



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.

The following information is being provided so that I can make an informed decision about having KeraVision Intacs to correct my nearsightedness (myopia). I may take as much time as I need to read, fully understand, and ask any questions I may have before signing this consent form.

INTRODUCTION

This information is to help you make an informed decision about having KeraVision Intacs to correct your nearsightedness (myopia). Every surgery has risks as well as benefits and each person must evaluate this risk/benefit ratio for himself/herself based on the patient information given to you as well as the conversation with your physician and staff. You are encouraged to ask any questions and have them answered to your satisfaction before you give your permission for surgery.

EXPECTED BENEFITS

- KeraVision Intacs may correct nearsightedness between -1.00 and -3.00 diopters with 1.00 diopter or less of astigmatism.
- KeraVision Intacs may reduce overall nearsightedness while also reducing or eliminating dependency upon eyeglasses.
- KeraVision Intacs corrects nearsightedness without permanently altering the central part of the cornea which is critical for clear vision.
- KeraVision Intacs can be removed and replaced, if desired.

POSSIBLE RISKS

As with any refractive surgery procedure, there are certain risks and complications you need to be aware of when considering KeraVision Intacs.

- If the results of KeraVision Intacs are not satisfactory or sufficiently effective, you may need to have an additional procedure to replace your KeraVision Intacs or to have them removed.
- You may have discomfort and/or pain for up to 48 hours following the procedure. Your doctor may recommend a medication to help ease your discomfort.
- You may have blurred vision, fluctuating vision and tearing following the procedure.
- You may be sensitive to bright light or glare following the procedure.
- You may experience 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 is a risk with any surgical procedure.
- Certain patients have reported continued visual distortion related to KeraVision Intacs.
- The US Studies showed that the following potential vision-threatening events happened less than 1% of the time after KeraVision Intacs. All patients returned to the vision they had prior to the procedure.
 - Infection (0.2%)
 - Stromal thinning due to shallow placement (0.2%)

There are 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.

BY SIGNING THIS FORM I ACKNOWLEDGE THAT I UNDERSTAND THE FOLLOWING

- The procedure to be performed on my eye consists of inserting two small transparent half rings into the peripheral cornea through a tiny incision. KeraVision Intacs are designed to remain permanently in the eye, yet they can also be removed and replaced, if desired.
- KeraVision Intacs is purely an elective procedure.
- The alternatives to KeraVision Intacs for correcting nearsightedness include eyeglasses, contact lenses, and other kinds of refractive surgery procedures such as Radial Keratotomy (RK), Photorefractive Keratectomy (PRK) and Laser in situ keratomileusis (LASIK).
- KeraVision Intacs will not prevent the development of naturally occurring eye problems such as glaucoma, cataracts, retinal degeneration or detachment. KeraVision Intacs do not correct the condition known as presbyopia (or aging of the eye) which may require reading glasses for close-up work.
- I understand that having KeraVision Intacs does not necessarily mean total freedom from eyeglasses because excellent vision without eyeglasses cannot be guaranteed.
- It has been brought to my attention that KeraVision Intacs are not risk-free. The complications that may occur include improper correction, decrease in best-corrected visual acuity, fluctuating vision, glare, halo, corneal edema, corneal perforation and infection. There is a possibility of other complications due to anesthetic drops, eye drop reaction or other factors.
- I understand that there are risks associated with any surgery including this procedure. There may be risks and complications associated with this surgery that are unknown because this is a relatively new procedure.
- I understand that there is a possibility that my surgeon may not be able to insert INTACS into my cornea and that the surgery may have to be cancelled.
- In signing this form, I am stating that I have read this consent (or it has been read to me) and understand the complications. I have had the opportunity to ask questions and have had them answered to my satisfaction. It is understood that further procedures may be required to reach the desired result. However, there is no guarantee with an additional procedure the desired change in refractive error can be obtained, though there could be significant improvement in uncorrected vision.
- I authorize the sharing of my relevant medical information among doctors regarding my pre- and post- operative care.
- 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 KeraVision Intacs. These include the procedure itself, possibly 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 doctors instructions and attend regular postoperative visits to reduce the risk of long-term complications.
- Although it is impossible to be informed regarding every possible complication that may occur, all my questions have been answered to my satisfaction. The decision to undergo KeraVision Intacs has been my own and been made without duress of any kind. I understand that I will receive a copy of this form, if requested.
- I have been given a copy of the Patient Booklet, entitled "Facts You Need to Know About KERAVISION ® INTACS™ for Nearsightedness" and have discussed it with my doctor.

I GIVE PERMISSION TO 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 permission is voluntary 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'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 **three (3)** 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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I understand that it is impossible for the doctor who inform me of every possible complication that may occur. By signing below, I agree that my doctor has answered all of my questions, that I have been offered a copy of this consent form, and that I understand and accept the risks, benefits, and alternatives of _____ surgery.

I wish to have a _____ operation on my _____ Right eye _____ Left eye

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 :

Signature : stamp