CONSENT FOR OFF- FOR THERAPEUTIC USE OF INTACS® FOR POST-LASIK ECTASIA

This information is to help you make an informed decision about having Intacs® inserted in your eye to reduce the myopia (nearsightedness) and astigmatism that has developed after LASIK surgery due to a condition called ectasia. Ectasia is an abnormal bulging forward of the cornea, the clear front part of the eye that covers, the iris and pupil. Every surgery has risks as well as benefits and each person must evaluate this risk/benefit ratio based on the information given to you, as well as the conversations with your physician and staff. You are encouraged to ask any questions about this procedure and have them answered to your satisfaction before you give your permission for this surgery.

INDICATIONS AND BENEFITS OF INTACS® USED “OFF-LABEL” TO TREAT ECTASIA

Intacs® are intrastromal corneal ring segments available through Addition Technology, Inc. The ophthalmologist inserts one or two small transparent half-rings into the peripheral cornea through a tiny incision. Intacs® are approved by the Food and Drug Administration (FDA) to treat myopia. When the FDA approves a drug or device for medical use, the manufacturer produces a “label” to explain its use. Once a device or medication is approved by the FDA, physicians may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence, and maintain records of its use and effects.

Although initially approved for elective refractive surgery, ophthalmologists use Intacs® “off-label” as a therapeutic treatment for the myopia and astigmatism that accompanies post-LASIK ectasia. Intacs® do not provide a full correction or a full reversal back to your eye’s normal state. Rather, the goal is to reduce your myopia and astigmatism and/or alter the shape of your cornea so that you can be fitted for contact lenses. Intacs® can be removed and replaced if the results are not satisfactory, or if you want to have them removed.

ALTERNATIVE TREATMENT FOR POST-REFRACTIVE SURGERY ECTASIA

Instead of having the ophthalmologist insert Intacs®, you could have a full thickness corneal transplant. A corneal transplant procedure is not reversible. Your own cornea might reject the transplant or it could also develop a postoperative infection; these complications could compromise your vision.

POSSIBLE RISKS OF INSERTING INTACS®

The goal of inserting Intacs® is to reduce your myopia and astigmatism and/or alter the shape of your cornea so that you can be fitted for contact lenses. As with any surgical procedure, there are certain risks and complications you need to be aware of when considering Intacs®. As a result of the surgery and associated anesthesia, it is possible that your vision could be made worse. In some cases, complications may occur weeks, months or even years later. These and other complications may result in poor vision, total loss of vision, or even loss of the eye in rare situations. Although all of these complications can occur, their incidence following Intacs® surgery is low.
Risks of Intacs® surgery include, but are not limited to:

- Discomfort and/or pain for up to 48 hours following the procedure, which can be treated with medication
- Blurred vision, fluctuating vision, or tearing
- Sensitivity to bright light or glare
- Astigmatism (a temporary blurring or distortion of your vision) for several days after the procedure. This type of visual distortion is normal during the healing process and, in most cases, it decreases over time. However, in rare instances, it may be permanent.
- Infection, which if severe could result in the loss of the eye
- Corneal edema
- Corneal perforation, which could lead to infection, or, rarely, a cataract
- Decrease in best-corrected visual acuity
- Other procedures may be required to reach the desired result. While there is no guarantee that the goal will be reached with an additional procedure, uncorrected vision may improve.
- Stromal thinning due to shallow placement, which would require removal of the Intacs®
- If there are complications or problems during the surgery, the surgeon may not be able to insert Intacs®, and the surgery may have to be cancelled.
- Complications due to the anesthetic eye drops are possible.
- Certain patients have reported continued visual distortion related to Intacs®. The US Studies conducted to obtain FDA approval for myopia showed that the following potential vision-threatening events happened less than 1% of the time after Intacs®. All patients returned to the vision they had prior to the procedure. Some experienced infection (0.2%), and others had stromal thinning due to shallow placement (0.2%).
  - These studies were NOT conducted on patients with post-LASIK ectasia, and the risks for patients with ectasia may be higher.
- Intacs® will NOT prevent the development of naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration, or detachment.
- Intacs® do NOT correct the condition known as presbyopia (or aging of the eye), which may require reading glasses for close-up work at about age 40.
- There are other risks associated with any surgery. Since it is impossible to state every risk or complication that may occur as a result of any surgery, the possible risks and complications listed in this informed consent may be incomplete. There may be risks or complications associated with this surgery that are unknown because this is a relatively new procedure.

PATIENT RESPONSIBILITIES

- I have arranged for transportation after the procedure and to my next appointment. I understand that my doctor will advise me when I can safely resume driving.
- I accept full personal financial responsibility for payment of all fees related to my Intacs®. These include the procedure itself, necessary medications, eyeglasses required after the procedure, and expenses connected with my travel to and from the surgery site or office.
- I understand and am acknowledging my willingness to follow the doctor’s instructions and attend regular postoperative visits to reduce the risk of long-term complications.
PATIENT CONSENT

During Intacs® surgery, my ophthalmologist will insert one or two small transparent half-rings into the peripheral cornea of my eye through a tiny incision. The surgery is intended to be permanent, but the Intacs® can be removed if necessary. My surgeon has explained the basic procedures of Intacs® surgery, as well as the risks, benefits, and alternative treatments. I have been given a copy of “Patient Booklet: Facts You Need to Know About ® INTACS® ™ for Nearsightedness” and have discussed it with my doctor. Although it is impossible for the doctor to inform me of every possible complication that may occur, the doctor has answered all my questions to my satisfaction.

- I understand that Intacs® were approved by the FDA for myopia and keratoconus; they have not been approved for post-LASIK ectasia. Nevertheless, I wish to have Intacs® placed into my cornea, and I am willing to accept the potential risks that my physician has discussed with me.
  __________ (Patient initials)

- In signing this informed consent for the insertion of Intacs®, I am stating that I have been offered a copy, I fully understand the possible risks, benefits, and complications of Intacs® surgery and:
  o I have read this informed consent __________ (Patient initials)
  o The consent form was read to me by ________________________________ (name).

- I wish to have Intacs® inserted in my _____ Right eye _____ Left eye

I give the surgeon permission to:

- Record my procedure on video or photographic equipment for purposes of education, research or the training of other health care professionals. __________ (Patient initials)

- Use the data about my procedure in subsequent procedures without reference to my name, to further the understanding of refractive surgery. __________ (Patient initials)

_____________________________________________________________________________________

Patient Signature (or Person Authorized to Sign for Patient) Date