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The OMNIKNEE^{tm} 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, 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 prosthesis 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.

This implant is part of a system and should be used only in combination with their original OMNI Knee product belonging to the same system.

DESCRIPTION

The OMNI Knee System is a semi-constrained tri-compartmental total knee replacement for cemented and uncemented applications. The OMNI Knee consists of four modular components, with various sizes and options available for each component: a femoral component for resurfacing the distal femur (either uncoated [for cemented use only], or porous coated [uncemented or cemented use]), a tibial baseplate, an UHMWPE tibial articular component that locks to the tibial baseplate, and an UHMWPE patellar component (cemented use only). This configuration allows the user to choose a combination of femoral, tibial and patellar components to appropriately fit the anatomy of the patient. The tibial articular components are available in various thicknesses to aid in obtaining appropriate soft tissue balance and joint line height. The tibial articular inserts are size specific to the selected femoral component.

MATERIALS

- Femoral component (uncemented): cast cobalt chromium alloy (ASTM F75) with sintered cobalt chrome beads coating (ASTM 1377);
- Tibial baseplate (uncemented): cast cobalt chromium alloy (ASTM F 75)
- Insert locking bolt: wrought annealed Ti-6Al-4V titanium alloy (ASTM F 136);
- Tibial articular components: compression molded ultra high molecular weight polyethylene (UHMWPE) ASTM F648;

INDICATIONS FOR USE

The OMNI Knee^{tm} System is intended for use as a primary or revision total knee replacement. This prosthesis 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;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate, and patellar components are indicated for cemented use only.

The OMNI Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia baseplate and cemented to the prepared tibia.

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.

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 total knee replacements 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, 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.
- The tibial locking bolt must be firmly seated to prevent disassociation of the modular tibial articular and tray components. Scratching of the polished metal surfaces should be avoided. Repeated assembly and disassembly of the tibial components could compromise a critical locking action. The modular components should be changed only when clinically necessary. The interfaces should be clean and free from debris prior to assembly.
- 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.

POSSIBLE ADVERSE EFFECTS

The possible adverse effects of the OMNI Knee System are similar to those occurring with any total 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. 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.
- 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;
- Undesirable shortening or lengthening of the limb;
- 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.

Late postoperative complications can include:

- Aggravated problems of the hip or ankle of the affected limb or contralateral extremity by leg length discrepancy or muscle deficiency;
- Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
- Compression fracture of the proximal tibia by trauma or excessive loading, particularly in the presence of poor tibial bone density;
- Periarticular calcification or ossification, with or without impediment to joint mobility;
- Inadequate range of motion due to improper selection or positioning of components, boney impingement and periarticular calcification;
- Excessive joint pressures and pain with ambulation due to excessive scarring of the joint capsule and surrounding tissues;
- Infection;
- Patellar dislocation or subluxation due to soft tissue imbalance or component malalignment.

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 Knee™ System may be obtained from OMNIlife science, Inc.