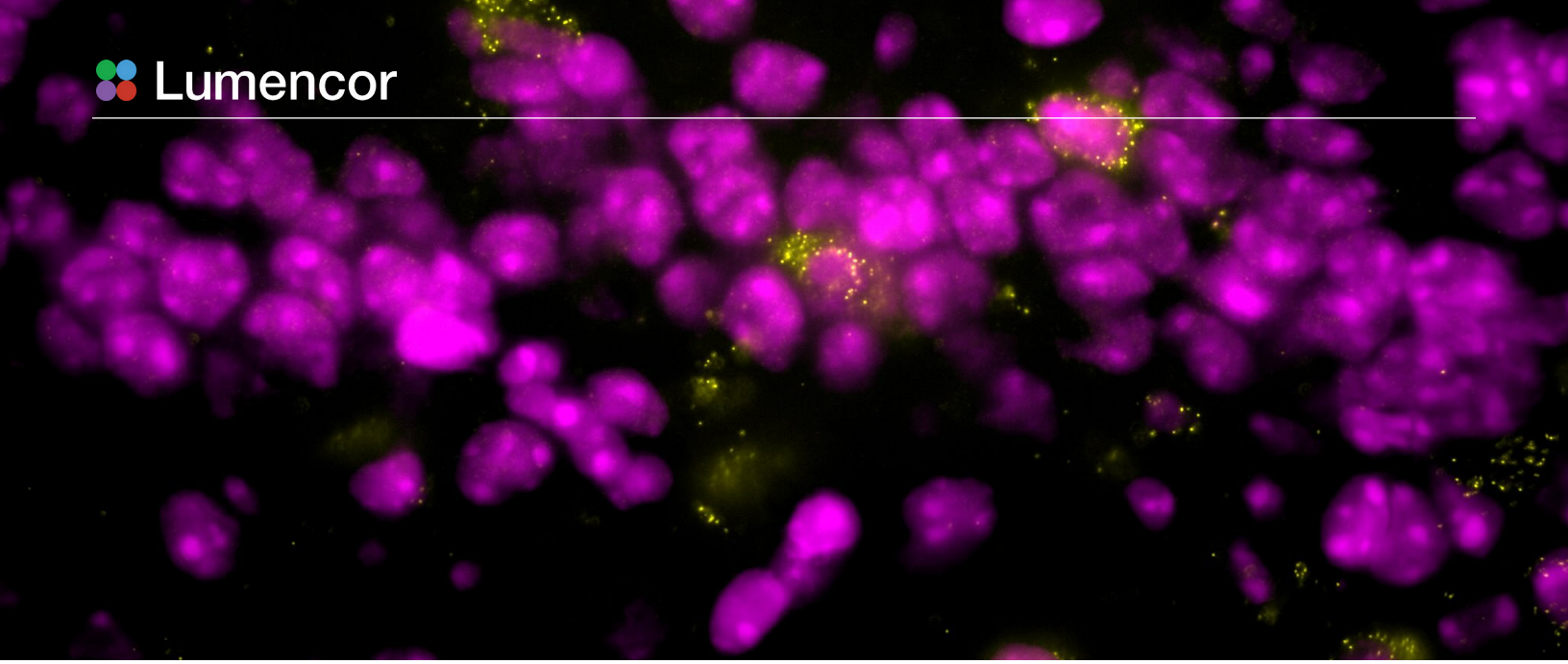
Lumencor



Advancing Clinical Insights with the Power of Light

Lumencor's solid-state illumination products support versatile applications throughout clinical research, diagnostics, and treatment. Beyond their well established role in light microscopy and a host of fluorescence imaging techniques for life science research (fluorescence *in situ* hybridization (FISH), histopathology, confocal spinning disk microscopy, structured illumination microscopy, etc.) these products also shine brightly in the realm of macroscopic imaging employed for endoscopy, exoscopy, and surgical guidance, including the use of near-infrared imaging in fluorescence guided surgery.

The landscape of gene expression analysis is undergoing a transformative evolution, shifting from a research technique to a platform technology. It now encompasses a wide spectrum of applications, from essential diagnostic testing and precise drug screening to advanced treatments such as photodynamic therapy and minimally invasive robotic surgery. In all these diverse domains, achieving optimized illumination for fluorescence detection necessitates meticulous attention to the spatial, spectral, and temporal characteristics of light. Moreover, when it comes to diagnostic testing and treatment, stringent regulatory requirements introduce an additional layer of complexity and rigor.

Lumencor stands ready to meet these illumination challenges with unmatched creativity, experience, and expertise. Our solid-state illumination products are designed to excel in even the most demanding clinical and diagnostic environments, ensuring precision, consistency, and confidence.

Lumencor's Light Engines are considered best in class and as such, are represented by each of the largest microscope houses in addition to a host of mid and smaller sized OEMs. Specifically, Lumencor lighting offers:

- High optical power and intense brightness
- UV - VIS - nIR and white solid-state outputs
- Tailored Color Rendering Index (CRI) and Color Temperature (CT)
- Solid-state 300 and 400W Xe bulb replacement
- Microsecond On/Off, color switching
- Unrivaled short and long term stability
- Accurate and stable light dosage
- 10 years of robust performance with no maintenance

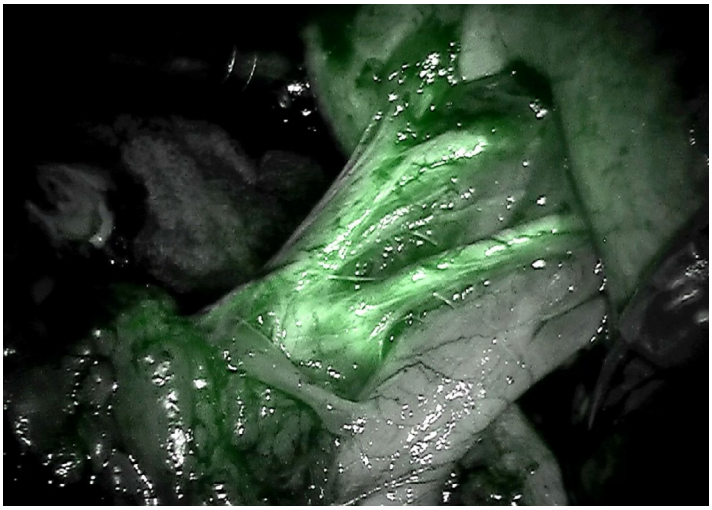
Engineered for Surgical Precision: Illumination for Minimally Invasive and Robotic-Assisted Surgery

Lumencor was the first global supplier to replace 300 W Xenon with a solid-state lamp replacement for minimally invasive robotic surgery. Today, we deliver custom-engineered white light and color-selective (AURA and SPECTRA) Light Engine, for applications including neurosurgery, gastrointestinal surgery, and advanced endoscopy, among others.

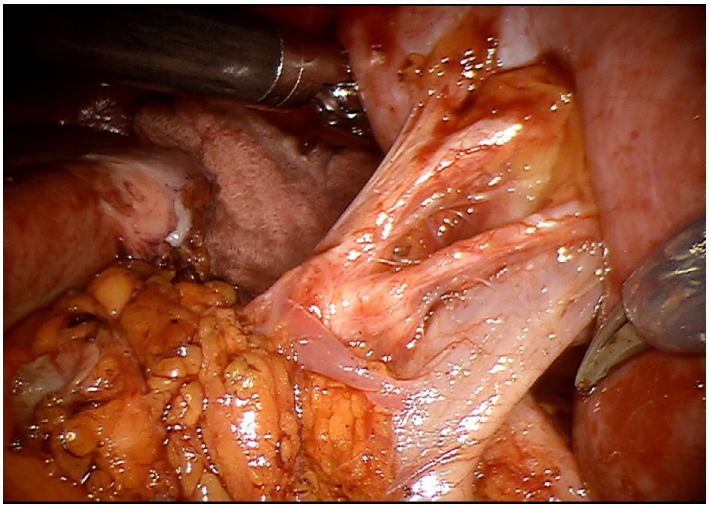
Key Features:

- Hybrid light source arrays include optimized LEDs, lasers, and proprietary light pipes
- White light of required CRI, CT
- As much as ~20W of UV, VIS, nIR power
- nIR excitation for enhanced vascular visualization and FDA-approved fluors
- Tailored control of angular light distribution

Lumencor Light Engines are optimized for optimal visualization, precision metrology and robustness. With spatial, temporal and spectral control as well as unmatched reliability, Lumencor enables next-generation imaging and surgical tools that offer the best of brightness, contrast, stability and longevity.



White light reflectance image of the renal hilum during robotic assisted minimally invasive partial nephrectomy.



Near-infrared fluorescence image of renal hilum vasculature during robotic-assisted minimally invasive partial nephrectomy.

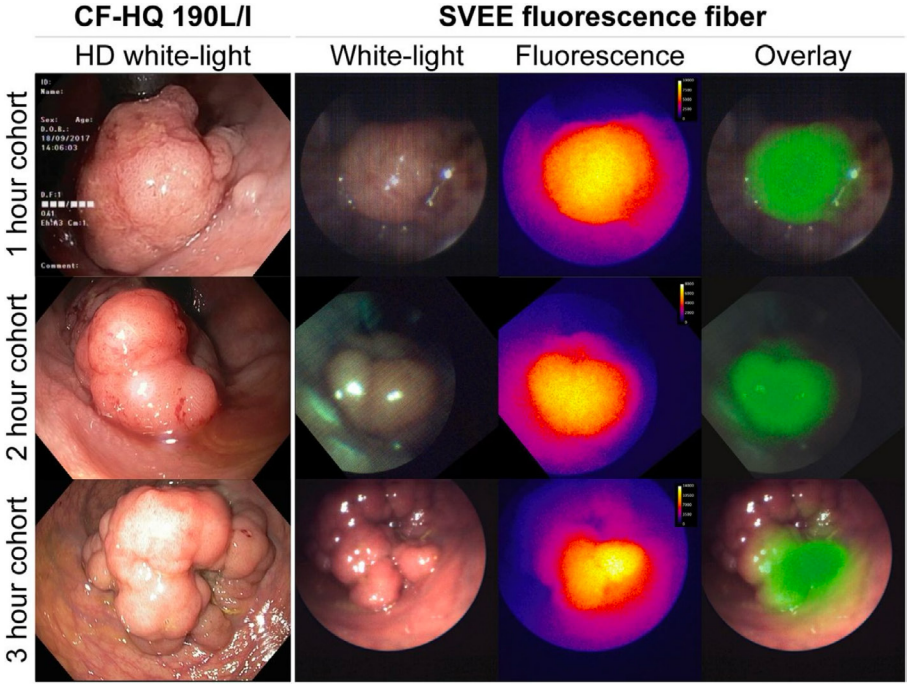
"Lumencor Light Engines provide strong light intensity, field uniformity, and many wavelengths. This allows us to quantify more samples in more colors, faster."

- Johan Paulsson, Professor of Systems Biology, Harvard Medical School

Next-Generation Imaging Solutions: Advancing Intraoperative Oncology Visualization

The identification of tumors during surgery or interventional endoscopy relies on visual inspection and palpation. Tumor tissue is sometimes difficult to distinguish from healthy tissue. So surgical resection of tumor is incomplete in up to 40% of procedures[1].

This has medical as well as financial implications, impairing patient treatment outcomes. Combining highly sensitive imaging systems with tumor targeted imaging agents to visualize tumors during surgical or interventional procedures in real-time enables more sensitive and accurate tumor detection[1].



[1]Lamberts et al. (2016) Clin. Cancer Res.; Koller et al. (2018) Nat. Comm.; Harlaar et al. (2016) Lancet Hepatol.; Nagengast et al. (2017) Gut; Tjalma et al. (2020) Gut; Hartmans et al. (2018).

Traditional and non-traditional diagnostics? Finding Circulating Tumor Cells with a SPECTRA Light Engine

Detection of circulating tumor cells (CTC) is in widespread development as a noninvasive “liquid biopsy” for early-stage cancer diagnosis. CTCs are cells that circulate in the blood and the lymphatic system after becoming detached from a primary tumor (Figure 1). The main challenge in detection of CTCs is their extremely low abundance. The critical level for diagnosis is about 1 CTC per milliliter of blood against a background of millions of white cells and billions of red cells. Detection of CTCs is accomplished by cellular enrichment, using one of several strategies followed by immunofluorescence discrimination of CTCs from normal blood cells (1).

Lumencor Light Engines provide illumination for immunofluorescence imaging in many commercial CTC detection systems currently undergoing development and validation. One such lighting system, recently described by Jou and co-workers (2), uses a microfluidic device with embedded streptavidin-coated nanopillar arrays to capture target cells preincubated with biotinylated anti-EpCAM and anti-N-cadherin

antibodies. Using high-performance, solid-state illumination from a SPECTRA Light Engine, CTCs are identified as FITC–EpCAM positive/TRITC–CD45 negative/DAPI positive. Increased specifi city can be achieved by expanding the multiplex immunostaining panel with the cancer stem cell specific marker CD13 (Figure 2). The entire process of CTC enrichment, immunostaining, slide scanning, image analysis and cell classification is automated, resulting in improved reproducibility and increased throughput compared to protocols involving manual processing.

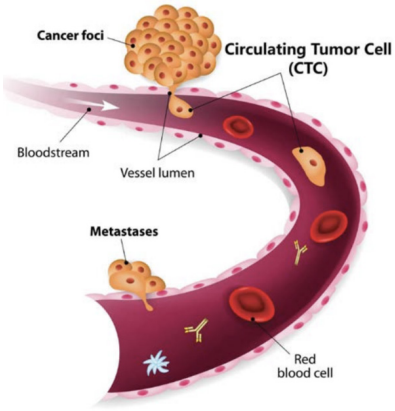


Figure 1. Dissemination of circulating tumor cells in the bloodstream.

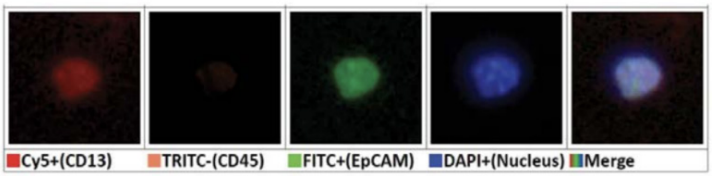


Figure 2. Circulating tumor cells from an epithelial ovarian cancer (EOC) patient (high-grade serous cystadenocarcinoma, FIGO stage Ic3 showing CD13+/EpCAM+/CD45-/DAPI+ immunostaining. Reproduced from Jou et al. (2021) under the terms of the Creative Common Attribution License.

Built for Quality and Sustainability: Best-in-Class Products, Proudly Made in the USA

Safety, product performance, exceeding customer expectations, and continual improvement of the quality management system are our primary goals. Light Engines and Light Engine accessories are each designed and manufactured in Beaverton, Oregon, in the United States under an ISO 9001:2015 certified quality management system. Products are thoroughly inspected and tested before shipping. Each unit ships with a unique certificate of conformance stating its compliance with Lumencor's manufacturing processes and performance criteria.

Laboratories (UL) and TÜV SÜD America:

• **All Lumencor's standard Light Engines are TÜV SÜD America CB and cNRTLus certified, CE marked, UKCA marked, REACH, and RoHS compliant.**

• UL accreditation gives Lumencor the ability to test Class 1 and Class 4 laser devices utilizing the IEC/EN 60825-1:2014 standard. This enables Lumencor to obtain CB certification for all laser products. This certification is used with Laser Notice No. 56 for all necessary FDA/CDRH reporting and submissions.

• Lumencor's on site Testing Laboratory affords in-house capabilities for all product safety and regulatory testing. Such in-house testing means merely weeks of time for full regulatory compliance and complete documentation and traceability, not the many months of time an outside agency typically demands. This greatly reduces time-to-market for all our products.

• Official product certifications testing is conducted in our IECEE CTF accredited testing laboratory. Lumencor's Testing Lab has a full ISO/IEC 17025 Quality Management System and is audited annually by the accrediting agencies issuing certifications.

What can Lumencor do for you?
We're here to illuminate the possibilities.