Approximately 3.6 million cataract surgeries were performed in the USA and more than 20 million worldwide in 2015.[1] Cataracts result from the progressive opacification of the crystalline lens and lead to degradation of vision. Using established surgical techniques, the natural lens is removed and replaced with an intraocular lens. This is among the most common procedures performed by ophthalmic surgeons.

Femtosecond-laser assisted cataract surgery, with imaging guidance, is a modern technique enabling several essential elements of effective surgery:

1) well-centered capsulotomies with consistent diameter to build a strong foundation for stable IOL fixation,
2) consistent and accurately placed corneal incisions for resistance to wound leakage as well as arcuate incisions to address residual astigmatism and
3) performance of key steps including capsulotomy, lens pre-fragmentation and corneal incisions in the pre-operative environment for greater Operating Room/procedure efficiency.
Both patients and healthcare systems expect good to excellent visual outcomes following cataract surgery.[2] Great strides towards meeting these expectations are being made to improve consistency and efficiency of cataract surgery. To obtain optimal predictable visual outcomes, there are several critical elements for the surgeon as summarized in Table 1.

Table 1. List of important attributes that contribute to consistency and efficiency in the OR.

<table>
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<tr>
<th>Surgical Element</th>
<th>Clinical Significance</th>
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| 1. Well-centered continuous circular capsulorhexis of consistent diameter | ➢ Minimization of tears during surgical manipulation and phacoemulsification. Such tears can significantly increase surgical time as the surgeon aims to avoid further extension of the tear or drop of the lens posteriorly.  
➢ Establish a strong foundation for stable IOL fixation by achieving a complete 360 degree IOL-capsulorhexis overlap that minimizes the risk of IOL tilt and decentration. This is particularly needed for premium IOLs with advanced optical designs. |
| 2. Consistent and accurately placed corneal incisions (primary, secondary, arcuate incisions or LRIs) | ➢ Creating multi-planar corneal incisions to minimize risks associated with penetrating incisions, such as internal gaping corneal wounds or Descemet’s membrane detachment. This will increase resistance of wound leakage for penetrating incisions.  
➢ Planning precise arcuate incisions during the procedure to avoid manual error. |
| 3. Operating Room (OR)/Procedure Efficiency | ➢ OR time is among the most expensive components of cataract surgery. A reduction in the complexity of the procedure achieved through pre-operative planning activities enables greater efficiency in the OR, and thus potentially decreased procedure time and increased number of daily procedures. |

This whitepaper describes a solution that addresses each of the listed surgical elements. Continuing to read will help to equip the reader with knowledge on how to achieve consistency and efficiency during cataract surgery using femtosecond-laser assisted technology.
The femtosecond laser assisted cataract surgery (FLACS), also called “bladeless” cataract surgery, replaces manual incisions and the continuous curvilinear capsulorhexis (CCC). In addition, FLACS is also able to pre-fragment the lens. FLACS uses a near-infrared laser that separates tissues based on the principle of photodisruption. One fundamental benefit of FLACS is the image guidance that allows for visualization and specific placement of incisions in the cornea, anterior capsule and lens. Generally, a 3D optical coherence tomography (OCT) or a 3D spectral confocal structural illumination (CSI) is being used to visualize key anatomical landmarks of the eye in a cross-sectional fashion.

As outlined in the surgical element #1 in Table 1, the size, centration and circularity of the CCC are important determinants for the final position of the intraocular lens (IOL) and may affect the visual outcome of the patient. CCCs that are constructed too small, too large, and/or decentered can cause hyperopic or myopic shifts, IOL decentration or tilt. Achieving a well-sized, centered and circular capsulorhexis manually requires a lot of practice as the lens capsule is extremely thin and sharp angles can result in unwanted tears. The femtosecond laser assists in minimizing intra- and inter-surgeon variation of the capsulorhexis by constructing a capsulotomy of consistent size, centration and circularity based on the image taken by the OCT or CSI (Figure 1). [3] The laser also automatically considers the corneal magnification (the cornea magnifies the anterior capsule approximately 1.15 times) and adjusts for it.

Lens pre-fragmentation, placed accurately with the help of image guidance, significantly softens the lens and aids with ease of cataract extraction. Removing the nucleus and cortex faster reduces effective phacoemulsification time (EPT), cumulative dissipated energy (CDE) and minimizes postoperative corneal thickness as well as endothelial cell loss,[4, 5] which are especially critical for difficult cases, such as white or very dense cataracts.

**Figure 1. Capsulotomy with the LenSx® femtosecond laser.** Following docking of the patient interface (PI) to the patient’s eye, the circle OCT scan guides the user in adjusting the capsulotomy to the contour of the anterior capsule. The femtosecond laser creates a well-centered circular capsulotomy with an optimal diameter that minimizes IOL tilt and decentration.
Surgical element # 2 in Table 1 describes the need for consistent and accurately placed corneal incisions. Femtosecond laser assisted corneal incisions can be constructed as multi-planar self-sealing incisions with higher precision than any blade-created incisions.[6] Single, two or three planar incisions may be varied in their geometry to either trapezoid-in, trapezoid-out, or rectangular patterns. Again, the images taken with the image guided system allow for precise positioning and sizing of the primary and secondary incisions as well as consistent depth, location and size of arcuate incisions.

Completing these crucial planning steps outside the sterile environment of the OR may help save expensive OR cost or, depending on the configuration of the surgery center, perhaps allow for additional patients to be treated in a day (see Figure 3). Efficiency of the procedures (surgical element #3 in Table 1) may even be further improved by changing the set up model of the surgery center from a 1 OR : 1 Laser to a model in which a laser serves 2, 3 or more ORs.

Fine-tuning of workflow elements related to the laser requires time and cooperation from the surgical staff. While the laser incision planning requires additional time outside the OR, once the workflow is in place and initial learning curve is overcome, significant efficiency and consistency advantages may be achieved in the OR.

In some cases, FLACS may not be an option and conventional cataract surgery may still be necessary. The femtosecond laser necessitates a clear cornea and a well-dilated pupil to optimally image and plan for surgery. Any corneal diseases that result in corneal scarring or opacities interfere with the completeness of the laser application and cuts may not be complete. However, these are generally cases that are being identified before the surgery day by careful pre-operative assessments of the patient’s eye and recording into the patient’s chart.

**Figure 2. Three-planar primary corneal incision with the LenSx® femtosecond laser.** Image left: The primary incision can be placed adjacent to the limbus (up to 12mm) as shown with yellow box. Image right: The primary corneal incision can be planned with a three-planar self-sealing architecture.

**Figure 3. OR timings (in minutes) between femtosecond laser assisted cataract surgery using LenSx® laser and conventional surgery as conducted by a study in the UK. [12]**
The LenSx® laser is Alcon’s femtosecond laser platform for cataract surgery. The high-definition 3D spectral domain OCT is unique amongst other platforms on the market as it provides a 360-degree circle scan in addition to line scans along all meridians. A full view of anatomical landmarks of the eye is obtained in seconds without missing data or the need of stitching several images together which is critical to identify unwanted tilt of the eye and for precise planning of incisions. The new update to the LenSx® laser enables the user to clearly identify the limbus by de-magnifying the OCT image. Like in no other system, primary and secondary corneal incisions can be placed adjacent to the limbus (up to 12mm) to have close access to the iris plane and therefore establishing greater mobility in the capsular bag during lens removal.

The LenSx® laser is the only cataract femtosecond laser platform to use a non-liquid based docking system; a curved applanation patient interface with the LenSx SoftFit® insert. Hard surface interfaces produce posterior corneal folds during the docking procedure.[7] These folds alter the laser beam energy delivered to the anterior capsule and result in capsular tags. Alternative interfaces, such as the liquid based docking systems, have been introduced to reduce the occurrence of folds. Liquid based docking systems compress liquid that was added into the patient interface. The compressed liquid does not, however, compensate for the heart movement of the patient resulting in more than 150 micron movements of the eye.[8] To counteract the movement, more laser pulses and energy are needed to achieve incisions and lens fragmentation patterns. The LenSx® laser patient interface with a surgical field of view of 12.5 mm utilizes a proprietary soft hydrogel contact lens insert (SoftFit®) to minimize corneal distortion with lower IOP increase of 16 mmHg and to permit treatment of patients with glaucoma (except ocular hypotony in glaucoma).[9] The SoftFit® closely mimics the natural curvature of the eye and is available in several curvatures to accommodate for exceptionally flat corneas (less than 41D), normal corneas (41D to 46D) and exceptionally steep corneas (greater than 46D). An essential feature is also the live high-definition circle OCT as it assists the user in docking and minimizing tilt of the eye.

The LenSx® laser is the only laser today with the patented variable numeric aperture technology (see Figure 4). The variable numeric aperture allows the laser to focus precisely on each tissue and to set optimal laser settings for each tissue. The XYZ-focusing ability together with the SoftFit® patient interface enables the laser pulses to be placed evenly for optimal tissue bridge creation which the surgeon may choose to open during or after surgery.
Creating a linear laser pulse pattern is particularly important when creating a capsulotomy. Manual construction of a capsulorhexis has an anterior capsular tear complication rate that varies widely from 0.79 to 5.6%.[10] Capsular tags that occur with the femtosecond laser created cataractomies can result in a capsular tear. In a recent report of 3355 eyes, the anterior capsule tear rate with the LenSx® laser was 0.21%.[11] The rate was even less (0.08%) when only eyes with the SoftFit® patient interface were analyzed.[11]

The LenSx® laser has a wide variety of fragmentation patterns ranging from chop, cylinder to cubes to help soften the cataract. Fragmentation patterns can be combined based on surgeon’s preference. For example, the LenSx® laser is the one laser in which the cube pattern can be combined with the chop pattern. Resulting benefits of pre-softening the lens are easier removal of the cataract and reduction in EPT, CDE, postoperative corneal thickness and endothelial cell loss as well as surgical OR time.[4, 5, 12]

Figure 4. The LenSx® laser with patented variable numeric aperture technology allows focusing of the laser beam on each tissue in the eye (red dots). With the variable numeric aperture each laser pulse is placed at evenly spaced distances to create easy to open tissue bridges. Other platforms require more laser pulses, thereby higher amounts of energy.

Compared to some other femtosecond lasers, the LenSx® laser has a non-fixed patient bed which can provide additional time saving as the patient does not need to be transferred from the gurney to the laser bed and back.

In summary, femtosecond laser cataract surgery provides a well matched tool to meet the technical and workflow needs for cataract surgery today. The femtosecond laser with its integrated imaging capabilities enables the surgeon to visualize key anatomical landmarks to plan for a targeted treatment with greater efficiency during cataract surgery.
References

LenSx® Laser Important Product Information for Cataract Treatment

Caution
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 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 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.

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.