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KNEE PROSTHESIS: EVOLIS, GMK® UNI, GMK® Primary, GMK® Sphere, GMK® Revision, MOTO®

CAUTION

This Instruction For Use is dedicated to Australian market.

SYMBOLS / SIMBOLI / PICTOGRAMMES / PIKTOGRAMME / PICTOGRAMAS / PICTOGRAMAS / PICTOGRAMMES / ΕΙΚΟΝΟΣΎΜΒΟΛΑ

	Manufacturer / Produttore / Fabrikant / Hersteller / Fabricante / Fabricante / Fabricant / Κατασκευαστής / Producent
	Date of manufacture / Data di fabbricazione / Fabricagedatum / Herstellungsdatum / Fecha de fabricación / Data de fabricação / Date de fabrication / Ημερομηνία παραγωγής / Data produkcji
	Do not reuse / Non riutilizzare / Niet hergebruiken / Nicht wiederverwenden / No reutilizable / Não reutilizar / Ne pas réutiliser / Μην επαναχρησιμοποιείτε / Nie używaj ponownie
	Do not resterilize / Non risterilizzare / Niet resteriliseren / Bitte nicht re-sterilisieren / No resterilize / Não resterilizar / Ne pas restériliser / Να μην αποστειρωθεί ξανά / Nie sterylizować ponownie
	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 / Uwaga, przeczytaj załączone dokumenty
	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 / Zapoznaj się z instrukcją użytkowania
	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 / Nie wystawiać na działanie promieni słonecznych
	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 / Przechowywać w suchym miejscu
	Temperature limit / Limite di temperatura / Temperatuur limiet / Temperaturbegrenzung / Límite de temperatura / Limite de temperatura / Limite de température / Όριο θερμοκρασίας / Limit temperatury
	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 κατεστραμένη / Nie używać, jeśli opakowanie jest uszkodzone
	Use by / Utilizzare entro il / Te gebruiken voor / Zu verwenden bis / Utilizar antes de / A utilizar antes de / A utiliser avant / Ημερομηνία λήξης / Używany przez
	Lot number / Numero di lotto / Nummer van de partij / Waren-Lot-Nummer / Número de lote / Número de lote / Numéro de lot / Αριθμός παρτίδας / Numer partii
	Reference number / Riferimento commerciale / Handelsreferentie / Referenznummer / Numero de Referencia / Referência comercial / Référence commerciale / Νούμερο παραπομπής / Numer referencyjny
	Serial number / Numero seriale / Serienummer / Seriennummer / Número de serie / Número de série / Numéro de série / Σειριακός Αριθμός / Numer seryjny
	Sterilized by irradiation / Sterilizzato mediante irradiazione / Gesteriliseerd door doorstraling / Sterilisiert durch Bestrahlung / Esterilizado por irradiación / Esterilizado por irradiação / Stérilisé par irradiation / Αποστειρωμένο με ακτινοβολία / Sterylizowane przez napromieniowanie
	Sterilized by ethylene oxide / Sterilizzato con ossido di etilene / Gesteriliseerd met ethyleenoxide / Mit Ethylenoxid sterilisiert / Esterilizado por óxido de etileno / Esterilizado por óxido de etileno / Stérilisé à l'oxyde d'éthylène / Αποστειρώθηκε με αιθυλενοξείδιο / Sterylizowany tlenkiem etylenu
	Double sterile barrier system /Sistema a Doppia Barriera Sterile/ Dubbele steriele verpakking/ Doppeltes steriles Barrieresystem/ Sistema de doble barrera estéril/ Sistema de Dupla Barreira Estéril/ Système à barrière stérile double/ Σύστημα διπλού στείρου εμποδίου / Podwójny system bariery sterylnej
	Containing hazardous substances/contiene sostante pericolose/Bevat gevaarlijke stoffen / Contienen sustancias peligrosas / Contendo substâncias perigosas / Contenant des substances dangereuses /Περιέχει επικίνδυνες ουσίες

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ENGLISH: KNEE PROSTHESIS SYSTEM - INSTRUCTIONS FOR USE

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 literature and operative technique and must read carefully these instructions for use. Patient selection is as important as implant placement or positioning. Overweight or unsuitable functional requirements may generate exceptional stresses and reduce the implant life. These warnings must be heeded, and the instructions for use must be strictly followed.

2. PRODUCT DESCRIPTION

Total knee prosthesis, comprising individually packaged femur, tibial, patellar component, extension stems, offset connectors, augmentations, and screws (Evolis only), are designed for tricompartmental replacement of the natural knee joint. The femoral component is made of CoCr cemented or cementless version or CoCr coated by a layer of SensiTiN (only cemented version). The tibial components consist of a metal baseplate, made of Ti6Al4V (Evolis) or CoCr, cemented or cementless (GMK Primary and Sphere), or coated by a layer of SensiTiN (only cemented version) and a liner made of Ultra-High Molecular Weight Polyethylene (UHMWPE). The patellar component is made of Ultra-High Molecular Weight Polyethylene (UHMWPE). Screws (Evolis only) are made of Ti6Al4V. Extension stems are made of Ti6Al4V. Offset connectors are made of Ti6Al4V. Femoral augmentations (GMK Revision only) are made of stainless steel or Ti6Al4V with a fixing screw made of Ti6Al4V, cemented tibial augmentations are made of Ti6Al4V, tibial augmentations fixed by screws (GMK Revision only) are made of stainless steel or Ti6Al4V with two fixing screws of Ti6Al4V. Semi-constrained liner (GMK Revision only) is made of Ultra-High Molecular Weight Polyethylene (UHMWPE) with a support peg of CoCr alloy. All the auxiliary components of the prosthesis are supplied in single-use individual packages. A unicompartmental knee prosthesis (GMK UNI, MOTO), comprising individually packaged femoral and tibial components, is designed to replace the natural articular surface of a femoral condyle: The femoral component is made of CoCr, cemented or cementless version (MOTO, GMK UNI). The tibial component can consist of a tibial tray made of CoCr, cemented or cementless version (only GMK UNI), or Ti6Al4V cemented or cementless version (only MOTO) and an insert made of ultra-high molecular weight (UHMWPE) (GMK UNI, MOTO). A bone cancellous screw is mandatory for the cementless version of the GMK UNI Fixed Plus tibial tray and MOTO, while optional for the cemented version (only GMK UNI). Metal components are all made of implant-grade materials as per ISO 5832 and Polyethylene is compliant with ISO 5834.

Cementless Implants

Cementless implants must not be implanted with cement, unless otherwise specified on the label.

Cemented Implants

It is essential to follow carefully the instructions for use provided by the cement manufacturer because cement handling may influence the effectiveness of implant fixation.

3. INTENDED USE / INDICATIONS

Total (Evolis, GMK Primary, GMK Sphere, GMK Revision) or unicompartmental (GMK UNI, MOTO) knee arthroplasty is intended to provide increased patient mobility and reduced pain by replacing the damaged knee joint, if there is evidence of sufficient sound bone to seat and support the components. Candidates for total or unicompartmental knee replacement are patients with a severely painful and/or severely disabled joint as a result of osteoarthritis, post-traumatic arthritis, rheumatoid polyarthritis, or primary implantation failure (only for the cemented version). In unicompartmental knee arthroplasty, only one compartment of the joint is affected (the medial or lateral compartment). If, in the opinion of the surgeon, an unequivocal indication for total or unicompartmental knee replacement outweighs the risks associated with the age of the patient, and if limited demands regarding activity and knee joint loading can be assured, total or unicompartmental knee replacement may be considered for young patients. This includes severely disabled patients with multiple joint involvement for whom and immediate gain in knee mobility may lead to significant improvement of their quality of life.

4. CONTRAINDICATIONS AND ADVERSE EFFECTS AND COMPLICATIONS

Contraindications

Total (Evolis, GMK Primary, GMK Sphere, GMK Revision) or unicompartmental (GMK UNI, MOTO) knee replacement is 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
- Severe instability secondary to advanced destruction of osteochondral structures or loss of integrity of the lateral ligament
- Unicompartmental replacement is contraindicated in patients who have a permanent valgus or varus deformity that requires correction in order for the knee to function satisfactorily postoperatively
- Mental or neuromuscular disorders may create an unacceptable risk to the patient and can be a source of postoperative complications.

It is the surgeon's responsibility to ensure that the patient has no known allergy to the materials used.

Adverse effects and complications

1. General

- Early or late loosening, tibial subsidence, bending, fissure fracture, fracture, deformation or wear of one or more prosthetic components. Loosening can also occur as a result of incorrect fixation or positioning of the components.
- Early or late infection which may require removal of the implant followed by arthrodesis.
- Pain, dislocation, subluxation, flexion contracture, mobility reduction, leg shortening or lengthening, resulting from malposition, loosening or wear of the components.
- Excessive wear of the polyethylene components due to damage to the femoral component, loose cement or bone fragments and/or high levels of activity or weight.
- Fracture of the tibia or femur. Perioperative fractures are usually associated with revision surgery, severe deformations and/or osteoporosis.
- Postoperative fractures are generally 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.
- Tissular 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.
- Possible paralysis of the anterior tibial nerve after unicompartmental knee arthroplasty.

2. Immediate Postoperative
- Haematoma
- Delayed healing, or wound dehiscence
- Uncontrolled varus or valgus
- Sinking associated with all polyethylene components
- Poor range of motion due to incorrect selection or positioning.

3. Late Postoperative
- Periarticular calcification or ossification with or without mobility reduction
- Fracture of the patella resulting from excessive stress or peroperative weakening
- Aggravation of the problems of the operated or contralateral limb caused by a difference in leg length.

The incidence and severity of the complications related to total or unicompartmental knee replacement are usually higher with revision surgery than with primary surgery. During revision surgery, there is an increased risk of longer operative times and higher incidence of infection, embolism and hematoma.

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.

Risk factors
The following conditions may cause excessive loading of the affected limb, exposing the patient to greater risk:

- Obesity or overweight
- Manual work
- Intensive sporting activity
- High level of activity
- Probability of falling
- Alcoholism or drug addiction
- Other handicaps which could compromise the outcome of the operation

The following conditions will make fixation of the knee prosthesis 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, etc.)
- History of disseminated or local infection
- Significant deformations preventing correct fixation or placement of the prosthesis
- Tumours of the supporting bone structures
- Hypersensitivity reactions to the prosthesis materials or cement
- Tissular reaction to implant corrosion or wear debris
- Functional incapacity of the other joints

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 which is 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. 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 that scanning of patients who have the implant may result in patient injuries. Polyethylene implants should be stored for at least 3 hours at 20°C (+/- 3 °C) before the operation. The components of a knee prosthesis should never be reimplanted. While an implant may appear undamaged, microscopic imperfections or deformations may occur and cause implant failure. The label can indicate some limitations, the surgeon should take this information into consideration before implantation. One Medacta label for each device must be properly applied to the Medacta Implant Card provided and delivered to the patient.

6. MEDACTA INTERNATIONAL IMPLANTS

Under no circumstances should a Medacta International modular implant component be used in combination with a component from another manufacturer. The components of the various Medacta International systems must not be combined unless the operative technique recommends it. Component compatibility and assembly must be checked using appropriate instrumentation. It is important to inspect the contact surfaces for cleanliness and check that there is nothing interposed before assembling them.

INSTRUCTIONS FOR USE

7. 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, etc.) should be set out to improve the patient's chances to avoid complications. The necessity to follow 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 by the operator before surgery.

The prerequisites for total or unicompartmental knee replacement should be met and include:

- Osteoarthritic damage to the femorotibial and/or femoropatellar surfaces
- Stability of lateral ligaments, or possible ligament repair
- Existing or restorable physiological axis
- Integrity of the quadriceps and popliteal tendon
- Natural patella capable of accepting the patellar component, if needed.

8. HANDLING

The surgeon and operating theatre personnel should wear sterile surgical gloves. Under no circumstances should the components come into accidental contact with hard objects. Under no circumstances should the porous surfaces come into contact with any cloth or material which can release fibers. Before use, each component must be visually inspected for imperfections. Special surgical instruments are required for knee surgery. It is important to refresh any training related to the use and handling of these instruments. The alignment and cutting templates must be inspected visually before the operation. Distorted or damaged instruments may result in malposition of the prosthesis and arthroplasty failure. Careful cleaning and correct preparation of the bone surfaces are essential for fixation of the prosthesis. Bone resection must be kept minimal. Excessive bone resection or excessive use of pins to secure the instruments 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 must be carefully checked and corrected, if necessary, to avoid incorrect sealing, instability, or encroachment.

To avoid scratching or damaging the implants, the implants should be handled with the utmost care by qualified personnel and 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, that are damaged, or that are beyond their expiration date.

9. 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, documented by X-rays, is essential. MOTO specific templates are available.

10. 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 as regards exercises, treatments and limitations on activities, as well as exposure to magnetic fields. Periodic follow-up and X-rays are recommended to make comparisons with the immediate postoperative condition and anticipate displacement, loosening, bending or fissuring of the prosthetic components. 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.

11. PACKAGING

All the components of a total knee prosthesis are supplied in single-use individual packages. For sterile components, 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.

12. 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

13. STORAGE

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

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