

RECOMMENDATIONS FOR STORAGE AND HANDLING OF CRYOPRESERVED CARDIAC AND VASCULAR TISSUES

1. Healthcare facility staff members that handle tissue should become familiar with the tissue source facility's (tissue processor's) **Instructions for Use**. Different processors may have different protocols. Using the incorrect protocol could adversely affect the tissue and recipient clinical outcome.
2. Freezers should be placed in a well-ventilated room or area and the liquid nitrogen (LN₂) supply monitored on a daily basis. If a freezer is allowed to run dry or to reach a critically low LN₂ level, the freezer chamber temperature must be confirmed, documented, and evaluated prior to refilling. If an acceptable temperature (-100°C or colder) cannot be verified, the tissue must immediately be quarantined so none of the inventory is inadvertently used for patients, and the entire inventory must be properly discarded/disposed (human tissue to be discarded as biohazardous waste).
3. LN₂ freezers should be located in a secure area and only trained personnel should have access to the inventory. Staff training should be documented.
4. Each hospital should develop an inventory system that allows tissue to be quickly placed into or retrieved from the freezer to minimize warming and transient temperature spikes.
5. Upon tissue receipt at the hospital, the integrity of the cryogenic shipping container as well as the individual graft packages must be assessed and the cryopreserved grafts should be placed in an LN₂ freezer as soon as possible. All incoming tissue should be handled according to the manufacturer's recommendations with regards to storage in either the liquid or vapor phase of LN₂.
6. Handling cryopreserved cardiac or vascular tissues must be done with extreme care (packages cannot withstand bumps or drops). Special-order, protective cryogenic gloves **MUST** be used when handling these deep-frozen grafts and personal protective garb is recommended when working with LN₂ inventory racking systems.
7. Removal and replacement of storage racks into LN₂ should be done slowly and carefully to prevent violent boiling of the LN₂. Bumping or dropping storage racks may cause damage to the stored tissue and its packaging.
8. Cryopreserved tissue is fragile and can become damaged if dropped or mishandled. The tissue may sustain damage even though the package remains intact, therefore, packages

accidentally dropped must immediately be quarantined/segregated from other grafts, then discarded.

9. When transferring tissue into or out of the freezer, either in inventory racks or when handling individual grafts, exposure to room temperature air should be minimized. Maximum exposure should not exceed the time recommended by the processor. If no specific guidance is given, the maximum exposure time should not exceed 5 minutes, unless the tissue is to be used immediately.
10. Use tissue storage racking systems only as directed. Storage racks are designed to hold a specific number of tissues. Overcrowding may damage the packaging or the tissue.
11. When thawing tissue, carefully follow the processor's instructions and document the identity of staff involved in preparing and the date and time of preparation.
12. Any damage to the packaging or tissue noted upon receipt of the shipment or at issuance for use, should be reported to the processor regardless of the cause of the damage. Do not use damaged allografts.
13. The final disposition of each graft, whether implanted or discarded, is the responsibility of the end user and this information must be shared with the processor by completing and returning the graft implant card or other document that accompanies each graft. Refer to The Joint Commission's Tissue Storage and Issuance Standards at Standard PC.17.20, which states, "The organization's record keeping permits the traceability of all tissues from the donor or source facility to all recipients or other final disposition" and, "The organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities."

NOTE: Two sections and many parts of The Joint Commission's Tissue Storage and Issuance Standards support the above list of recommendations and compliance is expected. A short list of relevant parts is provided for your reference below:

Standard PC.17.10 The organization uses standardized procedures to acquire, receive, store, and issue tissues.

Elements of Performance for PC.17.10 (*relevant parts only*)

The organization develops, maintains and follows procedures to do the following:

4. Transport, handle, store, and use tissue according to the source facilities' or manufacturers' (for example, for synthetic tissue) written directions.
5. Log in all incoming tissue.
6. Maintain continuous temperature monitoring for storage refrigerators and freezers.
7. Maintain daily records to show that tissues were stored at the required temperatures. Note: Main types of tissue storage used are: "ambient" room temperature (for example, freeze-dried bone), refrigerated, frozen (for example, deep freezing colder than -40°C), and liquid nitrogen.

8. Storage equipment has functional alarms and emergency back-up.
9. Comply with state and/or federal regulations when acting as a source facility that supplies tissues.
10. Verify at receipt that package integrity is met and transport temperature range was controlled and acceptable.

Standard PC.17.20 The organization's record keeping permits the traceability of all tissues from the donor or source facility to all recipients or other final disposition.

Elements of Performance for PC.17.20

1. The organization's records permit tracing of any tissue from the donor or source facility to all recipients or other final dispositions, including discarding of tissue.
2. The organization's records track and identify materials used to prepare or process tissues and instructions used for preparation.
3. The organization's records identify the following: Identity of staff involved in preparing or issuing tissue; Identity of staff who accepts the tissue; Dates and times of the preceding activities
4. The organization's records include documentation in the recipient's clinical record of tissue use, including documentation of the unique identifier of the tissue.
5. The organization's records including storage temperatures, and all superseded procedures, manuals, and publications, are retained for a minimum of ten years, or longer if required by state and/or federal laws.
6. The organization's records document the source facility, the original numeric or alphanumeric donor and lot identification, all recipients or other final dispositions of each tissue, and expiration dates, and are retained for a minimum of ten years beyond the date of distribution, transplantation, disposition or expiration of tissue (whichever is latest), or longer if required by state and/or federal laws.
7. The organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities. Note: Regarding protected health information, the HIPAA Privacy Rule provides at 45 CFR §164.512: "Uses and disclosures for which consent, an authorization, or opportunity to agree or object is not required... (h) Standard: uses and disclosures for cadaveric organ, eye or tissue donation purposes."

The American Association of Tissue Banks (AATB) supports full compliance to The Joint Commission's Tissue Storage and Issuance Standards.

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