

## **Guidelines for the Blood Transfusion Services**

### **21.4: Bacteriostasis and disinfection**

<http://aws-lon-jpac.targetservers.uk/red-book/chapter-21/21-4-bacteriostasis-and-disinfection>

### **21.4: Bacteriostasis and disinfection**

Storage conditions and expiration periods must be supported by validation. Historical data, experience and documented literature are acceptable as evidence of validation. Any new processing or significant changes to existing processing are subject to pre-authorisation by the HTA.

#### **21.4.1: Tissue without terminal antimicrobial processing**

Tissue must be subjected to one of the following treatments, as soon as possible and within 24 hours of retrieval:

- antibiotic disinfection
- an alternative disinfection method
- frozen storage at  $-20^{\circ}\text{C}$  or lower.

In the case of tissue taken from heart-beating donors in the operating theatre at the time of organ retrieval, this period may be extended to 48 hours.

#### **21.4.2: Tissue with terminal antimicrobial processing**

Tissue with terminal antimicrobial processing must be subjected to one of the treatments detailed in the above section within 24 hours of retrieval with a maximum of 72 hours following death. A summary of the guidance regarding temperature/time relationships contained in these guidelines is given in Tables 21.1 and 21.2.

#### **Table 21.1 Temperature/time relationships for banked tissues from living donors**

Retrieved tissue	Must be placed at a temperature of between 0–10°C within 4 hours of retrieval. <sup>1</sup>
Bacteriostasis	Freezing tissue to –20°C or colder within 24 hours of retrieval can be used as a bacteriostatic treatment.  Bone from living donors which is not frozen until 24–48 hours after retrieval must be subjected to terminal antimicrobial processing.
Long-term storage	Bone from living donors may be stored at –20°C or colder for up to 6 months or at –40°C or colder for up to 5 years. Temporary storage of frozen living donor bone between –20°C and –40°C is limited to 6 months in total. Grafts stored at this temperature must then be transferred to –40°C or colder to give an expiry of up to a maximum of 5 years from donation. Amnion preserved in low-concentration (50%) glycerol may be stored at –40°C or colder for up to 2 years.
Transportation and local storage	Must be transported and stored locally prior to clinical use, at –20°C or colder in order to have the designated expiry (specified above).
<sup>1</sup> As the tissue itself is taken directly from a living individual, setting temperature criteria for the tissue itself during this initial storage and transport is not feasible, therefore only the ambient temperature it must be kept at is specified.	

**Table 21. 2 Temperature/time relationships for banked tissues from deceased donors**

Retrieval	For eyes, retrieval must be completed within 24 hours after death and the body should preferably be refrigerated For all other tissues, if the body has not been refrigerated, procurement of tissues must be completed within 12 hours after death. If the body has been refrigerated within 6 hours of death procurement should preferably start within 24 hours and must be completed within 48 hours of death.
Retrieved tissue	Must be placed at a temperature of between 0–10°C within 4 hours of retrieval. <sup>1</sup>
Bacteriostasis	Freezing tissue to a temperature of –20°C or colder within 24 hours of retrieval (or up to a maximum of 72 hours of death) can be used as a bacteriostatic treatment.

Long-term storage	<p><b>Frozen* tissue may be stored:</b></p> <ol style="list-style-type: none"> <li>1. At <math>-20^{\circ}\text{C}</math> or colder for up to 6 months.</li> <li>2. At <math>-40^{\circ}\text{C}</math> or colder for up to 5 years. Temporary storage of frozen musculoskeletal tissue between <math>-20^{\circ}\text{C}</math> and <math>-40^{\circ}\text{C}</math> is limited to 6 months in total. Grafts stored at this temperature must then be transferred to <math>-40^{\circ}\text{C}</math> or colder to give an expiry of up to a maximum of 5 years from donation.</li> </ol> <p><b>Cryopreserved** tissue:</b></p> <p>At <math>-135^{\circ}\text{C}</math> or colder to claim a 10-year expiry for all grafts to maintain a reasonable inventory of size-matched grafts (e.g. heart valves and menisci). Other cryopreserved tissues should have a 5-year expiry.</p> <p><b>Glycerol-preserved tissue:</b></p> <p>Skin preserved in high-concentration (<math>&gt;90\%</math>) glycerol may be stored at between <math>0-10^{\circ}\text{C}</math> for up to 2 years.</p> <p><b>Freeze dried tissue:</b></p> <p>Freeze-dried tissue may be stored at ambient temperature for up to 5 years. This includes freeze dried demineralised bone tissue mixed with a glycerol carrier</p> <p><b>Decellularised Tissue:</b></p> <p>Decellularised dermis tissue that has been terminally sterilised may be stored at colder than <math>-40^{\circ}\text{C}</math> for up to five years, or at up to <math>+40^{\circ}\text{C}</math> for up to two years.</p>
Transportation and local storage	<p><b>Frozen* tissues</b> must be transported and stored locally prior to clinical use, at colder than <math>-40^{\circ}\text{C}</math> if they are to retain their original expiry date. If they are stored locally at temperatures colder than <math>-20^{\circ}\text{C}</math> or warmer than <math>-40^{\circ}\text{C}</math>, the expiry date must be reduced to a maximum of 6 months or the balance of the original expiry date, whichever is lower.</p> <p><b>Cryopreserved** tissues</b> may be transported in the vapour phase of liquid nitrogen (<math>-135^{\circ}\text{C}</math> or colder) or on dry ice (<math>-79^{\circ}\text{C}</math> or colder). If tissues are transported on dry ice they should continue to be stored locally at <math>-80^{\circ}\text{C}</math> or colder for a maximum of 6 months.</p>
<p>For the purposes of this guidance, the following definitions apply:</p> <p>* Frozen tissue – Tissue stored at sub-zero temperatures, with or without cryoprotectant.</p> <p>** Cryopreserved tissue – Tissue preserved and stored at sub-zero temperatures using a cryoprotectant, either by controlled slow freezing or by vitrification.</p>	
<p><sup>1</sup> As the tissue itself is taken directly from a living individual, setting temperature criteria for the tissue itself during this initial storage and transport period is not feasible, therefore only the ambient temperature it must be kept at is specified.</p>	

### 21.4.3: Positive bacteriology or mycology

It is the responsibility of the designated medical officer or designated microbiologist to develop written policies regarding the selection and conduct of tests for bacterial and fungal contamination and the acceptance criteria for specific tissues.

Where tissues are shown to carry viable bacteria or fungi they may be suitable for clinical use (e.g. skin grafts) depending on microbial types and densities of growth on culture. For other tissues the material may be approved for use provided that a validated antimicrobial processing technique is used.