## CARDIAC CATHETERIZATION / TREATMENT FOR CORONARY VESSEL HERZKATHETER-UNTERSUCHUNG / BEHANDLUNG VON KORONARSTENOSEN STENOSIS

Information and medical history for adults and young patients for preparation of an informative talk with the doctor

Data about the patient: [Patientendaten:]

The clinic/doctor's office [Klinik / Praxis]



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

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Dear patient,

the discomfort you have had and present findings indicate a narrowing of the coronary vessels, mitral valve disease or some other heart disease.

1

In order to find the cause of your discomfort, the doctor recommends cardiac catheterization. If the X-ray shows narrowing in your coronary vessels, they can often be treated after the examination. Thus, improved blood flow to your heart will be achieved, your discomfort will be mitigated and a possible heart attack will be prevented.

We will inform you and where applicable your family members about the course of the procedure, possible complications and measures before and after the procedure in the following text. Where required a short film will be shown to you. This form and the film will serve to prepare you for the talk with the doctor. In the talk, the doctor will explain benefits and risks of the planned surgery in comparison to alternative methods. He will explain risks which are specific for you and possible complications. Please, continue to read the following information and complete the form carefully. It is understood that your data will be treated confidentially.

During the talk, the doctor will answer all your questions in order to reduce your worries and concerns. Then you can give or refuse consent to the proposed procedure. The doctor will give you a copy of the completed and signed form after the talk.

# **CAUSES OF HEART DISORDERS** URSACHEN DER HERZBESCHWERDEN

In addition to mitral valve diseases and congenital heart defects, the most common cause of heart disorders is a narrowing of the coronary blood vessels.



Coronary vessels are responsible for supplying the heart muscle with blood containing oxygen. Due to the ageing process, increased levels of fat in the blood or as a consequence of diseases, such as high blood pressure or diabetes, changes occur on the inner walls of the coronary arteries. These changes facilitate a deposition of fat in the blood and

blood platelets, leading to deposition of calcium, which is referred to as calcification of the artery. These blockages, also called plagues, narrow the blood vessel and can possibly lead to circulatory disturbances of the heart muscle. Especially in case of physical strain or stress, disorders such as breathing difficulties and chest tightness can occur. If the narrowing in the affected blood vessel is not removed, it may cause damage to the tissues of the heart muscle, which cannot supply enough blood and over a long period of time lead to heart weakness. If the calcifications loosen or a blood clot reaches the narrowed blood vessel, then a sudden obstruction of the blood vessel, a myocardial infarction, occurs.

### THE COURSE OF EXAMINATION/TREATMENT ABLAUF UNTERSUCHUNG / BEHANDLUNG

In order to clarify the causes of your discomfort and to be able to make a decision on further treatment, the doctor advises cardiac catheterization to you.

Cardiac catheterization is done primarily under local anaesthesia. If you want, or the doctor considers it necessary, you can get a small dose of sedatives or sleeping pills. To prevent the formation of blood clots during the procedure, you can possibly get medication that prevent blood clotting.

After a thorough disinfection of the skin and local anaesthesia at the injection site, the doctor will punctuate a suitable artery (for examination of the right heart ventricle, vein) in the groin or wrist area (in rare cases in the upper arm).



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Release 26.7.2018



Patient:

Then the catheter (a flexible synthetic tube) is inserted through the blood vessels in the arm, leg or the blood vessels of the abdomen to the heart. Then the following measures can be implemented:

- Myocardial biopsy: Myokardbiopsie: If certain diseases of the heart muscle are suspected, it is possible to take small tissue samples of the heart muscle by means of the catheter.
- □ Levo cardiography: Laevokardiographie: Here the catheter is inserted up to the left heart ventricle and the contrast medium is injected into the left half of the heart. Thus, it is possible to see with the help of X-ray the pumping capacity of the left heart ventricle and to assess the function of the aortic and mitral valve.

During the injection of the contrast medium you may feel a bit warm. This is completely normal and is no cause for concern.

Examination of the right heart with the catheter: Rechtsherzkatheteruntersuchung: Here the catheter is inserted through the vein up to the right heart ventricle and the pulmonary aorta, or it is inserted into the heart through the blood flow. By measuring blood pressure and saturation, or injecting a contrast medium, together with an X-ray, the pumping capacity of the heart, as well as the function of the pulmonary and tricuspid valves can be assessed.

Coronary angiography: Koronarangiographie: The doctor inserts the catheter into the orifice of the coronary artery which is to be examined. Contrast medium is injected through the catheter into the coronary artery and thus permeability of the blood vessel is assessed, together with the X-ray.

- Measurement of pressure with a wire: Druckdrahtmessung: By pressure measurement with the help of a wire that is inserted into the coronary artery which is to be examined, obstructions in the blood flow can be determined (FFR, measurement of fractional flow reserve).
- Intravascular ultrasound: Intravaskulärer Ultraschall: By special catheter at the top of which is a tiny ultrasound head, the quality of the blood vessel's wall, as well as the shape and thickness of blockages are assessed.

□ **Treatment of the narrowing:** Behandlung von Verengungen: If there are narrowings in the coronary arteries, they can often be treated immediately after the examination. Narrowing can be treated depending on the type and severity of the narrowing using the following methods.

### Balloon dilatation: Ballondilatation:



Here the doctor firstly inserts the wire, which serves as a guide and then the catheter with a tiny balloon which is folded at the top up to the stenotic coronary artery.

Then, the balloon will be filled once or several times, thereby increasing the diameter of the blood vessel and improving the blood flow. During the balloon dilatation, short-term pain in the chest and nausea may occur. Such discomforts are completely normal, but you should definitely inform the doctor, who may interrupt the treatment until symptoms ease off. Then the doctor checks permeability of the coronary artery once again by injection of the contrast medium, together with X-ray.



In some cases, e.g. in case of narrowing of some branchings of the blood vessels, the balloon with medicines will be used. Inflating the balloon, the active substance is

transferred to the wall of the blood vessel and thus recurring narrowing of the blood vessel is prevented, i.e. slowed down.

• Stent implantation: Stent-Implantation:



To keep the vessel open enough, a support for the blood vessel is often needed, a so called stent, which is inserted into the narrowed site of the coronary artery. Sup-

ports for the blood vessels are grid tubules made of metal or other materials. The stent, which is to be implanted, is folded, mounted on the special balloon catheter or it is in a small capsule, and that way it is inserted into the narrowed site of the coronary artery. Inflating the balloon or pulling the capsule, the stent unfolds and supports the inner wall of the blood vessel. Then the doctor checks proper position and unfolding of the stent by X-ray.

Depending on the length of the narrowed passage, the size of the blood vessel and accompanying diseases, such as Diabetes mellitus or in case of recurring narrowing, stents coated with medicines are used. Medicines prevent increased ingrowth of the new inner layer tissue into the stent, thereby reducing the likelihood of recurring narrowing.

In addition, there is a possibility for very hard or large blockages to be removed from the coronary arteries by laser, ultrasound catheters and catheters for scraping and cutting. These methods are used if applicable, prior to stent inserting.

After the surgery, the catheter is removed, the access on the artery in the groin or the arm, i.e. the vein is closed and usually compression bandage is put.

### POSSIBLE ADDITIONAL MEASURES MÖGLICHE ERWEITERUNGSMASSNAHMEN

In some cases reaching the heart through the selected blood vessel or successful performance of catheterization, i.e. the treatment fails. Therefore, it may be necessary to choose another approach, to repeat the surgery or to resort to other diagnostic or therapeutic measures.

In extreme cases, e.g. in acute blockage of the blood vessel, it may be necessary to perform heart surgery by opening the thorax.

### ALTERNATIVE PROCEDURES ALTERNATIV-VERFAHREN

There are various recording methods for assessing the condition of the heart and coronary arteries, such as CT of the heart (X-radiation) or cardiac MRI (nuclear spin tomography). The advantage of these methods is that they are non-invasive, i.e. they are performed without insertion of the catheter into the body. However, chances of success are not as high as for cardiac catheterization; therefore the observed narrowings cannot be treated during the same procedure.

Depending on the findings, apart from stretching of the blood vessel and stent implantation, the following therapies are possible:

In the early stages of the disease, medicines, together with a lifestyle change are sometimes enough to improve blood flow in the narrowed coronary artery, i.e. to slow down the progression of the artery's blockage.

If balloon dilatation with stent implantation is insufficient, i.e. not possible, or if there is a large number of narrowings, bypass surgery is advised. After opening the thorax, the narrowing is bypassed with the blood vessel.

# OUTLOOK ON SUCCESSFULNESS OF TREATMENT ERFOLGSAUSSICHTEN

Success of the catheterization depends on many factors, such as degree and position of the narrowings and their number. Generally, there is an easing-off of discomforts and an increase in resilience. However, it is possible that recurring narrowing of the coronary artery occurs from a few weeks up to a few months later. Further stretching is possible in most cases. In the long run, bypass surgery may be necessary.

To slow down blockage of the artery and prevent recurring narrowing of the possibly inserted stent, you will be prescribed various medicines. Please take them regularly to avoid endangering the result of the treatment.

### ADVICE FOR PREPARATION AND AFTERCARE HINWEISE ZUR VORBEREITUNG UND NACHSORGE

Unless otherwise specified, please note the following advice:

### **Preparation**:

Administration of medicines: It is important to tell the Doctor which medicines, i.e. injections you have to take regularly (especially anti-clotting remedies, such as Aspirin<sup>®</sup> [ASS], Plavix<sup>®</sup>, Xarelto<sup>®</sup>, Pradaxa<sup>®</sup>, Eliquis<sup>®</sup>, Marcumar, etc., antidiabetics containing metformin, the so-called "Biguanides" for diabetic patients) or you took them irregularly in the last 8 days prior to the surgery. This includes any medicines without prescription and herbal remedies. The Doctor will inform you which medicines must be discontinued during this period.

**Eating**, drinking and smoking: Please stop smoking at least one day before the planned surgery. As a rule, 6-8 hours before the surgery you must not eat nor drink, such as juice with pulp, milk, soup or alcohol. Up to about 2 hours before the surgery, you can drink clear liquids, such as water or tea.

### Aftercare:

Please stay in bed after the surgery and keep your leg, i.e. arm stretched and do not move it until the cannula has been removed. The medical staff will compress the puncture site for 10-20 minutes, or use special closing system and put on a compression bandage. In order to prevent subsequent bleeding, in most cases it is necessary **to rest in bed for several hours.** The compression bandage can be removed after 4-24 hours.

If there is any **bleeding** at the puncture site, please press the site and immediately notify the medical staff, i.e. the doctor.

Please avoid **smoking and alcohol consumption** for 24 hours after the surgery.

In order to prevent **subsequent bleeding**, avoid greater efforts, lifting heavy objects or severe pressure in the days after the surgery.

Take, if prescribed, **medicines against blood clotting** to prevent narrowing of blood vessels.

After an **outpatient surgery**, it is necessary for an adult to pick you up. Follow the doctor's advice (e.g. bed rest), to ensure complete wound closure. Make sure that someone is staying with you during the period recommended by the doctor. In any case you should not take part in road traffic **for 24 hours after the surgery** (not even as a pedestrian). Furthermore, during this period do not make decisions that concern you personally or that are important regarding your personal property. Please inform the doctor immediately or come to the medical clinic, if there is **bleeding**, **swelling**, **pain**, **severe redness of the wound or fluid from the puncture site**, **a sense of paralysis or paleness on the limbs or chest pain**, **heart discomfort**, **temperature or shivering attack**.

### POSSIBLE RISKS, COMPLICATIONS AND SIDE EF-FECTS RISIKEN, MÖGLICHE KOMPLIKATIONEN UND NEBENWIRKUNGEN

It is well known that every **medical surgery bears certain risks.** Partially, they may require additional measures of treatment or operation and in the further course - **can be life-threatening** or lead to permanent damages. Please, show understanding that due to legal reasons we have to mention all risks specific to the surgery, although partly they relate only to exceptions.

The frequency of side effects and complications depends on several factors, e.g. age, general condition and lifestyle. Your doctor will explain to you during the talk which risks are specific for you. However, you can also reject detailed explanation. In that case, skip the chapter on risk and confirm that at the end of explanation.

**Bruises (hematoma)** at the puncture sites or surrounding sites occur frequently. Thus hard, painful swellings may arise. Mostly they disappear without treatment after several days or weeks. Otherwise, it may be necessary to remove hematoma surgically.

In some cases, the blood vessel does not close properly at the puncture site, thus it may cause enlargement of the blood vessel (pseudoaneurysm). It is treated normally by placing a compression bandage over it or injecting into the enlargement of the blood vessel (atrophy).

In rare cases, a **fistula** may develop between the artery and the vein, which usually must be occluded surgically.

**Damage of the skin, soft tissues, i.e. nerves** (e.g. by puncture, hematoma, abscess, disinfectants, compression bandage or despite the correct position of the patient), are rare. The consequences can be numbness, paralysis and pains. It rarely happens that the symptoms do not withdraw despite the treatment, or that the scars may remain.

During insertion of the catheter into the heart, **cardiac rhythm disorder** may occur. It is mostly harmless and of temporary character. Serious heart rhythm disorders that require treatment with medications or electric shock (defibrillation) are rare.

**Injuries of the coronary artery** from the catheter which have as a result bleeding in the pericardium, are extremely rare. If this is the case, then the pericardium must be punctured with a needle and the blood must be aspirated. Injury of the heart wall or mitral valve occurs rarely. Injuries may also require operational correction.

In some cases, while inserting the catheter, a **loop** can be created. If it cannot be removed, then the catheter will be removed surgically.

Insertion of the catheter, wire under pressure, ultrasonic probe or expansion of the narrowing, may cause **tearing of the inner blood vessel's wall (dissection)** with bleeding and narrowing of the blood vessel or complete **blockage of the blood vessel** with the risk of a heart attack. By means of re-stretching or insertion of the support for the blood vessel, these complications are generally dealt with successfully. In some cases, urgent bypass surgery is required.

In case of very unfavourable circumstances, the support of the blood vessel (stent) may be separated during the insertion of the catheter and by its transfer lead to the blockage of the blood vessel (possible consequence can be heart attack or stroke). If the stent cannot be recovered with the catheter, then it must be removed surgically. Since during the surgery with the catheter, medicines against blood clotting must be taken, the risk of **(subsequent) bleeding** is high, especially at the injection site, but also in other parts of the body. In extreme cases bleeding may occur, e.g. in the brain, which can lead to speech disorders or paralysis. When heparin is administered against blood clotting, it may lead to **severe coagulation disorder** (HIT) with formation of blood platelets and blockage of the blood vessel.

In case of **severe bleeding**, in exceptional cases receiving donor blood / blood components (**transfusion**) may be necessary. This may lead to infection with germs causing diseases, such as, very rarely hepatitis viruses (the cause of dangerous inflammation of the liver), extremely rarely HIV (AIDS), BSE (Creutzfeldt-Jakob), or other dangerous - and unknown – germs. Receiving one's own blood is generally not recommended.

Existing blood clots (**thrombi**) may become detached e.g. during insertion of the catheter and cause blockage of the blood vessel (**embolism**). Even new clots may be formed or be transferred and block blood vessels of other organs. Despite urgent measures, this may cause permanent damages to the affected organs (e.g. **pulmonary embolism, stroke** with permanent paralysis, **myocardial infarction**).

**Infections**, e.g. at the site of catheter insertion with the formation of pus (abscess), necrotizing or scars, are rare. They are manifested as swelling, redness, pain, skin overheating and temperature. In most cases, such infections are successfully treated with antibiotics. In extreme cases, there may occur a transfer of germs in the blood (bacteremia) and dangerous blood poisoning (sepsis), inflammation of the inner lining of the heart (endocarditis), in case of the support of the blood vessel's infection, even **inflammation of the pericardium** or **myocardial infarction** may occur. Then urgent medical measures will be taken. It is extremely rare that an infection, despite the treatment, can lead to death.

Allergic reactions (reactions of intolerance) can appear, e.g. to anaesthetics, X-ray contrast media, sedatives or other medicines with skin rashes, itching, swelling, as well as nausea and cough. Symptoms usually disappear by themselves. A severe reaction, such as breathing difficulties, spasms, tachycardia, or cardiovascular shock is rare. Due to circulatory disorders and despite urgent medical surgery, this may lead to temporary or permanent damages, such as brain damage, paralysis or kidney failure.

**Disorders of blood circulation** in the leg, i.e. arm can occur if the punctured blood vessel is injured or closed after the surgery due to a clot. In exceptional cases, it may cause loss of function of the respective limb and in an extreme case loss of the leg or arm.

**Lymph stasis** can lead to permanent swelling of the punctured leg or arm.

In patients with existing renal disease, X-ray contrast medium can lead to **deterioration of renal function**. It is treated mainly successfully with high intake of fluids or medicines. In case of severe previous damage, **kidney failure** can occur and this condition requires permanent dialysis.

In diabetic patients who take biguanides in the form of metformin, **dangerous metabolic disorder** may occur (excessive acidity of the blood).

In case of disorders of the thyroid gland, X-ray contrast medium that contains iodine can cause **excessive thyroid function**, so-called hyperthyroidism. It is manifested as tachycardia, feeling of heat, anxiety and diarrhea, but it is successfully treated with medicines.

A medicine that is administered during wire measures under pressure, can lead to a **feeling of heat**, **drop in blood pressure and pulse rate**.

**Radiation exposure** (x-ray) during surgery with the catheter is at a minimum level, therefore surgery can be repeated. There are no reliable data on subsequent consequences. Though, in case of pregnancy, it may cause damage to the foetus.

Primarily during the first weeks after the treatment, blood clots can lead to reoccurrence of acute **blockage of opened blood vessel** and therefore to a **heart attack**. This can be prevented by medicines against blood clotting.

**Side effects** of medicines that are coated on the special stent cannot be excluded completely.

### Important Questions for Outpatients Wichtige Fragen für ambulante Eingriffe

Who will pick you up when you are discharged from the hospital/ clinic/surgeon's practise? Wer wird Sie abholen, sobald Sie aus Klinik/Praxis entlassen werden?

Name and age of the person picking you up: [Name und Alter des Abholers]

Where can you be reached within the 24 hours after surgery? Wo sind Sie in den nächsten 24 Stunden nach dem Eingriff erreichbar?

Street, house number, postcode, place: [PLZ, Ort, Straße, Hausnummer]

Telephone: [Telefonnummer]

Name and age of person looking after your: [Name und Alter der Aufsichtsperson] Who is your physician (the one whose care you are in/who referred you/family surgeon)? Wer ist Ihr überweisender / weiter betreuender Arzt / Hausarzt?

Name: [Name]

Street, house number: [Straße, Hausnummer]

postcode, place: [PLZ, Ort]

Telephone: [Telefonnummer]

Red.Dat.: 01/2014 EN KA-04

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.

Do you have an X-ray passport,	Were there any complications?	🗌 yes 🗌 no
Marcumar <sup>®</sup> passport, pacemaker/ICD card?  yes n	o If so, which ones?	
If so, please bring them with you.	Ergaben sich dabei Komplikationen? Wenn ja, welche?	
Besitzen Sie einen Röntgenpass, Marcumarpass, Herzschrittmacher-/ICD-Ausweis? Wenn ja, bitte mitbringen.	Have you ever received	
Have you ever had a cardiac catheterisation?	Contrast medium? Haben Sie schon einmal Kontrastmittel erhalten?	∟yes ∟no
If so, when?	Were there any complications?	🗆 yes 🗌 no
Wurde bei Ihnen schon einmal eine Herzkatheteruntersuchung durchgeführt? Wenn ist wann?	If so, which ones?	
Terzketteteruntersuchung durengeruntet menning, wunn.	Ergaben sich dabei Komplikationen? Wenn ja, welche?	

Have you ever received a blood transfusion? Use Single and Bluttransfusion ethalten?	dine, $\Box$ sticking plaster, $\Box$ latex (e.g. rubber gloves, balloons), $\Box$ pollen (grass, trees), $\Box$ anaesthetics,
Were there any complications? <b>yes no</b> Ergaben sich dabei Komplikationen?	imited is (itching caused by metal spectacles frames, jewellery, jeans buttons).  Allergie/Überempfindlichkeit?  Medikamente,  Lebensmittel,  Kon- trastmittel,  Hod,  Pflaster,  Latex (z.B. Gummihandschuhe, Luftballon),
If so, which ones? Wenn ja, welche?	□ Pollen (Gräser, Bäume), □ Betäubungsmittel, □ Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten). Any other:
Are you pregnant? Inot certain nicht sicher yes no Besteht eine Schwangerschaft?	Sonstiges: Heart, circulatory or blood vessel diseases?
Is there any surgery planned for the next couple of months? Ust in den nächsten Monaten ein operativer Eingriff geolant?	□ Heart attack, □ chest pain and/or tightness (angina pectoris), □ heart defect, □ irregular heart rhythm □ inflammation of heart musc-
Do you take any diabetes medications? yes no Nehmen Sie Diabetesmedikamente ein?	$ e, \Box $ heart valve disease, $\Box$ heart surgery (pos-
$\Box$ insulin injections, $\Box$ drugs containing metformin (e.g. Gluco-phage <sup>®</sup> , Metformin <sup>®</sup> , Janumet <sup>®</sup> )	pacemaker, defibrillator), $\Box$ high blood pressure, $\Box$ stroke, $\Box$ varicose veins, $\Box$ inflammation of a
Any other:	vein, L thrombosis, e embolism. Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), Herzfehler, Herzrhyth- musstörungen, Herzmuskelentzündung, Herzklappenerkrankung, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herz- schrittmacher, Defibrillator), hoher Blutdruck, Schlaganfall, Krampfadern, Venenentzündung, Thrombose, Embolie.
taken any or have any been injected during the past 8 days?	Any other:
Aspirin <sup>®</sup> (ASS), Heparin, Marcumar <sup>®</sup> , Plavix <sup>®</sup> , Ticlopidin, Clopidogrel, Xarelto <sup>®</sup> , Eliquis <sup>®</sup> , Brilique <sup>®</sup> , Efient <sup>®</sup> , Pradaxa <sup>®</sup> . Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Jaspirin <sup>®</sup> (ASS), Heparin, Marcumar <sup>®</sup> Plavix <sup>®</sup> , Ticlopidin, Clopidogrel, Xarelto <sup>®</sup> , Eliquis <sup>®</sup> , D	Metabolic diseases? yes no Diabetes (sugar sickness) Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Any other:
Any other:	Sonstiges:         Thyroid diseases?         Underactive thyroid,          Underactive thyroid,          Sedow disease,          Inodes,          Schilddrüsenerkrankungen?         Unterfunktion,
<b>Do you take any other medications?</b> yes no	Basedowsche Krankheit, Knoten, Kropf.
such as pain medications, hormones, prostate medications, metfor- min-containing antidiabetic medications, so-called biguanides, or	Sonstiges:
Viagra <sup>®</sup> , Levitra <sup>®</sup> , Cialis <sup>®</sup> in the last two days? Wie z. B. Schmerzmittel, Hormone, Prostatamittel, metforminhaltige Antidiabetika, sog. Biguanide oder in den letzten 2 Tagen Viagra <sup>®</sup> , Levitra <sup>®</sup> , Cialis <sup>®</sup> ?	Kidney diseases?  Yes no Kidney insufficiency, kidney inflammation. Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz),
If so, which ones: Wenn ja, bitte auflisten:	Any other:
(including non-prescription medications, natural or herbal medications, vitamins, etc.)? (auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)	Sonstiges:
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:	Gastrointestinal diseases?
Blood diseases / blood clotting disorders? yes no	Any other:
bleeds, increased bleeding after surgery, minor wounds or dental treatment),  tendency to bruise (frequent bruising possibly for no particular reason). Bluterkrankung/Blutgerinnungsstörung? Frhöhte Blutungs- neigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach	Communicable (contagious) diseases?       yes       no         Hepatitis,       tuberculosis,       HIV.         Infektionskrankheiten?       Hepatitis,       Tuberkulose,         Any other:       Sonstings:
Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).	Any other acute or chronic diseases /
Do you have any blood relatives with signs of blood disease / clotting disorders? <b>yes no</b>	illnesses?
Bluterkrankungen/Blutgerinnungsstörungen?         Allergies / Oversensitivity?       yes         Medications,       foods,         contrast media,       io-	Bitte kurz beschreiben:

### Medical documentation for the informative talk

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the doctor Wird vom Arzt ausgefüllt

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

### I have proposed: Vorgeschlagen habe ich:

- Levo cardiography Laevokardiographie
- Coronary angiography, possibly with IVUS, FFR когопагалgiographie ggf. mit IVUS, FFR
- Coronary surgery, possibly with balloon dilatation, stent Koronarintervention ggf. mit Ballondilatation, Stent

Examination of the right heart with catheter Rechtsherzkatheteruntersuchung

Myocardial biopsy Myokardbiopsie

(additional measures) (weitere Maßnahmen).

# Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

The patient is capable of making decision on the recommended CT examination by himself/herself and issuing its consent for the procedure. Der/Die Patient/in besitzt die Eibinkeit eine eigenständige Entscheidung über die erwingen.

Der/Die Patient/in besitzt die Fähigkeit, eine eigenständige Entscheidung über die empfohlene Behandlung zu treffen und seine/ihre Einwilligung in das Verfahren zu erteilen.

□ The patient is represented by the guardian, i.e. carer with the evidence of guardianship. This person is entitled to make a decision on behalf of the patient.

Der/Die Patient/in wird von einem Betreuer bzw. Vormund mit einer Betreuungsurkunde vertreten. Dieser ist in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.

City, date, time (Ort, Datum, Uhrzeit)

Doctor's signature (Unterschrift der Ärztin / des Arztes)

### Refusal by the patient Ablehnung des/der Patienten/in

Ms./Mr. Dr \_\_\_\_\_\_ informed me in detail about the proposed anaesthesia and explained to me the consequences arising from my refusal. I understood the explanation and discussed with the doctor the information he/she gave 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. Hiermit lehne ich die mir vorgeschlagene Untersuchung/Behandlung ab. City, date, time (Ort, Datum, Uhrzeit)

Signature of patient / legal guardian [Unterschrift der Patientin / des Patienten / Vormund]

### Statement and consent of the patient Erklärung und Einwilligung des/der Patienten/in

Please tick the appropriate boxes and confirm your statement with a signature: Bitte kreuzen Sie die zutreffenden Kästchen an und bestätigen Sie Ihre Erklärung anschließend mit

Bitte Kreuzen Sie die zutreffenden Kästchen an und bestätigen Sie Ihre Erklärung anschließend mit Ihrer Unterschrift:

Hereby I confirm that I understood all integral parts of the explanation for patients. I read completely this form with explanations (6 pages). In an talk with Ms./Mr. Dr

course of planned surgery, risks, complications and side effects in my special case and I was thoroughly informed about the benefits and risks of alternative methods.

Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe. Diesen Aufklärungsbogen (6 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit Frau/Herrn Dr. \_\_\_\_ wurde ich über den Ablauf des geplanten Eingriffs, dessen Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativ-methoden umfassend informiert.

L I saw and understood the informative film on planned catheterization/treatment. Den Informationsfilm über die bei mir geplante Untersuchung habe ich gesehen und verstanden.

# □ I deliberately renounce a detailed explanation. How-

ever, hereby I confirm that the doctor who heals me, informed me about the necessity of surgery, type and scope, as well as circumstances that the procedure entails risks.

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.

# I confirm that I do not have additional questions and that I do not need additional time to make a decision. I agree with the proposed cardiac catheterization / treatment. I also agree with all necessary auxiliary and subsequent measures (e.g. receiving someone else's blood).

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Herzkatheter-Untersuchung/Behandlung zu. Ich willige ebenfalls in alle notwendigen Neben- und Folgemaßnahmen (z. B. Übertragung von Fremdblut) ein.

My consent also refers to necessary changes or extensions of the procedure, e.g. treatment of multiple narrowings. Meine Einwilligung bezieht sich auch auf die erforderlichen Änderungen oder Erweiterungen des Verfahrens, z. B. Behandlung mehrerer Verengungen.

I answered the questions about my medical history (anamnesis) completely to the best of my knowledge.

Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

I confirm that I am capable of respecting the doctor's advice. 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-Adresse

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

Signature of patient / legal guardian [Unterschrift der Patientin / des Patienten / Vormund]

Copy/Kopie: received/erhalten

waived/verzichtet

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