



KYOCERA Medical Technologies, Inc.



Rev. I



Instructions For Use

Recommendations for the Care and Handling for Kyocera Medical Technologies, Inc. (“KMTI”) S100 Pedicle Screw System

DESCRIPTION:

The Kyocera Medical Technologies, Inc. (“KMTI”) S100 Pedicle Screw System is an internal spinal fixation system comprised of longitudinal rods, polyaxial screws and transverse link assemblies.

IMPORTANT NOTE:

This product is marked for the specific indications described in its labeling. The use of this product for other than its intended purpose(s) is either contraindicated (see CONTRAINDICATIONS) or is without evidence to support the safety and effectiveness of such use. For the information of individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use), such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIAL:

All implant components of the S100 Pedicle Screw System are made of the following materials:

1. Titanium Alloy: Ti6Al4V according to ISO 5832-3 and ASTM F-136
2. Pure Titanium: CP Ti grade 4 according to ISO 5832-2 and ASTM F-67
3. Cobalt-Chromium Molybdenum Alloy #1: according to ISO 5832-12 and ASTM F-1537

INDICATIONS FOR USE:

The KMTI S100 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 the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors.

When used as a pedicle screw system, the KMTI S100 Pedicle Screw System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

GENERAL CONDITIONS OF USE:

The safe implantation of pedicle screw systems requires an in-depth knowledge of human vertebral anatomy as well as a specific patient's anatomical variations. The implantation of the S100 Pedicle Screw System should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw fixation. In addition, the surgeon must be knowledgeable of the mechanical and metallurgical limitations of this implant. The S100 Pedicle Screw System should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. Under no circumstances should any component of the S100 Pedicle Screw System be reused after implantation or any other circumstance that has subjected an individual component to mechanical stress. After spinal fusion occurs, these devices serve no functional purpose and may be removed. The decision to explant the surgical devices is made between the surgeon and the patient with due regard to the risks associated with a second surgery compared to the benefits of such. The S100 Pedicle Spinal System has been tested as a bipedicular, bilateral construct. This device has not been tested or proven to provide sufficient mechanical support as a unipedicular or unilateral device. The S100 Pedicle Screw System spinal implants must not be relied upon to provide sole support to the spine. The implants require additional spinal support in the form of anterior column integrity or associated anterior column reconstruction.

CONTRAINDICATIONS:

Contraindications to using the S100 Pedicle Screw System are similar to those of other pedicle screw systems and consist of the following:

1. Patients that are overweight, obese, or are occupationally or recreationally subject to heavy lifting, twisting, repetitive bending, or stooping, to a degree that would produce loads on the spinal system leading to failure of fixation or implant failure.
2. Any patient not needing a bone graft and fusion, or where fracture healing is not required.
3. Patients with bony abnormalities that grossly distort anatomy and/or prevent placement of the screws and their fixation without risk of impairment to anatomical structures or physiologic performance.
4. Patients with a suspected or documented metal allergy or intolerance.
5. Inadequate tissue coverage over the operative site.
6. Recent or active infection, particularly if in or adjacent to the spine or spinal structures.
7. Relative contraindications include open wounds as well as fever, leukocytosis, or other signs of systemic infection. Diminished bone quality is a relative contraindication. This may limit the surgeon's ability to achieve adequate implant fixation, structural support, or anatomic correction. These conditions include certain degenerative diseases, postoperative irradiation, smoking, and a history of previous spinal fixation failure. Diminished ability to comprehend and adhere to post-operative care instructions is a relative contraindication. These conditions include diminished mental capacity, mental illness, alcohol or drug abuse and Pregnancy.

WARNINGS AND CAUTIONS:

These warnings do not include all possible adverse surgical effects, but are particular to metallic internal fixation devices. Explain general surgical risks to the patient before surgery.

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 and 4) of the L5-S1 vertebrae, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown. Based on fatigue testing results, when using the S100 Pedicle Screw System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

The S100 Pedicle System has not been evaluated for safety and compatibility in the MR environment. The S100 Pedicle System has not been tested for heating or migration in the MR environment.

POTENTIAL RISKS:

Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, vertebral fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper implant size, shape, and design increases the potential for satisfactory fixation. While proper selection can help minimize risks, the size and shape of human bones present implant size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that are used to obtain alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels among other conditions will dictate implant longevity. Notches, scratches or implant bending during the surgery may also contribute to early failure. Fully inform patients of the implant failure risks.
3. Mixing metals can cause corrosion. There are many forms of corrosion damage, and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel, and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., that come into contact with other metal objects, must be made from like or compatible materials.

PATIENT SELECTION:

The following factors can be extremely important to the eventual success of the procedure:

1. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
2. Senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the device use, leading to implant failure or other complications.
3. Certain degenerative diseases. In some cases, degenerative disease progression may be so advanced at implantation that it may substantially decrease the device's expected useful life. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
4. Foreign body sensitivity. No pre-operative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
5. Smoking. Patients who smoke have been observed to experience higher rates of pseudoarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

WARNING: If bony fusion does not occur within an expected period of time, the screws may break due to the high and sustained loading of these devices. This has been noted in patients with pseudoarthrosis, delayed or non-union and can result in the need to revise the device(s).

PRECAUTIONS:

Only experienced spinal surgeons with specific training in the use of this pedicle screw spinal system should implant pedicle screw spinal systems, because this is a technically demanding procedure presenting a risk of serious injury to the patient

1. Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
2. Correct implant handling is vital. Only contour metal implants with proper equipment. Avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses that may become the focal point for eventual breakage. Do not use the implant if damage is suspected.
3. Bending the construct. Titanium alloy components should never be bent sharply or reverse bent. If a construct is over-contoured, contour a new construct correctly rather than reverse bending the over-contoured construct.
4. Implant removal after healing. If the device is not removed after the completion of its intended use, any of the following complications may occur:
 - a. Corrosion, with localized tissue reaction or pain;
 - b. Implant migration resulting in injury;
 - c. Risk of additional injury from postoperative trauma;
 - d. Bending, loosening, and/or breakage, which could make removal impractical or difficult;
 - e. Pain, discomfort, or abnormal sensations due to device presence;
 - f. Possible increased risk of infection;
 - g. Bone loss due to stress shielding. Carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the surgeon may choose not to remove implant thus eliminating the risks involved in a second surgery.
5. Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. Inform the patient about the implant limitations, and to limit physical activities, especially lifting and twisting motions and participating in any type of sports. Tell the patient that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. Active, debilitated, or demented patients who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

KMTI Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The Implants in the Pedicle Screw System are manufactured from non-ferromagnetic materials as listed in the materials section of this IFU. Potential risks of placing implants in or near the magnetic field include:

1. Movement of ferromagnetic components through magnetically induced force and torque.
2. Localized heating of components caused by radio frequency induction heating.
3. Image artifacts created by interaction between metallic components and the magnetic field.

MRI SAFETY:

KMTI S100 Pedicle Screw System implants are manufactured from non-ferromagnetic materials. The implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the KMTI S100 Pedicle Screw System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

ADVERSE EFFECTS:

In addition to the obvious risk that any orthopaedic implant may fail, loosen, or fracture, the following risks of adverse tissue responses and possible complications must be explained to and discussed with the patient:

1. There have been reports in literature that a variety of metals, polymers, chemicals, and other materials used in the manufacturing of orthopaedic implants may cause cancer and other adverse reactions. Because of the long latency period required to induce tumors in humans, there is no conclusive evidence of the relationship between orthopaedic implants and malignant tumors. Even though no clear association has been established, any risks and uncertainties regarding the long term effects of artificial joints and fixation devices should be discussed with the patient prior to surgery. The patient should also know that any condition that causes chronic damage to tissues may be oncogenic. Cancer found in the vicinity of an implant may be due to factors unrelated to the implant materials such as: metastasis from soft tissue sites (lung, breast, digestive system, and others) to bone or seeded to those locations during operative and diagnostic procedures such as biopsies, and from progression of Paget’s disease. Patients suffering from Paget’s disease who are candidates for implantation procedures in the affected areas should be warned accordingly.
2. Implantation of foreign materials in tissues can elicit an inflammatory reaction. Recent literature suggests that wear debris (including metal, polyethylene, ceramic, and cemented particles) can initiate the process of histiocytic granuloma formation and consequent osteolysis and loosening. While formation wear debris may be an inevitable consequence of motion at bone-to-implant surfaces, optimal technique for fixation of the device should be employed in order to minimize motion that can generate such particles at the bone/prosthesis or prosthesis/prosthesis interface.
3. Metal sensitivity has been reported following exposure to orthopaedic implants. The most common metallic sensitizers (nickel, cobalt, and chromium) are present in orthopaedic grade stainless steel and cobalt-chrome alloys. Titanium and its alloys (such as Ti-6AL-4V) are markedly less antigenic and are recommended for use in persons with a history of allergies or metal sensitivity.

SURGICAL TECHNIQUE:

Patient Positioning

Position the patient in a prone position using a suitable positioning method, such as chest rolls or a positioning frame designed for such purposes, ensuring decompression of the abdomen and sufficient protection for all bony prominences. Maintain hips in extension to preserve lumbar lordosis for fusion and instrumentation of the lumbosacral junction. Care should be taken to avoid undue intra-abdominal pressure that can increase venous congestion and lead to excessive intra-operative bleeding.

Surgical Exposure

Exposure is accomplished using a standard midline incision over the spinous processes, extended to include one level above and one level below the intended instrumentation levels. Expose the spinal column in routine fashion, proceeding to decompression as indicated. Care should be taken to avoid disruption of the facet joint capsules above and below the intended fusion segments.

Placement of Components

NOTE: Decortication and placement of bone graft is typically performed after preparation of pedicle screw pilot holes, but before actual pedicle screw insertion. Meticulous attention to proper fusion technique is critical to success of the procedure.

PEDICLE SCREWS

As with all surgical procedures involving pedicle screw instrumentation systems, pre-operative evaluation of CT scans and MRI scans is essential in planning the appropriate size, angle, and depth of pedicle screws. Intra-operative attention to several pedicle screw placement factors such as entry point, orientation, and depth of placement can help ensure safety, optimize fixation, and enhance ultimate surgical outcome.

Entry Point

Identify the pedicle entry point at the intersection of the horizontal line bisecting the middle of the transverse processes and vertical line connecting the lateral edges of the pars inter-articularis. Decorticate the intended pedicle entry point using a rongeur or burr then create a small cortical opening using an awl. Repeat the process at each intended point of pedicle screw insertion.

Orientation

Insert the pedicle probe through the entry point and advance into the pedicle canal, in the sagittal and axial direction, to a depth determined by preoperative imaging. Repeat the process at each intended point of pedicle screw insertion. Utilize a ball tipped feeler gage to palpate the superior, inferior, medial, and lateral walls of the pedicle canal.

Confirm proper positioning and orientation radiographically by first placing guide pins into each of the pedicle canals. Use grooved guide pins for one side of the patient and non-grooved pins for the other side to aid in radiographic identification. Angle the image intensifier along the pedicle axis to ensure proper positioning in the sagittal and axial directions.

Length

After confirming satisfactory guide pin positioning in the axial and sagittal directions, obtain a lateral image to confirm appropriate length. Advance the guide pin to between 60% and 80% of the depth of the vertebral body as projected on a true lateral image. Determine pedicle screw length using the pedicle marker.

Screw Insertion

Tap: Use the appropriate size tap to thread the proximal portion of the pedicle screw pilot hole. Use the ball tipped feeler gage to again assess the integrity of the pedicle after tapping.

Driver: Affix the pedicle screw to the appropriate screwdriver assembly by engaging the female hexalobular tip of the driver with the proximal male hexalobular end of the screw then sliding the sleeve of the driver down and threading the sleeve into the tulip. Ensure that the sleeve is fully engaged in order to keep the axis of the screwdriver and pedicle screw properly aligned. Finally, lock the sleeve by engaging the adaptor at the proximal end of the driver.

NOTE: While assembling the pedicle screw to the screwdriver assembly it is important to keep the ratcheting mechanism of the large axial ratcheting driver handle in the reverse position.

Insertion: Insert the pedicle screw to the desired depth by turning the driver in a clockwise fashion. After satisfactory placement, the driver is disengaged by disengaging the locking adapter and thereafter turning the sleeve counter-clockwise while holding the handle stationary and withdrawing in an axial manner.

RODS

Selection

Rods included in the S100 Pedicle Screw System are available in straight and lordotic contours of various lengths. Rod contour selection is based on surgeon preference and depends on the specific correction goals of each individual procedure. Rod length determination should allow for at least 5mm extension beyond the most superior and most inferior pedicle screw bodies.

Contour

The polyaxial design of the S100 Pedicle Screw System helps limit the degree of rod bending necessary for achieving adequate rod seating. If necessary, rods may be contoured using a rod bender and/or bending irons to enhance correction or to help ensure complete seating within the body (proximal end) of each pedicle screw. Care should be taken to avoid off-plane or bi-directional bending.

Placement

Rods are placed within the open portions of the bodies of the top-loading pedicle screws. The polyaxial design of the S100 Pedicle Screw System allows adjustment to the position and orientation of the rod.

LOCKING CAPS

Locking caps are inserted into the pedicle screw bodies after the rods have been placed into position. Locking caps should not be fully tightened at this point but should remain loose and in place until the rod derotation, compression or distraction is accomplished.

Rod Rotation

After the rods are placed within the pedicle screw bodies and all locking caps are in place, the rod holders are used to turn the contoured rod into lordosis, if necessary. Following derotation, the superior locking cap is tightened to hold the rod in position. The rod should remain loose in all other pedicle screw bodies to accommodate compression and distraction as needed.

Alignment and Tightening

Alignment: After the construct has been properly assembled, each locking cap is tightened provisionally beginning at the superior end of the construct and proceeding distally. Segmental compression or distraction is accomplished (using the compressor or distractor, respectively) to correct deformities in the frontal and/or sagittal planes as indicated. As each segmental interval is adjusted, the locking cap is provisionally tightened.

Final Tightening: Final tightening of the locking caps is conducted after provisional tightening has been accomplished and satisfactory compression and distraction have been achieved. Instrumentation used for final locking cap tightening consists of the large hexalobular driver with the torque limiting handle and the anti-torque device.

The anti-torque device is employed to limit force applied to the rod while torque is applied to the locking cap to achieve final tightening. The torque driver handle is pre-set to transmit a torque of 100 inch-pounds to the locking cap.

Final tightening is accomplished by first placing the anti-torque device over the pedicle screw and rod, and thereafter inserting the hexalobular driver within the barrel of the anti-torque device until the locking cap is engaged. Tightening is accomplished by turning the driver in a clockwise manner, while holding the anti-torque device steady, until the torque limiter prevents further tightening. The anti-torque device is then withdrawn in an axial manner.

TRANSVERSE LINKS

Transverse Link Placement

One or more transverse links may be placed between adjacent rods to enhance torsional stability of the overall construct. The transverse link is adjustable in length and, if desired, can be placed with the rods in slight horizontal compression by use of the compressor. After the transverse link is in position and its length adjusted as appropriate, the setscrew is tightened using the transverse link driver shaft with the ratchet handle.

Closure

A layered closure of the deep fascia, superficial fascia, subcutaneous tissue and skin is performed in a standard fashion. Drains are used at the discretion of the surgeon and decided on a case-by-case basis.

Post-operative Care

Standard post-operative management protocols are utilized. Post-operative bracing is ordered at the discretion of the surgeon and is somewhat dependent upon the location and strength of bone fixation and the degree of pre-operative instability. Radiographs to assess alignment and fusion maturation are generally taken at one month, three months and six months post-operatively.

REMOVAL

All locking caps must first be removed. Use the hexalobular driver to engage the locking cap and remove it from the pedicle screw. Using the small rod holder, disengage the rod from the pedicle screws. Then, using the inner hexalobular driver, back out and remove the polyaxial screw. If the inner driver cannot engage with the screw shaft, then use the revision driver assembly to back out and remove the screw.

STERILITY:

KMTI S100 Pedicle Screws are provided non-sterile. Sterilization is recommended as follows:

Cycle	Dynamic-air-removal Steam
Minimum Temperature	132° C (270° F)
Exposure	4 Minutes
Drying Time	40 Minutes

These parameters are validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and a new cycle must be established by the user. The autoclave must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

It is the end user’s responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

The packaging in which non-sterile implants are supplied should not be used for sterilization methods in the hospital. Repackaged and resterilized items must be properly labeled and marked with the expiration date mandated by hospital policy.

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling Kyocera Medical Technologies, Inc. at +1 (909) 557-2360.

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



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