

GAK REVISION SYSTEM

GLOBAL MEDACTA KNEE

DIFFERENT NEEDS... ...YOUR GLOBAL SOLUTION



Design Rationale

Joint

Spine

Sports Med

GMK REVISION SYSTEM - DESIGN RATIONALE

INDEX

1	INTRODUCTION	4
2	MODULARITY	5
2.1	Full transition across the system	5
2.2	Modular instruments layout	6
2.3	MyKnee Crossover technique	7
3	ANATOMIC FIT	8
3.1	360° offset	8
3.2	Asymmetric tibial baseplate	8
3.3	Comprehensive range of sizes and options	9
3.4	Bone preserving design	11
3.5	Anatomic patello-femoral joint	12
4	STABILITY AND MOBILITY	12
4.1	Level of constraint	12
4.2	Range of motion	13
5	LONGEVITY	14
5.1	Extensive mechanical tests campaign	14
5.2	Reproducible implant assembly	16
6	BIBLIOGRAPHY	17

1. INTRODUCTION

The GMK Revision System is designed for the orthopaedic surgeon to be a reliable and intuitive tool for basic and complex revisions, and to provide maximum ease of use and flexibility for the surgical team.

The GMK Revision System features a condylar constrained implant (GMK Revision), as well as a totally constrained (GMK Hinge) option.

- **MODULARITY**
Different levels of constraint and a smooth transition across the various options available.
- **ANATOMIC FIT**
A vast range of surgical solutions to address the unique anatomy of each patient.
- **STABILITY AND MOBILITY**
A system designed to provide residual mobility at different levels of flexion while stabilizing the knee according to the level of soft tissue deficiency.
- **LONGEVITY**
More than 50 different mechanical tests or computational analyses with excellent results, to deliver maximum confidence in the surgeon's hands.

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GMK HINGE
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2. MODULARITY

2.1 FULL TRANSITION ACROSS THE SYSTEM

A modern knee system should provide different levels of constraint and benefit from a smooth transition across the various options available, ensuring maximum intraoperative flexibility for the surgeon. The GMK System has been designed to allow a full transition with intuitive minimal surgical steps to switch from a cruciate retaining to a totally constrained implant.

All GMK Revision System options are modular so the final implant construct can be built step-by-step according to the patient's needs.

Every femoral component within the GMK System offers the same internal profile (as shown in image below), which provides the surgeon with the freedom to choose the appropriate constraint for the patient. This can be done even after the cuts have been performed.

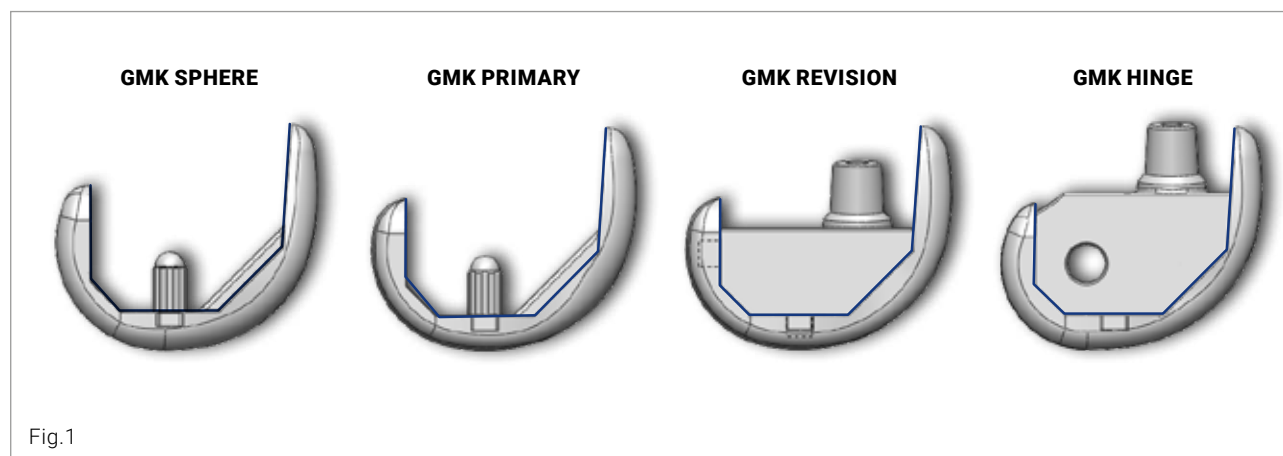
In addition, the articular profiles of GMK Revision and GMK Primary femoral components are the same, which allows compatibility with the same ultra-congruent primary inserts in case of stemmed or augmented primary implants with acceptable collateral ligaments stability.

In the presence of moderate varus/valgus deficiencies, the semi-constrained insert may be considered to stabilize the knee. When there is major varus/valgus instability, the totally constrained hinge insert may be the most suitable solution.

The system's modularity may provide intra-operative advantages:

- All stems can be utilized with an offset.
- All cemented or cementless stems are interchangeable between the femur and tibia.
- Femoral and tibial augments are interchangeable between medial and lateral side as well as between the GMK Revision and GMK Hinge.

A knee revision system should provide a wide range of options without overstressing hospital inventory. The highly modular configuration of GMK Revision System dramatically decreases hospital inventory.



2.2 MODULAR INSTRUMENTS LAYOUT

Many competitive knee revision sets are considered bulky and require multiple trays during a case. This may increase set up time as well as sterilization costs for each case.

GMK Revision System instrumentation has been conceived with a modular layout as a combination of add-on trays that can be opened only when needed, limiting the number of instruments to sterilize and optimizing the operative room efficiency.

The GMK Revision System modularity provides multiple advantages:

- Allows for procedure-specific selection of instrument tray options.
- Potentially reduces the number of trays to open for any given procedure.
- Allows the surgeon to follow different surgical workflows, flawlessly adapting the procedure to his own preferences or the patient's conditions.

Starting from the intramedullary canal: this procedure is indicated when revising a primary failed implant and no reliable anatomic landmarks are available except the intramedullary canal. In this scenario there are two possible workflows, according to the extent of bone loss:

- Inside-out technique (from bone to trials): the IM canal is reamed first, the construct is built off the reamer and then the bone is prepared to accommodate the trial implant. Finally the components are assembled on the back table and implanted in the femur and tibia.
- Outside-in technique (from trials to bone): in case of huge bone loss on femoral condyles and proximal tibia, the trial implant can be pre-assembled on the back table, eyeballing the offset position and then inserted into the bone that can be shaped later on through the trials.

Starting from the bone cuts (i.e. crossover technique): the bone cuts are done first and then the stem position is adapted according to the resections. This may be the typical situation in a primary stemmed case when switching from a less to a more-constrained insert intraoperatively. In such a scenario, a short cemented stem may be advisable.

GENERAL REVISION TRAYS



GMK REVISION SPECIFIC TRAYS



GMK HINGE SPECIFIC TRAYS



2.3 MYKNEE CROSSOVER TECHNIQUE

Planning for a knee revision surgery is a key factor in ensuring its success.

Preoperative radiographic planning includes estimation of the components size, the joint line position assessment, the stem fitting and the bone loss management options.

The GMK Revision System can benefit from the proven accuracy of MyKnee Patient Matched Technology in order to provide the surgeon preoperative information that are crucial for a successful revision surgery.

Combining the vision provided by Medacta MyKnee patient matched technology and the straightforward crossover technique, a highly reproducible surgical technique can also be used to implant GMK Revision or GMK Hinge in difficult primary cases, where ligament are highly unstable.



Fig.2
CT scan acquisition and bone model reconstruction.

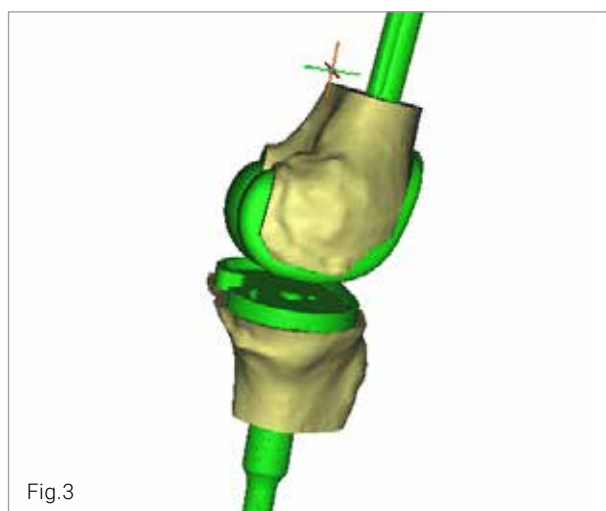


Fig.3
MyKnee planning with 3D simulation of the implant positioning.



Fig.4
Bone resections through the MyKnee cutting blocks.

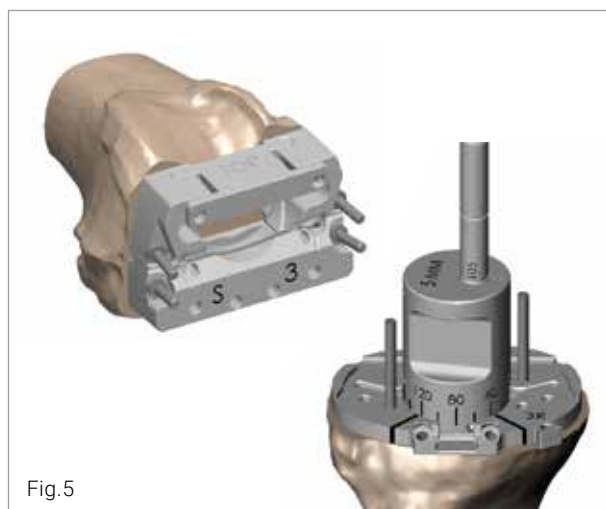


Fig.5
Femoral and tibial finishing to accommodate the final implant.

3. ANATOMIC FIT

3.1 360° OFFSET

Managing revision surgeries often requires re-establishing the original joint line^[1], to create balanced flexion and extension gaps^[2] and proper patellar tracking^[3].

GMK Revision System offers 360° offset options for both femur and tibia, to improve flexibility in positioning the components.

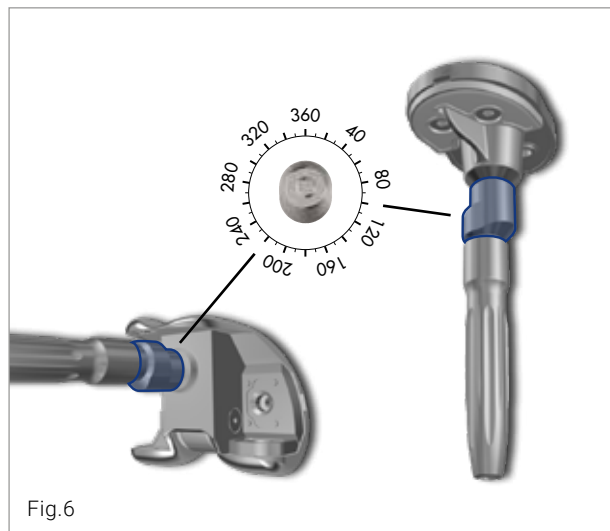


Fig.6

The 360° offset option allows the properly-sized femoral component to be properly positioned in the antero-posterior direction to match the anterior cortex. It also allows the fine-tuning of the medio-lateral position of the femoral component. It is important to note that implant overhang may be cause of postoperative pain due to impingement with soft tissue^[4].

The stem connection on the femur is set anteriorly so that a 3mm offset option is enough to move the femoral component and align the anterior flange on the residual femoral anterior cortex.

The 360° offset option allows the tibial component to properly cover the tibial resection without compromising the antero-posterior and medio-lateral position. The final goal is to find a position that provides stable cortical bone support thus potentially limiting the risk of implant subsidence.

3.2 ASYMMETRIC TIBIAL BASEPLATE

Building a stable tibial platform is a key factor for a successful revision surgery, especially when revising a primary implant due to loosening or subsidence.

The main goal is to transfer as much load as possible to the tibial cortical rim, which shows better mechanical properties than the inner cancellous bone.

Both GMK Revision and GMK Hinge feature an anatomic asymmetric tibial tray to facilitate cortical bone coverage, minimizing compromises.

With the GMK Revision System the surgeon can manage multiple factors to optimize the tibial cut coverage:

- Size of the baseplate (from 1 to 6)
- Tibial offset (3 or 5 mm)
- Offset angle (360 degrees)
- Tibial rotation
- Anatomic shape, i.e. left and right version, with a wider medial side to reproduce the geometry of a resected tibia^[5].



Fig.7

3.3 COMPREHENSIVE RANGE OF SIZES AND OPTIONS

Patients are not all the same. To address the unique anatomy of each patient, having a wide range of options available in the operative room is a crucial requirement. The GMK Revision System has been designed to provide the surgeon with a vast range of surgical solutions.



Fig.8

Addressing instability

Different levels of constraint are available (ultracongruent, condylar constrained, hinge) in order to provide the most suitable stabilization for the knee prosthesis.



Fig.9

Addressing bone loss

Various augmentation blocks are available to fill asymmetric defects on the distal and posterior femur as well as on the proximal tibia.

3D Metal tibial cones are available to assist in recreating a proximal structural foundation to support the intended revision implant, by achieving proximal fixation in remaining host bone and transmitting forces to it.



Fig.10

Addressing fixation

Both press-fit and cemented stems are available in the GMK Revision System portfolio. They can be chosen intra-operatively, depending on bone quality.

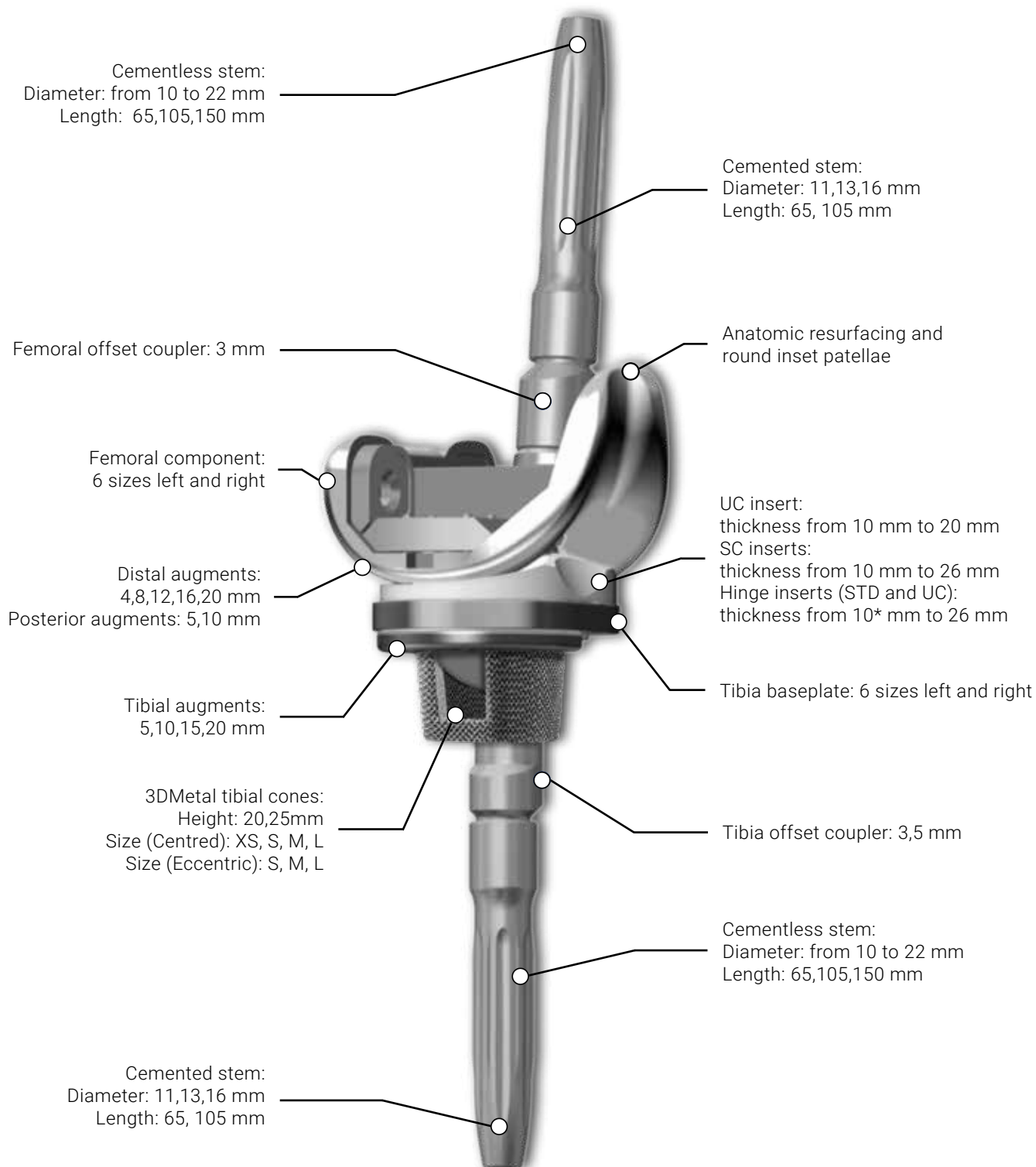


Fig.11

Addressing joint line restoration

Multiple inlay thicknesses are available to restore the proper joint line position. This is a crucial step in order to maintain correct patellar tracking, thereby reducing the risk of "patella baja" syndrome.

The following picture summarizes all the available options for GMK Revision System.



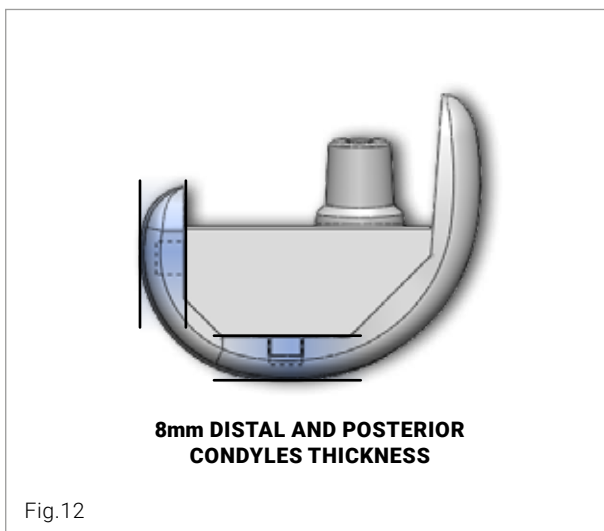
*10 mm Hinge tibial insert (STD and UC) not available in the US market

3.4 BONE PRESERVING DESIGN

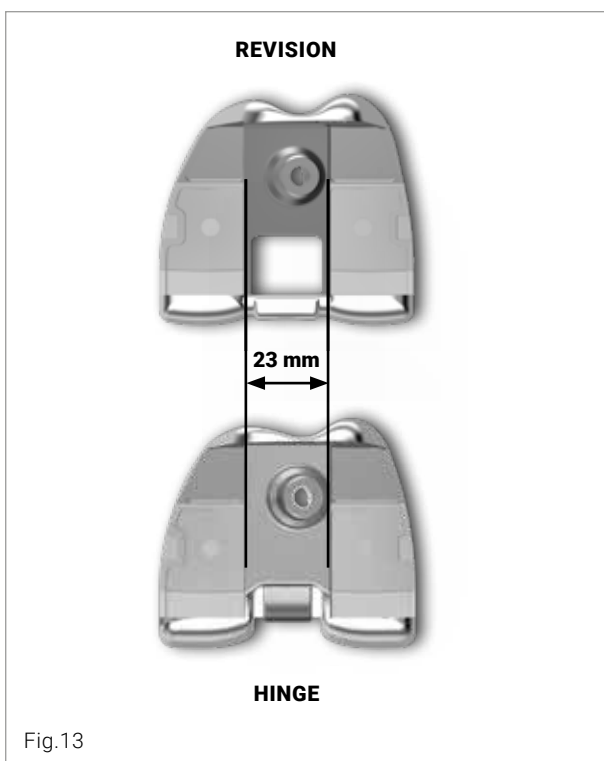
When performing a revision surgery in a compromised knee joint, preserving as much bone stock as possible is imperative.

The GMK Revision System has been designed to preserve bone stock on both the femur and tibia.

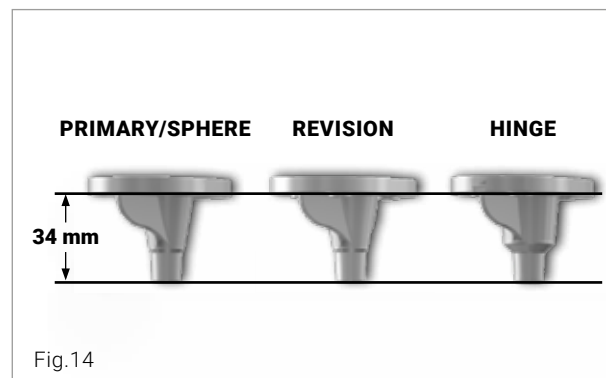
For this reason the distal and posterior condyles are only 8mm thick, which is the same as GMK Primary.



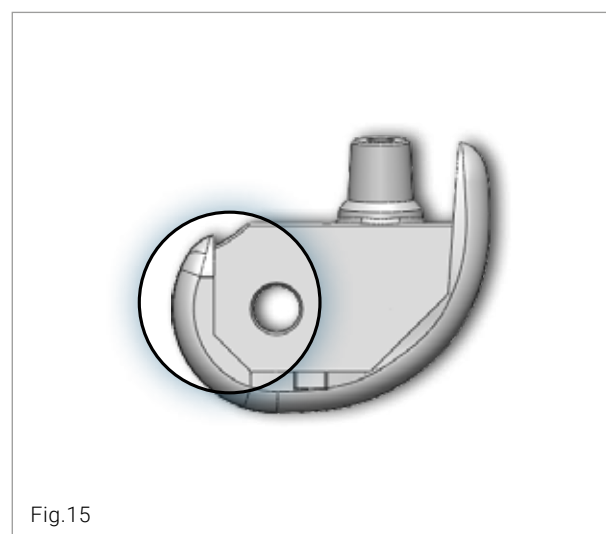
The medio-lateral dimension of the femoral box is the same for all GMK Revision and Hinge sizes. It does not increase with size.



The tibial keel depth is the same as a GMK Primary; this allows the use of an offset coupler to adapt the tibial baseplate position. Wide fins provide additional torsional stability to the construct.



Differently from many other designs on the market, the hinge mechanism does not extend on the posterior condyles, remaining embedded in the intercondylar notch. This dramatically reduces the amount of bone to be cut on the posterior femoral condyles, which preserves precious bone stock.



3.5 ANATOMIC PATELLO-FEMORAL JOINT

Clinical data confirm that a trochlea angle between 5° and 7° aligns the patellar tendon in the same direction as the acting forces, reducing unnatural and undesired stress values while optimizing the patellar tracking (natural or prosthetic)^[6].

The trochlea groove for the GMK System (Primary, Sphere, Revision and Hinge) has been designed 7mm deep and 6° oriented, to accommodate the patellar component (natural or prosthetic) thus reducing the risk of subluxation^[12].

The lateral wall of the anterior flange is higher to counteract forces acting to dislocate the patella laterally^[7]. To further improve patella stability, the patella component has a design with a medialized dome mimicking the natural patella shape^[8].

The trochlear groove extends into the intercondylar notch to accommodate the patella tracking in mid-flexion, thus reducing the risk of clunk and instability^[3,9,10].



4. STABILITY AND MOBILITY

4.1 LEVEL OF CONSTRAINT

Condylar constrained and totally constrained knees should provide adequate stability without excessively limiting mobility. GMK Revision System has been designed to provide residual mobility at different levels of flexion while stabilizing the knee according to the level of soft tissue deficiency.

The following table shows the residual mobility allowed by GMK Revision and GMK Hinge^[12].

GMK REVISION

Residual mobility VS Size matching	Femur X - Tibia X	Femur X+1 - Tibia X
Hyperextension	6°	6°
Rotational freedom at 0° flexion	± 3°	± 3°
Rotational freedom at 90° flexion	± 14°	± 12°

GMK HINGE

Residual mobility VS Size matching	Femur X - Tibia X	Femur X+1 - Tibia X
Hyperextension	3°	3°
Rotational freedom at 0° flexion	± 9°	± 8°
Rotational freedom at 90° flexion	± 12°	± 12°

GMK HINGE (UC INSERT)

Residual mobility VS Size matching	Femur X - Tibia X	Femur X+1 - Tibia X
Hyperextension	± 1°	± 0°
Rotational freedom at 0° flexion	± 2°	± 1°
Rotational freedom at 90° flexion	± 12°	± 12°

4.2 RANGE OF MOTION

Among the most common daily activities, the movements requiring high flexion are: stair ascent (60°), rising from a chair (90°) and rising from a double-leg kneel (135°).^[11]

GMK Revision and GMK Hinge have been designed to allow high flexion, patient conditions permitting.

GMK Revision implant design theoretically allows up to 140 degrees of flexion^[12], according to femur-tibia size combination and when the overall patient conditions are optimal.

Similarly, GMK Hinge implants allow up to 134 degrees of flexion^[12], according to femur-tibia size combination and when the overall patient conditions are optimal.

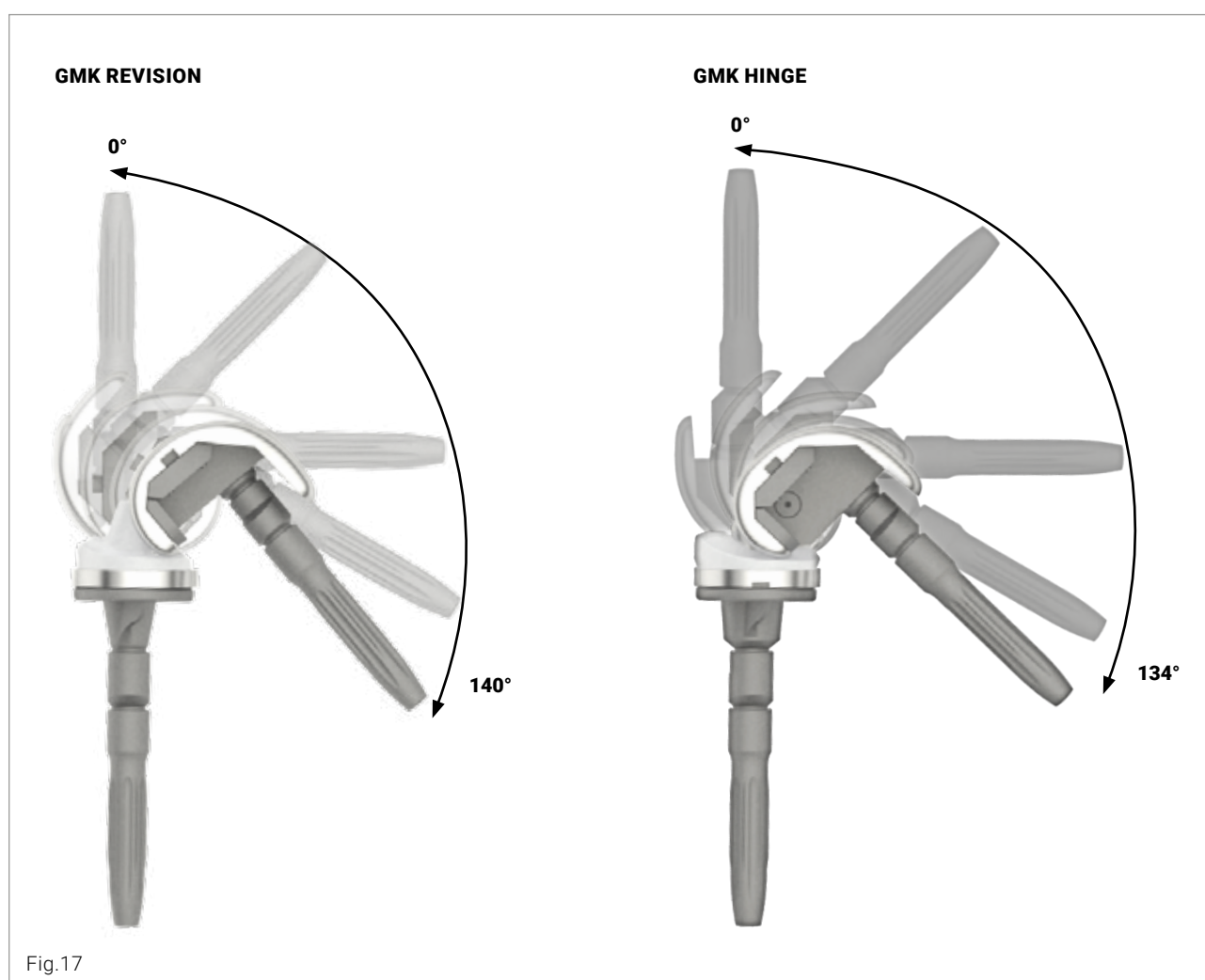


Fig.17

5. LONGEVITY

A knee revision system has to bear significant load, so it must be accurately tested to ensure high durability under physiological conditions.

The GMK Revision System has undergone more than 50 different mechanical or FEA simulation tests with excellent results^[12], to deliver maximum confidence in the surgeon's hands.

5.1 EXTENSIVE MECHANICAL TESTS CAMPAIGN

A comprehensive panel of static, dynamic and fatigue tests have been conducted to test the different components of GMK Revision and Hinge under physiological conditions.

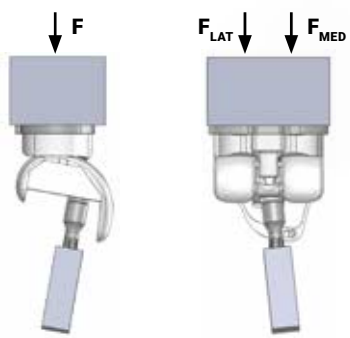
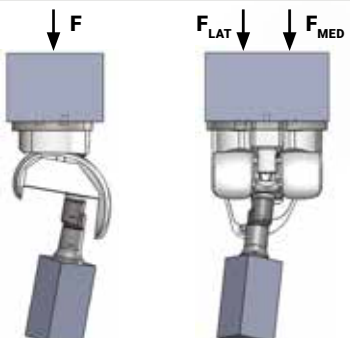
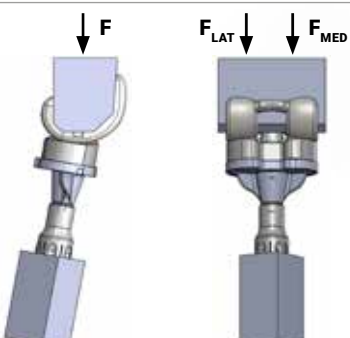
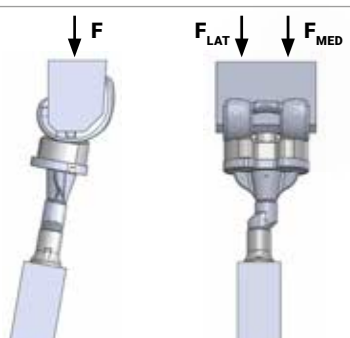
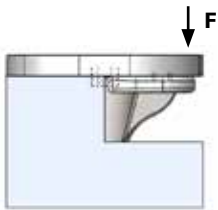

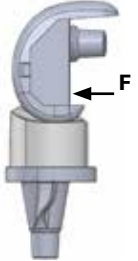

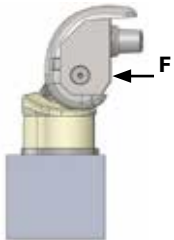
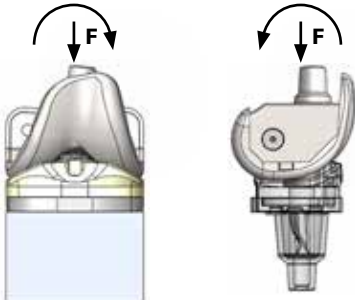
Image	Test Description	Results
	<p>Femoral extension stem - Fatigue test</p> <p>GMK Revision femoral component assembled with extension stem to prove the safety and effectiveness of the modular connection and the endurance of the extension stem.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the modular parts. No evident signs of fretting and/or corrosion on the tapers at the end of the test.</p>
	<p>Femoral extension stem + offset - Fatigue test</p> <p>GMK Revision femoral component assembled with offset and extension stem to prove the safety and effectiveness of the modular connections.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the modular parts. No evident signs of fretting and/or corrosion on the tapers at the end of the test.</p>
	<p>Tibial extension stem - Fatigue test</p> <p>GMK tibial tray assembled with extension stem to prove the safety and effectiveness of the modular connections and the endurance of the extension stem.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the modular parts. No evident signs of fretting and/or corrosion on the tapers at the end of the test.</p>
	<p>Tibial extension stem + offset - Fatigue test</p> <p>GMK tibial tray assembled with extension stem and offset connector to prove the safety and effectiveness of the modular connections.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the modular parts. No evident signs of fretting and/or corrosion on the tapers at the end of the test.</p>

Image	Test Description	Results
	<p>Mechanically attached tibial wedges - Endurance test</p> <p>GMK tibial tray in combination with mechanically attached tibial wedges to prove the endurance of the tibial wedges.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the parts.</p>
	<p>Mechanically attached femoral wedges - Endurance test</p> <p>GMK Revision femoral component in combination with mechanically attached femoral wedges to prove the endurance of the femoral wedges.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the parts. No evident signs of fretting and/or corrosion on the tapers at the end of the test.</p>
	<p>GMK Revision A/P dynamic test</p> <p>Dynamic test at 90° flexion to prove the safety and effectiveness of the connection between SC tibial insert and tibial tray and the endurance of the CoCrMo peg.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the parts. No evident signs of fretting and/or corrosion on the tapers at the end of the test.</p>
	<p>Hinge post system - Endurance test</p> <p>Endurance test of the hinge post system under hyperextension loads</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the parts. The test shows how the connections are stable and fixed after dynamic loading conditions.</p>
	<p>GMK Hinge A/P dynamic test</p> <p>GMK Hinge AP dynamic test to validate the ability of the implant to withstand physiological dynamic AP loads.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the parts. The test shows how the connections are stable and fixed after dynamic loading conditions.</p>
	<p>GMK Hinge V/V dynamic test</p> <p>GMK Hinge Varus/Valgus dynamic test to validate the ability of the implant to withstand physiological dynamic V/V loads.</p>	<p>All the five tested specimens reached 10 million cycles without any signs of breakage or disengagement of the parts. The test shows how the connections are stable and fixed after dynamic loading conditions.</p>

5.2 REPRODUCIBLE IMPLANT ASSEMBLY

To ensure the implant is safely assembled intraoperatively, specific instruments are provided, such as torque wrenches and special impactors.



Fig.18

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NOTES



**REDEFINING BETTER
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GMK Revision System
Design Rationale

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