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The Apex Hip System** Bipolar Heads

SYMBOLS Glossary per ISO 15223-1

5.1.1



Medical Device Manufacturer

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

5.2.8



Rx only

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

QTY

5.2.3



Sterilized Using Ethylene Oxide

5.1.5



Batch Code

5.1.6



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 its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

DESCRIPTION

The Apex Hip System Bipolar Heads are a semi-constrained hemi hip replacement. The Bipolar Heads consist of an outer cobalt chromium articulating component, an inner UHMWPE articulating component, a UHMWPE locking ring and a titanium locking ring spring. The Apex Hip System Bipolar Heads are intended to articulate with an Apex Hip

System metal (cobalt chromium) or ceramic (alumina) femoral head.

MATERIALS

- Bipolar Head: cobalt chromium alloy (ASTM F 75), calcium stearate-free UHMWPE (ASTM F648), titanium alloy (ASTM F 136);

All UHMWPE components are sterilized using ethylene oxide (EO).

INDICATIONS FOR USE

The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other treatments or devices for these indications have failed.

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 that can produce loads on the prosthesis, which can lead to failure of the fixation of the device or the device itself;
- Use of the Apex 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 which may impair bone formation or bone quality;
- Distant foci of infections.

WARNINGS AND PRECAUTIONS

While 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, which 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, 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 mating surfaces and polished bearing 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 Apex Hip System Bipolar Heads have not been evaluated for safety and compatibility in the MR environment. The Apex Hip System Bipolar Heads have not been tested for heating or migration in the MR environment.
- The modular head components must be firmly seated to prevent disassociation. Scratching of modular heads should be avoided. Repeated assembly and disassembly of the head components could compromise a critical locking action. The head 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 Apex 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 which 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 liner due to neck-liner 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, which 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

- May cause image distortions in MRI (Magnetic Resonance Imaging) and CT (Computed Tomography).
- Disposal of implants should be carried out using the hospital's standard method for non-biodegradable non-combustible medical waste.

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

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