CARDIAC RESYNCHRONISATION THERAPY
KARDIALE RESYNCHRONISATIONSTHERAPIE

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

Clinic / Doctor:

Patient data:

Procedure scheduled to take place on (date):

☐ Biventricular pacemaker
☐ Biventricular pacemaker with defibrillatior function

Dear patient,

you have been diagnosed with a weakness of the heart which cannot be controlled with medication alone and thus requires the implantation of a special type of pacemaker, a so-called biventricular pacemaker. This pacemaker sends impulses to the heart to support the contraction of the cardiac chambers, thus improving the pumping function of the heart.

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 THE 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 conduction of the electrical impulses is disturbed, the pumping function of the heart decreases. Oedema will form and the body will not be supplied with sufficient oxygen any more. The results are shortness of breath, tiredness and a feeling of weakness. The disturbance in conduction can also lead to life-threatening tachycardia.

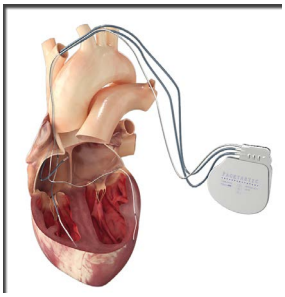
FUNCTION OF A PACEMAKER

A pacemaker is intended to reinstate a regular heartbeat (resynchronisation therapy). For this purpose, both halves of the heart need to be stimulated. The pacemaker consists of a generator emitting electrical impulses, also referred to as the aggregate, which sends electrical impulses to the heart via three probes. One probe is placed in the right atrium, the second in the right cardiac chamber, the third in the left chamber via a coronary vein.

If there is an additional risk of sudden cardiac death, the pacemaker implanted will have an additional electrical surge function, a so-called defibrillator function.

COURSE OF IMPLANTATION

The implantation of the pacemaker 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 makes an incision below the collar bone and 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, the first probe is then moved all the way into the right cardiac chamber and fixed to the inner wall of the heart.

Afterwards, the doctor will verify the probe is in the ideal place and carry out a test stimulation. If you are awake during that test, you may feel your heart rate increase. This is perfectly normal and no cause for concern.

A second probe is placed inside the atrium in a similar manner and tested. Then, the doctor will insert a special type of plastic tube, a steerable catheter, into a vein on the outer wall of the left cardiac chamber. Under X-ray guidance, he will inject a contrast medium via the catheter into the veins branching off and thus identify a suitable coronary vein. Once a suitable vein has been found, the third probe can be placed into it.

Finally, the doctor will connect the three probes to the aggregate and insert the latter into the prepared skin pouch. He will check the correct position of the probes under X-ray guidance and carry out a function test. The impulses now being emitted into the heart by the pacemaker will improve the contraction of the chambers and thus increase the pumping function of the heart.

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If the procedure is carried out under a local anaesthetic and if you are to receive a pacemaker with electrical surge function, you will be tranquillised to a deep sleep for a short period of time if the electrical surge function needs to be tested. 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.

Finally, the doctor will close the incision and apply a dressing to the wounds.

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 implantation of the third probe into a coronary vein cannot be carried out, it or one of the other probes can also 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.

If the doctor expects that such additional measures will be necessary in your case, he/she will inform you accordingly.

ALTERNATIVE METHODS

Various types of medication can be used to relieve or support your heart. However, the medications used 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 a pacemaker in your particular case.

PROSPECTS OF SUCCESS

A pacemaker can improve your heart's performance and improve your quality of life. Dizziness, tiredness or faintness usually disappear reliably.

Even though the pacemaker will start supporting your heartbeat right after implantation, it may take up to three months for you to adjust to the new situation. 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.

The battery of the aggregate is meant to last two to five 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.

Many patients fear that their pacemaker could prevent a natural death. However, a pacemaker does not extend anyone's life artificially and does not have any effect on the proces of dying.

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 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.

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

After a pacemaker has been implanted, regular check-ups will be necessary. Those check-ups serve to verify that the pacemaker 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 two to twelve months. Please be conscientious in keeping those appointments.

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 pacemakers 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 an increase in your heart rate, cardiac arrhythmia or dizziness.

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

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

POSSIBLE RISKS, COMPLICATIONS AND SIDE EFFECTS

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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 catheter was inserted, including syringe abscess, tissue death (necrosis) and scarring or vein inflammation (phlebitis) rarely occur. Infections of the skin pouch carrying the pacemaker may require

the removal of the pacemaker 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. Adequate intensive care 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.

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.

The iodine-containing contrast medium administered may lead to **thyroid hyperfunction**. This will result in **heart palpitations, restlessness, sweating, diarrhoea**, but can be treated with medication. An **impairment of kidney function** may occur in patients with pre-existing kidney damage or diabetes. Permanent kidney damage even requiring dialysis only occurs in rare cases.

When the 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 probes. 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 pacemaker probes may cause **injuries** or **perforation** of **the vein**, **the wall of the heart** or the **cardiac vein**. **Bleeding** is usually noticed immediately and can then be stopped. Sometimes, bleeding may require additional measures; 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 respiratory assistance 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.

Since the probe inserted into the cardiac vein is very close to the phrenic nerve, an uncomfortable pulsating **spasm of the diaphragm** may occur. If reprogramming the generator does not remove this problem, the probe will have to be relocated in the heart.

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 **pacemaker function**, to an extent which will require a corrective procedure in which the probes inside the heart will have to be relocated.

Since the pacemaker 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 skin alterations is 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 a pacemaker. In that extremely rare event, the pacemaker 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]

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.

(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), ☐ 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)?

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:

☐ Biventricular pacemaker

☐ Biventricular pacemaker with defibrillatior function

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