

ELECTRICAL CARDIOVERSION FOR CARDIAC ARRHYTHMIA ELEKTRO-KARDIOVERSION BEI HERZRHYTHMUSSTÖRUNGEN

Information and medical history for patients for preparation of a talk with the doctor

Klinik / Praxis:



Data about the patient: Patientendaten:

englisch

The procedure is scheduled for (the date): Der Eingriff ist vorgesehen am (Datum):

Dear patient,

Your cardiac arrhythmia (such as atrial fibrillation) is to be cured with a direct power surge. This will make it possible to eliminate symptoms you have experienced, e.g. tachycardia, shortness of breath or fainting spells.

The following text is intended to inform you about the course of an electrical cardioversion procedure, related risks and any measures you need to take before and after the procedure as well as to prepare you for your pre-procedure interview with the doctor. During the talk, 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 and of any potential complications which could result from them. During the talk, 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 suggested procedure of electrical cardioversion or reject it.

Please read the following information and complete the form carefully. It is understood that your data will be treated as confidential. Your doctor will provide you with a copy of the completed and signed form after the interview.

CAUSES OF CARDIAC ARRHYTHMIA URSACHEN DER HERZRHYTHMUSSTÖRUNG

The heart consists of four cavities, two atria and two chambers. The heart's own electrical impulses normally maintain a regular heartbeat. These impulses are produced by special muscle cells located in the right atrium, the so-called sinus node, and are then transmitted via the muscles of the atrium and the heart chambers. This leads to the heart contracting and pumping 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 most common form of arrhythmia is atrial fibrillation. This condition leads to the atria not contracting in a coordinated fashion anymore. The heart will then beat too rapidly or irregularly.

This can lead to uncomfortable tachycardia and to a decrease in cardiac output. Moreover blood clots may develop in an atrium affected by fibrillation and can then travel to the brain or other organs. This increases the risk of a stroke.

COURSE OF ELECTRICAL CARDIOVERSION PROCEDURE ABLAUF DER ELEKTRO-KARDIOVERSION

To facilitate the administration of medication, a peripheral venous cannula will be inserted into your lower arm. If necessary, an ultrasound examination of the heart through the oesophagus will be performed prior to the cardioversion procedure to exclude the risk of blood clot formation in the atrium. During this procedure, a throat anaesthetic will be given to you as well as a mild sleep-inducing drug if need be. Then, an ultrasonic probe will be inserted through the mouth into the oesophagus in order to examine the heart with ultrasound.

The electrical cardioversion will then be performed under deep sedation or short anaesthesia. You will fall into a deep sleep lasting approx. 5-10 minutes and will not feel or be aware of anything during the actual procedure. For a cardioversion procedure, two large electrodes will be placed on your chest. Through them, a brief power surge will be sent through the heart in order to discharge the heart muscle cells. This will enable the heart's own pacemaker, the sinus node, to provide for a regular heartbeat again.

ALTERNATIVE METHODS ALTERNATIVEN

It is often possible to treat cardiac arrhythmia with medication. However, the success rate of this type of treatment is lower than that of electrical cardioversion. Certain types of cardiac arrhythmia can also be treated with so-called catheter ablation. This procedure involves the advancement of a flexible catheter towards the

heart through the groin in order to ablate (destroy) the abnormal tissue causing arrhythmia using high-frequency alternating current.

PROSPECTS OF SUCCESS ERFOLGSAUSSICHTEN

Putting an end to arrhythmia is usually possible with only one single electrical impulse. If this does not suffice, a second impulse can be administered straight away. With some patients, the arrhythmia may recur within a few days or weeks. The procedure can then be repeated at any time, or treatment with medication can commence. Even after electrical cardioversion, it can be necessary to continue taking medication in order to stabilise the cardiac rhythm.

DIRECTIONS FOR PREPARATION AND AFTERCARE

HINWEISE ZUR VORBEREITUNG UND NACHSORGE

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

Preparation:

If you have suffered from **atrial fibrillation for more than 48 hours**, it will be necessary to take an anticoagulant agent for a period of several weeks prior to the electrical cardioversion procedure. Alternatively, the formation of blood clots in the atrium can be excluded through an ultrasound examination of the heart via the oesophagus (transoesophageal echo).

Medication:

It is important for you to inform your doctor of any medication you take on a regular basis (in particular any medication to treat cardiac arrhythmia). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know when to stop taking your medication and for how long.

Food and drink:

In order to prepare for the procedure, you may not eat, drink or smoke for at least six hours before your electrical cardioversion procedure is scheduled to take place. Clear fluids in small amounts (e.g. 1-2 cups of water or unsweetened tea with no milk or cream) may be allowed up to two hours prior to the cardioversion procedure.

Aftercare:

After the electrical cardioversion procedure, your heartbeat will be monitored via an ECG for several hours.

If the procedure is performed **on an out-patient basis**, it is necessary for an adult to 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 after a short anaesthesia or sedation. Therefore, for a period of **24 hours you must not actively participate in road-traffic** (not even as a pedestrian) nor participate in any risky activities, especially those without secure support. You should also refrain from taking any important personal or economic decisions during this period.

Since the atria will require some time after electrical cardioversion to return to a normal level of pumping, it will be necessary for a period of approx. four weeks to take an **anticoagulant agent**.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

RISIKEN, MÖGLICHE KOMPLIKATIONEN UND NEBENWIRKUNGEN

It is well known that **any medical procedure is accompanied by certain risks**. These may sometimes require additional treatment or surgery and can sometimes even be **life-threatening** or lead to permanent damage. 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.

Damage to the skin and soft tissue or nerves (e.g. through the power surge and the contact gel or the peripheral venous cannula) may occur. Damage to the skin, paraesthesia, sensory disturbance, numbness and pain may then result. Most of these symptoms can be treated successfully. On very rare occasions, these symptoms may persist.

In the event of the existence or formation blood clots (**thromboses**) in the atrium despite the administration of anticoagulants, they may separate from the vein after electrical cardioversion and obstruct a blood vessel (**embolism**). Even despite immediate treatment, this may lead to permanent damage to the affected organ (e.g. **lung embolism, stroke** including paralyses, **kidney failure**).

The power surge may lead to further **cardiac arrhythmia**. It usually disappears without treatment or can be treated successfully with medication. Severe cardiac arrhythmia may require another power surge in extreme cases or be relieved through insertion of a pacemaker.

Specific risks related to sedation/short anaesthesia

Administering an anaesthetic or a sedative can lead to **trouble breathing** or **circulatory problems** (e.g. a drop in blood pressure, slowing of the heart rate) accompanied by **nausea and vomiting**. These symptoms can usually be treated effectively by administering oxygen or medication. However, if **breathing arrest** occurs, artificial respiration will be necessary in order to prevent damage to the brain or other organs. In extreme, exceptional cases, damage to individual organs (such as the kidneys or the brain) may occur despite immediate treatment.

On very rare occasions, stomach contents may enter the lungs undetected, which may then lead to **obstructed airways** or **pneumonia** accompanied by permanent damage to the lungs or even to **lung failure** in some cases. This risk especially applies if the order not to eat, drink or smoke prior to the procedure has not been followed.

In extremely rare cases, patients with a genetic predisposition may experience a rise in body temperature through the medication administered (**malignant hyperthermia**). This may result in cardiac and breathing arrest as well as in multiple organ failure. In these cases, immediate intensive care will be undertaken in order to prevent the aforementioned risks.

Specific risks related to Transoesophageal Echocardiography (TOE)

Injuries of the oesophagus, the **larynx** or the **windpipe** usually do not occur unless the patient already had problems swallowing, constrictions, varicose veins or aneurysms into the oesophagus. Any **bleeding, hoarseness** or **problems swallowing** experienced as a result usually disappear without treatment. A **puncturing** of the oesophagus is extremely rare and may require surgery if it occurs.

Important Questions for Outpatients

Wichtige Fragen für ambulante Eingriffe

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

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

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

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

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

Telephone: [Telefonnummer]

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

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

Name: [Name]

Street, house number: [Straße, Hausnummer]

postcode, place: [PLZ, Ort]

Telephone: [Telefonnummer]

Questions about Your Medical History Fragen zu Ihrer Krankengeschichte (Anamnese)

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 of treatment 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.

yes=ja no=nein

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), Heparin, Marcumar®,
 Plavix®, Eliquis®, Pradaxa, Efient®,
 Brilique®, 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), Heparin, Marcumar®, Plavix®, Eliquis, Pradaxa, Efient®, Brilique®, Xarelto®.

Other: Sonstiges: _____

When did you take the last dose? _____

Wann war die letzte Einnahme?

Do you need regularly medications for high blood pressure or heart rhythm problems? yes no

- Amiodaron, Multaq®

Benötigen Sie regelmäßig Medikamente gegen hohen Blutdruck oder Herzrhythmusstörungen? Amiodaron, Multaq

Other: Sonstiges: _____

When did you take the last dose? _____

Wann war die letzte Einnahme?

Do you take any other medications? yes no

Nehmen Sie andere Medikamente ein?

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 electrical cardioversion?

yes no

Wurde schon einmal eine Elektro-Kardioversion durchgeführt?

Do you have a pacemaker or a defibrillator?

yes no

Haben Sie einen Herzschrittmacher oder Defibrillator?

Do you smoke?

yes no

If so, what and how much daily: _____

Rauchen Sie? Wenn ja, was und wie viel täglich:

Do you drink alcohol regularly?

yes no

If so, what and how much: _____

Trinken Sie regelmäßig Alkohol? Wenn ja, was und wie viel:

Are you pregnant? not certain nicht sicher yes no

Besteht eine Schwangerschaft?

Do you have or have you ever had any of the following diseases or symptoms thereof?

Liegen oder lagen nachstehende Erkrankungen oder Anzeichen dieser Erkrankungen vor:

Diseases of the oesophagus?

yes no

swallowing symptoms, varices of the oesophagus, outpouchings of the oesophagus.

Erkrankungen der Speiseröhre? Schluckbeschwerden, Krampfadern der Speiseröhre, Aussackungen der Speiseröhre.

Any other: _____

Sonstiges: _____

Blood diseases / blood clotting disorders?

yes no

increased tendency to bleed (e.g. frequent nosebleeds, increased bleeding after surgery, minor wounds or dental treatment), tendency to bruise (frequent bruising possibly for no particular reason).

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

Bluterkrankung/Blutgerinnungsstörung? Erhöhte Blutungsneigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung), Neigung zu Blutergüsse (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?

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. Gummihandschuh, Luftballon), Pollen (Gräser, Bäume), Betäubungsmittel, Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosenknieten).

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, Herzkloppenerkrankung, 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.

Erkrankung der Atemwege/Lungen? Asthma, chronische Bronchitis, Lungenentzündung, Lungenemphysem.

Any other: _____
Sonstiges:

Thyroid diseases?

yes no

Underactive thyroid, overactive thyroid, nodes, thyroid swelling (goitre).

Schildrüsenerkrankungen? Unterfunktion, Überfunktion, Knoten, Kropf.

Any other: _____
Sonstiges:

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 talk

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the surgeon 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 Alternativ-Methoden, mögliche Konsequenzen, wenn die Behandlung verschoben oder abgelehnt wird) habe ich den Patienten im Gespräch näher aufgeklärt:

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is capable of making decision on the recommended procedure by himself/herself and issuing its consent for the procedure. Der/Die Patient/in besitzt die Fähigkeit, eine eigenständige Entscheidung über die empfohlene Behandlung zu treffen und seine/Ihre Einwilligung zu erteilen.
 - The patient is represented by the carer, i.e. guardian with the evidence of guardianship. This person is entitled of making a decision on behalf of the patient. Der/Die Patient/in wird von einem Betreuer bzw. Vormund mit einer Betreuungsurkunde vertreten. Dieser ist in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.

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

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

Refusal by the patient Ablehnung des/der Patienten/in

Ms/Mr. Dr. _____ informed me in detail about the upcoming procedure and explained me the consequences arising from my refusal. I understood the explanation and discussed with the surgeon the information he/she gave me. Hereby I decline the proposed procedure.

Frau/Herr Dr. _____ hat mich umfassend über den bevorstehenden Eingriff und über die sich aus meiner Ablehnung ergebenden Nachteile informiert. Ich habe die diesbezügliche Aufklärung verstanden und konnte meine Erkenntnisse über die mir erteilten Informationen mit dem Arzt diskutieren. Hiermit lehne ich die mir vorgeschlagene Behandlung ab.

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

Signature of the patient/guardian/tutor/possible witness [Unterschrift Patientin /Patient / Betreuer / ggf. des Zeugen]

Statement and consent of the patient Erklärung und Einwilligung

Please tick the appropriate fields and confirm your statement with a signature: Bitte kreuzen Sie die zutreffenden Kästchen an und bestätigen Sie Ihre Erklärung anschließend mit Ihrer Unterschrift:

- Hereby I confirm that I understood all integral parts of the information.** I read completely this form with explanations (5 pages). During a talk with Ms/Mr. Dr. _____ I was given an explanation of the course of planned procedure, risks, complications and side effects in my special case and I was thoroughly informed about the benefits and risks of alternative methods. **Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe.** Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit Frau/Herrn Dr. _____ wurde ich über den Ablauf der geplanten Behandlung, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.

I deliberately renounce a detailed explanation. However, hereby I confirm that the surgeon whose patient I am, informed me about the necessity of the procedure, type and scope, as well as the circumstances and risks that this type of procedure entails and possible alternatives. **Ich verzichte bewusst auf eine ausführliche Aufklärung.** Ich bestätige hiermit allerdings, dass ich von dem behandelnden Arzt über die Erforderlichkeit der Elektro-Kardioversion, deren Art und Umfang sowie über den Umstand, dass die Behandlung Risiken bringt, informiert wurde.

I confirm that I do not have any additional questions and that I do not need additional time to make a decision. I agree with the proposed procedure. I also agree with all necessary auxiliary and subsequent measures. I answered the questions about my medical history (anamnesis) completely to the best of my knowledge.

Ich versichere, dass ich **keine weiteren Fragen** habe und **keine zusätzliche Bedenkzeit** benötige. **Ich stimme den vorgeschlagenen Elektro-Kardioversion zu.** Ich willige ebenfalls in alle notwendigen Neben- und Folgemaßnahmen ein. Die Fragen zu meiner Kengengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

- 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 patient/legal guardian(s)
[Unterschrift Patient /in / Betreuer / Vormund]

Copy/Kopie: received/erhalten
 waived/verzichtet

Signature Copy received/waived
[Unterschrift Kopie erhalten/verzichtet]