

Hospital or practice [Klinik / Praxis]:

zoom zentrum für
orthopädisch/
unfallchirurgische
medizin

Patient data [Patientendaten]:

Surgery planned for (date) [Die Eingriff ist vorgesehen am (Datum)]:

- Left knee** linkes Knie
 Right knee rechtes Knie

Dear patient,

Your knee joint is so badly damaged that it needs to be replaced with an artificial knee joint. This should alleviate your pain and improve the mobility and weightbearing ability of your knee.

This information serves for your preparation for the explanatory discussion with the doctor. In the discussion the doctor will explain the benefits and drawbacks of the planned operation and of alternative modalities, and explain to you the risks. He will answer your questions and address your fears and concerns. After this you will have the opportunity to give your consent for the proposed operation. After the discussion you will receive a copy of the completed and signed form.

CAUSES OF THE DISEASE URSACHEN DER ERKRANKUNG

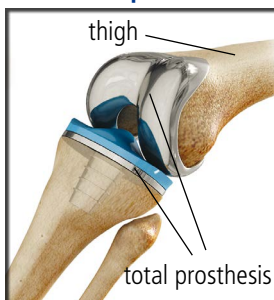
The joint surfaces of the knee are coated by a layer of cartilage. Flexion, extension as well as limited rotational movements are made possible by the cruciate and collateral ligaments. The external and internal menisci form the gliding surfaces of the knee joint and absorb shocks. The joint capsule produces joint fluid. This makes it possible for the joint surfaces to glide frictionfree. The destruction of the knee joint can be caused by malalignments such as x- or o-malalignments, joint injuries, rheumatic diseases, joint infections or metabolic diseases. First the joint cartilage is damaged. It develops fissures and wears away (osteoarthritis). Later the knee joint becomes deformed, and painful inflammation and limitations of movement develop.

COURSE OF THE OPERATION ABLAUF DER OPERATION

The operation is performed under regional anaesthesia or general anaesthesia. You will receive information separately about anaesthesia.

The operation is performed in a bloodless field. The entire leg is wrapped in a special rubber band. A blood pressure cuff is attached and pumped up to block off the supply of blood. This reduces loss of blood and provides a better view of the operative site. The knee joint is exposed through an incision, the kneecap is pushed to the side and the femur (thigh bone) and the tibia are prepared for the implant of the prosthesis. Various implants can be used depending on your age and the condition of your knee joint:

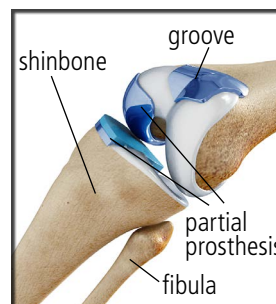
Total knee prosthesis Knie-Totalendoprothese



(bicompartmental knee replacement):

The worn cartilage is replaced by metal implants anchored to the femur and tibia. A plastic spacer facilitates frictionfree movements. In this operation the anterior cruciate ligament is removed, the other ligaments are retained.

Partial knee prosthesis Knie-Teilprothese



(unicompartmental knee replacement / femoral groove): Only the inner part or outer part of the knee joint is replaced with a partial prosthesis. In addition, a femoral groove for the kneecap can be inserted. All ligaments are retained.

Partially or completely constrained knee prosthesis: Teil-/Gekoppelte Knieprothese:

In certain cases when the knee is severely damaged, stabilisation can be achieved only with a prosthesis in which the two components are mechanically linked.

The prosthesis can be anchored in the bone with or without bone cement.

If the kneecap shows wear, it is either trimmed or covered with an artificial layer.

Thin plastic tubes, called drains, are placed in the wound so that secretions can drain out. The drains can also be used to collect blood which is then processed and later returned to the patient through a vein. This serves to reduce blood loss and to minimise administration of donor blood.

Finally, the incision is closed, the wound is covered with a dressing, and the tourniquet is removed.

Sometimes computer-guided navigation is used for planning and executing the prosthesis implant. Metal pins must be placed in the bone in the thigh and lower leg for this procedure.

POSSIBLE SUPPLEMENTARY MEASURES

MÖGLICHE ERWEITERUNGSMASSNAHMEN

Sometimes it becomes clear during the operation that the planned prosthesis cannot be implanted and another model is more suitable (for instance a total prosthesis instead of a partial prosthesis). In certain cases, the insertion of the kneecap tendon must be cut and reattached. If any bone defects are found, it could be necessary to use additional metal implants.

Implantation of a constrained knee prosthesis could be necessary if the collateral ligaments are damaged during the operation.

ALTERNATIVE PROCEDURES

ALTERNATIV-VERFAHREN

Conservative measures, such as physical therapy, pain control, weight loss or shoe inserts can produce significant improvement only in the early stages.

When incorrect load distribution is the cause of the wear, surgery that corrects the axis can be helpful. Cartilage damage can sometimes be corrected by cartilage transplantation. When implantation of a prosthesis is no longer possible, it is necessary to perform operative fusion of the knee joint (arthrodesis).

The physician will explain to you during your explanatory appointment why he is recommending a prosthesis in your case.

PROSPECTS OF SUCCESS

ERFOLGSAUSSICHTEN

The goal of the operation is to give you pain-free mobility and normal ability to bear weight on the knee. It will take a couple of months after the procedure to get used to the new joint. Later, joint-protective sports, such as swimming, cycling or walking, are possible in many cases. Even with careful surgical technique, the condition could worsen, potentially resulting in restricted mobility or instability in the knee. The doctor will be glad to explain what the expected outcome in your case is.

The average lifespan of knee implants is 8-15 years. However, the implant or other inserted metal parts (such as screws) could loosen or break earlier. One to two implant replacements are usually possible.

PREPARATION AND POSTOPERATIVE CARE

HINWEISE ZUR VORBEREITUNG UND NACHSORGE

Please follow the instructions of the physician and nursing staff. If nothing else is ordered, please follow the instructions below:

Preparation:

Medications: It is important to tell your physician which medications you take regularly by mouth or injection (especially blood thinners like Aspirin®, Marcumar®, heparin, Plavix®) and which other medications you have taken in the eight days before the procedure (for instance pain killers like ibuprofen, paracetamol). This includes all non-prescription and herbal medications. Your physicians will tell you if and for how long you need to stop your medications.

Postoperative care:

Postoperative pain can be well controlled with medications. The operated knee should be elevated as much as possible in the first postoperative days.

Early after the operation you will be instructed on physical therapy exercises. Please do these very conscientiously.

You should mobilise all other joints regularly in order to prevent blood clot formation. If a compression bandage or stocking is necessary, please wear it as ordered.

Regarding other aspects such as use of medications (for instance prescribed blood thinners) or protection of the operated knee, please follow the instructions of your physician exactly.

Please notify your physician immediately if the pain and swelling increase, if the wound is warmer than normal and red, if you have fever or weakness, if the leg is pale or blue, or if you have chest pain or breathing or circulation problems.

Spread of organisms (germs) from infected areas of the body via the blood stream can lead to infection of the joint prosthesis. It is important to eliminate infections, such as dental, before the implant. Bacterial infections, for instance of the skin, soft tissues or urinary tract, must be treated early with antibiotics. Antibiotics should be administered, as a precaution, before procedures that can lead to spread of organisms.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

MÖGLICHE RISIKEN, KOMPLIKATIONEN UND NEBENWIRKUNGEN

It is generally known that **every medical procedure has certain risks**. These can sometimes require additional therapeutical interventions or operations, and in extreme cases they can progress to **life-threatening** situations or leave permanent damage. Please understand that, for legal reasons, we have to inform you about all known procedure-specific risks, even though some only occur in exceptional cases. Your doctor will go over your individual risks in the discussion. You can also avoid an extensive patient education. In this case, skip this risk section and confirm this at the end of the patient education.

A **bone fracture** can occur during the implant of prosthesis. Additional interventions, such as introduction of stabilising material like wires, plates, screws, or the selection of another implant, could become necessary.

Infections of the soft tissues can usually be treated effectively with antibiotics. An **infection** of the **bone** or **joint** can require surgical treatment. In certain cases the implant must be removed. In most cases a new implant can be inserted after resolution of the infection. Sometimes, however, a fusion operation of the knee becomes necessary. In rare cases, an uncontrolled infection can lead to loss of the leg or **life-threatening blood poisoning** (sepsis).

Allergic reactions, for instance to medications or latex, can cause rash, itching, swelling, nausea and cough. Serious reactions, such as shortness of breath, seizures, heart racing or life-threatening circulatory shock, are rare. Permanent injury to organs, such as brain damage, paralysis or kidney failure requiring dialysis may result in such cases. In rare cases allergy against the materials of the implant can develop. This causes the implant to loosen, possibly necessitating replacement.

Even with careful surgical technique, **injury to the nerves, bones, tendons, muscles or large vessels** can occur. If a vessel is injured, surgery to stop the bleeding may be necessary. Nerve injuries might require nerve suture. Even with treatment **permanent sensitivity disorders**, pain and weakness or even paralysis (such as foot drop) can develop. Section of small skin nerves during the operation can cause transient or **permanent numbness feeling** in the area of the surgical incision.

Severe bleeding can require **transfusion** of donor blood or blood components. This can lead to infections with pathologic organisms. Infection with hepatitis viruses (cause of dangerous liver infection) is very rare. Infections with HIV (cause of AIDS), BSE (cause of variant Creutzfeldt-Jacob disease) or other dangerous organisms, some unknown, are extremely rare. Testing several weeks after a transfusion is reasonable in order to rule out definitively transmission of HIV or hepatitis viruses. Please discuss with your physician the option of own donation or other blood-saving procedures.

Damage to skin, soft tissues and nerves (caused by injections, disinfection agents, electrical current, or poor positioning) are possible. Sense disturbances, numbness, paralysis or pain could be the

consequences. In most cases these are transient. Occasionally persistent nerve damage or tissue death can occur, and scars can form.

Blood clots can form (**thrombi**) and cause blockage of vessels (**embolism**). The blood clots can be transported and block the blood vessels of other organs. This can cause **stroke, kidney failure necessitating dialysis, or pulmonary embolism** with permanent damage. If blood thinners are given for prevention, the risk of intraoperative or postoperative bleeding increases. The administration of heparin can cause a serious immune reaction (HIT) with clumping of blood platelets and vessels blockages in veins and arteries.

Fat, bone marrow or cement entering the circulation during the operation could cause **vessel blockages**, such as a heart attack.

Breakage of drills and screws can occur during the implant. The fragments might need to be abandoned in the bone.

Delayed wound healing can lead to painful scar formation and overgrowths (keloids). This can occur in patients with tendency to **wound healing problems**. **Scarring in the joint** can lead to mobility limitation and in certain cases requires surgical removal.

Postoperative bleeding can cause a joint effusion. This can persist weeks and could require sometimes one or more needle drainages. **Postoperative bleeding** in a muscle sheath can cause pressure damage to nerves (compartment syndrome). A decompression operation must be performed to prevent permanent paralysis or the loss of the leg. Large blood collections may need to be drained surgically.

The procedure can precipitate a **complex regional pain syndrome** (formerly called reflex sympathetic dystrophy) with circulation problems, soft tissue swelling, and pain. This can lead to muscle and bone loss and to stiffening of the joint.

Abnormal positions, leg length discrepancies or instability of the knee can develop after the operation. Dislocation of the knee or kneecap can require reoperation.

In case of poor bone fabric or osteoporosis, **stress fractures** of the bone in the area of the implant may occur. Recovery of the bone and replacement of the implant will then be necessary.

Questions about Your Medical History

Before the explanatory discussion, please answer the following questions as best you can and tick the applicable items. It goes without saying that your information will be treated confidentially. Based on your information, the doctor will be better able to assess the procedure risk in your particular case. He will take measures if necessary to prevent complications and side effects.

yes=ja no=nein

Information about medications:

Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days? yes no

Aspirin® (ASS), Heparin, Marcumar®, Plavix®, Ticlopidin, Clopidogrel, Xarelto®, Pradaxa®.

Angaben zur Medikamenteneinnahme: Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Aspirin® (ASS), Heparin, Marcumar®, Plavix®, Ticlopidin, Clopidogrel, Xarelto®, Pradaxa®.

Other: _____
Sonstiges:

When did you take the last dose? _____
Wann war die letzte Einnahme?

Do you take any other medications? yes no
Nehmen Sie andere Medikamente ein?

If so, which ones: _____
Wenn ja, bitte auflisten:

(Please include non-prescription medications, herbal and other natural remedies, vitamins, etc.)
(Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)

Do you smoke? yes no

If so, what and how much daily: _____
Rauchen Sie? Wenn ja, was und wie viel täglich:

Are you pregnant? not certain nicht sicher yes no
Besteht eine Schwangerschaft?

Do you have or have you ever had any of the following diseases or symptoms thereof:

Liegen oder lagen nachstehende Erkrankungen oder Anzeichen dieser Erkrankungen vor:

Blood diseases / blood clotting disorders? yes no

increased tendency to bleed (e.g. frequent nosebleeds, increased bleeding after surgery, minor wounds or dental treatment), tendency to bruise (frequent

bruising possibly for no particular reason).

Bluterkrankung/Blutgerinnungsstörung? Erhöhte Blutungsneigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).

Do you have any blood relatives with signs of blood disease / clotting disorders? yes no

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

Allergies / Oversensitivity? yes no

Medications, foods, contrast media, iodine, sticking plaster, latex (e.g. rubber gloves, balloons) pollen (grass, trees), drugs that depress consciousness, metals (itching caused by metal spectacles frames, jewellery, jeans buttons).

Allergie/Überempfindlichkeit? Medikamente, Lebensmittel, Kontrastmittel, Jod, Pflaster, Latex (z.B. Gummihandschuhe, Luftballon), Pollen (Gräser, Bäume), Betäubungsmittel, Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten).

Other: _____
Sonstiges:

Heart, circulatory or blood vessel diseases? yes no

Heart attack, chest pain and/or tightness (angina pectoris), heart defect, irregular heart rhythm, inflammation of heart muscle, heart valve disease, shortness of breath while climbing stairs, heart surgery (possibly with insertion of an artificial heart valve, pacemaker, defibrillator), high blood pressure, low blood pressure.

Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), Herzfehler, Herzrhythmusstörungen, Herzmuskelentzündung, Herzklappenerkrankung, Luftnot beim Treppensteigen, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, niedriger Blutdruck.

Other: _____
Sonstiges:

Blood clot (thrombosis), blood vessel occlusion (embolism)?

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

 yes no**Metabolic diseases?** Diabetes (sugar sickness), Gout.Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht. yes no

Other: _____

Sonstiges:

Thyroid diseases? Underactive thyroid, overactive thyroid.Schilddrüsenerkrankungen? Unterfunktion, Überfunktion. yes no

Other: _____

Sonstiges:

Communicable (contagious) diseases? Hepatitis, tuberculosis, HIV.Infektionskrankheiten? Hepatitis, Tuberkulose, HIV. yes no

Other: _____

Sonstiges:

Predisposition to impaired wound healing, abscesses, fistulas, excessive scar formation (keloids)?

Neigung zu Wundheilungsstörungen, Abszessen, Fisteln, starker Narben-Bildung (Keloide)?

 yes no**Any other acute or chronic diseases / illnesses?**

Nicht aufgeführte akute oder chronische Erkrankungen?

 yes no

Please describe: _____

Bitte kurz beschreiben:



Medical documentation of explanatory appointment

Ärztl. Dokumentation zum Aufklärungsgespräch

To be filled in by the physician Wird vom Arzt ausgefüllt

During the explanatory appointment I explained the following subject matter to the patient in detail (e.g. possible complications that can result from the risks specific to the patient, details of the alternative methods, prospects of success):

Über folgende Themen (z. B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativmethoden, Erfolgsaussichten) habe ich den Patienten im Gespräch näher aufgeklärt:

Planned procedure: Geplanter Eingriff

- Total knee replacement (bicompartamental knee replacement)
Knie-Totalendoprothese (bikondylärer Oberflächenersatz)
- Partial knee implant (unicompartamental implant)
Knie-Teilprothese (Schlittenprothese oder femorale Gleitrinne)
- Partially constrained or constrained knee prosthesis
Teilgekoppelte oder gekoppelte Knieprothese
- Cemented Cementless Partially cemented
mit Zement ohne Zement teilweise zementiert

Patient's ability to take an independent decision on granting consent: Fähigkeit der eigenständigen Einwilligung

- The patient has the ability to make an independent decision on the operation that has been recommended and to grant consent to the operation.
Der/Die Patient/in besitzt die Fähigkeit, eine eigenständige Entscheidung über das empfohlene Operations-Verfahren zu treffen und seine/ihre Einwilligung in die Operation zu erteilen.
- The patient was represented by a custodian or other legal guardian with official proof of authority. This person is in a position to make a decision in the interests of the patient.
Der/Die Patient/in wird von einem Betreuer bzw. Vormund mit einer Betreuungsurkunde vertreten. Dieser ist in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.

Place, date, time [Ort, Datum, Uhrzeit]

Signature of physician [Unterschrift der Ärztin / des Arztes]

Patients's refusal Ablehnung des/der Patienten/in

Dr. _____ has given me a full explanation of the operation recommended for me and of the disadvantages that will result from my refusal. I have understood this explanation. I was also able to discuss with this physician my knowledge and understanding of the information given to me. I hereby refuse the operation that has been recommended for me.

Frau/Herr Dr. hat mich umfassend über den bevorstehenden Eingriff und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und konnte meine Erkenntnisse über die mir erteilten Informationen mit dem Arzt diskutieren. Hiermit lehne ich die mir vorgeschlagene Operation ab.

Place, date, time [Ort, Datum, Uhrzeit]

Signature of patient / legal guardian / witness if applicable
[Unterschrift Patientin / Patient / Betreuer / Vormund / ggf. des Zeugen]

Patient's declaration and consent

Erklärung und Einwilligung des/der Patienten/in

Please mark your declaration in the applicable boxes and then confirm it with your signature:

Bitte kreuzen Sie die zutreffenden Kästchen an und bestätigen Sie Ihre Erklärung anschließend mit Ihrer Unterschrift:

- I hereby confirm that I have understood all the parts of this explanation for patients. I have read this explanatory document in its entirety (five pages). During my explanatory appointment, Dr. _____ has given me a comprehensive explanation of the planned operation, its risks, complications and side effects in my specific case, and the advantages and disadvantages of the alternative methods.

Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe. Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit Frau/Herrn Dr. wurde ich über den Ablauf der geplanten Operation, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.

- I have seen and understood the film about the operation that has been scheduled for me.

Den Informationsfilm über die bei mir geplante Operation habe ich gesehen und verstanden.

- I hereby deliberately waive my rights to more detailed explanations. However I also confirm that I have been informed by the treating physician of the necessity of this operation, of its type and extent, and of the fact that this operation has its risks.

Ich verzichte bewusst auf eine ausführliche Aufklärung. Ich bestätige hiermit allerdings, dass ich von dem behandelnden Arzt über die Erforderlichkeit des Eingriffes, dessen Art und Umfang sowie über den Umstand, dass der Eingriff Risiken birgt, informiert wurde.

I affirm that I have **no further questions** and do not need **any more time** in which to think the matter over. I consent to the recommended operation. I have answered the questions about my medical history in full and to the best of my knowledge.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkenzeit benötige. Ich stimme der vorgeschlagenen Operation zu. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

My approval also covers all necessary additional and postoperative interventions (transfusion of donor blood, thrombosis prophylaxis), as well as all required changes or extensions of the operation, such as the implant of a different type of prosthesis than the one planned.

Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen (Fremdblutübertragung, Thromboseprophylaxe), sowie auf erforderliche Änderungen oder Erweiterungen des Eingriffes, z. B. Implantation einer anderen als der vorgesehenen Prothesenart.

I affirm that I am in a position to follow the medical instructions I have received in regard to what is expected of me.

Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

I consent to the presence of representatives of medical product manufacturers or medical colleagues during the operation.

Ich bin damit einverstanden, dass eventuell Medizinprodukteberater oder medizinische Kollegen bei der Operation anwesend sind.

- I agree that my copy of this explanatory form may be sent to the following e-mail address:

Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

E-mail-address [E-Mail-Adresse]

Ort, Datum, Uhrzeit [Ort, Datum, Uhrzeit]

Signature of patient / legal guardian
[Unterschrift der Patientin / des Patienten / Betreuer / Vormund]

Copy/Kopie: received/erhalten
 waived/verzichtet

Signature of patient / legal guardian
[Unterschrift Patientin/Patient/Betreuer/Vormund]