

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

- including tissue sample
 including urethrotomy
 including photodynamic diagnosis

Dear patient,

A cystoscopy is planned in your case to examine your bladder and urethra more closely. If necessary, minor therapeutic procedures can be undertaken during the examination, such as treatment of a urethral stricture.

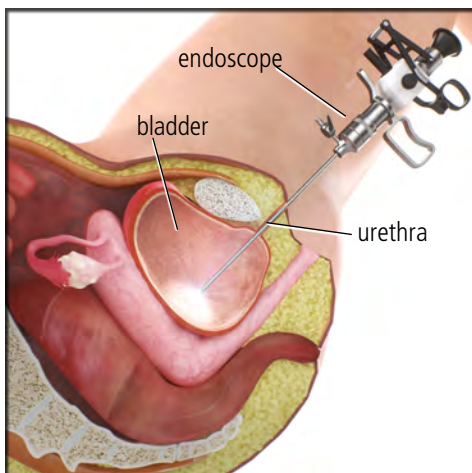
This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. The doctor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

REASONS FOR EXAMINATION/TREATMENT

Cystoscopy enables the doctor to view the bladder or the urethra directly and also, if possible and necessary, to treat any diseases which may be discovered. Cystoscopy can be a useful examination method if, for instance, there is blood in your urine, in the case of a urinary emptying disorder, a suspected bladder tumour, urethral stricture, bladder sphincter dysfunction, bladder stones or prostatic enlargement.

COURSE OF EXAMINATION/TREATMENT

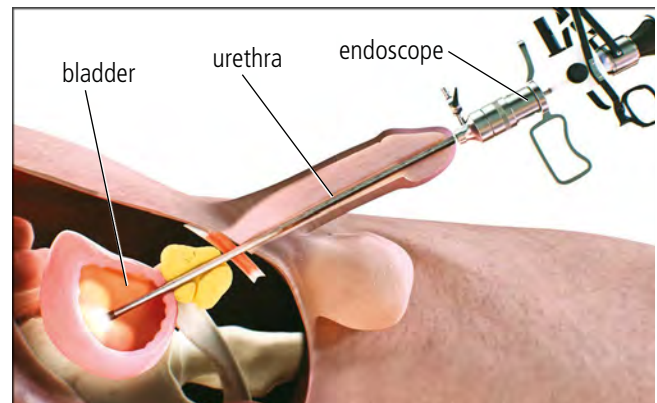
The procedure is usually carried out under local anaesthesia. If the procedure is to be carried out under a general anaesthetic or spinal anaesthesia in your particular case, you will receive a separate information sheet.



For local anaesthetisation, the doctor will inject a glide gel with an anaesthetic into the urethra prior to the examination. The examination requires the use of an endoscope. An endoscope is a flexible, steerable or inflexible, thin device

which can be equipped with a camera. During cystoscopy, the endoscope is inserted through the urethra into the bladder. The small camera constantly transmits images to a monitor so that the doctor can see where he/she is steering the endoscope, or the doctor will control the steering using the optics for direct viewing. With a

flexible endoscope, the tip of the instrument can be steered actively and angled. This will ensure the procedure is gentle even for a man.



The bladder will be filled with a fluid for the examination. In order to make any changes in the mucous membrane visible, a special colourant can also be injected into the bladder before the examination (photodynamic diagnosis).

Should the doctor discover any changes in the mucous membrane, a tissue sample can be taken using small pincers, which will then be examined histologically in a lab.

Bleeding or minor tissue changes can be ablated, small bladder stones can be removed directly with the endoscope.

If there is a urethral stricture, it can be relieved with urethrotomy. For this procedure, a small knife or a laser probe will be inserted via the endoscope and an incision will be made in the stricture, thus widening the urethra.

After such an additional procedure, a urinary catheter will often be inserted and left there for several days to ensure proper draining of urine. If cystoscopy is used only for diagnostic purposes, the insertion of a urinary catheter is usually not necessary.

POSSIBLE ADDITIONAL MEASURES

During the procedure, it may become apparent that further measures need to be taken (for instance the insertion of a suprapubic bladder drainage through the abdominal wall in the case of urine stasis). 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. Should additional measures be predictable in your case, the doctor will inform you accordingly prior to the procedure.

ALTERNATIVE METHODS

The bladder can also be examined using ultrasound, CT scanning, MRI or excretion urography. However, minor tissue alterations may not be detected with those methods and they do not allow for a tissue sample to be collected.

Stones can also be treated with analgesics and waiting (for spontaneous passage) or with dissolution therapy using medication.

A urethral stricture can also be treated with dilation treatment or in open surgery.

Your doctor will explain to you which procedure is best in your particular case.

PROSPECTS OF SUCCESS

After a tissue sample has been collected and examined under a microscope, it is usually possible to make a clear diagnosis. However, the collected tissue sample may be too small, so that pathological alterations may be overlooked.

Any symptoms caused by urethral stricture, such as bladder emptying disorders, bladder or prostate infections, will usually disappear after the procedure. However, a urethral stricture may reform through scarring, making it necessary for the procedure to be repeated.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Please read the following section carefully and follow the instructions of the doctor and of the assistance personnel closely.

Preparation:

Medication: It is important for you to inform your doctor of any medication you take or inject on a regular basis or have taken irregularly over the course of the past eight days prior to the procedure. This applies in particular to any anticoagulant agents such as Aspirin® (ASA), Marcumar®, Heparin, Plavix®, Ticlopidin, Clopidogrel, Apixaban (Eliquis®), Edoxaban (Lixiana®), Rivaroxaban (Xarelto®), Dabigatran (Pradaxa®) etc. Please also let your doctor know if you take any over-the-counter medication and herbal remedies or pain killers such as ibuprofen, paracetamol or morphine-based medication. Your doctor will let you know if and for how long you need to stop taking your medication.

Urinary tract infection: If you are already suffering from a urinary tract infection, it should be treated with antibiotics prior to the procedure.

Food, drink and smoking: If a general anaesthetic or spinal anaesthesia is to be used, you may not smoke or eat anything any more for several hours prior to the procedure and not drink any juices with pulp, milk, broth or alcohol. Please follow the respective instructions of your anaesthetist.

Aftercare:

If **antibiotics** have been prescribed as a precautionary measure in your case, please take them as instructed.

Small **amounts of blood** in the urine are common after cystoscopy and usually disappear within a matter of a few days. If you discover blood in your urine, it may be necessary to drink more fluids. Should there be a lot of blood in your urine, please contact your doctor immediately.

Please inform your doctor immediately or come to the clinic if you

experience symptoms such as **pain, circulatory problems, shortness of breath, nausea, fever or chills or any other side effects**. 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 24 hours after the procedure. Your reaction capacity may be impaired after the procedure. Therefore, for a period of **24 hours after the procedure**, you must not actively participate in road-traffic (not even as a pedestrian) nor participate in any risky activities, especially activities without secure support, and you should refrain from taking any important decisions.

Please make sure you drink **enough fluids per day**, between 1.5-2 litres, unless you cannot drink that much for other medical reasons.

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.

Urinary tract infections may sometimes occur after the procedure, resulting in a temperature, flank pain or discomfort when urinating. In most cases, such infections can be treated successfully with antibiotics. In rare cases, germs may be introduced into the bloodstream, leading to dangerous blood poisoning (toxaemia) or inflammation of the endocardium (endocarditis) as a result. Epididymitis, if it occurs on both sides, can lead to **infertility** in a man.

Blood in the urine may sometimes appear and usually disappears after a few days. In rare cases, the bladder will have to be rinsed via a urinary catheter.

Due to **irritation of the mucous membrane of the bladder** or after urethrotomy, **urinating may be painful** after the procedure. These injuries usually heal without treatment within a few days. On rare occasions, **urination may also be temporarily impaired** after the procedure. In very rare cases, urinating may even be impossible (urinary retention). In that event, a plastic tube (urinary catheter) will have to be inserted into the bladder.

If **injuries** to the **urethra** or the **bladder** occur, additional surgery may be needed, if necessary even open surgery. In exceptional cases, urethrotomy can lead to injuries of the bladder sphincter, resulting in **urinary incontinence**.

In the event of an **injury** of a **larger blood vessel, bleeding** and **post-procedure bleeding** may occur; surgery may be required to stop the bleeding. Should **severe blood loss** occur, the use of donor blood/blood components (**transfusion**) may be required in exceptional cases. 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.

If a tissue sample is taken from a malignant tumour in the bladder, **tumour cells can theoretically be introduced to other areas of the body**, leading to the formation of metastases, or the tumour may grow more aggressively after the procedure.

Allergic reactions, for instance to medication or latex (or colourants), 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, paralyses or kidney failure requiring dialysis.

Damage to the skin, soft tissue or nerves (for instance through injections, disinfectants or positioning during the procedure) is rare. Sensory disturbance, numbness, paralysis and pain may then result. They are usually temporary. Permanent nerve damage or scars are rare.

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. lung embolism, stroke or kidney failure resulting in permanent damage. If anticoagulant agents are administered to prevent formation of blood clots, the risk of bleeding or post-procedure bleeding is increased. If Heparin is administered, it may result in **severe coagulopathy** (HIT), leading to thromboses

and obstruction of blood vessels.

Through urethrotomy, but also through minor injuries of the urethra caused by the endoscope, a **urethral stricture through scar tissue** may form, which may then have to be treated surgically.

Specific risks related to urethrotomy

Urethrotomy may lead to **injuries** of the **cavernous body of the penis**. Scarring of the cavernous body can lead to **penile curvature** when it is erect. Corrective surgery may then become necessary.

Erectile dysfunction, meaning a reduction in or **loss of penile erection**, may occur as a direct or indirect consequence in extremely rare cases.

Through urethrotomy **irrigation fluid may be introduced into the bloodstream**. This will lead to the blood thinning, which may result in cardiovascular stress accompanied by nausea, vomiting and restlessness.

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), Brilique®, Efixent®, Eliquis®,
 Heparin, Iscover®, 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), Brilique®, Efixent®, Eliquis®, Heparin,
 Iscover®, 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 had surgery on the urinary tract? yes no

Hatten Sie bereits eine Operation am Harntrakt?

Were there any complications? yes no

Traten dabei Komplikationen auf?

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

Have you taken an antibiotic recently (in the last four weeks)? yes no

Haben Sie in letzter Zeit (4 Wochen) ein Antibiotikum eingenommen?

Wenn ja, welches? _____
If so, which antibiotic?

Do you have frequently recurring urinary tract infections (more frequent than twice a year)? yes no

Leiden Sie unter häufig wiederkehrenden Harnwegsinfektionen (öfter als 2x/Jahr)?

Do you suffer from stiffness of the hips or knees? yes no

Leiden Sie unter einer Versteifung der Hüft-, Kniegelenke?

Are you pregnant? not certain yes no

Sind Sie schwanger? nicht sicher

Do you drink alcohol regularly? yes no

Trinken Sie regelmäßig Alkohol?

If so, what and how much: _____
Wenn ja, was und wie viel:

Do you smoke? yes no

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

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 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?

Blood clot (thrombus) / blood vessel occlusion (embolism)? yes no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Allergies / Oversensitivity? yes no

Medications, foods, contrast media, iodine, sticking plaster, latex (e.g. rubber gloves, balloons), pollen (grass, trees), anaesthetics,

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

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), high blood pressure.

Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), hoher 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:

Kidney diseases?

yes no

kidney insufficiency, kidney inflammation.

Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung.

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?

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:

- including tissue sample
- including urethrotomy
- including photodynamic diagnosis
- _____

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/verzichtet

Signature Copy received/waived
Kopieerhalt/-verzichtet