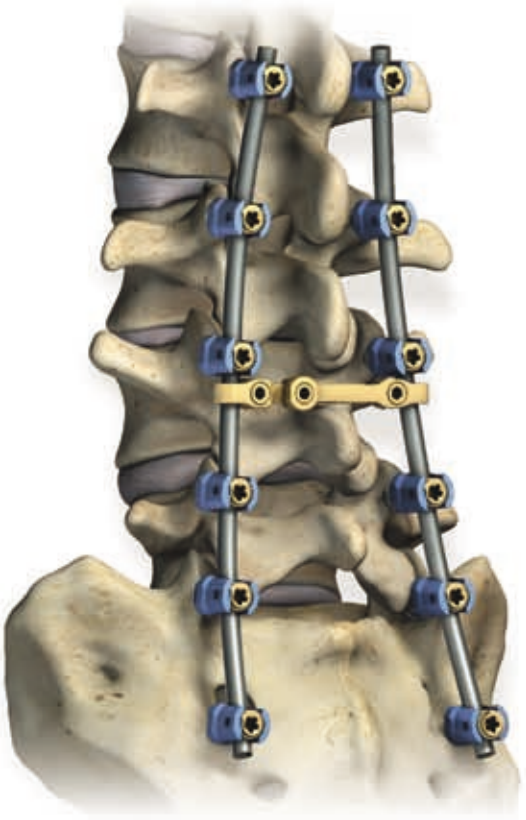


Surgical Technique

Polaris™ System
Translation™ Screw

Game Changing Technology

- 3mm 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

BIOMET
SPINE

Contents

Section 1: Introduction

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 3mm 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.

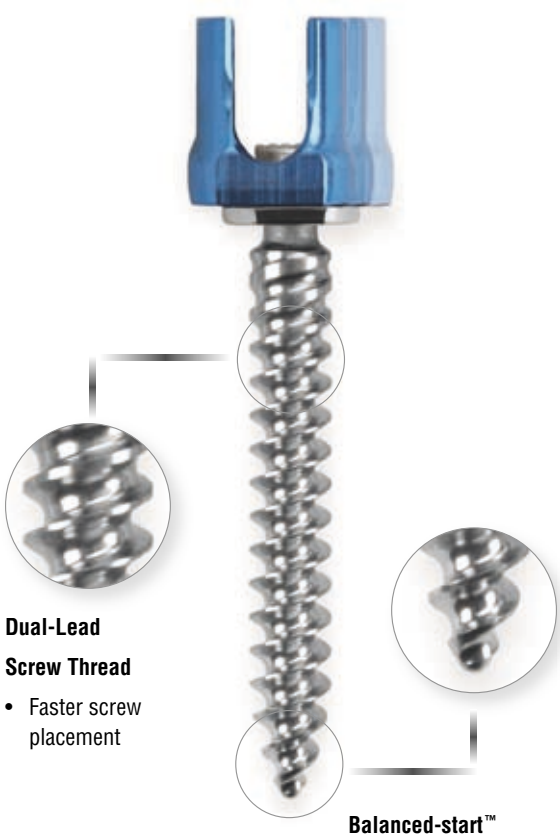
The extensive clinical experience gained from the Polaris™ Spinal System is reflected in every design aspect of the screw. The Balanced-start™ Tip immediately engages the pedicle and accurately leads the screw into the pilot hole. The dual lead thread profile reduces insertion time while maximizing bone 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.

Features and Benefits

Feature	Benefit
Translation™ Screw Technology	3mm of medial-lateral translation relative to the screw shaft
	Encourages optimal screw placement
	Less rod manipulation, easier rod introduction
Balanced-start™ Tip	Minimizes toggle during insertion
	Accurate placement and screw trajectory
	Immediate bone engagement
Double Lead Thread	Fast and efficient screw placement
Thread Profile	Tactile insertion
	Thread form maximizes bone purchase and performance
	Constant outer diameter
Friction Fit Seat	Maintains position of screw seat
Helical Flange® Technology	Starts easily
	Minimizes cross threading and seat splay
	Forces are concentrated inward
Multi-axial Screws	40° of conical angulation for optimum versatility
5.5mm rod system	Low profile
	Anatomical fit
Color-coded implants	Ease of screw identification

Thread Profile

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

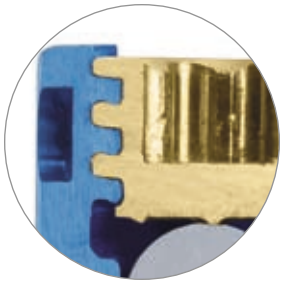


Dual-Lead Screw Thread

- Faster screw placement

Balanced-start™ Tip Geometry

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



Helical Flange® Technology

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Implants

Figure 1: Polaris™ Translation™ Screws are available in 4.75, 5.5, 6.5, and 7.5mm diameters in 30-55mm lengths

Figure 2: Polaris™ Translation™ Iliac Screws are available in 6.5, 7.5 and 8.5mm diameters in 35-100mm lengths

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

Figure 3: Helical Flange® Plug

Figure 4: Lateral Connector - 25mm size shown

Figure 5: Multi-axial Screws are available in 4.75, 5.5, 6.5, 7.5 and 8.5mm diameters in 30-55mm lengths.

Figure 6: Multi-axial Reduction Screws are available in 4.75, 5.5, 6.5, 7.5 and 8.5mm diameters in 30-55mm lengths.

Figure 7: Pre-Cut, Contoured Rods are available in 5mm increments

Figure 8: Telescoping and Angulating Cross Connectors*

Figure 9: Double Lead Taps are available in 4.0, 4.75, 5.5, 6.5 and 7.5mm diameters

Figure 10: Double Lead Iliac Taps are available in 6.5, 7.5, 8.5, 9.5 and 10.5mm diameters

Figure 11: Button Lock Screw Inserter

Figure 12: Bone Planer

Figure 13: Head Positioner

Figure 14: Screw Shaft Remover

Instruments (Continued)

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

Figure 15: Fixed Handle - T

Figure 16: Fixed Handle - Straight

Figure 17: Ratchet Handle - Straight

Figure 18: Ratchet Handle - T

Figure 19: Fixed Teardrop Handle

Figure 20: Ratchet Teardrop Handle

Figure 21: Awl Shaft

Figure 22: Thoracic Pedicle Probe

Figure 23: Straight Pedicle Probe

Figure 24: Curved Pedicle Probe

Figure 25: Single Lead Tap

Figure 26: Stiff Pedicle Sound

Figure 27: Flexible Pedicle Sound

Figure 28: Trial Pins

Figure 29: Multi-axial Screw Inserter

Instruments (Continued)

Figure 30: Dorsal Height Adjuster

Figure 31: Rod Template

Figure 32: Rod Holder

Figure 33: Rod Bender

Figure 34: Teardrop Plug Inserter

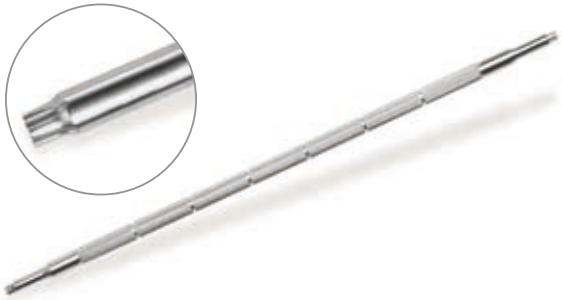

Figure 35: Double End Plug Starter

Figure 36: Rod Rocker

Figure 37: Short Rocket™ Threaded Reducer

Figure 38: Long Rocket™ Threaded Reducer

Figure 39: Offset T-Handle

Figure 40: Offset T-Handle

Figure 41: QC Adaptor

Figure 42: Perpendicular Rod Persuader

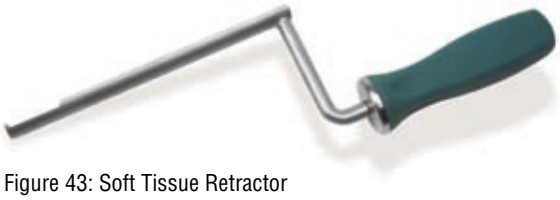

Figure 43: Soft Tissue Retractor

Figure 44: Compressor

Figure 45: Distractor

Figure 46: Cross Connector Torque Wrench

Figure 47: Torque Limiting Wrench. Assembled from Plug Driver and Torque Limiting Handle.

Figure 48: Plug Driver

Figure 49: Torque Limiting Handle

Figure 50: Torque Stabilizer

Figure 51: Reduction Screw Break-Off Stabilizer

Figure 52: Reduction Screw Break-Off Pliers

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.

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 30-40mm using the depth markings as a guide. The Probes are laser marked and have 10mm visual bands to help indicate the depth to which the Probe has been inserted.

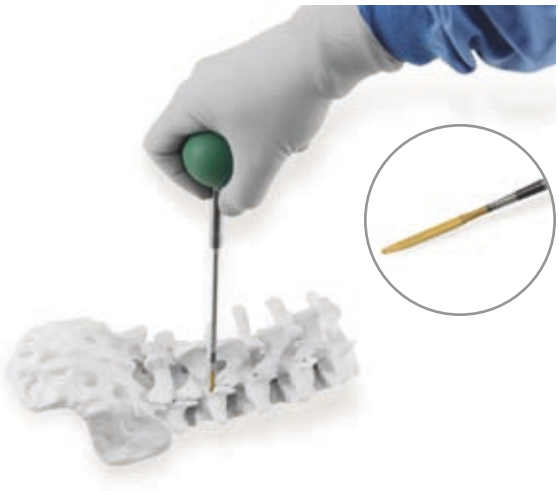

Figure 53: Pedicle Probe is utilized

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.

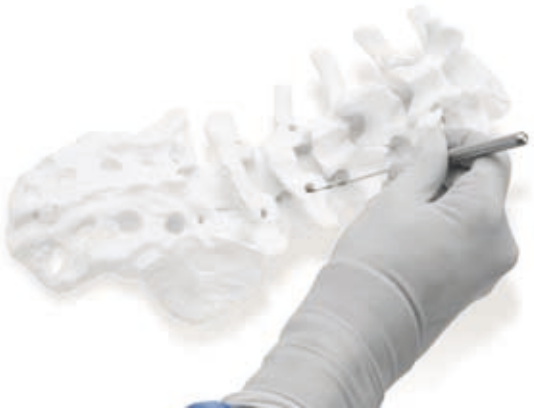

Figure 54: Confirming pedicle containment with Pedicle Sound

Trial pins may be utilized to confirm the proper orientation and trajectory.

Figure 55: Use the Trial Pins to ensure proper orientation and trajectory

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.

Figure 56: Prepare the pedicle hole with the Tap

Screw Selection and Insertion

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.

Figure 57: Insert the tip of the Inserter into the pentalobe of the Screw

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 58: Rotate the knurled barrel and thread the outer shaft into the seat. Push Slider distally to secure.

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.

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 59: Insert the screw into the pedicle

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.

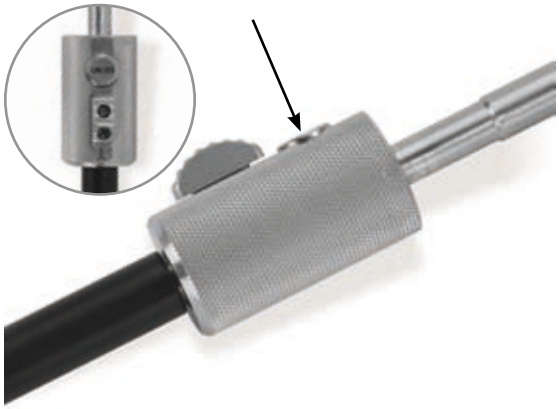

Figure 60: To disengage depress the "Unlock" button and rotate the barrel counterclockwise

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.

Figure 61: Screw head adjustment with Head Positioner

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.

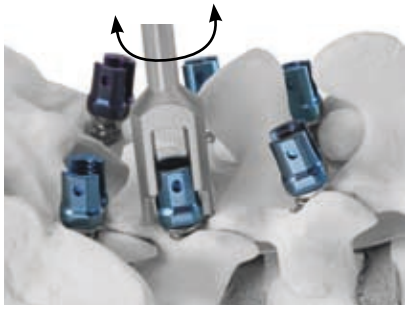

Figure 62: Bone Planer removing bone

Figure 63: Bone Planer

Section 3: 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 2mm beyond the Screw seats at the end of the construct. Be sure to account for large curves and distractions when choosing Rod length.

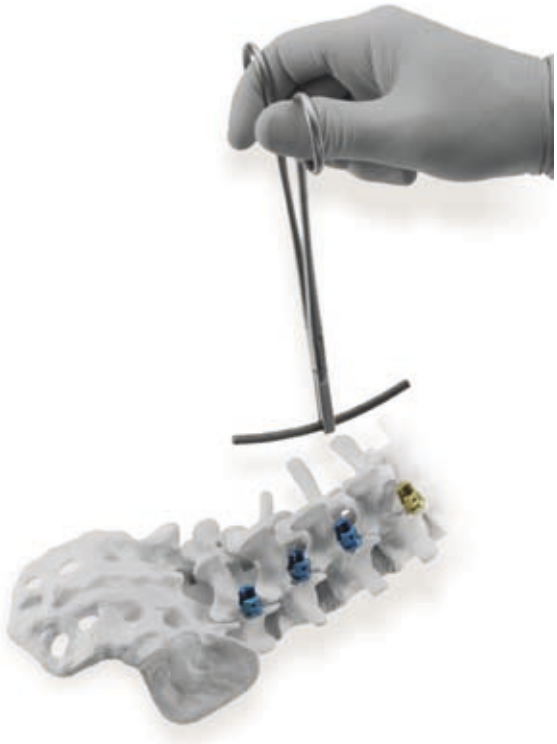

Figure 64: Measure length of the Rod using the Rod Template

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.

Figure 65: Insert Rod using the Rod Holder

Figure 66: Utilize the Rod Bender to add additional curvature to Rod

Rod Reduction

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 Section 2 for Bone Planer use.

Rod Rocker

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 10mm of simple Rod reduction.

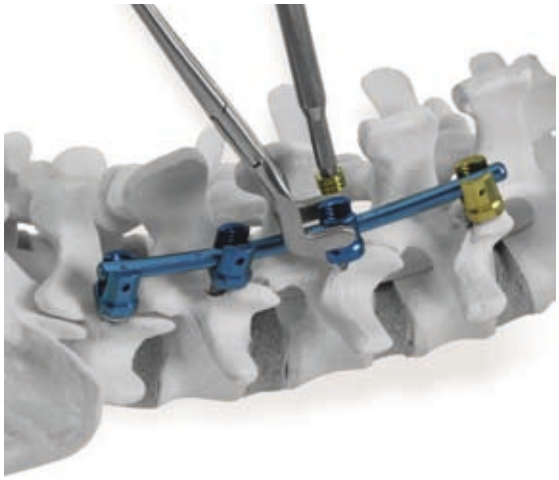

Figure 67: Rod Rocker

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.

Figure 68: Attachment of Short Rocket™ Threaded Reducer

NOTE: To properly attach and remove the Short Rocket™ Threaded Reducer, ensure that the Reducer is completely unthreaded.

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.

Figure 69: Self-centering reduction design

Figure 70: Rod Reduction

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 30mm of tactile Rod reduction.

To disengage the Short Rocket™ Threaded Reducer, rotate the proximal barrel counterclockwise. Once the Reducer is completely unthreaded, depress the spring loaded arms and remove the Reducer.

Figure 71: Plug Insertion through the Short Rocket™ Reducer

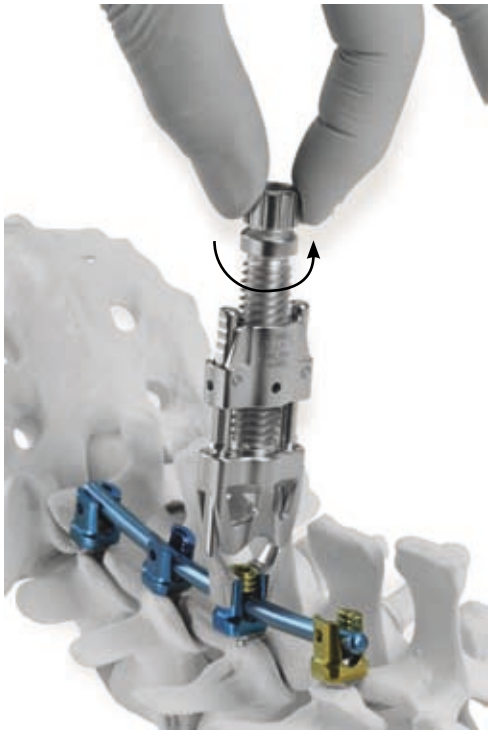

Figure 72: Partial Removal of the Short Rocket™ Reducer

Figure 73: Proper removal of the Short Rocket™ Threaded Reducer

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. Attach the Long Rocket™ Threaded Reducer by positioning the spring loaded arms into the mating Screw seat geometry. The internal stop ensures proper positioning.

Figure 74: Attachment of Long Rocket™ Threaded 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.

Figure 75: Self-centering reduction design

Figure 76: Rod reduction

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 30mm of tactile Rod reduction.

Figure 77: Plug Insertion through the Long Rocket™ Reducer

Figure 78: Partial Removal

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.

Figure 79: Easy removal of the Long Rocket™ Reducer

Refer to the chart below for proper instrument operation

	Attachment	Complete Rod Reduction	Disengagement
Position of the visual red band at the proximal end			
Position of laser marked line and text on shaft of the Reducer			

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.

Figure 80: Proper positioning of Rod Persuader

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 45mm of controlled Rod reduction.

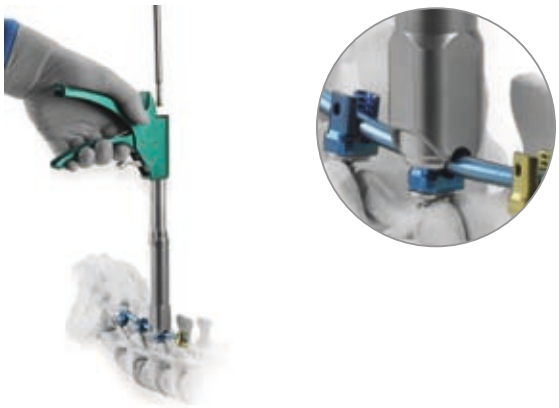

Figure 81: Plug Insertion through Rod Persuader

To release the Persuader, press the metallic trigger located underneath the colored handle. Once released, the Persuader may then be removed from the implant.

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.

Figure 82: Load a Plug onto the Teardrop Plug Inserter

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

Final Locking

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.

Figure 83: Proper positioning of the Torque Limiting Wrench into the Pentalobe of Plug

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.

Figure 84: Final Tightening

NOTE: Use the Torque Limiting Wrench in combination with the Torque Stabilizer for proper final tightening of the Helical Flange® Plugs.

Section 5: 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.

Figure 85: L5/S1 Spondylolisthesis

In order to aid in the reduction of the spondylolisthesis, it is recommended to first perform a Transforamenal 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.

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 86: Attachment of Long 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.

Figure 87: Self-centering reduction design

Figure 88: Rod reduction

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, Plug application can be executed. The Long Rocket™ Reducer facilitates 30mm of tactile Rod reduction.

Figure 89: Plug Insertion through 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 and the red proximal band will be completely visible.

Figure 90: Full Reduction of the L5/S1 Spondylolisthesis

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.

Figure 91: Compression

Figure 92: Distraction

If needed, the Rod Gripper can be utilized as a point of fixation in the absence of an implant.

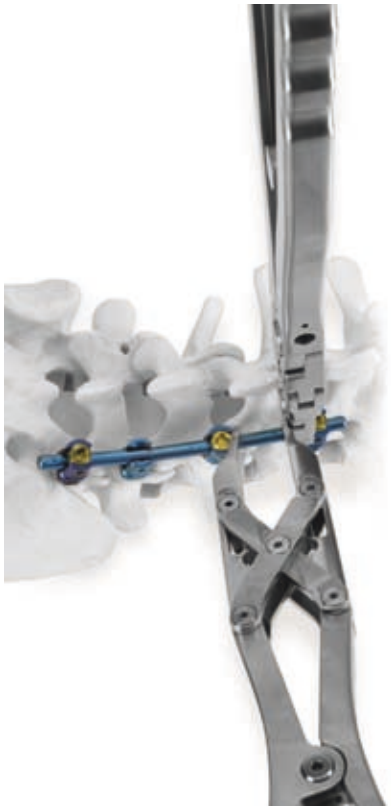

Figure 93: Distracting off Rod Gripper

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.

Figure 94: Select appropriate sized Cross Connector

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.

Figure 95: Torque the set screws on the cross connector. Torque until an audible click is heard to apply 40 in-lbs.

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.

Figure 96: Select appropriate size Lateral Connector

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 in Section 4.

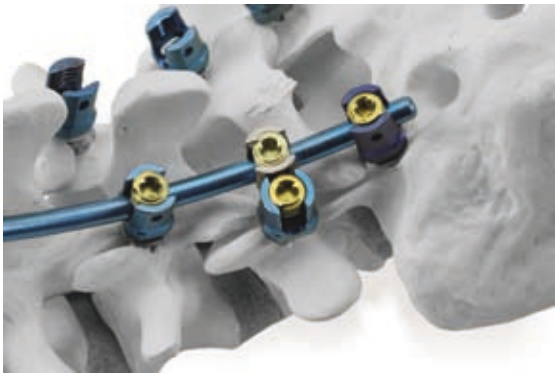

Figure 97: Lateral Connector placement

Screw Height Adjustment

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 98: Dorsal Height Adjustment

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.

Figure 99: Plug Removal

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.

Once the Screw Inserter is tightened, the Screw may be backed out of the pedicle.

Figure 100: Use the Screw Inserter to remove the Screw

To remove a screw shaft utilize the Screw Shaft Remover.

Figure 101: Screw Shaft Remover

Position the Screw Shaft Remover securely over the implant and rotate counterclockwise.

Section 7: Closure, Post Operative Care

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

Section 8: 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.

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

1. Spinal infection
2. Morbid obesity
3. 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.)
4. Pregnancy
5. Metal sensitivity/foreign body sensitivity
6. Patients with inadequate tissue coverage over the operative site
7. Open wounds local to the operative area

Warnings

1. 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.
2. 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.
3. 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.
4. Metabolic bone disease such as severe osteoporosis may adversely affect adequate fixation of the implants due to the poor quality of the bone.
5. 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.
   Biomet Spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.
6. 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.
7. 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 the AccuVision® Instruments, the system is limited to the implantation of rod lengths of 100mm or less, and excludes the use of system cross connectors or hooks.

Precautions

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. The Bullet End Rods are intended for use with the Jackson Intrasacral Fixation Technique.

Sterilization Information

The Polaris™ Spinal System is provided nonsterile and must be sterilized prior to use. All instrument components should be sterilized in a loosened state such that components may move freely. All packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended.

U.S. Sterilization Parameters:

Cycle:	High Vacuum
Temperature:	270°F/132°C
Time:	4 minutes
Drying Time:	30 minutes
NOTE:	**Allow for cooling**

Sterilization Parameters for Use Outside the U.S.:

Cycle:	Pre-vacuum Steam
Temperature:	275°F/135°C
Time:	3 minutes
Drying Time:	30 minutes
NOTE:	**Allow for cooling**

FDA cleared sterilization wraps should be used to maintain sterility after processing.

Biomet does not recommend stacking of trays during the sterilization process.

Individuals not using the recommended method, temperature and time are advised to validate any alternative methods or cycles using an approved method or standard.

Sterile packaged components are sterilized by exposure to a minimum dose of 25-kGy gamma radiation or by EtO, according to individual component labeling. Components labeled for single use only cannot be re-sterilized. Do not use if package has been compromised.

Please see the package insert for additional information on the system.

Polaris™ Translation™ Screw Standard Implant Kit

Catalog Number: 14-509669

Catalog #	Description	Qty.
14-500070	Polaris™ 5.5 Button Lock Screw Inserter	2
14-500071	Translating Screw Bone Planer	1
14-500085	Double-Lead Tap, 4mm	1
14-500086	Double-Lead Tap, 4.75mm	1
14-500088	Double-Lead Tap, 5.5mm	1
14-500089	Double-Lead Tap, 6.5mm	1
14-500090	Double-Lead Tap, 7.5mm	1
14-578325	5.5 Ti 5.5 x 25mm Translation	2
14-578330	5.5 Ti 5.5 x 30mm Translation	6
14-578335	5.5 Ti 5.5 x 35mm Translation	8
14-578340	5.5 Ti 5.5 x 40mm Translation	8
14-578345	5.5 Ti 5.5 x 45mm Translation	8
14-578350	5.5 Ti 5.5 x 50mm Translation	4
14-578355	5.5 Ti 5.5 x 55mm Translation	2
14-578430	5.5 Ti 6.5 x 30mm Translation	4
14-578435	5.5 Ti 6.5 x 35mm Translation	6
14-578440	5.5 Ti 6.5 x 40mm Translation	8
14-578445	5.5 Ti 6.5 x 45mm Translation	8
14-578450	5.5 Ti 6.5 x 50mm Translation	8
14-578455	5.5 Ti 6.5 x 55mm Translation	6
14-578530	5.5 Ti 7.5 x 30mm Translation	4
14-578535	5.5 Ti 7.5 x 35mm Translation	6
14-578540	5.5 Ti 7.5 x 40mm Translation	8
14-578545	5.5 Ti 7.5 x 45mm Translation	8
14-578550	5.5 Ti 7.5 x 50mm Translation	8
14-578555	5.5 Ti 7.5 x 55mm Translation	6

Polaris™ Translation™ Screw Standard Implant Kit

Catalog Number: 14-509669 *(Continued)*

Catalog #	Description	Qty.
2000-1005	Plug	30
2000-1020	Lateral Connector, Open, 25mm	2
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
2000-5190	90mm Ti Alloy Curved Rod	4
2000-5199	100mm Ti Alloy Curved Rod	4
2000-5405	510mm Ti Alloy Rod with 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

Polaris™ Translation™ Screw Iliac Implant Kit

Catalog Number: 14-509668

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

Polaris™ Translation™ Screw 4.75 Implant Kit

Catalog Number: 14-509682

Catalog #	Description	Qty.
14-578225	5.5 Ti 4.75 x 25mm Translation	4
14-578230	5.5 Ti 4.75 x 30mm Translation	6
14-578235	5.5 Ti 4.75 x 35mm Translation	6
14-578240	5.5 Ti 4.75 x 40mm Translation	6
14-578245	5.5 Ti 4.75 x 45mm Translation	2

Polaris™ 5.5 Standard Instrument Kit A

Catalog Number: 14-509680

Catalog #	Description	Qty.
14-500980	Surgical Tray, Standard	1
124797	Ratcheting Screw Inserter	1
124799	Ratcheting Screw Inserter	2
14-500001	Thoracic Pedicle Probe	1
14-500002	Straight Lumbar Pedicle Probe	1
14-500003	Curved Lumbar Pedicle Probe	1
14-500007	Firm Pedicle Sound	1
14-500018	Torque Stabilizer	1
14-500072	Screw Head Positioner	1
14-500170	Plug Starter With Fixed Handle	2
14-500185	Multi-axial Screw Inserter	2
14-500197	Polaris™ 5.5 Rocker, Ext Throw	1
14-501680	Dorsal Height Adjuster	1
2000-6481	Ratcheting Tear Drop Handle	1
2000-9015	Flexible Pedicle Sound	1
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
2000-9061	Plug Driver	2
94505	Pedicle Awl - QC Shaft	1
94522	QC Torque Wrench Handle	2
94613	Rod Holder	1

Polaris™ 5.5 Standard Instrument Kit B

Catalog Number: 14-509681

Catalog #	Description	Qty.
14-500009	Reduction Screw Break-Off Tool	1
14-500198	Perpendicular Rod Persuader	1
2000-9044	Rod Bender	1
94624	Cross Connector Torque Wrench	1
94686	Parallel Compressor	1
94687	Parallel Distractor	1

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

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

Further Information

This brochure describes a surgical technique used by Sabatino Bianco, M.D., FAANS and Paul Suh, M.D. 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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For complete product information, including indications, contraindications, warnings, precautions, and potential adverse effects, see the package insert.

This technique was prepared in conjunction with a licensed health care professional. Biomet does not practice medicine. The treating surgeon is responsible for determining the appropriate treatment, technique(s), and product(s) for each individual patient.

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At Biomet, engineering excellence is our heritage and our passion. For over 25 years, through various divisions worldwide, we have applied the most advanced engineering and manufacturing technology to the development of highly durable systems for a wide variety of surgical applications.

Polaris™ System
Translation™ Screw

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