

Osteochondral Cryopreserved Femoral Condyle

Product codes T0165 & T0167 - T0171,
T0188 - T0196

Product description

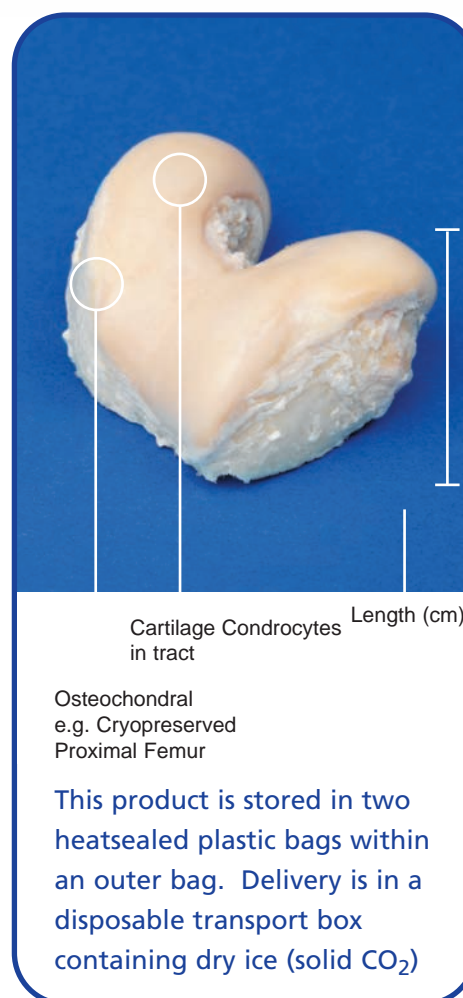
A condyle from a deceased multi-tissue donor. Tibial condyles available on request. The whole knee is retrieved, in a mortuary or dedicated donation suite, by highly trained NHS Blood and Transplant (NHSBT) staff using aseptic procedures. The condyle is isolated from the knee by careful dissection and is processed, packaged, measured/sized and cryopreserved within 48 hours of donation. Aerobic and anaerobic bacterial and fungal cultures are taken and assessed against rejection criteria. The product is processed in-house in licensed pharmaceutical grade cleanrooms (minimum GMP classification B) to remove excess fat and connective tissue, and 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), hydrochloride (0.05g/l), prepared in medium 199 with 25mM HEPES. The bone is measured/sized and cryopreserved in a protectant medium comprising Hanks' Balanced Salt Solution supplemented with 25mM HEPES and 15% (v/v) dimethyl sulphoxide. Stored below -135°C and supplied at -79°C. Supplied as an individual unit. Dimensions taken as per surgical requirements.

Clinical applications

For use in orthopaedic surgery. The bone must be thawed in a 37°C waterbath containing sterile saline before use, after first being brought to a temperature above -80°C to prevent damage.

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 file is reviewed and if appropriate cleared by highly trained clinical staff specialising in tissue donation according to set criteria.
- Pathogen reduction is achieved during processing by treatment with antibiotics. Product quality is assessed by highly trained Tissue Services staff.



- Uniform product presentation with minimal variation.
- This is a cellular product and therefore requires a user storage licence.
- There are no reported cases of patient harm of this type of graft supplied by Tissue Services.

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 standards across all donation programs (blood, tissue and organ), which are written by UK blood services in compliance with MSBTO (advisory committee in the Microbiological Safety of Blood, Tissues and Organs). Many of these standards are above 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 licenses under the HTA (Human Tissue Authority). The services and facilities include pharmaceutical grade cleanrooms which comply with Good Manufacturing Practice. All aspects of the supply chain from staff education to 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 computer using barcodes, 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 -135°C with full audit trail for stock location. Final product release is undertaken as an independent function by specialist NBS Quality Assurance personnel. All activity is regularly reviewed against international best practice with professional links to the British, European and American Tissue Banking Associations.

Labelling and Packaging

Inner and secondary packs are heat-sealed nylon bags (a monomer cast semi-crystalline thermoplastic similar to nylon 6,6) within an outer foil pack of 15 micron oriented nylon laminated to 50 micron modified polyethylene. This is placed within a cardboard box. The outer pack is labelled with graft type, unique batch number, expiry date, surface area and storage requirements. Batch number, product type, status and expiry date are ISBT 128 barcoded. Enclosed within the box used for transporting the bone is a transplant reporting form with a freepost envelope which can be used for 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 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.

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Product codes

T0165 - Osteochondral Cryopreserved Proximal Femur Left

T0167 - Osteochondral Cryopreserved Proximal Femur Right

T0168 - Osteochondral Cryopreserved Distal Femur Left

T0169 - Osteochondral Cryopreserved Distal Femur Right

T0170 - Osteochondral Cryopreserved Proximal Tibia Left

T0171 - Osteochondral Cryopreserved Proximal Tibia Right

T0188 - Osteochondral Cryopreserved Femoral Condyle Left Lateral

T0189 - Osteochondral Cryopreserved Femoral Condyle Right Lateral

T0190 - Osteochondral Cryopreserved Proximal Tibia Left Lateral

T0191 - Osteochondral Cryopreserved Proximal Tibia Right Lateral

T0193 - Osteochondral Cryopreserved Femoral Condyle Left Medial

T0194 - Osteochondral Cryopreserved Femoral Condyle Right Medial

T0195 - Osteochondral Cryopreserved Proximal Tibia Left Medial

T0196 - Osteochondral Cryopreserved Proximal Tibia Right Medial