

A new dimension in cataract surgery

LENSAR™ Laser System



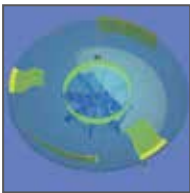
A NEW DIMENSION IN CATARACT SURGERY



Patient docking

Proprietary, fluid filled, “no corneal touch” patient interface and servo-controlled docking system create a comfortable patient experience with a very low rise in IOP. The wide angle view allows for a variety of treatments according to surgeon preference.

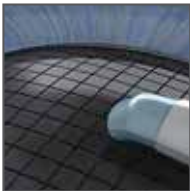
The two piece system is easy for the physician to use and dock. The suction ring is located on the patients’ sclera leaving the cornea untouched. Then the laser console and servo-controlled docking system is moved employing the joystick and aiming system to the patients’ eye in order to dock to the patient prior to imaging and treatment.



3D-CSI

3D-CSI is a unique automated imaging and measurement technology that allows high fidelity views of all the ocular surfaces from the anterior surface of the cornea to the posterior capsule of the lens. From this image all of the surfaces are automatically located, measured and the biometric values are provided. The imaging and measurement system utilizes ray tracing to automatically create a true 3D reconstruction of the patients’ anterior segment and treatment patterns are generated.

CSI stands for “Confocal Structured Illumination”. The laser and optics are aligned, sharing the same pathway to eliminate errors in beam placement and delivery. The proprietary system varies the SLD scan rates creating four illumination zones to maintain the high resolution accounting for surfaces with different reflective properties. These zones are the central cornea, outer cornea to limbus (adjusting for reflectance light from pupil) anterior portion of the lens and posterior portion of the lens to account for different lens opacities. This allows the system to produce the highest quality images with greater depth of field and the software automatically initiates 3D reconstruction and treatment patterns for the entire procedure.



Anterior capsulotomy and lens fragmentation

As the proprietary 3D CSI diagnostic system has created a biometric reconstruction of the anterior segment, the software provides automatic placement options for size, shape and location of the anterior capsulotomy according to the true anatomy of the eye. This can make ELP (effective lens position) more predictable, improving patient outcomes by helping to control intraocular lens tilt and decentration.

The treatment algorithms have been optimized for each cataract grade and this purpose designed integrated system is highly efficient and can eliminate or significantly reduce the amount of ultrasound energy required to complete the cataract removal. The proprietary 3D CSI diagnostic system improves treatment efficiency and safety significantly by automatically adjusting for any tilt and decentration of the crystalline lens that might be present through docking or patient anatomy.



Workflow

The LENSAR™ Laser System was designed for convenience and efficiency for the patient, surgeon and OR staff. The system is adaptable to different environments. It can be used directly in the OR to do the complete cataract procedure or placed in a laser suite adjacent to the OR. The physician can approach the patient from the superior or temporal position.

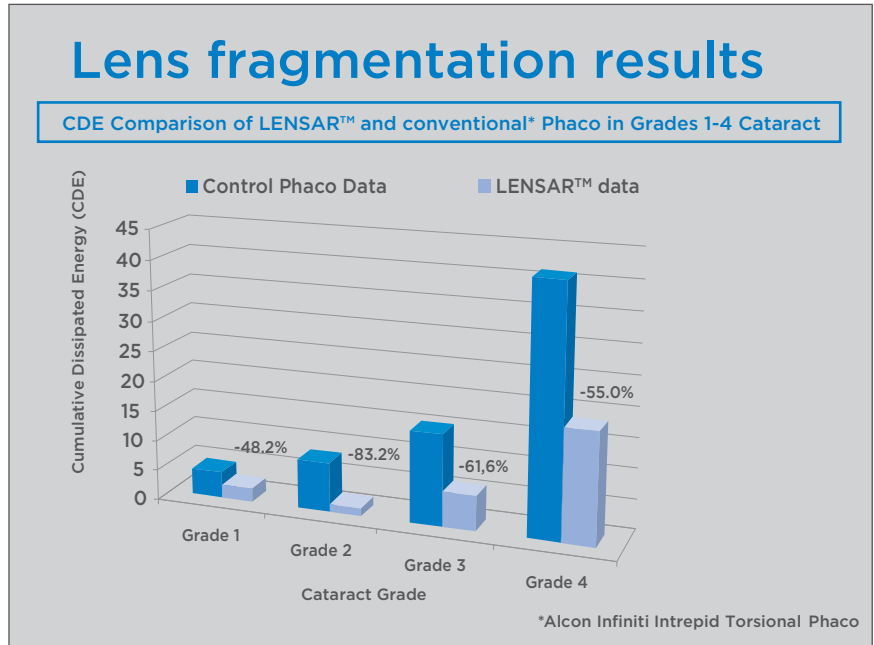
This is due to the unique design and footprint with its retractable laser console and motorized main unit, requiring minimal patient movement. The laser moves to the patient, the patient does not move to the laser.

CLINICAL EXPERIENCE WITH THE LENSAR™ LASER SYSTEM

Since the introduction, thousands of eyes have been treated. Many more are treated routinely every day on five different continents. A series of clinical papers have been produced and published on the treatment of crystalline lens with the system.

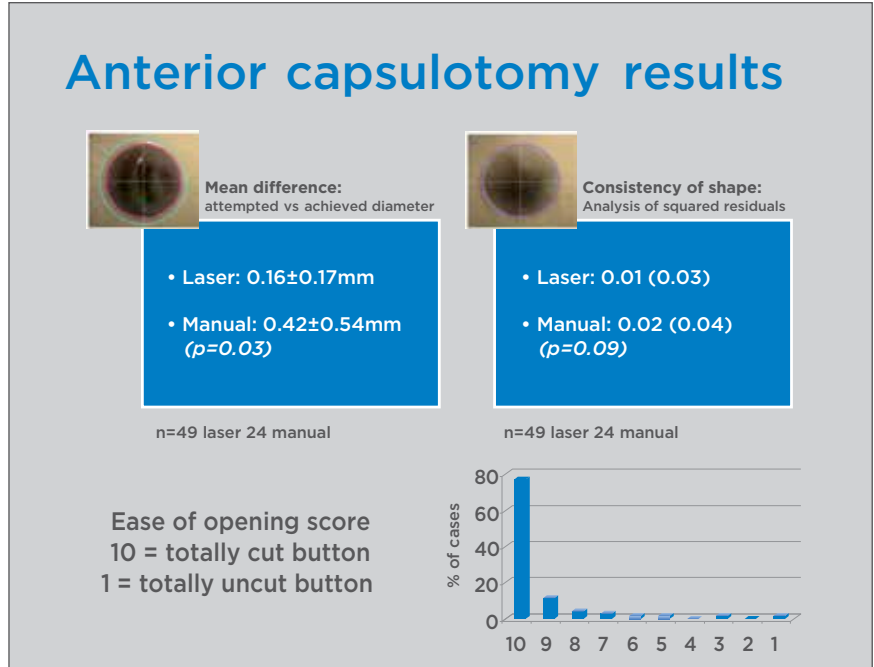
New efficiency

The LENSAR™ Laser System has shown to date the most efficient phaco fragmentation data across all cataract grades (FDA data on file). This has resulted in a significant reduction in ultrasound energy, especially in high grade cataracts. The data below is from the investigational site in the Philippines led by Dr Harvey Uy.



New precision

This new technology introduced by LENSAR™ will significantly increase the precision and relative ease with which the anterior capsulotomy is performed. In the clinical data above over 90% of buttons were removed very easily. In addition, the intended diameter and shape of the buttons were consistently achieved. Reproducible and precise capsulotomy location and size are closely related to a more predictable effective lens position (ELP). ELP is recognized as a significant factor in determining refractive outcomes.



	6-months	
	Laser	Manual
% within		
0.00 of target	11.6%	1.4%
≤0.25 of target	47.4%	22.0%
≤0.50 of target	78.7%	52.8%
≤1.00 of target	93.2%	90.2%
n	249	123
p-value	0.003	

LENSAR™ Laser System specifications

System location	Operating room or laser suite	
Indications for use	Capsulotomy Fragmentation Arcuate Limbal relaxing incisions/ Astigmatic Keratotomy incisions Clear corneal incisions / Paracentesis incisions	
Patient docking	2 Piece fluid filled docking device with controlled force docking system	
Scanning technology	3D Confocal Structured Illumination with automatic biometry, ocular surface identification – capsulorhexis placement and lens tilt measurement, image processing, and wave tracing 3D reconstruction,	
Laser technology	Femtosecond	
System foot print	X axis	80.8 ± 10 cm
	Y axis	151.9 ± 197.6 cm
	Z axis	144.7 ± 165 cm
Weight	454 kg	
System mobility	Yes – two separate mechanisms. 1 - Unit on wheels with motorized movement by joystick control 2 - Laser platform movement by software and joystick control.	
Electrical	208-240VAC, 10A Potentiometer lighting control (ability to darken the treatment room)	
Environmental control	Humidity: 35%-70% range, non-condensing Temperature: 65-86°F/18-27°C range, above dew point. Note: It is recommended that the room temperature be maintained around 71°F/21°C during surgery because of the thermal output of laser Environmental control box (Thermostat) is in room with available access	



IMPORTANT

Subject to change in design and/or specifications without advanced notice.

In order to obtain the best results with this instrument, please be sure to review all user instructions prior to operation.

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