

By Howard Larkin



Technical leadership and flexibility put WaveLight on the cutting edge

German laser manufacturer branching into IOLs to meet rising refractive demand

Max Reindl is bullish on refractive surgery. He's got good reason. In Germany alone as many as 20 million people are candidates for well-established LASIK procedures while only about 250,000 received them in 2003 and 2004. Worldwide, the market is vast – last year 2 million LASIK procedures were done in the United States and demand in East Asia is growing exponentially, points out the founder and CEO of WaveLight Laser Technologie AG in Erlangen, Germany.

"There is great opportunity for surgeons and for us," Reindl says. "We believe we can best help patients and surgeons, and expand our market share, by offering technology that anticipates the future needs and technical developments."

Indeed, developing systems that respond to unique market needs – wherever those markets may be – has helped WaveLight carve out a major slice of the world refractive market. This fall, WaveLight installed its 600th laser worldwide, including 150 in China and 100 in the United States, the company's two largest growth markets. WaveLight projects it will continue to grow about 30% per year in a world refractive market that is expected to expand about 10% annually over the next five years.

WaveLight isn't buying market share. Since fiscal year 2000-2001 – the first year in which the company turned a profit – net income has tripled, to more than \approx 3.2 million in fiscal year 2004-2005. Those profits arose while revenues grew over the same period from \approx 24 million to \approx 80 million. Quite a feat, given the competition.

While all of WaveLight's systems are based on a common platform, four separate models target the needs and finances of specific markets. The major differences are in the software and diagnostic equipment integrated into each system.

For developing markets, such as China and South America, WaveLight offers the basic ALLEGRETTO system, which is usable over a limited range of applications. The mature ALLEGRETTO WAVE incorporates custom technology and a wider treatment range. Both systems provide wavefront-optimised ablation in standard treatments and can be further upgraded.

For more-advanced markets seeking a

technology edge, WaveLight offers the ALLEGRETTO WAVE Eye-Q, which incorporates a 400 Hz laser, making it the fastest excimer laser available (besides the ALLEGRETTO WAVE Concerto).

"The speed of the laser is very important because once you make the cut you only have 30 to 40 seconds before the eye dries out, and then you have a different ablation volume that affect the refraction," Reindl notes. High-speed repetition rates also help to keep ablation times short and consistent, he adds.

In addition to wavefront and topographic guidance, Eye-Q also offers advanced Q-value adjustment capability to customise corneal asphericity, reducing the chances of impaired night vision post-surgery.

WaveLight's most sophisticated system is the ALLEGRETTO WAVE Concerto, which integrates diagnostic equipment directly into the treatment system, allowing intra-operative adjustments. "After you cut the flap you can measure the remaining depth of the cornea without touching it," Reindl observes. "This is the technology platform for the next generation of surgery."

Integrating IOLs and refractive surgery

WaveLight has developed and continually refines a wide range of wavefront-optimised options that will suit most patients without developing a full custom wavefront algorithm, Reindl says. This simplifies set up for most patients, saving time and reducing the chances that calculation errors will be introduced, he says. "We think that only about 5% really need custom. Normally, it is better to do a non-custom ablation; they are less difficult."

In keeping with this focus on meeting patient needs, WaveLight is integrating intraocular lenses into its product line, Reindl says. "You don't know if the problem is with the cornea or the lens or both before you examine the patient."

As part of that focus, WaveLight has recently acquired the German IOL manufacturer ACRIMED, as well as a 30% interest in Netherlands-based lens and implant aid producer Medical Device Production.

Not only will adding IOLs open much larger potential markets – Reindl estimates the potential worldwide lens

market to be four or five times that for LASIK – it also strategically positions WaveLight to take advantage of converging IOL and refractive markets.

As implanting IOLs becomes safer and they become more effective in correcting refractive errors and even presbyopia, Reindl anticipates that more patients interested in refractive surgery who have borderline lens problems will opt to wait a few years for an IOL rather than go through LASIK knowing they will soon develop cataracts.

"People are blind before they have cataract surgery now. The median age is 68 in Germany today. In the next 10 years it will come down to 45 to 50 years. The risks are coming down and the outcomes are better. If you are 40 years old and looking for LASIK, wait to three years and do a lens extraction."

Reindl envisions many patients choosing IOLs with a LASIK touch up to fine tune the correction. "It is not a replacement of the laser surgery, it is an add-on; another solution."

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Staying in touch with the market

WaveLight stays close to practicing surgeons through user groups and educational programs across the globe. The firm's growth has also made it possible to move from distributing to partners to setting up distribution subsidiaries in major markets. Three years ago, WaveLight founded a subsidiary in the United States and acquired a distributor in Spain last year to ensure it stays close to customers.

These subsidiaries allow WaveLight to provide customers with both technical and marketing support. The firm also customises its financing arrangements to market needs, using per-procedure fees in the United States and a combination of

leases, procedure fees, and outright sales in other parts of the world.

Innovation has been a WaveLight hallmark since Reindl and three equity partners founded the firm in 1996. Reindl had experience – he worked for a competitor that moved to the east – before striking out on his own. His first product was a solid-state laser. It worked well on pig eyes, but failed in tests on blind human eyes. "It was slow healing," Reindl remembers.

But that initial stumble didn't keep WaveLight down long. By 1997, Reindl had products licensed for Europe and was recognised with a product design award for the ADAGIO ophthalmic laser system. The company also successfully introduced lasers for dermatologic and urologic surgery.

In 1999, the company went public; in 2000, it began FDA trials for marketing the ALLEGRETTO WAVE system in the United States. "U.S. approval gives you entry into a lot of other markets," Reindl observed. Beyond that, the U.S. market is the largest in world in terms of revenue generated.

However, the U.S. and many European markets are also fairly saturated, making most sales replacements of existing systems. Breaking into these markets requires becoming a technology leader – which WaveLight has done by introducing its 500 Hz ALLEGRETTO WAVE Concerto system.

But as advanced as its systems are, Reindl emphasises the clinical flexibility WaveLight systems offer rather than technology for its own sake. "What people want to know is how many patients are happy after one treatment? How many need re-treatment? Sure, there are a lot of techniques like custom wavefront you can use, but they only add value if they make the patients happy."