ResTrial GastroEndo s.r.o.

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Patient Informed Consent Form with Endoscopy of Upper Intestinal System

(esophago – gastro – duodenoscopy)

Patient:
name, surname, personal birth number

Dear Patient,

Your informed consent form is essential for the conduct of the examination recommended to you. To help you make your decision regarding undergoing the procedure we inform you hereby about the method, the importance, as well as any potential complications of the examination.

Why do we recommend the endoscopy of upper intestinal system to you?

The sooner and more accurately the physician determines the nature and extent of the disease, the more successful is usually the treatment. Based on the difficulties you experience, endoscopy of esophagus, stomach and duodenum is being recommended to you or it can also be recommended as a preventive examination for early detection of possible pathological changes in your intestinal tract. At the current state of medicine, there is no alternative procedure that would allow for examination of the esophagus, stomach and duodenum, collection of samples of the mucous membrane for further testing and performance of any medical intervention altogether within only one medical procedure.

Examination process

Prior to the beginning of the examination, a local anesthetic in spray (at the physician's discretion) may be administered to you, specifically to your pharynx ("spray into throat"). You may also be applied calming premedication intravenously (to help you relax). In the position on your left side, the endoscopy instrument will be introduced through your mouth with a mouthpiece into the esophagus, stomach and duodenum and you will be holding the mouthpiece with your lips and teeth during entire examination (the respiratory tract will remain free during the procedure). During examination and if necessary, samples of the mucous membrane may be collected, or certain medical procedures may be performed, such as removal of mucous membrane abnormalities, treatment of bleeding veins or ulcers, or removal of foreign bodies. All these procedures are painless. You may feel the urge to vomit, or burp and you may feel abdominal pressure. However, these difficulties are usual and they will pass after the examination. The procedure takes about 5-10 minutes.

Diagnostic and therapeutic procedures during examination:

Biopsy – painless collection of samples of tissue is performed with small scissors.

Polypectomy – mucous membrane excrescence removal – polyp. The procedure is performed with a polypectomy instrument using a electrocoagulancy device and it is painless, too.

Clamping – application of special clamps to treat the mucous membrane perforations or to stop bleeding.

Injections – medication administration to the mucous membrane with a special endoscopic needle.

Medication

Patients taking medication such as Warfarin (Lavarin), Clopidogrel (Plavix, Trombex), Prasugrel (Efient) and anticoagulants such as Pradaxa, Arixtra, Xarelto which affect blood clotting must inform their physician about such medication. Inform the nurse or the physician about possible allergic reaction to medication and serious diseases you are being treated for. Information about glaucoma is important, too.

Potential complications

Gastroscopy is an invasive procedure and thus, complications may occur, as is possible with any other invasive procedure, however, complications are very rare in performing gastroscopy. Unless you have increased tendency to bleed, collecting tissue samples will only lead to small amount of bleeding. The occurrence of allergic reactions to calming medication or stronger bleeding are very rare, as well as any instrument injury. **Please, answer following questions** to avoid the risk of bleeding and



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occurrence of any complications with the local anesthetic to minimum:

Do you have increased tendency to bleeding in the event of small injuries or tooth	Yes - No
extraction?	
2. Do you take any medication which affects blood clotting? (Anopyrin, Godasal, Warfarin, Lawarin, Xarelto, Pradaxa, Arixtra etc.)	Yes - No
3. Do you suffer from hay fever, hypersensitivity to food, medications, plasters or local anesthetic medication?	Yes - No
4. Are you pregnant?	Yes - No
5. Do you suffer from any chronic disease (such as glaucoma, epilepsy)? Please, specify?	Yes - No

In case of serious complications after gastroscopy (such as abdominal pressure, black feces) contact immediately the nearest surgical department.

Behaviour before and after examination

Please, arrive for examination on an empty stomach, do not eat for at least 6 hours before the examination, do not drink for 4 hours, do not smoke on the day of the examination. After examination you will wait in waiting room until the administrated medication will pass. Local anesthetic (injected into the neck) affects swallowing. That is why you may eat and drink until the anesthetic pass (about 30 minutes). If you are injected any calming medication for the procedure, avoid driving and other activities requiring attention. Please, follow any and all instructions provided to you after the examination by your physician.

Ask any questions or for any clarification.

I hereby represent and confirm that I have received full guidance and explanation about what this informed consent form contains. I declare that I have understood the above-stated and I had a sufficient opportunity to ask the physician any additional questions to which he answered in a clear and satisfactory manner, and I hereby agree with: Esophago-gastro-duodenoscopy examination, collecting biological samples and, if necessary, polypectomy. I have made this decision freely and with full awareness of my actions.

In Prague on:	Patient's signature:	
Physician's name:		
In case of your first visit please fill out	the following:	
Diseases you are being treated with:		
Medicines you take:		
Allergies:		
Operations:		
Suffered accidents:		
Alcohol: yes x no		Smoker: yes x no
Have you ever undergone a stomach exar	mination – Gastroscopy? Year	
Have you ever undergone an intestine exa	mination - Colonoscopy? Year	
Your address		
Tel.:	E-mail:	