

IMPORTANT PRODUCT INFORMATION:

CONSTELLATION® VISION SYSTEM

CAUTION: Federal 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.

INDICATIONS FOR USE: The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery.

The ULTRAVIT® Vitrectomy Probe is indicated for vitreous cutting and aspiration, membrane cutting and aspiration, dissection of tissue and lens removal. The valved entry system is indicated for scleral incision, canulae for posterior instrument access and venting of valved cannulae. The infusion cannula is indicated for posterior segment infusion of liquid or gas.

The PUREPOINT® Laser is indicated for use in photocoagulation of both anterior and posterior segments of the eye including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including: Proliferative and nonproliferative retinopathy (including diabetic); choroidal neovascularization secondary to age-related macular degeneration; retinal tears and detachments; macular edema, retinopathy of prematurity; choroidal neovascularization; leaking microaneurysms.
- Iridotomy/Iridectomy for treatment of chronic/primary open angle glaucoma, acute angle closure glaucoma and refractory glaucoma.
- Trabeculoplasty for treatment of chronic/primary open angle glaucoma and refractory glaucoma.
- And other laser treatments including: internal sclerostomy; lattice degeneration; central and branch retinal vein occlusion; suturelysis; vascular and pigment skin lesions.

The FlexTip* laser probe is intended to be used with ALCON® 532nm laser systems.

The CONSTELLATION Vision System is also indicated for emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intra-ocular lens injection. The INTREPID® AutoSert® IOL Injector Handpiece is intended to deliver qualified AcrySof® intraocular lenses into the eye following cataract removal. The following system modalities additionally support the described indications:

- Ultrasound with UltraChopper® Tip achieves the functionality of cataract separation.
- The INTREPID® AutoSert® IOL Injector Handpiece achieves the functionality of injection of intraocular lenses. The INTREPID® AutoSert® IOL Injector Handpiece is indicated for use with AcrySof® lenses SN60WF, 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 AND PRECAUTIONS:

- The disposables used in conjunction with ALCON® instrument products constitute a complete surgical system. Use of disposables and handpieces other than those manufactured by Alcon may affect system performance and create potential hazards.
- Attach only Alcon supplied consumables to console and cassette luer fittings. Do not connect consumables to the patient's intravenous connections.
- Mismatch of consumable components and use of settings not specifically adjusted for a particular combination of consumable components may create a patient hazard.
- Vitreous traction has been known to create retinal tears and retinal detachments.
- The closed loop system of the CONSTELLATION® Vision System that adjusts IOP cannot replace the standard of care in judging IOP intraoperatively. If the surgeon believes that the IOP is not responding to the system settings and is dangerously high or low, this may represent a system failure. Note: To ensure proper IOP Compensation calibration, place infusion tubing and infusion cannula on a sterile draped tray at mid-cassette level during the priming cycle.
- Leaking sclerotomy may lead to post operative hypotony.
- Back scattered radiation is of low intensity and is not harmful when viewed through a protective filter. All personnel in the treatment room must wear protective eyewear, OD4 or above at 532nm, when the system is in Standby/Ready mode as well as during treatment. The doctor protection filter is an OD greater than 4 at 532nm.
- The infusion cannula is contraindicated for use of oil infusion.
- Attach only Alcon supplied products to console and cassette luer fittings. Improper usage or assembly could result in a potentially hazardous condition for the patient. Mismatch of surgical components and use of settings not specifically adjusted for a particular combination of surgical components may affect system performance and create a patient hazard. Do not connect surgical components to the patient's intravenous connections.
- Each surgical equipment/component combination may require specific surgical setting adjustments. Ensure that appropriate system settings are used with each product combination. Prior to initial use, contact your Alcon sales representative for in-service information.
- Care should be taken when inserting sharp instruments through the valve of the Valved Trocar Cannula. Cutting instrument such as vitreous cutters should not be actuated during insertion or removal to avoid cutting the valve membrane. Use the Valved Cannula Vent to vent fluids or gases as needed during injection of viscous oils or heavy liquids.
- Visually confirm that adequate air and liquid infusion flow occurs prior to attachment of infusion cannula to the eye.
- Ensure proper placement of trocar cannulas to prevent sub-retinal infusion.
- Minimize light intensity and duration of exposure to the retina to reduce the risk of retinal photic injury.
- 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

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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.

- Adjusting aspiration rates or vacuum limits above the preset values, or lowering the IV pole below the preset values, may cause chamber shallowing or collapse which may result in patient injury.
- When filling handpiece test chamber, if stream of fluid is weak or absent, good fluidics response will be jeopardized. 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.

ADVERSE EVENTS/COMPLICATIONS: Use of handpieces during intraocular procedures in the absence of irrigation flow and/or in the presence of reduced or lost aspiration flow can cause excessive heating and potential thermal injury to adjacent eye tissues.

ATTENTION: Please refer to the CONSTELLATION® Vision System Operators Manual for a complete listing of indications, warnings, and precautions.

*Trademarks are property of their respective owners.

GRIEBHABER® DSP INSTRUMENTS

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

INDICATIONS FOR USE: GRIESHABER® DSP instruments are a line of single-use vitreoretinal micro-instruments which are used in ophthalmic surgery, for cases either in the anterior or the posterior segment. The GRIESHABER® Advanced Backflush Handles DSP are a family of instruments for fluid and gas handling in vitreoretinal surgery.

WARNINGS AND PRECAUTIONS:

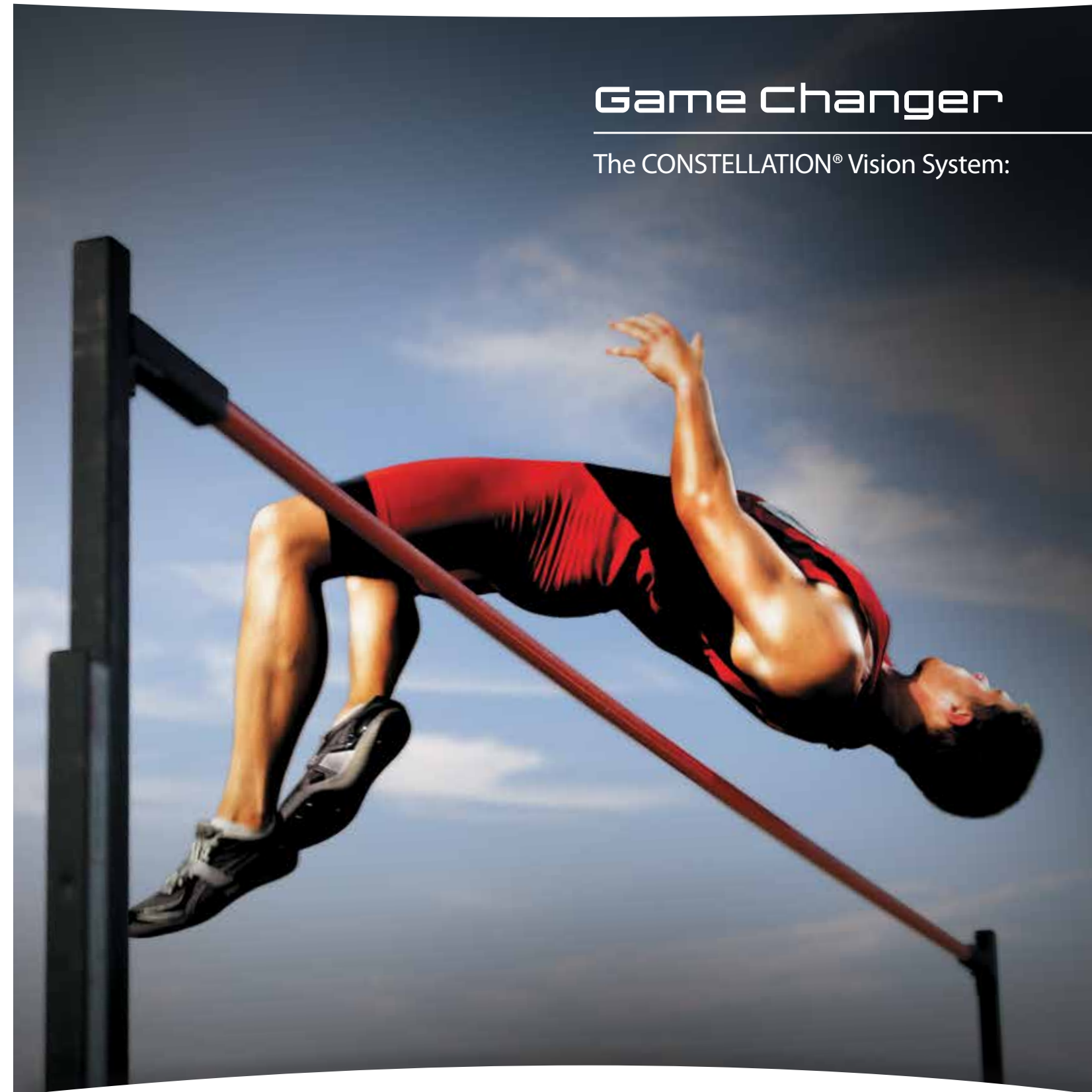
- Potential risk from reuse or reprocessing GRIESHABER® DSP instruments include: foreign particle introduction to the eye; reduced cutting or grasping performance; path leaks or obstruction resulting in reduced fluidics performance.
- Verify correct tip attachment, function and tip actuation before placing it into the eye for surgery.
- For light fiber instruments: Minimize light intensity and duration of exposure to the retina to reduce risk of retinal photic injury. The light fiber instruments are designed for use with an ALCON® illumination source.
- Good clinical practice dictates the testing for adequate irrigation and aspiration flow prior to entering the eye. If stream of fluid is weak or absent, good fluidics response will be jeopardized.
- Use appropriate pressure supply to ensure a stable IOP.
- If unwanted tissue gets engaged to the aspiration port, it should be released by interrupting aspiration before moving the instrument.

ATTENTION: Please refer to the product labeling for a complete listing of indications, warnings, and precautions.

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2. Buboltz, DC. New Method for Evaluating Flow Rates and Intraocular Pressures During Simulated Vitreoretinal Surgeries. Poster, ARVO Congress, 2010. Fort Lauderdale, FL.
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4. Nagpal M, Wartikar S, Nagpal K. Comparison of clinical outcomes and wound dynamics of sclerotomy ports of 20, 25, and 23 gauge vitrectomy. *Retina*. 2009;29(2):225-231.
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¹Based on bench lab testing.



Game Changer

The CONSTELLATION® Vision System:

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mivs
THE MICROINCISIONAL EDGE

constellation
VISION SYSTEM

Vitreoretinal surgery has changed forever

Experience the CONSTELLATION® Vision System

Featuring some of the most advanced technologies ever developed for vitreoretinal surgery, the CONSTELLATION® Vision System has raised the bar in surgical efficiency, speed and control. Not just an evolution, but a quantum leap forward, the CONSTELLATION® Vision System puts game-changing surgical capabilities and techniques within reach. What was once only imaginable is now possible:

- The ULTRAVIT® High-Speed probe provides the benefit of faster cutting and smaller vitreous bites without fluidic compromise.¹
- Trust in integrated and stable IOP compensation^{2,3}
- Helps to enhance patient outcomes and achieve faster visual recovery with ALCON® MIVS platforms⁴
- Increase efficiency during cataract removal with OZil® Torsional Handpiece^{5,6}
- Improve your OR set up time by 36% with V-LOCITY® Efficiency Components⁷

An unprecedented level of performance and control has arrived.⁸

Please refer to the back cover for important product information about these products.

Indications for Use: The CONSTELLATION® Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e., phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery.



“The CONSTELLATION® Vision System allows for completely new approaches and techniques in vitreoretinal surgery. I am convinced that this machine has made me a better and more efficient surgeon.”

– Pravin Dugel, MD*

*Pravin Dugel, MD is a paid consultant for Alcon.

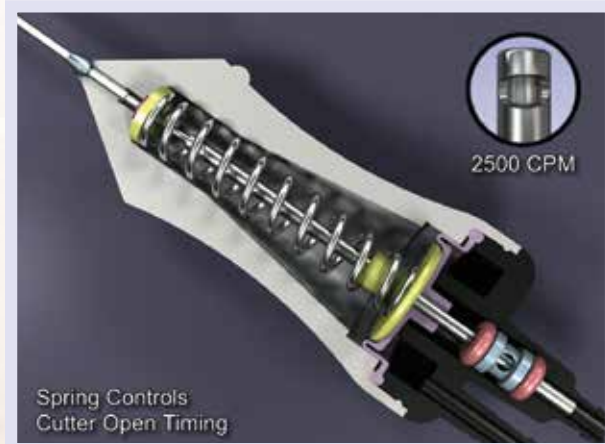
Rewriting the rules of vitreoretinal surgery

Surgeon-Controlled Duty Cycle

The high-speed ULTRAVIT® probe with variable duty cycle is unique to the CONSTELLATION® Vision System, allowing surgeons to experience true versatility and control every time. By controlling flow independent of vacuum and at any cut rate, surgeons can do more than ever before:

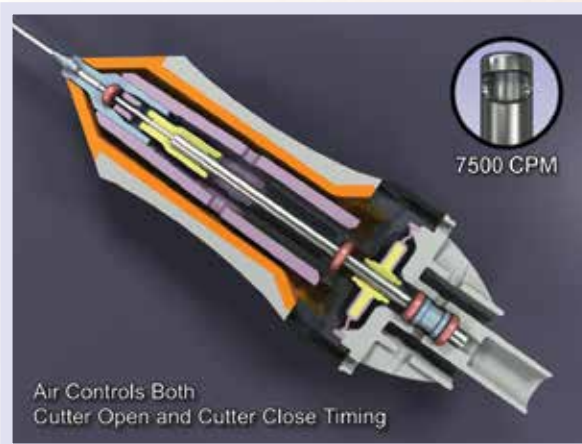
- Features proprietary ALCON® ULTRAVIT® dual pneumatic drive technology
- Ensures precision and confidence for the most delicate procedures⁹
- Optimizes cutting and aspiration control⁸
- Features multiple duty cycle options: core (biased-open), 50/50 and shave (biased-closed)

Spring-driven probe interior



Traditional spring-driven probes have duty cycle limitations at high cut speeds, causing flow limitations.¹⁰

ULTRAVIT® dual pneumatic drive interior

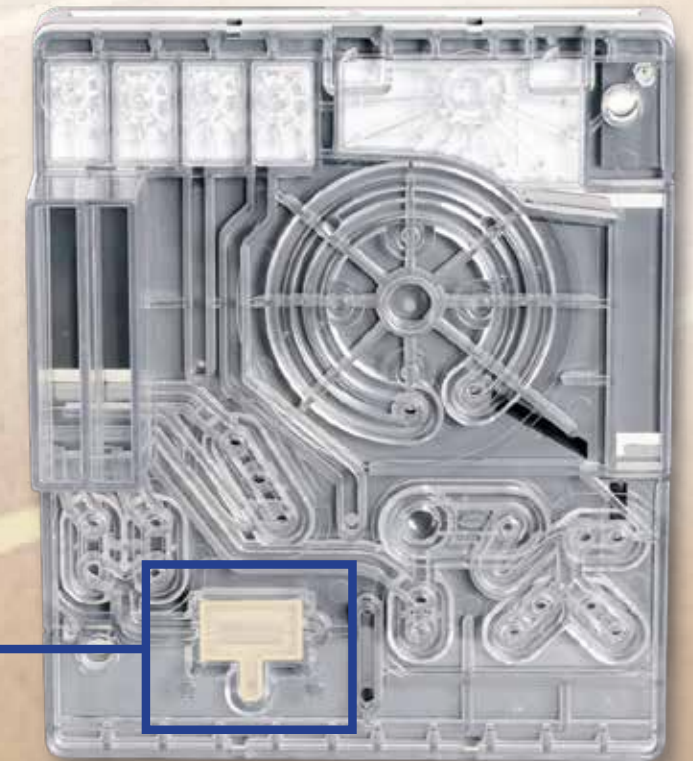


With duty cycles that are independent of cut rate, the CONSTELLATION® Vision System allows for easy alteration from core to peripheral vitrectomy and shaving of mobile retina.

Stable IOP Control

The CONSTELLATION® Vision System compensates for and provides command of infusion pressure for more stable¹⁰ IOP control. With real-time infusion adjustments, the CONSTELLATION® Vision System adds a new measure of stability to vitrectomy procedures:

- Features proprietary ALCON® Non-Invasive Flow Sensor technology
- Enables excellent control and constant globe stability¹¹
- Allows surgeons to implement bottle changes without procedure interruption
- Includes low and empty bottle alerts



Non-Invasive Flow Sensor

The CONSTELLATION® Vision System's with premium cassette **Non-Invasive Flow Sensor** facilitates exceptional IOP stability during vitrectomy, cataract and combined procedures.¹¹

Please refer to the back cover for important product information about these products.

"IOP stability with the CONSTELLATION® Vision System, matched with the valved cannulas may reduce peri-operative pressure changes."¹²

– Carl Claes, MD*

*Carl Claes, MD is a paid consultant for Alcon.

The closed loop system of the CONSTELLATION® Vision System that adjusts IOP cannot replace the standard of care in judging IOP intraoperatively. If the surgeon believes that the IOP is not responding to the system settings and is dangerously high or low, this may represent a system failure.

Efficient vitrectomy and cataract procedures in a single system

OZil® Torsional Handpiece

Only the OZil® Torsional Handpiece delivers patented side-to-side oscillating ultrasonic movement. With reduced repulsion, it is the new standard in followability and efficiency:

- Decreases repulsion and improves followability^{5,6}
- Facilitates occlusion and effective energy delivery into nuclear fragments¹³
- Potentially decreases dispersion of nuclear fragments^{6,14}
- Offers an improved thermal profile¹⁵⁻¹⁷
- Provides a platform for effective micro-coaxial cataract surgery^{5,18}



V-LOCITY® Efficiency Components

The proprietary V-LOCITY™ Efficiency Components found only on the CONSTELLATION® Vision System are helping to optimize OR setup, enhance the surgical experience and increase productivity⁷:

- ENGAUGE® RFID automatically recognizes each device being connected
- Video tutorials help users conduct a faster, error-free setup
- Articulating tray arm allows for sterile setup between cases
- End-case metrics reports track laser shot counts, procedure time and more
- One-button Push Prime helps speed priming sequence
- Integrated VGFI™ tubing eliminates pre-spike and snorkel placement



RFID Ports improve efficiency, safety and setup

Perfect your technique while discovering completely new ones.

Please refer to the back cover for important product information about these products.

“The V-LOCITY® Efficiency Components on the CONSTELLATION® Vision System makes the procedure more seamless and have improved our OR set-up time.”

– Dawn Williams, RN*

Back scattered radiation is of low intensity and is not harmful when viewed through a protective filter. All personnel in the treatment room must wear protective eyewear, OD4 or above at 532nm, when the system is in Standby/Ready mode as well as during treatment. The doctor protection filter is an OD greater than 4 at 532nm.

Integrated PUREPOINT® Laser

With the fully integrated PUREPOINT® Laser, the CONSTELLATION® Vision System gives surgeons exceptional laser precision and control. Intuitively designed for improved functionality and ease of use, the PUREPOINT® Laser features:

- Laser control from the CONSTELLATION® Vision System monitor
- Thin disc laser technology
- The assurance of voice confirmation technology
- Dual ports for simplified transition from endoprobe to LIO
- Customizable multi-function foot pedal for complete surgeon control



Illuminated Laser Probe

Combining laser with illumination in a curved, flexible tip, the Illuminated Laser Probe offers a wide range of benefits:

- Can be used in 23G, 25+® and 27+® series procedures
- Probe tip temporarily straightens to pass through trocar cannula
- The flexible nitinol tip extends from a rigid tapered cannula



Chandelier Lighting System

The ALCON® Chandelier Lighting System gives surgeons the ability to clearly perform vitreoretinal surgery with broad illumination:

- Able to engage in either 23G or 25+™ cannula hubs
- Provides a wider coverage area than standard or wide-angle systems
- Offers an illumination angle of 106°



Additional ALCON® lighting and laser probe accessories are available.

