

STREAMLINE® TL

SPINAL FIXATION SYSTEM

SURGICAL TECHNIQUE



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STREAMLINE TL SYSTEM OVERVIEW

The Streamline TL System allows the surgeon to create a rigid construct in the thoracolumbar spine using titanium 6AL4V alloy pedicle screws, set screws, rods, and X-Link connectors.

Pedicle Screws

- Standard screw sizes: Ø5.5mm, Ø6.5mm and Ø7.5mm
- Optional screw sizes: Ø4.5mm, Ø8.5mm and Ø9.5mm
- Lengths range from 20mm – 100mm, depending on screw diameter
- 60° conical screw angulation provides intraoperative flexibility
- Friction fit screw head designed for greater control



Set Screws

- Designed to reduce the incidence of cross-threading
- Fits all screw sizes



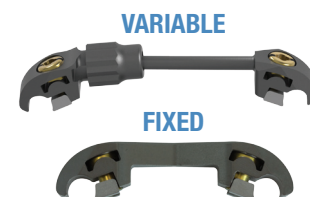
Rapid Reducer

- A robust rod reduction instrument
- Reduction capability of 25mm or less
- Fast and easy-to-use



X-Link® Connectors

- For additional construct stability
- Variable X-Link size range: 30mm – 80mm
- Fixed X-Link size range: 11mm – 30mm
- Etched lines on X-Link to provide visual verification of locked position



STEP 1

PATIENT POSITIONING

Place the patient in the prone position. Clean the operative area and make an incision at the appropriate level(s). Apply lateral C-arm fluoroscopy or other radiographic techniques during surgery to ensure correct implant placement.

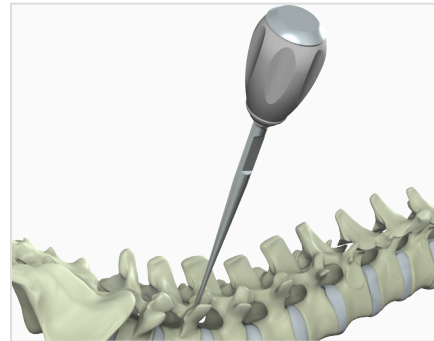


Figure 1

STEP 2

PEDICLE PREPARATION

Use the Bone Awl to perforate the pedicle's cortex. Use the Pedicle Finder to dissect through the cancellous bone to the appropriate depth for tapping and screw insertion. Etched markings on the Pedicle Finder indicate its depth (Figure 1).

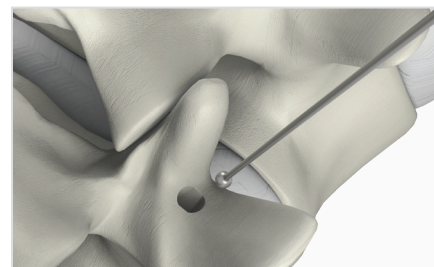


Figure 2

STEP 3

CHECK CORTEX INTEGRITY

Insert the Probe in the hole to check cortex integrity in all directions (Figure 2).



Figure 3

STEP 4

PEDICLE TAP

Attach the appropriate Tap to a handle, insert the Tap in the hole prepared in the pedicle and rotate the handle clockwise to tap a thread in the pedicle (Figure 3). The Taps are marked to indicate depth. The rotating sleeve of the Tap may be held for additional stability.



STEP 5

SCREW INSERTION

Attach the Screw Inserter to a Handle, then insert the Screw Inserter into the head of a pedicle screw mounted in its caddy (Figure 4A). Rotate the collar on the Screw Inserter clockwise to engage the threads in the pedicle screw head (Figure 4B). Verify the threads on the Screw Inserter are fully engaged into the pedicle screw head (Figure 4C).

Insert the screw into the prepared pedicle and rotate the Handle clockwise to advance (Figure 5). The rotating sleeve of the Screw Inserter may be held for additional stability.

NOTE: Upon insertion of the screw into the pedicle, leave the screw head slightly proud to ensure polyaxial capability is maintained.

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 6).

NOTE: Avoid using the Screw Inserter to adjust screw depth after disengaging. Use the 02-FINALDRIVER and/or 10-SWIZZLESTIK to readjust the screw.

SURGICAL PEARL: It is recommended to keep the Screw Inserter completely on axis with the screw shaft when removing the Driver from the implanted screw (Figure 7). 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 4A

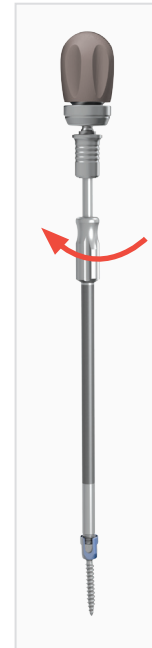


Figure 4B



Figure 4C



Figure 5



Figure 6



Figure 7

STEP 6

ROD CONTOUR (IF NECESSARY)

To make changes to the contour of the rod, select an appropriate bend radius, and place the rod between the rollers of the Rod Bender (Figure 8). There are three different bend radius settings on the center roller. Compress the Rod Bender until the desired contour is achieved.

NOTE: 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 Pioneer Surgical at (888) 778-8771 with any questions in regard to contouring rod prior to surgery.

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

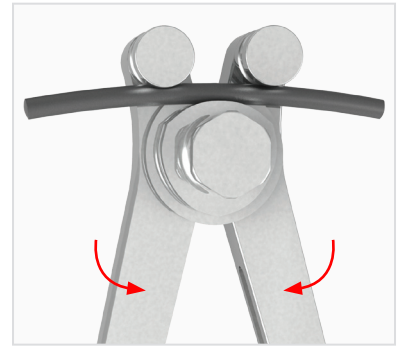


Figure 8



STEP 7

ROD AND SET SCREW INSERTION, ROD REDUCTION

Insert the rod in the most cephalad or caudal pedicle screw head (Figure 9).

Use the Rod Forceps (10-RODFORCEP-S) to control insertion of the rod into the construct.

NOTE: Ensure that the rod extends slightly beyond the cephalad and caudal ends of the screw head.

Insert the Set Screw Inserter into a set screw mounted in its caddy until it is retained on the tip of the instrument (Figures 10A and 10B). A second set screw can be loaded onto the other end of the Inserter, to save time.

With the rod seated in the screw head, insert the Set Screw Inserter and rotate clockwise until the set screw rests on top of the rod (Figure 11). Pull straight back to disengage the Set Screw Inserter from the set screw.

NOTE: In order to reduce the incidence of cross-threading, slowly rotate the set screw counter-clockwise until it drops and seats in the screw head. Turn clockwise until resistance is felt and construct is locked.

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

Rod Reduction Technique

If needed, the rod can be reduced into the screw head to assist with set screw insertion. Either of the following instruments may be used.

Manipulator, Angled (02-MANIPANGLED)

Fit the forked end of the Manipulator over the rod and engage the sides of the pedicle screw head (Figure 12). Tilt the instrument to reduce the rod into the screw head, then use the Set Screw Inserter to deploy a set screw into the screw head as described above (Figure 13).

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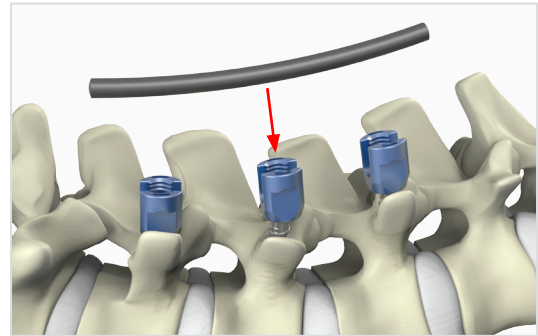


Figure 9



Figure 10A

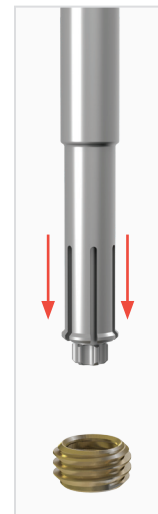


Figure 10B



Figure 11

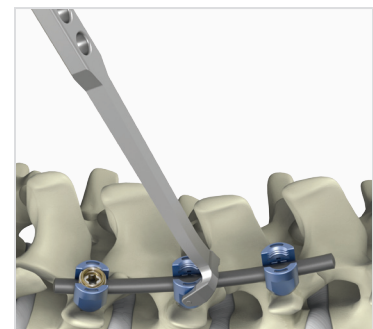


Figure 12

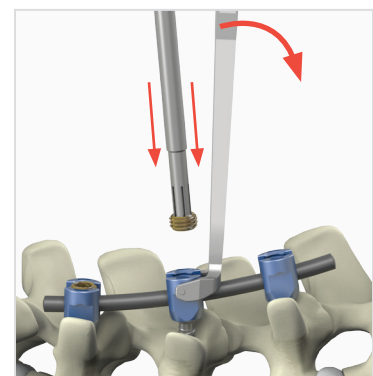


Figure 13

Rapid Reducer (02-RAPIDREDUCR)

To prepare the Rapid Reducer for use, rotate the silver collar counterclockwise in the “REMOVE” direction. Rotate the T-Handle counterclockwise until the driver fully retracts and the jaws flare out to accept the screw head (Figure 14).

Position the tip of the instrument over the rod and screw (Figure 15). Rotate the silver collar clockwise in the “ADVANCE” direction. Rotate the T-Handle clockwise allowing the jaws to engage both sides of the screw head. Continue rotating the T-Handle until the rod is fully reduced. Verify full reduction, etch line labeled “REDUCED” should be visible and the T-handle should be parallel with the spinal rod.

Load a set screw onto the Set Screw Inserter as described previously. Pass the set screw and Inserter through the Rapid Reducer until the set screw reaches the screw head (Figure 16). Rotate the Inserter clockwise to deploy the set screw in the screw head until it reaches the rod (Figure 17), then pull the inserter straight back to disengage it from the set screw. Remove the Inserter from the Rapid Reducer.

To disengage the Rapid Reducer from the screw head, rotate the silver collar counterclockwise to the “REMOVE” position and rotate the T-Handle counterclockwise (Figure 18).

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



Figure 14



Figure 15

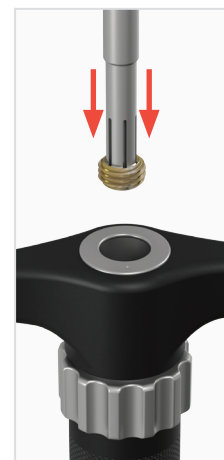


Figure 16



Figure 17

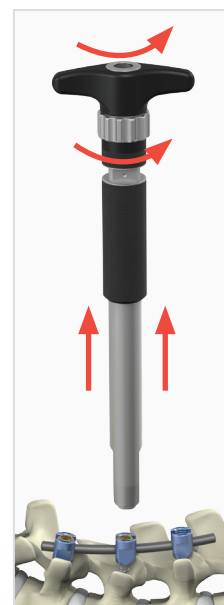


Figure 18



STEP 8

FINAL LOCKING

Complete the construct by repeating the preceding steps for the contra-lateral side.

Attach the Final Driver (02-FINALDRIVER) to the Torque-Limiting Handle (02-TL-HANDLE). Seat the tip of the Counter-Torque Handle over a pedicle screw and rest it on top of the rod (Figure 19). Insert the Final Driver through the Counter-Torque Handle and engage the set screw (Figure 20).

Holding the Counter-Torque Handle in place, rotate the Torque-Limiting Handle clockwise until it emits an audible and/or tangible “click” (Figure 20). Apply no more torque.

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

Alternate Locking Option

The Rapid Reducer can also be used during final locking of the construct. Attach the Final Driver to the Torque-Limiting Handle and pass it through the Rapid Reducer as shown. Attach the Rapid Reducer Counter-Torque Handle to the Rapid Reducer and hold it in place while rotating the Torque-Limiting Handle clockwise until it emits an audible and/or tangible click. Apply no more torque (Figure 21).

NOTE: Final Driver (PN 02-FINALDRIVER) must be used in combination with Torque-Limiting T-Handle (PN 02-TL-HANDLE) to complete final set screw locking.



Figure 19



Figure 20



Figure 21

STEP 9

X-LINK ATTACHMENT

Use the X-Link Gauges to determine the appropriate X-Link length, measuring the distance between the centers of the construct's two rods (Figure 22). Select the fixed or variable X-Link connector that is closest to this measurement.

Use the X-Link Holder to place the ends of the X-Link connector on the construct's rods (Figure 23). Verify that the X-Link connector is fully seated on the rods. If bending is required, follow "Optional Step: Bending" on the following page.

To lock the X-Link connector to the rods, align the etch lines on the X-Link Driver with the lines on the X-Link Connector Fastener, and insert the Driver. Rotate the Driver clockwise one quarter turn to lock the end of the X-Link Connector to the rod (Figure 24). Visually verify that the etched lines on the X-Link Connector are aligned to ensure that the connector is in a locked position. Repeat this step for the other end of the X-Link Connector.

If using a variable X-Link connector, its centerlink must also be tightened. First, finger tighten the centerlink. Note the direction in which the arrow indicator on the centerlink points, and orient the X-Link Wrench such that its arrow indicator points in the same direction. Grasp the end of the X-Link Wrench (Figure 25) and engage the centerlink. Tighten the centerlink, stopping when the break-away handle activates (Figure 26).

To loosen the centerlink, engage it with the Centerlink Removal Wrench and rotate it in the opposite direction.

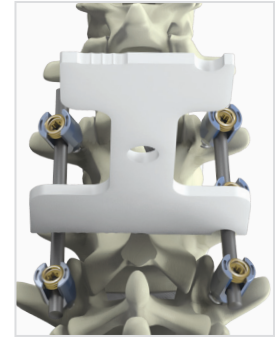


Figure 22

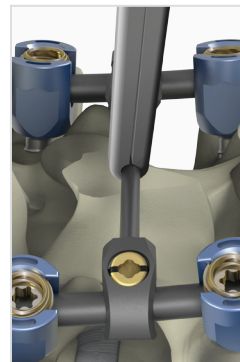


Figure 23

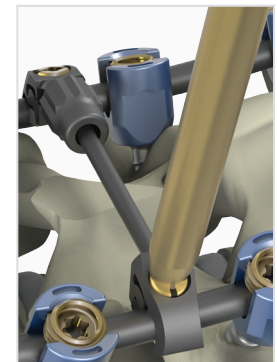


Figure 24

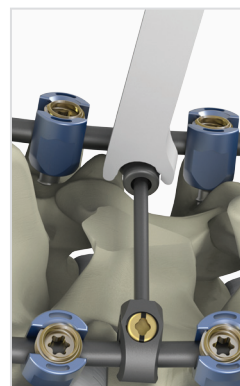


Figure 25

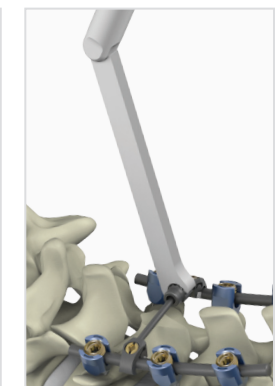


Figure 26

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Optional Step: Bending

Place one end of the X-Link connector in the Parallel Bender (Figure 27A).

Place the free end of the X-Link connector in the Perpendicular Bender (Figure 27B and 27C), ensuring that the pin is seated in the X-Link connector's gold-colored fastener.

Apply appropriate force to achieve the desired bend in the coronal plane (Figure 28).

NOTE: Avoid creating a sharp bend or reversing a contour in the X-Link, as this may lead to premature material fatigue of the implant. Do not bend the X-Link in the reverse direction, as this may introduce micro fractures that compromise its strength. IF REVERSE X-LINK BENDING OR EXCESSIVE BENDING HAS OCCURRED, THE BENT X-LINK MUST BE DISCARDED. Please contact Pioneer Surgical Technology at (888) 778-8771 with any questions in regard to contouring X-Link prior to surgery.

NOTE: Ensure X-Link is properly seated on rod prior to locking ends. Improper rod engagement may result in compromised construct performance. Inadequate rod engagement may inhibit proper locking or provide permanent damage to the X-Link.

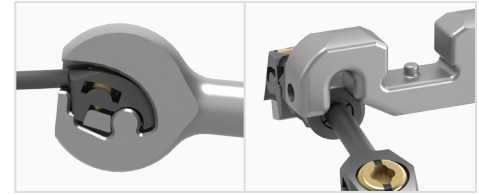


Figure 27A

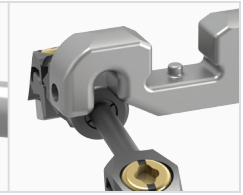


Figure 27B

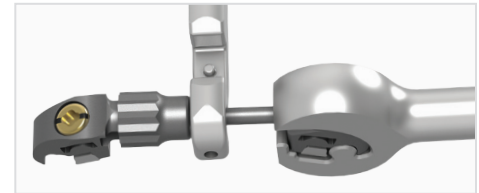


Figure 27C



Figure 28

STEP 10

CONSTRUCT REMOVAL

To remove the construct, apply counter-clockwise rotation to loosen its components and remove them in the opposite order in which the construct was built. Use Ratcheting Palm or T-Handle with Final Driver for set screw removal.

PRIMARY INSTRUMENT TRAY COMPONENTS

10-AWL

Bone Awl
 For creating a pilot hole in cortical bone through which a Pedicle Finder can be inserted



10-SFINDER

Pedicle Finder, Straight
 For dissecting through cancellous bone in pedicle, in preparation for screw insertion



10-CFINDER

Pedicle Finder, Curved
 For dissecting through cancellous bone in pedicle, in preparation for screw insertion



10-CBALLTIP

Probe, Curved
 For checking cortex integrity in pedicles



10-SBALLTIP

Probe, Straight
 For checking cortex integrity in pedicles



DOUBLE LEAD TAPS

For tapping holes prior to inserting screws in pedicles

Standard

- 02-TAP-45 Tap, 4.5 mm diameter
- 02-TAP-55 Tap, 5.5 mm diameter
- 02-TAP-65 Tap, 6.5 mm diameter

Optional

- 02-TAP-35 Tap, 3.5 mm diameter
- 02-TAP-75 Tap, 7.5 mm diameter
- 02-TAP-85 Tap, 8.5 mm diameter

NOTE: Taps are labeled according to actual major cutting diameter





PRIMARY INSTRUMENT TRAY COMPONENTS

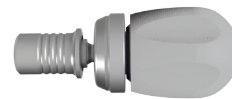
10-RTHANDLE

Ratcheting T-Handle
 For use with Taps and Screw Inserter



10-RPHANDLE

Ratcheting Palm Handle
 For use with Taps and Screw Inserter



10-RSHANDLE

Ratcheting Straight Handle
 For use with Taps and Screw Inserter



02-SCREWINSRTR

Screw Inserter
 For inserting screws into pedicles



10-SWIZZLESTIK

Swizzle Stick
 For adjusting screw head orientation of an implanted pedicle screw



10-RODTEMPLATE

Rod Template
 For temporary insertion in implanted pedicle screws, to determine the contour needed for the rod that will be used in the construct. Rod template is 150mm in length.
 For Single Use Only.



PRIMARY INSTRUMENT TRAY COMPONENTS

10-GRIPPER-S

Rod Gripper, Small
 For holding a rod during insertion into the head of a pedicle screw



10-RODFORCEP-S

Rod Forceps, Straight
 For controlling the insertion of the rod in the construct



10-BENDER-55

Rod Bender, 5.5mm diameter
 For contouring rods



02-SETSCREWINS-1

Set Screw Inserter
 For the insertion of set screws into pedicle screws; holds one set screw at a time; not used for final locking



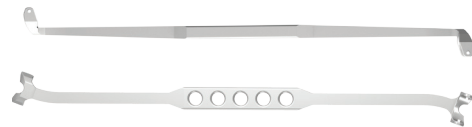
02-SETSCREWINS-2

Set Screw Inserter, Double-Ended
 For inserting set screws into pedicle screws; holds up to two set screws at a time; not used for final locking



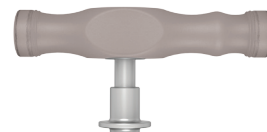
02-MANIPANGLED

Manipulator, Angled
 For reducing the rod into the pedicle screw head prior to insertion of a set screw; can also be used to change medial/lateral position of the pedicle screw head



02-TL-HANDLE

Torque-Limiting Handle
 For applying final locking torque to a set screw that has been inserted in a pedicle screw





PRIMARY INSTRUMENT TRAY COMPONENTS

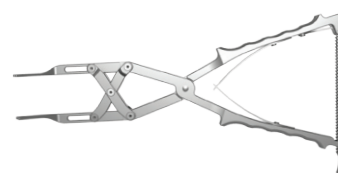
02-C-TORQUE

Counter-Torque Handle
 For applying counter-torque during final locking of a set screw



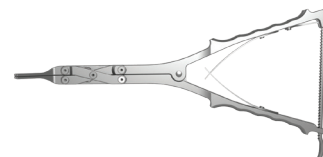
10-COMPRESSOR

Compressor
 For compressing a level as needed



10-DISTRACTOR

Distractor
 For distracting a level as needed



02-FINALDRIVER

Set Screw Final Driver
 For applying final locking torque to a set screw that has been inserted in a pedicle screw



02-RAPIDREDUCR

Rapid Reducer
 For reducing the rod into the pedicle screw head in preparation for insertion of a set screw



02-RR-HANDLE

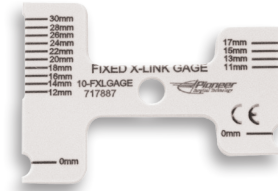
Rapid Reducer Counter-Torque Handle
 For use with the Rapid Reducer, to apply counter-torque during final locking of a set screw



X-LINK TRAY COMPONENTS

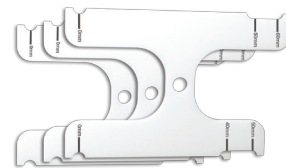
10-FXLGAGE

Fixed X-Link Gauge
 For determining the appropriate length of a fixed X-Link connector



10-VXLG-3040 - 10-VXLG-6080

10-VXLG-3040 Variable X-Link Gauge, 30-40 mm
 10-VXLG-4060 Variable X-Link Gauge, 40-60 mm
 10-VXLG-6080 Variable X-Link Gauge, 60-80 mm
 For determining the appropriate length of a variable X-Link connector



10-XLINKDRIVER

X-Link Driver
 For tightening the fasteners at the ends of an X-Link connector to attach it to the rods of a construct



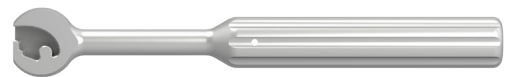
10-XLINKWRENCH

X-Link Wrench
 For tightening the centerlink of an X-Link connector



10-XLNKBNDRPAR

X-Link Bender, Parallel
 For bending an X-Link connector; use in conjunction with the Perpendicular Bender



10-XLNKBNDRPER

X-Link Bender, Perpendicular
 For bending an X-Link connector; use in conjunction with the Parallel Bender



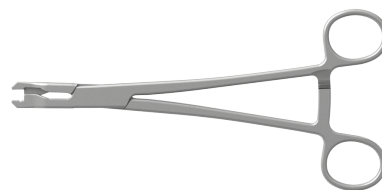


X-LINK TRAY COMPONENTS

10-XLNKHOLDER

X-Link Holder

For controlling an X-Link connector when attaching it to the rods of a construct



10-REMWRENCH

X-Link Centerlink Removal Wrench

For loosening the centerlink of an X-Link connector



IMPLANT LIST - 02-STRMLN-IMP (DOUBLE LAYER CASE LAYOUT)

TOP TRAY IMPLANTS				
Part Number	Description	Diameter	Length	Quantity
01-PA-55-30	Poly-Axial Screw	5.5mm	30mm	8
01-PA-55-35	Poly-Axial Screw	5.5mm	35mm	8
01-PA-55-40	Poly-Axial Screw	5.5mm	40mm	8
01-PA-55-45	Poly-Axial Screw	5.5mm	45mm	8
01-PA-55-50	Poly-Axial Screw	5.5mm	50mm	8
01-PA-55-55	Poly-Axial Screw	5.5mm	55mm	6
01-PA-55-60	Poly-Axial Screw	5.5mm	60mm	4
01-PA-65-30	Poly-Axial Screw	6.5mm	30mm	8
01-PA-65-35	Poly-Axial Screw	6.5mm	35mm	8
01-PA-65-40	Poly-Axial Screw	6.5mm	40mm	8
01-PA-65-45	Poly-Axial Screw	6.5mm	45mm	8
01-PA-65-50	Poly-Axial Screw	6.5mm	50mm	8
01-PA-65-55	Poly-Axial Screw	6.5mm	55mm	6
01-PA-65-60	Poly-Axial Screw	6.5mm	60mm	4
01-PA-75-30	Poly-Axial Screw	7.5mm	30mm	4
01-PA-75-35	Poly-Axial Screw	7.5mm	35mm	4
01-PA-75-40	Poly-Axial Screw	7.5mm	40mm	6
01-PA-75-45	Poly-Axial Screw	7.5mm	45mm	6
01-PA-75-50	Poly-Axial Screw	7.5mm	50mm	4
01-PA-75-55	Poly-Axial Screw	7.5mm	55mm	4
01-PA-75-60	Poly-Axial Screw	7.5mm	60mm	4
10-55-PR-35	Pre-Bent Rod	5.5mm	35mm	4
10-55-PR-40	Pre-Bent Rod	5.5mm	40mm	4
10-55-PR-50	Pre-Bent Rod	5.5mm	50mm	4
10-55-PR-60	Pre-Bent Rod	5.5mm	60mm	4
10-55-PR-70	Pre-Bent Rod	5.5mm	70mm	4
10-55-PR-80	Pre-Bent Rod	5.5mm	80mm	4
10-55-PR-90	Pre-Bent Rod	5.5mm	90mm	4
10-55-PR-100	Pre-Bent Rod	5.5mm	100mm	4
10-55-PR-110	Pre-Bent Rod	5.5mm	110mm	4
10-55-PR-120	Pre-Bent Rod	5.5mm	120mm	4
10-55-PR-130	Pre-Bent Rod	5.5mm	130mm	4
10-55-PR-140	Pre-Bent Rod	5.5mm	140mm	4
10-55-PR-150	Pre-Bent Rod	5.5mm	150mm	4
01-SETSCREW	Set Screw			40

BOTTOM TRAY IMPLANTS - OPTIONAL				
Part Number	Description	Diameter	Length	Quantity
01-PA-45-20	Poly-Axial Screw	4.5mm	20mm	6
01-PA-45-25	Poly-Axial Screw	4.5mm	25mm	6
01-PA-45-30	Poly-Axial Screw	4.5mm	30mm	6
01-PA-45-35	Poly-Axial Screw	4.5mm	35mm	6
01-PA-45-40	Poly-Axial Screw	4.5mm	40mm	6
01-PA-45-45	Poly-Axial Screw	4.5mm	45mm	6
01-PA-85-35	Poly-Axial Screw	8.5mm	35mm	6
01-PA-85-40	Poly-Axial Screw	8.5mm	40mm	6
01-PA-85-45	Poly-Axial Screw	8.5mm	45mm	6
01-PA-85-50	Poly-Axial Screw	8.5mm	50mm	6
01-PA-85-55	Poly-Axial Screw	8.5mm	55mm	6
01-PA-85-60	Poly-Axial Screw	8.5mm	60mm	6
01-PA-95-40	Poly-Axial Screw	9.5mm	40mm	4
01-PA-95-45	Poly-Axial Screw	9.5mm	45mm	4
01-PA-95-50	Poly-Axial Screw	9.5mm	50mm	4
01-PA-95-55	Poly-Axial Screw	9.5mm	55mm	4
01-PA-95-60	Poly-Axial Screw	9.5mm	60mm	4

BOTTOM TRAY IMPLANTS - OPTIONAL LONG SCREWS				
Part Number	Description	Diameter	Length	Quantity
01-PA-65-65	Poly-Axial Screw	6.5mm	65mm	4
01-PA-65-70	Poly-Axial Screw	6.5mm	70mm	4
01-PA-65-75	Poly-Axial Screw	6.5mm	75mm	4
01-PA-65-80	Poly-Axial Screw	6.5mm	80mm	4
01-PA-65-85	Poly-Axial Screw	6.5mm	85mm	4
01-PA-65-90	Poly-Axial Screw	6.5mm	90mm	4
01-PA-65-95	Poly-Axial Screw	6.5mm	95mm	2
01-PA-65-100	Poly-Axial Screw	6.5mm	100mm	2
01-PA-75-65	Poly-Axial Screw	7.5mm	65mm	4
01-PA-75-70	Poly-Axial Screw	7.5mm	70mm	4
01-PA-75-75	Poly-Axial Screw	7.5mm	75mm	4
01-PA-75-80	Poly-Axial Screw	7.5mm	80mm	4
01-PA-75-85	Poly-Axial Screw	7.5mm	85mm	4
01-PA-75-90	Poly-Axial Screw	7.5mm	90mm	4
01-PA-75-95	Poly-Axial Screw	7.5mm	95mm	2
01-PA-75-100	Poly-Axial Screw	7.5mm	100mm	2
01-PA-85-65	Poly-Axial Screw	8.5mm	65mm	4
01-PA-85-70	Poly-Axial Screw	8.5mm	70mm	4
01-PA-85-75	Poly-Axial Screw	8.5mm	75mm	4
01-PA-85-80	Poly-Axial Screw	8.5mm	80mm	4
01-PA-85-85	Poly-Axial Screw	8.5mm	85mm	4
01-PA-85-90	Poly-Axial Screw	8.5mm	90mm	4
01-PA-85-95	Poly-Axial Screw	8.5mm	95mm	2
01-PA-85-100	Poly-Axial Screw	8.5mm	100mm	2
01-PA-95-70	Poly-Axial Screw	9.5mm	70mm	4
01-PA-95-80	Poly-Axial Screw	9.5mm	80mm	4
01-PA-95-90	Poly-Axial Screw	9.5mm	90mm	2
01-PA-95-100	Poly-Axial Screw	9.5mm	100mm	2



IMPLANT TRAY COMPONENTS

- 1 5.5mm Poly-Axial Screw Caddy
- 2 6.5mm Poly-Axial Screw Caddy
- 3 7.5mm Poly-Axial Screw Caddy
- 4 Set Screw Caddy
- 5 Pre-Bent Caddy (Short)
35mm - 70mm
- 6 Pre-Bent Caddy (Medium)
80mm - 120mm
- 7 Pre-Bent Caddy (Long)
130mm - 150mm



TOP TRAY

INSTRUMENT LIST - 02-STRMLN-INS (TRIPLE LAYER CASE LAYOUT)

TOP TRAY INSTRUMENTS		
Part Number	Description	Quantity
10-RTHANDLE	Ratcheting T-Handle	2
10-RPHANDLE	Ratcheting Palm Handle	1
10-AWL	Bone Awl	1
10-CFINDER	Curved Pedicle Finder	1
10-SFINDER	Straight Pedicle Finder	1
02-SCREWINSRTR	Screw Inserter	2
10-CBALLTIP	Curved Balltip Probe	1
10-SBALLTIP	Straight Balltip Probe	1
02-TAP-45	Ø4.5mm Double Lead Tap	1
02-TAP-55	Ø5.5mm Double Lead Tap	1
02-TAP-65	Ø6.5mm Double Lead Tap	1
02-TAP-SLEEVE	Universal Tap Sleeve	2
02-SETSCRWINS-1	Set Screw Inserter	2
02-SETSCRWINS-2	Set Screw Inserter DBLEND	2

TOP TRAY INSTRUMENTS - OPTIONAL		
Part Number	Description	Quantity
02-TAP-35	Ø3.5mm Double Lead Tap	1
02-TAP-75	Ø7.5mm Double Lead Tap	1
02-TAP-85	Ø8.5mm Double Lead Tap	1

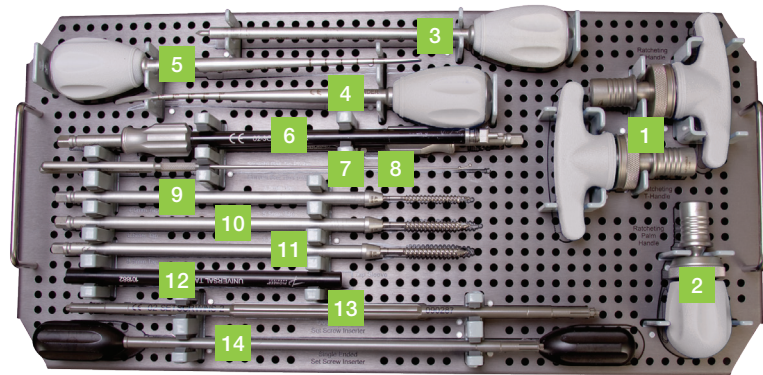
MIDDLE TRAY INSTRUMENTS		
Part Number	Description	Quantity
10-RSHANDLE	Straight Ratcheting Handle	1
02-FINALDRIVER	Final Driver	2
10-SWIZZLESTIK	Screw Adjuster	1
10-GRIPPER-S	Small Rod Gripper	1
10-RODTEMPLATE	Rod Template	1
10-RODFORCEP-S	Straight Rod Forcep	1
02-C-TORQUE	Counter Torque Tube	1
02-TL-HANDLE	Torque Limiting Handle	1

BOTTOM TRAY INSTRUMENTS		
Part Number	Description	Quantity
10-COMPRESSOR	Fixed Parallel Compressor	1
10-DISTRACTOR	Fixed Parallel Distractor	1
02-MANIPANGLED	Angled Manipulator	1
02-RAPIDREDUCR	Rapid Reducer	2
02-RR-HANDLE	Rapid Reducer Handle	1
10-BENDER-55	Ø5.5mm Rod Bender	1



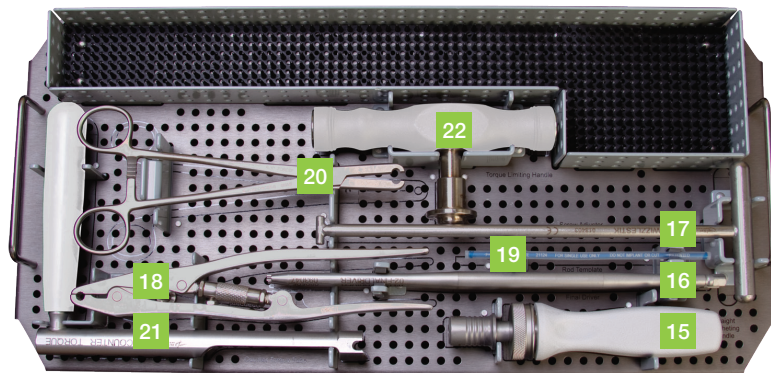
INSTRUMENT TRAY COMPONENTS

- 1 Ratcheting T-Handle
- 2 Ratcheting Palm Handle
- 3 Bone Awl
- 4 Curved Pedicle Finder
- 5 Straight Pedicle Finder
- 6 Screw Inserter
- 7 Curved Balltip Probe
- 8 Straight Balltip Probe



TOP TRAY

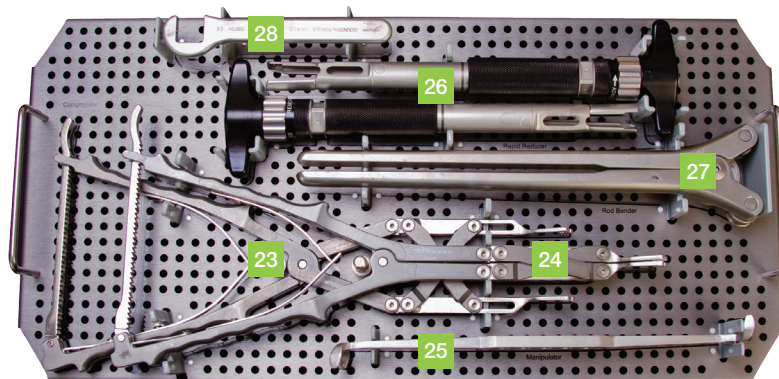
- 9 4.5mm DL Tap
- 10 5.5mm DL Tap
- 11 6.5mm DL Tap
- 12 Universal Tap Sleeve
- 13 Double-ended Set Screw Inserter
- 14 Set Screw Inserter



MIDDLE TRAY

- 15 Straight Ratcheting Handle
- 16 Final Driver
- 17 Screw Adjuster
- 18 Small Rod Gripper
- 19 Rod Template
- 20 Straight Rod Forcep
- 21 Counter Torque Tube

- 22 Torque Limiting Handle
- 23 Fixed Parallel Compressor
- 24 Fixed Parallel Distractor
- 25 Angled Manipulator
- 26 Rapid Reducer
- 27 5.5mm Rod Bender



BOTTOM TRAY

- 28 Rapid Reducer Counter Torque Handle

RECOMMENDED STERILIZATION PARAMETERS:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuum (wrapped)	272°F	6 minutes	20 minutes



INDICATIONS

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), sacral/ilic screw fixation or as an anterolateral fixation system (T8 - L5). 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, pseudoarthrosis, or failed previous fusion.

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 and lumbar 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 TL Spinal 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

PRECAUTIONS

informed of the risks of implant bending, loosening, or breakage.

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, accelerates 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.

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.

Only rods and X-Links are intended to be bent or contoured. Bending of components other than rods and X-links may lead to premature material fatigue of the implant. If bending or contouring of components other than rods or X-Links occurs, those components must be discarded.

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

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. 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. 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. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of 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.*



NOTES

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