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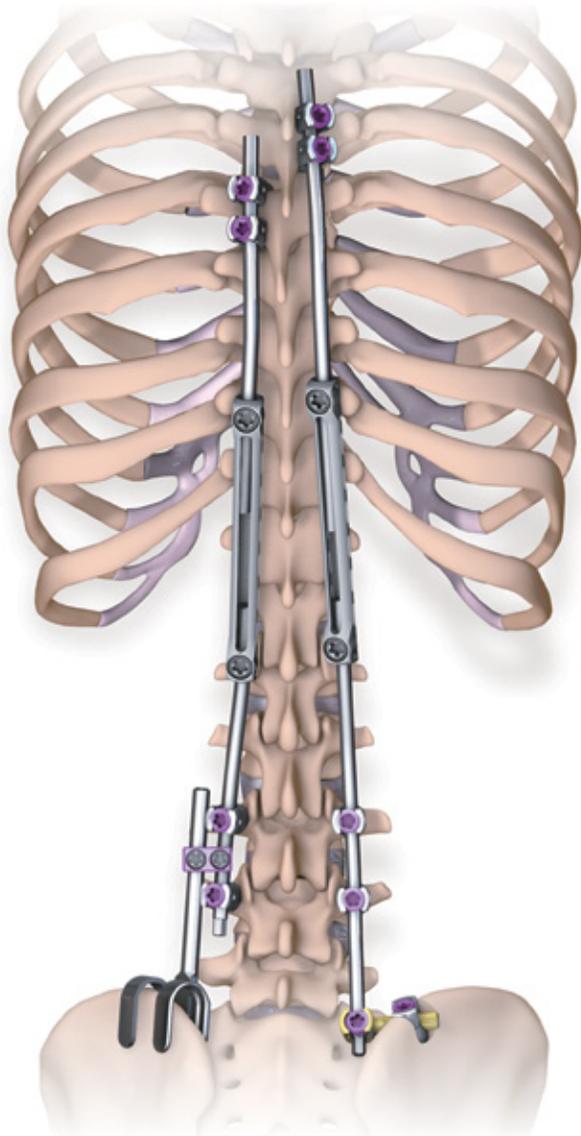


Thoracolumbar Solutions

Polaris™ 4.75

Deformity System

Surgical Technique Guide



*Comprehensive System
Accommodates 4.5mm
and 4.75mm Rods*

*Axial Connectors to Suit
Patient Anatomy*

Intuitive Instrumentation

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

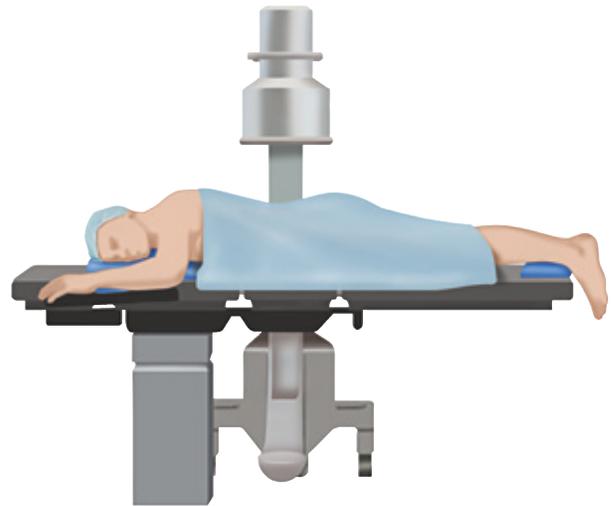
SURGICAL APPROACH AND PREPARATION

The **Polaris 4.75 Deformity System** takes the next step in the evolution of treatment for pediatric deformity systems.

The system features a complete array of treatment options to support:

- Adolescent idiopathic scoliosis.
- First-to-market curved axial connectors for internal distraction capabilities.
- Supports both a 4.5mm or 4.75mm rod.

Polaris 4.75 also carries on the tradition of its predicate system for deformity correction with its simple, intuitive instrumentation to support the needs of each patient.



The patient is positioned prone and prepared and draped aseptically per standard OR protocol. Based on preoperative planning the desired anatomy is exposed subperiosteally and a mid-line incision.

PEDICLE SCREW PLACEMENT



Should the patient require pedicle screw fixation, the appropriate pedicles are identified.

The pedicle is perforated with an awl or burr.

Utilizing a **pedicle probe**, the pedicle trajectory is identified and the path of the pedicle screw is prepared accordingly.

Note: The tips of the pedicle probes have a 20mm gold coating and laser lines to aid in identifying depth.

The medial, superior, lateral and inferior pedicle walls and bottom of the pedicle canal are verified for integrity with the pedicle sound.



Optional: The pedicle is prepared for the subsequent pedicle screw utilizing the appropriately sized tap. Depending on surgical preference, the pedicle screw path may be under-tapped 1.0mm for the eventual larger diameter screw. The pedicle wall is again verified for integrity with the pedicle sound.

Note: The taps have a 20mm gold coating and laser lines to aid in identifying depth.

PEDICLE SCREW PLACEMENT *(continued)*



STEP 1

Confirm Pedicle Integrity

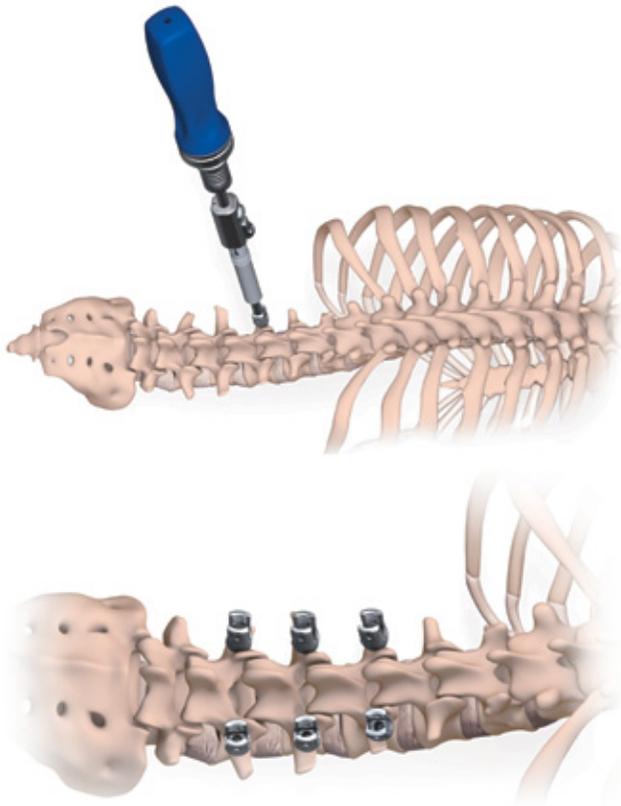
- After removing the pedicle probe, verify the integrity of the pedicle and the vertebral body walls using the **ball tip probe**.
- When fully inserted, a forceps can be clamped onto the ball tip probe to determine the hole depth for choosing the screw length.

Note: *Optional pedicle markers for fluoroscopic visualization are available upon request.*



STEP 2

- Identify the appropriate style and size pedicle screw and load onto the associated fixed, closed or **multi-axial screw inserter**.
- Assemble the desired quick-connect handle to the multi-axial screw inserter.
- Align the distal end of the multi-axial screw inserter to the proximal end of the screw shaft.
- Lock the pedicle screw onto the inserter by sliding the thumb-switch forward to the “lock” position.
- Turn the central barrel of the screw inserter clockwise until tight.



STEP 3

- Align the pedicle screw into prepared path.
- Turn the handle clockwise until the pedicle screw is properly placed to the desired depth.
- Remove the screw inserter by pushing down on the button and turning the central barrel counterclockwise until the screw inserter is fully released from the pedicle screw.
- Repeat the steps for the subsequent pedicles.

HOOK APPLICATION

Hook Selection

The Polaris 4.75 System comes complete with a comprehensive selection of hook options to suit the needs of each individual patient.



OFFSET HOOKS

- Offset hooks can be utilized for fixation on the lamina in an up-going intra-laminar position, or a down-going supra-laminar position in order to engage a rod which is laterally positioned due to anatomy or placement of a pedicle hook or pedicle screw.



ANGLED HOOKS

- Can be placed supra-laminar in the upper thoracic spine, in a down-going manner. The **angled hooks** should be placed intimate to the lamina and engage to the rod.



EXTENDED HOOKS

- The longer body allows the user to connect to a rod due to differences in the depth of the patient. Can be placed down-going supra laminar in the lumbar spine, because the superior edge of the lamina in the lumbar spine is deeper and allows the hook to meet the rod.



LAMINAR HOOKS

- Can be placed in cephalad or caudal direction and thus can be placed “up-going” under the inferior edge of the lamina.



MIDSTEM HOOKS

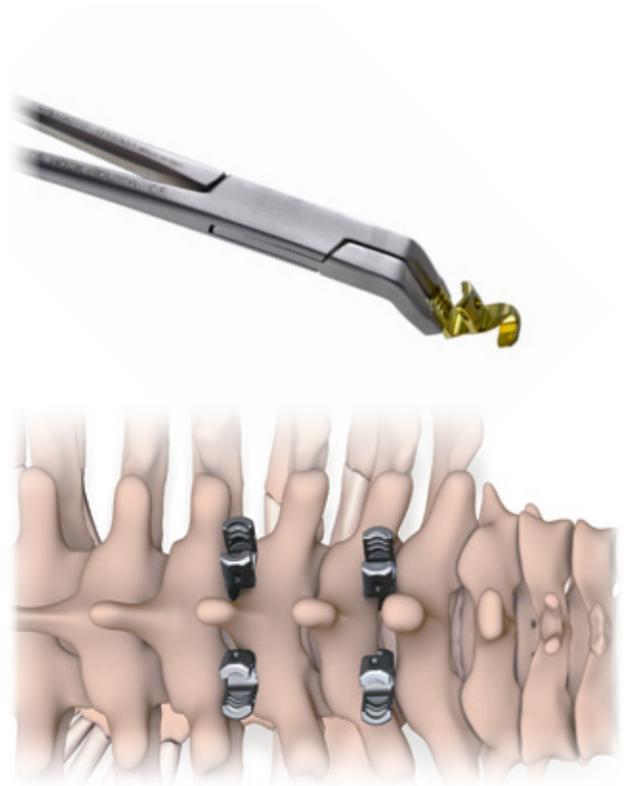
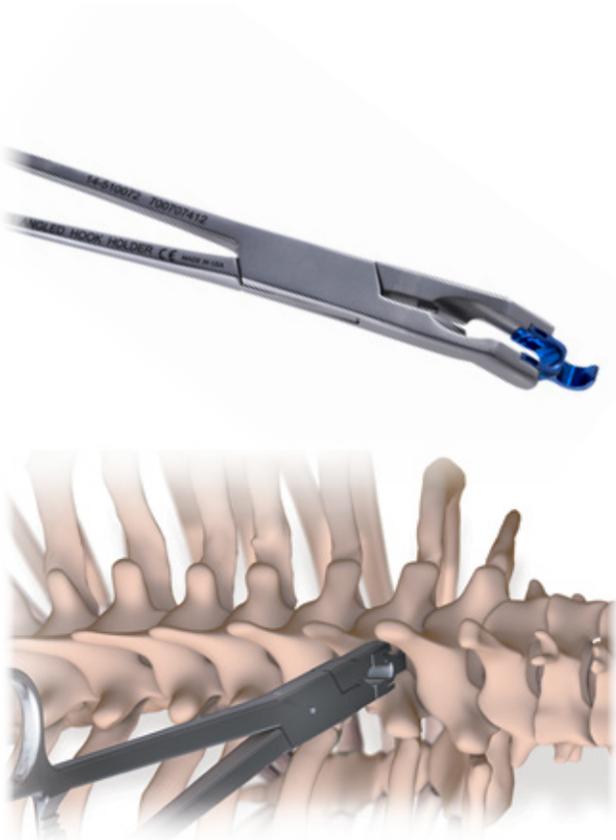
- Can be utilized in upper thoracic spine (T1–T3) where there is little space between the laminar edges to pass a wider blade hook through.



PEDICLE HOOKS

- Pedicle hooks can be placed up-going from T10 proximally. The bifurcated blade is designed to engage the pedicle and prevent translation.

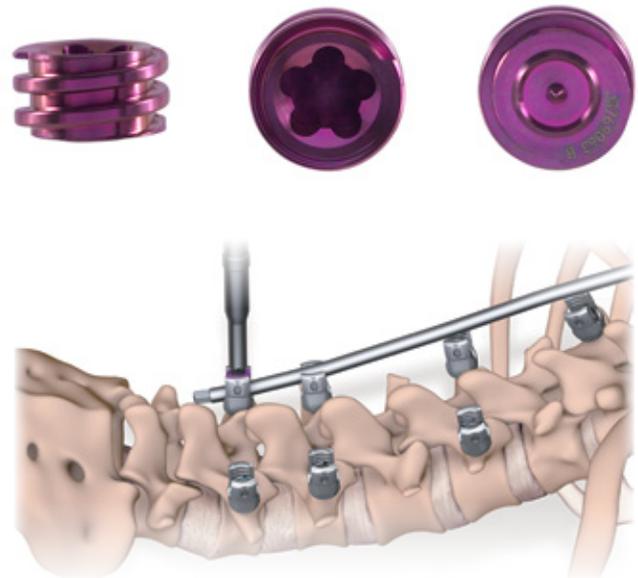
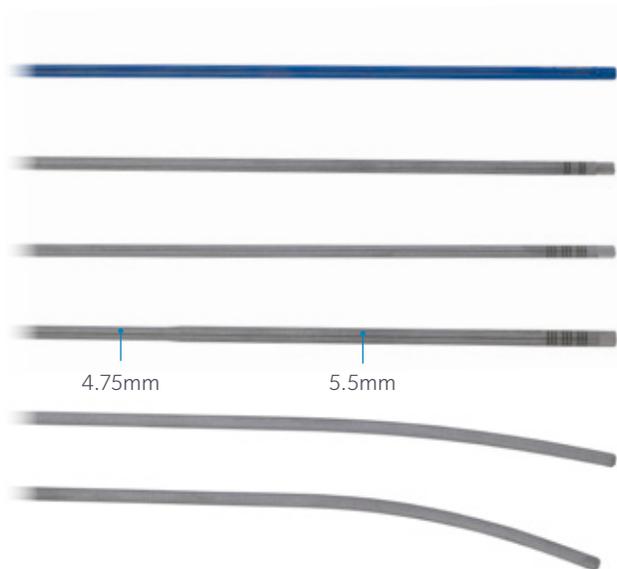
HOOK APPLICATION (*continued*)



STEP 4

- Upon selection of the appropriate style hook, the site is prepared using a variety of different instruments. A laminar **hook starter** can be used to simulate the path and placement of the eventual hooks.
- Assemble the hook to the desired **hook holder** by aligning the pockets at the proximal end of the hook to the corresponding pockets on the hook holder and squeeze the handle until tight.
- Insert the hook onto the anatomy, and remove the **hook inserter**. Care is needed to insure the hook fits intimately to the bone without excessive canal compromise that occurs when a large hook is placed with a throat size wider than the lamina.
- Repeat the steps as necessary for the remaining hook sites.

ROD APPLICATION



STEP 5

- Upon placement and confirmation of the fixation points, hooks and/or screws, select the appropriate style rod necessary for the patient.
- The Polaris 4.75 System comes with high and standard strength Cobalt Chrome (CoCr) options. Titanium alloy rods are available upon request.
- Straight rods have hexes on both sides. Curved rods and transition rods have a hex on one side only.
- The rod should be contoured as required.

Warning: High strength CoCr rods should not be used when moderate to high in situ bending might be required. CoCr standard should be used when in situ bending is anticipated.

Upon proper placement of the rod, **Helical Flange® (magenta) plugs** are placed into the fixation points to seat the rod into place.

- Place the Helical Flange plugs onto the **plug starter** and turn the handle clockwise until provisionally tightened.
- Repeat the steps for the subsequent fixation points.

ROD APPLICATION (continued)

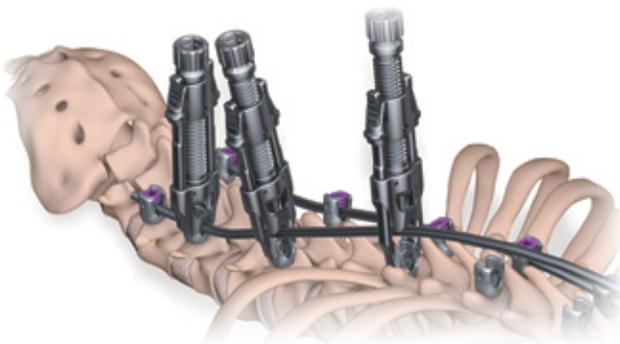


STEP 5 (continued)

- Due to the anatomy of the patient, the rod may not be fully seated into the screw head, limiting the ability to place the Helical Flange plug properly.
- The Polaris 4.75 System provides several options for rod reduction including **rockets**, **rod rockers** and **reduction forks**.

STEP 6

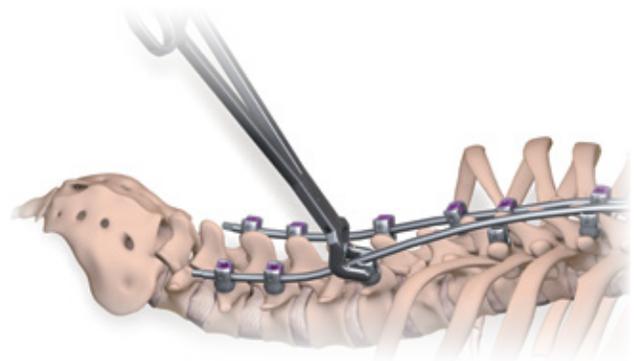
- Attach the **rocket reducer** to the screw seat by depressing the spring-loaded arms and aligning to the proximal aspect of the implant.
- Rotate the central barrel clockwise a half turn to lock the rocket reducer onto the implant.
- Continue to rotate the central barrel clockwise until the rod has been completely seated into the implant.
- Insure the rod has been seated to the screw without inadvertent screw pullout.



STEP 7

- Place the Helical Flange plug through the barrel and turn the handle clockwise until the Helical Flange plug has been provisionally tightened.
- Remove the rocket reducer by turning the central barrel counterclockwise until it stops.
- Depress the spring-loaded arms and lift the rocket reducer off of the implant.

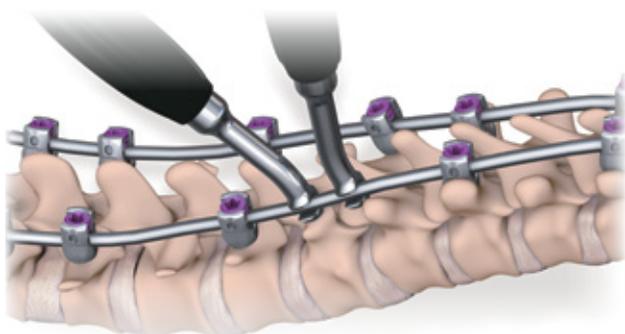
Note: Rocket reducers were designed to mate with **DeRoduction handles**. However the DeRoduction handles must be ordered separate (P/N 14-509648).



STEP 8

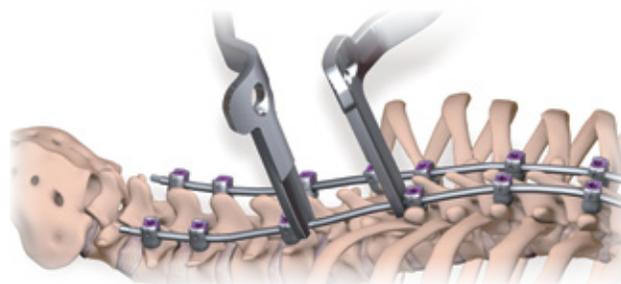
- Align the posts at the distal end of the **rod rocker** to the pockets in the walls of the implant and squeeze the forceps handle until tight.
- Rotate the rod rocker down against the rod until the rod has been fully seated within the implant.
- Insert the Helical Flange plug into the implant head and provisionally tighten.

ROD APPLICATION (continued)



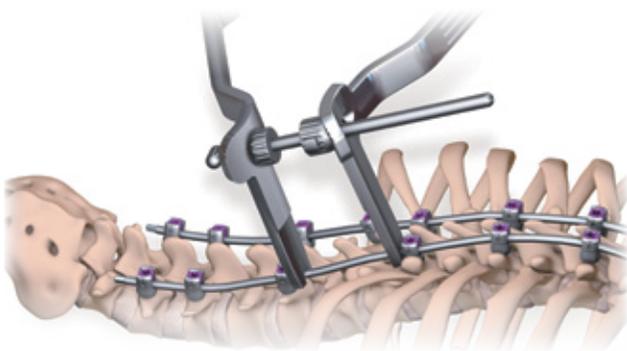
STEP 9, OPTION A

- The **sagittal benders** contain a unique “J” slot to minimize slipping during rod contouring, and are double ended with straight and angled ends.
- Align the end of the sagittal benders to the rod and contour the rod as necessary.



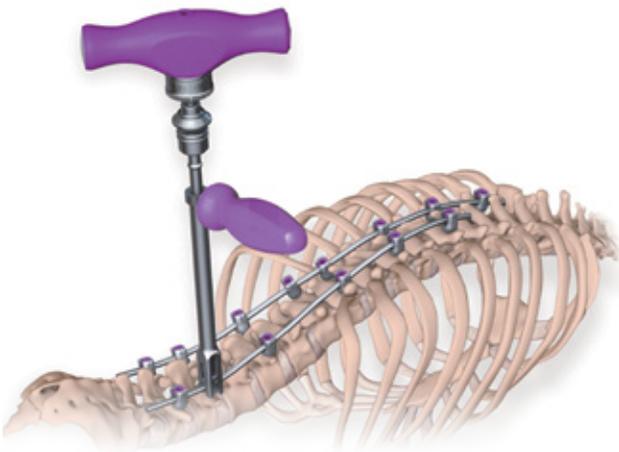
STEP 9, OPTION B

- The **coronal benders** also contain the unique “J” slot to minimize slippage of the rod during contouring.
- Place the coronal benders against the rod and contour as necessary.



- To contour the rod over a wider distance, the system comes with an **adjustable fulcrum**.
- Press the button on the adjustable fulcrum and slide the mechanism to the desired separation distance.
- Assemble the T of the adjustable fulcrum to one of the coronal benders by aligning into the slot and rotating 90°.
- Place the coronal bender against the rod.
- Align the opposite end of the adjustable fulcrum into the second coronal bender and place the coronal bender against the rod.
- Contour the rod as necessary.

AXIAL CONNECTOR APPLICATION



STEP 10

Upon completion of rod contouring, final tightening of the Helical Flange plugs is performed.

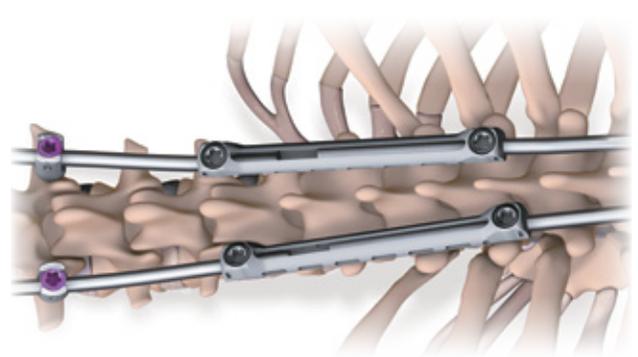
Note: The system torque for final tightening is 80in-lb.

- Assemble the **ratcheting torque handle** to the **plug driver**.
- Guide the assembled torque wrench through the **counter torque** and place over the fixation point.

Note: The handle of the counter torque should be oriented perpendicular to the spine.

- Turn the T-handle clockwise until a click is heard and felt.
- Repeat the steps as necessary for the rest of the fixation points.

Note: When using Polaris™ 5.5 DeRoders (Kit P/N 14-500204) with the 4.75 rockets, the plug starter will fit down the cannulated instrument to provisionally tighten, but the DeRoders and rockets will need to be removed and a torque stabilizer should be used to final tighten.



The Polaris 4.75 System provides the ability to perform *in situ* distraction of the spine via unique axial connectors. These connectors come in a variety of lengths with straight and curved varieties available.

	STRAIGHT CONNECTORS	LESS-CURVED CONNECTORS (LIGHT GREEN)	MORE-CURVED CONNECTORS (LIGHT BLUE)
LENGTHS	60mm	80mm	80mm
	85mm	100mm	100mm
	115mm	120mm	120mm
RADIUS	N/A	500mm	250mm

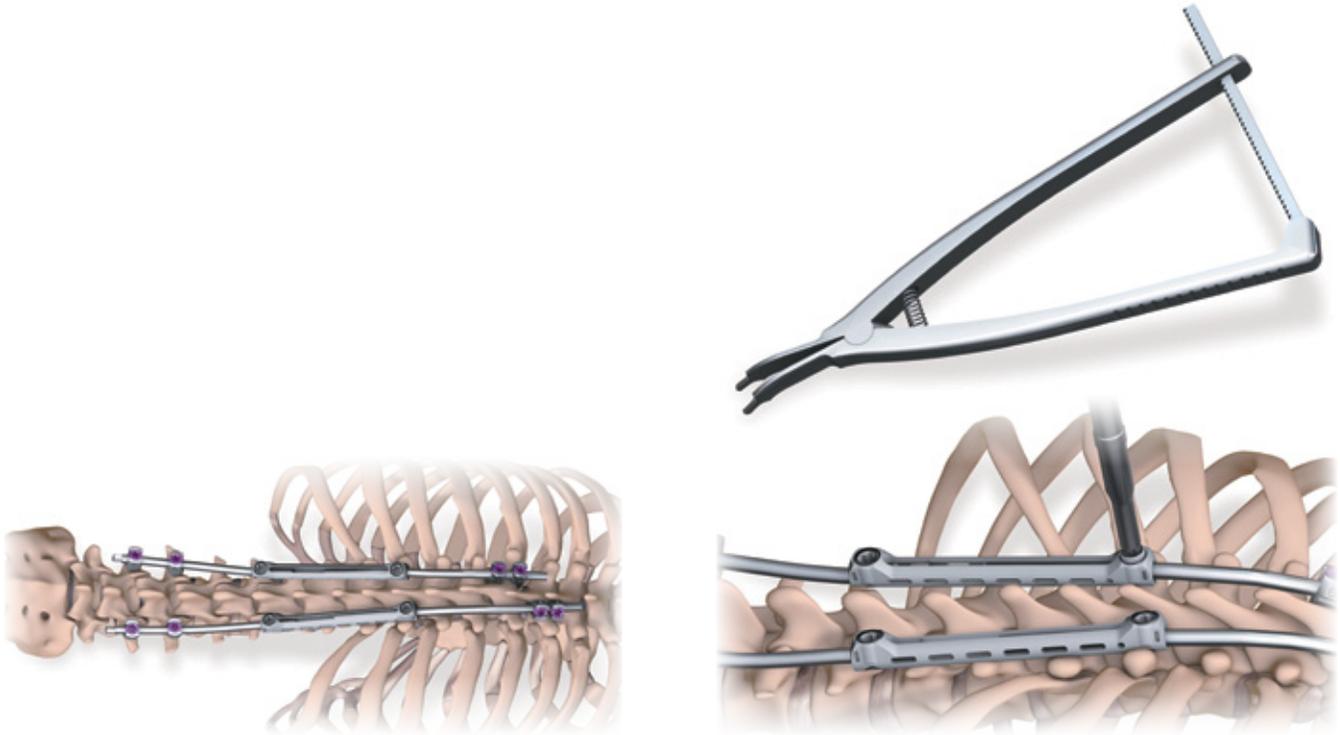
STEP 11

Upon placement of all fixation points, assemble the proximal and distal rods into the appropriate **axial connector** and provisionally tighten the set screws.

Tip: Please note that due to the different radii of the connectors, the appropriate rods must be utilized with the corresponding connectors. Do not contour the portion of the rod that will be inside the curved connector, or it may not fit.

Tip: When measuring the rod to cut to length, place rod next to the axial connector to account for the full length of the connector and allow for the maximum amount of distraction.

AXIAL CONNECTOR APPLICATION (*continued*)



STEP 12

- Contour the proximal/distal rods as necessary to suit the needs of the patient accordingly as described on pages 11–17.
- Upon placement of the assembled construct, place and perform final tightening of the Helical Flange plugs in the fixation points as described on pages 11–17.
- Perform *in situ* distraction with the axial connectors.
- Utilizing the plug starter, loosen the proximal set screws of the axial connectors by rotating counterclockwise $\frac{1}{4}$ turn.

Tip: Take care to note when using the curved rods and connectors, the overall curvature doubles once the rod is fully distracted.



STEP 13

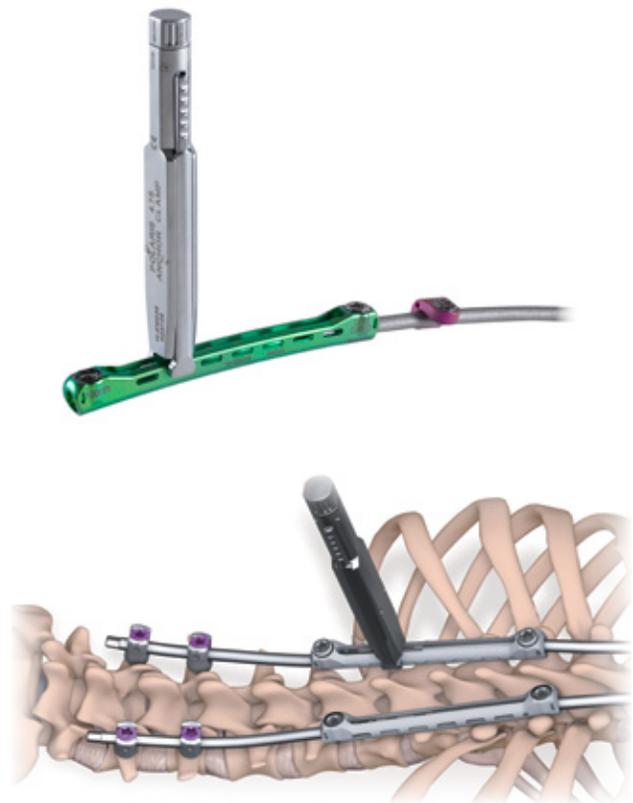
Internal Distraction (*Within the Connector*)

- After loosening the desired set screw(s), align the **in-slot distractor** into the axial connector, between the connector rods.

Note: Leave a gap between the cephalad/caudal rods to allow access for the in-slot distractor.

- Squeeze the handle to achieve the desired amount of distraction.
- Provisionally tighten the set screw(s) on the axial connector and remove the distractor.
- Perform final tightening of the proximal set screw(s).

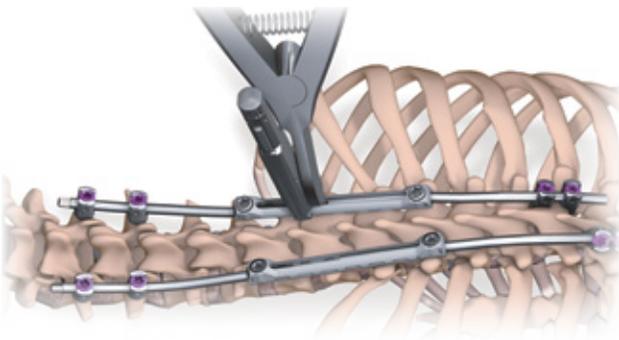
Note: There is no counter torque specifically for the axial connectors. Utilize the standard counter torque by placing over the rod adjacent to the axial connector and final tighten.



STEP 14

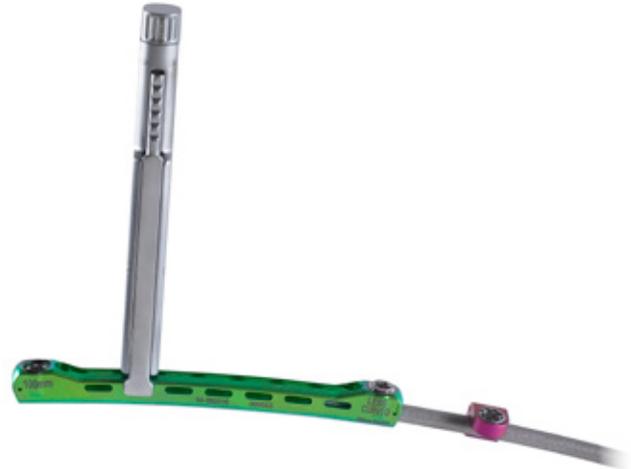
- Based on patient anatomy, the amount of distraction required may exceed the travel of the internal distractor.
- Place the **anchor clamp** on the axial connector.
- Rotate the proximal knob 90° counterclockwise to release the spring-loaded arms on the medial-lateral sides of the anchor clamp.
- Depress the spring-loaded arms and guide the anchor clamp distal to the proximal rod and onto the axial connector until it mates with the slots on the longitudinal aspect of the axial connector.
- Rotate the proximal knob 90° clockwise to lock the anchor clamp onto the axial connector.

AXIAL CONNECTOR APPLICATION (*continued*)



STEP 15

- Place the in-slot distractor against the anchor clamp and the proximal rod.
- Squeeze the handle of the in-slot distractor until the desired amount of distraction is achieved.
- Provisionally tighten the proximal set screw(s), and remove the anchor clamp.
- Turn the proximal knob counterclockwise 90°.
- Depress the spring loaded arms and remove the **distractor stop**.



STEP 16

- Perform final tightening of the proximal set screw(s).

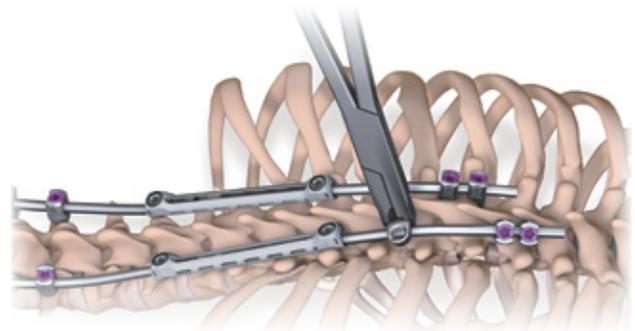


STEP 17

External Distraction (*Outside the Connector*)

- Place a **C-clamp** on the proximal or distal rod adjacent to the axial connector.
- Assemble the C-clamp to the **C-clamp holder**.

Note: The C-clamp is pre-assembled with a **Cobalt Chrome set screw**.

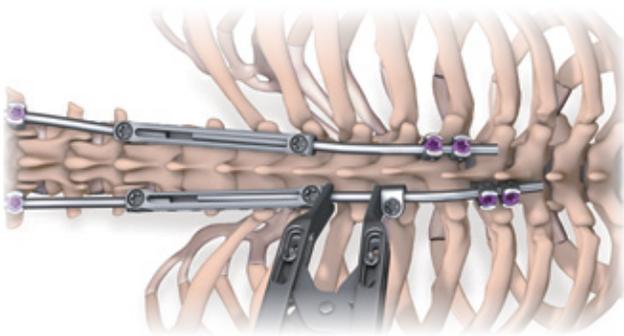


STEP 18

- Guide the throat of the C-clamp onto the rod.
- Utilize the plug starter to provisionally tighten the set screw, holding the C-clamp in place.
- Remove the C-clamp holder.
- Final tightening for the C-clamp set screw is performed.

Tip: Ensure that the C-clamp is placed at a sufficient distance from the axial connector to allow for placement of the distractor.

PELVIC SADDLE APPLICATION

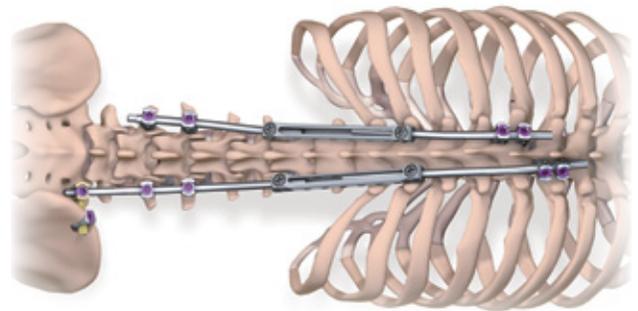


STEP 19

- Loosen the set screw of the axial connector with the plug starter.
- Place the distractor between the axial connector and C-clamp against the rod.
- Squeeze the handle of the distractor until the desired amount of distraction is achieved.
- Provisionally tighten the set screw of the axial connector and remove the distractor.
- Final tightening of the axial connector proximal set screw is performed.



Pelvic saddles are offered with the Polaris 4.75 System to provide an additional point of fixation on the ilium.

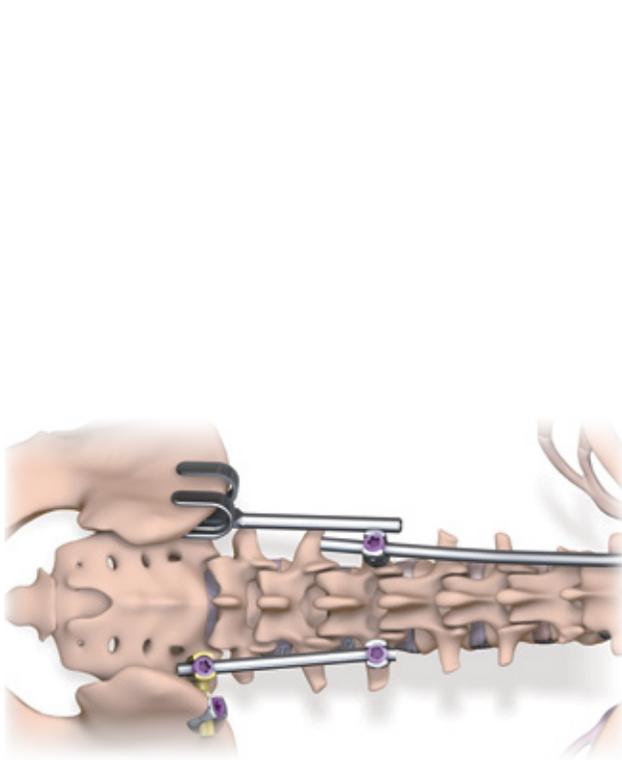


STEP 20

- Pelvic saddles will be an adjunct point of fixation for the patient and links up with the primary fixation points along the spine via a **wedding band domino**.
- Select the appropriate size pelvic saddle, based on throat size, and place against the ilium in the desired location for preliminary positioning.
- Based on the anatomical alignment of the patient, and the rest of the construct, it may be necessary to cut and/or contour the **pelvic saddle extension** prior to final implantation.
- When inserting the pelvic saddle, it needs to coddle both sides of the apex.

Tip: To aid in the contouring of the pelvic saddle extension, use the vice grip holder with a sagittal bender.

PELVIC SADDLE APPLICATION (*continued*)



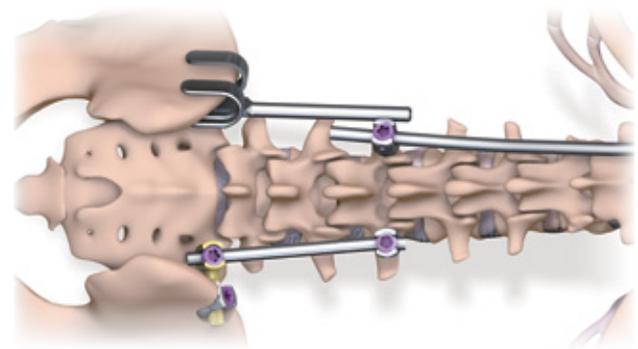
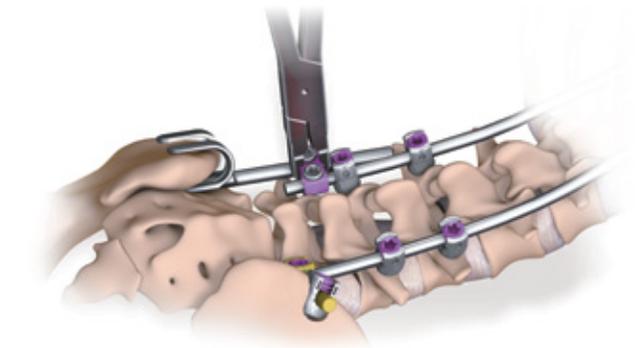
STEP 20 (*continued*)

- After completion of pelvic saddle extension contouring, place the pelvic saddle against the ilium.
- The pelvic saddle extension should be parallel with the primary fixation points.

Tip: While there is not a specific instrument for insertion of the pelvic saddle, a rod holder, or forceps can be utilized as necessary.

- Connect the pelvic saddle to the primary fixation points with a wedding band domino.

Note: The pelvic saddle extension is a 5.5mm diameter rod. Select the 5.5mm x 4.75mm closed wedding band domino (P/N 14-589635) to bridge the parallel rods together.



STEP 21

- Guide the domino onto the ends of the rods and place in the appropriate position to bridge the rods together.
- The closed dominos are pre-assembled with set screws.
- Using the plug starter, provisionally tighten the set screws.
- Final tightening is performed for the set screws contained within the domino.

UNIVERSAL HOOK APPLICATION



Universal hooks are offered with the Polaris 4.75 System as a unique clamping option for fixation at the costo-vertebral junction in the thoracic spine.



Tapered Starter



45° Hook Starter



90° Hook Starter

STEP 22

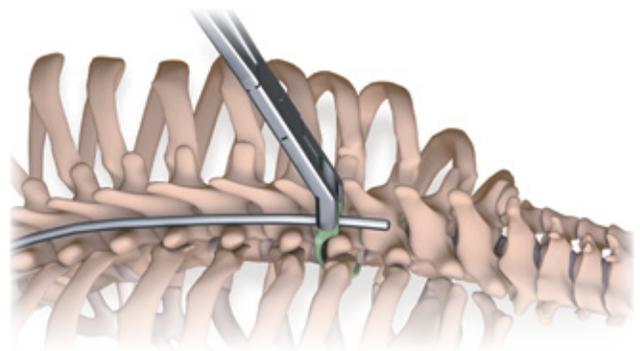
- Prepare the hook site with the universal hook starters, provided with the Polaris 4.75 System.

UNIVERSAL HOOK APPLICATION (continued)



STEP 23

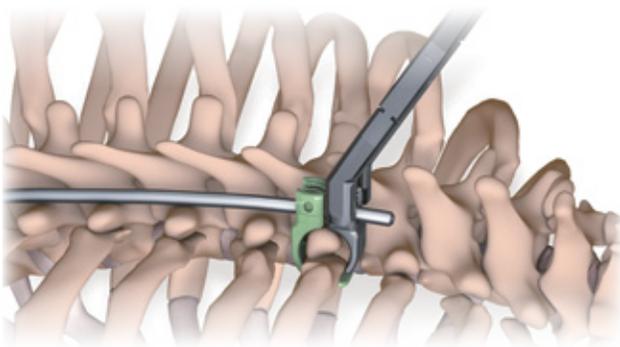
- Select the appropriate universal hook and assemble to the **angled hook holder**.



STEP 24

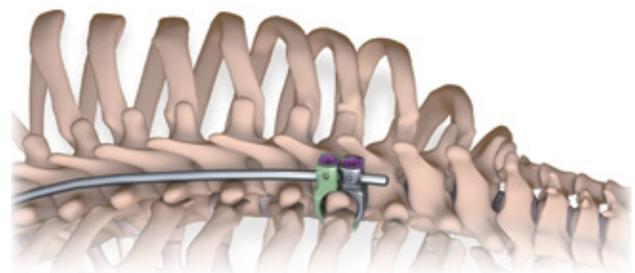
- Place the universal hook into the appropriate anatomic position with the throat of the hook facing cephalad.

Note: Universal hooks have a medial spike to aid in fixation to the anatomy and prevent migration.



STEP 25

- If desired, select the appropriate closing hook and assemble to the **angled hook holder**.
- Note:** Ensure that the proper closing hook is selected based on the throat size of the universal hook. Small = 6.5mm and 8.0mm, Large = 11mm and 16mm.
- Place the **closing hook** adjacent to the universal hook with the throat facing caudal.



STEP 26

- The rod is contoured and placed into the universal hook/closing hook assembly.
- Assemble a Helical Flange plug to the plug starter.
- Place the Helical Flange plug into the universal hook and provisionally tighten.
- Place a second Helical Flange plug into the closing hook and provisionally tighten.
- Remove the **side hook holder** from the closing hook.
- Final tightening is performed for the universal hook and closing hook.

SUPPORTING INSTRUMENTATION AND IMPLANTS

Please Note: The Polaris 4.75 System is supplied with three types of set screws. See the below chart to determine which set screw is utilized for various applications.

	Helical Flange Plug	Open Connector Set Screw	Closed Connector Set Screw
Image			
Usage	Closed Head Multi-axial Screws Open Head Multi-axial Screws Fixed Multi-axial Screws Standard Hooks Universal Hooks Lateral Connectors Bridge Connectors	Open Wedding Band Dominos C-clamp Connectors Offset Connectors	Straight Axial Connector Curved Axial Connector Closed Wedding Band Dominos
Final Tightening Requirements	80in-lb		
Identifier	Magenta	Dashed Circle Laser Etch	Solid Circle Laser Etch

SET SCREWS

Note: All set screws have the identical pentalobe interface, and utilize the plug starter and plug driver for final tightening.



PEDICLE SCREWS

The Polaris 4.75 System **pedicle screws** are color coded to denote the various diameters as follows:

DIAMETER	COLOR CODING
4.0mm	Gray
4.5mm	Dark Magenta
5.0mm	Light Blue
5.5mm	Gold
6.0mm	Light Magenta
6.5mm	Dark Blue

Note: 6.0mm diameter screws are additionally available



PEDICLE PROBES

A variety of pedicle probes are provided with the Polaris 4.75 System, each with their own unique application as described below.

Ghost-grip handle minimizes obstruction during fluoroscopic imaging.

SUPPORTING INSTRUMENTATION AND IMPLANTS *(continued)*



PEDICLE SOUNDS

Two pedicle sounds are provided with the Polaris 4.75 System, stiffness of the sound is identified by the band on the proximal end of the instrument.

2 Bands = Medium

3 Bands = Stiff



SCREW INSERTERS

To assist in cleaning and proper maintenance, the screw inserters can be disassembled. Adhere to the following steps to ensure proper disassembly:

- Take a rod gripper and hold the proximal portion of the screw inserter.
- Align the cross connector driver into the central barrel of the screw inserter.
- Turn the cross connector driver counterclockwise until the central shaft can be removed.
- Remove the central shaft from the inserter.
- Disassemble the rotating sleeve and locking barrel.
- To reassemble the screw inserter, follow the steps as outlined above in reverse order.



Standard Counter Torque



Closed Head Counter Torque

FINAL TIGHTENING

When performing final tightening, note that the Polaris 4.75 System has two different counter torque instruments.

Note: The handle of the counter torque should be oriented perpendicular to the spine.

Application

Open Multi-axial Screws

Fixed Screws

Standard Hooks

Universal Hooks

Note: The **closed head counter torque** does not have a handle. Assemble one of the **quick-connect handles** to the instrument prior to utilization.

Application

Closed Head Screws

SUPPORTING INSTRUMENTATION AND IMPLANTS *(continued)*



Angulating Cross Connectors



Fixed Cross Connectors

CROSS CONNECTORS

- To support the needs of each patient pathology, the Polaris 4.75 System comes with a variety of cross connectors.

Sizing, Angulating

Extra-extra Small = 23mm–29mm

Extra Small = 28mm–38mm

Small = 35mm–53mm

Medium = 52mm–86mm

Note: To identify the appropriate length cross connector required for the patient, utilize the **cross connector measuring template**.

Sizing, Fixed

10mm–24mm (2mm increments)



Lateral Connectors



Bridge Connectors

MISCELLANEOUS CONNECTORS

To support the needs of each patient pathology, the Polaris 4.75 System comes with a variety of connectors.

Sizing, Lateral

25mm

75mm

Application

Pelvic Screw Connection

Lateralized Screw Placement

Sizing, Bridge

25mm

75mm

Application

Connect a 5.5mm screw to a 4.75mm rod
(bridge connectors are gold)

SUPPORTING INSTRUMENTATION AND IMPLANTS *(continued)*



Offset Connectors

Note: The lateral and bridge connectors accept a Helical Flange set screw, while the offset connectors are pre-assembled with the open connector set screws.

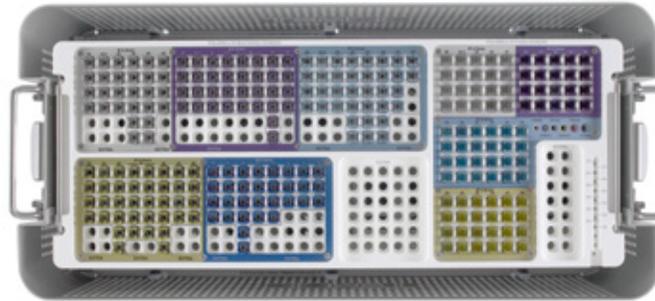
Sizing, Offset

25mm

75mm

KIT CONTENTS

Polaris 4.75, Deformity Combined Implants 14-509889

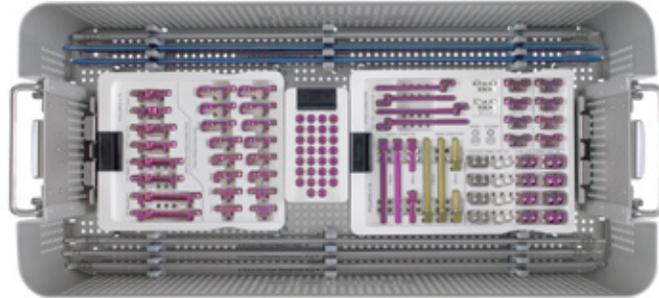


DESCRIPTION	QUANTITY	PART NUMBER
Multi-axial Screw, ø4.0mm × 20mm	4	14-562020
Multi-axial Screw, ø4.0mm × 22.5mm	4	14-562022
Multi-axial Screw, ø4.0mm × 25mm	4	14-562025
Multi-axial Screw, ø4.0mm × 30mm	6	14-562030
Multi-axial Screw, ø4.0mm × 35mm	4	14-562035
Multi-axial Screw, ø4.0mm × 40mm	4	14-562040
Multi-axial Screw, ø4.5mm × 20mm	4	14-562120
Multi-axial Screw, ø4.5mm × 22.5mm	4	14-562122
Multi-axial Screw, ø4.5mm × 25mm	4	14-562125
Multi-axial Screw, ø4.5mm × 27.5mm	4	14-562127
Multi-axial Screw, ø4.5mm × 30mm	8	14-562130
Multi-axial Screw, ø4.5mm × 35mm	6	14-562135
Multi-axial Screw, ø4.5mm × 40mm	4	14-562140
Multi-axial Screw, ø5.0mm × 20mm	4	14-562220
Multi-axial Screw, ø5.0mm × 22.5mm	4	14-562222
Multi-axial Screw, ø5.0mm × 25mm	4	14-562225
Multi-axial Screw, ø5.0mm × 30mm	6	14-562230
Multi-axial Screw, ø5.0mm × 35mm	6	14-562235
Multi-axial Screw, ø5.0mm × 40mm	6	14-562240
Multi-axial Screw, ø5.0mm × 45mm	4	14-562245
Multi-axial Screw, ø5.0mm × 50mm	4	14-562250
Multi-axial Screw, ø5.5mm × 20mm	4	14-562320
Multi-axial Screw, ø5.5mm × 25mm	4	14-562325
Multi-axial Screw, ø5.5mm × 30mm	6	14-562330
Multi-axial Screw, ø5.5mm × 35mm	10	14-562335
Multi-axial Screw, ø5.5mm × 40mm	6	14-562340
Multi-axial Screw, ø5.5mm × 45mm	4	14-562345
Multi-axial Screw, ø5.5mm × 50mm	4	14-562350
Multi-axial Screw, ø6.5mm × 30mm	4	14-562530

DESCRIPTION	QUANTITY	PART NUMBER
Multi-axial Screw, ø6.5mm × 35mm	4	14-562535
Multi-axial Screw, ø6.5mm × 40mm	6	14-562540
Multi-axial Screw, ø6.5mm × 45mm	4	14-562545
Multi-axial Screw, ø6.5mm × 50mm	4	14-562550
Multi-axial Screw, ø6.5mm × 65mm	3	14-562565
Multi-axial Screw, ø6.5mm × 70mm	3	14-562570
Multi-axial Screw, ø6.5mm × 75mm	3	14-562575
Fixed Screw, ø4.0mm × 20mm	4	14-584020
Fixed Screw, ø4.0mm × 22.5mm	4	14-584022
Fixed Screw, ø4.0mm × 25mm	4	14-584025
Fixed Screw, ø4.0mm × 30mm	4	14-584030
Fixed Screw, ø4.0mm × 35mm	4	14-584035
Fixed Screw, ø4.0mm × 40mm	4	14-584120
Fixed Screw, ø4.5mm × 25mm	4	14-584125
Fixed Screw, ø4.5mm × 30mm	4	14-584130
Fixed Screw, ø4.5mm × 35mm	4	14-584135
Fixed Screw, ø4.5mm × 40mm	4	14-584140
Fixed Screw, ø5.0mm × 25mm	4	14-584225
Fixed Screw, ø5.0mm × 30mm	4	14-584230
Fixed Screw, ø5.0mm × 35mm	4	14-584235
Fixed Screw, ø5.0mm × 40mm	4	14-584240
Fixed Screw, ø5.0mm × 45mm	4	514-584245
Fixed Screw, ø5.0mm × 50mm	4	14-584250
Fixed Screw, ø5.5mm × 25mm	4	14-584325
Fixed Screw, ø5.5mm × 30mm	4	14-584330
Fixed Screw, ø5.5mm × 35mm	4	514-584335
Fixed Screw, ø5.5mm × 40mm	4	14-584340
Fixed Screw, ø5.5mm × 45mm	4	14-584345
Fixed Screw, ø5.5mm × 50mm	4	14-584350

KIT CONTENTS (continued)

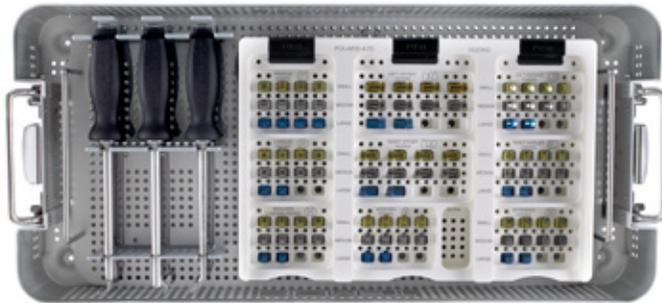
Polaris 4.75, Deformity Combined Implants 14-509889 (continued)



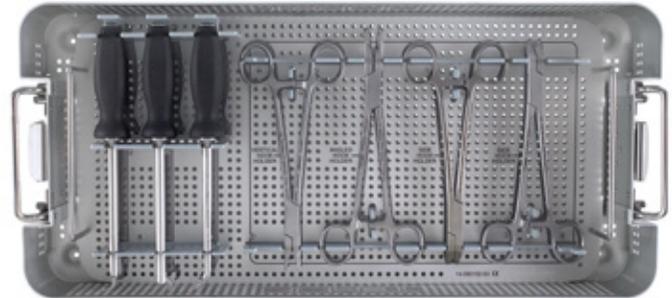
DESCRIPTION	QUANTITY	PART NUMBER
CoCr Standard Rod, with Hex, ø4.75mm × 510mm	3	14-587151CS
CoCr High Rod, with Hex, ø4.5mm × 510mm	3	14-585151CH
CoCr High Rod, with Hex, ø4.75mm × 510mm	3	14-587151CH
CoCr High Rod, with Hex, ø4.75mm/ø5.5mm × 510mm	3	14-588551CH
Ti Alloy Rod, with Hex, ø4.5mm × 510mm	3	14-585151T
Ti Alloy Rod, with Hex, ø4.75mm × 510mm	3	14-587151T
Standard Helical Flange Plug	30	14-589001
Angulating Cross Connector, Extra-extra Small	2	14-589505
Angulating Cross Connector, Extra Small	2	14-589506
Angulating Cross Connector, Small	2	14-589507
Angulating Cross Connector, Medium	2	14-589508
Fixed Cross Connector, 10mm	2	14-589510
Fixed Cross Connector, 12mm	2	14-589512
Fixed Cross Connector, 14mm	2	14-589514
Fixed Cross Connector, 16mm	2	14-589516

DESCRIPTION	QUANTITY	PART NUMBER
Fixed Cross Connector, 18mm	2	14-589518
Fixed Cross Connector, 20mm	2	14-589520
Fixed Cross Connector, 22mm	2	14-589522
Fixed Cross Connector, 24mm	2	14-589524
Standard Lateral Connector, 25mm	2	14-589725
Standard Lateral Connector, 75mm	2	14-589775
Bridge Connector, 25mm	2	14-589825
Bridge Connector, 75mm	2	14-589875
Offset Connector, Medium	2	14-589703
Offset Connector, Extra Large	2	14-589705
Open Wedding Band Domino, ø4.75mm/ø4.75mm	4	14-589674
Open Wedding Band Domino, ø4.75mm/ø5.5mm	4	14-589675
Closed Wedding Band Domino, ø4.75mm/ø4.75mm	4	14-589634
Closed Wedding Band Domino, ø4.75mm/ø5.5mm	4	14-589635
Open/Open Parallel Domino, ø4.75mm/ø4.75mm	4	14-589604
Open/Open Parallel Domino, ø4.75mm/ø5.5mm	4	14-589605

Polaris 4.75, Standard Hooks 14-509892



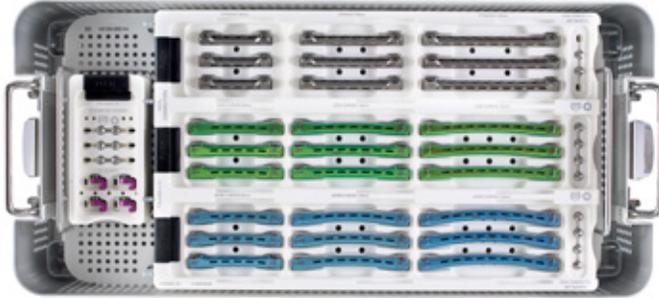
DESCRIPTION	QUANTITY	PART NUMBER
Pedicle Hook, Small	4	14-581130
Pedicle Hook, Medium	4	14-581145
Pedicle Hook, Large	4	14-581160
Left Angled Hook, Small	4	14-581230L
Left Angled Hook, Medium	4	14-581245L
Left Angled Hook, Large	2	14-581260L
Right Angled Hook, Small	4	14-581230R
Right Angled Hook, Medium	4	14-581245R
Right Angled Hook, Large	2	14-581260R
Laminar Hook, Small	4	14-581430
Laminar Hook, Medium	4	14-581445
Laminar Hook, Large	2	14-581460
Reduced Laminar Hook, Small	4	14-581530
Reduced Laminar Hook, Medium	4	14-581545
Reduced Laminar Hook, Large	2	14-581560
Left Offset Hook, Small	4	14-581630L
Left Offset Hook, Medium	4	14-581645L
Left Offset Hook, Large	2	14-581660L
Right Offset Hook, Small	4	14-581630R
Right Offset Hook, Medium	4	14-581645R
Right Offset Hook, Large	2	14-581660R
Extended Hook, Small	4	14-581830
Extended Hook, Medium	4	14-581845
Extended Hook, Large	2	14-581860
Midstem Hook, Small	4	14-581030
Midstem Hook, Medium	4	14-581045
Midstem Hook, Large	2	14-581060



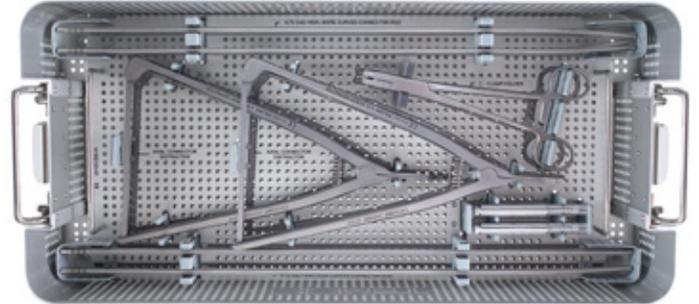
DESCRIPTION	QUANTITY	PART NUMBER
Side Hook Holder	2	14-510070
Vertical Hook Holder	1	14-510071
Angled Hook Holder	1	14-510072
Hook Impactor	1	14-510073
Laminar Hook Starter	1	14-510077
Thoracic Hook Starter	1	14-510078

KIT CONTENTS (continued)

Polaris 4.75, Connectors 14-509893

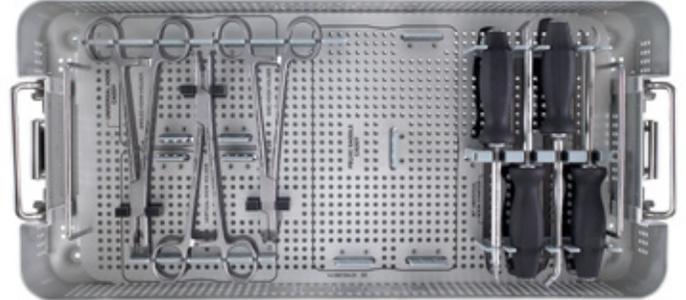
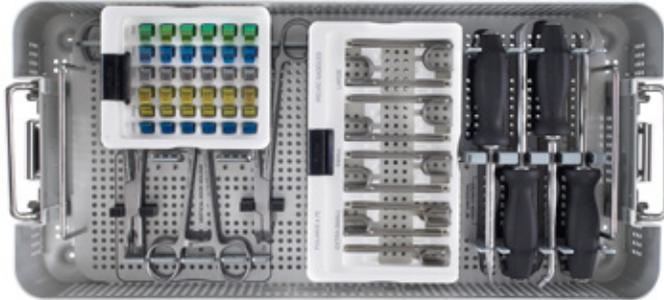


DESCRIPTION	QUANTITY	PART NUMBER
Straight Axial Connector, 60mm	3	14-589106
Straight Axial Connector, 85mm	3	14-589108
Straight Axial Connector, 115mm	3	14-589111
Less Curved Axial Connector, 80mm	3	14-589308
Less Curved Axial Connector, 100mm	3	14-589310
Less Curved Axial Connector, 120mm	3	14-589312
More Curved Axial Connector, 80mm	3	14-589208
More Curved Axial Connector, 100mm	3	14-589210
More Curved Axial Connector, 120mm	3	14-589212
C-clamp	4	14-589700
Connector Set Screw, Closed	10	14-589099
Connector Set Screw, Open	6	14-589799



DESCRIPTION	QUANTITY	PART NUMBER
CoCr High More Curved Rod, ø4.75mm × 510m	4	14-587251CH
CoCr High Less Curved Rod, ø4.75mm × 510mm	4	14-587351CH
Anchor Clamp	2	14-510036
In-Slot Distractor	2	14-510037
C-clamp Holder	1	14-510076

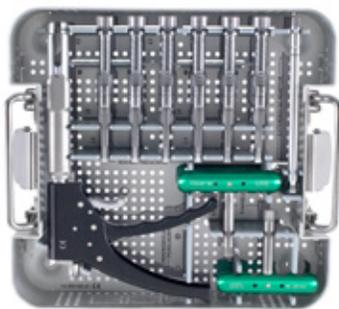
Polaris 4.75, Specialty Hooks
14-509894



DESCRIPTION	QUANTITY	PART NUMBER
Pelvic Saddle, Small	3	14-589091
Pelvic Saddle, Large	3	14-589092
Pelvic Saddle, XSmall	3	14-589093
Universal Hook, 6mm	6	14-580906
Universal Hook, 8.5mm	6	14-580908
Universal Hook, 11mm	6	14-580911
Universal Hook, 16mm	6	14-580916
Universal Closing Hook, Small	6	14-580920
Universal Closing Hook, Large	6	14-580921

DESCRIPTION	QUANTITY	PART NUMBER
Side Hook Holder	1	14-510070
Vertical Hook Holder	1	14-510071
Angled Hook Holder	1	14-510072
Hook Impactor	1	14-510073
Universal Hook Starter, 45°	1	14-510079
Universal Hook Starter, 90°	1	14-510089
Tapered Hook Starter	1	14-510090

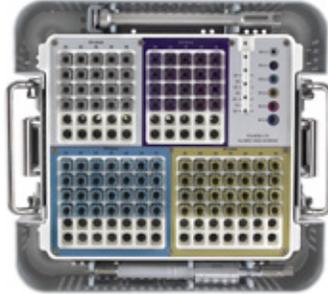
Polaris 4.75, Rocket Reducers
14-509895



DESCRIPTION	QUANTITY	PART NUMBER
T-handle	2	14-500201
Extended QC Adaptor	1	14-500205
Rocket Reducer	6	14-510013
Perpendicular Persuader	1	14-510103

KIT CONTENTS (continued)

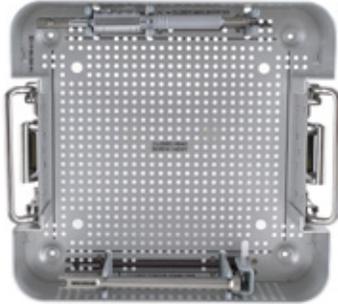
Polaris 4.75, Closed Head Screws 14-509896



DESCRIPTION	QUANTITY	PART NUMBER
Closed Head Multi-axial Screw, ø4.0mm × 20mm	4	14-563020
Closed Head Multi-axial Screw, ø4.0mm × 25mm	4	14-563025
Closed Head Multi-axial Screw, ø4.0mm × 30mm	4	14-563030
Closed Head Multi-axial Screw, ø4.0mm × 35mm	4	14-563035
Closed Head Multi-axial Screw, ø4.0mm × 40mm	4	14-563040
Closed Head Multi-axial Screw, ø4.5mm × 20mm	4	14-563120
Closed Head Multi-axial Screw, ø4.5mm × 25mm	4	14-563125
Closed Head Multi-axial Screw, ø4.5mm × 30mm	4	14-563130
Closed Head Multi-axial Screw, ø4.5mm × 35mm	4	14-563135
Closed Head Multi-axial Screw, ø4.5mm × 40mm	4	14-563140
Closed Head Multi-axial Screw, ø5.0mm × 20mm	4	14-563220
Closed Head Multi-axial Screw, ø5.0mm × 25mm	4	14-563225

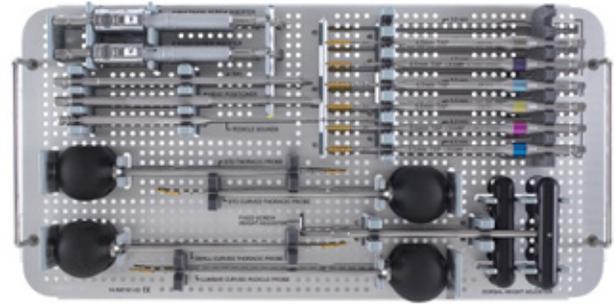
DESCRIPTION	QUANTITY	PART NUMBER
Closed Head Multi-axial Screw, ø5.0mm × 30mm	4	14-563230
Closed Head Multi-axial Screw, ø5.0mm × 35mm	4	14-563235
Closed Head Multi-axial Screw, ø5.0mm × 40mm	4	14-563240
Closed Head Multi-axial Screw, ø5.0mm × 45mm	4	14-563245
Closed Head Multi-axial Screw, ø5.0mm × 50mm	4	14-563250
Closed Head Multi-axial Screw, ø5.5mm × 20mm	4	14-563320
Closed Head Multi-axial Screw, ø5.5mm × 25mm	4	14-563325
Closed Head Multi-axial Screw, ø5.5mm × 30mm	4	14-563330
Closed Head Multi-axial Screw, ø5.5mm × 35mm	4	14-563335
Closed Head Multi-axial Screw, ø5.5mm × 40mm	4	14-563340
Closed Head Multi-axial Screw, ø5.5mm × 45mm	4	14-563345
Closed Head Multi-axial Screw, ø5.5mm × 50mm	4	14-563350

**Polaris 4.75, Closed Head Screws
14-509896 (continued)**



DESCRIPTION	QUANTITY	PART NUMBER
Multi-axial Screw Inserter, Closed Head	2	14-510033
Torque Stabilizer for Closed Head Screws	1	14-510059

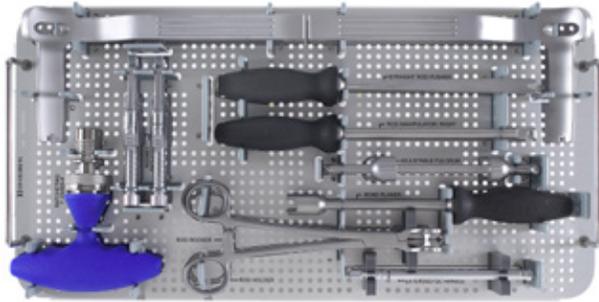
**Polaris 4.75, Deformity Instruments A
14-509891**



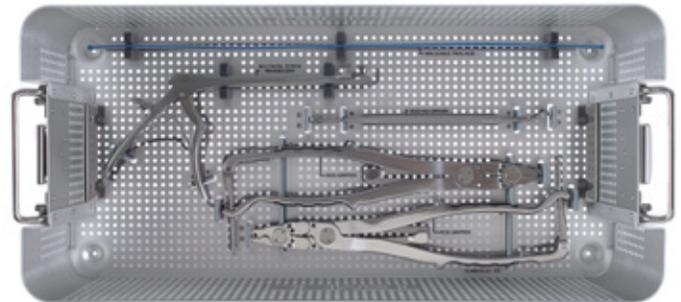
DESCRIPTION	QUANTITY	PART NUMBER
Multi-axial Screw Inserter	2	14-510031
Fixed Screw Inserter	2	14-510032
Tap, 3.5mm	1	14-510020
Tap, 4mm	1	14-510021
Tap, 4.5mm	1	14-510022
Tap, 5mm	1	14-510023
Tap, 5.5mm	1	14-510024
Tap, 6mm	1	14-510025
Tap, 6.5mm	1	14-510026
Pedicle Sound, Medium	1	14-510094
Pedicle Sound, Stiff	1	14-510095
Awl	1	14-510029
Rod Gripper	2	14-510044
Rod Hex Driver	1	14-510046
Thoracic Probe, Curved	1	14-510151
Thoracic Probe, Straight	1	14-510152
Lumbar Probe, Curved	1	14-510153
Thoracic Probe, Small, Curved	1	14-510054
Dorsal Height Adjuster	1	14-510063
Fixed Screw Height Adjuster	1	14-510064
Axial Head Turner	1	14-510065

KIT CONTENTS (continued)

Polaris 4.75, Deformity Instruments A 14-509891 (continued)



DESCRIPTION	QUANTITY	PART NUMBER
Coronal Bender, Left	1	14-510008
Coronal Bender, Right	1	14-510009
Adjustable Fulcrum	1	14-510010
Rod Rocker	1	14-510011
Rocket Reducer	2	14-510013
Quick Connect Ratcheting T-handle	1	12479-7
Straight Rod Pusher	1	14-510040
Rod Manipulator	1	14-510041
Rod Holder	1	14-510043
Bone Planer	1	14-510066
Extended Quick Connect Handle	1	14-500205

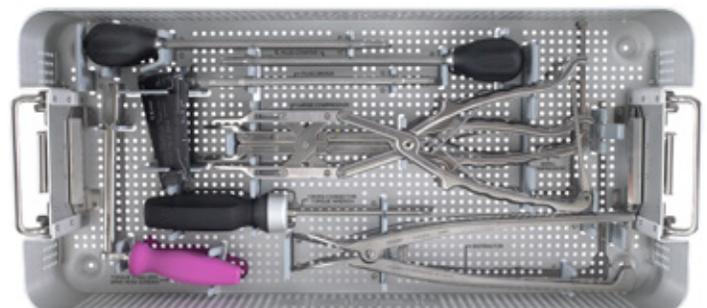


DESCRIPTION	QUANTITY	PART NUMBER
Rod Gripper	2	14-510044
Rod Hex Driver	1	14-510046
Malleable Trial Rod	1	14-510083
Screw Head Mobilizer	1	14-510101

Polaris 4.75, Deformity Instruments B 14-509897

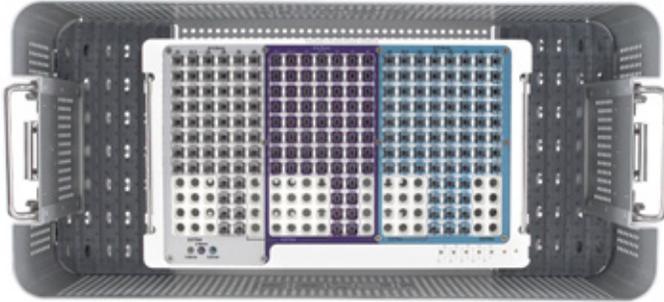


DESCRIPTION	QUANTITY	PART NUMBER
Offset Connector Bender	1	14-510004
French Rod Bender	1	14-510005
<i>In situ</i> Bender, Left	1	14-510006
<i>In situ</i> Bender, Right	1	14-510007
Ratcheting Tear Drop Handle	2	2000-6481
Quick Connect Ratcheting Handle, Straight	2	12479-9
Ratcheting Torque T-Handle	2	14-510030
Offset Connector Vise Grips	1	14-510081



DESCRIPTION	QUANTITY	PART NUMBER
Distractor	1	14-510016
Compressor, Small	1	14-510018
Compressor, Large	1	14-510019
Torque Stabilizer for Open Head Screws	1	14-510058
Plug Starter	2	14-510060
Plug Driver	2	14-510062
Cross Connector Measuring Template	1	14-510080
Cross Connector Torque Wrench	1	14-510082

Polaris 4.75, Deformity Small Diameter Multi-axial Screws 14-509890



DESCRIPTION	QUANTITY	PART NUMBER
Multi-axial Screw, ø4.0mm × 20mm	8	14-562020
Multi-axial Screw, ø4.0mm × 22.5mm	8	14-562022
Multi-axial Screw, ø4.0mm × 25mm	8	14-562025
Multi-axial Screw, ø4.0mm × 30mm	12	14-562030
Multi-axial Screw, ø4.0mm × 35mm	12	14-562035
Multi-axial Screw, ø4.0mm × 40mm	8	14-562040
Multi-axial Screw, ø4.5mm × 20mm	8	14-562120
Multi-axial Screw, ø4.5mm × 22.5mm	8	14-562122
Multi-axial Screw, ø4.5mm × 25mm	8	14-562125
Multi-axial Screw, ø4.5mm × 27.5mm	8	14-562127
Multi-axial Screw, ø4.5mm × 30mm	12	14-562130
Multi-axial Screw, ø4.5mm × 35mm	12	14-562135
Multi-axial Screw, ø4.5mm × 40mm	8	14-562140
Multi-axial Screw, ø5.0mm × 20mm	8	14-562220
Multi-axial Screw, ø5.0mm × 22.5mm	8	14-562222
Multi-axial Screw, ø5.0mm × 25mm	8	14-562225
Multi-axial Screw, ø5.0mm × 30mm	12	14-562230
Multi-axial Screw, ø5.0mm × 35mm	12	14-562235
Multi-axial Screw, ø5.0mm × 40mm	12	14-562240
Multi-axial Screw, ø5.0mm × 45mm	8	14-562245
Multi-axial Screw, ø5.0mm × 50mm	8	14-562250

Polaris 4.75, Fixed Screws 14-509898



DESCRIPTION	QUANTITY	PART NUMBER
Fixed Screw, ø4.0mm × 20mm	6	14-584020
Fixed Screw, ø4.0mm × 22.5mm	6	14-584022
Fixed Screw, ø4.0mm × 25mm	6	14-584025
Fixed Screw, ø4.0mm × 30mm	8	14-584030
Fixed Screw, ø4.0mm × 35mm	8	14-584035
Fixed Screw, ø4.5mm × 20mm	6	14-584120
Fixed Screw, ø4.5mm × 25mm	6	14-584125
Fixed Screw, ø4.5mm × 30mm	8	14-584130
Fixed Screw, ø4.5mm × 35mm	8	14-584135
Fixed Screw, ø4.5mm × 40mm	6	14-584140
Fixed Screw, ø5.0mm × 25mm	8	14-584225
Fixed Screw, ø5.0mm × 30mm	12	14-584230
Fixed Screw, ø5.0mm × 35mm	12	14-584235
Fixed Screw, ø5.0mm × 40mm	12	14-584240
Fixed Screw, ø5.0mm × 45mm	8	14-584245
Fixed Screw, ø5.0mm × 50mm	8	14-584250
Fixed Screw, ø5.5mm × 25mm	8	14-584325
Fixed Screw, ø5.5mm × 30mm	12	14-584330
Fixed Screw, ø5.5mm × 35mm	12	14-584335
Fixed Screw, ø5.5mm × 40mm	12	14-584340
Fixed Screw, ø5.5mm × 45mm	12	14-584345
Fixed Screw, ø5.5mm × 50mm	8	14-584350
Fixed Screw, ø6.5mm × 30mm	6	14-584530
Fixed Screw, ø6.5mm × 35mm	6	14-584535
Fixed Screw, ø6.5mm × 40mm	8	14-584540
Fixed Screw, ø6.5mm × 45mm	8	14-584545
Fixed Screw, ø6.5mm × 50mm	6	14-584550
Fixed Screw, ø6.5mm × 55mm	6	14-584555

KIT CONTENTS (continued)

Polaris 4.75, Deformity Implants
14-509899

DESCRIPTION	QUANTITY	PART NUMBER
Multi-axial Screw, ø5.5mm × 20mm	8	14-562320
Multi-axial Screw, ø5.5mm × 25mm	8	14-562325
Multi-axial Screw, ø5.5mm × 30mm	12	14-562330
Multi-axial Screw, ø5.5mm × 35mm	12	14-562335
Multi-axial Screw, ø5.5mm × 40mm	12	14-562340
Multi-axial Screw, ø5.5mm × 45mm	12	14-562345
Multi-axial Screw, ø5.5mm × 50mm	12	14-562350
Multi-axial Screw, ø5.5mm × 55mm	12	14-562355
Multi-axial Screw, ø6.5mm × 30mm	8	14-562530
Multi-axial Screw, ø6.5mm × 35mm	8	14-562535
Multi-axial Screw, ø6.5mm × 40mm	12	14-562540
Multi-axial Screw, ø6.5mm × 45mm	12	14-562545
Multi-axial Screw, ø6.5mm × 50mm	12	14-562550
Multi-axial Screw, ø6.5mm × 55mm	12	14-562555
Multi-axial Screw, ø6.5mm × 60mm	12	14-562560
Multi-axial Screw, ø6.5mm × 65mm	8	14-562565
Multi-axial Screw, ø6.5mm × 70mm	8	14-562570
Multi-axial Screw, ø6.5mm × 75mm	8	14-562575
Ti Alloy Straight Rod, with Hex, 4.5mm × 510mm	3	14-585151T
Ti Alloy Straight Rod, with Hex, 4.75mm × 510mm	3	14-587151T
Straight Rod, with Hex, 4.75mm × 510mm CoCr Standard	3	14-587151CS
CoCr High Rod, with Hex, 4.75mm × 510mm	3	14-587151CH
CoCr High Transition Rod, with Hex, 4.75mm to 5.50mm × 510mm	3	14-588551CH
CoCr High Straight Rod, with Hex, 4.5mm × 510mm	3	14-585151CH
Standard Helical Flange Plug	30	14-589001

DESCRIPTION	QUANTITY	PART NUMBER
Angulating Cross Connector, Extra-extra Small	2	14-589505
Angulating Cross Connector, Extra Small	2	14-589506
Angulating Cross Connector, Small	2	14-589507
Angulating Cross Connector, Medium	2	14-589508
Fixed Cross Connector, 10mm	2	14-589510
Fixed Cross Connector, 12mm	2	14-589512
Fixed Cross Connector, 14mm	2	14-589514
Fixed Cross Connector, 16mm	2	14-589516
Fixed Cross Connector, 18mm	2	14-589518
Fixed Cross Connector, 20mm	2	14-589520
Fixed Cross Connector, 22mm	2	14-589522
Fixed Cross Connector, 24mm	2	14-589524
Lateral Connector, 25mm	2	14-589725
Lateral Connector, 75mm	2	14-589775
Bridge Lateral Connector, 4.5mm to 5.5mm × 25mm	2	14-589825
Bridge Lateral Connector, 4.5mm to 5.5mm × 75mm	2	14-589875
Offset Connector, Medium	2	14-589703
Offset Connector, Extra Large	2	14-589705
Top Loading Domino, 4.75/4.75	4	14-589674
Top Loading Domino, 4.75/5.50	4	14-589675
Closed Wedding Band Domino, 4.75/4.75	4	14-589634
Closed Wedding Band Domino, 4.75/5.50	4	14-589635
Open/Open Parallel Domino, 4.75/4.75	4	14-589604
Open/Open Parallel Domino, 4.75/5.50	4	14-589605

IMPORTANT INFORMATION ON THE POLARIS 4.75 DEFORMITY SYSTEM

Device Description

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

Indications for Use

The Polaris Spinal System is a non-cervical spinal fixation device intended for immobilization and stabilization as an adjunct to fusion as a pedicle screw fixation system, a posterior hook and sacral/ilic screw fixation system, or as an anterior or anterolateral fixation system for use with autograft and/or allograft. The Polaris Spinal System is indicated for the following conditions: 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, Scheuermann's disease and/or lordosis), tumor, stenosis, pseudarthrosis or failed previous fusion.

The Ballista® instruments are intended to be used with Ballista/Polaris 5.5mm implants. Cannulated screws and percutaneous rods may be used with the Ballista instruments to provide the surgeon with a percutaneous approach for posterior spinal surgery for the above indications.

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

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

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

Contraindications

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

Sterilization Recommendations

The Polaris Spinal System is provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization.

The following steam sterilization parameters are recommended:

Sterilization Parameters

Cycle	Temperature	Exposure Time	Minimum Dry Time
High Vacuum	132° C (270° F)	4 minutes	30 minutes

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

IMPORTANT INFORMATION ON THE POLARIS 4.75 DEFORMITY SYSTEM (*continued*)

Warnings

- The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. Potential risks identified with the use of this device, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.
- **Implant Strength and Loading:** The Polaris Spinal System is intended to assist healing and is not intended to replace normal bony structures. Loads produced by weight bearing and activity levels will dictate the longevity of the implant. These devices are not designed to withstand the unsupported stress of full weight bearing or load bearing, and cannot withstand activity levels and/or loads equal to those placed on normal healthy bone. If healing is delayed or does not occur, the implant could eventually break due to metal fatigue.
- Therefore, it is important that immobilization of the operative site be maintained until firm bony union (confirmed by clinical and radiographic examination) is established. The surgeon must be thoroughly knowledgeable in the medical, surgical, mechanical and metallurgical aspects of the Polaris Spinal System. Postoperative care is extremely important. The patient should be warned that noncompliance with postoperative instructions could lead to breakage of the implant and/or possible migration requiring revision surgery to remove the implant.
- **Selection of Implants:** Selection of the proper size, shape and design of the implant increases the potential for success. While proper selection can help minimize risks, the size and shape of human bones present size limitations on the implants.
- **Metabolic bone disease** such as severe osteoporosis may adversely affect adequate fixation of the implants due to the poor quality of the bone.
- 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 corrosive environments. They should be carefully unpacked and inspected for damage prior to use. All non-sterile components and instruments must be cleaned and sterilized before use.

Zimmer Biomet Spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.
- **Corrosion:** Contact of dissimilar metals accelerates the corrosion process, which could increase the possibility of fatigue fracture of the implants. Therefore, only use like or compatible metals for implants that are in contact with each other. Never use stainless steel and titanium implant components in the same construct. Cobalt Chrome Alloy rods should not be used with Stainless Steel Components. Cobalt Chrome Alloy rods are to be used ONLY with titanium implant components in the same construct.
- The 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.
- The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Limits of System Compatibility

When used with the Ballista Instruments, the use of the Ballista cannulated 5.5 screws and percutaneous 5.5 rods is limited to the implantation of rod lengths of 510mm or less, and excludes the use of system cross connectors or hooks. 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

- Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been even momentarily placed in or used on a different patient.
- Handling of Implants: If contouring of the rod is required, avoid sharp bends and reverse bends. Avoid notching or scratching of the device, which could increase internal stresses and lead to early breakage.
- Implant Removal After Healing: After healing is complete, the implant is intended to be removed since it is no longer necessary. Implants that are not removed may result in complications such as implant loosening, fracture, corrosion, migration, pain or stress shielding of bone, particularly in young, active patients. Implant removal should be followed by adequate postoperative management.
- Adequate Patient Instructions: A patient must be instructed on the limitations of the metallic implant and should be cautioned regarding physical activity and weight bearing or load bearing prior to complete healing.
- Surgical Techniques: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The adjustable length rod is intended for in situ adjustment after placement of the hooks or screws during spinal fusion surgery and is intended for use as part of either a single or double rod assembly. It allows for distraction at a central location once bone anchors have been secured.
- The bullet end rods are intended for use with the Jackson Intrasacral Fixation Technique.
- Pain, discomfort, or abnormal sensations including back/leg pain due to presence of the implant or surgical procedure.
- Nerve, soft tissue, or blood vessel damage due to surgical trauma including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage.
- Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium.
- Fracture of bony structures at, above or below the level of surgery (fracture of the vertebra).
- Nerve root or spinal cord impingement.
- Bursitis.
- Necrosis of bone.
- Hemorrhage of blood vessels, blood clots, and/or hematomas.
- Malalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height.
- Bone graft donor site pain.
- Inability to resume activities of normal daily living.
- Neurological, vascular or visceral injury.
- Reoperation.
- Infection/sepsis.
- General surgical complications including cardiac or respiratory issues, exposure to radiation, thrombosis, skin irritation, wound problems, issues related to anesthesia and/or allergic reaction to grafting material.
- Implant malposition.
- Graft settling/displacement.
- Death.

Possible Adverse Effects

- Nonunion (pseudarthrosis), fibrous union (pseudarthrosis), delayed union or mal-union.
- Loss of fixation or malfunction, disassembly, pull-out, bending, fracture, loosening or migration of the implant or instruments.
- Metal sensitivity or foreign body reaction to implant materials including corrosion by-products due to use of dissimilar implant materials, possible tumor formation, or skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications.
- Decrease in bone density due to stress shielding.

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



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.



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0332.1-GLBL-REV1016