

Implantable contact lens (ICL) and phakic intraocular lens (PIOL) surgery Informed consent document

This document is a legal document. You need to sign it to give the surgeon your written permission to treat you. It is important that you bring this document with you on the day of your treatment. 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

Informed consent

Background information

We aim to tell you all about the risks, benefits and alternative treatment options of implantable contact lenses (ICL) and phakic intraocular lens (PIOL) surgery.

It is important for you to understand that there are risks with any type of surgery. This informed consent document, along with the information you received at your pre-treatment consultation, is designed to make sure that you can fully consider the risks and benefits of the surgery you have been scheduled for and 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 before your surgery.

The information in this document applies to all types of ICL and PIOL surgery.

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

Your surgeon will decide whether you are fit 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.

Your Surgeon may elect to postpone your procedure to a future day should they believe that additional diagnostic tests or additional medical specialist support is required to allow delivery of your treatment.

Please tell your GP that you are considering ICL or PIOL surgery, 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. 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 surgeon or

an independent practitioner at the end of this form.

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 a different surgical approach would be safer or would provide a better outcome.

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 cardiac pacemaker, insulin implant or other electronic implanted device.
- You are allergic to any medications 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 any type of lens surgery or laser 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 vital that you have fully and accurately filled in the health questionnaire that you received at your pre-treatment consultation before you meet your surgeon for treatment.

This information is extremely important as it will help your surgeon to decide whether you are suitable for treatment.

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

Write your initials here:

General information

There are two types of surgical procedures described in this document. Both ICL or PIOL surgery are intended to

reduce or eliminate the need for you to wear glasses or contact lenses.

Both procedures involve inserting an artificial lens implant into your eye. The natural lens of the eye is not removed.

There are several types of lenses which can be implanted during ICL or PIOL surgery. Each type of lens essentially works in the same way. The main differences are related to the way they are positioned and held in place.

The procedures involved in ICL or PIOL surgery are explained in more detail in the information you received at your pre-treatment consultation.

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

Write your initials here:

Just before your surgery, we may give you a sedative to help you relax. We will also give you a local anaesthetic to numb the eye, and we may give you eye drops to dilate the pupil, depending on the type of lens we are using. During surgery you will be in a comfortable lying position. You will need to lie as still as possible.

You will be awake and be aware of a bright light, but you will not be able to see what is happening. Your surgeon will make a tiny incision at the side of the cornea (the clear front part of the eye). They will insert the lens through the incision and position it in the space between the cornea and the natural lens of the eye. Some lenses are positioned in front of the iris (the coloured part of the eye) and some behind the iris. The incisions are made with the intention that they will seal on their own, but occasionally one or two stitches may be needed. If you need stitches, we will do these under local anaesthetic. The stitching procedure is painless and takes about 20 minutes in total. We will give you antibiotic eye drops to reduce the risk of infection. After your surgery we will place a protective shield over the eye.

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

Write your initials here:

There is a significant amount of medical evidence which shows that ICL and PIOL procedures are safe and effective. However, it is not possible to absolutely guarantee that ICL or PIOL surgery will improve your vision or that you will not need other types of treatment to correct your vision.

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.

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

Write your initials here:

ICL or PIOL surgery involves inserting an artificial lens into your eye. We decide the power of the new lens as accurately as we reasonably can before the treatment, to reduce or correct short-sightedness, long-sightedness

or astigmatism. However, because healing patterns are unpredictable and because of other surgical factors (for example, the exact position the artificial lens settles in after the surgery), we may not achieve the result we are aiming for after one or several treatments, even with the correct lens power. So, even after treatment, you may still need glasses or contact lenses, or need laser eye surgery or further lens replacement surgery, to achieve the best vision possible.

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

Write your initials here:

As part of your lens surgery you can choose to have a monofocal (single focus) lens implant to correct your vision at one distance, typically for far vision and wear separate glasses for close-up work. The aim of this approach is that you are left with very clear distance vision with both eyes. The disadvantage is that you will need to wear glasses, typically for near vision.

I have read and understand this section. I understand that if I choose monofocal lens implants to correct my vision at one distance, I may 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 (like 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 you are about 60 years old, at which time you 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 process (called 'presbyopia') happens in everyone.

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.

The most important thing to remember is that if you have presbyopia and choose to have both eyes treated to give you the best distance vision, you will need to wear glasses for most near-vision activities after 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.

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 presbyopia and choose to have my distance vision corrected in both eyes, I will need to wear glasses for most near-vision activities after having laser eye surgery.

Write your initials here:

An alternative method of treatment for patients with presbyopia is a technique called 'monovision', 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).

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, it may be necessary for you to have further treatment.

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 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:

ICL and PIOL surgery will not correct other causes of poor vision such as amblyopia (lazy eye), vitreous opacities (floaters), cataracts, glaucoma, diabetes, age-related macular degeneration or other conditions of the retina or optic nerve.

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

Write your initials here:

After having ICL or PIOL surgery, it is possible that you may develop eye conditions that are unrelated to, and not caused by or prevented by, ICL or PIOL surgery, such as glaucoma, cataracts, vitreous opacities (floaters), 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:

Alternatives to ICL or PIOL surgery

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

There are other ways to correct your vision, some which involve surgery and some which do not, including glasses, contact lenses, another type of lens surgery and laser eye surgery, which may be able to help with your condition.

You have received this document because we have recommended ICL or PIOL surgery 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 ICL or PIOL surgery is an elective procedure and that I do not have to have the treatment. I understand that there are effective alternatives to ICL or PIOL surgery.

Write your initials here:

Cataracts develop when the natural lens inside your eye becomes discoloured and cloudy and reduces your vision. Patients aged 60 or older have a higher risk of developing cataracts than younger patients. This is a natural ageing process that happens in everyone, but progresses at different rates in different people. It is impossible to predict

the age at which cataracts will begin to affect your vision. Some patients never get to a point where cataracts affect their vision.

There is a small risk that the lens that is implanted during ICL or PIOL surgery could cause a cataract to develop early. It is also possible that you could develop cataracts as part of the natural ageing process after having ICL or PIOL surgery, even if there were no signs of cataracts at your pre-treatment consultation. The treatment for cataracts is a surgical procedure during which the natural cloudy lens is replaced with a clear artificial lens that is implanted inside the eye. If you develop cataracts after ICL or PIOL surgery to improve your vision, you may need to have a cataract procedure in which both the natural lens and the lens that was implanted as part of the ICL or PIOL surgery are both removed and replaced with a different type of artificial lens designed for cataract surgery.

It is important to understand that there is an alternative treatment to ICL or PIOL surgery which also prevents cataracts. The treatment is called 'refractive lens exchange' (RLE), and is a form of ICL or PIOL surgery. The advantages of RLE are that it could permanently correct your vision (like laser eye surgery) and that it will prevent you from developing cataracts later in life. Some disadvantages of RLE include the possibility that you may still need a laser procedure or other treatment to 'fine tune' your vision after RLE. Your refractive optometrist or surgeon will discuss RLE with you if you would like more information. For most patients under 40 who are unsuitable for laser eye surgery, ICL or PIOL surgery is likely to be the best option, but it is important that you understand that RLE can be an alternative.

I understand the issues relating to cataracts, and that RLE is an alternative to ICL or PIOL surgery. All of my questions have been answered. I would like to go ahead with ICL or PIOL surgery instead of RLE surgery.

Write your initials here:

Possible risks, complications and desired results

Due to uncertainties in healing patterns and other aspects of surgery, we may not fully achieve the desired result from the treatment you are scheduled for after a single procedure. So, even after surgery, you could be short-sighted, long-sighted or have astigmatism and may need to wear glasses or contact lenses or have more surgery. Your eyes may also go back towards their original prescription.

Laser enhancement surgery may be possible when your prescription is stable, there is enough corneal tissue available and there are no medical reasons why laser eye surgery could not be safely carried out.

Although laser enhancement surgery is generally very effective, there are extra risks involved, and we cannot guarantee we will achieve the result we are aiming for. We normally consider laser enhancement surgery three to six months after ICL or PIOL surgery.

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:

At some point in the future, due to unforeseeable circumstances, we may need to reposition, remove or exchange the lens that is implanted as part of the ICL or PIOL surgery, regardless of the type of lens that is used.

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

Write your initials here:

ICL or PIOL surgery can, in certain circumstances, be reversible. If there is a complication that is related to the implanted lens, such as a significant increase in pressure in the eye (secondary pupil block glaucoma), it may be possible to remove the lens or replace it with a different type that may correct the problem.

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

Write your initials here:

Night-vision disturbance, such as glare and 'halos', or double vision or seeing 'ghosts' around things are common immediately after ICL or PIOL surgery, but in most cases these symptoms 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.

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 ICL or PIOL surgery. 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:

In rare cases, ICL or PIOL surgery can lead to an infection within the eye (endophthalmitis) or on the outer surface of the eye (microbial keratitis), bleeding inside the eye, cataracts, swelling of the cornea, a detached retina, uncomfortable or painful eyes, droopy eyelids, increased astigmatism, dislocation of the lens implant, glaucoma or double vision. ICL or PIOL surgery could result in blindness, or even the loss of an eye. This is extremely rare but the possibility has been reported in scientific literature.

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 ICL or PIOL surgery. 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:

We do not recommend that you travel alone for at least two hours after your eye surgery (even if you are travelling a route you know well) or for a week following eye surgery (where you are travelling a route you do not know well).

We cannot predict how you will feel after your eye surgery, and whether you will be able to safely use transport (either public transport or your own transport). For example, you may feel drowsy or disorientated, or have restricted vision.

I understand that if I decide to travel on my own following the treatment, this is at my own risk.

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.

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.

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:

Treating both eyes

ICL or PIOL surgery is carried out on one eye at a time. If there are no complications, the surgery on the second eye can usually take place within one week of the surgery on the first eye. During the time between the first and second eye treatments, you may notice an imbalance between the two eyes. If this causes you to have unwanted symptoms, these can usually be corrected with a temporary contact lens.

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

Write your initials here:

Patient consent

Your surgeon will help you with the choices in this section. I give my consent to having the following treatment. (Tick the appropriate box.)

I choose to have the following ICL or PIOL surgery:

Implant a monofocal lens Right eye Left eye

I choose to have cataract or NLR surgery to implant **monofocal lenses** to correct:

Near vision Right eye Left eye

Distance vision Right eye Left eye

Write your initials here:

Use of personal information

I understand personal information relating to my treatment will be used to help you provide my treatment, review my treatment, give me advice about additional treatment, carry out any 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 understand information relating to my treatment will be used for research purposes, for statistical analysis, in connection with academic and scientific papers, presentations and other publications. I understand that that information relating to my treatment and used for these purposes will not reveal my identity.

Write your initials here:

I understand that Optical Express may receive my medical records, including, but not be limited to, reports, charts, medical history and record entries by different doctors or healthcare professionals, photographs, findings, ophthalmic (eye) or other scans, radiographs (x-rays), prescriptions, diagnosis, medical testing, test results, billing, and other treatment records in my doctor's possession ("Medical Records") to the extent necessary for treatment, determination of clinical management plans, customer service, and billing. My Medical Records will only be shared with third parties if this is covered by my consent or otherwise permitted by the applicable law. Optical Express may also use this information for internal educational and internal data review and analysis purposes.

I will not, nor shall anyone on my behalf seek legal, equitable or monetary damages or remedies for such disclosure. I acknowledge that use of my Medical Records is without compensation and that I will not nor shall anyone on my behalf have any right of approval, claim of compensation, or seek or obtain legal, equitable or monetary damages or remedies arising out of any use such that comply with the terms of this Consent.

Write your initials here:

Patient declaration

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 or understood all of this information, please let us know and do not go ahead with the treatment.

Further to my consultation with my optometrist I have taken part in a discussion with a second clinician who also discussed with me the risks, benefits and alternatives to laser eye surgery.

Write your initials here:

At my consultation I watched the ICL or PIOL consent video which explained the risks and benefits of, and alternatives to, ICL or PIOL surgery, and emphasised the importance of this informed consent document.

Write your initials here:

I was provided with my ICL or PIOL terms and conditions and informed consent documents at the time of my consultation.

Write your initials here:

I received my ICL or PIOL terms and conditions and informed consent documents at least 24 hours before my surgery.

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.

Write your initials here:

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 ICL or PIOL surgery (whichever applies) is mine alone, and should be based on the information I have received in this document and during my pre-treatment consultation.

Write your initials here:

I confirm that all my questions have been answered, and I am satisfied with the answers. I understand that ICL or PIOL surgery 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 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 the 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 optometrist, second clinician and 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:

Witness profession:

Role in informed consent process:

Date of witness's signature:

Witness declaration

Witness's signature:

Witness's full name (print):

Witness's date of birth:

Witness profession:

Role in informed consent process:

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 laser eye surgery. 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 Independent practitioner

Notes: