

NEWS RELEASE

LenSx[®] Femtosecond Laser Receives 510(k) Clearance for Anterior Capsulotomy

First Femtosecond Laser Clearance in Cataract Surgery.

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Aliso Viejo, California - LenSx Lasers, Inc., global leader in the development of femtosecond technology for cataract surgery, announced today the FDA clearance of its LenSx[®] femtosecond laser for anterior capsulotomy during cataract surgery.

This clearance represents an important milestone in the development of surgical technology for cataract surgery, and further establishes the role of femtosecond lasers in the field of ophthalmology. The first ophthalmic femtosecond lasers were introduced as alternatives to automated mechanical blades used in LASIK. Since 2001, over 2 million femtosecond laser procedures have been performed, offering refractive surgery patients enhanced precision and safety. Surgeons soon will be able to offer patients a computer-guided laser alternative during cataract surgery.

Initial clinical evaluation, conducted by Professor Dr. Zoltan Nagy of Semmelweis University in Budapest, has shown that when compared to manually created capsulorrhexis the achieved diameter of laser capsulotomies was significantly more uniform and reproducible. While the intended diameter was achieved in 100% of LenSx femtosecond laser capsulotomies, diameter accuracy of ± 0.25 mm was observed in only 10% of manual procedures. Dr. Richard L. Lindstrom, Minneapolis, commented that, "A proper size and shape to the capsulorrhexis is critical to IOL centration and the proper performance of an accommodating IOL. The accuracy and reproducibility of the LenSx femtosecond laser in achieving the ideal capsulorrhexis cannot be duplicated with our current handheld instruments."

According to Dr. Stephen G. Slade, Medical Director for the company, "While current cataract surgery techniques can achieve excellent outcomes, the procedure still relies on multiple manual steps. The LenSx femtosecond laser has been designed to advance the precision and reproducibility of key portions of the procedure, something we have seen lasers do repeatedly in other ophthalmic procedures.

LenSx Lasers, Inc. is located in Aliso Viejo, California. For more information, please contact Trudy Larkins, Global Marketing Director.

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