



Optovue Announces FDA 510(k) Clearance for iStand™

New stand adds versatility to the iVue® SD-OCT Device

FREMONT, CA, June 14, 2011 – Optovue, a pioneer in spectral-domain optical coherence tomography (SD-OCT), announces that the new iStand, a multi-directional stand for universal positioning of the iVue SD-OCT system, received FDA 510(k) clearance in June.

The iStand expands the clinical utility of the iVue SD-OCT device delivering enhanced clinical decisions, procedure planning and documentation. The system enables eye-care professionals to follow patients from diagnosis through post-operative care. By mounting the iVue onto iStand, clinicians can now take further advantage of iVue's compact size and portability to easily move their OCT between the exam lane, hospital facilities, and satellite offices. The simple, easy-to-use articulating arm facilitates scanning supine patients as well as patients in other positions.

“We’ve been evaluating the iVue with iStand in our procedure rooms and find the system useful for a number of applications,” said Nalin Mehta, MD, in private practice at The Colorado Retina Center in Denver. “These include assessment of the macula for epiretinal membranes, macular holes and subclinical choroidal effusions. Other potential uses include evaluation of cataract surgery patients at risk for acute post operative CME. The iVue with iStand could assist in identifying which of these high-risk patients may benefit from aggressive perioperative pharmacologic treatment. Additional anterior segment applications may include evaluation of surgical wound structure, corneal graft-host interface, and assessment of IOL positioning. The additional knowledge provided by the iVue SD-OCT with iStand enhances control over procedural variability, resulting in greater predictability of results, and potentially reducing the rate of re-operations.”

About RTVue®, iVue® and iStand™

RTVue was the first FDA cleared Spectral-Domain OCT launched in the United States, and also the first OCT cleared by the U.S. Food and Drug Administration for both corneal and retinal imaging. The iVue is the compact spectral-domain version of the RTVue OCT, offering the same scanning speed and resolution as the larger system, that includes scanning and reports for retina, retina nerve fiber and cornea assessment by the clinician. iStand is a rolling floor stand option for iVue. When mounted to iStand, patients are able to be scanned in various positions including the supine position.

About Optovue® (www.optovue.com)

Optovue Inc. is a privately-held ophthalmic device company dedicated to working with eye care professionals and clinical researchers to lead the commercialization of new imaging modalities that improve diagnosis and therapy of ocular disease. Optovue has achieved widespread market success through a combination of unique data analysis design, a reputation for excellent customer service, and rapid innovation of its technology in response to physician feedback. The company is headquartered in Fremont, CA, with operations in Carlsbad, CA and European operations in Germany.

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