KYOCERA Medical Technologies, Inc.

4706-003

Rev. D

Instructions For Use

Recommendations for the Care and Handling for Kyocera Medical Technologies, Inc. (“KMTI”) X-Stand accessory to the T710 Large External Fixation System

DESCRIPTION:

The X-Stand is an accessory to the KMTI T710 Large External Fixation System which is designed to act as a skin pressure protector by elevating the heel off a bed or similar surface to prevent decubitus ulcers. The X-Stand is a fully external device which interacts with the KMTI T710 Large External Fixation System when configured in an ankle-spanning construct in order to elevate the patient’s heel. The X-Stand and all KMTI T710 Large External Fixation System components are intended for single use only.

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. Individuals and institutions contemplating use of this product for other than labeled indications (i.e., off-labeled use) should be aware that such use may be experimental and may be the subject of restrictions under applicable laws and regulations.

MATERIAL:

The X-Stand is made from durable, high-impact cast urethane.

INDICATIONS FOR USE:

The KMTI T710 Large External Fixation System is indicated for the following:

- Stabilization/fixation of: Long bone fractures in tibia and femur, fractures of pelvis and ankle and peri-articular and intra-articular fractures of knee joint and ankle joint
- Joint arthrodesis
- Non-unions and mal-unions
- Osteotomies

The X-Stand is intended to be applied to an external fixator construct spanning the ankle with a centrally threaded calcaneal pin passing through the calcaneus.

GENERAL CONDITIONS OF USE:

The safe implantation of external fixation systems and use of accessories requires an in-depth knowledge of human anatomy as well as common anatomical variations along with a thorough understanding of the specific clinical circumstances. The use of the KMTI T710 Large External Fixation System and X-Stand should be performed only by experienced surgeons with specific training in the use of external fixation. In addition, the surgeon must be knowledgeable of the mechanical and material limitations of this system. The X-Stand should only be used with the KMTI T710 Large External Fixation System and should not be used in conjunction with components from a different source, a different manufacturer, or made of a different material. After bone healing occurs, these devices serve no functional purpose and should be removed. The decision regarding when to remove the external fixation device is made between the surgeon and the patient with due regard to treatment options. The X-Stand should be removed from the external fixator construct if the patient is mobile.

CONTRAINDICATIONS:

1. Patients with a suspected or documented metal allergy or intolerance.
2. Recent or active infection.
3. Patients who due to bone or soft tissue disease cannot accept bone pins.
4. Patients who are uncooperative/noncompliant and may cause traumatic damage to the X-Stand or other external fixator components.

WARNINGS AND PRECAUTIONS:

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

WARNINGS

1. Bone pin placement requires accurate anatomic alignment to avoid damage to nerves, blood vessels and tendons.
2. Pre-drilling should be done using a low drill speed to minimize heat that can injure bone and soft tissue.
3. Use caution when handling the sharp tip of the Bone Pin. If the Bone Pins are to be cut, the pin ends should be held by the surgeon or an assistant during this process. Eye protection is recommended for all operating room personnel.
4. As with all percutaneous skeletal fixations, pin track care is important in reducing the incidence of infection.

PRECAUTIONS

1. Surgeon familiarity with the device, instrumentation, and surgical technique prior to surgery is crucial to proper device installation.
2. Patient cooperation and participation are important to effective use of the KMTI T710 Large External Fixation System. Advise your patient to report adverse or unanticipated effects as soon as possible.
3. Skeletal pin security in bone and device integrity should be routinely checked by the surgeon. Pin track infections need prompt recognition and treatment and may require early device removal.
4. 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 system limitations, and to limit physical activities.

MRI SAFETY:

The KMTI T710 Large External Fixation System and X-Stand have not been evaluated for safety and compatibility in the MR environment. The KMTI T710 Large External Fixation System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the KMTI T710 Large External Fixation System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

POTENTIAL RISKS:

Potential risks identified with the use of the KMTI T710 Large External Fixation System, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture, neurological injury, and vascular or visceral injury.

1. Correct implant selection is vital. Selecting the proper component 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 component size, shape, and strength limitations. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No component can be expected to withstand indefinitely the unsupported stress of full weight bearing.
2. Components 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 component 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 component longevity. Notches, scratches or component bending during the surgery may also contribute to early failure. Fully inform patients of the component 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 that come into contact with other metal objects, must be made from like or compatible materials.

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 ELI) 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.

TECHNIQUE

Basic principles of technique apply to all large external fixator frames. The exact frame construct chosen should be dictated by the soft tissue injury and fracture pattern. The X-Stand is intended for use with an ankle-spanning construct utilizing a centrally threaded calcaneal pin. Major Technique Principles include: Pin Insertion, Frame Completion and X-Stand Installation.

PIN INSERTION

- Insert Drill Sleeve Assembly
  - Make a stab incision. Pass the trocar assembly through the soft tissue until the trocar contacts the desired pin placement site on the bone.
- Drill Both Cortices
  - Remove the trocar and drill both cortices using the 3.5mm drill bit.
- Insert the Threaded Pin
  - Insert the desired pins into the bone, through the pin guide handle or pin cannula.
    - Note: If the Multiple Pin Clamp will be used in the final construct, it must be used in the pin placement procedure. Use the pin cannula within the Multiple Pin Clamp to guide the direction of all pins.

FRAME COMPLETION

- Frame constructs are completed by the addition of various rods and clamps. The exact construct is determined by the soft tissue and bony injury.
  - It is important to orient both pin clamps on the calcaneal pin such that the pin opening is facing superior relative to the patient. The lateral hole of each clamp must be on the inferior side of the pin.
  - Once the pins are in the desired positions, the construct can be built using the 11mm diameter rods and clamps. The clamps can be tightened by hand until the final positioning of the clamp is complete. The T-Handle Wrench should be used to final tighten all bolts.

X-STAND INSTALLATION

- The X-Stand is installed by sliding the pin hole over the centrally threaded calcaneal pin. The snap tab must be aligned with the oblong cutout of the rod-pin clamp.
- Press the X-Stand on the area labeled "Push Here" in order to engage the snap tab with the rod-pin clamp. An audible snap indicates X-Stand is fully engaged.
  - Warning: Do not cover the pin hole with fingers or hand during installation. Sharp edges on the calcaneal pin could cause injury as it protrudes through the X-Stand.
- It may be necessary to apply a lateral force to the snap tab to initially insert the tab into oblong cutout of the rod-pin clamp. Once the snap tab is inside the cutout, push in firmly on the X-Stand for full engagement.
- To remove the X-Stand, push the snap tab away from the calcaneal pin and pull outward on the X-Stand.

STERILIZATION:

The X-Stand is provided clean but not sterile and must be removed from packaging prior to use. The X-Stand is a non-sterile product and is not designed to be sterilized. Do not autoclave the X-Stand. The intense heat from the autoclave process will distort the dimensions of the X-Stand and may compromise structural integrity.

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

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

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