KYOCERA Medical Technologies, Inc.

Instructions For Use

IFU 4401-002 Rev. B

Recommendations for the Care and Handling for KYOCERA Medical Technologies, Inc. ("KMTI")
Acetabular Liners: MAX™ and E-MAX™ Highly Crosslinked Polyethylene

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.						

DESCRIPTION
KYOCERA Medical Technologies, Inc. "KMTI" manufactures a variety of acetabular liners of various designs and sizes from KMTI E-MAX Highly Crosslinked Polyethylene, which is composed of UHMWPE alone or UHMWPE blended with Vitamin E (α-tocopherol). The acetabular liners are utilized with other hip prostheses as part of a total joint system. Hip joint replacement components include: femoral stems, femoral heads, acetabular shells, and acetabular liners. Components are available in a variety of designs and size ranges intended for both primary and revision applications. Specialty components are available including: acetabular screws, centering sleeves, and canal plugs.

MATERIALS
Acetabular Liners:
KMTI MAX™ Highly Crosslinked Ultra-High Molecular Weight Polyethylene (UHMWPE)
KMTI E-MAX™ Highly Crosslinked Ultra-High Molecular Weight Polyethylene (UHMWPE) with Vitamin E (α-tocopherol)

INDICATIONS FOR USE
The KMTI Hip Replacement System is indicated for patients suffering from:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
2. Rheumatoid arthritis;
3. Correction of functional deformity;
4. Treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; and
5. Revision procedures where other treatment or devices have failed.

CONTRAINDICATIONS
Absolute contraindications include:

1. Infection.
2. Sepsis.
3. Osteomyelitis.

Relative contraindications include:

1. Uncooperative patient or patient with neurologic disorders who are 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, or neuromuscular disease.

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. 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. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.
2. Prior to seating the liner into the shell component, all surgical debris (tissue fragments, etc.) must be removed from the interior of the shell component, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell component.
3. 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.
4. Acetabular shells should only be used with compatible FDA cleared acetabular liners.
5. The use of an elevated lip or offset polyethylene liner to correct for cup/liner malposition (cup abduction and/or anteversion) can lead to adverse loading of the unsupported portion of the polyethylene liner and increase the risk of liner fracture.

KMTI hip 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 limitation of the reconstruction and the need for protection of the implants from full load bearing until adequate fixation and healing have occurred. Excessive activity, trauma and weight gain have been implicated with premature failure of the implant by loosening, fracture, 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. Good nutritional state of the patient.
4. The patient must have reached full skeletal maturity.

PRECAUTIONS

Specialized instruments are designed for KMTI hip 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 wear and disfigurement.

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.

POSSIBLE ADVERSE EFFECTS

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. Further, there has been a report regarding an association between articulating surfaces of:
    a. CoCrMo alloy on CoCrMo alloy.
    b. CoCrMo alloy on polyethylene.
    c. Titanium alloy on polyethylene in hip replacements and increased genotoxicity. This report, however, did not assess either the clinical relevance of the data or make any definite conclusions as to which metal ions or interactions between metal ions or particulate metals might be responsible for the observed data. The report further cautioned that an association does not necessarily mean a causal relationship, and that any potentially increased risk associated with metal ions needs to be balanced against the benefits resulting from hip replacement.
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 or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, or excessive 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 and improper positioning. 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. Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing, or inadequate reattachment.
13. Problems of the knee or ankle of the affected limb or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies.
14. Postoperative bone fracture and 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 made of different metals separated. Store the 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 the manufacturer.

IMPLANT STERILITY

Polyethylene liners are sterilized using ethylene oxide gas. Do not resterilize any implant. Do not use any component from an opened or damaged package. Do not use implants after expiration date.

MRI SAFETY
The KMTI MAX™ and E-MAX™ Acetabular Liner components have not been evaluated for safety and compatibility in the MR environment. The KMTI MAX™ and E-MAX™ Acetabular Liner components have not been tested for heating, migration, or image artifact in the MR environment. The safety of the KMTI MAX™ and E-MAX™ Acetabular Liner components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

References: References to relevant literature including the Surgical Technique Manual may be obtained by calling KYOCERA Medical Technologies, INC. at 1 (909) 557-2360.

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