

Palladian™

SPINAL FIXATION SYSTEM

Surgical Technique Guide





Palladian[™]

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.

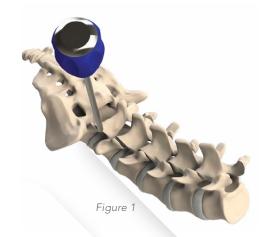
Important Note: This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments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

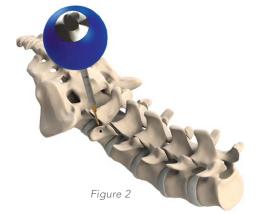
Pedicle Preparation (Option 1)

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.

Aw

An Awl is used to mark the pedicle entrance point. It is inserted just past the hard cortical bone of the pedicle.





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

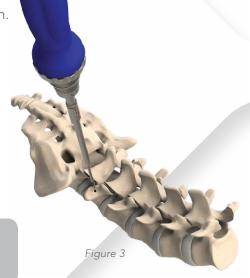
probe shaft is laser etched in 10mm intervals to help indicate the depth and help determine proper screw length.

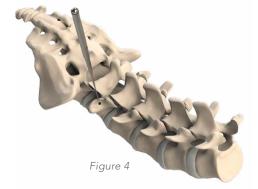


The Palladian Screws are self-tapping, however, taps may be used to facilitate screw insertion.

Select appropriate tap size and connect with a Quick Connect handle.

Note: Taps are undersized 0.5mm but threac pitch is consistent with the screw. Taps are color-coded by diameter.





Pedicle 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.

Screw Driver Assembly

Attach a Quick Connect handle to the Screwdriver.

Place the polyaxial Screwdriver over the selected screw and engage the driver tip with the recessed feature of the screw.

Push the sleeve down and rotate the knob clockwise to engage the screwdriver with the screw.

Note: Verify screw length and diameter prior to delivery.







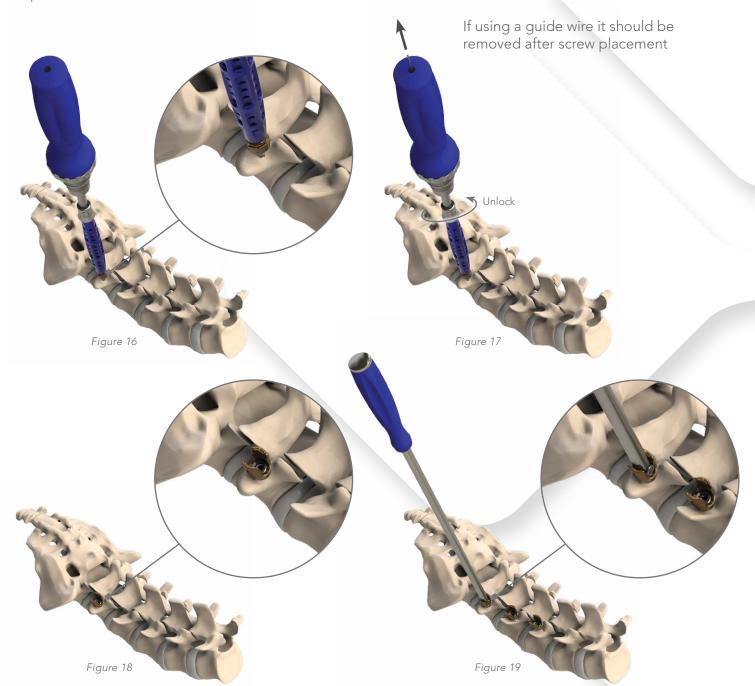
Screw Insertion

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

To disengage the screwdriver, turn the knob counterclockwise and remove.

Position and align the screw heads with the head positioner as needed.

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

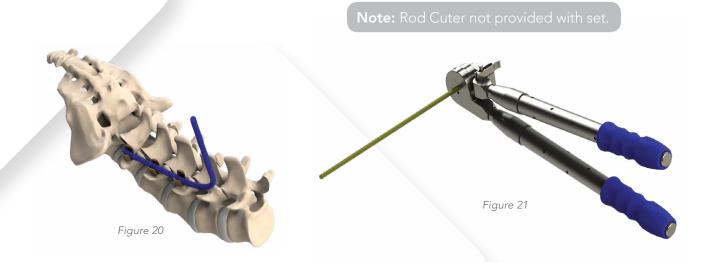


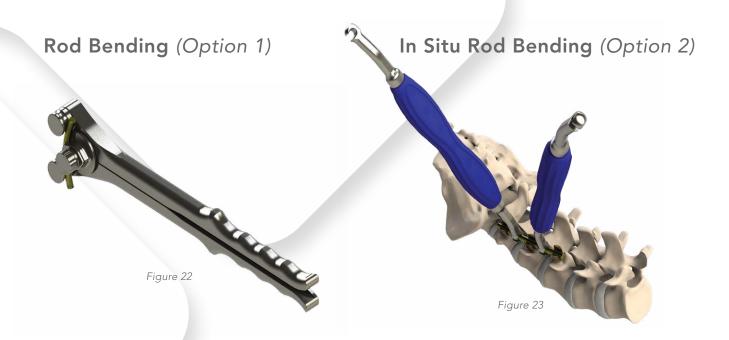
Rod Preparation

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.

To contour the rod, place the rod in the rod bender and apply bending pressure appropriately to achieve the desired profile.





Rod Placement

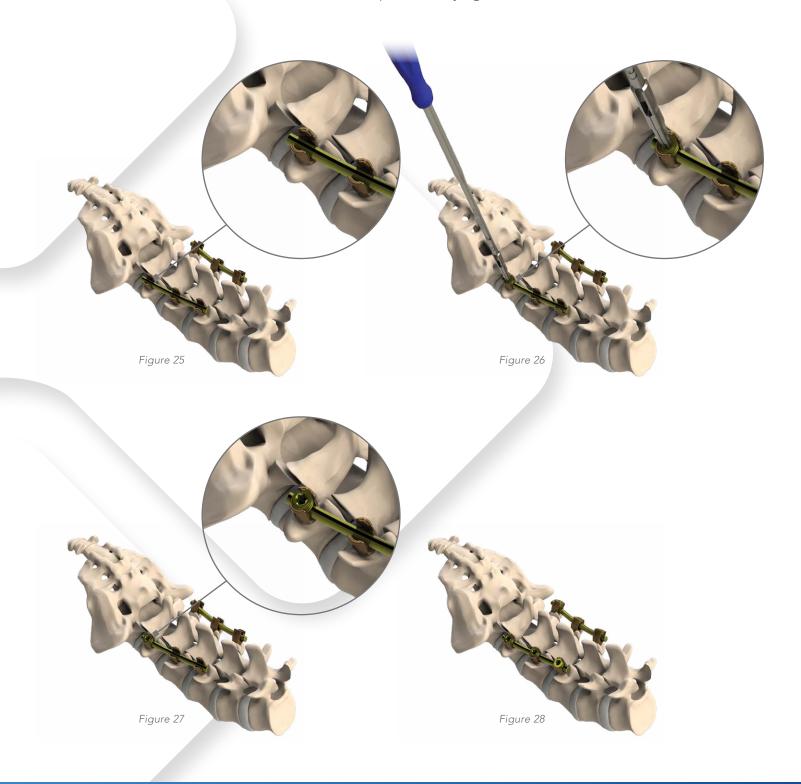
Grasp the selected rod with the rod holder and place into the screw heads.

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



Rod Capture

Load set screws from the caddy with the setscrew inserter. Place the set screws into the screw heads and rotate clockwise until provisionally tightened.



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.

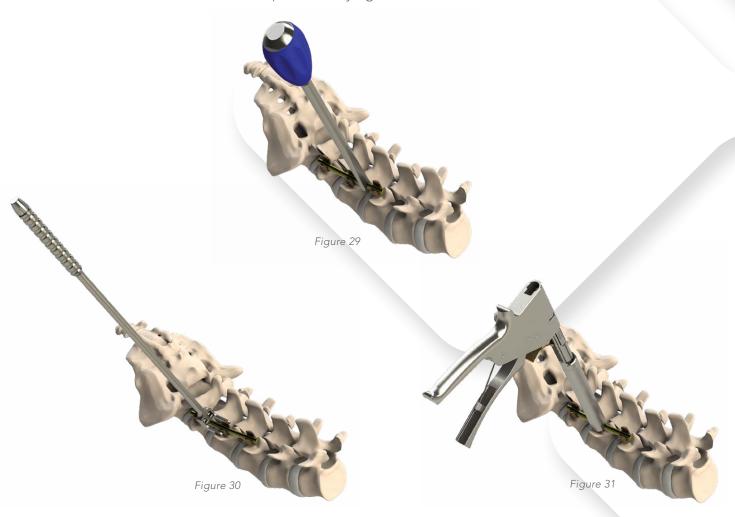
The Adjustable Rod Rocker can be placed over the rod and hooked underneath the seat. When levered back the rod is persuaded or reduced into position. A set screw can then be placed to secure the rod into the seat.

Rod Reduction (Optional)

The rod reducer can be used to reduce the rod into the seat.

Attach the Persuader to the screw by placing the tip on the screw head and rod and rotating the lock mechanism. Once persuader is firmly attached to screw head, squeeze trigger handle until desired reduction is achieved.

Insert Set Screw with set screw inserter through the inner cannula into the screw head and turn clockwise until provisionally tightened.

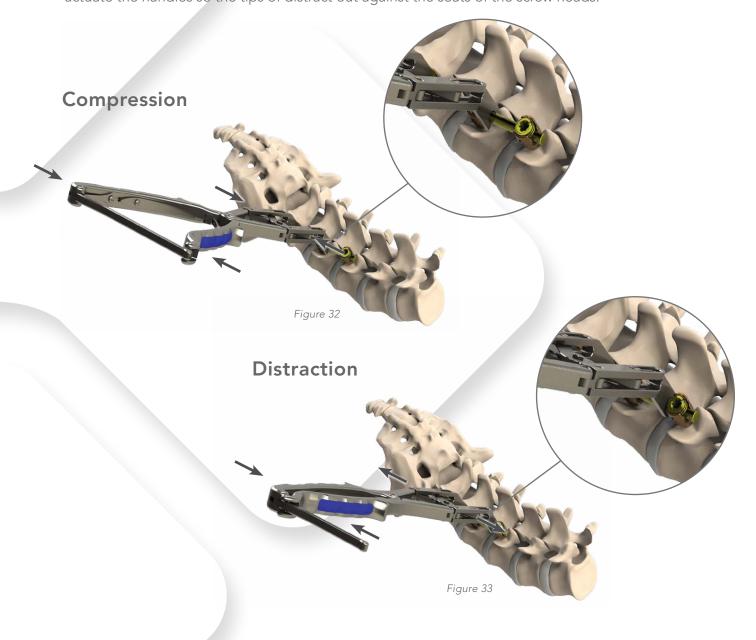


Compression & Distraction

After inserting the setscrews, 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.

Distraction – Place the tips of the spreader over the rod and between the screw heads, actuate the handles so the tips of distract out against the seats of the screw heads.



Final Tightening

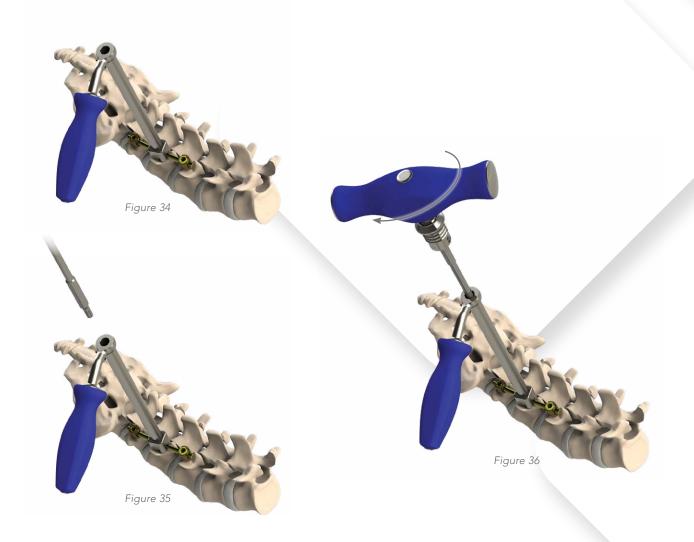
After the set screws have been placed the torque stabilizer is applied to each screw over the rod. This is to help control and minimize the movement, torque and stress to the construct during a provisional or final tightening.

Assemble the 100 in-lb T-handle torque handle with the driver shaft.

The torque driver is passed through the cannula of the torque stabilizer until the tip engages the set screw driving feature. Turn clockwise. Torque is applied until the recommended torque of 100 in-lb is reached.

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.



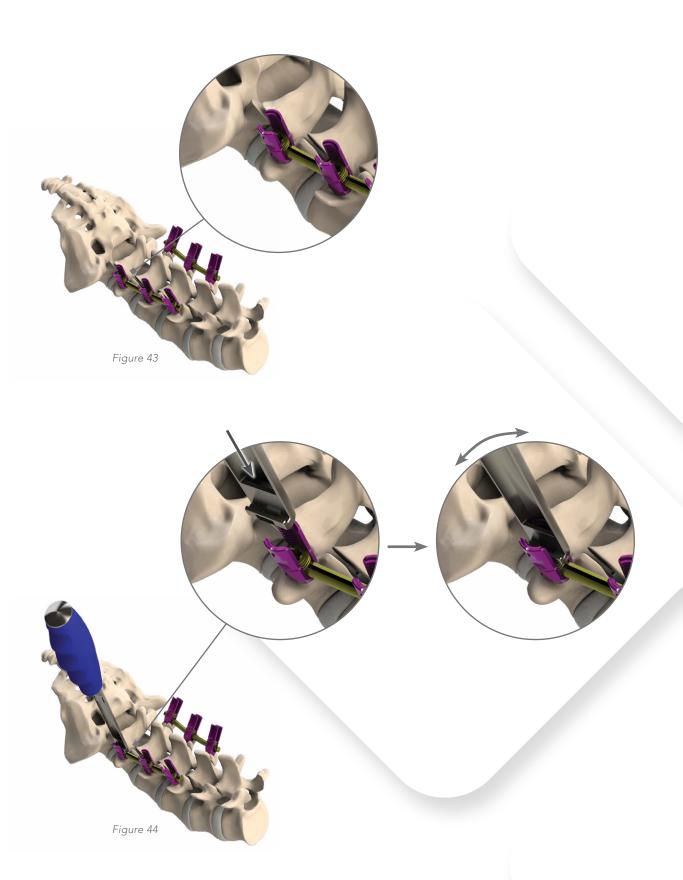
10 Additional Components (cont.)

Reduction Seat (Option 1)

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

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



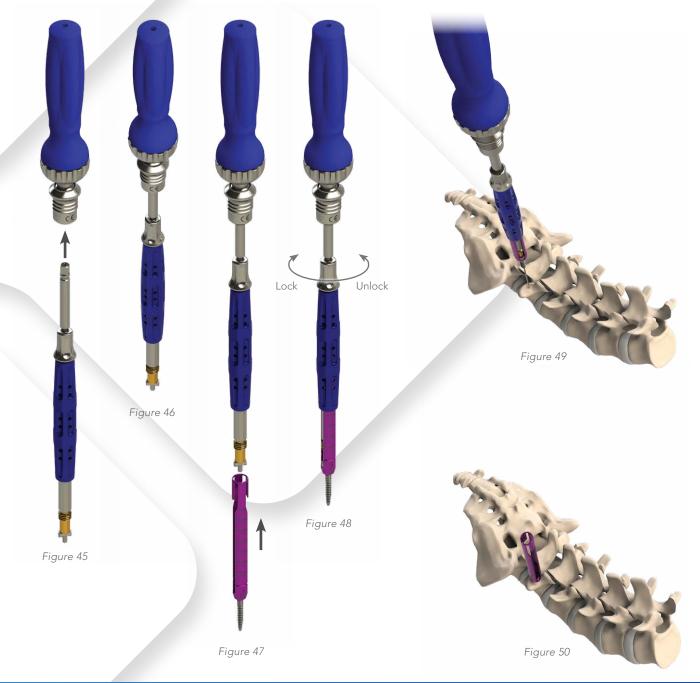


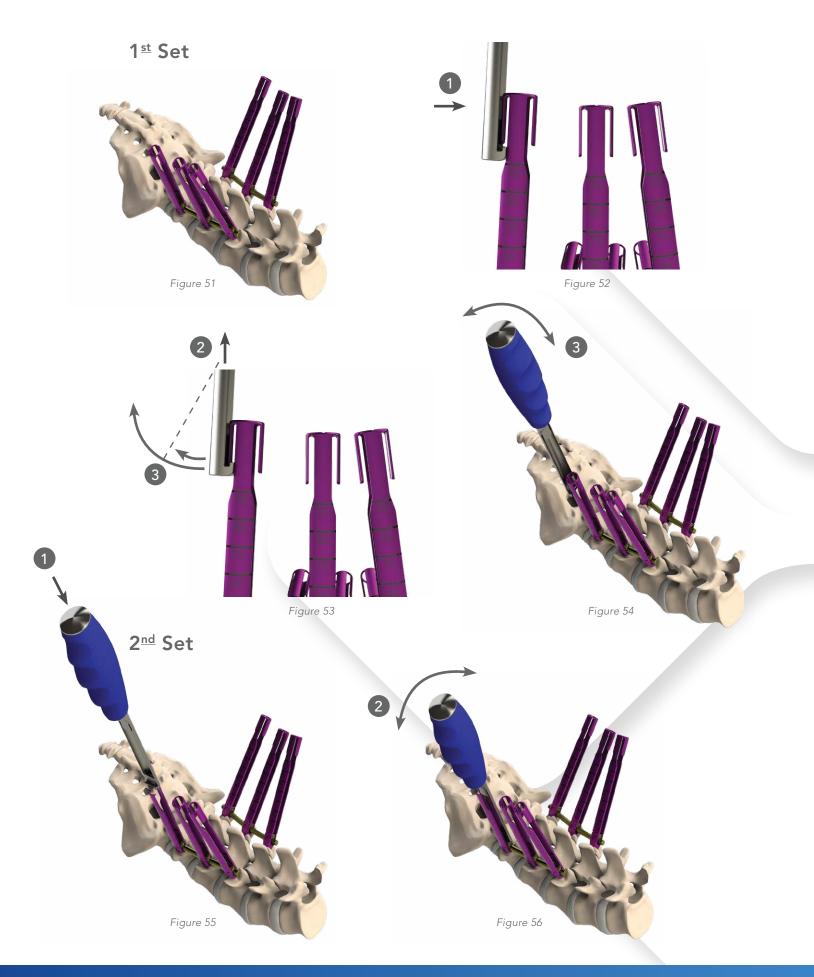
10 Additional Components

Extended Seat (Option 2)

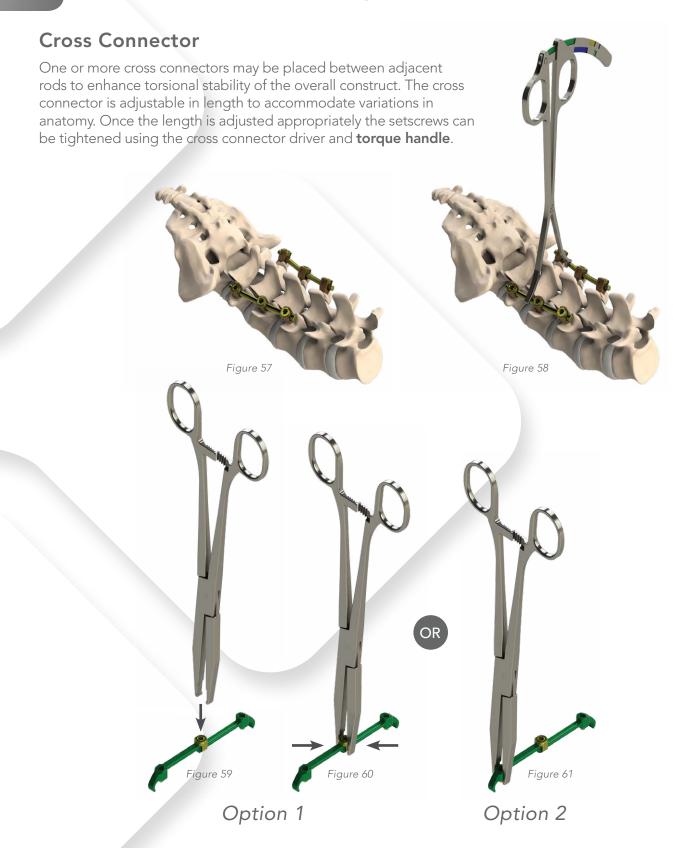
The Palladian Extended Seat Screws may be utilized to facilitate rod reduction in cases with difficult anatomy.

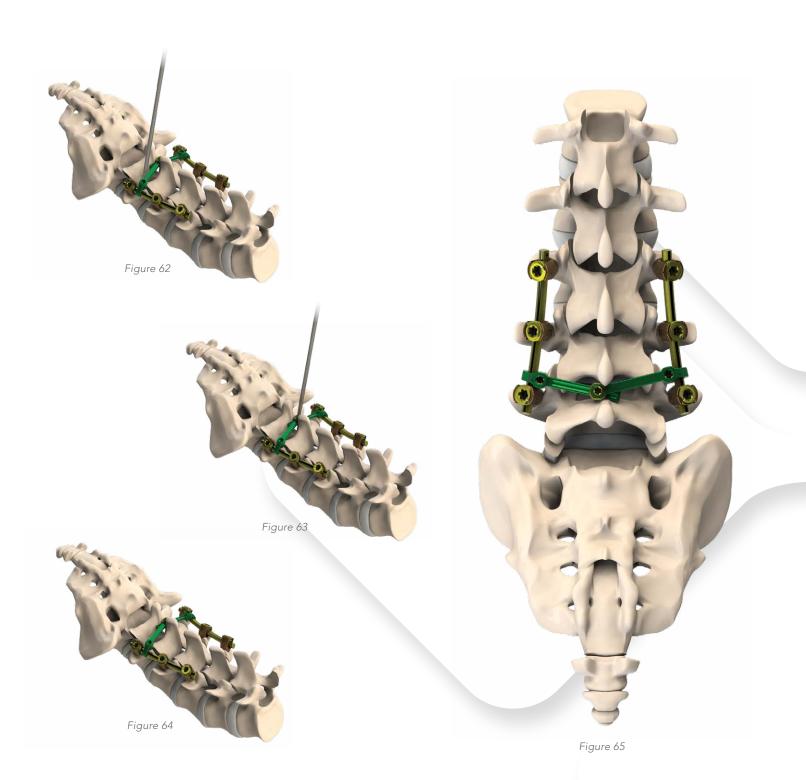
Once the rod has been fully seated and final tightening performed, break off the two sets of tabs. For the first set slide the screw tab breaking tool under and up. Use an upward articulating movement to break tab. Perform the same step on the opposite side. For the second set of tabs, slide the screw tab breaker over each tab and lever back and forth until the tabs break off.





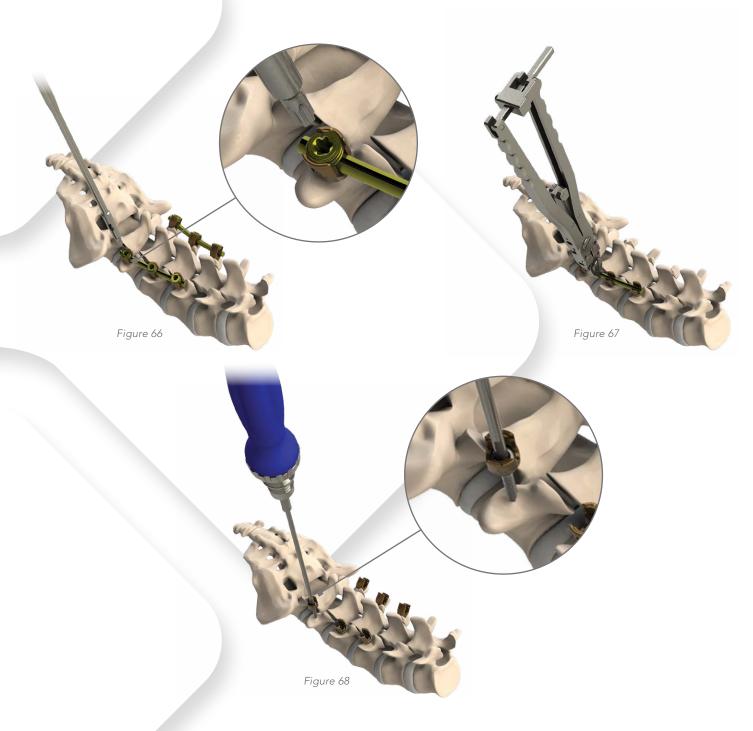
10 Additional Components (cont.)





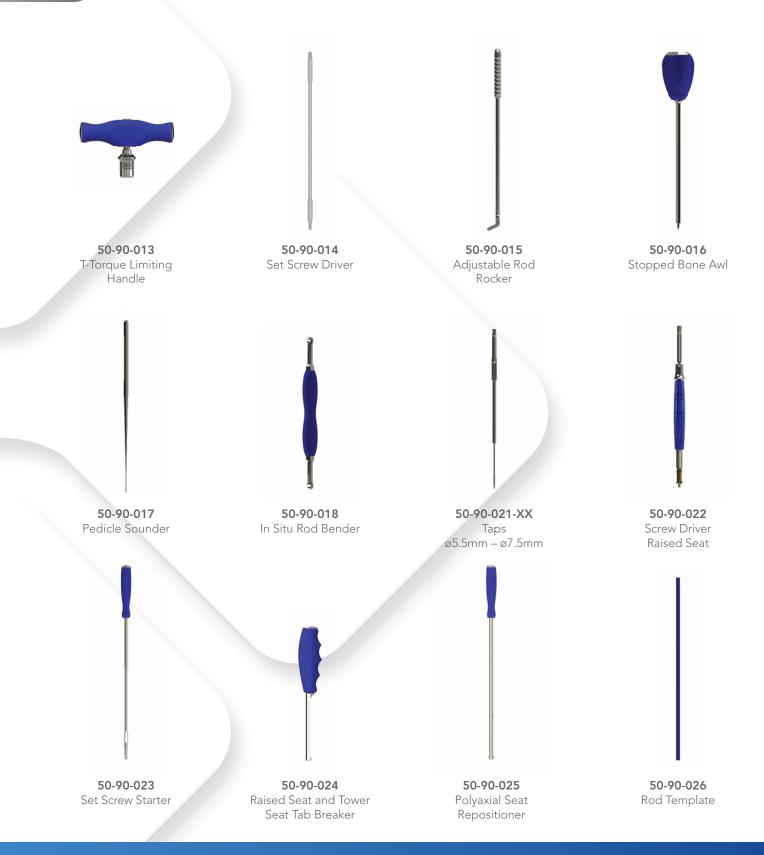
11 Revision and Removal

Posterior fixation implants may be explanted or revised. The instrument set contains all imperative instruments to perform these procedures. Remove all necessary setscrews using the setscrew driver. The rod inserter may be used to adjust or completely remove the previously implanted rods. Remove the pedicle screws using the screws drivers.



12 Instruments











50-90-029 Rod Pusher



50-90-030 Cross Connector Inserter



50-90-031 Cross Connector Caliper



50-90-032 Cross Connector Torque Handle



50-90-033 Cross Connector Set Screw Driver

13 IFU

Purpose:

The Palladian™ Lumbar Pedicle Screw System is a multiple component, posterior spinal fixation system which consists of pedicle screws, rods, cross-connectors, and locking cap set screws. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are intended for posterior interbody screw fixation of the 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.

Description:

The Palladian Lumbar Pedicle Screw System implants are manufactured from medical grade titanium alloy per ASTM F-136.

NeuroStructures 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 prepares Surgical Technique Guides showing the use of NeuroStructures implants and instruments. Please contact your NeuroStructures sales representative to obtain copies of these Surgical Technique Manuals.

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

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EFFECTS.

Indications:

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.

WARNING:

Contradictions:

Contraindications include, but are not limited to:

- 1. Infection, local to the operative site
- 2. Signs of local inflammation
- 3. Fever or leukocytosis
- 4. Morbid obesity
- 5. Pregnancy
- 6. Mental illness
- Any medical or surgical condition which would preclude the
 potential benefit of spinal implant surgery, such as the elevation of
 sedimentation rate unexplained by other diseases, elevation of white
 blood count (WBC), or a marked left shift in the WBC differential
 count
- 8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount

- of mechanical fixation, and/or the quality of the bone graft.
- 9. Suspected or documented metal allergy or intolerance
- Any case not needing a bone graft and fusion or where fracture healing is not required
- 11. Any case requiring the mixing of metals from different components
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition
- 13. Any case not described in the Indications
- Any patient unwilling to cooperate with the postoperative instructions
- 15. Any time implant utilization would interfere with anatomical structures or expected physiological performance

Potential Adverse Events:

- 1. Infection, early or late
- 2. Metal sensitivity or allergic reaction to the implant
- 3. Pain, discomfort, or abnormal sensations due to the presence of the device
- 4. Bending or fracture of implant
- 5. Loosening of the implant
- 6. Screw back out, possibly leading to implant loosening, and/or further surgical procedures device removal.
- 7. Nonunion, delayed union
- 8. Decrease in bone density due to stress shielding
- 9. Bursitis
- 10. Nerve damage due to surgical trauma or presence of the device
- Neurological difficulties, such as, bowel and/or bladder dysfunction, impotence, retrograde ejaculation, and paresthesia.

- 12. Spinal cord impingement or damage
- 13. Paralysis
- Degenerative changes or instability in segments adjacent to fused vertebral levels.
- 15. Dural tears
- 16. Fracture of bone structures
- Further surgery, for instance for dural repair, a chronic CSF leak or fistula, and meningitis
- 18. Lymphatic vessels damage and/or lymphatic fluid exudation.
- 19. Vascular damage due to surgical trauma or presence of the device (NOTE: Vascular damage could result in catastrophic or fatal bleeding. Positioning implants adjacent to large arter-ies or veins may result in erosion of these vessels and cause catastrophic bleeding in the last postoperative period)
- 20. Death

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 Palladi-nTM 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 PalladianTM 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 utiliza-tion of the PalladianTM 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, and/or abuse alco-hol or other drugs are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion.

Magnetic Resonance Environments

The Palladian $^{\text{TM}}$ Lumbar Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Palladian $^{\text{TM}}$ 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 pro-tected during storage especially from corrosive environments.
- 4. 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 sur-gery, 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 PalladianTM 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

Intraoperative:

- 1. 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.
- 3. 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 con-touring 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 neuro-logic damage and bone necrosis.
- 7. Before closing the soft tissues, all of the screws should be seated onto the implant. 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.

Packaging:

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.

- 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 mus-cular 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 spi-nal position.
- 2. 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.
- 4. 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 immobi-lize 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.
- 5. The Palladian™ Lumbar Pedicle Screw System implants are

- temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the nor-mal 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 in-tended 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 complica-tions may occur:
- a. Corrosion, with localized tissue reaction or pain
- b. Migration of implant position possibly resulting in injury
- c. Risk of additional injury from postoperative trauma
- d. Bending, loosening and or breakage, which could make removal impractical or difficult
- e. Pain, discomfort, or abnormal sensations due to the presence of the device
- f. Possible increased risk of infection
- g. Bone loss due to stress shielding
- 6. 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 deci-sion 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.
- 7. 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 PalladianTM Lumbar Pedicle Screw System components should ever be reused under any circumstances.

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. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

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. Also, many instruments require disassembly before cleaning. No visual contamination shall be present after cleaning, so the instruments shall be re-cleaned if they are not visually clean.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

Sterilization:

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

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. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and resterilize 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), or is suspected of doing so, the manufacturer should be notified immediately. If any NeuroStructures, Inc. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone or written correspondence. 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 operative techniques) are available at no charge upon request. If further information is required, please contact: NeuroStructures, Inc., 16 Technology Drive, Suite 165, Irvine, CA 92618, 800-352-6103

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