KYOCERA Medical Technologies, Inc.

Instructions For Use

IFU 4201-001 Rev. C

Recommendations for the Care and Handling for Kyocera Medical Technologies, Inc. ("KMTI")
A200 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	Caution: Consult instructions for use	Quantity of items in package.	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 Knee Joint Replacement Prostheses

DESCRIPTION :
KMTI manufactures a knee joint replacement prostheses intended for application with bone cement. Knee joint replacement components include femoral, tibial, and patellar 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: CoCrMo Alloy or Ti6Al4V Alloy
3. Tibial Bearings: Ultra-High Molecular Weight Polyethylene (UHMWPE) with Vitamin E (α-tocopherol) or Ultra-High Molecular Weight Polyethylene (UHMWPE)
4. Patellar Components: Ultra-High Molecular Weight Polyethylene (UHMWPE) or Ultra-High Molecular Weight Polyethylene UHMWPE with Vitamin E (α-tocopherol)

INDICATIONS FOR USE:
The A200 Knee System is intended for use in total knee arthroplasty for the following indications:
1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

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.

WARNINGS
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. 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 TOTAL 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.

MRI SAFETY

The KMTI Surgical A200 Knee System implants have not been evaluated for safety and compatibility in the MR environment. The effects of the MR environment have not been determined for the A200 Knee System implants. The implants have not been tested for heating, migration, or image artifact in the MR environment. The safety of the KMTI Surgical A200 Knee System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STERILITY

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

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling Kyocera Medical Technologies, INC. at 1 (800) 736-6847.

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KYOCERA

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