BIOCERAM AZUL HEAD

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 BIOCERAM AZUL HEAD is a ceramic femoral head component with a 12/14 taper bore designed to be used together with the Initia Total Hip System femoral stem. This component is available in outer diameters of 22, 26, 28, 32, 36, 40 and 44mm. There are 2 offsets (+0, +3mm) for the 22mm size. There are 2 offsets (+0, +3.5mm) for the 26mm size. There are 4 offsets (-3.5, +0, +3.5, +7mm) for the 28 to 44mm sizes. The articulation surface is highly polished to a very low surface roughness in accordance with ISO 7206-2. This ceramic femoral head component is sterilized by gamma irradiation.
The BIOCERAM AZUL HEAD is provided sterile and non-pyrogenic in unopened undamaged packaging.

The following BIOCERAM AZUL HEADS cannot be used with A400 Cemented Hip stems released by KYOCERA Medical Technologies, Inc. (“KMTI”):
- 22mm size, offset +0, +3
- 26mm size, offset +0, +3.5
- 28mm size, offset +7

The other sizes and offsets of the BIOCERAM AZUL HEAD can be used with any hip products released by KMTI excluding the following combinations.
- KMTI femoral stems / 22mm, 28mm BIOCERAM AZUL HEAD / KMTI bipolar heads
- Initia femoral stems / 22mm BIOCERAM AZUL HEAD / KMTI bipolar heads
- KMTI femoral stems / BIOCERAM AZUL HEAD / KMTI plasma sprayed acetabular shells

MATERIAL
BIOCERAM AZUL® (high purity alumina matrix with zirconia reinforcement, ISO 6474-2)

INDICATIONS FOR USE
The BIOCERAM AZUL HEAD is a single use modular femoral head component 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.

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, 10) poor nutritional state and 11) revision surgery of a previous hip joint arthroplasty without removing the stem component.

IMPORTANT INFORMATION FOR THE SURGEON
Allowed combinations of prosthetic components
The BIOCERAM AZUL HEAD must only be used with the femoral stems released by KYOCERA Medical Corporation (“KMD”) or KYOCERA Medical Technologies, Inc. (“KMTI”) excluding unapproved combinations (see DESCRIPTION).
KMD advises against the use of their prosthetic components with implants offered by other companies unless explicitly recommended. KMD will accept no responsibility for any malfunction if the BIOCERAM AZUL HEAD is used with components offered by other companies not specifically recommended.

The BIOCERAM AZUL HEAD is allowed only in combination with Polyethylene liners.

MRI Safety Information
The BIOCERAM AZUL HEAD 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 BIOCERAM AZUL HEAD in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

WARNINGS
The following precautions must be taken:
The BIOCERAM AZUL HEAD should be used only with prostheses which have tapers - within the specified tolerances - matching KMD's or KMTI's 12/14 taper shape. The taper shape, 12/14, is shown on the product label and on the implant itself.
Use only new tapers. Do not ever use tapers that have been previously mated with another femoral head as they may be damaged, even if the damage is not evident. This is important to prevent head fracture.

In extremely rare cases, fracture of the ceramic femoral head may occur. To minimize this risk, each part is proof-tested to eliminate parts that may pose such a risk.

Reasons for ceramic femoral head fracture may include:
• Excess loading of the prosthesis, for example through incorrect placement of the ceramic femoral head on the stem taper or improper fit between the ceramic femoral head and the stem taper.
• Mismatched ceramic femoral head and stem tapers.
• Modified implants.
• Damaged stem taper or damaged ceramic femoral head
• Impact loads such as may occur due to a fall

PRECAUTIONS
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 levels, 3) good nutritional state of the patient and 4) the patient must have reached full skeletal maturity.

Do not use instruments from other systems as this could result in inaccurate fit, excessive wear and device failure.

Momentary overloading in a fall or accident may cause failure of the implant, sometimes long after the event.

PRECAUTIONS FOR HANDLING
Improper preoperative or intraoperative implant and instrument handling or damage (scratches, dents, etc.) can lead to crevice corrosion, fretting, fatigue fracture, improper assembly and/or excessive wear. Do not modify implants.
The surgeon should be thoroughly familiar with the implants and instruments prior to performing surgery.
Prior to opening the package, confirm the implant type and size on the package label.

Femoral head fixation to the stem taper
For proper functioning of the prosthesis, it is essential to fit the femoral head to the stem taper with meticulous care.
Protect the stem taper from damage until immediately before the femoral head is put on.
Before fitting the femoral head to the stem:
• Thoroughly clean the stem taper with water.
• Dry the stem taper using a clean towelette.
• Scrupulously inspect the stem taper and femoral head taper, and remove any foreign matter, such as tissue particles, bone fragments or cement residues.
• Place the femoral head on the stem taper by twisting lightly.
• Place the plastic head impactor on the pole of the femoral head and with a light tap of the hammer in an axial direction, firmly and definitively fix it on the stem taper.
Caution:
Never strike the femoral head directly with a metal mallet or hammer. Use only the plastic head impactor provided for this purpose.
Never place the femoral head on the stem taper before the stem is fixed and stable in the host bone.
Off-axis impaction or seating of the femoral head may increase the risk of fracture.

Reoperation and Reuse
If, during revision surgery, the stem can be left in place while the femoral head must be replaced, a metal femoral head must be used. Never use a BIOCERAM AZUL HEAD in a revision procedure that does not include revision of the femoral stem, because of the increased risk for fracture of the ceramic head.
With ceramic femoral heads that have already been used, there is a risk that they could have damages invisible to the naked eye. Since any kind of damage can adversely affect the ceramic's functionality and/or stability, a safe use cannot be guaranteed. For this reason, only unused and undamaged new ceramic femoral heads packaged in their original packaging may be implanted.
A ceramic femoral head which has suffered an impact (fall to the ground) must not be implanted.
A ceramic femoral head with any kind of damage should not be used.
A ceramic femoral head which has been fixed to the taper of a stem and then removed must not be reused.

In the event of fracture of the ceramic femoral head with a polyethylene liner: remove the polyethylene liner because ceramic particles could damage the new femoral head, which would result in increased wear of the polyethylene.
In case of peri-operative fracture of the ceramic femoral head, remove all ceramic particles.

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

The BIOCERAM AZUL HEAD is sterilized by gamma irradiation. Gamma irradiation is indicated by the STERILE R symbol on the labeling. 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 medical device labels, labeling and information to be supplied -- Part 1: General requirements			
Symbol	Symbol Reference	Title of symbol	Description of symbol
	5.1.1	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	5.1.4	Use-by date	Indicates the date after which the medical device is not to be used.
	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.
	5.2.4	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	Indicates a medical device that should not be used if the package has been damaged or opened.
	5.4.2	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	5.4.3	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
Other standards or originally defined			
	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).