KYOCERA Medical Technologies, Inc.

4706-002

Rev. D

Instructions For Use

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

DESCRIPTION:

The KMTI T710 Large External Fixation System includes a variety of components including clamps, rods, posts and pins that, when used in conjunction, provide the surgeon a broad range of frame construct options that can be used to stabilize/immobilize fractures or surgically created instability of the femur, tibia, knee joint, ankle, and pelvis. The clamps, fabricated from titanium and stainless steel, are offered in the following configurations: open rod clamp, closed rod clamp, adjustable rod pin clamp, rod pin clamp, and multiple pin clamp. The open rod clamp, closed rod clamp, adjustable rod pin clamp, and rod pin clamp are used to connect rods to pins or to connect a rod to another rod. The large multiple pin clamp is used to connect rods to multiple bone pins. The rods are 11mm in diameter and are provided in a range of lengths. All rods are fabricated from radiolucent carbon fiber to provide strength and rigidity while minimizing interference with x-rays. The bone pins incorporate fixation threads and are offered in two diameters and in two lengths with either blunt trocar or self-drilling tips. All bone pins are available in either titanium alloy or stainless steel. 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:

Materials in the KMTI T710 Large External Fixation System components are as follows:

- Bone pins: titanium alloy or 316LVM stainless steel
- Rods: reinforced carbon fiber
- Clamps: titanium alloy and 316 stainless steel
- Posts: 316L stainless steel.
- Accessory components: Silicone (USP Class VI), polyphenylsulfone (Radel R5500) or vinyl
- All titanium alloy conforms to ASTM F136 (Ti-6Al-4V ELI). All stainless steel conforms to ASTM F138.

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

GENERAL CONDITIONS OF USE:

The safe implantation of external fixation systems 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 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 metallurgical limitations of this system. The KMTI T710 Large External Fixation System 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.

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.

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 has 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 this device 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. Major Technique Principles include: Pin Insertion, Frame Completion and Dynamization.

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.
  - Once the Pins are in the desired position 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 can be used to final tighten all bolts.

DYNAMIZATION

- Dynamization is the optional process of altering the frame so that the proximal (or larger) fragment can move axially while movement in all other planes remains restricted. This allows load transference to the fracture site while maintaining anatomic alignment. This functional loading appears to increase the strength of the callus and decrease the immobilization after frame removal.
- Dynamization technique: "Crosswise release," or the loosening of adjacent clamp nuts on a frame, permits dynamization. In order to perform crosswise release there must be two parallel rods, both in line with the bone axis and connected to the longer fragment.
  - Double stack the frame:
    - Double-stack a short second rod over the selected fragment with a universal joint for two tubes and two adjacent clamps.
  - Crosswise release
    - Crosswise release is achieved by loosening the rod-clamping nut of the universal joint for two tubes on the short rod and the rod-clamping nuts of the two adjacent adjustable clamps on the long rod.

STERILIZATION:

KMTI T710 Large External Fixation components are provided non-sterile, and must be removed from packaging, cleaned, and sterilized prior to use. KMTI recommends use of an FDA-cleared wrap followed by sterilization according to the following parameters:

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

These parameters have been validated to sterilize only these devices. If other products are added to the sterilizer, the recommended parameters are not valid and updated sterilization parameters 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. Once sterilized, items must be properly labeled and marked with the expiration date mandated by institutional policy.

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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