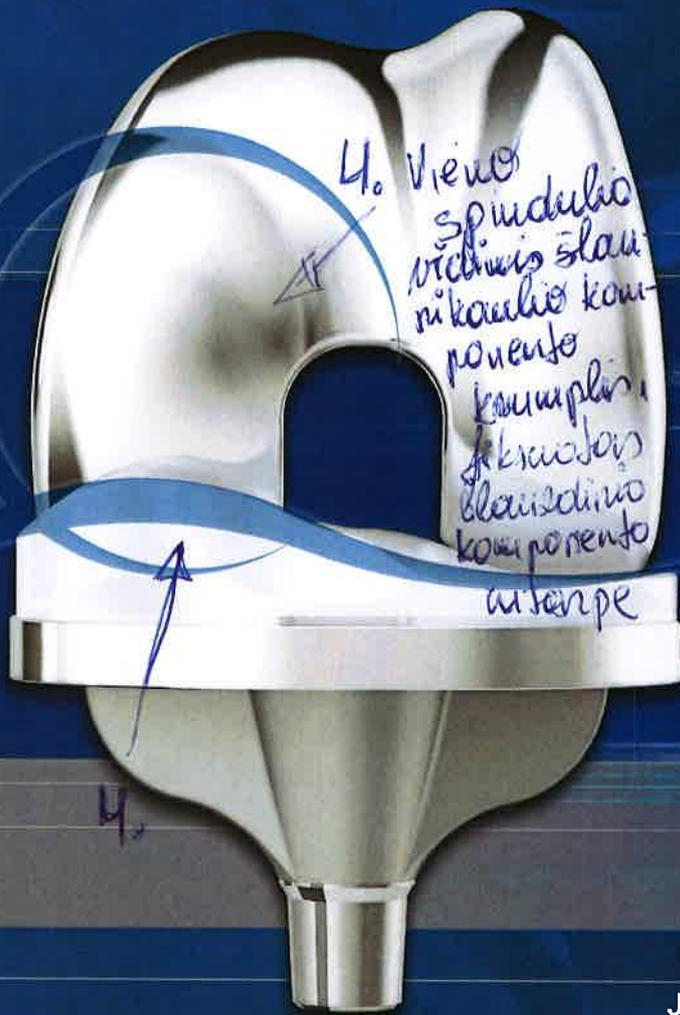


13.

GAAK[®] SPHERE

MEDIALY STABILIZED KNEE

STABILITY FOR LIFE



Surgical Technique

Joint

Spine

Sports Med

14.

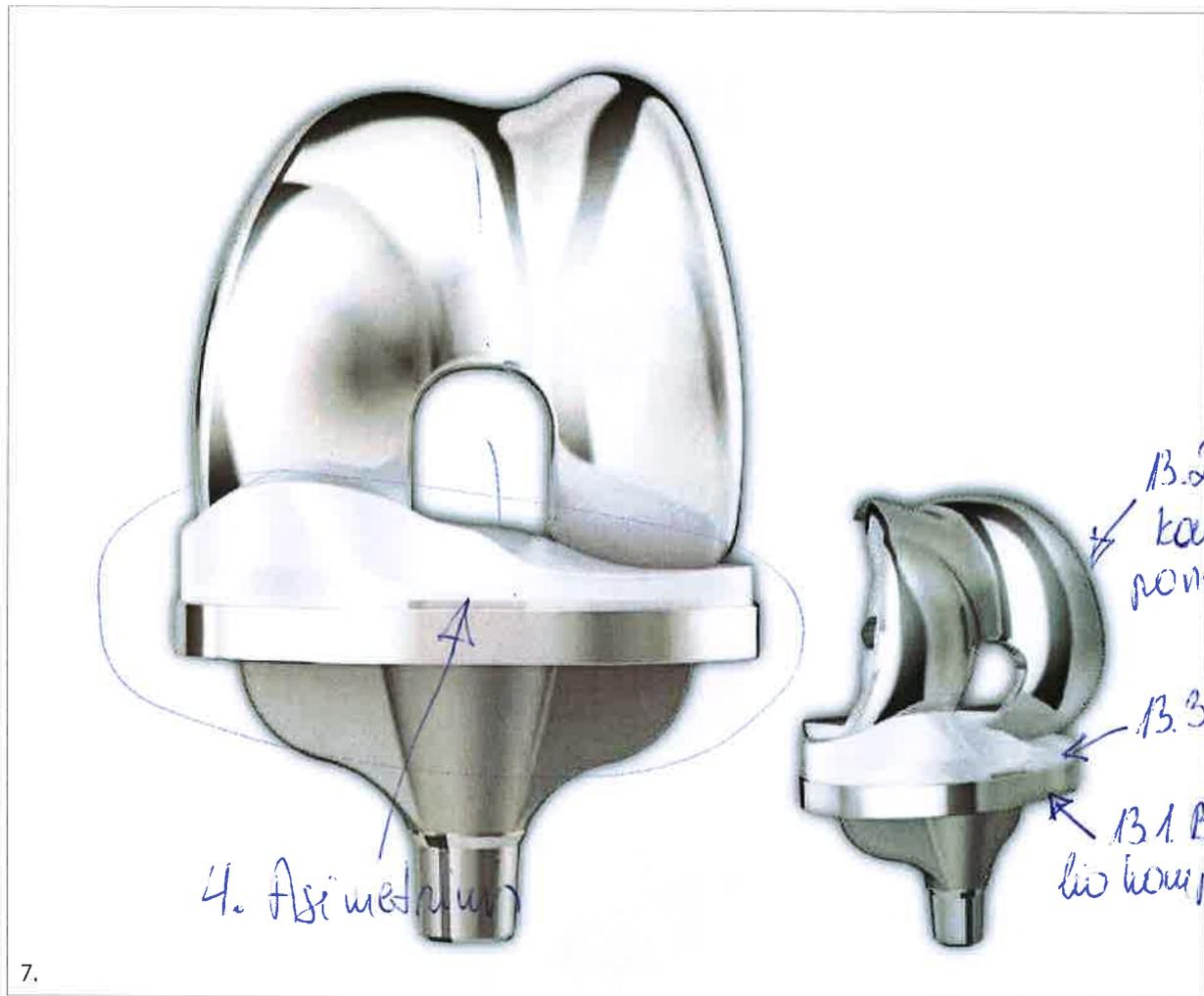
Medacta
International

3. GMK SPHERE: STABILITY FOR LIFE

Based on the knee anatomy and kinematic studies performed by Prof. Michael Freeman and Prof. Vera Pinskerova, the 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.

The GMK Sphere is characterized by four key features:

- STABILITY**
 A stable, fully conforming medial compartment providing AP stability in mid-flexion and throughout the range of motion.
- NATURAL PATELLAR TRACKING**
 An innovative patellar tracking design conceived to reduce the patellofemoral joint pressure and address anterior knee pain.
- PATIENT-SPECIFIC KINEMATICS**
 A design that accommodates the best pattern of kinematic motion for each patient rather than imposing some assumed «norm».
- ANATOMICAL FIT**
 A design resulting from an extensive anthropometric research from a global database.



5. STABILITY IN TKA IMPROVES PATIENT SATISFACTION

Patients who receive a total knee replacement prefer a feeling of «stability.» In a study in which bilateral patients had a conventional knee designs CR or PS in one knee and a more stable knee prostheses (designs with a medial “ball in socket”) in the other, 76% of patients preferred the knee with the medial “ball in socket” (Pritchett 2004) (Pritchett 2011).

These patients gave the following reasons for their preference:

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

Patient preference regarding their knee arthroplasty (Patients were asked: Which is your better knee overall?)

Type of Implant	n	Prefer Knee 1	Prefer Knee 2	Cannot Tell	P*
MS vs PS	42	32 (76.2%)	4 (9.5%)	6 (14.3%)	<.001
MS vs CR	50	38 (76.0%)	6 (12.0%)	6 (12.0%)	<.001
MS vs MB	83	51 (61.4%)	25 (30.1%)	7 (8.4%)	.003

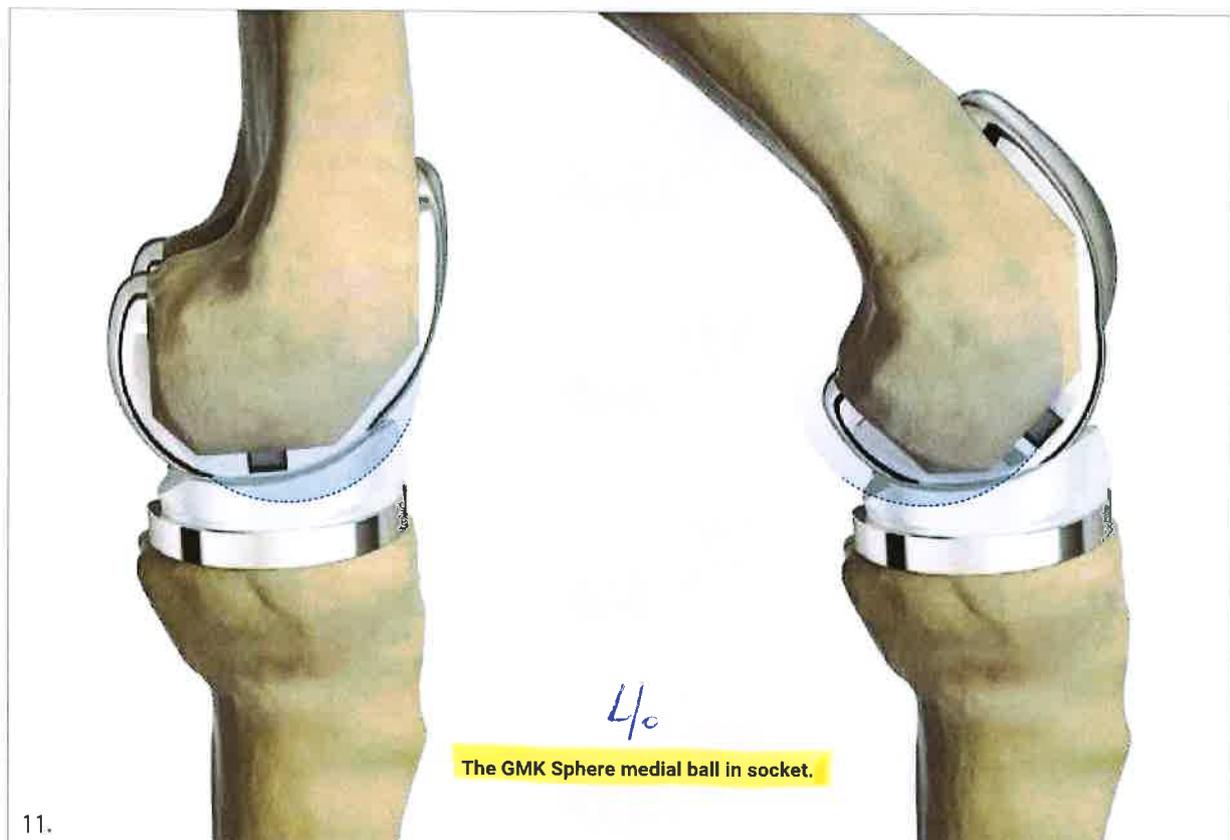
*Likelihood ratio test for equal percentage of preferred procedures

MS = Medially stabilized knee (with a medial “ball in socket”)

PS = Posterior stabilized knee

CR = Posterior cruciate retaining knee

MB = Mobile bearing knee



11.

10

*Verkauf, welches kausale Prinzipien in verschiedenen
 nicht-mechanischen Komponenten, kausale Prinzipien
 bei Stabilität, nicht-mechanische Prinzipien, kausale Prinzipien
 3*

4.

The GMK Sphere is designed with a spherical and fully congruent medial compartment which provides anterior-posterior stability in mid-flexion and during the range of motion. This mechanism is also named "ball-in-socket mechanism" (Hossain F 2011).

In vivo and in vitro studies show that the GMK Sphere fully congruent medial compartment provides:

- High stability throughout the range of motion (Morra and Greenwald 2013) (Imam M 2014)
- No paradoxical motion between femur and tibia (Morra and Greenwald 2013) (Imam M 2014)
- No implant-related "mid-flexion" instability (Morra and Greenwald 2013) (Imam M 2014)

The fully conforming design of the GMK Sphere medial compartment could reduce also noise (i.e. pops, clicks, and clunks) that may be generated by the replaced knee (Sharkey PF 2011).

The GMK Sphere medial ball-in socket mechanism can replicate the function and the stability provided by the ACL and PCL and the medial meniscus.



14. Constant femoral radius between - 45° and 115° degrees of flexion in the medial compartment. Same radius in the medial and lateral sagittal profile.



15. The posterior medial condyle is wider than the lateral one to increase medial stability throughout the range of motion, to maximize the contact area and to better accommodate natural anatomy.





FEMORAL COMPONENT

13 sizes

Anatomical: left and right

Cemented: 0.5 mm deep pockets

Material: Cobalt-Chrome (Co-Cr-Mo ISO 5832-4)



Material: Cobalt-Chrome (Co-Cr-Mo ISO 5832-4) + SensiTIN coating



1. INTRODUCTION

This brochure describes the Surgical Technique to implant the GMK Sphere. This technique is designed to be used with arthritic knees that do not have significant bone loss, major contractures or soft tissue laxity.

This technique focuses on knee alignment and in setting tibial and femoral resections based on bone references. Soft tissues are then managed "around" the resections. The technique can be used in both tibia first and femur first approaches.

The surgical technique involves extramedullary (EM) alignment for the tibial cut and intramedullary (IM) alignment for the femoral cut. The distal femoral resection is made with respect to the intramedullary canal. The surgeon has the option of making the distal cut with different degrees of valgus relative to the anatomical axis of the femur, in accordance with the patient's anatomy. The A/P 4in1 cutting block positioning can be based on a choice of anatomical references (posterior condyles, epicondyles or Whitesides line).

CAUTION

Some instruments are fixed to the bone using dedicated pins. Before using the pins, ensure that they are intact and fully functional. BENT OR DEFECTIVE PINS CAN NOT BE USED AND MUST BE REPLACED BY NEW ONES. When extracting pins it is important not to bend them. This results in axial alignment between the pin and the dedicated extractor. It is strongly recommended not to impact or hammer on any instruments unless otherwise specified in the surgical technique. For detailed instructions contact your local Medacta sales representative.

Please note

In the surgical technique described hereafter, the resections are performed in the following order:

- A. Tibial resection
- B. Distal femoral resection
- C. A/P femoral resections and chamfers

Nevertheless, the surgeon can change the order of the resections, choosing the following sequence:

- A. Distal femoral resection
- B. A/P femoral resections and chamfers
- C. Tibial resection

It is compulsory to perform the distal femoral resection before the A/P resection and chamfers.

1.1 INDICATIONS

The GMK Sphere is designed for cementless and 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.

1.2 CONTRAINDICATIONS

GMK Sphere 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 condralar structures or loss of integrity of the medial or 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.

1.3 PREOPERATIVE PLANNING

Radiological planning

This is performed from the scanogram, anterior-posterior, lateral and sunrise knee radiographs. The goals are to determine the angle formed by the anatomical axis and the mechanical axis, the tibial slope, to trace and measure bone resections, to establish the intramedullary guide introduction points, to assess the sizes of the femoral and tibial components, the height of the tibial insert, the thickness of patella to be resected, to study the topography of the operative site (localization of osteophytes and particularly posterior osteophytes).

Clinical planning

The goal is to assess the range of motion of the joint and patellar centring and to assess whether deformities and ligamentous instability exist or not.

*3. Klyuz na nuz
na is ay barua*

1.4 SURGICAL APPROACH

The most common surgical approach is the vertical midline skin incision and a medial parapatellar approach. Other approaches may be used depending on the surgeon's preferences. After exposing the joint via elevation of the medial retinaculum, flex the knee. Prior to any bone resection define the normal bony architecture by removing the osteophytes (including those at the intercondylar notch) as collectively these contribute to the maintenance of any malalignment and conceal the true bone size. Resect the anterior cruciate ligament. If you are using a GMK Sphere FLEX insert (not E-CROSS), resect also the posterior cruciate ligament which also aids exposure by permitting easier subluxation of the tibia for its subsequent osteotomy.

CAUTION

- GMK Sphere FLEX tibial insert was not designed to allow preservation of the posterior cruciate ligament (PCL).
- GMK Sphere CR tibial insert or GMK Sphere CR tibial insert E-CROSS require that the PCL be preserved and efficient.
- GMK Sphere FLEX tibial insert E-CROSS allows to stabilize the knee also in absence of an efficient PCL. The possibility to preserve the PCL must be verified intraoperatively.

*kompenzatsiya abizy
na is ay barua*

*Is ang
uspatrali
ny reisiy.*

During all procedures it is the intention to replace the bone and cartilage, that has been lost secondary to the arthritic process and resected as part of the arthroplasty, with a similar thickness of polyethylene and metal provided by the prosthetic components.

1. GMK SPHERE FEMORAL COMPONENT

1.0 Cementless femur
GMK SPHERE FEMUR CEMENTED



MATERIALS:
 Co28-Cr6-Mo - ISO 5832-4

GMK SPHERE SensiTiN FEMUR CEMENTED



SensiTiN

MATERIALS:
 Co28-Cr6-Mo - ISO 5832-4 + TiNbN coating

GMK SPHERE FEMUR CEMENTLESS



DeltaGrip

MATERIALS:
 Co28-Cr6-Mo - ISO 5832-4

Kaunai puse

5.0

Desini puse

LEFT SIDE	SIZE	RIGHT SIDE
02.12.0001L	1	02.12.0001R
02.12.0021L	1+	02.12.0021R
02.12.0002L	2	02.12.0002R
02.12.0022L	2+	02.12.0022R
02.12.0003L	3	02.12.0003R
02.12.0023L	3+	02.12.0023R
02.12.0004L	4	02.12.0004R
02.12.0024L	4+	02.12.0024R
02.12.0005L	5	02.12.0005R
02.12.0025L	5+	02.12.0025R
02.12.0006L	6	02.12.0006R
02.12.0026L	6+	02.12.0026R
02.12.0007L	7	02.12.0007R

LEFT SIDE	SIZE	RIGHT SIDE
02.12.0701L	1	02.12.0701R
02.12.0721L	1+	02.12.0721R
02.12.0702L	2	02.12.0702R
02.12.0722L	2+	02.12.0722R
02.12.0703L	3	02.12.0703R
02.12.0723L	3+	02.12.0723R
02.12.0704L	4	02.12.0704R
02.12.0724L	4+	02.12.0724R
02.12.0705L	5	02.12.0705R
02.12.0725L	5+	02.12.0725R
02.12.0706L	6	02.12.0706R
02.12.0726L	6+	02.12.0726R
02.12.0707L	7	02.12.0707R

LEFT SIDE	SIZE	RIGHT SIDE
02.12.1001L	1	02.12.1001R
02.12.1021L	1+	02.12.1021R
02.12.1002L	2	02.12.1002R
02.12.1022L	2+	02.12.1022R
02.12.1003L	3	02.12.1003R
02.12.1023L	3+	02.12.1023R
02.12.1004L	4	02.12.1004R
02.12.1024L	4+	02.12.1024R
02.12.1005L	5	02.12.1005R
02.12.1025L	5+	02.12.1025R
02.12.1006L	6	02.12.1006R
02.12.1026L	6+	02.12.1026R
02.12.1007L	7	02.12.1007R

4
13 dydisis

13.2. Skaunikausio komponentas



3. GMK SPHERE TIBIAL BASEPLATE

As Bureaus, mio + vnt, nio
GMK SPHERE TIBIAL BASEPLATE CEMENTED



8. GMK Tibial Baseplate
Sizes 1 to 6



GMK Sphere Tibial Baseplate
Size t3-i4 (Tibia size 3 for insert size 4)



GMK Sphere Tibial Baseplate
Size t4-i3 (Tibia size 4 for insert size 3)

MATERIALS: Co28-Cr6-Mo - ISO 5832-4
UHMWPE - ISO 5834-2 TYPE 1 (PLUG)

Keine neue

REFERENCE NUMBERS

<i>7.</i> LEFT SIDE	SIZE	<i>7.</i> RIGHT SIDE
02.07.1201L	1	02.07.1201R
02.07.1202L	2	02.07.1202R
02.07.1203L	3	02.07.1203R
02.07.1204L	4	02.07.1204R
02.07.1205L	5	02.07.1205R
02.07.1206L	6	02.07.1206R
02.12.t3i4L	t3-i4	02.12.t3i4R
02.12.t4i3L	t4-i3	02.12.t4i3R

Desine neue

13.1. Blausedihou bio kompo nendai



DIMENSIONS

SIZE	MEDIAL A/P (mm)	LATERAL A/P (mm)	OVERALL M/L (mm)	LENGTH (mm)	α
1	40	38	60	34	130°
2	43	41	65	34	130°
3	46	44	70	34	130°
4	50	47	75	34	130°
5	53	50	80	34	130°
6	58	54	87	34	130°
t3-i4	46	44	70	34	130°
t4-i3	50	47	75	34	130°

2. GMK SPHERE TIBIAL INSERT



10. Kozice puzi

9. Judo po medijaga
MATERIALS: UHMWPE - ISO 5834-2 TYPE 1
Ti6-Al4-V - ISO 5832-3 (SCREW)

10. Dydziaci

10. Desine
 ← puzi

REFERENCE NUMBERS - SIZE 1

LEFT SIDE	THICKNESS (mm)	RIGHT SIDE
02.12.0110FL	10	02.12.0110FR
02.12.0111FL	11	02.12.0111FR
02.12.0112FL	12	02.12.0112FR
02.12.0113FL	13	02.12.0113FR
02.12.0114FL	14	02.12.0114FR
02.12.0117FL	17	02.12.0117FR
02.12.0120FL	20	02.12.0120FR

10. Stornice

REFERENCE NUMBERS - SIZE 2 10.

LEFT SIDE	THICKNESS (mm)	RIGHT SIDE
02.12.0210FL	10	02.12.0210FR
02.12.0211FL	11	02.12.0211FR
02.12.0212FL	12	02.12.0212FR
02.12.0213FL	13	02.12.0213FR
02.12.0214FL	14	02.12.0214FR
02.12.0217FL	17	02.12.0217FR
02.12.0220FL	20	02.12.0220FR

REFERENCE NUMBERS - SIZE 3 10.

LEFT SIDE	THICKNESS (mm)	RIGHT SIDE
02.12.0310FL	10	02.12.0310FR
02.12.0311FL	11	02.12.0311FR
02.12.0312FL	12	02.12.0312FR
02.12.0313FL	13	02.12.0313FR
02.12.0314FL	14	02.12.0314FR
02.12.0317FL	17	02.12.0317FR
02.12.0320FL	20	02.12.0320FR

REFERENCE NUMBERS - SIZE 4 10.

LEFT SIDE	THICKNESS (mm)	RIGHT SIDE
02.12.0410FL	10	02.12.0410FR
02.12.0411FL	11	02.12.0411FR
02.12.0412FL	12	02.12.0412FR
02.12.0413FL	13	02.12.0413FR
02.12.0414FL	14	02.12.0414FR
02.12.0417FL	17	02.12.0417FR
02.12.0420FL	20	02.12.0420FR

REFERENCE NUMBERS - SIZE 5 10.

LEFT SIDE	THICKNESS (mm)	RIGHT SIDE
02.12.0510FL	10	02.12.0510FR
02.12.0511FL	11	02.12.0511FR
02.12.0512FL	12	02.12.0512FR
02.12.0513FL	13	02.12.0513FR
02.12.0514FL	14	02.12.0514FR
02.12.0517FL	17	02.12.0517FR
02.12.0520FL	20	02.12.0520FR

REFERENCE NUMBERS - SIZE 6 10.

LEFT SIDE	THICKNESS (mm)	RIGHT SIDE
02.12.0610FL	10	02.12.0610FR
02.12.0611FL	11	02.12.0611FR
02.12.0612FL	12	02.12.0612FR
02.12.0613FL	13	02.12.0613FR
02.12.0614FL	14	02.12.0614FR
02.12.0617FL	17	02.12.0617FR
02.12.0620FL	20	02.12.0620FR

6. STEM EXTENSION



M. Prailginiūno stebėliai

REFERENCE NUMBERS AND DIMENSION

REFERENCE	LENGTH (mm)	DIAMETER (mm)
02.07.F11030	30	11
02.07.F11066	65	11

MATERIALS: Ti6-Al4-V - ISO 5832-3
 Ti6-Al4-V - ISO 5832-3 (SCREW)

4. GMK RESURFACING PATELLA

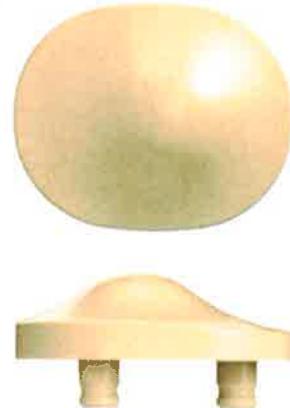
GMK RESURFACING PATELLA



12. Simetris forms

E-CROSS

GMK RESURFACING PATELLA E-CROSS



MATERIALS: UHMWPE - ISO 5834-2 TYPE 1

MATERIALS: VITAMIN E HIGHLY CROSSLINKED UHMWPE

REFERENCE NUMBERS

SIZE	REFERENCE
1	02.07.0033RP
2	02.07.0034RP
3	02.07.0035RP
4	02.07.0036RP

12. Dytarou

REFERENCE NUMBERS

SIZE	REFERENCE
1	02.12.E001RP
2	02.12.E002RP
3	02.12.E003RP
4	02.12.E004RP

Thickness



Peg Length



M/L

A/P



Peg Diameter

DIMENSIONS

SIZE	M/L (mm)	THICKNESS (mm)	A/P (mm)	PEG LENGTH (mm)	PEG DIAMETER (mm)
1	32	10	26	5.5	4.5
2	35	10	29	5.5	4.5
3	38	10	32	5.5	4.5
4	41	10	35	5.5	4.5



INSET PATELLA

Symmetrical shape

4 sizes

Machined Ultra High Molecular Weight Polyethylene (UHMWPE ISO 5834-2)

Cemented

M. Gwendolyn



TIBIAL EXTENSION STEM

Diameter x length: 11x 30 mm and 11 x 65 mm

Cemented

M. Gwendolyn



GAMK PRIMARY

60

SIZE	6	Tibial Tray	
SIDE	RIGHT	CEMENTED	
TYPE	FIXED	REF	02.07.1206R
LOT	2401728	GTIN	07630030819957
	2029-04-17	Tibial Tray Embase Tibiale Plattform Base Tibial Base Tibiale	
		Co-Cr-Mo ISO 5832-4 Plug: UHMWPE ISO 5834-2 Type 1	
STERILE R			



(01)07630030819957(17)290417(10)2401728

CE 0476

Made in Switzerland



15