

Repositioning, removing or replacing an ophthalmic device

Informed consent document

This is a legal document. You need to sign it to show that you have read and accepted the information in this document before we can accept you for treatment. For your own benefit and protection you should read this document carefully before signing it. If you do not understand anything in this document, please ask us for more information.

Patient's name:

Patient's central ID:

Eye (or eyes) to be treated: Right eye Left eye

Background information

We want to make sure you are fully aware of all the possible risks, the intended benefits and alternative treatment options to repositioning, removing or replacing an ophthalmic device. It is important for you to understand that there are possible risks with any type of medical treatment.

Medical devices, such as intraocular lenses (IOLs), that have been surgically placed into the eye may need to be repositioned, replaced or even removed (explanted).

This informed consent document, along with the information you received at your pre-treatment consultation, is designed to make sure that you are fully aware of and consider the possible risks and intended benefits of the surgery that has been recommended to you to allow you to make an informed decision on whether or not to go ahead with the treatment.

We are giving you all this information before your treatment so that you have enough time to consider all aspects of your treatment.

We ask that you read this information in full before the day of your surgery.

Please initial each point below to confirm that you understand the information.

Your surgeon will make the final decision on whether you are suitable for treatment after carrying out a careful examination, discussing the treatment with you and considering your optometrist's opinion. The surgeon's decision will be based on your individual needs.

Please tell your GP that you are considering surgery to reposition, remove or replace an ophthalmic device, as they can give you independent medical advice.

If you have any questions about your treatment, you should ask your surgeon before you sign this document.

The purpose of this part of the document is to confirm that you have understood all of the information you have received and to keep a record of your decision to go ahead with the treatment.

I have read and understood the points discussed in this section.

Write your initials here:

I understand that my surgeon will be registered with the General Medical Council (or Irish Medical Council). If my treatment is in the UK, I understand I should visit www.gmc-uk.org for the benefits this offers me. I also understand my surgeon may be an independent practitioner using facilities you have provided.

You will tell me whether my surgeon is an Optical Express employee or an independent practitioner at the end of this document.

I am aware of the facts stated above.

Write your initials here:

I understand that my surgeon may decide to change the type of procedure I have if they believe that a different surgical approach would be safer or is more likely to provide a better outcome.

I understand that my surgeon will have the final decision on whether I am suitable for treatment.

I have read and understood the points discussed in this section.

Write your initials here:

Before your treatment you must tell your surgeon if any of the following applies.

- You have any eye problems, including amblyopia (lazy eye), strabismus (muscle imbalance which can cause double vision), severe dry eyes or any recurrent (keeps coming back), residual (an after-effect of another condition) or active eye conditions.
- You are a carrier of methicillin-resistant staphylococcus aureus (MRSA) or have been exposed to MRSA.
- You have any general health conditions, including back problems, claustrophobia or other psychological

conditions (including any history of anxiety or depression).

- You have any implants, including a pacemaker, defibrillator, insulin pump or any other implanted device.
- You are allergic to any medication or latex.
- You are taking or using any medications, eye drops or supplements, including vitamins or nutritional supplements you have bought 'over the counter' without a prescription.
- Your current or planned occupation prevents you from having eye surgery.
- You have had an eye injury or eye surgery in the past.
- You are pregnant, breastfeeding or could possibly be pregnant.

It is essential that you have fully and accurately filled in the health and lifestyle questionnaire you received at your pre-treatment consultation before you meet your surgeon for treatment.

The information in this document is extremely important as it will help your surgeon to decide whether you are suitable for treatment.

It is important to let us know if there have been any changes to your health and lifestyle after you filled in this questionnaire.

I have read and understood this section and have met all the conditions.

Write your initials here:

General information

Repositioning, replacing or removing an ophthalmic device is surgery that is carried out after initial corrective eye surgery.

There may be medical complications or other reasons that mean this extra

surgery is necessary. Or you may ask for the surgery or your surgeon may recommend it for other reasons, such as severe visual disturbances at night. For these procedures, the eye will be numbed with an anaesthetic injection, and will be properly prepared and covered with a drape. The surgeon will then reposition, remove or replace the device using similar techniques, technology and instruments that were used to originally implant the device.

You will be prescribed antibiotic and anti-inflammatory drops to use after your surgery to prevent infection and to help your eye (or eyes) to heal.

I have read and understand this section. I understand that if I have a monofocal lens implant to correct my vision at one distance, I will need to use glasses after my treatment.

Write your initials here:

When we are young, our eyes can focus at all distances, from very distant objects to very near objects (in the same way as an auto-focus camera). This ability to focus weakens throughout life.

From about the age of 40, this loss of near focus begins to affect our ability to read and see close-up things clearly. This weakening continues until we are about 60, at which time we have almost no ability to change focus.

The loss of ability to focus results in the need for reading glasses, even for people who have previously had excellent distance and near vision without glasses. This age-related eye condition which affects the natural lens is called presbyopia and happens in everyone, regardless of whether they have had treatment or not.

When an intraocular lens procedure is first carried out, the natural lens is removed and presbyopia no longer

happens. Although technically not the same process, the near-vision symptoms that can develop after an intraocular lens (for example a monofocal lens) is implanted can be similar to presbyopia.

People with presbyopia usually need bifocal, varifocal or separate reading glasses to see clearly at close range. If you are short-sighted, you can compensate for this loss of near focus simply by taking your glasses off or your contact lenses out. If you are short-sighted and choose to have both eyes treated to give you the best distance vision, you will lose the ability to compensate for your loss of near focus.

As part of your surgery to reposition, replace or remove an ophthalmic device, you and your surgeon can decide on a monofocal (single focus) lens implant to correct your vision at one distance, typically for far vision, and for you to wear separate glasses for close-up work. The aim of this approach is that you are left with very clear distance vision.

The disadvantage is that you will need to wear glasses for all near-vision tasks.

A multifocal intraocular lens has the advantage of improving your distance, intermediate and near vision with one lens which can overcome the symptoms or effects of presbyopia. If your multifocal lens is removed and replaced with a monofocal lens, it is important that you understand that you will need to wear glasses for most, if not all near-vision activities after your treatment, not just reading. This includes most close-up tasks, such as using a computer, looking at your mobile phone, applying make-up, reading a menu and so on.

For many patients, when a multifocal lens is removed it is replaced with a

monofocal lens which improves distance vision. This may be for a medical reason, or to achieve the best-possible quality of distance vision.

I have read and understand this section. I understand the issues of presbyopia, loss of ability to read and focus, and the need for glasses. I understand that if I have a monofocal lens to correct my distance vision in both eyes, I will need to wear glasses for most or all near-vision activities after having surgery to reposition, remove or replace an ophthalmic device.

Write your initials here:

Another method of treatment to improve distance and near vision is a technique called 'monovision'. This is where a single-focus lens for best distance vision is implanted in one eye and a single-focus lens for best near vision is implanted in the other eye. The possible advantage of this technique is that it gives you a better range of vision and reduces the need for glasses.

This combination of a distance eye and a reading eye may allow you to see clearly at both far and near distances without glasses. Monovision has been used successfully for many contact lens wearers and for patients who have had laser eye surgery. Possible disadvantages include reduced overall quality of vision and a reduced ability of both eyes to work together to help with depth of vision (depth perception). Night driving can be more difficult. Also, your range of clear near vision is likely to be restricted.

It can also take some time for your eyes to adapt to the new lenses and you may still need glasses for certain tasks.

If your eyes do not adapt, you may need further treatment, which would result in you needing to wear glasses for all close-vision tasks.

I understand that if I choose to be treated using the 'monovision' technique, my depth perception and overall quality of vision may be reduced and I may still need glasses for certain distance or close-vision tasks. I understand that with the 'monovision' technique, my eyes can take time to adapt to the new lenses and I may need further treatment.

Write your initials here:

Multifocal lenses are an advanced form of intraocular lens technology. They can provide excellent distance, intermediate and near vision using multiple optical powers in the same lens. This can improve your near vision and reduce your need to rely on reading glasses, although it is possible that it will not restore all of the ability to focus at near (or intermediate) distances, so you may still need glasses for close-up tasks. Possible disadvantages of this type of lens can be glare, shadowing or 'halos' around lights in situations with low lighting such as at night, and this may make driving at night more difficult.

I understand the benefits and possible side effects of multifocal lenses and that they may not restore all of the ability to focus at near (or intermediate) distances, and so I may still need glasses for certain tasks.

Write your initials here:

Surgery to reposition, remove or replace an ophthalmic device will not correct other causes of poor vision such as amblyopia (lazy eye), vitreous opacities (floaters), glaucoma, diabetes, age-related macular degeneration or any other conditions affecting the retina or optic nerve.

I understand the above and all of my questions have been answered.

Write your initials here:

After having surgery to reposition, remove or replace an ophthalmic device, it is possible that you may develop eye conditions that are unrelated to, and not caused by or prevented by, that surgery, such as glaucoma, age-related macular degeneration and other conditions of the retina.

I understand the above and all of my questions have been answered.

Write your initials here:

The results of surgery cannot be guaranteed and you may need further treatment or surgery (or both) to achieve a result you are happy with.

I understand the above and all of my questions have been answered.

Write your initials here:

Alternatives to surgery to reposition, remove or replace an ophthalmic device

This surgery is an elective procedure. This means you can choose whether or not to have it.

There can be other ways to correct your vision (some which involve surgery and some which do not, including glasses, contact lenses and lens surgery) which may be able to help with your condition.

You have received this document because we have recommended surgery to reposition, remove or replace an ophthalmic device as the best procedure to meet the goals you have identified during your pre-treatment consultation. However, if you would like more information about other treatment options, please ask us.

I understand that there are alternatives to surgery to reposition, remove or replace an ophthalmic device. These include having no surgery at all. I understand that surgery

to reposition, remove or replace an ophthalmic device is an elective procedure and that I do not have to have treatment.

Write your initials here:

The risk of complication is greater following a procedure to reposition, remove or replace an ophthalmic device than following a primary surgery. A complication can lead to permanent sight loss. There is no guarantee that surgery to reposition, remove or replace an ophthalmic device will be possible.

Surgery to reposition, remove or replace an ophthalmic device can lead to an infection in the eye (endophthalmitis) or on the outer surface of the eye (microbial keratitis), damage to the structures within the eye with bleeding inside the eye, damage to the capsule that supports the lens, or any other structure, damage to the zonules (fibres that support the capsule) meaning that a second intraocular lens may not be able to be implanted and resulting in abandoning the procedure and referring you for other treatment as appropriate, endothelial decompensation (when a layer of the cornea no longer works normally), a significant rise in the intraocular pressure (IOP), swelling of the cornea, intraocular lens calcification or fogging, swelling in the central area of the retina, a detached retina, an uncomfortable or painful eye, droopy eyelids, scarring, inflammation in the eye, reduced vision, glare, halos, night-vision disturbances, dry eye symptoms, vitreous opacities (floaters), dislocation of the lens implant, glaucoma or double vision. Surgery to reposition, remove or replace an ophthalmic device may result in you being unable to drive or work, needing further surgery, going blind, or even losing an eye.

As part of the normal healing process, it is possible that there may be some swelling in the central part of the retina (the macula). The swelling is called cystoid macular oedema, CMO or CME. This can affect the improvement in vision achieved by the treatment, though in most cases it is a temporary condition that is treated with eye drops or tablets (or both). In rare cases this condition can come back and affect your vision in the long term. If this is the case, you may need more tests and treatment. This may involve extra costs.

I understand the above and all of my questions have been answered.

Write your initials here:

It is impossible to list every complication which could arise from surgery to reposition, remove or replace an ophthalmic device. We have not told you about risks and complications that are considered to be unforeseeable or extremely rare, or which have not previously been reported. Also, there may be long-term effects that we do not yet know about or cannot expect at the current time.

I understand the above and all of my questions have been answered.

Write your initials here:

Although we confirmed that your prescription was stable at the time of your pre-treatment consultation, it is still possible for you to develop further short-sightedness, long-sightedness or astigmatism over time after treatment, even if the treatment is successful in correcting your vision.

Write your initials here:

I understand that I may still need to

wear glasses or contact lenses after surgery to reposition, remove or replace an ophthalmic device, or that I may need further treatment to achieve the best result possible.

Write your initials here:

Due to uncertainties in healing patterns and other aspects of surgery, you may not fully achieve the result you want from the treatment you are scheduled for.

Most patients who have surgery to reposition, remove or replace an ophthalmic device have had an improvement in their sight from their primary surgery. It is important to understand that surgery to reposition, remove or replace an ophthalmic device may lead to a deterioration (worsening) in your level of vision at one particular distance (far, intermediate or near) or at all distances. You must be certain that you want to have surgery to reposition, remove or replace an ophthalmic device despite this.

If you have not already had a YAG procedure to treat posterior capsular opacification (PCO), following surgery to reposition, remove or replace an ophthalmic device, there is the risk that you could develop this PCO (also known as secondary cataract). Although the natural lens is removed during surgery, the capsule surrounding the back of the lens is left intact to support the lens implant. It is possible for the capsule to become cloudy and reduce your vision during the months or even years following your surgery. However, if this happens, your vision can usually be successfully and quickly restored using a specialised laser called a YAG laser. This procedure takes only minutes to carry out, is not painful and produces almost immediate improvement in

vision. In rare cases, the intraocular lens itself may become opaque (cloudy) and need to be removed and replaced.

I understand the above and all of my questions have been answered.

Write your initials here:

You will be given an anaesthetic as part of the surgery to reposition, remove or replace an ophthalmic device. There are risks associated with the use of anaesthetic, including a squint or 'lazy eye', droopy eyelids, enlarged pupils, partial or complete blindness, and cardiac and respiratory problems.

I understand the above and all of my questions have been answered.

Write your initials here:

I agree to follow the aftercare advice you give me relating to protecting my eyes and I will take my medications, including my antibiotic and anti-inflammatory drops, as prescribed. I also understand that I must go to consultations in the early stages after my surgery.

Write your initials here:

Due to the position of the lens within the eye, it is important that your eye health is checked every year and the thickness of certain layers of the outer surface of the eye (known as the cornea) is measured.

I understand the above, acknowledge your recommendation and agree to have yearly eye examinations.

Write your initials here:

The results of surgery to reposition, remove or replace an ophthalmic device cannot be guaranteed and you may not

be satisfied with the outcome of the procedure.

I understand the above and all of my questions have been answered.

Write your initials here:

During the first few days and weeks after your treatment, including on the day of your surgery, you may have varying degrees of pain and discomfort, feel as though there is something in your eye and your eye may be sensitive to light. It is common for your eyes to water, and your eyelids may look red and swollen.

There may also be differences in the level or quality of your vision. If you have any discomfort, we will give you eye drops to use, if necessary.

I understand the above and all of my questions have been answered.

Write your initials here:

Dry eye is a condition that some patients may have before treatment, especially people who wear contact lenses. Dry eye is a common symptom early in the healing process and you may experience it following surgery to reposition, remove or replace an ophthalmic device, even if you haven't had it before.

Most dry eye symptoms, which may include differences in the quality of your vision, can be managed with artificial tears, ointments and other treatments and will usually disappear gradually over the first few months following your surgery. However, in a small percentage of patients the dry eye symptoms may not fully disappear and will need long-term treatment. Patients at greatest risk of dry eye include those with long-standing dry eye symptoms, women aged over 40, and people who

are long-sighted.

I understand the above and all of my questions have been answered.

Write your initials here:

Night-vision disturbance such as glare and 'halos', double vision or seeing 'ghosts' around things are common immediately after surgery to reposition, remove or replace an ophthalmic device. In most cases these symptoms (which are more common with multifocal lenses) gradually disappear over a period of weeks or months following the treatment. In rare cases, night-vision problems may last for longer or could be permanent.

We have not told you about risks and complications that are considered to be unforeseeable or extremely rare, or which have not previously been reported. Also, there may be long-term effects that we do not yet know or cannot expect at the current time.

I understand the above and all of my questions have been answered.

Write your initials here:

To achieve the best result and reduce the risks, I agree to follow the medication regime the surgeon or optometrist prescribes and the aftercare routine described in the information documents.

The requirement for a further procedure

I understand that up to 20% of patients will need prescription glasses, contact lenses or further surgery following surgery to reposition, remove or replace an ophthalmic device.

Write your initials here:

Use of medical information

I give permission for you to use information relating to my treatment to help you provide my treatment, review my treatment, give me advice on additional treatment, carry out any such additional treatment, and manage your business properly, for example to allow you to keep accurate records and for quality-control purposes.

Write your initials here:

I give permission for you to use information relating to my treatment for research purposes, for statistical analysis, in connection with academic and scientific papers, presentations and other publications, and for marketing purposes. I understand that the information relating to my treatment will not reveal my identity.

Write your initials here:

Patient declaration

Your primary treatment

I confirm that before having my primary procedure I understood and accepted the information provided to me at my pre-treatment consultations and in the informed consent document that I filled in.

Write your initials here:

I confirm that before having my primary procedure you told me about, and I understood, the possible risks, range of possible treatment outcomes, the intended benefits and the alternatives to the procedure, including the option of having no treatment at all.

Write your initials here:

I confirm that before having my primary procedure I had enough time to consider the possible risks, complications, side effects and

treatment outcomes explained to me, and all my questions were answered and I was satisfied with the answers I received.

I was not placed under any pressure to have treatment.

Write your initials here:

I confirm that before the primary procedure, you explained that the outcome I experienced following my treatment was one of the possible outcomes of the procedure. I provided my fully informed consent to this possible outcome before having the treatment. I accept that the outcome of my treatment was not caused by your fault or negligence, or the fault of negligence of any eye-care professional who provided my treatment on your behalf.

Write your initials here:

Your consultation before surgery to reposition, remove or replace an ophthalmic device

We advise you to take enough time to carefully and thoroughly read and understand the information in this document, and the other information you receive during your pre-treatment consultation. If you have not read and understood all of this information, please let us know and do not go ahead with the treatment.

At my consultation I watched a video about the surgery to reposition, remove or replace an ophthalmic device, which explained the possible risks and benefits of, and alternatives to, surgery to reposition, remove or replace an ophthalmic device and emphasised the importance of this informed consent document.

Write your initials here:

I confirm that I have taken enough

time to carefully and thoroughly read and understand the information in this document and the other information I received during my pre-treatment consultation.

I confirm that I have not been placed under any pressure and I do not feel obliged to have treatment. I understand that the decision whether to go ahead with surgery to reposition, remove or replace an ophthalmic device is mine alone, and should be based on the information I have received in this document and during my pre-treatment consultation.

I confirm that I have had enough time to read this document and the other documents in the patient information folder, including the terms and conditions document, which I received at my pre-treatment consultation.

I confirm that all my questions have been answered, and I am satisfied with the answers.

I understand that surgery to reposition, remove or replace an ophthalmic device is an elective procedure (which means that I can choose whether or not to have this procedure). I understand that there are other ways to correct my vision, some which involve surgery and some which do not. The risks and benefits of treatment have been thoroughly explained to me.

I give my consent to go ahead with surgery.

Write your initials here:

Confirmation of declaration

Please confirm you want to go ahead with the surgery by writing the following statement in the box below.

‘Having considered the information I received at my pre-treatment consultation and the information in this document, and discussed the risks, side effects, possible outcomes and benefits of treatment with my surgeon, I am happy to go ahead with the surgery. I understand I am under no obligation to do so.’

Your signature:

Your full name (print):

Your date of birth:

Date of your pre-treatment consultation:

Date of your signature:

Witness declaration

Witness's signature:

Witness's full name (print):

Witness's date of birth:

Date of witness's signature:

Surgeon declaration

I have discussed the intended procedure with the patient. I am satisfied that the patient has read this informed consent document, and understands it and the risks and benefits of, and alternatives to, the treatment. The patient has told me that I have answered all their questions to their satisfaction. The patient has also told me they are willing to accept the risks associated with the intended treatment, and voluntarily agrees to have surgery to reposition, remove or replace an ophthalmic device. I agree to accept this patient on the above terms and provide treatment as set out in this document.

Surgeon's signature:
Surgeon's full name (print):
Date of surgeon's signature:
Surgeon's status (please tick as appropriate): Employee of Optical Express <input type="checkbox"/> Independent practitioner <input type="checkbox"/>

Notes:

