

# Blood Vessel Cryopreserved Superficial Femoral Artery

Product code T070

## Product description

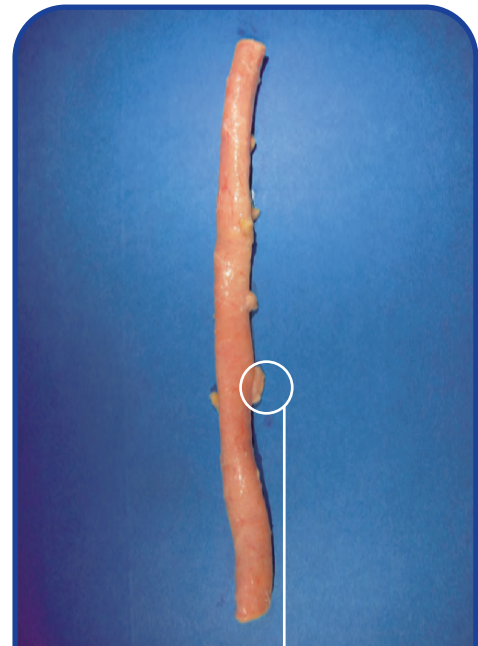
A superficial femoral artery from a deceased donor. The femoral vascular bundle is retrieved by appropriately trained NHS Blood and Transplant (NHSBT) staff using aseptic procedures in a mortuary. The superficial femoral artery is carefully dissected from the vascular bundle and is decontaminated, measured/sized, packaged and cryopreserved within 48 hours of donation. Aerobic and anaerobic bacterial and fungal cultures are taken both pre- and post decontamination and assessed against rejection criteria including pathogenic organisms and gross contaminants. The grafts are processed in-house in licensed pharmaceutical grade cleanrooms (minimum GMP classification B) to remove excess fatty and connective tissue. The vessel is washed in isotonic buffered saline 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), nystatin ( $2.5 \times 10^6$  U/l), polymyxin B sulphate (0.2g/l), and vancomycin hydrochloride (0.05g/l), prepared in medium 199 supplemented with 25mM HEPES buffer. The vessel is measured and sized, and cryopreserved in a protectant medium comprising Hanks' Balanced Salt Solution supplemented with 25mM HEPES and 15% (v/v) dimethyl sulphoxide. The grafts are stored below  $-135^{\circ}\text{C}$ , and supplied on dry ice at  $-79^{\circ}\text{C}$  as individual units of specified size.

## Clinical applications

For use in vascular surgery. The vessel must be thawed in a  $37^{\circ}\text{C}$  waterbath containing sterile saline before use, after first being brought to a temperature above  $-80^{\circ}\text{C}$  (where necessary) to prevent vessel damage.

## 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 retrieval.
- The donor is cleared by highly trained clinical staff specialising in tissue donation.
- Pathogen reduction is achieved during processing by treatment with antibiotics.
- Vessel quality is assessed by highly trained Tissue Services staff.
- Product presentation is uniform with minimal variation.
- This is a cellular product and therefore requires a user storage license if stored for longer than 48 hours.
- There are no reported cases of this type of graft supplied by Tissue Services causing patient harm.



Superficial femoral artery graft, ready for disinfection and cryopreservation. The artery has been dissected from the vascular bundle and adherent soft tissue removed, ensuring that at least 5mm of each small branching artery remains.

# 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 expertise 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 for Tissue Banks scheme 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, retrieval, 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 a 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  $<-135^{\circ}\text{C}$  with full audit trail for stock location. The release process is independently reviewed. 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

The grafts are packed in inner and outer pouches consisting of an amber coloured translucent Teflon-Kapton material. This material is validated to retain its integrity at very low temperatures. Inner and outer pouches are heat-sealed following packaging. Prior to despatch, the pack is vacuum sealed within a plastic bag containing a product label stating the graft type, overall length, unique batch number, expiry date and storage requirements, and a user information document. 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 to ensure appropriate follow up and reporting.

## Delivery

This product is usually delivered by same day courier direct to the point of use e.g. theatre. Delivery is included in the product price. 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 and will therefore require a storage licence from the HTA if stored for longer than 48 hours. For further information please visit [www.hta.gov.uk](http://www.hta.gov.uk). The graft may be stored at -80°C until the expiry date stated on the product label. This can be accomplished by maintaining the graft in dry ice, or transferring to an appropriate low temperature freezer. The product must not be returned to storage at or below -135°C or the tissue may crack when thawed.

## Alternative products

None

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