Streamline® TL

Cannulated Polyaxial Pedicle and Reduction Pedicle Screws

Supplement to **Streamline® TL** *Spinal Fixation System Surgical Technique*

SURGICAL TECHNIQUE

DESCRIPTION

The Streamline TL Spinal System consists of a variety of rods, screws (poly-axial, fixed, and reduction), rod connectors, crosslinks, set screws, hooks and other connecting components used to build a spinal construct. The implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case. The Streamline TL Spinal System includes Class I manual instrumentation to facilitate implantation of the device components.

INDICATIONS FOR USE

The Streamline TL Spinal Fixation System components are non-cervical spinal fixation devices intended as an adjunct to fusion for use as a pedicle screw (T1-S2), posterior hook (T1-L5) or sacral/iliac screw fixation. Pedicle screw fixation is limited to skeletally mature patients. These devices are indicated for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma, (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudarthrosis, and failed previous fusion.

INTRODUCTION

SURGICAL TECHNIQUES

PATIENT POSITIONING AND PEDICLE PREPARATION

CANNULATED POLYAXIAL PEDICLE SCREWS

CANNULATED POLYAXIAL REDUCTION PEDICLE SCREWS

INTRODUCTION

System Overview

The Streamline TL Spinal Fixation System allows a rigid construct to be created in the thoracolumbar spine using pedicle screws, set screws, rods and Streamline TL crosslinks. 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.

This supplement to the Streamline TL Spinal Fixation System Surgical Technique provides instructions to implant the cannulated polyaxial pedicle screws and cannulated polyaxial reduction pedicle screws. Rod contouring, rod insertion and use of other Streamline TL Spinal Fixation System instruments and implants should be completed as described in the Streamline TL Spinal Fixation System Surgical Technique.

Cannulated Polyaxial Pedicle Screw

- Double lead thread design for faster implantation
- 60° conical screw angulation provides intraoperative flexibility
- Friction fit screw head designed for greater control
- Standard diameters: 5.5, 6.5 and 7.5mm
- Optional diameters: 4.5 and 8.5mm
- Screw lengths: range from 20-60mm, depending on screw diameter
- Composed of Ti-6Al-4V

Cannulated Polyaxial Reduction Pedicle Screw

- Double lead thread design for faster implantation
- 60° conical screw angulation provides intraoperative flexibility
- Friction fit screw head designed for greater control
- Standard diameters: 5.5, 6.5 and 7.5mm
- Optional diameters: 4.5 and 8.5mm
- Screw lengths: range from 20-60mm, depending on screw diameter
- Composed of Ti-6Al-4V

Patient Positioning and Pedicle Preparation

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

- Insert the pedicle targeting needle (Figure 1) 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.

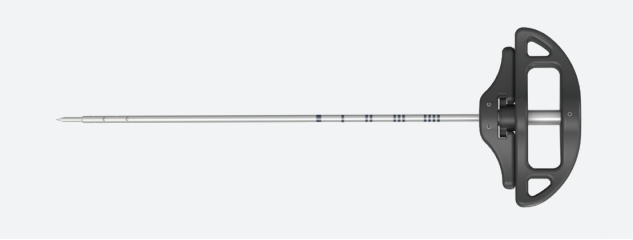


Figure 1

Pedicle Targeting and Guidewire Placement *continued*

- 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 degrees 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: Handles are located in the Streamline TL Instrument Set.

  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.

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

Figure 2

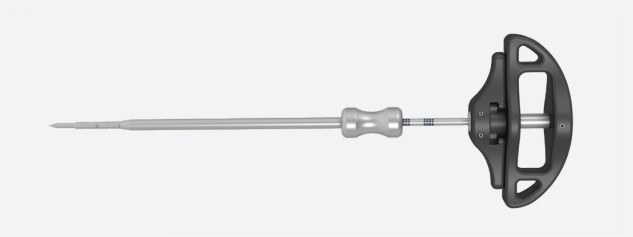


Figure 3

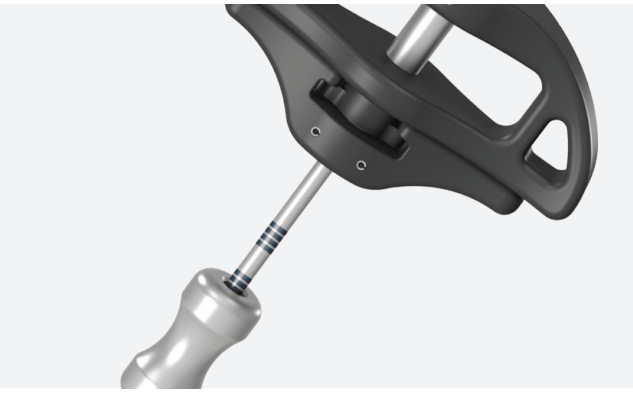


Figure 4

Figure 5

Figure 6

Step 3: Pedicle Preparation

If the patient has sclerotic bone, the cannulated bone awl (Figure 7) can be used to penetrate the cortex in order to gain access to the vertebral body.

Slide the universal tap sleeve (Figure 8) over the desired tap, then attach the tap to a handle (Figure 9) and slide it over the guidewire to the bone (Figure 10). Advance the tap by turning the handle clockwise while applying firm downward pressure, cutting threads into the pedicle (Figure 11).

Caution: 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.

Remove the tap while keeping the guidewire in place (Figure 12).

Figure 7

Figure 8

Figure 9

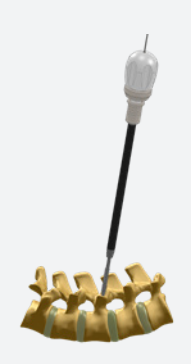


Figure 10

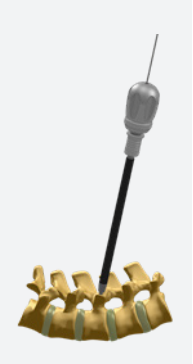
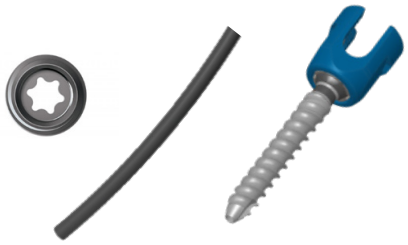


Figure 11

Figure 12

Cannulated Polyaxial Pedicle Screws

The Streamline TL cannulated polyaxial pedicle screw accepts the Streamline TL set screw (01-SETSCREW) and Ø5.5mm Streamline TL spinal rods.



Step 1: Cannulated Polyaxial Pedicle Screw Insertion

- Attach the cannulated pedicle screw inserter (02-SCREWINSRTR-C) to a handle, then insert the screw inserter into the head of a cannulated pedicle screw mounted in its caddy (Figure 13A). Rotate the collar on the screw inserter clockwise to engage the threads in the pedicle screw head and tighten (Figure 13B). Verify the threads on the screw inserter are fully engaged into the pedicle screw head (Figure 13C).

  After loading a screw onto the screw inserter, place it over the guidewire and slide it down to the bone. Rotate the handle clockwise to implant the screw into the pedicle (Figure 14). Continue rotating the handle until the screw is at the appropriate depth. Keep the screw and inserter in line with the guidewire during insertion. Use fluoroscopy to confirm the trajectory and depth of the screw.

  After the pedicle screw is implanted to the appropriate depth, rotate the collar on the screw inserter counterclockwise to disengage the screw inserter from the pedicle screw (Figure 15).

  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 when leverage forces are applied.

  It is recommended to keep the screw inserter completely on axis with the screw shaft when removing the screw inserter from the implanted screw (Figure 16). To accomplish this 1) retract any soft tissue that may be impinging against the screw inserter and 2) avoid bottoming the tulip head against the bony elements in order to maintain its polyaxial characteristics.

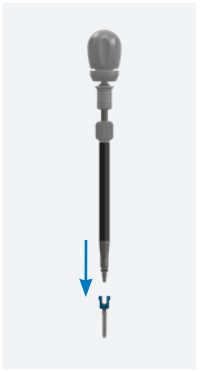


Figure 13A

Figure 13B

Figure 13C

Figure 14

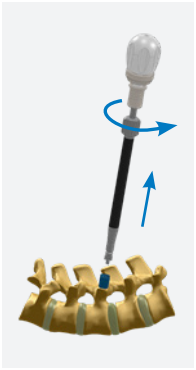


Figure 15

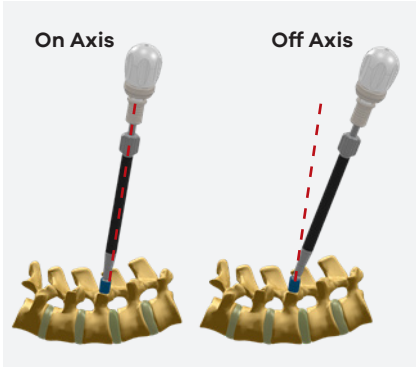


Figure 16

Step 2: Set Screw Insertion

- After screw insertion, place the desired rod into the pedicle screw head (Figure 17). Retain a set screw from the caddy on the tip of the set screw inserter. With the rod seated in the screw head, introduce the set screw with the inserter and rotate clockwise to advance the set screw until the set screw rests on top of the rod. Pull straight back to disengage the set screw inserter from the set screw.

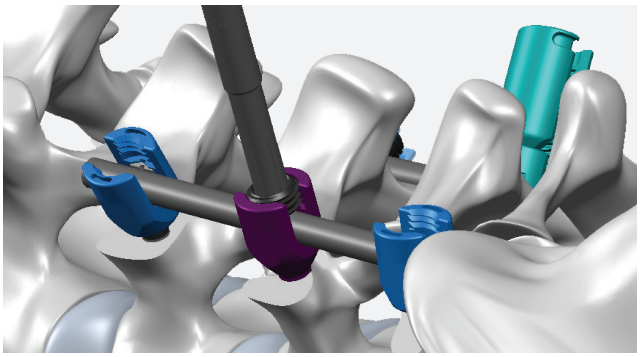


Figure 17

Step 3: Final Set Screw Locking

- Final lock by inserting the counter-torque tube (02-C-TORQUE) over the pedicle screw and down onto the rod (Figure 18A). Insert the final driver attached to the torque-limiting handle and engage the set screw. Holding the counter-torque tube in place, rotate the handle clockwise (Figure 18B) until it emits an audible or tangible "click." Remove all instruments and final lock all remaining set screws.

  Note: The 02-FINALDRIVER, 02-TL-HANDLE and 02-C-TORQUE are located in the Streamline TL Instrument Set.

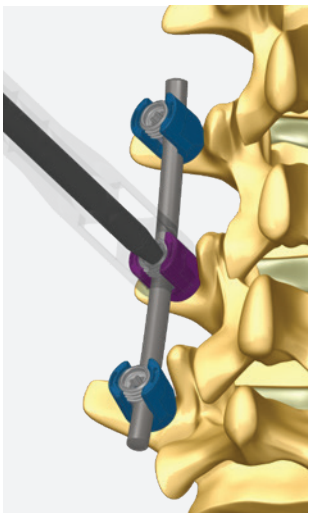


Figure 18A

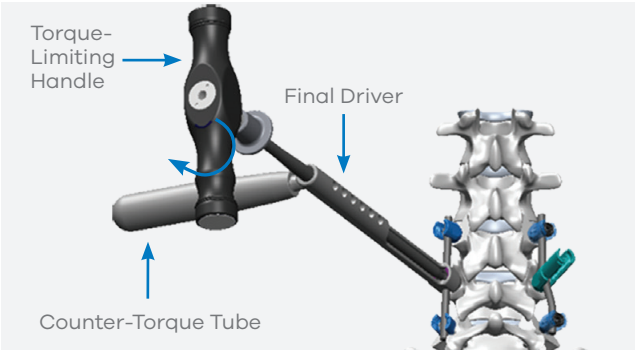
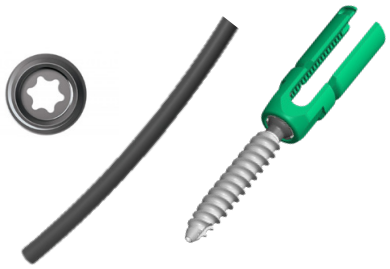


Figure 18B

Cannulated Polyaxial Reduction Pedicle Screws



The Streamline TL cannulated polyaxial reduction screw accepts the Streamline TL set screw (01-SETSCREW) and Ø5.5mm Streamline TL spinal rods. The Streamline TL reduction screw includes an implantable portion (similar to the Streamline TL cannulated polyaxial screw) with the addition of disposable reduction tabs that provide up to 20mm of reduction.

Step 1: Cannulated Polyaxial Reduction pedicle Screw Insertion

- Attach the cannulated reduction pedicle screw inserter (02-RS-INSERTER-C) to a handle, and then insert the screw inserter into the head of a cannulated reduction pedicle screw (Figure 19A). Rotate the collar on the screw inserter clockwise to engage the threads in the screw head and tighten (Figure 19B).

  After loading a screw onto the screw inserter (Figure 19C), place it over the guidewire and slide it down to the bone. Rotate the handle clockwise to implant the screw into the pedicle (Figure 20). Continue rotating the handle until the screw is at the appropriate depth, while maintaining clearance with the bony elements. Keep the screw and inserter in line with the guidewire during insertion. Use fluorocopy to confirm the trajectory and depth of the screw.

  After the pedicle screw is implanted to the appropriate depth, rotate the collar on the screw inserter counter-clockwise to disengage the screw inserter from the pedicle screw (Figure 21).

  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 when leverage forces are applied.

  It is recommended to keep the screw inserter completely on axis with the screw shaft when removing the screw inserter from the implanted screw (Figure 22). To accomplish this 1) retract any soft tissue that may be impinging the screw inserter and 2) avoid bottoming the tulip head against the bony elements in order to maintain its polyaxial characteristics.

Figure 19A

Figure 19B

Figure 19C

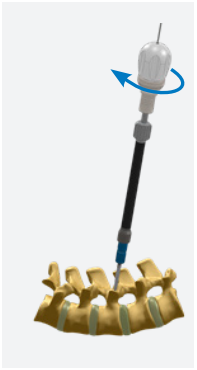


Figure 20

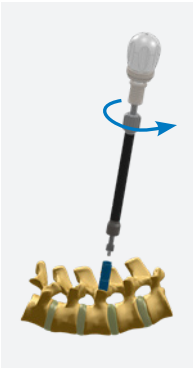


Figure 21

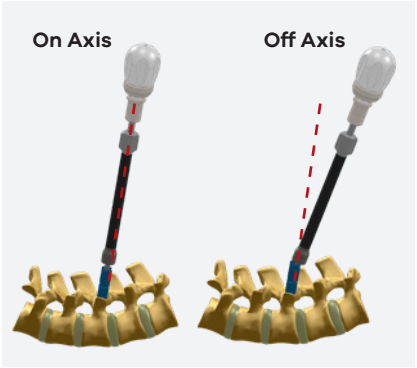


Figure 22

Streamline TL Cannulated Reduction

Step 2: Set Screw Insertion

- After screw insertion, place the desired rod into the reduction screw head (Figure 23A). Retain a set screw from the caddy on the tip of the set screw inserter (Figure 23B). With the rod in the screw head or within the reduction tabs, use the set screw inserter to insert the set screw and rotate clockwise until the set screw rests on top of the rod (initial engagement).

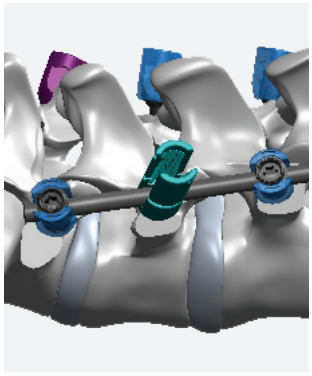


Figure 23A

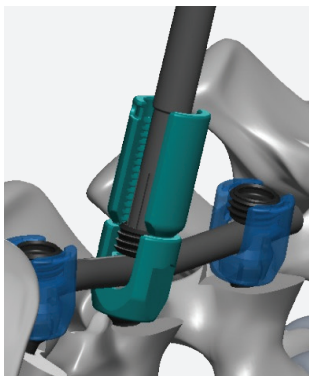


Figure 23B

Step 3: Final Set Screw Locking

- Final lock by inserting the reduction counter-torque tube (02-RS-C-TORQUE) over the reduction pedicle screw (Figure 24A) and down onto the rod (Figure 24B). Insert the final driver attached to the torque-limiting handle and engage the set screw. Holding the reduction counter-torque tube in place, rotate the handle clockwise (Figure 24C) until it emits an audible or tangible "click." Remove all instruments and final lock all remaining set screws.

  Note: After final locking of the set screw, use the tab breaker to remove the disposable reduction tabs.

  Orient the tab breaker (02-RS-TAB-BREAKER) by inserting the flat jaw inside the reduction tab and rest the plier on the inner flat surface of the reduction tab. Make sure that the outer curved jaw is aligned on the reduction tab before applying force (Figure 25A).

  Squeeze the handle of the tab breaker to retain the reduction tab (Figure 25B). Break the reduction tabs off by rocking in a side-to-side motion (Figure 25C).

  Repeat steps above to remove additional reduction tabs and discard.

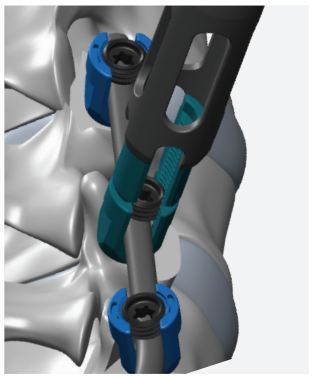


Figure 24A

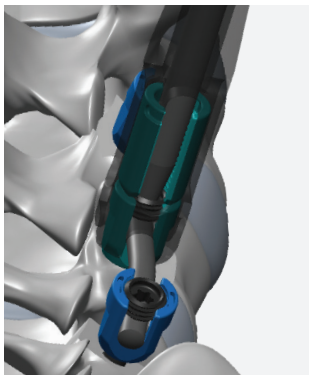


Figure 24B

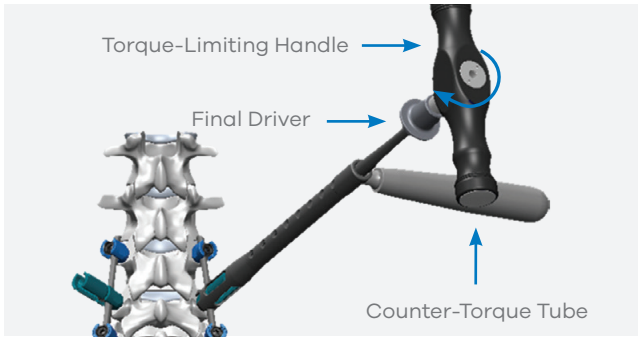


Figure 24C

Figure 25A

Figure 25B

Figure 25C

Crosslink Attachment (Optional)

- The Streamline TL crosslinks are designed to traverse two rods in a posterior spinal fixation construct (Figure 26). Crosslinks are utilized for additional construct stability of posterior constructs to support spinal fusion. The Streamline TL Crosslink System consists of both variable and fixed crosslinks to accommodate rod distances ranging from 16-85mm.

  Note: Streamline TL crosslinks are not part of the Streamline TL set. Please contact Customer Service to order Streamline TL Crosslink Set (02-STRMLN-XLNK).

  Note: Fixed crosslinks are not available in the standard set. Call Customer Service to order these crosslinks. (The fixed benders are standard in the set.)

  Note: For Streamline TL crosslink insertion or removal instructions, please reference the Streamline TL Crosslink Surgical Technique.

Figure 26

Removal (If necessary)

- To remove the construct, rotate counterclockwise to loosen its components and remove them in the opposite order in which the construct was built. Use the ratcheting palm or T-handle with final driver for set screw removal.

NOTES

NOTES

NOTES

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

LIMITED WARRANTY and DISCLAIMER: Xtant Medical products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information. CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Streamline® is a registered trademark of Xtant Medical.

XTANT MEDICAL

888-886-9354
cs@xtantmedical.com
xtantmedical.com