

ReLEX SMILE : Patient Information

The 3rd generation of laser vision correction.

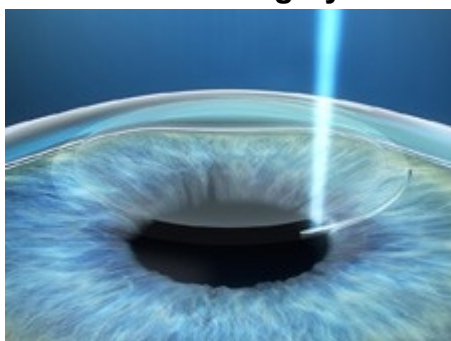
ReLEX® SMILE from ZEISS is the first and, until now, the only solution for performing small incision lenticule extraction, or SMILE for short. ZEISS is the only company to provide a way for treating patients with this minimally invasive, flapless procedure.

Surgical procedure for ReLEX SMILE

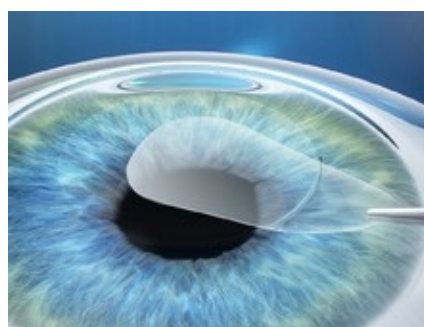
Whereas LASIK procedures involve cutting a flap, folding it back and removing the corneal tissue through point-by-point ablation using an excimer laser,

ReLEX® SMILE utilizes the high-precision femtosecond laser VisuMax® from ZEISS to create a lenticule inside the cornea and access incision in a single treatment step.

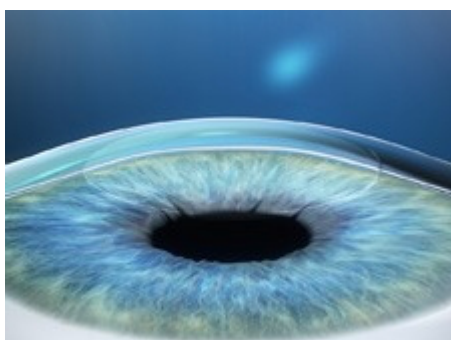
ReLEX SMILE surgery



A refractive lenticule and small incision are created inside the cornea – all in one step.



The lenticule is removed through the incision with minimal disruption to the corneal biomechanics.



Removal of the lenticule changes the shape of the cornea, thereby achieving the desired refractive correction.

Benefit

SMILE combines the advantages of PRK and LASIK. With ReLEx® SMILE, minimally invasive, flapless surgery is possible.

- **Flapless**

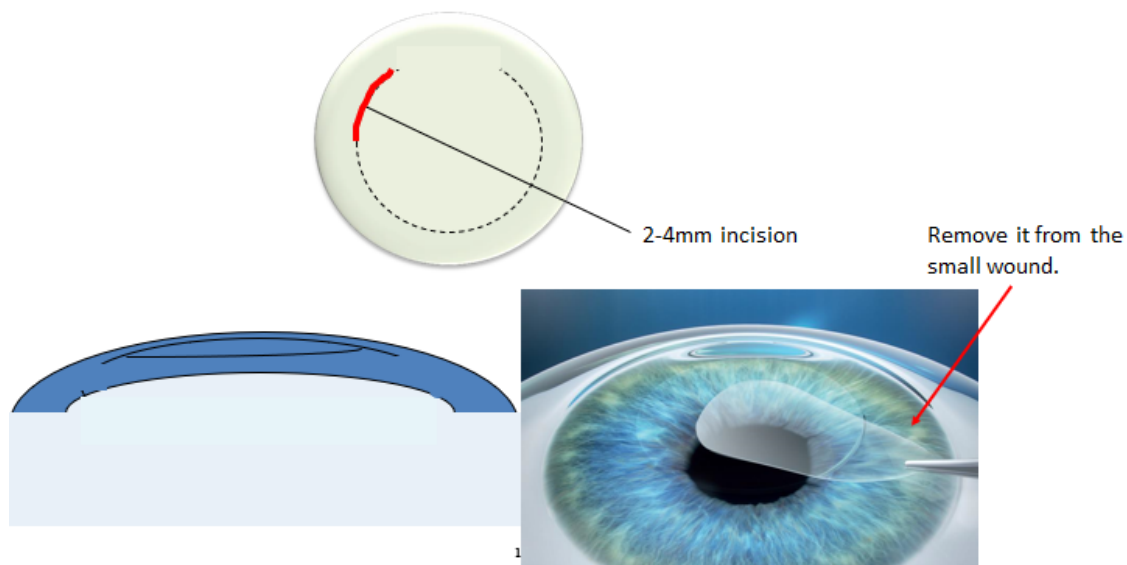
ReLEx SMILE enables to perform the flapless procedure. Because there is no flap, there are also no flap-related complications. In addition, ReLEx SMILE reduces the incidence of infections and epithelial ingrowth while expediting epithelial healing.

- **Up to 80 % smaller side-cut**

Femto-LASIK requires a side-cut of roughly 20 mm. With ReLEx SMILE, a small incision of 2 – 4 mm is sufficient.

- **Up to 30 % smaller cap incision area**

The lamellar incision area is roughly 1/3 smaller compared to Femto-LASIK.



- **Greater integrity of the upper corneal layers**

With SMILE, the majority of the upper corneal layers remain intact. This offers the potential for more biomechanical preservation and stability.

- **Less incidence of dry eye**

Requiring only a small incision makes fewer transected nerves than a LASIK flap. Consequently, a significantly reduced incidence of dry eye is likely to be correlated.

- **All-femto**

With ReLEx SMILE, the entire procedure is performed with the femtosecond laser technology of the VisuMax®. As a result, there is no need for complex nomograms or fluence tests. In a way, it

could be called one-step refractive surgery. With ReLEx SMILE, the entire correction is performed as a single step: on one laser, with one treatment plan and one laser process.

Risks

As with any surgical procedure, there are certain risks associated with ReLEx SMILE. The following is a list of possible risks.

- **Foreign body sensation or pain:** Most patients experience slight discomfort or pain, particularly during the first 24 hours after ReLEx SMILE surgery.
- **Blurred vision:** Vision may be somewhat blurred during the early postoperative period.
- **Delay in visual recovery:** In most patients, it takes a little more time than LASIK until the cut surface becomes smooth.
- **Subconjunctival bleeding:** Bleeding sometimes occurs from the subconjunctiva (white part of the eye) when the femtosecond laser is fixed on the eye to create the flap. In this case, about two weeks are required for the blood to be absorbed entirely. However, this will not affect your visual acuity.
- **Night vision problems, such as halos, glare, starbursts, and light sensitivity:** Patients commonly experience mild glare and haloes at night following ReLEx SMILE. In most patients, these symptoms are mild and dissipate over time. However, in rare cases, they may be severe and prolonged enough to require eye drops that constrict the size of the pupil.
- **Dry eye:** Dry eye may occur after ReLEx SMILE. Dry eye causes discomfort and can also reduce the quality of vision due to intermittent blurring and other visual complications. Eye drops are usually administered to counter this problem during the first few weeks after ReLEx SMILE surgery.
- **Presbyopia:** Presbyopia is a natural ageing process of the lens inside the eye. You may require near vision correction by reducing myopia if you are in the presbyopic age range.
- **Undercorrection and regression:** It is impossible to predict how your eyes will respond to the treatment accurately. Undercorrection is the most commonly noted inaccuracy and is generally very mild. If undercorrection is significant, you may need to wear glasses or contact lenses or eventually have additional refractive surgery to achieve your best vision. Additionally, it has been observed that some patients have mild regression of correction following ReLEx SMILE. However, in most cases, the correction is relatively stable after surgery.
- **Overcorrection:** Following ReLEx SMILE for low-to-moderate degrees of myopia, overcorrection occurs much less frequently than undercorrection. As with undercorrection, it is impossible to predict how your eyes respond to the treatment accurately. A mild degree of overcorrection may be well tolerated. More severe overcorrection may necessitate wearing glasses or contact lenses or may

require further refractive surgery.

- **Loss of best-corrected visual acuity:** A few patients lose lines of vision on the vision chart. Loss of best-corrected visual acuity cannot be corrected with glasses or contact lenses. It may be due to irregular astigmatism, which occurs if the cornea heals in a wavy fashion.
- **Re-operation:** It should be done by PRK surgery. It can not be alone by the ReLEx SMILE procedure.
- **Limited indication:** The indication range is narrower than LASIK.

ReLEx SMILE indication range for myopia and astigmatism: (APPX.)

- Sphere: -3.00 to -7.00 D
- Cylinder: 0 to 3.00 D
- Spherical equivalent: -3.00 to -8.00 D
- **DLK:** Diffuse lamellar keratitis(DLK)describes a rare, non-infectious refractive surgery complication characterized by inflammatory infiltrates beneath the corneal flap interface.
- **Infection:** Infection is a potential complication that accompanies all surgical procedures. Following LASIK, the risk of infection is less than 0.02%. To minimize the risk of postoperative infection, it is critical to precisely follow the prescribed postoperative medication regimen.
- **Retinal diseases:** It is unknown whether refractive surgery affects the retina. However, the frequency of retinal diseases, such as objects floating in the field of vision, retinal detachment, and retinal tears, maybe slightly more in myopic eyes.
- **Keratectasia:** Excessive corneal thinning (keratectasia) may result in weakness and abnormal shape of the cornea. Although uncommon, it is a serious complication severely impacting the patient's vision.
- **Elevated eye pressure:** Using steroid eye drops may result in elevated pressure inside the eye.
- **Epithelial defect:** Rarely, defects may be created on the flap surface while using the femtosecond laser. In most cases, the epithelial defect is corrected by using of a soft contact lens or eye drops. However, several days or weeks may be required for complete healing of the wound and improvement in visual acuity.

Precautions

Instructions for Patients Wearing Contact Lenses

Contact lenses alter the shape of the cornea. Therefore, people who wear contact lenses need to stop wearing them before the surgery, depending on the type of contact lenses used.

- Hard or gas permeable lenses (HCL) should not be used for 4 weeks before the final examination. Likewise, HCL should not be worn after the final examination.
- Soft contact lenses (SCL, Toric SCL) should not be used for 3 days before the final examination. SCL may be used after the final examination, but should not be worn 1 day before surgery.

Following the above instructions will ensure accurate measurement of refractive errors in patients.

On the Day of the Surgery

- Please do not wear makeup (except skin toner/emulsion).
- Please do not wear any sweater or garment made from mohair or similar yarn.
- Please avoid any outfit that exposes your shoulders or bring a jacket with you (the operating room is chilly).
- Please do not operate a vehicle.
- Please do not drink alcohol.
- Please do not put on any perfume, hair gel, or strongly scented cream when you come to the clinic for the surgery.
- Please remove earrings before the surgery.
- If you have long hair, please tie it to the side before the surgery.
- Please bring the informed consent document with your signature. If you are less than 20 years old, your parent's signature is necessary on the informed consent document.
- Please inform the doctor regarding any drug allergies that you have experienced.

Precautions after the Surgery

Significant improvement in vision will be noticeable approximately 1 day after LASIK surgery. Although complications can occur with any surgery, there is usually little to no postoperative discomfort, and some patients can return to daily activities the next day. Please follow the instructions mentioned below to prevent postoperative infection.

On the Day of the Surgery

- Please do not touch your eyes or eyelids.
- Please do not take a bath, shampoo your hair, or wash your face. Instead, please wipe your face gently with a wet towel. You may take a shower, but please avoid wetting your face. After examination by the physician on the day after the operation, if there are no complications, you may take a bath, shampoo your hair, and wash your face.
- Please be sure to come to the clinic on the day following the surgery.
- Please use eye drops according to the instructions provided.

During the First Week after Surgery

- Please use protective sunglasses outdoors and protective eye patches while sleeping.
- Please do not participate in sports.
- Please do not wear eye makeup.

During the First Month after the Surgery

- Please prevent water or sweat from entering your eyes and avoid vigorously rubbing your eyes.

Follow-up examinations will be conducted at 1 day, 1 week, 1 month, 3 months, 6 months, and every year after surgery. Don't hesitate to contact the clinic if you experience unusual symptoms or if your vision suddenly worsens.