EMINENT
SPINE

MIS Pedicle Screw System

Surgical Technique Manual

Step 1 : Patient Positioning

Place the patient in the posterior position. Confirm that there is enough clearance for a fluoroscopic C-arm to rotate freely for AP, oblique, and lateral views.

Step 2 : Pedicle Identification

The junction of the transverse process and superior articular facet is the typical landmark for entry into the pedicle. Anatomic variations in the individual patients may cause a slight difference of the entry site.

Make a small incision. Insert the Jamshidi Needle through the incision and dock the tip on the pedicle entry point at the intersection of the desired level's facet and transverse process (Figure 1).

Using both AP and lateral fluoroscopy, confirm that the appropriate pedicle starting point has been determined. Tap the Jamshidi Needle gently to engage the trocar tip in the pedicle.

Using AP fluoroscopy, progress the Jamshidi needle through the pedicle, guiding the tip towards the center of the pedicle. Starting from the lateral edge of the pedicle, the needle should not advance more than three-quarters of the way across the pedicle. Continue to advance the needle until it enters the vertebral body.

Use AP and lateral fluoroscopy to confirm placement and ensure that the Jamshidi Needle does not penetrate the pedicle wall.
Remove the Jamshidi Needle's inner stylet. (Figure 3)

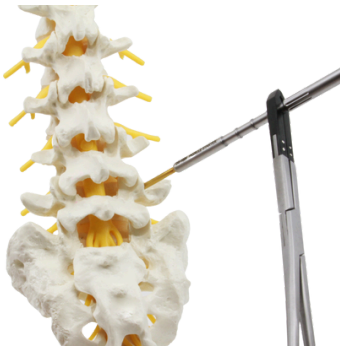


Figure 1

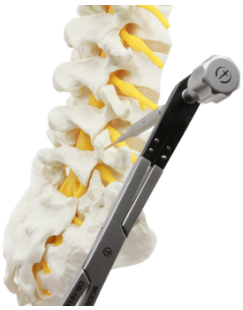


Figure 2

Figure 3

Step 3 : K-Wire Insertion

Insert the K-wire (Figure 4) through the MIS Target by hand or with the aid of the MIS Targeting tool (Figure 5). To ensure adequate fixation into the cancellous bone, extend the K-wire beyond the tip of the needle (approximately 20mm).

Confirm placement with AP and lateral fluoroscopy to ensure that the K-wire does not breach the pedicle or vertebral body wall.

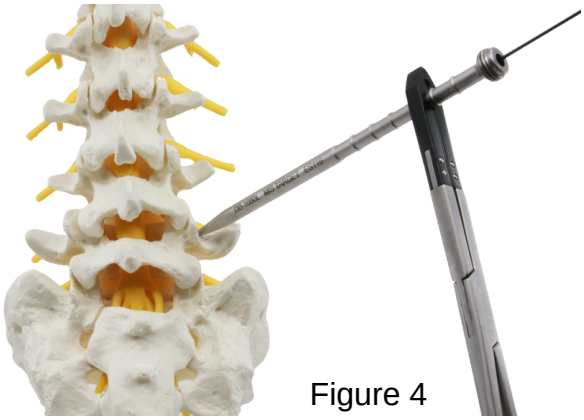


Figure 4

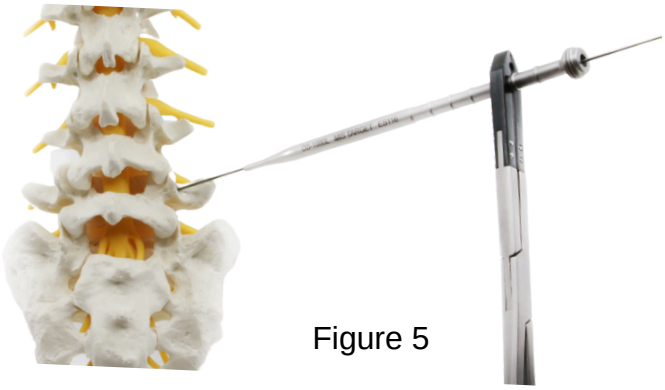


Figure 5

Once the K-wire has been placed to the desired depth, carefully remove the MIS Target while holding the K-wire in place. (Figure 6)

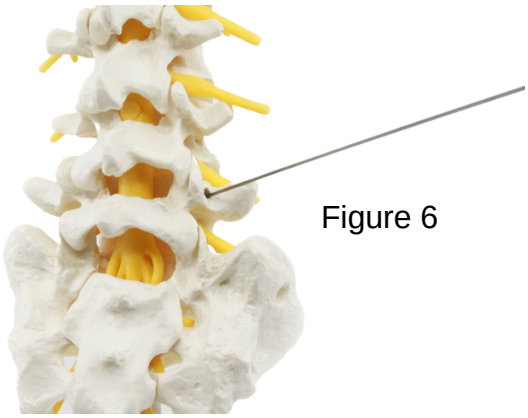


Figure 6

Step 4 : Tap

Insert the Tap over the K-wire (Figure 7).

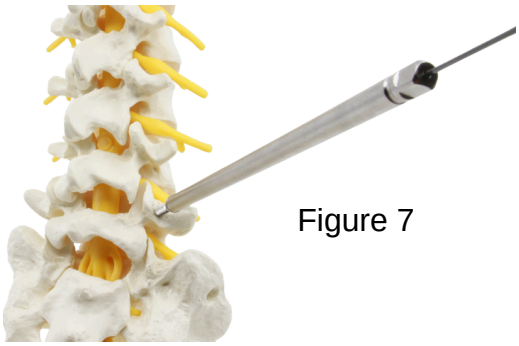


Figure 7

Step 5 : Dilation

Insert Dilator A over the K-wire through the tissue, twisting clockwise while directing it toward the pedicle, with the K-wire in place. Dilator A should be advanced through the thoracolumbar fascia until the tip of the tube is docked onto bony anatomy (Figure 8).
Using imaging, confirm the positioning of Dilator A.

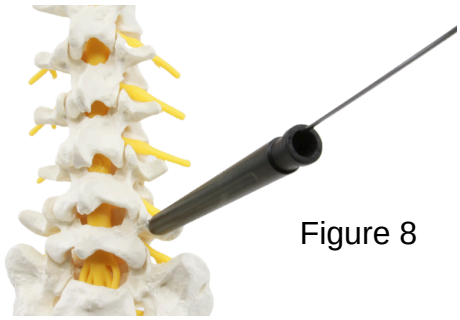


Figure 8

Dilator B should be slid over K-wire and Dilator A until the tube's tip is docked onto bony anatomy (Figure 9). Remove Dilator A with caution while keeping K-wire and Dilator B in place (Figure 10).

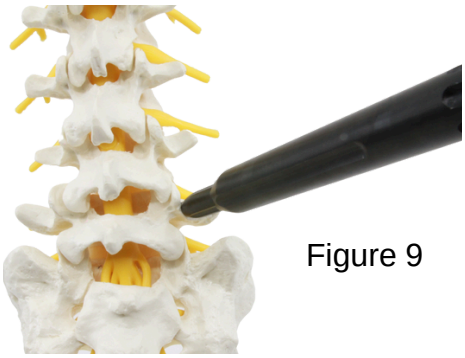


Figure 9

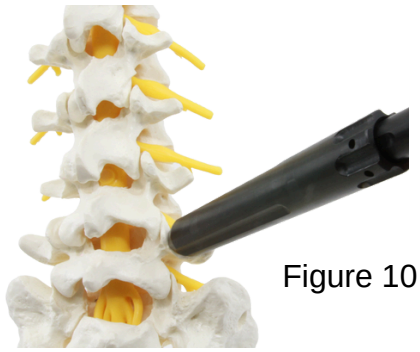


Figure 10

Step 6 : Screw Insertion

Connect the T-Handle ratchet to the Threaded MIS Screw Inserter. For screw insertion, set the handle to rotate clockwise (Figure 11).

Figure 11

Place the inserter into the Screw/Tower assembly and fully seat the tip into the hexalobe.

To secure the implant, rotate the primary locking collar clockwise (distal/wider collar), advancing the outer sleeve into the screw housing (tulip). Once the screw is securely fastened, depress the button on the secondary locking collar and slide it down until it comes into contact with the primary locking collar. The inserter has now been locked (Figure 12).

Figure 12

Advance the Tower/Screw assembly through Dilator B over the K-wire and into the prepared pedicle. The K-wire should be removed as soon as the Screw has passed through the pedicle and into the vertebral body (Figure 13).

Confirm screw depth using fluoroscopy. The Screw head (tulip) should not be fully seated against the bone to maintain full polyaxial capability.

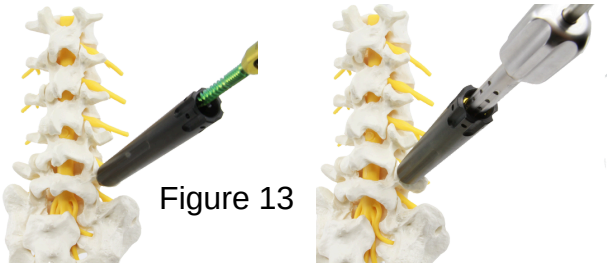


Figure 13

After inserting the screw to the desired depth, unlock the Screw Inserter by unscrewing the back spring-loaded outer shell. Pull the Inserter away from the tower by pulling upward. Rotate the tower in different directions to test its polyaxial capability. Then remove the K-wire (Figure 14).

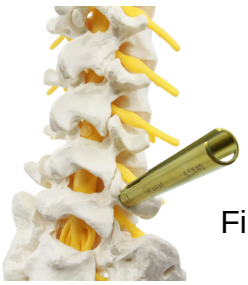


Figure 14

Step 6 : Screw Insertion Continued

Once all Screw/Tower assemblies have been installed, rotate the Towers as needed to ensure rod channels are oriented cephalad/caudal for rod insertion.

Rotate the Tower that will be used to introduce the Rod in the direction of Rod progression (Figure 15).

Check that the screw heads on a single level are all the same height. Check that the Screw heads replicate the curvature of the Pre-lordosed Rod in multi-level constructs.

Screw height can be confirmed using lateral fluoroscopy or by checking the alignment of the Towers' tops.

This process should be replicated for all necessary surgical levels.

Figure 15

Step 7 : Rod Measuring

Utilize the Rod Measuring Tool to ensure correct rod length for the construct (Figure 16).

Slide the Rod Measuring Tool into the Towers to the very bottom of each tower. The laser marking on both tool legs should be flush with the top of the tower. By lightly pulling up on the tool tips, you can check their retention within the screw housings (Figure 17).

Remove the tool from the towers and use to measure the correct rod, ensuring that there is the correct amount of overhang on each side (Figure 18).

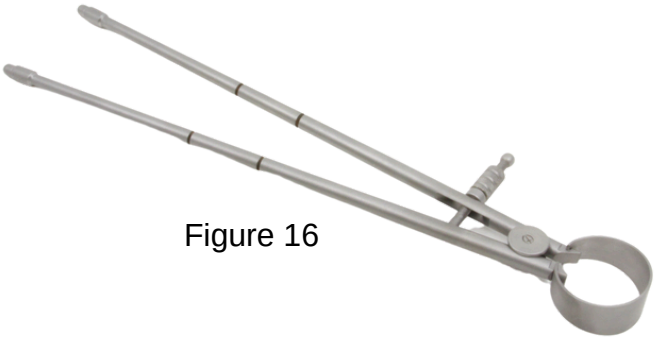
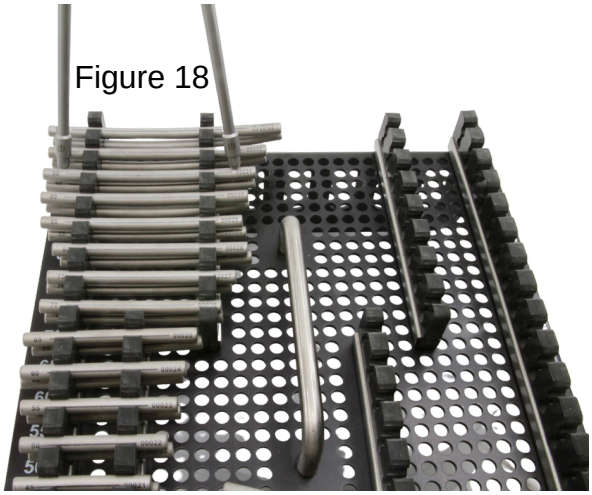


Figure 16

Before removal, adjust knob to confirm and record correct rod length.

Figure 17

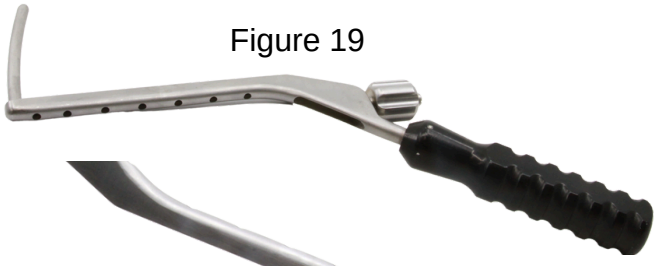
Figure 18



Step 8 : Rod Insertion

Once the correct rod is selected, connect to the Rod Inserter of your choice and tighten the knob (Figure 19).

Figure 19



Rotate the screw towers so that they are aligned for rod insertion.

Insert the rod in the towers at the desired depth, then ensure that the rod is rotated correctly. Confirm rod position frequently with fluoroscopy until the rod is in the correct position. A rod pusher may be used to push the rod further down the towers (Figure 20).

Figure 20

5.5mm straight and pre-bent rods are available in lengths starting at 40mm.

Step 9 : Set Screws

Three set cap starters are available to choose from. Once chosen, guide the cap starter into the set cap and press down to ensure proper connection (Figure 21). After this, the set caps are inserted into the threaded portion of the screw tulip. The set cap screws should not be fully tightened but should remain loose, so that the rod can be adjusted in the appropriate position. After the rod is in the correct position, one of the set screws should be provisionally tightened.

Figure 21

Step 10 : Compression/Distraction

If compression/distraction is needed, provisionally tighten one set screw, and slightly loosen the other set screw to allow for the rod to slide. The compression/distraction is accomplished to the correct frontal and/or sagittal plane, the set screw is provisionally tightened (Figure 22,23).

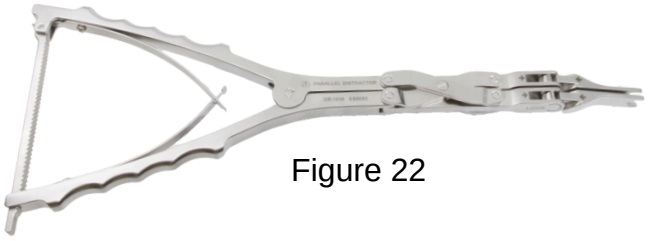


Figure 22

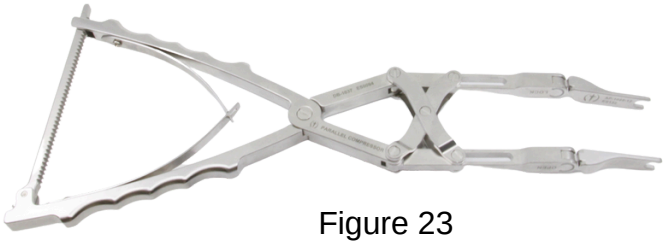


Figure 23

Step 11 : Final Tightening

The locking set screws are tightening to the rod using the counter-torque wrench, which is seated on the rod. The driver is then inserted through the counter-torque wrench onto the set screws. The final tightening device is a torque-limiting wrench preset to 10Nm. Turn the torque handle clockwise until a click is heard. The set screw is then fully tightened. Repeat on the remaining screws (Figure 24).

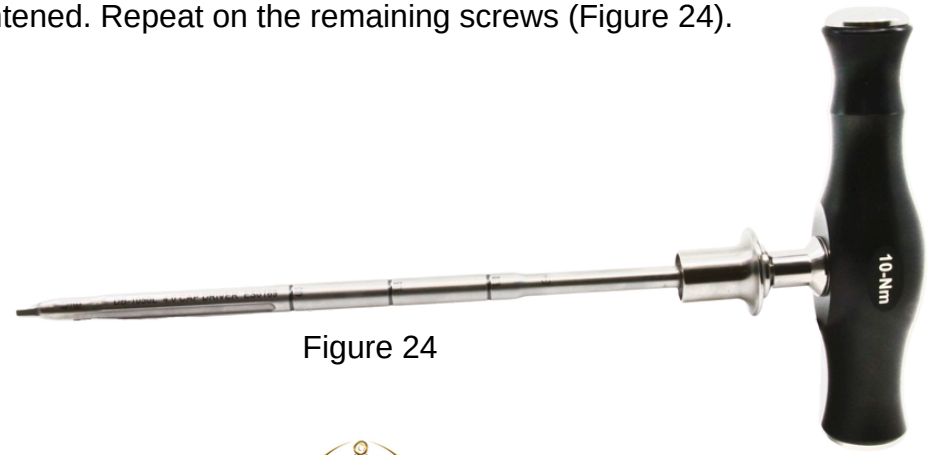


Figure 24

Step 12 : Tower Clip

Use the Tower Clip to break the top ridge of the pedicle MIS tower (Figure 25).

Figure 25

Step 13 : Tower Break

Push the tower break tool all the way down the tower and angle each side until the tulip snaps. Then pull out the tower break tool and remove the clipper off of the MIS tulip pieces (Figure 26).

Figure 26

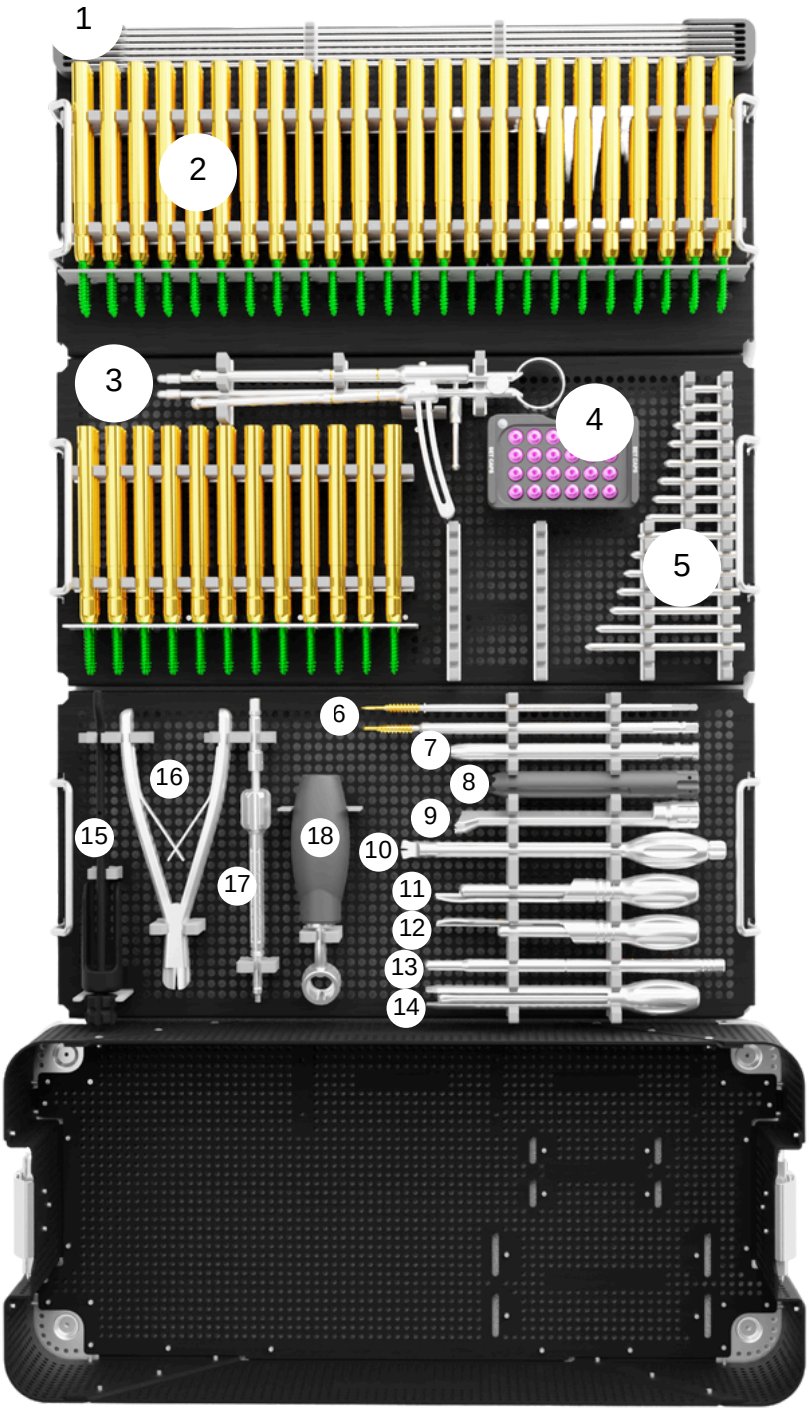
Step 14 : Closure

Wound closure is then performed in the customary manner.

Step 15 : Revision/Removal Procedure

Remove the set screws and lastly the pedicle screws. If revision is required, a larger diameter pedicle screw may be needed.

MIS Pedicle System Instrument Tray



Tray Layout:

1. K-Wires
2. MIS Pedicle Screws
3. Rod Measuring Tool
4. Set Cap Caddy
5. Rods
6. Taps
7. Dilator A
8. Dilator B
9. Facet Grinder
10. Fascia Cutter
11. Rod Pusher Right
12. Rod Pusher Left
13. Rod Checker
14. MIS Tulip Break
15. MIS-K Rod Inserter
16. MIS Tower Clip
17. MIS Threaded Inserter
18. Modular Handle

Diameter	Length
4.75 mm	25 – 60 mm
5.00 mm	25 – 60 mm
6.50 mm	25 – 60 mm
7.50 mm	25 – 60 mm

*5mm increments

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Eminent Spine LLC Pedicle Screw Systems:
Pedicle Screws and MIS Pedicle Screws

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System Contents

•Non-Sterile Implants – Single Use Only
•Non-Sterile Instruments - Reusable

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Carefully read all instructions and be familiar with the surgical technique(s) prior to using this product.

DESCRIPTION:
The Pedicle Screw Spinal System consists of rods; monoaxial and polyaxial pedicle screws with caps, locking set screws, and cross connectors with lock screws. Rods are available either straight or pre-contoured in a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations. The MIS Pedicle Screw Spinal system consists of rods, polyaxial screws with extended caps, and locking set screws. Rods are available pre-contoured in a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations.

INDICATIONS:
The Pedicle Screw and MIS Pedicle Screw Spinal Systems are designed to provide immobilization and stabilization to the thoracic, lumbar, and sacral spinal segments as an adjunct to fusion. The system is intended for posterior, pedicle fixation in skeletally mature patients for the treatment of the following acute and chronic instabilities or deformities: severe spondylolisthesis (grades 3 or 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor, pseudoarthrosis and failed previous fusion.

CONTRAINDICATIONS:
1. Active systemic infections or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to Titanium alloy 6Al-4V material.
3. Severe osteoporosis is a relative contraindication because it may result in implant subsidence and loss of fixation.
4. Any condition that significantly affects the likelihood of fusion may be a relative contraindication (e.g. cancer, diabetes, osteomalacia, heavy smoker, morbid obesity) and the surgeon must evaluate the relative risks and benefits individually with each patient.
5. Other relative contraindication may include mental illness, drug abuse or alcoholism as these may cause the patient to be non-compliant with post-operative guidance (e.g. bracing and physical therapy).
6. Prior fusion at the levels to be treated.
7. Any condition not described in the indications for use.

MATERIALS:
The implants for pedicle screw systems are manufactured from Titanium alloy 6Al-4V material. Surgical instruments provided with the pedicle screw systems are manufactured from stainless steel.

CLEANING of INSTRUMENTS and IMPLANTS:
1. Clean all instruments and implants prior to use, and as soon as possible after use. Do not allow blood or debris to dry on the instruments that were used in surgery. If cleaning must be delayed, place instruments that were used in surgery in a covered container with neutral pH detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts. Remove implants (in caddies) from set cases.
3. Immerse the instruments and implants in a neutral pH detergent or enzymatic solution prepared in accordance with the manufacturer's instructions and soak for 15 minutes.
4. Use a soft-bristle brush and a pipe cleaner to gently clean each instrument and implant (particular attention shall be given to cannulations, holes, and other hard-to-clean areas) until all visible soil has been removed.
5. Rinse the instruments and implants in running water for at least 3 minutes. Thoroughly flush cannulations, holes, and other hard-to-clean areas.
6. After manual cleaning has been completed, load the parts into a suitable automated cleaner and follow the manufacturer's recommended practices. Use only neutral pH enzymatic cleaners and detergents. Avoid excessively acidic or alkaline solutions.

INSPECTION:
1. Carefully inspect each instrument to ensure all visible blood and soil has been removed.
2. Inspect instruments and instrument cases for damage. Check action of moving parts to ensure proper operation, and ensure disassembled instruments readily assemble with mating components.
3. If damage or wear is noted that may compromise the proper function of the instrument or instrument case, do not use and contact customer service or your Eminent Spine LLC representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your Eminent Spine LLC representative for a replacement.

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STERILIZATION:

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use. The following are the recommended sterilization cycles for both systems:

Method: Steam
Cycle: Pre-Vacuum
Temperature: 270oF (132oC)
Exposure Time: 4 minutes
Number of Pulses: 4

Drying Time:
Pedicle Screw 30 minutes
MIS Pedicle Screw 40 minutes

Implants and instruments should be positioned to allow the steam to come into contact with all surfaces. All jointed instruments should be in the open or unlocked position with ratchets not engaged.

Instruments composed of more than one part or with sliding pieces or removable parts should be dissembled.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Cases (including instruments and implants) used in surgery should be cleaned and re-sterilized after surgery. Implants should not be used as templates in surgery. If an unused implant entered the surgical wound it should be cleaned and re-sterilized after surgery.

•Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
•Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
•Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: A4 2013 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
•For terminally sterilized devices, only FDA-cleared sterilization barriers (e.g., wraps, pouches, containers) should be used for packaging.

POSTOPERATIVE MOBILIZATION:

The surgeon should advise the patient to be careful not to place significant loads on the spine for the first three months after surgery. The surgeon may advise the patient to limit their activity or wear a brace. Careful management of the load will enable the fusion mass to heal and reduce the likelihood of non-union. Radiographic confirmation of a mature fusion mass may be as a guide in the lifting of these restrictions.

WARNINGS:

Following are specific warnings, precautions, and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general but are important considerations particular to spinal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 or 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal stenosis, scoliosis, kyphosis, lordosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
2. Patients with prior spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
3. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   a) A patient may have multiple pain generators due to advanced degeneration of the spine (e.g. intervertebral disc. Facets or bony stenosis). These conditions may be present at the index or adjacent levels. Careful review of the clinical record including radiographic studies and applicable diagnostic tests should be performed to make the appropriate diagnosis. Concomitant conditions may reduce the effectiveness of the surgery and should be discussed with the patient.
   b) The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the implant or subsidence.
   c) The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause failure of the implant.
   d) Patients that are non-compliant with postoperative guidance may place too much stress on the implant in the early postoperative period and compromise the maturing fusion mass.
   e) Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used.
   f) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

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PRECAUTIONS:

1. THE IMPLANTATION OF SPINAL FIXATION DEVICES SHOULD BE PERFORMED ONLY BY EXPERIENCED SURGEONS WITH SPECIFIC TRAINING IN THE USE OF SUCH DEVICES. THIS IS A TECHNICALLY DEMANDING PROCEDURE PRESENTING A RISK OF SERIOUS INJURY TO THE PATIENT.
2. PROPER SIZING OF THE IMPLANTS IS IMPORTANT. Based upon the fatigue test results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
3. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted spinal fixation device should never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to early breakage.
4. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. The operating surgeon should avoid any notching or scratching of the device during surgery. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
5. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the body's response to the implant and how the fusion mass is expected to develop. A patient that is noncompliant with postoperative guidance is particularly at risk during the early postoperative period.
6. MAGNETIC RESONANCE ENVIRONMENT. The Eminent Spine LLC Pedicle Screw Systems have not been evaluated for safety and compatibility in the MR environment. The Pedicle Screw Systems have not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS:

1. Nonunion, delayed union.
2. Bending or fracture of implant.
3. Anterior or posterior migration of the implant.
4. Allergic reaction to a foreign body.
5. Infection.
6. Decrease in bone density due to stress shielding.
7. Pain, discomfort, or abnormal sensations due to the presence of the device.
8. Loss of proper spinal curvature, correction height and/or reduction.
9. Vascular and/or nerve damage due to surgical trauma or presence of the device. Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paresthesia.
10. Paralysis.
11. Death.

LIMITED WARRANTY:

Eminent Spine LLC products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact Eminent Spine LLC for current information.

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For product information or questions pertaining to sales and service, please contact your local sales representative or Eminent Spine LLC customer service.