

Femoral Head Freeze Dried Washed Irradiated Slice

Product code T0013

Product description

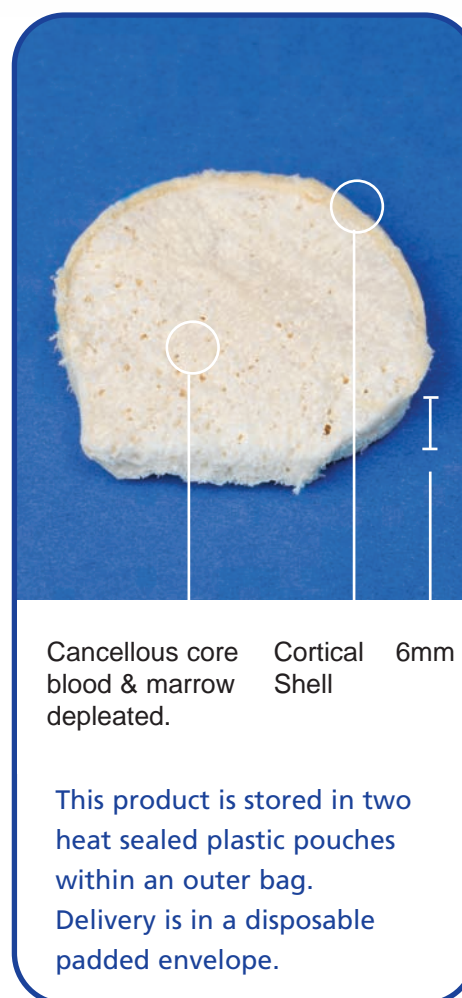
A 6mm depth slice of femoral head from a deceased multi-tissue donor. Packaged and frozen within 24 hours of donation. Aerobic and anaerobic bacterial and fungal cultures taken and assessed against rejection criteria including pathogenic organisms and gross contaminants. Processed in-house in licensed pharmaceutical grade cleanrooms (minimum GMP classification C) to remove cartilage and soft tissue, shaped to size (6mm thick) and washed to remove most blood and bone marrow cellular components. Freeze dried to less than 5% water and irradiated to minimum dose 25kGy in the final packaging. Stored and supplied at ambient temperature. Supplied as individual units.

Clinical applications

For use in orthopaedic surgery, primarily hip and knee revision. The graft must be rehydrated before use. Usually the graft is milled or further shaped by the theatre team prior to implantation.

Benefits - history of safe use

- Supplied by Tissue Services, a specialist function of NHS Blood and Transplant (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 including washes with hydrogen peroxide, ethanol, heated sterile water and sonication, followed by freeze drying and irradiation to a minimum dose 25kGy.
- Tissue Services are in the process of implementing a validated technique to remove over 99% of bone marrow components from bone.
- Bone quality assessed by highly trained Tissue Services staff.
- Uniform product presentation with minimal variation.



Cancellous core
blood & marrow
depleted.

Cortical
Shell

6mm

This product is stored in two heat sealed plastic pouches within an outer bag.
Delivery is in a disposable padded envelope.

- Flat packed to minimise storage space and stored at ambient temperature not requiring temperature monitoring.
- Non cellular and freeze dried therefore does not require a user storage licence.
- 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

Technical Specification

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 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 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 prior to freeze drying with full audit trail for stock location. Freeze dried bone is lyophilised to measure <0.5 aW (water activity) which equates to <5% moisture, eliminating the potential for microbial growth and minimising autodegradative reactions. Irradiation is carried out to an established protocol ensuring a minimum dose of 25kGy is received by the tissue. Processed bone grafts are non cytotoxic as per ISO 10993-5. Final product release is undertaken as an independent function by specialist NBS Quality Assurance personnel. 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

Inner and secondary packs are heat-sealed in a pouch consisting of a transparent lamination of polyester and polythene film sealed to Perfecseal coated Tyvec (spun bound polyethylene). The outer pack is labelled with graft type, unique batch number, expiry date, weight and storage requirements. Irradiation is indicated by the red dot. 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.

Delivery

This product is usually delivered by either NHSBT Transport or via the Royal Mail as special delivery in a padded envelope 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 away from direct sunlight at ambient temperature.

Alternative products

- Femoral Head Fresh Frozen (not cell depleted)
- Femoral Head Fresh Frozen Irradiated (not cell depleted)
- Femoral Head Frozen Washed Irradiated Products
- Ground Bone Products (ready milled)

References:

Title and Authors

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

Development of a bacteriophage model system to investigate virus inactivation methods used in the treatment of bone allografts. C.Bienek, L.MacKay, G.Scott, A.Jones, **R.Lomas, J.N.Kearney**, G.Galea

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

Impaction allografting in revision total hip replacement. Board TN, **Rooney P, Kearney JN**, Kay PR

Validation of Radiation Dose Received by Frozen Unprocessed and Processed Bone during Terminal Sterilisation. **Eagle MJ, Rooney P, Lomas R, Kearney JN.**

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.

Published In:

Nurs Stand. 2006; 21(1):51-6; quiz 58.

Cell Tissue Bank. 2007 [Epub ahead of print]

Cell Tissue Bank. 2006;7(4):259-64.

J Bone Joint Surg Br. 2006; 88(7):852-7.

Cell Tissue Bank. 2005; 6(3):221-30.

Cell Tissue Bank. 2005; 6(3):171-9.

Title and Authors

Clinical effectiveness of processed and unprocessed bone. Galea G, **Kearney J N**

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

Bone Banking in the UK Blood Services, **Fehily Deirdre, Warwick Ruth M, Kearney John**, Galea George

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**

An evaluation of the capacity of differently prepared demineralised bone matrices (DBM) and toxic residuals of ethylene oxide (EtOx) to provoke an inflammatory response in vitro. **Lomas RJ, Gillan HL, Matthews JB, Ingham E, Kearney JN.**

Cadaveric Tissue Supply to the Commercial Sector For Research: Collaboration between NHS Pathology and NBS Tissue Services in the U.K., Extending the Options for Donors. Womack C, Gray NM, **Pearson JE, Fehily D.**

Processing of whole femoral head allografts: a method for improving clinical efficacy and safety. **Lomas R, Drummond O, Kearney JN.**

A UK Survey of Virological Testing of Cadaver Tissue Donors. S.J. Stanworth, **R.M. Warwick**, M. Ferguson, J.A. Barbara

Tissue donation. **Pearson J**

BATB Medical SIG Survey 1996 Selection and Screening of Tissue Donors. HJ Stafford and **Ruth M Warwick**

Safe Tissue Grafts' should achieve the same standards as for blood transfusion **Fehily D, Warwick R**

Sterilisation of human tissue implants. **J N Kearney**

The role of the Blood Transfusion Service in Tissue Banking. **Warwick RM, Eastlund T & Fehily D**

Principles, practice and microbiological implications of bone banking. **Fehily D & Warwick R**

Ethylene oxide sterilisation of allogeneic bone implants. **J N Kearney**, R Bojar, K T Holland

Bone banks. **J N Kearney**

Evaluation of ethylene oxide sterilisation of tissue implants. **J N Kearney**, V C Franklin, V Agurregoicoa

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

Published In:

Transfus Med. 2005; 15(3):165-74.

Organs and Tissues. 2004; (2) 83-88.

Organs and Tissues 2004; (3), 177-182.

Council of Europe 1st edition June 2002. ISBN No: 92 - 875 - 48910 Council of Europe publishing

Biomaterials. 2001; 22(9):913-21.

Cell Tissue Bank. 2001;2(1):51-5.

Cell Tissue Bank. 2000; 1(3):193-200.

Vox Sang. 2000;79(4):227-30.

Nurs Stand. 1999; 13(45):14-15.

BATB News Issue 8 Summer 1997 page 3-4.

BMJ. 1997; 314: 1141-2.

Tissue & Cell Report. 1996; 4 (1): 33-36.

Vox Sanguinis, 1996; 71: 71-77.

PHLS Microbiology Digest. 1995; 12(3): 155-158.

Clin Mater. 1993;12(3):129-35.

BMJ. 1992;304:507-8.

J Hosp Infect. 1989; 13(1):71-80.

Lancet. 1987; 2(8555):402.