

INFORMATION PROTOCOL AND REQUEST FOR CONSENT TO COLONOSCOPY

Note: In cases of confirmed or suspected allergy to LATEX, please book the colonoscopy for 8.00 am (the first test of the day).

- For the 3 days before the procedure: eat a diet free of fruit, pulses, vegetables, seeds and red meat.
- The day before the test: Do NOT eat solid food, eat a clear-liquid only diet.
- At 10.00 am, take 4 tablets of **DULCOLAX** (all together).
- At 7.00 pm, take 4 sachets of **AGPEG PLUS** dissolved in 2 litres of water.

In specific cases in which the colonoscopy is booked for the afternoon (from 2.00 pm onwards), on the day of the procedure (early in the morning) take 1 sachet of AGPEG PLUS dissolved in ½ a litre of water.

Meals must be as light and liquid as possible.

Do not take any laxatives (e.g. lactulose or mannitol), and do not eat sugar-free products (such as sweets).

The product will cause painless but significant diarrhoea which in the end will mainly comprise clear water.

Note: Patients suffering from constipation must also follow the instructions below:

For the 3 days before the procedure take 1 tablet of **DULCOLAX** in the morning and 1 sachet of **ONLIGOL** in the morning + 1 in the evening, each dissolved in 250 cc of orange-flavoured Gatorade.

THE PATIENT MUST BRING:

- All the medical documentation relating to the clinical problem being investigated.
- Haematochemical tests: **COMPLETE BLOOD COUNT INCLUDING PLATELETS AND PROTHROMBIN ACTIVITY (*)**
- THE PATIENT SHOULD BE ACCOMPANIED TO THE TEST.

PREVENTIVE TREATMENT FOR BACTERIAL ENDOCARDITIS IS RECOMMENDED WHERE APPROPRIATE.

(*) or a statement from the patient's doctor that the patient does not have coagulation or heart problems.

PLEASE READ CAREFULLY THE INFORMATION SHEET.

INFORMATION SHEET AND INFORMED CONSENT FORM

COLONOSCOPY

Colonoscopies allow doctors to examine your colon directly using a flexible optic telescope (known as endoscope), which is passed through the anus and guided to the right-hand end of the colon and then withdrawn. The procedure takes around 15 minutes and may cause minor and generally well tolerated pain when the endoscope is introduced and as it moves along the colon. To help you tolerate the procedure better, you will be given a sedative and an intravenous analgesic, unless you ask not to or there is a clinical reason why it would be absolutely preferable not to. Air introduction, which is necessary to gain a correct picture of the intestinal walls, may cause a sensation of needing to take a bowel movement or a colic-like pain. During the investigation it may be necessary to take biopsies, which is a simple and painless procedure.

PREPARATION FOR THE ENDOSCOPY

It is very important for the intestine to be very clean in order to allow the operator a clear view, otherwise the exam will have to be repeated. Therefore, the instructions given by the nursing staff and the attached guidelines must be followed closely.

WHAT BIOPSIES ARE FOR

Biopsies are samples of mucosa taken for examination under the microscope. Biopsies are taken for the diagnosis of a very wide range of diseases (therefore, it does not automatically mean that they are being taken to check for cancer).

WHAT IS A POLYP

A polyp is an irregular area of mucosa, which may be flat or rounded, and can range from a few millimetres to a few centimetres in size. Not all polyps are the same and some can turn into malignant tumours with time. Therefore, every time a polyp is found during a colonoscopy, it is prudent to remove it, send it for histological testing and schedule regular examinations based on the histology results and other criteria, such as family history, intestinal cleanliness, patient's age, etc. The therapeutic alternative to polypectomy is surgical removal of the relevant section of the intestine, although this requires longer recovery time and leads to a higher number of complications.

POSSIBLE RISKS AND COMPLICATIONS

A colonoscopy is a safe procedure. Complications occasionally occur such as perforation (0.1%-0.3% of cases), haemorrhage (0.1%-0.5% of cases) and cardio-respiratory problems (0.4%). However, they are quite rare (less than one in 1,000 cases) and usually related to the existence of serious pathologies. In the case of a colonoscopy for treatment purposes, such as for the removal of polyps, the frequency of complications is higher. The percentage of haemorrhages rises to 0.6%-3% of cases, and perforation to 0.3%-2%. Literature mentions exceptional complications, such as hemoperitoneum and colonic explosion. The risk of infection transmission (from bacteria, viruses or fungi) is entirely negligible, as the instrument is decontaminated after each use and washed using instrument-washing machinery that guarantees a high level of disinfection. All the accessories used (biopsy forceps, polypectomy devices, needles for injections, etc.) are disposable or are sterilised like surgical instruments. The occurrence, albeit rare, of the complications described above may lead to changes or extensions of the planned procedure. The bleeding generally diminishes by itself or is stopped using the endoscopy instruments, and sometimes may lead to the patient being kept in hospital under observation, and rarely to surgery with the related risks of aesthetic damage.

Perforation is the most serious complication and may require corrective surgery with external deviation of the faeces (temporary stoma). In extremely rare cases such complications may put the patient's life in danger. Colonoscopies are **not** 100% accurate in providing a diagnosis. This could depend on preparation of the intestine, the anatomical conformation, e.g. dolichocolon or the presence of diverticulosis, and the intrinsic limitations of the method itself. Recent data in literature show that polyps may not be diagnosed in 0-15% of cases, while 2%-6% of neoplastic lesions may not be identified. It is also possible that the opposite could happen, i.e. that changes could be overestimated and then prove to be benign. **It is also possible that some polyps/adenomas might not be recovered during the colonoscopy. This is generally due to their small size, and to preparation of the patient's intestine.**

SEDATION

We normally perform colonoscopies on patients who are sedated and received analgesics (unless you specifically request not to), in order to considerably reduce discomfort and make the procedure far less stressful. Sedation not only improves the patient's ability to cooperate, it also offers a better guarantee that the endoscopic procedure will be carried out more easily and accurately. More information about sedation is provided on the informed consent form that will be given to you when you book the procedure. In order to have sedation you will need to be accompanied to the hospital by an adult. You will not be able to carry out activities which require you to be fully physically and mentally fit (such as driving) for the following 24 hours.

DIAGNOSTIC ALTERNATIVES TO A COLONOSCOPY

The diagnostic alternative to a colonoscopy is a double-contrast opaque enema or a virtual colonoscopy using the CAT method. These alternative investigations do not always provide all the answers needed, and sometimes need to be followed up by a colonoscopy to confirm diagnosis with biopsies (which cannot be taken with the other tests) and polypectomies.

EXPECTED CONSEQUENCES OF NOT HAVING THE PROCEDURE

Not having the procedure means not being able to have a diagnosis, and that the underlying pathology will worsen, with consequences such as haemorrhage, obstruction of the intestine and the possible development of malignant tumours.

I, the undersigned, confirm that I have received exhaustive answers from Dr. _____ including to all the questions and clarifications I spontaneously asked, and that I am fully conscious, aware and free to make choices about my person.

Patient's signature

Signature of parent or legal guardian

Signature of interpreter who states that he/she has translated the information sheet

Doctor's signature

Date

INFORMED CONSENT

Having understood the situation that has been explained to me, I hereby

CONSENT **DO NOT CONSENT**

by my own, spontaneous, informed will, to a:

COLONOSCOPY + POSSIBLE BIOPSIES + POSSIBLE POLYPECTOMIES

Personal data will be handled in full compliance with privacy laws (Italian Law 196/2003).

Patient's signature

Signature of parent or legal guardian

Signature of interpreter who states that he/she has translated the information sheet.

Doctor's signature

Date

Note: Patients that have given their consent are free to withdraw it and refuse to have the test at any time.

**INFORMATION PROTOCOL AND REQUEST FOR CONSENT
TO SEDATION AND ANALGESIA FOR THE ENDOSCOPY**

Date _____

Name and surname:

Test:.....

PATIENT INFORMATION

What is sedation/analgesia?

Dear Patient, the test that has been requested for you could cause discomfort and, in some cases, pain. In order to reduce discomfort and make the procedure more comfortable for you, we suggest you receive some drugs intravenously – opiates (to remove pain and/or retching) and benzodiazepine to make you a little sleepy, calm anxiety and make sure you don't have a bad memory of the procedure you have decided to undergo. While under sedation and analgesics, you will still be able to breathe on your own, respond to touch and to verbal instructions.

How am I given it?

The drugs most commonly used for sedation and analgesia are Diazepam and Midazolam (from the benzodiazepine family) and the opiates Alfentanil, Fentanyl and Pethidine, administered intravenously in gradually increased small doses until the desired level of sedation is reached. The choice of drugs is made by the endoscopy doctor based on an assessment of your general clinical conditions as well as the type and expected duration of the procedure. Topical anaesthetic of the oral cavity and pharynx may also be carried out using a spray anaesthetic.

Sedation and analgesia are carried out with constant monitoring of the patient's cardio-respiratory functions.

Why is it carried out?

The purpose of sedation during an endoscopy is to considerably reduce discomfort for the patient and make the examination less stressful. Sedation not only improves the patient's ability to cooperate (especially if they are frightened by the procedure), it also offers a better guarantee that the endoscopic procedure will be carried out more easily and accurately.

What are the complications?

Conscious sedation, like any medical procedure, may cause complications such as:

- nausea and vomiting – relatively more frequently (5%-7% of cases)
- respiratory depression, apnoea and in extremely rare cases, cardio-respiratory arrest
- muscular contractions
- changes in blood pressure and heart rate
- an allergic reaction with rare cases of bronchospasm
- euphoria
- possibility of failure to sedate – extremely rare – owing to individual resistance

The onset of such complications may be controlled and treated through the constant monitoring of vital functions and with mechanical medical aids and antidotes to hand. In extremely rare cases they may lead to an unfortunate outcome.

In rare cases there may be local complications in the sites where drugs are injected, such as pain, bleeding or thrombophlebitis, and adverse reactions to plasters.

Patients must not drive vehicles or use potentially dangerous machinery, carry out difficult work or take legal decisions for 24 hours after the endoscopy and may only leave the outpatient's clinic if accompanied.

What is the alternative?

To carry out the endoscopy without sedation or with local oropharyngeal anaesthesia only.

However, this will require greater cooperation on your part in order to be able to tolerate the procedure, and may further reduce the diagnostic reliability of the test.

Informed consent to sedation/analgesia

I, the undersigned

declare that I have been informed by Dr.

clearly and comprehensibly, about the possibility of undergoing the proposed endoscopic examination under sedation.

I declare that I have carefully read and have received explanations about the information on sedation provided, and therefore that I have clearly understood its application and method of execution, that I am fully aware of the objectives, benefits, failures and any risks and complications relating to the administration of the drugs used.

I have also been informed about the possible alternative of having the examination without sedation, which I choose to reject.

The information provided has been fully exhaustive and clearly understood and I therefore give my informed, conscious consent, to conscious sedation/analgesia

Date

Patient's signature

Signature of parent and/or guardian and/or interpreter

Doctor's signature

PATIENT'S MEDICAL HISTORY

SURNAME and NAME: _____

Dear Patient,

Please fill in all the items on this form and give it to the healthcare personnel at the Endoscopy Service. Your cooperation helps us to help you.

1) Do you suffer from heart disease or very high blood pressure?

YES NO

2) Do you suffer from neurological problems?

YES NO

3) Have you suffered from viral hepatitis, or are you suffering from any infections at the moment?

YES NO DON'T KNOW

4) Are you HIV-positive?

YES NO DON'T KNOW

5) Do you suffer from metabolic problems such as hypo/hyper-thyroidism or diabetes?

YES NO

6) Do you suffer from muscular pathologies?

YES NO

7) Do you take anticoagulant drugs?

YES NO

8) Are you allergic to any substances?

YES NO Which? _____

9) Which drugs do you take regularly?

Date

Patient's signature
