

Information and patient informed consent form

## **Interventional catheter-based mitral valve reconstruction or replacement in severe mitral valve failure**

Dear Patient,

### **Details of the heart defect**

You have been diagnosed with an inability to close the valve between the left antechamber and main chamber - the so-called mitral valve (mitral valve failure). This results in a backlog of blood in the lungs. Typical symptoms are shortness of breath and weakness. This disorder can lead to heart failure or can exacerbate an existing case of heart failure.

### **Treatment options/variants**

- A) The **standard treatment** for this valve failure is **(open) cardiac surgical reconstruction** or the **replacement** of the mitral valve. This surgery achieves good results; however, it always requires the full or partial opening of the chest cavity and the use of a heart-lung machine.
- B) **An alternative** to the cardiac surgery is a **catheter-based (minimally invasive)** procedure which does not require the opening of the chest cavity and the use of a heart-lung machine.

Whether open heart surgery or a catheter-based minimally invasive procedure is selected depends on various factors such as age, previous diseases, concomitant cardiac diseases, anatomical conditions and any previous surgery. The Heart Team recommends the most appropriate procedure. The Heart Team comprises various specialists, notably cardiologists, cardiac surgeons and anaesthetists.

The recommendation for you is a catheter-based minimally invasive procedure (**variant B**).

Both procedures (open or catheter-based) are performed on an inpatient basis with hospitalisation expected to last for 3-5 days. There are two options for restoring the function of the valve:

The following information relates to the catheter-based minimally invasive procedure (variant B):

#### **1. Minimally invasive mitral valve reconstruction using a clip**

A catheter (stable hollow plastic tube, which serves as a guide in the vessel) is advanced or placed into the left atrium via the access in the femoral vein by puncturing the atrial septum. A type of clamp or clip (Figure 1) is guided through the catheter

to the mitral valve to the location of the leak. After the clip is in place, it is attached to both flaps of the mitral valve at the point of the inability to close. Both flaps are secured at this point and the valve's inability to close is improved. The closure function is tested during the procedure using radioscapy and a swallowing ultrasound via the oesophagus. If the outcome is not satisfactory, the clip can be reopened and the flap connected in another location or another clip can be implanted. If the outcome is positive - i.e. an adequate improvement in valve function is achieved - the clip is removed from the catheter. The clip then remains on the valve. The catheter is removed again. If no satisfactory outcome can be achieved for anatomical reasons, the clip can be removed during the procedure provided that it is connected to the catheter.

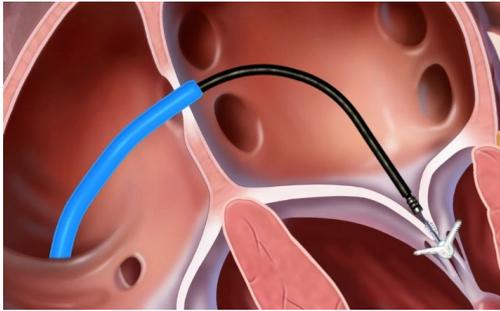


Figure 1: Clip opened under the flap.



Figure 2: Valve inserted over cardiac apex

### 1. Minimally invasive mitral valve replacement using a valve

If clipping of the valve is not possible for anatomical reasons, a replacement of the valve through the implantation of a new valve using a catheter is possible. The new valve can be implanted via the groin and through puncture of the atrial septum as with the clip, or via the jugular vein or the cardiac apex (Figure 2). The access route depends on the valve model. The new valve is embedded in the old valve. This means the leakage of the old valve is corrected. If the outcome is good, the valve is removed from the catheter. The new valve then remains in the old valve. The catheter is removed again. If no satisfactory outcome can be achieved, the valve can be removed during the procedure provided that it is connected to the catheter.

#### The following applies to both procedures (variant 1 and variant 2):

- They are usually performed under general anaesthesia due to the need for a longer swallowing ultrasound examination (transoesophageal echocardiography, echo through the oesophagus).
- Radioscapy is carried out. This means that there is exposure to a small amount of radiation but this is kept as minimal as possible. Therefore, such a procedure should only be carried out during pregnancy in an emergency.

#### Risks and complications of the procedure

**Bleeding:** A vessel injury may lead to bleeding. This bleeding may require surgery or even an emergency procedure. The administration of foreign blood may be required with all the related risks (e.g. allergic reaction, contamination with an infection). Bleeding can occur at the puncture site or in the blood vessel itself. Bleeding can also occur, for example, from stomach ulcers or other pre-existing sources of bleeding, since a certain amount of blood thinning is necessary after the procedure to prevent clots from forming on the clip.

Another source of bleeding can be the prolonged use of the ultrasound probe in the oesophagus during the procedure.

**Pericardial effusion/tamponade:** Due to the necessary puncture of the atrial septum, the heart wall may be injured and bleeding may occur in the pericardium. The blood may need to be drained or removed during surgery - even on an acute basis. In case of any bleeding, the administration of foreign blood may be required with all the related risks (e.g. allergic reaction, contamination with an infection).

**Separation and dislocation of the valve or clip:** Despite checks on the valve or clip position using radioscopy or ultrasound, there is no guarantee that the clip or valve will not separate either acutely or at a later date. The separated/dislocated clip or valve may block the blood vessels and may result in a stroke. In the event of separation, the clip or valve must be removed using a catheter-based or open procedure, as described above. If the closure ability of the valve deteriorates again, a new surgery must be attempted to remedy the valve failure.

**Infection:** Bacteria in the blood may lead to an infection around the clip or valve (endocarditis). An infection may occur during the procedure or at a later date. Therefore, an antibiotic will be administered during the procedure and you will be given a heart passport or endocarditis card afterwards. Antibiotic prophylaxis should also be given in future situations in which bacteria may enter the blood in significant numbers (e.g. knee surgery or root canal treatment). An infected clip or an infected valve must be removed surgically.

**Air displacement:** With the introduction of the catheter in the blood vessel, air may enter the blood vessel, which may lead to blockage of vessels and further consequences such as stroke, heart attack or shock.

**Cardiac arrhythmia:** The insertion of catheters in the cardiac cavities may lead to cardiac arrhythmia, which may require drug or electrical therapy.

**Atrial septum defect:** After puncture of the atrial septum, a small defect or hole may remain in the septum because it does not always heal on its own. Such a hole usually causes no symptoms and does not require treatment. The defect could also be closed using a cardiac catheter or heart surgery.

**Allergic reaction:** An allergic reaction to medicines, anaesthesia, disinfection material and other medical products may occur.

Other complications include damage to the cutaneous nerves or the worsening of heart failure.

In extreme cases, such complications may be fatal. Other specific

complications (to be completed by the doctor):

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## Advantages of a catheter-based procedure

The advantages arise from the fact that no open heart surgery has to be performed which means the associated risks (notably a (usually short term) deterioration of heart function, infection, lung, kidney or liver problems) and symptoms are avoided. There is also a shorter recovery time and an improvement in your symptoms and health can be expected.

## Selection of the procedure

The following procedure is recommended for you:

- Minimally invasive mitral valve reconstruction using a clip
- Minimally invasive mitral valve reconstruction using a valve

Please speak to us if there is something you don't understand or if something important occurs to you that is not covered in this letter or in your personal consultation with your doctor.

## Informed consent regarding data collection and analysis

I agree that data regarding my procedure and my medical history, gender and date of birth may be collected and assessed for quality assurance purposes and scientific evaluation in an encrypted electronic form. I have been informed of the scope and purpose of the data collection and assessment. All of my questions have been answered. I have been informed that my decision to consent to or to not consent to data collection and assessment will have no influence on my treatment. I am aware that I may withdraw my consent at any time without providing reasons for this.

- YES, I consent to my personal data being transferred to a register.
- NO, I do not consent to my personal data being transferred.

## Declaration of consent

I confirm with my signature that today I spoke to Dr ....., and, using this information form, I have been informed about the procedure, its purpose, the indication for the procedure and possible treatment alternatives, the procedure itself, the contraindications, the risks and possible complications, any necessary intraoperative surgical modifications or extensions and the recommended postoperative behaviour during an information and explanation session. I have been informed that Basel University Hospital is a training facility and that trainee doctors assist in the procedures and also carry out certain surgical steps themselves according to their level of experience, but that supervision by experienced doctors is always guaranteed. The doctor providing the information will not necessarily be performing the procedure.

I have understood the information and been able to ask any questions. I do not have any further questions. After having my questions answered, I confirm with my signature that I agree to the performance of the proposed procedure.

Patient's signature: \_\_\_\_\_

Doctor's signature: \_\_\_\_\_

Place and date: \_\_\_\_\_