KYOCERA Medical Technologies, Inc.

IFU 4210-001 Rev. A

Instructions for Use

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

KEY OF RECOGNIZED SYMBOLS										
 Manufacturer	 Use-by-date	 Batch code	 Catalogue number	 Sterilized using ethylene oxide	 Sterilized using irradiation	 Do not resterilize	 Non-sterile	 Do not use if package is damaged	 Keep away from sunlight	 Keep dry
 Do not re-use	 Consult instructions for use	 Quantity of items in package.	 Double sterile barrier system	 ONLY Caution: Federal law restricts this device to sale by or on the order of a physician		 Store in a cool place. Do not store in environments with the potential for extreme heat or direct sunlight.				

KMTI TRIBRID Partial Knee Replacement Prostheses

DESCRIPTION:
KMTI manufactures a partial knee replacement prostheses intended for application with bone cement. Partial knee replacement components include femoral and tibial components. Components are available in a variety of designs and size ranges intended for both primary and revision applications.

MATERIALS:
1. Femoral Components: CoCrMo Alloy
2. Tibial Implants: Ti6Al4V Alloy
3. Tibial Bearings: Ultra-High Molecular Weight Polyethylene (UHMWPE) with Vitamin E (α-tocopherol) or Ultra-High Molecular Weight Polyethylene (UHMWPE)

INDICATIONS FOR USE:
The Kyocera TRIBRID Unicompartmental Knee System is indicated for use in patients with the following:
1. Painful and disabled knee joint resulting from osteoarthritis, traumatic arthritis, or idiopathic osteonecrosis, of either medial or lateral compartments.
2. Correction of varus, valgus, or posttraumatic deformity.
3. As an alternative to tibial osteotomy in patients with unicompartmental NIDJD disease.
4. Revision procedures where other treatments or devices have failed.

This device is intended for cemented use only.

CONTRAINDICATIONS:
Absolute contraindications include: infection, sepsis, and osteomyelitis.

Relative contraindications include:
1. An uncooperative patient or a patient with neurologic disorders who is incapable of following directions
2. Osteoporosis
3. Metabolic disorders which may impair bone formation
4. Osteomalacia
5. Distant foci of infections which may spread to the implant site,
6. Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram,
7. Vascular insufficiency, muscular atrophy, neuromuscular disease
8. Incomplete or deficient soft tissue surrounding the knee.

Other relative contraindications include:

1. Conditions that place great stress on the implant, such as severe obesity, may lead to implant failure. The treating surgeon must weigh the benefits versus risks of using the device in order to decide what is in the best interest of the patient.

WARNINGS:

Preoperative planning should be performed. Improper selection, placement, positioning, alignment and fixation of the implant components may result in unusual stress conditions which may lead to subsequent reduction in the service life of the prosthetic components. Malalignment of the components or inaccurate implantation can lead to excessive wear and/or failure of the implant or procedure. Inadequate preclosure cleaning (removal of surgical debris) can lead to excessive wear. Use clean gloves when handling implants. Laboratory testing indicates that implants subjected to body fluids, surgical debris or fatty tissue have lower adhesion strength to cement than implants handled with clean gloves. Implant should be visually verified prior to use to ensure there are no defects. Improper preoperative or intraoperative implant handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture and/or excessive wear. Do not modify implants. The surgeon is to be thoroughly familiar with the implants and instruments prior to performing surgery.

1. Malalignment or soft tissue imbalance can place inordinate forces on the components, which may cause excessive wear to the patellar or tibial bearing articulating surfaces. Revision surgery may be required to prevent component failure.
2. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentrations, which may lead to failure of the procedure. Complete preclosure cleaning and removal of bone cement debris, metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces. Implant fracture due to cement failure has been reported.
3. It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability.
4. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

KMTI joint replacement prostheses provide the surgeon with a means of reducing pain and restoring function for many patients. While these devices are generally successful in attaining these goals, they cannot be expected to withstand the activity levels and loads of normal healthy bone and joint tissue. Accepted practices in postoperative care are important. Failure of the patient to follow postoperative care instructions involving rehabilitation can compromise the success of the procedure. The patient is to be advised of the limitations of the reconstruction, and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive, unusual and/or awkward movement and/or activity, trauma, excessive weight, and obesity have been implicated with premature failure of the implant by loosening, fracture, dislocation, subluxation and/or wear. Loosening of the implants can result in increased production of wear particles, as well as accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks, possible adverse effects as listed, and to follow the instructions of the treating physician including follow-up visits.

PATIENT SELECTION:

Patient selection factors to be considered include:

1. Need to obtain pain relief and improve function.
2. Ability and willingness of the patient to follow instructions, including control of weight and activity level.
3. A good nutritional state of the patient.
4. The patient must have reached full skeletal maturity.

PRECAUTIONS:

Specialized instruments are designed for joint replacement systems to aid in the accurate implantation of the prosthetic components. The use of instruments or implant components from other systems can result in inaccurate fit, sizing, excessive wear and device failure. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments should only be used for their intended purpose. KMTI recommends that all instruments be regularly inspected for excessive wear or damage.

Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat patients with implants that have been, even momentarily, placed in a different patient.

All trials, packaging, and instrument components must be removed prior to closing the surgical site, do not implant.

POSSIBLE ADVERSE EFFECTS ASSOCIATED WITH PARTIAL KNEE ARTHROPLASTY:

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis, or osteolysis may be a result of loosening of the implant.
2. Early or late postoperative infection and allergic reaction.
3. Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4. Loosening, migration, or fracture of the implants can occur due to loss of fixation, trauma, malalignment, malposition, non-union, bone resorption and/or excessive unusual and/or awkward movement and/or activity.
5. Periarticular calcification or ossification, with or without impediment of joint mobility.
6. Inadequate range of motion due to improper selection or positioning of components.
7. Undesirable shortening of limb.
8. Dislocation and subluxation due to inadequate fixation, malalignment, malposition, excessive unusual and/or awkward movement and/or activity, trauma, weight gain, or obesity. Muscle and fibrous tissue laxity can also contribute to these conditions.
9. Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10. Fretting and crevice corrosion can occur at interfaces between components.
11. Wear and/or deformation of articulating surfaces.
12. Valgus-varus deformity.
13. Transient peroneal palsy secondary to surgical manipulation and increased joint movement has been reported following knee arthroplasty in patients with severe flexion and valgus deformity.
14. Patellar tendon rupture and ligamentous laxity.
15. Interoperative or postoperative bone fracture and/or postoperative pain.

HANDLING OF IMPLANTS AND INSTRUMENTS:

1. Receipt: Carefully unwrap and handle non-sterilized instruments upon receipt to avoid scratching, marking or abrasion by other implants instruments, unpacking tools, or by dropping or otherwise endangering the surface finish or configuration. Implants are provided sterile. Wrappings should not be removed by receiving personnel.
2. Transport: Transport in a manner to preclude any damage or alteration to the received condition of the implant OR INSTRUMENT.
3. Storage: Store implants or instruments prior to use in such a manner as to maintain the device's surface finish or configuration, or both. Stock rotation – The principle of first in, first out, is recommended. Store implants in the operating room in such a manner as to isolate and protect the implant's surface, sterility, and configuration. Keep implants and instruments in the operating room in such a manner as to isolate the instruments from the implants.
4. Traceability: Implants are identified by a catalog number or lot number, or both, on the package label and surface of the device. Record these control numbers and retain for transfer to patient records, to facilitate inventory, stock rotation, medical device reporting and/or possible traceability to KMTI.

IMPLANT SELECTION:

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage, bending, or loosening of the device before the healing process is complete. This may result in further injury or the need to remove the device prematurely.

Use of the TRIBRID Knee System should only be considered when the following preoperative, intraoperative, and postoperative conditions exist.

PREOPERATIVE:

1. The surgeon should consider utilizing the TRIBRID Knee System only with those patients that meet the criteria described in the indications.
2. The surgeon should avoid utilizing this device with those patients who meet the criteria described in the listed contraindications.
3. The surgeon should have a complete understanding of the surgical technique, indications and contraindications.
4. The surgeon should have a complete understanding of the surgical technique guide.
5. The implants are provided sterile. Do not re-sterilize any implant. Do not use any implant from an opened or damaged package.
6. The surgical instruments provided are supplied non-sterile and must be thoroughly decontaminated, cleaned, and sterilized prior to surgical use. Instruments must be cleaned using validated methods before sterilization and introduction into the surgical field. Instrument sets are provided with a system specific tray suitable for transportation and steam sterilization.
7. Remove all packaging that individual instruments may be provided in prior to cleaning. Clean instruments may be placed in the supplied instrument tray, then into an approved sterilization wrap or container. All instruments that are fully or partially dismantlable must be disassembled prior to cleaning. Failure to disassemble a soiled device may lead to inadequate reprocessing, which poses a risk of infection to patients. Instruments must be placed into their respective locations in the sterilization tray to ensure proper steam sterilization. All instruments should be reassembled following cleaning, prior to sterilization.
8. Prior to use, instruments must be inspected for signs of wear, damage, and proper function. This includes inspecting the tips of awls, drivers, drills, and taps for wear, and the inner shafts of any dismantlable instruments. If an instrument is suspected to be damaged it must not be used and KMTI must be contacted for a replacement.

Follow the Cleaning and Sterilization procedures identified in 4001-001 for the cleaning and sterilization of instruments.

INTRAOPERATIVE:

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. Careful use of the implants and instruments should be taken. Misuse of the components may cause injury to the patient or operative personnel. This includes maintaining the sterility of the implant once opened.
3. Notching and scratching of implants should be avoided.
4. Thoroughly irrigate the wound to prevent debris associated with implantation from remaining within the joint space prior to wound closure.

POSTOPERATIVE

1. The physician's postoperative directions, warnings to the patient and the corresponding patient's compliance are extremely important.
2. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process.
3. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts, or other movements preventing proper healing.
4. The removed implants should be properly disposed of and are not to be reused under any circumstance.

MRI SAFETY:

The TRIBRID Knee System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of TRIBRID Knee System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.
Instruments: KMTI instruments used with the TRIBRID Knee System implants may be manufactured from ferromagnetic materials and may be MR unsafe. Potential risks of placing instruments 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.

STERILITY:

Prosthetic components with the exception of polyethylene are provided sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. All polyethylene components are provided sterile using ethylene oxide gas. Prosthetic components are for a single use only. Do not resterilize. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

PRODUCT COMPLAINTS:
Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance, should notify the manufacturer, Kyocera Medical Technologies, Inc (KMTI). Further, if any of the implanted TRIBRID Knee System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the manufacturer should be notified immediately. If any KMTI product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone and written correspondence. When filing a complaint, please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the manufacturer is requested.

FURTHER INFORMATION:
Recommended directions for use of this system (surgical technique manual) are available at no charge upon request. If more than two years have elapsed between the date of issue/revision of this insert and the date of consultation, contact Kyocera Medical Technologies, Inc (KMTI) customer service for current information at 909-557-2360.

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

If further information is needed or required, please contact:

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