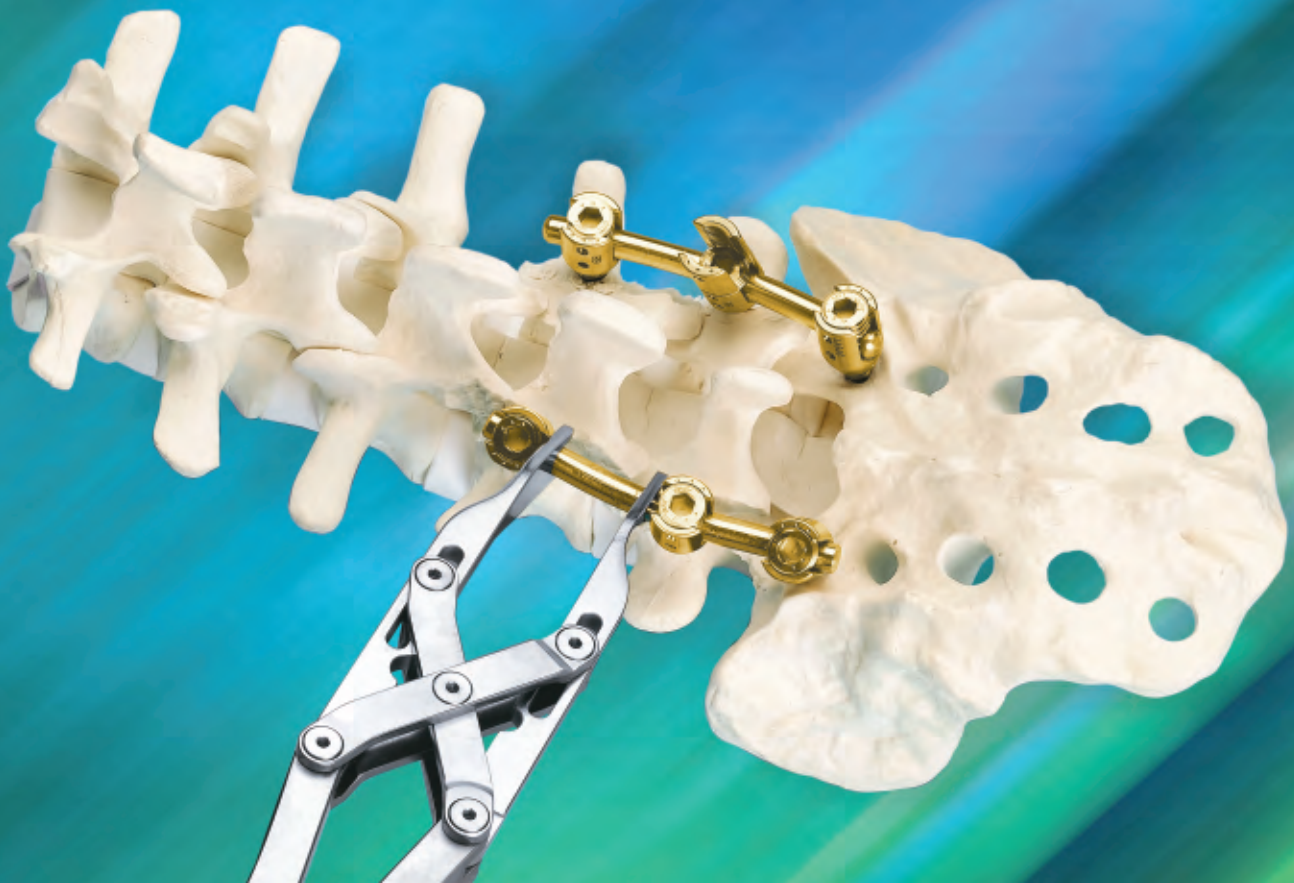
BIOMET SPINE

POLARIS™ 6.35

Surgical Technique

Contents



Introduction

Polaris™ 6.35, a low profile, top-loading system, is the next generation Synergy™ Spinal Fixation System. The design team built upon **Synergy's** long clinical history, resulting in a system that incorporates minimal, logical, and ergonomic instrumentation, while retaining options, speed, ease of use, and strength.

The **Polaris 6.35** Spinal System is designed to address the pathologies of the thoracic and lumbar spine. The System contains a wide selection of Multi-axial Screws, fixed head screws, lateral connectors, and cross connectors, providing versatility for multiple construct options.

The **Polaris 6.35** Spinal System incorporates a unique Helical Flange™ locking mechanism that minimizes seat splay and cross-threading. Knurled surfaces create a mechanical lock at the implant interface. The System has a short run on the rod comparable to systems with a smaller rod diameter, but provides the strength benefit of a 6.35mm rod.

System Design Features

Multi-axial Screw

- Consists of two components: the screw shaft and the seat
- The screw shaft has a knurled hex peak which interfaces with the rod, enhancing the grip on the rod
- The knurled undersurface of the screw locks with the knurled seat once the construct is tightened providing a truly secure, polyaxial design
- The cutting flutes enhance the screw's self-tapping function
- The polyaxial head allows 18° of angulation in any direction
- Two prong sites on the walls of the seat facilitate system manipulation, particularly with various rod reduction techniques

Multi-axial Screw

Seat

Cutting Flute

Knurled Hex Peak

Unique Locking Mechanism

- The interface between the seat and the plug incorporates **Helical Flange** Technology
- **Helical Flange** Technology allows the flanges on the plug and the seat to lock together to minimize head splay and cross-threading

Pre-cut, Pre-contoured Rods

- 6.35mm diameter
- Commercially Pure Titanium
- Minimize the need for rod bending

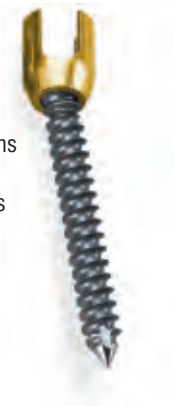
Modular Instrumentation

- Instrument shafts attach to Quick Connect Handles, offered in either a Straight or T-handle configuration

Implants

The **Polaris 6.35** Spinal System is a spinal fixation device made from titanium alloy (Ti-6Al-4V ELI) and Commercially Pure titanium (CP Ti). The System includes self-tapping multi-axial and fixed screws, CP Ti and titanium alloy rods, lateral connectors, and **Helical Flange** Plugs.

Multi-axial And Fixed Head Screws



- Multi-axial Screws:
  - 4.0 and 4.75mm diameters: 20-40mm lengths
  - 5.5mm diameter: 30-50mm lengths
  - 6.5 and 7.0mm diameters: 30-55mm lengths

- Reduction Screws (Multi-axial only):
  - 6.5mm diameter: 40 and 45mm lengths
  - 7.0mm diameter: 45 and 50mm lengths

NOTE: Fixed screw lengths vary from Multi-axial Screw lengths.

- 4.0 and 4.75mm diameters: 25-40mm lengths
- 5.5mm diameter: 25-45mm lengths
- 6.5 and 7.0mm diameters: 30-50mm lengths

- All lengths offered in 5.0mm increments

BIOMET SPINE

Plugs

- **Helical Flange** Technology

Rods

- 6.35mm diameter
- Pre-cut, pre-contoured, ranging in length from 3cm-10cm in 1cm increments. Pre-contoured rods are available in commercially pure titanium (CP Ti) only
- Pre-cut, straight rods are available in CP Ti
  - 10, 12, 14, 30, and 48cm (30 and 48cm CP Ti rods have a hex tipped end)
- Pre-cut, straight rods are available in Ti Alloy
  - 30cm and 48cm (with a hex tipped end)

NOTE: All CP Ti rods are gold

Cross Connectors*

- Low Profile
- Telescoping
- Small: 37-45mm
- Medium: 43-57mm
- Large: 55-80mm

Lateral Connectors

- Lateral connector: 24mm
- Extended lateral connector: 34mm

(Length is measured from the center of the plug to the end of the arm).

Instruments

Various instruments are available with the **Polaris 6.35** Spinal System for use by the surgeon to facilitate implantation of the device.

Quick Connect Handles

Pedicle Awl

Straight Pedicle Probe

Quick-Connect Taps

Ball Tip Probe

Trial Pins

Multi-axial Screw Bidirectional Driver
Fixed Screw Bidirectional Driver

Multi-axial Screw Lever Activated Driver

Multi-axial Screw Height Adjuster

Rod Bender

Rod Holder

Rod Rotator

Soft Tissue Bifid Retractor

4.8mm Hex Plug Starter

In-Situ Rod Benders

Instruments (Continued)

Screw Fork

Wing Rocker

Rod Persuader

Reduction Seat Depth Gauge

Reduction Seat Thread Gripper

Cross Connector Driver

Torque Measuring Wrench

Torque Stabilizer

Surgical Technique

1. Surgical Approach And Preparations

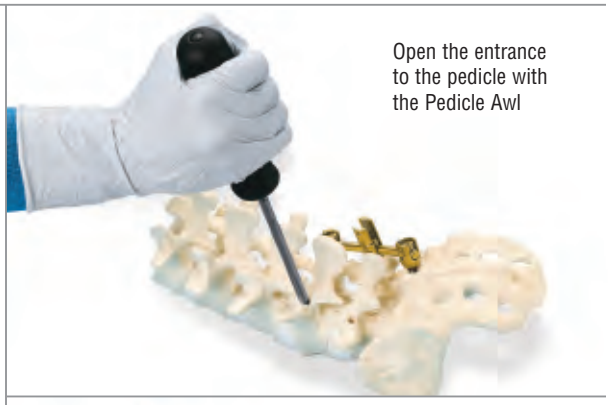
The patient is positioned prone as is customary for the surgeon, the spine is subperiosteally exposed through a midline or paramedian incision, and a decompression is performed, if indicated. Decortication must be meticulously performed. Graft may be placed into the posterolateral gutters either before or after the **Polaris 6.35** Spinal System has been implanted.

2. Pedicle Preparation

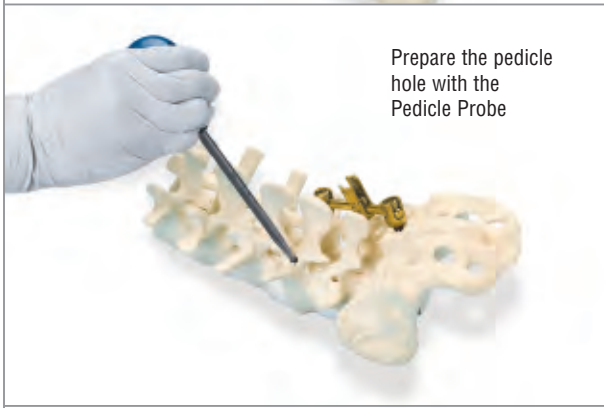
After adequate exposure, the appropriate pedicle entry point is selected and the entrance to the pedicle is opened with an awl, burr, or curette. The Pedicle Probe is used to create the pedicle hole by advancing the Probe to a depth of approximately 30-40mm using the depth guide on the Probe.

The Ball Tip Probe 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.

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, connected to the Quick Connect Handle into the pedicle hole.

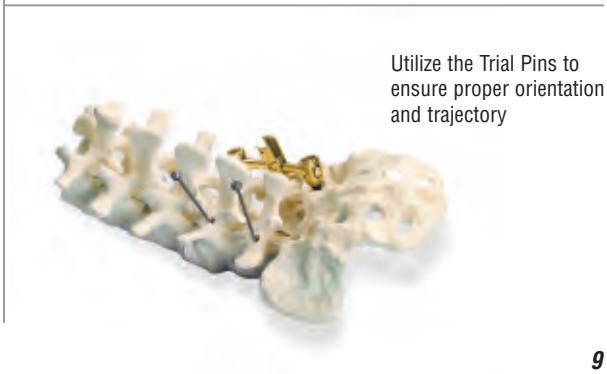


Open the entrance to the pedicle with the Pedicle Awl



Prepare the pedicle hole with the Pedicle Probe

Confirm containment of the pedicle with the Ball Tip Probe



Utilize the Trial Pins to ensure proper orientation and trajectory

3. Screw Selection And Insertion

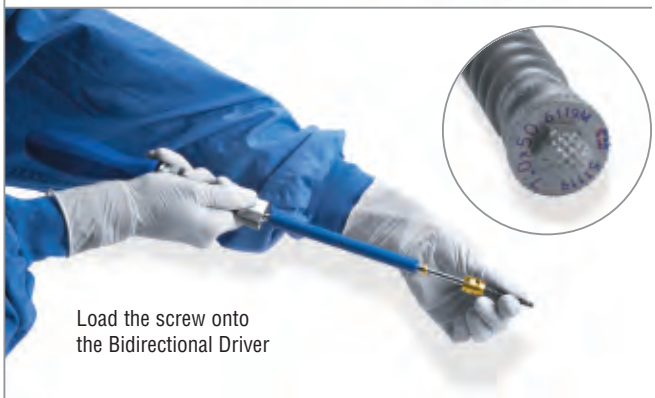
Self-tapping screws are available in several diameters and lengths. The appropriate screw length is determined by using the depth gauge on the Pedicle Probe. When using Multi-axial Screws, either the Bidirectional or Lever Activated Screw Driver may be used.

The Multi-axial Screws may be loaded freehand or while seated within the surgical tray. Attach the desired Multi-axial Screw driver 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.

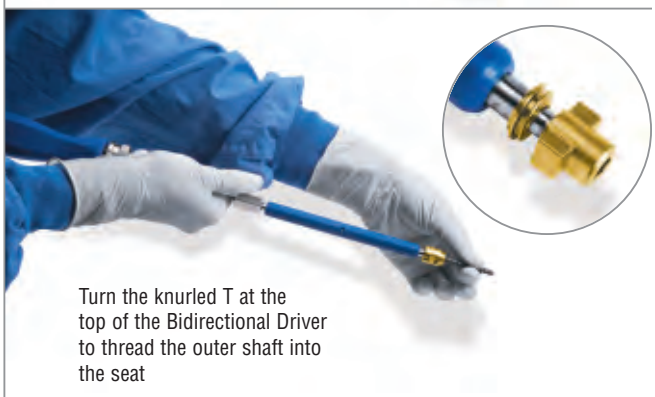
When using the Bidirectional Driver, first ensure that the knurled T is at the top of the driver shaft, preventing the outer shaft from prematurely dropping into the screw head. Next, hold the screw by the screw shaft and load the screw onto the tip of the Bidirectional Driver. Ensure that the male hex end at the top of the screw shaft is fully seated into the female hex of the Driver. Then turn the knurled T in a clockwise direction to thread the outer shaft into the seat. Confirm that the screw is straight and secure in the Driver.

The screw is advanced into the pedicle to the desired depth. During insertion, guide the Driver by holding the blue sleeve on the shaft of the instrument. The Bidirectional Driver is disengaged from the screw by rotating the knurled T in a counterclockwise direction, and then lifting the Driver from the screw.

Select the appropriate screw style and size



Load the screw onto the Bidirectional Driver



Turn the knurled T at the top of the Bidirectional Driver to thread the outer shaft into the seat

Insert the screw into the pedicle using the Bidirectional Driver

3. Screw Selection And Insertion (Continued)

When using the Lever Activated Driver, Multi-axial Screws may be loaded freehand or while seated within the surgical tray. First ensure the latch is perpendicular to the shaft of the Driver; this essentially "opens" the Driver. After attaching the Driver to the chosen Quick Connect Handle as previously described, place the male hex at the top of the screw into the female end of the driver. The latch is then pushed down (toward the Quick Connect Handle), locking the screw in place. Confirm the screw is straight and secure in the Driver.

The screw is advanced into the pedicle to the desired depth. The Lever Activated Driver is disengaged from the screw by releasing the latch so that the latch returns to the starting position, perpendicular to the Driver shaft.

NOTE: The Multi-axial Screw must not be driven into the pedicle hole so tightly that variable angulation of the seat on the screw is compromised.

Multi-axial Screw Lever Activated Driver

Multi-axial Screw

3. Screw Selection And Insertion (Continued)

Fixed Screws are inserted using the Fixed Bidirectional Driver. Attach the Fixed Screw Bidirectional Driver shaft to the Quick Connect Handle.

Ensure that the knurled T is at the top of the driver shaft, preventing the outer shaft from prematurely dropping into the screw head. Next, hold the screw by the screw shaft and load the screw into the tip of the Fixed Bidirectional Driver. Then, turn the knurled T in a clockwise direction to thread the outer shaft into the seat. Confirm the screw is secure in the Driver.

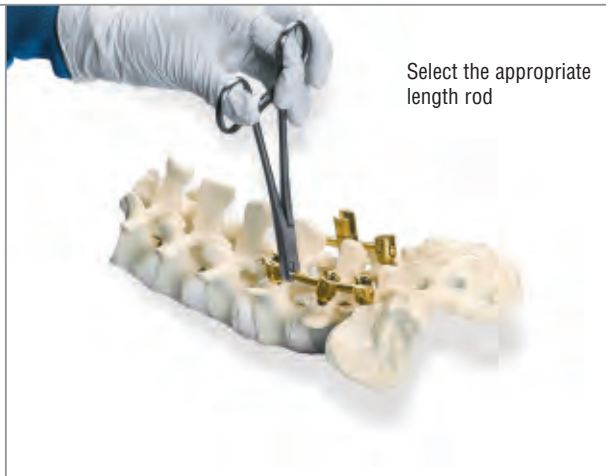
The screw is advanced into the pedicle to the desired depth. The Fixed Bidirectional Driver is disengaged from the screw by rotating the knurled T in a counter-clockwise direction, and then lifting the Driver from the screw.

Select the appropriate screw style and size

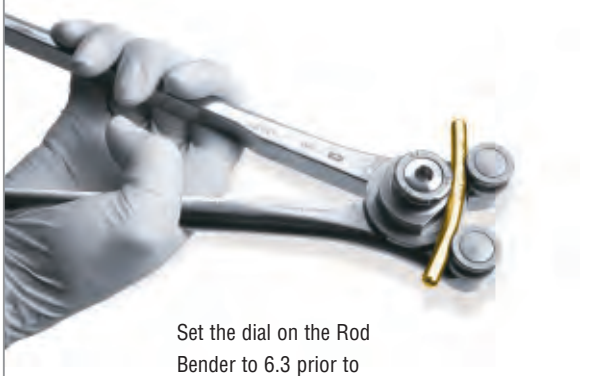
Fixed Screw Bidirectional Driver

4. Rod Application

Once all screws have been inserted, the appropriate length rod should be chosen according to the construct. The rod should project at least 2.0mm beyond the screw seats at the ends of the construct. Be sure to account for large curves and distractions when choosing rod length. If necessary, the selected rod may be contoured utilizing the Rod Bender. When using the Rod Bender, set the dial to the appropriate setting for the 6.35mm rod diameter (setting: 6.3).



Select the appropriate length rod



Set the dial on the Rod Bender to 6.3 prior to bending the rod

5. Helical Flange Plug Application

When all screws have been inserted and the rods placed in the screw seat, the construct is then secured using **Helical Flange** Plugs. The Plug is firmly pressed onto the tip of the 4.8mm Hex Plug Starter. All plugs should be placed and then provisionally tightened.

If necessary, the Plug Starter may be used in combination with the Rod Persuader, Screw Fork, or Wing Rocker.

When using the 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 handle of the Rod Persuader to fully seat the rod in the screw seat. The Plug Starter will fit through the cannulated portion of the Persuader, allowing for plug application with the Rod Persuader in place. To release the Persuader, press the trigger located underneath the handle. Once released, the Persuader may then be removed from the screw seat.

When using the Wing Rocker, place the prongs located at the distal end of the Rocker into either the top or bottom holes in the screw seat. Squeeze the instrument until tightened; tilt the Wing Rocker to persuade the rod into the screw seat.

Load the plug onto the Hex Plug Starter

The Persuader may be used to fully seat the rod in the screw seat

The Wing Rocker may be used to fully seat the rod in the screw seat

5. Helical Flange Plug Application (Continued)

When using the Screw Fork, position the Fork section underneath the screw seat. Tilt the Screw Fork to persuade the rod into the screw seat.

The Torque Stabilizer may be used to reposition the axis of the screw seat while simultaneously acting as a guide for the Plug Starter.

NOTE: If soft tissue is interfering with proper plug placement, the Soft Tissue Bifid Retractor may be utilized to retract the soft tissue away from the seat by placing the bifid tip of the retractor under the screw seat.

Place the Screw Fork under the seat and tilt the instrument back to fully seat the rod

The Bifid Retractor aids retraction of soft tissue away from the screw seat

6. Final Locking With The Torque Wrench

After provisional tightening, proper implant placement should be confirmed with radiographs. The plugs are then finally tightened with the Torque Measuring Wrench in combination with the Torque Stabilizer. Insert the Torque Measuring Wrench through the center of the Torque Stabilizer. Position the tip of the Torque Measuring Wrench into the female portion of 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 in the slots of the Stabilizer. The Torque Measuring Wrench is turned in a clockwise direction while the Torque Stabilizer is held with resistive force in a counterclockwise direction. Two etched arrows indicate when the appropriate torque is obtained. The first set of arrows lines up at zero, showing the start position. Upon reaching the intended final torque, two arrows will line up at 120in-lbs (13.6 N-m). THERE IS NO AUDIBLE CLICK.

Arrows on Torque Measuring Wrench line up at zero, signifying the starting position. When the torque level is reached, arrows will line up at 120
THERE IS NO AUDIBLE CLICK

Use the Torque Measuring Wrench with the Torque Stabilizer

Additional Surgical Options

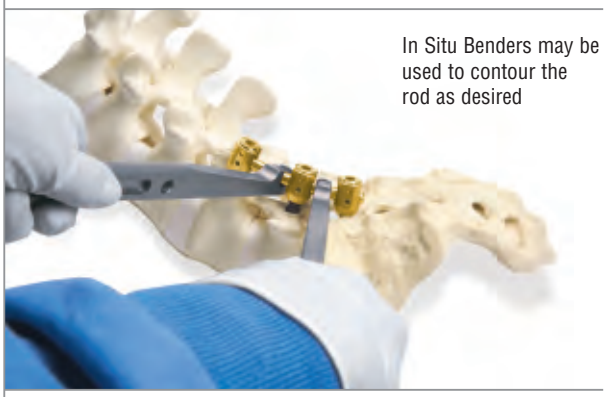
Rod Rotation

After the rods and plugs have been placed, the Rod Rotator may be utilized to rotate the rods in order to achieve the desired anatomical curvature. Open the Rod Rotator; squeeze the handle to tighten the instrument at any point on the 6.35mm rod. Adjust the vice grip, as needed, by turning the gear clockwise until appropriate force is applied to the rod and then rotate the rod to the desired position.

The Rod Rotator is used to rotate the rod

In Situ Rod Contouring

In situ rod contouring may be performed with the In Situ Benders prior to final torquing. The In Situ Benders are used to improve or adjust kyphosis and lordosis.

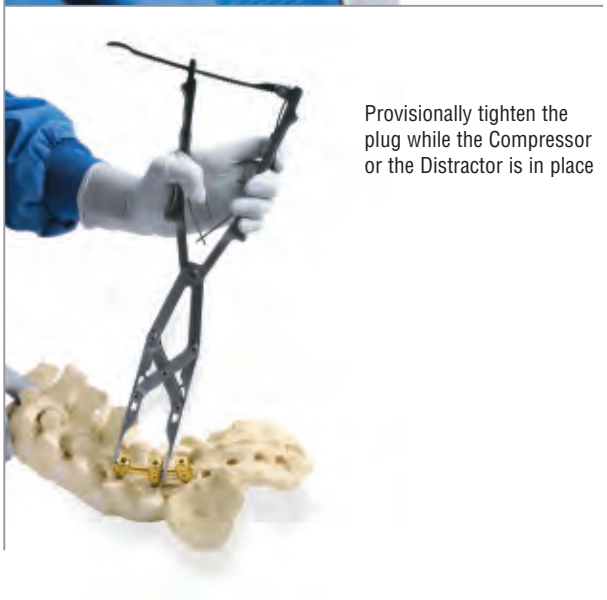


In Situ Benders may be used to contour the rod as desired

Distraction And Compression

Distraction and compression may be achieved by utilizing either the Parallel Distractor or Parallel 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 to the screw seats. The distraction or compression device will maintain the position of the vertebra until the plug is provisionally tightened with the Plug Starter.

NOTE: The Rod Rotator may act as a fixed point when compressing or distracting.



Provisionally tighten the plug while the Compressor or the Distractor is in place

Additional Surgical Options (Continued)

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 tightened. Apply the cross connector to the rods and tighten the screws with the blue handled Cross Connector Driver.

NOTE: The Cross Connector Driver is NOT a Torque Wrench; finger tightening is sufficient.

Lateral Connectors

Lateral connectors may be utilized if screw placement would require a severe bend in the rod. The lateral connectors allow for a 24mm or a 34mm 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 **Helical Flange** 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 (refer to page 14 "**Helical Flange** Plug Insertion" and page 16 "Final Locking With The Torque Wrench").

Select the appropriate sized Cross Connector

The Cross Connector Driver is not a torque wrench
THERE IS NO AUDIBLE CLICK

Lateral Connectors

Standard: 24mm
Extended: 34mm

(Length is measured from the center of the plug to the end of the arm)

Reduction Screws

For a spondylolisthesis, reduction screws with extended tabs may be utilized. The extended tab portion of the Multi-axial Screws allows for easier rod introduction in the slipped vertebra and may be used to reduce the spondylolisthesis if desired. The extended tabs are removed at the end of the procedure to give the screw the same profile as the standard Multi-axial Screw.

Example Of A Spondylolisthesis Reduction:

For an L5 spondylolisthesis, reduction may be accomplished by inserting reduction Multi-axial Screws with the extended tabs in L5 and standard self-tapping Multi-axial Screws in L4 and S1. The Reduction Screws are inserted in the same manner as the Multi-axial Screws. Once the screws have been inserted, the rod and **Helical Flange** Plugs are applied in the standard manner. The L4 and S1 **Helical Flange** Plugs are loosely tightened on both sides. Once the L4 and S1 plugs are partially secured, reduction is obtained by simultaneously and gradually tightening the **Helical Flange** Plugs on the reduction screws at the L5 level (refer to page 14 "**Helical Flange** Plug Application"). It may be necessary to distract L5-S1, or L4-L5, to aid in the reduction.

Once the spondylolisthesis is corrected, use the Reduction Seat Depth Gauge to ensure the **Helical Flange** Plug is fully seated in the seat. Place the distal tip (silver portion) into the top of the Multi-axial Screw and press the outer sleeve of the Gauge down. View the top of the Gauge and confirm the inner silver shaft is flush with the white outer sleeve.

Multi-axial Reduction Screw

Confirm the **Helical Flange** Plug is below the scored area of the tab

Additional Surgical Options (Continued)

Reduction Screws (Continued)

Once the **Helical Flange** Plug is inserted to the appropriate depth, the plugs must be torqued to 120in-lbs with the Torque Measuring Wrench in combination with the Torque Stabilizer (refer to page 16 “Final Locking With The Torque Wrench”). After final torquing, the tabs are removed from the Multi-axial Reduction Screw using the Reduction Screw Thread Gripper. Open to release the Gripper and place the rounded tip into the seat, resting on the top of the **Helical Flange** Plug. The blunt tip will be on the outside of the tab. Next, turn the knurled knob on the instrument in order to grip the tabs. Squeeze the handles together to tighten on one tab. Move the instrument back and forth until the excess tab portion breaks at the scored area. Release the Gripper and empty the disassembled tab. Repeat the process on the second tab.

Multi-axial Reduction Screw with break off tabs

The Reduction Screw Thread Gripper is used to remove the break off tabs after final torquing of the **Helical Flange** Plugs

Screw Height Adjustment

The Multi-axial Screw Height Adjuster may be used to adjust the Multi-axial Screw height prior to rod placement. Seat the female hex of the Multi-axial Screw Height Adjuster over the male of the screw shaft. Turn the adjuster one or two turns for minor manipulation of the screw height. For screw height adjustment (greater than one or two turns), use the Multi-axial Screw Bidirectional Driver.

Screw Removal

The Multi-axial Screw Bidirectional Driver is used to remove the Multi-axial Screws by seating the male hex of the Driver over the female hex of the screw shaft. Slide the outer sleeve down and turn the large ring clockwise to lock into the screw seat. Once the Driver is tightened, the screw may be backed out of the pedicle.

The Fixed Screw Bidirectional Driver is used to adjust the fixed screws. The Driver is also used to remove both the fixed screws and the Multi-axial Screws in a revision procedure (after final torquing has occurred).

Use the Multi-axial Screw Height Adjuster to adjust Multi-axial Screw height prior to rod placement

Seat the tip of the Multi-axial Screw Height Adjuster over the male hex located at the top of the screw shaft (screw seat removed for clarity)

Use the Fixed Screw Bidirectional Driver to remove both fixed and Multi-axial Screws

Closure, Post Operative Care

After implantation of the **Polaris 6.35** Spinal System is complete, wound closure is performed according to the standard protocol for the surgeon.

Implant Removal

Removal of the **Polaris 6.35** Spinal System is performed by reversing the order of the implant procedure. The Torque Measuring Wrench in combination with the Torque Stabilizer must be used first to remove the plugs. Refer to page 21 for additional screw removal details.

NOTE: When removing previously torqued plugs, turn the Torque Measuring Wrench in a slight clockwise direction before turning counterclockwise. Continue with this back and forth motion until the plug loosens.

Product Information

LTPI

Top

Catalog #	Description	Qty
4127	Sterilization Instrument Tray	1
4005	Awl	1
4010	Ball Tip Probe	1
4072	11cm Trial Pin	4
4077	9cm Trial Pin	4
4329	Ratcheting Straight Handle	2
4363M	4.0mm Tap	1
4364M	4.75mm Tap	1
4365M	5.5mm Tap	1
4366M	6.5mm Tap	1
4367M	7.0mm Tap	1
4373	Ratcheting T-Handle	1
4385	3.2 Straight Probe	1
4396	3.2 Curved Probe	1
4398M	Lever Activated Multi-axial Screw Driver	1
4500M	Multi-axial Screw Bidirectional Driver	2
4516M	Fixed Screw Bidirectional Driver	1

LTPI

Mid

Catalog #	Description	Qty
4046	Rod Holder	1
4088	Wing Rocker	1
4493	Multi-axial Screw Height Adjustor	1
4029	Rod Bender	1
4030	In Situ Bender, L	1
4031	In Situ Bender, R	1
4032	Bifid Retractor	1
4216M	4.8mm Plug Starter	1
4374M	Screw Fork	1
4377	Rod Rotator	1

LTPI

Base

Catalog #	Description	Qty
4055	Reduction Seat Thread Gripper	1
4484	Torque Stabilizer	1
4485	Reduction Seat Depth Gauge	1
4496	Compressor	1
4497	Distractor	1
4498	Rod Persuader	1
4513	Cross Connector Wrench	1
4490M	Torque Measuring Wrench	1

LTPL

Multi-axial Screw Caddy - TOP

Catalog #	Description	Qty
4128	LTPL Sterilization Tray	1

Catalog #	Description	Qty
50-6105MP	5.5mm Dia. x 30mm Multi-axial Screw	6
50-6106MP	5.5mm Dia. x 35mm Multi-axial Screw	6
50-6107MP	5.5mm Dia. x 40mm Multi-axial Screw	6
50-6108MP	5.5mm Dia. x 45mm Multi-axial Screw	6
50-6109MP	5.5mm Dia. x 50mm Multi-axial Screw	4
50-6110MP	6.5mm Dia. x 30mm Multi-axial Screw	4
50-6111MP	6.5mm Dia. x 35mm Multi-axial Screw	6
50-6112MP	6.5mm Dia. x 40mm Multi-axial Screw	8
50-6113MP	6.5mm Dia. x 45mm Multi-axial Screw	8
50-6114MP	6.5mm Dia. x 50mm Multi-axial Screw	6
50-6800MP	6.5mm Dia. x 55mm Multi-axial Screw	4
50-6115MP	7.0mm Dia. x 30mm Multi-axial Screw	2
50-6116MP	7.0mm Dia. x 35mm Multi-axial Screw	4
50-6117MP	7.0mm Dia. x 40mm Multi-axial Screw	6
50-6118MP	7.0mm Dia. x 45mm Multi-axial Screw	6
50-6119MP	7.0mm Dia. x 50mm Multi-axial Screw	6
50-6801MP	7.0mm Dia. x 55mm Multi-axial Screw	4
53-6112MP	6.5mm Dia. x 40mm Multi-axial Reduction Screw	2
53-6113MP	6.5mm Dia. x 45mm Multi-axial Reduction Screw	2
53-6118MP	7.0mm Dia. x 45mm Multi-axial Reduction Screw	2
53-6119MP	7.0mm Dia. x 50mm Multi-axial Reduction Screw	2
6451	**Helical Flange** Plug	20
6454	Lateral Connector	2
6455	Lateral Connector-Extended	2
6954	Cross Connector-Small	2
6955	Cross Connector-Medium	2
6956	Cross Connector-Large	2

LTPL

Base

Catalog #	Description	Qty
6015	6.35mm x 30cm CP Ti Rod w/hex	4
6420	6.35mm x 3cm Pre-bent CP Ti Rod	4
6421	6.35mm x 4cm Pre-bent CP Ti Rod	4
6422	6.35mm x 5cm Pre-bent CP Ti Rod	4
6423	6.35mm x 6cm Pre-bent CP Ti Rod	4
6424	6.35mm x 7cm Pre-bent CP Ti Rod	4
6425	6.35mm x 8cm Pre-bent CP Ti Rod	4
6426	6.35mm x 9cm Pre-bent CP Ti Rod	4
6427	6.35mm x 10cm Pre-bent CP Ti Rod	4

LTPTL

Catalog #	Description	Qty
4129	LTPTL Implant Sterilization Tray	1

LTPTL
Top

Catalog #	Description	Qty
50-6550MP	4.0mm Dia. x 20mm Multi-axial Screw	4
50-6551MP	4.0mm Dia. x 25mm Multi-axial Screw	6
50-6552MP	4.0mm Dia. x 30mm Multi-axial Screw	6
50-6553MP	4.0mm Dia. x 35mm Multi-axial Screw	4
50-6554MP	4.0mm Dia. x 40mm Multi-axial Screw	4
50-6803MP	4.75mm Dia. x 20mm Multi-axial Screw	4
50-6804MP	4.75mm Dia. x 25mm Multi-axial Screw	4
50-6805MP	4.75mm Dia. x 30mm Multi-axial Screw	6
50-6806MP	4.75mm Dia. x 35mm Multi-axial Screw	6
50-6807MP	4.75mm Dia. x 40mm Multi-axial Screw	4
50-6105MP	5.5mm Dia. x 30mm Multi-axial Screw	6
50-6106MP	5.5mm Dia. x 35mm Multi-axial Screw	6
50-6107MP	5.5mm Dia. x 40mm Multi-axial Screw	6
50-6108MP	5.5mm Dia. x 45mm Multi-axial Screw	6
50-6109MP	5.5mm Dia. x 50mm Multi-axial Screw	4
50-6110MP	6.5mm Dia. x 30mm Multi-axial Screw	4
50-6111MP	6.5mm Dia. x 35mm Multi-axial Screw	6
50-6112MP	6.5mm Dia. x 40mm Multi-axial Screw	8
50-6113MP	6.5mm Dia. x 45mm Multi-axial Screw	8
50-6114MP	6.5mm Dia. x 50mm Multi-axial Screw	6
50-6800MP	6.5mm Dia. x 55mm Multi-axial Screw	4
50-6115MP	7.0mm Dia. x 30mm Multi-axial Screw	2
50-6116MP	7.0mm Dia. x 35mm Multi-axial Screw	4
50-6117MP	7.0mm Dia. x 40mm Multi-axial Screw	6
50-6118MP	7.0mm Dia. x 45mm Multi-axial Screw	6
50-6119MP	7.0mm Dia. x 50mm Multi-axial Screw	6
50-6801MP	7.0mm Dia. x 55mm Multi-axial Screw	4
53-6112MP	6.5mm Dia. x 40mm Multi-axial Reduction Screw	2
53-6113MP	6.5mm Dia. x 45mm Multi-axial Reduction Screw	2
53-6118MP	7.0mm Dia. x 45mm Multi-axial Reduction Screw	2
53-6119MP	7.0mm Dia. x 50mm Multi-axial Reduction Screw	2
6451	**Helical Flange** Plug	20
6454	Lateral Connector	2
6455	Lateral Connector-Extended	2
6954	Cross Connector-Small	2
6955	Cross Connector-Medium	2
6956	Cross Connector-Large	2

LTPTL
Mid

Catalog #	Description	Qty
6310	4.0mm Dia. x 25mm Fixed Screw	6
6311	4.0mm Dia. x 30mm Fixed Screw	6
6312	4.0mm Dia. x 35mm Fixed Screw	6
6313	4.0mm Dia. x 40mm Fixed Screw	4
6385	4.75mm Dia. x 25mm Fixed Screw	6
6386	4.75mm Dia. x 30mm Fixed Screw	6
6387	4.75mm Dia. x 35mm Fixed Screw	6
6388	4.75mm Dia. x 40mm Fixed Screw	4
6719	5.5mm Dia. x 25mm Fixed Screw	4
6720	5.5mm Dia. x 30mm Fixed Screw	6
6721	5.5mm Dia. x 35mm Fixed Screw	6
6722	5.5mm Dia. x 40mm Fixed Screw	6
6723	5.5mm Dia. x 45mm Fixed Screw	4
6730	6.5mm Dia. x 30mm Fixed Screw	4
6731	6.5mm Dia. x 35mm Fixed Screw	4
6732	6.5mm Dia. x 40mm Fixed Screw	4
6733	6.5mm Dia. x 45mm Fixed Screw	4
6734	6.5mm Dia. x 50mm Fixed Screw	4
6749	7.0mm Dia. x 30mm Fixed Screw	2
6750	7.0mm Dia. x 35mm Fixed Screw	2
6751	7.0mm Dia. x 40mm Fixed Screw	2
6752	7.0mm Dia. x 45mm Fixed Screw	2
6753	7.0mm Dia. x 50mm Fixed Screw	2

LTPTL
Base

Catalog #	Description	Qty
6008	6.35mm x 10cm CP Ti Rod	2
6009	6.35mm x 12cm CP Ti Rod	2
6010	6.35mm x 14cm CP Ti Rod	2
6015	6.35mm x 30cm CP Ti Rod w/hex	4
6016	6.35mm x 48cm CP Ti Rod w/hex	4
6035	6.35mm x 30cm Ti Alloy Rod	4
6036	6.35mm x 48cm Ti Alloy Rod	4

Indications For Use

The **Polaris 6.35** Spinal System is a non-cervical spinal fixation system intended for use as a pedicle screw fixation system or as an anterolateral spinal fixation system. Pedicle screw fixation is limited to skeletally mature patients. The use of the device is indicated for the treatment of 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 lordosis), tumor, stenosis, pseudoarthrosis, and previous failed fusion. See package insert for additional information.

Contraindications

The **Polaris 6.35** Spinal System is contraindicated in patients with spinal infection or inflammation, morbid obesity, mental illness, alcoholism or drug abuse, pregnancy, metal sensitivity/foreign body sensitivity, patients with inadequate tissue coverage over the operative site or open wounds local to the operative area. See package insert for additional information.

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 previous failed 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 failure, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury. See package insert for additional information.

Sterilization Recommendations

High temperature steam sterilization should be used. All packaging materials must be removed prior to sterilization. The following cycles have been laboratory validated:

Method:	Steam	Steam
Cycle:	Gravity	Prevac
Temperature:	250°F (121°C)	270°F (132°C)
Exposure Time:	60 minutes	8 minutes
Drying:	20 minutes	

Further Information

The **Polaris 6.35** Spinal Implant System is covered by numerous U.S. and International patents. U.S. Patent numbers: 5,360,431; 5,466,237; 5,474,555; 6,726,689.

Helical Flange is a trademark of The Jackson Group.

* The Crossbar™ Cross Connector was developed by Sea Spine, Inc. Crossbar is a trademark of Sea Spine, Inc.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

This brochure describes a surgical technique used by J. Abbott Byrd III, M.D., John Ratliff, M.D. and John Rhee, M.D. Biomet, as the manufacturer of this device, does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient. The contents of this manual are intended to be only a guide and are not intended to set a standard of care.

For further information, please contact the Customer Service Department at:

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