

Amniotic Membrane Frozen Large

Product code T0118

Product description

Amniotic membrane dissected from placentas donated during elective caesarean section deliveries. Processed in-house in licensed pharmaceutical grade cleanrooms (minimum GMP classification C). The amnion is washed in isotonic citrate solution to remove blood and treated with an antibiotic cocktail to reduce microbial load. The antibiotic solution contains gentamicin sulphate (4g/l), imipenem (0.2g/l), nystatin (2.5x10⁶ U/l), polymyxin B sulphate (0.2g/l), and vancomycin hydrochloride (0.05g/l), prepared in medium 199 supplemented with 25mM HEPES.

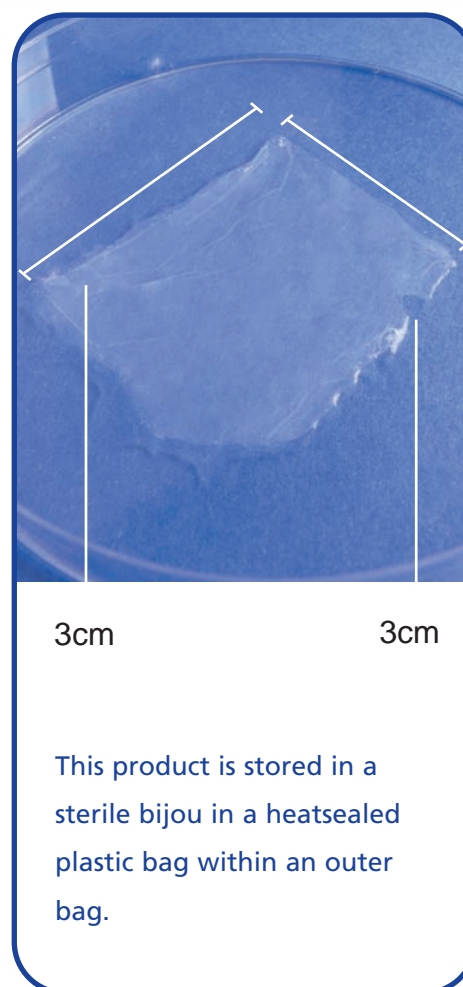
Frozen in the final packaging with 50% glycerol/Hanks solution. Stored at -80°C whilst on site at NHS Blood and Transplant (NHSBT) premises. Quarantined for 180 days to retest the donor for serological markers or tested at time of donation by PCR technology for hepatitis B & C and HIV, in addition to the routine serology. Supplied as individual units measurements approximately 3x3cm squares, mounted stromal side on to nitrocellulose paper. 5x5cm grafts will soon be available.

Clinical applications

For use in ophthalmic surgery, primarily for ophthalmic surface damage and scarring. The graft must be thawed at room temperature by the theatre team prior to use. Note that as this product contains minimal blood cells.

Benefits - history of safe use

- Supplied by Tissue Services, a specialist function of NHSBT undertaking all aspects of tissue donor evaluation, medical screening, consent, testing, storage, quality assurance and supply.
- Aseptic retrieval from a living donor. Face to face medical and social history interview.
- The donor is medically assessed by highly trained clinical staff specialising in tissue donation.
- Pathogen reduction is achieved during processing by decontamination with an antibiotic cocktail. Graft quality is assessed by highly trained Tissue Services staff.



This product is stored in a sterile bijou in a heatsealed plastic bag within an outer bag.

- Uniform product presentation with minimal variation. Flat packed to minimise storage space.
- This product is not irradiated.
- There are no reported cases of patient harm.

Technical Specification

For further information, clinical or scientific advice or to place an order, please contact your NHSBT tissue bank via the national order line

Tel 0845 607 6820 Fax 0845 607 6819

Quality and Safety

Tissue is sourced from UK donors in compliance with rigorous ethical and clinical standards. The consent process is approved by the Human Tissue Authority. In house experts on tissue donor selection and medical history influence the standard across all donation programmes (blood, tissue and organ). The standard, is written by UK blood services in compliance with MSBTO (advisory committee in the Microbiological Safety of Blood, Tissues and Organs). Much of the standard is above and beyond the minimum required by European/UK legislation and regulation. Tissue Services was previously licensed by the MHRA (Medicines and Healthcare product Regulatory Authority) under the UK code of practice and now holds establishment licences under the HTA (Human Tissue Authority). The services and facilities comply with Good Manufacturing Practice.

Hospitals donating placentas are carefully selected to ensure quality and continued proficiency. Theatre staff are trained in the donation procedure. Donation sites are audited every year.

All microbiology testing is performed by in-house accredited laboratories specialising in donation screening. Final donor assessment and selection is undertaken by in-house senior nurse specialists in tissue donation. Donations are tracked by barcode including automated test result transfer to the database (the same database used for blood donation, processing and supply). This database has automated controls to prevent release of non-conforming tissue. Tissue is stored at -80°C to ensure continued storage

below the required -40°C with full audit trail for stock location. Final product release is undertaken as an independent function by specialist NBS Quality Assurance personnel. Containers and transport boxes are validated in-house by the Tissue Development Laboratory.

All activity is regularly reviewed against practice considered best by international standards, with professional links to the British, European and American Tissue Banking Associations.

Labelling and Packaging

This product is attached stromal side to nitrocellulose paper contained within a 7ml translucent polypropylene sterile bijou. The secondary package is heat sealed in low density polyethylene bags compliant with EC Commission Directive 2002/72/EC. The outer bag is labelled with graft type, unique donation number, expiry date, size, and storage requirements. Donation number, product type, status and expiry date are ISBT 128 barcoded. Enclosed within the packaging is a transplant reporting form with a freepost envelope, which can be used for feedback. If an adverse event or reaction is suspected, telephone the tissue bank immediately.

Delivery

Transport protocols are validated to ensure that grafts arrive with the customer undamaged and in perfect condition. Packaging materials are validated to ensure that the integrity of the graft is maintained up the point of use. Delivery is in a disposable transport box containing dry ice (solid carbon dioxide) validated to keep the graft frozen until the time written on the box. It is delivered by either NHSBT Transport or via a courier, usually direct to the point of use e.g. theatre. Next working day delivery is included in the product price. More urgent delivery e.g. same day or by specified time can be arranged at additional cost. Where an operation is graft critical, the patient must not be taken to theatre before the graft has arrived and its condition checked.

References:

Title and Authors

Tissue donation: benefits, legal issues and the nurse's role. Gumbley E, **Pearson J.**

Yorkshire regional tissue bank-circa 50 years of tissue banking. **JN Kearney**

Traceability of human tissues for transplantation - the development and implementation of a coding system using ISBT 128. **D. Fehily, P.Ashford, S.Poniatowski**

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Tissue donation. **Pearson J**

Storage

This graft needs to be stored frozen. This product contains cells therefore if stored beyond 48 hours it will require a storage license from the HTA. For further information please visit www.hta.gov.uk. This product must be stored below -40°C. Freezers need to be designated for clinical use with 24/7 alarms and monitoring. Your blood bank may be able to store this tissue in these conditions. Once thawed, this product must be used immediately.

Alternative products

- Amniotic Membrane Frozen Small

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Allografts as vectors of infection. **J N Kearney**

Production of an Acellular Amniotic Membrane Matrix for Use in Tissue Engineering. S.Wilshaw, **J.Kearney**, J.Fisher, E.Ingham

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