



Warren Hill, MD

## The VERION Image Guided System

by Warren Hill, MD

**A** little-appreciated aspect of IOL power calculations is that it is a multi-part process, with each part individually having the potential to determine the refractive outcome. Axial measurements, keratometry, the formula being used, the construction of the capsulorhexis, etc., all play a role. The paradox of intraocular lens power calculations goes something like this: Make only one individual part of a multi-part process perfect, and overall outcomes are not necessarily improved. But, have one part incorrect, and a refractive surprise is guaranteed. Stated differently, all parts must be optimized for the best possible refractive outcomes.

A testament to continuously improving technology is that

cataract surgeons are now being judged by their patients and their peers by their refractive outcomes. If you visit 10 different ophthalmology practices, you are very likely to see a wide range of approaches and instrumentation for preoperative measurements and calculations. Optical biometry has gone a long way toward standardizing the measurement process, but there remains room for improvement.

The best approach is one that gives consistent results, with the overall purpose being accuracy. Both consistency and accuracy can be achieved by following a set plan: checking for accuracy during each step of a pre-determined and consistently repeated process.

The VERION Image Guided System (Alcon, Fort Worth, Texas) represents an integrated approach

developed to help improve the quality of refractive outcomes by streamlining the process of measurement, calculation, and implantation with the single goal of reducing variability.

### Preoperative measurements

The process begins with the reference unit, which captures a high-resolution image of the patient's eye. The software locates the limbus and auto-detects the location of scleral vessels and iris features, which are used for auto-registration with the intraoperative digital marker. The steep and flat meridians are also identified in an unambiguous way, and this is automatically transferred to the planning software. Axial measurements can be transferred to the planning software. For the

**“The VERION Image Guided System allows the surgeon to incorporate a new process to do better than what most surgeons are currently doing with best-in-class diagnostics and planning.”**

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The VERION Image Guided System is composed of the VERION Reference Unit, which would reside in the clinical practice, and the VERION Digital Marker, which can be attached to a LenSx Laser and/or the most currently available surgical microscopes.

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Please refer to pages 6 and 7 for important product information about the Alcon products described in this supplement.



Richard Mackool, MD

**“The advantages of the Centurion Vision System and AutoSert IOL Injector are indeed complimentary. Together they have increased our ability to perform atraumatic and precise cataract implant surgery with greater refractive accuracy through a smaller cataract incision.”**

*Click to view videos*



Centurion Vision System Active Fluidics



Centurion Vision System Fluid Management System

## Active Fluidics in a non-routine cataract case

by Richard Mackool, MD

**A**ctive Fluidics, by constantly monitoring and adapting to changes in target IOP, can benefit patients and surgeons during uneventful as well as unusual procedures.

As an example, I was performing cataract surgery under topical anesthesia on the highly nearsighted eye (axial length: 27 mm) of a 55-year-old ophthalmologist. The IOP setting on the Centurion Vision System (Alcon, Fort Worth, Texas) was 80 mmHg, which is equivalent to an infusion bottle height of 110 cm. As I inserted the phaco tip into the eye, he reported severe discomfort. In my experience, this very unusual problem occurs only in highly nearsighted eyes and is almost certainly the result of stretching of the thin sclera and adjacent choroid during periods of IOP elevation. Stretching choroidal nerves is not only extremely uncomfortable, it is downright painful.

In the past, options to deal with this situation have included the following:

- Performing a peribulbar or retrobulbar block. This solves the problem but of course exposes the patient to the potential complications of such injections. This is why many surgeons prefer topical anesthesia.
- Administering a large amount of intravenous sedation to render the patient unconscious or nearly so. This carries some systemic risks, as well as the risk of ocular complications associated with poor patient cooperation. As we are all aware, marginally conscious patients can do things that jeopardize the outcome of the procedure.
- Lowering the infusion bottle height to about 60 cm to reduce IOP to about 40 mmHg in foot pedal position 1. The good news with this option is that the patient will not have pain. The very bad news is that in order to avoid severe chamber instability, fluidic parameters would have to be so low that the duration of the procedure could be measured using a calendar. The prolonged procedure results in a large

amount of fluid passing through the eye, traumatizing the iris and cornea.

The Centurion Vision System changes all of this. It permits the surgeon to set a target IOP that is comfortable for each patient and to maintain it even when using fluidic parameters that will enable the cataract to be removed efficiently. Previously, we used an infusion bottle that remained at one height throughout the procedure. It would have been ideal, but physically impossible, to have someone in the OR rapidly elevating and lowering the bottle depending upon the rate at which fluid was leaving the eye in order to maintain a reasonably consistent IOP. Remarkably, this is essentially what the Centurion Vision System does (i.e., it monitors the pressure in the infusion and aspiration lines and instantaneously changes the amount of flow into the eye in order to maintain the targeted

IOP at or near the preset target IOP level). There is no other system on the market today that manages fluidics like the Centurion Vision System Active Fluidics.

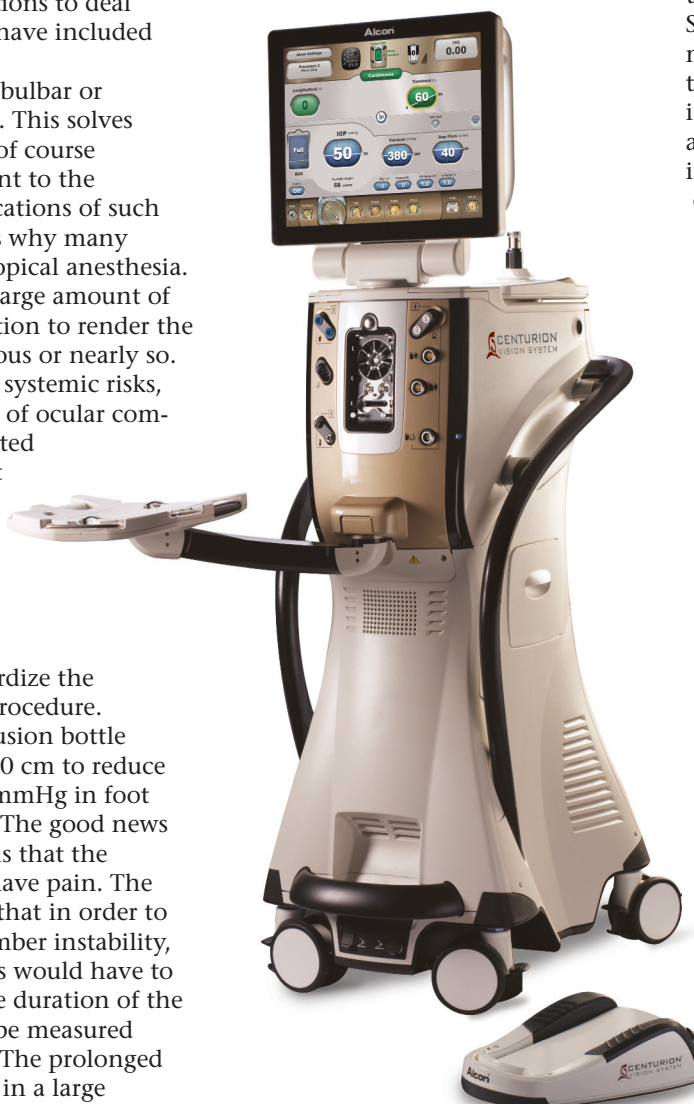
This patient had experienced pain at an IOP setting of 80 mmHg, so I reduced the target IOP to 55 mmHg. He experienced only mild and transient discomfort as the instrument was inserted, and the phacoemulsification procedure was safely completed using an aspiration flow rate of 25 cc/min and vacuum level of 400 mmHg during which time the target IOP would have been approximately 40 mmHg.

The fluidic advantages of the Centurion Vision System also helped to increase postoperative refractive accuracy. Because the instrument maintains a target IOP and chamber stability so well, even when the smallest of phaco incisions are employed, there is simply no advantage to using a larger infusion sleeve that typically requires an incision of 2.6 to 3.0 mm. All Centurion Vision System surgeons can therefore immediately reduce their incision size to 2.4 mm or less, thereby decreasing surgically induced astigmatism as well as the risk of postoperative incision leakage, suturing of the incision, and even endophthalmitis. There is virtually no learning curve associated with this switch to a smaller incision.

When inserting the IOL through these smaller incisions, the foot pedal control of the Intrepid AutoSert IOL Injector (Alcon) offers a great advantage because it frees the surgeon's non-dominant hand so that it can be used to both position the eye and the IOL as the lens enters the eye and capsular bag. It also permits precise control of the rate at which the IOL is delivered.

The advantages of the Centurion Vision System and AutoSert IOL Injector are indeed complimentary. Together they have increased our ability to perform atraumatic and precise cataract implant surgery with greater refractive accuracy through a smaller cataract incision.

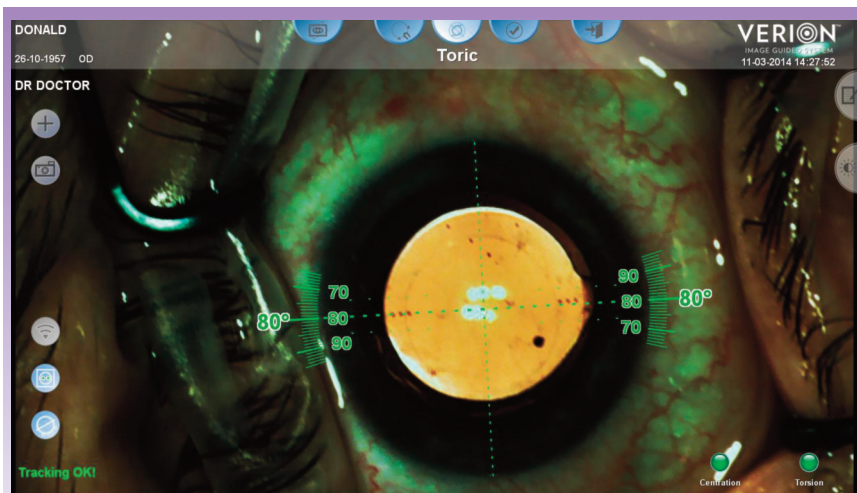
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Centurion Vision System



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An AcrySof Toric IOL is aligned to the pre-planned orientation of 80 degrees using the VERION Digital Marker. The overlay is projected live into the surgeon's oculars as well as viewable on the Digital Marker's monitor screen.

correction of corneal astigmatism by either arcuate incisions or a toric IOL, having this kind of information instantly available at the time of surgery is a quantum leap forward in the execution of a surgical plan.

### Planning for the procedure

Once the preoperative measurements have been captured and automatically transferred to the planning software, the user now has access to multiple IOL power calculation formulas, including Holladay 2. There is also a toric calculator and a way to plan for arcuate incisions. Here, the surgical plan is thoughtfully and completely developed well in advance of the procedure. The best part about surgical planning using the VERION Image Guided System is that it does not take additional time compared to what many surgeons and their staff members are already doing.

### Guidance during surgery

In the operating room, information is transferred to the digital marker from the planning software for each patient so that every aspect of the surgical plan can be carried out with precision. The digital marker image automatically rotates and aligns with cyclorotation. There is no need to mark the eye, as all aspects of the surgical plan are automatically registered. This is especially useful for toric intraocular lenses, where the incision location and the alignment of the toric intraocular lens significantly impact the refractive outcome. In fact, the VERION Image Guided System is a great addition for those who frequently use toric IOLs as it helps surgeons optimize their

process of measurement, calculation, digital marking, and placement.

### Process philosophy

Years ago, the automaker Toyota embarked on a plan to improve the quality of its automobiles. Rather than checking each car for defects as it came off the assembly line, they instead worked to limit variability by building quality into each step of the manufacturing process itself—in other words, removing aspects that could induce variability.

Eye surgery can be thought of in much the same way. Rather than just looking at outcomes over a range of surgeries, the better approach is to work to optimize each aspect of the process so that the final product is the sum of these optimized steps. Once again, cataract surgery refractive outcomes represent the summation of a multi-part process.

The VERION Image Guided System allows the surgeon to incorporate a new process to do better than what most surgeons are currently doing with best-in-class diagnostics and planning. Each step can be validated before moving on to the next.

### Toric planning

For example, cataract patients with low amounts of corneal astigmatism can be challenging. It is a well-known fact that low amounts of astigmatism are more common than higher amounts—the patients who we most frequently remember. In fact, a little more than 60% of eyes have 1 D of corneal astigmatism or less. Measuring low amounts of astigmatism may be difficult be-

cause the orientation of the steep meridian is often more difficult to determine with precision, and the power difference between the steep and the flat meridians may be less obvious. Additionally, there is more variation from one piece of equipment to the next. Physicians and their staff often try to make up for this by taking averages, or perhaps relying on one piece of equipment for some patients and something else for others. Such an approach induces variability.

With the orientation and the power difference between the steep and flat meridians unambiguously displayed, the planning software will next develop a surgical plan that displays the location of the incision and the orientation of the toric IOL without the surgeon placing a mark on the cornea.

The AcrySof IQ Toric (Alcon) is an excellent IOL to use with the VERION Image Guided System's new astigmatism management capabilities for planning and execution. An almost immediate interaction of the AcrySof IOL material with

the posterior capsule provides exceptional long-term rotational stability. This is a critical feature with toric IOLs, to have confidence it will remain at the axis you've preoperatively planned for and placed at during surgery.

The VERION Image Guided System is designed with accuracy as its purpose, reducing errors in measurement, translation, and execution. It represents an intuitive process by which the creation of a consistent plan helps reduce potential sources of error, intended to reduce variability and improve quality for refractive outcomes. Because of the unique capability of the reference unit to accurately and graphically represent corneal astigmatism and the planning software to generate the necessary calculations and intraoperative landmarks, it is a great compliment to the toric IOL and can help surgeons improve outcomes for all other types of intraocular lenses.

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## Treating astigmatism with AcrySof IQ Toric IOLs

by Stephen V. Scoper, MD

**W**hy do we treat astigmatism at the time of cataract surgery? I believe it is all about giving my patients the best possible quality of vision. My first objective when seeing a patient for a cataract evaluation is *managing the astigmatism*. We have learned from Warren Hill, MD, that 52.5% of all patients undergoing cataract surgery have 0.75 D or more of corneal astigmatism. These patients have the opportunity to have clear, crisp distance vision with reduced dependency on glasses.

Having my staff provide LENSTAR LS 900 Biometer measurements and topography *before* I see the patient allows me to make a specific IOL recommendation at this initial encounter. With confidence, I am able to recommend the AcrySof IQ Toric IOL because of the proven predictability and rotational stability. The acrylic AcrySof material binds extremely well to the capsule. Having the broadest range of cylinder correction (0.75 D to >4.0 D) allows me to treat the majority of cataract patients with astigmatism.

Attention to detail assures the best possible results. Understanding the role of *surgically induced astigmatism* and the *surgeon constants* in selecting the IOL power is critical to improving outcomes. Topography confirms the correct axis of the cylinder. Considering that posterior corneal astigmatism may add 0.5 D of ATR cylinder influences my final calculation. In my hands, marking the cornea at the YAG laser slit lamp is a more accurate technique before taking the patient to the OR. The new VERION Image Guided System is designed to obviate this need for pre-marking the patient before surgery as well as marking the patient on the operating table. This new technology will help me deliver results to my patients that they now expect—and deserve.



Curt Young, MD

**“Reproducible and accurate arcuate incisions are also a key reason why I use the LenSx Laser. The ability to accurately control arcuate length, depth, curve, radius, and angle of incidence gives me great control and consistency.”**

## Making the switch to the LenSx Laser

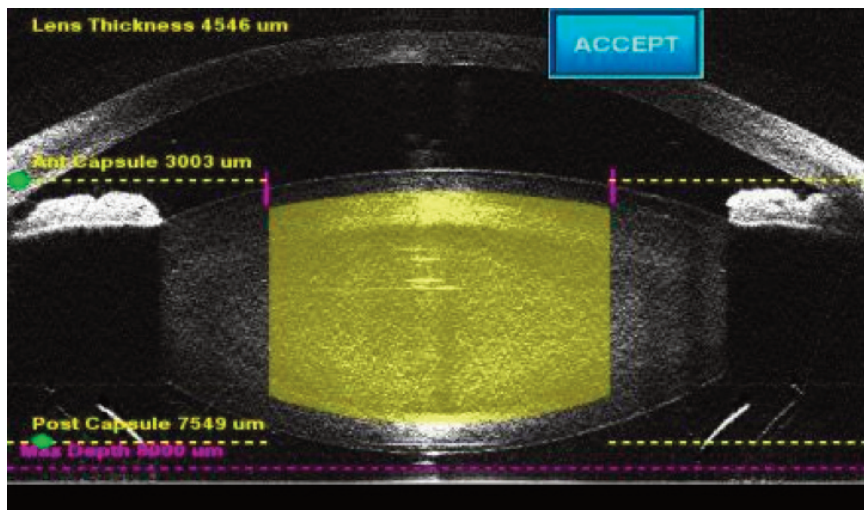
by Curt Young, MD

**W**e bought our Catalys (OptiMedica/Abbott Medical Optics, Santa Ana, Calif.) in July 2012. At the time we bought it, which was prior to the introduction of the LenSx Laser SoftFit Patient Interface (Alcon, Fort Worth, Texas), we felt that the Catalys system performed capsulotomy treatments better than the LenSx Laser system. However, with the introduction of the SoftFit Patient Interface (PI), the LenSx Laser dramatically improved its capsulotomy performance. The LenSx Laser's PI is part of the optical design and is considered the last lens on the laser system; it does not require a liquid interface. Compared to the original LenSx Laser PI, the LenSx Laser with SoftFit PI has not only improved its surgical performance, showing a 66% reduction in laser energy and a 33% reduction in laser time, but more importantly offers improved docking and centration. The SoftFit PI simplifies docking even with deep-set or small eyes due to its smaller diameter (19.8 mm). The diameter of the Catalys patient interface is nearly 5 mm larger than the LenSx Laser and 3.5 mm larger than the Intralase (Abbott Medical Optics) patient interface.

One of the main benefits of the SoftFit PI is that it fixates the cornea, eliminating the need to tape down the patient's head, and reduces IOP rise during the docking process (16 mmHg increase over baseline). There is no longer a contraindication for glaucoma patients with the SoftFit PI.

The LenSx Laser has the ability to make great corneal incisions: primary, secondary, and arcuate. In January of this year, I bought the LenSx Laser, and now I use it 100% of the time.

The LenSx Laser computer-programmed incisions provide reproducible primary and secondary incisions. Surgeons can easily control depth, length, and position. The user interface displays real-time corneal thickness, allowing us to create true “three-plane” primary incisions. With the LenSx Laser, I routinely use femto-incisions. They are easy to open, without leaking or deformation. Reproducible and accurate arcuate incisions are also a



**LenSx Laser high-definition OCT technology: Real-time image-guided planning and monitoring give the surgeon the ability to image anterior cornea to posterior capsule in one single image with low noise and high-contrast resolution.**

key reason why I use the LenSx Laser. The ability to accurately control arcuate length, depth, curve, radius, and angle of incidence gives me great control and consistency. I am able to create arcuate incisions that are titratable and easy to enhance during surgery or postop. These incisions have proven to be a great adjunct to multifocal IOLs.

A key technology that enables the LenSx Laser to perform well in the lens, capsule, and cornea plane is its unique “variable beam angle.” The laser focus angle changes for each surgical plane. A wide beam for the cornea gives the LenSx Laser the ability to perform complex incisions. A medium beam angle for the capsule provides a free-floating capsulotomy with pristine edges in most cases, while the narrow angle for the lens provides effective fragmentation. Most other femtosecond lasers have a single beam angle or aperture, which is maximized for either the cornea or the lens.

One of the misconceptions I had about the LenSx Laser when I made the initial decision to purchase the Catalys was that its imaging system is not accurate because it is based on imaging single points. I believed that it was fast but not accurate. Since purchasing the LenSx Laser with SoftFit PI, I have found that the circle scan enables fully characterized lens shape and orientation. It also extracts lens thickness, tilt, and radii of curvature (anterior and posterior capsules). The circle and linear OCT scans together give more information, which can be used to verify observations made with the video microscope in order

to help improve accuracy and reduce risk for the patient. While the Catalys performs multiple scans and assembles the images, the LenSx Laser's proprietary full-range integrated OCT captures the entire anterior segment and all tissue structures in a single, full-range, precise image. This allows me to perform OCT imaging during docking, showing all the internal ocular structures.

Importantly, the large depth range of the LenSx Laser OCT covers the entire anterior segment of the eye and does not require multiple scans to be stitched together. The customized treatment planning software involves complete visualization of the eye. Several OCT images are displayed for a surgeon to verify the placement of the different femto-incisions. The LenSx Laser performs a complete 360-degree circle scan and several line scans at very high resolution to precisely position the laser fragmentation pattern.

The way you can customize the surgical plan is very user friendly. There are a lot of treatment options with the LenSx Laser. If you wanted or needed to change the treatment plan based on the patient's needs (e.g., make a smaller capsulotomy or move the incisions), you are able to drag and position the incision quickly with a simple click on the interface. I think it is clear that LenSx Laser corneal incisions are placed more precisely and more consistently from the limbus.

Dr. Young is the medical director of Vision Care of Maine. He can be contacted at [tylercyoung@yahoo.com](mailto:tylercyoung@yahoo.com).



# ReSTOR +3.0D offers excellent computer distance vision

by Gary Foster, MD

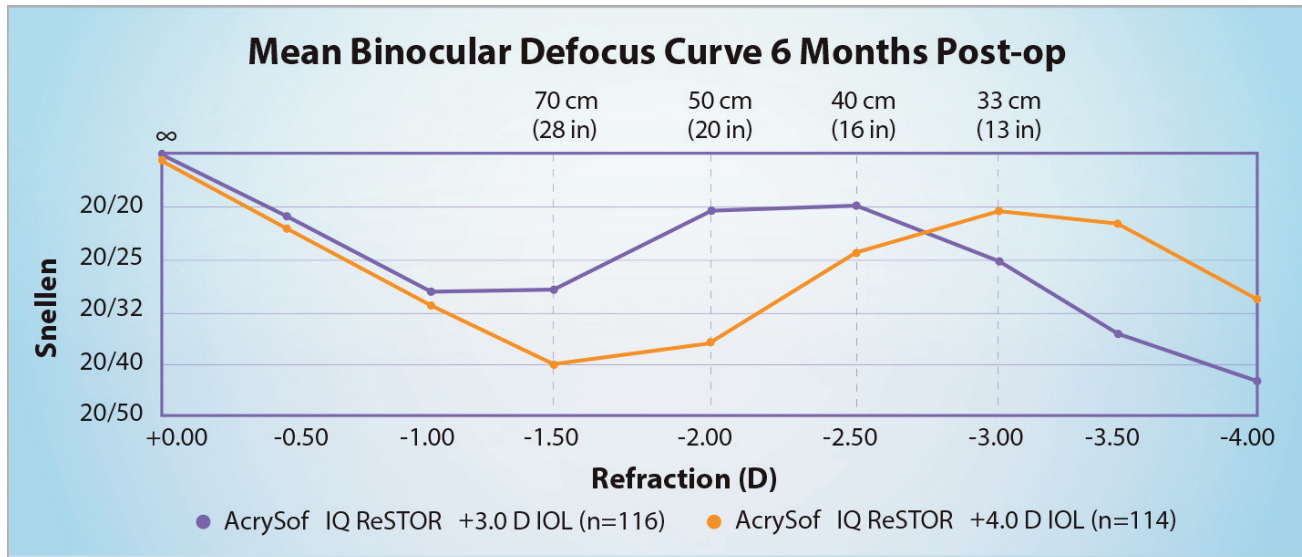


Figure 1

**M**any patients appreciate the increased freedom that comes from multifocal lenses that give them more than one focal length in focus. The ideal reading distance is moving out farther as more patients desire vision at the distance of a computer screen or a tablet.

The +4.0D add multifocal IOLs provide high-magnification reading, but relatively close to the patient at about 13 in., which is closer than most patients typically want to read. This distance makes the computer screen particularly difficult to read. As a result, +4.0D add multifocal lenses, like the ReSTOR +4.0D (Alcon, Fort Worth, Texas), have had very good reading at 13 in. but are only 20/40 at intermediate distance (see Figure 1). While this is acceptable for some patients, there is no question that our society is becoming more computer distance-oriented.

In comparison, the ReSTOR +3.0D supports reading at more typical distances. This moves the sweet spot closer to the intermediate zone, which is important to many patients. As a result, the ReSTOR +3.0D has an average visual acuity at intermediate distances of around 20/25, which is generally more acceptable to patients than the 20/40 vision achieved in the ReSTOR +4.0D.

Another advantage of the ReSTOR platform is that it features an apodized structure. In normal lighting, half of the light is allocated to the near image and half of the light is allocated to the distance image. However, when the patient's pupils become larger, a growing percentage of the light is directed to the distance object. The lens was designed this way to reduce the potential for nighttime glare and halos. This feature should be appreciated by patients who spend more time out at night.

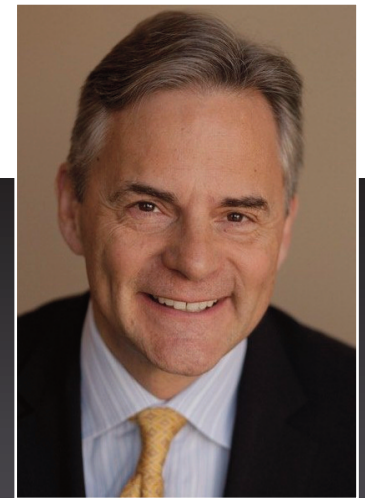
Another key feature is that ReSTOR lenses are made of the same material as the other AcrySof lenses, so the haptics are soft enough that the lens can be moved and centered where you desire. The AcrySof material adheres to the posterior capsule, which helps it remain in place. These features help the surgeon to better center the IOL.

I was involved in the FDA trial for the ReSTOR +3.0D lens, and in that study, patients were randomized to receive either the ReSTOR +4.0D in each eye or the ReSTOR +3.0D in each eye. They were not told which lens they had. I implanted lenses in two separate patients on a Tuesday, and the next morning they came in for their 1-day postop visit. These two patients struck up a conversation

with each other while they waited for their exam. As they talked, they figured out that both were in the trial and both had surgery on their first eye the day before. One patient was a pharmacist and the other was a dentist, and as they started talking about where they could see in the distance and where they could read, they figured out that one of them clearly had the ReSTOR +3.0D and the other had the +4.0D. They later told me their conclusions, and while I was not allowed to confirm this, I knew they were right. There is a noticeable difference in moving the focal length of the +4.0D lens out to the focal length of a +3.0D lens where patients read and see intermediate more comfortably.

Last week, I implanted a +3.0D in the second eye of a woman who had come to see me with a specific desire to be less dependent on glasses after her cataract surgery. We reviewed all of the lens options available to her, studied her lifestyle, and concluded that the ReSTOR +3.0D was the lens that was most likely to give her the near, intermediate, and distance vision that she desired. I called her a couple of days ago, and she said she was elated with her vision at all distances.

Dr. Foster is a cataract and laser eye surgeon in Fort Collins, Colo. He can be contacted at [FosterClinic@EyeCenterNoCo.com](mailto:FosterClinic@EyeCenterNoCo.com).



Gary Foster, MD

**“The ReSTOR +3.0D supports reading at more typical distances. This moves the sweet spot closer to the intermediate zone, which is important to many patients.”**

# Important product information

## AcrySof IQ Intraocular Lenses

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

**Indications:** The AcrySof IQ posterior chamber intraocular lens is intended for the replacement of the human lens to achieve visual correction of aphakia in adult patients following cataract surgery. This lens is intended for placement in the capsular bag.

**Warning/Precaution:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Caution should be used prior to lens encapsulation to avoid lens decentrations or dislocations.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof Natural IOL and normal color vision. The effect on vision of the AcrySof Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C; use only sterile irrigating solutions such as BSS or BSS PLUS Sterile Intraocular Irrigating Solutions.

**Attention:** Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

## AcrySof IQ ReSTOR Intraocular Lenses

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

**Indications:** The AcrySof IQ ReSTOR Posterior Chamber Intraocular Lens (IOL) is intended for primary implantation for the visual correction of aphakia secondary to removal of a cataractous lens in adult patients with and without presbyopia, who desire near, intermediate and distance vision with increased spectacle independence. The lens is intended to be placed in the capsular bag.

**Warning/Precaution:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Physicians should target emmetropia, and ensure that IOL centration is achieved. Care should be taken to remove viscoelastic from the eye at the close of surgery.

Some patients may experience visual disturbances and/or discomfort due to multifocality, especially under dim light conditions. Clinical studies with the AcrySof ReSTOR lens indicated that posterior capsule opacification (PCO), when present, developed earlier into clinically significant PCO. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof IQ ReSTOR IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof Natural IOL and normal color vision. The effect on vision of the AcrySof Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C; use only sterile irrigating solutions such as BSS or BSS PLUS Sterile Intraocular Irrigating Solutions.

**Attention:** Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

## AcrySof IQ Toric Intraocular Lenses

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

**Indications:** The AcrySof IQ Toric posterior chamber intraocular lenses are intended for primary implantation in the capsular bag of the eye for visual correction of aphakia and pre-existing corneal astigmatism secondary to removal of a cataractous lens in adult patients with or without presbyopia, who desire improved uncorrected distance vision, reduction of residual refractive cylinder and increased spectacle independence for distance vision.

**Warning/Precaution:** Careful preoperative evaluation and sound clinical judgment should be used by the surgeon to decide the risk/benefit ratio before implanting a lens in a patient with any of the conditions described in the Directions for Use labeling. Toric IOLs should not be implanted if the posterior capsule is ruptured, if the zonules are damaged, or if a primary posterior capsulotomy is planned. Rotation can reduce astigmatic correction; if necessary lens repositioning should occur as early as possible prior to lens encapsulation. All viscoelastics should be removed from both the anterior and posterior sides of the lens; residual viscoelastics may allow the lens to rotate.

Optical theory suggests that high astigmatic patients (i.e., >2.5 D) may experience spatial distortions. Possible toric IOL related factors may include residual cylindrical error or axis misalignments. Prior to surgery, physicians should provide prospective patients with a copy of the Patient Information Brochure available from Alcon for this product informing them of possible risks and benefits associated with the AcrySof IQ Toric Cylinder Power IOLs.

Studies have shown that color vision discrimination is not adversely affected in individuals with the AcrySof Natural IOL and normal color vision. The effect on vision of the AcrySof Natural IOL in subjects with hereditary color vision defects and acquired color vision defects secondary to ocular disease (e.g., glaucoma, diabetic retinopathy, chronic uveitis, and other retinal or optic nerve diseases) has not been studied. Do not resterilize; do not store over 45 degrees C; use only sterile irrigating solutions such as BSS or BSS PLUS Sterile Intraocular Irrigating Solutions.

**Attention:** Reference the Directions for Use labeling for a complete listing of indications, warnings and precautions.

## CENTURION Vision System

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

As part of a properly maintained surgical environment, it is recommended that a backup IOL injector be made available in the event the AutoSert IOL Injector Handpiece does not perform as expected.

**Indication:** The CENTURION Vision system is indicated for emulsification, separation, irrigation, and aspiration of cataracts, residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert IOL Injector Handpiece is intended to deliver qualified AcrySof intraocular lenses into the eye following cataract removal.

The AutoSert IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The AutoSert IOL Injector Handpiece is indicated for use with the AcrySof lenses SN6OWF, SN6AD1, SN6AT3 through SN6AT9, as well as approved AcrySof lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

**Warnings:** Appropriate use of CENTURION Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, power usage during occlusion conditions (beeping tones), failure to sufficiently aspirate viscoelastic prior to using power, excessively tight incisions, and combinations of the above actions may result in significant temperature increases at incision site and inside the eye, and lead to severe thermal eye tissue damage.

Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. Ensure that tubings are not occluded or pinched during any phase of operation.

The consumables used in conjunction with ALCON instrument products constitute a complete surgical system. Use of consumables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.

**AEs/Complications:** Inadvertent actuation of Prime or Tune while a handpiece is in the eye can create a hazardous condition that may result in patient injury. During any ultrasonic procedure, metal particles may result from inadvertent touching of the ultrasonic tip with a second instrument. Another potential source of metal particles resulting from any ultrasonic handpiece may be the result of ultrasonic energy causing micro abrasion of the ultrasonic tip.

**Attention:** Refer to the Directions for Use and Operator's Manual for a complete listing of indications, warnings, cautions and notes.

## LenSx Laser

**Caution:** United States Federal Law restricts this device to sale and use by or on the order of a physician or licensed eyecare 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 that 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.

**ProVisc**

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

**Indication:** ProVisc OVD is indicated for use as an ophthalmic surgical aid in the anterior segment during cataract extraction and intraocular lens (IOL) implantation. Ophthalmic viscoelastics serve to maintain a deep anterior chamber during anterior segment surgery allowing reduced trauma to the corneal endothelium and surrounding ocular tissues. They help push back the vitreous face and prevent formation of a flat chamber during surgery.

**Contraindications:** At present there are no known contraindications of the use of ProVisc Ophthalmic Viscosurgical Device when used as recommended.

**Warnings/Precautions:**

- Postoperative increases in intraocular pressure have been reported with sodium hyaluronate products. The IOP should be carefully monitored and appropriate therapy instituted if significant increases should occur. It is recommended that ProVisc OVD be removed by irrigation and/or aspiration at the close of surgery. Do not overfill anterior chamber. Although sodium hyaluronate is a highly purified biological polymer the physician should be aware of the potential allergic risks inherent in the use of any biological material; care should be used in patients with hypersensitivity to any components in this material. Cannula assembly instructions should be followed to prevent patient injury.
- Postoperative inflammatory reactions such as hypopyon and iritis have been reported with the use of ophthalmic viscoelastics, as well as incidents of corneal edema, corneal decompensation, and a transient rise intraocular pressure.

**Attention:** Reference the directions for use for a complete listing of indications, warnings and precautions.

**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 preoperative surgical planning functions that utilize the reference image and preoperative 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 preoperative measurement and surgery, an irregular elliptic 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 uninterruptible. 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.

**VISCOAT**

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

**Indication:** VISCOAT OVD is indicated for use as a surgical aid in anterior segment procedures including cataract extraction and intraocular lens (IOL) implantation. VISCOAT OVD maintains a deep chamber during anterior segment surgeries, enhances visualization during the surgical procedure and protects the corneal endothelium and other ocular tissues. The viscoelasticity of the solution maintains the normal position of the vitreous face and prevents formation of a flat chamber during surgery.

**Contraindications:** At present there are no known contraindications of the use of VISCOAT Ophthalmic Viscosurgical Device when used as recommended.

**Warnings/Precautions:**

- Failure to follow "Directions for Use" on attachment of the cannula or use of an alternate cannula may result in cannula detachment.
- Precautions are limited to those normally associated with the surgical procedure being performed. Although sodium hyaluronate and sodium chondroitin sulfate are highly purified biological polymers, the physician should be aware of the potential allergic risks inherent in the use of any biological material.
- A transient rise in intraocular pressure in the early postoperative period may be expected due to the presence of sodium hyaluronate, which has been shown to effect such a rise. It is therefore recommended that VISCOAT OVD be removed from the anterior chamber by thorough irrigation and/or aspiration at the end of the surgery to minimize postoperative IOP increases. Do not overfill anterior chamber.

**Attention:** Reference directions for use for a complete listing of indications, warnings and precautions.

