

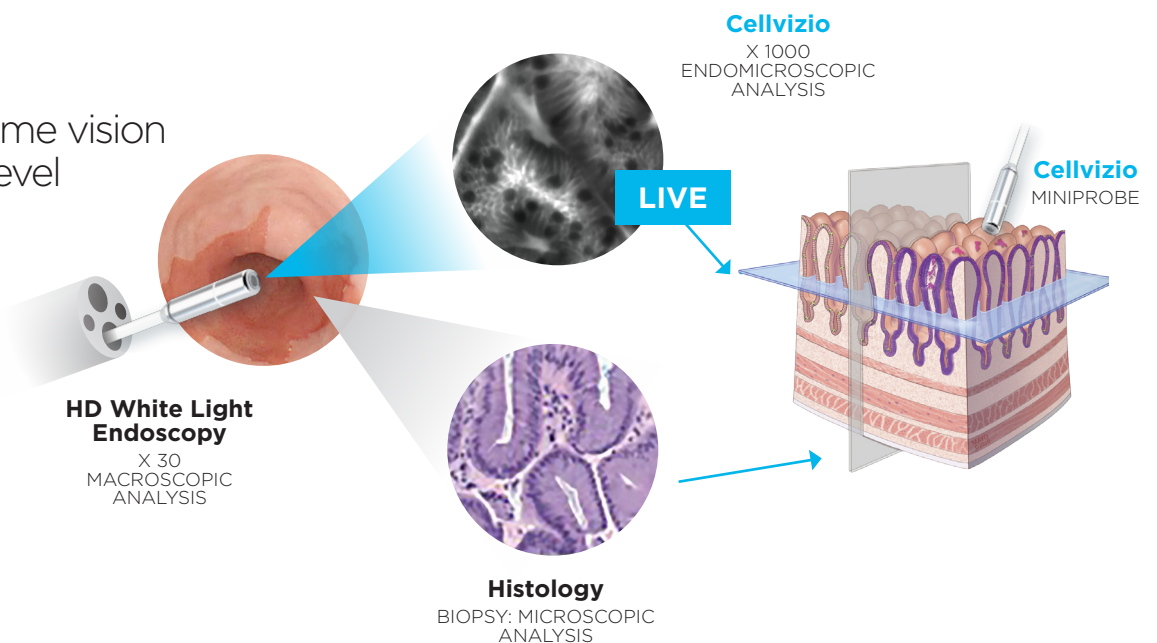
Cellvizio®

SEE CLEARLY, ACT FASTER



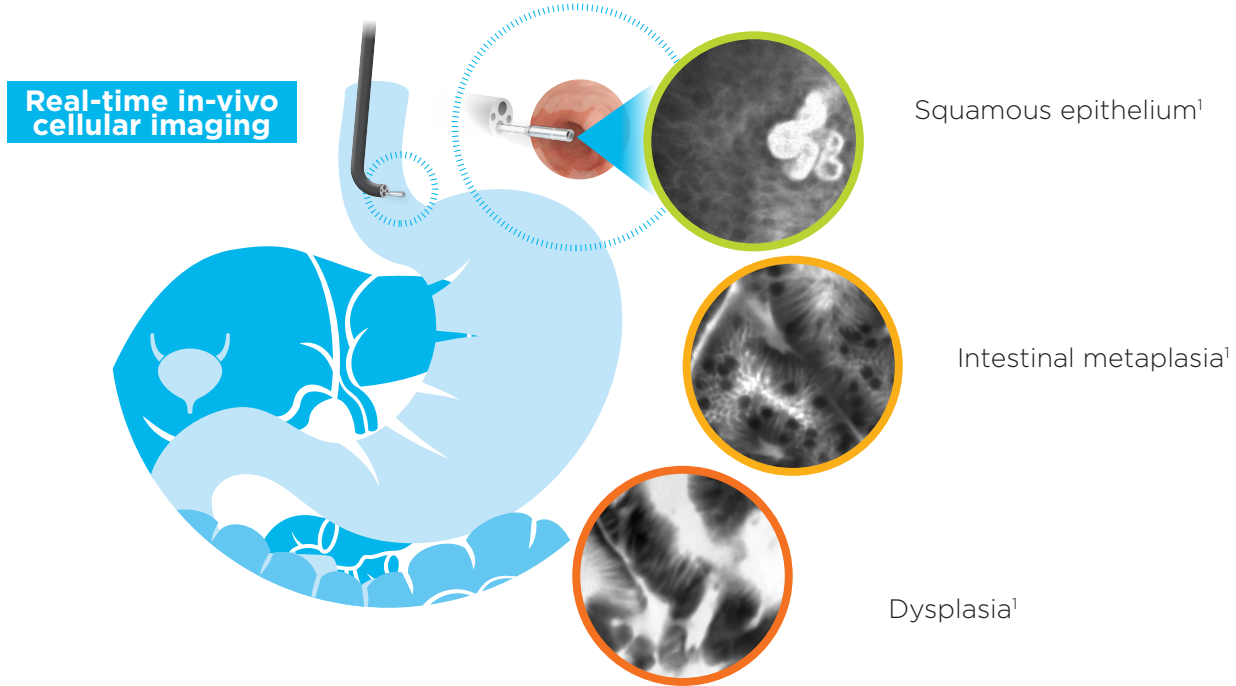
CONFOCAL LASER ENDOMICROSCOPY (CLE)

Cellvizio
provides real-time vision
at the cellular level



The Confocal Laser Endomicroscopy (CLE) solution

Rule-in or Rule-out Intestinal Metaplasia with more diagnostic accuracy



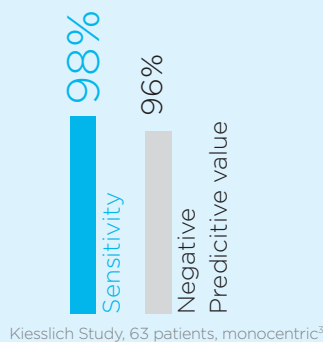
THE CLINICAL BENEFITS

Adding CLE to standard practice can help:

➔ Better understand the disease state of the Esophagus, thus enabling better patient care management^{2,3}

➔ Rule-in or Rule-out Intestinal Metaplasia with 98% sensitivity and 96% NPV¹

➔ Improve on the inefficient random sampling and low, 6% diagnostic yield provided by current techniques⁴



Canto Study, 192 patients, multi-centric⁴

GastroFlex™ UHD Miniprobe



Compatible operating channel	Length	Maximum # of uses	Field of view	Resolution	Confocal depth
≥ 2.8 mm	3 m	20	Ø 240 µm	1 µm	55 to 65 µm

Cleared intended use: The Cellvizio® 100 Series System with GastroFlex UHD™ 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, accessed by an endoscope or endoscopic accessories.

1. Kiesslich R. et al. In Vivo Histology of Barrett's Esophagus and Associated Neoplasia by Confocal Laser Endomicroscopy. Clinical Gastro and Hepatology, 2006. 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. Gastrointestinal Endoscopy, 2011 (DONT BIOPCE). 3. Bertani H. et al. Improved Detection of Incident Dysplasia by pCLE in a BE Surveillance Program. Dig Dis Sci, 2013. 4. M. Canto, et al. In vivo endomicroscopy improves detection of Barrett's esophagus-related neoplasia: a multicenter international randomized controlled trial, GIE 2013.

Society support and testimonials

Society support

“Cellvizio®, very clearly, is integral to the comprehensive assessment of patients suffering from reflux disease⁵”

American Society of General Surgeons - Position Statement

“...workshop panelists agreed that in the hands of endoscopists who have met the PIVI thresholds with specific enhanced imaging techniques (NBI & CLE), use of the technique in BE patients is appropriate⁶”

American Gastroenterological Association - White Paper

“In Vivo Microscopy (IVM) can help target higher-yield, more diagnostic sites⁷”

College of American Pathologists

Guidelines for surgical treatment of GERD *SAGES 2010*

According to the guidelines: “A finding of high-grade intraepithelial neoplasia or adenocarcinoma on preoperative biopsy requires immediate attention and may delay or exclude surgery.⁸”

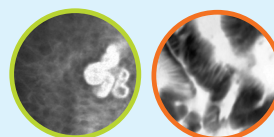


Use of Cellvizio may thus improve patient's management for selected patients¹⁻³

Physician's Testimonials



✓ Diagnostic accuracy



“With esophageal cancer rates having increased by 600% since the introduction of powerful acid reducing medications, the *accurate detection and determination of extent of Barrett's* is greatly enhanced by Cellvizio.”

Courtesy of JF. Paul (Tripp) Buckley, MD

✓ Digital Biopsy Monitoring



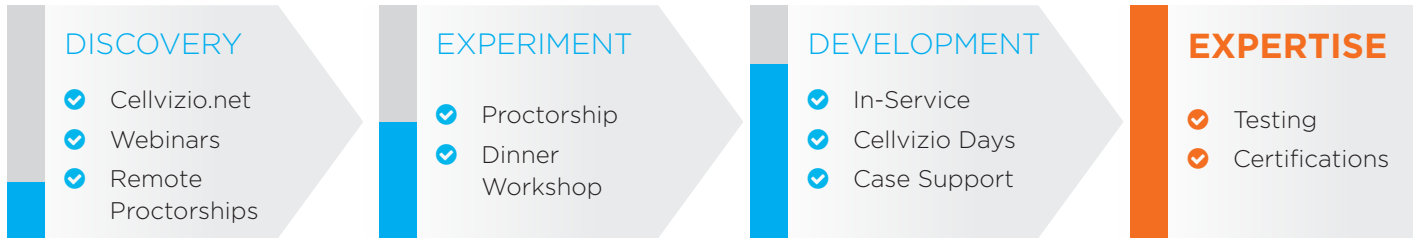
“Cellvizio makes it possible for us to: rule-in or rule-out the presence of pre-cancerous cells (...) perform improved surgical intervention (...) monitor for the presence of cancerous cells after the procedure.”

Courtesy of Joseph J. Burnette, MD, Coliseum Northside Hospital

Cellvizio® Academy

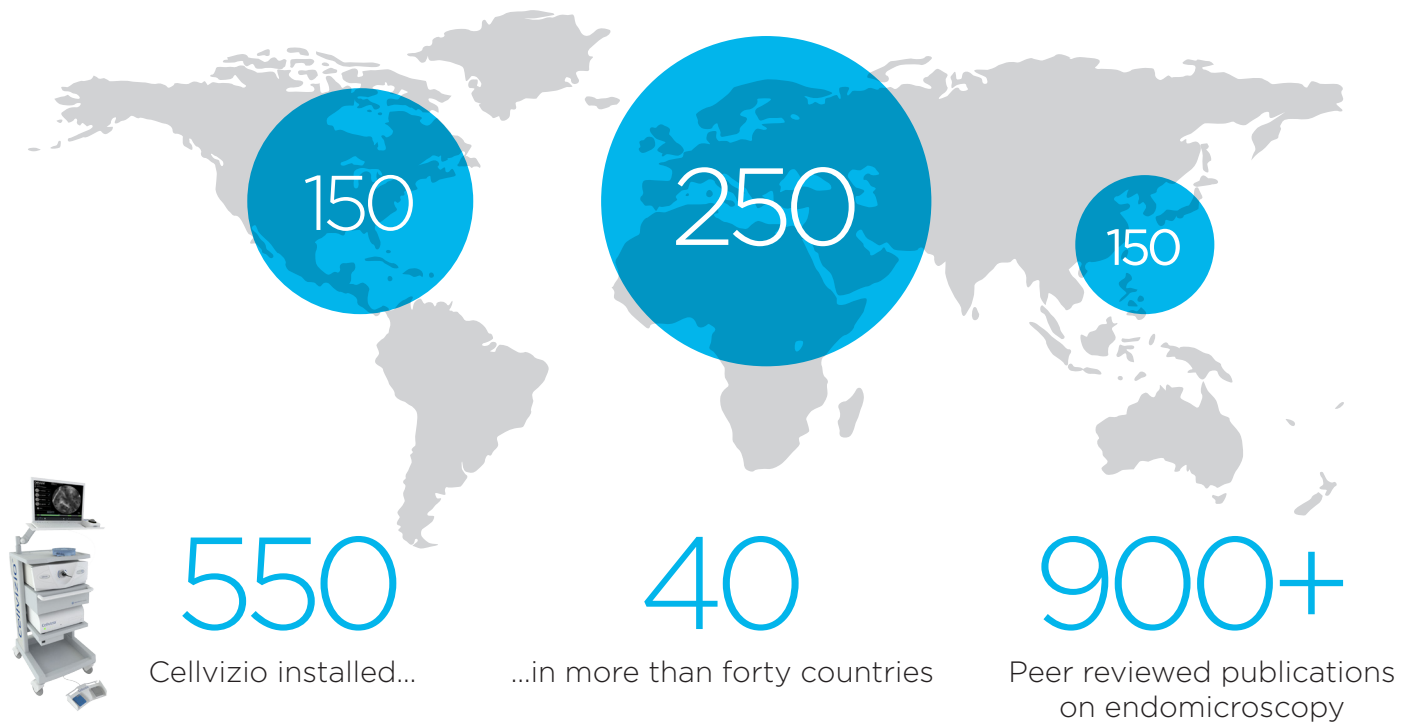


- ➔ A dedicated training website: cellvizio.net
- ➔ Best in Class Educationals Events
- ➔ A robust implementation program with case support



RAPID LEARNING CURVE →

CELLVIZIO WORLDWIDE



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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. 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 person. 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.