EyeMax patients are those who undergo a surgical procedure for the implantation of the iolAMD EyeMax Mono (EyeMax) lens into the eye to improve the vision for those living with age-related macular degeneration (AMD) and other diseases affecting the macular. The EyeMax lens is an artificial lens implanted into the eye, known as an intraocular lens or IOL. Surgical procedures include cataract extraction, clear lens extraction or implantation of the EyeMax lens in front of a pseudophakic lens. A pseudophakic lens is a man-made lens that has been implanted into the eye to replace the natural lens, typically as part of a cataract operation.

This form is a legal document that requires your signature before you can be accepted for surgery. It is signed by you and the consultant ophthalmic surgeon before surgery. This consent form is provided in addition to the information you have already received prior to your treatment day. We give you this information so you can consider all aspects of surgery in advance.

Please note that this information is applicable to everyone. Your final decision must be based on the specific advice of the consultant ophthalmic surgeon who counselled you during your consultation.

It is important that you make an informed decision before committing to surgery. Take as much time as you need to make a decision before signing this form. We encourage you to ask any questions you might have and have them answered to your satisfaction, before signing this document. As with any surgical procedure, the implantation of the EyeMax lens has its risks as well as benefits, so it is essential that you consider these carefully before making your decision.
Introduction

If you have not previously had cataract surgery, your consultant ophthalmic surgeon will replace the natural lens in your eye with the EyeMax lens in order to improve vision. If you have previously had cataract surgery we will implant the EyeMax lens in front of the pseudophakic lens that has been previously implanted during your cataract surgery.

It is important to understand that the EyeMax lens is a relatively new device so we have yet to fully understand which patients stand to benefit most from its implantation, particularly as AMD affects individual patients differently. The EyeMax lens is primarily designed to relieve the effort required by the brain on the visual system. It will not restore vision completely and will not stop the AMD from progressing and causing further damage to the centre of your visual field. It will, however, minimise the effects to your vision.

Non-surgical alternatives to surgical treatment

“Doing nothing” is always an alternative. Some patients manage very well with what they have and do not feel the need to take on the risks associated with surgery. Patients increasingly make use of devices such as iPads and Kindles to help with reading but many of the more established visual aids have been shown to have disadvantages that limit their usefulness. These include hand-held magnifiers, spectacle-mounted binoculars, high-powered spectacles and combinations of glasses and contact lenses. Many of these visual aids are available through the UK National Health Service and are worth trying if you haven’t already – referrals can be made via your local GP or ophthalmologist to the Low Vision Aid service in your local hospital.

Eccentric viewing (EV) training is a technique offered by some specialist optometrists with an interest in low vision. This involves training patients to make use of an area of healthy retina outside of their scotoma (the black space in the centre of their visual field) to enable them to read and see faces more easily. Some patients learn to do this naturally but there is only modest evidence for the effectiveness of training in improving near vision and reading. One study demonstrated greater effectiveness of training with the use of a magnifier. The EyeMax lens is likely to replicate this effect without the need for an external magnifier making it easier for the visual system to cope (without any effort from the patient) if the AMD progresses.
The risks of surgery include, but are not limited to, the following:

1. Complications related to the removal of the natural lens include;
   a. haemorrhage (bleeding); rupture of the capsule that supports the IOL; perforation of the eye; clouding of the outer lens of the eye (corneal edema), which can be corrected with a corneal transplant; swelling in the central area of the retina (called cystoid macular edema), which usually improves with time; retained pieces of cataract in the eye, which may need to be removed surgically; infection; detachment of the retina; uncomfortable or painful eye; droopy eyelid; increased astigmatism; glaucoma; and double vision. These and other complications may occur whether or not an IOL is implanted and may result in poor vision, total loss of vision, or even loss of the eye in very rare situations. **Additional surgery may be required to treat these complications.**

2. Complications associated with the IOL
   a. Those include increased night glare and/or halo, double or ghost images, and dislocation of the lens.

   b. If an IOL is implanted, it is done by a surgical method. It is intended that the IOL will be left in the eye permanently.

   c. The lens may detach itself which could result in its movement or dislocation. Dislocation of the lens can be caused when a blow or trauma to the eye/head requiring the removal or repositioning of the lens.

   d. If there are complications at the time of surgery, the doctor may decide not to implant an IOL in your eye even though you may have given prior permission to do so.

3. Complications of local anaesthetic;
   a. Surgery is carried out under a local anaesthetic (either eye drops or an eye injection). The injection can cause temporary partial or complete vision loss until it wears off: short-term complications include, induced squint, enlarged pupils, drooping of the eyelid and bruising of the eye.

4. Complications associated with surgery, medications and local anaesthesia injections around the eye;
   a. Those include perforation of the eye, destruction of the optic nerve, interference with the circulation of the retina, droopy eyelid, respiratory depression, hypotension, cardiac problems, and, in rare situations, brain damage or death. You will have a chance to discuss with your anaesthetist on the day of surgery.

   e. Other factors may affect the visual outcome of surgery, including eye diseases such as glaucoma, diabetic retinopathy, the natural progression of AMD; the power of the IOL and your individual healing ability.

   f. If you have the EyeMax lens designed to sit in front of a pseudophakic implant you are advised that your eyes should be examined every 6-12 months to ensure that the lens has not moved causing raised intraocular pressure. Eye pressures will need to be monitored after surgery, if the pressures are found to be high, it may need to be treated with eye pressure lowering drops or tablets. If the eye pressure does not settle after the appropriate treatment, the lens may need to be removed.
b. **The results of surgery cannot be guaranteed.** Additional treatment and/or surgery may be necessary.

c. If your consultant ophthalmic surgeon has informed you that you have a high degree of hyperopia (long-sightedness) and/or that the axial length of your eye is short, your risk for a complication known as nanophthalmic choroidal effusion is increased. This complication could result in difficulties completing the surgery and implanting a lens, or even loss of the eye.

d. If your consultant ophthalmic surgeon has informed you that you have a high degree of myopia (short-sightedness) and/or that the axial length of your eye is long, your risk of a complication called a retinal detachment is increased. If not promptly treated, retinal detachment can cause permanent vision loss.

e. Since only one eye will undergo surgery at a time, you may experience a period of imbalance between the two eyes called anisometropia. This usually cannot be corrected with spectacle glasses because of the marked difference in the prescriptions, so you will either temporarily have to wear a contact lens in the non-operated eye or will function with only one clear eye for distance vision.

f. Should any adverse reaction take place e.g. pain, swelling, irritation, infection or clouding of the vision it is your responsibility to contact us immediately as delay could lead to blindness. You should stop taking medication if an allergic reaction occurs and seek immediate medical attention.

g. **After surgery you will require glasses to get the full visual improvement. Your prescriptions will be issued at your post-operative appointments.**

h. Please note, if complications do arise, you will be required to attend further appointments than advised at the consultation.

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**Patient consent**

I have had the following explained to my satisfaction:

- the relevant surgical procedure for the implantation of the EyeMax lens,

- the reason for recommending this lens, the advantages, disadvantages, risks, possible complications and alternative treatments.

Although it is impossible for the consultant to inform me of every possible complication that may occur, the consultant has answered all my questions to my satisfaction.

I am satisfied that all of the above has been fully explained and understood and I have been given a copy of this form for my records.
Name of proposed procedure or course of treatment
(include brief explanation if medical term is not clear)

• I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

• I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

• I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

Patient:
Print name (block caps) Date of birth

Signature Date

Witness: The witness states that the patient has read the consent form in his/her own time and is under no pressure or duress to sign the form.

Print name (block caps) Postcode

Signature Date

Surgeon: I confirm that I have given the patient the opportunity to discuss the treatment, the information on this form and I have answered any questions they have raised.

Print name (block caps)

Signature Date