

Supplies & Equipment

Sterile Wraps & Bag(s)

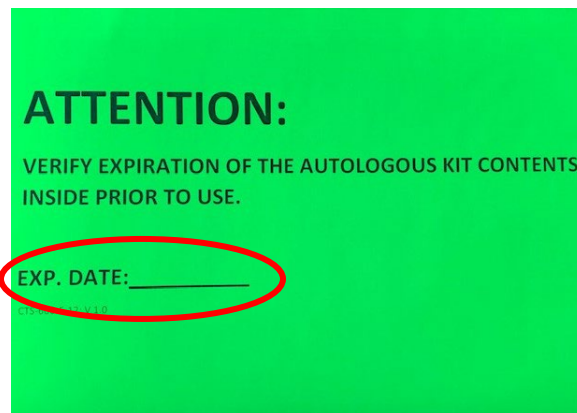
ID label

Ice & Ice Bag

Validated shipping box/container labeled with Autologous Tissue Return Label- Wet Ice

Acceptance Criteria

- 1.0 There are no patient-donor age limits for autologous tissue donation.
- 2.0 Donor suitability criteria is established and documented by the licensed physician caring for the patient-donor, not Solvita.
- 3.0 Tissue received by Solvita must be properly labeled, correctly packaged, and be accompanied by a completed **Request for Storage/Processing of Autologous Tissue** form (CTS-600-F-02).
 - 3.1 The hospital staff is responsible for verifying the expiration date for the autologous tissue kit prior to use. A label, as shown below, will be on the outside of the bag that contains the supplies and may be on the outside of the shipping box, documenting the expiration date of the autologous tissue kit.



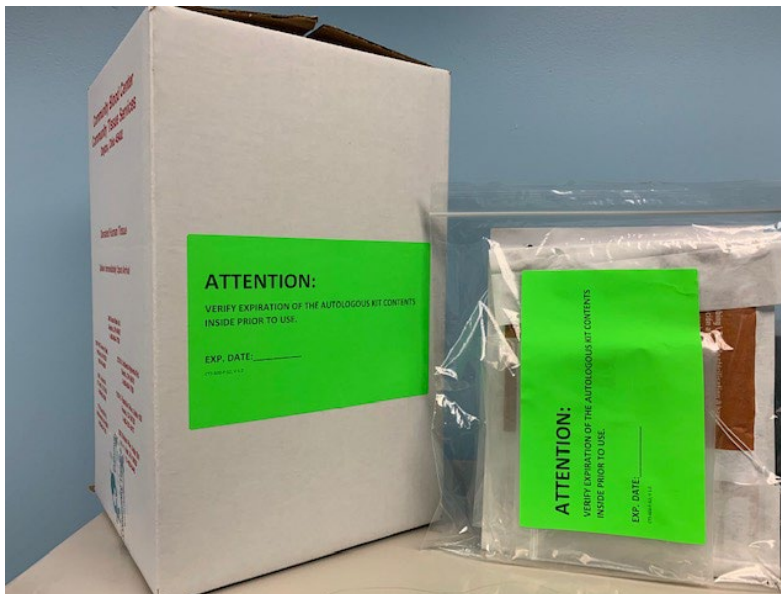
- 3.2 The hospital staff is responsible for the proper handling, wrapping, and labeling of the autologous tissue.

NOTE: In the event supplies are not readily available, hospital approved sterile supplies may be used for packaging purposes. Please notify Solvita when this occurs.
- 4.0 Identification of the donor is the responsibility of the hospital staff involved with the recovery of autologous donor tissue.
- 5.0 Obtaining informed consent for collection and storage of autologous tissue, along with maintaining the consent with the patient chart, is the responsibility of the hospital, not Solvita.
- 6.0 Methods for perioperative autologous tissue collection and transplantation shall be safe, aseptic, and ensure accurate identification of the autologous tissue.

- 7.0 Hospitals must notify the tissue bank on all autologous donors at high risk for hepatitis or HIV.
- 8.0 Autologous donation should not be undertaken when the donor-patient has or is being treated for bacteremia or other significant bacterial infection that can be associated with bacteremia, unless such cells and/or tissue will be secondarily sterilized prior to transplantation or treated in such a manner to minimize microbial infection.
- 9.0 Solvita does not open any autograft even if irradiation is ordered. Irradiation will occur in the packaging sent by the hospital.
- 10.0 Solvita has the right to refuse to store any tissue that does not meet the acceptance criteria.

Directions

1.0 Post Recovery Packaging:



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 tissue at the time of storage, irradiation, if necessary, and re-implantation.

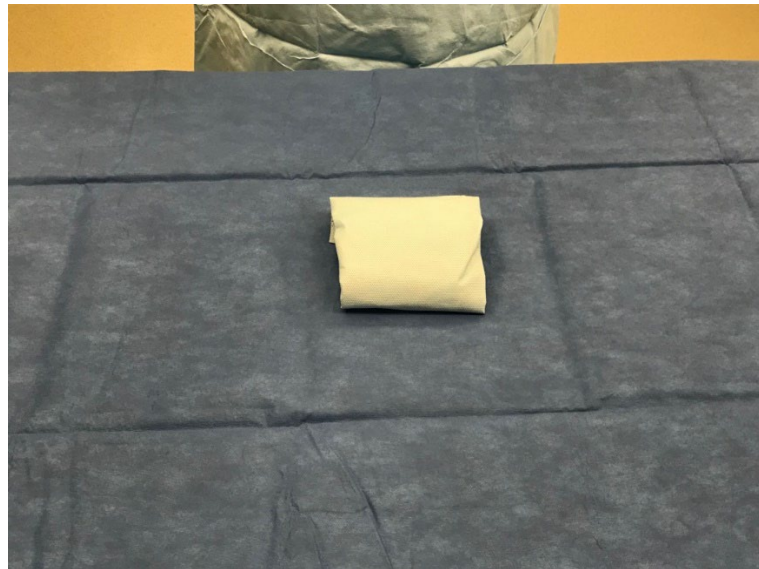
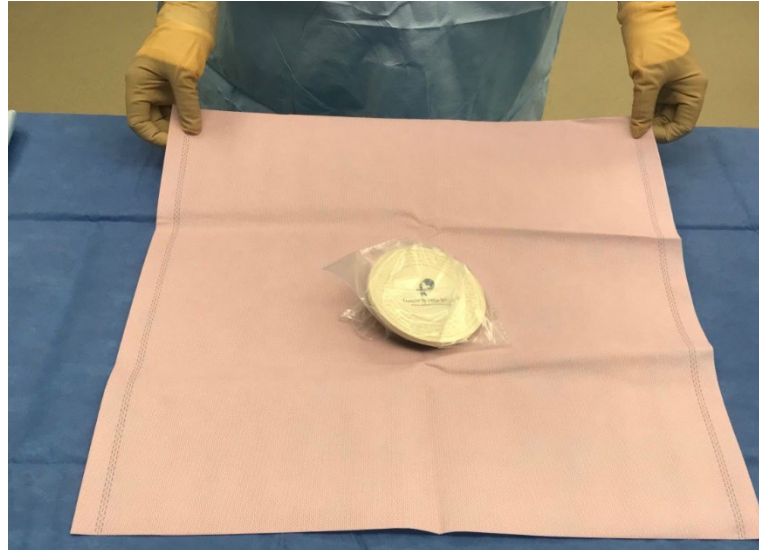
1.1 Bone (frozen storage):

Note: Do not wrap graft directly on absorbent material.

1.1.1 Insert the graft into a sterile bag/ container and tie off/ close the container.



1.1.2 Wrap the bag/container in sterile wrap.



1.1.3 Wrap again in a second sterile wrap.



- 1.1.4 Insert the wrapped graft into another sterile bag or container and tie off/ close the container.

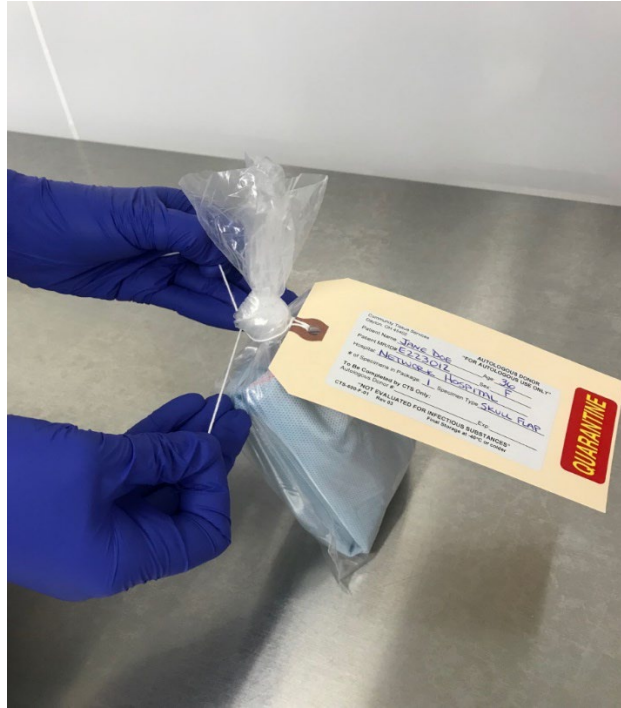


- 1.1.5 Hand off to the circulating nurse.

- 1.1.5.1 Solvita suggest utilizing the read back method to assure correct patient and graft.

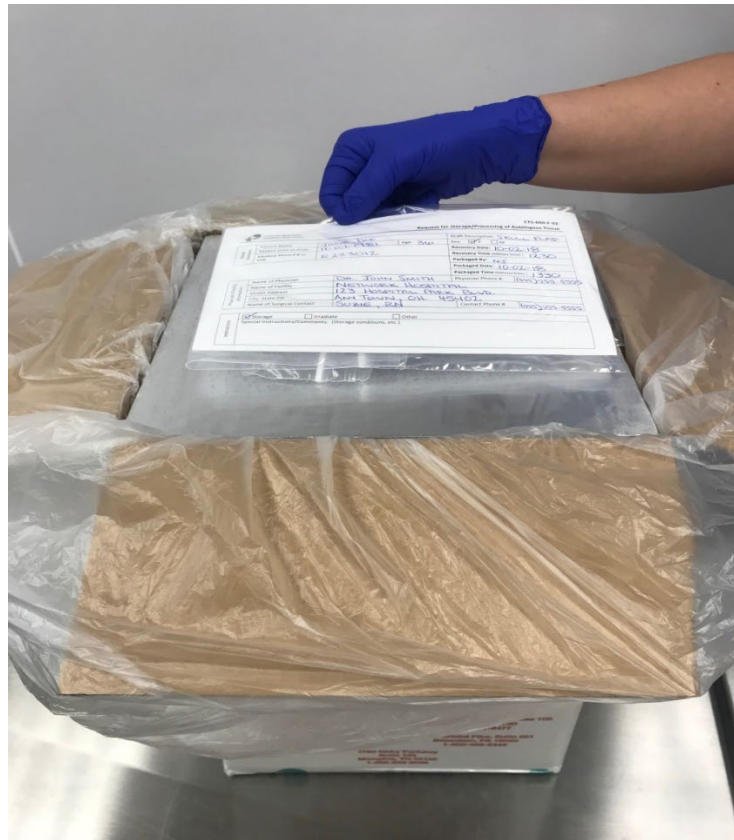
2.0 Labeling:

- 2.1 Complete CTS-600-F-01, Autologous Donor "For Autologous Use Only" label/tag.
- 2.2 Attach completed CTS-600-F-01 to the outside of packaging.





- 3.4 Cover with container lid.
- 3.5 All transportation boxes being shipped to Solvita must be labeled with the following:
 - CTS-600-F-14, Autologous Tissue Return Label- Wet Ice
 - Solvita name and address
- 4.0 Complete CTS-600-F-02, Request for Storage/Processing of Autologous Tissue form.
- 4.1 Place completed and **signed** form in a bag before putting it into the shipping box.



- 5.0 Seal the shipping box and contact Solvita to arrange for delivery and retrieval of autologous donor tissue. Please be sure to contact the appropriate Solvita Branch location.

NOTE: Be prepared to provide the following information: Your contact information. Patient name, DOB, MRN, Physician, and location to pick up.

- 5.1 **Solvita - Dayton, Ohio**
349 South Main Street
Dayton, OH 45402
1-800-684-7783 (Option 2)
- 5.2 **Solvita - Toledo, Ohio**
2736 North Holland-Sylvania Road
Toledo, OH 43615
1-800-684-7783 (Option 2)
- 5.3 **Solvita – Portland, Oregon**
18111 NE Sandy Blvd
Portland, OR 97230
6 AM – 6 PM: 1-503-408-9394
Non-Business Hours: 1-503-808-7000

- 6.0 Ensure the tissue has been picked up and/or delivered to Solvita.
- 7.0 Miscellaneous
- 7.1 **Cultures:**
- 7.1.1 If cultures are obtained at time of recovery, those cultures are to be sent to the hospital laboratory.
- 7.1.2 Culture results are to be returned directly to the physician, not Solvita.
- NOTE:** Solvita does not perform cultures. Solvita will not handle or process cultures.
- 7.2 **Expiration Dates:** Frozen autologous donor tissue expires 2 years from the date of recovery and will be discarded.
- NOTE:** If continued storage is requested, it can be stored for up to 2 additional years. A storage fee will be charged to the hospital with this request.
- 8.0 At the request of a hospital, pre- assembled autologous kits and applicable documents will be provided to those facilities for which a signed contract is on file.
- 9.0 In the event you are in need of the applicable documents, they can be printed from the following link: <https://solvita.org/tissue-donation/autologous-program/>
- 10.0 Upon request, Solvita will provide the requesting facility information regarding the status of the autologous tissue as needed.

END

Summary of Changes:

- Updated 5.1, 5.2, and 5.3 – changed CTS to Solvita
- Updated link in 9.0