Optimotion Implants Porous Metal-Backed Patella

Instructions for Use

Optimotion Implants, LLC.
6052 Turkey Lake Road, St 170
Orlando, FL 32819

Phone: 877-OPT-MOTN (877-678-6686)
Email: support@optimotionimplants.com
Website: www.optimotionimplants.com

Before using this product, read the following information thoroughly.

Description

The Optimotion™ Porous Metal-Backed Patella is an addition to the Optimotion™ Blue Total Knee System, a cruciate retaining (CR) total knee replacement system designed for patients suffering from disabling joint disease of the knee resulting from a multitude of factors including primary osteoarthritis, posttraumatic osteoarthritis, autoimmune mediated arthritis (rheumatoid), and avascular necrosis. The Optimotion Porous Metal-Backed Patella includes Onset and Inset Porous Patella Implants made from UHMWPE with Vitamin E with an additively manufactured titanium alloy metal back. The Porous Patella has an integrated ultra-porous titanium alloy bone apposition surface which is designed to be used with or without bone cement.

Features

Advanced Porous Additive Manufactured (AM) Technology: The **Porous Patella Components** have porous coatings on the majority of the bone contacting surfaces to maximize interface coverage for biological fixation. The **Porous Patella** is additively manufactured to include an Ultra-Porous Technology.

Advanced Polymer Bearing Surface Technology: The polyethylene portion of the **Patella Components** are machined from compression molded, highly cross-linked, Vitamin-E enhanced, Ultra High Molecular Weight Polyethylene (UHMWPE).

Modularity of the Implants: The Porous Patella is designed to be used with Optimotion™ Blue Total Knee System components, which allow for modularity and interchangeability between the components.

System Compatibility

The system includes a broad range of sizes to fit the normal skeletally mature patient population. The Porous Patella Components are universal and can be used on either the left or right knee. The Optimotion Porous Metal-Backed Patella is compatible for use with components of the Optimotion Blue Total Knee System components.

Indications

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from; noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis. Post-traumatic loss of knee joint configurations and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques.
- **Optimotion™ Porous Patella components are indicated for Cemented or Cementless use.**

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.

Precautions

- Surgeons must advise patients of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear to the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Surgeons should caution patients to limit activities and protect the replaced joint from unreasonable stresses and to follow the instructions of the physician with respect to follow-up care and treatment.
- Surgeons should warn patients of potential adverse effects, including the finite service life of the device and the need for post-operative protection of the implant. The surgeon should warn patients that the device does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint and that the implant can break or become damaged as a result of strenuous activity or trauma.
- Appropriate selection, placement and fixation of the total knee components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanical, and other extrinsic factors, which limit their service life.

Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.

- Surgeons should warn patients with metallic implants of the potential risks of undergoing a Magnetic Resonance Imaging (MRI) scan. The electromagnetic field created by MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, implant damage or malfunction, or other undesirable effects. In addition, the presence of a metallic implant can produce an image artifact that may appear as a void region or geometric distortion of the true image. If the image artifact is near the area of interest, it may make the MRI scan uninformative or may lead to inaccurate clinical diagnosis or treatment.

Utilization and Implantation

- Use the recommended trial components for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- Care should be taken to remove bone chips, bone cement fragments and metallic debris from the implant site to reduce the risk of debris induced accelerated wear of the articular surfaces of the implant.
- Optimotion™ Porous Metal-Backed Patella Surgical Technique Guide provides additional procedural information.

Information for patients

- The surgeon must advise the patient of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- The surgeon should caution the patient to limit activities and protect the replaced joint from unreasonable stresses and to follow the instructions of the physician with respect to follow-up care and treatment.
- The surgeon should warn the patient of surgical risks and possible adverse effects. The surgeon should warn the patient that the device does not replicate a normal healthy joint, that the implant can break or become damaged as a result of strenuous activity or trauma and that the device has a finite service life and may need to be replaced in the future.
- Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have also been associated with transient bacteremia. To prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

Warnings

In using this system, the surgeon should be aware of the following:

- In selecting patients for total joint replacements, the following factor is of extreme importance to the eventual success of the procedure: The patient's weight. The heavier the patient, the greater the load on the prosthesis. As the loads on the prosthesis increase, the chance a patient will suffer adverse reactions increases, including but not limited to failure of fixation, loosening, fracture and dislocation of the device and can lead to a decreased service life. The effect of these loads will be accentuated when a small sized prosthesis is used in larger patients. Overweight or obese patients impose greater loads on the prosthesis. As obesity is a clinical diagnosis, we leave it to the surgeon to make the diagnosis based on his/her own clinical judgement. However, the World Health Organization (WHO) defines "overweight" as a BMI equal to or more than 25, and "obesity" as a BMI equal to or more than 30.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must always be clean and free of debris prior to assembly
- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopedic device.
- Except where noted, Optimotion Implants, LLC. strongly advises against the use of another manufacturer's total knee component with any of Optimotion™ Blue Total Knee System or Optimotion™ Porous Metal-Backed Patella components. Any such use will negate the responsibility of Optimotion Implants, LLC. For the performance of the resulting mixed component implant.
- Intentional removal of a total knee component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces.
- Intentional removal of the plastic tibial insert after its assembly into the metal baseplate results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial baseplate during insert removal.
- Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**

Adverse Effects

- While the expected life of total knee replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration or mobility or reduction of pain. However, due to many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone. Surgeons should council patients against having unrealistic expectations about the lifetime of the device.
- Dislocation of the femoral, tibial, or patellar prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
- Loosening of total knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or

trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.

- Fatigue fracture of total knee components, including tibial, femoral and patellar components, has occurred in small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement surgery. These complications include but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Wear of polyethylene components has occurred, and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint and/or amputation of the limb.
- Soft tissue imbalance and/or laxity has been related to component malalignment, which may result in early wear and/or failure of the implant.
- With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, ultra-high molecular weight polyethylene (UHMWPE). Particulate is generated by interaction between components, as well as between components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particulate can also be generated by third body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.
- It is known that very small particles from metal and polyethylene components can be shed from the component during normal use and over time. Although most of this debris stays in the relevant joint (e.g. contained in the synovium) or is trapped by surrounding scar tissue, microscopic particles can possibly travel or migrate outside of the joint to different parts of the body. Currently, there are unanswered questions about debris and microscopic particles that can be generated from these components. It has been shown that microscopic debris particles can be disseminated (migrate) throughout the body and on occasion have been described as accumulating in lymph nodes and other parts of the body. Although to date no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. Given the insufficient time period during which patients with these devices have been followed and the fact that these devices are currently being used in younger patients and remain in the body for increasingly longer periods of time, it should be said that the long-term effects, if any, from these particles, is unknown. The long-term effects that have been theorized include:
    - **Cancer:** There is presently no scientific evidence that links metallic or polyethylene debris with cancer. However, the possibility cannot be ruled out.
    - **Lymphadenopathy and Accumulation in Other Tissues/Organs:** There have been a few reports of the accumulation of wear debris in lymph nodes (proximate and distal). Although no medical complications or disease processes have been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.

- **Systematic Disease:** There has been some speculation that there could be an associated between migration of debris and as yet unspecified systematic effects. It is possible that some long-term effects may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of debris and systematic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long-term effect.

Interaction with Magnetic Resonance Imaging

- The Optimotion™ Blue Total Knee System has not been evaluated for safety and compatibility in the MR environment. The Optimotion™ Blue Total Knee System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Optimotion™ Blue Total Knee System is unknown. Scanning a patient who has the device may result in patient injury.

Sterilization

- This total knee component has been sterilized by gamma radiation or ethylene oxide. Refer to the package label for the sterilization method.
- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the presence of such a flaw, the product must be assumed nonsterile. Special trial prosthesis are available to avoid having to open any aspect of the sterile package prior to component use.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product must be discarded.
- If the package is opened, but the product is not used, the component **must not be re-sterilized** and must be discarded or returned to the supplier.
- Device should not be used after the expiry date displayed on the label as packaging has not been validated beyond this date.
- Single use devices cannot be explanted and subsequently re-implanted as the physical forces exerted by these actions may compromise the physical integrity, dimensions and/or surface finishes of the devices. Also, sterility cannot be assured for reused devices as cleaning and re-sterilization procedures have not been verified.

CAUTION: FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

WARNING: Components labeled for “CEMENTED” are to be implanted only with bone cement.

Comments regarding the use of this device can be directed to

Attn: Customer Service, Optimotion Implants, LLC., 6052 Turkey Lake Road, Suite 170. Orlando, FL 32819, USA

SYMBOL LABEL KEY

 Manufacturer	 Date of Manufacture	 Do not use if package is damaged	 Do Not Reuse	 Batch Code	 Catalog Number
 Non Sterile	 Caution, consult Accompanying documents	 Use by YYYY-MM-DD	 Consult Instructions for Use	 Sterilized using Ethylene Oxide	 Sterilized Using Radiation