



PROLIMNT® Surgical Technique

# DETAILED OPERATIVE TECHNIQUE LOCATE AND PREPARE THE PEDICLE

Identify the pedicle and the entry hole location. The pedicle is typically located at the intersection of the superior articulate facet and the midline of the transverse process. Create an entry hole for the pedicle screw by using the Awl to puncture the cortex. With the Awl, penetrate the cortex by using a downward twisting force (Figure 1).

### PROBE THE PEDICLE

The Straight or Curved Pedicle Probe is used to create the screw path through the pedicle and into the vertebral body. Both of these instruments include depth markings at the tip of the instrument (Figure 2).

### **ENSURE THE INTEGRITY OF THE PEDICLE WALL**

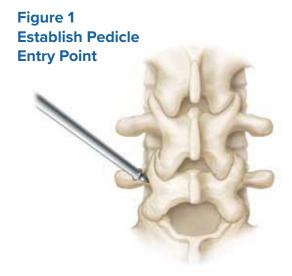
After the pedicle has been cannulated, the pedicle may now be sounded. Using the Straight Tester, verify the integrity of the interior pedicle walls by palpating the cephalad edge, the medial wall and the inferior edge, as well as the deepest portion of the opening (Figure 3).

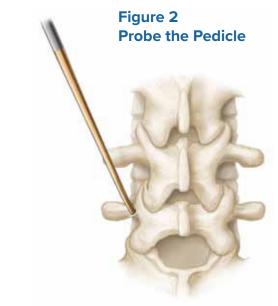
### **GUIDE PIN INSERTION (OPTIONAL)**

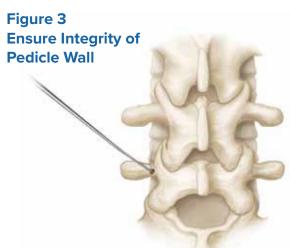
Guide Pins are available and may be inserted to confirm the pedicle location under visualization if desired (Figure 4).

### **TAPPING (OPTIONAL)**

All Proliant screws are self-tapping. However, if pre-tapping is desired, Taps are available in various sizes which correspond to the diameters of the Polyaxial Screws (Table 1). The Proliant Taps are undersized by .75mm, however if additional undertapping is desired a smaller diameter within the same group may be used. Attach the appropriately sized Tap to the Ratcheting Straight or T-Handle, slide on the Tissue Protector Sleeve and proceed to tap the Screw entry hole by rotating the handle clockwise. The Tissue Protector Sleeve may be used to determine tapping depth (Figure 5).







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Тар	Outer	Screw Compatibility			bility	
	Diameter	4.5	5.5	6.5	7.5	8.5
4.5mm Tap	3.75mm	Х				
5.5mm Tap	4.75mm	Х	X			
6.5 U Tap	4.75mm			X	X	X
6.5mm Tap	5.75mm			Х	X	X
7.5mm Tap	6.75mm				Х	X
8.5mm Tap	7.75mm					Х

Figure 4
Mark the Pedicle





Figure 5
Tap the Pedicle



### **LOAD POLYAXIAL SCREW**

After determining the appropriate Screw length, attach the Ratcheting Straight or T-Handle to the Retaining Polyaxial Screwdriver. Insert the Retaining Screwdriver into the inner hexalobe of the Screw and lock it by rotating the central locking wheel clockwise (Figure 6).

### **INSERT POLYAXIAL SCREW**

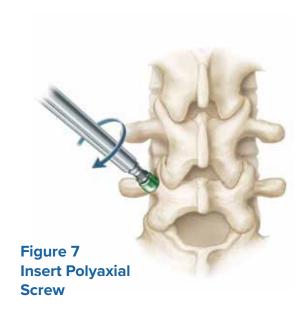
The Polyaxial Screws may now be inserted into pedicle to the pre-determined depth. Turn the Ratcheting Handle clockwise to insert the Screw (Figure 7). Once the Screw is fully inserted, disengage the Screw from the Retaining Polyaxial Screwdriver by turning the central locking wheel counter-clockwise. Repeat the steps for all remaining Pedicle Screws.

### **REDUCTION SCREWS**

If necessary, Reduction Polyaxial Screws are also available and can be inserted using the Retaining Polyaxial Screwdriver. The Retaining Polyaxial Screwdriver is inserted into the Screw tulip and tightened by rotating the central locking wheel clockwise.

### **ROD SELECTION**

After the Polyaxial Screws have been placed, the desired length of the Rod should be selected. The Curved Rods are in pre-cut lengths ranging from 40mm to 110mm. The Rod should extend no less than 2mm beyond the outer edges of the proximal Screw bodies of the most superior and most inferior Pedicle Screws. Straight Rods are also available in either 200mm or 300mm.



### **ROD BENDER**

The French Rod Bender is primarily used for curving or bending Straight Rods. If needed, it can also be used to increase or decrease the lordosis in the Curved Rod (Figure 8).

The degree of lordosis can be varied by adjusting the center button. A small, medium or large radius may be selected by pulling out the large center knob while rotating the knob as desired. The Rod should seat fully into the tulip of the Pedicle Screw. Note: In-Situ Benders may also be used to bend the Rod once it is placed within the construct.

### **ROD PLACEMENT AND TIGHTENING**

After the Rod has been contoured as desired, it is then placed into the Polyaxial Screw housing with the Rod Holder (Figure 9). The Polyaxial Screw allows up to 60 degrees of angulation, and the EZ Set Tulip Head allows the Screw to be placed in any angle and stay in that location as the Rod is inserted.

Once the Rod has been placed, load a Set Screw on each end of the double-ended Set Screw Starte and provisionally tighten each Screw.

### **ROD REDUCTION**

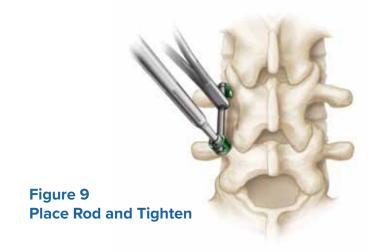
To assist with the reduction of the Rod into the Screw, there are several instruments that are available.

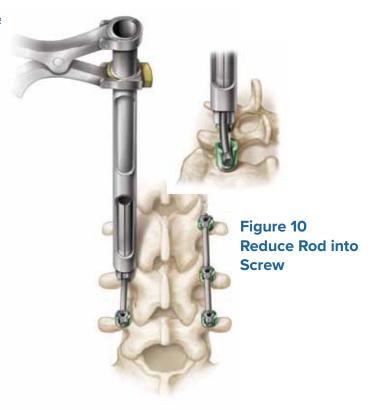
- 1) The Rod Pusher helps to persuade the Rod into the Screw head, without capturing the Screw head.
- 2) The Pistol Grip Rod Persuader is inserted over the Rod and Screw, and the Ratcheting Handle allows the Rod to be slowly reduced.
- 3) The Cylinder Style Rod Persuader is used to fully capture the Polyaxial Screw head in place, while the Ratcheting Handles reduce the Rod (Figure 10).

After the Rod is fully reduced into the Screw head, it can be provisionally tightened using the Set Screw Starter as described above.



Figure 8
French Rod
Bender





# DEROTATION, COMPRESSION AND DISTRACTION (OPTIONAL)

After all of the Set Screws have been provisionally inserted into the Screw housing, the De-rotator may be used to rotate the contoured Rod into the desired position. While the Rod is held in place with the De-rotator, the Set Screws are tightened using the Set Screwdriver attached to the T-Handle Torque Limiting Driver (Figure 11).

The Compressor or Distractor can also be used to apply final compression or distraction to the construct. Once the desired compression or distraction is accomplished, the Set Screws can be tightened using the Set Screwdriver attached to the T-Handle Torque Limiting Driver (Figure 12).

### **Counter TORQUE AND FINAL TIGHTENING**

After any desired derotation, compression and distraction have been performed, the Set Screwdriver should be attached to the T-Handle Torque Limiting Driver and inserted through the Counter Torque for final tightening of the Set Screws (Figure 13). The Set Screw should be rotated clockwise until the T-Handle clicks, indicating the necessary torque has been applied.

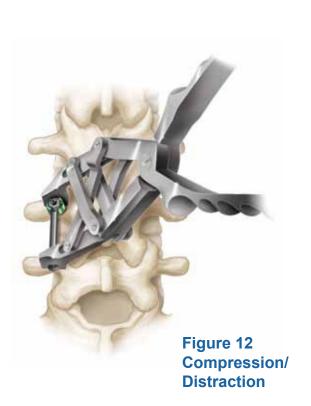
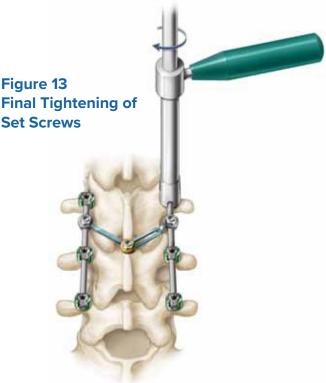


Figure 11
Derotate of Rod





### **CROSS CONNECTOR PLACEMENT**

A Cross Connector may now be used if desired. Cross Connectors are available in sizes ranging from 30 to 40mm in 5mm increments and in 40 to 70mm in 10mm increments.

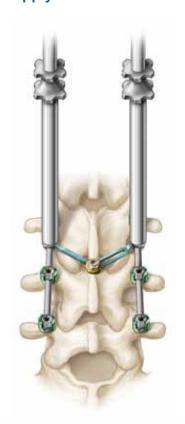
The Cross Connector is attached to the Rods either by hand or by using the Cross Connector Nut Starter. The Cross Connector Nut Starter snaps around the arm of the Cross Connector underneath the connector nut (Figure 14). This leaves the nut and rod clamp portion of the Connector free to rotate for proper positioning over the construct. The Connector is pushed down until the rod clamp mechanism clicks onto the Rod. Once positioned onto both Rods, attach the Cross Connector Torque Limiting Wrench to the Nut Driver. Place the Cross Connector Counter Torque onto the Cross Connector Nut that is positioned on either rod. Insert the Nut Driver into the Cross Connector Counter Torque and rotate clockwise until the handle clicks, indicating that the necessary torque has been applied. Repeat this step to tighten the Cross Connector Nut on the second rod. Lastly, place the Cross Connector Counter Torque on the central nut of the Cross Connector, and use the Nut Driver to tighten this nut (Figure 15).

Note: It is important to ensure that the nuts on both of the rods are tightened prior to tightening the central nut.

### **SCREW REMOVAL**

The Reversible Polyaxial Screwdriver is available for removal and readjustment of the Polyaxial Screws. To accomplish this, the Reversible Polyaxial Screwdriver must first be attached to the Screw by placing the driver shaft at the same angle as the Screw that was initially placed into the pedicle. Next, the Reversible Polyaxial Screwdriver needs to be secured tightly onto the Screw by rotating the central locking wheel clockwise. Now the Screw may be backed out by holding the shaft and turning the handle counterclockwise.

Figure 14
Apply Cross Connector



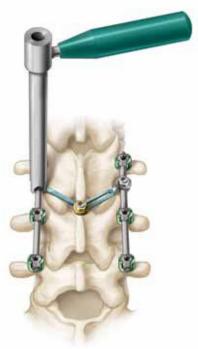


Figure 15
Final Tightening of
Cross Connectors

## **Proliant Implant Listing**

Catalog Number	Part Description	
05-050-00-4530 05-050-00-4535 05-050-00-4540 05-050-00-4545	Proliant 5.5mm Polyaxial Screw, 4.5mm x 30mm Proliant 5.5mm Polyaxial Screw, 4.5mm x 35mm Proliant 5.5mm Polyaxial Screw, 4.5mm x 40mm Proliant 5.5mm Polyaxial Screw, 4.5mm x 45mm	
05-050-00-5535 05-050-00-5540 05-050-00-5545 05-050-00-5550 05-050-00-5555	Proliant 5.5mm Polyaxial Screw, 5.5mm x 35mm Proliant 5.5mm Polyaxial Screw, 5.5mm x 40mm Proliant 5.5mm Polyaxial Screw, 5.5mm x 45mm Proliant 5.5mm Polyaxial Screw, 5.5mm x 50mm Proliant 5.5mm Polyaxial Screw, 5.5mm x 55mm	
05-050-00-6535 05-050-00-6540 05-050-00-6545 05-050-00-6550 05-050-00-6555	Proliant 5.5mm Polyaxial Screw, 6.5mm x 35mm Proliant 5.5mm Polyaxial Screw, 6.5mm x 40mm Proliant 5.5mm Polyaxial Screw, 6.5mm x 45mm Proliant 5.5mm Polyaxial Screw, 6.5mm x 50mm Proliant 5.5mm Polyaxial Screw, 6.5mm x 55mm	addadddddd - Com
05-050-00-7535 05-050-00-7540 05-050-00-7545 05-050-00-7550 05-050-00-7555	Proliant 5.5mm Polyaxial Screw, 7.5mm x 35mm Proliant 5.5mm Polyaxial Screw, 7.5mm x 40mm Proliant 5.5mm Polyaxial Screw, 7.5mm x 45mm Proliant 5.5mm Polyaxial Screw, 7.5mm x 50mm Proliant 5.5mm Polyaxial Screw, 7.5mm x 55mm	
05-050-00-8535 05-050-00-8540 05-050-00-8545 05-050-00-8550 05-050-00-8555	Proliant 5.5mm Polyaxial Screw, 8.5mm x 35mm Proliant 5.5mm Polyaxial Screw, 8.5mm x 40mm Proliant 5.5mm Polyaxial Screw, 8.5mm x 45mm Proliant 5.5mm Polyaxial Screw, 8.5mm x 50mm Proliant 5.5mm Polyaxial Screw, 8.5mm x 55mm	
05-050-04-0000	Proliant Set Screw for 5.5mm rod	8 and 8
05-050-02-5540 05-050-02-5545 05-050-02-5550 05-050-02-6540	Proliant 5.5mm Polyaxial Reduction Screw, 5.5mm x 40mm Proliant 5.5mm Polyaxial Reduction Screw, 5.5mm x 45mm Proliant 5.5mm Polyaxial Reduction Screw, 5.5mm x 50mm  Proliant 5.5mm Polyaxial Reduction Screw, 6.5mm x 40mm	
05-050-02-6545 05-050-02-6550	Proliant 5.5mm Polyaxial Reduction Screw, 6.5mm x 45mm Proliant 5.5mm Polyaxial Reduction Screw, 6.5mm x 50mm	WHIHHHHHHH
05-050-02-7540 05-050-02-7545 05-050-02-7550	Proliant 5.5mm Polyaxial Reduction Screw, 7.5mm x 40mm Proliant 5.5mm Polyaxial Reduction Screw, 7.5mm x 45mm Proliant 5.5mm Polyaxial Reduction Screw, 7.5mm x 50mm	

Proliant Implant Listing Catalog Number 05-052-01-0040 05-052-01-0045 05-052-01-0050 05-052-01-0055	Part Description  Rod, 5.5mm x 40mm, Curved  Rod, 5.5mm x 45mm, Curved  Rod, 5.5mm x 50mm, Curved  Rod, 5.5mm x 55mm, Curved	
05-052-01-0060 05-052-01-0065 05-052-01-0070 05-052-01-0075 05-052-01-0080 05-052-01-0090 05-052-01-0100 05-052-01-0110	Rod, 5.5mm x 60mm, Curved Rod, 5.5mm x 65mm, Curved Rod, 5.5mm x 70mm, Curved Rod, 5.5mm x 75mm, Curved Rod, 5.5mm x 80mm, Curved Rod, 5.5mm x 90mm, Curved Rod, 5.5mm x 100mm, Curved Rod, 5.5mm x 110mm, Curved	
05-052-00-0200 05-052-00-0300	Rod, 5.5mm x 200mm, Straight Rod, 5.5mm x 300mm, Straight	
05-054-00-3035 05-054-00-3540 05-054-00-4050 05-054-00-5060 05-054-00-6070	Proliant 5.5mm Cross Connector, 30mm-35mm Proliant 5.5mm Cross Connector, 35mm-40mm Proliant 5.5mm Cross Connector, 40mm-50mm Proliant 5.5mm Cross Connector, 50mm-60mm Proliant 5.5mm Cross Connector, 60mm-70mm	
27152	Straight Probe	
05-059-10-0000	Curved Probe	-
28254	Straight Tester	
28256	Guide Pin	
28257	Guide Pin, Grooved	
28258	Depth Gauge	
28277	Ratchet Straight Handle	=

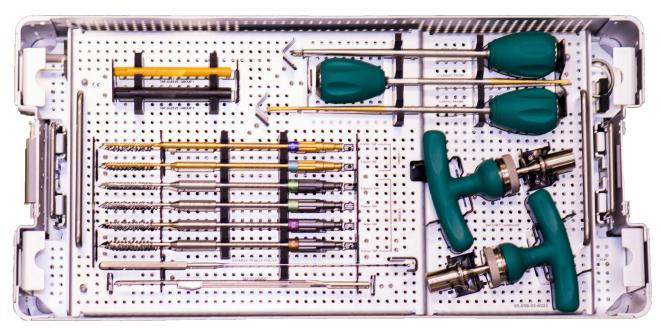
28278	Modular T-Handle	-
28279	Ratchet T-Handle	
05-059-00-0000	Counter Torque, Cross Connector	
05-059-01-4500 05-059-01-4555 05-059-01-5500 05-059-02-5500 05-059-02-6500 05-059-01-6585 05-059-02-7500 05-059-02-8500	Proliant Tap, 4.5mm Proliant Tap Sleeve Proliant Tap, 5.5mm Proliant Tap, 6.5mm Proliant Tap, 6.5mm Proliant Tap, Sleeve Proliant Tap, 7.5mm Proliant Tap, 8.5mm	
05-059-14-0001	Proliant Head Turner	
05-059-27-0000	Compressor	
05-059-28-0000 05-059-29-0000	In-situ Bender, Left, 5.5mm In-situ Bender, Right, 5.5mm	(d + stand 5 - 7)
05-059-42-0000	Bone Awl	
05-059-46-0000	Cross Connector Nut Starter	- W
05-059-50-0000	Tab Breaker, Reduction Screw	8

Proliant Instrument Catalog Number 05-059-02-0000	t Listing Part Description Cross Connector Nut Driver	
05-059-03-0000	Cross Connector Torque Limiting Driver Handle	
05-059-10-0000	Curved Probe	
05-059-12-0000	Proliant Screwdriver, Hexalobe	
05-059-12-0001	Proliant Retaining Screwdriver	-
05-059-13-0000	Torque Limiting T-Handle, Hudson	
05-059-14-0000	Counter Torque	
05-059-15-0000	Proliant Reversible Screwdriver	<del></del>
05-059-16-0000	Persuader, Cylinder Style	Ä
05-059-17-0000	Persuader, Pistol Grip	1
05-059-18-0000	Proliant Set Screw Starter	
05-059-19-0000	Proliant Set Screwdriver	
05-059-20-0000	Rod Pusher, 5.5mm	
05-059-22-0000	Rod Holder, 5.5mm	
05-059-24-0000	De-rotator	
05-059-25-0000	Rod Bender, French Style	3
05-059-26-0000	Distractor	~

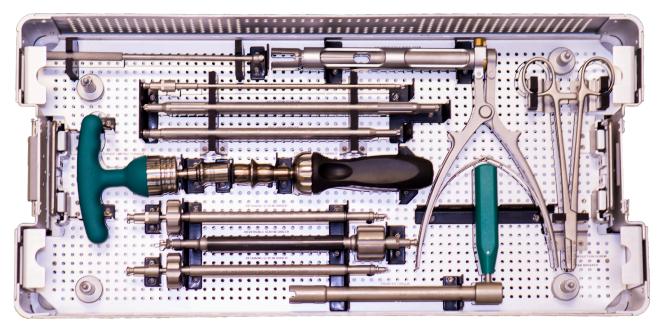
### **Proliant LE Part Numbers**

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	05-0
	05-0
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05-050-10-5530 PRO,LE, SCREW, MONO, 5.5 x 30	05-0
05-050-10-5535 PRO,LE, SCREW, MONO, 5.5 x 35	05-0
05-050-10-5540 PRO,LE, SCREW, MONO, 5.5 x 40	05-0
05-050-10-5545 PRO,LE, SCREW, MONO, 5.5 x 45	05-0
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05-050-10-6545 PRO,LE, SCREW, MONO, 6.5 x 45	
05-050-10-6550 PRO,LE, SCREW, MONO, 6.5 x 50	
05-050-10-6555 PRO,LE, SCREW, MONO, 6.5 x 55	
05-050-10-6560 PRO,LE, SCREW, MONO, 6.5 x 60 05-050-10-7540 PRO.LE. SCREW. MONO, 7.5 x 40	
05-050-10-7540 PRO,LE, SCREW, MONO, 7.5 x 40 05-050-10-7545 PRO,LE, SCREW, MONO, 7.5 x 45	
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05-050-10-7570 PRO,LE, SCREW, MONO, 7.5 x 70	
05-050-10-7575 PRO,LE, SCREW, MONO, 7.5 x 75	
05-050-10-7580 PRO,LE, SCREW, MONO, 7.5 x 80	
05-050-10-7585 PRO,LE, SCREW, MONO, 7.5 x 85	
05-050-10-7590 PRO,LE, SCREW, MONO, 7.5 x 90	
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05-050-12-0001 PRO,LE, HOOK, LAMINA, NARROW, SM 05-050-12-0003 PRO,LE, HOOK, LAMINA, NARROW, LG	
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05-050-12-1001 PRO,LE, HOOK, PEDICLE, SWALL 05-050-12-1003 PRO,LE, HOOK, PEDICLE, LARGE	
05-050-12-1003	
05-050-12-3003 PRO,LE, HOOK, OFFSET, RIGHT, LRG	
05-050-12-5520 PRO,LE, CONNECTOR, OFFSET, 20	

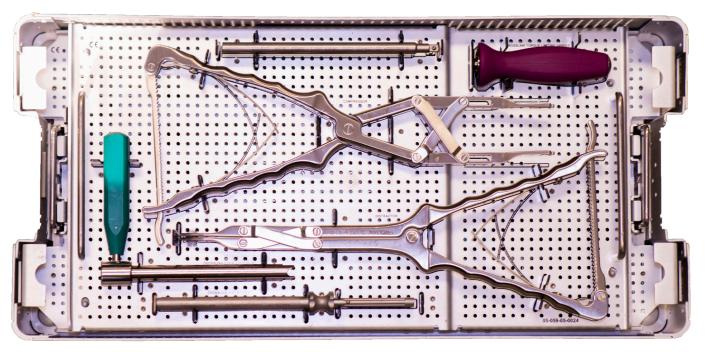
05-050-12-5530 PRO,LE, CONNECTOR, OFFSET, 30 050-12-5540 PRO,LE, CONNECTOR, OFFSET, 40 050-12-5550 PRO,LE, CONNECTOR, OFFSET, 50 050-12-5560 PRO,LE, CONNECTOR, OFFSET, 60 50-12-5599 PRO,LE, CONNECTOR, OFFSET, 100 )50-12-7001 PRO,LE, CONNECTOR, R TO R INLINE 50-12-7002 PRO,LE, CONNECTOR, SIDE BY SIDE PRO,LE, ROD, COCR, STRAIGHT, 200 052-02-0200 052-02-0300 PRO,LE, ROD, COCR, STRAIGHT, 300 PRO,LE, ROD, COCR, STRAIGHT, 480 052-02-0480 052-12-0040 PRO,LE, ROD, COCR, CURVED, 40 PRO,LE, ROD, COCR, CURVED, 45 052-12-0045 052-12-0050 PRO,LE, ROD, COCR, CURVED, 50 052-12-0055 PRO,LE, ROD, COCR, CURVED, 55 052-12-0060 PRO,LE, ROD, COCR, CURVED, 60 PRO,LE, ROD, COCR, CURVED, 65 052-12-0065 PRO,LE, ROD, COCR, CURVED, 70 052-12-0070 052-12-0075 PRO,LE, ROD, COCR, CURVED, 75 052-12-0080 PRO,LE, ROD, COCR, CURVED, 80 052-12-0090 PRO,LE, ROD, COCR, CURVED, 90 PRO,LE, ROD, COCR, CURVED, 100 052-12-0100 052-12-0110 PRO,LE, ROD, COCR, CURVED, 110



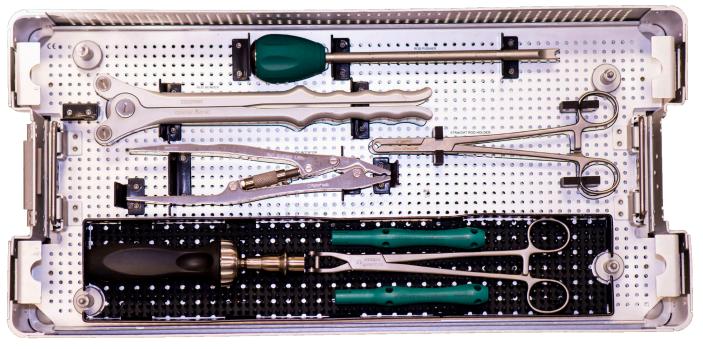
**Instrument Tray 1 Top** 



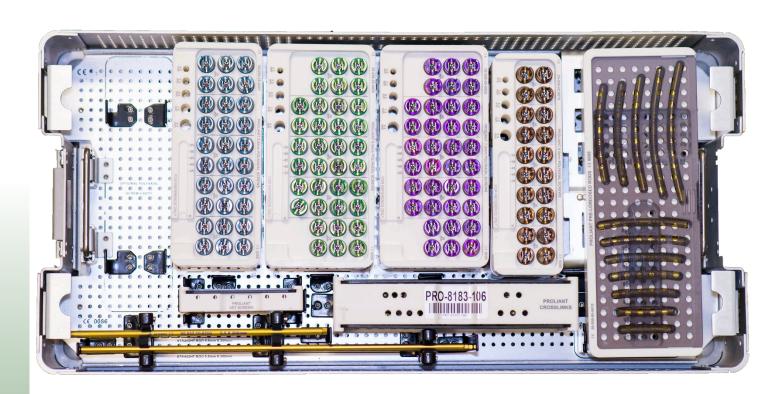
**Instrument Tray 1 Bottom** 



Instrument Tray 2 Top



**Instrument Tray 2 Bottom** 



**Implant Tray** 

## Indications for Use

### **DEVICE DESCRIPTION:**

The ChoiceSpine Proliant Posterior Pedicle Screw and Hook Fixation System is a top-loading spinal fixation system including screws, rods, and connectors for fixation to the thoracic, lumbar and sacral spine. Various sizes of the implants are provided. The components are manufactured from titanium alloy (Ti-6AI-4V ELI as described by ASTM F136) with rods being available in both titanium alloy and cobalt chrome alloy (Co-28Cr-6Mo, per ASTM F1537). The Proliant Posterior Pedicle Screw and Hook Fixation System components are provided clean and non-sterile. The products must be steam sterilized by the hospital prior to use.

### **INDICATIONS FOR USE:**

The Proliant Posterior Pedicle Screw and Hook Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The Proliant Posterior Pedicle Screw and Hook Fixation System is intended for posterior, noncervical pedicle and non-pedicle fixation for the following indications: (DDD) degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis including severe spondylolisthesis (Grade 3 & 4) of L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; trauma (i.e., fracture or dislocation); spinal stenosis; curvature (i.e., scoliosis, kyphosis, and/or lordosis); tumor; and failed previous fusion (pseudoarthrosis).

### **CONTRAINDICATIONS**

Contraindications for the Proliant Posterior Pedicle Screw and Hook Fixation System are similar to those of other systems of similar design, and include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Morbid obesity
- Pregnancy
- Grossly distorted anatomy (e.g., congenital abnormalities)

- and bone abnormalities (e.g., bone absorption, osteopenia, or osteoporosis) preventing safe screw fixation
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery
- •Suspected or documented metal allergy or intolerance

### WARNINGS AND PRECAUTIONS

The Proliant Posterior Pedicle Screw and Hook Fixation System should only be implanted 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. In addition, based on the fatigue test results, the surgeon should consider the levels of implantation, patient weight, patient activity level, and other patient conditions (e.g., smoking, occupation), which may impact on the performance of the system.

The Proliant Posterior Pedicle Screw and Hook Fixation System has not been evaluated for safety and compatibility in the MR environment. The Proliant Posterior Pedicle Screw and Hook Fixation System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Proliant Posterior Pedicle Screw and Hook Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.



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LIT# Proliant STG | REV E | 9/19