BY ORDER OF THE COMMANDER
59TH MEDICAL WING

59TH MEDICAL WING INSTRUCTION
44-156

2 JANUARY 2024

Medical

TISSUE IMPLANT PROGRAM

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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RELEASABILITY: There are no releasability restrictions on this publication.

OPR: 59 SGC/SGCU

Certified by: 59 MDW/SGH
(Colonel M. Teju Guest)

Supersedes: 59 MDWI 44-156, 30 March 2017

Pages: 11

This instruction implements Air Force Policy Directive 44-1, *Medical Operations*. This instruction outlines policies and procedures of the Tissue Implant Program. This instruction applies to all Military Medical Treatment Facilities (MTFs) and Clinics under the Authority, Direction, and Control of the Director, Wilford Hall Ambulatory Surgical Center, to include the 59th Medical Wing (MDW) medical staff while performing Defense Health Agency duties. However, this does not apply to 959th Medical Group personnel when using Brooke Army Medical Center (BAMC). The 59 MDW follows the Food and Drug Administration (FDA) of Health and Human Services, Code of Federal Regulation (CFR), Title 21, Part 1271–*Human Cells, Tissues, and Cellular and Tissue-Based Products* (HCT/Ps). The goal of this policy is to ensure the FDA and The Joint Commission (TJC) requirements are included in our process of identifying, tracking, storing, and handling of transplantable and implantable tissue-based products. This instruction applies to each tissue implant specialty service within 59 MDW that receives, stores, or issues human and nonhuman cellular-based implantable products classified by the FDA as a tissue or a medical device. Collagen and other tissue products derived from polymers are not considered cellular-based products and are discussed in this instruction. This instruction provides guidance for supplier qualifications, receipt, storing, recording, tracking, education, communicating tissue recalls/withdrawals, and reporting adverse events of HCT/Ps. Refer recommended changes and questions about this publication to the Office of Primary Responsibility (OPR) using the AF Form 847, *Recommendation for Change of Publication*. Requests for waivers must be submitted to the OPR listed above for consideration and approval. Ensure that all records generated as a result of processes prescribed in this publication adhere to Defense Health Agency Administrative

Instruction 5015.01, Records Management Program, and are disposed of in accordance with the OSD Records Disposition Schedules located at **https://www.esd.whs.mil/RIM/**.

SUMMARY OF CHANGES

This publication has been revised. This rewrite of 59 MDWI 44-156 includes updated procurement and documentation procedures as well as contingency for the 59th Surgical Operations Squadron Ultra-Low temperature storage freezer.

1. Responsibilities.

1.1. 59 MDW/SGH.

1.1.1. 59 MDW/SGH, in-conjunction with the Department Chair of Surgery, will assign responsibility for the medical oversight of the tissue program throughout the medical facility.

1.1.2. The 59 MDW/SGH must generate a letter of appointment identifying a privileged provider as the Medical Director of the Tissue Program, and/or the Facility Tissue Manager (FTM).

1.2. 59 MDW Medical Director of the Tissue Program (MDTP).

1.2.1. 59 MDW MDTP appointee must be knowledgeable of compliance standards and be able to ensure compliance with all state and/or federal regulations if facility is processing or modifying tissue after receipt.

1.2.2. The MDTP appointee will ensure:

1.2.2.1. A quality program is in place with guidelines for monitoring proper documentation.

1.2.2.2. Effectiveness of policies and procedures.

1.2.2.3. Qualifications of tissue suppliers.

1.2.2.4. Inventory management and proper storage.

1.2.2.5. Accuracy of records.

1.2.2.6. Traceability of tissue.

1.2.2.7. Investigation of infectious complications.

1.2.2.8. Investigation of transplant reactions and root cause analysis.

1.2.2.9. Management of recalls, and compliance with professional standards, federal laws, and accreditation standards, including TJC and the FDA.

1.2.3. 59 MDW will establish a tissue oversight function of Executive Committee of the Medical Staff (ECOMS) whose purpose is to monitor the safety, effectiveness, and availability of tissue allografts and to provide peer review of their clinical use.

1.2.4. Pertinent procedures, monitored parameters and essential reviews are presented, discussed and documented at this function.

1.2.5. The MDTP serves as the Deputy Chairman of the function and the minutes are forwarded to ECOMS.

1.2.6. Policies and procedures for ordering, receiving, transporting, handling, storing, issuing, appropriate use of tissue, and final disposition of all HCT/Ps are the responsibility of the MDTP in consultation with multidisciplinary representatives.

1.2.7. Policies and procedures will be reviewed annually. Any deviations from standard operating procedures must be approved by the MDTP and transplanting provider with justification documented in patient's medical record and the tissue tracking database [Champion Unique Device Identification (UDI) Tracker].

1.3. The Facility Tissue Manager(s).

1.3.1. The FTMs can be appointed to manage the day-to-day operations of the HCT/Ps. They will:

1.3.2. Verify all suppliers of allogeneic bone and tissue used for procurement are licensed and inspected by the FDA and/or other federal/state inspection agencies as may be required locally.

1.3.3. Request departments that handle HCT/Ps appoint Tissue Department Managers (TDM); FTMs will coordinate with TDMs to ensure facility program compliance.

1.3.4. Verify all personnel who order, handle, prepare and/or dispense transplantable tissues are knowledgeable of and trained in appropriate procedures. Tissue preparation, alteration and processing will be limited to providers, nurses, operating room, and dental treatment room personnel overseen by the patient's provider.

1.3.5. Verify tissues are stored appropriately, tracked from receipt to implantation, and that tracking information of implanted human tissues is provided to the vendor and maintained within the HCT/Ps program utilizing the Champion UDI Tracker.

1.3.6. Maintain current standardized operating instructions for ordering, receipt, storage, inspection, issuing, and processing of implantable tissues and provide quarterly input to ECOMS for review.

1.4. Tissue Department Managers.

1.4.1. TDMs will:

1.4.2. Manage, train, and provide oversight within facility departments that order, handle or utilize HCT/Ps products.

1.4.3. Coordinate and document the acquisition, receipt, storage, issuance and destruction of HCT/Ps in their department.

1.4.4. Have a process to verify that HCT/Ps ordered are obtained from FDA registered sources.

1.5. Medical Logistics Flight Commander or designee.

1.5.1. Manage, train, and provide oversight within the department regarding the handling of HCT/Ps products including the documentation within the Champion UDI Tracker.

1.5.2. Coordinate and document the receipt, visual inspection, storage, and issuance of HCT/Ps.

1.6. All personnel involved in the tissue program will have training completed annually on all regulatory requirements.

1.7. Policies and procedures will be reviewed annually and approved by ECOMS. All policies and procedures for the Tissue Program must be in compliance with the source facility's written instructions for tissue handling, FDA requirements, and guidelines from accreditation agencies as applicable. Policies and procedures for ordering, receiving, transporting, handling, storing, issuing, appropriate use of tissue and final disposition of all HCT/Ps are the responsibility of the MDTP in consultation with each representative from the clinical areas. Any deviations from standard operating procedures must be approved by the MDTP and the transplanting provider with justification documented in the patient's medical or dental record.

2. Tissue Supplier Qualification.

2.1. Applicable FDA Registration, State Licensing, and accreditation is maintained in the Champion UDI Tracker.

2.2. Tissues will only be procured from source facilities that are validated as licensed by their respective state agencies and/or are registered as a tissue establishment by the FDA.

2.3. The 59 MDW will not distribute tissues or tissue products to any health-care facility.

2.4. State Licensing is not required in Texas.

2.5. When seeking tissue, the 59 MDW will look for tissue that is accredited by a recognized standard-setting organization such as Accreditation by American Association of Tissue Banks or the Eye Bank Association of America. These are listed and documented in the Champion UDI Tracker.

2.6. Accreditation by American Association of Tissue Banks indicates that the tissue supplier has been inspected before being accredited and thereafter, at regular intervals, and found to meet standards for donor screening, tissue recovery, testing, tissue processing, labeling, storage, quality control, and quality assurance practices.

2.7. For ocular tissue, accreditation by the Eye Bank Association of America similarly provides assurance of compliance with recognized professional standards.

3. Tissue Procurement.

3.1. Record keeping must ensure tissue traceability from the supplier to the patient and back to the manufacturer. There will be a clear traceability for supplier recalls identifying affected patients. The 59 MDW retains tissue records, tissue manuals/guidance/publications to include outdated guidance, for a minimum of 10 years beyond the date of distribution, transplantation, disposition, or expiration of tissue (whichever is latest).

3.2. HCT/Ps will use local logistics ordering processes for initiating orders of tissue. One entry control point in medical logistics will ensure documentation and oversight of the program.

3.3. The requesting TDM will validate the potential supplier's licensure from an accredited source or the Champion UDI Tracker. Purchase requests will not be forwarded to the Procurement Contracting Office without validation of the HCT/Ps supplier.

3.4. Tissue will be delivered to the Medical Logistics receiving area and the date and time of receipt documented in the Champion UDI Tracker. Medical Logistics will complete a visual inspection of the packaging to ensure damage did not occur during shipping and environmental controls were maintained within manufacturer's specifications throughout the shipping process. Tissue shipping containers are certified to maintain temperature for 72 hours. Items received on dry ice are to be delivered immediately to the end user and placed in a controlled environment.

3.5. If discrepancies are noted, Medical Logistics will process the receipt and document the following on the Champion UDI Tracking System: the discrepancy, the date, the time of notification of the ordering departments, and the printed name and signature of the TDM rejecting the tissue(s). In addition, the TDM will immediately quarantine the tissue until disposition is determined between the Procurement Contracting Office, vendor, and ordering provider.

3.6. The TDM will follow the manufacturer guidelines for HCT/Ps that are not acceptable. Document in the Champion UDI Tracker all tissues returned to the supplier.

3.7. If the package is acceptable, Medical Logistics will immediately deliver the unopened package to the requesting TDM who will confirm that the product(s) and quantities are correct, the package is undamaged (checking to make sure item is still sealed with no tears, marks, or discrepancies), and temperature ranges are within acceptable limits.

3.7.1. The following data will be recorded before the items are stocked: date and time received, tissue ID number, (Lot #, code, reference), tissue supplier, type of tissue, expiration date, temperature of tissue when received and condition in the Champion UDI Tracker.

3.8. The requesting TDM will immediately transfer item to the unit's designated tissue storage area.

3.9. The 59 MDW will not act as a tissue supplier.

4. Tissue Storage.

4.1. All tissue is stored and handled according to manufacturer's recommendations.

4.2. Tissue will be received and stored in the designated tissue storage locations.

4.3. Tissues need to be tracked and logged in the Champion UDI Tracker by trained personnel, upon being entered into storage and upon removal from storage.

4.4. Stocking of Tissues.

4.4.1. Tissues will be stored/stocked separately by origin/source. For example, autografts and allografts will be separated from each other as they are stored.

4.5. Temperature Concerns. Temperatures are monitored according to manufacturer's specifications and documented. **Note:** Ambient temperature and room temperature storage are not the same. Refer to manufacturer's instructions for appropriate temperature storage.

4.6. Lyophilized tissues stored at ambient temperatures do not require continuous temperature monitoring. Tissues stored at frozen temperatures will be monitored 24/7 and temperature will be recorded on a daily basis.

4.7. Storage Requirements.

4.7.1. Storage room/areas will be orderly, dry and have appropriate ventilation.

4.7.2. Refrigerators and freezers must be appropriately designated and labeled for tissue storage and supplies.

4.7.3. Refrigerators and freezers will be equipped with the ability to have continuous temperature monitoring, functional alarms, and emergency generator back–up (emergency generator back-up if available).

4.8. Storage temperatures and alarm checks will be recorded and monitored by using an automated alarm check system or, if not available, manually recorded using a Daily Temperature Log or a 24-hour temperature chart that is reviewed daily. Temperature logs will be maintained for a period of 10 years.

4.9. Monthly inspections are conducted on all stored tissue. If storage temperatures were at any point outside the required ranges, the TDM will immediately quarantine the tissue until disposition is determined by manufacturer recommendations. If deemed appropriate, discard tissue IAW local procedures and record disposal/return on the Tissue/Bone Receipt and/or in the Champion UDI Tracker.

4.10. Storage Contingency Plan.

4.10.1. Ensure there is a secondary location for storage of all wet/dry tissues at the facility and confirm this location annually.

4.10.2. Annually ensure there is an emergency backup generator source.

4.10.3. Inform the appropriate persons/offices of the contingency storage location if utilized and when/if storage contingency plan is in effect.

4.10.4. Storage Contingency Plan for Ultra-Low Temperature freezer storage.

4.10.5. If the 59th Surgical Operations Squadron's Ultra-Low Temperature storage freezer were to become disabled, the 59th Surgical Operations Squadron has been preauthorized to move tissue products requiring said storage to the Ultra-Low temperature storage freezer located at Allergy and Immunizations Clinic's Ultra-Low temperature storage freezer.

4.10.6. Storage Inspection. Ensure monthly inspections on all tissues that are stored. Ensure temperatures have been maintained within range and no items have become expired.

5. Issue/Use of Tissue.

5.1. After the tissue package is opened, the preparer reviews the label, and any accompanying package inserts to ensure that all identifying numbers and/or letters match on both the label and accompanying tissue description. Any discrepancies must be resolved by the treatment team prior to implanting tissue. Each manufacturer's package insert will be reviewed prior to preparation and implantation, placing special emphasis on product limitations, precautions, and preparation requirements, ensuring appropriate use of the product.

5.2. Tissue will be prepared by nurse, technician, or provider, according to manufacturer guidelines and the following will be performed:

5.2.1. Document all manipulation to the tissue product.

5.2.2. Perform visual inspection of the product, expiration date and condition (integrity) of the package. Document hairline fractures in glass bottles, punctures in bagging, broken seals. Look for unexpected discoloration in the tissue or unusual structural defects. If such defects occur do not implant the tissue.

5.2.3. Confirm label is compatible with the visual inspection of the tissue and appropriate for the type of procedure to be performed.

5.2.4. Correctly transfer the graft aseptically from the packaging into the sterile field in the surgery-capable/treatment room.

5.2.5. Pay special attention to time required for reconstitution or thawing.

5.2.6. Identify, investigate and correct all discrepancies thoroughly prior to use.

5.3. Tissue implantation tracking will include but is not limited to:

5.3.1. Two patient identifiers (name and date of birth).

5.3.2. Tissue description.

5.3.3. Name of manufacturer/supplier.

5.3.4. Catalog number.

5.3.5. Lot and/or serial number.

5.3.6. Expiration date of tissue.

5.3.7. Identity of the person who accepted/received the tissue in the clinical area.

5.3.8. Quantity implanted.

5.3.9. Preparation information including date issued, name of person receiving the tissue, date prepared, time prepared, materials used, and name of staff preparing tissue.

5.3.10. Location where implanted.

5.3.11. Treating physician or provider.

5.3.12. Date of implantation.

5.3.13. Materials used to prepare tissue (along with lot # and exp. date of those items).

5.3.14. Additional comments or concerns.

5.4. At time of use, the provider staff is responsible for:

5.4.1. Documenting in the patient electronic medical record or dental health record and the Champion UDI Tracker that a patient has received the implant (i.e., date of use, provider, procedure, location of the implant, unique identifiers, and any description of abnormalities found).

5.5. The 59 MDW will return tissue usage information back to the manufacturer if applicable.

6. Disposition of Tissue.

6.1. Quarantine any tissue that is questionable until inspected by provider and decision about acceptability or rejection is documented. Store quarantined tissues in a separate, labeled location.

6.2. Identification of supplier errors will be reported to the tissue supplier by the TDM and documented in Champion UDI Tracker.

6.3. After each product has reached its expiration date or lost its packaging integrity, the product is immediately removed from storage and subsequently disposed of and documented in the Champion UDI Tracker.

6.4. Unused tissue not meeting manufacturer's guidelines will not be placed back into inventory and will be disposed of. If tissues become expired and/or reach/drop to temperatures that are out of range, these tissues will be discarded. Once tissue(s) are thawed the tissue will not be returned to the storage freezer and will be destroyed if not implanted.

6.5. The TDM will complete the Tissue/Bone Receipt if applicable to reflect the reason the tissues were removed from service and disposed.

7. Adverse Events due to Tissue or Donor Infections and Recalls.

7.1. Each facility utilizing tissue must maintain a quality assurance program to address all adverse events with appropriate formal reporting to the Facility Tissue Manager(s). The FTMs will brief adverse events to ECOMS.

7.2. Both infectious and malignant diseases have been documented to occur with graft implants. Clinical failures are known to be attributable to the quality of the auto-/allograft. It is the provider's responsibility to report any adverse reactions resulting from implanted tissue according to 59 MDWI 44-130, *Patient Safety*. It is the provider, diagnosing an infectious disease complication due to a tissue related disease problem, who is responsible to ensure the immediate reporting of suspected infectious disease complications to Infection Control Function, Patient Safety, and the originating source facility of the product. The provider will review the patient's medical or dental record for information relating to the implanted tissue and file an incident report IAW 59 MDW policy. Contact the Risk Manager and/or the SGH for appropriate notifications/actions as necessary.

7.3. Adverse events include but are not limited to:

7.3.1. Excessive hemorrhage.

7.3.2. Graft rejection.

7.3.3. Non-functioning grafts due to infection (bacterial, fungal, viral, and parasitic).

7.3.4. Disease transmission or other complication(s) suspected of being directly related to tissue use.

7.3.5. Fatalities.

7.3.6. Implantation of the wrong product/material.

7.3.7. Products that have been implanted and are recalled.

7.4. Process for handling adverse events.

7.4.1. Post-transplant adverse events will immediately be reported to the MDTP, the SGH, and squadron leadership.

7.4.2. The using department, provider and MDTP will work collaboratively, in conjunction with the pathologist if applicable, to work up the suspected transplant reaction identifying and investigating adverse events.

7.5. Steps to investigate a suspected transplant reaction will include:

7.5.1. Immediately quarantine all unused tissue from the same donor.

7.5.2. Transport tissue to Lab.

7.5.3. Annotate suspected adverse reaction in the patient's electronic medical or dental health record.

7.5.4. Notify the patient's providers and MDTP.

7.5.5. Create an adverse event file for the Tissue Program records.

7.5.6. Contact the tissue processor/supplier for review of suspected adverse event.

7.5.7. If nosocomial infection is suspected, contact the Patient Safety.

7.5.8. All suspected adverse events are reviewed by ECOMS and discussed at the appropriate clinic.

7.5.9. Tissue that is reported by a source facility as a cause of possible infection or tissue involved in an adverse outcome is sequestered and sent to the Lab with the proper order in Genesis Powerchart. The tissue will then be sent to BAMC for the transplant reaction workup.

7.5.10. Recipients of tissue who are subsequently found to have received tissue from donors who have Human Immunodeficiency Virus/ Human T-cell Lymphotropic Virus I and II, hepatitis infections, or other infectious agents known to be transmissible by tissue, are identified, confirmed, and informed of infection risk by the implanting provider. The provider will work with Risk Management and Patient Safety prior to informing the patient unless doing so would result in a delay in notification to the patient beyond the day in which this information becomes available. It may be appropriate to offer affected recipients testing, counseling, and treatment. Risk Management and Patient Safety will assure there is an entry into Patient Safety Report and Air Force Medical Operations Agency is notified.

7.5.11. All adverse reactions will be referred to the MDTP for peer/case review.

8. Training.

8.1. Each department implanting tissue will ensure a FTM approved training plan is utilized annually for training all members who play a role in the tissue program. Training may include but is not limited to:

8.1.1. Regulatory compliance with established guidelines.

8.1.2. Ordering, receiving, storing, and issuing tissue.

8.1.3. Follow-up (including patient evaluation and recalls).

8.1.4. Proper documentation and access/maintenance of all records.

8.1.5. Preparation and review of quarterly reports to ECOMS.

8.1.6. State and/or federal regulations if processing or modifying tissues after receipt.

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Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

59 MDWI 44-130, *Patient Safety*, 3 November 2020

AFPD 44-1, *Medical Operations*, 20 April 2020

AABB Hospital Tissue Management: A Practitioners Handbook, 2008

AABB Guidelines for Managing Tissue Allografts in Hospitals, 2009

Health and Human Services, Code of Federal Regulation (CFR), Title 21, Part 1271–*Human Cells, Tissues, and Cellular and Tissue-Based Products*

The Joint Commission for Ambulatory Centers 1 January 2023

Adopted Form

AF Form 847, *Recommendation for Change of Publication*

Abbreviations and Acronyms

BAMC—Brooke Army Medical Center

ECOMS—Executive Committee of the Medical Staff

FDA—Food and Drug Administration

FTM—Facility Tissue Manager

HCT/P—Human Cells, Tissues, and Cellular and Tissue-Based Products

IAW—In Accordance With

MDG—Medical Group

MDTP—Medical Director of the Tissue Program

MDW—Medical Wing

OPR—Office of Primary Responsibility

TDM—Tissue Department Manager

TJC—The Joint Commission

UDI—Unique Device Identification