

Omnigen : Disposal Information

Omnigen® should be <u>discarded in a clinical waste bin</u>, following your centres standard operating procedures. Residue of Omnigen® may remain in OmniLenz® when removed from the patient, thus, OmniLenz® should be discarded in the same way.

If the unit has not been used for human application, the disposal of the unit should be noted in your centres transplant book by stating the unit (Single European Code), date, reason and method of disposal for traceability purposes.

If you do not have a storage licence the units should be discarded within 48 hours.

If any serious adverse events or reactions occur regarding Omnigen®, please report this to NuVision Biotherapies without delay, by phone or email.



For enquiries and further information, please contact:

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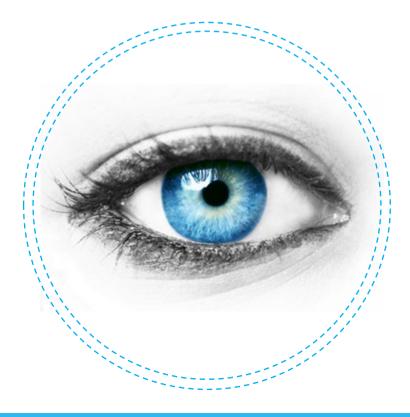


STERILE A



Dry preserved human amniotic membrane

Storage Guide (United Kingdom)





Omnigen® is dry preserved human amniotic membrane. This tissue has been donated by women undergoing elective caesarean section whom have given their voluntary consent.

As Omnigen is Human Tissue, in the UK, the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 must be followed. Therefore, you should:

- Store Omnigen between 2°C to 25°C and out of direct sunlight.
- <u>Do not</u> store Omnigen for more than 48 hours, unless your centre is licensed for the storage of human tissue for human application according to, Human Tissue (Quality and Safety for Human Application) Regulations 2007. This means an HTA license with:
 - Human Application sector.
 - Storage as licensable activity.
 - Amniotic membrane as authorised tissue type.
- The product identification, Single European Code (SEC), the date of application or disposal, the name of the recipient and end user or clinician must be recorded in your transplant book following your centres standard operating procedures to ensure full traceability of the tissue from donor to recipient and vice versa.

NuVision are here to help...

If you state the procedure date on your purchase order, NuVision will organise delivery for the day before your procedure to help you follow the 48 hour rule. If surgery is on Monday, we would suggest to book the patient in the afternoon to ensure delivery.

