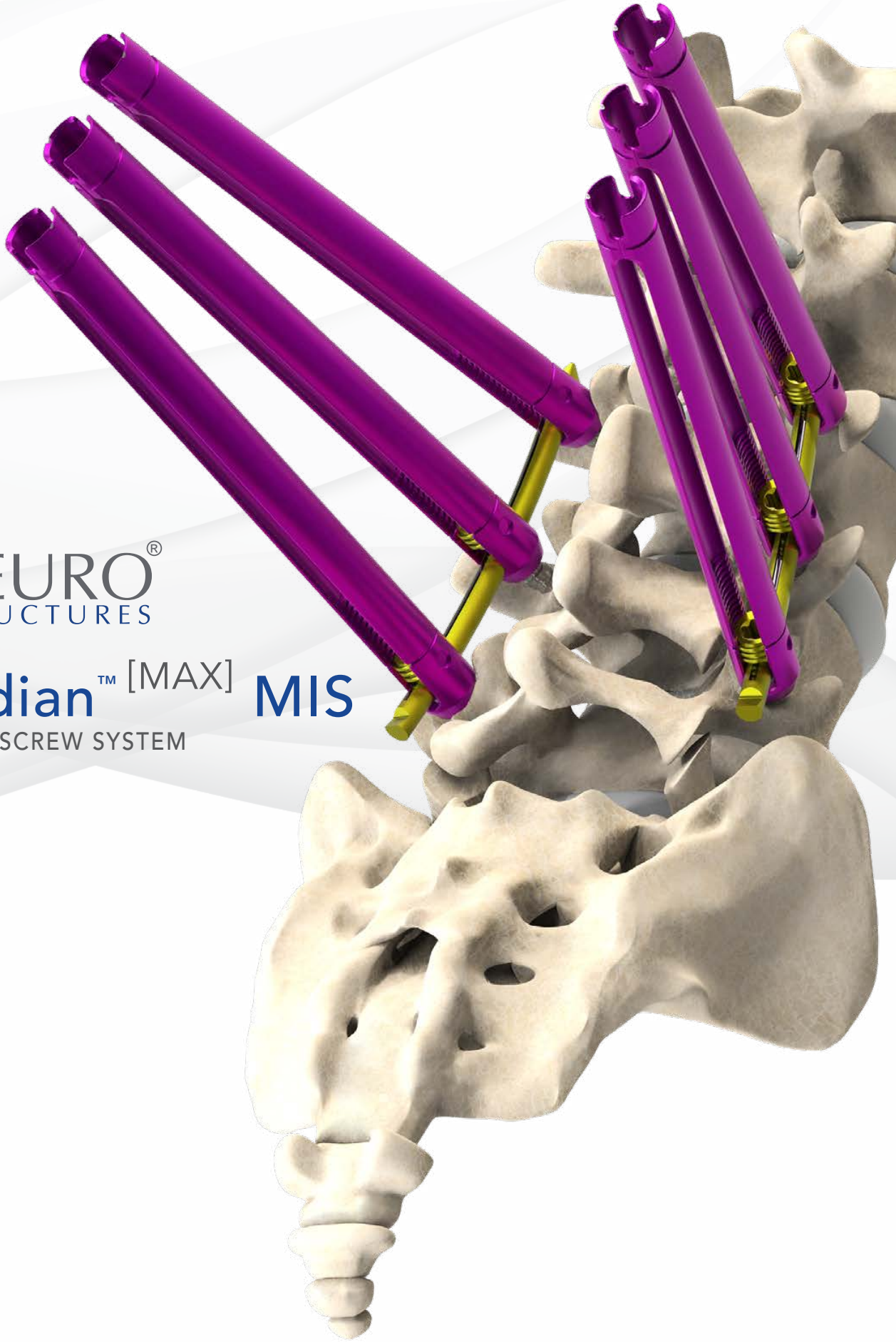
NEURO® STRUCTURES

Palladian™ [MAX] MIS

MIS SPINAL SCREW SYSTEM



Surgical Technique Guide

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SYSTEM INFORMATION

Screw Features

Quick & Simple Streamlined Procedure

Effortless Percutaneous Multi-Level Rod Placement

Allows for Percutaneous Compression & Distraction

Precise Rod Measuring Gauge

Wide Range of Pre-Bent MIS Rods to Accommodate Patient Anatomy

Low Profile Design & Smooth Contoured Edges to Optimize Patient Comfort

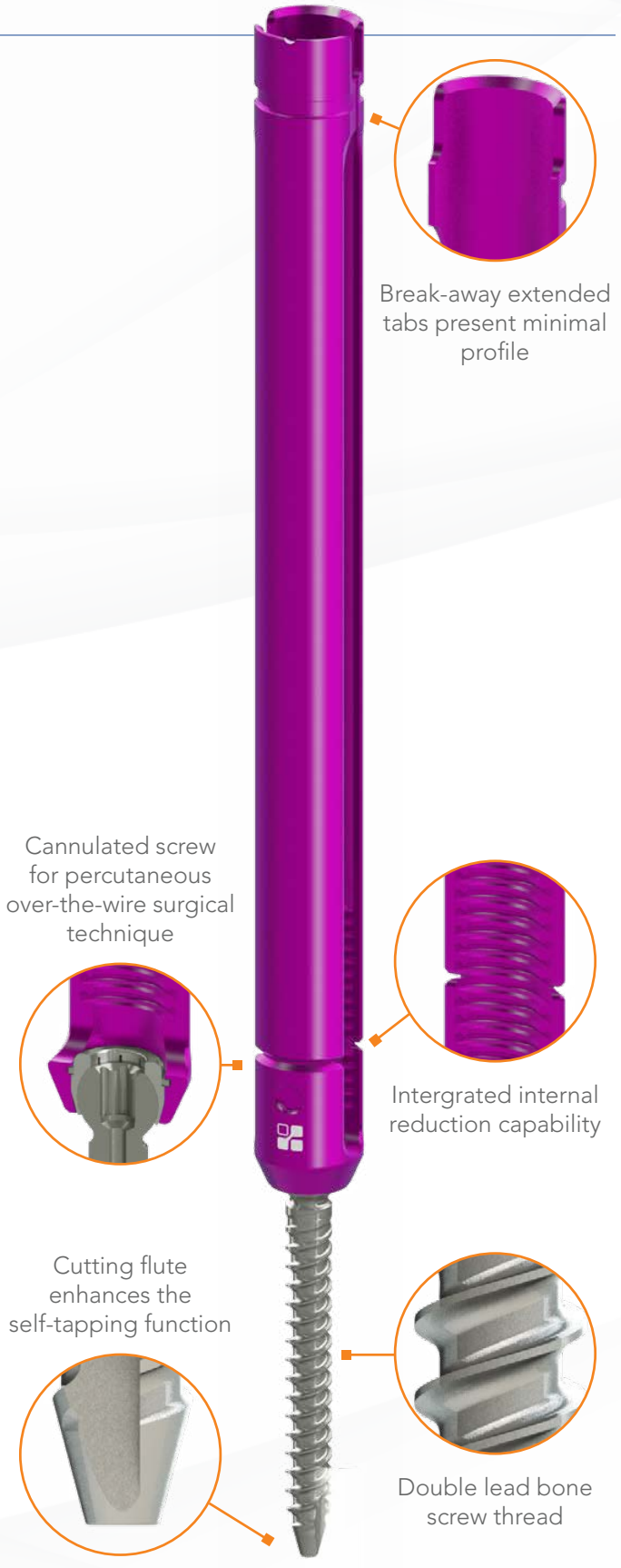
Screw Size

Diameter (mm)	Length (mm)			
5.5	40	45	50	55
6.5	40	45	50	55
7.5	40	45	50	55

Rods

MIS Curved Rod Length (mm)
35 – 80 in 5mm Increments 90 – 150 in 10mm Increments

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.



Patent Number:
US 10,368,923 B2

1 PEDICLE TARGETING & GUIDEWIRE PLACEMENT

It is recommended that preoperative planning be used to help determine the proper entry point and trajectory as the starting point is not usually at the point directly over the pedicle.

Identify the operative levels using A/P and lateral fluoroscopy. Plan the entry point to target the pedicle from a transverse trajectory lateral to the facet.

Make an incision through the skin and fascia. The typical starting point is 3 – 4cm off the midline.

Insert the Target Needle and guide down to the surface of the pedicle and dock the tip on the bony anatomy of the desired level and confirm placement with A/P fluoroscopy. Adjustments to the entry angle and the trajectory should be made until the proper position is attained.

Advance the Target Needle and guide down through the pedicle. Once proper placement is confirmed, remove the inner stylet of the targeting needle *(Figure 1)*.

Insert the Guidewire through the cannulated target needle sheath and advance the Guidewire just past the tip of the Target Needle *(Figure 2)*. Use caution when advancing the Guidewire under fluoroscopy ensure the location of the Guidewire. Once the Guidewire is in place remove the Target Needle and leave the Guidewire in place *(Figure 3)*.

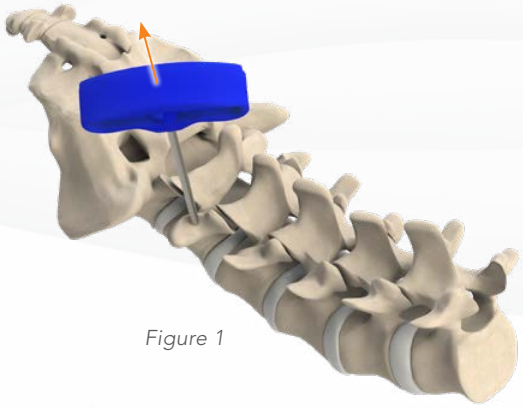


Figure 1

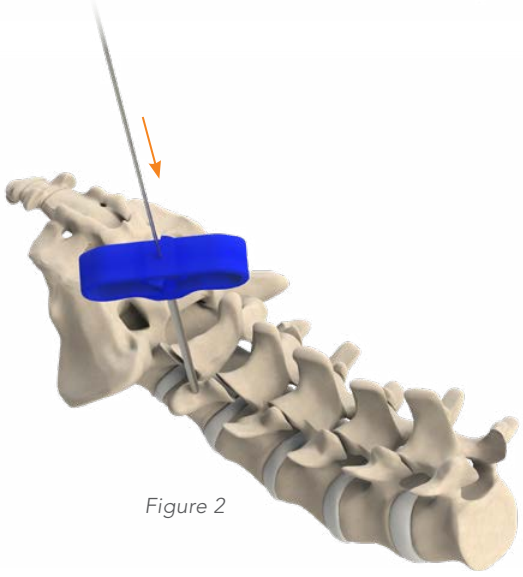


Figure 2

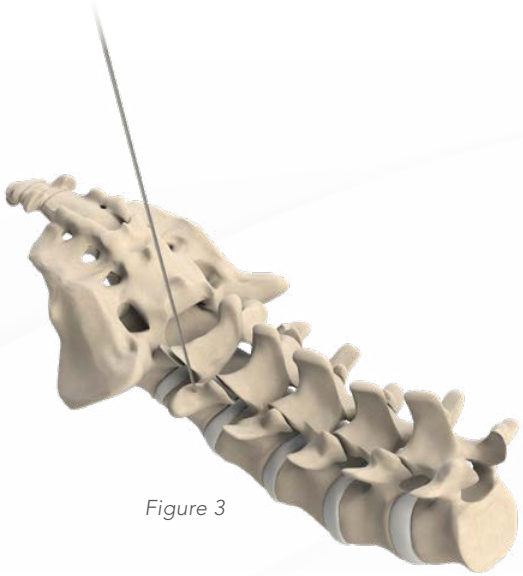
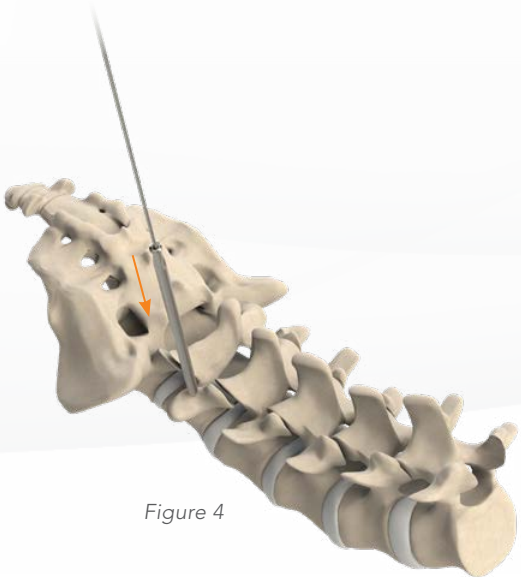


Figure 3

2 TISSUE DILATION & TAPPING

A longitudinal incision about 1.5cm is made through the skin and fascia. An incision of 1.5cm will facilitate the insertion of the towers used later in the procedure.

Prepare a pathway to the pedicle by sequentially using Dilators 1, 2, and 3 *(Figure 4 – 6)*. Once the largest Dilator 3 is placed remove the inner Dilators 1 and 2 and place them over the adjacent Guidewire *(Figure 6)*. Leave the Dilator 3 in place to protect the soft tissue while tapping *(Figure 7)*.



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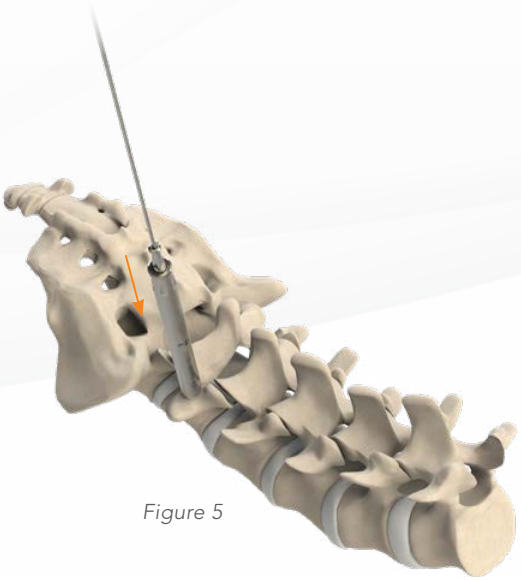
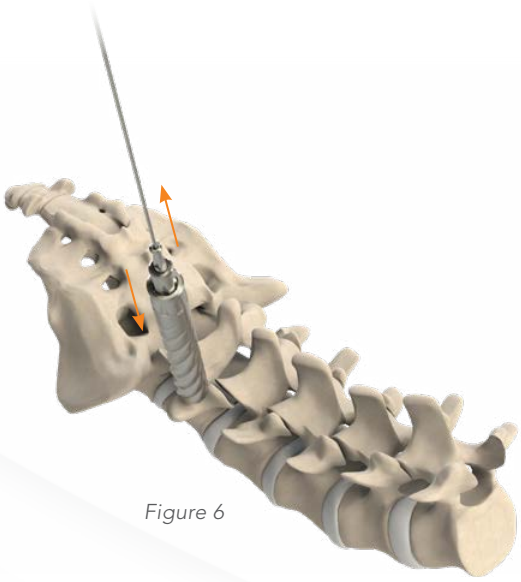


Figure 5



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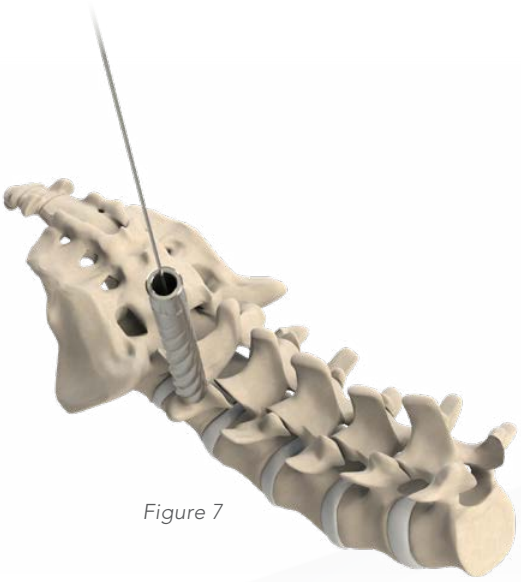


Figure 7

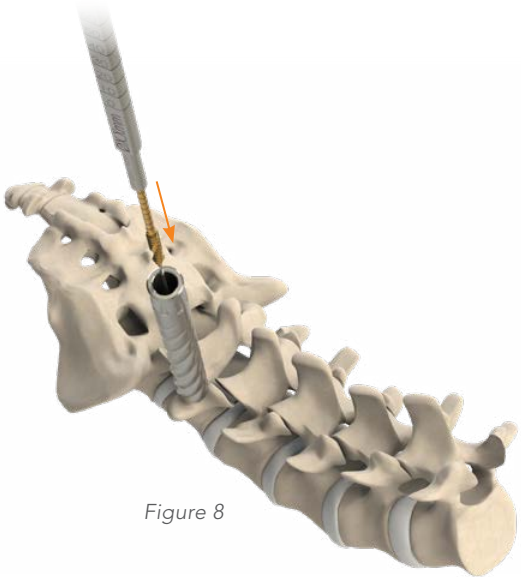
Caution: Use fluoroscopy to monitor guidewire advancement during dilation.

Attach the appropriate tap size to the preferred handle (axial or t-handle). Place the tap over the Guidewire and through Dilator 3 to the surface of the pedicle *(Figure 8)*. The depth markers on the tap shaft where the tap shaft meets the top of Dilator 3 are used to monitor insertion. They can also be used to determine screw length *(Figure 9)*.

Once desired depth has been achieved remove tap while maintaining control of guidewire.

Load the EMG Sleeve over Dilator 3 and advance to bony anatomy *(Figure 10)*. Depth can be verified by using fluroscapy to locate the ring at the distal tip of the EMG Sleeve.

When EMG Sleeve is in the proper position, remove Dilator 3 *(Figure 10)*.



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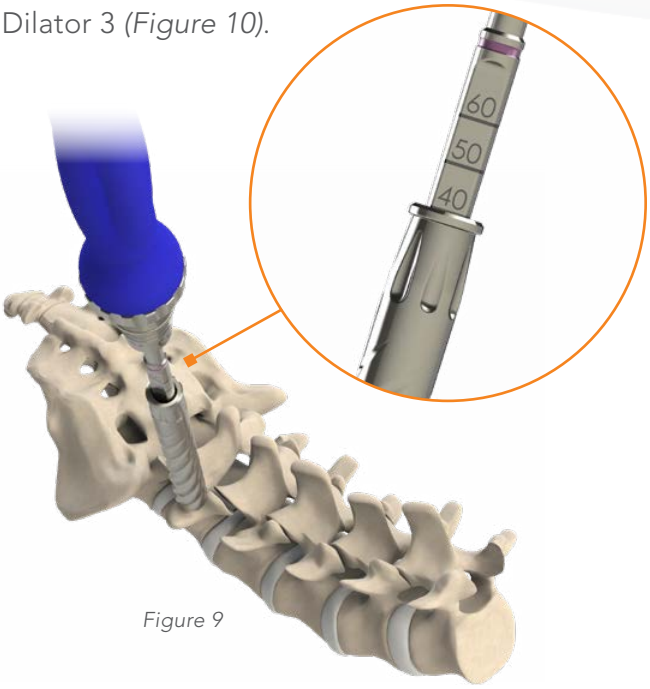

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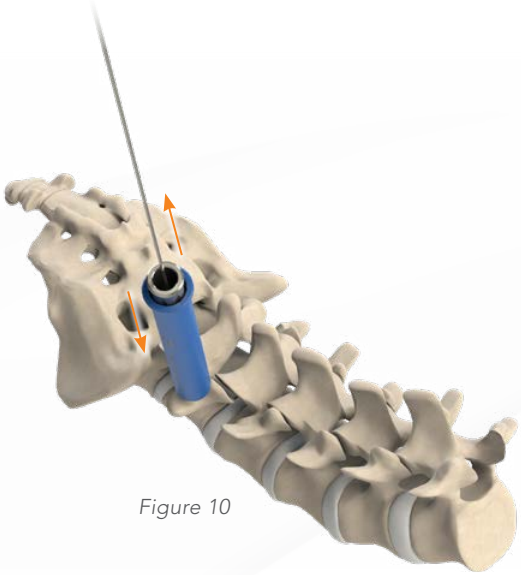


Figure 10

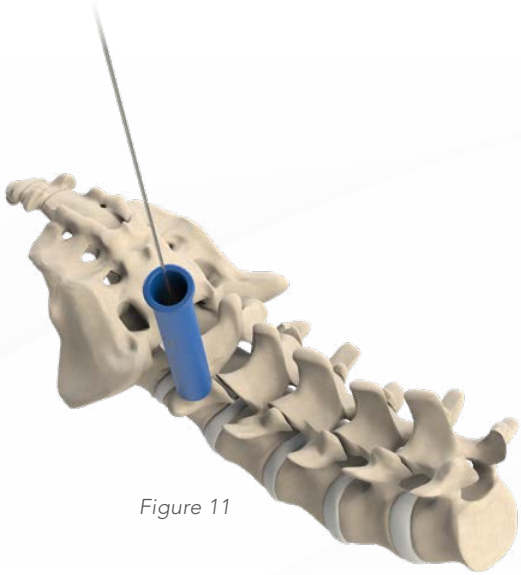


Figure 11

Alternative Option

The Palladian [MAX] MIS system offers a cannulated Awl for pedicle preparation. Advance the Awl till breaching the pedicle cortex *(Figure 12)*. Once positioned and confirmed under fluoroscopy, the Guidewire can be delivered. The Awl can then be removed while maintaining control of the Guidewire.

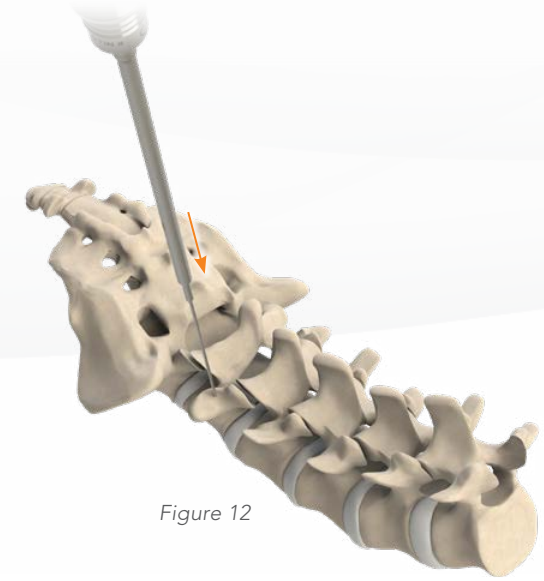


Figure 12

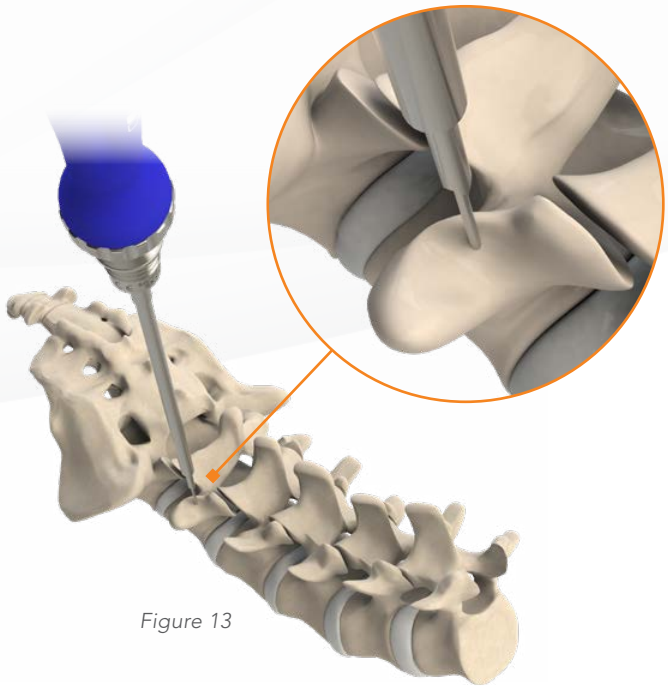


Figure 13

Caution: Use fluoroscopy to monitor guidewire advancement.

3 SCREW TOWER & DRIVER ASSEMBLY

Attach the Cannulated Locking Screw Driver to the preferred handle (axial or t-handle). Then insert the assembly into the Tower Screw until the tip of the Driver is fully engaged in the screw head *(Figure 14)*.

Turn the silver knob on the Cannulated Locking Screw Driver clockwise to thread the assembly to the Tower Screw *(Figure 15)*. After threading the assembly to the Tower Screw, press the buttons on the sides of the slide lock and it will spring down locking the screwdriver in place *(Figure 16)*.

To verify the screw is fully locked, ensure that the screw cannot be removed by pulling it away or rotating it.

Figure 14

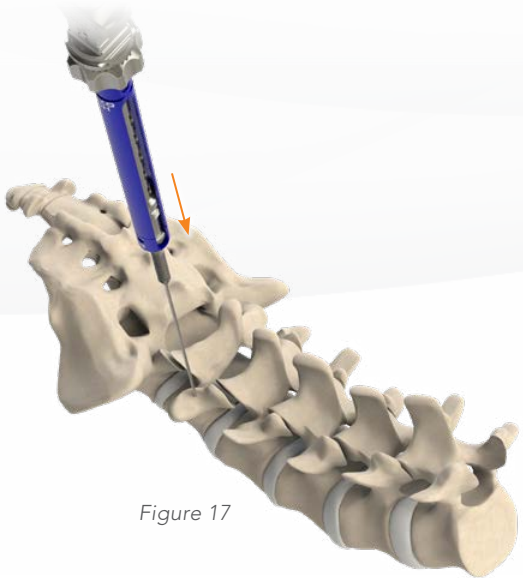
Figure 15

Figure 16

4 SCREW INSERTION

Guide the Tower Screw and Cannulated Locking Screw Driver assembly over the Guidewire and into the Pedicle *(Figure 17)*. Advance the Screw to the desired depth by turning the handle clockwise while using fluoroscopy to verify placement. After Screw placement, remove the Guidewire. To remove the Cannulated Locking Screw Driver, pull up on the locking tab until you hear an audible "click". You can then turn the silver knob counter-clockwise to remove it from the Tower Screw. Gently tug in an upward motion to remove the Driver assembly from the Tower *(Figure 18)*.

Repeat the steps above to place the second Tower Screw at the adjacent operable level.



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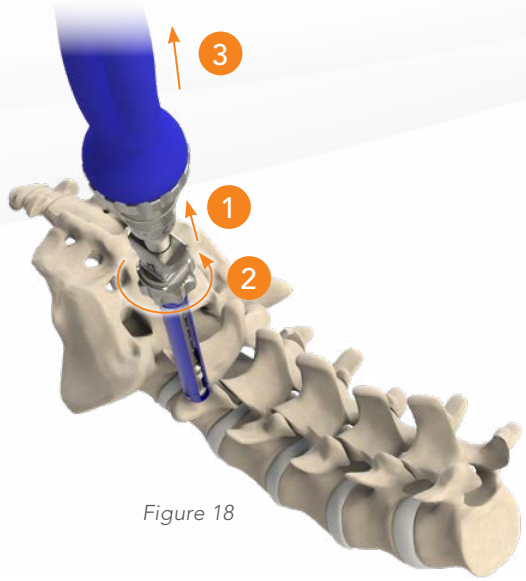

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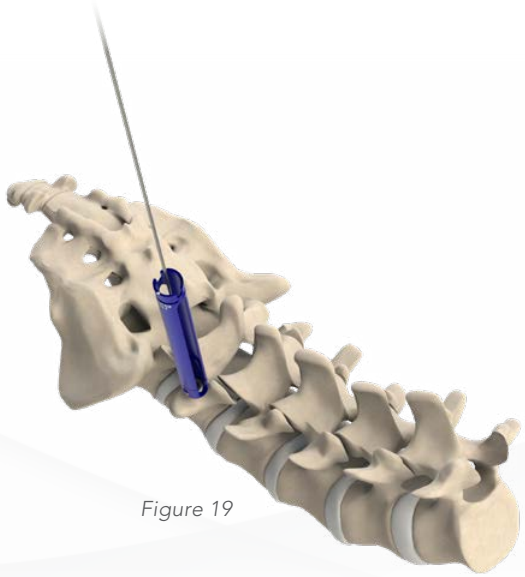


Figure 19

5 ROD MEASUREMENT

Aligning the Towers Screws and the Rod Gauge instrument will allow you to measure the exact length of the rod needed. Assemble the Rod Gauge to the proximal end of the towers *(Figure 20)*.

Based on the Tower Screw positions the pointer will indicate the appropriate rod length on the caliper *(Figure 21)*. Read rod measurement length from size marking on caliper, if the pointer falls between measurements the measurement should be rounded up to the next rod length. After determining the rod length, remove the Rod Gauge.

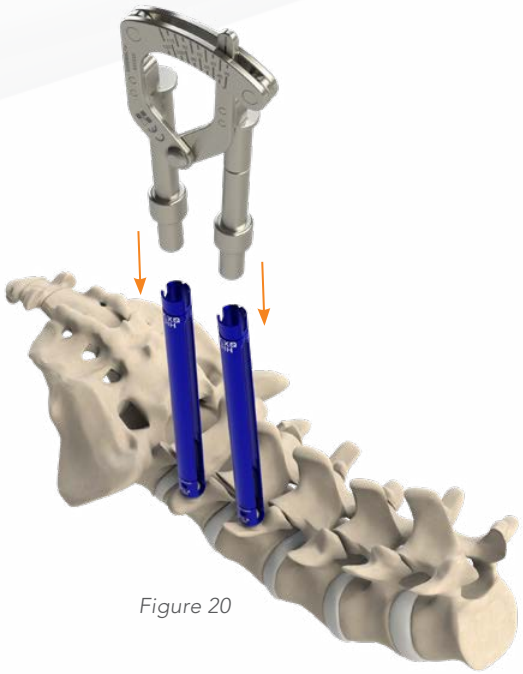


Figure 20

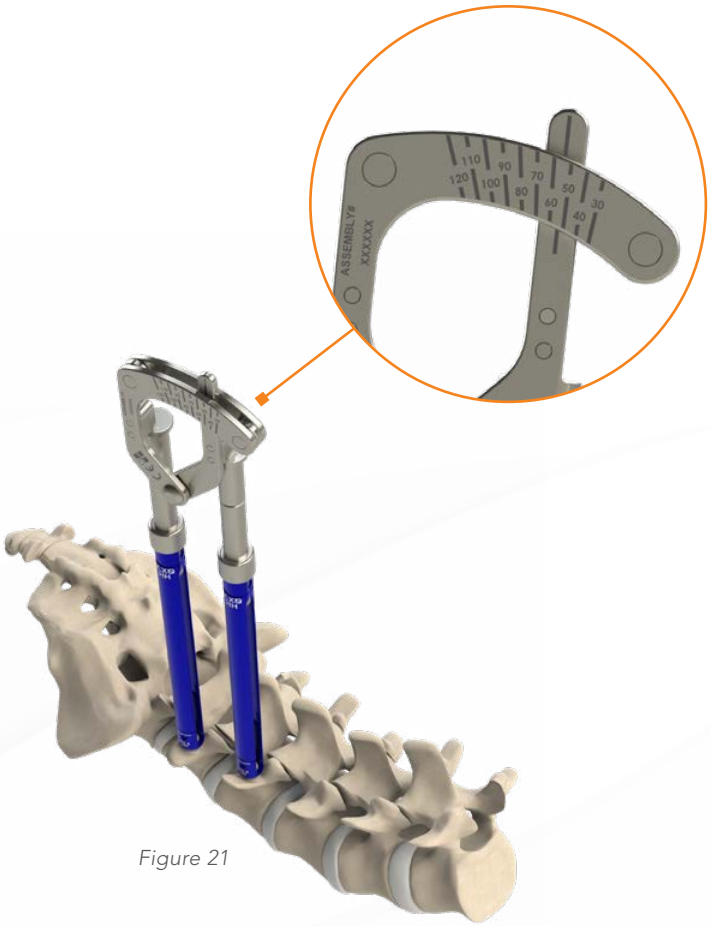


Figure 21

6 TISSUE PREPARATION

The Wanding Blade may be used to dissect interfering tissue to assist in rod placement.

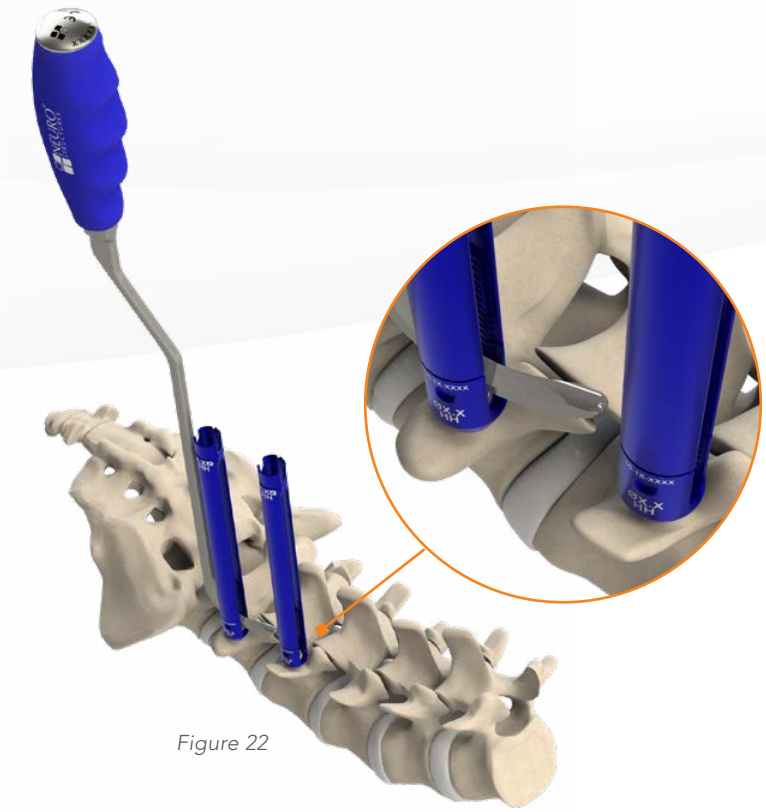


Figure 22

7 ROD INSERTION

Insert the rod end with the notch into the Rod Inserter. The flat side of the notch needs to be facing up *(Figure 23)*.

Once the rod is fully inserted into the Rod Inserter, use the Rod Inserter Locking Tool to tighten the locking screw by turning it clockwise *(Figure 24)*.

To verify the rod is fully locked, ensure that the rod cannot be removed by pulling it away or rotating it *(Figure 25)*.

Figure 23

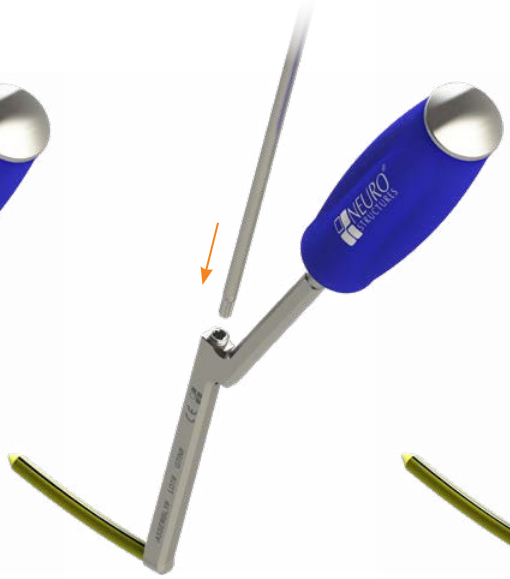


Figure 24

Figure 25

Advance the Rod Inserter down channel and seat rod into the polyaxial screw seat *(Figure 26)*. Confirm rod position using fluoroscopy.

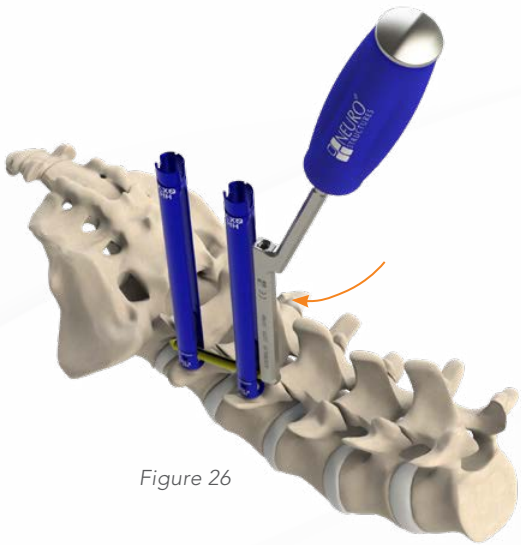


Figure 26

8 ROD PLACEMENT

Rod Gauge

Once the Rod Inserter with the rod attached are fully seated into the screw heads, insert the Rod Depth Gauge in the adjacent Screw Tower *(Figure 27)*.

If Rod Depth Gauge is not at zero, rod reduction will need to occur. Remove Rod Depth Gauge.

Figure 27

Note: If the rod is fully seated in the screw head and the Rod Depth Gauge reads zero, rod reduction will not be required.

Rod Reduction

The External Rod Reducer goes on the Tower Screw adjacent to the Tower Screw where the Rod Inserter was inserted *(Figure 28)*.

Align the "insert" etching on the Rod Reducer with the rod channel on the Tower Screw and slide the Rod Reducer down until it bottoms out *(Figure 28)*. When the alignment features are fully aligned, turn the Rod Reducer 90° clockwise *(Figure 29)*.

Once the Rod Reducer is in place, the outer sleeve can be inserted *(Figure 30)*. If additional torque is required, the t-handle may be used *(Figure 31)*.

Once the rod has been fully reduced, remove the External Rod Reducer.

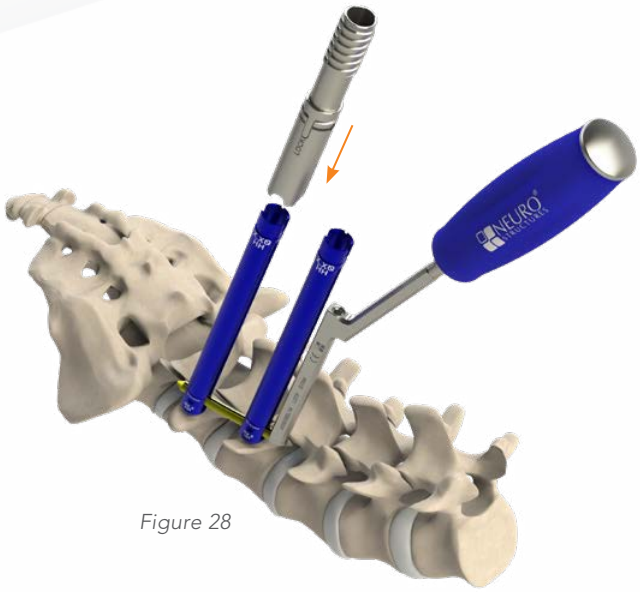
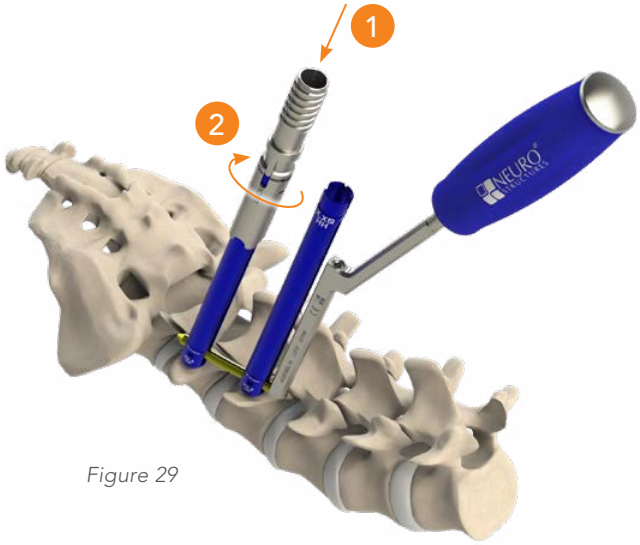


Figure 28



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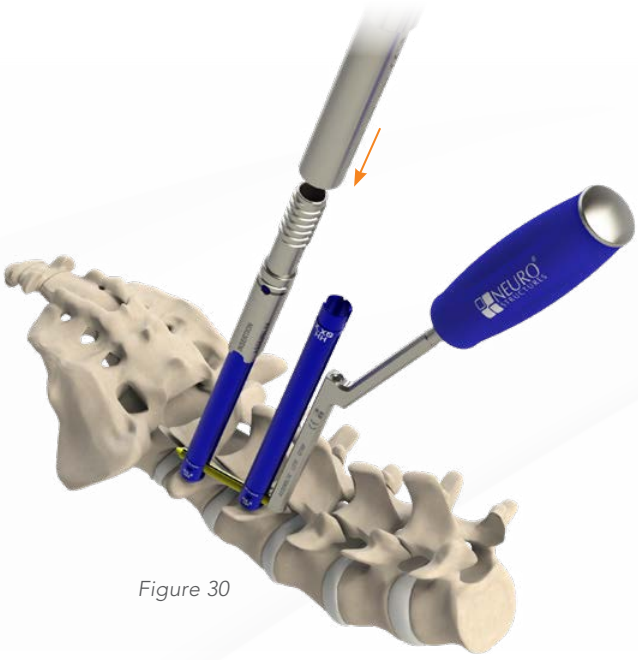

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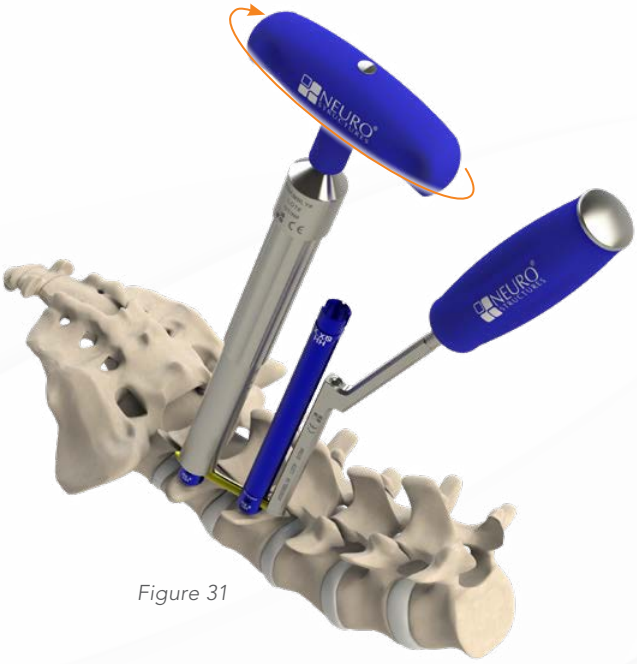


Figure 31

9 SET SCREW

Load the Set Screw from the caddy onto the Set Screw Starter and turn the silver knob on the end of the Set Screw Starter clockwise to tread it onto the Set Screw *(Figure 32 & 33)*.

Insert assembly into the Tower Screw adjacent the Tower Screw where the Rod Inserter was inserted *(Figure 34)*. Turn the Set Screw Starter clockwise to thread the Set Screw and capture the rod *(Figure 35)*.

Once Set Screw has been threaded into the screw head, turn the silver knob on the end of the Set Screw Starter counter-clockwise to release the Set Screw. Remove the Set Screw Starter *(Figure 35)*.

Figure 32

Figure 33

Figure 34

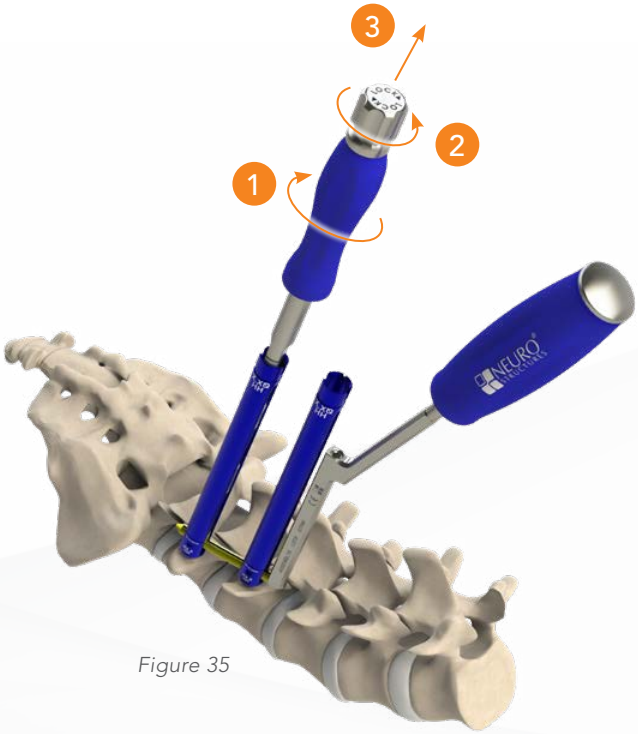


Figure 35

10 FINAL TIGHTENING

Slide the Counter Torque over the Tower Screw until it is fully engaged on the seat head *(Figure 36 & 37)*.

Assemble the Torque Limiting Handle to the Final Tightener. Guide the assembly through the Tower Screw held by the Tower Seat Counter Torque until it is fully engaged with the Set Screw *(Figure 38)*.

Turn the Torque Limiting Handle clockwise. Final tightening is achieved when the Torque Handle audibly clicks *(Figure 38)*.

Remove the Torque Limiting Handle assembly and Counter Torque. Repeat for all Set Screws.

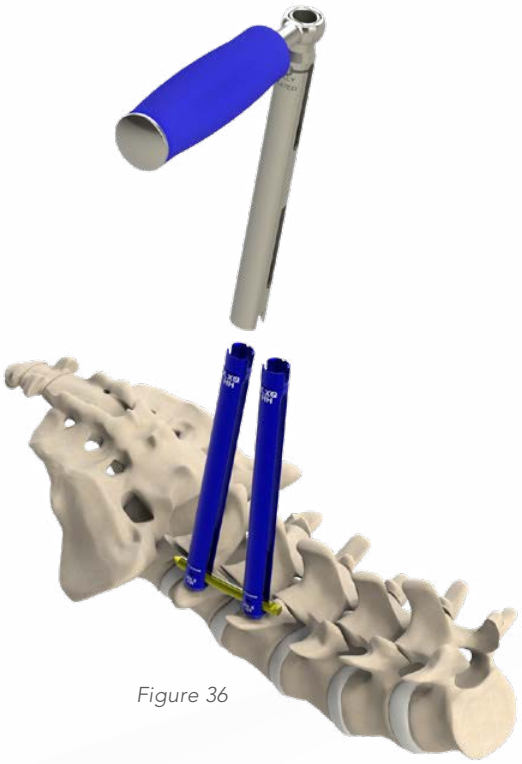
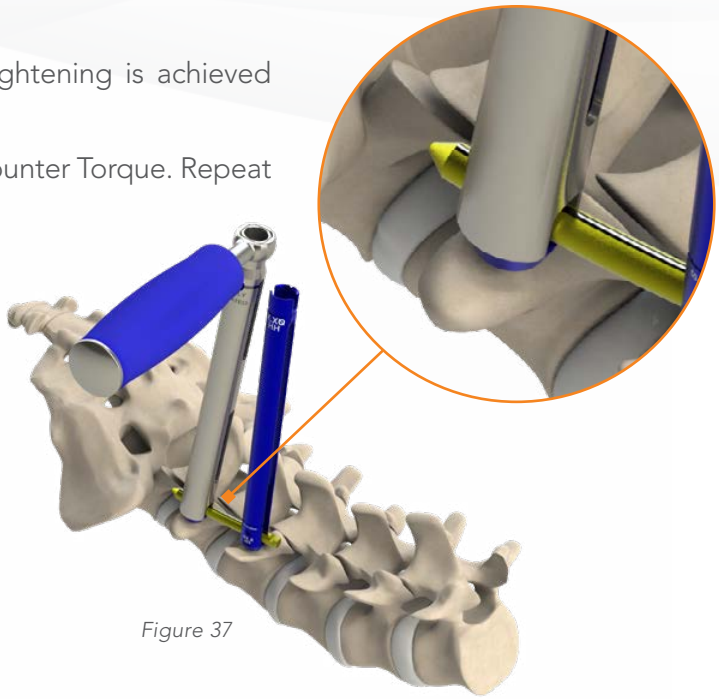


Figure 36



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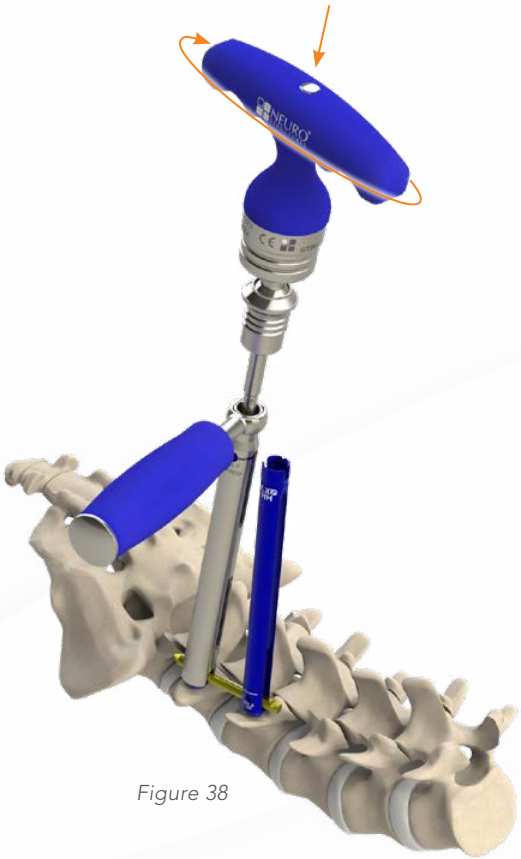
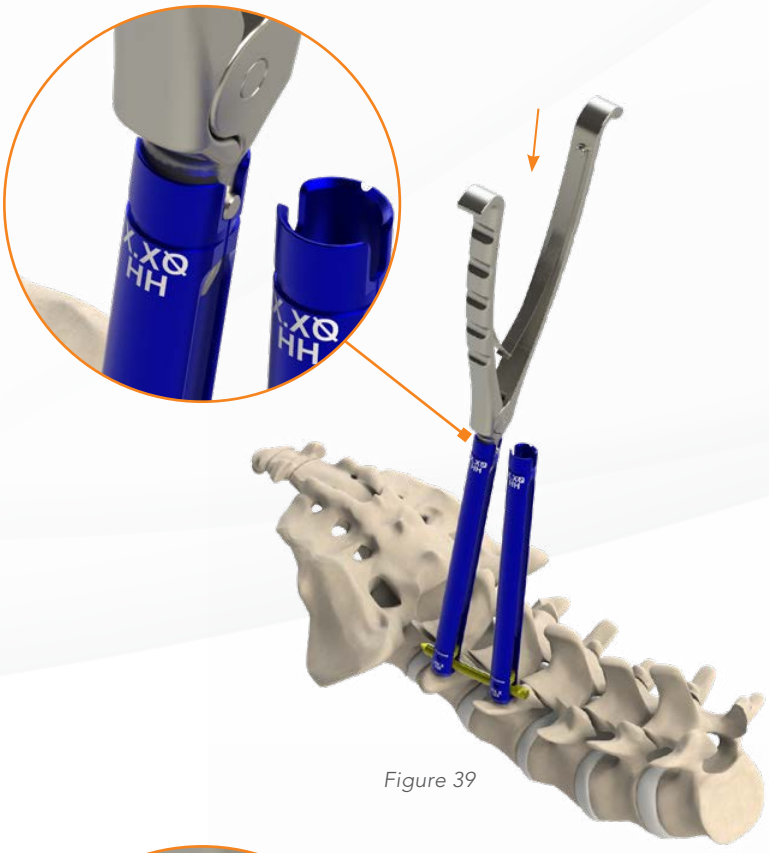


Figure 38

11 TAB REMOVAL

Insert the Tab Breaker into the top of the Tower Screw *(Figure 39)*. When the Tab Breaker has been fully inserter, compress the handle to seperate the Tower Screw tabs, breaking the connection on both side of the Tower Screw *(Figure 40)*.

Remove the Tab Breaker and repeat for all Tower Screws.



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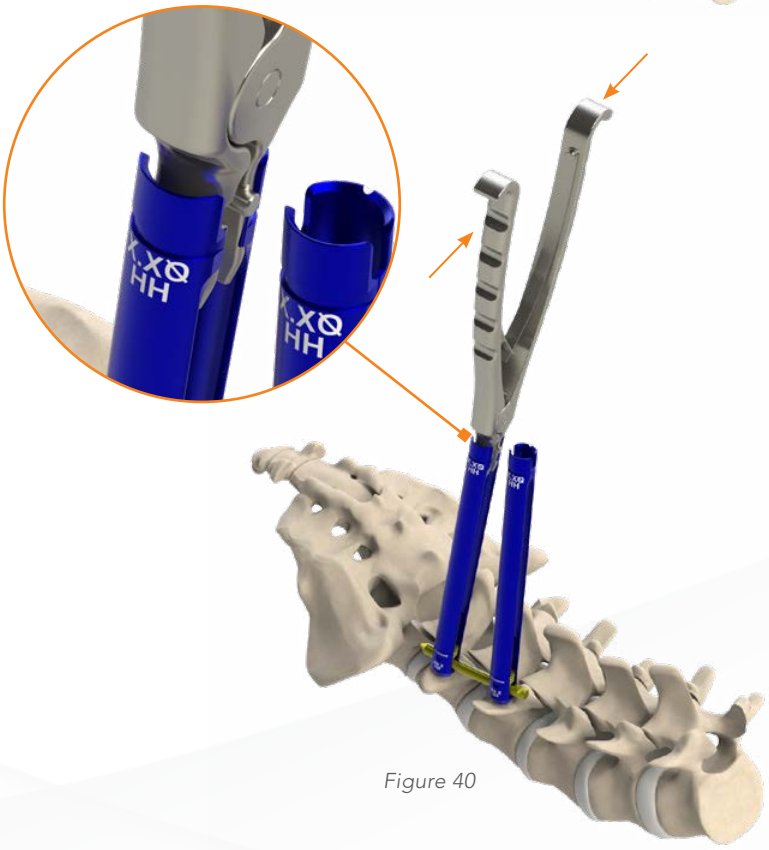
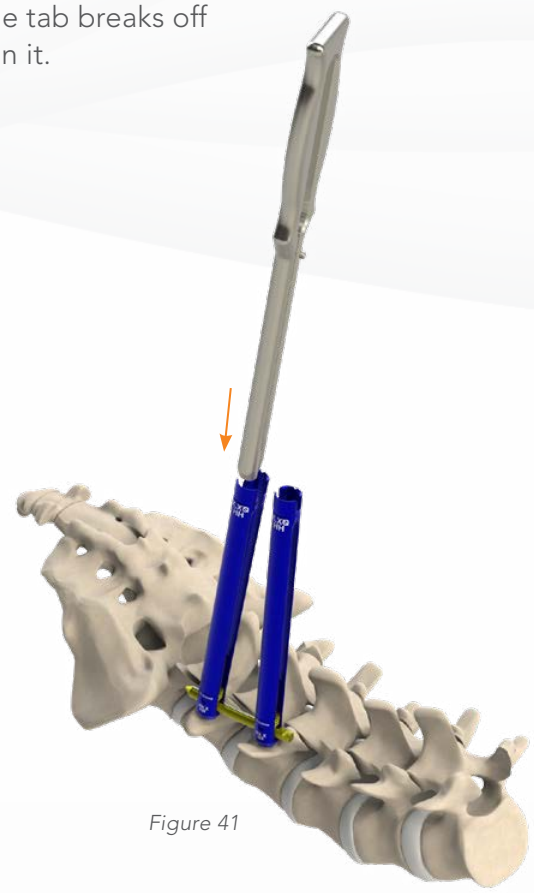


Figure 40

Place the Tab Remover over the tab *(Figure 41)*. Once the tab is fully captured in the Tab Remover, gently rock the tab back and forth until the tab breaks off from the Screw Head. Remove the Tab Remover with the tab in it.

Repeat for all tabs.



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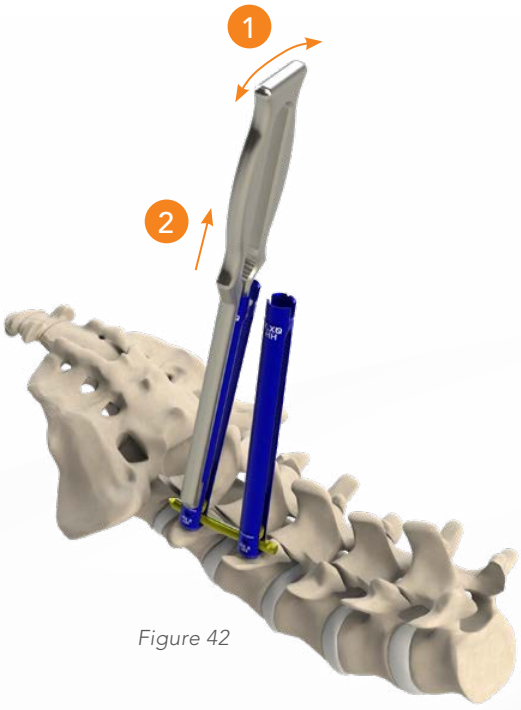

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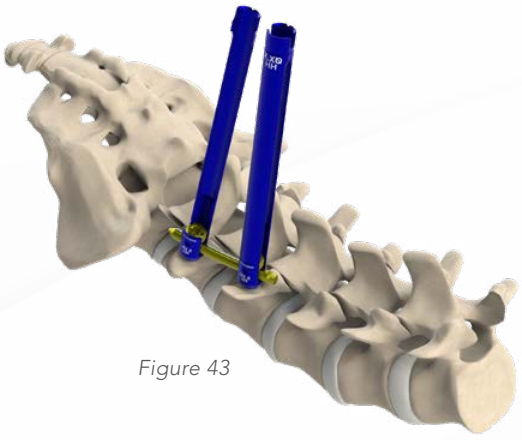


Figure 43

12 FINAL CONSTRUCT

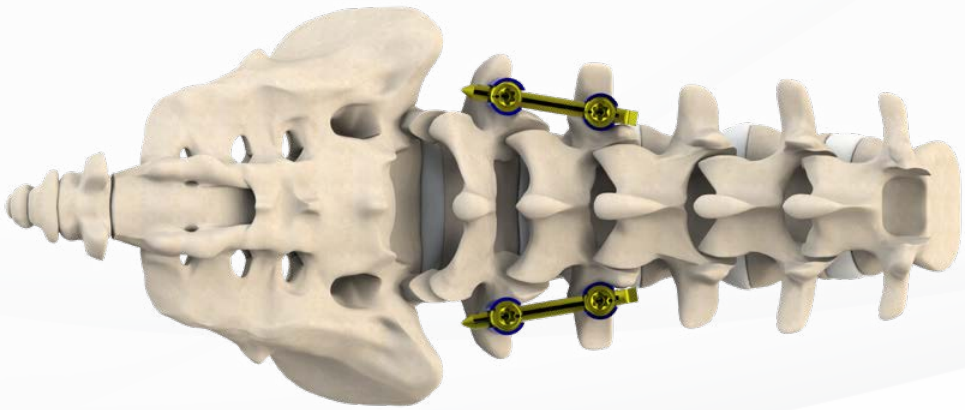


Figure 44

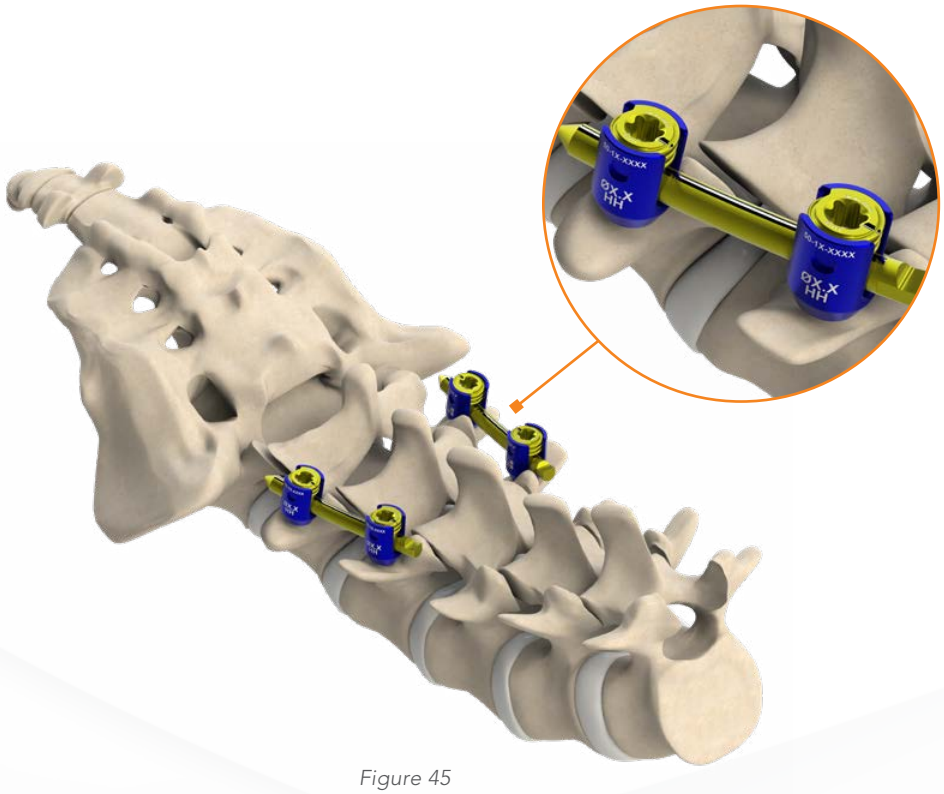


Figure 45

13 REVISIONS & REMOVALS

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 Starter *(Figure 46)*. The Rod Adjuster may be used to adjust or completely remove the preciously implanted rods *(Figure 47)*. Remove the pedicle screws using the Cannulated Locking Screw Driver tool *(Figure 48)*.

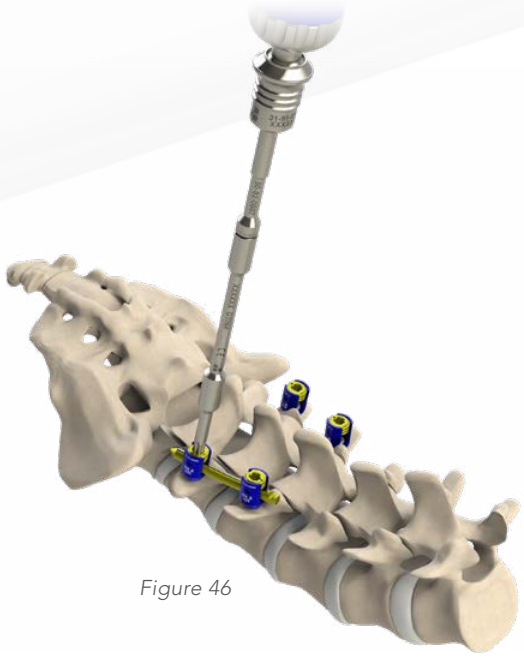


Figure 46

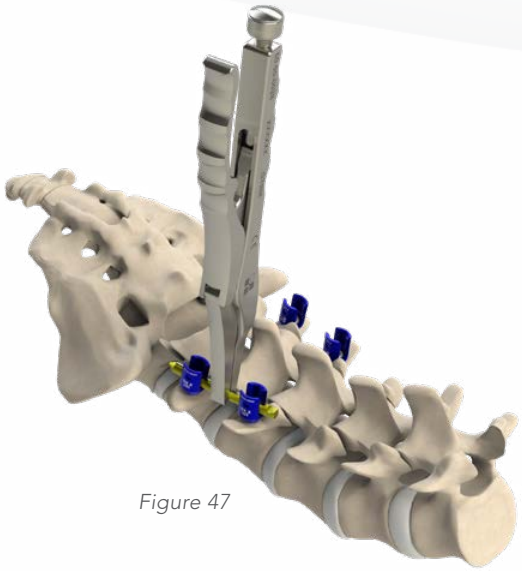


Figure 47

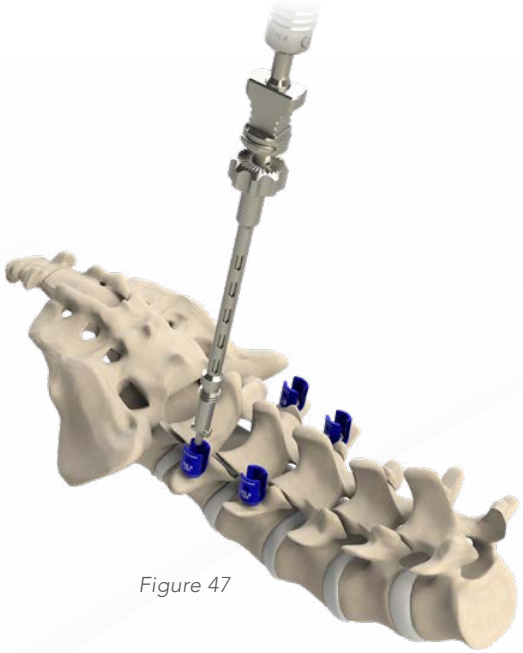


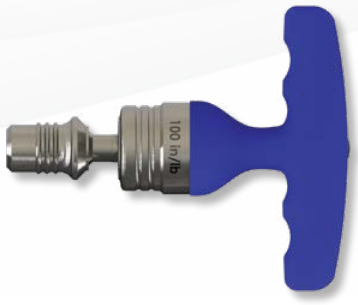
Figure 47

14 INSTRUMENTS

50-90-0011 | Axial Ratcheting Handle

50-90-0012 | Ratcheting T-Handle

50-90-0013 | Torque Limiting Handle



50-91-0006 | Dilator 1

50-91-0007 | Dilator 2

50-91-0008 | Dilator 3

50-91-0009 | EMG Sleeve

50-91-0010 | Obturator

50-91-0013 | Wanding Blade

50-91-0021 | Cannulated Awl

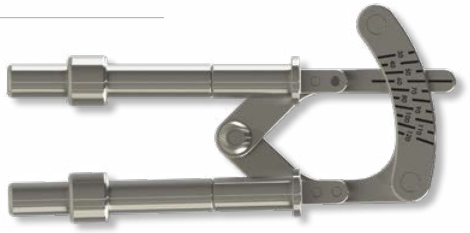
50-91-0024 | Threaded Non-Ratcheting Tear Drop Handle

50-91-0025 | Threaded Obturator

50-91-0026-XX | Cannulated Tap

50-91-0039 | Rod Inserter Locking Tool

50-91-0044 | Rod Gauge



50-91-0045 | Counter Torque

50-92-0001 | Screw Alignment Tool

14 INSTRUMENTS *(CONT.)*

50-92-0002 | Tab Breaker

50-92-0003 | K-Wire Holder

50-92-0004 | Rod Reducer Driver

50-92-0005 | External Rod Reducer

50-92-0006 | Set Screw Starter

50-92-0007 | Final Tightener

50-92-0010 | Rod Depth Indicator

50-92-0011 | K-Wire Driver

50-92-0012 | Rod Inserter

50-92-0013 | Sharp Guide Wire

50-92-0014 | Blunt Guide Wire

50-92-0015 | Compressor/Distractor

50-92-0016 | Cannulated Locking Screw Driver

50-92-0019 | Tab Remover

TNL0815 | Target Needle

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

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