

## Committed to Safety, Quality and Innovation



Patient safety and tissue quality are primary goals for Grand Biologics and our AATB-accredited tissue banks. Each of our accredited tissue banks have unmatched expertise and leadership in the field of allograft tissue, cryopreservation and irradiation for better patient safety and is a pioneer in gamma irradiation for terminal sterilization of allografts. Quality Assurance departments carefully monitor all aspects of tissue recovery,

processing and distribution, ensuring all allografts meet the exacting standards of the AATB (American Association of Tissue Banks) and the U.S. Food and Drug Administration (FDA).

Tissue banks continue to look for scientifically based methods to improve allograft quality and patient outcomes. Highly-trained Research and Development teams continually evaluate existing allografts and design new, innovative allografts to better meet patient and surgeon needs. Innovation is evident in the pioneering use of Computer Numerically Controlled (CNC) robotic machining technology, which allows our tissue banks to produce allografts with a very high degree of accuracy and precision. Using proprietary technology and equipment (patents pending), our staff produces allografts that are consistent in safety and quality. These allografts fit easily with surgical instruments, which reduces graft preparation time and makes procedures easier and outcomes more predictable for surgeons.

Our tissue banks' commitment to tissue safety begins with donor selection. Potential donors are screened for high risk behavior and contraindications for transplant through medical/social history screening, interview with the donor's primary care physician, review of medical records, physical assessment of the donor's body, and review of post-mortem examination/autopsy results (when available). Individuals with risk factors for, conditions indicating, clinical evidence of, and/or physical evidence of infection or other communicable disease at the time of death are ineligible for donation. Please see the backside of this brochure for examples.



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Donors are also excluded for conditions or behaviors that significantly affect tissue quality. Recovered tissue is tested for microbiological contamination and all donors undergo final review by a Medical Director before tissue is released for transplantation. Donors are subjected to viral marker testing by a CLIA Certified Laboratory on a hemodilutionally qualified blood sample including a minimum of: HIV 1 and 2 antibodies, HIV-PCR and/or HIV-NAT, Hepatitis B surface antigen (HBsAg), Hepatitis B core antibody total (HBcAb), Hepatitis C (HCV Ab and HCV-NAT), Human T-lymphotropic Virus Type 1 and 2 (HTLV-1 and HTLV-2), Syphilis by rapid plasma regain (RPR) or other serological tests.

Grand Biologics' Tissue Banks recognize that helping the patient is the primary purpose. At the heart of all our technical work remains that very human goal: making the most of each donated tissue, and stewarding that life-changing gift to its eventual recipient.

## Tissue Recovery and Aseptic Processing

All tissue is recovered under aseptic conditions using sterile supplies by specially-trained recovery technicians. Cadavers are refrigerated shortly after death and recovered tissues are frozen to slow degeneration. All allografts are processed under the strict supervision of a highly-trained Quality Assurance Department in a state-of-the-art processing facility and under conditions that minimize or eliminate any possible infectious disease contamination. Processing is performed in tightly-controlled environmental rooms. All processes, environmental controls and cleaning procedures are designed for quality performance and are qualified for use and routinely monitored. Prior to distribution, all allografts are inspected for package integrity, quality and proper labeling.

Donors who test positive for the following are ineligible:

- HIV/AIDS including risk factors such as injectable drug use
- Viral hepatitis
- Sepsis/systemic infection
- West Nile Virus
- Slow viral diseases such as Creutzfeldt-Jakob Disease (CJD), Epstein-Barr disease, or risk factors for infectious or unestablished neurological disorders
- Malaria
- Malignancy
- Disease of the bone or connective tissue
- Other infectious diseases or diseases of unknown etiology

## Sterilization and Irradiation

Some allografts (except burnt skin) are terminally sterilized by gamma irradiation to a Sterility Assurance Level of  $10^{-6}$  rendering them sterile, in accordance with ISO standards. A highly-controlled radiation dose is used, with low, controlled temperatures using a specialized, validated process. Each batch is carefully monitored to provide a precise indication of the actual dose received. This allows the tissue bank to keep the dose as low as possible to reduce damage to the allografts, while still providing assurance that each allograft is sterile. Dose Substantiation: NEW ANSI/AAMI/ISO 11137-2:2006, Method VD<sub>max</sub>15.

## Sterilization and Cryopreservation

Allografts are preserved by cooling to sub-zero temperatures, such as 77 K or -196 C (the boiling point of liquid nitrogen). At these low temperatures, any biological activity, including the biochemical reactions that would lead to cell death, is effectively stopped. To minimize cell damage and promote normal function our Tissue Banks process and preserve osteoarticular, tendon, skin and cardiovascular tissues with a cryoprotectant called dimethyl sulfoxide (DMSO). This allows us to freeze the recovered tissues at a controlled rate. Bone tissue is processed into frozen, freeze dried or demineralized products. These products provide a structural matrix to facilitate new bone growth.

## Accreditation

Grand Biologics Tissue Banks are accredited by the American Association of Tissue Banks and in compliance with all U.S. Food and Drug Administration regulations including Good Tissue Practices. **To order, call Grand Biologics at 1-800-675-2537.**