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PREPARING FOR A COLONOSCOPY

Preparing the bowel

- For 3 days before the examination: diet free of fruit, legumes, vegetables, seeds and red meats.
- On the day before the examination: DO NOT take solid foods but only clear liquids;
  - at 10.00 am, take 4 tablets of DULCOLAX (all together);
  - at 7.00 pm take 4 sachets of AGPEG PLUS dissolved in 2 L of cool water.

If the examination is booked for the afternoon (from 2.00 pm onwards) on the day of the examination (early morning) take 1 sachet of AGPEG PLUS dissolved in ½ L of water.

Meals must be as light and as liquid as possible.
Absolutely do not take any laxatives (e.g., lactulose or mannitol).

Note: furthermore, constipated patients must follow the indications given below:

Two days before the examination, in the evening, take 1 L of water with 2 sachets of AGPEG PLUS, and on the day before the examination, at 10.00 am, take four tablets of DULCOLAX followed by 3 L of cool water with 6 sachets of AGPEG PLUS to be taken over a period of about 3 hours, starting from 6.00 pm.

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INFORMATIVE NOTE AND INFORMED CONSENT FOR A COLONOSCOPY

A colonoscopy is a diagnostic examination that consists of introducing a flexible probe fitted with a camera at the tip (colonoscope) through the anal orifice to explore and see the mucosa of the colon (and, at times, of the terminal ileum), appropriately cleaned in advance by means of adequate preparation of the bowel.
The examination takes about 15 minutes but it might take longer if polypectomies or other therapeutic treatments have to be performed, or depending on the anatomy and cleanliness of the colon.
The examination is preferably performed on the left side but, during the procedure, it might be necessary to change the position and manual compression manoeuvres of the abdomen might be performed to facilitate progress of the endoscope.
During the examination you might experience moderate pain upon air insufflation and as the instrument makes it way along the bowel. This pain is generally well tolerated, also because a sedative and an analgesic can be administered intravenously, unless specifically refused by you or if there is an absolute clinical contraindication. Blood pressure, heart rate, oxygen saturation and, if necessary, electrocardiographic activity will also be monitored.
During the examination it might also be necessary to perform biopsies easily and painlessly, or additional diagnostic or therapeutic procedures.
The examination might not be completed in the case of inadequate bowel preparation, narrowing of the intestinal lumen (stenosis) that cannot be penetrated with the device, or of particular anatomical features of the bowel and/or intolerance to the examination. In such cases you will be provided correct indications to continue adequate investigations.

Preparing for the endoscopic examination

There is evidence that incomplete cleansing of the bowel increases the risk of not seeing lesions during the colonoscopy. Hence, it is crucial that the bowel is absolutely clean to ensure the operator has an excellent view and to avoid prolonging the examination; otherwise, the examination will have to be repeated. Hence the need to follow the preparation instructions provided above scrupulously.
During the interview that takes place before the examination, it is essential to inform the doctor about any diseases and/or allergies the patient may have, **WHETHER THE PATIENT IS TAKING ANY MEDICINES** and whether the patient is wearing a pacemaker or other implantable device that might interfere with the electro-medical instruments. If the patient is taking anticoagulant and/or antiaggregant medicines, in view of the examination they might have to be suspended or substituted following a consultation with the attending specialist. In view of the particular endoscopic operative procedures, the feasibility of performing blood tests to evaluate coagulation parameters will be considered.
In particular, it will not be necessary to suspend your habitual therapies, particularly antihypertensive agents or aspirin, with the exception of:

- **iron by mouth**: whatever the formulation, suspending it one week before the examination is recommended;
- **oral antidiabetics or insulin:** generally these medicines need not be taken considering the fast required to prepare for the examination.
  In case of doubt, talk to your GP and/or the prescribing specialist.

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- **Double antiaggregant therapy**: Aspirin + Plavix/clopidogrel or Brilique/ticagrelor or Duoplavin and similar medicines: contact the prescribing doctor to ascertain the feasibility of temporarily suspending them (generally Plavix-Brilique must be suspended 5 days before the procedure).
- **Therapies with ticlopidine/Tiklid prasugrel/Efient**: contact the prescribing doctor to ascertain the feasibility of temporarily suspending them (generally seven days before the procedure).
- **New anticoagulants:** Rivaroxaban, Apixaban, Dabigatran, Edoxaban (**Pradaxa**, **Xarelto**, **Eliquis, Lixiana**) talk to your GP or to the prescribing doctor (e.g., cardiologist) to evaluate the feasibility of suspending them and the appropriate timing (generally 48 hours before the procedure, except for cases of known renal failure).
- **Anticoagulants: Coumadin/Sintrom** must generally be suspended 3-5 days before the procedure, depending on the INR values. In any case, please talk to your GP or to the reference anticoagulation therapy centre about the feasibility of starting bridge therapy and the dosage of low molecular weight heparin, if required; its administration is allowed except on the morning of the examination.

We also recommend:

- bringing along the **GP's prescription**, medical documents regarding the clinical problem under investigation or important diseases, any previous endoscopic examination reports and the list of medicines being taken;
- coming accompanied by a person who can drive or using public transport because **driving is forbidden for 24 hours** given the type of sedative used**;**
- informing the doctor who will perform the examination whether you are wearing an **implanted pacemaker or defibrillator** that might interfere with electro-medical instruments; informing the doctor if you have serious heart, lung, liver or kidney diseases or allergies to any medicines or other substances;
- informing the doctor if you are wearing removable dental prostheses in order to remove them and place a protective mouthpiece on the instrument that will be placed between your teeth.

What are biopsies needed for?

During a colonoscopy small tissue samples might be collected, if necessary, with specific sterile forceps to identify the type of colon lesion (inflammatory, infectious, neoplastic).

What are chromoendoscopy and tattooing?

When indicated, staining of the mucosa might be performed by spraying stains directly on the mucosa through the operative canal of the endoscope or through submucosal infiltration to improve the morphological definition of some lesions or to facilitate their identification during an endoscopy or subsequent surgical procedures. The use of Indian ink is associated with a risk of severe complications (focal peritonitis, infected haematoma, abscess, postoperative adherences) in the range of 0.2% to 5.6%.

What is a polyp and what does polypectomy mean?

A polyp is an irregular mucosal area that is either elevated or flat, with dimensions ranging from a few millimetres to a few centimetres. Not all polyps are the same; some can transform into a malignant tumour in the course of time and, hence, some of them are removed during a colonoscopy by means of a polypectomy

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for histological analysis. Most of them can be easily removed during colonoscopy by using particular accessories (polypectomy loops) that can be connected to an electrosurgical knife that issues diathermic current. However, if it is either large or situated in a particular site, various removal techniques might be required, which will prolong the examination, or the examination might have to be repeated to ensure complete removal. The alternative to a polypectomy is surgical dissection of the intestinal segment concerned.

Advanced mucosa resection techniques: an EMR or mucosectomy (endoscopic resection of mucosal and submucosal tissue) and an ESD (endoscopic dissection of submucosal tissue) are advanced techniques to remove superficial neoplastic lesions. There are various execution techniques: the most common one is the "lift and cut" method, which entails a submucosal injection using a dedicated needle filled with either a saline or a colloidal solution to elevate the lesion (mucosa and submucosa) from the muscularis propria. The elevated block is then resected with a diathermic loop during the EMR or with the free dissector during the ESD. Haemorrhage and perforation are the most common complications. They have a higher incidence rate than complications that occur during a standard polypectomy. The risk of immediate bleeding is about 10%, while late bleeding occurs in about 1.5-14% of cases. Bleeding is usually treated endoscopically, and some cases might also need blood transfusions. Surgery is rarely resorted to. Perforation occurs in about 5-10% of ESDs of the colon and in up to 5% of EMRs. Most perforations are immediately diagnosed and endoscopically treated during the procedure. Mortality is rare in both procedures (0.25%).

Haemostatic treatments: their purpose is to stop bleeding. Haemostatic therapies include thermal techniques, injections and mechanical procedures. Two or more techniques might be combined. Perforation is a rare complication of endoscopic haemostasis. However, especially in the treatment of angiodysplasia, particularly when it is located in the right colon, perforation has been described in up to 2.5% of cases.

Possible risks and complications

A colonoscopy is a safe procedure. Some complications, such as perforation (0.07-0.3%), bleeding (0.1-0.5%) and cardiorespiratory problems (0.9%), might occur only exceptionally. Exceptional complications have been reported, such as rupture of the spleen, acute appendicitis, diverticulitis, subcutaneous emphysema, laceration of mesenteric vessels and intra-abdominal bleeding.
In any case, the incidence rate is rather low, and is usually related to severe diseases.
The incidence rate of complications increases for therapeutic colonoscopy and for removal of polyps: bleeding increases up to 0.3-6% of cases (up to 2% between the subsequent 7-30 days), and perforation rises to 0.04-1%. "Postpolypectomy syndrome" (0.003-0.1%) is also described. It usually manifests within 24-36 hours with fever, localised abdominal pain and increased white blood cell levels. It is generally resolved with conservative therapy through administration of intravenous hydration, antibiotic therapy and fasting until the symptoms have cleared.
Infections: transient penetration of bacteria into the blood (bacteriaemia) might manifest after colonoscopy performed either with or without biopsies. This occurs in approximately 4% of procedures with a percentage in the range of 0% to 25%. Signs or symptoms of infections are rare. Hence, antibiotic prophylaxis is not recommended for patients who submit to a colonoscopy.
In order to ensure safe administration, free of the risk of infection for the user and for healthcare professionals, reusable medical devices (endoscopic and multi-use accessories) are thoroughly cleaned (external surfaces and internal canals) immediately after every procedure with proteolytic detergents to remove all potentially contaminating organic material. Then, the material considered semi-critical (e.g., the

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endoscope) is subjected to a high level disinfection cycle in dedicated endoscope washers. At the end of the disinfection cycle the endoscopes are dried and, if they are not used immediately, they are placed in dedicated ventilated cabinets that allow them to be stored vertically in order to protect them from dust, from possible sources of contamination and from high temperatures.
Reusable accessories (forceps, polypectomy loops, etc.) are considered critical instruments and are subjected to a sterilisation process after having been subjected to thorough washing.
The rare occurrence of the above complications can cause a change in and extension of the scheduled surgery. Bleeding is generally either self-limited or stopped with the same endoscopic tools. At times it can generate the need for blood transfusions, admission to hospital for observation and, in rare cases, surgery. Perforation is the most severe complication. It might require corrective surgery even with an external derivation for stools (temporary stomy). in exceptional cases, these complications can be life-threatening.
The diagnostic accuracy of a colonoscopy is **not** 100%; hence, not all polyps or lesions might be identified. This can depend on bowel preparation, anatomical conformation and the intrinsic limitations of the method.
We must also report the possibility that some polyps/adenomas might not be recovered during colonoscopy. This generally depends on the small dimensions of the polyps and on the patient's bowel preparation.

Sedation

A colonoscopy is usually performed under sedo-analgesia (unless explicitly refused by the patient) in order to considerably reduce discomfort caused by the examination. Besides improving the user's cooperation, sedation guarantees easier and more precise execution of the endoscopic procedure. The main vital parameters will be constantly monitored during the procedure, and it will also be possible to administer medicines that are antagonists of sedation/analgesia to obtain adequate recovery. More details on sedation are provided in the dedicated **Informed Consent Form.**
For sedation, it is preferable to be accompanied to Hospital by an adult. ***You will not be able to perform activities that require complete psychophysical integrity (e.g., driving) during the subsequent 24 hours.***

After the examination

At the end of the examination, after a brief period of rest, you may return to your home.
If you were administered medicines for sedo-analgesia, or if therapeutic manoeuvres were performed during the examination, longer clinical observation might be indicated, depending on the doctor's opinion. However, for a few hours you might feel as though your abdomen is swollen (or tender), or there might be residual temporary drowsiness, dizziness and blurred vision, if sedatives and analgesic medicines were administered.
If, during the hours or days after the examination, you happen to experience abdominal pain, fever or be unable to pass wind, or if you notice the evacuation of stools with abundant blood or black stools, immediately contact your GP, or our Digestive Endoscopy Department (tel.: (+39) 02 2393 3055/2252 - during opening hours), or visit the Emergency Department, taking the endoscopic examination report with you.
If you have been administered sedo-analgesics, you will not be able to either drive or perform activities entailing risks or that require complete psychophysical integrity during the 24 hours after the procedure. Hence, it is preferable for you to be accompanied.
Recommencement of your current therapy, diet and fluid intake will be agreed with the medical professionals at the time you are discharged.
The examination report will be given to you immediately, while you will have to wait a few days for the histological report (the outcome of biopsies or polypectomies, if any).

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Diagnostic alternatives to a colonoscopy

The diagnostic alternative to a colonoscopy is a virtual colonoscopy with the TC method, a video capsule colonoscopy or a double-contrast barium enema.
However, they lack the diagnostic sensitivity and accuracy of a colonoscopy. Bowel preparation is, in any case, required and, at times, has to be integrated with a subsequent colonoscopy because none of these methods allows biopsies to be collected for histological analysis or surgical manoeuvres to be performed (polypectomies, etc.).
Hence, any indication to these alternative procedures must be evaluated with your doctor, considering both risks and benefits.

Predictable consequences of not performing the examination

Failure to perform the examination prevents the definition of a diagnosis. It might cause aggravation of the basic disease with possible consequences, such as haemorrhage, obstruction of the intestinal tract and any malignant evolution.

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INFORMED CONSENT

In a doctor-patient relationship it is deemed necessary and ethically correct for the patient to play an informed and active role in invasive diagnostic examinations and treatments to which he or she submits voluntarily.

Hence, this document provides the information, and the doctor who presents and explains it to you will provide the extensive and clear information required to understand it, ensuring that you have clearly understood the contents submitted to your attention below, which require your final signature.

It is important for you to deem the information provided as exhaustive and clear and, particularly, for you to have clearly understood the procedure proposed for an appropriate therapeutic treatment. The benefits of the procedure that will be performed, the possible risks and any alternatives will be explained to you, so that you can make a voluntary and, therefore, an informed decision in this regard. Hence you are also given written information that is as detailed and as complete as possible, to ensure that the explanation is both comprehensible and exhaustive. If you deem it necessary, do not hesitate to request further information which you might consider useful to clear any doubts or to clarify any parts of the explanation that you did not fully understand. Hence, we invite you, before you give your written consent by signing this form, to clarify with the doctor who explains it to you, every aspect you have not fully understood.

I, the undersigned, _____ confirm that today I had an informative interview with Dr.

_____

who explained that due to my disease,

DIAGNOSIS

_____

it is necessary/appropriate to perform the following invasive procedure:

COLONOSCOPY + BIOPSIES, IF ANY + POLYPECTOMIES, IF ANY, AND ANY THERAPEUTIC TREATMENTS INDICATED FOR THE CLINICAL CASE OR THAT MIGHT BECOME NECESSARY

In this regard I have been exhaustively and comprehensibly informed about:

- my diagnosis resulting from the visit and/or examination;
- the most appropriate treatment, schedule and implementation methods;
- the potential benefits of the treatment;
- the possible complications, risks and related additional medical procedures;
- the possibility of failure;
- the particular risks related to my case;
- the discomfort that might arise after the treatment;
- the timeline and methods of recovery;
- the alternative therapeutic options to the diagnostic/therapeutic treatment proposed to me;
- including refusal to accept treatment and the related risks;
- the instruments required.

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I also confirm:

- that I have had the opportunity to ask questions about the treatment proposed, and that the doctor was willing to provide any further clarifications I might require;
- that I am aware of the possibility of having to sign a new form, if the treatment is divided into various appointments, depending on which hazards might arise for my health;
- that I have been informed about the option of withdrawing my consent, if I do not want to continue the treatment;
- that I am aware of the fact that when changes are required to the already agreed procedures, I will have to express my consent once again;
- that I have understood that, if required, a change in the diagnostic/surgical strategy that cannot be foreseen at this moment might be necessary during surgery.

Hence, I freely provide my informed consent to submit to the recommended treatment, having received the information required to evaluate its feasibility.

ACT OF CONSENT

With this statement, which shall be effective as the full, free and unconditional expression of my will, I, the undersigned, declare that I have received and understood the information briefly described above and presented in the enclosed technical document, and:

☐ **I give my consent**	☐ **I do not give my consent/I withdraw my consent**
Patient's signature, guardian/parent _____ Doctor's signature _____ *(stamp or matriculation number and legible signature)*	Patient's signature, guardian/parent _____ Doctor's signature _____ *(stamp or matriculation number and legible signature)*
Date: _____	

Details of the declaring party:

- ❒ patient
- ❒ guardian of the incapacitated patient
- ❒ parents of the minor patient exercising parental authority

use upper case to enter the first and last name and date of birth of the declaring party, if different to the patient:
_____

Signature of the other parent _____

Specify the name of the mediator / interpreter, if any _____

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INFORMATIVE NOTE AND INFORMED CONSENT TO PERFORM SEDO-ANALGESIA FOR THE ENDOSCOPIC EXAMINATION

What is sedation/analgesia?

Dear User, the examination you have been requested to submit to might be uncomfortable and, in particular cases, painful.
To reduce the discomfort and to make your examination more comfortable, we suggest that you submit to the intravenous administration of certain medicines, opiates and benzodiazepines, to reduce the pain and sedate you. They might, at times, cause retrograde amnesia. During sedo-analgesia, you will preserve the capacity to breathe independently, to respond to tactile stimuli and to respond to verbal commands.
The choice of medicines is made by the endoscopist based on the evaluation of your general clinical conditions and on the type and estimated duration of the procedure. Sedo-analgesia is performed while constantly monitoring the patient's cardiorespiratory functions.

Why is it performed?

The aim of sedation during endoscopy is to considerably reduce discomfort for the user and to make the examination less uncomfortable. Besides improving patient cooperation, sedation guarantees easier and more precise execution of the endoscopic procedure.

What are the complications?

- Nausea and vomiting - relatively more frequent (5-7% of cases);
- respiratory depression, apnoea and, in very rare cases, cardiorespiratory arrest (severe complications 1-3 out of one thousand, with overall mortality < 0.3/1000);
- muscular contraction;
- altered blood pressure and cardiac rhythm;
- allergic reaction with rare cases of bronchospasm/hives;
- euphoria;
- possible failure of the sedation, which is quite rare, related to individual resistance.

The onset of such complications can be controlled and treated by continuously monitoring vital functions, and by having access to specialised skills, mechanical medical aids and antidotes.
They can have a fatal outcome in very rare cases. Finally, rare cases might manifest local complications at the injection site used for medicines, such as pain, bleeding or thrombophlebitis and adverse reactions to plaster patches.

The user must abstain from driving and using potentially dangerous machinery, from performing strenuous work and from making legal decisions during the 24 hours after the endoscopic examination.

What is the alternative?

To perform the endoscopic examination without sedation; conversely this entails the need for greater cooperation on your part to face the procedure, and can contribute to further limiting the diagnostic reliability of the examination.

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INFORMED CONSENT TO SEDATION/ANALGESIA

I, the Undersigned, declare that I have been clearly and comprehensibly informed by the doctor, who has signed this document below, of the possibility of performing the endoscopic examination proposed under pharmacological sedation.
I declare that I have carefully read and received explanations regarding the information about sedation, that I have, therefore, clearly understood the indications and methods of execution, and that I am fully aware of the objectives, benefits, failures and any risks and complications related to the administration of the medicines used.
I have also been informed about any alternative to being submitted to the examination without sedation.

ACT OF CONSENT

With this statement, which shall be effective as the full, free and unconditional expression of my will, I, the undersigned, declare that I have received and understood the information briefly described above and presented in the enclosed technical document, and:

☐ I give my consent	☐ I do not give my consent/I withdraw my consent
Patient's signature, guardian/parent _____ Doctor's signature _____ *(stamp or matriculation number and legible signature)*	Patient's signature, guardian/parent _____ Doctor's signature _____ *(stamp or matriculation number and legible signature)*
Date: _____	

Details of the declaring party:

- ❒ patient
- ❒ guardian of the incapacitated patient
- ❒ parents of the minor patient exercising parental authority

use upper case to enter the first and last name and date of birth of the declaring party, if different to the patient:
_____

Signature of the other parent _____

Specify the name of the mediator / interpreter, if any _____