

## Cardiology

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### Information and patient consent form

## **Electrophysiological examination and catheter ablation by epicardial access**

Dear patient,

You physician has referred you to us because you have arrhythmias that are difficult to treat with drugs and originate in the lower chambers of the heart, persistent as ventricular tachycardia or as ventricular extrasystoles in some beats. It is possible that the origin of these arrhythmias is on the outer side (epicardium) and not on the inside of the heart (endocardium). For this reason, we will create an access point from below the sternum to the outside of the heart during the procedure to locate the abnormal heart rhythm there and possibly treat it at the same time. Since this process involves certain risks, we want to present this method in more detail. This document supplements your personal consultation with your doctor.

### **Examination and treatment method**

The treatment is performed on fasting patients. After local anesthesia of the groin, different catheters are first advanced under X-ray control through the veins and/or arteries to the heart. These help as anatomical landmarks during placement of the epicardial access. The procedure is performed under local anesthesia below the sternum. After this, a needle is advanced towards the outside of the heart under X-ray control. The position of the needle is continuously monitored by administration of small quantities of contrast medium. After reaching the epicardial space, a thin wire is advanced, which reviews the position in the epicardial space and ensures it. Subsequently, a sheath is inserted through this wire, through which the catheter can then be guided for the electrophysiological studies and the ablation (the detailed information can be found in the informed consent "Electrophysiological study and catheter ablation of ventricular tachycardias and ventricular premature beats").

During an electrophysiological study through epicardial access, various potentially dangerous complications can occur (see below) and the study can be time consuming. To be able to monitor in the best possible way and to make the procedure as convenient for you as possible, we conduct it in collaboration with the doctors of the anaesthesiology department in general anesthesia and intubation i.e. with the use of a respiratory tube. Please inform your doctor if you have experienced problems during anaesthesia in the past.

## **Potential complications:**

Although these treatments can usually be performed without a problem, complications may occur in a few cases. "Rare" complications are those, which are expected to occur in approximately one of a hundred interventions and "very rare" are those which occur approximately once per thousand interventions. Serious complications are described in a total of about 5-10% of these interventions. "Serious" complications are those, which lead to a prolongation of hospital stay or additional treatment. However, this category also includes the rare complications that can lead to some permanent damage or very rarely even to death.

Risks specifically associated with this therapeutic procedure include:

- An injury to the heart wall may occur with subsequent bleeding into the pericardium (around 4%). If the insertion of the sheath, which is needed for the intervention anyway, does not help in stopping the bleeding, a cardiac surgery may be needed in some rare cases by creating an opening of the sternum to stop the bleeding.
- In rare cases, an injury of a coronary artery may occur. This can result in a bleeding as well as in a heart attack and usually requires cardiac catheterization with stenting or cardiac bypass surgery to repair the resulting damage.
- Rarely, blood vessels outside of the heart may be injured, which can lead to bleeding into the chest or abdomen. Depending on the severity of bleeding, a surgical intervention may be required to rectify the problem.
- In some rare cases, the lungs may also be injured. Air may penetrate into the chest cavity ("pneumothorax"), which could make the insertion of a chest tube necessary.
- Rarely an injury to the diaphragm may occur, either directly or through damage to the phrenic nerve, which innervates the diaphragm.
- Rarely, an injury to the liver or other abdominal organs such as the bowel may occur. In such cases, surgery is usually necessary to repair the resulting damage.
- Rarely an inflammation of the pericardium may also occur. For this reason, we will administer antibiotics before performing the procedure. If you suffer from allergies to antibiotics, please let us know.
- Fatal complications associated with the placement of an epicardial access are very rare, but have been described in studies.

## **After the examination**

Immediately after the examination, we will conduct an ultrasound examination of the heart to rule out the late accumulation of blood in the pericardium.

**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: .....