NHS
Blood and Transplant

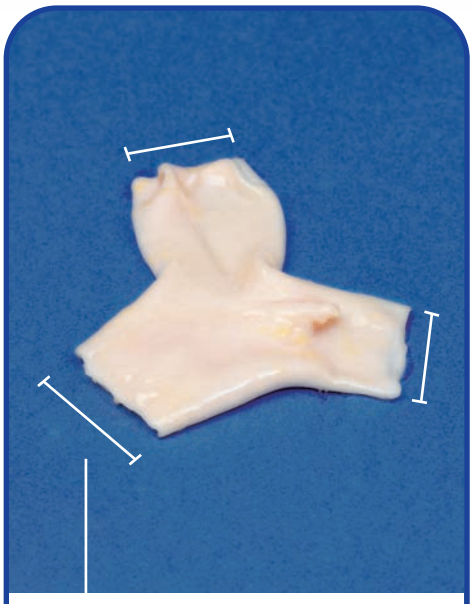
Conduit Non-Valved Cryopreserved Pulmonary

Product code T0125

Technical Specification

Product description

A non-valved pulmonary conduit from a deceased donor. The whole heart is retrieved either by appropriately trained NHS Blood and Transplant (NHSBT) staff using aseptic procedures in a mortuary or dedicated donation suite, or in an operating theatre environment by transplant surgeons when obtaining organs for organ donation. The conduit is carefully dissected from the donor heart and is decontaminated, measured/sized, packaged and cryopreserved within 48 hours of donation. Aerobic and anaerobic bacterial and fungal cultures are taken both pre- and post decontamination and assessed against rejection criteria including pathogenic organisms and gross contaminants. The grafts are processed in-house in licensed pharmaceutical grade cleanrooms (minimum GMP classification B) to remove excess myocardium, fat and connective tissue. The valve is washed in isotonic citrate solution (to remove blood) and treated with an antibiotic cocktail to reduce bioburden. The antibiotic solution contains gentamicin sulphate (4g/l), imipenem (0.2g/l), nystatin ($2.5x10^6$ U/l), polymyxin B sulphate (0.2g/l, and vancomycin hydrochloride (0.05g/l), prepared in medium 199 supplemented with 25mM HEPES. The conduit is measured and sized, and cryopreserved in a protectant medium comprising Hanks' Balanced Salt Solution supplemented with 25mM HEPES and 15% (v/v) dimethyl sulphoxide. The grafts are stored below -135°C, supplied on dry ice at -79°C and supplied as individual units of specified size. Each graft is provided with a diagram ith sizes and related pathology recorded.



Annular Diameter
(mm)

This product is stored in two heatsealed bags in an outer cardboard box. Delivery is in a disposable transport box containing dry ice (solid CO_2)

Clinical applications

For use in cardiovascular surgery. The valve must be thawed in a 37°C waterbath containing sterile saline before use, after first being brought to a temperature above -80°C (where necessary) to prevent valve damage.

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, cleanroom processing, quality assurance and supply.
- Donor selection includes medical history/lifestyle check from next of kin and GP and where applicable post mortem report.
- A donor physical examination is carried out at donation. The donor is cleared by highly trained clinical staff specialising in tissue donation.
- Pathogen reduction is achieved during processing by treatment with antibiotics.
- Valve quality and competency is assessed by highly trained Tissue Services staff.
- Product presentation is uniform with minimal variation.
- This is a cellular product and therefore requires a user storage license if stored for longer than 48 hours.
- There are no reported cases of this graft supplied by Tissue Services causing patient harm.

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 expertise 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 for Tissue Banks scheme and now holds establishment licences under the HTA (Human Tissue Authority). The services and facilities including pharmaceutical grade cleanrooms comply with Good Manufacturing Practice. All aspects of the supply chain from education through donor selection, donation, processing and supply are managed by Tissue Services staff in-house. Processes have been validated in-house by the Tissue Development Laboratory. All microbiology testing is performed in-house by accredited laboratories specialising in donation screening. Final donor assessment and selection is undertaken by in-house clinical specialists in tissue donation. Donations are tracked by barcode including automated test result transfer to a 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 <–135°C with full audit trail for stock location. The release process is independently reviewed. 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

The graft may be packaged in one of two ways. Grafts prepared prior to April 2007 are packaged in an inner nylon pouch (a monomer cast semi-crystalline thermoplastic similar to nylon 6,6) and outer foil pouch with 15 micron oriented nylon laminated to 50 micron modified polyethylene. Grafts prepared post April 2007 are packed in inner and outer pouches consisting of an amber translucent Teflon-Kapton material. All packaging materials are validated for storage at very low temperatures. Inner and outer pouches are heat-sealed following packaging. Prior to despatch, the pack is vacuum sealed within a plastic bag containing a product label stating the graft type, annular diameter, unique batch number, expiry date and storage requirements, and a user information document. Batch number, product type, status and expiry date are ISBT 128 barcoded. Enclosed within the vacuum packed polythene bag outermost packaging is a transplant reporting form with a freepost envelope that can be used for any feedback. If an adverse event or reaction is suspected, telephone the Tissue Bank immediately to ensure appropriate follow up and reporting.

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. Transport containers have been validated to be leak proof and capable of withstanding a dropping regime based on ASTM Standard D4169-01 (Standard Practice for Performance Testing of Shipping Containers and Systems). 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.

Storage

This graft needs to be stored frozen. This product does contain cells therefore if stored beyond 48 hours a storage licence from the HTA is required. For further information please visit www.hta.gov.uk. The graft should be stored at -80°C with a maximum shelf life of 6 months from the date of dispatch or until the expiry date if this is earlier. It cannot be returned to storage at -135°C. The expiry date on the label will be corrected for your storage requirement before dispatch. 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, the maximum storage time in a 4°C clinical alarmed and monitored refrigerator is 1 hour.

Alternative products

Cryopreserved Skin Allograft.

References:

Title and Authors	Published In:
Immunological responses to tissue grafts and tissue implants. ***JN Kearney***	*Advances in Tissue Banking. 1999; 3: 185-212.*
Tissue donation: benefits, legal issues and the nurse's role. Gumbley E, ***Pearson J.***	*Nurs Stand. 2006;21(1):51-6; quiz 58.*
Yorkshire regional tissue bank-circa 50 years of tissue banking. ***JN Kearney***	*Cell Tissue Bank. 2006; 7(4):259-64.*

Title and Authors	Published In:
Residual antibiotics in allograft heart valve tissue samples following antibiotic disinfection. Leeming JP, Lovering AM, ***Hunt CJ.***	*J Hosp Infect. 2005; 60(3):231-4.*
Challenges in the testing of non-heart-beating cadavers for viral markers: implications for the safety of tissue donors. Padley D, Ferguson M, ***Warwick RM****, Womack C, Lucas SB, Saldanha J.*	*Cell Tissue Bank. 2005; 6(3):171-9.*
Traceability of human tissues for transplantation - the development and implementation of a coding system using ISBT 128. ***D. Fehily****, P.Ashford,* ***S.Poniatowski***	*Organs and Tissues. 2004; (2) 83-88.*
Guide to safety and quality assurance for organs tissues and cells K Datsis, G Kirste, J Koller, W Lauchert, B Loty, M Madsen, M Manyalich, S Markovic, J Oberholzer, G Persijn, G Piccolo, E Pokorna, K Salmela, E Trias, A Vanderkalen, ***R M Warwick***	*Council of Europe 1st edition June 2002. ISBN No: 92 - 875 - 48910 Council of Europe publishing.*
A UK Survey of Virological Testing of Cadaver Tissue Donors. SJ Stanworth, ***RM Warwick****, M Ferguson, JA Barbara*	*Vox Sang. 2000;79(4):227-30*
Tissue donation. ***Pearson J***	*Nurs Stand. 1999; 13(45):14-5.*
BATB Medical SIG Survey 1996 Selection and Screening of Tissue Donors. HJ Stafford and ***Ruth M Warwick***	*BATB News Issue 8 Summer 1997 page 3-4.*
Safe Tissue Grafts' should achieve the same standards as for blood transfusion ***Fehily D****,* ***Warwick R***	*BMJ. 1997; 314: 1141-2.*
Donor valves as ideal substitutes for heart valve replacement. N Ketheesan, E Ingham, ***Kearney JN****, R Rasaretnam*	*Ceylon Med J. 1997; 42(2):85-90.*
The effect of cryopreservation on the immunogenicity of allogeneic cardiac valves. N Ketheesan, ***Kearney JN****, E Ingham*	*Cryobiology. 1996; 33(1):41-53.*
The role of the Blood Transfusion Service in Tissue Banking. ***Warwick RM****, Eastlund T &* ***Fehily D***	*Vox Sanguinis. 1996; 71: 71-77.*
Allografts as vectors of infection. ***JN Kearney***	*Lancet. 1987; 2(8555):402.*