

Gastroenterology Department

INFORMATION AND WRITTEN CONSENT FORM

Information document for Eco-endoscopy

1. The object of this document is for you, or your legal representative, to give your consent for this procedure. This means that you authorize us to perform it. You can revoke your consent when you wish. Signing this document does not oblige you to go ahead with the procedure. Should you revoke your consent, there will be no adverse consequences to the quality of the rest of the care you will receive. Prior to signing, it is important that you read the following information slowly. Tell us if you have any doubts or need more information and we will be pleased to help.
  - 1.1. What does it consist of/what is it for: The procedure to be performed on you is a mixed procedure using an endoscope (a cable with light and a camera) and echography. The procedure permits exploration with echography, taking of biopsies and specific treatments for lesions in the wall of the oesophagus, stomach and the first part of the small intestine (duodenum), neighbouring organs such as pancreas, bile ducts and lymph glands, done directly from the inside of the digestive tract. To achieve this, a flexible tube with an incorporated light source, endoscopic camera and echography attachment, is introduced through the mouth. This system avoids interference and enables us to study details inaccessible with other methods.

Sometimes a lesion may be detected from within the intestinal tube using the endoscope alone without ultrasound. In either case, the technique is similar
  - 1.2. How is it done? Unlike conventional diagnostic endoscopy, which is a day stay procedure, interventional eco-endoscopy requires hospital admission or day hospital admission. This is aimed to achieve adequate preparation and control maximally your safety after the procedure
  - 1.3. What effects may it produce? Tolerance to the procedure varies from patient to patient, although it is not painful and there is no respiratory difficulty. There may be some mild abdominal discomfort and nausea, although this generally disappears with deep breathing. Once finished there may be a residual numbness of the throat that will disappear after roughly an hour. The sedative given prior to the procedure will help you tolerate this.
  - 1.4. What are the benefits? Eco-endoscopy permits the study using ultrasound and enables the diagnosis of lesions.
  - 1.5. -Diagnostic Eco-endoscopy is limited to the study using ultrasound with or without the taking of biopsies and is not painful.  
-Interventional Eco-endoscopy permits the realization of endoscopic procedures on lesions e.g. biopsy (removal and study) of lymph glands or other lesions situated alongside the digestive tube, aspiration of

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cysts or collections of liquid that are in contact with the intestinal wall or decompression of an obstructed bile duct.

In some cases, it may be necessary to administer iodine based contrast material or x-rays.

1.6. Alternative procedures: Studies using conventional ultrasound, CT or MRI scanning will give sufficient information in many cases. However, eco-endoscopy may be the only option for studying the interior of the digestive tract wall and the small neighbouring structures, or for taking liquid samples, biopsies and even specific treatments in some cases.

1.7. In your case:

What are the risks? All medical procedures have risks. In the majority of cases however, these do not occur and the procedure does not cause any harm or undesired effects. Rarely this is not the case and for this reason it is important that you understand the possible risks of this procedure.

- **THE MOST FREQUENT:**

There may be an adverse reaction to a medication that has been administered, these are usually mild and have no long-term effects. Other minor complications include dental damage, tongue biting, mandibular luxation and speech problems.

- **THE MOST SEVERE**

These are very rare, particularly with diagnostic eco-endoscopy. In cases of eco-endoscopy with aspiration/biopsy, the most important is haemorrhage or perforation of any point within the digestive tube or neighbouring organs.

Other rare complications include infection, bleeding and pancreatitis. As a consequence of such a complication, it may be necessary to proceed to emergency treatment or a surgical procedure. Mortality: Some complications may be fatal. This is exceptionally rare but may occur.

- **THOSE RELATED TO YOUR PARTICULAR HEALTH PROBLEMS**

Special situations that should be taken into account: Allergy to medications: You must inform us beforehand if you are allergic to sedatives or anaesthetics, so that we can avoid their use if contraindicated. Although allergy to iodine based contrast media is not a contraindication, we should be informed if this is the case.

Patients with antiaggregant or anticoagulant treatment may have a greater risk of haemorrhage, particularly if biopsies are taken, and necessary precautions should be taken.

Pregnancy: In some procedures the use of x-rays may be required and this could be harmful to the foetus. In the case of pregnancy, alternative techniques or specific technique planning should be used and this must be notified.

Cardiac insufficiency, respiratory insufficiency or recent myocardial infarction may increase the risk of complications

#### 1.8. Other important information.

You must be fasted for 8 hours before the procedure

We must be informed if you have any allergies to medications or iodine contrast.

We must be informed with time before hand (at least a week) if you take anticoagulants (sintron, warfarina) or antiaggregant (Aspirin, AAS, Tromalyt, Iscover) as it may be necessary to stop them for a time before the procedure.

We must be informed if you are pregnant

Remove any dental prosthetics/false teeth

Come with a family member or friend.

Do not eat or drink anything for at least 90 minutes after the procedure. In the case of eco-endoscopy, it may be advisable to remain fasted for 24 hours after.

Do not drive or manage equipment during the rest of the day.

#### 1.9. Other issues for which we request your consent.

- Sometimes, during a procedure, unforeseen circumstances arise. This may result in the need to alter the form of performing the procedure or use variations not previously planned.

- Sometimes it is necessary to take biological samples to help study your case. These may be preserved and used at a later date for the study of the disease you have. Were they to be used for any other purpose, your prior consent will be required. If you do not consent for them to be used in investigation, they will be destroyed once their use is no longer required for the study of your case. , following the centres protocol. In all cases the confidentiality will be maintained.

- All personal details will be treated with confidentiality. This information will only be supplied to those professionals and institutions with accredited legitimate interest and who are necessary in order to assist you.

- It may also be necessary to take images, such as photos or videos. These serve to help with your case. These may be used for teaching purposes, only within the scientific community. These will only be used if you give your permission. Your identity will be confidential.

2.0: INFORMED CONSENT

- In the case of the patient's incapacity, consent must be given by the legal representative
- In the case of a minor when the patient is not considered sufficiently mature, consent must be given by the legal representative, although the minor will always be informed within the limits of their understanding and, if older than 12 years of age, their opinion will be listened to.
- if the patient is independent or older than 16 years of age, he/she will give the consent. However, in the case of a very dangerous procedure, according to the doctor's criteria, the opinion of the legal representatives will also be taken into consideration

2.1 Patient details and of the legal representative, if necessary

Patients surname and first name \_\_\_\_\_ DNI/

NIE.....

.....

**2.2 Professionals involved in the process of giving information and consent**

Surname and first name  
of legal representative

Surname name..... date.....

Surname name..... date.....

..... DNI/ NIE

and .....signature.....

and .....signature.....

Consent

I,.....

.....manifest that I am in agreement with the proposed procedure. I have read and understand the previous information. I have been able to ask questions and clear up any doubts. For this reason, I have decided to give my authorization. I also understand that I can withdraw my consent at any time.

...YES.....NO.. Authorize the necessary procedures, including necessary modification of the planned procedure, in order to prevent danger or potential harm to my health or life that might occur during the procedure.

..YES.....NO... ..Authorize the preservation and later use of biological samples for the further study of the disease I suffer with.

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YES.....NO.. ..Authorize that, in the case of such samples being used in different investigations, the investigators will previously seek my permission.

YES... ..NO... ..Authorize the use of images for teaching ends or for scientific knowledge.

In \_\_\_\_\_ on the \_\_\_\_\_ of \_\_\_\_\_ 20.....

THE PATIENT

Consent/Conformity of  
LEGAL REPRESENTATIVE

Signed..... Signed.....

2.4 Rejection of the procedure

I,.....  
do not authorize this procedure. I assume the consequences of this action on my life and health

In \_\_\_\_\_ on the \_\_\_\_\_ of \_\_\_\_\_ 20.....

THE PATIENT

Consent/Conformity of  
LEGAL REPRESENTATIVE

Signed..... Signed.....

2.5 Consent Withdrawal

I.....  
consciously and of my own free will have decided to withdraw my consent for this procedure. I assume the consequences that this action may have on my health and my life.

In..... on the..... of.....

THE PATIENT

Consent/Conformity of  
LEGAL REPRESENTATIVE

Signed.....

Signed. \_\_\_\_\_