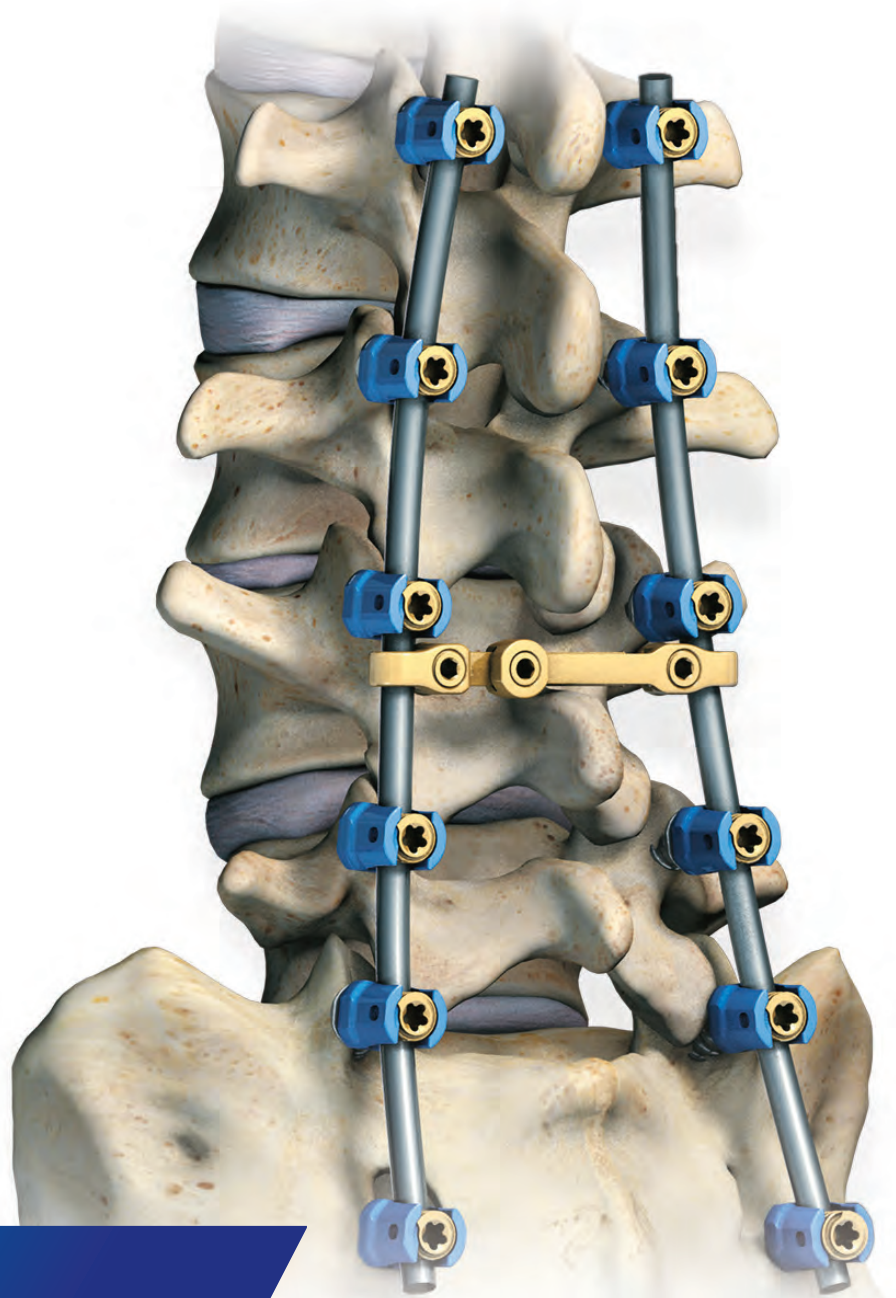




ZIMMER BIOMET

Your progress. Our promise.®



Thoracolumbar Solutions

Polaris™ System Translation™ Screw

Surgical Technique Guide



Game Changing Technology

- 3 mm of medial-lateral translation encourages optimal screw placement
- Less rod manipulation, easier rod introduction

Unparalleled Thread Performance

- Balanced-start™ Tip
- Maximizes screw interaction in various bone densities

Less Stress at Bone-to-Screw Interface

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

INTRODUCTION

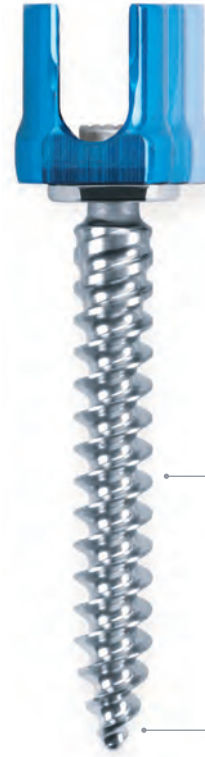
Zimmer Biomet proudly introduces the **Polaris Translation Screw**. Translation screw technology represents progressive innovation aimed at providing solutions for today's thoracolumbar fusion challenges.

The Polaris Translation screw provides 3 mm of medial-lateral translation and 40° of conical angulation allowing pedicle screws to be placed anatomically. This flexibility will permit the screw seats to adjust to the natural trajectory of the rod and minimize stress at the bone-to-screw interface that can be seen with traditional pedicle screw constructs.

The extensive clinical experience gained from the Polaris spinal system is reflected in every design aspect of the screw. The Balanced-start™ tip immediately engages the pedicle and accurately leads the screw into the pilot hole. The dual-lead thread profile reduces insertion time while maximizing bone purchase and strength. Reliable Helical Flange® technology minimizes cross threading and seat splay, while enhancing the strength of the locking mechanism. The screw seat features a robust engagement between the implant and the versatile portfolio of reduction instruments, such as the Rocket™ reducer.

Thread Profile

- Maximizes the screw interaction in various bone densities
- Tactile insertion
- Thread form maximizes bone purchase

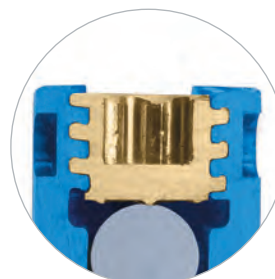


Dual-lead Screw Thread

- Faster screw placement

Balanced-start Tip Geometry

- Minimizes toggle during insertion
- Accurate placement and screw trajectory
- Immediate bone engagement



Helical Flange Technology

FEATURES AND BENEFITS



FEATURES

Translation Screw Technology

Balanced-start Tip

Double-lead Thread

Thread Profile

Friction Fit Seat

Helical Flange Technology

Translation Multi-axial Screws

5.5 mm Rod System

Color-coded Implants

BENEFITS

3 mm of medial-lateral translation relative to the screw shaft

Encourages optimal screw placement

Less rod manipulation, easier rod introduction

Minimizes toggle during insertion

Accurate placement and screw trajectory

Immediate bone engagement

Immediate bone engagement

Fast and efficient screw placement

Thread form maximizes bone purchase and performance

Constant outer diameter

Maintains position of screw seat

Starts easily

Minimizes cross threading and seat splay

Forces are concentrated inward

40° of conical angulation for optimum versatility

Low profile

Anatomical fit

Ease of screw identification

PATIENT POSITIONING AND PEDICLE PREPARATION

The patient is positioned prone with hips in extension to provide for maximal lumbar lordosis. The spine is subperiostally exposed through a midline or paramedian incision and a decompression is performed, if indicated. Decortication must be meticulously performed. Graft can be placed or packed into the posterolateral gutters either before or after the pedicle screws have been implanted.

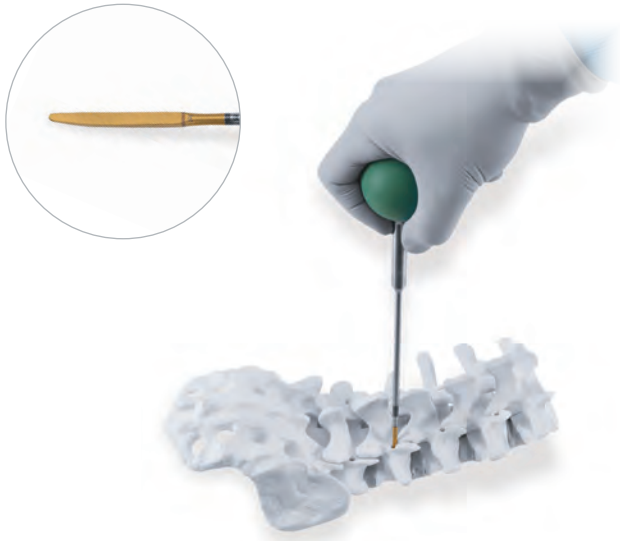


Figure 1
Pedicle probe is utilized



Figure 2
Confirming pedicle containment with pedicle sound



Figure 3
Use the trial pins to ensure proper orientation and trajectory

Pedicle Preparation

After adequate exposure is achieved, the appropriate pedicle entry point is selected and the entrance to the pedicle is created with an awl, burr, or curette.

- A pedicle probe may be utilized to create the pedicle hole by advancing the probe to a depth of approximately 30–40 mm using the depth markings as a guide. The probes are laser marked and have 10 mm visual bands to help indicate the depth to which the probe has been inserted.
- The pedicle sound is then used to confirm bony containment of the pedicle hole by palpating all four walls as well as the bottom of the hole through the pedicle and into the vertebral body.
- Trial pins may be utilized to confirm the proper orientation and trajectory.

**Figure 4**

Prepare the pedicle hole with the tap

TAPPING

- Although the screws are self-tapping, taps are available with the system and may be utilized to prepare the pedicle hole. Select the corresponding tap for the chosen screw diameter and advance the tap into the pedicle hole using the quick connect handle. The taps are laser marked and have visual bands to help indicate the depth to which the tap has been inserted.

Note: The taps are line-to-line with the diameter of the Polaris Translation screws.

PEDICLE SCREW LOADING

**Figure 5**

Insert the tip of the inserter into the pentalobe of the screw

SCREWDRIVER LOADING

Multi-axial screws are available in several diameters and lengths. The appropriate screw length is determined by using the depth markings on the pedicle probe or pedicle sound.

- The multi-axial screws may be loaded freehand or while seated within the surgical tray. Attach the button lock screw inserter to the quick connect handle by pulling back on the plunger at the base of the quick connect mechanism, inserting the shaft, and releasing the plunger to lock the shaft in place.
- Hold the screw by the screw shaft and load the screw onto the tip of the screw inserter. Ensure that the male pentalobe at the distal tip of the screw inserter is fully seated within the female pentalobe located at the top of the screw shaft.

PEDICLE SCREW INSERTION



Figure 6

Rotate the knurled barrel and thread the outer shaft into the seat. Push slider distally to secure.

SCREWDRIVER LOADING (*continued*)

- Rotate the knurled barrel in a clockwise direction to thread the outer shaft into the seat. Completely load the outer shaft into the seat. Secure it in place by pushing the slider distally, as indicated by the arrow. Confirm that the screw is straight and secure in the inserter.
- **Optional step:** if a tactile, audible and visual confirmation is desired, while the outer shaft is threaded into the seat, push the slider distally, as indicated by the arrow. Then follow the inserter and screw assembly instructions as described above.

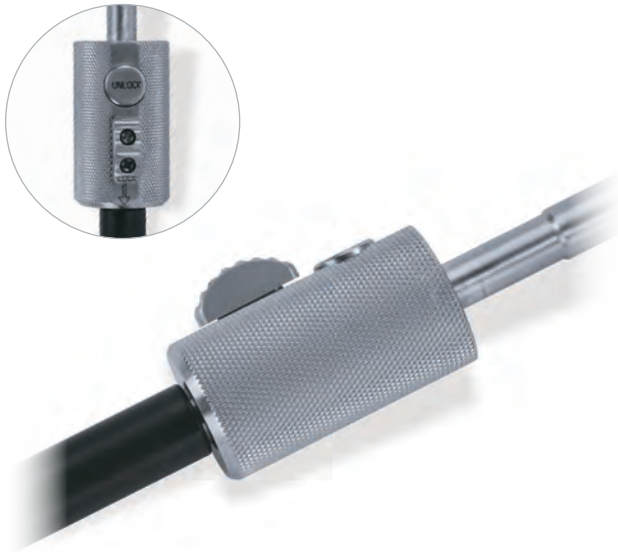


Figure 7

Insert the screw into the pedicle

SCREW INSERTION

- The screw is advanced into the pedicle to the desired depth. During insertion, guide the inserter by holding the black sleeve on the shaft of the instrument.

**Figure 8**

To disengage, depress the “unlock” button and rotate the barrel counterclockwise

RELEASE SCREWDRIVER

- The screw inserter is disengaged from the screw by depressing the “unlock” button on the knurled barrel and rotating the knurled barrel in a counterclockwise direction and then lifting the inserter from the screw.

**Figure 9**

Screw head adjustment with head positioner

**Figure 10**

Dorsal height adjustment

SCREW ADJUSTMENT

- Once the screws are properly positioned, the screw seat can be translated and oriented using the head positioner. A quick connect handle may be attached at the proximal end of the head positioner.

Note: The dorsal height adjuster may be used to adjust the screw height prior to rod placement. Seat the male pentalobe of the dorsal height adjuster into the female pentalobe located at the top of the screw shaft. Turn the adjuster for minor manipulation of the screw height.

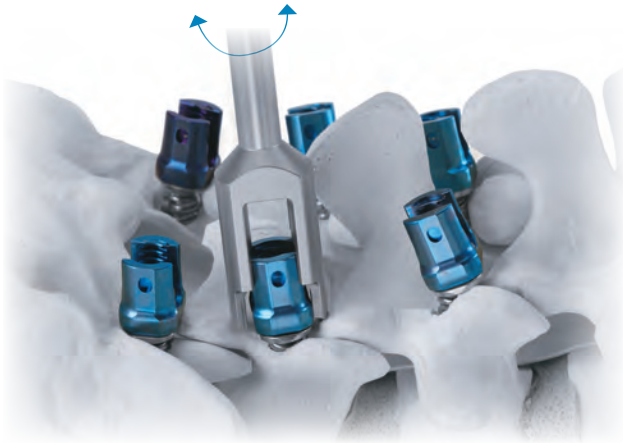


Figure 11
Bone planer removing bone

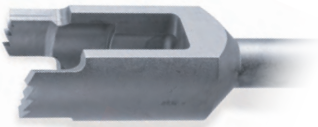


Figure 12
Bone planer

BONE PLANER

- The bone planer allows the surgeon to quickly remove a small amount of bone that may be interfering with the translation of the screw seat or application of a rod reduction instrument. A quick connect handle may be attached at the proximal end of the bone planer.

ROD SELECTION



Figure 13
Measure length of the rod using the rod template

ROD APPLICATION

- Once all screws have been inserted, choose the appropriate length rod according to the construct. The rod template may be used to aid in rod selection. The rod should project at least 2 mm beyond the screw seats at the end of the construct. Be sure to account for large curves and distractions when choosing rod length.

ROD BENDING AND INSERTION



Figure 14
Utilize the rod bender to add additional curvature to rod



Figure 15
Insert rod using the rod holder



Figure 16
Load a plug onto the teardrop plug inserter

ROD INSERTION

The unique design of the Polaris Translation screws will adapt to any required medial or lateral offset, thereby minimizing the need for coronal plane rod bend in the scoliotic spine. The rod should be contoured to correct the spine to the desired thoracic kyphosis and lumbar lordosis in the sagittal plane. The Polaris spinal system offers an array of titanium and cobalt chrome alloy rods with a strength range to match the demands of the clinical context.

PROVISIONAL TIGHTENING

Helical Flange Plug Application

- When all the pedicle screws have been inserted and the rods have been placed in the screw seats, the construct is then secured using Helical Flange plugs. Firmly press a plug onto the self-retaining proximal end of the teardrop plug inserter. All plugs should be placed and then provisionally tightened.
- The torque stabilizer may be used to reposition the axis of the screw seat while simultaneously acting as a guide for the plug driver.

ROD REDUCTION

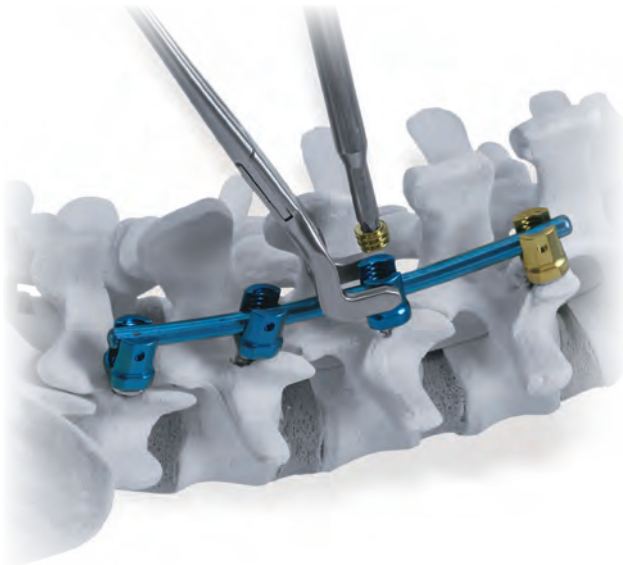


Figure 17
Rod rocker

OPTION 1: ROD ROCKER

It may be necessary to reduce the rod into the screw seat. Utilize the rod rocker, a rocket threaded reducer or the perpendicular rod persuader to properly position the rod within the screw seat.

- Utilize the bone planer to quickly remove a small amount of bone or tissue that may be impeding the positioning of a rod reduction instrument. Refer to page 10 for bone planer use.
- Attach the rod rocker to screw seat, and cantilever or tilt the rocker down to persuade the rod into the screw seat. Once the rod is properly seated, Helical Flange plug application can be executed. The rod rocker facilitates 10 mm of simple rod reduction.

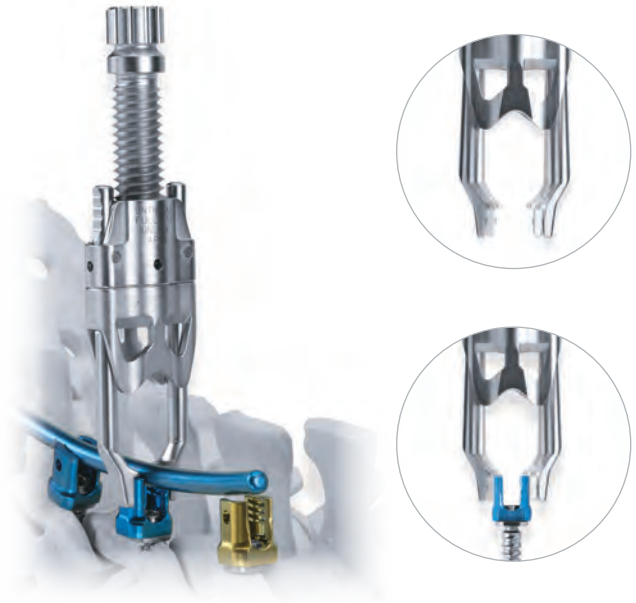


Figure 18
Attachment of short rocket threaded reducer

OPTION 2: SHORT ROCKET THREADED REDUCER

- Attach the short rocket threaded reducer by depressing the spring loaded arms and positioning it into the mating screw seat geometry. The internal stop ensures proper positioning.

Note: To properly attach and remove the short rocket threaded reducer, ensure that the reducer is completely unthreaded.



Figure 19
Self-centering reduction design



Figure 20
Rod reduction



Figure 21
Plug insertion through the short rocket reducer

- Rotate the proximal barrel clockwise to secure the reducer and simultaneously reduce the rod. As the rod is being reduced, the reducer's unique features guide the rod into proper screw head position.
- Utilize the T-handle or quick connect adaptor to rotate the proximal barrel until the rod is fully reduced and the positive stop is reached.
- Once the rod is properly seated, Helical Flange plug application can be executed. The short rocket reducer facilitates 30 mm of tactile rod reduction.

ROD REDUCTION (continued)

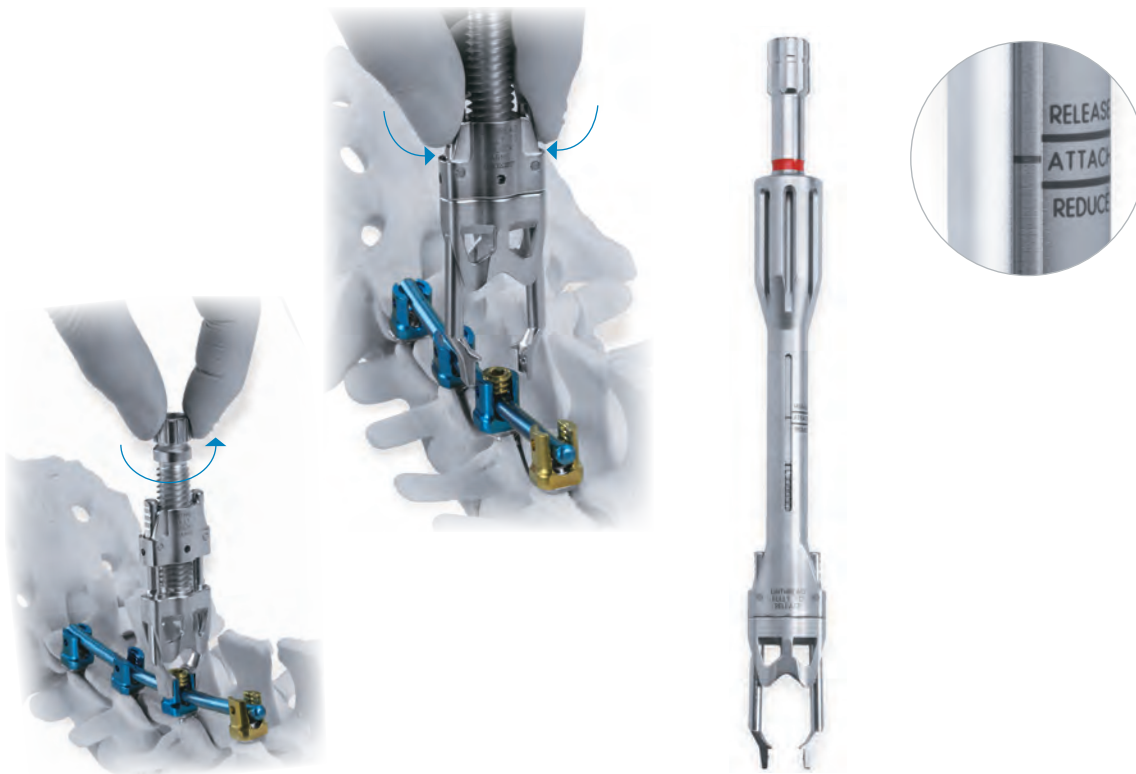


Figure 22

Partial removal of the short rocket reducer

- To disengage short rocket threader reducer, rotate the barrel counter clockwise. Once the reducer is completely unthreaded, depress the spring loaded arms and remove the reducer.

OPTION 3: LONG ROCKET THREADED REDUCER

- To facilitate attachment, ensure that the laser marked line is within the two laser marked lines and aligned to the “attach” text on the shaft of the reducer and a red proximal band is visible.

**Figure 23**

Attachment of long rocket threaded reducer

**Figure 24**

Self-centering reduction design

- Attach the long rocket threaded reducer by positioning the spring loaded arms into the mating screw seat geometry. The internal stop ensures proper positioning.
- Rotate the proximal barrel clockwise to secure the reducer and simultaneously reduce the rod. As the rod is being reduced, the reducer's unique features guide the rod into proper screw head position.

ROD REDUCTION (*continued*)



Figure 25
Rod reduction



Figure 26
Plug insertion through the long rocket reducer

- Utilize the T-handle options or quick connect adaptor to rotate the proximal barrel until the rod is fully reduced and the positive stop is reached.
- Once the rod is properly seated, Helical Flange plug application can be executed. The long rocket reducer facilitates 30 mm of tactile rod reduction.



Figure 27
Partial removal



Figure 28
Easy removal of the long rocket reducer

- To disengage the long rocket threaded reducer, rotate the proximal barrel counterclockwise.

- The spring loaded tips will automatically disengage from the implant when the red proximal band is completely visible.

Refer to the chart below for proper instrument operation

Position of the visual red band at the proximal end

ATTACHMENT	COMPLETE ROD REDUCTION	DISENGAGEMENT

Position of laser marked line and text on shaft of the reducer

ATTACHMENT	COMPLETE ROD REDUCTION	DISENGAGEMENT

ROD REDUCTION (*continued*)



Figure 29
L5/S1 spondylolisthesis

OPTION 4: SPONDYLOLISTHESIS REDUCTION

- Follow the steps as described in section 2 for pedicle preparation, pedicle screw insertion and rod placement. Place and provisionally tighten helical flange plugs in the screw seats of the cranial and caudal vertebrae.
- In order to aid in the reduction of the spondylolisthesis, it is recommended to first perform a transforaminal lumbar interbody fusion of the affected level. The addition of a TLIF will distract the interbody space allowing for partial reduction of the listhesis. Please refer to the Zyston® Surgical Technique Guide for proper utilization of the systems.

NOTE: Care should be taken in patients suspected of having osteopenia or osteoporosis when using reduction instruments.



Figure 30

- Utilize the long threaded rocket reducer to reduce the spondylolisthesis in a controlled and tactile manner. To facilitate attachment, ensure that the laser marked line is within the two laser marked lines and aligned to the “Attach” text on the shaft of the reducer and a red proximal band is visible. Attach the reducer by positioning the spring loaded arms into the mating screw seat geometry. The internal stop ensures proper positioning.



Figure 31
Self-centering
reduction design



Figure 32
Attachment of long rocket reducer



Figure 33
Rod reduction

- Rotate the proximal barrel clockwise to secure the reducer and simultaneously reduce the rod. As the rod is being reduced, the reducer's unique features guide the rod into proper screw head position.
- Utilize the T-handle options or quick connect adaptor to rotate the proximal barrel until the rod is fully reduced and the positive stop is reached.

ROD REDUCTION (*continued*)



Figure 34
Plug insertion through the long rocket reducer



Figure 35
Full reduction of the L5/S1 spondylolisthesis

- Once the rod is properly seated, plug application can be executed. The long rocket reducer facilitates 30 mm of tactile rod reduction.

- To disengage the long rocket threaded reducer, rotate the proximal barrel counterclockwise. The spring loaded tips will automatically disengage from the implant and the red proximal band will be completely visible.



Figure 36
Proper positioning of rod persuader



Figure 37
Plug insertion through rod persuader

OPTION 5: PERPENDICULAR ROD PERSUADER

- When using the perpendicular rod persuader, place the persuader over the top of the screw seat. The internal stop of the persuader will ensure the instrument is in the correct position on the seat to facilitate manipulation. Squeeze the colored handle of the rod persuader to fully seat the rod in the screw seat.
- The plug inserter will fit through the cannulated body of the persuader, allowing for plug application with the persuader in place. The perpendicular rod persuader facilitates 45 mm of controlled rod reduction.
- To release the persuader, press the metallic trigger located underneath the colored handle. Once released, the persuader may then be removed from the implant.

COMPRESSION AND DISTRACTION (*if necessary*)

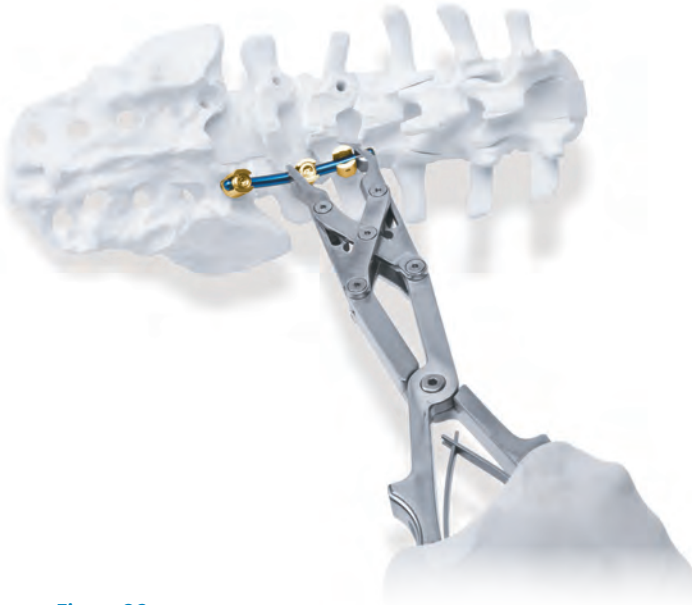


Figure 38
Compression

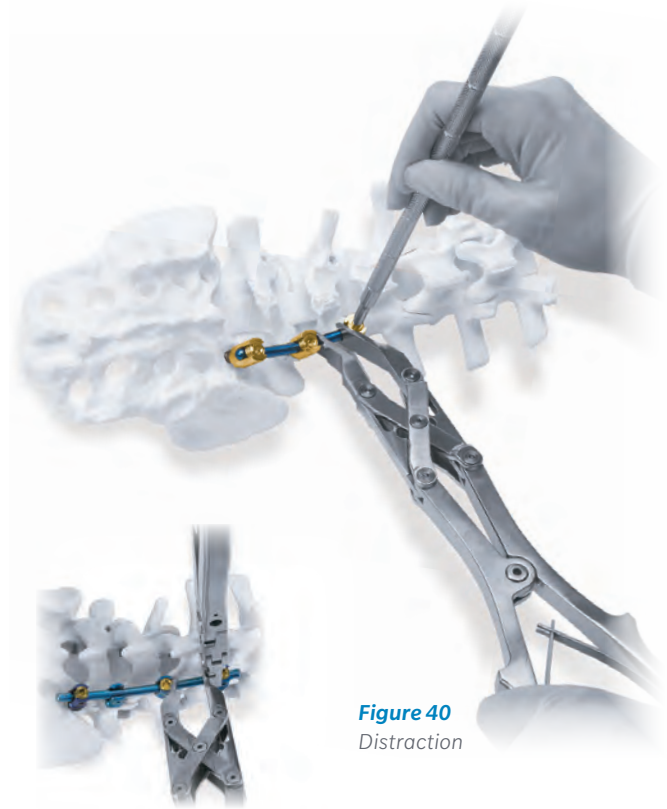


Figure 39
Distracting off rod gripper

Figure 40
Distraction

DISTRACTION AND COMPRESSION

Distraction and compression can be achieved by utilizing either the distractor or compressor. Both instruments permit intraoperative application of linear distraction or compression at any level.

- The distal tips of the distractor or compressor are placed on the rod and the desired degree of distraction or compression is applied. The distraction or compression device will maintain the position of the vertebra until the plug is provisionally tightened with the plug inserter.

Note: *If needed, the rod gripper can be utilized as a point of fixation in the absence of an implant.*

CROSS CONNECTOR (optional)



Figure 41

Select appropriate sized cross connector



Figure 42

Torque the set screws on the cross connector. Torque until an audible click is heard to apply 40 in-lbs.

CROSS CONNECTOR APPLICATION

- In the event that additional torsional stability is required, a cross connector may be utilized. The cross connector should be applied after the construct has been assembled and the plugs have been tightened.
- Apply the cross connector to the rods and tighten the screws with the cross connector torque wrench until an audible click is heard and a tactile indication felt, confirming proper tightening by applying 40 in-lbs of torque to the set screws. Tighten the outer set screws first followed by the central set screw.

LATERAL CONNECTORS (optional)



Figure 43

Select appropriate size lateral connector

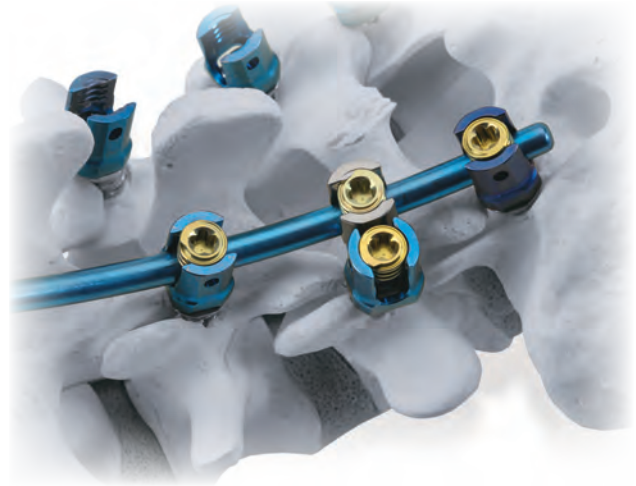


Figure 44

Lateral connector placement

LATERAL CONNECTORS

- Lateral connectors may be utilized if screw placement requires a severe bend in the rod. The lateral connectors allow for an offset, thus minimizing rod bending. The lateral connectors are secured with the same Helical Flange plug as the pedicle screws.
- Place the arm of the lateral connector in the pedicle screw seat and secure the lateral connector in place by provisionally tightening the plug. Place the longitudinal rod into the seat of the lateral connector. Once the rod has been placed, insert the Helical Flange plug into the seat of the lateral connector and tighten as described on page 22.

FINAL TIGHTENING



Figure 45
Proper positioning of the torque limiting wrench into the pentalobe of plug



Figure 46
Final tightening

FINAL TIGHTENING

- After provisional tightening, proper implant placement should be confirmed with radiographs. The plugs are then tightened with the torque limiting wrench in combination with the torque stabilizer. The torque limiting handle attaches to the plug driver. Insert the torque limiting wrench through the torque stabilizer. Position the tip of the torque wrench into the plug. Seat the distal end of the torque stabilizer over the screw seat and confirm that the stabilizer fits firmly on the rod. The rod will be positioned within the slots of the stabilizer.
- The torque limiting wrench is turned in a clockwise direction while the torque stabilizer is firmly held with resistive force in a counterclockwise direction. The torque limiting wrench should be turned until an audible click is heard and a tactile indication felt, confirming proper final tightening by applying 110 in-lbs. of torque.

Note: Use the torque limiting wrench in combination with the torque stabilizer for proper final tightening of the Helical Flange plugs.

CLOSURE

After implantation of the Polaris Translation screws is complete, wound closure is performed according to the standard protocol for the surgeon.

REMOVAL OR REVISION



Figure 47
Plug removal



Figure 48

IMPLANT REMOVAL

Removal of the Polaris spinal system is performed by reversing the order of the implant procedure. Identify the anatomical locations of the implants.

- The quick connect fixed T-handle attached to the plug driver in combination with the torque stabilizer must be used to first to remove the Helical Flange plugs.

Note: When removing previously tightened Helical Flange plugs, turn the fixed T-handle in a slightly clockwise direction before turning counterclockwise. Continue with this back and forth motion until the plug loosens.

- The button lock screw inserter is used to remove the multi-axial screws by seating the male pentalobe end into the female pentalobe at the top of the screw shaft. Rotate the knurled barrel in a clockwise direction to thread the outer shaft into the seat. Completely load the outer shaft into the seat. Secure it in place by pushing the slider distally, as indicated by the arrow. Confirm that the screw is straight and secure in the inserter.



Figure 49
Use the screw inserter to remove the screw

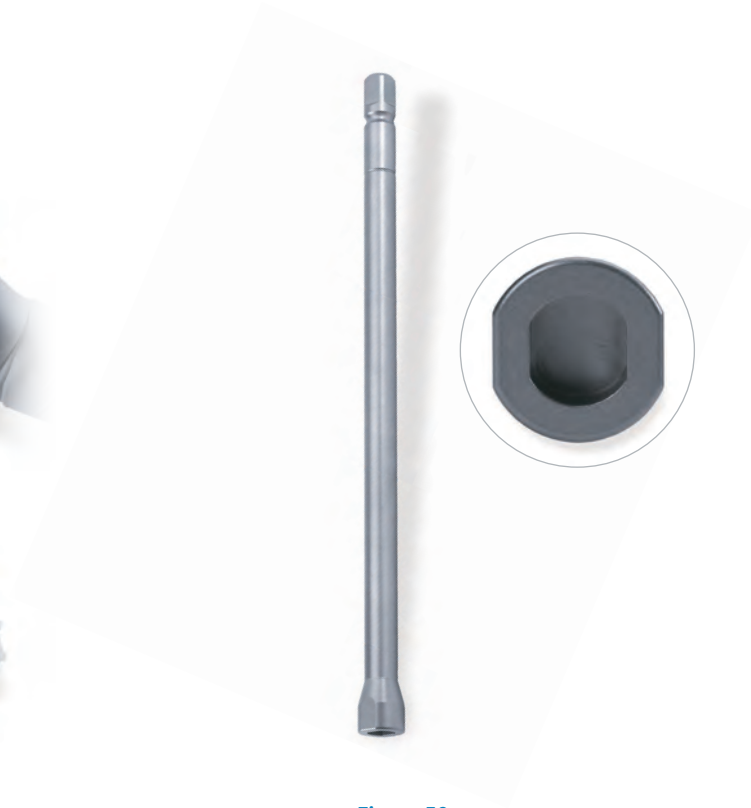


Figure 50
Screw shaft remover

-
- Once the screw inserter is tightened, the screw may be backed out of the pedicle.
 - To remove a screw shaft utilize the screw shaft remover.
 - Position the screw shaft remover securely over the implant and rotate counterclockwise.

POLARIS TRANSLATION SCREW IMPLANT AND INSTRUMENT KITS

Polaris Translation Screw Standard Implant Kit Kit Number: 14-509669

DESCRIPTION	QTY	PART NUMBER
Button Lock Screw Inserter	2	14-500070
Translating Screw Bone Planer	1	14-500071
Double-Lead Tap, 4 mm	1	14-500085
Double-Lead Tap, 4.75 mm	1	14-500086
Double-Lead Tap, 5.5 mm	1	14-500088
Double-Lead Tap, 6.5 mm	1	14-500089
Double-Lead Tap, 7.5 mm	1	14-500090
∅5.5 mm × 25 mm Translation Screw	2	14-578325
∅5.5 mm × 30 mm Translation Screw	6	14-578330
∅5.5 mm × 35 mm Translation Screw	8	14-578335
∅5.5 mm × 40 mm Translation Screw	8	14-578340
∅5.5 mm × 45 mm Translation Screw	8	14-578345
∅5.5 mm × 50 mm Translation Screw	4	14-578350
∅5.5 mm × 55 mm Translation Screw	2	14-578355
∅6.5 mm × 30 mm Translation Screw	4	14-578430
∅6.5 mm × 35 mm Translation Screw	6	14-578435
∅6.5 mm × 40 mm Translation Screw	8	14-578440
∅6.5 mm × 45 mm Translation Screw	8	14-578445
∅6.5 mm × 50 mm Translation Screw	8	14-578450
∅6.5 mm × 55 mm Translation Screw	6	14-578455
∅7.5 mm × 30 mm Translation Screw	4	14-578530
∅7.5 mm × 35 mm Translation Screw	6	14-578535
∅7.5 mm × 40 mm Translation Screw	8	14-578540
∅7.5 mm × 45 mm Translation Screw	8	14-578545
∅7.5 mm × 50 mm Translation Screw	8	14-578550
∅7.5 mm × 55 mm Translation Screw	6	14-578555

Polaris Translation Screw Standard Implant Kit Kit Number: 14-509669 (continued)

DESCRIPTION	QTY	PART NUMBER
Plug	30	2000-1005
Lateral Connector, Open, 25mm	2	2000-1020
30 mm Ti Alloy Curved Rod	4	2000-5130
35 mm Ti Alloy Curved Rod	4	2000-5135
40 mm Ti Alloy Curved Rod	4	2000-5140
45 mm Ti Alloy Curved Rod	4	2000-5145
50 mm Ti Alloy Curved Rod	4	2000-5150
55 mm Ti Alloy Curved Rod	4	2000-5155
60 mm Ti Alloy Curved Rod	4	2000-5160
65 mm Ti Alloy Curved Rod	4	2000-5165
70 mm Ti Alloy Curved Rod	4	2000-5170
75 mm Ti Alloy Curved Rod	4	2000-5175
80 mm Ti Alloy Curved Rod	4	2000-5180
90 mm Ti Alloy Curved Rod	4	2000-5190
100 mm Ti Alloy Curved Rod	4	2000-5199
510 mm Ti Alloy Rod with Hex	2	2000-5405
XXSmall Cross Connector	2	94669
XSmall Cross Connector	2	94670
Small Cross Connector	2	94671
Medium Cross Connector	2	94672
Large Cross Connector	2	94673

Polaris Translation Screw Iliac Implant Kit Kit Number: 14-509668

DESCRIPTION	QTY	PART NUMBER
Screw Shaft Remover	1	14-500073
Double-Lead Iliac Tap, 5.5 mm	1	14-500191
Double-Lead Iliac Tap, 6.5 mm	1	14-500192
Double-Lead Iliac Tap, 7.5 mm	1	14-500193
Double-Lead Iliac Tap, 8.5 mm	1	14-500194
Double-Lead Iliac Tap, 9.5 mm	1	14-500097
Double-Lead Iliac Tap, 10.5 mm	1	14-500098
ø6.5 mm × 60 mm Iliac Screw	4	14-578460
ø6.5 mm × 70 mm Iliac Screw	4	14-578470
ø6.5 mm × 80 mm Iliac Screw	2	14-578480
ø6.5 mm × 90 mm Iliac Screw	2	14-578490
ø7.5 mm × 60 mm Iliac Screw	4	14-578560
ø7.5 mm × 70 mm Iliac Screw	4	14-578570
ø7.5 mm × 80 mm Iliac Screw	4	14-578580
ø7.5 mm × 90 mm Iliac Screw	4	14-578590
ø7.5 mm × 100 mm Iliac Screw	2	14-578599
ø8.5 mm × 35 mm Iliac Screw	4	14-578635
ø8.5 mm × 40 mm Iliac Screw	4	14-578640
ø8.5 mm × 45 mm Iliac Screw	4	14-578645
ø8.5 mm × 50 mm Iliac Screw	4	14-578650
ø8.5 mm × 55 mm Iliac Screw	4	14-578655
ø8.5 mm × 60 mm Iliac Screw	4	14-578660
ø8.5 mm × 70 mm Iliac Screw	4	14-578670
ø8.5 mm × 80 mm Iliac Screw	4	14-578680
ø8.5 mm × 90 mm Iliac Screw	4	14-578690
ø8.5 mm × 100 mm Iliac Screw	2	14-578699

Polaris Translation Screw Implant Kit Kit Number: 14-509682

DESCRIPTION	QTY	PART NUMBER
4.75 mm × 25 mm Translation Screw	4	14-578225
4.75 mm × 30 mm Translation Screw	6	14-578230
4.75 mm × 35 mm Translation Screw	6	14-578235
4.75 mm × 40 mm Translation Screw	6	14-578240
4.75 mm × 45 mm Translation Screw	2	14-578245

Polaris 5.5 Standard Instrument Kit A Kit Number: 14-509680

DESCRIPTION	QTY	PART NUMBER
Ratchet T-Handle	1	124797
Ratchet Handle, Straight	2	124799
Thoracic Pedicle Probe	1	14-500001
Straight Pedicle Probe	1	14-500002
Curved Pedicle Probe	1	14-500003
Firm Pedicle Sound	1	14-500007
Torque Stabilizer	1	14-500018
Screw Head Positioner	1	14-500072
Plug Starter With Handle	2	14-500170
Multi-axial Screw Inserter	2	14-500185
Polaris 5.5 Rocker, Ext Throw	1	14-500197
Dorsal Height Adjuster	1	14-501680
Ratcheting Teardrop Handle	1	2000-6481
Flexible Pedicle Sound	1	2000-9015
4.75 mm Tap	1	2000-9023
5.5 mm Tap	1	2000-9024
6.5 mm Tap	1	2000-9025
7.5 mm Tap	1	2000-9026
8.5 mm Tap	1	2000-9027
Plug Driver	2	2000-9061
Awl Shaft	1	94505
Torque-limiting Handle	2	94522
Rod Holder	1	94613

POLARIS TRANSLATION SCREW IMPLANT AND INSTRUMENT KITS (*continued*)

Polaris 5.5 Standard Instrument Kit B Kit Number: 14-509681

DESCRIPTION	QTY	PART NUMBER
Reduction Screw Break-off Plier	1	14-500009
Perpendicular Rod Persuader	1	14-500198
Rod Bender	1	2000-9044
Cross Connector Torque Wrench	1	94624
Parallel Compressor	1	94686
Parallel Distractor	1	94687

Short Rocket Threaded Reducer Kit Kit Number: 14-509639

DESCRIPTION	QTY	PART NUMBER
Short Threaded Rod Persuader	6	14-500200
T-handle, Offset	2	14-500201
Quick-connect Adaptor	1	14-500202

Long Rocket Threaded Persuader Kit Kit Number: 14-509638

DESCRIPTION	QTY	PART NUMBER
Long Threaded Rod Persuader	2	14-500196
T-handle, Offset	1	14-500201
T-handle	2	14-500203
Quick-connect Adaptor	1	14-500202

Perpendicular Rod Persuader Kit Kit Number: 14-509637

DESCRIPTION	QTY	PART NUMBER
Perpendicular Rod Persuader	2	14-500198

The Polaris Translation Screw System is compatible with the kits utilized by the Polaris 5.5 Spinal System.

DESCRIPTION	KIT NUMBER
Reduction Multi-axial Screw Kit	14-509605
4.75 mm Multi-axial Screw Kit	14-509606
8.5 mm Multi-axial Screw Kit	14-509607
4mm Diameter Screw kit	14-509629
Titanium Deformity Fixed Screw Implant Kit	14-509630
Titanium Deformity Hook Implant Kit	14-509631
Titanium Deformity Standard Instrument Kit A	14-509632
Titanium Deformity Standard Instrument Kit B	14-509633
Trivium™ Derotation Kit	14-509634
Iliac Fixation Kit	14-509635
Uniplanar Screw Kit	14-509636
Perpendicular Persuader Kit	14-509637
Long Threaded Reduction Instrument Kit	14-509638
Short Threaded Reduction Instrument Kit	14-509639
Cobalt Chrome Implant Kit	14-509660
Ti Domino Standard Implant and Instrument Kit	14-509661

IMPLANTS

The Polaris Translation Screw System is compatible with the implant offering of the Polaris 5.5 Spinal System.



Polaris Translation Screw 4.75	PART NUMBER
ø4.75 mm × 25 mm Translation Screw	14-578225
ø4.75 mm × 30 mm Translation Screw	14-578230
ø4.75 mm × 35 mm Translation Screw	14-578235
ø4.75 mm × 40 mm Translation Screw	14-578240
ø4.75 mm × 45 mm Translation Screw	14-578245



Polaris Translation Screw 7.5	PART NUMBER
ø7.5 mm × 30 mm Translation Screw	14-578530
ø7.5 mm × 35 mm Translation Screw	14-578535
ø7.5 mm × 40 mm Translation Screw	14-578540
ø7.5 mm × 45 mm Translation Screw	14-578545
ø7.5 mm × 50 mm Translation Screw	14-578550
ø7.5 mm × 55 mm Translation Screw	14-578555



Polaris Translation Screw 5.5	PART NUMBER
ø5.5 mm × 25 mm Translation Screw	14-578325
ø5.5 mm × 30 mm Translation Screw	14-578330
ø5.5 mm × 35 mm Translation Screw	14-578335
ø5.5 mm × 40 mm Translation Screw	14-578340
ø5.5 mm × 45 mm Translation Screw	14-578345
ø5.5 mm × 50 mm Translation Screw	14-578350
ø5.5 mm × 55 mm Translation Screw	14-578355



Polaris Translation Iliac Screw 6.5	PART NUMBER
ø6.5 mm × 60 mm Translation Iliac Screw	14-578460
ø6.5 mm × 70 mm Translation Iliac Screw	14-578470
ø6.5 mm × 80 mm Translation Iliac Screw	14-578480
ø6.5 mm × 90 mm Translation Iliac Screw	14-578490



Polaris Translation Screw 6.5	PART NUMBER
ø6.5 mm × 30 mm Translation Screw	14-578430
ø6.5 mm × 35 mm Translation Screw	14-578435
ø6.5 mm × 40 mm Translation Screw	14-578440
ø6.5 mm × 45 mm Translation Screw	14-578445
ø6.5 mm × 50 mm Translation Screw	14-578450
ø6.5 mm × 55 mm Translation Screw	14-578455



Polaris Translation Iliac Screw 7.5	PART NUMBER
ø7.5 mm × 60 mm Translation Iliac Screw	14-578560
ø7.5 mm × 70 mm Translation Iliac Screw	14-578570
ø7.5 mm × 80 mm Translation Iliac Screw	14-578580
ø7.5 mm × 90 mm Translation Iliac Screw	14-578590
ø7.5 mm × 100 mm Translation Iliac Screw	14-578599

IMPLANTS (continued)



Polaris Translation Iliac Screw 8.5	PART NUMBER
ø8.5 mm × 35 mm Translation Iliac Screw	14-578635
ø8.5 mm × 40 mm Translation Iliac Screw	14-578640
ø8.5 mm × 45 mm Translation Iliac Screw	14-578645
ø8.5 mm × 50 mm Translation Iliac Screw	14-578650
ø8.5 mm × 55 mm Translation Iliac Screw	14-578655
ø8.5 mm × 60 mm Translation Iliac Screw	14-578660
ø8.5 mm × 70 mm Translation Iliac Screw	14-578670
ø8.5 mm × 80 mm Translation Iliac Screw	14-578680
ø8.5 mm × 90 mm Translation Iliac Screw	14-578690
ø8.5 mm × 100 mm Translation Iliac Screw	14-578699



Multi-axial Screw Kits	PART NUMBER
ø4.75 mm Multi-axial Screw Implant Kit	14-509606
ø5.5 mm Multi-axial Screw Implant Kit	55500147
ø8.5 mm Multi-axial Screw Implant Kit	14-509607



Helical Flange® Plug	PART NUMBER
	2000-1005



Lateral Connector—25mm	PART NUMBER
	2000-1020



Reduction Multi-axial Screw Kit	PART NUMBER
	14-509605



Pre-cut Contoured Rods	PART NUMBER
30 mm Ti Alloy Curved Rod	2000-5130
35 mm Ti Alloy Curved Rod	2000-5135
40 mm Ti Alloy Curved Rod	2000-5140
45 mm Ti Alloy Curved Rod	2000-5145
50 mm Ti Alloy Curved Rod	2000-5150
55 mm Ti Alloy Curved Rod	2000-5155
60 mm Ti Alloy Curved Rod	2000-5160
65 mm Ti Alloy Curved Rod	2000-5165
70 mm Ti Alloy Curved Rod	2000-5170
75 mm Ti Alloy Curved Rod	2000-5175
80 mm Ti Alloy Curved Rod	2000-5180
90 mm Ti Alloy Curved Rod	2000-5190
100 mm Ti Alloy Curved Rod	2000-5199



Cross Connectors	PART NUMBER
XXSmall Cross Connector	94669
XSmall Cross Connector	94670
Small Cross Connector	94671
Medium Cross Connector	94672
Large Cross Connector	94673

INSTRUMENTS



Double-lead Taps	PART NUMBER
4 mm	14-500085
4.75 mm	14-500086
5.5 mm	14-500088
6.5 mm	14-500089
7.5 mm	14-500090



Double-lead Iliac Taps	PART NUMBER
5.5 mm	14-500191
6.5 mm	14-500192
7.5 mm	14-500193
8.5 mm	14-500194
9.5 mm	14-500097
10.5 mm	14-500098



Polaris 5.5 Button Lock Screw Inserter PART NUMBER
14-500070



Translation Screw Bone Planer PART NUMBER
14-500071



Screw Head Positioner PART NUMBER
14-500072



Screw Shaft Remover PART NUMBER
14-500073



Fixed Handle-T PART NUMBER
95697

The Polaris Translation Screw System is compatible with the instrument offering of the Polaris 5.5 Spinal System.



Fixed Handle—Straight PART NUMBER
94699



Ratchet Teardrop Handle PART NUMBER
2000-6481



Ratchet Handle—Straight PART NUMBER
124799



Awl Shaft PART NUMBER
94505



Ratchet T-handle PART NUMBER
124797



Thoracic Pedicle Probe PART NUMBER
14-500100



Fixed Teardrop Handle PART NUMBER
2000-9006



Straight Pedicle Probe PART NUMBER
14-500101



Curved Pedicle Sound PART NUMBER
14-500102

INSTRUMENTS *(continued)*



Single Lead Tap	PART NUMBER
4.75 mm	2000-9023
5.5 mm	2000-9024
6.5 mm	2000-9025
7.5 mm	2000-9026
8.6 mm	2000-9027



Stiff Pedicle Sound	PART NUMBER
	4010



Flexible Pedicle Sound	PART NUMBER
	2000-9015



Trial Pins	PART NUMBER
9 cm	4077
11 cm	4072



Multi-axial Screw Inserter	PART NUMBER
	14-500185



Dorsal Height Adjuster	PART NUMBER
	14-501680



Rod Template	PART NUMBER
	94612



Rod Holder	PART NUMBER
	94613



Rod Bender	PART NUMBER
	2000-9044



Teardrop Plug Inserter

PART NUMBER

14-500170



Long Rocket Threaded Reducer

PART NUMBER

14-500196



Double End Plug Starter

PART NUMBER

2000-9060



Offset T-Handle

PART NUMBER

14-500201



Rod Rocker

PART NUMBER

2000-9051



T-handle

PART NUMBER

14-500203



Short Rocket Threaded Reducer

PART NUMBER

14-500200



Quick-connect Adaptor

PART NUMBER

14-500202

INSTRUMENTS *(continued)*



Rod Persuader	PART NUMBER
Parallel	2000-9055
Perpendicular	14-500198



Soft Tissue Retractor	PART NUMBER
	94614



Compressor	PART NUMBER
	94686



Distractor	PART NUMBER
	94687



Cross Connector Torque Wrench	PART NUMBER
	94624



Plug Driver	PART NUMBER
	2000-9061

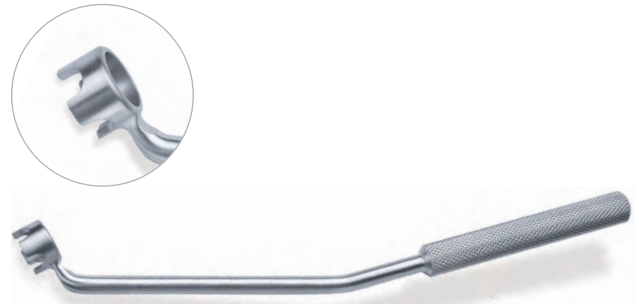


Torque Limiting Handle	PART NUMBER
	94522



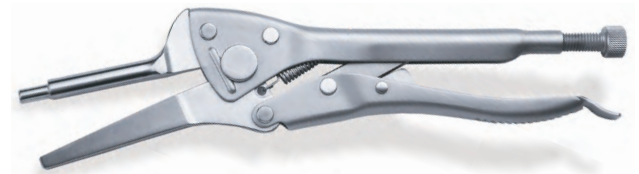
Torque Stabilizer

PART NUMBER
14-500018



Reduction Screw Break-off Stabilizer

PART NUMBER
2000-9019



Reduction Screw Break-off Pliers

PART NUMBER
2000-9074

IMPORTANT INFORMATION ON THE POLARIS TRANSLATION SCREW

Device Description

The Polaris Spinal System is a non-cervical spinal fixation system. The system includes screws, various types and sizes of rods, locking nuts, hooks, lateral connectors, plugs, washers, staples, rod connectors/dominos and various cross connectors. Various instruments are also available for use by the surgeon to facilitate implantation of the device.

Indications for Use

The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/iliac screw fixation system, or as an anterior or anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients and for use with autograft and/or allograft. The device is indicated for all 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), deformity or curvature (i.e., scoliosis, kyphosis, and/or lordosis), tumor, stenosis, pseudoarthrosis, or failed previous fusion.

For pediatric patients, the Polaris Spinal System may be used for posterior, non-cervical pedicle screw fixation as an adjunct to fusion to treat adolescent idiopathic scoliosis and is also indicated for treatment of the following conditions: spondylolisthesis/spondylolysis and fractures caused by tumor and/or trauma. Pedicle screw fixation is limited to a posterior approach.

The Polaris Spinal System may be used with the instruments in the AccuVision® Minimally Invasive Spinal Exposure System to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The dominos in the Polaris Spinal System can be used to connect the Polaris Spinal System to the Altius™ Spinal System, Lineum™ OCT Spine System, the Array® Spinal System, the Biomet Omega21™ Spinal System, or the Synergy™ Spinal System to achieve additional levels of fixation. Please refer to the individual system's Package Insert for a list of the indications for use for each system.

Contraindications

- Spinal infection
- Morbid obesity
- A patient who in the surgeon's opinion is not psychosocially, mentally or physically able to fully comply with the post-operative treatment regime (e.g., mental illness, alcoholism or drug abuse.)
- Pregnancy
- Metal sensitivity/foreign body sensitivity
- Patients with inadequate tissue coverage over the operative site
- Open wounds local to the operative area
- Direct current stimulation, when used in a construct that includes Translation Screws

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 severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. Potential risks identified with the use of this device, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
- **Implant Strength and Loading.** The Polaris Spinal System is intended to assist healing and is not intended to replace normal bony structures. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue.

Therefore, it is important that immobilization of the operative site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The surgeon must be thoroughly knowledgeable in the medical, surgical, mechanical and metallurgical aspects of the Polaris Spinal System. Postoperative care is extremely important. The patient should be warned that noncompliance with postoperative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the implant.

- Selection of Implants. Selection of the proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present size limitations on the implants.
- Metabolic bone disease such as severe osteoporosis may adversely affect adequate fixation of the implants due to the poor quality of the bone.

Warnings (continued)

- The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. They must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use. All nonsterile components and instruments must be cleaned and sterilized before use. Zimmer Biomet Spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.
- Corrosion. Contact of dissimilar metals accelerates the corrosion process, which could increase the possibility of fatigue fracture of the implants. Therefore, only use like or compatible metals for implants that are in contact with each other. Never use stainless steel and titanium implant components in the same construct. Cobalt Chrome Alloy rods should not be used with Stainless Steel Components. Cobalt Chrome Alloy rods are to be used ONLY with Titanium implant components in the same construct.
- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

MRI Safety Information

The Polaris Spinal System has not been evaluated for safety and compatibility in the MR environment. The Polaris Spinal System has not been tested for heating or migration in the MR environment.

Limits of System Compatibility

When used with AccuVision® Instruments, the system is limited to the implantation of rod lengths of 100 mm or less, and excludes the use of system cross connectors or hooks.

Precautions

- Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in or used on a different patient.
- Handling of Implants. If contouring of the rod is required, avoid sharp bends and reverse bends. Avoid notching or scratching of the device, which could increase internal stresses and lead to early breakage.
- Implant Removal After Healing. After healing is complete, the implant is intended to be removed since it is no longer necessary. Implants that are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone, particularly in young, active patients. Implant removal should be followed by adequate postoperative management.
- Adequate Patient Instructions. A patient must be instructed on the limitations of the metallic implant, and should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.
- Surgical Techniques. 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. Please refer to the specific surgical technique for this device for more information.
- The Adjustable Length Rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery and is intended for use as part of either a single or double rod assembly. It allows for distraction at a central location once bone anchors have been secured.
- The Bullet End Rods are intended for use with the Jackson Intracanal Fixation Technique.

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



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eLabeling: The Instructions for Use can be accessed online by visiting the website and using the KEY-CODE provided on the product label and as shown below. Additional translations are also available in electronic format for download. To request a paper copy of the Instructions for Use, contact Zimmer Biomet Spine at the phone number provided.



Consult Instructions for Use on this website:

<http://labeling.zimmerbiomet.com>

Key-Code: 060505-02



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