KNEE PROSTHESIS USER MANUAL

Instructions for Use

Before using **Otimed** brand Knee Prosthesis which is put on the market by **OTTOMAN GROUP IMPLANT**, specific information about the product (technical description about the product, surgical technical information) should be examined carefully by the doctor who will use the product.

1) Safety Instructions

1.1 General Instructions

Otimed products should only be implanted by a doctor who is familiar with the possible problems of replacement of the insertion device and is familiar with the product-specific operating techniques. Implants should be kept in the original package, should not be opened or damaged. Before implantation, the products should be checked for any damage. Before removing the sterile implants from the package, the protective packaging must be carefully examined to check for any damage that may impair the sterile nature of the product. The expiration date must be observed to maintain the sterile character of the product. Implants beyond the expiry date should be returned to the manufacturer.
Asepsis rules must be followed when removing the implant from its package.
The doctor is responsible for the complications and side effects caused by improper use of the indication instructions, faulty operation technique, selection of inappropriate material or treatment method, wrong surgical material usage and asepsis error. The manufacturer can never be held responsible, The manufacturer can never be held responsible.

Important Instructions

- The components of the system are prosthesis and prosthetic parts. They can only be combined with original parts of the same system and can only be implanted with original surgical materials of the same system.
- **Otimed** brand knee prosthesis and prosthesis parts should not be combined with the parts of different manufacturers and should not be used with surgical materials of different manufacturers. No liability is accepted for any surgical equipment purchased or used by third parties. Prosthesis should not be altered in any way unless specifiacally specified in its design and surgical methods. If there are doubts must be informed in writing from the manufacturer.
- General endoprosthetic risks; allergic reactions to the implant material used, corrosion of the material, loosening, incorrect positioning, dislocation, tear, rupture, breakage of the implant or implant part.
- İmplantların The use of implants for a different purpose is prohibited. Any additional instructions (such as intruction labels on the package) should be followed.

Using of Knee Prosthesis with Bone Cement

PRODUCT NAME	USE OF
FEMORAL COMPONENT	CEMENTED
TIBIAL COMPONENT	CEMENTED
TIBIAL INSERT	CEMENTLESS
PATELLAR COMPONENT	CEMENTED

Compliance of Knee Prosthesis Components

Femoral Component	Tibial Component	Tibial Insert
Size 1 Right and Left	Any size appropriate to the patient's bone structure is selected by the doctor. But if the femur is right, the tibia must be right. If the femur is left, the tibia should be left.	**1x8, 1x10, 1x12, 1x14, 1x16, 1x18, 1x20 any size matching the insert size can be used.**
Size 2 Right and Left	Any size appropriate to the patient's bone structure is selected by the doctor. But if the femur is right, the tibia must be right. If the femur is left, the tibia should be left.	**2x8, 2x10, 2x12, 2x14, 2x16, 2x18, 2x20 any size matching the insert size can be used.**
Size 3 Right and Left	Any size appropriate to the patient's bone structure is selected by the doctor. But if the femur is right, the tibia must be right. If the femur is left, the tibia should be left.	**3x8, 3x10, 3x12, 3x14, 3x16, 3x18, 3x20 any size matching the insert size can be used.**
Size 4 Right and Left	Any size appropriate to the patient's bone structure is selected by the doctor. But if the femur is right, the tibia must be right. If the femur is left, the tibia should be left.	**4x8, 4x10, 4x12, 4x14, 4x16, 4x18, 4x20 any size matching the insert size can be used.**
Size 5 Right and Left	Any size appropriate to the patient's bone structure is selected by the doctor. But if the femur is right, the tibia must be right. If the femur is left, the tibia should be left.	**5x8, 5x10, 5x12, 5x14, 5x16, 5x18, 5x20 any size matching the insert size can be used.**
Size 6 Right and Left	Any size appropriate to the patient's bone structure is selected by the doctor. But if the femur is right, the tibia must be right. If the femur is left, the tibia should be left.	**6x8, 6x10, 6x12, 6x14, 6x16, 6x18, 6x20 any size matching the insert size can be used.**

Note: Patellar Component is used in any size according to the bone structure of the patient. Besides, Otimed knee replacement components are not compatible with the components of other brands.

⚠ **Warnings**

- A previously used prosthesis or prosthesis part that has come into contact with the body fluid or tissue of another patient should never be reused.
- Used, damaged, altered prosthesis or prosthesis parts must not be reused.
- In case of overloading, damage, wrong implanted or improper use, prosthesis or prosthesis parts may break, dislodge, over-wear or lose function.
- The combined prosthesis or prosthesis components must be thoroughly clean before reduction, because contamination caused by foreign particles, bone debris, cement deposits can lead to erosion, loss of function or fracture of the prosthesis or prosthetic parts.

1.2 Cleaning and Sterilization

The products are supplied sterile by irradiation. Torn, perforated, and damaged packaging indicates sterility is impaired. Therefore, torn, perforated and damaged packaged products should not be used.

1.3Products Re-Sterilization

Products are offered for sale as sterile by irradiation. The products should not be resterilized.

Important Instructions

- If the Otimed product is sterilized or re-sterilized by the user, this should be indicated in the patient documentation (ie in the operation report).
- The equipment should be checked regularly for the validity of cleaning and sterilization procedures, in particular for correct placement.
- Asepsis rules should be followed during implantation.
- It is not possible to resterilize prosthesis and prosthetic parts made of polyethylene.

1.4 Pre-Operation Planning

Operation planning should be done according to X-ray findings. X-rays provide important information on the selection of the size and possible combinations of the appropriate implant type. The manufacturer of all types of implant and implant part combinations and surgical materials required for implantation should be recommended by the manufacturer, as it may be necessary to use a different length or implant. It should also be determined before the operation whether the patient will exhibit an allergic reaction to the implant material.

⚠ **Warning:**

Incorrect planning before the operation may have negative consequences. (Improper positioning, wrong denture and denture length selection)

1.5 General Information on Indications and Contraindications

- However, if all other treatment options are examined carefully and it is concluded that they are not suitable, prosthesis application should be considered.
- Even if the prosthesis has been successfully implanted, it is not of a natural healthy joint quality. However, prosthesis application can be a very useful replacement for the patient, because of this method, the patient may not feel pain, mobility and carrying capacity can be realized successfully.
- Aging and exposure to all kinds of artificial joints wear and tear is inevitable. Initially fixedly implanted artificial joint can lose this property over time or lose its function. A new operation may be required as a result of aging, wear and relaxation.
- Infection in the area where the implant is applied has negative consequences for the patient, since the implant must be removed.

1.6 Indications

- Wear as a result of degenerative, rheumatic and post-traumatic disorders.
- Bone fracture or vascular necrosis.
- Reconstruction, arthrodesis, hemi-arthroplasty or total knee prosthesis, early intervention in cases of total knee prosthesis.

1.7 Contraindications

- Acute or chronic, local or systemic infection.
- Muscular, neural and vascular disorders that can cause extremity disorders.
- Implant anchorage prevents bone loss.
- All conditions that may compromise the function and success of the implant.

1.8 Circumstances that may jeopardize the success of the operation

- Allergy to implant material, especially metal.
- Excess weight.
- Lokal kemik tümörü.
- Systemic and metabolic disorders.
- Irregular nutrition, excessive medicine use, smoking, alcohol and drug use.
- Physical activities that may cause severe shaking of the implant or subject to overload. (heavy physical activities, sports activities, marathon runs, downhill skiing, jumping, team sports, etc.)
- Patients who do not have the capacity to understand and follow the doctor's instructions.

1.9 Possible Adverse Effects

The most common negative outcomes after implantation are listed below:

- Application of overload and pressure, fracture or loosening of the prosthesis or parts of the prosthesis as a result of damaged or incorrect implantation.
- Changes in the shape of the charge transfer, abrasion or fracture of the bone layer and / or loosening of the implant as a result of reaction to the tissue on the implant.
- Early or late infection.
- Partial or total dislocation of the implant, inadequate mobility capacity, long or shorter than expected due to the positioning of the implant in less than required time.
- Fracture as a result of overloading of a bone or weak area.
- Transient or permanent neural lesion caused by pressure or hematoma. Wound hematoma and late wound healing.
- Cardiovascular disorders such as venous thrombosis, pulmonary embolism, cardiac arrest.
- Movement restriction.

1.10 Patient Information

Possible risks and effects of endoprosthesis implantation should be explained to the patient by the doctor. The patient should also be informed about what precautions to take to reduce the potential impacts. The patient should also be informed that the implants may affect the computed tomography and magnetic resonance results.

2) Implant Materials

Otimed endoprostheses are manufactured from the following materials.

- CrCoMo casting alloy (ISO 5832/4)
- Poliethylene UHMWPE (ISO 5834)

3) Stocking and Use of Prostheses

- Prostheses are extremely sensitive and can be damaged very quickly. A very small scratch or slight impact on the surface will cause wear and increase complications. Therefore it is necessary to show extreme sensitivity.
- The prosthesis surface should not be contacted with metal or other hard metals unless specifically provided for in the description of surgical techniques.
- Prostheses should be kept in their original packaging before opening.
- The protective cap and other protective devices must not be removed before use.
- Surgical materials are considered to be non-durable consumer goods because they are exposed to high corrosive effects. Before use, it must be checked whether it can perform its function or not, and if necessary, returned to the manufacturer.

⚠ **Warning:**

1. CoCrMo alloy used in knee prostheses is MR compatible.
2. Knee prostheses are not suitable for use other than their intended use.
3. Knee prostheses vary in performance depending on patient weight. Decreased product performance may be observed in overweight patients.

Symbols and their meanings used on the label and outer box and in the instruction manual

REF	Product Reference Code		Pay attention to the warnings
	Expiration Date		Store in a dry place
	Production Date	STERILE R	Sterilized by Irradiation.
LOT	Lot Number	CE 2292	Notified body ID
	Do not use torn hole packages		Do not Re-sterilize
	Please Read User Manual	MR	MR Safe
	Disposable Product		**Adres :** Göztepe Mah. Akgeyik Cad. Eski Tekel Depoları No:2/5 Battalgazi MALATYA / TURKEY **Tel: (0422) 311 44 01** **Faks : (0422) 311 44 05**