



Patient Name Surname : **BARCODE**
File Number :
Education :
Job :
State of mind :

GENERAL INFORMATION

This information is given to you to help you make an informed decision about having cataract and/or lens implant surgery. Once you have read this **Informed Consent**, you are encouraged to ask any questions you may still have about the procedure. It is impossible to list all of the possible risks and complications associated with surgery. Risks and complications that are considered to be unforeseeable, remote, or commonly known may not be specifically discussed in this consent.

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 LASİK 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-LASİK 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 overtime. 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’S ACCEPTANCE OF RISKS

Patient consent

I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- There is no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

DOCTOR NOTE:
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I have reviewed all **four (4)** pages of this Informed Consent. The cataract and/or lens implant surgery has been explained to me in terms that I understand. I have been informed about the possible benefits, risks, and contraindications associated with the surgery. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. I understand that no guarantee of a particular outcome has been given, and that my vision could become better or worse following surgery.

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- If my ophthalmologist has informed me that if I have a high degree of hyperopic (farsightedness) and/or that the axial length of my eye is short, I am at increases risk for a rare complication known as nanophthalmic choroidal effusion. This complication could result in difficulties completing the surgery and implanting a lens, or other problems.
- If my ophthalmologist has informed me that if I have a high degree of myopia (nearsightedness) and/or that the axial length of my eye is long, I am at increased risk for a retinal detachment, whether or not I have surgery. Retinal detachments can lead to vision loss or blindness. Recent studies indicate that risk doesn't increased by the surgery, although an older study using different techniques did find an increased risk.
- I authorize the physicians and other health care personnel involved in performing my cataract surgery and pre- and post-operative care to share with one another any information relating to my health, my vision, or my surgery that they deem relevant to providing me with care. I give my permission for Dr. to use my photograph for display or promotion.

DOCTOR NOTE:

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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:
 - I have read this informed consent _____ (Patient initials)
 - 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'S NOTE:.....

Date : .../.../.....

Hour : ...:....

PATIENT:

Name-Surname :

Signature :

Patient's Parent/ Legal Guardian (mother and father)/ Translator

Name-Surname :

Name-Surname :

Signature :

Signature :

DOCTOR- Ophthalmologist:

Name-Surname :

stamp

Signature :