Informed consent for catheter treatment of wall defects between the right and left heart cavities, i.e. atrial septal defect, closure of an patent foramen ovale (ASD, PFO), or a ventricular septal defect (VSD)

I have been informed about the planned procedure and agree to it.

I have been informed about the purpose, the success rate, risks of the procedure as well as other treatment options. I know that during the catheter treatment my doctor may have to take additional measures, depending on the situation, in order to achieve the best possible result. In particular, this may require the use of an ultrasound examination through the esophagus (transesophageal echocardiography) or an ultrasound examination in the heart (intracardiac ultrasound examination).

I am aware that in a few cases, the placement of the umbrella is not possible and an emergency or planned surgical treatment must follow. I am aware that in rare cases (< 1 %) the umbrella may become detached shortly after insertion and must then be removed from the heart or a blood vessel using a catheter or surgery. I know that the procedure requires treatment with anticoagulant medication for six months. Other serious complications include air embolism or injury to blood vessels. Overall, these occur very rarely (< 1%). I know that in some cases temporary arrhythmia might be present after the umbrella implantation, which must be treated with medication.

I have been informed that in a few cases, a gap may persist and a second procedure may be necessary.

I was also made aware of the general risks of a cardiac catheterization. I know that bleeding, e.g. at the insertion site, and disturbances of the heart rhythm can occur and must be treated. Other serious complications (severe allergy to the medication used, circulatory disorders of the arteries and clot formation in the arteries, kidney disorders, strokes, etc.) occur in less than 1% of patients.

As there is a small risk of bacterial infection, I will be given an antibiotic and will have to take antibiotics for a few months as a preventive measure in the event of dental or other procedures or febrile illnesses.

I have understood the information given to me.

My questions were answered satisfactorily.

Place / Date ..... Place /Date .....

Signature patient: Signature Physician:

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