TOTAL KNEE PROSTHESIS USER GUIDE

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1. Definition of Implant

Total Knee Replacement System consists of 5 different elements.These elements are generically named femoral component, tibial component, insert component and patellar component respectively. Model representations are as follows;

Femoral Component	
Tibial Component	
Insert Component	
Patellar Component	
Stem Extention	

Model displays are taken from ISO 7207-1: 2007 standard and do not meet the design of the Total Knee Replacement System.

2. The Intended Purpose of the Implant

Reconstruction of degenerated knee joints.

Total Knee Replacement provides reduced pain and increased functionality in the knee joint. Degenerated knee joints are reconstructed in accordance with the inferior feature of the femoral and tibial components with the help of special tools. More information is provided in the Surgical Technique.

3. Planned Performance

The relative angular motion between the parts of the Total Knee Replacement System is designed to be 0 ° - 130 °. The estimated maximum load motion to be transmitted to the bone parts to which the Total Knee Replacement System is attached is 8 times of the body weigh.The forces which correspond with the 8 times of the body weight have been designed to withstand of ,the Total Knee Replacement System It is suggested that the Total Knee Prosthesis System will wear to a certain extent due to the kinematics associated with the daily physical activities of the knee joint within the body .However, it has been considered that this wear will be at an acceptable level and it has been determined that the Total Knee Replacement System will have a lifetime of at least 10 years after implantation.

4. Unwanted Side Effects

• Abrasion of insert component made of UHMWPE,

• Broken tibia or femur,

• Temporary peroneal palsy secondary to surgical manipulation,

• Subluxation or dislocation of the patella,

• Instability, position changes or aseptic loosening of the components,

• Ligament laxity,

• Separation of components from each other,

• Infection,

• Weak range of motion,

• Shortening of extremities,

• Metal sensitivity reactions

5-Criterias for Obtaining a Safe Composition

In order to obtain a safe composition from the Total Knee Replacement System, the femoral, tibial and insert components should be used from the components of the original Total Knee Replacement System . In order to obtain a safe composition from the Total Knee Replacement System, the femoral, tibial and insert components should be used from the components of the original Total Knee Replacement System.In addition, the operation should be performed as described in the Surgical Technique document and the original Total Knee Replacement System Surgical Instruments should be used. The sizes stated in the table below can be used together. The thickness of the insert component is not a determining parameter for the compositions.

6. Precautions and Warnings

- The life of the Total Knee Replacement System depends on the patient's weight and daily activities. It is recommended that the patient is informed about this issue before and after the operation.
- Total Knee Replacement System is offered sterilized by gamma radiation and should always be stored unopened in protective boxes. Before use, check for any damage that could compromise the perforation of the packaging. Do not use implants if the packaging is opened or damaged.
- Do not resterilize the Total Knee Replacement System for any reason. Do not use implants with impaired sterility..
- Examine the labels to verify that the expiration date has not passed. Do not use implants if the product has expired.
- When unpacking the implant, verify the reference number and dimensions on the label on the product box and the labels that come out of it.
- Total Knee Replacement System is for single use.
- Keep Total Knee Replacement System between 20 ° - 30 °.
- Before each use, check each implant to make sure there is no visible damage.
- Do not expose Total Knee Replacement System to any chemical material in a clinical setting. Do not undergo alcohol cleaning and similar processes.
- Total Knee Replacement System is safe and compatible in MR environment. However, the insert component made of UHMWPE cannot be viewed in the MR environment.
- See the Surgical Technique document for the correct removal of the Total Knee Replacement System.
- If the destruction of the Total Knee Replacement System is required, it should be evaluated as medical waste and action should be taken accordingly.
- Care should be taken to protect polished surfaces, especially inside-convex surfaces, from notches and scratches that may be the focus of failure. Care should be taken not to expose the polished surfaces to any contact
- It can cause poor performance in overweight people.
- Do not use the prosthetic components of other knee systems with the Orthotonic knee components, as there may be incompatible sizing and bearing surfaces, resulting in premature wear, misalignment and failure..

MR. Compatibility

- The devices have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or displacement in the MR environment. The risks associated with a passive implant in the MR environment have been evaluated and are known to include image artifacts, warming and displacement in or near the implant site..

7-Product Description and Implant Materials

Component	Fixation Method	Material	ASTM Standart	ISO Standart
Femoral Componant	With cement, the femur is fixed on the distal head.	CoCrMo Alloy	ASTM F75	ISO 5832-4
Tibial Componant and Stopper	With cement, the tibia is fixed per proximal.	CoCrMo Alloy and Ti6Al4V	ASTM F75 ve ASTM F136	ISO 5832-4 ve ISO 5832-3
Insert	The conical protruding design is fixed in the proximal conical hole of the tibial plateau. This design, which restricts movement on the AP and ML axes, does not limit movement on the rotation axis.	Ultra High Molecular Weight Crosslinked Polyethylene (UHMWPE)	ASTM F648	ISO 5834-1 & 2
Patellar	The conical protruding design is fixed in the proximal conical hole of the tibial plateau. This design, which restricts movement in the AP and ML axes, does not limit movement in the rotation axis	Ultra High Molecular Weight Crosslinked Polyethylene (UHMWPE)	ASTM F648	ISO 5834-1 & 2
Stem Extension	It is used to strengthen fixation extending proximal to distal intramedularly to the tibia.	Titanium (Tl6AL4V)	ASTM F136	ISO 5832-3

Femur Components can be provided in left and right configurations. Tibial Components and Insert / Patella are not anatomical.

8-Indications

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

- Degenerative, posttraumatic, osteoarthritis or rheumatoid arthritis;
- Avascular necrosis in the femoral condyle;
- Posttraumatic loss of joint configuration, especially if there is patellofemoral erosion, dysfunction or pre-patellectomy;
- Moderate severity of 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. Although total knee changes are not intended to meet the loads or activity levels undertaken by normal healthy bone, it is a way for many patients to regain movement and reduce pain..

9-Contraindications

Joint replacement is contraindicated in the presence of:

• Infection (or history of infection), acute or chronic, local or systemic;

• Insufficient bone quality that can affect the implant stability;

• Muscular, neurological or vascular deficiencies that adversely affect the relevant extremities;

• Obesity;

• Alcoholism or other addictions;

• Sensitivity to materials;

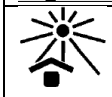
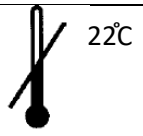
• Loss of ligament structures;

• High level of physical activity (eg racing sports, heavy physical work).

10-Preoperative Planning and Postoperative Care

See surgical technique document.

11- Symbols Shown on the Label and Their Meanings

Symbol	Definition
	Manufacturer identification
	Production date
	Expiration date
	Lot number
	Referance number
	Sterilization by Gamma Irradiation
	Do not resterilize.
	Do not use if the packaging is damaged
	Keep away from the sun.
	It is for single use
	Indicates the temperature limits to which the medical device can be safely exposed.
	Review User Manual
	Attention
	Marking that the product meets all the requirements of 93/42 / EEC MDD