

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

Scheduled procedure:

## Dear patient,

in order to determine the cause of your symptoms and/or treat them, or as a diagnostic measure in preparation for a planned procedure, laparoscopy has been recommended to you.

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.

### COURSE OF LAPAROSCOPY

Laparoscopy is usually carried out under a general anaesthetic. Regarding general anaesthesia as well as the possible risks and complications related to it, you will receive the appropriate information from the anaesthetist.

A urinary catheter is usually inserted prior to laparoscopy in order for the urine to be able to pass without any difficulties during and after the operation.

The operation will begin as soon as you are anaesthetised. First of all, a needle is inserted through the abdominal wall via a small incision in the navel area. Through this needle, a gas (carbon dioxide) is then injected into your abdominal cavity. Through the insertion of the gas, the abdominal wall will be lifted off the internal organs slightly, facilitating safe insertion of the optical instrument.

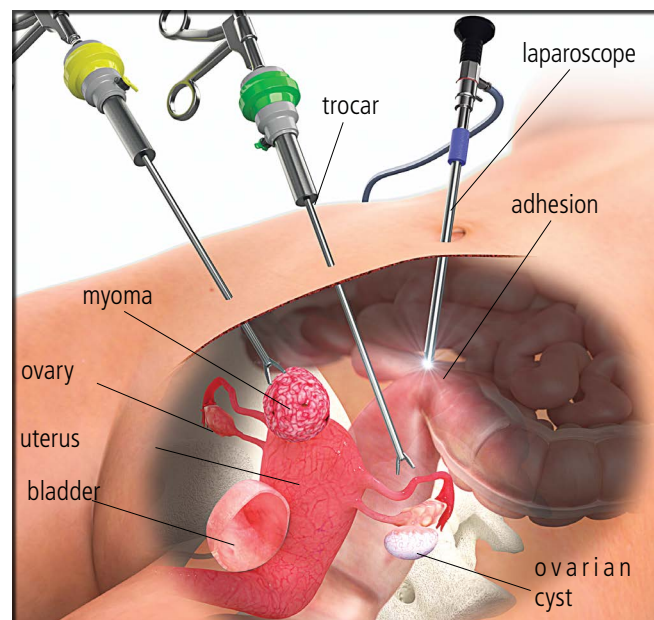
The optical instrument inserted through the navel is connected to a camera. With it, the doctor is able to view the internal reproductive organs (uterus, ovaries and fallopian tubes) as well as the abdominal lining and the neighbouring organs. If laparoscopy is carried out for purely diagnostic purposes, it will already be over after this detailed inspection of the abdominal area. If any anomalies, for instance of the abdominal lining, the ovaries, the uterus or other organs in the lesser pelvis, are discovered, they can be treated or examined more closely during the same procedure.

Two to three further small incisions (0,5-1 cm) in the lower abdominal area will be made in order to be able to insert sheaths (trocars) for gripping or cutting devices or other instruments under visual control.

This enables the doctor to treat e.g. ovarian cysts or uterine myomas (benign nodular growths). Moreover, entire organs such as the uterus, the fallopian tubes and/or ovaries can be removed. Should any other anomalies be discovered in the abdominal area, e.g. a metastasis of uterine lining on the abdominal lining (endometriosis), tubal pregnancy or tumours, these are also treated accordingly or tissue samples are taken from them.

At the end of the procedure, the abdominal cavity is checked for bleeding and any bleeding discovered will be stopped with electricity, laser or other methods. After the procedure is finished, the gas will be released, the sheaths will be removed and the incisions will be sutured or closed with adhesive bandages.

Sometimes a surgical drain will have to be inserted in order to remove fluids from the wound, blood, or pus in the event of an infection. If possible, the drains will be inserted through the already existing small incisions in order to avoid making further incisions.



### POSSIBLE ADDITIONAL MEASURES

In order to ensure a successful diagnosis or treatment, it is important to have clear view of the abdominal cavity. Therefore, it may sometimes be necessary as an additional measure to **remove any adhesions** in order to be able to view the organs well enough. In that event, **additional trocars** (for instance below the costal arch

or in some other area of the abdomen) may have to be inserted in order to be able to view areas of the abdominal cavity which are difficult to reach. If massive adhesions, for instance after several abdominal surgeries, large tumours or obesity prevent a clear view, it may also be necessary to switch from minimally invasive to **open surgery** including an **abdominal incision** (either horizontal or vertical). This may also become necessary if complications such as severe bleeding or injury of an organ occur.

If larger tissue samples which cannot/should not be cut into smaller pieces have to be removed, it may be necessary to **widen one of the incisions** in order to be able to remove the sample as a whole from the abdominal cavity (mini-laparotomy).

If there are benign tumours or cysts in the area of the ovaries and/or fallopian tubes, any surgical procedure will be carried out in the most organ-preserving manner possible. However, if the ovary or the fallopian tube is too severely damaged, the **preservation of the organ may not always be possible or reasonable**.

Prior to the operation, your doctor will discuss with you what should happen in the event of an unexpected diagnosis (for instance a more extensive diagnosis than expected, more severe tumour disease, neighbouring organs being affected in the event of benign or malignant diseases). There is always the possibility to switch to open surgery or to end the laparoscopy procedure prematurely in order to discuss the risks and complications of a more extensive surgical intervention.

### ALTERNATIVE METHODS

An examination from the outside using different **imaging methods** such as ultrasound, X-ray, CT or MRI often cannot replace the direct examination of the abdominal cavity with a laparoscope. Moreover, the targeted removal of tissue samples for diagnostic purposes under direct visual control or treatment through the removal of diseased tissue is not possible using these methods.

Opening the abdominal cavity (laparotomy) is one alternative which can be used instead of minimally invasive laparoscopy. An **open surgery** is more stressful for the body usually requiring an extended period of hospitalisation as well as taking longer to heal. With particular types of malignant tumours (ovarian cancer), or if you have a very large benign or malignant tumour or massive adhesions, your doctor may still recommend open surgery from the very beginning.

In some cases, **treatment with medication** may be possible as an alternative method or to prepare you for the surgical procedure. With myomas, for example, shrinking them with medication is an option in order to then make their laparoscopic removal possible. Endometriosis can also be treated with medication. Your doctor will explain to you in which cases this is reasonable.

### PROSPECTS OF SUCCESS

Laparoscopy is a routine procedure nowadays and can be used to reliably detect and treat many alterations of the internal female reproductive organs.

However, sometimes the examination or treatment may not be possible because of adhesions or because the affected area is too extensive. Also, pathological changes may be overlooked if the view is unclear due to previous operations, obesity or inflammation.

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:** It is important 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®, Plavix®, Eliquis®, Xarelto®, Pradaxa® etc., and metformin-containing anti-diabetic medicines, so-called biguanides) or have taken irregularly over the course of the past eight days prior to the procedure. 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 or change it.

**Food, drink and smoking:** Your doctor will let you know when you need to stop eating and drinking prior to the procedure. 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.

#### Aftercare:

Please keep the relative **bed rest** as instructed. Absolute bed rest is only necessary in very rare cases. In many cases, early mobilisation is preferable. Your doctor will advise you what to do in your individual case.

Post-surgical **pain** after laparoscopy can usually be alleviated with medication. **Shoulder pain** or crackling underneath the skin may be due to the inserted gas and should disappear within a short period of time.

You should refrain from eating and drinking for at least 4 hours after surgery.

Please inform your doctor immediately should you experience a **fever, intense abdominal pain, nausea or circulatory problems**. These symptoms may appear even days after the procedure and must be examined immediately.

To prevent **incisional hernia**, please refrain from lifting anything heavier than 5-10 kilos for a period of 3-4 weeks after the operation. The suture material can either remain if absorbable suture material was used, or the stitches will be removed after 5-10 days.

If the procedure is performed **on an out-patient basis**, it is necessary for an adult to come and collect you. Please also make sure there will be an adult at home to supervise you for the period of time recommended by your doctor. 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 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 colon or other organs (uterus, bladder, ureter, fallopian tubes, ovaries, stomach, liver, kidneys, spleen) are rare and usually occur especially in the presence of massive adhesions. Additional measures may then have to be taken during the operation, such as an abdominal incision (horizontal or vertical), or a life-threatening **inflammation of the abdominal lining** may occur. If the colon is injured, a colostomy may be required in exceptional cases. Obesity, massive adhesions, previous oper-

ations, inflammations or anatomic anomalies increase the risks involved in this procedure.

In rare cases, **urinary retention** (inability to empty the bladder) or **renal stasis** (impairment of urine flow from the kidneys) may occur after the operation. This can usually be alleviated by draining the urine via a catheter for a certain period of time. In rare cases, bladder nerve damage may occur and lead to permanent disorders.

**Wound infection** can be treated successfully with antibiotics in most cases, surgical treatment will rarely be required. In extreme and exceptional cases, germs may be introduced into the bloodstream, leading to dangerous blood poisoning (toxaemia) or inflammation of the endocardium (endocarditis) as a result. Patients who suffer from diabetes mellitus, obesity, a weakened immune system or who smoke have a higher risk of wound infection.

Sometimes **wound healing disorders** may occur, which may be accompanied by cosmetically undesirable and/or painful scarring (keloids) and may require surgical scar correction.

The gas injected into the abdominal cavity during the procedure can enter the chest cavity and push aside the lungs (pneumothorax), leading to shortness of breath, if the **diaphragm is injured**. The air will then have to be removed through puncture or insertion of a drain. If the gas enters a blood vessel, it may lead to dangerous gas embolism 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** after taking a tissue sample or caused by injury of a vessel is usually discovered and stopped immediately. In rare cases, post-operative bleeding may occur, which, depending on its intensity, may require additional surgery.

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.

Sometimes blood clots (**thromboses**) may form during or after the operation, causing obstruction of a blood vessel (**embolism**). The risk of thrombosis or embolism is increased in the presence of obesity, smoking, extended bed rest, infections or if hormone preparations are taken as well as if the patient suffers from certain bleeding disorders. Such blood clots may then travel to other parts of the body and block the vessels of other organs. Even despite immediate intensive care or operative intervention, this may lead to permanent damage (e. g. lung embolism, heart attack, stroke including permanent paralyses, kidney failure requiring dialysis). 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.

**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 requiring dialysis may occur even despite adequate intensive care.

Through the insertion of the gas or the manipulation of the abdominal cavity, the patient may suffer a sudden **drop in blood pressure**, which can often be treated successfully with medication.

**Adhesions** in the abdominal cavity may occur, especially in those cases where previous adhesions were removed during laparoscopy or if larger wounds resulted from the procedure. These may cause various symptoms, even obstruction of the bowels, (even years after the procedure) and may have to be treated surgically.

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

**Incisional hernias** are rare, but may have to be closed through surgery if they cause symptoms or if there is any risk of organs or other physical structures becoming trapped in them.

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

## 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 laparoscopy?**  yes  no

Wurde bei Ihnen schon einmal eine **Bauchspiegelung** 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)?

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

yes  no

### Are you pregnant?

Sind Sie schwanger?

not certain  yes  no  
 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/Bluterinnungsstörung?**  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?

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Bluterinnungsstörungen?

yes  no

#### Allergies / Oversensitivity?

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?

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,

yes  no

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?

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:

#### Metabolic diseases?

Diabetes (sugar sickness),  Gout.

**Stoffwechsel-Erkrankungen?**  Diabetes (Zuckerkrankheit),  Gicht.

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

Sonstiges:

#### Thyroid diseases?

Underactive thyroid,  overactive thyroid.

**Schilddrüsenerkrankungen?**  Unterfunktion,  Überfunktion.

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

Sonstiges:

#### Communicable (contagious) diseases?

Hepatitis,  tuberculosis,  HIV.

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

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

Sonstiges:

#### Any other acute or chronic diseases / illnesses?

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: \_\_\_\_\_

Bitte kurz beschreiben:

## 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]

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:

Multiple horizontal lines for handwritten notes.

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- Checkboxes for patient decision-making ability, representation by custodian or proxy, and submission of advance healthcare directives.

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.

Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt.

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:

- Checkboxes for 'I hereby confirm that I have understood all sections of this form' and 'I deliberately refrain from obtaining a more detailed explanation'.

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.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Maßnahme zu.

My consent also applies to any necessary additional measures as well as to any required changes or additions to the procedure.

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

- Checkbox: 'I agree that my copy of this explanatory form may be sent to the following e-mail address:'

e-mail address [E-Mail-Adresse]

Place, Date, Time [Ort, Datum, Uhrzeit]

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

Copy/Kopie:

- Checkboxes for 'received/erhalten' and 'waived/verzichtet'.

Signature Copy received/waived Kopieerhalt/-verzichtet