stahl
EYE CENTER

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INFORMED CONSENT FOR

IntraLASIK Correction of Nearsightedness, Farsightedness and Astigmatism Using IntraLase™ Technology

Circle One:

Patient's Name _____ **OU OD OS Date** ____/____/____

The IntraLASIK or "all-laser" LASIK procedure involves two steps. Instead of a microkeratome blade as in traditional LASIK, the FDA-approved IntraLase™ laser is first used to create a corneal flap with laser energy. The IntraLase™ laser is capable of creating extremely precise flaps by producing tiny bubbles inside the cornea that are 1/10,000 of an inch in diameter. The laser beam cannot penetrate into the eye beyond the cornea. After the flap is created, an excimer laser is used to reshape the eye by removing ultra-thin layers from the cornea in order to reduce farsightedness, nearsightedness, or astigmatism, just as in any LASIK procedure.
IntraLASIK is an elective procedure: there is no emergency condition or other reason that requires or demands that you have it performed. There are alternatives to this surgery: you could continue wearing contact lenses or glasses and have excellent vision. There are also other types of refractive surgery, including PRK and LASIK with a microkeratome.
This procedure, like all surgery, presents some risks, many of which are listed below. You should also understand that there may be other risks not known to your doctor, which may become known later. Despite the best of care, complications and side effects may occur; should this happen, you may end up with worse vision than you have currently.

In giving my permission for IntraLASIK , I declare that I understand the following information.
Please read but do not sign or initial your surgery consent form until a surgeon or counselor advises you.

1. _____ I understand that LASIK is a relatively recent technique, and although there have been millions of these procedures performed worldwide, complications might occur that have not yet been reported. Long-term results may reveal additional risks and complications. After the procedure, I will continue to have return check-ups to assess the condition of my eyes.

2. _____ I understand that as a result of surgery my vision may be made worse.

3. _____ I understand that the IntraLase™ laser or the excimer laser could malfunction requiring the procedure to be stopped before completion. Depending on the type of malfunction, this may be accompanied by visual impairment which may or may not be fully corrected by further treatment.

4. _____ **I understand that after any form of laser surgery there may be "starbursts", glare or haloes around lights, mainly at night or in dim light. I understand that this condition usually diminishes with time, but could be permanent. I understand that my vision may not seem as sharp at night as during the day, and that I might need to wear glasses or use eyedrops at night. I understand that I should not drive until my vision is adequate for driving both during the day and at night. Night vision disturbances, haloes, or glare can occur after surgery regardless of the size of my pupil and may not be correctable.**

5. _____ I understand a difference in focus between the two eyes (anisometropia) can occur after surgery.

6. _____ I understand that very rare complications threatening vision may occur, that include but are not limited to: corneal swelling, infection, corneal scarring, loss or damage of the corneal flap, retinal detachment, hemorrhage, vascular blockage, or cataract formation. Although complications that threaten vision are extremely rare, it is possible that if a significant reduction in vision is the result of corneal damage, then a corneal transplant may be required.

To assure that you have understood the information presented, please review the following statement and initial.

21. _____ **I understand the information presented and have had an opportunity to have all my questions answered. I have received no guarantee as to the success of my surgery and I am willing to accept the fact that I may need glasses or contact lenses or further surgery to achieve my best possible vision. I understand that side effects or complications may occur. The decision to undergo laser surgery has been my own.**

Operative Eye: ☐ **RT** ☐ **LT** ☐ **BOTH**

PATIENT NAME: (Print) _____ **DATE:** _____

PATIENT SIGNATURE: _____ **DATE:** _____

WITNESS SIGNATURE: _____ **DATE:** _____

OPHTHALMOLOGIST: _____ **DATE:** _____

I certify that I have read the pre-op instruction and I understand the importance of each.

PATIENT SIGNATURE: _____ **DATE:** _____

I certify that I have had the post-op instructions explained to me and I understand the importance of each.

PATIENT SIGNATURE: _____ **DATE:** _____

Addendum:

I give permission for my doctor to:

- Record on video or photographic equipment my procedure for purposes of education, research or the training of other health care professionals.
- Use the data about my procedure in subsequent procedures without reference to my name, to further the understanding of refractive surgery.
- Allow observers during this procedure for educational, medical and scientific purposes.

I understand that my participation is voluntary and that I may refuse to participate or may withdraw consent or discontinue participation at any time, without prejudice to my present or future care.

_____
Patient Signature

7. _____ I understand that scratches and loose patches of the corneal surface may occur during the procedure. Patients with loose corneal tissue, dry eyes, history of corneal abrasions, or even long term contact lens wearers are more likely to develop this. Patients who experience these problems may take longer to heal.

8. _____ **I understand that I may get dry eyes after IntraLASIK. The symptoms of dry eyes may be temporary or permanent. The dryness of the corneas may result in blurred vision and/or delayed healing and may require long term use of artificial tear lubricant, closure of my tear duct openings and/or use of prescription medication.**

9. _____ I understand that after surgery, glasses or contact lenses may still be required for sharpest vision. I understand further treatment may be recommended, including a variety of eyedrops, the wearing of hard or soft contact lenses or glasses, or further laser treatment.

10. _____ I understand that if I currently need reading glasses I will likely still need reading glasses after this treatment. I also understand that if I do not currently need reading glasses, I may need them at an earlier age.

11. _____ I understand that if I require an enhancement or additional laser treatment, this treatment may be delayed until my doctor deems my eyes stable.

12. _____ I understand that this is an elective procedure and that I do not have to have this procedure. I understand that IntraLASIK treatment is not reversible.

13. _____ I understand that if I am pregnant, think I might be pregnant, or am currently nursing, the procedure should not be performed. I understand that pregnancy may adversely affect my treatment result. I agree to inform my surgeon if I am or suspect I may be pregnant.

14. _____ I understand this treatment is generally not recommended on persons with uncontrolled vascular disease or autoimmune disease, or on patients who are immunocompromised or on drugs or therapy which suppress the immune system, so I will tell the doctor if I have any of these or other medical conditions.

15. _____ I understand that the following medications: 1. Cordarone, 2. Accutane, or 3. Imitrex, may interfere with healing after the laser procedure. I have advised the doctor if I am taking any of these medications.

16. _____ **I understand that very rarely the cornea may some months to years after laser surgery develop unpredictable thinning and bulging (ectasia) resulting in variable degrees of impaired vision. This may result from the natural course of an underlying condition such as keratoconus, which in subtle forms may not be detectable before surgery, or can even be induced by laser surgery in otherwise healthy eyes. Current medical information suggests that this uncommon occurrence may be much less likely after surface laser treatments (e.g. PRK, Epi-LASIK) than lamellar laser procedures (e.g. LASIK and IntraLASIK). While mild cases of corneal ectasia can be corrected with glasses or contact lenses, severe cases may require treatment by a corneal transplant.**

17. _____ I understand that the results from my procedure may not be perfect, nor is it realistic to expect that this procedure results in perfect vision at all times, under all circumstances, for the rest of my life. Moreover, the vision gained from the surgery could regress after some time. I understand I may need glasses or contact lenses to refine my vision, and that this might occur soon after surgery or many years later.

18. _____ I understand that after the treatment, it is essential that I attend all follow up examinations and take all medications. I understand that there are possible risks associated with steroid eyedrops which are prescribed after surgery and thus require monitoring at the center. These include elevated eye pressure which can rarely be permanent, as well as cataracts which can blur vision and possibly necessitate surgery to remove the cataract. These are rare and unusual occurrences.

19. _____ I have read this entire document and have had all medical terms defined and explained to my satisfaction.

20. _____ The IntraLASIK procedure and the risks and benefits of the treatment have been explained to me. Although it is impossible for me to be informed of every conceivable complication that may occur, all of my questions have been answered to my satisfaction.