

CERVICAL BIOPSY/ABLATION (CONISATION, AMONG OTHERS) GEWEBEENTNAHME/-VERÖDUNG AM GEBÄRMUTTERHALS (U.A. KONISATION)

Information and medical history for patients for preparation of the required pre-procedure interview with the doctor

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

Dear patient,

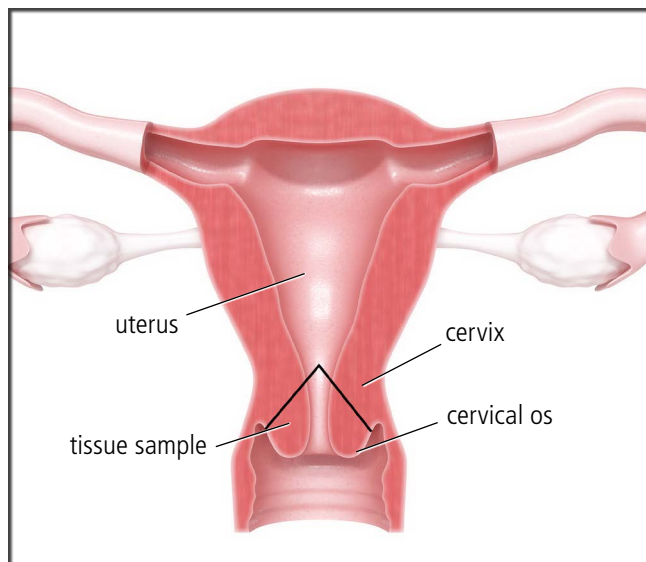
In order to determine the cause of or treat an alteration in cervical tissue, a cervical biopsy or ablation has been planned in your case. This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you what the scheduled treatment involves and inform you of any related risks. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

REASONS FOR CERVIX SURGERY

Unclear alterations of the cervical os, lightly bleeding vessels (so-called ectopia) or if a cervical smear (a so-called Pap smear) had abnormal results, it may be necessary to take a larger tissue sample from your cervix or to ablate the tissue.

COURSE OF PROCEDURE

The procedure can be carried out under general or local anaesthesia. If it is to be carried out under general anaesthesia, you will receive the appropriate information from an anaesthetist.



The procedure will begin as soon as you are under general anaesthesia or the local anaesthetic has anaesthetised the area sufficiently. You will be positioned as in gynaecological examinations, in what is called a lithotomy position. Using a mirror and magnification device (colposcopy), the doctor can view your cervix up close and insert various surgical instruments, such as an electrical sling, laser or scalpel, and remove a tissue sample large enough for analysis or ablate the tissue.

Sometimes, the biopsy may be followed by a curettage of the cervix and, if needed, of the uterine cavity.

After the procedure, a tamponade will be inserted to stop the bleeding, which can usually be removed after a few hours. In most cases, the patient can be allowed to go home on the same day after a short monitoring period.

PROSPECTS OF SUCCESS

Cervical biopsy and ablation constitute routine procedures nowadays. They can be used to remove altered tissue gently and safely. With conisation, malignant tissue alterations at an early stage can be removed entirely in some cases. Depending on the diagnosis resulting from the examination of the tissue samples taken, further treatment 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:

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 painkillers 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.

Food, drink and smoking: As a general rule, you may not eat anything any more 6 hours prior to the procedure (this includes soups or sweets such as candy, chewing gum) and not drink any juices with pulp, milk, broth or alcohol; you must also refrain from smoking. Clear fluids in small amounts (e.g. 1-2 cups of water or unsweetened tea with no milk or cream) may be allowed up to two hours prior to the procedure.

Aftercare:

During the wound healing process, you should refrain from **sexual intercourse**, the **use of tampons** as well as bathing and swimming for at least four weeks. Your doctor will inform you regarding the extent of **physical rest** needed during this time.

Light bleeding directly after the procedure and also between the fifth and ninth day after treatment is normal and no cause for concern. However, should you experience **abdominal pain, strong and persistent bleeding or a fever**, please inform your doctor immediately. These symptoms may appear even days after the procedure and must be examined immediately.

If an anaesthetic, sedative and/or analgesic has been administered to you, you must be collected by an adult if the examination has been performed **on an out-patient basis**. Also, for a period of **24 hours** after the procedure, you must not actively participate in road traffic (not even as a pedestrian), refrain from any risky activities and avoid taking any important decisions, unless otherwise instructed. Please also make sure there will be an adult at home to supervise you for the period of time recommended by your doctor.

POSSIBLE RISKS, COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure**, even a routine procedure such as the procedure described above, **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.

The procedure, especially if larger tissue samples were taken, may result in a weakening of the cervix and thus to an **increased risk of premature births or miscarriages**. The wound healing process may lead to **adhesion** or **scarring of the cervical os**. If blood or fluids accumulate inside the uterus, the adhesion will have to be treated in a separate procedure.

In rare cases, the procedure may result in a **perforation of the uterine wall**. This can lead to injury of neighbouring organs (colon, bladder, ureter). Surgery via laparoscopy, or an abdominal incision in rare cases, may then be required. Injuries of the colon can lead to dangerous **peritonitis**. A colostomy may be required

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]

in extreme cases. An **injury of the bladder and ureter** can lead to the formation of a fistula (unnatural connection). This can then result in urine entering the abdominal cavity or discharging through the vagina. Further surgery may be required.

Infections are rare and can be treated successfully with antibiotics in most cases, surgical treatment will rarely be required. In extreme and exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia) and even to inflammation of the endocardium (endocarditis). **Infections** of the uterus or fallopian tubes can result in **bleeding disorders, difficulties conceiving** and even to **infertility**. The possibility of a pregnancy outside of the uterus (so-called **ectopic pregnancy**) also increases as a result.

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, bleeding and pain may then result. They are usually temporary. Permanent damage or scars are very rare.

Bleeding during the procedure is usually noticed immediately and can then be stopped. Conisation may result in stronger **post-procedure bleeding**, making additional surgery necessary in some cases. In extreme cases, the uterus may have to be removed.

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 in extremely rare cases (causing AIDS), BSE ("mad cow 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.

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 requiring dialysis and result 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 lead to a severe immune response (HIT) involving clotting of the platelets (thrombocytes) and obstruction of veins and of arteries.

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.

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®, Efient®, 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®, Efient®, 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

Would you like to have more children? yes no
Besteht bei Ihnen noch Kinderwunsch?

Do you have any metal implant (such as artificial hip)? yes no
Haben Sie ein Metallimplantat (z. B. eine künstliche Hüfte)?

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?

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, 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, Herzmuskelentzündung, Herzklappenerkrankung, Luftnot beim Treppensteigen, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, niedriger Blutdruck, Schlaganfall, Krampfadern, Venenentzündung, Thrombose, Embolie.

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-Zwerverfellähmung.

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? 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:

Treatment with:

- Electrical sling** elektrische Schlinge
- Laser** Laser
- Scalpel** Skalpell

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is **capable of making a decision** on the recommended procedure on her own and giving her consent for the procedure.
Die Patientin besitzt die Fähigkeit, eine **eigenständige Entscheidung** über die empfohlenen Maßnahme zu treffen und 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 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 der Patientin zu treffen.
- Custodian's card healthcare proxy advance healthcare directive has been submitted.
 Betreuerausweis Vorsorgevollmacht Patientenverfügung liegt vor.

Copy for patient:

Kopie für Patient:

- yes** **no**
- ja nein

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 / 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.
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 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 / Betreuer]