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KNEE PROSTHESIS: GMK HINGE®

CAUTION

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

ENGLISH – GMK HINGE® KNEE PROSTHESIS - 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.

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.

This Instruction For Use will apply with extension stem, offset, tibial/femoral augment and patellar components of the GMK Knee system when used in connection with the GMK Hinge implant.

PRODUCT DESCRIPTION

GMK HINGE® total knee prosthesis, comprising individually packaged femur, tibial, patellar component, extension stems, offset connectors, femoral wedges and tibial augmentation, is designed for tricompartmental replacement of the natural knee joint.

The femoral component is made of CoCr with a ultra-high molecular weight polyethylene (UHMWPE) bush. The tibial component consists of a tibial baseplate made of CoCr and a liner made of ultra-high molecular weight polyethylene (UHMWPE). The inlay package also contains auxiliary parts such as a screw made of Ti6Al4V to fix the inlay on the tibial baseplate, a metal cylinder made of CoCr to be engaged into the hinge post, a screw made of Ti6Al4V to fix this metal cylinder on the femoral hinge post. The patellar component is made of ultra-high molecular weight polyethylene (UHMWPE). Extension stems are made of Ti6Al4V. Offset connectors are made of Ti6Al4V. Femoral wedges are made of stainless steel with a fixing screw made of Ti6Al4V, tibial augmentation screwed are made of stainless steel with two fixing screws made of Ti6Al4V.

INTENDED USE / INDICATIONS

The GMK HINGE® knee prosthesis is designed for cemented use in total knee arthroplasty when the preoperative diagnosis of the joint determines that the bone and stability situation require the implantation of a constrained prosthesis.

The GMK HINGE® knee system is indicated in the following cases:

- Severely painful and/or disabled joint as a result of arthritis, traumatic arthritis, rheumatoid arthritis or polyarthritis associated with bone loss and/or severe joint instability
- Considerable loss of function of the knee joint
- High-grade joint destruction requiring additional stabilization with stems and reconstruction of bone defects with metal augmentation
- Failure of a primary prosthesis (e.g. infection, loosening)
- Former revision arthroplasty
- Post traumatic loss of joint configuration
- Avascular necrosis of femoral condyle.

Tibial augmentation are to be screwed to the tibial baseplate with both the two provided fixing screws.

When a GMK HINGE® implant is used it is mandatory to implant both the femoral and tibial components with an extension stem.

CONTRAINDICATIONS

GMK HINGE[®] total knee prosthesis 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
- 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.

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 GMK HINGE[®] bone screws are not intended for spinal fixation.

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

The GMK HINGE[®] 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 GMK HINGE[®] in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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.

Demanding anatomical and functional preoperative conditions, individually or together, can present challenges to achieving optimal alignment of components. Poor alignment, as well as insufficient bone support and compromised adjacent anatomy, can cause abnormal and unpredictable stresses on the prosthetic components, which may result in loss of fixation, intra-prosthetic disassembly or prosthetic component fracture. Potentially related preoperative conditions include, but are not limited to, the following:

- 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 impairment of the surrounding muscles or of the other joints.

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 GMK HINGE[®] components only with other GMK HINGE[®] 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.

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

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
- Integrity of the quadriceps and popliteal tendon
- Natural patella capable of accepting the patellar component, if needed.

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.

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. GMK HINGE[®]-specific X-ray templates are available.

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.

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. Incorrect assembling of the final implant may lead to early mechanical failure. Following the correct procedure to assemble all the implant modular connections as described in the surgical technique is crucial for the implant survival rate. 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.

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.














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

STORAGE

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

SYMBOLS

	Do not reuse
	Do not resterilize
	Caution, read the accompanying documents
	Consult instructions for use
	Do not expose to sunlight
	Store in a dry place
	Do not use if package is damaged
	Use by
	Lot number
	Reference number
	Sterilized with ethylene oxide
	Sterilized by irradiation
	MR Unsafe

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