

Clinic / Doctor:



Patient data:

Surgery scheduled to take place on (date):

left lung
 right lung
 Disease: _____

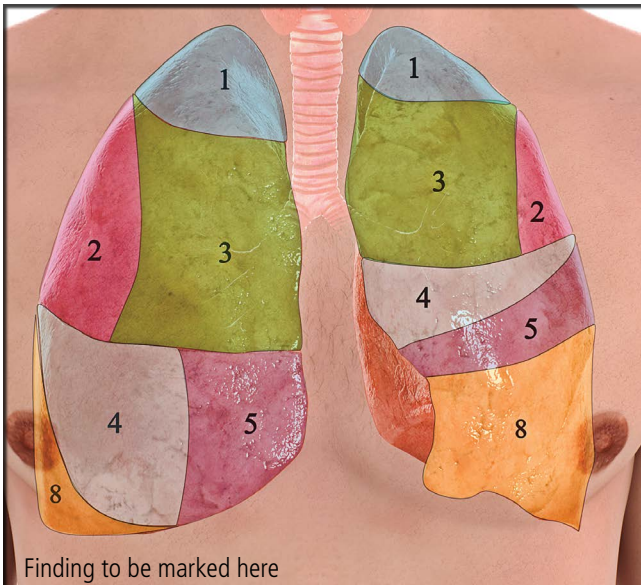
Dear patient,

lung surgery is planned in your case.

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

REASONS FOR SURGERY

The lung is located in the ribcage surrounded by your ribs and is divided into two parts. The left lung consists of two and the right lung of three lung lobes which are divided into several segments varying in size.



Certain types of lung disease, such as tumours, metastases, inflammation, malformation, emphysema, cysts or abscesses, can lead to impaired lung function, which may be severe in some cases.

If treatment with medication doesn't suffice, the affected lung tissue will be removed in a surgical procedure.

COURSE OF OPERATION

The operation will be carried out under general anaesthesia, regarding which you will receive a separate information sheet.

Access to the lungs can be effected in different ways:

Thoracoscopy

During this **minimally invasive procedure ("keyhole surgery")**, an optical instrument connected to a camera (thoracoscope) is inserted into the chest through one or several small incisions, various other surgical instruments can also be inserted. The doctor can then view the surgical area via a monitor.

Thoractomy

This **access via the side of the ribcage** is effected by the doctor opening the ribcage with an incision along the ribs.

Sternotomy

If large sections of the lung have to be removed, the ribcage will be opened by dividing the sternum.

Depending on the type of disease, different types of surgery are available. The doctor will mark the procedure planned in your case in the following and provide you with further information regarding the procedure:

Partial/full removal of the lining of the lungs (pleurectomy)

Removal of lung segments

Removal of one or several lung lobes (lobectomy)

If need be, a removal and subsequent reconstruction of affected bronchial and arterial sections will be carried out.

Removal of one lung (pneumonectomy)

Laser tissue removal

In case of lung metastases in particular, the malignant tissue is removed with a laser to protect the surrounding tissue.

Wedge removal (wedge excision)

The diseased area is removed in the form of a wedge from the surrounding lung tissue and the edges of the wound are closed with sutures or clips.

Extended removal

In case of a malignant finding, it may be necessary to remove tissue of other organs as well in addition to the affected section of the lungs (e.g. pericardium, diaphragm, oesophagus).

Removal and direct reconstruction of bronchial tissue (bronchoplasty)

If there is a disease of the bronchs, the affected sections will be removed and the resulting ends will be sutured.

Partial removal of the lung artery and subsequent reconstruction (vessel reconstruction)

Removal of lymph nodes

In case of a malignant finding, individual or all lymph nodes in the chest within the lymphatic flow area of the tumour will have to be removed.

After the operation, thin plastic tubes (so-called drains) are usually inserted into the chest to drain blood, fluids and air. The wounds are treated with a dressing. In some cases, short-term respiration or a cut in the windpipe (tracheotomy) may be required.

POSSIBLE ADDITIONAL MEASURES

In certain cases, for instance in case of adhesions, previous operations or stronger bleeding, the surgical method may have to be adjusted, e.g. switching to open surgery including the opening of the chest or division of the sternum.

In order to avoid having to undergo a separate procedure at a later point in time, you can already agree to any necessary changes or additional measures now.

ALTERNATIVE METHODS

In some cases, treatment with medication only may be an option. However, full recovery can only be achieved through surgery in most cases.

If there is a malignant tumour, radiotherapy, chemotherapy or a combination of both may be viable alternatives in particular cases.

Your doctor will explain to you why he would recommend surgery in your particular case.

PROSPECTS OF SUCCESS

The operation's success depends on the type and extent of the disease. In cases with clearly defined benign diseases, lung surgery can often result in the patient being symptom-free.

If a malignant finding is removed, the tumour may reappear after some time, even in other organs (recurrence), despite the surgery having been successful. For this reason, radio- and/or chemotherapy is often carried out in addition to an operation.

If only small parts of the lungs are removed, lung function will usually not be impaired after surgery, depending on the type of disease. If a larger part of the lungs, such as the entire right or left lung, has to be removed, it will result in significantly reduced lung function in some cases.

If the lung tissue has already been damaged by the disease, that damage cannot be reversed in a surgical procedure.

Your doctor will explain to you which outcome is most likely in your particular case.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Please follow the instructions of the doctor and of the nursing personnel closely. Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: Please inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASS], Marcumar®, Heparin, Plavix®, Ticlopidin, Clopidogrel, Eliquis®, Lixiana®, Xarelto®, Pradaxa® and metformin-containing antidiabetic medicines, so-called biguanides) or have taken irregularly over the course of the past eight days prior to the procedure (for instance pain killers such

as ibuprofen, paracetamol). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know if and for how long you should stop taking your medication.

The surgical procedure requires **pre-procedure fasting**. Please follow the respective instructions of your anaesthetist.

You should stop **smoking** prior to the operation to avoid serious complications.

Aftercare:

Post-surgical **pain** can usually be alleviated with medication.

Post-procedure **check-ups** will be required. Please be conscientious in keeping those appointments.

Your doctor will let you know whether you should refrain from **sports** for a period of time after surgery.

Please inform your doctor if you experience **fever, pain, circulatory problems, bleeding from the wound, shortness of breath, coughing** or **vomiting blood** after the surgery. These symptoms may appear even days after the procedure and **must be examined immediately**.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

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

Injury of neighbouring organs (e.g. the heart, oesophagus, liver, spleen) cannot be ruled out entirely. If injuries are severe, the surgical procedure may have to be extended and dangerous infection (mediastinitis) may result.

Bleeding can usually be stopped immediately during the operation. Post-procedure bleeding may require additional surgery. Should **severe blood loss** occur, the use of donor blood/blood components (**transfusion**) may be required. In very rare cases, this can lead to transmission of diseases, such as hepatitis (causing dangerous inflammation of the liver), HIV (causing AIDS), BSE (causing a form of Creutzfeldt-Jakob disease) or also of other dangerous – even unknown – diseases. Lung oedema leading to lung failure, a decrease in kidney function or other dangerous immune responses can be triggered.

The operation may lead to damage to the **vocal cord nerves** resulting in hoarseness, impaired speech, trouble swallowing and even acute shortness of breath. This may require vocal cord surgery or a cut in the windpipe (tracheotomy).

Damage to the phrenic nerve (Nervus phrenicus) can result in a weakening or even paralysis of the breathing activity of the diaphragm. If the **vagus nerve** in the ribcage is injured, it may lead to cardiac arrhythmia or disturbed stomach and colon function.

An **injury of the sympathetic nervous system** will lead to the so-called **Horner syndrome** including temporary, rarely permanent, symptoms such as pupil constriction, a sunken eyeball and a droopy upper eyelid.

If the **nerve bundle** in the ribcage **that supplies the arm is damaged** during surgery, it can lead to temporary or permanent sensory disturbance or even paralysis of the arm as a result.

Injury of the lymphatic vessels or the **mammary ducts of the breast** with fluids entering into the chest may require additional surgery.

Injury of a vessel in the lungs can lead to **air entering into the blood stream** (air embolism) and thus to obstruction of a blood vessel. Severe blood flow or circulatory disturbances may then result and may require intensive medical care.

Damage to the skin, soft tissue or nerves - for instance through injections, bruising, syringe abscess, disinfectants or despite proper positioning - may occur. Numbness, paralysis and pain may then result. They are usually temporary. In some cases, permanent nerve damage, tissue death or scarring may occur.

Sometimes **blood clots (thromboses)** may form, causing obstruction of a blood vessel. 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. **stroke, kidney failure requiring dialysis** or **lung embolism** and result in permanent damage.

With patients predisposed to delayed wound healing or **wound healing disorder**, painful scarring and abnormal proliferation of scar tissue (keloids) may occur. If the sternum doesn't grow back together stably, additional surgery may become necessary. Permanent **ribcage pain** (so-called intercostal neuralgia) is rare.

If an **incisional hernia** occurs, it may result in lung tissue protruding into the intercostal space.

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

Bruising (haematomata) is possible. This may lead to firm, painful swelling. Most of the time, this will disappear even without treatment.

Infections can usually be treated with antibiotics. If an **abscess** forms or if an **infection of the lining of the lungs** (so-called empyema) occurs, surgical intervention may be required. **Infections of the sternum** after open surgery on the chest often require the partial removal of the sternum. In extreme cases, germs may be introduced into the bloodstream (bacteraemia), leading to life-threatening **blood poisoning** (toxaemia) or inflammation of the endocardium (endocarditis) as a result.

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

Unnatural connections (**fistula**) may form, e.g. if the sutures on the bronchs or the lung tissue don't close up properly. This may require additional surgery, if needed including a closure using the patient's own tissue.

It cannot be ruled out entirely that tumour cells are introduced to other areas of the body, leading to the formation of **metastases** in exceptional cases.

If the entire right or left lung is removed, it may lead to a **dislocation of the heart or the oesophagus**, which may then have to be surgically corrected.

The stress of the procedure may lead to **stomach or intestinal ulcers**. Medication can be administered as a precautionary measure to prevent this.



Questions about Your Medical History

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

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), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Efiect®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

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), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Efiect®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

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.)

Are you pregnant? not certain yes no
Sind Sie schwanger? nicht sicher

Have you ever had surgery in the chest or abdomen? yes no

Wurden Sie schon einmal im Brust-/Bauchraum operiert?

If so, where? _____
Wenn ja, wo?

Were there any complications? yes no

Ergaben sich dabei Komplikationen?

If so, what complications? _____
Wenn ja, welche?

Do you have or have you ever had any of the following diseases: Liegen oder lagen nachstehende Erkrankungen vor:

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, heart valve disease, shortness of breath while climbing stairs, heart surgery (possibly with insertion of

an artificial heart valve, pacemaker, defibrillator), high blood pressure, low blood pressure, stroke, varicose veins, inflammation of a vein, thrombosis, embolism.

Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), Herzfehler, Herzrhythmusstörungen, Herzmuskelerkrankung, Herzklappenerkrankung, Luftnot beim Treppensteigen, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, niedriger Blutdruck, Schlaganfall, Krampfader, Venenentzündung, Thrombose, Embolie.

Any other: _____
Sonstiges:

Metabolic diseases? yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

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)?

Any other acute or chronic diseases / illnesses? yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: _____
Bitte kurz beschreiben:

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

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 Alternativmethoden, Erfolgsaussichten) habe ich den Patienten im Gespräch näher aufgeklärt:

Planned Procedure Folgende Operation ist geplant:

left links right rechts

Disease:

- Partial/full removal of the lining of the lungs (pleurectomy)
Teil-/Entfernung des Rippenfells (Pleurektomie)
- Removal of lung segments Entfernung von Lungensegmenten
- Removal of one or several lung lobes (lobectomy) Entfernung eines oder mehrerer Lungenlappen (Lobektomie)
- Removal of one lung (pneumonectomy) Entfernung eines Lungenflügels (Pneumonektomie)
- Laser tissue removal Gewebeentfernung mit dem Laser
- Wedge removal (wedge excision) Keilentfernung (Keilexzision)
- Extended removal Erweiterte Entfernung (z. B. mit Entfernung von)

- Removal and direct reconstruction of bronchial tissue (bronchoplasty) Entfernung von Bronchialgewebe (Bronchoplastik)
- Partial removal of the lung artery and subsequent reconstruction (vessel reconstruction) Teilentfernung der Lungenarterie (Gefäßplastik)
- Removal of lymph nodes Entfernung von Lymphknoten
- mit Thoracoscopy Thorakoskopie Thoractomy Thorakotomie
 Sternotomy Sternotomie

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is **capable of making a decision** on the recommended procedure on his/her own and giving his/her consent for the procedure. Der/Die Patient/in besitzt die Fähigkeit, eine **eigenständige Entscheidung** über die empfohlenen Maßnahme zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.
- The patient is represented by a **custodian** with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. These persons are capable of making a decision in the best interest of the patient. Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsvorsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.
- Custodian's card healthcare proxy advance healthcare directive has been submitted.
- Betreuerausweis Vorsorgevollmacht Patientenverfügung liegt vor.

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

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

Patient's refusal Ablehnung

The doctor _____ has provided me with detailed information regarding the procedure at hand and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the procedure suggested to me.

Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene Maßnahme ab.

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

Refusal of patient / legal guardian / witness if applicable
[Ablehnung Patientin / Patient / Betreuer / ggf. des Zeugen]

DECLARATION OF CONSENT

Please tick the appropriate boxes and confirm your statement with your signature below:

- I hereby confirm that I have understood all sections of this form.** I have read the entire form (5 pages). During the pre-procedure interview with the doctor _____, I received detailed information regarding the course of the scheduled procedure, the risks, complications and side effects associated with it as they apply to my particular case as well as the advantages and disadvantages of any alternative methods. **Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe.** Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit der Ärztin/dem Arzt wurde ich über den Ablauf der geplanten Maßnahme, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.
- I deliberately refrain from obtaining a more detailed explanation.** However, I hereby confirm that the doctor _____ instructed me regarding the necessity of the procedure, its type and scope as well as the fact that all medical procedures are accompanied by certain risks. **Ich verzichte bewusst auf eine ausführliche Aufklärung.** Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt über die Erforderlichkeit der Maßnahme, deren Art und Umfang sowie über den Umstand, dass alle medizinischen Maßnahmen Risiken bergen, informiert wurde.

I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the procedure proposed. I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Maßnahme zu. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

My consent also applies to any necessary additional measures as well as to any required changes or additions to the procedure. Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen, sowie auf erforderliche Änderungen oder Erweiterungen des Maßnahme.

I confirm that I am capable of following the instructions given to me by my doctor.

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 the patient / legal guardian(s) [Unterschrift Patientin / Patient / Betreuer]

Copy/Kopie:

- received/erhalten
 waived/verzichtet

Signature Copy received/waived
Kopieerhalt/-verzichtet