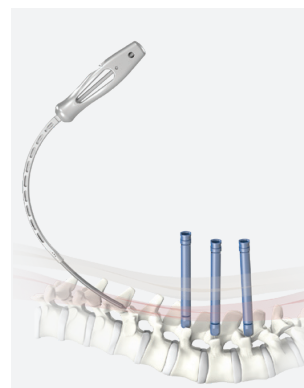


Figure 49

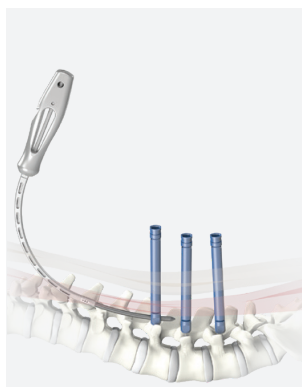


Figure 50



Figure 51

SURGICAL TECHNIQUE

Step 9: Set Screw Insertion

- Place the set screw inserter (Figure 52) into a set screw in the set screw caddy, retaining it on the tip of the instrument (Figure 53). Insert the loaded set screw inserter into the screw extension and thread the set screw into the tulip of the screw by rotating clockwise until the set screw and rod are fully seated in the tulip of the screw. Align the proximal end of the gold or silver band on the set screw inserter with the top of the screw extension to verify that the screw and rod are fully seated. When the set screw is fully seated, pull up on the set screw inserter to disengage it from the set screw.

Note: The gold band on the set screw inserter is used to indicate contact with the reduction threads. When the bottom of the gold band reaches the top of the extension sleeve, the set screw is at the reduction threads (Figures 54 and 55). When the top of the gold band reaches the top of the extension sleeve, the set screw is fully seated (Figure 56 and 57).

Repeat this step to insert set screws into the remaining pedicle screws.

Note: Do not cross-thread the set screw.

Note: The set screw inserter is intended for provisional locking only and should not be used for final locking.



Figure 52



Figure 53

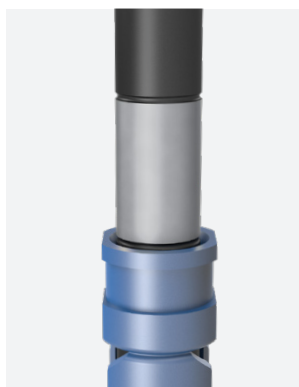


Figure 54



Figure 55



Figure 56

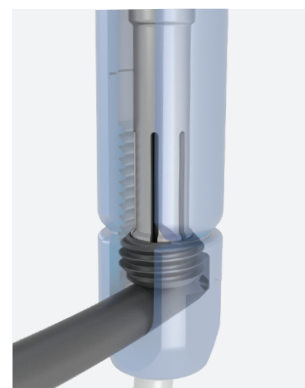


Figure 57

Step 10: Rod Reduction

- The Streamline® MIS system features multiple rod reduction capabilities. Each screw extension has 15mm of additional threads located above the tulip of the screw that allow for simple rod reduction with the set screw inserter. If greater rod reduction is required, the reducer (Figure 58) or threaded rod reducer can be used in combination with the reducing set screw inserter (Figure 59) to provide up to 30mm of reduction.

Caution: Reduction instrumentation provided within the Streamline MIS Spinal Fixation System is intended to aid in the reduction of vertebral spondylolisthesis. Streamline MIS reduction instrumentation should not be used to forcefully contour a rod in situ into a tulip head in a previously fused or otherwise immobile spinal level(s). In such cases, ensure rod contouring places the rod segment within the polyaxial tulip head. Improper rod contouring may also result in exceeding the $\pm 30^\circ$ or 60° conical range of motion of the polyaxial screw. Whether or not the maximum polyaxial range of motion is exceeded, forceful reduction of an improperly contoured rod may inhibit proper locking or cause permanent damage to the polyaxial screw, such as tulip head disassociation from the screw.

Caution: To facilitate MIS pedicle screw implantation, instrumentation is often extended in length versus instrumentation used for open techniques. Additional length can subject implants to increased leverage forces. Excessive leverage forces may increase the risk for premature extension breakage, tulip head dissociation, screw fracture, pedicle fracture and/or screw pullout.

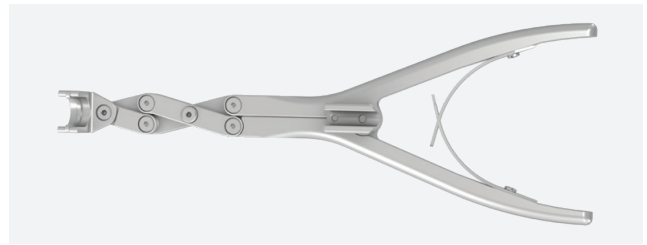


Figure 58



Figure 59

The Reducer

Press the reducing set screw inserter into a set screw in the set screw caddy, retaining it on the tip of the instrument. Push down on the tip of the inserter to get it to snap into the set screw. Insert the loaded reducing set screw inserter into the screw extension until it comes to a stop (Figure 63). While capturing the reducing set screw inserter within the proximal slot of the reducer (Figure 60), slide the distal end of the reducer onto the proximal collar of the extension sleeve (Figure 61). Final assembly is depicted in Figure 62. Squeeze the handle of the reducer until it comes to a stop. This will drive the reducing set screw inserter downward through the set screw, pushing the rod into the head of the pedicle screw (Figure 64), allowing the set screw to reach the reduction threads of the extension sleeve. While maintaining pressure on the reducer handle, turn the reducing set screw inserter clockwise to advance the set screw into the reduction threads of the extension sleeve (Figure 65). Advance the set screw until fully seated or until the set screw can advance no further.

Note: The reducing set screw inserter handle (Figure 66) can be used if additional torque is needed to turn the reducing set screw inserter.

Note: The gold or silver band on the reducing set screw inserter is used to indicate position of the rod in the screw extension. When the bottom of the gold or silver band reaches the top of the extension sleeve, the rod is below the reduction threads and the set screw is able to reach the reduction threads. When the top of the gold or silver band reaches the top of the extension sleeve, the rod is seated in the screw head and the set screw can be fully advanced.



Figure 60

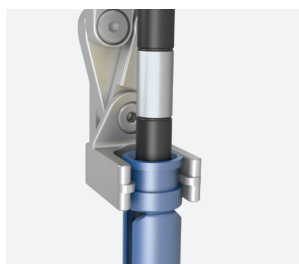


Figure 61

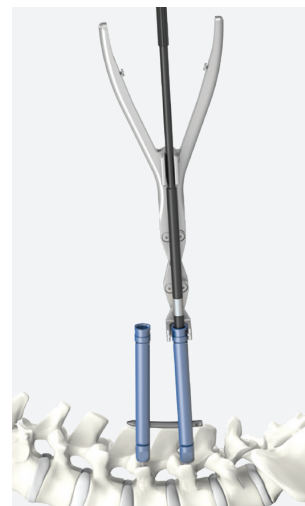


Figure 62



Figure 63



Figure 64



Figure 65

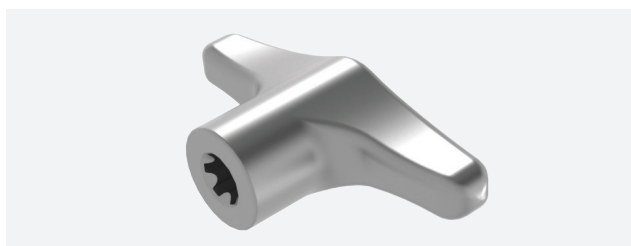


Figure 66

The Threaded Rod Reducer

Press the reducing set screw inserter into a set screw in the set screw caddy, retaining it on the tip of the instrument. Insert the loaded reducing set screw inserter into the screw extension until it comes to a stop. Assemble the threaded rod reducer by inserting the threaded reducer into the threaded reducer handle (Figure 67). Slide the assembled threaded rod reducer over the reducing set screw inserter and into the proximal reduction threads located in the collar of the extension sleeve (Figure 68). Rotate the handle of the assembled threaded reducer clockwise until it comes to a hard stop (Figure 69). With the assembled threaded reducer in place, turn the reducing set screw inserter clockwise to advance the set screw into the reduction threads of the extension sleeve. Advance the set screw until fully seated or until the set screw can advance no further (Figure 70).

Note: The reducing set screw inserter handle can be used if additional torque is needed to turn the reducing set screw inserter.



Figure 67

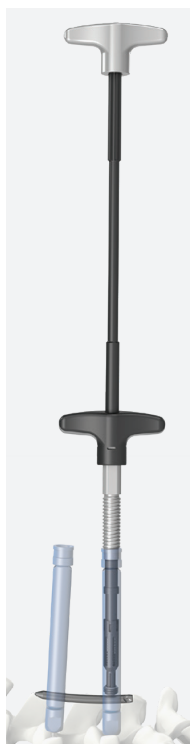


Figure 68



Figure 69



Figure 70

Step 11: Compression and Distraction

➤ **Caution:** To facilitate MIS pedicle screw implantation, instrumentation is often extended in length versus instrumentation used for open techniques. Additional length can subject implants to increased leverage forces. Excessive leverage forces may increase the risk for premature extension breakage, tulip head dissociation, screw fracture, pedicle fracture and/or screw pullout.

Compression

To apply compression to one or more levels utilizing the compressor, first provisionally lock one of the set screws of the level being compressed.

Assemble the final driver with the torque-limiting handle and insert this assembly into the extension of the unlocked screw. Engage the final driver in the set screw and loosen one-quarter to one-half turn. Insert the post of the compressor into the extension sleeve of the provisionally locked screw. While inserting the post of the compressor, swing the hook of the compressor onto the narrow portion of the final driver (Figures 71 and 72), then slide the compressor down until the post of the compressor bottoms out on the locked set screw (Figure 73). While applying downward pressure on the final driver, squeeze the compressor handles together to compress the level (Figure 74).

Once adequate compression is achieved, turn the final driver clockwise until the set screw is tight on the rod. Do not attempt to apply full locking torque to the set screw with the compressor in place. Remove the compressor and final driver, then proceed to final set screw locking (Step 12).

Caution: The compressor must be removed prior to final set screw locking. Additional forces and friction occur between the compressor and the final driver when tightening a set screw. This may result in insufficient torque for final set screw locking with the compressor in place. Refer to Step 12 for proper final set screw locking instructions.



Figure 71



Figure 72



Figure 73



Figure 74

SURGICAL TECHNIQUE

Distraction

To apply distraction to one or more levels utilizing the distractor, first provisionally lock one of the set screws of the level being distracted.

Assemble the final driver with the torque-limiting handle and insert this assembly into the extension of the unlocked screw. Engage the final driver in the set screw and loosen one-quarter to one-half turn. Insert the post of the distractor into the extension sleeve of the provisionally locked screw. While inserting the post of the distractor, swing the hook of the distractor onto the narrow portion of the final driver (Figures 75 and 76), then slide the distractor down until the post of the distractor bottoms out on the locked set screw (Figure 77). While applying downward pressure on the final driver, squeeze the distractor handles together to distract the level (Figure 78). Once adequate distraction is achieved, turn the final driver clockwise until the set screw is tight on the rod. Do not attempt to apply full locking torque to the set screw with the distractor in place. Remove the distractor and final driver, then proceed to final set screw locking (Step 12).

Note: Distractor is clearly identifiable by its gold handle.

Note: Do not overdistract the rod. The rod should remain in the tulip of the screw during distraction.

Caution: The distractor must be removed prior to final set screw locking. Additional forces and friction occur between the distractor and the final driver when tightening a set screw. This may result in insufficient torque for final set screw locking with the distractor in place. Refer to Step 12 for proper final set screw locking instructions.



Figure 75



Figure 76



Figure 77



Figure 78

SURGICAL TECHNIQUE

Step 12: Final Set Screw Locking

➤ **Caution:** To facilitate MIS pedicle screw implantation, instrumentation is often extended in length versus instrumentation used for open techniques. Additional length can subject implants to increased leverage forces. Excessive leverage forces may increase the risk for premature extension breakage, tulip head dissociation, screw fracture, pedicle fracture and/or screw pullout.

To final lock the set screw, attach the final driver to the torque-limiting handle. Seat the tip of the counter-torque tube over a screw and slide it down until it rests on top of the rod. The rod is held in the grooves of the counter-torque tube when the top of the extension sleeve is flush with the opening of the counter-torque tube. Insert the assembled final driver through the screw extension and engage the set screw.

Holding the handle of the counter-torque tube in place, rotate the torque-limiting handle clockwise until it emits an audible and/or tangible “click” (Figure 79). Do not apply any additional torque

Carefully remove the instruments and repeat this step for all screws.

Note: The final driver (05-FINALDRIVER) must be used in combination with the torque-limiting handle (02-TL-HANDLE) to complete final set screw locking.



Figure 79

Step 13: Screw Extension Removal

➤ **Caution:** To facilitate MIS pedicle screw implantation, instrumentation is often extended in length versus instrumentation used for open techniques. Additional length can subject implants to increased leverage forces. Excessive leverage forces may increase the risk for premature extension breakage, tulip head dissociation, screw fracture, pedicle fracture and/or screw pullout.

Note: Ensure all set screws have been final locked prior to removing the screw extensions.

Orient the extension removal pliers (Figure 80) so that the cephalad/caudal markings are facing the cephalad/caudal direction and the handle of the instrument is perpendicular to the rod. Place the extension removal pliers over the top of the screw extension so that the post of the instrument fits down into the collar of the screw extension (Figure 81). Slide the extension removal pliers down until the top of the screw extension is flush with the etched line on the instrument. This indicates that the extension removal pliers are fully seated.

Squeeze the handle of the extension removal pliers to separate one tab of the extension sleeve from the collar (Figure 82). Release the handle. Gripping the shaft of the extension removal pliers, rock the instrument and screw extension back and forth perpendicular to the rod, separating the screw extension from the screw head (Figure 83).

Remove all pieces of the screw extension and discard (Figure 84).

Caution: When using the extension removal pliers (05-EXTREM-PLIER) to break and remove the screw extensions, ensure that the instrument is fully seated over the proximal collar of the screw extension before applying force. Do not attempt to remove the screw extensions from the tulip without first separating at least one tab of the screw extension from the collar.

Note: When squeezing the extension removal pliers, the collar may become completely separated from the screw extension. If this occurs, remove the remaining pieces of the screw extension with a pair of forceps by rocking the individual extension tabs back and forth perpendicular to the rod.

Note: Using A/P and lateral fluoroscopy, ensure that all pieces of the screw extension have been removed.

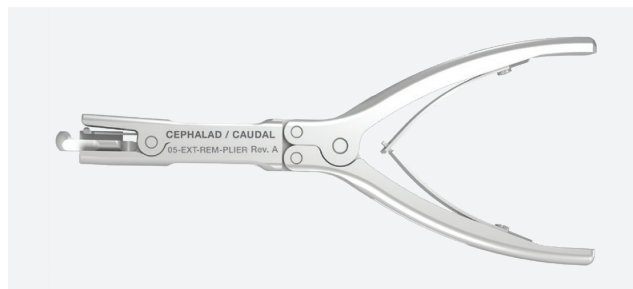


Figure 80



Figure 81

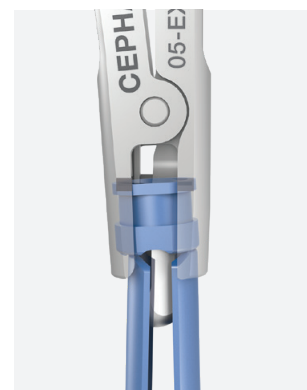


Figure 82



Figure 83

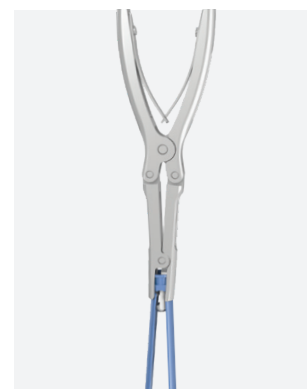


Figure 84








SURGICAL TECHNIQUE

Removal (if necessary)

- To remove construct, apply counterclockwise rotation to loosen its components and remove them in the opposite order in which the construct was built.






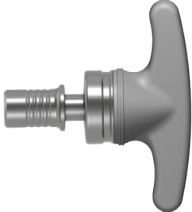


ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
04-PT-NEEDLE-11	11G Pedicle Targeting Needle	For creating a pilot hole in the pedicle and guidewire placement	
04-JAMCANN-11	11G Pedicle Targeting Cannula	For guidewire placement; subcomponent of 04-PT-NEEDLE-11, must be used with 04-JAMTROCAR-11	
04-JAMTROCAR-11	11G Pedicle Targeting Trocar	For creating a pilot hole in the pedicle; subcomponent of 04-PT-NEEDLE-11, must be used with 04-JAMCANN-11	
04-JAMDEPTH-11	11G Depth Gauge	For measuring the depth of the pedicle targeting needle	
04-MALLET	Cannulated Mallet	For impacting instruments when appropriate	
04-GWTUBE	Guidewire Tube	For housing the guidewires	
51-GW-500-BLUNT	Blunt-Tip Nitinol Guidewire, Ø1.5mm x 500mm	For guiding instruments and cannulated pedicle screws into the pedicle	

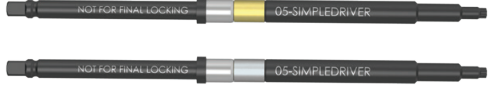



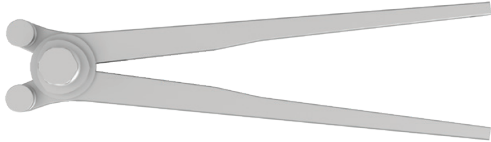



ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
05-DILATOR	Initial Dilator	For dilation of the soft tissues	
05-TAPSLEEVE	Tap Sleeve	For maintaining dilation of the soft tissues while tapping	
05-SCREWSLEEVE	Screw Sleeve	For maintaining dilation of the soft tissues while inserting a cannulated pedicle screw into the pedicles	
04-CANNAWL	Cannulated Bone Awl	For increasing the diameter of the pilot hole in the cortical bone of the pedicle	
04-CANNDRILL	Ø3.8mm Cannulated Drill	For increasing the diameter of the pilot hole in the pedicle	
10-RTHANDLE	Ratcheting T-Handle	For use with taps and screw inserters	
10-RSHANDLE	Ratcheting Straight Handle	For use with taps and screw inserters	
04-CANNTAP-X	Cannulated Tap	For tapping holes prior to inserting screws in pedicles Standard set includes 4.5, 5.5 and 6.5mm diameters (X)	






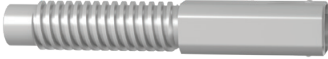

ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
05-SIMPLEDRIVER	Simple Driver	For inserting screws into pedicles	
05-SCREW-INS-THRD	Threaded Screw Insertion	For inserting screws into pedicles	
04-DRIVER-SLEEVE	Driver Sleeve	For stabilizing the taps, screw inserters, or drill during insertion into the pedicles	
04-RODCALIPER	Rod Caliper	For guidance prior to rod length selection	
10-BENDER-55	Ø5.5mm Rod Bender	For contouring rods	
04-FIXEDHOLDER	Fixed Rod Holder	For holding a rod during insertion into the head of the pedicle screws	
04-CURVEHOLDER	Curved Rod Holder	For holding a rod during insertion into the head of the pedicle screws	
04-WEDGE	Muscle Splitting Wedge	For dissection of the fascia and creating a plane through the muscle fibers prior to rod insertion	

ORDERING GUIDE

INSTRUMENT GUIDE

Part Number	Instrument	Description	
04-HEADADJUSTER	Head Adjuster - Rod Pusher	For adjusting screw head orientation of an implanted pedicle screw; for pushing the rod down into the head of the pedicle screw	
04-SETSCREWINS	Set Screw Inserter	For the insertion of set screws into the pedicle screws; for tightening the gold locking screw in the fixed rod holder; not used for final locking. The band on the shaft will either be gold or silver.	
04-RDSETSCR-INS	Reducing Set Screw Inserter	For introducing a set screw while using the reducer or threaded reducer. The band on the shaft will either be gold or silver.	
04-REDUCE-INS-HNDL	Reducing Set Screw Inserter Handle	For advancing the reducing set screw inserter	
04-REDUCER	Rod Reducer	For reducing the rod into the head of the pedicle screw	
05-THRDREDUCER	Threaded Rod Reducer	For reducing the rod into the head of the pedicle screw	
04-THRDRED-HANDLE	Threaded Rod Reducer Handle	For advancing the threaded reducer	

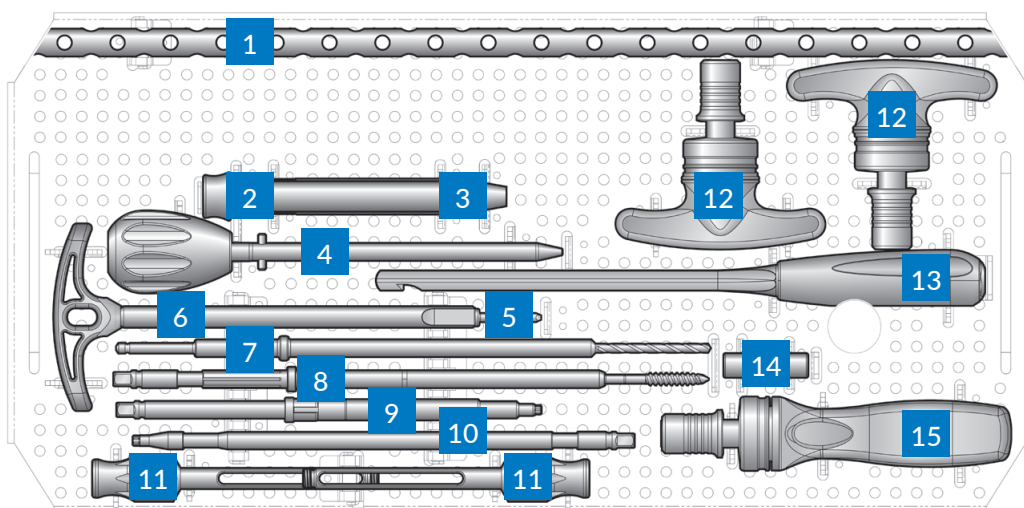
ORDERING GUIDE

INSTRUMENT GUIDE

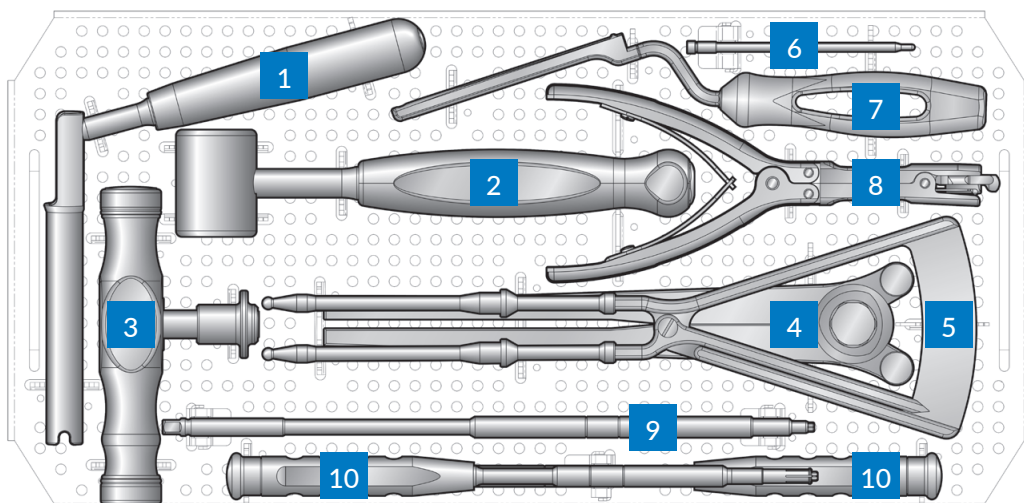
Part Number	Instrument	Description	
04-COMPRESSOR	Compressor	For compressing a level as needed	
04-DISTRACTOR	Distractor	For distracting a level as needed	
05-FINALDRIVER	Final Driver	For applying final locking torque to a set screw that has been inserted in a pedicle screw. The band on the shaft will either be gold or silver.	
02-TL-HANDLE	Torque-Limiting Handle	For applying final locking torque to a set screw that has been inserted in a pedicle screw	
05-CT-TUBE	Counter-Torque Tube	For applying counter-torque during final locking of a set screw	
05-EXT-REM-PLIER	Extension Removal Pliers	For removal of the extension sleeve	
04-RODRETRIEVE	Rod Retriever	For retrieval of a rod	

ORDERING GUIDE

Tray Layout					
1	Guidewire Tube	6	Head Adjuster - Rod Pusher	11	Threaded Screw Inserter Sleeves
2	Screw Sleeve	7	Ø3.8mm Cannulated Drill	12	Ratcheting T-Handles
3	Tap Sleeve	8	Cannulated Taps	13	Muscle Splitting Wedge
4	Initial Dilator		(Ø4.5, Ø5.5 and Ø6.5mm)	14	Driver Sleeve
5	Cannulated Bone Awl	9	Simple Drivers	15	Ratcheting Straight Handle
		10	Threaded Screw Inserters		

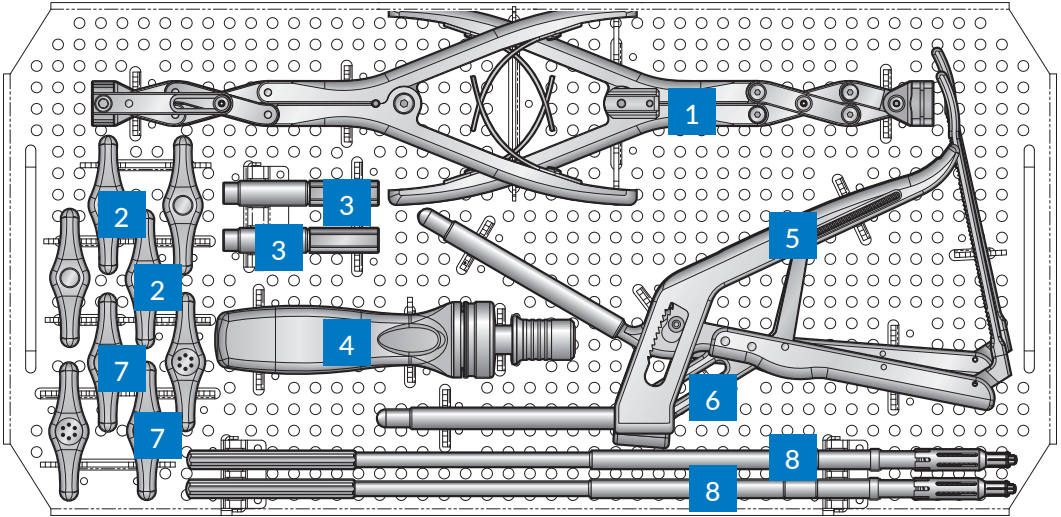


Tray Layout					
1	Counter-Torque Tube	5	Rod Caliper	9	Final Drivers
2	Cannulated Mallet	6	Fixed Rod Holder Locking Screw	10	Set Screw Inserters
3	Torque-Limiting Handle	7	Fixed Rod Holder		
4	Ø5.5mm Rod Bender	8	Extension Removal Pliers		

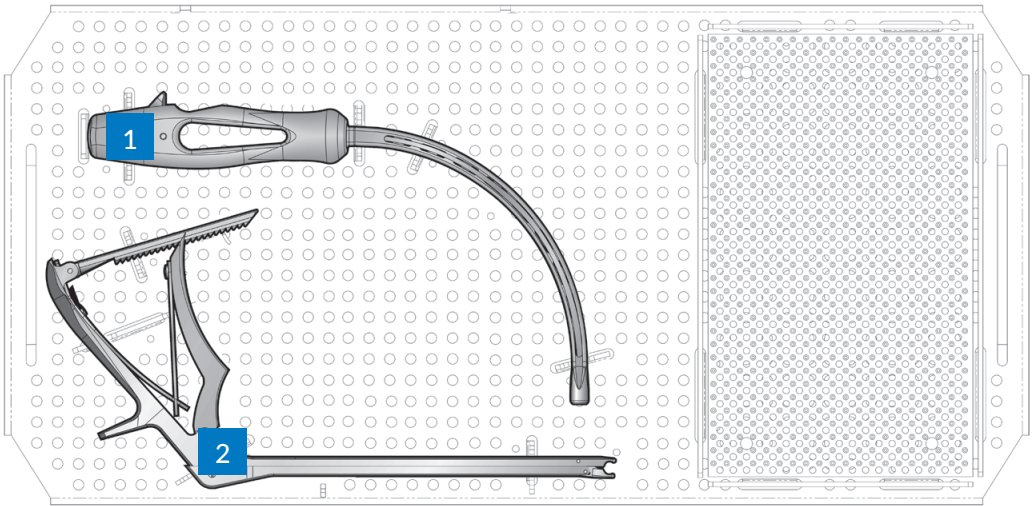


ORDERING GUIDE

Tray Layout		
1	Rod Reducer	4
2	Threaded Rod Reducer Handles	5
3	Threaded Rod Reducers	6
		7
		8



Tray Layout		
1	Curved Rod Holder	2



ORDERING GUIDE

STANDARD LOANER INSTRUMENT SET (05-LS-SLMIS-INS)

CASE 1 TOP TRAY INSTRUMENTS

Part Number	Description	Qty
04-GWTUBE	Guidewire Tube	1
51-GW-500-BLUNT	Blunt-Tip Nitinol Guidewire, Ø1.5mm x 500mm	10
05-DILATOR	Initial Dilator	1
05-TAPSLEEVE	Tap Sleeve	1
05-SCREWSLEEVE	Screw Sleeve	1
04-CANNAWL	Cannulated Bone Awl	1
04-HEADADJUSTER	Head Adjuster-Rod Pusher	1
04-CANNDRILL	Ø3.8mm Cannulated Drill	1
04-CANNTAP-45	Ø4.5mm Cannulated Tap	1
04-CANNTAP-55	Ø5.5mm Cannulated Tap	1
04-CANNTAP-65	Ø6.5mm Cannulated Tap	1
05-SIMPLEDRIVER	Simple Driver	2
05-SCREW-INS-THRD	Threaded Screw Inserter	2
04-WEDGE	Muscle Splitting Wedge	1
04-DRIVER-SLEEVE	Driver Sleeve	1
10-RTHANDLE	Ratcheting T-Handle	2
10-RSHANDLE	Ratcheting Straight Handle	1

CASE 1 BOTTOM TRAY INSTRUMENTS

Part Number	Description	Qty
04-RODCALIPER	Rod Caliper	1
10-BENDER-55	Ø5.5mm Rod Bender	1
04-FIXEDHOLDER	Fixed Rod Holder	1
04-SETSCREWINS	Set Screw Inserter	2
05-FINALDRIVER	Final Driver	2
05-CT-TUBE	Counter-Torque Tube	1
02-TL-HANDLE	Torque-Limiting Handle	1
05-EXT-REM-PLIER	Extension Removal Pliers	1
04-MALLET	Cannulated Mallet	1

CASE 2 TOP TRAY INSTRUMENTS

Part Number	Description	Qty
04-RDSETSCR-INS	Reducing Set Screw Inserter	2
04-REDUCE-INS-HNDL	Reducing Set Screw Inserter Handle	2
04-REDUCER	Rod Reducer	1
05-THRDREDUCER	Threaded Rod Reducer	2
04-THRDRED-HANDLE	Threaded Rod Reducer Handle	2
04-COMPRESSOR	Compressor	1
04-DISTRATOR	Distractor	1
10-RSHANDLE	Ratcheting Straight Handle	2

CASE 2 BOTTOM TRAY INSTRUMENTS

Part Number	Description	Qty
04-CURVEHOLDER	Curved Rod Holder	1
04-RODRETRIEVE	Rod Retriever	1

ORDERING GUIDE

STANDARD LOANER IMPLANT SET (05-LS-SLMIS-IMP)

TOP TRAY IMPLANTS

Part Number	Description	Diameter	Length	Qty
05-PA-55-30	MIS Pedicle Screw	5.5mm	30mm	4
05-PA-55-35	MIS Pedicle Screw	5.5mm	35mm	4
05-PA-55-40	MIS Pedicle Screw	5.5mm	40mm	4
05-PA-55-45	MIS Pedicle Screw	5.5mm	45mm	4
05-PA-55-50	MIS Pedicle Screw	5.5mm	50mm	4
05-PA-55-55	MIS Pedicle Screw	5.5mm	55mm	4
05-PA-65-30	MIS Pedicle Screw	6.5mm	30mm	4
05-PA-65-35	MIS Pedicle Screw	6.5mm	35mm	4
05-PA-65-40	MIS Pedicle Screw	6.5mm	40mm	6
05-PA-65-45	MIS Pedicle Screw	6.5mm	45mm	6
05-PA-65-50	MIS Pedicle Screw	6.5mm	50mm	6
05-PA-65-55	MIS Pedicle Screw	6.5mm	55mm	4
05-PA-75-30	MIS Pedicle Screw	7.5mm	30mm	4
05-PA-75-35	MIS Pedicle Screw	7.5mm	35mm	4
05-PA-75-40	MIS Pedicle Screw	7.5mm	40mm	6
05-PA-75-45	MIS Pedicle Screw	7.5mm	45mm	6
05-PA-75-50	MIS Pedicle Screw	7.5mm	50mm	6
05-PA-75-55	MIS Pedicle Screw	7.5mm	55mm	4
04-55-PR-35	MIS Pre-Bent Rod	5.5mm	35mm	4
04-55-PR-40	MIS Pre-Bent Rod	5.5mm	40mm	4
04-55-PR-45	MIS Pre-Bent Rod	5.5mm	45mm	4
04-55-PR-50	MIS Pre-Bent Rod	5.5mm	50mm	4
04-55-PR-55	MIS Pre-Bent Rod	5.5mm	55mm	4
04-55-PR-60	MIS Pre-Bent Rod	5.5mm	60mm	4
04-55-PR-65	MIS Pre-Bent Rod	5.5mm	65mm	4
04-55-PR-70	MIS Pre-Bent Rod	5.5mm	70mm	4
04-55-PR-75	MIS Pre-Bent Rod	5.5mm	75mm	4
04-55-PR-80	MIS Pre-Bent Rod	5.5mm	80mm	4
04-55-PR-90	MIS Pre-Bent Rod	5.5mm	90mm	2
04-55-PR-100	MIS Pre-Bent Rod	5.5mm	100mm	2
04-55-PR-110	MIS Pre-Bent Rod	5.5mm	110mm	2
04-55-PR-120	MIS Pre-Bent Rod	5.5mm	120mm	2
04-55-PR-130	MIS Pre-Bent Rod	5.5mm	130mm	2
04-55-PR-140	MIS Pre-Bent Rod	5.5mm	140mm	2
04-55-PR-150	MIS Pre-Bent Rod	5.5mm	150mm	2
01-SETSCREW	Set Screw			20

OPTIONAL LOANER IMPLANT SETS

OPTIONAL LOANER 4.5MM IMPLANT SET (05-LS-SLMIS-45)

Part Number	Description	Diameter	Length	Qty
05-PA-45-20	MIS Pedicle Screw	4.5mm	20mm	4
05-PA-45-25	MIS Pedicle Screw	4.5mm	25mm	4
05-PA-45-30	MIS Pedicle Screw	4.5mm	30mm	4
05-PA-45-35	MIS Pedicle Screw	4.5mm	35mm	4
05-PA-45-40	MIS Pedicle Screw	4.5mm	40mm	4
05-PA-45-45	MIS Pedicle Screw	4.5mm	45mm	4
04-CANNTAP-40	Ø4.0mm Cannulated Tap			1

OPTIONAL LOANER 8.5MM IMPLANT SET (05-LS-SLMIS-85)

Part Number	Description	Diameter	Length	Qty
05-PA-85-30	MIS Pedicle Screw	8.5mm	30mm	4
05-PA-85-35	MIS Pedicle Screw	8.5mm	35mm	4
05-PA-85-40	MIS Pedicle Screw	8.5mm	40mm	4
05-PA-85-45	MIS Pedicle Screw	8.5mm	45mm	4
05-PA-85-50	MIS Pedicle Screw	8.5mm	50mm	4
05-PA-85-55	MIS Pedicle Screw	8.5mm	55mm	4
04-CANNTAP-75	Ø7.5mm Cannulated Tap			1

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OPTIONAL LOANER STRAIGHT ROD SET (04-LS-SLMIS-STROD)

Part Number	Description	Diameter	Length	Qty
04-55-RR-35	MIS Straight Rod	5.5mm	35mm	4
04-55-RR-40	MIS Straight Rod	5.5mm	40mm	4
04-55-RR-45	MIS Straight Rod	5.5mm	45mm	4
04-55-RR-50	MIS Straight Rod	5.5mm	50mm	4
04-55-RR-55	MIS Straight Rod	5.5mm	55mm	4
04-55-RR-60	MIS Straight Rod	5.5mm	60mm	4
04-55-RR-65	MIS Straight Rod	5.5mm	65mm	4
04-55-RR-70	MIS Straight Rod	5.5mm	70mm	4
04-55-RR-75	MIS Straight Rod	5.5mm	75mm	4
04-55-RR-80	MIS Straight Rod	5.5mm	80mm	4
04-55-RR-90	MIS Straight Rod	5.5mm	90mm	4
04-55-RR-100	MIS Straight Rod	5.5mm	100mm	4
04-55-RR-110	MIS Straight Rod	5.5mm	110mm	4
04-55-RR-120	MIS Straight Rod	5.5mm	120mm	4
04-55-RR-130	MIS Straight Rod	5.5mm	130mm	4
04-55-RR-140	MIS Straight Rod	5.5mm	140mm	4
04-55-RR-150	MIS Straight Rod	5.5mm	150mm	4

OPTIONAL LOANER LONG ROD SET (05-LS-SLMIS-LNGROD)

Part Number	Description	Diameter	Length	Qty
04-55-PR-160	MIS Pre-bent Rod	5.5mm	160mm	4
04-55-PR-170	MIS Pre-bent Rod	5.5mm	170mm	4
04-55-PR-180	MIS Pre-bent Rod	5.5mm	180mm	4
04-55-PR-190	MIS Pre-bent Rod	5.5mm	190mm	4
04-55-RR-200	MIS Straight Rod	5.5mm	200mm	4
04-55-RR-210	MIS Straight Rod	5.5mm	210mm	4
04-55-RR-220	MIS Straight Rod	5.5mm	220mm	4
04-55-RR-230	MIS Straight Rod	5.5mm	230mm	4
04-55-RR-240	MIS Straight Rod	5.5mm	240mm	4
04-55-RR-250	MIS Straight Rod	5.5mm	250mm	4

MIS STRAIGHT ROD MEASUREMENT

Part Number	Etched Length	Functional Length
04-55-RR-160	160mm	163mm
04-55-RR-170	170mm	173mm
04-55-RR-180	180mm	184mm
04-55-RR-190	190mm	195mm
04-55-RR-200	200mm	206mm
04-55-RR-210	210mm	217mm
04-55-RR-220	220mm	228mm
04-55-RR-230	230mm	239mm
04-55-RR-240	240mm	251mm
04-55-RR-250	250mm	263mm
04-55-RR-300	300mm	323mm
04-55-RR-350	350mm	391mm

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TORQUE AND DRIVER INFORMATION

Part Number	Description	IN-LBS	N-m	For Usage With
02-TL-HANDLE	Torque-Limiting Handle	80	9	Final Driver

Part Number	Description	Tip	For Usage With
05-SIMPLEDRIVER	Simple Driver	T-25, Hexalobe	Cannulated Pedicle Screws
05-SCREW-INS-THRD	Threaded Screw Inserter	T-25, Hexalobe	Cannulated Pedicle Screws
04-SETSCREWINS	Set Screw Inserter	T-25, Hexalobe	Set Screws, Fixed Rod Holder Locking Screw
04-RDSETSCR-INS	Reducing Set Screw Inserter	T-25, Hexalobe	Set Screws
05-FINALDRIVER	Final Driver	T-25, Hexalobe	Set Screws

CLEANING AND STERILIZATION

CLEANING AND STERILIZATION

- Implants are provided non-sterile.
- Reusable instruments are provided non-sterile.

For specific cleaning and sterilization instructions, refer to the instructions for use provided with the device or contact Xtant Medical. See back page for contact information.

NOTES



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INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

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