INFINITI Vision System continues to expand capabilities

by Donald Serafano, M.D.

Two new innovations expand options in cataract surgery: AutoSert IOL Injector and ULTRACHOPPER tip

AutoSert IOL Injector

IO L insertion isn’t a simple “push” and it’s in. That’s a good thing, because investing a little time to understand IOL insertion—especially what is currently at the cusp of innovation—should help deliver superior outcomes for cataract patients.

The newest addition to my surgical portfolio on the INFINITI Vision System (Alcon, Fort Worth, Texas) is the INTREPID AutoSert IOL Injector (Alcon). AutoSert is an automated IOL injector handpiece that enables me to control advancement of the IOL with the INFINITI system foot pedal. This frees my other hand to stabilize the eye with a second instrument, which can also be used to adjust the position of the IOL as it is entering the capsular bag.

When I use MONARCH delivery systems (Alcon), I don’t have this same ability. I need both hands on the MONARCH insertion device to hold the injector and advance the plunger. Therefore I don’t have a convenient way to stabilize the eye. In that scenario, if the patient starts to move, I must press the cartridge against the incision to keep the IOL from being delivered outside the eye.

Other surgeons have used a one-handed injector or a three-handed technique (so to speak). In the three-handed technique, one hand is on the MONARCH injector, one hand is on the second instrument in the side port, and a surgical technician’s hand advances the MONARCH plunger and IOL. However, not everyone is willing to execute a three-handed delivery. Perhaps a more controlled velocity is going to make a difference in the integrity of the incision.

In my experience, the INTREPID AutoSert IOL Injector allows for a higher level of control in IOL delivery. In addition to the foot pedal control of the IOL advance, the INFINITI system software has three parameter settings the surgeon can control to meet his/her unique requirements. These parameters are: initial velocity, pause time, and final velocity. Based on my experience with hundreds of procedures with the AutoSert IOL Injector—from initial tests on cadaver eyes to clinical procedures on human eyes—these parameter settings offer advantages over using a manual injector.

With the AutoSert IOL Injector, the software will advance the IOL, using the initial velocity down the cartridge to the ready-to-insert position. Then when the surgeon presses the foot pedal, the AutoSert IOL Injector will advance the IOL to the end of the cartridge, where the software will pause the plunger advancement for a period of time. This pause time, set by the surgeon on the INFINITI system console, allows the IOL time to form in the tip of the cartridge and, in my experience, allows me time to prepare for insertion.

After the pause time elapses, and with my foot still depressed on the foot pedal, the AutoSert IOL Injector will begin to move the IOL out of the cartridge at the final velocity. The surgeon can set this final velocity to be fixed or linear. Linear velocity is like an accelerator you use when driving a car. As I push down on the foot pedal, it increases the velocity of insertion. If I want to slow down, I come off the foot pedal a bit.

Please refer to pages 10-12 for important safety information about the Alcon surgical products described in this supplement.

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Redefining control in single-hand IOL injection

by Robert H. Osher, M.D.

Insertion moves from one-handed devices—and even nurse-assisted methods—to foot pedals, and for good reason

In today’s age of refractive cataract surgery, as incision size has been reduced, inserting the IOL into the eye has become increasingly challenging. I think that as incisions get smaller, we have a number of challenges that have not been solved.

Placing the injector into the eye, for instance, could cause stretching or tearing of a small, tight incision. Yet a wider incision that facilitates the entry of the hardware of the injector cartridge into the eye seems contrary to our goal of achieving the smallest possible incision.

Surgeons have tried to use the incision tunnel as an extension of the cartridge. The problem is when we do that, several things can happen. The common issue is that the lens pushes the eye away.

Countertraction is necessary to stabilize the eye and is highly beneficial in small incision implantation. Surgeons require one hand to turn the screw on a screw-type injector. The other hand stabilizes the device. Yet there is no countertraction. In some cases, nurses also have helped turn the screw to inject the lens, but three hands are required to achieve countertraction.

It seems that we do not have a way of consistently inserting the lens through the smallest possible incision perfectly time after time.

European surgeons tried to develop a patient-assisted method, where patients look toward the cartridge, which provides some degree of resistance rather than countertraction. My observation is that this is not a very reliable method.

Some surgeons have designed a one-handed injector, myself included. This permits countertraction with an instrument held in the left hand through the side port while the right hand is used to inject. This is very effective.

But there is the issue of potential energy. As surgeons start to inject a lens using a smaller cartridge, the lens can occasionally demonstrate sudden behavior as it leaves the cartridge. That uncontrolled movement can cause some significant repercussions. To avoid that, some surgeons prefer a C cartridge, rather than a D cartridge, which has a greater internal surface area to reduce potential energy.

However, if we are trying to go through smaller incisions, we want to use the smallest cartridge. To achieve maximum control with the smallest cartridge, a screw-type injector rather than a one-handed injector would be preferable, as long as enough hands are available to reap the benefit of countertraction.

Several years ago, I modified the one-handed injection technique to insert the lens with less resistance. I found that it was an advantage to flare the internal incision. My external incision is slightly smaller than the internal opening. That’s my way of inserting the lens with a one-handed injector. Still, I knew that there was room for improvement.

Then Alcon (Fort Worth, Texas) developed the footswitch-driven AutoSert IOL Injector handpiece. The INTREPID AutoSert IOL Injector handpiece frees up the surgeon’s left hand for countertraction.

End velocity settings may be set in linear or fixed modes. I prefer a linear end velocity, but by no means is my preference absolutely standard. Each surgeon will find his/her own preferential settings as he/she gains personal experience with the instrument.

The directions for use detail that the AutoSert IOL Injector has been validated using the driving console default setting (1.7 mm/sec, 3 seconds, and 1.7 mm/sec for initial velocity, pause, and final velocity, respectively) at 18 degrees C. Using a higher velocity and shorter pause, especially with high diopter lenses, could induce damage to the IOL and/or the IOL cartridge, affecting successful IOL implantation.

While there are many insertion devices available today based on incision size and surgeon preference, I believe the AutoSert IOL Injector reduces risk variables because of its controlled and programmable velocity profile, and it frees my second hand.

This is a natural step in the evolution of IOL insertion. Now surgeons can have an automated delivery and have their second hand where they want it.

ULTRACHOPPER tip

The second addition to my surgical portfolio is the ULTRACHOPPER tip (Alcon). I use this new ultrasound tip to prepare the nucleus for pre-chop and/or ultrasound division of the nucleus. I ask for the ULTRACHOPPER tip if the patient has a dense nucleus or pseudoexfoliation.

After the capsulorhexis and hydrodissection, I use the ULTRACHOPPER tip with torsional ultrasound with 60% power as the maximum. I score the nucleus into four to six segments. Next I use my normal ultrasound tip to sculpt into the scored areas. Some surgeons may use a pre-chopper at this point to help separate the segments. My ULTRACHOPPER tip approach allows me to penetrate a dense nucleus with less ultrasound power and less stress on the zonules. From this point on, I divide the nucleus and remove each fragment in my normal manner.

After removal of the nucleus and cortex, I polish the capsule and then use the AutoSert IOL Injector to insert the IOL into the proper position.

On a dense cataract case, my order of the procedure is: CCC, hydrodissection, ULTRACHOPPER tip, ultrasound, I/A, AutoSert IOL Injector, and then OVD removal. Both the ULTRACHOPPER tip and AutoSert IOL Injector have been key additions to my surgical armamentarium, and they continue to help make cataract surgery a state-of-the-art procedure.

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EX-PRESS device compares favorably to trabeculectomy in many respects

by Malik Y. Kahook, M.D.

With fewer post-op visits needed and faster return to baseline visual acuity, the EX-PRESS device provides a viable surgical option for certain patient groups

The EX-PRESS Glaucoma Filtration Device, which is non-valved and made of medical grade 316L stainless steel, has been utilized as an alternative to standard trabeculectomy for several years. Use of the EX-PRESS device has increased steadily since its introduction because of perceived improvements in the reproducibility of aqueous filtration when compared with trabeculectomy while avoiding the need for a surgical sclerectomy and iridectomy.

My own clinical observations have revealed that the EX-PRESS device does have its advantages. While IOP reduction has been demonstrated to be similar between EX-PRESS device procedures and trabeculectomy, I have found a decrease in vascularity of blebs with continued on page 4

The right hand holds the device, the smallest cartridge can be used, and we don’t have to screw anything. We’re not pushing the plunger; the plunger is footswitch-driven.

The device also delivers the lens without the surgeon overcoming the buildup of potential energy. After a brief pause for seating the lens, the surgeon can select the speed at which the lens enters the eye. This gives the surgeon control over the initial and end velocity, and surgeons can opt for machine-control or linear-control based on the footswitch. It is also possible to select how far the plunger will extend into the eye.

Initially, I tested the device using cadaver eyes in a laboratory setting and was impressed. When I used it for the first time in a human eye, it was wonderful. The AutoSert IOL Injector handpiece does fulfill an unmet need because it allows surgeons to have their left hand available for countertraction while their right hand holds the device. Instead of the third hand to screw the device, the foot serves that purpose. It is simple and completely automated.

The AutoSert IOL Injector handpiece gives a reproducible, consistent way of injecting the lens through a very small incision. I believe it is going to turn out to be a gentler, less invasive way to insert the IOL. Because of increased control, and especially the countertraction that facilitates the lens insertion process, many surgeons are going to be very happy with this innovation.

Reference

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performing an incision and tissue punch thereafter, a sclerostomy with a 25- to 27-gauge needle is performed to implant the device. The conclusion of surgery also comes more in line with trabeculectomy, as suturing down the scleral flap and conjunctiva occurs in both procedures and in a similar fashion.

When implanting the EX-PRESS device, ensure the scleral flap is large enough to cover the faceplate of the device (3 mm by 3 mm is required).

At the entry site, a pilot hole is created with a 25- to 27-gauge needle; positioning and ensuring the plane is parallel to the iris is important. When placing the EX-PRESS device through the pilot hole, the faceplate needs to be flat on the sclera.

There is a learning curve with proper EX-PRESS device placement. Those surgeons who perform trabeculectomy routinely should be able to learn the skills for EX-PRESS device implantation relatively fast.

A multicenter, randomized study examining a standard trabeculectomy with mitomycin-C (MMC) compared to the EX-PRESS device with MMC is needed. Fortunately, there is a recently completed study that is currently being analyzed that may shed some light on both procedures in light of the multicenter nature of the study. How these procedures will fare with multiple surgeons involved, multiple skill sets, and different backgrounds will be enlightening.

Now is the golden age of glaucoma procedures—from minimally invasive procedures to therapy more tailored to a particular glaucoma patient’s needs. While trabeculectomy remains the gold standard, other devices are gaining ground in providing more predictable results in select cases. The EX-PRESS device is a large part of this new and effective device community and will likely continue to be so for some time.

Reference

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Please refer to pages 10-12 for important safety information about the Alcon surgical products described in this supplement.
The femtosecond that releases bubbles with ease

by Ronald Krueger, M.D.

The WaveLight FS200 laser has a different path for gas bubbles, management that has a positive effect on corneal biomechanics, and smooth integration in an all-laser LASIK workspace.

Opaque bubble layer (OBL)—the collection of gas bubbles in the intralamellar space after femtosecond application—can interfere with pupil tracking, iris registration, and other LASIK-related procedures. The WaveLight FS200 femtosecond laser (Alcon, Fort Worth, Texas) evacuates such bubbles in an ingenious way.

The mechanism by which the bubbles are evacuated by the eye is different from the IntraLase (Abbott Medical Optics, Santa Ana, Calif.). The IntraLase recommends creation of a pocket and incarcerating these bubbles deep into the tissue. The FS200 laser makes use of a canal that bubbles can be evacuated out of the eye. In their book Management of Complications in Refractive Surgery, editors Jorge L. Alió, M.D., and Dimitri T. Azar, M.D., explained that early or hard OBL occurs when femtosecond pulses “initially placed in the cornea have no space available, and water vapor and carbon dioxide produced have nowhere to go. Early or hard OBL can block subsequent pulses and lead to uncut or poorly cut tissue, making flap lifts more difficult.”

In late OBL, gases produced travel into intralamellar spaces and can make flap lifts difficult, they reported.

Ella G. Faktorovich, M.D., in Femtodynamics: A Guide to Laser Setting and Procedure Techniques to Optimize Outcomes with Femtosecond Lasers, further explained that OBL, which can interfere with excimer laser tracking and iris registration, may take as long as 30-45 minutes to clear—quite a long time considering the speed at which LASIK is performed nowadays.

With the FS200 laser bubble management system a surgeon can potentially have a bubble-free flap if the canal is the right length. In using the FS200 laser, a slightly longer canal allows for optimal release. Also, when centering the suction ring on the eye, it’s good to leave more sclera showing superiority where the hinge is so there is more room to release these bubbles.

It is advisable to make the length of the canal come right up to the edge of where the application is (typically this is around where the limbal vessels are located).

OBL can still occur despite the use of the canal, but when this happens, surgeons should evaluate if they are taking the canal length out to the edge of the limbus and application meniscus. It’s a little bit of an art and a science. When it is done properly, the surgeon should see bubbles moving through the canal. That’s the ideal situation.

Surgeons also can easily program the channel length with the FS200 laser. The only issue is, how long should they make it? Although it’s hard to say exactly, take it at least out to the scleral vessels and where the edge of the meniscus ends.

Biomechanics of the FS200 laser are improved in other ways as well. There is a Beam Control Check, for example, which takes only 10 seconds. This measures the variance of the PI glass and change in hydration and temperature that could lead to changes in flap thickness.

Making sure there is a relatively thin flap of uniform thickness will ensure few biomechanical effects on the cornea. The Beam Control Check might make a difference in the accuracy of flap creation, and today that can be measured by doing OCT and other types of measurements.

In 2007, my colleagues and I published research observing wavefront aberrations created after flaps that were made with femtosecond lasers versus microkeratomes. Because of the uniformity of the femtosecond laser flaps, there were fewer aberrations created with these in comparison to two of the most popular microkeratomes.

I look forward to publishing new research on the FS200 laser comparing it to other femtosecond lasers. Currently I am collecting data and plan to release results after one more year.

In the meantime, I am pleased by the convenience of the FS200 laser.

It’s nice to have the excimer laser directly coupled with the femtosecond laser with the same bed. When I finish with the flaps, the bed automatically moves over to the excimer laser where I lift the flaps and go. This saves a step, and in the future, the two lasers will actually “talk” to each other in terms of information to further integrate the two components.

I especially look forward to when topographic and wavefront analysis can be linked up with laser outcomes to get better nomograms and better outcomes. That is the goal for the future.

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Figure 1: The appearance of the FS200 flap with the canal and hinge rotated to an oblique axis, which can be set at any orientation.

Source: Ronald Krueger, M.D.
No more high dives: The FS200 laser is anxiety free, like swimming laps

by James Davison, M.D.

Surgeon says the FS200 laser is a relatively worry-free device that delivers consistently good outcomes with confidence

I recall that when I was using a mechanical microkeratome for LASIK, I always had the feeling that I was at the end of a 3-meter diving board about to make a dive—there was a sense, however faint, of unease.

Using a similar analogy, upgrading to femtosecond technology was like being on a 1-meter board, but performing a more difficult dive like a one-and-a-half.

Upgrading to the new WaveLight FS200 femtosecond laser (Alcon, Fort Worth, Texas) was as simple as swimming laps. You just need to dive into the water from the starting block and apply steady effort and good turns to perform well.

I have performed about 300 cases since the installation of the FS200 laser in the summer of 2011, and I can say it’s not only a nice addition to the practice, but my anxiety level has been substantially reduced using it compared to other flap-cutting devices. I don’t get nervous about what it’s going to do. It accomplishes fast, safe, and precise flaps.

Suction is acquired gently and gradually, and it is not high so there’s no pain, intense pressure, or momentary complete loss of vision. The laser only takes about 6 seconds to create the flap and then the suction is gently released.

Many patients feel like they have experienced almost nothing—many feel like they expected more to happen and they’re delighted to find out that it’s over. That being said, because this is surgery, flap complications are always a possibility, and I make sure my patients understand that. I used to say that the hard part is done and the easy part (the excimer laser) is coming. Now I just say we are done with this (femtosecond) part and the next part is coming. Many patients remark something to the effect of, “Oh, that’s interesting. I hardly knew anything happened.” For them, this is a non-event—no sense

Figure 1. The glass surface area is 30% greater with the FS200 laser versus the IntraLase

Figure 2. Gas is exiting the superior canal vent through the conjunctiva during 9.0 mm flap creation in a hyperope. The edge of the active applanation can be seen peripherally

Figure 3. Dr. Davison’s foot is pressing on the left footswitch to activate the laser. He had used the right one to activate suction

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of impact, no intense pressure, no tense moments. In my experience, it can be that quick and effortless for the patient, our staff, and myself.

An important feature of the FS200 laser is that there are essentially two pumps running simultaneously to ensure continuous active suction. This is a major reassurance to me as it helps prevent suction loss during treatment.

The system is designed to create the most consistent flaps. I measured some of the patient interface hardware dimensions of both the FS200 laser and the IntraLase (Abbott Medical Optics, Santa Ana, Calif.). The cone glass surface that applanates the cornea has 30% more surface area (Figure 1), while the external diameter of the suction ring is 10% shorter for the FS200 laser compared to the IntraLase.

Because the applanation diameter is larger, I can always get a perfectly centered 9 mm flap. This is important especially in treating hyperopic patients where I need the full 9 mm diameter. Because of the shorter external diameter, I have an easy time placing the suction ring in eyes with smaller palpebral fissures or compact orbital anatomy. With canal venting, I can minimize opaque bubble layer (OBL) overall (Figure 2).

There are some important steps to consider when using the FS200 laser. The FS200 has two foot switches. One is for suction, and the adjacent foot switch activates the energy (Figure 3). There are two joysticks (Figure 4)—one for the patient bed and the other to control the laser head position. The laser head is a little larger so the patients’ faces need to be turned slightly more to avoid nose contact while the cone settles into the suction ring (Figure 5). These differences are not a big deal—it’s like being in a car and knowing the difference between the brake and the accelerator or the transmission and turn signal controls and adjusting the rear view mirror—but you have to take note of the differences. In my experience, there was a minimal learning curve—it’s just learning to operate a different device, much like driving different brands of automobile.

Alcon was very helpful in training our clinic personnel on the new device. We had a training session the night before we operated on our first patients. In that night session, two Alcon trainers came out and we operated on pig eyes. We learned important steps in transitioning to the FS200 laser, and the trainers even stayed with us the following day and during the next session as well with our live patients. Surgeries were uneventful. We liked it so much, we acquired another FS200 laser for our other refractive surgery center in Eastern Iowa.

Finally, one of the main reasons we acquired the FS200 lasers is that they complete a matched set with the WaveLight Allegretto Wave Eye-Q 400 Hz excimer lasers (Alcon) we acquired in 2008. The technologies are meant to be companion units, so after femtosecond laser flap creation, the patient bed electronically pivots over for the excimer laser portion of the procedure (Figure 6). Before, we had one room for the IntraLase and one room for the excimer laser. Now everything is seamlessly integrated.

Overall, what I have now is more confidence. The new FS200 laser satisfies our triad needed for acquisition of new equipment—in my practice it’s fast, safe, and precise.

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Femtosecond and excimer lasers combine for excellent outcomes

by William Culbertson, M.D.

Speed, convenience, customization—the list goes on for why integrated lasers work so well

W
gen up and walk across the hall and can’t see well, it could be problematic. Now all the patient has to do is lay there during the transfer.

The FS200 laser has many advantages. It’s fast, for one. A flap is made in just 6 seconds. This is helpful not only for speed purposes, but also because it means there is less time for suction to become dislocated.

Second, the pressure is not high enough for patients to have a complete temporary loss of vision. The culmination of the speed and minimal pressure can potentially enhance the overall procedure.

The FS200 laser is capable of making a large LASIK flap up to 10 mm long. This is nice for doing large ablations, such as ones for hyperopic treatments. It has the ability to customize a flap in any way you want. For example, it can make an oval flap, move the hinge around, change the size of the hinge, etc.

You can modify flaps for other problems going on in the cornea, such as pterygium being present. You can optimize the thickness of the flap—depending upon the starting thickness of the cornea versus the planned ablation. You can customize flap shape based on the excimer treatment that will be carried out. If an excimer treatment pattern is more or less oblong or oval, for example, then a flap can be made to that same shape. You’re not making the flap any larger than it needs to be. These all are ways you can customize the procedure for the patient and for the surgical technique.

All in all, I think the integration of the FS200 and the Allegretto Wave Eye-Q lasers makes for extraordinary outcomes.

Notably, we are also having good experiences performing穿透性角膜移植（PK），前部 lamellar keratoplasty（ALK），and deep anterior lamellar keratoplasty（DALK）using the FS200 laser. We are very happy with these procedures. For example, a patient was treated recently with a corneal scar from a previous infection and an irregular flat cornea as a result. We performed ALK. We turned the donor lamella that was created with the FS200 laser upside down and did a steepening treatment on the backside of it. We then transplanted that into the recipient, hoping to steepen the cornea to a more normal configuration as opposed to what she had. So both the Allegretto Wave Eye-Q and the FS200 lasers had roles to play in facilitating this lamellar corneal transplantation. It is interesting that we did the transplantation under the WaveLight optics, because they are so good. The fact that the surgeon can see so well is helpful in this type of procedure. Without the optics, surgeons should ask if they know what they are missing.

There’s no doubt in my mind that from LASIK to keratoplasty, the integration of femtosecond and excimer systems help provide excellent outcomes.

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The combination of the femtosecond and excimer lasers works extremely well together. They were built to match each other, so they work in an integrated surgical way.”

The WaveLight Refractive Suite
Source: Alcon

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Practical uses of the femtosecond laser for cataract surgery

by Richard Mackool, M.D., and R.J. Mackool, M.D.

Femtosecond surgeon and phacoemulsification surgeon team up to get the most out of laser cataract surgery

Efficient utilization of expensive operating suites is mandatory for all ASCs and hospitals. It is obviously impossible for one surgeon to simultaneously perform both femtosecond laser and phacoemulsification surgery. We have therefore employed a schedule that permits one of us to perform the femtosecond treatment while the other continues to use the operating room for completion of the phacoemulsification and the IOL implantation procedure.

At our practice, Dr. R.J. Mackool performs the LenSx Laser (Alcon, Fort Worth, Texas) surgery, while Dr. Richard Mackool is performing phacoemulsification with the INFINITI system (Alcon). The patient is then transported to the operating room where either Dr. R.J. Mackool or Dr. Richard Mackool completes the procedure. Because the surgeon who does the LenSx Laser procedure doesn’t necessarily have to do the phacoemulsification, the OR runs continuously and efficiently.

We believe that the most difficult part of phacoemulsification is dividing the nucleus, and the ability of the LenSx Laser to fragment the lens prior to phacoemulsification is a major advantage. In our experience, we have observed the manual completion of nuclear division is subsequently performed with less effort and stress on the zonule. It is likely one of the reasons the effective lens position (ELP) of the IOL has been shown to be more predictable after LenSx Laser cataract surgery.1 The ability to reduce zonular stress can be of critical importance in eyes with pre-existing zonular laxity, e.g., pseudoexfoliation.

The LenSx Laser is capable of performing both radial and cylindrical fragmentation patterns. The nucleus can therefore be fragmented in order to create either four or six segments, and these segments can be further divided utilizing cylindrical laser application of various diameters. After femtosecond treatment of the nucleus, the completion of nuclear division can usually be accomplished without significant sculpting of the nucleus. The reduction of ultrasonic energy use after femtosecond treatment, coupled with reducing the amount of time you have instrumentation in the eye, has been shown to reduce endothelial cell loss. This is especially important for eyes with Fuchs’ endothelial dystrophy, eyes with shallow chambers, and pseudoexfoliation with or without lax zonules.2 The latter often have endothelial cell abnormalities as well. In all of these patients with underlying issues, the use of a femtosecond laser to perform some of the steps with little manual manipulation helps provide protection for the endothelium.

Occasionally, patients may have a low endothelial cell count without guttata, and therefore the condition is unknown to the operating surgeon. If the LenSx Laser has been utilized prior to cataract surgery, we know we are sparing the endothelium to the best of our ability, and patients are at reduced risk of developing post-op corneal edema.

The LenSx Laser produces a predictable capsulorhexis, both in terms of diameter and location, and is capable of making very precise arcuate incisions. The arcuate incisions can either be opened at the time of the phacoemulsification surgery, or this can be done during the early post-op period depending upon the surgeon’s discretion.

References

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**Important safety information**

**EX-PRESS Glaucoma Filtration Device**

**Caution:** Federal (U.S.) law restricts this device to sale by or on the order of a physician.

**Indication:** The EX-PRESS Glaucoma Filtration Device is intended to reduce intraocular pressure in glaucoma patients where medical and conventional surgical treatments have failed.

**Guidance regarding the selection of the appropriate version:** Prior clinical studies were not designed to compare between the various versions of the EX-PRESS Glaucoma Filtration Device. The selection of the appropriate version is according to the doctor’s discretion.

**Contraindications:** The use of this device is contraindicated if one or more of the following conditions exist:
- Presence of ocular disease such as uveitis, ocular infection, severe dry eye, severe blepharitis.
- Pre-existing ocular or systemic pathology that, in the opinion of the surgeon, is likely to cause post-operative complications following implantation of the device.
- Patients diagnosed with angle-closure glaucoma.

**Warnings/precautions:**
- The surgeon should be familiar with the instructions for use.
- The integrity of the package should be examined prior to use, and the device should not be used if the package is damaged and sterility is compromised.
- This device is for single use only.
- MRI of the head is permitted, however not recommended, in the first 2 weeks post-implantation.

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

**INFINITI Vision System**

**Caution:** Federal (U.S.) law restricts this device to sale by or on the order of a physician.

**Indication:** The INFINITI Vision System is indicated for emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation, and intraocular lens injection. The AutoSert IOL Injector handpiece is intended to deliver qualified AcrySof intraocular lenses into the eye following cataract removal.

The following system modalities additionally support the described indications:
- Ultrasound with UltraChopper tip achieves the functionality of cataract separation.
- The AutoSert IOL Injector handpiece achieves the functionality of injection of intraocular lenses. The AutoSert is indicated for use with AcrySof lenses SN60WF and SN60AD1, as well as approved AcrySof lenses that are specifically indicated for use with this inserter, as indicated in the approved labeling of those lenses.

As part of a properly maintained surgical environment, it is recommended that a backup IOL inserter be made available in the event the AutoSert IOL Injector handpiece does not perform as expected.

**Warnings:** Appropriate use of INFINITI Vision System parameters and accessories is important for successful procedures. Use of low vacuum limits, low flow rates, low bottle heights, high power settings, extended power usage, and extended power usage during occlusion can lead to thermal damage.

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

**MONARCH II/III IOL Delivery System**

**Caution:** Federal (U.S.) law restricts this device to sale by or on the order of a physician.

**Indications:** MONARCH II and III are titanium handpieces that are indicated for use with corresponding MONARCH cartridges for the surgical implantation of Alcon foldable intraocular lenses (IOLs). AcrySof IOLs are qualified for use with specific MONARCH handpiece/cartridge combinations. No unqualified lenses should be used with the MONARCH II or III IOL Delivery Systems.

The MONARCH II and III cartridges are single-use devices. The MONARCH II and III handpieces may be reused after sterilization.

**Precautions:**
- Consult the cartridge product information for the correct MONARCH handpiece/cartridge combination to use with a specific AcrySof lens model.
- Only use an Alcon qualified viscoelastic for use with the Monarch cartridges.
- The MONARCH II and III handpieces are non-sterile and must be thoroughly cleaned and sterilized prior to each use.
- Improper cleaning and rinsing of the handpieces has been linked to toxic anterior segment syndrome.
- Potential risks from reuse or reprocessing the MONARCH cartridges include a damaged cartridge, a damaged lens, or an unexpected delivery outcome.
- If in the medical opinion of the physician, a patient with a prior related disease undergoes a high-risk procedure, the instrument should be destroyed or be processed according to local requirements.

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

**The WaveLight FS200 Laser System**

**Caution:** Federal (U.S.) law restricts this device to sale by or on the order of a physician.

As with any surgical procedure, there are risks associated with the use of the WaveLight FS200 Femtosecond Laser System. Before treating patients with this device, you should carefully review the Procedure Manual, complete the Physician WaveLight System Certification Course, and discuss the risks associated with this procedure and questions about the procedure with your patients.

**Indications:** The WaveLight FS200 Laser System is indicated for use in the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea; patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; in the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty; and in the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting.

The WaveLight FS200 delivery system is used in conjunction with a sterile disposable Patient Interface, consisting of pre-sterilized suction ring assemblies and pre-sterilized application cones, intended for single use.

The WaveLight FS200 Laser System should only be operated by, or under the direct supervision of, a trained physician with certification in laser safety and in the use of the WaveLight FS200 Laser.

**Contraindications:** LASIK treatments are contraindicated in: pregnant or nursing women; patients with a diagnosed collagen vascular, autoimmune, or immunodeficiency disease; and patients who are taking one or both of the following medications: isotretinoin (Accutane®) and amiroidone hydrochloride (Cordran®).

**Flap contraindications:** Lamellar resection for the creation of a corneal flap using the WaveLight FS200 laser is contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list: corneal edema; corneal lesions; hypopyon; glaucoma; existing corneal implant; and keratoconus.

**Keratoplasty contraindications:** Penetrating cut/incision (for penetrating keratoplasty) is contraindicated in any corneal opacity adequately dense to obscure visualization of the iris; descemetocele with impending corneal rupture; previous corneal incisions that might provide a potential space into which the gas produced by the procedure can escape; and corneal thickness requirements that are beyond the range of the system.

**Other considerations:** The following conditions should also be considered: severe corneal thinning; subjects with pre-existing glaucoma; a history of steroid responsive rise in intraocular pressure; pre-operative intraocular pressure greater than 21 mm Hg in the operative eye; subjects with more than 1,000 μm corneal thickness at the 9 mm peripheral zone; active intraocular inflammation; and active ocular infection.

**Complications:** Possible complications that may result from flap cutting include (potential complications are not limited to those included in this list): corneal edema; corneal pain; epithelial ingrowth; epithelial infection; flap delamination; incomplete flap creation; flap tearing or incomplete lift-off; free cap; photophobia; corneal inflammation, such as diffuse lamellar keratitis (DLK), corneal infiltrates and irritis; thin or thick flaps; flap striae; and corneal ectasia (secondary keratoconus).

**Warnings:** Any treatment with the WaveLight FS200 is not recommended in patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; and a history of glaucoma or ocular hypertension.

We recommend discussing the following potential complications of this device with your patients:
Transient Light Sensitivity Syndrome (TLSS): Transient Light Sensitivity Syndrome is characterized by symptoms of mild to severe light sensitivity, which manifests between 2 and 6 weeks post-operatively. Patients experience no decrease in uncorrected or best spectacled-corrected visual acuity. The incidence of this sensitivity was observed in approximately 1% of patients who undergo flap creation with a femtosecond laser.1 Patients respond to the use of topical steroids such as Pred Forte (Allergan), and most report improvement of symptoms within the first week of the treatment.

Peripheral Light Spectrum (PLS): Peripheral Light Spectrum is a temporary phenomenon whereby patients report the perception of a spoke-like spectrum of light in the periphery of their vision. PLS has no clinical examination findings and no effect on visual acuity; however, the potential photic effects may be bothersome to some patients. Reported in only a small amount of cases, the onset of these symptoms occurs during the immediate post-operative period and typically resolves within 3 months but may be slightly persistent in rare cases. The visual impact of PLS is clinically inconsequential for the vast majority of patients.

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

1. Accutane is a registered trademark of Hoffmann-La Roche Inc.
2. Cordarone is a registered trademark of Sanofi.

The WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

Statements regarding the potential benefits of wavefront-guided and Wavefront Optimized laser-assisted in situ keratomileusis (LASIK) are based upon the results of clinical trials. These results are indicative of not only the WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System treatment but also the care of the clinical physicians, the control of the surgical environment by those physicians, the clinical trials’ treatment parameters, and the clinical trials’ patient inclusion and exclusion criteria. Although many clinical trial patients after wavefront-guided and Wavefront Optimized procedures saw 20/20 or better and/or had or reported having better vision during the day and at night, compared to their vision with glasses or contact lenses before the procedure, individual results may vary. You can find information about the clinical trials below and in the Procedure Manuals for the WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System. As with any surgical procedure, there are risks associated with the wavefront-guided and Wavefront Optimized treatment. Before treating patients with these procedures, you should carefully review the Procedure Manuals, complete the Physician WaveLight System Certification Course, provide your patients with the Patient Information Booklet, and discuss the risks associated with this procedure and questions about the procedure with your patients.

Indications: The WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System is indicated to perform LASIK treatments in patients with documented evidence of a stable manifest refraction defined as less than or equal to ±0.50 diopters (D) of pre-operative spherical equivalent shift over one year prior to surgery, exclusive of changes due to unmasking latent hyperopia in patients 18 years of age or older; for the reduction or elimination of myopic refractive errors up to –12.0 D of sphere with and without astigmatic refractive errors up to –6.0 D for the reduction or elimination of hyperopic refractive errors up to +6.0 D of sphere with and without astigmatic refractive errors up to +5.0 D at the spectacle plane, with a maximum manifest refraction spherical equivalent of +0.0 D. WaveLight ALLEGRETTO WAVE Eye-Q Excimer Laser System is contraindicated for patients with a diagnosis of keratoconus or any clinical pictures suggestive of keratoconus; and patients who are taking one or both of the following medications: isotretinoin (Accutane1) and amiodarone hydrochloride (Cordarone2).

Long-term risks of LASIK for myopia with and without astigmatism beyond 12 months have not been studied.

Clinical data hyperopia: The WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System has been studied in clinical trials in the United States with 290 eyes treated, of which 100 of 290 eligible eyes were followed for 12 months. Accountability at 3 months was 95.2%, at 6 months was 93.9%, and at 12 months was 99.9%. The studies found that of the 212 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 98.3% were corrected to 20/20 or better, and 67.5% were corrected to 20/20 or better without spectacles or contact lenses.

The studies showed that the following subjective patient adverse events were reported as much worse by at least 1% of the subjects (in order of increasing frequency) at 6 months post final treatment: glare from bright lights (3.0%); night driving glare (4.2%); light sensitivity (4.9%); visual fluctuations (6.1%); and halos (6.4%). Long-term risks of LASIK for hyperopia with and without astigmatism beyond 12 months have not been studied.

Clinical data mixed astigmatism: The WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System has been studied in clinical trials in the United States with 162 eyes treated, of which 111 were eligible to be followed at 6 months. Accountability at 1 month was 99.4%, at 3 months was 96.0%, and at 6 months was 100.0%.

The studies found that of the 142 eyes eligible for the UCVA analysis of effectiveness at the 3-month stability time point, 95.8% achieved acuity of 20/40 or better, and 67.6% achieved acuity of 20/20 or better without spectacles or contact lenses. The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: sensitivity to light (43.3% at baseline versus 52.9% at 3 months); visual fluctuations (32.1% at baseline versus 43.0% at 3 months); and halos (37.0% at baseline versus 42.3% at 3 months).

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment: sensitivity to light (43.3% at baseline versus 52.9% at 3 months); visual fluctuations (32.1% at baseline versus 43.0% at 3 months); and halos (37.0% at baseline versus 42.3% at 3 months). Long-term risks of LASIK for mixed astigmatism beyond 6 months have not been studied.

Clinical data wavefront-guided treatment of myopia: The WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System used in conjunction with the WaveLight ALLEGRETTO device was studied in a randomized clinical trial in the United States with 374 eyes treated. 188 with wavefront-guided LASIK (Study Cohort) and 186 with Wavefront Optimized LASIK (Control Cohort). 178 of the Study Cohort and 180 of the Control Cohort were eligible to be followed at 6 months. In the Study Cohort, accountability at 1 month was 96.8%, at 3 months was 96.8%, and at 6 months was 93.3%. In the Control Cohort, accountability at 1 month was 94.6%, at 3 months was 94.6%, and at 6 months was 92.8%.

The studies found that of the 180 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point in the Study Cohort, 99.4% were corrected to 20/40 or better, and 93.4% were corrected to 20/20 or better without spectacles or contact lenses. In the Control Cohort, of the 176 eyes eligible for the UCVA analysis of effectiveness at the 6-month stability time point, 99.4% were corrected to 20/40 or better, and 92.8% were corrected to 20/20 or better without spectacles or contact lenses.

The clinical trials showed that the following subjective patient adverse events were reported as moderate to severe at a level at least 1% higher than baseline of the subjects at 3 months post-treatment in the Study Cohort: light sensitivity (37.2% at baseline versus 47.8% at 3 months); visual fluctuations (13.8% at baseline versus 20.0% at 3 months). In the Control Cohort: halos (36.6% at baseline versus 45.4% at 3 months) and visual fluctuations (18.3% at baseline versus 21.9% at 3 months). Long-term risks of wavefront-guided LASIK for myopia with and without astigmatism beyond 6 months have not been studied.

Contraindications: LASIK treatments using the WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System are contraindicated if any of the following conditions exist. Potential contraindications are not limited to those included in this list: pregnant or nursing women; patients with a diagnosed collagen vascular, autoimmune, or immunodeficiency disease; patients with diagnosed keratoconus or any clinical pictures suggestive of keratoconus; and patients who are taking one or both of the following medications: isotretinoin (Accutane1) and amiodarone hydrochloride (Cordarone2).

Warnings: Any LASIK treatment with the WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System is not recommended in patients who have: systemic diseases likely to affect wound healing, such as connective tissue disease, insulin dependent diabetes, severe atopic disease or an immunocompromised status; a history of Herpes simplex or Herpes zoster keratitis; significant dry eye that is unresponsive to treatment; severe allergies; and unreliable pre-operative wavefront examination that precludes wavefront-guided treatment. The wavefront-guided LASIK procedure requires accurate wavefront examination to ensure that the wavefront data is used properly. Wavefront measurement that may be used as the basis for a wavefront-guided LASIK procedure must be validated by the user. Inaccurate or unreliable data from the wavefront examination will lead to an inaccurate treatment.

Precautions: Safety and effectiveness of the WaveLight ALLEGRETTO WAVE/ALLEGRETTO WAVE Eye-Q Excimer Laser System have not been established for patients with: progressive myopia, hyperopia, astigmatism and/or mixed astigmatism; ocular disease: previous corneal or intraocular surgery, or trauma in the ablation zone; corneal abnormalities including, but not limited to, scars, irregular astigmatism, and corneal warpage; residual corneal thickness after ablation of less than 250 microns increasing the risk for unexpected ectasia; pupil size below 7.0 mm after mydriatics where applied for wavefront-
Adverse events and complications: Certain adverse events and complications occurred after the wavefront-guided LASIK surgery. Certain adverse events and complications occurred after the wavefront-guided LASIK surgery. The following adverse events did NOT occur: corneal edema at 1 month or later visible in the slit lamp exam; any complication leading to intraocular surgery; melting of the flap of >1 mm²; epithelium of >1 mm² in the interface with loss of two lines or more of BSCVA; uncontrolled IOP rise with increase of >15 mmHg or any reading above 25 mmHg; and decrease in BSCVA of >10 letters not due to irregular astigmatism as shown by hand contact lens refraction.

The following complications occurred 3 months after wavefront-guided LASIK during this clinical trial: corneal epithelial defect (0.6%); foreign body sensation (0.6%); and pain (0.6%).

The following complications did NOT occur 3 months following wavefront-guided LASIK in this clinical trial: corneal edema; any epithelium in the interface; ghosting or double images; and need for lifting and/or reseating of the flap/cap.

Attention: The safety and effectiveness of LASIK surgery has only been established with an optical zone of 6.0-6.5 mm and an ablation zone of 9.0 mm.

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

1. Accucat is a registered trademark of Hoffmann-La Roche Inc.
2. Cordran is a registered trademark of Sanofi A. B.
3. Imix is a registered trademark of Glaxo Group Limited.

LenSx Laser

Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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.
- Patients 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 application of the cornea or transmission of laser light at 1030 nm wavelength
- Descemetomectomy 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 that 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 application 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 coupled capsulotomy, flap, or incision
- Capsulotomy
- 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