

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

Dear patient, dear parents,

for the monitoring/treatment method planned in your case/your child's case, we recommend the placement of a catheter inside the superior caval vein, a so-called central venous catheter (CVC).

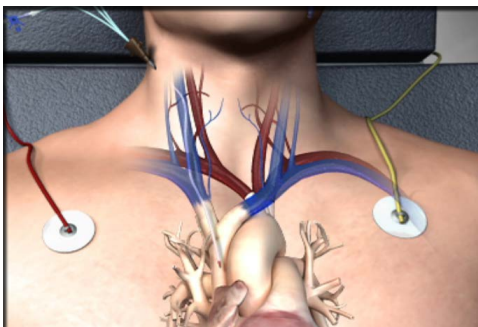
The following text is intended to inform you and - if applicable - your family about the course of this procedure, related risks and any measures you need to take before and after the procedure. This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available. He will inform you of any risks specific to your case and of any potential complications which could result from them. Please read the following information and complete the form carefully. It is understood that your data will be treated as confidential.

During the interview, 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 or reject the procedure. Your doctor will provide you with a copy of the completed and signed form after the interview.

COURSE OF PROCEDURE

A CVC is a long, thin plastic tube. It is usually inserted through a large vein located at the throat or below the collar bone into the caval vein leading to the heart. In rare cases, the catheter is inserted through a vein in the arm or groin.

For the procedure, the upper body may be positioned low and the head moved to the side opposite the puncture site. After the skin has been thoroughly disinfected, the injection site will be anaesthetised locally.



The doctor will first look for a vein suitable for inserting the catheter, using ultrasound guidance if needed. He then punctures the vein and

inserts the catheter into the superior caval vein. The tip of the catheter is usually placed close to the right atrium. Alternatively, it can also be placed inside the superior caval vein or the right atrium (e.g. a dialysis catheter). If any problems occur while the catheter is being moved forward (e.g. a blocked vein), a different suitable vein will be punctured or the procedure will be stopped.

The doctor will usually check the correct position of the catheter via X-ray, using contrast media if need be, or with an ECG. Finally, the catheter is fixed to the skin.

For long-term outpatient treatment, other catheter systems, some of which are implanted under the skin, can be used (Hickman, Broviac, Groshong catheter). For this purpose, a small incision is made in the chest area and the catheter is inserted beneath the skin all the way to the shoulder. The advantage of those systems is a lower risk of infection.

ADVANTAGES OF THE PROCEDURE

The CVC provides safe vein access with little strain on the patient. It can also be used in patients where normal vein access is not possible.

The catheter enables at any time the infusion of fluids or artificial feeding as well as injection of medication or chemotherapeutics directly into the bloodstream, the measuring of venous blood pressure or repeated blood sample collection.

Repeated puncturing of a vein, which carries a higher risk of complications (such as inflammation of a vein, vein constriction), can be avoided with the CVC.

ALTERNATIVE METHODS

Long-term medical therapy (e.g. chemotherapy) or permanent artificial feeding can also be effected via a so-called port system consisting of a chamber and a thin catheter. The catheter is also inserted into the main vein and is then connected to a chamber, which is implanted beneath the skin in the upper chest. The port chamber is sealed air-tight with a silicone membrane. It can easily be punctured through the skin with a special needle in order to administer medication and infusions.

This system, however, has its advantages and disadvantages compared to a CVC. Your doctor will let you know what they are.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Please follow the instructions of the doctor and of the nursing personnel closely. Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: It is important to inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASS], Marcumar®, Plavix® etc. and metformin-containing antidiabetic medicines, so-called biguanides) or have taken irregularly over the course of the past eight days prior to the procedure. 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.

Food and drink: Your doctor will inform you whether pre-procedure fasting is advisable for the procedure.

Aftercare:

If the position of the catheter was checked using a contrast medium, you should drink a lot of clear fluids in order to flush the contrast medium out via the kidneys as quickly as possible.

Please inform your doctor immediately or come to the clinic should you experience **bleeding, swelling, pain, intense reddening of the wound, secretion from the puncture site, pain in your chest, heart problems, shortness of breath, fever, chills, swelling of the punctured limb (if applicable)**.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. They may sometimes require additional treatment or surgery and can 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. The occurrence of side effects and complications depends on several factors, such as the patient's age, overall health and lifestyle. 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.

Bruises (haematomata) in the area of the punctured vein can lead to firm, painful swelling. In most cases, this will disappear after a few days or weeks without treatment. The unintended puncturing of the carotid artery or coagulopathy in particular can lead to large bruising causing shortness of breath and trouble swallowing.

The moving forward of the catheter may be accompanied by **cardiac arrhythmia**. Once the position of the catheter has been adjusted, it will usually disappear without treatment. In extreme cases, dangerous tachycardia may occur, which will then have to be stopped with a power surge.

In rare cases, **neighbouring structures can be injured**, in particular:

- **injury of nerves**, for instance of the vocal cords, leading to hoarseness and speech impairments, of the diaphragm, leading to impaired breathing, or of the arm, resulting in paraesthesia and impaired movement.
- **injury of the lining of the lungs** (pleura) resulting in air or blood entering into the chest and pushing aside the lungs (pneumothorax/haemothorax). Coughing, restlessness, sweating, increased heart rate and shortness of breath may then

result. The air will then have to be removed through puncture or insertion of a drain.

- **injury of the central lymphatic system** leading to the collection of lymph fluid in the throat or the chest. The insertion of drains can usually help remove the fluid.
- **injury or perforation of the vein**, in extremely rare events of **the wall of the heart**, a **heart valve** or of the **carotid artery** located near the puncture site. Scarring, vessel constriction, circulatory problems, swelling, tissue death, bleeding into the pericardial sack, travelling of blood clots to other parts of the body, or arterial plaque accompanied by the risk of obstruction of a vessel (e.g. in the brain, leading to stroke accompanied by impaired vision, hearing, speech or paralyses) may result.

Severe bleeding is rare. It is usually noticed immediately and stopped. **Post-procedure bleeding** requiring treatment may occur in some cases. Should severe blood loss occur, the use of donor blood/blood components (**transfusion**) may be required in exceptional cases. 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.

In rare events, **damage to the skin, soft tissue**, or **skin nerves** around the puncture site can lead to paraesthesia, sensory disturbance, numbness or pain.

Wound infection accompanied by abscess formation (including syringe abscess through injections) and tissue death (necrosis) rarely occurs. Wound healing is then delayed. With patients predisposed to wound healing disorder, painful scarring and abnormal proliferation of scar tissue (keloids) may occur.

Infections in and around the **catheter** may occur during the entire time the catheter remains in place. Swelling, redness and warming of the skin, unusual secretion at the puncture site as well as high fever – even recurring – are signs of inflammation. In most cases, this can be treated with antibiotics. If the infection is severe, the catheter will have to be removed or replaced. In extreme cases, germs may be introduced into the bloodstream (bacteraemia), leading to life-threatening **blood poisoning** (toxaemia) or inflammation of the endocardium (endocarditis) as a result. Adequate intensive care will then be required. In extremely rare cases, an infection may result in the death of a patient despite proper treatment.

Allergic reactions (intolerance symptoms), e.g. to local anaesthesia, contrast media, sedatives or other medication, or, in extremely rare cases, to the catheter material, may occur. Reddening of the skin, wheal formation, swelling or nausea and coughing may then occur as a result. They normally disappear without treatment. Severe reactions, e.g. disturbances in the function of the cardiovascular system and the lungs are very rare. The shortness of breath, tachycardia or circulatory shock which may then result require adequate intensive care. Temporary or permanent organ damage, such as brain damage, kidney failure, paralyses, may occur despite proper treatment.

During on after the procedure, the insertion of the catheter may lead to the formation of new blood clots (**thromboses**) or existing blood clots may become detached, which can lead to obstruction of a blood vessel (**embolism**). Painful swelling in arms, legs or the throat including blue discolouration, a feeling of tightness and paraesthesia, muscles weakness, impaired function, or swelling of the face and shortness of breath may then result. The risk is increased the longer the catheter remains in place, in bedridden or overweight patients and smokers, especially if hormones (such as birth control pills) are taken at the

same time. Blood clots may travel to other parts of the body and block the vessels of other organs. Despite immediate intensive medical care or surgical intervention, permanent damage may result (such as lung embolism, stroke). If a catheter thrombosis (catheter obstruction) occurs, the catheter will have to be removed or replaced.

Further, very rare complications requiring a correction, removal or replacement of the catheter are: **wrong placement, subsequent entry of the catheter end into a neighbouring vessel, convolution of the catheter, catheter fracture, drifting of the catheter tip** into the pericardial sac, lungs, the lining of the lungs

or the chest area. If the catheter starts leaking, medication, nutrition solution etc. will leak into the surrounding tissue (**extravasation**). Pain, swelling or reddening and, in some cases, formation of blisters on the skin, will then result; they are usually harmless and can be easily treated. If chemotherapeutics leak from the catheter, it can lead to tissue death.

If air enters through the catheter, it may lead to dangerous **air embolism** requiring intensive medical care.

If the catheter is inserted through a vein in the arm, **venous irritation (thrombophlebitis)** and vein obstruction cannot be ruled out entirely. However, these can usually be easily treated.

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®, Ticlopidin, Xarelto®.

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

Any other: _____
Sonstiges:

When did you take the last dose? _____
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.)

Have you ever had an operation or radiation in the area of the puncture? yes no

Wurden Sie jemals im Punktionsgebiet operiert oder bestrahlt?

Have you ever received contrast medium? yes no

Haben Sie schon einmal Kontrastmittel erhalten?

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

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

Are you currently breast feeding a baby? yes no
Stillen Sie?

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).

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

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

Has a transfusion of blood or blood components ever been necessary? yes no

War jemals eine Übertragung von Blut/Blutbestandteilen notwendig?

If so, were there any complications? yes no

Wenn ja, kam es dabei zu Komplikationen?

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, Herzmuskelentzündung, Herzklappenerkrankung, Luftnot beim Treppensteigen, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, niedriger Blutdruck, Schlaganfall, Krampfadern, Venenentzündung, Thrombose, Embolie.

Any other: _____
Sonstiges:

Diseases of the respiratory tract (breathing passages) or lungs?

 yes no

Asthma, chronic bronchitis, inflammation of the lungs, emphysema, sleep apnoea (intense snoring with breathing interruptions), vocal cord/diaphragm paralysis.

Erkrankung der Atemwege/Lungen? Asthma, chronische Bronchitis, Lungenentzündung, Lungenemphysem, Schlafapnoe (starkes Schnarchen mit Atemaussetzern), Stimmband-Zwerchfellähmung.

Any other: _____
Sonstiges:

Metabolic diseases?

 yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
Sonstiges:

Thyroid diseases?

 yes no

Underactive thyroid, overactive thyroid.

Schilddrüsenerkrankungen? Unterfunktion, Überfunktion.

Any other: _____
Sonstiges:

Kidney diseases?

 yes no

kidney insufficiency, kidney inflammation.

Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung.

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:

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:

The attachment of following catheter is scheduled:

Die Anlage folgenden Katheters ist geplant:

- _____
- Access via: Zugang über: _____

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. The child is represented by a parent/both **parents** or a legal guardian. These persons are capable of making a decision in the best interest of the patient/the child.

Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht bzw. das Kind von seinen **Eltern**/einem Elternteil oder einem Vormund vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten/des Kindes 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 the patient / parent(s)* / legal guardian(s) / witness, if any
(Ablehnung Patient/ Eltern*/ Betreuer / Vormund / ggf. des Kindes/ggf. des Zeugen)

DECLARATION OF CONSENT

Einwilligungserklärung

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 Bedenkzeit 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 / der Eltern* / Betreuer]

Copy/Kopie:

received/erhalten

waived/verzichtet

Signature Copy received/waived
Kopieerhalt/-verzichtet

*If only one parent signs, then by so doing this parent declares that he/she has sole rights of custody or is acting with the consent of the other parent.

