Manchester Royal Eye Hospital
Corneal Services

Information for Patients

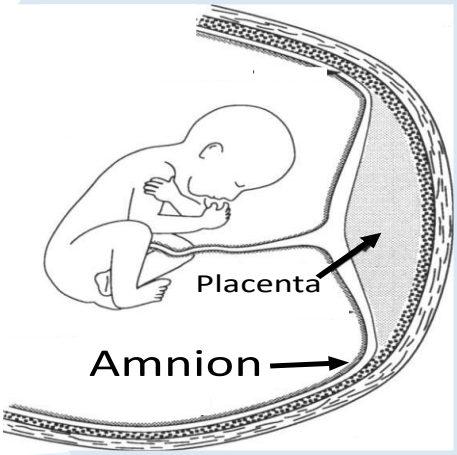
Omnigen (Amniotic Membrane)

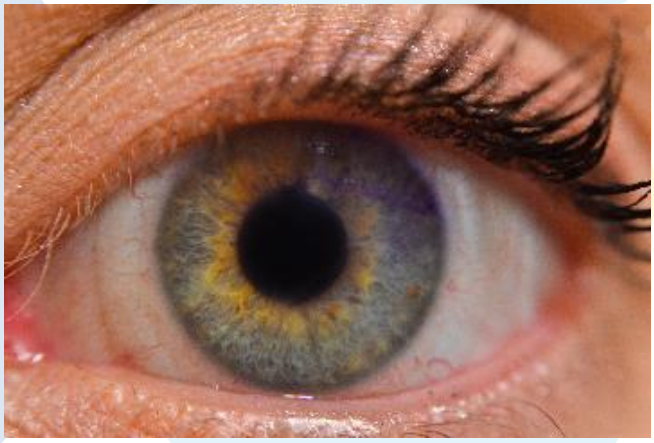
Introduction

Your clinician has decided you are suitable for treatment with amniotic membrane. This is a thin, transparent sheet placed on the surface of the eye, followed by the application of a contact lens (OmniLenz) to hold it in place. This lens will be removed in the clinic in about 7-10 days time. However, before this procedure is performed we would like to provide you with the following information which outlines the potential benefits and risks. Once you have read this document and if you agree to continue, you will be asked to sign a separate consent form. If you have any questions about the procedure or the information provided, please ask the clinical staff in charge of your care.

Background

During pregnancy, the amniotic membrane forms a sac that protects the baby as they develop. We know from treating patients over many years that amniotic membranes have many natural properties which help the baby develop. This quality of amniotic membrane has been shown to help damaged or inflamed eye surfaces heal, and also to reduce pain and inflammation.





Amnion donation

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

Potential donors are screened including medical history such as infectious or autoimmune disease and aspects of their life that may increase their risk of contracting an infectious disease. They undergo a number of blood tests including:

- HIV I & II
- Hepatitis B
- Hepatitis C
- HTLV-I
- Syphilis
- Cytomegalovirus

Amnion processing

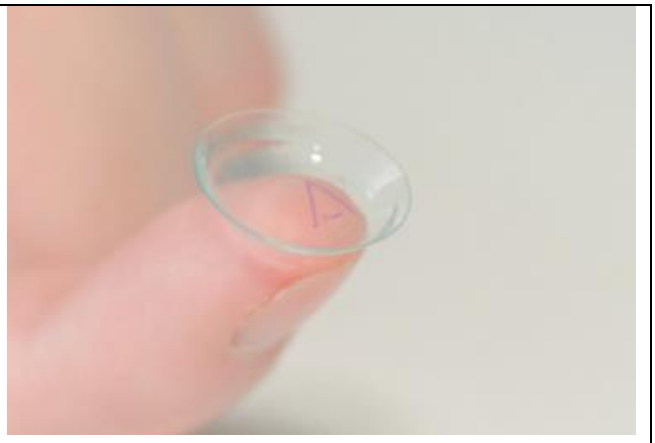
Amniotic membranes are processed according to regulations established by the United Kingdom Human Tissue Authority (HTA). They apply the following acts:

- The Human Tissue Act 2004
- The Human Tissue (Quality and Safety for Human Application) Regulations 2007
- The Quality and Safety of Organs Intended for Transplantation Regulations 2012

The HTA inspect the manufacturers of the amniotic membrane in the UK and grant them a licence to operate if they meet and maintain the required standards set by these Acts of Parliament.

During processing, the donated amniotic membrane undergoes a number of steps that aims to reduce the transmission of potential infections. In particular the membrane is treated with a number of antibiotics. If you know that you are allergic or sensitive to any antibiotic you should inform your clinician.

What will the Omnigen and OmniLenz procedure involve?



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

The application of Omnigen begins with you sitting comfortably. Anaesthetic eye drops will be put if your eye to numb the corneal surface. Whilst this takes effect, the Omnigen will be placed inside a OmniLenz contact lens. This is a standard lens that has been modified to hold Omnigen in place. The lens will then be placed on your eye in a similar fashion to a normal contact lens.

Specific risks

Contact lens wear can sometimes cause complications, especially when worn overnight as in the case of this procedure. However, this is unlikely with the short-term wear of the OmniLenz, and the risks can be minimised by contacting your clinician straight away if your eye becomes painful, looks red or your vision is reduced.

Whilst NuVision© the company that supplies the material takes every step to minimise the risk of infection from transmissible diseases through appropriate screening, these methods are limited and may not detect 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 be determined as part of the 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 have been analysed and no association to tissue-transplant, including treatment of eyes has been found.

Amniotic membrane has been used to treat eyes since the 1930s. The number of patients treated is in the millions although we cannot be more precise. Amniotic membrane continues to be an important clinical option with its use expanding in recent years. Omnigen itself has been used in over 50 NHS hospitals. There is no reported literature evidence of amniotic membrane causing an allergic reaction in the eye even after repeat application from different donors.

Raffinose pentahydrate is a sugar found in beans, cabbage, brussel sprouts, broccoli, asparagus, other vegetables, and whole grains. It is used in the processing of amniotic membrane. To date there is no evidence of any cases of where a patient has been sensitive to raffinose pentahydrate.

The risk of you being allergic to amniotic membrane is low but if you think you are at risk and particularly in respect of antibiotics please discuss this with the clinical staff before the procedure. Following the procedure if you think you are having an allergic reaction you should contact the clinical staff immediately.

If you wish to discuss anything further information please contact

Corneal specialist Nurse: (0161) 701 4224 Monday – Friday 09.00am – 4.00pm.