WRITTEN INFORMATION AND CONSENT FORM

DIGESTIVE SERVICE

1. **INFORMATION DOCUMENT FOR (*) UPPER ENDOSCOPY, ALSO KNOWN AS ESOPHAGOGASTRODUODENOSCOPY, GASTROSCOPY OR PANENDOSCOPY**

This document is for you or, whoever represents you, to authorize the performance of this procedure. This means that you authorize us to perform it.

You can withdraw this consent at any time. Signing it does not oblige you to undergo the procedure. Revoking this consent does not imply any adverse consequences that could compromise the quality of the care received.

Please let us know if you have any questions or need further information. We will be glad to assist you.

(*) Please indicate the name of the procedure to be performed and, if possible, as well as the technical name that should always be specified, you can also use an easier name.

1.1 WHAT YOU SHOULD KNOW:

WHAT IS ITABOUT? WHAT IS THIS FOR?

Upper endoscopy allows the doctor to comprehensively examine your esophagus, stomach and duodenum using a flexible tube with a lighted camera (endoscope) endoscope through your mouth. This procedure serves to diagnose injuries in that area and treat some of them.

HOW IS IT DONE?

During the procedure, you lie on a comfortable position on your left side. It takes about 10-15 minutes. During that time, you can breathe normally through your nose or your mouth. You will be asked to put a mouth guard, through which the endoscope passes. To help to better tolerate the procedure, a local anesthetic will be sprayed in your throat.
You may also be given an injectable sedative.

WHAT EFFECTS WILL IT HAVE ON YOU?

- Upper endoscopy tolerance is different for each patient. In any case, it is painful and does not make it difficult to breathe. After this procedure, you may feel abdomen discomfort and nauseas, which are usually managed by taking a deep breathe. Once the upper endoscopy is finished, you may have a lack of feeling in your throat, which disappears in about 1 hour, as well as due to the air pumped into your stomach. If given an injectable sedative, residual sedative may persist for many hours.

WHAT BENEFITS WILL IT HAVE ON YOU?

Upper endoscopy is used when your doctor suspects that you may have any disease related to your esophagus, stomach or duodenum. For example, if you have symptoms such as difficulty swallowing, burning or stomach pain, among others.

Endoscopic treatments, such as widening a narrowed area that keeps the food from passing through, the removal of polyps and swallowed and stuck objects, esophageal variceal sclerosis or banding, the application of heat to the injuries that can cause bleeding or anemia, or the destruction of some lesions by using argon gas or laser may be used during the procedure.

OTHER ALTERNATIVES AVAILABLE:

The diagnostic alternative procedure would be an x-ray examination after a barium swallow to obtain images from your gastrointestinal duct. However, this is less accurate than the endoscopy, since the biopsy and visualization of very small lesions are not possible. Bleeding or polyp removal would never be treated by this procedure. As a result, upper endoscopy can often be needed even after an x-ray examination.

For similar reasons, capsule endoscopy (pill sized video camera that you swallow) does not replace upper endoscopy.

In most cases, the therapeutic alternative is a surgery, involving further risks and complications.

WHAT ARE THE RISKS?

Any medical procedure has its risks. Risks do not usually occur and the procedure does not produce damage or undesirable side effects at all. However this is not always the case. That is why you have to know all risks that this procedure may lead to.

- THE MOST FREQUENT:

Upper endoscopy is a very safe procedure. Most complications, such as an allergic reaction to the medication given, are mild and have no repercussions. Complications are more likely to occur when the endoscope is used to offer treatments, such as widening, polypectomies, ligation of esophageal varices or the removal of foreign bodies.

Other minor complications are broken teeth, tongue bite, dislocated-jaw or no voice.

- THE MOST SEVERE:

Severe complications include: perforation, bleeding, allergic reactions to the medicines, cardiopulmonary disorders and infections. If any of these risks show up, the patient may need urgent treatment, even surgery.

- RISKS RELATED TO YOUR OWN MEDICAL CONDITION:

SPECIAL SITUATIONS THAT MUST BE TAKEN INTO ACCOUNT:

Allergic reactions to medicines. Your doctor must know in advanced if you have allergic reactions to anesthetics or sedatives in order to shy away from using them if they are contraindicated.

Patients following an anti-aggregant or anti-clotting treatments: they may have more risk of bleeding, especially if biopsies are needed to be taken. In that regard, precautions must be taken.

Heart and respiratory failures, and recent acute myocardial infarction increase the risk of complications.

OTHER INFORMATION OF INTEREST (to be taken into consideration by the healthcare professional):

You have to be 8 hours fasting.

Tell your doctor if you have any allergic reaction to medicines.

Tell your doctor (at least one week before the procedure) if you are taking any anticlotting (Sintrom…) or anti-aggregant drug (aspirin, ASA, Tromalyt, Iscover…), since you may have to stop taking them.

You must remove your dentures, if you have them.

You have to be accompanied by someone.

Do not eat or drink anything within an hour and a half.

Do not drive or use dangerous machinery during the day if sedatives have been given.

OTHER ISSUES WE NEED YOUR CONSENT FOR:

- Sometimes, during the procedure, there are some unexpected findings. These might oblige to change the way for performing the procedure and to use variants of the same that were not initially planned.
- Sometimes, it is necessary to take biological samples to better study your case. These samples might be saved and used later for research related to the disease you have. They will not be used directly for commercial purposes. If they were to be used for other purposes rather than the ones stated herein, your previous consent will be requested. If you don´t consent for them to be used for research purposes, the samples will be destroyed once your case has been documented, according to the policies of our Healthcare Facility. In any case, your identity will be kept confidential at all times.
- It may also be necessary to take images such as photographs or videos. They serve to better document the case. They can also be used for educational purposes or for the diffusion of scientific knowledge. In any case, they will be used only if you give your consent. Your identity will be kept confidential at all times.

1.2 EXPLANATORY IMAGES:

(Optional explanatory images, anatomical pictures, pictograms, etc. may be inserted in this space to facilitate and allow an easy explanation of the information provided to the patient).

2. INFORMED CONSENT

(In case of PATIENT'S DISABILITY the informed consent must be obtained from the legal representative).

(In case of MINORS, when it is considered that he/she lacks sufficient maturity, the informed consent must be obtained from the legal representative, although the minor should be always informed in accordance with the child's level of understanding and if the child is over the age of 12, his/her opinion will be heard.

If the patient is emancipated or is at least 16 years-old, he/she will be entitled to grant his/her own consent. However, in case of an action implying a severe risk, according to the judgment of the physician, legal representatives will also be informed and their opinion will be taken into account for the decision-making).

2.1 PATIENT´S INFORMATION AND THAT OF HIS/HER LEGAL REPRESENTATIVE (if required)

PATIENT'S LAST AND FIRST NAMES, _____

ID / PASSPORT NUMBER _____

LEGAL REPRESENTATIVE'S LAST AND FIRST NAMES

_____

ID / PASSPORT NUMBER _____

2.2 PROFESSIONALS INVOLVED IN THE INFORMATION AND/OR CONSENT PROCESS

LAST AND FIRST NAMES _____DATE_____SIGNATURE_____

LAST AND FIRST NAMES _____DATE_____SIGNATURE_____

LAST AND FIRST NAMES _____DATE_____SIGNATURE_____

LAST AND FIRST NAMES _____DATE_____SIGNATURE_____

2.3 CONSENT

I, Mr/Mrs _____,

do hereby certify that I agree with the procedure proposed to me. I have read and understood the information contained above. I was able to ask questions and address all my concerns. Therefore, I have consciously and freely decided to authorize the procedure. I am also aware that I can revoke my consent at any time I deem appropriate. ___I DO, ___ I DO NOT Authorize the performance of all appropriate actions, including modifications to the way of performing the procedure in order to avoid any danger or potential harm to my life or health, that could arise during the procedure. ___I DO, ___ I DO NOT Authorize the preservation and further use of any biological samples for research related to the disease I suffer.

___I DO, ___ I DO NOT Authorize that, in the event that the mentioned biological samples were to be used in different investigations, the researchers contact me in order to request my consent.

___I DO, ___ I DO NOT Authorize the use of the images for educational purposes or diffusion of scientific knowledge.

Dated in the city of _____,

PATIENT Consent/Approval by: Signed by: THE LEGAL REPRESENTATIVE Signed by:

2.4 REJECTION OF THE PROCEDURE

I, Mr/Mrs _____ do not authorize the performance of this procedure. I do hereby assume the consequences that could arise related to my health or my life.

Dated in the city of _____,

PATIENT
Signed by:

Consent/Approval by:
THE LEGAL REPRESENTATIVE
Signed by:

2.5 REVOCATION OF CONSENT

I, Mr/Mrs _____

have freely and consciously decided to revoke my consent for this procedure.

Dated in the city of _____, _____

PATIENT
Signed by:

Consent/Approval by:
THE LEGAL REPRESENTATIVE
Signed by: