

CATALYS® Precision Laser System

INDICATION & IMPORTANT SAFETY INFORMATION FOR THE CATALYS™ Precision Laser System

Indications

The CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of 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.

Contraindications

The CATALYS® System is contraindicated in patients with corneal ring and/or inlay implants, severe corneal opacities, corneal abnormalities, significant corneal edema or diminished aqueous clarity that obscures OCT imaging of the anterior lens capsule, patients younger than 22 years of age, descemetocoele with impending corneal rupture, and any contraindications to cataract surgery.

Warnings

Prior to INTEGRAL GUIDANCE System imaging and laser treatment, the suction ring must be completely filled with sterile buffered saline solution. If any air bubbles and/or a meniscus appear on the video image before treatment, do not initiate laser treatment. Before initiating laser treatment, inspect images created from the OCT data, surface fits, and overlaid pattern in both axial and sagittal views, and review the treatment parameters on the Final Review Screen for accuracy. Safety margins for all incisions are preserved only if Custom Fit Adjustments to ocular surface(s) are applied in accordance with the instructions for use. Purposeful misuse of the Custom Fit Adjustment to ocular surfaces can result in patient injury and complication(s), and therefore must be avoided. Standard continuous curvilinear capsulorhexis (CCC) surgical technique must be used for surgical removal of the capsulotomy disc. The use of improper capsulotomy disc removal technique may potentially cause or contribute to anterior capsule tear and/or a noncircular, irregularly shaped capsulotomy. Verify that the suction ring is correctly connected to the disposable lens component of the LIQUID OPTICS Interface during the initial patient docking procedure.

Precautions

The CATALYS® System has not been adequately evaluated in patients with a cataract greater than Grade 4 (via LOCS III); therefore no conclusions regarding either the safety or effectiveness are presently available. Cataract surgery may be more difficult in patients with an axial length less than 22 mm or greater than 26 mm, and/or an anterior chamber depth less than 2.5 mm due to anatomical restrictions. Use caution when treating patients who may be taking medications such as alpha blockers (e.g. Flomax) as these medications may be related to Intraoperative Floppy Iris Syndrome (IFIS); this condition may include poor preoperative dilation, iris billowing and prolapse, and progress intraoperative miosis. These conditions may require modification of surgical technique such as the utilization of iris hooks, iris dilator rings, or viscoelastic substances. Surgical removal of the cataract more than 30 minutes after the laser

capsulotomy and laser lens fragmentation has not been clinically evaluated. The clinical effects of delaying surgical removal more than 30 minutes after laser anterior capsulotomy and laser lens fragmentation are unknown. The LIQUID OPTICS Interface is intended for single patient use only. Full-thickness corneal cuts or incisions should be performed with instruments and supplies on standby, to seal the eye in case of anterior chamber collapse or fluid leakage. Patients who will undergo full-thickness corneal incisions with the CATALYS® System should be given the same standard surgical preparation as used for patients undergoing cataract surgery for the removal of the crystalline lens. During intraocular surgery on patients who have undergone full-thickness corneal incisions with the CATALYS™ System, care should be taken if an eyelid speculum is used, in order to limit pressure from the speculum onto the open eye. Patients who will be transported between the creation of a full-thickness corneal incision and the completion of intraocular surgery should have their eye covered with a sterile rigid eye shield, in order to avoid inadvertent eye injury during transport. Patients must be able to lie flat and motionless in a supine position and able to tolerate local or topical anesthesia.

Adverse Effects

Complications associated with the CATALYS® System include mild Petechiae and subconjunctival hemorrhage due to vacuum pressure of the LIQUID OPTICS Interface Suction ring. Potential complications and adverse events generally associated with the performance of capsulotomy and lens fragmentation, or creation of partial-thickness or full-thickness cut or incision of the cornea, include: Acute corneal clouding, age-related macular degeneration, amaurosis, anterior and/or posterior capsule tear/rupture, astigmatism, capsulorhexis notch during phacoemulsification, capsulotomy/lens fragmentation or cut/incision decentration, cells in anterior chamber, choroidal effusion or hemorrhage, conjunctival hyperemia/injection/erythema/chemosis, conjunctivitis (allergic/viral), corneal abrasion/depithelization/epithelial defect, corneal edema, cystoid macula edema, Descemet's detachment, decentered or dislocated intraocular lens implant, diplopia, dropped or retained lens, dry eye/superficial punctate keratitis, edema, elevated intraocular pressure, endothelial decompensation, floaters, glaucoma, halo, inflammation, incomplete capsulotomy, intraoperative floppy iris syndrome, iris atrophy/extrusion, light flashes, meibomitis, ocular discomfort (e.g., pain, irritation, scratchiness, itching, foreign body sensation), ocular trauma, petechiae, photophobia, pigment changes/pigment in corneal endothelium/ foveal region, pingueculitis, posterior capsule opacification, posterior capsule rupture, posterior vitreous detachment, posteriorly dislocated lens material, pupillary contraction, red blood cells in the anterior chamber (not hyphema), residual cortex, retained lens fragments, retinal detachment or hemorrhage, scar in Descemet's membrane, shallowing or collapsing of the anterior chamber, scoring of the posterior corneal surface, snailtrack on endothelium, steroid rebound effect, striae in Descemet's, subconjunctival hemorrhage, thermal injury to adjacent eye tissues, toxic anterior shock syndrome, vitreous in the anterior chamber, vitreous band or loss, wound dehiscence, wound or incision leak, zonular dehiscence.

Caution

Federal law (USA) restricts this device to sale by or on the order of a physician. The system should be used only by qualified physicians who have extensive knowledge of the use of this device and have been trained or certified.

Attention

Reference the Directions for Use for a complete listing of indications, warnings, and precautions.

