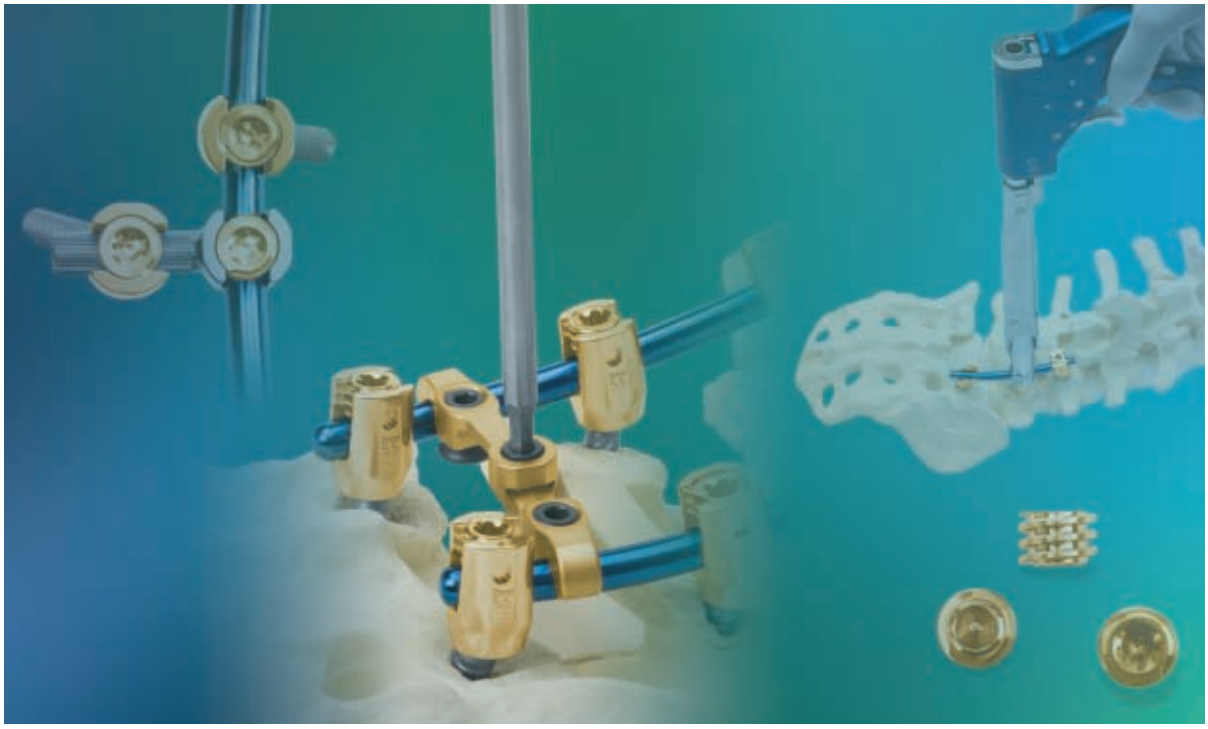
BIOMET SPINE

POLARIS™ 5.5

Surgical Technique



Contents

Introduction

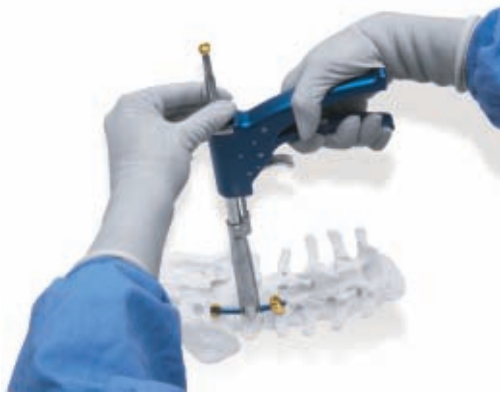
Biomet Spine's newest addition to the thoracolumbar product line is the Polaris™ 5.5 Spinal System. The system has been created to offer a streamlined lumbar fixation system that uses a superior locking mechanism.

The System incorporates **Helical Flange**™ Technology that minimizes seat-splay and cross threading. The forces are concentrated inward thus enabling the seat and plug to create a reliable mechanical lock.

The **Polaris 5.5** Spinal System is a load sharing, top loading, low profile system. The seat enables secure interface with the instruments for maximum manipulation agility. The design goals were to aid the surgeon with intra-operative efficiency and effectiveness while maintaining integrity and ease.

The **Polaris 5.5** Spinal System is designed to address degenerative pathologies. The trays are configured to include Multi-axial Screws, extended screws, pre-cut pre-contoured rods, cross connectors, lateral connectors, and ergonomic instrumentation for maximum tactile feedback. **Polaris** continues to advance the spinal fixation needs of the aging population by providing fixation, variability, and ease of use.

System Design Features And Benefits



Features	**Benefits**
Helical Flange Technology	Starts easily Minimizes cross threading and seat splay Forces are concentrated inward
5.5mm rod system	Low profile Anatomical fit
Color-coded implants	Easy determination of screw sizes and instruments
Streamlined instruments	Logical and ergonomic
Screw drivers	One piece, easy to use Provide for maximum visualization Control of screw trajectory
Minimum number of trays in O.R.	Only two trays necessary per case
One site hole on seat	Easy rod manipulation and excellent interface with instruments
Rod Reducer	Very powerful and controlled User-friendly Locks onto seat for easy rod reduction
Multi-axial Screws	Allow for 60° of angulation for optimum versatility
Friction Fit Seat	Once the seat is in place it remains in place for ease of rod introduction
Connection to Biomet Spine Posterior systems	Easy addition to the Altius™ M-INI™ system
Extended Seat Multi-axial Screws	Allows for reducing a spondylolisthesis

Implants

Helical Flange Plug

Lateral Connector - 25mm

Multi-axial Screws are available in 4.75, 5.5, 6.5, and 7.5 and 8.5mm diameters in 30-55mm lengths.

Multi-axial Reduction Screws are available in 5.5, 6.5 and 7.5mm diameter in 30-55mm lengths.

Pre-Cut, Contoured Rods available in 5.0mm Increments

Telescoping and Angulating Cross Connectors*

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

Instrumentation

Fixed Handle-T

Fixed Handle-
Straight

Ratchet
Handle-Straight

Ratchet
Handle-T

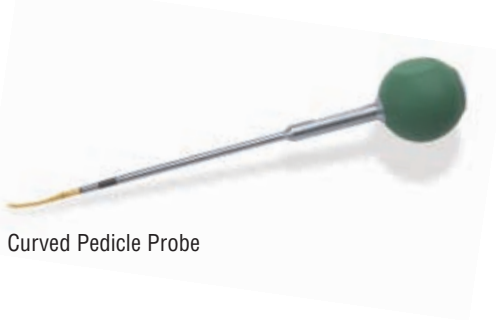
Fixed
Tear Drop Handle

Ratcheting Tear Drop Handle

Awl Shaft

Thoracic Pedicle Probe

Straight Pedicle Probe



Curved Pedicle Probe

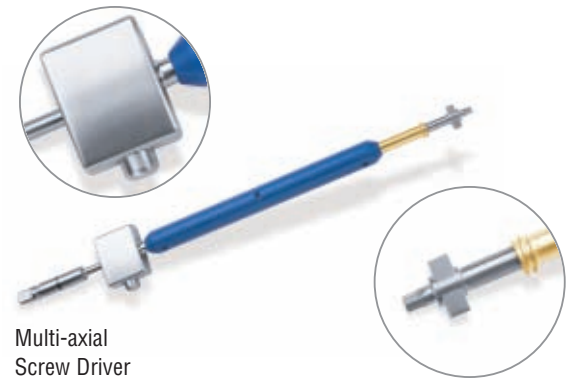
Reamer Probe

Tap

Stiff Pedicle Sound

Flexible Pedicle Sound

Trial Pins



Multi-axial
Screw Driver

Dorsal Height
Adjuster

Rod Template

Instrumentation (Continued)

Rod Bender

Rod Holder

Plug Driver

Double End
Plug Starter

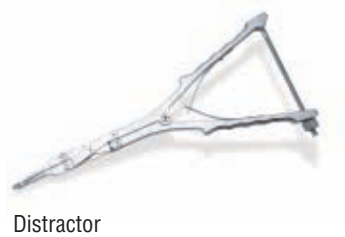
Straight Rod Pusher

Reduction Fork

Rod Persuader

Soft Tissue Retractor

Compressor



Distractor

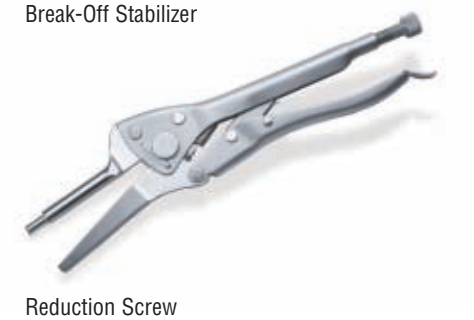
Cross Connector
Torque Wrench

Torque Limiting
Wrench

Torque Indicating
Wrench

Torque Stabilizer

Reduction Screw
Break-Off Stabilizer

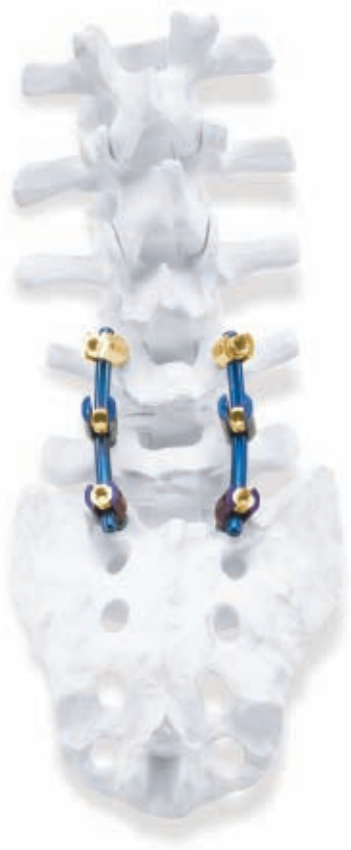


Reduction Screw
Break-Off Plier

Surgical Technique

Surgical Approach And Preparation

The patient is positioned prone as is customary for the surgeon, 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 **Polaris 5.5** Spinal System has been implanted.



Pedicle Preparation

After adequate exposure is achieved, the appropriate pedicle entry point is selected and the entrance to the pedicle is opened with an awl, burr, or curette. The appropriate diameter Reamer Probe is used to prepare the pedicle using a slow circular motion, allowing the Reamer Probe to center itself along the longitudinal axis of the pedicle. Each Reamer Probe is marked with the major diameter of the screw with which it is to be used. The Reamer Probe is initially advanced to a depth of approximately 30mm using the depth markings as a guide.

Instead of a Reamer Probe, a Pedicle Probe may be utilized. The Pedicle Probe is used to create the pedicle hole by advancing the Probe to a depth of approximately 30-40mm using the depth markings as a guide. 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.

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 Trial Pins may be utilized to confirm proper orientation and trajectory.

Open the entrance to the pedicle with the Pedicle Awl.

Prepare the pedicle hole with the Reamer Probe.

Prepare the pedicle hole with the chosen Tap.

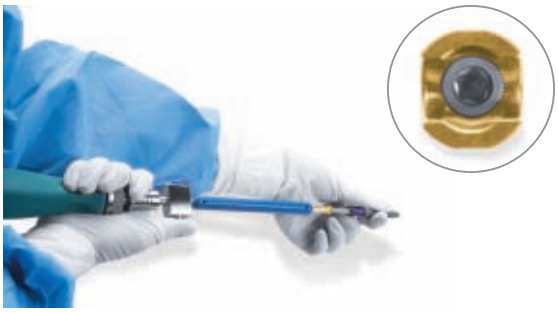
Confirm containment of the pedicle with the Pedicle Sound.

Use the Trial Pins to ensure proper orientation and trajectory.

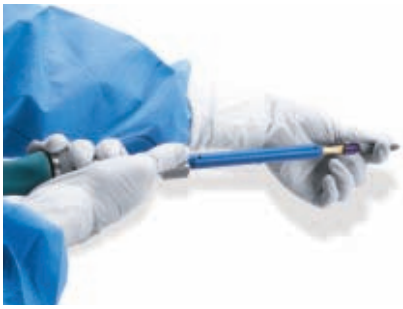
Screw Selection And Insertion

Self-tapping screws are available in several diameters and lengths. The appropriate screw length is determined by using the depth markings on the Pedicle Probe or Reamer Probe. The Multi-axial Screws may be loaded freehand or while seated within the surgical tray. Attach the 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. Hold the screw by the screw shaft and load the screw onto the tip of the Multi-axial Screw Driver. Ensure that the male pentalobe at the distal tip of the Multi-axial Driver is fully seated within the female pentalobe located at the top of the screw shaft. Push the button in located on the knurled T. Next, turn the knurled T in a clockwise direction to thread the outer shaft into the seat. Upon fully loading, the button on the T will release. 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 Driver is disengaged from the screw by pushing the button on the knurled T in and rotating the knurled T in a counterclockwise direction and then lifting the Driver from the Screw.

Select the appropriate screw size.



Push the button located at the top of the knurled T and Load the screw onto Multi-axial Screw Driver.



Push the button located at the top of the knurled T to thread the outer shaft into the seat.

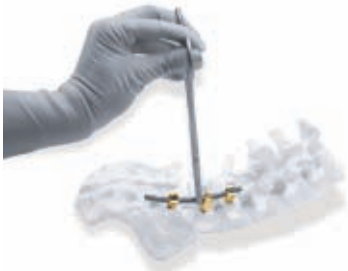
Insert the screw into the pedicle.

Once inserted to desired depth, push the button in.

Turn the knurled T counterclockwise to release from the screw.

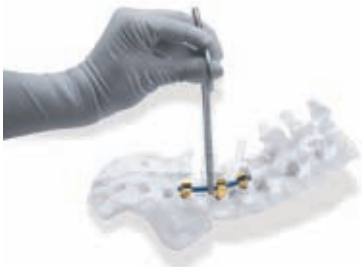
Rod Application

Once all screws have been inserted, the appropriate length rod should be chosen according to the construct. The Rod Template may be used to aid in rod selection. The rod should project at least 2.0mm beyond the screw seats at the end of the construct. Be sure to account for large curves and distractions when choosing rod length. If necessary, the selected rod may be contoured with the Rod Bender.



Measure length of the rod using the Rod Template.

Select appropriate length rod.



Insert rod using the Rod Holder.

Set the dial on the Rod Bender to achieve the desired curvature.

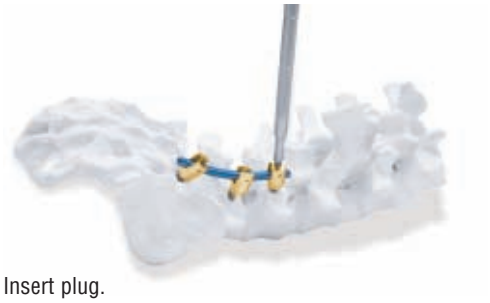
Helical Flange Plug Application

When all screws have been inserted and the rods have been placed in the screw seats, the construct is then secured using **Helical Flange** Plugs. One plug is firmly pressed onto each end of the Double End Plug Starter. All plugs should be placed and then provisionally tightened.

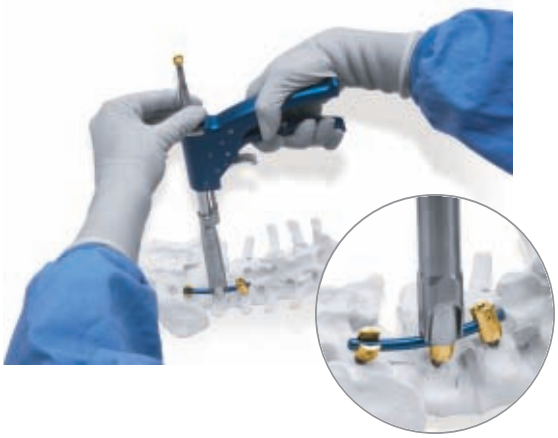
If necessary, the Plug Starter may be used in combination with the Rod Persuader, Reduction Fork, or Rod Pusher.

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.

Load plug onto the Double End Plug Starter.



Insert plug.



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

Helical Flange Plug Application (Continued)

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

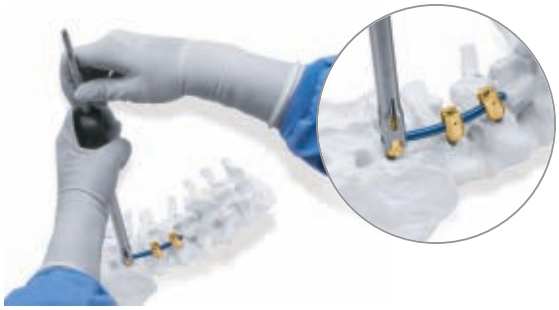
When using the Rod Pusher, place the distal tip onto the rod and push the rod down to persuade the rod into the screw seat.

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 Retractor may be utilized to retract the soft tissue away from the screw by placing the bifid tip of the retractor under the screw seat.

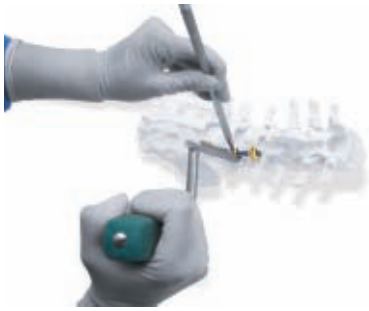
Reduction Fork.

Position the Reduction Fork under the screw seat and tilt the instrument to persuade the rod into the screw seat.



Push the rod down to persuade rod into the seat and insert the plug.

Torque Stabilizer may be used to guide the Plug Starter.



The Soft Tissue Retractor aids retraction of the soft tissue away from the screw seat.

Final Locking

After provisional tightening, proper implant placement should be confirmed with radiographs. The plugs are then tightened with either the Torque Indicating Wrench or the Torque Limiting Wrench in combination with the Torque Stabilizer. Insert the chosen torquing device through the center of 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 Indicating 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 showing the start position at zero. Upon reaching the intended final torque, two arrows will line up at 110in-lbs.

THERE IS NO AUDIBLE CLICK with the Torque Indicating Wrench. Over-torquing with the Torque Indicating Wrench (turning beyond the point where the arrows line up) may damage the wrench. Always ensure the wrench indicates 0in-lbs. of torque prior to use.

The Torque Limiting Handle attaches to the Plug Driver. The Torque Limiting Wrench is turned in a clockwise direction while the Torque Stabilizer is held with resistive force in a counter clockwise direction. The Torque Limiting Wrench should be turned until an audible click is heard, applying 110in-lbs. of torque.

Arrows of the Torque Indicating Wrench line up at 0, signifying the start position. When the torque level is achieved, the arrow will line up at 110in-lbs.
THERE IS NO AUDIBLE CLICK.

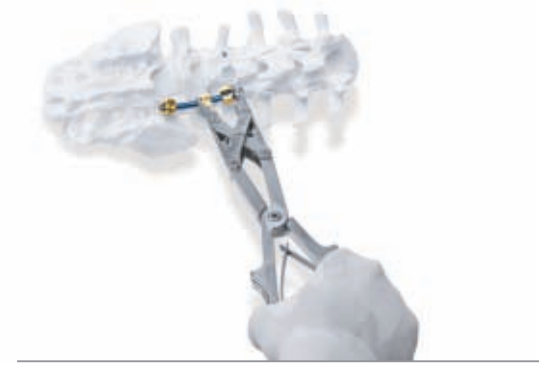
Turn the Torque Limiting Wrench clockwise until an audible click is heard at 110in-lbs of torque.

NOTE: Use the chosen torque instrument in combination with the Torque Stabilizer.

Additional Surgical Options

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 Starter connected to the chosen Quick Connect Handle.



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

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, applying 40in-lbs of torque to the set screws (tighten the outer set screws, then the central set screw).

Select the appropriate sized cross connector.

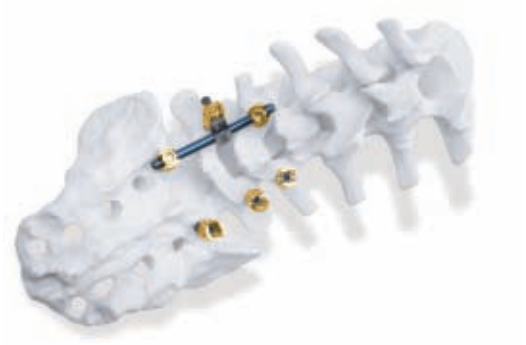
Torque the set screws on the cross connector.
Torque until an audible click is heard to apply 40in-lbs.

Additional Surgical Options (Continued)

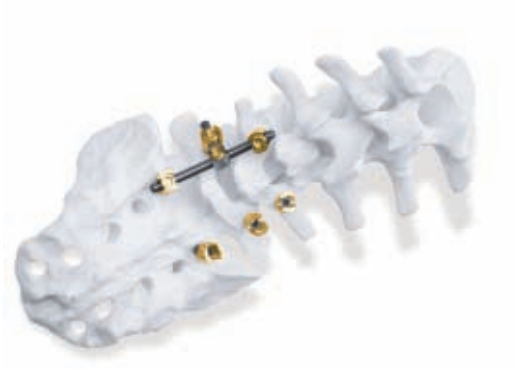
Lateral Connectors

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 (refer to "**Helical Flange** Plug Application" and "Final Locking").

Lateral connector=25mm (Length is measured from center of the seat to the end of the rod)



The lateral connector is applied to the lateral screw at L5.



Final construct.

The lateral connectors are secured with the same **Helical Flange** Plugs as the screws.

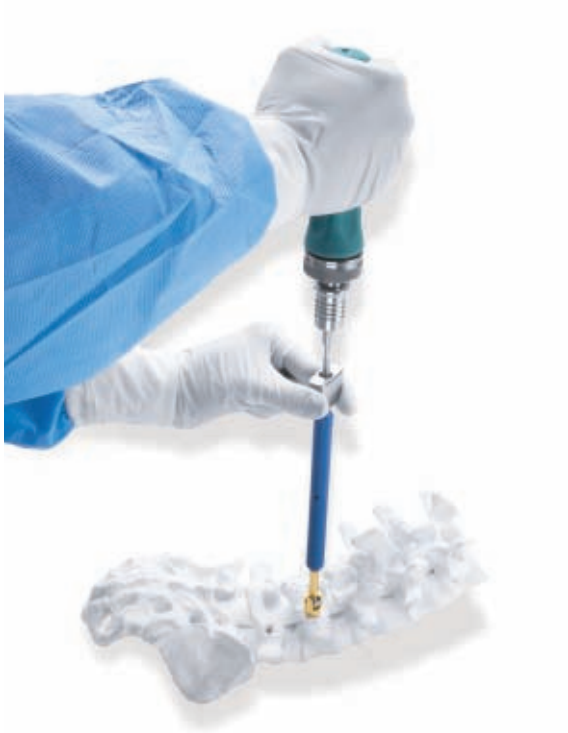
Screw Height Adjustment

The Dorsal Height Adjuster may be used to adjust the Multi-axial 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.

Use the Dorsal Height Adjustor to adjust the screws.

Screw Removal

The Multi-axial Screw Driver 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. Slide the outer sleeve down and turn the large knurled-T clockwise to lock into the screw seat. Once the Driver is tightened, the screw may be backed out of the pedicle.



Use the Multi-axial Screw Driver to remove the screw.

Closure, Post Operative Care

After implantation of the **Polaris 5.5** Spinal System is complete, wound closure is performed according to the standard protocol for the surgeon.

Implant Removal

Removal of the **Polaris 5.5** Spinal System is performed by reversing the order of the implant procedure. The Quick Connect Fixed T-Handle attached to the Plug Driver in combination with the Torque Stabilizer must be used first to remove the plugs. Refer to “Screw Removal” section for additional details.

NOTE: When removing previously torqued Plugs, turn the Fixed T-Handle in a slight clockwise direction before turning counterclockwise. Continue with this back and forth motion until the Plug loosens.

Indications For Use

The **Polaris 5.5** 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 5.5** 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.

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	

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.

Ordering Information

Standard Instrument Case (Catalog No. 55500146)

Catalog #	Description	Qty/Kit
2000-9061	Plug Driver	2
14-500108	Multi-axial Screw Inserter	2
2000-9075	Torque Stabilizer	1
2000-9082	Torque Indicating Wrench, 110In-lbs	1
94522	Torque Limiting Wrench, 110In-lbs	1
94505	Awl Shaft	1
14-500100	Thoracic Pedicle Probe	1
14-500101	Straight Pedicle Probe	1
14-500102	Curved Pedicle Probe	1
2000-9015	Flexible Sound	1
4010	Stiff Sound	1
4077	9cm Trial Pin	4
4072	11cm Trial Pin	4
2000-9023	4.75mm Tap	1
2000-9024	5.5mm Tap	1
2000-9025	6.5mm Tap	1
2000-9026	7.5mm Tap	1
2000-9027	8.5mm Tap	1
2000-9054	Reduction Fork	1
2000-9055	Rod Persuader	1
2000-9059	Straight Rod Pusher	1
2000-9060	Double End Plug Starter	2
2000-9072	Dorsal Height Adjuster	1
2000-9074	Reduction Screw Break-Off Plier	1
2000-9091	4.75mm Reamer Probe	1
2000-9092	5.5mm Reamer Probe	1
2000-9093	6.5mm Reamer Probe	1
2000-9094	7.5mm Reamer Probe	1
124797	Ratchet Handle-T	1
124799	Ratchet Handle-Straight	1
94612	Rod Template	1

Standard Instrument Case (Continued)

Catalog #	Description	Qty/Kit
94613	Rod Holder	1
94614	Soft Tissue Retractor	1
94624	Cross Connector Torque Wrench	1
94686	Compressor	1
94687	Distractor	1
2000-9044	Rod Bender	1
94697	Fixed Handle-T	1
94699	Fixed Handle-Straight	1
2000-9006	Tear Drop Handle-Fixed	1
2000-9019	Reduction Screw Break-Off Stabilizer	1
2000-6481	Tear Drop Handle-Ratcheting	N/A

Standard Implant Case (Catalog No. 55500147)

Catalog #	Description	Qty/Kit
2000-1005	Plug	30
2000-1020	Lateral Connector - 25mm	2
2000-2330	5.5mm Dia. x 30mm Multi-axial Screw	6
2000-2335	5.5mm Dia. x 35mm Multi-axial Screw	6
2000-2340	5.5mm Dia. x 40mm Multi-axial Screw	6
2000-2345	5.5mm Dia. x 45mm Multi-axial Screw	6
2000-2350	5.5mm Dia. x 50mm Multi-axial Screw	6
2000-2355	5.5mm Dia. x 55mm Multi-axial Screw	4
2000-2430	6.5mm Dia. x 30mm Multi-axial Screw	4
2000-2435	6.5mm Dia. x 35mm Multi-axial Screw	6
2000-2440	6.5mm Dia. x 40mm Multi-axial Screw	8
2000-2445	6.5mm Dia. x 45mm Multi-axial Screw	8
2000-2450	6.5mm Dia. x 50mm Multi-axial Screw	8
2000-2455	6.5mm Dia. x 55mm Multi-axial Screw	4
2000-2530	7.5mm Dia. x 30mm Multi-axial Screw	4
2000-2535	7.5mm Dia. x 35mm Multi-axial Screw	4
2000-2540	7.5mm Dia. x 40mm Multi-axial Screw	6
2000-2545	7.5mm Dia. x 45mm Multi-axial Screw	6
2000-2550	7.5mm Dia. x 50mm Multi-axial Screw	6
2000-2555	7.5mm Dia. x 55mm Multi-axial Screw	4
2000-5130	30mm Ti Alloy Curved Rod	4
2000-5135	35mm Ti Alloy Curved Rod	4
2000-5140	40mm Ti Alloy Curved Rod	4
2000-5145	45mm Ti Alloy Curved Rod	4
2000-5150	50mm Ti Alloy Curved Rod	4
2000-5155	55mm Ti Alloy Curved Rod	4
2000-5160	60mm Ti Alloy Curved Rod	4
2000-5165	65mm Ti Alloy Curved Rod	4
2000-5170	70mm Ti Alloy Curved Rod	4
2000-5175	75mm Ti Alloy Curved Rod	4
2000-5180	80mm Ti Alloy Curved Rod	4

Standard Implant Case (Continued)

Catalog #	Description	Qty/Kit
2000-5190	90mm Ti Alloy Curved Rod	4
2000-5199	100mm Ti Alloy Curved Rod	4
2000-5405	510mm Rod Ti Alloy (W/ Hex)	2
94669	XXSmall Cross Connector	2
94670	XSmall Cross Connector	2
94671	Small Cross Connector	2
94672	Medium Cross Connector	2
94673	Large Cross Connector	2
2000-5110	105mm Ti Alloy Curved Rod	N/A
2000-5111	110mm Ti Alloy Curved Rod	N/A
2000-5112	115mm Ti Alloy Curved Rod	N/A
2000-5113	120mm Ti Alloy Curved Rod	N/A
2000-5114	125mm Alloy Curved Rod	N/A
2000-5115	130mm Alloy Curved Rod	N/A

Ordering Information (Continued)

4.75mm Multi-axial Screw Implant Case (Catalog No. 14-509606)

Catalog #	Description	Qty/Kit
2000-2220	4.75mm Dia. x 20mm Multi-axial Screw	12
2000-2225	4.75mm Dia. x 25mm Multi-axial Screw	12
2000-2230	4.75mm Dia. x 30mm Multi-axial Screw	12
2000-2235	4.75mm Dia. x 35mm Multi-axial Screw	12
2000-2240	4.75mm Dia. x 40mm Multi-axial Screw	12
2000-2245	4.75mm Dia. x 45mm Multi-axial Screw	6
2000-2250	4.75mm Dia. x 50mm Multi-axial Screw	6

8.5mm Multi-axial Screw Implant Case (Catalog No. 14-509607)

Catalog #	Description	Qty/Kit
2000-2630	8.5mm Dia. x 30mm Multi-axial Screw	4
2000-2635	8.5mm Dia. x 35mm Multi-axial Screw	4
2000-2640	8.5mm Dia. x 40mm Multi-axial Screw	4
2000-2645	8.5mm Dia. x 45mm Multi-axial Screw	4
2000-2650	8.5mm Dia. x 50mm Multi-axial Screw	4
2000-2655	8.5mm Dia. x 55mm Multi-axial Screw	4

Multi-axial Reduction Screw Implant Case (Catalog No. 14-509605)

Catalog #	Description	Qty/Kit
2000-7330	5.5mm Dia. x 30mm Multi-axial Reduction Screw	4
2000-7335	5.5mm Dia. x 35mm Multi-axial Reduction Screw	4
2000-7340	5.5mm Dia. x 40mm Multi-axial Reduction Screw	4
2000-7345	5.5mm Dia. x 45mm Multi-axial Reduction Screw	4
2000-7350	5.5mm Dia. x 50mm Multi-axial Reduction Screw	4
2000-7355	5.5mm Dia. x 55mm Multi-axial Reduction Screw	2
2000-7430	6.5mm Dia. x 30mm Multi-axial Reduction Screw	4
2000-7435	6.5mm Dia. x 35mm Multi-axial Reduction Screw	6
2000-7440	6.5mm Dia. x 40mm Multi-axial Reduction Screw	8
2000-7445	6.5mm Dia. x 45mm Multi-axial Reduction Screw	8
2000-7450	6.5mm Dia. x 50mm Multi-axial Reduction Screw	6
2000-7455	6.5mm Dia. x 55mm Multi-axial Reduction Screw	4
2000-7530	7.5mm Dia. x 30mm Multi-axial Reduction Screw	2
2000-7535	7.5mm Dia. x 35mm Multi-axial Reduction Screw	6
2000-7540	7.5mm Dia. x 40mm Multi-axial Reduction Screw	6
2000-7545	7.5mm Dia. x 45mm Multi-axial Reduction Screw	6
2000-7550	7.5mm Dia. x 50mm Multi-axial Reduction Screw	4
2000-7555	7.5mm Dia. x 55mm Multi-axial Reduction Screw	2

Further Information

The **Polaris 5.5** Spinal System is covered by numerous U.S. and International patents. U.S. Patent numbers: 5,360,431; 5,466,237; 5,474,555 and Patents Pending.

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., John Rhee, M.D. and Paul Suh, M.D. Biomet Spine 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.

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