

GUIDELINE ESSENTIALS

KEY TAKEAWAYS

Autologous Tissue



TAKEAWAY

Facilities that manufacture autologous tissue must register with the US Food and Drug Administration (FDA) as a tissue establishment.

EXPLANATION

- The FDA requires establishments that manufacture human cells, tissue, or cellular or tissue-based products (HCT/Ps) to register and list their HCT/Ps. **1.1**
- The FDA defines manufacture as any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue and the screening or testing of the cell or tissue donor. **1.1, 1.2**
- Refer to the FDA for information regarding tissue establishment registration and exceptions.

An interdisciplinary team should provide oversight of managing autologous tissue practices in the organization.

- **NEW** An interdisciplinary, collaborative approach to determining standardized methods for autologous tissue handling can facilitate implementation of comprehensive protocols in the organization and serve as the basis for clear policies and procedures and team education. **2.2**

The interdisciplinary team should determine the cranial bone flap preservation method in consideration of patient-specific factors.

- **NEW** Patient-specific considerations include age, primary decompressive craniectomy etiology, comorbidities, body mass index, history of previous cranial surgeries, presence of hydrocephalus shunts, scalp tissue quality, size of the skull defect, number of cranial flap fragments, and smoking history. **3.1.1**
- **NEW** The anticipated storage duration of the cranial bone flap and the availability of a freezer with ultra-low temperature capabilities are important considerations when determining the best preservation method. **3.2.2**

The interdisciplinary team should design and implement a standardized method for the maximum storage duration for autologous tissue.

- The FDA requires that, when applicable, establishments assign an expiration date or maximum storage duration to tissue based on specific factors (eg, type, preservation method, storage conditions, packaging). The AATB recommendations for duration of preservation vary based on the tissue type. **3.4, 4.3.1, 5.5, 16.4**

Personnel who perform microbial tissue culturing should have demonstrated competency before performing the task.

- **NEW** Microbial cultures are important in determining effective and directed antibiotic therapy for prevention or treatment of patient infections but swab culture results may be prone to error because of variation in swab methods. **3.8.3, 18.2.1**

TAKEAWAY

EXPLANATION

Anticipated autologous tissue preservation or autotransplantation should be discussed during the procedural briefing.

- Discussion promotes perioperative team efficiency, decreases delays, and improves patient outcomes. **12.1**
- Discussion may include preparation method(s), preservation method, microbial culture orders, storage location and availability, transport coordination, thawing method, and microbial culturing results (if applicable). **12.1.1**

Initial and ongoing education and competency verification activities should be provided to personnel responsible for any step of autologous tissue management.

- **NEW** Initial and ongoing education facilitates the development of knowledge, skills, and attitudes that affect safe patient care. **18.1**
- **NEW** Education and competency verification activities related to autologous tissue management include policies and procedures, factors that contribute to contaminated or lost tissue, organization- and tissue type-specific standardized methods, preservation methods, handling methods, storage methods, transportation methods, decontamination methods, preparation methods, tissue culture techniques, team communication components, disposal protocols, and tissue tracking documentation requirements. **18.2.1**
- **NEW** Perioperative personnel assigned to procedures involving research should be provided with education about the research protocols for autologous tissue collection to promote an understanding of the processes used for research tissue collection in the facility, reduce time spent during the patient assessment and collection process, and provide assurances of tissue viability for research purposes. **18.3**

Quality assurance (QA) and performance improvement (PI) activities consistent with the health care organization's plan for compliance with current good tissue practices and autologous tissue management should be conducted.

- **NEW** A QA/PI program can facilitate the identification of problem areas and assist perioperative personnel in analyzing data and evaluating patient outcomes related to autologous tissue management and provides a mechanism to evaluate the effectiveness of processes and adherence to established policies and procedures for autologous tissue management. **19.2**
- **NEW** The QA/PI activities related to autologous tissue management should include audits of tissue tracking documentation; audits of compliance with autologous tissue management policies and procedures; identification, documentation, implementation, and evaluation of corrective actions; and personnel training and education activities. **19.2.1**