DESIGNED TO HELP YOU CONSISTENTLY HIT YOUR Cataract Refractive TARGET

VERION™
IMAGE GUIDED SYSTEM

Image.
Plan.
Guide.

Alcon
a Novartis company
What is the VERION™ Image Guided System*?

Joining other leading technologies from Alcon, the VERION™ Image Guided System is designed to offer enhanced precision, consistency and control in cataract refractive surgery.

The VERION™ Image Guided System can help give you the confidence to successfully deliver advanced technology outcomes.

* The VERION™ Image Guided System is composed of the VERION™ Reference Unit and the VERION™ Digital Marker.
Why do you need the VERION™ Image Guided System?

Today’s ophthalmic surgeons have the ability to not only treat patients’ cataracts but to help deliver targeted refractive outcomes. In fact, as patient expectations continue to increase, achieving consistent refractive outcomes is more important than ever.

However, postoperative refractive error can be impacted by many different factors, both in surgical planning and execution of the plan. Limitations in current technologies and measurement methods can impact patients’ visual outcomes.

Comprehensive IOL and astigmatism planning, as well as incision and IOL positioning that account for cyclorotation and visual axis landmarks, need to be performed precisely every time to achieve consistent refractive results.

With so many variables, this level of precision and consistency can be difficult to implement.
The VERION™ Reference Unit

The VERION™ Reference Unit allows surgeons to create a customized procedure for each patient by performing key diagnostic measurements and capturing a high-resolution image of the eye in a single step. This “fingerprint of the eye” is used for registration and tracking of the eye for position reference of the incisions, capsulotomy and the IOL.

Measurement data is automatically imported into the planning software. With the VERION™ Reference Unit, surgeons can now confidently create the comprehensive blueprint for cataract refractive surgery.
The VERION™ Digital Marker

The surgical plan and eye image are transferred by USB stick from the VERION™ Reference Unit to the VERION™ Digital Marker during the execution phase of the procedure.

Using the reference image as a “fingerprint,” the VERION™ Digital Marker allows surgeons to position all incisions and alignment in real time while accounting for the variable impact of cyclorotation.
The VERION™ Digital Marker

The VERION™ Digital Marker can be used with the LenSx® Laser as well as most surgical microscopes.
The Image, Plan, Guide Workflow

From imaging to planning to guiding your surgical execution, the VERION™ Image Guided System is designed to help reduce the potential for refractive error, allowing you to confidently make your surgical plan and consistently deliver the corrected vision your patients expect and deserve.

Learn how the VERION™ Image Guided System facilitates each stage of the cataract surgery workflow. (Tap an image.)
The VERION™ Reference Unit creates a high-resolution digital image of the patient’s eye, capturing scleral vessels, limbus and iris features.

Measurements taken by the VERION™ Reference Unit include:

- Dynamic keratometry
- Limbus position and diameter
- White-to-white horizontal distance
- Pupillometry
- Corneal reflex position
- Eccentricity of the visual axis
Convenient Customized Surgical Planning

You can also use the VERION™ Image Guided System to simply and confidently develop your surgical plan — on patients with or without astigmatism.

Patient measurement data is automatically imported into the planning software. This streamlined prepopulating of data fields helps optimize planning efficiency and minimize transcription errors.

In addition, all ALCON® IOLs — including toric and multifocal lenses — come preloaded in the VERION™ Reference Unit for easy planning. This allows for optimization of A-constants over time for more reproducible outcomes.
Convenient Customized Surgical Planning

You can efficiently select the IOL and lens power for your patients using your choice of multiple established formulas provided in a simple drop-down format.

(Tap the image to expand.)
Convenient Customized Surgical Planning

The VERION™ Reference Unit also provides comprehensive astigmatism management. Surgeons can now determine optimum incision locations to individualize surgically induced astigmatism and toric lens powers at the same time.
Optimized Incision and IOL Positioning

With the LenSx® Laser, the VERION™ Digital Marker facilitates streamlined data entry as well as pre-positioning of the surgical incision overlays using the reference image. The LenSx® Laser uses auto-focus and image-focus tracking to dock and align the patient under the laser, and to position the corneal incision, capsulotomy and fragmentation patterns.

Working in concert with a Microscope Integrated Display, or MID, the VERION™ Digital Marker also provides real-time tracking overlays through the optics of a surgical microscope. These computer-generated overlays offer a new measure of consistency and control for every surgical step of the procedure, including:

- An incision guide
- Capsulorhexis guide for precise ELP
- Centration guide for multifocal IOL positioning
- Toric alignment guide for lens positioning
- Elimination of the need for manual toric marking
GUIDE.

Synchronized Workflow

Every procedure can benefit from an improved workflow experience. The VERION™ Image Guided System synchronizes with the CENTURION® Vision System using the VERION™ Link:

- Connects with the CENTURION® Vision System wireless foot pedal
- Allows surgeons to activate and deactivate digital overlays
- Provides the right overlay at exactly the right time
Summary

The VERION™ Image Guided System is designed to help you consistently achieve your refractive target.

See what the VERION™ Image Guided System can do for you. It might just change the way you perform cataract surgery.
**VERION™ REFERENCE UNIT AND VERION™ DIGITAL MARKER IMPORTANT PRODUCT INFORMATION**

**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.
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. Descemetocele 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.


ATTENTION: Refer to the LenSx® Laser Operator’s Manual for a complete listing of indications, warnings and precautions.
CENTURION® VISION SYSTEM IMPORTANT PRODUCT INFORMATION

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.

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