

OPEN HEART VALVE OPERATION

HERZKLAPPEN-OPERATION OFFEN

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

Clinic / Practice [Klinik / Praxis]



Patient data: [Patientendaten:]

englisch

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

Dear Patient,

We have ascertained that your complaints such as fatigue, feelings of weakness, laboured breathing and possibly loss of consciousness or possibly irregular heart rhythm are to be attributed to a functional disorder of one or more heart valves. This disorder is to be treated by means of an operation.

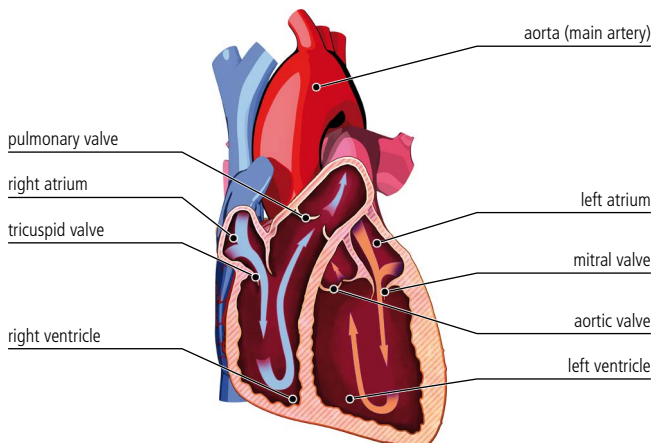
By providing the explanations below, we wish to inform you and your family of the various surgical procedures, the possible complications, and what you should do before and after the operation. You might be shown a short film. This form and the film are designed to prepare you for the explanatory appointment with your physician. He or she will describe the advantages and disadvantages of the procedure selected for you relative to those of alternative methods and explain and clarify the risks that apply to your case and the complications that can ensue. Please read the following explanations and fill in the questionnaire with care. Of course, the information you provide will be treated as strictly confidential.

Your physician will also answer all of your questions to help relieve you of worry and fear. At the end of your explanatory appointment you can give or refuse your consent to performance of the operation recommended for you. Your physician will give you a copy of the completed, signed form at the end of your explanatory appointment.

CAUSES AND TYPES OF VALVE DISEASE

URSACHEN UND ARTEN DER KLAPPENERKRANKUNGEN

The heart consists of four hollow chambers, namely 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 abnormalities 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 stricture). The result is impeded blood flow through the heart and frequently blood congestion in the systemic or lung circulation. 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 heart 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 organs, especially in the liver, in the lungs and in the legs. At the last stage there is danger of irregular heart rhythm with sudden unconsciousness 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, the number of heart valves affected and your age and general condition.

Heart valve operations are carried out under general anaesthesia. This will be explained to you separately. During the operation, your organ functions will be monitored without interruption and if there are any problems, remedial action will be taken immediately. In principle, there are the following possibilities for treatment.

Valve Reconstruction (Restoration of the valve)

Klappenrekonstruktion (Wiederherstellung der Klappe)

With valve reconstruction, the valve is retained. The function of the valve is restored by loosening adhesions and agglutinations and removing calcium deposits. Overstretched or torn tendons which, for example, in the case of the mitral valve cause the valvular leaflet to be pushed back into the atrium, are replaced by artificial tendinous material. With protrusion of a valvular leaflet (prolapse), the leaflet can be cut out and re sewn and leaflet thereby made taught.

If the valve ring is extended or flaccid, a ring can be inserted at the boundary of the valve to keep the valve in form.

Valve Replacement Klappenersatz

The diseased valve is removed and replaced by a prosthesis. Various valve models are available for this.

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



hold up for decades and are hardly subject to wear and tear. However, then the patient must take anticoagulant medications for the rest of his or her life.

Biological valves Biologische Klappen (of tissue of human [homo graft] 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, it is not necessary to take anticoagulants once the healing phase is over.

- Valve from patient's body** (Autograft) **Körpereigene Klappe:** A diseased aortic valve (outflow valve from the left ventricle to the body's circulatory system) can also be replaced by the pulmonary valve (outflow valve from the right ventricle to the lung's circulatory system) by means of the so-called Ross operation. Then, during the same operation, the pulmonary valve is replaced by tissue from the patient's own body or from an animal. This method is especially suitable for young patients because if they were given a mechanical prosthesis they would have to take anticoagulant medications for their entire life.

The operation proceeds as follows. After thorough disinfection and draping, the chest is opened through an incision along the middle of the breastbone, and the heart is exposed. The heart is attached to a heart-lung machine by means of two plastic tubes. In order to interrupt the flow of blood through the heart, the surgeon clamps off the aorta and the heart is stopped by injection of a medication. The machine takes over the job of the heart and the lungs to provide the body with oxygen during the operation.

After the operation, the heart is supplied with blood and begins to beat again, possibly upon stimulation by electrical impulses. When the heart's beat is regular, the heart is allowed to take over from the machine step by step.

It can be necessary to regulate the heartbeat with a temporary pacemaker. Thin pacemaker cables are attached to the heart muscle and run through the skin to outside the body. Drains (thin plastic tubes) are placed in the patient's chest to divert wound secretions to outside the body. The pacemaker cables and drains can be removed a few days later.

After the operation, the breastbone is closed with wires and the wound in the chest is stitched together and provided with a sterile dressing.

POSSIBLE SUPPLEMENTARY MEASURES

MÖGLICHE ERWEITERUNGSMASSNAHMEN

During the operation it can become evident that further operations on the heart are necessary; for example: reconstruction or replacement of further heart valves, installation of one or more bypasses, closure of a cardiac septum defect, correction of blood vessel protrusions (aneurysms) or a switch from valve reconstruction to valve replacement. If there is no other choice and the risk of a second operation is too great, the additional necessary procedures will be carried out. If such a possibility can be foreseen, your physician will advise you accordingly.

ALTERNATIVE PROCEDURES

ALTERNATIV-VERFAHREN

Various medications can be applied in an attempt to lessen the burden on the heart or reduce collections of water in the legs or lungs. Medications can also be applied to alleviate irregular heart rhythm. In some cases, narrowed valves can be opened or even a new valve implanted by means of a minimally invasive procedure.

Your physician will be glad to explain to you why an open heart valve operation is advisable in your case.

PROSPECTS OF SUCCESS

ERFOLGSAUSSICHTEN

A valve operation can improve the capacity of your heart to perform and increase the quality of your life. Many patients still have no complaints and lead a largely normal life for many years after the operation.

The success of this treatment will depend significantly on the severity and duration of your heart valve disease as well as on the degree of damage to your heart muscle.

Over the long term, a biological heart valve can calcify again or some other heart valve can become diseased so that another operation is necessary again.

PREPARATION AND POST-OPERATIVE CARE

HINWEISE ZUR VORBEREITUNG UND NACHSORGE

Please strictly follow the instructions of the physician and his or her assistants. Insofar as they have not ordered anything else, the following instructions apply.

Preparation:

Intake of Medications: It is important that you tell your physician which medications you take or are injected on a regular basis (especially anticoagulants such as aspirin [ASS], Marcumar®, heparin, Plavix®, etc.) and which other medications you have taken in the 8 days before the medical procedure (e.g. pain killers like ibuprofen, paracetamol). This includes all non-prescription medications and herbal preparations. You will then be told which medications, if any, must be discontinued and for how long.

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, your operation wounds might cause some pain, which can be alleviated by medications. You might also have some initial, unpleasant pain in your shoulder, but this usually goes 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, for example, pain with 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.

Your breastbone might be in pain for a few weeks because an incision was made through it for the operation. The healing process lasts about 6 to 8 weeks, as with a broken bone. During this time you should avoid jerky motions and heavy lifting.

After a heart operation, some patients suffer from a feeling of depression. If you notice such a change in yourself, do not hesitate to speak about it. If you need it, your physician can offer you assistance in various forms.

Please take the blood thinning medications prescribed for you exactly as directed and have your blood clotting functions 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 physician.

Chronic foci of inflammation, for example at teeth, must be cleaned. 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, gastroscopy (examination of the stomach), must be preceded by administration of antibiotics as a precaution.

Mechanical valves cause a clicking sound when they close. Some patients feel affected by this.

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, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

RISIKEN, MÖGLICHE KOMPLIKATIONEN UND NEBENWIRKUNGEN

Every medical procedure has its risks. The frequency of possible side effects and complications depends on several factors such as, for example, age, general condition, other diseases and lifestyle.

Here we list possible unforeseeable occurrences that might, under certain circumstances, require subsequent treatment or operations or even – possibly later on – become **life-threatening**. During your explanatory appointment, your physician will explain the risks that apply to you in greater detail. If you do not wish to receive these detailed explanations of risks and complications, please confirm this wish with your signature in the relevant section of the patient consent form at the end of this document.

Confused state and impaired speech, memory or concentration can occur after the operation, but most of them recede by themselves within 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 point of an injection needle are rare. An infected wound expresses itself in swelling, reddening, pain, excessive warmth in the skin and fever. In most cases infections can be treated well with antibiotics. Operative 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. In rare cases the germs can enter the bloodstream (bacteraemia) and cause dangerous blood poisoning (sepsis) or even an infection of the inner lining of the heart (endocarditis). Intensive medical treatment will then be required. In extremely rare cases, blood poisoning can lead to death in spite of all efforts to treat it.

With delayed wound healing or in patients with a predisposition to **impaired wound healing** there can be painful formation of scars and overgrowths (keloids). If the **breastbone** does **not** grow back together again so that it is **stable**, a second operation can be necessary.

Allergic reactions, such as to medications (antibiotics, pain killers, etc.), disinfectants or latex are rare. They can result in reddening of the skin, rashes, lumps in the skin, itching, and swelling as well as nausea

and coughing. These symptoms usually go away on their own without treatment. Severe allergic reactions such as swelling of the laryngeal mucous membrane, disturbances of the cardiovascular system or of the functioning of the lungs are very rare. The resulting laboured breathing, cramps excessively rapid heartbeat or circulatory shock require intensive medical care. Temporary or even permanent damages to organs such as brain damage, impaired vision, impaired sensations, or even paralyses, impaired kidney function or kidney failure can occur despite the best of treatment.

In rare cases, **nerves** or **major blood vessels** can be **injured**. Injuries to blood vessels can lead to impaired circulation and necroses (death) of soft tissue. Injuries to nerves, such as, for example, the recurrent laryngeal nerve (vocal cords), the phrenic nerve (diaphragm), or the brachial (arm) plexus (nerves) can lead to temporary speech impairment, hoarseness, laboured breathing or paralysis of the arm, which only become permanent in rare cases.

During or after the operation, existent blood clots (**thromboses**) can become detached or new ones can form and cause a blood vessel to be blocked (**embolism**). Blood clots can also be carried along to block the blood vessels of other organs. This can lead to permanent damage to the affected organ (e.g. lung embolism, stroke with permanent paralyses, kidney failure) despite immediate intensive medical or surgical treatment. On the other hand, treatment with blood-thinning agents increases the risk of bleeding or secondary bleeding. If heparin is used, the probability of a **serious impairment of blood clotting** (HIT) increases and the risk of thrombus formation and vessel blockages rises too.

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** might form with severely restricted blood flow or major circulatory disturbances or 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 products from another person. This can lead to infections with pathogens such as, for example, in very rare cases the hepatitis virus (cause of dangerous liver infections), in extremely rare cases with HIV (cause of AIDS), with BSE (cause of a variant of the Creutzfeldt-Jakob, or mad cow, disease) or with other dangerous pathogens that might still be unknown. A prior donation of the patient's own blood is generally not advisable for heart operations.

Bruises (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.

Post-operative bleeding of the heart can lead to blood collecting in the heart sac (**pericardium**) and interfere with the heart's pumping function. Then it is necessary to perform a puncture of or open the heart sac.

Irritation of the **heart sac** during the operation can cause it to become **inflamed**.

Impaired breathing, for example due to a weakness of the diaphragm, can make it necessary to provide mechanical ventilation (breathing) in the intensive care unit for a few days. This can give rise to an inflammation of the lungs.

After the operation, air might find its way into the chest and be trapped next to a lung (**pneumothorax**), fluid might collect (**pleural effusion**), or one of the lungs might collapse in part. The results can be coughing, disquiet, sweating, elevated pulse, and laboured breathing. If conservative treatments such as breathing therapy and administra-

tion 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 nerve irritations (for example, due to injections, disinfectants, heating pads, electrical surgical instruments or despite proper bedding) is rare. This can result in bedsores (decubitus), impaired sensations, disturbed feeling, numbness, paralysis and pain. Most of these complaints are temporary. In very rare cases such complaints can become permanent despite efforts to treat them, or scars can remain.

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, the patient's **blood pressure** might **drop** or there might be **circulatory disorders**. In extremely rare cases this can cause **damage to the optic nerve with blindness**, possibly in both eyes.

When a heart-lung machine is used, the patient's blood comes in contact with foreign bodies (parts of the machine) and this causes signalling substances to be released. These substances trigger an **immune response** throughout the body and this can lead to life threatening organ failures. Moreover, microscopically small blood clots, air bubbles

or calcification that has become detached from a vascular wall can find its way into the brain and lead **to impaired brain performance** or even to a **stroke** with possibly permanent **paralyses**. Blood vessel occlusions in the **arms and legs** can lead to **circulatory disorders**. Functional disorders can also occur in other organs such as the liver, gall bladder, pancreas, and the intestines. Most of these problems 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. And then the **lungs**, which were not supplied with blood during the operation, might react with an **inflammation** or **functional disorder**.

Possible late complications

With a valve replacement, the stitches can loosen, so that they leak, or break up. With a valve reconstruction, abnormal strictures or malfunctions can reoccur. In both cases, another operation can become necessary.

Small blood clots can form on the artificial surface of a mechanical heart valve and impact its function or obstruct a blood vessel if it breaks free and is transported. This risk also applies to biological and reconstructed valves for the first few months. The result, for example, can be a stroke. A medicinal anticoagulant 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 of anaesthesia 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

Information about medications:

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

Würden 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?

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

yes no

Has a transfusion of blood or blood components ever been necessary?

War jemals eine Übertragung von Blut/Blutbestandteilen notwendig?

yes no

If so, were there any complications?

Wenn ja, kam es dabei zu Komplikationen?

yes no

Blood clot (thrombus) / blood vessel occlusion (embolism)?

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

yes no

Allergies / Oversensitivity?

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).

yes no

Any other: _____
Sonstiges:

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

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.

yes no

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), Nierentzündung.

Any other: _____

Sonstiges:

Communicable (contagious) diseases?

yes no

Hepatitis, tuberculosis, HIV.

Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

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)?



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:

I have recommended: Vorgeschlagen habe ich:

- Reconstruction of valve(s) Rekonstruktion der Klappe(n)
- Reconstruction of valve(s) Ersatz der Klappe(n)
- mechanical valve mechanische Klappe
- biologic valve biologische Klappe
- Ross operation (transplant and replacement of the pulmonary valve) Ross-Operation (Verpflanzung und Ersatz der Pulmonalklappe)

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

- The patient has the ability to make an independent decision on the operation that has been recommended and to give his or her consent to this operation.
Der Patient besitzt die Fähigkeit, eine eigenständige Entscheidung über das empfohlene Operations-Verfahren zu treffen und seine Einwilligung in die Operation zu erteilen.
- The patient was represented by a custodian or other legal guardian with proof of authority. This person is in a position to make a decision in the interests of the patient.
Der Patient wird von einem Betreuer bzw. Vormund mit einer Betreuungsurkunde vertreten. Dieser ist in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.
- The patient, custodian or other legal guardian has refused the operation that has been recommended. The possible disadvantages of refusing were explained to him or her in detail.
Der Patient/Betreuer/Vormund lehnt das empfohlene Operations-Verfahren ab. Er wurde über die möglichen Nachteile einer Ablehnung umfassend aufgeklärt.

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

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

Patient's Refusal Ablehnung des Patienten

Dr. _____ 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. I was also able to discuss with this physician my knowledge and understanding of the information given to me.

Frau/Herr Dr. _____ hat mich umfassend über den bevorstehenden Eingriff und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und konnte meine Erkenntnisse über die mir erteilten Informationen mit dem Arzt diskutieren.

- I hereby refuse the heart valve operation that has been recommended for me. Hiermit lehne ich die mir vorgeschlagene Herzklappen-Operation ab.
- While I refuse the heart valve operation that has been recommended for me, I would like to learn more about the possible alternatives. Ich lehne zwar die mir vorgeschlagene Herzklappen-Operation ab, jedoch möchte ich mehr über die möglichen Alternativen erfahren.

I hereby refuse all further treatment. Ich lehne jegliche Behandlung ab.

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

Signature of patient / legal guardian / witness

[Unterschrift der Patientin / des Patienten / Betreuer / Vormund / ggf. des Zeugen]

Patient's Declaration and Consent

Erklärung und Einwilligung des Patienten

Please mark your declaration in the applicable box and then confirm it with your signature. Bitte kreuzen Sie Ihre Erklärung im zutreffenden Kästchen an und bestätigen Sie diese 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 and answered the questions about my medical history to the best of my knowledge. During my explanatory appointment, Dr. _____ 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 und die Fragen zu meiner Krankengeschichte (Anamnese) nach bestem Wissen beantwortet. Im Aufklärungsgespräch mit Frau/Herrn Dr. _____ 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 Herzklappenoperation 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 attending physician of the necessity of this operation, of its type and extent, and of the circumstance that this operation has its risks. I have answered the questions about my medical history in full and to the best of my knowledge. **Ich verzichte bewusst auf eine ausführliche Aufklärung.** Ich bestätige hiermit allerdings, dass ich von dem behandelnden Arzt über die Erforderlichkeit des Eingriffes, dessen Art und Umfang sowie über den Umstand, dass der Eingriff Risiken birgt, informiert wurde. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

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)).

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.

My approval also covers any required changes or extensions of the operation, e.g. switch from a valve reconstruction to a valve replacement, or to reconstruction or replacement of further valves.

Meine Einwilligung bezieht sich auch auf die erforderlichen Änderungen oder Erweiterungen des Verfahrens, z.B. das Umsteigen von einer Rekonstruktion auf einen Klappenersatz oder Rekonstruktion oder Ersatz weiterer Klappen.

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.

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]

Copy/Kopie: received/erhalten
 waived/verzichtet

Signature Copy received/waived
[Unterschrift Kopie erhalten/verzichtet]