

Clinic / Doctor:



Patient data:

Procedure scheduled to take place on (date):

Dear patient,

In order to determine the cause of your symptoms, treat your illness or as a preventive check-up, we recommend an endoscopic examination of your rectum. Alterations such as polyps (mostly benign growths of the mucous membrane), bleeding or haemorrhoids can be recognised early on and often treated immediately.

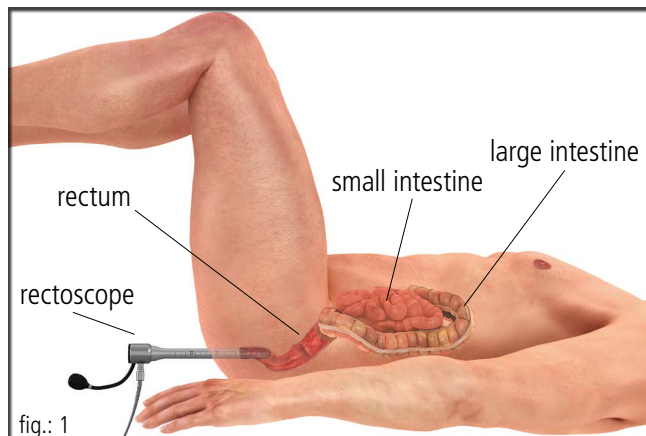
The following text is intended to inform you about the course of the examination/treatment, the related risks and any measures you need to take before and after the endoscopic procedure as well as to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain 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. You may then consent to the suggested examination or reject it.

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

The examination is usually carried out using an inflexible, short instrument (rectoscope, proctoscope) (fig. 1) or a flexible endoscope with a very small camera at its tip. Small surgical instruments can be introduced through an operation cannula inside the endoscope.

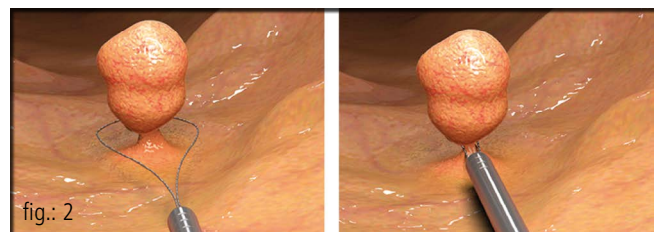
Procto-rectoscopy is carried out with the patient lying down on their left side, in knee-ellbow position or in supine position. If need be, a peripheral venous cannula will be inserted into your lower arm, through which a sedative and/or analgesic can be administered to you.



The endoscope is inserted carefully into your intestine under visual control. The injection of air will lead to the intestine unfolding, facilitating a clearer view of the mucous membrane. The spraying-on of dyes (chromoendoscopy) can make any changes in the mucous membrane even more clearly visible. The taking of tissue samples, which is called a biopsy, will make it possible for even the subtlest changes or those which are not yet visible to be detected.

COURSE OF TREATMENT

One of the advantages of this examination method is that changes which are discovered during the procedure can often be treated immediately. The doctor will remove any polyps using an electrical loop (fig. 2) or pincers.



Abnormal tissue can be treated superficially using what is called Argon Plasma Coagulation. Flat growths on the mucous membrane are removed directly or after they have been injected. Bleeding, for instance after the removal of a polyp, can be stopped through injection with medication, with metal clips or with medical adhesives. Haemorrhoids can be ablated by injecting them with special medication or they can be dried up through banding, using small rubber bands.

ALTERNATIVE METHODS

An examination from the outside, such as ultrasound, X-ray, CT or MRI cannot replace the direct examination of the rectum with an endoscope. Also, treating any changes in the mucous membrane of the rectum and taking tissue samples are impossible when those other methods are used. Therefore, those methods do not constitute a viable alternative to an endoscopic examination and should only be used for specific purposes.

Your doctor will explain to you why he would recommend procto-rectoscopy in your particular case.

PROSPECTS OF SUCCESS

Procto-rectoscopy and endoscopic treatment methods are routine procedures nowadays. Many pathological changes can be treated easily and gently using this method. In patients with anatomic anomalies – such as strictures or changes resulting from previous operations – the examination may not be possible or only in part, or pathological changes may be overlooked. Also, the treatment of changes may not be successful and will then have to be repeated, or a different treatment method may become necessary.

Any polyps discovered during the examination will be removed and examined if possible. This is a preventive measure, since over the course of several years, these benign growths of the mucous membrane can turn into intestinal cancer. In order to be able to detect a reformation of polyps early on and to treat them, regular check-ups or an endoscopic examination of the entire large intestine may then be recommended, depending on the result of the histological examination of the tissue samples taken.

Only first-degree and second-degree haemorrhoids can be treated during a procto-rectoscopy procedure. The haemorrhoids may reappear later on, however. If the haemorrhoidal disease has progressed, the haemorrhoids will have to be surgically removed.

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: For a **procto-rectoscopy** your rectum will have to be emptied and be as clean as possible. For this purpose, a strong laxative will be administered to you about an hour before the examination in the form of a clyster or suppository, which will lead to your bowels emptying within 15 to 20 minutes. Your doctor will provide you with specific instructions regarding the purging of your bowels. You normally do not have to fast prior to the procedure.

Laxatives can influence the effectiveness of other medication you have taken, such as the pill. Therefore, you will have to use additional contraceptive methods until your next menstrual cycle starts.

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: Pain as a result of the air remaining in your intestine is temporary and no cause for concern. Nevertheless, please inform your doctor immediately if you experience symptoms such as **fever, severe abdominal pain, nausea, circulatory problems** or **bloody diarrhoea**. These symptoms may appear even days after the procedure and must be examined immediately.

If you have had an anaesthetic, sedative or analgesic 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. If you have been given 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.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure**, even a routine procedure such as procto-rectoscopy, **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 ex-

ceptional 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.

Severe injuries of the intestinal wall are rare, even in the case of pathological changes or their treatment, since the doctor will carry out all measures under visual control. If, however, a puncture of the abdominal cavity does occur, surgery may be required and life-threatening infections 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 into the bloodstream, leading to dangerous blood poisoning (toxæmia) or inflammation of the endocardium (endocarditis) as a result.

Injury of neighbouring organs such as the **sphincter** through the insertion or steering of the endoscope as well as **damage to the skin, soft tissue or nerves** (e. g. through injections, disinfectants, the use of electrosurgical instruments or despite proper positioning) are rare. Sensory disturbance, numbness, bleeding and pain may then result. They are usually temporary. Permanent damage or scars are very rare.

Bleeding after taking a tissue sample, treatment measures or caused by small injuries is usually discovered and stopped immediately. Sometimes, further measures may have to be taken; 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.

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

Trouble breathing or **circulatory problems**, for instance as side effects of administered sedatives or analgesics, can usually be treated effectively by administering oxygen or medication.

After pathological changes have been treated, **strictures through scarring or inflammation** may occur, requiring further treatment.

For several days after the treatment of haemorrhoids, you may experience a **sensation of pressure with an urge to defecate, pain** or **bleeding** when defecating. Permanent difficulties when defecating are extremely rare.

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 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]

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 surgery on the gastrointestinal tract? yes no

Wurden Sie schon einmal am Magen-Darm-Trakt operiert?

Have you ever had a colonoscopy? yes no

Wurde bei Ihnen schon einmal eine 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 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 Metallbrillengestelle, Modeschmuck oder Hosennieten).

Any other: _____

Sonstiges:

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

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

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

Any other: _____

Sonstiges:

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:

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:

Any other acute or chronic diseases / illnesses? Nicht aufgeführte akute oder chronische Erkrankungen? yes no

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:

ASA-01 ASA-02 ASA-03 ASA-04

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 (4 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 (4 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/-verzicht