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 **Manufactured by:**
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Knee Prosthesis: Evolis/GMK Sphere/GMK Primary/GMK Revision

CAUTION

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

SYMBOLS

	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
	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 utilize 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
	Sterilized with ethylene oxide / Sterilizzato con ossido di etilene / Gesteriliseerd met ethyleenoxide / Ethylenoxid-sterilisiert / Esterilizado con óxido de etileno / Esterilizado com óxido de etileno / Stérilisé à l'oxyde d'éthylène / Αποστειρωμένο με οξειδίο του αιθυλενίου
	Sterilized by irradiation / Sterilizzato mediante irradiazione / Gesteriliseerd door doorstraling / Sterilisiert durch Bestrahlung / Esterilizado por irradiación / Esterilizado por irradiação / Stérilisé par irradiation / Αποστειρωμένο με ακτινοβολία
	Manufacturer / Produttore / Fabrikant / Hersteller / Fabricante / Fabricante / Fabricant / Κατασκευαστής
	MR Unsafe / Non sicuro per RM / MR onveilig / MR ungeeignet / Inseguro RM / Não seguro para RM / MR non sécurisé / Μη ασφαλές στην μαγνητική τομογραφία

GMK SPHERE - 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 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

Total knee prosthesis, comprising individually packaged femur, tibial, patellar component, extension stems, offset connectors (GMK® Revision only), wedges (GMK® Revision only) and screws (Evolis® only), is designed for tricompartmental replacement of the natural knee joint.

The femoral component is made of CoCrMo the tibial components consist of a metal baseplate, made of Ti6Al4V (Evolis®) or CoCrMo (GMK®), a liner made of ultra-high molecular weight polyethylene (UHMWPE) or Highly Crosslinked UHMWPE with Vitamin E (E-CROSS™, GMK Sphere only) and a tibial insert fixing screw made of Ti6Al4V.

The patellar component is made of ultra-high molecular weight polyethylene (UHMWPE) or Highly Crosslinked UHMWPE with Vitamin E (E-CROSS™, Resurfacing Patella only). Screws (Evolis® only) are made of Ti6Al4V. Extension stems are made of Ti6Al4V. Offset connectors (GMK® Revision only) are made of Ti6Al4V. Femoral wedges (GMK® Revision only) are made of stainless steel with a fixing screw made of Ti6Al4V, cemented tibial wedges are made of Ti6Al4V, tibial augmentation screwed (GMK® Revision only) are made of stainless steel 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 CoCrMo alloy.

GMK Sphere, GMK Primary PS, GMK Revision and Evolis PS tibial insert fixing screws are made of Ti6Al4V. The use of GMK Primary PS, GMK Revision and Evolis PS fixing screws is mandatory. The use of GMK Sphere fixing screw is optional.

All the auxiliary components of the prosthesis are supplied in single-use individual packages.

GMK Revision ultracongruent hybrid liners can be used only with standard Evolis femoral components and fixed GMK tibial trays; GMK Revision posterior-stabilized hybrid liners can be used only with posterior-stabilized Evolis femoral components and fixed GMK tibial trays.

Tibial wedges cemented can be used only with GMK Primary tibial trays. Tibial augmentation screwed can be used only with GMK Revision tibial trays.

GMK® Full PE tibial component is made of ultra-high molecular weight polyethylene (UHMWPE) with two radiopaque wires made of stainless steel.

3. INTENDED USE / INDICATIONS

The Evolis®/GMK® knee prosthesis is designed for cemented use in total knee arthroplasty, if there is evidence of sufficient sound bone to seat and support the components.

This knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Avascular necrosis of femoral condyle.
- Post traumatic loss of joint configuration.
- Primary implantation failure.

GMK Sphere can be implanted using a kinematic alignment approach. When a kinematic alignment approach is utilized, this knee replacement system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Moderate valgus, varus, or flexion deformities.

Tibial wedges cemented are to be attached to the tibial baseplate with both the fixing cylinders and bone cement. The screwed tibial augments are for screwed fixation to the tibial baseplate.

In case a semi-constrained liner is used, an extension stem must be implanted both on the tibial and on the femoral components.

In case a GMK Revision tibial tray is used, an extension stem must be implanted.

4. CONTRAINDICATIONS

Total 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 condylar structures or loss of integrity of the lateral ligament.

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.

The Kinematic Alignment Surgical Technique is contraindicated also for patients with greater than 5° valgus deformity with MCL insufficiency.

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.

The Evolis® bone screws are not intended for spinal fixation.

The surgeon should implant this system only in patients with sufficient intact soft tissue.

The Evolis®/GMK® Knee Systems 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 Evolis®/GMK® Knee Systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Only authorized Medacta® combinations should be used. Use Evolis® components only with other Evolis® components.

Use GMK® components only with other GMK® components. To determine whether these devices have been authorized for use in a proposed combination, please contact your Medacta® sales representative.

The components of a knee prosthesis 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.

PE implants should be stored for at least three hours at 20°C (+/- 3°C) before the operation.

7. RISK FACTORS

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

- Obesity or overweight of the patient
- Hard manual work
- Intense 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, individually or together, 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, immunosuppressives, etc.)
- History of disseminated systemic or local infection
- Significant deformations preventing correct fixation or placement of the prosthesis
- Tumors of the supporting bone structures
- Allergic reactions to the prosthesis materials or cement
- Tissue reaction to implant corrosion or wear debris
- 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 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 before surgery.

The prerequisites for total knee replacement include:

- Osteoarthritic damage to the femorotibial and/or femoropatellar surface
- Stability of lateral ligaments, or possible ligaments repair
- Integrity of the quadriceps and popliteal tendon
- Natural patella capable of accepting the patellar component, if need be.

HANDLING

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.

Evolis® bone screws are self-tapping unless otherwise declared.

Ensure that the connection between screwdriver and screw's head is exactly aligned in vertical direction. An adequate pressure should be applied to ensure that the blade of the screwdriver correctly fits the screw's head. Careful tightening should be applied to the insertion of the bone screws to avoid any risk of damaging the screw, the orthopaedic implant and/or the bony hole.

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. X-ray templates are available for most implants.

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, tibial subsidence, bending, fissure fracture, fracture, deformation or wear of one or more of the prosthetic components, 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 components.
- Excessive wear of the polyethylene component 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. 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 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 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 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

- Poor range of motion due to incorrect selection or positioning
- 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 implant components of the total knee prosthesis 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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