

GAAK[®] SPHERE

MEDIALY STABILIZED KNEE

STABILITY FOR LIFE



Brochure

Joint

Spine

Sports Med

PATIENT SATISFACTION AFTER KNEE ARTHROPLASTY

Despite the excellent longevity of total knee arthroplasty, many patients continue to experience functional deficits after surgery.

Patient expectations are not as well fulfilled by TKA as by total hip replacement, with fewer knee patients achieving a "forgotten joint" replacement. Studies show that around 20% of TKA patients are not satisfied^[1, 2, 3]. Excessive A/P motion may result in anterior knee pain and continued swelling. In many P/S designs, the stabilizing mechanism only engages after 70°-80° of flexion, leaving the knee vulnerable to A/P instability during the most commonly encountered functional activities^[4].

GMK[®] SPHERE

MEDIALLY STABILIZED KNEE

Based on the knee anatomy and kinematic studies conducted by Prof. Michael Freeman and Prof. Vera Pinskeroval^[6], GMK Sphere is an innovative total knee implant designed to deliver **maximum functional stability** with the goal of increasing TKA **patient satisfaction** during activities of daily living and **decreasing post-operative knee pain**.

STABILITY IN TKA IMPROVES PATIENT SATISFACTION

In a study conducted on patients with a conventional CR or PS in one knee and a medially stabilized device in the other, 76% preferred the knee with the "ball in socket" medial compartment^[5]. Patients reported:

- It feels more normal
- It is stronger when ascending/descending stairs
- It has superior single-leg weight bearing
- It feels more stable during flexion and in overall performance
- There are fewer clunks, pops and clicks

KEY FEATURES

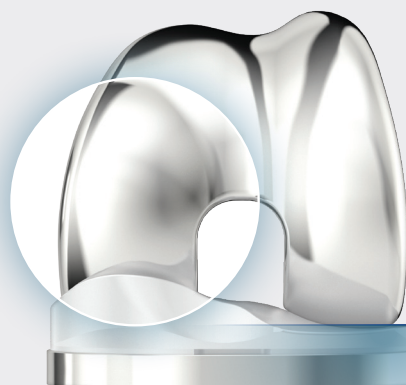


PATIENT-SPECIFIC KINEMATICS

GMK Sphere accommodates the best pattern of kinematic motion for each patient, rather than imposing an assumed "norm"^[11]. This is achieved with:

- "Ball in socket" stability throughout the range of motion in the medial compartment^[7,10,11]
- Freedom of movement in the lateral compartment^[10,11]

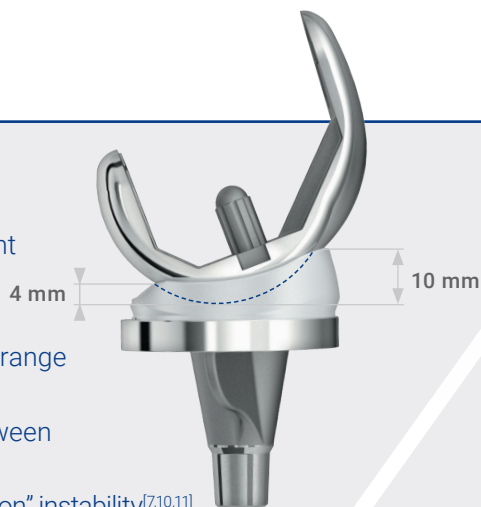
SPHERICAL MEDIAL COMPARTMENT


 UNCONSTRAINED
LATERAL
COMPARTMENT

STABILITY

GMK Sphere features a fully congruent medial compartment providing:

- High stability throughout the range of motion^[7,10,11]
- No paradoxical motion between femur and tibia^[7,10,11]
- No implant-related "mid-flexion" instability^[7,10,11]



NATURAL PATELLAR TRACKING

GMK Sphere replicates the natural lateralized patella tracking to reduce patello-femoral joint pressure and address anterior knee pain^[8,9]:

- Trochlea groove lateralized by 2 mm to enable natural patella tracking^[9]
 - Flattened medial trochlear wall prevents patello-femoral overstuffing, minimizing retinacular tension^[8]
 - Anatomic patellar implant with medialized dome allows for optimal bony coverage with reduced soft tissue tension, improved stability and greater contact area^[12]

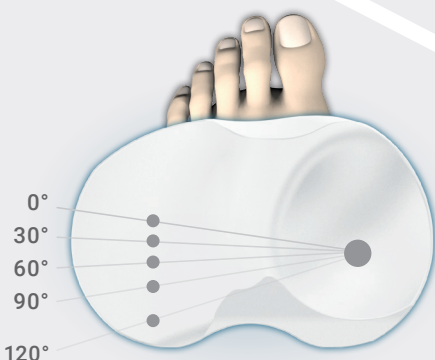
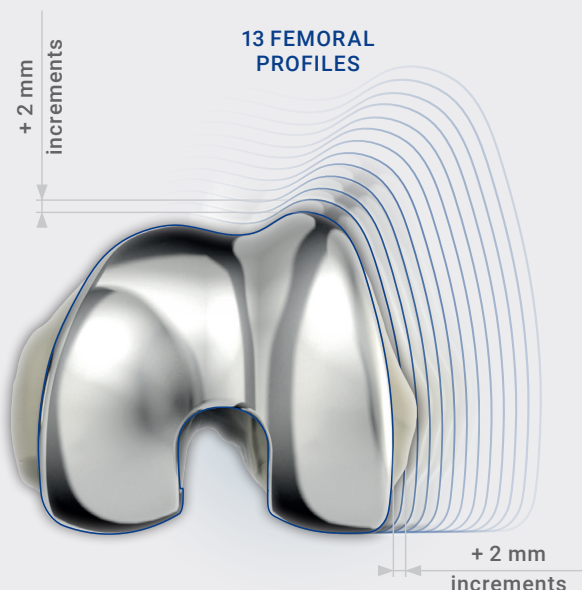


ANATOMICAL FIT

An extensive anthropometric research performed in the MyBody database* containing more than 15,000 CT and MRI scans of knees led to the validation of the following^[12]:

- Range of 13 femoral sizes with 2 mm increments that best fit a broad spectrum of anatomic profiles
- Anatomically shaped tibial baseplate
- Range of inserts with 1 mm increments

The combination of 13 femoral sizes and inserts with 1 mm increments allows the surgeon to "fine tune" ligament balance and improve stability throughout the range of motion.



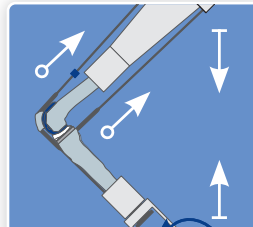
RESPONSIBLE INNOVATION

Medacta is committed to providing innovative and safe solutions for patients with an evidence-based approach.

GMK Sphere was tested over 3 years prior to launch through an intensive evaluation program, including *in vitro* and *in vivo* trials and Laboratory tests^[8,10,11,14].



1. Extensive laboratory tests and computer simulations^[10]



2. Cadaver validation^[8]



3. Sophisticated clinical evaluation in centers around the world^[11,14]

SYNERGY



REFERENCES

[1] Bourne RB et al. "Patients satisfaction after total knee arthroplasty: who is satisfied and who is not?" Clin Orthop Relat Res. 2010. [2] Tippet SR et al. "Collecting Data with Palm Technology: Comparing Preoperative Expectations and Postoperative Satisfaction in Patients Undergoing Total Knee Arthroplasty." J Bone Joint Surg Am. 2010. [3] Behrend et al. "The 'Forgotten Joint' as the Ultimate Goal in Joint Arthroplasty", The Journal of Arthroplasty vol 27, n 3, 2012. [4] Blaha D "The Rationale for a Total Knee Implant That Confers Anteroposterior Stability Throughout Range of Motion" The Journal of Arthroplasty Vol. 19 No. 4 Suppl. 1 2004. [5] Pritchett JW "Patients Prefer A Bicruciate-Retaining or the Medial Pivot Total Knee Prosthesis", The Journal of Arthroplasty, 2011. [6] Freeman MAR, Pinskerova V "The movement of the normal tibio-femoral joint", J Biomech. 2005 Feb;38(2):197-208. [7] Hossain F et al. "Knee arthroplasty with a medially conforming ball-and-socket tibiofemoral articulation provides better function", Clin Orthop Relat Res. 2011 Jan;469(1):55-63. [8] Jansson V et al, "Kinematics and contact patterns before and after TKA: an in vitro comparison of GMK PS vs. GMK Sphere", Podium presentation at DKOU 2014, October 28-31 2014. [9] Meijerink HJ et al, "The trochlea is medialized by total knee arthroplasty. An intraoperative assessment in 61 patients". Acta Orthopaedica, 2007. [10] Morra EA, Greenwald AS "Simulated kinematic performance of The GMK-Sphere Total Knee Design During A Stand to Squat Activity", Study Report 2013. [11] Banks S et al, "In Vivo Kinematics of a Medially Conforming & Rotationally Unconstrained TKA Design", Podium presentation at the 27th Annual Meeting of the International Society for Technology in Arthroplasty, Kyoto, Japan, September 25-27, 2014. [12] Data on file: Medacta. [13] Haider H, Kaddick C, "Wear of Mobile Bearing Knees: Is It Necessarily Less?", Journal of ASTM International, 2012. [14] Field R et al, "Preliminary results of GMK Sphere". 7th M.O.R.E. International Symposium, Proceedings. Distributed with The Bone & Joint Journal, June 2014 issue.

* The CT and MRI scans contained in the "MyBody" database are anonymous and do not permit in any way the identification of patients. Medacta recognizes the importance of personal data protection and considers that preserving the confidentiality of personal data is one of the main objectives of its activity, in compliance with any applicable privacy law and regulation.

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