

AORTIC VALVE IMPLANTATION BY CATHETER

AORTENKLAPPEN-IMPLANTATION KATHETERGEFÜHRT

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:]

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 unconsciousness or irregular heart rhythm are due to dysfunction of your heart's aortic valve, which is the outlet valve of your heart's left ventricle to your body's circulatory system. Your physician has recommended that you have a new valve implanted by means of a catheter.

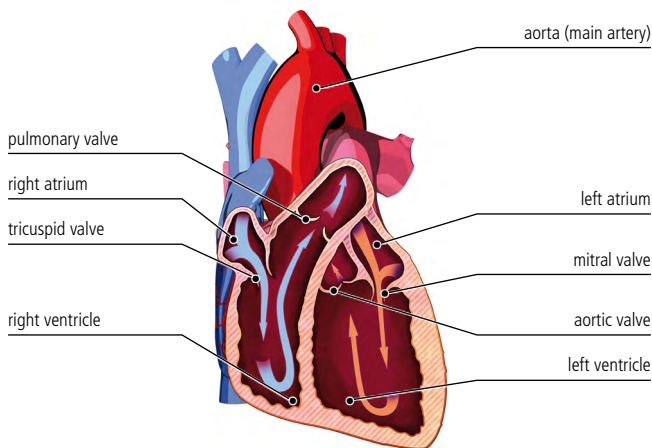
By providing the explanations below, we wish to inform you and your family of the various surgical procedures, the possible complications, and what you should do before and after the operation. You might be shown a short film. This form and the film are designed to prepare you for the explanatory appointment 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 grant or refuse your consent to use 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 DISEASES

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 stenosis). The result is impeded blood flow through the heart and frequently blood congestion in

the 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 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 lungs. At the last stage there is danger of irregular heart rhythm with sudden unconsciousness or even life threatening heart failure.

The new aortic valve should preferably be implanted before the heart muscle has been damaged appreciably.

COURSE OF THE VARIOUS PROCEDURES

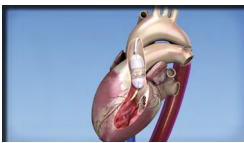
ABLAUF DER VERSCHIEDENEN VERFAHREN

Selection of the operative procedure suitable for you will depend on a number of factors, including the size and condition of your femoral (leg) and pelvic arteries, in addition to your age and general condition.

This operation is usually carried out while the patient is under general anaesthesia. This will be explained to you separately as applicable. It might also be possible to perform the operation through the femoral artery under local anaesthesia. During the operation, your organ functions will be monitored without interruption and if there are any problems, remedial action will be taken immediately. There are basically two possible approaches for this operation.

□ **Valve implantation through the femoral artery** (transfemoral)
Klappenimplantation über die Beinschlagader (transfemorale)

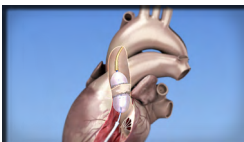
After placement of a catheter for a contrast agent and a pacemaker wire, usually in an artery and a vein in the groin, the surgeon opens an artery through a small skin incision in the groin on the other side. Then he advances a guide wire up to the left ventricle of the heart and lays a work channel along this wire. Now the diseased aortic valve has to be dilated to create space for the new valve to be implanted. This will be done with a balloon. The surgeon advances the balloon up the channel and inflates it when it reaches the aortic valve. The valve to be implanted is folded, mounted on another balloon catheter and introduced into the opening of the dilated aortic valve. Then this balloon is inflated to position the new valve. Some valves are introduced while packaged in a sheath. The sheath is pulled back and the valve unfolds by itself.



When the new aortic valve has been securely anchored, the surgeon checks its functions by means of x-ray contrast and ultra sound imaging. Then the work channel and guidewire are removed from the groin and a thin plastic tube, called a drain, is placed to divert wound secretions to outside the body. Finally, the incision in the groin is closed with sutures or a special closure system.

□ **Valve implantation through the cardiac apex** (transapical)
Klappenimplantation über die Herzspitze (transapikal)

With this method, the surgeon makes a small incision in the left side of the chest to expose the cardiac apex (tip of the heart). Then he performs a puncture of the apex and places a work channel for introducing the surgical instruments into the left ventricle of the heart. The diseased aortic valve is dilated with a balloon to create space for the new valve. The valve to be implanted is folded, mounted on another balloon catheter and introduced into the opening of the stretched aortic valve. It is positioned there by inflating the balloon.



When the new aortic valve has been securely anchored, the surgeon checks its functions by means of x-ray contrast and ultra sound imaging. Then the work channel is removed and the opening in the apex of the heart is closed.

It can be necessary to regulate the heartbeat with a temporary pacemaker. Thin pacing wires 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. Finally, the incision in the chest is closed with sutures.

The pacing wires and drains can 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 (e.g. continuation with an open operation if it was not possible to implant the valve properly using a catheter).

For the open operation, the chest has to be opened through an incision along the middle of the breastbone. The aorta is clamped off and medications are administered to generate an artificial cardiac arrest until the operation is over. During this time, your bodily circulation is connected to a heart lung machine by means of two plastic tubes.

If there is no other choice or the risk of a second operation is too great, your physician will carry out these necessary changes and 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 dilate the constricted aortic valve by means of a catheter procedure.

Your physician will be glad to explain to you why an aortic valve implantation by catheter is advisable in your case rather than an open operation.

PROSPECTS OF SUCCESS

ERFOLGSAUSSICHTEN

Implantation of a new aortic valve can improve the capacity of your heart to perform and increase the quality of your life. The success of this treatment will be greatly dependent on the severity and duration of your aortic valve disease and on the degree of damage to your heart muscle.

Since implantation of an aortic valve using a catheter is a relatively new treatment method, it is not possible today to make exact statements about the long-term results, complications and durability of the implanted, biological valve.

Over the long term, a new aortic valve can calcify again or fail due to premature wear and tear, so that another operation is necessary.

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 antidiabetics containing metformin) 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 nonprescription 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.

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.

Please take the blood thinning medications prescribed 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.

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

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.

General Risks

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 or catheter are rare. A purulent infection expresses itself in swelling, reddening, pain, excessive warmth in the skin and fever. In most cases infections can be treated well with antibiotics. In rare cases 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).

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, **major blood vessels** can be **injured**. Injuries to blood vessels can lead to impaired circulation and necrosis (death) of soft tissue. Injury to the aortic wall (**aortic dissection**) with haemorrhaging between the wall layers can make it necessary to operate immediately.

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 (**embolisms**). 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 early and late 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.

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. 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 Creutzfeld-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.

Damage to the skin, soft tissue, or nerve irritations (for example, due to injections, disinfectants, heating pads or despite proper positioning) 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.

With an operation, calcium deposits can become detached and be carried off into a coronary or cerebral vessel to cause a **heart attack** or **stroke**. Moreover, blockages in blood vessels can give rise to **circulatory disorders** in other organs, including the **arms and legs**.

Examinations with contrast agents can lead, especially if there is a preexistent kidney condition, to a **reduction of the kidney function**, possibly even to acute kidney failure. In such cases temporary, or in rare cases even long-term, dialysis (blood cleansing) can become necessary.

Administration of contrast agents containing iodine to patients with overactive thyroid function can cause a **thyrotoxic crisis** with disquiet, irregular heart rhythm, diarrhoea, and sweating, which must be treated with medications.

Since implantation through a catheter is a relatively **new procedure**, it is not yet possible to make any definite statements about rare and as yet **unknown risks**.

Special risks of Implantation through the groin

The guidewire wire which is advanced through the heart can **injure the mitral valve**. Another operation can be necessary if there is a high degree of functional disorder.

Damage to blood vessels in the area of the groin, pelvis and abdomen can make it necessary to reconstruct them by means of blood vessel surgery.

Special risks of Implantation through the cardiac apex
Post-operative bleeding at the heart can cause blood to collect in the heart sac (pericardium) and interfere with the pumping function of the heart. Then a puncture or operative opening of the heart sac will be necessary.

Irritation of the heart sac during the operation can cause the **heart sac** to become **inflamed** (pericarditis).

After the operation, air can find its way into the chest (**Pneumothorax**) or fluids might accumulate there (**pleural effusion**). Coughing, disquiet, sweating, elevated pulse and laboured breath can result. This must be treated by a puncture procedure or a suction drain must be placed.

An inflammation of the chest area that cannot be handled by antibiotics can require an operation.

Possible late complications

The new valve can **leak** or **slip**. In both cases, another operation can become necessary.

Small **blood clots** can form on the surface of the new aortic valve during the first few months and impact its function or obstruct a blood vessel if they break free and are transported. The result, for example, can be a stroke. An anti-coagulant in tablet form can be taken to reduce this risk.

Additional risks of the open operation

If the valve implantation has to be continued in an open operation, the following complications can occur.

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 paralyses of the arm, which only become permanent in rare cases.

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.

When a heart lung machine is used, an **immune response** throughout the body can be triggered and this can lead to life threatening organ failures. Moreover, microscopically small blood clots and air bubbles can find their way into the brain and lead **to impaired brain performance** or even to a **stroke** with possibly permanent paralyses. Functional disorders can also occur in other organs such as the liver, gall bladder, pancreas, and the intestines. Also, if the kidneys already sustained damage before the operation, there might be **renal (kidney) dysfunction** or even **renal failure**. Also the **lungs** might react with an **infection** or **functional disorder**.

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

Impaired breathing, for example due to a weakness of the diaphragm, can make it necessary to provide mechanical ventilation (artificial breathing) in the intensive care unit for a few days. This can also cause the lung to become infected.

If the **breastbone** does not grow back together again so that it is stable, another operation might be necessary.

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, Efiect®, 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, Efiect®, 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?

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?

Has a transfusion of blood or blood components ever been necessary? yes no

War jemals eine Übertragung von Blut/Blutbestandteilen notwendig?

If so, were there any complications? yes no

Wenn ja, kam es dabei zu Komplikationen?

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:

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)?

If certain answers are preselected, please correct them if anything has changed.)

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:

- Aortic valve implantation through the femoral artery (transfemoral)
Aortenklappenimplantation über die Beinschlagader (transfemorale)
- Aortic valve implantation through the cardiac apex (transapical)
Aortenklappenimplantation über die Herzspitze (transapikal)

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 valve implantation that has been recommended for me. Hiermit lehne ich die mir vorgeschlagene Klappen-Implantation ab.
- While I refuse the valve implantation that has been recommended for me, I would like to learn more about the possible alternatives. Ich lehne zwar die mir vorgeschlagene Klappen-Implantation 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 valve implantation 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 Klappen-Implantation, 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 valve implantation operation that has been scheduled for me.
Den Informationsfilm über die bei mir geplante Klappen-Implantation 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 valve implantation 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 Bedenkenzeit benötige. Ich stimme der vorgeschlagenen Klappen-Implantation 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 to an open operation with heart lung machine. Meine Einwilligung bezieht sich auch auf die erforderlichen Änderungen oder Erweiterungen des Verfahrens, z.B. das Umsteigen auf eine offene Operation mit Herz-Lungen-Maschine.

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 / Vormund]

Copy/Kopie: received/erhalten
 waived/verzichtet

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