

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

- New insertion** **left** **arm**
 Correction **right** **groin**
 Removal

Dear patient,

you are to receive a bypass (shunt) between an artery and a vein in order to achieve sufficient blood flow for blood purification (haemodialysis).

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

REASONS FOR THE INSERTION OF A SHUNT

Due to a kidney disease, regular blood purification is necessary in your case. This so-called haemodialysis procedure requires a larger amount of blood being taken from the body, purified and fed back into the body.

For the purpose of dialysis, a blood vessel would have to be punctured several times a week. A normal vein is not entirely suitable for this and the arteries located on the arm are too thin and often located too deeply underneath the skin. For this reason, the insertion of a bypass between an artery and a superficial vein is helpful. The blood will then flow directly from the artery into the vein, making the vein stronger and easier to puncture. Blood flow is also increased through the bypass, making dialysis more effective.

In most cases, the shunt is inserted right above the wrist as a connection between the radial artery (Arteria radialis) and the cephalic vein (Vena cephalica) (referred to as Cimino fistula). Alternatively, the shunt can also be inserted at the level of the crease of the arm, on the upper arm or in the groin.

If the patient's vessels are generally weak, a shunt prosthesis made of plastic or biological material can also be inserted.

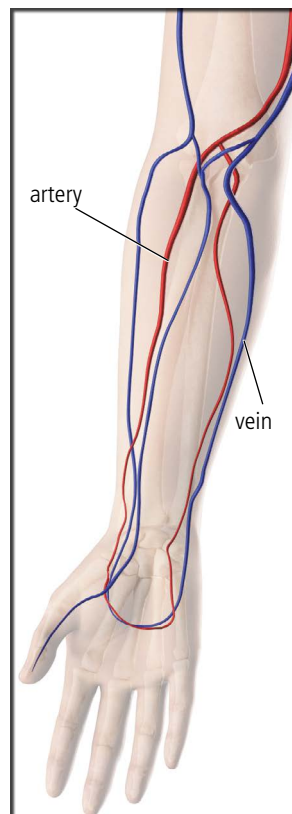
COURSE OF OPERATION

The procedure is usually carried out under a local or regional anaesthetic, in rare cases under general anaesthesia.

Insertion of a dialysis shunt

Through small incisions, the vein and the artery are exposed. Depending on the type and location of the shunt to be inserted, the two vessels are then connected with each other directly or a shunt prosthesis is inserted. It is also possible to take vein sections from other areas of the body, such as the lower leg, and insert them as a shunt connection.

Depending on the type of surgical procedure, it will take six to eight weeks for normal shunts and three weeks for artificial shunt prosthesis to be healed and functioning.



Shunt location to be marked here

Correction of a dialysis shunt

Occasionally, blood flow isn't sufficient or blood doesn't flow properly through the shunt any more. In those events, surgical intervention can often serve to remove plaque, replace altered vessel sections or reposition the shunt connection to accelerate the flow.

In rare cases, blood flow in the shunt may be too fast, requiring a slowing down of the blood flow through surgical intervention in order to improve perfusion in the limbs or to counteract a strain on the heart.

Removal of a dialysis shunt

If a dialysis shunt is no longer needed, it is often advisable to remove the connection between the vein and the artery in a minor procedure.

POSSIBLE ADDITIONAL MEASURES

Sometimes it will not become apparent until the procedure is already under way that it cannot be carried out as planned, veins have to be repositioned, prosthesis have to be inserted or vessel constrictions have to be alleviated. Should additional measures be predictable in your case, the doctor will inform you accordingly prior to the procedure. Aside from this, we would ask you to

already give your consent to necessary additional measures now in order to prevent the risk of another operation.

ALTERNATIVE METHODS

If the insertion of a shunt is not possible or advisable, dialysis can also be carried out via special catheters. One option is peritoneal dialysis through a peritoneal catheter in the abdomen, or a catheter is inserted into a jugular vein up to the right atrium of the heart. Unlike shunts, these catheters can be used for dialysis immediately and are often used as an interim solution until the shunt is ready for use.

PROSPECTS OF SUCCESS

As a rule, a shunt can be used for dialysis for one to two years. Direct shunts without a prosthesis may even be used a lot longer. You can also contribute to maintaining the functionality of the shunt by checking it daily. Small congestions and other complications can usually be alleviated through a minor procedure. However, if scarring, bulges or infections occur, an additional shunt, for instance on the opposite side or the leg, can be inserted.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: Please inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASS], Marcumar®, Heparin, Plavix®, Ticlopidin, Clopidogrel, Eliquis®, Lixiana®, Xarelto®, Pradaxa® and metformin-containing antidiabetic medicines, so-called biguanides) or have taken irregularly over the course of the past eight days prior to the procedure (for instance pain killers such as Ibuprofen, Paracetamol). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know if and for how long you should stop taking your medication.

Aftercare:

The operated limb should be mostly **immobilised** and **propped up** for two days.

If the procedure is **performed on an out-patient basis**, it is necessary for an adult to come and collect you. Please also make sure there will be an adult at home to supervise you after the procedure for the period of time recommended by your doctor. Your reaction capacity may be impaired after the procedure through the medication administered. Therefore, you must not actively participate in road traffic for a period of 24 hours after you have been released from the clinic/surgery (not even as a pedestrian) nor participate in any risky activities. You should also refrain from taking any important personal or economic decisions during this period.

After the wound has healed, the shunt won't impair you. **Avoid** any injuries around the shunt though in order to prevent severe bleeding.

Check your shunt daily through **palpitation or listening** and inform your doctor immediately should you notice anything abnormal.

Please inform your doctor immediately should you experience **fever, redness around the wound, numbness, paling or paralysis of the operated limb**. They may occur even days or weeks after the procedure. These symptoms require immediate medical attention.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. If complications occur, they may sometimes

require additional treatment or surgery and, in extreme cases, can sometimes even be **life-threatening** or lead to permanent damage – even after some time. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You may also choose to waive a detailed explanation. In that event, please pass over this section on risks and confirm your waiver with your signature in the final section of this form.

Injuries of neighbouring structures (e.g. nerves, muscles, tendons) are possible. This will often result in additional surgery being required. **Injuries of nerves** can lead to temporary, rarely to permanent **sensory disturbances, pain, numbness and paralyses in the arm or hand**.

Bleeding can usually be stopped immediately during the operation. **Post-procedure bleeding**, due to a leaky vessel suture for instance, may require additional surgery. Should severe blood loss occur, the use of donor blood/blood components (**transfusion**) may be required. This can lead to transmission of diseases, such as hepatitis in very rare cases (causing dangerous inflammation of the liver), HIV in extremely rare cases (causing AIDS), BSE (causing a form of Creutzfeldt-Jakob disease) or also of other dangerous – even unknown – diseases.

Bruising (haematomata) often occurs. This may lead to firm, painful swelling. Most of the time, this will disappear after a few days or weeks even without treatment.

Allergic reactions, for instance to medication or latex, can lead to skin rash, itching, swelling, nausea and coughing. Severe reactions such as shortness of breath, spasms, tachycardia or **life-threatening circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage or paralyses. In rare cases, the body may reject the prosthesis material, which will then have to be removed or exchanged.

Damage to the skin, soft tissue or nerves, for instance through injections, bruising, syringe abscess, disinfectants, may occur. Numbness, paralysis and pain may then result. They are usually temporary. Permanent nerve damage or tissue death rarely occur, scars may remain.

Swelling of the muscle fascia may lead to **impaired blood circulation** and **compression injury of nerves** (compartment syndrome), which will then require surgery to relieve the pressure in order to prevent permanent paralyses or the loss of the affected limb.

Small nerves in the skin can be severed during surgery and lead to temporary or, in rare cases, even **permanent numbness** around the surgical scar.

With patients predisposed to delayed wound healing or **wound healing disorder**, cosmetically unattractive scarring and abnormal proliferation of scar tissue (keloids) may occur.

Infections of the shunt may occur directly after it has been inserted, but also after every puncture. Infections can usually be treated with antibiotics. If the shunt is severely infected, it can no longer be used for dialysis; an infected shunt prosthesis may then have to be removed. In extreme and exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia).

Especially inside the shunt, **blood clots (thromboses)** can form and lead to **painful vein inflammation** (thrombophlebitis) or obstruction of a vessel. Vessel obstruction will then have to be removed surgically or through a catheter in order to maintain the functionality of the shunt. Blood clots may also travel to other parts of the body and block the vessels of other organs

(**embolism**). This may then lead to e.g. **stroke** or **lung embolism** and result in permanent damage. If anticoagulant agents are administered to prevent formation of blood clots, the risk of bleeding or post-procedure bleeding is increased. If Heparin is administered, it may lead to a severe immune response (HIT) involving clotting of the platelets (thrombocytes) and obstruction of veins and of arteries.

Increased blood flow through the shunt can lead to a **strain on the heart** and the development of a **weakness of the heart**. The acceleration of the blood flow in the shunt may then have to be surgically corrected.

The bypass created by the shunt can lead to **lack of blood circulation in the limb** accompanied by **paling or blue discoloration, coldness, pain** and even **tissue death**. Further surgery to correct the blood flow or the insertion of a different shunt may then be required. If blood flow is additionally impaired through arteriosclerosis, amputation of the limb may become necessary in extreme cases.

In the area of the shunt, the **shunt vein may be widened** (aneurysm). With prosthesis shunts, the frequent puncturing of the shunt can lead to the formation of a pseudoaneurysm. Aneurysms bear a **risk of rupture** and therefore have to be removed surgically if they are severe, for instance through shortening of the shunt vein and thus removing the aneurysm or through partial replacement of the shunt prosthesis.

Over time, a **constriction** of the shunt may occur, making further surgical intervention (e.g. widening of the constricted part via a catheter or surgical repositioning of the shunt) necessary.

Since venous blood flow is accelerated, a constriction of the superior caval vein accompanied by **chronic swelling** of the shunt arm/leg, **pain** and **ulceration** may occur.

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 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.

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), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Efixent®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Angaben zur Medikamenteneinnahme: Werden regelmäßig blutgerinnungshemmende Mittel benötigt oder wurden in der letzten Zeit (bis vor 8 Tagen) solche eingenommen/gespritzt? Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Efixent®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Any other: _____
Sonstiges:

When was the last dose taken? _____
Wann war die letzte Einnahme?

Do you take any other medications? yes no

Werden andere Medikamente eingenommen?

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.)

Are you pregnant? not certain yes no
Sind Sie schwanger? nicht sicher

Do you smoke? yes no

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

Do you have or have you ever had any of the following diseases: Liegen oder lagen nachstehende Erkrankungen vor:

Blood diseases / blood clotting disorders? yes no

Increased bleeding tendency (e.g. frequent nose bleeds, increased post-operative bleeding, increased bleeding from minor injuries or after dentist treatment, stronger or longer menstrual bleeding), 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, verstärkte oder verlängerte Regelblutung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).

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).

Any 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, stroke, varicose veins, inflammation of a vein, thrombosis, embolism.

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

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

fibrillator), hoher Blutdruck, niedriger Blutdruck, Schlaganfall,
 Krampfadern, Venenentzündung, Thrombose, Embolie.

Any other: _____
 Sonstiges:

Metabolic diseases?

 yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
 Sonstiges:

Communicable (contagious) diseases?

 yes no

Hepatitis, tuberculosis, HIV.

Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any 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:

Important Questions for Outpatients

Wichtige Fragen für ambulante Eingriffe

Who will pick you up when you are discharged from the hospital/ clinic/surgeon's practise? Wer wird Sie abholen, sobald Sie aus Klinik/Praxis entlassen werden?

 Name and age of the person picking you up: [Name und Alter des Abholers]

Where can you be reached within the 24 hours after surgery?

Wo sind Sie in den nächsten 24 Stunden nach dem Eingriff erreichbar?

 Street, house number, postcode, place: [Straße, Hausnummer, PLZ, Ort]

 Telephone: [Telefonnummer]

 Name and age of person looking after you: [Name und Alter der Aufsichtsperson]

Who is your physician (the one whose care you are in/who referred you/family surgeon)? Wer ist Ihr überweisender Arzt / Hausarzt / weiter betreuender Arzt?

 Name: [Name]

 Street, house number: [Straße, Hausnummer]

 postcode, place: [PLZ, Ort]

 Telephone: [Telefonnummer]



Medical documentation for the informative interview

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the doctor Wird vom Arzt ausgefüllt

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:

- New insertion left arm
- Correction right groin
- Removal

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is **capable of making a decision** on the recommended procedure on his/her own and giving his/her consent for the procedure. Der/Die Patient/in besitzt die Fähigkeit, eine **eigenständige Entscheidung** über die empfohlenen Maßnahme zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.
- The patient is represented by a **custodian** with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. These persons are capable of making a decision in the best interest of the patient. Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.
 - Custodian's card healthcare proxy advance healthcare directive has been submitted.
 - Betreuerausweis Vorsorgevollmacht Patientenverfügung liegt vor.

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

Doctor's signature [Unterschrift der Ärztin/des Arztes]

Patient's refusal Ablehnung

The doctor _____ has provided me with detailed information regarding the procedure at hand and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the procedure suggested to me.

Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene Maßnahme ab.

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

Refusal of patient / legal guardian / witness if applicable
[Ablehnung Patientin / Patient / Betreuer / ggf. des Zeugen]

DECLARATION OF CONSENT

Please tick the appropriate boxes and confirm your statement with your signature below:

- I hereby confirm that I have understood all sections of this form.** I have read the entire form (5 pages). During the pre-procedure interview with the doctor _____, I received detailed information regarding the course of the scheduled procedure, the risks, complications and side effects associated with it as they apply to my particular case as well as the advantages and disadvantages of any alternative methods. **Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe.** Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit der Ärztin/dem Arzt wurde ich über den Ablauf der geplanten Maßnahme, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.
- I deliberately refrain from obtaining a more detailed explanation.** However, I hereby confirm that the doctor _____ instructed me regarding the necessity of the procedure, its type and scope as well as the fact that all medical procedures are accompanied by certain risks. **Ich verzichte bewusst auf eine ausführliche Aufklärung.** Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt über die Erforderlichkeit der Maßnahme, deren Art und Umfang sowie über den Umstand, dass alle medizinischen Maßnahmen Risiken bergen, informiert wurde.

I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the procedure proposed. I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge.

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

My consent also applies to any necessary additional measures as well as to any required changes or additions to the procedure. Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen, sowie auf erforderliche Änderungen oder Erweiterungen des Maßnahme.

I confirm that I am capable of following the instructions given to me by my doctor. Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

- 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]

Copy/Kopie:

- received/erhalten
- waived/verzichtet

Signature Copy received/waived
Kopieerhalt/-verzichtet

