**CONSTELLATION® System with PUREPOINT® Laser Brief Statement**

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

**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.

**Contraindications:**

- Patients with a condition that prevents visualization of target tissue (cloudy cornea, or extreme haze of the aqueous humor of the anterior chamber of vitreous humor) are poor candidates for LIO delivered laser treatments.
- The infusion cannula is contraindicated for use of oil infusion.

**Complications:** Corneal burns, inflammation, loss of best-corrected visual acuity, loss of visual field and transient elevations in intraocular pressure can occur as a result of ophthalmic laser treatment. Unintentional retinal burns can occur if excessive treatment beam power or duration is used.

**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 sclerotomies 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.

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

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