INFORMATIONAL CONSENT FORM FOR THE USE OF MITOMYCIN-C

Background:
The correction of myopia using the excimer laser is associated with a higher chance of corneal scarring or “haze” when it is applied to the corneal surface in PRK/LASEK/ASA procedures. This corneal haze may occur relatively early or years after the original procedure and can result in decreased vision.

Since 1997, a medication called mitocycin-C (MMC) has been used to treat patients who developed this potentially visually debilitating condition. Since that time, some advanced refractive surgeons have begun using MMC prophylactically (as a preventative measure) to decrease the possibility that corneal haze will develop after Photorefractive Keratectomy (PRK), Laser-Assisted Subepithelial Keratomileusis (LASEK) and more recently in a procedure known as Advanced Surface Ablation (ASA). These procedures have been associated with corneal haze in certain individuals.

It has now been shown in several studies that the proper use of MMC has significantly and safely decreased the likelihood of developing haze in individuals receiving these procedures. However, MMC is not indicated for every patient, but only for individuals who have significant haze or scarring from a prior procedure or if LASIK cannot be performed safely due to thin corneas (either primarily or for enhancements).

Mitomycin-C:
MMC is an antibiotic that has been used in the medical field for a number of decades. It has been used as an anti-cancer drug because it can stop the proliferation or growth of certain types of cells such as those seen in tumors, and also those cells in the eye which produce scarring or haze. MMC has been used in the eye since the 1980s to prevent scarring after surgical procedures such as glaucoma filtration and pterygium surgeries. The use of MMC for treatment and prevention of corneal haze is a relatively new and exciting potential indication for this medication.

As good as this is, it is important to understand that MMC is very potent and potentially toxic. Some of the eye-related complications that have been reported following the use of MMC (for other conditions) include, but are not limited to: conjunctival injection (redness of the eye), permanent stem cell deficiency, corneal or scleral thinning or perforation requiring corneal transplant or scleral grafting, corneal decompensation, cataract, and retinal vascular occlusion.

The complications listed above were seen following various types of surgeries, but no complications have been reported following the technique used at our center. Our technique uses a low dose (0.02%) of MMC delivered to the cornea for one to two
minutes only (depending on the purpose). This technique minimizes but may not entirely eliminate the chance of MMC associated complications and there is no guarantee that you will obtain a similar result. The possibility does exist that over long periods or time corneal haze and/or unforeseen toxicity may develop in the future and this may require additional treatments or even corneal transplantation.

Consent:
My surgeon has indicated to me that I either have existing corneal haze, or that I may be more likely to develop corneal haze following PRK, LASEK, ASA or for an enhancement over an existing LASIK flap. I have read and understood the above, and understand the benefits, risks and alternatives to using MMC as described to me. I have had the opportunity to ask questions, and understand that the use of MMC is considered experimental and an “off-label” use of a FDA-approved medication. I understand there are no guarantees as to the success of the procedure in removing or preventing haze and I understand that toxic side effects may develop.

I give my informed consent to my surgeon (indicated below), and/or their assistants to use MMC on my □ RIGHT eye □ LEFT eye □ BOTH eyes as described above.

Patient’s Name (PRINT)

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Patient’s Signature

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Date

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Witness’ Name (PRINT)

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Witness’ Signature

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Date

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Surgeon’s Name (PRINT)

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Surgeon’s Signature

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Date