

Tissue Recovery, Processing, and Safety

DCI Donor Services Tissue Bank is a non-profit, industry-leading allograft provider setting the standard in tissue quality and safety. Our dedicated team of professionals provide an extraordinary commitment to science, health and hope serving to link the gift of donation to saving and enhancing patient lives. This uncompromising, patient-centered focus generates allografts ideally suited for optimal results in a variety of surgical applications.

Donor Selection

DCI Donor Services maintains intimate control of donor selection and procurement through its federally licensed organ procurement territories. Potential donors originating in Tennessee, New Mexico, Sacramento, and Reno are evaluated against the strict, pre-established eligibility criteria and transported to the Nashville facility for processing. This unsurpassed control and stringent criteria ensures the highest level of tissue quality and safety in the industry.

Donor Screening

DCI Donor Services Tissue Bank's robust quality systems are built into every stage of allograft production starting with donor screening and eligibility determination. Quality standards are established to meet or exceed the regulations and guidelines of the U.S. Food and Drug Administration, the American Association of Tissue Banks, and individual state health departments.

Processing begins with a comprehensive donor screening procedure that includes behavioral and lifestyle risk assessments, medical and social history evaluations, and a detailed physical assessment. Extensive microbiological testing is conducted to further reduce the risk of disease transmission. Tissue samples are evaluated by a CLIA certified, FDA registered laboratory for the following:

- HIV-I & II antibodies
- Hepatitis B surface antigen
- Hepatitis B core antibody
- Hepatitis C antibody
- HIV-I, HBV, and HCV nucleic acid test
- Syphilis antibody
- Aerobic and anaerobic microbiological cultures

Only donors non-reactive or negative for all testing are considered for transplantation and final donor eligibility is determined by licensed medical director.



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Tissue Processing

DCI Donor Services Tissue Bank's advanced tissue processing procedures maximize the gift of donation while assuring safety and quality. Allografts are processed in accordance with current Good Tissue Practices in a class 100 clean room under stringent aseptic technique compliant with AORN standards.

A combination of biological detergents work in conjunction with biocompatible, aqueous solvents and antibiotic solutions to effectively clean and disinfect allografts without compromising the tissue's native biomechanical and biochemical properties. Procedures are validated to ensure allografts meet stringent release criteria with quality assurance inherently built into every step of the process. Independent testing has demonstrated the process:

- Eliminates essentially all blood elements, bone marrow, and lipids from allografts
- Disinfects the tissue against a panel of clinically relevant bacterial, fungal, and viral pathogens
- Removes residual processing agents to safe and biocompatible levels

Allograft Release

Following processing, allografts are subjected to terminal sterilization or aseptic testing according to the specific allograft specifications.

- Sterile allografts are subjected to low-dose, gamma irradiation validated to Sterility Assurance Level (SAL) of 10^{-6} .
- Aseptic grafts are subjected to USP <71> lot release microbiological testing including sampling 10% of the grafts produced for each donor and performing swab cultures on 100% of the final product.

Only allografts producing no microbial growth are considered for distribution and transplantation. Finally, a comprehensive review of the processing records, labeling documentation, and donor eligibility charts, are completed by a dedicated quality associate prior to the tissue being released to distribution.

DCI Donor Services Tissue Bank is registered with the FDA, certified by the AATB and licensed with the states of Florida, California, New York, Illinois, Oregon and Maryland.

MK 114 Rev 001 2/2018

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an extraordinary commitment to science, health and hope

