













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The OMNI Interface™** Acetabular Hip System

SYMBOLS Glossary per ISO 15223-1

	Medical Device Manufacturer
	Date of Manufacture
	Use By Date
	Do not Re-use
	See Instructions for Use
	Do Not Use if Package is Damaged
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
QTY	Quantity
	Sterilized Using Ethylene Oxide
	Batch Code
	Catalogue Number
	Medical Device
	MRI Safety Information

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 its 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 Interface is a modular acetabular cup system intended to replace a hip joint and is designed for cementless fixation to bone. The system consists of porous coated shells, polyethylene inserts, and optional screws.

- Use of skirted heads with hooded acetabular cup inserts is not indicated.
- Use of the OMNI cancellous bones screws with acetabular shells other than OMNI's Interface Acetabular Shells is not indicated.

For more details regarding the compatibility between implants, please contact your OMNI representative or you could find more details on the following link www.coringroup.com/compatibility.

MATERIALS

OMNI Interface Acetabular System

- Cup shell: titanium alloy (ASTM F 136), 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.
- Cancellous bone screws: Titanium alloy (ASTM F 136)

WEAR CLAIM

The ApeX-LNK™ Poly Acetabular Cup Inserts (H5-44828) show an 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 Interface™ Acetabular System is designed to be used in hip arthroplasty. The specific indications for use include -

- 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.

The OMNI Interface Acetabular System is intended for cementless and single use implantation only.

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;

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-arthroplasty 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 coatings.

- 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 Interface Acetabular 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..

- 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.

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**U.S. Patents 6,702,854 and 7,044,975, other patents pending.

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