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The OMNIHIP™ System**

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, that may compromise sterility. If packaging has been opened or damaged, contact manufacturer's representative. When unpacking the implant, verify the labeling for correct REF number (Product Code). and size. When removing the implant from it's packaging, the relevant aseptic handling must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Visually inspect each implant prior to use for damage. Procedures for implanting and removal are available upon request.

DESCRIPTION
The OMNI Hip System is a semi-constrained total hip replacement for uncemented applications, and includes the OMNI Modular Hip System and the OMNI K1™ Hip Stems. The OMNI Modular Hip System consist of three modular components, with various sizes available for each component: the uncemented femoral stem, a modular neck that connects to the proximal end of the femoral stem, and a modular head that connects to the tapered trunnion on the neck. The uncemented modular femoral stems are available in three versions: the OMNI Mod™ stem (with and without HA), the OMNI K2™ stems.

MATERIALS
- OMNI Modular stem, K2 stems: titanium alloy (ASTM F 136), and unalloyed titanium (ASTM F 1580), pin is wrought cobalt chromium alloy (ASTM F 1537);
- K1 stem: titanium alloy (ASTM F 136) and unalloyed titanium (ASTM F 1580);
- HA versions: hydroxyapatite (ASTM F 1185)
- OMNI Modular Neck and K2 Necks: titanium alloy (ASTM F 136);
- Heads: wrought cobalt chromium alloy (ASTM F 1537); BIOLOX® forte alumina ceramic (CeramTec AG); BIOLOX® delta alumina matrix composite ceramic (CeramTec AG)

OMNI Interface™ Acetabular System
- Cup shell: titanium alloy (ASTM F 136) and coated with sintered unalloyed titanium beads (ASTM F 1580);
- Acetabular cup inserts: compression molded, calcium stearate-free (GUR 1050) ultrahigh molecular weight polyethylene (UHMWPE). Two types of acetabular cup inserts are available: the standard cup inserts, that are non-irradiated, and the ApeX-LNK Poly™ cup inserts, that are radiation crosslinked and annealed for improved wear resistance.

WEAR CLAIM
The ApeX-LNK Poly™ Acetabular Cup Inserts (H5-44828) show a 88% reduction in gravimetric wear rate versus the same acetabular inserts fabricated from standard polyethylene (414828). These inserts mate with 60-66 mm acetabular shells, have a 28 mm inner diameter, and a minimum 12.0 mm bearing thickness (within 57° of the apex). All inserts were machined from compression molded GUR 1050 UHMWPE (calcium stearate free). The UHMWPE for the ApeX-LNK inserts was gamma irradiated to 78.5 kGy and stored in inert gas and gas impermeable packaging until just prior to machining. After machining, the ApeX-LNK Poly inserts were annealed in a nitrogen oven for 24 hours, at 85-90°C. The standard and ApeX-LNK Poly inserts were packaged and sterilized using EO as per our standard protocols. Testing was performed in a Shore Western (Monrovia, CA) hip simulator, for 5 million cycles, with 28 mm cobalt chromium femoral heads, in bovine calf serum (with sodium azide and EDTA). The average wear rate for the ApeX-LNK inserts was 9.2 mg/million cycles, the average wear rate for the standard inserts was 75.5 mg/million cycles. The results of *in vitro* hip wear simulator tests have not been shown to quantitatively predict clinical wear performance.

INDICATIONS FOR USE
The OMNI Hip System is intended for primary or revision total hip replacement. The femoral hip stems and acetabular cup are intended for uncemented fixation and single use implantation. The OMNI Acetabular Cup Inserts, standard and ApeX-LNK Poly, are intended for use with the OMNI Modular Acetabular Cup, in combination with the OMNI Modular, OMNI K2, OMNI K2 mid length or OMNI K1 Hip in total hip replacement procedures. The acetabular cup inserts are intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. These prostheses 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 that may affect the stability of the implant;
- Rapid joint destruction or bone absorption;
- Skeletal immaturity;
- Muscular, ligamentous, neurological, vascular deficiencies or poor skin coverage, that 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 that can produce loads on the prosthesis that can lead to failure of the fixation of the device or the device itself;
- 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 (both versions) is contraindicated due to the lack of fatigue strength data for these combinations.
- Use of the +10.5mm offset head with the OMNI Modular or OMNI K2 or OMNI K2 mid length femoral stems (any neck) is contraindicated.
- Use of skirted heads with hooded acetabular cup inserts is contraindicated.
- Use of the OMNI Hip System Bipolar Head in the presence of degenerative arthritis is contraindicated.

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

WARNINGS AND PRECAUTIONS
While total hip arthroplasty and hemi-arthroplasy components 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 joint replacement 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 joint replacement is increased by the selection of the proper size, shape and design of the implant. Joint replacement 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 implants, instruments, and surgical procedure prior to performing surgery.
- In selecting patients for joint replacement surgery, 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 that can lead to failure of the prosthesis. This becomes a major consideration when a small prosthesis must be used.
2. The patient's occupation or activity. If the patient is involved in an occupation or activity, that 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 mating surfaces and polished bearing surfaces from nicks and scratches that 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 that 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.
- Range of motion is decreased with the use of the skirted +10.5mm offset head.
- 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.

POSSIBLE ADVERSE EFFECTS

The possible adverse effects of the OMNI Hip System are similar to those occurring with any hip arthroplasty 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.
- Fatigue fracture of the implant as the result of strenuous activity, improper alignment, inadequate fixation, extreme duration of service, or obesity.
- Urological complications, especially urinary retention and infection.
- Dislocation, wear, dissociation, or fracture of the acetabular cup insert due to neck-insert impingement.
- Dislocation of the bipolar head from the acetabulum due to soft tissue laxity and/or femoral component impingement at extremes of joint motion.
- Wear, erosion, or abrasion of the acetabular cartilage and/or underlying bone secondary to articulation of the bipolar head in the acetabulum, that may result in pain and/or disability.
- 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.

Additional information about the OMNI Hip System may be obtained from OMNIlife science, Inc.