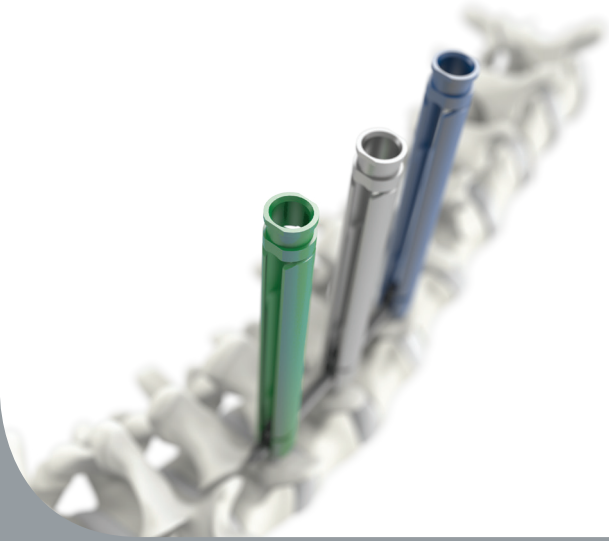
rti surgical®

# Streamline® MIS
## Spinal Fixation System
## Surgical Technique



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## SYSTEM OVERVIEW

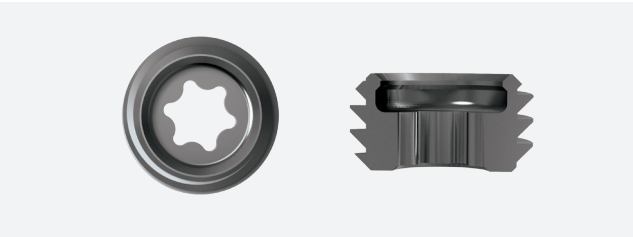
The Streamline MIS Spinal Fixation System allows a rigid construct to be created in the thoracolumbar spine via a percutaneous or mini-open approach using cannulated pedicle screws, set screws and rods. The system offers a broad range of implants and instruments providing the ability to tailor treatment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

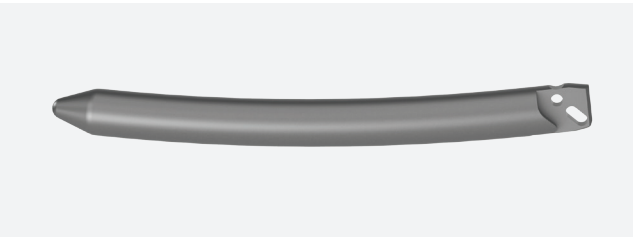

## SET SCREWS

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



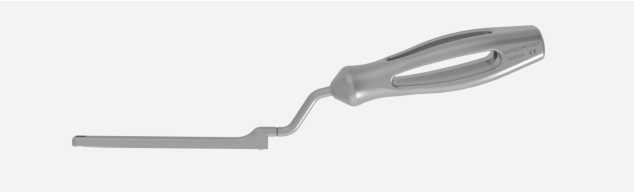
## MIS RODS

- 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



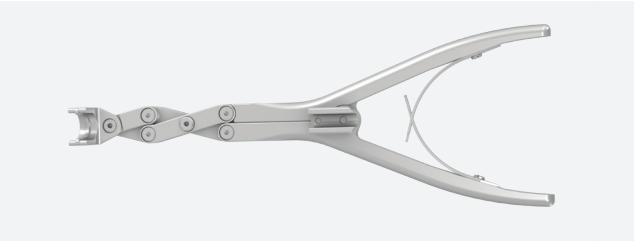
## ROD INSERTION OPTIONS

- 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



## 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.

## 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**

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

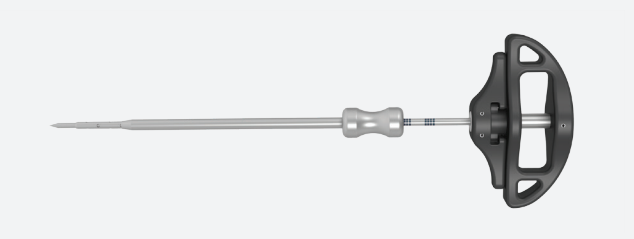


Figure 3

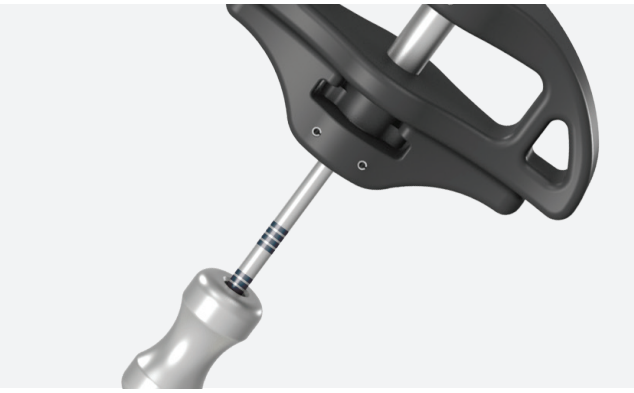


Figure 4

Figure 5

Figure 6

## 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.*

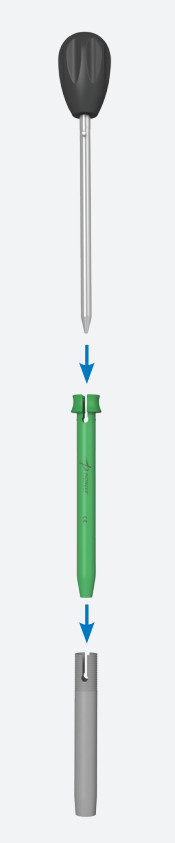


Figure 7

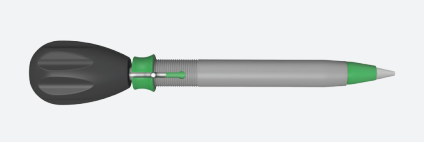


Figure 8

Figure 9

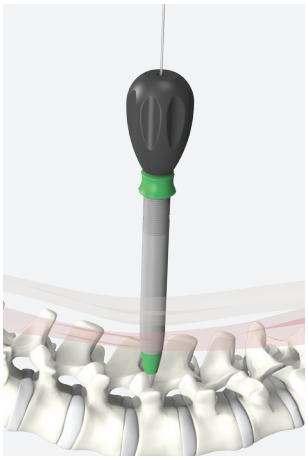


Figure 10

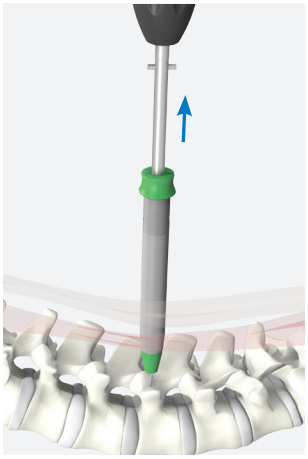


Figure 11

## 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. Over-tapping can result in 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

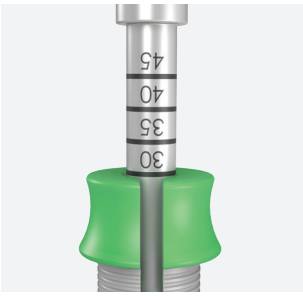



Figure 13

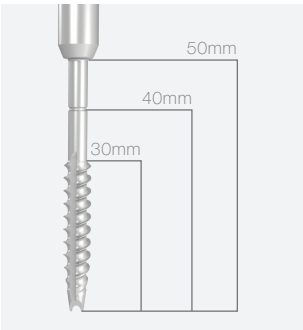



Figure 14

Figure 15

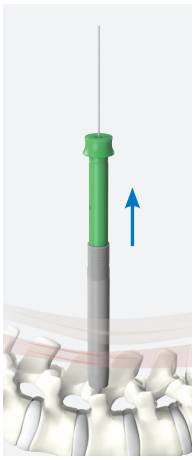


Figure 16

Figure 17

## 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.*


**Figure 18**

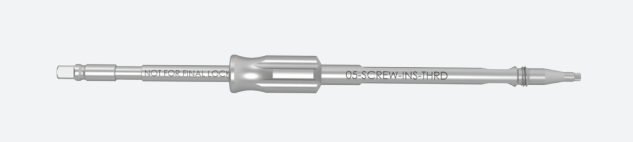



**Figure 19**

**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).

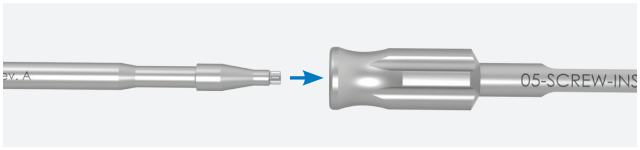



Figure 23

Figure 24

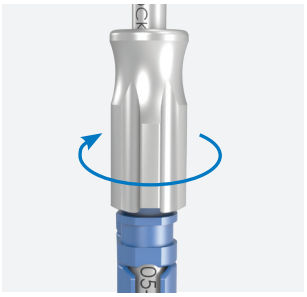


Figure 25

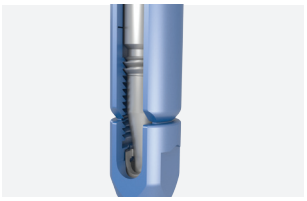


Figure 26

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 27

## 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.


## 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

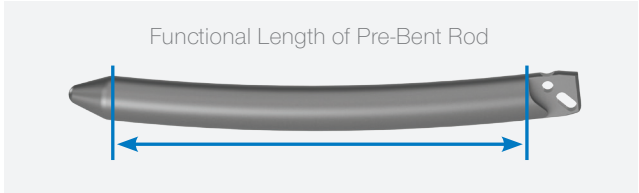



Figure 30

## 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**

## 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 three 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 ±30° 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.*

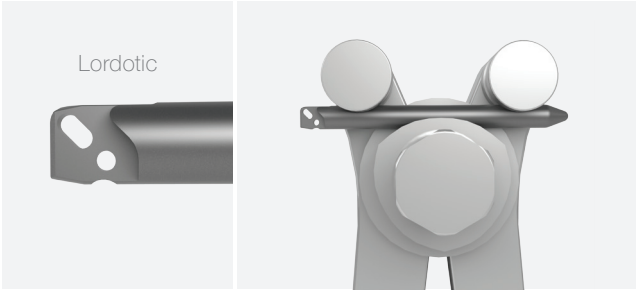



**Figure 31**

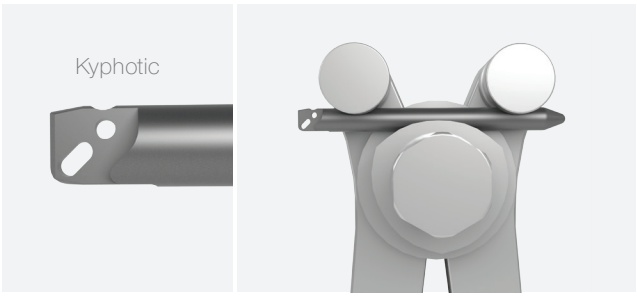



**Figure 32**

## 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.


## 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).*

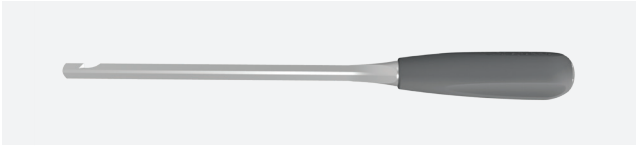


Figure 33

### 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).

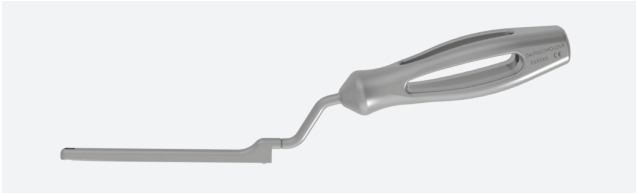


Figure 34

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

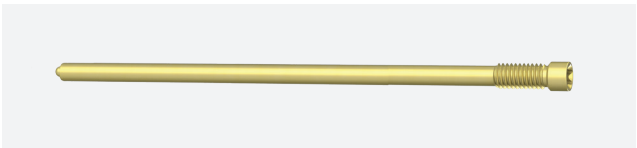


Figure 35

Figure 36

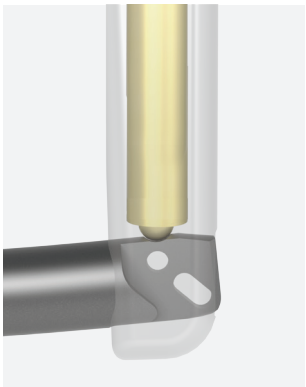


Figure 37

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.

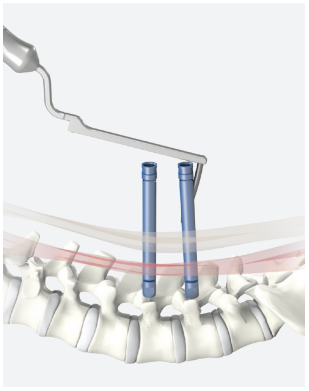


Figure 38

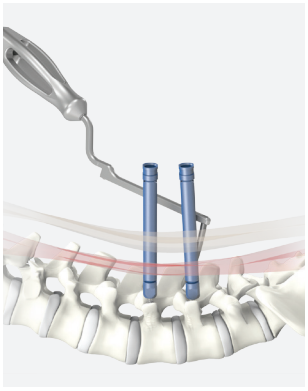


Figure 39

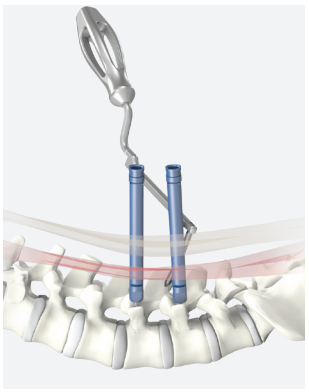


Figure 40

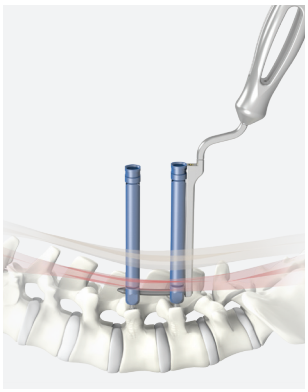


Figure 41

Figure 42

## 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.


**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

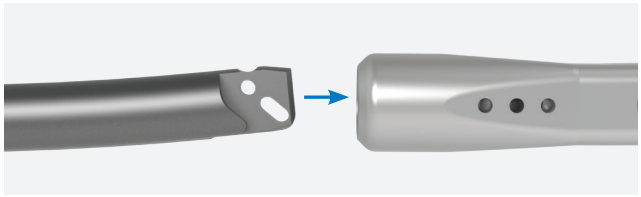


Figure 46

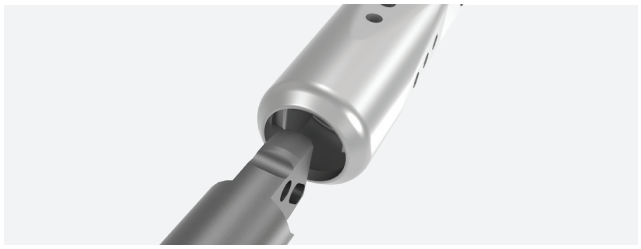


Figure 47

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.

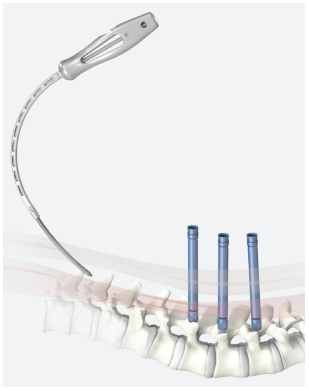


Figure 48

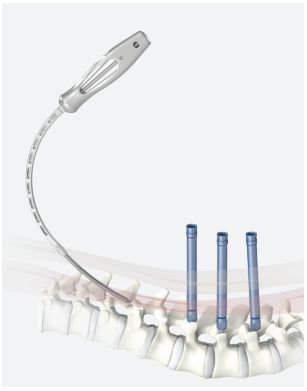


Figure 49

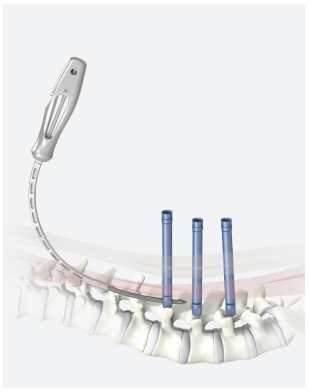


Figure 50

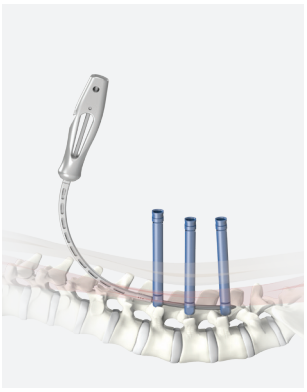


Figure 51

## 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 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

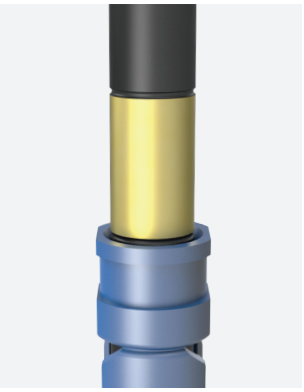


Figure 54

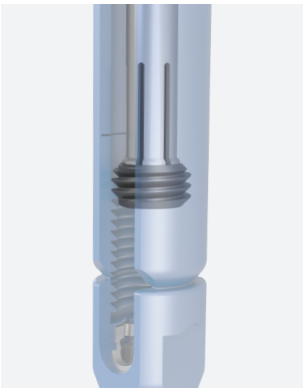


Figure 55

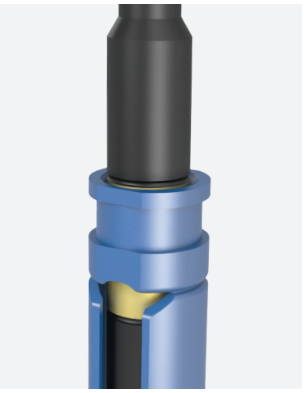


Figure 56

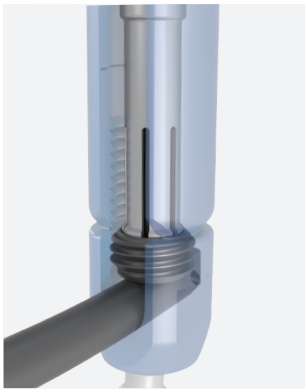


Figure 57

## 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 ±30° 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 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 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 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

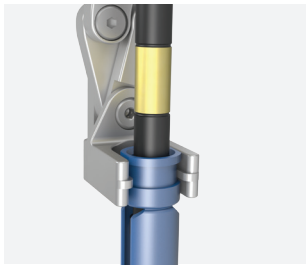


Figure 61

Figure 62

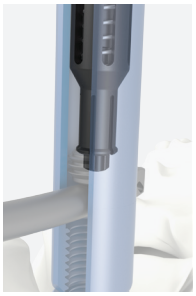


Figure 63

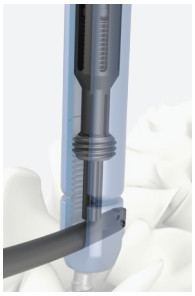


Figure 64

Figure 65

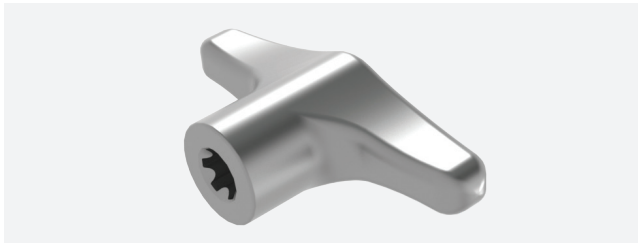


Figure 66

**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

## 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.*

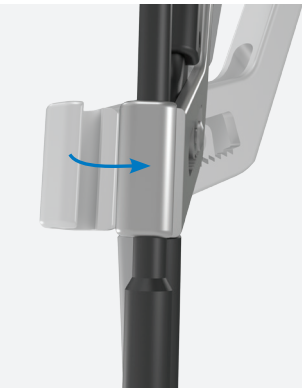


Figure 71

Figure 72

Figure 73

Figure 74

### 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 over distract 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.*

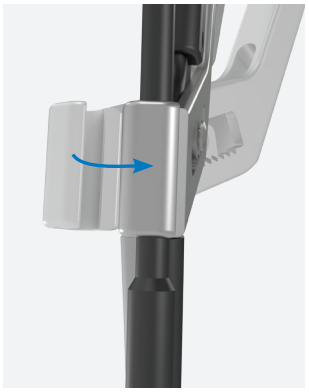


Figure 75

Figure 76

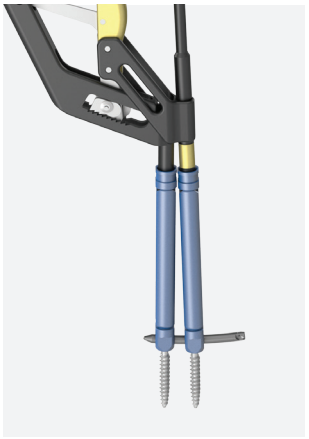


Figure 77

Figure 78

## 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). Apply no more 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**

## 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

### 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.

## STREAMLINE MIS SPINAL FIXATION SYSTEM

### INDICATIONS

The Streamline MIS Spinal Fixation System is intended for posterior, noncervical pedicle fixation, T1-S2. 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 of 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.

### WARNINGS

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 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.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- Device component fracture
- Loss of fixation
- Non-union
- Fracture of the vertebrae
- Neurological injury
- Vascular or visceral injury

The components of this device are manufactured from biocompatible implant grade materials. Mixing of certain implant components with different materials is not recommended, for metallurgical, mechanical and functional reasons.

No implant and screw system can withstand the forces of sudden dynamic loads such as falls or other accidents.

This system has not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment.

### PRECAUTIONS

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. Preoperative planning and patient anatomy should be considered when selecting pedicle screw diameter and length. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

**Implants can break when subjected to the increased loading associated with delayed union or non-union.** Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. Based on fatigue testing results, when using the Streamline MIS Spinal Fixation System, the physician/ surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early bending, loosening, or breakage. Patients should be fully informed of the risks of implant bending, loosening, or breakage.

**Only rods and crosslinks are intended to be bent or contoured.** Bending of components other than rods and crosslinks may lead to premature material fatigue of the implant. If bending or contouring of components other than rods or crosslinks occurs, those components must be discarded. Scratched or notched components, bent components other than rods or crosslinks, and components that have received a reverse bend must not be used and should be returned to Pioneer* Surgical Technology for evaluation.

**Avoid creating a sharp bend or reversing 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 Pioneer Surgical at (888) 778-8771 with any questions in regard to contouring rod prior to surgery.

**Mixing metals can cause corrosion.** There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc. which come into contact with other metal objects, must be made from like or compatible metals.

**Surgical implants must never be reused.** An explanted metal implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

**Do not reuse instruments that are labeled for single use only.** Reuse may adversely affect performance and may compromise patient and/or operator safety.

**Check packaging of sterile products.** For product that is provided sterile, do not use if sterile package has been opened or damaged. If sterile package has been opened or damaged, return the product to Pioneer Surgical Technology.

**Correct handling of the implant is extremely important.** Contouring of the metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease fatigue life and may cause fracture.

**Removal of the implant after healing.** Metallic implants can loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain, or stress shield bone even after healing, particularly in young, active patients. The surgeon should carefully weigh the risk versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risk involved with a second surgery.

**Adequately instruct the patient about the risks and benefits of the surgery and the device prior to and after the surgery.** Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in bending or fracture of the device. The product is neither designed or intended to withstand such use. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing (non-union). An active, debilitated, or demented patient who cannot properly use weight supporting devices or follow instructions may be particularly at risk of bending or fracture during postoperative rehabilitation. It is extremely important that the physician provides clear directions and warnings and obtains the utmost compliance from the patient postoperatively:

- Partial- or non-weight bearing may be recommended or required to achieve firm bone union.
- Warn patient against sudden changes in position, strenuous activity, falls, smoking, consuming alcohol or other drugs not
- prescribed by the physician, steroids, non-steroidal anti-inflammatory agents, aspirin, and mechanical vibrations or shocks that may loosen the devices.
- If appropriate, restrict patient's mobility to allow bony union.
- Device presence may cause pain, discomfort, abnormal sensations, and increased risk of infection. Instruct the patient to seek medical attention if sudden changes in appearance at the surgical site are noticed or if an unexplained increase in pain is experienced.

**The patient must be made aware of the limitations of the implant prior to agreeing to surgery.** Internal fixation devices are temporary devices that cannot support the patient's weight or movement beyond the time typically necessary for bone healing or fusion. Physical activity and full weight bearing have been implicated in bending or fracture. The patient should understand that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing including falls or other high energy events such as auto accidents. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be advised that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. Provide the patient with load bearing restrictions. The patient should be advised to inquire if any questions exist regarding the appropriate activities or environments during the healing process.

## CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of non-union and/or implant breakage.

Mental or physical impairment which compromises or prevents a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

*See product insert for complete labeling limitations related to this device.*

**Manufactured by Pioneer Surgical Technology, Inc.*
*375 River Park Circle, Marquette, MI 49855 USA.*

*Pioneer Surgical Technology, Inc. DBA RTI Surgical, Inc.*

International Sales & Marketing:
**Pioneer Surgical Technology BV**
Voorveste 7, 3992 DC Houten
The Netherlands
t: 31 30 693 47 20
f: 31 30 693 47 21
**www.rtisurgical.com**
**info-houten@rtix.com**
CoC Utrecht 30214021

**RTI Surgical, Inc.**


CE
0086

Distributed by:
**RTI Surgical, Inc.**
375 River Park Circle
Marquette, MI 49855 USA
t: 800.557.9909
**www.rtisurgical.com**



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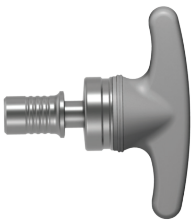
# Streamline® MIS
## Spinal Fixation System
## US Ordering Guide

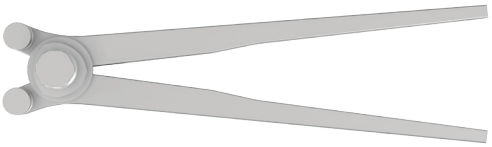
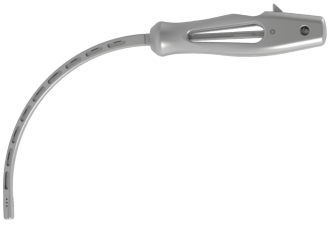
## INSTRUMENT GUIDE

| 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 Guide-wire, Ø1.5mm x 500mm | For guiding instruments and cannulated pedicle screws into the pedicle |  |

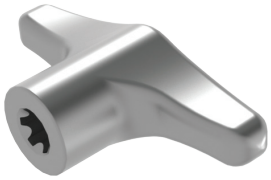
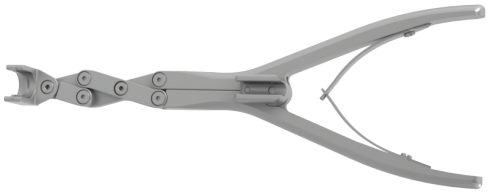
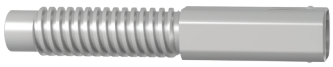
## INSTRUMENT GUIDE

| 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<br>Standard set includes 4.5, 5.5 and 6.5mm diameters (X) |  |

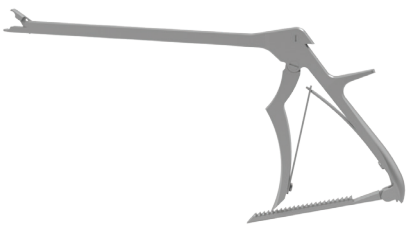
## INSTRUMENT GUIDE

| Part Number | Instrument | Description | |
|---|---|---|---|
| 05-SIMPLEDRIVER | Simple Driver | For inserting screws into pedicles |   |
| 05-SCREW-INS-THRD | Threaded Screw Inserter | 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 |  |

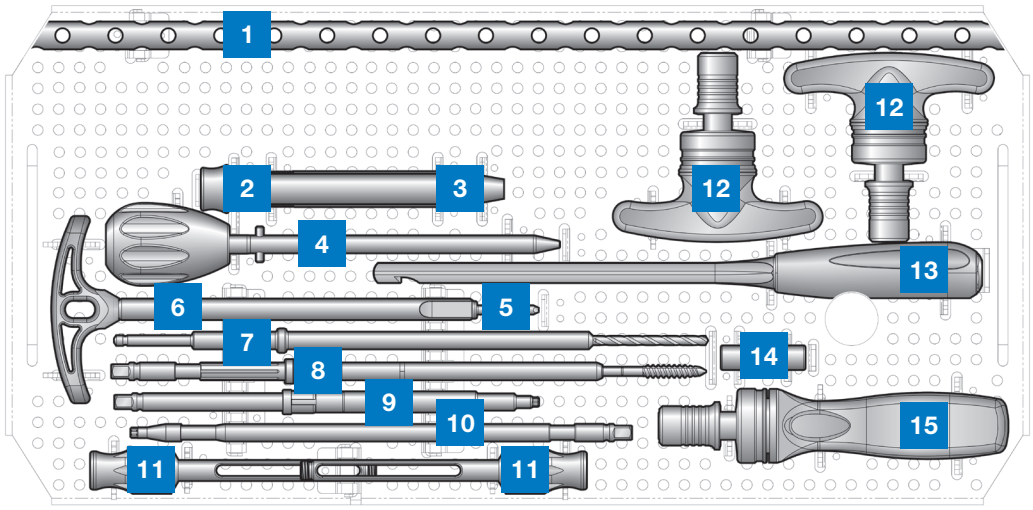
## INSTRUMENT GUIDE

| 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 |  |
| 04-RDSETSCR-INS | Reducing Set Screw Inserter | For introducing a set screw while using the reducer or threaded reducer |  |
| 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 |  |

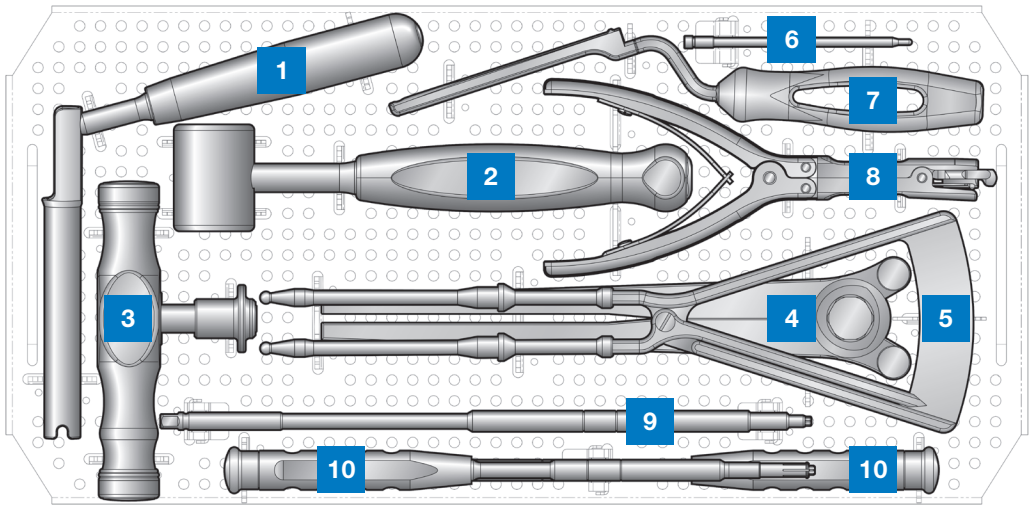
## INSTRUMENT GUIDE

| 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 |  |
| 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 |  |

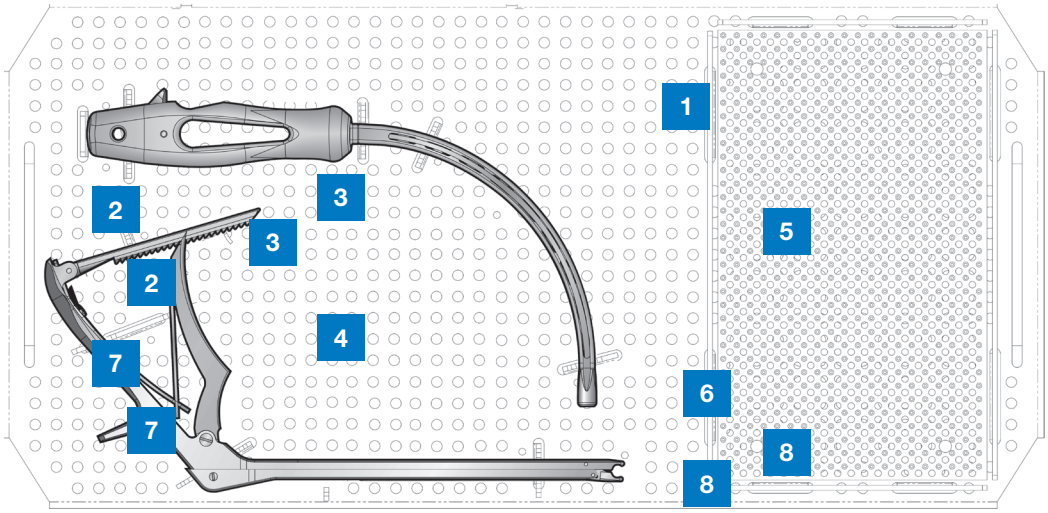
| Tray Layout | | | | | |
|---|---|---|---|---|---|
| 1 | Guidewire Tube | 6 | Head Adjuster - Rod Pusher | 11 | Threaded Screw Inserter Sleeves |
| 2 | Screw Sleeve | 7 | Ø3.8mm Cannulated Drill | 12 | Ratcheting T-Handles |
| 3 | Tap Sleeve | 8 | Cannulated Taps (Ø4.5, Ø5.5 and Ø6.5mm) | 13 | Muscle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



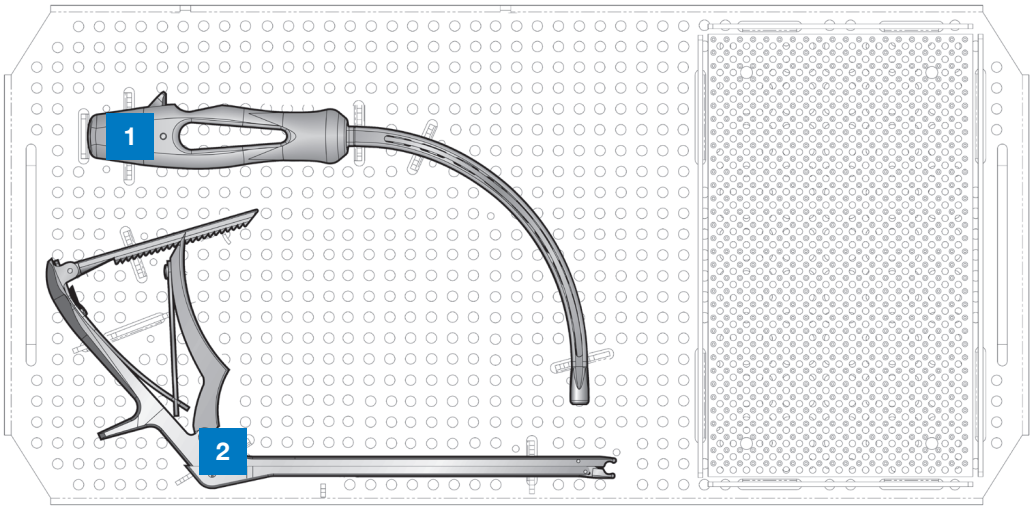

| Tray Layout | | | | | |
|---|---|---|---|---|---|
| 1 | Counter-Torque Tube | 5 | Rod Caliper | 9 | Final Drivers |
| 2 | Cannulated Mallet | 6 | Fixed Rod Holder Locking Screw | 10 | Set Screw Inserters |
| 3 | Torque-Limiting Handle | 7 | Fixed Rod Holder | | |
| 4 | Ø5.5mm Rod Bender | 8 | Extension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



| Tray Layout | | | | | |
|---|---|---|---|---|---|
| 1 | Rod Reducer | 4 | Ratcheting Straight Handle | 7 | Reducing Set Screw Inserter Handles |
| 2 | Threaded Rod Reducer Handles | 5 | Compressor | 8 | Reducing Set Screw Inserters |
| 3 | Threaded Rod Reducers | 6 | Distractor | | |




| Tray Layout | | | | |
|---|---|---|---|---|
| 1 | Curved Rod Holder | 2 | Rod Retriever | |



## 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-DISTRACTOR | 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 |

## 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 |

## 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 |

## 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 |

## 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 |

## CLEANING

### MANUAL CLEANING:

1. Disassemble the device, if applicable.
2. Rinse soiled device under running, cold tap water for a minimum of two (2) minutes. Remove gross soil using a soft bristle brush or soft, lint-free cloth.
3. Make an Enzymatic solution per the manufacturer's recommended instructions in warm tap water (approximately 33 - 43°C).
4. Soak devices in freshly prepared neutral pH enzymatic solution for a minimum of ten (10) minutes.
5. Rinse device using cool running tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water.
6. Manually clean devices for a minimum of five (5) minutes in freshly prepared neutral pH enzymatic solution. Use a syringe, pipette, or water jet to flush lumens and channels. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles, and other movable device features to expose all areas to detergent solutions. Clean device under water to prevent aerosolization of contaminants.
7. Rinse device using deionized (DI) running water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable device features in order to rinse thoroughly under running water.
8. Visually inspect device for residual soil. If present, repeat steps 1 - 7 above.
9. Gently wipe down the device components with a soft lint-free cloth. Ensure the device is completely dry. Visually inspect the device; it should be clean, dry and residue-free.

### MANUAL DISINFECTION:

1. Ensure device is clean, free of residual detergents, and dry prior to manual disinfection using validated manual cleaning instructions.
2. Prepare instrument(s) for disinfection by using appropriate size container to accommodate full submersion into solution.
3. Fully submerge instrument(s) into CIDEX OPA solution. Ensure all lumens are filled with solutions to prevent air pockets.
4. Soak devices in CIDEX OPA solution for twelve (12) minutes at 20°C.
5. Rinse device using cool running water for a minimum of one (1) minute. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water.
6. REPEAT the rinse procedure, as described in Step 5, for an additional two (2) times using fresh water for a total of three (3) separate rinses.
7. Rinse device with 70% IPA (Isopropyl Alcohol) to promote drying.

## AUTOMATED (MECHANICAL) CLEANING:

### Pre-Cleaning Method for Automated Process

1. Rinse the device components under running lukewarm running tap water (22° - 43°C) for a minimum of one (1) minute. After rinsing, remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth.
2. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
3. Fully immerse the device components in the fresh, newly prepared enzymatic cleaning solution for a minimum of five (5) minutes.
4. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft-bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10mL of the cleaning solution.
5. Remove the device components from the cleaning solution and place the device components in a bath of lukewarm tap water (22 - 43°C) for a minimum of one (1) minute. Ensure that the water immerses the device components. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10mL of the water.

### Automated Process

1. Place the device components in the automated washer.
2. Perform the automated cycle in Table 1.
3. Visually inspect the device; it should be clean, dry and residue-free.

| Cycle | Time (Minutes:Seconds) | Minimum Temperature | Type of Detergent |
|---|---|---|---|
| Enzyme Wash | 4:00 | Heated Hot Water (60°C) | Enzymatic Cleaner Per MFG's Instruction |
| Wash | 2:00 | Hot Water | Neutral Detergent per the MFG's Instructions |
| Rinse | 2:00 | Heated Deionized or High Purity Water (70°C) | NA |
| Dry | 15:00 | 80°C | NA |

**Table 1**

## AUTOMATED THERMAL DISINFECTION:

- Thermal disinfection at 93°C for ten (10) minutes with demineralized water.

## STERILIZATION

The Streamline MIS Spinal Fixation System is supplied clean with both sterile and non-sterile components. ISO 8828 or AORN recommended practices for in-hospital sterilization should be followed for all non-sterile components. Use of an FDA cleared wrap is recommended to ensure product sterility.

### RECOMMENDATIONS FOR STEAM STERILIZATION:

Independent testing has shown the following minimum conditions to be effective:

Within USA:

| Method | Cycle | Temperature | Exposure Time | Dry Time |
|---|---|---|---|---|
| Steam | Pre-vacuum (Wrapped) | 132°C (270°F) | 4 Minutes | 40 Minutes |

**Table 2**

- Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted.
- The values specified here (duration/temperature) can achieve a safety level (SAL = Sterility Assurance Level) of at least $10^{-6}$ (according to DIN EN 556).
- A 40 minute Dry Time is recommended.

## 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 |

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Distributed by:
**RTI Surgical, Inc.**
375 River Park Circle
Marquette, MI 49855 USA
t: 800.557.9909
**www.rtisurgical.com**



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