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# OMNI Anseris Hip Stem

**SYMBOLS Glossary per ISO 15223-1**

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| 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 Anseris Hip stem is a press-fit femoral hip stem for uncemented applications. It is available in sizes 1 to 8 in standard and lateral neck options. The distal stem surface is glass bead blasted with a proximal plasma sprayed CP titanium porous coating. The OMNI Anseris Hip Stem is for use with Apex Modular Heads (cobalt chrome or ceramic) and the Apex Interface™ Acetabular System (Insert and Shell).

## MATERIAL

- Titanium alloy (ASTM F 136) and unalloyed (CP) titanium (ASTM F 1580).

## INDICATIONS FOR USE

The OMNI Anseris Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement when used with the Apex Interface™ Acetabular System. The Apex Interface™ Acetabular System articulates with the Apex Modular Femoral Head (cobalt chrome or ceramic).The femoral hip stem is intended for uncemented fixation and single use implantation. These prostheses may be used for hip arthroplasty to treat 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.

The OMNI Anseris Hip Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head. For further details, please refer to the Apex Bipolar Head Instructions for Use.

## 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 skirted heads with hooded acetabular cup inserts 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

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.
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 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.
- Range of motion is decreased with the use of the skirted +10.5mm offset head.
- The modular head must be firmly seated to prevent disassociation. Scratching of modular heads and tapers should be avoided. Repeated assembly and disassembly of the head components could compromise a critical locking action. The head should be changed only when clinically necessary. The interfaces should be clean and free from debris prior to assembly.
- See Instructions for Use of The Apex Hip System Ceramic Heads for additional considerations regarding use of ceramic femoral heads.

**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 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.
- 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 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, 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;
- Trochanteric non-union due to inadequate reattachment and/or early weight bearing;
- Trochanteric avulsion as a result of excessive muscular weakening.

**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 Anseris Hip Stem 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 Anseris Hip Stem 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.