

HEART VALVE OPERATION MINIMALLY INVASIVE

HERZKLAPPEN-OPERATION MINIMALINVASIV

Information and history for patients in preparation of the required explanatory appointment with the physician

┌ Clinic / Practice : [Klinik / Praxis]



┌ Patient data: [Patientendaten]:

englisch

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The operation is scheduled for (date): [Der Eingriff ist vorgesehen am (Datum)]

Dear Patient,

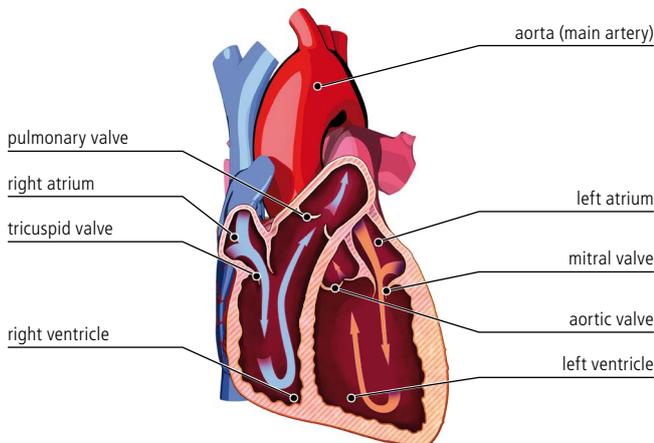
It has been determined that your complaints of weariness, feelings of weakness, laboured breathing and even loss of consciousness or irregular heart rhythm are due to dysfunction of one or more heart valves. This dysfunction is to be treated with a minimally invasive technique.

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

CAUSES AND TYPES OF VALVE DISEASES

URSACHEN UND ARTEN DER KLAPPENERKRANKUNGEN

The heart consists of 2 atria and 2 ventricles. Four heart valves that function like doors ensure that blood flows through the heart in only one direction.



Heart valve disorders can be inherited or acquired. Most heart valve abnormalities do not arise until adulthood. The causes can be bacterial infections and inflammations of the heart, calcifications or other heart diseases. These cause a heart valve to change so that it no longer closes properly (valve insufficiency) and/or becomes stiff and inflexible and narrows (valve stenosis). The result is impeded blood flow through the heart and frequently blood congestion in the body or lung circulatory system. In order to compensate for this, the heart at first pumps harder. Consequently, the heart muscle thickens over time and the heart's performance declines. Shortness of breath with bodily exertion can be a first sign of valve disease. If the disease progresses, problems such as chest pain and laboured breathing with the lips turning blue can arise even at rest. In addition, there are frequently accumulations of water (oedema) in the legs and organs, especially in the liver and lungs. At the last stage there is danger

of irregular heart rhythm with sudden loss of consciousness or even life threatening heart failure.

The heart valve operation should preferably be performed before the heart muscle has been damaged appreciably.

COURSE OF THE VARIOUS PROCEDURES

ABLAUF DER VERSCHIEDENEN VERFAHREN

Selection of the operative procedure suitable for you will depend on a number of factors, including the type and severity of your heart valve disease, in addition to your age and general condition.

The operation is carried out while the patient is under general anaesthesia. This will be explained to you separately as applicable. During the operation, your organ functions will be monitored without interruption and if there are any problems, remedial action will be taken immediately.

Usually, an incision is made in the groin, a vein and an artery are exposed, and two plastic tubes, called cannulas, are advanced up to the abdominal aorta and the right atrium of the heart respectively and then connected to a heart-lung machine.



After thorough disinfection and draping, the surgeon creates an access to the heart by placing an incision between the ribs on the side of the ribcage, or else in the middle of the chest.

In many cases the surgeon then makes a second small opening between the ribs and inserts a small camera, called an endoscope, into the chest so that it transmits images of the interior of the body to a monitor.

In order to interrupt the flow of blood through the heart, the surgeon clamps off the aorta through a small incision between the ribs and stops the heart by injecting a medication. The heart-lung machine performs the work of the heart and lungs and supplies oxygen to the body during the operation.

Basically, the following surgical treatments are available:

Valve reconstruction (repair)

Klappenrekonstruktion (Wiederherstellung der Klappe)

With this approach, the valve is retained. Adhesions and agglutinations are detached and calcium deposits are removed to restore the function of the valve. Overstretched or torn chordae tendineae (chord-like tendons), which, for example, in the case of the mitral valve cause the valvular cusp to go back into the atrium, are replaced by artificial tendon material. With prolapse of a valvular cusp, the prolapsed tissue can be cut out and the cusp resewn and made taut again. If the valve ring is stretched, a ring can be placed around the edge of the valve to hold the valve in form.

Valve replacement **Klappenersatz**

The diseased valve is removed and replaced by a prosthesis. Therefore there are different types of valve prosthesis available.

Mechanical valves (e.g. of plastic or metal) **Mechanische Klappen**



They last for decades and hardly wear down. However, when a mechanical valve has been installed, lifelong intake of anti-coagulant medications is required.

Biological valves **Biologische Klappen**



(of tissue of human [homograft] or animal [xenograft] origin). These valves last only for a limited amount of time and might have to be replaced after a couple of years, depending on the type of

valve, the patient's age and other diseases and individual risk factors. However, with these valves it is not necessary for the patient to take anti-coagulant medications after the healing phase.

Once the new or reconstructed valve is able to work, the heart is de-aired and the clamp on the aorta is removed. In most cases the heart will then start to beat again by itself. If necessary, the heart beat can be stimulated electrically via cardiac pacemaker cables.

As soon as the heart is beating firmly again, the cannulas attached to the heart-lung machine are removed and thin plastic tubes, called drains, are placed in the chest. These serve to divert wound secretions to outside the body.

Finally, the openings in the ribcage and the groin are closed and covered with a sterile dressing. Pacemaker cables and drains will be removed by your physician in a few days.

POSSIBLE SUPPLEMENTARY MEASURES

MÖGLICHE ERWEITERUNGSMASSNAHMEN

During the operation it can become evident that it is necessary to switch to a different procedure. For example, from a planned valve reconstruction to valve replacement, or even from a minimally invasive operation to one with the breast bone cut vertically to open the chest ("open operation"). If there is no other choice and the risk of a second operation is too great, your physician will carry out the necessary supplementary measures.

ALTERNATIVE PROCEDURES **ALTERNATIV-VERFAHREN**

Various medications can be applied in an attempt to lessen the burden on the heart or reduce accumulations of water in the legs or lungs. Medications can also be applied to alleviate irregular heart rhythm. In some cases it is possible to expand the constricted valves or even to implant an aortic valve prosthesis by means of a catheter procedure. The valve can also be replaced or reconstructed in an open operation with complete separation of the breastbone.

Your physician will be glad to explain why a minimally invasive heart valve operation is advisable in your case.

PROSPECTS OF SUCCESS **ERFOLGSAUSSICHTEN**

The heart valve operation can improve the capacity of your heart to perform and increase the quality of your life. Many patients have no complaints for a long time and lead a virtually normal life.

The success of this treatment will be greatly dependent on the severity and duration of your aortic valve disease as well as on the degree of damage of your heart muscle.

Over the long term, a biological heart valve can calcify again or one of the other heart valves can become diseased, so that another operation might be necessary.

PREPARATION AND POST-OPERATIVE CARE

HINWEISE ZUR VORBEREITUNG UND NACHSORGE

Please strictly follow the instructions of the physician and of the nursing personnel. Unless they have arranged otherwise, the following instructions shall apply.

Preparation:

Medication: Please inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASS], Marcumar®, Heparin, Plavix®, Ticlopidin, Clopidogrel, Eliquis®, Lixiana®, Xarelto®, Pradaxa® and metformin-containing antidiabetic medicines, so-called biguanides) or have taken irregularly over the course of the past eight days prior to the procedure (for instance pain killers such as ibuprofen, paracetamol). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know if and for how long you should stop taking your medication.

Post-Operative Care:

After the operation your bodily functions will be monitored for a few days in an intensive care unit. When your vital functions are stable again, you will be moved to a general care unit.

During the first few days, the operation wounds cause pain that can be alleviated well with medications. There can also be early pain in the shoulder that can be uncomfortable, but this is likely to go away without treatment.

You will be shown some physical therapy exercises for strengthening your muscles and stabilising your circulation. Please be sure to practise them conscientiously.

Please be sure to inform your physician immediately in the event of any complaints such as pain while breathing, heart problems, respiratory or circulatory disorders, fever or tingling or numbness. Such complaints can also occur several days or weeks after the operation. They must be treated immediately.

After a heart operation, some patients suffer from a depressive mood. If you notice such a change in yourself, do not hesitate to speak about it. Your physician will be able to offer you various types of assistance, as required.

Please take the blood thinning medications prescribed exactly as directed and have your blood clotting values checked on schedule.

Please have your heart valve pass, and your Marcumar pass if you have one, on your person at all times and show them to your attending physicians.

Chronic foci of inflammation, for example at teeth, must be treated. Bacterial infections of the breathing passages, the urinary tract and the jaw, which are otherwise harmless, must be treated early with antibiotics as a precaution against infections of the inner lining of the heart and the heart valve. Medical procedures that can lead to passage of bacteria into the bloodstream, such as, for example, root canal treatment, must be preceded by administration of antibiotics as a precaution.

Mechanical valves cause a clicking sound when they shut. Some patients feel hindered by this even after they have had time to become familiar with it.

You must be sure to follow the instructions of your physician regarding other activities such as, for example, taking other medications and physical exertion.

RISKS, COMPLICATIONS AND SIDE EFFECTS

MÖGLICHE RISIKEN, KOMPLIKATIONEN UND NEBENWIRKUNGEN

It is well known that **any medical procedure is accompanied by certain risks**. If complications occur, they may sometimes require additional treatment or surgery and, in extreme cases, can sometimes even be **life-threatening** or lead to permanent damage – even after some time. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You may also choose to waive a detailed explanation. In that event, please pass over this section on risks and confirm your waiver with your signature in the final section of this form.

Disoriented state, speech disorders, memory loss and lacks of concentration can occur after the operation, but are likely to recede by themselves after a few days.

Infections, for example with necrosis (tissue death) and formation of scars, injection abscess or vein inflammation (phlebitis) in the area of the operation wound or at the entry point of injection needles may occur. A septic wound expresses itself in swelling, reddening, pain, excessive warmth in the skin and fever. Infections are easily treated with antibiotics in most cases. A surgical treatment is necessary if there is an infection of the breastbone or chest area or if the infection cannot be brought under control with antibiotics. An infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia).

With delayed wound healing or in patients with a predisposition to **impaired wound healing** there can be painful formation of scars and overgrowths (keloids).

Allergic reactions, for instance to medication or latex, can lead to skin rash, itching, swelling, nausea and coughing. Severe reactions such as shortness of breath, spasms, tachycardia or **life-threatening circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage, paralyses or kidney failure requiring dialysis.

In rare cases, **nerves** or **major blood vessels** can be **injured**. Injuries to blood vessels can lead to impaired circulation and necrosis (death) of soft tissue.

Blood clots (thromboses) can form and lead to obstruction of a vessel. Blood clots may also travel to other parts of the body and block the vessels of other organs (**embolism**). This may then lead to e.g. **stroke, kidney failure** requiring dialysis or **lung embolism** and result in permanent damage. If anticoagulant agents are administered to prevent formation of blood clots, the risk of bleeding or post-procedure bleeding is increased. If Heparin is administered, it may lead to a severe immune response (HIT) involving clotting of the platelets (thrombocytes) and obstruction of veins and of arteries.

During the operation, the reduced blood circulation through the heart muscle can lead to a **heart attack** in rare cases. Most of these attacks are recognized at once and treated.

If air finds its way into a blood vessel during the operation, an air embolism can form, possibly disrupting blood supply and causing major circulatory disorders.

Bleeding is generally recognized at once and stopped. With high losses of blood it might be necessary to administer a **transfusion**

of blood or blood components from another person. In very rare cases, this can lead to transmission of diseases, such as hepatitis (inflammation of the liver), HIV (AIDS), BSE (brain disease) or also of other dangerous – even unknown – diseases. Lung oedema leading to lung failure, a decrease in kidney function or other dangerous immune responses can be triggered. A prior donation of the patient's own blood is generally not advisable.

Blood accumulations (haematomas) occur occasionally and can cause formation of hard, painful swellings. Most of them disappear by themselves without treatment after a few days or weeks.

Late bleeding of the heart can cause blood to accumulate in the heart sac (pericardium) and interfere with the heart's functioning as a pump. Then a pericardial tap is necessary and drains must be placed, or the heart sac must be opened in an operation.

Irritation of the heart sac during the operation can lead to **inflammation of the heart sac**. Then it can be necessary to place a drain.

In open surgery on the chest, a rib spreader is used, which may lead to **rib fractures**.

After the operation, air can penetrate into the chest (**pneumothorax**), fluids can accumulate (**pleural effusion**) or a lung might fail to expand completely. These conditions can cause coughing, disquiet, outbreaks of sweat, increased pulse and respiratory distress (laboured breathing). If conservative treatments such as breathing therapy and administration of diuretic medications do not suffice, then it can be necessary to perform a tap or to place a suction drain.

Damage to the **skin, soft tissue or nerves** (for instance through injections, disinfectants, electrical surgical instruments heating pads, or despite proper bedding) is possible. Numbness, paralysis and pain may then result. They are usually temporary. In some cases, permanent nerve damage, tissue death or scarring may occur.

For a certain amount of time after the operation, the heart might be too weak to maintain blood circulation (**heart failure**). **Irregular heart rhythms** also occur frequently. These problems can usually be treated well with medications. However, it can also be necessary to temporarily support the heart with a special pump or to implant a defibrillator or pacemaker, possibly on a permanent basis.

During or after the operation there can be a **drop in blood pressure** or **disruptions of blood supply**. In extremely rare cases this can lead to **damage of the optic nerve with loss of sight**, possibly in both eyes.

When a heart-lung machine is used, the resulting contact of blood with foreign bodies can release signalling substances that trigger an immune response in the entire body and can lead to life threatening organ failure. Moreover, microscopically small blood clots, air bubbles or loose vascular wall calcium deposits can find their way into the brain and cause **disruptions of brain performance** or even a **stroke**, possibly with permanent **paralyses**. Occluded blood vessels can also **disrupt the blood supply** to the **arms and legs**. But functional disturbances can also result at other organs such as the liver, the gall bladder, the pancreas and the intestines; most of these can be treated with conservative measures. Moreover, if the **kidneys** had already suffered damage before the operation, they might develop **functional disorders** or even **fail completely**, in which case temporary or, in the worst case, permanent dialysis can become necessary. Also, a **lung** that did not receive a sufficient supply of blood during the operation can react with an **inflammation** or **functional disorder**.

Injuries to nerves, such as the vocal chords nerve, the diaphragm nerve and the brachial plexus (originates near the neck and shoulders) lead to speech disorders, hoarseness, laboured breathing and paralysis of an arm which are usually temporary and rarely permanent.

Breathing disorders, for example because of weakness of the diaphragm, can make it necessary to use mechanical respiration in the intensive care unit. This can give rise to an inflammation of the lungs.

Possible late complications

If a heart valve was replaced, the **stitches** can become **loose** or break. If a heart valve was reconstructed, there can be a recurrence of **pathologic narrowing or malfunction**. In both cases it can be necessary to perform another operation.

Small **blood clots** can form on the artificial surface of the mechanical heart valves and interfere with its function or they can obstruct a blood vessel if they break free and are transported. This risk exists in the first few months even in the cases of biological valves and valve reconstruction. The result, for example, can be a stroke. An anti-coagulant medication can be taken to reduce this risk.

Questions about Your Medical History

Please fill in the following questionnaire carefully before your information talk. **Please tick the applicable box!** It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects.

yes=ja no=nein

Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days? yes no

- Aspirin® (ASS), Brilique®, Clopidogrel, Efient®, Eliquis®, Heparin, Iscover®, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.

Angaben zur Medikamenteneinnahme: Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Aspirin® (ASS), Brilique®, Clopidogrel, Efient®, Eliquis®, Heparin, Iscover®, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.

Any other: _____
Sonstiges:

When did you take the last dose? _____
Wann war die letzte Einnahme?

Do you take any other medications? yes no

Werden andere Medikamente eingenommen?
If so, which ones: _____
Wenn ja, bitte auflisten:

(Please include non-prescription medications, herbal and other natural remedies, vitamins, etc.) (Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)

Have you ever had an operation in the chest area or on your heart? yes no

Wurden Sie schon einmal im Brustbereich oder am Herzen operiert?

If so, which operation? _____
Wenn ja, welche Operation?

Are you pregnant? not certain yes no

Sind Sie schwanger?

nicht sicher

Are you currently breast feeding a baby? yes no

Stillen Sie?

Do you smoke? yes no

If so, what and how much daily: _____
Rauchen Sie? Wenn ja, was und wie viel täglich:

Do you have or have you ever had any of the following diseases or symptoms thereof:

Liegen oder lagen nachstehende Erkrankungen oder Anzeichen dieser Erkrankungen vor:

Blood diseases / blood clotting disorders? yes no

Increased bleeding tendency (e.g. frequent nose bleeds, increased post-operative bleeding, increased bleeding from minor injuries or after dentist treatment, stronger or longer menstrual bleeding), tendency to bruise (frequent bruising possibly for no particular reason).

Bluterkrankung/Blutgerinnungsstörung? Erhöhte Blutungsneigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung, verstärkte oder verlängerte Regelblutung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).

Do you have any blood relatives with signs of blood disease / clotting disorders? yes no

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

Have you ever received a blood transfusion? yes no

Haben Sie schon einmal eine Bluttransfusion erhalten?

If so, when? _____
Wenn ja, wann?

Were there any complications? yes no

Ergaben sich dabei Komplikationen?

If so, which ones? _____
Wenn ja, welche?

Blood clot (thrombus) / blood vessel occlusion (embolism)? yes no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Allergies / Oversensitivity? yes no

Medications, foods, contrast media, iodine, sticking plaster, latex (e.g. rubber gloves, balloons), pollen (grass, trees), anaesthetics, metals (itching caused by metal spectacles frames, jewellery, jeans buttons).

Allergie/Überempfindlichkeit? Medikamente, Lebensmittel, Kontrastmittel, Jod, Pflaster, Latex (z.B. Gummihandschuhe, Luftballon), Pollen (Gräser, Bäume), Betäubungsmittel, Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten).

Any other: _____
Sonstiges:

Diseases of the respiratory tract (breathing passages) or lungs?

 yes no

Asthma, chronic bronchitis, inflammation of the lungs, emphysema, sleep apnoea (intense snoring with breathing interruptions), vocal cord/diaphragm paralysis.

Erkrankung der Atemwege/Lungen? Asthma, chronische Bronchitis, Lungenentzündung, Lungenemphysem, Schlafapnoe (starkes Schnarchen mit Atemaussetzern), Stimmband-Zwerchfelllähmung.

Any other: _____
Sonstiges:

Metabolic diseases?

 yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
Sonstiges:

Thyroid diseases?

 yes no

Underactive thyroid, overactive thyroid.

Schilddrüsenerkrankungen? Unterfunktion, Überfunktion.

Any other: _____
Sonstiges:

Kidney diseases?

 yes no

kidney insufficiency, kidney inflammation.

Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung.

Any other: _____
Sonstiges:

Predisposition to impaired wound healing, abscesses, fistulas, excessive scar formation (keloids)?

 yes no

Neigung zu Wundheilungsstörungen, Abszessen, Fisteln, starker Narben-Bildung (Keloide)?

Communicable (contagious) diseases?

 yes no

Hepatitis, tuberculosis, HIV.

Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any other: _____
Sonstiges:

Any other acute or chronic diseases / illnesses?

 yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe:

Bitte kurz beschreiben:



Medical Documentation of Explanatory Appointment

Ärztl. Dokumentation zum Aufklärungsgespräch

To be filled in by the physician Wird vom Arzt ausgefüllt

During the explanatory appointment I explained the following subject matter to the patient in detail (e.g. possible complications that can result from the risks specific to the patient, details of the alternative methods and possible consequences if the operation is postponed or refused.)

Über folgende Themen (z.B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativ-Methoden, mögliche Konsequenzen, wenn der Eingriff verschoben oder abgelehnt wird) habe ich den Patienten im Gespräch näher aufgeklärt:

Planned is: Geplant ist:

- Reconstruction of heart valve Rekonstruktion der Klappe
- Replacement of heart valve Ersatz der Klappe
- Mechanical valve mechanische Klappe
- Biological valve biologische Klappe

Patient's ability to take an independent decision on granting consent: Fähigkeit der eigenständigen Einwilligung:

- The patient is capable of making an independent decision regarding the recommended treatment and giving his/her consent to the procedure. Die Patientin/Der Patient besitzt die Fähigkeit, eine eigenständige Entscheidung über die empfohlene Maßnahme zu treffen und ihre/seine Einwilligung in das Verfahren zu erteilen.
- The patient is represented by a **custodian** with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. This person is capable of making a decision in the best interest of the patient. Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese ist in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.
- Custodian's card healthcare proxy advance healthcare directive has been submitted.
- Betreuerausweis Vorsorgevollmacht Patientenverfügung liegt vor.
- Since there is no advance healthcare directive and since the necessary surgical intervention is extensive, permission has been obtained by the competent German guardianship court (Betreuungsgericht). Da keine Patientenverfügung vorliegt, wurde aufgrund der Schwere des Eingriffs die Genehmigung des Betreuungsgerichts eingeholt.

Copy for patient: yes no

Kopie für Patient: ja nein

Place, Date and Time [Ort, Datum, Uhrzeit]

doctor's signature [Unterschrift der Ärztin / des Arztes]

Refusal Ablehnung

The doctor _____ has given me a full explanation of the operation recommended for me and of the disadvantages that will result from my refusal. I have understood this explanation and refuse the operation that has been proposed for me.

Die Ärztin/Der Arzt _____ hat mich umfassend über den bevorstehenden Eingriff und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne den empfohlenen Eingriff ab.

Place, Date and Time [Ort, Datum, Uhrzeit]

Refusal of patient / legal guardian / witness
[Ablehnung der Patientin / des Patienten / Betreuer / ggf. des Zeugen]

DECLARATION AND CONSENT EINWILLIGUNGSERKLÄRUNG

Please mark the applicable boxes and then confirm the resulting declaration with your signature. Bitte kreuzen Sie die zutreffenden Kästchen an und bestätigen Sie Ihre Erklärung anschließend mit Ihrer Unterschrift:

- I hereby confirm that I have understood all the parts of this explanation for patients. I have read this explanatory document (6 pages) in its entirety. During my explanatory appointment, the doctor _____ has given me a comprehensive explanation of the heart valve operation scheduled for me, its risks, complications and side effects in my specific case, and the advantages and disadvantages of the alternative methods.

Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe. Diesen Aufklärungsbogen (6 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit der Ärztin/dem Arzt _____ wurde ich über den Ablauf der geplanten Herzklappen-Operation, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.

- I have seen and understood the film about the heart valve operation that has been scheduled for me.

Den Informationsfilm über die bei mir geplante Herzklappen-Operation habe ich gesehen und verstanden.

- I hereby deliberately waive my rights to more detailed explanations. However, I also confirm that I have been informed by the doctor _____ of the necessity of this operation, of its type and extent, and of the fact that this operation has its risks.

Ich verzichte bewusst auf eine ausführliche Aufklärung. Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt _____ über die Erforderlichkeit des Eingriffes, dessen Art und Umfang sowie über den Umstand, dass der Eingriff Risiken birgt, informiert wurde.

- I affirm that I have **no further questions** and do **not need any more time** in which **to think the matter over. I consent to the recommended heart valve operation.** I also consent to all required auxiliary and follow-up measures (e.g. blood transfusions, mechanical ventilation (breathing)). I have answered the questions about my medical history in full and to the best of my knowledge.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Herzklappen-Operation zu. Ich willige ebenfalls in alle notwendigen Neben- und Folgemaßnahmen (z.B. Bluttransfusion, Nachbeatmung) ein. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

My approval also covers all required changes or extensions of the operation, if any, such as a switch from reconstruction to replacement of the heart valve, or from the minimally invasive to the open operation.

Meine Einwilligung bezieht sich auch auf die erforderlichen Änderungen oder Erweiterungen des Verfahrens, z.B. das Umsteigen von einer Rekonstruktion auf einen Klappenersatz oder von der minimal-invasiven zur offenen Operation.

I affirm that I am in a position to follow the medical instructions I have received in regard to what is expected of me.

Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

If treatment is subject to an elective service agreement (referred to as treatment by senior consultant), the patient's consent also applies to the procedures being carried out by the senior consultant's permanent representatives as specified in the elective service agreement. Im Falle einer Wahlleistungsvereinbarung (sog. Chefarztbehandlung) erstreckt sich die Einwilligung auch auf die Durchführung der Maßnahmen durch die in der Wahlleistungsvereinbarung benannten ständigen ärztlichen Vertreter des Wahlarztes.

- I agree that my copy of this explanatory form may be sent to the following e-mail address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

e-mail address [E-Mail-Adresse]

Place, Date, Time [Ort, Datum, Uhrzeit]

Signature of patient / legal guardian(s) [Unterschrift Patientin / Patient / Betreuer / Vormund]