OHST
medical technology

Knee joint replacement

Patient information

Dear patient,

You have received a knee joint replacement from OHST Medizintechnik AG. In the following we would like to give you important information in relation to the product. Please read the information carefully and follow the instructions.
This document is intended to fulfil the requirements arising from Article 18 and Section 23 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Intended purpose

Knee prostheses are implants that remain in the body permanently and either partially or fully replace the damaged knee. The knee joint in its entirety is replaced by three components: the femoral component, the tibial component and the patellar component.
Irrespective of the shape and fixation manner of the individual joint components, they always perform the same functions (ISO 7207-1, ISO 21536):

Femoral component: the component of a total knee joint replacement intended to be secured to the femur to replace its articulating surfaces. These implants can be manufactured as one component or a set of components to be assembled by the user.

Tibial component: the component of a total knee joint replacement intended to be secured to the tibia to replace its articulating surfaces. These implants can be manufactured as one component or a set of components to be assembled by the user.

Patella component: the component of a total or partial knee joint replacement which is used to replace the articulating surface of the patella. These implants can be manufactured as one component or a set of components to be assembled by the user.

The aim is to relieve pain and improve the function of the knee joint in patients who have undergone surgery.

Safety and performance

Register data show[1] that about 82 % of all total knee arthroplasties can last 25 years. Depending on the type of fixation in the bone, the following failure probabilities are possible in the course of the wearing time of the prosthesis[2] :

Type of fixation in the bone	Probability of failure within...						
	1 year	2 years	3 years	4 years	5 years	6 years	7 years
cemented	1,7 %	2,6 %	3,0 %	3,4 %	3,6 %	3,9 %	4,2 %
hybrid	1,9 %	2,8 %	3,3 %	3,5 %	3,8 %	4,1 %	4,4 %
cementless	2,0 %	3,2 %	3,9 %	4,1 %	4,3 %	4,6 %	4,6 %

The lifespan of the artificial knee joint replacement can be significantly influenced by factors such as age, gender, body mass index (BMI) and concomitant diseases. The earlier a prosthesis is inserted, the more likely it is that the implant will be changed. Male patients have a higher probability of failure than female patients. A high BMI as well as the number of concomitant diseases can reduce the life span of the prosthesis. Hospitals with high experience due to higher treatment numbers tend to reduce the risk of prosthesis replacement.

Reasons for a subsequent intervention on the knee joint can be: Infection, loosening, osteolysis, fracture, instability, implant wear, implant malalignment or movement restrictions.

Summary of safety and clinical performance

The EU is in the process of setting up a European Database for Medical Devices (EUDAMED). As soon as this is available, you will be able to view a so-called "summary of safety and clinical performance" for your specific implant, which will be updated regularly. Until EUDAMED is launched, this report can be requested from OHST Medizintechnik AG.

[1] Evans JT et al: How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. Lancet. 2019 Feb 16;393(10172):655-663
[2] Endoprosthesis Register Germany (EPRD) Annual Report 2022. DOI: 10.36186/reporteprd062022

Important information related to your implant

Clinical experience shows that the presence of one or more of the following concomitant circumstances (risk factors) can lead to shorter service life, more frequent complications or an overall poorer outcome of knee arthroplasty. This list is not exhaustive.

General risk factors and conditions:

- Overweight
- Alcoholism or substance abuse
- Patient groups with mental disorders or addictions
- Pregnancy
- Intake of high-dose cortisone or cytotoxicics
- History or risk of infectious diseases with potential joint manifestation
- History of deep vein thrombosis and/or pulmonary embolism
- All general surgical risks

Risk factors and conditions specific to knee arthroplasty:

- Disorders of the bone metabolism (osteoporosis, osteomalacia)
- Circulatory disorders of the affected limb
- Neurological disorders of the affected limb
- Muscle dysfunction of the affected joint
- Growth in children and adolescents
- Expected extreme stresses, e.g. due to work or sports
- Epilepsy or other causes of repeated accidents with an increased risk of fracture
- Joint deformities that complicate fixation of the implant
- Weakening of the supporting structures due to a tumour

Adverse effects

The negative effects listed below are among the most typical and common consequences of surgery:

- Infection
- Venous thrombosis and pulmonary embolism
- Cardiovascular disorders
- Haematomas
- Paresthesia
- Numbness
- Swelling
- Nerve damage
- Oedema

The negative effects listed below are among the most typical and common consequences of knee arthroplasty:

- Tibial or femoral fracture
- Sub-dislocation or dislocation of the patella
- Instability, migration or loosening of components
- Detachment of components
- Insufficient freedom of movement
- Metal hypersensitivity reactions
- Patellofemoral complications
- Neurovascular complications
- Paralysis/palsy of the peroneal nerve
- Fat embolism
- Arterial insufficiency and damage
- Arthrofibrosis / accretions
- Implant fractures
- Implant noises
- Reduced quality of life (pain, sleep disorders and a restricted range of motion, especially when lying down)
- Inflammations
- Metallosis
- Increase in the level of metal ions in the blood
- Pseudotumours

Revision surgery may become necessary due to the occurrence of specific undesirable effects.

All serious incidents occurring in connection with the product must be reported to the manufacturer and the Federal Institute for Drugs and Medical Devices (BfArM).

Activities of daily living

Depending on the profession, the prosthesis used and the course of recovery, it usually takes 2 to 3 months before it is possible to work again. Sometimes a gradual work reintegration is possible, starting with a few hours per day and then gradually increasing the amount[3] .

Strong muscles, tendons and ligaments provide support for the prosthesis, which is why movement is important even with a joint replacement. However, the lifespan of a prosthesis also depends on how much it is used. Therefore, there are activities and sports that are more suitable for people with an artificial knee joint than others.

Activities that put less stress on the joint include:

- Walks or easy (not too mountainous) hikes
- Swimming
- Dance
- Light gymnastics

Activities and sports that put a lot of stress on the artificial joint are:

- Jogging
- Sports such as tennis, squash or football where the joints are exposed to impacts, twists or jerky movements
- Sports with physical contact and corresponding risk of falling, for example martial arts

For many sports, it depends on how well they were mastered before the joint replacement[4] . If you are starting a new sport, you do not yet have a routine and therefore have an increased risk of awkward movements and accidents. Jobs that require a lot of kneeling, squatting or heavy lifting are not well suited with an artificial knee joint. The same applies to activities that require frequent standing on ladders, scaffolding, roofs or uneven surfaces.

It is best to consult with your doctor about which activities are possible.

Follow-up examinations

The prosthesis implantation is followed by clinical and radiological checks of the patients. The aim of these follow-up examinations is to detect possible complications at an early stage and thus to be able to treat them before more extensive damage to the joint or bone has occurred[5] .

There are no fixed intervals for a follow-up examination. Your treating doctor will therefore have established his or her own routine. Clinical examinations may be more frequent than radiological examinations in the first few months. The reason for this is the radiation exposure associated with each X-ray examination.

[3] Aresti N et al: Primary care management of postoperative shoulder, hip, and knee arthroplasty. BMJ. 2017 Oct 18;359:j4431
[4] Witjes S et al: Return to Sports and Physical Activity After Total and Unicondylar Knee Arthroplasty: A Systematic Review and Meta-Analysis. Sports Med. 2016 Feb;46(2):269-92
[5] Hass H: Stellungnahme zur Durchführung von Ganzbeinstandaufnahmen postoperativ April 2016. https://endocert.de/news/rueckfragen-zur-postoperativen-ganzbeinstandaufnahme (accessed 17.02.2023)

With regard to radiological follow-up examinations, we refer to the following recommendations of the German Society for Endoprosthetics (AE)[6] :

- Since aseptic loosening and wear of cemented total knee arthroplasties only occur in late failures, these arthroplasties only need to be checked at 2-3 year intervals from the 5th postoperative year onwards in patients with no or few complaints after an unremarkable postoperative check.
- Cementless total knee arthroplasties should also be checked one year after surgery. If no abnormalities are identified during this time, the control intervals can be the same as for cemented prostheses in patients with no or few complaints.
- The recommended check-ups should be communicated to the patients after the operation so that they can make use of them in a self-determined manner.

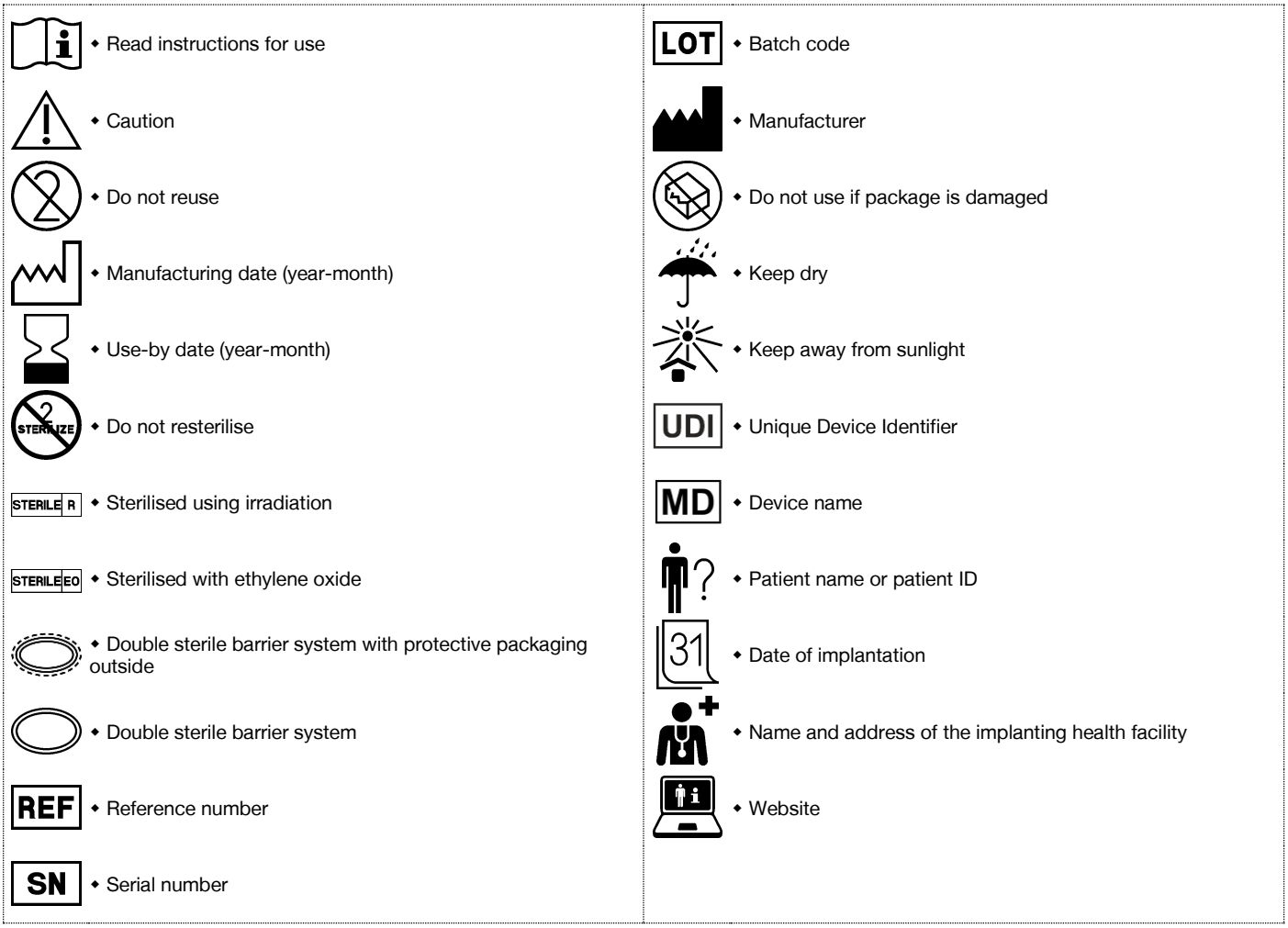
Patients with leg axis deviations after implantation of the prosthesis may require shorter check intervals than patients without axis deviations. The reason for this is that asymmetrical loading of the artificial knee joint can lead to increased wear and thus to the premature occurrence of osteolysis or loosening of the prosthesis.

In your own interest, you should therefore attend all agreed follow-up appointments, even if you have no complaints! If you have any complaints, contact your doctor immediately.

Information on your prosthesis / endoprosthesis passport

When you are discharged from the clinic after the operation, you will receive an implantation pass (endoprosthesis pass). This contains all the important information about your implant.

The meaning of the symbols used, e.g. in the instructions for use or on the labels of OHST Medizintechnik AG, is listed below.



[6] Von Roth et al: Die radiologische Verlaufskontrolle von primären Hüft- und Knieendoprothesen – Empfehlung der Deutschen Gesellschaft für Endoprothetik (AE). Z Orthop Unfall 2020; 158(03): 276-279

Knee joint prostheses from OHST Medizintechnik AG are made of the materials listed below.

Stainless steel according to ISO 5832-1 (chemical composition)	
Element	**Mass fraction in %**
Carbon	max. 0.030
Silicon	max. 1.0
Manganese	max. 2.0
Phosphorus	max. 0.025
Sulphur	max. 0.010
Nitrogen	max. 0.10
Chromium	17.0 to 19.0
Molybdenum	2.25 to 3.00
Nickel	13.0 to 15.0
Copper	max. 0.50
Iron	Balance

Titanium 6-aluminium 4-vanadium wrought alloy according to ISO 5832-3 (chemical composition)	
Element	**Mass fraction in %**
Aluminium	5.5 to 6.75
Vanadium	3.5 to 4.5
Iron	max. 0.3
Oxygen	max. 0.2
Carbon	max. 0.08
Nitrogen	max. 0.05
Hydrogen	max. 0.015
Titanium	Balance

Cobalt-chromium-molybdenum casting alloy according to ISO 5832-4 (chemical composition)	
Element	**Mass fraction in %**
Chromium	26.5 to 30.0
Molybdenum	4.5 to 7.0
Nickel	max. 1.0
Iron	max. 1.0
Carbon	max. 0.35
Manganese	max. 1.0
Silicon	max. 1.0
Cobalt	Balance

Cobalt-chromium-molybdenum forging alloy according to ISO 5832-12 (chemical composition)	
Element	**Mass fraction in %**
Chromium	26.0 to 30.0
Molybdenum	5.0 to 7.0
Iron	0.75 Maximum value
Manganese	1.0 Maximum value
Silicon	1.0 Maximum value
Carbon	0.35 Maximum value
Nickel	1.0 Maximum value
Nitrogen	0.25 Maximum value
Cobalt	Balance

Ultra-high molecular weight polyethylene (UHMWPE) according to ISO5834-1/2 (ash and trace elements)	
Element	**Maximum permitted quantity in mg/kg**
Ash	125
Titanium	40
Calcium	5
Chlorine	30
Aluminium	20

Highly cross-linked ultra-high molecular weight polyethylene with the addition of vitamin E (alpha-tocopherol) (ash and trace elements)	
Element	**Quantity**
Ash	max. 125 mg/kg
Titanium	max. 40 mg/kg
Calcium	max. 5 mg/kg
Chlorine	max. 30 mg/kg
Aluminium	max. 20 mg/kg
Vitamin E	1000 ±150 ppm

The following coatings can also be applied:

Titanium Plasma Spray (TPS) according to ASTM F1580 (chemical composition)	
Element	**Mass fraction in %**
Aluminium	max. 6.75
Vanadium	max. 4.5
Oxygen	max. 0.4
Iron	max. 0.5
Carbon	max. 0.08
Hydrogen	max. 0.05
Nitrogen	max. 0.05
Copper	max. 0.1
Tin	max. 0.1
Silicon	max. 0.04
Chlorine	max. 0.2
Yttrium	max. 0.005
Titanium	Balance

BONIT®	
Phase composition	≥ 70 % Bruschite [$CaH(PO_4)$ x 2 H_2O] ≤ 30 % Hydroxyapatite [$Ca_5(PO_4)_3OH$]
Ca/P ratio	1,1 ± 0,1
Trace elements	Arsenic: max. 3 ppm Cadmium: max. 5 ppm Mercury: max. 30 ppm Lead: max. 50 ppm

Titanium niobium nitride (TiNbN)	
Element	**Mass fraction in %**
Titanium	max. 70
Niobium	max. 30
Iron	< 0,05
Oxygen	< 0,2
Carbon	< 0,2
Nitrogen	<0,05
Hydrogen	< 0,02

Further information

AE - German Society for Endoprosthetics e.V.

The AE - German Society for Endoprosthetics was founded as a non-profit association. Its members are leading orthopaedic surgeons and trauma surgeons as well as scientists who deal with questions of endoprosthetics and alternative joint-preserving treatment methods.
It is a section of the German Society for Orthopaedics and Trauma Surgery (DGOU) and is thus responsible for all questions concerning arthroplasty.
Here you will find answers to frequently asked questions about diseases and treatments, including the provision of an artificial joint (endoprosthesis).

Internet address (German language only): https://www.ae-germany.com

Federal Institute for Drugs and Medical Devices (BfArM)

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) is an independent federal higher authority within the portfolio of the Federal Ministry of Health.
The BfArM's tasks with regard to medical devices are mainly the central collection, analysis, and evaluation of risks arising from use or application of the devices and the co-ordination of the necessary measures to be taken. This work is based on incoming incident reports on medical devices.

Internet address: https://www.bfarm.de/EN/Home/_node

German Society for Orthopaedics and Orthopaedic Surgery

The Society sees itself as responsible for scientific issues vis-à-vis the public and the medical profession and thus as a contact for other societies and associations, institutions and authorities.
The purpose of the association is the promotion of orthopaedic science in research, teaching and practical application including the rehabilitation of physically disabled persons.
Here you will find information about orthopaedic issues.

Internet address (German language only): https://dgooc.de

EPRD German Endoprosthesis Register gGmbH

The German Arthroplasty Registry (EPRD) has been established to ensure and improve the quality of endoprosthetic surgery and thereby increase patient safety. The EPRD's extensive data pool will make it easier than ever to identify causes of failure in endoprosthetic interventions in future. By this, it will be easier to sort out whether the implants used, the surgical procedure and/or patient-specific features are responsible for a revision.
Since 2020, the EPRD has published its own patient information annually and in addition to its annual report. The publication contains key results of the data evaluation from the respective annual report - summarised briefly and in a way that is easy for patients to understand.

Internet address: https://www.eprd.de/en

EUDAMED - European Database for Medical Devices

EUDAMED will provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). It will integrate different electronic systems to collate and process information about medical devices and related companies (e.g. manufacturers). In doing so, EUDAMED aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU.

Internet address: https://ec.europa.eu/tools/eudamed

Institute for Quality and Efficiency in Health Care (IQWiG)

The Institute for Quality and Efficiency in Health Care (IQWiG) is an independent, scientific institution of the private and non-profit Foundation for Quality and Efficiency in Health Care. The foundation aims to support evidence-based decision making.
InformedHealth.org is the English-language version of the German website Gesundheitsinformation.de. By publishing this bilingual website, the Institute for Quality and Efficiency in Health Care (IQWiG, Germany) fulfills part of its legal

mandate to inform the public in matters of health. The website addresses both patients and (healthy) consumers by offering a wide range of different topics.
IQWiG health information is written with the aim of helping people understand the advantages and disadvantages of the main treatment options and health care services.

Internet address: https://www.informedhealth.org

Association of Statutory Health Insurance Funds Germany (vdek)

The data basis of the vdek Kliniklotsen are the quality reports provided by the individual hospitals, which were prepared in accordance with the valid regulations of the Federal Joint Committee. Thus, the Kliniklotse is able to provide you with comprehensive information on, for example, treatment, equipment and quality in hospitals.
Via the online portal www.vdek-arztlotse.de, users can search specifically for established doctors, dentists, psychological psychotherapists and emergency outpatient clinics in Germany. In addition, the vdek doctor's guide provides comprehensive information on the respective practice, such as accessibility and office hours or the degree of accessibility, but also on the doctor's therapeutic focus.

Internet address (German language only): https://www.vdek-kliniklotse.de
https://www.vdek-arztlotse.de

Weisse Liste

The core component of the project is the portal www.weisse-liste.de which has been online since 2008. The title stands for an orderly overview (Liste = “List”) and indicates a strong affinity with the fields of medicine and health (Weisse = “White”). The portal provides highly practical help for its users in their search for the right provider in their area or as the case may be, nationwide. In this, it differs from other mostly commercial services: first of all, it is carries absolutely no advertising and is free of charge. But more than this: there is a strong emphasis throughout on the quality of the information in all areas, underscored for example by the use of scientifically developed questionnaires or measures designed to prevent the manipulation of information.
The Weisse Liste aims to provide citizens with direction and enable them to make informed choices. Its purpose is to prepare and provide access to information on the services and quality offered by health care providers in a way that non-specialists can understand. It aims to create transparency and thereby to ensure that providers compete fairly to provide the best quality. In turn, this competition benefits the populace through improved quality across the board.

Internet address: https://www.bertelsmann-stiftung.de/en/our-projects/weisse-liste

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