PATIENT INFORMATION LEAFLET

Knee Replacement

1. Device identification

Component	Model
Femur + Tibia module	GKS Butterfly cemented CrCoMo/UHMWPE
	GKS AM cemented Ti6Al7Nb
Femur	GKS Prime Flex cemented CrCoMo; GKS Prime Flex cementless CrCoMo; GKS Prime Flex Titanium cemented Ti6Al4V; GKS Prime Flex Titanium cementless Ti6Al4V; GKS Prime Flex Traser cementless Ti6Al4V; GKS Prime Flex MP cemented CrCoMo; GKS Prime Flex MP cementless CrCoMo; GKS Prime Flex MP Traser Ti6Al4V; GKS Prime Flex MP Titanium cemented Ti6Al4V; GKS Prime Flex MP Titanium cementless Ti6Al4V; GKS Prime Flex Mobile cemented CrCoMo; GKS Prime Flex Mobile cemented Ti6Al4V; GKS Prime Flex cementless CrCoMo; GKS Prime Flex cementless Ti6Al4V; GKS Prime Flex RK cemented CrCoMo; GKS Prime Flex PS cemented CrCoMo
	GKS Prime cemented CrCoMo; GKS Prime cementless CrCoMo
	GKS One cemented CrCoMo; GKS One cementless CrCoMo
	GKS One Evo cemented CrCoMo; GKS One Evo cementless CrCoMo
	GK Spacer CrCoMo
Tibia	GKS Prime Flex Fix Universal cemented Ti6Al4V; GKS Prime Flex Fix Universal cementless Ti6Al4V; GKS Prime Flex Traser cementless Ti6Al4V; GKS Prime Flex Mobile cemented CrCoMo; GKS Prime Flex Mobile cementless CrCoMo; GKS Prime Flex Mobile cemented Ti6Al4V; GKS Prime Flex Mobile cementless Ti6Al4V; GKS Prime Flex RK cemented Ti6Al4V; GKS Prime Flex TOP cementless Ti6Al4V; GKS Prime Flex TOP cemented Ti6Al4V
	GKS Prime cemented CrCoMo; GKS Prime cementless CrCoMo
	GKS One UHMWPE; GKS One Vital-E; GKS One Metal Back cementless Ti6Al4V; GKS One Metal Back cemented Ti6Al4V
	GKS One Evo Metal Back cemented Ti6Al4V; GKS One Evo Metal Back Traser cementless Ti6Al4V; GKS One Evo All-Poly UHMWPE; GKS One Evo All-Poly Vital-E
	GK Spacer UHMWPE
Insert	GKS Prime Flex CR UHMWPE; GKS Prime Flex CR Vital-E; GKS Prime Flex AS UHMWPE; GKS Prime Flex AS Vital-E; GKS Prime Flex UC UHMWPE; GKS Prime Flex UC Vital-E; GKS Prime Flex MP UHMWPE; GKS Prime Flex MP Vital-E; GKS Prime Flex SS UHMWPE; GKS Prime Flex SS Vital-E; GKS Prime Flex PS UHMWPE; GKS Prime Flex PS Vital-E; GKS Prime Flex PS rotating UHMWPE; GKS Prime Flex PS rotating Vital-E
	GKS Prime UHMWPE; GKS Prime Vital-E
	GKS One UHMWPE; GKS One Vital-E
	GKS One Evo UHMWPE; GKS One Evo Vital-E
Patella	GKS Prime Flex UHMWPE; GKS Wing UHMWPE; GKS Wing Vital-E
Stem	GKS Butterfly cemented CrCoMo, GKS Butterfly cemented Ti6Al4V, GKS Butterfly cementless Ti6Al4V
	GKS Prime Flex for Tibia Fix/Top cemented Ti6Al4V; GKS Prime Flex for Tibia Traser cementless Ti6Al4V
	GKS Prime Flex RK cemented Ti6Al4V; GKS Prime Flex RK cementless Ti6Al4V
	GKS Prime cementless Ti6Al4V
Other components	GKS Butterfly distal centralizer UHMWPE; GKS Butterfly compensatory plate/half-plate cemented PM734; GKS Butterfly compensatory plate/half-plate cemented Ti6Al4V; GKS Butterfly compensatory plate screws Ti6Al4V; GKS Butterfly femoral spacer UHMWPE. Spare parts: GKS Butterfly insert + screw UHMWPE/Ti6Al4V; GKS Butterfly femoral bush sleeve UHMWPE; GKS Butterfly femoral bush sleeve CrCoMo
	GKS AM module locking screw Ti6Al7Nb; GKS AM stem locking screw Ti6Al7Nb
	GKS Prime Flex compensatory half-plate for Tibia Fix Ti6Al4V; GKS Prime Flex compensatory half-plate screw Ti6Al4V
	GKS Prime Flex RK Offset for stems Ti6Al4V; GKS Prime Flex RK femoral Wedge Ti6Al4V; GKS Prime Flex RK tibial Wedge Ti6Al4V; GKS Prime Flex RK tibial cone Ti6Al4V; GKS Prime Flex RK femoral cone Ti6Al4V; GKS Prime Flex RK femoral sleeve Ti6Al4V
	GKS Prime Flex PS module for femur Ti6Al4V
	GKS Prime Flex RK screw for Wedge Ti6Al4V
	GKS One compensatory half-plate Ti6Al4V; GKS One Metal Back fixation screw Ti6Al4V
	GK Spacer Femoral Extension Ti6Al4V
--	Custom made devices

2. Intended purpose & kind of patients for whom device is intended

Knee joint prostheses are indicated in primary and revision total or partial knee arthroplasties, in all cases of severely painful and/or severely disabled joint as a result of arthritic, rheumatic, dysplastic or post-traumatic pathologies, fractures or avascular necrosis or primary implantation failure.

A joint prosthesis is intended to reduce joint pain and to properly restore a healthy joint function and bearing capacity allowing patient to return to normal daily living activities

Knee joint prostheses are intended for adult patients with a mature skeleton. If, according to the surgeon's opinion, an unequivocal indication for total or partial knee replacement outweighs the risks associated with the age of the patient, knee replacement may be considered also for young patients.
For further information about knee replacement, please visit Permedica website: https://www.permedica.it/en/patients/knee/ .

3. Special operating instructions

The patient is not required to follow any operating instructions for the use of the device. The patient should always refer to the instructions of his/her orthopaedic surgeon.
The operating instructions for the use of the implanted device are competence of the orthopaedic surgeon. It could be advisable that the patient follows some of the mentioned precautions by mutual agreement with his/her orthopaedic surgeon.

4. Intended performance & undesirable side effects

A joint prosthesis is meant to reproduce the natural joint that it replaces. However, even if successfully implanted, a replaced joint will be inferior to a natural, healthy joint.
An excessive physical activity may reduce the expected implant life or lead to early reintervention. On the other side for the patient, a joint prosthesis can be a beneficial replacement for a severely altered, pathological joint, eliminating pain and restoring good mobility and bearing capacity.

Patient conditions that may reduce the effectiveness of a joint replacement include:

- Systemic infections and any septic condition in the region surrounding the joint;
- Allergy to implant component materials.
- Chronic or acute local infections, even far from the implant site (risk of hematogenous spread of the infection towards the implant site);
- Insufficient bone structures at the proximal or distal level of the joint, which do not guarantee stability to the anchoring of the prosthetic components;
- Severe vascular, neurological or muscular diseases compromising the involved extremities;
- Obesity, overweight;
- Osteoporosis;
- Hypotrophy of the periarticular soft parts;
- Dysmetabolic diseases (eg. Kidney failure);
- Skeletal immaturity.

The possible side effects listed below are among the known consequences of a joint replacement implant:

- Pain;
- Bone fractures as a result of unilateral overloads or weakening of the bone substance;
- Metal hypersensitivity reactions. The release of foreign material debris in the tissue can cause the formation of histocytosis granulomas and consequent osteolysis;
- Allergic reactions;
- Metallosis and consequent osteolysis;
- Failure due to fatigue, wear or mobilization of the prosthetic components as a result of: excessive overloads; overweight; non-physiological stresses (local trauma); superficial damage; partial or total detachment; improper handling or execution of the implant (wrong choice of component type or size, incorrect alignment, improper assembly of components, inadequate anchoring);
- Mobilization of the joint prosthesis following a change in load transmission conditions (wear and tear of the bone cement and / or reaction of the tissues to the implant) or early and late infections;
- Mobilization of the joint prosthesis following inflammatory phenomena due to the production and migration of wear debris;

- Dislocation, subluxation, limited execution of movements, unwanted shortening or lengthening of the affected extremity due to imperfect implant placement or muscle or fibrous laxity resulting from the implant;
- Intra-operative or post-operative complications such as: perforation or fracture of the bone segments; vascular injuries; temporary or permanent nerve lesions that can cause pain and numbness throughout the limb or causing dysfunction; varus or valgus deformity; cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction; local haematomas; late wound healing; local or systemic, acute or late infections.

5. Residual risks due to shortcoming of protection measures

The following risk factors can lead to unsatisfactory results for the implantation of a joint prosthesis:

- patient's inability to understand and follow the surgeon's recommendations and the physical therapy program;
- carrying out physical, work or sports activities associated with strong stresses that can subject the system to shocks and / or excessive loads;
- uncontrolled body weight gain;
- abuse of medicines, nicotine, alcohol and use of drugs.

6. Warnings & Precautions

Implantable prosthetic devices have not been tested for safety and compatibility in an MRI (Magnetic Resonance) environment, nor to determine their specifications for conditional status. They have not been tested for heating, migration, or image artefacts in the MR environment.

Therefore, the safety of implants in the MR environment is unknown, and the scan could result in injury to patients with the implant. The surgeon should make the patients aware about the risks connected to the exposure to magnetic fields. The patient must also be informed that implants can affect the results of magnetic resonance imaging (MRI) scans.

The implant does not require any maintenance by the patient. During postoperative cares, rehabilitation and in the following years the patient should follow the indications of his/her orthopaedic surgeon and undergo periodically follow-up visits to detect early signs of wear, loosening of the prosthesis, etc., and to consider the actions to be taken. Patient should not increase bodyweight, avoid high impact sports or highly demanding repetitive physical activities, pay attention to prevent accidental trauma, avoid alcoholism or drug addiction. The level of activity should be reasonably controlled and excessive loads on the replaced joint should be avoided.

Patient should refer immediately to his/her orthopaedic surgeon if complaining any kind of pain or knee deficiency or dysfunction. Common symptoms of device dysfunction may include, but are not limited to, pain, reduction of knee mobility, impossibility or limitations in knee weight bearing, fever, skin rashes, swelling, squeaking, clicking noises or feeling, or any other anomalous symptom.

The expected lifetime of a joint prosthesis is limited as it is subject to inevitable wear and aging. Mechanical endurance tests have performed and each component was required to sustain many million cycles with no significant reduction of performance, as recommended by applicable international standards.
The expected lifetime can be reduced or increased depending on the activity level or events that could compromise implants integrity. Furthermore, a joint prosthesis initially implanted in a stable way can over time undergo to mobilization and be compromised in functionality. Wear, aging, loosening can imply a reoperation.

7. Materials and substances included in device

The following tables refer to the reference standards for raw materials:

ISO5832/3: Titanium 6-Aluminium4-Vanadium alloy (Ti6Al4V)	
ELEMENT	*PERCENT MASS FRACTION*
Aluminium	From 5,5 to 6,75 %
Vanadium	From 3,5 % to 4,5 %
Iron	Max. 0,3%
Oxygen	Max. 0,2%
Carbon	Max. 0,08%
Nitrogen	Max. 0,05%
Hydrogen	Max. 0,015%
Titanium	Balance

ISO5832/4: Cobalt-chromium-molybdenum casting alloy (CrCoMo)	
ELEMENT	*PERCENT MASS FRACTION*
Chromium	From 26,5 to 30,0 %
Molybdenum	From 4,5 % to 7,0 %
Nickel	Max. 1,0%
Iron	Max. 1,0%
Carbon	Max. 0,35%
Manganese	Max. 1,0%
Silicon	Max. 1,0%
Cobalt	Balance

ISO5832/11: Titanium 6-Aluminium 7-Niobium alloy (Ti6Al7Nb)	
ELEMENT	*PERCENT MASS FRACTION*
Alluminium	From 5,5 to 6,5 %
Niobium	From 6,5 % to 7,5 %
Tantalum	Max. 0,50 %
Iron	Max. 0,25%
Oxygen	Max. 0,20%
Carbon	Max. 0,08%
Nitrogen	Max. 0,05%
Hydrogen	Max. 0,009%
Titanium	Balance

ISO5832/12: Cobalt-chromium molybdenum alloy (CrCoMo)	
ELEMENT	*PERCENT MASS FRACTION*
Chromium	From 26,05 to 30,0 %
Molybdenum	From 5,0 % to 7,0 %
Nickel	Max. 1,0%
Iron	Max. 0,75%
Carbon	Max. 0,14% for low carbon alloy; from 0,15% to 0,35% for high carbon alloy
Manganese	Max. 1,0%
Silicon	Max. 1,0%
Nitrogen	Max. 0,25%
Cobalt	Balance

ASTM F2924: Titanium-6 Aluminum-4 Vanadium Powder (Ti6Al4V) for Additive Manufacturing	
ELEMENT	*PERCENT MASS FRACTION*
Aluminum	From 5,50 to 6,75
Vanadium	From 3,50 to 4,50
Oxygen	Max. 0,20
Nitrogen	Max. 0,05
Hydrogen	Max. 0,015
Iron	Max. 0,30
Carbon	Max. 0,08
Yttrium	Max. 0,005
Residuals: Each	Max. 0,10 %
Total	Max. 0,40 %
Titanium	Remainder

ISO5834/1-ISO5834/2 – ASTM F648: Ultra-high molecular-weight polyethylene (UHMWPE) ASTM F2695: Ultra-high molecular-weight polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications (Vital-E)	
ELEMENT	*MAXIMUM QUANTITY PERMITTED [mg/kg]*
Titanium	40
Calcium	5
Chlorine	30
Aluminum	20

The following tables refer to the reference standards for coating materials:

ASTM F1580: Pure Titanium (Ti) for coatings (HaX-Pore)	
ELEMENT	*PERCENT MASS FRACTION*
Oxygen	0.40%
Nitrogen	0.05%
Hydrogen	0.05%
Carbon	0.08%
Iron	0.50%
Silicon	0.04%
Chlorine	0.20%
Sodium	0.50%
Titanium	Remainder

ISO 13779/2 – ASTM F1185: Thermally sprayed coatings of hydroxyapatite (HaX-pore)	
TRACE ELEMENT	*MAXIMUM LIMIT [mg/kg]*
Arsenic	3
Cadmium	5
Mercury	5
Lead	30
Heavy Metals	50

Physical vapour deposited coating of titanium niobium nitride (TiNbN - Bioloy)	
TRACE ELEMENT	*MAXIMUM LIMIT – No reference standard available*
Titanium	--
Oxygen	--
Nitrogen	--
Carbon	--
Niobium	--

The reference to the raw material and to the coating material (if any) is reported on the device label placed on the implant card.

8. Serious Incident Reporting

Please report all serious incidents to the manufacturer (contact details reported below) and, for Australia only, to the TGA **https://www.tga.gov.au/reporting-adverse-events**

Manufacturer

Permedica S.p.A. - via Como 38, 23807 Merate (LC) - ITALY
tel: +39.039.9514811 - fax: +39.039.9903078
info@permedica.it - www.permedica.it