Cellvizio®

the Fastest Way to See Cancer™

TURN TO OPTICAL BIOPSY
Because an endoscope can go anywhere, but can’t show everything.
Because a microscope can show everything, but can’t go anywhere.
With Cellvizio, a microscope is threaded through an endoscope.
This is called endomicroscopy.

1. Area of interest is identified during endoscopic procedure. A Cellvizio miniprobe is introduced into the working channel of an endoscope.
2. The miniprobe appears on an endoscopic image and is positioned in contact with the mucosa.
3. A Cellvizio video is displayed in real-time. As many relevant Optical Biopsies as appropriate are recorded and saved.

*Instantaneous images assist the physician in making immediate patient management decisions.*
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Only Cellvizio provides unlimited Optical Biopsies with immediate results

Cellvizio is an endomicroscopy system which generates Optical Biopsies, providing physicians with microscopic images of tissue instantaneously and in a minimally invasive manner. This assists them to determine whether the tissue is benign or malignant.

“The term ‘optical biopsy’ refers to methods that use the properties of light to enable the operator to make an instant diagnosis at endoscopy, previously possible only by using histological or cytological analysis. This (traditional) method of evaluation creates a significant delay in diagnosis, introduces the possibility of sampling error, and adds to the risk and cost of the procedure.”

Thomas D. Wang, MD, PhD
Associate Professor, Gastroenterology
University of Michigan, USA
Optical Biopsies provide benefits at each step of the patient management, assisting physicians in:

- Surveillance and treatment of Barrett’s Esophagus\(^2-5\)
- Characterization of pulmonary lesions\(^6, 7\)
- Characterization of gastric lesions\(^8, 9\)
- Detection of biliary\(^10-12\) and pancreatic\(^13, 14\) cancers
- Treatment and monitoring of Inflammatory Bowel Diseases\(^15, 16\)
- Follow up of colorectal EMR\(^17\)
- Detection and treatment of bladder cancer\(^18, a\)
The following clinical studies have demonstrated the benefits of Cellvizio in various indications:


2. Sharma P. et al., Real-time Increased Detection of Neoplastic Tissue in Barrett's Esophagus with Probe-based Confocal Laser Endomicroscopy: Final Results of a Multi-center Prospective International Randomized Controlled Trial. GIE, 2011


8. Guo YT, et al., Diagnosis of Gastric Intestinal Metaplasia with Confocal Laser Endomicroscopy In Vivo: a Prospective Study. Endoscopy, 2008


Cellvizio®

• Over 450 publications and clinical studies validate the accuracy and the impact of endomicroscopy.

• Over 15,000 patients in more than 30 countries have benefited from Cellvizio.

• A list of physicians routinely performing Optical Biopsy is available.

• Interested physicians are welcome to experience Optical Biopsy routinely performed by Cellvizio users.

CAN YOU AFFORD TO WAIT?

Intended use

The Cellvizio® Systems are regulated Medical Device, CE marked (Class IIa - NB: LNE/G-MED) and FDA cleared. Cellvizio systems are intended to allow confocal laser imaging of the internal microstructure of tissues in anatomical tracts, i.e. gastrointestinal, or respiratory, accessed through an endoscope or endoscopic accessories. Please consult labels and instructions for use.

a) The Confocal Miniprobes for use in the urinary tract (UroFlex™B and CystoFlex™F) are CE marked but have not been cleared by the FDA.

These statements and the associated references to specific clinical studies, are not intended to represent claims of safety or effectiveness for detecting or treating any specific condition or disease state. Rather this information is intended to provide useful reference to selected published literature describing physician experiences with the associated clinical uses. These statements have not been reviewed, cleared, or approved by the U.S. FDA.

Please note that the interpretation criteria are suggested descriptive features and do not represent definitive diagnostic landmarks and are a result of input from trained and well qualified personnel. The page titles used are for convenience and not intended for diagnostic claims. Any diagnostic assessment should always be made by the attending physician, based on the evaluation of all sources of clinical, endoscopic and other relevant information. Please consult labels and instructions for use.

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