

CHANGES TO AATB STANDARDS FOR TISSUE BANKING

SECTION D - ACQUISITION OF TISSUE: AUTHORIZATION, INFORMED CONSENT, DONOR SCREENING, AND TISSUE RECOVERY AND COLLECTION

D5.000 RECOVERY AND COLLECTION POLICIES AND PROCEDURES

Current (13th edition)

D5.700 Post-Recovery Packaging

Immediately following either Recovery of each individual tissue or Processing at the Recovery Site, tissue obtained shall be individually and aseptically wrapped or enclosed and the receptacle shall be immediately labeled with the unique donor identifier and the type of tissue enclosed (abbreviations may be used if defined in the SOPM). Tissue shall be maintained at defined environmental temperatures until the time of transport to the Processing center. Maintenance of such temperatures shall be documented.

- (A) Immediately following *Recovery* of the *Autograft*, the tissue shall be individually and aseptically wrapped in a manner to prevent contamination of the contents, preserve cellular structure and viability, if desired, and to allow for aseptic delivery of the specimen at time of *Processing*, if necessary, or reimplantation. The receptacle shall be labeled immediately with the donor's name, age, sex, hospital medical record number and/or social security number, and institution name, and shall be prominently labeled "FOR AUTOLOGOUS USE ONLY."
- (C) Recovered cardiac tissue shall be rinsed and packaged in an isotonic, *Sterile* solution such as normal saline, lactated Ringer's solution, PlasmaLyte®, transplant organ perfusate (e.g., Belzer's UW solution, Collin's solution) or tissue culture media, immediately following *Recovery*. The volume of the transport solution should be adequate to cover the entire heart, including the vessels and valves. The type, *Lot* number, manufacturer, and expiration date shall be documented. The transport container should be fluid tight, designed to prevent contamination of the contents, and allow for aseptic delivery of the specimen at the time of *Processing*.
- (V) Immediately following *Recovery*, vascular tissue shall be gently flushed and packaged in an isotonic *Sterile* solution such as tissue culture media. Normal saline solution should not be used. The type, *Lot* number, manufacturer, and expiration date of all reagents used for *Recovery* and packaging shall be documented. The transport container should be fluid tight, designed to prevent contamination of the contents, and allow for aseptic delivery of the specimen at the time of *Processing*.
- (S) Recovered skin tissue shall be packaged in a *Sterile* solution immediately following *Recovery* or packaged by another method that maintains the integrity of the tissue for its intended use (e.g., decellularized dermis). If in solution, the volume of transport solution must be adequate to cover the entire skin. The type, *Lot* number, manufacturer, and expiration date(s) shall be documented. If in solution, the transport container must be fluid tight and designed to prevent contamination of the contents.

(with amendments, relevant part only)

D5.700 Post-Recovery Packaging Labeling and Handling

Immediately following ~~either Recovery~~ of each individual tissue ~~or Processing~~ at the *Recovery Site*, recovered tissue ~~obtained~~ shall be individually and aseptically wrapped or enclosed ~~and the receptacle~~ and shall be immediately labeled with the unique donor identifier and the description according to the SOPM (see G1.100) ~~type of tissue enclosed (abbreviations may be used if defined in the SOPM)~~. Tissue shall be maintained at defined environmental temperatures until the time of transport to the *Processing* center. Maintenance of such temperatures shall be documented.

...

(as amended, relevant part only)

D5.700 Post-Recovery Labeling and Handling

Immediately following *Recovery* of each individual tissue at the *Recovery Site*, recovered tissue shall be individually and aseptically wrapped or enclosed and shall be immediately labeled with the unique donor identifier and the description according to the *SOPM* (see G1.100). Tissue shall be maintained at defined environmental temperatures until the time of transport to the *Processing* center. Maintenance of such temperatures shall be documented.

...

Publication date: March 30, 2015 (AATB Bulletin No. 15-7)

Effective date: September 30, 2015 (in 6 months)