

Tendon Patellar Frozen Irradiated Whole

Product code T0074

Product description

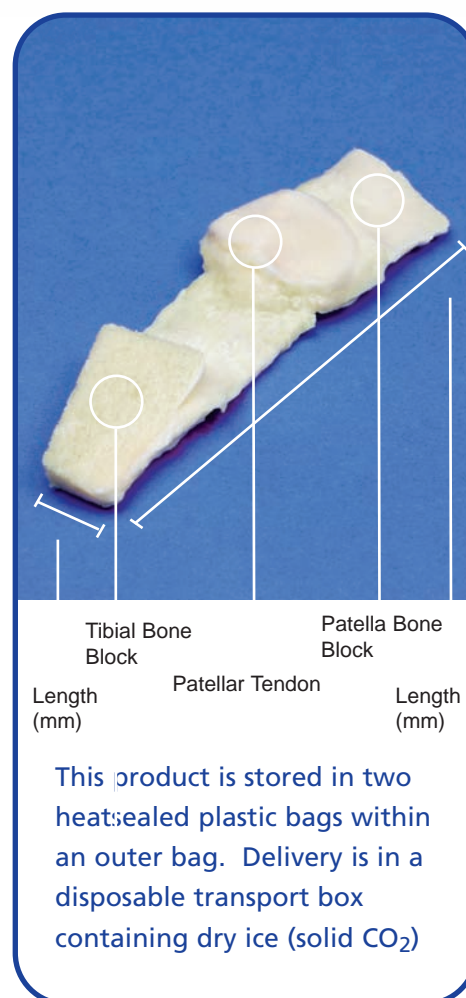
A whole bone-patella tendon-bone graft from a deceased multi-tissue donor. Packaged and frozen within 24 hours of donation. Aerobic and anaerobic bacterial and fungal cultures taken and assessed against rejection criteria including pathogenic organisms and gross contaminants. Processed in house in licensed pharmaceutical grade cleanrooms (minimum GMP classification C) to remove soft tissue, washed to remove traces of blood and bone marrow cellular components. Decontaminated with 70% filter sterilised ethanol and frozen in the final packaging. Irradiated to minimum dose 25kGy in dry ice. Stored at -80°C whilst on site at NHS Blood and Transplant (NHSBT) premises. Supplied as individual units with minimum measurements: tendon width 2cm, bone block width 2cm, length 3cm.

Clinical applications

For use in orthopaedic surgery, primarily knee revision. Usually the graft is thawed by the theatre team prior to implantation.

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 a series of sterile water washes; decontamination with 70% filter sterilised ethanol and irradiation to a minimum dose 25kGy.



- Tendon quality is assessed by highly trained Tissue Services staff. Uniform product presentation with minimal variation.
- Flat packed to minimise storage space.
- There are no reported cases of this graft supplied by Tissue Services causing 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 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 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. 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 which can be used for any feedback. If an adverse event or reaction is suspected, telephone the tissue bank.

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 to 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.

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

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Storage

This graft needs to be stored frozen. Non cellular therefore does not require a user storage license. For further information please visit 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

- Tendon Patellar Frozen Whole
- Tendon Patellar Frozen Irradiated Shaped

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