Information for patients on ERCP (imaging of the biliary tract and pancreas using contrast medium)

Label	

Information protocol submitted by:

Date:

Dear patient

Please read these documents <u>immediately</u> upon receiving them. Fill in the questionnaire, if possible date and sign the documents on the day before the examination. If you have any questions, please contact your doctor or specialist (gastroenterologist).

You have been advised to have a procedure known as a **ERCP** (imaging of the biliary tract and pancreas using contrast medium). Before the examination you'll receive the following:

- an information leaflet
- a questionnaire
- informed consent form

Information leaflet:

On the information leaflet you can find information about the course of the examination as well as its objectives and risks. Please read this leaflet carefully.

If you have further questions about the necessity and urgency of the examination, about alternatives or any risks posed by the examination, please contact your doctor. Most of these questions can be answered by the doctor who registered you for the examination. Specific questions about the examination's technical details or specific problems can be answered by the specialist (gastroenterologist) who will carry out the procedure, if necessary. If you wish to do so, we kindly ask you to contact us or the referring doctor in good time.

Questionnaire:

You are kindly asked to fill out the enclosed questionnaire in full to clarify the bleeding tendency and to answer the questions about medication, intolerances or allergies. If you are taking **anticoagulant medication** for blood thinning (e.g. Sintrom, Marcoumar, Xarelto) or or regularly take **Aspirin**, **Alcacyl**, **Tiatral**, **Plavix**, **Clopidogrel etc.**, please discuss with your doctor in good time (at least 1 week before before the examination) the possibility of stopping the medication. Please bring the questionnaire with you to the examination. You are kindly asked to date and sign the questionnaire one day before the examination if possible. If you have any problems or there are ambiguities in answering the questions, please contact your doctor or us in good time.

Informed consent:

Please read the informed consent form through very carefully. Also date and sign it no later than <u>the day before</u> the examination.

The information leaflet is yours to keep.

The questionnaire and the informed consent will be kept by us in the medical files.

Aufklärungsunterlagen empfohlen durch die Schweizerische Gesellschaft für Gastroenterologie SGGSSG, die Verbindung der Schweizer Ärztinnen und Ärzte FMH sowie der Stiftung Patientenschutz SPO.







Information sheet about ERCP

Why is an ERCP carried out?

You are suspected of having or have already been diagnosed with a disease of the biliary tract and/or pancreas. The ERCP enables such diseases to be detected and treated if necessary.

What preparations are necessary for an ERCP?

Before the ERCP, from midnight on, please do not eat solid food as the upper digestive tract must be free of food residue for the gastroscopy. Drinking clear, fat-free liquids (not milk) is permitted up until 2 hours before the start of the examination. Do not take your regular medication unless your doctor tells you to take it.

Ability to drive/ability to work?

You will be given sedation and or pain medication before the examination. You should not drive after receiving this medication. Do not come with your own vehicle. Make sure that someone personally accompanies you. After these medications have been administered you are not capable of signing any documents for the next 12 hours. This means that during this time you should not conclude any contracts.

What happens during an ERCP?

First of all, in order to administer sedative or sleep medication an infusion is put in the arm. During the examination a specially trained nurse is also present in addition to the doctor. As a rule, the examination is painless. The examination is carried out using a thin movable 'tube' at the tip of which a light source and a camera are attached. This allows the doctor to advance it through the mouth, oesophagus, stomach and duodenum to the entrance of the biliary tract and the pancreatic duct. A contrast medium is then injected into the biliary tract through a fine catheter and X-rayed. If pathological changes are seen, treatment is carried out during the examination.

What additional interventions are possible during ERCP?

The following procedures and treatments are carried out depending on the existing findings: removal of gallstones in the biliary tract, removal of tissue from the bile duct, widening of constrictions in the bile or pancreatic duct, insertion of a tube to bridge constrictions and drainage of bile or pancreatic secretions. These treatments may require a papillotomy, i.e. a splitting of the sphincter muscle at the end of the bile duct when it opens into the small bowel. An electric cutting device is used for this, which is inserted through the endoscope. In some cases, it can only be decided during the examination which additional procedures are necessary. You will be informed in detail about possible extensions before the procedure. The doctor will decide during the procedure about the necessary pre-discussed extensions.

What are the risks associated with ERCP?

X-ray examination of the bile and pancreatic ducts, papillotomy and further treatment measures are routine procedures with a low risk. However, despite the greatest care being taken, complications can occur, which can be life-threatening in exceptional cases. Above all inflammation of the pancreas (5-10%) should be mentioned, bleeding (<5%), infection of the biliary tract (<5%), perforation (rupture of the intestinal wall) (1-2%), rarely, the administration of sleep medication can lead to the impairment of respiratory and cardiac function. In rare cases an operation or longer hospitalisation may be necessary. These include allergic reactions, possible damage to teeth due to pre-existing defective teeth, and injury to the larynx. Slight hoarseness, difficulty swallowing or unpleasant flatulence (caused by air remaining in the stomach and small intestine) may occur temporarily after ERCP.

What about after the examination?

After local anaesthesia of the throat with a spray, you may not eat or drink anything for at least an hour. If <u>abdominal pains</u> or other disturbances of well-being occur after the ERCP (e.g. dizziness, nausea, vomiting) or if there is bleeding from the anus (usually in the form of black, thin fluid stools), inform your doctor immediately or go to a hospital emergency department.

Questions about the examination?

If you have any further questions about the planned examination, please contact your GP. If you are still unclear, contact the specialist (gastroenterologist) who is carrying out your examination.

You can contact the following doctors if you have any questions or problems:

General practitioner	Tel:
Gastroenterology	Tel:

Aufklärungsunterlagen empfohlen durch die Schweizerische Gesellschaft für Gastroenterologie SGGSSG, die Verbindung der Schweizer Ärztinnen und Ärzte FMH sowie der Stiftung Patientenschutz SPO.







Questionnaire

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Questions to clarify bleeding tendency:

yes no

1. Do you have heavy nosebleeds for no apparent reason?	
2. Do your gums bleed for no apparent reason (brushing your teeth)?	
3. Do you have "bruises" (Haematomas) or small bleeds under the skin without obvious injuries?	
4. Do you have the impression that you bleed longer after minor injuries (e.g. when shaving)?	
5. Women: do you have the impression that you have prolonged menstrual bleeding (>7 days) or that you must change tampons or sanitary towels very frequently?	
6. Have you had prolonged or heavy bleeding during or after dental treatment?	
7. Have you had prolonged or heavy bleeding during or after surgery (e.g. tonsillectomy, appendectomy, birth)?	
8. Have you received any blood or blood products during surgery?	
9. Does anyone in your family (Parents, siblings, children, granchildren, uncles, aunts) have a disease with increased bleeding tendency?	

Questions about medication, allergies, concomitant disease:

1. Are you taking anticoagulants for blood thinning (e.g. Sintrom, Marcoumar, Xarelto) or have you been taking Aspirin , Alcacyl , Tiatral , Plavix , Clopidogrel , etc . or flu medication , pain killers or rheumatism medication in the last 7 days? If 'yes', what exactly?	
Do you have an allergy/ hypersensitivity reaction (to medications, latex, local anaesthetics, sticking plasters)? If 'yes', which ones?	
3. Do you suffer from a heart valve defect, heart or lung disease? Do you have an ID card for endocarditis-prophylaxis?	
4. Do you have a heart pacemaker / defibrillator or a metal implant?	
5. Are you aware of a renal dysfunction (renal insufficiency)?	
6. Are you diabetic?	
7. Women: are you pregnant or is there a possibility that you could be pregnant?	
8. Do you have any loose teeth, dentures or a dental disease?	

I. the undersigned, have completed the guestionnaire to the best of my knowledge.

Place, date Patient's name Patient's signature

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Informed consent Label for a ERCP (imaging of the biliary tract and pancreas using contrast medium) Information protocol submitted by: Date: I, the undersigned, have read the information sheet. I have been informed by the doctor of the reason (Indication) for the ERCP. I understand the nature, procedure and risks of a ERCP. My questions have been answered to my satisfaction. (Check the appropriate box) I agree to having a ERCP yes no I agree to a sedative and/or pain relief being administered during the yes no examination Patient's name Doctor's name Place, date Patient's signature Place, date Doctor's signature For patients who cannot give consent themselves:

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Place, date

Legal representative

Representative's name

or proxy



Place, date





Doctor's name

Doctor's signature