PATIENT CONSENT FORM
ADVANCED SURFACE ABLATION (ASA) – PRK / LASEK

I. Introduction
Advanced Surface Ablation, or ASA, is a permanent vision correction procedure in which tissue is removed from the surface of the eye (the cornea) using an excimer laser. Precise control of tissue removal and management of the healing process can result in reduced dependence on corrective lenses for distance vision for most patients.

The U.S. Food and Drug Administration (FDA) regulates the manufacture and use of excimer laser systems. Manufacturers are restricted from selling their lasers for the performance of refractive correction procedures until approval has been granted by this agency. The VISX Star S4 Laser System, has been approved by the FDA for the treatment of nearsightedness and farsightedness, with or without astigmatism, on the surface of the cornea. The Wavelight Allegretto Wave Excimer Laser Excimer system, has also been approved by the FDA for the treatment of nearsightedness and farsightedness, with or without astigmatism for use under a corneal flap (LASIK). Treatment on the surface of the cornea (Advanced surface ablation – ASA) is consider to be an off-label usage of the laser but is well within the scope of acceptable procedure in the practice of medicine.

This Patient Consent Form generally describes the ASA procedure and outlines certain risks and possible benefits. Before electing to undergo ASA, you must have a complete eye examination and should fully discuss the potential risks, complications, and alternatives with an eye care professional. You are encouraged to ask questions at any time about ASA or about any statements made in this form.

II. How the Eye Works
To better understand ASA and how the excimer laser can be used to correct vision problems resulting from refractive error, a short review of how the eye works may be helpful. Refractive errors (nearsightedness or myopia, farsightedness or hyperopia, and astigmatism) generally result from an abnormally or irregularly shaped eye.

When light enters the eye, it is bent (refracted) by a clear, strong tissue at the front of the eye called the cornea. The cornea, in effect, acts like a lens to focus incoming light onto the retina at the back of the eye. In nearsightedness, or myopia, light entering the eye does not focus on the retina as it should, but instead focuses images at a point in front of the retina. Nearsightedness is frequently caused either by an eye shape, which is abnormally long, or by an excessively steep curvature of the cornea. The result of nearsightedness is that distant objects appear blurry, while objects near to the viewer can be seen in focus.

In farsightedness, or hyperopia, light entering the eye focuses images at a point behind the retina. Farsightedness is frequently caused by an eye shape, which is abnormally short, or by an excessively flat cornea. The result of farsightedness is that objects near to the viewer appear blurry, while objects in the distance may be seen in focus.

In astigmatism, the problem is not the length of the eye, but the fact that the cornea is not spherical and contains different curvatures and is typically shaped more like a football than a basketball. The result of astigmatism is that objects are not focused into a single image and vision is distorted or blurry. Often, people who have nearsightedness also suffer from astigmatism.

Presbyopia, or the inability to see close-up objects, usually becomes apparent to most people in their early forties. This condition occurs normally with age and results from a change within the eye in which the internal lens loses...
its ability to focus on close-up objects. ASA, which only treats the surface tissue of the eye, cannot be used to correct presbyopia.

III. Vision Correction Alternatives
Vision problems resulting from refractive error (nearsightedness, farsightedness, and astigmatism) have historically been corrected either with eyeglasses or contact lenses.

A procedure known as Radial Keratotomy (RK) was frequently used in the early to mid 1990’s nearsightedness and astigmatism. Although RK sounds similar to Photorefractive Keratectomy (PRK), one of the two variants of ASA procedures, they are different and should not be confused. In RK, a surgeon reshapes the cornea by using a hand-held blade to make a pattern of incisions in the cornea that look like the spokes of a wheel. The incisions weaken the structure of the eye and permit the cornea to flatten, thus shortening the length of the eye and correcting the refractive error.

LASIK, or laser assisted in situ keratomileusis, is another procedure for treatment of nearsightedness, farsightedness and astigmatism. In LASIK, an ophthalmologist uses a microkeratome, an automated device with a blade, to create a layer of tissue about 160 microns thick (one third of the cornea) across the surface of the eye. This flap of tissue, which remains attached on one side, is folded back, and the excimer laser is used to remove the underlying corneal tissue. Following laser treatment, the flap is laid back in place. Sutures are not required. If laser retreatment is required, the flap can be lifted since it is primarily held in place by the epithelium, or thin protective layer of tissue on the surface of the eye.

IV. The Excimer Laser
ASA uses an FDA approved excimer laser for vision correction. No blades are used and no incisions are made to the eye. In ASA, the cornea is reshaped using the energy from pulses of light emitted by an excimer laser. Ultraviolet light with wavelengths less than 300 nanometers will not penetrate through the surface of the eye. Because of this particular phenomenon, the excimer laser with a wavelength of 193 nanometers does not transmit energy through the cornea to the internal tissues of the eye. Instead, the ultraviolet light is absorbed in the surface cells of the eye giving the excimer laser its unique ability to reshape these surface tissues. As the ultraviolet light is absorbed by the surface of the eye, tissue is vaporized. Essentially no heat is generated in the process; therefore, the risk of scarring the corneal tissue is minimized. The energy of the laser is controlled so that each pulse precisely removes thin layers of tissue from the cornea, 1/4000 of a millimeter at a time. In fact, it would take about 200 pulses from an excimer laser just to etch through one human hair. The laser is programmed specifically for each patient and is controlled by a computer that determines the location, number of pulses, and surface area to be impacted by the laser light beam based on that individual patient's particular vision problems and correction needs.

V. Patients Who Wear Contact Lenses
The chronic use of contact lenses may distort the curvature of the cornea. Therefore, before being evaluated for LASIK and before the treatment can be performed, the shape of the eye must be allowed to stabilize and return to its natural shape.

Patients who wear daily soft contact lenses must totally stop wearing their lenses at least three days prior to their procedure. Patients who sleep in their lenses should be out a minimum of seven to ten (7-10) days and those patients whose contacts correct for astigmatism, should be out of them for ten (10) days to two (2) weeks. Patients who wear gas permeable or hard contact lenses must totally stop wearing such lenses for one month per every decade of wear. You should confirm compliance with these requirements prior to undergoing LASIK. The period required to stabilize the natural shape of the cornea may be longer for some patients. Therefore, you

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should tell your surgeon and eye care provider if you suspect that your vision is continuing to fluctuate as your eyes return to their normal shape. Failure to do so will increase your odds of requiring fine-tuning, also known as an enhancement procedure, months after your initial procedure.

VI. Contraindications
An individual is a poor candidate for ASA if any of the following conditions exist: unstable refractive error, large pupils (greater than 8 millimeters in diameter in low light conditions), history of keloid formation, keratoconus (progressive thinning/steepeing of the cornea), keratitis sicca (advanced dry eyes), diabetes, glaucoma, expectant or nursing mothers, cataracts, heart condition requiring pacemaker regulation, recurring ocular herpes simplex, or active ocular inflammatory disease. If you know that you have any of these conditions, you must inform your eye doctor.

VII. The Laser-ASA Procedure
Upon arriving at the laser center, you will be greeted and have the opportunity to ask any remaining questions regarding this consent. Before proceeding with your ASA procedure, a final check of your eyes may be completed. Eyes to be treated are measured and mapped and the information is reviewed to detect and isolate any irregularities in the shape of the cornea. The ophthalmologist performing your procedure or the staff at Millennium will be available to review the procedure with you, answer any questions, and conduct additional examinations as appropriate.

Most patients dress casually, comfortably and warmly, since the room is kept cold for optimum laser performance. You are not allowed to wear make-up, colognes, perfumes or scented lotions, as it will interfere with the performance of the laser. We encourage patients to bring a companion with them to see the ASA procedure since you will not be permitted to drive home by yourself following the procedure. Your companion may accompany you through the entire process.

If your procedure is performed using the Autonomous LADARVision Excimer Laser System, a picture of your corneas will be taken and your pupils will be dilated to prepare for use of the eye-tracking system.

You will not be given a general anesthetic, and pre-operative sedation is not routinely needed. The eyes are totally numbed by topical anesthetic. Topical antibiotic and a non-steroidal anti-inflammatory drop will also be instilled. While allergic reactions to these medications are rare, please advise your doctor of any drug allergies you may have.

In the laser room, you will be seated in a chair, which reclines and rotates for proper positioning with respect to the laser used for performing ASA. The eye that is not being treated will be covered and the chair will be adjusted to align the eye that is to be treated with the excimer laser system. Then, an instrument called an eyelid speculum will be placed between your upper and lower eyelids to prevent you from blinking.

To begin the actual ASA treatment, the ophthalmologist will remove the protective layer on the surface of your eye, which is called the epithelium. There are various ways the epithelium can be removed. The ophthalmologist can either remove the epithelium i) Exclusively with the laser, ii) partially with the laser and wiping the remainder away with a special instrument (laser scrape), iii) by exclusively wiping with a special instrument, iv) with a small rotating brush, v) using a dilute alcohol preparation to then either remove completely or vi) reposition it following the laser treatment (LASEK aka epi-LASIK). In whichever method is employed, you will not feel any pain. However, some patients experience a mild pressure sensation or an awareness that something is being done.

Next, the surgeon will ask you to stare at a blinking red light in the microscope. The ophthalmologist will activate the excimer laser and begin re-shaping your cornea. The red light will become more difficult to see as the laser
treatment progresses. While the laser is in use, you will be asked to keep your head and eye as still as possible. A small amount of eye movement should not affect the outcome of the procedure because all of the lasers utilize automated tracking systems. If significant movement occurs, the laser will stop until excessive movement ceases.

Total laser treatment time for most patients is less than 30 seconds per eye. The ophthalmologist performing ASA will tell you how you are doing throughout the procedure.

During the procedure, you will notice distinctive sounds and smells. For example, the laser emits a clicking or snapping sound whenever it is in use. The ophthalmologist will let you know before the pulses begin so that the noise will not startle you. Laser treatment of the eye tissues also produces an odor similar to that of a singed hair.

Once reshaping of the cornea is complete, additional eye drops are instilled, a protective soft contact lens is inserted, and the eyelid speculum is removed.

If you are having both eyes done on the same day, it will take a few minutes to program the computer and prepare for laser treatment of your other eye. The total time in the laser room is usually less than 20 minutes.

VIII. Post-Procedure Expectations

After the procedure, you'll be advised to rest for the remainder of the day and to continue using prescribed eye drops as instructed. During your ASA procedure, the protective layer of tissue on the surface of the eye, the epithelium, is removed or gently rolled back (LASEK) then repositioned over the central portion of the cornea. When removed (PRK), this protective tissue regenerates itself, and normally over a two to four day period the healing process is sufficiently completed such that the epithelium once again covers the entire surface of the eye.

During this healing process, some patients will experience varying degrees of discomfort. This can vary from a mild irritation to more severe discomfort that may be only minimally responsive to OTC oral medications. Two options are available to reduce discomfort and promote healing. An eye patch can be applied to keep the eye closed or a soft contact lens can be inserted to protect the treated area while healing is under way. Studies have shown that most patients are more comfortable with a contact lens and eye drops than if the eye is patched. Patients who have difficulty wearing contact lenses may not be able to successfully wear the protective lenses and may experience greater than normal discomfort following ASA.

Although there is a minimal risk of infection with either the use of the contact lens or the patch, the risk is thought to be slightly higher with the contact lens. In addition to the probability of experiencing less post-procedure discomfort, patients with the contact lens have their eye open, permitting useful (although blurry) vision, which is obviously not possible, if the eye is patched.

Before you leave the laser center, you will be supplied a kit containing antibiotic and anti-inflammatory eye drops, along with a schedule for their use. You may also be provided anesthetic eye drops, which may be used during the first 24-48 hours following ASA. These anesthetic drops are to be used only in the case of significant discomfort. Care must be taken to avoid any contact with the eye during the period in which the sensitivity of the eye is reduced through use of the anesthetic drops. Because of the reduced sensitivity of the eye while using anesthetic eye drops, you might accidentally damage your eye without feeling the contact. You may also be provided with a prescription for oral medications, which can be used, should you experience discomfort, pain, or difficulty in getting to sleep.

You are likely to be sensitive to light and may not be able to see well enough to accomplish some simple tasks like reading a menu for several days following ASA. You should bring a companion with you to the center. You will not feel comfortable driving home or for several days following your procedure.

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Patients typically return to the laser center on the day following the procedure to confirm the fit of the protective contact lens and to ensure that the healing process is progressing satisfactorily. The epithelium usually regenerates itself sufficiently to cover the treated area within two to four days. During this period, a visit to your managing doctor may be required if discomfort persists.

If all is healing as anticipated and no particular discomfort is present, the protective lens is removed by your doctor on the third to fourth day following the procedure. In some cases, an additional day or two is required prior to removing the protective lens to ensure that the healing process is adequately advanced.

Your eye doctor will monitor your recovery and your continued use of eye drops. Steroid eye drops are often used after the procedure to reduce redness, eye irritation, and to regulate the healing response. Regular follow-up visits are required, as the use of steroid eye drops can cause an increase in internal eye pressures for some patients. Follow-up evaluation visits are generally scheduled for one, four (to remove the contact), and ten days after the procedure: Then at one and three months to access stability.

IX. Risks and Other Considerations
No vision correction procedure is entirely risk free. In addition, because Advanced Surface Ablations, are relatively new procedure introduced in 1987, there may be longer-term risks, which are unknown at this time. Risks and discomforts that might be associated with the ASA procedures are as follows:

1. **Discomfort.** Many patients experience mild discomfort for a few days following ASA, although patient reactions range from no discomfort at all to moderate pain. Some patients may experience a burning sensation for a few moments when instilling the eye drops in the first two to three days following the procedure. Loss or excessive movement of the protective contact lens can be quite painful. Patients losing the protective contact lens should keep their eye closed and contact an eye doctor to reinsert a protective lens. Most patients who have discomfort describe it as the sensation of having grains of sand or an eyelash in their eyes or having a torn contact lens. Some sensitivity to light exists among most patients during the period in which the epithelium is regenerating.

2. **Blurry Vision.** During the period in which the epithelium (the protective layer on the surface of the eye) is healing (generally two to four days), vision is blurry for most patients. This is because a smooth epithelial surface is essential for good vision. Once the protective lens is removed, vision when looking at objects within six to ten feet will appear as if looking through glasses coated with a thin film of petroleum jelly. This condition clears for most people in a week or two as the surface of the eye heals and again becomes smooth. However, complete smoothing of the surface tissue of the treated eye may take as much as four to six weeks. During this period, some fluctuation in vision may occur. The healing process is very much individualized and varies from patient to patient.

3. **Reading Difficulty.** Most patients will find it difficult to read in the first few days following ASA. People with greater levels of correction and those over forty who are experiencing the effects of presbyopia may have greater difficulty reading without the use of corrective lenses for longer periods immediately following the procedure. ASA cannot currently be used to correct presbyopia, which occurs naturally as one ages.

4. **Corneal Haze.** Corneal haze, which in most cases can only be detected by an eye care professional using a microscope, is not uncommon following ASA. When present, is most noticeable in the period one to four months following the laser procedure. Mild haze generally has little or no effect on vision and usually resolves spontaneously as the cornea remodels itself over a six to twelve months period. A
few patients however, may experience more significant corneal haze. Additional treatment with the excimer laser can generally correct this problem; thus haze rarely causes permanent visual impairment. Your surgeon may give you a prescription for oral Vitamin C to be taken twice daily beginning three days prior to and continued until three days following your procedure. Studies have indicated that this may help lessen the chance of your developing haze postoperatively.

5. **Loss of Night Time Visual Acuity.** Some patients who have undergone ASA may experience halo or glare presumably as a byproduct of haze or based upon a treatment zone diameter that is significantly smaller than the size of the pupil. This effect is most noticeable in dim light conditions, particularly for those patients with large pupils, and may, in some cases, interfere with night driving. Significant corneal haze can also result in loss of visual acuity in all lighting conditions.

6. **Raised Eye Pressure.** Elevated intraocular pressure can occur in patients who use topical steroid eye drops following an ASA procedure. Typically, intraocular pressure returns to normal, with no long-term ill effects, once the use of steroid eye drops has been discontinued. However, if intraocular eye pressure is elevated on a long-term basis, permanent loss of vision can result. Since raised intraocular eye pressure is painless, periodic evaluation by an eye doctor in patients given topical steroid for longer durations is imperative. Monitoring intraocular pressure is an important part of the follow-up care provided by your eye care professional.

7. **Slow Healing of the Epithelium.** In ASAs, the epithelium is removed (PRK), or gently rolled back (LASEK) just before the laser procedure begins. In PRK, the epithelium usually regenerates in two to four days, while in LASEK, it may take several days for it to secure itself to the underlying cornea and smooth itself out. Patients who experience delayed epithelial healing may experience a prolonged period of discomfort and may be at greater risk of infection.

8. **Undercorrection.** There is no guarantee that, for a particular patient, ASA will be successful in providing the desired level of vision correction. The chance of being under-corrected increases in cases where higher grades of nearsightedness are being treated. If the desired level of vision correction is not achieved, corrective lenses may still be necessary for good vision. Corrective lenses may also continue to be necessary for certain activities. In some, but not all cases, undercorrections can be retreated with an enhancement procedure. Retreatment is usually not performed until vision has totally stabilized, typically about three months after the original procedure is completed.

9. **Overcorrection.** In some cases too much tissue can be removed from the central area of the cornea resulting in an overcorrection. In such circumstances the patient will be farsighted and will not be able to clearly distinguish "near" objects. Corrective lenses would be required may be required, especially in older individuals, until such time as an enhancement treatment can be safely performed.

10. **Regression.** In some patients, the vision correction effects of the treatment diminish several months after the procedure. This complication is more common in patients who are very nearsighted. In some, but not all cases of significant regression, another ASA procedure helps to remedy the effect.

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11. **Presbyopia.** Patients with Presbyopia or approaching Presbyopia (the need for reading glasses, prevalent over 40 years of age) must understand that ASA vision correction does not treat this age-related process.

12. **Loss of Best-Corrected Visual Acuity.** Some patients can lose the ability to read one to two lines on the eye chart in comparison to their previous best-corrected vision. This loss of acuity can occur as a result of microscopic corneal surface irregularities. Loss of acuity can also occur as a result of decentration. Decentration is exceedingly uncommon with currently used tracking technologies.

13. **Inconvenience Between Procedures.** In the event that a patient has ASA performed on just one eye at a time, the two eyes may not work well together in the time between the performance of the procedure on the first eye and the second. A patient's ability to work and drive may be impaired unless the patient procures a temporary set of corrective lenses. Glasses may not adequately compensate for the difference in refraction between the eyes. Contact lenses are more likely to provide acceptable vision correction in cases of significant differences in the refractive capabilities of one's eyes. Contact-intolerant patients must consider the implications in cases where both eyes are not treated at the same time.

14. **Sensitivity.** Some patients, experience increased sensitivity to any contact with the surface of the eye following ASA. The condition tends to diminish over time.

15. **Remote Risks.** As with any procedure of this type, there is a remote possibility of infection, drug reaction, or other rare complication, which could cause partial loss of vision.

16. **Long-Term Effects.** Because Advanced Surface Ablation, or ASA, is a relatively new procedure, the long-term effects and consequences of the procedure have not been fully determined.

**IX. Possible Benefits**

In many cases, ASA results in a person's reduced dependence on eyeglasses and contact lenses. Studies conducted by laser manufacturers and reviewed by the U.S. Food and Drug Administration suggest that more than 94% of patients achieve 20/40 or better distance vision (sufficient to qualify for a driver's license without corrective lenses in most states and provinces) with one ASA treatment when correcting nearsightedness of less than -6.0 diopters of refractive error.

Some patients may elect to correct their distance vision in one eye while leaving the other eye slightly nearsighted. This technique called monovision may allow improved distance vision with one eye and may allow the other eye to be effective for reading, forestalling the effect of Presbyopia and the need for reading glasses.

There may also be psychological and social benefits for patients who feel that they look better, or can function better, without glasses or contacts.

**Consent to Laser-ASA**

1) I have read this consent form.

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2) I have discussed it with my eye doctor and have been given the opportunity to ask questions. All of the questions, which I have asked, have been answered to my satisfaction. I understand how ASA is performed and acknowledge its possible risks and complications.

3) I understand that:
   a) The manufacture and use of the excimer laser for refractive surgery is regulated by the U.S. Food and Drug Administration (FDA).
   
   b) ASA’s are elective procedures. There is no health or medical reason why I need to have ASA.
   
   c) Alternative treatments to ASA, including eyeglasses contact lenses and LASIK are available.
   
   d) The results of the ASA procedure cannot always be predicted. The safety and efficacy of ASA cannot be guaranteed. I may still need eyeglasses or contact lenses to achieve satisfactory vision after the procedure.
   
   e) ASA is not risk free. Complications from the procedure, as described in this consent form, are possible. Retreatment may be necessary, but there is no guarantee that Retreatment will be successful. As with any procedure of this type, there are remote risks, such as partial loss of best-corrected visual acuity.
   
   f) Adherence to the recommended eye drop regimen and periodic follow-up visits with an eye doctor after the ASA procedure are required to reduce the risk of longer-term complications and increase the likelihood that the desired outcome will be achieved.
   
   g) I confirm that I am neither pregnant nor a nursing mother and that I will notify my doctor if I become pregnant in the period following ASA treatment. I understand that pregnancy may affect my healing response. I also understand that some medications may pose a risk to an unborn or nursing child.
   
   h) My decision to undergo ASA has been my own and has been made without duress of any kind. I understand that, if at any time prior to my procedure, I decide that I do not want to go forward with ASA, I may withdraw my consent.
   
   i) I authorize the eye doctors involved in performing my ASA procedure and in providing my pre- and post-procedure care to share with one another any medical information relating to my health, my vision, or my ASA procedure, which they deem relevant to providing me with care.
   
   j) I understand that information gathered about my procedure and my post-procedure care may be used to study the ASA procedure. I give permission for my medical records to be released to persons involved in such studies and for my case to be presented at professional or scientific meetings or published in journals, as long as I am not identified by name. I also give permission for my ASA procedure to be observed and for the procedure to be photographed by still camera, movie camera, or videotape, and for these photographs, films or tapes to be shown at professional, scientific, educational, promotional, or similar meetings or published in journals, so long as my name is not revealed.
   
   k) I understand that third parties may be contracted to provide certain services, including patient scheduling, medical data processing, quality assurance analysis, patient billing, and practice

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management. I give permission for the release of my medical information relating to my ASA procedure to such third parties.

l) I agree to accept personal financial responsibility for the payment of all charges and fees related to my ASA procedure, including charges for the procedure itself, for medications I may need, for pre- and post-procedure care, for any eyeglasses or contact lenses required after the procedure, and for the expenses connected with my travel to any Millennium ASA vision correction center. In the event that I have insurance, which covers all or part of the cost of my ASA procedure and follow-up care, I authorize the release of information relating to my ASA procedure for insurance or payment purposes.

m) I understand the risk in undergoing Advanced Surface Ablation, or ASA. I wish to have ASA performed and hereby consent to the procedure and to any pre- or post-procedure care, which my eye doctors deem necessary or advisable.

n) I verify that I will not wear/have not worn gas permeable or hard contact lenses at any time in the one-month period prior to undergoing ASA, and I will not wear/have not worn soft contact lenses at any time in the one-week period prior to undergoing ASA.

o) I understand, that should I need additional ASA vision correction, such an enhancement treatment will be performed by the ophthalmologist who performed the prior ASA procedure. I also understand that I will be required to return to the Laser Center in which the prior procedure was performed and that expenses for transportation and lodging will be my responsibility.

I consent to undergo ASA for correction of (circle one):

- [ ] nearsightedness
- [ ] nearsightedness & astigmatism

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☐ farsightedness       ☐ farsightedness & astigmatism

I elect to wear a protective contact lens, rather than a patch during the initial 2-4 day period in which my eye is healing. (Check one)  ☐ No  ☐ Yes

Patient's Signature: ______________________________________  Date: ____________________

Patient's Name (Print): ____________________________________________________________

Witness/Companion Signature: ______________________________________________________

Witness/Companion Name (Print): ____________________________________________________

I am a duly licensed eye care professional in good standing. I am knowledgeable about ASA and its risks and benefits. I have personally discussed the consent form with the patient, have given the patient the opportunity to ask questions, and have answered those questions to the best of my ability.

Signature:__________________________________________Date:_________________________

Name (Print): __________________________________________

I understand that after undergoing ASA surgery, it is important that I have appropriate post-operative care from an eye care professional that knows my case and is qualified to render this necessary care. This post-operative care may be provided by my surgeon, or alternatively, if I so chose, by another trained optometrist or ophthalmologist, provided that my surgeon determines it is clinically appropriate. I recognize that if problems develop during the post-operative period, I must notify my surgeon and that I may need to return to Millennium for treatment.

Signature: ____________________________________    Date:_________________________