

Clinic / Doctor [Klinik / Praxis]:



Patient data: [Patientendaten:]

englisch

Procedure scheduled to take place on (date): [Der Eingriff ist vorgesehen am (Datum):]

inguinal hernia repair
Leistenhernien-Operation

left side
links

femoral hernia repair
Schenkelhernien-Operation

right side
rechts

Dear patient, dear parents,

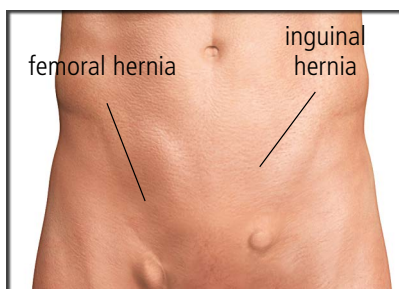
you have/your child has been diagnosed by your doctor with a rupture in the area of the groin, a so-called inguinal hernia or a so-called femoral hernia, and he recommends that you undergo repair surgery.

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

STRUCTURE AND FUNCTION OF THE GROIN

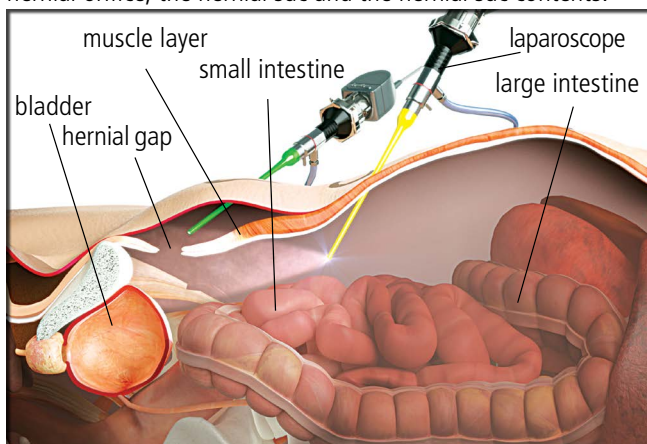
AUFBAU UND FUNKTION DER LEISTE

The human body naturally has a number of vulnerable areas in which so-called hernias may occur. This includes the inguinal canal as well as the area of the thigh near the groin just below the inguinal ligament.



The abdominal organs and the muscles of the abdomen constantly put pressure on the area of the groin. When we cough, sneeze, have a bowel movement or lift something, this pressure is increased, but is

usually absorbed by the muscles and the connective tissue of the inguinal canal. However, if the tissue yields, the lining of the abdominal cavity or even the intestines may push through the resulting gap, forming a rupture. This hernia consists of the hernial orifice, the hernial sac and the hernial sac contents.



An inguinal hernia can be present at birth or develop over time. In case of an indirect hernia, the hernial sac pushes through the natural openings of the inguinal canal and can protrude into the scrotum in a male (which is then referred to as scrotal hernia), which mostly occurs in children and youths. A direct hernia develops due to a weakness in the posterior wall of the inguinal canal. This type of hernia is more common in elderly people. If a hernia develops below the inguinal ligament towards the thigh, it is referred to as femoral hernia.

Generally, any inguinal or femoral hernia should be repaired surgically since protruding organs may become trapped in the hernia and be damaged.

COURSE OF OPERATION ABLAUF DER OPERATION

The procedure is usually carried out under a general anaesthetic, regarding which you will receive a separate information sheet. In certain cases, operating under local anaesthesia is also possible.

There are different methods which can be used to repair an inguinal or a femoral hernia. The overall goal is retrocession of the hernial sac content, removal of the hernial sac and closing of the hernial orifice along with reinforcement of the posterior wall of the inguinal canal with or without surgical mesh implants. This can be done in open or minimally invasive surgery.

With open surgery, a somewhat longer incision will be needed to treat the hernia and to reinforce the abdominal wall. This will be achieved either through sutures, with the abdominal wall layers being doubled over on themselves and sutured (using the Shouldice technique, for instance), or through the use of surgical mesh (using the Lichtenstein technique, for instance). The two methods can also be combined.

With minimally invasive surgery, 1-3 incisions are made and a small camera (laparoscope) as well as various surgical instruments are then inserted through them (keyhole surgery). In order to close up the hernial gap, a mesh is always inserted, either through the abdomen or between layers of the abdominal wall which have been stretched apart for this purpose. The mesh is

inserted behind the muscles and the lining of the abdominal cavity in order to serve as permanent reinforcement of the abdominal wall.

Depending on the type and location of the hernia, a flexible plastic tube may also be inserted as a surgical drain to drain fluids from the wound. With minimally invasive surgery, a urinary catheter may also have to be inserted temporarily. Your doctor will inform you as to which type of procedure is suitable in your particular case and which procedure has been scheduled for you.

ALTERNATIVE METHODS ALTERNATIV-VERFAHREN

Surgery is the only treatment available for a hernia. All alternative treatment methods, such as the use of a so-called hernia truss, do not constitute effective ways of treating a hernia.

Treating the hernia without inserting a mesh carries a higher risk of the hernia reappearing (recurrence). The implantation of surgical mesh, however, is accompanied by risks such as mesh infection, mesh shrinkage, chronic pain and foreign body reaction.

POSSIBLE ADDITIONAL MEASURES

MÖGLICHE ERWEITERUNGSMASSNAHMEN

If there are any additional findings during the operation, additional measures or changes in procedure may become necessary (for instance a larger incision).

If further findings requiring medical intervention are uncovered during the operation, it is often possible to treat them during the same procedure.

In order to avoid having to undergo a separate surgical procedure at a later point in time, we would ask you to already agree to any additional measures now.

PROSPECTS OF SUCCESS

ERFOLGSAUSSICHTEN

In most cases, the hernial gap can be closed successfully and permanently. In some cases, however, a hernia may reappear in the same place or in a neighbouring area (recurrence), or incisional hernia may occur. This will often result in additional surgery being required.

DIRECTIONS FOR PREPARATION AND AFTERCARE

HINWEISE ZUR VORBEREITUNG UND NACHSORGE

Preparation:

Medication: It is important for you to inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as aspirin [ASA], Marcumar®, heparin, Plavix®, Xarelto®, Pradaxa® etc.). Your doctor will let you know if and for how long you need to stop taking your medication.

Aftercare:

Post-surgical pain can usually be alleviated with medication. You will be given additional pain medication if need be.

You should refrain from eating and drinking for at least 4 hours after surgery. After that period of time, diet progression can commence in accordance with your doctor's instructions.

In order to avoid recurrence of hernias, lifting of loads exceeding a total weight of 5-10 kilos should be avoided for the period of time recommended by your doctor.

The suture materials are usually removed 10-14 days after surgery. If absorbable suture materials are used, removing the sutures may be superfluous.

If the procedure is performed **on an out-patient basis**, it is necessary for an adult to come and collect you. Please also make sure there will be an adult at home to supervise you for the period of time recommended by your doctor. You must not actively participate in road traffic for a period of **24 hours after the procedure** (not even as a pedestrian) nor participate in

any risky activities. You should also refrain from drinking alcohol and from taking any important personal or economic decisions during this period.

RISIKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS RISIKEN, MÖGLICHE KOMPLIKATIONEN UND NEBENWIRKUNGEN

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

Injury of neighbouring organs (e.g. bowel, bladder, muscles, seminal duct, testicles, blood vessels) is generally possible. Additional surgical measures may then have to be taken. Injury of the seminal duct can result in male fertility disorder, injury of blood vessels in the leg may lead to permanently impaired blood circulation. The small or the large bowel may have protruded into the hernial sac. Injury of those organs is rare; however, it can lead to the formation of fistulas and adhesions requiring surgery in the long run. In a man, injury of the blood vessels of the inguinal canal can even lead to a **loss of a testicle** in very rare cases. **Nerve damage** can lead to **numbness** in the area of the groin, the pubic region, the thigh, abdominal wall or leg paralysis or to **protracted pain**.

If part of the bowel has to be removed, the bowel will have to be sutured, which may result in **anastomotic leakage** in very rare cases. In extreme and exceptional cases, a **colostomy** may be required.

Through the retrocession of hernial sac content, the **pressure inside the abdominal cavity may increase** in case of severe hernias, leading to impaired blood circulation of the abdominal organs (compartment syndrome). Surgery to relieve the pressure involving the opening of the abdomen can then be required.

Infections of the surgical wound or at the site where injection needles were inserted, including syringe abscess, tissue death (necrosis) and scarring, rarely occur. In most cases, infections can be treated successfully with antibiotics. Abscesses may have to be opened and drained. In very rare cases, germs may be introduced into the bloodstream, leading to dangerous blood poisoning (toxaemia), inflammation of the endocardium (endocarditis) or, especially if the colon has been injured during surgery or treated surgically, an inflammation of the lining of the abdominal cavity (peritonitis).

Allergic reactions (intolerance symptoms), for instance to medication (pain killers, anaesthesia) or to the mesh used rarely occur. Skin rash, itching, swelling or nausea and coughing may then occur as a result. They normally disappear without treatment. Severe reactions such as shortness of breath, spasms, tachycardia or life-threatening circulatory shock are rare. Due to insufficient perfusion, temporary or permanent organ damage, e. g. brain damage, paralysis or kidney failure may occur even despite adequate intensive care.

Every operation involves a **risk of bleeding**. Most bleeding can be stopped immediately during the operation. On very rare occasions, postoperative bleeding may occur, requiring an additional surgical intervention at worst. Should severe blood loss occur, the use of donor blood/blood components (**transfusion**) may be required. This can lead to transmission of diseases, such as

hepatitis in very rare cases (causing dangerous inflammation of the liver), HIV in extremely rare cases (causing AIDS), BSE (causing a form of Creutzfeldt-Jakob disease) or also of other – even unknown – diseases.

Bruising around the groin is a common risk; these haematoma usually disappear without treatment. Seroma formation (discharge of serous fluids from the operative area) may require puncturing or additional surgery.

Damage to the skin, soft tissue or nerves (e. g. through injections, disinfectants, the use of electrosurgical instruments or despite proper positioning) is rare. Sensory disturbance, numbness and pain may then result. They are usually temporary. Permanent nerve damage, tissue death or scarring occur very rarely.

The operation itself or the immobilisation afterwards can lead to the formation of blood clots (**thromboses**) in very rare cases. Such blood clots may then travel to other parts of the body and block the vessels of other organs (**embolism**). This may then lead to e.g. lung embolism, stroke or kidney failure resulting in permanent damage despite proper treatment. Compression stockings, early mobilisation and anticoagulant agents (Heparin) are used to decrease the risk of thromboses. If Heparin is administered, it may result in severe coagulopathy (HIT) on very

rare occasions. This means that the risk of thrombosis formation and thus obstruction of blood vessels is increased.

The injection of gas during minimally invasive surgery can lead to gas entering into a blood vessel (**air embolism**), or gas can enter into the chest and push aside the lungs (pneumothorax).

In case of delayed wound healing or with patients predisposed to **wound healing disorder**, cosmetically disfiguring scarring and abnormal proliferation of scar tissue (keloids) may occur. This may require additional corrective surgery.

Adhesions may lead to protracted pain or dangerous **intestinal obstruction** even after several years.

Specific risks related to the use of mesh implants

The use of a mesh implant may lead to **foreign body sensation, pain** or **adhesion or inflammation of the mesh**, also sometimes affecting neighbouring organs. In severe cases, the mesh may then have to be surgically removed.

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: [Straße, Hausnummer, PLZ, Ort]

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 Arzt / Hausarzt / weiter betreuender Arzt?

Name: [Name]

Street, house number: [Straße, Hausnummer]

postcode, place: [PLZ, Ort]

Telephone: [Telefonnummer]

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 treatment 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

Gender: M / F, **age:** _____ **years, weight:** _____ **kg, height:** _____ **cm,**

Geschlecht: m / w, **Alter:** _____ **Jahre, Gewicht:** _____ **kg, Größe:** _____ **cm,**

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), Heparin, Marcumar®, Plavix®, Ticlopidin, Clopidogrel.

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), Heparin, Marcumar®, Plavix®, Ticlopidin, Clopidogrel.

Any other: _____
Sonstiges:

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

Do you take any other medications? yes no

Nehmen Sie andere Medikamente ein? Wenn ja, bitte auflisten:

If so, which ones: _____

(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 surgery on the abdomen? yes no

Wurden Sie schon einmal am **Bauchbereich** operiert?

If so, which operation? _____

Wenn ja, welche Operation?

Were there any complications? yes no

Ergaben sich dabei Komplikationen?

If so, what complications? _____

Wenn ja, welche?

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

Are you pregnant? not certain nicht sicher yes no

Besteht eine Schwangerschaft?

Do you drink alcohol regularly? yes no

If so, what and how much: _____

Trinken Sie regelmäßig Alkohol? Wenn ja, was und wie viel:

Do you have metal implant (e.g. hip implant)? yes no

Haben Sie ein Metallimplant (z. B. künstliche Hüfte)?

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 tendency to bleed (e.g. frequent nose-bleeds, increased bleeding after surgery, minor wounds or dental treatment), 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), 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?

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:

Heart, circulatory or blood vessel diseases? yes no

Heart attack, chest pain and/or tightness (angina pectoris), heart defect, irregular heart rhythm, inflammation of heart muscle, Inflammation of the inner layer of the heart, heart valve disease, heart surgery (possibly with insertion of an artificial heart valve, pacemaker, defibrillator), high blood pressure, stroke, varicose veins, inflammation of a vein, Brain aneurysm.

Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), Herzfehler, Herzrhythmusstörungen, Herzmuskulenzündung, Herzinnenhautentzündung, Herzklappenerkrankung, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, Schlaganfall, Krampfadern, Venenentzündung, Gefäßbaussackung im Gehirn.

Any other: _____

Sonstiges:

Diseases of the respiratory tract (breathing passages) or lungs? yes no

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

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

Any other: _____

Sonstiges:

Metabolic diseases? yes no

Diabetes (sugar sickness), gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____

Sonstiges:

Do you take diabetes medications? yes no

metformin-containing tablets

insulin injection

Nehmen Sie Diabetesmedikamente ein? Spritzen (Insulin), metforminhaltige Tabletten

Any other: _____

Sonstiges:

Kidney diseases? yes no

Kidney insufficiency, kidney inflammation,

kidney operations, kidney or ureter stones,

blood in the urine, plasmocytoma.

Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung, Nieren-OP, Nieren- oder Harnleitersteine, Blut im Urin, Plasmocytom.

Any other: Sonstiges: _____

Liver diseases? liver inflammation. yes no

Lebererkrankungen? Leberentzündung.

Any other: Sonstiges: _____

Communicable (contagious) diseases? yes no

Hepatitis, tuberculosis, HIV.

Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any other: _____

Sonstiges:

Do you have a malignant tumour (cancer)? yes no

Leiden Sie an einer Tumorerkrankung (Krebs)?

Are you receiving or have you received chemotherapy? yes no

Erhalten oder erhielten Sie eine Chemotherapie?

Any other acute or chronic diseases / illnesses? yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: _____

Bitte kurz beschreiben:

Medical documentation for the informative interview

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, nähere Informationen zu den Alternativ-Methoden, mögliche Konsequenzen, wenn der Eingriff verschoben oder abgelehnt wird) habe ich den Patienten im Gespräch näher aufgeklärt:

Recommended procedure:

Vorgesehene Operation:

- | | |
|--|--|
| <input type="checkbox"/> inguinal hernia repair
Leistenhernien-Operation | <input type="checkbox"/> left side
links |
| <input type="checkbox"/> femoral hernia repair
Schenkelhernien-Operation | <input type="checkbox"/> right side
rechts |
| <input type="checkbox"/> minimally invasive
minimal-invasiv | <input type="checkbox"/> open
offen |
| <input type="checkbox"/> with mesh mit Netz | |

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is capable of making a decision on the recommended procedure by himself/herself and issuing its consent for the procedure. Der/Die Patient/in besitzt die Fähigkeit, eine eigenständige Entscheidung über den empfohlenen Eingriff zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.
- The patient is represented by the carer, i.e. guardian with a document of evidence of guardianship. This person is entitled to making a decision on behalf of the patient.
Die Patientin wird von einem Betreuer bzw. Vormund mit einer Betreuungsurkunde vertreten. Dieser ist in der Lage, eine Entscheidung im Sinne der Patientin zu treffen.

City, date, time [Ort, Datum, Uhrzeit]

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

Patient's refusal Ablehnung

Ms./Mr. _____ informed me in detail about the suggested surgery and the resulting negative effects due to my rejection. I understood the information relating to this and could discuss my insights on this information with the surgeon. I hereby declare that I reject the suggested surgery. 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 Operation ab.

City, date, time [Ort, Datum, Uhrzeit]

Signature of the patient/guardian/tutor/possible witness
[Unterschrift der Patientin / des Patienten / Betreuer / Vormund / ggf. des Zeugen]

DECLARATION OF CONSENT

Einwilligungserklärung

Please tick the appropriate box and confirm your statement with a signature: 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 (5 pages). During the talk with Ms./Mr. _____ I was given an explanation of the course of planned treatment, risks, complications and side effects in my /my child's specific 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 (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit Frau/Herrn Dr. _____ wurde ich über den Ablauf der geplanten Behandlung, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall/im speziellen Fall unseres Kindes und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.
- I renounce deliberately detailed information.** I declare that, nevertheless, the surgeon in charge informed me about the necessity of the surgery the kind and extent as well as possible risks of the treatment. **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 hereby assure that I have no further questions and do not need further time for consideration. I agree with the suggested surgery. I also agree with any necessary lateral or follow-up measures. The questions to my anamnesis I have answered in all conscience.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkenzeit benötige. Ich stimme der vorgeschlagenen Operation zu. Ich willige ebenfalls in alle notwendigen Neben- und Folgemaßnahmen ein. Die Fragen zu meiner Krankengeschichte habe ich nach bestem Wissen vollständig beantwortet.

I assure that I am capable of following medical 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 email address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

email address: [E-Mail-Adresse]

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

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

- Copy/kopie: received/erhalten
 waived/verzichtet

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

*If only one parent signs, then by so doing this parent declares that he/she has sole rights of custody or is acting with the consent of the other parent.

