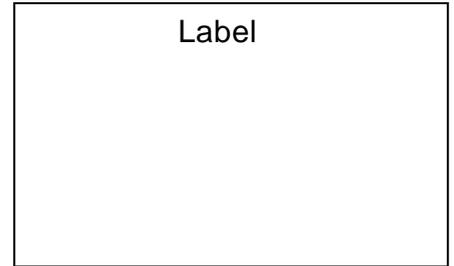


## Patient information/declaration of consent for capsule endoscopy



Declaration of informed consent

provided by:

Date:

Dear Patient,

Please be so kind as to read these documents as soon as you receive them. You should then complete the questionnaire and date and sign the documents, where possible on the day before the examination. If you have any questions, please contact your GP or the consultant performing the procedure (gastroenterologist).

You are to undergo a procedure known as capsule endoscopy. We now enclose the following documents for this examination:

- an information sheet
- a questionnaire
- the declaration of consent form

### Information sheet:

The information sheet contains details about the procedure used for the examination as well as its purpose and risks. Please make sure you read it through carefully.

If you have any further questions about the necessity and urgency of the examination, alternative procedures or the risks it involves, please contact your GP. The doctor who referred you for this procedure can answer most questions about it. Specific problems or queries about the technical details of the procedure can be answered as necessary by the consultant performing the examination (gastroenterologist). If you require this, please contact us or the doctor making the referral in good time.

### Questionnaire:

Please be so kind as to complete the enclosed questionnaire in full to assess the risks of capsule endoscopy. Please bring the questionnaire with you to the examination. Where possible, make sure you sign and date the questionnaire one day before the examination. If you have any problems or are unclear about answers to your questions, please contact us or your GP in good time.

### Declaration of consent:

Please also read the declaration of consent form through carefully. Here too, please make sure you sign and date the questionnaire at the latest on the day before the examination.

The information sheet is yours to keep, while the questionnaire and declaration of consent form are held on file by us with your medical records.

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association (FMH) and the Swiss organisation of patients (SPO Stiftung Patientenschutz)

# Information sheet for capsule endoscopy

Why do I need capsule endoscopy?

Capsule endoscopy makes it possible to see the parts of the small intestine which cannot be viewed during gastroscopy or colonoscopy. This involves swallowing a video capsule the size of a large pill, which then passes through the gastrointestinal tract without any effort on your part. This capsule contains a camera which records around two pictures a second. These images are directly transmitted to a receiver worn round the body and stored by a portable computer. The pictures recorded during this process can be viewed afterwards by a doctor to identify any abnormalities in the small intestine (e.g. inflammation, ulcers, polyps or tumours) which are possibly causing your symptoms. This procedure does not allow samples of tissue to be taken or any procedures performed.

What preparations are necessary for capsule endoscopy?

As in the case of colonoscopy, the bowel has to be completely empty to ensure optimum results during this examination of the small intestine (see separate instructions). Please follow the instructions for intestinal cleansing carefully. You should stop taking iron tablets 5 days before the examination.

What happens during capsule endoscopy?

On the day of the examination you should not have taken anything by mouth beforehand (from midnight do not eat or drink anything). When the capsule is swallowed, no particles of food should remain in the upper part of the digestive tract. You can drink clear fluids not containing fat (i.e. not milk) up to 2 hours before the examination starts. After a discussion to prepare you for the procedure, sensors and a recording device will then be attached to your body. You can then leave the hospital / surgery after swallowing the video capsule. The belt with the sensors and recording device must not be removed during the examination, which takes around 8 hours. You can have a drink of water two hours after swallowing the capsule, and eat normally another two hours after that. The nursing staff will have told you when to remove the recording device and instructed you about the correct functioning of the recording device. If there are any problems, please contact the nursing staff responsible without delay.

Interference with transmission of the capsule's image data to the recording device is possible (e.g. remote control units, mobile phones, radio antennas, etc.). We therefore ask you to keep well away from such wireless transmission equipment. The capsule will then be eliminated naturally as part of a bowel movement.

What risks are associated with capsule endoscopy?

Capsule endoscopy is a low-risk procedure.

In rare cases you might experience intestinal obstruction after swallowing the capsule, and it would then have to be removed via endoscopy or surgery (< 1%). This risk is increased for patients who have already had such an obstruction in the past or are suspected of having narrowing of the bowel (so-called stenosis). Under these circumstances it is not possible to carry out capsule endoscopy, or the risks would have to be weighed up against the benefit. To minimise the level of risk, X-rays would be taken beforehand, or you would be given a "dummy capsule" that dissolves itself.

What should I (not) do after the examination?

You can eat and drink normally after the examination. The capsule will be eliminated in the customary manner. As it is disposable, it does not need to be recovered.

Please contact your GP or go to Accident & Emergency if you experience stomach ache, run a temperature or feel nauseous during or after the examination.

Please make sure that you eliminate the capsule. If you are unable to confirm its elimination with certainty, an X-ray examination may then be necessary.

The performance of an MRI scan before the capsule has been eliminated may cause serious injury to the bowel and is therefore absolutely forbidden. If you are unable to confirm elimination of the capsule with certainty, an X-ray examination is essential before an MRI scan is carried out.

Any questions about the procedure?

If you have any further questions about the planned examination, please contact your GP. If you still aren't entirely clear about the procedure, get in touch with the consultant performing the procedure (gastroenterologist).

You can contact the following doctors about any queries or problems you might have:

GP		Tel:
Gastroenterologist		Tel:

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association (FMH) and the Swiss organisation of patients (SPO Stiftung Patientenschutz)



Questionnaire



Assessment of risk involved in capsule endoscopy

Have you ever experienced intestinal obstruction?	Yes	No
Have you ever had surgery on the stomach? If so, which procedure?  - Appendix - Operation on the stomach - Operation on the colon - Operation on the small intestine - Operation on the liver or pancreas - Operation on the womb or ovaries - Other?		
Are you suspected of having Crohn's disease or ulcerative colitis?		
Are you suspected of having narrowing (stenosis) of the intestine?		
Do you have a cardiac pacemaker, neurostimulator or other electronic implants?		
Do you take painkillers, rheumatism tablets or aspirin? If so, which and in what doses?		

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

Place, date

Patient's name

Patient's signature

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association (FMH) and the Swiss organisation of patients (SPO Stiftung Patientenschutz)



# Declaration of consent for capsule endoscopy

Label
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## Declaration of informed consent

provided by: Date:

I, the undersigned, have taken note of the information sheet.

I have received detailed information from the physician about the reason (indication) for capsule endoscopy. I understand the nature of capsule endoscopy as well as the procedure and risks involved. My questions have been answered to my satisfaction.

(Mark with a cross as appropriate)

I consent to the performance of capsule endoscopy

Yes	No
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Patient's name

Physician's name

Place, date

Patient's signature

Place, date

Physician's signature

For patients who are unable to give consent themselves:

Legal or authorised representative

Physician's name

Place, date

Representative's signature

Place, date

Physician's signature

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