

Informed Consent Documentation Combined Colonoscopy with Endoscopic Resection of tissue/Polypectomy and Oesophago- gastro-duodenoscopy (OGD)



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Full name..... Date of birth:

Dear Patient!

General information:

An endoscopy of the colon and of the upper digestive tract (oesophagus, stomach, duodenum) is proposed to you to determine and possibly treat the cause of your symptoms. Endoscopy is also often used as a cancer screening technique.

The endoscopy itself can be unpleasant or even painful. Therefore, you will normally receive a mild sedative, if required or desired. **If you have received an injection of a sedative, you must not cycle or drive a car within the following 24 hours.** In general, taking precautions is recommended. Heart rate, blood pressure and oxygen saturation are monitored continuously during the endoscopy. The examination takes about 60min. After the examination you should rest for about 15min before you can go home.

How is the Colonoscopy performed:

The colonoscopy involves inserting a flexible optical instrument (the endoscope) into the anus and advancing it through the colon to the junction of the large and small intestine, in certain cases into the adjoining section of the small intestine (terminal ileum). Air is insufflated into the bowel to distend it and permit better visualization of pathological changes.

During the endoscopy, tissue samples can also be taken (pain free). If Polyps are detected during the endoscopy, they will be treated immediately and removed with forceps or electronic loops (depending on the size). Sometimes polyps in inaccessible areas or large polyps have to be removed in hospital because of the risk of complications for a registered doctor. To improve the view, air (CO₂) is insufflated.

How is the gastroscopy performed?

A flexible optical instrument (the endoscope) is inserted through the oral cavity into the oesophagus, the stomach and into the duodenum. The digestive tract is inflated by insufflation of air in order to provide the doctor with better visualization and to make it easier to identify pathological changes. During the endoscopy tissue samples can also be taken (painless). If a mucosal overgrowth is detected during the endoscopy, it will be treated immediately and removed with forceps or electronic loops (depending on the size) and sent to microscopic tissue examination.

Possible complications:

Despite the greatest care taken, complications can arise which can become necessitate additional treatment or further surgery under certain circumstances. Difficulty swallowing, mild hoarseness, pain and mild bleeding can ensue. These symptoms tend to subside of their own accord and do not generally need treatment. Rarely a damage of the intestinal wall or the sphincter tonus can occur. In an occasional case, severe bleeding can occur as a result of tissue-sampling. This can usually be stopped via the endoscope by injection of medication and/or techniques involving the application of heat, or mechanically by application of clips. A dangerous injury to the organs is due to the good visibility by using sophisticated endoscopes with camera even in pathological changes (narrow or inflammatory swelling) extremely rare. Medication for sedation can cause respiratory disorders, cardiac arrhythmias and a drop of blood pressure. This consequently affects the ability to drive and use machines.

Before endoscopy:

Before Endoscopy, the colon must be cleansed thoroughly. To do this, please follow the instructions carefully. The stool should look like chamomile tea without any solid stool parts. You have to start drinking the intestinal cleansing a day before endoscopy. You will receive a detailed instruction. For the gastroscopy no special preparation is necessary.

After endoscopy:

If you have received an injection of a sedative, as a rule, you are **not allowed to actively participate in road traffic until the next morning**; in addition, you should not make important decisions nor engage in dangerous activities (e.g. working with dangerous machinery). Please arrange transportation to and from our ordination by family members/adults.

Symptoms such as mild nausea, dysphagia, discomfort in the throat area (such as a burning sensation), painful bloating caused by remaining air in the stomach and duodenum are harmless and disappear after a short time. If the throat is anesthetized, you must not eat and drink for at least 1 hour, unless the doctor has prescribed otherwise. Inform us/emergency service/hospital immediately in case of appearing complaints like bloody stool or persistent abdominal pain.

Anamnesis before combined endoscopy:

In order for you and your doctor to identify any risks involved in this procedure as early as possible, we ask you to answer the following questions with care:

- Are you regularly or currently taking medications? o No o Yes
- Are you taking anticoagulant medications e.g. Aspirin/ThromboASS, Brilique, Plavix/Clopidogrel, Marcoumar, Sintrom, Pradaxa, Eliquis, Xarelto, Lixiana, or o No o Yes
- Do you have or did you have a cardiovascular disorder? E.g. heart defect, angina pectoris, cardiac infarct, stroke, cardiac arrhythmia, hypertension, or..... o No o Yes
- Do you have a metabolic disease? E.g. diabetes, or..... o No o Yes

- Do you have an increased tendency to bleed? E.g. frequent nose-bleeds, bruises, or..... No Yes
- Do you have an allergy or hypersensitivity to certain substances? E.g. soy, peanuts, medications, sedatives, plaster, hay fever, asthma, X-ray contrast media, latex, or..... No Yes
- Do you have metal implants? E.g. cardiac pacemaker/defibrillator, endoprosthesis, or No Yes
- Additional question for women of childbearing age: Could you possibly be pregnant? No Yes
- Have you ever needed an operation on the digestive tract or a gynaecological operation before? No Yes
- Do you have or did you ever had an infectious disease? E.g. No Yes
- Do you have loose teeth or dentures in place (e.g. removable dentures, bridges,...) ? No Yes

Important notice:

For obvious reasons we would like to point out, if you cancel the examination after the informed consent discussion, we have to charge you with a € 50,- cancellation fee. In case you cancel the scheduled colonoscopy within 3 days before examination (except acute illness), we have to charge you with a € 150,- cancellation fee.

Patient's statement of consent:

The proposed combined endoscopy, the nature and significance of the procedure, the risks and possible associated complications and a more extensive procedure (e.g. removal of tissue sample, ablation of polyps, haemostasis) that may become necessary have been fully explained to me in a consent discussion. I was given the opportunity to ask any questions that I consider important.

Scheduled date of examination

Signature patient

Signature doctor/nurse

Date,