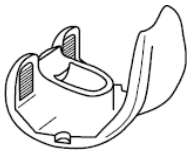
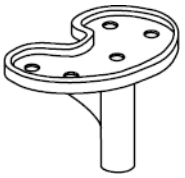
INSTRUCTIONS FOR USE

PASİFİK MEDİKAL TİCARET ANONİM ŞİRKETİ

Adres: Ostim OSB Mah. Atisan Sanayi Sitesi 241. Sokak No: 2 Yenimahalle /Ankara / Türkiye
+90 312 211 12 32

1. EXPLANATION OF IMPLANT

PMG Motion Total Knee Prosthesis System consists of 4 different elements. These elements are generically named as femoral component, tibial component, insert component and patellar component, respectively. Model representations are as follows;

Femoral Components	
Tibial Components	
Insert Components	
Patellar Components	

Model illustrations are taken from the ISO 7207-1:2011 standard and do not exactly match the design of the PMG MOTION Total Knee Replacement System.

2. DESIGNED PURPOSE OF THE IMPLANT

PMG Motion Total Knee Prosthesis System aims to increase the mobility of the patient by reducing the pain in partial knee deformities, knee deformities with complete deformation, severely deformed knee deformities requiring lengthening/support, with the change of the knee joint, if the patient has enough bone to place and support the components.

3. DESIGNED PERFORMANCE

The relative angular movement between the parts to which the PMG Motion Total Knee Prosthesis System is connected is designed as 135°. The estimated maximum load motion to be transmitted to the bone parts to which the PMG Motion Total Knee Replacement System is attached is 8 times the body weight. PMG Motion Total Knee Prosthesis System is designed to dynamically withstand forces corresponding to 8 times body weight. It is predicted that the PMG Motion Total Knee Prosthesis System will wear out to a certain extent due to the kinematics of the knee joint in the body due to daily physical activities. However, it has been considered that this wear will be at an acceptable level and it has been determined that the PMG Motion Total Knee Prosthesis System will have a lifetime of at least 10 years after implantation. In addition, this product lifetime has been validated with cycle (aging) tests.

4. THINGS TO BE CONSIDERED IN PATIENT SELECTION-PATIENT POPULATION

- Patients with pain and dysfunction
- The patient's ability to follow instructions and control their weight and mobility
- The patient's bone growth has stopped

The patient population is defined as adult patients.

5. UNDESIRED SIDE EFFECTS

Common negative consequences after implantation are listed below:

- Breakage or loosening of the prosthesis or parts of the prosthesis as a result of excessive loading and pressure, damaged or incorrect implantation
- Loosening of the implant as a result of changing the shape of the loading transfer, abrasion or fracture of the bone layer, and/or reaction to the tissue on the implant
- Early or late infection
- Partial or complete displacement of the implant, insufficient mobility, longer or shorter than desired exterminity caused by positioning the implant in a shorter time than required
- Fracture of the bone as a result of overloading a region or weak area
- Temporary or permanent neural lesion as a result of pressure or hematoma
- Wound hematoma and delayed wound healing
- Cardiovascular disorders such as venous thrombosis, pulmonary embolism, cardiac arrest
- Movement restriction

6. CRITERIA FOR OBTAINING A SAFE COMPOSITION

In order to obtain a safe composition from the PMG Motion Total Knee Replacement System, the femoral, tibial, insert and patella components must be used from the components of the original PMG Motion Total Knee Replacement System. In addition, the operation should be performed as described in the TF.001.App06-02 Surgical Technique document and the original PMG Motion Total Knee Prosthesis System Surgical Instruments should be used. The relevant document can be accessed on our website. While the right or left configurations of the Femoral and Tibial components to be used must be the same, their dimensions do not have to be the same. The insert size to be used should be chosen according to the Femoral component size if a mobile knee prosthesis operation is performed, and according to the Tibial component size if a fixed knee prosthesis operation is performed. This is due to the variability of the patient's anatomical structure. The thickness of the insert component is not a decisive parameter for compositions. The dimensions indicated in the table below can be used in combination with each other.

İnsert Component Size	Femoral Componen t Size	Tibial Component Size
2	2	2
	4	4
4	2	2
	4	4
	6	6
6	4	4
	6	6
	8	8
8	6	6
	8	8
	10	10
10	8	8
	10	10
	12	12
12	10	10
	12	12

7. PRECAUTIONS AND WARNINGS

- The lifespan of the PMG Motion Total Knee Replacement System depends on the patient's weight and activities in daily life. It is recommended to inform the patient about this issue before and after the operation.

- PMG Motion Total Knee Prosthesis System is supplied sterilized with gamma radiation and should always be stored unopened in its protective boxes. Before use, inspect for damage that could jeopardize puncture of the packaging. Do not use the implants if the packaging is opened or damaged.

- Do not re-sterilize the PMG Motion Total Knee Prosthesis System for any reason. Do not use implants that may have been sterilized.

- PMG Motion Total Knee Replacement System Surgical Instruments are supplied non-sterile and must be sterilized before use. It should be subjected to a 4 minute sterilization cycle at 132°C in superheated steam. If sterilized by other methods, it is recommended that the user validate the sterilization process.

- Examine labels to verify that the expiration date has not passed. Do not use the implants if the product has expired.

- When unpacking the implant, verify the reference number and dimensions on the label on the product box and on the labels that come out of it.

- PMG Motion Total Knee Prosthesis System is disposable.

- Store the PMG Motion Total Knee Prosthesis System between -40° and 60°.

- Before use, inspect each implant to ensure there is no visible damage.

- Do not expose the PMG Motion Total Knee Prosthesis System to any chemical material other than bone cement in a clinical setting. Do not subject it to cleaning with alcohol and similar processes. PMG Motion Total Knee Prothesis System is safe and compatible in MR environment. However, the insert and patellar component made of UHMWPE cannot be visualized in MR environment.

• For the correct removal of the PMG Motion Total Knee Replacement System, see the TF.001.App06- 02 Surgical Technique document.

• If the PMG Motion Total Knee Prosthesis System needs to be disposed of, it should be considered as medical waste and treated accordingly.

• Care should be taken to protect polished surfaces, especially convex and convex surfaces, from nicks and scratches that may be the focus of failure. Care should be taken not to expose the polished surfaces to any contact.

• Protect the product from being nicked, scratched or bumped.

• In case of any serious adverse event related to our products, please report this immediately to our company and the competent authority of the European Union member state in which you are established.

8. PRODUCTS DESCRIPTIONS AND IMPLANT MATERIALS

Component	Fixation Method	Material	ASTM Standard	ISO Standard
Femoral Component	It is fixed to the distal head of the femur with cement.	CoCrMo alloy	ASTM F75	ISO 5832-4
Tibial Component	It is fixed to the proximal head of the tibia with cement.	CoCrMo alloy	ASTM F75	ISO 5832-3
Insert	The conical ridge design is fixed by fitting into the proximal conical hole of the tibial plateau. This design, which restricts the movement in the AP and ML axes, does not restrict the movement in the rotation axis.	Ultra High Molecular Weight Cross-Linked Polyethylene (UHMWPE)	ASTM F648	ISO 5834-1 & 2
Patella	It is fixed to the patella (knee cap) with cement.	Ultra High Molecular Weight Cross-Linked Polyethylene (UHMWPE)	ASTM F648	ISO 5834-1 & 2

PMG Motion Femoral and Tibial Components are available in left and right configurations. Insert/Patella is not anatomical.

9. INDICATIONS

Joint replacement is indicated in patients with disability due to the following problems:
• Degenerative, posttraumatic or rheumatoid arthritis;
• Avascular necrosis of the femoral condyle;
• Posttraumatic loss of joint configuration, especially if there is patellofemoral erosion, dysfunction or prior patellectomy;
• Moderate valgus, varus or flexion deformities;
• Fractures that cannot be treated with other techniques.
This device can also be used to correct previous failed surgical interventions. All devices are designed for cementitious applications. While total knee replacements are not intended to meet the loads or activity levels assumed by normal healthy bone, for many patients they are a way to regain mobility and reduce pain.

10. CONTRAINDICATIONS

Joint replacement is contraindicated in the presence of the following conditions:

- Infection (or history of infection), acute or chronic, local or systemic;
- Inadequate bone quality that may affect implant stability;
- Muscular, neurological or vascular deficiencies affecting the involved extremity;
- Obesity;
- Alcoholism or other addictions;
- Sensitivity to materials;
- Loss of ligament structures;
- High levels of physical activity (eg racing sports, strenuous physical work).

11. INFORMING THE PATIENT

- The patient should be informed about general surgery risks, side effects and post-operative instructions (daily activities, actions to be avoided, etc.).
- The surgeon should inform the patient that he should pay more attention to his post-operative care.
- The surgeon should inform the patient that loosening, wear and/or breakage of the implant may occur as a result of tension, excessive mobility, impacts, weight gain, and overload.
- The patient should be warned about the need for regular follow-up after surgery.
- Be warned that medical advice should be sought before entering potentially adverse environments (electromagnetic field, extreme pressure/temperature changes)

12. INTENDED USER

This product is intended for use by operators, orthopedidists and physicians.

13. SHELF LIFE

Shelf Life of Knee Surgery device is 5 years.

14. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

There are no warranties of any kind, express or implied, including, without limitation, the implied warranties of merchantability or fitness for a particular purpose for the PASİFİK MEDİKAL product(s) described in this publication. Under no circumstances will PASİFİK MEDİKAL be liable for any direct, incidental or consequential damages other than those expressly stated in the specific law. No one has the authority to bind PASİFİK MEDİKAL to any representation or warranty other than what is specifically stated here. The definitions or specifications in this publication and printed material of PASİFİK MEDİKAL are for general recognition of the product at the date of manufacture only and do not imply any express warranty.

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15. DISPOSAL OF PROSTHESIS

15.1. Collection and Temporary Storage of the Prosthesis

The discarded or removed knee prosthesis is considered medical waste.

The prosthesis should be placed in red medical waste bags that are puncture-resistant, leak-proof and labelled with a biological hazard symbol.

If necessary, prostheses containing infected or contagious material should be disinfected separately.

Collected prostheses should be transported to the temporary medical waste storage area.

15.2. Disposal of Prosthesis

Medical waste should be delivered to the relevant licensed waste disposal companies.

Keep the certificate from the disposal company that the prosthesis has been properly disposed of.

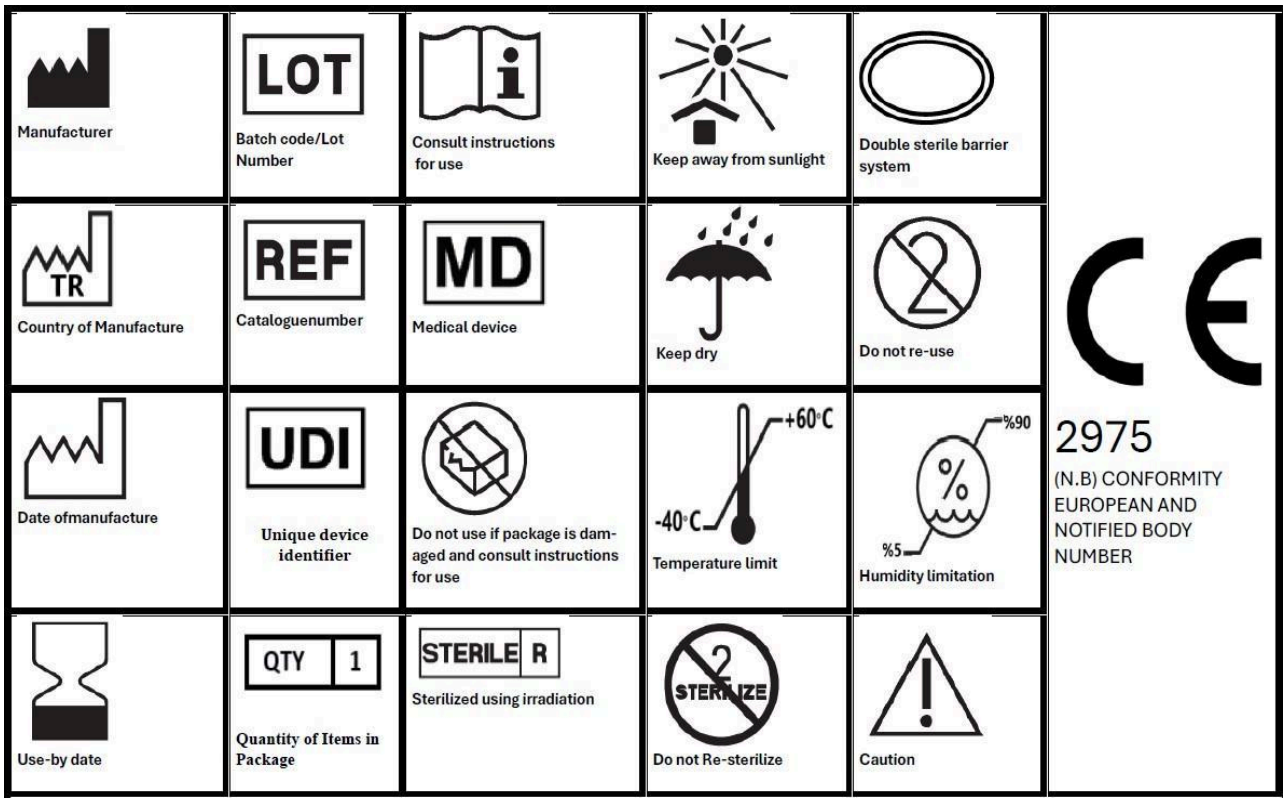
If sterile and unused prostheses are to be disposed of, recycling or donation options can be considered before they become medical waste.

15.3. Recording and Reporting

The disposal process of medical waste must be recorded and reported in accordance with the relevant legislation.

An annual waste management report must be prepared by the Waste Management Unit and submitted to the competent authorities. ***It should not be forgotten that all healthcare institutions must have a Disposal Procedure within their own quality systems. The healthcare institution's Disposal Procedure will also apply to Pacifik Medikal PMG Motion products. However, it has been deemed appropriate to have a destruction procedure within Pacifik Medikal***

16. LABELING/MARKING REMARKS



16. IMPLANT CARD

This User Manual covers the following parts of PMG Motion Total Knee Prosthesis;

- Femoral Component
- Tibial Component
- Insert Component
- Patella Component

For each of these components, the Implant Card appropriate for the implanted component must be filled and delivered to the patient. This card has been designed in accordance with Article 18 of the Medical Device Regulation published in the Official Gazette dated June 2, 2021 and numbered 31499 and is available in the product box.

The symbols and their explanations on the Implant Card are given below. In addition, the table contains the details of the sections to be printed on the card or to be filled manually.

17. ASSOCIATED EQUIPMENT AND ACCESSORIES

No accessories are intended to be used in conjunction with the Total Knee Implant. The implant is applied to the patient utilizing dedicated surgical instruments. The list of these instruments is provided in document TF.001.App06-07 *Non-Sterile Surgical Instruments – Knee Surgery*. Detailed information regarding the surgical procedure is available in document TF.001.App06-02 *Surgical Technique*.

This information is provided in accordance with the requirements of Regulation (EU) 2017/745 (MDR) to ensure proper identification of intended use, associated components, and procedural guidance.

Symbol	Explanation	Fill Detail
	Patient Name/ID Number	To be filled manually
	Implantation Date	To be filled manually
	Name and Address of the Health Center applying the implant	To be filled manually
	Patient Information Website	Available as Printed on Card
	Device Type	Available as Printed on Card According to Component Type
	Lot number	Available as Printed on Card
	Unique Device Identifier Code in Automatic Identification and Data Capture Format	Available as Printed on Card
	Manufacturer's Name and Address	Available as Printed on Card