

Guidelines for the Blood Transfusion Services

21.4: Bacteriostasis and disinfection

<http://www.transfusionguidelines.org/red-book/chapter-21-tissue-banking-tissue-retrieval-and-processing/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°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 an ambient temperature of 0–10°C within 4 hours of retrieval.
Bacteriostasis	Freezing tissue to at least –20°C 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 lower for up to 6 months or at –40°C or lower 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 below –40°C for up to 2 years.
Transportation and local storage	Must be transported and stored locally prior to clinical use, at –20°C or lower in order to have the designated expiry (specified above).

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 an ambient temperature of 0–10°C within 4 hours of retrieval.
Bacteriostasis	Freezing tissue to at least –20°C 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>Frozen* non-viable tissue may be stored:</p> <ol style="list-style-type: none"> 1. At –20°C or lower for up to 6 months. 2. At –40°C or lower for up to 5 years. Temporary storage of frozen musculoskeletal tissue 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. <p>Cryopreserved** viable tissue: At –135°C or lower 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>Glycerol-preserved tissue: Skin preserved in high-concentration (>90%) glycerol may be stored at 0–10°C for up to 2 years.</p> <p>Freeze dried tissue: 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>Decellularised Tissue: Decellularised dermis tissue that has been terminally sterilised may be stored at below -40oC for up to five years, or at below +40oC for up to two years.</p>
Transportation and local storage	<p>Frozen* tissues must be transported and stored locally prior to clinical use, at –20°C or lower in order to have the designated expiry (specified above).</p> <p>Cryopreserved** tissues may be transported in the vapour phase of liquid nitrogen (–135°C) or on dry ice (–79°C). If tissues are transported on dry ice they should continue to be stored locally at around –80°C for a maximum of 6 months.</p>
<p>For the purposes of this guidance, the following definitions apply:</p> <p>* Frozen tissue – tissue frozen and stored under conditions unlikely to be compatible with preservation of cells.</p> <p>** Cryopreserved tissue – tissue treated with a cryoprotectant and/or cooled at a controlled rate in order to preserve cells.</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.