Laser Refractive Cataract Surgery with the LenSx® Laser
LenSx® Laser Important Safety 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 1030nm 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, glaucoma, 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)
• This device is not intended for use in pediatric surgery
• A history of lens with zonular instability.
• Any contraindication to cataract or keratoplasty surgery.

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

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.

AEs/Complications:
• Capsulotomy, phacofragmentation, or cut or incision decenteration
• 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
The Changing Face of Cataract Surgery

The Baby Boomer Generation

- Large, rapidly growing demographic
- Educated, financially secure
- Increased life expectancy
- Longer working careers
- Demand high quality vision (reading, distance, night vision)
- New requirement for near vision (computers)
- Unwilling to compromise active lifestyle
- Embracing demand driven healthcare
The Need for Improvement

Adapted from FDA Clinical Data: Crystalens* and WaveLight® Trials

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# Limitations of Traditional Cataract Surgery

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Improved Refractive Cataract Surgery

IOL Position Predictability
- Uniform Shape and Size Capsulotomy

Corneal Astigmatism
- Reproducible Corneal Entry and Arcuate Incisions

Early Wow Factor
- Reduced Phaco Power and Corneal Edema

Norrby SJ, J Cataract Refract Surg 2008;34:368–376
The LenSx® Laser

A dynamic, platform technology designed to:

• Deliver the precision of a femtosecond laser to Refractive Cataract Surgery

• Rapidly advance the evolution of true image-guided intraocular surgery

• Advance the development of a more digitized, predictable approach to lens replacement surgery
Image-Guided Refractive Cataract Surgery
Manual Clear Corneal Incisions

Dynamics of wound architecture created with hand-held instruments¹:

- imprecise tunnel length and geometry
- frequently require stromal hydration to seal
- may result in cascading intraoperative difficulties (fluid control, anterior chamber maintenance)
- incisions may be unstable at low IOPs

Recent literature suggests an increased incidence of post-op infection²

LenSx® Laser Corneal Incisions

Customized wound architecture and placement

Self-sealing incisions
Effective Lens Position (ELPo)

• “The key to highly accurate IOL power calculation is being able to correctly predict ELPo for any given patient and IOL”

• ELPo for the 5 formulas commonly in use are:
  – SRK/T d = A-constant
  – Hoffer Q d = pACD
  – Holladay 1 d = Surgeon Factor
  – Holladay 2 d = ACD
  – Haigis d = a0 + (a1 * ACD) + (a2 * AL)

• ELPo is assumed value, from empirical data (A constant and surgeon factor)
• A significant source of IOL power error and key to post surgery refraction
• Size of capsulorhexis effects ELPo


Factors Affecting IOL Predictability

If IOL is 0.5 mm posterior to the assumed plane, a 21 D lens will produce only 20 D of correction.

If IOL is 0.5 mm anterior to the assumed plane, a 21 D lens will produce 22 D of correction.

Consistent capsulorhexis diameter is critical to Effective Lens Position¹,²

- A 4 mm capsulorhexis results in longer post-operative ELPo than does a 6 mm capsulorhexis for the type of IOL used³

- To ensure that an IOL’s position in the bag matches the anticipated formula used to calculate its power, the capsulorhexis should be round, centered and smaller than the IOL optic²

Laser Fragmentation
Mechanism of Action

Chop Patterns

Cylinder Patterns
LenSx® Laser Phacofragmentation

- Cylinder pattern, utilized for the softer lens, enables removal with I & A only, no phaco power

- Chop pattern efficiently fragments the lens for removal with reduced phaco power and time

\[ \text{Comparison of Average Phaco Power} \]

\[ \text{Comparison of Effective Phaco Time} \]

\[ \begin{align*}
\end{align*} \]
Hybrid Fragmentation Pattern*

- Combination of Cylinder and Chop Patterns
- Efficient for All Cataract Grades
- Rapid Lens Removal with Minimal Phaco Required
- Number of Cuts/Cylinders Totally Customizable

Manual Arcuate Incisions

- Manually executed by “tracing” corneal marks with handheld diamond knife
- Inconsistent depth control
- Unpredictable effect due to imprecise wound architecture and depth
- No image-guided surgical planning or visualization
LenSx® Laser Arcuate Incisions

Image-guided surgical planning with 3D visualization:

- Real time corneal thickness
- Computer programmed incisions
  - % depth
  - incision length and position
  - 3D visualization of incision placement
- Predictable incision width, tunnel length
- Titratable incisions
  - adjustable during surgical procedure
  - adjustable post-op at slit lamp


LSX12241SK
LenSx® Laser Arcuate Incision

- Square edge
- Uniform depth (no ripples)
- Precise, reproducible
  - Arc shape
  - Arc length
  - Diameter

Steinert RF, Application of the Femtosecond Laser in Cataract Surgery for the Creation of Multi-Planar, Self-Sealing Incisions, ASCRS 2010, Boston

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LenSx® Laser: Peer Reviewed Publications


LenSx® Laser vs Manual CCC, Monofocal IOL*

Analysis:

• Non-randomized, prospective, single site, single surgeon study
• Single lens type (Alcon SN60WF)
• Manual group (n=26)
  - Attempted 5.0mm capsulotomy
    Mastel 5.75 mm OZ marker to create 5.0 mm CCC
• LenSx® Laser group (n=22)
  - Femtosecond laser created 5.0 mm capsulotomy
• Accuracy to Target, Actual ELPo (LENSTAR® Optical Biometer – ACD)
• No significant difference in baseline between cohorts


LENSTAR is a registered trademark of Haag-Streit

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LenSx® Laser vs Manual CCC
Actual vs Predicted ELPo

Better ELPo predictability
➢ 71% of the variable’s variance result for the LenSx® Laser group Vs. only 29% for the manual group.

95% Confidence Intervals

R² = 0.709

R² = 0.2877

LenSx® Laser Group (n=22)

Manual Group (n=26)
Prediction Error Distribution

Frequency Distribution (%) of Eyes

Hyperopic

Spherical Equivalent Prediction Error (D) = Pred. Ref. - Actual 1M PostOP Ref.

Myopic

LenSx (n=22)
Manual (n=26)
Where Are We Today?

The LenSx® Laser

- The first femtosecond laser cleared in the US for all indications in cataract surgery:
  - Anterior Capsulotomy
  - Laser Phacofragmentation
  - Cataract Incisions, including Arcuate Incisions

- The only femtosecond laser globally commercialized to date for cataract surgery indication
Where Are We Today?

The LenSx® Laser

• More than 250 LenSx® Laser installations globally
• More than 60,000 LenSx® Laser procedures globally
• More than 1000 surgeons from 42 countries trained; utilizing LenSx® Laser in daily practice
• Accelerated innovation based upon actual user feedback
• Rapid practice conversion – intuitive benefits of laser refractive cataract surgery validated in clinical practice
• Early results demonstrate that the image-guided, LenSx® Laser capsulotomy positively influences the predictability of effective lens positioning.

1 Alcon LenSx Physician Training Records
Patient Expectations

• The medical milestone of cataract will be increasingly re-defined by lifestyle requirements
• This younger, active patient population will seek a surgical resolution much earlier than previous generations

LenSx® Laser technology provides the patient:

• Perceived benefits of a laser procedure
  - Computer controlled precision
  - Procedural predictability
• A comprehensive, advanced technology approach to lens replacement surgery
• An advanced technology, value-added surgical experience
Opportunity for Eyecare Providers

LenSx® Laser technology provides:

• Known benefits of femtosecond technology
  - Improved accuracy of all incisions
  - Predictability at every step

• True image-guided intraocular surgery
  - Opportunity to create optimal wound architecture
  - Precise capsulotomy design for every IOL

• A strong value proposition
  - A message that easily resonates with patients and staff
Thank You