

EUROPA™

Pedicle Screw System
4.5mm

Surgical Technique Guide



SURGICAL TECHNIQUE

Open Surgical Procedure

Patient Positioning

Place the patient on a radiolucent operating table in the prone position. Drape the patient for posterior spinal fusion.

Pedicle Preparation

Prepare the Pedicle

Make an incision to expose the pedicles that will be instrumented during surgery. Clean the facet joints and remove the inferior facet and the articular cartilage on the superior facet. Identify the intersection of the mid-portion of the transverse process and the pars interarticularis to locate a starting point for each pedicle screw.

At each starting point, use the supplied Bone Awl to breach the cortical exterior of the instrumented vertebrae (Figure 1).



Figure 1

Create Intrapedicular Path

Use a Pedicle Probe to create a path through intrapedicular cancellous bone by advancing the probe through the pedicle and into the vertebral body (Figure 2).

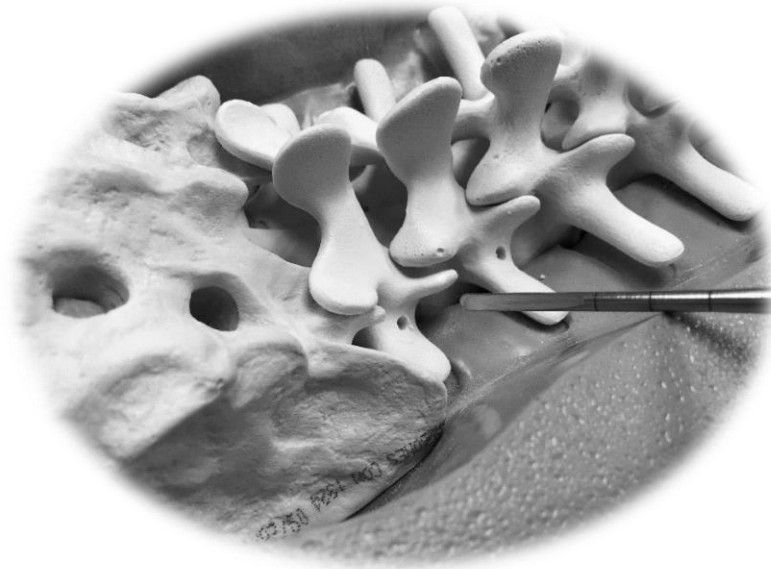


Figure 2

Confirm Pedicle Integrity

Remove the Pedicle Probe and use the flexible ball-tipped Pedicle Sounder to determine the integrity of the medial, lateral, anterior and posterior walls, as well as the base of the hole created by the probe. If observation reveals a breached pedicle, use the probe again, this time with a different trajectory to mitigate any further cortical breach. With the ball tipped Pedicle Sounder, confirm the integrity of the planned pedicle screw path (Figure 3). Clamp forceps to the exposed shaft of the sounder to determine the length of the hole.



Figure 3

Tap the Pedicle

Appropriate screw diameter and length are determined by a combination of preoperative planning, measurement, and intraoperative observation. Tap the pedicle with a diameter approximately 1mm under the planned screw diameter by rotating the tap clockwise (Figure 4). After reaching the desired depth, remove the tap by rotating counterclockwise, maintaining the integrity of the track prepared by the tap's threads. Next, use the pedicle sounder to confirm the integrity of the tapped threads in the interior of the pedicle.

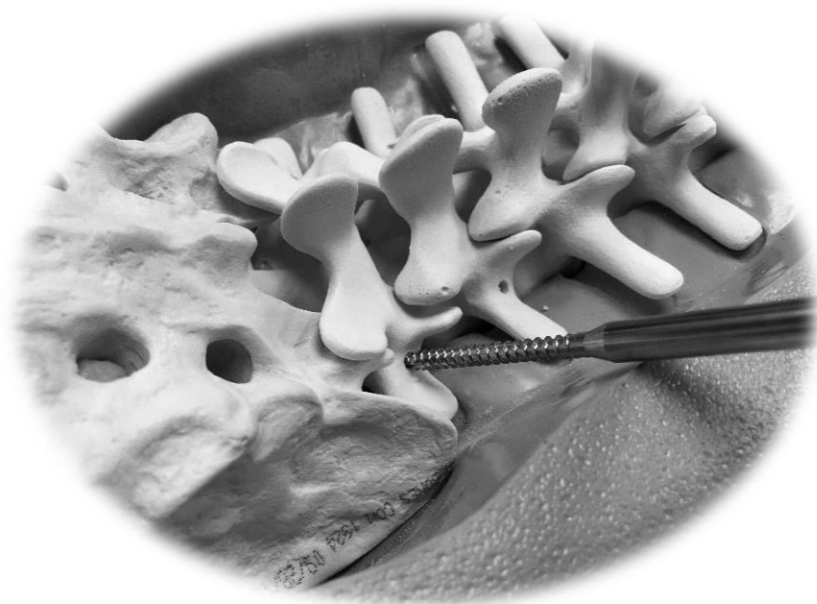


Figure 4

Screw Placement

Inserting the Pedicle Screws

Assemble the appropriately sized polyaxial screw onto the Pedicle Screwdriver by aligning the male T25 hexalobe of the screwdriver with the female T25 hexalobe of the screw. Assemble the Pedicle Screwdriver into the Quick Connect handle and thread the retention sleeve of the Pedicle Screwdriver into the screw head and hand-tighten to eliminate screw toggle. Advance the screw down the prepared pedicle until it is seated in the bone with the correct dorsal height (Figure 5). Release the driver from the polyaxial screw by turning the retention sleeve counterclockwise while holding the driver shaft in a fixed position. Instrument each level as needed and check screw positioning radiographically to ensure proper screw placement.



Figure 5

Rod Placement

Prepare & Insert the Rod

Once all screws have been placed and their positions verified radiographically, determine the appropriate lordosis and rod length required for optimal correction. Straight and Lordosed rods are offered standard in the set. If neither of these suffice as is, use the supplied rod benders to achieve the lordosis desired (Figure 6). Insert the rod into the tulip openings of the pedicle screws using the rod holder (Figure 7).



Figure 6

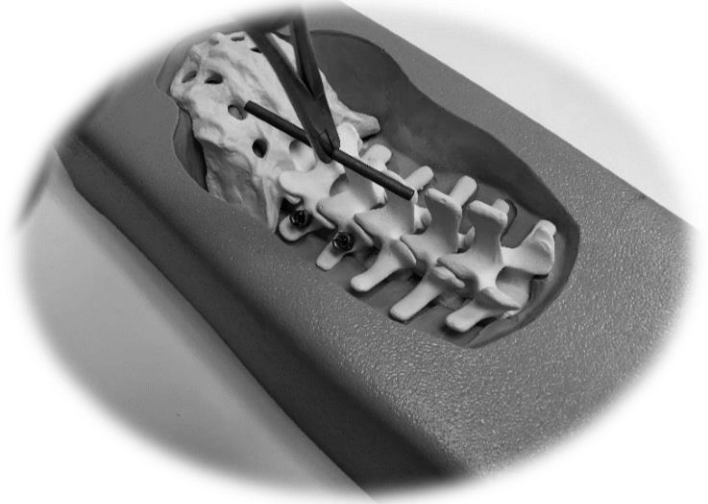


Figure 7

 Note: Reverse bending can weaken the rod and is not recommended.

Set Screw Placement

Secure Set Screws on the Set Screw Starter by firmly pressing down the Male T25 hexalobe into the Female T25 hexalobe of the Set Screw to remove it from the caddy. Turn the set screw starter clockwise to introduce the set screw into the polyaxial screw heads and provisionally tighten.

⚠ *Note: Provisional tightening is classified as hand tightening while not fully locking the screw head into place.*

Rod Reduction (If Necessary)

If rod reduction is necessary, the Head turner can be used as a rod pusher to allow for the rod to be seated and allow for the insertion of the set screw for provisional tightening.

Compression and Distraction

After provisionally securing the rod to EUROPA™ implants, distraction (Figure 8) and compression (Figure 9) can be performed to translate implants axially along the rod.

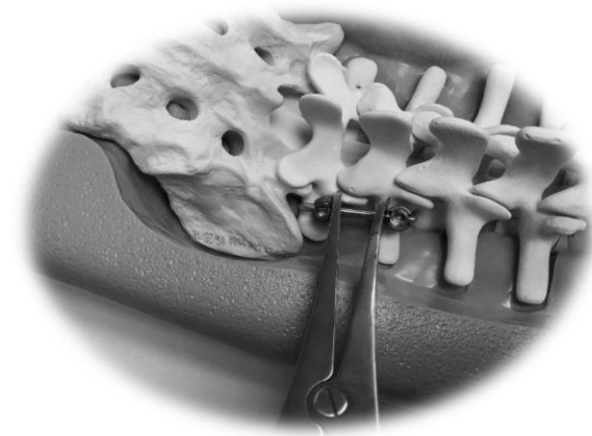


Figure 8

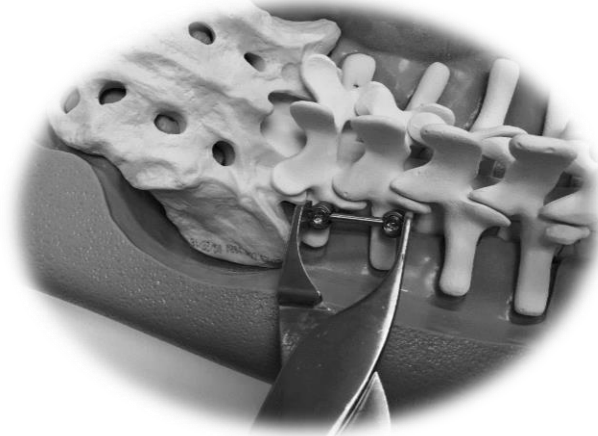


Figure 9

Final Tightening

Place the Counter Torque over the pedicle screw that is to be final tightened ensuring the notches on the distal end are engaged with the rod. Insert T25 Driver into the Torque limiting T-handle set to 75 in-lb. of torque. Engage the female T25 of the set screw and torque the T-handle while maintaining counter torque on the rod until it clicks indicating the final tightening torque was reached (Figure 10). Repeat these steps on the entire construct.

⚠ Note: Once the device has been fully tightened, it cannot be loosened and re-tightened. Loosening of the fully tightened device during implantation can damage the device and cause a reduction in strength.



Figure 10

Optional Cross Connector

A cross connector may be added to the construct at this point to increase structural rigidity if desired. To do this, choose the appropriate size based on the distance between the two rods. Place the cross connector on the rods ensuring the hooks are fully engaging the rods. Insert the T20 Driver into the Torque limiting T-handle set to 25 in-lb. of torque. Engage the female T20 of the first rod lock screw and torque the T-handle until it clicks indicating the final tightening torque was reached. Repeat these steps on the second rod lock screw, and finally the center length adjustment screw.

Removal or Revision

If removal or revision is necessary, the EUROPA™ Pedicle Screw System can be removed using a T-25 hexalobe driver. To do this, insert the T-25 driver into the Set Screws and rotate counterclockwise and remove the set screws and rods from the construct. Next, use the T-25 Driver to engage the pedicle screws and rotate them counterclockwise until they are fully removed from the pedicle.

SURGICAL TECHNIQUE

Minimally Invasive Surgical (MIS) Procedure

Patient Positioning

Place the patient on a radiolucent operating table in the prone position. Drape the patient for posterior spinal fusion.

Incision and Exposure

Make an incision to allow for the introduction of a Jamshidi for all the pedicles that will be instrumented in the pedicle screw construct. Use radiographic imaging to find the optimal trajectory for the Pedicle Screw and create a pilot hole in the pedicle with the Jamshidi (Figure 11). Remove the inner needle and place the guide wire down the cannula of the Jamshidi, anchoring it into the bone (Figure 12). Once the guide wire is in place the Jamshidi can be removed using care to not dislodge the guide wire (Figure 13).

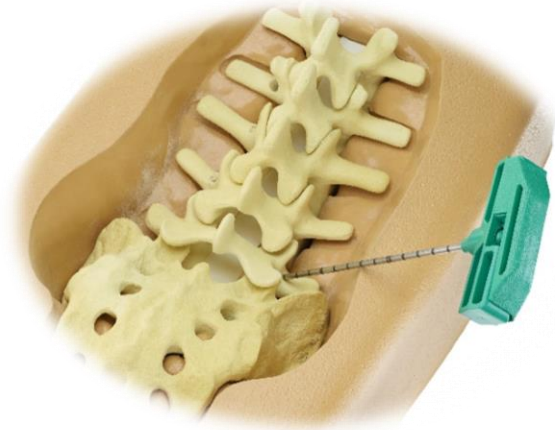


Figure 11

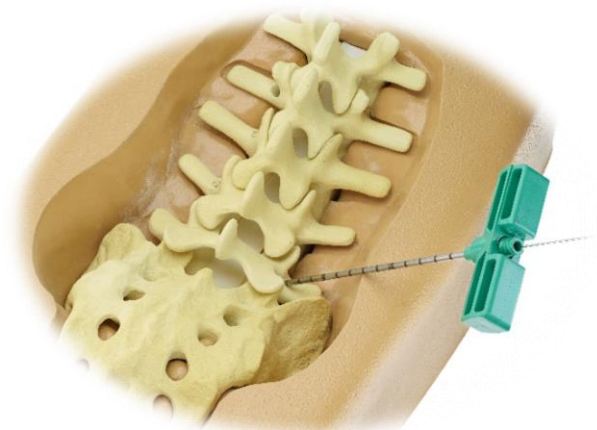


Figure 12

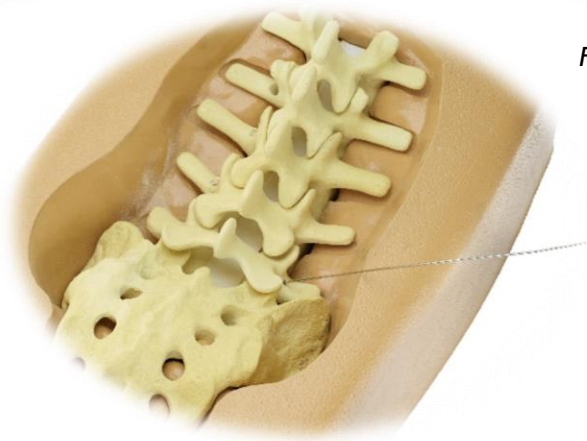


Figure 13

Tap the Pedicle

Appropriate screw diameter and length are determined by a combination of preoperative planning, measurement, and intraoperative observation. Place the dilator over the guide wire until it reaches the pedicle, followed by the tap sleeve (Figure 14). Remove the dilator, holding the tap sleeve in place. Tap the pedicle with a diameter approximately 1mm under the planned screw diameter by placing cannulated tap over the guide wire and rotating the tap clockwise ensuring the guide wire remains fixed in place (Figure 15). Note the tap depth markings relative to the tap sleeve to approximate the screw length needed (Figure 16). Remove the tap by rotating counterclockwise, maintaining the integrity of the track prepared by the tap's threads. Using the depth tapped as a guide, select the proper screw length.



Figure 14

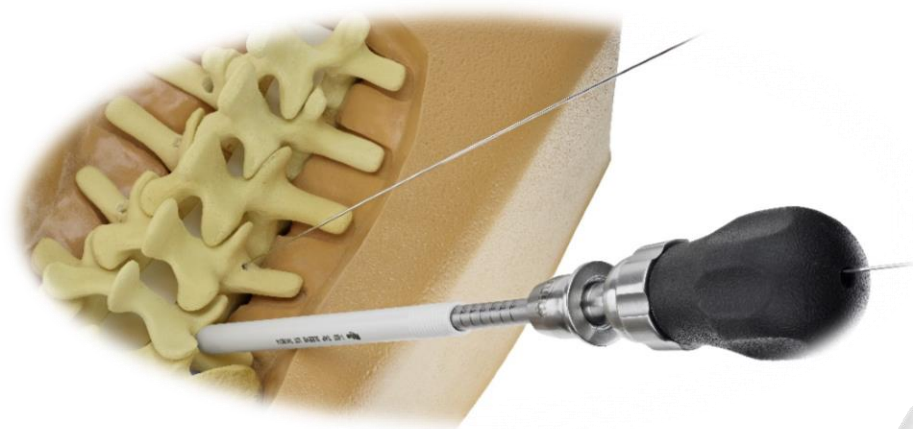


Figure 15



Figure 16

Screw Placement

Place the Pedicle Screw

Attach the T-25 Driver with the Retention knob installed between the flange and the quick connect handle. Assemble the appropriately sized polyaxial screw onto the T-25 Driver by aligning the female hexalobe of the screw with the male hexalobe of the driver. Thread the Retention Knob of the T-25 driver into the tulip tower and tighten to eliminate screw toggle (Figures 17 & 18). Advance the screw down the prepared pedicle until it is seated in the bone with the correct dorsal height (Figure 19). Release the driver from the polyaxial screw by turning the retention knob counterclockwise while holding the driver fixed. Instrument each level as needed and check screw positioning radiographically to ensure proper screw placement.



Figure 17



Figure 18



Figure 19

Rod Placement

Inserting the Rod and Set Screw Placement

Once all screws have been placed and their positions verified radiographically, use the rod size estimation caliper to determine rod length required for optimal correction. Straight and Lordosed rods are available in the EUROPA™ implant tray and may be bent using the supplied rod bender to achieve the desired lordosis. Once the rod has been selected and prepared, insert the rod into the rod inserter and tighten the knob on rod inserter locking shaft until the rod is secure (Figures 20 & 21). Insert the rod through the incision using the top of the EUROPA™ tower as a guide (Figure 22). Slide the rod down the inside of the first tower until it sits below the muscle fascia. Pivot the rod inserter to direct the tip of the rod into the adjacent towers. Use the set screw starter to provisionally lock the rod in place before turning the knob on the locking shaft counter clockwise to release the rod (Figure 23). Repeat these steps for the contralateral side.

 *Note: Reverse bending can weaken the rod and is not recommended.*

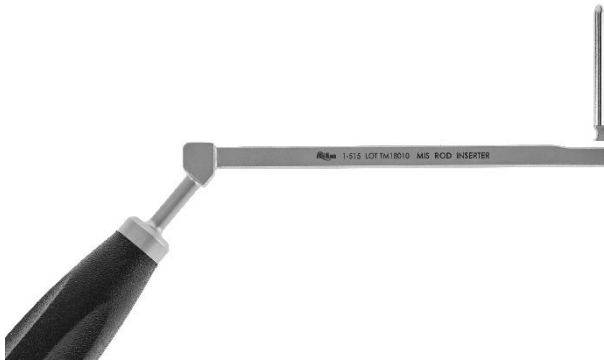


Figure 20

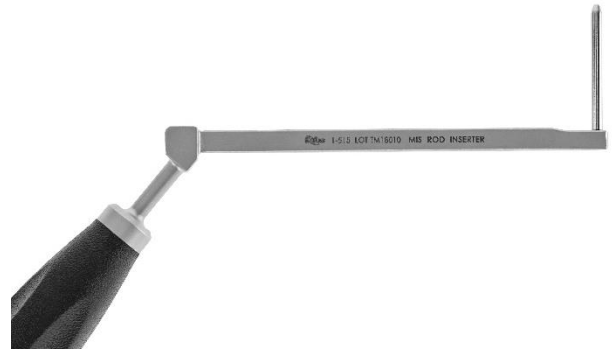


Figure 21



Figure 22



Figure 23

Rod Reduction (If Necessary)

Reducing the Rod

The EUROPA™ pedicle screw towers contain 15mm of reduction threads that can be used to reduce the rod by inserting the set screw with the T-25 Driver and using the threads to translate the rod down until it is fully seated.

Compression and Distraction

After provisionally securing the rod to EUROPA™ implants, distraction and compression can be performed to translate implants axially along the rod by placing the wedge in-between the levels being compressed or distracted. Use a compressor placed below the Wedge to compress the level or above the wedge to distract the level.

Final Tightening

Place the Counter Torque over the pedicle screw that is to be final tightened ensuring the notches on the distal end are engaged with the rod. Insert the T-25 Driver into the Torque limiting T-handle set to 75 in-lb torque. Place the T-25 driver into the tower of the pedicle screw and engage the female T-25 hexalobe of the set screw. Torque the T-handle while maintaining counter torque on the rod until it clicks indicating the final tightening torque was reached (Figure 24). Repeat these steps on the entire construct.

⚠ Note: Once the device has been fully tightened, it cannot be loosened and re-tightened. Loosening of the fully tightened device during implantation can damage the device and cause a reduction in strength.



Figure 24

Tab Removal

To remove the tabs cut the top rings on the towers with the Double Action Tab Cutter (Figure 25). Once cut, attach the needle holders or forceps to the top of the tab and bend until the tab breaks free (Figure 26). Repeat until all tabs have been removed.



Figure 25



Figure 26

Removal or Revision

If removal or revision is necessary, the EUROPA™ Pedicle Screw System can be removed using a T-25 hexalobe driver. To do this insert the T-25 driver into the Set Screws and rotate counterclockwise and remove the set screws and rods from the construct. Next use the T-25 Driver to engage the pedicle screws and rotate them counterclockwise until they are fully removed from the pedicle.

INSTRUCTIONS FOR USE

DESCRIPTION:

The EUROPA™ Pedicle Screw System is a rigid thoracolumbar pedicle screw system comprised of both Open and Minimally Invasive Surgery (MIS) polyaxial pedicle screws, rods, set screws, and optional transverse cross connectors that can be connected to form a stabilization construct. The pedicle screw and rod components are available in different sizes to accommodate various patient anatomical and physiological requirements.

INDICATIONS:

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

The EUROPA™ Pedicle Screw System is intended for posterior, noncervical pedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

CONTRAINDICATIONS:

1. Active systemic infection or infections localized to the site of the proposed implantation are contraindications to implantation.
2. Known sensitivity to Ti-6Al-4V ELI titanium alloy or Cobalt-28Chromium-6Molybdenum alloy.
3. Severe osteoporosis is a relative contraindication because it may result in implant 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 EUROPA™ Pedicle Screw System implants (Screws and Locking Set Screws) are manufactured from Ti-6Al-4V ELI alloy (ASTM F136-13). The rods are manufactured from Cobalt-28Chromium-6Molybdenum alloy (ASTM F1537-11). Adjustable-length transverse rod cross connectors are available and are manufactured from Ti-6Al-4V ELI alloy (ASTM F136-13).

The EUROPA™ Pedicle Screw System includes a complete instrument system to assist the surgeon in the implantation of components according to an MIS or traditional open surgical procedure. All instruments and transport cases are manufactured from stainless steels, aluminum alloys and polymers.

CLEANING of INSTRUMENTS and IMPLANTS:

1. Clean all instruments prior to use, and as soon as possible after use. Do not allow blood and debris to dry on the instruments. If cleaning must be delayed, place instruments in a covered container with appropriate detergent or enzymatic solution to delay drying.
2. Loosen and/or disassemble instruments with removable parts.
3. Immerse the instruments and implants in a neutral pH detergent 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. If ultrasonic cleaners and/or washer decontamination equipment are used, follow equipment manufacturers recommended practices. MiRus™, LLC recommends performing manual cleaning prior to using automated cleaning equipment. Avoid excessively acidic or alkaline solutions. MiRus™, LLC recommends removing implants (in caddies) from set cases.

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 MiRus™, LLC representative for a replacement.
4. If corrosion is noted, do not use and contact customer service or your MiRus™, LLC representative for a replacement.

STERILIZATION:

All implants and instruments are supplied visually clean and non-sterile and must be sterilized prior to use, using an approved FDA wrap. The following are the sterilization cycles for both systems:

Method:	Steam
Cycle:	Pre-Vacuum
Temperature:	270° F (132° C)
Exposure Time:	4 minutes
Drying Time:	80 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 disassembled.

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 not be reused.

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 used 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.
 - g) Known sensitivity to Ti-6Al-4V ELI titanium alloy or Cobalt-28Chromium-6Molybdenum alloy.

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

MAGNETIC RESONANCE (MR) SAFETY:

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

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 paraesthesia
10. Paralysis
11. Death

FURTHER INFORMATION

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

The EUROPA™ Pedicle Screw System is covered by numerous U.S. and International patents. U.S. See www.mirusmed.com/productpatents for more information.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

For further information, please contact the Customer Service Department at:

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EUROPA™

Pedicle Screw System 4.5mm

To learn more about this product, contact your local MiRus Sales Representative



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