INITIA TOTAL HIP SYSTEM

ATTENTION OPERATING SURGEON

GENERAL
Before using this product, the operating surgeon should carefully study the following recommendations, warnings and instructions, as well as the available product-specific information (e.g., product literature, written surgical technique).

DESCRIPTION
The Initia Total Hip System includes femoral stems, CoCr modular femoral heads, cross-linked polyethylene acetabular liners, acetabular shells, and bone screws which are designed to be used together to replace the hip joint. All Initia Total Hip System components are available in a range of sizes to best fit each patient's anatomy.
The Initia Total Hip System is provided sterile in unopened undamaged packaging.

The ceramic femoral heads compatible with the Initia Total Hip System femoral stems are the BIOCERAM AZUL heads released by KYOCERA Medical Corporation ("KMD") and the BIOLOX delta heads released by KYOCERA Medical Technologies, Inc. ("KMTI"). Do not use the Initia Total Hip System femoral stems with any other ceramic femoral heads.
Please refer to the separate package insert for the BIOCERAM AZUL Heads for instructions for use.

Initia Total Hip System can be used with any hip products released by KMTI excluding the KMTI plasma sprayed acetabular shells, Initia T3 MAX Liner and the following combinations.
- KMTI stems / KMTI 22mm heads / Initia acetabular cups
- KMTI stems / KMD heads / KMTI bipolar heads
- Initia femoral stems / KMTI 22mm heads / KMTI acetabular cups
- Initia femoral stems / KMTI heads / Initia acetabular cups
- Initia femoral stems / KMTI BIOLOX delta heads / KMTI bipolar heads
- Initia femoral stems / KMTI 28mm CoCr heads / KMTI bipolar heads
- Initia femoral stems / KMD 22mm heads / KMTI bipolar heads

MATERIALS

Femoral Stems	Titanium Alloy-ASTM F136 with Titanium Plasma Spray – ASTM F1580
Modular Femoral Heads	CoCrMo Alloy-ASTM F1537
Acetabular Shells	Titanium Alloy-ASTM F136 with Titanium Plasma Spray – ASTM F1580
Acetabular Liners	UHMWPE (cross-linked)-ASTM F-2565, ASTM F648
Bone Screws	Titanium Alloy-ASTM F136
Apical Hole Plug	Titanium Alloy-ASTM F136

INDICATIONS FOR USE
The Initia Total Hip System is a single use total hip system for use in hip arthroplasty procedures for the following indications:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,

The Initia Total Hip System femoral stems are intended for cementless press-fit use. The Initia Total Hip System acetabular shells are intended for cementless use with biological fixation.

CONTRAINDICATIONS
Absolute contraindications include: infection, sepsis, osteomyelitis and patients without sufficient bone stock to provide adequate fixation and/or support to the implant(s).
Relative contraindications include: 1) an uncooperative patient or a patient with neurologic disorders who is incapable of following directions, including control of weight and activity level 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) neuromuscular disorders affecting stability or postoperative complications, 9) weight, age, or activity levels that would put extreme loads on the implants causing premature wear and/or system failure and 10) poor nutritional state.

IMPORTANT INFORMATION FOR THE SURGEON
Allowed combinations of prosthetic components
Do not use instruments or implant components from other systems, with the exception of allowable KMTI hip products (see DESCRIPTION) as this could result in inaccurate fit, sizing, excessive wear and device failure.

MRI Safety Information
The Initia Total Hip System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Initia Total Hip System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

WARNINGS
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.

PRECAUTIONS
Initia Total Hip System joint replacement prostheses provide the experienced 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 indefinitely.

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 activity, trauma and excessive weight have been implicated in premature failure of implants by loosening, fracture, and/or wear. Loosening of implants can result in increased production of wear particles, and accelerate damage to bone, making successful revision surgery more difficult. The patient is to be made aware and warned of general surgical risks and possible adverse effects as listed. The importance of following the instructions of the treating physician including making follow-up visits must be explained.

Patient selection factors to be considered include: 1) need to obtain pain relief and improve function, 2) ability and willingness to follow instructions, including control of weight and activity levels, 3) a good nutritional state and 4) the patient must have reached full skeletal maturity.

Specialized instruments are designed for the Initia Total Hip System to aid in the accurate implantation of the prosthetic components. Intraoperative fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced extensive use or excessive force are most susceptible to fracture. Surgical instruments should only be used for their intended purpose. KMD recommends that all instruments be regularly inspected for wear and damage.

The potential for deep sepsis can be minimized by using biocontamination controls. Continued surveillance for new or recurrent sources of infection should be continued as long as the device is in place.

Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

PRECAUTIONS FOR HANDLING
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.

Prior to opening packages, confirm the implant type and size on the labeling.

Malalignment of the acetabular shell may cause excessive wear of the articulating surface.

Revision surgery may be required to prevent component failure.

Complete preclosure cleaning and removal of metallic debris, and other surgical debris at the implant site is critical to minimize wear of the implant articular surfaces.

It is the responsibility of the operating surgeon to determine whether there is adequate initial fixation and stability.

Tight fixation of all press-fit components at the time of surgery is critical to success of the procedure. Each component must be properly press fit into the host bone. This necessitates precise operative technique and the use of specified instruments. Bone stock of adequate quality must be present and appraised at the time of surgery.
Prior to seating the acetabular liner into the acetabular shell, all surgical debris (bone and tissue fragments etc.) must be removed from the interior of the shell, as debris may inhibit the locking mechanism from engaging and securing the liner into the shell or may result in excessive wear.

If used, acetabular screws or an apical plug must be fully seated to assure stable fixation and to avoid interference with the acetabular liner component.

Perforation entirely through the pelvic bone with bone screws must be completely avoided. Caution must be used when selecting the length of the screws to use 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.

Never place the femoral head on the stem taper before the stem is fixed and stable in the host bone.
Firmly seat modular head components to prevent dissociation. Thoroughly clean and dry the taper prior to attachment of the modular head component to avoid crevice corrosion and improper seating.

POTENTIAL ADVERSE EFFECTS ASSOCIATED WITH TOTAL HIP ARTHROPLASTY
- Loosening and/or migration of the prosthetic components
- Fracture/damage of the prosthetic components
- Removal and/or replacement of the device system or its components
- Soft tissue impingement or damage
- Dislocation and/or joint instability
- Malalignment of the prosthetic components
- Bone fracture
- Nerve damage
- Early or late post-operative infection
- Swelling
- Leg length discrepancies
- Problems of the knee or ankle of the affected or contralateral limb aggravated by leg length discrepancy, too much femoral medialization or muscle deficiencies
- Inadequate range of motion
- Delayed wound healing
- Periarticular calcification or ossification with or without impediment of joint mobility
- Trochanteric avulsion or non-union as a result of excess muscular tension, early weight bearing or inadequate reattachment
- Temporary or permanent neuropathies
- Pain
- Cardiovascular disorders including venous thrombosis, pulmonary embolism or myocardial infarction
- Histological reactions resulting in inflammation
- Metal sensitivity
- Corrosion of metal components
- Excessive wear secondary to damage of mating wear surfaces and/or debris that can initiate osteolysis which may result in loosening of the implant
- Death

STERILIZATION
Gamma irradiation is indicated by the STERILE R symbol on the labeling. Where available, ethylene oxide sterilization is indicated by the STERILE EO symbol on the label. These devices remain sterile as long as the package integrity has not been violated.

Sterilized devices must be kept in their sealed original package until opened for use. The expiration date shown on the label and package integrity must be checked. Any damage to the package may compromise sterility. Do not use implants after the expiration date. Do not use any component from an opened or damaged package. When the implant is removed from the package and during the entire implantation the rules of asepsis must be observed.

Do not open a package in a non-sterile field.
Do not resterilize.

STORAGE AND HANDLING CONDITIONS
These products must be stored away from heat, moisture and direct sunlight.

COMMENTS REGARDING THE USE OF THIS DEVICE CAN BE DIRECTED TO ATTN:
Initial Importer:
KYOCERA Medical Technologies, Inc.
1289 Bryn Mawr Ave. Ste. A
Redlands, CA 92374

Manufacturer:
KYOCERA Medical Corporation
6 Takeda Tobadono-cho, Fushimi-ku, Kyoto
612-8450 Japan

SYMBOL GLOSSARY DEFINITIONS

ISO 15223-1, Medical Devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirements			
Symbol	Symbol Reference	Title of symbol	Description of symbol
	5.1.1	Manufacturer	Indicates the medical device manufacturer.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	5.1.5	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	5.1.6	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	5.1.7	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	5.2.3	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	5.2.4	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.
	5.2.6	Do not resterilize	Indicates a medical device that is not to be resterilized.
	5.2.8	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one single use only.
	5.4.3	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
	5.4.4	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
Other standards or originally defined			
	-	Quantity	Indicates the quantity of device(s) contained within the packaging.
	21 CFR 801.109	Prescription Device	Indicates that the product is a medical device as defined in 21 CFR 820.3(l) and Federal Law (USA) restricts this device to sale by or on the order of a physician (21 CFR 801.109).