KYOCERA Medical Technologies, Inc.

4701-001 Rev. L

Instructions For Use

Recommendations for the Care and Handling for Kyocera Medical Technologies, Inc. ("KMTI")
Cannulated Screw System

Description: The KMTI Cannulated Screw System is designed to provide secure fixation of various fractures (see INDICATIONS FOR USE). The screw is cannulated for use over guide pins allowing for accurate placement of the screw. A full range of sizes are available in partially threaded or fully threaded designs. Additional features include a self drilling/tapping tip.

Materials: The KMTI Cannulated Screw System is made from 23Mn-21Cr-1Mo low nickel stainless steel alloy, 316L stainless steel or Ti-6AL-4V titanium alloy. Washers to prevent the screw head from pulling through the cortex are available for use where the cortical bone is soft or thin. Special cannulated instruments are also available for insertion of the screws.

U.S. Indications for use: Indications for the KMTI Cannulated Screws include long and small bone fracture fixation, including: fractures of the tarsals and metatarsals; metatarsal and phalangeal osteotomies; fractures of the carpals and metacarpals; carpal and metacarpal arthrodesis; small fragments of the hand and wrist; ligament fixation as appropriate; sacroiliac joint disruptions; fractures of the distal femur and proximal tibia; intracapsular fractures of the hip; ankle arthrodesis; and pelvis and acetabulum fractures. This system is not indicated for use in the spine.
NOTE: Surgical techniques are available upon request.

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 then labeled indications (i.e., off-labeled use). Such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

Contraindications: Contraindications to usage of these devices include: sepsis, pre-existing joint disease, arthritis, osteoporosis or inadequate bone stock, long delay after injury, advanced age, chronic renal failure, foreign body sensitivity, and patient inability to follow imposed restrictions on activities due to mental or neurological illness.

Warnings: These devices are not approved by the United States Food and Drug Administration for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

The threads of the screw must not lie across the fracture site as this not only reduces fatigue life but has a tendency to distract the fracture fragments. Detailed instructions on the use and limitations of this device must be given to the patient. If limited or full weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending or breakage of the device and loss of fixation are complications that can occur. These complications may necessitate surgical revision. Weight-bearing to tolerance can be undertaken under strict patient supervision whenever the surgeon is confident of the reduction and satisfactory impaction and rigid fixation are achieved. Use of a walker should be continued until the fracture is firmly united.

Stability and durability of fixation are compromised by loss of cortical bone support by comminution, nonparallel screws not engaging subchondral bone, and osteoporosis. Any of these conditions would increase patient risk during unprotected weight bearing.

The KMTI Cannulated Screw System has not been evaluated for safety and compatibility in the MR environment. The device has not been tested for heating or migration in the MR environment.

KMTI Cannulated Screw System: When the device is used for fixation of reducible intracapsular fracture of the femoral neck, it is important to emphasize the significance of accurate reduction. Excessive valgus (over 180˚) can be associated with an increased incidence of aseptic necrosis. Varus positioning may lead to a poor result with loss of fixation and reduction. The calcar should support the head.

When securing femoral neck fractures, a minimum of three screws is required. A washer should be used under the screw head to prevent the head from pulling through the cortex in cases where the cortical bone is soft or thin. The threads of the screw must not lie across the fracture site as this not only reduces screw fatigue life, but has a tendency to distract the fracture fragments. Overdrilling of the near hole to the major diameter of the screw threads can be done to prevent fracture fragment distraction in cases where the threads are unavoidably near the fracture line. A washer or plate should be used with the screw when this type of lag screw technique is completed.

Preoperative and operating procedures, including knowledge of proper technique, good reduction, and proper selection and placement of the implant, are important considerations in the successful utilization of the screw. Accurate placement of the guide wires, drilling, countersinking, tapping, and screw position should be verified at surgery by multiple tangential views using image intensification fluoroscopy. When using the multiple wire guide or the guide wire sleeve, guide wires should be directed into the bone with caution and utilizing fluoroscopic control.

Precautions: A temporary internal fixation device must never be reused. Reuse can cause small defects and internal stress patterns which may result in premature breakage. If metal screws, wire, bands, or other metallic devices are used together with KMTI Cannulated Screws, all such devices must be manufactured from a compatible alloy with respect to chemical composition and metallurgical state to avert the possibility of galvanic corrosion or other metallic reactions. Components are to be examined for physical damage prior to use.

Internal fixation devices are designed to stabilize the fracture site during the normal healing process. After healing occurs, these devices serve no functional purpose and therefore, should be removed. In most cases, removal is indicated because these implants are not intended to transfer support forces developed during normal activities. If the device is not removed, any of the following complications may occur: corrosion, with localized tissue reaction or pain; migration, resulting in injury to soft tissue, visceral organs, or joints; risk of additional injury from postoperative trauma; breakage, which could make removal impractical or difficult; pain, discomfort, or abnormal sensations which may occur due to the presence of the device; possible increased risk of infection; bone loss due to stress shielding; and in children, the longitudinal growth of long bones where the fracture and the implant are near the growth plate may be significantly retarded (i.e., femoral neck, proximal tibia).
Any decision to remove the device must take into consideration the potential risk to the patient of a second surgical procedure. Implant removal should be followed by adequate postoperative management to avoid refracture.

KMTI Implants and Instruments have not been tested for adverse effect in a Magnetic Resonance Imaging (MRI) environment. The Implants in the Cannulated 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 Cannulated 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 Cannulated Screw System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Adverse Effects: Screw breakage can occur. This can happen due to fatigue failure as a result of prolonged loading upon the screw or due to excessive forces during insertion or removal.

Aseptic necrosis and nonunion can occur with Garden Type II, III, and IV fractures. Garden Type III and IV fractures may not be amenable to achieving a satisfactory result with KMTI Cannulated Screws.

Other possible adverse effects include: Chondrolysis resulting from screw penetration into the subchondral bone of the joint; screw penetration resulting in pain and erosive joint changes; and screw migration into joint area and encroachment of the articular surface of the joint.

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

1. Insert a guide wire through the guide wire cannula to the appropriate depth under image intensification. Remove the guide wire cannula.

2. Use the Cannulated Countersink to create a recess for the screw head if needed.

3. In hard dense bone; a tap may be used.

4. Slide the Cannulated Measuring Device over the guide wire, down to the bone and read the measurement off of the exposed guide wire.

   a. Note: This measurement will place the screw even with the tip of the guide wire.

5. Place the appropriate length screw over the guide wire. Use the cannulated Hexagonal screw driver or the cannulated cruciform driver. Remove and discard the Guide Wire.

   a. Note: A compatible washer may be used in osteoporotic bone.

Sterility: KMTI Cannulated 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 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.

KYOCERA Medical Technologies, Inc.
1200 California St. Ste. 210
Redlands, CA 92374 USA
+1 (909) 557-2360