



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.

If you elect to have surgery performed on both eyes at the same time, you should understand both the possible advantages and disadvantages of your decision.

SAFETY

The risk of infection, delayed clouding of the cornea, corneal scarring and internal bleeding or retinal damage are very rare but potentially devastating. If these serious but rare complications occur in one eye, they may also occur in the other eye. Should any of these complications happen, you could experience significant loss of vision and even legal blindness. By choosing to have surgery on separate days, you avoid the risk of having one or more of these complications in both eyes at the same time.

ACCURACY

If there is an over-correction or under-correction in one eye, chances are it may happen in both eyes. If a re-operation is required in one eye, it is quite possible that your fellow eye may also require a re-operation. By having surgery on separate days, the doctor can monitor the healing process and visual recovery in the first eye and may be able to make appropriate modifications to the treatment plan for the second eye if necessary. In some patients, this might improve the accuracy of the result in the second eye. By correcting both eyes simultaneously, there is no opportunity to learn from the healing patterns of the first eye before treating the second eye.

VISUAL RECVOERY

Although most Intacs patients experience a rapid recovery in their vision, some may experience symptoms such as blurred vision, night glare or ghost images that can result in prolonged recovery of normal vision. Blurred vision may continue for several weeks, which could make driving difficult or dangerous and could interfere with your ability to work if it occurs in both eyes. There is no way of predicting how long your eyes will take to heal. If the eyes are operated separately, you can generally function with your fellow eye while the first eye is healing. However, there may be a period of imbalance in vision between your two eyes, producing a form of double vision. If you are able to wear a contact lens in your unoperated eye, the corrective lens could minimize this imbalance. The balance in vision between your two eyes will usually be restored more rapidly if they are operated on the same day.

SATISFCATION

Both eyes tend to experience similar side effects. If you experience undesirable side effects such as glare, ghost images, increased light sensitivity, or corneal haze in one eye, you will likely experience them in both eyes. These side effects may cause a decrease in vision or other negative effects, and some patients have elected to not have their second eye treated. By having each eye treated on separate dates, you will have the opportunity to determine whether the Intacs procedure has produced satisfactory visual results without loss of vision or other undesirable side effects. If you are over age 40, you will also have an opportunity to experience the

change in your close vision that results from the correction of your nearsightedness. This could influence your decision on whether to fully correct your other eye to maintain some degree of close vision without the need for glasses (monovision).

CONVENIENCE

It may be inconvenient for you to have each eye treated at separate visits because it would necessitate two periods of recovery from the surgery and might require additional time away from work.

COST

Professional and facility fees may be greater if the eyes are operated on different days, and the additional time off work can be costly.

CONSENT STATEMENT

“I have read and understand the above risks and benefits of bilateral simultaneous Intacs for treatment of myopia, and I understand that this summary does not include every possible risk, benefit and complication that can result from bilateral simultaneous Intacs. My doctor has answered all of my questions about the Intacs procedure. I wish to have both of my eyes treated during the same treatment session if my doctor determines that the treatment in the first eye appeared to be technically satisfactory.”

The reason(s) I wish to have both eyes treated at the same time are:

- Greater convenience
- Possible faster recovery
- Less time away from work
- Contact lens intolerance and/or difficulty wearing contacts
- Elimination of possible vision imbalance between treated and untreated eye
- Other: _____

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