

MANDATORY INFORMED CONSENT FORM FOR CATARACT OPERATION WITH OR WITHOUT PHAKOEMULSIFICATION AND/OR IMPLANTATION OF INTRAOCULAR LENS

INTRODUCTION: This information is given to you so that you can make an informed decision about having eye surgery. Take as much time as you wish to make your decision about signing this informed consent. You have the right to ask questions about any procedure before agreeing to have the operation.

Except for unusual problems, a cataract operation is indicated only when you cannot function adequately due to poor sight produced by the cataract. You must remember that the natural lens within your own eye with a **slight** cataract, although not perfect, has some distinct advantages over any man made lens.

After your doctor has told you that you have a cataract, you and your doctor are the only ones who can determine if or when you should have a cataract operation - based on your own visual needs, and medical considerations, unless you have an unusual cataract that may need immediate surgery.

ALTERNATIVE TREATMENTS:-

I understand that I may decide Not to have a cataract operation, **at all**. However, should I decide to have an operation, I understand these are the three methods of restoring vision after surgery.

1. Spectacles (Glasses) - Cataract spectacles required to correct your vision are usually thicker and heavier than conventional eyeglasses. Cataract spectacles increase the size of object by about 25% and clear vision is obtained through the central part of cataract spectacles, which means you must learn to turn your head to see clearly on either side. Cataract spectacles usually **cannot** be used if a cataract is only in **one eye** (and the other is normal) because they may cause double vision. However, cataract spectacles have been, and are, the most common method of correcting vision after cataract surgery.

2. Contact Lens - A hard or soft contact lens increases the apparent size of objects only about 8%. Handling of a contact lens is difficult for some individuals. Most lenses must be inserted and removed daily and not everyone can tolerate them. For near tasks, plus power near reading glasses (Not cataract spectacles) may be required in **addition** to contact lenses.

3. Intraocular Lens - This is a small plastic artificial lens made of perspex methacrylate, silicone or HEMA material with polypropylene, nylon or methacrylate supports surgically placed **inside** the eye, permanently. With the intraocular lens, there is no apparent change in the size of objects seen. Conventional eyeglasses (not cataract spectacles) for both distance and near, are usually required in addition in an intraocular lens.

TECHNIQUES FOR CATARACT REMOVAL :-

There are three ways for cataract extraction whether an implant is inserted or not. A cataract is opacity in the human lens. Removal of the cataract refers to removal of the lens, either partly or fully.

a) **Intracapsular cataract extraction** : Here the entire opaque lens consisting of the central hard nucleus region with the covering, the capsule is removed fully using a special instrument called a cryo extractor which uses cold to extract the lens.

b) **Extra capsular cataract extraction** : The outer covering of the lens, namely the capsule is left almost intact while the central hard nucleus of the lens is removed through an opening in the eye. The residual lens matter is removed by either manual or automated aspiration techniques. This is the most commonly done procedure today.

c) **Phakoemulsification**: In this method of cataract removal not only is the capsule left intact, but the central nucleus of the lens is softened and sucked out using ultrasound focused in the form of a beam along a needle inserted in the eye. This procedure is applicable to virtually all types of cataracts running the gamut from soft to immature to mature or even hyper mature cataracts. . It is the method of choice in children and young adults as the cataract is usually soft. The recovery time following the surgery is directly proportional to the density of the cataract. The very hard cataracts may take up to 2 months for full recovery of vision.

CONSENT FOR OPERATION:-

In giving my permission for a cataract extraction and/or for the possible implantation of an intraocular lens in my eye, I declare, I understand the following information:

1. Cataract surgery, by itself, means the removal of the natural lens of the eye by a surgical technique: in order for an intraocular lens to be implanted in my eye. I understand, I must have cataract surgery performed either at the time of the lens implantation or before lens implantation.

2. If an intraocular lens is implanted, it is done by surgical method. It is intended that the small plastic lens (with supports) will be left in my eye permanently. At the time of surgery, my doctor may decide **not** to implant an intraocular lens in my eye, if for any reason he feels that the lens is not indicated or may prove deleterious to the well being of the eye even though I may have given prior permission to do so.

3. The visual results of surgery in my case cannot be guaranteed. Though the intraocular implant power is calculated on the basis of the latest formula, utilising an electronic computerised ultrasound biometer (A-Scan), since the Intraocular lens is fitted into the soft tissue of the eye, a maximum accuracy of about +/-2.00 dioptres is to be considered optimal which again depends upon the type of wound closure, and the rate of healing of the wound, which again differs from patient to patient, a residual astigmatism (number with an axis) of about 3-4 dioptres which may reduce with time is to be taken as inevitable and normal. Usually the astigmatism will decrease with time. Intraocular implants are being prescribed so that I may see without visual distortion, and be able to use both eyes simultaneously with the presence of glasses. Some glasses will be there for both distance and near and should be expected.

4. The caliber of vision obtained after a successful cataract surgery depends upon the status of the retina behind. In a mature cataract, even with the most sophisticated instruments in the world including an ultrasound B scan or CT scans, it is not possible to be certain that the retina inside is normal. Removal of the cataract is like opening a door to a room, if the retina is normal you will see well, but is not possible in a majority of advanced cataract cases to ascertain the visual status of the retina. The retina in your eye may be detached partially or totally, or may have wrinkles or oedema or have hemorrhages old or new or have a vascular blockade that may be impossible to ascertain before surgery.

5. Complication of surgery to remove the cataract: As a result of the surgery, it is possible that my vision could be made worse. In some cases, complications may occur weeks, months or even years later. Complications may include a hemorrhage (bleeding), loss of corneal clarity, infection, detachment of the retina, glaucoma and or double vision. These and other complications may occur, as a complication of cataract surgery, whether or not a lens is implanted and may result in poor vision, total loss of vision, or even loss of the eye.

6. Complications due to the Cornea affection in cataract surgery. The innermost layer of the cornea, the clear watch glass in front of the eye has a layer of cells known as the Endothelial cell layer. This layer may have less cells which in doing a cataract surgery may diminish further leading to either temporary fall in vision or in the worst scenario, total corneal opacity requiring a corneal graft. This problem is amplified when Phakoemulsification is used. Especially in a patient who is ill or infirm or has a past history of injury, or has a very firm, hard or supahard cataract of the ultrasound energy is liable to affect the endothelial cells. The use of the Laser assisted Phakoemulsification diminishes the risk, which nonetheless still exists. This is also the reason why in some patients with cataracts which are not mature recover their vision fast while other patients with very dense cataracts may need a longer time for recovery of their vision..

7. Complications due specifically to the type of lens extraction method utilized. Intracapsular cataract extraction may lead to vitreous loss and hemorrhage. Extra capsular cataract extraction may lead to inflammatory reaction like uveitis, and to cortical remnants and to capsular thickening at a later stage. Phakoemulsification may lead to corneal opacity and to corneal oedema at a later stage and to vitreous prolapse and loss of lens fragments.

8. Specific complications of lens implantation: Insertion of an intraocular lens may induce complications which otherwise would not occur. In some cases complications may develop during surgery from implanting the lens or days, weeks, months or even years later. Complications may include loss of corneal clarity, infection, uveitis, iris atrophy, glaucoma, bleeding in the eye, inability to dilate the pupil, slippage of the lens from its proper place which may lead to reflections which may be multiple and to seeing coloured rings or distortion of objects. In some cases there is a possibility of a dislocation of the lens, either partial or total. Dislocation problems are also there with the new foldable implants that may suddenly shift out of place especially after any minor injury. Retinal problems are also liable to occur with or without an implant being inserted in the eye and irrespective of the type of cataract surgery used. It may range from simple hemorrhages to oedema in the back of the retina or the formation of fibrous bands or folds or even a retinal detachment, which may be partial, subtotal or total. All retinal complications could lead to partial or total loss of vision, which may or may not be possible to restore

again. It is possible that at some future time the lens implanted in my eye may have to be repositioned or removed surgically.

9. Complications due to infection, prior, during, or after surgery, immediately, after a week, months, or even later may occur leading to fall in vision, late development of vision or even loss of vision. The infection may be from the body blood, throat or external. There is also a risk of late development of fungal infection, which may even, commence a month after surgery. Though every effort is made to minimise the chances of infection, it cannot be eliminated and the risk factor must be taken into account prior decision for surgery. However, intra ocular lenses are sterile, there is no additional risk of infection with an implant or without an implant.

10. Complications of surgery in general: As with all types of surgery, there is the possibility of other complications due to an anesthesia, drug reactions or other complications due to an anesthesia, drug reactions or other factors which may involve other parts of my body, including a possibility of brain damage or even death. Since it's impossible to state every complication that may occur as a result of surgery, the list of complications in this form is incomplete.

The basic procedures of cataract surgery and the advantages and disadvantages, risks and possible complications of alternative treatments have been explained to me by the 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 the implanting of an intraocular lens in my eye requires periodic visits to the doctor by me for at least a year to assess the results of the operation. I also understand that in my case the speed at which the recovery of vision occurs is not possible to anticipate in advance. I also understand that it may be possible that I may need to be re-operated again to stabilise the problem that may have occurred or to solve a new problem that may have occurred.

I am stating I have read this informed consent (or it has been read to me) and I fully understand it and the possible risks, complications and benefits that can result from the surgery. If I decide to have an operation, I know my surgeon is going to make every possible effort to assist me in the recovery of my eye, and I unequivocally confirm and agree not to hold my surgeon or his assistants, responsible in any way for the surgery, nor to institute, against him or his assistants, any proceeding, legal or otherwise, in any forum, in any fashion, of any type, with regards to the pre operative management, the diagnosis, the operation, the type of surgery or its technique, its results, any complications or problems, either during or after the surgery and the post operative care in the immediate or late future.

Patient's Name (Printed): _____ Age: _____

Patients signature: _____

Witness Name: _____ Witness signature: _____

Date: _____ Time: _____ Place: _____

Surgeon Doctor's Name: Dr..

Surgeon Doctor's Address

Doctor's signature: _____

Be informed your physician will furnish any additional information you require to be certain you are fully informed about the operation and the lens.