

Femoral Head Fresh Frozen Irradiated

Product code T0002

Product description

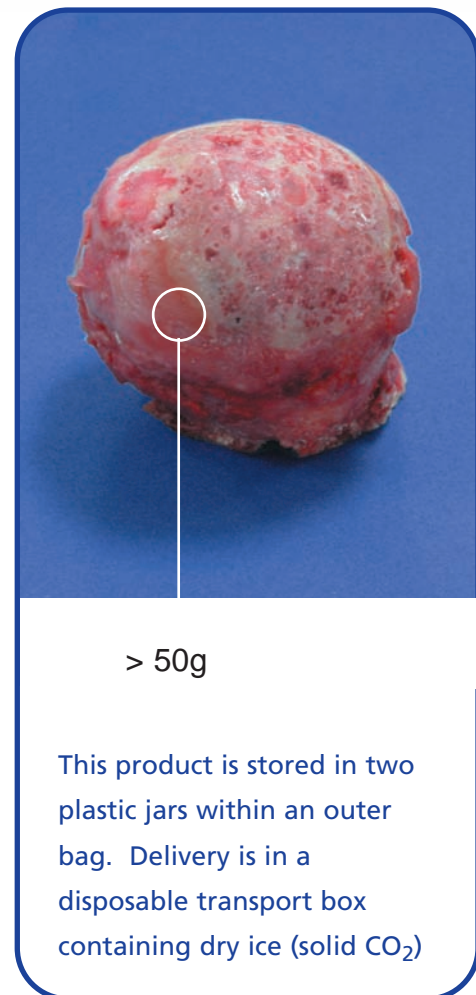
A femoral head from a living donor undergoing a total hip replacement. Packaged and frozen within 24 hours of donation. Chips from the bone taken by the retrieving surgeon are placed into aerobic and anaerobic broths for culture. Irradiated to minimum dose 25kGy in dry ice and supplied frozen. Quarantined for 180 days to retest the donor for serological markers or tested at time of donation by PCR technology for Hepatitis B & C and HIV, in addition to the routine serology. No processing other than irradiation exposure within the collection container is applied. Supplied as individual units, not less than 50g weight. Weight is recorded on the label to enable calculation as to the number of femoral heads (amount of bone) required for a particular patient. Where a specified weight of bone is required, then best efforts will be made to match the required weight from the inventory.

Clinical applications

For use in orthopaedic surgery, primarily hip and knee revision. The graft must be thawed at room temperature by the theatre team prior to use. Usually the graft is milled or further shaped by the theatre team prior to implantation. We recommend the graft is washed prior to implantation to reduce the donor blood and marrow components. Note that as this product contains blood cells, RhD negative women of childbearing potential should only be given RhD negative grafts (please specify on order).

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, quality assurance and supply.
- Aseptic retrieval from a living donor.
- Face to face medical and social history interview.
- The donor is cleared by highly trained clinical staff specialising in tissue donation.
- This product is irradiated to a minimum dose of 25 kGy giving further assurance the product is free of microbial growth.
- There are no reported cases of this graft supplied by Tissue Services causing patient harm.



> 50g

This product is stored in two plastic jars within an outer bag. Delivery is in a disposable transport box containing dry ice (solid CO₂)

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 comply with Good Manufacturing Practice. Hospitals donating femoral heads are carefully selected to ensure quality and continued proficiency. Link nurses undergo detailed training regarding donor consent and selection, and theatre staff are trained in the donation procedure. Donation sites are audited every year. Storage of femoral heads on collection sites is monitored using calibrated dataloggers. Containers and transport boxes are validated in-house by the Tissue Development Laboratory. All microbiology testing is performed by in-house accredited laboratories specialising in donation screening. Final donor assessment and selection is undertaken by in-house senior nurse 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 outer pots are tamper evident 250ml and 500ml Polypropylene jars with High Density Polyethylene lids sterilised prior to supply using ethylene oxide. The outer pot is labelled with graft type, unique donation number, expiry date, weight, RhD status (if tested) and storage requirements. Irradiation is indicated by the red dot. Donation number, product type, status and expiry date are ISBT 128 barcoded. Enclosed within the 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 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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Storage

This graft needs to be stored frozen. This product contains cells therefore if stored beyond 48 hours will require a storage licence from the HTA. 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

- Femoral Head Fresh Frozen (same product but not irradiated)
- Femoral Head Frozen Washed Irradiated Products (cell depleted)
- Femoral Head Freeze Dried Washed Irradiated Products (cell depleted)
- Ground Bone Products (cell depleted and ready milled)

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