

# Shaped Bone Frozen Washed Irradiated Cortical Strut

Product code T0036

## Product description

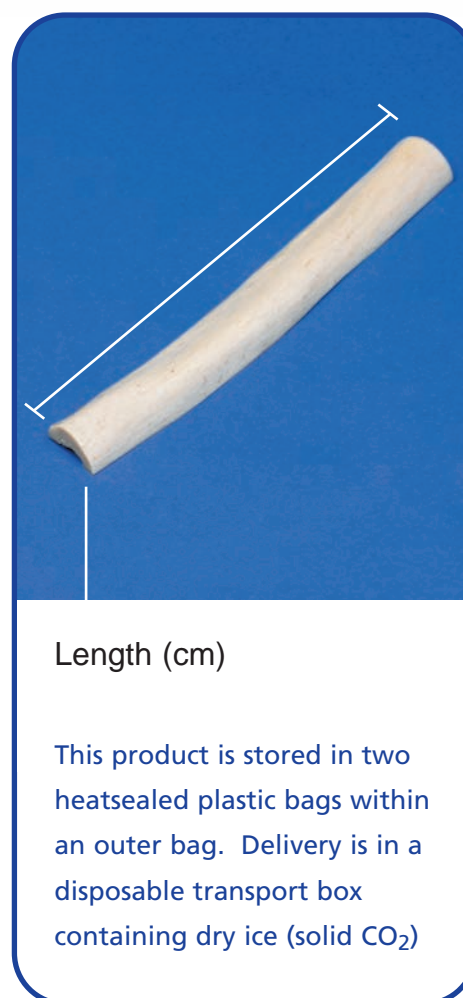
Bone derived from the femoral shaft of a deceased multi-organ donor. Packaged and frozen within 24 hours of donation. Aerobic and anaerobic bacterial and fungal cultures taken and assessed against rejection criteria including pathogenic organisms and gross contaminants. Processed in-house in licensed pharmaceutical grade cleanrooms (minimum GMP classification C) to remove cartilage and soft tissue, cut in half longitudinally to varying lengths of 5-23cm long washed to remove most blood and bone marrow cellular components. Frozen and irradiated to minimum dose 25kGy in the final packaging within dry ice and supplied frozen. Supplied as individual units.

## Clinical applications

For use in orthopaedic surgery, primarily as a structural support in femoral reconstruction surgery. The graft must be thawed at room temperature by the theatre team prior to use.

## 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 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, reducing potential risk.
- Bone quality assessed by highly trained Tissue Services staff.
- Uniform product presentation with minimal variation.
- Flat packed to minimise storage space.
- Non cellular therefore does not require a user storage licence.
- There are no reported cases of this graft supplied by Tissue Services causing patient harm.



Length (cm)

This product is stored in two heatsealed plastic bags within an outer bag. Delivery is in a disposable transport box containing dry ice (solid CO<sub>2</sub>)

# 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 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. 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. 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 low density polyethylene bags compliant to EC Commission Directive 2002/72/EC. 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 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

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 not contain cells therefore will not require a storage licence from the HTA. For further information please visit [www.hta.gov.uk](http://www.hta.gov.uk). The expiry date depends on the freezer (the full shelf life is given if lower than -40°C, the shelf is reduced to 3 months if stored between -20°C and -40°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 24 hours.

## Alternative products

- Shaped Bone Freeze Dried Washed Irradiated Cortical Strut

## 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**

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

### 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.

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

## Title and Authors

*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.

*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 Vanderkallen, **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:

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

*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.