Dear patient,

Endoscopy of the upper digestive tract (esophagogastroduodenoscopy) is proposed for you. The purpose of this informed consent is to provide you with information and help you to prepare for the patientdoctor discussion. Please read everything carefully before the discussion.

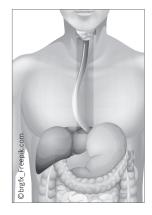
Why is gastroscopy recommended?

Endoscopy of the upper digestive tract has been recommended for you to determine the cause of your symptoms. Although there are alternative imaging techniques, including X ray examinations with contrast, computed tomography or magnetic resonance imaging, your doctor is recommending endoscopy because it is considered the best diagnostic/treatment method to directly visualize the digestive tract and to take tissue samples at the same time.

How is the endocopy performed?

Before endoscopy is performed, you will receive either local anaesthesia of the pharynx or a mild sedation (with propofol) if required as the endoscopy itself can be unpleasant. A flexible optical instrument (the endoscope) is then inserted

through the oral cavity and advanced into the esophagus, the stomach and into the duodenum under direct visualization. By insufflating air into the digestive tract, the walls of the tract can be expanded which enables better visualization of pathological findings. During the procedure, tissue samples can also be taken. Removing tissue samples is usually not painful. If additional therapeu-



tic procedures are planned during the endoscopy (e.g. removal of polyps, dilation of the esophagus) you will be informed about these in a separate patient-doctor discussion. If upper gastrointestinal bleeding is the reason for referral and/or noted during the procedure, this will usually be effectively stopped by injection of medications or application of clips and an operation is rarely necessary.

Necessary preparations

Please do not eat anything for at least 6 hours before endoscopy. Sips of water can be taken until 2 hours before endoscopy. Your doctor will inform you whether or not you should take your regular medication prior to the procedure.

Are there any risks or complications to be expected?

Despite the greatest care taken, complications may occur which can even become life-threatening under rare circumstances and necessitate further, treatment or surgery. Overall, complications occur in less than 0.05% of endoscopic procedures.

- Occasionally, injury can be caused to the larynx, the trachea or to the wall of the digestive tract by the endoscope. Difficulty swallowing, mild hoarseness, pain or mild bleeding can ensue. In very rare cases, a rupture (perforation) can occur which necessitates surgical treatment.
- In rare cases, severe bleeding may occur secondary to therapeutic procedures or removal of tissue for biopsy. Bleeding can usually be stopped via the endoscope by injection of medications or application of clips. Transfusion of blood or blood products may become necessary in rare cases only. The risk of transmission of HIV by transfusion of foreign donor blood has become extremely rare (less than 1 in a million).
- In very rare cases, infections with fever or even blood poisoning (sepsis) may occur necessitating further treatment and care. Allergy or hypersensitivity to latex, sedatives, anaesthetic agents or other medications may cause circulatory shock, necessitating intensive care treatment.
- Medications for sedation can cause respiratory disorders and/or cardiocirculatory failure, causing respiratory or cardiac arrest which necessitated immediate treatment and intensive care.
- In rare cases, damage to teeth/dentures occurs, in particular with loose teeth. Oral piercings must be removed prior to the endoscopy.

Please note that you need to be picked up at the front desk after the procedure if you have received a sedation for colonoscopy. Moreover, you must not drive a car or any other vehicle for 12 hours after the procedure.

Patient's statement of consent

The recommended endoscopy, its nature and significance, risks and possible associated complications, possible alternatives as well as additional/subsequent treatments that may become necessary have been fully explained to me. I was given the opportunity to ask any questions that I considered important. A copy of this consent was handed to me after the patient-doctor discussion. I have no further questions and feel that the counselling was satisfactory. Therefore, after adequate time for consideration, I consent to the proposed examination. I also consent to any unforeseeable additional procedures that may become necessary for medical reasons.

□ No □ Yes

Doctor's note

Wiesbaden, __

Signature Patient or Supervisor/Authorized Representative

Signature Doctor