



Surgical Esthetics™
more vital bone

Safety & Testing

Premium Quality Bone Allografts



Our Tissue Bank Quality Systems meet or exceed all:

- FDA Regulations
- AATB Standards
- Federally mandated Current Good Tissue Practice guidelines

Donor Eligibility Screening

- Strict quality systems and validated processes ensure patient safety from the initial donor consultation to the surgeon's transplantation of our allograft
- Comprehensive medical and social histories are thoroughly reviewed by qualified personnel on every donor
- All donations are reviewed for eligibility by a qualified and trained Medical Director
- Recovery technicians are trained by their respective agencies, receiving continuing education to assure consistent knowledge and application of our strict donor acceptance standards
- All our cadaveric tissue donations come from not-for-profit OPOs and recovery agencies

Bone Allograft Testing

- All tissue and blood samples are tested for infectious diseases by a CLIA Certified Lab
- Tissue is thoroughly tested for AIDS, using Nucleic Acid Testing (NAT by TMA), the newest and most reliable test to confirm the absence of HIV and HCV
- As an accredited member of the American Association of Tissue Banks (AATB), our tissue bank's testing and processing of donated tissue meet or exceed all FDA and AATB regulations, and are tested using FDA-required test kits
- Comprehensive battery of testing includes:
 - HBsAG: Hepatitis B Surface Antigen
 - HBcAb: Hepatitis B Core Antibody
 - HCVAb: Hepatitis C Antibody
 - HBV NAT RPR/STS or Equivalent: Syphilis
 - HCV NAT: Hepatitis C Virus
 - HIV NAT: Human Immunodeficiency Virus
 - HIV1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody

Bone Allograft Sterilization

- Our allografts are terminally sterilized via low dose gamma irradiation
- Gamma irradiation dosage was determined by performing a VDMAX validation, and is verified on a quarterly basis
- Our allografts have a Sterility Assurance Level (SAL) of 10^{-6}

