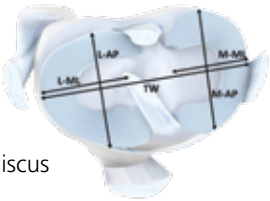
NHS
Blood and Transplant

Tissue Services

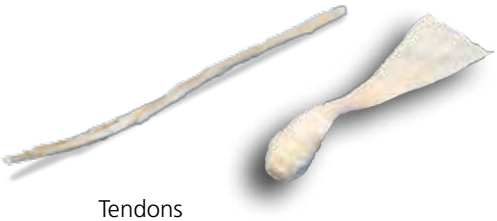
For all your allograft requirements

Product Brochure



Meniscus

Demineralised Bone Matrix


Tendons


Arteries


Heart valves


Processed and Unprocessed bone

Contents

Introduction

This brochure provides information on NHS Blood and Transplant (NHSBT) Tissue Services, and the allografts and services we provide.

Technical details of the range of orthopaedic, burns, cardiovascular and amnion tissue allografts available from NHSBT Tissue Services are provided along with technical information on the correct storage and handling to facilitate the appropriate use of these grafts.

Why you should come to us first:

- Ethically sourced from UK donors
- From the NHS for the NHS
- Use with confidence – a specialist service
- Provided direct from the NHS's own Tissue Service
- Largest Tissue Bank in the UK
- Cost effective.

Who are we?

NHSBT is a Special Health Authority. We were established in 2005 to take over the responsibilities of the National Blood Service (NBS) and UK Transplant. We manage the national voluntary donation system for blood, tissue, organs and stem cells, turning these precious donations into grafts that can be used safely for the benefit of the patient.

Our role is to co-ordinate, recover, process, bank and supply human tissue grafts for use in surgery within the NHS and independent UK hospitals. As part of the NHS we operate as a not-for-profit organisation with patient safety at our core.

Because we are part of the NHS we have access to the vast knowledge and experience available including research, clinical expertise and quality systems providing a strong foundation for maintaining our high standards in tissue banking.

What do we do?

We provide safe and effective allografts for use in grafting/ transplantation and are the UK's major provider of human tissue for transplant.

We bank and supply tissue grafts from around 400 deceased tissue donors per year and respond on a 24 hour basis to over 4,000 donor referrals.

We manage one of the largest tissue banks in Europe with continuous experience of tissue banking of almost 60 years.

Every effort is made to ensure the safety and efficacy of our allografts, and by operating through a cost recovery model we are able to supply high quality, cost effective tissue grafts for the benefit of patients.

Our Facilities

In 2005 we moved in to the first purpose built state of the art facility for tissue donation in the UK based in Liverpool. The facility provides a base for the largest tissue bank in the UK, and is staffed by highly trained, dedicated doctors, scientists, technicians, nurses and support staff.

The facility is a major step forward in donation of tissue, allowing the donation process to be undertaken in a facility which reduces the risk of contamination. Our clean rooms are continually monitored as a part of the NHSBT Tissue Services Quality Management System.

All processed tissues are banked in temperature controlled storage facilities either at room temperature, deep frozen or cryopreserved dependant on the product requirements.

Tissue bank facility in Liverpool

Research

We are the only UK tissue bank with a dedicated research and development team and a purpose built Tissue Development Laboratory. We are constantly working to improve processes and products and to develop new innovative procedures and therapies.

Including:

- Development of advanced washing procedures to reduce disease transmission and aid tissue incorporation
- Tissue engineering to develop grafts which can grow with the patient
- Improved disinfection/sterilisation procedures
- Novel and improved methods for preserving tissues.

Our unique access to fully consented human tissue allows us to use the tissues to improve grafts and graft processes and also allows us to provide the scientific and clinical community with access to human tissue for ethically approved research through our research tissue bank – NHSBT Tissues for Research.

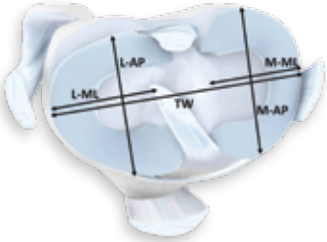
For further information or to place an order please contact us by email: NHSBT.TissuesforResearch@nhsbt.nhs.uk

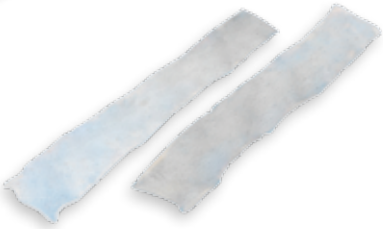
Our Tissue

We control the whole clinical pathway of tissue in the UK from initial donor referral by the National Referral Centre (NRC) through to the issue of the tissue to clinicians across the UK.

Our unique service allows us to offer a wide range of tissue for grafting or transplantation in various specialities including:

- Orthopaedic
- Burns
- Cardiovascular
- Ocular
- Wound Care.





National Referral Centre (NRC)

The National Referral Centre (NRC) based at the facility is the primary source for deceased tissue donation in England, Wales and Northern Ireland. The NRC is nurse led and managed by specially trained senior nurses and nurse practitioners.

The NRC is responsible for taking referrals from hospitals, hospices and the wider community, seeking clinical information, assessing the suitability of each case for donation and discussing options with the donor family and gaining consent.

It operates under the Nursing and Midwifery Council Code of Conduct and is professionally accountable for its activity and hold a duty of care to all clients. The NRC is governed by the Human Tissue Act 2004 ensuring robust practices are in place regarding consent and conduct.

In 2012-13 the NRC received 6,500 referrals for donation and facilitated 1,814 eye donations and 496 multi-tissue donations to improve the lives of thousands of NHS patients.

For advice and information regarding tissue donation please contact our national pager on 0800 4320559.

National Referral Centre in Liverpool

Quality

We work within a highly regulated environment of blood centres and operate the same quality system. The system ensures traceability of tissues from donor to hospital with the highest standard of virology and bacteriology testing complying with the EU Regulations and Guidance on Microbiological Safety of Human Organs, Tissue and Cells used in Transplantation. The facility follows the principles of Good Manufacturing Practice.

We comply with all relevant UK national and European legislation relating to tissue banking. NHSBT is licenced by the Human Tissue Authority (Licence No: 11018) to procure, test, process, store and distribute human tissues for clinical application under the Human Tissue Act. We meet and exceed the European Cell & Tissue Directive requirements for selection and testing of donors and processing of tissue. We are licenced by the Medicines and Healthcare Regulatory Authority (Licence No: MS25224) covering the manufacture of more specialised blood and tissue based products.

Clinical Pathway Management

We control the whole tissue 'clinical pathway' with responsibility for the tissue from identification and screening of donors through to final issue to the clinician, including tissue retrieval, processing and banking. We do not rely on third parties for the performance of any of these critical steps. All stages are carried out by our own retrieval teams and production staff to ensure compliance with regulations, and to guarantee high safety and quality standards throughout the process thus minimising risk to patients.

Safety

NHSBT Tissue Services are committed to providing safe and effective tissue grafts and work within a highly regulated environment. We are committed to supplying high quality and safe products.

NHSBT are licenced by the Human Tissue Authority under the Human Tissue Act 2004, Human Tissue (Scotland) Act 2006 and the associated Codes of Practice.

All donations are subject to microbiological and bacteriological screening. The bacteriological screening for contamination with bacteria and fungi is undertaken independently from the tissue bank.

We operate a quality system based on the principles of Good Manufacturing Practice (GMP). All tissue provided by NHSBT is subject to independent Quality Assurance release with all batch records checked by a Tissue Bank Manager and an independent Quality Assurance Manager to ensure that all tissues are safe and efficacious.

Our quality system is regularly reviewed and updated to ensure best practice is followed and ensure that we remain compliant with all relevant regulations and authorities.

Screening of Donations and Donor Selection

Tissue donors are rigorously screened for their suitability to donate by specially trained nurses working for NHSBT, against nationally agreed criteria determined by specialist Department of Health committees. All staff undertaking consent and donor selection do so only after completing a thorough training programme and successful assessment of competence. This ensures that tissues that may be unsafe or unsuitable for transplantation are not donated, and in practice less than 10% of potential donors actually meet the criteria for donation. All donors accepted for donation are also screened for transmissible diseases (Table 1 below), using both traditional serology testing and more sensitive genomic nucleic acid testing.

Table 1 – Transmissible diseases that tissue donors are screened for:

Human Immunodeficiency Virus types 1 & 2
Hepatitis B
Hepatitis C
Syphilis
Human T-cell Lymphotropic Virus

Donated tissues are retrieved from donors by our own Retrieval Teams using surgical procedures and strict aseptic technique to reduce any risk of contamination. They are then transported immediately to our central tissue bank for storage or further processing.

Most tissue grafts are processed, either to make them:

- More effective – through, for example, the removal of donor cells that could provoke an immunological response in the recipient
- Safer – through disinfection or sterilisation
- More amenable for surgical use, for example, pre-dissection and shaping to the size required for implantation.

vCJD statement

NHSBT undertakes full donor screening for every donor. Donors who are at high risk of infectious diseases eg HIV, Hepatitis or vCJD are not eligible for donation.

NHSBT is undertaking a feasibility study testing deceased tissue donors for vCJD using the spleen and optic nerve. It is the first study of its kind in the world.

For further details please contact your regional Tissue Services Specialist. (See page 36 for contact details.)

Processing of Donations

In addition to the transmissible diseases listed in Table 1 (on page 12), the bacteriological and mycological status of donated tissues are assessed both before and after processing to ensure no infection can be transmitted from the donor to the recipient.

We process all donated tissue in GMP grade cleanrooms which undergo regular validations including particle counts, room recovery rates and HEPA filter integrity tests. The cleanrooms are subject to continuous monitoring.

Clean room

Dedicated donation facility

Full Product Range

Orthopaedic

Femoral Heads	Description	Product Code
Fresh, Frozen	• Whole femoral head from our living donor program • Unprocessed • Available in two sizes: >50g in weight and <50g in weight (small) • Stored frozen	**TP1001 (Large) >50g** **TP1002 (Small) <50g** 
Fresh, Frozen, Irradiated	• Whole femoral head from our living donor program • Unprocessed and >50g in weight • Terminal sterilisation achieves SAL 10-06 • Stored frozen	**TP1003** 
Frozen, Washed, Irradiated, Whole	• Whole femoral head from a deceased donor • Processed in cleanrooms to remove soft tissue, blood and marrow • Supplied as individual units weighing approx 40g • Stored frozen	**TP1004** 
Frozen, Washed, Irradiated, Half	• Half a femoral head from a deceased donor • Processed in cleanrooms to remove soft tissue, blood and marrow • Supplied as individual units weighing approx 20g • Stored frozen	**TP1005** 
Freeze Dried, Washed, Irradiated, Whole	• Whole femoral head from a deceased donor • Processed in cleanrooms to remove soft tissue, blood and marrow • Supplied as individual units weighing at least 40g • Stored away from sunlight, does not require specific storage • Keep at room temperature	**TP1006** 

Femoral Heads	Description	Product Code
Freeze Dried, Washed, Irradiated, Half	• Half a femoral head from a deceased donor • Processed in cleanrooms to remove soft tissue, blood and marrow • Supplied as individual units weighing at least 20g • Stored away from sunlight, does not require specific storage • Keep at room temperature	**TP1007** 
Freeze Dried, Washed, Irradiated, Slice	• 6mm slice of femoral head from a deceased donor • Processed in cleanrooms to remove soft tissue, blood and marrow • Supplied as individual units • Stored away from sunlight, does not require specific storage • Keep at room temperature	**TP1008** 

Cortical Strut	Description	Product Code
Cortical Strut	• Derived from the femoral shaft of a deceased donor • Processed in cleanrooms to remove soft tissue, cut in half longitudinally • Washed to remove blood and marrow • Supplied as individual units • Stored frozen or if freeze dried keep at room temperature	
Frozen, Washed, Irradiated, (Small 15cm)		**TP2001**
Frozen, Washed, Irradiated, (Medium 19cm)		**TP2001**
Frozen, Washed, Irradiated, (Large 24cm)		**TP2001**
Freeze, Dried, Washed, Irradiated, (Small 15cm)		**TP2002**
Freeze, Dried, Washed, Irradiated, (Medium 19cm)		**TP2002**
Freeze, Dried, Washed, Irradiated, (Large 24cm)		**TP2002**

Cubes, Chips, Wedge, Humeral Shaft, Humeral Head	Description	Product Code
Freeze Dried, Washed, Irradiated, Cancellous Cubes 10 x 10 x 10mm	• Derived from the cortical and cancellous bone from deceased donors • Processed in cleanrooms to remove soft tissue, cut to 10 x 10 x 10mm • Washed to remove blood and marrow • Supplied as units of 5 cubes per pack • Stored away from sunlight, does not require specific storage • Keep at room temperature	TP2003 
Freeze Dried, Washed, Irradiated, Cancellous Chips 6 x 6 x 30mm	• Derived from the cortical and cancellous bone from deceased donors • Processed in cleanrooms to remove soft tissue, cut to 6 x 6 x 30mm • Washed to remove blood and marrow • Supplied as units of 5 chips per pack • Stored away from sunlight, does not require specific storage • Keep at room temperature	TP2005 
Freeze Dried, Washed, Irradiated, Tricortical, Wedge 30 x 15mm	• Derived from the cortical and cancellous bone of the iliac crest from a deceased donor • Processed in cleanrooms to remove soft tissue, cut to 30 x 15mm • Washed to remove blood and marrow • Supplied as individual units • Stored away from sunlight, does not require specific storage • Keep at room temperature	TP2006 
Frozen, Washed, Irradiated, Humeral Shaft	• Soft tissue removed • Processed in cleanrooms to remove blood and marrow • Supplied as individual units • Stored frozen	TP2007 
Frozen, Washed, Irradiated, Humeral Head	• Whole humeral head from a deceased donor • Processed in cleanrooms to remove soft tissue, blood and marrow • Supplied as individual units • Stored frozen	TP2008 

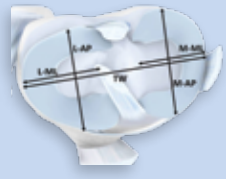
Cancellous/ Cortical Grafts	Description	Product Code
Cancellous/ Cortical	• Derived from the cortical and cancellous bone from deceased donors • Processed in cleanrooms to remove soft tissue, cut and ground to the following particle sizes: – Coarse >4mm – Medium <4mm – Fine <2mm • Stored away from sunlight, does not require specific storage • Stored frozen or if freeze dried keep at room temperature	
Frozen, Irradiated, Ground Mix – 35cc		**TP3001**
Frozen, Irradiated, Ground Mix – 70cc		**TP3002**
Freeze Dried, Washed, Irradiated, Coarse – 15cc		**TP3003**
Freeze Dried, Washed, Irradiated, Coarse – 35cc		**TP3004**
Freeze Dried, Washed, Irradiated, Medium – 15cc		**TP3005**
Freeze Dried, Washed, Irradiated, Medium – 35cc		**TP3006**
Freeze Dried, Washed, Irradiated, Fine – 15cc		**TP3007**
Freeze Dried, Washed, Irradiated, Fine – 35cc		**TP3008**

Cryopreserved Osteochondral Grafts	Description	Product Code
Cryopreserved Osteochondral	• Processed in cleanrooms to dissect away surplus tissue, decontaminated with antibiotics and sized with sterile instruments • Supplied as an individual unit of a specified size • Issued at –80°C and must not be returned to storage at or below –135°C	
Whole Patella		**TP4001**
Femoral Condyle, Left Lateral		**TP4008**
Femoral Condyle, Right Lateral		**TP4009**
Proximal Tibia, Left Lateral		**TP4010**
Proximal Tibia, Right Lateral		**TP4011**
Femoral Condyle, Left Medial		**TP4012**
Femoral Condyle, Right Medial		**TP4013**
Proximal Tibia, Left Medial		**TP4014**
Proximal Tibia, Right Medial		**TP4015**

Massive Allografts	Description	Product Code
Massive Allograft	• Prepared with articular cartilage and soft tissue removed • Processed in cleanrooms to remove blood and marrow • Supplied as individual units • Stored frozen	
Frozen, Washed, Irradiated, Hemi Pelvis		TP2010
Frozen, Washed, Irradiated, Proximal Femur Right		TP4002
Frozen, Washed, Irradiated, Proximal Femur Left		TP4003
Frozen, Washed, Irradiated, Distal Femur Left		TP4004
Frozen, Washed, Irradiated, Distal Femur Right		TP4005
Frozen, Washed, Irradiated, Proximal Tibia Left		TP4006
Frozen, Washed, Irradiated, Proximal Tibia Right		TP4007
Frozen, Washed, Irradiated, Proximal Humerus Left		TP4019
Frozen, Washed, Irradiated, Proximal Humerus Right		TP4020

Demineralised Bone Matrix (DBM)	Description	Product Code
DBM Putty	• Prepared from cortical bone derived from long bones from a deceased donor • Processed in cleanrooms to remove soft tissue and marrow components and ground into a finer powder • Prepared by mixing DBM powder with glycerol in the ratio 65% DBM to 35% glycerol (v/v) • The mixture has a solid consistency and can be moulded into shape • Available in pots and blunt ended syringe • Stored away from sunlight does not require specific storage • Keep at room temperature	 
Putty 1cc		TP5009
Putty 5cc		TP5010
Putty 10cc		TP5011

Demineralised Bone Matrix (DBM)	Description	Product Code
DBM Paste	• Prepared from cortical bone derived from long bones from a deceased donor • Processed in cleanrooms to remove soft tissue and marrow components and ground into a finer powder • DBM powder is mixed with glycerol in the ratio 55% DBM to 45% glycerol (v/v) • The mixture has a fluid consistency • Available in blunt ended syringe • Stored away from sunlight does not require specific storage • Keep at room temperature	
Paste 1cc		**TP5012**
Paste 5cc		**TP5013**
Paste 10cc		**TP5014**
DBM Powder	• Prepared from cortical bone derived from long bones from a deceased donor • Processed in cleanrooms to remove soft tissue and marrow components and ground into a finer powder • Provided with a particulate size range of 250 to 710μm. Can be mixed with patient's blood or bone marrow. • Available in pack size of 1cc • Stored away from sunlight does not require specific storage • Keep at room temperature	**TP5015** 
DBM Cubes	• Product available 2014	

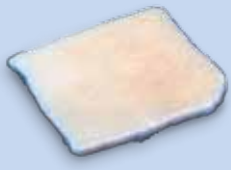
Tendons and Meniscus	Description	Product Code
Frozen, Whole	• From a deceased donor • Processed in cleanrooms to remove soft tissue, washed to remove blood and marrow and decontaminated with 70% filter sterilised ethanol • Supplied as individual units • Stored frozen **All tendons available either decontaminated or irradiated. Please specify at time of order.**	
Achilles, with bone block (>16cm)		**TP6001**
Achilles, with bone block (<16cm)		**TP6019**
Patellar, with bone block		**TP6002**
Patellar, with pre-shaped bone block		**TP6003**
Semi-Tendinosus Long (>27cm)		**TP6004**
Semi-Tendinosus Medium (20 to 27cm)		**TP6005**
Semi-Tendinosus Short (<20cm)		**TP6006**
Tibialis Anterior, Long (>35cm)		**TP6020**
Tibialis Anterior, Medium (30 to 35cm)		**TP6021**
Tibialis Anterior, Short (<30cm)		**TP6022**
Extensor Mechanism, Custom		**TP6015**
Meniscus Cryopreserved	• From a deceased donor attached to a tibial block • Processed in cleanrooms to dissect away surplus tissue, decontaminated with antibiotics and measured/sized with sterile instruments • Supplied as individual units of a specific size • Issued at –80°C and must not be returned to storage at or below –135°C, as this would risk tissue damage	
Whole, Custom		**TP6016**
Medial		**TP6017**
Lateral		**TP6018**

Cardiovascular

Cryopreserved	Description	Product Code
Cryopreserved	• From a deceased donor • Processed in cleanrooms to dissect away surplus tissue, decontaminated with antibiotics and measured/sized with sterile instruments • Packaged in sterile pouches and cryopreserved • Supplied as an individual unit • Stored frozen	
Aortic Valve		**TP7001**
Pulmonary Valve		**TP7002**
Non-Valved Aortic Conduit		**TP7003**
Non-Valved Pulmonary Conduit		**TP7004**
Superficial Femoral Artery (per cm)		**TP7005**
Pericardium Patch	• From a deceased donor • Processed in cleanrooms to dissect away surplus tissue, decontaminated with antibiotics and measured/sized with sterile instruments • Packaged in sterile pouches and cryopreserved • Supplied as individual units • Stored on a nitrocellulose paper in a sterile bijou containing a freezing solution	
Small		**TP7006**
Medium		**TP7007**
Large		**TP7008**
Pericardium (cryopreserved)		**TP7010**

Skin

Split Skin	Description	Product Code
Cryopreserved Split Skin, Large Pack (min 330cm^2)	• Skin allografts produced from a deceased donor • Processed in cleanrooms using antibiotic treatments to reduce microbial contamination and a solution to protect the graft when it is frozen • Supplied as individual units of different surface areas, minimum 330cm^2 • Stored frozen • Available as a large pack	**TP8001** 
Irradiated Split Skin, Large Pack (min 330cm^2)	• Skin allograft produced from a deceased donor • Processed in cleanrooms using antibiotic treatments to reduce microbial contamination and a solution to protect the graft when frozen • Frozen and irradiated in the final pack • Supplied as individual units of different surface areas, minimum 330cm^2 • Available as a large pack	**TP8003** 

dCELL® Human Dermis	Description	Product Code
dCELL® Human Dermis	• Decellularised Dermis allografts produced from a deceased donor • Processed to remove donor cells and cell remnants in cleanrooms to reduce microbial contamination • Irradiated in final pack • Supplied as individual units of defined surface areas • Stored at room temperature	
dCELL® Human Dermis 1, Small (3 x 3cm)		**TP8006**
dCELL® Human Dermis 2, Medium (5 x 5cm)		**TP8007**
dCELL® Human Dermis 3, Large (5 x 10cm)		**TP8008**

Amnion

Amniotic Membrane	Description	Product Code
Frozen	• Amniotic membrane of placentas from elective caesarean section deliveries • Decontaminated using an antibiotic cocktail and frozen in 50% glycerol/ Hanks solution • Supplied as individual units • Stored on a nitrocellulose paper in a sterile bijou containing a freezing solution	
2 x 2cm		**TP9001**
3 x 3cm		**TP9002**
5 x 5cm		**TP9003**

Demineralised Bone Matrix (DBM)

Demineralised bone is prepared by exposing bone to dilute acid. This gradually dissolves the mineral component of the bone, exposing its protein scaffold.

Why does it work?

The protein scaffold of bone is comprised primarily of collagen, with a small quantity of non-collagenous proteins. These include a group of powerful growth factors called Bone Morphogenic Proteins (BMPs). BMPs are capable of inducing the formation of new bone by influencing the migration and differentiation of stem cells into bone forming cells. They are thought to originate during osteogenesis, and subsequently become incorporated into the mineralising matrix of new bone. The combination of an osteoconductive scaffold and osteoinductive growth is very effective in inducing the formation of new bone.

DBM Paste

This is prepared by mixing DBM powder with glycerol (55% DBM to 45% glycerol v/v). This mixture has a fluid consistency. Available in 1, 5 and 10cc blunt ended syringe.

DBM Putty

This is prepared by mixing DBM powder with glycerol (65% DBM to 35% glycerol v/v). This mixture has solid consistency and can be moulded into shape. Available in 1, 5 and 10cc pot or blunt ended syringe.

Clinical Applications of DBM

DBM has a long history of successful clinical use in applications where bone regeneration is needed.

These include:

- Oral and maxillofacial
- Spine
- Trauma
- Joint replacement
- Tumour repair.

Indications

DBM is indicated for the filling of gaps in bone, or for bone surface augmentation in non-weight bearing sites.

Supply and Storage

All DBM grafts supplied by NHSBT Tissue Services can be stored at room temperature until the expiry date shown on the label. Under the terms of the Human Tissue Act, DBM grafts are not considered to be 'relevant materials' and therefore a licence to permit storage is not required.

Product Datasheets

Tissue Risks

All biological tissue and tissue of human origin carries some risk of disease transmission. Tests which can be performed on a blood sample from tissue donors for transmissible agents can reduce the risk of infection and current testing for transmissible agents is described below. **There is at present no testing available for vCJD infectivity nor any means of treatment. Although the risk of vCJD transmission by tissues is thought to be very low, it must be considered when implanting human tissue.** There are well documented cases of transmission of vCJD in blood components. Tissues containing significant quantities of blood/marrow (eg marrow-containing allografts that have not undergone a validated blood cell depletion protocol) **may** therefore pose a higher risk than other tissues. The risk of transmission of infectious diseases by allogeneic human tissue, including the risk of vCJD infection, should be discussed fully with the patient before surgery. Tissue should only be used for life saving or significant life enhancing improvement.

Donor Exposure

It is recommended that the number of donors' tissue transplanted to each patient is minimised. Therefore, if more than one pack of tissue is required for a patient, the same batch number (barcode top left) should be allocated where possible. NB each batch comes from a single donor.

Frozen Surgical Allografts

It is a contraindication to use non-RhD-grouped FFH in Rh D neg women of child bearing potential.

Preparation

This tissue has been collected aseptically under standard operating theatre conditions from a donor who has met the Tissue Services donor selection criteria.

Testing

The blood sample may also have been tested for NAT, HIV, HCV and HBV. For non-irradiated tissue, samples taken at retrieval for microbiological culture showed no growth.

Packaging

Femoral Heads are stored in a double container system. Please inspect the outer packaging before storage. The tissue must not be used if the security seal has been broken or the container has been damaged. If the seal/pack is damaged please contact Customer Care immediately and return the bone marked 'NOT FOR CLINICAL USE'. Only the inner pot is sterile on both the inner and outer surfaces.

Frozen Irradiated Allografts

Preparation

These allografts have undergone a procedure which includes washes with hydrogen peroxide and ethanol and have been irradiated to a minimum of 25kGy in its frozen state and confirmed with a red irradiation indicator.

Testing

Additional tests for Hepatitis B, core antibody. The blood sample may also be tested for NAT, HIV, HCV and HBV.

Packaging

This allograft is packaged in two inner packs with an outer plastic waterproof pack. Only the innermost pack is sterile on the inner and outer surfaces. Please note the allograft must not be used if the inner seals have split or the pack has been damaged. If the seal/pack is damaged please contact Customer Care.

Frozen Irradiated Skin Allografts

Preparation

This skin has been decontaminated with an antibiotic cocktail containing Nystatin, Polymyxin B, Vancomycin, Imipenem (plus Cilastatin) and Gentamycin. It has then been terminally sterilised in the frozen state by application of a 25-40kGy dose of gamma irradiation. The skin is spread dermal side down onto a gauze strip and is cryopreserved in Hank's Balanced Salt Solution with HEPES and glycerol.

Testing

This tissue is prepared from donors who have met NHSBT donor selection guidelines including microbiological screening tests for markers of transmissible diseases as per 'Guidance on the Microbiological Safety of Human Organs, Tissues and Cells used in Transplantation' (MSBT) and the Guidelines for the Blood Transfusion Services in the UK (Red Book). This includes testing for HIV 1/2, Hepatitis B surface antigen, HCV antibody and syphilis.

Packaging

The allograft is packaged in a sterile nylon pouch inside a sterile foil pouch within an outer plastic waterproof pack. This is packaged in an outer protective cardboard box. Both surfaces of the inner nylon pouch and the inner surface of the outer foil pouch are sterile. The tissue must not be used if the inner seals have split or the pack has been damaged. If the seal/pack is damaged please contact Customer Care.

Tissue Storage Requirements for Hospitals

Frozen Tissue

Hospital Storage Facilities	Time
–20°C	Six months
–40°C	Five years from date of donation
–80°C	Five years from date of donation

NB: Frozen Amnion to be stored at –40°C or below and for two years from date of donation.

Cryopreserved Tissue

Hospital Storage Facilities	Time
–20°C	n/a
–40°C	n/a
–80°C	Six months

Freeze Dried Tissue

Hospital Storage Facilities	Time
Room temperature	Five years from date of donation

If the hospital has no storage licence or appropriate freezer or storage facilities for the type of tissue being stored then the following applies:

Product Group	Storage Instructions
Meniscus, heart valves, cryopreserved skin, arteries	Must be used within one hour once thawed
Tendons, frozen bone, fresh frozen femoral heads, amnion and irradiated skin	Can be kept in a clinical refrigerator at 2°C to 8°C for 24 hours once thawed

Freezer storage nitrogen vessels

Starter Pack

We offer Starter Packs which are a selection of our Demineralised Bone Matrix (DBM) and Freeze Dried Ground Bone and Shaped Cancellous Chips or Cubes.

The contents of the Starter Packs can be tailored to your specific requirements and your Tissue Product Specialist will be able to advise. Details of the Tissue Product Specialists can be found in the Contacts section at the end of the brochure.

The Starter Packs will be subject to regular audits and you will only be charged for the tissue which is used. It is a cost effective way for you to try our Allografts and choose which products are most appropriate for you.

Returns

NHSBT Tissue Services offer a returns service for Femoral Heads and Tendons. This service provides an option of ordering a returnable Femoral Head or Tendon Allograft. Should this tissue not be used, it can be returned and the cost of the tissue will not be charged.

The tissue is packed individually in a validated 48 hour transport box to ensure the tissue remains within a temperature controlled environment.

If the tissue is returned this will only incur a nominal restocking fee and courier fee including dispatch and return.

This means that:

- Donated tissue is not discarded
- The Trust saves money – if it is not used it can be returned
- Each returnable Allograft is packed separately in a validated sealed transport box.

Contacts

If you would like to order or require further information on any of the tissue products in this brochure please contact us:

Customer Care (ordering and queries):
Our dedicated Customer Care team is available from 08.00 to 18.00 Monday to Friday and there is also an on-call facility to advise and assist with your requirements. NHSBT Tissue Services provides an out-of-hours service to give assistance 24 hours a day, 365 days a year.

Telephone: **0845 607 6820**
Email: **tscustserv@nhsbt.nhs.uk**

Contact our regional Tissue Services Specialists:
South: Christine Chikurunhe – **07718 155 273**
Christine.Chikurunhe@nhsbt.nhs.uk
Midlands: Donna Jefferies – **07894 392510**
Donna.Jefferies@nhsbt.nhs.uk
North: Kay Thind – **07889 304400**
Kay.Thind@nhsbt.nhs.uk

Head of Business Development and Customer Relations:
Christine Smith – **07889 304404**
Christine.Smith4@nhsbt.nhs.uk

National Referral Centre
Pager: **0800 4320559**

Tissue Donation Programme:
tissuedonation@nhsbt.nhs.uk

Visit our website: **www.nhsbt.nhs.uk/tissueservices**

Additional Information

Questions to ask your Supplier

- Does your Tissue Bank use third parties to collect tissue on their behalf or do they employ their own retrieval teams?
- Are your products inspected and released by an independent Quality Assurance department?
- Do you process your tissues in a GMP environment?
- How can you assure me that the tissue you use for grafts has been obtained from donors with lawful consent?

Why you should come to NHSBT Tissue Services first:

- Ethically sourced from UK donors
- From the NHS for the NHS
- Use with confidence – a specialist service
- Provided direct from the NHS's own Tissue Service
- Largest Tissue Bank in the UK
- Cost effective.

Notes

NHS Blood and Transplant

NHS Blood and Transplant (NHSBT) saves and improves lives by providing a safe, reliable and efficient supply of blood and associated services to the NHS in England and North Wales.

We are the organ donor organisation for the UK and are responsible for matching and allocating donated organs. We rely on thousands of members of the public who voluntarily donate their blood, organs, tissues and stem cells.

For more information
Visit **nhsbt.nhs.uk**