

# PROCEDURE Corewell Health East - Handling of Autologous Tissue

## This Procedure is Applicable to the following Corewell Health sites:

Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Farmington Hills Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

#### 1. Principle

The purpose of this document is to provide the laboratory staff with specific guidance for accepting autologous tissues from surgery into Transfusion Services for storage. Compliance to this procedure will promote the quality and integrity of the autologous tissue.

Autologous tissue intended for re-implantation and storage may arrive at Transfusion Services from surgery. Incoming tissue shall be inspected, and documentation of receipt must be recorded electronically in the Transfusion Medicine tissue information system (IS) for traceability and integrity. Transfusion Services may receive, store, and issue autologous tissue for the intended patient only.

# 2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.

### 3. Definitions

- A. **Autologous**: Cells and/or tissue intended for implantation, transportation or infusion into the individual from whom they were collected.
- B. **Designee**: The designee is the Medical Technologist at Farmington Hills, Grosse Pointe, and Royal Oak. The designee is the Blood Bank technical director, or transfusion medicine fellow at Troy.

# 4. Specimen

- A. Autologous bone or skin may be procured in the operating room from a patient for future implantation Tissue containers must be clearly labeled with the following:
  - 1. Patient's complete name
  - 2. Medical Record Number (MRN)
  - 3. Birthdate
  - 4. Date of tissue removal from patient
  - 5. Procuring surgeon
  - 6. Contents: 1 of 2, right flap, etc.

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#### 5. Procedure

#### A. RECEIPT AND INSPECTION OF TISSUE:

# Action **Notes** 1. Inspect the container for damage and proper Tissue may be inadvertently dropped identification of the patient: off at other locations in the laboratory. A. Patient's complete name Instruct the recipient of the tissue to B. MRN bring the tissue to Transfusion C. Birthdate Services and inform the blood bank D. Date of tissue removal technologist that an autologous tissue E. Procuring surgeon was received and needs to be F. Contents: 1 of 2, right flap, etc. processed for storage. If autologous tissue cannot be received at the time of delivery, the technologist should inspect the graft for proper labeling and put the autologous tissue in its proper storage 2. Complete the Autologous Donor label (Green sticker: Note: Any discrepancies in the receipt 7205 JAN OS). of the autologous tissue on a variance A. Document patient's name, medical record and notify the Supervisor, Lead number and date of surgery at the bottom of the Technologist, Tissue Technologist, or label. the Corporate Tissue Coordinator B. Cross out "AS-5 Red Blood Cells" box and add regarding the submission of the the description of the contents of the container on variance. Refer to Transfusion the Autologous Donor label. Example: Medicine policy, Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals. AUTOLOGOUS DONOR C. Affix a downtime unique identifying number sticker to the unit number area on the Autologous Donor label.

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- D. Write the expiration date on the autologous donor label. The expiration date is one year from the removal date for bone tissue, and one week for skin.
- Affix the label to the tissue package/container as well as any additional downtime unique identifying numbers.
- Input all tissue into Transfusion Medicine tissue IS, TrackCore.. Refer to <u>Corewell Health East</u> -<u>TrackCore (Tissue) Application - Farmington Hills,</u> <u>Grosse Pointe, Royal Oak, Troy</u>, (F) Receiving Autografts.
- 5. Place tissue in a biohazard transport bag for additional package/container safety.
- Place the bone/tissue in the appropriate storage area.
- 7. Notify the tissue technologist, supervisor, manager, or Tissue Coordinator in writing of the receipt of an autologous tissue with the following:
  - Patient's complete name
  - Medical record number
  - Birthdate
  - Date of tissue removal
  - Procuring surgeon
  - Contents: 1 of 2, right flap, etc.

- If the tissue is delivered in a container with a lid, make sure both the side of the container as well as the lid has the patient information as well as the unique identifying unit number.
- Quarantine any questionable tissue in the TrackCore and place tissue in the designated quarantine storage area until resolved.
- Bone storage is -40°C or below.

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- Skin storage is 1-6°C.
- It is the tissue technologist, supervisor, manager, Tissue Coordinator, or designees' responsibility to review all autologous tissue submissions for proper labeling, storage, and integrity once the storage process is completed by the technologist.

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• Mark note as 'receipt completed' or 'receipt incomplete- needs attention'.

# B. FINAL DISPOSITION OF AUTOLOGOUS TISSUE: Re-implantation processes are as follows: Frozen bone will be transported on dry ice. 1. Locate the requested autologous tissue Refrigerated tissue will be sent in a cooler with an ice pack. 2. Issue the requested autologous tissue Refer to Corewell Health East - TrackCore (Tissue) Application - Farmington Hills, Grosse Pointe, Royal Oak, Troy, (G) Issuing Tissue. Discard process of autologous tissue from a deceased patient: 1. Confirm patient death. 2. Access Hospital Chart. Enter medical record number of the patient. EPIC alerts the user that you are about to enter a deceased person's chart. 3. Create a screen shot of Epic screen with the patient's status. 4. Perform Discard of Autologous Tissue. Refer to Corewell Health East - TrackCore (Tissue) Application - Farmington Hills, Grosse Pointe, Royal Oak, Troy, (L) Removing Vendor Items From Inventory. 5. Print the Item Detail Report. Refer to Corewell Health East - TrackCore (Tissue) Application -Farmington Hills, Grosse Pointe, Royal Oak, Troy , (K) Item Detail Report. 6. A cosigner must confirm patient name, date of birth, MRN, and confirmation of death. Both cosigner and technologist must sign and date the Unit History report. 7. Attach the Epic screen print of the patient's status to the autologous unit history, and file with paper discard records. 8. Physically discard the autologous tissue in a red biohazard bin. Release of autologous tissue from a deceased Family of a deceased patient may patient to funeral home: request the autologous bone flap 1. Confirm patient death in Epic: hospital chart. collected in operating room to be sent to the funeral home with the 2. Perform Issue of Tissue. Refer to Corewell Health

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East - TrackCore (Tissue) Application - Farmington

patient. This notification may come

from the floor, funeral home, the



<u>Hills, Grosse Pointe, Royal Oak, Troy</u>, (G) Issuing Tissue.

- 3. Release and document the full name and badge ID of the hospital personnel taking the autologous bone flap on the Tissue Graft Information form.
- 4. Add a written comment on form, *Tissue Graft Information*, stating the following: The patient is deceased and the autologous bone flap is being released to (hospital staff ID#) as requested by the family. Initial & date the comment.
- Implant the graft in Trackcore. Refer to <u>Corewell Health East TrackCore</u> (<u>Tissue</u>) <u>Application Farmington Hills, Grosse Pointe, Royal Oak, Troy</u>, (P) Implant Documentation.
- 6. Add a comment in the notes section that states the following: The patient is deceased and the autologous bone flap is being released to (hospital staff ID#) as requested by the family.
- 7. File the Tissue Graft Information form appropriately, ensuring the yellow copy is sent to medical records.

- bereavement representative, or surgical services. Autologous bone flaps may only be released to hospital personnel.
- If Transfusion Medicine is notified of a request for an autologous bone flap from the funeral home, contact the area the patient is currently on or has been discharged from and provides the hospital staff with the name of the funeral home, phone number, and contact name.

## Audit and discard of expired autologous tissue:

- 1. Review the autologous tissue in inventory periodically.
- 2. Identify all expired autologous tissues.
- 3. Investigate all expired autologous tissues by contacting the procuring physician with the form letter regarding status of the autologous tissues. See the attachments.
- 4. Discard or continue to save the autologous tissues as directed by the patient's physician written response.
- Discard the expired autologous tissues in TrackCore. Refer to <u>Corewell Health East - TrackCore (Tissue)</u> <u>Application - Farmington Hills, Grosse Pointe, Royal Oak, Troy</u>, (L) Removing Vendor Items From Inventory.
  - <u>Corewell Health East TrackCore (Tissue)</u>
    <u>Application Farmington Hills, Grosse Pointe, Royal Oak, Troy</u>
- 6. Print the Item Detail Report. Refer to <u>Corewell Health East TrackCore (Tissue) Application Farmington Hills, Grosse Pointe, Royal Oak, Troy</u>, (K) Item Detail Report.
- A cosigner must confirm patient name, date of birth, MRN, and confirmation of death. Both cosigner and technologist must sign and date the Item Detail report.

 See attachments for site specific letters to the doctor regarding autologous tissue in storage.

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- 8. Attach the physician's response letter to the autologous tissue Item Detail Report and file with paper discard records. See site specific letters attached to this policy.
- 9. Physically discard the autologous tissue in a red biohazard bin.

#### 6. Limitations

Tissues are bio-hazards. Any broken packaging or compromised tissues should be handled using standard precautions. Autologous tissue is not disease marker tested nor is it processed or changed in anyway.

#### 7. Revisions

Corewell Health reserves the right to alter, amend, modify or eliminate this document at any time without prior written notice.

#### 8. References

- A. 21. CFR 1271: Human cells, tissues, and cellular and tissue based products. April 2013. US Food and Drug Administration. <u>Tissue Establishment Registration</u>
- B. AABB, Standards for Blood Banks and Transfusion Services, current edition.
- C. American Association of Tissue Banks, Standards for Tissue Banking, current edition.

## 9. Procedure Development and Approval

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## 10. Keywords

Autologous

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