

**LASER REFRACTIVE CENTER  
INFORMED CONSENT DOCUMENT  
SMALL INCISION LENTICULE EXTRACTION  
(SMILE)*****GENERAL INFORMATION***

The purpose of this document is to provide written information regarding the risks, benefits and alternatives of Small Incision Lenticule Extraction (SMILE). This material serves as a supplement to the discussion you have with your physician. It is important that you fully understand this information, so please read this document thoroughly. If you have any questions regarding the procedure, ask your physician prior to signing the consent form. We appreciate your selecting UCLA Health System to meet your needs.

This procedure, like all surgery, presents some risks, many of which are listed below. It is impossible to list all of the possible risks and complications associated with this proposed surgery or any other treatment. Risks and complications that are considered to be unforeseeable or remote are not discussed.

***AN OVERVIEW OF THE SMILE PROCEDURE***

SMILE permanently changes the shape of the cornea. The surgery is performed using topical anesthetic (drops placed on the eye). The procedure involves using a high precision femtosecond laser, the same laser that is used to create a laser assisted in situ keratomileusis (LASIK) flap, to create a lenticule (i.e. lens-shaped tissue) within the cornea. Instead of creating a flap that has to be lifted back before the underlying tissue can be removed, the laser cuts a thin lenticule of tissue underneath the corneal surface that is then removed through a smaller incision than LASIK. The precise shape of the lenticule is based on the level of nearsightedness being corrected. The laser creates the lenticule by producing tiny bubbles at extraordinary speed, with ultra-high precision, in a three-dimensional pattern in the shape of the lenticule within the cornea. The laser beam does not penetrate into the eye beyond the cornea. The laser then creates a connecting tunnel to access the lenticule. The surgeon removes the lenticule created by the laser from the eye through the connecting tunnel under the operating microscope. After removal, the corneal curvature is flatter in the case of nearsightedness, and more rounded, in the case of astigmatism. No stitches are required. The procedure takes approximately 10 minutes to complete both eyes. The vision is instantly better than before surgery without glasses. Typically, on the first post-operative day the vision is about 80% improved and usually reaches 100% by 1 week.

***LIMITS OF SMILE***

Although the goal of SMILE is to improve vision to the point of not being dependent on glasses or contact lenses, or to the point of wearing thinner (weaker) glasses, this result is not guaranteed. Additional procedures, spectacles or contact lenses may be required to achieve

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adequate vision. SMILE surgery will not prevent you from developing naturally- occurring eye problems such as glaucoma, cataracts, macular degeneration or retinal detachment.

SMILE does not correct the condition known as presbyopia (aging of the eye), which occurs in most people around age 40 and requires them to wear reading glasses for close-up work, sometimes including computer distance. The key question you must ask yourself is: Can you read up close while looking through the top part of your distance glasses? If you must take off your distance glasses or use bifocals to read up close, then you have presbyopia. Patients with presbyopia who get both eyes fully corrected for distance vision will then need to use reading glasses to see clearly up close. This sometimes includes computer distance. Therefore, if you presently need reading glasses, you will likely still need reading glasses after this treatment. If you do not need reading glasses because you take off your distance glasses to read, you will likely need reading glasses after this treatment if you have both eyes corrected fully for distance. If you do not need reading glasses now, you will need them at a later age. You may consider having one eye weighted for mid-range near vision. Many patients over the age 40 make this decision and are pleased with both their distance and mid-range near vision (example: computer screen, shopping tags, grocery shelves) and then use simple reading glasses for close-range and for smaller printed materials (example: newspapers, some magazines, mobile phone).

***ALTERNATIVES TO SMILE***

SMILE is an elective procedure. There is no emergency condition or other reason that requires or demands you have it performed. If you decide not to have SMILE, there are other methods of correcting your nearsightedness, farsightedness or astigmatism. The alternatives include eyeglasses, contact lenses, and other refractive surgical procedures. You may wish to discuss these options with your physician.

***RISKS AND CONTRAINDICATIONS***

**Risks:** The risks of SMILE surgery include, but are not limited to:

- **Loss of Vision:** SMILE surgery can possibly cause loss of best-corrected vision. This can be due to infection (internal or external), scarring or other causes. Unless successfully controlled by antibiotics, steroids, or other necessary treatment, it could even cause loss of the infected eye. Vision loss can be due to the cornea healing with an irregular surface, which could cause astigmatism and make wearing glasses or contact lenses (soft or hard) necessary. Irregular cornea healing could result in an uneven corneal surface so that distorted vision or “ghosting” occurs. This could mean that glasses or contact lenses may not correct the vision to the level and/or quality possible before undergoing SMILE. The femtosecond laser could malfunction, requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may or may not be accompanied by visual loss.

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- **Visual Side Effects:** Your vision after surgery may not be clear immediately, and you might not notice improvement for several days to several weeks. There may be increased sensitivity to light, glare, and fluctuations in the sharpness of vision. These usually occur during the normal stabilization period for one to three months, but they may also be permanent. After refractive surgery, a certain number of patients experience glare, a “star bursting” or halo effect around lights, or other low-light vision problems that may interfere with the ability to drive at night or see well in dim light. This is more likely in patients with large pupils or high degrees of correction. For most patients, this is a temporary condition that diminishes with time or is correctable by wearing glasses at night or taking eye drops. However, for some patients this is permanent.

Other visual complications and conditions that can occur with SMILE surgery include: epithelial ingrowth (epithelial cells growing underneath the corneal flap) which can induce astigmatism or cause foreign body sensation; anisometropia (difference in power between the two eyes); aniseikonia (difference in imaging size between the two eyes); double vision; hazy vision; reduced contrast sensitivity; diminished depth perception.

- **Conversion to LASIK or PRK procedure:** For SMILE, the laser takes about 35-40 seconds to create the lenticule and the small tunnel. During this time the laser is docked to the eye using suction in exactly the same fashion as when it is used to create a LASIK flap. With SMILE, because the laser is creating a lenticule instead of a LASIK flap, the lenticule creation takes about twice as long as the LASIK flap creation. If the patient moves or squeezes the eye during the initial portion of the lenticule creation, the SMILE procedure may need to be aborted. If the procedure is not completed, the vision should return to its pre-surgical state. In most cases, an alternative procedure such as LASIK or photorefractive keratectomy (PRK) can be performed either the same day or at another time. If you wish to have this potential option, a separate consent will need to be reviewed and signed giving your permission for this alternative procedure.
- **Residual nearsightedness, farsightedness and/or astigmatism:** It may be that SMILE surgery will not give you the result you desired. Some procedures result in the eye being under corrected. If this occurs, it may be possible or necessary to have additional surgery to fine-tune or enhance the initial result. It is also possible that your eye may be overcorrected to the point of becoming farsighted (by over treating myopia), or that your initial results could regress over time. In some, but not all cases, re-treatment, glasses or contact lenses could be effective in correcting vision. Retreatment surgeries can be performed when vision is stable UNLESS it is unwise or unsafe. Retreatment surgery can be performed no sooner than three months after surgery. Generally, this is done using a PRK procedure which has a longer visual recovery than SMILE. Sometimes it is possible to perform a LASIK procedure after SMILE if a retreatment is required. Whether or not this can be done is determined on a case by case basis during the post-operative period. An assessment and consultation will be

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held with the surgeon at which time the benefits and risks of a retreatment surgery will be discussed.

- **Redness and/or dryness of eyes:** There is a chance that the whites of the eyes may temporarily appear pink or red for several days to several weeks after surgery. There is an increased risk of eye irritation related to drying of the corneal surface following SMILE. All of the cornea procedures used to correct vision are associated with increased dry eye for a period of time (e.g. 6-12 months) following the surgery. Most patients who do a lot of reading and computer work will notice the post-operative dryness and need to use lubricant drops during these activities. Patients over the age of 40 and female patients tend to have more dryness. Your surgeon will discuss with you the various treatments for post-operative dry eye.
- **Keratoconus:** It is a degenerative corneal disease affecting vision that occurs in approximately 1/2000 in the general population. While there are several tests that suggest which patients might be at risk, this condition can develop in patients who have normal preoperative topography (a map of the cornea obtained before surgery) and pachymetry (corneal thickness measurement). Since keratoconus may occur on its own, there is no absolute test that will ensure a patient will not develop keratoconus following laser vision correction. Severe keratoconus may need to be treated with a corneal transplant while mild keratoconus can be corrected by glasses or contact lenses.
- **Contact lens intolerance:** If you wear contact lenses now, there is a chance you may not be able to do so after surgery because of the changes to the shape of your eye.
- **Other Risks:** Other reported complications include corneal ulcer formation; clouding or hazing of the cornea; cornea scarring; endothelial cell loss (loss of cell density in the inner layer of the cornea, possibly resulting in corneal swelling); ptosis (droopy eyelid); contact lens intolerance; blepharitis (inflammation of eyelids or scaly eyelids); rosacea (eyelid nodules); retinal detachment; new or increased floaters; hemorrhage; cataract formation; corneal epithelial (skin) abrasion or defect which can slow the recovery process and may lead to reoccurring corneal erosions (outer surface cell detachment) with eye discomfort and blurred vision. If you have had previous eye surgery it is possible that during the procedure that the incisions could re-open. This could decrease the healing and lead to irregular healing. A contact lens may need to be worn as a bandage until the incisions close. Sutures may also be required which could induce astigmatism. Complications could also arise requiring further corrective procedures including either a partial (lamellar) or full-thickness corneal transplant using donor cornea. These complications include lenticule decentration causing irregular astigmatism; partial lenticule retention causing irregular astigmatism, and progressive corneal thinning (ectasia). Ectasia could necessitate the wearing of a rigid corneal or scleral contact lens for best correction. It could even lead to a need for corneal transplantation. The laser may need to be aborted if an improper lenticule is created. If this occurs, another procedure may be used to attempt vision correction. There are also potential

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complications due to anesthesia and medications that may involve other parts of your body. Since it is impossible to state all potential risks of any surgery or procedure, this form does not provide a comprehensive listing of every conceivable problem.

- **Employment Risk:** You should be aware that having this surgery may affect future employment opportunities with certain military or law enforcement agencies. This procedure may impair your ability to perform your job.
- **Later-Discovered Complications:** SMILE is a relatively new technique. You should be aware that other complications might occur that have not yet been reported. Longer-term results may reveal additional risks and complications. After the procedure, you should continue to have routine check ups to assess the condition of your eyes.
- **Risks of Not Undergoing SMILE:** The risks of not having the surgery are limited to those associated with your current visual condition. These include but are not limited to the dangers that may be associated with losing glasses or contact lenses, the risks of corneal distortion and/or infection from wearing contact lenses, and the risks of trauma to the eye caused by breakage of plastic spectacles or contact lenses in the eye.

You may choose to have this procedure performed on both eyes at the same time. This will reduce your total recovery time and minimize the unbalance between eyes. However, treatment of both eyes could lead to complications, as discussed above, occurring in both eyes at the same time. Also, if you have both eyes treated at the same time, your vision may be blurred, in both eyes, making it harder to drive and function for a period of time afterward.

**Contraindications:** The treatment should not be performed on persons:

- with uncontrolled vascular disease;
- with uncontrolled autoimmune disease;
- who are immune-compromised or on drugs or therapy that suppress the immune system;
- who are pregnant, nursing, or expecting to become pregnant within the six months following the SMILE procedure;
- with residual, recurrent, or active ocular disease(s) or abnormality except for myopia with/without astigmatism, hyperopia with/without astigmatism or presbyopia in either eye;
- with active or residual disease(s) likely to affect wound-healing capability;
- with unstable or uncontrolled diabetes;
- with progressive myopia or hyperopia;
- with uncontrolled glaucoma;
- with uncontrolled dry eyes or blepharitis.

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If you know that you have any of these conditions, you should inform your physician. In addition, if you have any other concerns or possible conditions that might affect your decision to undertake SMILE surgery, you should discuss them with your physician.

***PRE- AND POST- TREATMENT CARE*****Before SMILE surgery:**

- **Pregnancy:** Pregnancy could adversely affect your treatment result since your refractive error can fluctuate during pregnancy; In addition, pregnancy may affect your healing process, and some medications may pose a risk to an unborn or nursing child. If you are pregnant, or expecting to become pregnant, you should not undergo the SMILE procedure until after the pregnancy.
- **Taking medications and allergies:** You should inform your physician of any medications you may be taking in order to account for the risk of allergic reactions, drug reactions, and other potential complications during the SMILE surgery and subsequent treatment.
- **Contact lens wearers:** Patients who wear gas-permeable or hard contact lenses must completely stop wearing such lenses at least 3 weeks prior to the initial eligibility examination. (This period may be longer for some patients.) Patients who wear soft contact lenses must completely stop wearing their soft contact lenses at least 3 days prior to the eligibility examination. After the eligibility exam, you may wear your contacts up until 24 hours prior to surgery.

**After SMILE surgery:**

- **Eye Protection:** Avoid exposing the eye to tap water in the bath or shower, as such nonsterile water may expose the eye to increased risks of infection. Wear sunglasses during the first day after having surgery. Avoid rubbing the eye. The eye may be more fragile to trauma from impact. It is advisable that you wear protective eye wear when engaging in contact or racquet sports or other activities in which the possibility of a ball, projectile, elbow, fist or other traumatizing object contacting the eye may be high.
- **Operating Motor Vehicles:** After SMILE, in order to operate motor vehicles, glasses, contact lenses, eye drops, or other measures may be needed. After surgery, you may experience starburst-like images or “halos” around lights, your depth perception may be slightly altered, and image sizes may appear slightly different. Some of these conditions may affect your ability to drive and judge distances. Driving should only be done when you are certain that your vision is adequate. On the day of the SMILE procedure and for your day one postoperative appointment, you should arrange to have a driver.

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- **Pain and Discomfort:** The amount of pain and discomfort that can be expected soon after the SMILE procedure varies with the individual. You should expect that the eye will be sore to some extent after the surgery. Vision may be blurry, and you may experience some redness and/or corneal edema (swelling of the cornea). This may lead to the vision seeming like underwater or looking through a cloudy window. This can persist for several days and up to 1 week. Some patients report the sensation of a foreign object in the eye, tearing, light sensitivity, itching, or dryness of the eye.

***PATIENT STATEMENT***

- I have read this Informed Consent form (or it has been read to me). The SMILE procedure has been explained to me in terms that I understand.
- I understand that the SMILE procedure has been approved by the FDA for the treatment of myopia (nearsightedness) with/without astigmatism.
- I have been informed about the possible benefits and possible complications, risks, consequences, and contraindications associated with SMILE. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to any questions I have asked. I understand that no guarantee of a particular outcome was given and that my vision could become better or worse following treatment.
- My decision to undertake the SMILE procedure was made without duress of any kind. I understand that SMILE is an elective procedure, and my myopia and/or astigmatism may be treated by alternative means, such as spectacles, contact lenses, or other forms of refractive surgery. It is hoped that SMILE will reduce or possibly eliminate my dependence on glasses or contact lenses. I understand that the correction obtained may not be completely adequate and that additional correction with glasses or contact lenses may be needed.
- I authorize the physicians and other health care personnel involved in performing my SMILE procedure and in providing my pre- and post-procedure care to share with one another any information relating to my health, my vision, or my SMILE procedure that they deem relevant to providing me with care.
- I understand that my surgical measurements may be entered into a database (without any personally identifiable information) for the purposes of surgical planning, research, marketing and publication and that this non-identifiable data will be accessible to parties outside of UCLA.

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- I have had sufficient time to review this consent form. A physician or an associate has adequately addressed my questions and concerns. By signing below, I am making an informed decision to undergo the SMILE procedure. I have received (or been offered) a copy of this consent for my own records.
- I authorize the release of my medical records in order to process medical claims or requests for further information from insurance companies.
- I understand that I have had an interpreter or legal guardian read this consent that they will sign under the surrogate consent area for me.
- I understand that if I elect to have another physician and/or optometrist (outside of UCLA) follow my postoperative care that I will sign the management consent form.

I consent to have Dr. \_\_\_\_\_ perform SMILE on my:  
 (circle one) right eye/ left eye/ both eyes.

\_\_\_\_\_  
 Patient Printed Name

\_\_\_\_\_  
 Patient Signature

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Witness Printed Name

\_\_\_\_\_  
 Witness Signature

\_\_\_\_\_  
 Date

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**FOR SURROGATE CONSENT**

I am the guardian, next-of-kin, or legal representative of the patient whose name appears above on the patient signature line. I have read and fully understand the foregoing information and have discussed this information and its terms with the patient to the extent of the patient's understanding. Due to the patient's inability to provide informed consent, I consent to have SMILE performed on the patient's right eye/ left eye/ both eyes.

\_\_\_\_\_  
Printed Name of Surrogate

\_\_\_\_\_  
Surrogate Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Nature of Relationship to Patient

\_\_\_\_\_  
Witness Signature

**MANAGEMENT CONSENT FORM**

It is my desire to have Doctor \_\_\_\_\_, perform my preoperative/postoperative follow-up care for refractive surgery. I have been assured that UCLA Laser Refractive Center will be contacted immediately if I experience any complications related to my eye surgery.

Reason for Management by this doctor, is: (please check one)

- Maintain established eye care relationship.
- Difficult to return to UCLA for follow-up care because of location.
- Other (please give reason) \_\_\_\_\_

Patient Signature \_\_\_\_\_ Date \_\_\_\_\_

Witness Signature \_\_\_\_\_ Date \_\_\_\_\_