

EVENT RECORDER IMPLANTATION IMPLANTATION EINES EREIGNISREKORDERS (EVENTREKORDER)

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

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

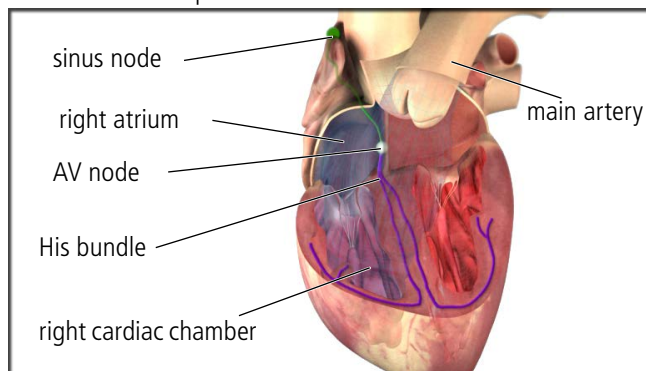
Dear patient,

In order to determine the cause of your cardiac arrhythmia, the implantation of an event recorder has been planned in your case. With the help of this device, your heart rhythm can be monitored over an extended period of time.

The following text is intended 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.

FUNCTION OF THE HEART

The heart consists of two atria and two chambers. The heart's own electrical impulses maintain a regular heartbeat. These impulses are normally produced by special muscle cells in the right atrium, the so-called sinus node, and are then transmitted via the muscles of the atria. This leads to the atria contracting and pumping the blood into the cardiac chambers. A second group of muscle cells, the so-called AV node, then picks up the signal and transmits it via a special bundle of fibres (His bundle) to the cardiac chambers. The chambers contract shortly after the atria and, by doing so, pump the blood into the aorta and the lungs. In a healthy adult in a resting state, the heart normally beats at a rate of 70 times per minute.



If any malfunctions occur during the development or transmission of the electrical impulses, the heart will end up beating arrhythmically, which is then referred to as cardiac arrhythmia. The heart will then beat too rapidly, too slowly or irregularly. This may lead to the body not being supplied with sufficient amounts of oxygen and to dizziness, faintness or fainting as a result.

COURSE OF PROCEDURE

An event recorder is designed to record cardiac arrhythmia over an extended period of time. An event recorder is particularly

useful for patients whose arrhythmia only occurs on occasion and irregularly, patients who suffer from sudden fainting spells, or to monitor the therapeutic success after catheter ablation.

The procedure is carried out under a local anaesthetic and only takes a few minutes. If need be, a mild sedative or sleep-inducing drug can be administered to you. The doctor will then make an incision of a few centimetres length on the left side of your chest between the first and the fourth rib. He will then form a small "pouch" underneath the skin and insert the event recorder. Afterwards, the incision will be sutured with small stitches.

The event recorder is small and can remain inside the body for 12 months or longer if need be. It automatically records major changes in heart rhythm. Additionally, the patient can control the recording via a remote control device when the arrhythmia occurs. The data can then be transferred to the doctor on a regular basis via the mobile network (home monitoring) and thus be analysed by the doctor.

After the collection of data has been completed, the event recorder will be removed in the same manner it was inserted in a minor procedure.

ALTERNATIVE METHODS

As an alternative to event recorder implantation, cardiac arrhythmia can also be recorded via a portable event recorder. This involves the patients placing the external device onto their chest whenever they experience cardiac symptoms and recording the data for a few minutes. This requires the patients being capable of recognising their cardiac arrhythmia symptoms and using the device in a proper manner. If this is not the case, an external recorder can also be fixed to the skin with adhesive electrodes. The device will then record data continuously.

Cardiac arrhythmia can also be recorded via a long-term ECG over a period of 24 hours. However, if the symptoms only occur occasionally, there may not be any changes in heart rhythm within that period of time, meaning there won't be any useful data to record.

Your doctor will explain to you what the alternatives are and why he would recommend the insertion of an event recorder in your particular case.

PROSPECTS OF SUCCESS

An event recorder is usually a reliable device for diagnosing cardiac arrhythmia. However, even if it is used to monitor the heart rate over an extended period of time, the arrhythmia may still not be recorded. This may then require the use of a different examination method.

In rare cases, the recorder may mistake intense muscle activity for cardiac arrhythmia.

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: Please inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASA], 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.

The implantation requires **pre-procedure fasting**. Therefore, you may not eat or drink anything for at least six hours prior to the procedure and must refrain from smoking. Small amounts of clear fluids (e.g. one glass of water) are allowed up until shortly before the implantation.

Aftercare:

The stitches can be removed a few days after the implantation by your general practitioner.

The event recorder automatically records data and may even transfer it electronically to your doctor. However, if you notice a cardiac arrhythmia event, you should still see your doctor as soon as possible.

You can also control the recorder **autonomously** via remote. Your doctor will provide you with specific instructions.

For as long as the device is in place to record data, seeing your doctor for **regular check-ups** will be required. Please be conscientious in keeping those appointments.

Please inform your doctor immediately or go to the clinic if you experience **bleeding from the wound, swelling, pain or intense reddening around the wound** or if you notice **chest pains, severe cardiac arrhythmia or shortness of breath**.

If a sedative and/or analgesic has been administered to you, you must be collected by an adult if the examination has been performed **on an out-patient basis**. Also, for a period of **24 hours after the procedure**, you must not actively participate in road traffic (not even as a pedestrian), refrain from any risky activities and avoid taking any important decisions, unless otherwise instructed.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure**, even a low-risk procedure such as event recorder implantation, 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.

Bruising (haematomata) occasionally occurs around the wound. This may lead to firm, painful swelling. Most of the time, this will disappear even without treatment.

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

Damage to the skin, soft tissue or nerves (for instance through bruises, syringe abscess, disinfectants or despite proper positioning) is rare. Numbness, paralysis and pain may then result. They are usually temporary. On rare occasions, these symptoms may persist even after treatment, or scars may remain.

Infections can usually be treated with antibiotics. Surgical treatment is only necessary in rare cases. In exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia).

Allergic reactions, for instance to medication, latex or the event recorder, 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, paralysis or kidney failure requiring dialyses.

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

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 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]

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®, EfiEnt®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

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®, EfiEnt®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

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.)

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)?

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 Metallbrillengestelle, Modeschmuck oder Hosennieten).

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:

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

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 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]

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 (4 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 (4 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-/verzichtet

I consent to the removal of the event recorder and do not need any further explanation.

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

Signature of the patient / legal guardian(s)

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