Cellvizio®
SEE CLEARLY, ACT FASTER

CONFOCAL LASER ENDOMICROSCOPY (CLE)

Cellvizio provides real-time vision at the cellular level

HD White Light Endoscopy
X 30
MACROSCOPIC ANALYSIS

Cellvizio
X 1000
ENDOMICROSCOPIC ANALYSIS

Histology
BIOPSY; MICROSCOPIC ANALYSIS

Cellvizio MINIPROBE
PANCREATIC CYSTS

1/5

Over 50% of cysts are missing cytological confirmation.
Cytology misses half of the mucinous cysts, and CEA levels overlap yielding unspecific result.

CONSEQUENCE
- 4 out of 10 patients with benign pancreatic cysts undergo unnecessary surgery due to uncertain diagnoses.
- Repeat EUS-FNA procedures are required.

THE CELLVIZIO SOLUTION
ADDITION nCLE TO STANDARD PRACTICE CAN HELP:
- Improve characterization for indeterminate cysts.
- Confirm the EUS impression, when cytological confirmation is missing.

Clinical studies have shown that nCLE provides on-the-spot characterization of various types of cysts.

Serous cystadenoma can be confirmed with very high specificity in 7 out of 10 cases.
Mucinous cysts can be confirmed with very high specificity in about 7 out of 10 cases.

THE CELLVIZIO SOLUTION

AQ-Flex™ 19 Miniprobe

Compatible operating channel
ø 0.91 mm (19G EUS-FNA needle)
Length
4 m
Maximum # of uses
10
Field of view
Ø 325 µm
Resolution
3.5 µm
Confocal depth
40 to 70 µm

Cleared 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. The AQ-Flex 19™, member of the GastroFlex M™ series of Confocal Miniprobes, can be used within anatomical tracts, i.e., gastrointestinal, accessed by an endoscope or endoscopic accessories, including through EUS-FNA needles.

BILIARY STRICTURES

Over 60% of patients remain histologically indeterminate after ERCP

CONSEQUENCE
- Up to 3 ERCP procedures may be required to obtain a diagnosis
- 15-24% of surgical resections for suspected biliary malignancy reveal benign etiologies

THE CELLVIZIO SOLUTION
Adding pCLE to standard practice can help:
- Rule out cancer with more confidence for strictures that appear benign
- Document a malignant ERCP impression, when tissue sampling comes back indeterminate

Clinical studies have shown that pCLE reduces the number of patients with indeterminate strictures after ERCP

- 82% NPV of ERCP with tissue sampling and pCLE
- 73% NPV of ERCP with tissue sampling
- 89% Sensitivity of ERCP with tissue sampling and pCLE
- 56% Sensitivity of tissue sampling alone

CholangioFlex™ Miniprobe

Compatible operating channel ≥1.0 mm
Length 4 m
Maximum # of uses 10
Field of view Ø 325 µm
Resolution 3.5 µm
Confocal depth 40 to 70 µm

BARRETT’S ESOPHAGUS

6% yield

Inefficient random sampling with a low diagnostic yield at 6%\textsuperscript{15}

Limited insight on the choice of treatment modality and on the completeness of treatment

CONSEQUENCE

- Increased patient anxiety & procedural costs
- Treatment delay
- Recurrence and residual dysplasia

THE CELLVIZIO SOLUTION

ADDING pCLE TO STANDARD PRACTICE CAN HELP:

- Reduce the number of biopsies needed while increasing diagnostic yield\textsuperscript{15-16}
- Map an area prior to treatment and evaluate the completeness of treatment upon follow up\textsuperscript{17}

Clinical studies have shown that pCLE increases the diagnostic yield of procedures

60% Biopsies can be avoided for 60% of patients* (When WLE, NBI and pCLE all look normal)

68% Sensitivity of pCLE with WLE

34% Sensitivity of WLE alone

76% Sensitivity of pCLE with WLE or NBI

45% Sensitivity of WLE or NBI

GastroFlex™ UHD Miniprobe

<table>
<thead>
<tr>
<th>Feature</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compatible operating channel</td>
<td>≥ 2.8 mm</td>
</tr>
<tr>
<td>Length</td>
<td>3 m</td>
</tr>
<tr>
<td>Maximum # of uses</td>
<td>20</td>
</tr>
<tr>
<td>Field of view</td>
<td>Ø 240 (\mu)m</td>
</tr>
<tr>
<td>Resolution</td>
<td>1 (\mu)m</td>
</tr>
<tr>
<td>Confocal depth</td>
<td>55 to 65 (\mu)m</td>
</tr>
</tbody>
</table>

DONT BIOPCE study, 101 patients, multi-centric\textsuperscript{*}


\textsuperscript{16} 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).


**COLORECTAL LESIONS AND IBD**

**25%**

25% of patients with colorectal lesions show residual or recurring neoplasia at follow-up post EMR.\(^{11}\)

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**CONSEQUENCE**

- **Patients must await results of follow-up biopsies** before potentially returning for additional EMR if needed.
- Increased medication, pain and anxiety for the patient.

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**THE CELLVIZIO SOLUTION**

Adding pCLE to standard practice can help:

- Assess in real-time the extent of a flat lesion, allowing immediate and complete endoscopic resection in a single procedure.\(^{11}\)
- Assess the disease state at the mucosal level (remission, relapse) and adapt treatment immediately.\(^{13-14}\)

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**Clinical studies** on colorectal lesions have shown that pCLE increases the diagnostic yield of your procedure.

**Sensitivity of pCLE with HRE-VCE**

- 100%

**NPV of pCLE with HRE-VCE**

- 100%

**Sensitivity of High-Resolution Endoscopy with Virtual Chromoendoscopy (HRE-VCE)**

- 72%

**NPV of HRE-VCE**

- 91%

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**ColoFlex™ UHD Miniprobe**

- **Compatible operating channel**: ≥ 2.8 mm
- **Length**: 4 m
- **Maximum # of uses**: 20
- **Field of view**: Ø 240 µm
- **Resolution**: 1 µm
- **Confocal depth**: 55 to 65 µm

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Cleared intended use: The Cellvizio® 100 Series System with ColoFlex 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.

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**Cellvizio® in Gastroenterology**
- Barrett’s esophagus
- Gastric lesions
- Bilio-pancreatic strictures
- Inflammatory bowel diseases
- Pancreatic cysts
- Colorectal lesions

**Cellvizio® Academy**
- A dedicated training website: cellvizio.net
- Educational events around the world, led by endomicroscopy experts

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**The Cellvizio® Systems** are regulated Medical Devices, 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.

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