

Intended use of confocal Miniprobes for Gastroenterology, Pulmonology and Urology

Important notice : The information below are extracted from the Instructions for Use the Cellvizio Miniprobes™ and are not exhaustive. For more information, please review the appropriate Instructions for use delivered with each Confocal Miniprobe™.

Intended use

Confocal Miniprobes™ are exclusively for use with the Cellvizio® system. Cellvizio® is intended to allow confocal laser imaging of the internal microstructure of tissues within or adjacent to anatomical tracts, i.e. gastrointestinal or respiratory or urinary, accessed through an endoscope or endoscopic accessories.

Indications For Use

• Gastroenterology

ColoFlex™, ColoFlex™ UHD, GastroFlex™, GastroFlex™ UHD, CholangioFlex™, and AQ-Flex™ 19 Confocal Miniprobes™ are intended to be used during standard gastrointestinal endoscopy procedures. Once connected to the Cellvizio® system, ColoFlex™, ColoFlex™ UHD, GastroFlex™, GastroFlex™ UHD, CholangioFlex™, and AQ-Flex™ 19 Confocal Miniprobes™ are inserted through the lumen of endoscopes or endoscopic accessories to provide imaging through direct contact of their distal tip with tissues within or adjacent to the gastrointestinal tract.

Confocal Miniprobe™	Endoscope or accessory
ColoFlex™,ColoFlex™UHD	Endoscope designed for lower gastrointestinal tract with operating channel internal diameter ≥ 2.8mm
GastroFlex™,GastroFlex™UHD	Endoscope designed for upper gastrointestinal tract with operating channel internal diameter ≥ 2.8mm
CholangioFlex™	Endoscope or catheter designed for biliary and pancreatic ducts with operating channel or lumen internal diameter ≥ 1.0mm
AQ-Flex™19	Endoscopic needle with needle lumen internal diameter ≥ 0.91mm (19G)

• Pulmonology

AlveoFlex™ Confocal Miniprobes™ are intended to be used during standard bronchoscopy procedures. Once connected to the Cellvizio® system, AlveoFlex™ Confocal Miniprobes™ are inserted through the lumen of bronchoscopes or bronchoscopic accessories to provide imaging through direct contact of their distal tip with tissues with in or adjacent to the respiratory tracts.

Confocal Miniprobe™	Endoscope or accessory
AlveoFlex™	Endoscope or catheter designed for pulmonary tract with operating channel or lumen internal diameter ≥ 1.9mm

• Urology

UroFlex™ B Confocal Miniprobess™ are intended to be used during standard cystoscopy and ureteroscopy procedures. Once connected to the Cellvizio® system, UroFlex™ B Confocal Miniprobess™ are inserted through the lumen of cystoscopes, ureteroscopes or cystoscopic accessories to provide imaging through direct contact of their distal tip with tissues within or adjacent to the urinary tracts.

CystoFlex™ F Confocal Miniprobess™ are intended to be used during flexible cystoscopy procedures. Once connected to the Cellvizio® system, CystoFlex™ F Confocal Miniprobess™ are inserted through the lumen of flexible cystoscopes to provide imaging through direct contact of their distal tip with tissues within or adjacent to the urinary tracts.

CystoFlex™ UHD R Confocal Miniprobess™ are intended to be used during rigid cystoscopy procedures. Once connected to the Cellvizio® system, CystoFlex™ UHD R Confocal Miniprobess™ are inserted through the lumen of rigid cystoscopes to provide imaging through direct contact of their distal tip with tissues within or adjacent to the urinary tracts.

Confocal Miniprobe™	Endoscope or accessory
UroFlex™B	Cystoscope or ureteroscope with operating channel internal diameter ≥ 1.0mm (3Fr)
CystoFlex™F	Flexible Cystoscope with operating channel internal diameter ≥ 1.0mm (3Fr)
CystoFlex™ UHD R	Rigid Cystoscope with operating channel internal diameter ≥ 2.8mm (8.4Fr)