



*Multimodal highly-sensitive photonics endoscope for improved in-vivo colon cancer diagnosis and clinical decision support



NOTE: The preceding information of this leaflet is intended only to provide general information about a study within PICCOLO project. More detailed information is included in the patient information sheet and informed consent provided by your hospital that you will need to read and sign if you are willing to participate in the study.



PICCOLO*

study



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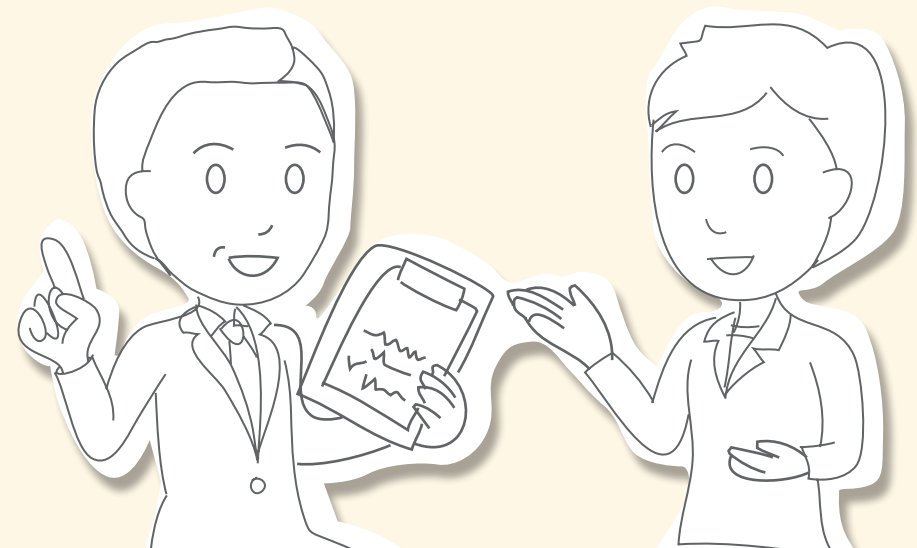
 [@piccolo-project.eu](https://twitter.com/piccolo-project.eu)



This is a study within the PICCOLO project, which has received funding from the European Union's Horizon 2020 research and innovation Programme under grant agreement No. 732111.

This information reflects only the institution's view, so the Agencies and the Commission are not responsible for any use that may be made of the information it contains.

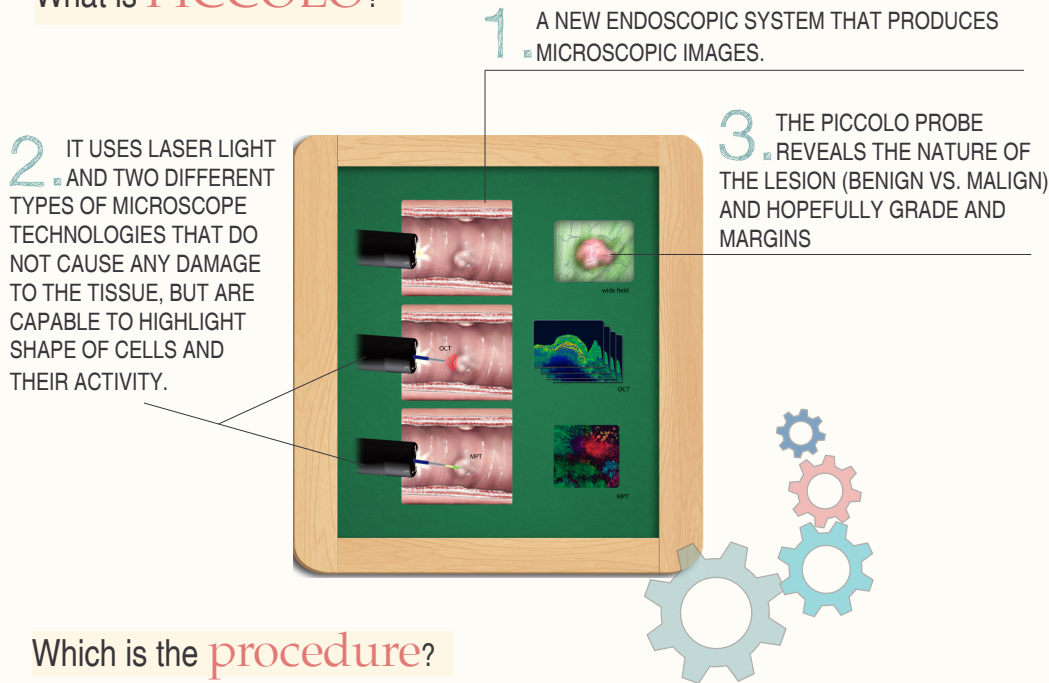
Patient Information



Purpose of this study*

- ▶ The current procedure of colonoscopy aims to check for the presence of polyps that are removed and sent to histopathologic analysis to test whether or not it carries a risk of developing into cancer.
- ▶ The PICCOLO probe is only used to gather information (no decision about your treatment or care will be made with this new system).
- ▶ The PICCOLO probe, after collecting data, tries to differentiate, in real time, whether polyps have or not a risk of developing into cancer (future help to clinicians for not removing harmless polyps).

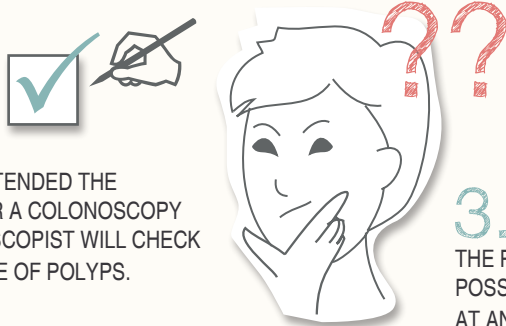
What is PICCOLO?



Which is the procedure?

- ▶ Your colonoscopy will be exactly the same as patients who do not participate in this study (no additional tissue samples or procedural time will be required). The difference is that your colonoscopy will be anonymously recorded.
- ▶ After the standard colonoscopy, the PICCOLO probe will examine the piece of tissue before it is sent to the lab for standard examination and diagnosis.

Why me?

1. YOU HAVE ATTENDED THE HOSPITAL FOR A COLONOSCOPY WHERE THE ENDOSCOPIST WILL CHECK FOR THE PRESENCE OF POLYPS.
 2. WE WOULD LIKE TO GATHER IMAGES OF A VARIETY OF POLYPS TO CHECK THE PICCOLO DEVICE THAT CAPTURES THEM.
 3. ENTIRELY VOLUNTARY PARTICIPATION IN THE PICCOLO STUDY, WITH POSSIBILITY OF WITHDRAWAL AT ANY TIME.
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What about my colonoscopy?

- ▶ Standard colonoscopy: no additional pain or recovery period, same routine procedure, same diagnosis and treatment process.
- ▶ **Nothing to do, more than approve the collection of images with the PICCOLO probe from tissue already removed.**
- ▶ Video recorded and PICCOLO data will be used to research future assessments of any polyps (completely anonymised, you will not be identifiable).
- ▶ The removed tissue could be stored in a biobank for research projects.

What about my data?

- ▶ Any images acquired during your colonoscopy would help us to reach the PICCOLO study goals.
- ▶ You can be informed about published research results if you wish.
- ▶ Confidentiality rules will be maintained.
- ▶ You will not receive any payment for your involvement in this study neither benefits from any inventions.
- ▶ We thank you for time, trust and data provision



(*) The study has been approved by the hospital Ethics Committee