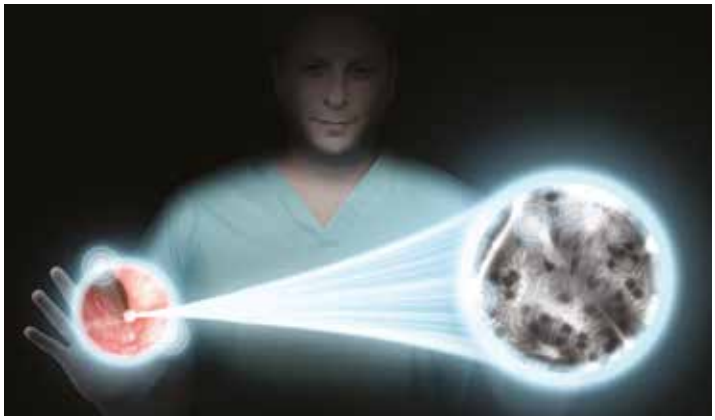
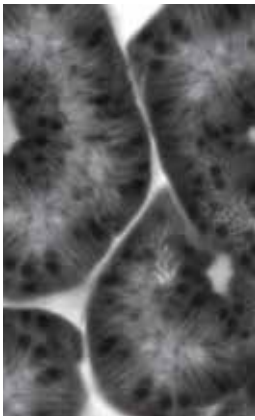
Cellvizio®

the Fastest Way to See Cancer™





TURN TO OPTICAL BIOPSY

Mauna Kea Technologies

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.

Dr. Helga Bertani, Nuovo Ospedale Civile S. Agostino - Estense, Modena, Italy and Dr. Michel Kahaleh, Weill Cornell Medical College, New York, USA, performing a probe-based confocal laser ***endomicroscopy*** *(pCLE) procedure with Cellvizio*

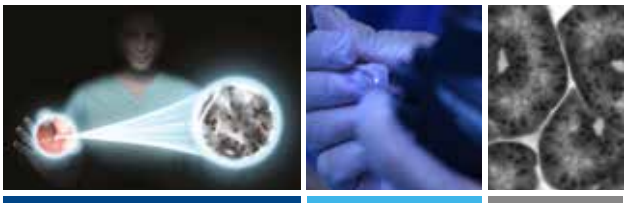
1. Area of interest is identified during endoscopic procedure. A Cellvizio miniprobe is introduced into the working channel of an endoscope
2. The miniprobe appears on an endoscopic image and is positioned in contact with the mucosa
3. A Cellvizio video is displayed in real-time. As many relevant Optical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

Instantaneous images assist the physician in making immediate patient management decisions.

Cellvizio® the Fastest Way to See Cancer

Only Cellvizio provides unlimited Optical Biopsies with immediate results

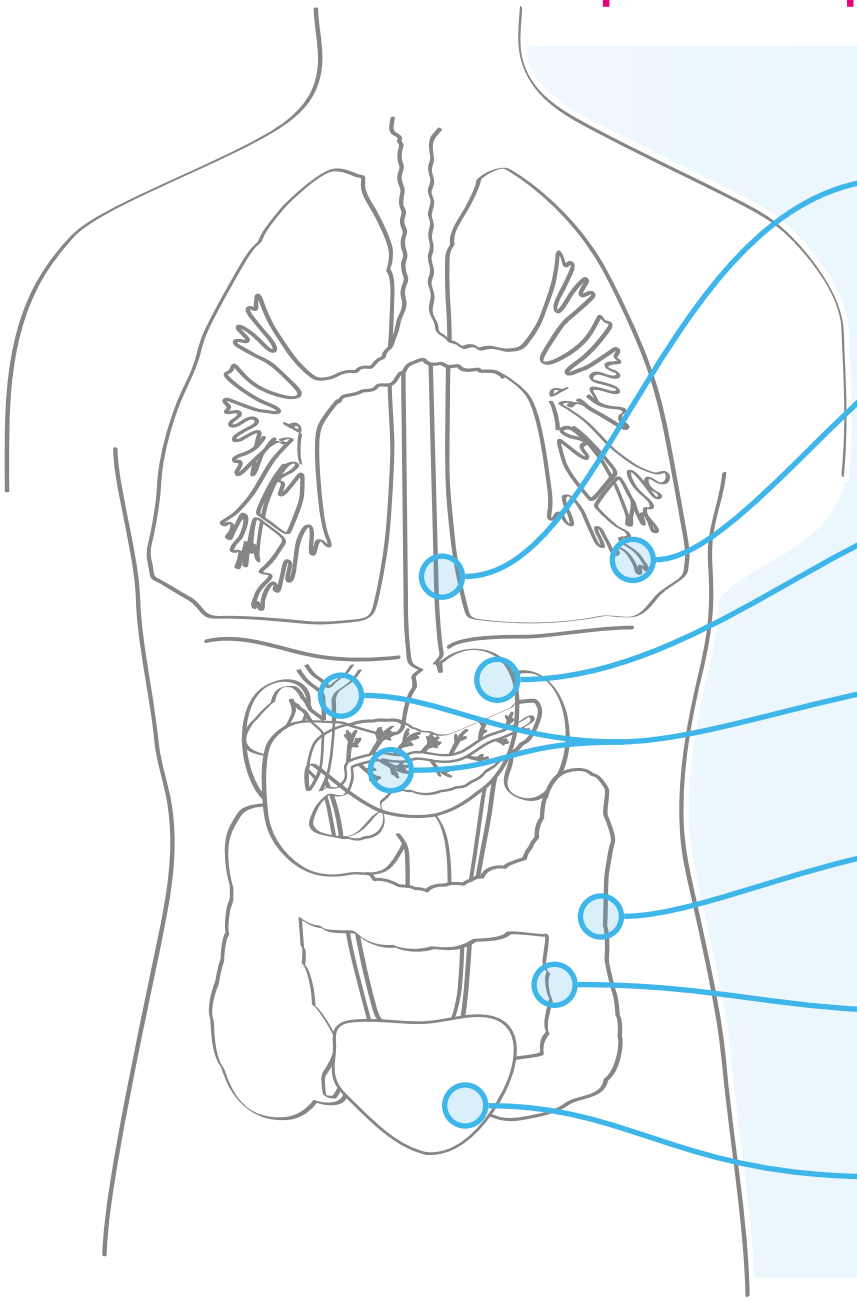
Cellvizio is an endomicroscopy system which generates **Optical Biopsies**, providing physicians with microscopic images of tissue instantaneously and in a minimally invasive manner. This assists them to determine whether the tissue is benign or malignant.

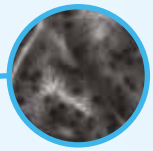


"The term 'optical biopsy' *refers to methods that use the properties of light to enable the operator to make an instant diagnosis at endoscopy, previously possible only by using histological or cytological analysis. This (traditional) method of evaluation creates a significant delay in diagnosis, introduces the possibility of sampling error, and adds to the risk and cost of the procedure."* [1]

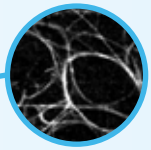
Thomas D. Wang, MD, PhD
Associate Professor, Gastroenterology
University of Michigan, USA

Optical Biopsies provide benefits at eac





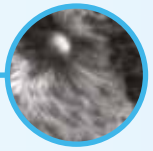
Surveillance and treatment of Barrett's Esophagus[2-5]



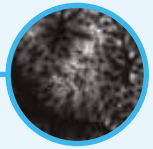
Characterization of pulmonary lesions[6, 7]

Characterization of gastric lesions[8, 9]

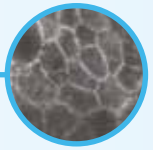
Detection of biliary[10-12] and pancreatic[13, 14] cancers



Treatment and monitoring of Inflammatory Bowel Diseases[15, 16]



Follow up of colorectal EMR[17]



Detection and treatment of bladder cancer[18, a]

h step of the patient management, assisting physicians in:

- Detecting more cancers and pre-cancerous conditions[2-18]
- Triggering instantaneous intervention[2, 4, 5, 17]
- Picking the right treatment modality[2, 4, 5]
- Prescribing the right drug[15, 16]
- Delineating resection margins[2, 4, 5, 17]
- Monitoring treatment response[5, 15]
- Assessing completeness of resection[2, 4, 5, 17]
- Managing recurrent or residual disease[4, 5, 17]

The following clinical studies have demonstrated the benefits of Cellvizio in various indications:

1. Wang TD. et al., Optical Biopsy: A New Frontier in Endoscopic Detection and Diagnosis. Clinical Gastroenterology and Hepatology, 2004

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

3. Bertani, H. et al., Improved Detection of Incident Dysplasia by Probe-based Confocal Laser Endomicroscopy in a Barrett's Esophagus Surveillance Program. Digestive Disease Science, 2012

4. Konda VJ. et al., Confocal Laser Endomicroscopy: Potential in the Management of Barrett's Esophagus. Diseases of the Esophagus, 2010

5. Johnson EA, et al., Probe-based Confocal Laser Endomicroscopy to Guide Real-Time Endoscopic Therapy in Barrett's Esophagus with Dysplasia. Case Rep. Gastroenterology, 2012

6. Fuchs, FS, et al., Fluorescein-Aided Confocal Laser Endomicroscopy of the Lung. Respiration, 2011

7. Thiberville, L., et al., Human in-vivo Fluorescence Microimaging of the Alveolar Ducts and Sacs during Bronchoscopy. Eur Respir J, 2009

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

9. Bok G.H. et al., The Accuracy of Probe-based Confocal Endomicroscopy versus Conventional Endoscopic Biopsies for the Diagnosis of Superficial Neoplasia (with videos). GIE, 2013

10. Meining A. et al., Detection of Cholangiocarcinoma In Vivo Using Miniprobe Based Confocal Fluorescence Microscopy. Clinical Gastroenterology and Hepatology, 2008

11. Meining A. et al., Direct Visualization of Indeterminate Pancreaticobiliary Strictures using Probe-based Confocal Laser Endomicroscopy - A multi-center experience. GIE, 2011

12. Giovannini M. et al., Results of Phase I-II study on Intraductal Confocal Microscopy in Patients with Common Bile Duct Stenosis. Surgical Endoscopy, 2011

13. Meining, A., et al., An International, Multi-center Trial on Needle-based Confocal Laser Endomicroscopy (nCLE): Results from the In vivo nCLE Study in the Pancreas with Endosonography of Cystic Tumors (INSPECT). Presented at DDW 2012

14. Giovannini, M., et al., Feasibility of intratumoral confocal microscopy under endoscopic ultrasound guidance. Endoscopic Ultrasound, 2012

15. Kiesslich, R., Local Barrier Dysfunction Identified by Confocal Laser Endomicroscopy Predicts Relapse in Inflammatory Bowel Disease. Gut, 2011

16. Neumann, H. et al., Assessment of Crohn's Disease Activity by Confocal Laser Endomicroscopy. Inflammatory Bowel Diseases, 2012

17. Shahid MW, et al. Diagnosis Accuracy of Probe-based Confocal Laser Endomicroscopy (pCLE) in Detecting Recurrence of Colorectal Neoplasia after Endoscopic Mucosal Resection. GIE, 2012

18. Liu, J., et al. Dynamic Real-time Microscopy of the Urinary Tract Using Confocal Laser Endomicroscopy. Urology, 2011

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, respiratory or urinary, 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™ and CystoFlex™ types) 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.

Mauna Kea Technologies

www.maunakeatech.com
www.cellvizio.net

cellvizio@maunakeatech.com

Europe
Mauna Kea Technologies SA
9, rue d'Enghien
75010 Paris, France

Ph: + 33 1 48 24 03 45
Fax: +33 1 48 24 12 18

North America
Mauna Kea Technologies, Inc.
1325 Satellite Boulevard Suite #108
Suwanee, GA, 30024

Ph: +1 (678) 731 7544
Fax: +1 (888) 797 6640
Toll free: + 1 (888) 590 1798

Asia-Pacific
Mauna Kea Technologies
58 Duchess Avenue
Unit 01-03
Singapore 269200