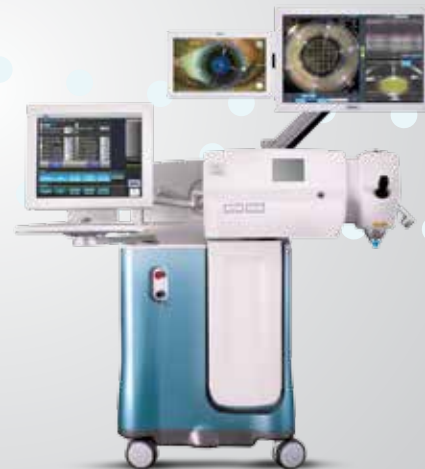




LenSx® Quick Reference Guide



Time Out

- Verify Patient Information with surgeon.
- Sterile Patient Interface (PI) positioned for correct eye.
- "PI" displayed on the Status Bar of the User Interface.
- Primary Incision placement is correct for operative eye.
- Verify Arcuate Incision Depth%, Arc Angle and Arc Position match surgeon's pre-op notes / treatment plan.

Docking Sequence

- Using gantry / delivery system touch screen, select Camera Focus preset "P1"
- Use the joystick to center and lower the gantry ("Z-Down") until PI is approx. 1" to 1.5" from patient's eye.
- Activate fixation light by touching "Fixation Light" button.
- Select "DOCK" on User Interface to activate Auto-Focus.
- Wait 2 seconds and then continue to "Z-Down" until Patient Interface contacts the eye.
- "CONTACT" is displayed on the Status Bar of the User Interface and Video Microscope/OCT (VM/OCT).

PI Suction

- Continue to "Z-Down" until a fluid meniscus encompasses at least 1/2 of the eye on the VM.
- Enable suction by touching the "PI SUCTION" button on the lower left corner of the User Interface touchscreen.
- "SUCTION" should appear on the Status Bar of the User Interface.
- After suction is applied, continue to "Z-Down" until the Applanation Indicator's white bar on is in the Green Zone.
- "DOCKED" should be displayed on the Status Bar of the User Interface.

Video Microscope Incision Placement Advanced Pre-Positioning **

- With Suction On and the Applanation Indicator in the Green, Press ONE TIME on the Joystick Button to activate Pre-Positioning.
- At the top of the VM/OCT Limbus, Primary, Secondary, Lens, and Arcuate Pattern Placement Indicators should change from Gray to Green.

Cyclorotation Registration

- Adjust for cyclorotation by clicking on the clockwise or counter-clockwise arrows on the bottom of the VM. Each click = 1° of rotation. This rotates all incisions.
- Select "SCAN".

OCT Depth Measurements Circle Scan OCT Adjustments

- Verify Phase Control Point (pink vertical line) - intersects the highest point of the Posterior Capsule
- Verify placement of capsulotomy control points (pink & yellow crosshairs on the Anterior Capsule) - Make adjustments if necessary and click "ACCEPT".

Line Scan OCT Adjustment

Two solid purple vertical line segments are displayed representing the Capsulotomy Pattern. The lens treatment volume is represented by the yellow overlay defining diameter and depth of lens treatment.

- Make adjustments if necessary and click "ACCEPT".

Cornea Thickness OCT measurements (Primary, Arcuate incisions)

Corneal thickness value is determined by setting the Epithelial and Endothelial control points. The numeric values are updated as these control points are moved.

- Click "ACCEPT" after reviewing/adjusting control points for Primary OCT and Arcuate OCT.

Preparing the System to Treat

- Click "VERIFY AND ACCEPT" (bottom of VM/OCT).
- On User Interface touch "APPLY TO PATIENT" button.
- On User Interface touch "TREAT" button.
- Depress and hold Footswitch to treat.
- Lift Footswitch to interrupt treatment.

** To manually place incisions in the event Pre-Positioning does not register:

Video Microscope Manual Incision Placement Limbus centration, Primary, & Secondary Placement

- Place the cursor on the control point and drag to center of limbus, click control point again.
- Click on the Primary Incision control point and move the graphical overlay to the desired position.
- Click on the Secondary Incision control point and move the graphical overlay to the desired position.
- To manually override programmed placement (degree location) of Primary or Secondary, click Corneal Incision Position at bottom left corner of screen and reselect incision to move to desired position.

Lens Centration

- Click "LENS CENTR" button on VM screen.
- Click the center control point to adjust the Lens / Capsulotomy Pattern to within the dilated pupil as desired.

Arcuate Incision Position and Diameter Adjustment

- Click the center Arcuate Incision control point and adjust to corneal center as desired.
- Select "SCAN".

Trouble-Shooting guide for replacing a PI during a LenSx® procedure:

If a user experiences any event requiring a Patient Interface (PI) replacement during the LenSx® procedure:

1. Disconnect the PI from the LenSx® suction port. The suction port light will turn from green to amber. **If a suction error occurs clear the Error.**
2. **Return to The PI Suction window by clicking “QUIT” or “STOP” on the VM/OCT**
3. Return to the Programming Window by clicking the Back Arrow Button (red circle) **on The PI Suction Window.**
4. You will then see the **Programming Window** with the incision “Select” buttons.
5. Connect a new PI with new SoftFit to the suction port and take note that the suction port light will turn from amber to green.
6. **Reprogram, Re-Dock and Proceed, taking care to deselect any completed or partially completed incisions.**

PI Suction Window



Programming window



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 appplanation 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 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 appplanation 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.

While the risk of fire is extremely low, the LenSx® Laser should not be operated in the presence of flammable anesthetics, volatile substances, or oxygen flow lines.