FOR IMMEDIATE RELEASE

LENSAR Laser System™ Receives FDA Clearance for Arcuate Incisions in Cataract Surgery

Latest Clearance for LENSAR’s System Provides Cataract Surgeons with Enhanced Incision Functionality for All Cornea Cutting Procedures

Orlando, FL, April 3, 2013 – LENSAR Inc., developer of the next generation LENSAR Laser System™ for refractive cataract surgery, announced today that the company’s laser system has received 510(k) clearance from the United States Food and Drug Administration (FDA) for the execution of arcuate incisions during cataract surgery. Arcuate incisions are precise incisions made on the periphery of the cornea in the context of cataract surgery. With this latest regulatory milestone, the LENSAR Laser System is now cleared to perform both corneal and arcuate incisions, as well as lens fragmentation and anterior capsulotomy (with or without phacofragmentation), during cataract surgery. The LENSAR Laser System is currently available for sale to cataract surgeons in the U.S., Europe and several other countries around the world.

Featuring the company’s proprietary Augmented Reality technology, the LENSAR Laser System enables cataract surgeons to execute arcuate incisions with precision and repeatability. Previously, these incisions were made as part of manual, highly variable procedures. With its several FDA cleared indications supporting the capabilities of the laser system, LENSAR is providing physicians the most advanced platform for conducting bladeless cataract surgery and achieving consistent, predictable outcomes.

“The execution of the arcuate incision with LENSAR’s proprietary Augmented Reality Imaging system and advanced laser technology is one of the key recent advances in the area of cataract surgery. Until recently, these small and challenging incisions in the cornea were made manually, leading to variability in predictable outcomes,” said Dr. Louis “Skip” Nichamin, member of LENSAR’s medical advisory board. “LENSAR’s advanced technology platform will help cataract surgeons achieve consistent, predictable arcuate incision outcomes, regardless of the challenges and complexity of the procedure. With this latest clearance from FDA, LENSAR is
once again reaffirming its commitment to meeting all of the rapidly evolving needs of the cataract surgeon community.”

The LENSAR Laser System combines the most advanced laser technology with unique product features to meet the advancing needs of refractive cataract surgeons committed to enhancing the outcomes of their patients. The platform showcases LENSAR’s next generation differentiating Augmented Reality technology which consists of proprietary high-resolution imaging and measurement technology providing precise biometric information and 3D reconstruction of the anterior anatomy of the eye. Unlike traditional imaging systems, LENSAR’s Augmented Reality platform provides low noise images with high contrast and resolution from the anterior surface of the cornea to the posterior capsule of the crystalline lens even if dense cataracts are present. At the same time, the technology corrects for lens tilt or centration during the customized treatment to adapt to each patient’s individual anatomy. The LENSAR Laser System provides precise capsulotomy incision size, shape, and location, thereby enhancing effective IOL lens positioning and fitting for each individual patient, leading to optimized patient outcomes.

Furthermore, the laser system’s sophisticated phacofragmentation techniques provide cataract surgeons with advantages in more efficient removal of all grades of cataracts and a major reduction or complete elimination of the use of the ultrasound energy required in conventional cataract surgery. The mobile design of the LENSAR Laser System easily adapts to existing surgical facilities, allowing the system to be placed in the operating room or in a separate room.

“LENSAR is deeply committed to providing cataract surgeons with the most advanced and sophisticated tools that support their delivery of optimal clinical outcomes to their patients. By adding arcuate incisions to our growing list of FDA cleared indications for the LENSAR Laser System, we have further strengthened our position as the provider of the industry’s most advanced, versatile, surgeon-and patient centric laser cataract system,” said Nick Curtis, LENSAR’s Chief Executive Officer. “Milestones of this type underpin the significant traction that we have experienced in rapidly accelerating the adoption of the LENSAR platform among cataract surgeons around the world. We expect this latest development will only serve to further increase the growing demand for our system.”

About LENSAR, Inc.
LENSAR, Inc. is a leader in the development and commercialization of a next generation laser and advanced imaging, measurement and 3D modeling technology for refractive cataract surgery. For more information please visit www.lensar.com

LENSAR™ Laser System has been cleared by FDA for anterior capsulotomy, lens fragmentation and corneal and arcuate incisions. For other indications it is an investigational device limited by US law to investigational use only. The system has been used in about 5,000 eyes in and outside the US to date.

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