Cellvizio®

the Fastest Way to See Cancer



Cellvizio[®]

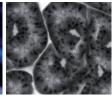
the Fastest Way to See Cancer

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

Can you afford to wait?

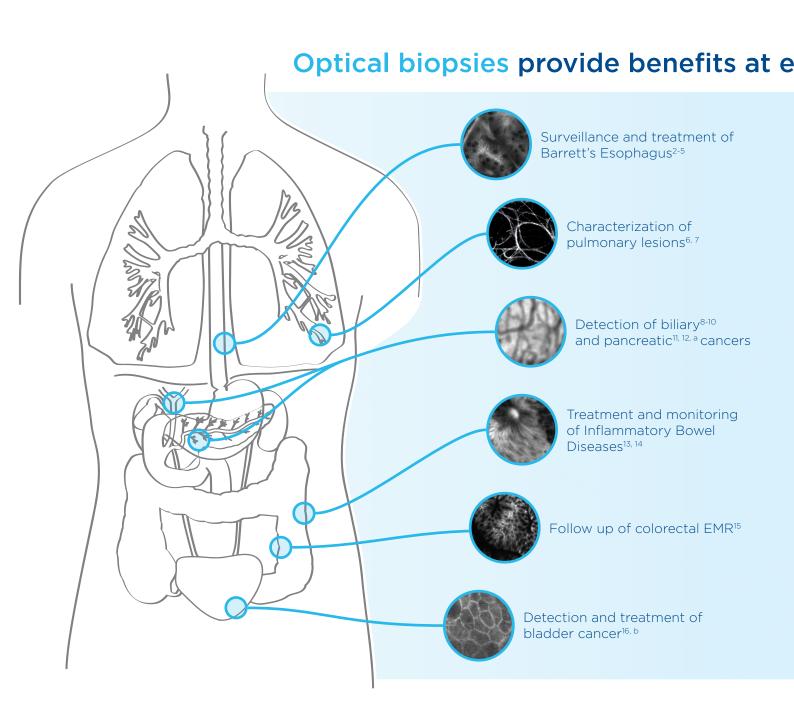






"The term 'optical biopsy' refers to methods that use the properties of light to enable the operator to make an instant diagnosis at endoscopy, previously possible only by using histological or cytological analysis. This (traditional) method of evaluation creates a significant delay in diagnosis, introduces 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



ach patient management stage, enabling physicians to:

- Detect more cancers and pre-cancerous conditions²⁻¹⁶
- Trigger instantaneous intervention^{2, 4, 5, 15}
- Pick the right treatment modality^{2, 4, 5}
- Prescribe the right drug^{13, 14}
- Delineate resection margins^{2, 4, 5, 15}
- Monitor treatment response^{5, 13}
- Assess completeness of resection^{2, 4, 5, 15}
- Manage recurrent or residual disease^{4, 5, 15}



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

- Sharma P.et al., Real-time Increased Detection of Neoplastic Tissue i Barrett's Esophagus with probe-based Confocal Laser Endomicroscopy Final Results of a Multi-center Prospective International Randomize Controlled Trial. GIE, 2011.
- Pohl H et al., Miniprobe Confocal Laser Microscopy for the Detectic of Invisible Neoplasia in Patients with Barrett's Esophagus. Gut, 2008
- 4. Konda VJ, et al., Confocal laser endomicroscopy: potential in the management of Barrett's esophagus. Diseases of the Esophagus. 2010.
- Johnson EA, et al., Probe-Based Confocal Laser Endomicroscopy to Guide Real-Time Endoscopic Therapy in Barrett's Esophagus with Dysplasia. Case Rep Gastroenterol. 2012.
- Fuchs, FS, et al., Fluorescein-aided confocal laser endomicroscopy o 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. Meining A. et al., Detection of Cholangiocarcinoma In Vivo Using Miniprobe based confocal Fluorescence Microscopy, Clinical Gastroenterology and Hepatology, 2008.
- Meining A, Chen YK. et al., Direct visualization of indeterminate pancreaticobiliary strictures using probe based Confocal Laser Endomicroscopy - A multi-center experience. Gastrointestinal Endoscopy. GIE 2011
- 10. Giovannini M. et al., Results of Phase I-II study on Intraductal Confocal Microscopy in Patients with Common Bile Duct Stenosis, Surgical Endoscopy, 2011.
- 11. Meining, A., et al., An International, Multi-center Trial on Needlebased Confocal Laser Endomicroscopy (nCLE): Results from the In vivo NCLE Study in the Pancreas with Endosonography of Cystic Tumors

- 12. Giovannini, M., et al., Feasibility of intratumoral confocal microscopy under endoscopic ultrasound guidance. Endoscopic Ultrasound, 2012.
- Kiesslich, R., Local barrier dysfunction identified by confocal laser
- 2011.
- 15. Shahid MW, et al. Diagnosis accuracy of probe-based Confocal Laser
- Endomicroscopy (pCLE) in detecting recurrence of colorectal neoplasia after endoscopic mucosal resection. Gastrointestinal Endoscopy, 2012.
- 6. Liu, J., et al. Dynamic Real-time Microscopy of the Urinary Tract

Because an endoscope can go anywhere, but not 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 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 enable the physician to make immediate patient management decisions



Cellvizio[®]

- •Over **300** publications and clinical studies validate the accuracy and **impact** of endomicroscopy
- •Over 11,000 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* 100 Series System with Confocal Miniprobes is a confocal laser system with fiber optic probes that is intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal or respiratory accessed by an endoscope or endoscopic accessories.

The Cellvizio System is a regulated Medical Device, CE marked (Class IIa - NB: LNE/GMED) and FDA cleared

Product availability cannot be guaranteed in all countries. For further information please contact your local sales representative. Specifications are subject to change without prior notice and without any obligation on the part of the manufacturer.

- a. The AQ-Flex™ 19 is CE marked but has not been cleared by the FDA.
- b. The confocal miniprobe for use in the urinary tract has not been CE marked or cleared by the FDA.

Please consult labels and instructions for use.



www.maunakeatech.com cellvizio@maunakeatech.com

North America

Mauna Kea Technologies, Inc. 3240 South White Road, PMB#122 San Jose, CA 95148, USA

Tel: +1 408 729 3155 Fax: +1 408 729 1889 Toll free: + 1 888 590 1798

Europe

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

Ph: + 33 1 48 24 03 45 Fax: +33 1 48 24 21 28