SSCP Reference No	:	SSCP/PMG-PKP-01	**Report Date**	:	26.12.2024
Last Update No	:	**00**			
Last Update Content	:				

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE/SSCP

This summary of safety and clinical performance (SSCP) is intended to provide public access to an updated summary of key aspects of the safety and clinical performance of the device

The SSCP is not intended to replace the instructions for use as the main document to ensure the safe use of the device and is not intended to provide diagnosis or treatment recommendations to target users or patients

The following information is intended for users/healthcare professionals. This information is followed by a summary for patients

1. DEVICE DESCRIPTION AND GENERAL INFORMATION

1.1. Trade Name(s) of the Device and General Description:

PMG Motion Primary Knee Prosthesis

Primary Knee Prosthesis is designed to provide reconstruction of degenerated knee joints in specified indications. It is suitable for use in patients who have completed bone development. This prosthesis is used when the native knee joint is affected by conditions such as osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, or severe knee injury that results in pain, reduced mobility, or joint deformity. 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.

1.2. Name and Address of the Manufacturer:

PASİFİK MEDİKAL TİCARET ANONİM ŞİRKETİ / OSTİM OSB MAHALLESİ ATİSAN SANAYİ SİTESİ 241. SOKAK NO:2 YENİMAHALLE/ANKARA/TÜRKİYE

1.3. Manufacturer's Single Registration Number (SRN):

TR-MF-000015717

1.4. Basic UDI-DI:

Basic UDI-DI Code of Primary Knee Prosthesis is determined as follows;

Femoral Component	86810722KFED
Tibial Component	86810722KTF9
Insert Component	86810722KIEK
Patella Component	86810722KPEZ

1.5. **Medical Device Nomenclature Description- Text**: (EMDN Code)

P0909, Knee Prosthesis (IMPLANTABLE PROSTHETIC AND OSTEOSYNTHESIS DEVICES)

P09090301 Biocompartmental primary implant femoral components

P09090302 Biocompartmental primary implant tibial components

P09090302 Biocompartmental primary implant tibial components

P0909030202 Biocompartmental primary implant tibial inserts

P0909030202 Biocompartmental primary implant tibial inserts

P0909030202 Biocompartmental primary implant tibial inserts

P0909070202 Patellar components, modular

1.6. Device Class:

In accordance with the EU 2017/745 MDR Medical Device Regulation, the conformity assessment route and risk class of our product are as follows;

2017/745/EU Annex-IX Quality Management System and Conformity Assessment Based on Evaluation of Technical Documentation
Annex-VIII Rule-8 Class IIb

All classification rules under the heading EU 2017/745 MDR Medical Device Regulation Annex VIII Part III Classification Rules were examined. The following explanation is written in **Rule 8**, which is the only rule regarding our device among the classification rules;

All implantable devices and long-term surgically invasive devices are classified as class IIb. But these are:
- if intended for placement on teeth, it is classified in class IIa;
- classified as class III if intended for use in direct contact with the heart, central circulatory system or central nervous system;
- if it has a biological effect or is completely or mostly absorbed, it is classified as class III;
- are classified as class III if they are intended to undergo chemical change in the body, excluding devices implanted in the teeth;
- if it is intended to administer medicinal products, it is classified as class III.
- if they are active implantable devices or their accessories, they are classified as class III;
- if breast implants or surgical patches, they are classified as class III;
- total or partial joint replacement devices, excluding auxiliary components such as screws, wedges, plates and tools, are classified as class III, or
- spinal disc replacement implants or implantable devices that contact the spine, excluding components such as screws, wedges, plates and instruments, are classified as class III.

Based on the above statement, the risk class of our **Primary Knee Prosthesis** products has been determined as **Class III**.

1.7. **Year of the First Certificate (CE) covering the Device:**
The first CE certificate for the products was given on 2014.

1.8. If any, Authorised Representative Name and SRN:
Our company does not have an authorized representative.

1.9. **Notified Body Name (the notified body that will validate the SSCP) and Identification Number**:

Notified Body	:	SZUTEST Konformitätsbewertungsstelle GmbH
Address	:	Friedrich-Ebert-Anlage 36, 60325 Frankfurt am Main
Notified Body Number	:	2975

2. INTENDED USE OF THE DEVICE

2.1. Intended Use:
Primary Knee Prosthesis provides reconstruction of degenerated knee joints in certain indications.

2.2. Indication(s) and Target Population(s):
Joint replacement is indicated in patients with disabilities due to the following problems:

- Degenerative, posttraumatic or rheumatoid arthritis;
- Avascular necrosis in 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 cemented applications. Although total knee replacements are not intended to replace the loads or activity levels assumed by normal healthy bone, they are a way to regain mobility and reduce pain for many patients.

Target Patient Population:
The target patient population is expected to be patients who have completed bone development, experience pain and have difficulty climbing stairs and moving in daily activities. Our products can be used by both male and female genders.

- 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.

2.3. Contraindications and-or Limitations:

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).

3. DEVICE DESCRIPTION

3.1. Description of the device:

Primary Knee Prosthesis is designed to provide reconstruction of degenerated knee joints in specified indications. It is suitable for use in patients who have completed bone development. This prosthesis is used when the native knee joint is affected by conditions such as osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, or severe knee injury that results in pain, reduced mobility, or joint deformity. 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.

3.1.1. Working Principles and Effect of the Device: (Mode of Action)

Primary Knee Prosthesis basically replaces the degenerated knee joint and enables the patient to easily carry out movements and daily activities such as going up and down stairs, just like a healthy joint.

Total knee arthroplasty refers to the replacement of the degenerated knee joint with an artificial knee joint. The degenerated knee joint is cut with incision guides in accordance with the internal angles of the femoral and tibial components of the knee prosthesis, and the femoral and tibial prosthesis components are placed in their places. Thus, friction is eliminated and the nerve endings on the condyles of the femur and tibia regain their daily movement mechanism without pain.

The Total Knee Prosthesis System produced by Pasifik Medical allows the knee kinematics to be repositioned with a completely physical effect.

There are no pharmaceutical or metabolic effects.

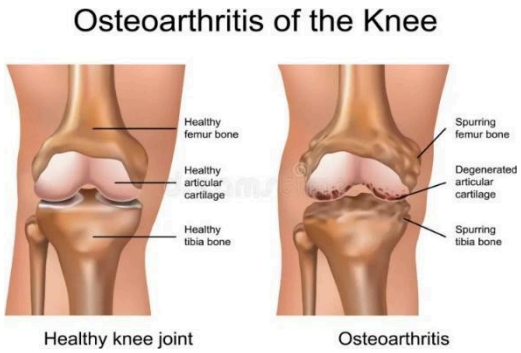


Figure 1. Illustration of healthy knee joint and degenerated knee joint

Figure 2. Knee joint with knee prosthesis.

3.1.2. List of Raw Materials in Contact with the Body and Biocompatibility Evaluation:

Our products that come into contact with the patient's body are manufactured from CoCrMo alloy and UHMWPE raw materials. The biocompatibility classification of our products is determined according to the table below of the EN ISO 10993-1 Standard.

Medical device categorization by			Endpoints of biological evaluation														
Nature of body contact		Contact duration															
Category	Contact	A – limited (≤24 h) B – prolonged (>24 h to 30 d) C – Long term (>30 d)	Physical and/or chemical information	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Material mediated pyrogenicity[a]	Acute systemic toxicity[b]	Subacute toxicity[b]	Subchronic toxicity[b]	Chronic toxicity[b]	Implantation effects[b,c]	Hemocompatibility	Genotoxicity[d]	Carcinogenicity[d]	Reproductive/developmental toxicity[d,e]	Degradation[f]
Implant medical device	Tissue/bone[i]	A	X	E	E	E	E	E									
		B	X	E	E	E	E	E	E			E		E			
		C	X	E	E	E	E	E	E	E	E	E		E	E		
	Blood	A	X	E	E	E	E	E				E	E	E			
		B	X	E	E	E	E	E	E			E	E	E			
		C	X	E	E	E	E	E	E	E	E	E	E	E	E		

[a] Refer to ISO 10993-11:2017, Annex F.

[b] Information obtained from comprehensive implantation assessments that include acute systemic toxicity, subacute toxicity, subchronic toxicity and/or chronic toxicity may be appropriate if sufficient animals and timepoints are included and assessed. It is not always necessary to perform separate studies for acute, subacute, subchronic, and chronic toxicity.

[c] Relevant implantation sites should be considered. For instance medical devices in contact with intact mucosal membranes should ideally be studied/ considered in contact with intact mucosal membranes.

[d] If the medical device can contain substances known to be carcinogenic, mutagenic and/or toxic to reproduction, this should be considered in the risk assessment.

[e] Reproductive and developmental toxicity should be addressed for novel materials, materials with a known reproductive or developmental toxicity, medical devices with relevant target populations (e.g. pregnant women), and/or medical devices where there is the potential for local presence of device materials in the reproductive organs.

[f] Degradation information should be provided for any medical devices, medical device components or materials remaining within the patient, that have the potential for degradation.

[g] X means prerequisite information needed for a risk assessment.

[h] E means endpoints to be evaluated in the risk assessment (either through the use of existing data, additional endpoint-specific testing, or a rationale for why assessment of the endpoint does not require an additional data set). If a medical device is manufactured from novel materials, not previously used in medical device applications, and no toxicology data exists in the literature, additional endpoints beyond those marked "E" in this table should be considered. For particular medical devices, there is a possibility that it will be appropriate to include additional or fewer endpoints than indicated.

[i] Tissue includes tissue fluids and subcutaneous spaces. For gas pathway devices or components with only indirect tissue contact, see device specific standards for biocompatibility information relevant to these medical devices.

[j] For all medical devices used in extracorporeal circuits.

It was carried out according to "Table 1 – Evaluation experiments to be taken into account". In this regard, product biocompatibility class;
It is designated as a Long Term (> 30 days) Implant Device that comes into contact with tissue and bone. Accordingly, the product must have successfully passed the biocompatibility tests specified below according to EN ISO 10993-1 Standard Table-1.

- **Cytotoxicity (Cell toxicity)**
- **Sensitization**
- **Irritation or intradermal reactivity**
- **Pyrogenicity**
- **Acute Systemic toxicity**
- **Subacute Toxicity**
- **Subchronic Toxicity**
- **Chronic Toxicity**
- **Genotoxicity**
- **Implantation**
- **Carcinogenicity**

In this regard, the biocompatibility tests of the product were carried out in impartial laboratories and the results were evaluated in the App 13 Tests – A. Biological Evaluation Report folder in the technical file.

3.1.3. Single Use/Reusable Status:

The products are disposable. There is absolutely no reusability.

3.1.4. Product Sterility Status, Sterilization Method and Second Time Sterility Status:

The products are sterilized by gamma method and presented to users in sterile form. Products should not be sterilized a second time.

3.2. A Reference to Previous Generation(s) or Variants, if any, and an Explanation of Differences:

There is no previous generation or similar generation of our product.

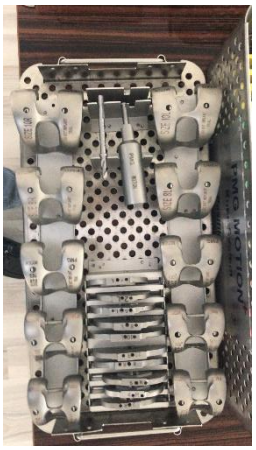
3.3. Description of all kinds of accessories designed to be used with the device:

There is no accessory of our Femur, Tibia, Insert and Patella products. There are Surgical Instruments used with Femur, Tibia, Insert and Patella.

3.4. Description of other devices and products designed to be used with the device:

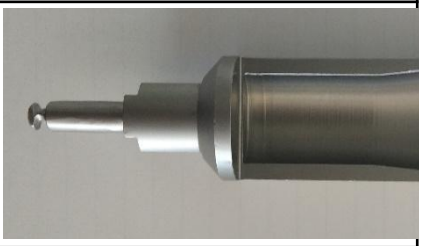
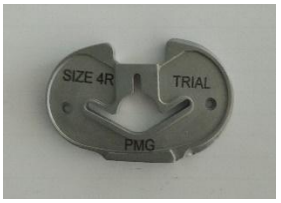
Our products are used with the following surgical instruments during surgical operations.

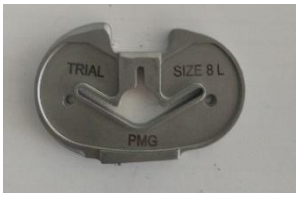
Box KA tray 1 TRIALS



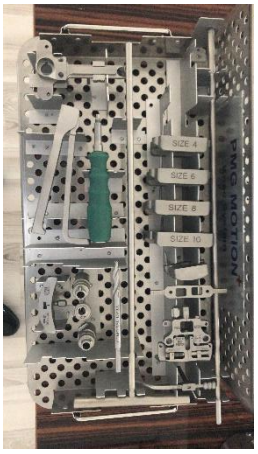
PRODUCT NAME	REF NO	LOT NO	SIZE / QNT.	PIC.
FEM TRIAL R	02-025-001	KA001-XXXX	2 / 1	
FEM TRIAL R	02-025-002	KA002-XXX	4 / 1	
FEM TRIAL R	02-025-003	KA003-XXXX	6 / 1	
FEM TRIAL R	02-025-004	KA004-XXXX	8 / 1	

FEM TRIAL R	02-025-005	KA005-XXXX	10 / 1	
FEM TRIAL L	02-025-006	KA006-XXXX	2 / 1	
FEM TRIAL L	02-025-007	KA007-XXXX	4 / 1	
FEM TRIAL L	02-025-008	KA008-XXXX	6 / 1	
FEM TRIAL L	02-025-009	KA009-XXXX	8 / 1	
FEM TRIAL L	02-025-010	KA010-XXXX	10 / 1	

FEM PEG DRILL	02-020-001	KA011-XXXX	-/ 1	
GROW RECEIVER	02-029-001	KA012-XXXX	1	
TIBIAL TRIAL	02-024-001	KA013-XXXX	2 R – 1	
TIBIAL TRIAL	02-024-002	KA014-XXXX	4 R – 1	
TIBIAL TRIAL	02-024-003	KA015-XXXX	6 R – 1	
TIBIAL TRIAL	02-024-004	KA016-XXXX	8 R – 1	
TIBIAL TRIAL	02-024-005	KA017-XXXX	10 R – 1	

TIBIAL TRIAL	02-024-006	KA018-XXXX	2 L – 1	
TIBIAL TRIAL	02-024-007	KA019-XXXX	4 L – 1	
TIBIAL TRIAL	02-024-008	KA020-XXXX	6 L – 1	
TIBIAL TRIAL	02-024-009	KA021-XXXX	8 L – 1	
TIBIAL TRIAL	02-024-010	KA022-XXXX	10 L – 1	

Box KB tray 1 FEMOR PREPARATION



PRODUCT NAME	REF NO	LOT NO	SIZE / QNT.	PIC

FEMORAL SIZER	02-001-001	KB001-XXXX	- / 1	
VALGUS CUT GUIDE / BOOSH	02-004-001	KB002-XXXX	5 ^{0} - 1	
VALGUS CUT GUIDE / BOOSH	02-004-002	KB003-XXXX	6 – 1	
VALGUS CUT GUIDE / BOOSH	02-004-003	KB004-XXXX	7 – 1	
VALGUS CUT GUIDE / BOOSH		KB005-XXXX	3 – 1	
VALGUS CUT GUIDE / BOOSH		KB006-XXXX	9 – 1	
VALGUS CUT GUIDE / BOOSH		KB007-XXXX		
FEMORAL DRİL	02-003-001	KB008-XXXX	1	

SCREW DRIVER	02-030-001	KB009-XXXX	1	
FEMORAL CUTTING BLOCK /4 IN 1 CHAMFER CUT GUIDE	02-011-001	KB010-XXXX	2 – 1	

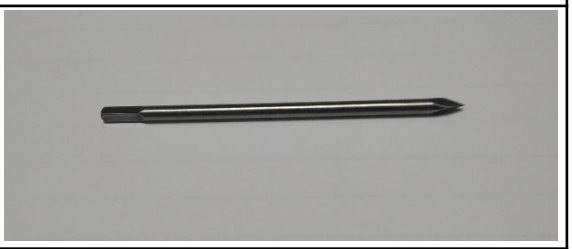
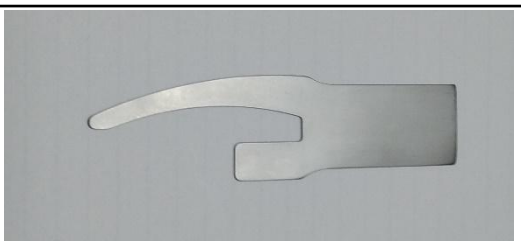
	02-011-002	KB011-XXXX	4- 1	
	02-011-003	KB012-XXXX	6- 1	
	02-011-004	KB013-XXXX	8 – 1	
	02-011-005	KB014-XXXX	10 -1	
FEMOR DISTAL CUT GUIDE	02-009-001	KB015-XXXX	0 – 1	
PIN PULLER	02-015-001	KB016-XXXX	0 – 1	
T – HANDLE	02-026-001	KB017-XXXX	0 – 1	

Anterior reference guide	02 -023-001	KB018-XX XX		
FEMORAL DISTAL CUT BLOCK	02-023-0 01	KB019-XX XX	0 – 1	
ALIGNMEN T ROD	02-012-0 01	KB020-XX XX	0- 1	

Box KC tray 2 PREPARATION

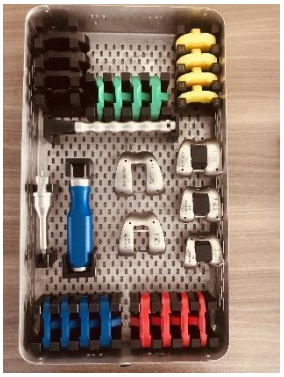
PRODUCT NAME	**REF NO**	**LOT NO**	**SIZE / QNT.**	**PIC**
TIBIAL CLAMPS	02-016-001	KC001-XXX X		

TIBIAL SPIKE	02-016-001	KC002-XXXX		
TIBIAL BASE STRUCTURE	02-016-001	KC003-XXXX		
FEMORAL IMPACTOR	02-017-001	KC004-XXXX	1	
TIBIAL IMPACTOR	02-018-002	KC005-XXXX	1	
INSERT IMPACTOR	02-018-001	KC006-XXXX	1	
UNIVERSAL HANDLE	02-006-001	KC007-XXXX		
PIN BOX	02-014-001	KC010-XXXX		

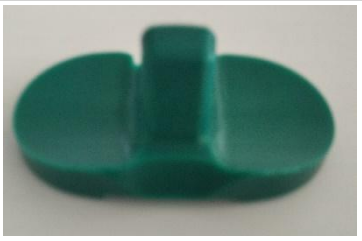
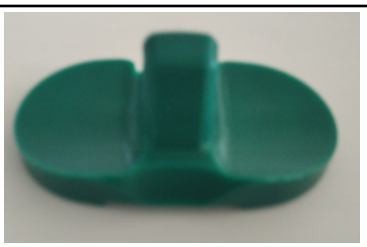
SHORT tipped PIN	02-028-001	KC011-XXXX	AT MINIMUM 4	
Long tipped pin	02-028-002	KC012-XXXX	AT MINIMUM 4	
Long pin	02-010-001	KC013-XXXX	AT MINIMUM 4	
Pin holder	02-010-002	KC014-XXXX	1	
Saver cut or Angles wing	02-007-001	KC015-XXXX	1	
Tibial stylus	02-005-001	KC016-XXXX	1	

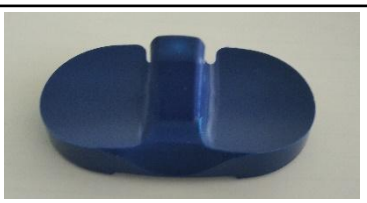
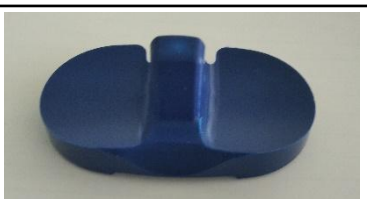
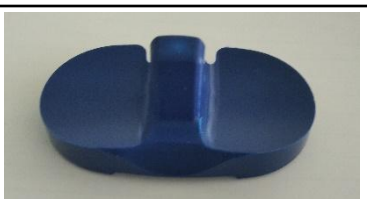
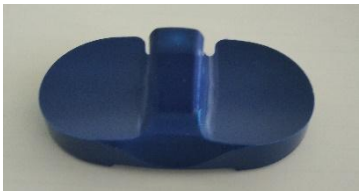
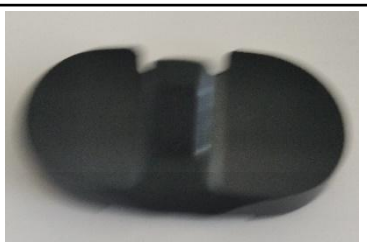
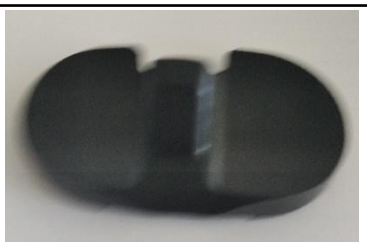
MAIN FEMORAL COMPONENT IMPACTOR	02- 017 -002	KC017-XXXX	1	

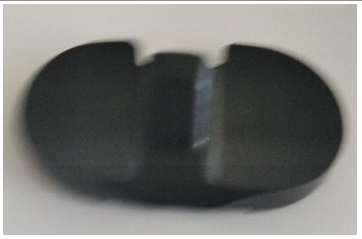
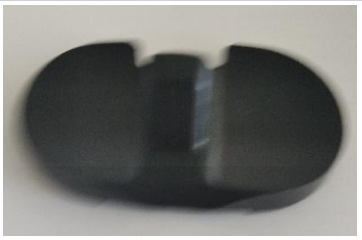
Box KD tray 1 P/S PREPARATION



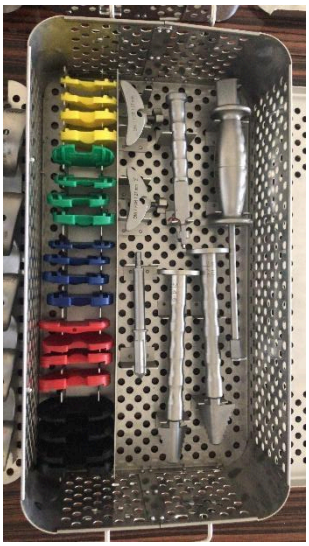
PRODUCT NAME	REF NO	LOT NO	SIZE / QNT.	PIC
FEMORAL PS DRILL	02-031-001	KD001-XXXX		
FEMORAL PS PUNCH	02-032-001	KD002-XXXX		
INSERT TRIAL P/S	02-033-001	KD003-XXXX	2 – 9 /1	
	02-033-002	KD004-XXXX	2 – 11/1	
	02-033-003	KD005-XXXX	2 – 13 /1	

	02-033-004	KD006-XXXX	2 – 15 /1	
INSERT TRIAL P/S	02-033-005	KD007-XXXX	4 – 9/1	
	02-033-006	KD008-XXXX	4 – 11 /1	
	02-033-007	KD009-XXXX	4 – 13 /1	
	02-033-008	KD010-XXXX	4 – 15 /1	
INSERT TRIAL P/S	02-033-009	KD011-XXXX	6 – 9 /1	
	02-033-010	KD012-XXXX	6 – 11 /1	

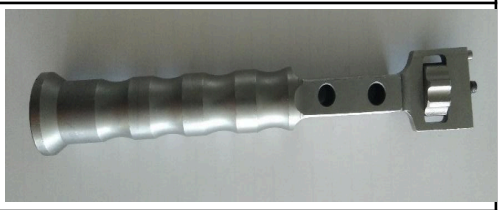
	02-033-011	KD013-XXXX	6 – 13 /1	
	02-033-012	KD014-XXXX	6 – 15 /1	
INSERT TRIAL P/S	02-033-013	KD015-XXXX	8 – 9 /1	
	02-033-014	KD016-XXXX	8 – 11 /1	
	02-033-015	KD017-XXXX	8 – 13 /1	
	02-033-016	KD018-XXXX	8 – 15 /1	
INSERT TRIAL P/S	02-033-017	KD019-XXXX	10 – 9 /1	
	02-033-018	KD020-XXXX	10 – 11 /1	

	02-033-019	KD021-XXXX	10 – 13 /1	
	02-033-020	KD022-XXXX	10 – 15 /1	
P/S FEMORAL BLOCK	02-034-001	KD023-XXXX	2 – 1	
	02-034-002	KD024-XXXX	4 – 1	
	02-034-003	KD025-XXXX	6 – 1	
	02-034-004	KD026-XXXX	8 – 1	
	02-034-005	KD027-XXXX	10 – 1	
P/S IMPACTOR	02-035-001	KD028-XXXX	1	

Box KE tray 2
TIBIAL FINALIZATION



PRODUCT NAME	REF NO	LOT NO	SIZE / QNT.	PIC

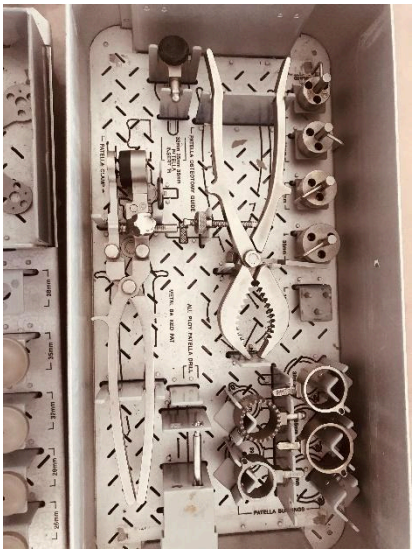
UNIVERSAL EXTRACTOR	02-027-001	KE001-XXXX	1	
PROXIMAL TIBIA CUT BLOCK	02-021-001	KE002-XXXX	0 DERECE / 1 ADET	
	02-021-002	KE003-XXXX	3 DERECE / 1 ADET	
TIBILA PLATEU HANDLE	02-013-001	KE004-XXXX	1	
TIBIAL PUNCH	02-019-001	KE005-XXXX	SIZE 2/4/6 / 1	
	02-019-002	KE006-XXXX	SIZE 8/10 /	
TIBIAL PLATEU DRILL	02-002-001	KE007-XXXX		
CR TRIAL INSERTS	02-008-001	KE008-XXXX	2-9 / 1	

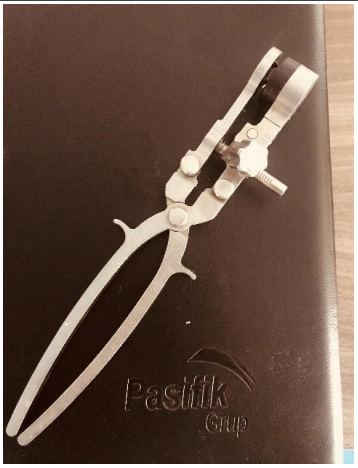
	02-008-002	KE009-XXXX	2 – 11 / 1	
	02-008-003	KE010-XXXX	2 – 13 / 1	
	02-008-004	KE011-XXXX	2 – 15 / 1	
CR TRIAL INSERTS	02-008-005	KE012-XXXX	4 – 9 / 1	
	02-008-006	KE013-XXXX	4 – 11 / 1	
	02-008-007	KE014-XXXX	4 – 13 / 1	
	02-008-008	KE015-XXXX	4 – 15 / 1	

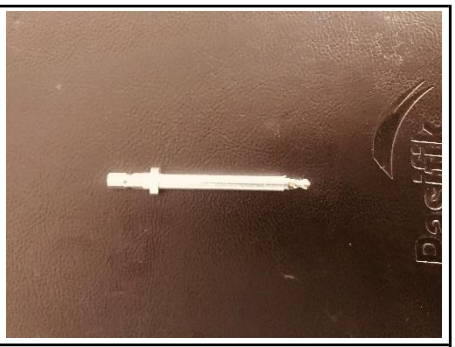
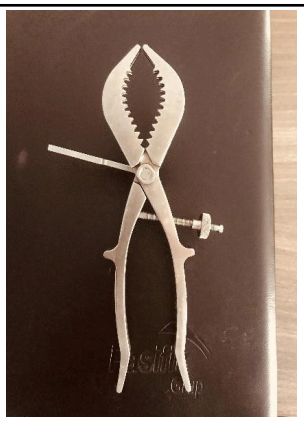
CR TRIAL INSERTS	02-008-009	KE016-XXXX	6 – 9 / 1	
	02-008-010	KE017-XXXX	6 – 11 / 1	
	02-008-011	KE018-XXXX	6 – 13 / 1	
	02-008-012	KE019-XXXX	6 – 15 / 1	
CR TRIAL INSERTS	02-008-013	KE020-XXXX	8 – 9 / 1	
	02-008-014	KE021-XXXX	8 – 11 / 1	
	02-008-015	KE022-XXXX	8 – 13 /1	

	02-008-016	KE023-XXXX	8 – 15 / 1	
CR TRIAL INSERTS	02-008-017	KE024-XXXX	10 – 9 / 1	
	02-008-018	KE025-XXXX	10 – 11 / 1	
	02-008-019	KE026-XXXX	10 -13 / 1	
	02-008-020	KE027-XXXX	10 – 15 / 1	

Box KF



PRODUCT NAME	REF NO	LOT NO	SIZE / QNT.	PIC
Sizer and drill guide	03-001-001	KF001-XXXX	1	
PATEELAR CLAMP	03-003-001	KF002-XXXX	1	

PATELLAR DRILL	03-004-001	KF003-XXXX	1	
PATELLAR COMPONENT IMPACTOE	03-005-001	KF004-XXXX	1	
PATELLA CUTTING CLAMP	03-006-001	KF005-XXXX	1	
PATELLAR TRIAL	03-007-001	KF006-XXXX	8 - 29	
PATELLAR TRIAL	03-008-001	KF007-XXXX		

4. RISKS AND WARNINGS

4.1. Residual Risks and Unintended Effects:

Risk No	Harm	Danger(s)	Potential Cause (Dangerous Situations and Event Sequence)	Reason for Not Reduction
R03	Implantation Failure	Functionality - Critical performance	Displacement or breakage of the Primary Knee Prosthesis due to excessive	Since the determined risk cannot be reduced by the information provided to the

		Mechanical Energy Potential energy	force applied by the doctor while implantation	user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R04	Implantation Failure	Functionality - Critical performance Mechanical Energy Potential energy	Dislocation of the implant as a result of the product not being fully fixed to the bones due to doctor's carelessness	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R08	Patient Harm	**Biological Agents;** - Bacteria - Mushroom - Parasites - Prions - Toxins - Viruses **Chemical Agents;** - Carcinogenic, mutagenic, reproductive - Pryogenic Toxic	Deterioration of product structure due to re-sterilization of products by the user	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R14	Patient Harm	**Biological Agents;** - Bacteria - Mushroom - Parasites - Prions - Toxins - Viruses **Chemical Agents;** - Carcinogenic, mutagenic, reproductive - Pryogenic Toxic	Re-use of disposable products on the patient	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.

R23	Damage to the Device and the Patient	**Functionality** Critical Performance	Using the device in contraindication areas	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R30	Failure of Products to Fulfill Their Function	**Functionality** - Critical Performance	Failure to select the appropriate product according to the operation site and type of fracture (indication) during product selection by the doctor	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R36	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	The patient is not informed about the expected life of the product and the process is negatively affected	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R37	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Damage to or opening in the packaging of gamma sterilized products	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R38	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Failure to check products for reference number and size before use	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum

				levels.
R39	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Products are not stored at appropriate temperatures	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R40	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Failure to check products for damage before use	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R41	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Contacting the products with different chemical materials other than bone cement	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R42	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing whether the products are suitable for MR environment and whether they are safe in MR environment	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R43	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing how to carry out the removal of products	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be

				reduced to the minimum levels.
R44	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing which process should be applied when products need to be disposed of	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R45	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Scratching of polished surfaces of the product	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R46	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	The product is scratched or damaged by impact	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R47	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing what to do in case of a serious adverse event related to the product	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.

4.2. Warnings and Precautions:

- 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.

4.3. If Any, Other Relevant Aspects of Safety, Including a Summary of Site Safety Corrective Actions (FSCA Including FSN):

There have been no Serious Adverse Event Notifications, Field Safety Corrective Action (FSCA) Notifications, Preventive and/or Corrective Action (CAPA) Notifications or product recalls regarding the **Primary Knee Prosthesis** products we manufacture since their first production.

5. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

A clinical evaluation study has been conducted by us for **Primary Knee Prosthesis** products in accordance with Meddev 2.7.1 Rev.4 and EU 2017/745 MDR Annex XIV. In the clinical evaluation conducted, clinical data were obtained from scientific literature on similar products. The clinical benefit, clinical safety and performance and clinical risks of our products have been confirmed with the obtained data. As a result of the obtained data, it has been seen that the clinical benefit to be obtained outweighs the risks that may occur in our products and the clinical benefit outweighs the risks of our products.

Specific and general PMCF activities have been planned for our **Primary Knee Prosthesis** products that we manufacture, and the plans made are recorded with TF.001.App14-02.02 Post Market Clinical Follow-up(PMCF) Plan.
As a result of PMCF activities, the clinical safety and performance of our **Primary Knee Prosthesis** products have been verified.

5.1. If any, Summary of Clinical Data on the Equivalent Device,:

See: PMCF Report and Clinical Evaluation Report

5.2. Summary of Clinical Data Obtained from Research Conducted Prior to CE Marking of the Device, if any::

No clinical investigation studies have been conducted prior to CE marking for our products.

5.3. Summary of Clinical Data Obtained from Other Sources, If Available:

See: PMCF Report

5.4. General Summary of Clinical Performance and Safety:

A clinical evaluation study has been conducted by us for **Primary Knee Prosthesis** products in accordance with Meddev 2.7.1 Rev.4 and EU 2017/745 MDR Annex XIV. In the clinical evaluation conducted, clinical data were obtained from scientific literature on similar products. The clinical benefit, clinical safety and performance and clinical risks of our products have been confirmed with the obtained data. As a result of the obtained data, it has been seen that the clinical benefit to be obtained outweighs the risks that may occur in our products and the clinical benefit outweighs the risks of our products.

5.5. Ongoing or Planned Post-Marketing Clinical Follow-up

Our products have been on the market for many years. For this reason, the data obtained from product users in the past period for our products continue to be collected and reported with high quality surveys. In this direction, the study protocol has been prepared and evaluation processes are ongoing.

6. POSSIBLE DIAGNOSIS OR TREATMENT ALTERNATIVES

Primary knee prostheses represent a fundamental solution in orthopedic surgery for the management of advanced joint diseases such as osteoarthritis, rheumatoid arthritis, and post-traumatic degenerative conditions. In cases where conservative treatments (e.g., physical therapy, analgesics, intra-articular injections) fail to alleviate symptoms, surgical intervention with total or partial knee arthroplasty becomes the primary treatment alternative for restoring function and relieving pain.

Over time, significant advancements have been made in the field of knee arthroplasty, especially regarding materials, implant design, and surgical techniques. These developments can be categorized into innovations in biomaterials, implant geometry, and integration of emerging technologies.

Cobalt-chromium alloys and titanium-based materials remain the standard for implant manufacturing due to their high mechanical strength, corrosion resistance, and biocompatibility. In modern state-of-the-art systems, highly cross-linked polyethylene is widely used for the tibial insert component, offering improved wear resistance and reduced particle generation. Additionally, ceramic components are being studied for their potential to further reduce wear and enhance longevity.

Alongside material innovations, surface modifications play a crucial role in improving the osteointegration and reducing infection risks. Technologies such as porous coatings, hydroxyapatite layers, and antibacterial surface treatments (e.g., silver or antibiotic coatings) are being investigated to enhance biological fixation and minimize postoperative complications like periprosthetic joint infections.

Design advancements have also shaped the evolution of knee prostheses. Modern implants are increasingly anatomically contoured to better replicate natural joint kinematics. Modular implant systems allow for patient-specific customization, while gender-specific designs and high-flexion prostheses aim to restore greater range of motion and functionality. Furthermore, improvements in femoral and tibial component fixation—such as cementless press-fit or hybrid fixation—are being explored to optimize stability and longevity.

In parallel, the adoption of future technologies is influencing the field. Robotic-assisted surgery and computer-navigated systems enhance implant alignment accuracy, thereby reducing complications and improving long-term outcomes. Patient-specific instrumentation (PSI), 3D-printed cutting guides, and customized implants based on preoperative imaging are increasingly being adopted to personalize treatment. Moreover, smart prosthesis systems integrated with sensors are being developed to monitor implant function and patient recovery postoperatively.

Alternative surgical approaches, such as unicompartmental knee arthroplasty (UKA), may also be considered in patients with localized joint degeneration, preserving more of the natural knee structures and enabling faster recovery. However, the indication for UKA is limited to specific cases with isolated compartment involvement.

In summary, total and partial knee arthroplasty using modern primary knee prostheses stands as the most effective treatment alternative when conservative options are insufficient. Ongoing innovations in materials, surface technologies, implant design, and surgical planning tools continue to enhance the safety, efficacy, and long-term success of these orthopedic devices.

7. PROPOSED USER PROFILE AND TRAINING

It is used by specialist physicians who have completed the necessary training and have operational experience. Clinical users of a primary knee prosthesis are orthopedic surgeons—often specialized in joint replacement—who are trained to evaluate, select, and surgically implant the device in patients requiring total knee arthroplasty. User Manuals and Surgical Technique documents containing detailed information about the use of our products are provided together with the products. Users are trained in this way.

8. REFERENCE TO APPLIED HARMONISED STANDARDS AND COMMON SPECIFICATIONS (CS)

For **Primary Knee Prosthesis** products manufactured and sold by us, standards, regulations, common specifications, guidelines and guidance documents accepted in our country or worldwide are taken into consideration and applied. The updates of documents such as standards, regulations, guidance documents applied for our products and system are constantly monitored and when any update occurs in the documents, this situation is examined by us and the requirements of the current documents are fulfilled.
See: TF.001.App07-03 List of Standards

Rev. No	Rev. Date	Amendment Explanation	Revision Validated by NB
00	**---**		☐ **Yes** **Validated Language:** ☐ **No**
			☐ **Yes** **Validated Language:** ☐ **No**

A summary of the safety and clinical performance of the device for patients is given below.

Prepared by /Approval **Controlled by /Approval**

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE/SSCP

Document Revision: 00
Date Organised: 26.12.2024

This summary of safety and clinical performance (SSCP) is intended to provide public access to an updated summary of key aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more comprehensive summary of the safety and clinical performance of the device for healthcare professionals is included in the first section of this document.

The SSCP is not intended to provide general advice on the treatment of a medical condition. If you have any questions about your medical condition or the use of the device in your condition, please contact your healthcare professional. This SSCP is not intended to replace an implant card or instructions for use to provide information on the safe use of the device.

1. DEVICE DESCRIPTION AND GENERAL INFORMATION

1.1. Trade Name(s) of the Device and General Description:

PMG Motion Primary Knee Prosthesis

Primary Knee Prosthesis is designed to provide reconstruction of degenerated knee joints in specified indications. It is suitable for use in patients who have completed bone development. This prosthesis is used when the native knee joint is affected by conditions such as osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, or severe knee injury that results in pain, reduced mobility, or joint deformity. 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.

1.2. Name and Address of the Manufacturer:

PASİFİK MEDİKAL TİCARET ANONİM ŞİRKETİ / OSTİM OSB MAHALLESİ ATİSAN SANAYİ SİTESİ 241. SOKAK NO:2 YENİMAHALLE/ANKARA/TÜRKİYE

1.3. Basic UDI-DI:

Basic UDI-DI Code of Primary Knee Prosthesis is determined as follows;

Femoral Component	86810722KFED
Tibial Component	86810722KTF9
Insert Component	86810722KIEK
Patella Component	86810722KPEZ

1.4. Year of the First Certificate (CE) covering the Device:

The first CE certificate for the products was given on 2014.

2. INTENDED USE OF THE DEVICE

2.1. Intended Use:

Primary Knee Prosthesis provides reconstruction of degenerated knee joints in certain indications.

2.2. Indication(s) and Target Population(s):

Joint replacement is indicated in patients with disabilities due to the following problems:

- Degenerative, posttraumatic or rheumatoid arthritis;
- Avascular necrosis in 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 cemented applications. Although total knee replacements are not intended to replace the loads or activity levels assumed by normal healthy bone, they are a way to regain mobility and reduce pain for many patients.

Target Patient Population:

The target patient population is expected to be patients who have completed bone development, experience pain and have difficulty climbing stairs and moving in daily activities. Our products can be used by both male and female genders.

- 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.

2.3. Contraindications and-or Limitations:

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).

3. DEVICE DESCRIPTION

3.1. Description of the device:

Primary Knee Prosthesis is designed to provide reconstruction of degenerated knee joints in specified indications. It is suitable for use in patients who have completed bone development. This prosthesis is used when the native knee joint is affected by conditions such as osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, or severe knee injury that results in pain, reduced mobility, or joint deformity. 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.

3.1.1. Working Principles and Effect of the Device: (Mode of Action)

Primary Knee Prosthesis basically replaces the degenerated knee joint and enables the patient to easily carry out movements and daily activities such as going up and down stairs, just like a healthy joint.
Total knee arthroplasty refers to the replacement of the degenerated knee joint with an artificial knee joint. The degenerated knee joint is cut with incision guides in accordance with the internal angles of the femoral and tibial components of the knee prosthesis, and the femoral and tibial prosthesis components are placed in their places. Thus, friction is eliminated and the nerve endings on the condyles of the femur and tibia regain their daily movement mechanism without pain.

The Total Knee Prosthesis System produced by Pasifik Medical allows the knee kinematics to be repositioned with a completely physical effect.
There are no pharmaceutical or metabolic effects.

Figure 1. Illustration of healthy knee joint and degenerated knee joint

Figure 2. Knee joint with knee prosthesis.

3.1.2. List of Raw Materials in Contact with the Body and Biocompatibility Evaluation:

Our products that come into contact with the patient's body are manufactured from CoCrMo alloy and UHMWPE raw materials. The biocompatibility classification of our products is determined according to the table below of the EN ISO 10993-1 Standard.

3.2. Description of all kinds of accessories designed to be used with the device:

There is no accessory of our Femur, Tibia, Insert and Patella products. There are Surgical Instruments used with Femur, Tibia, Insert and Patella.

4. RISKS AND WARNINGS

If you think you are experiencing any side effects or are concerned about risks related to the device or its use, contact your healthcare professional. This document is not intended to replace consultation with your healthcare professional when appropriate.

4.1. How potential risks are controlled or managed

Potential risks that may arise regarding our products are determined by our Risk Management Team and our company takes precautions for these potential risks. Potential risks are determined by examining under the headings of “Published standards, Scientific or technical research, Field data obtained from similar medical devices currently in use including published reported cases, Easy usability tests performed by typical users, Clinical evidence, Related research or simulation results or Expert opinion”. The control methods and order of importance applied for the determined potential risks are as follows;

a) Safe design and manufacturing to be applied due to the nature of the product: The measures taken in the product design based on the purpose of use of the product, the areas where it will be used and the product users have been defined and the risks have been evaluated.

b) Protective measures in the medical device itself or in the manufacturing process: Risks have been evaluated with the controls and measures taken during production.

c) Safety information and, where appropriate, training for users: All necessary warnings regarding the measures taken by us for product safety and the issues to be considered regarding safety and the issues to be followed during use are presented to the user with labels prepared in accordance with the EN 15223-1 Standard and user manuals prepared in accordance with the EN ISO 20417 Standard. In this context, risks have been addressed and necessary definitions have been made.

The appropriate one(s) from the 3 control methods mentioned above are selected according to the risk type and the potential risk is reduced to the minimum level that it can be reduced to. Risks that cannot be reduced to the minimum level are considered as residual risks by us. For these residual risks, “User Manual, Surgical Technique and Labeling” documents are presented to users and risks are tried to be prevented.

4.2. Residual Risks and Unintended Effects:

Risk No	Harm	Danger(s)	Potential Cause (Dangerous Situations and Event Sequence)	Reason for Not Reduction
R03	Implantation Failure	Functionality - Critical performance Mechanical Energy Potential energy	Displacement or breakage of the Primary Knee Prosthesis due to excessive force applied by the doctor while implantation	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R04	Implantation Failure	Functionality - Critical performance Mechanical Energy Potential energy	Dislocation of the implant as a result of the product not being fully fixed to the bones due to doctor's carelessness	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R08	Patient Harm	**Biological Agents;** - Bacteria - Mushroom - Parasites - Prions - Toxins - Viruses **Chemical Agents;** - Carcinogenic, mutagenic, reproductive	Deterioration of product structure due to re-sterilization of products by the user	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.

		- Pryogenic Toxic		
R14	Patient Harm	**Biological Agents;** **-** Bacteria - Mushroom - Parasites - Prions - Toxins - Viruses **Chemical Agents;** - Carcinogenic, mutagenic, reproductive - Pryogenic Toxic	Re-use of disposable products on the patient	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R23	Damage to the Device and the Patient	**Functionality** Critical Performance	Using the device in contraindication areas	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R30	Failure of Products to Fulfill Their Function	**Functionality** - Critical Performance	Failure to select the appropriate product according to the operation site and type of fracture (indication) during product selection by the doctor	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R36	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	The patient is not informed about the expected life of the product and the process is negatively affected	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.

R37	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Damage to or opening in the packaging of gamma sterilized products	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R38	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Failure to check products for reference number and size before use	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R39	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Products are not stored at appropriate temperatures	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R40	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Failure to check products for damage before use	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R41	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Contacting the products with different chemical materials other than bone cement	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum

				levels.
R42	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing whether the products are suitable for MR environment and whether they are safe in MR environment	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R43	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing how to carry out the removal of products	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R44	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing which process should be applied when products need to be disposed of	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R45	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Scratching of polished surfaces of the product	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.
R46	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	The product is scratched or damaged by impact	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be

				reduced to the minimum levels.
R47	Failure of Products to Fulfill Their Function	**Functionality** Critical Performance	Not knowing what to do in case of a serious adverse event related to the product	Since the determined risk cannot be reduced by the information provided to the user and since there is no other precaution to be taken by us on this issue, the determined risk cannot be reduced to the minimum levels.

4.3. Warnings and Precautions:

- 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.

4.4. If Any, Other Relevant Aspects of Safety, Including a Summary of Site Safety Corrective Actions (FSCA Including FSN):

There have been no Serious Adverse Event Notifications, Field Safety Corrective Action (FSCA) Notifications, Preventive and/or Corrective Action (CAPA) Notifications or product recalls regarding the **Primary Knee Prosthesis** products we manufacture since their first production.

5. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

A clinical evaluation study has been conducted by us for **Primary Knee Prosthesis** products in accordance with Meddev 2.7.1 Rev.4 and EU 2017/745 MDR Annex XIV. In the clinical evaluation conducted, clinical data were obtained from scientific literature on similar products. The clinical benefit, clinical safety and performance and clinical risks of our products have been confirmed with the obtained data. As a result of the obtained data, it has been seen that the clinical benefit to be obtained outweighs the risks that may occur in our products and the clinical benefit outweighs the risks of our products.

Specific and general PMCF activities have been planned for our **Primary Knee Prosthesis** products that we manufacture, and the plans made are recorded with TF.001.App14-02.02 Post Market Clinical Follow-up(PMCF) Plan.
As a result of PMCF activities, the clinical safety and performance of our **Primary Knee Prosthesis** products have been verified.

5.1. Clinical History of the Device:

The first CE certification process was completed on 2014. After this date, the products were manufactured and launched on the market. Since the first certification date, no negative situation has been experienced in the clinical safety and performance of our products and our company has not been notified in this direction. Considering this information, the clinical history of our products is quite safe and problem-free.

5.2. Clinical Evidence for CE Marking:

During the initial CE certification of our products, scientific literature and similar product data were used. In light of the scientific literature and data obtained from similar devices, it was seen that our products have a sufficient level of clinical evidence. Within the scope of EU 2017/745 MDR, clinical evidence for our products was provided by using our own products on real patients and evaluating the data obtained from these uses. This process was carried out by our company within the scope of Post-Sales Clinical Follow-up (PMCF). The clinical evidence obtained with the study conducted revealed that our products are clinically safe and have good performance.

5.3. Safety:

A clinical evaluation study has been conducted by us for **Primary Knee Prosthesis** products in accordance with Meddev 2.7.1 Rev.4 and EU 2017/745 MDR Annex XIV. In the clinical evaluation conducted, clinical data were obtained from scientific literature on similar products. The clinical benefit, clinical safety and performance and clinical risks of our products have been confirmed with the obtained data. As a result of the obtained data, it has been seen that the clinical benefit to be obtained outweighs the risks that may occur in our products and the clinical benefit outweighs the risks of our products.

6. Possible diagnostic or treatment alternatives

When considering alternative treatments, it is recommended that you consult your healthcare professional who can take your individual situation into account.

Primary knee prostheses represent a fundamental solution in orthopedic surgery for the management of advanced joint diseases such as osteoarthritis, rheumatoid arthritis, and post-traumatic degenerative conditions. In cases where conservative treatments (e.g., physical therapy, analgesics, intra-articular

injections) fail to alleviate symptoms, surgical intervention with total or partial knee arthroplasty becomes the primary treatment alternative for restoring function and relieving pain.

Over time, significant advancements have been made in the field of knee arthroplasty, especially regarding materials, implant design, and surgical techniques. These developments can be categorized into innovations in biomaterials, implant geometry, and integration of emerging technologies.

Cobalt-chromium alloys and titanium-based materials remain the standard for implant manufacturing due to their high mechanical strength, corrosion resistance, and biocompatibility. In modern state-of-the-art systems, highly cross-linked polyethylene is widely used for the tibial insert component, offering improved wear resistance and reduced particle generation. Additionally, ceramic components are being studied for their potential to further reduce wear and enhance longevity.

Alongside material innovations, surface modifications play a crucial role in improving the osteointegration and reducing infection risks. Technologies such as porous coatings, hydroxyapatite layers, and antibacterial surface treatments (e.g., silver or antibiotic coatings) are being investigated to enhance biological fixation and minimize postoperative complications like periprosthetic joint infections.

Design advancements have also shaped the evolution of knee prostheses. Modern implants are increasingly anatomically contoured to better replicate natural joint kinematics. Modular implant systems allow for patient-specific customization, while gender-specific designs and high-flexion prostheses aim to restore greater range of motion and functionality. Furthermore, improvements in femoral and tibial component fixation—such as cementless press-fit or hybrid fixation—are being explored to optimize stability and longevity.

In parallel, the adoption of future technologies is influencing the field. Robotic-assisted surgery and computer-navigated systems enhance implant alignment accuracy, thereby reducing complications and improving long-term outcomes. Patient-specific instrumentation (PSI), 3D-printed cutting guides, and customized implants based on preoperative imaging are increasingly being adopted to personalize treatment. Moreover, smart prosthesis systems integrated with sensors are being developed to monitor implant function and patient recovery postoperatively.

Alternative surgical approaches, such as unicompartmental knee arthroplasty (UKA), may also be considered in patients with localized joint degeneration, preserving more of the natural knee structures and enabling faster recovery. However, the indication for UKA is limited to specific cases with isolated compartment involvement.

In summary, total and partial knee arthroplasty using modern primary knee prostheses stands as the most effective treatment alternative when conservative options are insufficient. Ongoing innovations in materials, surface technologies, implant design, and surgical planning tools continue to enhance the safety, efficacy, and long-term success of these orthopedic devices.

7. Recommended training for users

User Manuals and Surgical Techniques documents containing detailed information about the use of our products are provided together with the products. Users are trained in this way.

Prepared by /Approval **Controlled by /Approval**