Universitätsspital Basel

Cardiology

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Information and patient consent form
Implantation of a cardioverter defibrillator (ICD)

Dear patient,

Your doctor has determined,

- ☐ that at times your heart was beating too rapidly or, alternatively, that you survived a so-called sudden cardiac death due to very dangerous cardiac arrhythmias (ventricular flutter / fibrillation). Since life-threatening arrhythmias can be expected in the future, the implantation of a cardioverter defibrillator (ICD) was recommended to you.
- ☐ that you have an increased risk for potentially life-threatening cardiac arrhythmias and therefore recommends the implantation of a cardioverter defibrillator (ICD).

How does an ICD work and the surgical procedures:

An ICD is a small device similar to a pacemaker, which can automatically detect and treat rapid, life-threatening arrhythmias. The ICD is implanted under the skin of the left side of the chest. One or more probes are inserted into the heart under x-ray control, and then connected to the ICD. After establishing that the probes are in a good position and the corresponding dimensions are measured satisfactorily, a rapid-acting, but very strong sleeping aid is injected into the vein. While you sleep deeply, we induce a ventricular fibrillation 2 times, the most dangerous arrhythmia, and observe the termination of ventricular fibrillation through an electric shock, which is applied by the ICD. If the ICD shock is ineffective, an electric shock is delivered by an external defibrillator, which should usually bring the ventricular fibrillation to an end safely.

The procedure or examination is performed under X-ray radiation. Consequently there is a certain radiation exposure, that however is kept as low as possible. Based on general considerations, in case of pregnancy this kind of examination should only be performed in emergency cases.

Potential complications:

The local anesthesia, which is necessary for the implantation of ICDs, briefly leads to an unpleasant, burning sensation. After this, the surgical field is usually fully anesthetized. Occasionally, a haematoma may be formed in the area of the surgical wound, especially if blood-thinning drugs are taken. In exceptional cases, the introduction of the probe can cause an injury to the vessels, heart valves or the heart muscle itself, and possibly even bleeding into the pericardium.
If thus the heart function is impaired, the blood must be withdrawn with a syringe. An emergency surgery is very rarely required. If the vein below the sternum needs to be injected with

a syringe for insertion of the probe, this may lead to an injury of the lung and formation of an air outlet into the chest cavity. This air must be evacuated under certain circumstances.

Severe damage to health or even death as a result of technical failures are very rare. Complications due to the proposed implantation of an ICD are usually rare and in your case present a much lower risk than in the case when an ICD system is avoided.

Follow-up checks after replacing an ICD:

These are carried out at regular intervals on the day after the implantation and thereafter in 3-6 month intervals. If the ICD is implanted prophylactically, you should not drive for 2 weeks. If the ICD was implanted because arrhythmias were diagnosed in the lower chambers of your heart, you are not allowed to drive for 3 months. The same applies when discharges of the ICD occur.

☐ For the treatment of heart failure, an additional probe is implanted that specifically stimulates the left main chamber. This probe is advanced to the heart like the other, above-mentioned probes and then inserted into a special vein (coronary sinus). The insertion of this probe is a technically sophisticated process and can prolong the operation significantly. In rare cases (less than 1%), it may lead to an injury of a vessel (coronary sinus), which may lead to bleeding into the pericardium. Then this blood must be removed with a syringe. In about 5% of the cases, the probe may simultaneously irritate the diaphragm, resulting in an unpleasant twitching of the diaphragm. However, this twitching can almost always be healed by reprogramming the device.

Space for a sketch / personal notes:

Please contact us,

if you do not understand something or if something seems to be important that was not mentioned in this document or in the personal consultation with your doctor.

Declaration of consent

Dr. med. ……..……..……

held an informed consent discussion with me. I have understood the information provided to me and could make all the pertinent questions. After sufficient time to think and answering of all my questions I hereby declare myself ready for the proposed therapy. I express my consent for any follow-up procedures that may become necessary.

Signature of patient: _____

Signature of doctor: _____

Place and date: _____

Consent to data collection and evaluation

I agree with the collection and analysis of scientific data of my treatment in an encrypted, electronic form. If necessary, the traceability of data for quality assurance is ensured. We assure you with an unrestricted right of access to inspect the data archived about you.

Signature of patient: ……...…….

Place and date: ……..……..