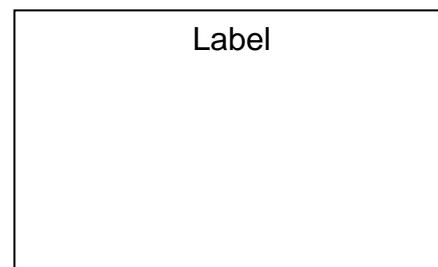


## Information for patients on endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)



Information protocol submitted by:

Date:

Dear patient

Please read these documents immediately 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 an **endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)**. 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 the day before 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 on endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)**

### **Why is a endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule) carried out?**

In this examination a continuous acid measurement (pH measurement) can be carried out over 48 hours in the area of the gastroesophageal junction. The wireless pH measurement is particularly suitable for patients who cannot tolerate a probe through the nose into the oesophagus. By determining acidity measurements in the oesophagus, a definite statement can be made about the presence of reflux disease (gastric acid reflux), even if it was not seen in a gastroscopy.

### **What preparations are necessary for a endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)?**

Before the examination, from midnight on, please do not eat solid food. Drinking clear, fat-free liquids (not milk) is permitted up until 2 hours before the start of the examination. You may take your regular medication. The appropriate clothing for the examination is a shirt or blouse.

Important: in order for the acidity measurement to be meaningful, medication that suppresses stomach acid may have to be discontinued:

- **One week before the examination: Aogpton, Antra, Lansoprazole, Nexium, Omeprazole, Pariet, Pantozol or equivalent generic drugs**
- **48 hours before the examination: Cimetidine, Ranitidine, Ulcidine, Zantic or equivalent generic drugs**

**The referring physician will decide when you stop taking the medication and will inform you.**

### **Ability to drive/ ability to work?**

As a rule 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 a endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)?**

To administer sleeping and sedative drugs, an infusion is first applied to the arm. At your request, this can also be dispensed with and only a local throat anaesthetic spray can be used. The Bravo capsule with the help of a thin movable 'tube' at the tip of which a light source and a camera are attached, placed in the lower oesophageal region. Apart from a slight sensation of a foreign body in the oesophagus, you will not feel the capsule. You may eat and drink normally for the next 48 hours. The data is transmitted wirelessly to a portable receiver and stored. The examination causes no pain. During the examination a specially trained nurse is also present in addition to the doctor. After inserting the Bravo capsule and installing the receiver, which takes about two hours, you will leave the hospital/practice and return after 48 hours to hand in the receiver. The Bravo capsule itself falls off spontaneously within 7-14 days and is naturally excreted.

### **What are the risks associated with endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)?**

Complications due to a gastroscopy to insert the Bravo capsule are extremely rare (0.2%). However, despite the greatest care being taken, complications can occur, which can be life-threatening in exceptional cases. These include allergic reactions, possible damage to teeth due to pre-existing defective teeth, infection, bleeding, injury to the wall of the upper digestive tract (perforation) and injury to the larynx. Rarely, the administration of sleep medication can lead to the impairment of respiratory and cardiac function. Slight hoarseness, difficulty swallowing or unpleasant flatulence (caused by air remaining in the stomach and small intestine) may occur temporarily after gastroscopy.

### **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 abdominal pains or other disturbances of well-being occur after the gastroscopy (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

Label
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## Questions to clarify bleeding tendency:

yes    no

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

## Questions about medication, allergies, concomitant disease:

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

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

Place, date

Patient's name

Patient's signature

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**Informed consent**

**for a endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)**

Label

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 endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule). I understand the nature, procedure and risks of a endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule). My questions have been answered to my satisfaction.

*(Check the appropriate box)*

**I agree to having a endoscopically placed, wireless pH measurement of the oesophagus over 48 hours (Bravo capsule)**

yes	no
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**I agree to a sedative and/or pain relief being administered during the examination**

yes	no
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Patient's name

Doctor's name

Place, date

\_\_\_\_\_  
Patient's signature

Place, date

\_\_\_\_\_  
Doctor's signature

**For patients who cannot give consent themselves:**

Legal representative  
or proxy

Doctor's name

Place, date

\_\_\_\_\_  
Representative's name

Place, date

\_\_\_\_\_  
Doctor's signature

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