HIP JOINT PROSTHESIS
HÜFTGELENK-ENDOPROTHESE

Information and history for patients for the preparation for the required explanatory discussion with the doctor

englisch

Hospital or practice [Klinik / Praxis]:

Patient data [Patientendaten]:

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

☐ **Left hip** [linke Hüfte]

☐ **Right hip** [rechte Hüfte]

Dear patient,

Your hip is so badly damaged that it needs to be replaced with an artificial joint. This should alleviate your pain and improve the mobility of your hip. Joint replacement could also be necessary if there is a fracture of the thigh bone neck.

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 hip is a ball joint consisting of the head of the thigh bone and the socket of the pelvic bone. The cause of your problem could be a congenital malformation (hip dysplasia), a joint injury, a rheumatic disease, a joint infection or a metabolic disease. At first the cartilage suffers wear-and-tear (osteoarthritis). Later, the hip joint becomes deformed and movement becomes restricted and painful. It is also painful to bear weight.

COURSE OF THE OPERATION
ABLAUF DER OPERATION

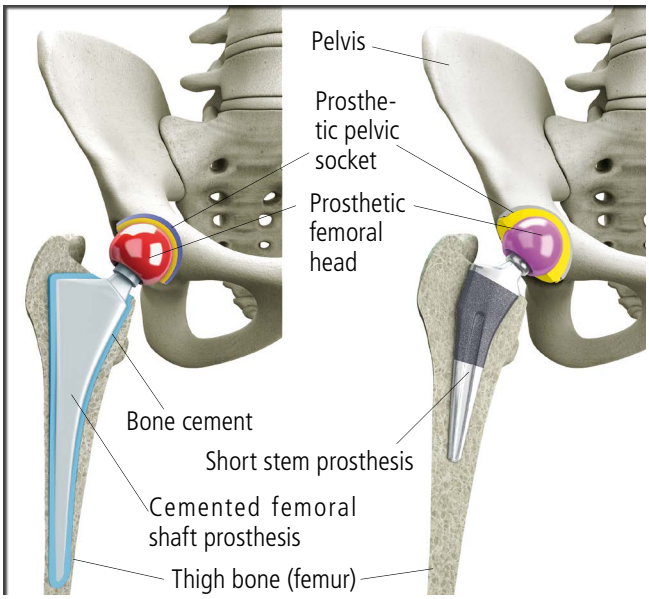
Many different models of prosthetic joints are available. They are of the following types:

☐ **Hemiarthroplasty** Hüft-Kopf-Prothese
In certain cases only the head of the thigh bone needs to be replaced. The head and the neck of the thigh bone are removed and replaced with a stem prosthesis.

☐ **Total hip replacement** Hüft-Totalendoprothese
In most cases both the thigh bone head and the pelvic socket need to be replaced. The head and neck are replaced with a stem prosthesis and the socket with a socket prosthesis.

☐ **Other procedures:** Sonstiges Verfahren

The operation is performed either under regional (spinal) anaesthesia or general anaesthesia. You will receive information on anaesthesia separately. One or more incisions are required, depending on the surgical technique.



The joint capsule is opened and the damaged joint surfaces and, if necessary, the thigh bone head and neck, are removed. Then the prosthetic components are implanted. They can be anchored to the bone with or without cement. The socket can also be anchored with screws. After adjusting the prosthesis, the physician manipulates the new hip joint into position and closes it. 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 and return it later to the patient through a vein after processing. This serves to reduce blood loss and to minimise administration of donor blood. A cemented prosthesis can bear weight immediately after the operation. If the prosthesis is not implanted with cement, it can only bear weight in accordance with the physician`s instructions, because first it has to grow into the bone for permanent stability.

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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 head prosthesis, or a resurfacing procedure). You can give your consent now to such changes or extensions, if any, so that it is not necessary to postpone them to a second operation.

ALTERNATIVE PROCEDURES
ALTERNATIV-VERFAHREN

The physician will discuss with you the advantages and disadvantages of the various prosthesis types and anchoring methods. He will select the model most suitable for you based on your age, physical activity, and the damage to your hip joint.

PROSPECTS OF SUCCESS
ERFOLGSAUSSICHTEN

The goal of the operation is to enable you to move your hip without pain. A shorter or longer period of use of walker or crutches for protection will be necessary in the initial phase, depending on the type of anchoring. In most cases, the gait is secure and the hip-stabilising musculature sufficiently trained after a couple of weeks. In few cases a limp or a waddling gait may persist. In most cases joint-protecting physical activities such as swimming, cycling, or hiking are possible again. If complications occur, the condition could also deteriorate. In most cases the result is good or satisfactory.

The average lifespan of hip implants is 10-20 years. Loosening or breakage of the implant or other implanted metal components, such as screws, could occur earlier. A replacement of the implant is possible in most cases.

PREPARATION AND POSTOPERATIVE CARE
HINWEISE ZUR VORBEREITUNG UND NACHSORGE

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

Preparation:

Medications: It is important to tell your physician what 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. 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 taking medications (for instance prescribed blood thinners) and avoiding extra weight on the operated hip, 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
RISIKEN, MÖGLICHE 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 need to inform you about all procedural risks, even though some occur only in exceptional cases. Your physician will discuss in detail your individual risks. You may forgo a thorough presentation. In this case skip this risk section.

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** may 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. Otherwise, significant leg shortening and loss of mobility will result. In rare cases, an uncontrolled infection can lead to loss of the leg or **life-threatening blood poisoning** (sepsis).

Allergic reactions, such as 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. An allergic reaction to the materials in the implant may occur in rare cases. This causes the implant to loosen, possibly necessitating replacement.

Even with careful surgical technique, **injury to the nerves, bones, tendons, muscles** or **large vessels** may occur. If a vessel is injured, surgery to stop the bleeding may be necessary. If the pelvic socket is broken during surgery and pelvic organs or vessels are injured, it may be necessary to open the abdomen. **Nerve injuries** occur occasionally and can cause **permanent sensibility disturbances**, pain and weakness or even **paralysis** (such as foot drop). If the sciatic nerve is injured, paralysis of the whole leg can occur. Nerve injuries may require nerve suturing. 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. High blood loss can cause poor blood supply of the optic nerve and visual disturbances, and, in extremely rare cases, even **blindness**.

Breakage of drills and screws can occur during the implant, especially while working on the socket. The fragments might need to be abandoned in the bone.

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.

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. These are transient in most cases. They only persist or leave scars behind in rare cases.

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 lung embolism, stroke or kidney failure with permanent damage. Administration of blood thinners increases the risk of bleeding during and after surgery. Administration of heparin can lead to a serious **dysfunction of blood clotting** (HIT) with thrombus formation and vessel blockages.

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

Delayed wound healing can lead to painful scar formation and growths (keloids). This can occur in patients with tendency to **wound healing problems**.

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.

Bone formation and **calcification** in the area of the prosthesis can limit mobility and cause pain.

With certain types of implants without artificial inlay (such as large-head implants), **metal abrasion** may release metal ions into the body. This can lead to neurological disorders such as nerve damage, optic nerve disorders, trigeminal nerve pain, dementia, tremor, tinnitus or shortness of breath.

Bone loss can cause **fractures** in the area of the prosthesis even after many years.

Even with careful surgical technique **malalignment, leg length discrepancies** or **instability** of the hip can occur. If dislocation of the hip occurs, another operation could be necessary.

Questions about Your Medical History

Please fill in the following questionnaire carefully before your information talk. **Please tick the applicable box!** It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks of treatment in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects.

yes=ja no=nein

(If certain answers are preselected, please correct them if anything has changed.)

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.)

Have you ever received a blood transfusion? ☐ **yes** ☐ **no**
Haben Sie schon einmal eine Bluttransfusion erhalten?

If so, when? _____
Wenn ja, wann?

Were there any complications? ☐ **yes** ☐ **no**
Ergaben sich dabei Komplikationen?

If so, which ones? _____
Wenn ja, welche?

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), ☐ anaesthetics, ☐ 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)? ☐ yes ☐ no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Metabolic diseases? ☐ yes ☐ no

☐ Diabetes (sugar sickness), ☐ Gout.
Stoffwechsel-Erkrankungen? ☐ Diabetes (Zuckerkrankheit), ☐ Gicht.

Other: _____
Sonstiges:

Thyroid diseases? ☐ yes ☐ no

☐ Underactive thyroid, ☐ overactive thyroid.
Schilddrüsenerkrankungen? ☐ Unterfunktion, ☐ Überfunktion.

Other: _____
Sonstiges:

Communicable (contagious) diseases? ☐ yes ☐ no

☐ Hepatitis, ☐ tuberculosis, ☐ HIV.
Infektionskrankheiten? ☐ Hepatitis, ☐ Tuberkulose, ☐ HIV.

Other: _____
Sonstiges:

Predisposition to impaired wound healing, abscesses, fistulas, excessive scar formation (keloids)? ☐ yes ☐ no

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

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

Nicht aufgeführte akute oder chronische Erkrankungen?

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

☐ Femoral head prosthesis Hüft-Kopf-Prothese
☐ Total hip replacement Hüft-Totalendoprothese
☐ Other procedures: _____
Sonstige Verfahren:

☐ Cemented mit Zement ☐ Cementless ohne Zement ☐ Partially cemented 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]

Patient'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

Einwilligungserklärung

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 Bedenkzeit 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 Eingriffs, 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.

Copy of this explanatory form: ☐ requested ☐ waived

☐ 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]

Place, Date, Time [Ort, Datum, Uhrzeit]

Signature of the patient / legal guardian(s) [Unterschrift Patientin / Patient / Betreuer]