

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

### Dear patient,

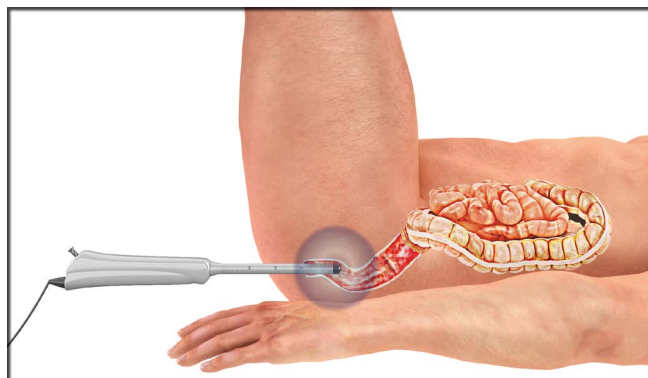
In order to determine the cause of your symptoms, we recommend that you undergo an endoscopic ultrasound examination of the upper and lower digestive tract (endosonography). Since this examination method allows for the ultrasonic probe to be moved closer to the structures and organs to be examined, it ensures a clear view and assessment of any pathological changes. If necessary, tissue samples can also be taken or minor treatment measures can be taken immediately.

The following text is intended to inform you about the course of the examination and possible treatment methods, related risks and any measures you need to take before and after the procedure as well as 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 and of any potential complications which could result from them. The doctor will answer all of your questions in order to reduce any fears or concerns you may have and to inform you in detail regarding the examination/treatment. You may then consent to the procedure suggested to you or reject the procedure. Please read the following information and complete the form carefully. It is understood that your data will be treated as confidential. Your doctor will provide you with a copy of the completed and signed form after the interview.

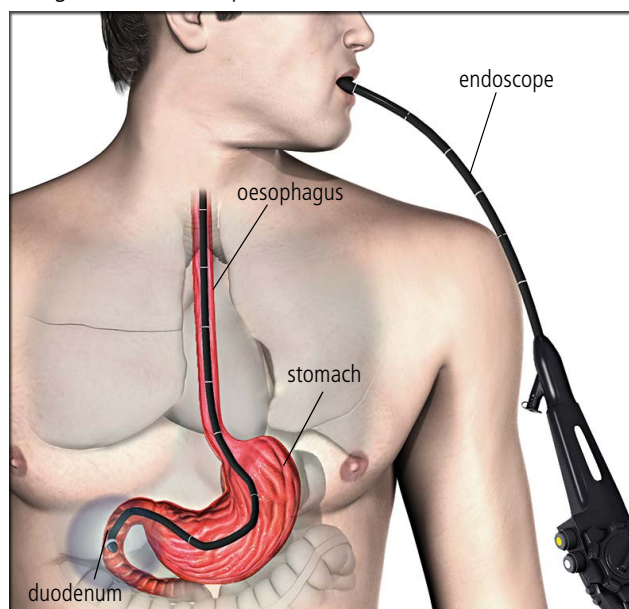
### COURSE OF EXAMINATION/TREATMENT

The course of the examination is similar to that of a gastroscopy or proctoscopy and is carried out with the use of an endoscope. An endoscope is a flexible, steerable, thin tube with a very small camera, a source of light and an ultrasound transducer attached to its tip. Inflexible endoscopes are also used in proctoscopy. If need be, small surgical instruments can be introduced through an operation cannula inside the endoscope. Miniature ultrasound imaging probes inserted via the operation cannula of the endoscope are used to examine the bile duct.

Usually, a peripheral venous cannula is inserted into your lower arm for the examination. Through it, a sedative and/or analgesic can be administered. Alternatively, you will be injected with an anaesthetic (such as Propofol or Dormicum®), which will put you in a sleep-like state. Oxygen can be administered via a nasal tube.



In order to facilitate the insertion of the endoscope to examine the oesophagus, stomach and duodenum, your throat will be anaesthetised locally with a spray. In order to protect your teeth, you will receive a teething ring. It will also prevent accidental biting on the endoscope tube.



The advantage of endoscopic ultrasound examination is that it not only allows for the surface of the mucous membranes of the oesophagus, stomach or intestine to be viewed. It also enables the examiner to assess the extent of any pathological changes in deeper tissue layers through the ultrasonic imaging

of the surrounding tissue. Compared to ultrasound examination which is carried out from the body's surface, it also reaches tissue which is difficult to access and which can then be examined using higher-resolution images. If any changes are discovered, tissue samples can be taken from them directly with a puncture needle with ultrasound guidance. Endoscopic ultrasound examination also allows for any build-up of fluids in the tissue, so-called cysts, to be drained by puncturing them with a needle (cyst drainage).

### ALTERNATIVE METHODS

Compared to examinations which are carried out from the outside, such as ultrasound, X-ray, CT scan or MRI, endosonography usually provides more conclusive results. In addition, the surface of the mucous membrane can be viewed directly and tissue samples or small treatment measures can be taken immediately. For this reason, examination methods from the outside do not constitute viable alternative methods.

### PROSPECTS OF SUCCESS

In patients with anatomic anomalies – such as strictures in the digestive tract or resulting from previous operations – the examination may not be possible or only in part, or pathological changes may be overlooked. Also, the procedure may not be successful as planned when it comes to treating any changes and will then have to be repeated, or a different treatment method may become necessary.

### 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:

An **examination of the upper digestive tract** requires pre-procedure fasting. Therefore, you may not eat or drink anything for at least five hours prior to the procedure and must refrain from smoking. Small amounts of clear fluids such as water up until two hours prior to the procedure are allowed.

An **examination of the lower digestive tract** requires that the intestine be cleansed. If only the lower section of the intestine is to be examined, the intestine can be cleansed using an enema. You may be required, however, to drink a laxative as well as two to three litres of a special rinsing solution to purge your bowels. Your doctor will provide you with specific instructions regarding the purging of your bowels.

**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® [ASS], 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:

If you have received a throat anaesthetic, you may not eat or drink anything for two hours after the examination since there is a risk of choking.

An urge to vomit, a burning sensation in your throat or pain as a result of the air remaining in your stomach or intestine are temporary and no cause for concern. Nevertheless, please inform your doctor immediately if you experience symptoms such as **fever, severe pain, nausea, circulatory problems or vomiting blood or bloody diarrhoea**. These symptoms may appear even days after the procedure and must be **examined immediately**.

If you have had an analgesic and/or sedative administered to you, it is necessary for an adult to come and collect you if the procedure has been performed **on an out-patient basis**. Please also make sure there will be an adult at home to supervise you

for the period of time recommended by your doctor. Since your reaction capacity will be impaired through the administration of analgesics and/or sedatives, unless otherwise instructed, 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. If certain sedatives are used, you may not remember the procedure or a short period of time prior to it (retrograde amnesia).

### 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.

**Injuries** of the larynx, oesophagus, stomach or the duodenum during an endosonographic examination of the upper digestive tract or of the intestine during a proctoscopy are rare, even if there are pathological changes present. If, however, a puncture of the thoracic or abdominal cavities does occur, surgery may be required and life-threatening infections (such as an inflammation of the abdominal lining) may occur.

**Infections** can also occur at the site where injection needles, such as a peripheral venous cannula, were inserted. In most cases, infections can be treated successfully with antibiotics. In rare cases, germs may be introduced to the bloodstream, leading to dangerous blood poisoning (toxaemia) or inflammation of the endocardium (endocarditis) as a result.

Administering an anaesthetic or sedative can lead to **trouble breathing or circulatory problems** (e.g. a drop in blood pressure, slowing of the heart rate) accompanied by **nausea and vomiting**. These symptoms can usually be treated effectively by administering oxygen or medication. However, if **breathing arrest** occurs, artificial respiration will be necessary in order to prevent damage to the brain or other organs. In extreme, exceptional cases, damage to individual organs (such as the kidneys or the brain) may occur despite immediate treatment.

**Allergic reactions** (intolerance symptoms), for instance to medication (analgesics, sedatives), 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 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.

**Bleeding** after taking a tissue sample, treatment measures or caused by small injuries is usually discovered and stopped immediately. Sometimes, bleeding may require additional measures; 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 dangerous – even unknown – diseases.

**Injury of neighbouring organs** such as the **sphincter** very rarely occur when the endoscope is inserted to examine the rectum or during a puncture and may require surgical treatment.

**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, paralysis and pain may then result. They are usually temporary. Permanent nerve damage or scars are rare.

Stomach contents may enter the oesophagus in exceptional cases, causing **pneumonia**.

**Tooth damage** caused by the endoscope occurs very rarely. In patients with loose teeth, a loss of teeth may occur.

After a puncture for taking a tissue sample or after cyst drainage, **inflammation** may occur, which will then require further treatment.

If a malignant tumour is punctured, tumour cells may be introduced to other areas of the body, leading to the formation of **metastases** in exceptional cases.

On the whole, **serious complications** are very rare and, through careful monitoring of the patient, they can usually be recognised and treated in due time.

## 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 you: [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 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®,  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),  Clopidogrel,  Eliquis®,  Heparin,  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 on the oesophagus, stomach or intestine?  yes  no

Wurden Sie schon einmal an Speiseröhre, Magen oder Darm operiert?

Have you ever had a stomach endoscopy or a colonoscopy?  yes  no

Wurde bei Ihnen schon einmal eine Magen- oder Darmspiegelung durchgeführt?

Were there any complications?  yes  no

Ergaben sich dabei Komplikationen?

If so, what? \_\_\_\_\_  
Wenn ja, welche?

Do you have any metal implant (such as artificial hip)?  yes  no

Haben Sie ein Metallimplantat (z. B. eine künstliche Hüfte)?

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

Do you smoke?  yes  no

If so, what and how much daily: \_\_\_\_\_  
Rauchen Sie? Wenn ja, was und wie viel täglich:

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

## Do you have or have you ever had any of the following diseases? Liegen oder lagen nachstehende 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?

### 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.

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

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-Zwerchfellähmung.

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:

### Communicable (contagious) diseases? yes no

Hepatitis,  tuberculosis,  HIV.

**Infektionskrankheiten?**  Hepatitis,  Tuberkulose,  HIV.

Any other: \_\_\_\_\_

Sonstiges:

### Damages to teeth / dental prostheses? yes no

Cavities,  paradontosis,  loose teeth,  crown,  bridge,  implant,  pivot tooth,  removable artificial teeth.

**Zahnschäden/Zahnersatz?**  Karies,  Parodontose,  lockere Zähne,  Krone,  Brücke,  Implantat,  Stiftzahn,  herausnehmbarer Zahnersatz.

Any other: \_\_\_\_\_

Sonstiges:

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

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 ASA-01    ASA-02    ASA-03    ASA-04    ASA-05
**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 Gesundheitsorge 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/verzichtetSignature Copy received/waived  
Kopieerhalt/-verzichtet