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The OMNIHIP™ System** Ceramic Heads

SYMBOLS Glossary per ISO 15223-1

5.1.1	Medical Device Manufactuer
5.1.4	Use-By Date
5.4.2	Do not Re-use
5.4.4	See Instructions for Use
5.2.8	Do Not Use if Package is Damaged
Rx only	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
QTY	Quantity
5.2.3 STERILE EO	Sterilized Using Ethylene Oxide
5.1.5 LOT	Batch Code
5.1.6 REF	Catalogue Number

PRODUCT HANDLING

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage which may compromise sterility. If packaging has been opened or damaged, contact manufacturer's representative. When unpacking the implant, verify the labeling for correct Cat. No. and size. When removing the implant from it's packaging, the sterile technique must be observed. Protect the implant from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage. Procedures for implanting and removal are available upon request.

DESCRIPTION

The OMNI Hip System Ceramic Heads are modular ceramic heads for use with the OMNI Hip System stems and the OMNI Interface™ Acetabular System. The OMNI Hip System Stems include the following stems; OMNI Mod™ Stem, OMNI K1™ Stem, OMNI K2™ Stem, OMNI Anseris™ Stem and the OMNI ARC™ Stem. At this time the OMNI Modular Stem, OMNI Anseris™ Stem and the OMNI K2 Stems are not approved for sale in the EU. The OMNI Interface Acetabular System includes shells and inserts. Several offset options are available for the heads to appropriately fit the anatomy of the patient.

MATERIAL

- BIOLOX® *delta* alumina matrix composite ceramic (CeramTec AG)
- CeraSurf®-p (CoorsTek, Inc.)

INDICATIONS FOR USE

The OMNI Hip system Ceramic Femoral Heads are intended for use in combination with the OMNI Hip System Stems as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with the OMNI Interface Acetabular System or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

CONTRAINDICATIONS

Absolute contraindications include:

- Infection or sepsis or osteomyelitis;
- Insufficient bone structure or quality which may affect the stability of the implant;
- Rapid joint destruction or bone absorption;
- Skeletal immaturity;
- Muscular, ligamentous, neurological, vascular deficiencies or poor skin coverage, which may compromise the affected extremity;
- Alcoholism or other addictions;
- Sensitivity to the implant materials;
- High levels of physical activity (e.g. competitive sports, heavy physical labor);
- Obesity can produce loads on the prosthesis, which can lead to fixation failure or prosthesis breakage or fracture.
- Use of head/neck combinations with a lateral offset greater than 47.5mm with the Size 2 or Size 3 x 9mm OMNI Modular stem is contraindicated due to the lack of fatigue strength data for these combinations.

Relative contraindications include:

- Uncooperative patient or a patient with neurological disorders and incapable of following instruction;
- Metabolic disorders which may impair bone formation or bone quality;
- Distant foci of infections.

WARNINGS AND PRECAUTIONS

The implants are provided sterile. Sterile technique should be used when opening the package.

While these implants are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients.
In using total joint implants, the surgeon should be aware of the following:

- The correct selection of the modular implant components is extremely important. The potential for success in total joint replacement is increased by the selection of the proper size, shape and design of the implant. Total joint prostheses require careful seating and adequate bone support, and should be restricted to limited functional stress. The surgeon is to be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery.
- In selecting patients for total joint replacements, the following factors can be of extreme importance to the eventual success of the procedure:

1. The patient's weight. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when a small prosthesis must be used. Patients receiving joint replacements should be adv ised that the longevity of the implant may depend on their weight and level of activity.
2. The patient's occupation or activity. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device or both.
3. A condition of senility, mental illness or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions, leading to failure or other complications.
4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
5. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the

appliance. For such cases, total joint replacement can only be considered a delaying technique or temporary relief.
- The correct handling of the implant is extremely important. Care must be taken to protect surfaces from nicks and scratches which could become the focal point for failure. Do not tamper with the implant as contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load.
- Standard cleaning procedures cannot be relied upon to remove contamination from porous coating.
- A surgical implant should not be reused. Even though a used implant may appear undamaged, it may have small defects and internal stress patterns, which may lead to failure. Use only new prosthesis of the current design.
- Resterilization of the device is not recommended.
- Bone excision should be limited to the amount necessary to accommodate the implants. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, bone cement or other detritus that may cause a third body wear problem. Range of motion should be checked for impingement or instability.
- Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, ranges of motion, and activity levels permissible. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture and/or wear of the prosthesis implant. Early load-bearing should be carefully controlled. The patient should be advised to report any related pain, decrease in range of motion, swelling, fever, and unusual incidences.
- The modular head and neck components must be firmly seated to prevent disassociation. Scratching of modular heads and tapers should be avoided. Repeated assembly and disassembly of the head or neck components could compromise a critical locking action. The head or neck components should be changed only when clinically necessary. The interfaces should be clean and free from debris prior to assembly.

ADDITIONAL CONSIDERATIONS FOR CERAMIC HEADS

The OMNI Modular Ceramic Femoral Heads are only for use with OMNI Hip System femoral stems and cups. No other ceramic heads should be used with these hip stems. Other considerations for the ceramic heads include the following:
- The ceramic head must not be sterilized on the hip stem.
- The ceramic heads should not be resterilized.
- The neck trunnion and head bore should be dry and free of contamination.
- Ceramic heads are recommended for use on new trunnions only.
- The ceramic head should not be implanted if the head, or the neck trunnion, are possibly damaged.
- The ceramic head should be gently placed on the neck trunnion while keeping the head and neck aligned. Securing the head to the trunnion requires a single, moderate blow using the head impactor. Not using the head impactor may damage the head.
- The OMNI Modular ceramic heads are contraindicated for use with anything other than an UHMWPE cup or a metal backed UHMWPE cup.

POSSIBLE ADVERSE EFFECTS

The possible adverse effects are similar to those occurring with any hip or knee replacement and include the following:
- Dislocation or subluxation due to improper positioning or muscle and fibrous tissue laxity.
- Loosening or migration of components due to trauma and/or loss of fixation.
- Accelerated wear of the polyethylene articulating surfaces of acetabular components. Such wear may be initiated by particles of cement, metal, or other debris that can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prostheses, and leads to early revision surgery to replace the worn components.
- Histiocytic granuloma formation and osteolysis around the implant due to wear debris.
- Fracture of the implant as the result of strenuous activity, improper alignment, inadequate fixation or extreme duration of service.
- Urological complications, especially urinary retention and infection.
- Dislocation, wear, dissociation, or fracture of the acetabular cup liner due to neck-liner impingement.
- Other complications associated with general surgery, drugs or ancillary devices used, blood, etc.

Intraoperative and early postoperative complications can include:
- Damage to blood vessels;
- Temporary or permanent neuropathies;
- Traumatic arthrosis of the knee from Intraoperative positioning of the extremity;
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- Hematoma;
- Delayed wound healing;
- Infection;
- Femoral Perforation;
- Fracture of the femur while press-fitting the femoral stem component;
- Undesirable shortening or lengthening of the limb.

Late postoperative complications can include:
- Aggravated problems of the Knee or ankle of the affected limb or contralateral extremity by leg length discrepancy too much femoral medialization, or muscle deficiency;
- Femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- Periarticular calcification or ossification, with or without impediment to joint mobility;
- Inadequate range of motion due to improper selection or positioning of components, by femoral impingement and periarticular calcification;
- Excessive joint pressures and pain with ambulation due to excessive scarring of the joint capsule and surrounding tissues;
- Infection;
- Trochanteric avulsion as a result of excessive muscular weakening;
- Trochanteric non-union due to inadequate reattachment and/or early weight bearing.

CAUTION

Disposal of implants should be carried out using the hospital's standard method for non-biodegradable non-combustible medical waste.

MRI SAFETY INFORMATION

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