



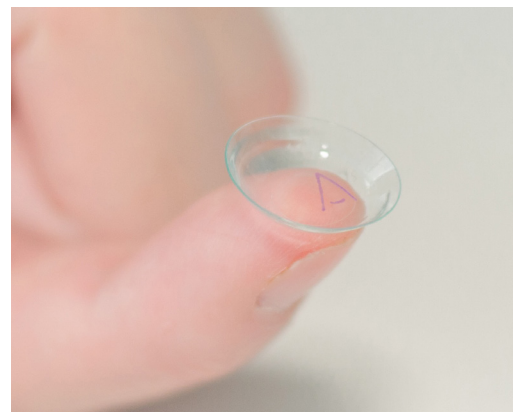
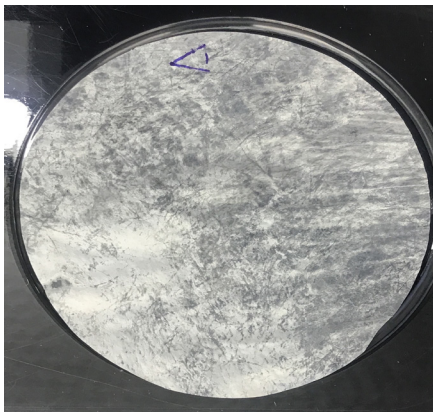
Omnigen/OmniLenz

Information for patients from Ophthalmology

After discussions with your doctor, you have been referred for treatment with amniotic membrane for your eye condition. This leaflet will outline the possible benefits and risks to having this treatment, and will hopefully answer any questions you may have about the procedure. If however, after reading this you still have questions please speak to your doctor/optometrist.

What is Omnigen/OmniLenz?

This is a thin, transparent (clear) sheet of preserved human tissue (amniotic membrane) which is placed on the surface of your eye, with a contact lens to hold it in place.



Pictures of a large piece of Omnigen (total eye coverage) and a much smaller piece inside an OmniLenz.

How can amniotic membrane help my condition?

During pregnancy, the amniotic membrane lines the sac that protects and nurtures the baby during development in the womb. After years of research and experience, it has been shown that as well as helping babies to develop, the amniotic membrane also helps with reducing pain and wound healing, including healing damaged and inflamed eye surfaces.



Are there alternatives?

The alternatives to this procedure are:

- a regular bandage contact lens – with no Omnigen material; or
- Omnigen material inserted as a day case procedure in the surgical unit.

How long will I be in hospital?

This is an outpatient procedure, and will be completed in the eye clinic. So there is no need to stay in hospital overnight.

How long will the contact lens stay in place for?

The contact lens will be removed in clinic in about seven to 10 days' time [as a minimum], or may stay in the eye for up to two months.

How is the amniotic membrane donated?

The amniotic membrane, that would be used in your procedure, has been donated by mothers who are having an elective (planned) caesarean section. They have consented for their tissue to be used to help others and receive no payment or benefit from this.

Donors are asked questions about their medical and social history to make sure the donated tissue is safe and to reduce the risk of disease transmission. All our donors also have a blood test which checks for HIV, Hepatitis B, Hepatitis C, HTLV-I, Syphilis, and Cytomegalovirus.

If you know that you are allergic or sensitive to any antibiotic you should tell your doctor.

What happens during my procedure?

1. You will arrive at the hospital and be greeted by a member of staff. Please refer to your appointment letter for where your procedure will take place.
2. The member of staff will ask you some medical questions. Please use this time to ask any last minute questions; remember you can withdraw consent for the procedure at any time.
3. Once you are sitting comfortably, your doctor/optometrist will place anaesthetic drops in your eye to numb it and make sure the procedure is as comfortable as possible.
4. The Omnigen will be prepared by first placing the tissue inside an OmniLenz contact lens. This is a standard lens that has been specially modified to hold Omnigen in place. The Omnigen will be prepared in the OmniLenz in the eye clinic while you wait.
5. The Omnigen/OmniLenz will then be placed over the surface of your eye, similar to a normal contact lens. You may feel some mild discomfort to begin with; this is normal. You can use eye drops to help with this.

How will I feel afterwards?

Your eyesight may be a little blurred after your procedure, as the Omnigen material is not completely clear. Hopefully, your eyes will feel better than they did when you arrived at hospital.

How do I look after my eye when I return home?

- You can use your eye drops as normal, but do not use any gels or ointments in your eye with the Omnigen.
- Be gentle when rubbing or touching your eye, so you do not dislodge the material. This includes when you are having a bath or shower.

Can I drive home?

If you usually drive you should still be safe to do so after your procedure.

You can resume normal activities (such as housework or exercise) straightaway.

Will I have a follow-up appointment?

You will normally have a follow-up appointment two weeks after your procedure. This appointment will be booked before you leave hospital.

What are the risks to this procedure?

- Wearing contact lenses can sometimes cause complications, especially when worn overnight or for long periods of time, as in the case of this procedure. However, this is unlikely with the controlled duration of wear of the treatment, with any risks being minimised by contacting your doctor.
- If you do experience any pain, your eye looks red, or your eyesight becomes reduced, please contact the urgent eye clinic on 01233 61 62 32 or, out of hours, call the switchboard on 01233 63 33 31 and ask to speak to the on call eye doctor straightaway.
- Steps are taken to minimise the risk of infection from transmissible diseases through screening, but these methods are not perfect and may not find all diseases or unidentifiable pathogens. In particular, for the use of any human tissue, it is not possible to test for the type of organism called prions. Prions are known to cause variant Creutzfeldt-Jakob disease (vCJD) a rare but fatal human degenerative condition. If a donor was at higher risk of prion infection, this would have been determined as part of their lifestyle/medical history screening process.

Strict surveillance has been in place since May 1990 in the UK, with 178 cases of vCJD reported to date, of which 177 has been analysed and no links have been found to tissue transplant, including treatment of eyes has been found.

- It is estimated that over one million amniotic membrane transplantation procedures have been performed worldwide over the last 20 years. There is no reported evidence of amniotic membrane causing an allergic reaction in the eye. However, should you experience any signs that you are having an allergic reaction, please contact the emergency eye clinic on 01233 61 62 32 or, out of hours, call the switchboard on 01233 63 33 31 and ask to speak to the on call eye doctor straightaway.

Informed Consent Form for application of Amniotic membrane

Patient name _____

I agree to having Amniotic membrane(s) derived from human tissue, Omnigen, applied to the front surface of my eye.

The donor tissue will be provided by NuVision Biotherapies.

I have been informed that amniotic membrane lines the sac that surround a baby when it is developing during pregnancy. I understand that amniotic membrane may have positive wound healing effect when used clinically.

I acknowledge that my doctor's/optometrist's explanation included a description of the procedure, the reasonable benefits and potential risks as stated above of the procedure with human tissue. I understand that the risks of infection associated with receiving human tissue(s) have been reduced at least by required infectious disease tests, careful donor selection and end product testing.

I acknowledge that the risks of the use of any human tissue, or tissue derived product, must always consider the potential risk of prion infection. I understand that whilst precautions to minimise risk have been performed, risk cannot be eliminated entirely.

While the precautions taken by my eye clinician and the testing and screening of the donor and donor tissue generally prevent complications associated with tissue implants, I understand that I may still be subject to ill effects as a result of receiving donor tissue.

I acknowledge that I have had the opportunity to ask all questions of my doctor/optometrist with regard to this treatment and that they have been answered to my satisfaction. I fully understand what I am now signing of my own free will.

Patient Signature: _____ Date: _____

If you would like this information in **another language, audio, Braille, Easy Read, or large print** please ask a member of staff. You can ask someone to contact us on your behalf.

Any complaints, comments, concerns, or compliments please speak to your doctor or nurse, or contact the Patient Advice and Liaison Service (PALS) on 01227 78 31 45, or email ekh-tr.pals@nhs.net

Patients should not bring in large sums of money or valuables into hospital. Please note that East Kent Hospitals accepts no responsibility for the loss or damage to personal property, unless the property had been handed in to Trust staff for safe-keeping.

Further patient leaflets are available via the East Kent Hospitals web site www.ekhufft.nhs.uk/patientinformation