

Information Statement

Use of Musculoskeletal Tissue Allografts

This Information Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

The American Academy of Orthopaedic Surgeons (AAOS) believes that for appropriate patients musculoskeletal allografts represent a therapeutic alternative. These tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology, and follow Food and Drug Administration (FDA) Good Tissue Practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards^{1,2} and recommends the use of tissue from banks that are accredited by the American Association of Tissue Banks (AATB).

Musculoskeletal allografts, including bone, cartilage, tendons and ligaments, are being used to address the reconstructive needs of a growing number of patients each year. As such, these scarce human resources are part of larger national programs involving a variety of transplantable organs and tissues. While the incidence of disease transference with allografts is very low, careful donor screening and tissue processing are crucial in order to minimize potential risk to the recipient. Collaboration by the orthopaedic community with a broad range of scientific, tissue bank, regulatory organizations, and clinical interest groups can help ensure that the musculoskeletal allografts available for human transplantation can be used safely.

The AAOS strongly favors on-site inspection and accreditation of tissue banks that demonstrate compliance with appropriate standards. All tissue recovery partners of AATB accredited banks are also subject to the same standards, as required by FDA regulations.²

Guidelines and standards for the acquisition, processing, and banking of musculoskeletal tissues for human transplantation have been developed.^{1,2} The guidelines are based on current scientific information and the consensus of a broad representation of knowledgeable professionals from the government, academia, medical professionals, and industry. Having been subjected to repeated scrutiny and frequent revisions, these guidelines have become widely used and accepted.

The comprehensive allograft tissue guidelines and standards address donor selection and screening, tissue recovery techniques, graft processing methodology, storage solutions, and record keeping. The use of such guidelines and standards best protect patients receiving these allografts and, thereby, best serve the interests of patients and orthopaedic surgeons. It is particularly important that donors be screened using past medical history, serologic and bacteriologic tests and, when available, autopsy findings to mitigate the potential for disease transference.

The AAOS supports informed consent, for both the donor family and the recipient of human tissue, in accordance with local, state and federal regulations and laws.

The AAOS encourages orthopaedic surgeons to cooperate with efforts by local, regional and national organizations to educate the public and health care professionals concerning the need for tissue and organ donation in support of both clinical transplantation and research, and to participate in the implementation of these important efforts. The AAOS additionally encourages the establishment of a national network to maximize the availability, equitable distribution, and use of these scarce transplantable musculoskeletal tissues. Such a network should also serve as a means to acquire data and information reflecting the ongoing clinical experience with musculoskeletal allografts, while providing a vehicle for public and professional education.

In fulfilling the Joint Commission³ requirements for hospitals, the orthopaedic surgeon should when possible, facilitate the tracking of the allograft with the tissue recipient. This includes participation in standardized processes for tissue handling in the hospital, facilitating record keeping for traceability, participating in the investigation of recalls or adverse events as related to an implanted allograft, and reporting adverse patient outcomes to the hospital, tissue bank, and the FDA's adverse event reporting system, Medwatch (www.fda.gov/medwatch).

References:

1. "Standards for Tissue Banking," American Association of Tissue Banks, 1320 Old Chain Bridge Rd., Suite #450, McLean, VA 22101, (703) 827-9582. <http://www.aatb.org/>
2. FDA, 21 CFR Part 1271. Human Cells, Tissues and Cellular and Tissue Based Products: Registration and Listing, Donor Eligibility Requirements and Recommendations, and Current Good Tissue Practices. Final Rule May 25, 2005 <http://www.fda.gov/cber/tissue/docs.htm>.
3. Joint Commission Comprehensive Accreditation Manual for Hospitals (CAMH):The Official Handbook, Transplant Safety Chapter (January 2015) available at: <http://www.jcinc.com/2015-comprehensive-accreditation-manuals/2015-comprehensive-accreditation-manual-for-hospitals-camh/>

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Information Statement 1011

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