

enlightenVue™ Expanding the Frontiers of Endoscopy

enlightenVue™ has developed a novel single-use micro-endoscope platform with the industry's smallest diameter (2mm) with 2 working channels, that can be used in a single procedure for both diagnostic and therapeutic interventions. The surgiVue™ platform's dual functionality is based on a patented, expandable tip to provide access for multiple instruments along with superior imaging.

The system, which has 510(k) clearance, has a wide range of indications that enables use across multiple specialties and healthcare settings to provide significant benefits to patients, clinicians, and the healthcare system with no endoscopic cross patient contamination infection risk.

Growing Opportunity for Single-Use Micro-endoscopes

Single-use endoscopes are rapidly emerging as the highest growth sector of the \$9 billion endoscopy market, with a projected CAGR of more than 3x the rate (22%) of the overall endoscopy segment (7%). Key growth drivers for single-use endoscopes include:

- Efforts to eliminate hospital acquired infection risk associated with re-usable endoscopes (56,000 infections/year costing \$1.8B). FDA guidance is encouraging a shift to disposable endoscopes to mitigate this risk.
- Reduced costs and barriers for use due to sterilization/ reprocessing needed for re-useable endoscopes.
- Technology advances allowing for development of smaller endoscopes, with potential for minimally invasive access to smaller body cavities.
- Emergence of several interventional instruments and devices compatible with use in small endoscopes such as forceps, brushes, and stone baskets.

enlightenVue's Differentiated Platform

The platform has unique capabilities for therapeutic as well as diagnostic use in a single procedure. The endoscope employs the industry's smallest diameter (2mm) with an expandable tip and two working channels allowing passage of instruments up to 1.1 mm.

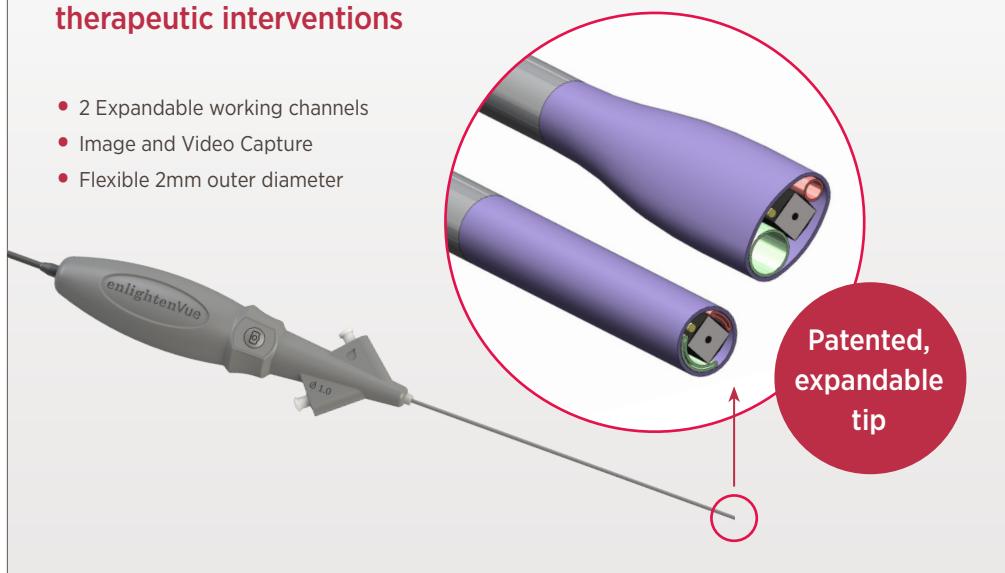
The endoscope has the flexibility to be used across multiple specialties and it can be used seamlessly with several available interventional instruments. As a single use device, surgiVue eliminates hospital acquired infection risk and the costs of recycling/sterilization. The endoscope delivers superior visualization through its surgiTrac™ device that provides high intensity laser light (20x the light of conventional sources) and enhanced image quality.

In addition, the endoscope has potential utility in a wide range of settings. It can be used both percutaneously and intra-surgically. The device's small size and ability to be connected to any monitor.

The enlightenVue technology is protected by three patent families, with multiple U.S. patents and international patents. The patents include the endoscope's expandable tip and novel vascular applications.

surgiVue™ Single-use 2mm Micro-endoscope with channels for diagnostic and therapeutic interventions

- 2 Expandable working channels
- Image and Video Capture
- Flexible 2mm outer diameter



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510(K) Cleared with Broad Labeling – Wide Range of Potential Applications

The platform has received 510(k) clearance from the U.S. FDA. The device has potential for broad application due to its small size and functionality in many areas where endoscopy is already in use – e.g., urology, hepatobiliary, ENT, and OBGYN – as well as in areas that have to date not been accessible for endoscopic procedures.

The hepatobiliary opportunity for enlightenVue is based on the high rate of re-useable endoscope contamination, and growing use of both interventional procedures, including intra-surgical interventions. For example, enlightenVue allows in-depth visualization of the biliary tree and pancreatic duct well beyond the reach of existing endoscopes.

ENT is an emerging area for endoscopy, with specific applications such as in pediatrics where enlightenVue's small size and interventional function provide a significant advantage.

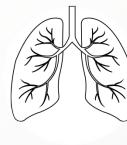
Vascular applications, which enlightenVue has patented, represent a new area of untapped opportunity. To date there is no available tool for direct visualization of vasculature or performance of therapeutic interventions with direct visual guidance.

By combining single-use with the capability to both diagnose and perform interventions in one procedure, the surgiVue™ micro-endoscope and the surgiTrac™ unit create significant opportunities to be used in multiple minimally invasive procedures across many specialties, and clinical settings while also offering unmatched protection against hospital acquired infections.

EnlightenVue is focusing initially on several high value applications:



HEPATO-BILIARY



PULMONARY



UROLOGY

Company Profile

INDUSTRY | Endoscopy

BUSINESS MODEL

surgiVue™ single-use, disposable micro-endoscope | surgiTrac™ image processing hardware and software

ADDRESSABLE MARKET

~\$1.3B U.S. – 6.4M/Yr.

PATENTS | Multiple US and International patents and pending applications

CLINICAL LEADERSHIP:

Desmond Birkett, MD, Beth Israel Lahey Health, General Surgery

Craig Derkay, MD, Eastern Virginia Medical School, Pediatric Otolaryngology Surgeon

Naomi Garland, MD, Cambridge Health Alliance, Department of Surgery

David Feller-Kopman, MD, Dartmouth Hitchcock Medical Center, Pulmonologist

Lee Gorden, MD, Vanderbilt University Medical Center, Hepatobiliary Surgeon

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CONTACT

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Strong Value Proposition for Patients, Clinicians and the Healthcare System

	PATIENTS	CLINICIANS	HEALTHCARE SYSTEM
Reduced pain/discomfort	✓		
Accelerated recovery	✓		
No contaminated endoscope infection risk	✓	✓	✓
Single diagnostic/therapeutic procedure	✓	✓	✓
Added reimbursement opportunities*		✓	
Lower costs per procedure			✓
Enhanced workflow/increased surgical throughput		✓	✓
New healthcare setting opportunities		✓	✓

*based on combining diagnostic and therapeutic intervention in a single procedure