



AUTOLOGOUS TISSUE MANAGEMENT



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MEDICAL ABBREVIATIONS & ACRONYMS

- AATB** – American Association of Tissue Banks

CDC – Centers for Disease Control and Prevention

CFR – Code of Federal Regulations

CHG – Chlorhexidine gluconate

CLIA-88 – Clinical Laboratory Improvement
Amendments of 1988

DMEM – Dulbecco’s modified Eagle’s medium

EO – Ethylene oxide
- FDA** – US Food and Drug Administration

H₂O₂ – Hydrogen peroxide

IFU – Instructions for use

PSI – Pounds per square inch

RCT – Randomized controlled trial

RPMI – Roswell Park Memorial Institute

SSI – Surgical site infection

THA – Total hip arthroplasty

GUIDELINE FOR AUTOLOGOUS TISSUE MANAGEMENT

The Guideline for Autologous Tissue Management was approved by the AORN Guidelines Advisory Board and became effective as of December 9, 2019. Information about the systematic review supporting this guideline, including a description of the evidence review, the PRISMA flow diagram, the evidence rating model, and the evidence summary table is available at <https://www.aorn.org/evidencetables/>.

Purpose

This document provides guidance for preserving **autologous tissue**, including cranial bone flaps, parathyroid glands, skin, vessels (eg, veins, arteries), femoral heads, incus, and adipose tissue, in the perioperative setting. Guidance is also provided for team communication related to autologous tissue management; handling, packaging, labeling, storage, disposal, cleaning, transport, and documentation of autologous tissue; and policies and procedures for preservation and delayed **replantation** or **autotransplantation** of autologous tissue within the same facility.

Preserving and replanting autologous tissue may improve the patient's long-term outcomes. Some types of autologous tissue (eg, cranial bone flaps, parathyroid glands) are preserved because the patient's clinical symptoms (eg, swelling, hormone levels, infection) prevent the tissue from being replanted or autotransplanted during the same procedure in which it was removed. Other types of autologous tissue (eg, veins, skin, adipose tissue) are preserved because the tissue was harvested but was not all used during the original procedure and may be needed for a future procedure (eg, cardiovascular bypass graft, skin graft). In addition, the use of autologous tissue may be preferred over the use of **allograft** tissue or synthetic tissue implants in certain situations. Following good tissue practices described in 21 Code of Federal Regulations (CFR) Part 1271 Subpart D¹ and evidenced-based guidance for autologous tissue management may

- decrease the patient's risk for infection;
- decrease the risk for a packaging, labeling, or tissue identification error;
- decrease the risk to perioperative personnel of exposure to blood and other potentially infectious materials; and
- preserve the clinical viability of the tissue.

The following topics are outside the scope of this document:

- autologous tissue that is replanted into the patient during the same procedure in which it was removed (eg, tendons, ligaments, osteochondral grafts, fractional skin grafts, epidermal grafts);

- autologous blood products;
- autologous islet cell or stem cell transplantation;
- autologous cartilage used for staged microtia reconstruction procedures;
- autologous bone that is exposed to cryotherapy, radiation, or thermal therapy for eradication of cancer and replanted during the same procedure in which it was removed;
- tissue-engineered grafts grown from autologous cells;
- allograft organ or tissue transplantation;
- allograft fecal microbiota transplantation; and
- xenogeneic tissue (eg, bovine or porcine implants).

Refer to the AORN Guideline for Specimen Management² for information regarding surgical specimens and the AORN Guideline for Sterilization Packaging Systems³ for recommendations on packaging systems for sterilization.

1. Tissue Establishment Registration

- 1.1** Facilities in which autologous tissue is handled must register with the US Food and Drug Administration (FDA) as a **tissue establishment** unless the tissue is recovered, packaged, labeled, and stored in the original form for replantation or autotransplantation in the same patient at the same facility. *[Regulatory Requirement]*

In 21 CFR 1271.15(b), the FDA provides an exception from registration as a tissue establishment as long as the autologous tissue is removed from and replanted or autotransplanted in the original form back into the same individual during the same surgical procedure.¹ In 2017, the FDA clarified that procedures involving the removal of and replantation or autotransplantation of the autologous tissue back into the same individual at the same facility are generally considered to be the same surgical procedure.⁴ Surgical removal and subsequent replantation or autotransplantation of cranial bone flaps or portions of parathyroid tissue that occur a number of days apart may be considered the same surgical procedure under the 21 CFR 1271.15(b) exception. Processing steps for storage may include cleaning, rinsing, packaging, and labeling. However, the tissue must remain in its original form with no additional manufacturing steps (eg, sterilization, centrifuge for cell isolation).⁴ The method used to store autologous tissue (eg, refrigeration, freezing, **cryopreservation**) does not, in itself, affect whether an establishment meets the same surgical procedure exception.

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- 1.2** Facilities must register with the FDA as a tissue establishment if autologous tissue handling includes manufacturing steps such as sterilization or other processing that changes the tissue from the original form.^{1,4} *[Regulatory Requirement]*

Registering with the FDA as a tissue establishment is required by 21 CFR 1271 when a facility manufactures tissue.¹ Manufacturing of tissue includes the steps involved in recovery, processing, storage, labeling, packaging, and distribution. Processing may include sterilization or other steps to inactivate or remove contaminants.¹ The FDA has clarified that the only processing steps that allow autologous tissue to stay in the original form are cleaning, rinsing, sizing, and shaping.⁴ In general, use of only the specified processing steps allows facilities to use the exception in 21 CFR 1271.15(b) that eliminates the need for registration.⁴

- 1.3** A facility that routinely distributes tissue to other facilities must register as a tissue establishment using the FDA's electronic Human Cell and Tissue Establishment Registration System and must comply with the applicable regulations in 21 CFR 1271.¹ *[Regulatory Requirement]*

Under 21 CFR 1271.3(e), distribution of tissue from one facility to another is considered part of manufacturing and requires registration with the FDA as a tissue establishment.¹

- 1.3.1** A facility may not be required to register as a tissue establishment when tissue distribution is only for the purpose of burial or cremation. *[Conditional Recommendation]*

Facilities that are asked to send tissue for burial or cremation are not required to register as a tissue establishment because the tissue is not intended for replantation or autotransplantation into a human recipient.¹

2. Cranial Bone Flap

- 2.1** Autologous cranial bone flaps may be frozen, cryopreserved, or stored in a subcutaneous pocket for replantation. *[Conditional Recommendation]*

Moderate-quality evidence supports the preservation of autologous cranial bone by freezing, cryopreservation, and subcutaneous pocket storage.⁵⁻¹⁰

Corliss et al⁵ conducted a systematic review of 48 studies that included 5,346 patients and compared cryopreservation and subcutaneous storage of autologous cranial bone flaps. The researchers found there was no significant difference between cryopreservation and subcutaneous storage for the outcomes of infection rates, bone resorption rates, or the need for

revision procedures. The researchers concluded that both the cryopreservation and subcutaneous preservation methods for preserving autologous cranial bone flaps were safe and effective.

The evidence conflicts regarding the viability of bone after cryopreservation and the effect on patient outcomes (eg, resorption, infection). Some researchers have found that cranial bone flaps had some or complete viability after cryopreservation,^{8,11-13} while others have reported limited or no viability after cryopreservation.¹⁴⁻¹⁶ Only a few studies have investigated the outcomes of both bone viability and patient outcomes after cryopreservation.^{8,11,16} However, because of variability in the study methodologies and the reported results, no conclusion can be drawn as to how cryopreservation affects viability or how cranial bone flap viability affects patient outcomes. Further research is needed.

The benefits of autologous bone flap preservation may exceed the harms. The benefits include no risk of immunoreactivity,¹⁷ better insulation,¹¹ improved cosmetic appearance,¹⁸⁻²⁰ and reduced costs compared to use of synthetic cranial bone flap replacements.⁷ The harms may include risks of

- reduced **osteoblast** viability after cryopreservation,^{14,15}
- bone flap resorption compared to almost no risk of resorption with synthetic material use,^{8,21-23}
- skin breakdown or necrosis when the **subgaleal** scalp area is used for preservation,²⁴ and
- bone formation in a subcutaneous pocket.²⁵

In a nonexperimental study, Ernst et al⁷ found a significant difference in cost between **cranioplasty** procedures involving autologous bone and procedures involving custom implants. The average cost of procedures involving autologous bone was \$2,156.28 ± \$1,144.60, whereas the average cost of procedures involving synthetic implants was \$35,118.60 ± \$2,067.51 (2017 dollars).

Conversely, Honeybul et al²⁶ conducted a randomized controlled trial (RCT) to compare patient outcomes and hospital costs for cranioplasty procedures (N = 64) and found that the use of titanium implants was associated with a reduction in reoperations and hospital costs compared with the use of autologous cranial bone flaps. However, the results were not statistically significant.

- 2.1.1** When an autologous cranial bone flap is stored in a subcutaneous pocket, provide the patient and the patient's designated caregiver(s) with instructions regarding the care of the surgical incision storage area. *[Recommendation]*

Providing patient education on care of the surgical wound area where the tissue is stored may help the patient understand how to help

the area heal and prevent actions (eg, touching, rubbing, scratching) that might increase the risk of skin breakdown, bone formation in the subcutaneous pocket, or resorption or atrophy of the preserved tissue.

2.2 Determine a method for preparing cranial bone flaps for preservation, which may include

- preparing the bone for packaging as soon as a decision is made to preserve the bone,^{27,28}
- removing blood^{19,28,29} and excess soft tissue,^{29,30}
- irrigating or immersing the bone in normal saline solution or a mixture of normal saline and antibiotics or povidone-iodine solution,^{6,8,17,29-32}
- using low-linting sterile material to dry excess fluid from the bone,^{6,28,29}
- wrapping the bone flap in sterile gauze,³²
- using sterile technique and sealing the bone in at least two sterile bags^{6,11,17,19,27-29,31,33} or a sterile container that can be sealed,
- packaging and labeling^{11,27} the bone (See Recommendation 11),
- placing the packaged bone flap in a third sterile bag before handing it off the sterile field⁶, and
- placing the bone in the tissue freezer as soon as possible.^{11,27}

[Conditional Recommendation]

The benefits of preparing autologous cranial bone flaps for preservation are likely to exceed the harms. Wrapping the bone flap in sterile gauze may reduce the risk of the sharp edges of the bone flap puncturing the sterile bags. A potential harm of using nonradiopaque sterile gauze may be increased risk of a retained surgical item or foreign body reaction from contact with the fibers, although further research is needed.

No studies were found that specifically compared the effect of autologous cranial bone flap preparation on patient outcomes (eg, infection, resorption). However, several researchers reported how cranial bone flaps were prepared for storage as part of their study methodology. Bhaskar et al¹⁷ reported a high level of variability in cranial bone flap preparation methods used in 25 major neurosurgical health care facilities in Australia. From a survey, the researchers found that in 52% of the facilities, cranial bone flaps were cryopreserved in a facility freezer, whereas in the remaining 48% of the facilities, cranial bone flaps were stored at a local **tissue bank**. Further research is needed to determine the effect of autologous bone flap preparation on patient outcomes.

2.2.1 Follow the manufacturer's instructions for use (IFU) when using a prepackaged cranial bone flap storage kit from a manufacturer or tissue establishment to freeze or cryopreserve cranial bone flaps. [Recommendation]

2.3 Determine the temperature range for freezing or cryopreserving autologous cranial bone flaps based on the anticipated length of storage, risk for microbial growth, and preservation of osteocyte viability. [Recommendation]

Moderate-quality evidence shows a wide variation in temperature ranges used for cryopreservation or freezing of autologous cranial bone flaps. In a systematic review of 48 studies, Corliss et al⁵ reported that the storage temperatures for cranial bone flaps ranged from 8° C to -86° C (46.4° F to -122.8° F) with a mean temperature of -57° C (-70.6° F). Results of a survey of 25 major neurosurgical centers in Australia showed that bone flaps were cryopreserved at temperatures between -18° C to -83° C (-0.4° F to -117.4° F), with a mean of -62.1° C (-79.8° F).¹⁷ The American Association of Tissue Banks (AATB) recommends that frozen or cryopreserved allograft musculoskeletal tissue be stored at temperatures between -20° C and -40° C (-4° F and -40° F) for temporary storage less than 6 months and -40° C (-40° F) or colder for storage durations longer than 6 months.³⁴ No studies comparing different temperature ranges were found, and further research is needed to determine the ideal temperature.

In a nonexperimental study, Tahir et al²⁷ investigated surgical site infection (SSI) rates associated with cranial bone flaps stored at -26° C (-14.8° F). The researchers found that only three patients (3.4%) who received the bone flaps developed an SSI. Two patients had superficial infections that resolved with oral antibiotics and the third patient required a second procedure for washout of the infection. No bone flap resorption was reported. The researchers concluded that storage at -26° C (-14.8° F) resulted in an acceptable rate of infection. Additionally, the researchers questioned the need to store autologous cranial bone flaps at deep freezer temperatures, stating that deep freezer storage temperatures may affect the viability of osteocytes and increase the risk of bone resorption. They recommended that cranial bone flaps be kept at a minimum temperature that prevents microbial growth, preserves osteocyte viability, and reduces the risk of bone resorption.

2.4 Determine the maximum storage duration for frozen or cryopreserved cranial bone flaps based on the preservation method, temperature range, packaging method used, and patient-specific needs. [Recommendation] P

There may also be patient-specific considerations (eg, chronic infections) that necessitate the storage of autologous cranial bone flaps for longer periods of time.

According to the AATB, the maximum storage period is determined by the type of tissue preserved,

preservation method, temperature range, and packaging method used.³⁴ Moderate-quality evidence varies regarding the optimal length of storage time between **craniectomy** and cranioplasty procedures. The studies had high levels of variability in methodology^{6,8,35-37} and, therefore, the study results cannot be compared for the purposes of making a clinical practice recommendation for maximum storage duration. No studies were found that specifically compared the effects of varying lengths of storage durations on patient outcomes (eg, infection, resorption), and further research is needed (See Recommendation 12.5).

Several researchers reported the average or mean duration of storage in their results or study methodology. In a systematic review of 48 studies, Corliss et al⁵ found that the mean storage duration for cryopreserved cranial bone flaps was 69.9 days. In a survey by Bhaskar et al¹⁷ of 25 major neurosurgical facilities in Australia, the reported duration of cryopreservation storage was

- 6 months (16%),
- 9 months (4%),
- 2 years (8%),
- 5 years (56%),
- until the patient is deceased (4%), and
- not specified (12%).

Cheah et al⁶ conducted a prospective study that compared the effect of cryopreservation and subcutaneous pocket storage methods on SSI rates. The bone flaps that were cryopreserved (n = 55) had a mean storage duration of 168 days; the shortest and longest storage durations were 25 days and 538 days, respectively. The infection rate was 5.45% (n = 3) in the cryopreservation group. The only variable associated with an increased infection rate was repeated cranioplasty procedures.

In a nonexperimental study, Wui et al¹⁶ stated that cranial bone flaps were kept for 6 months then discarded due to concerns about the viability of bone after deep freezer preservation. Bhaskar et al¹⁴ conducted a quasi-experimental study and concluded that replantation of cranial bone flaps after 6 months of storage should be discouraged unless there are exceptional circumstances.

There is also conflicting evidence on how storage duration of cryopreserved cranial bone flaps affects the risk of cranial bone flap resorption in children younger than 18 years of age. In a nonexperimental study, Piedra et al³⁷ found that children younger than 18 years were at a higher risk for bone flap resorption when the cranioplasty was performed after 6 weeks. Conversely, Bowers et al³⁸ conducted a nonexperimental study on pediatric patients younger than 16 years and did not find an association between the duration of the time in the freezer and bone flap resorption.

In a nonexperimental study, Chan et al³³ evaluated contamination rates by the duration of storage and size of 18 cranial bone flaps. Although the study sample was too small to reach statistical significance, the researchers concluded that longer storage durations for cranial bone flaps may increase the risk for contamination. Contaminated cranial bone flaps had been stored for a mean duration of 32.9 months ± 15.1 months, whereas bone flaps free of contamination had been stored for a shorter mean duration of 19.9 months ± 17.9 months. Additionally, the mean size of the infected bone flaps was considerably larger than the size of noninfected bone flaps. The infected bone flaps had a mean size of 117.7 cm² ± 44.96 cm² compared to uninfected bone flaps that had a mean size of 76.8 cm² ± 50.24 cm².

2.5 No recommendation can be made regarding the use of **cryoprotectants** or storage solutions for cranial bone flaps that are cryopreserved. [No Recommendation]

The balance between the benefits and harms of using cryoprotectants or storage solution is unclear. The benefits of cryoprotectants may include protection of the tissue while in deep frozen cryopreservation temperatures (eg, -80° C to -196° C [-112° F to -320.8° F]).³⁹ The harms may include incomplete removal of the cryoprotectant before reimplantation, which may increase the risk of exposing the patient to chemicals or solutions and potential loss of cell viability from intracellular ice formation or recrystallization.³⁹

The following cryoprotectants and solutions were used in studies of cryopreservation of cranial bone flaps with varying results:

- dimethyl sulfoxide,⁸
- 20% glycerol solution,⁴⁰
- povidone iodine,⁴¹ and
- 100% ethanol.⁴²

Several studies reported positive patient outcomes from cryopreservation of cranial bone flaps without cryoprotectants.^{5,6,27,28} No studies were found that specifically compared the use of cryoprotectants versus no cryoprotectants on cell viability or patient outcomes.

2.6 Determine a method for preparing frozen or cryopreserved cranial bone flaps for replantation, which may include

- retrieving the bone flap after the patient is in the OR and the surgeon has confirmed that it will be replanted^{29,32};
- thawing the bone flap in the sterile package at OR room temperature^{11,19,27,29,32,33};
- removing the bone flap from the packaging as close to the time of use as possible²⁷;

- thawing the bone flap in warm solution⁴¹;
- wiping the bone flap of excess dust, soft tissue, and loose fragments^{8,27}; and
- immersing, washing, or rinsing the bone flap in a solution (eg, normal saline solution, Ringer's solution, povidone iodine, a mixture of a solution and antibiotics or povidone iodine).^{8,11,17,19,27,29-31}

[Conditional Recommendation]

Although no studies were found that investigated the effect of cranial bone flap thawing and preparation methods on patient outcomes, several researchers reported thawing and preparation procedures in the description of their study methodology. Bhaskar et al¹⁷ found that 68% of 25 major neurosurgical facilities surveyed in Australia did not have a specific procedure or instructions for thawing autologous cranial bone flaps.

2.7 Cultures may be used to screen for microbial contamination of the cranial bone flap when clinically indicated. [Conditional Recommendation]

The benefits of microbial culturing of the cranial bone flap when a patient presents with clinical signs and symptoms of infection may outweigh the harms. However, implementing routine cultures of cranial bone flaps prior to preservation may not provide an accurate indication of infection risk after a cranioplasty procedure.

Moderate-quality evidence varies on the use of culture results as a predictor of microbial contamination of cranial bone flaps and postoperative infection. In nonexperimental studies, Cheng et al⁴³ and Morton et al³⁶ found that bacteria on the cranial bone flap prior to preservation were different from the type of bacteria that cause SSIs.

Cheng et al⁴³ found no statistical association between positive or negative bone flap culture results and SSIs. This led the researchers to conclude that a negative culture result does not guarantee that there will be no infection, and conversely, a positive culture result is not predictive of a cranial bone flap infection. Cheng et al found that the use of cultures was not a cost-effective method for preventing infection. They recommended that cranial bone flap cultures only be performed in patients with a confirmed infection after craniectomy procedures.

Morton et al³⁶ also recommended against performing routine microbial cultures when there are no clinical indications of infection at the time of craniectomy since the results are not a useful predictor of cranioplasty infection rates. Additionally, they reported that routine discarding of the cranial bone flaps because of positive culture results led to an increased use of synthetic prostheses, which increased health care costs.

In a nonexperimental study, Cho et al¹⁵ did not find bacterial growth on bone flaps (n = 47) that had been cryopreserved for an average of 83.2 months. In another nonexperimental study, Elwatidy et al¹³ reported no microbial contamination of cranial bone flaps (n = 14) cryopreserved for a mean of 313 days. Conversely, Chan et al³³ found a 27.8% contamination rate for 18 cranial bone flaps that had been in cryopreservation and were removed for microbial culturing. Although the study sample was too small to reach statistical significance, the researchers concluded that cranial bone flaps that are larger in size and stored for longer durations may be more susceptible to contamination.³³

In a nonexperimental study, Piitulainen et al⁴⁴ reported that any bone flap found to have a positive culture was discarded but also reported that of patients who had cranial bone flaps replanted (N = 20), 40% subsequently had the bone flap removed because of either infection (25%) or resorption (15%).

Herteleer et al³¹ conducted a nonexperimental study comparing two protocols for bone flap preparation, one that included microbial culture screening and one that did not. In the culture screening protocol, cranial bone flaps with a positive culture were radiated and then cryopreserved again at -80° C (-112° F). Of the bone flaps that had microbial cultures taken, 36.8% (n = 14) were found to be contaminated and were radiated. It is unclear whether the bones were removed from sterile packaging for the radiation. The researchers reported that there were slightly lower complication rates for cranial bone flaps that had microbial cultures taken; however, the result was not statistically significant.

2.7.1

Select the microbial culturing method (eg, swab, liquid, sponge) in collaboration with the surgeon(s), infection preventionist, and laboratory personnel. [Recommendation]

Moderate-quality evidence exists on the effectiveness of different culturing methods.⁴⁵⁻⁴⁷ Ronholdt and Bogdanský⁴⁵ conducted an RCT to compare two different culture swab products using the traditional method of swabbing. The method included swabbing the tissue in a “zig-zag” pattern to ensure that the greatest surface area of the allograft was swabbed. Both swab culturing systems tested exhibited low and variable microorganism recovery from allograft tissues. However, the researchers noted that moist swabs were more likely to capture and retain microorganisms than dry swabs.

In a nonexperimental study by Dennis et al⁴⁶ and a quasi-experimental study by Nguyen et al,⁴⁷ the researchers found that other methods of

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culturing (ie, liquid cultures, sponge cultures) had higher levels of efficacy than traditional methods of culture swabbing. Dennis et al⁴⁶ compared swabbing cultures to liquid cultures obtained by immersing the tissue in 4,000 mL of sterile normal saline solution for 10 minutes, shaking the tissue for 1 minute, then injecting 10 mL of the rinse solution into a culture medium. The results showed that the swab method detected only 20% of organisms while the liquid culture method detected 90%. Nguyen et al⁴⁷ found that a 4 cm x 8 cm sponge that was cut, moistened with 20 mL of sterile saline, and then rubbed on the tissue prior to placement in a specimen container inoculated with thioglycolate had a sensitivity and negative predictive value of 100%.

2.7.2

When obtaining and performing cultures,

- collect the sample before the tissue is treated with antibiotics or cleansing agents,
- test for aerobic and anaerobic bacteria, and
- perform the test in a laboratory that is either certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88)⁴⁸ or another laboratory-accrediting organization that has deemed status for CLIA-88.³⁴

[Recommendation]

Using antibiotics or other cleansing agents before obtaining the culture may inhibit the detection of viable organisms and may produce a false-negative culture result. Using a certified laboratory for microbiologic culture testing is an AATB standard.³⁴

2.7.3

When the culture results are available, consult with the surgeon to determine whether the **autograft** may be placed on the sterile field.

[Recommendation]

2.7.4

Provide education and competency verification for personnel who perform microbial tissue culturing. [Recommendation]

Microbial culture results are important in determining effective and directed antibiotic therapy for prevention or treatment of patient infections. However, swab cultures may be prone to error as a result of variation in the way that the swab is manipulated. The ability of the swab to recover microorganisms is dependent on the ability to pick up viable microorganisms from the surface of the item being swabbed and to release those microorganisms from the swab into the cul-

ture medium.⁴⁵ The swab tip may be relatively small compared to the surface area of the autograft.⁴⁷ A small amount of bioburden reduces the potential for the swab to collect all microorganisms on the surface.⁴⁷ In addition, some microorganisms that are collected may become trapped in the matrix of the swab itself and thus not transferred to the culture medium and not detected.

2.8

Determine a process for reducing the risk of dropping or contaminating a cranial bone flap, which may include

- stabilizing the bone flap during elevation, replantation, or drilling processes^{49,50};
- holding a sterile container or sterile bag below the bone flap elevation and insertion site⁵⁰;
- designating an area on the sterile instrument table with a sterile towel, drilling tools, implants, and a toothed instrument (eg, Kocher forceps) or a radiopaque gauze sponge (eg, laparotomy sponge) for holding the bone flap steady while drilling⁴⁹;
- having the person who removed the bone flap place it on the instrument back table⁵⁰; and
- transferring the bone flap in a container when moving it from the surgical incision site to the instrument table.

[Conditional Recommendation]

Moderate-quality evidence indicates the rates of occurrence and reasons for dropped cranial bone flaps.^{49,50} Two nonexperimental studies showed that occurrences of dropped cranial bone flaps are low, around 0.3%.^{49,50} However, Jankowitz and Kondziolka⁵⁰ reported that 66% (n = 33) of neurosurgeons surveyed had experienced a dropped bone flap and that 83% (n = 45) would replant the bone flap after it was disinfected.⁵⁰ Bone flaps were dropped during the following events:

- bone flap elevation,^{49,50}
- moving of the bone flap from the surgical site to the sterile table,⁵⁰
- bone flap insertion,⁴⁹ and
- placement of implants in the bone flap on the sterile table.^{49,50}

2.9

In collaboration with the surgeon(s) and an infection preventionist, select a mechanical method (eg, scrubbing, low-pressure **pulsatile lavage** of 6 pounds per square inch [PSI] to 14 PSI, tissue bank decontamination) for decontaminating contaminated cranial bone flaps for replantation.

[Recommendation]

Moderate-quality evidence shows that decontamination of bone has eliminated or reduced contamination⁵¹⁻⁵³ or infection rates,^{49,50,54} especially when

mechanical methods of decontamination (eg, scrubbing, low-pressure pulsatile lavage) were used.⁵²⁻⁵⁶

Cruz et al⁵⁴ found that when the contaminated bone was irrigated with 100 mL of any of the decontamination solutions used in the study (ie, normal saline solution, povidone-iodine solution, cefazolin 1 g/L), there was a significant reduction in infection rates.

Bruce et al⁵² found that soaking bone flaps for 5 or 10 minutes followed by mechanical scrubbing of the osteoarticular fragments with the bristles of a scrub brush resulted in no positive cultures regardless of which solution (ie, 0.9% normal saline solution, povidone iodine) was used for decontamination. However, when bulb syringe lavage was used, povidone iodine was effective in eliminating microbial contamination but normal saline solution was not.

Hirn et al⁵⁵ found a statistically significant reduction in contamination with the use of low-pressure pulsatile lavage with sterile saline solution compared to soaking in antibiotic solutions.

In two quasi-experimental studies, Bhandari et al^{53,57} found that the use of low-pressure pulsatile lavage (14 PSI) was effective in removing bacteria from bone,⁵³ whereas the use of high-pressure pulsatile lavage (70 PSI) was correlated to bone damage and seeding of bacterial contamination into a bone fracture near the site of the lavage.⁵⁷ It is important to note that there is some disagreement in the literature about whether decontamination processes need to eliminate all potentially infectious material⁵⁸ or just reduce bacterial contamination to noninfectious levels.^{50,54,55}

Four quasi-experimental studies evaluated the contamination levels of bone that had been on the floor for varying lengths of time, including 30 seconds, 1 minute, 5 minutes, or 60 minutes.^{51,52,54,55} Two of the studies found that contamination from the OR floor did not lead to significant rates of microbial contamination⁵¹ or infection⁵⁴ after the bone was decontaminated. Cruz et al⁵⁴ concluded that contact with the OR floor for 5 minutes did not correlate to levels of contamination that resulted in clinical infections. The researchers stated that contaminated bone flaps do not have to be discarded because decontamination through mechanical cleansing with any of the solutions used in the study would make the bone suitable for replantation.

Conversely, two of the studies reported higher levels of contamination from specimens that had been on the OR floor.^{52,55} However, these two studies had important differences in methodology compared to the other studies on OR floor contamination, including the type of specimen used⁵² and the length of time the specimen was on the floor.⁵⁵ Hirn et al⁵⁵ reported contamination rates of 55% and 73%

depending on the swabbing method used on bone that had been rubbed on the OR floor and left there for 60 minutes.

Two studies that reviewed rates of dropped bone flaps and subsequent methods of decontamination found that there were no infections in the postoperative follow-up period,^{49,50} which was as long as 20 to 44 months in one study.⁴⁹ In a nonexperimental study, Abdelfatah⁴⁹ found that 89.3% (n = 25) of the microbial cultures sent from the saline used during the initial rinse of the dropped cranial bone flaps were negative. In the remaining 10.7% (n = 3) of positive cultures, the patient's postoperative antibiotics were changed to cover the organisms identified in the culture.

The benefits of decontaminating contaminated cranial bone flaps that will be replanted exceed the harms. The benefits include reduction or elimination of potentially infectious material from the contaminated autologous bone flap, which may reduce the risk for infection. The harms associated with mechanical decontamination of contaminated cranial bone may include loss of cell viability.^{56,59}

2.9.1

The methods for decontaminating contaminated bone flaps may include

- a mechanical rinse with normal saline solution,⁵⁴
- soaking in normal saline solution for 5 minutes followed by a 1-minute mechanical scrub with the bristles of a scrub brush and normal saline solution,⁵²
- pulsatile lavage at low-pressure settings (eg, 6 PSI to 14 PSI) with normal saline solution,^{53,55} and
- processing at a tissue bank.

[Conditional Recommendation]

2.9.2

No recommendation can be made for the use of antiseptic (eg, povidone iodine) or antibiotic additives in irrigation solution used during decontamination of cranial bone flaps.

[No Recommendation]

It is unclear whether additional solutions are necessary for decontamination of contaminated cranial bone flaps when 0.9% normal saline solution is used with a mechanical method of decontamination.⁵³⁻⁵⁵ Additionally, the effect of povidone iodine and antibiotics on cell viability^{56,58,59} and the effectiveness of different solutions to decrease or eliminate microbial contamination of contaminated bone flaps^{18,52,53,55,56,58} is unclear.^{49,50,54}

Adding antiseptics or antibiotics to irrigation solution may be unnecessary and potentially harmful. Antiseptics and antibiotics may not

have been validated for use in irrigation solutions and may therefore pose a risk to the patient. Antiseptic solutions are intended for external use and may be ineffective or toxic when used internally. Facility antimicrobial stewardship programs may provide additional guidance on the best use of antibiotics for prevention of infection. Additionally, manufacturer's IFU clarify the intended use of the product and how to use the product for maximum effectiveness. For instance, the IFU of some antiseptic agents may specify a dry time. See the AORN Guideline for Sterile Technique⁶⁰ for additional guidance on the use of items not labeled as sterile (eg, antiseptic solution) or not packaged for sterile delivery to the sterile field (eg, vancomycin powder).

There is low-quality evidence on the effects of different solutions on decontamination of bone,^{18,52,53,55,56,58} infection rates,^{49,50,54} and cell viability.^{56,58,59} The evidence is limited because the researchers used varying methodologies and reported conflicting results.

Normal saline solution was used for bone decontamination in four quasi-experimental studies.⁵³⁻⁵⁶ One study showed that a 100-mL normal saline solution rinse prevented infection of bone in an animal model.⁵⁴ The other three studies showed that use of normal saline solution with low-pressure pulsatile lavage (6 PSI and 14 PSI) was effective in eliminating⁵³ or reducing microbial contamination.^{55,56} Bruce et al⁵² found that a 5-minute or 10-minute saline soak followed by a mechanical scrub with the bristles of a scrub brush and saline solution resulted in no positive cultures from contaminated osteoarticular bone fragments.

Povidone iodine was used for bone decontamination in five quasi-experimental studies^{52,54,56,58,59} and one nonexperimental study.⁵⁰ The use of a povidone-iodine solution rinse or irrigation was found to be effective for preventing infection^{50,54} and microbial growth.⁵² Yaman et al⁵⁸ found that povidone iodine can be used to effectively decontaminate bone without damaging the bone structure. Conversely, Kaysinger et al⁵⁹ found that the use of povidone-iodine solutions at concentrations typically found in the OR were **cytotoxic** to osteoblasts. Bhandari et al⁵⁶ found that povidone-iodine solution decreased the number of **osteoclasts** and impaired osteoblast function. In a quasi-experimental study, Lacey⁶¹ found that the antibacterial effect of povidone iodine was inactivated in the presence of significant amounts of hemoglobin and whole blood.

Various antibiotics were used for bone decontamination in five quasi-experimental studies.^{54-56,58,59} Cruz et al⁵⁴ found that rinsing bone flaps with 100 mL of cefazolin solution (1 g/L) prevented infection. Yaman et al⁵⁸ reported that immersion in cephalosporin sodium, neomycin with polymyxin, or rifampicin effectively decontaminated bone without damaging the bone structure. However, they also found that only rifampicin was effective in eliminating all bacterial contamination.⁵⁸ Conversely, Hirn et al⁵⁵ concluded that cephalosporins and rifampicin should not be used in decontamination of bone but have applications in preoperative prophylaxis and treatment of severe infections, respectively.

There were also conflicting results about the use of bacitracin. One study found that bacitracin solution was safe for use on bone and osteoblasts,⁵⁹ but another study reported that exposure to 2 minutes of low-pressure pulsatile lavage using bacitracin resulted in a 70% decrease in cell density and decreased the number of osteoblasts.⁵⁶ Other solutions studied for their effects on decontamination of bone include liquid soap solution⁵⁶ and combinations of solutions used in succession (eg, normal saline followed by povidone iodine then antibiotic solution).^{49,50,52,58}

2.9.3

Do not use hydrogen peroxide (H₂O₂), chlorhexidine gluconate (CHG), or ethanol to decontaminate bone flaps. [Recommendation]

There is an increased risk of patient harm from either ineffective decontamination^{18,56,58} or cell toxicity^{56,59} when H₂O₂, CHG, or ethanol are used for decontaminating bone.

Hydrogen peroxide solution was used for bone decontamination in three quasi-experimental studies and one experimental study. Jankowitz and Kondziolka⁵⁰ reported no incidents of infection in the follow-up period, which varied from 2 months to 176 months. However, this retrospective review of 14 dropped bone flaps only included one bone flap that was soaked in povidone iodine and then H₂O₂ solution. Two studies showed that H₂O₂ solution was either not effective for bacterial disinfection⁵⁸ or was not effective against all bacterial contamination used in the study.¹⁸ Kaysinger et al⁵⁹ reported that concentrations of H₂O₂ typically used in the OR setting caused toxicity in bone.

Quasi-experimental studies have found CHG to be effective⁵² and ineffective^{56,58} for decontaminating contaminated bone grafts, and CHG has also been found to be toxic to bone cells, even at very low concentrations (ie, 1%).⁵⁶ Bhandari et al⁵⁶

found that ethanol was toxic to osteoblasts and that 2 minutes of exposure to low-pressure pulsatile lavage using ethanol decreased cell density.

2.9.4

When decontaminating a contaminated cranial bone flap,

- use a separate sterile field for decontamination of the flap⁶⁰;
- use interventions to prevent contamination of the sterile field during decontamination (eg, covering the main sterile field, covering the active hand piece of the pulsatile lavage)⁶⁰;
- change gown and gloves after decontamination is complete⁶⁰;
- change the wound classification to Class III, Contaminated⁶⁰; and
- conduct a debriefing session with the team members involved to determine the root cause of the event and interventions to prevent another occurrence.

[Recommendation]

Creating and using a separate sterile field for decontamination of a cranial bone flap reduces the risk of contaminating the main sterile field. The use of pulsatile lavage can cause splash, splatter, and spray.⁶⁰ Interventions to minimize the effect of contaminated spray from the use of pulsatile lavage are detailed in the AORN Guideline for Sterile Technique.⁶⁰ Changing the gown and gloves after decontamination helps prevent the transfer of contaminants to the main sterile table.⁶⁰

Replantation of a contaminated autograft constitutes a major break in sterile technique. According to the Centers for Disease Control and Prevention (CDC) surgical wound classification system, a surgical wound with a major break in sterile technique is classified as Class III, Contaminated.⁶²

Debriefing with the perioperative team after an event has occurred may help prevent future incidents by examining underlying factors and system flaws that may have contributed to the event.

2.9.5

Do not use sterilization to decontaminate cranial bone flaps. [Recommendation]

Tissue sterilization is only allowed when a facility or health care organization is registered with the FDA as a tissue establishment (See Recommendation 1.2).¹

The benefits of sterilizing cranial bone flaps for the purposes of decontamination do not outweigh the harms. The benefits include the

potential for reduced microbial load,¹⁸ but exposure to the OR floor may not be a significant source of contamination⁵¹ and other methods of decontamination besides sterilization have been shown to be effective.^{49,50,54} The harms include an increased risk for SSI.^{16,42}

Moderate-quality evidence exists on steam sterilization as a method for decontaminating cranial bone flaps.^{16,18,42} In a quasi-experimental study, Schültke et al¹⁸ found that sterilization at 75° C (167° F) for 20 minutes was the only method that eradicated all the bacteria from cranial bone flap pieces that had been purposefully contaminated. However, Wui et al¹⁶ found that sterilization after cryopreservation significantly increased the patient's risk for SSI. In a nonexperimental study, Matsuno et al⁴² found a significantly higher rate of infection in patients for whom sterilized autologous bone or skull defect treated with polymethyl methacrylate was used during the cranioplasty procedure.

Sterilization was reported as a method for decontamination in two surveys on decontamination of dropped cranial bone flaps.^{49,50} In both surveys, respondents reported soaking bone flaps in various solutions as the more prevalent method of decontamination. The total number of sterilized bone flaps between both surveys was 12. Neither study reported infections in the follow-up period, which in one survey was only 2 months. No information was provided on the sterilization parameters used.^{49,50}

Yaman et al⁵⁸ reviewed the histological effects of steam sterilization on bone and found increased infiltration of lymphocytes, irregularity of blood vessels, and edema causing necrosis in the Haversian canals.

2.10

No recommendation can be made regarding sterilization of cranial bone flaps for the purpose of preservation. [No Recommendation]

Tissue sterilization is only allowed when a facility or health care organization is registered with the FDA as a tissue establishment (See Recommendation 1.2).¹

Low-quality evidence varies on sterilization of cranial bone flaps as a preservation method.^{23,63-66} All of the studies used different methodologies (eg, type of sterilization, preparation of the bone for sterilization, storage after sterilization, use of a second sterilization prior to replantation) and had varying results. The inconsistency between the study methodologies and the results prevent a clear understanding of the risks and benefits of sterilization as a method for preservation. The harms associated with sterilization of cranial bone flaps are

bone flap resorption^{23,64} and the potential for SSI after storage longer than 10 months.⁶⁶ Further research is needed.

Anto et al⁶³ and Mracek et al⁶⁴ conducted non-experimental studies on the use of steam sterilization as a method of preservation. Anto et al⁶³ exposed cranial bone flaps to sterilization at 132° C (269.6° F) for 20 minutes then stored them at ambient temperatures in a cupboard. On the day of the scheduled cranioplasty, the cranial bone flaps were sterilized a second time. The researchers reported that complications occurred in 10 of the 72 patients (13.9%). Five patients had bone fracture or fragmentation, four patients had osteomyelitis, and one patient had bone resorption. The researchers concluded that the use of steam sterilization for bone flap preservation had good outcomes but required further study.

Conversely, Mracek et al⁶⁴ cleaned the bone flaps, boiled the flaps in distilled water for 30 minutes, and then sterilized the bone flaps at 121° C (249.8° F) for 20 minutes prior to storage in a refrigerator at 8° C (46.4° F). If the bone flap had been stored longer than 3 months, the bone flap was sterilized again prior to cranioplasty. The researchers reported that SSI occurred in 3.3% of patients (n = 5) and resorption occurred in 20% of patients (n = 22). They concluded that there was a low rate of SSI but a significant rate of bone resorption when this method was used.

A nonexperimental study by Jho et al⁶⁶ and quasi-experimental study by Missori et al⁶⁵ investigated ethylene oxide (EO) sterilization as a preservation method and found it to be safe and effective. Jho et al⁶⁶ reviewed the effect of EO sterilization and room temperature storage of cranial bone flaps on infection rates. Cranial bone flaps were replanted after an average of 4 months with a follow-up period averaging 14 months. The infection rate was 7.8% (n = 8). The researchers found that preservation beyond 10 months was significantly correlated to an increased risk for infection. This finding led the researchers to recommend that cranial bone flaps preserved after 10 months be discarded or sterilized a second time.

Missori et al⁶⁵ compared EO sterilization, steam sterilization at 121° C (249.8° F) for 45 minutes, and H₂O₂ gas plasma sterilization methods. Cranial bone flaps were replanted after a mean of 10 weeks with an average follow-up period for the EO sterilization group of 42 months. The infection rate was 2% (n = 1), with the only infection in the study occurring in the EO group. The researchers also described one case of partial bone resorption in a child from the EO sterilization group.

Neither study discussed precautions (eg, aeration time) used to mitigate any potential patient risks from

EO sterilization. The harms of using EO sterilization methods are unknown. Ethylene oxide is a known human carcinogen, with a half-life of 69 to 149 days, that may damage the central nervous system.⁵⁷

Kim et al²³ conducted a nonexperimental study of the infection and bone resorption rates for cranioplasty patients, using cranial bone flaps that had been sterilized with low-temperature H₂O₂ gas plasma as a preservation method compared to the use of polymethyl methacrylate used during the cranioplasty. The follow-up period was at least 1 year but averaged 15 months. To prepare the cranial bone flap for preservation, the bone flap was first cleaned of soft tissue then placed in a sterile drier at between 110° C and 120° C (230° F and 248° F) for 24 to 48 hours. Then the bone flap was placed in a low-temperature H₂O₂ gas plasma sterilizer at 70° C (158° F) for 75 minutes. After sterilization, the bone flap was placed in two layers of sterile bags and stored in a refrigerator at 8° C (46.4° F). Prior to replantation, the bone flap was sterilized a second time using the same method. The researchers found that use of the sterilized bone resulted in significant rates of bone flap resorption compared to the use of polymethyl methacrylate.

3. Parathyroid Tissue

3.1 Parathyroid tissue may be cryopreserved and autotransplanted. [Conditional Recommendation]

The benefits of parathyroid tissue cryopreservation are likely to exceed the harms. A benefit of cryopreserving autologous parathyroid tissue is having tissue available for patients who develop permanent hypoparathyroidism.⁶⁸⁻⁷² Permanent hypoparathyroidism is a serious condition that decreases quality of life⁶⁹ and increases risk of morbidity^{69,73} but has limited treatment options.^{69,74,75} Patients with permanent hypoparathyroidism can develop paresthesia⁷⁴ and adynamic bone disease^{69,71,76} that requires life-long serum monitoring and dependence on supplements.^{72,74,75} The harms of cryopreserving parathyroid tissue include the potential for reduced cell viability,^{70,73,77,78} risk of decreased graft success,⁷¹ limited space at facilities that store cryopreserved tissue,⁷⁴ and increased cost.^{69,74}

Low-quality evidence supports cryopreservation of parathyroid tissue.^{68-75,77,78} The evidence is limited due to the small sample size of most of the available studies.^{68,69,71-73,77,78} Although several studies have shown that cryopreservation of parathyroid tissue may reduce cell viability^{70,73,77,78} or potentially decrease graft success,⁷¹ the same studies still support its use with additional recommendations,^{70,71,73,77,78} including autotransplantation of additional tissue^{70,73} and tissue viability testing.^{73,77,78} Researchers in two

studies recommended autotransplantation of additional amounts of parathyroid tissue to increase the probability of a functioning graft.^{70,73}

Several studies discussed low rates of cryopreserved parathyroid tissue use and associated costs.^{59,71,75} In a nonexperimental study, Cohen et al⁷¹ reported that 448 parathyroid tissue samples from 436 patients were cryopreserved, but only 29 of the patients underwent autotransplantation procedures (6.6%). In a high-quality organizational experience article, Agarwal et al⁷⁵ stated that the cryopreservation rate of parathyroid tissue from more than 2,000 parathyroid procedures was 31% but that only 1.5% of samples were subsequently autotransplanted. In a nonexperimental study, Guerrero et al⁷⁴ noted that 501 specimens were cryopreserved from 149 patients during a 15-year period and that the facility was experiencing a surplus of cryopreserved parathyroid tissue at the storage facility. Conversely, Agarwal et al⁷⁵ stated that space and cost requirements were minimal. Guerrero et al⁷⁴ also stated that cryopreservation processing and storage uses multiple resources and is costly. Barreira et al⁷⁶ concurred that the special laboratory needed for cryopreservation may have high assembly and maintenance costs.

Because of the lifelong consequences of permanent hypoparathyroidism, Cohen et al⁷¹ recommended cryopreservation of parathyroid tissue, regardless of the associated costs, as a treatment option for patients who do not respond to immediate autotransplantation. Agarwal et al⁷⁵ noted that parathyroid tissue cryopreservation, preparation, and storage fees have specific billing codes that can be used for facility reimbursement, but that patients at their facility are not billed beyond 2 years of storage.

3.2 Parathyroid tissue may be prepared in the OR for cryopreservation by

- placing the tissue in enough cold sterile 0.9% normal saline solution^{69,71-75,78} or cold Roswell Park Memorial Institute (RPMI)-1640 medium^{68,72} to cover the tissue;
- placing the specimen cup⁷⁴ on sterile ice^{68,70,71} and covering it to prevent airborne contamination^{60,79,80};
- dividing tissue into 1 x 1 x 1 mm or 2 x 2 x 2 mm pieces^{68-75,77,78};
- sending a small portion of the specimen for a frozen section to confirm the tissue type, if requested by the surgeon^{69,75,80};
- collecting 5 mL to 10 mL of the patient's blood into a tube with no additives to be sent with the tissue, if requested by the surgeon^{71,75};
- transporting the prepared tissue as soon as possible⁷⁵ in an enclosed and labeled container

(eg, specimen cup,⁷⁴ tuberculosis syringe,⁷⁵ cryovials⁷⁵) within a biohazard-marked specimen bag on ice with required, completed, facility documentation⁷⁵ to an accredited clinical laboratory for cryopreservation^{68,69,75,76,79,81}; and

- alerting the clinical laboratory when the tissue for cryopreservation is en route.

[Conditional Recommendation]

3.3 If temporary storage or transport of parathyroid tissue is necessary before cryopreservation, determine the method of preservation, temperature, and duration of storage. [Conditional Recommendation]

Some facilities may need to temporarily store⁷⁹ or transport parathyroid tissue before cryopreservation because the facility does not have personnel immediately available or does not have laboratory specializing in cryopreservation on site.⁷⁶ However, the ideal method of preserving parathyroid cell viability before cryopreservation is unknown because of limited and low-quality evidence on the subject.

In a quasi-experimental study, Barreira et al⁷⁶ compared the effects of refrigerated storage at 4° C (39.2° F) for different time intervals on the structural integrity of parathyroid tissue (N = 11). The parathyroid tissue was stored in a cell culture medium that included **Dulbecco's modified Eagle's medium** (DMEM), streptomycin 500 µg/mL, ampicillin 500 µg/mL, amphotericin B 3 mg/mL, and 25 mM of a buffering solution. Parathyroid tissue stored in the cell culture medium at 4° C (39.2° F) was found to be viable for as long as 12 hours. However, the researchers also found that all the samples had at least one structural change after 24 hours in refrigerated storage.

One quasi-experimental study⁷⁷ and two organizational experience articles^{75,79} also described temporary storage of parathyroid tissue. Alvarez-Hernandez et al⁷⁷ stated that specimens were stored at 4° C (39.2° F) in RPMI medium for 16 to 20 hours prior to experimentation. Stotler et al⁷⁹ reported that part of the institutional process of parathyroid tissue preservation included either same-day cryopreservation or refrigerated storage overnight at 4° C (39.2° F). Agarwal et al⁷⁵ stated that specimens were occasionally placed in refrigerated storage between 2° C and 8° C (35.6° F and 46.4° F) if processing was delayed.

3.4 Determine the maximum storage duration for cryopreservation of parathyroid tissue based on tissue viability and patient-specific needs. [Recommendation]

The balance between the benefits and harms of storing cryopreserved parathyroid tissue longer than 24 months is unclear. A benefit of storing cryopreserved parathyroid tissue longer than 24 months

is that a very small number of patients may develop delayed symptoms related to parathyroid hormone deficiency⁶⁹ and have limited treatment options.⁷⁵ Conversely, cryopreservation of parathyroid glands may affect the viability of the tissue or graft success rates. There may also be facility limitations including costs or storage availability.⁷⁴

Low-quality evidence on the duration of cryopreserved parathyroid tissue in relation to cell viability^{68,70,74,77,78} or patient outcomes^{69,71,72,75,81,82} is limited due to small sample sizes, varying methodologies, and conflicting results. Four quasi-experimental^{68,70,77,78} and four nonexperimental^{69,71,72,74} studies supported a duration of cryopreservation between 6.66 months and less than 24 months. However, Schneider et al⁶⁹ reported that four of the 15 patients (26.6%) in a non-experimental study had autotransplant procedures more than 2 years after the initial procedure. Additionally, two case reports described positive patient outcomes (eg, elevated parathyroid hormone, reversed hypoparathyroidism) after 30 months and 36 months.^{81,82} The author of an organizational experience article stated that the facility stored cryopreserved parathyroid tissue longer than 24 months due to the available space, low cost of storage, and the lack of treatment options for patients.⁷⁵

Specific findings of the studies conflict. Two quasi-experimental studies found no significant difference between fresh parathyroid tissue and cryopreserved parathyroid tissue regardless of storage duration.^{68,77} Three studies did not find a correlation between cell viability^{70,78} or patient outcomes⁷² and the duration of cryopreservation. Conversely, Cohen et al⁷¹ found a significant difference between the cryopreservation storage duration of functional and nonfunctional grafts. The mean cryopreservation period was 7.9 months for functional grafts and 15.3 months for nonfunctional grafts.⁷¹ The researchers concluded that the duration of cryopreservation was a significant predictor of graft failure.⁷¹ Two studies stated that even though cryopreservation was not found to be detrimental to the tissue, the process of freezing or thawing may be.^{70,72}

Guerrero et al⁷⁴ concluded that facilities would benefit from challenging the idea of storing cryopreserved parathyroid tissue indefinitely. They recommended that facilities establish a maximum period of preservation that balances the considerations of tissue viability, storage ability, and cost.

4. Skin

4.1 Autologous skin may be preserved and autotransplanted. *[Conditional Recommendation]*

The benefits of storing autologous skin (eg, split-thickness skin grafts) for delayed autotransplantation

may exceed the harms (**Figure 1**). The benefits include minimizing the area of the donor site needed,⁸³ the potential elimination of a secondary donor site,⁸⁴ and cost efficiency.^{83,85,86} The harms may include reduced graft success rates due to decreased skin viability over time⁸⁷⁻⁸⁹ and risk for infection from contaminated skin grafts.^{90,91}

Moderate-quality evidence indicates that preserved skin is viable, but the viability declines during the duration of storage.⁸⁷⁻⁸⁹ Therefore, most of the available research on autologous skin seeks to determine which variables (eg, medium) may extend storage duration while optimizing graft success rates or some aspect of skin cell viability.^{85-89,91,92} Five quasi-experimental studies^{85-88,91} and four nonexperimental studies^{83,84,89,90} compared the effect of tissue preservation on graft success rates or different aspects of skin cell viability. The evidence is limited by

- the small number of high-quality studies conducted on this practice issue,
- the small sample sizes of the studies,^{83,84,86-89,91-93}
- missing information in the study methodology descriptions (eg, graft preparation, temperature, storage duration),^{84,89,90,93}
- differences between the study methodology and how autologous skin is prepared in clinical practice (eg, not meshed, skin biopsies used),^{83-87,93} and
- variable results in studies that investigated the same outcome (ie, graft success rates, skin viability).

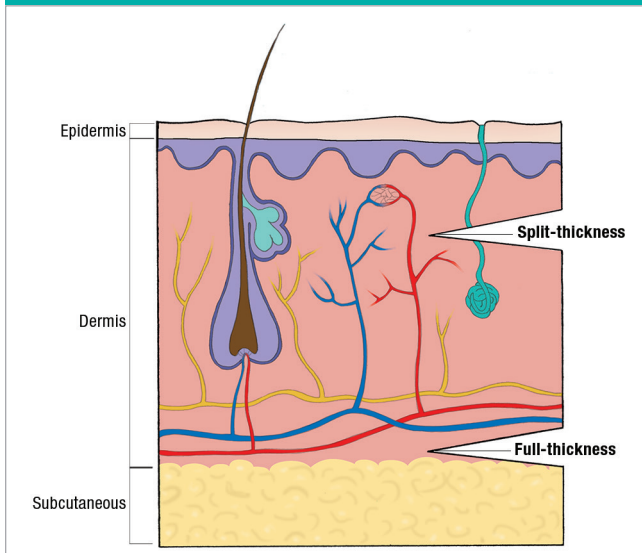
Further research is needed to examine how skin viability after preservation affects the clinical outcomes of graft success rates in humans.

4.2 No recommendation can be made regarding meshing skin prior to preservation. *[No Recommendation]*

The balance between the benefits and harms of meshing the skin is unclear. Meshing the skin allows the skin graft to stretch and cover a larger area. Meshing the skin during the initial procedure when it is harvested may reduce time during a subsequent procedure. However, meshing the skin exposes it to mechanical trauma that may compromise cellular function,⁸⁸ which may affect clinical outcomes.

Moderate-quality evidence conflicts regarding meshing the skin prior to preservation. A quasi-experimental study that reviewed graft success rates of preserved and transplanted skin in an animal model found that the results for skin meshed before preservation were not significantly different from those for nonmeshed skin.⁹² Two quasi-experimental studies compared the effects of meshing split-thickness skin grafts on different aspects of skin cell viability after preservation.^{88,91} Li et al⁹¹ found decreases in cell viability of **meshed skin** over the duration of storage time.

Figure 1. Split-Thickness and Full-Thickness Skin Grafts



A split-thickness skin graft includes the epidermis and part of the dermis. A full-thickness skin graft includes the epidermis and all of the dermis.

Illustration by Kurt Jones.

These findings led the researchers to recommend using meshed skin within 7 days of harvesting.

Sterne et al⁸⁸ found that meshed skin had initial swelling and pleomorphism that subsided by the 21st day of storage. However, the researchers suggested that after 3 weeks of preservation, the rates of successful skin grafts would be severely diminished. The study results also showed that meshed skin had more shrinkage and epidermal clefting, which predisposed the meshed skin to more deterioration than nonmeshed skin. The researchers recommended not meshing the skin and storing it in a roll.

No studies were found in which the results of graft success rates for skin meshed before and after preservation were compared. Further research is needed.

4.3 Determine a method of preparing the skin for preservation, which may include

- placing the epithelial side of the graft down⁸⁸ onto a sheet of **tulle gras**,^{88,90}
- folding the graft in half dermis-to-dermis^{83,88,90} then rolling it,^{83,88}
- wrapping the graft in saline moistened gauze,^{83,86-91} and
- placing the wrapped tissue into a sterile container.^{88,91}

[Conditional Recommendation]

Low-quality evidence indicates that the viability of preserved skin was improved when the tissue was rolled during storage. In a quasi-experimental study, Sterne et al⁸⁸ reviewed the histological changes in split-thickness skin grafts from meshing and graft configuration during storage. The skin

was stored either rolled or flat and wrapped in saline-soaked gauze sponges for a 4-week period. The researchers found that both rolled nonmeshed skin and rolled meshed skin had less shrinkage in the later weeks of storage and had less clefting between the dermis and epidermis than the skin that was stored flat. The researchers thought that rolling the skin might reduce moisture loss during the storage period. They concluded that the viability of the stored grafts was greatest when the grafts were stored as an unmeshed roll at 4° C (39.2° F) for fewer than 7 days. Further research is needed.

4.4 Preserve autologous skin by refrigeration at 4° C (39.2° F). **[Recommendation]**

The benefits of skin preservation exceed the potential for patient harm and have been found to be cost efficient.⁸⁵

Moderate-quality evidence consistently shows that skin viability is preserved when autologous skin is stored at 4° C (39.2° F) for varying durations.⁸⁵⁻⁹¹ However, the evidence is limited because the methodology, medium used, storage duration, and conclusions were highly varied between studies. It is important to note that while stored skin remains viable for a period of time, at some point, the viability of the preserved skin diminishes.^{87,88,90,91} Diminished skin viability may increase the rate of failed skin grafts in patients.⁸⁹ The AATB recommends that skin be preserved by refrigeration above freezing to 10° C (50° F) or by freezing or cryopreservation at -40° C (-40° F) or colder.³⁴

In a nonexperimental study, Titley et al⁹⁰ investigated bacterial contamination and rates of graft success in eight patients and found that the skin of all eight patients was contaminated at the time of recovery. Interestingly, the researchers noted that except for *Acinetobacter* organisms, the other bacteria found in the study would not replicate in temperatures below 4° C (39.2° F).

4.5 In collaboration with the surgeon(s), an infection preventionist, and a pharmacist, determine which **storage medium** or solution will be used and if antibiotics will be added. **[Recommendation]**

4.5.1 Store skin in a storage medium or normal saline solution. **[Recommendation]**

The benefits of using a storage medium or solution, including retained pliability of the skin, exceed the harms, which may include loss of moisture.

High-quality evidence shows that normal saline solution was inferior to other storage media with which it was compared.^{85-87,91} Storage

media reported in studies to be superior to normal saline solution for preservation include

- RPMI-1640 medium,⁸⁶
- RPMI-1640 medium with antibiotics,⁸⁷
- DMEM,⁹¹
- DMEM/Ham F12 (DMEM/F12, 3:1 mixture),⁹¹ and
- **McCoy's 5A medium**.⁸⁵

However, most researchers also found that normal saline solution is the most commonly used solution^{86-88,90,91} and that it demonstrated some preservation of skin viability for a period of time that was usually shorter than for other media.^{85,87,91}

Furthermore, in their nonexperimental study, Knapik et al⁸⁹ discussed the common practice of using normal saline as a storage solution and that the corresponding patient outcomes (ie, graft success rates) may be clinically acceptable. The researchers questioned whether the use of more expensive storage media is of clinical interest.

4.5.2

Determine whether antibiotics will be added to storage media or solutions based on the patient's allergies, manufacturer's IFU, and the facility antibacterial stewardship program (if applicable). *[Conditional Recommendation]*

Moderate-quality evidence demonstrates that storage of skin in media with antibacterial properties may be useful.^{90,91}

In a nonexperimental study, Titley et al⁹⁰ reviewed bacterial contamination rates of the skin at the moment of harvest and after 3 weeks of storage. Split-thickness skin grafts taken from patients were put on tulle gras and then wrapped in saline-moistened gauze prior to placement in a refrigerator. The preserved skin was grafted to 10 patients and data were available for eight patients. The researchers found that all eight skin grafts were contaminated at harvest with bacterial counts between 2.2×10^1 and 5.3×10^7 organisms per gram of skin and included seven different organisms. Of the eight grafts included in the study, three failed completely. The researchers found a significant correlation between lower numbers of organisms found on the skin at harvest and higher percentages of graft success rates. The researchers concluded that commonly used storage practices facilitate bacterial multiplication.

In a quasi-experimental study, Li et al⁹¹ compared meshed split-thickness skin grafts from surgical burn patients. The grafts were stored in different storage solutions and reviewed for cell viability and microbial contamination over 28

days. The researchers found that storage in DMEM or DMEM/Ham F12 was better than storage in normal saline solution or Hartman's solution. They also found microbial contamination in 43.3% (n = 13) of the skin samples stored in antibiotic-free media compared with only 10% (n = 3) of the samples stored in media with antibiotics. The researchers concluded that use of storage solutions with antimicrobial agents may help minimize the risk of contamination, especially from skin recovered from burn patients that may be prone to higher levels of contamination.

4.5.3

No recommendation can be made regarding changing storage solution or medium every 72 hours. *[No Recommendation]*

No evidence was found on the effectiveness of changing storage solutions or media for preserved skin. The benefits of changing the solutions are unknown and the harms could include an increased risk of contaminating the skin.

4.6

Determine the maximum storage duration for autologous split-thickness skin grafts. *[Recommendation]*

Moderate-quality evidence suggests varying lengths of time that skin may be stored at 4° C (39.2° F).⁸⁵⁻⁹¹ The evidence is limited because the studies used different storage media and varying techniques for assessing the viability of preserved skin. The researchers reported findings of acceptable storage durations between 7 days and 4 weeks, which were conditional based on the methods used in the research.^{85,88-91} Two of the studies did not report a cut-off point for when stored skin grafts may no longer be used.^{86,87} In a quasi-experimental study, Boekema et al⁸⁷ concluded that it was not possible to determine a cut-off point when split-thickness skin grafts could no longer be used because the decline in skin viability was gradual. The researchers also concluded that more research is needed to correlate viability of preserved skin to graft success rates in patients.⁸⁷ The AATB recommends that refrigerated autologous skin not be stored for longer than 14 days.³⁴

4.7

Split-thickness skin grafts procured during free flap procedures may be stored on the patient's donor site for delayed autotransplantation. *[Conditional Recommendation]*

The benefits of storing autologous split-thickness skin grafts at the donor site during free flap procedures are likely to exceed the harms. The benefits may include

- reduced surgical time,⁸³
- elimination of a second procedure,^{83,93}

- the ability to see the flap area during the immediate postoperative period,^{83,93}
- increased flap survival rates,⁹³
- no risk of a graft being placed on the wrong patient,^{83,93}
- reduced size of the skin graft required,^{83,93}
- decreased donor site morbidity,⁸³
- improved healing of the unused skin graft left at the donor site,⁸³
- decreased risk of scarring,⁸³
- increased patient satisfaction,⁸³
- elimination of biohazardous waste disposal,⁹³
- cost efficiency,^{83,93} and
- availability for all patients because refrigeration is unnecessary.⁹³

The harms associated with storing autologous split-thickness skin grafts at the donor site include harvesting a larger split-thickness skin graft than is needed because it can be hard to estimate the size of graft needed. Additional high-quality research is needed to clarify the risks and confirm the benefits of storing split-thickness skin grafts at the donor site for delayed autotransplantation.

Low-quality evidence supports storage of the patient's autologous skin at the donor site for delayed autotransplantation over a free flap site.^{83,93} One nonexperimental study⁸³ and one case report⁹³ discussed patient outcomes from storage of autologous skin at the donor site for delayed autotransplantation over the free flap site.

Ciudad et al⁸³ studied graft success rates from lymph node flap transfer procedures for grafts stored at the donor site in 10 patients. The bedside procedure to autotransplant the skin from the donor site to the recipient site was completed between the fourth and sixth postoperative day. The researchers reported that a single patient needed slightly more medication during the bedside graft transfer. There was a 100% flap survival rate and a 97% graft success rate. The researchers concluded that delayed skin grafting may reduce flap complications as well as decrease operative time and costs. A study limitation was that the researchers did not include patients with coagulopathy or diabetes mellitus.

Mardini et al⁹³ reviewed the clinical outcomes of initial free flap voice reconstruction procedures using skin grafts stored at the donor site in 10 patients. The bedside procedure was performed between 3 and 8 days after the initial procedure. The researchers stated that elevation of the stored graft was well tolerated. They reported 95% **engraftment** in all cases and that all the grafts healed completely during the 5- to 12-month follow-up period. The researchers concluded that storage of the skin autograft at the donor site for as long as 8 days was a reliable and cost-effective technique.⁹³

5. Vessels

5.1 Autologous vessels may be preserved and autotransplanted. [*Conditional Recommendation*]

The benefits of preserving autologous vessels are likely to exceed the harms. Preservation of remaining vessel segments results in the availability of autologous tissue during the initial recovery period when patients' vessels may occlude, requiring subsequent grafts.⁹⁴ Potential harms include occlusions in vascular grafts and subsequent graft failure.⁹⁴

Moderate-quality evidence supports the preservation of autologous veins for delayed autotransplantation.⁹⁴⁻⁹⁹ Two RCTs,^{96,98} three quasi-experimental studies,^{95,97,99} and one nonexperimental study⁹⁴ reviewed the effects of various storage solutions on veins or arteries for periods longer than several hours.

5.2 Store vessels submerged in a buffered storage solution or tissue culture medium between 2° C and 8° C (35.6° F and 46.4° F) for no longer than 14 days. [*Recommendation*]

Moderate-quality evidence addresses vessels stored at 4° C (39.2° F),^{94-96,98} at a range from 0° C to 4° C (32° F to 39.2° F),⁹⁷ and at 21° C (69.8° F).⁹⁹ Additionally, the Organ Procurement and Transplantation Network states that extra vessels that come packaged separately with organs for transplant may be stored between 2° C to 8° C (35.6° F to 46.4° F) in an FDA-approved preservation solution and destroyed within 14 days of the recovery date of the organ.¹⁰⁰

Two RCTs^{96,98} and four quasi-experimental studies^{94,95,97,99} reviewed the long-term effects of different storage solutions on vessels for preservation periods between 24 hours and 4 weeks. Several studies found that buffered solutions protect the endothelial cell lining⁹⁹ or maintain vessel function^{94,96-99} better than other solutions studied. A secondary finding was that storage in normal saline solution had an adverse effect on the endothelial lining of the vessel⁹⁹ or did not preserve vessel function^{94,96-99} compared to other solutions.

The specific period used for storage of vessels is dependent on the storage solution used. The evidence is limited due to the variability in the storage solutions studied, research methodologies, and reported results. The AATB recommends packaging allograft vascular tissue in **isotonic** sterile solution (eg, tissue culture media) but not normal saline solution.³⁴ Buffered solutions and media found to preserve vessels include

- **TiProtec** solution for 4 days⁹⁴ and 7 to 14 days⁹⁶;
- tissue culture medium for up to 4 weeks¹⁰¹;
- University of Wisconsin solution for 24 hours⁹⁸;

- GALA (glutathione, ascorbic acid, and L-arginine) solution for 24 hours⁹⁹; and
- N-acetyl histidine–buffered, potassium chloride–enriched, amino acid–fortified solution augmented with iron chelators deferoxamine and LK 614 for 4 days.⁹⁷

Harskamp et al¹⁰² conducted an RCT involving 107 US facilities and 3,014 patients to compare intraoperative preservation solutions used on veins of patients undergoing coronary artery bypass graft procedures. The study revealed that the highest percentage of patients (44%) had veins stored in saline solution for intraoperative preservation. However, the study results showed that intraoperative vein preservation in buffered saline solution resulted in significantly lower vein graft failure rates at the 1-year follow-up period and improved but nonsignificant long-term clinical outcomes (ie, lower death rates, fewer cases of myocardial infarction, greater revascularization) than veins stored in saline or blood-based solutions.

However, contrary to other study findings, in a quasi-experimental study, Ebner et al⁹⁵ investigated the effects of storage in TiProtec solution at 4° C (39.2° F) for 2 hours and for 2 days and found that storage for 2 days or longer significantly impaired vessel tone development. Importantly, the study also found significant molecular alteration in the vessels after storage for 2 hours. This was a central finding because changes at the molecular level were evident before functional vessel changes, and alterations at the molecular level may affect graft function. The researchers concluded that further study is needed to understand the effects of these findings on graft success rate outcomes in patients.

5.2.1

No recommendation can be made regarding changing storage solution or medium every 72 hours. [No Recommendation]

No evidence was found on the effectiveness of changing storage solutions or media for preserved veins. The benefits of changing the solutions are unknown and the harms could include an increased risk of contaminating the vessels.

5.3

No recommendation can be made regarding cryopreservation of vessels. [No Recommendation]

The balance between the benefits and harms of preserving autologous vessels through cryopreservation is unclear. Vessels may be damaged by cryopreservation,^{101,103} but vascular and cardiac patients who undergo multiple procedures may be more likely to have vessel disease that limits the number of vessels available for grafting¹⁰⁴ or may have vessels used during a previous procedure that could be cryopreserved for a future procedure as a method of

longer-term storage than refrigeration.¹⁰⁴ The AATB recommends freezing or cryopreserving allograft vascular tissue at -100° C (-148° F) or colder.³⁴

Low-quality evidence on cryopreservation of vessels includes one RCT,¹⁰¹ one experimental study,¹⁰³ and one case report.¹⁰⁴ The evidence is limited because of considerable variability between study methodologies (eg, type of vessels used, tests used for comparison) and reported results. The researchers found that cryopreserved vessels had a significant decrease in lumen size,¹⁰¹ a significant increase in vessel wall thickness,¹⁰¹ and increased vessel stiffness as duration of storage increased.¹⁰³ Conversely, the studies also reported that vessels retained elastic properties and some contractility,¹⁰¹ and that the mechanical properties of the vessels were similar before and after cryopreservation.¹⁰³

Chang et al¹⁰³ reported that atherosclerotic areas of the cryopreserved arteries were more likely to have fragmentation. The authors of a case report on three patients who had greater saphenous vein grafts using autologous cryopreserved vein segments reported that no occlusions or aneurysmal dilations were found during the follow-up period.¹⁰⁴ No studies were found that examined the effect of using cryopreserved vessels on rates of successful grafts in patients. Further research is needed.

5.4

No recommendation can be made regarding prewarming vessels before autotransplantation. [No Recommendation]

The balance between the benefits and harms of vessel prewarming is unclear because there is no research on the subject.

No studies were found that compared prewarming processes for vessels that had been in cold storage. Three moderate-quality studies reported vessel prewarming processes used in the study methodology.⁹⁵⁻⁹⁷ In all three studies, vessels were warmed to 37° C (98.6° F).⁹⁵⁻⁹⁷ The vessels were placed in physiological saline solution⁹⁶ or phosphate-buffered saline solution⁹⁵ for warming. The prewarming process took place within 1 hour⁹⁷ and more than 1.5 hours.⁹⁶

6. Femoral Head

6.1

No recommendation can be made regarding freezing or cryopreserving the autologous femoral head. [No recommendation]

No evidence was found on preservation of autologous femoral heads through cryopreservation or freezing. The benefits and risks of freezing or cryopreserving femoral heads are unknown. More research is needed.

6.2 The patient's femoral head may be preserved within an iliac pocket. *[Conditional Recommendation]*

The benefits of placing the femoral head from a total hip arthroplasty (THA) procedure into a newly created pocket in the patient's iliac area for preservation may exceed the harms. In a nonexperimental study, Shinar and Harris¹⁰⁵ reported that THA revision procedures were necessary in 60% of procedures using allograft tissue (n = 9 of 15) and 29% of procedures using autologous tissue (n = 16 of 55). Other sources agree that the use of autologous bone grafts is preferable to the use of allograft tissue.^{106,107}

The benefits include

- having autologous bone available for future use,¹⁰⁷ including if the patient moves out of the area¹⁰⁶;
- elimination of screening procedures, sterilization, risk of rejection,¹⁰⁶ storage facilities, and expenses associated with allograft bone use¹⁰⁷;
- cost effectiveness^{106,107};
- minimal time needed for the pocket creation procedure¹⁰⁷; and
- exposure of the iliac crest if additional autologous graft volume is needed.¹⁰⁶

The harms may include

- infection, incisional hernia, or discomfort at the pocket site¹⁰⁷;
- morbidity of the pouch site¹⁰⁶;
- damage to the lateral cutaneous nerve of the thigh¹⁰⁶;
- potential preservation of a femoral head with malignancy¹⁰⁶; and
- unnecessary storage of the femoral head if it is not used.

Low-quality evidence includes one organizational experience article¹⁰⁶ and one case report¹⁰⁷ that describe preservation of the femoral heads removed during THA procedures for use during future THA revision procedures. The femoral head was placed in an iliac pocket on the same side of the patient's body from which it was removed.^{106,107} The pouch was subperiosteal¹⁰⁶ or extraperiosteal with iliocapsular muscle preservation.¹⁰⁷

In an article by Hing et al,¹⁰⁶ patient selection criteria for femoral head preservation included a planned primary THA procedure for osteoarthritis and a previous THA procedure on the patient's other hip that had evidence of symptomatic loosening. The authors reported that the femoral head was cut in half and placed in the pocket with the cut surface closest to the iliac crest. Thirteen patients had the femoral head preserved in a pouch, and six of the patients had revision procedures using the preserved bone from 8 months to 8 years and 11 months after the preservation of the femoral head. The fem-

oral head was morselized during the revision procedure and used as bone graft.

Hing et al¹⁰⁶ found that after preservation, the bone was viable and not contaminated. They also reported that postoperative mobilization was the same as for patients who had a conventional primary THA procedure performed. There was no morbidity at the implant site in any patient. Interestingly, the authors found that tissue viability appeared to be related to the distance of the cut surface to the ilium, with the cartilage and bone furthest from the ilium showing some signs of necrosis. They concluded that preservation of the femoral head is a viable option for specific patients; however, further study is needed.

A 2014 case report by Mohan et al¹⁰⁷ included patients having either partial hip arthroplasty or THA procedures but not patients with suspected joint infection. They reported that femoral heads from 17 patients were preserved within iliac pouches from 2008 to 2012 but none had been used. There were no complications at the pocket site except for discomfort in the initial postoperative period that resolved over a few weeks. The authors stated that younger patients may have increased risk for revisions in the future.¹⁰⁷ A regression analysis performed by Shinar and Harris¹⁰⁵ also showed that a younger age at the time of surgery was one factor correlated with the need for revision procedures.

6.2.1

Preparation of the autologous femoral head may include

- rinsing thoroughly with sterile normal saline,¹⁰⁷
- wiping the surface,¹⁰⁷
- removing articular cartilage,¹⁰⁷
- removing periosteum from the neck,¹⁰⁷ and
- dividing the bone in half.¹⁰⁶

[Conditional Recommendation]

In a case report, Mohan et al¹⁰⁷ discussed the preparation methods used for the femoral head prior to placement in the iliac pouch.

6.2.2

Provide the patient and the patient's designated caregiver(s) with instructions regarding the care of the surgical incision storage area for the autologous femoral head.

[Recommendation]

Providing patient education on care of the surgical wound area where the tissue is preserved may help the patient understand how to help the area heal and prevent actions (eg, touching, rubbing, scratching) that might increase the risk of resorption, atrophy, or necrosis of the preserved tissue.

7. Incus

- 7.1** No recommendation can be made regarding autologous incus preservation within the patient's body. *[No Recommendation]*

The balance between the benefits and harms of preserving the autologous incus in a postauricular or posttragal pocket for staged ossicular chain reconstruction procedures is unclear. The benefits of storing the autologous incus within the patient between procedures may include elimination of the need for bone banking or tissue tracking¹⁰⁸ and cost effectiveness.¹⁰⁸ A limitation of storing the autologous incus inside of the patient between procedures is that the incus may resorb, atrophy, or fixate to surrounding tissue, therefore becoming unusable.¹⁰⁸ Additionally, between staged procedures, the patient's stapes superstructure may atrophy,¹⁰⁸ causing the surgeon to need a different implant type instead of the stored incus to reconstruct the ossicular chain.¹⁰⁹

Low-quality evidence exists regarding the preservation of the autologous incus. Two nonexperimental studies^{108,109} and one case report¹¹⁰ support the preservation of the autologous incus in a postauricular pocket,¹⁰⁸ in the mastoid area,¹⁰⁹ or in a posttragal pocket.¹¹⁰ Researchers considered the reconstructive surgery to be successful if the patient achieved an air-bone gap within 15 or 20 decibels.^{108,109} Both nonexperimental studies reported acceptable postoperative air-bone gap rates of 78.9%¹⁰⁸ and 65%.¹⁰⁹ Reported resorption or atrophy rates of the preserved incus were 11.1%¹⁰⁸ and 4.1%.¹⁰⁹

Faramarzi et al¹⁰⁸ asserted that in developing countries the cost of an allograft implant, synthetic incus, or bone bank preservation of the autologous incus may be prohibitive. The researchers concluded that the use of a postauricular pocket for preservation of the autologous incus may make ossicular chain reconstruction procedures more affordable.

Gyo et al¹⁰⁹ reported that after a follow-up period of between 5 and 9 years, 57% of patients still met the expected hearing outcomes. Both Faramarzi et al¹⁰⁸ and Gyo et al¹⁰⁹ concluded that preservation of the autologous incus in the postauricular area was safe and effective.

Fritsch and Moberly¹¹⁰ preserved an incus for 8 months in the posterior tragus area. Upon removal, they found the incus to be intact with no absorption, and it was placed successfully during the second procedure. The authors stated that the tragal area had been used successfully in 16 procedures that included 14 incus bones and two malleus-head bones.

7.1.1

Provide the patient and the patient's designated caregiver(s) with instructions regarding the care of the surgical incision storage area for the autologous incus. *[Recommendation]*

Providing patient education on care of the surgical wound area where the tissue is preserved may help the patient understand how to help the area heal and prevent actions (eg, touching, rubbing, scratching) that might increase the risk of resorption or atrophy of the preserved tissue.

8. Adipose Tissue

- 8.1** No recommendation can be made regarding the cryopreservation and delayed autotransplantation of cryopreserved adipose tissue. *[No Recommendation]*

The balance between the benefits and harms of using cryopreserved adipose tissue for delayed autotransplantation is unclear. The benefits include reduced numbers of procedures to procure adipose tissue, thereby reducing procedure-related risks, postoperative pain, additional procedure time,¹¹¹ and costs.¹¹² Additional benefits include higher patient satisfaction rates compared to traditional adipose procurement and grafting methods.^{112,113} The harms include the potential for partial or complete resorption of adipose tissue at the graft site, leading to graft failure.¹¹⁴

Low-quality evidence, including one quasi-experimental study,¹¹¹ two nonexperimental studies,^{113,114} and one organizational experience article,¹¹² supports the use¹¹¹⁻¹¹³ and further research^{111,113,114} of cryopreservation of adipose tissue for patient injection. The evidence is limited by the small number of studies on the topic, including limited high-quality studies done on patient outcomes, and the use of varied study methodologies.^{111,113,114}

Because of the conflicting study methodologies, there is limited consistency in the reported outcomes and reported rates of resorption. Conti et al¹¹⁴ found that 50% (n = 13) of the mice that received cryopreserved subcutaneous adipose injections in a study had limited resorption, and the other 50% had high levels of resorption after 1 week. Ibrahim et al¹¹² found that only 8.65% (n = 9) of patient grafts had resorption. Ha et al¹¹¹ found the lowest resorption rate (13%) for adipose tissue that had been cryopreserved for less than 1 month and included added adipose tissue-derived stem cells in the injection.

Ma et al¹¹³ reported a 0.6% complication rate (n = 1) from cryopreserved adipose autotransplantation, which was a case of lump formation on a patient's upper lip. Conversely, Ibrahim et al¹¹² reported several cases of complications including nine infections, seven cases of formation of multiple tiny firm

nodules that resolved spontaneously, three hematomas, and three cases of fat necrosis.

Injecting either smaller amounts of adipose tissue per graft¹¹² or smaller-sized pieces of adipose tissue per graft¹¹³ may affect the graft success rate by improving the ability of the tissue to neovascularize. Other studies have suggested that stem cells were viable after cryopreservation¹¹⁴ and that the addition of stem cells to adipose autotransplantation may be important because of the ability of the cells to differentiate into various cell types, thereby increasing the potential for regeneration and graft success.¹¹¹ Although some researchers performed part of the cryopreservation process in a laboratory,^{111,114} the authors of one nonexperimental study and one organizational experience article performed all or portions of the process in the OR.^{112,113}

One nonexperimental study¹¹³ and one organizational experience article¹¹² reported positive patient satisfaction rates related to the use of delayed autotransplantation of cryopreserved adipose tissue.

9. Team Communication

- 9.1** During the procedural briefing process, include a discussion of anticipated autologous tissue preservation, replantation, or autotransplantation.¹¹⁵ [\[Recommendation\]](#)

Including a discussion of anticipated preservation, replantation, or autotransplantation of autologous tissue during the briefing allows perioperative personnel to discuss tissue availability, the thawing process (if applicable), or preparation for tissue preservation.

- 9.2** During the hand-over process between OR personnel, include a review of autologous tissue that is on the sterile field, is in the room, or has been sent for preservation.^{115,116} [\[Recommendation\]](#)

In a nonexperimental study of root causes of misplaced or dropped reconstructive free flaps, Wax et al¹¹⁶ found that the durations of the procedures in which the incidents occurred were long enough that the personnel may have changed.

- 9.3** During the procedural debrief, confirm the name of the autologous tissue and preservation method for tissue that has been or will be preserved.¹¹⁵ [\[Recommendation\]](#)

The benefits of confirming the name of the autologous tissue and the preservation method during the procedural debrief include clear identification of the autograft and the preservation method and the potential to reduce or eliminate errors related to tissue management.

10. Handling

- 10.1** Implement measures to minimize the risk of contamination and cross contamination throughout the steps of tissue handling. [\[Recommendation\]](#)

Minimizing the risk of contamination and cross contamination is important and is required in 21 CFR 1721 for facilities registered as tissue establishments when handling, recovering, processing, packaging, labeling, storing, and tracking tissue.¹

- 10.1.1** Transfer autologous tissue intended for preservation off the sterile field as soon as possible. [\[Recommendation\]](#)

No studies comparing tissue contamination or integrity and the timing of tissue packaging were found. However, Hirn et al⁵⁵ stated that a method of minimizing bacterial contamination is to process and package tissue as soon as possible.

- 10.1.2** Verify the patient and tissue information verbally with the surgeon using a read-back technique before transferring the tissue from the sterile field. [\[Recommendation\]](#)

The benefits of using a read-back technique include a potential reduction in labeling or documentation errors and the prevention of patient or tissue misidentification.

A 2017 report from the ECRI Institute stated that the top two types of specimen errors involved mislabeled specimens and specimens with incomplete or missing labels.¹¹⁷ The report also stated that most specimen errors occur in phases of specimen handling (eg, collection, ordering, handling, transport) that take place before the specimen's delivery to the laboratory.

In a nonexperimental study, Greenberg et al¹¹⁸ investigated communication breakdowns from surgical malpractice claims and found that the majority of breakdowns were in verbal communication. The researchers suggested that one method to prevent the communication breakdown would be to read back the information to verify that it was received correctly.¹¹⁸ AORN recommends using a read-back technique when transferring patient information.¹¹⁵

- 10.1.3** Use standard precautions¹¹⁹ and sterile technique⁶⁰ when transferring autologous tissue from the sterile field. [\[Recommendation\]](#)

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10.1.4

Measures to prevent contamination of autologous tissue that is on the sterile field may include

- minimal handling of tissue,
- sterile glove changes before handling tissue, and
- containing or covering recovered tissue until a tissue disposition decision is made.⁶⁰

[Conditional Recommendation]

10.2

Keep autologous tissue moist or in solution when it is on the sterile field. Do not place tissue on dry, absorbent surfaces or materials. *[Recommendation]*

The benefits of keeping tissue moist or in solution include prevention of desiccation. The AATB recommends aseptically wrapping tissue in at least one moisture barrier.³⁴

10.3

Clearly label, sequester, and monitor autologous tissue that is kept on the sterile field. *[Recommendation]*

The benefits of identifying, sequestering, and monitoring autologous tissue kept on the sterile field include reduced risk of the tissue being contaminated, compromised, or lost.

Wax et al¹¹⁶ reviewed reasons for dropped free flaps and found 13 instances of free flaps that were dropped or misplaced (eg, wrapped in a sponge and discarded as waste) out of 8,382 reconstructive head and neck procedures performed at five institutions. The researchers reported that the root cause of the dropped or misplaced flaps was miscommunication in nine of the 13 instances (69.2%). In seven of the 13 incidents (53.8%), the flap had been wrapped in a sponge or towel and then discarded later during the procedure in a bucket off the sterile field. The study also reported that personnel in one facility wrapped the flap in a moist, countable sponge and then placed it in a clear plastic bag within a basin, with distinct labeling to facilitate tissue identification.

10.4

Before placing tissue on the sterile field, visually inspect the package or container for maintained sterility⁶⁰ and verbally verify the patient's autologous tissue information with the scrub person, including

- facility-approved patient identifiers,
- the name of the preserved tissue,
- the preservation solution (when applicable), and
- the expiration date (when applicable).

[Recommendation]

11. Packaging and Labeling

11.1

Package and label autologous tissue immediately after it is transferred from the sterile field.

[Recommendation]

The benefits of containing and labeling autologous tissue immediately after transfer from the sterile field include preservation of tissue integrity (eg, moisture content) and prevention of contamination, damage, or loss. Correctly labeling the tissue may also help prevent mix-ups or transplantation of the tissue into an unintended recipient.

11.2

Packaging materials for autologous tissue must be leak proof and puncture resistant.¹²⁰

[Regulatory Requirement]

11.2.1

Packaging material should be designed to prevent contamination and the introduction, transmission, or spread of communicable diseases. *[Recommendation]*

Use of packaging material that meets these recommendations is required in 21 CFR 1271 for tissue establishments.¹

11.3

Use autologous tissue packaging materials that

- are large enough to fit and protect the tissue,
- will maintain the integrity of the tissue during processing (eg, cryopreservation, thawing), and
- are validated to meet the anticipated temperature range (eg, -26° C [-14.8° F]) and duration of storage (eg, 5 years).

[Recommendation]

It is an AATB standard to use packaging materials that are validated to meet the anticipated storage conditions.³⁴ Use of packaging materials that will protect the tissue for the anticipated temperature range and duration of the storage prevents tissue compromise that may cause the tissue to become contaminated or unusable.

11.4

The autograft package must be labeled

- “For Autologous Use Only,”^{1,34}
- “Not Evaluated for Infectious Substances” if infectious disease testing has not been performed,^{1,34}
- with the biohazard legend if infectious disease testing was performed and any results were positive or if donor screening was performed and risk factors were identified,^{1,34}
- “Warning: Reactive Test Results for (name of disease or agent)” when there is a reactive test result,¹ and
- with an expiration date (when available).^{1,34}

[Regulatory Requirement]

Specific labeling practices are a regulatory requirement and part of good tissue practices.¹ See [Recommendation 12.5](#) for information on determining expiration dates and maximum storage duration for tissue.

- 11.4.1** Clearly label autologous tissue with the
- unique patient identifiers (eg, patient's name and medical record number) as specified by the facility and
 - tissue type and laterality (when applicable).³⁴ [\[Recommendation\]](#)

Facilities registered as tissue establishments with the FDA are required to label tissue with a distinct identification code, a description of the tissue, and an expiration date if there is one.¹ Clear labeling with similar requirements is also an AATB standard.³⁴

- 11.5** Facilities may use a bar-code labeling system for labeling when available. [\[Conditional Recommendation\]](#)

The benefits of using a bar-code labeling system may exceed the harms. The benefits of a bar-code labeling system may include improved accuracy in matching tissue to the recipient, fewer identification errors, and improved tissue tracking.^{121,122} The harms may include increased facility costs. Labeling the autograft in a manner that minimizes the risk for errors is a regulatory requirement for good tissue practice¹ and an AATB standard.³⁴

- 11.6** Evaluate labels to confirm that the material will remain affixed to the packaging of autologous tissue throughout processing (eg, cryopreservation) and the anticipated storage parameters (eg, temperature range and duration). [\[Recommendation\]](#)

The AATB recommends using labels designed to be firmly affixed to the container under the anticipated storage conditions for the length of use.³⁴

- 11.7** Securely affix the label to both the inner and outer package or container. [\[Recommendation\]](#)

Use of both an internal and external label is recommended because the outer label may fall off or become unreadable during frozen storage (eg, smudged from condensation).

12. Storage, Disposal, and Cleaning

- 12.1** Autologous tissue must be stored in a manner that prevents exposure of health care personnel to blood, body fluids, or other potentially infectious materials.¹²⁰ [\[Regulatory Requirement\]](#)

- 12.2** Store autologous tissue in a secured location. [\[Recommendation\]](#)

Securing the storage area is a regulatory requirement for facilities registered with the FDA as tissue establishments.¹

- 12.3** Store autologous and allograft tissue separately. [\[Recommendation\]](#)

The benefits of storing autologous and allograft tissue separately include reduced risk of misidentification of tissue types (eg, autologous, allograft).

No research comparing different storage configurations of autologous and allograft tissue was found. However, autologous tissue is not usually tested for contamination or communicable diseases, whereas allograft donors are screened and the tissue is tested.³⁴ Therefore, separating allograft and autologous tissue within a shared storage space (eg, different shelves of a freezer) may minimize the risk for cross contamination, contamination, or mix-ups.³⁴

- 12.4** Store autologous tissue at temperatures that
- are established in accordance with federal and state regulations,
 - prevent contamination or degradation of the tissue, and
 - are maintained and periodically reviewed to confirm that the temperatures are within acceptable limits.

[\[Recommendation\]](#)

It is crucial to store autologous tissue at a temperature that maintains tissue integrity. Additionally, facilities registered with the FDA as tissue establishments are required to store tissue within acceptable temperature limits; however, acceptable temperature limits for each tissue type are not specified.¹

- 12.5** In collaboration with the surgeon(s) and an infection preventionist, determine the expiration date or a maximum storage duration for autologous tissue based on the

- tissue type,
- preservation method (eg, refrigerated, frozen, cryopreserved),
- storage conditions (eg, temperature range),
- packaging type, and
- packaging expiration dates.

[\[Recommendation\]](#)

According to 21 CFR 1271.260(c), facilities registered with the FDA as tissue establishments must assign an expiration date to tissue based on specific factors (eg, type, preservation method, storage conditions, packaging) when appropriate.¹ The AATB recommendations for duration of preservation vary based on the tissue type.³⁴

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- 12.6** On an established schedule, review the inventory of stored autografts for package integrity and identification of tissue that is nearing expiration or the maximum storage duration. *[Recommendation]*

Periodic review provides an opportunity to look at packaging for compromised integrity and identify items nearing expiration or the maximum storage duration. Compromised tissue packages may be contaminated and using the tissue within a compromised package may increase the risk of infection. Comparing the preserved packages to the storage records during the autologous tissue inventory may help maintain accurate tissue tracking.

Cheah et al⁶ discussed that the cranial bone flap freezer log in one facility was reviewed every 6 months to confirm the need for continued specimen storage. Bhaskar et al¹⁷ found that 8% of 25 major neurosurgical facilities surveyed in Australia required periodic reviews of the stored bone flaps.

- 12.6.1** Sequester any compromised tissue packages and determine, in collaboration with the surgeon and an infection preventionist, whether the tissue should be discarded. *[Recommendation]*

Sequestering compromised tissue packages that are under investigation may reduce the risk of cross contamination with other stored tissue. Discussing the finding with an interdisciplinary team may help confirm whether the tissue needs to be discarded or if it can be decontaminated.

- 12.7** In collaboration with the surgeon(s) and an infection preventionist, determine a process for managing tissue that is nearing the expiration date or the maximum storage duration for the packaging. *[Recommendation]*

- 12.7.1** The process for managing tissue that is nearing the expiration date or the maximum storage duration for the packaging may include
- reviewing the patient's status (eg, alive, deceased),
 - assessing the condition of the tissue packaging,
 - discussing tissue that is nearing expiration or the maximum storage duration with the patient's surgeon, and
 - contacting the patient or patient's legal representative for release of tissue (eg, for burial or cremation) prior to disposal. *[Conditional Recommendation]*

- 12.8** Remove and discard autologous tissue by the expiration date or at the end of the maximum storage duration. *[Recommendation]*

When an expiration date is specified by health care organization or facility policy for a specific tissue type, discarding the tissue by the expiration date is important to prevent the tissue from being used when it may have reduced viability and a decreased chance of graft success. The AATB recommends against using autologous tissue after the expiration date has passed.³⁴

- 12.8.1** Tissue must be disposed of as regulated waste in accordance with state and local regulations. *[Regulatory Requirement]*

Regulated medical waste includes items that contain blood or other potentially infectious materials.¹²⁰ Hazardous waste disposal of human tissue may prevent exposure of health care personnel to blood, body fluids, or other potentially infectious materials. Local and state regulations related to disposal of human tissue vary.

- 12.9** Regularly scheduled calibration checks must be performed on refrigerators and freezers used for storage of tissue¹ in accordance with the manufacturer's IFU. *[Regulatory Requirement]*

- 12.9.1** Maintenance, calibration, and other activities performed on refrigerators and freezers used for storage of tissue must be recorded, and the records must be readily available.¹ *[Regulatory Requirement]*

- 12.10** Equipment used to store tissue (ie, freezers, refrigerators, nitrogen tanks) should have
- continuous temperature monitoring,³⁴
 - daily temperature recording,
 - an alarm,³⁴ and
 - an emergency power source.^{123,124} *[Recommendation]*

It is an accreditation standard to continuously monitor equipment, use a functioning alarm, and have a back-up plan for equipment used to store tissue.^{123,124} The use of an alarm will alert personnel when the temperature is out of range.³⁴

Two moderate-quality studies on autologous skin reviewed the effects of the type of refrigerator used (eg, domestic, monitored) on tissue preservation. In a quasi-experimental study, Sterne et al⁸⁸ hypothesized that use of domestic refrigerators might subject tissue to a wide range of temperature fluctuations. The researchers took a series of random temperature readings from an unmonitored refrigerator and found that the temperatures were higher and more variable than in the monitored

refrigerator. The researchers stated that higher temperatures resulted from frequent door opening, the door being left open for a period of time, or items of warmer temperature being placed in the refrigerator and that refrigerator temperatures that are out of range may cause ice to form. Additionally, they reported that skin stored in the unmonitored domestic refrigerator displayed more severe clefting between the epidermis and the dermis than skin stored in the monitored refrigerator.

In an experimental study, Titley et al⁹⁰ tested the effectiveness of a domestic-style refrigerator by placing temperature probes on the top, middle, and bottom shelves. The researchers found that the mean temperatures were 9.8° C (49.6° F), 7.3° C (45.1° F), and 4° C (39.2° F) on the top, middle, and bottom shelves respectively. When the refrigerator was opened once during the monitoring period, the temperature on the top shelf reached 13.9° C (57° F). The researchers also found significant levels of contamination of tissue that was stored longer than 21 days in the domestic refrigerator. Based on the study findings, they concluded that strict temperature monitoring of refrigerators is necessary and that domestic-style refrigerators are not appropriate for tissue storage.

12.10.1

The alarm system should

- sound in an area where an individual is always present to initiate corrective action or
- notify personnel who are available to respond.

[Recommendation]

Rapid corrective action may be required to prevent compromise or degradation of tissue when storage equipment malfunctions or fails.

12.11

Have a back-up plan for malfunctioning or broken equipment (eg, refrigerators, freezers, nitrogen tanks) that is used to store tissue. [Recommendation]

It is an accreditation standard to have a back-up plan for equipment used to store tissue.^{123,124}

12.12

Establish a process for

- maintaining the temperature of stored tissue in the event of an equipment malfunction and
- responding to malfunctioning storage equipment when the facility is closed or the area where the tissue is stored is unoccupied.

[Recommendation]

Proactively creating a process for the possibility of equipment malfunction or failure may decrease the time spent responding to the event and reduce the possibility of tissue loss. The AATB recommends developing policies and procedures to designate alternative storage facilities and monitoring methods.³⁴

During process development, the AATB also recommends clarifying the temperature and time limits for emergency tissue transfer and the steps to take when the temperature or time limits have been exceeded.³⁴

12.13

Clean, sanitize, and maintain equipment and devices used for storage of tissue on an established schedule. [Recommendation]

Cleaning, disinfecting, and maintaining equipment and devices used for tissue storage may prevent malfunctions, contamination, or cross contamination.³⁴ It is also a regulatory requirement for a facility registered with the FDA as a tissue establishment to establish procedures for cleaning and sanitation for the purposes of preventing the introduction, transmission, or spread of communicable diseases.¹

12.13.1

Record cleaning and disinfection of equipment and devices used in tissue management, including the methods used, cleaning schedule, and personnel responsible. Maintain the records for 3 years. [Recommendation]

13. Transport

13.1

Tissue must be transported in a manner that

- prevents exposure of health care personnel to blood, body fluids, or other potentially infectious materials,¹²⁰
- secures the confidentiality of protected patient information,¹²⁵⁻¹²⁷ and
- is clearly labeled with the fluorescent orange or orange-red biohazard legend.¹²⁰

[Regulatory Requirement]

13.2

Transport tissue in a manner that maintains tissue integrity (eg, temperature, sterility). [Recommendation]

13.3

In collaboration with the surgeon, an infection preventionist, and a risk manager, determine a method for preventing contamination or cross contamination of autologous tissue during unanticipated distribution from one facility to another. [Conditional Recommendation]

According to 21 CFR 1271.3(e), distribution of tissue from one facility to another is considered part of manufacturing and requires registration with the FDA as a tissue establishment.¹ However, the FDA has clarified that in limited circumstances, transfer of tissue for the medical needs of a specific patient may be acceptable.⁴ The clarifying statement from the FDA specifically references distribution of cranial bone flaps and parathyroid tissue.⁴

AUTOLOGOUS TISSUE MANAGEMENT

- 13.4** An AATB-accredited tissue source facility may be contacted for assistance with packaging and shipping of autologous tissue to other facilities when the originating facility is not registered as a tissue establishment. *[Conditional Recommendation]*

Transferring tissue from one facility to another is considered distribution under 21 CFR 1271.¹ An AATB-accredited tissue source facility can offer expert assistance with packaging and shipping of autologous tissue.

14. Documentation

- 14.1** Maintain records for tracking of autologous tissue. *[Recommendation]*

Maintaining records for tracking of tissue is an accreditation standard,^{128,129} an AATB recommendation,³⁴ and a regulatory requirement for facilities registered as tissue establishments.¹

- 14.1.1** Records related to tissue must be maintained for 10 years after the tissue is dispensed or expired, whichever is longer. *[Regulatory Requirement]*

- 14.2** Record the following information for autologous tissue:

- type of autologous tissue being preserved;
- date of recovery, procedure, and name of the surgeon;
- if the tissue was cultured and applicable results;
- date and time the autograft was placed in storage;
- identity of the person placing the autograft in storage;
- method of preservation;
- storage temperature;
- processing steps (eg, sterilization) performed (when applicable);
- method of decontamination (when applicable);
- solution(s) and medication(s) used in decontamination (when applicable);
- date and time the autograft was removed from storage;
- identity of the person removing the autograft from storage;
- date of subsequent use and the procedure (when applicable); and
- final disposition of the autograft (eg, replantation, autotransplantation, transfer to another facility, release to the patient or family, disposal).

[Recommendation]

Recording information is a regulatory requirement for good tissue practice¹ and an AATB standard.³⁴ Accurate recording of autologous tissue infor-

mation is important for tissue tracking, quality monitoring, and investigations. The AATB recommends documenting the following in regard to autologous tissue recovery: patient identifiers (eg, name, medical record number, date of birth), tissue type, date and time of recovery, and the name of the physician recovering the tissue.³⁴

15. Policies and Procedures

- 15.1** Facilities must maintain procedures for autologous tissue that meet the core current good tissue practice requirements (eg, labeling, storage, records, tracking) for all steps performed in tissue management. *[Regulatory Requirement]*

Maintaining procedures for tissue management is a regulatory requirement according to 21 CFR 1271.180(a).¹ It is also a Joint Commission accreditation standard specific to autologous tissue to have policies and procedures that clarify tissue management practices including identifying, tracking, storing, handling, and adverse event management.^{123,124} The AATB recommends that facilities maintain policies and procedures, including a written policy for discarding autologous tissue.³⁴

Glossary

Allograft: A graft taken from a living or nonliving donor for transplantation to a different individual.

Autograft: Tissue recovered from an individual for implantation or transplantation exclusively on or in the same individual.

Autologous: Cells or tissues obtained from the same individual.

Autotransplantation: Transplantation of tissue from one site to another in the same individual.

Craniectomy: Surgical removal of a portion of the skull.

Cranioplasty: Surgical repair of a defect or deformity of the skull.

Cryopreservation: A process for freezing cells or tissue at very low temperatures.

Cryoprotectant: A chemical substance (eg, glycerol, dimethyl sulfoxide) used to protect biological tissue from damage caused by ice formation during the cryopreservation and thawing process.

Cytotoxic: A substance that is poisonous to living cells.

Dulbecco's modified Eagle's medium: A modified version of Eagle's minimum essential medium that contains iron, phenol red, four times the number of vitamins and amino acids, and two to four times more glucose.

Engraftment: A process that occurs when a piece of tissue (eg, skin) that has been surgically transplanted begins to function normally.

Isotonic: Having the same solute concentration as a reference solution.

McCoy's 5A medium: A sterile nutrient medium made up of amino acids, vitamins, minerals, antibiotics, and buffers.

Meshed skin: A skin graft with multiple cuts that allow it to be stretched to cover a larger area.

Osteoblasts: Large cells responsible for synthesis and mineralization of bone during bone formation and regeneration. Osteoblasts are the major cellular component of bone.

Osteoclasts: Large multinuclear bone cells that resorb bone tissue.

Pulsatile lavage: A method of delivering irrigation under pressure with pulsation. Used to remove microorganisms and debris from the surface of a wound.

Replantation: Replacing an organ or body part (eg, cranial bone flap) into its original site and reestablishing its circulation.

Storage medium: A physiologic solution that closely replicates conditions that help to preserve the viability of cells.

Subgaleal: The space between the skin and the skull.

TiProtec: A sterile, hypothermic solution enriched with potassium chloride and N-acetyl histidine used for long-term protection and storage of tissue.

Tissue bank: A facility that participates in procuring, processing, preserving, or storing human cells and tissue for transplantation.

Tissue establishment: A facility that manufactures human cells, tissues, and cellular and tissue-based products (HCT/PS) and must follow applicable requirements of 21 CFR 1271.

Tulle gras: A fine-meshed gauze impregnated with vegetable oil or soft paraffin.

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