

Cataract & Refractive Surgery

TODAY

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EXPLORING THE CATARACT REFRACTIVE SUITE



FEATURING

The LenSx Laser

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Melvin Sarayba, MD, is head of global medical affairs, cataract franchise, for Alcon Laboratories, Inc., in Fort Worth, TX. He has been a part of the LenSx Laser team since its inception. Dr. Sarayba may be reached at (817) 568-6687; Melvin.sarayba@alcon.com.



Richard J. Mackool, MD, is the director of the Mackool Eye Institute and Laser Center in Astoria, NY. He is a paid consultant for Alcon Laboratories, Inc. Dr. Mackool may be reached at (718) 728-3400, ext. 256; mackooleye@aol.com.



Richard J. Mackool Jr, MD, is the assistant director of the Mackool Eye Institute and Laser Center in Astoria, New York. He is a paid consultant to Alcon Laboratories, Inc. Dr. Mackool may be reached at (718) 728-3400, ext. 256; mackooleye@aol.com.



Jack Chapman, MD, is in private practice at Gainesville Eye Associates in Georgia. He is a paid consultant and speaker for Alcon Laboratories, Inc. Dr. Chapman may be reached at (770) 532-4444; JChapmd@aol.com.

The LenSx Laser: Built for Continual Innovation

An overview of the laser's beginnings that led to its most recent upgrade.

BY MELVIN SARAYBA, MD

The team of engineers who developed the LenSx Laser (Alcon Laboratories, Inc.; Figure 1) had previously helped design a femtosecond laser whose application was strictly limited to corneal procedures. For Alcon, this team built the LenSx Laser from the ground up for cataract surgery, which involves three different target tissues: the cornea, the lens capsule, and the lens nucleus. I joined the LenSx team the same year it was founded in 2008. As an ophthalmologist, my role is to provide the clinical requirements for the laser. I interview our medical advisors as to their requirements for cataract surgery with a femtosecond laser, and then I communicate this knowledge to the engineering team.

BUILT TO EXACTING STANDARDS

Initial femtosecond lasers for the cornea were limited to an ablation depth of 1,200 μm . Thus, our first challenge in designing the LenSx Laser was the ability to go deeper into the lens nucleus—about 8 mm into the eye. We also needed a wider field of view for cataract surgery. Whereas LASIK flaps are approximately 7 to 8.5 mm in diameter, cataract surgeons needed to be able to place the laser incisions far into the periphery of the cornea, up to 12 mm out. These requirements then necessitated a higher energy output to be able to treat deeper into the eye. Thus, we built the LenSx Laser with a higher-powered engine, a fast repetition rate for a quick procedure, and a unique optical delivery system to be able to focus the light beam both deeper into the eye and across a wide field of view.

Next, we needed to be able to image the entire anterior segment of the eye, including the ability to identify the posterior capsule, so that surgeons could avoid it when the laser fired. Thus, the engineers designed the LenSx Laser's proprietary OCT technology. Early on in the laser's development, in response to surgeons' feedback,

we increased the depth of the OCT imaging device from 5 mm to 8.5 mm deep. That was a major achievement, because current OCT technology at the time required multiple scans, stitched together, to be able to image the entire anterior segment. We were able to develop the technology to only take one scan to accurately image the entire anterior segment of the eye. We also increased the resolution of the LenSx Laser's OCT imaging system so that it offered excellent detail and contrast.

Ergonomically, we created a system of control panels, user interface, and video display that is user friendly—an important feature, especially for a high-volume, fast-paced operating room environment. With all of these components, we were proud to launch the LenSx Laser as the first of its kind for femtosecond cataract surgery.

Another early enhancement was to decrease the laser's procedural time by increasing its repetition rate and by refining the algorithm for delivering the laser pulses into the eye. These two improvements shortened the treatment time significantly, which of course heightened patients' comfort level.

We also modified the patient interface (PI) that connects patients' eyes to the laser. The most recent version of the PI is called SoftFit, which closely matches the curvature of the cornea so that there is little-to-no corneal distortion that may possibly affect the laser's performance. Thus, patients are more comfortable during the treatment, and the laser performs even more effectively.



Figure 1. The LenSx Laser.

THE LATEST UPGRADE: SOFTWARE VERSION 2.23

The latest and greatest improvement to the LenSx Laser is software upgrade 2.23, which offers several important new functions. The first feature is enhanced automatic prepositioning of the capsulotomy, so the surgeon can now preoperatively select one of four land-

marks by which to center it: over the dilated pupil, the undilated pupil, the visual axis, or the limbal center. The LenSx Laser's OCT imaging system locates those landmarks and automatically centers the capsulotomy over the chosen one. There is also prepositioning capability for corneal incisions that automatically identifies the limbus and compensates for cyclorotation (when used with the VERION Image Guided System [Alcon Laboratories, Inc.]).

A second feature of the upgrade is the shortest procedural time on the market. The LenSx Laser cannot claim the highest repetition rate, but its high-repetition rate coupled with the algorithm for making the corneal incisions creates the shortest procedural time of all other femtosecond lasers for cataract surgery.

The 2.23 software includes a new lens fragmentation pattern that makes aspiration of the nucleus even faster. Previous fragmentation patterns either sliced the nucleus into pie slices or created multiple cylinders of different diameters in order to core out the nucleus. This newest fragmentation pattern creates a grid pattern of tiny cubes within the nucleus that are very easy to aspirate (Figure 2).

Last but certainly not least, the new software upgrade enables the laser to communicate with the new VERION Image Guided System. The VERION Image Guided System is responsible for automated preoperative measurements and surgical planning. Those data can now be electronically transferred to the LenSx Laser, thereby eliminating manual entry and the potential for transcription error. The VERION Image Guided System offers the potential to further broaden the capabilities of laser cataract surgery with the LenSx Laser.

PROPRIETARY DESIGN FOR CONTINUED IMPROVEMENT

I think it is important to note that the LenSx Laser team designed all the laser's components internally; Alcon does not purchase modular parts, which I believe

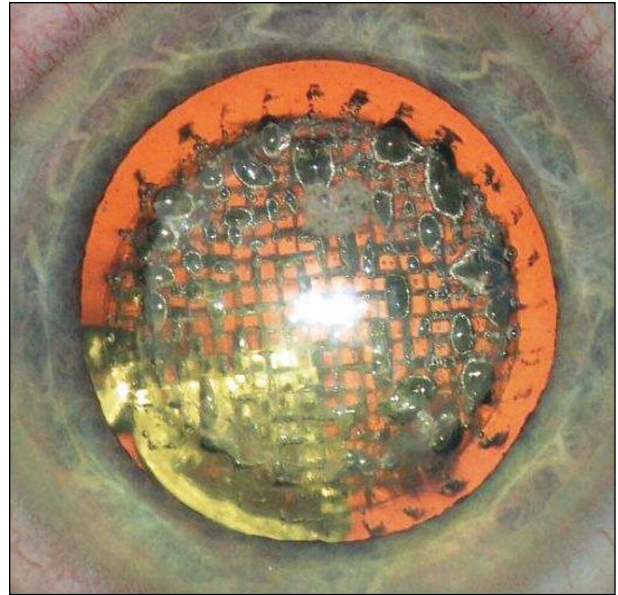


Figure 2. The new lens fragmentation pattern, available with the 2.23 software upgrade on the LenSx Laser, is being called the *matrix* pattern.

is one of the company's key strengths. Developing our own parts allows us to control the evolution of our products, because we are not limited to the technology available in the marketplace. We prefer to identify a clinical need and then design the appropriate hardware and software to meet those demands. This philosophy also enables Alcon to control the iteration of its products so that they can adapt quickly when needed.

In short, we built the LenSx Laser as a clinical tool to be adaptable to constant surgeon feedback and innovation. With this latest software upgrade, our team is excited to offer surgeons first-of-its-kind technology for laser cataract surgery. The following articles in this monograph nicely detail how surgeons are already using the LenSx Laser's expanded capabilities clinically to achieve new levels of surgical precision.

Evolving Technology: The LenSx Laser

Recent software upgrades offer even greater flexibility in surgery.

BY RICHARD J. MACKOOL, MD, AND RJ MACKOOL JR, MD

The LenSx Laser (Alcon Laboratories, Inc.) has been used in our practice for 2 years. During this time, we have had the opportunity to observe the remarkable

evolution of the technology. Its capability to rapidly and accurately create corneal incisions, perform the capsulorhexis, and incise the lens has dramatically increased,

and the number of software improvements the laser has undergone have been most impressive.

It is therefore appropriate to note how far femtosecond technology has advanced in such a short period of time, permitting surgeries to be performed faster, better, and with more flexibility.

EVOLUTION OF THE LENSX FEMTOSECOND LASER

Free-Floating Capsulotomies

The LenSx Laser's capabilities and performance with regard to creation of the capsulorhexis have improved exponentially. Whereas we originally obtained a complete, free-floating capsulotomy in the minority of eyes, software and hardware changes now permit us to accomplish this the majority of the time (Figure 3).

Improved Precision

The precision of a femtosecond laser is undeniable. A human hand has the ability to create incisions within tenths of a millimeter of that which is desired; the LenSx Laser does this with micron-level accuracy. Furthermore, the laser is able to adjust the location and shape of a capsulotomy with the same level of precision. This permits the capsulotomy to be created to suit the situation, including the type of IOL, etc. An example of the importance of this accuracy follows.

A 30-year-old man had sustained penetrating trauma to his right eye 20 years previously, and he subsequently developed a progressive cataract which was now completely white. The optical coherence tomography (OCT) of the LenSx Laser revealed that the white lenticular opacity was only 1 mm thick. In addition, this scan revealed that the morphology of the anterior capsule was undulating; ie, the thickness of the cataract was variable. Without the femtosecond laser, the creation of a precise capsulotomy would have been extremely difficult, if not impossible. Furthermore, without the knowledge that the lens was extremely thin, the surgeon (Richard J. Mackool, MD) might easily have sculpted through the nucleus and into the posterior capsule during the earliest application of ultrasonic energy.

In this case, the precision of the femtosecond laser's treatment (performed by RJ Mackool, Jr, MD) permitted the surgeon to create the capsulorhexis in the safest location, thereby easily avoiding the posterior capsule. Such is the advantage of femtosecond precision and the high-resolution OCT technology that is proprietary to the LenSx Laser.

Shortened Treatment Times

Software and hardware upgrades to the LenSx Laser have further reduced our treatment times and increased

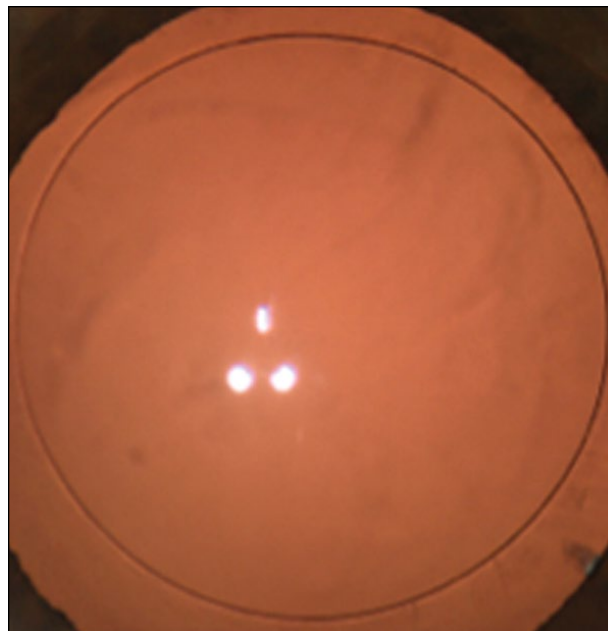


Figure 3. A perfectly round and centered free-floating capsulotomy made with the LenSx Laser.

our efficiency. The laser now completes incisions and lenticular fragmentations three times faster than the manual technique, requiring less than 1 minute to perform corneal and lenticular incisions and to create the capsulorhexis. Even complex division of the nucleus into smaller cubes, achieved with the new fragmentation available with the recent upgrade to the LenSx Laser, requires approximately 40 to 45 seconds.

As with any new technology, treatment time with femtosecond lasers is likely to continue to shorten. Remember, phacoemulsification used to take an hour and a half!

THE VERION IMAGE GUIDED SYSTEM

The recent software upgrade to the LenSx Laser (version 2.23) enables its compatibility with the VERION Image Guided System (Alcon Laboratories, Inc.), which features imaging, planning, and guidance software that can transfer the surgical plan to the LenSx Laser. The VERION Reference Unit, which is the diagnostic part of this new system, is first used in the office to capture a high-resolution image of the globe, including the calculations of keratometry, pupillometry, biometry, and IOL power (Figure 4). The image, along with these measurements, is transferred to the VERION Digital Marker, which is compatible with the LenSx Laser. The VERION Digital Marker then creates an overlay of corneal axis information on the real-time image of the eye, automatically compensating for cyclorotation (Figure 5). With the desired axis precisely indicated, the corneal incisions are then customized to the preoperative measurements of

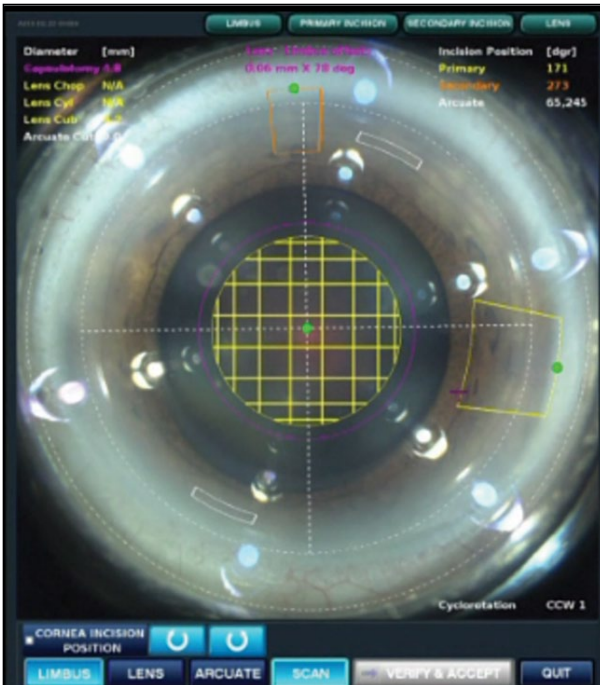


Figure 4. LenSx Laser software includes advanced positioning of the capsulotomy and incisions (primary, secondary, and arcuate) and allows for user-selectable fragmentation settings (size and spacing of the grid pattern).

the patient. The data gathering and application process is streamlined, and “on-the-fly” calculations are eliminated.

TECHNOLOGY AND YOUR PRACTICE

Informed patients want to know that their surgeon is prepared to solve their ocular problems, and that they

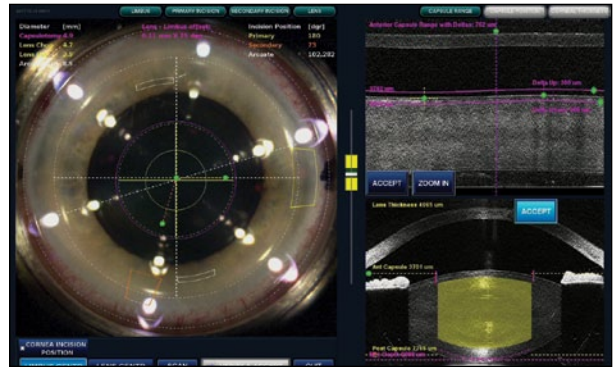


Figure 5. Using the reference image and data from the VERION Reference Unit, the (LenSx Laser) Digital Marker automatically prepositions the capsulotomy and all incisions based on the surgeon’s predetermined surgical plan.

will receive a treatment plan customized to their specific needs. Such individuals are reassured to learn that such customized treatments—and the technology that enables them—are available, and that their surgeon will utilize the latest and best advancements in the field. The practice that can offer all available technologies is thereby able to comfortably answer the inquiries of discerning patients, explaining which technologies are advisable to them as opposed to delivering qualified responses as to why the practice does not have access to certain modalities. To put it another way, not every patient is a candidate for femtosecond laser cataract technology, but the patient who inquires about the technology and is not a candidate may be reassured to learn that the surgeon does indeed utilize femtosecond technology where indicated and appropriate.

Incision Precision With the LenSx Laser

New LenSx Laser software enhances the incisional and fragmentation options.

BY JACK CHAPMAN, MD

I have been using the LenSx femtosecond Laser (Alcon Laboratories, Inc.) since December 2011, and I have witnessed it undergo some important improvements with the latest software upgrade that have reduced the energy usage and enhanced its precision. There are many advantages that I feel the LenSx Laser offers surgeons over traditional manual techniques, though perhaps the one I most appreciate is the ability to make customized, reproducible incisions with a level of control that is not possible manually. This article describes how the LenSx Laser has changed my surgery.

VARIABLE BEAM APERTURE AND INCISIONAL CONTROL

One of the key features of the LenSx Laser is its Variable Beam Aperture. This technology allows the LenSx Laser to change the beam’s angle, depending on whether it is directed toward the lens, capsule, or cornea. A large beam focus angle gives me the ability to perform complex corneal incisions, whereas the small focus angle allows for enhanced lenticular fragmentation. This technology is one of the reasons I am able to achieve free-floating capsulotomies and pristine capsular edges.

The level of incisional control afforded by the LenSx Laser is invaluable. I am able to control the axis on which I want to place an incision, and I can change the positioning of the incision easily by degrees if necessary. I currently use a 3-plane incision, the length and size of which I can preset on the laser, and these incisions seal very well.

The LenSx Laser's user interface is very helpful in setting the parameters for incisions. I can easily visualize and manipulate the placement of an incision. The interface also enables me to find the limbus, position the center of the IOL, and determine its degree of rotation. It allows total control over all of these decisions.

I believe two key elements to creating any incision is to be consistent in making them and to track their results. By making consistent incisions, we can then make slight adjustments during the procedure according to the patient's needs. Before the LenSx Laser, I used to struggle with creating arcuate incisions. I felt that there was too much variability with diamond blades. I rarely achieved a consistent depth; I fluctuated between 70% and 90% depth. With the LenSx Laser, I can control the length and the depth of the arcuate incision, which gives me a reproducible result that I can track. I place the arcuate incision exactly where I want it, staying at 90% depth all the way through. Thus, the LenSx Laser has helped me not only to make a reproducible incision, but also to control the optical zone at which I want to create the incision. If I am able to control those variables, then I will be able to achieve the outcomes that I want to provide for my patients in a cataract refractive situation.

NEW FRAGMENTATION PATTERNS

The ability to use fragmentation patterns to break up the nucleus with less phaco time and energy is important. Obviously, reducing the time and energy spent inside the eye is safer for the endothelium and leads to clearer corneas the next day.

The LenSx Laser's latest software upgrade includes new fragmentation patterns that are continuing to evolve as surgeons gain experience with them. Originally, the laser offered a single cylinder and two chop patterns; now, I use five cylinder patterns and two chop patterns. Soon, we will have a new matrix or cube pattern that offers a combination of linear and radial incisions. The new matrix pattern allows surgeons to change the size and spacing of the laser's grid pattern. I really value the ability to pick fragmentation patterns based on my patients' needs or pathology.

I foresee that as we progress with femtosecond laser technology, we will be able to apply certain fragmentation patterns to various types of cataracts. For example, softer cataracts may need only one cylinder and a chop to keep the energy levels low in the eye. Harder cataracts,

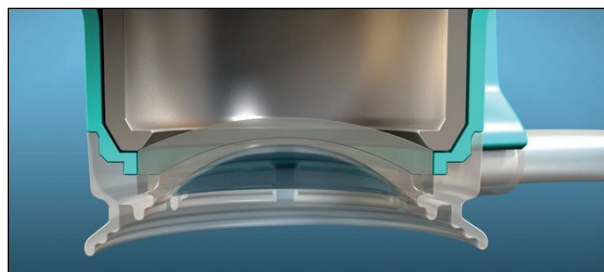


Figure 6. The SoftFit Patient Interface conforms to the natural curvature of the cornea for comfort and safety.

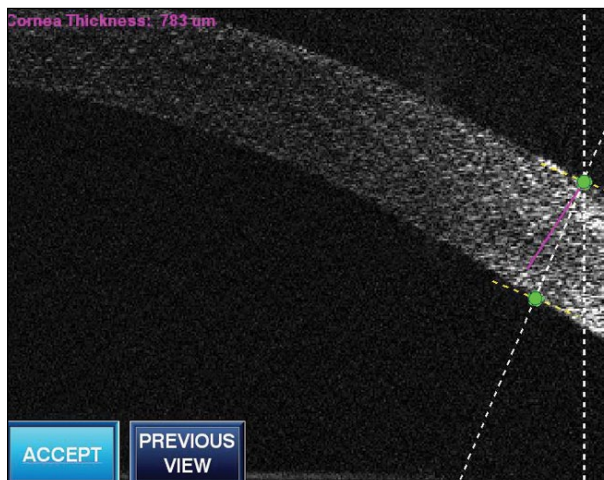


Figure 7. The LenSx Laser's proprietary OCT technology allows for clear visualization of the cornea.

on the other hand, may respond better to using five cylinders and two chops, or even the new matrix-cube pattern. It is something I look forward to.

THE SOFTFIT PATIENT INTERFACE

The addition of the SoftFit Patient Interface (PI) to the LenSx Laser (Figure 6) has changed how I perform surgery. The SoftFit PI has made the centering and docking of the eye much simpler, and all of the capsulotomies are free-floating and now much more efficient to perform. This proprietary soft contact lens insert preserves the natural curvature of the cornea during the treatment. I also like how the SoftFit PI fixates the eye, not the head, for greater patient comfort.

Finally, the small, universal 19.8-mm size of the PI accommodates a wider range of patients and facilitates the precise placement of incisions.

PROPRIETARY OCT IMAGING

The LenSx Laser's integrated and proprietary optical coherence tomography (OCT) is perhaps the backbone of the laser system, because it produces anterior and posterior images of the eye on which all of the incisions

are based (Figure 7). The clear OCT images enable the surgeon to set the location and parameters for incisions and the safety zone within which to chop a nucleus.

LENSX IN MY PRACTICE

It was an easy decision for me to adopt the LenSx Laser in my practice when I realized that it would improve my surgical consistency for my patients. Approximately half

of my patients are currently choosing surgery with the LenSx Laser, thanks to the efforts of our onsite surgery counselor who is highly educated about ophthalmology and the practice and meets with each one of our cataract candidates. The upgrades to the LenSx Laser platform have helped me use lower levels of energy when performing surgery, a benefit I am glad to be able to offer my patients. ■

LenSx® Laser Important Product Information Caution

United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eye care practitioner.

Indication

The LenSx® Laser is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of single plane and multi-plane arc cuts/incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure.

Restrictions

Patients must be able to lie flat and motionless in a supine position.
Patient must be able to understand and give an informed consent.
Patients must be able to tolerate local or topical anesthesia.
Patients with elevated IOP should use topical steroids only under close medical supervision.

Contraindications

Corneal disease that precludes applanation of the cornea or transmission of laser light at 1030 nm wavelength
Descemetocoele with impending corneal rupture
Presence of blood or other material in the anterior chamber
Poorly dilating pupil, such that the iris is not peripheral to the intended diameter for the capsulotomy
Conditions which would cause inadequate clearance between the intended capsulotomy depth and the endothelium (applicable to capsulotomy only)
Previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape
Corneal thickness requirements that are beyond the range of the system
Corneal opacity that would interfere with the laser beam
Hypotony or the presence of a corneal implant
Residual, recurrent, active ocular or eyelid disease, including any corneal abnormality (for example, recurrent corneal erosion, severe basement membrane disease)
History of lens or zonular instability
Any contraindication to cataract or keratoplasty
This device is not intended for use in pediatric surgery.

Warnings

The LenSx® Laser System should only be operated by a physician trained in its use.
The LenSx® Laser delivery system employs one sterile disposable LenSx® Laser Patient Interface consisting of an applanation lens and suction ring. The Patient Interface is intended for single use only. The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables other than those manufactured by Alcon may affect system performance and create potential hazards.
The physician should base patient selection criteria on professional experience, published literature, and educational courses. Adult patients should be scheduled to undergo cataract extraction.

Precautions

Do not use cell phones or pagers of any kind in the same room as the LenSx® Laser.
Discard used Patient Interfaces as medical waste.

AEs/Complications

Capsulotomy, phacofragmentation, or cut or incision decentration
Incomplete or interrupted capsulotomy, fragmentation, or corneal incision procedure
Capsular tear
Corneal abrasion or defect
Pain
Infection
Bleeding
Damage to intraocular structures
Anterior chamber fluid leakage, anterior chamber collapse
Elevated pressure to the eye
Attention
Refer to the LenSx® Laser Operator's Manual for a complete listing of indications, warnings and precautions.

Important Product Information for the VERION™ Reference Unit and VERION™ Digital Marker

Caution

Federal (USA) law restricts this device to sale by, or on the order of, a physician.

Intended Uses

The VERION™ Reference Unit is a preoperative measurement device that captures and utilizes a high-resolution reference image of a patient's eye in order to determine the radii and corneal curvature of steep and flat axes, limbal position and diameter, pupil position and diameter, and corneal reflex position. In addition, the VERION™ Reference Unit provides pre-operative surgical planning functions that utilize the reference image and pre-operative measurements to assist with planning cataract surgical procedures, including the number and location of incisions and the appropriate intraocular lens using existing formulas. The VERION™ Reference Unit also supports the export of the high-resolution reference image, preoperative measurement data, and surgical plans for use with the VERION™ Digital Marker and other compatible devices through the use of a USB memory stick.
The VERION™ Digital Marker links to compatible surgical microscopes to display concurrently the reference and microscope images, allowing the surgeon to account for lateral and rotational eye movements. In addition, the planned capsulorhexis position and radius, IOL positioning, and implantation axis from the VERION™ Reference Unit surgical plan can be overlaid on a computer screen or the physician's microscope view.

Contraindications

The following conditions may affect the accuracy of surgical plans prepared with the VERION™ Reference Unit: a pseudophakic eye, eye fixation problems, a non-intact cornea, or an irregular cornea. In addition, patients should refrain from wearing contact lenses during the reference measurement as this may interfere with the accuracy of the measurements.

Only trained personnel familiar with the process of IOL power calculation and astigmatism correction planning should use the VERION™ Reference Unit. Poor quality or inadequate biometer measurements will affect the accuracy of surgical plans prepared with the VERION™ Reference Unit.
The following contraindications may affect the proper functioning of the VERION™ Digital Marker: changes in a patient's eye between pre-operative measurement and surgery, an irregular elliptical limbus (e.g., due to eye fixation during surgery, and bleeding or bloated conjunctiva due to anesthesia). In addition, the use of eye drops that constrict sclera vessels before or during surgery should be avoided.

Warnings

Only properly trained personnel should operate the VERION™ Reference Unit and VERION™ Digital Marker.
Only use the provided medical power supplies and data communication cable. The power supplies for the VERION™ Reference Unit and the VERION™ Digital Marker must be uninterrupted. Do not use these devices in combination with an extension cord. Do not cover any of the component devices while turned on.
Only use a VERION™ USB stick to transfer data. The VERION™ USB stick should only be connected to the VERION™ Reference Unit, the VERION™ Digital Marker, and other compatible devices. Do not disconnect the VERION™ USB stick from the VERION™ Reference Unit during shutdown of the system.
The VERION™ Reference Unit uses infrared light. Unless necessary, medical personnel and patients should avoid direct eye exposure to the emitted or reflected beam.

Precautions

To ensure the accuracy of VERION™ Reference Unit measurements, device calibration and the reference measurement should be conducted in dimmed ambient light conditions. Only use the VERION™ Digital Marker in conjunction with compatible surgical microscopes.

Attention

Refer to the user manuals for the VERION™ Reference Unit and the VERION™ Digital Marker for a complete description of proper use and maintenance of these devices, as well as a complete list of contraindications, warnings and precautions.

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Alcon®
a Novartis company