IMPLANTATION OF A CARDIOVERTER-DEFIBRILLATOR
IMPLANTATION EINES KARDIOVERTER-DEFIBRILLATORS

Information and medical history for adult and juvenile patients for preparation of the required pre-procedure interview with the doctor

englisch

Clinic / Doctor:

Ammerland Klinik GmbH ...wir für Sie

Patient data:

Procedure scheduled to take place on (date):

Dear patient,

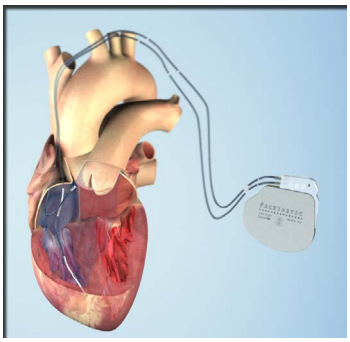
you have been diagnosed with a heart disease which cannot be controlled with medication alone and thus requires the implantation of a cardioverter-defibrillator, a so-called ICD. If needed, it emits an electrical impulse to the heart to end any dangerous tachycardia.

The following text is intended to inform you and - if applicable - your family about the course of the operation, related risks and any measures you need to take before and after the procedure. You may have a short film shown to you. This form and the film 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.

FUNCTION OF A HEALTHY HEART

The heart consists of four cavities: two atria and two chambers. It also contains heart valves, which ensure that the blood only flows through the heart in one direction. The heart's own electrical impulses and a special conduction system produce a regular and coordinated heartbeat.



In a healthy heart, the atria and the chambers contract shortly after each other and thus pump the blood through the lungs and the body.

If the heart muscle has been altered by a disease, these alterations may affect proper transmission of the impulses. The heart will end up being out of sync and will start racing. In extreme cases, heart muscle function will even be reduced to quick, uncoordinated twitches, which is referred to as fibrillation. The cardiac chambers cannot fill properly and the pumping function of the heart abruptly goes down to zero. This is also called ventricular fibrillation including circulatory arrest, which will lead to sudden cardiac death if untreated.

HOW AN ICD WORKS

In order to prevent this, an ICD is to be implanted in your case. The ICD consists of a generator, also referred to as the aggregate, emitting electrical impulses into the heart via probes.

The ICD can recognise a heartbeat that is too fast right away and end it by emitting electrical impulses. The patients often don't even notice this. If ventricular fibrillation occurs, a stronger impulse, a so-called defibrillation, is emitted and a regular heart rhythm is restored.

Many ICDs nowadays also include a pacemaker function, emitting impulses if the heartbeat is too slow in order to stimulate it.

COURSE OF IMPLANTATION

Implantation can be carried out under local anaesthesia or general anaesthesia; if the latter is to be done in your case, you will receive a separate information sheet.

The aggregate is usually implanted in the area of the major pectoral muscle. The operation area is disinfected thoroughly, covered with a sterile cover and anaesthetised locally if need be. The doctor will then make a small incision below the collar bone. He then prepares a small "pouch" for the aggregate.

Afterwards, he will identify a vein leading to the heart, usually below the collar bone, and puncture it with a hollow needle. Under X-ray guidance, a probe is then moved all the way into the right cardiac chamber and fixed to the inner wall of the heart. An additional probe will be inserted in a similar manner inside the atrium in some cases.

Afterwards, the doctor will check the correct, ideal positioning of the probe(s) and test the conductivity of the heart. In some cases, the function of the ICD will also be tested. If the procedure is carried out under a local anaesthetic, you will usually be tranquillised to a deep sleep for a short period of time for the test.

During the test, an episode of tachycardia is artificially provoked to test whether the defibrillator can stop the cardiac arrhythmia reliably by emitting a strong impulse. If the test result is good, the doctor will connect the probe to the aggregate and insert the latter into the prepared skin pouch. He will then close the

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incision and adjust the final settings of the ICD to your individual needs. Programming the ICD settings may also be done on the following day.

If the procedure was carried out under a general anaesthetic, this will be ended at this stage and you will awake slowly. After the operation, you may be kept in the cardiological monitoring ward for some time.

POSSIBLE ADDITIONAL MEASURES

In some cases, placing the probe in the best-possible position will not be successful right away. The position of the probe will then have to be corrected in a repeat procedure. If the probes cannot be implanted, they can be attached to the heart muscle from the outside during the same procedure. This will require open surgery in order to access the heart. In order to avoid having to undergo a separate procedure at a later point in time, please agree to any necessary changes or additional measures now.

ALTERNATIVE METHODS

Various types of medication can be used to suppress your cardiac arrhythmia or to relieve or support your heart. In some cases, a catherisation of the heart can be carried out in order to ablate the area of the heart muscle responsible for the cardiac arrhythmia. However, these alternatives have side effects of their own and may not suffice in some cases.

If your heart is extremely weak, a heart transplant may also be called for.

Your doctor will explain to you why he would recommend the implantation of an ICD in your particular case.

PROSPECTS OF SUCCESS

An ICD can usually end a life-threatening episode of cardiac arrhythmia reliably by emitting an electric surge. Often, the ICD will emit small impulses unnoticed by you even if the cardiac arrhythmia event is only minor in order to prevent an episode of dangerous tachycardia. The ICD also records any cardiac arrhythmia event in the form of an ECG, which can then be accessed by your doctor using a programming device during your check-ups in order to ensure that the ICD is working correctly.

Sometimes, the ICD may emit a wrong impulse despite ideal programming. This cannot be ruled out entirely.

The ICD will reduce the symptoms of your underlying heart disease and improve your quality of life. It will not have any or only a minor influence on the actual heart disease.

It may take up to three months for you to adjust to the new situation after the implantation. If you feel unsettled, do not hesitate to talk about it. We will readily answer any questions you might have regarding your expectations and fears.

Depending on the frequency of the impulses emitted, the battery of the aggregate is meant to last five to ten years. After that, a so-called aggregate or generator replacement will be required, during which the aggregate below the skin will be removed and a new one implanted.

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 for you 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®, Heparin, Plavix® etc. or metformin-containing antidiabetic medicines (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 need to stop taking your medication.

Aftercare:

Your vital functions will be monitored for a certain period of time after the procedure. Please inform your doctor immediately if you experience symptoms such as pain when breathing, heart problems, breathing or circulatory problems, fever or paraesthesia. These symptoms may appear days or even weeks after the procedure and must be examined immediately.

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 for 24 hours after the procedure or for the period of time recommended by your doctor. Your reaction capacity will be impaired through the administration of analgesics and/or sedatives. Therefore, for a period of 24 hours after having been released from the clinic/surgery, you must not actively participate in road-traffic (not even as a pedestrian) nor participate in any risky activities, especially activities without secure support. You should also refrain from taking any important personal or economic decisions during this period.

With regard to additional guidelines regarding e.g. taking medication or physical activity, please follow the instructions of your doctor closely. In the first weeks you should avoid major physical exertion as well as intense movement of your arm on the side of your body where the device has been implanted.

Before you are allowed to go home, you will receive an ICD identification card. It contains all important information regarding the type and settings of your ICD. Please carry this card with you at all times and present it to the doctor or dentist before any examination.

Please also consult your doctor regarding when you may drive a car again.

After an ICD has been implanted, regular check-ups will be necessary. Those check-ups serve to verify that the ICD settings still match your individual needs. The first check-up will usually take place four to six weeks after you have been released. Further check-ups will then be scheduled, depending on the case, within three to six months. Please be conscientious in keeping those appointments.

Please also inform the doctor whose care you are under even between check-ups should you notice any clearly perceptible impulse. This is important in order to verify that the ICD is programmed correctly and is counteracting your cardiac arrhythmia reliably.

Please make sure that the area where the aggregate has been implanted into your chest is not subjected to mechanical irritation, such as through braces. Otherwise, the aggregate may break through the surface of the skin.

Modern ICDs are not overly sensitive to electronic devices and electrical fields. However, please remove yourself from any devices or turn them off, and inform us or the doctor who is continuing your treatment, should you notice anything unusual or receive an electric surge.

To be safe, mobile phones should always be carried and held on the side of the body opposite the ICD.

If you are taking a flight, please inform security and adhere to their instructions regarding security checks.

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 life style. 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.

Infections, for instance at the site where an injection needle or probe(s) was inserted, including syringe abscess, tissue death (necrosis) and scarring or vein inflammation (phlebitis) rarely occur. Infections of the skin pouch carrying the ICD may require the removal or the implantation of the aggregate on the other side of the chest. An infection of the wound will lead to swelling, redness, pain, warm skin and a temperature. In most cases, infections can be treated successfully with antibiotics. In rare cases, germs may be introduced into the bloodstream, leading to dangerous blood poisoning (toxaemia) or even to inflammation of the endocardium (endocarditis) as a result. Intensive medical care or removal of the ICD will then be required. In extremely rare cases, an infection may result in the death of a patient despite proper treatment.

Bruising (haematomata) sometimes occurs and may lead to firm, painful swelling. In most cases, they disappear after a few days or weeks without treatment.

Damage to the skin, soft tissue or **nerves** (e. g. through injections, disinfectants, the use of electrosurgical instruments or despite proper positioning) is rare. A pressure ulcer (decubitus), sensory disturbance, numbness, paralyses and pain may then result. They are usually temporary. On rare occasions, these symptoms may persist even after treatment, or scars may remain.

Allergic reactions (intolerance symptoms), for instance to medication (antibiotics, analgesics etc.) or to disinfectants or latex rarely occur. Reddening of the skin, skin rash, wheal formation, itching, swelling or nausea and coughing may then occur as a result. They normally disappear without treatment. Severe reactions, e.g. swelling of the laryngeal mucous membrane, disturbances in the function of the cardiovascular system and the lungs are very rare. The shortness of breath, spasms, tachycardia or circulatory shock which may then result require adequate intensive care. Temporary or even permanent organ damage such as brain damage, vision disorders, nerve damage and even paralyses, kidney dysfunction and even kidney failure can occur despite adequate treatment.

When the ICD probes are inserted and positioned inside the heart, you may experience uncomfortable **cardiac arrhythmia**. In extreme cases, dangerous tachycardia may occur, which will then have to be stopped with a power surge.

During or after the operation, existing blood clots (**thromboses**) may become detached or new blood clots may form, for instance through the insertion of the probe(s). A blocked vessel may then result (**embolism**), for instance in the arm, including circulatory disturbances and swelling. Such blood clots may travel to other parts of the body and block the vessels of the lungs (lung embolism), for instance, or cause a stroke with permanent paralyses or kidney failure. Treatment with anticoagulant agents may promote the risk of bleeding or post-operative bleeding. If Heparin is administered, the risk of **severe coagulopathy** (HIT) is increased. This means that the risk of thrombosis formation and thus obstruction of blood vessels is increased.

The insertion and attachment of the ICD probe(s) may cause **injuries** or **perforation** of **the vein** or **the wall of the heart**. **Bleeding** is usually noticed immediately and can then be stopped. Sometimes, further measures may have to be taken; 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. Donation of your own blood usually isn't useful.

Post-procedure bleeding of the heart may lead to blood collecting inside the pericardium and impair the pumping function of the heart. A puncture or surgical opening of the pericardium will then be required.

If air enters through the vein during probe implantation, it may lead to dangerous **air embolism** requiring intensive medical care.

Air may enter into the chest during the procedure through an injury of the lining of the lungs (**pneumothorax**) or blood may collect inside the chest. Coughing, restlessness, sweating, increased heart rate and shortness of breath may then result. If conservative treatments such as breathing therapy or diuretics do not suffice, a puncture or suction drain may be needed.

Nerve injuries e.g. of vocal chord nerves, the phrenic nerve or the nerve bundle that supplies the arm, will lead to temporary, in rare cases to permanent speech impairments, hoarseness, shortness of breath or paralysis of the arm.

Breathing disturbances due, for instance, to diaphragmatic weakness may require respiration in intensive care for several days after the procedure. This may cause pneumonia.

With patients predisposed to delayed wound healing or **wound healing disorder**, **painful scarring** and abnormal proliferation of scar tissue (keloids) may occur. The area around the surgical scar may remain numb.

Especially in the beginning, the heartbeat itself or sudden jolting movements may lead to **slipping of the probes** inside the heart. The generator will then have to be reprogrammed or the probes will have to be fixed inside the heart again.

Alterations of the heart muscle through inflammation or impaired blood circulation may also lead to an **impairment** of **ICD function**, to an extent which will require a corrective procedure in which the probes inside the heart will have to be relocated.

Since the ICD probes are highly flexible and thus move with every heartbeat, the mechanical wear and tear of several years may lead to a **probe fracture** or to a short circuit. The probe will then have to be replaced.

Since the implantation procedure has to be carried out under X-ray control, the body is **exposed to radiation**. Acute damage such as local skin alterations are rare. Long-term effects cannot be ruled out entirely.

Medical devices are subject to very high quality standards. Nevertheless, **malfunctioning** cannot be ruled out entirely even with an ICD. In that extremely rare event, the ICD may have to be replaced.

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 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 your: [Name und Alter der Aufsichtsperson]

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

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 in the chest area or on your heart? Do you have a breast implant? ☐ yes ☐ no

Wurden Sie schon einmal im Brustbereich oder am Herzen operiert oder haben Sie ein Brustimplantat?

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).

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

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/ Blutgerinnungsstörungen?

Blood clot (thrombus) / blood vessel occlusion (embolism)? ☐ yes ☐ no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

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:

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-Zwerchfelllähmung.

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)?

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:

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 Gesundheitssorge 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 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 / Betreuer]

Copy/Kopie:
☐ received/erhalten
☐ waived/verzichtet _____
Signature Copy received/waived
Kopieerhalt/-verzicht