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3D METAL TIBIAL CONES AND FEMORAL CONES

CAUTION

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

SYMBOLS / SIMBOLI / PICTOGRAMMES / PIKTOGRAMME / PICTOGRAMAS / PICTOGRAMAS / PICTOGRAMMES / ΕΙΚΟΝΟΣΥΜΒΟΛΑ

	Manufacturer / Produttore / Fabrikant / Hersteller / Fabricante / Fabricante / Fabricant / Κατασκευαστής
	Date of manufacture / Data di fabbricazione / Fabricagedatum / Herstellungsdatum / Fecha de fabricación / Data de fabricação / Date de fabrication / Ημερομηνία παραγωγής
	Do not reuse / Non riutilizzare / Niet hergebruiken / Nicht wiederverwenden / No reutilizable / Não reutilizar / Ne pas réutiliser / Μην επαναχρησιμοποιείτε
	Do not resterilize / Non risterilizzare / Niet resteriliseren / Bitte nicht re-sterilisieren / No resterilize / Não resterilizar / Ne pas restériliser / Να μην αποστειρωθεί ξανά
	Caution, read the accompanying documents / Attenzione, consultare i documenti di accompagnamento / Opgelet, raadpleeg de bijgeleverde documenten / Achtung, Begleitdokumente beachten / Atención, consulte los documentos que se acompañan / Atenção, consultar os documentos de acompanhamento / Attention, consulter les documents d'accompagnement / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα
	Consult instructions for use / Consultare le istruzioni di utilizzo / Gebruiksaanwijzing / Bitte lesen Sie die Gebrauchsanweisung / Consulte las Instrucciones antes de su uso / Consulte as instruções de uso / Consultez les instructions d'utilisation / Οδηγίες χρήσης
	Do not expose to sunlight / Non esporre alla luce del sole / Niet blootstellen aan zonlicht / Vor Sonnenlicht schützen / No exponer a la luz solar / Não expor à luz solar / Ne pas exposer à la lumière du soleil / Μην εκθέτετε σε ηλιακό φως
	Store in a dry place / Conservare in luogo asciutto / Droog bewaren / Trocken aufbewahren / Conservar en lugar seco / Conservar em local seco / Conserver au sec / Φυλάσσετε σε ξηρό χώρο
	Temperature limit / Limite di temperatura / Temperatuur limiet / Temperaturbegrenzung / Límite de temperatura / Limite de temperatura / Limite de température / Όριο θερμοκρασίας
	Do not use if package is damaged / Non utilizzare se la confezione è danneggiata / Niet gebruiken als verpakking beschadigd is / Bitte nicht verwenden, falls Verpackung beschädigt ist / No utilice si el envoltorio está dañado / Não utilizar se a embalagem estiver violada / Ne pas utiliser si l'emballage est abîmé / Να μην χρησιμοποιηθεί εάν η συσκευασία είναι κατεστραμμένη
	Use by / Utilizzare entro il / Te gebruiken voor / Zu verwenden bis / Utilizar antes de / A utilizar antes de / A utiliser avant / Ημερομηνία λήξης
	Lot number / Numero di lotto / Nummer van de partij / Waren-Lot-Nummer / Número de lote / Número de lote / Numéro de lot / Αριθμός παρτίδας
	Reference number / Riferimento commerciale / Handelsreferentie / Referenznummer / Numero de Referencia / Referência comercial / Référence commerciale / Νούμερο παραπομπής
	Serial number / Numero seriale / Seriennummer / Seriennummer / Número de serie / Número de série / Numéro de série / Σειριακός Αριθμός
	Sterilized by irradiation / Sterilizzato mediante irradiazione / Gesteriliseerd door doorstraling / Sterilisiert durch Bestrahlung / Esterilizado por irradiación / Esterilizado por irradiação / Stérilisé par irradiation / Αποστειρωμένο με ακτινοβολία
	MR Unsafe / Non sicuro per RM / MR onveilig / MR ungeeignet / Inseguro RM / Não seguro para RM / MR non sécurisé / Μη ασφαλές στην μαγνητική τομογραφία

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Important notice: the device(s) can be prescribed and implanted only by a doctor legally authorized to perform this type of surgery.

1. GENERAL

Before any surgery, the surgeon must be familiar with the sales product literature and operative technique and must carefully read these instructions for use. Patient selection is as important as implant placement or positioning. Overweight patients or unsuitable functional requirements may generate exceptional stresses and reduce the implant life. The warnings must be heeded, and the instructions for use must be strictly followed

2. PRODUCT DESCRIPTION

In case of severe bone loss, the tibial cones and femoral cones may be used to reinforce respectively the proximal tibia cavity and the distal femoral cavity, providing structural support and load re-distribution on the remaining bone. The cone implant is made of Ti6Al4V.

3. INTENDED USE / INDICATIONS

The 3DMetal Tibial Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the GMK tibial extension stems and offsets.

The 3DMetal Femoral Cones are indicated for use with the GMK Revision and GMK Hinge knee systems, as well as the GMK Femoral extension stems and offsets.

Specific indications are as follows:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Post traumatic loss of joint configuration.
- Considerable loss of function of the knee joint.
- High-grade joint destruction requiring additional stabilization and reconstruction of bone defects.
- Primary implantation failure.
- Former revision arthroplasty.

4. CONTRAINDICATIONS

3DMetal Tibial and femoral cones are contraindicated in the following cases:

- Progressive local or systemic infection.
- Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable.

It is the surgeon's responsibility to ensure that the patient has no known hypersensitivity to the materials used. Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications..

5. WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the instrumentation supplied and specially designed for that range of implants. The trial instrumentation must be used to confirm the choice of sizes and verify the functionality of the joint.

One Medacta label for each device must be properly applied to the Medacta Implant Card provided and delivered to the patient.

MRI Compatibility

Medacta implants have not been tested for heating, migration, or to determinate the specifications for conditional status in the MR (magnetic resonance) environment. The safety of the implants in the MR environment is unknown, and the scanning of patients who have the implant may result in patient injuries.

6. MEDACTA INTERNATIONAL IMPLANTS

Under no circumstances should a Medacta International modular implant component be used in combination with a component from another manufacturer, unless otherwise specified by Medacta International. Use 3DMetal Tibial Cones and Femoral Cones only with other Medacta components. To determine whether these devices have been authorized for use in a proposed combination, please contact your Medacta sales representative. The 3DMetal Tibial Cones and Femoral Cones should never be reimplanted. While an implant may appear undamaged, microscopic

imperfections may occur and cause implant failure. Always use a trial prosthesis for trial purposes only. Trial prostheses should not be assembled with components intended for permanent placement. Never adapt or alter trial prostheses.

7. RISK FACTORS

The following conditions, individually or together, may cause abnormal loading of the affected limb, exposing the patient to greater risk of a knee arthroplasty failure:

- Obesity or excessive weight of the patient
- Hard manual work
- Intense sporting activity
- High level of activity
- Probability of falling
- Other handicaps which could compromise the outcome of the operation.

The following conditions, individually or together, will make fixation of the implants challenging:

- Advanced osteoporosis or insufficient bone stock
- Metabolic disorders or systemic medications leading to gradual loss of bone support for the prosthesis (e.g. diabetes mellitus, treatment by steroids, immunosuppressive, etc.)
- History of disseminated systemic or local infection
- Significant deformities preventing correct fixation or placement of the prosthesis
- Bone tumors in the limb to be operated
- Known hypersensitivity to the prosthesis materials or cement
- Tissue reaction to implant corrosion or wear debris
- Alcoholism or drug addiction
- Functional incapacity of the other joints.

8. INSTRUCTIONS FOR USE

PREOPERATIVE PHASE

The surgeon should verify possible patient physical limitations and mental deficiencies and should also discuss with the patient all the details of the procedure and prosthesis. The discussion should consider the limitations of the procedure and the constraints imposed by the selected implant. The factors which could limit the performance and stability of the implant, e.g. level of activity, patient's weight, should be set out to improve the patient's chances of avoiding complications. The necessity of following the postoperative instructions given by the surgeon should be fully understood by the patient. A stock of sterile implants of suitable sizes should be available and checked before surgery.

HANDLING

To avoid scratching or damaging the implants, the implants should be handled with the utmost care by qualified personnel in an environment where conditions of hygiene are controlled. The implants should be kept in their undamaged packages until needed for use. Do not use implants from opened packages, implants that are damaged, or that are beyond their expiration date.

SURGICAL TECHNIQUE

The surgeon should be fully familiar with the surgical technique. Supplementary information about the surgical techniques and products are available on request. Careful preoperative planning, based on X-rays, is essential. X-ray templates are available for 3D metal tibial cones and femoral cones.

POSTOPERATIVE CARE AND FOLLOW-UP

The surgeon should caution the patient to control their level of activity and avoid excessive loads on the replaced joint and make them aware of the precautions to be taken with regards to exercise, treatments and limitations on

activities, as well as avoiding exposure to magnetic fields. Periodic follow-up and X-rays are recommended to make comparisons with the immediate postoperative condition and identify implant displacement, loosening, etc. Excessive physical activity, and operated limb traumas may cause early failure of the arthroplasty through implant displacement, fracture and/or wear. If the case occurs, it is necessary to place the patient under supervision, evaluate the possible progression of the deterioration, and weigh the benefit of early revision.

9. ADVERSE EFFECTS AND COMPLICATIONS

GENERAL

- Prosthesis dislocation often related to the above-mentioned risk factors.
- Early or late loosening, bending, fissure fracture, fracture, deformation or wear, often related to the above-mentioned risk factors. Loosening can also occur as a result of an incorrect fixation or positioning of the components.
- Early or late infection which may require removal of the implant followed by arthrodesis or 2-stage reimplantation.
- Pain, dislocation, subluxation, flexion contracture, mobility reduction, leg shortening or lengthening, resulting from improper positioning, loosening or wear of the component.
- Fracture of the femur or of the tibia. Intra-operative fractures are usually associated with revision surgery, severe deformations and /or osteoporosis. Postoperative fractures are generally traumatic or fatigue fractures. They may result from cortex defects, multiple pin holes, former screw holes, misdirected reaming and/or uneven distribution of bone cement.
- Cardiovascular disorders and thromboembolic diseases, including thrombosis, embolism, and myocardial infarction.
- Tissue reactions, osteolysis and/or implant loosening caused by metal corrosion, allergy, wear debris, or loose cement particles.
- Myositis ossificans, especially in osteoarthritic males having a limited range of motion before the operation and/or a previous myositis. The incidence of myositis ossificans increases with past surgical history and in case of infection.

INTRA-OPERATIVE

Under no circumstances should the components come into contact with hard or sharp objects. Before use, each component must be visually inspected for imperfections. Special surgical instruments are required for knee surgery. It is important to review the use and handling of these instruments based on the surgical technique. The alignment and cutting templates must be inspected visually before operation. Distorted or damaged instruments may result in improper positioning of the prosthesis and arthroplasty failure. Careful cleaning and correct preparation of the bone surfaces are essential for the fixation of the prosthesis. Bone resection should be limited to the minimum required. Excessive bone resection may induce mechanical problems and bone resorption resulting in failure of the surgery. When preparing the bone surfaces and placing the components, it is necessary to check the components for correct alignment. Before closing the wound, the surgical site must be cleaned free of bone particles, residual cement and any foreign particles that may cause excessive wear. The range of motion and the level of constraint must be carefully checked and corrected, if necessary, to avoid incorrect seating, instability or encroachment.

IMMEDIATE POSTOPERATIVE

- Cardiovascular disorders, including vein thrombosis, embolism, and myocardial infarction.
- Hematoma and/or delayed healing.
- Pneumonia and/or atelectasis.
- Subluxation or dislocation.
- Uncontrolled varus or valgus.

LATE POSTOPERATIVE

- Aggravation of the problems with the knee and ankle of the ipsilateral or contralateral limb caused by difference in leg length, femur displacement and/or muscular deficiency.
- Fracture of the patella resulting from excessive stress or intraoperative weakening.
- Bone resorption which may damage the fixation or result in implant loosening.
- Periarticular calcification or ossification which may reduce mobility and the articular range of motion, and or encroachment.
- Subluxation or dislocation.
- The incidence and severity of the complications related to total knee replacement are usually higher with revision surgery than with primary surgery. During revision surgery, there is an increased risk of longer operative times, blood losses and higher incidence of infection, embolism and hematoma.

10. PACKAGING

All the implants are supplied in single-use individual packages. For components delivered sterile, the sterilization method is indicated on the label. The expiration date and package integrity must be checked to ensure that sterility of the contents has not been compromised. If the package is damaged, do not use the component. Do not resterilize.

11. INSTRUMENTS

Instruments are supplied non-sterile and must be cleaned and sterilized prior to use. Recommended cleaning, decontamination and sterilization instructions are provided on www.medacta.com

12. STORAGE

The packages must be stored in a cool, dry place, away from light.

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