NEURO® STRUCTURES

Palladian™
SPINAL FIXATION SYSTEM

Surgical Technique Guide

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SYSTEM INFORMATION

The use of the Palladian Lumbar Pedicle Screw System is indicated for the treatment of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radio-graphic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformity, or curvature (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and previous failed fusion.

The Palladian Lumbar Pedicle Screw System is a non-cervical spinal fixation system. Pedicle screw fixation is limited to skeletally mature patients.

Preoperative Planning

The patient should be positioned prone, lying flat on the table. A radiolucent frame or chest rolls may be used but the knee to chest position should be avoided.

Using fluoroscopic imaging, it should be verified that true views of both anterior/posterior (AP) and lateral images of the spine are obtained. It is also recommended that preoperative planning should be used to help determine a proper entry point and trajectory as the starting point is not usually at the point directly over the pedicle.

Screw Features

Top-Loading and Tightening System

Proven Helical-Flange™ Closure Mechanism Minimizes Cross-Threading

Up to 60° of Conical Screw Variability to Minimize Rod Contouring

The Unique Helical-Flange™ Technology Minimizes Seat Splay

Double Lead Thread Effectively Reduces Insertion Time

Pre-Contoured Rods to Minimize the Need for Rod Bending

Wide Range of Sizes to Accommodate Patient Anatomy

Screw Size

Diameter (mm)	Length (mm)								
4.5	25	30	35	40	45				
5.5		30	35	40	45	50	55		
6.5		30	35	40	45	50	55	60	
7.5		30	35	40	45	50	55		
8.5				40	45	50		70	80

Raised Seat Screw Size

Diameter	Length (mm)		
5.5	40	45	50
6.5	40	45	50
7.5	40	45	50

Non-Cannulated, Non-Standard Standard Sizes Non-Standard Sizes

Patent Number:
US 10,368,923 B2

This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications, and warnings.

1 PEDICLE PREPARATION

The appropriate pedicle entry point is selected and the pedicle is prepared utilizing an awl, and a selection of bone probes, taps, and ball tip feeler probe.

Awl

An Awl is used to mark the pedicle entrance point. It is inserted just past the hard cortical bone of the pedicle *(Figure 1)*.

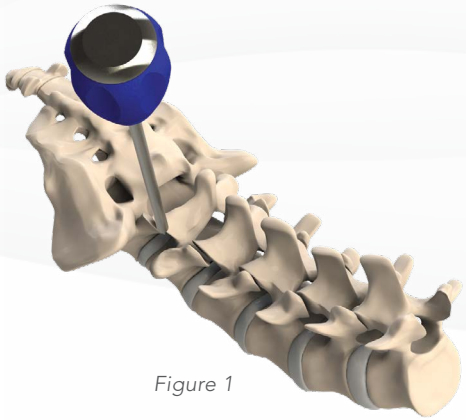


Figure 1

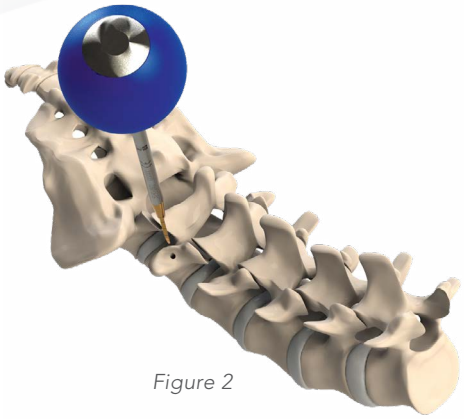


Figure 2

Bone Probe

A Bone Probe is used to open up a pathway for the screw through the cancellous bone into the vertebral body. The bone probe shaft is laser etched in 10mm intervals to help indicate the depth and help determine proper screw length *(Figure 2)*.

Tapping (Optional)

The Palladian Screws are self-tapping, however, taps may be used to facilitate screw insertion.

Select appropriate tap size and connect with a T-Handle or Axial Handle *(Figure 3)*.

Caution: Taps are undersized 0.5mm, but thread pitch is consistent with the screw. Taps are color-coded by diameter.

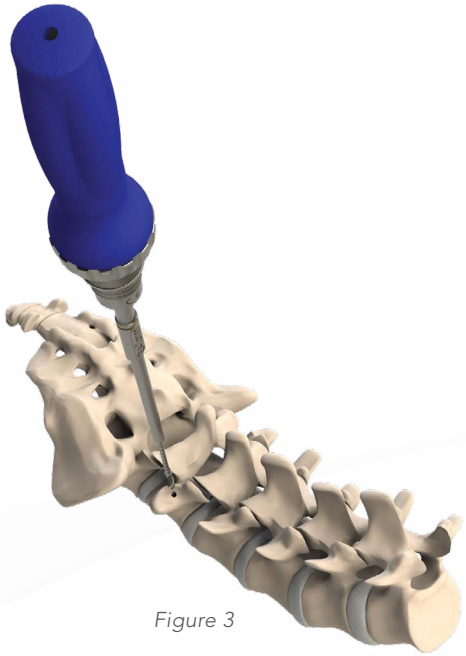


Figure 3

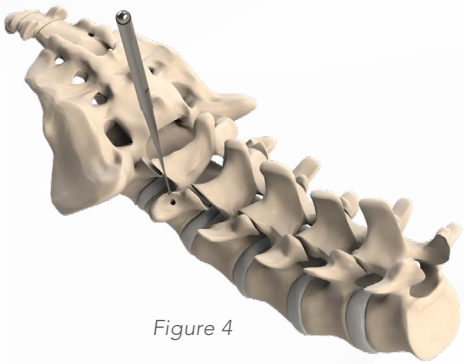


Figure 4

Pedical Sounder

The Pedicle Sounder is used after the hole is created, or after tapping. It is used to check the integrity of the pedicle walls or anterior vertebral body wall to help identify and ensure that the wall has not been breached prior to screw insertion *(Figure 4)*.

2 SCREW DRIVER ASSEMBLY

Attach a T-Handle or Axial Handle to the Screwdriver *(Figure 5)*.

Figure 5

Attach the selected screw to the Screwdriver *(Figure 6)*.

Figure 6

Turn the knob to engage the seat *(Figure 7)*.

Figure 7

Press the buttons on the sides of the slide lock and it will spring down locking the screw in place *(Figure 8)*.

Figure 8

Note: Verify screw length and diameter prior to delivery.

3 SCREW INSERTION

Place the tip of the screw directly at the hole in the pedicle and advance the screw *(Figure 9)*.

To disengage the Screwdriver, pull the slide lock up until you hear an audible "click", turn the knob counterclockwise until disengaged from screw head, and then remove construct *(Figure 10)*.

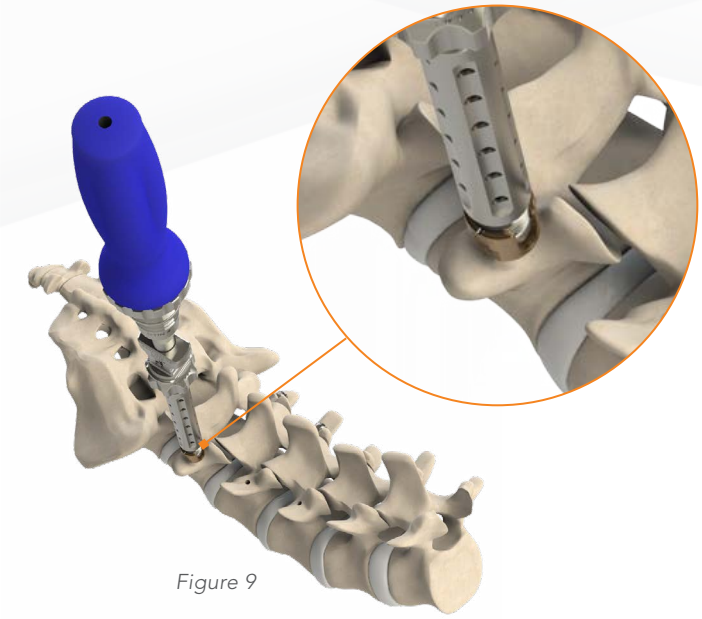


Figure 9

Figure 10

Note: It is recommended to leave screw head slightly above bony surface. This will facilitate screw variability.

Position and align the screw heads with the Polyaxial Seat Repositioner as needed *(Figure 11 & 12)*.

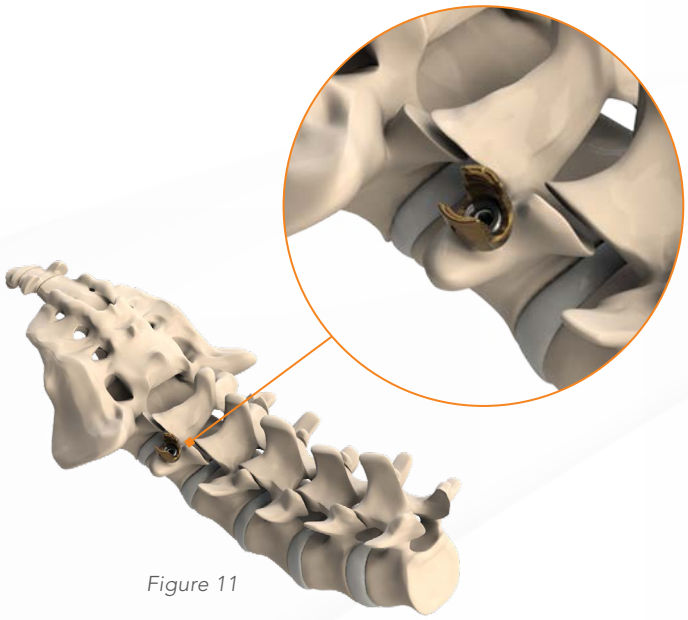


Figure 11

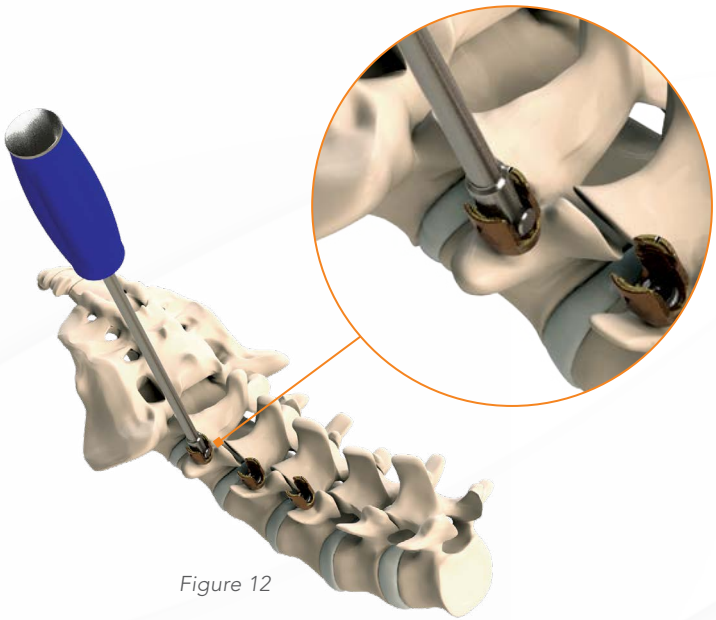


Figure 12

4 ROD PREPARATION

The desired rod length and contour can be achieved using the rod template and rod benders.

Use the rod template to determine the appropriate rod contour and length *(Figure 13)*.

To contour the rod, place the rod in the rod bender and apply bending pressure appropriately to achieve the desired profile *(Figure 15)*.

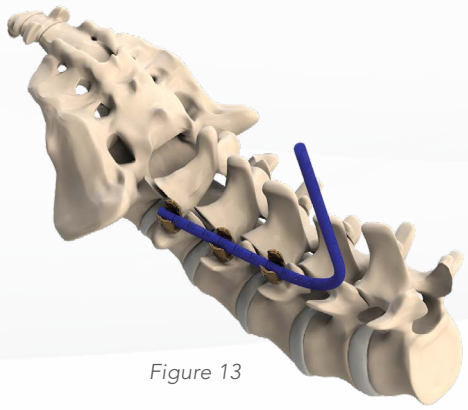


Figure 13

Figure 14

Optional: Cut to length.

Rod Bending *(Optional 1)*

Figure 15

In Situ Rod Bending *(Optional 2)*

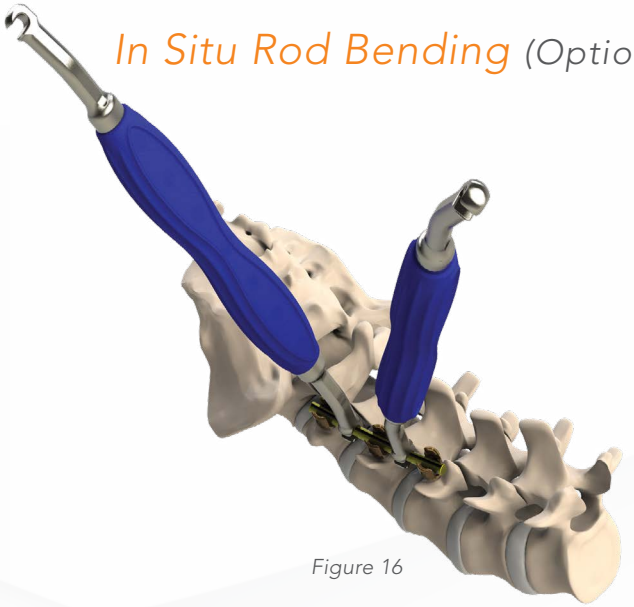


Figure 16

5 ROD PLACEMENT

Grasp the selected rod with the Simple Rod Inserter *(Figure 17)* or Dual Action Rob Gripper *(Figure 18)* and place into the screw heads.

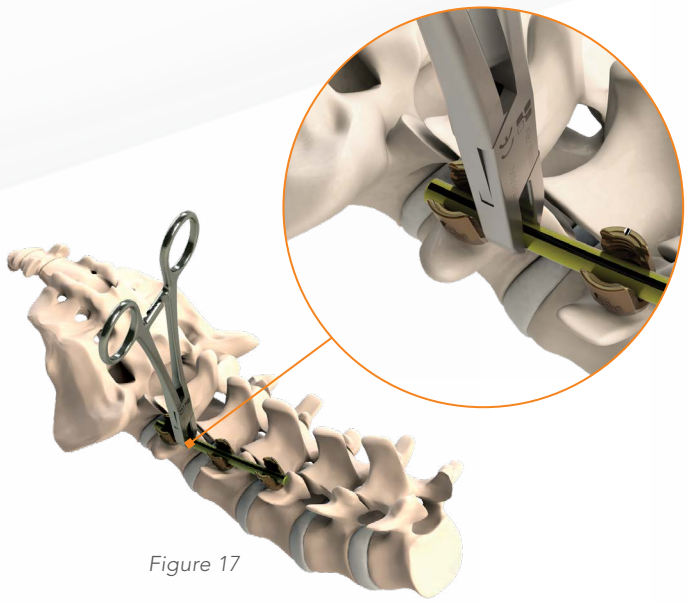


Figure 17

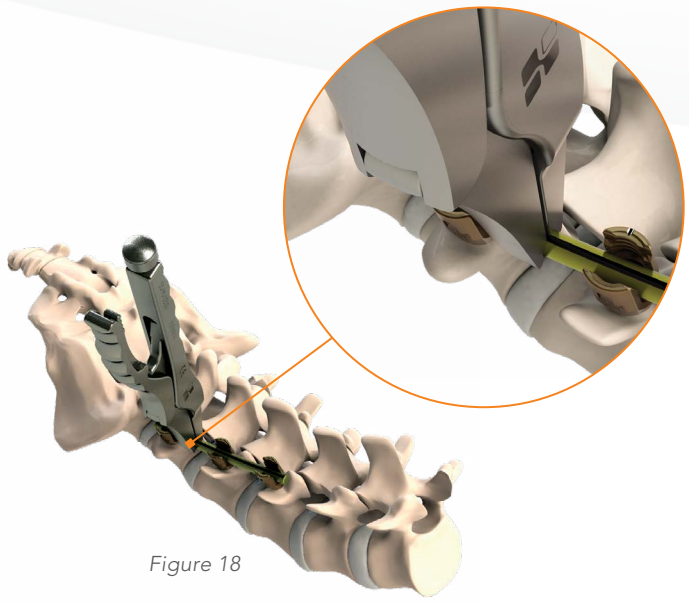


Figure 18

Note: Ensure the rod is fully seated in the screw heads. The rod pusher may be used to seat the rod as needed *(Figure 19)*.

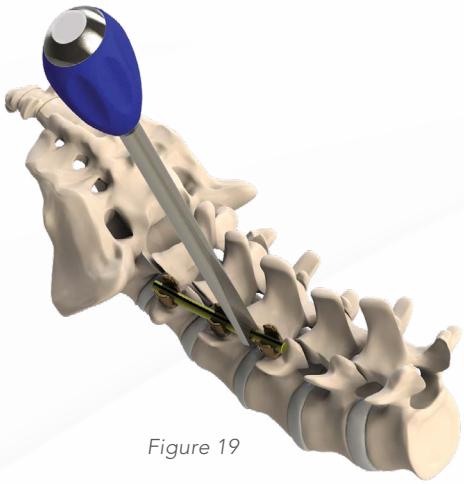


Figure 19

6 ROD CAPTURE

Load set screws from the caddy with the Set Screw Starter. Place the set screws into the screw heads and rotate clockwise until provisionally tightened *(Figure 20 – 22)*.

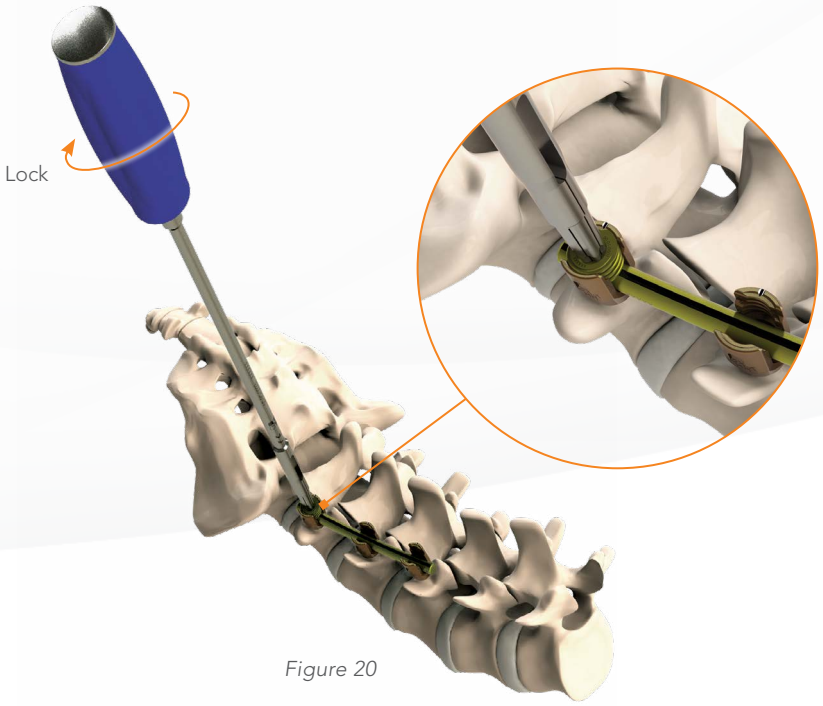


Figure 20

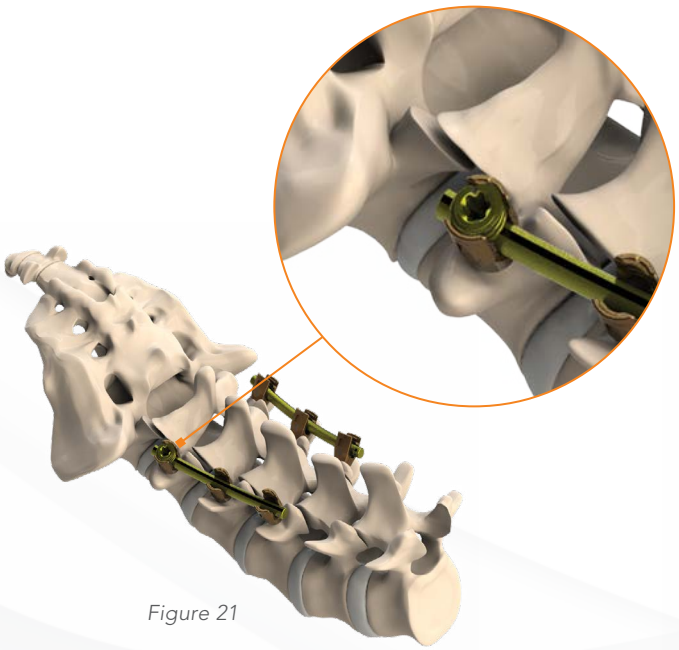


Figure 21

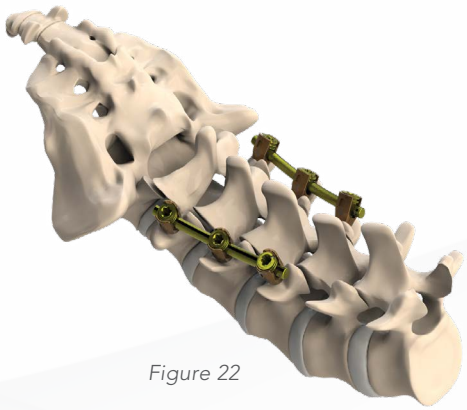


Figure 22

7 ROD REDUCTION

The Rod Pusher can be used to seat the rod as needed.

The Adjustable Rod Rocker can be used to help reduce the rod into the seat of the screws.

The Adjustable Rod Rocker can be placed over the rod and hooked underneath the seat *(Figure 23)*. When levered back the rod is persuaded or reduced into position. A set screw can then be placed to secure the rod into the seat.

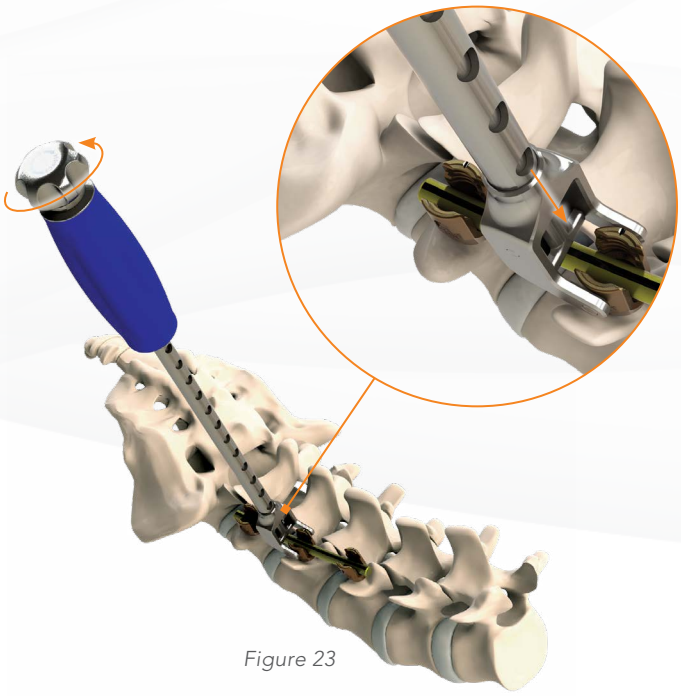


Figure 23

Rod Reduction (Optional)

Attach the Axial Persuader over the screw head and rod by pressing and holding the tabs on the sides to spread the tangs *(Figure 24)*. Once the Axial Persuader is fully seated over the screw head, release the tabs and turn the lock clockwise to lock position *(Figure 25)*.

Attach the Axial Persuader Driver to end of the Axial Persuader *(Figure 26)*. Turn the driver clockwise to reduce the rod into the screw head *(Figure 27)*.

To remove the Axial Persuader, make sure it is in the fully open position, turn lock counter-clockwise to the unlocked position, press the tabs, and remove the device straight out.

Note: The Axial Persuader needs to be in the fully open position in order to be attached and removed from the screw head.

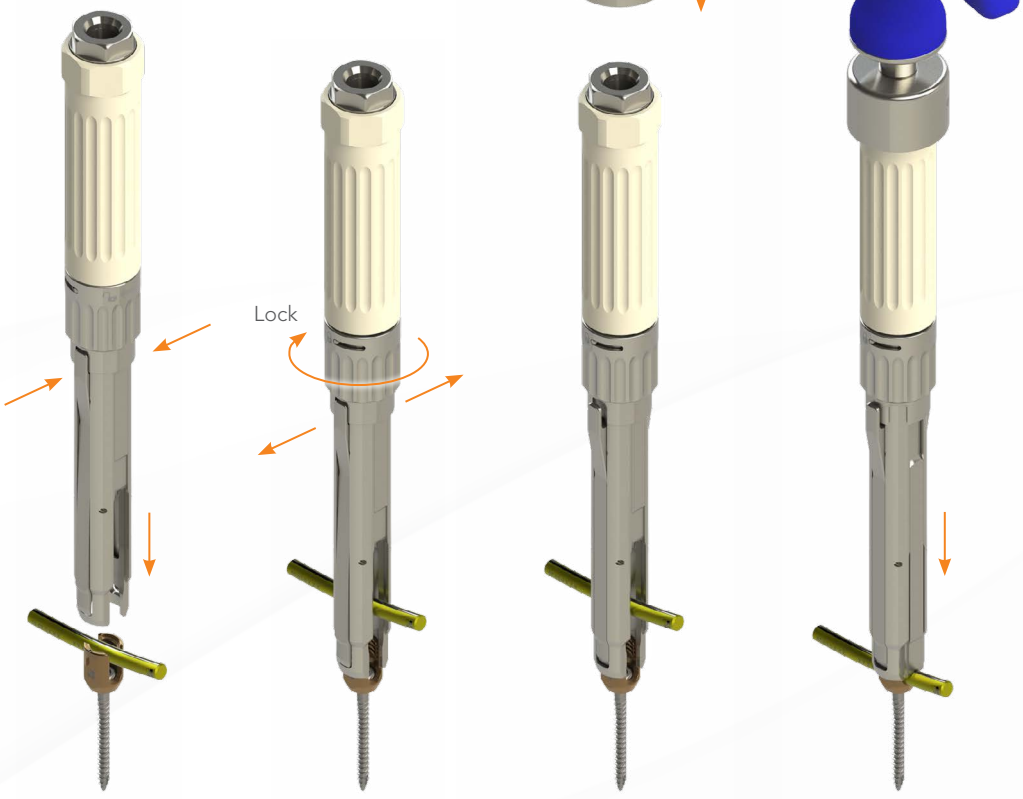


Figure 24 *Figure 25* *Figure 26* *Figure 27*

8 COMPRESSION & DISTRACTION

After inserting the Set Screws, distraction or compression can be applied to the screws to manipulate the vertebral bodies.

Compression – Place the tips of the compressor over the rod on the outer end of the screw heads and actuate the handle so the tips compress against the seats of the screw heads *(Figure 28)*.

Distraction – Place the tips of the distractor over the rod and between the screw heads, actuate the handles so the tips of distract out against the seats of the screw heads *(Figure 29)*.

Compression

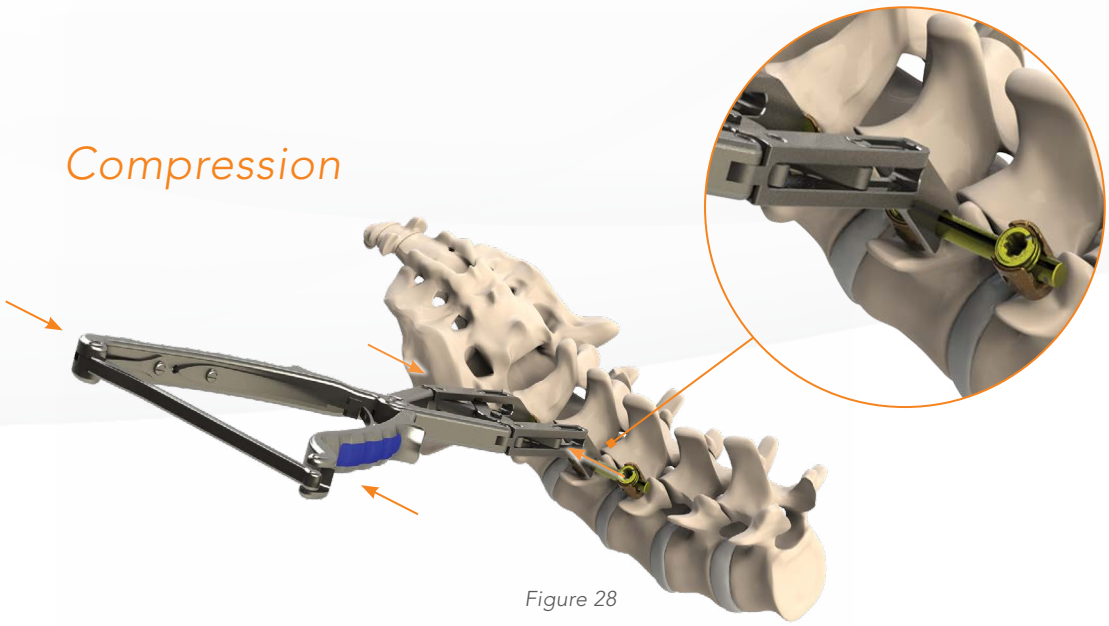


Figure 28

Distraction

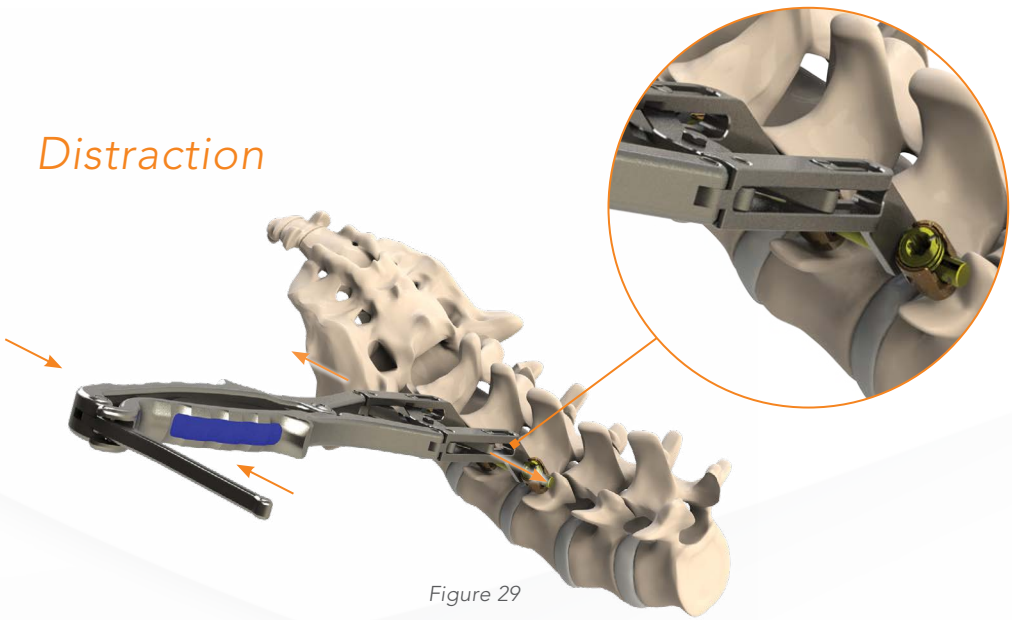


Figure 29

9 FINAL TIGHTENING

After the Set Screws have been placed the Counter Torque Raised Seat is applied to each screw over the rod. This is to help control and minimize the movement, torque, and stress to the construct during a provisional or final tightening *(Figure 30)*.

Assemble the **Off Center Counter Torque** with the Set Screw Driver.

The torque driver is passed through the cannula of the Counter Torque Raised Seat until the tip engages the Set Screw driving feature *(Figure 31)*. Turn clockwise. Torque is applied until the recommended torque of 100 in/lb is reached *(Figure 32)*.

Note: Make sure the male portion of the set screw inserter is fully engaged with the female portion of the set screw.

Caution: Do not over torque.

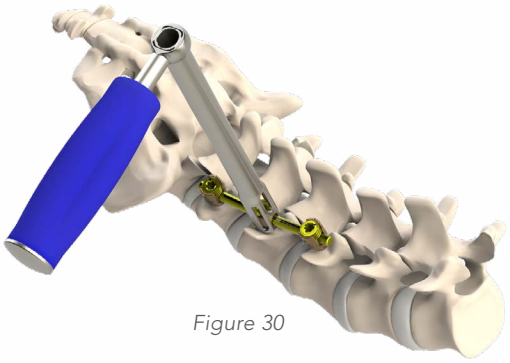


Figure 30

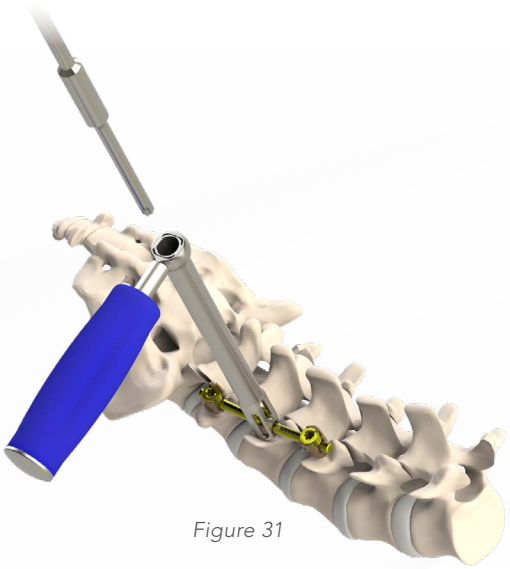


Figure 31

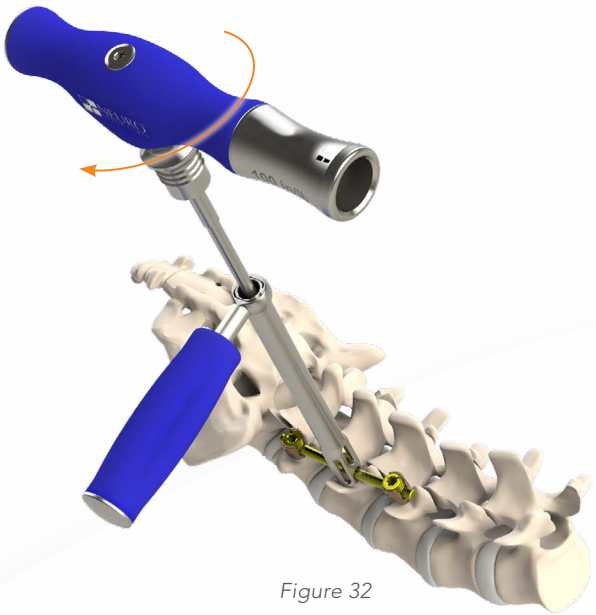


Figure 32

Raised Seat (Optional 1)

The Palladian Raised Seat Screws may be utilized to facilitate rod reduction in cases with difficult anatomy.

Attach a T-Handle or Axial Handle to the Screwdriver *(Figure 33)*.

Figure 33

Attach the selected screw to the Screwdriver *(Figure 34)*.

Figure 34

Turn the knob to engage the seat *(Figure 35)*.

Figure 35

Press the buttons on the sides of the slide lock and it will spring down locking the screw in place *(Figure 36)*.

Figure36

Place the tip of the screw directly at the hole in the pedicle and advance the screw.

To disengage the Screwdriver, pull the slide lock up until you hear an audible "click", turn the knob counterclockwise until disengaged from screw head, and then remove construct *(Figure 37)*.

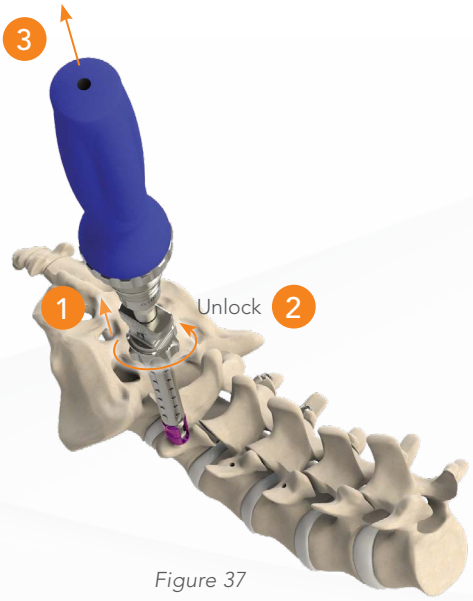


Figure 37

Once the rod has been fully seated and final tightening performed *(Figure 38)*, break the tabs off by sliding the screw tab breaker over each tab and levering back and forth until the tabs breaks off *(Figure 39)*.

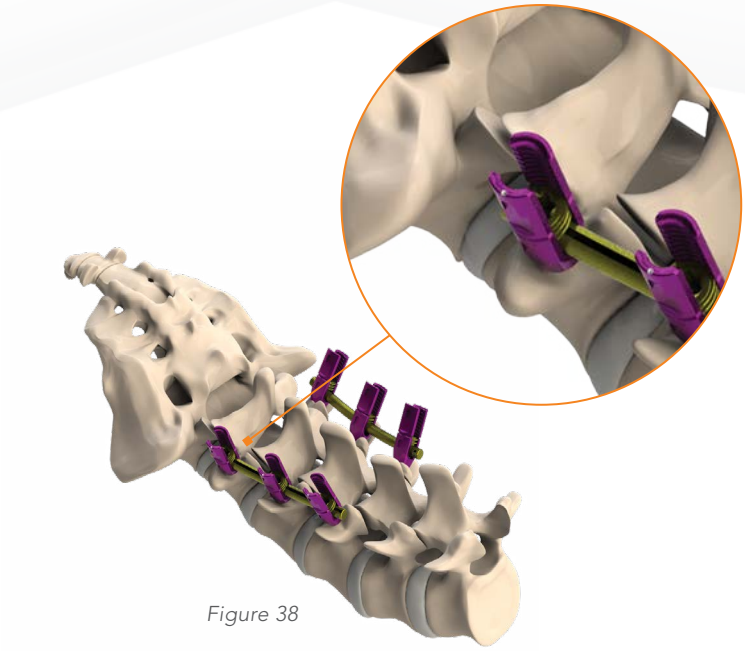


Figure 38

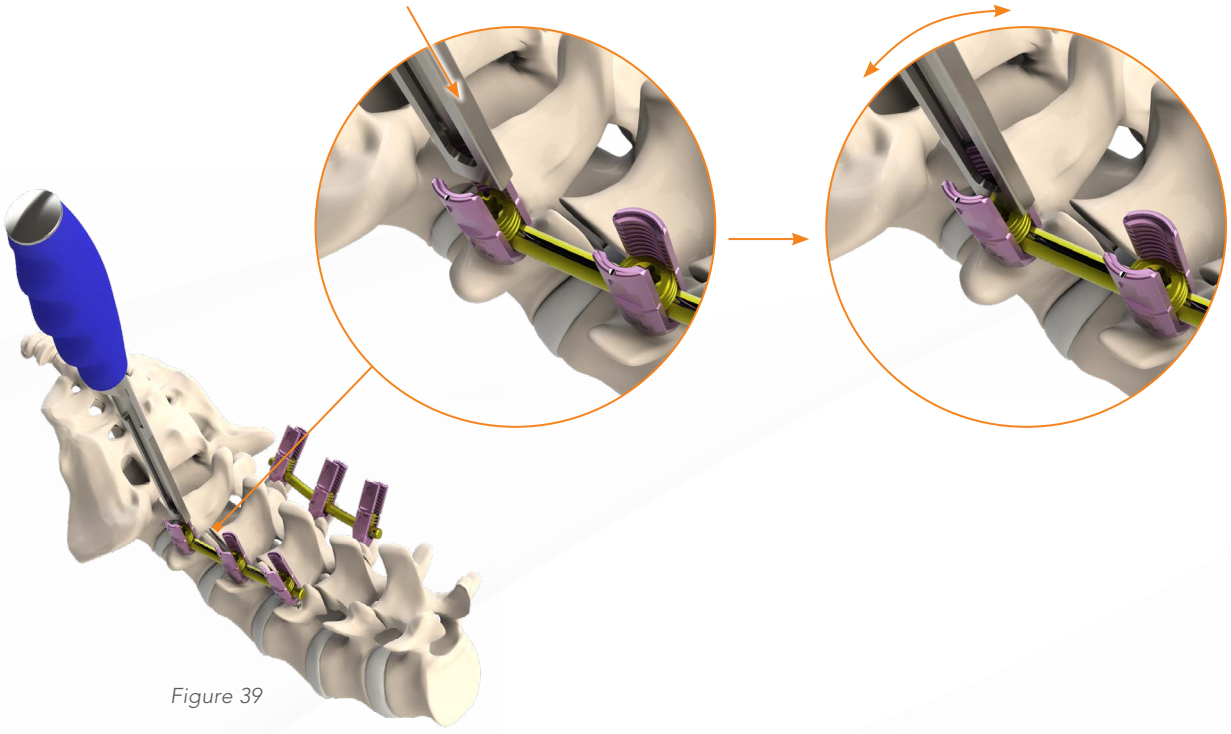


Figure 39

Cross Connector

One or more cross connectors may be placed between adjacent rods to enhance torsional stability of the overall construct. The cross connector is adjustable in length to accommodate variations in anatomy.

Use the Gauge Card to measure the distance between the rods *(Figure 41)*.

Select the appropriate cross connector and attach the Cross Connector Inserter *(Figure 42 – 44)*. The Tubular Cross Connector Holder may also be attached and used to insert the cross connector *(Figure 45 – 46)*.

Once the length is adjusted appropriately the set screws can be tightened using the cross connector screw driver and torque handle *(Figure 47)*.

Raised Cross Connector

Raised Connector Sizing	
Size	Span (mm)
XSmall	28 – 30
Small	30 – 34
Medium	34 – 42
Large	42 –58
XLarge	58 – 90

Flat Cross Connector

Flat Connector Sizing	
Size	Span (mm)
XSmall	28 – 30
Small	30 – 34
Medium	34 – 42
Large	42 –58
XLarge	58 – 90

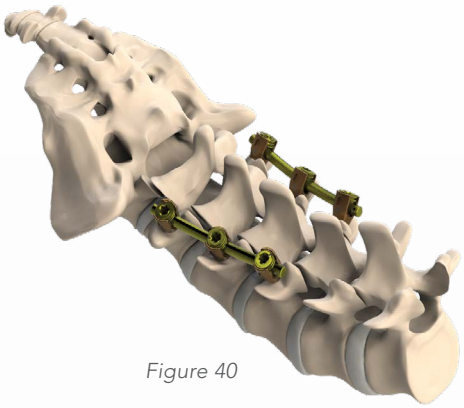


Figure 40

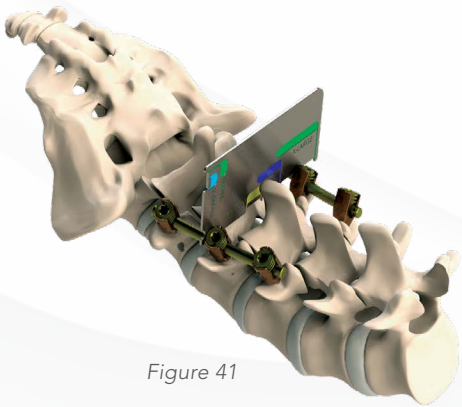


Figure 41

Figure 42

Figure 43

OR

Figure 44

Option 1

Option 2

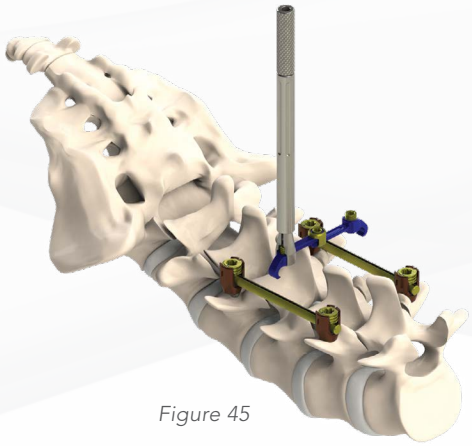


Figure 45

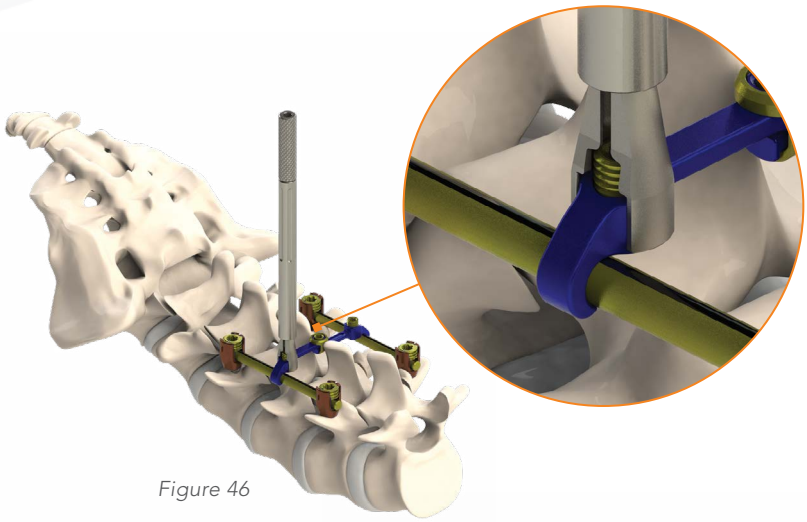


Figure 46

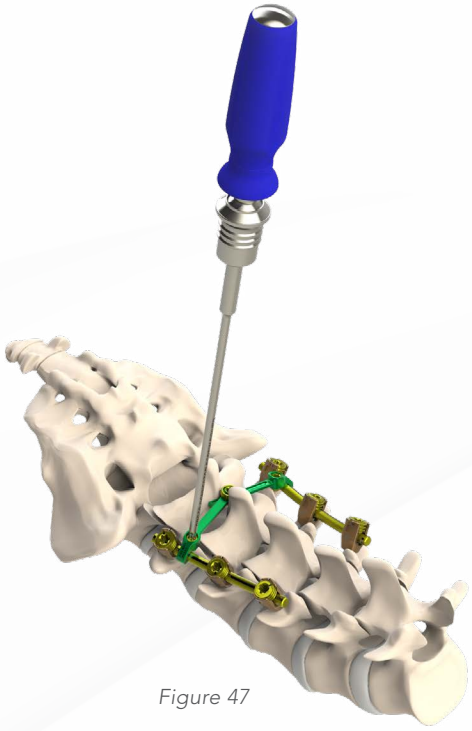


Figure 47

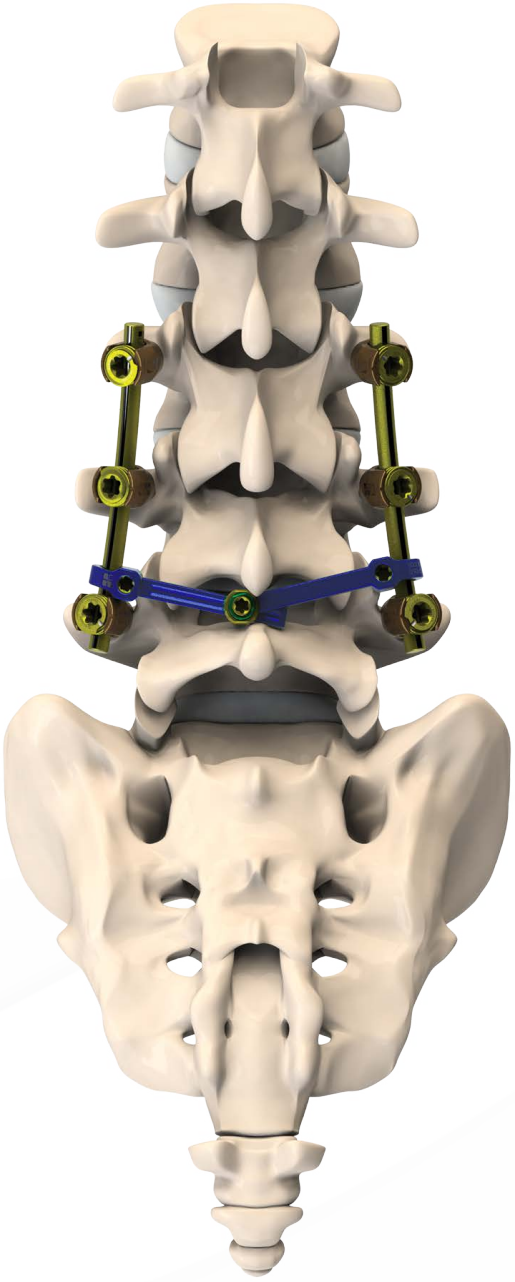


Figure 48

11 REVISION & REMOVAL

Posterior fixation implants may be explanted or revised. The instrument set contains all imperative instruments to perform these procedures. Remove all necessary set screws using the Set Screw Driver *(Figure 49)*. The rod inserter may be used to adjust or completely remove the previously implanted rods *(Figure 50)*. Remove the pedicle screws using the Screw Adjuster tool *(Figure 51)*.

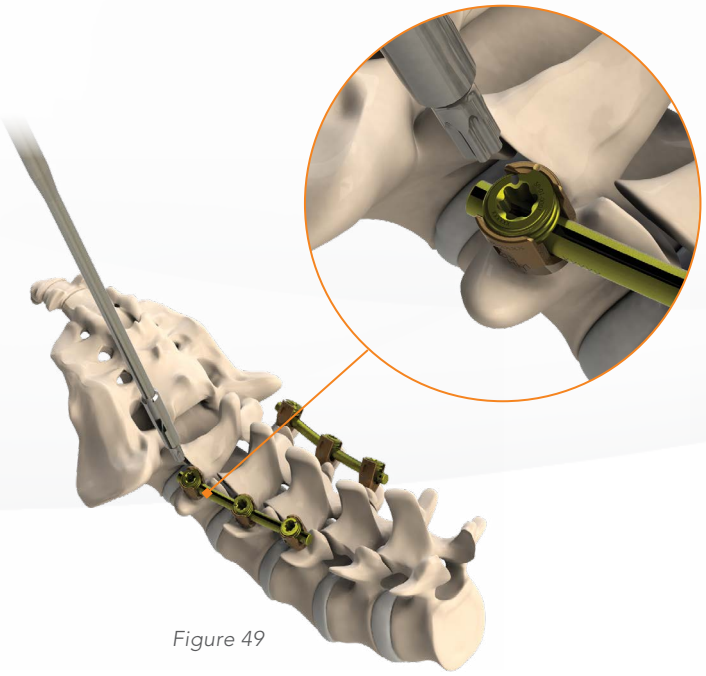


Figure 49

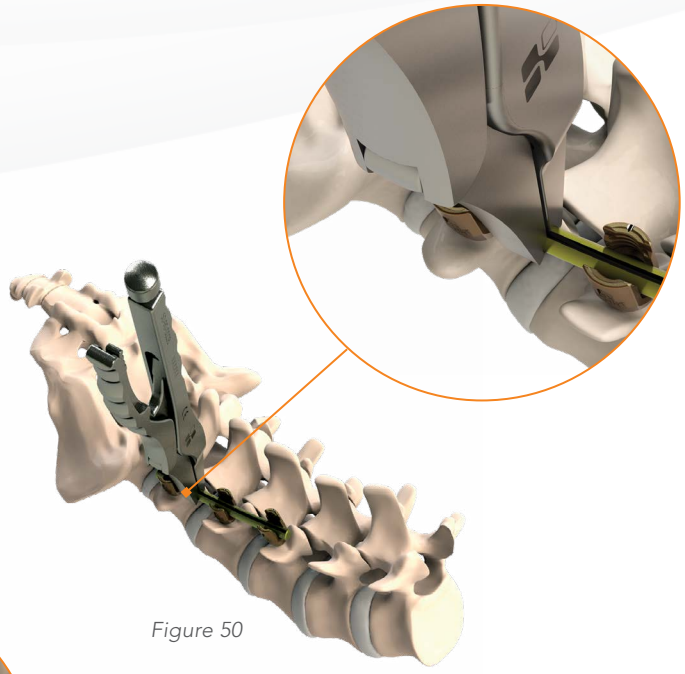


Figure 50

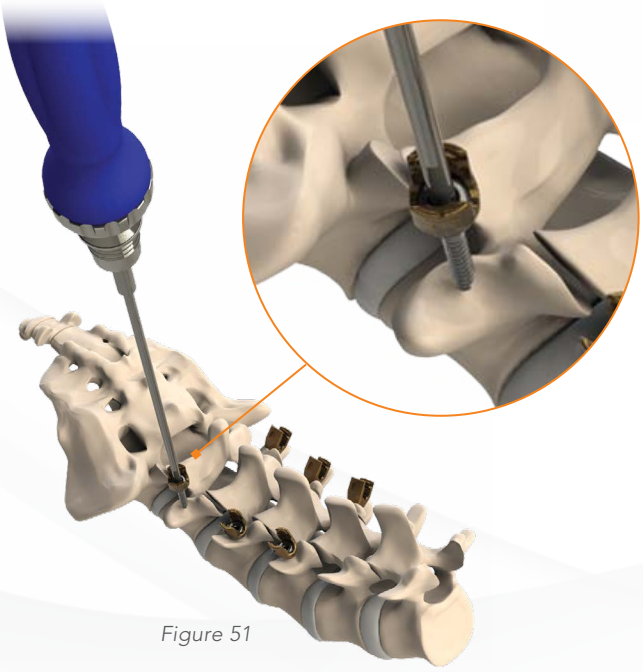


Figure 51

12 INSTRUMENTS

50-90-0002 | Narrow Curved Pedical Probe

50-90-0004 | Curved Duck Bill Probe

50-90-0006 | Parallel Compressor

50-90-0007 | Parallel Distractor

50-90-0010 | Screw Remover

50-90-0011 | Ratcheting Axial Handle

50-90-0012 | Ratcheting T-Handle

14 INSTRUMENTS *(CONT.)*

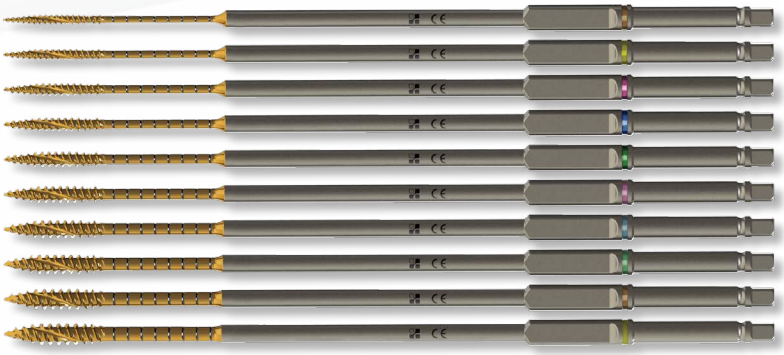
50-90-0014 | Set Screw Driver

50-90-0016 | Stopped Bone Awl

50-90-0017 | Pedicle Sounder

50-90-0018 | In Situ Rod Bender

50-90-0021-XX | Taps
ø5.5mm – ø7.5mm



–OR–

50-90-0034-XX | Straight Taps
ø5.5mm – ø7.5mm

50-90-0023 | Set Screw Starter

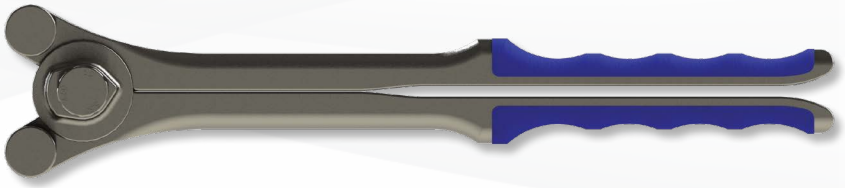
50-90-0025 | Polyaxial Seat Repositioner

50-90-0026 | Rod Template

–OR–

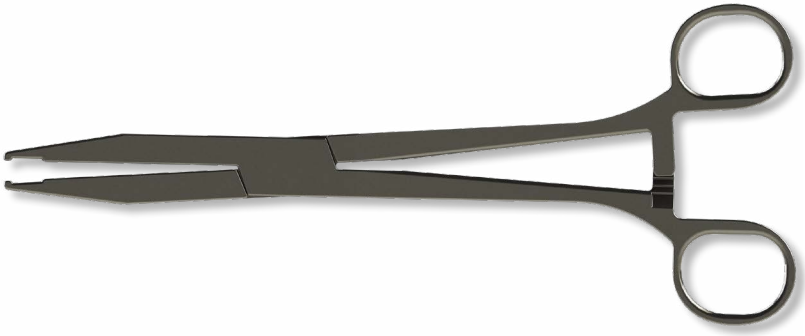
50-90-0057 | Holmed Rod Template

50-90-0027 | French Rod Bender



50-90-0029 | Rod Pusher

50-90-0030 | Cross Connector Inserter



50-90-0033 | Cross Connector Screw Driver

50-90-0035 | Small Head Pedicle Sounder

50-90-0036 | Axial Rod Pusher

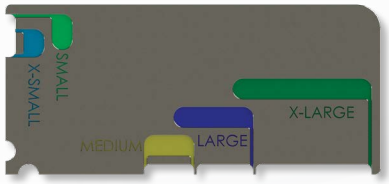
50-90-0038 | Straight Duck Bill Probe

50-90-0040 | Screw Adjuster

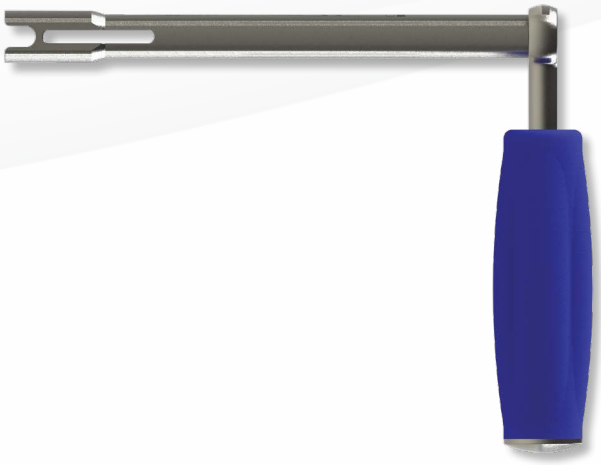
14 INSTRUMENTS *(CONT.)*

50-90-0042 | Simple Rod Inserter

50-90-0049 | Gauge Card



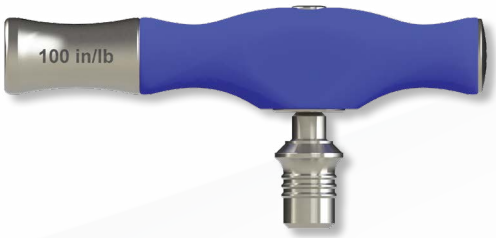
50-90-0050 | Counter Torque Raised Seat



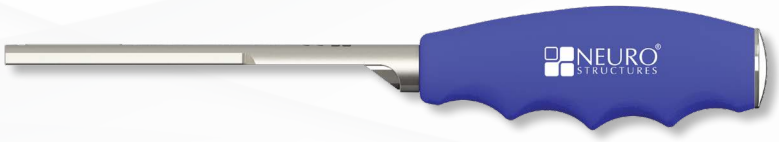
50-90-0052 | Cross Connector Axial Torque Handle

50-90-0056 | Narrow Straight Pedicle Probe

50-90-0058 | Off Center Torque Handle



50-90-0063 | Raised Seat Tab Breaker



50-90-0064 | Tubular Cross Connector Holder

50-90-0066 | Tri Lobe Adapter with Quick Lock

50-90-0072 | Adjustable Rod Rocker

50-90-0073 | Stab and Grab Screw Driver

50-90-0077 | Axial Persuader

50-90-0078 | Axial Persuader Driver

50-90-0079 | Non-Cannulated Locking Screw Driver – Regular Seat

50-90-0081 | Non-Cannulated Screw Driver – Raised Seat

Device Description:

The Palladian Lumbar Pedicle Screw System implant components are top-loading temporary implants that are intended for posterior interbody screw fixation of the non-cervical spine during the development of a lumbar spinal fusion. The implantation of the Palladian Lumbar Pedicle Screw System is via a posterior surgical approach. The Palladian Lumbar Pedicle Screw System implants are manufactured from medical grade titanium alloy per ASTM F-136.

NeuroStructures, Inc. implants are NOT compatible with the implants of other manufacturers unless otherwise specified. Implants designed to interface with the specific rod diameter are NOT compatible with other rod diameters unless otherwise specified. Implants designed to interface with a specific rod diameter are compatible with rods from other systems having the same diameter and same material.

NeuroStructures, Inc. prepares Surgical Technique Guides showing the use of NeuroStructures, Inc. implants and instruments. Please contact Customer Service to obtain copies of these Surgical Technique Manuals.

Please refer to the Surgical Technique Guides for additional important information about specific NeuroStructures, Inc. implants, in addition to the information described herein.

Indications:

Contraindications include, but are not limited to:

Potential Complications and Adverse Effects:

The use of the Palladian Lumbar Pedicle Screw System is indicated as an adjunct to fusion of the L5-S1 vertebra for the treatment of; degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformity, or curvature (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and previous failed fusion.

The Palladian Lumbar Pedicle Screw System is a noncervical spinal fixation system, and intended for use with autograft, and/or allograft. Pedicle screw fixation is limited to skeletally mature patients.

Warning:

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with acute and chronic instabilities or deformities of thoracic, lumbar, and sacral/iliac spine (T1–S1/Ileum), degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological 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.

Contraindications:

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to implantation.

Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.

Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system.

Any entity or condition that totally precludes the possibility of fusion (i.e. cancer, kidney dialysis, osteopenia) is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

Potential Adverse Events:

The implantation of pedicle screw spinal systems is a technically demanding procedure that presents a risk of serious injury to the patient. Accordingly, such a procedure should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system.

Warnings and Precautions:

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. The Palladian Lumbar Pedicle Screw System is only a temporary implant used for the correction and stabilization of the spine. This system is also intended to be used to augment the development of a spinal fusion by providing temporary stabilization. This device system is not intended to be the sole means of spinal support. Bone grafting must be part of the spinal fusion procedure in which the Palladian Lumbar Pedicle Screw System is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone.

In this event, bending, loosening, disassembly, and/or breakage of the device(s) will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the Palladian Lumbar Pedicle Screw System by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Patients who are obese, malnourished, abuse alcohol or drugs are also not good candidates for spine fusion. Patients with poor muscle, bone quality, and/or nerve paralysis are also not good candidates for spine fusion.

Magnetic Resonance Environments

The Palladian Lumbar Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Palladian Lumbar Pedicle Screw System has not been tested for heating or migration in the MR environment.

Physician Note:

Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings, and precautions given in this document must be conveyed to the patient.

Caution:

FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS:

Implant Selection:

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending; or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
- The type of construct to be assembled for the case should be determined prior to beginning the surgery. Adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The Palladian Lumbar Pedicle Screw System components are not to be combined with the components from another manufacturer. Different metal types should not be used together.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

Intraoperative:

- Any available instruction manuals should be carefully followed.
- At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
- When the configuration of the bone cannot be fitted with an available temporary internal fixation device, and contouring is absolutely necessary, it is recommended that such contouring be gradual and great care be used to avoid notching or scratching the surface of the device(s). The components should not be repeatedly or excessively bent any more than absolutely necessary. The components should not be reverse bent at the same location.
- The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
- Bone grafts must be placed in the area to be fused and the graft must be extended from the upper to the lower vertebrae to be fused.
- Bone cement should not be used since this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
- Before closing the soft tissues, all of the screws should be seated onto the rod. Recheck the tightness of all screws after finishing to make sure that none has loosened during the tightening of the other screws. Lock the anti-migration caps over the heads of the bone screws. Failure to do so may result in screw loosening.

  Caution: Excessive torque on the threads may cause the threads to strip in the bone, reducing fixation.

Postoperative:

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, or breakage of the components are complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented; or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
- The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

- If a non-union develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
- The Palladian Lumbar Pedicle Screw System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. In most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur:
  (1) Corrosion, with localized tissue reaction or pain;
  (2) Migration of implant position possibly resulting in injury;
  (3) Risk of additional injury from postoperative trauma;
  (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult;
  (5) Pain, discomfort, or abnormal sensations due to the presence of the device;
  (6) Possible increased risk of infection; and
  (7) Bone loss due to stress shielding.

  While the surgeon must make the final decision on implant removal, it is the position of the Orthopedic Surgical Manufacturers Association that whenever possible and practical for the individual patient, bone fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients. Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of removal. Implant removal, should be followed by adequate postoperative management to avoid fracture.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Palladian Lumbar Pedicle Screw System components should ever be reused under any circumstances.

Sterility:

HA coated Palladian Lumbar Pedicle Screws only are packaged sterile. All other Palladian Lumbar Pedicle implants are packaged Non-sterile.

The AAMI guidelines for the various sterilization cycles have been tested to meet a Sterility Assurance Level (SAL) of 10^{-6}. NeuroStructures, Inc. has validated the sterilization parameter, using the biological Indicator (BI) overkill half cycle method.

Unless otherwise indicated, the HA coated Palladian Lumbar Pedicle Screws has been sterilized by a minimum of 25 kGy (2.5 MRads) of Radiation and is supplied packaged in protective tube and tray with Tyvex cover. This sterilization is validated by AAMI TIR33:2005 Sterilization of Healthcare Products – Requirements for Validation and Routine Control – Radiation Sterilization and Sterilization of health care products – Radiation sterilization-Substantiation of 25 kGy as a sterilization dose-Method VDmax to an SAL of 10^{-6}. Inspect packages for punctures and other damage prior to surgery.

Packaging:

The Palladian Lumbar Pedicle Screw System implants, are packaged non-sterile. All implants are for single use.

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to NeuroStructures, Inc. All products should be treated with care. Improper use or handling may lead to damage, and/or possible improper functioning of the device.

Decontamination and Cleaning:

Unless just removed from an unopened package, all instruments and implants must be disassembled, if applicable, and thoroughly cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to NeuroStructures, Inc.

PRE-CLEAN PROCEDURE – INSTRUMENTS ONLY

- It is recommended that instruments should be reprocessed as soon as is reasonably practical following use.
- Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.
- Open instruments with ratchets, box locks, or hinges.
- Remove sharp instruments for manual cleaning or place into a separate tray.
- Lumen/cannula of instruments should be manually processed prior to cleaning. Lumen/cannula should first be cleared of debris. Lumen/cannula should be brushed thoroughly using appropriately sized soft- bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannula to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannula may not effectively clean the surface of a lumen/cannula. After brushing lumen/cannula, blow clean compressed air through lumen/cannula to clear debris, if necessary.
- Soak and/or rinse heavily soiled instruments or cannulated instruments prior to cleaning to loosen any dried soil or debris. Use a neutral pH enzymatic soak or detergent to soak devices. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration. Use cold tap water to rinse instruments.
- Do not use saline or chlorinated solutions.
- Palladian Lumbar Pedicle Screw System instruments must be cleaned separately from Palladian Lumbar Pedicle Screw System instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable.

MANUAL CLEANING PROCEDURE – INSTRUMENTS ONLY

Equipment: Various sized soft-bristled brushes, lint-free cloths, syringes, pipettes, and/or water jet, neutral enzymatic cleaner or neutral detergent with a pH between 7 and 9.

- Rinse soiled instrument under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.
- Soak instrument in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.
- Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels, and other hard to reach areas.
- Manually clean instrument for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles, and other movable instrument features to expose all areas to the detergent solution, if applicable. Clean instrument under water to prevent aerosolization of contaminants.

  Note: Fresh solution is a newly made, clean solution.
- Rinse instrument thoroughly with deionized (DI) or purified (PUR) water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable instrument features in order to rinse thoroughly under running water, if applicable.
- Visually inspect instrument. Repeat the manual cleaning procedure (steps 2 – 6) until no visible soil remains on instrument.
- Perform a final rinse on instrument using DI or PUR water.
- Dry device using a clean, soft, lint-free cloth, or clean compressed air.

Cycle	Minimum Time (Minutes)	Minimum Temperature/Water	Type of Detergent
Rinse 1	2	Cold tap water	N/A
Soak	10	Cold to warm tap water	Neutral enzymatic pH between 7 – 9
Rinse 2	2	Cold tap water	N/A
Wash	5	Warm tap water (>40°C)	Detergent with pH between 7 – 9
Rinse 3	2	Warm DI or PUR water (>40°C)	N/A
Final Rinse	2	Cold DI or PUR water	N/A

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach, and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. All devices should be routinely inspected to ensure there are no signs of unacceptable deterioration, such as corrosion, discoloration, pitting, or signs of wear and tear.

Sterilization:

Unless noted otherwise on the package labeling, the Palladian Lumbar Pedicle Screw System components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Steam Sterilization Cycle Type	Exposure time at 132 °C (270 °F)	Drying Times
Dynamic Air Removal: Pre-Vacuum	4 min	20 – 30 min

Remove all packaging materials prior to sterilization. Only FDA-cleared wraps should be used. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and re-sterilize before handling or (if applicable) return to NeuroStructures, Inc.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the manufacturer, NeuroStructures, Inc. Further, if any of the implanted Palladian Lumbar Pedicle Screw System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), may have caused or contributed to the death or serious injury of a patient, and/or is suspected of doing so, the manufacturer should be notified immediately. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the manufacturer is requested.

Further Information:

Recommended directions for use of this system (surgical technique guide) are available at no charge upon request. If further information is needed or required, please contact:

NeuroStructures, Inc., 199 Technology, Suite 110, Irvine, CA 92618, 800-352-6103.

www.neurostructures.com

NOTES

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02/20 Rev. 003 NS-100-130