PATIENT DETAILS or LABEL

FIRST NAME, SURNAME DATE OF BIRTH

STREET

POSTCODE, CITY

PATIENT INFORMATION AND INFORMED CONSENT FOR MINIMALLY INVASIVE HETEROTOPIC TRICUSPID VALVE IMPLANTATION (BICAVAL VALVE REPLACEMENT, CAVI)

Dear patient,

You have a leakage of the tricuspid valve (tricuspid insufficiency). This valve defect causes the blood to flow backwards from the right ventricle into the atrium and the vena cava (Figure 1). As a direct result of the disorder, the heart is strained by the additional blood volume and blood pressure increases in the inferior and superior vena cava, impairing the function of other organs (e.g. liver, intestines) and leading to complications. Other symptoms of tricuspid insufficiency can be severely restricted physical endurance, breathlessness or frequent water retention in the abdominal cavity and the legs. The most successful treatment consists of replacing the tricuspid valve with an artificial valve in a surgical procedure. When left untreated, there is the risk of increasing heart failure along with a growth in the aforementioned complaints and a reduced life expectancy (Figure 1).

Based on previous operations on the heart and several serious accompanying diseases, however, in your individual case the risk is considerably higher during a conventional operation according to the assessment of the attending doctors. Following detailed discussion of your examination results and findings with all specialist areas involved, a conventional operation could not be performed or could only be performed with extremely high risk. There are currently no effective alternative treatments, even treatment with medication may not alleviate your symptoms in the long term.

A possible alternative treatment is implantation of two heart valve substitutes in the inferior and superior vena cava guided by catheters (Figure 2). In contrast to valve replacement surgery, these substitutes are embedded in the vena cava with the help of a catheter in the immediate vicinity of the heart. The procedure is currently under development, which means that there is currently

only limited experience in applying this treatment to humans. A reduction in the backflow of blood into the vena cava was achieved in patients previously treated with this procedure. Experience has shown that the heart valve substitutes can be used without problems, still the procedure has to be considered as investigational and is currently only used within clinical trials.

The treatment procedure takes place under the conditions of a treatment attempt, i.e. subject to individual examination in the event of lacking treatment alternatives. The following **risks** of the operation are known based on data collected thus far and may materialize despite the greatest care:

- Damage to vessels caused by the implantation catheter or the valve replacements. Internal bleeding of the vascular wall as well as perforations may occur which
    - may require an operation or transfusion of blood products
    - may lead to life-threatening bleeding
- Formation of blood clots (thrombus) that can form on the heart valve. Dislodging and displacement of a blood clot may lead to an embolism.
- Serious cardiac arrhythmia which may require defibrillation
- Heart failure due to the potential increase of stress on the heart in the event of implantation of a functioning valve replacement, which may require longer intensive care and hospital treatment.
- Unexpected device failure or device migration

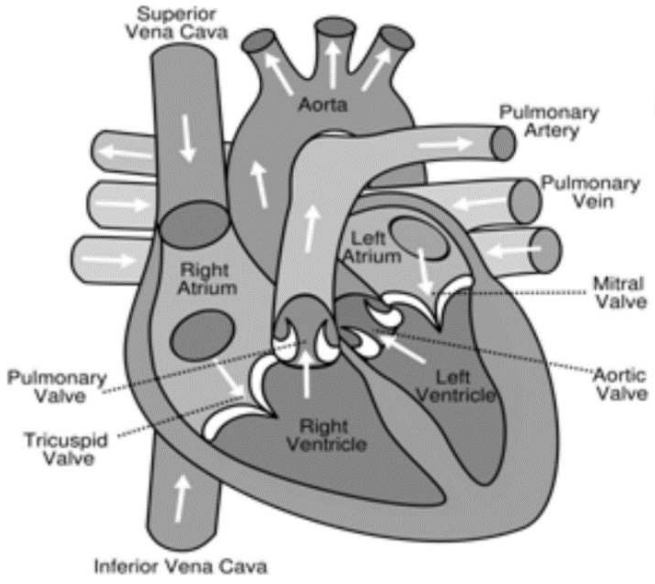

Figure 1

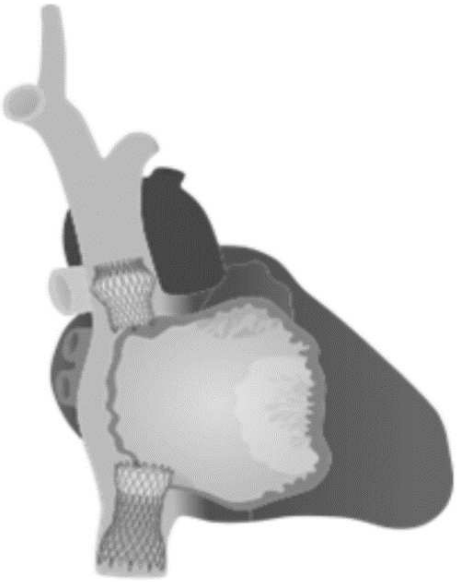

Figure 2

Despite the greatest care in the production of the valve replacement and the catheter as well as the treatment procedure, the success of the treatment cannot be predicted, meaning that alleviation of the symptoms and improvement of the physical capacity is not guaranteed.

Space for additional comments:

DECLARATION OF CONSENT

I have been provided with detailed information on the planned treatment in an informed consent discussion. All important questions I had regarding the nature and significance of the treatment, specific risks and possible complications as well as treatment alternatives have been answered. I am aware that the planned operation is a treatment attempt. I have no further questions, I feel adequately informed and hereby consent to the planned treatment following a sufficient period of reflection. I also agree to additional and follow-up measures required during the operation.

I have been informed that I can withdraw my consent at any time without giving a specific reason.

Patient's name, signature

date, place

Physician's name, signature

date, place