

Visiogen Receives the European CE Mark for its Synchrony IOL

The Synchrony dual-optic accommodating IOL (Visiogen, Irvine, California) has received the CE Mark, signifying the conformity to essential requirements of the Medical Devices Directive (MDD).

The CE Mark allows the company to expand its European postmarketing research studies, which, according to a company news release, will increase the technology's scientific foundation. "As a result of this milestone, our product has moved beyond the early investigational stages and has been validated as a commercially viable product by an international regulatory body," said Reza Zadno, PhD, president and CEO, in the news release.

The Synchrony IOL is the first dual-optic accommodating lens developed for both cataract and refractive surgery. Cataract patients with and without presbyopia may gain accommodation with the use of the lens. Its unique dual-optic design provides vision at all distances, without the optical limitations from multifocality.

The dual-optic lens is complete with a proprietary easy-to-use preloaded injector. The system is self-contained and ready to use without lens handling. The dual optic lens may be inserted through a 3.6-mm to 3.8-mm clear corneal incision. The single-piece silicone lens unfolds in the eye upon insertion and features two optics that are connected by a spring system. The springs connect a 5.5-mm high-power anterior optic and a 6-mm negative-power posterior optic; the spring action moves the front optic and changes the eye's focus from near to far. This unique combination of



positive- and negative-powered optics is customized for each individual patient.

"My patients are satisfied with the lens and the outcomes. Most are able to read without glasses and can comfortably see distant images," said H. Burkhard Dick, MD, professor and chairman of the University Eye Hospital of Bochum, Germany. Dr. Dick, who is a member of the CRSTODAY EUROPE Editorial Board, has implanted more than 20 Synchrony lenses in clinical study patients. "My overall impression of the safety and effectiveness is extremely good."

Worldwide, the Synchrony dual-optic accommodating lens has been implanted in more than 300 patients in seven countries and at multiple clinical sites over the past 4 years. Currently, a US Federal Drug Administration clinical study for Synchrony is being conducted in the United States.

FDA Approves Biologic Treatment for AMD

The US Food and Drug Administration (FDA) approved ranibizumab (Lucentis; Genetech, San Francisco) for the treatment of neovascular (wet) age-related macular degeneration (AMD). Lucentis is a monthly dose treatment that maintains vision in >90% of patients.

According to the FDA, ranibizumab is a new molecular entity (ie, it contains an active substance never before approved for marketing in the United States).

"This approval is of great importance for the 155,000 Americans who are diagnosed each year with AMD, a common cause of severe and irreversible vision loss in older adults," said Dr. Andrew von Eschenbach, acting commissioner of food and drugs, in a news release. "At a time when our elderly population is rapidly increasing, this product preserves quality of life for those affected

by this disease, helping them to regain the ability to participate in everyday activities such as reading and driving.”

Lucentis was shown to be safe and clinically effective in three multicenter randomized studies. In clinical trials, nearly 95% of participants who received a monthly injection maintained their vision at 12 months compared with approximately 60% of patients who received a control treatment. In a single study carried out for 24 months, these findings have been maintained with continued monthly dosings. Serious adverse events were rare and often related to the injection procedure (ie, endophthalmitis, intraocular inflammation, retinal detachment, retinal tear, increased eye pressure and traumatic cataract).

Lenstec Launches European Expansion

Lenstec (St. Petersburg, Florida), a provider of lens implants and devices used in cataract and refractive surgery, has opened a new Barcelona sales office to help meet growing European product demands.

Lenstec Spain expanded the existing European operations that include a Yorkshire, England, UK sales and marketing office. The Barcelona office will serve France, Portugal and the fast-growing Spanish market, accounting for one of Europe’s highest volumes of refractive surgery procedures.

“Lenstec Spain will advance our global strategy by enabling us to sell products directly to surgeons in these high-growth regions,” said John Clough, Lenstec CEO and chairman, in a news release. “Our goal is to make new technologies such as the Tetraflex accommodating IOL and Softec aberration-controlled cataract lenses readily available across key markets in Europe, Southeast Asia and the Americas.”

The company also announced the appointment of Josep Manuel Aler to lead the Barcelona office. He joins Lenstec with >15 years of ophthalmic and high-tech industry experience. Prior to joining Lenstec, Mr. Aler held senior level sales, marketing and product management positions with leading international ophthalmic firms including Eyeonics (Aliso Viejo, California) and Wavelight Laser Technologie AG (Erlangen, Germany), as well as regional diagnostic and clinical device supplier Bloss Group (Barcelona, Spain).

“We are delighted to have Josep on board to spear-

head our expanded presence in Europe,” said Mr. Clough. “He brings the ideal blend of skills and experience necessary to position Lenstec for growth as we become a truly global company.”

Mr. Aler said: “Lenstec already has high brand awareness among European surgeons. I look forward to helping the company expand in nations where demand for refractive surgery is growing rapidly.”

The Tetraflex accommodating IOL has been available commercially in Europe since 2003. The Softec HD lens, recently introduced to the European market, is a new aspheric aberration-controlled IOL. Both join Lenstec’s expanding line of technologically advanced IOL implants.

The company’s new Barcelona office joins its existing sales office in the UK, as well as corporate/research and development headquarters in Florida and manufacturing facilities in Barbados.

Wavelight Names New CEO, Reports Strong Revenue Growth

Wavelight AG (Erlangen, Germany) has named a new Chief Executive Officer for its US division, Wavelight Inc (Sterling, Virginia). Wolfgang Tolle will assume the position at the beginning of August to replace Ralph Saettele, who had been temporarily running the US business. A German, Mr. Tolle is a certified computer scientist who has spent the past 16 years working in the US. Most recently, he was CEO of Launchdreams (Ashburn, Virginia), a company that helped international businesses become established in the US market. The US operation of Wavelight currently employs 30 people.

Wavelight AG has also reported revenue numbers for the first 9 months of its current fiscal year. The company said it improved its revenues from €62 million up from €54 million for the same period 1 year ago. Wavelight still reported a net loss of €4.7 million for the first 9 months of 2006. The company said in a news release that the loss was due to increased costs associated with higher forecast sales volumes, as well as one-time expenses related to its US and aesthetics divisions.

Wavelight’s ophthalmology business saw a revenue increase of approximately 18%, but indicated that it had been impacted by a temporary reduction in the demand for refractive surgery treatments in the United

States. Wavelight indicated that it plans to more aggressively market its products in the United States to “communicate the clear advantages offered by Wavelight’s product in the field of refractive surgery, as well as high quality and efficient customer service and support,” according to the news release.

Wavelight AG CEO Max Reindl said in the statement that he believes the company is positioned to end their current fiscal year in the black.

Christian Blind Mission International Provides More Than 600,000 Cataract Surgeries

According to statistical analysis, the Christian Blind Mission International (CBMI; Greenville, South Carolina) assisted >12.5 million people in 2005. An organizational goal to provide 1 million cataract surgeries by its centennial year of 2008 has been set.

More than 600,000 people received operations from CBMI volunteer doctors or doctors trained by the organization last year. In many cases, these surgeries cost the recipients nothing.

“I am excited about the numbers of lives being affected by the life-changing services of Christian Blind Mission. The impact on families to help them take care of their children and other family members is key to the work of this organization,” said Alan Harkey, president of CBMI USA, in a news release.

The organization has also increased its distribution of Mectizan tablets, used to prevent river blindness, by 1 million. Vitamin A tablet distribution was also increased to >800,000. More than 45,000 nationals were trained in eye care and are working with people with other disabilities at >1,000 locations worldwide. CBMI also partners with >700 other organizations to ensure that those needing medical assistance receive it.

“People are important — their needs are important to CBMI — people like Katunda Wiliam of Uganda. Before we were able to reach him with cataract surgery, he depended on one of his youngest sons to guide him. Now he can see,” Mr. Harkey said. “He can work and help provide a living for himself and his loved ones. To this little family in Uganda, Katunda’s cataract surgery will always be remembered as the miracle that changed their lives.”

A \$35 gift to CBMI would cover cataract surgery for

an adult, said Jeff Watson, who served as CBMI’s Oncho Control Program Coordinator in Nigeria for >10 years. “This simple sight-giving surgery can mean the difference between poverty and life to a family in Uganda and many other countries in Africa, Asia and South America.”

UK Ophthalmologists Work to Block Private Insurers Credentialing Plan

The British Medical Association (BMA) and key ophthalmic organizations have joined to oppose a plan by a private health insurer to create a preferred-provider network in the UK. The plan by British United Providence Association (BUPA) would put together an approved list of ophthalmologists to whom patients could be referred if the insurer covers them. In an interview with the British Broadcasting Company (BBC), a BUPA spokeswoman said the registry was designed to provide patients with more information about physicians as well as to help the insurers refer patients to the correct specialist.

Both the BMA and the Royal College of Ophthalmology (RCO) maintain that the network is BUPA’s attempt to regulate ophthalmology and to force down physicians’ fees. A letter from the BMA, the RCO, the United Kingdom and Ireland Society of Cataract and Refractive Surgeons, as well as five other groups was sent to all ophthalmologists and anesthesiologists in the UK. The letter urged them not to participate in the network.

The organizations maintain that it is not the role of the health insurer to regulate ophthalmologists and that there is ample oversight by the General Medical Council and the Healthcare Commission.

The organizations are continuing talks with BUPA in an attempt to reach a compromise.

TASS Task Force Issues Preliminary Report

A press release issued by the American Society of Cataract and Refractive Surgery and the American Society of Ophthalmic Administrators on June 22, presented a preliminary report from the ad hoc task force

TABLE 1. PRELIMINARY RESULTS OF TASS SURVEYS

Survey	Potential Contributing Factors
Product Questionnaire	Preoperative NSAIDs
	Intracameral anesthetics
	Improperly dosed, mixed or injected intracameral antibiotics
	Possible preservative in epinephrine added to balanced salt solution
	Residue on reusable cannulas
Instrument Reprocessing Questionnaire	Use of IOLs or improperly cleaned reusable inserters manufactured by Alcon Laboratories (Fort Worth, Texas)*
	Short time between cases for processing and cleaning instruments
	Reusable ultrasound and I/A handpieces and tips that may have a buildup of material such as viscoelastic
	Failure to flush enzymes and detergents from reusable instruments with sterile, deionized water
	Possible gram-negative bacteria in ultrasound water baths and subsequent contamination of instruments with heat-stable endotoxin.†
*According to the press release, the majority of reported lenses were manufactured by Alcon, but it is unclear if this finding is significant due to the company's market share. †The press release states that an alcohol rinse will remove endotoxin.	

investigating an outbreak of toxic anterior segment syndrome (TASS) at >100 North American surgical centers. To date, the task force has received completed Intermountain Ocular Research Center protocol forms from 23 centers. Sixteen surgeons and 16 surgical centers have submitted short protocol forms that were developed by the ad hoc task force.¹

Responses to the Intermountain Ocular Research Center to date have not identified a single cause of the TASS outbreak, but a review of the data suggested several potential etiologic factors (Table 1).

To learn more about the preliminary results or to report

new cases of TASS, contact Nick Mamalis, MD, director of the Intermountain Ocular Research Center at:

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1. Toxic Anterior Segment Syndrome (TASS) outbreak preliminary report [press release]. Fairfax, Virginia: ASCRS/ASOA; June 21, 2006.

Corrections:

In the May/June 2006 issue of CRSTODAY EUROPE, there was an error in the article, Filtering Ambient Light With IOLs, by Dirk van Norren, PhD. The author explained that lens absorption increases substantially with age. Thus, the lens of an old patient looks more yellow than that of a young patient. He argued that a healthy old lens reduces vision but offers extra protection against light damage. The second-to-last paragraph should read:

What does this mean for the filter in an implant lens? Nothing can be said with certainty, but the choices are clear: (1) Do you want to change nature in your old patient, hoping for an extra improvement in vision or (2) Do you want to imitate the healthy natural lens? (1) If you reason the first, 'When I have an irreparable hole in my tire, I do not replace it with a tire that has already covered 40,000 km.' You therefore cut back significantly in virtual age of the implant lens, for instance by taking one that mimics a young adult's. You might even go further and aim at your patients' lens being born again. In that case, you take a baby lens in terms of filtering. Such lenses hardly filter out any violet, let alone blue light. Those are the implant lenses that are widely available. (2) If mimicking nature is your aim, you implant a lens with a filter that resembles a healthy one at about the patient's age. At present that is impossible, because no ≥ 80-year-old implant lenses are available, but the closest you can get are 50 to 60 years of virtual age, and that seems close enough.

We apologize for the error and regret any confusion it may have caused.

In the May/June 2006 issue of CRSTODAY EUROPE, John Marshall, PhD, was listed as John Marshall, MD. We apologize for the error and regret any confusion it may have caused.