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Part# 4401-001 REV. E

Hip Replacement System

ATTENTION OPERATING SURGEON

DESCRIPTION

KYOCERA Medical Technologies, Inc. "KYOCERA" manufactures a variety of hip joint replacement prostheses. Hip joint replacement components include: femoral stems, femoral heads, bipolar heads, acetabular shells, and acetabular liners. Specialty components such as acetabular screws are also available. Primary and revision components are available in a variety of configurations and size ranges intended for total hip replacement and hemi-arthroplasty applications. All hip implants have a 12/14 Morse-type taper designed for specific use with CoCr femoral heads or BIOLOX® *delta* ceramic femoral heads manufactured for KYOCERA by CeramTec AG.

For implant and instrument part numbers and sizes, refer to the KYOCERA Hip Replacement System surgical technique manuals.

MATERIALS

Femoral Stems	CoCrMo Alloy or Titanium Alloy
Femoral Heads	CoCrMo Alloy
Femoral Heads	Transition-Toughened-Platelet Alumina Composite Ceramic
Bipolar Heads	CoCrMo alloy
Bipolar Liner/Locking Ring	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Acetabular Shells	Titanium Alloy
Acetabular Liners	Ultra-High Molecular Weight Polyethylene (UHMWPE)
Acetabular Screws	Titanium Alloy
Teresa Trabecular Technology™ Acetabular Implants	Titanium Alloy
Porous Coating	Commercially Pure Titanium
Cemented stem distal centralizer/plug	Polymethyl Methacrylate (PMMA)
Plasma Coating	Commercially Pure Titanium

INDICATIONS FOR USE

The 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.

The A400 Hip System is intended for cementless applications unless used with the Cemented Hip Stem.

The Porous Coated Acetabular Shell System is intended for cementless applications.

The Cemented Hip Stem is intended for cemented applications.

The Tesera Trabecular Technologies (T^3) Acetabular Shell System is intended for cementless applications.

The Bipolar Head is for use in conjunction with femoral heads and femoral stems.
Bipolar outer heads are not for use with acetabular shells and liners.

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, and 4) the patient must have reached full skeletal maturity.

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, and 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, and 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. Only use modular femoral head component(s).
2. Firmly seat modular head components to prevent dissociation. Thoroughly clean and dry taper prior to attachment of the modular head component to avoid potential corrosion and improper seating.
3. Acetabular screws are to be fully seated to assure stable fixation and to avoid interference with acetabular liner component.
4. 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.
5. Perforation entirely through the pelvic bone with dome fixation screws or rim screws is to be completely avoided. Caution is to be used when determining and selecting the length of screws to be used, as perforation through the pelvic bone with screws that are too long can cause damage to body structures (blood vessels, etc.) located on the interior side of the pelvis.
6. Tight fixation of all non-cemented components at the time of surgery is critical to the success of the procedure. Each component must properly press fit into the host bone which necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and evaluated at the time of surgery.
7. 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.
8. Acetabular shells should only be used with compatible FDA cleared acetabular liners.
9. Ceramic heads should only be used with new, unengaged hip tapers.
10. Remove the polyurethane femoral stem taper protector before the femoral stem comes in contact with the patient. The polyurethane taper protector is not intended to come in contact with the patient.

KYOCERA arthroplasty implants provide surgeons with a means of reducing patient pain and restoring patient function. 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.

PRECAUTIONS
Specialized instruments are designed for the Hip Replacement System 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. KYOCERA recommends that all instruments be

regularly inspected for wear and disfigurement. For more information on instruments, refer to the KYOCERA Instruments Instructions for Use (p/n 4001-001).

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 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. Osteolysis may also be the result of implant loosening. Further, there has been a report regarding an association between articulating surfaces of: 1) CoCrMo alloy on CoCrMo alloy, 2) CoCrMo alloy on polyethylene, and 3) 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 – Implants are provided in pre-sterilized packages. The wrapping 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 serial or lot number on the package label and on the 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

All metal prosthetic components are sterilized by exposure to a minimum dose of 25 kGy of gamma radiation. All polyethylene liners are sterilized using ethylene oxide gas with the exception of the Bipolar liners and locking rings, which are gamma sterilized because they are assembled into the metal outer Bipolar shells prior to sterilization. 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 Hip Replacement System components have not been evaluated for safety and compatibility in the MR environment. The Hip Replacement System components have not been tested for heating, migration or image artifact in the MR environment. The safety of Hip Replacement System components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Comments regarding this device can be directed to:

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