

Shaped Bone Freeze Dried Washed Irradiated Cortical Strut

Product code T0037

Product description

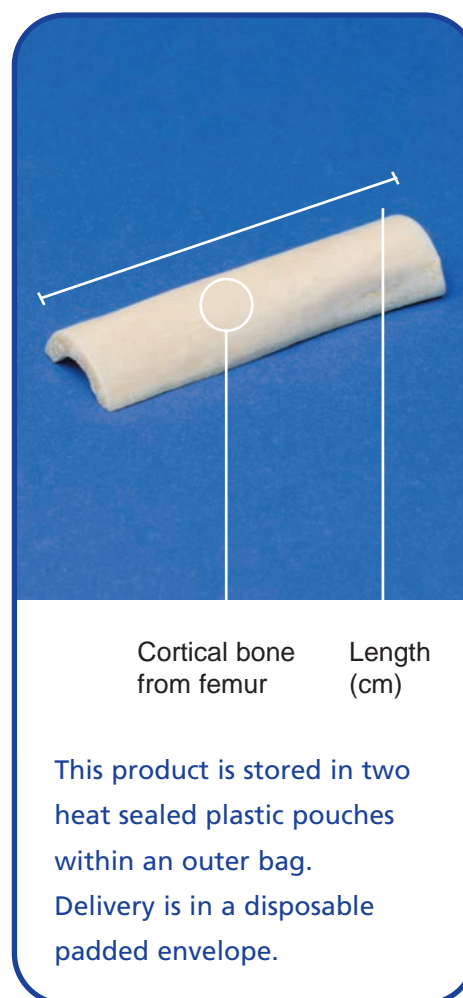
Bone derived from the femoral shaft of a deceased multi-tissue donor. Packaged and frozen within 24 hours of donation. Aerobic and anaerobic bacterial and fungal cultures taken and assessed against rejection criteria including pathogenic organisms and gross contaminants. Processed in-house in licensed pharmaceutical grade cleanrooms (minimum GMP classification C) to remove cartilage and soft tissue, cut in half longitudinally to varying lengths of 5-23cm long 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 as a structural support in femoral reconstruction surgery. The graft must be rehydrated before 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 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, reducing potential risk.
- Bone quality assessed by highly trained Tissue Services staff.
- Uniform product presentation with minimal variation.



- 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 and can be stored at ambient temperature.
- 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

- Shaped Bone Frozen Washed Irradiated Cortical Strut

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