

enlightenVue

enlightenVue Begins First Clinical Trial of its Single-Use Micro-endoscope

Study Comparing enlightenVue's Pediatric Ear, Nose and Throat Endoscope Use vs. Reusable Endoscopes

Denver, CO – September 29, 2021 – enlightenVue, Inc. announced today that the first patient was successfully enrolled and treated as part of a clinical trial using its 510(k) cleared, single-use micro-endoscope. The clinical trial, which is evaluating the endoscope's use in pediatric ear, nose, and throat (ENT) applications, is the first of several planned studies to assess the potential advantages of the single-use micro-endoscope's small (2mm) working diameter, with two working channels, and enhanced visualization capabilities.

"The emergence of single-use nasopharyngoscopes has provided the opportunity to reduce the risk of pathogen transmission from reusable devices," said Craig Derkay, M.D., Director of Pediatric Oncology and Fine-endowed Professor and Vice-Chairman of the Department of Otolaryngology at Eastern Virginia Medical School and the trial's principal investigator. "This trial will investigate the enlightenVue endoscope's utility, image quality and ergonomics in a real world setting to help inform hospitals as to the advantages of migrating towards this new technology."

The trial is designed to compare the use of the enlightenVue disposable micro-endoscope with conventional reusable endoscopes. The study will enroll 30 patients needing the use of a nasopharyngoscope who will be randomized between the enlightenVue micro-endoscope or a traditional reusable nasopharyngoscope. The study will include use in the operating room, emergency departments, neonatal ICU, and hospital step down and floor unit settings. The study will evaluate image quality; ease of obtaining the necessary view; ergonomic aspects; patient comfort and cooperation; patient, guardian and clinician satisfaction; and use of the working channel for biopsy, suction, and other interventions.

The enlightenVue endoscope is the only 2 mm single-use endoscope with 2 working channels and a laser light source currently on the market. The presence of the working channels is designed to allow health care providers to go beyond a simple diagnostic approach and perform a variety of interventional procedures, improving a patient's outcome and decreasing the overall cost of treatment.

"The enlightenVue micro-endoscope was designed for applications such as pediatric ENT, where the system's small size and interventional capability may provide a significant advantage in addition to a reduced infection risk," said enlightenVue's Co-founder and CEO, Giacomo Basadonna, M.D., Ph.D. "This trial, and others we are planning in additional applications, will allow us to demonstrate its value in a variety of medical and surgical applications."

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About enlightenVue

enlightenVue has developed a novel single-use micro-endoscope platform with the industry's smallest working diameter (2mm) and multiple working channels that can be used in a single procedure for both diagnostic and therapeutic interventions. TheurgiVue™ platform's dual functionality is based on a patented, expandable tip to provide access for multiple instruments along with superior optics. The system, which has 510(k) clearance, enables use across multiple specialties and healthcare settings to provide significant benefits to patients, clinicians, and the healthcare system, and removing the risk of infection transmission. Learn more at enlightenVue.com.

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